

Comparison of Immediate vs. Delayed Recall of Orthodontic Information Following an Electronic Reminder

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COMPARISON OF IMMEDIATE VS. DELAYED RECALL OF
ORTHODONTIC INFORMATION FOLLOWING
AN ELECTRONIC REMINDER

by

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ABSTRACT
COMPARISON OF IMMEDIATE VS. DELAYED RECALL OF
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Marquette University, 2018

Patients and parents in dentistry often do not remember important information disclosed during the informed consent process, so improvement in the delivery of information is needed. This study explored the effect of an emailed narrated instructional PowerPoint on the immediate vs. delayed recall and comprehension of informed consent information in orthodontics.

Thirty-two subjects were recruited from a university and private practice orthodontic clinic. At the initial visit, subjects were alternately assigned to one of two groups and were presented with a mock orthodontic treatment plan and informed consent presentation for a pretend patient. Immediately following the presentation, the subjects' verbal recall and comprehension of information required for informed consent was assessed. Within 24 hours, subjects in the treatment group were emailed an informational PowerPoint video reinforcing information about the treatment plan and risks and benefits of treatment, while the remaining participants did not receive additional information. A week after the initial meeting, all subjects were contacted by phone and the assessment they received at the initial visit was readministered.

A statistically significant interaction was found between the effects of the PowerPoint and the time of patient recall. Those subjects who received the PowerPoint video were more likely to recall and comprehend the treatment plan and informed consent information seven days following the initial visit than did participants who had not received the adjunct material. Additionally, for the subjects who received the PowerPoint, there was a statistically significant improvement in recall and comprehension of the factors that would increase orthodontic treatment time beyond the original estimate. All subjects within the study recalled and comprehended that orthodontic treatment results are not guaranteed for life.

Few studies have examined the retention of informed consent material in orthodontics beyond the initial visit, and the present results are consistent with the need for improvement of this process. With the use of an emailed home informational video reviewing treatment plan and informed consent information, delayed recall and comprehension in orthodontics can be improved. By improving the parent's recall and comprehension, a higher quality of care can be delivered in orthodontics.

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TABLE OF CONTENTS

ACKNOWLEDGMENTS.....	i
LIST OF TABLES.....	iv
LIST OF FIGURES.....	v
CHAPTER	
INTRODUCTION	1
LITERATURE REVIEW	5
<i>Statement of the Problem</i>	20
METHODS	21
<i>Subjects</i>	21
<i>Materials and Setting</i>	23
<i>Design</i>	24
<i>Procedure</i>	26
<i>Dependent Measures</i>	27
RESULTS	30
<i>Analysis of individual test items</i>	32
<i>Willingness to agree to treatment</i>	41
DISCUSSION.....	43
<i>Demographic Data</i>	51
<i>Limitations of the study</i>	51
CONCLUSION.....	54
REFERENCES	57
APPENDIX A:.....	59

APPENDIX B:	61
APPENDIX C:	62
APPENDIX D:	63
APPENDIX E:	64
APPENDIX F:	65
APPENDIX G:	68
APPENDIX H:	71
APPENDIX I:	72
APPENDIX J:	73
APPENDIX K:	75

LIST OF TABLES

Table 1: Group Design.....	25
Table 2: Questionnaire Assessment of Comprehension and Recall	29
Table 3: Means, Standard Deviations, and Number of Participants for Each Group	30
Table 4: Analysis of Variance Summary Table for the Effect of Time and Educational Intervention on Parents' Comprehension and Recall of Informed Consent Information..	31
Table 5: Informed Consent Recall and Comprehension Assessment Description, Significance, Statistical Test, and Statistical Interpretation.....	34

LIST OF FIGURES

Figure 1: Mean Total Recall and Comprehension Scores for Informed Consent Information Immediately Following Presentation at 1 Week With and Without Electronic Educational Intervention.....	32
Figure 2: Range of Informed Consent Recall and Comprehension Assessment Scores for All Groups.....	35
Figure 3: Mean Assessment Scores for both Traditional Care Group and Electronic Educational Intervention Group at Time 1, Immediately Following the Delivery of Informed Consent Information	36
Figure 4: Average Assessment Scores for Recall and Comprehension of Informed Consent Information Immediately After Presentation (Time 1) and After 7 Days Without Intervention (Time 2) for the Traditional Care Group.....	38
Figure 5: Average Assessment Scores for Recall and Comprehension of Informed Consent Information Immediately After Presentation (Time 1) and 7 Days Later (Time 2) With Narrated PowerPoint Intervention	40
Figure 6: Mean Assessment Score of Recall and Comprehension 1 Week Following the Initial Informed Consent Delivery for Traditional Care and Intervention Groups.....	41
Figure 7: Likert Scale Scores for Likelihood to Accept Treatment for both Traditional Control Group and Electronic Educational Intervention Group Immediately Following Informed Consent Information Delivery	42

INTRODUCTION

The patient-doctor fiduciary relationship in an orthodontic practice is one that must be valued and respected. Because orthodontics is a true profession and has a social contract with the community they serve, orthodontists must put the needs of the patients and society ahead of themselves. In order to fully enter into this relationship the orthodontist must have comprehensive knowledge of the procedure, uncompromising veracity, and give an unbiased presentation of all reasonable alternatives and consequences including risks, benefits, complications, and responsibilities involved in orthodontic treatment (American Dental Association, 2016; American College of Dentists, 2012). Additionally, the orthodontist will need to communicate clearly and effectively to be able to assure comprehension by the patient or parent as well as to be sure they have sufficient understanding to make an informed decision.

Despite the ethical and legal importance of full patient disclosure and comprehension to obtaining informed consent, it has been shown that patients often do not always comprehend the informed consent disclosures that dentists offer them (Moreira, Pacheco-Pereira, Keenan, Cummings, & Flores-Mir, 2016; Schenker, Y., Fernandez, A., Sudore, R., & Schillinger, D., 2010). In the August 2016 issue of the Journal of the American Dental Association, an article entitled *Informed consent comprehension and recollection in adult dental patients: A systematic review* concluded that although patients generally report that they understand informed consent information given to them by their dental provider, they may have limited comprehension and recall of this information, ranging from 27% to 85% and 20% to 86% of the total information delivered respectively, when being assessed both verbally and on multiple choice

questions (Brons, S., Becking, A. G., & Tuinzing, D. B. 2009; Brosnam, T., & Perry, M. 2009; Cassileth, B. R., Zupkis, R. V., Sutton-Smith, K., & March, V. 1980; Moreira et al. 2016). These results indicate that it is possible that many of the patients and parents within a dental practice may not understand or remember all of what was explained in the informed consent process. With this information, a signed informed consent form may only represent an acceptance of a partially understood medical or dental procedure or method, offering potential legal, ethical, and moral quandaries.

To date, there has only been one study to test delayed recall and comprehension as it relates to informed consent in the entire field of dentistry (Moreira et al., 2016; Thomson, A. M., Cunningham, S. J., & Hunt, N. P. 2001). However, from the medical literature, we know that as time passes from the date of informed consent information delivery, the patient's comprehension and recall of important details decreases (Bergler, J., Pennington, C., Metcalfe, M., & Freis, E., 1980; Schenker et al. 2010). Bergler et al. (1980) showed that following an informed consent procedure regarding high blood pressure medication, a multiple-choice quiz that evaluated patient comprehension and recall was 71.6% at the time of information delivery and decreased to a score of 61.2% three months later (Bergler et al., 1980). This decrease in recall and comprehension of important information about patient compliance and side effects over time is especially important as it relates to orthodontics because orthodontic treatment can typically take two to three years to complete. Patients and parents need to be able to retain all the important information for the entire duration of treatment to obtain the best treatment result.

We know Americans have been spending increasing amounts of time using multimedia, and in 2015, it was reported Americans were using their smartphones on the average of over 5 hours each day, and this number is expected to keep increasing (Andrews, Ellis, Heather, & Lukasz, 2015a, 2015b). With the increasingly important role of technology in our everyday lives, researchers, as well as educators, are beginning to investigate how technology can assist recall and learning, and more specifically, the informed consent process. Several studies have found that the use of multimedia can enhance a student's understanding of certain material in the classroom (Hoffler & Leutner, 2007; Schwan & Riempp, 2004; Zhang, Zhou, Briggs, & Nunamaker, 2006).

By introducing additional media, such as audio, video or leaflets, comprehension and recollection of informed consent information given in dentistry has been found to improve from 44% to 93% and 30% to 94%, respectively, when being assessed both verbally and by multiple-choice questions (Moreira et al., 2016). Consistent with these findings, in medicine, evidence suggests that the addition of audiovisual/multimedia programs can improve patient comprehension in informed consent (Schenker et al., 2010). Greater comprehension and recall means that patients and parents are better suited to make more appropriate and informed decisions about their treatment (Mortensen, M. G., Kiyak, H. A., & Omnell, L. 2003), which is an important finding for dentistry. Because multimedia has been shown to be an effective tool to inform patients and parents about their treatment, and smartphones are readily available and frequently used, delivering an electronic booster to patients and parents they can view online at any time might be an effective method to improve delayed recall and comprehension in orthodontics.

Little is known about patient's long-term recollection of treatment planning information, and the use of new technologies to improve patient recall of this information is just starting to be explored (Moreira et al. 2016; Schenker et al. 2010; Thomson et al. 2001). With dentists and orthodontists having an obligation to their patients and community that is based on trust, and the patient or parent's understanding of the proposed procedure being vital to honoring their autonomous decisions, orthodontists and the profession of dentistry as a whole must find a way to the improve patients' informed consent comprehension and recall.

LITERATURE REVIEW

According to the American Dental Association (ADA) Code of Ethics, the dental profession holds a special position of trust within society and in return, the dental profession makes a commitment to adhere to high ethical standards of conduct (American Dental Association, 2016). The first principle of the professional code of conduct for all ADA members is patient autonomy, or “self-governance” and is also known as “respect for persons”(American Dental Association, 2016; American College of Dentists, 2012). Autonomy allows patients to choose what they want to do with their own body and oral health and this ethical principle forms the foundation of informed consent. This means the dentist has the ethical duty to involve the patient in the treatment decision-making process and in doing so, honor the patient’s right to self-determination in the informed consent and treatment decision processes. It is important for patients to fully understand the entire treatment plan and any reasonable alternatives they are offered, because without this understanding, the patient cannot make a voluntary and meaningful informed decision that is consistent with their own values about their own oral health. However, it should be noted the patients’ decision is not absolute and the orthodontist has the duty to weigh the benefits and harms to the patient in a treatment procedure before they agree to provide the orthodontic treatment (Ozar, D. T., & Sokol, D. J., 2002).

Informed consent is both an ethical and legal requirement for dentists and there are multiple steps to the process (American College of Dentists, 2012; American Dental Association, 2016; Graskemper, 2011). First, the dentist must disclose the diagnosis and recommended treatment options to the patient along with all other reasonable alternative treatment options, including the option of no treatment. The dentist must also explain all

the reasonable risks and benefits associated with each of these treatment options.

However, the dentist is not required to explain all the detailed and technical information related to these alternatives (that probably the patient would not understand) as well as remote possibilities.

The dentist must also be sure the patient has the mental capacity to engage in decision-making, that they are of legal age, and that they do not have a mental or cognitive disability that would prevent them from making an informed decision. Capacity is a legal term used to describe the patient's ability to utilize information about proposed treatment and make a decision consistent with his or her own values and preferences, while competency refers to the dentist's assessment of the patient's ability to participate in the informed consent process. Allowing a patient a decision consistent "with their own values and preferences" honors not only beneficence (doing good for the patient), but also serves autonomy, and respecting the patient's right to make a decision that reflects their wishes and values (Ozar et al. 2002). If the health care provider has any doubt the patient has the competency to make their own decision, they can request assistance in making this determination. Usually, this request is for a medical and psychological evaluation to assess the patient's current mental status.

The patient's decision must be voluntary and be made without any coercion, a vital requirement to protect the patient's autonomy. Once the decision is made, it should be articulated by the patient and documented in the doctor's notes. Finally, the dentist has the responsibility to make sure the patient was able to comprehend the information that was given in the informed consent process; otherwise the signed document may represent the patient's acceptance of a partially understood procedure. This outcome would not be

ethically acceptable because true informed consent was not obtained, and autonomy was not honored (American Dental Association, 2016; American College of Dentists, 2012; Graskemper, 2011). Moreover, legally informed consent is expected and is regulated by state law, and if not done it can result in malpractice lawsuits (Graskemper, 2011).

Given the ethical and legal importance of informed consent, several studies have demonstrated that even after being informed of the diagnosis, proposed treatment plan and alternative options, along with the associated risks and benefits of each, a large number of patients do not completely comprehend or recall the information given to them (Brons et al. 2009; Cassileth et al. 1980; Mohamed Tahir, Mason, & Hind, 2002; Moreira et al. 2016; Mortensen et al. 2003). Moreira et al. (2016) conducted a systematic review that examined informed consent comprehension and recollection in adult dental patients; these studies used verbal, written, and multiple-choice assessments. The review found the conventional informed consent processes in dentistry yield comprehension results ranging from 27% to 85% (Moreira et al. 2016). This wide range of results can be attributed to the fact that all the studies reviewed used a different assessment tool to measure the subject's comprehension and recollection. Additionally, the method used to perform the assessment also varied (multiple choice, open-ended conversation, verbal exam, etc.), with certain types of measures (multiple choice) being easier for the subjects to answer because they require recognition rather than patient-produced recollection and comprehension. Further, each study assessed the patients at different times after the initial presentation of information; some participants were assessed immediately after the informed consent presentation, while others were not asked to recall information until 14 days later, and other studies used follow-up times that fell somewhere in-between. With

the lack of standardization in the informed consent comprehension and recall assessment, it is likely there will continue to be a wide range of assessment scores.

