# *Zimmer PCL Project*

**ME 282: Biomedical Product Design and Evaluation**
**Biomechanical Engineering Division**
**Mechanical Engineering Department**
**Stanford University**

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**Zimmer Incorporated**

**Zimmer PCL Team**

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# I Executive Summary

Total knee arthroplasty (TKA), a surgery that replaces a painfully damaged or diseased knee joint with a prosthesis, was performed in 267,000 patients in the year 2000 alone. A critical factor in PCL-sparing (posterior cruciate ligament) TKA is the proper tensioning of the PCL. An under tensioned PCL increases wear of the bearing surface of the prosthesis, which leads to premature failure. Over tensioning the PCL limits the degree of knee flexion, thus limiting range of motion. Additionally, a tight PCL increases the possibility of a sudden failure of the prosthesis due to the high level of stress exerted on the prosthesis components. Not only is an increasing percentage of the population elderly, but also this aged group is leading a more active lifestyle, in which mobility is a critical factor. Proper tensioning of the PCL will increase quality of life by increasing mobility and self-reliance, and by minimizing the frequency and severity of TKA revision surgery.

Current methods of evaluating PCL function or tension involve the surgeon either palpating the ligament or applying a load or torque to the knee and subjectively determining the suitability of the tension for the patient in question. While these methods can be effective, they require a surgeon to have considerable experience. A device capable of quantitatively measuring PCL tension and/or function would deliver surgical expertise in to the hands of otherwise lesser experience surgeons. The primary goal of the Stanford Zimmer PCL Team (the "Team") is to design and prototype such a device.

Zimmer Holdings Inc., an Indiana based developer and manufacturer of orthopedic implant components (specifically knees, hips, and fracture fixation plates) with $1 billion annually in sales, seeks to increase their share in the $7 billion knee replacement market through the manufacture and sale of said device to be used in conjunction with existing Zimmer knee implant products, specifically the NexGen prosthesis kit.

The Team has explored two approaches for PCL evaluation: the direct and the indirect. The direct method involves palpating the PCL with a device that measures both reaction force and deflection and then calculates tension. The indirect method utilizes contact force measurement, both magnitude and location, between the tibia and femur to calculate the tension in the PCL and the location of rollback. The Team has determined that the indirect method has more potential for success.

The final design uses a metal plate mounted with subminiature load cells to measure forces between Zimmer TKA trial components. Since the metal TKA trial inserts are immobile, the forces that the load cells measure are the contact forces between the tibia and the femur. A portable, palm sized, component will house a signal conditioning circuit and microprocessor module that will analyze the signal inputted from the load cells, and indicate whether the PCL is too tight, too loose, or in the appropriate range. This device will also display the magnitude of femoral rollback.

The major accomplishments of this quarter include a background and patent search, defining the problem, determining the existence of related technologies, conceptualizing several design possibilities, and deciding on the final candidate. Our first task next quarter is to construct a functional prototype of the device. Accuracy and repeatability testing will be done in conjunction with testing of the prototype, possibly in cadavers. Testing on human subjects can occur only after failure and safety testing have been completed.

# II Table of Contents

# III Background

## *Sponsor Background*

Zimmer Holdings, Inc, "Zimmer", is a Warsaw, Indiana based developer and manufacturer of orthopedic implant components. Comprised of nearly 3400 employees worldwide, with sales of $1 billion per year, Zimmer is a major player in the orthopedic implant market, specifically in the total knee, total hip, and fracture fixation plate arenas.

The knee replacement market is made up of 267,000 surgeries per year at an average cost of $26,000, for a total market value of just under $7 billion [1,2]. In an attempt to gain more market share, Zimmer seeks to create a competitive advantage through the development of novel and innovative products that will increase the understanding of dynamics and loading on the knee joint, and ensure the proper alignment of the knee during surgery. Consequently, Zimmer is sponsoring two related ME282 projects at Stanford University. One is a 3D knee joint tibiofemoral internal loading model with a graphical user interface, that will aid Zimmer engineers in the development of stronger and longer-lasting artificial knees. The other project, which is the focus of this report, is the development and prototyping of a posterior cruciate ligament (PCL) function and tension evaluator for use during surgery. Such a device shall enable the proper alignment of the knee joint during total knee arthroplasty (TKA), and thus prolong the life of the surgical implant.

## *Clinical Background*

Total knee arthroplasty (TKA) is a surgery that replaces a painful damaged or diseased knee joint with an artificial joint (prosthesis). The operation is performed under anesthesia by an orthopaedic surgeon. The surgery starts with an incision over the affected knee and the temporary removal of the patella. Next, the ends of the femur and tibia are sawed off and the corresponding parts of the prosthesis are implanted using bone cement. Usually, the femur-end of the prosthesis is made of metal while the tibia surface is made of polyethylene (UHMWPE). After the prosthesis is in place, the patella is reattached and all knee wounds are closed using sutures and staples.[6]

In a PCL-sparing TKA, the knee prosthesis that is used is designed so that the PCL does not need to be removed (Fig. 1). However, sparing the PCL results in a complication in the surgery: the PCL must be properly tensioned right after the prosthesis is inserted. An undertensioned PCL (with respect to normal PCL tension) leads to an increase in the anteroposterior translation of the tibia relative to the femur. This results in increased wear on the polyethylene tibia implant component. An overtensioned PCL results in limiting the degree of knee flexion. This results in sudden failure of the tibia implant due to high stress concentrations at contact surfaces of the prosthesis. Limiting the degree of flexion angle also limits the type of daily activities that the patient can perform and thus their quality of life. The importance of properly tensioning the PCL is also illustrated by the amount of time spent during TKA on the process.

**Figure 1. Zimmer Inc. NexGen CR PCL-sparing total knee prosthesis. [9]**

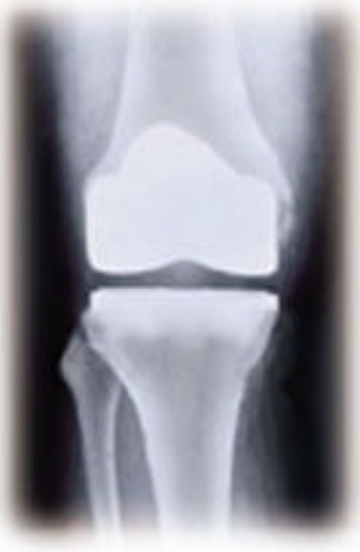

**Figure 2. Implanted Zimmer NexGen CR prosthesis. [9]**

Currently, two different methods are employed for evaluating PCL tension during PCL-sparing TKA. One method of measuring the tension in the PCL is palpating the PCL during TKA at a specific flexion angle. In other words, the surgeon touches the PCL to feel whether it has the right tension to produce a successful TKA. This method has many drawbacks since it is a purely qualitative method. First, this method will only allow experienced TKA surgeons to perform the procedure since less experienced surgeons would not know where to feel the PCL and how tense the PCL should be. Second, qualitative methods are always plagued by the question of repeatability. Although an experienced TKA surgeon might have the ability to feel whether a PCL has the right tension every time, this value changes with different patients due to different individual body structures (height, weight, etc.) and genetic variability (different knee joint anatomy).[8]

Another method that is currently used to evaluate PCL tension is visual inspection of the rollback mechanism of the knee joint during TKA. Tibial inserts (anterior portion) of different heights are inserted into the knee to determine which insert produces the most normal rollback mechanism. Similar to measuring the PCL through palpation, this method can only be used by experienced TKA surgeons. However, this method is repeatable on different patients since normal knee rollback mechanism is very similar for all individuals.[8]

## *Need/Market Analysis*

In 2000, approximately 267,000 total knee arthroplasty (TKA) were performed at a cost of $26,000 each.[1,2] This translates into $6.94 billion spent by patients and health insurance providers each year on the procedure. One of the indications of a successful PCL-sparing TKA is the proper tensioning of the posterior cruciate ligament (PCL). An undertensioned PCL results in increased PE wear while an overtensioned PCL results in limiting the degree of knee flexion.[3,4] Increased PE wear reduces the lifespan of the PCL-sparing prosthesis and therefore increases resurgery occurrence. Limiting the degree of knee flexion decreases the patient's quality of life due to restrictions on normal activities.

