Team 22: TKR Robotics

Robot Assisted Total Knee Replacement

D. Auld, C. Páyer, J. Van Dyke, B. Waanders
Engineering 339 & 340
Senior Design Project Calvin College
8 May 2017

Executive Summary

Total knee replacement (TKR) is the 14th most common surgery in the United States[1]. The introduction of automation elements into surgery like robotic assistance will increase the life of artificial knees by reducing misalignment of the implant due to imperfect shaping of the bone. To pave the way for the future further automation of TKR, Team 22 will produce a fixturing system which will hold the knee in place while a robotic six axis arm precisely machines the joint. This document details the proposed product, design principles, and methods used by the senior design team to produce a proof of concept prototype. Challenges inherent to both the prototyping process and the team structure are discussed and solutions are proposed. To demonstrate feasibility of the project, a planned schedule for the remaining semester is submitted which addresses possibly disruptive issues and allows some flexibility to address the issues if they arise.

Table of Contents

Index of Figures

Index of Tables

1 Introduction

1.1 Description of the Project

Total knee replacement is a common surgery to which several products have already introduced autonomation. This team would like to help improve the surgery by smoothing the transition into true automation. To advance automation in total knee replacement operations, this team attempted to design and produce a fixturing system which will hold a patient's leg still within tolerance during the operation. To validate the design, the team also constructed an automation test station using the loaned Fanuc and analogous surgical tooling.

1.2 Context

The average patient receiving a knee replacement implant is a 70-year-old woman with advanced arthritis characterized by a growth of bone spurs causing painful friction in her joints, but 4 million adults in the U.S. currently live with a total knee replacement which is 4.2% of population older than 50, prevalence is higher among females (4.8%) than among males (3.4%) and increased with age. The lifetime risk of primary total knee replacement from the age of twenty-five years was 7.0% for males and 9.5% for females[1]. The pain of arthritis is often severe. Arthritis describes any inflammation of the joints, this then causes pain, swelling, reduced range of motion, and stiffness, and is ultimately a chronic and degenerative disease. In patients with arthritis, vulnerable cartilage is slowly damaged by use and once cartilage is damaged enough the joint can begin to grind bone to bone. What begins as simple inflammation often progresses over the years. Prescribed medication strength escalate with the pain up to and including the prescription of opiates. Even then the pain can still be crippling when moving or sitting. Replacing the damaged bone is the best long term solution.

Current Technologies

In order to understand the ways the implant can fail, insight into the surgical process is required. While each hospital and surgeon has their own slight variations to the process described below, this will serve as a basis for understanding the full context of the issue. Currently, the surgeon begins by making a medial incision through the skin on the joint to access the knee. A second cut bisects the layers of muscle and fat, which are then rotated away from the knee along with the patella in order to expose the bone. Then the bone must be cut to fit the prosthetic, which in most cases is five cuts total must be made to the Femur; one Anterior (front), one Posterior (back), one Distal (bottom) and and two chamfer cuts one anterior and one posterior,and one leveling cut is made to the tibia, and some patella resurfacing if necessary.

In the traditional (manual) operation these six cuts are made with the use of careful measurements and experienced approximations, several templates are used to assure that the cuts are at the correct angles relative to each other. Each template is temporarily attached to the bone itself; clamped, screwed on, or pounded in depending on the tool path which it dictates. A similar process is enacted on the end of the tibia. Once the planes are carved, trial implants are placed and hammered in to check the fit of the planes. If need be further carving can be performed after the trial fit. Often a layer of thick bone cement is spread on the ends of the joint and the true implants are finally tapped into place. However, many implants are designed to be cementless and instead rely upon a porous metal structure which the bone grows directly into. The back of the patella is usually resurfaced with a plastic component to fit against new implants and then re-attached before the incision is sewn shut.[2]

Since 2002 the computer navigation option has been a widely available (though not necessarily the most widely implemented/accepted in US) technology for TKR a recent study showed that the“computer navigation for total knee arthroplasty has improved alignment compared with that resulting from non-navigated total knee arthroplasty” which leads to “reduced the overall rate of revision and the rate revision for loosening/lysis following total knee arthroplasty” especially in patients less than 65 there was a 1.5% reduction in need for revision in the first nine years following the operation (from 7.8% without to 6.3% with failure rate) [3] The top of the line systems would be the collaborative robots, Omnibotics for total knee replacements and Mako for partial. While both of these systems are advanced, especially when it comes to the software behind them, they are expensive and the operations are still performed entirely manually by surgeons with only slight robot assistance/intervention (encouraging/enabling surgeon to stick to presurgical plan).

Failure Modes

There are several ways in which the implants can fail. The most common cause of failure for the average knee implant (as described earlier) is a worn clearance fit due to aseptic loosening. As described earlier, aseptic loosening can be caused by improper fixturing of an implant, slight movements of the implant relative to the bone, and osteocytosis caused by particles knocked loose from the implant by the friction between the surfaces. These three are deeply inter-related. The next most likely cause of failure is a wearing through of the layer of plastic mock-cartilage between the implants. This is more easily corrected than either of the implants being damaged, but still requires a revision surgery. As with any other invasive surgery the act of opening the body risks infection, which can be fought with antibiotics or further surgery to remove and replace infected tissue. 1 to 3 percent of all surgical incisions will become infected, even with the present sanitation standards in place.[4] Periprosthetic fractures refer to any broken bone (femur or tibia) near prosthetic, looking from a mechanics, TKR replaces damaged bone with steel and drills several holes for cutting guides or positioning systems(computer navigation or robot) and these holes (before healing) and the bone to prosthetic interfaces (before and after healing) are stress risers for any abuse like falling. Instability is usually due to improper alignment between prosthetic and ligaments or ligament damage (surgical or arthritic), if it can not treated through nonsurgical means such as bracing and physical therapy, revision surgery may be needed.

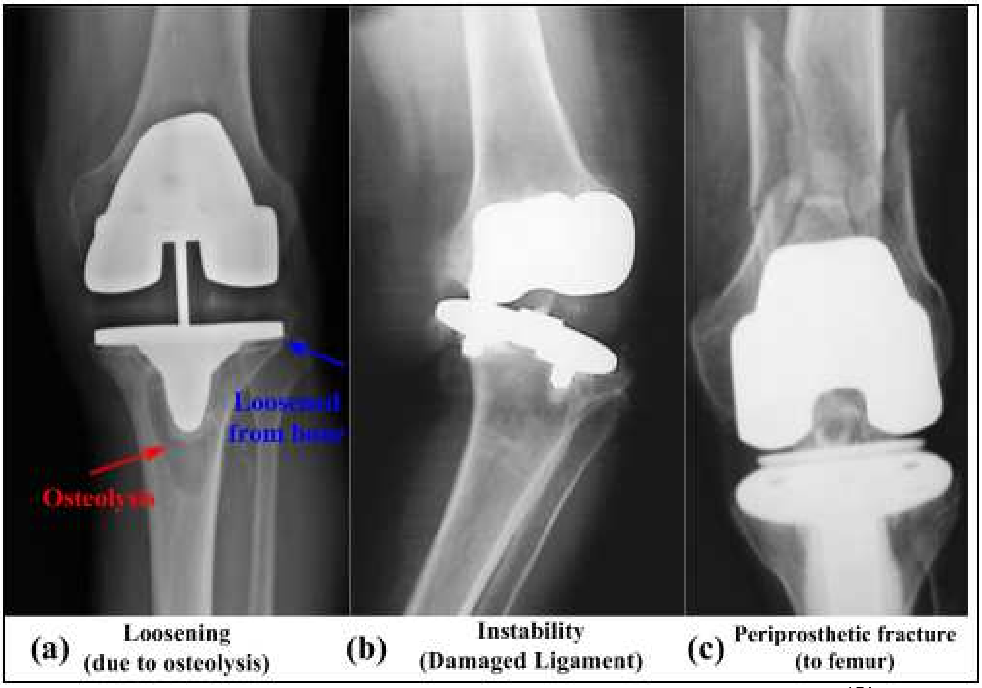

Figure 1. Common Total Knee Replacement Failure Modes[5]