Reviewed as part of the Moreira et al. (2016) systematic review was the Brons et al. (2009) study, which examined the value of informed consent in surgical-orthodontic patients. Brons et al. (2009) used twenty-four patients who needed surgical mandibular advancements and received consent for this treatment using a standard procedure consisting of verbal explanations along with illustrations and drawings (Brons et al. 2009). Immediately after the information was given to patients, they were given a questionnaire that consisted of three multiple-choice questions and two open-ended questions about the proposed treatment. The open-ended questions were used to assess recall of contraindications and potential complications with surgical treatment. They found that the mean recall of the risks and possible complications for surgical-orthodontic treatment immediately after an informed consent interview was just 40% of the relevant information presented (Brons et al. 2009).

Mortensen et al. (2003) researched informed consent recall in a population of low-income patients and their parents during a child's Phase 1 orthodontic treatment. Overall, twenty-nine children along with their parent or guardian were verbally given the informed consent information by their orthodontist (Mortensen et al. 2003). Immediately following the informed consent presentation, patients and parents were separated and were asked to recall the details of the treatment plan while they were assessed in private rooms. The Mortensen study found that when evaluating recall of the orthodontic procedures to be expected during treatment, parents had a maximum recall rate of 64.3% of the information presented, while the children's rate of recall was higher, reporting

85.7% of the relevant information. However, when examining recall of the need for orthodontic retention, which is an important part of treatment and a patient responsibility, only two of the fourteen adults studied (14.3%) remembered anything about retainers and none of the children (0%) verbally mentioned anything about removable appliances (Mortensen et al. 2003). This study concluded that the current standard procedure for engaging patients in the informed consent process needs to be improved for patients and parents to be able to give true informed consent.

Patient recall of informed consent information is a particularly salient topic in orthodontics due to the extended length of time required for orthodontic treatment. Active orthodontic treatment can commonly take between twenty-four to thirty-six months to complete, followed by the retention phase of treatment, which lasts for the patient's lifetime. Since some consequences of treatment may not appear until several months to years later, orthodontists need their patients to recall information presented to them at the start of treatment for the duration of this lengthy period. Moreira et al. (2016) found recollection of the details of informed consent in dental patients to be between 20% to 86% (Moreira et al. 2016). As stated previously, this wide range from this review is due to the lack of standardization in the assessments themselves, the method of delivery of the assessment, as well as the time of assessment, but in all cases, is far from ideal.

From the medical literature, Cassileth et al. (1980) studied the reasons patients fail to recall major portions of information on consent forms. Within a day of signing consent forms for chemotherapy, radiation, or surgery, two hundred cancer patients completed a questionnaire regarding their opinions of the proposed treatment's purpose and implications (Cassileth et al. 1980). Cassileth et al. found only 60% of the patients

studied could identify the purpose of the procedure and only 55% could correctly identify even one major potential complication with the cancer treatment. Cassileth et al. (1980) found one important reason patients could not recall the information was because they did not read carefully enough; this conclusion is based on patient self-reports that only 40% of the patients read the form “carefully” (Cassileth et al. 1980). Although orthodontic patients are not in a life-or-death situation like the cancer patients in this study (i.e., perhaps dental patients are not as stressed and have more time to make a decision about treatment), the medical data coincides with the dental literature in that informed consent disclosures do not seem to be well remembered, and healthcare providers need to find a better way to draw the patient’s attention to important information that could affect their decision to agree to treatment.

In an effort to assess the effects of directing patient’s attention to adjunct information, Moreira et al. (2016) also found that when delivering informed consent with additional media such as leaflets, multimedia devices or decision boards, the range for comprehension and recollection of important treatment information both improved slightly from 44% to 93% and 30% to 94% of relevant information, respectively, slightly enhancing the information available for the informed consent process (Moreira et al. 2016).

This finding is not unique. Choi et al. (2015) examined informed consent recollection for fifty-one adult patients who needed surgical removal of impacted mandibular 3rd molars (Choi et al. 2015). Twenty-five subjects received an audiovisual slideshow to deliver the informed consent information and twenty-six subjects received the standard written form. At the follow-up visit, one week after the surgical procedure,

the subjects were verbally assessed on their recollection of the informed consent information. The audiovisual slideshow group performed better in all categories assessed, remembering significantly more information than the control group about potential allergic reaction to local anesthesia or medication as well as the potential for the side effect of trismus (Choi et al. 2015). In addition to Choi et al. (2015), of the studies included in the systematic review, all studies that used enhanced processes such as multimedia devices and leaflets, when compared to conventional informed consent delivery, showed significantly better results when compared to control groups which gave patients none of these learning aids. The only exception to an intervention not improving recall for informed consent was a group that received a leaflet without any prompting to read the material, suggesting that without patient awareness or an instruction from the health care professional that the patient would benefit from using the extra material, these types of interventions may not be as effective in helping patients to recall important information. It is of note that none of these dental studies sent information home with the patients and then re-assessed their comprehension and recall later, so it is not known if attempts to help patients recall important information last even a week past the initial treatment plan presentation. In today's digital culture, one might suggest a digital platform to deliver this informed consent information might be novel and the ease of access and availability would make patients likely to use them.

Although information about treatment options, risk, benefits and alternatives is very important to patient decision making, several studies have indicated that although patients were found to have limited comprehension of the provided information, when asked about their knowledge of the proposed treatment, they self-report a higher level of

comprehension than they likely actually have. Brosnam et al. (2009) obtained informed consent from patients undergoing 3rd molar removal surgeries. When Brosnam et al. assessed the patients on the day of surgery before their teeth were removed, 92% of them reported understanding “all of it” or “most of it” when being asked about awareness of the complications associated with 3rd molar removal surgery (Brosnam, T., & Perry, M. 2009). Additionally, 92% of the patients said they received the perfect amount of information from the oral surgeon during the informed consent process. However, when assessed, only 36% of these patients knew all the complications that had been explained to them before the procedure (Brosnam et al. 2009; Moreira et al. 2016; F. Ryan et al., 2011). Although it is beneficial to have patients feel good about their experiences at the dental office, and these results indicate that in the moment, patients felt confident of their understanding of the procedure, it is also of concern that this false confidence about the accuracy of their recall could lead to future problems. It may be that some patients are making decisions about treatment based on incomplete information, and they may not even be aware that they do not have all the facts. Importantly, patients might have made a different decision had they had a better initial understanding of the details. Moreover, patient might be more cooperative with treatment if they recall all the patient obligations presented to them and might have different expectations and reactions if faced with a rare bad outcome.

Although overall recollection of informed consent information in adult dental patients was found to be low (20-86%), it is not possible to assess the effect of the passage of time on a patient’s recollection in dentistry because there are no studies in the dental literature in which the investigators have assessed the effect of time on patient

recall of information disclosed during the informed consent procedure (Moreira et al. 2016). Although evidence from the medical literature in this area points to the idea that recall for important treatment information decreases with time regardless of the intervention used, there are differences in dental procedures that need to be considered when generalizing these results. Orthodontics differs from other dentistry due to the mainly “elective” nature of this treatment. Orthodontic patients have plenty of time to make their informed decision about treatment and need not be rushed to decide about dental treatment, as possibly a patient in the medical emergency room may feel. To improve recall, the use of repetition of information delivered over time to the patient, especially when the treatment times are as extended as they are in orthodontics, could potentially prove to be very beneficial in enhancing true informed consent and the positive effects that accompany it.

Through the literature review, it is recommended that additional media such as leaflets, multimedia, and decision boards to be added to the routine informed consent process in dentistry since these tools were found to significantly improve the patients’ understanding and recall of key information. It was found that the doctor-patient personal and verbal interaction is an important part of an effective informed consent process, but “the informed consent process in dentistry has room for improvement.” This paper suggests that one evidence-based way to do this is with the use of adjunct educational materials, along with the suggestion to the patient that they attend to the materials (Moreira et al. 2016).

Thomson et al. (2001) is the only study in the dental literature that has attempted to examine the effects of time on the recall of important informed consent information in

orthodontics (Thomson et al. 2001). This study was a questionnaire-based study in which the effectiveness of written, verbal and visual methods for providing orthodontic informed consent information were compared. It assessed the retention of this information, both in the short (10-15 minutes) and long (8 weeks) term. Twenty-eight patients and their parents were assigned into three groups and received the same information but through different methods. These methods were written (leaflet), verbal (recording) or visual (PowerPoint). The first assessment was given ten to fifteen minutes after receiving the information in one of the three methods. The second assessment was delivered via a mailed letter eight weeks later. The subjects filled out the assessments on their own time in their homes and returned the letters via mail. Overall, little significant difference was found between the three different methods, but the written information group obtained the highest scores. These findings suggest that if informed consent information is given verbally, it should be supplemented by visual and/or written information.

Unfortunately, this study had limitations in testing delayed recall. First, the questionnaire for the second assessment was sent through the mail. This allows the subjects to look up information for the test, work together with someone else, and take as much time as they need to complete the test. The assessment used a multiple-choice format and therefore it is more of a test of recognition than recall, and we would expect higher scores with the former format because recognition of a multiple-choice answer (or often times guessing) is a lot simpler than recall, which requires patients to come up with the answer all on their own. Second, the patient and parent were able to take the delayed questionnaire together and they were not able to do that at the initial assessment. Recall

that it has already been established that parents and patients may have different experiences with recall (Moreira et al. 2016). This makes the delayed responses possibly unreliable in this study because we don't know who took the assessments, as well as what additional information they used or referenced to give their delayed responses.

During the informed consent process, dentists are educating patients about an array of topics related to the treatment dentist's provide and on the patient's role in the treatment. To improve this process, dentistry can learn from studying the educational literature. In the recent years, there has been debate in the educational community on the different uses of e-learning and questions have been raised about these interventions' efficacy in improving learning. Hoffler et al. (2007) performed a meta-analysis of 26 primary studies which examined whether animation or video is superior to static photos in enhancing student learning (Hoffler & Leutner, 2007). Previously, it had been widely accepted in the educational field that student learning outcomes are improved by presenting information with both text and pictorial information in a coordinated way – the Mayer's “multimedia principle” (Hoffler & Leutner, 2007). This theory asserts that when a student is shown words and graphics together, they have a better chance of learning the information presented than they would if they were shown only words or only pictures alone. A demonstration of this principle is with the use of PowerPoint, which uses a combination of words and pictures. This modality is viewed as an effective way to teach people in the classroom. Animation or video, which is different from just static pictures, is something that provides a “mental picture” for the student when he or she is unable to imagine the motions that are depicted in the photo or described in the text. Static pictures or written words allow the students to use more of their own

imagination than a video or animation would allow (Hoffler & Leutner, 2007; Zhang et al. 2006). This interpretation of the educational stimulus by the learner can lead to more misinterpretation and error than learning with the use of video. In relation to dentistry, if you show a patient a picture of the temporomandibular joint (TMJ) and explain how it works and what could go wrong with it versus showing the patient a video of the information you are trying to describe, it is highly likely that the patient will have a better understanding of the jaw joint after the video presentation. Hoffler et al. (2007) found there to be a clear advantage to animations compared to static pictures and these advantages were found to be “educationally significant” (Hoffler & Leutner, 2007). If this is true in the classroom, it may be beneficial for dentists who are trying to educate patients about different procedures during the informed consent process.

However, it makes a difference whether the topic or area to be learned is depicted in the animation or not; the animation or video needs to be representational of the task or effort it is showing to be effective. Animation videos just for the sake of having a video do not have any added teaching effect as compared to a photograph. (Hoffler & Leutner, 2007) In relation to dentistry, a photo of a retainer on the informed consent form would be just as effective as a video showing what a retainer looks like. The educational literature would suggest that an effective video might show the patient what a retainer looks like, how to wear it, how to remove it and clean it (Hoffler et al. 2007; Zhang et al. 2006). This latter video does not require the patient to imagine these skills.

Additionally, there is evidence that suggests that there are greater benefits to the use of animation when procedural-motor knowledge rather than problem-solving or declarative knowledge is being taught. When applied to dental informed consent, this

suggests that a video of how to brush and floss your teeth with braces on would be effective use of that modality, rather than to use a video to show facts about how the braces work and move the teeth. Overall, Hoffler et al. (2007) concluded there is a substantial overall advantage of animations over static pictures (Hoffler et al. 2007; Zhang et al. 2006). If we translate this information to dentistry, it suggests that the most effective adjunct for improving informed consent recall and comprehension would be an animated video as opposed to a paper handout leaflet or the standard informed consent paper form.

Video is a rich and powerful medium being used in e-learning and it can present information in an attractive and consistent manner over time. Zhang et al. (2006) showed that learning through information technologies is gaining momentum, particularly in response to the demand for reduction in the “time-to-competency” (Zhang et al. 2006). They showed that to get people “up to speed” in a shorter amount of time, e-learning has many applications and benefits. Using PowerPoint slides and lecture videos, users can select or play a segment with minimal search time and learn at their own speed. The educational literature supports online-learning for its time and locational flexibility, self-directed and self-paced nature, and for its unlimited access to the student (Zhang et al. 2006). In an American society where people are constantly on the move, e-learning allows the learner to fit the information into their busy lifestyle. Zhang concluded that because interactive video provides individual control over content, this may lead to better learning outcomes and higher learner satisfaction (Zhang et al. 2006). Extrapolating from this information, if orthodontist were able to create a video that was online for patients and parents to watch any time, at their own pace, and at any location they desire, it may

give the patients and parents a better chance to digest all the treatment-related information and make a more educated decision about treatment.

Although there is strong evidence to support e-learning in the educational literature, this topic has not been as well studied in the medical and dental fields. A Cochrane systematic review by Ryan, Prictor, McRyan et al. (2008) found that there was low quality evidence to support audio-visual consent interventions in dental and medical settings. (Ryan et al. 2008) This review found audio-visual consent interventions may only “slightly improve knowledge or understanding” of the information given. However, these authors asserted that the quality of evidence was lacking due to small sample sizes and overall poor quality of the studies; they assert that existing studies likely do not adequately test the hypothesis that informational interventions aren’t consistently beneficial to the patient (R. E. Ryan et al. 2008). It would have clinical significance to the medical and dental fields to further research e-learning interventions to see if they can make a positive change for patients’ ability to understand and recall information important to the informed consent process; this is an area of research that is yet to be explored.