The introduction of a medical device to quantitatively monitor/evaluate the tension of the PCL during TKA will initiate the creation of a scientific standard for successful TKAs. This will

ensure more reproducible and satisfactory TKA surgical outcomes. Another benefit of the PCL tension monitor/evaluator is that it will greatly aid a less experienced orthopaedic surgeon in performing a successful TKA. Both benefits will result in a decrease in premature failure of the artificial knee joint. In turn, this will decrease the total amount spent on TKAs each year.

## *Benchmarking and Related Technology*

Related technologies can be separated into three categories: 1) existing biomedical devices that measure or evaluate ligament tension, 2) existing biomedical devices that use ligaments as a positioning guide, and 3) existing devices which measure tension of for non biomedical applications. Some category 1 and 2 devices are described below, while category 3 device patent first pages are included in the appendix because many of the methods used by category 3 devices are not suitable for *in vivo* applications.

There is no exact product on the market capable of *in vivo* measurement of tension in ligament during TKA. However, some similar products and technologies exist to aid us in designing a new product. The Tension Isometer Model TI-1000 ($1200), provided by the MEDmetric® Corporation (San Diego, CA) is an instrument used during reconstructive surgery of the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL). The function of the Tension Isometer (fig 3) is to assist in locating the path for isometric graft placement and to measure tension of ligament. This is done in order to provide appropriate tension and displacement prior to graft fixation. The instrument is operated by a thumb wheel-driven lead screw and has a linear gauge based on a spring scale.

**Figure 3. Tension Isometer**

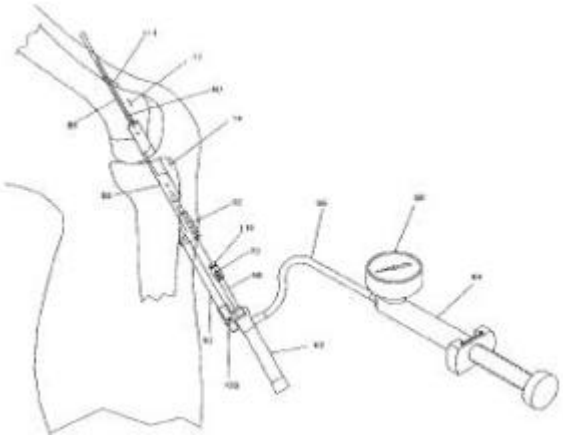

**Figure 4. US6001105 System for Tensioning Ligament**

US patent #6001105 describes a System for Tensioning a Ligament (fig. 4). This device measures the elongation of the ligament graft, while moving the joint through a range of motion. The ligament graft is removed from patient and temporarily mounted on tension board. In our case, however, it is not possible to remove the ligament for evaluation.

The MEDmetric® Corporation also produces the KT1000™, and KT2000™ Knee Ligament ARTHROMETER®. These devices test the integrity of the anterior and posterior cruciate ligaments via the passive drawer and active drawer motion test. This device is the commercialized product from US. Patent # 4583555; the inventor founded the MEDmetric Corporation.

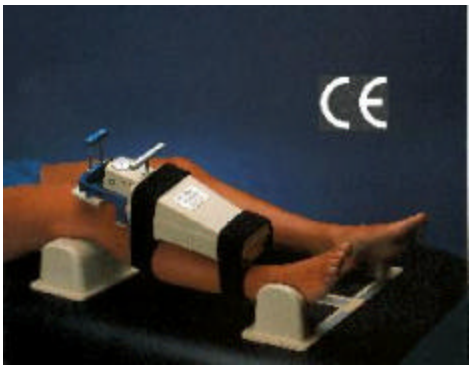

**Figure 5. KT 1000 Knee Ligament Arthometer**

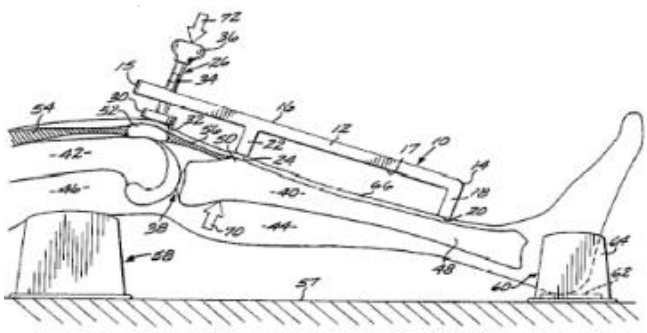

**Figure 6. US4583555 Knee Ligament Testing System**

The US patent No.5409494, a PCL oriented placement tibial guide, locates the ideal position of the tibial tunnel during reconstructive surgery of the ACL (fig. 7). The guide has an outrigger, which fits in the tibiofemoral gap and grasps the PCL. The device aligns itself based partially on the PCL position. This design provides insight into how to gain access to the PCL to directly measure tension.

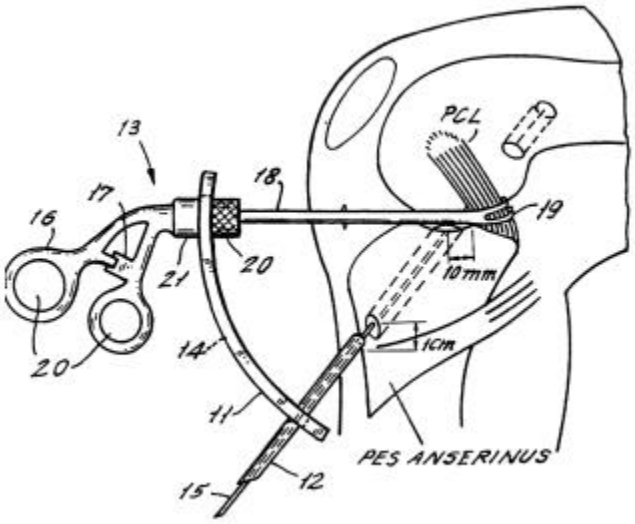


**Figure 7. US5409494 PCL Oriented Placement Tibial Guide**

There are some relevant technologies available for indirect measurement. One such technology could be used to measure contact pressure in the tibiofemoral surface. Tekscan (South Boston, MA) provides a force and pressure distribution measurement system named K-Scan, a flexible pressure assessment platform. It is primarily used by orthopedic implant industries in the study of prostheses design and articulating joint research. The K-Scan system is an effective tool for determining contact area and dynamic stress analysis. A less expensive force sensor is the FlexiForce Sensor and ELF (Economic Load & Force). Similar products from other manufacturers are available including: Novel (Munich, Germany), which visualizes pressure distributions. Specifically, the *High Conform Pad* can be used to measure the pressure distribution on a curved or irregular surface, such as the articular surface of an artificial knee joint.