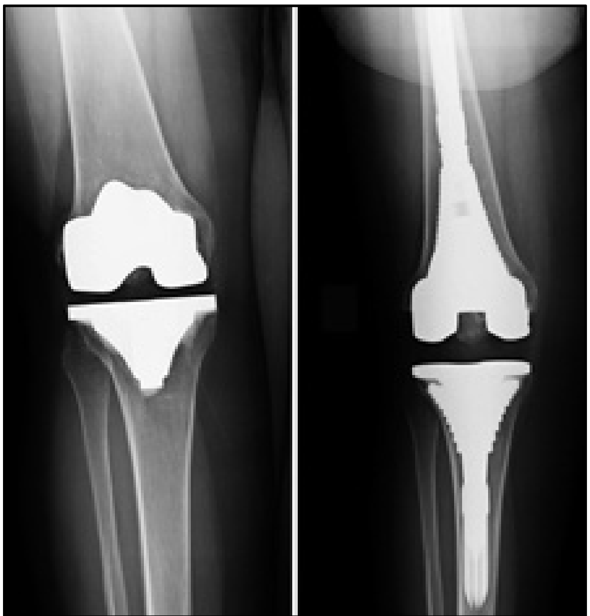

Figure 2. Normal and Revised Knee Implants[5]

Knee replacement revision surgery is not uncommon, but the need for revision can be avoided with accurate initial surgery and careful aftercare of the joint. When a common primary joint implant fails in any of the ways mentioned above, some surgery becomes necessary. In cases of simple implant wear, often the insert can be replaced with minimal fuss, thought careful observation is required as to the possible cause of implant insert wear for risk of abnormal structuring of the implant. However, if the prosthetic becomes damaged or loose it disfigures the ends of the bone in such a way that easy replacement of the failed piece or pieces is impossible. Instead, a much more complex operation takes place, boring holes deep inside the femur and tibia to insert much larger revision implants. They serve the same purpose as the original end-cap model implants, relieving pain and improving function of a damaged knee, but the surgery requires extensive planning and specialized tools and implants.[5] While the leading reasons for revision are preventable, there are still some causes of failure, like excessive wear, that cannot be prevented by improved surgical intervention.

1.3 Need

Supervised Autonomy

There are robotic systems in existence that assist orthopaedic surgeons in operation, but they do not function autonomously. However, they could technically have that capability. The Mako, for instance, collects enough data to make a comprehensive map of the bones and will stop the dremel from moving if and when the surgeon tries to guide that tool past the edges of the area that has been approved for removal. Another system, called the Smart Tissue Autonomous Robot (Or STAR for short) has been proven to outperform human surgeons in the act of stitching flesh together[6]. This proves that independent robotic surgeons are possible, if not trusted enough to be applied.

The team firmly believes that supervised autonomy is the next step in the evolution of modern surgery. This means that a surgeon observes the robot performing the surgery, ready to deactivate it and take its place in the surgery if something begins to go wrong. While advances have been made in this field as demonstrated in the previous sections, design and implementation of surgical automation is still inhibited by physical limitations. For instance, when a human surgeon is operating on the knee, the leg is held in place by a nurse. When they inevitably shift their hold, the knee shifts and so does the doctor to compensate. Robots still lack the ability to account for the unexpected efficiently. To eliminate the possibility of unexpected movement of the bone, some system must exist to accurately fixture the bones in place for the precise robots to operate upon. This is the essence of the project.

1.4 Project Goals

Initially, the plan was to construct a full surgical station, but the team narrowed scope from designing and building a model automated surgery station to designing, building, and testing a fixturing system and creating a simplified workstation for the fixture and the FANUC LR mate to show this procedure could soon be used in fully automated surgeries (risky but autonomous).This choice was made after consulting with multiple advisors and refining the core goals of the team. The original idea was born out of a desire to make a holistically positive difference in people's lives, as well as the desire to work with robotic surgical technology. In accordance with advice from Wesley Richards, the team's industrial consultant, a Fishbone diagram was created to define what success looks like. First, the team reduced “success” within the context of a senior design project to four attributes:

- Passion Centered: meaning that the subject of the senior design project represented the interests of the team members.
- Design Oriented: meaning that the project outcomes demonstrate the ability of the team to design a product which meets the specifications of a customer, real or modeled.
- Demonstrates Learning: meaning that the project will have demonstrated the teams accrued skills over the course of a calvin engineering education and the ability to adapt to new challenges.
- Achievable: meaning that the project should have meaningful and attainable goals and deadlines to keep the team on track and show honestly to others what the team is doing.

These attributes were coupled with the team's personal definition of success in a fixturing project to help in decision making. The team to conclude that designing fixturing was more achievable, equally relevant to personal passions, better focused on design, and a more obvious demonstration of analysis techniques learned at Calvin College.

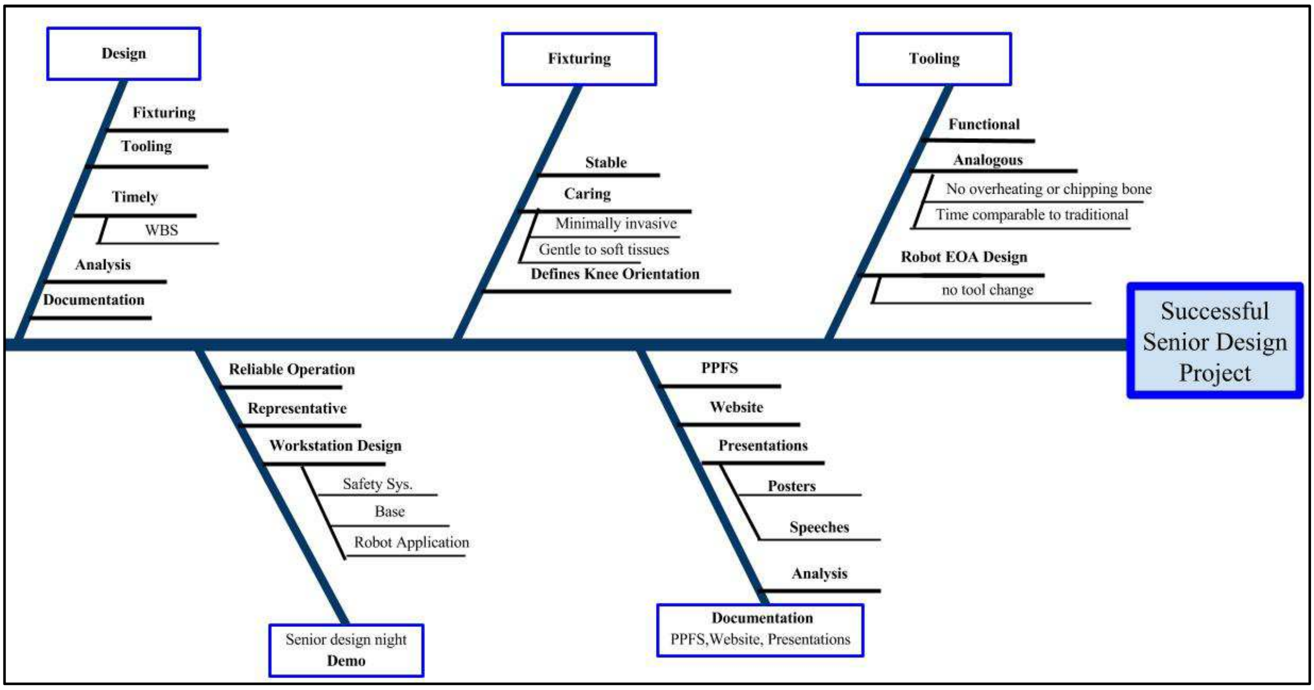

Figure 3. Fishbone Diagram

To advance surgical automation in total knee replacement operations with a feasible project, this team will design and produce fixturing which will hold a patient's leg still within tolerance during the operation. To validate the design, the team will also construct an automation test station using the donated Fanuc and analogous surgical tooling.

2 Project Management

This project demanded a multidisciplinary team to tackle all aspects of process, controls, tooling, and system design. Both people and tasks had to be organized so that tasks critical to later work were accomplished in a timely manner without over taxing any one individual. More material regarding team organization can be found in *Section 2.1 Team Organization*, and scheduling information is found in *Section 2.2 Schedule*. This project has been more complex and rigorous than any other previously attempted by the students and so this team has had to adapt their experience and learn as the project progressed. The evolution of project management in response to this learning is addressed in *Section 2.4 Method of Approach*.

