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Process planning for the rapid machining of custom bone implants

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ABSTRACT

This thesis proposes a new process planning methodology for rapid machining of bone implants with customized surface characteristics. Bone implants are used in patients to replace voids in the fractured bones created during accident or trauma. Use of bone implants allow better fracture healing in the patients and restore the original bone strength. The manufacturing process used for creating bone implants in this thesis is highly automated CNC-RP invented at *Rapid Manufacturing and Prototyping Lab (RMPL)* at Iowa State University. CNC-RP is a 4^{th} axis rapid machining process where the part is machined using cylindrical stock fixed between two opposing chucks. In addition to conventional 3 axes, the chucks provide 4^{th} rotary axis that allows automated fixturing setups for machining the part. The process planning steps for CNC-RP therefore includes calculating minimum number of setup orientations required to create the part about the rotary axis. The algorithms developed in this thesis work towards calculating a minimum number of orientations required to create bone implant with their respective surface characteristics.

Usually bone implants may have up to 3 types of surfaces *(articular/periosteal/fractured)* with *(high/medium/low)* finish. Currently CNC-RP is capable of creating accurate bone implants from different clinically relevant materials with same surface finish on all of the implant surfaces. However in order to enhance the functionality of the bone implants in the biological environment, it is usually advisable to create implant surfaces with their respective characteristics. This can be achieved by using setup orientations that would generally isolate implant surfaces and machine them with individual finishes.

This thesis therefore focuses on developing process planning algorithms for calculating minimum number of orientations required to create customized implant surfaces and control related issues. The bone implants created using new customization algorithms would have enhanced functionality. This would reduce the fracture healing time for the patient and restore the original bone strength. The software package created using new algorithms will be termed as CNC-RP$_{bio}$ throughout in this thesis

The three main tasks in this thesis are a) calculating setup orientations in a specific sequence for implant surfaces b) Algorithms for calculating a minimum number of setup orientations to create implant surfaces c) Machining operation sequence. These three research tasks are explained in details in chapter 4 of this thesis.

The layout of this thesis is as follows. *Chapter 1* provides introduction, background and motivation to the research in this thesis. *Chapter 2* provides a literature review explaining different researches conducted to study the effects of different surface finish on the bone implants on their functionality. It also presents different non-traditional and RP techniques used to create bone implant geometries with customized surfaces, their advantages and limitations. *Chapter 3* gives the overview of process planning algorithms used for CNC-RP and those needed for CNC-RP$_{bio}$. *Chapter 4* is the main chapter of the thesis including process planning algorithms for rapid machining of bone implants with customized surfaces using CNC-RP in details, while *Chapter 5* provides Conclusions and Future work.

CHAPTER 1: INTRODUCTION

1.1 Background

Bone implants or bone grafts are used in the fracture treatments (*figure 1.1*) to replace missing pieces or severely damaged sections of bone, whether due to high energy trauma, deformity, or after tumor removal in the case of bone cancer. These bone implants integrate with the human body when inserted and restore the original strength of the fractured area. The natural ability of the human body to adapt with the implant material allows the healing and integration of the inserted implant with the bone. The process that allows this integration is called *Osseointegration (Osseo-"bone" integration).* In this process the body allows the growth of natural bone into the inserted implant and forms a well formed structure. This restores the original strength at the implant site. These bone implants can be made from clinically relevant materials like artificial bone substitutes, or natural bone in the form of an Allograft obtained from a donor or an Autografted bone taken from a healthy area of the patient's skeleton itself, respectively. Due to advancements in the field of biomaterials, many materials like solid and porous metals including stainless steel, titanium, tantalum, cobalt-chromium (Co-Cr) alloys, bio-ceramics, bio-polymers, and natural coral, among others have been used successfully in the bone repair or the joint replacements. In any case,

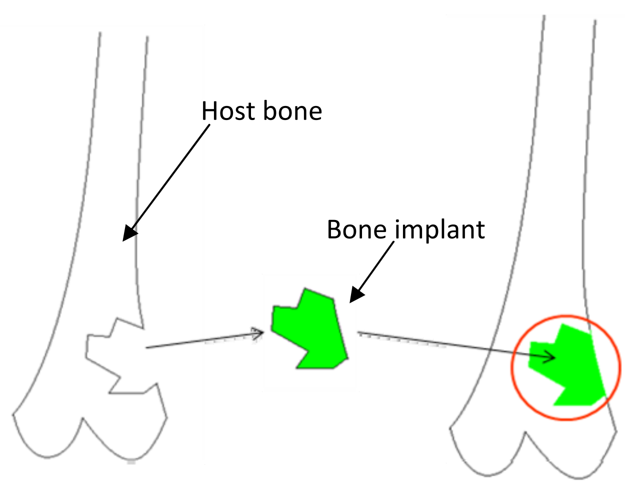


Figure 1.1: Typical bone implant (green)

there is always a challenge of creating the correct shaped implant from an appropriate material. In surgery, the patient specific implant geometries are hand crafted by the surgeon to the best of their ability. However handcrafted implants could have geometric errors that can make them less effective in the long term.

1.2 Bone implant manufacturing using Rapid Prototyping

Rapid Prototyping is a layer based manufacturing technology used to create functional or prototype models directly from the Computer-Aided Design (CAD) model of the component at hand. This technology has been around since the late 1980's and is divided into two basic categories: (1) *(Additive)* processes and (2) (*Subtractive*) processes. Additive processes are exceedingly more popular methods that involve depositing 2½ D layers of material upon each other to build the desired geometry *(figure 1.2)*. 2½ D corresponds to the geometries of the layer varying in standard X and Y directions, but having a constant Z-height. Additive processes utilize a wide variety of materials such as papers, polymers, ceramics, and some metals. There are many different commercially available examples of RP technologies that use additive concepts such as stereo lithography (SLA), 3-dimensional printing (3DP), laminated object manufacturing (LOM), fused deposition modeling (FDM), laser engineered net shaping (LENS), selective laser sintering (SLS), direct metal laser sintering (DMLS), and electron beam melting

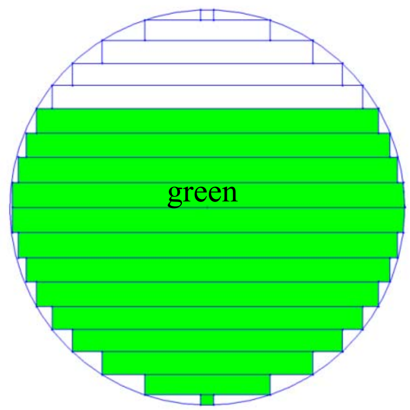


Figure1.2: 21/2 D Layers (Green) deposited sequentially to create geometry (green sphere)

(EBM) for biomedical implant fabrication[1-6]. These additive techniques have been used in limited ways for the creating bone implants specific to patients.

1.3 Subtractive Rapid Prototyping

As opposed to *Additive* processes, *Subtractive* processes involve sequentially removing material from stock to create specific geometric shapes (*figure 1.3*); these processes mainly include machining processes like milling, turning, and drilling. As an example Subtractive Rapid Prototyping, the CNC-RP technique uses a rotary

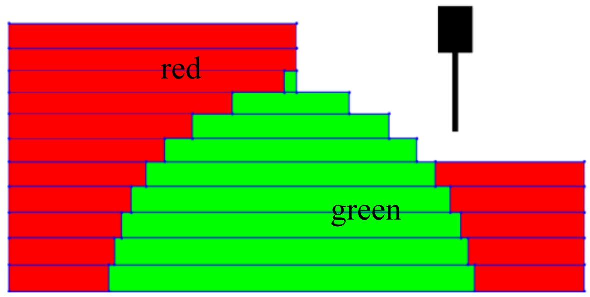


Figure1.3: 2 1/2 D Layers (red) subtracted sequentially to create geometry (green sphere), cutting tool (black)

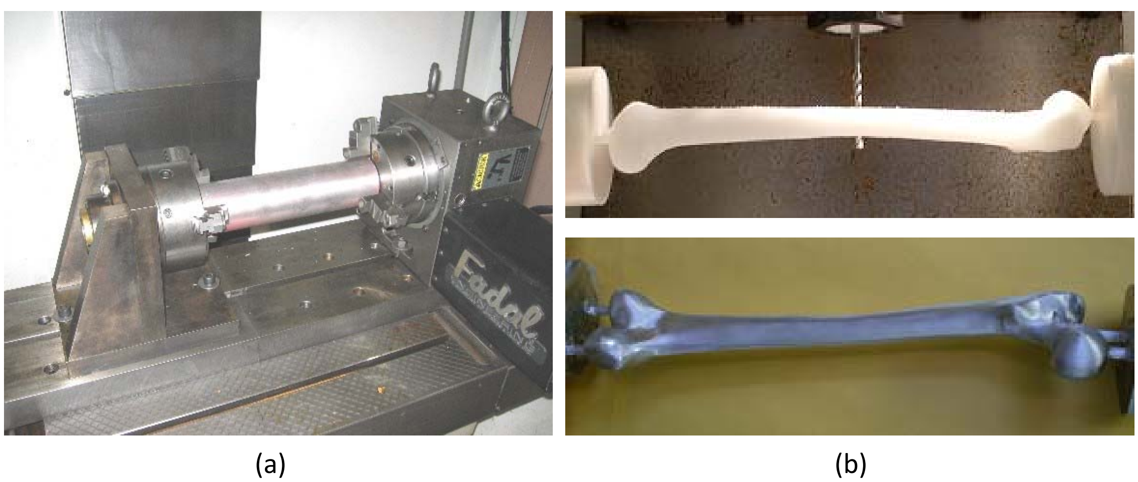


Figure 1.4: Femur bone machined using CNC-RP from different stock materials a) Biocompatible polymer b) Aluminum

4th axis with a 3-axis mill to incrementally machine components about the rotary axis. There has been limited or no work in the field of subtractive rapid manufacturing of bone implants prior to the current research of this thesis.

Subtractive Rapid Manufacturing using CNC-RP is a promising new approach for creating accurate patient specific bone implant from different materials. This CNC-RP process is based on a setup strategy, whereby a rotary device is used to orient cylindrical stock material fixed between two opposing chucks. For each orientation, all visible surfaces of the bone sample are machined and the part geometry is created. Figure 1.4.a shows a cylindrical aluminum stock fixed between two opposing chucks while 1.4.b & 1.4.c shows human femur bone machined from aluminum and polymer using CNC-RP. The goal of this thesis is to create accurate patient specific bone implants using CNC-RP that will provide initial fixation strength better than hand shaped fillers by the surgeon, while still being able to use variety of materials. The sample in Figure 1.4.b is of an entire human femur; implants for practical use would be orders of magnitude smaller "pieces" of bone.

Fixation stability of a bone implant is its ability to maintain its position stably with respect to the host bone without any abrupt movements at the *implant/ host bone* interface. This would allow bone in growth into the implant for fracture healing. Usually the bone implant is attached to the host bone by using bone cement which is made of a biocompatible material called as Poly Methyl Methacrylate (PMMA). This type of implant is called as cemented implant. The fixation stability of cemented implants may be compromised either due to wearing out of the bone cement itself, or because of frequent movements at the *implant/host bone* interface. Eventually the failure of the implant occurs either due to harmful inflammatory responses from the body or due to the wear debris generated [14].

One of the alternatives to the cemented bone implants is using them without bone cement *(uncemented bone implants)*. Substantial research has been done in order to increase the fixation stability of the uncemented implants. The initial fixation stability of an uncemented bone implant is affected by the interfacial friction between the implant and the host bone. A higher *implant/host bone* interfacial friction not only increases the implant's initial fixation stability, but also keeps the interfacial motion low. This leads to higher rate of bone in growth into the implant. The bone in growth then allows long term fixation stability of the implant. This higher initial fixation stability between the uncemented implants and the host bone interface can be achieved by creating rough implant surfaces in order to aid mechanical interlocking [15-19].

Providing mechanically interlocking features on the implant surface also increases the contact area between the implant and host bone which promotes the implant fixation stability and increase of osseointegration rate. Preliminary friction studies were conducted with collaborators at the University of Iowa Orthopaedic Biomechanics Lab to measure the impact on friction by altering the surface finish of the implant material. As perhaps expected, the preliminary experimental results show that the interfacial friction at the implant/host bone surface increased as the interface roughness increased.

Currently the CNC-RP process is capable of creating patient specific bone implant geometries using many biocompatible materials but only with same surface characteristics all over. The research work presented in this thesis allows rapid machining of patient specific bone implants using CNC-RP with **different** features/roughness on the respective bone implant surfaces. The effort is to increase its initial fixation stability and eventually leading to long term fixation stability and good quality fracture healing.

1.4 Generation of bone implant 3D CAD geometry using 3D Puzzle solving

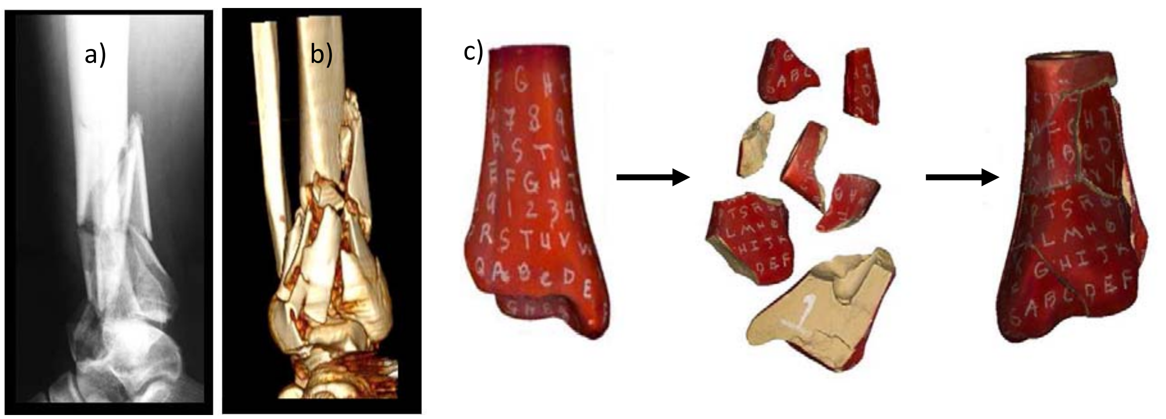
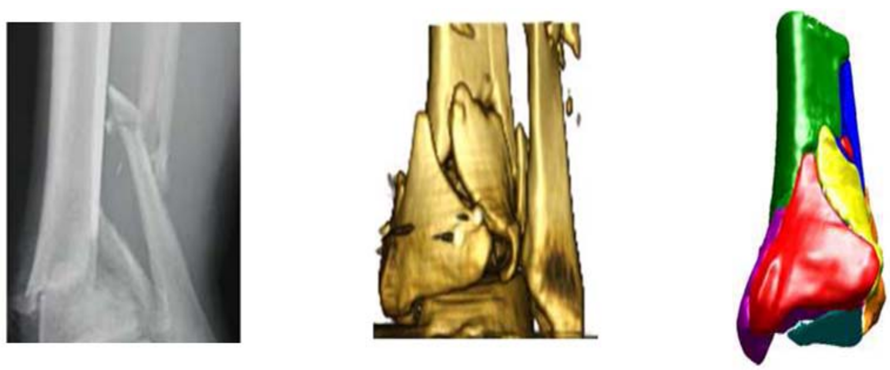


Figure 1.5: a) CT scan of comminuted fracture, b) 3D rendering of comminuted fracture c) 3D puzzle solving concept

For the fabrication of accurate bone implant geometry, using any manufacturing process, it is of prime importance to have an accurate 3D CAD model of the corresponding bone implant geometry. Researchers at the University of Iowa and UNC-Charlotte have developed a new method of generating accurate 3D CAD models of the corresponding geometries of segmental defect fillers using 3D puzzle solving methods (*figure* 1.5.c). The technique of 3D puzzle solving is used in the treatment of highly comminuted fractures (*figure* 1.5.a/b). This technique was derived from 3D puzzle solving methods for geometric reconstructions of broken archeological artifacts like pottery. In the cases related to comminuted fractures, a part of bone is damaged/ crushed (comminuted) to the point of being missing altogether. As an example this type of trauma could occur from military injuries like gunshot wounds, explosives, motor vehicle accidents, or falling from excessive heights; all where, substantially high energy is involved. The developed 3D puzzle solving software enables accurate reconstruction of the comminuted fracture. This 3D puzzle solving technique allows surgeons to practice reconstruction of the broken bone fragments prior to surgery in order to avoid errors in reconstruction.



(a) (b) (c)

Figure 1.6: a) CT scan of a comminuted fracture b) Fracture reconstruction using hand crafting c) Fracture reconstruction using 3D puzzle solution

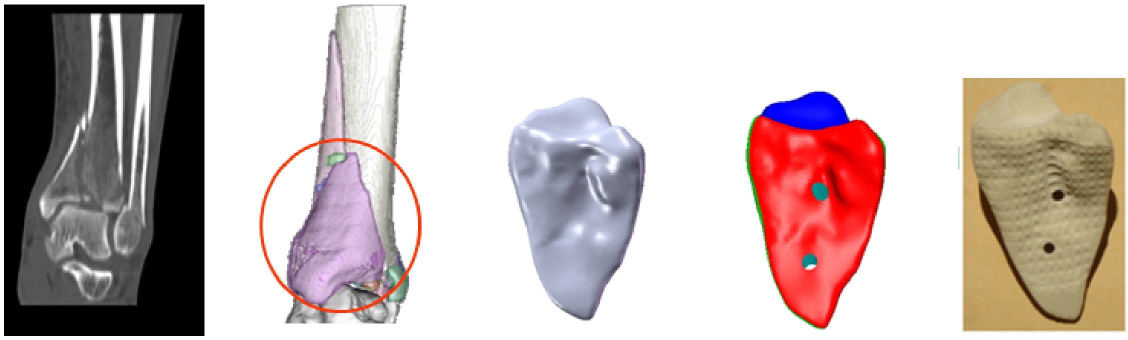


Figure 1.7: a) CT scan of a comminuted fracture, b) 3D rendering of the fracture (implant geometry in circle), c) Implant geometry in CAD format, d) Implant geometry with designed fixation screw holes, e) Implant geometry machined with surface texture and fixation screw holes using CNC-RP

The 3D puzzle solving technique can also be used to create accurate geometries of the missing parts of bone. In these cases the geometry of the implant is generated from the profile of the void in the fracture area. Figure 1.7.e shows one an example where an accurate geometry of a bone fragment was generated using 3D puzzle solving. This fragment geometry was then created using CNC-RP_{bio} from bone substitute with different surface textures. In order to increase the fixation stability of the implant geometry pyramidal shaped textures were created *(figure 1.8)*. The fixation stability of bone implants can be further increased by inserting fixation screws. Therefore two fixation screw holes were designed on the generated 3D CAD model of the fragment geometry and were machined after surface texture creation.

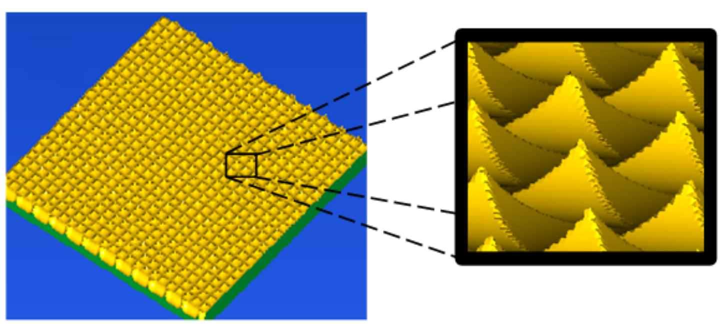


Figure 1.8: Simulated surface texture on the bone fragment geometry

The software package created using this research is called as CNC-RP_{bio}. The overarching goal of this research is to automate the process of creating accurate segmental defect filler geometries with surface specific characteristics from clinically relevant materials using CNC-RP_{bio}. This will provide initial fixation stability that is better than hand crafted fillers by surgeons. Since most of the clinically relevant materials can be machined, bone implants made using CNC-RP_{bio} would be free from biocompatibility issues.

1.5 Thesis layout

The layout of this thesis is as follows. *Chapter 2* provides a literature review which explains different researches conducted to study the effects of different surface textures on the bone implants on their fixation stability and biocompatibility. It also presents different non-traditional and RP techniques used to create bone implant geometries with customized surfaces, their advantages and limitations. *Chapter 3* is the overview of the thesis which summarizes process planning algorithms for CNC-RP and also those needed for machining bone implant geometries with customized surfaces using CNC-RP_{bio}. *Chapter 4* is the main chapter of the thesis which involves detailed explanation of process planning algorithms for rapid machining of bone implants with customized surfaces using CNC-RP_{bio}, while *Chapter 5* provides Conclusions and Future.