**Figure 8. FlexiForce Sensor**

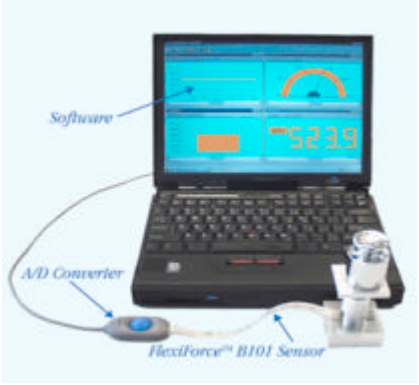


**Figure 9. ELF System**

**Figure 10. High Conform Pad**

## *Scientific Background*

**Key Scientific Areas:**

**Anatomy of PCL.** The posterior cruciate ligament (PCL) is a band of regularly orientated, dense connective tissue that connects the posterior aspect of the lateral surface of the medial condyle (femur) with the posterior articular surface of the tibia (Fig. 12). The PCL has a mean length of 3.8 cm (?0.4 cm) and a mean midportion width of 1.3 cm (?0.1 cm). It is surrounded by a mesentery-like fold of synovium, which provides the avascular PCL with blood and nerves (Fig. 13). The microanatomy of the PCL consists of multiple fascicles, of which the basic unit is collagen (Fig. 11). Fiber recruitment (into tension) of the PCL fascicles starts with the recruitment of fibers spanning the isometric point. The remaining nonisometric fibers are recruited into tension when there is an increased biomechanical demand on the ligament[5]. Functionally, the PCL is responsible for the knee joint rollback mechanism and prevents anteroposterior translation of the tibia.

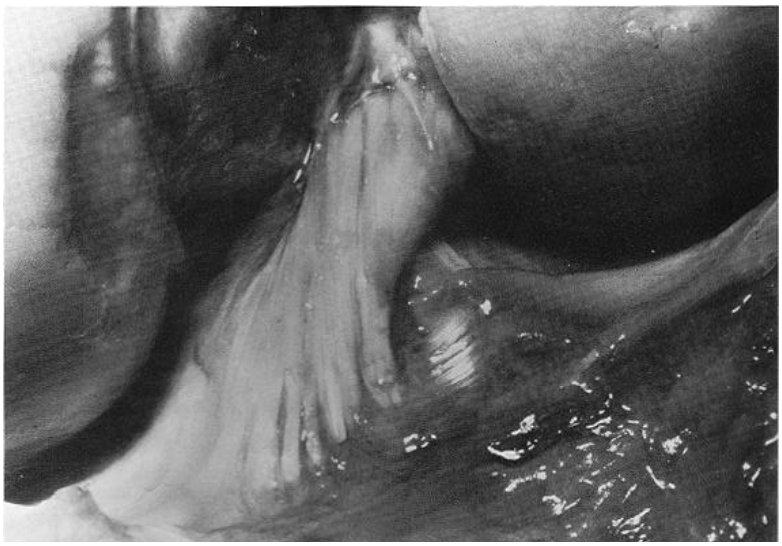

**Figure 11. Multifascicular nature of the ACL structure (same for PCL). [5]**

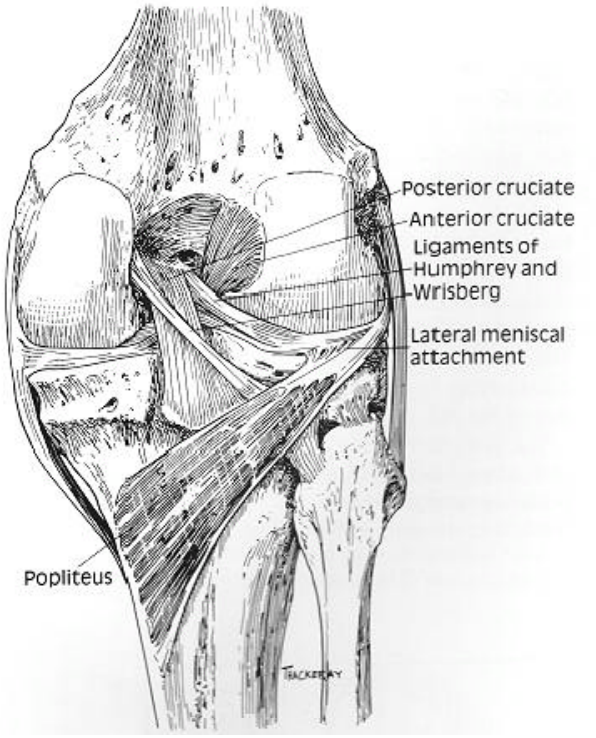


**Figure 12. Posterior view of the right knee joint. [5]**

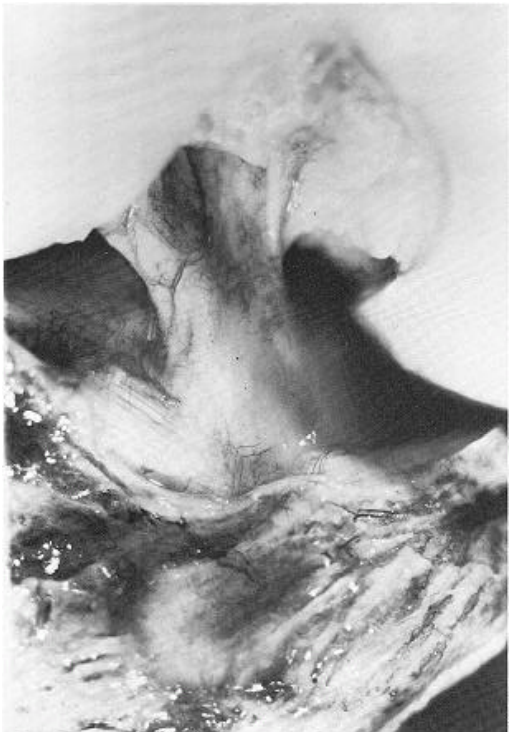

**Figure 13. ACL (same physiology as PCL) injected with India ink demonstrating the synovial vasculature. [5]**

**Scientific Basis of Problem:**

There are two main methods to evaluate the potential success of TKA: direct and indirect. The direct method would involve the measurement of the PCL tension at a specific degree of flexion to determine whether the tension is in the normal range (as specified by research studies done on cadavers). There is an agreement that the force generated in the PCL is greatest when the knee is in 90? of flexion.[27] *In situ* forces in the PCL ranged from 6.1 ± 6.0 N under 22-N of posterior tibial load at 0° of knee flexion to 112.3 ± 28.5 N under 110-N load at 90°.[28] However, due to differences in age and body structure of TKA patients, the "normal" range of PCL tension would not always apply to every patient. Therefore, it would be necessary to construct a database of the normal range of tension for different type of patients. Currently, a method that is employed by surgeons to directly evaluate PCL tension is to "poke" the PCL.

