Validating and Improving Single-Stage Cranioplasty Prosthetics with Ground Truth Models:

An expansion of single-stage cranial defect repairs and implants

Project Proposal

Project 12

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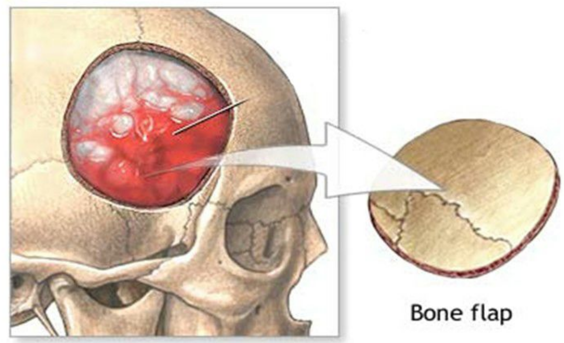
Mentors: Dr. Mehran Armand, Dr. Chad Gordon, Dr. Ryan Murphy

Summary/Abstract

During some cranial surgeries, pieces of the skull must be removed in order to gain access to the brain. Directly following these surgeries, cranioplasty procedures are used to repair defects in the skull. However, in many cases the original bone flap is damaged during removal from the skull is unable to be replaced. In these cases, a cranial implant must be made to cover the exposed defect. A implant that perfectly conforms to the defect shape is ideal as it prevents "dead space" in the skull and associated infection. However, creating a fitted implant presents its own challenges. Using a machine to create one requires the patient to come back at a separate time creating a two-stage surgery which during the interim the patient does not have an ideal implant. To prevent the necessity of two-stage surgery, many reconstructive surgeons will have an oversized implant of the expected defect area machined beforehand and then manually carve it to be the correct shape of the actual defect during the surgery. This is done by trial and error and takes a considerable amount of time (10 - 80 min). Recently Dr. Gordon, Dr. Armand, and Ryan Murphy developed a method that projects the implant outline onto the oversized implant which reduces this time significantly, but this method is limited by the complexity of implant. Last year, a new system was developed for using 3D scanner to create a machined single-stage implant, but the effectiveness of using 3D scanners and point cloud models to completely capture defect geometry and accurately register it back into the patient space is currently unknown. This project will create ground truth models of cranial defects to test and validate accuracy of the 3D scanning system. During this process we will refine and improve the 3D scanning system from implant capture to patient registration.



Background and Current Issues

Cranioplasties are used to reconstruct the site of craniotomies and other cranial surgeries that remove sections of the skull. These cranioplasties are also known as secondary cranial reconstructions and are performed for patients who require staged reconstruction after craniotomies. These craniotomy procedures involve the removal of a section of the skull. The resulting skull flap is often not suited for immediate replacement due to issues such as risk of infection or excess removed material. As a result, these skull flaps are often frozen or thrown away altogether and a cranioplasty is performed instead. The cranioplasty is usually performed to alleviate concerns of safety and protection, cosmetic appearance restoration, and treatment of issues associated with leaving a portion of the skull removed, but can carry its own risks. These procedures are generally performed with an implant made of Poly-Methyl Methacrylate (PMMA) or a titanium mesh.

Due to risk of infection after such a procedure, creating a well-fitting prosthetic is important for increasing quality of life and risk management. Recently, an alternative method which involves the implementation of on-site fabrication of the prosthesis has been effective in cutting down on the number of separate surgeries performed. In this system, surgeons use a Customized Cranial Implant, or CCI, made of PMMA. These CCIs are fabricated preoperatively from patient CT scans and modified through omputer Aided Design. These CCIs are made as an oversized section of the operating area based on information from the CT scan. The main advantage of these CCIs is their ability to conform more closely to the unique curvature of the skull. Specifically, the thickness of the skull is taken into account when making these CCIs whereas a prosthetic made of titanium would be unable to achieve the same precision. During the surgery, the surgeon machines the CCI to match the size and shape of the defect. However, this is labor intensive and can take upwards of an hour.

Although this single-staged format is already a significant advancement from previously used multi-staged reconstruction, there is still room for improvement. In an effort to further improve procedure times, Dr. Gordon, Dr. Armand, and Ryan Murphy have devised a system which includes a Polaris optical tracker and a laser projection system. This system projects the trace onto the oversized CCI for more accurate cutting and shorter operation times. However, the system is not without its drawbacks. Specifically, it struggles with more complicated geometries and has difficulty collecting points describing the bevel angle of the defect. Additionally, the polaris system itself can be difficult to setup and is very expensive.

