University of Waterloo

Faculty of Engineering

Design of Hardware Components for a Surgical Navigation Application

A report prepared for Intellijoint Surgical Inc.
Waterloo, Ontario

By

Rowan Ferrabee
2B Mechatronics Engineering

Sept. 2 2016

379 Berkley Ave.
Ottawa, Ontario
K2A 2G9

September 2, 2016

Professor William Melek,
Director of Mechatronics Engineering
Department of Mechanical and Mechatronics Engineering
University of Waterloo
Waterloo, Ontario

Dear Professor Melek:

This report, entitled “Design of Hardware Components for a Surgical Navigation Application” was prepared as my 2A Work Report for Intellijoint Surgical Inc. This was my first work term report. The purpose of this report is to detail the design of various hardware components created throughout this work term.

Intellijoint Surgical is involved in assisting surgeons take accurate anatomical measurements during surgery. Intellijoint currently has one main product, the IntellijointHIP, which aids orthopaedic surgeons when preforming hip replacement surgeries.

I was employed by the software department at Intellijoint Surgical, which is managed by Richard Fanson and primarily develops the software for Intellijoint products. The software department also coordinates all co-op students and engages in various research and development work.

The report was written entirely by me and has not received any previous academic credit at this or any other academic institution. I would like to thank Richard Fanson and Andre Hladio for their technical assistance and management throughout the term, and for helping me with the various decisions detailed in this report. I would also like to thank Rafa Narciso for helping me as a dedicated co-worker. I received no other assistance.

Sincerely,

Rowan Ferrabee
ID 20555514
2B Mechatronics Engineering

Table of Contents

List of Figures

List of Tables

Summary

In the following report, the design of various hardware components for a surgical navigation application is detailed. The components include a system to aid in the measurement of the dimensions of a surgeon's tool as well as a sterilizable camera clamp. The design requirements and considerations are discussed before detailing the specifics of the design of the various components. The implementation of each product is then explained and the analysis of the product's success is reviewed.

A component involved in assisting with the measurement of the surgeon's tool, known as the calibration jig, was designed primarily to optimize accuracy of tool measurement as well as ease of use of the system. It was found that the system increased the accuracy of calibration by 91.7%.

Another component was designed to aid in the sterilization of the product's camera system. Many designs were proposed to make the camera sterilizable, however a design was selected which was thought to optimally balance usability and difficulty of development. User testing revealed that the system was more than sufficiently usable for its application.

It is highly recommended to create a list of top-level system requirements and use this list to design each sub-component of the system. This methodology ensures that the initial vision of the system stays intact throughout its development. It is also recommended to create quantitative tests to measure usability of any product.

1 Introduction

Surgical navigation is the process by which surgeons use technology to assist them through the workflow of their surgery. Often this entails providing them with information relevant to the tasks they are performing, quantitative measurements of anatomical features, or assistive visualizations of the patient's body.

Intellijoint Surgical Inc. (IJS) is a medical device company which specializes in developing tools for hip surgery. Their primary product, known as the Intellijoint HIP, is a tool which allows orthopaedic surgeons to take precise measurements while performing full hip replacements. This ensures that they reach their targeted measurements for the patient's leg length as well as other important anatomic dimensions. Their tool uses a camera and tracking system to collect measurements and displays them to the surgeon using a Mac application.

The company was involved in the development a more general-use surgical navigation application as a research project. The project was intended to investigate the capabilities of such an application, and then to develop a complete system that could assist through every step of the surgery and demo these capabilities to non-technical individuals. The motivation for this was to potentially use the core technologies from this system in more specific targeted systems. This could be useful to break into markets involving other types of surgeries, which could greatly expand the company's scalability since hip surgeries only make up 40.9% of the orthopaedics market (Orthoworld, 2014).

A co-op student was hired to assist with the development of the hardware required for this project. The objective of this internship was to design and build all hardware components required for this application.

The general procedure for IJS surgery cases is that the company prepares a tray of tools to undergo sterilization before the surgery. The IJS sales representative then brings the required non sterile tools into the operating room on a cart known as the workstation.

