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USING FOOT PRESSURE ANALYSIS TO PREDICT REOCCURRENCE OF DEFORMITY FOR CHILDREN WITH UNILATERAL CLUBFOOT

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USING FOOT PRESSURE ANALYSIS TO PREDICT REOCCURRENCE OF DEFORMITY FOR CHILDREN WITH UNILATERAL CLUBFOOT

DISSERTATION

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the College of Education at the University of Kentucky.

By

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Lexington, Kentucky

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ABSTRACT OF DISSERTATION

USING FOOT PRESSURE ANALYSIS TO PREDICT REOCCURRENCE OF DEFORMITY FOR CHILDREN WITH UNILATERAL CLUBFOOT

Reoccurrence of deformity can affect upwards of 64% of children with clubfoot. The ability to use foot function as a measure of reoccurrence has not been previously assessed. The purpose of this investigation was to utilize foot pressure analysis to predict the probability of reoccurrence in children with unilateral clubfoot. Retrospective foot pressure data revealed predictive algorithms detecting the probability of experiencing any type of reoccurrence (overall reoccurrence) and for experiencing a tibialis anterior tendon transfer (TATT). The equation for overall reoccurrence reported sensitivity and specificity of 0.82 and 0.81 and the equation for TATT reported values of 0.81 and 0.84.

These algorithms were then applied prospectively to a cohort of children with unilateral clubfoot. Interim sensitivity and specificity results at a 1.5-year follow-up demonstrate that the equations for overall reoccurrence and TATT were highly specific but not sensitive (0.84, 0.73 specificity; 0.11, 0 sensitivity). This is an indication that these algorithms were more accurate when identifying the absence of reoccurrence. However, these results may change as the prospective subjects continue to age.

Overall, the results of this investigation show that foot pressure analysis can predict the presence/absence of reoccurrence. The algorithms developed herein have the potential to improve long and short-term outcomes for children with clubfoot. Providing clinicians with the probability of reoccurrence will improve their ability to be proactive during the treatment decision making process.

KEYWORDS: Unilateral Clubfoot, Children, Reoccurrence of Deformity, Foot Pressure Analysis, Prediction Algorithms

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8/8/2018

Date

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Chapter 1 - Introduction

Clubfoot is a common musculoskeletal problem that affects 1-2 out of every 1000 children [1-5]. Clubfoot deformity consists of equinus, hindfoot varus, forefoot adductus and cavus [1, 4-9]. Fifty percent of all clubfeet are bilateral in nature[10, 11] and males are affected more than females at a 2.5:1 ratio[4, 10]. The exact cause of clubfoot deformity is unknown. However, genetics, abnormal muscle insertions, utero position, environmental factors and vascular deficiencies have all been cited as potential causes[1, 12].

The severity of clubfoot deformity can vary widely from mild and flexible, to highly involved and rigid [1]. Despite severity, the recommended treatment for clubfoot is Ponseti Management; consisting of manipulation, progressive casting, Achilles tenotomy for residual equinus, and foot abduction orthosis wear (23 hours per day for the first 3 months, followed by nighttime wear until the age of 4 or 5)[1, 6, 9, 13]. Researchers have reported good initial correction in >90% of Ponseti treated clubfeet [4, 6-8, 11, 14]. Despite good results, 7-64% of children with clubfoot will experience a reoccurrence of deformity [5, 15-17]. Reoccurrence has been defined as any treatment post abduction orthosis initiation; which consists of repeat casting and/or surgical intervention to treat regression of deformity[5].

The most cited cause of reoccurrence is non-compliance with foot abduction orthosis wear [4, 5, 7, 11, 13, 15, 17, 18]. Researchers have found that 78% of children who are noncompliant with brace wear will experience a reoccurrence, compared to only 7% in those who are compliant[17]. Other cited causes of reoccurrence include: low socioeconomic status[5], parental education level of less than high school [7], gender (5x increased chance in females) [11, 19], initial severity rating (the higher the initial severity rating the more likely to reoccur) [19], decreased dorsiflexion range of motion [11, 15], and everter muscle weakness [11, 15]. Possible treatments for reoccurrence include: repeat casting, Achilles tenotomy or Achilles lengthening for residual equinus [1, 20], tibialis anterior tendon transfer for dynamic supination [18], and soft tissue release or boney procedures (i.e. osteotomy) for persistent deformities [4]. However, the use of invasive surgical procedures can lead to a stiff, painful and less functional foot; resulting in worse short and long-term outcomes when compared to non-operative treatments [1, 2, 4, 7, 12, 21-23]. Therefore, invasive surgical interventions should only be used in children who experience a reoccurrence that does not respond to less invasive treatments.

Recently, researchers sought to use commonly reported parameters in clubfoot literature to predict the variables that would explain the variance in proportion effect sizes for the rate of clubfoot recurrence [24]. The purpose of the study was to identify factors that may contribute to the increased chance of reoccurrence. The results of the meta-regression show that children with unilateral clubfoot, who underwent a tenotomy as part of Ponseti management and who were less than 2 years follow-up were at the highest risk of reoccurrence. It was recommended that clinicians treating children who met this criteria be cautious and employ more frequent follow-ups to monitor disease progression. The ability to accurately predict the probability that a patient will experience a reoccurrence, would allow clinicians to customize treatment plans that utilize less invasive measures prior to reoccurrence. The goal would be to lessen the use of invasive surgical interventions and improve long-term patient outcomes.

Statement of the Problem

Despite the multitude of research conducted on causes of and rates of reoccurrence in children with clubfoot, to date no researcher has sought to use a quantitative measure of foot function as a means to predict reoccurrence. Foot pressure analysis has been shown to be a valuable tool that can assist clinicians and researchers with diagnosis, assessing severity of deformity, treatment decision making and documenting short and long-term outcomes in children and adolescents with clubfoot [25]. Foot pressure analysis uses specialized sensors, contained in a mat on the floor, to measure the forces acting on the foot when walking [25] and provides quantitative information on foot function, contact pattern, pressure distribution, pressure magnitude, and progression of the center of pressure [26]. To date, quantitative methods have not been utilized to predict reoccurrence and no studies have been undertaken to use foot pressure analysis to predict reoccurrence.

Purpose

Therefore, the purpose of this investigation is to use foot pressure analysis to predict the probability of reoccurrence in children with clubfoot deformity. To fulfill the purpose of this dissertation, validate the study methodology and test the hypotheses, three individual studies will be carried out. First, the accuracy and validity of the foot pressure methodology to be used will be measured. Second, retrospective foot pressure data will be used to build algorithms that predict reoccurrence. Lastly, the algorithms will be applied to a prospective cohort of children who will be followed to assess the accuracy of the algorithms.

The hypotheses of this dissertation are as follows:

1. Retrospective foot pressure data, from children over the age of 6 years and whose outcome is already known, will create predictive algorithms that accurately predict the presence of reoccurrence.
2. The algorithms, when applied prospectively, will accurately and precisely predict reoccurrence.

The individual investigations used to address methodology validation and the two hypotheses are described below.

First, in *Chapter 2: Foot Pressure Masking Inaccuracies Due to Deformity in Children with Unilateral Clubfoot*, the reliability and accuracy of the foot pressure methodology used in this investigation will be established. Graphically, foot pressure analyses are reported as color coded pictures that represent the maximum pressure within each sensor during the stance phase of gait [27]. The foot pressure picture can be divided into regions of interest (ROI), corresponding to foot anatomy [25], using a technique called masking. The exact configuration of the ROI is based on the needs of the clinician or researcher. Researchers have found that masking ROI is more beneficial than assessing the foot pressure picture as a whole [28]. However, researchers have found that masking techniques may be inadequate when assessing feet with deformity [29], due to incomplete contact with the floor [26]. Therefore, it may be necessary to edit an auto-generated mask or employ manual masking for foot pressure data to be accurate [30]. The ability of expert and novice clinicians to identify when automated masking is inaccurate and the ability to correct those inaccuracies will be measured. To the author's knowledge, this is the first study to measure the frequency of masking inaccuracies, the first to measure intra- and inter-clinician reliability in novice and experienced maskers and the first to present a standard method of identifying and manually correcting foot pressure masking inaccuracies for children with clubfeet.

Second, *Chapter 3: Algorithm Development* will use retrospective foot pressure data to build algorithms that predict the probability of reoccurrence for children with unilateral clubfoot deformity. Previously, researchers have found that reoccurrence rates range between 7-64% in children below the age of five and 6% in children over the age of seven [5, 15-17]. The first goal of this chapter will be to develop algorithms that will predict the probability of experiencing a reoccurrence. Children with unilateral clubfoot, who were treated with Ponseti casting, who received a foot pressure analysis at the age of two years, who are now over the age of six years and whose outcome is known will be utilized. Foot pressure data (i.e. pressure, force, contact area, & contact time) will be used to assess the difference between children with unilateral clubfoot who did not experience a reoccurrence and those that did experience a reoccurrence of deformity. Reoccurrence will be defined as any conservative or operative treatment post initial correction. Binary logistic regression will be used to identify the parameters that predict the difference between the non-reoccurred and the reoccurred groups. Algorithms will be developed for the overall chance of reoccurrence and for each of the following interventions: repeat casting, repeat tenotomy, Achilles lengthening and tibialis anterior tendon transfer (TATT). If clinicians are aware of a child's increased chance of experiencing a reoccurrence, treatment and follow-up plans can be tailored to address the increased risk.

In *Chapter 4: Using Foot Pressure Data to Predict Reoccurrence in Children with Clubfoot Deformity: A Prospective Study*, the algorithms developed in Chapter 3 will be applied to a prospective cohort of children with unilateral clubfoot. Children will be recruited at the age of two years and followed for three years. The algorithms will be applied to predict the overall chance of experiencing a reoccurrence and the chance of requiring specific surgical and non-surgical interventions. The medical history and clubfoot disease progression of each prospective subject will be followed to ascertain the accuracy of the algorithms. The goal of this chapter is to demonstrate the algorithms effectiveness at predicting reoccurrence, thus validating their use in a clinical setting.

In *Chapter 5: Discussion and Conclusion* connections between the subsequent chapters will be made. Explanations of how each chapter helped fulfill the overall purpose, using foot pressure data to predict reoccurrence in children with clubfoot deformity, will be provided. This chapter will also describe how the utilization of these algorithms could radically alter the treatment of clubfoot deformity.

Lastly, four appendices will provide additional in-depth information on the topics covered in this dissertation. *Appendix A: Foot Pressure Analysis in Children with Clubfoot: A Summary of Literature from 1995-2018*, provides a review of the current literature on the use of foot pressure analysis in children with clubfoot. This review provides a summary of foot pressure data that can be used for comparison and provides caution to clinicians and researchers when utilizing data from previously published research. *Appendix B: Foot Pressure Analysis using the emed® in Typically Developing Children and Adolescents: A Summary of Current Techniques and Typically Developing Cohort Data for Comparison with Pathology*, seeks to present a summary of the foot pressure data pertaining to children without musculoskeletal deformities and provides clinicians and researchers with information on the factors that can affect foot pressure data collection and reduction. *Appendix C: Clubfoot a Summary*, provides a summary of clubfoot deformity including etiology, treatments and outcomes. Lastly, *Appendix D: Reoccurrence Rate in Ponseti Treated Clubfeet: A Meta-Regression*, seeks to use previous literature to assess the factors that may contribute to an increased risk of reoccurrence for children with clubfoot.

Significance of the Study

This dissertation is the first of its kind to provide clinicians and researchers with the ability to use a functional measure, foot pressure analysis, to predict reoccurrence for children with clubfoot. The ability to accurately predict the chance of experiencing a reoccurrence allows clinicians to be more proactive during treatment decision making and care management. Physicians will be able to utilize more preventative and non-operative treatments to lessen a patient's chance of requiring an invasive surgical procedure. Treatments such as casting, splinting, ankle foot orthoses, physical therapy, home stretching programs and employing more frequent follow-ups will allow patients to pre-empt the need for surgical intervention.

Chapter 2: Foot Pressure Masking Inaccuracies Due to Deformity in Children with Unilateral Clubfoot

Introduction

Pedobarography uses specialized sensors to measure the forces acting on the foot [25] and provides quantitative information on foot function, contact pattern, pressure distribution, pressure magnitude, and progression of the center of pressure [26] while walking. Foot pressure analysis is a valuable tool that can assist with diagnosis, assessing severity, treatment decision making and documenting short- and long-term outcomes for individuals with foot deformities [25]. Graphically foot pressure analyses are reported as a color coded picture that represents the maximum pressure within each sensor, referred to as the maximum pressure picture (MPP) [27]. This picture is a representation of the peak pressure, or the highest pressure within each sensor during the stance phase of gait, also known as the roll over process (ROP). Data about the pressure, force, contact area and timing of the foot pressure can be analyzed.

Previous research has shown that data from the foot pressure as a whole does not give a complete picture of the forces affecting the foot when walking [31]. Therefore, clinicians and researchers have concluded that it is more beneficial to examine pressure under specific regions of interest (ROI) instead of the total foot print [28]. The MPP can be divided into different ROI based on the needs of the clinician or researcher [25] using a technique called masking. The purpose of creating masks is to define ROI on the plantar surface of the foot that correspond to anatomical structures of the foot [25, 28]. The needs of the clinician or researcher will determine the number of ROI identified, the technique used to define the ROI and the parameters that will be calculated for each ROI [25]. The most common parameters previously reported are peak pressure (PP), maximum force (MF) and contact area (CA) [32].

When interpreting PP, MF, or CA data it is important to be conscious of the masking technique utilized, as this will define how the ROI were identified. The most common automated masking techniques used to define ROI are pressure gradients, geometric algorithms and custom fit based on percentage of foot length and width [29]. However, it has been suggested that these techniques may be inadequate when assessing feet with deformity [29], due to incomplete contact with the floor [26]. Recently, researchers have utilized motion capture technology to create anatomy based masking [33] which may account for foot deformity. While this technique is useful, it requires the purchase of additional hardware and software beyond that of a pressure mat.

The goals of a foot pressure assessment are to be reliable, reproducible and accurate [34]. Previous research has shown that accurate identification of the ROI strongly affects reliability when collecting foot pressure data for individuals with foot deformity [35]. This is especially true for children with clubfoot because only part of the foot may make contact with the pressure plate. Therefore, adjustments may need to be made to the ROI in order for data output to be accurate [30].

The justification for using an automated masking technique in both clinical and research settings is that it is standardized [28, 35]. For example, the PRC mask [27, 36] is a valid method of dividing the foot into ROI based on percentages of foot length and width [37]. However, this masking technique makes assumptions about the boundaries of the ROI and some areas may be underrepresented [37], especially when deformity is present [28]. Therefore, it may be necessary to either edit the automated mask to eliminate inaccuracies or forgo automated masking techniques altogether and mask the ROI based on visual analysis of the foot print (manual masking). Both manual masking and adjusting a predefined mask are based on the subjective interpretation of the clinician and may be limited by the spatial resolution of the plate [28, 30]. While manual masking is flexible and can overcome problems due to deformity, there is some question of its clinical application due to its subjective nature and the potential problems with repeatability.

Several researchers have alluded to the problems with automated masking techniques when foot deformity is present [28, 30, 33, 38]. However, to date there is no standard methodology for identifying when an automated program inaccurately identifies ROI for children with clubfeet. Additionally, to the authors knowledge there has been no previous research reporting the intra- and inter-clinician reliability for manual masking for children with clubfoot. Therefore, the purposes of this paper are to:

1. Describe the common masking inaccuracies, due to clubfoot deformity, that are found when utilizing automated masking.
2. Report the ability of novice and experienced clinicians to identify inaccuracies of one commonly used automated masking technique for children with unilateral clubfoot (PRC mask).
3. Report intra-clinician reliability for correcting automated masks and when manually masking.
4. Report inter-clinician reliability for experienced and novice maskers when correcting inaccuracies to automated techniques.

This is the first study to report the frequency of masking inaccuracies, the first to measure intra- and inter-clinician reliability in novice and experienced maskers and the first to present a standard method of identifying and manually correcting foot pressure masking inaccuracies for children with clubfeet.

Methods

Twenty-six children, ages 2.6-12.9 years, diagnosed with unilateral clubfoot underwent pedobarography as part of their routine clinical care. Foot pressure analyses were collected for both the affected and unaffected sides using the Novel emed® x platform and Novel Database Pro M v.23.3.52 software (Novel Electronics, Munich Germany). Three trials per subject per side were collected for a total of 156 foot pressure trials. Post-processing of the data consisted of masking the foot into a 10 area ROI mask (PRC) using the Novel Database Automask program [27]. To find the incidence of inaccuracies, one clinician with 8 years' experience masking foot pressures (Rater 1), assessed the accuracy of the 156 foot pressure trials. Twenty trials were then chosen at random for the intra- and inter- masker reliability and accuracy assessment between three different maskers. A physical therapist (Rater 2) and a biomedical engineer (Rater 3), both with >20 years' experience working with children with clubfeet, volunteered as the two novice maskers. Raters 2 and 3 had no previous experience masking foot pressures. All statistical analysis was performed using SPSS v.23 (SPSS Inc, Chicago, IL).

The PRC mask utilized in this study was first published by Hennig in 1984. It divides the foot into medial/lateral hindfoot, medial/lateral midfoot, first metatarsal, second metatarsal, third-fifth metatarsal, hallux, second toe and third-fifth toes [27, 36] (Figure 2.1). The dividing lines are based on a rectangle drawn around the boundary of the foot print whose sides are parallel and perpendicular to the foot axis [27, 36]. The foot axis is a line drawn from the center of the hindfoot to the center of the second toe [27, 36]. The boundaries separating the foot horizontally between the hindfoot, midfoot and forefoot are defined as 73% and 45% of foot length when measuring from toe to hindfoot [27, 36]. The medial/lateral hindfoot and midfoot vertical dividing lines are defined by the foot axis [27, 36]. The forefoot vertical dividing lines are defined as 30%, 25% and 45% of forefoot width with the vertical lines parallel to the foot axis [27, 36].

Identifying Deformity and Mask Inaccuracies

Different deformities can cause different inaccuracies in the PRC mask. While assessing the accuracy of the PRC mask in the 156 foot trials, the authors of this study identified five deformities that may have an impact on masking accuracy in children with clubfoot: forefoot adductus, hindfoot varus/valgus, incomplete hindfoot contact (equinus), missing toes/incomplete toe contact and lateral weight bearing (supination). The five deformities can cause four inaccuracies in the PRC mask; rotated vertical dividing lines, vertical dividing lines shifted medially/laterally, horizontal dividing lines shifted distally, and inaccurate toe mask identification. Each of these deformities in isolation can cause inaccuracies in the MPP (Figure 2.2). However, children with clubfoot can have more than one deformity which can result in multiple inaccuracies. Figures 2.3A-F present examples of clubfeet that have been masked using the PRC automask. Examples of the anomalies present and the masking inaccuracies are listed below each example.

Forefoot adductus, missing toes and hindfoot varus/valgus can all affect the foot axis and the boundary surrounding the foot print. Forefoot adductus and hindfoot varus will cause the foot axis and boundary to be rotated internally. Whereas, hindfoot valgus will cause external rotation of the foot axis and boundary. Both will result in the inaccurate identification of the dividing lines between the medial/lateral hindfoot and midfoot and between the first, second and third-fifth metatarsals. Additionally, if the second toe is missing then the third toe may be inaccurately identified in its place. This will also cause the vertical dividing lines of the foot to be rotated externally, as the foot axis is defined as the middle of the hindfoot to the second toe. Therefore, to make manual corrections, the vertical dividing lines will need to be rotated internally/externally or shifted medially/laterally depending on the foot deformity presented.

With incomplete hindfoot contact (equinus) the horizontal dividing lines that separate the hindfoot, forefoot and midfoot may be shifted distally toward the toes. This will cause the hindfoot mask to be superimposed onto the midfoot, the midfoot onto the proximal metatarsals and the metatarsal masks on the distal metatarsals. To manually correct this, the dividing lines need to be shifted proximally to accurately identify the incomplete or absent hindfoot region. The horizontal lines can then be estimated based on the predefined relationship of 73% and 45% of foot length when measuring from toe to hindfoot.

With lateral weight bearing the first metatarsal and medial hindfoot may not be in full contact with the pressure plate. Lateral weight bearing will result in the inaccurate identification of the vertical diving lines that define the metatarsals and hindfoot. To manually correct this, the metatarsal masks and the hindfoot masks may need to be shifted medially to account for the first metatarsal and hindfoot not being in full contact with the plate.

If the second toe is missing or if there is not a clear pressure gradient change between the toes and the forefoot, the toe masks may be inaccurately identified. Additionally, dynamic supination or tight tendons on the dorsum of the foot may result in the toes not contacting the pressure plate. If there is no hallux the automated program will define the first toe that comes into contact with the plate as the hallux and the next toe as the second toe. There may be instances when the second toe is inaccurately identified as the hallux and the third toe is inaccurately identified as the second toe, resulting in an inaccurate foot axis. In addition, if there is not a clear pressure gradient change from the hallux to the first metatarsal, the hallux may be included in the first metatarsal mask. To manually correct toe mask inaccuracies, the clinician will need to move the toe masks and/or create new masks on the correct toes.

Accuracy

Masking inaccuracy for this study was reported as a percentage of the total number of trials which required manual corrections based on the previously described criteria. The decision for manual corrections was based on a visual assessment of the PRC mask superimposed onto the MPP. Rater 1 assessed the accuracy of all 156. Subsequently, Raters 2 and 3 assessed the accuracy of the 20 randomly selected foot pressure trials. A Chi-Square test ($p<0.05$) was used to assess the difference between the three masker's ability to rate when changes to the automated masks were required.

Reliability

Intra-clinician reliability was calculated for identifying and correcting an automated mask (PRC) and for manual masking. Rater 1 identified and corrected inaccuracies to the automated PRC masks in the 20 random trials on two separate days (<10 days between measures). In addition, Rater 1 manually applied a mask to the 20 random trials, using the PRC mask description [27] as a guide, on two separate days (<10 days between measures). CA, PP and MF were collected and exported for all ROI and for the total foot print. Due to the large amount of data generated in this study, only CA results will be presented. PP and MF data will be available as supplemental material (Supplemental Tables 2.S1-2.S6). Interclass correlation coefficient (ICC) (mixed effect, absolute agreement, single measure)[39] were performed for:

1. Days 1 and 2 for Rater 1 while editing the automated PRC mask.
2. Days 1 and 2 for Rater 1 when manually masking based on the PRC description.

A repeated measure ANOVA with a Bonferroni correction was performed to assess differences in CA, PP and MF between the automated PRC masking technique (with inaccuracies included), Rater 1 day 1 when mask editing (correcting inaccuracies) and Rater 1 day 1 when manually masking based on the PRC mask description.

For inter-clinician reliability, Raters 1, 2 and 3 all identified inaccuracies and made corrections to the automated mask for the 20 foot pressure trials. The two inexperienced raters (2 and 3) were given a written description of the PRC mask, a description of the common inaccuracies and were given a tutorial by Rater 1 on using the Novel software. ICC values (two-way mixed effect, consistency, average measure) [39] between the three raters for CA, PP and MF were calculated for all ROI. An ANOVA with a Bonferroni correction was used to determine if the changes in CA, PP and MF within each mask were statistically different between Raters when correcting masking inaccuracies.

In addition, the difference between the automated masking program (with inaccuracies) and the edited masks (corrected for inaccuracies) was calculated for each Rater. This difference was used to assess if the three Raters edited the automask the same way. For example, if the hallux was included in the first metatarsal mask, did each of the Raters increase the contact area of the hallux mask? For this example, if the average difference is negative then the hallux ROI was made larger and if the average difference was positive the Hallux mask was made smaller. An ANOVA was used to assess if the average difference between the clinicians corrected ROI were different from the automated program.

Results

Accuracy

Rater 1 measured the accuracy of 156 foot pressure trials, the results were split into affected (78) and unaffected (78) sides. The affected side ROI required corrections in 24% trials. For the affected side the 2 most common inaccuracies reported were inaccurate toe mask identification (15/19) and a rotation of the vertical dividing lines of the hindfoot, midfoot and forefoot (11/19) (Table 2.1). Some trials on the affected side had more than one inaccuracy. For the unaffected side only 4% of trials required corrections. The most common inaccuracies reported for the unaffected side were the complete inability to apply the mask (2/3) and the inclusion of the hallux in the first metatarsal mask (1/3) (Table 2.1).

Raters 1, 2, and 3 all measured the accuracy of the 20 randomly selected foot pressure trials. A summary of the number of trials that required corrections is presented in Table 2.2. A Chi-Square test was used to assess the difference between the three rater's ability to identify inaccuracies in the automated masking. The Chi-Square statistic was 6.52 with a non-significant p-value of 0.638; indicating that there was no difference between the novice and experienced clinician's ability to identify mask inaccuracies (Table 2.3).

Reliability

Intra-clinician reliability results for manual masking (Table 2.4) and editing of the automated masks (Table 2.5) for Rater 1 are reported. ICC results were quantified based on guidelines published by Koo and Li (2016) where: <0.5 poor reliability, 0.5-0.75 moderate reliability, 0.75-0.90 good reliability and >0.90 excellent reliability [39]. For mask editing, CA results show excellent reliability for all ROI (Table 2.5). Reliability results are not as consistent for manual masking where a range of poor to excellent reliability was found (Table 2.4).

ANOVA results for Rater 1 between manual masking Day 1 and automask editing Day 1 are presented in Table 2.6. Despite the identification of mask inaccuracies and the subsequent changes to the ROI, significant differences were only found in the CA of the medial midfoot. A Bonferroni post-hoc test revealed that the differences found in the CA of the medial midfoot were between the manual masking technique and the automated technique (p=0.016) and between the manual masking and mask editing (p=0.041). There was no significant difference in the CA of the medial midfoot between the automated technique and mask editing.

ICC values for inter-rater reliability for mask editing are presented in Table 2.7. ROI repeatability of the CA was ranked as good to excellent in 5 ROI (medial midfoot, lateral midfoot, and the metatarsals), moderate to excellent in 2 ROI (medial hindfoot, 2nd toe) and poor to good in 3 ROI (lateral hindfoot, hallux, 3rd-5th toes). Additionally, ANOVA results between Rater 1, Rater 2, Rater 3 and the Automated Masking Program are presented in Table 2.8. Despite 3 ROI reporting less than desirable reliability (poor to good), there were no significant differences between the three raters and the automated masking program.

The average difference in CA for each ROI between mask editing (Raters 1, 2, 3) and the automated program is presented in Table 2.9. This analysis was conducted to assess if the clinicians changed the ROI similarly. For example, if the automated hallux mask was inaccurate, did the three raters change the mask boundaries to increase or decrease the hallux CA? This comparison is a way to assess a clinician's ability to identify and edit a ROI mask similar to other clinicians. An ANOVA was used to assess the difference between the average differences of the automated program CA minus the raters edited CA for each ROI. Despite a wide range in the average differences in CA across all ROI, which ranged from -1.0cm^2 to 2.1cm^2, there was no significant difference between the clinicians. Indicating that the ability to identify inaccuracies and edit the automated mask are similar between novice and experienced maskers.

Discussion

Previous researchers have not presented a clear consensus of procedures for foot pressure ROI masking and reporting [28]. In addition, no data are available on inter- and intra-clinician reliability for ROI masking. Therefore, the purposes of this study were to: 1) Describe the common masking inaccuracies, due to clubfoot deformity, that are found when utilizing automated masking; 2) Report the ability of novice and experienced clinicians to identify inaccuracies of one commonly used automated masking technique for children with unilateral clubfoot (PRC mask); 3) Report intra-clinician reliably for correcting automated masks and when manually masking; 4) Report inter- clinician reliability for experienced and novice maskers when correcting inaccuracies to automated techniques. This is the first study to report the reliability and accuracy of masking techniques in a pediatric unilateral clubfoot population, the first to quantify the inaccuracies found and the first to report ICC values for novice and experienced maskers. Additionally, this is the first study to present a standard method to address inaccuracies in automasking.

Researchers and clinicians use automated masking techniques to identify ROI because of the inherent repeatability [28, 35]. However, for foot pressure analysis to be useful in a clinical setting the ROI need to be correlated with the anatomy of the foot [33]. While automated masking has been found to be highly repeatable [28, 35], repeatability does not always translate to accuracy. This study reported the incidence of inaccuracies in automated foot pressure masking (in a PRC mask) and three clinician's ability to identify these inaccuracies. This study found that for children with unilateral clubfoot the incidence of masking inaccuracies was 24% for the affected side and 4% for the unaffected side. This is an indication that automated masking techniques are inadequate in 1 out of 4 affected cases. The higher incidence of mask inaccuracy in the affected side, as compared to the unaffected, is a clear indication that clubfoot deformity decreases the automated masking programs ability to accurately identify foot anatomy.

This study also attempted to quantify the exact types of inaccuracies present in the PRC mask for children with unilateral clubfoot. The inaccuracies identified were; vertical dividing lines rotated, vertical dividing lines shifted medially/laterally, horizontal dividing lines shifted distally, and inaccurate toe mask identification. The two most common inaccuracies found in unilateral clubfeet were inaccurate toe mask identification and rotation of the vertical dividing lines of the hindfoot, midfoot and forefoot.

In addition to listing the common inaccuracies, this study compared two novice and one experienced maskers' ability to identify inaccuracies. There were no significant differences found in the three masker's ability to identify inaccuracies in the automated mask. Therefore, the standard method used in this study could be used in future studies when manual corrections are required. To the authors knowledge this is the first study to assess inter-clinician differences in ROI masking inaccuracies and the first to quantify the types of inaccuracies found.

The accurate identification of ROI affects the reliability of foot pressure data [35]. The coefficient of repeatability has been previously reported to be <10% for most parameters (PP, MF, CA, etc.) and ROI [40]. In addition, coefficients of variation have previously indicated that variability intra-individually for typically developing subjects is <5% for CA [41]. This would indicate that when subjects walk consistently between trials, automated techniques are highly repeatable and have low variability for typically developing children. Theoretically, this concept could be applied to children with foot deformities. If children with clubfeet walk consistently across the foot pressure plate the data will have low variability and be highly repeatable. However, problems arise when assessing the ability of the automated technique to accurately identify foot anatomy when foot deformity is present.

The results of the present study show that intra-masker reliability for CA ranges from good to excellent for manual masking in all ROI except for the second metatarsal, which reports poor to good reliability. When manually masking, the clinician must identify the ROI and the bony anatomy based off of their own subjective observation of the foot pressure picture, which previous research has found to be questionable [33]. On the other hand, mask editing reports excellent reliability in all ROI. When editing a mask, the clinician is only changing the ROI that were not accurately identified by the automated algorithms. Therefore, the majority of the foot print will be accurate and repeatable. To improve repeatability in future studies it is recommended that automasking techniques be used first, with manual corrections performed as needed. In addition, the incidence or rate of manual corrections should be reported.

A study by Deschamps et al (2009) reported inter- and intra-clinician ICC values when manually masking one ROI and then in multiple ROI in adults with first ray deformity. It was found that in both single and multiple ROI masking, inter-masker repeatability was high in the medio-lateral direction and good in the proximal-distal directions[35]. Intra-observer ICC values reported moderate to excellent repeatability for single ROI mask [35], which is similar to the findings reported in this study. The current study reported ICC values ranging from 0.84-1.0 and the study by Deschamps et al (2009) reported values between 0.86-0.99. Despite the subjective nature of manual masking, high repeatability can be achieved for children and adults with foot deformities.

The significant differences between manual masking, automask editing and the PRC automated masking technique for the experienced masker was assessed using a repeated measure ANOVA. The only difference found was in the CA of the medial midfoot, the other ROI were not significantly different. The lack of significant difference in CA in the majority of ROI would indicate that changing the ROI boundaries to correct inaccuracies did not change the overall contact area. This could be interpreted as both a positive and negative finding. Positively, this would indicate that clubfoot deformities do not severely compromise the automated techniques or the masker's ability to identify anatomically correct ROI. As a negative, these findings indicate that making changes to perceived inaccurate masks, does not significantly change the CA reported for those specific masks. Bonferroni post hoc test revealed that the significant differences in the medial midfoot CA were found between the automated program and manual masking (p=0.016) and for manual masking and mask editing (p=0.041). This would indicate that the ability to manually mask the medial midfoot was compromised. These findings are consistent with previous research in a typically developing population; where better reliability was found for higher loaded areas, such as the forefoot and hindfoot, and less reliability was found for smaller loaded areas such as the medial midfoot and toes [37].The medial midfoot is a small ROI and not a heavily loaded area compared to other ROI.

Inter-rater reliability, using ICC, was compared between two novice maskers and an experienced masker. Data analysis revealed good to excellent reliability in all ROI except for the lateral hindfoot, hallux and toes 3-5, which reported poor to good reliability. Despite the lower repeatability in 3/10 ROI, an ANOVA revealed no significant differences between the three clinicians and the automated program. These results support the conclusion that when editing the PRC mask for inaccuracies, the CA is not significantly changed. Furthermore, the difference between the automask CA values and the values post ROI editing was assessed. The clinicians edited ROI values were subtracted from the automated technique values. ANOVA results revealed that there were no significant differences in the mean change for any ROI between the three clinicians. This would indicate that both novice and experienced maskers are able to identify and correct inaccuracies consistently.

Limitations to this study include the spatial resolution of the foot pressure plate and the geometry based masking technique used to identify the ROI. The spatial resolution of the plate, in conjunction with small pediatric feet, may have influenced the clinicians ability to identify ROI [28, 35]. Researchers have found that a higher resolution biases to a higher variability, especially in smaller ROI [35]. The pressure measurement device used in this study was the emed® x, which has the highest accuracy and precision and the lowest variability compared to other commercially available devices[42]. The device used in this study has 4 sensors/cm^2, which is the highest sensor resolution available. Despite the high resolution of the foot pressure plate used in this study, the significant differences found in intra-rater repeatability for CA in the medial midfoot could have been influenced by the combination of a small foot size and the limitations of spatial resolution. Moreover, the PRC mask utilizes a geometry based algorithm to identify ROI. Previous research has found that geometry based automated masking techniques are severely limited when there is incomplete contact with the plate or when significant foot deformity is present [33]. Despite these limitations ICC values reported in this study are similar to previously reported data [35].

Conclusions

The results of this study led to some interesting conclusions about foot pressure masking and identification of mask inaccuracies. First, masking inaccuracies were found in 24% of unilateral clubfeet with the most common inaccuracies being rotation of the vertical dividing lines and inaccurate toe identification. Second, inexperience with masking does not alter a clinician's ability to identity inaccuracies and edit the ROI to reflect a more accurate alignment of the mask boundaries with the boney anatomy of the foot. Third, editing inaccuracies in an automated masking technique did not significantly change the CA of any ROI in a PRC mask. Despite the inherent flaws of ROI masking, editing the predefined masks of children with unilateral clubfoot did not significantly change the CA within the 10 ROI. This would indicate that, unless there is significant deformity or very little contact with the foot pressure plate, both automated techniques and manual masking techniques will be accurate and reliable for almost all areas of the foot print. However, the lowest reliability and repeatability will most often be found in the less loaded areas such as the midfoot and toes.

The results of this study also reveal several conclusions and recommendations that will impact how clinicians utilize foot pressure analysis in the assessment of children with unilateral clubfoot. To obtain accurate and reliable foot pressure data clinicians should first utilize automasking techniques and only employ manual editing when the masked ROI do not correspond with the boney anatomy of the foot. Second, both experienced and novice clinicians can accurately and reliably identify and edit inaccurate ROI. This conclusion indicates that experience with foot pressure technology is not a requirement for the subjective identification of foot anatomy on the MPP. Third, it is recommended that caution and attentiveness be used when editing small and less loaded ROI, as these areas are prone to less accuracy and reliability. The conclusions and recommendations of this study can be utilized in a clinical and research setting to influence foot pressure data reduction in children with clubfeet. With more accurate foot pressure data, clinicians and researchers will be better able to utilize foot pressure analysis as a diagnostic tool in the management of clubfoot deformity.

Table 2.1: Accuracy of the Automask ROI by Rater 1. Ability of the PRC mask to accurately identify ROI in 156 foot pressure trials, assessed by Rater 1. *Several trials had more than one inaccuracy.

	Total Inaccurate	**Vertical Lines Rotated**	**Vertical Lines Shifted**	**Horizontal Lines Shifted**	**Inaccurate Toe Masks**	**Would Not Mask**
Unaffected	3	1	0	0	0	2
Affected	19	11	4	3	15	1

Table 2.2: Accuracy stratified by Rater for 20 random trials.

Rater	**Side**	**Total Inaccurate**	**Vertical Lines Rotated**	**Vertical Lines Shifted**	**Horizontal Lines Shifted**	**Inaccurate Toe Masks**	**Would Not Mask**
Rater 1	Affected	7	3	1	1	7	1
	Unaffected	2	2	0	0	2	0
	Total	9	5	1	1	9	1
Rater 2	Affected	9	2	7	4	14	1
	Unaffected	3	2	0	0	2	0
	Total	12	4	7	4	16	1
Rater 3	Affected	6	4	4	4	10	1
	Unaffected	5	1	1	3	5	0
	Total	11	5	5	7	15	1

Table 2.3: ANOVA results between Raters assessing their ability to identify inaccuracies in the automated PRC mask.

Inaccuracies	p<0.05)
Total Inaccurate	0.638
Vertical Lines Rotated	0.915
Vertical Lines Shifted Medially/Laterally	0.065
Horizontal Lines Shifted Proximally/Distally	0.060
Inaccurate Toe Mask Identification	0.459

Table 2.4: Intra-Clinician Reliability for Contact Area: Interclass Correlation Coefficient (ICC) - Manual Masking for Rater 1

Contact Area (cm^2)	**Rater 1 Day 1**	**Rater 1 Day 2**	**ICC**	**95% CI** *Lower Bound*	**95% CI** *Upper Bound*	**ICC Rating Based on 95% CI**
Total Foot	80.3(21.0)	80.3(21.0)	1.00	1.00	1.00	
Medial Hindfoot	12(3.6)	11.85(3.8)	0.94	0.86	0.98	good-excellent
Lateral Hindfoot	13.0(3.9)	12.6(4.0)	0.93	0.84	0.97	good to excellent
Medial Midfoot	2.9(3.7)	4.1(3.8)	0.84	0.52	0.94	moderate to excellent
Lateral Midfoot	11.7(5.6)	10.1(4.7)	0.84	0.56	0.94	moderate to excellent
Metatarsal 1	7.8(2.9)	8.0(2.5)	0.93	0.83	0.97	good to excellent
Metatarsal 2	7.4(2.6)	7.9(3.3)	0.75	0.48	0.89	poor to good
Metatarsals 3-5	15.4(5.1)	15.9(5.0)	0.83	0.62	0.93	moderate to excellent
Hallux	5.3(2.0)	5.3(2.0)	1.00	1.00	1.00	excellent
Toe 2	1.4(1.1)	1.4(1.0)	0.98	0.95	0.99	excellent
Toes 3-5	1.0(1.0)	1.0(1.0)	0.99	0.99	1.00	excellent

Table 2.5: Intra-Rater Reliability for Contact Area: Interclass Correlation Coefficient (ICC) - Mask Editing for Rater 1

Contact Area (cm^2)	**Rater 1 Day 1**	**Rater 1 Day 2**	**ICC**	**95%CI** *Lower Bound*	**95% CI** *Upper Bound*	**ICC Rating Based on 95% CI**
Total Foot	80.3(21.0)	80.3(21.0)	1.00	1.00	1.00	excellent
Medial Hindfoot	10.1(2.7)	10.1(2.8)	0.97	0.93	0.99	excellent
Lateral Hindfoot	10.2(3.1)	10.1(3.1)	0.98	0.94	0.99	excellent
Medial Midfoot	5.6(4.7)	5.4(4.7)	1.00	0.97	1.00	excellent
Lateral Midfoot	13.2(4.9)	13.4(4.8)	0.99	0.98	1.00	excellent
Metatarsal 1	8.1(3.5)	8.0(3.4)	0.99	0.98	1.00	excellent
Metatarsal 2	7.6(2.5)	7.5(2.5)	0.99	0.96	0.99	excellent
Metatarsals 3-5	15.9(5.5)	16.2(5.1)	0.99	0.97	1.00	excellent
Hallux	5.3(2.2)	5.2(2.2)	1.00	1.00	1.00	excellent
Toe 2	1.4(0.9)	1.4(0.9)	0.97	0.93	0.99	excellent
Toes 3-5	3.0(2.4)	3.1(2.3)	0.99	0.99	1.00	excellent

Table 2.6: Intra-Rater Repeated Measures ANOVA Results for Contact Area: Automated Masking, Mask Editing and Manual Masking. * PRC Mask and Manual Masking (p=0.016); Manual Masking and Mask Editing (p=0.041)

Contact Area (cm^2)	**Rater 1 Day 1** *Manual Masking*	**Rater 1 Day 1** *Mask Editing*	**PRC AutoMask** *Automated Program*	**p-value**
Total Foot	80.3(21.0)	80.3(21.0)	80.8(21.2)	1.00
Medial Hindfoot	12(3.6)	10.1(2.7)	9.7(3.6)	1.00
Lateral Hindfoot	13.0(3.9)	10.2(3.1)	9.8(3.7)	0.07
Medial Midfoot	2.9(3.7)	5.6(4.7)	5.5(5.3)	0.01*
Lateral Midfoot	11.7(5.6)	13.2(4.9)	12.6(5.4)	0.12
Metatarsal 1	7.8(2.9)	8.1(3.5)	8.9(4.1)	0.66
Metatarsal 2	7.4(2.6)	7.6(2.5)	7.5(3.0)	0.64
Metatarsals 3-5	15.4(5.1)	15.9(5.5)	14.9(6.7)	0.98
Hallux	5.3(2.0)	5.3(2.2)	4.5(2.5)	0.87
Toe 2	1.4(1.1)	1.4(0.9)	1.5(0.8)	0.47
Toes 3-5	1.0(1.0)	3.0(2.4)	0.5(0.5)	0.94

Table 2.7: Mask Editing Inter-Rater Reliability Interclass Correlation Coefficient (ICC) for Contact Area: Rater 1 Day 1, Rater 2 and Rater 3

Contact Area (cm^2)	**Rater 1 Day 1**	**Rater 2**	**Rater 3**	**ICC**	**95% CI** *Lower Bound*	**95% CI** *Upper Bound*	**ICC Rating Based on 95% CI**
Total Foot	80.3(21.0)	80.3(21.0)	80.3(21.0)	1.00	1.00	1.00	
Medial Hindfoot	10.1(2.7)	10.0(4.3)	9.7(4.7)	0.81	0.60	0.92	moderate to excellent
Lateral Hindfoot	10.2(3.1)	10.5(4.0)	10.1(4.8)	0.73	0.44	0.89	poor to good
Medial Midfoot	5.6(4.7)	4.7(4.8)	3.5(4.4)	0.93	0.84	0.97	good to excellent
Lateral Midfoot	13.2(4.9)	13.2(6.1)	12.3(6.4)	0.93	0.85	0.97	good to excellent
Metatarsal 1	8.1(3.5)	7.8(3.4)	6.9(4.4)	0.93	0.85	0.97	good to excellent
Metatarsal 2	7.6(2.5)	7.6(2.6)	7.4(2.5)	0.91	0.82	0.96	good to excellent
Metatarsals 3-5	15.9(5.5)	15.4(5.6)	14.4(5.7)	0.88	0.75	0.95	good to excellent
Hallux	5.3(2.2)	5.4(1.7)	6.1(3.7)	0.61	0.18	0.83	poor to good
Toe 2	1.4(0.9)	4.6(1.1)	1.6(0.9)	0.86	0.71	0.94	moderate to excellent
Toes 3-5	3.0(2.4)	3.8(3.9)	3.1(2.3)	0.75	0.47	0.89	poor to good

Table 2.8: Inter Rater Repeated Measures ANOVA Results for Contact Area when mask editing: Rater 1, Rater 2, Rater 3 and Automated Masking

Contact Area (cm^2)	**Rater 1 Day 1** *Mask Editing*	**Rater 2** *Mask Editing*	**Rater 3** *Mask Editing*	**PRC AutoMask** *Automated Program*	**p-value**
Total Foot	80.3(21.0)	80.3(21.0)	80.3(21.0)	80.8(21.2)	1
Medial Hindfoot	10.1(2.7)	10.0(4.3)	9.7(4.7)	9.7(3.6)	0.984
Lateral Hindfoot	10.2(3.1)	10.5(4.0)	10.1(4.8)	9.8(3.7)	0.949
Medial Midfoot	5.6(4.7)	4.7(4.8)	3.5(4.4)	5.5(5.3)	0.490
Lateral Midfoot	13.2(4.9)	13.2(6.1)	12.3(6.4)	12.6(5.4)	0.946
Metatarsal 1	8.1(3.5)	7.8(3.4)	6.9(4.4)	8.9(4.1)	0.490
Metatarsal 2	7.6(2.5)	7.6(2.6)	7.4(2.5)	7.5(3.0)	0.996
Metatarsals 3-5	15.9(5.5)	15.4(5.6)	14.4(5.7)	14.9(6.7)	0.875
Hallux	5.3(2.2)	5.4(1.7)	6.1(3.7)	4.5(2.5)	0.278
Toe 2	1.4(0.9)	4.6(1.1)	1.6(0.9)	1.5(0.8)	0.930
Toes 3-5	3.0(2.4)	3.8(3.9)	3.1(2.3)	0.5(0.5)	0.765

Table 2.9: Repeated Measure ANOVA: Average difference* in Contact Area between Raters 1, 2, & 3 and Automated Masking Program. *Computer Generated Value - Rater Value

Contact Area (cm^2)	**Rater 1**	**Rater 2**	**Rater 3**	**p-value**
Total Foot	0.5(23.4)	0.5(23.4)	0.5(23.4)	1.00
Medial Hindfoot	-0.4(3.8)	-0.3(4.0)	0.0(5.7)	0.97
Lateral Hindfoot	-0.4(3.6)	-0.7(3.6)	-0.3(5.8)	0.95
Medial Midfoot	-0.02(5.0)	0.8(5.1)	2.1(5.5)	0.46
Lateral Midfoot	-0.1(6.2)	-0.5(7.4)	0.4(7.6)	0.89
Metatarsal 1	0.8(3.6)	1.1(3.9)	2.0(5.1)	0.65
Metatarsal 2	-0.1(2.7)	-0.1(3.5)	0.1(2.8)	0.98
Metatarsals 3-5	-1.0(6.8)	-0.5(4.8)	0.5(5.7)	0.72
Hallux	0.8(2.2)	-1.0(2.2)	-1.7(4.9)	0.68
Toe 2	0.1(0.7)	-0.1(1.4)	-0.1(1.1)	0.86
Toes 3-5	0.0(2.3)	-0.8(4.4)	-0.1(2.2)	0.67

Table 2.S1: Intra-Clinician Reliability: Interclass Correlation Coefficient (ICC) for Peak Pressure and Maximum Force - Manual Masking for Rater 1

Peak Pressure (kPa)	**Rater 1 Day 1**	**Rater 1 Day 2**	**ICC**	**95% CI** *Lower Bound*	**95% CI** *Upper Bound*	**ICC Rating Based on 95% CI**
Total Foot	407.3(191.4)	407.3(191.4)	1.00	1.00	1.00	
Medial Hindfoot	319.3(172.5)	318.5(173.1)	1.00	1.00	1.00	excellent
Lateral Hindfoot	291.0(141.3)	285.5(131.0)	0.98	0.95	0.99	excellent
Medial Midfoot	63.0(49.5)	77.0(43.0)	0.82	0.71	0.96	moderate to excellent
Lateral Midfoot	119.3(79.6)	117.3(78.8)	0.98	0.94	0.99	excellent
Metatarsal 1	154.3(87)	155.5(87.6)	0.99	0.93	0.99	excellent
Metatarsal 2	217.3(109.7)	218.8(116.0)	0.95	0.87	0.98	good to excellent
Metatarsals 3-5	235.5(94.3)	234.8(91.6)	0.98	0.94	0.99	excellent
Hallux	243.0(202.5)	242.5(202.6)	1.00	1.00	1.00	excellent
Toe 2	96.5(80.9)	100.0(78.0)	0.98	0.95	0.99	excellent
Toes 3-5	102.5(63.1)	102.5(63.1)	1.00	1.00	1.00	excellent
Maximum Force (N)						
Total Foot	442.7(169.9)	442.7(169.9)	1.00	1.00	1.00	
Medial Hindfoot	155.0(70.8)	157.1(76.2)	0.97	0.93	0.99	excellent
Lateral Hindfoot	156.6(78.9)	153.7(78.3)	0.98	0.95	0.99	excellent
Medial Midfoot	16.4(27.7)	22.9(28.1)	0.91	0.74	0.97	moderate to excellent
Lateral Midfoot	84.2(67.8)	75.9(60.7)	0.95	0.88	0.98	good to excellent
Metatarsal 1	65.5(45.5)	66.3(43.0)	0.99	0.99	0.97	excellent
Metatarsal 2	79.4(47.2)	84.9(53.8)	0.92	0.82	0.97	good to excellent
Metatarsals 3-5	151.2(83.0)	150.5(81.9)	0.96	0.91	0.99	excellent
Hallux	56.0(41.2)	55.9(41.3)	1.00	1.00	1.00	excellent
Toe 2	9.9(8.2)	10.1(8.0)	0.99	0.98	1.00	excellent
Toes 3-5	15.9(14.4)	15.6(14.5)	1.00	0.99	1.00	excellent

Table 2.S2: Intra-Clinician Reliability: Interclass Correlation Coefficient (ICC) for Peak Pressure and Maximum Force - Mask Editing for Rater 1

Peak Pressure (kPa)	**Rater 1 Day 1**	**Rater 1 Day 2**	**ICC**	**95% CI** *Lower Bound*	**95% CI** *Upper Bound*	**ICC Rating Based on 95% CI**
Total Foot	407.3(191.4)	407.3(191.4)	1.00	1.00	1.00	excellent
Medial Hindfoot	321.0(173.4)	320.3(172.6)	1.00	1.00	1.00	excellent
Lateral Hindfoot	279.8(130.4)	283.0(136.1)	0.99	0.98	1.00	excellent
Medial Midfoot	155.3(107.9)	155.3(107.9)	1.00	1.00	1.00	excellent
Lateral Midfoot	156.5(88.7)	157.5(88.8)	1.00	1.00	1.00	excellent
Metatarsal 1	157.5(91.1)	153.0(88.8)	0.97	0.93	0.99	excellent
Metatarsal 2	217.0(110.0)	218.0(109.3)	1.00	1.00	1.00	excellent
Metatarsals 3-5	234.5(90.0)	236.0(87.3)	1.00	0.99	1.00	excellent
Hallux	243.0(202.5)	243.0(202.5)	1.00	1.00	1.00	excellent
Toe 2	101.8(76.0)	100.0(78.0)	1.00	0.99	1.00	excellent
Toes 3-5	100.8(67.9)	103.0(65.0)	0.99	0.98	1.00	excellent
Maximum Force (N)						
Total Foot	442.7(169.9)	442.7(169.9)	1.00	1.00	1.00	excellent
Medial Hindfoot	148.8(68.6)	148.6(68.6)	0.98	0.95	0.99	excellent
Lateral Hindfoot	132.7(62.6)	133.0(64.3)	0.98	0.94	0.99	excellent
Medial Midfoot	44.9(52.8)	44.1(53.2)	1.00	0.99	1.00	excellent
Lateral Midfoot	93.0(60.4)	93.7(60.1)	1.00	1.00	1.00	excellent
Metatarsal 1	67.4(50.3)	66.4(50.0)	1.00	0.99	1.00	excellent
Metatarsal 2	80.6(51.5)	80.2(51.7)	1.00	1.00	1.00	excellent
Metatarsals 3-5	151.3(84.0)	154.2(82.8)	1.00	0.99	1.00	excellent
Hallux	55.8(41.6)	55.8(41.6)	1.00	1.00	1.00	excellent
Toe 2	10.1(7.5)	9.9(7.6)	1.00	0.99	1.00	excellent
Toes 3-5	15.3(14.3)	15.5(14.0)	1.00	1.00	1.00	excellent

Table 2.S3: Intra-Clinician Repeated Measures ANOVA Results for Peak Pressure and Maximum Force: Automated Masking, Mask Editing Rater 1 and Manual Masking Rater 1 **PRC Mask and Manual Masking (p=0.036); Manual Masking and Mask Editing (p=0.006)

Peak Pressure (kPa)	**Rater 1 Day 1** *Manual Masking*	**Rater 1 Day 1** *Mask Editing*	**PRC AutoMask** *Automated Program*	**p-value**
Total Foot	407.3(191.4)	407.3(191.4)	407.3(191.4)	1.00
Medial Hindfoot	319.3(172.5)	321.0(173.4)	315.8(181.6)	1.00
Lateral Hindfoot	291.0(141.3)	279.8(130.4)	274.5(139.7)	0.93
Medial Midfoot	63.0(49.5)	155.3(107.9)	136.5(100.0)	0.005**
Lateral Midfoot	119.3(79.6)	156.5(88.7)	146.8(89.5)	0.37
Metatarsal 1	154.3(87)	157.5(91.1)	163.0(93.4)	0.95
Metatarsal 2	217.3(109.7)	217.0(110.0)	214.3(115.6)	1.00
Metatarsals 3-5	235.5(94.3)	234.5(90.0)	225.3(104.4)	0.93
Hallux	243.0(202.5)	243.0(202.5)	230.3(211.7)	0.98
Toe 2	96.5(80.9)	101.8(76.0)	109.5(67.2)	0.86
Toes 3-5	102.5(63.1)	100.8(67.9)	99.3(69.8)	1.00
Maximum Force (N)				
Total Foot	442.7(169.9)	442.7(169.9)	442.7(169.9)	1.00
Medial Hindfoot	155.0(70.8)	148.8(68.6)	147.3(76.9)	0.94
Lateral Hindfoot	156.6(78.9)	132.7(62.6)	124.0(64.8)	0.40
Medial Midfoot	16.4(27.7)	44.9(52.8)	38.0(50.1)	0.12
Lateral Midfoot	84.2(67.8)	93.0(60.4)	88.2(61.9)	0.91
Metatarsal 1	65.5(45.5)	67.4(50.3)	74.3(51.7)	0.84
Metatarsal 2	79.4(47.2)	80.6(51.5)	80.5(53.9)	1.00
Metatarsals 3-5	151.2(83.0)	151.3(84.0)	144.4(89.7)	0.96
Hallux	56.0(41.2)	55.8(41.6)	49.1(44.8)	0.85
Toe 2	9.9(8.2)	10.1(7.5)	10.5(6.9)	0.97
Toes 3-5	15.9(14.4)	15.3(14.3)	15.3(14.3)	0.99

Table 2.S4: Mask Editing Inter-Clinician Reliability Interclass Correlation Coefficient (ICC) for Peak Pressure and Maximum Force: Rater 1 Day 1, Rater 2 and Rater 3

Peak Pressure (kPa)	**Rater 1 Day 1** *Mask Editing*	**Rater 2** *Mask Editing*	**Rater 3** *Mask Editing*	**ICC**	**95% CI** *Lower Bound*	**95% CI** *Upper Bound*	**ICC Rating Based on 95% CI**
Total Foot	407.3(191.4)	407.3(191.4)	407.3(191.4)	1.00	1.00	1.00	
Medial Hindfoot	321.0(173.4)	321.0(173.4)	285.8(198.7)	0.96	0.91	0.98	excellent
Lateral Hindfoot	279.8(130.4)	283.8(136.8)	248.5(153.2)	0.93	0.84	0.97	good to excellent
Medial Midfoot	155.3(107.9)	122.8(79.9)	92.8(84.7)	0.70	0.36	0.87	poor to good
Lateral Midfoot	156.5(88.7)	128.7(42.4)	139.3(104.1)	0.68	0.33	0.87	poor to good
Metatarsal 1	157.5(91.1)	152.3(88.6)	138.5(99.7)	0.96	0.92	0.98	excellent
Metatarsal 2	217.0(110.0)	211.8(110.2)	209.0(109.5)	0.99	0.97	0.99	excellent
Metatarsals 3-5	234.5(90.0)	234.5(90.0)	228.0(89.5)	0.73	0.43	0.88	poor to good
Hallux	243.0(202.5)	243.0(202.5)	239.5(208.9)	0.99	0.97	0.99	excellent
Toe 2	101.8(76.0)	100.0(78.0)	105.3(72.4)	0.99	0.99	1.00	excellent
Toes 3-5	100.8(67.9)	96.8(69.3)	102.3(64.2)	0.58	0.13	0.82	poor to good
Maximum Force (N)							
Total Foot	442.7(169.9)	442.7(169.9)	442.7(169.9)	1.00	1.00	1.00	
Medial Hindfoot	148.8(68.6)	151.4(82.6)	136.1(88.5)	0.94	0.86	0.97	good to excellent
Lateral Hindfoot	132.7(62.6)	139.8(65.4)	128.6(80.1)	0.85	0.68	0.93	moderate to excellent
Medial Midfoot	44.9(52.8)	38.8(50.4)	23.4(39.2)	0.88	0.75	0.95	good to excellent
Lateral Midfoot	93.0(60.4)	84.6(64.3)	89.8(68.8)	0.93	0.85	0.97	good to excellent
Metatarsal 1	67.4(50.3)	64.8(51.0)	57.8(52.3)	0.96	0.92	0.98	excellent
Metatarsal 2	80.6(51.5)	76.5(51.3)	77.2(52.1)	0.99	0.97	0.99	excellent
Metatarsals 3-5	151.3(84.0)	155.6(87.9)	141.4(73.1)	0.94	0.88	0.98	good to excellent
Hallux	55.8(41.6)	55.8(41.1)	69.0(61.5)	0.82	0.62	0.92	moderate to excellent
Toe 2	10.1(7.5)	9.9(7.6)	10.6(7.2)	0.98	0.97	0.99	excellent
Toes 3-5	15.3(14.3)	15.1(14.4)	15.6(14.1)	1.00	0.99	1.00	excellent

Table 2.S5: Inter-Clinician ANOVA for Peak Pressure and Maximum Force: Rater 1, Rater 2, Rater 3 and Automated Masking

Peak Pressure (kPa)	**Rater 1 Day 1** *Mask Editing*	**Rater 2** *Mask Editing*	**Rater 3** *Mask Editing*	**PRC AutoMask** *Automated Program*	**p-value**
Total Foot	407.3(191.4)	407.3(191.4)	407.3(191.4)	407.3(191.4)	1
Medial Hindfoot	321.0(173.4)	321.0(173.4)	285.8(198.7)	315.8(181.6)	0.914
Lateral Hindfoot	279.8(130.4)	283.8(136.8)	248.5(153.2)	274.5(139.7)	0.857
Medial Midfoot	155.3(107.9)	122.8(79.9)	92.8(84.7)	136.5(100.0)	0.202
Lateral Midfoot	156.5(88.7)	128.7(42.4)	139.3(104.1)	146.8(89.5)	0.763
Metatarsal 1	157.5(91.1)	152.3(88.6)	138.5(99.7)	163.0(93.4)	0.859
Metatarsal 2	217.0(110.0)	211.8(110.2)	209.0(109.5)	214.3(115.6)	0.996
Metatarsals 3-5	234.5(90.0)	234.5(90.0)	228.0(89.5)	225.3(104.4)	0.985
Hallux	243.0(202.5)	243.0(202.5)	239.5(208.9)	230.3(211.7)	0.997
Toe 2	101.8(76.0)	100.0(78.0)	105.3(72.4)	109.5(67.2)	0.978
Toes 3-5	100.8(67.9)	96.8(69.3)	102.3(64.2)	99.3(69.8)	0.995
Maximum Force (N)					
Total Foot	442.7(169.9)	442.7(169.9)	442.7(169.9)	442.7(169.9)	1
Medial Hindfoot	148.8(68.6)	151.4(82.6)	136.1(88.5)	147.3(76.9)	0.993
Lateral Hindfoot	132.7(62.6)	139.8(65.4)	128.6(80.1)	124.0(64.8)	0.952
Medial Midfoot	44.9(52.8)	38.8(50.4)	23.4(39.2)	38.0(50.1)	0.549
Lateral Midfoot	93.0(60.4)	84.6(64.3)	89.8(68.8)	88.2(61.9)	0.981
Metatarsal 1	67.4(50.3)	64.8(51.0)	57.8(52.3)	74.3(51.7)	0.789
Metatarsal 2	80.6(51.5)	76.5(51.3)	77.2(52.1)	80.5(53.9)	0.992
Metatarsals 3-5	151.3(84.0)	155.6(87.9)	141.4(73.1)	144.4(89.7)	0.949
Hallux	55.8(41.6)	55.8(41.1)	69.0(61.5)	49.1(44.8)	0.617
Toe 2	10.1(7.5)	9.9(7.6)	10.6(7.2)	10.5(6.9)	0.990
Toes 3-5	15.3(14.3)	15.1(14.4)	15.6(14.1)	15.3(14.3)	0.999

Table 2.S6: Repeated Measure ANOVA for Peak Pressure and Maximum Force: Average difference* between Raters 1,2,3 and Automated Masking Program. *(Computer Generated Value - Rater Value)

Peak Pressure (kPa)	**Rater 1**	**Rater 2**	**Rater 3**	**p-value**
Total Foot	0(0)	0(0)	0(0)	-
Medial Hindfoot	-5.3(23.5)	-5.3(23.5)	30.0(112.8)	0.18
Lateral Hindfoot	-5.3(22.3)	-9.3(41.0)	26.0(107.8)	0.21
Medial Midfoot	-18.8(83.9)	13.8(116.8)	43.8(83.6)	0.13
Lateral Midfoot	-9.8(35.9)	18.8(86.5)	7.5(106.2)	0.56
Metatarsal 1	5.5(31.5)	10.8(33.3)	24.5(56.2)	0.34
Metatarsal 2	-2.8(10.7)	2.5(19.0)	5.3(39.3)	0.61
Metatarsals 3-5	-9.3(39.1)	-9.3(39.1)	-2.8(120.4)	0.95
Hallux	-12.75(34.5)	-12.75(34.5)	-9.3(92.0)	0.98
Toe 2	7.8(20.0)	9.5(20.8)	4.3(23.5)	0.74
Toes 3-5	-1.5(6.7)	2.5(20.6)	-3.0(29.8)	0.70
Maximum Force (N)				
Total Foot	0(0)	0(0)	0(0)	-
Medial Hindfoot	-1.5(19.8)	-4.0(32.9)	11.2(57.8)	0.44
Lateral Hindfoot	-3.7(12.7)	-10.8(21.4)	0.4(68.7)	0.70
Medial Midfoot	-7.0(40.4)	0.8(48.0)	14.6(33.5)	0.24
Lateral Midfoot	-4.8(15.0)	3.6(25.2)	-1.7(48.8)	0.72
Metatarsal 1	6.9(15.0)	9.5(15.7)	16.4(34.3)	0.42
Metatarsal 2	0.0(4.8)	4.0(13.0)	3.3(17.3)	0.57
Metatarsals 3-5	-6.9(23.3)	-11.2(29.2)	3.0(61.4)	0.54
Hallux	-6.6(16.5)	-6.6(15.6)	-19.8(58.8)	0.42
Toe 2	0.4(1.2)	0.6(1.3)	-0.1(3.0)	0.57
Toes 3-5	0.0(0.2)	0.2(2.0)	-0.4(2.6)	0.65

Figure 2.1. PRC Mask: Example of a typically developing foot masked using an automated 10 ROI (PRC) mask. Percentages of length and width were used to identify the ROI. Regions identified: hallux (M01), Second Toe (M02), Third-Fifth Toes (M03), First Metatarsal (M04), Second Metatarsal (M05), Third-Fifth Metatarsals (M06), Medial Midfoot (M07), Lateral Midfoot (M08), Medial Hindfoot (M09) and Lateral Hindfoot (M10).