2.1 The Team

Bethany is a senior mechanical engineering major with a math minor. She started working as a robot service/controls engineering intern at JR Automation in Holland last summer. JR Automation is sponsoring team 22 with a FANUC LR Mate 200id, due to her familiarity with the company and robot she will be the team's controls engineer as well as the team's connection to their sponsor(JR Automation) as well as to the orthopedic surgeons Nicholas Waanders and Dirk Bakker who will be providing the medical perspective, and she is responsible for maintaining the website.

Carlos Payer Vivas is an industrial engineer and an exchange student from the University of Oviedo in Spain, with experience in steel manufacturing and project management. He is at Calvin College studying to obtain his master's degree in electrical engineering speciality. His responsibilities include experiment design, quality management, and electrical design.

Joel is a senior mechanical engineering student with experience in public speaking and writing, who helped to polish each aspect of the project and explain it to the public at large while performing ongoing topical research in his role as Presentation Manager. He is also in charge of making and coordinating the team budget. Joel also directly handles or supervises communication with the various mentors and advisors who keep the team grounded and realistic.. He has spent the last few summers on the production line of the Herman Miller Main Site in Zeeland, Michigan.

Devin is a senior mechanical engineering student with experience in automation design and engineering research with the honors program at Calvin College. He hopes to graduate with honors and continue to graduate school to study mechatronics and engineering education. He was unanimously elected to be the team leader, responsible for task delegation defining and allocating tasks and responsibilities as needed as well and watching and reminding the team of upcoming deadlines. He is also lead on the mechanical design which means he manages brainstorming, drafting, alternative consideration, assembly, and testing regarding mechanical systems.

2.2 Team Organization

Members of Team 22 are responsible for specific areas of project and design management which are assigned based on experience, talent, and personal preference, shown in Table 1.

Table 1. Team Member Responsibilities

Name	Directly Responsible For...
Devin Auld	Schedule Management, Task Delegation, Mechanical Systems Design
Joel Van Dyke	Presentation Management, Budget Management, Safety Assurance, Communications
Carlos Páyer	Quality Management, Electrical Systems Design
Bethany Waanders	Robot & Workspace Management, Website Management, Robot Training

All team members are encouraged to delegate as necessary. The team member maintains responsibility for the completion of all assigned duties, but the tasks necessary to complete each duty are often executed by two or more team members at a time. In this way, the load of responsibility is always distributed evenly but particular tasks can always be given to those best suited to them.

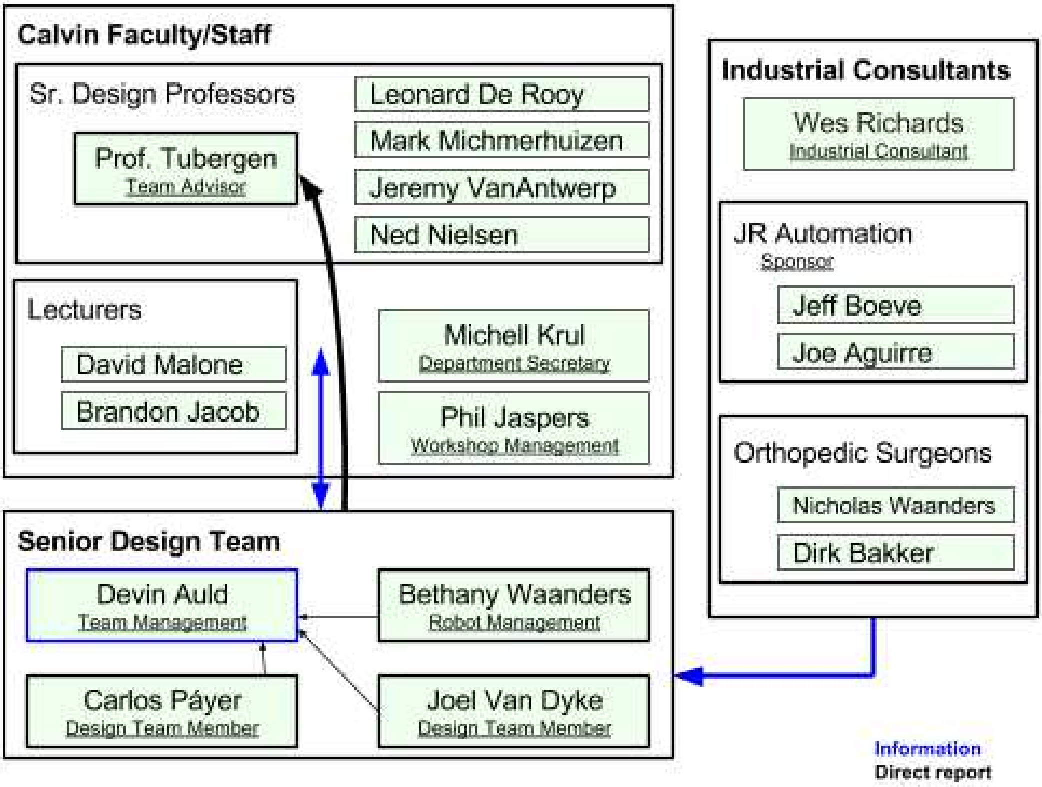

Figure 4. Organization Chart

Team 22 also depends on input and support from members of the engineering department, JR Automation, and other organizations as seen in Figure 1. In this Organization Chart, blue lines show the general flow of information (colors are shown in the key in the lower right of the figure). Communication between Industrial Consultants, Department Management, and the Senior Design Team is maintained and facilitated by the team manager, but available through every team member.

Team meetings are held every Monday and Friday for one hour at 3:30. In the second semester this was changed to one 90 minute meeting Thursday (often with the industrial advisor), with a 10 minutes standing meeting on Monday. Meetings consist of reading minutes, reviewing design alternatives, discussing group decisions, and assigning tasks. This team has found that regular meetings of less than 90 minutes are essential to coordination of work and the communication of ideas. Over the course of the semester team documents, including meeting minutes, have been stored in a google drive to facilitate communication and real time feedback. Completed documents are saved on the TKR Robotics website and the team 22 folder in the engineering shared drive.

2.3 Schedule

Tasks were broken down based on top down deliverables, beginning with the final products and ending with a large organized set of task objectives. In this way the team was able to see how scope affects necessary work, and manage goals accordingly. These incremental deliverables indicated the necessary tasks and the amount of time needed to complete each task. This process can be seen in the WBS chart, where final deliverables like *Project Proposal*, *Website*, and *Final System Design* are broken down from objects into tasks like *Define Process Layout* and *Take Team Photos*.

In November, with the help of advisors and consultants, the team realized that the workload associated with the original scope would be excessive. At this point, a new WBS was drafted and has been adhered to since. The latest Work Breakdown Schedule can be seen on the team website. The WBS has been reviewed updated as necessary to keep the tool useful and realistic. At the end of each month the WBS is reviewed for possible revision. Older versions are saved on the shared drive and the latest version is kept on the team website. In addition the team utilized an open issues deck to keep track of new or unforeseen tasks, noting the task, proposed solution, responsible person, and deadline on the card.

2.4 Budget

Several parts of the final project were donated or lent to the team free of charge. The FANUC, the cart it was mounted on, the sawbones, and a knee implant were all approved for team use by their respective owners.

Table 2. Team Budget

Date	Team member	Description	Cost	Remaining Balance
9/30/16	n/a	Beginning Balance		500.00
2/27/17	Bethany Waanders	Meijer Supplies	47.99	452.01
3/3/17	Bethany Waanders	Meijer Supplies for Re-testing	12.28	439.73
3/3/17	Devin Auld	Lowe's Supplies	5.06	434.67
3/10/17	Devin Auld	Amazon Dremel Bit Order	31.75	402.92
4/10/17	Bethany Waanders	Dremel +Insurance	114.91	288.01
4/18/17	Devin Auld	Payment for 3D scans	250.00	38.01

Once the general design for the fixturing was decided upon, it was realised that the budget would be spent primarily on the tooling for the system. $200 was set aside to purchase a motor that could be run off the compressed air feed controlled by the FANUC, as well as a spherical bit and a few backups in case the bit failed. However, the team's advisor Professor Renard Tubergen was able to lend the team a dremel for free. When the free dremel broke down, the funds were reallocated to purchase a new one for $114.91. The wood used for the prototype was purchased from Lowe's for $5.06. When it was decided that the leg needed to be modeled with ballistics gel, $50 were approved to be spent on equipment to make and form the gel around the bone. Of that, $47.99 was spent. A further $12.28 was used to buy more molding materials a week later, when alternative solutions were needed. It was arranged for a 3D scan to take place for free, but upon delivery the team was told that it would cost $250. Thankfully, there was enough of the original budget left to cover this, and the team finished out the year with $38.01 as outlined in the budget included above.

