Title
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Enhancing the care of pilon fractures with 3D printed models.

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Category: Scientific Research

Abstract

Three dimensional printing is an additive manufacturing process by which a 3D structure is created from a digital blueprint. It is a technology that is increasingly utilized by surgeons as a resource for preoperative planning and intraoperative guidance. In the field of orthopedic surgery, 3D printed models have not been thoroughly evaluated as an educational resource. The current study aims, first, to evaluate 3D models of pilon fractures for their fidelity compared to the corresponding CT blueprints and, second, to evaluate 3D printed models as teaching tools. Pilon fractures of the distal tibial articular surface are complex in nature and a good representation of high-energy injury. They pose challenges to both learning with traditional two-dimensional or virtual three-dimensional resources and to adequate understanding of fracture anatomy. It is hypothesized that 3D printed models will be accurate compared to corresponding clinical CT datasets. This study showed through distances between landmarks and by surface characteristic analysis that micro-CTs of 3D printed models are accurate compared to the corresponding clinical CTs, but that variation is introduced when converting clinical CTs to 3D printed models to micro-CTs.

Background

Designing a preoperative plan is a central principle of surgical care [1]. Historically, surgeons relied on two-dimensional (2D) radiographs, fluoroscopy, computed tomography (CT), and magnetic resonance imaging (MRI) for representation of fracture characteristics. 2D visualization can make fracture orientation difficult to conceptualize especially if cases involve complex anatomy [2-3]. Limited viewing capabilities are associated with difficult reductions and are linked to increased surgical errors and complication rates [1, 4]. Demand for more precise imaging modalities prompted advances in radiology and computer technology, which made three-dimensional (3D) representation of anatomical structures a reality [2]. Originally, 3D representation of anatomical structures was limited to fluoroscopy, CT, and MRI [4-5]. These imaging modalities allowed for more precise characterization of fractures, better preoperative planning, virtual simulation of surgery, clearer intraoperative guidance, and better training of medical staff [1, 3-5]. However, 3D imaging is still limited by visualization on a flat screen. 3D printing, a newer application to the surgical field, overcomes this limitation by producing a graspable three-dimensional model [6].
3D printing is an additive manufacturing process by which layers of a chosen material are laid down to create a 3D structure from a digital blueprint [7-8]. In 1979, Alberti and colleagues established the medical application of 3D printing when they created a 3D pelvic model from CT data to construct a customizable implant for a patient with fibrosarcoma [9]. Since then, the use of 3D printing was explored in a variety of surgical fields including neurosurgery, craniofacial reconstructive surgery, cardiothoracic surgery, and orthopedic surgery [8, 10, 11-12]. In orthopedic surgery the application of 3D printing is often focused on cases involving complex anatomy, including: chronic fractures, joint reconstruction, and spinal deformities. Orthopedic research demonstrated 3D printing to be a beneficial tool for preoperative planning, surgery simulation, customization of implants, planning screw trajectory, and intraoperative guidance [2-3, 13-17]. An application that can be further research is the use of 3D printed models as educational resources.

It has been said that patient education is just as important as preoperative planning, surgical technique, and postoperative treatment in optimizing patient compliance and functional outcome [18]. The goal of patient education is to increase patient knowledge and clarify misconceptions about medical conditions through information regarding specific diagnosis, risk factors, treatment options, and prognosis [19]. Education has an impact on the degree to which patients follow prescribed therapeutic regiments, and, in the field of orthopedic surgery, patient education improves postoperative outcomes [20-21]. In 2004, Ashe and colleagues studied the effect of patient education on postoperative osteoporosis treatment rates after low impact distal radius fractures. Their results showed that patients were more likely to seek treatment if educated regarding the link between osteoporosis and fracture compared to patients who did not receive such education [22]. In 2005, Gardner and colleagues showed that subjects randomized to a patient education cohort were twice as likely to seek postoperative management of osteoporosis following low impact fracture compared to those randomized to the standard of care cohort [23-24]. In related research, the quality of educational resources is related to patient satisfaction, medical knowledge, and level of adherence [25]. In terms of anatomy education and training, Challoner and Erolin evaluated the use of 3D imaging compared to 3D models to teach anatomical principles, and subjects preferred the tactile 3D models for learning anatomy [13].

