Automated Production of Artificial Bone Implants

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Introduction

We are engaged in the development of new tools that will enable surgeons to easily design and fabricate custom-fitting biocompatible bone substitutes. These 'artificial' bone implants will be accepted by the human body, which will eventually absorb and replace them with human bone. Our goal is the translation of this concept into a viable toolset for regular clinical practice. In order to accomplish this, we are focused on three areas: 1) development of computer algorithms that mostly automate the implant design process; 2) validated designs for the tissue-engineered scaffolds that these implants will be made from; and 3) a fabrication device that will translate the surgeon's design into a physical implant scaffold formed from a biocompatible ceramic material. This poster focuses on design automation, with references to the other areas. Our approach brings together a broadly-gathered interdisciplinary team, and aims to dramatically improve upon current treatment options for bone defects, the best of which requires harvesting of human bone from another site on the patient's body. Pain, suffering, and surgery complications will be reduced. Further, we project a cost savings of $1 billion/year for the U.S. health care system.

Motivation

The need for this technology is clear and substantial. Whether on the battlefield in Iraq or a car accident at home, people encounter trauma and disease to their bones every day.

Figure 1: Photograph (left) and CT image (right) of a patient with extensive bone and soft tissue loss resulting from blunt force trauma in Iraq.

Figure 1 illlustrates a battlefield injury incurred months ago by an American soldier serving in Iraq and currently being treated by one of us (Goldwasser). This type of injury is unfortunately not unusual in the current conflict and is representative of the extent and complexity of bone loss in such patients. Rapid evacuation of injured soldiers to mobile surgical hospitals and improvements in body and head armor have reduced the lethality of battlefield injuries. In all previous conflicts dating to World War I, the lethality of combat wounds experienced by U.S. soldiers was approximately 25 percent. In the current Iraq war, lethality of battlefield injuries has been dramatically reduced to 9 percent (Gawande, 2004). Approximately half of these non-lethal injuries are to the head, neck, and extremities, and often require extensive reconstruction procedures to replace the missing tissue.

This injury or condition can dramatically reduce their ability to perform routine tasks, and negatively impact quality of life. In many of these cases, the preferred medical response calls for replacement of the missing bone to restore normal function. The current best practice to accommodate this is to use autograft bone: harvested healthy bone from one part of the body for implantation elsewhere. The surgical procedures for harvesting such bone can result in complications that are "minor" (hematoma, temporary sensory loss, acute pain); or "major" (permanent sensory loss, chronic pain, infection, and gait disturbances). Complication rates exceeding 30% have been reported for autograft harvesting from the iliac crest of the pelvis, a common source for autograft bone (Younger, 1989).

While this bone harvesting surgery often works very well, it is counterproductive to injure a healthy part of the body in order to cure another part somewhere else. In fact, the extraction of healthy bone from a patient's body is often significantly more traumatic than the corrective implant surgery itself—causing longer recovery times, increased pain, extended hospital stays, and more expensive surgeries. If we are to successfully move bone regeneration scaffolds out of the laboratory and into clinical practice, several steps will have to be completed. The literature describes a number of approaches to the engineering of these scaffolds but few to our knowledge examine the technological issue of building a tool meant for surgeons to design implants. If surgeons are to utilize scaffolds for complex shapes and purposes such as those required for the mandible, they will need an automated implant design tool that requires little user input and no 3-D modeling skills (i.e. surgeon-friendly) so they can easily and quickly design and have fabricated custom-fitting implants.

Methods: The Automated Design Process

1 Build a shape database of healthy mandibles

We start by obtaining CT scans of a number of adult mandibles taken from a variable collection of adults (age and gender). Each scan is segmented to isolate the mandibles from the rest of the scan. We represent the morphology of these mandibles by the selection of a small number of "landmark" feature points (currently five), as shown below. We build a "shape space" that describes individual variations of these mandibles using the principal component analysis (PCA) method. This shape database can then be used for comparisons to a specific patient's defect bone.

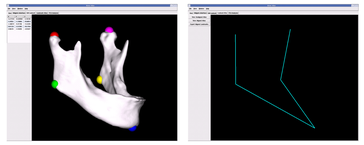

Figure 2: Five landmarks are used to indicate mandible morphology (left). These landmarks, once measured and aligned across a number of different mandibles, indicate the range of variation in mandible morphology (right).

2 Scan patient's defect bone and prepare data for a shape matching search

Next we obtain a routine CT scan of the patient's defect area, and segment the area of interest (see Figure 3). In this example, we have used the case of a 73 year-old female that has experienced severe bilateral bone loss in the mandible. Once segmented, the model is loaded in our bone atlas software for landmark placement.

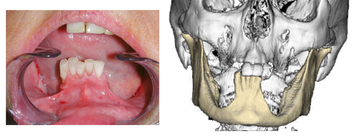

Figure 3: Photograph (left) and CT scan (right) of a 73 year-old female that has experienced severe mandibular bone loss. The mandible in the CT scan is segmented and indicated in yellow.

3 Search the healthy mandible database for the closest match

Based on the shape "fingerprint" of the scanned injured bone, we search the database for the closest healthy match. Then we align and rescale the healthy bone to best match the proportions and shape of the injured bone, using the "Procrustes" alignment method available in the Visualization Toolkit (VTK), or through a level-set evolution on the volume data (D.E. Breen, 2001).