Another important concept for the application of video in the informed consent process is the lack of health-literacy among many dental patients. Campbell et al. (2004) showed that half of all Americans read at the eight-grade level or below. In addition, Campbell classified up to 44 million adult Americans as “functionally illiterate” with another 50 million as only “marginally illiterate” (Campbell, Goldman, Boccia, & Skinner, 2004). This lack of understanding of dental and medical information is problematic for health care providers because although many of the health related

education materials are designed and written for patient with a lower health literacy level to make sure all patients can understand the information, it has been suggested that over 80% of the health education materials provided to patients are actually above the average tested reading level displayed in the materials given to the patient. Alexander (2000) reported that 42% of the published dental education materials they sampled were written at the high-school level or above, and almost all materials reviewed contained jargon that would not be recognized or understood by many patients (Alexander, 2000).

In contrast to written information, video-based presentations allowed patients with low literacy levels to achieve posttest scores comparable to those of patients with higher literacy skills. When testing modifications and comprehension on recall in low-income patients, it was found that the strongest predictor of the amount recalled by the patient was the patient's reading comprehension score. To examine these findings further, when Campbell et al. (2004) statistically controlled for patient's reading comprehension, it was found that PowerPoint presentation was more effective than original print materials when subjects were prompted for recall scores. On the other hand, for the poorest readers, it was found that the modified print version containing informed consent information was more effective than the original print or PowerPoint in enhancing recall (Campbell et al. 2004). These seemingly contradictory results can be explained by noting that a document that is intended to be read and understood by most adults should be written at a sixth-grade level or lower and adults who read below the fourth-grade level might not benefit from any written material, no matter how simple or what form it is in (Campbell et al. 2004). Thus, it is very important for the practitioners to be aware of the level of reading comprehension possessed by their patients. Moreover, if patient's initial understanding of

information needed to consent to and participate in treatment is less than optimal, these patients are even more in need of adjuncts to assist their understanding and recall of important health information.

Statement of the Problem

Throughout this review of the literature, it has been shown that patients' and parents' understanding, and recollection of information presented to them during the informed consent process could use improvement. Dentists and orthodontists have a legal and ethical duty to completely educate and inform their patients about the treatments they may undergo, and the profession must seek new ways to try and improve this process.

With the success shown by research in the educational field using animations and video, as well as technological improvements in enhancing learning associated with e-learning, it may be helpful to dental patients to try to use these new technologies to improve the informed consent process. This study will examine the efficacy of an electronically delivered educational adjunct by creating a narrated PowerPoint that reinforces key informed consent information. A link to this PowerPoint will be emailed to patients and parents of orthodontic patients to view on their own. Immediate and delayed recall and comprehension will be assessed using items from the American Association of Orthodontics standard informed consent form. Past studies suggest that patients will have difficulty recalling key information both immediately after, and at a week after presentation, and that the failure to recall important elements of the informed consent presentation will be more marked at one week. The emailed intervention should increase both comprehension and recall of informed consent information.

METHODS

Subjects

The inclusion criteria for the study specified that subjects had to be a guardian of a minor patient at either a university or private orthodontic clinic practice in Southeastern Wisconsin. Participants were recruited while they waited for their minor child to receive treatment. Approximately 70 subjects were approached to participate in the study, and approximately one-half of the adults invited to participate agreed to be part of the study (N = 35). This research was approved by Marquette University's Institutional Review Board for the Protection of Human Subjects Office of Research Compliance (Protocol Number: HR-1709019113).

In summary, potential volunteer participants were told that the study involved two parts, that their participation in the study was strictly voluntary, and there was no financial benefit or reward for participating in the study (Appendix A). They were also informed that they could withdraw from the study at any time and that their minor child's orthodontic care would not be affected in any way by their decision to participate. All adult guardians accompanying an underage patient were invited to participate except for those who did not speak or read English or who had psychological or cognitive disabilities that would prevent them from understanding the informed consent agreement. In addition, since this study required subjects to view a narrated PowerPoint delivered by email to a valid email address and subsequently take an assessment administered over the telephone, subjects who did not have access to a phone, email, or internet were also excluded from participation.

In total, thirty-five participants were recruited for the study; fifteen of the subjects were assigned to the group receiving the intervention, and seventeen subjects to the control group, who received no additional educational reinforcement after the initial informed consent presentation. Approximately half of the participants in the study were recruited from the university orthodontic clinic and half were recruited from an orthodontic private practice in southeastern Wisconsin. Data from three subjects were excluded from the final analysis: two participants were excluded because they could not be reached for a follow-up phone call, and one subject was excluded because of a procedural error (i.e., Although the guardian agreed to participate, a manipulation check revealed that the subject had not watched the PowerPoint video).

When considering the age of the participants, guardians accompanying their minor orthodontic patients can be divided into two groups, parents (N =29) and grandparents (N = 3). There were 29 parents of minor children who agreed to participate in the study; there were 16 mothers and 13 fathers who ranged in age from 23 to 60 years old with an average age of 43 years of age for this group ($\bar{M} = 43$; $SD = 10.7$). Of the three grandparents who participated in the study, two participants identified as female and one as male ($\bar{M} = 72$, $SD = 5.18$). All the subjects in the study identified as white, except for two participants who identified as Latino. Educationally, one subject reported having had some high school credit but no high school diploma, and two others in the sample did not receive any additional education after graduating from high school. The rest of the sample all indicated that they had additional education after high school, with 60% of the sample (N =19) reporting having a bachelor's degree or higher. Twenty-eight of the subjects (88%) reported they were currently employed, one person was out of work

and looking for work, two participants were homemakers, and one was retired. Thirteen subjects (40%) had previous orthodontic treatment in their own life, and 18 subjects (56%) have had a child who experienced previous orthodontic experience.

To assess for uneven distribution of potentially confounding factors to either the traditional care group vs. the electronic educational intervention group, crosstabs matrices that examined the distribution of several relevant demographic and experiential factors were constructed and whenever possible; Cohen's Kappa statistic was computed to examine a measure of agreement. Appendix B contains crosstabs data for patient's gender, ethnicity, education, marital status, employment status and the patient's/minor patient's experiences with previous orthodontic treatment sorted by these variables assignment to the no intervention and educational enhancement conditions. A review of these data indicates a single significant result; there were more participants who reported orthodontic experience in the group that didn't receive the narrated PowerPoint. Finally, the subject's occupations were categorized using the Hollinghead's Occupation Scale and an analysis of this data shows that a diverse group participated in the study. This data can be viewed graphically in Appendix C.

Materials and Setting

The subjects who were assigned to the electronic educational intervention group received a link to a narrated PowerPoint video within 24 hours after the original meeting. The video was designed to reinforce information that was presented in the first session and the subject was told that they could access the narrated PowerPoint any time over the course of the next seven days. Information used for the fictional case and PowerPoint was adopted from a published case in the Journal of Clinical Orthodontics (Janson et al. 2011;

Appendix D) and selected information abstracted was from the American Association of Orthodontics (AAO) informed consent form (Appendix E) with their consent. This form was chosen because the AAO is an established professional organization for orthodontists, and their standard informed consent form is likely representative of the type of information that is usually given to patients in orthodontic practices.

Each subject received the same treatment plan presentation and informed consent process. The records included facial and intra-oral photos, x-rays, and pictures of dental models. The narrated PowerPoint video consisted of a total of 12 slides, was 5 minutes in length, and was narrated with a female voice. The video described similar topics to what was reviewed in the original informed consent process such as what treatment was involved, the length of treatment, the patient's role in treatment, discomfort, orthodontic relapse, oral hygiene, root resorption, jaw pain, and complications associated with third molars. The subjects were also instructed that they could view the additional information as many times as they desired.

With the help of an informatics faculty member, unique Internet links for each participant were designed and individually emailed to each subject in the group receiving the educational intervention. At the end of the study, the principal investigator examined each unique link to make sure the link was opened. Information on how long, or how many times the link was used was not available to the investigator.

Design

All subjects were assigned to two groups in an alternate order at the start of the study, the standard care informed consent group and electronic educational intervention group, which received the PowerPoint presentation to augment their understanding

(Table 1). The study was designed to be analyzed with a 2 x 2 repeated measure analysis of variance (ANOVA).

At the initial visit, Time 1, the subjects in both groups were given the same information and were treated identically. After being given the informed consent information, both groups were given the same assessment and the results were recorded (Appendix G). This design allowed 1) each subject to be used as their own control and 2) assessment of how much and what information people forgot over time and 3) assessment of if the electronic educational intervention (the narrated PowerPoint video) enhanced recall in anyway.

Within 24 hours of the first visit, the subjects in the electronic educational intervention group received an email (Appendix H) with a unique link to the PowerPoint video, while the subjects in standard care control group received no email or no additional information about the study. In 7 days, the participants in both groups were called by phone (Appendix I) and were verbally given the same assessment they received at Time 1 (Appendix G).

Table 1: Group Design

	Time 1	Time 2
Control	Control: Traditional Care	Control: Traditional Care
Intervention	Intervention: Traditional Care Receive Electronic Educational Video within 24 hours	Intervention: Electronic Educational Intervention

Procedure

Subjects were approached in the waiting room and invited to be in the study. Parents were told that they would be pretending to be the parent of a fictional child, Jimmy, who needed orthodontic care, and that the author would be describing a treatment plan for Jimmy including information about the benefits, risks, cost, time required and patient responsibilities for treatment. Subjects were asked to agree to be tested on this information twice, once after the presentation (on the day they were recruited) and once over the phone, a week later. Subjects were also told that they might be contacted via email (Appendix H) within one week of the original meeting. The script (Appendix A) describes the information that was given to the participants. All guardians agreeing to participate in the study were given a copy of the informed consent form to sign (Appendix J) and their questions were answered.

An informed consent for a mock orthodontic case was presented to the participant and their questions about the case were answered. A short assessment about the case was then presented to the participants along with a demographic survey (Appendix K), which included questions about the participant's age, education and occupation. All subjects supplied their email address and phone number and agreed to be contacted by the primary investigator again. Depending on the subject's assignment to the traditional care control or the electronic educational intervention group, the subject received an email with a unique link to a video (Appendix H). The participants in the intervention group were asked to view the approximately five-minute narrated presentation during the week before the phone call from the investigator. A female voice narrated the video, which described several topics relevant to risks, benefits, and procedures for treatment. The

twelve-item PowerPoint included information on the length of treatment, the patient's role in treatment, discomfort, orthodontic relapse, patient's responsibility for oral hygiene, root resorption, jaw pain, as well as third molars (Table 5). Participants were instructed that they could view the presentation as many times as they desired and that at the completion of the study, the researcher would be able to see if they opened and viewed the video online. The subjects in the control group did not receive an email or any additional information after the original meeting.

One week after the original meeting, all participants were called on the phone by the principal investigator and the same thirteen-question assessment that was administered after the initial treatment planning presentation of the mock case was given a second time (Appendix G). After this final assessment, all subjects were thanked for their effort and time.

Dependent Measures

To assess subject's recall and comprehension of the informed consent information in the mock case, the principal investigator administered a thirteen-item assessment after the first and second encounters with all participants (Appendix G). Participants were also given a ten-point Likert scale, ranging from 1 (highly likely) to 10 (highly unlikely), and asked to indicate their willingness to agree to treatment for the fictional child. Finally, the participants filled out a demographic survey seeking information about their age, ethnicity, education level, marital status, employment status, and occupation (Appendix K), and whether they or their child had ever received orthodontic treatment before.

The thirteen areas that were included as part of the assessment for this study corresponded to key items on the American Orthodontics Association informed consent

form. Since obtaining true informed consent requires a guardian to understand the risks, benefits, treatment options and patient responsibilities, the areas examined in the questions were the reason for wanting treatment, different treatment options, length of treatment, frequency of appointments, the type of treatment that will be done, factors effecting the results of treatment, factors affecting the length of treatment, retention, oral hygiene, root resorption, jaw pain, third molars, discomfort during treatment, and the option of no treatment.

The best possible total test score was 25 points and included questions that required both recall, along with true-false items. Each question had a different point value depending on the type of question that was asked. For example, a correct answer to a True/False question was only worth one point. A question about the possible effects on the results of treatment had four possible acceptable answers (Four reasons that had been disclosed from the AAO informed consent form), with each correct answer being worth a point, allowing the subject to potentially receive four points for this one question if they could correctly identify all of reasons that were given during the informed consent presentation. The questions were not weighted relative to the importance of the subject; rather, a point was given for each possible acceptable answer given. Of the thirteen questions asked, all assessed patient recall and seven questions additionally assessed patient comprehension (Table 2). Question numbers 2, 4, 5, 6, 8, 9 and 10 assessed the subject's comprehension because the subject not only had to retrieve the information they were told, but also to some extent, explain the information in their own words.

Table 2: Questionnaire Assessment of Comprehension and Recall

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13
Recall	X	X	X	X	X	X	X	X	X	X	X	X	X
Comprehension		X		X	X	X		X	X	X			

Planned analyses and the information they would yield included the following: 1) Examining the regular treatment and control test scores at the start of the study will reveal pre-intervention differences between the two groups; 2) Examining test scores at the first visit will reveal how much patients understand and recall after a standard informed consent discussion; 3) Examining differences between the group who received the intervention and those who did not will indicate whether the narrated PowerPoint had any effect on subjects' delayed recall and comprehension; 4) by observing the differences and possible interaction between all four groups, this design will assess what a patients' comprehension and recall of information is immediately after an informed consent presentation and how the recall changed over one week's time, and if an electronically viewed and delivered take home video presentation had any effect on that recall; 5) Finally, by examining whether subjects in the intervention group actually viewed the narrated PowerPoint, the study can demonstrate that an electronically delivered presentation is something parents of patients are interested in having for their child's orthodontic treatment. Additional information that can be gathered from this study include qualitative and non-parametric analyses of test items to learn which items are more likely to be recalled by subjects at both testing.