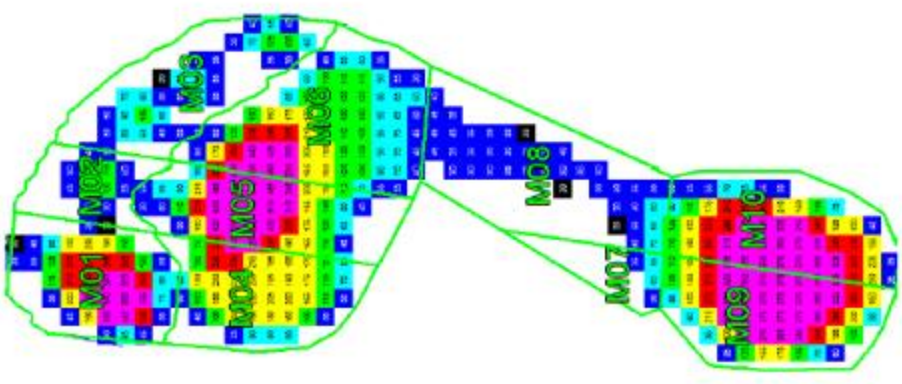


Figure 2.2. Masking Inaccuracies: Flow chart of clubfoot deformities that result in inaccuracies in the regions of interest (ROI).

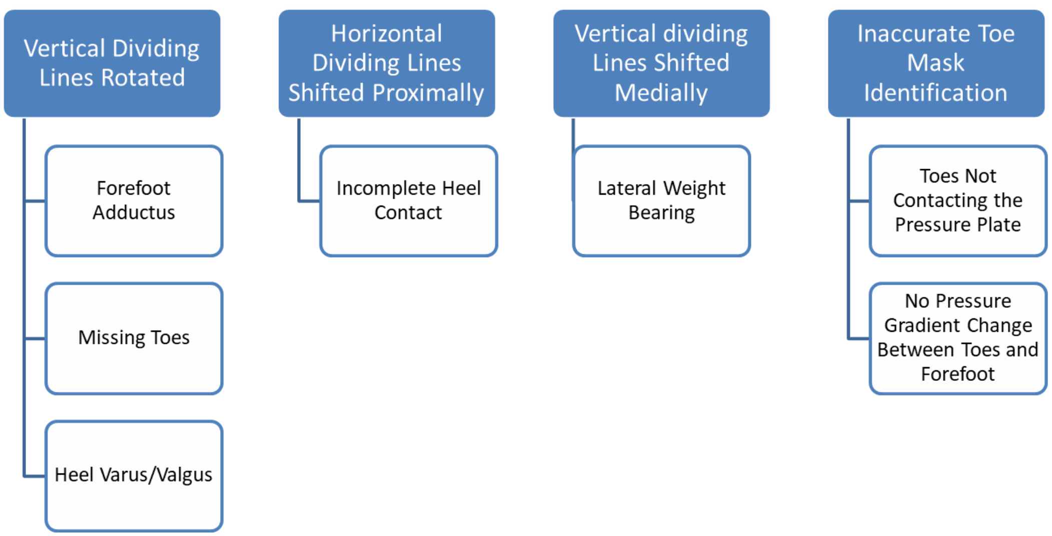


Figure 2.3A-3F: Examples of clubfeet with inaccuracies in the 10 ROI PRC automask.

Figure 2.3A: Inaccurate identification of 2nd toe (missing)

Inaccuracies: Vertical dividing lines rotated. Need to correctly identify the second toe, create a mask for the 3rd-5th toes and rotate all the vertical dividing lines internally.

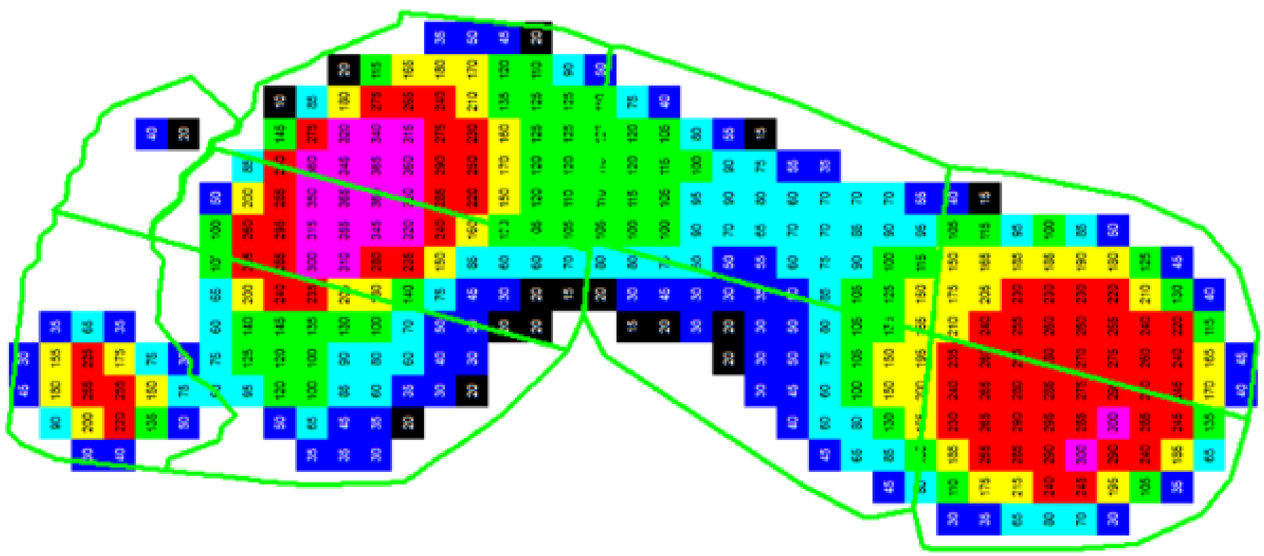


Figure 2.3B: Hallux included in 1st metatarsal and forefoot adductus

Inaccuracies: Edit the 1st metatarsal and hallux masks to identify the ROI more accurately. Rotate the vertical dividing lines externally to correct the adductus.

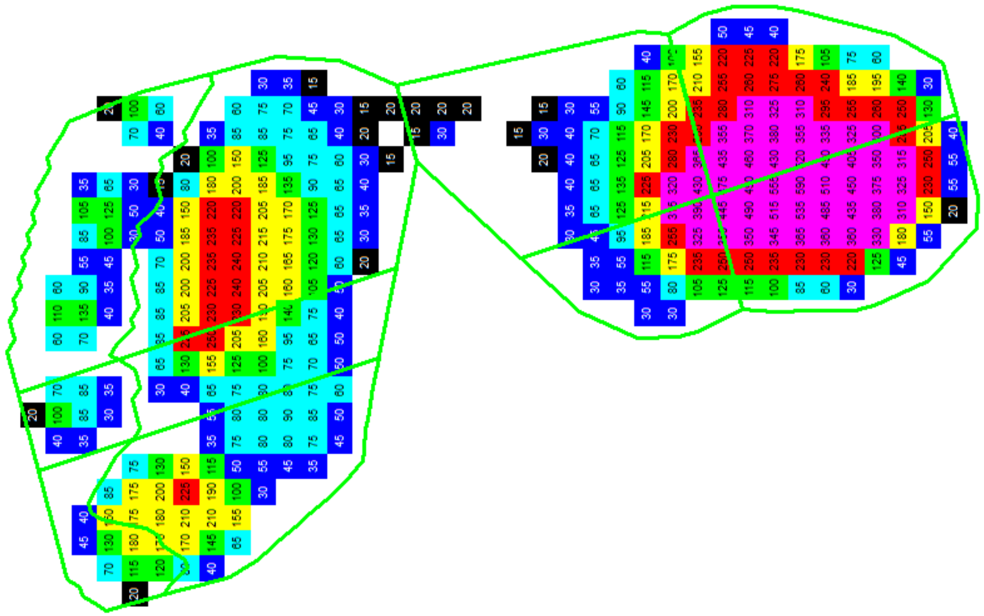


Figure 2.3C: Supination and inaccurate identification of the 2nd toe (missing).

Inaccuracies: Correctly identify the second toe and then rotate the vertical dividing lines to reflect where the second toe should be. Shift the vertical diving lines internally to reflect that the 1st metatarsal may not be fully in contact with the ground.

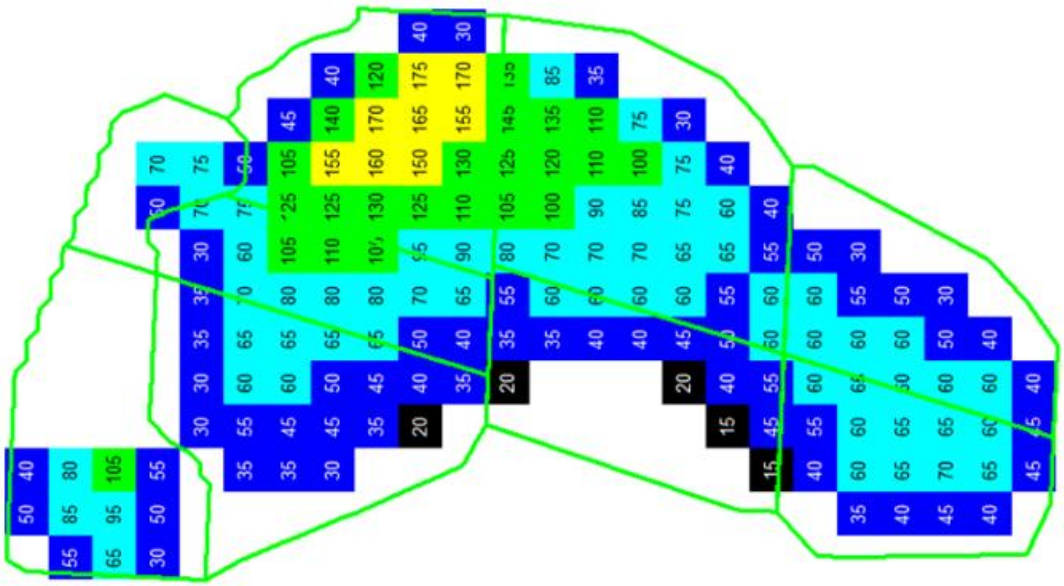


Figure 2.3D: Incomplete Hindfoot Contact, No hallux (questionable missing 2nd Toe) and Forefoot Adductus

Inaccuracies: Correctly identify the missing hallux and second toes by shifting inaccurate masks and creating a new mask for the lateral toes. Shift the vertical dividing lines in the forefoot internally to accurately identify the metatarsals.

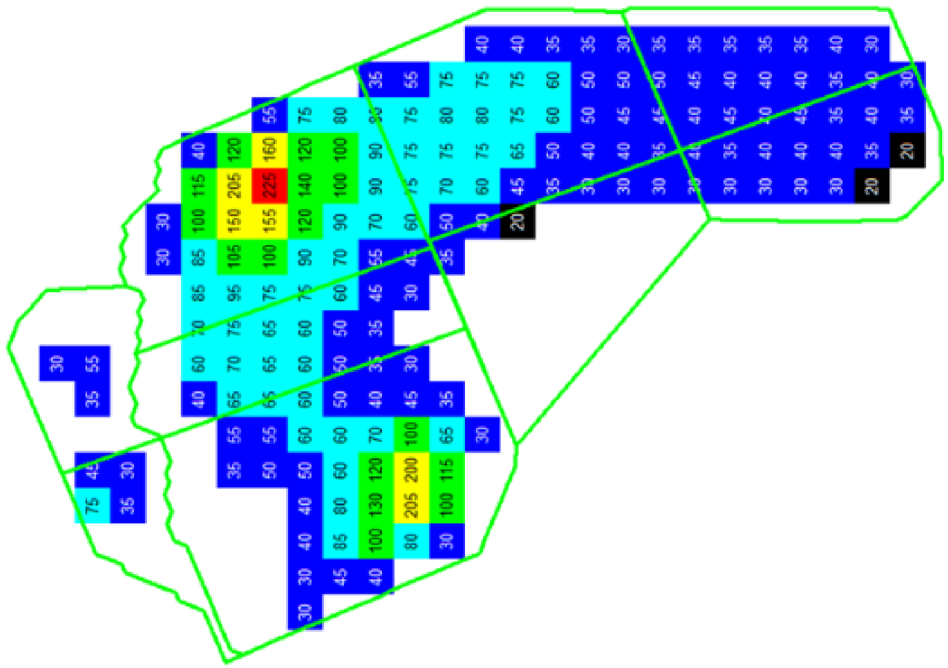


Figure 2.3E: Supination, incomplete hindfoot contact, and inaccurate hallux and 2nd toe identification.

Inaccuracies: Correctly identify the hallux and second toe. Shift the horizontal dividing lines proximally to account for incomplete hindfoot contact. Reimagine the foot axis by rotating the horizontal dividing lines to accurately represent the center of the 2nd toe and center of the partial hindfoot. Shift the vertical dividing lines internally to account for supination.

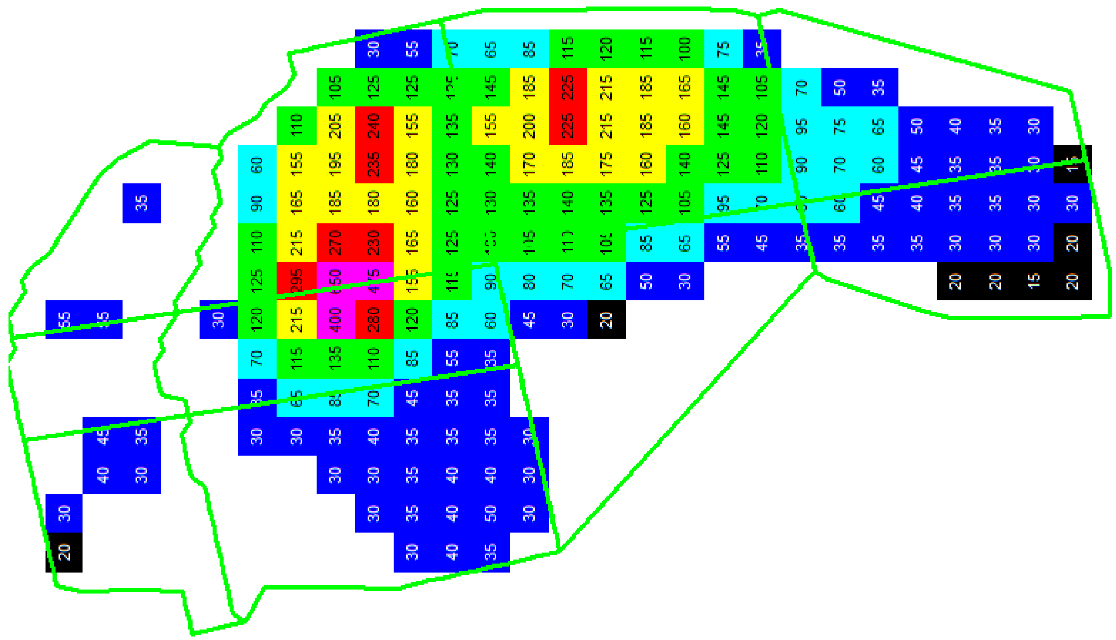
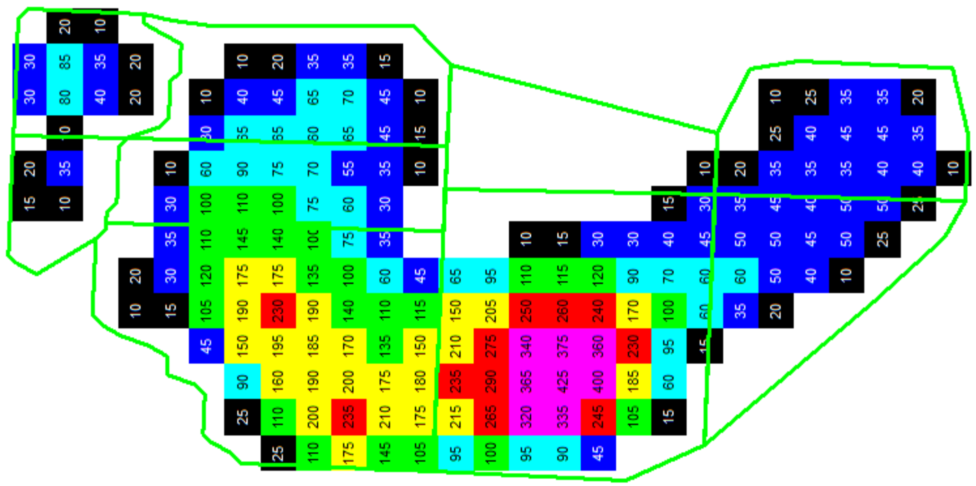


Figure 2.3F: Hindfoot valgus/varus, incomplete hindfoot contact and supination.

Inaccuracies: Externally rotate the hindfoot vertical dividing line to bisect the center of the hindfoot. For hindfoot valgus and varus only shift the hindfoot vertical dividing line, do not shift the forefoot. Shift the horizontal dividing lines proximally to account for the incomplete hindfoot contact. The forefoot appears to be accurate despite the supination.



Chapter 3 - Algorithm Development

Introduction

The goal of clubfoot treatment is to eliminate deformity resulting in a functional, pain-free, mobile, plantigrade foot that is free of calluses and does not require modified shoes [7, 9, 23]. Despite initial success rates >90%, the risk of reoccurrence after Ponseti Management is still high [4, 6-8, 11, 14]. Previous literature reports that 7-64% of children with clubfoot will experience a reoccurrence of deformity [5, 15-17]. A reoccurrence is defined as any deformity that requires treatment (surgical or non-surgical) post initial correction [5]. Previously, the most cited cause of reoccurrence was non-compliance with foot abduction orthosis [4, 5, 7, 11, 13, 15, 17, 18]. Bracing compliance is typically self-reported by the parent, however, self-report and actual wear rates are questionable [43]. Researchers have found that 78% of children who are noncompliant with bracing experience a reoccurrence, compared to only 7% of children who are compliant [17]. Other cited causes of reoccurrence are: low socioeconomic status [5], parental education level of less than high school [7], gender (females are 5x more likely to reoccur) [11, 19], initial severity rating (the higher the rating the more likely to reoccur) [19], decreased dorsiflexion range of motion [11, 15], and everter muscle weakness [11, 15].

Treatment for reoccurrence that is <6 months post initial correction is classified as incomplete correction [44]. Whereas, treatment for reoccurrence that is >6 months post initial correction is typically referred to as reoccurrence [44]. Early reoccurrence is considered to be at <3 years of age and can be treated successfully with repeat casting and adherence with foot abduction orthosis management [1]. Late reoccurrence is considered to be after the age of 4 years, with 44% of patients experiencing pain with ambulation [20]. Characteristics of a late reoccurring clubfoot are limited dorsiflexion, hindfoot varus, supination and in some cases cavus [20]. Treatment for late reoccurrence can be bracing, casting, tibialis anterior tendon transfer (TATT) with/or without tendon Achilles lengthening (TAL) and for severe cases comprehensive soft tissue release may be warranted [20].

Hindfoot equinus and varus deformities reoccur most often while midfoot and forefoot malalignments are less common [15]. The first symptom of hindfoot reoccurrence is when the hindfoot does not stay in shoe or abduction orthosis brace due to a plantar flexion contracture [18]. Mild dorsiflexion loss can be managed by repeat casting, however, if persistent dorsiflexion loss occurs the Achilles may need to be lengthened [18]. A repeat Achilles tenotomy or an Achilles lengthening can be performed if the clubfoot is not capable of 15 degrees of dorsiflexion [1]. Increased lateral contact during the stance phase of gait, due to supination or hindfoot varus, after the age of 2.5 years, can be an indication for tibialis anterior tendon transfer (TATT) [18]. After children with clubfoot are treated for reoccurrence, upwards of 20% will experience a second reoccurrence that requires additional interventions [45].

Clubfoot progression and reoccurrence is monitored through yearly, bi-yearly or quarterly office visits where a physician examines the patient. Treatment and intervention is typically only prescribed after the patient shows signs of reoccurrence. Clinicians are treating physical signs and symptoms of reoccurrence instead of prescribing preventative measures. If physicians could identify the patients at the highest risk of reoccurrence, a more proactive and individualized treatment plan and follow-up schedule could be devised. Early identification of patients at risk of reoccurrence would allow physicians to prescribe non-invasive interventions (i.e. bracing, casting, ankle foot orthosis, and physical therapy) that target the specific reoccurrence and reduce the patient's risk of requiring an invasive surgical procedure. Surgical releases, such as the posterior medial release, have a high complication rate (including infection, neurovascular injury, loss of limb and over-correction) and a 13-50% second recurrence rate [2, 6]. Less invasive methods, manipulation and casting have been shown to have the same or better long-term and short-term outcomes as surgical correction [3]. Therefore, the first course of treatment for a reoccurrence should be non-operative.

Foot pressure analysis is one of the most common biomechanical tools physicians utilize to track and monitor clubfoot progression. Researchers have found foot pressure analysis to be a valuable tool that provides an objective and reliable assessment of foot deformity and function [46]. The overall purpose of this study is to utilize foot pressure data to predict clubfoot reoccurrence for children with unilateral clubfoot deformity. The goal is to utilize retrospective foot pressure data, for subjects whose outcome is known, to build algorithms that predict the probability of developing a reoccurrence. Algorithms for the following reoccurrence scenarios will be developed: overall presence of reoccurrence (any non-operative or operative intervention), repeat casting, repeat tenotomy, Achilles lengthening and tibialis anterior tendon transfer. The hypothesis is that foot pressure data will be able to produce algorithms that can adequately explain the majority of the variance (≥50%) when predict the probability of reoccurrence. This is the first study to utilize foot pressure parameters to predict reoccurrence and the first to build algorithms for specific reoccurrence scenarios.

Methods

At the author's institution, foot pressure analyses are routinely collected using the Novel emed® x platform and stored in the Novel Database Pro M v.23.3.52 software (Novel Electronics, Munich Germany). Foot pressure data were exported, between the years of 2002 and 2012, for children who met the following inclusion criteria: underwent a foot pressure analysis between one to three years of age, diagnosis of unilateral clubfoot, treated with Ponseti casting and currently over the age of six years. A total of 77 subjects met the inclusion criteria (Figure 3.1).

A representative foot pressure trial for the affected side was chosen for analysis. Foot pressures were masked using a 10 area automated PRC mask (Figure 3.2) [27]. From this mask, a total of 11 regions of interest (ROI) were assessed; the total foot, hallux, 2nd toe, lateral toes, first metatarsal, second metatarsal, lateral metatarsals, medial midfoot, lateral midfoot, medial hindfoot and lateral hindfoot. Manual corrections, per guidelines outlined in Chapter 2, were used to address errors present in the automated mask.

Eighty-five parameters were identified for analysis: six foot pressure parameters applied to the 11 ROI, 10 foot pressure parameters unrelated to ROI and nine demographic parameters (Table 3.1). SPSS v.24 was used for all analyses (IBM, Armonk, NY). Utilizing all 85 parameters for prediction would not be appropriate due to a negative degrees of freedom(df); where df=sample size-number of predictors (77-85 = -8df). Previous researchers have recommended a 15:1 ratio for the number of subjects to the number of predictor variables [47]. Therefore, no more than six degrees of freedom will be utilized in this analysis.

In addition to degrees of freedom, multicolinearity can be a confound when moderate to high correlations exist among predictors [47]. Variance inflation factor (VIF) will be utilized to address multicolinearity. VIF assesses the degree of multicolinearity between the 85 variables when predicting the presence of reoccurrence. The parameter with the highest VIF is eliminated and the analysis is repeated. This process is repeated until the VIF for each remaining parameter is <0.5 [47].

The parameters with VIF of <0.5 were then used in a binomial logistic regression, backward elimination using the Wald Statistic. This analysis predicts the probability that an observation is classified into one dichotomous dependent variable based on the foot pressure and demographic predictor parameters. For this analysis, the reoccurrence scenarios were used as the dichotomous dependent variable, with the presences of the reoccurrence coded as 1 and the absence of reoccurrence 0. The model with the highest Nagelkerke R Square and with ≤6 predictor parameters was used to build the prediction algorithms. Less than 6 predictors were utilized to ensure proper degrees of freedom during analysis [47]. This process was repeated for each of the reoccurrence scenarios, resulting in five prediction equations. The result of each equation is a probability (p) between $0<p<1$, with ≥0.5 indicating the presences of reoccurrence and <0.5 indicating no reoccurrence.

Lastly, for each equation the odds ratio for each predictor parameter and the critical values for each continuous parameter will be reported. The odds ratio indicates the likelihood of reoccurrence based on each predictor variable. For every one unit increase in the parameter, the odds of reoccurrence will either increase (Odds Ratio >1) or decrease (Odds Ratio <1). This is only true for each parameter when all other parameters remain constant. For the continuous parameters, a critical value can be calculated using the following formula Critical Value = Intercept Constant/Parameter Constant. If the value of the parameter constant is positive, the critical value can be interpreted as a value greater than the critical value indicates reoccurrence. If the parameter constant is negative, the critical value can be interpreted as any value less than the critical value indicates reoccurrence.

Results

Population Demographics

Seventy-seven subjects were utilized in this retrospective analysis. Of these subjects, 74% (57/77) were male and 78% (60/77) had no family history of clubfoot deformity. The average age of the subjects at the time of foot pressure analysis was 2.5(0.7) years (Range 1.2-3.9 years). At the foot pressure evaluation, the average height of the subjects was 89.6(7.9) cm (Range 73-108 cm) and the average weight was 14.0(2.7) kg (Range 9-22.8 kg). Forty-two of the affected feet were left side involved (54.5%) and 35 were right (45.5%).

The following information on Ponseti management was limited as this was a retrospective review of the subject's medial record. The percentage of subjects for which data were available will be reported. Age at the initiation of Ponseti casting was 18.4(17.4) days (Range 4-88 days) for 69% (53/77) of the study population. The total number of casts required in 70% (54/77) of the subjects was 5.1(1.8) casts (Range 2-14 casts). At the end of casting, 78% (60/77) of subjects required a percutaneous tenotomy at the age of 67.3(24.5) days (Range 26-141 days). Age at the initiation of abduction orthosis wear was 81.8(44.3) days (Range 31-327 days) in 79% (61/77) of subjects. Age at the cessation of abduction orthosis wear for 95% (73/77) of subjects was 966.8(333.8) days (Range 136-1694 days).

Initially, the Dennis Brown Bar abduction orthosis was prescribed for all 77 subjects (Figure 3.3). Per review of the medical record, 56% (43/77) of subjects were compliant with the prescribed abduction orthosis bracing protocol. Of the 43 compliant subjects, four switched to Ponseti Shoes due to non-tolerance with the Dennis Brown Bar and were subsequently compliant. Of the 34 subjects (44%) that were non-compliant, the most cited cause was patient self-removal (25/34). Additionally, five subjects were lost to follow-up during the bracing period, three discontinued abduction orthosis use due to skin breakdown and one incident was due to parental non-compliance.

The age at the time of the first foot pressure analysis was 2.5(0.7) years. Age at the last follow up was 9.9(2.7) years (Range 5-15 years). At this time 79% of subjects (61/77) had private insurance and 70% (54/77) of subjects currently live above the poverty level. At follow-up, 55.8% (43/77) of subjects had experienced a reoccurrence. Table 3.2 presents the number of subjects and age at which they experienced the following reoccurrences: repeat casting, daytime wear of ankle foot orthosis, repeat percutaneous tenotomy, Achilles Lengthening (open or closed), tibialis anterior tendon transfer, plantar fascia release and a controlled ankle movement (CAM) boot. No subject in this retrospective study experienced a reoccurrence that required an extensive soft tissue release or boney procedure.

Masking Errors

Clubfoot deformity may cause the ROI to be inaccurately identified; in which case manual corrections need to be made [30]. A total of 19 subjects (25%) required corrections. Twenty inaccuracies were identified: the hallux was included in the first metatarsal region in eight subjects, the entire footprint could not be masked in eight subjects, the second toe mask was inaccurate in three subjects, and no hindfoot contact was present in one subject. For additional information on the cause and effect of each masking inaccuracy, refer to Chapter 2.

Algorithm Results

Binary Logistic Regression was used to build algorithms for the following reoccurrence scenarios: overall presence of reoccurrence, repeat casting, repeat tenotomy, Achilles lengthening, and tibialis anterior tendon transfer. The final prediction equation for each reoccurrence scenario is in Table 3.3 and the sensitivity and specificity of each equation is in Table 3.4.

The sensitivity of the algorithms ranged from 0.667-0.822, indicating that there is a 66.7-82.2% probability that the algorithms will correctly identify the subjects experiencing a reoccurrence. The specificity of the equations ranged from 0.813-0.932, indicating that there is an 81.3-93.2% probability that the algorithms will correctly identify the subjects that will not reoccur. The positive predictive values (PPV) range from 0.286-0.860. This indicates that if the algorithm predicts the patient will reoccur, there is a 28.6-86.0% chance that the subject actually reoccurred. The negative predictive values (NPV) range from 0.765-0.986. This indicates that if the algorithm predicts the patient will not reoccur there is a 76.5-98.6% chance that they will not reoccur.

Overall Reoccurrence Rate

Binary logistic regression indicates an overall model significance of $p<0.001$ that explains 55.5% of the variance in the overall rate of clubfoot reoccurrence for children with unilateral clubfoot (Chi-Square = 41.219, df = 6). Contact time of the first metatarsal, instant of peak pressure of the lateral metatarsals, contact area of medial hindfoot, age at the first emed visit, and abduction orthosis compliance are all significant predictors at an alpha level of 0.05 (Table 3.5). Age at the last follow-up was not a significant predictor. Odds ratio and critical values are presented in Tables 3.6 and 3.7. The model correctly predicts 76.5% of subjects that will not reoccur and 86% of subjects that will reoccur, with an overall percentage correct prediction rate of 81.8% (Table 3.8).

Repeat Casting

Binary logistic regression indicates an overall model significance of $p<0.001$ that explains 35% of the variance when predicting the probability of repeat casting (Chi-square=18.01, df=3). Abduction shoe compliance was significant at $p=0.001$ and contact area of the medial hindfoot was significant at the $p=0.05$ (Table 3.9). Contact area of the first metatarsal was not a significant predictor. The odds ratio and critical value calculations are presented in Table 3.10 and Table 3.11 respectively. The model correctly predicts 96.9% of subjects that will not require repeat casting and 38.5% of subjects that will require repeat casting, with an overall percentage correct prediction rate of 87.0% (Table 3.12).

Repeat Tenotomy

Binary logistic regression indicates that abduction orthosis compliance is the only significant ($p=0.021$) predictor of repeat tenotomy (Chi-square=17.195, df=4 and $p<0.001$). Instant of peak pressure in the medial midfoot, maximum force in the lateral midfoot and instant of peak pressure of the lateral toes are all non-significant predictors of repeat tenotomy. The model explains 43.9% of the variability of repeat tenotomy as a treatment for clubfoot reoccurrence in children with unilateral clubfoot (Table 3.13). The odds ratio and critical values are listed in Tables 3.14 and 3.15 respectively. The model correctly predicts 98.6% of subjects that will not require repeat tenotomy and 26.8% of subjects that will require repeat tenotomy, with an overall percentage correct prediction rate of 92.2% (Table 3.16).

Achilles Lengthening

Binary logistic regression indicates a significant model ($p<0.001$) that explains 50.3% of the variability when predicting the probability of Achilles lengthening for children with unilateral clubfoot (Chi-square=29.173, df=6). Instant of peak pressure in the lateral midfoot and peak pressure of the hallux were significant at $p<0.05$ and gender, instant of maximum force in the first metatarsal, contact area of the hallux and the forefoot width were significant at $p<0.001$ (Table 3.17). The odds ratio and critical value are listed in Tables 3.18 and 3.19 respectively. The model correctly predicts 96.8% of subjects that will not require Achilles lengthening and 53.3% of subjects that will require Achilles lengthening, with an overall percentage correct prediction rate of 88.3% (Table 3.20).

Tibialis Anterior Tendon Transfer

Binary logistic regression indicates a significant model ($p<0.001$) that explains 58.9% of the variance when predicting the probability of TATT for children with unilateral clubfoot (Chi-square=44.456, df=6). Midfoot width and maximum force of the lateral midfoot were significant at $p<0.05$ and contact area of the medial hindfoot, instant of maximum force of the lateral midfoot, and instant of maximum force for the second metatarsal were significant at $p<0.01$ (Table 3.21). Instant of peak pressure of the total foot was not a significant predictor. The odds ratio and critical value are presented in Tables 3.22 and 3.23 respectively. The model correctly predicts 86.4% of subjects that will not require TATT and 78.8% of subjects that will require TATT, with an overall percentage correct prediction rate of 83.1% (Table 3.24).

Discussion

The purpose of this study was to use retrospective foot pressure data to build algorithms that predict the following reoccurrence scenarios for children with unilateral clubfoot: overall presence of reoccurrence, repeat casting, repeat tenotomy, Achilles lengthening and tibialis anterior tendon transfer. The resulting five equations (Table 3) utilized a combination of foot pressure parameters and demographic parameters to predict reoccurrence. Table 3.25 presents a summary of the predictor parameters utilized in the five prediction equations.

The Nagelkerke R Square (R^2) for the five reoccurrence scenarios ranged from 0.35-0.59. This is a measure of the goodness of fit of the overall model and describes the percentage of variability the predictor parameters explain[47]. The models with the highest R^2 predicted TATT (R^2=0.59) and the overall chance of any reoccurrence (R^2=0.56). In addition, these models reported PPV values of 0.86 for overall reoccurrence and 0.79 for TATT. Indicating that in the case of the model predicting the subject would experience a reoccurrence, the overall reoccurrence model would be accurate 86% of the time and the TATT model would be correct 79% of the time. The models for repeat casting (R^2=0.35), repeat tenotomy (R^2=0.44) and Achilles lengthening (R^2=0.50) had moderate to low positive predictive values, 0.38, 0.29 and 0.53 respectively. However, the negative predictive values were high for these three measures: 0.97, 0.99, and 0.90 respectively. Indicating that these models were more accurate when predicting the absence of reoccurrence than the presence of reoccurrence.

Overall Reoccurrence Model

The odds ratio explains the likelihood of reoccurrence for every one unit of increase in the significant predictor parameter, with <1 indicating decreased odds of reoccurring and >1 an increased odds of reoccurring. However, the interpretations are only true when all other parameters remain constant. The model for overall reoccurrence utilized six parameters, five of which were significant predictors. Odds ratios report that bracing compliance, increased contact area in the hindfoot and increased contact time in the first metatarsal decrease the odds of reoccurring. Increased contact area in the hindfoot and increased contact time on the first metatarsal indicate that there is not equinus and that proper hindfoot to forefoot gait is observed. In addition, increased time to peak pressure in the lateral metatarsals and the age at the initial foot pressure are all indicators of increased odds of reoccurring. The chance of reoccurrence increases between ages 3-5 due to rapid growth [15], therefore as age of the subject when the prediction algorithms are applied increases, so does the chance that the subject will be of an age to experience a reoccurrence.

Repeat Casting Model

The model for repeat casting utilized three parameters, two of which were significant; abduction orthosis compliance (p=0.005), contact area medial hindfoot (p=0.014) and contact area of the first metatarsal (p=0.071). Odds ratio indicate that an increase in contact area of the hindfoot and bracing compliance both decrease the odds of requiring repeat casting. Repeat casting is a non-operative treatment utilized for equinus reoccurrence. The odds ratio concurs with previous literature, where casting has been shown to increase the contact area in the hindfoot [48]. However, the matter of early versus late recasting was not addressed when devising the model for repeat casting. Early casting, within the first six months post-initial correction, could be due to incomplete correction (4 subjects); whereas late casting is more likely due to reoccurrence of deformity (9 subjects) [44]. All 13 subjects that required repeat casting were included for statistical analysis; no distinction was made between incomplete corrections versus reoccurrences.

Repeat Tenotomy Model

The presence of hindfoot equinus, that may or may not have responded to repeat casting, is an indicator that a repeat percutaneous Achilles tenotomy may be required. The model predicting repeat tenotomy utilizes four parameters, of which only one was significant: abduction orthosis compliance (p=0.021), instant of peak pressure in the medial midfoot (p=0.178), maximum force lateral midfoot (p=0.053) and instant of peak pressure in the lateral toes (p=0.132). Odds ratio states that bracing compliance will decrease the odds of repeat tenotomy by 0.963. These results support the findings of previous researchers; where hindfoot equinus is one of the most common reoccurrences of deformity and the most important factor for preventing reoccurrence is bracing compliance [4, 5, 7, 11, 13, 15, 17, 18].

Achilles Lengthening Model

Achilles lengthening has been found to be a successful treatment for persistent or worsening equinus and if often performed in conjunction with TATT [18, 20]. Dorsiflexion of less than 15 degrees is the clinical criteria for performing an Achilles lengthening [18]. The model for predicting Achilles lengthening utilizes six significant predictor parameters: gender (p=0.01), instant of peak pressure lateral midfoot (p=0.05), instant of maximum force first metatarsal (p<0.001), contact area of the hallux (p=0.01), peak pressure of the hallux (p=0.01) and forefoot width (p<0.001). Odds ratios state that as instant of peak pressure in the lateral midfoot, instant of maximum force of the first metatarsal, peak pressure of the hallux and forefoot width increase the odds of requiring an Achilles lengthening also increase. In addition, the odds of Achilles lengthening decreases as the contact area of the hallux increases. Interestingly, being female will also decrease the odds of Achilles lengthening by 0.946. Previous research has presented confounding evidence on the issue of gender and clubfoot deformity. Several researchers have concluded that gender does not influence the severity of clubfoot deformity [49] and was not a predictor for Achilles tenotomy [50]. Contrastingly, other researchers found that females were 5x as likely to have a reoccurrence as males [11, 19]. Due to the conflicting evidence on the effects of gender on clubfoot disease progression, clinicians should take caution when utilizing gender as a predictor of Achilles lengthening.

Tibialis Anterior Tenon Transfer (TATT) Model

Dynamic supination originates from a combination of over pull of the anterior tibialis tendon (ATT) and weak peroneal muscles [11, 51]. TATT is the most often performed surgery for the treatment of supination deformity and 14-50% of children with clubfoot will require a TATT [4, 5, 11, 13, 21, 51, 52]. The model for TATT includes six parameters, four of which are significant: instant of peak pressure total foot (p=0.134), contact area medial hindfoot (p=0.013), instant of maximum force lateral midfoot (p=0.007), maximum force lateral midfoot (p=0.011), instant of maximum force second metatarsal (p=0.002) and midfoot width (p=0.07). These results are in agreement with previous research. TATT has been shown to decrease pressure, force, contact area and contact time on the lateral side of the foot and increase these parameters on the medial side of the foot [30, 53]. In addition, decreased supination will increase the contact area of the medial foot, thus increasing the midfoot width.

Prevalence of Reoccurrence

The prevalence of subjects that required a treatment for reoccurrence was high for overall reoccurrence (55.8%) and TATT (45%) and low for repeat casting (17%), repeat tenotomy (9%) and Achilles lengthening (19%). The equations with high prevalence of reoccurrence also had the highest R^2 values. The models for overall reoccurrence and TATT had close to a 2:1 ratio of subjects with reoccurrence to those without reoccurrence. This allowed the models to be more robust when identifying outcomes. In addition to high R^2 values, the models reported high sensitivity and specificity; indicating that the algorithms for TATT and overall reoccurrence are accurate and reliable and should be taken into consideration by physicians.

The models for repeat casting (R^2=0.35 and PPV=0.39), repeat tenotomy (R^2=0.439 and PPV=0.286) and Achilles lengthening (R^2=0.50 and PPV=0.53) had low R^2 and low positive predictive values (PPV). Overall, the algorithms were more likely to detect the absence of reoccurrence than the presence of reoccurrence. One possible explanation for this disparity could be the few number of subjects that required these interventions. A lower prevalence of reoccurrence would allow for a larger margin of error because the ratio of the number of subjects that experienced these reoccurrences to the total population was small. Clinicians should take caution when interpreting predictive results for repeat casting, repeat tenotomy and Achilles lengthening due to the low sample sizes utilized.

Potentially Important Predictive Parameters

Three parameters were found to be significant variables in more than one prediction equation; abduction orthosis compliance, contact area of medial hindfoot and maximum force in the lateral midfoot (Table 3.25). This is an indication that these parameters may be of unique importance when predicting reoccurrence for children with unilateral clubfoot.

Abduction orthosis compliance is a predictor for overall reoccurrence, repeat casting and repeat tenotomy. Bracing non-compliance has been cited by numerous researchers as one of the most important indicators of reoccurrence [4, 5, 7, 11, 13, 15, 17, 18]. Researchers have found that 91% of subjects will comply with brace wear in the first month, 74% will be compliant by the 3rd month and by age 4 only 54% will continue to be compliant [5, 43, 54]. On average, 78% of children who are noncompliant with brace wear will have a reoccurrence, compared to only 7% in those who are compliant[54]. In addition, 30-49% of families self-report non-compliance with foot orthosis bracing [7, 52]. The most common reasons for non-compliance as the inconvenience of wearing the brace 23 hours a day [7] and improper fit due to deformity [52]. Children who are intolerant of bracing, for any reason, are at a high risk for reoccurrence [1]. It is therefore no surprise that bracing compliance is a significant predictor utilized in three equations.

Contact area of the medial hindfoot is also utilized in three equations: overall reoccurrence, repeat casting and TATT. Odds ratios for these equations indicate that an increase in contact area of the medial hindfoot decreases the odds of reoccurrence. Thus, a decrease in contact area of the medial hindfoot would increase the odds of reoccurrence. Hindfoot equinus and supination will both decrease the contact area of the hindfoot. Non-surgical treatment for hindfoot equinus is repeat casting and the treatment for supination is TATT [1, 18]. Therefore, the utilization of this parameter in more than one prediction equation is evident.

Maximum force of the lateral midfoot is a significant parameter in two equations, repeat tenotomy and TATT. High force on the lateral foot is an indication of supination deformity, which is a clinical indicator for TATT. The odds ratio for this parameter is in agreement with the clinical indicator, an increase in maximum force of the lateral midfoot increases the odds of TATT. In addition, odds ratio indicates that an increase in contact area of the lateral midfoot decreases the odds of requiring a repeat tenotomy. Equinus deformity causes excessive plantar flexion. This leads to a decrease in hindfoot ground contact, and in severe cases, only forefoot contact. If there is more contact in the lateral midfoot, this could be an indication that there is increased contact proximally (i.e. less equinus).

Limitations

Fifty percent of all clubfoot cases are bilateral l[55], however, researchers and clinicians have yet to conclude on the effects of laterality on clubfoot disease progression. Several researchers have found using bilateral and unilateral clubfeet in the same analysis confounding [3]. Bilateral clubfeet tend to be highly correlated; 85% have the same severity classification score, 89% of bilateral patients reoccur bilaterally, the need for tenotomy is not different bilaterally and the mean number of casts applied bilaterally is not significantly different [56]. It has been recommended that only one side for a subject with bilateral clubfoot be used for data analysis, as the use of both clubfeet could artificially inflate sample size and lead to false conclusions [55, 56]. Due to these recommendations, only unilateral clubfoot subjects were utilized in this study. Therefore, the use of the algorithms developed in this study should only be applied to children with unilateral clubfoot. The effects of bilaterality on the predictive algorithms needs to be investigated. Separate algorithms may need to be developed for bilateral clubfoot subjects.

When assessing the presence of reoccurrence, no distinction was made between incomplete corrections versus reoccurrence. Interventions that are <6 months post initial correction should be referred to as incomplete correction [44]. Whereas, interventions >6 months post initial correction should be referred to as reoccurrence [44]. Repeat casting is an intervention that could take place during the first 6 months post initial treatment. Of the 13 subjects that required repeat casting, 4 were cast at the age of 79(9) days of age (Range 68-88 days of age) and should be classified as incomplete correction. The remaining 9 subjects were cast at the age of 1204(1210) days of age (range 239-4245 days of age) and should be classified as reoccurrence. However, all 13 subjects were utilized during the formation of the prediction equation for repeat casting. This is a potential confound and could explain the low sensitivity and positive predictive value of this equation. In future iterations of this research, a distinction between incomplete correction and recurrence should be made.

The equation for overall reoccurrence utilized two age related predictors; age at the foot pressure visit and age at the follow-up. The algorithms for TATT and overall reoccurrence were developed utilizing foot pressure data from children at age 2 years. Therefore, it is recommended that the algorithms be utilized between the ages of 1.5-2.5 years. If the algorithms are applied at the same time the initial foot pressure is collected, then the two age parameters would be the same. However, these algorithms could be applied to children who are >2 years of age. If the subject is younger than 5 years, they are still at a high risk of reoccurring. The algorithms could be applied at any time, from age 3-7, when a child with clubfoot is at the highest risk of reoccurring. However, application at a time other than that of the first foot pressure visit, may influence algorithm results; as the age at the last follow-up may will be different from the age at the first foot pressure analysis.

Conclusions

The purpose of this study was to utilize retrospective foot pressure data to build algorithms that predict reoccurrence of clubfoot deformity. Algorithms for the following reoccurrence scenarios were developed: overall presence of reoccurrence, repeat casting, repeat tenotomy, Achilles lengthening and tibialis anterior tendon transfer. A combination of foot pressure parameters and demographic information was utilized to produce algorithms that explained the highest amount of variance while utilizing six degrees of freedom. The equations predicting overall reoccurrence and TATT were robust, with high R^2 and high sensitivity and specificity, when predict the probability of reoccurrence. Whereas, the equations for repeat casting, repeat tenotomy and Achilles lengthening were less robust due to the lower prevalence of subjects who required these interventions. Therefore, the hypothesis of this study was accepted for overall reoccurrence and TATT, but was rejected for repeat casting, repeat tenotomy and Achilles lengthening.

Future direction of this research will be to validate the use of these algorithms in a clinical setting. Based on the results of this investigation, the following recommendation can be made for the prospective application of the algorithms:

1. The algorithms for overall reoccurrence and TATT are robust and should be utilized in the clinical setting. The algorithms for repeat casting, repeat tenotomy and Achilles lengthening should be used with caution.
2. These algorithms should only be used in unilateral clubfoot subjects. More investigation is required for the application of these algorithms in a bilateral clubfoot population.
3. The application of the algorithms should be at the age of 2 years. Application after this time may influence algorithm results, as the age at the last follow-up may well be different from the age at the first foot pressure analysis. An investigation of algorithm results with increasing/decreasing age at application should be undertaken. It may be necessary to develop algorithms for different/multiple ages of application.

This is the first study to utilize foot pressure parameters to predict reoccurrence and the first to build algorithms for specific reoccurrence scenarios. The algorithms developed in this study have the potential to change standard treatment protocols of clubfoot deformities. Previously, the most common way to identify reoccurrence was to wait until the subject presented with visible signs and symptom. By utilizing the predictive algorithms herein, clinicians will be able to proactively utilize non-operative treatments prior to reoccurrence. This may lessen the chance of the subject reoccurring, and potentially lessen the chance that the subject will undergo an invasive surgical procedure. The use of these algorithms will help clinicians treat a reoccurring clubfoot efficiently and proactively, thus achieving the goal of clubfoot treatment; eliminate deformity resulting in a functional, pain-free, mobile, and plantigrade foot [7, 9, 23].

Table 3.1: Parameters utilized for analysis. Descriptions of foot pressure parameters were taken from the Novel Manual[27].