In addition to transporting tools, the workstation holds a Mac laptop on top of it which connects to the camera system and runs the surgical application. The sales representative then prepares the system while the nurses prepare the operating room and the patient. Once everything is prepared, the surgeon enters the room and interacts with the IJS system via the Mac application. The set of steps that the surgeon then takes throughout their surgery is known as the workflow. The IJS system then aids the surgeon through every step of this workflow, providing them with all of the tools, measurements, and assistance required along the way.

2 Design Requirements

Before the initial investigation, the problem was very loosely defined. All that was requested was that a system be developed which would help a surgeon to accurately visualize the inside of a patient's body. The overall purpose of the application was to investigate the possibilities of such an application and to determine whether it was a worthwhile long-term research pursuit.

After investigation was done into potential markets, technical difficulty, and the field of image-guided surgical navigation, various system requirements were formulated with the help of the management team. The basic system requirements were listed as illustrated by table 1.

Table 1: Basic System Requirements

System Requirements:
Patient Selection: User must be able to load patient data from either usb or network
Tool Calibration: User must be able to calibrate tools of various sizes for use in the surgery
Patient Localization: Must provide method to localize the patient in the camera's frame of reference
Navigation: User must be able to render 3D models of the patient and the tool on the screen together
Sterilization: Must provide a method of sterilizing the system in the middle of the navigation step

From these basic requirements as well as additional requirements from the management team, the system's constraints and criteria were decided upon. The constraints and criteria relevant to the hardware system are listed in tables 2 and 3 respectively.

Table 2: Hardware Relevant System Constraints

Constraints:
Tool calibration must calculate tool dimensions with less error than detectable by the human eye
System must be intraoperatively sterilizable
Hardware system must include a static reference point that can be localized by the camera
All hardware components must either be storable on the sterilization tray or on the workstation

Table 3: Hardware Relevant System Criteria

Criteria:
Maximize ease of use for surgeon
Maximize ease of use for nurses and sales representatives
Minimize cost
Maximize ease of development
Maximize portability
Use as much of the current system's hardware components as possible

These criteria and constraints were used to determine exactly what components needed to be designed by the hardware team. Furthermore, they then remained essential when creating the components and continued to be used throughout the analysis of the components as a measure of their success.

3 Initial Design

The design of the application was split into two major sections: the top level user workflow and the underlining implementation. The workflow of the application was designed first such that is fit the requirements set out for the project, and the sub-components of the project were then designed and implemented to fit this top-level workflow. This order of product design ensures that all requirements are fulfilled and that the overall vision for the product is kept intact throughout the implementation of each component of the product.

To fulfill the criteria and constraints fully, the workflow of the application was designed to include the steps outlined in figure 1 as well as separate steps for setup and cleanup.