RESULTS

To examine the effect of the narrated PowerPoint on patient recall and comprehension one week after an informed consent presentation, a 2 (Week 1 vs. Week 2) x 2 Intervention (Narrated PowerPoint vs. Traditional Care) repeated measures Analysis of Variance was conducted on subjects scores on the test of comprehension and recall. This analysis revealed no significant main effects for time or the electronic educational intervention, but a significant interaction effect for Time x Intervention, $F(1, 30) = 7.89, p < 0.05$ (See Table 3). Post-hoc paired comparison tests of participant's test scores indicated a single significant pair-wise comparison using a Student's t-test, $t(16) = 3.1, p < .01$. These results indicate that watching the narrated PowerPoint did assist with patient comprehension and recall on details from the mock case, and that recall and comprehension significantly decreased over one week's time if the participant did not receive the additional reinforcement of that information during the week.

Table 3: Means, Standard Deviations, and Number of Participants for Each Group

	Time 1	Time 2
Traditional Care	17.76, (2.08) N = 17	15.47, (3.50) N = 17
Electronic Educational Intervention	17.60, (2.82) N = 15	18.40, (3.16) N = 15

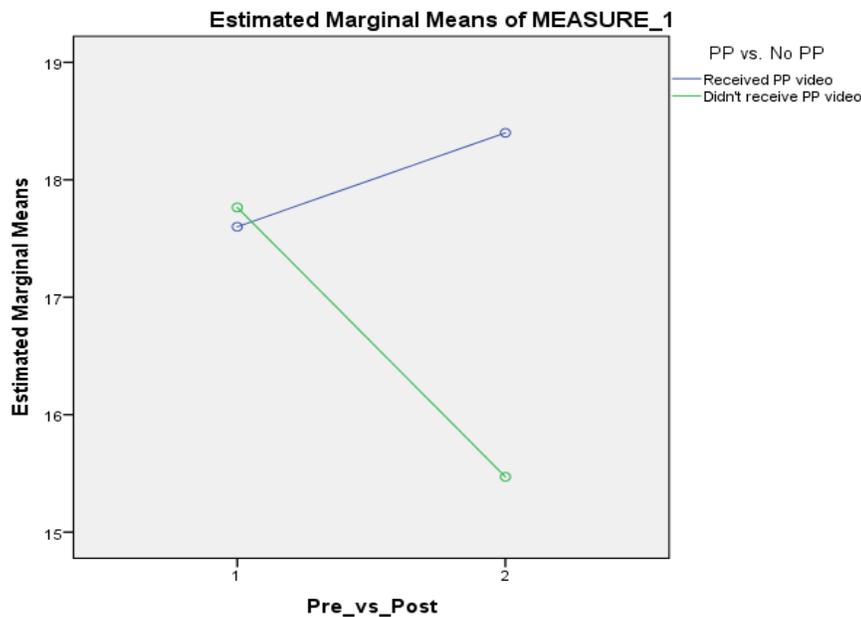
These results can be seen in the means table shown in Table 4 and are graphically presented in Figure 1. A closer examination of the test scores (Table 4) revealed that as expected, at the initial visit, the average scores for the electronic educational intervention

group and the traditional care group were very similar, traditional care, $\bar{M} = 17.76$; SD = 2.078; electronic educational intervention, $\bar{M} = 17.60$, SD = 2.823. Recall that these two groups were alternately assigned, and not treated differently, so as expected, these scores did not significantly differ. As expected, after a week, the group that did not get the narrated PowerPoint had their average score decrease by 12.89% to 15.47 (SD = 3.502). Conversely, the group that received and viewed the narrated PowerPoint presentation showed an average assessment score of 18.40 (SD = 3.16), indicating an increase of 4.54% from the baseline measure. The graph in Figure #1 demonstrates the change in scores.

Table 4: Analysis of Variance Summary Table for the Effect of Time and Educational Intervention on Parents' Comprehension and Recall of Informed Consent Information

	Sums of Squares	Degrees of Freedom	Mean Square	F value	P value
Time	8.895	1	8.89	1.84	0.19
Intervention	30.46	1	30.46	2.46	0.13
Time x Intervention	38.15	1	38.15	7.89	<.01
Error	144.96	30	4.83		

Figure 1: Mean Total Recall and Comprehension Scores for Informed Consent Information Immediately Following Presentation at 1 Week With and Without Electronic Educational Intervention



Analysis of individual test items

An analysis of individual test items revealed considerable variability in test scores among subjects, suggesting that there is room for improvement in helping patients understand and recall informed consent information (Table 5). The assessment looked at multiple areas of informed consent information including: reason for treatment, treatment options, treatment length, treatment procedure, effects on treatment results, effects on treatment time, retention, oral hygiene, root resorption, TMD, 3rd molars, discomfort with braces, and the no treatment option. When observing what subjects recall and comprehend from the standard informed consent procedure immediately following the delivery of information, the assessment results from all participants at the first visit indicates that the highest score obtained on the assessment was 22 points out of 25

possible points (88%) and the low score on the test was 13 out of 25 possible points (52%). At the second contact with the patients in the traditional care group, the high score was a 20 out of 25 possible points (80%) and the low score was 10 out of 25 possible points (40%). In comparison, at the second contact for the electronic educational intervention group, the high score was 23 out of 25 possible points (92%) and the low score was 11 out of 25 possible points (44%). A graphical analysis of the above information can be seen in Figure 2. These results were expected because people tend to forget information over time unless they are helped in some way.

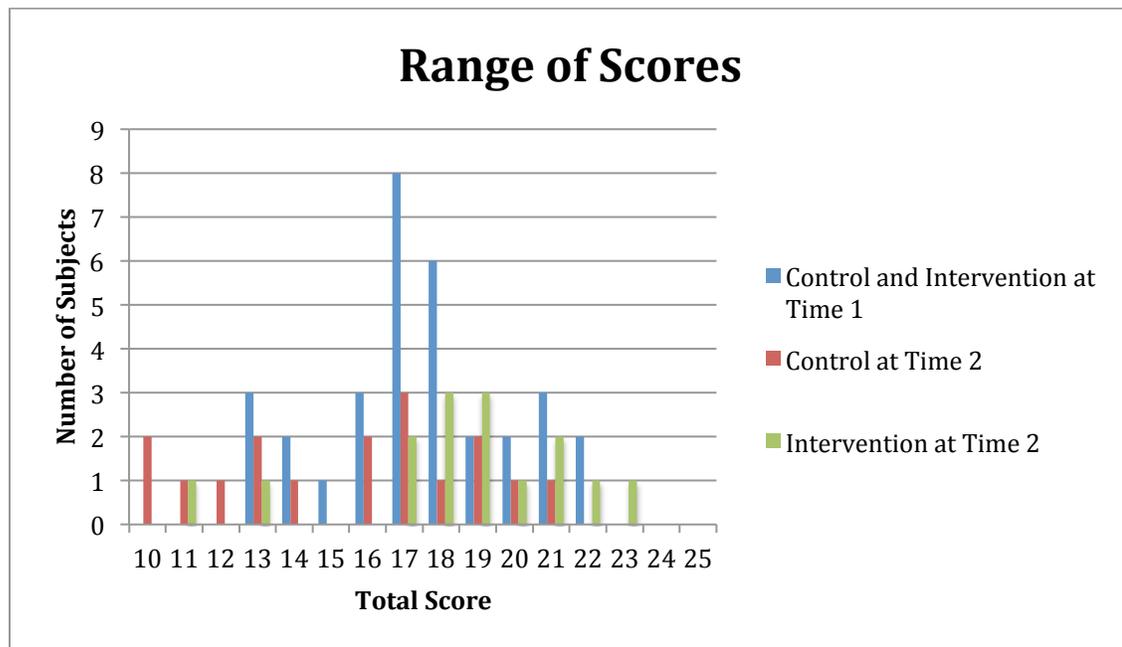
Table 5: Informed Consent Recall and Comprehension Assessment Description, Significance, Statistical Test, and Statistical Interpretation

Question Number	What was Assessed	Significance	Test Used	Interpretation
1	Reason for treatment	N too small Not Tested	Chi-Square	
2	Treatment Options	Not Significant	Chi-Square	
3	Treatment Length	Significant; p ≤ 0.05	Chi-Square	Subjects in the control group were more likely to remember treatment length
4	Treatment Procedure	N too small Not Tested	Chi-Square	
5	Effects on Treatment Results	Not Significant	Wilcoxon Signed Ranks	
6	Effects of Treatment Time	Significant; p ≤ 0.05	Wilcoxon Signed Ranks	Subjects in the intervention group were more likely to remember the effects of treatment time
7	Retention	N too small Not Tested	Wilcoxon Signed Ranks	
8	Poor Oral Hygiene Effects	Not Significant	Wilcoxon Signed Ranks	
9	Root Resorption	Not Significant	Chi-Square	
10	TMD	Not Significant	Wilcoxon Signed Ranks	
11	3rd Molars	N too small Not Tested	Chi-Square	
12	Discomfort/Pain With Braces	N too small Not Tested	Chi-Square	
13	No Treatment Option	N too small Not Tested	Chi-Square	

At the first meeting, both traditional care and electronic educational intervention groups tested similarly with an average total score for the 32 subjects of 17.54 out of 25 possible points, or a 70.16%. For questions assessing reason for treatment, treatment options, retention, 3rd molars, and discomfort with treatment the participants scored an average of 95% or higher. For questions assessing retention and the no treatment option, parents scored perfectly, 100%. Questions assessing treatment length and treatment procedure were scored 81% and 84% respectively. Questions assessing effects on

treatment results (59%), the effects of dental hygiene (58%), and root resorption (63%) all averaged above 50%. The two lowest scoring questions were questions assessing parent's recall of the effects of treatment time at 49% and TMD side effects at 41%.

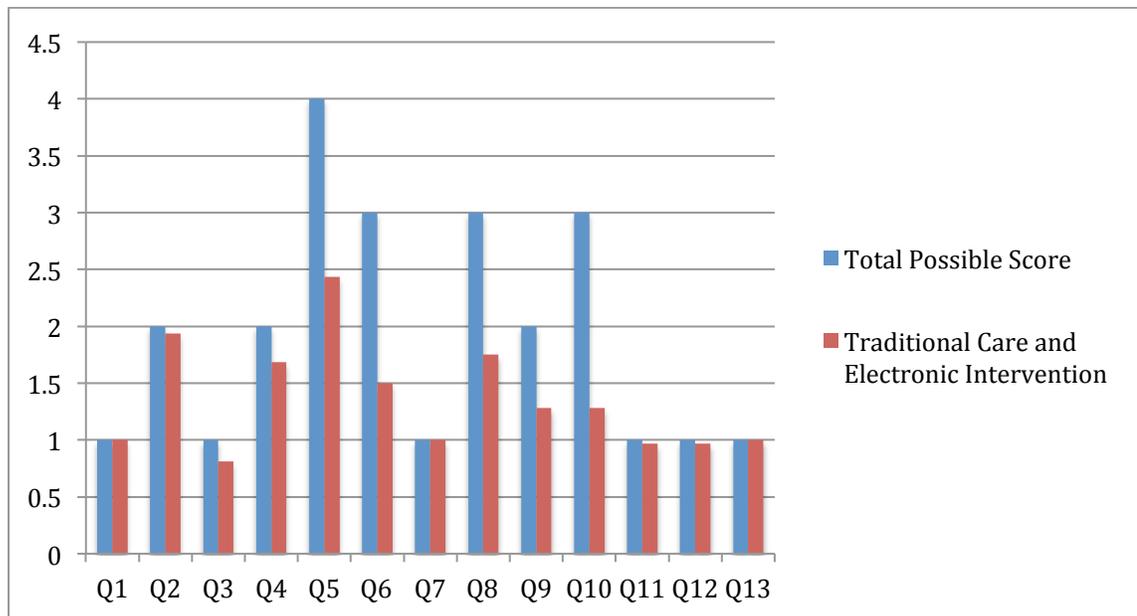
Figure 2: Range of Informed Consent Recall and Comprehension Assessment Scores for All Groups



When the scores of the traditional care and electronic educational intervention groups combined, the high score was 22 out of 25 possible points (88%) and the low score was 13 out of 25 possible points (52%). For the highest scoring questions (retention and no treatment option) the subjects were required to give a True/False response testing only recall. Conversely, the lowest scoring questions (effects of treatment time and TMD) required multiple answers and assessed both recall and comprehension simultaneously. This information can be seen graphically in Figure #3. Overall, this information tells us

there is a great variability in what subjects recall and comprehend at the initial visit and certain topics are more challenging for the parents to remember.

Figure 3: Mean Assessment Scores for both Traditional Care Group and Electronic Educational Intervention Group at Time 1, Immediately Following the Delivery of Informed Consent Information

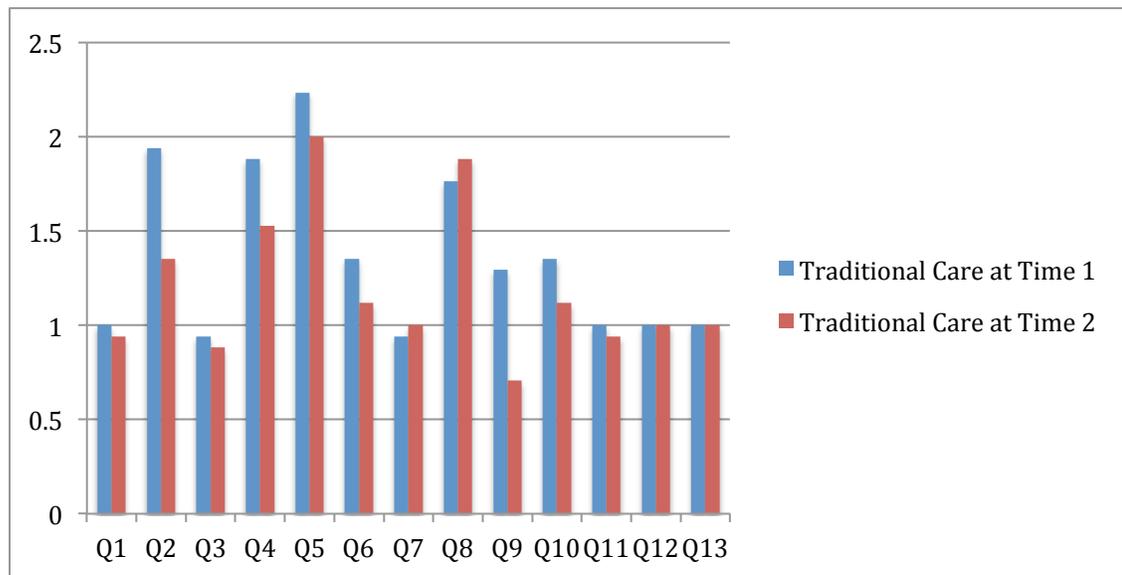


During the phone call at the second contact, the traditional care group was assessed for recall and comprehension on the details of the treatment plan presentation seven days later. This group had not received a narrated PowerPoint or any additional information about the case. On the average, these parents' scores decreased 12.89% (Figure 4). These parent's scores decreased for all questions on the test except the question assessing retention, where the score remained the same (100%) as the first assessment and for the question assessing oral hygiene where the score increased 6.85% from 1.75 to 1.87. The largest decrease in score was for the assessment of root resorption where the score decreased 45.74% from 1.29 to 0.70. Other notable score decreases for the group that

received not additional information were for assessment of treatment options, decreasing 30.9% from 1.94 to 1.34, and the question asking about the treatment procedure, decreasing 19.1%, from 1.88 to 1.52. Of the questions that did not decrease, the question on retention required a True/False response, (thus only assessing recall) and this score remained the same from first contact with the patient as when assessed a week later. The question that assessed a patient's recall and comprehension of oral hygiene care assesses information that parents and patients receive education about from many different sources (general dentists, other specialists, advertisements, etc.) and thus this information appeared to be unaffected by the seven-day delayed assessment.

