Patient-Specific Bone Implants using Subtractive Rapid Prototyping

Matthew C. Frank, PhD, Ashish Joshi
Department of Industrial and Manufacturing Systems Engineering
Iowa State University, Ames, IA, USA

Donald D. Anderson, PhD, Thaddeus P. Thomas, MS, M. James Rudert, PhD, Yuki Tochigi, MD, PhD, J. Lawrence Marsh, MD, and Thomas D. Brown, PhD
Department of Orthopaedics and Rehabilitation
The University of Iowa, Iowa City, IA, USA

Abstract

This research involves the development of rapid manufacturing for patient-specific bone implants using a Subtractive Rapid Prototyping process. 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 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, 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

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 needs for acceptable biocompatible materials with accurate geometric shapes. 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 the 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 ingrowth into the implant. This bone ingrowth 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 creation of bone implant fillers.

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].

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 p art directly from a CAD file [16-22]. 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, 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 operation and part is removed. The setup and steps to this process are illustrated in figure 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 2; where a fragment from a human tibia was reverse engineered from a CT scan and then rapid machined from clinically relevant materials using the CNC-RP process.

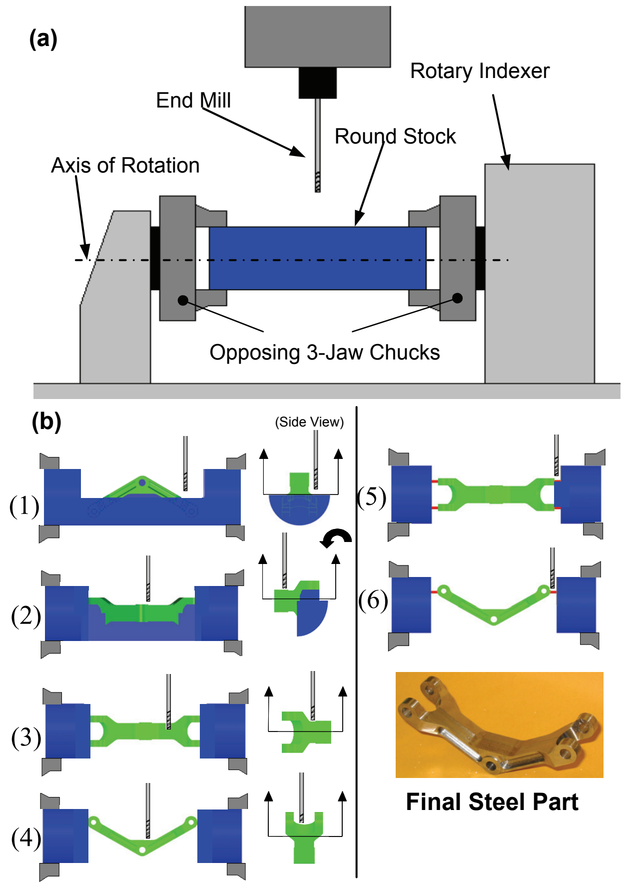

Figure 1 - (a) CNC-RP setup; (b) steps b.1-b.4 expose component geometry while b.5-b.6 expose sacrificial supports

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 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 the one that is created during the fracture event (trauma). In the prior versions of CNC-RP, 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 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). A small experiment was conducted to measure frictional coefficients at the interface of the proposed fractured bone implant surfaces and natural cancellous bone.