2.5 Method of Approach

Throughout the semester, the team has approached problems with an attitude of generosity, dedication, open communication, and honesty. Each stage of design is completed by one or two members, then submitted to the rest of the group for critique and approval. Research is presented in a similar fashion but only for information and reports critical to the work of all team members. All research and design must be supported by academic or expert sources, be free of plagiarism, and be reviewed by the whole team before implementation. In this way, the team promotes awareness and communication between sections of the project. Additionally, team building events are encouraged to promote holistic relationships between co-workers which improve performance and develop community.

3 Requirements

In this section, specifications that the product needs to meet in order to satisfy the customer's needs are discussed. The product is aimed at developers of surgical automation and the doctors, nurses, and patients who will be interacting with the product. The goal is to design a fixturing system to work alongside an automated system so requirements will be based on this application. The requirements were classified under: hardware, functionality, and safety. Throughout this section, “Expected Loads” refers to preliminary estimates of cutting force through analogous materials found in *Section 5. Design*. Further study is necessary to validate the expected loads and is accounted for in the WBS. In the second semester, all efforts were focused on improving rigidity and validating the fixation method, as the team decided to go with a more experimental fixation technique to avoid potential harm to the patient and reduce unknowable variables. This decision is detailed in the design section of the report.

3.1 Basic Function

The device will be comprised of a femur fixturing device and comply with the following requirements.

- Mobile: The system will be transferred from one surgery room to another by the medical staff. During surgery, once the cutting process is over, the rigid fixturing will be removed by the medical staff. It must be adjustable and removable by one person with at most a single hand tool, with each piece weighing less than 10 lb. The system will be Small enough in size to fit in a surgery gurney (0.5 m by 0.75 m)
- Rigid: The maximum deflection of the fixture itself due to the tooling forces in any direction must be less than a tenth of a millimeter, which corresponds with the FANUC's maximum point to point accuracy. This will establish the fixture error around 0.2 mm for expected loads. The system will minimize the relative movement between the bone and the clamp (0.3 mm maximum) under expected work loads. Any measurable (more than 0.01 mm) displacement between the device and the operating table will be eliminated.
- Easily sanitized: All fixture components not small enough to be autoclaved will be contained by a plastic sheet. Surface of exposed areas must be polished to avoid crevices in which bacteria may grow.
- The system will minimize potential injury to the patient.
- The system will be designed for an expected life of at least 12 years, to be measured by expected life of materials and similar products.

3.2 Features

- The device won't get in the way of the doctor or the assistants complicating the after-cut maneuvers, eventually, it will be partially removable, leaving just the ankle holder in place to continue the procedure similarly as the Mako procedure.
- The height and horizontal position of the clamps will be adjustable to be able to fit in different types of lengths and legs' shapes.
  - Bone diameter, three centimeters above the knee, ranging from 5 cm diameter to 8 cm diameter.
  - Leg length, femoral length, ranging from 40 cm to 55 cm.
  - Leg circumference, three centimeters above the knee, ranging from 25 cm to 55 cm.

3.3 Safety

- Lockout/tagout procedure will be developed before installation and use.
- The robot will either be off and locked out in off position or be supervised by a team member.
- The station base will be stable.
- The controller and teach pendant E-stops will be depressed when not actively in use.

4 Task Specifications and Schedule

Tasks have been scheduled in blocks using approximate work day estimations. The breakdown of tasks into daily subtasks seemed to introduce unnecessary error, so tasks are instead specified down to the weekly level. After a general estimate of the total process time was produced, total time required was multiplied by a safety factor of 1.25 to assure the team would be done before final presentations and reports would be due. Other considerations include generous estimates for shipping time, blocking out weekends and holidays as non-work days, and considering who will be assigned to each task to optimize concurrent tasks. The full WBS can be found on the team website or on the engineering shared drive. Areas of focus with regard to task assignment include, presentation preparations, designing and comparing alternatives for systems and subsystems, ordering components based on finalized designs, assembling and troubleshooting, potential gaps for re-design, and final prototype testing.

Total person work hours are reported starting October 8th to aid in work time estimations and are shown below. Average team work time per week is 24.5 hours, based on a daily average of 3.5 hours. This boils down to an average weekly load of about 6 hours per team member, which is in line with the original estimate. Time spent in meetings is reported but time spent in senior design class is not.

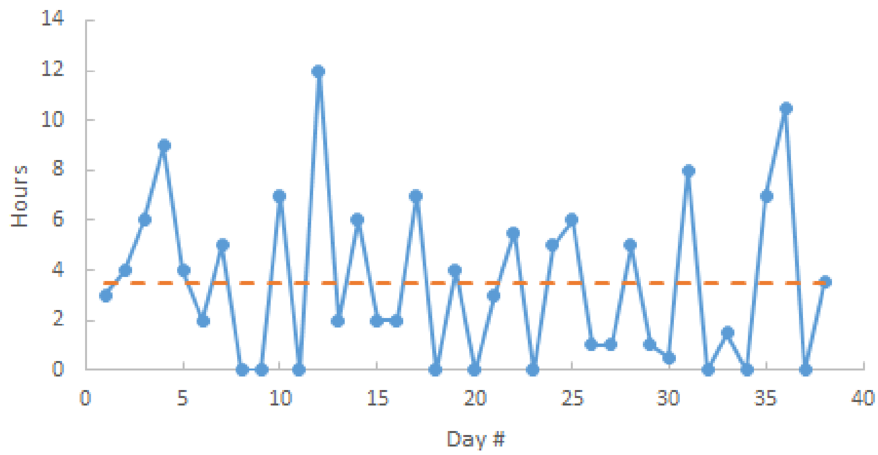

Figure 5. Team Work Hours and Average Team Hours per day in November

An open issues deck was also utilized to great effect in the second semester. 15 were created and all but 2 were closed by the end of the semester. These cards can be found in the design notebooks.

5 Design

5.1 System Architecture

While the primary focus is on designing fixturing, another important goal for the team is a senior design night demo incorporating the robot (FANUC LR mate 200id/7c) the sponsor JR Automation is generously lending us. In expected build order the project subsystems are: tooling, fixturing, and robot cell.

5.2 Final Design

The final fixturing design is complete, and the architecture of the cell is as follows.

- One FANUC LR Mate 200 iD/7C
- End of Arm Interface Attachment
- Dremel 4000 series
- Interchangeable Bit
- The TKR Fixturing Structure
- Mobile Cart
- Press Brakes

Figure 6. Final Design Architecture

5.3 Design Criteria

Several criteria were used to tank potential designs and eventually decide on which design to pursue. These are shown below in order with a short description.

1. **Safety**; The team cannot and will not claim that the fixturing is perfect, or able to eliminate the advantage of keeping secondary safety systems such as the vision systems employed by both Omnibotics and MAKO, but it is their hope to not be dependent upon them in autonomous surgery because the robot interacts with the human body in a very vulnerable state. In order to gain and retain the trust of the doctors, nurses, and patients directly or indirectly in contact with it, the robot must perform without endangering their lives more than necessary, and come equipped with redundant failsafe measures.
2. **Applicability**; the system should be a reliable tool without being arduous to obtain or cumbersome to apply or adjust. This is also relevant when discussing size and transportability, though that ranked lower overall.
3. **Ease of Sanitation**; The fixturing will be a combination of clean sheet cover for the central structures and disposable pin/screws. This is necessary and ethical for any surgery.
4. **Adaptation**; anything dealing with something as varied as the damage to an organic material needs to be able to take some deviations into account. This is essential to the robot's ability to function as a better surgery alternative.
5. **Transportability**; the system retain the multipurpose function of an operating room containing the system.
6. **Ease of Use;** the plan includes having a technician and a surgeon in the operating room to use the robot so while this is still an important part of the design it is less important than other aspects.
7. **Cost**; normally purchased medical equipment is already expensive,

5.4 Design Alternatives

Originally, the Team pursued the idea of fixturing the bone by pinning it to a rigid external framework. Three general shapes were considered and rough mock ups of each idea are pictured below, the first of which is the crane. The crane would be a support mounted to the table, floor, or automation station which reaches over the knee and holds it in place. The femur clamp would be held by the "boom" of the crane. This configuration allows for quick and secure removal of the rigid fixturing by spinning the "boom" around the z-axis. One of the problems with this configuration is its flexibility. In order to have a rigid system, both, the main pillar and the boom have to be thicker and therefore heavier than in the alternatives.