Indirect evaluation of TKA requires the measurement of the tibiofemoral forces on the surface of the polyethylene (PE) tibial plate. A comparison of the stress distributions found on the tibial plate of a patient during TKA with those reported in literature for cadavers can determine whether too much or too little forces are present in different areas of the tibial plate surface. Another method to indirectly evaluate TKA performance is the measurement of the femoral rollback during TKA. In TKA operations, surgeons would manually flex the knee while observing the amount of posterior translation of the tibiofemoral contact point.

**Potential Solutions and Expected Difficulties:**

**Using the direct approach, the posterior cruciate ligament (PCL) tension can be directly measured (Fig. 14).** This can be done in the following ways:

1. Strain gauges could be placed along the PCL and thus give an indication of the stresses, as long as we are familiar with the material properties of the PCL.
2. The deflection of the PCL following a force exerted on it could be measured and then having a good theoretical model of the material and shape properties of the ligament, we could come up with the required tension. A simple sketch of this idea is presented (Fig 15). According to this idea, the instrument consists of two main parts, one to go behind the PCL where it is inserted to the femur and one to push on the PCL. The distance of those two force-applying parts should be enough so that we avoid measuring shear stresses. The instrument can be used with one hand if designed properly. The measurement will include force and displacement and so results can be quantitative, so operator can decide whether the joint tension is within the physiologic range. There will be some initial point calibration need in order to introduce the initial dimensions of the PCL.

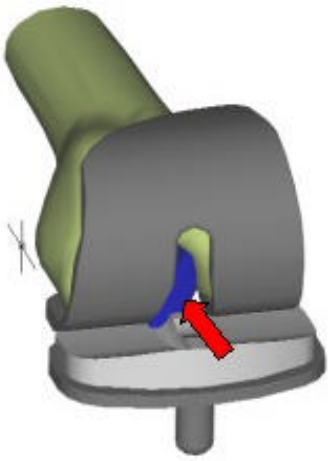

**Figure 14. Direct measurement of PCL**

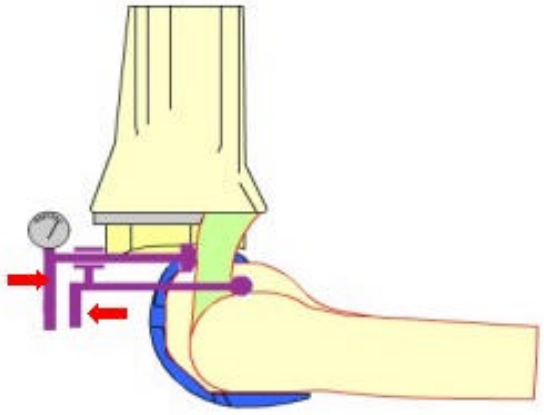

**Figure 15. Device that measures the deflection of the PCL.**

**Advantages / Disadvantages of Direct Approach.**

+ can be compact
+ one unit, one hand operated
+ noninvasive
+ short procedure
+ direct measurement, quantitative
+ measurement relative to insertion point of PCL
+ no need to mount on a base part (like the other Zimmer design proposal)
+ generic application (for every operation using not only Zimmer's TKA product)

- need for removal of synovial and local fat in order to have a clear surface
- PCL material properties and inner structure quite complicate to model
- might be difficult to design a single device for both left and right knees
- limited entry space

With the indirect approach a physical feature that is connected to the tension condition in the joint is measured.

1. **Measurement of the tibiofemoral roll-back (Fig 16).** This can be done with radiographic (fluoroscopy) methods. It can also be done with some mechanical or electronic method of tracking. However these methods would require mounting of the equipment in order to get relative measurements, and that could prove to be complicated for the surgery.

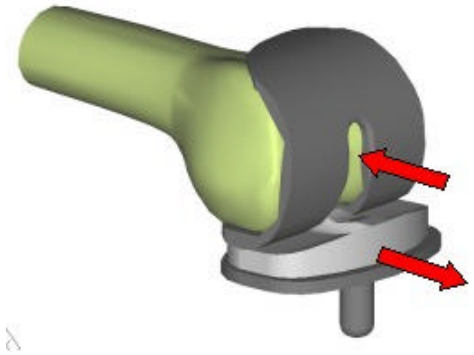

**Figure 16. Tibiofemoral rollback measurement**

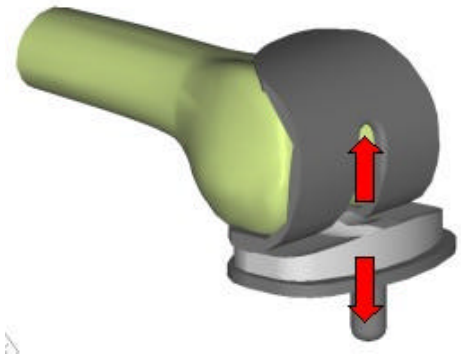

**Figure 17. Contact force measurement**

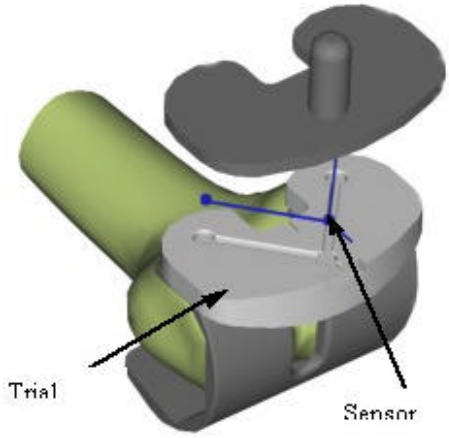


**Figure 18. Embedded sensors in tibial insert to indirectly evaluate PCL function.**

2. **Measurement of the contact forces between the tibia and the femur (Fig 17).** This can prove to be a very good approach since what interests us most is the general stress condition on the articulating surface. There have been attempts to perform similar measurements using sensor surfaces (Tekscan) but this results to complicated systems that wouldn't be used in an operating theatre. An interesting idea is to modify a little bit the articulating tibial part (Fig 18). Some small grooves are needed between the articulating plastic part and the metallic base part. A number of sensors can be introduced. Interesting results can be concluded if there are more than two (in the picture there are three). In this case an estimation of the stress distribution on the whole articulating surface can be performed. These sensors might be electronic, piezo-electric or can be little air chambers that inflate separately and their individual pressure is measured. The indication might be also quantitative, but since electronics are involved a LED indicator can show if the tension is between the expected range. A palm-size reading device could be connected.

**Advantages / Disadvantages of Indirect Approach.**

+ Can be compact
+ Non invasive
+ Short procedure
+ Indirect measurement, quantitative, very precise, total perception of the stress condition of the articular surface
+ Single device for both left and right knees

+ Non-generic application (only Zimmer's TKR product). More attractive TKA system. Depends on company strategy.
+ Might be made disposable (the sensor part). Again depends on company strategy.