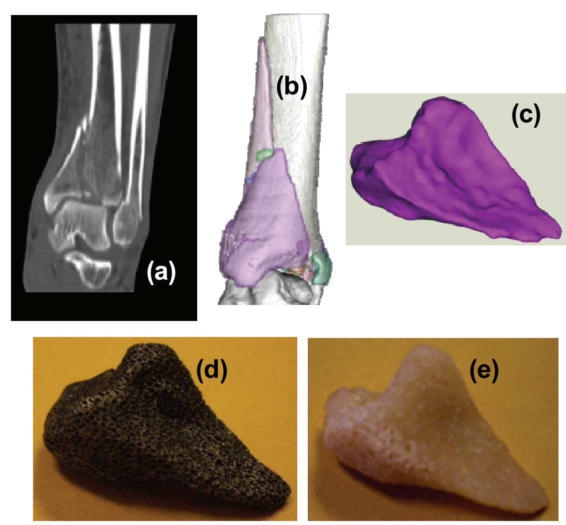

Figure 2 – Example implant machining; a) CT scan, b) Segmented image c) CAD model, d-e) implants in porous metal and bone

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 cubes (Figure 5). This was accomplished through 90degree 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 increase in the roughness on the Delrin cubes. 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.

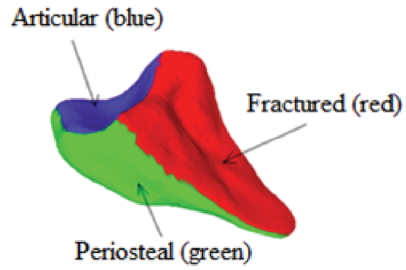

Figure 3 – Types of surfaces on a bone implant

Proposed Solution for new Process Planning Method

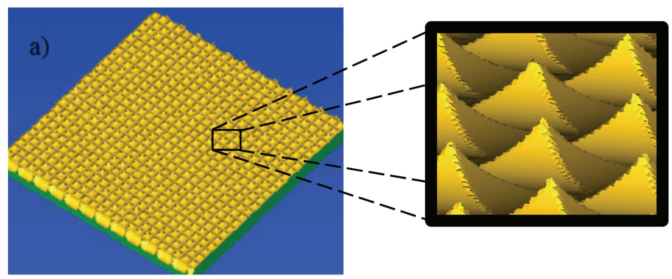

Figure 4 – Simulation of created texture on *fractured* surface

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 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. 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 file, and then setup axis and setup orientations calculations are done 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 previous versions of 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 each surface. Figure 6 illustrates the overall process flow for creating custom machined segmental defect fillers using CNC-RP. 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.

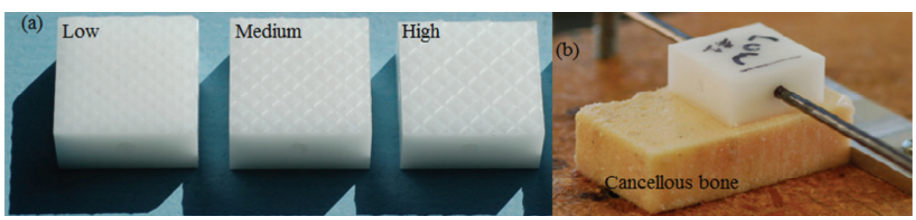

Figure 5 – Surface texture friction testing; a) delrin test blocks on increasing roughness, b) test block on cancellous bone sample during friction testing