Interestingly, a Chi-Squared test indicated a statistically significant ($p \leq 0.05$) difference between the traditional care group and electronic educational intervention group for the question assessing treatment length (Table #5). The traditional care group was more likely to remember how long orthodontic treatment was expected to take than the electronic educational intervention group. It should be noted the statistical testing associated with the individual questions should be interpreted with caution due to the small number of participants included in the study and therefore many individual analyses could not be conducted.

Figure 4: Average Assessment Scores for Recall and Comprehension of Informed Consent Information Immediately After Presentation (Time 1) and After 7 Days Without Intervention (Time 2) for the Traditional Care Group

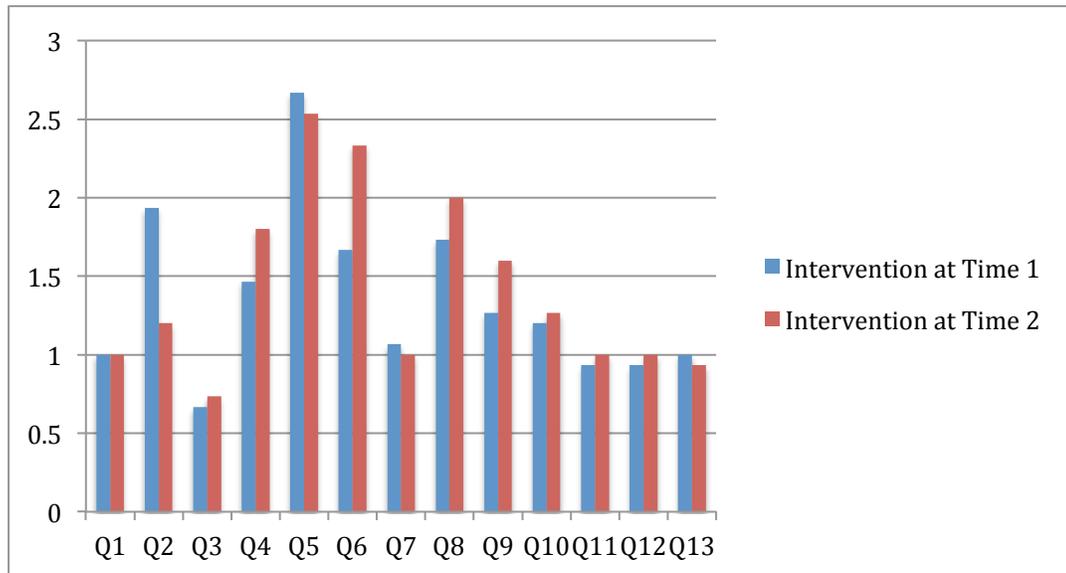


Recall that the electronic educational intervention group received an email with the narrated PowerPoint presentation within 24 hours of the original meeting with the experimenter, and one week later, these subjects were reassessed for their recall of the pretend treatment plan. Overall, the scores for this group increased 4.54% on average. All mean scores for these participants increased except for questions about treatment options, the effects on treatment results, and the no treatment option. The questions assessing the reason for treatment and retention remained the same for this group. It is of note that the question assessing retention received 100% correct answers for all four groups and was not missed by any subject, so there was a ceiling effect for this question. The question that assessed recall and comprehension of different treatment options decreased 73%, from 1.93 to 1.20. The question that assessed recall and comprehension of the effects on results of treatment for this group decreased, on the average, by 13.3%. The question assessing recall of “treatment vs. no treatment” decreased 6.67% (it was missed by one

person). Questions assessing information about treatment length, TMD, 3rd molars, and discomfort with braces all increased 6.67% for the group. The question assessing information about the treatment procedure increased by 33.3% for the group, while the questions assessing oral hygiene and root resorption both increased 26.7%. Note that these scores indicated that these participants remember more after the intervention and that all these questions assessed both recall and comprehension.

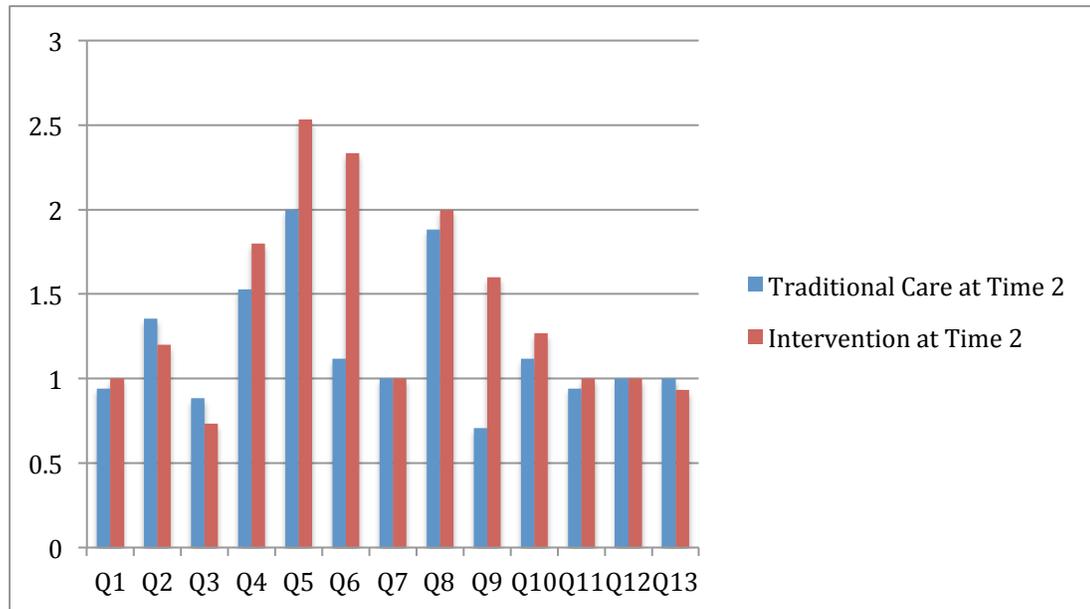
Using a Wilcoxon Signed Rank Test, T ($Z = -2.64, p \leq 0.05$) the question that assessed participant's knowledge about the effects of treatment time indicated a statistically significant increase from the first meeting to the second contact, which was the assessment that occurred after they viewed the PowerPoint. Parents in this group showed a mean increase of 66.7%, reflecting an increase from 1.67 to 2.34 (Table 5). It appeared that questions that assessed both recall and comprehension tended to increase over time with the use of the narrated PowerPoint, while the questions that only assessed recall tended to remain the same. This data can be seen graphically below in Figure #5.

Figure 5: Average Assessment Scores for Recall and Comprehension of Informed Consent Information Immediately After Presentation (Time 1) and 7 Days Later (Time 2) With Narrated PowerPoint Intervention



When comparing the traditional care group vs. the electronic educational intervention group, the latter group scored higher on all questions except for items assessing treatment options, treatment length, and no treatment options where the scores were between 6.67% to 15.0% higher for the traditional care group. The question assessing effects on treatment time was 121.6% higher for the electronic educational intervention group. Questions assessing effects on treatment results and root resorption were 53.3% and 89.4% higher respectively, for the electronic educational intervention group. All other scores were between 5.9% to 27% higher for the electronic educational intervention group. This data can be seen in Figure 6. The results indicate that overall, on items that require both recall and recognition after one week, the electronic educational intervention group outperformed the traditional care group.

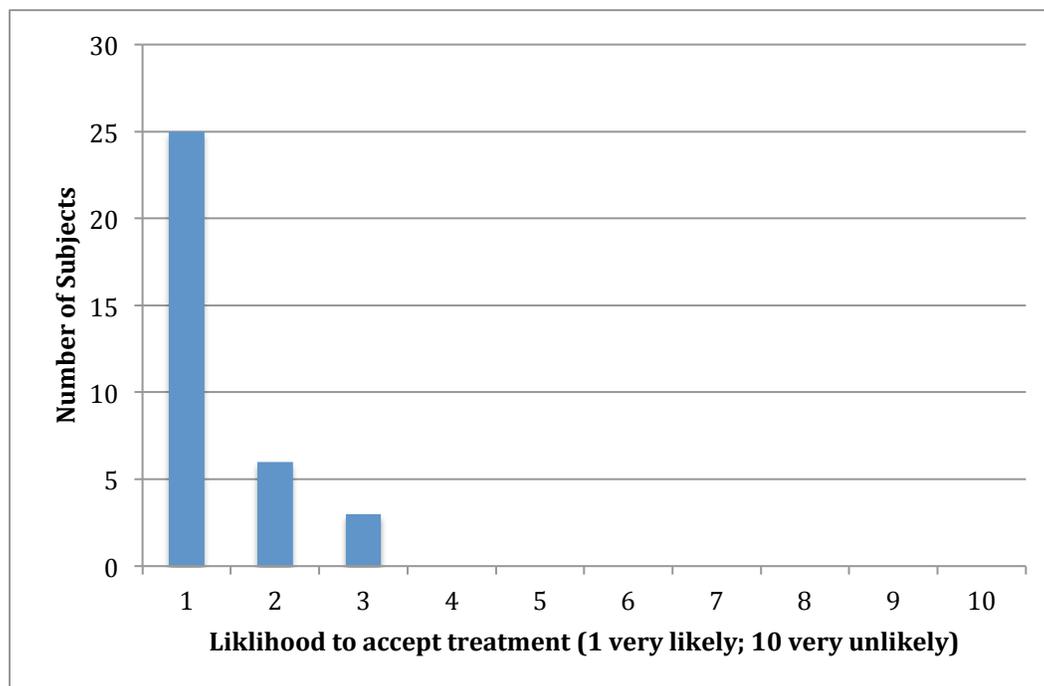
Figure 6: Mean Assessment Score of Recall and Comprehension 1 Week Following the Initial Informed Consent Delivery for Traditional Care and Intervention Groups



Willingness to agree to treatment

At Time 1, both the traditional care group and the electronic educational intervention group were assessed on a ten-point Likert scale, asking them about their willingness to accept or deny treatment for the fictional patient. On a scale of 1-10, with 1 being highly likely to accept treatment and 10 being highly unlikely to accept treatment, 25 out of the 33 subjects, or 75.8%, provided a rating of “1” on the scale as a “1.” Six out of 33 participants (18.1%) indicated a rating of “2”, and 2 participants out of 33 (6.10%) provided a rating a 3. There were no scores higher than a 3, indicating that all patients in the study would have authorized treatment for the mock child patient, despite evidence that some patients were not able to recall all the details that were provided in the informed consent discussion.

Figure 7: Likert Scale Scores for Likelihood to Accept Treatment for both Traditional Control Group and Electronic Educational Intervention Group Immediately Following Informed Consent Information Delivery



DISCUSSION

This study demonstrated that patients do not recall all the important details of an informed consent presentation when recall is assessed immediately following the disclosure of this information (70% of the details were recalled). Moreover, there is evidence that recall gets poorer over time if nothing is done to help the patient remember. At the initial meeting, subjects were most likely to not recall or comprehend what they were told about predicted treatment time as well as causes and possible consequences of TMD. Most importantly, and consistent with previous research, the present study shows that an easily accessible narrated PowerPoint was able to improve recall and comprehension of information presented during an informed consent presentation, rather than have the patient's recall decrease over time, as it did with the traditional care group (Brons et al. 2009; Campbell et al. 2004; Moreira et al. 2002; Schenker et al. 2010).

This study also showed that by using a widely available and inexpensive electronic learning aid, parents of orthodontic patients could increase their recall and comprehension of the details of a child's informed consent presentation over time. This increased recall and comprehension could potentially prove to be very beneficial to many patients, parents and orthodontic practitioners since it is likely to improve patient understanding, compliance and participation in their own treatment.

At the first meeting with the experimenter, the traditional care group and the electronic educational intervention group's recall and comprehension scores were very similar and some questions yielded very high scores, indicating that parents remember and understood some pieces of information after the presentation. Parents did well on questions that identified the reasons for treatment (question #1) and the alternative

treatment options (question #2) for the mock patient. These questions assessed key parts of the informed consent process: what issues treatment will address and the viable options available to the mock patient to correct his orthodontic concerns. This assessment of the reasons for treatment appear to be something parents focus on during the initial treatment plan presentation and is something orthodontists can expect the parents of their patients to pay close attention to. Interestingly, the question that assessed the patient's recall of the long-term effects of orthodontic treatment and the potential for relapse of tooth position received a 100% correct response rate. These data suggest that many patients seeking orthodontic treatment are aware of the potential for orthodontic relapse. This finding is contrary to the research by Mortensen et al. (2003), who found that patient recall of the need for retention following orthodontic treatment was very low in the population they studied (Mortensen et al. 2003). A potential distinction between these two findings could be that in the present study, the assessment instrument asked if subjects recalled whether the results of orthodontic treatment are guaranteed for life and Mortensen et al. (2003) specifically assessed the need for retainers to maintain the orthodontic correction.