ROI Foot Pressure Parameters	**Description**	**Abbreviation**
Contact Area (cm^2)	The average area over which pressure is applied within a mask.	CA
Contact Time (ms)	Amount of time a masked ROI is in contact with the pressure plate.	CT
Instant of Maximum Force (%ROP)	The instant of time, as a percentage of the entire roll over process, where the highest total force occurs within a mask.	IMF
Instant of Peak Pressure (%ROP)	The instant of time, as a percentage of the entire roll over process, where the highest pressure value occurred in a mask.	IPP
Maximum Force (%Bodyweight)	The highest total force that occurred within a mask, normalized to body weight.	MF
Peak Pressure (kPa)	The highest pressure within a mask at any point in the roll over process.	PP
Non-ROI Foot Pressure Parameters	**Description**	**Abbreviation**
Hindfoot Width (cm)	Distance between the two widest points on the hindfoot	HW
Forefoot Width (cm)	Distance between the lateral border of the forefoot to the medial border of the forefoot at the widest point.	FFW
Midfoot Width (cm)	Distance between two points across the widest portion of the midfoot.	MW
Foot Length (cm)	The length of the foot contact area, from proximal to distal.	FL

Table 3.1: Continued

Medial Force-Time Integral	Area under the force time curve for the medial foot	MFTI
Lateral Force-Time Integral	Area under the force time curve for the lateral foot	LFTI
Lateral/Medial Force-Time Integral Index	The difference between the lateral and the medial force-time integral.	LMFTII
Medial Contact Area (cm^2)	Area for the medial side of the gait line	MCA
Lateral Contact Area (cm^2)	Area for the lateral side of the gait line	LCA
Lateral/Medial Area Index	The ratio of the difference between the lateral and medial area to the total area over time	LMAI
Demographic Parameters	**Description**	**Abbreviation**
Age at First Foot Pressure Analysis (years)	The age of the subject at the foot pressure visit that was between the ages of 1-3 years. If the subject had multiple visits during this age range, the visit closest to 2 years of age was utilized.	Initial Age
Age at Last Follow-up (years)	The age of the subject at the last clinical follow-up. Per inclusion criteria all subjects will be at least 6 year of age or older at the time of the last follow-up.	Follow-up Age
Gender	Male (1) or Female (0)	Gender
Affected Side	Right (1) or Left (0) Side Involved	Affected Side

Table 3.1: Continued

Insurance Type	Medicaid was classified as public insurance (1), non-Medicaid was classified as private (0).	Insurance
Poverty	The subject's zip code was entered into the United States Census Bureau Fact Finder website (https://factfinder.census.gov). Using the 2016 census data, income, family size and age of family members was used to define the percentage of the population in a given area that is considered to live in poverty. If >20% of the population is below the poverty line, the subject was considered to live in an impoverished tract [1]. Poverty(0), Non-Poverty(1)	Poverty
Family History of Clubfoot	The subject was considered to have a family history of clubfoot if a member of the immediate or extended family was also diagnosed with clubfoot deformity. Family History (1), No Family History (0)	Family History
Abduction Orthosis Compliance	The treating physician documents abduction orthosis compliance in the subject's medical record. If the physician stated that the subject was complaint and the orthosis was worn until physician ended, then the subject was considered compliant. Compliance (1), Non-compliance (0)	Compliance
Tenotomy	Tenotomy refers to the use of percutaneous tenotomy of the Achilles tendon at the end of Ponseti casting. A tenotomy is warranted in the presence of residual equinus post-casting. Tenotomy (1), No Tenotomy (0)	Tenotomy

Table 3.2: Reoccurrence rates for the 77 subjects.

Reoccurrence	**Number of Subjects**	**% of Total Subjects**	**Average Age (days)**	**Age Range (days)**	**Note**
Total Repeat Casting	13	17%	858(1126)	68-4245	Combined early and late recasting.
Early Recasting	4	5%	79(9)	68-88	3.8(1.0) Casts; Range 3-5
Late Recasting	9	12%	1204(1210)	239-4245	2.7(1.7) Casts; Range 1-6
Second Repeat Casting	5	6%	1543(1056)	127-2626	
Ankle Foot Orthosis	16	21%	1660(941)	202-4018	
Repeat Tenotomy	7	9%	495(310)	108-945	
Achilles Lengthening	15	19%	1572(792)	658-3974	
Tibialis Anterior Tendon Transfer	35	45%	1592(638)	694-3974	
Plantar Fascia Release	4	5%	2510(1024)	1475-3919	
Controlled Ankle Movement Boot	10	13%			

Table 3.3: Equations used to predict reocurrence.

Type of Reocurrence	Equation	Parameters
Overall Reocurrence	$p = \frac{e^{(-0.005_a+0.087_b+1.53_c-1.311_d-1.022_e+0.192_f-4.364)}}{1-e^{(-0.005_a+0.087_b+1.53_c-1.311_d-1.022_e+0.192_f-4.364)}}$	a)contact time first metatarsal, b)instant of peak pressure lateral metatarsals, c)age at initial foot pressure (years), d)abduction orthosis compliance (compliance=1, non-compliance=0), e)contact area medial hindfoot, f)age at last follow-up (years)
Repeat Casting	$p = \frac{e^{(-2.619_a-0.941_b+0.414_c+3.137)}}{1-e^{(-2.619_a-0.941_b+0.414_c+3.137)}}$	a)abduction orthosis compliance (compliance=1, non-compliance=0), b)contact area medial hindfoot, c)contact area first metatarsal
Repeat Tenotomy	$p = \frac{e^{(-3.283_a-0.074_b-0.066_c+0.090_d-3.628)}}{1-e^{(-3.283_a-0.074_b-0.066_c+0.090_d-3.628)}}$	a)abduction orthosis compliance (compliance=1, non-compliance=0), b)instant of peak pressure medial midfoot, c)maximum force lateral midfoot, d)instant of peak pressure lateral toes
Achilles Lengthening	$p = \frac{e^{(-2.92_a+0.050_b+0.070_c-1.380_d+0.020_e+1.330_f-11.54)}}{1-e^{(-2.92_a+0.050_b+0.070_c-1.380_d+0.020_e+1.330_f-11.54)}}$	a)gender (male=1,female=0), b)instant of peak pressure lateral midfoot, c)instant of maximum force first metatarsal, d)contact area hallux, e)peak pressure hallux, f)forefoot width
Tibialis Anterior Tendon Transfer	$p = \frac{e^{(0.018_a-1.013_b-0.073_c+0.048_d+0.116_e-0.950_f-1.882)}}{1-e^{(0.018_a-1.013_b-0.073_c+0.048_d+0.116_e-0.950_f-1.882)}}$	a)instant of peak pressure total foot, b)contact area medial hindfoot, c)instant of maximum force lateral midfoot, d)maximum force lateral midfoot, e)instant of maximum force second metatarsal, f)midfoot width

Table 3.4: Sensitivity, specificity, positive predictive value and negative predictive value for each prediction equation.

Type of Reoccurrence	**Sensitivity**	**Specificity**	**Positive Predictive Value**	**Negative Predictive Value**
Overall Reoccurrence	0.822	0.813	0.860	0.765
Repeat Casting	0.714	0.886	0.385	0.969
Repeat Tenotomy	0.667	0.932	0.286	0.986
Achilles Lengthening	0.800	0.896	0.533	0.968
Tibialis Anterior Tendon Transfer	0.813	0.844	0.788	0.864

Table 3.5: Predictors for overall reoccurrence rate.

Parameter	Constant (B)	Standard Error	Wald	p-value	Odds Ratio (ExpB)	95% Confidence Interval for Odds Ratio	
						Lower	Upper
Contact Time First Metatarsal	-0.005	0.002	5.622	0.018	0.995	0.990	0.999
Instant of Peak Pressure Lateral Metatarsals	0.087	0.041	4.566	0.033	1.091	1.007	1.182
Age at Initial Foot Pressure	1.530	0.571	7.174	0.007	4.620	1.508	14.155
Abduction Orthosis Compliance Yes = 1, No=0	-1.311	0.656	4.002	0.045	0.269	0.075	0.974
Contact Area Medial Hindfoot	-1.022	0.392	6.792	0.009	0.360	0.167	0.776
Age at Last Follow-up	0.192	0.125	2.371	0.124	1.212	0.949	1.547
Constant	-4.364	3.590	1.478	0.224	0.013		

Table 3.6: Odds ratio interpretation for predicting overall reoccurrence. *These interpretations are only true when all other parameters remain constant.

Parameter	**Odds Ratio**	**Interpretation**
Contact Time First Metatarsal	0.995	For every 1ms increase in contact time of the first metatarsal the odds of reoccurring decrease by 0.005
Instant of Peak Pressure Lateral Metatarsals	1.091	For every 1% increase in ROP time of the lateral metatarsals the odds of reoccurring increase by 1.091.
Age at Initial Foot Pressure	4.620	For every 1 year of age increase the odds of reoccurring increase by 4.620.
Abduction Orthosis Compliance Yes = 1, No=0	0.269	Bracing compliance decreases the odds of reoccurrence by 0.731.
Contact Area Medial Hindfoot	0.360	For every $1cm^2$ increase in contact area of the medial hindfoot the odds of reoccurrence decrease by the odds of 0.640

Table 3.7: Critical value interpretation for predicting overall reoccurrence for continuous variables.

Parameter	**Constant**	**Critical Value**	**Interpretation**
Contact Time First Metatarsal	-0.005	818.929	If the contact time of the first metatarsal is <818.9ms the model predicts the subject will experience a reoccurrence
Instant of Peak Pressure Lateral Metatarsals	0.087	49.934	If the instant of peak pressure of the 3rd-5th metatarsals is >50% of the ROP the model predicts the subject will experience a reoccurrence.
Age at Initial Foot Pressure	1.530	2.852	If the age at the first foot pressure visit is >2.85 years of age, the model predicts the subject will experience a reoccurrence.
Contact Area Medial Hindfoot	-1.022	4.270	If the contact area of the medial hindfoot is <4.2cm^2 the model predicts the subject will experience a reoccurrence.

Table 3.8: 2x2 Classification Table for predicting overall reoccurrence rate.

	Predicted Did Not Reoccur	**Predicted Reoccurred**	**Percentage Correct (%)**
Observed Did Not Reoccur	26	8	76.5
Observed Reoccurred	6	37	86
Overall Rate			81.8

Table 3.9: Predictors for repeat casting.

Parameter	Constant (B)	Standard Error	Wald	p-value	Odds Ratio (ExpB)	95% Confidence Interval for Odds Ratio	
						Lower	Upper
Abduction Orthosis Compliance	-2.619	0.927	7.983	0.005	0.073	0.012	0.448
Contact Area Medial Hindfoot	-0.941	0.384	6.007	0.014	0.39	0.184	0.828
Contact Area 1st Metatarsal	0.414	0.229	3.268	0.071	1.513	0.966	2.372
Constant	3.137	2.065	2.308	0.129	23.036		

Table 3.10: Odds ratio interpretation for predicting repeat casting. *These interpretations are only true when all other parameters remain constant.

Parameter	**Odds Ratio**	**Interpretation**
Abduction Orthosis Compliance	0.073	Bracing compliance decreases the odds of repeat casting by 0.927.
Contact Area Medial Hindfoot	0.390	For every 1 cm^2 increase of contact area in the medial hindfoot, the chance of repeat casting decreases by the odds of 0.610.

Table 3.11: Critical value interpretation for predicting repeat casting for the significant continuous variable of contact area of the medial hindfoot.

Parameter	**Constant**	**Critical Value**	**Interpretation**
Contact Area Medial Hindfoot	-0.941	-3.330	If the contact area of the medial hindfoot is <3.3cm^2 then the model predicts the subject will require repeat casting.

Table 3.12: 2x2 Classification Table for predicting repeat casting.

	Predicted No Repeat Casting	**Predicted Repeat Casting**	**Percentage Correct**
Observed No Repeat Casting	62	2	96.9
Observed Repeat Casting	8	5	38.5
Rate			87

Table 3.13: Predictors for repeat tenotomy.

						95% Confidence Interval for Odds Ratio	
Parameter	**Constant (B)**	**Standard Error**	**Wald**	**p-value**	**Odds Ratio (ExpB)**	**Lower**	**Upper**
Abduction Orthosis Compliance	-3.283	1.420	5.343	0.021	0.037	0.002	0.607
Instant of Peak Pressure Medial Midfoot	-0.074	0.055	1.810	0.178	0.928	0.833	1.035
Maximum Force Lateral Midfoot	-0.066	0.034	3.745	0.053	0.936	0.876	1.001
Instant of Peak Pressure Lateral Toes	0.090	0.060	2.273	0.132	1.094	0.973	1.230
Constant	-3.628	5.077	0.511	0.475	0.027		

Table 3.14: Odds ratio interpretation for predicting repeat tenotomy. *These interpretations are only true when all other parameters remain constant.

Parameter	Odds Ratio	Interpretation
Abduction Orthosis Compliance	0.037	Bracing compliance decreases the odds of reoccurrence by 0.963.
Instant of Peak Pressure Medial Midfoot	0.928	For every 1(%ROP) increase in the instant of peak pressure in the medial midfoot the odds of requiring a repeat tenotomy decreases by 0.072.
Maximum Force Lateral Midfoot	0.936	For every 1(%bw) increase in the maximum force of the lateral midfoot, the odds of requiring a repeat tenotomy decreases by 0.064.
Instant of Peak Pressure Lateral Toes	1.094	For every 1(%ROP) increase in the instant of peak pressure in the lateral toes the odds of requiring a repeat tenotomy increases by 1.094.

Table 3.15: Critical value interpretation for predicting repeat tenotomy for the significant continuous variable of contact area of the medial hindfoot.

Parameter	**Constant**	**Critical Value**	**Interpretation**
Instant of Peak Pressure Medial Midfoot	-0.074	49.027	If the Instant of Peak Pressure of the Medial Midfoot is <49(%ROP) the model predicts the subject will require repeat tenotomy.
Maximum Force Lateral Midfoot	-0.066	54.970	If the Maximum Force of the Lateral Midfoot is <55(%bw) the model predicts the subject will require repeat tenotomy.
Instant of Peak Pressure Lateral Toes	0.090	-40.311	If the Instant of Peak Pressure of the Lateral Toes is >40(%ROP) the model predicts the subject will require repeat tenotomy.

Table 3.16: 2x2 Classification Table for predicting repeat tenotomy.

	Predicted No Repeat Tenotomy	**Predicted Repeat Tenotomy**	**Percentage Correct**
Observed No Repeat Tenotomy	69	1	98.6
Observed Repeat Tenotomy	5	2	28.6
Rate			92.2

Table 3.17: Predictors for Achilles lengthening.

						95% Confidence Interval for Odds Ratio	
Parameter	**Constant(B)**	**Standard Error**	**Wald**	**p-value**	**Odds Ratio (ExpB)**	**Lower**	**Upper**
Gender	-2.924	1.071	7.459	0.006	0.054	0.007	0.438
Instant of Peak Pressure Lateral Midfoot	0.049	0.025	3.882	0.049	1.050	1.000	1.102
Instant of Maximum Force First Metatarsal	0.067	0.022	9.309	0.002	1.069	1.024	1.117
Contact Area Hallux	-1.383	0.506	7.466	0.006	0.251	0.093	0.676
Peak Pressure Hallux	0.017	0.008	4.970	0.026	1.017	1.002	1.033
Forefoot Width	1.331	0.467	8.113	0.004	3.784	1.514	9.455
Constant	-11.536	3.879	8.844	0.003			

Table 3.18: Odds ratio interpretation for predicting Achilles lengthening. *These interpretations are only true when all other parameters remain constant.

Parameter	**Odds Ratio**	**Interpretation**
Gender	0.054	Being female decreases the odds of requiring an Achilles lengthening by 0.946
Instant of Peak Pressure Lateral Midfoot	1.050	For every 1(%ROP) increase in the instant of peak pressure of the lateral midfoot, the odds of requiring Achilles lengthening increase by 1.05.
Instant of Maximum Force First Metatarsal	1.069	For every 1(%ROP) increase in the instant of maximum force of the first metatarsal, the odds of requiring Achilles lengthening increase by 1.069.
Contact Area Hallux	0.251	For every 1(cm^2) increase in contact area of the hallux, the odds of requiring an Achilles lengthening decrease by 0.749
Peak Pressure Hallux	1.017	For every 1kPa increase in peak pressure of the hallux, the odds of requiring an Achilles lengthening increase by 1.017.
Forefoot Width	3.784	For every 1cm increase in forefoot width, the odds of requiring an Achilles lengthening increase by 3.784.

Table 3.19: Critical value interpretation for predicting Achilles lengthening for the significant continuous variable of contact area of the medial hindfoot.

Parameter	**Constant**	**Critical Value**	**Interpretation**
Instant of Peak Pressure Lateral Midfoot	0.049	-237.394	No physiologic value would satisfy the critical value. Therefore, this parameter is uninterpretable.
Instant of Maximum Force First Metatarsal	0.067	-171.798	No physiologic value would satisfy the critical value. Therefore, this parameter is uninterpretable.
Contact Area Hallux	-1.383	8.345	If the contact area of the hallux is <8cm^2, the model predicts the subject will require an Achilles lengthening.
Peak Pressure Hallux	0.017	-675.724	If the peak pressure of the hallux is >676kPa, the model predicts the subject will require an Achilles lengthening.
Forefoot Width	1.331	-8.672	If the forefoot width is >8.7cm, the model predicts the subject will require an Achilles lengthening.

Table 3.20: 2x2 Classification Table for predicting Achilles lengthening.

	Predicted No Achilles Lengthening	**Predicted Achilles Lengthening**	**Percentage Correct**
Observed No Achilles Lengthening	60	2	96.8
Observed Achilles Lengthening	7	8	53.3
Overall Rate			88.3

Table 3.21: Predictors for tibialis anterior tendon transfer.

Parameter	Constant (B)	Standard Error	Wald	p-value	Odds Ratio (ExpB)	95% Confidence Interval for Odds Ratio	
						Lower	Upper
Instant of Peak Pressure Total Foot	0.018	0.012	2.245	0.134	1.019	0.994	1.044
Contact Area Medial Hindfoot	-1.013	0.407	6.206	0.013	0.363	0.164	0.806
Instant of Maximum Force Lateral Midfoot	-0.073	0.027	7.327	0.007	0.93	0.882	0.98
Maximum Force Lateral Midfoot	0.048	0.019	6.512	0.011	1.049	1.011	1.088
Instant of Maximum Force Second Metatarsal	0.116	0.038	9.361	0.002	1.123	1.043	1.21
Midfoot Width	-0.95	0.525	3.275	0.07	0.387	0.138	1.082
Constant	-1.882	3.652	0.266	0.606	0.152		

Table 3.22: Odds ratio interpretation for predicting tibialis anterior tendon transfer. *These interpretations are only true when all other parameters remain constant.

Parameter	**Odds Ratio**	**Interpretation**
Instant of Peak Pressure Total Foot	1.019	For every 1(%ROP) increase in the instant of peak pressure of the total foot, the odds of requiring TATT increase by 1.019
Contact Area Medial Hindfoot	0.363	For every 1cm^2 increase in contact area of the medial hindfoot the odds of requiring TATT decrease by 0.637.
Instant of Maximum Force Lateral Midfoot	0.930	For every 1(%ROP) increase in the maximum force of the lateral midfoot, the odds of requiring TATT decrease by 0.07.
Maximum Force Lateral Midfoot	1.049	For every 1(%bw) increase in the maximum force of the lateral midfoot, the odds of requiring TATT increase by 1.049.
Instant of Maximum Force Second Metatarsal	1.123	For every 1(%ROP) increase in the instant of maximum force of the second toe, the odds of requiring TATT increase by 1.123.
Midfoot Width	0.387	For every 1cm increase in midfoot width, the odds of requiring TATT decrease by 0.613.

Table 3.23: Critical value interpretation for predicting tibialis anterior tendon transfer.

Parameter	**Constant**	**Critical Value**	**Interpretation**
Instant of Peak Pressure Total Foot	0.018	-104.556	No physiologic value would satisfy the critical value. Therefore, this parameter is uninterpretable.
Contact Area Medial Hindfoot	-1.013	1.858	If the contact area of the medial hindfoot is <1.86cm^2, the model predicts the subject will require TATT.
Instant of Maximum Force Lateral Midfoot	-0.073	25.781	If the instant of maximum force of the lateral midfoot occurs at <27.8(%ROP) the model predicts the subject will require TATT.
Maximum Force Lateral Midfoot	0.048	-39.208	If the maximum force of the lateral midfoot is >39(%bw) the model predicts the subject will require TATT.
Instant of Maximum Force Second Metatarsal	0.116	-16.224	If the instant of maximum force of the second metatarsal occurs at >16(%ROP), the model predicts the subject will require TATT.
Midfoot Width	-0.950	1.981	If the midfoot width is <2 cm, the model predicts the subject will require TATT.

Table 3.24: 2x2 Classification Table for predicting tibialis anterior tendon transfer.

	Predicted No Tibialis anterior Tendon Transfer	**Predicted Tibialis anterior Tendon Transfer**	**Percentage Correct**
Observed No Tibialis anterior Tendon Transfer	38	6	86.4
Observed Tibialis anterior Tendon Transfer	7	26	78.8
Rate			83.1

Table 3.25: Predictor parameters and the equations in which each parameter was used. Shaded boxes indicate the parameter was used in the prediction equation for the reoccurrence scenario. The total column indicated the number of equations in which each parameter was utilized.

	Overall Reoccurrence	**Repeat Casting**	**Repeat Tenotomy**	**Achilles Lengthening**	**TATT**	**Total**
Abduction Orthosis Compliance	■	■	■			3
Contact Area Medial Hindfoot	■	■			■	3
Maximum Force Lateral Midfoot			■		■	2
Age at Follow-up	■					1
Age at Initial Foot Pressure	■					1
Contact Area 1st Metatarsal		■				1
Contact Area Hallux				■		1
Contact Time 1st Metatarsal	■					1
Forefoot Width				■		1
Gender				■		1
Instant of Maximum Force 1st Metatarsal				■		1
Instant of Maximum Force Lateral Midfoot					■	1

Table 3.25: Continued

Instant of Maximum Force Second Toe						1
Instant of Peak Pressure Lateral Metatarsals						1
Instant of Peak Pressure Lateral Midfoot						1
Instant of Peak Pressure Lateral Toes						1
Instant of Peak Pressure Medial Midfoot						1
Instant of Peak Pressure Total Foot						1
Midfoot Width						1
Peak Pressure Hallux						1

Figure 3.1: Flow chart of subject inclusion and exclusion.

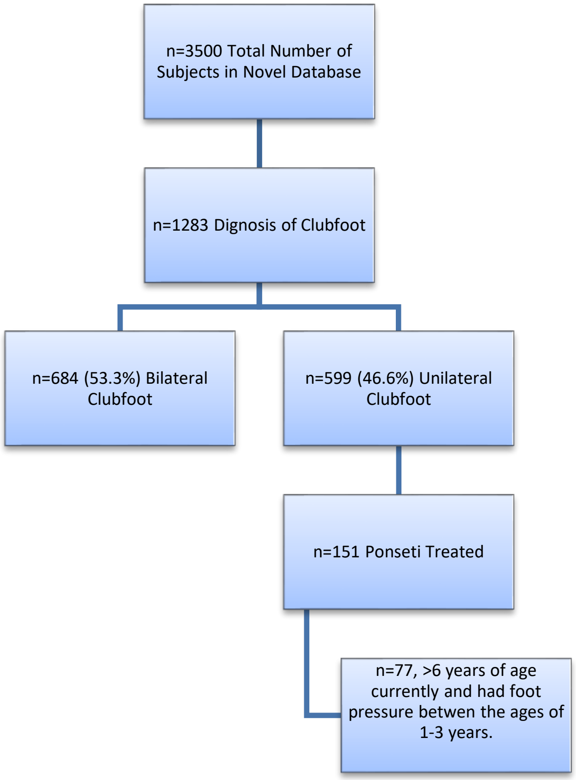


Figure 3.2: PRC mask with 10 ROI: Hallux (M01), 2nd toe (M02), lateral toes (M03), lateral hindfoot (M04), medial hindfoot (M05), lateral midfoot (M06), medial midfoot (M07), 1st metatarsal (M08), 2nd metatarsal (M09) and lateral metatarsals (M10).

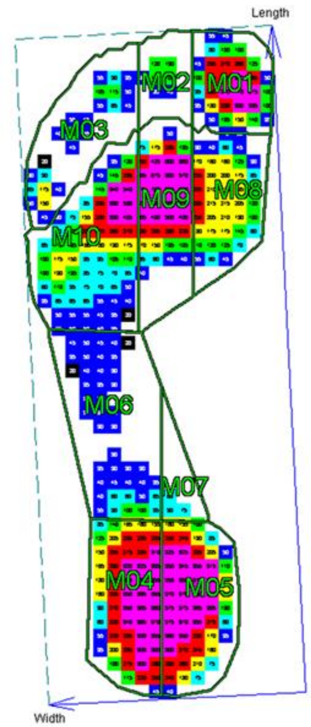


Figure 3.3: Dennis Browne Bar Abduction Orthosis[57]

Chapter 4: The Use of Foot Pressure Algorithms for Predicting Reoccurrence in Children with Unilateral Clubfoot: Midterm Results

Introduction

Reoccurrence of deformity occurs in 7-64% of children with clubfoot [5, 15-17]. A reoccurrence is defined as any deformity that requires treatment (surgical or non-surgical) post initial correction [5]. Cited causes of reoccurrence include: non-compliance with foot abduction orthosis [4, 5, 7, 11, 13, 15, 17, 18], low socioeconomic status [5], parental education level of less than high school [7], gender (females are 5x more likely to reoccur) [11, 19], initial severity rating (the higher the rating the more likely to reoccur) [19], decreased dorsiflexion range of motion [11, 15], and everter muscle weakness [11, 15]. Non-surgical treatment for reoccurrence includes repeat casting, bracing and physical therapy. Surgical treatment for reoccurrence includes tenotomy, Achilles lengthening, tibialis anterior tendon transfer (TATT) and soft tissue releases.

Despite the abundant research on clubfoot reoccurrence, there is no standard way for predicting which patients will experience a reoccurrence of deformity. Treatment and intervention is typically only prescribed after the patient shows signs of reoccurrence. Clinicians treat physical signs and symptoms instead of routinely prescribing preventative measures. If clinicians could identify the patients at the highest risk of reoccurrence, a more proactive and individualized treatment plan and follow-up schedule could be devised.

Foot pressure analysis is one of the most common biomechanical tools physicians utilize to track and monitor clubfoot progression. The most commonly reported foot pressure parameters include peak pressure (PP), maximum force (MF) and contact area (CA) [32]. Data from foot pressure analyses can be used by clinicians to assist with diagnosis, assessing severity, treatment decision making and documenting short- and long-term outcomes for children with clubfoot [25].

In Chapter 3, algorithms were developed to predict the probability of a patient with clubfoot experiencing a reoccurrence. These algorithms were based on retrospective foot pressure data, at age 2 years, and demographic information. Five algorithms were developed to predict the following reoccurrence scenarios: overall reoccurrence, repeat casting, repeat tenotomy, Achilles lengthening and tibialis anterior tendon transfer (TATT). The clinical use of these algorithms was postulated to help clinicians treat clubfoot deformity more efficiently and proactively. However, results of the study show that only two of the five algorithms, overall reoccurrence and TATT, had sufficient R^2, sensitivity and specificity to be recommended for use.

Contact time of the first metatarsal of less than 818.9ms, instant of peak pressure of the lateral metatarsals greater than 50% of the roll over process (ROP), age at the initial foot pressure of greater than 2.85 years, non-compliance with abduction orthosis and less than 4.2cm^2 of contact area in the medial hindfoot were significant predictors of overall reoccurrence. Less than 1.86cm^2 of contact area in the medial hindfoot, instant of maximum force in the lateral midfoot of less than 27.8(%ROP), maximum force on the lateral midfoot greater than 39% of total body weight (%bw), instant of maximum force in the second metatarsal greater than 16(%ROP) and a midfoot width of less than 2cm were all significant predictors of TATT. In order to properly assess the effectiveness of the algorithms in a clinician setting, a prospective assessment should be conducted.

Therefore, the purpose of this study is to present interim results when using the previously developed algorithms to predict reoccurrence of deformity in a prospective cohort of children with unilateral clubfoot. The results presented herein are considered interim because the subjects are still being followed per study guidelines. The goal of this study is to validate the predictive models for overall reoccurrence and TATT, in the hope that clinicians will adopt their use. The hypothesis of this study is that the algorithms predicting overall reoccurrence and TATT will be able to accurately predict the probability of reoccurrence.

Methods

Patients from the outpatient clinic, at the author's institution, were screened for the following inclusion criteria: unilateral clubfoot, treated with Ponseti management, no record of subsequent surgical procedures post Ponseti, between the ages of 1-3 years and scheduled to undergo a foot pressure analysis as part of their routine clinical care. Subjects were excluded if the patient was not physically or cognitively able to complete a foot pressure analysis and if the patient had undergone a surgical procedure post Ponseti treatment, excluding a tendon Achilles lengthening (TAL). Subjects recruited for this study were to be followed for a period of three years post consent. The results presented herein are for a 1.5-year follow-up, as the subjects are still being followed per research study guidelines. The research protocol states that the routine clinical care for each subject will not be altered. However, each subject is required to complete a foot pressure assessment at each follow-up visit during the study duration.

The foot pressure assessment collected at the time of consent will be used for analysis. One representative foot pressure trial for the affected side will be used. Foot pressures will be masked using a 10 area automated PRC mask (Figure 4.1)[27]. From this mask, a total of 11 regions of interest (ROI) will be assessed; the total foot, hallux, 2nd toe, lateral toes, first metatarsal, second metatarsal, lateral metatarsals, medial midfoot, lateral midfoot, medial hindfoot and lateral hindfoot. Manual corrections, per guidelines outlined in Chapter 2, were used to address errors present in the automated mask.

Algorithms will then be applied to predict the overall probability of experiencing a reoccurrence and for predicting the probability of requiring a TATT. The algorithms for predicting overall reoccurrence and TATT were robust and report R^2 values of 55.5% and 58.9% respectively (Table 4.1). The result of each prediction equation is a probability (p) between $0<p<1$; with ≥ 0.5 indicating the presence of reoccurrence and <0.5 indicating no reoccurrence. Three classifications will be applied to the probability results; reoccurrence ($p>0.5$), no reoccurrence ($p<0.5$) and inconclusive ($p>1$ or $p<0$). The three remaining algorithms predicting repeat casting, repeat tenotomy and Achilles lengthening, will not be utilized due to the small sample sizes for these reoccurrences. It was concluded that these algorithms were not robust and caution was recommended when utilizing them. For more information on the formation these algorithms see Chapter 3.

Using the subject's electronic medical record, the progression of clubfoot deformity will be reported at a 1.5-year interim follow-up. Subjects will be screened for the presence of any surgical or non-surgical reoccurrence and for a TATT specifically. The presence of a reoccurrence will be compared to the predicted probability of reoccurrence. The accuracy of the algorithms will be reported in a 3x2 table; reporting the sensitivity and specificity of the two algorithms.

In addition, a t-test and ANOVA will be utilized for each prediction equation. Student's t-test will assess the difference between those that did experience a reoccurrence and those that did not experience reoccurrence. The differences will be reported for the parameters used in each prediction equation; see Table 4.1 for a list of the parameters utilized. If Levenes Test for Equality of Variances is significant ($p < 0.05$) then the t-test results for equal variance not assumed were used [47]. An ANOVA will assess the difference between the three classifications that resulted from the prediction equations: reoccurrence, no reoccurrence and inconclusive. The differences will be reported for the parameters used in each prediction equation; see Table 4.1 for a list of the parameters utilized. A Bonferroni post-hoc test was used to assess where the significance occurred[47].

Results

Thirty children with unilateral clubfoot were initially consented for this study. At this time subjects are at a 1.5(0.7) year interim. Two subjects are currently lost to follow-up, resulting in 28 subjects for analysis. Seventeen subjects are male (60%) and 11 are female (40%). Fifteen subjects (54%) are left side involved and 13 (46%) are right side involved. Nineteen subjects (68%) have no family history of clubfoot, 16 subjects live in an impoverished area (57%) and 18 subjects are reported to have public insurance (64%).

The age at the first clinical visit and initiation of Ponseti casting was 22(28) days (range 6-120 days). The study cohort required that application of 5.03(1.22) casts (range 3-8 casts). At the cessation of casting, 17 subjects (61%) required an Achilles tenotomy at the age of 68(40) days (Range 34-169 days). Post casting and tenotomy, subjects were placed in abduction orthoses at 78(44) days of age (range 30-201 days). Per the medical record, 15 subjects (54%) were not compliant with the prescribed bracing protocol. Intolerance at night, with self-removal, was the most cited cause of non-compliance. Two subjects who were initially non-compliant with abduction orthosis were transitioned into Ponseti Shoes and were subsequently compliant. Abduction orthoses were discontinued at 861(316) days of age (Range 103-1433 days). Age at the foot pressure utilized for prediction was 2.4(0.7) years and age at the current follow-up is 3.8(0.5) years (Range 2.2-5.1 years).

Actual Reoccurrence

The overall rate of reoccurrence was 43% (12/28). Ten subjects (36%) required repeat casting with an average of 3(1.2) casts (Range 2-5). Two subjects required a second repeat casting with an average of 3(.96) (Range 2-4) casts and one subject required a third repeat casting with 3 casts. Only one subject required a repeat tenotomy, which was performed at 341 days of age. Six subjects (21%) required an Achilles lengthening at the age of 1197.3(527.4) days (Range 455-1942 days). Four subjects went on to require TATT at the age of 1559.3(265.22) days (Range 1281-1942 days). Six subjects (21%) were prescribed daytime use of ankle foot orthosis.

Predicted Reoccurrence

Tables 4.2 and 4.3 are 3x2 tables representing the actual and predicted rates for overall reoccurrence and TATT. Also included are the valid inconclusive test results [58]. Table 4.4 summarizes the sensitivity and specificity for each equation. Overall the interim results show that the prediction equations for overall reoccurrence and TATT are specific but not sensitive. This is an indication that the equations are able to accurately predict subjects that will not experience a reoccurrence and are inaccurate when predicting those that will experience a reoccurrence.

Overall Reoccurrence Group Differences

A t-test was used to assess the difference between the group of subjects that had an actual reoccurrence (12) and those that did not have a reoccurrence (16). The results for the overall reoccurrence prediction are in Table 4.5. There were no significant differences between the subjects who did experience a reoccurrence and those that did not experience a reoccurrence. In addition, an ANOVA with a Bonferroni post-hoc test was used to assess the difference between the three classifications produced by the prediction equation for overall reoccurrence: reoccurred (3), not reoccurred (19) and the inconclusive (6). The results of this analysis are also in Table 4.5. Age at the first visit and contact time of the first metatarsal reported a significance of $p=0.027$ and $p=0.026$ respectively. The post hoc test revealed that the age at the first visit was approaching significance with a $p=0.07$ and the contact time of the first metatarsal was significantly different with a $p=0.025$ between the no reoccurrence group and the inconclusive group.

TATT Group Differences

A t-test was used to assess the difference between the group of subjects that had an actual TATT reoccurrence (4) and those that did not have a TATT (24). The results for the overall reoccurrence prediction are in Table 4.6. There was a significant difference in the maximum force of the lateral midfoot in these two groups ($p=0.016$). In addition, an ANOVA with a Bonferroni post-hoc test was used to assess the difference between the three classifications produced by the prediction equation for TATT reoccurrence: reoccurred (4), not reoccurred (15) and the inconclusive (9). The results of this analysis are also in Table 4.6. Midfoot width reported a significant difference at $p=0.004$. Post hoc test revealed that the no TATT group and the inconclusive group were significantly different at p=0.006.

Discussion

This study sought to use previously developed algorithms to predict the probability of reoccurrence for children with unilateral clubfoot deformity. Prediction equations for the probability of any reoccurrence and for TATT were applied to foot pressure data at 2 years of age. The prediction equations classified the individual subject's outcome into one of three categories; reoccurred, did not reoccur and inconclusive. Inconclusive results indicate that the probability value was either >1 or <0. All subjects in this study are still within the three year-follow-up window, thus all data presented herein is for a 1.5 year interim follow-up.

Forty-three percent (12/28) of the study population experienced a reoccurrence of any type at the interim follow-up. The equation for overall reoccurrence predicted that 68% (19/28) of the population would not reoccur, 11% (3/28) would reoccur and 21% (6/28) had an inconclusive probability. Of the six subjects with an inconclusive probability, three had an actual reoccurrence and three did not reoccur. This overall reoccurrence rate is slightly lower than the reoccurrence rate seen in the subjects that were used to build the algorithms, where 55.8% (43/77) subjects reoccurred. However, the subjects in the retrospective analysis were age 9.9(2.7) years at the time of follow-up, whereas subjects in this interim analysis are only 3.8(0.5) years. Researchers have stated that there is an increased risk of reoccurrence between the ages of three to five years, due to rapid growth [15]. All subjects in this study fall into the category of increased risk. Therefore, it is imperative that the entire three-year follow-up be utilized in order to accurately capture the final rate of reoccurrence.

Fourteen percent of the study population required a TATT at the interim follow-up. The equation for TATT predicted that 54% (15/28) did not require a TATT, 14% (4/28) would require a TATT and 32% (9/28) had an inconclusive probability. All nine subjects with inconclusive probability did not report a TATT at the interim follow-up. Previous researchers have reported that 14-50% of children with clubfoot will required a TATT [4, 5, 13, 51, 52]. Since the percentage of subjects requiring a TATT is on the low end of the previously reported range, it could be concluded that more subjects from the study population will require at TATT by the end of the three year follow-up.

The overall accuracy of the algorithms for overall reoccurrence and TATT were 0.59 and 0.79, indicating that the algorithms were able to correctly identify the study population's outcome 59% and 79% of the time. The equation for overall reoccurrence reported a sensitivity of 11% and the equation for TATT had a sensitivity of 0%; indicating that the algorithms were not able to accurately identify the subjects that did experience a reoccurrence. On the other hand, the equations reported specificity values of 0.85 and 0.73, indicating that the equation for overall reoccurrence was able to correctly identify those that did not reoccur 85% of the time and the equation for TATT was correct in 73% of the population. A test with high specificity and low sensitivity increases the chance of false negative results. Therefore, these highly specific algorithms are more likely to be accurate in the presence of a positive reoccurrence. The pneumonic for a highly specific test with a positive test result is SpPin, high **Sp**ecificity, **P**ositive test, rule **IN**[59].

The sensitivity and specificity results of this study differ slightly from those reported in Chapter 2; where the overall reoccurrence and TATT prediction equations reported high sensitivity (overall=0.82, TATT=0.81) and high specificity (overall=0.81, TATT=0.84). The specificity of the TATT equation is on par with that reported in Chapter 2 and the specificity of the overall reoccurrence equation is only slightly less than in Chapter 2. However, as stated above, the predictions equations were not accurately able to identify the subjects who would experience a reoccurrence. Possible explanations for the low sensitivity could be the sample size and the length of follow-up. The population of this prospective study was 28 subjects with a follow- up at age 3.8(0.5) years. The prediction equations were developed utilizing 78 subjects with a follow up at age 9.9(2.7) years. At the end of the three-year follow-up, the disease progression for the study population will more than likely change. It is the expectation that with a longer follow-up, the sensitivity and specificity of these equations will increase.

Another possible explanation for the low sensitivity could be that there were outliers. Foot pressure data for children with clubfoot deformity can have large standard deviations. It is not uncommon for the standard deviation to be larger than that of the mean (See Appendix B). If a subject's foot pressure data are considered to be an outlier, it could explain the presence of inaccurate or inconclusive prediction results. To address this possible complication, an assessment of multivariate outliers was conducted using Mahalanobis distance. This assessment looks for subjects who fall outside of the multi-dimensional mean distribution, which could in turn affect the prediction result [47]. This analysis was conducted separately for the overall reoccurrence and the TATT predictor parameters. However, results show that there were no multivariate outliers.

Since no multivariate outliers were present, box plots were then used to assess for individual outliers for each predictor parameter. If an individual's parameter fell 1.5 times outside the interquartile range, the subject could be considered an outlier for that parameter [47]. For overall reoccurrence, four subjects had one parameter that was an outlier and one subject had two parameters as outliers. Of these five subjects, three were incorrectly classified; two experienced an actual reoccurrence while the algorithm predicted they did not reoccur and one subject did experience a reoccurrence and was classified as inconclusive. For TATT, two subjects had one parameter that was an outlier, two subjects had two outlier parameters and two subjects had four parameter outliers. Of the six subjects with outliers, five were classified incorrectly by the prediction algorithm. Two subjects required TATT while the prediction algorithm predicted no TATT and three subjects were predicted to have a TATT and had not yet reoccurred. None of the TATT subjects with outlier data were classified as inconclusive.

One of the more interesting results that should be considered is the number of subjects, for each reoccurrence, that were predicted to reoccur or that had inconclusive results and had not yet reoccurred. For the overall reoccurrence prediction, two subjects were predicted to reoccur and three subjects were inconclusive that had yet to reoccur. For the TATT prediction, four were predicted to reoccur and nine were inconclusive that had yet to reoccur. These are the subjects that clinicians should consider to be at the highest risk of reoccurrence. This increased risk should then be proactively taken into consideration when implementing treatment protocols. By employing non-operative interventions early, clinicians could preemptively decrease a patient's probability of requiring a surgical intervention.

Several limitations may have affected the interim results of this study. A first limitation is that the subjects in this prospective study may have been different from those that were utilized in Chapter 3 to build the predictive algorithms. A t-test was used to assess the difference in the prospective and retrospective subject's data that was utilized in the algorithms, see Table 4.1 for a list of the parameters utilized. For abduction orthosis compliance, whose data is binary, a Chi-square test was used to assess the difference between the prospective and retrospective groups. Results of these analyses show that the Age at the last follow-up, contact time of the first metatarsal and the midfoot width were significantly different (Table 4.7).

The second limitation is the use of a representative foot pressure trial instead of an average. The gait of children has been reported to be variable between foot pressure trials [34]. Therefore, it is not uncommon to conduct a large number of walking trials and eliminate the trials that are not consistent for temporal spatial parameters (i.e. contact time, contact area, peak pressure)[41, 60]. To limit intra-individual differences and increase reliability between foot pressure trials, researchers have recommend utilizing an average of ≥ 3 foot pressure trials and only utilizing trials with the same walking speed [25, 29, 34]. However, gait maturation in children might not be fully complete until age 13, causing increased variability during these early developmental years [61]. Therefore, it is not uncommon for researchers to utilize a representative trial for data analysis [26, 62, 63]. The advantage of a representative trial is that there is less post-processing time required and there is less chance of averaging outlier data that could potentially skew results. The effect of utilizing a retrospective trial versus an average of trials for algorithm application is unknown. Future researchers should consider addressing this potential confound.

The third limitation of this study is the high incidence of inconclusive results. The subjects whose probability of reoccurrence is >1 or <0 are classified as inconclusive/indeterminate [58]. Inconclusive probability results occurred in 6 (21%) of subjects for the prediction of overall reoccurrence and 9 (33%) for the prediction of TATT. Inconclusive results in medicine are not uncommon, the reporting of which is regulated by the Standards for the Reporting of Diagnostic Accuracy Studies (STARD) [58]. STARD recommends that a 3x2 table (Tables 4.2 and 4.3), with indeterminate/inconclusive test results included, be presented when providing sensitivity and specificity data to clinicians [58]. The subjects whose results are categorized as inconclusive should be brought to the attention of the clinician, as more investigation is needed to ascertain the likelihood of reoccurrence [58].

The last and potentially most important limitation of this study is that these are interim results and all subjects are still within the three years follow-up window. Researchers have found that children, between the age of 3-5 years, are at an increased risk of reoccurrence due to rapid growth [15]. Reoccurrence rates are as high as 64% in children below the age of 5, whereas only 6% of children over the age of 7 will reoccur [5, 15-17]. The current age of the subjects in this study is 3.8(0.5) years (Range 2.2-5.1 years); indicating that the majority of subjects are still at a high risk of experiencing a reoccurrence. As seen in Table 4.7, the age at follow-up of the subjects used in this study is significantly different from those used retrospectively to build the algorithms. It is likely that more subjects will experience a reoccurrence by the end of the three-year follow-up. Therefore, it is imperative that the remaining study duration be carried out, in order to properly report reoccurrence rates.

Conclusions

The purpose of this interim analysis was to present a 1.5-year follow-up when using algorithms to predict the probability of reoccurrence in a prospective cohort of children with unilateral clubfoot. The results of this analysis show that the algorithms are highly specific, have low sensitivity and have a high incidence of inconclusive results. The hypothesis that the algorithms will accurately predict the probability of reoccurrence, is currently rejected. To increase the applicability of these equations it is necessary to increase the follow-up time and increase the sample size. It is imperative that the subjects in this study be followed until the end of the consent period (3 years). This will allow the average age of subjects to be >5 years, thus decreasing the rate of recurrence. Currently 28 subjects are being prospectively followed in this study. In order to properly assess the accuracy of these algorithms more subjects may need to be recruited. If the recommendations are followed, the algorithms for overall reoccurrence and TATT will be of use to clinicians for predicting the probability of reoccurrence of deformity for children with unilateral clubfoot.

Table 4.1: Prediction equations for overall reoccurrence and TATT. A list of the parameters utilized in each equation is presented along with the R^2 value for each equation. The R^2 is a representation of the total amount of variance explained by the predictors.

Type of Reocurrence	**Equation**	**Parameters**	**R^2**
Overall Reocurrence	$p = \frac{e^{(-0.005_a + 0.087_b + 1.53_c - 1.311_d - 1.022_e + 0.192_f - 4.364}}{1 - e^{(-0.005_a + 0.087_b + 1.53_c - 1.311_d - 1.022_e + 0.192_f - 4.364}}$	a)contact time first metatarsal, b)instant of peak pressure lateral metatarsals, c)age at initial foot pressure (years), d)abduction orthosis compliance (compliance=1, non-compliance=0), e)contact area medial hindfoot, f)age at last follow-up (years)	0.556
Tibialis Anterior Tendon Transfer (TATT)	$p = \frac{e^{(0.018_a - 1.013_b - 0.073_c + 0.048_d + 0.116_e - 0.950_f - 1.882)}}{1 - e^{(0.018_a - 1.013_b - 0.073_c + 0.048_d + 0.116_e - 0.950_f - 1.882)}}$	a)instant of peak pressure total foot, b)contact area medial hindfoot, c)instant of maximum force lateral midfoot, d)maximum force lateral midfoot, e)instant of maximum force second metatarsal, f)midfoot width	0.589

Table 4.2: 3x2 table for the actual and predicted overall reoccurrence rates.

	Predicted No Overall Reoccurrence	Inconclusive	Predicted Overall Reoccurrence
Actual No Overall Reoccurrence	11	3	2
Actual Overall Reoccurrence	8	3	1

Table 4.3: 3x2 table for the actual and predicted TATT reoccurrence rate.

	Predicted No TATT Reoccurrence	Inconclusive	Predicted TATT Reoccurrence
Actual No TATT Reoccurrence	11	9	4
Actual TATT Reoccurrence	4	0	0

Table 4.4: Sensitivity and specificity of the prediction equations for overall reoccurrence and TATT.

	Overall Reoccurrence	TATT
Overall Percent Correct	59.1	78.95
Sensitivity	0.11	0
Specificity	0.84	0.73
Positive Predictive Value	0.08	0
Negative Predictive Value	0.58	0.73
Positive Likelihood Ratio	0.72	0
Negative Likelihood Ratio	1.17	1.36

Table 4.5: T-test for the actual rate of overall reoccurrence and ANOVA results for the prediction of overall reoccurrence. *ANOVA significant between the no overall reoccurrence and inconclusive groups at $p<0.05$.

T-TEST	Number of Subjects (%Total Subjects)	Age at Visit (Years[SD])	Age at Follow-up (Years[SD])	Abduction Orthosis Non-Compliant (%)	Contact Area Medial Hindfoot (cm^{2})	Contact Time First Metatarsal (ms)	Instant of Peak pressure Lateral Metatarsals (%ROP)
No Reoccurrence	16 (57%)	2.4(0.8)	3.7(0.9)	9 (56%)	6.2(1.4)	400.4(153.1)	80.5(9.8)
Yes Reoccurrence	12 (43%)	2.4(0.5)	4.0(0.9)	6 (50%)	5.5(1.9)	343.7(234.5)	76.7(19.4)
ANOVA							
No Reoccurrence	19 (68%)	2.2(0.6)	3.7(0.9)	7 (37%)	6.1(1.3)	425.1(165.2)*	76.0(10.6)
Yes Reoccurrence	3 (11%)	2.9(0.6)	4.2(1.1)	1 (33%)	6.1(0.1)	426.7(51.8)	84.8(3.3)
Inconclusive	6 (21%)	2.9(0.8)	4.1(0.9)	4 (66%)	5.2(2.7)	195.7(216.2)*	84.8(25.1)

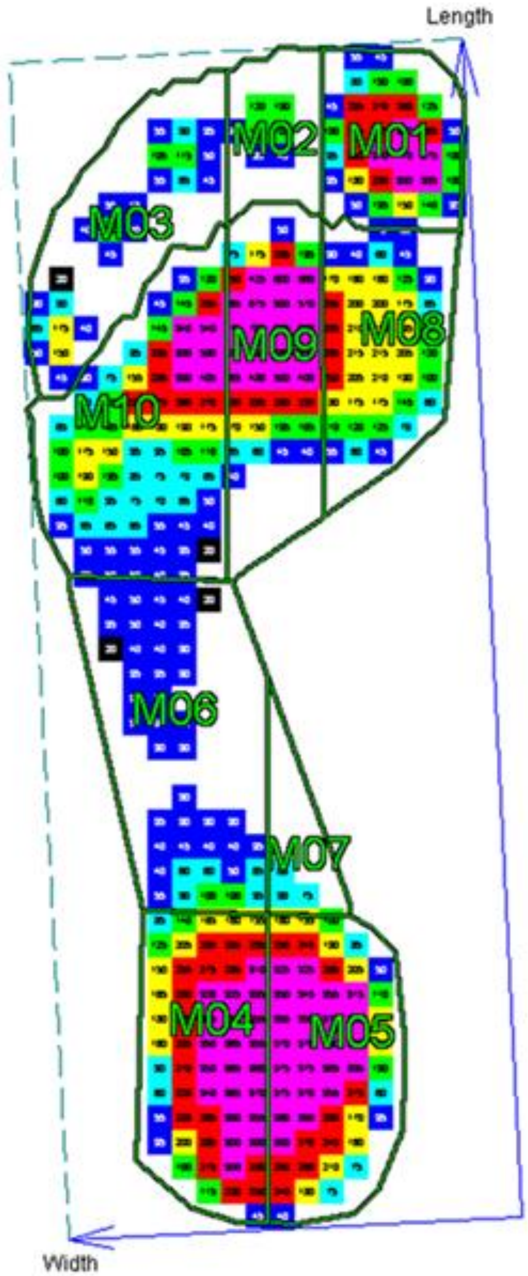
Table 4.6: T-test for the actual rate of TATT and ANOVA results for the prediction of TATT. ^T-test significant difference between the actual reoccurrence and no actual reoccurrence groups at p<0.05. *ANOVA significant difference between the no TATT reoccurrence group and the inconclusive group p<0.05.

T-TEST	Number of Subjects (%Total Subjects)	Instant of Peak Pressure Total Foot (%ROP)	Contact Area of the Medial Hindfoot (cm^2)	Instant of Maximum Force Lateral Midfoot (%ROP)	Maximum Force Lateral Midfoot (%bw)	Instant of Maximum Force Second Metatarsal (%ROP)	Midfoot Width (cm)
No Reoccurrence	24 (86%)	70.2(25.7)	6.1(1.2)	34.6(23.4)	59.9(19.5)^	77.7(9.6)	4.4(1.7)
Yes Reoccurrence	4 (14%)	54.2(41.3)	4.6(3.1)	37.6(43.3)	32.1(24.1)	64.3(36.7)	3.7(0.7)
ANOVA							
No Reoccurrence	15 (54%)	58.3(33.3)	6.2(2.1)	38.4(28.9)	55.6(26.1)	72.4(20.3)	4.2(0.9)*
Yes Reoccurrence	4 (14%)	76.8(24.7)	5.6(1.1)	46.0(38.7)	44.7(17.6)	82.6(12.0)	3.3(0.4)
Inconclusive	9 (32%)	80.0(9.8)	5.6(0.9)	24.6(7.7)	61.6(15.2)	78.2(4.9)	3.2(0.3)*

Table 4.7: A comparison of the prospective subjects utilized in this study and the retrospective subjects utilized in Chapter 3 to build the predictive algorithms. T-test and Chi-square test results a presented for the parameters that are included in the overall reoccurrence and TATT equations. *Denotes Chi-square test

Parameters	Prospective Subject Mean(sd)	Retrospective Subject Mean(sd)	p-value
Age at Initial Foot Pressure (years)	2.40(0.69)	2.47(0.74)	0.64
Age at Last Follow-up (years)	3.85(0.89)	9.98(2.69)	<0.001
Instant of Peak Pressure Total Foot (%ROP)	67.94(27.98)	67.09(31.49)	0.90
Contact Area Medial Hindfoot (cm^2)	5.92(1.63)	5.61(1.22)	0.30
Instant of Maximum Force Lateral Midfoot (%ROP)	35.01(26.02)	32.35(15.22)	0.52
Maximum Force Lateral Midfoot (%bw)	55.94(22.03)	60.23(22.47)	0.39
Contact Time First Metatarsal (ms)	376.11(190.39)	276.10(171.45)	0.01
Instant of Maximum Force Second Metatarsal (%ROP)	75.75(15.87)	71.00(14.70)	0.15
Instant of Peak Pressure Lateral Metatarsals (%ROP)	78.86(14.48)	77.73(16.62)	0.75
Midfoot Width (cm)	3.76(0.89)	3.28(0.62)	<0.01
Abduction Orthosis Compliance Rate*	46%	56%	>0.05

Figure 4.1: PRC mask with 10 ROI: Hallux (M01), 2nd toe (M02), lateral toes (M03), lateral hindfoot (M04), medial hindfoot (M05), lateral midfoot (M06), medial midfoot (M07), 1st metatarsal (M08), 2nd metatarsal (M09) and lateral metatarsals (M10).



Chapter 5: Discussion and Conclusion

Summary

The overall purpose of this investigation was to use foot pressure analysis to predict the probability of reoccurrence in children with unilateral clubfoot deformity. From this purpose two hypotheses and a methodology validation were developed:

1. Retrospective foot pressure data, from children over the age of 6 years and whose outcome is already known, will create predictive algorithms that accurately predict the presence of reoccurrence.
2. The algorithms, when applied prospectively, will accurately and precisely predict reoccurrence.

To fulfill this purpose and test the hypotheses, three individual investigations were carried out. In Chapter 2, the accuracy and validity of the foot pressure methodology utilized in this investigation was assessed. In Chapter 3, retrospective foot pressure data were used to build algorithms that predicted the probability of clubfoot reoccurrence. Lastly, in Chapter 4, the predictive algorithms were applied to a cohort of children who were prospectively followed for 1.5 years.

Chapter 2 and Methodology Validation

The purpose of Chapter 2, *Foot Pressure Masking Inaccuracies Due to Deformity in Children with Unilateral Clubfoot,* was to describe masking inaccuracies present when applying one automated masking technique (PRC). In addition, this chapter reported novice and expert clinician's ability to identify and correct masking inaccuracies. Results of this study present a standard procedure for identifying foot masking inaccuracies. Five foot deformities were found to impact masking accuracy: forefoot adductus, heel varus/valgus, incomplete heel contact (equinus), missing toes/incomplete toe contact and lateral weight bearing (supination). These five deformities cause four inaccuracies in the PRC mask; vertical dividing lines are rotated, vertical dividing lines are shifted medially/laterally, horizontal dividing lines are shifted distally, and inaccurate toe mask identification.