As 3D handheld scanners become cheaper and more accurate, the viability of replacing the polaris system with newer technology becomes more feasible. In the previous year, there was a group that built upon Dr. Gordon, Dr. Armand, and Ryan Murphy's system by incorporating a relatively inexpensive 3D scanner in the form of the Structure Sensor (an attachment for the iPad) as a cheaper and more effective alternative to the Polaris system. The project was generally a success, but was limited in that it did not incorporate defect bevels and more complicated geometries and also did not evaluate scan-to-patient registration accuracy. This project proposes to further develop this system with updated segmentation algorithms that allow for more complex feature detection and incorporate defect-to-patient registration in order to put the oversized CCI implant and the scanned defect in the same space (a necessary step for later implant fabrication). Will will do this using ground truth test cases that incorporate a variety of realistic defect geometries.

Proposed Solution

This projects proposes to further expand on the previous years project of integrating a new subsystem into the cranioplasty pipeline. Specifically, the subsystem includes the use of a

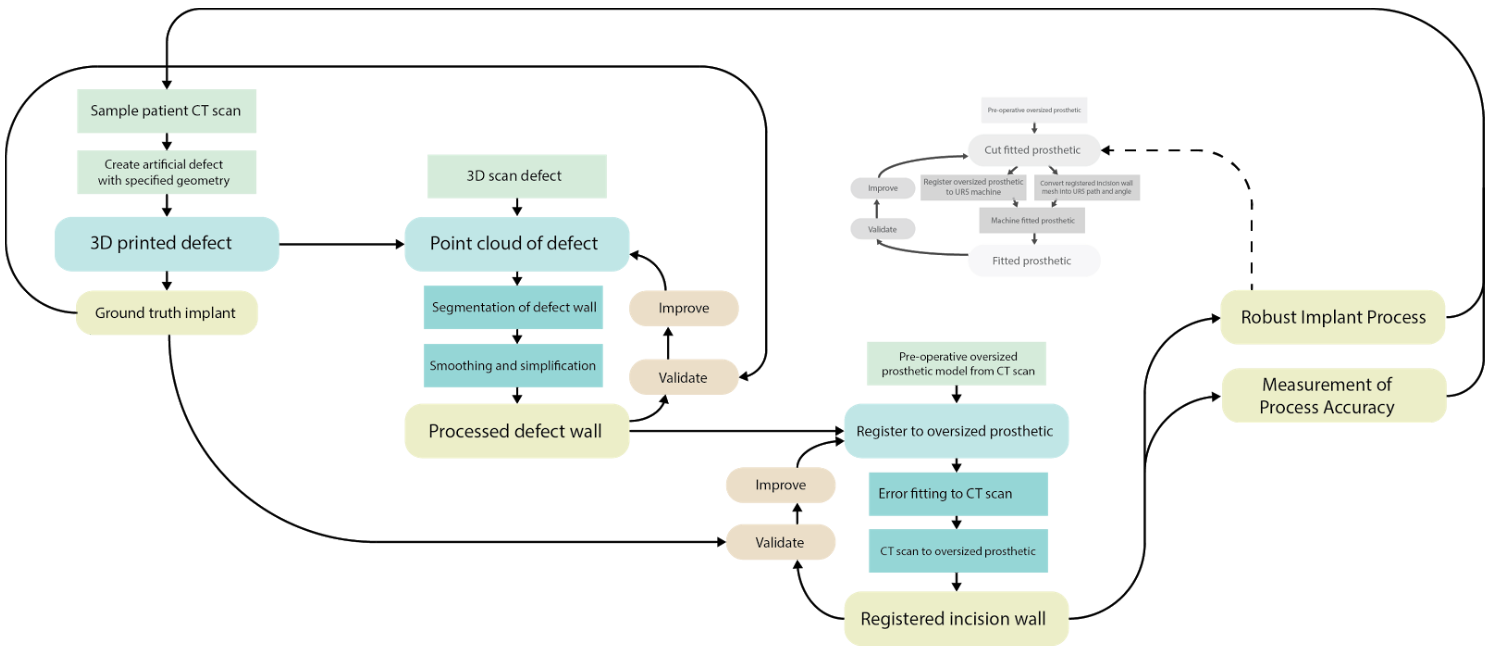
3D scanning hardware to render a mesh model of the defect. This model is then registered to the patient's CT scan and subsequently the CCI to allow for quick and accurate machining. This project will be focusing on extending the segmentation subroutines to allow for faster and more accurate parsing of the bevel angles. An issue in the past has been that determining the point where the skull wall meets with the brain's surface has been difficult. Depth-based image segmentation based on slope of subsections of the mesh will be implemented to aid in determining this. With this in place, the system will become more robust to more complex geometries of defect areas. Additionally, implementation of a quick and automated patient registration system using ICP will be conducted to allow integration between the software-rendered mesh and the real-world ground truth.