CHAPTER 2: LITERATURE REVIEW

2.1 Rapid Prototyping for bone implant manufacturing

Biomedical implant manufacturing using layer based additive techniques has made significant progress in creating patient specific implants. Due to the nature of the human body and the way its components are unique to the specific individual, it is a very challenging task to create accurate fragments of bone implants that can be implanted during surgery. The layer based additive techniques like Stereolithography (SLA), Electron Beam Melting (EBM), Selective Laser Sintering (SLS), Direct Metal Laser Sintering (DMLS), 3-dimensional printing (3DP), laser engineered net shaping (LENS), Fused Deposition Modeling (FDM) have been used successfully in creating custom designed bone implants. These implants have been created using a wide array of clinically relevant materials like solid Stainless Steel, porous metals like Titanium, Trabecular metal; Co-Cr alloys biopolymers like Ultra High Molecular Weight Polyethylene (UHMWPE), Polyurethane, ceramics like Zirconia, Alumina, Hydroxypatite, etc [1-7].

Stereolithography (SLA) is one of the successfully used layer based additive techniques for creating orthopedic implants from ceramics, polymer and composite materials. In previous work, CT and CAD data has been used to create Stereolithography (SLA) parts [9-10]. These SLA parts were then used to cast maxillofacial implants out of titanium. A similar process was used to create wax models from SLA parts for investment casting of craniofacial implants [1-2]. These SLA techniques have been useful in creating custom designed SLA bio-models of the facial skeleton, which were used in treatment planning related to the facial surgeries. In another work a custom designed spine model of a patient created by SLA technique was used for spine surgery planning [1-2]. The custom designed bio-models created by SLA techniques also play an important role in allowing surgeons to practice the surgery on these models before conducting the actual surgery [1-2]. This allows them to pre plan their surgical steps in order to avoid any complexities arising during the actual surgical procedure. There has been a little research involving the use of CT data for the manufacturing of medical implants via machining of metal. There are outlined methodologies for the design and manufacture of a custom femur endoprosthesis. Again, in this methodology the CAD data for the specific bone came from a CT scan. From this CT data, a 3D geometric model of the femur was created and used to generate tool paths for a CNC mill. However, the accuracy of the finished product was limited due to their machining process. This part required an elaborate fixing system and only utilized two cutting orientations. In a similar research a method that involved machining an elbow bone from titanium stock was developed. The machined titanium implant took approximately 104 hours of machining, over eight days [22-23]. EBM has also been used to create function hip prosthesis, sockets, knee joints, spinal implants, fracture joining plates, and fixation screws etc from Co-Cr, Ti-6Al-4V, and stainless steel. However the strength of the implants manufactured using EBM have less strength compared to those manufactured using machining process. SLS has also been used in order to create 3D functional implants out of Co-Cr, titanium, Stainless steel alloys successfully. However the implant created using SLS has less surface finish as compared to the machining process [7]. Additive processes like FDM and 3DP have been useful in creating controlled porous structure for applications in tissue engineering [4]. These materials range from bio polymers like polyurethane, polyethylene, polystyrene, poly methyl methacrylate to bio ceramics like zirconia, alumina, hydroxypatite which can be used for creating scaffolds for drug delivery systems, various joint reconstructions like maxillofacial, craniofacial, mandibular joints etc [4]. However use of FDM and 3DP restricts the types of materials to polymers and ceramics which is a prominent limitation considering the importance of bio compatible metals like titanium, tantalum, Co-Cr alloys etc.

2.2 Implant fixation stability

Maintaining the biocompatibility of the manufactured implant and avoiding any harmful immune responses from the body is of prime importance once the implant is inserted into the body. Every human body is unique in the way it reacts biologically to the implant. There has been an extensive research on behavior of bio implants once they are inserted into the body. It is desired that the interaction between the implant and the body doesn't produce any toxic or harmful responses that lead to implant failure or the implant site failure in general. Implant failures are categorized into two types, mechanical and chemical failures. Chemical failures of the orthopedic implants occur due to the chemical interactions between the body fluids and the implant surfaces leading to the different types of corrosions and ultimately implant failure. Mechanical failure of implants fall into 3 categories, plastic, brittle and fatigue failure [21]. Plastic failure is one in which the device fails to maintain its original shape resulting in a clinical failure. Brittle failure, an unusual type of implant failure, is caused by defect in design or metallurgy. Fatigue failure occurs as a result of repetitive loading on the device or frequent movements at the implant host bone interface. In cases related to fatigue failures, frequent movements between the implant host bone interfaces lead to creation of wear debris either from the implant itself or the host bone.

This leads to the fixation instability of the implant ultimately leading to the implant failure. In order to increase the initial fixation stability at the implant-host bone interface, a bonding material called as bone cement (Poly Methyl Methacrylate, PMMA) is normally used. This material helps in maintaining the position of the implant with respect to the host bone and avoids any interfacial movements. Researches on the behavior of the cemented bone joints have revealed that the implant failure is still prominent due to the frequent movements at the implant host bone interface which creates wear debris from the bone cement itself. This decreases the initial fixation stability of the implant ultimately and leads to the implant failure [33]. Therefore in order to have a successful implanted joint it is absolutely necessary to have higher initial fixation stability of the implant. In cases of uncemented orthopedic implant the initial fixation stability is affected by the interfacial friction and movements between the implant's surface and the host bone. A higher implant/bone interfacial friction not only increases the implant's initial fixation stability, but can also keep the interface motion low enough to enhance bone in growth (osseointegration) into the implant. This bone in growth then allows long-term fixation of the implant increasing the rate of bone in growth. The friction between the implant-host bone interfaces can be increased by creating rough surfaces on the implants [25-26]. Surface roughness is usually divided into three levels depending on the scale of the features: macro-, micro- and nano-sized topologies. The macro level is defined for topographical features as being in the range of millimeters to tens of microns. This scale is directly related to implant geometry. Features at this scale include like threads, groves, holes, beads, hemispherical shapes, textures like pyramid shape, hexagonal, circular shape etc. Research has shown that both the initial fixation and long-term mechanical stability of the prosthesis can be improved by a high roughness profile compared to smooth surfaces of the orthopedic implant. The high roughness results in mechanical interlocking between the implant surface and increased bone in growth [25-28]. The micro topographic profile on implants is defined for surface roughness in the range of 1–10μm. Surface profiles in the nanometer range play an important role in the adsorption of proteins, adhesion of osteoblastic cells (bone building cells) and thus the rate of osseointegration rather than promoting mechanical fixation stability. However, reproducible surface roughness in the nanometer range is difficult to produce with chemical treatments. Additionally, the optimal surface topography at nano scale for rapid bone in growth is unknown. Also in order to promote bone in growth at cellular level it is primarily important to maintain the initial fixation stability of implant at mechanical level. In vitro and in vivo studies have provided strong indication that biological responses to titanium are influenced by its surface texture (roughness). In other research to study the amount of fixation stability and bone in growth, commercially available Titanium implants were implanted in twelve sheep at the proximal (top) end of both femurs. Each femur received four implants with a rough surface (type 1) in the right femur and four with a smooth surface (type 2) in the left one. The quantity of bone in growth around implants was measured (bone volume, bone thickness) together with bone in growth rate. It was found that implants with rough surfaces seemed to be associated with stronger bone response as compared to the smooth surface implants [34]. In another study two implants made out of commercially available titanium implants, first machined smooth surfaced and second plasma sprayed rough surfaced were inserted into a rabbit's femur. The percentage of implant-host bone contact and bone volume in the implant with rough surface was higher as compared to the implant with smooth surface at the end of 42 weeks [35].

2.3 RP techniques for better implant functionality

There has been little to no research in the field of additive technique for creating biomedical implants with customized surface characteristics for increase in their primary fixation stability and finally bone in growth rate. In one example, a titanium implant created using Electron Beam Melting (EBM) had wavy surface structures and rounded protrusions; multiple crevices and invaginations showed increased bone in growth into the implant [36]. Selective Laser Sintering (SLS) has also been used in creating Hydroxyapatite (HA) coated pyramidal and stipple shaped porous implants made out of Co-Cr alloys. These implants have shown increased rate of bone in growth. 3D fiber deposition is also an additive technique that has been used in manufacturing of metallic scaffolds with accurately controlled pore size, porosity and interconnecting pore sizes. The manufactured scaffold with designed porosity would allow the fixation stability to the scaffold and ultimately aid in the bone in growth in to the implant [37]. Laser Engineered Net Shaping (LENS) has also been successfully used in creating load bearing porous or non porous implants from materials like Ti, Ti6Al4V, Ni-Ti and Co-Cr-Mo alloys. The surface porosities and load bearing properties of the manufactured implants depend on parameters like laser power, powder feed rate and scan speed. However implants produced using LENS need post processing techniques like CNC machining in order to improve their wear resistance, create accurate shape and improve the surface finish of the manufactured implants [4]. There have also been investigations in the manufacturing of patient specific porous craniofacial implants and orthopedic spacers made from PMMA using Fused Deposition Modeling (FDM). In this experiment the building parameters and procedures to properly and consistently extrude PMMA filament in FDM for building 3D implants were determined. Experiments were performed that examined the effects of different fabrication conditions, including tip wipe frequency, layer orientation, and air gap (AG) (distance between filament edges) on the mechanical properties and porosity of the fabricated structures. The samples were characterized through optical micrographs, and measurements of weight and dimensions of the samples were used to calculate porosity. However the number and types of materials used in FDM for creating patient specific implants are limited to non metals. This limits the types of materials that can be used for manufacturing functional patient specific orthopedic implants using FDM leaving out clinically relevant metals like titanium, tantalum, Co-Cr alloys, stainless steel etc [5].

2.4 Non-Traditional techniques for implant manufacturing

Several nontraditional processes like die sinking EDM, acid etching, grit blasting, Titanium Plasma Spraying (TPS), anodization, alkali- and heat-treatment (AHT) techniques, have also been used to create orthopedic implants with rough surface characteristics at different scales. Die sinking EDM can be used for producing accurate surface textures by plunging a graphite electrode on a plain machined, cast or forged metal implants. However such a process is limited to simple 2-D patterns because of constrained unidirectional motion of the electrode. The use of EDM also leads to localized heat stresses, creating a white layer on the part surface which reduces the fatigue strength of the bulk implant [20]. Titanium plasma-spraying (TPS) has also been used for producing rough implant surfaces. This method involves injecting titanium powders into a plasma torch at high temperature. The titanium particles are projected on to the surface of the implants where they condense and fuse together, forming textures of about 30 µm thick. The measured thickness of the film was around 40–50 µm to be uniform. However, particles of titanium have sometimes been found in the bone adjacent to these implants. The presence of metallic wear particles from implants in the liver, spleen have also been reported [29]. Metal ions released from implants may be the product of dissolution, fretting and wear, and may be a source of concern due to their potentially harmful local and systemic carcinogenic effects [30-31]. Grit blasting is another method that can be used to roughening the titanium surfaces by blasting the implants with hard ceramic particles. The ceramic particles are projected through a nozzle at high velocity by means of compressed air. Depending on the size of the ceramic particles, different surface roughness can be produced on titanium implants. Various ceramic particles have been used, such as alumina, titanium oxide and calcium phosphate particles. Alumina (Al_2O_3) is frequently used as a blasting material and produces surface roughness more than5µm. However, the blasting material is often embedded into the implant surface and residue remains even after ultrasonic cleaning, acid passivation and sterilization. Alumina is insoluble in acid and is thus hard to remove from the titanium surface. In some cases, these particles have been released into the surrounding tissues and have interfered with the osseointegration of the implants. Moreover, this chemical heterogeneity of the implant surface may decrease the excellent corrosion resistance of titanium in a biological environment. Titanium oxide is also used for blasting titanium dental implants. Titanium oxide particles with an average size of 25µm produce a moderately rough surface in the 1–2µm range on dental implants. Experimental studies using micro implants in human body showed a significant improvement for implant host bone contact for the TiO_2 blasted implants in comparison with smoothed machined surfaces [37-45]. In summary highly roughened implants from techniques such as TPS or grit blasted has been shown to favor mechanical anchorage and increase initial fixation to bone. Chemical treatments of the implant surfaces by surface etching are other alternative to providing rough surfaces at the micro scale to increase their fixation stability. In one of these methods commercially pure titanium plate was etched in 48% H_2SO_4 (Sulphuric acid) for 8 hours. The weight loss of the implant was derived from the weight differences before and after etching. The surfaces after etching were characterized by surface roughness, X-ray diffractometry, and scanning electron spectroscopy. It was found that the surface roughness of the titanium plate increased with acid temperature and the etching time. However chemical etching has limitations similar to those of die sinking EDM, which is limited to simple 2-D patterns because of uncontrolled action of the chemicals. Chemical treatments might also reduce the mechanical properties of titanium. For example, acid-etching can lead to hydrogen embrittlement of the titanium, creating micro cracks on its surface that could reduce the fatigue resistance of the implants [46]. Experimental studies have reported the absorption of hydrogen by titanium in a biological environment. This hydrogen embrittlement of titanium is also associated with the formation of a brittle hybrid phase, leading to a reduction in the ductility of the titanium [46]. Different types of anodization techniques like potentiostatic or galvanostatic anodization are used to create micro- or nano-porous surfaces on titanium in strong acids (H_2SO_4, H_3PO_4, HNO_3, HF) at high current density (200A/m2) or potential (100 V). Anodization results in thickening of the oxide layer to more than 1000nm on titanium. Using strong acids in an electrolyte solution causes the oxide layer to be dissolved along current convection lines and thicken in other regions. This dissolution of the oxide layer along the current convection lines creates micro or nano-pores on the titanium surface.

Anodization results in modification of the microstructure and the crystallinity of the titanium oxide layer. The anodization is a complex process and depends on various parameters such as current density, concentration of acids, composition and electrolyte temperature [47-50]. In summary topographies in the nanometer range can be used to promote body fluid adsorption, osteoblastic cell (bone cell) adhesion (for promoting bone growth) and the rate of bone tissue healing in the implant region.

In summary the surface characterization of the implants increases their primary fixation stability which aid in long term fixation stability due in increase in the rate of bone in growth in to the implant. The research in this thesis aims to manufacture the bone implants with customized surfaces at the macro level using CNC-RP_{bio} that would increase their initial fixation stability, reduce implant host bone interfacial movements and promote increase in osseointegration rate. This would maintain their biocompatibility once the bone implants are inserted in to the body.

CHAPTER 3: OVERVIEW

3.1 CNC-RP process planning steps

The research in this thesis presents a new methodology to manufacture bone implants with customized surface textures/finishes using CNC-RP (Subtractive Rapid *Manufacturing/Machining).* CNC-RP has been successfully used in creating accurate industrial parts in previous versions, and now for patient-specific bone implants made out of various materials. It uses a standard 3-axis CNC milling machine with a 4th axis for multiple setup orientations (*figure 3.1*). It features completely automated setup axis planning, fixture planning, tooling and setup planning including generation of NC code for creating a part directly from a CAD file. The process planning time for creating NC code for machining parts is between 15-45 minutes on average, while the machining time of the part depends upon its complexities. The use of a rotation axis eliminates the need for re-clamping of the part as in case of conventional fixturing methods. For each orientation,

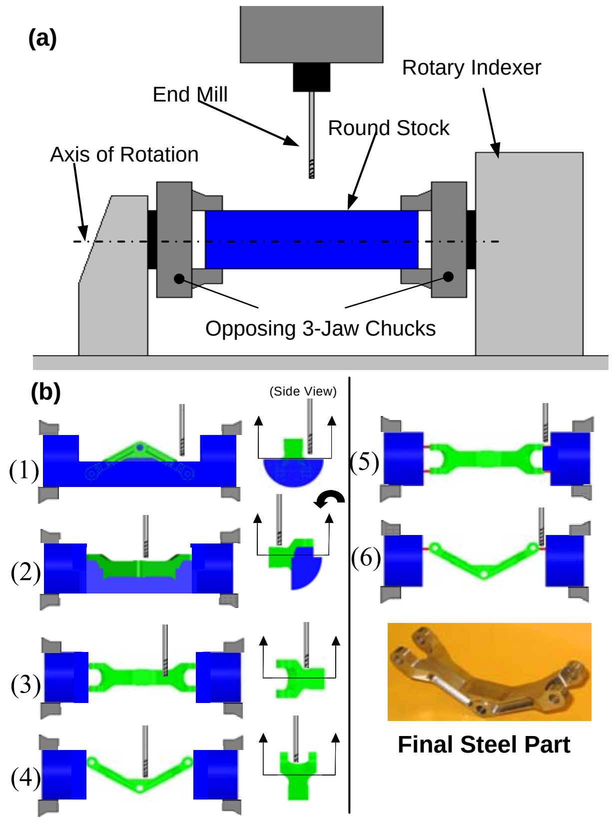


Figure 3.1: (a) CNC-RP setup; (b) steps b.1-b.4 expose component geometry while b.5-b.6 exposes sacrificial supports

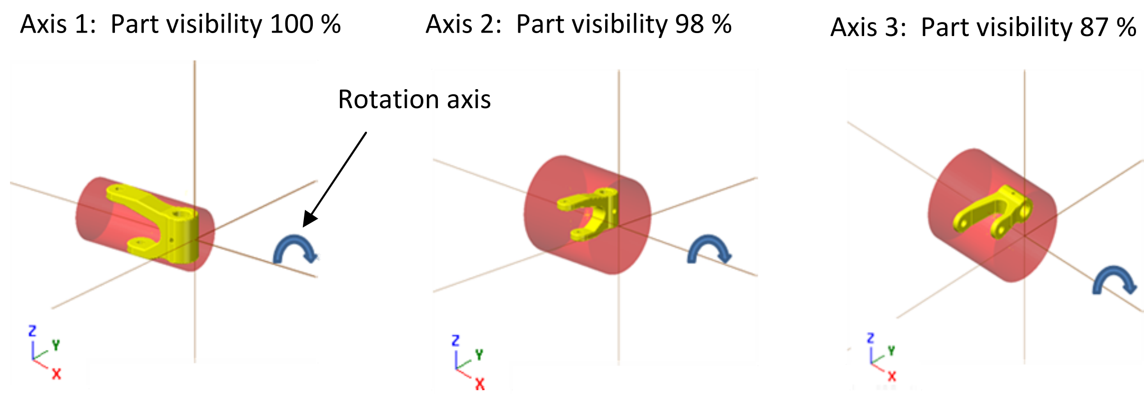


Figure 3.2: Setup axis decisions for the model; checking % visibility about the three orthogonal rotation axes

all the visible surfaces are machined and a set of sacrificial supports keep it connected to the uncut ends of the stock material. Once all the operations are complete, the supports are severed (sawed or milled) in a final series of operation and the part is removed. The setup and steps to this process are illustrated in Figure 3.1

3.1.1 Setup Axis decisions

In the setup axis decisions, the % visibility of the part is analyzed for all three orthogonal axes (X, Y and Z) and the best setup axis is chosen based on the maximum visibility of the part about a given axis, and minimum stock diameter that is required if the % visibility of the part model is equal for more than one setup axis (*figure 3.2*).

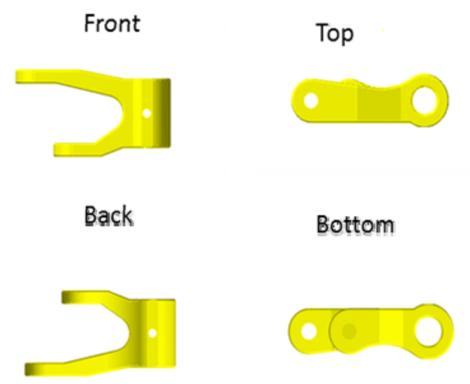


Figure 3.3: Visible part surfaces in 0° to 360° range

3.1.2 Setup Orientation Calculations

In the process planning for setup orientation calculations, a minimum number of setup orientations are calculated that will machine the entire part

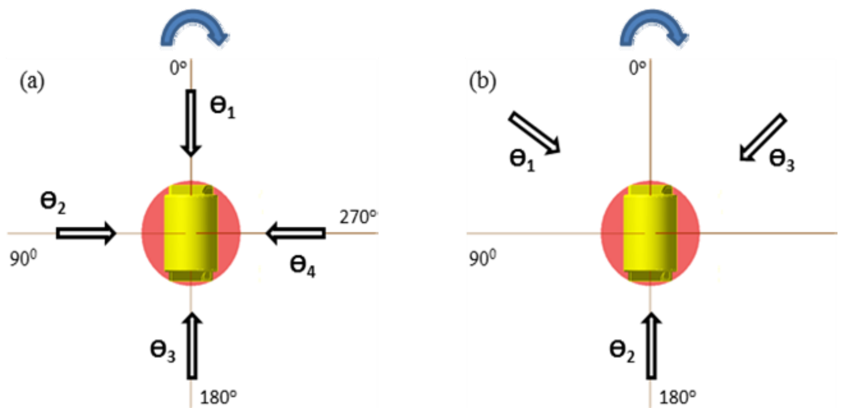


Figure 3.4: Feasible sets of setup orientations for machining the part about the chosen setup axis

about the chosen setup axis. The problem of calculating the solution set of setup orientations is termed as a *set cover* problem, where all the surfaces of the part visible (*figure 3.3*) in the range of 0^o to 360^o are included in the universal set. The algorithms designed in the previous version of CNC-RP ensures that each surface of part that is visible from the range of 0^o to 360^o about the chosen setup axis will be machined from at least one orientation from the calculated solution set. Figure 3.4 shows different feasible sets of setup orientations for the machining a sample part about a chosen setup axis.