Chapter 2 also sought to measure novice and expert clinician's ability to identity masking inaccuracies and subsequently make corrections. Both experienced and novice clinicians were able to accurately and reliably identify and edit inaccurate regions of interest (ROI). This finding indicates that experience with foot pressure technology is not a requirement for identifying ROI that correspond to foot anatomy. However, it was recommended that caution and attentiveness be used when editing small and less loaded ROI (i.e. second toe and medial midfoot), as these areas are prone to less accuracy and reliability.

The results of Chapter 2 prove that the foot pressure methodology utilized in this investigation is reliable and accurate. We concluded that foot pressure accuracy is maximized by utilizing automasking techniques with manual corrections employed for masking inaccuracies. In addition, it was recommended that future investigations report the incidence or rate of manual corrections applied. The conclusions and recommendations of this study can be utilized in a clinical and research setting to influence foot pressure data reduction for children with clubfeet. With more accurate foot pressure data, clinicians and researchers are better able to utilize foot pressure analysis as a diagnostic tool in the management of clubfoot deformity.

Chapter 3 and Hypothesis 1

In Chapter 3, *Algorithm Development*, retrospective foot pressure data were used to build algorithms that predicted the probability of developing a reoccurrence. Algorithms for the following reoccurrence scenarios were developed: overall presence of reoccurrence (any non-operative or operative intervention), repeat casting, repeat tenotomy, Achilles lengthening, and tibialis anterior tendon transfer (TATT). Seventy-seven children with unilateral clubfoot who had a foot pressure analysis at 2.5(0.7) years of age were utilized. At a follow-up of 9.9(2.7) years of age 56% (43/77) subjects had experienced any type of reoccurrence, 17% (13/77) required repeat casting, 9% (7/77) required repeat tenotomy, 19% (15/77) required Achilles lengthening and 45% (35/77) required TATT.

A combination of foot pressure data and demographic information was used to build the predictive algorithms. The equations predicting overall reoccurrence and TATT were robust, with high R^2 and high sensitivity and specificity. These equations also had a large prevalence, utilizing 56% and 45% of the total population. Whereas, the equations for repeat casting, repeat tenotomy and Achilles lengthening were less robust due to a lower prevalence. These results suggest that clinicians should take caution when interpreting predictive results for repeat casting, repeat tenotomy and Achilles lengthening.

In addition, three parameters were found to be significant variables in more than one prediction equation; abduction orthosis compliance, contact area of medial hindfoot and maximum force in the lateral midfoot. Previous researchers have cited brace compliance as the most important indicator of reoccurrence [4, 5, 7, 11, 13, 15, 17, 18]. The results of this study are in agreement with previous research, as bracing compliance was utilized in three prediction equations (overall reoccurrence, repeat casting and repeat tenotomy). Contact area of the medial hindfoot was utilized in three equations (overall reoccurrence, repeat casting and TATT). Less contact area in the medial hindfoot can be an indicator of hindfoot equinus or dynamic supination; which can be treated with repeat casting and TATT respectively. Maximum force for the lateral midfoot was utilized in two equations, repeat tenotomy and TATT. Increased lateral weight bearing (i.e. increased force on the lateral side of the foot) is the clinical indicator for TATT. Results indicate that these parameters may be of unique importance when predicting reoccurrence for children with unilateral clubfoot.

The results of Chapter 3 led to the acceptance of Hypothesis 1; retrospective foot pressure data were able to create reliable and accurate algorithms for the prediction of overall reoccurrence and TATT. The utilization of these algorithms will allow clinicians to proactively and efficiently treat clubfoot reoccurrence. These algorithms have the potential to improve the standard of treatment for children with unilateral clubfoot.

Chapter 4 and Hypothesis 2

The purpose of Chapter 4, *The Use of Foot Pressure Algorithms for Predicting Reoccurrence in Children with Unilateral Clubfoot: Midterm Results*, was to present interim results when using algorithms to predict reoccurrence in a prospective cohort of children with unilateral clubfoot. The goal was to validate the predictive models for overall reoccurrence and TATT, in the hope that they could be used clinically to improve outcomes for children with clubfoot. The 28 subjects in this study are still within the three year-follow-up window, thus all results were for a 1.5 year interim follow-up.

At the interim, the overall reoccurrence rate was 43% (12/28) and the rate of TATT was 14% (4/28). The algorithms for overall reoccurrence and TATT classified each subject as reoccurred, not reoccurred or inconclusive. Inconclusive results were found for 6 subjects when predicting the probability of overall reoccurrence and for 9 subjects when predicting the probability of TATT. For those who were able to be classified, overall reoccurrence and TATT prediction equations reported accurate classifications in 59% and 79% of subjects. The prediction equations for overall reoccurrence and TATT were specific (0.84, 0.73) but not sensitive (0.11, 0.00). This is an indication that the equations were able to accurately classify subjects that did not experience a reoccurrence and were inaccurate when classifying those that did experience a reoccurrence.

The results of Chapter 4 led to the rejection of Hypothesis 2; the interim results show that these algorithms are not yet accurate at predicting overall reoccurrence or TATT. The algorithms are highly specific, have low sensitivity and have a high incidence of inconclusive results. To increase the applicability of the algorithms it was recommended that the entire three-year follow-up be utilized and the sample size should be increased. If the recommendations are followed, the algorithms for overall reoccurrence and TATT will increase sensitivity and specificity and become useful to clinicians.

Appendices

The four appendices included in this investigation provided additional in-depth information on the topics covered in this dissertation. Appendices A and B respectively provide literature reviews on the topic of foot pressure analysis in children with clubfoot and in typically developing children. Appendix C provides a detailed description of the clubfoot deformity. Appendix D provides the results of a meta-regression on the current literature pertaining to clubfoot reoccurrence.

Appendix A: Foot Pressure Analysis in Children with Clubfoot: A Summary of Literature from 1995-2018, provided a review of the current literature on the use of foot pressure analysis in children with clubfeet who were treated with Ponseti management. The data summary herein can be used as a reference for future researchers and clinicians who wish to compare data from their institution to that of other institutions. In addition, this appendix provides caution to clinicians and researchers when utilizing data from previously published research. Due to differences in approach, masking protocols and parameters reported, researchers should be cautious when choosing previous data to compare with their current research. The past and current research study protocols for data collection, reduction and reporting should be similar in order to have data that are comparable.

Appendix B: Foot Pressure Analysis using the emed® in Typically Developing Children and Adolescents: A Summary of Current Techniques and Typically Developing Cohort Data for Comparison with Pathology, presented a summary of the foot pressure data pertaining to children without musculoskeletal deformities. This appendix provided clinicians and researchers with information on the factors that can affect foot pressure data collection and reduction. The controllable and uncontrollable factors that influence foot pressure data were discussed. The controllable factors include: walking speed, stride length, approach and masking techniques. The uncontrollable factors include: gender, age, obesity, asymmetry, intra- and inter-individual differences and foot pressure plate specifications.

Appendix C: Clubfoot a Summary, provided a summary of clubfoot deformity. This appendix presented a detailed description of clubfoot deformity, classification scales and treatment methods. In addition, the long and short-term outcomes for the Ponseti Method and for surgical management of clubfeet are discussed.

Lastly, *Appendix D: Reoccurrence Rate in Ponseti Treated Clubfeet: A Meta-Regression*, used previous literature to assess the factors that contributed to an increased risk of reoccurrence for children with clubfoot. This study reported a mean reoccurrence rate of 30% (95% CI 28%-33%) for 17 research studies. Meta-regression results reported that children with unilateral clubfoot, who are less than 2 years post initial treatment and who underwent a tenotomy are at the highest risk of reoccurrence. It was recommended that clinicians consider these factors when managing the treatment of children with clubfoot deformity.

Significance

This investigation provides novel findings that have the potential to change the standard of care for children with unilateral clubfoot. This is the first study to use foot pressure analysis to predict reoccurrence of deformity for children with clubfoot. The ability to accurately predict the chance of experiencing a reoccurrence allows clinicians to be more proactive during treatment decision making and care management. Physicians will be able to utilize more preventative and non-operative treatments that lessen a patient's chance of requiring an invasive surgical procedure. The use of these algorithms will help clinicians treat a reoccurring clubfoot efficiently and proactively.

In addition, this is the first study to present a standardized methodology for the identification and correction of masking inaccuracies. Prior to this investigation, inaccuracies in masking were alluded to but never fully explained. Reporting the incidence of masking inaccuracies and the rate of manual correction will provide methodology transparency. This will allow for improved communication and education among researchers and clinicians who utilize foot pressure analysis for assessing pediatric clubfeet.

Lastly, this investigation utilized foot pressure parameters that are not routinely reported. The most commonly reported foot pressure parameters include peak pressure (PP), maximum force (MF) and contact area (CA), see Appendix A and B for more information on commonly reported parameters [32]. While these parameters were utilized in the five prediction equations from Chapter 3 (see Table 3.25), other parameters not typically reported were also utilized. Of the 16 foot pressure parameters utilized for prediction, only 5 were commonly reported (1 peak pressure, 1 maximum force and 3 contact areas). The less common parameters included: 1 contact time, 3 instants of maximum force, 5 instants of peak pressure, midfoot width and forefoot width. Additionally, at the author's institution, clinicians do not routinely utilize masking when assessing foot pressure analyses of children with clubfeet. The results of this investigation show that foot pressure analyses should be masked and less common parameters utilized. This investigation found novel and innovative outcomes that would otherwise have been overlooked by including less common parameters and masking ROI.

Limitations

Several limitations and delimitations became apparent during the course of this investigation. The first was the exclusion of bilateral clubfeet. Previous research has not come to a consensus on the effect of laterality. Some researchers suggest that there is no difference between bilateral and unilateral clubfeet [49], while others suggest that bilateral clubfeet confound data analysis [3]. Due to these discrepancies, the decision to only include unilateral subjects was made. However, this presents a disadvantage because fifty percent of all clubfoot cases are bilateral [55]. The prediction equations developed in this investigation are only applicable to the unilateral half of the clubfoot population and therefore should not be applied to bilateral clubfeet. Separate algorithms may need to be developed for bilateral clubfeet.

The second limitation is that no distinction was made between incomplete corrections and true reoccurrence. Interventions that are <6 months post initial correction are considered incomplete correction and interventions >6 months post initial correction are considered true reoccurrence [44]. Of the reoccurrences assessed in this investigation, only repeat casting and repeat tenotomy typically occur during the first six months post initial correction. Achilles lengthening and TATT are typically performed after the patient has commenced walking. During algorithm development, no distinction was made between incomplete correction and true reoccurrence. In future iterations of this research, this distinction should be used as it has the potential to influence algorithm results.

A third limitation is that the algorithms should only be applied to a foot pressure assessment at the age of 2-3 years. The retrospective data utilized for algorithm development were at the age of 2.5 years. However, what should clinicians do if a subject did not receive a foot pressure assessment at the recommended age? Four of the five algorithms currently developed do not take age/growth into account. For repeat casting, repeat tenotomy, Achilles lengthening and TATT, it may be advantageous to develop algorithms at different age ranges in order to accommodate a subject's disease progression as they grow. The equation for overall reoccurrence was the only equation that utilized age as a predictor. This equation has the potential to be iterative in nature, as the two age related parameters, age at pedobarograph visit and age at follow-up, will change over time.

Another limitation is that the current algorithms do not consider past or future interventions. It is possible for a subjects to experience a reoccurrence prior to the first foot pressure assessment. Repeat casting, repeat tenotomy and Achilles lengthening could all be performed prior to 2-3 years of age. The presence of treatment after the initial correction was not utilized when creating the prediction algorithms. Future iterations of this research should include previous treatment when predicting the probability of a future reoccurrence. In addition, researchers have reported that 20% of clubfeet will experience a second reoccurrence [45]. Since 1 in 5 clubfoot subjects will reoccur a second time [45], it may be advantageous to create an algorithm that will predict second reoccurrence based on previous treatments.

The utilization of a representative trial could be considered a delimitation. Previous researchers have recommended the utilization of an average of ≥3 foot pressure trials that have the same walking speed [25, 29, 34]. An average was recommended because children with clubfeet have immature gait patterns[61] and deformities that can cause incomplete contact with the foot pressure plate. However, several authors have utilized a representative foot pressure trial for data analysis [26, 62, 63]. The advantage of a representative trial is that there is less post-processing time required and there is less chance of averaging outlier data that could potentially skew results. The effect of utilizing a retrospective trial versus an average trial for algorithm application is unknown. Future research should consider addressing this potential confound.

Another limitation of this study is the inconclusive results found in Chapter 4. The overall reoccurrence and TATT prediction equations produced six (21%) and nine (32%) inconclusive results respectively. The subjects whose probability of reoccurrence was >1 or <0 were classified as inconclusive/indeterminate [58]. None of the subjects in the prospective study were multivariate outliers and there was no obvious reason for the large number of inconclusive results. The subjects whose results are categorized as inconclusive should be brought to the attention of the clinician, as more investigation is needed to ascertain the likelihood of reoccurrence[58]. It may be likely that an increase in the number of subjects used to retrospectively build the algorithms would allow for more applicability across all the larger clubfoot population, thus lessening inconclusive, false positive and false negative results.

The last limitation of this study is that the time of follow-up for the prospective subjects was significantly different ($p<0.001$) from that of the retrospective subjects utilized for algorithm development. At follow-up the retrospective subjects were age 9.9(2.7) years and the prospective subjects are currently 3.9(0.9) years of age. Follow-up age could account for the algorithms low sensitivity when predicting the probability of overall reoccurrence and TATT in the prospective subjects. These results suggest that the accuracy of the algorithms should not be measured until the subject is over the age of 9 years. However, the rate of reoccurrence was not significantly different between the prospective (43%) and retrospective (56%) subjects. The difference between the two reoccurrence proportions was calculated using a Z score. This result could have been influenced by the large difference in sample sizes between the two groups, 28 and 77 respectively. This limitation also supports the need for multiple algorithms at difference ages. As different regression models may fall out at different ages that could better predict the different reoccurrence scenarios.

Future Directions

The future direction of this investigation includes standardization across multiple institutions and a multicenter study that utilizes retrospective and prospective foot pressure data. The first step is to create standardization, of foot pressure data collection and reduction, across multiple sites. Creating a cohort of institutions that collect and analyze foot pressure data using standardized procedures would allow for improved communication and comparison of foot pressure data for clinical practice and research investigations. In addition, standardization would allow for the widespread use of the algorithms that predict reoccurrence. For more information on the benefits of standardization, see Appendix B.

The second step is to create a large scale retrospective investigation utilizing foot pressure data from multiple institutions. An investigation of this magnitude would produce a large data set from various geographical regions. From this, prediction algorithms that are more applicable to the entire clubfoot population could be developed.

The last step would be to recruit a large cohort of children with clubfoot into a longitudinal prospective study. This investigation would also be multi-center, recruiting subjects from various regions. This study would measure the accuracy of the prediction algorithms and evaluate the long-term progression of clubfoot deformity.

These multicenter studies would also address the limitations of the current investigation. The following recommendations should be considered:

1. Bilateral clubfeet: Either combine unilateral and bilateral clubfeet into one subject group or generate separate equations based on laterality.
2. Incomplete Correction: Repeat casting or repeat tenotomy is <6 months post initial correction should be classified as incomplete correction and should not be classified as reoccurrence.
3. Age: Create algorithms that are iterative in nature and include changes due to growth or create algorithms at various age ranges.
4. Past and Future Interventions: Create algorithms that will predict second reoccurrence. In addition, consider previous interventions as a possible predictor of reoccurrence.

5. Representative Trial: Utilize a representative trial if the foot pressure data are variable due to immature gait and deformity.
6. Inconclusive Results: Investigate the causation of inconclusive results.

Conclusion

The three separate investigations in this study (Chapter 2-4) combined to help achieve the overall purpose of this study; to use foot pressure analysis to predict the probability of reoccurrence in children with unilateral clubfoot deformity. First, the methodology utilized in this investigation was proven to be reliable and accurate. Second, algorithms that predicted the probability of overall reoccurrence and TATT were developed and interim results for the application of these algorithms were presented. One of the two hypotheses of this study were accepted.

ACCEPTED

- Hypothesis 1. Retrospective foot pressure data, from children over the age of 6 years and whose outcome is already known, created predictive algorithms that accurately predicted the presence of overall reoccurrence and TATT.

REJECTED

- Hypothesis 2: The algorithms, when applied prospectively, did not accurately and precisely predict reoccurrence. The rejection of Hypothesis 3 could be due to the interim nature of the results in Chapter 4. The prospective subjects recruited in Chapter 4 are still in the midst of a three-year follow-up. It is possible that the final results will lead to an acceptance of Hypothesis 3.

Future direction of this research includes reporting the final results of the prospective analysis and the formation of a multicenter research study. The goal of this investigation and future research is to utilize foot pressure analysis to predict reoccurrence for children with clubfoot. With an accurate and reliable measure of reoccurrence, clinicians may be able to treat clubfeet efficiently and proactively. The incorporation of the predictive algorithms developed in this study into clinical practice may result in continued pursuit of fewer surgical interventions. This may lead to the utilization of more preventative and non-operative interventions when treating children with clubfoot deformities. Fewer surgical procedures may increase patient satisfaction and improve outcomes for children with clubfoot deformity.

Appendix A: Foot Pressure Analysis in Children with Clubfoot: A Summary of Literature from 1995-2018

Introduction

Research on clubfoot has become extremely popular, with over 530 articles published between 2011-2016 [11]. Clubfoot is cited as one of the most common foot deformities in children, with 1-4 per 1000 children affected [11]. Approximately 50% of clubfeet are bilateral in nature, and males are affected more often than females at a ratio of 2:1 [4]. Despite the prevalence of this deformity, the etiology of clubfoot is not well understood, and several factors have been cited as theories of causation [4]. Some of the more cited theories as to the cause of congenital clubfoot include genetics, neurological and positional [4]. Research has shown that gene variations and chromosomal abnormalities are potential contributors with a 20% chance of transmission from parent to child [4]. Muscle weakness and position during gestation are also cited as potential factors contributing to clubfoot deformity [4]. Diagnosis of clubfoot typically occurs at birth or in utero by ultrasound.

Clubfoot is a multi-planar deformity consisting of hindfoot varus, equines, forefoot adductus and cavus [4]. The historical treatment of clubfoot consisted of surgical procedures such as soft tissue release and osteotomy [64]. However, long-term outcomes for children treated with soft tissue release include decreased power generation during gait, indicating decreased function, and lower scores on quality of life surveys due to pain [65]. Since the 1990's, the preferred treatment for clubfoot deformity is the Ponseti Method [11, 22, 52]. The Ponseti Method consists of progressive serial casts that slowly reduce each deformity and return the foot to a typical posture. Following casting, Achilles tenotomy may or may not be warranted, depending on residual equinus [11, 22, 52]. After this initial course of treatment, children with clubfeet are fitted with abduction orthoses, worn for 23 hours a day for three months and then night-time bracing for up to 3 years [43]. Long-term results of Ponseti management show functional outcomes that are more similar to age matched typically developing populations than the traditional surgical approach [65]. However, despite early casting, surgical intervention is warranted in 7-48% of subjects under the age of 6 when residual deformity or reoccurrence is present [18].

Previous research has reported the need for a biomechanical assessment of clubfeet [66-68]. Having a valid and reliable tool provides clinicians and researchers with quantifiable information about foot function and structure [66, 68, 69]. Biomechanical assessments previously used in children with clubfoot include range of motion, functional assessments of pain, gait deviations, kinematic and kinetic analysis and foot pressure analysis [66-68]. Foot pressure analysis has been found to be a valuable tool that provides an objective and reliable assessment of foot deformity and function for both clinicians and researchers [46].

Several commercial hardware and software companies specialize in foot pressure assessment. Foot pressure measurement devices are typically flush with the floor/walkway and use specialized sensors (capacitive, piezoelectric, etc.) to measure parameters such as contact area, force, pressure and time underneath the foot during the stance phase of gait. The output can be graphical or numerical in nature and is designed to reflect the clinician's or researcher's needs.

It is advantageous to identify regions of interest (ROI) on the visual foot print based on the underlying boney anatomy of the foot. Clinicians and researchers benefit from identifying ROI because total foot data does not give an adequate representation of the pressure, force or area under different anatomical regions of the foot [25]. For example, data from the total food would not differentiate increased pressure from the lateral to medial side of the foot. For a more detailed summary of foot pressure analysis and the factors that can affect data collection, see Appendix B - Foot Pressure Analysis using the emed® in Typically Developing Children and Adolescents: A Summary of Current Techniques and Typically Developing Cohort Data for Comparison with Pathology.

Clubfoot is a multi-planar deformity that can affect multiple foot pressure parameters simultaneously. For example, hindfoot varus and supination are representative of increased pressure, force, time and area on the lateral side of the foot and corresponding decreases in these measures on the medial side of the foot. In addition, equinus deformity results in the hindfoot not fully contacting the ground and is represented as decreased pressure, force, area and time in the hindfoot region. Moreover, forefoot adductus can be visualized as a rotational deformity where the forefoot contact area is angled medially in relation to the hindfoot. Lastly, cavus is indicative of a high arching foot and is resented as a decrease in the contact area, force and pressure in the midfoot area.

The ability to quantify changes in contact area, force, pressure and time during the stance phase of gait due to growth, increasing deformity or intervention is an invaluable tool for clinicians and researchers. Foot pressure analysis provides a quantitative and graphic assessment of dynamic foot function during walking that is not otherwise appreciated through visual and clinical analysis. Foot pressure analysis has been validated, as early as the 1970's, as a useful tool in the management of clubfeet [69]. However, to date, no review of foot pressure analysis in children with clubfoot currently exist. Therefore, the purpose of this paper is to present a review of recent literature pertaining to the use of foot pressure analysis in children with clubfeet.

Methods

A retrospective review of literature from1995-2018, focusing on foot pressure analysis and children with clubfeet, was conducted. A search was conducted of PubMed, Google Scholar, and the Cochrane Library for the terms "Clubfoot and Foot Pressure" and "Clubfoot and Pedobarographs". The terms "clubfoot and foot pressure" returned 57, 12,900 and 1 results respectively. The terms "clubfoot and pedobarograph returned 10, 141, 2 results respectively. To narrow down the Google Scholar results the word "children" was added to the search; resulting in the following searches: "clubfoot, pedobarographs, children" and "clubfoot, foot pressure, children". The Google Scholar search returned 131 and 11,300 results respectively.

Study titles were first screened to identify articles for further consideration; approximately 1,000 article abstracts were screened for inclusion criteria. Inclusion was based on the following criteria: foot pressure analysis was used as the primary method of assessment, the primary population consisted of children age birth to 21 or adults with clubfoot, diagnosis of unilateral or bilateral congenital clubfoot, treated with Ponseti management and the article publication date was between 1995 and 2018. In addition, priority was given to articles that focused on foot pressure analysis as a means to compare between the following: affected and unaffected sides of children with unilateral clubfoot deformities, a typically developing population or similarly aged cohort with clubfoot deformities and between different treatment regimens. In addition, a summary of the relationship between other clinical measures (radiographs and outcome scales) and foot pressure data and a summary of the long-term follow-up of adults previously treated for clubfoot deformities were prioritized. Only full-length peer reviewed journal articles were used in this review; abstracts, meeting notes and presentations were not assessed. A total of 102 articles were identified for potential inclusion. The methods section for each of the 102 articles was screened in detail to ensure inclusion criteria was met. This resulted in a total of 26 articles chosen for review.

Results

A list of the 26 articles chosen for review is presented in Table A1. There were seven retrospective studies and 19 prospective studies that assessed the various pedobarographic outcomes of patients with clubfoot (Table A2). Three of the studies reported long-term outcomes in adults that were treated with Ponseti casting [70-72]. Ten studies focused on foot pressure differences between treatment techniques [48, 53, 54, 73-79]. Six studies reported descriptive data for foot pressure analysis in children with clubfeet [33, 80-84] and two studies focused on correlations with radiographic measurers [85, 86]. Additionally, three studies used the contralateral foot for comparison [87-89] and two centered on differences with typically developing populations [30, 90].

Foot pressure measurement details are present in Table A3. Six different pedobarograph devices were utilized in the 26 reviewed studies: emed (Novel gmbh; Munich, Germany), a light emitting glass plate [91], Footscan (RSScan; Paal, Belgium), Podotrack (Foot Care Technology; Zutphen, The Netherlands), Tekscan (Tekscan, Inc.; Boston, MA) and FreeMED (Bodytech; Noosaville, QLD). The number of trials utilized for data analysis ranged from 1-10 trials and data were analyzed using either an average of all trials or a representative trial. Nineteen of the studies utilized a self-selected walking speed and the speed in the remaining studies [71, 73, 74, 84-86, 90] was not specified. The approach (number of steps taken before contacting the plate) was variable among the articles (2-step vs. mid-gait) and 22 studies did not specify approach. Parameters utilized in each study are listed in Table A3. Masking the ROI ranged from one specific target area to a 10 area mask; see Table A3 for more information about the specific areas masked in each study.

Foot pressure data from each study are listed in Tables A4-A17. These data are intended to be used as a comparison within the clubfoot population and could be useful for physicians or researchers who want to compare foot pressure data within a cohort of similarly aged children that have been diagnosed with clubfoot deformity. For a summary of foot pressure data in a typically developing cohort of children, which can also be used for comparison, please refer to Appendix B.

Discussion

Comparisons between affected and unaffected sides of children with unilateral clubfoot deformities; comparisons between a typically developing population with similarly aged children with clubfoot deformities; and comparisons between different treatment regimens will first be presented. In addition, a summary of the relationship between clinical measures and foot pressure data and the long-term follow-up of adults previously treated for clubfoot deformities will be presented. Lastly, considerations for clinicians and researchers will be presented.

Typically Developing vs. Clubfoot

The differences in foot pressure data between a typically developing population and that of a clubfoot population has been explored in children aged 2 to 15 years. The type of foot pressure data presented varied between studies (see Table A3). Significant differences were found in foot pressure data between children with clubfoot and age matched peers, regardless of the age at assessment and the varying degrees of success of clubfoot treatment. This is an indication that despite age and treatment, a clubbed foot will never be "normal". This would suggest that foot pressure analysis is sensitive to the structural and functional differences of children with clubfoot. It can be concluded that foot pressure analysis is a valuable tool that will allow clinicians and researched to distinguish differences during gait that are not otherwise appreciated with visual analysis.

Sinclair et al. (2009) assessed the difference between children with clubfoot who were successfully treated with Ponseti casting, based on range of motion and Pirani classification, and an age, height and weight matched typically developing cohort. Twenty children (28 clubfeet) age 36.8 months (range 29-45 months) post initial treatment were compared to a cohort of twenty typically developing children [88]. A 10 area mask was used to assess peak pressure (kPa), maximum force (%BW), force-time integral (% total) and contact area (%Total) in the 10 ROI and in the total foot print [88]. Results demonstrate that there are significant differences between successfully treated clubfeet and a matched cohort of typically developing children. Clubfeet are smaller and have higher pressure and force on the lateral side of the foot. These results demonstrate successful Ponseti treatment does not normalize long-term foot pressure results in children with clubfoot to that of a matched control group.

Pauk et al. (2010) assessed the long-term difference in 20 typically developing children and 7 children with clubfeet treated with Ponseti, age range 10-15 years. Maximum pressure, contact area and contact time was measured in the five ROI (hindfoot, medial midfoot, lateral midfoot, metatarsal heads and toes) [82]. Results of this study show that children with clubfeet and children with typically developing feet both demonstrate maximal pressure in the hindfoot and metatarsal heads and lowest pressure under the medial midfoot [82]. The typically developing population had an overall lower contact time in all masked areas of the foot than the clubfoot subjects[82]. However, the results of this study should be interpreted with caution, because of the drastic difference in the number of subjects in the clubfoot and typically developing groups. This study utilized 20 typically developing subjects and seven children with clubfeet. Previous research has found that comparisons with small and unequal sample sizes have low statistical power, are prone to Type II errors and have an unequal variance[92]. The incorporation of more subjects into the clubfoot sample may have produce more reliable and accurate results. Clinicians and researchers should use caution when using the results of this study, in isolation, for comparison.

Jeans and Karol (2010) prospectively compared foot pressure data of 56 children (79 clubfeet) treated with Ponseti casting, 46 children (72 clubfeet) treated with physiotherapy and a control group of 17 age-matched controls. All subjects underwent foot pressure analysis at the age of 2 years and all were post initial treatment protocol [48]. A seven area ROI mask included the medial hindfoot, lateral hindfoot, medial midfoot, lateral midfoot, first metatarsal, second metatarsal, and the third-fifth metatarsals [48]. Out of 35 parameters assessed, significant differences ($p<0.05$) were found for 24 parameters between the physiotherapy and control group [48]. The physiotherapy group reported significantly higher results for the lateral midfoot (peak pressure, maximum force, contact area, contact time and pressure-time integral) and in the third-fifth metatarsals (maximum force, contact area, contact time) as compared to the control group. [48]. The control group reported significantly higher values in the remaining parameters as compared to the physiotherapy group: medial hindfoot (peak pressure, maximum force, contact time, pressure-time integral), lateral hindfoot (peak pressure, maximum force, pressure-time integral), medial midfoot (peak pressure), first metatarsal (peak pressure, maximum force, contact area, contact time, pressure time integral) and the second metatarsal (peak pressure, maximum force, pressure-time integral) [48]. These results suggest that physiotherapy treated clubfeet are under corrected compared to a control population.

Significant differences were also found between the Ponseti treated and the age matched typically developing cohort. The Ponseti group reported significantly higher values in eight parameters: lateral midfoot (peak pressure, maximum force, contact area, contact time, pressure-time integral) and in the third-fifth metatarsals (maximum force, contact area, contact time) [48]. The following parameters were significantly higher in the control group: medial hindfoot (peak pressure, maximum force, pressure-time integral), lateral hindfoot (peak pressure, pressure-time integral), first metatarsal (peak pressure, maximum force, contact area, contact time, pressure-time integral) and second metatarsal (peak pressure, maximum force, pressure-time integral) [48]. The results were similar between the Ponseti and physiotherapy treated clubfeet, as compared to age matched controls. Regardless of the initial treatment, the lateral midfoot and third-fifth metatarsal region parameters were significantly higher in the clubfeet [48]. This would indicate that both types of conservative treatment do not normalize parameters on the lateral side of the foot. The results of this study indicate that clubfeet remain significantly different from their able-bodied peers regardless of treatment type. Increased lateral weight bearing in clubfeet, as compared to controls, is a sign of dynamic supination, which is typically treated with a transfer of the anterior tibialis tendon [30].

Tibialis Anterior Tendon Transfer has been used to treat clubfeet that exhibit dynamic supination; which is due to over pull of the anterior tibialis in conjunction with weak ankle evertors. Jeans et al. (2014) compared the post-operative outcome of thirty seven children that underwent transfer of the anterior tibialis tendon to a group of 20 typically developing subjects. Foot pressure, area and time data were collected for a 10 ROI mask (medial hindfoot, lateral hindfoot, medial midfoot, lateral midfoot, first metatarsal, second metatarsal, third-fifth metatarsals, hallux, second toe and lateral toes). Foot pressure analysis revealed that clubfeet, post Tibialis Anterior Tendon Transfer, continue to exhibit significantly higher ($P<0.0021$) peak pressure, contact time and contact area in the lateral midfoot and higher contact area and contact time on the third-fifth metatarsals [30]. This study indicates that despite the lateralization of the anterior tibialis, children with clubfeet continue to have residual supination deformity compared to able bodied subjects [30]. While results of this study do show significant decreases in pressure, time and area pre- to post-transfer, the decreases are not enough to be considered on par with typically developing foot pressure values [30].

Salazar-Torres et al. (2014) compared the outcome of surgically treated (posterior-medial release (PMR)) clubfeet 33) and Ponseti treated clubfeet (42) to a control group of twenty-six typically developing children. The PMR group was aged 9.1(0.9) years and the Ponseti group was aged 6.5(0.9) years at the time of foot pressure analysis. The PMR group received treatment between the years of 1999-2001 and the Ponseti group received treatment between the years of 2001-2003. A five area ROI mask (medial and lateral hindfoot, midfoot and forefoot including toes) was used to measure pressure, force, pressure-time integral and force-time integral. Children treated with Ponseti management had significantly ($p<0.05$) more maximum peak pressure and peak force in the lateral midfoot than both the typically developing and surgically treated clubfoot populations [77]. This would indicate that Ponseti treated clubfeet may have residual dynamic supination and may require a tibialis anterior tendon transfer. On the other hand, surgically treated clubfeet demonstrated significant differences in the force-time integral of the medial midfoot and medial forefoot as compared to both a typically developing and Ponseti treated clubfoot populations; indicating that surgically treated clubfeet may be subject to overcorrection or planus deformity. [77]. This study demonstrates that both surgically treated clubfeet and Ponseti treated clubfeet have different outcomes as compared to a typically developing population. This would indicate that these two population should not be combined for outcome comparison.

Similarly, Church et al. (2012) compared the coronal plane pressure index (varus-/varus+), the hindfoot impulse, lateral midfoot pressure and the medial forefoot pressure of typically developing children to a group of Ponseti Treated clubfeet (22 subjects, 35 feet, age 6.3(1.4) years) and a group of clubfeet treated operatively (26 subjects, 43 feet, age 9.2(1.3) years). The operative group was treated with posterior medial release at a mean age of 10 months (2-33 months). Previously published normative data for typically developing, varus and valgus foot types, by Chang, Miller and Schueler (2002), was used for comparison in this study. Both the Ponseti and operative groups were significantly different from the typically developing subjects for medial foot pressure, lateral midfoot pressure, and coronal plane pressure index [74]. The Ponseti treated group also had a significantly different hindfoot impulse from the typically developing controls [74]. The Ponseti treated group was closer to the normative group in terms of coronal plane pressure index, medial forefoot pressure and lateral midfoot pressure; indicating that Ponseti treated clubfeet were slightly more typical than the operative group [74].

Trobisch et al. (2009) quantified the difference in peak pressure and contact time between a group of typically developing children and children with clubfoot treated by casting (type unspecified) prior to undergoing a Turco posteriomedial release at age 7 months (range 3-14 months). Foot pressure studies were conducted at age 64 months (range 47-105 months) in the children with clubfoot and the typically developing cohort was age and weight matched to this time point [90]. Peak pressure and contact time comparison between the two groups were reported for seven ROI: medial hindfoot, lateral hindfoot, midfoot, first metatarsal, third metatarsal, fifth metatarsal, hallux [90]. Significantly longer contact times were reported in the midfoot and fifth metatarsal for the children with clubfoot and significantly longer contact times were reported for the typically developing cohort in the first and third metatarsal [90]. For peak pressure, significant differences were found to be lower in the clubfeet in the medial and lateral hindfoot, first metatarsal and hallux [90]. In addition, peak pressure was significantly higher in the medial midfoot for the clubfoot group [90]. The significantly higher peak pressure and longer contact time in the midfoot of children treated with Turco release, as compared to a typically developing cohort, could be indicative of overcorrection. However, one potentially complicating factor is that no differentiation was made between the medial and lateral midfoot. It is important for researchers and clinicians to remember that significant differences were found when isolating the medial and lateral midfoot when comparing clubfoot treatment groups [30, 48, 76, 77, 79].

Giacomozzi et al. (2017) assessed the difference in pressure, force, area and time between children with clubfeet treated conservatively (20, 11±3.3 years) and a group of typically developing subjects (20,11.5±2.8 years) [33]. The authors sought to quantify the difference between groups when masking the ROI using a geometry based algorithm (built into the software) and anatomical masking (using 3D kinematic data) [33]. A five area ROI mask was used to measure foot pressure parameters in the medial hindfoot, lateral hindfoot, midfoot, medial forefoot and lateral forefoot (including the toes). Analysis comparing foot pressure data between the two masking methods was not statistically different within each group [33]. This would indicate that anatomical masking is as reliable as the previously accepted geometry based method. In addition, the significant differences found between the clubfoot and typically developing group were the same when using both the anatomical and geometry based methods [33]. Significant differences found include contact time (increased in children with clubfoot in the lateral hindfoot, midfoot and lateral forefoot; decreased in the medial forefoot), maximum force (decreased in the medial/lateral hindfoot, medial forefoot; increased in midfoot), force-time integral (increased in the midfoot; decreased in the medial forefoot) and contact area (increased in the medial/lateral hindfoot, midfoot and lateral forefoot) [33]. The authors concluded that similar significant differences can be found using a variety foot pressure methodologies.

It is common for researchers and clinicians to take an often used foot pressure parameter, like peak pressure, and create a ratio between a medial foot ROI and a lateral foot ROI. These comparison ratios can be indicative of dynamic foot function and deformity [80]. Herd et al. (2009) developed four foot pressure ratios using thirteen children, with sixteen Ponseti treated clubfeet, age range 26 months to 13.5 years. A cohort of 18 unaffected feet was used for comparison [80]. The bean shape ratio is a ratio between foot width/foot length and is a measure of forefoot adduction and hindfoot varus [80]. A bean shape value over 0.267 is indicative of a wider and shorter foot [80]. A value of 0.34 or above denotes a moderate deformity and a value above 0.6 is a severe deformity [80]. However, caution was noted when using the bean shape ratio in subjects with first-ray adductus, which can skew the results [80]. The medial/lateral ratio is between the peak pressure of the first and fifth metatarsal heads and a low value is indicative of lateral loading [80]. The hindfoot/forefoot ratio is between the peak pressure of the hindfoot and forefoot and a low value is indicative of equinus [80]. Lastly, the hindfoot/lateral arch ratio is between the peak pressure of the hindfoot and the fifth metatarsal head and a low value is indicative of equinovarus [80]. A comparison of affected and unaffected feet show that the bean shape ratio is significantly higher in affected feet and can be used as an objective measure of foot posture [80].

Ramanathan et al. (2009) continued work with the bean shape ratio and developed a novel clinical and biomechanical scoring system that was used to quantify foot function and deformity in children with clubfeet. The authors saw a need for a new way for clinicians to quantify foot function and track small subtle changes that may be indicative of reoccurrence or treatment [93]. The same subjects used in the Herd et al. (2008) study were used to develop the unique scoring system. The system consisted of a subjective questionnaire on foot function, clinical examination of the foot, calf size discrepancies, in toeing, bean shape ratios, peak pressure and center of pressure measurements [81]. The parameters combine for a 100 point scoring system where >70 is an excellent outcome with no treatment recommended, >70 with a leg length discrepancy is a good outcome with a shoe raise prescribed, 50-69 is a satisfactory outcome with orthotics prescribed and <50 is a poor outcome with major orthotic support and/or surgery recommended [81]. The scoring system was applied to thirteen children (16 clubfeet) between the ages of 26 months and 13.5 years of age. The results classified four clubfeet as excellent/good outcomes, eight as a satisfactory outcome and four as a poor outcome. The results of the scoring system were in agreement with clinical recommendations, therefore the scoring system was deemed to be feasible. One limitation of the study is that the scoring system should only be used in children who can ambulate independently, as the foot pressure parameters are measured dynamically [81]. In addition, the scoring system needs to be applied to a larger sample size to see if the agreement with clinical recommendations holds true.

Similarly, Yapp et al. (2012) sought to use the previously developed foot shape ratios to quantify the short-term outcome of five children (8 clubfeet) treated with Ponseti casting over the course of 3 years. The average age of the subjects at the last follow-up ranged from 40-56 months and foot pressure results were measured one time per year for three years [83]. Foot pressure data for this study were assessed using the protocol of Herd et al. (2008), which assesses the foot shape using a bean shape ratio, hindfoot:forefoot ratio, medial:lateral ratio and hindfoot:lateral arch ratio [80, 83]. Normative ratio data previously published [80] were used as a comparison at the three year follow-up. All five subjects were within a "normal" range for three of the ratios (hindfoot:forefoot, medial:lateral and hindfoot:lateral arch) [83]. A bean shape ratio of >0.267 has been established as the critical value for determining deformity or reoccurrence [80]. Results show that all five subjects had a bean shape ratio above the critical value at all three follow-up visits [83]. This was an indication that residual clubfoot deformity continued to exist after successful conservative treatment [83].

Contralateral Foot vs. Clubfoot

Many researchers have utilized an age matched typically developing cohort for comparison when assessing foot pressure data in children with clubfoot. However, there have been several studies that utilize the unaffected foot, in children with unilateral clubfoot, as a comparison. Using the contralateral unaffected foot as a control accounts for differences in growth over time and may be used to assess symmetry for within subject comparisons. However, it has been established that the contralateral unaffected foot is not "normal" and should not be used as a typically developing control.

Sinclair et al. (2009) compared foot pressure results in a cohort of 12 children (mean age 36.8 months; range 29-45 months) with unilateral clubfoot treated successfully with Ponseti, with their contralateral unaffected sides. A 10 area mask was used to assess peak pressure (kPa), maximum force (%BW), force-time integral (% total) and contact area (%Total) in 10 ROI (medial and lateral hindfoot, medial and lateral midfoot, medial forefoot, central forefoot, lateral forefoot, hallux, second toe and lateral toes) and in the total foot print [88]. Results of this study show that there were no significant differences in contact area, however differences were found in the 2^{nd} toe and the 3^{rd}-5^{th} toes for force-time integral and maximum force respectively [88]. The affected side reported higher maximum force in the 3^{rd}-5^{th} toes and the unaffected side reported a larger force-time integral in the second toe [88]. For peak pressure, all areas reported significant differences except for the medial midfoot, first metatarsal, 3^{rd}-5^{th} metatarsals and the hallux [88]. All peak pressures were smaller in the affected side except for the lateral midfoot, where the affected side was larger [88]. This study demonstrates that successfully treated clubfeet have residual supination deformity as compared to their unaffected sides. This is the same trend that was seen when comparing clubfeet to a typically developing population, therefore, it may be reasonable to use the contralateral side for comparison. However, proper precautions should be noted in study methodology and potential limitations should be clearly stated.

Wallace et al. (2016) measured short-term foot pressure differences between two groups of clubfeet: twenty-eight Ponseti treated clubfeet that underwent tibialis anterior tendon transfer to correct residual supination and thirty-one unilateral clubfoot subjects without residual deformity. For a typically developing comparison, the unaffected side of the thirty one unilateral clubfeet subjects was used. There was no difference in the age (surgical 3.1(0.7) years; non-surgical 3.0(0.8) years), height or weight of the two groups at the initial visit or at the three year follow-up (age: surgical 6.0(0.9) years; non-surgical 6.1(1.0) years) [53]. A 10 ROI mask was used in this study: medial and lateral hindfoot, medial and lateral midfoot, first metatarsal, second metatarsal, third-fifth metatarsals, hallux, second toe and lateral toes A time-by-surgery interaction was assessed for the surgical clubfeet compared to the contralateral side and changes due to growth were assessed between the non-surgical clubfeet and the contralateral side [53]. The pressure-time integral of the lateral midfoot and the lateral force-time integral demonstrated significant changes over time; where the surgical group was not significantly different from the contralateral side post-op and the non-surgical group was significantly different from the contralateral side at visit two [53]. The results of this study indicate that the lateral pressure and force of clubfeet that did not undergo surgical intervention are less like their contralateral side, than clubfeet that did undergo surgical intervention[53]. This would suggest that both groups of clubfeet have varying degrees of supination deformity. Children with a larger supination deformity that undergo tendon transfer will have short-term outcomes that are more like the contralateral side than children with clubfoot that have smaller or less noticeable supination deformities initially.

Favre et al. (2007) attempted to quantify the difference between the contralateral foot and the clubbed foot in sixteen children (mean age 5.6 years; range 4-8 years) with unilateral deformity. All clubfeet underwent conservative treatment with splints prior to undergoing soft tissue surgical intervention. Treatment decision making was decided on an individual basis by one physician and carried out at 330 (246) days of age with an average follow up time of 5.5 (1.3) years. Peak pressure was measured in a ten area ROI mask; hindfoot, midfoot, first metatarsal, second metatarsal, third metatarsal, fourth metatarsal, fifth metatarsal, hallux, second toe, and lateral toes. Significant differences ($p<0.05$) were found for peak pressure in the hindfoot, midfoot and hallux [87]. The contralateral foot reported higher peak pressure values in the hindfoot and hallux, whereas the clubfeet reported higher peak pressures in the midfoot [87]. In addition to comparing the contralateral foot and clubfoot, this study also compared the contralateral clubfoot with a typically developing cohort of children (68) age 5.5(1.4) years [87]. Peak pressure results were higher in all areas of the typically developing feet, except for the lateral toe region [87]. Significant differences ($p<0.05$) in peak pressure were found in the hindfoot, first metatarsal, third metatarsal and fourth metatarsal [87]. The results of this study show that the peak pressure on the contralateral side of unilateral clubfoot patients is different from typically developing feet, and should not be used as a "normal" comparison.

Copper et al. (2014) also assessed the difference between the contralateral foot, in children with unilateral clubfoot, and a typically developing population. Subjects were split into three age groups; <2 years, 2-5 years and >5 years[89]. The contralateral group had 38, 79 and 60 feet and the typically developing group had 20, 126 and 146 feet respectively[89]. Maximum force, contact time and force-time integral was measured in a five area ROI mask; hindfoot, medial midfoot, lateral midfoot, medial forefoot and lateral forefoot. Foot pressure values for maximum force, average force-time integral and the % of stance time at initiation, maximum and termination of force was assessed for the five ROI [89]. For the <2 years age group, significant differences ($p<0.05$) were found between the % of stance at initiation of force in the lateral midfoot, % of stance at maximum force in the lateral forefoot and the % of stance at termination of force in the medial forefoot[89]. The unaffected side had a decreased % of stance in the lateral midfoot and an increased % of stance in the medial forefoot and lateral forefoot. Significant differences ($p<0.05$) were reported in all 5 ROI for the 2-5 years group[89]. The contralateral feet reported significantly less maximum force and % of stance at force termination than the typically developing population[89]. On the lateral side of the foot, the contralateral feet reported significantly decreased % of stance at initiation and maximum force in the lateral midfoot; and significantly less maximum force and average force-time integral in the lateral forefoot[89]. In the >5 years of age group, the contralateral side again demonstrated significant differences ($p<0.05$) from the typically developing group in all five ROI[89]. The results of this study demonstrate that foot pressure variables are not static and do change as children grow. In addition, the contralateral foot is consistently different throughout growth in comparison to an age matched typically developing cohort and caution should be used when utilizing the contralateral foot as a "normal" control.

Relationship of Foot Pressure Data and Clinical Measurements

Radiographic measures of children with clubfoot are useful for identifying treatment resistant clubfoot and predicting recurrence [11]. Radiographs measure angles between the different boney anatomies in the foot and can reveal structural abnormalities that result from clubfoot deformity. However, the drawback to radiographs is the exposure to radiation. While radiographs reveal the structure of the foot, foot pressure analysis measures the dynamic function of the foot and can be administered often without the concern of radiation. When examining clubfeet, previous researchers have recommended that both a structural (radiograph) and functional assessment be conducted [68]. The relationship between radiographs and foot pressure analysis in children with clubfoot was investigated in the following five studies.

Thometz et al. (2005) assessed the relationship between anterior-posterior and lateral radiograph angles with contact area, peak pressure and pressure-time integral in 39 children with 61 clubfeet (mean age 8 years; range 4.3-14.1 years). Three significant correlations were found with the anterior-posterior radiograph talus/first metatarsal angle: contact area lateral hindfoot (-0.37), peak pressure of the fifth metatarsal (0.40) and peak pressure of the hallux (-0.42) [85]. Nine significant correlations were found in the lateral radiograph measurements [85]. The lateral talo-calcaneal angle was negatively correlated with the contact area of the lateral hindfoot (-0.36) and the medial hindfoot (-0.34) [85]. The lateral talus/first metatarsal angle was correlated with the contact area of the midfoot (-0.49) and the contact area of the fifth metatarsal (0.42) [85]. The lateral calcaneal/ first-metatarsal angle was correlated with the contact area of the lateral hindfoot (-0.41) and the contact area of the midfoot (-0.72) [85]. Lastly the first metatarsal/fifth metatarsal angle was correlated with the contact area of the lateral hindfoot (-0.34), the contact area of the midfoot (-0.52) and the peak pressure of the first metatarsal (-0.33) [85]. These correlations demonstrate that lateral radiograph angles have more significant correlations than that of the anterior-poster radiograph and that the contact area reported more correlations (9) than peak pressure (3). The highest correlation reported was a strong negative correlation (-0.72) between the lateral calcaneal/first-metatarsal angle and the contact area of the midfoot[85]. Contact area of the midfoot is an indicator of pes cavus (less contact area) and pes planus (larger contact area). The lateral calcaneal first-metatarsal angle can indicate residual midfoot deformity, with more cavus (a larger angle) causing less contact area in the midfoot[85]. The correlations seen in this study indicate that radiographs should be used in conjunction with foot pressure analysis to provide clinicians with a more complete picture of foot functional and structural changes over time.

Oto et al. (2011) also assessed correlations between anterior-posterior and lateral standing radiographs with the contact time of the hindfoot. Fifty subjects, with seventy clubfeet, failed initial Ponseti treatment and underwent posterior release [86]. Age at the time of surgical release was 11.2 months (range 3-30.6) and follow-up x-ray and pedobarographs were measured on average 8.7 years (range 4.3-15 years) post treatment [86]. Pearson correlation revealed a significant positive correlation between contact time of the left hindfoot and the left lateral tibio-calcaneal angle ($r=0.42$, $p=0.01$) and left anterior-posterior calcaneal/fifth metatarsal angle ($r=0.37$, $p=0.03$) [86]. Right hindfoot contact time was positively correlated with right anterior-posterior talo-first metatarsal angle ($r=0.48$, $p=0.003$) and anterior-posterior calcaneal/fifth metatarsal angle ($r=0.54$, $p=0.001$) [86]. The contact time of the hindfoot can be a measure of equinus and the anterior-posterior calcaneal-fifth metatarsal angle is a measure of forefoot adduction [86]. Results of this study demonstrate that there are significant correlations between radiographic and pressure measurements in clubfeet with equinus and forefoot adduction [86]. A limitation of this study is that only one pedobarographic measurement was used, which ignores potential relationships between x-ray measurements and other ROI.

While the relationship between the tibio-calcaneal angle and foot contact time measured in the Oto et al. (2011) was significantly positive, another investigation of the tibio-calcaneal angle reported poor correlations with force and time measurements. Jean and Karol (2010) assessed the correlation between the tibio-calcaneal angle with contact time and maximum force of the medial and lateral hindfoot in order to assess dynamic equinus in children (age 2) with clubfeet. Results of this study show poor and weak negative correlations (range -0.0023 to -0.2085) between force and time in the medial and lateral hindfoot with the tibio-calcaneal angle [48]. It was concluded that foot pressure measurements offer a unique set of information as compared to radiographic measure of the tibio-calcaneal angle [48]. In addition, it was suggested that using pedobarographs and radiographs together might present a more holistic view of foot function that using the two methods in isolation [48].

The results of the Jeans and Karol (2010) article are in direct contrast to the Oto et al. (2011) article. The differences seen may be contributed to the age of the subjects at the time of analysis. Oto et al. (2011) measured angles and foot pressure in a group of children age 8.7 years (range 4.3-15 years). Whereas, children assessed in the Jeans and Karol (2010) article were 2 years of age. Previous research has found that children's gait does not mature until after the age of three and full maturation may not occur until age 13 [60, 61]. The children assessed by Oto et al. (2011) may have had more mature gait patterns than that of the 2-year-old children assessed by Jeans and Karol (2010). The more mature gait pattern could have been less variable and able to demonstrate higher correlations between foot pressure and radiographic measures.

Differences in Treatment/Surgical Intervention

Treatment regimens for clubfoot can vary by physician and the differences due to treatment protocol can have an effect on foot pressure outcomes. Currently, most physicians prescribe a conservative non-operative treatment initially and vary the prescription of follow-up treatment based on the clinical presentation. Reoccurrence of deformity has been reported in 26-48% of children with clubfoot[18]. Treatment for reoccurrence can range from repeat casting, to tendon transfers, to soft tissue releases and bony realignments. The following studies outline foot pressure results between different surgical interventions and for reoccurrence of deformity.

As previously mentioned, Ponseti management is the initial non-operative treatment choice for most physicians [11, 22, 52]. An alternative non-operative approach is French Physiotherapy treatment, which consists of mobilization, stretching, strengthening of ankle musculature and taping/splinting to maintain correction[2]. The difference between these two non-operative methods is that the casts cannot be removed; whereas the splints/tapings are changed on a daily or weekly basis by a physical therapist. Jeans and Karol (2010) compared 56 subjects (79 clubfeet) age 2.3(0.2) years treated with Ponseti casting with 46 subjects (72 clubfeet) age 2.2 (0.3) years treated with physiotherapy. Dynamic foot pressure analysis for peak pressure, maximum force, contact area, contact time and pressure-time integral was analyzed for a ten area ROI mask (medial hindfoot, lateral hindfoot, medial midfoot, lateral midfoot, first metatarsal, second metatarsal and third-fifth metatarsals) [48]. Significant differences ($p<0.05$) were found in the medial hindfoot (peak pressure, maximum force, pressure-time integral), lateral hindfoot (maximum force) and medial midfoot (peak pressure) [48]. For all parameters, children treated with Ponseti casting reported significantly larger results [48]. These results indicate that clubfeet treated with physiotherapy have more residual equinus (less pressure in the hindfoot) than their Ponseti counterparts [48]. The Ponseti protocol includes an optional Achilles tenotomy to treat residual equinus after removing the last cast. This optional procedure is not part of the initial physiotherapy protocol and this lack of standardizing may have led to the increased equinus in the physiotherapy group. However, one limitation of this study is that the percent of Ponseti treated subjects that underwent an Achilles tenotomy was not reported.

Previous research has stated that upwards of 33% of children treated with French Physiotherapy would go on to require an extensive soft tissue release [2]. Jeans, Erdman and Karol (2017) sought to quantify the difference, at age five, between clubfeet treated with the Ponseti protocol (84 subjects with 122 clubfeet) and clubfeet treated with French Physiotherapy (80 subjects with 116 clubfeet). The center of pressure path was the only significant foot pressure difference between the two groups; where the path was more medial in the Ponseti treated feet (p=0.0379) [79]. With medialization of the center of pressure path, care needs to be taken that there is not an over correction, which would be indicative of pes planus. Lateralization of the center or pressure is indicative of lateral weight bearing in the Physiotherapy treated feet. This could suggest a higher need for tibialis anterior tendon transfer to correct dynamic supination in the Physiotherapy group[79].

While many previous studies have reported the superior outcomes of Ponseti treated clubfeet, Hayes et al. (2018) used foot pressure analysis to quantify overcorrection in Ponseti treated clubfeet. Foot pressure analysis of eighty-one subjects (115 clubfeet), at age 9.5 years, were included in this retrospective review[84]. Overcorrection was quantified as elevated medial forefoot and midfoot pressures[84]. Fourteen subjects were found to have overcorrection [84]. Despite the overall good outcomes seen in Ponseti treated clubfeet, upwards of 12% may be quantified as having an overcorrection deformity. Overcorrection can predispose patients to limited function and pain [84]. This study advocates for the use of foot pressure as a means to quantity overcorrection in Ponseti treated clubfeet [84]. One limitation of this study is that the foot pressure methodology utilized was not listed in detail.