This study aims to manufacture 3D printed models of pilon fractures, and measure the utility of the models as educational resources. By definition, pilon fractures involve the distal articular surface of the tibia. They represent intra-articular injury at the tabiotalar joint resulting from high-energy axial load on the tibia with or without accompanying rotational force [26]. Previous studies have shown the importance of patient education in postoperative management of low impact fractures [22-24]. The current study aims to evaluate the use of 3D models for patient, student, and physician education and training regarding high impact fractures.
Objectives

The primary goal of this project is to analyze the 3D models and determine their fidelity compared to corresponding clinical CT datasets. The hypothesis is that 3D printed models will be accurate copies of the clinical CTs.

A secondary hypothesis is that there is overlap in the specific needs and design goals of 3D printed fracture models intended for education and training of (A) patients, (B) medical students, (C) physicians, and (D) bioengineers, but there are also distinct requirements. A secondary goal is to determine the distinct needs and design goals for 3D printed fracture models for groups A-D. We hope to accomplish this goal by querying the orthopedic and bioengineering departments to elicit what differences exist between groups in terms of specific needs and design goals in order to establish a qualitative metric from which to customize models according to group (A-D). Once the distinct needs and design goals are understood for each group, we hope to customize 3D fracture models to meet the requirements of the group for which the models are designed.

Methods

Steps 1-4 of the methods were completed by UCSD Bioengineering course BE01 under the direction of Dr. Sah and his laboratory in the Spring quarter of 2015. Step 5 was completed for this ISP.

1) Image Preparation

After IRB approval (HRPP #071983X), Dr. Schwartz and Dr. Craft (UCSD Orthopaedic Surgery Trauma Service) selected seven clinical CT datasets of pilon fractures for this project. The 7 clinical CT datasets were received on CDs as DICOM image stacks. For each CT, datasets were reformatted from DICOM to BMP format and re-sliced into isotropic voxels. All datasets were assigned random identification numbers.

2) Image Processing

The 7 clinical CT datasets were processed by two different sections (12pm section, 1pm section) of an introductory bioengineering course at UCSD (BE01). The 12pm section and 1pm section each processed the same 7 clinical CTs, which produced 2 groups of unique datasets for 3D printing (14 total). Clinical CTs were cropped to selectively include the large tibial bone fragments, excluding the talus and fibula, in a 3D volume of interest. The volume was then thresholded (0-255, varying depending on scan) to binary. The binarized dataset was despeckled to remove noise and filled to remove pores and internal cavities. A 3D model (STL) was then exported, which is a 3D-printable volume model format. STL files were optimized for 3D printing by removing mesh defects and inspected.

3) 3D Printing

The 14 STL files (7 from 12pm section, 7 from 1pm section) were each 3D printed at full scale in Acrylonitrile Butadiene Styrene (ABS) plastic on a desktop fused deposition modeling 3D printer (TAZ 4, Lulzbot, Loveland, Colorado, USA). Models were printed using 0.27mm layer height at 100% infill with automatically generated supports. Following printing, support material was removed manually and 3D prints were labeled. A total of 14 3D prints were created.
4) 3D Print Micro-CT

Each 3D print was scanned using micro-CT at a voxel resolution of (36μm)$^3$. A total of 14 micro-CT datasets from the 3D prints (7 from the 12pm section, 7 from the 1pm section) were created.

5) 3D Print Analysis

Quantification of the 3D printed models was executed through two different modalities: the first was a comparison of measureable landmarks, the second by comparing surface deviation between clinical CT and 3D print micro-CT.