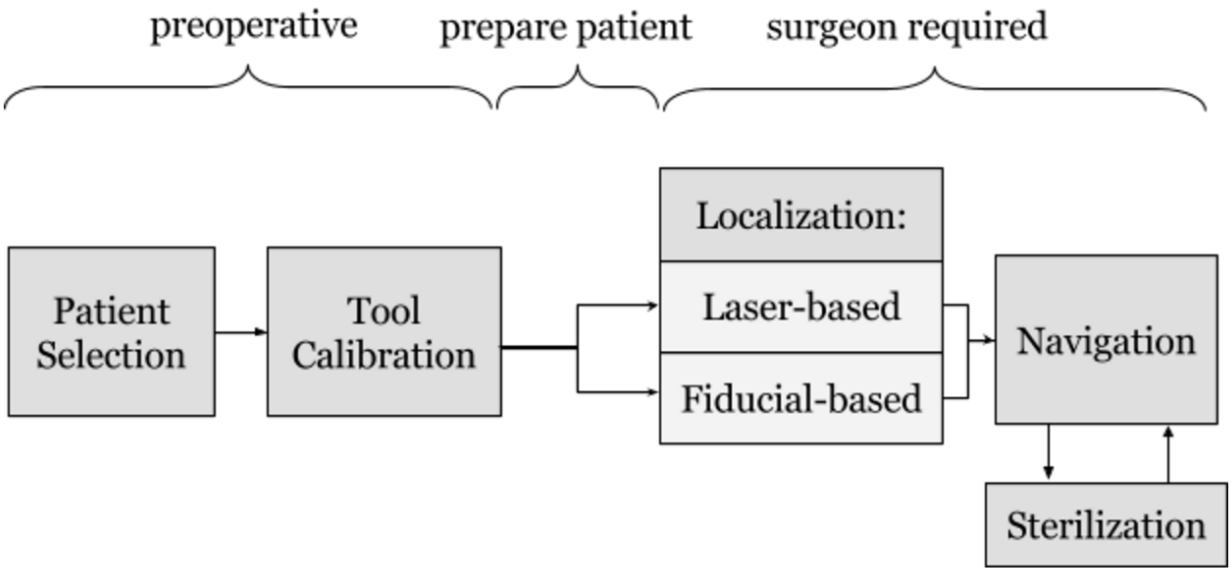

Figure 1: Top Level Workflow Design

Many of the hardware components from the Intellijoint HIP application could be ported over to this model, however certain significant changes had to be made to achieve the goals of the project. Specifically, the tool calibration step and the sterilization step all required new hardware.

In the interest of increasing ease of use for the surgeon, much of the workflow was designed to be able to be done by the nurses or sales representatives preoperatively. The sections that can be done by non-surgeons are patient selection and tool calibration. A tool calibration jig was designed to facilitate this process. These steps were placed at the beginning of the workflow so that if they are completed before the surgery, the surgeon could simply enter the room and do as little work as possible. A natural break was put after this point in the workflow, wherein the surgeon and nurses could prepare the patient for surgery before performing the registration. Due to software requirements, a static reference point which was visible to the camera had to be designed. Next, the workflow was designed to move directly into navigation so that the surgeon could use the system at it's full functionality to plan their surgery non-sterilely. The navigation step was designed to allow the surgeon to sterilize their operating field at any time without disrupting the flow of their surgery. To allow for this versatility, a new hardware system had to be designed.

Many of the specifics sub components of the system then had to be implemented, however since the high-level design was available for reference and the criteria and constraints were well defined, each individual component could be implemented with the goals of the project as a whole in mind.

4 Implementation

Implementation level was then designed to fit top level design. The features which required the most engineering consideration regarding the design of additional hardware components were the system's tool calibration step, and sterilization of the camera system.

From a hardware perspective, the system consists of two main sections: a workstation and an equipment tray. The workstation is a rolling cart that holds the laptop and also carries all the non-sterilized components such as the camera system and non sterile tools. The equipment tray is put through an autoclave to sterilize it and all of the equipment it carries before the surgery. All system components must be brought into the operating room on one of these two parts. Several new hardware components had to be designed and built so that the system could fulfill the requirements set out by the initial design. Firstly, a tool calibration jig had to be designed to make the calibration process easier, more accurate, and doable both preoperatively and intraoperatively.

4.1 Calibration Jig

The tool calibration step is essential because it informs the software system of the dimensions of the surgeon's tool. This is accomplished by placing the tip of the tool on a static point and rotating the tool around that point. The system captures the tool's location at various times during this articulation and can use the captured data to solve for the tool's dimensions. Through user feedback, it was determined that this was one of the most cumbersome steps of the procedure. In addition to often triggering software errors, the procedure was awkward and difficult for nurses and sales representatives alike. Furthermore, after doing a significant amount of testing and analysis it was determined that the process was not sufficiently accurate for our applications when done of a flat surface. For this reason, it was concluded that something also must be done to make the process easier and more accurate.

In summary, the initial design problem for this component is to redesign the calibration process so that it is easier, more accurate, and able to be done at any point in the workflow.

A few solution ideas were brought up initially. The first was to rely on manufacturer's specifications for various tool dimensions. This solution was popular since it would remove the process of tool calibration entirely, however it had the risk of being very inaccurate if the manufacturers specs are wrong which can occur due to manufacturer error or tool damage. This solution was also not very versatile since it did not allow for the use of tools which were not saved in the application. The second promising solution that was introduced was to create an additional hardware component which would simplify the calibration process. This could consist of a small divot to place the tip of the tool in during calibration as well as a mount to keep the camera steady. This would be a significant design and implementation effort, however it could potentially improve the accuracy of the process and the ease of use due to a reduction in microscopic and macroscopic slipping.