Chen et al. (2015) measured the difference in bracing protocols post Ponseti treatment for children with clubfoot at the age of 3-4. A comparison was made between three treatment groups: 1) 15 children following standard treatment with Dennis Brown Bar Shoes for nighttime wear; 2) 20 children using Dennis Brown Bar Shoes at night and a foot orthosis during the day; 3) 18 children that used a foot orthosis during the day and a forefoot abduction shoe for nighttime wear [78]. Foot pressure analysis was conducted at an average follow up of 44 months [78]. Average pressure, peak pressure and Bean Shape Ratio were measured using a six area ROI mask that defines the medial and lateral hindfoot, midfoot and forefoot. The results of this study show that using a foot orthosis in combination with nighttime wear of a foot abduction orthosis provides significantly more correction of equinus, varus and adduction, as measured by a ratio of the pressure in the hindfoot (<0.8 indicative of equinus, <0.4 severe equinus) and bean shape ratio (normal value is 0.23±0.02) [78]. The foot abduction orthosis and daytime orthotic wear resulted in a significantly smaller bean shape ratio of 0.27, whereas the Dennis Brown Bar alone had a non-significant value of 0.31 and the Dennis Brown Bar and daytime orthosis had a non-significant value of 0.29 [78]. A bean shape ratio over 0.267 is indicative of a wider and shorter foot, >0.34 denotes a moderate deformity and a value >0.6 indicates a severe deformity [80].The use of orthosis had a significant impact on the level of equinus; the use of orthotics with Dennis Brown Bar resulted in a significantly higher hindfoot/forefoot ratio of 0.72, whereas the Dennis Brown Bar alone had a hindfoot/forefoot ratio of 0.44 [78]. A hindfoot/forefoot ratio of <0.8 is indicative of equinus and below 0.4 is a severe equinus deformity[78]. A bean shape value over 0.267 is indicative of a wider and shorter foot [80]. A value of 0.34 or above denotes a moderate deformity and a value above 0.6 is a severe bean shape deformity[78]. The results of this study suggest that children with clubfoot would benefit from the use of daytime orthosis in conjunction with nighttime wear of the Dennis Brown Bar or foot abduction shoes [78].

Church et al. (2012) compared the coronal plane pressure index (varus-/varus+), the hindfoot impulse, lateral midfoot pressure and the medial forefoot pressure of children with clubfoot treated with Ponseti (22 subjects, 35 feet, age 6.3(1.4) years) versus those treated with posterior medial release (26 subjects, 43 feet, age 9.2(1.3)years). Fourteen of the operatively treated subjects required additional surgical procedures to treat reoccurrence [74]. Comparatively, only five subjects in the Ponseti group required further treatment [74]. Peak pressure and pressure indexes were measured using a three ROI mask (hindfoot, medial column and lateral column). Foot pressure results reveal that there was a significant difference between the Ponseti and operatively treated groups for coronal plane pressure index (more varus in the operative group), hindfoot impulse (higher impulse in the Ponseti group) and medial forefoot pressure (higher pressure in the Ponseti group) [74]. The results of this study show that there is over correction in the Ponseti group and residual varus in the operative group. However, the exact number or percent of subjects with overcorrection was not quantified. One limitation of this study is the three year age difference between the two groups, which could bias the results [74].

Electrical stimulation of the peroneal muscles, post-Ponseti treatment was investigated by El-Shamy, El-Kafy and Ibrahim (2013). Thirty children, age range 2-3, with clubfoot were prospectively recruited and split into two groups; there was no significant differences in age, height, weight or gender between the two groups [75]. Over the course of 12 weeks, the control group did not receive additional intervention beyond abduction orthosis, whereas the experimental group received 30 minutes of daily electrical stimulation to the Peroneal evertors in conjunction with orthosis [75]. Electrical stimulation was applied for 30 minutes daily, at a frequency of 40 hertz, using a 14s on and off burst with the aim of producing active eversion of the foot[75]. Foot pressure analysis was measured pre- and post-intervention for [75]. Peak pressure, as a percentage of bodyweight, was measured for three ROI; the hindfoot, midfoot and forefoot (including the toes) [75]. Results show no significant differences between the control group and electrical stimulation group pre-intervention [75]. Post stimulation, the experimental group had a significant increase in peak pressure in all three ROI, as compared to the control group [75]. Despite this increase, the experimental group's peak pressure was still below that of typically developing children [75]. This study suggests that the use of electrical stimulation on the ankle evertors as an intervention, may increase the peak pressure of the entire foot. Increasing the overall peak pressure indicates more force generation and absorption during the stance phase of gait. The efficacy of using electrical stimulation for treatment has yet to be established, additional testing was recommended [75].

Jeans et al. (2014) assessed the foot pressure changes at 6 or fewer months preoperatively and 1 to 2 years post- tibialis anterior tendon transfer for 30 subjects with 37 clubfeet. The peak pressure (kPa), contact area (%total) and contact time (%total) for ten ROI (medial hindfoot, lateral hindfoot, medial midfoot, lateral midfoot, first metatarsal, second metatarsal, third-fifth metatarsal, hallux, second toe, and lateral toes) were assessed with significance of p=0.0021[30]. As a result of the tibialis anterior tendon transfer, significant decreases were seen in the pressure and contact area of the lateral midfoot and third-fifth metatarsals[30]. Whereas, all significant parameters on the medial side of the foot increased in value post-operatively[30]. The results of this study indicate that tibialis anterior tendon transfer is effective at decreasing contact and pressure on the lateral side of the foot that was caused by dynamic supination[30].

Additionally, the difference between reoccurred clubfeet treated with tibialis anterior tendon transfer (20 subjects; 24 clubfeet; age 53(10) months) and a cohort of clubfeet that did not reoccur (12 subjects, 18 clubfeet; age 48(12) months) were compared in a 2014 study by Gray et al. Ponseti treated clubfeet were assessed at a baseline/pre-operative, 3 months, 6 months and 12 months follow-up/postoperative [76]. Contact area (cm^2), peak pressure (kPa) and maximum mean pressure (kPa) was measured in three ROI; total foot, medial foot and lateral foot [76]. At baseline, the reoccurred group demonstrated significant differences ($p<0.05$) from the non-reoccurred group. The reoccurred group reported significantly less contact area, total peak pressure, medial peak pressure and medial maximum mean pressure [76]. At a 12 month follow-up/post-operative, no significant differences were reported between the tibialis anterior tendon transferred clubfeet and those that did not require transfer [76]. This study shows that, in terms of foot pressure analysis, tibialis anterior tendon transfer effectively brings reoccurred clubfeet on par with age matched clubfeet that did not reoccur.

Moreover, another study by Wallace et al (2016) sought to assess foot pressure differences between 28 children with clubfoot treated with tibialis anterior tendon transfer and age, height, weight and time to follow-up (2 Years) matched children (31) with unilateral clubfeet not treated with tibialis anterior tendon transfer [53]. Age for the surgical group was 3.1(0.7) years and 3.0(0.8) years in the non-surgical group. Significant differences ($p<0.05$) were found between the two clubfoot groups at visit one/pre-op on the lateral midfoot. Peak pressure, contact time and force-time integral were all significantly higher in the clubfoot group, indicating that tibialis anterior tendon transfer was warranted [53]. At the post-operative/visit two time point, there were no significant differences between the two clubfoot groups on the lateral side of the foot [53]. This study demonstrates that clubfeet with a supination recurrence deformity can be treated with a tibialis anterior tendon transfer and subsequently have foot pressure results on par with their non-recurred clubfoot counterparts.

Hosseinzadeh et al. (2016) went on to use the hindfoot/forefoot angle, as measured on a pedobarograph, to predict recurrence of forefoot adduction in children with clubfeet. Results demonstrate that for every one degree decrease in hindfoot/forefoot angle (below 140 degrees), the risk of needing an tibialis anterior tendon transfer increased by 4%[54]. Quantifying the change in risk of recurrence of forefoot adductus will aid in treatment and surgical decision making for clinicians[54]. The relationship between the hindfoot/forefoot angle was measured on a pedobarograph and the corresponding measurements from a radiograph have not been previously measured in a clubfoot population.

Salazar-Torres et al. (2014) compared the short-term results of children treated with Ponseti versus those treated with soft tissue procedures (i.e. Turco, Cincinnati, postero-lateral release). A comparison of foot pressure results in thirty-three feet treated surgically and forty-two feet treated with Ponseti was carried out at age 9.1(0.9) years and 6.5(0.9) years respectively [77]. Pressure, force, pressure-time integral and pressure ratios were measured using a five ROI mask (hindfoot, medial midfoot, lateral midfoot, medial forefoot, lateral forefoot). Significant differences ($p<0.05$) were found in the hindfoot (maximum peak pressure, force-time integral), lateral midfoot (maximum peak pressure, peak force, force-time integral), medial midfoot (force-time integral, average peak pressure) and in the medial forefoot (average peak pressure) [77]. The results show that the Ponseti group was somewhat under-corrected due to the increased force and pressure in the lateral midfoot [77]. In addition, the Ponseti group had less pressure and force in the hindfoot; which may be indicative of residual equinus compared to the surgical group [77]. Both insufficient initial treatment and recurrence could be the cause of the under correction and residual equinus. However, this distinction was not discussed by the authors.

Hutchinson et al. (2001) reported pre- to post-operative changes in peak pressure in Ponseti treated children whose reoccurrence was treated with Ilizarov external fixation. This study assessed a total of 39 children (56 clubfeet) before (18 subjects) and after (21 subjects) external fixation treatment for a reoccurred clubfoot [73]. The subjects were on average 11 years of age (range 3-11) with a 12 months average follow-up after surgery [73]. The peak pressure (kPa) in a seven area mask (hindfoot, hallux, and 1st-5th metatarsal heads) was assessed during walking [73]. Results of this study show that post-operatively, children treated with Ilizarov have significantly ($p<0.005$) lower peak pressure in the fifth metatarsal and significantly higher peak pressure in the hindfoot and first metatarsal [73]. Post-operative peak pressure results demonstrate that Ilizarov treatment helped to redistribute the pressure more evenly between the medial and lateral metatarsals and increased the pressure/weight bearing on the hindfoot for children with reoccurred clubfoot [73].

Long-Term Follow-up

Cooper and Dietz (1995) assessed the long-term outcome of clubfeet treated with the Ponseti method. The functional outcome of fifty-four subjects (71 clubfeet, average age 34 years (range 25-42)) were assessed 30 years after initial treatment. The purpose was to compare adults with clubfoot to a cohort of typically developing adults using several outcome measures [70]. Foot pressure analysis was performed using an average of three trials collected at a self-selected walking speed [70]. A five area mask (hindfoot, midfoot, forefoot, lateral toes, and hallux) was used to assess four parameters: peak pressure, force, pressure-time integral, contact area and force-time integral [70]. Results of the study show that adults with clubfeet did not differ from their typically developing counterparts in terms of the total foot print [70]. However, when regional analysis was conducted, significant differences ($p<0.05$) were found in the hindfoot (lower force and lower peak pressure), midfoot (higher force, higher peak pressure, higher pressure-time integral, and higher force-time integral), forefoot (smaller area), and lateral toes (larger area and higher force-time integral)[70].

In addition to comparing to a typically developing cohort, these authors sought to assess if there were differences between clubfeet with superior/good outcomes vs poor outcomes. Using pain and limited function as measures of outcome; 62% of subjects with clubfoot rated their outcome as superior, 16% good and 22% poor [70]. In terms of foot pressure analysis, the only parameter that was significantly different ($p=0.04$) between excellent/good vs poor outcomes was pressure-time integral of the total foot [70]. Clubfeet with excellent/good outcome reported an average pressure-time integral value of 27(6)Ns/cm^2, as compared to 21(7) Ns/cm^2 in the poor outcome group[70]. The results of this study suggests that adults treated with Ponseti had foot pressure results more alike, than different from their typically developing counter parts. In addition, the study suggests that pressure-time integral of the total foot may be an important variable when assessing the long-term outcome of clubfoot treatment.

Similarly, Huber and Dutoit (2004) sought to quantify the long-term outcome of children treated with Ponseti that subsequently underwent posterior release for recurrence. Nineteen adults, with twenty-four clubfeet, were assessed with foot pressure analysis at a mean age of 41 years (range 39-46 years) [71]. Peak pressure was measured for an eight area ROI mask, medial hindfoot, lateral hindfoot, first-fifth metatarsals and hallux[71]. In terms of peak pressure, the highest pressure area for adults with clubfeet was under the third metatarsal. In a typically developing cohort (20) the highest pressure point was reported under the second metatarsal head[71]. In addition, there was a medialization of the center of pressure path in adults with clubfeet treated with posterior release, indicating more pronation as compared to typically developing counterparts[71].

Holt et al. (2015) quantified the long-term outcome of children with recurrent clubfoot treated with tibialis anterior tendon transfer. A group of 14 adults (47.6(6) years) served as the treatment group that underwent tibialis anterior tendon transfer and a group of 21 adults (47.1(4.1) years) served as the reference group of subjects whose Ponseti treatment was successful and did not experience reoccurrence [72]. The two groups were not different in terms of initial Ponseti treatment; with similar numbers of casts (5.8 transfer group, 5.4 non-transfer group) and similar percentage receiving Achilles tenotomy (76% transfer group, 66% non-transfer group) [72]. A pedobarograph comparison of pressure, contact area, force and time was conducted between the transfer and non-transfer groups using a five ROI mask (hindfoot, midfoot, forefoot, hallux, and lateral toes) [72]. Results show that there were not significant differences between the two groups [72]. This would indicate that tibialis anterior tendon transfer was successful at correcting reoccurrence and influencing long-term outcomes so that reoccurred clubfeet are on par with their non-reoccurred clubfoot peers [72].

Considerations for Clinicians and Researchers

A review of the literature has brought to light several factors related to foot pressure analysis data collection and reduction protocols when assessing children with clubfeet. There are a multitude of parameters that can be calculated from a foot pressure analysis. The most commonly reported parameter across the board was peak pressure, utilized in 23/26 studies. Pressure is defined as force divided by area and peak pressure is the highest pressure recorded in a sensor during the entire stance phase of gait [27]. While peak pressure could reveal to researchers and clinicians the areas where the most pressure is occurring, this parameter does not reveal when the peak occurred. For children with clubfeet, who are not prone to ulcers due to excessive pressure under the sole of the foot, peak pressure alone does not reveal information on the biomechanical behavior of the foot during stance phase. Parameters that could be more indicative of foot function during stance phase are pressure-time integral, force-time integral, pressure ratios (i.e. medial/lateral, bean shape), and mean/average pressure. Mean pressure is calculated as the average pressure over the entire stance phase[27], this parameter includes time and could reveal more information about foot function during stance phase and not just the point when the highest pressure occurred. Pressure-time integral is the area under the pressure-time curve and also takes into account the temporal aspect of gait.

No two studies were exactly the same in terms of the units utilized, the data collection device used, the approach, the mask chosen to define the ROI and the subject demographics (Tables A2 & A3). The units used when reporting data need to be considered. For example, pressure data expressed in kilopascals (kPa) will be different than when expressed in Newton's-centimeters squared (N/cm^2). It is imperative to transform data into similar units when comparing data between studies. What's more, the way in which a subject approaches, walks up to the data collection device, can affect the foot pressure data collected. Walking speed and the number of steps take prior to device contact can change the pressure, force, time and area output [34, 94, 95]. Moreover, masking is an important factor to consider when assessing foot pressure data. The calculations used to define the boarders of each ROI can change depending on the number of areas and software program utilized [28, 29, 31]. For example, Table A3 lists the different ROI used in each study. A 5 area ROI mask was used in a total of six studies, however, there were four combinations of different ROI identified. Therefore, it is important to ensure that the data with which you want to compare, utilizes similar ROI masking. Lastly, subject demographics are vastly different between studies. The range of subjects is from months (youngest age 11 months) to years (a range of 2-15 years of age) to decades (largest age 47 years) different. For more information about how foot pressure device parameters can affect data collection and reduction refer to Appendix B.

This large variation in data collection protocols brings into question the feasibility of comparison between research studies. Different devices, software programs, and masks chosen will result in slightly different data output. Therefore, it would be remiss not to note that the data summarized in Tables A4-A17, should be approached with caution. In order to reduce the risk of inaccurate or inappropriate data comparison, clinicians and researchers should choose wisely the data used for comparisons.

Conclusions

The purpose of this paper was to present a consolidated summary of the literature pertaining to the use of foot pressure analysis in children with clubfeet and to the author's knowledge, this is the first study to do so. Overall analysis of foot pressure literature in children with clubfeet informed the following conclusions:

1. Comparison of Clubfoot and Typically Developing Feet
    a. Clubfeet have increased lateral weight bearing despite conservative or surgical treatment approaches.
    b. Surgically treated clubfeet have a tendency to be overcorrected.
    c. Ponseti treated clubfeet demonstrate foot pressure outcomes closer to a typically developing population as compared to both surgical and physiotherapy groups.
    d. Pressure ratios, such as the bean shape ratio, reveal valuable information on foot function and structure.
2. Comparison of Clubfoot and the Contralateral Foot
    a. Regardless of treatment protocol, a clubbed foot is significantly different from the contralateral foot.
    b. The contralateral foot has significant differences in pressure from typically developing feet.
3. Relationship Between Foot Pressure Data and Clinical Measurements
    a. In combination, radiographs and foot pressure can provide a relatively complete picture of foot structure and function.
    b. There are significant correlations between foot pressure parameters and radiograph angle measurements.
4. Differences in Treatment/Surgical Interventions
    a. Physiotherapy treated feet have more equinus and lateral weight bearing compared to Ponseti treated clubfeet.
    b. Ponseti has the potential to cause overcorrection, seen as increased medial pressure and force.
    c. Foot orthosis daytime wear can enhance foot abduction orthosis effectiveness.
    d. Operative clubfeet tend to have residual varus, whereas Ponseti feet have residual equinus and supination.
    e. Tibialis Anterior Tendon transfer is effective at treating residual supination.
    f. Overall treatment and intervention brings foot pressure data of clubfeet closer to their able bodied peers.
5. Long-term Outcomes
    a. Ponseti treatment results in a more "typical foot" compared to other operative and non-operative treatments.
    b. Foot pressure results are not static and change over time as a child grows.
    c. Posterior medial release treated clubfeet tend to have residual pes planus (increased pressure and contact in the medial midfoot).

d. Initial Ponseti and follow-up with tibialis anterior tendon transfer results in foot pressure parameters on par with able bodied peers in adulthood.

6. Foot Pressure Parameters with Diagnostic Potential - Based on the literature reviewed, certain parameters and methodologies should be considered when conducing foot pressure analysis for children with clubfeet.
    a. It is important to note that regional analysis is more indicative of foot function than total foot analysis [28, 29, 31].
    b. Clubfoot Foot Pressure Data as Compared to a Typically Developing Population
        i. Increased pressure and force on the lateral midfoot and 3rd-5th metatarsals is indicative of supination [48, 77, 82, 88].
        ii. Increased time in the fifth metatarsal and decreased pressure in the hallux and the first metatarsal, again indicating supination [90].
        iii. Decreased total contact area indicates a smaller foot [88].
        iv. Pre- and post-operatively, pressure and contact time remains higher in the lateral midfoot and 3rd-5th metatarsals; again indicating supination [30].
        v. Bean shape ratio, foot width divided by foot length, is indicative of forefoot adduction and hindfoot varus. A ratio of >0.267 is a mildly wider and shorter foot, >0.34 is a moderate deformity and >0.6 is severe deformity. Clubfeet remain above the 0.267 cutoff range [80, 83].
    c. Clubfoot Foot Pressure Data Difference in Treatment and Surgical Intervention
        i. Physiotherapy treated clubfeet have lower pressure in the hindfoot than Ponseti treated clubfeet, indicating residual equinus [48].
        ii. Center of pressure path is more lateral in physiotherapy treated clubfeet, indicating more supination [79].
        iii. Bean shape ratio can be used to differentiate between abduction bracing protocols. Abduction bracing in conjunction with orthosis had significantly lower bean shape ratio (0.27) compared to bracing in isolation (0.31) [78].
        iv. Ponseti treated clubfeet had significantly less pressure and force in the hindfoot, indicating more equinus, as compared to surgically released clubfeet [77].
        v. Clubfeet treated with tibialis anterior tendon transfer, as compared to those that were not, have decreased pressure and contact area in the lateral midfoot and 3rd-5th metatarsals and increased pressure and contact area in the medial midfoot and first metatarsals[30, 53, 76]. This is indicative that tibialis anterior tendon transfer decreases dynamic supination.

In summary, foot pressure analysis is an effective biomechanical tool that leads to the following conclusions; children with clubfeet are different from their able bodied peers, the contralateral unaffected foot is not “normal” and should not be used for in term of a typically developing reference, foot pressure data are correlated with radiographic measures, foot pressure data can distinguish between treatment protocols and surgical interventions and can adequately quantify long-term outcomes. In addition, this study provided a summary of foot pressure data for children with clubfoot that can be readily assessable and used for comparison by clinicians and researchers. However, the wide range of foot pressure data collection protocols and subject demographics utilized in previous research makes comparison between results difficult. Future research should focus on large scale studies, with wider age ranges, increased sample sizes, and standardized methodology across research pertaining to children with clubfoot.

Table A.1: List of journal articles chosen for review. Data includes: author, title, year, journal, volume: edition and page numbers.

Authors	Title	Year	Journal	Volume: Edition	Pages
Cooper, DM; Dietz, FR	Treatment of idiopathic clubfoot. A thirty-year follow-up note	1995	J Bone and Joint Surg Am.	77	1477-1489
Hutchinson, RJ; Betts, RP; Donnan, LT; Saleh, M	Assessment of Ilizarov correction of clubfoot deformity using pedobarography	2001	J Bone and Joint Surg Br.	83-B	1041-1045
Huber, H; Dutoit, M	Dynamic Foot-Pressure Measurement in the Assessment of Operatively Treated Clubfeet	2004	J Bone and Joint Surg Am.	86-A:6	1203-1210
Thometz, J; Lie, X; Tassone, J; Klein, S	Correlation of Foot Radiographs With Foot Function as Analyzed by Plantar Pressure Distribution	2005	J Pediar Orthop	25	249-252
Favre, P; Exner, G; Drerup, B; Schmid, D; Wetz, H; Jacob, H	The Contralateral Foot in Children with Unilateral Clubfoot	2007	J Pediart Orthop	27	54-59
Herd, F; Ramanathan, A; Cochrane, L; Macnicol, M; Abboud, R	Foot pressure in clubfoot - The development of an objective assessment tool	2008	The Foot	18	99-105
Ramanathan, A; Herd, F; Macnicol, M; Abboud, R	A new scoring system for the evaluation of clubfoot: The IMAR-Clubfoot scale	2009	The Foot	19	156-160
Sinclair, M; Bosch, K; Rosenbaum, D; Bohm, S	Pedobarographic Analysis Following Ponseti Treatment for Congenital Clubfoot	2009	Clin Orthop Relat Res	467	1123-1230

Table A.1: Continued

Trobisch, P; Neidel, J	Comparison of clinical and pedobarographic measures in clubfeet treated with posteromedial soft-tissue release	2009	Current Orthopaedic Practice	20:2	170-174
Jeans, K; Karol, L	Plantar Pressures Following Ponseti and French Physiotherapy Methods for Clubfoot	2010	J Pediart Orthop	30	82-89
Pauk, J; Daunoraviciene, K; Ihnatouski, M; Griskevicius, J; Raso, J	Analysis of the plantar pressure distribution in children with foot deformities	2010	Acta of Bioengineering and Biomechanics	12:1	29-34
Oto, M; Thabet, A; Miller, F; Holmes, L	Correlation between selective pedobarographic and radiographic measures in the assessment of surgically treated CTEV patients	2011	Joint Disease and Related Surgery	22:3	145-148
Church, C; Coplan, J; Poljak, D; Thabet, A; Kowtharapu, D; Lennon, N; Marchesi, S; Henley, J; Starr, R; Mason, D; Belthur, M; Herzenberg, J; Miller, F	A comprehensive outcome comparison of surgical and Ponseti clubfoot treatments with reference to pediatric norms	2012	J Child Orthop	6	51-59
Yapp, L.Z.; Nasir, Arnold; Wang, W.; Maclean, J.G.B.; Abboud, R.J	Assessment of talipes equinovarus treated by Ponseti technique: Three-year preliminary report.	2012	The Foot	22	90-94

Table A.1: Continued

El-Shamy, S; Mohamed, E; El-Kafy, A; Ibrahim, M	Effect of Neuromuscular Electrical Stimulation on Foot Pressure Distribution in Congenital Clubfoot	2013	Journal of American Science	9:6	178-183
Cooper, A; Chhina, H; Howren, A; Alvarez, C	The contralateral foot in children with unilateral clubfoot, is the unaffected side normal?	2014	Gait and Posture	40	375-380
Gray, K; Burns, Joshua, Little, D; Bellemore, M; Gibbons, P	Is Tibialis Anterior Tendon Transfer Effective for Recurrent Clubfoot?	2014	Clin Orthop Relat Res	472	750-758
Jeans, K; Tulchin-Francis, K; Crawford, L; Karol, L	Plantar Pressures Following Tibialis Anterior Tendon Transfers in Children With Clubfeet	2014	J Pediatr Orthop	34	552-558
Salazar-Torres, J; McDowell, B; Humphreys, L; Duffy, C	Plantar pressures in children with congenital talipes equinovarus - A comparison between surgical management and the Ponseti technique	2014	Gait and Posture	39	321-327
Chen, W; Pu, F; Yang, Y; Yao, J; Wang, L; Liu, H; Fan, Y	Correcting Congenital Talipes Equinovarus in Children Using Three Different Corrective Methods	2015	Medicine	94	28
Holt, J; Oji, D; Yack, J; Morcuende, J	Long-Term Results of Tibialis Anterior Tendon Transfer for Relapsed Idiopathic Clubfoot Treated with the Ponseti Method	2015	J Bone and Joint Surg Am.	97	47-55

Table A.1: Continued

Hosseinzadeh, P; Peterson, E; Walker, J; Muchow, R; Iwinski, H; Talwalkar, V; Milbrandt, T	Residual forefoot deformity predicts the need for future surgery in clubfeet treated by Ponseti casting	2016	J Pediatr Orthop B	25	96-98
Wallace, J; White, H; Xi, J; Kryscio, R; Augsburger, S; Milbrandt, T; Talwalkar, V; Iwinski, H; Walker, J	Pedobarographic changes in Ponseti-treated Clubfeet with and without anterior tibialis tendon transfer: changes due to growth and surgical intervention	2016	J Pediatr Orthop B	25:2	89-95
Giacomozzi, C; Stebbins, J	Anatomical masking of pressure footprints based on the oxford foot model: validation and clinical relevance	2017	Gait and Posture	53	131-138
Jeans, K; Erdman, A; Karol, L	Plantar Pressures After Non-operative Treatment for Clubfoot: Intermediate Follow-up at Age 5 Years	2017	J Pediar Orthop	37:1	53-58
Hayes, C; Murr, K; Muchow, R; Iwinski, H; Talwalkar, V; Walker, J; Milbrandt, T; Hosseinzadeh, P	Pain and overcorrection in clubfeet treated by Ponseti method	2018	J Pediatr Orthop B	27	52-55

Table A.2: Article demographics and purpose. Data included: article type, number of subjects, age range, and study purpose. (number)

Authors	Year	Article Type	Subjects	Age Range	Purpose Summary
Cooper & Dietz	1995	Prospective	54 Adults, 71 Clubfeet	Mean 34 Years (Range 25-42 Years)	Long-Term Follow-up Clubfeet vs. Typically Developing
Hutchinson et al.	2001	Prospective	39 Children, 56 Clubfeet	Mean 11 Years (Range 3-17 Years)	Compare foot pressure before and after Ilizarov treatment for relapsed clubfoot.
Huber & Dutoit	2004	Prospective	19 Adults, 24 Clubfeet	Mean 41 Years (Range 39-46 Years)	Assess how decreased mobility of the subtalar joint changes foot pressure distribution.
Thometz et al.	2005	Prospective	39 Children, 61 Clubfeet	Mean 8 Years (Range 4.3-14.1 years)	Show a relationship between foot structure, as measured by radiographs, and foot function measured by foot pressure analysis in surgically treated clubfeet.
Favre et al.	2007	Prospective	16 Children	Mean 5.6 Years (Range 4-8 Years)	Comparison of the contralateral foot in clubfoot patients and typically developing feet.
Herd et al.	2008	Retrospective	13 Children, 16 Clubfeet	Range 26 Months - 13.5 Years	Use foot pressure ratios to assess structural deformity and loading characteristics in children with clubfeet.
Ramanathan et al.	2009	Prospective	13 Children, 16 Clubfeet	Range 26 Months - 13.5 Years	Devise a scoring system for clinical assessment using biomechanical and clinical data.

Table A.2: Continued

Sinclair et al.	2009	Prospective	20 Children, 28 Clubfeet	Mean 36.8 Months (Range 29-45 Months)	Assess if pedobarographs detect differences between successfully treated Ponseti clubfeet and the contralateral foot.
Trobisch & Neidel	2009	Prospective	23 Children, 33 Clubfeet	Mean 64 months (Range 47-105 Months)	Measure differences between aged matched controls and clubfeet.
Jeans & Karol	2010	Prospective	56 Children, 79 Clubfeet Ponseti Treated; 46 Children, 72 Clubfeet French Physiotherapy Treated	2.3(0.2) Years, 2.2(0.3) Years	Compare foot pressure differences in Ponseti treated clubfeet, Physiotherapy treated clubfeet, and aged matched controls using foot pressure and x-ray measurements.
Pauk et al.	2010	Prospective	7 Clubfeet	Range 10-15 Years	Compare load distributions in children with foot deformities.
Oto et al.	2011	Retrospective	50 Children (70 feet)	Mean 11.2 Months (Range 3-30.6 Months)	Compare x-ray measurements and pedobarographs.
Church et al.	2012	Retrospective	26 Children, 43 Clubfeet Operatively Treated; 22 Children, 45 Clubfeet Ponseti Treated	9.2 (1.3) Years (Range 5-11 Years); 6.3(1.4) Years (Range 5-10 Years)	Long-term follow-up of surgically treated clubfeet, Ponseti treated clubfeet and a typically developing population.

Table A.2: Continued

Yapp et al.	2012	Prospective	5 Children, 8 Clubfeet	Range 40-56 Months	Three-year follow-up of five subjects with clubfoot treated with Ponseti casting.
El-Shamy et al.	2013	Prospective	15 Clubfeet Ponseti Treated with Electrical Stimulation; 15 Clubfeet Ponseti Treated	3.13(0.22) Years, 3.28(0.24) Years	Investigate the effect of muscle stimulation on foot pressure distribution by facilitating peroneal muscle activity.
Cooper et al.	2014	Retrospective	103 Subjects, 177 Clubfeet	Three Ranges; <2 Years, 2-5 Years, >5 Years	Assess the difference between the unaffected side in children with clubfoot and typically developing feet.
Gray et al.	2014	Prospective	20 Children Treated with Anterior Tibialis Tendon Transfer; 12 Children Not Surgically Treated	53(10) Months; 48(12) Months	Compare Ponseti treated clubfeet that did not require surgical intervention to those that required tibialis tendon transfer.
Jeans et al.	2014	Prospective	30 Children, 37 Clubfeet	Range 2.2 - 7.8 Years	Compare Ponseti treated clubfeet that required tibialis tendon transfer to a typically developing cohort.
Salazar-Torres et al.	2014	Prospective	23 Children Treated with PMR; 29 Treated with Ponseti	9.1(0.9) Years; 6.5(0.9) Years	Compare between Ponseti treated clubfeet and Posterior Medial Release treated clubfeet.

Table A.2: Continued

Chen et al.	2015	Prospective	15 Children Using Dennis Brown Bar Shoes; 20 Children Using Dennis Brown Bars Shoes and Orthosis; 18 Children Using Orthosis and Forefoot Abduction Shoes	Range 4-5 Years	Assess the outcome of using orthoses instead of the Dennis Brown Bar Shoes for Ponseti treated clubfeet.
Holt et al.	2015	Prospective	14 Adults Ponseti Treated With Anterior Tibialis Tendon Transfer; 21 Ponseti Treated No Surgery	47.4(6) Years; 47.1(4.1) Years	Assess the long-term outcome of anterior tibialis tendon transfer on foot function of adults treated for relapsed clubfoot during childhood.
Hosseinzadeh et al.	2016	Retrospective	77 Children, 98 Clubfeet Ponseti Treated With Anterior Tibialis Tendon Transfer; 66 Children, 103 Clubfeet Ponseti Treated No Surgery	3.7 Years (Range 2-5.75 years); 7.6 Years (Range 5-11.9 Years)	Assessing short-term outcome in children with clubfoot undergoing anterior tibialis tendon transfer as compared to clubfeet that did not undergo surgical intervention.
Wallace et al.	2016	Retrospective	28 Children with Unilateral Clubfoot Ponseti Treated with Anterior Tibialis Tendon Transfer; 31 Unilateral Clubfeet Ponseti Treated No Surgery	3.1(0.7) Years; 3.0(0.8) Years	Assess pre-operative and three-year post-operative changes in foot pressure between clubfeet with and without anterior tibialis tendon transfer.

Table A.2: Continued

Giacomozzi & Stebbins	2017	Prospective	20 Children	11(3.3) Years	Assess the difference in masking foot pressure with and without kinematic markers.
Jeans, Erdman & Karol	2017	Prospective	84 Children, 122 Clubfeet Ponseti Treated; 80 Children, 116 Clubfeet French Physiotherapy Treated	5.2(0.3) Years Mean All Subjects	Assess, at 5 years of age, the outcome difference between Ponseti treated and French Physiotherapy treated clubfeet.
Hayes et al.	2018	Retrospective	81 Children, 115 Clubfeet	Mean 9.5 Years	Quantify overcorrection and pain in Ponseti treated clubfeet.

Table A.3: Foot pressure data measurement details. Information included: data collection device, number of trials analyzed, walking speed and approach, regions of interest (ROI) and parameters analyzed.

Authors	**Year**	**Device**	**Trials**	**Speed and Approach**	**ROI**	**Parameters**
Cooper & Dietz	1995	emed	3 Trials	Self-Selected Speed	5 Area: Hindfoot, Midfoot, Forefoot, Lateral Toes, Great Toe	Peak Pressure (N/cm^2), Force (%BW), Pressure-Time Integral (Ns/cm^2); Force-Time Integral (%BWs)
Hutchinson et al.	2001	Light Emitting Glass Plate	Not Specified	Not Specified	7 Area: Hindfoot, Hallux, 1st-5th Metatarsal Heads	Peak Pressure (kPa)
Huber & Dutoit	2004	RSScan	Not Specified	Not Specified	8 Area: Medial Hindfoot, Lateral Hindfoot, 1st-5th Metatarsal Heads, Hallux	Pressure Time Curve, Peak Pressure (N/cm^2)
Thometz et al.	2005	emed	3 Trials	Not Specified	8 Area: Lateral Hindfoot, Medial Hindfoot, Midfoot, First Metatarsal, Third Metatarsal, Fifth Metatarsal, Lateral Toes, Hallux	Contact Area (cm^2), Peak Pressure (N/cm^2), Pressure-Time Integral (Ns/cm^2)

Table A.3: Continued

Favre et al.	2007	emed	3 Trials	Self-Selected Speed, 2 Step Approach	10 Area: Hindfoot, Midfoot, 1st-5th Metatarsal Heads, Hallux, Second Toe, Lateral Toes	Peak Pressure (kPa)
Herd et al.	2008	Podotrack and Dynamic Pedobarograph	4 Trials Averaged	Self-Selected	None	Peak Pressure Ratios: Medial/Lateral Ratio, Hindfoot/Forefoot Ratio, Hindfoot/Lateral Arch Ratio
Ramanathan et al.	2009	Podotrack	4 Trials Averaged	Self-Selected	None	Bean Shape Ratio, Medial/Lateral Ratio, Hindfoot/Forefoot Ratio, Hindfoot/Lateral Arch Ratio, Center of Pressure
Sinclair et al.	2009	emed	5 Trials, Averaged	Self-Selected	10 Area PRC: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, First Metatarsal, Second Metatarsal, Lateral Metatarsals, Hallux, Second Toe, Lateral Toes	Peak Pressure (kPa), Maximum Force (%BW), Force Time Integral (%Total), Contact Area (%Total)

Table A.3:Continued

Trobisch & Neidel	2009	emed	3 Trials	Not Specified	7 Area: Medial Hindfoot, Lateral Hindfoot, Midfoot, First Metatarsal, Third Metatarsal, Fifth Metatarsal, Hallux	Peak Pressure (N/cm^2) and Contact Time (%ROP)
Jeans & Karol	2010	emed	5 Trials, Representative Trial	Self-Selected Speed, 3 Steps Minimum	10 Area PRC: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, First Metatarsal, Second Metatarsal, Lateral Metatarsals, Hallux, Second Toe, Lateral Toes	Contact Area (cm^2), Peak pressure (N/cm^2), Pressure-Time Integral (Ns/cm^2), Maximum Force (%BW), Contact Time (%ROP), hindfoot-forefoot angle, Medial Center of Pressure, Lateral Center of Pressure
Pauk et al.	2010	pressure insoles, T&T medilogic Medizintechnik	10 Trials, Averaged	Self-Selected	5 Area: Hindfoot, Medial Midfoot, Lateral Midfoot, Forefoot, Toes	Contact Area (cm^2), Contact Time (s), Peak Pressure (N/cm^2), Center of Pressure
Oto et al.	2011	Teckscan	Not Specified	Not Specified	Hindfoot	Contact Time (s)

Table A.3: Continued

Church et al.	2012	Teckscan	Not Specified	Not Specified	3 Area: Hindfoot, Medial and Lateral Column	Peak Pressure
Yapp et al.	2012	emed	3 Trials, Averaged	Self-Selected	Hindfoot, Lateral Arch, 1st-5th Metatarsal Heads	Bean Shape Ratio, Medial/Lateral Ratio, Hindfoot/Forefoot Ratio, Hindfoot/Lateral Arch Ratio
El-Shamy et al.	2013	RSScan	3-5 Trials	Self-Selected	3 Area: Forefoot (including toes), Midfoot, and hindfoot	Peak Pressure (%Total)
Cooper et al.	2014	Tekscan HR Mat	3 Trials	Self-Selected	5 Area: Hindfoot, Medial Midfoot, Lateral Midfoot, Medial Forefoot, Lateral Forefoot	FTI(Ns), Max Force (% BW), Time (s)
Gray et al.	2014	emed	3 Trials	Self-Selected, Midgait Approach	Total, Medial and Lateral	Peak Pressure (kPa), Maximum Mean Pressure (kPa), Contact Area (cm^2)

Table A.3: Continued

Jeans et al.	2014	emed	5 Trials, Representative Trial	Self-Selected	10 Area PRC: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, First Metatarsal, Second Metatarsal, Lateral Metatarsals, Hallux, Second Toe, Lateral Toes	Peak Pressure (kPa), Contact Area (%Total), Contact Time (%Total), Hindfoot/Forefoot Angle, COP Displacement
Salazar-Torres et al.	2014	Tekscan HR Mat	5 Trials, Representative Trial	Self-Selected	5 Area: Hindfoot, Medial Midfoot, Lateral Midfoot, Medial Forefoot and Lateral Forefoot	Peak Pressure (kPa), Maximum Peak Pressure (kPa), Pressure Time Integral (kPa), Peak Force (N/kg), Force Time Integral (Ns/kg), Medial/Lateral Ratio, Hindfoot/Forefoot Ratio, Hindfoot/Lateral Arch Ratio
Chen et al.	2015	FreeMed	4 Trials, Averaged	Self-Selected	6 Area: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, Medial Forefoot, Lateral Forefoot (including toes)	Average Pressure (kPa), Peak Pressure (kPa), Bean Shape Ratio

Table A.3: Continued

Holt et al.	2015	Not Specified	2 Trials	Self-Selected, 3 mph	5 Areas: Hindfoot, Midfoot, Forefoot, Lateral Toes, Hallux	Peak Pressure (N/cm^2), Contact Area (cm^2), Total Force (N), Pressure Time Integral (Ns/cm^2), Force Time Integral (Ns)
Hosseinzadeh et al.	2016	emed	1 Representative Trial	Self-Selected, Midgait Approach	Foot Angles	Hindfoot Forefoot Angle
Wallace et al.	2016	emed	3 Trials : Representative Trial	Self-Selected	10 Area PRC: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, First Metatarsal, Second Metatarsal, Lateral Metatarsals, Hallux, Second Toe, Lateral Toes	All Pressure, Force, Area, Time Parameters

Table A.3: Continued

Giacomozzi & Stebbins	2017	emed	3 Trials: Used all trials	Self-Selected, <105 steps/minute	5 Areas: Medial Hindfoot, Lateral Hindfoot, Midfoot, Medial Forefoot, Lateral Forefoot (including toes)	Contact Time (%Total), Maximum Force (%Total), Instant of Maximum Force (%), Peak Pressure (kPa), Instant of Peak Pressure (%), Force Time Integral (kPa*s), Pressure Time Integral (kPa*s), Contact Area (%Total)
Jeans, Erdman & Karol	2017	emed	5 Trials: Representative Trial	Self-Selected	10 Area PRC: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, First Metatarsal, Second Metatarsal, Lateral Metatarsals, Hallux, Second Toe, Lateral Toes	Max force (%BW), Peak Pressure (N/cm^2), Pressure Time Integral (Ns/cm^2), Contact Area (cm^2), Contact Time (%Total)
Hayes et al.	2018	emed	Representative trial	Not Specified	Not Specified	Medial and Lateral Pressure (kPa)

Table A.4: Cooper & Dietz (1995) - Long-term follow-up of 54 adults treated with Ponseti.

	Hindfoot	**Midfoot**	**Metatarsal Heads**	**Lateral Toes**
Total Force (%BW)	66(12)	35(14)		
Peak Pressure (N/cm^2)	30(8)	18(8)		
Pressure-Time Integral (Ns/cm^2)		6(2)		
Contact Area (cm^2)			51(7)	9(2)
Force-Time Integral (%BWs)		11(5)		2(1)

Table A.5: Hutchinson et al (2001) - Pre- and Post-Ilizarov for 39 children with relapsed clubfoot.

		Dynamic Peak Pressure (kPa)	**Static Peak Pressure (kPa)**
Pre-Operative	First Metatarsal	131(231)	27(45)
	Fifth Metatarsal	665(458)	102(105)
	Hindfoot	46(84)	39(47)
Post-Operative	First Metatarsal	261(360)	45(72)
	Fifth Metatarsal	334(402)	66(78)
	Hindfoot	249(235)	125(138)

Table A.6A: Sinclair et al (2009) - 28 Clubfeet post Ponseti Age Range (29-45 Months)

	Peak Pressure (kPa)	**Maximum Force (%BW)**	**Force-Time Integral (%Total)**	**Contact Area (%Total)**
Total Foot	169(40.8)	113.9(14.5)	98.3(7.3)	100(0.1)
Lateral Hindfoot	121.4(37.4)	29.6(6.8)	10.4(3.7)	11.0(0.6)
Medial Hindfoot	124.4(40.8)	30.9(7.1)	11.7(3.8)	11.3(0.7)
Lateral Midfoot	94.9(15.5_	35.1(9.3)	21.0(7.0)	17.3(2.0)
Medial Midfoot	91.8(18.2)	20.8(9.0)	9.0(4.7)	11.3(3.1)
1st Metatarsal	66.7(27.7)	13.1(6.1)	6.7(4.2)	9.0(1.8)
2nd Metatarsal	96.2(25.4)	16.9(3.7)	9.4(2.9)	8.8(0.7)
3-5th Metatarsal	103.1(22.1)	32.9(8.7)	18.6(5.7)	16.5(2.1)
Hallux	145.7(46.3)	20.5(6.3)	8.4(3.3)	7.9(0.8)
Toe 2	48.5(19.6)	2.8(1.3)	1.1(0.5)	2.4(0.6)
Toes 3-5	48.1(16.2)	4.8(2.6)	1.9(1.2)	4.6(1.6)

Table A.6B: Sinclair et al (2009) - 12 Unilateral Clubfeet, post Ponseti, Affected Side Age Range (29-45 Months)

	Peak Pressure (kPa)	**Maximum Force (%BW)**	**Force-Time Integral (%Total)**	**Contact Area (%Total)**
Total Foot	179.5(39.1)	117.8(12.2)	99.8(0.7)	100(0.1)
Lateral Hindfoot	149.6(40.1)	23.1(8.6)	9.1(3.5)	7.8(1.1)
Medial Hindfoot	130.0(43.0)	32.5(7.9)	10.1(3.4)	10.7(0.3)
Lateral Midfoot	94.1(16.8)	26.5(10.6)	14.4(8.0)	15.6(2.8)
Medial Midfoot	133.8(52.4)	38.2(11.8)	13.0(5.1)	11.0(0.8)
1st Metatarsal	87.7(20.4)	23.5(11.2)	8.9(4.6)	12.5(4.1)
2nd Metatarsal	67.5(33.5)	19.8(7.3)	11.4(5.3)	10.4(2.1)
3-5th Metatarsal	101.0(30.8)	18.4(2.5)	11.1(2.1)	8.8(0.7)
Hallux	113.3(19.8)	31.8(8.7)	18.2(5.8)	15.7(2.0)
Toe 2	58.8(16.9)	3.4(1.7)	1.2(0.6)	2.4(0.7)
Toes 3-5	52.3(16.0)	6.4(3.0)	2.4(1.2)	5.1(1.7)

Table A.6C: Sinclair et al (2009) - 12 Unilateral Clubfeet Unaffected Side Age Range (29-45 Months)

	Peak Pressure (kPa)	**Maximum Force (%BW)**	**Force-Time Integral (%Total)**	**Contact Area (%Total)**
Total Foot	243.9(68.6)	117.5(18.7)	99.9(1.7)	100(0.1)
Lateral Hindfoot	215.8(71.5)	24.5(7.0)	10.6(4.0)	8.0(0.8)
Medial Hindfoot	149.2(54.5)	31.6(7.2)	10.0(2.7)	10.8(0.8)
Lateral Midfoot	79.6(14.2)	34.0(11.8)	17.5(6.7)	16.8(2.1)
Medial Midfoot	176.7(82.7)	33.7(7.5)	11.4(2.6)	11.0(0.7)
1st Metatarsal	85.8(19.0)	21.4(10.2)	8.4(5.4)	11.7(4.4)
2nd Metatarsal	110.6(44.8)	16.2(8.6)	9.0(6.3)	9.6(2.3)
3-5th Metatarsal	100.4(17.4)	17.0(3.7)	10.0(3.1)	8.6(0.6)
Hallux	96.9(21.5)	33.2(10.2)	19.1(5.2)	16.3(2.8)
Toe 2	73.3(32.6)	3.9(1.8)	1.6(0.7)	2.5(0.7)
Toes 3-5	74.7(32.0)	5.5(2.3)	2.3(1.2)	4.7(1.3)

Table A.7A: Jeans & Karol (2010) - 56 Children with Clubfoot Treated with Ponseti Age 2.3(0.2) Years.

	Peak Pressure (N/cm^2)	Maximum Force (%BW)	Contact Area (cm^2)	Contact Time (%Total)	Pressure-Time Integral (Ns/cm^2)
Medial Hindfoot	9.68(2.91)	28.22(9.16)	11.48(1.27)	48.11(14.65)	1.35(0.68)
Lateral Hindfoot	9.82(2.76)	29.15(9.81)	11.77(1.95)	53.32(13.38)	1.51(0.62)
Medial Midfoot	8.22(2.67)	15.94(12.79)	8.65(4.10)	58.33(16.37)	1.41(0.71)
Lateral Midfoot	10.34(2.72)	49.65(13.83)	20.09(3.28)	79.19(6.21)	2.60(0.74)
1st Metatarsal	5.48(2.76	9.79(7.12)	7.58(3.37)	64.00(22.51)	1.01(0.62)
2nd Metatarsal	9.23(3.2)	16.17(5.57)	8.75(1.43)	81.31(11.24)	1.81(0.63)
3-5th Metatarsals	12.11(3.94)	44.31(14.15)	19.39(4.27)	89.19(6.19)	2.73(0.94)

Table A.7B: Jeans & Karol (2010) - 46 Children with Clubfoot Treated with Physiotherapy Age 2.2(0.3) Years. *Ponseti significantly different from Physiotherapy ($p<0.05$)

	Peak Pressure (N/cm^2)	Maximum Force (%BW)	Contact Area (cm^2)	Contact Time (%Total)	Pressure-Time Integral (Ns/cm^2)
Medial Hindfoot	8.15(2.19)*	21.44(7.25)*	10.93(1.34)	42.74(18.1)	1.02(0.57)*
Lateral Hindfoot	8.69(2.09)	24.50(9.32)*	12.04(3.55)	51.43(14.66)	1.31(1.61)
Medial Midfoot	6.90(2.51)*	44.71(8.47)	7.64(3.78)	53.74(22.16)	1.16(0.74)
Lateral Midfoot	11.08(3.79)	51.18(11.91)	21.50(3.07)	81.18(7.12)	2.79(0.95)
1st Metatarsal	4.84(2.72)	9.42(7.58)	8.06(4.20)	66.31(24.53)	0.97(0.58)
2nd Metatarsal	8.27(2.89)	13.79(5.60)	8.62(1.18)	82.89(12.49)	1.72(0.60)
3-5th Metatarsals	13.28(5.80)	46.58(14.68)	20.13(2.84)	91.52(7.76)	2.91(1.13)

Table A.8A: Herd et al (2008) - Reoccurred Clubfeet (3), Non-Reoccurred (12); Bean Shape Ratio is foot width divided by foot length and a value of >0.267 indicates a short and wide foot deformity.

	Bean Shape Ratio
Reoccurred Clubfeet	0.313(0.01)
Non-Reoccurred Clubfeet	0.217(0.01)

Table A.8B: Yapp et al (2012) - 8 Clubfeet, three year follow-up.

	Bean Shape Ratio
Year 3	0.279(0.048)
Year 2	0.28(0.038)
Year 1	0.270(0.040)

Table A.8C: Chen et al (2015) - 15 Dennis Brown Bar Shoes (DBBS), 20 DBBD+Orthosis, 18 Orthosis+Forefoot Abduction Shoes; Mean (95%CI). *Significant from other two parameters (P<0.01)

	Bean Shape Ratio
DBBS	0.31(0.29-0.33)
DBBS+Orthosis	0.29(0.27-0.30)
Orthosis+Foot Abduction Shoes	0.27(0.25-0.28)*

Table A.9: Church et al (2012) - 43 Operatively Treated Clubfeet, 45 Ponseti Treated Clubfeet. *Significant difference (p<0.05). There were no units listed. CPPI is the ratio of the medial to lateral pressure impulse.

	Ponseti	**Operative**
Coronal Plane Pressure Index (CPPI)	-15.7(18.9)*	-36.8(24.7)
Medial Forefoot Pressure	39.8(11.9)*	19.1(8.8)
Lateral Midfoot Pressure	23.7(11.2)	25.0(13.8)

Table A.10: Cooper et al (2014) - 177 Clubfeet, Unaffected Side Only.

	Maximum Force (%Max)	**Average Force-Time Integral (Ns)**
Subject <2 Years		
Hindfoot	51.8(15.5)	26.4(13.4)
Lateral Midfoot	33.7(9.7)	23.6(8.0)
Medial Midfoot	33.7(9.7)	14.0(8.1)
Lateral Forefoot	23.2(11.0)	12.1(6.9)
Medial Forefoot	44.2(13.2)	23.4(10.4)
Subjects 2-5 Years		
Hindfoot	65.3(16.9)	30.3(11.2)
Lateral Midfoot	26.9(11.8)	17.33(9.0)
Medial Midfoot	13.4(10.8)	7.7(6.8)
Lateral Forefoot	28.1(11.0)	16.3(7.3)
Medial Forefoot	48.3(13.9)	28.8(9.8)
Subjects >5 Years		
Hindfoot	77.6(14.0)	37.8(10.1)
Lateral Midfoot	22.5(12.4)	13.0(8.7
Medial Midfoot	4.5(3.3)	2.3(2.1)
Lateral Forefoot	32.9(9.0)	18.0(5.7)
Medial Forefoot	49.5(13.0)	55.4(32.2)

Table A.11A: Gray et al (2014) - 20 Clubfeet Treated with Tibialis Anterior Tendon Transfer (TATT); measured pre-operatively and at 3, 6 and 12 post-operative follow-up.

	Contact Area (cm^2)	**Peak Pressure (kPa)**	**Maximum Mean Pressure (kPa)**
Baseline			
Total Foot	58(10)	157(54)	63(21)
Medial Foot		129(33)	51(41)
Lateral Foot		151(52)	60(21)
3 Month Follow-up			
Total Foot	62(9)	156(49)	61(17)
Medial Foot		134(35)	50(10)
Lateral Foot		127(73)	48(31)
6 Month Follow-up			
Total Foot	65(10)	196(75)	73(23)
Medial Foot		164(72)	61(25)
Lateral Foot		181(62)	65(18)
12 Month Follow-up			
Total Foot	69(10)	226(67)	74(21)
Medial Foot		189(67)	59(21)
Lateral Foot		204(60)	67(17)

Table A.11B: Gray et al (2014) - 12 Clubfeet Not Treated with TATT; measured at baseline and at 3, 6 and 12 months follow-up. * Significant difference ($p<0.05$) between operative and non-operative groups.

	Contact Area (cm^2)	**Peak Pressure (kPa)**	**Maximum Mean Pressure (kPa)**
Baseline			
Total Foot	66(11)*	200(55)*	69(13)
Medial Foot		185(55)*	63(14)*
Lateral Foot		165(56)	55(13)
3 Month Follow-up			
Total Foot	65(12)	188(59)	73(26)
Medial Foot		164(55)	59(24)
Lateral Foot		154(62)	59(24)
6 Month Follow-up			
Total Foot	69(11)	188(60)	67(18)
Medial Foot		179(53)	64(19)
Lateral Foot		154(50)	50(9)*
12 Month Follow-up			
Total Foot	73(10)	221(115)	68(13)
Medial Foot		175(56)	63(11)
Lateral Foot		152(90)	57(14)

Table A.12A: Jeans et al (2014) - 37 Clubfeet assessed pre- and post- Tibialis Anterior Tendon Transfer (TATT). *Significant difference (p<0.0021) pre- to post-operative.

	Peak Pressure (kPa)	**Contact Area (%Total)**	**Contact Time (%Total)**
Pre-Operative			
Medial Hindfoot	103.8(66.6)	9.8(3.3)	40.8(21.4)
Lateral Hindfoot	106.8(47.8))	12.8(4.5)	48.9(18.8)
Medial Midfoot	46.8(28.0)	2.1(2.0)	32.5(21.8)
Lateral Midfoot	162.8(65.0)	24.4(2.7)	80.4(8.1)
1st Metatarsal	45.7(47.6)	5.6(3.0)	51.3(25.8)
2nd Metatarsal	92.2(38.6)	8.2(2.2)	73.1(15.5)
3-5th Metatarsals	233.4(100.5)	27.1(5.3)	94.7(5.3)
Post-Operative			
Medial Hindfoot	169.2(102.8)*	11.2(1.7)	54.7(16.3)*
Lateral Hindfoot	161.4(111.3)	12.2(2.1)	57.1(14.6)
Medial Midfoot	68.1(29.3)*	3.8(3.3)*	49.8(18.4)*
Lateral Midfoot	102.0(35.3)*	20.4(2.4)*	75.1(9.8)
1st Metatarsal	91.4(53.3)*	8.2(3.0)*	83.1(13.6)*
2nd Metatarsal	125.7(7.1)*	8.5(1.3)	87.2(10.5)*
3-5th Metatarsals	163.1(41.5)*	22.3(3.9)*	91.4(4.5)*

Table A.12B: Jeans et al (2014) - 9 Split TATT and 28 Full TATT Post-operative Results. *Significant difference (p<0.0021) between operative approaches.