- Perhaps need for modification of Zimmer's articulating surface part
- PCL material properties and inner structure quite complicate to model
- Limited entry space
- Non-generic application (only Zimmer's TKR product). Limited market if not using Zimmer's products. Depends on company strategy.

Another similar idea is to use special force plates that can be inserted between the two components.

## *Problem/Needs Statement*

An incorrectly tensioned PCL reduces the life of the orthopedic implant. This is particularly problematic in a society where aged people constitute an increasing percentage of the population, and where those individuals are living longer and more actively. This requires artificial knees that last in order to reduce the number, frequency, and severity of revision surgeries.

Currently, evaluation of PCL tension is qualitative and its success rests on the experience of the surgeon. A PCL tension evaluator that could quantitatively measure PCL function and/or tension would deliver surgical expertise into the hands of otherwise lesser-experienced surgeons, thereby decreasing the premature failure of artificial knees and producing more predictable and satisfactory surgical results.

## *Project Team*

**Picture and Bio of Team Members:**

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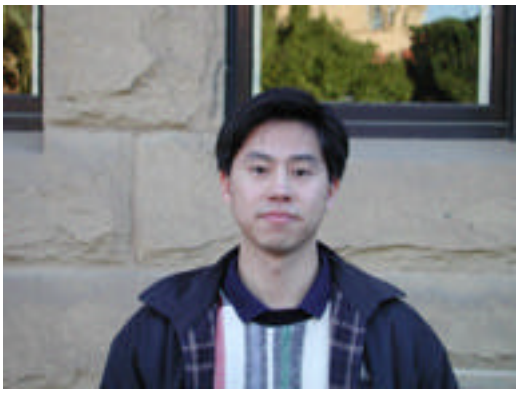
Eric Bean will graduate in December 2002 with a Master's of Science in Engineering: Biomechanical Engineering (MSE:BME), specializing in Biomechanical Device Design. He received a B.S. from the University of Virginia in Aerospace Engineering in 1998 and has worked for NASA and Space Systems/Loral in the aerospace field. He currently splits his time between studies at Stanford, working as a hardware engineer at CBYON (a surgical navigation software company), and coaching and racing triathlon.



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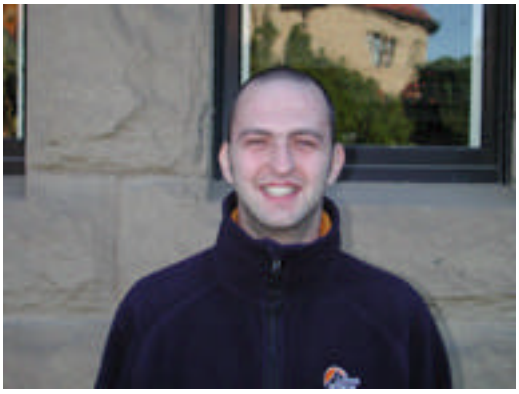
Choongsoo Shin graduated in 2001 with a Master's of Science in Mechanical Engineering (Design Division) from Stanford University and is pursuing Ph.D in Biomechanical Engineering. He received a M.S and B.S from Hanyang University in Korea in Mechanical Design & Production Engineering in 1999 and 1997 respectively. He worked on numerous projects including control of tunneling infrared detector, design/evaluation of power paper stacker, point cluster methods for human knee movement and robust optimization of structure using design axioms.



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Lampros Kourtis is expected to graduate June 2002 with a Master's of Science in Engineering: Biomechanical Engineering (MSE:BME), specializing in Biomechanical Device Design. He has received a Diploma in Mechanical Engineering from Aristotle University Thessaloniki, Greece. He has participated in a number of biomedical engineering projects mainly related to biomechanics and medical device design resulting currently applied systems, also has worked as a design engineer.

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Kai Jair is a first year Masters student in Mechanical Engineering at Stanford University with a depth in Biomechanical Device Design. He did his undergraduate work at University of California, San Diego and obtained a B.S. in Premedical Bioengineering. A research project that

he did during his undergraduate years was the creation of a 3-D ultra-structural model of the pig heart using CAD programs. This model was created in order to simulate induced heart failure in pigs.

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# IV Design Definition

## *Purpose of Design*

The purpose of the Zimmer PCL Team is to design and prototype a portable medical device to ensure the success of a TKA through measurements of tibiofemoral forces. Currently, all methods of evaluating the potential success of a TKA are qualitative. The ability to quantitatively determine the success of a TKA will create a scientific standard for successful TKAs. This will ensure more reproducible and satisfactory TKA surgical outcomes. Also, this device will greatly aid less experienced orthopaedic surgeons in performing a successful TKA. Both benefits will result in a decrease in premature failure of the artificial knee joint and therefore increase the lifespan of the total knee prosthesis. In turn, this will decrease the yearly medical cost ($6.94 billion) associated with TKAs.

## *Project Goals*

The main goal of the Zimmer PCL Team is to design and prototype an easy to use device to indirectly evaluate the PCL during total knee arthroplasty. The device must be designed to be "surgeon friendly" since many surgeons do not have a background in engineering. Sterilize-ability issues have also to be considered.

## *Scope of the Project*

The conception of a design and prototype is essential to the project. This must be completed as soon as possible since surgeon feedback is needed to determine whether the design is "surgeon friendly". Anything that seems too complicated to figure out in a short time will not be utilized by surgeons due to time constraints. Also, the design must comply with the functional and physical requirements as specified by our sponsor- Zimmer Inc. However, the need for the creation of a refined design suitable for high volume manufacturing production is beyond the scope of this project.

Upon completion of the final prototype, validation experiments must be conducted to determine the relationship between the magnitude of tibiofemoral forces and the amount of tension in the PCL. Force ranges must be derived for a tight PCL, a loose PCL, and a PCL within the normal range of tension. This can be accomplished by testing our prototype device in cadavers or in real TKAs. Accuracy and reliability testing will be conducted in conjunction with validation tests.

## *Functional/Customer Requirements*

The design requirements based on the voice of the customer are broken into the broad categories of operation, ease of use, cost and safety, as shown in Table 1. Each element of the design requirement table is scored subjectively on a scale of 1-10, with 10 being mission critical, and 1 being of peripheral importance.

Clearly, all safety issues are of critical importance, thus the PCL tension evaluator must be steralizable, safe, and non-catastrophic in its operation. All safety issues have been scored the maximum 10.

Cost is also an important issue. Manufacturing cost will be reduced if the same device can be used to evaluate both the right and left knee (score=9). Using components that are FDA pre-approved will reduce time-to-market and development costs (score=5). The $1000 manufacturing cost criteria is a goal set forth by Zimmer, although they seem willing to revise that (score=5). Lastly, a product durability of 5 years will allow the user to amortize the purchase over a number of years (score=7).

Ease of use is a must and has been given a score of 9. A product cannot significantly interrupt the standard operation workflow if surgeons are to incorporate it into their surgeries. A sub-criterion of this is that the procedure is one step and takes less than 5 minutes, which is admittedly an arbitrary time constraint. This has been scored a 6. One-handed operation and push-button calibration both fall in between convenience and a must, and therefore have been scored 5.