Table 4: Calibration Difficulty Decision Matrix

Decision Matrix	Accuracy	Ease of Use	Ease of Implementation	Versatility	Total
Weighting	0.45	0.3	0.1	0.15	1.0
Calibration Jig	9	6	5	9	7.7
Manufacturer Spec Reliance	5	9	8	4	6.35

After consulting the results of the decisions matrix, it was decided to begin implementation on the calibration jig. To resolve issues with the solution's low ease of implementation, a quick prototype was developed which could be used to investigate the solution's potential.

The jig required a mount to hold the camera steady as well as a divot to place the tip of the tool in such that the tool remained somewhere in the camera's field of view. The system's camera clamp has a predefined magnetic mounting interface on it which standardizes the way it is attached to accessory devices. This made the design of the jig's camera mount relatively straightforward since it necessarily had to be designed to fit the interface. The design of the mount is shown in figure 2.

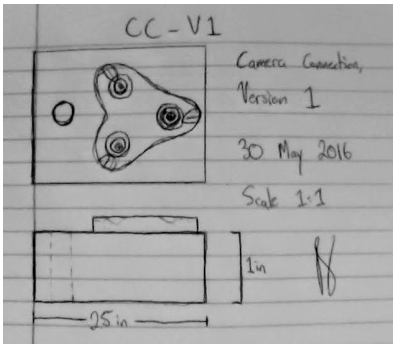

Figure 2: Calibration Jig Camera Mount

Various different sized divots were then tested with until an optimal size was found. Finally the divot and mount were placed on the same platform at various distances from each other. The process was tested and it was found that the closest distance that the divot could be placed to the camera without it losing sight of a large tool was about 20cm.

The prototype jig was then assembled with wood as seen in figure 3. The jig was placed on the system's workstation so that it could be used either preoperatively or postoperatively. This is because the sales representatives and nurses have access to the workstation at any time. It was decided that the easiest way to configure the jig would be to place it on the flat top surface of the workstation beside the laptop. This made the process of calibration very straightforward outside the operating room since it simply required the nurse to open the computer, place the camera on the magnetic mount, and articulate the tool. It also made the process of intraoperative calibration very simple since the user would need to simply place a section of sterile cloth over the divot and they would be able to calibrate via the same straightforward process.

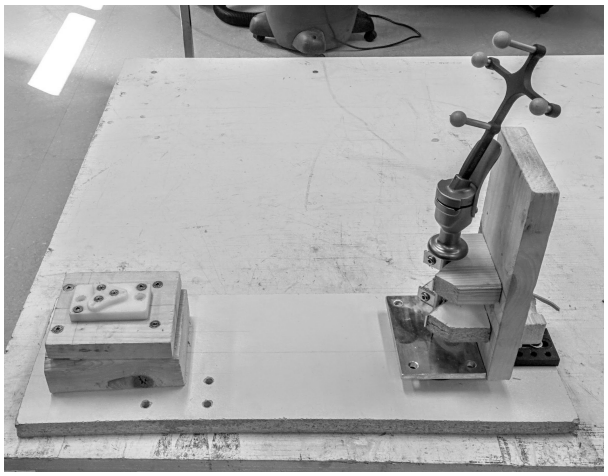

Figure 3: Calibration Jig Prototype

4.2 Sterilizable Camera Clamp

Another new component which needed to be designed and built was a mechanism to allow the camera system to be sterilized during the procedure. The accepted way to sterilize the camera is to cover it in a transparent sterile drape and then attach that drape to the front of the camera with a component called a shroud. In Intellijoint cases, this shroud is then clamped by the camera clamp which has a magnetic mount to allows it to be attached to various accessories. The sterile system is illustrated in figure 4.

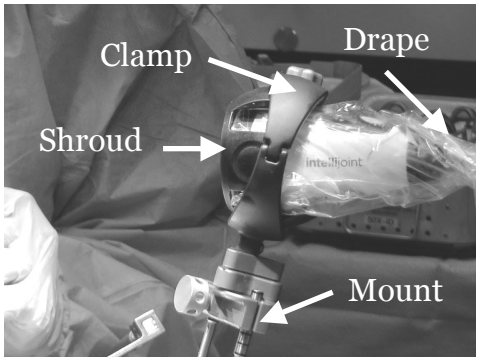

Figure 4: Sterile Camera System (Intellijoint, 2016)