Figure 7. Crane model sketch

Secondly, a tower model design was taken into consideration. In this case, a support mounted on the table would reach directly up to the knee and hold it in place. A direct benefit of this model would have been the reduction of material needed. Also, the distances between elements would be shorter and therefore the moments would have displaced the structure less. However, there was little room beneath the crook of the leg (around $0.25m^2$) to install the system and this would also be a problem when trying to remove the rigid fixturing.

Figure 8. Tower Mock Up

Finally, there was the arc model. A square based support that reaches up and supports the knee from the directions needed. This is the most stable option as the shape of the arc reduces flexibility inherently. It would also reduce the material necessities and the weight of the device. The main problem with this option is that it would be harder to manufacture. It would also be hard to find a mechanism that allows it to be adjustable for different leg shapes and lengths.

Figure 9. Arc Mock Up

With further research into current knee surgery, it was discovered that another way to immobilize the knee was with an operation that would allow a rod to be inserted into the medullary cavity of the femur. It was considered to be a less invasive option than the pins since it required only one hole to be made in the bone. This option would have also isolated an axis of the bone rather than a point, leaving only a rotational force to be negated by the hip.

Finally, Dirk Bakker recommended a strapping solution that would expand upon the existing tourniquet system used in knee replacement surgery to keep the patient from bleeding out. This was the least invasive of the three, though the hardest to model, as it required an analog to human flesh for proper testing, since the straps acted on the flesh rather than the bone directly.

5.5 Design decisions

All of these alternatives refer to the rigid fixturing and for all of them, the ankle fixturing will be a boot clamp model which will hold the foot static. A stopper can be loosen to rotate the foot around a spherical joint and be tighten again as needed. A design matrix was used to discern the best solution of the options presented. At first, the pinning solution won out. However, it was brought to the Team’s attention that the stress risers caused by the pins combined with the nature of the vibrating tooling could cause the bone to fracture, ruining the surgery. In the same meeting, it was revealed that the intramedullary rod risked drawing fat emboli from the intramedullary cavity which could find its way into the bloodstream and from there into the lungs, causing a pulmonary embolism. With the factor of patient safety added to the matrix, it was clear that the winner was the strap design.

Table 3. The Team's Design Matrix

		Two Screw Design		Rod & Lock Design		Rod & Screw		Strap	
	Weight	opt	pes	opt	pes	opt	pes	opt	pes
Stabilty	10	9	4	10	6	9	4	8	6
Positioning difficulty	6	9	7	10	8	10	9	10	9
complexity--failure	6	10	9	8	5	9	7	10	9
complexity-- sanitation	4	10	10	10	10	10	10	10	9
cost to prototype	6	10	10	6	4	9	8	10	10
risk to patient	10	8	6	8	5	7	6	10	8
recovery time	5	9	7	10	8	9	8	10	10
current parrallels	2	9	6	7	6	9	6	8	6
accomidate patient variability	5	9	8	10	7	10	8	7	6
Weighted Average		**44.73**	**34.82**	**43.45**	**30.82**	**43.73**	**34.18**	**45.55**	**39.64**

When it came to carving the bone, there were two relevant tool types considered for the job of cutting down the femur. These were a traditional oscillating bone saw and a milling end effector. After observing the cuts made on a model bone made by the existing Mako robotic surgery assistant, it was decided that the milling end effector was the tool most capable of the accuracy demanded by the team's goals. Additionally, oscillating friction forces are minimized when using a milling bit compared to an oscillating saw which reduces the vibration forces the fixturing had to compensate for. An electric dremel was selected to be used rather than an air powered motor due to the availability of a dremel for the team to use, free of charge.

The final aspect of the design under consideration was the test subject, the bone or bone-like substance the dremel would be operating upon. First, wooden approximations were considered. The difference in density would affect the forces created by the milling operation. While this difference could be partially corrected for in speed, depth of cut, and bit selection, the porosity and hardness of bone would not be fully replicated. Bethany's contacts were kind enough to give the team a few model Sawbones; foam replicas which approximated bone density and structure with a rigid foam. Since the sawbones more closely replicate the porosity and density shift between outer shell and inner bone, the team decided that performing additional tests with sawbones would be worth the additional cost of $15.50[7] . Once it was decided that the fixturing would be as non-invasive as possible, it was realized that a human flesh analogue was needed around the bone analogue to model how the system would respond to an actual human patient. Ballistics gelatin was molded into the right shape with a plastic pitcher.

6 Implementation

After designing the major components, the system was constructed. As expected, not everything went as planned. The following describes each piece of the final prototype, how it was constructed, and any changes from the original design that were made.

6.1 Fixture

The fixture base was built, as discussed in the previous section. The initial design was composed of two boards connected by a hinge, therefore allowing for adjustable height. Some slots where to be carved in the top board to allow for the straps.

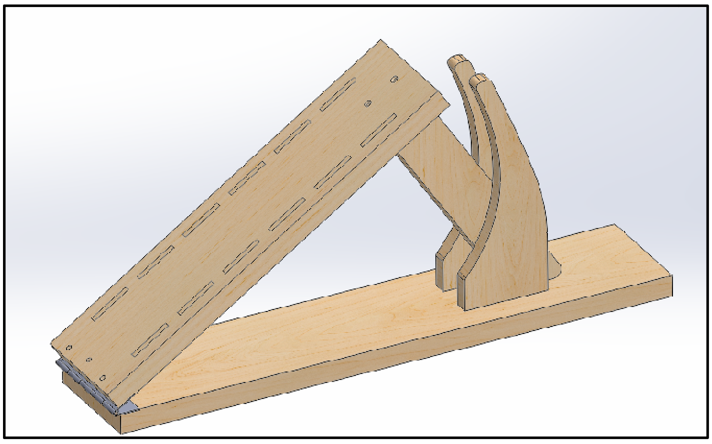

Figure 10. CAD model and first model leg fixture

Early testing of this prototype proved that the external fixation of the straps around flesh provided insufficient resistance to lateral forces expected, this led to a design iteration in which rigid but adjustable lateral clamps were added.

Lateral Clamps

As a team, several possibilities were brainstormed for preventing lateral motion to occur. It was decided that the solution should be built off of the original adjustable angle base, obtaining an improved version. It would be built in as rigid supports on either of the device that would prevent the leg from moving laterally. This needed to be snug and yet remain accommodating to a range of leg sizes thus needed adjustability that would not compromise upon the stability/rigidity. Taking inspiration from handscrew clamps, the braces in Figure 11 were added to the structure.

Figure 11. Final model leg fixture

By adjusting the screw/nut that holds both side-clamps together the brace could accommodate the pressure for different sizes of legs. Also, a shim was added later on to improve the contact surface between the flat sides and the conical shape of the thigh.

6.2 Tooling

The rotary tool itself was a Dremel brand die grinder, lent to the team by Professor Tubergen. A tool adapter was designed to hold the Dremel steady relative to the robot via a keyed nut around the tool's grip adapter, and a hole into which the nut fit with a retention screw to hold the tool in place. In this way, it could be assured that the tool itself was in a standard position by keeping the front surface of tool flush with the tool adapter. At one point the borrowed dremel failed internally and rather than repair it the team opted to replace it with a new dremel purchased from Lowes. This new dremel, a Dremel 4000, had a simpler speed change interface and wider speed range and came with a selection of parts and bits. Notably, the 565 Multipurpose Cutting Kit including a spare of the tool grip adapter, already incorporated into the bracket design and the 561 multipurpose cutting bit mentioned below.