Table 1: Friction coefficient test results for different surface textures

Slider	Coefficient
Smooth	0.25
Low	0.35
Medium	0.44
High	0.48

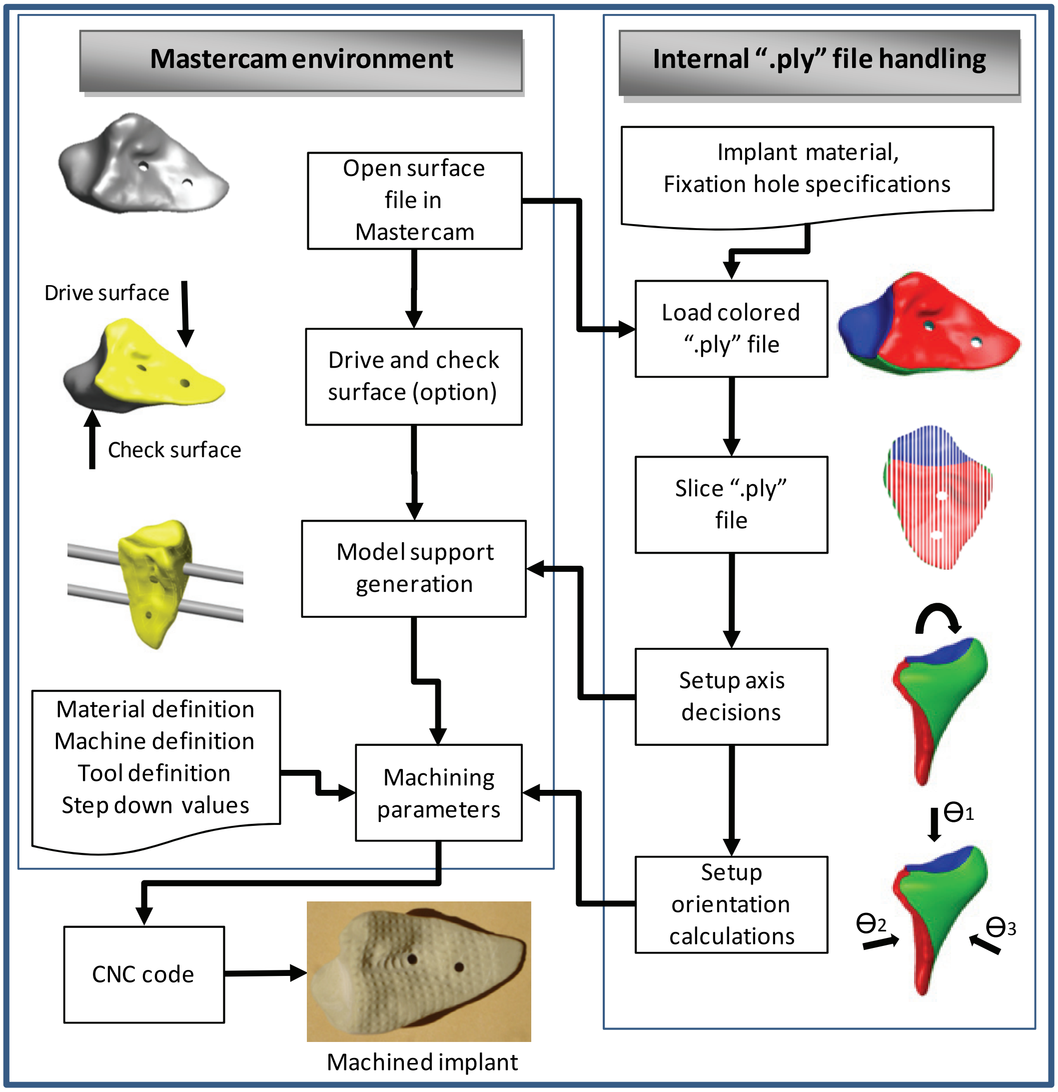

Figure 6 – Flowchart illustrating the automated process planning steps, from CT-derived CAD model to machined implant

In order to calculate the setup orientations required for creating the three surfaces, current CNC-RP visibility algorithms using set cover method are used [17]. The basic set cover approach is used here, but with a difference of achieving set cover for each surface individually rather than the whole model. Thus achieving a set cover for each surface individually would ensure the set cover for whole model ensuring its 100% machining. An optimization step using a multiple objective function is then used that chooses the best set of setup orientations aimed at specific surfaces. In order to maintain characteristics on specific surfaces, the fractured surface is always machined first in sequence followed by the periosteal and articular surface. Creating the periosteal surface after fractured surface eliminates any surface texture created on it by fractured surface ball milling routine. Similarly, creating the articular surface after periosteal eliminates any rougher machining done for periosteal surface ball milling and also the surface texture created on it due to fractured surface ball milling.