This configuration is not designed to be useable in a non sterile setting and be sterilized mid use. Since sterilizability is a constraint of the project as a whole, the system had to be redesigned. The main constrain of this component was to create a sterilizable camera

system that uses the current camera, while the criteria were to minimize the implementation effort while maximizing ease of use for the nurses. A few solutions to this problem were proposed. The first idea was to remove the drape from the inside of the clamp and redesign a new drape which could encapsulate the whole camera system. This way the system could be set up in the same way it is in the Intellijoint HIP product and then draped when needed. This method's downsides are that a new drape would have to be designed that is much larger than the current one, and the mechanism to hold the new drape to the outside of the camera clamp would be very large and difficult to design. The second idea was to redesign a clamp that was small enough to fit inside the current drape. This clamp would have to hold the camera from the back so that it would not get in the way of the shroud which would be reused to attach the drape to the camera system. This solution is illustrated in figure 5.

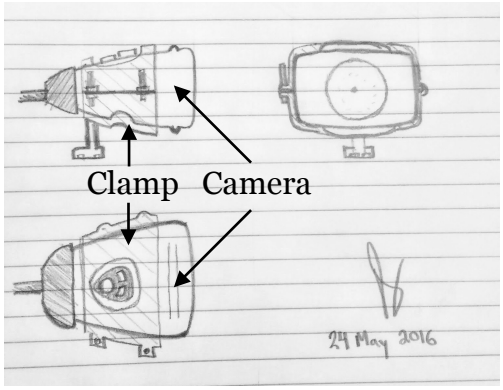

Figure 5: Revised Camera Clamp Design

The final solution was to have two camera shrouds and two camera clamps, and place one of the sets in the sterile tray while placing the other with the non sterile tools. The procedure would then be to use the non sterile equipment with no camera drape before the sterilization, and then remove the shroud and clamp during sterilization, place the drape on the camera, and clamp it with the sterile shroud and clamp. The main issue with this solution is that the arm that the camera is mounted to would still be non sterile. Therefore a drape for the mounting arm would have to be designed. One of the designs for this drape is illustrated in figure 6.

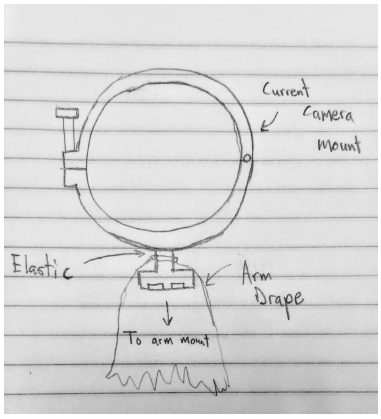

Figure 6: Elastic Mounting Arm Drape

The potential solutions were then compared using a standard decision matrix to find which solution most optimally fit the criteria for this problem. All three sterilization designs were compared based on ease of use and ease of development in table 5.

Table 5: Sterilization Decision Matrix

Design	Ease of Use	Ease of Development	Total
Weighting	0.75	0.25	1.0
Large Drape Design	7	4	6.25
Camera Clamp Design	9	7	8.5
Two Clamp Design	3	8	4.25

Since the camera clamp design so clearly fit the criteria best, implementation on it was started immediately.

The only task was to design a clamp that held the camera from the back, did not interfere with the drape clamp, and could fit inside the drape itself. Several designs were done in SolidWorks which fit these constrains. One successful design which would hold the camera well was created which involved using four screws to supply the clamping mechanism (figure 7).

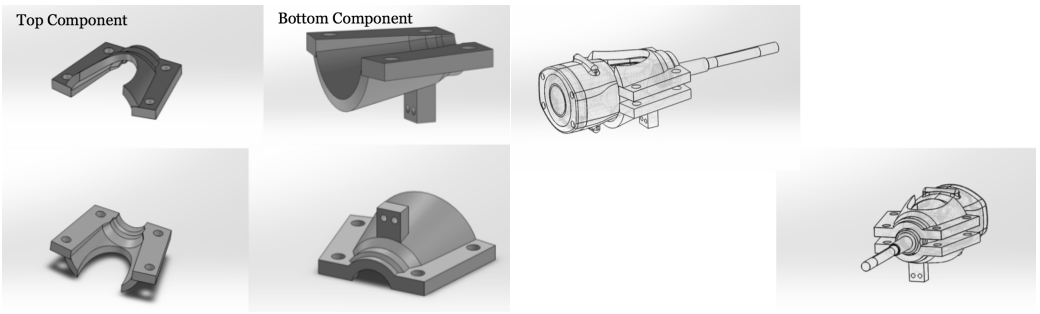

Figure 7: Four-Screw Clamp Design

Another design was eventually created which was slightly more complicated but fulfilled the criteria of ease of use much more effectively (figure 8). This second design employed a hinge and only one screw to supply the clamping mechanism and was found to hold the camera in place sufficiently well.