3.1.3 Sacrificial supports generation

In the process planning for sacrificial supports creation, the supports are generated such that they can fixture the part end-to-end between chucks on a rotary axis and position the part between successive setup orientations for machining (*figure 3.5*). The geometry of the sacrificial supports is cylindrical and their diameter varies depending on the strength of the stock material used for machining and the required tolerance to be achieved. Thus stronger material/lower tolerances would allow supports that are lesser in diameter as compared to weaker material/tighter tolerances.

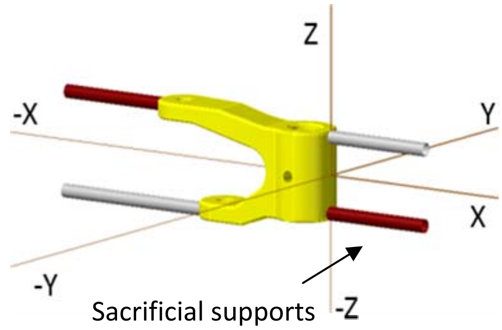


Figure 3.5: Sacrificial supports creation for part fixturing

3.2 Bone implant manufacturing using CNC-RP

The manufacturing of bone implants provides a very well suited challenge for CNC-RP, especially due to the fixturing issues and the need for specialty materials, in particular, human allograft bone. CNC-RP using current process planning methods for setup axis decisions, setup orientation calculation and sacrificial supports generation has been used successfully to machine patient specific segmental defect fillers. This includes use of clinically relevant materials. like Trabecular Metal® (porous tantalum), stainless steel, bio

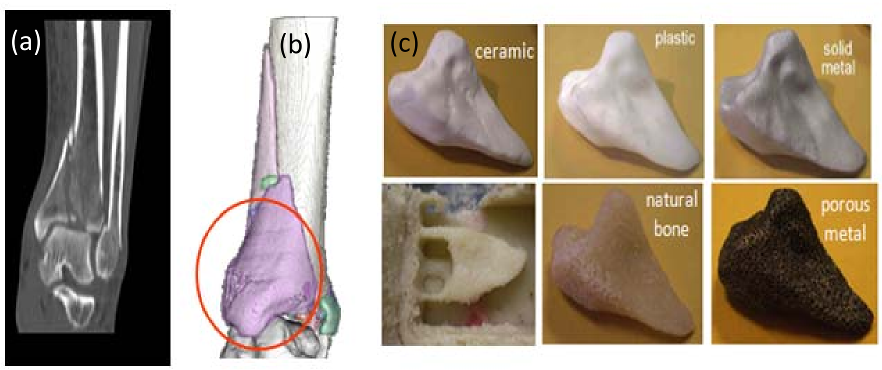


Figure 3.6: CNC-RP process flow: a) CT scan of fracture b) rendered image of the fracture c) bone fragments rapid machined using different materials

polymers, bio-ceramics, natural bone, etc. A 3D CAD model of a patient specific functional bone implant generated using CT scanning is shown in Figure 3.6, where a fragment from a human tibia was reverse engineered from CT. It was then rapid machined from different clinically relevant materials using CNC-RP. However unlike an industrial part, bone fragments may consist of different surfaces with different physical characteristics and functionalities. For a bone implant to be successful it is important that these surfaces maintain their functionality after the implant is inserted into the body.

3.3 Bone implant geometry

The segmental defect filler (bone fragment) can have up to 3 types of surfaces; *articular*, *periosteal* and *fractured*, as shown in Figure 7. The *articular* surface is the one which is in contact with other bones in a moving joint; the *periosteal* surface is in contact with muscles, tissues, veins, etc, while the *fractured* surface is the one that is created during the fracture event (trauma). It is intuitive that the periosteal and the articular surfaces should have smoother surface finishes in order to maintain their compatibility and functionality in the biological environment. On the other hand fractured surface lacks a well-defined geometry and is rough in general. The literature review has proved that the rougher fractured surfaces for attachment with the host bone would increase the frictional coefficient at the implant host bone interface. This would eventually increase

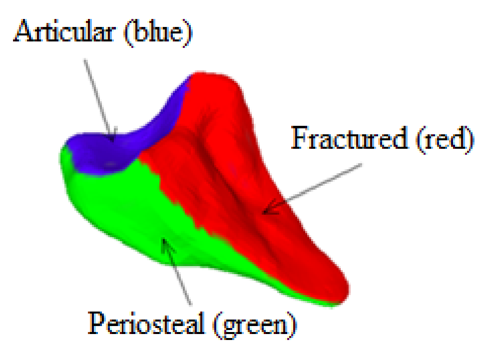


Figure 3.7-: Types of surfaces on a bone implant

primary fixation stability of the implant and aid in bone in growth which will improve the overall effectiveness of the inserted bone implant.

3.4 Preliminary friction testing

In order to measure the friction coefficients between the implant and the host bone interface, experiments were conducted at the Orthopedics Biomechanics Laboratory at the University of Iowa. Different levels of surface textures designated as *low*, *medium* and *high* were created on one side of 25.4 x 25.4 x 12.7 mm (1 x 1 x 0.5 inch) Delrin blocks (*figure 3.8.a*). This was accomplished through 90^0 offset parallel tool path machining with varying depths and step-overs of a ball-end mill (*figure 3.9.a*). The results for the friction test are given in Table 1, showing that friction at the implant/cancellous bone interface increased with increase in the roughness on the Delrin blocks. This implies that increase in the roughness of the fractured surface could reduce the implant/bone interface motion and improve the primary fixation stability of implants. The smooth surface finishes on the periosteal and articular surfaces could be created by controlling the step downs during the ball milling operation (*figure 3.9*). This would eventually allow having rougher texture on the fractured surface while having smoother periosteal and articular surfaces on the bone implant geometry. This would in turn increase the overall effectiveness of the inserted bone implants created using CNC-RP_{bio}.

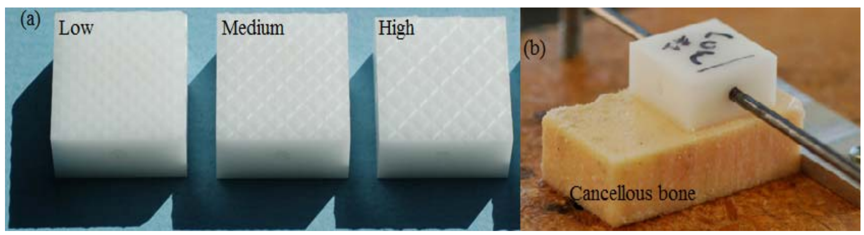


Figure 3.8: a) Delrin blocks with different intensity textures b) Test block on cancellous bone sample during friction testing

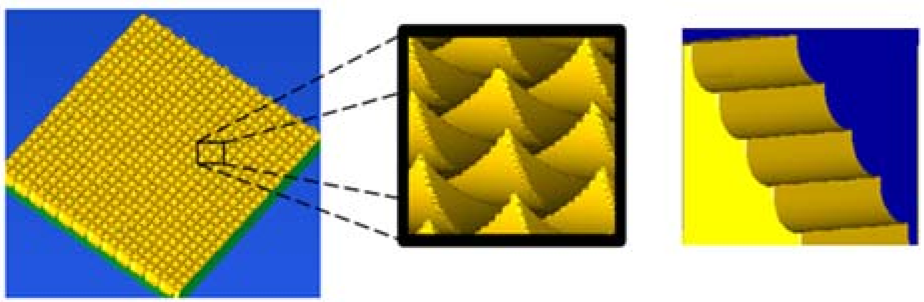


Figure 3.9: Simulation of created texture on fractured & periosteal/articular surface

3.5 Fixation screws and K wires

For increased strength of attachment between the implant and the host bone, biomedical hardware like titanium fixation screws and K wires are also used (*figure 3.10*). These fixation screws further reduce movement at the implant and the host bone interface. Ideally, bone implant geometries could be created with holes predrilled into them, which would further reduce surgeon's efforts in creating holes during surgery.

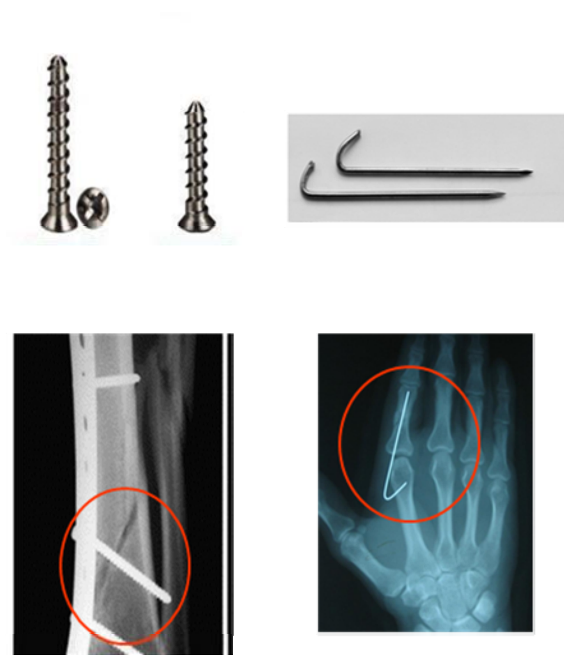


Figure 3.10: a) Fixation screws and K-wires for implant/bone attachment b) CT-scan of inserted fixation screw and X-ray of insert k-wire for fracture treatment

In CNC-RP, the setup axis for machining the accurate bone implant geometries is chosen based on its % visibility and the minimum stock diameter required. Going forward, one would need to consider these fixation holes as part of the setup axis decision problem.

For example, having the axis of the fixation screw holes orthogonal to the axis of rotation at any given setup orientation would enable machining of these screw holes (*figure 3.11*). However due to the complexities in the bone implant geometries, the number of required predrilled holes and the vector directions of these hole axes can vary over a large range. Figure 3.12 shows different combinations where the number of holes and the direction in which the position vectors of the hole axes point can be either same or different.

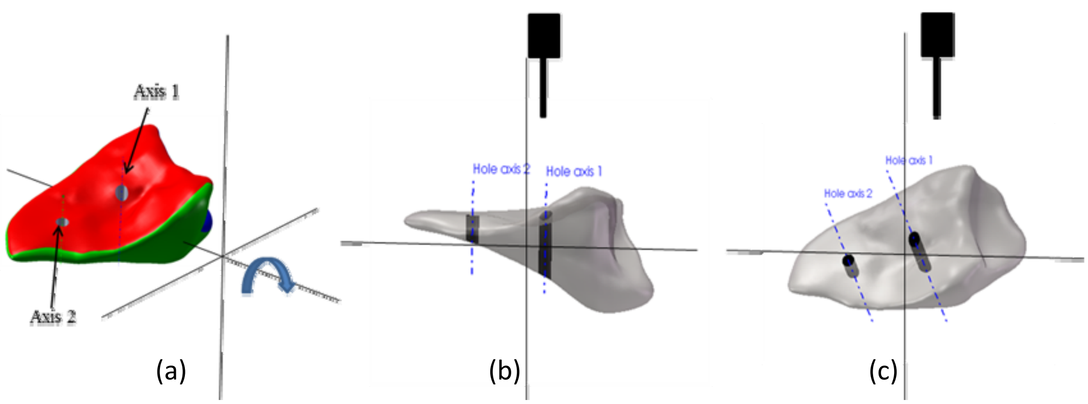


Figure 3.11: a) Setup axis for bone implant with fixation screw holes b) Setup axis allowing pre-drilling of fixation screw holes c) Setup axis not allowing pre-drilling of fixation screw

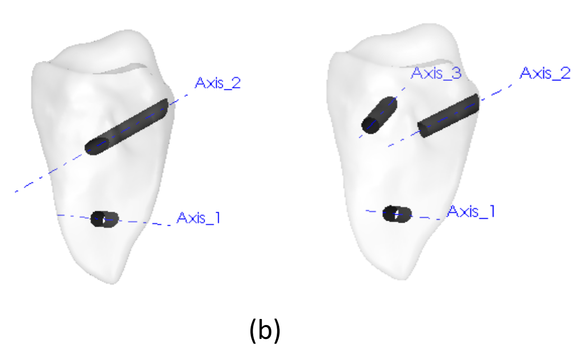


Figure 3.12: a) Bone implants with multiple parallel axes fixation screw holes b) Bone implants with multiple skewed axes fixation screw holes

A future addition to the CNC-RP_{bio} process will be to create additional process planning capabilities to create custom fixation holes, but will not be addressed further in this thesis.

3.6 Process planning for customized machining of bone implants

3.6.1 Setup orientation calculations for customized machining of bone implants

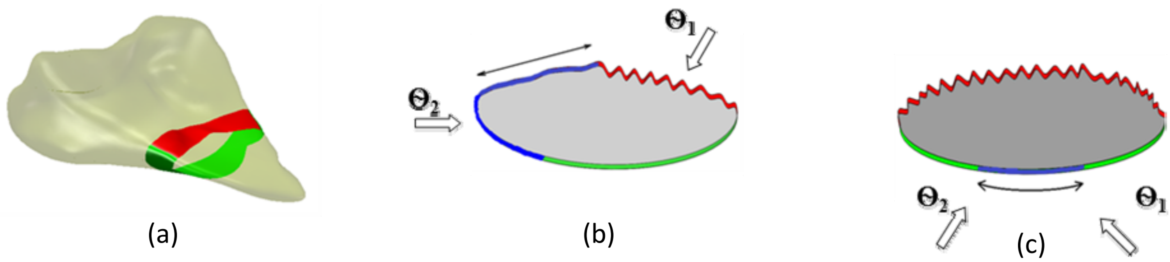


Figure 3.13: (a) Rough Fractured surface (red), Smooth Periosteal surface green b) Tool Path Crossover to fractured surface c) Tool Path Redundancy on periosteal surface

The setup orientations for custom machining of bone implants must be calculated such that the fractured surfaces are created with rough surfaces textures while the periosteal and the articular surfaces are created with smooth surfaces. Roughness on the fracture surfaces should increase the primary fixation stability of the implant while smooth periosteal and articular surfaces will maintain the biocompatibility of the implant. Therefore it would be necessary to calculate setup orientations that would target each surface and create surface specific characteristics on each surface individually while avoiding machining of other surfaces unintentionally. The process planning algorithms developed in this thesis for choosing surface specific setup orientations consider two primary issues of 1) Tool Path Crossover 2) Tool Path Redundancies.

3.6.1.1 Tool Path Crossover

Tool Path Crossover is the idea of "Crossing over", or machining onto another surface while machining the surface of interest (e.g.: machining the fractured surface when you were planning toolpaths for the periosteal surface), as illustrated in Figure 3.13.b. Tool Path Crossover can have two harmful effects on the functionality of bone implants. First, it can reduce the primary fixation stability of the implant and other, potentially making the implant unusable. For example Tool Path Crossover from fractured to periosteal surface would create rough texture on periosteal surface and make the implant unusable. However Tool Path Cross over from periosteal to fractured surface would create smooth surface on the fractured surface and reduce primary fixation stability of the implant; but in this case, would still would maintain implant's biocompatibility and maintain its usability. Regardless, the goal is simple; machine each surface with customized toolpaths, and avoid machining others while doing so.

3.6.1.2 Tool Redundancy

Tool Path Redundancy is simply redundant machining of a surface perimeter from multiple surface specific orientations (*figure 3.13.c*). In general, this is simply inefficient to do; machining an area that was machined from a previous angle. However, redundant machining of fractured surfaces could also lead to reduction of texturing effects (or wiping out completely) on the fractured surface of the implant. This would eventually lead to reduction in primary fixation stability of the implant. Tool Path Redundancy on periosteal or articular surface would just be inefficient, since additional smoothing of those surfaces is not physically undesirable. In this work, we will consider both functionality and efficiency since machining time could impact the practical use of this technology in a clinical setting (cost, machine capacity, etc.). The intent of this work is to provide an improved heuristic method to solve for setup orientations that reduce both Tool Path Crossover and Tool Path Redundancy. This work is presented in the following sections.

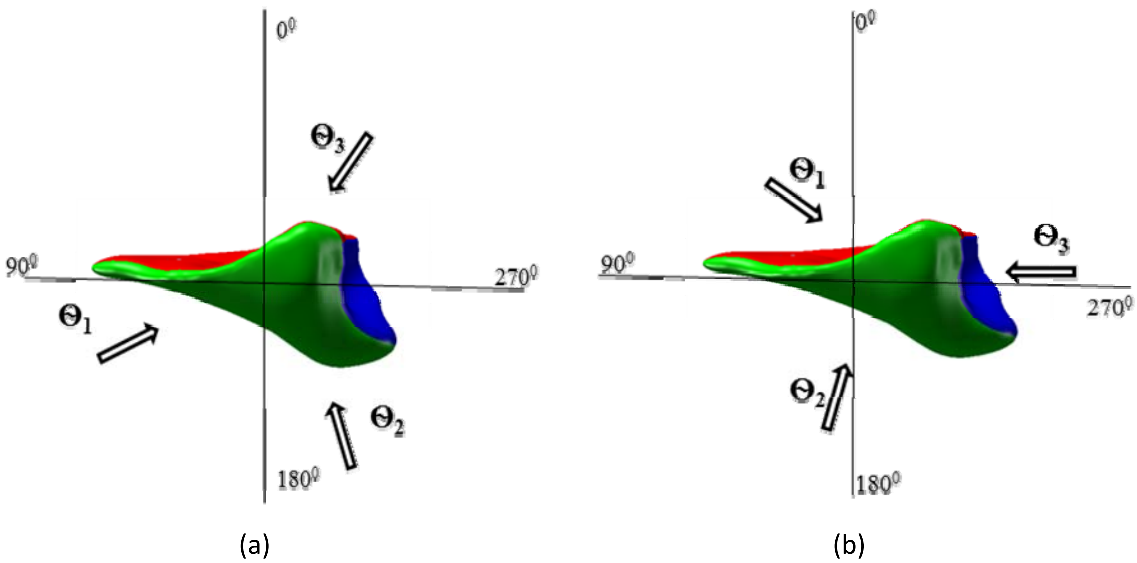


Figure 3.14: a) Setup orientations preventing surface customization b) Setup orientations allowing surface customization

Hence, in the case of three individual surfaces present on the bone implant, it would be necessary to have at least three setup orientations one for each surface that would create implant geometry surfaces with desired characteristics. Figure 3.14 illustrates a case for a bone fragment where in for Figure 3.14.a, orientation (Θ_1) will machine the periosteal surface only, orientation (Θ_2) is aimed at periosteal and articular surface and orientation (Θ_3) is aimed at fractured and articular surface. This shows that none of the orientations are aimed at any particular surface and would lead to significant Tool Path Crossover and

Redundancy. However Figure 3.14.b shows a better solution for setup orientations; where each angle is dedicated to one surface and would reduce both Tool Path Crossover and Redundancy to a great extent. This problem can be considered as a linear optimization problem where the surface specific setup orientations can be calculated based on the increase or reduction in the % visibility of the surfaces about the chosen setup axis. For example, if a setup orientation for a periosteal surface is to be calculated, the setup orientation will be chosen such that it simultaneously maximizes the visibility to the periosteal surface AND minimizes the visibility to the other two surfaces. In other words, it is not sufficient to only make a surface visible; one needs to make the other surfaces **not** visible. This overarching goal is addressed in detail in chapter 4 and is the primary goal of the work of this thesis.

3.6.2 Sacrificial supports generation and setup axis decisions for customized machining of bone implant

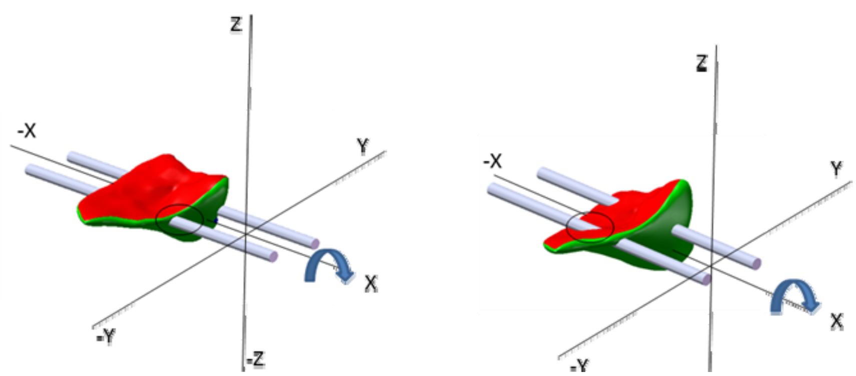


Figure 3.15: Sacrificial supports on different implant surfaces

Creating sacrificial supports on the bone implant geometries presents new challenges, in particular, not wanting to attach supports to certain functionally important parts of the bony surface and/or surfaces we are intentionally trying to make smooth or rough. The process planning for supports creation could actually be included in the early setup axis decisions, such that a surface chosen for adding supports could be oriented along the axis of rotation in the beginning planning stages. However the issue of setup axis decisions and sacrificial supports creation is again, outside the scope of this thesis and will be addressed in future work

3. 7 File format for custom machining of bone implants using CNC-RP$_{bio}$

The overall objective of this research is to automate the process of custom machining accurate bone implants made from clinically relevant materials using CNC-RP$_{bio}$ while providing surface-specific characteristics. This requires the use of a file format that allows identification of the individual surfaces on the bone implant geometry. As such, a PLY file format is proposed, instead of the de-facto standard STL file typically used in RP. Similar to the STL file format the PLY file format comprises of triangular facets that are used for approximating the part geometry. However, in addition to accurate geometry approximation, the PLY file format can store color information that can serve as the main identifier for the surface type (*figure 3.16*). The PLY file can be generated directly from a CT scan and subsequent surface identification of the individual surfaces.