	Peak Pressure (kPa)	**Contact Area (%Total)**	**Contact Time (%Total)**
Split Transfer			
Medial Hindfoot	198.9(171.9)	10.4(2.0)	61.0(14.4)
Lateral Hindfoot	205.6(199.0)	12.9(0.0)	63.1(12.1)
Medial Midfoot	78.3(24.9)	5.1(0.1)	58.1(17.8)
Lateral Midfoot	103.9(14.5)	20.3(2.1)	76.3(6.3)
1st Metatarsal	103.9(65.7)	9.6(2.9)	81.0(15.8)
2nd Metatarsal	128.3(43.0)	8.9(1.5)	87.1(6.6)
3-5th Metatarsals	172.2(53.6)	21.5(5.3)	92.1(3.2)
Full Transfer			
Medial Hindfoot	159.6(70.4)	11.4(1.6)	52.6(16.6)
Lateral Hindfoot	147.1(62.5)	12.0(2.2)	55.1(15.0)
Medial Midfoot	64.8(30.2)	3.4(2.4)	47.2(18.1)
Lateral Midfoot	101.4(39.9)	20.5(2.5)*	74.8(10.7)*
1st Metatarsal	87.3(49.3)	7.8(3.0)*	83.8(13.0)
2nd Metatarsal	124.8(49.0)	8.4(1.2)	87.3(11.6)
3-5th Metatarsals	160.2(37.6)	22.5(3.4)*	91.1(4.8)*

Table A.13: Salazar-Torres et al (2014) - 23 children treated with posterior medial release (PMR) and 29 children treated with Ponseti; Mean(95% Confidence Interval).
*Significant difference (p<0.05) between the two treatment groups.

	Average Peak Pressure (kPa)	**Maximum Peak Pressure (kPa)**	**Pressure-time Integral (kPas)**	**Peak Force (N/kg)**	**Force-time Integral (Ns/kg)**
PMR					
Hindfoot	90.53 (78.75-102.31)	248.80 (208.36-289.23)	37.77 (32.24-43.31)	7.84 (6.90-8.79)	1.24 (1.06-1.42)
Lateral Midfoot	37.74 (30.20-45.28)	93.91 (57.60-130.22)	31.40 (19.79-43.00)	2.62 (1.97-3.26)	0.46 (0.35-0.57)
Medial Midfoot	25.74 (21.02-30.46)	47.14 (35.66-58.62)	9.57 (6.38-12.77)	0.52 (0.34-0.69)	0.07 (0.05-0.10)
Lateral Forefoot	74.15 (62.02-86.28)	233.880 (187.74-259.85)	23.15 (17.90-28.39)	3.63 (3.06-4.17)	0.65 (0.51-0.80)
Medial Forefoot	79.24 (68.79-89.69)	280.86 (226.91-334.80)	24.30 (20.16-28.44)	3.34 (2.32-4.37)	0.78 (0.62-0.94)
Ponseti					
Hindfoot	82.88 (72.41-93.35)	183.83 (147.90-219.76)*	32.25 (27.34-37.16)	6.99 (6.15-7.83)	0.76 (0.6-0.92)*
Lateral Midfoot	57.02 (50.32-63.72)	167.89 (135.65-200.14)*	44.89 (34.59-55.19)	4.29 (3.72-4.87)*	0.67 (0.57-0.77)*
Medial Midfoot	28.48 (24.29-32.68)*	56.68 (46.47-66.88)	10.40 (7.57-13.24)	0.36 (0.21-0.51)	0.03 (0.01-0.06)*
Lateral Forefoot	91.84 (81.07-102.62)	233.92 (201.90-265.94)	24.82 (20.15-29.48)	4.31 (3.83-4.79)	0.69 (0.56-0.81)
Medial Forefoot	77.65 (68.36-89.93)*	256.23 (208.23-304.14)	22.87 (19.19-26.55)	4.15 (3.24-5.07)	0.64 (0.50-0.78)

Table A.14: Chen et al (2015) - 15 Children wearing Dennis Brown (DB) Splints at Night; 20 Children wearing DB at night and orthopedic shoes (OS) during the day (DB+OS); 18 Children using OS during the day and forefoot abduction shoes (FAS) at night (OS+FAS). Mean(95% Confidence Interval). Significant differences ($p<0.05$) between: ^DB and DB+OS, *DB and OS+FAS, #DB+OS and OS+FAS

	Average Peak Pressure (kPa)	**Maximum Peak Pressure (kPa)**
DB		
Hindfoot	57.48(39.47-75.49)*	105.51(85.73-125.29)^*
Lateral Midfoot	94.97(66.38-123.59)^*	105.89(84.27-127.52)*
Medial Midfoot	59.58(43.14-76.01)	56.8(45.64-67.96)
Lateral Forefoot	66.09(50.02-82.15)	120.53(104.55-136.51)
Medial Forefoot	89.34(66.31-112.33)*	101.26(81.02-121.51)*
DB+OS		
Hindfoot	74.1(64.02-84.18)	148.71(135.49-161.94)
Lateral Midfoot	62.21(53.35-71.06)	99.14(89.06-109.22)#
Medial Midfoot	55.51(41.82-69.21)	63.69(51.88-75.50)
Lateral Forefoot	55.44(46.02-64.87)	118.48(105.96-131.00)
Medial Forefoot	95.54(83.89-107.19)	115.00(101.83-128.16)#
OS+FAS		
Hindfoot	83.18(71.78-94.58)	164.05(148.22-179.90)
Lateral Midfoot	60.9(49.26-75.54)	82.38(71.87-92.90)
Medial Midfoot	47.5(41.20-53.80)	56.44(46.69-66.20)
Lateral Forefoot	55.15(42.37-67.94)	129.77(112.98-146.55)
Medial Forefoot	122.58(100.78-124.38)	135.87(122.10-149.64)

Table A.15: Wallace et al (2016) - 28 Unilateral clubfoot patients treated with Tibialis Anterior Tendon Transfer measured preoperative and two years post-operative (CF+ATT). 31 Matched unilateral clubfoot patients without surgical intervention measured at baseline and two year follow-up (CFnoATT). *Significant difference ($p<0.05$) between treatment groups.

	CFnoATT	**CF+ATT**	**CFnoATT**	**CF+ATT**
	Baseline	**Pre-Operative**	**2 Year Follow-Up**	**2 Year Post-Operative**
Peak Pressure Lateral Midfoot (kPa)	108.0(41.3)	137.4(54.9)*	137.4(49.0)	123.9(38.9)
Contact Time Lateral Midfoot (%Total)	67.8(15.1)	77.3(10.8)*	69.3(10.4)	68.1(12.4)
Pressure-Time Integral Lateral Midfoot (kPas)	28.1(14.1)	36.0(15.9)*	41.3(18.2)	33.7(16.4)
Instant of Peak Pressure Lateral Midfoot (%Total Time)	26.7(40.4)	40.4(18.5)*	28.9(13.3)	27.9(13.8)
Maximum Mean Pressure Lateral Midfoot (kPa)	45.8(22.3)	58.3(22.0)*	49.1(23.6)	47.8(21.0)
Force-Time Integral Lateral Midfoot (%BW)	8.4(4.5)	10.8(6.0)*	10.3(5.2)	8.0(4.1)
Lateral Force-Time Integral (Ns)	35.6(12.6)	42.9(14.7)	75.7(34.3)	62.9(31.5)
Lateral Medial Force-Time Integral Index	16.2(11.8)	26.9(12.4)*	26.8(26.8)	19.7(27.1)
Lateral Force/Medial Force Index	1.54(0.5)	2.3(0.3)*	1.4(0.5)	1.4(0.6)
Peak Pressure Metatarsals 3-5 (kPa)	141.5(79.3)	174.4(91.2)	213.0(85.5)	200.7(103.0)
Peak Pressure Total Foot (kPa)	180.4(71.6)	217.1(90.4)	278.9(76.6)	256.6(87.5)
Pressure-Time Integral Total Foot (kPas)	55.7(19.4)	64.1(18.7)	97.0(23.6)	85.4(30.7)

Table A.16: Giacomozzi and Stebbins (2017) - 20 Subjects with Clubfoot, ROI identified using kinematic foot markers.

	Contact Time (%Total)	**Maximum Force (%Total)**	**Instant Maximum Force (%Total)**
Medial Hindfoot	54.0(16.2)	37.8(21.1)	18.6(6.2)
Lateral Hel	57.2(15.7)	34.8(15.8)	20.5(9.0)
Midfoot	61.7(15.1)	21.7(14.0)	44.6(17.8)
Medial Forefoot (with toes)	84.9(13.1)	55.7(19.0)	80.1(7.5)
Lateral Forefoot (with toes)	86.9(12.3)	45.3(15.6)	69.4(13.6)
	Force-Time Integral (kPas)	Peak Pressure (kPa)	Instant of Peak Pressure (%Total)
Medial Hindfoot	8.2(6.0)	256.5(149.5)	14.0(10.9)
Lateral Hel	7.4(4.0)	214.7(84.7)	14.6(8.2)
Midfoot	5.8(4.8)	131.0(75.9)	39.3(17.4)
Medial Forefoot (with toes)	14.7(6.6)	361.2(200.7)	83.5(6.5)
Lateral Forefoot (with toes)	14.7(7.4)	302.0(176.6)	81.0(8.8)
	Pressure-Time Integral (kPas)	Contact Area (%Total)	
Medial Hindfoot	54.2(34.4)	15.5(7.1)	
Lateral Hel	50.3(27.3)	16.9(6.6)	
Midfoot	39.5(29.1)	14.2(6.8)	
Medial Forefoot (with toes)	90.3(47.8)	28.7(7.9)	
Lateral Forefoot (with toes)	83.4(44.9)	28.5(7.6)	

Table A.17: Jeans, Erdman and Karol (2017) - 84 Children with clubfoot treated with Ponseti, 80 Children with clubfoot treated with French Physiotherapy. Outcomes at 5 years of age. *Significant difference (p<0.05) between treatment groups.

	Peak Pressure (N/cm^2)	**Maximum Force (%Body Weight)**	**Contact Area (%Total)**	**Contact Time (%Total)**	**Pressure-Time Integral (Ns/cm^2)**
Ponseti					
Medial Hindfoot	130.5(52.4)	29.6(9.7)	11.4(2.1)	46.7(16.4)	19.5(10.3)
Lateral Hindfoot	126.5(44.3)	28.6(8.8)	11.3(1.7)	49.3(14.9)	19.6(9.3)
Medial Midfoot	85.3(28.5)	8.8(6.1)	6.0(3.2)	49.9(18.3)	14.6(8.0)
Lateral Midfoot	118.2(36.5)	43.3(14.3)	20.7(3.3)	76.4(7.8)	30.4(11.0)
1st Metatarsal	71.8(41.6)	10.8(7.3)	8.1(2.7)	69.9(18.8)	15.7(10.2)
2nd Metatarsal	140.0(49.6)	17.8(6.2)	8.9(1.4)	82.2(10.6)	28.5(10.7)
3rd-5th Metatarsals	190.5(70.8)	48.8(12.7)	20.6(4.9)	89.3(6.0)	40.8(16.9)
French Physiotherapy					
Medial Hindfoot	137.4(60.1)	30.9(10.6)	11.2(2.3)	46.5(15.4)	19.2(9.2)
Lateral Hindfoot	132.0(52.9)	29.7(8.8)	11.3(2.1)	48.6(14.2)	19.1(8.4)
Medial Midfoot	81.3(27.3)	8.5(6.9)	5.6(3.4)	48.6(17.4)	13.1(6.3)
Lateral Midfoot	114.5(44.2)	43.1(11.2)	21.0(3.8)	74.4(11.2)	29.8(16.1)
1st Metatarsal	71.5(38.6)	11.3(7.2)	7.8(2.8)	67.3(23.0)	16.1(10.8)
2nd Metatarsal	139.7(56.7)	18.3(6.8)	8.9(1.7)	82.4(11.3)	29.4(13.5)
3rd-5th Metatarsals	195.3(87.2)	52.1(11.5)	21.4(4.2)	90.0(5.2)	43.2(20.0)

Appendix B: Foot Pressure Analysis using the emed® in Typically Developing Children and Adolescents: A Summary of Current Techniques and Typically Developing Cohort Data for Comparison with Pathology

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Introduction

Foot pressure analysis (FPA) uses specialized sensors contained in a mat on the floor to measure the forces acting on the foot when walking [25] and provides quantitative information on foot function, contact pattern, pressure distribution, pressure magnitude, and progression of the center of pressure [26]. FPA is a valuable tool that can assist clinicians and researchers with diagnosis, assessing severity of deformity, treatment decision making and documenting short and long-term outcomes in children and adolescents [25]. Clinicians and researchers use typically developing data for comparison of subjects with pathology. However, differences between foot pressure collection technology, data collection procedures and post-processing techniques make comparisons between devices, as well as direct comparisons of pediatric foot pressure data, difficult. When comparing data from multiple studies it is imperative that the studies utilize the same data collection and processing techniques, otherwise the data should not be directly compared. The purpose of this paper is to present a summary of foot pressure techniques and provide clinicians and researchers with a source of previously collected typically developing data to use in comparison with pathologic data. The specific aims of this study are to 1) Provide an overview of data collection and post processing methods in foot pressure studies, since the year 1990, that used the emed® in a child and adolescent typically developing population; 2) Provide a summary of typically developing data, collected by the emed®, that can be used for comparison with pathology for other emed® users; 3) Explore the controllable and uncontrollable factors that affect foot pressure data collection and post processing and emphasize the problems when combining data from multiple data collection systems and different collection protocols; 4.) Provide suggestions for standardizing foot pressure data collection and post processing for typically developing children.

Materials and Methods

A PubMed, Cochrane Library and Google Scholar search for the following key word combinations since the year 1990 were searched; emed®, children; foot pressure analysis, children. PubMed returned 23 and 195 results respectively. The Cochrane Library returned 3 and 3 results respectively. Google Scholar returned the most results with 3090 and 26,800 results respectively. Of the studies found, 23 studies were identified as involving foot pressure analysis when walking, in typically developing children without intervention or experimental conditions. Only 16 of the 23 studies utilized the emed® foot pressure systems when walking in typically developing children, the remaining seven studies used other manufacturers such as Tekscan® or RSscan®. Previous research has found that compared data needs to use the same data collection procedures, post processing procedures and needs to utilize the same foot pressure device[37, 61]. When reviewing the 16 studies it became apparent that there were many inconsistencies in the methodology and technology used. Therefore, the foot pressure data summary will focus on one device and will only be relevant for other institutions that use the emed® system. This overview only focused on studies that utilized the emed® platform because it is the device in use at the authors institution for over 20 years. The ability to have access to a summary of the typically developing cohorts previously published, that utilize the emed®, would be an invaluable resource for researchers and clinicians at this and other institutions. However, findings and conclusions from studies that utilized other foot pressure systems will be used to support arguments proposed throughout this overview.

Results

Twelve of the 16 studies reported data values that could be used for comparison with pathologic data. Due to the large amount of foot pressure data that can be summarized in the 12 studies, tables that can be used for comparison are presented as Supplemental Tables at the end of this chapter (Tables B.S1-B.S15). All data reported as supplemental were collected using the emed® foot pressure system and were classified as longitudinal, cross-sectional, or averaged cohort studies.

Table B.1 shows the differences between the data collection and post processing techniques for all 16 studies that used the emed®. For data collection, all studies reported a self-selected walking speed and the participants age ranged from 1-17 years. Four studies reported collecting three trials [29, 62, 96, 97], one reported using 3-5 trials[98], one reported using 4 trials [33] and the remaining 10 studies reported using five trials[26, 41, 60, 63, 99-104]. However, three of the studies that reported collecting multiple trials only used a representative trial for data analysis [26, 62, 63]. Reporting on the approach was varied; with seven studies specifying the midgait approach[26, 29, 63, 99-101], seven reporting the two-step approach[41, 60, 96-98, 102-104], and two not reporting the approach[62].

For post processing, the parameters and masked regions of interest (ROI) chosen varied between the 16 studies. Eight studies utilized a five area ROI masking technique. However, among these studies, there are three different arrangements of ROI on the foot pressure with the most often utilized five area ROI being the hindfoot, midfoot, forefoot, hallux and toes [41, 60, 99-102]. The remaining eight studies utilized between one and 12 ROI. Examples of automated foot pressure masking using different ROI's is presented in Figure B.1.

Table B.2 is a summary of the parameters that can be calculated with built in software based on data collected within the emed® hardware. Peak Pressure (PP) was analyzed in 15/16 studies with the parameter reported as kPa, kPa/bw or N/cm^2. Force-time Integral

(FTI) was analyzed in 11/16 studies as Ns or as a percent of the total FTI. Contact Area (CA) was reported in 11/16 studies as cm^2 or percent total CA. Maximum Force (MF) was reported in 8/16 studies as N, percent total MF or percent bodyweight. Contact Time (CT) was reported in 6/16 studies as ms or percent total CT. Pressure-time Integral (PTI) was reported in 4/16 studies as either kPa*s or Ns/cm^2. Instant of Peak Pressure (IPP) was reported in one study and Instant of Maximum Force (IMF) was reported in two studies; all reported as the percentage of stance. Maximum Mean Pressure (MMP) was reported in one study as N/cm^2. Center of Pressure Index (COPI) was reported in one study and Arch Index (AI) was reported in 5/16 studies.

Discussion

Novel emed®

Novel emed® is one of the most commonly used foot pressure systems worldwide [40]. Currently there are six different emed® plates available for commercial use, each with different specifications (Table B3) [27]. Novel emed® pressure plates have capacitive sensors; two electrically conducting surfaces separated by rubber, a dielectric material[25]. Accuracy for the emed® is +-5% [40]. The error for the emed® system is less than 5% within session [105] and 16.9% between days [40]. The emed® also demonstrates test-retest reliability Interclass Coefficient (ICC) values of >0.8 when walking [106]. Additionally, previous research found the reliability of pressure data and the number of trials have a direct linear correlation, so as the number of trials increases so does the reliability[105]. The emed® has a reported reliability coefficient >0.9 for force, area and pressure when the mean of three trials is used [29, 105].

Foot pressure data can be divided into different regions of interests (ROI) based on the needs of the clinician or researcher[25], this technique is called masking. The accurate identification of the ROI can affect the reliability of foot pressure data. Coefficient of repeatability for the emed® is <10% for most parameters and ROI; where the lower the coefficient of repeatability the higher the repeatability [40]. Gurney et al. (2008) showed a good level of reliability for masking between days in typical adult subjects across different ROI at ICC=0.847 overall, with ranges from 0.687 in the lateral toes to 0.909 in the central forefoot [37]. This study also reported better reliability for higher loaded areas, such as the forefoot and hindfoot, and less reliability for less loaded areas such as the medial midfoot [37]. However, these data were reported using healthy adults and caution should be used when applying this data to children.

Summary of Foot Pressure Data

Foot pressure data that can be used for comparison with pathology were presented as Supplemental Material. These data were split into three classifications; longitudinal, cross-sectional, or averaged cohort studies. Each type of study provides valuable information on changes due to growth, which researchers can use for comparison. Longitudinal studies tend to have smaller sample sizes, due to the difficulty of tracking subjects over time, and provide data from the same set of children over time. The advantage of longitudinal studies is that they allow for intra-individual changes in foot development to be documented within the same set of children [15]. Cross-sectional studies provide data from different children at different stages of development and the advantage is that they tend to have large sample sizes. Averaged cohort studies take data from children at different ages and average the results together, providing one data point and standard deviation, which is easy to use for comparison. It should again be noted that for the reported studies, the data collection procedures and post processing procedures were not consistent between studies. Table 1 summarizes the data collection and post processing procedures for each study. Clinicians should note the differences between the procedures and account for them when choosing data in which to compare with pathological.

Longitudinal Assessments

Longitudinal foot pressure assessments in typically developing children have been conducted for ages 1.21-10.23 years in three publications. Bertsch et al. (2004) evaluated foot size and shape of 42 children at the onset of walking (14.8[1.8] months) and again every three months for the first year of independent walking. It was found that as children grow there is an increase in CA, MF and FTI[41]. In addition, the development of the medial longitudinal arch was documented by an increasing indentation on the medial boarder of the foot pressure picture over time[41]. Due to the cartilaginous nature of the foot at the onset of walking, a fat pad in the midfoot allows for even distribution of the forces on the foot [41]. This fat pad is slowly absorbed during the first 3-4 years of independent walking[41].

Bosch et al. (2007) repeatedly assessed foot development in 90 children over the course of four years starting at the onset of independent walking. This study developed typically developing cohort data ranges from the 3rd, 50th and 97th percentile for PP and FTI. Results show a continuous increase in PP and FTI in all areas of the foot, except the midfoot[60]. To prevent overloading at the onset of walking, when gait patterns are variable, a fat pad in the midfoot acts to evenly distribute forces within the foot [60]. Where Bertsch et al. (2004) only reported a visual change in the midfoot shape during the first year of walking; Bosch et al. (2007) found that the CA consistently decreases in the midfoot over the four years post initiation of independent walking.

Bosch et al., (2010), went on to assess foot pressure analysis in 36 children from the onset of walking until the age of 10. Similar to both Bertsch et al. (2004) and Bosch et al. (2007), this study found that all parameters increased across all foot areas except in the midfoot[99]. This study also reported results as a range of percentiles. The advantage of having a set of typically developing percentiles for different ages throughout growth is that it allows clinicians to rate affected feet similarly to rating children according to height or weight. However, it was noted that there were large inter-individual differences within the typically developing data, as evidenced by the large standard deviations [99].

Cross-Sectional Assessments

Five studies reported cross-sectional data for foot pressure in typically developing children at specific ages, at the onset of walking and at the age of seven years. Hennig and Rosenbaum (1991) assessed 15 children at age of two years. It was found that young children show an even distribution of load under the foot, with the highest area of PP and FTI under the hallux [62]. Hillstrom et al. (2013) found that early walkers had the highest PP in the hallux, followed by the medial and lateral hindfoot and the first metatarsal[104]. Bosch et al. (2009) studied 26 children age 1.3(0.4) years and 26 children 7(0.5) years of age. New walkers demonstrated significantly less PP under the hindfoot, more CA and CT in the midfoot, and a larger arch index than children seven years of age[100].

Muller et al. (2012) and Mueller et al. (2016) assessed large cohorts of children across different ages and tracked the changes in foot pressure parameters at different stages of growth. Muller et al. (2012) studied 7788 children between the ages 1-13 years of age and Mueller et al. (2016) assessed 6456 children between the ages of 1-12 years of age. Both studies found a general increase in all parameters with increasing age [96, 98]. It was found that the arch index is larger in children under six years of age, indicating a more flat foot; however, after the age of seven the arch index remains relatively consistent[98]. Furthermore, the foot grows more in length than in width during childhood leading to a more narrow foot after the age of 8 years[98].

Averaged Cohort Assessments

For studies with a small sample size across a large age range, averaging the data is a way to garner potentially meaningful results. The advantage of averaged data is that you have one reference value per foot pressure parameters, instead of having many reference values stratified by age, in which to compare. The disadvantage is that important data related to specific stages of growth is lost when the data are averaged. For studies that do not need to factor in growth as a covariate, averaging the data is the simplest way to compare with a typically developing population.

Liu et al. (2005) reported results of 66 children between the ages of 6-16 years of age. They reported results for 9 areas of the foot for CA, CT, PP, MMP, PTI, FTI, IPP and IMF. Results show that the largest CA, FTI and CT is in the middle forefoot, the largest PP is in the hindfoot and hallux, and IPP and IMF are similar with the origination in the hindfoot, medial forefoot and then middle forefoot [29]. Similarly, Jameson et al. (2008) measured the COP in 23 children between the ages of 6-17 years. They found that typical COP progression starts in the middle of the hindfoot for the first 23.7% of the CT, the moves into the midfoot for next 28.7% of the CT and then progresses into the forefoot for the last 47.6% of the CT [26]. By assessing the displacement of the COP it is possible to quantify the foot as a varus, adduction or supinated loading pattern, which can be helpful for interpretation of pathologic foot pressure assessments [26]. Dowling et al. (2004) compared the difference in a cohort of 10 typical weight (8.9(2.1)y, BMI 16.8(2.0)) and 10 obese children (8.8(2.0)y, BMI 25.8(3.8)). It was found that children who are obese generate significantly higher force and pressure across all areas of the foot (except the toes) when walking[103].

Giacomozzi and Stebbins (2017) measured the CT, PP, MF, IPP, IMF, PTI, FTI, and CA in 20 adolescents average age 11.5(2.8) years with a BMI of 18.1(3.1)kg/m^2. What stands out for this study is that the foot pressure masking technique utilized foot kinematics to help mask the foot[33]. The advantage of using kinematics to mask foot pressures is that it can help overcome the inaccuracies due to deformity in a pathologic population. The Giacomozzi and Stebbins (2017) article validated that masking using kinematics is valuable and accurate tool for both healthy and pathologic populations. Data for the healthy population in this study is presented in supplemental data.

Factors Affecting Foot Pressure Data Collection and Post Processing

Foot pressure analysis has been widely used in children; however the process for data collection and post processing varies widely between studies [26]. Reliability of foot pressure data in children can be affected by both data collection methodology, data reduction technique and the data collection device[61]. Gurney et al. (2008) reports that the reliability of the one collection system cannot be transferred to other measurement systems and vice versa because of differences in sensor technology[37]. Therefore, not only does compared data need to use the same data collection and post processing procedures, it also needs to utilize the same foot pressure device. Giacomozzi (2010) compared emed® x to MatScan®. It was found that MatScan® required a special on-site calibration in order to report variability, accuracy and precision results that were comparable to those reported by emed® x[42]. In this study, the emed® x plate performed better than other commercially available platforms in the areas of linearity, creep, hysteresis, accuracy, precision and variability[42]. Therefore, it is imperative that clinicians and researchers use the same data collection device and methodology for data collection and post processing for all foot pressure studies[107]. However, as seen in the 16 studies presented here (Table 1), there is a definite lack of consistency in collection and post processing of results even when multiple studies utilize the same data collection device[28].

Differences in post processing could cause variations within the foot pressure data. Data from the 16 studies was collected using the same device, however, different masking techniques were used to identify the ROI. Masking techniques were variable between the studies and could not be averaged or combined as there were nine different ROI groupings used between the 16 studies. This complicates direct comparison between studies as the ROI for the hindfoot can be calculated several different ways. Clinicians and researchers should bear in mind that even when multiple studies use the same data collection device, the post processing procedures can make it difficult to directly compare data.

As indicated above, many factors, both uncontrollable and controllable, can affect the reliability and accuracy of foot pressure measurements during data collection and post processing. Uncontrollable factors include gender, age, obesity, asymmetry and intra-individual differences of the subjects. These are factors that the clinician cannot change, however they may need to be considered as covariates or as stratification factors when analyzing data. Controllable factors include approach, walking speed, stride length and masking techniques. These factors can be influenced by the researcher or clinician and need standardization in order to make studies directly comparable.

Uncontrollable Factors

Gender

There is a trend in previous research involving children and foot pressure analysis to combine all subjects together regardless of gender; as previous research stated there were no differences in foot pressure parameters between genders[29]. However, conflicting research has found differences between boys and girls for leg length, foot length, arch angle and foot width during growth [102]. Previous research also reports that boys have a statistically larger midfoot area; an overall 9-12% larger CA, 10-18% higher FTI, 14-18% longer CT and an 11% higher MF [102]. Also, girls show a larger CA and FTI in the forefoot, larger PP in the hindfoot and forefoot and a smaller CA in the midfoot [102]. Bosch et al. (2007) reported that boys had increased PP and FTI in the hallux and a larger midfoot width compared to girls. Bosch et al. (2010) further quantified that boys had a 6mm wider midfoot and a 4% smaller CA in the forefoot. These differences could necessitate the need to analyze data separately by gender.

Age

Children's gait can be similar to adults as early as 3 [60], however complete gait maturation may not be fully complete until age 13 [61]. Henning et al. (1991) and Bosch et al. (2007) showed a reduced PP for all areas of the foot by a factor of 2.96 in children compared to adults and demonstrated the load under the foot moves laterally with growth [60, 62]. Additionally, adults have high areas of FTI under the hallux, third metatarsal head and first metatarsal head whereas children demonstrate a more evenly distributed load under the foot [62]. Adults have higher PP and longer CT than both toddlers and children [100]. Toddlers have lower PP in the hindfoot, increased CA (% of total CA) in the midfoot due to the fat pad [60], increased hindfoot CA [29] and a higher arch index [100].

Obesity

Mueller et al. (2016) reported the effect of obesity (>97th percentile) (371) and of being overweight (≥90th and<97th percentile) (746) on the foot pressure of typically developing children ages 1-12. Children who are overweight have larger total CA than typical weight children and children who are obese have the largest total CA [96]. The FTI was the highest in children who were obese, with a 1.26-1.75 fold increase as compared to children within typical weight ranges [96]. In addition, children who are obese have a 1.25 fold increase in PP compared to typically weighted children [96]. In addition, children who are obese also have as high as a 3.5 increase in PP and FTI in the medial midfoot area as compared to typically developing children [96]. Bosch et al. (2010) also found that body weight had a significant influence on midfoot width, where every one kilogram increase in body mass leads to a 0.08cm increase in foot width for children[101].

Asymmetry

Foot loading can be asymmetric between the left and right sides at the onset of independent walking until up to 3-4 years of age [99]. Asymmetry Index (ASI) is defined as $ASI = \left|\frac{2(X_L - X_R)}{X_L + X_R}\right| * 100\%$, where X_L and X_R is the same variable on the left side and right side respectively and where an ASI of 0 is perfect symmetry [101]. Previous research has found that an ASI value of <10% is acceptable [101]. Research has also shown that typically developing children's midfoot AIS values were <5% for CA, 13-20% for PP, 5-14% for FTI, 4-12% for MF and 5-15% for CT[101]. However, with increasing age, right and left symmetry does improve due to increased postural stability and motor control [99]. Contrastingly, Bosch et al. (2007) reported that there was no difference between the left and right feet in typically developing children at the onset of walking (15 months) [60].

Intra- and Inter-individual Differences

Gait has been reported to be variable between walks and between subjects[34]. It has been suggested that controlling for intra-individual differences within subjects is more important than controlling inter-individual differences [34, 108]. Furthermore, it has been found that different masking techniques produce different reliability and variability among foot pressure measurements in children. Masked regions with larger PP tend to be less variable and more reliable[108]. Therefore it has been concluded that reliability between subjects, while important, is not as clinically relevant as having lower intra-individual variability[108]. If the goal of clinical foot pressure analysis is to identify change, high variability within a subject's foot pressure data will introduce error into clinical outcome reporting. Coefficients of variation measurements indicate that variability within subjects was as low as <5% for CA, 10-20% for MF, and between 20-25% for PP, CT and FTI[41]. Inter-individual differences between subjects was slightly higher, ranging from 10-12% for CA, 18-22% for MF, 23-30% for PP, 19-28% for CT and 18-24% for FTI [41]. For masking, ICC values demonstrated excellent reliability >0.92, with the lowest average session uncertainty (as estimated from the standard error) in the medial midfoot region[108]. The medial midfoot region is again a region with lower PP, which would support the inference that regions with lower PP values would be less reliable.

Plate Specifications

The ability to consistently measure the same loading is crucial for clinical use and comparisons between repeated measurements [37]. When comparing between studies, specifications of the foot pressure technology that should be considered are the resolution, sampling frequency, reliability and calibration [32, 109]. The higher the resolution, number of sensors/cm^2, and the greater the number of sensors [5] has a tendency to be bias to a higher variation, especially when small masks are used [12]. Therefore, the small size of children's feet, compared to adults or adolescents, may be more affected by the foot pressure plate resolution [32, 60]. This is due to the fact that when a force is applied to a large sensor, it doesn't produce the same pressure reading as the same force applied to a small sensor [32, 109]. Sampling frequency also becomes important for the temporal parameters being reported and it is recommended that a sampling frequency of 45-100Hz should be used for walking [32]. Sampling frequencies below those recommended may not produce reliable data. Additionally, calibration is important in establishing accurate and valid data; all emed® plates are self-calibrating [32], as opposed to others that may require manual calibration. However, proper maintenance and self-assessments should be conducted to ensure that all devices are still functioning properly, as device wear may impact plate function.

Controllable Factors

Walking Speed and Stride Length

The majority of foot pressure studies in typically developing children utilize self-selected walking speeds. Rosenbaum et al. (2013) reported that the average typical walking speed for children was 1.2 m/s and only a 0.15 m/s difference was seen in a cohort of 7788 children when walking at a self-selected walking speed[98]. Taylor et al. (2004) showed a linear increase in pressure and force when transiting from slow walking to a fast pace and an overall medial shift in pressure with faster speeds. It was also stated that when assessing foot pressure in children, gait speed should be similar between follow-ups [63]. Furthermore, increasing stride length by 20% will lead to a 36% increase in PP in the hindfoot and decreasing stride length by 20% will decrease PP in the hindfoot by 13% [95]. It has been suggested that when assessing foot pressures, if walking speed cannot be controlled, parameters affected by time (FTI, PTI) should be interpreted with caution [63] or corrected for speed variations [94].

Approach

There are two approaches that have been used in previous foot pressure research involving children; the midgait and the two step method [34, 94]. The midgait method is considered the gold standard and is when the subject strikes the foot pressure plate in the middle of a 12 meter walkway at a self-selected speed[107]. Whereas, the two-step approach is when the subject strikes the foot pressure plate on the second step [107]. It is important to note that steady-state walking speed is not achieved until the end of the second or third step, resulting in a walking speed that may not be optimum when using the two step approach [94]. However, it has been reported that both the two step and midgait methods produce reliable results [107]. The two step approach reports ICC values for PP in children's ROI ranging from 0.799-0.951 for three walking trials and 0.905-0.969 for five walking trials [107]. The midgait method reports ICC values for PP ROI's ranging from 0.841-0.980 for five walking trials and 0.776-0.975 for three walking trials [107]. Despite the differences between approaches, there were no significant differences in foot pressure data between the midgait and two step approaches [34].

These data were reported in adults and cannot always be directly applied to children. Children demonstrate differences from adults when assessing foot pressure analysis due to differences in stability, muscle force, and coordination[99]. It has been stated that children's gait can be similar to adults as early at 3 [60], however complete gait maturation might not be fully complete until age 13 [61]. It has also been established that foot function and tissue characteristics change throughout life [100] and that with maturation structure, strength, size and motor skills all increase [98]. Therefore, understanding the differences between child and adult foot pressure patterns can help when attempting to apply adult foot pressure results to that of children, especially in instances when there is a lack of research on children and the only available research utilized adults.

Masking Techniques

Clinically it is more beneficial to examine pressure under specific regions of interest (ROI) instead of the total foot [28]. Previous research has shown that data from the whole foot does not give a complete picture of the forces affecting the foot when walking [31]. The purpose of creating masks is to define different ROI on the surface of the foot that correspond to anatomical regions of the foot [25, 28]. When interpreting data from masks it is important to bear in mind the masking technique used in the study, as this will define the ROI. The needs of the clinician or researcher will determine the number of masked ROI and the technique used to define these regions [25]. The most common automated techniques used to define the ROI are pressure gradient, geometric algorithm or custom fit based on percentage of foot length and width [29]. The inherent differences between the three automated techniques, how they define a ROI, make it nearly impossible to assume that a ROI is exactly the same between techniques or between studies. In addition, it has been suggested that the three techniques may be inadequate when assessing pediatric feet with deformity [29] due to incomplete contact with the floor [26] and the small foot size.

The justification for having an automated masking technique is that it is standardized [28, 35]. However, previous research has stated that automated ROI masking techniques are not as accurate when deformity is present [28]. Therefore, it may be necessary to forgo automated masking techniques and mask the ROI based on visual analysis of the foot pressure data; known as manual masking. Manual masking is based on the subjective interpretation of the clinician and may be limited by the spatial resolution of the plate [28]. Furthermore, to avoid problems with both manual masking and automated masking, some studies have utilized foot kinematics from a motion capture system synchronized with the foot pressure assessment to identify foot anatomy [28]. Each reflective marker is projected vertically onto the foot pressure picture and then automated masking techniques are used to identify the boundaries of the ROI [28]. This technique has been found to be just as reliable as masking using built in algorithms[33].

Suggestions for Standardizing Collection and Data Reporting

Suggestions for standardization can be made using the data collection and post processing techniques used in the 16 studies reviewed here and previous recommendations by MacWilliams and Armstrong (2000). MacWilliams and Armstrong (2000) reported the clinical applications of foot pressure analysis for children. They recommended that the midgait method be used to collect a minimum of three walking trials at the subject's self-selected walking speed [110]. However, since both the midgait method and two step method report similar repeatability [34, 107], either approach could be utilized for data collection in children. The two step method is especially useful in very young children or for children that have difficulty walking.

MacWilliams and Armstrong also recommended that masking protocols be as simple as possible while still adequately testing the hypothesis [110]. However, MacWilliams and Armstrong did state that there was a need for the standardization of masking so that data can be compared between studies [110]. The masking technique used most often in the 16 studies of typically developing children presented here is a 5 area ROI mask: hindfoot, midfoot, forefoot, hallux and toes. This masking technique may be sufficient for assessing typically developing subjects or if the data are not to be used as comparison data for pathologic data. The five area ROI masking technique most often used in the referenced studies will not give clinicians data on the differences between the medial to lateral sides of the hindfoot, forefoot or midfoot, which can be an important factor for deformities such as clubfoot. Eight of the 16 studies presented here reported data for the medial and lateral foot [26, 29, 62, 63, 96, 97, 103, 104], with varied medial and lateral ROI's utilized within these eight studies. Therefore, if typically developing cohort data are to be used for comparison with pathologic data, it is recommended that at minimum, the forefoot, midfoot and hindfoot be divided into medial and lateral sections and that the hallux and toes be masked separately from the forefoot. Additionally, further dividing the forefoot into individual metatarsal regions may be advantageous when assessing forefoot pathology such as forefoot adductus. However, clinicians need keep in mind the limitations of the foot masking algorithms to identify medial/lateral or metatarsal regions on small plantar pressure areas with or without deformity. Despite the need for medial and lateral masking for deformity, there still may be limitations with masking small pediatric feet. Small feet with deformity may not present enough contact area or have all of the areas of the foot contacting the foot pressure plate. It has been suggested that complicated masking, with more ROI are more error prone and less reliable than a masking technique with larger ROI [108]. Clinicians need to be aware that masking incomplete and small feet present their own limitations and that including more ROI, such as medial/lateral or individual metatarsal regions might not be accurate or feasible.

In the 16 studies, force, pressure, area and time parameters were reported using varying units. This is not a problem when converting from one unit of measure to another such as kPa to N/cm^2. However, for comparison between different ages or different weights it is sometimes more advantageous to normalize parameters to either body weight or the total foot value. This can present a problem because there is no way to transform data from percentages back to standard units, unless the body weight for all participants and the total foot parameter values (in standard units) are reported. Therefore, parameters should always be reported in a standard unit of measurement, either within the main body of the article or as supplemental data (if percentages are reported).

Conclusions

Foot pressure analysis is a valuable tool that can be used by clinicians and researchers to quantify foot function and pathology. This paper focused on data collected from one device and data collection and post processing procedures in typically developing children only. This paper was not meant to be a comprehensive review of foot pressure literature, but a tool to be used clinically to aid physicians in collecting, post-processing and using previously collected typically developing data as a comparison with pathological feet. Supplemental material was provided that gives clinicians and researchers typically developing cohort data to compare with pathologic data. Suggestions for minimum data collection and processing recommendations were identified. These include: using a midgait or two-step approach, allowing subjects to walk at their self-selected speed, collecting a minimum of three trials per foot, identifying at minimum medial and lateral hindfoot, forefoot, midfoot, the hallux and toes, and that parameters be reported in standard units. In the future, investigation is needed to assess the standards of reporting and post processing and data collection techniques in prior research that involves children with pathology. Lastly, the establishment of a cohort of experts or a committee is needed in order to standardize foot pressure data collection and post processing protocols for typically developing children and for children with pathology.

Table B.1: Summary of Typically Developing Foot Pressure Studies Using Novel Emed System. * Representative trial chosen for analysis. **Walking speed, number of trials and approach are reported as stated in the original manuscripts.

Study	Number of Subjects	Age of Subjects	Number of Trials Averaged	Approach	FP Parameters used	Regions of Interest (ROI)	Emed System	# of Sensors	Resolution	Foot Pressure Plate Size (mm)	Frequency (Hz)
Hennig et al (1991)	15	23.5(5.7)	3*	not specified	PP(kPa), FTI(%Total)	7: Medial Hindfoot, Lateral Hindfoot, Midfoot, First Metatarsal, Third Metatarsal, Fifth Metatarsal, Hallux	EMED F01		2	200x340	20
Bertsch et al (2004)	42	13.5 months	5	A Few Steps	PP(kPa), FTI (Ns), CA(cm^2), MF(N), CT(ms), CT(%Stance) (all values normalized to foot size and body weight)	5: Hindfoot, Midfoot, Forefoot, Hallux, Toes	EMED ST 4	2736	4	190x360	50

Table B.1: Continued

Unger & Rosenbaum (2004)	42	onset of walking	5	Several Steps Before and After	PP(kPa/bw), FTI(%Total), CA(%Total), MF(%Total), CT(%Stance)	5: Hindfoot, Midfoot, Forefoot, Hallux, Toes	EMED ST 4	2736	4	190x360	50
Liu et al (2005)	66	6 to 16 years	3	Midgait (5m walkway)	PP(N/cm^2), FTI(Ns), CA(cm^2), CT(%Stance), PTI(Ns/cm^2), IPP(%Stance), IMF(%Stance), MMP(N/cm^2),	9: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, First Metatarsal, Second-Fourth Metatarsals, 5th Metatarsal, Hallux, Lateral toes	EMED NT 4	2736	4	360x190	
Bosch et al (2007)	90	15.3(2.3) months	5	A Few Steps	PP(kPa), FTI(%Total), CA(%Total)	5: Hindfoot, Midfoot, Forefoot, Hallux, Toes	EMED ST 4	2736	4	190x360	50
Bosch et al (2009)	104	1.3 and 7 years	5	During Full Gait	PP(kPa), CA(%Total), MF(%bw), CT(ms), CT(%Total), Arch Index	5: Hindfoot, Midfoot, Forefoot, Hallux, Toes	EMED ST 4 & EMED XR		4		

Table B.1 Continued

Bosch et al (2010)	36	14.6-122.8 months	5	During Full Gait	PP(kPa), MF(%bw), CA(%Total) Arch Index	5: Hindfoot, Midfoot, Forefoot, Hallux, Toes	EMED ST 4 & EMED XR		4		
Bosch & Rosenbaum (2010)	62	15.1 months	5	During Full Gait	PP(kPa),FTI (Ns), CA(cm^2), CT(ms), MF(%bw), Arch Index	Total Foot Only	EMED ST 4 & EMED XR		4		
Muller et al (2012)	10,382	1-13 years	3-5	2 Step Approach	PP(N/cm^2), FTI(Ns), CA (cm^2), Arch Index	3: Hindfoot, Midfoot, Forefoot	EMED X		4	400x 680	50
Rosenbaum et al (2013)	20	8 (2)	5*	Midgait (5m walkway)	PP(kPa), FTI(%total), MF(%bw), CT(ms)	10: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, First Metatarsal, Second Metatarsal, Third-Fifth Metatarsal, Hallux, Second Toe, Lateral Toes	EMED ST 4	2736	4	360x 190	50

Table B.1: Continued

Riddiford-Harland et al (2016)	34	5-9	3	2 Step Approach	PP(kPa), PTI(kPa/s)	5: Medial Midfoot, Lateral Midfoot, Medial Forefoot, Middle Forefoot, Lateral Forefoot	EMED AT 4	1377	2	360x190	50
Mueller et al (2016)	7575	7(2.9) years	3	2 Step Approach	PP(kPa), FTI(Ns), CA (cm^2), Arch index	5: Hindfoot, Medial Midfoot, Lateral Midfoot, Forefoot, Toes,	EMED X		4	400X680	
Jameson et al (2008)	23	11.4 (3.3) range 6-17	5*	Midgait (6m walkway)	COP, COPP, both were normalized to foot size and stance phase time	6: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, Medial Forefoot, Lateral Forefoot	EMED ST 2		4	380x720	
Hillstrom et al (2013)	25	Early Walkers	5	2 Step Approach	PP(kPa)	12: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, First Metatarsal, Second Metatarsal, Third Metatarsal, Fourth Metatarsal, Fifth Metatarsal, Hallux, Second Toe, Third-Fifth Toes	EMED X	6080	4		

Table B.1: Continued

Giacomozzi and Stebbins (2017)	20	11.5(2.8) years	4	not specified	CT(%Stance), PP(kPa), MF(%bw), IPP (%Stance), IMF(%Stance), PTI(kPa*s), FTI(%bw*s), CA(%total)	5:Medial Hindfoot, Lateral Hindfoot, Midfoot, Medial Forefoot, Lateral Forefoot	EMED M		4	475x320	50
Dowling et al (2004)	20	8.8(2)years non-obese 8.9(2.1) Obese	5	2 Step Approach	MF(N), CA(cm^2), PP (Ncm^2), PTI(Ns/cm^2), FTI(Ns)	10: Medial Hindfoot, Lateral Hindfoot, Medial Midfoot, Lateral Midfoot, First Metatarsal, Second Metatarsal, Third-Fifth Metatarsal, Hallux, Second Toe, Lateral Toes	EMED AT 4				

Table B.2: emed® Parameters. * Ten area mask includes: hallux, 2nd toe, 3rd-5th toes, lateral heel, medial heel, lateral midfoot, medial midfoot, 1st metatarsal, 2nd metatarsal and 3rd-5th metatarsals. Table adapted from Novel User Manual: Welcome to Novel Projects v.24 (April 2014)

Parameter Name	Definitions	Abbreviation
Absolute Value of Ar-Al	Absolute value difference between the area to the right and the area to the left of the foot axis	ArAlabs
Al (cm^2)	The area left of the axis that is enclosed by the axis and the gait line	Al
Anterior Plantar Angle (°)	Defined by anthropometric regions of the foot.	APA
Ar (cm^2)	The area right of the axis that is enclosed by the axis and the gait line	Ar
Ar+Al	The total area between the foot axis and the gait line.	ArAl
Arch Index	The ratio of the midfoot area divided by the total foot area (without the toes)	AI
Average Mean Pressure (kPa)*	Calculated over all sensors in a given mask and over all frames in a file	AMP
Begin of Contact (%ROP)*	When contact within a given mask begins	BC
Center of Pressure Excursion Index (H or L)	Calculated according to H.J.Hillstorm	COPEI
Center of Pressure Index (COPI)	The ratio between the medial and lateral areas of the foot as determined by the center of pressure	COPI
Coefficient of Spreading	The forefoot width divided by the foot length	COS
Contact Area (cm^2)*	The average area that pressure is applied within a mask	CA
Contact Area (LAMAI)*	Describes the area that pressure is applied to (within the mask).	CA(LAMAI)
Contact Area for MVP*	Area of pressure within the MVP	CA(MVP)
Contact Time (ms)*	Amount of time contact is present within a mask	CTms
Contact Time (P)*	The amount of time contact is present as a percentage of the total time	CT%
Distance	The distance the COP traveled during the roll over process.	D

Table B.2: Continued

Distance ®*	The distance the COP traveled during the roll over process within the mask.	Dr
End of Contact (%ROP)*	When contact within a given mask ends	EC
Foot Length (cm)	The length of the foot from the heel to the point most distal to the heel	FL
Foot Progression Angle (°)	Angle between the foot axis and the vertical axis of the foot.	FPA
Foot Width (instep)	Distance between the most distant midfoot point and a point on the lateral aspect of the foot, a straight line is drawn from the most distant midfoot point perpendicular to the medial tangent.	FWin
Foot Width (narrowest)	Distance between the two narrowest points across the flash potion of the foot, a straight line is drawn from the narrowest place of the foot parallel to the forefoot width line.	Fwna
Force for MVP (N)*	The sum of products of pressure beneath the sensor and area of the MVP	F(MVP)
Force-Time Integral (N/s)*	The area under the force-time curve	FTI
Force-Time Integral (normalized to bodyweight (%BW)*	The area under the force-time curve normalized to body weight	FTI(%bw)
Forefoot and Heel Coefficient	Heel width divided by forefoot width	FFHcoe
Forefoot Angle	The angle between the medial tangent and the line defining the forefoot width	FFA
Forefoot Coefficient	Medial forefoot width divided by the lateral forefoot width as defined by the long plantar angle bisection	FFCO
Forefoot Width (cm)	Distance between the lateral boarder of the forefoot to the medial boarder of the forefoot at the widest point	FFW
Hallux Angle	Angle between the medial tangent and the big toe tangent	HA
Heel Angle	The angle between the medial tangent and the tangent to the heel	HeA
Heel Width	Distance between the two widest points on the heel	HeW

Table B.2: Continued

Heel Width (cm)	Distance between the lateral boarder of the heel to the medial boarder of the heel at the widest point	HeW(cm)
Instant of Maximum Force (%ROP)*	The instant of time where the highest total force occurs within each mask	IMF
Instant of Maximum Velocity (r)*	Calculates the time at which the maximum velocity of the COP occurred within the mask.	IMVr
Instant of Maximum Velocity (%ROP)	Calculates the time at which the maximum velocity of the COP occurred.	IMV
Instant of Peak Pressure (%ROP)*	The instant of time where the highest pressure values occurred in a mask	IPP
Instep Width	Distance between the two most distant midfoot point and the point of the medial tangent. A straight line is drawn from the most distant midfoot point perpendicular to the medial tangent.	IW
Intermetatarsal Angle	Formed by the intersection of the longitudinal axes of the first and the second metatarsal heads.	IA
Lateral Contact Area (cm^2)	Area for the lateral side of the gait line	LCA
Lateral Force / Medial Force Index	Lateral force/medial force	LFMFI
Lateral Force-Time Integral(N/s)	Area under the force time curve for the lateral foot	LFTI
Lateral Plantar Angle	The angle between the lateral tangent and the bisection of the long plantar angle.	LPA
Lateral Tarsal Angle	Defined by anthropometric regions of the foot.	LTA
Lateral-Medial Area Index	The ratio of the difference between the lateral and medial area to the total area over time	LMAI
Lateral-Medial Force-Time Integral Index	The difference between the lateral and the medial force time integral	LMFTII
Long Plantar Angle (°)	Medial and Lateral tangents drawn on the foot print and meet to form this angle	LongPA
Maximum Force (N)*	The highest total force that occurred within a mask	MF
Maximum Force (normalized to body weight) (%bw)*	The highest total force that occurred within a mask normalized to body weight	MF(%bw)
Maximum Mean Pressure (kPa)*	The highest mean value calculated over all sensors for a given mask	MMP

Table B.2: Continued

Maximum Velocity (r) (m/s)*	The highest velocity achieved by the COP within a given mask	MaxVr
Maximum Velocity (m/s)	The highest velocity achieved by the COP	MaxV
Mean Pressure (kPa)*	This is the mean pressure derived from the MPP and is calculated over all sensors in a given mask	MP
Mean Pressure for MVP (kPa)*	This is the ratio of force and loaded area for the MVP for each mask	MP(MVP)
Mean Velocity (r) (m/s)*	The mean velocity achieved by the COP in a given mask	MVr
Mean Velocity (m/s)	The mean velocity achieved by the COP	MV
Medial Contact Area (cm^2)	Area for the medial side of the gait line	MCA
Medial Force-Time Integral (N/s)	Area under the force time curve for the medial foot	MFTI
Medial Plantar Angle	The angle between the medial tangent and the bisection of the long plantar angle.	MPA
Medial Tarsal Angle	Defined by anthropometric regions of the foot.	MTA
Midfoot and Forefoot Coefficient	Midfoot Width divided by the forefoot width	MFC
Midfoot Width	Distance between two points across the flash portion of the midfoot.	MW
Peak Mean Pressure (kPa)*	Peak of the mean pressure values as calculated over all sensors in a given mask	PMP
Peak Pressure (kPa)*	The highest pressure within a mask	PP
Posterior Plantar Angle	Defined by anthropometric regions of the foot.	PPA
Pressure-Time Integral (kPa/s)*	The area under the pressure-time curve	PTI
Subarch Angle (°)	The angle formed from the forefoot and heel medial boarders, meeting at the most lateral aspect of the arch	SA
Transverse Plantar Angle	The transverse axes are formed by drawing two lines connecting the two focal points of the forefoot and the two focal points of the heel. They meet to form this angle.	TPA

Table B.3: emed® System Specifications. * Table reprinted from http://www.novelusa.com/index.php?fuseactiosystems.emed

	emed-a	emed-c	emed-n	emed-q	emed-x	emed-xL
dimensions	610x323x16 (18)	610x323x16 (18)	690x403x16 (18)	690x403x16 (18)	690x403x16 (18)	1,529x504x18
sensor area	380x240	380x240	475x320	475x320	475x320	1,440 x 440
number of sensors	1760	3840	6080	6080	6080	25,344
platform thickness (mm)	18	18	18	18	18	18
sensor resolution (sensors/cm^2)	2	4	4	4	4-Jan	4
sampling frequency (Hz)	50/60	50/60	50/60	100	100/400	100
pressure range (kPa)	10-950	10-1200	10-1270	10-1270	10-1270	10-1270
pressure threshold (kPa)	10	10	10	10	10	10
accuracy	±7% ZAS	±5% ZAS	±5% ZAS	±5% ZAS	±5% ZAS	±5% ZAS
hysteresis	<3%	<3%	<3%	<3%	<3%	<3%
temperature range (°C)	15-40	15-40	Oct-40	Oct-40	Oct-40	Oct-40
maximum total force (N)	67,000	120,000	193,000	193,000	193,000	804,670
crosstalk (db)	-40	-40	-40	-40	-40	-40
cable length (m)	5	5	5	5	5	5
connection to computer	USB	USB	USB	USB	USB	USB
synchronization	None	sync pulse at first loaded frame	sync pulse at first loaded frame	sync pulse at first loaded frame	frame by frame in- and out-synchronization	sync pulse at first loaded frame

Table B.S1 – Longitudinal Studies in Typically Developing Children: Peak Pressure (PP) * Data presented for the 3rd-97th percentile ranges.