In terms of operation, accuracy is most important and is weighted with a factor of 8. The ability to numerically quantify PCL tension, as opposed to simply lighting a red or green indicator light as in a black-box approach, is weighted 7. A self-contained device would greatly increase the ease-of-use and has thus been scored 8. Even more critical is the issue of compatibility between our device and Zimmer's NexGen TKA prosthesis, which has been given a score of 10.

**Table 1. Design Requirements Based on Voice of Customer (As Specified by Zimmer Inc.)**

| | **Requirements -Goals** | **Importance (1-10)** |
|---|---|---|
| **Operation** | Quantifying device | **7** |
| | Self-contained device (no cables, external power supplies) | **8** |
| | Accuracy (less than 10% error) | **8** |
| | Repeatability (more than 90%) | **8** |
| **Ease of Use** | No need to calibrate before use (or push button calibration) | **5** |
| | One step procedure (less than 5 min) | **6** |
| | One-hand operation | **5** |
| | Procedure does not significantly interrupt the standard surgical workflow | **9** |
| | Compatibility in NexGen TKA prothesis | **10** |
| **Cost** | Durability (up to 5 years) | **7** |
| | Cost (less than $700) | **7** |
| | Capability of arthroscopic use | **3** |
| | FDA pre-approved technology | **5** |
| | One device for both knees | **9** |
| **Safety** | Sterilizable using current standardized methods | **10** |
| | Non-catastrophic operation | **10** |
| | Safe (for patient, for surgeon and for nurses) | **10** |

## *Physical Requirements*

The functional/customer requirements have been translated into physical requirements in Table 2. If a direct measurement approach is to be used, the device, or part of the device, must fit within the tibiofemoral gap. If the measurement is indirect, the sensor must be smaller than the articular surface, and must easily be adapted to this shape. These requirements are absolutely necessary, consequentially they have been scored 10. A palm sized measuring device to interpret the

indirect method sensors would be an attractive feature. To reduce cost, the PCL tension evaluator should incorporate standard Zimmer manufacturing procedures. This requirement had been weighted 7, because as a new device, it is reasonable to predict that a new manufacturing process may need to be developed, but it is acknowledged that this could be costly. Weight should be kept to a minimum, to increase ease-of-use. An arbitrary, but sensible, limit of 3 pounds has been weighted—no pun intended—as an 8. The material constraint is that the device should be made from FDA approved materials for the operating room. In other words, the material must be non-toxic and not interfere or negatively react with any substances commonly found in the OR, or substances which one could reasonably expect it to come into contact with during the course of the surgery.

**Table 2. Design Requirements Based on Physical Requirements (As Specified by Zimmer Inc.)**

| | **Requirements** | **Importance (1-10)** |
|---|---|---|
| **Size - Shape** | -If direct measurement, must fit within the tibiofemoral gap | **10** |
| | -If indirect measurement, sensor must fit within the articular surface without deforming it; reading device palm size | **10** |
| **Manufacturability** | Manufacturability (in relation to Zimmer's manufacturing potential) | **7** |
| **Weight** | Less than 3 pounds | **8** |
| **Material** | Device made from FDA approved materials for the operating room | **10** |
| | Material should remain intact and not shed. | **10** |
| **Shelf – life** | Not applicable | **N/A** |

## *Regulatory Considerations*

The PCL Tension/Function Evaluator is classified as a template for clinical use, Class I. Such devices are used during surgery to position or guide the cutting of tissues or alignment of orthopedic implants. This device will be exempt from pre-market notification procedures. Table 3 displays the FDA device classification. More detailed information may be found in the appendix. Another regulatory consideration is the selection of materials that have been approved by the FDA as suitable for patient contact.

**Table 3: FDA Classification for PCL Tension Evaluator**

| | |
|---|---|
| Medical Specialty | Orthopedic |
| Product Code | 21 CFR 888 |
| Device Class | Class I |
| 510(k) Exempt? | Yes |
| Regulation Number | 888.4800 |

### *Other Constraints on Design*

Time and budget constraint is a great challenge for this project. Because this project involves both mechanics and electronics, it will be difficult to combine the two in our device. Furthermore, the Zimmer PCL Team does not have a member with a background in electrical engineering. To be certain that the project will be completed within two quarters, we need to accelerate the whole design process, including conceptual design, prototyping, and validating. In other words, we need to make the decision for our final design a little prematurely.

In addition, the team budget of $5,000 constrains the type of materials and the amount of realization methods that can be employed. Many precise electronic components, which are ideal for medical applications, have high costs and are not readily available.

# V Design Development

## *Vision/Strategy*

To successfully develop a functional and "surgeon friendly" design, the Zimmer PCL Team has attacked the problem presented by Zimmer Inc. in a structured manner. A review of the anatomy and physiology of the PCL has helped us determine size and sensitivity constraints of our device. Brainstorming sessions both as a team and with Zimmer Inc. has given us insight on which of our preliminary designs is desirable, marketable, and can be manufactured. Evaluation of our designs via Pugh analysis revealed, as a whole, the best design. FEA was utilized to validate and predict load distribution on the final design model.

## *Overview of Work Completed*

As of the end of winter quarter, the design of our medical device, which measures and analyzes the position and magnitude of tibiofemoral forces, has been finalized. A CAD model of the "insert probe" and of the modified articular surface design has been made to produce feasible dimensions for the metal insert plate. A FEA was done on the Zimmer tibial trial insert to analyze and validate the positioning of the load cells. The circuit design for our signal conditioning circuit was simulated to ensure its functionality. Lastly, a PCL evaluation algorithm was written for the software portion of our device. Most of the supplies needed for building our device has either been bought or are being sent by Zimmer Inc.

The most expensive single component that we purchased, as of date, is the Entran ELFM-B1 subminiature load cell ($395). We made phone calls to many load cell companies requesting an educational discount on load cells with similar specifications. However, many of these companies told us that their main consumers are educational institutions and thus cannot give educational discounts. Therefore, the load cell was purchased at full price from Entran Technologies since other companies requested a higher price for the same model.

Due to the high price of subminiature load cells, we have asked Zimmer Inc. whether it was acceptable for our final prototype to cost approximately $1400. Zimmer Inc. responded that it was permissible since manufacturing costs could be reduced through bulk purchases from the load cell suppliers. They were also very excited by the load cell design and wanted our team to implement this idea (load cell).

Two other preliminary designs, which were considered, were balloon pressure measurement and K-scan system (see Design Concepts Generated section). However, the physical specifications of the balloon needed for the balloon pressure measurement design was determined to be very difficult to prototype. Requested information obtained from Novel Electronics Inc., a company, which makes a pad (pressure distribution sensor) similar to the K-scan system, has revealed that each knee joint system had a price tag of US$ 50,000. A comparison of the "LEGO" sizing plate and "insert probe" design has revealed that the "LEGO" sizing plate will require more alterations of the original Zimmer Inc. TKA components than the "insert probe" design, which is not desirable.

Comparing our current design with functional and physical design requirements that were developed in this middle of this quarter has shown that our device will fulfill operation, safety, size, and weight requirements. For ease of use, our device will not completely satisfy the "no need to calibrate before use" requirement since load cells require calibration before use. The cost of the device will be greater than the $700 limit, which is listed. Lastly, since Zimmer Inc. needs to outsource the production of the electric circuit that our device will employ, Zimmer Inc. does not have the potential to manufacture the entire device by themselves.