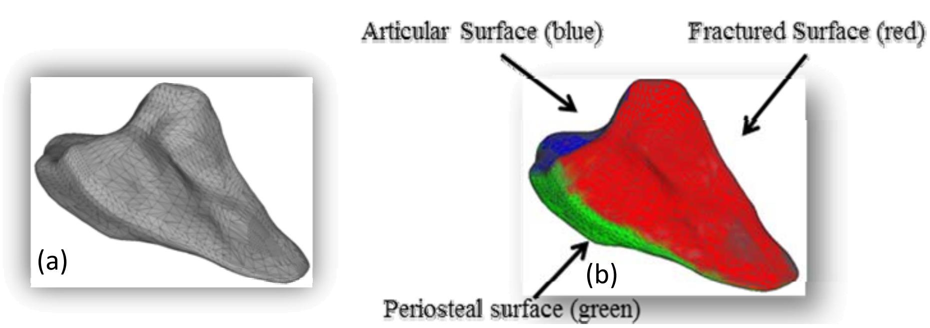


Figure 3.16: File formats a) STL format b) Colored PLY format

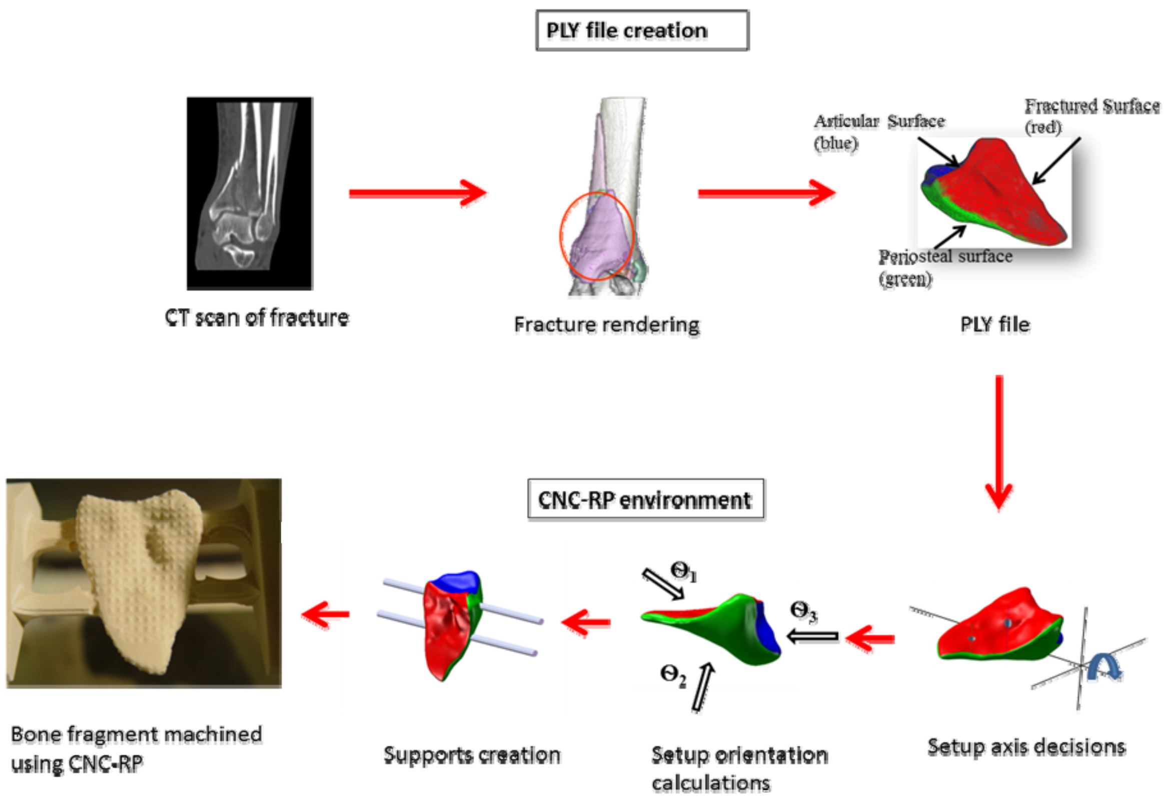


Figure 3.17: Process planning steps for rapid machining of bone implants

Figure 3.17 summarizes the process planning steps from CT-Scan fracture image to the custom machining of patient specific functional bone implants using CNC-RP_{bio}. However this thesis focuses primarily on the development of process planning algorithms for calculating surface specific setup orientations about the chosen setup axis. Next, chapter 4 presents a journal paper entitled "*Patient-Specific Bone Implants using Subtractive Rapid Prototyping*" which in particular focuses on developing a new set of process planning methodologies and algorithms for calculating setup solutions for surface specific machining of implants.

CHAPTER 4: PATIENT-SPECIFIC BONE IMPLANTS USING SUBTRACTIVE RAPID PROTOTYPING

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Abstract

This research involves the development of a rapid manufacturing process for patient-specific bone implants using Subtractive Rapid Prototyping. The geometry of segmental defects in bone, resulting from traumatic injury or cancerous tumor resection, can be reverse-engineered from medical images (such as CT scans), and then accurate defect fillers can be automatically generated in advanced synthetic or otherwise bioactive/biocompatible materials. This paper presents a general process planning methodology that begins with CT imaging and results in the automatic generation of process plans for a subtractive rapid prototyping (RP) system. This work uniquely enables the rapid manufacturing of implant fillers with several key characteristics including suitable bio-compatible materials and custom surface characteristics on specified patches of the filler

geometry. This work utilizes a PLY input file, instead of the more common STL file used in RP, since color texture information can be utilized for advanced process planning depending on whether the surface is fracture, periosteal or articular in origin. The future impact of this work is the ability to create accurate filler geometries that improve initial fixation strength and stability through accurate mating geometry, fixation planning and inter-surface roughness conditions.

Keywords: Rapid Machining, Rapid Prototyping, Bone Implants, Surface Texturing

4.1 Introduction

Bone implants are used to replace missing pieces or severely damaged sections of bone, whether due to high energy trauma or after tumor removal in the case of bone cancer. These implants can be made from artificial bone substitutes, or using natural bone in the form of Allo- or Autografted bone taken from a donor or the patient, respectively. For example, implants used in bone repair and joint replacement have been made from solid and porous stainless steel, ceramics, natural coral, allograft and autograft bone, and different alloys of titanium and cobalt, among others. In any case, there is the challenge of having the correct shaped implant created from an appropriate material. In surgery, the geometric construction of these implants is usually done by hand crafting from the surgeon. The field of rapid prototyping and additive manufacturing has offered several new methods for creating implants, ranging from solid to porous materials, bioactive scaffolds, etc. There has been limited or no work in the field of subtractive rapid prototyping of bone implants prior to the current research of this paper. However, there has been clinical use of machining for the shaping of bone implants prior to surgery. This paper presents work in the ISU Rapid

Manufacturing and Prototyping Laboratory (RMPL), in collaboration with the Orthopedic Biomechanics Laboratory from the University of Iowa Hospitals and Clinics. Using advanced 3D puzzle solving software developed by researchers at the University of Iowa and UNC-Charlotte [1], accurate 3D CAD model reconstructions of the missing bone can be created directly from CT scanning of the patient.

The research of this paper attempts to combine the use of acceptable biocompatible materials with accurate geometric shape machining capabilies. The overarching goal is to create implants that will provide initial fixation strength that is better than hand shaped fillers by the surgeon, while still being able to use the variety of materials desired. There is previous research that has addressed the issue of fixation with respect to implant use. The fixation stability of a cemented orthopedic implant and the host bone may be compromised either due to degradation of the bone cement itself, or there may be modeling and remodeling of the bone that occurs at the bone-implant interface [2]. Eventually, failure of the implant occurs either due to stress shielding or host inflammatory response due to wear debris [3-4]. The initial fixation stability of an uncemented orthopedic implant is affected by the interfacial friction between the implant's surface and the host bone. A higher implant/bone interfacial friction not only increases the implant's initial fixation stability, but can also keep the interface motion low enough to enhance bone in growth into the implant. This bone in growth then allows long-term fixation of the implant [5]. Mechanical interlock between the implant and host bone may be achieved by providing surface textures or features like threads or grooves that help to maintain the position of implant with respect to the host bone [6-7].

The ability to create accurate geometries could be achieved using additive RP, except in some cases where porous materials are to be created and support structures (loose powder, etc.) could not be removed completely. Otherwise, additive RP would be more capable than subtractive RP for the creation of complex and/or hollow geometries. However, the more niche area that this paper's work addresses is in bio-materials that cannot be created using additive means, such as real bone in the form of Allografts, or clinically used forms of bone substitutes such tantalum foams (Trabecular Metal®). To this end, we present a method using Subtractive Rapid Prototyping using a method called CNC-RP, in conjunction with 3D puzzle solving, for the accurate and highly automated creation of bone implant fillers.

4.2 Related Work

Biomedical implant manufacturing using layer based additive techniques has made significant progress in creating patient specific implants. Due to the nature of the human body and the way its components are unique to the specific individual, it is a very challenging task to create accurate fragments of bone implants that can be implanted during surgery. In previous work, CT and CAD data has been used to create SLA parts [9-10]. These SLA parts were then used to cast maxillofacial implants out of titanium. A similar process was used to create wax models from SLA parts for investment casting of craniofacial implants [11-12]. Conventional CNC machining has also been used to create human femur models; however, the accuracy of the finished product was limited due to the availability of only two machining orientations [13]. There have also been substantial studies on the biological effects of surface textures (roughness) on implants with host bones. In vitro and in vivo studies have provided strong indication that biological responses to titanium are influenced by surface texture (roughness). In one example, a titanium implant created using Electron Beam Melting (EBM) had wavy surface structures and rounded protrusions; multiple crevices and invaginations showed increased bone ingrowth into the implant [14]. Selective Laser Sintering (SLS) has also been used in creating Hydroxyapatite (HA) coated pyramidal and stipple shaped porous implants made out of Co-Cr alloys. These implants have shown increased rate of bone ingrowth [15].

Several nontraditional processes such as chemical etching, grit blasting, die sinking EDM, and ultrasonic machining can be used to produce fine and accurate surface textures. For example, die sinking EDM can be used for producing accurate surface textures by plunging a graphite electrode on a plain machined, cast or forged metal implants. However such a process is limited to simple 2-D patterns because of constrained unidirectional motion of the electrode. The same limitation applies to chemical etching, which is limited to simple 2-D patterns because of uncontrolled action of the chemicals. The use of EDM also leads to localized heat stresses, creating a white layer on the part surface which reduces the fatigue strength of the bulk implant [8].

4.3 Rapid manufacturing using CNC-RP

CNC-RP is a fully functional Subtractive Rapid Prototyping system (SRP) using a standard 3-axis CNC milling machine with a 4th axis for multiple setup orientations. It features completely automated fixture planning, tooling and setup planning including generation of NC code for creating a part directly from a CAD file [16-22]. The use of a rotation axis eliminates the need for re-clamping of the part; a common task in conventional fixturing methods. For each orientation, all the visible surfaces are machined and a set of sacrificial supports keep it connected to the uncut end of the stock material. Once all the operations are complete, the supports are severed (sawed or milled) in a final series of operations and the part is removed. The setup and steps to this process are illustrated in Figure 4.1. The manufacturing of biomedical implants provides a very well suited challenge for CNC-RP, especially due to the fixturing issues and the need for specialty materials, in particular, human allograft bone. Preliminary trials have been conducted and are illustrated in Figure 4.2; where a fragment from a human tibia

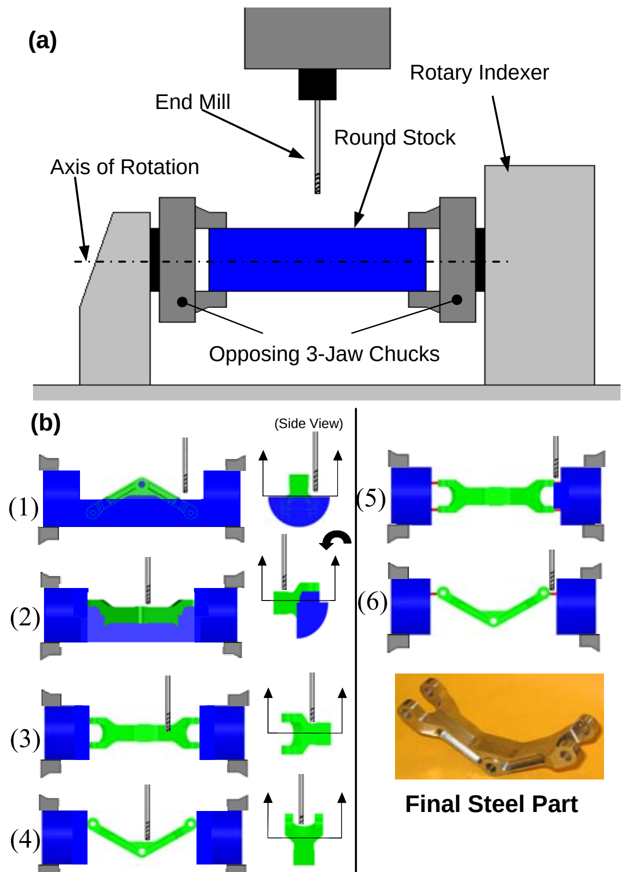


Figure 4.1 - (a) CNC-RP setup; (b) steps b.1-b.4 expose component geometry while b.5-b.6 exposes sacrificial supports

was reverse engineered from a CT scan and then rapid machined from clinically relevant materials using the CNC-RP process.

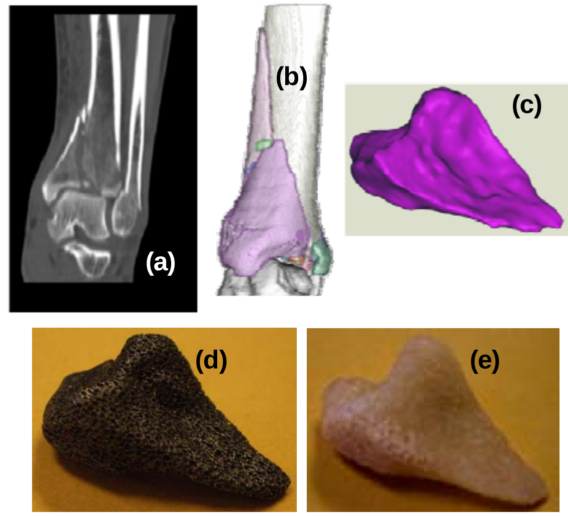


Figure 4.2: Example implant machining; a) CT scan, b) Segmented image c) CAD model, d-e) implants in porous metal and bone

4.4 Problem Formulation and Preliminary Studies

A segmental defect filler can have up to 3 types of surfaces; *articular*, *periosteal* and *fractured*, as shown in Figure 4.3. The *articular* surface is the one which is in contact with other bones in a moving joint; the *periosteal* surface is in contact with other tissue, while the *fractured* surface is created during the fracture event

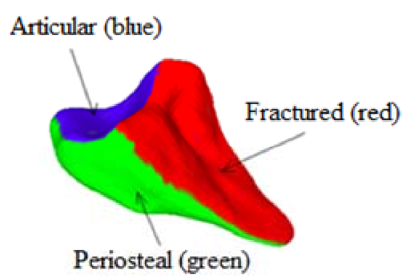


Figure 4.3: Types of surfaces on bone implant

(trauma). In CNC-RP_{bio}, implants would be created with the same surface finish on all surfaces. However, providing a rougher surface texture on the fractured surface, for example, could increase the interfacial friction between the implant and the host bone and thereby improve its corresponding fixation stability. This texture could be imparted onto the surface through machining, rather than designed in CAD, by using specifically planned toolpaths on the implant surface (*figure 4.4*). A small experiment was conducted to measure friction coefficients at the interface of the proposed fractured bone implant surfaces against natural cancellous bone.

Different intensities of surface textures designated as *low*, *medium* and *high* were created on one side of 25.4 x 25.4 x 12.7 mm (1 x 1 x 0.5 inch) Delrin blocks (*figure 4.5*). This was accomplished through 90-degree offset parallel toolpath machining with varying depths and step-overs of a ball-end mill. The results for the friction test are given in Table 1, showing that friction at the implant/ cancellous bone interface increased with increasing roughness on the Delrin blocks. This should imply that increases in the roughness of the fractured surface could reduce the implant/bone interface motion and improve the initial fixation stability of implants. Smoother surface finishes on the periosteal and articular surfaces would be similarly created by controlling the step downs during the ball milling operation.

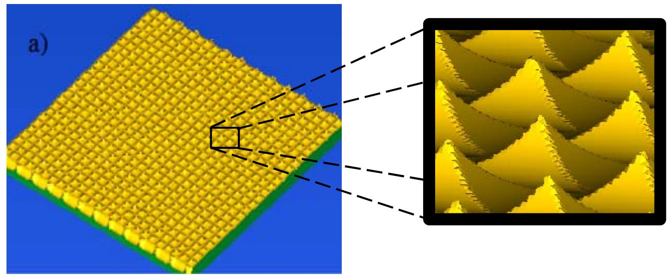


Figure 4.4: Simulation of created texture on fractured surface

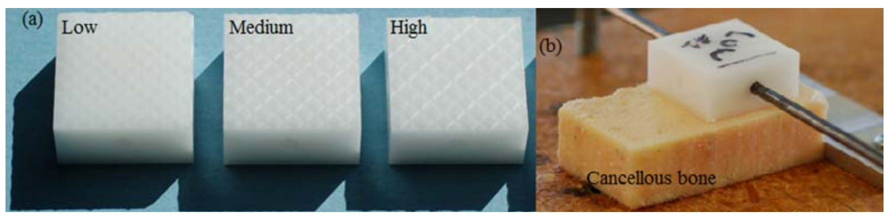


Figure 4.5: Surface texture friction testing; a) delrin test blocks on increasing roughness, b) test block on cancellous bone sample during friction testing

Table 4.1: Friction coefficient test results for different surface textures friction testing

Slider	Coefficient
Smooth	0.25
Low	0.35
Medium	0.44
High	0.48

4.5 Proposed Solution for new Process Planning Method

The overall objective of this research is to automate the process of custom machining accurate bone implants made from clinically relevant materials using CNC-RP_{bio} while providing surface-specific characteristics. In order to customize the surface roughness on separate implant areas, we propose the use of a PLY file format, instead of the de-facto standard STL file typically used in RP. Similar to the STL format, the PLY file format uses triangular facets for approximation of the part geometry. Additionally, the PLY file format offers the ability to store color information on the model which will serve as the main identifier for the surface type. In this new solution method, the PLY file is sliced similar to the STL, and then setup axis and setup orientations calculations are conducted on these colored slice files. The setup orientations are calculated using a set covering *greedy* heuristic in conjunction with a new objective function to measure the goodness of a given setup orientation specific to a surface. As in the CNC-RP, layer based toolpaths for rough machining the model surfaces are executed at each prescribed setup orientation. However, the PLY file format now allows us to further customize finishing operations for each surface type, since we will now have setup orientations that are isolated to individually cover (machine) each surface. Figure 4.6 illustrates the overall process flow for creating custom machined segmental defect fillers using CNC-RP_{bio}. The flowchart shows the path from the initial opening of the surface model within MasterCAM (left column) and the offline analyses of the PLY file color slices in the right column. The flowchart illustrates both previously developed methods and the current, new methods using PLY files. For brevity, we do not describe the steps of sacrificial support addition, or setup axes decisions. The major contribution of this paper is focused on solving the newly prescribed setup orientation problem as it relates to customizable surfacing