In previous work for CNC-RP process planning, it was only deemed necessary that *all* surfaces of the part model were machined after *all* orientations were completed. In other words, we did not consider a feature based approach wherein any particular feature of the part needed to be *completely* machined from any orientation. In the current problem, we still avoid the strict connotation of feature-based process planning, but we are interested in targeting each of the three surfaces individually. As shown in Figure 7, although numerous combinations of toolpaths could combine to solve the set cover problem, the goal is to target the surfaces and avoid regions where visibility and accessibility to more than one surface exists. There are two important issues that need to be addressed. One of them was avoiding crossover of surface specific tool paths to other surfaces to avoid having undesired characteristics on other surfaces. Thus if a tool path is designed for creating smoother periosteal or articular surface, crossover of these tool paths to fractured surface would lead to *damage* of surface texture created on the fractured surface. The other issue is avoiding overlap of more than one surface specific tool paths on each other. This could lead to destructive interference and also redundant machining on a given surface. In the case of periosteal and articular surfaces, this is merely a problem of wasted machining time; whereas, destructive interference among fracture surface toolpaths could literally wipe away the intended surface roughness.

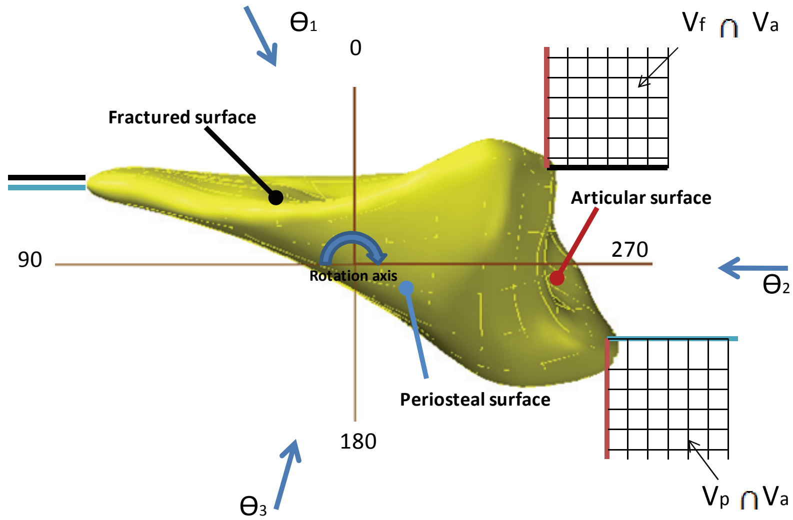

Figure 7 – Illustration of visibility to each of the 3 surfaces on an implant, and regions where visibility intersects

In order to avoid tool path cross over to other surfaces there was a need to find setup orientations that would generally isolate a given surface and machine it without the tool paths crossing over to other surfaces. In order to calculate setup orientations specific to a given surface, a multiple objective function was developed that maximizes visibility of the intended surface while minimizing the visibility of the undesired surfaces. This would avoid other surfaces having undesired characteristics, and also save machining time by sparing redundant machining on a given surface. There can also be a case where a certain percentage of surface is visible but is not accessible because of limited tool length available. Thus comparing against the maximum tool length available, it can be decided whether a certain visible surface area is accessible or not. The objective function also helps in minimizing or maximizing the accessible area of a specific surface.

Modified Greedy Heuristic using a Multiple Objective Function

The multiple objective function developed helps in choosing the setup orientations that a) maximizes the visibility and accessibility of the desired surface b) minimizes the visibility and accessibility of the undesired surfaces, c) minimizes overlap of a setup orientation with other orientations calculated previously. Maximizing the visibility and accessibility of the desired surface helps in isolating the tool paths on that surface. Minimizing the visibility and accessibility of undesired surfaces helps in avoiding crossover of tool paths on to those surfaces. Avoiding a new setup orientation near another one previously calculated reduces tool path overlaps on each other and also the redundant machining of the surface.

The objective function is as follows:

$$Max\,\{\mathrm{V} + \mathrm{IP} - \Delta\Theta - \mathrm{O}\}$$

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

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

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

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

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

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

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

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

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

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

O is the overlap between accessible perimeters visible from more than one setup angle:

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

And, $\Delta\Theta$ is simply the difference between the setup angle chosen (Θ) and the middle of the visibility range of the surface it is intended to cover.