For all participants at the first assessment, the question examining the effects of behavior on treatment time (question #6), and the question regarding TMD (question #10), were the two lowest scoring questions on the test and the only two items that fell below the 50% correct response rate (these two items require both patient recall and comprehension of these topics to answer them correctly). Many orthodontists are aware that the actual treatment time extending past the pre-treatment estimate is an eventuality that all practitioners encounter during their career, and many times the need to extend

treatment is related to patient non-compliance. It is of note that two of the three possible answers to this question apply to poor patient compliance (i.e., patient not following the directions they are given or poor oral hygiene) along with a third option, which involves a patient's unexpected growth. The present data indicated that this important information was not effectively passed along to the parent during the informed consent discussion, and if it had been, it could prevent future problems for the patient and the orthodontist down the road in treatment.

Along the same line, the question that assessed TMD (question #10) demonstrated a lack of recall and comprehension on the participant's part as it applies to potential jaw pain during treatment. Although orthodontic treatment does not cause or prevent TMJ disorders, it can arise during treatment and can cause a lot of confusion for patients and parents during treatment. It may be that these potential complications were not recalled or comprehended by the subjects because these problems appear unlikely and if they happened, were far in the future and thus, did not appear relevant to immediate decisions that were being made.

We hypothesized the electronic educational intervention group recall and comprehension assessment scores would increase over time while the traditional care group scores would decrease over time. Additionally, it was expected that the traditional care group scores would be the lowest out of any group. We found that indeed, the narrated PowerPoint group's recall and comprehension assessment scores were higher than the traditional care scores, and the traditional care group scores were the lowest score out of all four groups. As several other researchers have suggested (Mortensen et al. 2003; Schenker et al. 2010; Thomson et al. 2001), as time passes, people forget more and

more information about the ongoing treatment. The goal of this study was to find a way to diminish the amount of information that patients or parents forgot over time. In line with expectations, the traditional care group, who went seven days without any additional information about the informed consent process, showed a decrease in their recall and comprehension as evidenced by their lower assessment scores, which were the lowest scores of any group in the study. In contrast, the group who received the narrated PowerPoint evidenced an increase in their comprehension and recall assessment scores over the seven days. By providing parents information to review once they are out of the clinic on any device that can stream a narrated PowerPoint, such as a phone, tablet, or computer, they could potentially remember more of the information delivered at the initial exam appointment. This would greatly benefit the patients and parents due to better awareness of treatment, risks and complications. Additionally, it benefits the orthodontist because they can be more confident that their patients have an accurate understanding of the material they provided, as well as possible decreased time reviewing information at appointments. Finally, it could potentially motivate better compliance from patients throughout treatment.

Another hypothesis that this study investigated was that if parents of patients were supplied with an easily accessible electronic educational aid, they would be willing to use it. As would be predicted from the increase in use of portable electronics (Andrews et al. 2015), all the subjects in the intervention group opened the link to view the narrated PowerPoint except for one subject. This demonstrates the viability of using an easily accessible electronic-based application to enhance patient understanding since most participants who received a link to a video were willing to open the link to view it.

After seven days, the traditional care group scores decreased on average 12.89% and decreased on all questions except for the questions assessing information about orthodontic retention (question #7) and issues related to oral hygiene (question #8). The question assessing retention remained the same at a 100% correct response rate at both assessments, reaffirming the idea that patients understand that orthodontic correction is not guaranteed for life without retainers after treatment, and this is likely something that parents may know when seeking orthodontic treatment for their children. The question assessing the effects of poor oral hygiene (question #8) was the only question with a score increase; this item reviewed what happens to the gums and teeth when patients don't brush or floss during orthodontic treatment (i.e., cavities, gum disease, and discoloration of teeth). An explanation as to why this score would increase over time without intervention is that this information is reinforced for the patient in many places, from their general dentist, dental hygienist, school nurse, as well as numerous advertisements that patients are exposed to daily. Given a second opportunity to answer the question, some subjects appeared to be able to revert to knowledge they have gained in other instances and answer the question more accurately.

The largest decrease in a score for an individual item within the traditional care group after one week was the question assessing the parents' comprehension and recall of the potential complication of root resorption during treatment (question #9). The data suggests that when presenting the parent with a rare potential complication of treatment it is not something that is remembered long term by the patient. This is consistent with the results of previous studies where Mortensen et al. (2003) found the parents only recalled root resorption as a potential risk of orthodontic treatment 24% of the time (Mortensen et

al. 2003). This can present a potential source of confusion for the parent and patient as well as a problem for the orthodontist when the eventuality of root resorption arises within their practice. Another notable decrease for the traditional care group at Time 2 was the question assessing alternative treatment options (question #2). This suggests the parents of orthodontic patients do remember the treatment plan selected for the patient but do not remember the alternative treatment plan presented to them at the initial consultation. One possible explanation for this finding may be that when parents receive so much information at one time, they must prioritize the information that they need to remember, and it appears the alternative treatment options are something they “push to the side.” Interestingly, it was found the traditional care group at Time 2 was statistically significantly more likely to remember estimated treatment length (question #3) than the electronic educational intervention group at Time 2. This unexpected finding may have happened because when considering the number of items about treatment that these parents had to remember, the traditional care group participants may have prioritized remembering the estimated treatment time as an important item to recall, more so than the narrated PowerPoint group did, and thus, members of this group more easily recalled this item at the second assessment without receiving any additional information.

As predicted by the previous literature, participants who received additional information in the form of a narrated PowerPoint showed statistically significantly higher overall scores on the test of recall and comprehension after a seven-day delay than they did immediately after the treatment plan presentation. In fact, receiving the information a second time and in a different format that may have been more salient to the participants, and allowed one participant to obtain the highest score of any subject tested at either

time. However, there was some variability in responding and some subjects did not improve their performance at the second assessment. It is presumed these subjects may have opened the link to the narrated PowerPoint but may not have carefully attended to it. It is promising that patient's performances in the intervention group were enhanced by the additional information but is concerning that participants were not able to get a perfect score on an assessment that contained critical items of information needed for true informed consent. This finding suggests that Orthodontists should be concerned that many patients do not understand all the information given to them during the treatment plan presentation, and additional reinforcement of key information is likely to be needed over time. However, even with additional information from multiple sources, parents and patients will not recall and comprehend all the information given to them. Repeated presentations may be a useful adjunct.

Participants who received additional information via an emailed narrated PowerPoint presentation, on average, evidenced higher scores on a test of recall and comprehension. The question assessing recall about the reasons for treatment for the pretend patient (Question #1) as well as the question assessing retention (question #7) remained the same over both weeks. The question assessing recall of retention gain received a 100% correct response rate and was not missed a single time for any group in the entire study. This strongly suggests parents of potential orthodontic patients are acutely aware of the fact that orthodontic correction of tooth alignment and occlusion are not guaranteed for life. It also suggests they pay close attention to this information at the initial appointment. Like the traditional care group, the scores for the question assessing different treatment options (question #2) decreased for the narrated PowerPoint group

over time, however, it decreased by a greater margin than it did in the traditional care group. This suggests that over time, parents forget the alternative treatment options presented at the treatment plan appointment or they see the alternative treatment options as irrelevant once a different treatment option has been decided upon, and no longer recall these options.

Parent's responses to the question which assessed recall and comprehension of what could make orthodontic treatment time extend longer than anticipated (question #6), had a statistically significant increase ($Z = -2.64, p \leq 0.05$) in assessment scores between week one and week two for the intervention group. Interestingly, this question examined the important information about factors that could extend orthodontic treatment times and had the second lowest overall recall and comprehension score for both the traditional care and electronic educational intervention groups immediately after the initial information delivery. This suggests a take home informational narrated PowerPoint could help parents and patients better comprehend and remember the things that could increase treatment times well past the first visit. Having patients remember this information could decrease a lot of confusion when treatment does extend longer than anticipated. Additionally, from the orthodontists' perspective, if you treat a more educated patient, it increases the likelihood they will follow directions given during treatment and potentially decrease the rate of patient non-compliance.

In addition to the recall and comprehension assessment following the treatment plan presentation and informed consent information delivery at the initial visit (Time 1), both the traditional care group and the electronic educational intervention group were asked to indicate their willingness to accept treatment for the mock patient. Patients

indicated their responses on a Likert scale of 1-10, with 1 being “highly likely to accept treatment” and 10 being “highly unlikely to accept treatment.” Almost all subjects reported they would be highly likely to accept treatment, while a small fraction deviated slightly from “highly likely” to “likely.” No subjects indicated that they were unlikely to accept treatment. The data suggests that even after a lengthy informed consent discussion explaining all the risks of orthodontic treatment, length of treatment, and possible complications, parents of potential orthodontic patients are not deterred by potential consequences and still strongly desire orthodontic treatment for their child. It also indicates that patients may consider starting treatment even when they may not be able to recite all of the side effects associate with the elected treatment.

Demographic Data

Crosstabulation analyses for our demographic data demonstrated that except for endorsing an item that indicated that the participant had experience with orthodontic care, demographic characteristics were fairly well distributed between the control and intervention group. The demographic data analysis showed that significantly more parents who had prior orthodontic experience were assigned to the group that did not receive the narrated PowerPoint. It would be assumed that parents who had prior orthodontic experience would have more general knowledge about orthodontics and thus would have an advantage on the informed consent recall and comprehension assessment, yet this group still did worse than the narrated PowerPoint group.

Limitations of the study

In addition to the demographic data, there are some other potential sources of bias within the study to consider. True random assignment was not used, the sample size was

relatively small, and the assessment was administered by the principal investigator and was not masked; since there was some subjectivity in the scoring and the subject's assignments were known to the principal investigator, this is also a potential source of experimental error. Another shortcoming of this study is the informed consent recall and comprehension assessment instrument itself. The assessment was created for this study and there is no data supporting its validity or reliability in assessing recall and comprehension. Since delayed recall and comprehension has not been studied in dentistry before and no published assessment measure could be found, the direct use of content from an established informed consent document was used as the best available alternative. Importantly, it must be kept in mind this study was an analog study and although the experimental situation allowed for good control of factors affecting informed consent, it may lack ecological validity. Specifically, participant's responses may have been influenced by the artificial nature of this situation (i.e., they may have "studied" for the "test"). In addition, the potential patient in this scenario was not the parent's real child, and parent's recall may be better when it involves a family member. However, it is plausible that patients may show equal (or even more) interest in their own treatment, and it is assumed if the treatment plan was for their own child, the parents would be even more likely to view the narrated PowerPoint.

An additional limitation to this study is that we know the subjects opened the link to the narrated PowerPoint, but that is where our data stops. We do not know if they watched the video and if so, how much of the narrated PowerPoint they attended to and comprehended. It is possible that some of the subjects in the intervention group did not watch the entire narrated PowerPoint, or may not have watched it at all, after initially

opening it. However, it is very promising that such a high percentage of the parents were willing to open the video that was sent to them, and that their recall appear to be changed by this intervention. It is now in the orthodontists' hands to create a narrated PowerPoint that will keep patient's attention for the entire length of the required message.

Lastly, a limitation to the Likert Scale analysis of treatment acceptance is there was no mention of finances or treatment fee within this treatment plan or informed consent discussion. Invariably, fees play a role in the parent's final decision to pursue orthodontic treatment. However, the data above suggests that when treatment fee is not a part of the equation, the parents strongly desire their children to have orthodontic treatment.

CONCLUSION

A patient's right to autonomy in orthodontic treatment is unquestioned, but to make informed decisions, patients must comprehend and recall the information given to them. As the literature has shown, many patients have a limited understanding of the information needed to make an informed decision about treatment and they may not retain important facts when they leave the dental or orthodontic office. Additionally, since orthodontic treatment times typically last two years or more, parents and patients must retain this information for extended periods of time. Orthodontists need to find a better way to educate their patients and provide them with the means to retain this information for the duration of treatment.

Within the limitations of this study, the results suggest that the use of narrated PowerPoint electronically given to parents of potential orthodontic patients following an orthodontic treatment plan and informed consent discussion had a statistically significant increase on a score measuring the delayed recall and comprehension of the parents when compared to the same parent's scores collected immediately after receiving the informed consent information. Additionally, when delaying the assessment of recall and comprehension, the narrated PowerPoint demonstrated a statistically significant increase in the amount of information recalled and comprehended when patients were asked to recall the factors that can lengthen orthodontic treatment times.

Parents and patients being able to better comprehend and recall information given to them by their orthodontist could give them more confidence in their treatment decisions. Understanding what to expect could help them have a more pleasant experience during orthodontic treatment because retaining important treatment

information will help inform their efforts during treatment. Also, in the rare occasion that the treatment extends past the anticipated treatment time, the parent and patient would likely be more accepting of this event because they are aware of the factors that can cause such things to happen. Moreover, because the parent can access the treatment plan and informed consent information in a digital format, they can view and review the information as many times throughout treatment as they would like.

From the orthodontist's perspective, first and foremost, they can feel more comfortable with the treatment they are providing because they know their parents and patients are better informed and made an autonomous decision about treatment. Furthermore, the orthodontist may have a better experience treating patients in practice when his or her patient base is more educated on the treatment and the risks involved. This would allow the orthodontist to spend more time during the day devoted to patient care and less time re-educating parents and patients on topics forgotten from the informed consent process.

In this study, the assessment of long-term orthodontic results suggests that within the population of people who seek orthodontic treatment, there is an awareness that the results of orthodontic treatment are not guaranteed for life and retainers will be required to maintain tooth alignment. In contrast, orthodontists can remain confident that when presenting informed consent information to parents, they do not understand all of what we are explaining to them and many may understand very little. Although recall and comprehension show an increase after a narrated PowerPoint is given to parents, this fact endures during treatment and needs to be addressed.