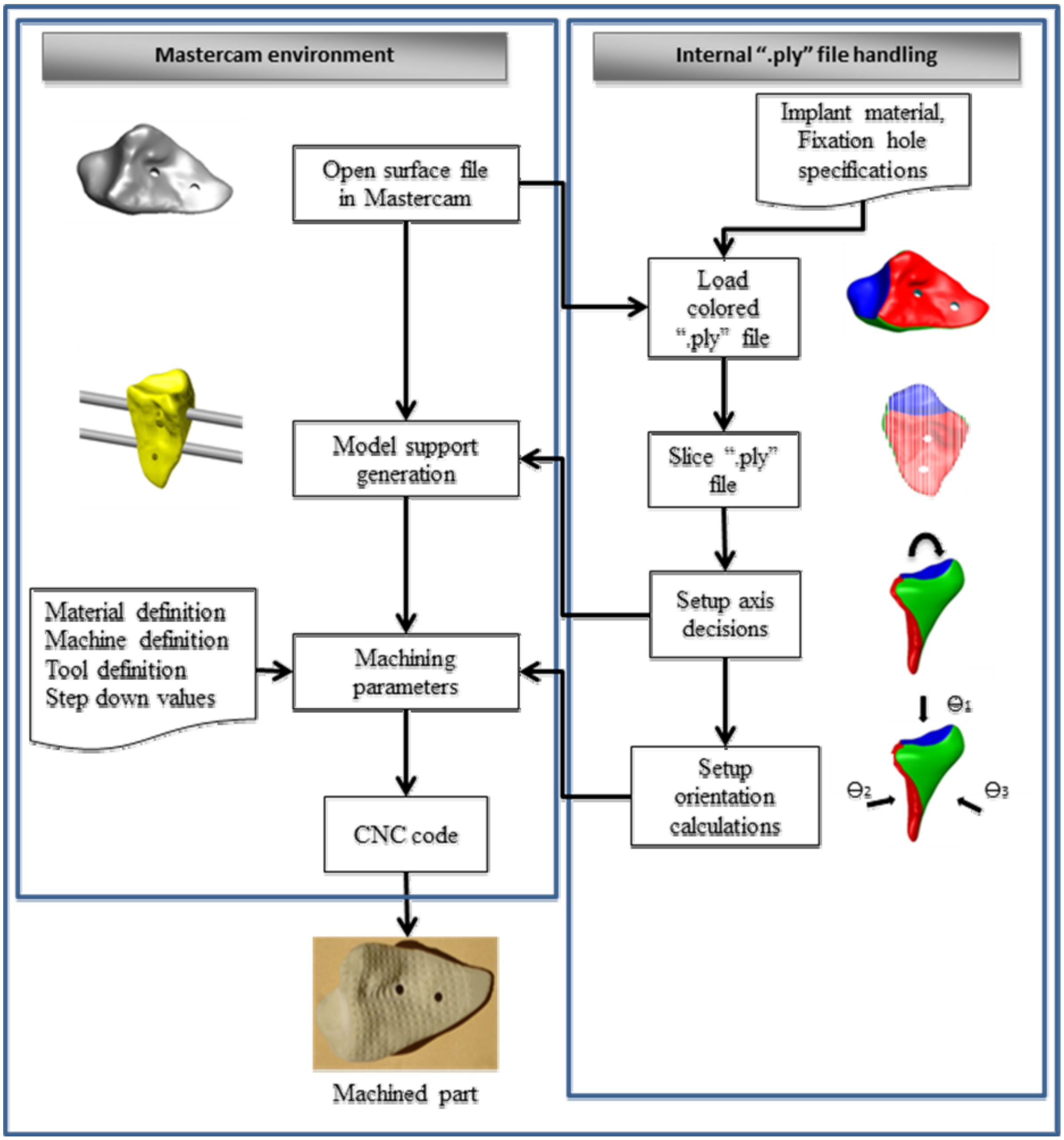


Figure 4.6: Flowchart illustrating the automated process planning steps, from CT-derived CAD model to machined implant friction testing

4.6 PLY files for rapid machining of customized bone implants

The PLY format is a boundary representation of the 3D CAD model approximated by triangular facets similar to the STL format. Additionally, the PLY format provides texture (color) information (*figure 4.8*) on the part as opposed to the STL format. This color information on the PLY file can serve as the main identifier for each surface on the part geometry. The PLY files have the ability to be painted using any commercial CAD software available. For this work in bone implants, the fractured surface is painted red, periosteal green and articular blue. Figure 4.8 shows a sample PLY file compared with the STL format while Figure 4.9 provides the PLY file data structure.

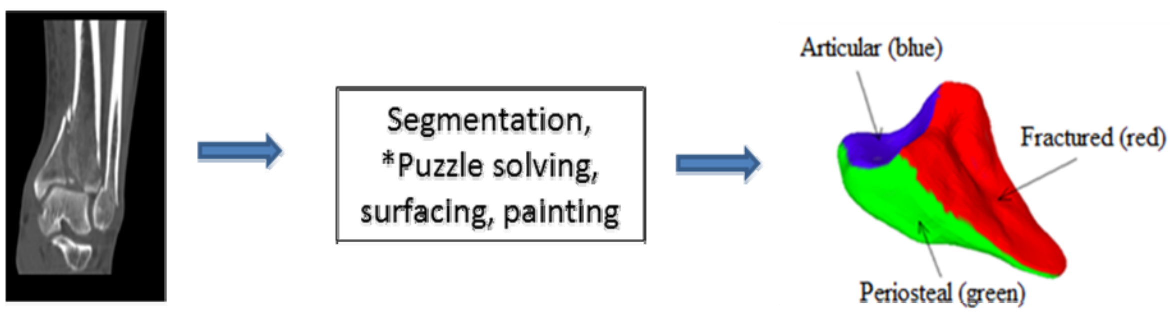


Figure 4.7: Process flow for generating PLY file

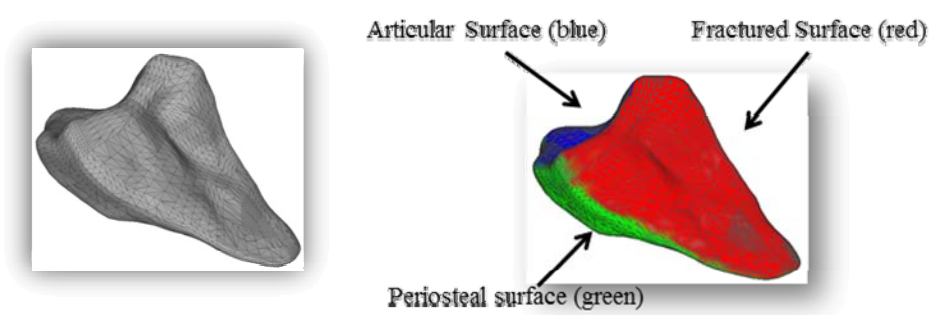


Figure 4.8: Sample STL and PLY file

Facet vertex coordinates "float" value
-13.2149 -63.4122 -7.8075
-13.1107 -63.2037 -8.24142
-13.1987 -63.8419 -7.69453
-12.9995 -62.9494 -8.6638
-13.0603 -63.6425 -8.1625
-12.9129 -62.7087 -9.08072

Vertex index & Facet pointers
3 5 1 2
3 5 3 1
3 7 2 4
3 7 5 2
3 8 5 7
3 11 4 6

File Header
Ply
format ascii 1.0
comment
element vertex 45744
property float x
property float y
property float z
property uchar red
property uchar green
property uchar blue
element face 80882
property list uchar int vertex_indices
end_header

RGB color values "uchar" per vertex		
165	145	138
176	159	152
160	72	84
188	169	163
189	162	153
232	218	205

Figure 4.9: PLY file data structure

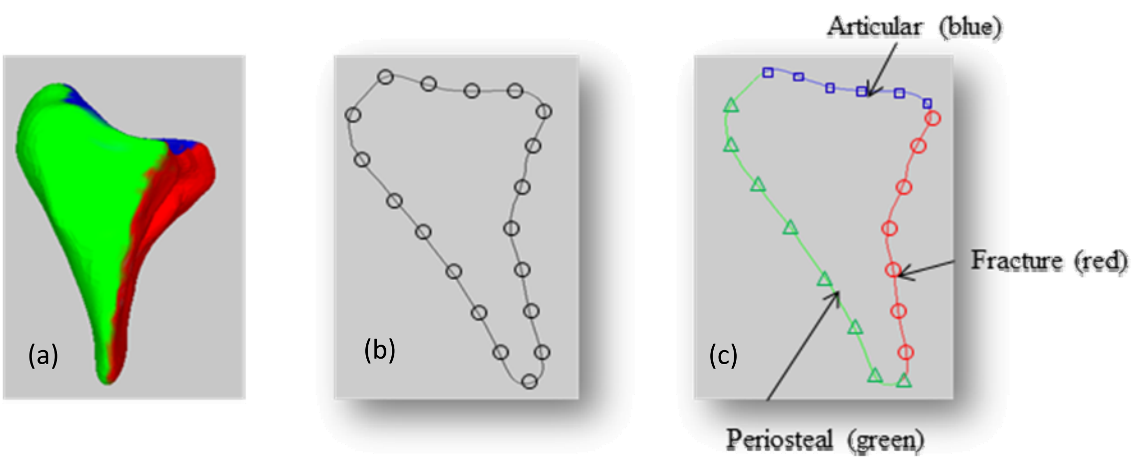


Figure 4.10: a) 3D Colored PLY model b) 2D uncolored STL slice c) 2D colored PLY slice segments of the bone implant

During process planning for the rapid machining of customized bone implants using CNC-RP$_{bio}$, the PLY files are sliced similar to the STL files orthogonal to the chosen axis of rotation. Each slice is comprised of multiple simple polygons (chains) represented by the end points of the polygon segments (edges of the polygon) *(figure 4.10.b/c)*. For distinguishing surfaces from one another, the points on the 2D segments on articular/periosteal/fractured surface slices are represented with both color and the symbols (○,△,□), respectively hence forth in this thesis (*figure 4.10c*).

4.7 Process planning for calculating surface specific orientations

In the previous work for CNC-RP process planning, it was only deemed necessary that **all** surfaces of the part model were machined after **all** setup orientations were completed. This problem of calculating the set of setup orientations for machining the entire part is classified as a *Set Cover* problem; where all the surfaces of the part model visible in the range of 0° to 360° are included in the universal set (*figure 4.11*).

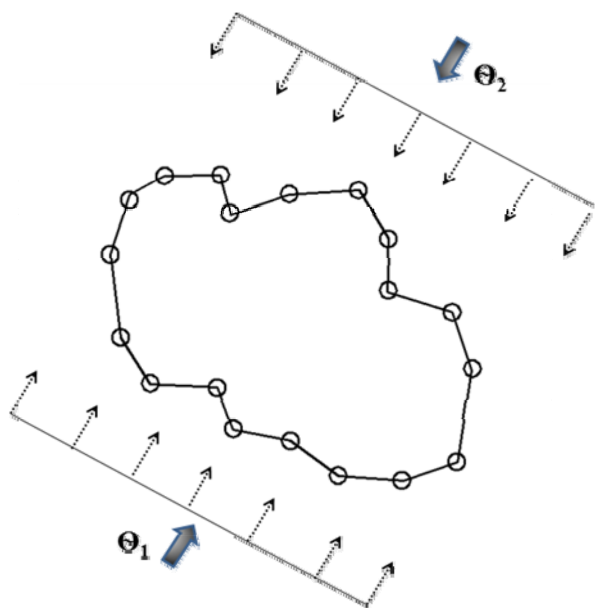


Figure 4.11: Setup orientations using STL

The algorithms designed for the CNC-RP ensure that each surface of the part visible in the range of 0° to 360° is machined from at least one setup orientation from the solution set.

Using the mapped visibility ranges for each segment on the slice file, the minimum number of setup orientations required for machining the part is calculated (*figure 4.11*). Due to the lack of surface identification on the STL file, the previous algorithms for calculating setup orientations are designed to target the entire model geometry but do not create different finishes on each surface. Colored PLY files will now allow for setup orientations that are aimed at specific surfaces and create specific characteristics; while avoiding machining other surfaces. The basic Set Cover approach is used here, but with a difference of achieving set cover for each set of segments for each surface individually rather than the entire model. Thus in order to target individual surfaces, setup orientations have to be chosen such that they are aimed at surfaces individually as shown in Figure 4.12 rather than multiple surfaces together. In this work, setup

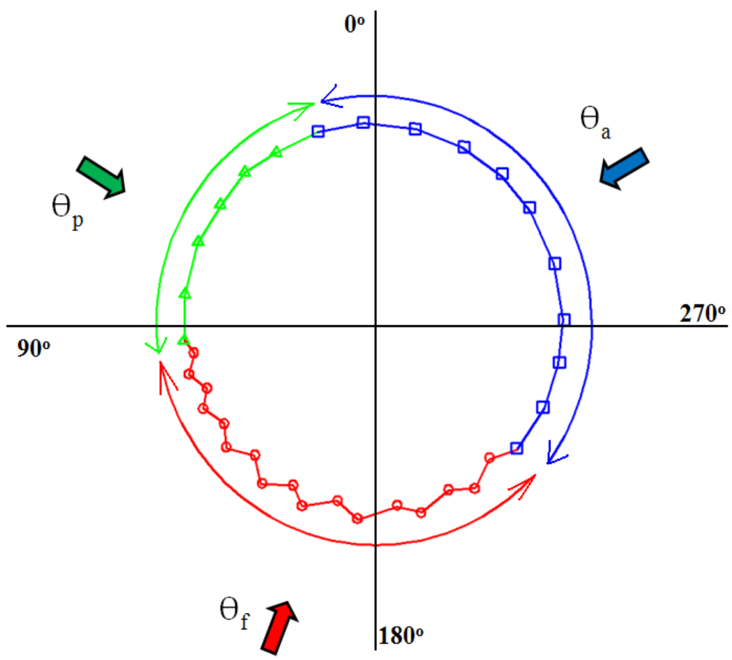


Figure 4.12: Setup orientations targeting individual surfaces

orientations specific to articular/perioste al/fractured surfaces are designated as $\theta_{a/p/f}$. The process planning algorithms developed in this thesis for choosing surface specific setup orientations consider two primary issues of 1) Tool Path Crossover 2) Tool Path Redundancies, which are explained in the next section.

4.7.1 Tool Path Crossover

Tool Path Crossover is the idea of "Crossing over", or machining onto another surface while machining the surface of interest (e.g.: machining the periosteal surface when you were planning toolpaths for the fracture surface), as illustrated in Figure 4.13. Tool Path Crossover can have two harmful effects on the functionality of bone implants. First, it can reduce the primary fixation stability of the implant and other, potentially making the implant unusable. For example Tool Path Crossover from fractured to periosteal surface would create rough texture on periosteal surface and make the implant unusable. However Tool Path Cross over from periosteal to fractured surface would create smooth surface on the fractured surface and reduce primary fixation stability of the implant; but in this case, would still would maintain implant's biocompatibility and maintain its usability. Regardless, the goal is simple; machine each surface with customized toolpaths, and avoid machining others while doing so.

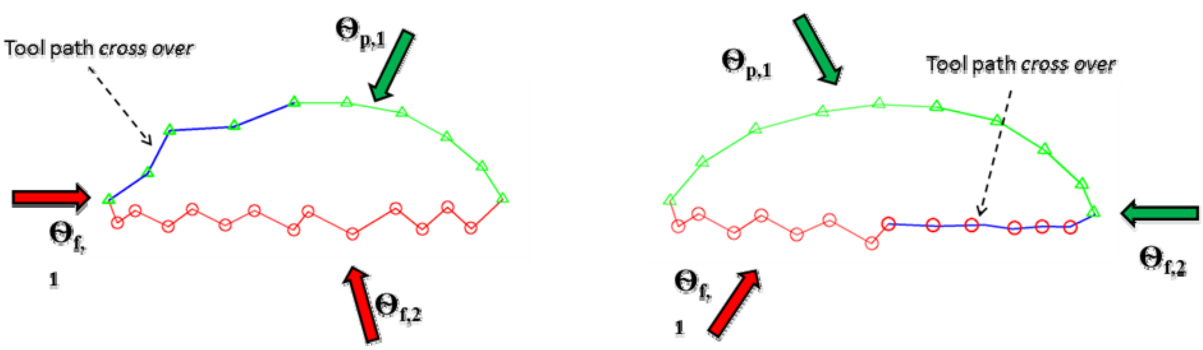


Figure 4.13: Tool path Crossover

4.7.3 Tool Redundancy

Tool Path Redundancy is simply redundant machining of a surface perimeter from multiple surface specific orientations (*figure 4.14*). In general, this is simply inefficient to do; machining an area that was machined from a previous angle. However, redundant machining of fractured surfaces could also lead to reduction of texturing effects (or wiping out completely) on the fractured surface of the implant. This would eventually lead to reduction in primary fixation stability of the implant. Tool Path Redundancy on periosteal or articular surface would just be inefficient, since additional smoothing of those surfaces is not physically undesirable. In this work, we will consider both functionality and efficiency since machining time could impact the practical use of this technology in a clinical setting (cost, machine capacity, etc.)

The intent of this work is to provide an improved heuristic method to solve for setup orientations that reduce both Tool Path Crossover and Tool Path Redundancy. This work is presented in the following sections.

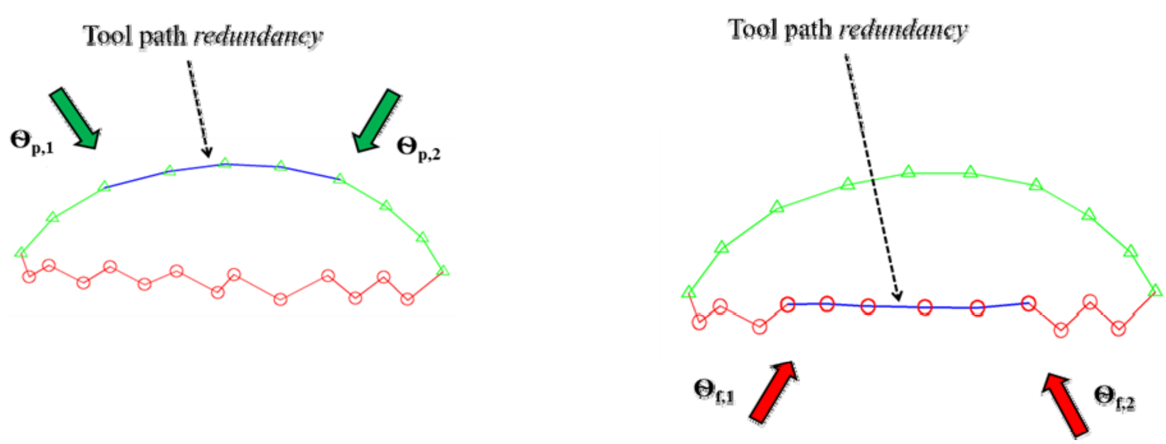
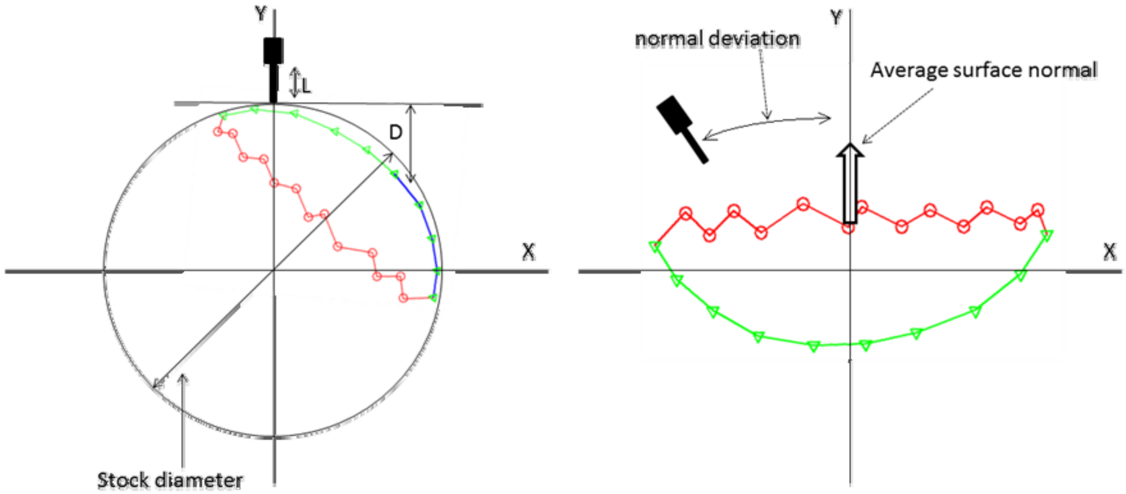


Figure 4.14: Tool path Redundancy

4.8 Modified Greedy Heuristic using an Objective Function

In order to find setup orientations that would generally isolate a given surface and machine it with minimum Tool Path Crossover and Redundancy, a multiple objective function is developed that maximizes visibility of the intended surface and minimizes the visibility of the undesired/other surfaces. There can also be a case where a certain percentage of a surface is visible from a current orientation but is not accessible because of limited tool length available. Thus comparing the maximum tool length available against the perpendicular distance from each visible point to the tangent line at the solution orientation, the total accessible perimeter out of the visible perimeter is calculated (*figure 4.15.a*). Another factor to be considered is the magnitude of the intended surface roughness that can be imparted onto the fractured surface. In other words, not only do we wish to target the fractured surface, but we also want to be better positioned to impart a desired rough surface. There has been a significant research in the field of machining to achieve custom surface roughness values by varying tool axis inclination with respect to surface normal (*figure 4.15.b*). It has been found that the surface roughness decreases with increase in tool axis inclination away from the surface normal, which reduces scallop height. However in the case of articular and periosteal surfaces, increase in normal deviation actually increases surface roughness. This occurs because at a higher normal deviation the tool happens to go further for a constant step over and create sharp ridge lowering the finish of these surfaces. Since this work intends to increase surface roughness for fractured surface and reduce it for other two surfaces, it would be desirable to minimize the tool axis inclination from normal for each surface.