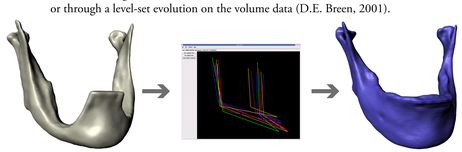

Figure 4: PCA analysis of the defect mandible (left) is compared to other mandibles in the bone database (center) in order to find the closest healthy match (right).

4 Identify the defect area of interest

So that the computer knows where to focus, the surgeon needs to identify the defect area. This will be done by "painting" those parts of the mandible model that represent the edges of the damaged portion. This lets the software know not to worry about morphing to fit damaged areas.

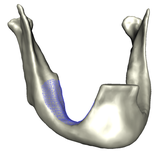

Figure 5: Areas of the mandible that illustrate edges of the defect area are outlined in blue.

5 Morph the healthy mandible to match the shape of the damaged mandible

Given the unique qualities of every individual, we will not find an exact match in the database of mandibles, but will instead find one or several close mandibles. We will then need to interpolate and deform these mandibles to construct a healthy match to the injured query. We perform this using an energy minimization algorithm that ignores the previously outlined damaged areas, using a similar method to one implemented in Allen, 2003.

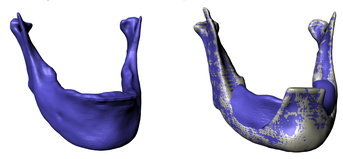

Figure 6: Healthy mandible (left), before morphing to match the shape of and overlay on the damaged mandible (right).

6 Subtract the defect mandible from the healthy morphed mandible

Now that we have matching models of the healthy and damaged mandible, we subtract the damaged model from the healthy one to reveal an implant design. Automatic morphological operations are applied to smooth out the noise from the final model of the implant.

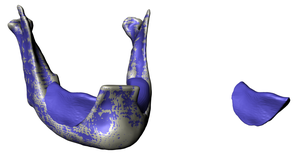

Figure 7: Overlay of healthy mandible on damaged mandible (left), and implant design result after damaged mandible is subtracted from healthy mandible (right).

7 Tweak subtraction result to accommodate unique patient factors

An automated subtraction won't be able to account for all physiological and other features. The surgeon will be presented with the subtraction result for final adjustments, such as canals for nerves and hole placement for screws.

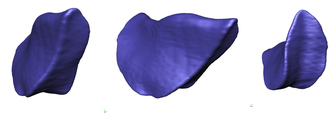

Figure 8: The implant model as seen from the front (left), side (center), and rear (right).

8 Electronically transfer final implant model to a fabrication facility

Once finished, the model is converted to an STL format for fabrication by a Robocaster 3-D printing device using validated materials that will withstand the biting forces of the jaw and encourage bone regrowth in the area.

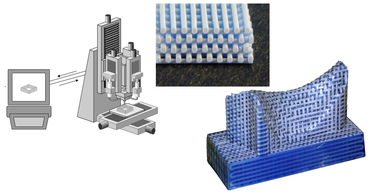

Figure 9: The implant model file is sent to a Robocaster (left) for fabrication. In a previous proof-of-concept, we used the Robocaster to manufacture a block of hydroxyapatite scaffold (center), embedded it with wax, and then milled an implant part from that block (right).

9 Surgically insert implant scaffold

After manufacture, the wax is melted out, the implant is sterilized in an autoclave, and the implant is inserted into the body. In this fit-test, the implant was removed since the device is not yet approved by the FDA.

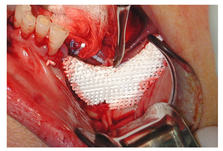

Figure 10: An implant model is test-fit in a patient just prior to a traditional autograft surgery.

Results

We have validated the feasibility of this approach through the construction of a number of software packages that enable the various steps outlined above. These packages include software for landmark placement and PCA analysis, routines for finding the closest match within the shape space of a bone database, methods for alignment and scaling of the healthy bone to match the defect bone, algorithms for morphing that healthy bone into the shape of the defect, and finally, for performing the subtraction that yields an implant design result.

In a previous phase of the project (Grosser, 2004), we validated the potential for translating the intuitive knowledge about implant design from a surgeon to a 3-D modeler to a fabricator to an implant, culminating in a successful test-fit. The images in steps 9 and 10 come from this phase of the project.

We are also working on experiments (not detailed here) that aim to optimize the physical and chemical properties of bone scaffolds to function safely and effectively in regenerating new bone to restore the form and function of the original bone.

We see this work as a proof-of-concept. It will require significantly more work to refine our algorithms for automated implant design in order to accommodate the maximal number of cases. We have yet to develop an application that supports surgeon adjustments to the implant, or to wrap any of our work into a software tool that is easy to use. Efforts towards these goals are ongoing.

Conclusion

This project presents a new and significantly different approach to the surgical treatment of patients who have experienced bone loss through disease or trauma. This approach will dramatically improve the efficiency of pre-operative planning, improve the quality and congruency of the defect-filling implant, eliminate the necessity for bone harvesting surgery, and reduce the cost and morbidity of such procedures. Our diverse team has the right expertise (materials science, biology, imaging, design, fabrication, and maxillofacial surgery) and the right experience (two recently completed proofs-of-concept), to tackle this complex problem. It is our shared recognition of the importance of the human dimension of our research that has cemented our collaboration and motivates the current proposal.

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