The workflow of the solution will begin by using the patient's CT scan to create a model of the skull and establish ground truth defects of various shapes and complexities. Solidworks and Blender will be used to create a majority of the varying defects. 3D printing will then be used to fabricate physical representations of the ground truth models. A 3D scanner will then be used to make a point cloud representation of the defect site. In this case, the 3D scanner used will be the Structure Sensor adaptor for the iPad and its related SDK package. The SDK package already contains processes for converting the point cloud into a mesh; however, various point cloud to mesh algorithms will be tested for accuracy and effectiveness for the project's particular purposes.

Once the initial scanning and rendering is complete, the data will be exported to a computer for final rendering. At this point, color-based image segmentation will be used to identify the defect area from the rest of the skull. This takes advantage of the fact that the surgical pen leaves clear markings around the site of the operation to provide an easy contour to segment along. Once this outlined area is isolated from the rest of the skull, depth-based segmentation can occur to more accurately clean the defect area. The segmentation algorithm used here will be required to provide information about more intricate cuts and bevel angles. This final rendering of the isolated defect will be registered to the patient's initial CT scan. The rendering of the defect can then be registered to the real world CCI for fabrication. For validation, the accuracy of the rendering will be compared to determine the accuracy of the mesh to the defect fit.

Our maximum deliverables also includes the construction of an on-site fabrication method of the CCI from the mesh. If time allows, work will be done with a UR5 machine to allow quick and accurate machining of the final CCI from the final 3D mesh rendering.

Technical Approach



Procedure Outline

1. Use patient CT scan to create a patient-specific model of skull.
    a. Convert image stack into binary surface using lab program.
2. Create artificial defect using 3D modeling program.
    a. Subtract defined geometries from skull sections using Solidworks. Incorporate a range of bevels and shapes.
    b. 3D print defect and area surrounding it.
3. After ground truth defect is made, use a 3D scanner to make a point cloud representation of the defect site.
    a. Perform color and depth based segmentation of defect site.
    b. The point cloud will be converted into a mesh of the defect through the patient's skull.
4. Process the mesh's contours and register it to the oversized implant.
    a. Use a smoothing algorithm to eliminate noise and harsh angles on the interior wall of the defect.
    b. Find best fit of defect mesh's surface to surface of patient CT scan model and evaluate accuracy
5. Using a fabrication device, cut the oversized implant into the form of the mesh.
    a. Mesh representation must be converted into a machining path
    b. Oversized implant must be registered to machine space

Procedure Evaluation Metrics and Testing

Our expansion of the 3D scanning system will be evaluated on the following metrics:

1. Accuracy
   The 3D scanner in this procedure is documented to have an accuracy of within 1mm when placed within 0.5m of the scanning target. The 3D printer which we will be making the models has an accuracy of 0.5mm. Therefore we optimally want to achieve an accuracy of 2mm when comparing our processed defect to the ground truth defect. We plan to evaluate the accuracy using the maximum surface-to-surface distance with an additional metric being the average surface-to-surface.

2. Robustness
   The 3d scanning application should be able to handle the defect geometries that typically occurs in cranioplasty operations. We will test the 3D scanning system with a variety of ground truth defects that vary bevel, shape, and complexity. For all of these, robustness will be gauged on whether the fitted implant model maintains a consistent level of accuracy.

3. Ease of Use
   When completed, this system should greatly increase ease of use compared to the current standard of care.There is no quantitative measurement for this procedure evaluation metric, but using an iPad and an automated implant process will easier to implement than the current standard of care which involves larger machines or trial-and-error cutting of the implant.

4. Time
   This system would not require extensive equipment setup and would not require manual cutting of the implant. This will reduce time costs before, during, and after the surgery compared to current single-stage and double-stage cranioplasty workflows.