The original milling bit was chosen to resemble the Mako robotic system with a spherical head, which is advantageous in that it would leave a standard cut profile even used at different tool angles. However, while working on a tool path for this type of bit (discussed below in Section 6.6), the team realised its inefficiency. So in a discussion with Dr. Nicholas Waanders and Hannah Halcolm, it was suggested that an endmill would fit better with the shape of the cuts and would still generate acceptable forces, wisely cutting to the final plane directly and leading to drastically shorter surgery time without increasing the vibrations to a significant degree. A standard FANUC end of arm bracket was modified to hold the dremel in such a way that it could be operated at any angle.

6.3 Workstation

To mount the robot, a workstation had to be constructed. Early in the process, this workstation was designed for robust use in a demo environment, but due to cost this was scaled back to simply producing a station on which tests could be performed. The cart was constructed using a frame found in storage in the engineering building, scrap and stock from the engineering building machine shop, and breaks which were provided by Wesley Richards. The wheels on the original cart were discarded, and replaced with blocks which offset the new wheels from the floor, so that the breaks could be effectively engaged and disengaged. The final wheel construction can be seen in Figure 12.

Figure 12 . New wheels on the cart

6.4 Interface

In order for the robot to accurately execute a programmed path in space, it needed to know where the bone was. Ordinarily, the work piece would be registered into a predetermined location, or the robot would identify it with a vision system. In this case, neither of these options would be accurate enough. The first method would fail because each leg could potentially have a different size and shape and so cannot be locked into a standard fixture. The second method could work if coupled with another, more accurate system, but for the project's scope, vision alone would not accurately locate a shape with multiple soft edges on a rotational axis. So a new system was devised. The proposed system would use a scan of the leg (generated by an MRI in a final procedure), to produce a molded end piece which would be registered to the leg during the surgery, and utilized to establish a user plane from which the robot could operate.

The first iteration of this piece utilized a free model of a femur found online. While it was a useful proof of procedure, it did not yield a piece that would fit any of the sawbones owned by the team. Even with careful scaling, the end of the femur in the digital model and the end of the femur on the physical sawbones would not register reliably. At this point a simplified version which utilized measurements from the bone to produce a tightly fitting box was attempted. While more useful than the last rendition, the box required far too much guess work and iteration to produce a reliable position. Finally, a 3-D scan of the bone was procured at a price within budget and the final piece shown below was manufactured.

Figure 13. 3D printed mold fitting the sawbone

This piece worked for the bone scanned, but not for slightly varied bones given and purchased for the team's use. In order to accommodate these other shapes, several molded locating pieces were also made. The final rendition used a silicon and cornstarch mix to form to the bone, and flat square of clear polymer to provide the plane of reference, as shown in Figure 14.

Figure 14. Final locating method

6.5 Soft Tissue Model

When it became obvious that the fixturing was going to be inflicted on the leg exclusively from the outside of the flesh, a soft tissue model needed to be developed. Ballistics gel was chosen for this purpose as it is recognized to be behave similar to the human muscle and have the correct density (around 980 kilograms per meter cubed). It was also easy to cast in the right shape. Once a structure was established in order to hold the bone in the correct orientation as the gel solidified, it was simple to generate a standardized leg model for testing purposes. An artificial "skin" of elastic bandages was used to further encase the gel and, therefore, prevent the outer surface of the "leg" from splitting when been put under pressure by the fixturing. When tested, it was proven to respond in a similar way than human flesh, although it was less stiff under loads.

Figure 15. Testing station including final fixture, tool and leg model

6.6 Programming

Goal

In order to obtain the final shape of the knee that would fit the implant, the robot would have to drive the tool to perform the desired cuts. The original idea was to use a 3D model of one of the sawbones to calculate the positions of the cut planes relative to the reference at the end of the bone.

Procedure

The procedure involved training the the robot from the interface tool 6.4 which ought to be a plane normal to the mechanical axis (our Z direction) of the bone and rotationally have a x direction line in line with the Epicondylar axis, this would be used to teach the user frame that the robot made all cuts relative to that plane, and it's offsets, the overall user frame offset from possible interface inaccuracy (X,Y,Z, W,P,R), the distal resection depth and angle offsets from the user frame, and the using position register offsets for the locations of planes of the five different cut planes relative to the original interface zero plane, the start and stop X positions. Then program was setup to set one/each in turn of the 5 planes as "current plane" and cut from "start X" to "stop X" and back to "start X" for a finishing pass all with "tool offset" and "plane offset" before moving to a safe distance to rotate tool into position for the new/next "current plane." Cutting the tool path was mostly practiced on foam to perform any necessary adjustments without wasting sawbones, and once repeatedly succeeding at that, practicing (and failing and learning) with some practice on half sawbones before finally successfully running on a sawbone held only in the fixture within the ballistics gel proving the proof of concept.

Challenges

The programing had many challenges some better foreseen than others. The team knew at the outset that the FANUC robots were designed primarily for pick and place and not the CNC applications. This is primarily derived from their internal positioning system which optimizes for repeatability of point to point accuracy, not the adaptability of old programs to new reference frames. Additionally, when selecting a non-invasive fixation method the team understood that the interface would need to be a high tolerance cut, and indirect (through soft tissue) clamping would lead to a partially uncontrollable deflection of the workpiece. Additionally if forces are too high on any one or all of the 6 axes, because each is controlled by servo motor containing potentiometers which tell the robot where the arm is, can accumulate error easily overtime contributing to error and in some cases causing the robot to crash into its environment or itself. The program was tested on sawbones which were sourced from a local Zimmer representative, however many of the bones collected were dissimilar enough (ranging in size from adult male to child) that tests were costly to execute. Several bones were purchased in the end to finish testing with. Finally, scheduled time for programming was reduced in the second semester due to a WBS adjustment, which limited the scope of programming possible for the demonstration.

Programming the Spherical tool

Figure 16. Current tooling used by the Mako system[12]

The original milling bit was chosen to resemble the Mako robotic system with a spherical head because it would leave a standard cut profile even used at a different tool angles. However after programming it to cut a square spiral plane pass to be scaled and used within a changing user and tool frame several flaws were brought to the forefront. To achieve this each surface was removed by a series of concentric spirals, removing the bone layer by layer until a final surface was reached. Unfortunately due to material limitations this proceeded 1.5 mm of depth per pass, a rather inefficient approach in terms of time.

Programing the Endmill tool bit

After consulting with Hannah Halcome who had some experience with FANUC machining applications and the teams surgeon Nicholas Waanders, who recommended switching tool and even provided us with figure __ while giving helpful reassurance and cautions concerning the tool path obstacles inspired the team to switch to an extra long end mill bit, (or at least the 561 multipurpose cutting bit which provided identical programming but ever so slightly inferior flatness/finish to the final result). This program procedure as is described in 6.6.2 simply plunges (laterally for all but posterior which must plunge to avoid ligaments) to final cut plane and moves very slowly across drastically reducing cycle time.

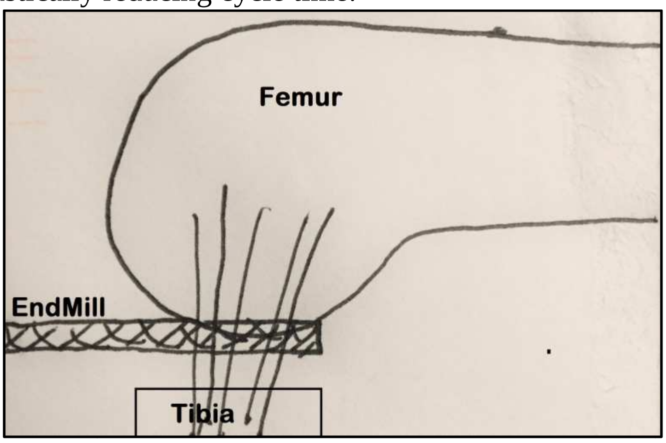

Figure 17. Final tool design as suggested by Dr. Nicholas Waanders

7. Testing

One of the main concerns of the project was validating the design in the face of unknown parameters, the largest of which was the elastic properties of tissue around the leg. To better understand this, stress tests were performed on the leg and the ballistics gel model in the prototype fixture, including the sawbones. These tests were used to gain three things; a beam based model of the leg, a simple tool force constraint, and a validation for the response of ballistics gel. The procedure of the experiment can be read below.

Objectives:

- Obtain the displacement of the tip of the bone when applying force with the robot.
- Measure the relationship mm/lb.
- Comparing between real leg deflexion versus bone/gelatin deflexion.