(a) (b)

Figure 4.15: a) Tool Length L < Depth D, inaccessible blue surface b) Difference ΔN between orientation and average surface normal

A multiple objective function is proposed that can aid in choosing setup orientations that a) maximize the visibility and accessibility of the desired surface b) minimizes the visibility and accessibility of the undesired surfaces to reduce Tool Path Crossovers c) minimizes visibility of common surface perimeter between multiple orientations to reduce Tool Path Redundancy. Maximizing the visibility and accessibility of the desired surface helps in isolating the tool paths on that surface. Lastly, the objective function tries to reduce the difference between an orientation and average surface normal for the sake of imparting respective surface roughness for each surface.

The objective function is as follows:

$$Max\ \{\mathrm{V} + \mathrm{IP} - \Delta\mathrm{N} - \mathrm{R}\}$$

Where: V is the visibility of each of the three surfaces:

$$\left\{\sum_{j=0}^{n}[\pm\ \alpha(X)_{p,j} \pm\ \beta(X)_{a,j} \pm\ \gamma(X)_{f,j}]\right\}$$

$(X)_{p,a,f}$: Visible perimeter of the periosteal, articular or fractured surface

IP is the inaccessibility of surfaces visible from a particular orientation:

$$(\mathrm{IP}) = \{\pm\ (IX)_p\ \pm\ (IX)_a \pm\ (IX)_f\}$$

Where inaccessibility is given for each of the three surface types:

$$(IX)_p = \lambda\left\{\sum_{j=0}^{n}[(X)_{p,j} - (AX)_{p,j}]\right\}$$

$$(IX)_a = \eta\left\{\sum_{j=0}^{n}[(X)_{a,j} - (AX)_{a,j}]\right\}$$

$$(IX)_f = \sigma\left\{\sum_{j=0}^{n}[(X)_{f,j} - (AX)_{f,j}]\right\}$$

$(AX)_{p,a,f}$: Accessible perimeter of the surfaces based on the maximum tool length used

ΔN is the difference between the setup orientation and the average surface normal.

And R is the Tool Path Redundancy between accessible perimeters visible from more than one setup angle:

$$R = Min\left\{\sum_{i=0}^{m}\sum_{j=0}^{n}[(AX)_{p/a/f,i,j}] - 100\right\}$$

In addition to the previous implementation of a visibility algorithm to solve for the setup angles, we now use this objective function to evaluate the "goodness" of a feasible solution. A feasible solution is simply one set of setup orientations that will solve the set cover problem for visibility of the entire implant surface. Now, we iterate among a series of feasible solutions, taking the solution that maximizes the objective function. Under the assumption that only three types of surfaces exist on a bone implant, the problem can be tightly bound to a limited set of feasible and likely solutions; hence a semi exhaustive search can be practically used.

4.9 Impact of Tool Path Crossover and Redundancy on different implant surfaces

The tool path requirements for each surface on the bone implant is different. The primary goal in this thesis is to *reduce* Tool Path *Crossover* and *Redundancy* for all the surfaces. This will preserve smooth finish on the articular and periosteal surface and provide the fracture surface with rough texture; all with minimum machining time. The main issue here is to maintain implant biocompatibility and further increase its primary fixation stability. However Tool Path Crossovers and Redundancy on different surfaces have different level of impact on the implant's biocompatibility and primary fixation stability, or in some cases can only lead to increased machining time as shown in the Table 4.2. This affects the design of coefficient weights and maximizing/minimizing decisions for a surface-specific objective function. In terms of biocompatibility it would always be better to have a smoother-than-desired finish on the fractured surface and compromise fixation stability instead of having a rougher-than-desired finish on articular or periosteal surfaces, which could affect the implant's biocompatibility. Resolving this issue requires a certain machining operation sequence which will **always** create articular and periosteal surfaces with required finishes irrespective of the finish on the fractured surface. This means that it would **always** be ok to have a surface with smoother finish rather than having a rougher finish.

Table 4.2: *Impacts* on different surfaces due to tool path *Crossover* and *Redundancy*

Tool path requirements	**Surface to Surface**	**Impact**
Tool path cross over	Articular to Periosteal	*Maintains implant biocompatibility and primary fixation stability*
	Articular to Fracture	*Reduction in primary fixation stability*
	Periosteal to Articular	*Affects biocompatibility*
	Periosteal to Fracture	*Reduction in primary fixation stability*
	Fracture to Articular	*Affects biocompatibility*
	Fracture to Periosteal	*Affects biocompatibility*
Tool path redundancy	Articular	*Wasted machining resources*
	Periosteal	*Wasted machining resources*
	Fracture	*Reduction in primary fixation stability*

4.10 Objective function variables and coefficients

The coefficients and variables in the objective functions are designed based on the impact level of Tool Path Crossovers and redundancies on the functionality of the implant surfaces. The coefficient weights are shown by different type of arrows (⬆, high) (⇧, low) while the direction of the arrows shows whether the variable is to be maximized (↑) or minimized (↓). For example, for orientations specific to the articular surface $\boldsymbol{\theta}_{a}$, it is very important to maximize visibility of the articular surface and inaccessibility of the fractured surface while minimizing inaccessibility of the articular surface and visibility of the fractured surface. In this case it would also be important to reduce normal deviation since increase in normal deviation would increase articular surface roughness. However here it would be of low importance to reduce ToolPath Redundancy on the articular surface since it would only affect machining time and not the implant's functionality. In the same case, for periosteal surface it would be of low importance to maximize its inaccessibility and minimize its visibility.

Table 4.3: Variable design for surface specific objective functions

	Surfaces											
	Articular				Periosteal				Fractured			
θ_i	X_a	IX_a	ΔN_a	R_a	X_p	IX_p	ΔN_p	R_p	X_f	IX_f	ΔN_f	R_f
θ_a	⬆	⬇	⬇	⇩	⇩	⇧	—	—	⬇	⬆	—	—
θ_p	⇩	⇧	—	—	⬆	⬇	⬇	⇩	⬇	⬆	—	—
θ_f	⇩	⇧	—	—	⇩	⇧	—	—	⬆	⬇	⬇	⬇

4.11 Setup orientation calculation sequence

Redundant machining orientations for the bone implant surfaces can be reduced by using a specific sequence in which they are calculated. Figure 4.16.a shows a chain having a relatively small periosteal surface and larger fractured surface. In this Figure, 4.16.a, it can be seen that there is a need for at least two setup orientations for the fractured surface while machining the periosteal surface only requires one setup orientation. The orientation Θ_{f1} will machine the fractured surface that is visible in the range of 90^o to 270^o, while the orientation Θ_{f2} will create the rest of the fractured surface visible between 270^o to 90^o and will also create the rough texture on the periosteal surface. The orientation Θ_{p1} will create the required finish on the periosteal surface; however it will also destroy a portion of the rough texture created on the fractured surface created by Θ_{f2}. The "*destructive*

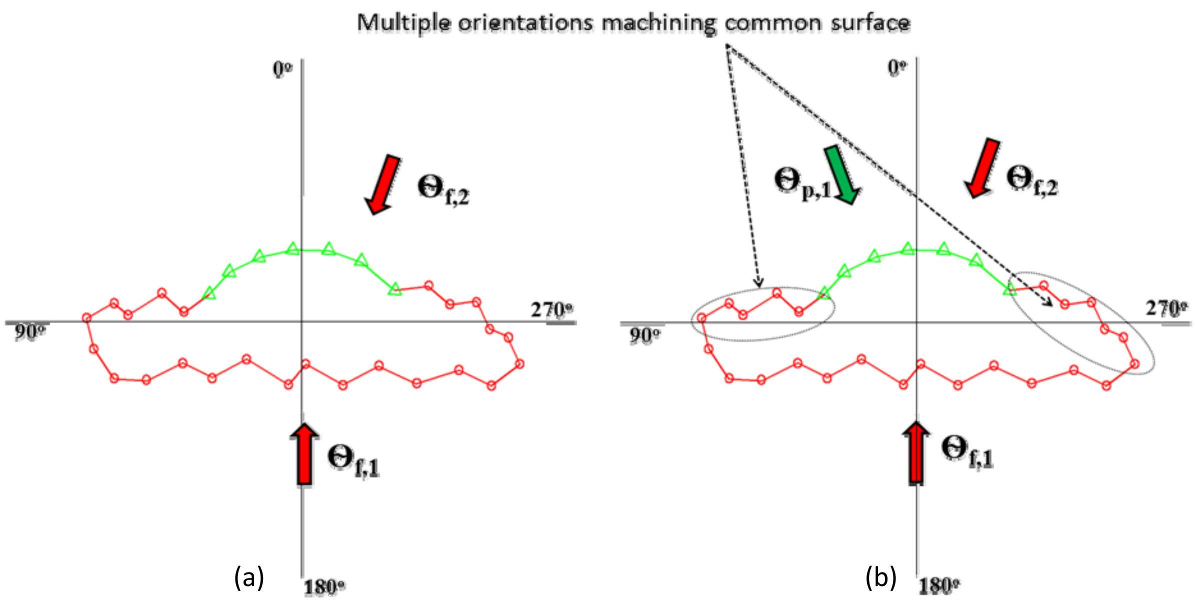


Figure 4.16: a) Θ_{f1} and Θ_{f2} calculated b) Θ_{p1} calculated

interference" on the fractured surface in this case is inevitable due to the visibility of both surfaces from a common range (*270^o and 0^o*). This issue can also be resolved by using a specific sequence of machining operations, which will be addressed in detail in section 4.3. The scope for improvement here would be to eliminate the redundant machining of both surfaces by eliminating the orientation Θ_{f2}. Thus the redundant setup orientations could be eliminated if a certain sequence is followed while calculating them. If the setup orientations for the periosteal surface are calculated first, the fractured surface perimeter visible from those orientations are excluded when calculating orientations for the fractured surface. This would ultimately reduce the redundant machining of both -surfaces present on the implant geometry by eliminating redundant orientations. However, in the case of the implant having all three surfaces on it, since the articular surface would have the smoother surface finish it would be an obvious choice to calculate the setup orientations for the articular surface first, followed by the periosteal and finally the fractured surface.

4.12 Setup orientation calculation algorithms

4.12.1 Algorithms for calculating articular surface specific orientations

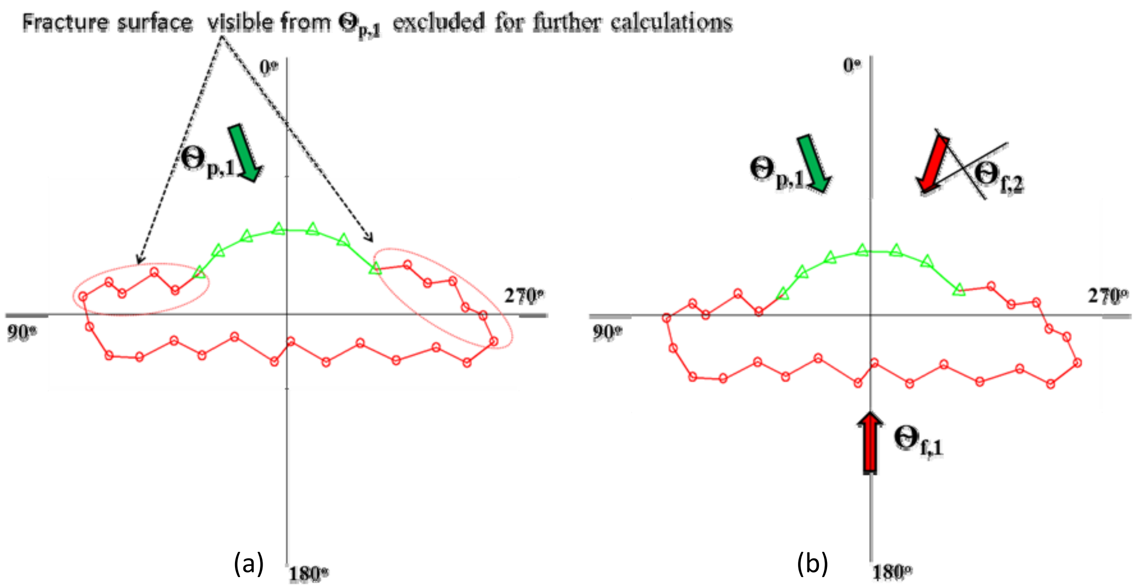


Figure 4.17: a) Θ_{p1}calculated first b) Redundant orientation Θ_{f2} eliminated

This section explains the algorithm for calculating articular surface specific setup orientations. This algorithm focuses more on choosing setup orientations that will isolate the articular surface to the best possible extent and avoid Tool Path Crossover to other surfaces. In the case of articular specific Tool Path Crossover to the periosteal surface, it will only increase the quality of the periosteal surface which is not a significant/detrimental issue since higher finish on periosteal surface is always acceptable.

However, in the case of fractured surfaces, the Tool Path Crossover will partially destroy the fractured surface texture and reduce the implant's primary fixation stability.

It should also be intuitive here that it would be better to choose a minimum number of setup orientations (more efficient/shorter cycle time) to machine a surface and reduce Tool Path Crossover and Redundancy. However there may also be some instances where the % of fractured surface visible from a *set* of articular/periosteal specific orientations may be less than that visible from a single set cover orientation. Since the main purpose here is to isolate the surfaces and maintain created textures/finishes on other surfaces, this algorithm focuses primarily on calculating orientations with least Tool Path Crossover irrespective of the number of orientations required. Figures 4.18,19 and20 are provided to more clearly explain algorithm 4.1. The orientations (/ *set cover orientations*/ $\theta_{a,sc}$) are those which satisfy the set cover for the chain individually while (/ *simple orientations*/ Θ_a) are those which may form a part of a feasible set cover solution. This means that a **set** of multiple simple orientations $\{S_a\} = \{\theta_a \mid 0 < \theta_a < 360\}$ would be necessary to satisfy the set cover for the chain in case there is no single *set cover orientation* available/suitable for creating the articular surface chain. A *good Set Cover solution* would be one that would have least Tool Path Crossover and Redundancy for the orientation/s chosen to machine the surface. The algorithm 4.12.1 is explained in detail below. The algorithm for calculating orientations for the periosteal surface will generally be same as the articular surface, except that Tool Path step-down values to be used will be greater.

For ($\Theta = 0$; $\Theta = 360$; Θ++) *(figure 4.19)*

{

Calculate objective function score for Θ

Check if set cover is achieved for the surface using Θ

If (set cover achieved) *(figure 4.19 ,)*

{

$\Theta = \Theta_{a,sc}$

Save $\Theta_{a,sc}$ as a feasible Set Cover solution

}

Else *(figure 4.19 ,)*

{

$\Theta = \Theta_a$

Save Θ_a as a **part** of feasible Set Cover solution

}

Save the objective function score

}

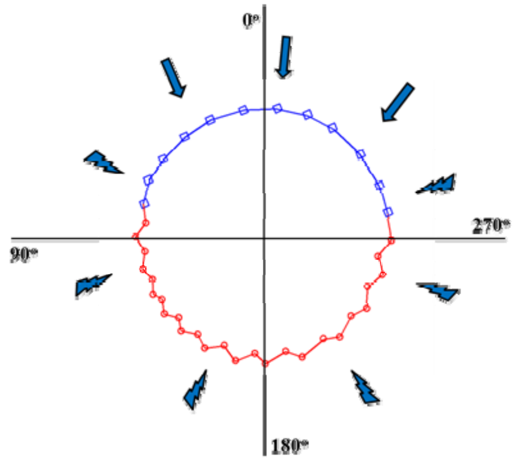


Figure 4.19: Articular surface orientations

If (set cover achieved) *(figure 4.19,)*

{

$\Theta_{a,sc}$ = Set Cover orientation with maximum score of objective function

Check if there is a ***set of simple orientations*** {S_a} achieving ***set cover*** and have ***Tool Path Crossover*** lesser as compared to that using $\Theta_{a,sc}$ **only**

If (yes) *(figure 4.20.a,)*

{

Choose {S_a} as a ***good set cover solution*** for machining the articular surface.

Exclude the ***periosteal/fractured*** surface segments visible from {S_a}

}

Else *(figure 4.20.b,)*

{

Choose $\Theta_{a,sc}$ as a ***good set cover solution*** for machining the articular surface

Exclude the ***periosteal/fractured*** surface segments visible from $\Theta_{a,sc}$

}

Proceed to calculate orientations for the ***periosteal surface***

}

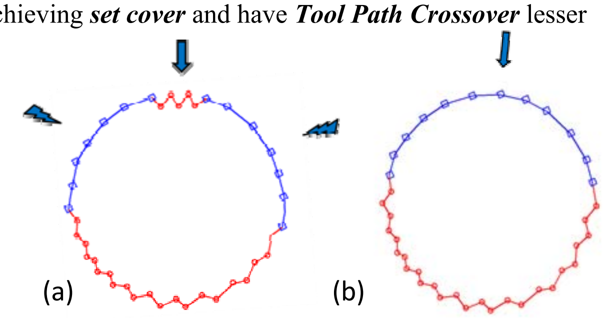


Figure 4.20: a) Multiple orientations *preferred* as a good Set Cover solution b) Set Cover orientation as a good Set Cover solution

Else *(figure 4.21,)*

{

Θ_a = Simple orientation with maximum score of objective function

Exclude the ***periosteal/fracture*** surface segments visible from Θ_a

Proceed to calculate remaining orientations to get a ***good set cover solution*** for ***articular surface*** with minimum ***Tool Path Crossover***

}

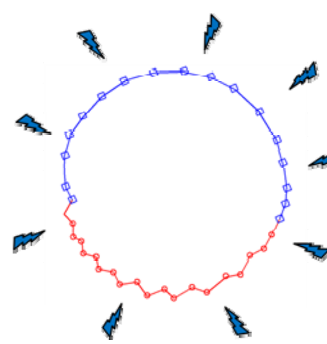


Figure 4.21: Multiple orientations *necessary* for set cover

Figure 4.18: Algorithms for calculating articular surface specific orientations

4.12.2 Algorithms for calculating fractured surface specific setup orientations

This section presents an algorithm for calculating fractured surface specific setup orientations. In order to create texture, the tool path requirements for the fractured surface are different from those of articular or periosteal surfaces. In the case of articular or periosteal surfaces, the primary need is to isolate them and create smooth finishes. Because of this requirement, the effect of having large Tool Path Redundancy due to multiple orientations is never an issue except that it would lead to inefficiencies. However, in the case of fracture surfaces, Tool Path Redundancy will lead to reduction/destruction of desired rough texture imparted on the fractured surface.

The algorithm 4.12.2 for calculating fractured surface specific orientations is explained in detail below and the notations for the orientations are similar to those used for articular surface. This algorithm focuses more on minimizing Tool Path Redundancy. To achieve this, the orientations should be spaced as far as possible (angular difference) from each other yet machine the entire surface. Hence it is obvious in this case that it would be always better to have the least number of setup orientations (ideally one orientation) spaced away from each other to create texture on the fractured surface. There is always a strong possibility that due to spatial placement of multiple orientations, texture would also be created on the other two surfaces. However this issue can be tackled by using a specific sequence of machining operations. This is described in the next section.

For (Θ = 0; Θ = 360; Θ++) (figure 4.21)

{

Calculate score of objective function for Θ

Check if setcover is achieved using Θ

If (set cover achieved) (figure 4.23,)

{

$\Theta = \Theta_{f,sc}$

Save Θ_f as a feasible Set Cover solution

}

Else (figure 4.23,)

{

$\Theta = \Theta_f$

Save Θ_f as a **part** of a feasible Set Cover solution

}

Save the objective function score

}

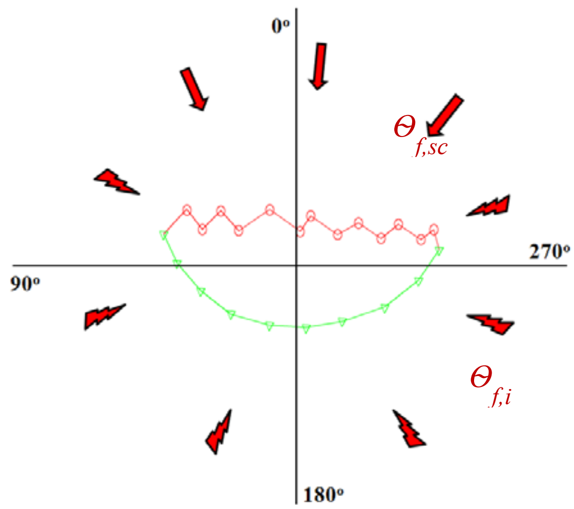


Figure 4.23: Fractured surface orientations

If (set cover achieved) (figure 4.23)

{

$\Theta_{f,sc}$ = Set Cover orientation with maximum score of objective function

}

Else (figure 4.23,)

{

Θ_f = Simple orientation with maximum score of objective function

Proceed to calculate remaining orientations for
fractured surface with minimum ***Tool Path Redundancy***

}

Figure 4.22: Algorithms for calculating fractured surface specific orientations

4.13 Machining sequence for rapid machining of customized bone implants

In addition to the sequence in which the setup orientations are calculated, the actual physical machining operation sequence for the bone implant surfaces is also important. Considering the complex geometry of a bone implant, there can always be a unique fractured surface specific orientation which could unintentionally create texture on the periosteal or articular surfaces. This can occur due to the cutting tool gouging into the undesired surface accidentally and significantly affect the implant's biocompatibility. It would be quite unacceptable to have even the slightest rough texture on either periosteal or articular surface in order to maintain implant biocompatibility. Therefore it would always be better to machine the fractured surface first followed by periosteal and then articular surface. The idea here is to rather allow a smoother finish on a surface (more than intended/desired) and maintain implant bio-compatibility by compensating for Tool Path Crossover. Figure 4.22 illustrates a case in which periosteal and the fracture surfaces are present on the chain. Orientation Θ_{p1} is necessary to create a smooth periosteal surface while orientation Θ_{f1} is necessary to create the rough texture on the fractured surface. If the machining sequence used in this case is $\Theta_{p,1}$ and then $\Theta_{f,1}$ (*figure 4.23)*, the smoother periosteal surface will be created first followed by rough fractured surface. However there are chances that the tool paths from orientation Θ_{f1} would gouge into the created periosteal surface and partially destroy the smooth surface finish which will make the bone implant unusable. However if the fractured surface on the implant is machined first using Θ_{f1} , the rough finish created on the periosteal surface due to orientation Θ_{f1} will be replaced with the smooth finish using orientation Θ_{p1} *(figure 4.24)*. The orientation Θ_{p1} however will also destroy the rough texture on the fractured surface which could reduce the implant's fixation stability but will still maintain its biocompatibility. In the case of the implant having all the three surfaces on its geometry, it would be an obvious choice to machine the fractured surface first followed by the periosteal and then articular surface in order to maintain respective finishes on these surfaces.