5. Cost
   This system should cost less than $2000 to implement. The In addition, the reduction in cranioplasty time and reoperations due to complications associated with ill-fitting prosthetics should significantly reduce the overall cost of the cranioplasty procedure.

Deliverables

- Minimum
  - Segment and process point cloud of defect to create defect mesh
  - Register defect mesh to patient
  - Register mesh to oversized prosthetic
- Expected
  - Create ground truth models
  - Validate and improve process accuracy
  - Quantify accuracy of implant creation
  - Package process as Slicer module
- Maximum
  - Test process with cadavers
  - Register oversized prosthetic to UR5 machine
  - Define UR5 path for cutting fitted prosthetic

Dependencies

Status	**Dependency**	**Description**
Completed	Structure Sensor	Sensor to be used for scanning incision site. Provided by Dr. Armand.
Completed	iPad	iPad to use with structure sensor. Provided by Dr. Armand.
Completed	Software Repository	Provided by Ryan Murphy. Contains existing lab code, system, and test data. This will also be where we store and document our software modules.
Completed	Patient CT Scans	Will be used to create ground truth models. Provided by Ryan.
In Progress	3D Printer	Needed to fabricate ground truth models. DMC, BME Design Studio, or Shapeways.
In Progress	Operation Observation	Currently scheduling operation viewing to better motivate understanding of the problem.
On Hold	UR5 Machine	Machine for fabricating prosthetic. Not current priority.

Management Plan

The division of labor for this project will be distributed equally with both team members working on all components of the project. However, the primary responsibilities of the two members will be as follows:

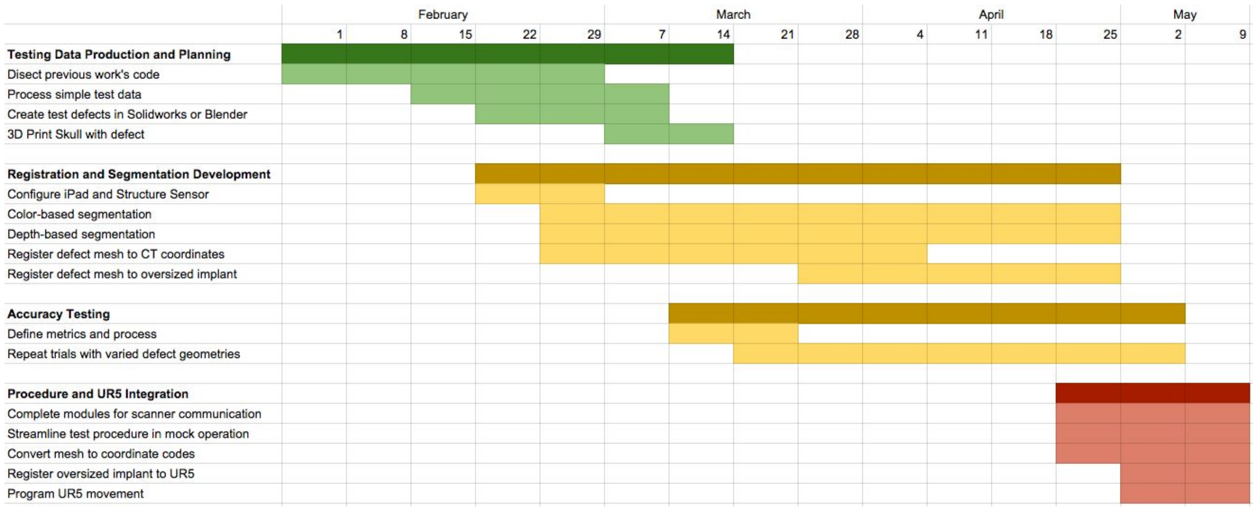
- Erica Schwarz: Refining defect point cloud processing (i.e. smoothing and deleting outliers, simplifying geometry for later machining). Creating robust ground truth models from test data.
- Willis Wang: Refining segmentation method of incision point cloud. Researching best ways to compare fit of meshes to ground truth.

Team meetings will be weekly on Wednesday mornings with additional meetings planned based on the discussion during that time. Meetings with Ryan Murphy will take place weekly on Thursday mornings to review progress.

Milestones

Date	**Objective**
2/15 - 3/14	Testing Data Production and Planning
2/22 - 4/25	Registration and Segmentation Development
3/14 - 5/02	Accuracy Testing
4/25 - 5/9	Procedure and UR5 Integration

Timeline and Gantt Chart



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