With this study confirming that a parent's comprehension and recall of informed consent information is not fully recalled either immediately after the presentation and is even less well remembered a week later, the profession of orthodontics, and dentistry as a profession, needs to find a way to help patients remember and understand important information about dentistry. Novel electronic approaches and evidence based educational theory can assist dentists with this problem. Implementing a system where parents and patients are emailed an informational narrated PowerPoint containing the treatment plan and informed consent information, which can be viewed from any electronic device at any time, may allow the parents, patients, and orthodontists to improve the quality of orthodontic care provided to the public.

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Appendix A:

Key points for patient recruitment/informed consent discussion to be done by Dr. Lenz:

- Hello, my name is Dr. Michael Lenz and I am wondering if you are willing to help me with my masters' thesis research project.
- My research project is aimed at trying to learn how we can improve our understanding of the informed consent process, that is, the discussion that dentists have with their patients about their planned treatment, including how long treatment will take, what it will cost, what outcomes patients can expect from treatment, and what the possible side effects of treatment might be.
- It is important that patients understand and remember this discussion, and we are trying to find ways that would help patients do that better. Smartphones, computers and email are an easy and effective way to communicate with patients and we would like to see if we could use email to help patients better understand and remember important information about orthodontic treatment.
- If you agree to be in the study, you will be given a demographic survey where we will ask you questions about your age, education and other information along these lines. This information will be collected without your name and we will report the results in group form. We need this information to be able to describe the participants in our study when we report the results.
- Next, I will talk to you about a pretend orthodontic case for a patient called Joey. I will tell you all about Joey's orthodontic treatment, why he is here, what treatment we will be doing, how long it might take, how much it will cost, how it will help Joey, and what the possible side effects of treatment are. When I am done telling you about Joey, I will then ask you a few questions about Joey's treatment and ask you if you would agree to allow Joey to have this treatment.
- The presentation will present information that applies to Joey's case. If you have questions about your child's dental treatment, please ask your child's dentist.
- After I have talked to you about Joey's case, I will ask you for your email and/or phone number. For some mothers, after you leave today, I also will email you a link where you can watch a short, narrated PowerPoint about Joey's treatment. If you get this link by email, I would ask that you view the link at least once. You can look at the video as much as many times as you want, anytime during the week.
- In one week, I will call you and ask you some questions about Joey's treatment. I will call you in exactly one week (indicate day) sometime between 9 am and 9 pm at the number that you give me, if that is okay with you. If you get the link for the video, please watch it before the day I call. I will ask you a few questions about Joey's treatment and thank you for helping. At this point, the study is done.

- The whole study will take about 10 to 15 minutes today to hear about Joey's case and answer some questions, 5 minutes to watch the link if you get it by email and 5 minutes for the phone call.
- We greatly appreciate your help but understand if you do not want to participate. Please know that helping us is totally voluntary, and your participation (or lack of participation) in this research project will not affect your child's treatment in the Marquette Orthodontic or Pediatric clinic or at Dr. Lenz' office in any way. You may discontinue participation in the study at any time and that will be okay with us.
- We don't anticipate anything bad happening because of your participation in this study, and we are not offering any payment for your participation. We will not be recording your name on your answers to the questions that we ask, and we will throw away your text and phone number one year after the end of the study. Your phone number or email will not be shared with anyone outside of this study.
- We will keep the information we collect on a University file, it will be password protected, and unless something happens that is totally out of our control (like a data breach), no individual data will be shared with anyone.
- If our findings are of interest to other researchers, we may present our findings in group form to other researchers in a poster presentation or published research report. We will only do this if the results might help other dentists communicate better with their patients. The data will be used for a Master's Degree project. Again, the information we collect will be in a group form and no individual information will be disclosed.
- We'd be happy to answer any questions that you have.

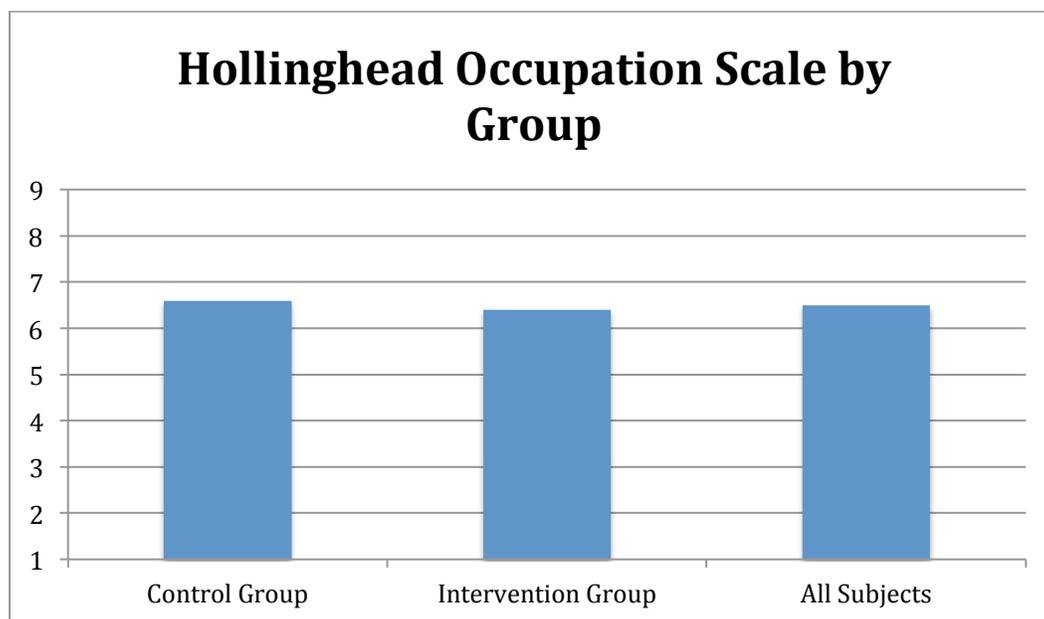
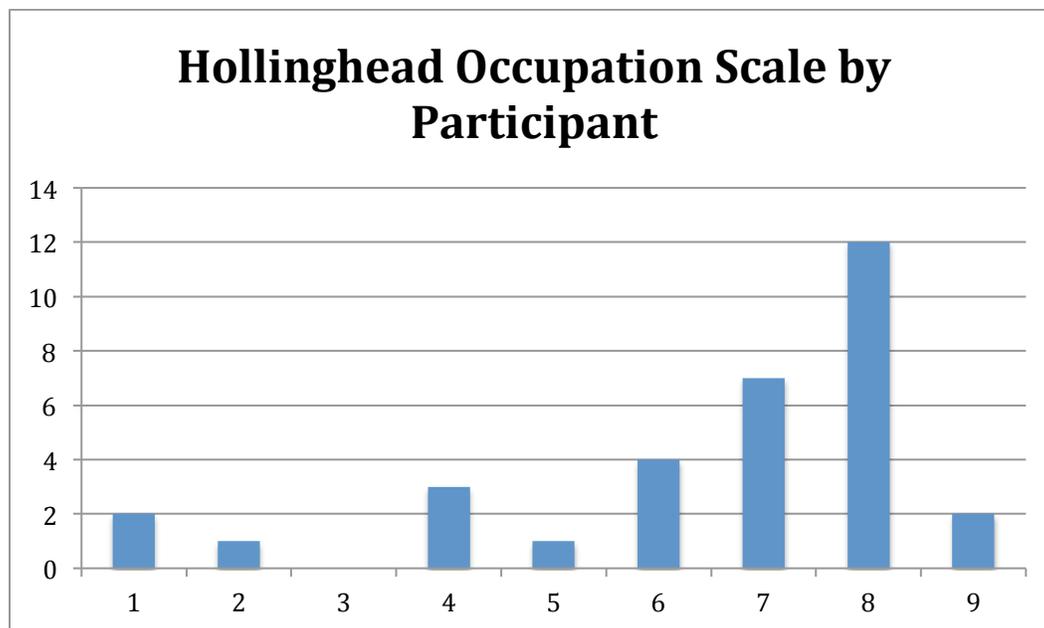
Appendix B:

Demographic Crosstabulation Data

Crosstabs	Significance	Test Used	Interpretation
Gender - All Cases	Not Significant	Kappa	
Gender - Received P.P.	N too small	Kappa	
Gender - No P.P.	Not Significant	Kappa	
Ethnicity - All Cases	Not Significant	Kappa	
Ethnicity - Received P.P.	N too small	Kappa	
Ethnicity - No P.P.	N too small	Kappa	
Education - All Cases	N too small	Kappa	
Education - Received P.P.	N too small	Kappa	
Education - No P.P.	N too small	Kappa	
Marital Status - All Cases	Not Significant	Kappa	
Marital Status - Received P.P.	N too small	Kappa	
Marital Status - No P.P.	Not Significant	Kappa	
Employment - All Cases	Not Significant	Kappa	
Employment - Received P.P.	N too small	Kappa	
Employment - No P.P.	N too small	Kappa	
Ortho Experience Parent - All Cases	Significant; $p \leq 0.05$	Kappa	More parents who had previous orthodontic experience did not receive a P.P. video
Ortho Experience Parent - Received P.P.	N too small	Kappa	
Ortho Experience Parent - No P.P.	N too small	Kappa	
Ortho Experience Child - All Cases	Not Significant	Kappa	
Ortho Experience Child - Received P.P.	N too small	Kappa	
Ortho Experience Child - No P.P.	N too small	Kappa	

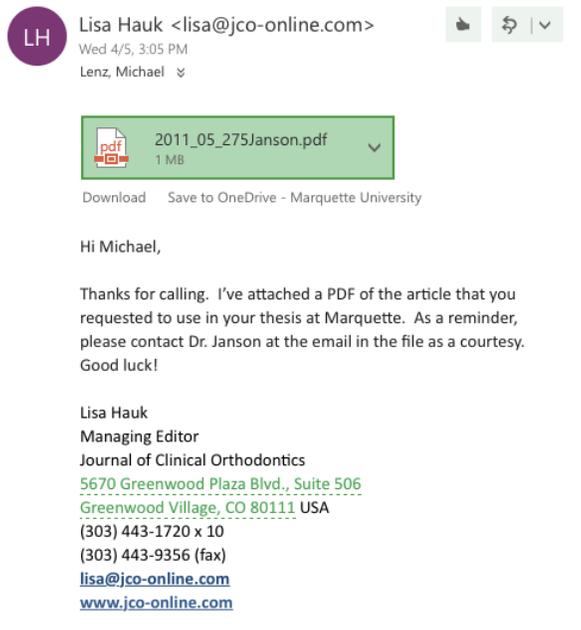
Appendix C:

Hollinghead Occupation Scale Data



Appendix D:

Email of permission to use photos from published article in the Journal of Clinical Orthodontics:



Appendix E:

Permission to use American Association of Orthodontics Informed Consent Form

LM Lenz, Michael
 Fri 9/1, 6:45 PM
 mmcculloch@aaortho.org

Hello Melissa,

I am a 2nd year ortho resident at Marquette University. I am doing a masters thesis relating to the informed consent process in orthodontics. I am wondering if I can have permission to use part of the AAO informed consent paper in part of my research project?

Thank you and please let me know if you have any questions,

Michael Lenz

AAO Informed Consent

SB Simon, Barb <bsimon@aaortho.org>
 Yesterday, 4:27 PM
 Lenz, Michael

Dear Dr. Lenz,

It is fine for you to use the Informed Consent paper. Please let me know if we can be of any further assistance.

Sincerely,
 Barb

Simon, Barbara
 Education Manager
 314-993-1700, Ext. 588
bsimon@aaortho.org

Appendix F:

Treatment Planning Presentation for Parents at the First Visit:

Presenting Problem:

Here are pictures (below) of Jimmy and his teeth. He is thirteen-and-half years old and his mother brought him to the Orthodontic Clinic because his dentist felt that his teeth were too crowded in front. Jimmy's mother agreed with Jimmy's dentist, she also felt that his teeth looked not only crowded, his smile was unattractive. She was concerned that Jimmy's crooked teeth would present dental problems for Jimmy in the future. She also felt that the teeth looked funny the way they were and she wanted them to look less noticeable, so Jimmy would not get teased at school. His general dentist, Dr. Shane, said that Jimmy's teeth are normal in the back, but not in the front. She was at the orthodontist's office and wanted to know if Jimmy could be helped by orthodontic treatment.

The Orthodontist agreed that Jimmy needs treatment. As you can see in the photos of his teeth (above), the orthodontist is concerned because the top tooth in the front is behind one of the bottom teeth. This is a problem because all the top teeth should be in front of all the lower teeth, and as you can see, that is not the case here. Having the teeth positioned the way they should is important because it will help Jimmy have a nice healthy bite and smile. On the positive side, the x-rays (below) show that all of Jimmy's teeth are present except for one tooth, the bottom right wisdom tooth. This is not a problem for Jimmy because this tooth is not necessary; many people have their wisdom teeth removed anyway. Jimmy's dentist thinks that orthodontic treatment can help Jimmy.

In the orthodontic exam process, the dentist took x-rays of Jimmy's teeth, checked his teeth for cavities and gum disease, and evaluated his bite and smile. Based on his findings, the plan to best help Jimmy is to line up all his teeth using braces, but there are two ways to do this.

Option #1: One way to fix Jimmy's teeth would be to remove four teeth (two teeth on the top and two teeth on the bottom) to make space for the crowded and crooked teeth so they can line up nicely.

Option #2: The second way to fix the problem is to slightly tip the teeth to make room for all of them; this would give Jimmy a good bite and a nice smile.

Luckily, because there is only a little bit of crowding, the teeth are not markedly out of line and because Jimmy is still young enough, the dentist does not think removing four teeth will be needed. Therefore, the second treatment option of tipping the teeth and not removing any teeth would be recommended for Jimmy.

To do this, the dentist will need to do a few things for Jimmy. First, the dentist will put braces on all of Jimmy's top and bottom teeth at the initial appointment. Using wires that place a light force on the teeth, the dentist will very slowly move Jimmy's teeth into the desired positions. The dentist will need to see Jimmy for check-ups and adjustments every six to eight weeks. The duration of treatment will be about one and a half to two years, but may take longer if Jimmy has a growth spurt, if he has gum disease or cavities during treatment, if he does not cooperate with wearing rubber bands, or if he breaks his appliances.