5a) Measurable landmarks: Landmarks of interest on the distal tibial articular surface were chosen and measured on the clinical CTs and the 3D print micro-CTs. The two distances chosen (Image 1) were: the medial malleolus to fibular notch (MM-FN) distance and the anterior plafond to posterior plafond (AP-PP) distance. These landmarks were chosen because they are easily identifiable at the distal tibial joint surface on CT. The MM and FN are both identifiable on coronal CT slices allowing for distance between the two points to be measured. The AP and PP are both identifiable on axial slices allowing for the distance between the two points to be measured. The tibial components of the clinical CT's were cropped at different points along the tibial shaft and fibulas were removed before 3D printing making points on the tibial joint surface the easiest to identify and therefore measure. These two distances (MM-FN, AP-PP) were measured using DataView for each of the three CT datasets: clinical CTs, 12pm section micro-CT, and 1pm section micro-CT.

The research question asked in this study was whether micro-CTs generated in this manner could appropriately mimic their corresponding clinical CTs. The hypothesis was that the scans would be virtually similar - that no statistically significant difference would be found to exist between clinical CTs and the corresponding micro-CTs.

To address this research question, two separate parameters (MM-FN and AP-PP distances) from the clinical CTs were compared to those on micro-CT. The measurable difference in each parameter between clinical CT and micro-CT were then calculated for each section (12pm and 1pm).

These measured differences between clinical CT and micro-CT were analyzed for each section (12pm and 1pm) using a one-sample t-test to determine if either parameter differed significantly from micro-CT to clinical CT.

In order to minimize the risk of type-II error, we then combined the measured differences for both sections (12pm and 1pm) into one section with 14 measurements. With the benefit of this larger sample size, we ran a one-sample t-test on this combined group to again determine the extent of any significant difference between micro-CT and clinical CT.
5b) Comparison of Surface Deviation: Surface characteristics were compared between clinical CTs and corresponding 3D model micro-CTs using CloudCompare software (version 2.6.1) to evaluate the fidelity of the 3D print surface characteristics compared to the clinical CT datasets. CloudCompare allows for clinical CTs to be aligned with the corresponding micro-CTs (see Image 2). Once aligned, thousands of points on the clinical CT were compared to their corresponding points on micro-CT. For each pair of corresponding points, the software generated an absolute distance measurement (in millimeters). These distance measurements were summed and averaged across all points for each scan, allowing for the generation of a mean “absolute distance” and standard deviation.

Results
Measureable Landmarks: Analysis of the 12pm section measured differences yielded a mean MM-FN distance difference of 1.00 mm, (95% CI: -1.72, 3.72, p = 0.403). The mean 12pm AP-PP distance difference was -0.11 mm, (95% CI: -3.60, 2.83, p = 0.927).

Analysis of the 1pm section measured differences yielded a mean MM-FN distance difference of 0.26 mm, (95% CI: -0.79, 2.31, p = 0.769). The mean 1pm AP-PP distance difference was -0.46 mm, (95% CI: -4.01, 3.09, p = 0.763). See Figure 1 for box plot of MM-FN and AP-PP measured differences.

Secondary analysis, which combined the 12pm and 1pm sections (Figure 1), yielded a mean MM-FN measured difference of 0.63 mm, (95% CI: -0.83, 2.09, p = 0.370). The mean AP-PP measured difference was -0.29 mm, (95% CI: -2.25, 1.67, p = 0.758).

Figure 1: Box plots overlaid with scatter plots representing the mean difference data for the two parameters (AP-PP and MM-FN) after combining groups (12pm section, 1pm section). Median values for each parameter are represented by the bolded horizontal lines within the box plots. The scatter plots represent the individual parameters (AP-PP and MM-FN) for each model. Values are connected by colored lines to link parameters by model.
**Surface Analysis:** CloudCompare “absolute distance” values, as well as their respective standard deviations, are shown in Figure 2. Taken together, the mean “absolute distance” across all models was 1.59 mm with a standard deviation (SD) of 0.53 mm. The range of the means was 0.41 mm to 2.49 mm.