	Number of Subjects	Age (months)	Mean height (cm)	Mean weight (kg)	PP (kPa) Total	PP(kPa) Hindfoot	PP (kPa) Midfoot	PP (kPa) Forefoot	PP (kPa) Hallux	PP(kPa) Toes 2-5
Bertsch (2004)	42	14.8 (1.8)	78.5 (3.3)	10.7 (1.3)	148.1 (40.9)	109.8 (35.2)	73.1 (14.8)	87.4 (37.1)	12.7 (40.9)	49.4 (20)
	42	17.8 (2)	81.4 (3.3)	11.6 (1.6)	157.9 (46.8)	127.2 (48.7)	78.2 (17.4)	102.6 (23.1)	123.5 (47.4)	54.1 (22.6)
	42	21 (1.9)	85.2 (3.4)	12.4 (1.5)	169.9 (45)	141.7 (48.1)	80.1 (21.5)	110 (27.3)	124.6 (50.2)	50.5 (18.9)
	42	23.9 (1.9)	88 (3.8)	13 (1.6)	171.8 (42.3)	143.4 (46.6)	74.8 (16.5)	110.9 (24.8)	133 (43.5)	57.3 (20.5)
	42	27.1 (1.9)	90.5 (4)	13.6 (1.3)	181.4 (43.1)	149.1 (44.7)	74.3 (17.8)	117.1 (25.6)	135.3 (49.2)	57.2 (23.6)
Bosch (2007)*	89	15.3 (2.3)	77.8 (3.3)	10.6 (1.2)	90-239.1	64.6-182.4	49.3-107.4	48.6-136.8	63.8-242.2	19-91.7
	89	18.3 (2.3)	81.1 (3.4)	11.3 (1.4)	93.8-288.4	69.3-250.7	53.1-113.2	65-170.9	57.4-264.8	16.7-102.2
	90	21.3 (2.3)	84.7 (3.4)	12 (1.3)	108-281.9	73.2-246.3	49-116.6	72.7-165.4	58.3-257.3	17.4-90.6
	84	24.3 (2.4)	87.2 (3.4)	12.6 (1.5)	105-278.9	80-269	48.8-102	75-169	66.7-227	23-95

Table B.S1: Continued

	84	27.4 (2.4)	89.9 (3.7)	13.2 (1.4)	122-306	93.3-282.5	51-108	81-165	69-248	23-98.3
	78	33.3 (2.3)	94.8 (3.9)	14.4 (1.5)	129.3-345.2	92.9-312.8	44-109	87-195.1	73.9-259.4	25.3-96.4
	66	39.3 (2.6)	98.9 (4.6)	15.5 (1.7)	156.9-412.4	113.7-362.5	43.9-106.1	95.9-192.6	69.5-305.3	30.7-122.1
	59	45.5 (2.5)	102.4 (4)	16.5 (1.8)	148.5-400	116-372.5	40.5-92	108.2-211	59.6-328.7	25.5-132
	55	51.6 (2.5)	106.7 (4.3)	17.9 (2)	174.3-491.9	136.4-491.9	39.5-99	112.5-244.5	81.1-325.4	38.5-155.3
	48	57.5 (2.5)	110.2 (4.7)	18.9 (2)	180.6-453.8	159-414	39.7-103.3	105.8-281.3	85.9-345.7	31-194.7
	43	63.3 (2.7)	114.1 (5)	20.6 (2.2)	187.1-555.6	168-509	42.2-121	133.4-320.2	96.6-352.2	45.6-199.8
Bosch (2010)*	36	14.6 (1.8)	78 (3.3)	10.5 (1.2)	84.7-229.1	63.2-182.7	51.2-107.2	45.9-117.9	63.8-222.6	24.1-93.7
	36	17.5 (1.9)	81 (3.3)	11.5 (1.5)	92.2-311.8	65.5-284.9	53.9-111.5	65.6-161.5	57.7-228.7	18.2-123.5
	36	20.7 (1.9)	84.8 (3.2)	12.2 (1.4)	106.3-255.5	77.6-233.8	55.2-130.8	72.8-158.8	50.3-252.6	23-87.7
	36	23.6 (87.5)	87.5 (3.5)	12.9 (1.5)	106.8-265.1	75.4-251.1	48.8-104.8	78.4-150.9	51.2-220.5	25-104.3
	36	26.8 (1.8)	90.1 (3.7)	13.4 (1.3)	122.1-283.1	93.4-262.8	51-107.8	86.5-174.4	66.2-219.8	25.3-107
	36	32.8 (1.9)	95.2 (3.7)	14.6 (1.6)	128.5-336.4	95.5-293.6	44.5-133.3	78.5-170.4	75.3-261.4	24.8-96.1
	36	38.8 (2.1)	99.1 (4.1)	15.7 (1.7)	159.1-331.9	116.4-306.9	46.1-99.8	104.1-204	68.3-268.3	25.1-116.5
	36	44.9 (1.9)	103.1 (4.2)	16.8 (1.9)	149.1-355.1	118.3-323.2	46.5-90	106.7-211.9	54.7-312.2	25.1-151.1
	36	50.9 (1.9)	106.7 (4.2)	18.1 (2)	163.6-365.9	132.5-352-8	39.4-106.8	112.3-245.4	79.1-303.6	38-146.8

Table B.S1: Continued

	36	56.8 (2)	109.9 (4.5)	18.9 (2.1)	173.3-397.9	159-387.3	41.1-104.4	103.2-264.1	80.5-307.2	31-183.8
	36	62.7 (1.9)	113.3 (5.1)	20.4 (2.5)	424.1-186.1	168-424.1	44-109.7	130.4-386.6	95.2-348.5	44.2-201.7
	36	68.5 (1.9)	117 (4.6)	21.8 (16)	220-511.6	216.3-511.6	40-133.6	139.1-309.4	102.6-377.4	51.3-237.2
	36	74.5 (1.8)	120.6 (5.1)	23.8 (2.9)	245.1-603.1	216-603	43.4-146	150.4-390.6	126.4-381.5	58.9-271.4
	36	86.6 (1.8)	127.3 (5.5)	26.6 (3.3)	271.3-641.4	264-631.7	38.6-150.5	148.7-421.2	145.8-446.2	58.1-266.8
	36	98 (4.7)	133.3 (5.6)	29.7 (4.1)	233.5-669.9	223.3-669.9	34.4-147.1	154-410.1	99.3-428.8	49.4-249.2
	36	110.5 (1.7)	138.8 (5.9)	32.9 (4.3)	283.4-654.8	244.2-635.9	33.1-131	170.1-540.7	132.9-502.6	63.1-275.6
	36	122.8 (2)	145.5 (6.3)	37.1 (5.5)	274.3-688.3	251.4-649.3	33-138.7	191.6-522.1	123.3-538.4	62.8-261.4

Table B.S2 - Longitudinal Studies in Typically Developing Children: Force-Time Integral (FTI) * Data presented for the 3rd-97th percentile ranges. ^ Data were reported as either Ns or as a percent of total foot value (indicated by a %).

	Number of Subjects	Age (months)	FTI(% or Ns) Hindfoot^	FTI(% or Ns) Midfoot^	FTI (% or Ns) Forefoot^	FTI (% or Ns) 2-5th Toes^	FTI(% or Ns) Hallux^	FTI(% or Ns) Total^	FTI (Ns) Lateral	FTI (Ns) Medial	FTI(%total) Hindfoot	FTI(%total) Midfoot	FTI(%total) Forefoot	FTI(%total) Hallux	FTI(%total) Toes 2-5
Bertsch (2004)	42	14.8 (1.8)	9.8 (4.4)	11.7 (4.5)	12.4 (3.5)	1.3 (.9)	2.7 (1.2)	37.9 (9.1)	19.7 (5.7)	18.2 (4.6)	25.4 (8.1)	30.4 (7.3)	33.3 (9.2)	7.3 (3)	3.5 (2.4)
	42	17.8 (2)	8.5 (3.5)	8.3 (3)	14.2 (3.5)	1.3 (.8)	2.7 (1.5)	35 (6.8)	17.5 (4.2)	17.5 (3.8)	23.7 (7.4)	23.4 (6.4)	41 (8.7)	7.9 (4.2)	3.9 (2.6)
	42	21 (1.9)	9.5 (3.3)	7.7 (3.1)	15.7 (4.1)	1.1 (.7)	2.8 (1.3)	36.8 (7)	18.1 (4.3)	18.6 (3.9)	25.6 (6.8)	20.6 (6.7)	42.8 (7.6)	7.8 (3.6)	3.3 (2.4)
	42	23.9 (1.9)	9.7 (3.8)	7..3 (3.5)	18(4.6)	1.5 (1.2)	3.6 (1.9)	40.1 (7.5)	19.7 (3.8)	20.5 (4.7)	24.2 (8.1)	18 (6.9)	45.1 (8.6)	8.9 (3.7)	3.9 (2.9)
	42	27.1 (1.9)	12.1 (5.1)	7.5 (3.2)	20.8 (5.3)	1.5 (.9)	4.1 (2.2)	46.1 (9.9)	22.5 (5)	23.2 (6.5)	25.7 (7.5)	16.5 (6..2)	45.6 (8.4)	8.8 (3.7)	3.4 (2)
Bosch (2007)*	89	15.3 (2.3)	12.8-44.8	17.5-43%	18.3-50.2%	.4-8.6%	2.3-15.7%								
	89	18.3 (2.3)	12.2-37%	12.2-37%	25.3-56.5%	.4-8.8%	2.1-17.4%								
	90	21.3 (2.3)	12-38.3%	8.5-32.8%	28.2-57.3%	.4-7.4%	2.6-16.9%								
	84	24.3 (2.4)	12.4-38.4%	6.3-33.5%	31.5-61.8%	.5-7.4%	3.5-16.9%								

Table B.S2: Continued

	8 4	27.4 (2.4)	13.1- 40.6%	5.1- 28.8%	29.3- 60.2%	.6- 7.7%	3.1- 17.5%								
	7 8	33.3 (2.3)	14.1- 40.4%	3.3- 27.8%	30.7- 61.8%	.6- 7.1%	2.9- 16.4%								
	6 6	39.3 (2.6)	18.1- 41%	2.6- 24.7%	30.8- 62.6%	.9- 7.1%	3.4- 15.8%								
	5 9	45.5 (2.5)	17.3- 44.7%	1.9- 23%	33.5- 61.4%	.5- 7.2%	2.5- 16.2%								
	5 5	51. 6(2.5)	19.3- 44.1%	1.5- 18.4%	36.5- 60.3%	1- 8.3%	3.2- 16.4%								
	4 8	57.5 (2.5)	21.7- 44.4%	1.4- 19.5%	34- 56.9%	.8- 8.6%	3.3- 14.9%								
	4 3	63.3 (2.7)	21.6- 44.8%	1.4- 17.9%	36.2- 59.6%	1.1- 7.8%	2.8- 14.2%								

Table B.S3 - Longitudinal Studies in Typically Developing Children: Maximum Force (MF) * Data presented for the 3rd-97th percentile ranges.

Study #	Number of Subjects	Age (months)	MF (N) Total	MF(N) Hindfoot	MF(N) Midfoot	MF(N) Forefoot	MF(N) Hallux	MF(N) Toes 2-5	MF (%BW) Total	MF(%BW or %MForce) Hindfoot	MF(%BW or %MForce) Midfoot	MF(%BW or %MForce) Forefoot	MF(%BW or %MForce) Hallux	MF(%BW or %MFoce) Toes 2-5
Bertsch (2004)	42	14.8 (1.8)	107.8 (19.4)	54.7 (14.9)	45.7 (11.9)	52.7 (13.6)	17.1 (6.1)	7.7 (4.5)	95 (13.7)	47.9 (11.2)	40.1 (9.1)	46.5 (11.3)	15.2 (5.3)	6.8 (4)
	42	17.8 (2)	129 (27.9)	67.9 (18.8)	49.9 (16)	68.2 (12.7)	19.1 (8.1)	8.2 (4.3)	113.5 (21.4)	59.7 (15.2)	43.6 (12.5)	60.2 (10.4)	16.8 (6.7)	7.2 (3.7)
	42	21 (1.9)	142.7 (31.4)	79.2 (23.1)	50.2 (16.2)	76.7 (11.9)	19.5 (7.4)	7.8 (4.1)	117.6 (22.8)	65.1 (16.4)	41.3 (12.9)	63.2 (7.8)	16.1 (6)	6.5 (3.4)
	42	23.9 (1.9)	149.9 (31)	81.3 (21.2)	48.8 (16.2)	84.4 (14.5)	22.6 (8.2)	9.5 (5.2)	118.1 (22.2)	63.9 (16)	38.5 (12.8)	66.2 (9.4)	17.8 (5.5)	7.6 (4.2)
	42	27.1 (1.9)	153 (32.1)	86.5 (20.7)	46.4 (17.7)	92.3 (18.6)	23.5 (8.9)	9.5 (6)	114.7 (22.1)	64.9 (15.1)	34.6 (12.4)	69.2 (12.3)	17.4 (6)	7.1 (3.7)
Bosch (2007)*	89	15.3 (2.3)												
	89	18.3 (2.3)												
	90	21.3 (2.3)												
	84	24.3 (2.4)												

Table B.S3: Continued

	84	27.4 (2.4)												
	78	33.3 (2.3)												
	66	39.3 (2.6)												
	59	45.5 (2.5)												
	55	51.6 (2.5)												
	48	57.5 (2.5)												
	43	63.3 (2.7)												
Bosch (2010)*	36	14.6 (1.8)	83.1-133.2							32.5-69.9	27.4-62.3	27.9-67.1	7.4-27.9	2.4-16.2
	36	17.5 (1.9)	86-162.2							34.4-92.9	26.8-74.6	41.1-76.2	7.4-29.9	1.6-14.9
	36	20.7 (1.9)	86.7-163.9							40.9-85.8	17.8-68.4	49.3-75.6	7.0-30.2	1.7-13.7
	36	23.6 (87.5)	86.2-159.5							34.3-90.3	14.6-59.9	54.8-85.4	6.8-29.2	2-16.6
	36	26.8(1.8)	86.7-157.9							44.9-98.5	14.3-55.7	52.5-99.5	7.8-29.9	1.8-15.9
	36	32.8 (1.9)	86.9-211.2							43.6-126.5	9.0-50.3	51.4-95.3	9.9-33.1	2.5-12.8
	36	38.8 (2.1)	88.8-137.3							54.1-90.8	9.0-57.8	59.5-97	8.4-31.4	2-14.8
	36	44.9 (1.9)	89.3-126.9							55-87.1	5.1-39.2	57.1-84.7	7.6-33.4	1.9-16.6
	36	50.9 (1.9)	92.9-133.7							56.2-100.8	4.8-40.2	63-87.4	10.2-34.9	2.7-19.4

Table B.S3: Continued

	36	56.8 (2)	94.9-123.2							59-94.4	5.1-35.3	59.9-90.1	9.8-34.5	2-19.5
	36	62.7 (1.9)	99-141.7							61.6-101.5	4.0-31.9	67.2-90.2	10.5-36.5	3.3-21.3
	36	68.5 (1.9)	100.3-137.5							63.9-104.6	2.5-30.1	71.7-96.9	10.4-41.6	3.5-18.5
	36	74.5 (1.8)	105.7-133.8							70.4-108.2	2.3-31	60.8-102.3	15.5-39.5	3.8-22.6
	36	86.6 (1.8)	111.1-159.4							76.2-117.1	2.2-35.3	73.8-110.4	16.2-43.6	3.1-26.5
	36	98 (4.7)	98.8-126.9							64.6-99.1	1.6-31.9	63.2-98.6	8.1-38.1	2-20.9
	36	110.5 (1.7)	102.1-129.2							70.1-98.4	1.2-29.7	69.1-98.1	12.5-34.5	2.3-17.4
	36	122.8 (2)	107.5-130.8							67.7-101.5	1.4-35	77.8-103.9	8.3-36.7	2.4-19.2

Table B.S4 - Longitudinal Studies in Typically Developing Children: Contact Area (CA) * Data presented for the 3rd-97th percentile ranges.

	Number of Subjects	Age (months)	CA (cm^2) Total	CA(cm^2) Hindfoot	CA(cm^2) Midfoot	CA(cm^2) Forefoot	CA(cm^2) Hallux	CA(cm^2) Toes 2-5	CA(%) Hindfoot^	CA(%) Midfoot^	CA(%)Forefoot^	CA(%) Hallux^	CA(%) Toes 2-5^
Bertsch (2004)	42	14.8 (1.8)	43.8 (5.3)	9.8 (1.3)	12.9 (1.8)	14.2 (2)	3.6 (.7)	3.2 (1.2)	22.4 (1.9)	29.5 (2.2)	32.5 (2.6)	8.2 (1.1)	7.3 (2.4)
	42	17.8 (2)	48.2 (5.5)	10.7 (1.3)	13.5 (2.3)	16.8 (1.9)	3.9 (.8)	3.4 (1.2)	22.2 (1.7)	27.8 (2.6)	34.9 (2.9)	8 (1.4)	7 (2.3)
	42	21 (1.9)	50.5 (5.4)	11.6 (1.3)	13.8 (2.5)	17.9 (1.9)	4 (.8)	3.2 (1.1)	23 (1.8)	27.1 (3.1)	35.6 (2.6)	7.9 (1.3)	6.4 (2.1)
	42	23.9 (1.9)	53.2 (5.8)	12.2 (1.3)	14.1 (2.9)	18.9 (1.9)	4.4 (.9)	3.6 (1.3)	23 (2)	26.3 (3.6)	35.7 (2.9)	8.2 (1.3)	6.8 (2.1)
	42	27.1 (1.9)	55 (6)	12.7 (1.2)	14.4 (3)	19.8 (2.1)	4.5 (.9)	3.7 (1.2)	23.1 (1.7)	25.9 (3.6)	36.1 (2.7)	8. 2(1.4)	6.7 (2.1)
Bosch (2007)*	89	15.3 (2.3)								24.4-32.7			
	89	18.3 (2.3)								23.2-32			
	90	21.3 (2.3)								20.2-31.4			

Table B.S4: Continued

	84	24.3 (2.4)								17.2-31.7			
	84	27.4 (2.4)								16-30.5			
	78	33.3 (2.3)								13.8-31.6			
	66	39.3 (2.6)								10.2-30.4			
	59	45.5 (2.5)								10.0-29.0			
	55	51.6 (2.5)								7 -27.1			
	48	57.5 (2.5)								7.3-26.7			
	43	63.3 (2.7)								6.5-26.1			
Bosch (2010)*	36	14.6 (1.8)							19.6-25.6	26-33	28.5-36.8	5.8-10.3	3.5-11.8
	36	17.5 (1.9)							19.8-25.8	23.2-32.3	28.9-39.5	5.6-10	3.0-11.0
	36	20.7 (1.9)							20.3-26.9	20.2-31.8	31.5-40.9	5.7-10	3.2-10.1
	36	23.6 (87.5)							20.2-28	18.5-32.1	30.8-43	6.1-10.1	3.3-10.5
	36	26. 8(1.8)							20.4-268	17.7-31.5	32.6-42.6	6.3-10.2	3.3-10.1
	36	32.8 (1.9)							20.6-28.9	13.4-30.9	33.7-42	6.4-9.8	3.5-9.6
	36	38.8 (2.1)							21-2 9.6	13.3-30.3	33.4-41.1	6.7-10	3.1-10.4
	36	44.9 (1.9)							20.7-29.4	10.2-28.4	34-42.9	6.1-10.7	3.3-11.1

Table B.S4: Continued

	36	50.9 (1.9)							21.6-30.2	7.3-26.9	35.4-42.5	6.9-11.2	4.5-11.4
	36	56.8 (2)							21.6-29.3	8.6-26.1	34.7-44.8	6.9-10.6	3.8-12.3
	36	62.7 (1.9)							22-30.1	6.8-25.9	34.6-44.5	6.5-11.4	4.3-11.9
	36	68.5 (1.9)							22.9-31.9	3.9-24.3	36-45.1	6.4-11.6	3.7-11.8
	36	74.5 (1.8)							23.7-33.1	2.8-24.3	36.1-45.9	6.9-11.9	3.5-11.4
	36	86.6 (1.8)							23.9-33.7	2.9-23.5	35.4-45.3	7.2-12.3	3.2-11.7
	36	98 (4.7)							23-33.7	2.5-25.2	34.2-46	7-11.9	2.9-11.7
	36	110.5 (1.7)							24.1-33.7	3.1-23.6	35.9-46.2	6.9-10.8	3.7-11.3
	36	122.8 (2)							24.2-33.2	2.4-24.4	36.6-47.2	6.6-11.9	3-11.5

Table B.S5 - Longitudinal Studies in Typically Developing Children: Contact Time (CT) ^ Data is a percent of the CT Total(ms).

	Number of Subjects	Age (months)	CT(ms) Total	CT(%) Hindfoot^	CT(%) Midfoot^	CT(%) Forefoot^	CT(%) Hallux^	CT(%) Toes 2-5^
Bertsch (2004)	42	14.8 (1.8)	554.9 (151.9)	62.9 (9.5)	75.8 (7.6)	90 (5.4)	65.7 (16.1)	60.3 (1.2)
	42	17.8 (2)	450.3 (96.1)	53.4 (11.1)	67.7 (9.5)	87.9 (4.9)	65 (15.2)	64.4 (17.8)
	42	21 (1.9)	433 (84.3)	52.3 (10.1)	65.4 (9.5)	88.1 (4.2)	68 (14.1)	60.4 (17.5)
	42	23.9 (1.9)	446 (98)	50.2 (9.3)	63.6 (8.7)	87.6 (4.5)	71.8 (14.3)	65.2 (14.6)
	42	27.1 (1.9)	496.9 (134.4)	51.4 (10.2)	65.2 (8.7)	87.5 (4.7)	71.9 (13.7)	64.1 (17.4)

Table B.S6 - Longitudinal Studies in Typically Developing Children: Other Parameters * Data presented for the 3rd-97th percentile ranges.

	Number of Subjects	Age (months)	Lateral-Medial Index	Midfoot Width(cm)	Arch Index	Foot Length(cm)	Foot Shape Index (Breadth/length)
Bertsch (2004)	42	14.8 (1.8)					1.1 (0.29)
	42	17.8 (2)					1.01 (0.23)
	42	21 (1.9)					0.99 (0.26)
	42	23.9 (1.9)					0.98 (0.21)
	42	27.1 (1.9)					0.99 (0.22)
Bosch (2007)*	89	15.3 (2.3)	3.2 (0.5)	9.9 (0.6)		32.8 (4.5)	
	89	18.3 (2.3)	3.4 (0.8)	10.5 (0.6)		31.6 (4.6)	
	90	21.3 (2.3)	3.3 (1)	10.9 (0.8)		29.3 (6.1)	
	84	24.3 (2.4)	3.1 (0.8)	11.4 (0.8)		27.6 (6.9)	
	84	27.4 (2.4)	3 (0.9)	11.8 (0.6)		25.9 (7.3)	

Table B.S6: Continued

	78	33.3 (2.3)	2.9 (1)	12.3 (0.7)		23.3 (8.2)	
	66	39.3 (2.6)	2.6 (1.1)	13 (0.7)		20.2 (8.6)	
	59	45.5 (2.5)	2.6 (1.2)	14.2 (9.2)		19 (9)	
	55	51.6 (2.5)	2.5 (1.1)	13.9 (0.7)		17.9 (8.1)	
	48	57.5 (2.5)	2.7 (1.1)	14.4 (0.7)		19.1 (8)	
	43	63.3 (2.7)	2.8 (0.9)	14.9 (0.7)		18.6 (6.1)	
Bosch (2010)*	36	14.6 (1.8)	2.2-3.9	10.0-12.7	0.3-0.4		
	36	17.5 (1.9)	2.3-4	10.8-13.5	0.27 -0.38		
	36	20.7 (1.9)	1.9-4.2	11.1-13.9	0.24-0.36		
	36	23.6 (87.5)	1.4-4.6	11.8-14.4	0.21-0.36		
	36	26.8 (1.8)	1.3-4.1	12-14.5	0.22-0.36		
	36	32.8 (1.9)	1.4-4.3	12.7-15.4	0.16-0.36		
	36	38.8 (2.1)	1.4-4.1	13.2-16	0.16-0.355		
	36	44.9 (1.9)	0.3-4	13.7-16.4	0.13-0.34		
	36	50.9 (1.9)	0.8-4.3	14.1-17.3	0.1-0.31		
	36	56.8 (2)	1.3-4.6	14.7-17.5	0.11-0.3		

Table B.S6: Continued

	36	62.7 (1.9)	1.3-4.2	15.2-18.2	0.08-0.3		
	36	68.5 (1.9)	1.2-4.2	15.57-18.7	0.05-0.28		
	36	74.5 (1.8)	0.9-4	16.4-19.5	0.03-0.2		
	36	86.6 (1.8)	1.1-4.1	16.9-20.8	0.04-0.27		
	36	98 (4.7)	1.2-3.7	17.9-21.8	0.03-0.27		
	36	110.5 (1.7)	0.6-4.1	18.6-22.3	0.04-0.26		
	36	122.8 (2)	0.6-4.7	19-23.2	0.03-0.27		

Table B.S7A - Cross-Sectional Studies in Typically Developing Children: Peak Pressure (PP) *Reported as two standard deviations. # Reported as N/cm^2 and converted to kPa.

	Number of Subjects	Age	Mean height (cm)	Mean weight (kg)	PP (kPa) Total	PP(kPa) Hindfoot	PP (kPa) Medial Hindfoot	PP(kPa) Lateral Hindfoot	PP (kPa) Midfoot	PP(kPa) Medial Midfoot	PP (kPa) Lateral Midfoot	PP (kPa) Forefoot
Hennig (1991)	15	1.95 (0.4)	88.4 (7.5)	12.8 (1.9)	681		119 (61)	99 (61)	41 (20)			
Bosch (2009)	26	1.3 (.4)	75.5 (2.7)	10.2 (0.9)		108.6 (31.49)			72.69 (12.69)			76.35 (16.06)
	26	7 (0.5)	125.9 (5)	25.5 (2.7)		383.5 (115.64)			82.81 (27.02)			256.15 (86.14)
Muller (2012)*	157	1	83 (8)	12.4 (4.2)	206.1 (130.6)	169.6 (145.5)			99.3 (54.8)			120.5 (68.3)
	455	2	92 (10)	14.5 (3.8)	251.6 (167.6)	223.6 (186.2)			100 (48.8)			130.5 (70)
	676	3	100 (10)	16.5 (5)	273.6 (171.2)	245.2 (188.7)			93.3 (45.7)			144.9 (75.3)
	834	4	107 (10)	18.7 (5.2)	289.7 (169.3)	267.4 (185.6)			87.2 (44.7)			159.4 (82.2)
	938	5	114 (10)	21 (5.8)	306.1 (175.1)	280.4 (185.1)			81.5 (42.9)			175.2 (89.2)
	931	6	120 (12)	23.8 (8)	3111.7 (171.7)	286.3 (181.6)			79.9 (48.3)			188.2 (99.5)

Table B.S7A: Continued

	787	7	127 (13)	27.1 (10.2)	330.1 (182.8)	301 (193.1)			77 (46.4)			207.7 (55.2)
	762	8	133 (13)	30.4 (11.4)	340.5 (175.5)	300.6 (186.6)			78.7 (49)			228.1 (125.6)
	675	9	139 (13)	34.2 (13.6)	366.4 (225.1)	312.4 (197.6)			27.1 (54.1)			243.4 (156.2)
	653	10	144 (14)	38.6 (17)	383 (236.3)	320.2 (190.9)			84.8 (62.3)			268.6 (176.6)
	398	11	148 (15)	41.4 (17.8)	388.6 (214)	313.9 (174.9)			88.9 (69.6)			281.5 (180.5)
	346	12	154 (16)	46.4 (21.2)	416.9 (255.9)	315.3 (190.4)			91.2 (74.4)			300.2 (205.8)
	176	13	159 (17)	51.4 (22)	456.4 (302.1)	324.7 (188.7)			97.5 (82.8)			332.9 (275.1)
Hillstrom (2013)#	25	Early Walkers	-	-	131 (33)		85 (29)	92 (35)		64 (12)	64 (13)	
Mueller (2016)	108	1	122 (18)	25.4 (9)	209 (67)	171 (75)				96 (28)	93 (23)	120 (35)
	348	2			253 (86)	226 (95)				94 (24)	91 (21)	130 (35)
	572	3			274 (86)	248 (96)				87 (23)	85 (19)	143 (36)
	723	4			289 (85)	268 (92)				80 (24)	81 (23)	157 (40)
	845	5			306 (89)	282 (94)				74 (22)	75 (20)	17 3(43)
	804	6			310 (84)	287 (91)				69 (23)	72 (20)	184 (45)
	682	7			329 (92)	300 (81)				63 (21)	69 (19)	202 (52)
	657	8			339 (88)	300 (95)				63(21)	73(30)	223 (61)

Table B.S7A: Continued

	571	9			361 (107)	312 (99)				62(22)	73(32)	234 (71)
	535	10			373 (111)	317 (100)				61(20)	76(26)	25 6(77)
	323	11			379 (100)	312 (89)				62(23)	81(44)	270 (84)
	288	12			409 (124)	311 (93)				64 (22)	85(47)	291 (100)

Table B.S7B - Cross-Sectional Studies in Typically Developing Children: Peak Pressure (PP) *Reported as two standard deviations. # Reported as N/cm^2 and converted to kPa.

	Number of Subjects	Age	Mean height (cm)	Mean weight (kg)	PP (kPa) First Met	PP (kPa) Second Met	PP (kPa) Third Met	PP (kPa) Fourth Met	PP (kPa) 5th met	PP (kPa) Hallux	PP(kPa) Toes 2-5	PP (kPa) All Toes
Hennig (1991)	15	1.95 (0.4)	88.4 (7.5)	12.8 (1.9)	95 (38)		99 (32)		87 (45)	141 (72)		
Bosch (2009)	26	1.3 (0.4)	75.5 (2.7)	10.2 (0.9)						129.13 (42)	42.92 (19.9)	
	26	7 (0.5)	125.9 (5)	25.5 (2.7)						272.92 (84.53)	143.5 (62.84)	
Muller (2012)*	157	1	83 (8)	12.4 (4.2)								
	455	2	92 (10)	14.5 (3.8)								
	676	3	100 (10)	16.5 (5)								
	834	4	107 (10)	18.7 (5.2)								
	938	5	114 (10)	21 (5.8)								
	931	6	120 (12)	23.8 (8)								

Table B.S7B: Continued

	787	7	127 (13)	27.1 (10.2)								
	762	8	133 (13)	30.4 (11.4)								
	675	9	139 (13)	34.2 (13.6)								
	653	10	144 (14)	38.6 (17)								
	398	11	148 (15)	41.4 (17.8)								
	346	12	154 (16)	46.4 (21.2)								
	176	13	159 (17)	51.4 (22)								
Hillstrom (2013)#	25	Early Walkers	-	-	82 (29)	70 (18)	60 (11)	51 (11)	41 (10)	108 (33)		
Mueller (2016)	108	1	122 (18)	25.4 (9)								160 (60)
	348	2										179 (57)
	572	3										184 (68)
	723	4										188 (62)
	845	5										199 (72)
	804	6										205 (690
	682	7										223 (83)
	657	8										234 (89)

Table B.S7B: Continued

	571	9										265 (112)
	535	10										263 (120)
	323	11										276 (116)
	288	12										310 (146)

Table B.S8 - Cross-Sectional Studies in Typically Developing Children: Force Time Integral (FTI) *Reported as two standard deviations.^ Reported as a percentage of the total foot.

	Number of Subjects	Age	FTI(% or Ns) Hindfoot	FTI(% or Ns) Medial Hindfoot	FTI(% or Ns) Lateral Hindfoot	FTI(% or Ns) Midfoot	FTI(Ns) Medial Midfoot	FTI (Ns) Lateral Midfoot	FTI (Ns) Forefoot	FTI(% or Ns)Frist Met	FTI(% or Ns) Third Met	FTI(% or NS) Fifth Met	FTI(% or Ns) All Toes	FTI(% or Ns) Hallux	FTI(% or Ns) Total
Hennig ^ (1991)	15	2		14.6 (6.2)	13.1 (6.3)	6.7 (5)				16 (5)	16.3 (6.4)	13.5 (6.2)		19.9 (12.2)	
Muller (2012)*	157	1	8.2 (8.3)			7.5 (5.9)			15.3 (13.7)						35.6 (21.5)
	455	2	12.4 (11.7)			7.0 (6.6)			18.1 (15.0)						43.9 (26.3)
	676	3	17.8 (14.4)			6.5 (6.4)			24.7 (18.7)						57 (29.2)
	834	4	23.9 (17.8)			6.5 (7.5)			31.9 (23.9)						71.36 (39.0)
	938	5	28.3 (20.3)			6.4 (8.3)			38.9 (24.9)						84.1 (40.7)
	931	6	33.7 (23.5)			7.5 (11.6)			48.3 (30.7)						101.6 (53.7)
	787	7	40.4 (27.5)			8.0 (12.9)			57.9 (38.3)						119.9 (32.8)
	762	8	46.5 (31.6)			9.8 (16.2)			68.3 (42.9)						139.8 (72.8)
	675	9	53.8 (36.5)			11.2 (19.7)			79.2 (50.0)						161.7 (85.1)

Table B.S8: Continued

	653	10	63.4 (44.6)			13.9 (27.2)			93.4 (58.0)						189.4 (107.9)
	398	11	66.6 (42.2)			15.4 (27.4)			104.7 (68.1)						206.9 (115.8)
	346	12	76.7 (55.7)			18.5 (33.5)			117.8 (73.2)						236.7 (135.9)
	176	13	82.6 (50.2)			21.2 (37.6)			131.5 (82.1)						262.8 (27.3)
Mueller (2016)	108	1	7.6 (3.4)				2.6 (1.7)	4.1 (1.8)	14.1 (5.8)				105 (5)		32.8 (7.8)
	348	2	12 (5.7)				2.4 (1.6)	4.1 (2.2)	17.3 (6.4)				348 (6.7)		42.2 (11.8)
	572	3	17.4 (7)				2 (1.6)	4.2 (2)	23.8 (8.4)				572 (8.2)		55.3 (12.9)
	723	4	23.4 (8.6)				1.6 (1.2)	4.5 (2.7)	30.8 (11.2)				723 (9.3)		69.2 (18)
	845	5	27.7 (9.4)				1.3 (1.2)	4.6 (3.2)	37.8 (11.4)				845 (10.5)		81.8 (18.2)
	804	6	32.4 (10.6)				1.2 (1.1)	5.3 (4.2)	46 (13.7)				804 (12.2)		96.8 (23.3)
	682	7	38.6 (11.6)				1.2 1.2)	5.7 (4.6)	54.8 (15.6)				682 (13.6)		113.7 (24.8)
	657	8	44.4 (14.1)				1 (1)	7.2 (5.90	64.9 (19.2)				657 (15.2)		132.7 (30)
	571	9	51.1 (15.9)				1.9 (1.9)	8 (6.9)	74.5 (21)				571 (17.3)		152.2 (33.6)
	535	10	60 (18.4)				1.2 (1.3)	9.9 (8.3)	87 (23.9)				535 (18.1)		176.2 (28.9)
	323	11	63.3 (18.3)				1.4 (2.4)	11.3 (10)	97 (26.6)				323 (19)		192.4 (44.1)
	288	12	72.2 (23.5)				1.4 (1.2)	13.6 (11)	109.5 (28.5)				288 (22.4)		220.3 (48.4)

Table B.S9 - Cross-Sectional Studies in Typically Developing Children: Maximum Force (MF)

	Number of Subjects	Age	MF (%BW) Total	MF(%BW) Hindfoot	MF(%BW) Midfoot	MF(%BW) Forefoot	MF(%BW) Hallux	MF(%BW) Toes 2-5
Bosch (2009)	26	1.3 (0.4)	102.54 (11.71)	53.15 (14.89)	43.06 (8.51)	49.85 (11.2)	16.93 (7)	6.27 (4.2)
	26	7 (0.5)	128.45 (12.93)	93.61 (13.59)	16.13 (11.16)	91.85 (10.09)	29.09 (8.54)	11.72 (7.59)

Table B.S10 - Cross-Sectional Studies in Typically Developing Children: Contact Area (CA) *Reported as two standard deviations.

	Number of Subjects	Age	CA (cm^2) Total	CA(%) Hindfoot	CA(%) Midfoot	CA(%)Forefoot	CA(%) Hallux	CA(%) Toes 2-5
Bosch (2009)	26	1.3 (0.4)		23.33 (3.73)	29.49 (1.98)	32.84 (3.93)	7.94 (1.24)	6.41 (2.86)
	26	7 (0.5)		27.72 (3.19)	15.21 (6.48)	40.49 (3.12)	9.35 (1.38)	7.22 (2.4)
Muller (2012)*	157	1	47.16 (11.49)					
	455	2	55.39 (15.12)					
	676	3	58.57 (15.66)					
	834	4	62.28 (17.29)					
	938	5	65.76 (18.33)					
	931	6	70.58 (21.57)					
	787	7	75.29 (23.33)					

Table B.S10: Continued

	762	8	80.22 (25.75)					
	675	9	84.84 (27.31)					
	653	10	90.62 (26.69)					
	398	11	94.44 (30.25)					
	346	12	101.47 (34.47)					
	176	13	108.4 (38.75)					

Table B.S11 - Cross-Sectional Studies in Typically Developing Children: Contact Time (CT)

	Number of Subjects	Age	CT(ms) Total	CT(ms) Hindfoot	CT(%) Hindfoot	CT(ms) Midfoot	CT(%) Midfoot	CT(ms) Forefoot	CT(%) Forefoot	CT(ms) Hallux	CT(%) Hallux	CT(ms) Toes 2-5	CT(%) Toes 2-5
Bosch (2009)	26	1.3(0.4)	541.7 (117.1)	363.7 (102.1)	65.9 (9.9)	247.0 (110.4)	78.1 (6.6)	487 (105.3)	90.0 (4.0)	323.0 (108.2)	92.0 (18.1)	295.7 (148.5)	55.1 (24.3)
	26	7(0.5)	554.4 (67.3)	291.7 (72.9)	52.0 (8.3)	298.2 (81.1)	53.1 (10.3)	466.2 (62.6)	84.1 (3.6)	312.6 (63.7)	56.6 (10.1)	284.1 (63.1)	51.7 (10.8)

Table B.S12 - Cross-Sectional Studies in Typically Developing Children: Other Parameters *Reported as two standard deviations.

	Number of Subjects	Age	Arch Index	Midfoot Width(cm)	Foot Length(cm)	Foot Shape Index (Breadth/length)
Bosch (2009)	26	1.3 (0.4)	0.36 (0.02)			
	26	7 (0.5)	0.18 (0.07)			
Muller (2012)*	157	1	0.32 (0.07)	5.73 (0.75)	13.7 (1.59)	0.44 (0.05)
	455	2	0.3 (0.09)	610 (0.84)	14.58 (1.82)	0.42 (0.05)
	676	3	0.26 (0.11)	6.41 (0.83)	15.71 (2)	0.41 (0.04)
	834	4	0.23 (0.12)	6.69 (0.84)	16.74 (1.95)	0.4 (0.04)
	938	5	0.21 (0.13)	6.94 (0.84)	17.71 (2.04)	0.39 (0.04)
	931	6	0.2 (0.13)	7.21 (0.93)	18.69 (2.17)	0.39 (0.04)
	787	7	0.19 (0.14)	7.46 (0.90)	19.74 (2.35)	0.38 (0.04)

Table B.S12: Continued

	762	8	0.19 (0.13)	7.7 (0.99)	20.63 (2.43	0.37 (0.04)
	675	9	0.19 (0.14)	7.97 (0.99)	21.53 (2.43)	0.37 (0.03)
	653	10	0.19 (0.13)	8.2 (1.06)	22.39 (2.59)	0.37 (0.03)
	398	11	0.19 (0.13)	8.3 6(1.03)	22.91 (2.57)	0.37 (0.03)
	346	12	0.20 (0.13)	8.63 (1.13)	23.7 (2.67)	0.36 (0.04)
	176	13	0.20 (0.13)	8.86 (1.30)	24.4 (2.96)	0.36 (0.04)

Table B.S13 - Averaged Cohort Studies: A)Dowling (2004) n=10 ages 8.9(2.1) years; B)Liu (2005) n=66ages 6-16.

		Lateral Hindfoot	Medial Hindfoot	Lateral Midfoot	Medial Midfoot	Lateral Forefoot	Middle Forefoot	Medial Forefoot	Toes 2-5	Hallux
Liu (2005)[B]	PP (kPa)	249 (100)	277 (122)	63 (35)	44 (20)	140 (113)	223 (113)	168 (93)	143 (80)	270 (149)
	MMP(kPa)	103 (29)	122 (33)	24 (8)	33 (15)	63 (32)	102 (31)	83 (34)	46 (18)	106 (39)
	CA(cm^2)	13.6 (5.7)	12.2 (3.1)	14.8 (6.4)	5 (4.5)	5.3 (1.5)	18.3 (4.3)	8.1 (2.4)	6.5 (2)	7.4 (1.7)
	CT(%)	54 (11.1)	54.5 (11)	61.9 (11.7)	51.8 (17)	77.2 (9.9)	86.1 (6.7)	80.4 (9.7)	59.7 (18.2)	64.3 (18)
	PTI(Ns/cm^2)	5.3 (5.5)	5.8 (5.7)	2.3 (6.7)	1.5 (5.6)	4.2 (8.3)	7.1 (8.6)	5.4 (8.3)	3.5 (8.5)	6.5 (9.1)
	FTI(Ns)	22.5 (13.1)	25.7 (13.7)	11.7 (11.3)	1.8 (2.3)	8.3 (6.4)	50.1 (28.4)	17.7 (11.8)	13.9 (9.7)	4.8 (3.9)
	IPP(%stance)	13.3 (8.2)	14.5 (8.7)	41.7 (16)	35.9 (17.4)	64 (14.7)	79.6 (8)	70 (14.9)	83.6 (10.2)	81.5 (9.6)
	IMF(%stance)	18.4 (8.1)	20.2 (5.5)	45 (13.3)	40.9 (15.4)	60.6 (14)	71.2 (10.2)	68.6 (13.2)	85.1 (4.9)	83.8 (4.5)
Dowling (2004)[A]	PP (kPa) Right	262 (85)								
	MF(N) Right	348.4 (125.4)								
	CA(cm^2) Right	54.2 (12.1)								
	PP (kPa) Left	341 (141)								
	MF(N) Left	440.2 (142.1)								
	CA(cm^2) Left	60.1 (13.0)								

Table B.S14A – Peak Pressure for Obese and Overweight Children

	Number of Subjects	Age (y)	Weight Category	PP(kPa) Hindfoot	PP(kPa) Medial Midfoot	PP (kPa) Lateral Midfoot	PP (kPa) Forefoot	PP (kPa) All Toes	PP (kPa) Total
Mueller (2016)	20	1	Obese	171 (59)	97 (29)	100 (32)	130 (42)	168 (52)	205 (57)
	35	2	Obese	221 (92)	116 (31)	111 (24)	134 (36)	204 (72)	261 (86)
	24	3	Obese	23 3(45)	108 (24)	104 (23)	181 (50)	218 (78)	286 (55)
	25	4	Obese	312 (120)	94 (29)	97 (26)	197 (48)	208 (760	335 (105)
	31	5	Obese	292 (68)	95 (33)	96 (30)	204 (72)	214 (93)	320 (78)
	42	6	Obese	291 (99)	96 (27)	110 (48)	236 (75)	200 (74)	322 (102)
	35	7	Obese	300 (97)	100 (26)	110 (21)	253 (62)	231 (103)	34 3(86)
	38	8	Obese	305 (73)	89 (25)	100 (24)	271 (80)	253 (111)	358 (90)
	34	9	Obese	333 (119)	97 (30)	111 (28)	306 (76)	326 (199)	428 (168)
	41	10	Obese	343 (80)	92 (30)	129 (53)	372 (133)	302 (176)	467 (151)
	24	11	Obese	320 (64)	98 (32)	117 (32)	351 (76)	344 (152)	441 (104)

Table S.14A: Continued

	22	12	Obese	352 (126)	99 (33)	129 (44)	384 (111)	374 (204)	512 (177)
	29	1	Over weight	165 (73)	101 (39)	98 (33)	115 (25)	148 (42)	196 (63)
	69	2	Over weight	213 (85)	101 (26)	97 (20)	131 (36)	170 (52)	240 (70)
	78	3	Over weight	239 (95)	97 (27)	95 (21)	148 (38)	177 (68)	270 (90)
	81	4	Over weight	252 (86)	90 (28)	89 (22)	167 (39)	206 (76)	28.4 (74)
	59	5	Over weight	154 (79)	85 (23)	89 (19)	18 7(37)	213 (83)	298 (75)
	82	6	Over weight	280 (80)	87 (27)	90 (23)	211 (59)	238 (107)	323 (96)
	68	7	Over weight	309 (101)	81 (28)	90 (22)	239 (63)	216 (76)	336 (93)
	64	8	Over weight	304 (90)	76 (21)	91 (22)	255 (52)	237 (105)	351 (81)
	67	9	Over weight	308 (83)	79 (23)	99 (33)	294 (100)	266 (125)	386 (114)
	73	10	Over weight	331 (100)	78 (27)	97 (23)	305 (88)	298 (142)	414 (125)
	44	11	Over weight	326 (82)	80 (27)	111 (44)	337 (110)	315 (165)	438 (137)
	32	12	Over weight	339 (86)	87 (31)	110 (42)	342 (88)	322 (116)	436 (95)
Dowling (2004)	10	9 (2)	Obese (Left Foot)						455 (22.4)
	10	9 (2)	Obese (Right Foot)						371 (94)

Table B.S14B – Force Time Integral for Obese and Overweight Children

	Number of Subjects	Age (y)	Weight Category	FTI(% or Ns) Hindfoot	FTI(% or Ns) Medial Midfoot	FTI (% or Ns) Lateral Midfoot	FTI (% or Ns) Forefoot	FTI(% or Ns) All Toes	FTI(% or Ns) Total
Mueller (2016)	20	1	Obese	10.8 (5.2)	3.5 (1.6)	6.5 (2.8)	18.8 (9.6)	20 (5.8)	45.1 (14)
	35	2	Obese	14.3 (5.5)	4 (2.3)	6.4 (2.9)	20.9 (7.7)	35 (7.7)	53.1 (14.4)
	24	3	Obese	25.4 (10.2)	3.2 (2.4)	8.4 (5.6)	34.1 (13.2)	24 (11.9)	81.3 (23.5)
	25	4	Obese	32.3 (11.1)	2.7 (2.4)	9.1 (4.5)	45.6 (14.1)	25 (11)	100.7 (29.1)
	31	5	Obese	38.3 (18.1)	2.3 (1.5)	8.6 (4.3)	55.4 (21.4)	32 (12.2)	116.5 (29.7)
	42	6	Obese	45.8 (16.9)	3.1 (2.7)	14.1 (7.7)	71 (15.3)	42 (12.7)	146.7 (29.6)
	35	7	Obese	56.9 (22.3)	3 (2.6)	17.3 (8.20	89.1 (32.2)	35 (17.5)	183 (59.8)
	38	8	Obese	68.9 (22.2)	3.5 (3.5)	20.5 (12.2)	99.7 (21.3)	38 (17.9)	210.6 (40.8)
	34	9	Obese	77.5 (27.5)	4 (3.8)	23.3 (13.4)	118.6 (36.80	34 (21.2)	244.6 (54.6)
	41	10	Obese	95.7 (38.9)	4.2 (5.6)	34.3 (26.4)	137.7 (32.4)	41 (21.3)	293.5 (81.6)
	24	11	Obese	93.9 (28.4)	3.8 (1.80	30.4 (17.5)	155.4 (40.7)	24 (27.3)	310.7 (66.3)

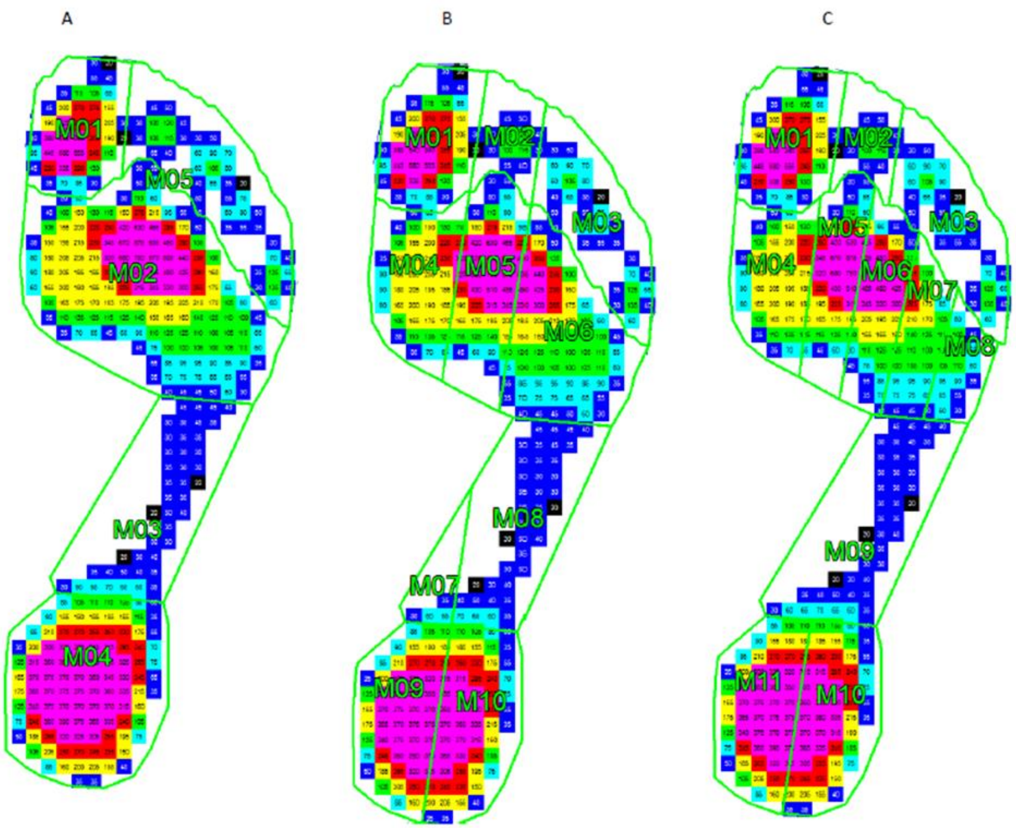
Table B.S14B: Continued

	22	12	Obese	122.4 (39.5)	6.1 (7)	44.1 (26.8)	180.1 (39.8)	22 (27.1)	379.8 (88.9)
	29	1	Over weight	8.8 (5.1)	3.4 (2.2)	5.1 (1.9)	17.2 (7.2)	29 (5.6)	39.8 (12.8)
	69	2	Over weight	13.2 (6.8)	2.7 (1.5)	5 (2)	20.6 (10.9)	69 (6.7)	47.8 (16)
	78	3	Over weight	18.5 (6.5)	2.4 (1.5)	5.3 (2)	28.5 (11.8)	78 (7.7)	62.2 (14.8)
	81	4	Over weight	25.9 (8.5)	2.2 (1.6)	5.9(3.2)	28.5 (13.2)	81 (10.4)	82.6 (17.7)
	59	5	Over weight	32.3 (11.1)	2 (1.7)	8.1 (4.3)	46.8 (13.1)	59 (12.4)	101.1 (21.3)
	82	6	Over weight	41 (13.4)	2.2 (1.7)	8.8 (4.7)	60.1 (15.7)	82 (13.7)	125.5 (23.7)
	68	7	Over weight	49.4 (17.8)	1.9 (1.5)	11.3 (6.5)	73 (21.2)	68 (13.9)	150.1 (32.5)
	64	8	Over weight	54.8 (15.8)	1.8 (1.3)	14.9 (8.4)	86.2 (19.9)	64 (15.2)	172.5 (31.1)
	67	9	Over weight	64.9 (19.4)	2.1 (2.2)	16.5 (10.9)	99.7 (21.7)	67 (18.6)	202.3 (33.9)
	73	10	Over weight	71.6 (19.1)	2.1 (3)	17.8 (10.9)	117.1(28)	73 (22.2)	230.7 (45.6)
	44	11	Over weight	77.6 (22.9)	2.3 (1.8)	23.6 (14.6)	139.8 (33.6)	44 (20.9)	265.9 (47.7)
	32	12	Over weight	89 (22.3)	3.5 (3.70	26.1 (13.7)	153.9 (36.5)	32 (24.2)	296.7 (50.1)
Dowling (2004)	10	9 (2)	Obese (Left Foot)						
	10	9 (2)	Obese (Right Foot)						

Table B.S15 - Gender Differences. Data reported as the 3rd-95th percentile for +month intervals.

		Onset of Walking	+3	+6	+9	+12	+18	+24	+30	+36	+42	+46
FL (cm)	Males	9.3-11.3	9.8-11.6	10.2-12.1	10.5-12.8	10.8-13	11.3-13.7	12.1-14.1	12.4-15	12.8-15.5	13.4-16	13.7-16.1
	Females	8.4-10.8	9-11.6	9.6-11.8	10.4-12.2	10.6-12.8	11-13.2	11.6-14	12.2-14.2	12.7-15	13.2-15.6	13.7-16.1
MFW (cm)	Males	2.7-4	2.3-4.1	1.9-4.4	1.6-4.4	1.7 -4.4	1.3-4.6	1.1-4.5	1.1-4.3	1.2-4.5	1.4-4.6	1.3-4.6
	Females	2.1-4	2.3-4	1.9-4.5	1.4-4.1	1.1 -4.2	1-4.1	1.2-3.9	0.1-4	0.5-4.1	-0.2-4.3	1.3-4.3

Figure B.1A-1C: Example of automated masking techniques utilizing progressively more ROI. A) Five area mask identifying the hallux (MO1), lateral toes (MO5), forefoot (MO2), midfoot (MO3) and heel (MO4). B) Ten area mask identifying the hallux (MO1), second toe (MO2), lateral toes (MO3), first metatarsal (MO4), second metatarsal (MO5), lateral metatarsals (MO6), medial midfoot (MO7), lateral midfoot (MO8), medial heel (MO9) and lateral heel (MO10). C) Eleven area mask identifying the hallux (MO1), second toe (MO2), lateral toes (MO3), first metatarsal (MO4), second metatarsal (MO5), third metatarsal (MO6), fourth metatarsal (M07), fifth metatarsal (MO8), midfoot (MO9), lateral heel (MO10) and medial heel (MO11).



Appendix C: Clubfoot A Summary

What is Clubfoot?

Idiopathic clubfoot is one of the most common congenital deformities involving the musculoskeletal system. There are four components of clubfoot deformity; equinus, hindfoot varus, forefoot adductus and cavus [1, 4-9]. Clubfoot presents in 1-2 cases per 1000 live births [1-5] and the diagnosis of clubfoot can occur as early as the 12th week of gestation [4, 12]. Clubfoot deformity is twice as common in males [4], with a male to female ratio of 2.5 to 1 [10], and 50% of cases are bilaterally involved [10, 11]. If left untreated children with clubfeet may be unable to wear standard shoes, have limited mobility, could be prone to skin and bone infections, could develop calluses and may walk on the top or side of their foot [1]. Functionally, children with clubfeet have been shown to meet gross motor skill milestones later than typically developing cohorts[16].

There are many theories as to the cause of idiopathic clubfoot: genetics, abnormal muscle insertions, utero position, environmental factors, and vascular deficiencies [1, 12]. Researchers have found that 25% of children with clubfeet have a family history; with a parent to child transmission rate of 20% [4] and a 33% chance that twins will both be afflicted [1]. Previous research suggests that females require a greater genetic load to inherit clubfoot, which could explain why males are more than two times as likely to have clubfoot [1]. Ethnicity may also play a role, with the highest incidence of clubfoot in the Polynesian population and the lowest in the Chinese population[4].

Clubfoot Classification Scales

The severity of clubfoot deformity can vary widely from mild and flexible to highly involved and rigid [1]. Having a standardized method of classifying clubfoot severity allows for subject comparison, gives clinicians the ability to assess disease progression and facilitates accurate information exchange [111]. A classification system should be reproducible, reliable, clinically applicable, and able to predict treatment [14]. For clubfoot deformity the two most common classification systems are the Dimeglio and Pirani Scales[1, 4]. A good correlation exists between these two scales[1].