Equipment necessary:

- Fish scales to measure the force versus displacement.
- Micrometer to accurately measure the displacement of the tip of the bone.
- Stand to support the dial gauge.
- Robot to apply the force
- Stand to support the bone/gelatin system and real leg.
- Bone/gelatin system.
- A Patient.

Procedure:

The patient was laid on the operating table with their leg strapped into the fixture. The distance from the touch point to the edge of the clamp was measured to maintain consistency. The dial gauge was zeroed against one condyle of the knee before testing began. Next, force was applied to the opposite condyle with a spring scale. In this way the displacement of the tip of the bone was obtained for forces ranging from 5 to 50 N with an interval of 5 N. This test was repeated 3 times. The data plotted was the average of the three values. The experiment was then repeated with a ballistics gel leg analog as well as a sawbone alone, and a board to establish the displacement of each component of the system.

Figure 18. Leg model test station

After running several tests on both, human and simulated legs, a comparison chart was obtained as displayed in Figure 19.

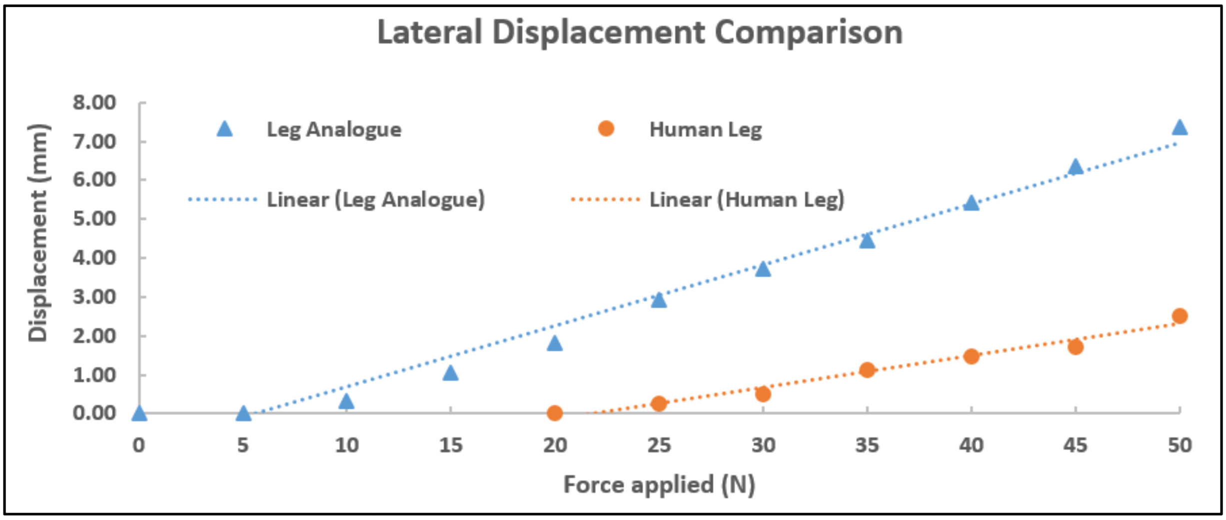

Figure 19. Comparison chart between lateral displacement of a real knee compared to a ballistics gelatin model

It was concluded that both relationships were linear in response to force and that the ballistics gelatin leg analog deflects around 3 times as much as a real leg.

8. Analysis

The data gathered in the tests was used to estimate the rigidity of the system and check whether or not the fixture would hold the knee within the prescribed 0.5 mm displacement. Additionally, the displacement of each portion of the system was isolated and associated with a stiffness. Each of the following sections solves for the portion of the deflection associated with one of the three components of the system.

Sawbone

The sawbones used were made of two materials: a foam core and a hard plastic shell. For this analysis it was assumed that the internal material would not have a significant rigidity compared to the external layer, similar to the relationship of the layers in living bones. Therefore, the displacement equation for an embedded beam was used to estimate the modulus of elasticity of the sawbones.

$$\delta = \frac{L^3}{3EI} W; \text{ Test model : y = A x - B}$$

Using the analogy:

$$A = \frac{L^3}{3EI} = \frac{\delta}{W} = 0.0393 \text{ in/lb. f} \pm 0.0006$$

where the quadratic error $R^2 = 0.995$. For the test,

$$L = 9.25\ in \pm 0.01$$
$$I_{tb} = 0.098 in^4 \pm 0.001$$

A modulus of Elasticity of 473 MPa for the sawbone composite material was computed.

To estimate the error the following expression was used:

$$\Delta E = \frac{\delta E}{\delta L}\Delta L + \frac{\delta E}{\delta I}\Delta I + \frac{\delta E}{\delta A}\Delta A$$

Using the above equation the elasticity was found to be 472.78 $\pm$11.42 MPa

The same process was followed for the lateral forces, applying the corresponding moments of inertia. The modulus of elasticity of the material should be the same in both cases, though the results reported were E = 456.23 $\pm$1.15 MPa. The frames in which the E was enclosed for each test should at least overlap. That was not the case so it can be concluded that the inner material of the sawbone has a notable influence in the rigidity behaviour of the sawbone. However, it was assumed that the modulus of elasticity of a sawbone was between 472.78 + 11.42 and 456.23 - 1.15 MPa. Therefore, the final result of the study was found to be:

$$E_{\text{sawbone}} = 469.64 \pm 14.56 \text{ MPa}$$

Ballistics Gel

While ballistics gel is accepted by the scientific community as an analog for human flesh, its function is usually applied in impact tests. It is known that the gelatin can model what happens to human muscle tissue when a bullet hits it, but the steady application of low pressure does not have a well documented response. However, enough testing has been done to establish that light force applied to the surface of gelatin generates “a static repulsive force without a jump into contact,”[gelatin viscoelasticity source] though drag forces exists if the force in question penetrates the block of gel. This means that as long as the pressure does not cleave the gelatin, the resistance to force can be modeled as a spring constant. This spring constant (k) was calculated experimentally.

The model used takes into account the spring force (Fs) fighting against the test load (W) at different distances, creating a displacement at the end of the beam (□) that is theoretically smaller than the one found for the sawbone alone. It was assumed that the spring load was a point load.

$$\delta = \frac{F_S l_1^2 \,(2l_1+3b)}{6EI} - \frac{W l_2^3}{3EI};\ F_S = \frac{l_1}{l_2} k\delta$$

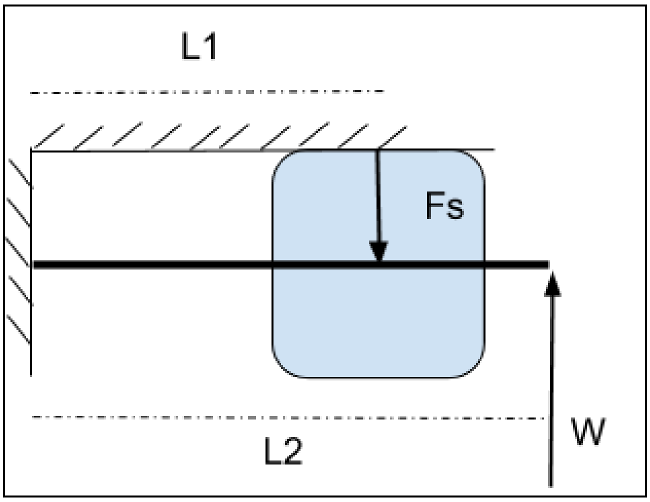

Figure 20. Assumed Beam Model

For the test,

L1 = 14 $in \pm 0.01$
L2 = 17.5 $in \pm 0.01$
b = L1 - L2
$E_{sawbone}$ = 469.64±14.56 MPa
I_{lat} = 0.070±0.001.

The test results were plotted in Excel and the trendline□=AW + B was found, where

$$A = \frac{2l_2^2}{\frac{l_1}{l_2}k\, l_1^2\,(2l_1+3b) - 6EI} = 0.0314\ \text{in/lb.f} \pm 0.0006$$

and the quadratic error is $□^2 = 0.985$. Next, the value of the spring constant was found and recorded below.

k = 10.75 N/mm.

Fixture

The original fixturing system was constructed out of plywood and assumed to be quite stiff, with minimal flexion originating in the structure itself. This was tested as above with a stiff board in the fixture instead of a flexible leg. The deflection was found to be negligible (less than 0.01 mm at the maximum force of 50 Newtons).