The scientific basis for our design concepts was generated through a literature review of the articles given to us by Zimmer Inc. at the beginning of the quarter. We brainstormed devices for both direct and indirect methods of evaluating tension of the PCL. However, a review of the anatomy and physiology of the PCL has revealed that to design an instrument to directly measure PCL tension during TKA would be quite difficult. The PCL is surrounded by a synovium and is only 3.8 cm in length, making it difficult to access. Since fiber recruitment in the PCL is not simultaneous, it will be difficult for TKA surgeons to determine when all fibers are recruited. Due to the abundant amount of research performed cadaver knee joints, the indirect method seemed more favorable. Cadaver validation tests can be used to compare data obtained from our device and the data reported for cadavers in literature.

## *Preliminary Design Concepts Generated*

**1. Load Cells on bottom of Trial Insert**

Since the bottom of the tibial trial insert is relatively flat, small industrial load cells can be implanted into the surface to assess tibiofemoral forces (Fig. 19). The distribution of the load cells (3 to 4 in number) will allow the creation of an electronic measurement device to analyze the forces and display qualitatively "how good the fit is" to orthopaedic surgeons (during TKA) (Fig. 20). The grid shown on the electronic device was taken off of the Zimmer NexGen info sheet.

The load cell that is currently being investigated for this purpose is the Entran ELFM-B1 subminiature model. The dimensions of the load cell are 12.05 mm in diameter, 3.5 mm in height. The placement of 4 load cells (2 on each condyle) will allow the analysis of medial-lateral and anterior-posterior forces, however placement of more than three load cells could be difficult, because of alignment issues. Software will be created to analyze the distribution and intensity of these forces and return a simple qualitative result (1 to 9).

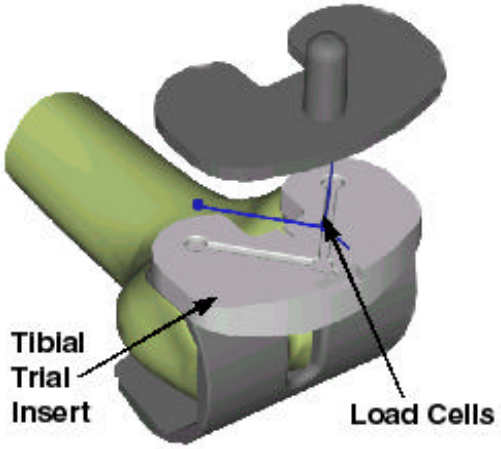



**Figure 19. Load cell on bottom of trial insert**

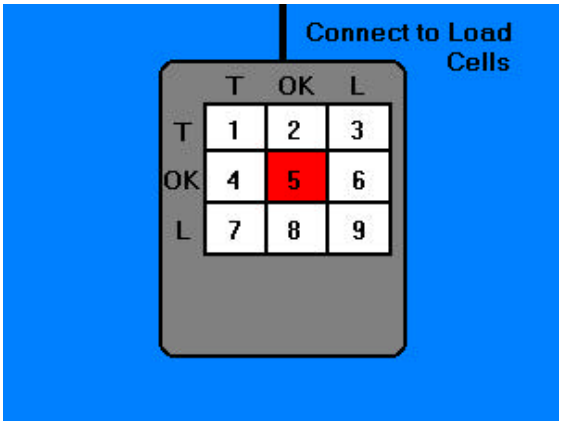



**Figure 20. Electronic load cell measurement device**

**2. Pressure Measurement using Balloons**

Similar to design #1, the distribution of the 4 balloons allows medial-lateral and tibiofemoral force measurements. An electronic measurement device will analyze pressures in the balloons and display qualitatively "how good the fit is". A manual hand pump, similar to the ones used in blood pressure measurement, will be used to inflate the balloons.

This design intrigued us since it is an external device, which only requires slight modification of the tibial trial insert. This allows the device to be marketed in a different fashion than the other two designs.

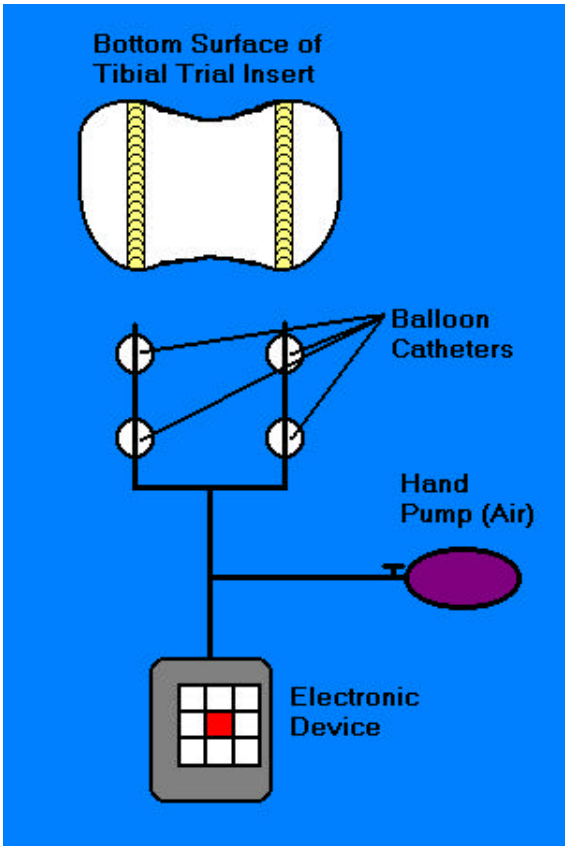



**Figure 21. Pressure measurement using balloons**

**3. K-Scan System (Tekscan)**

The K-scan system is a commercially available pressure measurement system used by orthopaedic implant companies and research institutions. However, it is unclear whether the system is currently used for the assessment of tibiofemoral contact forces during TKA. One possible reason why it is not used in TKA is that fact that the system requires laptop and computer software. The price of the system and the complicated analysis, which it provides is not attractive to orthopaedic surgeons.

In our preliminary design, Zimmer PCL team proposes to construct a more surgeon-friendly electronic readout device, which will evaluate the amount of force in the medial and lateral condyles of the trial insert during TKA. Different colored LEDs will be used to indicate the amount of force exerted.