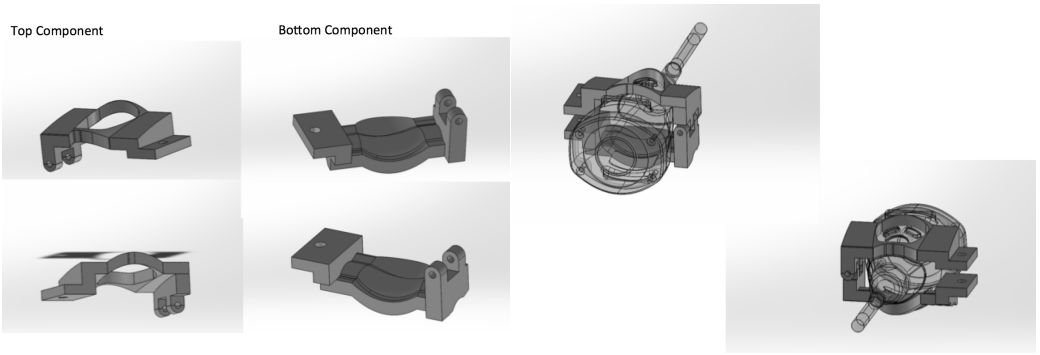

Figure 8: Screw/Hinge Clamp Design

Since this hinged joint so obviously fit the ease of use criteria better and was only slightly harder to implement, it was selected to be built. It was recognized that a easier to use “snap-on” clamp could be designed, however it was determined that the screw/ hinge was sufficiently easy to use and that implementing a snap-on clamp that fit inside the drape would be too difficult.

5 Results

Various methods were used to evaluate the success of the designs ranging from quantitative tests which measured the statistical accuracy of the solution to user stories which qualitatively measured how individuals reacted to designs.

5.1 Calibration Jig

After implementation of the calibration jig prototype was done, the accuracy was tested using various custom-build python scripts and analyses through simple statistical methods. Twenty-five test cases were executed and saved without the jig and twenty-five others were done with its use. The case data was then collected and visualized using various plotting programs. The accuracy was then calculated by measuring the average deviation of the measured value from the accepted value. This analysis revealed that the calibration system greatly improved the accuracy of the system. Figure 9 illustrates the measured dimensions of the tool in all three axes across 25 test cases while plotting a dashed grey line at the accepted value. Although the actual dimensions of the tools are concealed due to confidentiality of the system's actual accuracy, it is clear that the dimensions are much closed to the accepted value in the cases wherein the jig was used. According to the analysis, accuracy was increased by 91.7%.

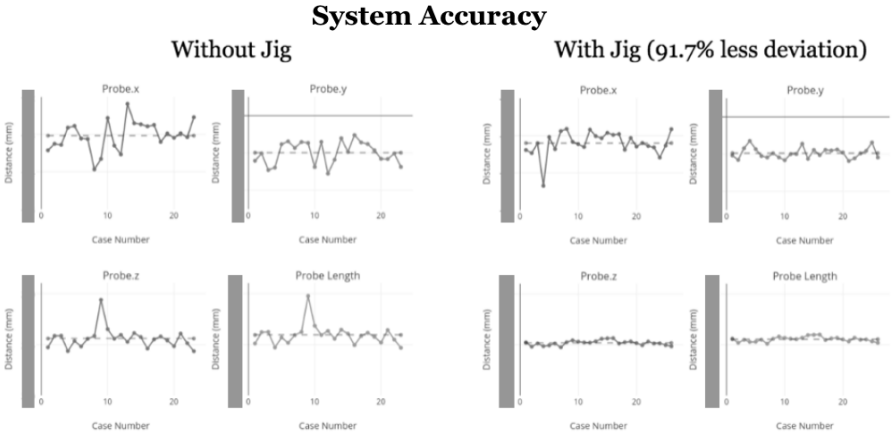

Figure 9: Calibration System Accuracy Plot

The system was also found to be highly more useable after the introduction of the jig. Not only does the increased accuracy nearly half the number of times users are forced to redo the step, but during test cases the calibration process was found to be much less awkward and take much less time when the jig is in use. No quantitative measure of the system's usability was taken, however the feedback from users was strictly positive. Due to the success of the initial prototype, a more sophisticated metal calibration jig was implemented and placed on the workstation for the final product.