There are many benefits for Jimmy if he completes orthodontic treatment. Most notably, he will have a nicer looking smile and appearance to his teeth. He will also have a healthier bite and will better be able to optimally care for and clean his teeth for the rest of his life. If Jimmy does not get orthodontic treatment, his teeth will not correct by themselves, they would remain crooked, will likely to be difficult to care for and he would continue to have difficulty with his bite, which can result in other oral health issues in the future.

The orthodontist expects Jimmy to have a good result with a beautiful and healthy smile at the end of treatment, but there are some factors that will contribute to the results of treatment. These factors are cooperation with treatment including keeping all his appointments, maintaining good oral hygiene while he is wearing braces (that is, regular brushing and flossing his teeth), making sure he doesn't lose or break any of his orthodontic appliances and consistently following all the orthodontist's instructions. While the dentist anticipates that things will go smoothly for Jimmy, sometimes difficulties can arise, and the dentist wants Jimmy's parents to know what those are. The dentist will not cover all the possible problems with Jimmy's orthodontic treatment here, but here are some important issues that could be a problem for Jimmy during treatment. While the dentist thinks that treatment can take a year and half to two years, treatment could take longer than expected. Sometimes, things happen that can extend the time that orthodontic treatment will take. This can happen because of things that Jimmy can control, like following the dentist's directions and taking care of his teeth so he doesn't get gum disease or decay, but other times, things out of Jimmy's control, like a growth spurt or individual differences in responding to treatment, can extend the time that treatment takes. It can be disappointing when a patient has their heart set on having treatment be done by a certain date and it is not possible.

There are some other downsides to treatment. Jimmy can experience some soreness during treatment. Some patients complain about sensitivity and discomfort at certain times during treatment. The orthodontist will work with Jimmy to help keep him comfortable during treatment.

When Jimmy is finished with treatment, his teeth may shift slightly from the desired final position. To prevent this, Jimmy will need to wear retainers for some time after treatment to try to keep his teeth in the right position. Unfortunately, there's no guarantee that the results will last for the rest of Jimmy's life.

Wearing braces can have some other downsides. Jimmy is at an increased risk of cavities, gum diseases or discolored teeth when he has braces on his teeth. Oral care is always important, but is especially important when you are wearing braces or orthodontic appliances. It is harder to keep your teeth clean when you are wearing braces, so Jimmy must pay extra attention when brushing, and will need gentle reminders to brush and floss regularly. It makes no sense to have straight teeth if they are not healthy and clean. The office staff will show Jimmy the proper way to clean your teeth.

Another problem that could occur for Jimmy is shortened tooth roots. This problem is sometimes called root resorption. Teeth have roots; you can see on this x-ray. (Use visual aid.) Occasionally, for reasons that we do not fully understand or predict, the roots on a patient's teeth can become shorter during orthodontic treatment. If Jimmy's dentist sees this happening when he/she takes a mid-treatment x-ray, the dentist will likely pause

treatment and/or take the braces off before the end of treatment. It is important to note that if this does happen, it will likely not have a harmful effect on his oral health.

Another possible difficulty is TMJ (Temporal Mandibular or Jaw) Pain. It is possible that Jimmy could experience pain in his jaw joint during treatment. Jimmy is more likely to have this problem during treatment if he ever had an injury to this joint in the past, if anyone in his family ever had this problem, or if grinds or clenches his teeth. We mention the possibility of this problem even though it can happen without orthodontic treatment, and even though braces are not the main cause of this issue.

Jimmy can also be affected by changes associated with third molars. Since Johnny is only 13-years-old, his bite may change when his third molars come in and this could affect his orthodontic status. There is a possibility that these molars may need to be removed; the orthodontist will watch out for these molars affecting treatment.

In summary, the orthodontist thinks he/she can help Jimmy have straighter teeth, better overall oral health and a nicer smile. The dentist recommends that Jimmy start treatment today.

Do you have any questions?

If Jimmy were your child, would you let him start treatment?

Appendix G:

Assessment of Patient Recall and Understanding
Key

Thank you for helping us by thinking about Jimmy's case.

We just talked with you (or last week) about some things that might affect Jimmy's treatment. We'd like to ask some questions about that discussion. We know that we gave you a lot of information and it will be hard to remember it all. Just do the best you can.

1. Why does Jimmy want to have orthodontic treatment? (1)

Give credit for straighter teeth, to correct Jimmy's bite, to avoid future problems.

2. What were the two options for orthodontically treating Jimmy's teeth? (2)

Give credit for 1) removing teeth or 2) tipping teeth to make them fit.

3. How long does the dentist think that treatment will take? _____ (1)

Give credit for any answer in the range of one and half to two years.

4. What will the orthodontist be doing to straighten Jimmy's teeth? How frequently will Jimmy need to be seen? (2)

Give credit for placing wires and braces on teeth; give credit for every six to eight weeks.

5. We told you the results of treatment depend on many factors; what are the factors that would affect orthodontic work that were mentioned? (4)

Give one point for any response on this list:

- a. Cooperation in keeping appointments
- b. Maintaining good oral hygiene
- c. Avoiding loose or broken appliances
- d. Following the orthodontists instructions carefully

6. You may recall that we said the actual treatment time is usually close to the estimated treatment time that we tell you, but treatment may take longer if certain things happen. What kinds of things might lengthen Jimmy's treatment? (3)

Give one point for any response on this list:

- a. Unanticipated growth occurs
- b. Jimmy does not follow the directions he is given
- c. Periodontal or other dental problems occur

7. True or false? Orthodontic treatment guarantees perfectly straight teeth for the rest of Jimmy's life. (1)

Give one point for the response "false."

8. You may recall that bad or improper oral hygiene could result in a number of issues that affect Jimmy's oral health. What things does poor oral hygiene result in? (3)

Give one point for any response on this list.

- a. Cavities
- b. Discolored teeth
- c. Periodontal disease

9. We talked about how moving teeth can cause root resorption; what is root resorption? What will happen if the dentist finds root resorption during treatment? (2)

Give one point for the answer: Roots become shorter (resorption), and the dentist will delay or stop treatment.

10. We mentioned problems can arise in Jimmy's jaw joints during braces treatment: what factors can affect problems with the jaw joints (TMJ) during orthodontic treatment? (3)

Give one point for each correct response: Past trauma, Hereditary tendency to joint/jaw problems; Excessive tooth grinding or clenching

11. True or false?

Third molars (i.e., wisdom teeth) can affect the bite and oral health as they develop.

(1)

Give one point for the response “true.”

12. True or False?

Few patients have discomfort from wearing braces, and if Jimmy has discomfort, it's probably psychological. (1)

False, some discomfort may occur and you should consult your orthodontist.

13. If Jimmy does nothing, there is a good chance that his teeth will correct by themselves. (1)

Give one point for the response “false.”

Please rate your likeliness to agree to treatment for Jimmy on a scale of 1-10 with 1 being very unlikely and 10 being extremely likely.

Given everything that we have explained to you, if you were Jimmy's parents, do you think that Jimmy should have orthodontic treatment?

Participant Number _____

I think Jimmy
should have
treatment

I think Jimmy
should not have
treatment

1 2 3 4 5 6 7 8 9 10

Appendix H:

Copy of email that will be sent to participants

Hi,

Thanks so much for participating in our study about helping patients better understand and remember information about their dental treatment.

Today we told you about a child named Jimmy and explained to you what type of treatment we thought Jimmy should have. The following link will review that information for you, and will go over what the treatment is, how long it will take, how Jimmy will benefit from the treatment, and some difficulties that might happen during or after treatment.

Here is the link to review information about Jimmy's case: _____ Please look at this PowerPoint when you have time.

I will call you in about a week to talk to you about Jimmy's case again.

Thank you so much for your help,

Michael Lenz,
Phone number.

Appendix I:

Script for Phone call to Participants One Week after Study Enrollment

Hello, this is Dr. Michael Lenz.

We met last week and I presented a pretend orthodontic case to you followed by some questions about the case.

If you have about five minutes of time, I would like to ask you the same questions one more time.

To remind you, I am doing this for my education requirements and we are researching ways to better help patients and parents understand and remember things about their orthodontic treatment.

Appendix J:



INSTITUTIONAL REVIEW BOARD
Informed Consent for Research
 Protocol Number: HR-1709019113
 IRB Approved 10/16/2017

MARQUETTE UNIVERSITY
 AGREEMENT OF CONSENT FOR RESEARCH PARTICIPANTS

Informed Consent recall and comprehension in orthodontics: Immediate vs. delayed recall following a take-home video presentation

Michael Lenz D.D.S., Marquette University Orthodontics

You have been invited to participate in this research study. Before you agree to participate, it is important that you read and understand the following information. Participation is completely voluntary. Please ask questions about anything you do not understand before deciding whether to participate.

PURPOSE:

- The purpose of this research study is to evaluate the effect of a view at home video on a parent's immediate and delayed recall and comprehension following an informed consent procedure.
- You will be one of approximately sixty participants in this research study.

PROCEDURES:

- Each subject will be invited to participate at either the Marquette University School of Dentistry Orthodontic clinic or at Mark D. Lenz Orthodontics office.
- Participation will take place in the Marquette University School of Dentistry Orthodontic department, Mark D. Lenz Orthodontics office and over the phone.
- Every participant agreeing to participate will take a demographic survey.
- Dr. Michael Lenz will present a mock orthodontic case and treatment plan to each participant.
- Once the informed consent procedure is finished, each participant will verbally answer a short assessment that will assess comprehension, recall and case acceptance of the treatment plan presentation.
- Approximately half of the participants in the study will be emailed a PowerPoint video presentation covering some of the information in the informed consent presentation and will be asked to view it during the following week.
- If you are emailed a video, it will be via a unique link that will allow us to know if the video has been played or not.
- Finally, the principle investigator will call each subject one week after the first meeting and administer the same assessment that participants answered while at the clinic. The assessment will test comprehension and recall of the informed consent information after one week.

DURATION:

- Your participation will consist of two meetings. The first will take approximately fifteen minutes face-to-face in the clinic. The second will take approximately five minutes and can be done over the phone. For some participants, there will be a short, narrated PowerPoint presentation/video that mothers will examine during the week between the first meeting and the follow up phone call.

RISKS:

- The risks associated with participation in this study are no greater than you would experience in everyday life.
- Use of Internet to view PowerPoint video presentation and 5-minute phone call involves the same risks that a person would encounter in everyday use of the Internet or phone.

BENEFITS:



Office of Research Compliance

INSTITUTIONAL REVIEW BOARD
Informed Consent for Research
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 IRB Approved 10/16/2017

- There is no direct benefit to participants, but this research may benefit future researchers by improving understanding and comprehension of treatment plan presentations for future orthodontic patients.

CONFIDENTIALITY:

- Data collected in this study will be anonymous.
- All your data will be assigned a code number rather than using your name or other identifying information.
- The key linking names to identification numbers will be stored in a separate and secure folder.
- If the results of the study are published or presented at a professional meeting, you will not be identified by name and data will be presented in a group format.
- Your personal data will be destroyed by shredding paper documents and deleting electronic files at the end of the study. (De-identified data will be combined and only reported in group format. This data will be retained by the researcher.)
- Although your responses will be deleted from the survey provider website at the end of the study your data may exist on backups or server logs beyond the timeframe of this research project.
- Your research records may be inspected by the Marquette University Institutional Review Board or its designees, and (as allowable by law) state and federal agencies.

VOLUNTARY NATURE OF PARTICIPATION:

- Participating in this study is completely voluntary and you may withdraw from the study and stop participating at any time without penalty or loss of benefits to which you are otherwise entitled. Specifically, your participation or declining participation will not affect your treatment in the clinic or with the researcher in any way.
- You may skip any questions you do not wish to answer and you may decline participation in the study at any time. Information already collected will be destroyed if you would like us to do this.

ALTERNATIVES TO PARTICIPATION:

- There are no known alternatives other than to not participate in this study.

CONTACT INFORMATION:

- If you have any questions about this research project, you can contact Dr. Michael Lenz at 262-902-2468 or his Master's thesis advisor, Dr. Evelyn Donate-Bartfield at (414) 288-7470.
- If you have questions or concerns about your rights as a research participant, you can contact Marquette University's Office of Research Compliance at (414) 288-7570.

I HAVE HAD THE OPPORTUNITY TO READ THIS CONSENT FORM, ASK QUESTIONS ABOUT THE RESEARCH PROJECT AND AM PREPARED TO PARTICIPATE IN THIS PROJECT.

(Printed Name of Participant)

(Signature of Participant)

Date

(Printed Name of Individual Obtaining Consent)

(Signature of Individual Obtaining Consent)

Date

Appendix K:

Demographic Survey

1. How old are you? _____
2. Ethnicity origin (or Race)
 1. White
 2. Hispanic or Latino
 3. Black or African American
 4. Native American or American Indian
 5. Asian / Pacific Islander
 6. Other
3. Education: What is the highest degree or level of school you have completed? (If you are currently enrolled, indicate the highest degree received.)
 1. No schooling completed
 2. Nursery school to 8th grade
 3. Some high school, no diploma
 4. High school graduate, diploma or the equivalent (for example: GED)
 5. Some college credit, no degree
 6. Trade/technical/vocational training
 7. Associate degree
 8. Bachelor's degree
 9. Graduate or professional school
4. Marital Status: What is your marital status?
 1. Single, never married
 2. Married or domestic partnership
 3. Widowed
 4. Divorced
 5. Separated
5. Employment Status: Are you currently?
 1. Employed for wages
 2. Self-employed
 3. Out of work and looking for work
 4. Out of work but not currently looking for work
 5. A homemaker
 6. A student
 7. Military
 8. Retired
 9. Unable to work
6. What is your usual occupation? _____

7. Have you ever had orthodontic treatment? Yes ____ No ____

8. Has your child who is currently a clinic patient ever had orthodontic treatment?

Yes ____ No ____