9 Recommendations

While the team was able to produce and test a prototype fixation system, they were not able produce a final fixturing system which met the original specifications. In order to meet specifications, more testing must be done to ensure that an external fixation method can produce the rigidity required for the high precision machining as attempted in this operation. Additionally, some factors of total knee replacement surgery disregarded by the team to ensure completion of the project must be addressed. Potential obstacles, further research required, and design suggestions for such a future project are given below. While this project has produced both research and many unique opportunities to learn, the team recommends that those pursuing this fixation method first consider medical training in order to fully understand the project. Furthermore, while the FANUC performed admirably, more robust systems which don't require fixation at all, like the Mako system by Stryker should be used as a more direct inspiration than the project Team 22 put together this year.

9.1 Future Obstacles

Some future obstacles will include:

- Optimizing clamp for anatomical factors. Some points on the leg have higher concentrations of fat (which will compress more readily than muscle), or an overall thinner layer of tissue between the skin and the bone. This could be taken advantage of to more rigidly clamp the leg without applying more pressure. Additionally, some clamping surface shapes will reduce shear forces applied to the tissue, reducing bruising, while allowing for greater concentrations of force at specific points while still exerting the same amount of pressure.
- Optimizing machining path to reduce soft tissue damage. The tool used, while able to perform all cuts, is only a rough simulation of the tool loads that might be incurred in legitimate surgery. A final rotary tool system should be designed and tested with the clamping system and a cadaver to verify that all required clearances between soft tissue and tooling can be met. Additionally, reducing the machining time required by re-optimizing the tool and tooling path would reduce time the leg spends in a stretched position during the surgery, which would in turn reduce soft tissue damage, itself a serious concern during the patient's recovery.
- Creating feedback to alert the robot if the leg moves. For the safety of all concerned, and for the robustness of the system, the robot must be able to discern whether or not the knee remains in the same position from moment to moment, and whether or not anything enters the working area. This would potentially require the integration of a vision system, and perhaps sensors in the fixture to determine vibrational loads and correct the tools lateral and rotational speed to maintain control over the piece.

9.2 Future Research

To fully address the obstacles listed above, more research will be required. Some of that research will have to include:

- Significance and cause of periprosthetic fractures. One of the reasons this fixturing system was chosen was the greatly lowered potential for fractures incurred by pin based methods. While the stress risers that form at the points of penetration appear to be a significant downside to a pin method, further research is required to determine the effect of such stress risers on the overall mechanical durability of a complex composite structure like bone in order to completely dismiss or approve the idea. If periprosthetic fractures are less likely than previously thought, then an invasive fixation method may be recommended over the non-invasive method.
- Dynamics of muscles, adipose, and tendons under pressure: Non-invasive fixation relies upon predicting the potential deflection of composite tissues under particular loads. The current method of estimating deflection is based on a spring model, but other papers recommend using a “Neo-Hookean Hyperelastic Model”[11]. This is popular for materials like rubber where cross linking between polymers is a large factor. It would not only serve to advance understanding of such tissues but improve the accuracy of the model, especially with regard to directional stresses.
- Costs: very little cost estimation was possible within the confines of the prototype, but a few are given below to guide future cost estimates. The first is the cost of producing or purchasing a 6 axis robot arm of the appropriate size and capability. The fanuc LR mate used in the demo is not recommended for a final product, as other models and brands are be better equipped to accurately compute the coordinate translations necessary for the type of locating system proposed. While further research would be required to optimize the choice of brand and model, it is safe to assume that purchasing the robot and associated equipment could cost between $40,000 and $50,000. Additionally, the manufacturing costs for a final fixture, assuming they are to be made in low quantities of less than 100 per year by a job shop, may be estimated at around $400, due to their stainless steel composition, the number of components, and the average amount of welding necessary to construct a system similar to the prototype. This estimate is based on a $25 per weld/cut cost to include finishing costs, assuming 4 hours of labor at $50 an hour of labor and overhead, and a per ft usage of 6 in by ¼ in stainless steel sheet cost of $12.00. The cart is simple enough to estimate by looking at similar products, which sell for around $200, and adding features like brakes and reinforcements which are estimated to cost another $300 including materials and labor. Industrial tooling estimates are based on the current cost of rotary tools and tool mounting systems for robots, which can reach up to $300.. With the addition of a computer interface ($300) and a cabinet which includes better wire management ($400), the cost per unit comes out to around $2,000 not including the cost of the robot itself. The cost of a final system is vastly dominated by the robot system as well as the investment required to research and design a final system.

10 Conclusion

In conclusion the team was able to adequately test their concept and produce a demonstration of the proposed method. It was found that the tissue around the tissue of the leg was not stiff enough to be purely clamped down and must be worked around, either by fixing directly to the bone or by holding the leg with an excessive, concentrated force that could potentially injure the patient. Throughout development the team learned how to better utilize time by identifying and prioritizing value adding tasks. Some decisions or practices that the team would change if given the opportunity would be establishing better and more open channels of communication, dedicating more time to prototype iterations, and using their professional contacts and advisors more readily in order to gain useful information rather than researching ineffectively in the wrong directions. As a result of their limited knowledge some time was used inefficiently, and because of this the team was unable to make a new iteration of the fixturing station before the deadline. However, there is potential for non-invasive fixation in the future, especially for the interfacing system like the one outlined above.

11 Acknowledgements

Staff Advisor: Dr. Ren Tubergen

Sponsor: Epoch Robotics/ JR Automation Service Division

Medical Consultants: Nicholas Waanders, Dirk Bakker

Industrial Consultant: Wesley Richards

Robot Specialists: Jeff Boeve, Joseph (Joe) Aguirre

Senior Design Professors: Leonard De Rooy, Mark Michmerhuizen, Ned Nielsen, Jeremy VanAntwerp, Ren Tubergen

Department Secretary: Michelle Krul

Workshop Management and Consulting: Phil Jaspers

12 References/Bibliography

[1] Vazquez-Vela Johnson, G, R L. Worland, J Keenan, and N Norambuena. "Patient demographics as a predictor of the ten-year survival rate in primary total knee replacement." The Bone and Joint Journal. http://www.bjj.boneandjoint.org.uk/content/85-B/1/52.short.

[2] Greengard, Samuel. "Step-by-Step Explanation of Knee Replacement Surgery." last modified April 30, 2012, Healthline. http://www.healthline.com/health-slideshow/total-knee-replacement-surgery-step-by-step.

[3] de Steiger, Liu, and Graves. "Computer navigation for total knee arthroplasty reduces revision rate for patients less than sixty-five years of age." last modified April 15, 2015, The Journal of Bone and Joint Surgery. https://www.ncbi.nlm.nih.gov/pubmed/25878307.

[4] Johns Hopkins Medicine. "Surgical Site Infections." Accessed November 30, 2016. http://www.hopkinsmedicine.org/healthlibrary/conditions/surgical_care/surgical_site_infections_134,144/.

[5] Cross, Michael B. "Revision Total Knee Replacement." last modified May 2016, American Academy of Orthopedic Surgeons. http://orthoinfo.aaos.org/topic.cfm?topic=A00712.

[6] Strickland, Eliza. "Autonomous Robot Surgeon Bests Humans in World First." last modified May 4, 2016, IEEE Spectrum.http://spectrum.ieee.org/the-human-os/robotics/medical-robots/autonomous-robot-surgeon-bests-human-surgeons-in-world-first.

[7] Pacific Research Laboratories. "Femur." Accessed November 19, 2016. http://www.sawbones.com/Catalog/Orthopaedic%20Models/Femur/1121.

[8] Gerfanov, Eldar. HSMAdvisor. Accessed December 8, 2016. http://zero-divide.net/.

[9] Sanyal, Gupta, Bayraktar, Kwon, and Keaveny. Journal of Biomechanics. https://www.ncbi.nlm.nih.gov/pubmed/22884967.

[10] Engineer's Edge. http://www.engineersedge.com/thread_strength/thread_bolt_stress.htm.

[11]https://www.resna.org/sites/default/files/legacy/conference/proceedings/2009/Wheelchair%20Seating/StudentScientific/Akins.html

[12]https://www.strykermeded.com/medical-devices/robotics-navigation/robotics-navigation/mako-pka/