The Dimeglio Scale grades clubfeet based on the reducibility of the initial deformity [111]. Four parameters are graded on a scale of 1-4 based on the ability of the foot to be reduced to a neutral position (Figure C.1): 1. Equinus; 2. Varus deviation in the frontal plane; 3. De-rotation of the calcano-forefoot block in the horizontal plane; 4. Adduction of the forefoot relative to the hindfoot in the horizontal plane [111]. Based on the clubfoot's ability to be de-rotated, the foot will be assigned 1-16 points [111]. The remaining points are assigned based on the presence of a posterior crease, mediotarsal crease, plantar retraction or cavus, and the condition of the shank muscles (hypertonic, contraction, fibrous, weakness) [111]. The foot is then assigned a grade (Grade I, II, III or IV) based on the 20 point scale [4, 111]. Grade I (benign) is the least involved with a score of <5 points, grade II (moderate) is =5<10 points, grade III (severe) is =10<15 points and grade IV (very severe) is =15<20 points[111]. The Dimeglio score is able to assess change over time in children with clubfoot deformity. Chaudhry et al (2012) measured the change in Dimeglio score from the initial presentation and after every cast change. It was found that scores remained higher in those who required more casts and in those that required Achilles tenotomy [23]. It is believed that clubfeet classified as either a III or IV are more likely to require surgical intervention[6].

The Pirani scale is a clinical measure that has been validated and used to rate the severity of clubfoot deformity [14]. The Pirani scale divides the foot into six components; three in the hindfoot (posterior crease, empty hindfoot and rigid equinus) and three in the midfoot (medial crease, lateral foot border curve and the position of the talus) [4, 112]. The components are graded on a scale of 0 (no abnormality), 0.5 (moderate abnormality) or 1 (severe abnormality) with a total score of 6 a severe clubfoot deformity [112]. Previous research has found that the initial Pirani score can predict the need for casts and tenotomy; 92% of clubfeet with a score >4 required 4 or more casts and 72% of clubfeet that scores >2.5 on the hindfoot components required a tenotomy[14]. Another study found that a Pirani score of >5 would indicate the need for tenotomy[52].

Bilaterality

Fifty percent of all clubfoot cases are bilateral[55], however, researchers and clinicians have yet to conclude on the effects of laterality on clubfoot disease progression. For statistical analysis it is common to pool bilateral and unilateral clubfeet into one subject group, with the total number of subjects and the total number of clubfeet being reported [55]. Typically, children with bilateral clubfoot are included with both feet as independent observations [56]. However, several researchers have found using bilateral and unilateral clubfeet in the same analysis confounding [3]. Bilateral clubfeet tend to be highly correlated; 85% have the same severity classification score, 89% of bilateral patients reoccur bilaterally, the need for tenotomy is not different bilaterally and the mean number of casts applied bilaterally is not significantly different [56]. These results would indicate that it is not always proper to include both sides of bilateral subjects, as it can artificially inflate sample size and lead to false conclusions [55, 56]. One solution is to use the subject as the unit of measure for analysis, however this is complicated if the two clubfeet are different in terms of severity or treatment [3]. Contrastingly, no difference in severity between bilateral and unilateral clubfoot has also been found [49]. Due to the confounding nature of past literature, no consensus can be established as to the effect of laterality on clubfoot deformity.

Clubfoot Treatments

The goal of clubfoot treatment is to eliminate the four components of deformity resulting in a functional, pain-free, mobile, plantigrade foot that is free of calluses and does not require modified shoes [7, 9, 23]. The two most common methods of treatment for clubfoot are a surgical approach and a non-surgical approach. A rigid clubfoot with weak musculature will often require surgical correction, whereas a soft clubfoot with adequate range of motion can be managed non-operatively [12]. Surgical approaches often involve a soft tissue release of foot structures (ligaments and capsule) between the age of 3 months and 1 year [6]. However, surgical releases have a high complication rate (including infection, neurovascular injury, loss of limb and over-correction) and a 13-50% recurrence rate [2, 6]. Therefore, researchers and clinicians prefer using a non-operative approach involving serial casting, which is less likely to cause serious complications. Less invasive methods, such as manipulation and casting, have been shown to have the same or better long-term and short-term outcomes as surgical corrections [3]. Despite the advancement of non-surgical techniques researchers have concluded that the clubfoot will never be fully normalized [21].

Early casting techniques, forcible manipulation of the foot followed by casting while under anesthesia, led to incomplete correction and/or complications [1, 7]. In recent years, the two most common serial casting techniques used by clinicians are Kite and Ponseti [6]; both of which involve gentle manipulation and casting at weekly intervals [7]. Both techniques address the same four clubfoot deformities; midfoot adductus, cavus, hindfoot varus and equinus[6]. However, the differences between techniques are: 1. The fulcrum point, with the Kite method using the calcaneocuboid and the Ponseti method using the talonavicular joint[6]; 2.The Kite method attempts to correct each component separately, whereas the Ponseti method addresses multiple components simultaneously[1]. Many clinicians prefer the Ponseti method because the Kite technique requires up to 2 years of casting with upwards of 50-75% of patients still requiring surgery to achieve full correction [1].

Another non-operative technique for the treatment of clubfeet is the French Physiotherapy Method (FPM)[2]. This technique involves gentle mobilization and stretching daily, stimulation and strengthening of the lower leg and ankle musculature, and taping and splinting for each of the clubfoot deformities [2]. To perform this technique correctly, daily visits with a trained physical therapist for up to three-five months is required [2]. After initial correction is achieved, splints are worn until the age of 2-3 years [2]. This technique is time consuming and requires extensive participation by clinicians, patients and parents [2]. Additionally, upwards of 33% of children who undergo FPM will require surgical releases and 32% of children will undergo Achilles lengthening to treat hindfoot equinus [2]. Due to the high incidence of treated patients needing surgical correction and the time commitment to complete FPM, clinicians prefer the Ponseti Method for non-operative treatment of clubfoot deformities.

The Ponseti Method

The Ponseti casting technique was developed at the University of Iowa in 1950 by Dr. Ignacio Ponseti [6]. The goal of Ponseti treatment is to achieve a foot that is functional, plantigrade, mobile, callus free and pain free [22] with a less invasive approach [1]. Ponseti casting has been shown to produce more effective results and less complications than traditional surgical approaches [14]. A 2009 survey of American Pediatric Orthopedic Surgeons reported that 65% of physicians surveyed used the Ponseti method as the standard of treatment for clubfoot [52].

The Ponseti method has two phases, correction (casting with or without Achilles tenotomy) and maintenance (foot abduction orthosis wear) [5]. The Ponseti method utilizes a series of progressive casts (changed every 5-7 days for 4-6 weeks), gentle manipulation, percutaneous release of the Achilles tendon and long-term use of a foot abduction orthosis to address the four components of clubfoot deformity [1, 6, 9, 13]. On average children with clubfeet require an average of 4-7 casts (range 3-7) [6-8, 52].

Ponseti casting corrects clubfoot deformities in the following order: cavus, adductus, varus and equinus (the CAVE acronym) [4]. The first cast positions the foot into maximal supination addressing pronation of the first metatarsal and foot cavus [1, 6]. The second through the fourth casts' incrementally increase the amount of abduction to correct hindfoot equinus, hindfoot varus and forefoot adduction simultaneously [1, 6]. Ponseti believed that the calcaneus would move out of varus on its own during manipulation, therefore the key to the Ponseti method is not directly manipulating the calcaneus [6].

When the foot can be passively dorsiflexed to 15 degrees above neutral, a final cast is placed in the dorsiflexed position [6]. If the foot cannot be passively dorsiflexed, a percutaneous release of the Achilles tendon is completed and the final cast is placed for three weeks[6]. After the final cast, the patient is placed in a foot abduction orthosis; which will be worn full time for three months and then only at night until age of 3-4 years [1, 6]. During abduction bracing, the clubfoot is in 70 degrees of external rotation and the unaffected foot is in 40 degrees of external rotation [1, 4].

Alves et al (2009) assessed if the age at initial presentation had a bearing on the effectiveness of Ponseti management. A retrospective review was conducted of 68 children with clubfeet that presented for initial casting between the age of 1 day to 31 months[22]. All subjects had a minimum follow-up of 30 months post initial presentation [22]. The subjects were divided into two groups based on their age at initial presentation; <6 months (50) and >6 months (18) of age [22]. Results show that age at presentation did not affect the number of casts required, the rate of reoccurrence or the number of clubfeet that reached full correction [22]. Both groups reported that no subjects required surgical releases, each group had a relapse rate of <8% and the rate of tibialis anterior tendon transfer surgery for each group was 5% [22]. Additional researchers also found that the age at presentation does not affect the range of motion of the ankle at the end of Ponseti casting [52]. Therefore, it can be concluded that the Ponseti method is effective regardless of the age at initial presentation.

Due to the success of the Ponseti method, researchers have suggested streamlining the Ponseti method further. Some have tried to use an accelerated Ponseti technique, where the casts are changed 2x a week instead of weekly [113]. Early results of this methodology show that traditional Ponseti is more effective, with 11% of subjects relapsing in the Ponseti group and 20% relapsing in the accelerated Ponseti group[113]. Ponseti recommended that plaster casts be used during the initial casting however fiberglass has also been successfully used when serial casting [1]. Pittner et al (2008) assessed the two most common materials used in Ponseti casting, plaster of paris and semi-rigid fiberglass. Thirty-nine clubfeet were randomized into either the plaster or fiberglass casting groups and were rated using the Dimeglio scale [8]. The plaster and fiberglass groups were not significantly different at initial presentation with an average Dimeglio score of III for both groups [8]. The two materials tested were not significantly different when comparing the incidence of skin irritation, cast slippage, cast convenience, cast weight and cast durability [8]. However, at the end of casting the plaster cast group has a significantly lower Dimeglio score compared to those in the fiberglass group [8]. These results would suggest plaster casts are more likely to decrease the Dimeglio score post-casting, however the final decision for casting material should be left up to family and clinician discretion.

Achilles Tenotomy

Equinus is the most difficult of the clubfoot deformities to correct [17]. Between 12-90% of clubfeet will require an Achilles tenotomy to correct residual equinus post Ponseti casting [1, 4, 5, 7, 13, 16, 54, 112, 114]. Tenotomy is recommended when the foot cannot be adducted to 60 degrees and there is less than 15-20 degrees of dorsiflexion [4, 13, 50]. Tenotomy has be shown to be safe and effective in the clinical setting (both under general and local anesthetic). However, researchers have recommended that tenotomy be performed in a clinical setting using topical and injectable local anesthetic and that sectioning of the tendon should be completed as opposed to a lengthening [1, 4, 13, 114]. Post tenotomy, the patient is placed into a cast that positions the foot into 5-10 degrees of dorsiflexion [1].

Scher et al (2004) tried to use initial severity as a way to predict which patients would require an Achilles tenotomy. Thirty-five children with 50 clubfeet were assessed using the Dimeglio and Pirani scales. The severity of the clubfeet was classified during each clinic visit during the Ponseti casting protocol [112]. At the initial evaluation the higher the score (the higher the severity) the more likely the subject would require a tenotomy [112]. Clubfeet that rated as >5 on the Pirani score required a tenotomy in 85.2% of cases and 94.7% of clubfeet that rated as a Grade IV on the Dimeglio scale required a tenotomy [112]. It was also found that the subjects who required a tenotomy also required significantly more casts (mean 5.7, range 4-9) than the group that did not require a tenotomy (mean 4.7, range 3-6) [112]. Despite these differences, at the final cast there was no statistical difference between the clubfeet that did or did not require a tenotomy [112]. This would indicate, that despite requiring a tenotomy and more casts, the more severe clubfeet still achieve similar correction as the clubfeet that did not require a tenotomy. Similarly, Aydins et al (2015) found that the initial severity score (Pirani of >5) was predictive of the need for Achilles tenotomy, whereas unilateral/bilateral and gender did not have an effect on the prediction of tenotomy[50].

Outcomes in Ponseti Treated Clubfeet

The use Ponseti management has produced short and long-term success rates of >90% [4, 6-8, 11, 14]. A short-term 5 year follow-up found that the Ponseti method had favorable results in 89% of subjects, whereas non-Ponseti methods only produced favorable results in 43% of cases [52]. Lehman et al (2003) assessed the outcome of Ponseti treatment for

30 children with 45 clubfeet using a change in Dimeglio score as the outcome measure. Post Ponseti treatment the Dimeglio score decreased from a mean of 14.4 to 4.2[6]. Thirty-eight feet were classified as having a good outcome; with a change of >6 points as an indicator of a good outcome[6]. Of the thirty-eight clubfeet with good outcomes, only five feet went on to require either recasting or an Achilles tenotomy and only one foot required an Achilles lengthening and posterior release[6]. Overall, only14% of Ponseti feet will require a surgical release, as compared to 45% in other non-operative treatment programs such as the Kite Method[115].

Clinicians typically use objective measures to evaluate outcome in children with clubfeet; examples include range of motion, pressure distribution, calf circumference, gait analysis, radiographs and foot size [10]. For example, dorsiflexion range of motion at the end of Ponseti casting has been shown to be adequate in 89% of subjects[52]. However, the subjective interpretation of outcome, as reported by the parent and/or child, has recently become a topic of interest to researchers and clinicians. Chesney et al (2007) evaluated the correlations between objective clinical outcome measures with the subjective interpretation of outcome by the parent. They evaluated 204 children with clubfeet that were initially treated non-operatively (adhesive strapping and casting), with 53% eventually requiring surgery [10]. For children with unilateral clubfoot only calf circumference was correlated with the subjective outcomes score, as the size difference between the affected and unaffected sides increased the subjective outcome score decreased [10]. For children with bilateral clubfeet, as foot length discrepancies between the left and right sides increased so did the negative subjective outcome scores [10]. The results of this study suggest that it is the appearance of the foot and leg (length and calf size) that have the most profound effect on patient reported subjective outcomes [10]. Interestingly, females tend to report a worse subjective outcome, despite having similar objective outcomes as males[10], suggesting that appearance may be more important to females than males.

Parent reported outcomes for clubfoot can be measured using the clubfoot Disease Specific Instrument (DSI) [116]. The DSI consists of 10 questions and measures both function of and satisfaction with the clubfoot (Table C.1)[116]. The DSI has been found to be reliable, valid and discriminatory for children that have undergone surgical and non-surgical treatment for clubfoot[116]. Researcher have found that the Ponseti method has a satisfaction rate of 74-90% [13, 115]. Additionally, a long-term follow-up (range 10-30 years) of children treated with the Ponseti method show a good to excellent outcome with satisfaction scores of 78-89% [7, 8].

Reoccurrence of Deformity

The goal of non-operative treatment is to maintain correction, however reoccurrence occurs despite the initial 95% correction rate in Ponseti treated clubfeet [4]. The definition of a reoccurrence, sometimes referred to as a relapse, is when deformity is present that requires repeat casting or surgical intervention [5]. Reoccurrence can occur months or years after initial correction in rigid clubfeet with weak leg musculature[12, 15] and can occur in clubfeet that were resistant to the initial casting. Reoccurrence ranges between 7-64% for children below the age of 5, whereas only 6% of children over the age of 7 will reoccur [5, 15-17]. During rapid growth, between ages 3-5, is when children with clubfoot are at the highest risk of reoccurrence[15]. Researchers have found that the chance of reoccurrence can be lessened by overcorrecting the foot during the last cast and ensuring parental adherence to the nighttime bracing protocol for upwards of 3-4 years [15]. If reoccurrence happens within the first few months after the last cast it is sometimes considered incomplete correction instead of reoccurrence[15].

Noncompliance with foot orthosis bracing is the most common cause of reoccurrence following treatment with the Ponseti method [4, 5, 7, 11, 13, 15, 17, 18]. Researchers have found that 91% of subjects comply with brace wear in the first month, 74% are still compliant by the 3rd month and by age 4 only 54% are compliant [5, 43, 54]. On average, 78% of children who are noncompliant with brace wear will have a reoccurrence, compared to only 7% in those who are compliant[54].

Anywhere from 30-49% of families self-report non-compliance with foot orthosis bracing [7, 52]. The most common reasons reported for not wearing the orthosis were; 1.The inconvenience of wearing the brace 23 hours a day[7] and 2. Improper fit due to deformity [52]. Children who are intolerant of bracing are at the highest risk for reoccurrence [1]. Dobbs et al (2004) reported the rate of recurrence following initial treatment in 51 children (68 clubfeet) that were treated with the Ponseti method. Initial correction was obtained in all 68 clubfeet [7]. However, at the 6 month follow-up, the rate of recurrence was 31% (16 children, 27 feet) [7]. All 16 children that reoccurred at 6 months were non-compliant with bracing [7]. However, re-correction was obtained through repeat casting for all 16 children who had a recurrence [7]. Of the 16 who reoccurred, three children reported continued non-compliance with bracing, and all subsequently went on to require a soft tissue release[7]. It is imperative that clinicians educate parents on the importance of brace wear and increase the frequency of clinical visits to encourage adherence [2].

Other factors that put a child with clubfoot at risk of reoccurrence are socioeconomic status, parental education level, gender, initial severity rating, range of motion, and muscle weakness. Children whose parents only have a high school education have a 10 fold increase in recurrence [4, 7]. In addition, a low parental education level is correlated with an annual family income of less than $20,000 per year, both of which are predictors of brace compliance and reoccurrence[4, 5]. When assessing variables that may predict reoccurrence, researchers also found that females were 5x as likely to have a reoccurrence as males [11, 19] and those with more than 6 cast's had a higher incidence of reoccurrence [19]. Additionally, peroneal nerve palsy and everter muscular weakness, found in 4% of children with clubfoot, can be predictive of a reoccurrence for up to 3.5 years after initial treatment [11, 15]. What's more, the initial Dimeglio classification score can be predictive of outcome at age 2 years, where every 1 point increase in severity score is a 1.5x increase in the need for surgery [19]. Researchers found that 92% of moderate clubfeet (average Dimeglio score 8.9) went on to have a good outcome and only 63% of the clubfeet classified as very severe (average Dimeglio score 16.6) had a good outcome [19].

Reoccurrences that happen early can be treated successfully with repeat casting and foot abduction orthosis [1]. Early reoccurrence will also respond well to repeat manipulation and casting followed by Achilles lengthening and TATT [20]. Late reoccurrence is considered to be after the age of 4 years and 44% of late relapsing subjects will experience pain with ambulation [20]. Characteristics of a late reoccurring clubfoot are limited dorsiflexion, hindfoot varus, supination and in some cases cavus[20]. Treatment for a late reoccurrence can be bracing, casting, TATT w/or without TAL and in some cases comprehensive soft tissue release [20].

Hindfoot equinus and varus deformities tend to reoccur most often with midfoot and forefoot malalignments less common [15]. Children with clubfoot that have a high lateral tibiocalcaneal angle on x-ray at age 2 years, have a high Pirani score and a low degree of ankle dorsiflexion may also be prone to an increased incidence of hindfoot equinus [117]. The first symptom of hindfoot deformity reoccurrence is when the hindfoot does not fit or stay in a shoe or brace due to a plantar flexion contracture [18]. Mild dorsiflexion loss can be managed by repeat casting, however, if persistent or worsening dorsiflexion loss occurs the Achilles can be lengthened [18]. A repeat Achilles tenotomy or an Achilles lengthening can be performed if the clubfoot is not capable of 15 degrees of dorsiflexion [1]. Increased lateral contact during the stance phase of gait, due to supination or hindfoot varus, after the age of 2.5 years can be an indication for tibialis anterior tendon transfer (TATT) [18]. Even after treatment for reoccurrence, upwards of 20% of clubfeet can experience a second reoccurrence [45].

Tibialis Anterior Tendon Transfer (TATT) for Reoccurrence

One of the most common recurrent deformities, after both non-operative and operative management, is dynamic supination. Dynamic supination stems from over pull of the anterior tibialis tendon (ATT) and weak peroneal muscles [11, 51]. Researchers have found that children with clubfoot have muscle imbalances in the calf that may result from fiber type disproportion, decreases in the number of muscle fibers, arterial abnormalities and/or increases in neuromuscular junctions [51]. Typically developing children have a ratio of 1:2 for type 1 to type 2 muscle fibers in the lower leg and children with clubfoot demonstrate a 7:1 relationship[51].

Previous researchers have reported that between 14-50% of children with clubfoot will required a tibialis anterior tendon transfer (TATT) [4, 5, 13, 51, 52]. TATT is the most often performed surgery for the treatment of supination deformity in children with clubfeet [4, 11, 21]. During TATT, the ATT is transferred subcutaneously (either above or below the retinaculum) to the lateral dorsum of the midfoot[51]. The transfer can be either a full transfer or a split transfer, where only part of the tendon is transferred [51]. Post-operatively the subject is placed in a cast for 6 weeks with weight bearing as tolerated [51]. The ideal age for a TATT is between 3-4 years of age [51].

Thompson et al (2009) retrospectively reviewed 95 subjects with 137 clubfeet that underwent a soft tissue release and subsequently required a TATT. Short-term results (2 year follow-up) show 87% of clubfeet had a good outcome (no residual supination and adequate strength) [51]. Long-term follow-up of children who underwent TATT, for reoccurrence after Ponseti management, found that 78% were functional and pain-free[118]. In one study, 15% (15/102) clubfeet experienced a second reoccurrence after TATT [118]. Of those that had the second reoccurrence, more initial Ponseti casts were required (9.6 compared to 7.4), 80% of the relapsed clubfeet were not-compliant with bracing, and the subjects who reoccurred had their first TATT on average 1.4 years earlier than those who did not experience a second reoccurrence [118].

Surgical Management of Clubfeet

Traditional treatment of clubfeet required the use of an extensive soft tissue release[119], the most common methods are Turco and Cincinnati releases[9]. The soft tissue release focuses on the medial release of the subtalar joint, ankle and talonavicular joints and has a success rate of 45% [1]. Specifically, the subtalar joint and posterior capsule are released and the Achilles tendon, flexor tendons and posterior tibialis is lengthened [4]. The incidence of surgical release before the age of 1 year decreased from 1641 cases in 1996 to 230 in 2006, with 96.7% of physicians stating that Ponseti management was their preferred treatment method [13].

Rigid and persistent clubfeet, that were initially treated non-operatively, will go on to require invasive operative procedures such as releases, osteotomies and correction with external fixation [4]. Operative treatment is indicated when non-operative methods have failed and there is a reoccurrence that is resistant to manipulation and casting[4, 120]. Osteotomy of the midfoot may be indicated in children who are 4-9 years of age if there is adduction in the forefoot (bean shaped foot) [18]. Severe clubfeet that have failed operative treatment can undergo an Ilizarov correction where the clubbed foot undergoes osteotomies, soft tissue releases and sometimes an arthrodesis, which is then manipulated into position using an Ilizarov device [18]. Less than 7% of children with clubfoot who were treated with Ponseti will require a posterior medial release and only 4.5% of children will require multiple surgical procedures [12, 52]. Researchers have found that early TATT can help prevent the need for surgical release [12].

Surgical Management Outcomes

Shor-term and long-term outcomes of soft tissue release demonstrate incomplete correction or overcorrection, stiffness, scaring, arthritis, pain, neuromuscular/neurovascular complication and decreased function [1, 2, 4, 7, 12, 21-23]. When stratified by gender, males have been found to have a successful outcome in 56% of cases and females in 44% of cases [120]. Overcorrection is one of the negative outcomes following surgical release of clubfeet, with the foot appearing flat and hyper mobile[119]. This overcorrection could be due to the division of the interosseous ligament, aggressive casting, complete subtalar release or ankle valgus [119]. Haslam et al (2006) reported that overcorrection was significantly more prevalent in children that are prone to joint laxity; with 62.5% of feet in a hyper-mobile group reporting overcorrection and only 10% of patients with normal joint laxity reporting overcorrection. To address severe overcorrection, a triple fusion of the foot is performed, which can lead to a poor outcomes and limited function [119].

With increased utilization of the Ponseti Method, researchers have found the incidence of release surgery decreasing by a rate of 0.041 per 100 births per year [9]. Halanski et al (2010) compared a 3.5-3.8 year outcome between children with clubfoot treated with surgical release (29, 40 feet) and those treated with the Ponseti method (26, 46 feet). There were no differences between the two groups for age, sex, ethnicity, laterality, initial severity score or time to follow-up [3]. Fifteen feet in the Ponseti group and 14 feet in the surgical group had an initial recurrence of deformity that required further treatment (surgical or non-surgical). However, only 1 foot in the Ponseti group and all 14 feet in the surgical group required a further round of treatment for a second recurrence [3]. In a 21 year follow up of 120 clubfeet that underwent release, good outcomes were only reported in 58% of feet, whereas Ponseti reports long-term outcomes >90% [4, 9]. In addition, Ponseti treatment is overall more cost effective than surgical management for clubfoot [4, 9].

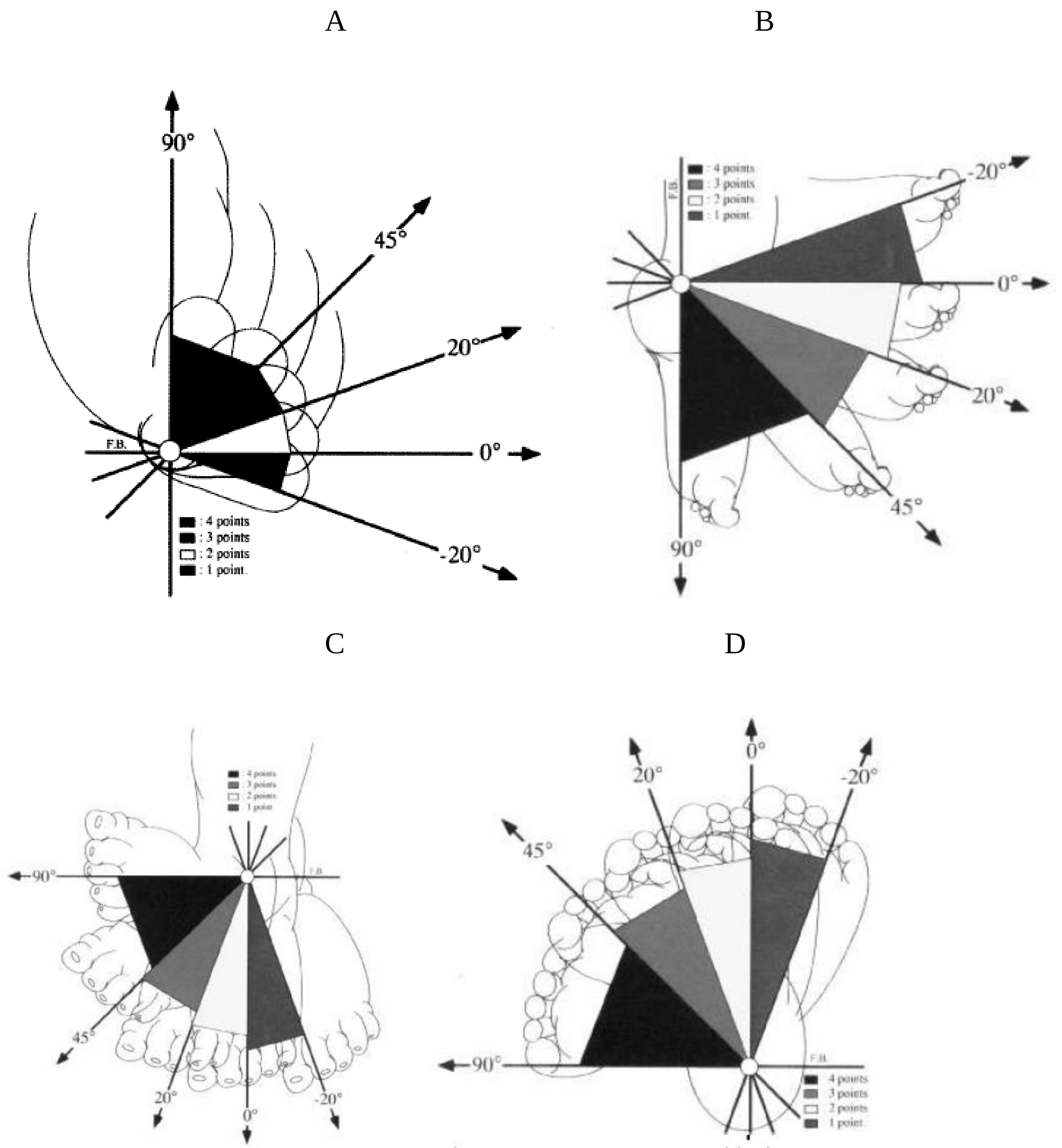
Conclusions

Clubfoot is a common musculoskeletal problem that affects 1-2 out of 1000 children. Clubfoot deformity is defined by equinus, hindfoot varus, forefoot adductus and cavus. Fifty percent of all clubfeet are bilateral in nature and males are affected more than females at a 2:1 ratio. Standard treatment for clubfoot deformity is Ponseti Management; consisting of manipulation, progressive casting, with or without Achilles tenotomy, and foot abduction orthosis wear (23 hours per day for the first 3 months and then nighttime wear until the age of 4 or 5). Ponseti treatment results in good initial correction in >90% children. Despite this, between 7-64% of children with clubfoot will experience a reoccurrence of deformity. Reoccurrence is defined as repeat casting or surgical intervention to treat regression of deformity. The most cited cause of reoccurrence is non-compliance with the foot abduction orthosis. Treatments for reoccurrence are: casting, Achilles tenotomy or Achilles lengthening for residual equinus; tibialis anterior tendon transfer for dynamic supination; and posterior medial release or other invasive soft tissue/boney procedure (osteotomy) for persistent deformity. However, children with clubfoot that undergo invasive procedures, posterior medial release or osteotomy, tend to have worse short and long-term outcomes. Invasive procedures can lead to a stiff, painful and less functional foot. Therefore, it is recommended that children with clubfoot first be treated with non-operative methods and only employ surgical interventions for children who experience a reoccurrence.

Table C.1: Disease Specific Instrument [116]

	Question	Score
1	How satisfied are you with the status of your child's foot?	1=very satisfied, 2=somewhat satisfied, 3=somewhat dissatisfied, 4=very dissatisfied
2	How satisfied are you with the appearance of your child's foot?	1=very satisfied, 2=somewhat satisfied, 3=somewhat dissatisfied, 4=very dissatisfied
3	How often is your child teased because of his or her clubfoot?	1=never, 2=sometimes, 3=usually, 4=always
4	How often does your child have problems finding shoes that fit?	1=never, 2=sometimes, 3=usually, 4=always
5	How often does your child have problems finding shoes that he or she likes?	1=never, 2=sometimes, 3=usually, 4=always
6	Does your child ever complain of pain in his or her (affected) foot?	1=yes, 2=no; recoded 1=no, 4=yes
7	How limited is your child in his or her ability to walk?	1=not at all limited, 2=somewhat limited, 3=moderately limited, 4=very limited
8	How limited is your child in his or her ability to run?	1=not at all limited, 2=somewhat limited, 3=moderately limited, 4=very limited
9	How often does your child complain of pain during heavy exercise?	1=never, 2=sometimes, 3=usually, 4=always
10	How often does your child complain of pain during moderate exercise?	1=never, 2=sometimes, 3=usually, 4=always

Figure C1: Dimeglio Classification Scale[111]: A) Sagittal plane evaluation of varus; B) Sagittal plane evaluation of equinus; C) Horizontal plane evolution of derotated caneopedal block; D) Horizontal plane evaluation of forefoot relative to the hindfoot.



Appendix D: Reoccurrence Rate in Ponseti Treated Clubfeet: A Meta-Regression

Introduction

Reoccurrence of deformity, defined as any surgical or non-surgical treatment post initial correction, occurs in 7-64% of children with clubfeet [5, 15-17]. Previously, the most cited cause of reoccurrence was non-compliance with foot abduction orthosis [4, 5, 7, 11, 13, 15, 17, 18]. Researchers found that 78% of children who are noncompliant with brace wear experience a reoccurrence, compared to only 7% of children who are compliant [17]. Other cited causes of reoccurrence are: low socioeconomic status [5], parental education level less than high school [7], gender (females are 5x more likely to reoccur) [11, 19], initial severity rating (the higher the rating the more likely to reoccur) [19], decreased dorsiflexion range of motion [11, 15], and everter muscle weakness [11, 15]. While previous researchers have reviewed the topic of clubfoot reoccurrence, statistical techniques have not been used to assess the overall rate and cause of reoccurrence for children with clubfeet. Therefore, the purpose of this study is to conduct a literature review, of studies that report reoccurrence rates in children with clubfoot, and use meta-regression to predict the variables that explain the variance in proportion effect sizes for clubfoot recurrence rate. This analysis will identify factors that contribute to an increased chance of reoccurrence.

Methods

A PubMed, Medline and Google Scholar search was conducted for the years of 1990-2017 using the following key words: “clubfoot” or “talipes equinovarus” and “reoccurrence” or “relapse”. PubMed and Medline returned a manageable number of articles to review. However, Google Scholar returned too many articles to reasonably screen. Therefore, the word “children” was added to the Google Scholar search in order to decrease the number of results (Table D.1). Articles were screened using the criteria in Figure D.1. A total of 17 studies were chosen for inclusion, with three studies providing an additional three subject groups, for a total of 20 samples for analysis.

The effect size statistic (ESp) utilized in this study was proportion (p), where the number of subjects who reoccurred (k) was divided by the total number of subjects (n): $ES_p = p = \frac{k}{n}$ [121]. For statistical analysis in clubfoot literature, it is common to pool bilateral and unilateral clubfeet into one subject group, with the total number of subjects and the total number of clubfeet being reported [55]. Due to this, the proportion of the study population that experienced reoccurrence will be calculated one of two ways; *n* is either the total number of subjects or the total number of clubfeet and *k* is either the number of subjects or number of clubfeet that reoccurred.

After an extensive review of the methods and procedures of the studies included herein, eight parameters were chosen for inclusion in the meta-regression (Table D.2). The parameters chosen were: gender, sample size, laterality, age at initial presentation, mean number of casts, percent of subjects who underwent tenotomy as part of Ponseti treatment, mean follow-up time, and brace compliance. These parameters were chosen as they were commonly reported and have been listed in previous literature as possible causes or contributors of reoccurrence. Other parameters previously reported to be important factors (height, weight, parental education level, and socioeconomic status) were assessed and subsequently discarded due the sparse inclusion of these parameters in the methods and results of the studies utilized in this study.

IBM SPSS Statistics v.24 (IBM Corporation, Armonk, NY, 2016) was used to run custom macros that calculated central tendency statistics, a one-way ANOVA analysis with a fixed effects model, and a weighted generalized least squares regression with a fixed effects model. The effect sizes calculated were outside the predefined range of <0.20 or >0.80, therefore logits were utilized in all statistical analyses[121]. Upon completion of data analysis, the Logit results were then converted back into effect sizes using the following equation $effect\ Size = \frac{e^{Effect\ Size\ Logit}}{e^{Effect\ Size\ Logit}+1}$ [121]. Interpretation of results will be discussed in terms of the original values and the final effect sizes converted from logits.

Central tendency macros, custom built for use in SPSS, were used to calculate the following statistics for the 20 samples: mean, minimum, maximum, weighted standard deviation, ±95% confidence interval, standard error, z score, p-value, random effects variance, and homogeneity analysis (Q). The mean and 95% confidence interval describe the average proportion of children with clubfoot that will experience a recurrence in deformity. The homogeneity analysis is an indicator of how heterogeneous the distribution of effect sizes is among the 20 samples. A significant homogeneity analysis indicates that the variability across effect sizes is greater than what is expected from sampling error alone. Indicating that the parameters listed above may influence reoccurrence and that further analysis is warranted.

Each parameter was then coded into dummy variables (Table D.2), which were then fed into a one-way ANOVA using a fixed effect model[121]. This analysis partitions the variability of effect size explained by the parameters (Q, between) and the remaining residual portion (Q, within). When Q between is significant, the mean effect sizes across categories differ by more than sampling error. When Q within is not significant, the parameters are sufficient to explain the excess variability in the effect size distribution.

Lastly, a weighted generalized least squares regression with a fixed effect model was used to predict which parameters explained the excess variance in effect sizes. This approach assesses the relationship between the effect size and the study parameters. The regression will be calculated for each individual parameter dummy variable and then the significant variables will be combined into one regression analysis. If the combined regression homogeneity test is significant, then the model will sufficiently explain variability across effect sizes. If the homogeneity sum-of-squares is not significant, then the unexplained variability is no greater than that from sampling error alone[121].

Results

Table D3 presents the effect size statistics for the proportion of subjects/clubfeet that experienced a reoccurrence. Sixteen of the twenty subject groups used the number of clubfeet to calculate reoccurrence rate, the remaining four measurements utilized the number of subjects. Reoccurrence rates ranged from 11-83%, therefore the effect size statistics ranged from 0.11 to 0.83.

Table D4 presents the central tendency results of the logit and converted data. The mean effect size is 0.30 with a 95% confidence interval of 0.28-0.33. This indicates that on average 30% of subjects will experience a reoccurrence. The overall homogeneity Q was equal to 97.6 with a p-value of <0.001, indicating that the variance in effect sizes is due to more than random sampling error. Since the overall Q was significant, a one-way ANOVA using a fixed effects model was run to assess the homogeneity for each individual study parameter from Table D2. The results of the one-way ANOVA are summarized in Table D5. Both Q between and Q within are significant for each study parameter; this indicates that no single parameter can be used to explain the variance in effect sizes.

Therefore, a weighted generalized least squares regression with a fixed effect model was used to predict which study variables, in combination, would explain the excess variance in the proportion of subjects who experience a reoccurrence. The 12 dummy parameters from Table D2 were entered into the regression analysis, Table D6 presents the regression results. Four dummy variables were found to be significant: Laterality (Unilateral or Bilateral), Tenotomy (yes or no), mean follow-up time A < 2 years (MFUTA) and mean follow-up time B >2 years (MFUTB). These four variables were then entered into a regression analysis, which resulted in the variable MFUTB falling out. A final regression was run with three variables: Affected, Tenotomy and MFUTA (Table D7). The model was significant and explained 46.5% of the variance in effect size. The coefficients for Affected, Tenotomy and MFUTA are 0.77, 0.60, and 0.29 respectively.

Discussion

The purpose of this study was to review previously reported reoccurrence rates for children with clubfoot and use a meta-regression to predict the variables that would explain the variance in proportion effect sizes for clubfoot recurrence rate. The goal was to identify factors that could help identify children that may be at risk of a reoccurrence. Seventeen studies, with a total of 20 samples, were identified and used to calculate effect size. The mean effect size for the 20 samples was 0.30 (95% Confidence Interval 0.28-0.33). This indicates that the average proportion of children that experience a recurrence of deformity is 30% and that the majority of researchers report a recurrence percentage between 28%-33%. Having an overall mean and confidence interval for the rate of clubfoot reoccurrence is advantageous for clinician. There is a wide range in past reported rates of reoccurrence (7-64%) [5, 15-17]. Creating a mean rate of reoccurrence, using the 20 samples from this study, is more representative of the entire clubfoot population and not a specific studies population. Using a mean reoccurrence rate of 30%

allows clinicians to more accurately inform patients and families of the average chance reoccurrence.

Overall, the homogeneity for the 20 samples was 97.6 with a p-value of <0.001. This indicates that the variance in proportion of children who experience a reoccurrence can be attributed to more than random sampling error and that additional factors should be taken into account. Eight parameters were assessed for each of the 20 samples; percentage of males and females, the study sample size, laterality (percent of bilateral vs. unilateral), age at initial presentation, mean number of casts, percent with tenotomy as part of Ponseti treatment, mean follow-up time and brace compliance. The homogeneity for each parameter was calculated using an ANOVA, which resulted in no individual parameter sufficiently explaining the excess variability in the proportion of clubfoot subjects who experience a reoccurrence. Therefore, a logistic regression was used to assess the study parameters in combination. A final model, explaining 46.5% of the variance in the proportion of children experiencing a reoccurrence, was found using three variables (laterality, tenotomy and follow-up time). The coefficients for laterality, tenotomy and follow-up time are 0.77, 0.60, and 0.29 respectively. These coefficients indicate that children who have unilateral clubfoot deformity, who have had a tenotomy and are less than 2 years of follow-up are at the highest risk of experiencing a recurrence.

Previously, researchers have reported conflicting evidence on the difference in the severity of deformity between bilateral and unilateral clubfeet. Some researchers found no difference between unilateral and bilateral clubfeet [49], whereas others found that bilateral clubfeet are more severe [55]. Despite conflicting reports in the past, the results of this meta-regression show that children with unilateral clubfoot are at a higher risk of experiencing a reoccurrence. The exact mechanism for why laterality is a significant predictor of reoccurrence is unclear and the conflicting results reported previously are a further confound. More research is needed to ascertain the effect of laterality on the rate of reoccurrence for children with clubfoot.

Equinus is the most difficult of the clubfoot deformities to correct [17] and researchers have found that performing an Achilles tenotomy, as part of Ponseti management, can help increase the amount of ankle dorsiflexion [114]. The range of children that will receive a tenotomy as part of their Ponseti management is from 12-90% [1, 4, 5, 7, 13, 16, 54, 112, 114]. Children who require a tenotomy may have a foot that is rigid and less complaint with non-operative treatment, whereas those whose equinus deformity is flexible may better accommodate non-operative treatments. Despite successful correction of equinus with the initial tenotomy, logistic regression shows that the positive history of tenotomy is a predictor of reoccurrence. Researchers have found that the first deformity to reoccur is the last addressed, equinus [122]. The rate of revision for persistent equinus, post initial tenotomy, is 18% [19], indicating that almost 1 in 5 children who receive a tenotomy will experience a reoccurrence of equinus deformity. Therefore, children who require the initial tenotomy may be predisposed to reoccurrence, due to a more rigid foot, as opposed to those children who do not receive a tenotomy, who may have a more flexible foot.

Previous researchers have found that only 6% of children past the age of 7 will reoccur, whereas, upwards of 64% will reoccur before the age of 5 years [5, 15-17]. Additionally, the highest risk of reoccurrence has been reported during the rapid growth period between 3-5 years of age [15]. Previous research supports the results of this study, children whose follow-up time is less than 2 years post-initial treatment are at the highest risk of reoccurrence. Clinicians would benefit from the knowledge that children under the age of 5 years, that are not yet 2 years post treatment, should be followed more closely.

One potential limitation of this study is the use of clubfeet vs. subjects to calculate effect size. For statistical analysis on clubfeet it is common to pool bilateral and unilateral clubfeet into one subject group, with the total number of subjects and the total number of clubfeet being reported [55]. Typically, children with bilateral clubfoot are included with both feet as independent observations [56]. However, several researchers have found using bilateral and unilateral clubfeet in the same analysis is confounding [3]. Bilateral clubfeet tend to be highly correlated; 85% have the same severity classification score, the mean number of casts applied for each side is not significantly different, the need for tenotomy is not different, and 89% of patients who reoccur do so bilaterally [56]. Therefore, it may not always be proper to include both sides of bilateral subjects, as this could artificially inflate sample size and lead to false conclusions [55, 56] The subjects utilized in the 20 samples from this meta-regression, were a mixture of bilateral and unilateral clubfeet. However, due to the nature of meta-regression, the problem of pooling data from both sides of bilateral subjects cannot be addressed. The results of this study do indicate that unilateral clubfeet are at a higher risk of reoccurring. However, due to the problems stated above caution may need to be taken when stating that unilateral clubfeet are at higher risk. It may behoove future researchers to consider bilaterality as a potential confound and the utilization of statistical methodologies that account for laterality should be considered.

Conclusion

The purpose of this study was to use meta-regression to assess reoccurrence rates in children with clubfoot. This study is the first to use statistical methodology to assess the variance in the proportion of clubfoot subjects who experience a reoccurrence. This study can be used to help guide clinicians in the management and follow-up of clubfoot deformity. Results show that 30% of children with clubfoot with reoccur. In addition, children with unilateral clubfoot, who underwent a tenotomy as part of Ponseti management and who were less than 2 years follow-up were at the highest risk of reoccurrence. Therefore, clinicians who treat children meeting this criterion should be cautious, as it could be an indication that the child is at risk for a reoccurrence of deformity. Additionally, children meeting this criterion may need to be monitored more closely with more frequent follow-ups.

Table D.1: The number of articles returned for three electronic databases; PubMed, Medline and Google Scholar.

Key Words	PubMed	Medline	Google Scholar	Google Scholar + Children
Clubfoot and Reoccurrence	226	564	10100	8920
Clubfoot and Relapse	326	114	2620	2410
Talipes Equinovarus and Recurrence	270	50	5620	5260
Talipes Equinovarus and Relapse	332	29	1790	1750

Table D.2: List of the study variables to be used for meta-regression; Dummy Variables used in the regression are listed.

Variable	**Code**	**Dummy Variables**	**Notes**
Gender	1=Majority Male, 2=Majority Female, 3=Mixed Gender (Equal % of males to females.)	**MalesA**: 1=1, 2&3=0; **MalesC:** 3=1, 1&2=0	Majority= >75%
Subject Sample Size	1=<50, 2=>50	**SS:** 1=1, 2=0	
Laterality	1=Majority Unilateral, 2=Majority Bilateral, 3=Mixed	**Affected:** 1=1, 2&3=0	Majority= >75%
Average Age at Initial Presentation	1=<3 months, 2=>3months, 3=Classified as Infants no age given	**Age:** 1&3=1, 2=0	
Mean Number of Casts	1=<5 Casts, 2=>5 Casts, 3=Not Specified	**CastsA:** 1=1, 3&2 = 0; **CastsB:** 2=1; 1&3=0	
Percent with Tenotomy As Part of Ponseti Treatment	1=>90%, 2=80-89%, 3=70-79%, 4=<69%, 5=Not Specified	**Tenotomy:** 1&2=1, 3-5 = 0	
Mean Follow-Up Time	1=<2 years, 2=>2 years, 3=Not Specified	**MFUTA:** 1=1, 2&3=0; **MFUTB:** 2=1, 1&3=0	
Brace Compliance	1=<50%, 2=>50%, 3=Not Specified	**BraceA:** 1=1, 2&3=0; **BraceB:** 2=1, 1&3=0	

Table D.3: Effect Size Statistic: The percent of subjects/clubfeet that experiences a reoccurrence.

Samples	Total Number of Subjects	Total Number of Clubfeet	Total Number Reoccurred	Effect Size Statistic	Percent Reoccurred
Dobbs(2004)	51	86	27 feet	0.31	31%
Haft (2007)	51	73	21 subjects	0.41	41%
Richards (2008)	176	267	93 feet	0.37	37%
Avilucea(2009)	50	68	8 feet	0.16	16%
Avilucea(2009)	50	74	18 feet	0.36	36%
Park (2009)	33	48	19 feet	0.40	40%
Goriainov (2010)	50	80	17 feet	0.21	21%
Janicki (2011)	17	30	25 feet	0.83	83%
Janicki (2011)	28	39	12 feet	0.31	31%
Ramirez (2011)	53	73	24 feet	0.33	33%
Zionts(2012)	57	84	40 feet	0.48	48%
Goldstein (2015)	86	86	28 subjects	0.33	33%
Ohalloran (2015)	45	71	18 feet	0.18	18%
Hosseinzadeh (2016)	101	148	42 feet	0.28	28%
Mageshwaran (2016)	20	26	3 feet	0.15	15%
Mageshwaran (2016)	20	25	4 feet	0.20	20%
Changulani (2006)	66	100	31 feet	0.32	32%
Abdelgawad (2007)	89	137	14 feet	0.14	14%
Goksan (2006)	92	134	27 subjects	0.31	31%
Colburn (2003)	34	57	4 subjects	0.11	11%

Table D.4: Logit and Converted Central Tendency Results

	Effect Size Logit	**Converted Effect Size**
Mean	-0.83	0.30
Minimum	-2.17	0.10
Maximum	1.61	0.83
Weighted Standard Deviation	0.55	0.63
-95% Confidence Interval	-0.94	0.28
+95% Confidence Interval	-0.72	0.33
Standard Error	0.01	
Z Score	-15.03	
P-value	<0.001	
Random Effects Variance (v)	0.26	
Homogeneity Analysis (Q)	97.55	
Homogeneity P-Value	<0.001	

Table D.5: One-Way ANOVA Results Summarized for Q between and Q within.

Variable	**Q between**	**P-value**	**Q within**	**P-value**
Gender	22.339	<0.001	154.424	<0.001
Subject Sample Size	3.142	0.076	173.621	<0.001
Affected Side	73.377	<0.001	103.387	<0.001
Average Age at Initial Presentation	0.367	0.832	176.396	<0.001
Mean Number of Casts	8.766	0.013	167.997	<0.001
Percent with Tenotomy as part of Ponseti Treatment	53.085	<0.001	123.678	<0.001
Mean Follow-up Time	55.794	<0.001	120.969	<0.001
Brace Compliance	10.055	0.007	176.763	<0.001

Table D.6: Results of the Logistic Regression on individual dummy variables. Grey indicates a significant homogeneity analysis.

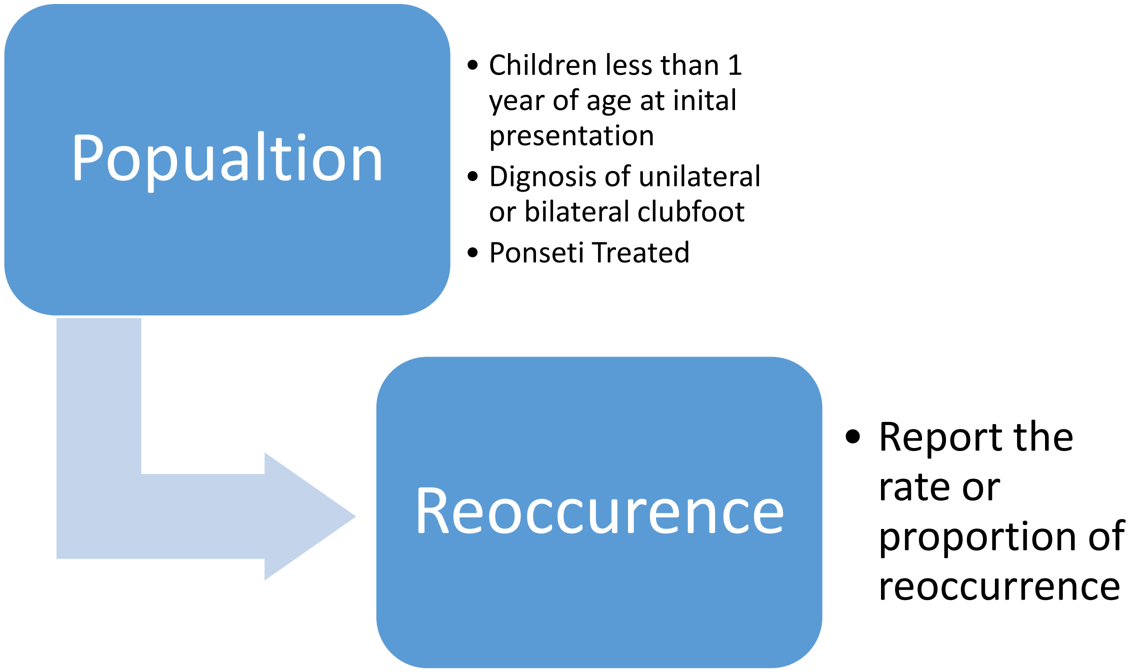
	Q	df	p-value	Mean Effect Size (Logit)	R-Square	k	Mean Effect Size Converted
SS	0.005	1	0.9437	-0.830	0.0001	20	0.30
MalesA	3.301	1	0.0692	-0.830	0.0338	20	0.30
MalesC	3.301	1	0.0692	-0.830	0.0338	20	0.30
Affected	7.409	1	0.0065	-0.830	0.0759	20	0.30
Age	0.037	1	0.8471	-0.830	0.0004	20	0.30
CastA	0.770	1	0.3802	-0.830	0.0079	20	0.30
CastB	0.382	1	0.5364	-0.830	0.0039	20	0.30
Tenotomy	10.215	1	0.0014	-0.830	0.1047	20	0.30
MFUTA	21.664	1	0.0000	-0.830	0.2221	20	0.30
MFUTB	21.870	1	0.0000	-0.830	0.2242	20	0.30
BraceA	0.008	1	0.9281	-0.830	0.0001	20	0.30
BraceB	0.074	1	0.7855	-0.830	0.0008	20	0.30

Table D.7: Final Logistic Regression with three significant variables.

Significant Parameter Regression Results				
	Q	**P-value**	**Mean Effect Size (Logit)**	**R-Square**
Model	45.3318	<0.001	-0.83	0.4647
Residual	52.2209	<0.001		
Total	97.5527	<0.001		

Regression Coefficients Logits							
	B	**Standard Error**	**-95% CI**	**+95% CI**	**Z**	**P-value**	**Beta**
Constant	-0.879	0.071	-1.018	-0.740	-12.4	<0.001	<0.001
Tenotomy	0.407	0.117	0.179	0.636	3.50	<0.001	0.3562
MFUTA	-0.865	0.161	-1.182	-0.549	-5.36	<0.001	-0.5504
Affected	1.190	0.373	0.460	1.921	3.19	<0.001	0.3268
Regression Coefficients Converted							
Constant	0.293	0.518	0.265	0.323			
Tenotomy	0.600	0.529	0.545	0.654			
MFUTA	0.296	0.540	0.235	0.366			
Affected	0.767	0.592	0.613	0.872			

Figure D.1: Screening criteria for article review.



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Curriculum Vita

Juanita Jean Wallace

Education

Eastern Kentucky University
Richmond, Kentucky
M.S. Exercise Science
2008-2009

Berea College
Berea, Kentucky
B.A. Physical Education
Minor: Health
2004-2008

Professional Positions

1. Assistant Professor of Exercise Science at Transylvania University, Lexington, KY; 2018-Present
2. Lecturer Exercise Science at Transylvania University, Lexington, KY; 2017-2018
3. Part-Time Faculty at University of Kentucky, Kinesiology and Health Promotion Department; Lexington, KY; Summer 2017, Summer 2018
4. Kinesiologist at Shriners Hospitals for Children Medical Center; Lexington, KY; 2010-2017
5. Part-Time Faculty Exercise and Sports Science Department at Eastern Kentucky University; Richmond, KY; 2013-2014
6. Adjunct Faculty at Spencerian College; Lexington, KY; 2010-2012
7. Research Specialist at Shriners Hospitals for Children Medical Center; Lexington, KY; 2009-2010
8. Graduate Assistant at Eastern Kentucky University; Richmond, KY; 2008-2009

Book Chapters

1. Handbook of Human Motion (2017) Springer International Publishing; Editors: Muller B, Wolf S, Brueggemann G, Deng Z, McIntosh A, Miller F, Selbie W; Chapter: Oxygen Consumption in Cerebral Palsy; White H, **Wallace J**, Augsburger S. pp:1-21; DOI 10.1007/978-3-319-30909-1_41-1; Online ISBN 978-3-319-30808-1

Publications

1. **Wallace J**, White H, Augsburger S, Shapiro R, Walker J. (2018) Foot Pressure Analysis using the emed® in Typically Developing Children and Adolescents: A

Summary of Current Techniques and Typically Developing Cohort Data for Comparison with Pathology. The Foot, In Press

2. Hank White, Morgan Hall, **JJ Wallace**, Sam Augsburger. Changes for Shriners Hospitals for Children — Lexington; Published in 2017 ACPOC News Letter
3. **Wallace J**, White H, Augsburger S, Kryscio R, XI J, Milbrandt T, Talwalkar V, Iwinski H, Walker J. (2016) Pedobarographic changes in ponseti treated clubfeet with and without anterior tibialis tendon transfer: changes due to growth and surgical intervention. Journal of Paediatric Orthopaedics –B, 25(2), 89-95.
4. White H, **Wallace J**, Augsburger S, Iwinski H, Milbrandt T. (2015) A Prospective Comparison of Pulmonary Function using Traditional and Kinematic Measures in Children with and without Adolescent Idiopathic Scoliosis. Spine Deformity, 3(6), 554-559.
5. **Wallace J**, White H, Augsburger S, Iwinski H, Milbrandt T. (2014) A Cross-Sectional Study of Chest Kinematics and VO2 in Children with Adolescent Idiopathic Scoliosis During Steady State Walking. Spine, 41(9), 778-784.