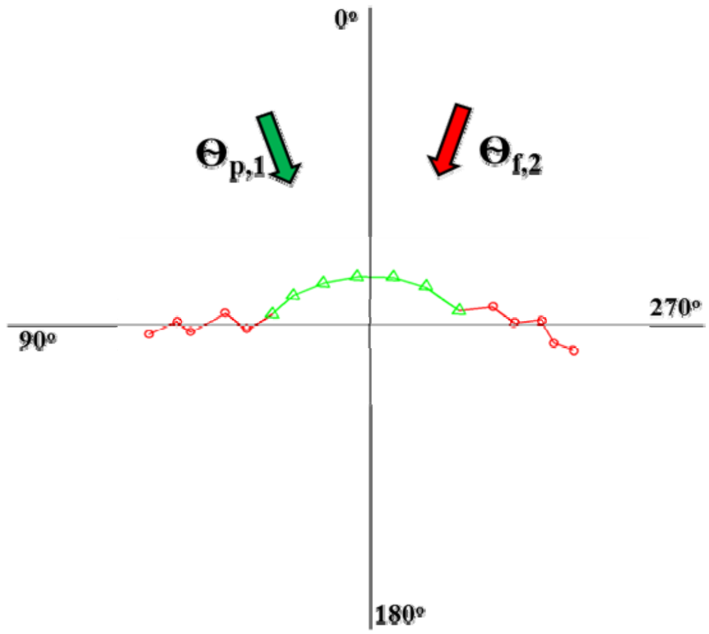


Figure 4.24: $\Theta_{p1}$and Θ_{f1} required for creating periosteal and fractured surface respectively

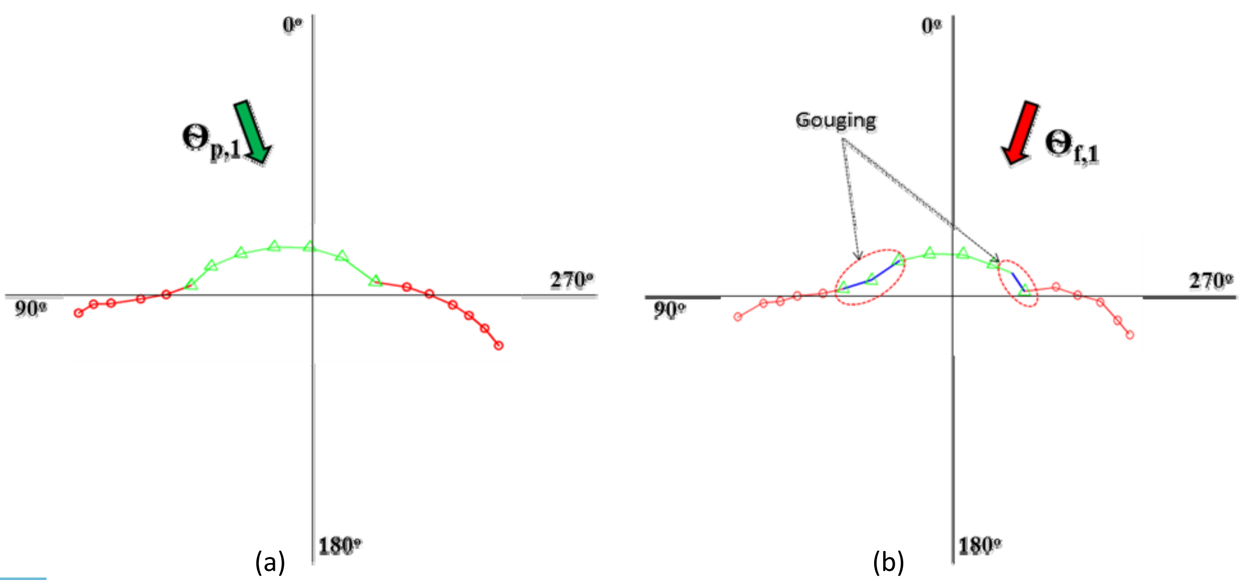
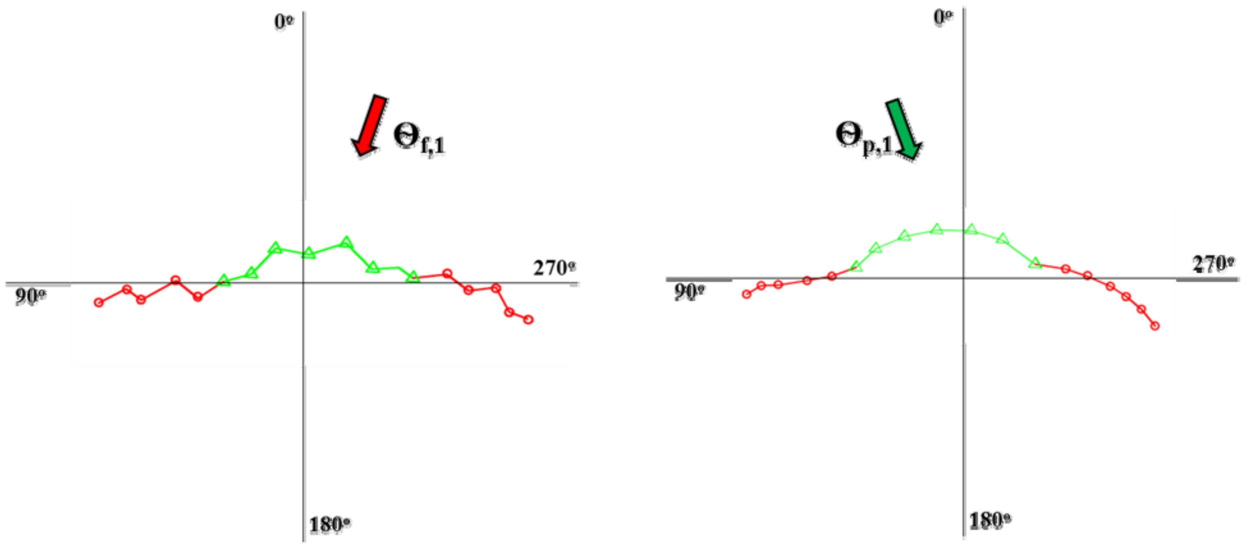


Figure 4.25: a) Θ_{p1} creating periosteal surface first b) Θ_{f1} gouging in to periosteal surface



(a) (b)

Figure 4.26: a) Θ_{f1} creating fractured surface first b) Θ_{p1} creating smooth periosteal surface

4.14 Slice spacing for visibility algorithms

The setup orientation calculation algorithms described previously calculate these orientations for the colored 3D bone implant model using only colored 2D slices of the geometry. This is appropriate since the visible ranges are restricted to the polar angles about the axis of rotation. However, it should be noted that the colored 2D slices are an approximation of the actual part surface. One must consider the spacing of the slices that should be used in the model approximation, since it directly impacts the accuracy of this approximation. Infinitely thin slice spacing approaches the true 3D shape of the geometry, of course, that is not practical. The algorithms developed for CNC-RP considered positional accuracy of the CNC machine (0.0001"), and the smallest diameter of the Tool at 1/16" in the determination of slice spacing. In previous practice for industrial components the actual slice spacing used was 0.005" assuming that the manufacturable parts would have features with dimensions greater than or equal to 0.005".

Similarly for creating surface specific textures on the bone implants, any of the above considerations could work. However the creation of customized surface texture is a finishing operation wherein the geometry of the model surface is already created by the roughing operation previously. Therefore using a very low slice interval for calculating orientations for finishing operation would be generally a redundant consideration. This would also lead to a larger computation time. Hence it would be appropriate to use the slice spacing according to the least diameter of the tool to be used which is 1/16" inch. This would still allow creating required finish/texture on the surface of the bone implants with required accuracy.

4.15 Tool selection for customized machining of bone implants

Proper tool selection must ensure creation of accurate textures/finishes on different surfaces on the bone implants in addition to ensuring collision free machining for any model complexity. The tool diameter to be used will be dictated by the implant dimensions, texture dimensions and the surface finish values to be created on different surfaces. Firstly, the tool length must be greater than or equal to the distance to the furthest visible surface with respect to the current setup orientation. This would ensure accessibility to the deepest visible surface from the current orientation without collision of the tool holder. Second, in order to ensure that no portion of the tool itself collides with any previously machined layers, the tool shank diameter must be less than or equal to the flute diameter.

A desired goal is to choose tools that would enable precise texture and high surface finish creation on the bone implants with different complexities and desired accuracy without any of the above issues. This necessitates use of a ball end mill which would allow creation of specific type of texture on the fractured surface while additionally allowing finishing of small radii surfaces.

4.16 Implementation and Results

The above described algorithms for calculating surface specific setup orientation were implemented in C++ and an OpenGL user interface and tested on an Intel Core2Duo, 2.8 GHz PC, and running Windows 7. The software accepts colored 2D slice files from 3D ply models as input and returns several analytical results. The minimum number of orientations necessary to create customized bone implant surfaces is calculated. The analytical results also show % customization for each surface of the bone implant and also the computation time required for different numbers of slices

Six models of different complexities and different types and number of surfaces were used for calculating surface specific setup orientations (*figure 4.25*). These models are of bone fragment samples created in the University of Iowa Orthopedic Biomechanics Lab drop tower test. Distal Tibia models were created using Barium Sulfate doped polyurethane foam as a bone surrogate material, using the CNC-RP process in the ISU RMPL lab. Next, the tibias were potted in ballistics gel and fractured in drop tower, and subsequently CT scanned to generate CAD models of fractured pieces. The models were hand painted in CAD and sent to the ISU team. Three contained one instance of all three surfaces *(articular/periosteal/fracture)*, and other three contained at least one instance each of two surfaces *(periosteal/fracture)*. Surface specific setup orientations for three of the chosen models are shown below compared with CNC-RP orientations

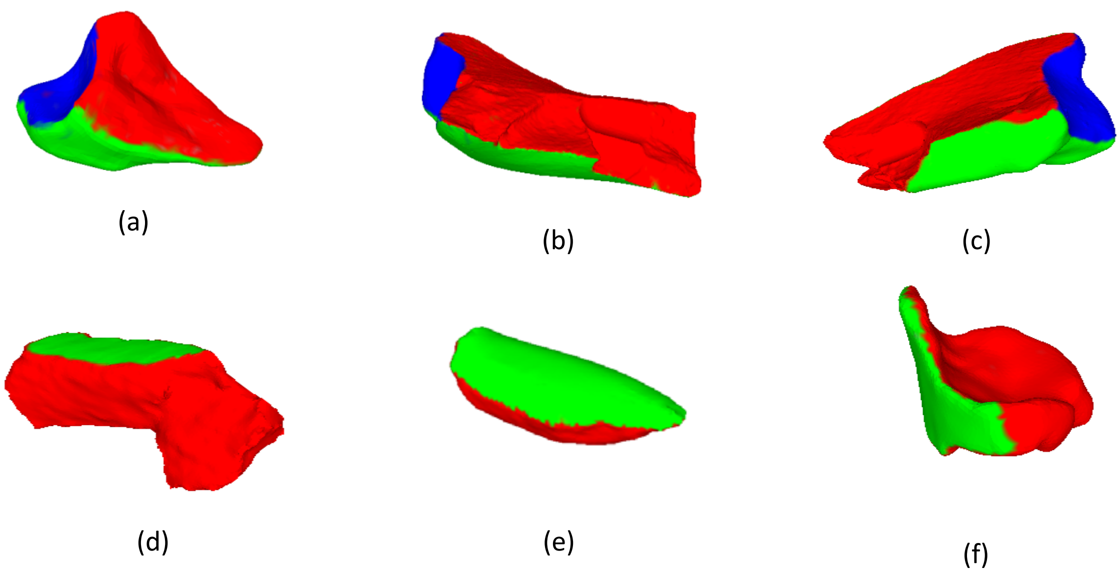


Figure 4.27: Different PLY models used for calculating surface specific setup orientations

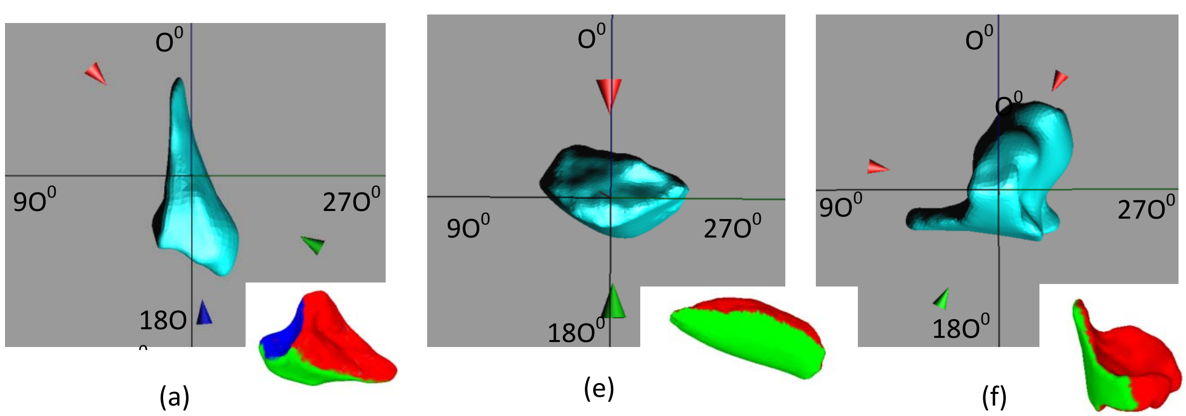


Figure 4.28: Setup orientations for different models

Table 4.4: Setup orientation comparison for previous CNC-RP and CNC-RPbio

Model a			Model e		Model f	
Surfaces	CNC-RP	CNC-RP$_{bio}$	CNC-RP	CNC-RP$_{bio}$	CNC-RP	CNC-RP$_{bio}$
Fracture	49	43	32	2	56/264	88/313
Periosteal	264	241	189	181	186	153
Articular	169	185	-	-	-	-

Table 4.5: Surface customization comparison for CNC-RP and CNC-RP$_{bio}$ (number of slices = 200)

Models	CNC-RP				CNC-RP$_{bio}$			
	process time (secs)	% customization of the bone implant surfaces			Process time (sec)	% customization of the bone implant surfaces		
		Fracture	Articular	Periosteal		Fracture	Articular	Periosteal
a	4	8	98	85	97	97	100	100
b	5	0	97	98	126	95	100	100
c	3	13	0	76	115	98	100	100
d	5	0	-	100	85	46	-	100
e	4	82	-	100	60	99	-	100
f	5	67	-	88	82	96	-	100

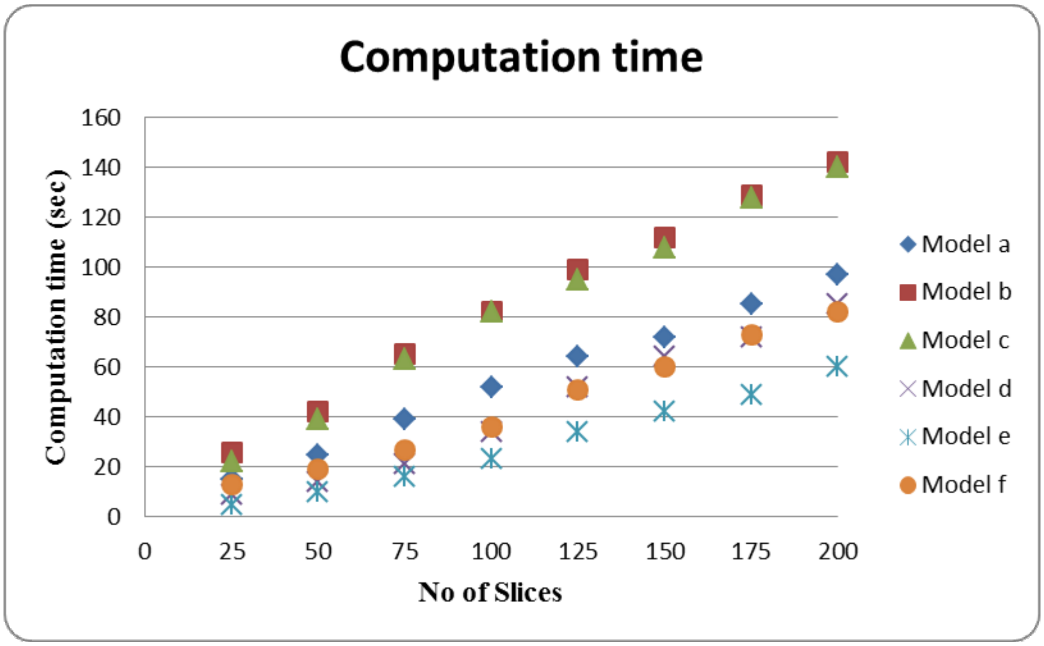


Figure 4.29: Computation time (secs) Vs Number of Slices

From the results in Table 4.5 and Figure 4.27 it can be seen that previous set cover algorithms calculate the setup orientations much faster as compared to the new customization algorithms. However the % customization of each bone implant surface achieved using orientations from the new methods is significantly higher. On average, the new algorithms provided a 44% increase in customization of surfaces, with a minimum improvement of 33% to a maximum improvement of 69% as seen in Figure 4.28. Figure 4.29 shows a graph comparing the % customization for a fractured surface achieved using CNC-RP and CNC-RP_{bio}. This shows that using CNC-RP % customization for fractured surface was random with maximum being 82% and minimum 0 %. However the % customization achieved using CNC-RP_{bio} for fractured surface was consistently near 100% and always greater than that achieved using CNC-RP. The % customization for the other two surfaces is 100% which is a necessary condition to maintain the implant biocompatibility. This shows that using the new methods significantly increases % customization for the implant; with the intended outcome of increasing primary fixation stability. Although further studies would be necessary to provide better statistical evidence, the experiment was conducted on relatively expected fracture conditions and samples using an accurate bone surrogate sample and fracture creation method.