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 used. As such, we simply conduct a local search about the middle of the visibility bounds for each surface type, computing all permutations with small angle increments about the middle of the visible range.

Implementation

Figure 8a shows the calculated setup angles aimed at the three surfaces of a fracture implant from a human Tibia. The implementation was done using C++ with MFC as a user interface. The developed process planning and algorithms are integrated with MasterCAM. The specifications of the computer used is 3.2 GHz processor, with OS Windows XP, 4GB RAM. Figure 8b shows a segmental defect filler created with surface texture on the fractured surface and different finishes on periosteal and articular surfaces using CNC-RP. The material used is barium sulphate doped polyurethane foam that can be used as a bone surrogate material. The CNC machine used for creating the bone segment was a 4-axis Fadal VMC 15.

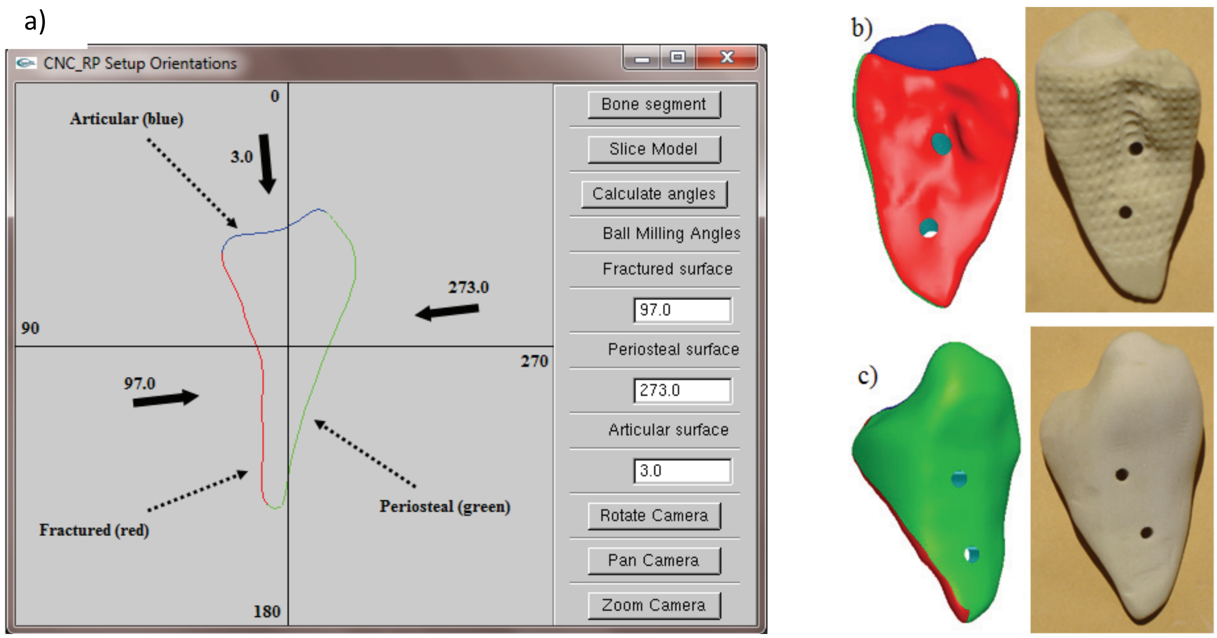

Figure 8: a) Implementation using C++ b) Textured fracture surface on the machined bone fragment and smooth articular surface c) Smooth periosteal surface on machined bone segment

Conclusions and future work

The CNC-RP process is shown to be a successful and suitable method for the custom machining of bone implants. This current work shows that it can be used 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 initital fixation stability. This should also lead to increased rate of bone ingrowth into the implant. Future work could also 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 be too time consuming.

Acknowledgments

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