5.2 Sterilizable Camera Clamp

After the design was accepted, the camera clamp was 3D printed and assembled in house. The clamp is shown in figure 10 holding the Intellijoint camera.

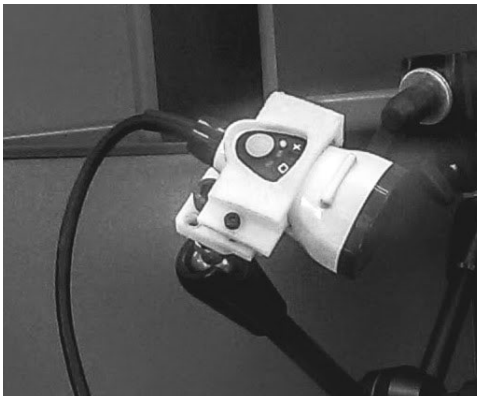

Figure 10: Sterilizable Camera Clamp In Use

Initial testing revealed that the system met all of the constraints it set out to accomplish. The criteria of ease of use was then tested more rigorously. The clamp was given to members of the company in various technical and non-technical roles. Their attempts to use the system were observed and informally timed. It was found that all users were able to understand the system and assemble it with ease. Some users had a bit of difficulty holding the bolt in place while closing the clamp but when instructed on how to hold it they all were able to open and shut the clamp very quickly and easily. It was determined

that a useful feature would be to physically attach the bolt to the clamp so that the user needs not hold it in place while screwing the clamp closed.

6 Conclusion

Throughout the term, all hardware components required for the Intellijoint surgical navigation application were successfully completed.

It was concluded that to solve the issues of calibration accuracy and calibration difficulty, the best solution was to create a calibration jig to execute the calibration on. The jig was designed to consist of a camera mount and a tool divot, and was placed on the surface of the workstation so that it could be used pre- or intraoperatively. The jig was then prototyped out of wood and tested. Test analysis revealed that the jig increased the performance accuracy of the calibration system by 91.7%.

It was further determined that to fulfil the constraint of intraoperative sterilizability, a custom camera clamp should be designed. The camera clamp was designed to fit inside the standard camera drape and holds the camera from the back so that it does not interfere with the current shroud mechanism which holds the drape to the camera system. A screw and hinge clamping mechanism was selected for the clamp design and the entire component was 3D printed and assembled. User testing revealed that it was successful in fulfilling the constraint of being easy to use.

7 Recommendations

From a design perspective, the most important recommendation taken from this project is that one should always make a physical list of design requirements of the top-level of the system and then use these requirements to outline the requirements of any sub-components created for the system. This method proved extremely useful in the development of the surgical navigation application. This is because having these lists available for quick reference allowed the development team to implement all features of the project without breaking any of the system's top-level requirements. This is a very common problem when developing complex systems that was easily fixed by the use of this method.

Finally, from an implementation perspective, it is highly recommended to find a way to quantitatively measure a hardware component's usability. Having quantitative measurements of success are essential to effective analysis of any system. This measurement could simply mean designing a test in which a new user is introduced to the system, is timed in using it, and fills out a questionnaire after. Such a test would be highly effective in determining if the system's constraints were met and how well its criteria were met.

8 References

Intellijoint Surgical Inc. (2016). Intellijoint HIP OR 4. Retrieved from https://www.intellijointsurgical.com/solution/. [online]. Accessed Sept 7 2016

Orthoworld. (2014) *The Orthopaedic Industry Annual Report*. Sample retrieved from https://www.orthoworld.com/docs/pdf/oiar/IndustryAnnualReport_2014_Sample.pdf. [online]. Accessed Sept 7 2016