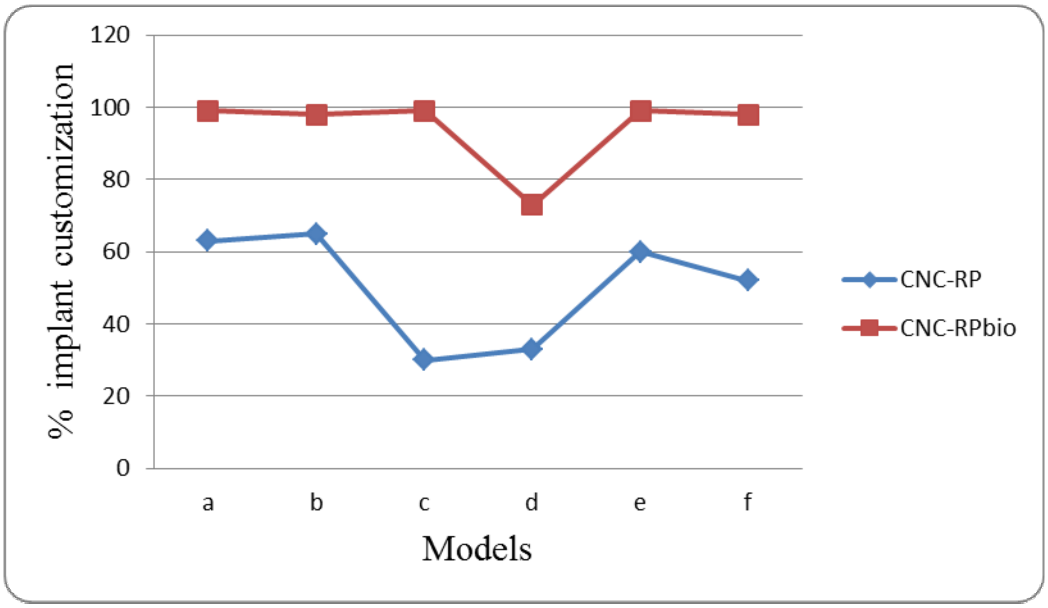


Figure 4.30: % implant customization

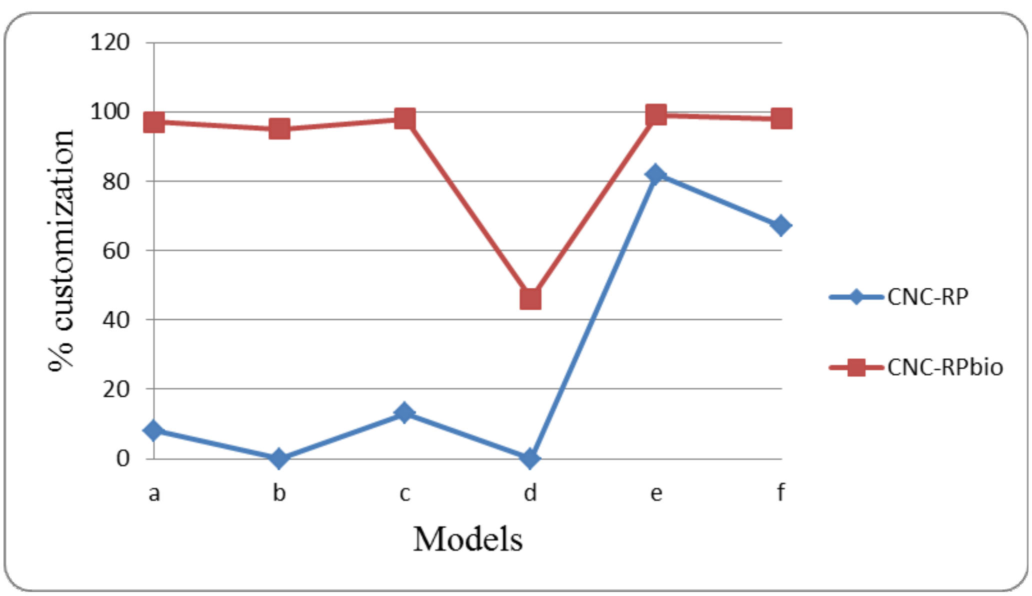


Figure 4.31: % customization fractured surface

4.17 Conclusions

This paper presented a new method for calculating setup orientations in an effort to create customized bone implant surfaces using CNC-RP_{bio}. The implementation showed that the % customization for the bone implant surfaces achieved using the proposed algorithms is significantly higher as compared to CNC-RP algorithms. This work illustrates the ability to provide surface-specific characteristics through targeting of surfaces and then applying parametric changes to machining tool paths. The texture on the fractured surface could lead to low implant/host bone interfacial movement and increased initial fixation stability and the smooth periosteal and articular surfaces will maintain implant biocompatibility, reduce abrasion, etc. However in term of the processing time, this new method does extend planning efforts in order to find better setup angle solutions. That being said, considering the total processing time is still on the order of minutes (approximately 30 - 45 minutes), this technique would still be considered a rapid and highly automated method. Additionally considering the impact factor for this application, the higher computation time would still be justifiable for getting a unique solution for each patient's implant.

4.18 Future work

In future work, it would be beneficial to develop better use of tool containment boundaries for better customization of bone implant surfaces. Using tool containment boundaries could limit the tool paths to a specific surface and target it to a better extent, leading to better surface texturing/finishing. If utilized completely, one could almost eliminate the use of the proposed algorithms and objective function. However, one would still expect to need them for two reasons; 1) although tool paths could be contained, they still may not be targeted in a correct angular apposition for machining and 2) the use of containment boundaries relies heavily on feature recognition development in order to ascertain the proper boundaries. The proposed algorithms could also be modified for industrial purpose which could include developing the process planning strategy for different applications where the number and/or types of surfaces present on the model may be more than three. This would make the optimization routine more difficult to solve; brute force methods would obviously be too time consuming.

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Reference

[1] Willis A, Anderson D, Thomas T, Brown T, Marsh JL. 3D reconstruction of highly fragmented bone fractures. *SPIE Medical Imaging, Image Processing* # 6512-60, 2007

[2] John Alan Hunt, Jill T. Callaghan, Chris J. Sutcliffe, Rhys H. Morgan, Ben Halford, Richard A. Black, “Enhanced bone integration of implants with increased surface roughness: a long term study in the sheep”, Biomaterials 26 ,(2005) ,5890–5897

[3] Song Y, Beaupre G, Goodman SB. Osseointegration of total hip arthroplasties: studies in humans and animals. J Long Term Eff Med Implants 1999; 9:77–112.

[4] Willert HG, Buchhorn GH. Osseointegration of cemented and noncemented implants in artificial hip replacement: long-term findings in man. J Long Term Eff Med Implants 1999;9:113–30.

[5] AD. Heiner, Thomas D.Brown, “Frictional Coefficients of A New Bone Ingrowth Structure”, Orthopedics Research Society, 2007

[6] Bobyn JD, Pilliar RM, Cameron HU, Weatherly GC. The optimum pore size for the fixation of porous surfaced metal implants by the ingrowth of bone. Clin Orthop 1980; 150:263–70.

[7] Callaghan JJ. The clinical results and basic science of total hip arthroplasty with porous-coated prostheses. J Bone Joint Surg 1993; 75A (2):299–310.

[8] Williams DF, Roaf R. Implants in surgery. Saunders: London; 1973.

[9] Thomas KA, Cooke SD. An examination of variables influencing implant fixation by direct bone apposition. J Biomed Mat Res 1985; 19:875.

[10] Alain Curodeau, Emanuel Sachs, Salvatore Caldarise,” Design and Fabrication of Cast Orthopedic Implants with Freeform Surface Textures from 3-D Printed Ceramic Shell”, 2 May 2000,525-535.

[11] Singare, S, Yaxiong, L., Dichen, L., Bingheng, L., Sanhu, H., and Gang, L., "Fabrication of Customised Maxillo-Facial Prosthesis Using Computer-Aided Design and Rapid Prototyping Techniques." Rapid Prototyping Journal 12 (2006): 206-213

[12] Singare, S., Dichen, L., Bingheng, L., Zhenyu, G., and Yaxiong, L., "Customized Design and Manufacturing of Chin Implant Based on Rapid Prototyping." Rapid Prototyping Journal 11 (2005): 113-118

[13] A. Werner, Z. Lechniak, K. Skalski, K. Kedzior, "Design and Manufacture of anatomical hip joint endoprostheses using CADCAM system", Journal of Materials Processing Technology,107, 2000, 181-186

[14] Peter Thomsen,Johan Malmstrom, Lena Emanuelsson, Magnus Rene´, Anders Snis, "Electron Beam-Melted, Free-Form-Fabricated Titanium Alloy Implants: Material Surface Characterization and Early Bone Response in Rabbits", August 2008.

[15] John Alan Hunt et al., "The design and production of Co-Cr allow implants with controlled surface topography by CAD-CAM method and their effects on osseointegration", Biomaterials 26 (2005) 5890–5897

[16] Matthew C. Frank, PhD, Christopher V. Hunt, Donald D. Anderson, PhD, Todd O. McKinley, M.D., Thomas D. Brown, PhD, "Rapid Manufacturing in Biomedical Materials: Using Subtractive Rapid Prototyping for Bone Replacement", Proceedings of the Solid Freeform Fabrication Symposium, 2008

[17] Frank, M.C., Wysk, R.A., and Joshi, S.B., "Determining Setup Orientations from the Visibility of Slice Geometry for Rapid CNC Machining", Journal of Manufacturing Science and Engineering, Transactions of the ASME, Vol. 128, No. 1, pp. 228-238, 2006

[18] Frank, M.C., Wysk, R.A., and Joshi, S.B., "Rapid Planning for CNC Machining – A New Approach to Rapid Prototyping", Journal of Manufacturing Systems, SME, Volume 23, No. 3, pp. 242-255, 2004

[19] Frank, M.C. "Implementing Rapid Prototyping Using CNC Machining (CNC-RP) Through a CAD/CAM Interface", Proceedings of the Solid Freeform Fabrication Symposium, 2007

[20] LI, Y. and Frank, M.C., "Computing Non-Visibility of Convex Polygonal Facets on the Surface of a Polyhedral CAD Model", Computer Aided Design, Vol. 39, No. 9, pp. 732-744, 2007

[21] LI, Y. and Frank, M.C., "Machinability Analysis for 3-axis Flat End Milling", Journal of Manufacturing Science and Engineering, Transactions of the ASME, Vol. 128, No. 2, pp. 454-464, 2006

CHAPTER 5: CONCLUSION AND FUTURE WORK

5.1 Conclusion

This thesis presented a new method for calculating setup orientations in an effort to create customized bone implant surfaces using CNC-RP_{bio}. The implementation showed that the % customization for the bone implant surfaces achieved using the proposed algorithms is significantly higher as compared to previous CNC-RP algorithms. This work illustrates the ability to provide surface-specific characteristics through targeting of surfaces and then applying parametric changes to machining toolpaths. The texture on the fractured surface could lead to low implant/host bone interfacial movement and increased initial fixation stability and the smooth periosteal and articular surfaces will maintain implant biocompatibility, reduce abrasion, etc. However in term of the processing time, this new method does extend planning efforts in order to find better setup angle solutions. That being said, considering the total processing time is still on the order of minutes (approximately 30 - 45 minutes), this technique would still be considered a rapid and highly automated method. Additionally considering the impact factor for this application, the higher computation time would still be justifiable for getting a unique solution for each patient's implant.

5.2 Future work

In future work, it would be beneficial to develop better use of tool containment boundaries for better customization of bone implant surfaces. Using tool containment boundaries could limit the tool paths to a specific surface and target it to a better extent, leading to better surface texturing/finishing. If utilized completely, one could almost eliminate the use of the proposed algorithms and objective function. However, one would still expect to need them for two reasons; 1) although toolpaths could be contained, they still may not be targeted in a correct angular apposition for machiniong and 2) the use of containment boundaries relies heavily on feature recognition development in order to ascertain the proper boundaries. The proposed algorithms could also be modified for industrial purpose which could include developing the process planning strategy for different industrial applications where the number and/or types of surfaces present on the model may be more than three. This would make the optimization routine more difficult to solve; brute force methods would obviously be too time consuming.

The future work in other research areas for bone implant customization using CNC-RP_{bio} includes developing algorithms for setup axis decisions and supports generation. This would enable better customization of implant geometries and capability addition for pre-drilling/machining of fixation screw holes. Setup axis decisions may be influenced by the axes orientations of fixation screw holes while the supports generation may be influenced by the choice of the surfaces on which the supports will have to be avoided. This research can also be applied for industrial purposes where a component might need different finishes on different surfaces. The setup axis decisions and supports generation for industrial can have requirements more complex as compared to just consideration of hole axes. In addition to fixation holes the industrial components may have more complex features which will affect the setup axis decisions and supports generation.

BIBLIOGRAPHY

[1] JanFeijen, DirkW.Grijpma, "A review on Stereolithography and its applications in Biomedical Engineering, Biomaterials 31(2010) 6121 – 6130

[2] Ignacio Madrazo et al, "Stereolithography in spine pathology: a 2-case report" Surgical Neurology 72 (2009) 272–275.

[3] Peter Thomsen et al, "Electron Beam-Melted, Free-Form-Fabricated Titanium Alloy Implants: Material Surface Characterization and Early Bone Response in Rabbits, 8 August 2008

[4] David Espalin, Karina Arcaute, David Rodriguez and Francisco Medina, "Fused deposition modeling of patient-specific polymethyl methacrylate implants",Rapid Prototyping Journal, 16/3 (2010) 164–173.

[5] Félix A. España et al, " Design and fabrication of CoCrMo alloy based novel structures for load bearing implants using laser engineered net shaping" Materials Science and Engineering, C 30 (2010) 50–57.

[6] John Alan Hunt, The design and production of Co–Cr alloy implants with controlled surface topography by CAD–CAM method and their effects on osseointegration, Biomaterials 26 (2005) 5890–5897

[7] *T. Traini et al,* "Direct laser metal sintering as a new approach to fabrication of an isoelastic functionally graded material for manufacture of porous titanium dental implants" dental materials, 24 (2008) 1525–1533.

[8] Matthew C. Frank, PhD, Christopher V. Hunt, Donald D. Anderson, PhD, Todd O. McKinley, M.D., Thomas D. Brown, PhD, "Rapid Manufacturing in Biomedical Materials: Using Subtractive Rapid Prototyping for Bone Replacement", Proceedings of the Solid Freeform Fabrication Symposium, 2008

[9] Frank, M.C., Wysk, R.A., and Joshi, S.B., "Determining Setup Orientations from the Visibility of Slice

[10] Geometry for Rapid CNC Machining", Journal of Manufacturing Science and Engineering, Transactions of the ASME, Vol. 128, No. 1, pp. 228-238, 2006

[11] Frank, M.C., Wysk, R.A., and Joshi, S.B., "Rapid Planning for CNC Machining – A New Approach to Rapid Prototyping", Journal of Manufacturing Systems, SME, Volume 23, No. 3, pp. 242-255, 2004

[12] Frank, M.C. "Implementing Rapid Prototyping Using CNC Machining (CNC-RP) Through a CAD/CAM Interface", Proceedings of the Solid Freeform Fabrication Symposium, 2007

[13] LI, Y. and Frank, M.C., "Computing Non-Visibility of Convex Polygonal Facets on the Surface of a Polyhedral CAD Model", Computer Aided Design, Vol. 39, No. 9, pp. 732-744, 2007

[14] LI, Y. and Frank, M.C., "Machinability Analysis for 3-axis Flat End Milling", Journal of Manufacturing Science and Engineering, Transactions of the ASME, Vol. 128, No. 2, pp. 454-464, 2006

[15] AD. Heiner, Thomas D.Brown, "Frictional Coefficients of A New Bone Ingrowth Structure", Orthopedics Research Society, 2007

[16] Thomas KA, Cooke SD. An examination of variables influencing implant fixation by direct bone apposition. J Biomed Mat Res 1985; 19:875.

[17] John Alan Hunt, Jill T. Callaghan, Chris J. Sutcliffe, Rhys H. Morgan, Ben Halford, Richard A. Black, "Enhanced bone integration of implants with increased surface roughness: a long term study in the sheep", Biomaterials 26 ,(2005) ,5890–5897

[18] Willert HG, Buchhorn GH. Osseointegration of cemented and noncemented implants in artificial hip replacement: long-term findings in man. J Long Term Eff Med Implants 1999; 9:113–30.

[19] Callaghan JJ. The clinical results and basic science of total hip arthroplasty with porous-coated prostheses. J Bone Joint Surg 1993; 75A (2):299–310.

[20] Williams DF, Roaf R. Implants in surgery. Saunders: London; 1973.

[21] L. Le Gu´ehennec, "Surface treatments of titanium dental implants for rapid osseointegration et al" dental materials 2 3 (2007) 844–854

[22] Thomas Thaddeus, Brown, Thomas et al, "A Computational/Experimental Platform for Investigating Three-Dimensional Puzzle Solving of Comminuted Articular Fractures, Computer Methods in Biomechanics and Biomedical Engineering

[23] Truscott, Michele, Deon De Beer et al, "Using RP to Promote Collaborative Design of Customised Medical Implants." Rapid Prototyping Journal 13 (2007): 107-114. 29 May 2008

[24] Deglurkar Mukund, Dwight T. Davy et al, "Evaluation of Machining Methods for Trabecular Metal Implants in a Rabbit Intramedullary Osseointegration Model." Journal of Biomedical Materials Research Part B: Applied Biomaterials 80B (2006): 528-540.

[25] Wennerberg A, Albrektsson T, Albrektsson B, Krol JJ. Histomorphometric and removal torque study of screw-shaped titanium implants with three different surface topographies. Clin Oral Implant Res 1996;6:24–30.

[26] Brett PM, Harle J, Salih V, Mihoc R, Olsen I, Jones FH, et al. Roughness response genes in osteoblasts. Bone 2004;35: 124–33.

[27] Buser D, Schenk R, Steinemann S, Fiorellini J, Fox C, Stich H. Influence of surface characteristics on bone integration of titanium implants. A histomorphometric study in miniature pigs. J Biomed Mater Res 1991;25:889–902.

[28] Wennerberg A, Hallgren C, Johansson C, Danelli S. A histomorphometric evaluation of screw-shaped implants each prepared with two surface roughnesses. Clin Oral Implants Res 1998;9:11–9.

[29] Buser D, Schenk R, Steinemann S, Fiorellini J, Fox C, Stich H. Influence of surface characteristics on bone integration of titanium implants. A histomorphometric study in miniature pigs. J Biomed Mater Res 1991;25:889–902.

[30] Urban RM, Jacobs JJ, Tomlinson MJ, Gavrilovic J, Black J, Peoch M. Dissemination of wear particles to the liver, spleen and abdominal lymph nodes of patients with hip or knee replacement. J Bone Jt Surg Am 2000;82:457–77.

[31] Browne M, Gregson PJ. Effect of mechanical surface pretreatment on metal ions release. Biomaterials 2000; 21:385–92.

[32] Martini D, Fini M, De Pasquale V, Bacchelli B, Gamberini M, Tiniti A, et al. Detachment of titanium and fluorohydroxyapatite particles in unloaded endosseous implants. Biomaterials 2003;24: 1309–16.

[33] John Alan Hunt, Jill T. Callaghan, Chris J. Sutcliffe, Rhys H. Morgan, Ben Halford, Richard A. Black, "Enhanced bone integration of implants with increased surface roughness: a long term study in the sheep", Biomaterials 26 ,(2005) ,5890–5897

[34] F. Grizon, E.Aguado, G.Hure, M.F. Basle, D.Chappard, "Enhanced bone integration of implants with increased surface roughness:a long term study in the sheep" Journal of Dentistry 30 (2002) 195–203

[35] Peter Thomsen, Johan Malmstrom, Lena Emanuelsson, Magnus Rene´, Anders Snis, "Electron Beam-Melted, Free-Form-Fabricated Titanium Alloy Implants: Material Surface Characterization and Early Bone Response in Rabbits", August 2008.

[36] Jia Ping Lia, Bone ingrowth in porous titanium implants produced by 3D fiber deposition" Biomaterials 28 (2007) 2810–2820

[37] Aparicio C, Gil FJ, Fonseca C, Barbosa M, Planell JA. Corrosion behavior of commercially pure titanium shot blasted with different materials and size of shot particles for dental implant applications. Biomaterials 2003;24:263–73.

[38] Ivanoff CJ, Hallgren C, Widmark G, Sennerby L, Wennerberg A. Histologic evaluation of the bone integration of $TiO_{(2)}$ blasted and turned titanium micro implants in humans. Clin Oral Implants Res 2001;12:128–34.

[39] Rasmusson L, Kahnberg KE, Tan A. Effects of implant design and surface on bone regeneration and implant stability: an experimental study in the dog mandible. Clin Implant Dent Relat Res 2001; 3:2–8.

[40] Gotfredsen K, Karlsson U. A prospective 5-year study of fixed partial prostheses supported by implants with machined and TiO2-blasted surface. J Prosthodont 2001; 10:2–7.

[41] Rasmusson L, Roos J, Bystedt H. A 10-year follow-up study of titanium dioxide-blasted implants. Clin Implant Dent Relat Res 2005;7:36–42.

[42] van Steenberghe D, De Mars G, Quirynen M, Jacobs R, Naert I. A prospective split-mouth comparative study of two screw-shaped self-tapping pure titanium implant systems. Clin Oral Implants Res 2000;11: 202–9.

[43] Astrand P, Engquist B, Dahlgren S, Engquist E, Feldmann H, Grondahl K. Astra Tech and Branemark System implants: a prospective 5-year comparative study. Results after one year. Clin Implant Dent Relat Res 1999; 1:17–26.

[44] Abron A, Hopfensperger M, Thompson J, Cooper L. Evaluation of a predictive model for implant surface topography effects on early osseointegration in the rat tibia model. J Prosth Dent 2001;85:40–6.

[45] Gotfredsen K, Wennerberg A, Johansson C, Skovgaard LT, Hjorting-Hansen E. Anchorage of TiO2-blasted, HA-coated, and machined implants: an experimental study with rabbits. J Biomed Mater Res 1995; 29: 1223–31.

[46] Yokoyama K, Ichikawa T, Murakami H, Miyamoto Y, Asaoka K. Fracture mechanisms of retrieved titanium screw thread in dental implants. Biomaterials 2002;23:2459–65.

[47] Sul YT, Johansson CB, Jeong Y, Roser K, Wennerberg A, Albrektsson T. Oxidized implants and their influence on the bone response. J Mater Sci Mater Med 2001;12:1025–31.

[48] Sul YT, Johansson C, Wennerberg A, Cho LR, Chang BS, Albrektsson T. Optimum surface properties of oxidized implants for reinforcement of osseointegration: surface

[49] Huang YH, Xiropaidis AV, Sorensen RG, Albandar JM, Hall J, Wikesjo UM. Bone formation at titanium porous oxide (TiUnite) oral implants in type IV bone. Clin Oral Implants Res 2005;16:105–11.

[50] Sul YT, Johansson CB, Roser K, Albrektsson T. Qualitative and quantitative observations of bone tissue reactions to anodised implants. Biomaterials 2002;23:1809–17.

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