**Discussion**

The process of converting clinical CT datasets to 3D printed models to 3D model micro-CT would yield accurate copies of the original dataset at each step in a perfectly controlled environment. The primary goal of this study was to determine the fidelity of the 3D printed models compared to correlated clinical CTs. Unfortunately the graspable 3D models were not available for analysis, so this was accomplished by comparing 3D model micro-CTs to the corresponding clinical CTs. Evaluation of the 3D models was achieved in two ways: first by comparing distances between measurable points of interest, and second by surface analysis of the clinical CTs to corresponding micro-CTs. The hypothesis tested was that no difference existed between clinical CTs and the corresponding micro-CTs, in other words the “measured differences” (clinical CT minus micro-CT) is no difference (0 mm).

The primary analysis revealed no significant difference (p > 0.05) in measured differences for both parameters (MM-FN distance and AP-PP distance) for each section (12pm, 1pm). A secondary analysis aimed to increase power by combining the 12pm and 1pm sections for both parameters. The secondary analysis also did not show significant difference in measured differences for the MM-FN or AP-PP distances. When comparing surface characteristics of the clinical CTs to corresponding micro-CTs the average distance between two corresponding points was 1.59 mm (SD = 0.53 mm) with a range of 0.41 mm to 2.49 mm.

Although the data analysis resulted in no significant difference between the micro-CTs and corresponding clinical CTs when comparing measured differences for both parameters, a fair amount of variation can be seen in the data (Figure 1). In general terms it can be said that models with lines closer to a “measured difference” of 0mm and with a slope approaching 0 are accurate, while models with lines further from 0mm and with
larger slopes are inaccurate when examining the scatter plots. As can be seen in Figure 1, some of the 3D print micro-CTs were accurate compared to correlated clinical CTs, and some were less so. It can be concluded from the analysis that the micro-CT's closely resemble the corresponding clinical CTs, but the process of converting clinical CTs to 3D models to micro-CTs introduces variability.

There are a number of steps during the process of converting clinical CTs to 3D models to micro-CTs that can introduce variability when examining the methods. First, the clinical CTs are cropped to exclude the fibula, talus, and proximal tibia during image processing thus removing data from the clinical CTs and possibly some aspects of the fracture. Tibial volume of interest is then cleaned to remove noise, also removing data. Second, each 3D printed model was manually cleaned to remove excess ABS print material, possibly also removing material correlating to the original clinical CT. Third, the process of micro-CT involved imaging the 3D models on a platform that appeared homogenous to the models on final imaging. When performing measurements on distances of interest it was sometimes difficult to distinguish model from platform, and occasionally the images were cropped, excluding parts of the models. Finally there was human error in the way the distance measurements were performed. It was difficult to ensure measurements were recorded in the exact same x, y, and z coordinates because the clinical CTs and micro-CTs had different units of measure per slice. There was also human error introduced in the surface analysis because alignment of the clinical CT to micro-CT was achieved by approximation.

Analysis of the micro-CTs to corresponding clinical CTs revealed the “measured differences” in MM-FN and AP-PP distances were not statistically different than no difference or 0 mm. The mean difference in surface deviation between points on the clinical CTs and points on corresponding micro CTs was 1.49 mm. The results indicate the micro-CTs, and by extension the 3D models, were accurate replications of the clinical CT datasets. Variation in the data was likely introduced in the steps previously outlined. It should also be noted in this pilot study that the study groups are small, with n = 7 for the primary analysis and n = 14 in the secondary analysis. It is possible that a difference between measured differences exists, but was not exposed because the study is underpowered (type 2 error).

**Achievements**

The first accomplishment of this study was completion of the background research on 3D printing as a surgical resource, which set the framework for the evaluation of 3D printed models of pilon fractures in the field of orthopaedic surgery. As part of the background research portion of the project I was also able to help Dr. Sah’s lab design a syllabus for undergraduate bioengineering students (BE01) interested in learning more about 3D printing. To date 14 pilon models have been printed from 7 clinical CT datasets. The 3D models were subsequently imaged via micro-CT and analyzed to determine fidelity compared to corresponding clinical CTs. What remains to be accomplished is the full evaluation of the 3D printed models, which were unavailable at the time of data analysis. In the future it would be useful to evaluate the fidelity of the graspable 3D models in relation to their original CT data sets. Once accomplished, they can be further evaluated for usefulness as resources for patients, medical students, physicians, and bioengineers.
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