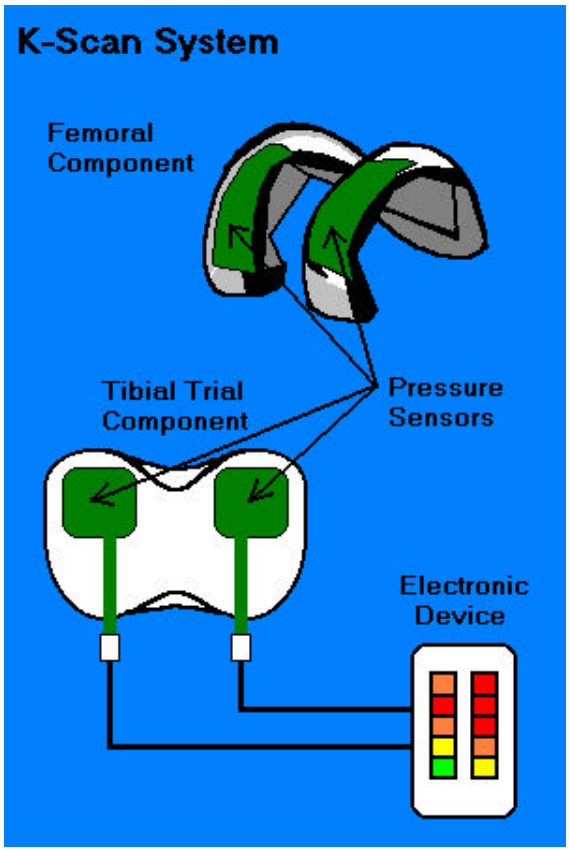



**Figure 22. K-Scan System**

**4. "Lego" Sizing Plate Design**

Another approach, in order to facilitate both tension measurement and balancing procedure is to introduce an articular surface that would have the load cells integrated. That would increase the cost of the device, since Zimmer currently produces 4 different size articular surface trial components that also vary in height, starting from 10mm, going up to 20mm in increments of 2 or 3mm. The idea is to use a building unit (just like LEGO pile up), a slice, of specific height that could attach on the bottom side of the trial part and give the desired height to the whole complex. Building units can be made out of plastic and can have some kind of interconnecting mechanism in order to attach and detach to the trial component or to each other. This would save Zimmer from all the variations in articular surface trial components that they have to produce. The system would have a reading device, handheld, where the collected data are processed.

## *Evaluation of Designs*

We have conducted the Pugh Analysis to evaluate the preliminary concept designs, which are generated from brainstorming. The sixteen design requirements based on voice-of-customer are selected as evaluation criteria. Among four preliminary designs, three designs utilize the indirect approach while one design utilizes the direct approach. After we selected one of the concepts as a reference, we evaluated each concept against the datum for each of the criteria. Our evaluating criteria is whether it is better (+), the same (0) or worse (-) than the baseline. Table 4 and Table 5 show the process and the results of Pugh Analysis.

**Table 4. Pugh Analysis of Preliminary Designs**

| Criteria | a) | b) | c) | d) | a) | b) | c) | d) | a) | b) | c) | d) | a) | b) | c) | d) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Quantifying device | Datum | - | + | 0 | + | Datum | + | + | - | - | Datum | 0 | 0 | - | 0 | Datum |
| Self-contained device | | 0 | 0 | + | 0 | | 0 | + | 0 | 0 | | + | - | - | - | |
| Accuracy | | - | + | - | + | | + | 0 | - | - | | 0 | + | 0 | 0 | |
| Repeatability | | - | + | - | + | | + | + | - | - | | - | + | - | + | |
| No calibration before use | | - | 0 | - | + | | + | 0 | 0 | - | | - | + | 0 | + | |
| One step procedure ( 2 min) | | - | 0 | 0 | + | | 0 | + | 0 | 0 | | 0 | 0 | - | 0 | |
| One-hand operation | | - | - | 0 | + | | - | - | + | + | | 0 | 0 | + | 0 | |
| No significant interrupting surge | | - | - | + | + | | 0 | 0 | + | 0 | | 0 | - | 0 | 0 | |
| Durability (up to 5 years) | | 0 | 0 | + | 0 | | 0 | + | 0 | 0 | | 0 | - | - | 0 | |
| Cost (less than $700) | | + | 0 | 0 | - | | - | 0 | 0 | + | | + | 0 | 0 | - | |
| Capability of arthroscopic use | | 0 | + | - | 0 | | + | - | - | - | | - | + | + | + | |
| FDA pre-approved technology | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | |
| One device for both knees | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | |
| Sterilizable by autoclaving | | + | 0 | - | - | | 0 | - | 0 | 0 | | - | + | + | + | |
| Non-catastrophic operation | | + | 0 | + | - | | 0 | 0 | 0 | 0 | | 0 | - | 0 | 0 | |
| Safe (for patient, surgeon) | | + | 0 | 0 | - | | - | 0 | 0 | + | | + | 0 | 0 | - | |
| Score | | 4+ | 4+ | 4+ | 7+ | | 5+ | 5+ | 2+ | 3+ | | 3+ | 5+ | 3+ | 4+ | |
| | | 5o | 10o | 7o | 5o | | 8o | 8o | 10o | 8o | | 9o | 7o | 8o | 9o | |
| | | 7- | 2- | 5- | 4- | | 3- | 3- | 4- | 5- | | 4- | 4- | 5- | 3- | |

Design a): Load cell on bottom of the trial insert design
Design b): Pressure measurement using balloon type sensor design
Design c): Tekscan (Novel) pressure distribution sensor design
Design d): Direct ligament tension meter

**Table 5. Summary of Pugh Analysis**

| | Design a) | Design b) | Design c) |
|---|---|---|---|
| Positive(+) | 14 | 10 | 13 |
| Neutral(o) | 22 | 21 | 27 |
| Negative(-) | 12 | 17 | 8 |

Table. 5 shows the summary of Pugh Analysis. As can be seen, the design a) has the most advantages (14). However it has also many disadvantages such as need to generate various shapes to fit existing trials and difficulty in sterilization. On the whole, it appears to be sufficiently accurate and convenient for operation. The design b) has the lowest rating. It seems to be simple, inexpensive but of overall poor performance. The design c) has the least disadvantages and the most neutral points. Though it seems to be accurate, reliable and generic, the post-processor will be complicated in order to process unnecessary, overwhelming data. We contacted Novel Company and obtained the price of the whole kit including currently used post-process equipment that is $5,000. It is expensive because the Novel compliance system is designed for a comprehensive pressure distribution research. The last preliminary design utilizes direct approach to measure tension. The design d) has evenly distributed advantages and disadvantages. It appears to be advantageous in terms of durability, self-containment and generic application. However, it has also critical weakness such as sterilization and repeatability problems. In addition, the protocol of seizing ligament sites seems to be vague as well as difficult and then results differ depending upon subjective manipulation. Though the removal of synovial and local fat is required in order to access the PCL, we cannot urge surgeon to remove and measure tension of PCL during TKA operation.

While evaluating preliminary design concepts by Pugh Analysis, we looked over many possible ways to fulfill each requirement and reached the finalized design concept, which

modified the design a) with incorporating ideas from other concepts. The finalized design concept considered specific features as followed:

-Indirect method using load cells to measure tibiofemoral contact force
-Appropriate protocol or configuration of sensor to guarantee reliable/repeatable output
-Generic configuration to fit various tibial plates, which reduces manufacturing cost
-Sterilization issues if reusable device

## *First Prototype of Product*

The final model is the result of careful balance between design requirements. The idea of a probe inserted between the articular surface and the tibial sizing plate is pursued. The probe is connected to a handheld electronic device that supplies all the information obtained in a friendly display.

### Probe plate:

One of the main concerns in our design process is to modify the existing products as little as possible. Due to the dimensional diversity of Zimmer's product, a generic probe is designed, that can fit in all different configurations.

Zimmer uses two different models for tibial sizing plates that come in various dimensions (Fig. 23); articular surfaces come in one configuration but in various sizes and various heights. These dimensions had to be closely examined, so the proposed model is able to function in combination with all different types and sizes for Zimmer's parts.

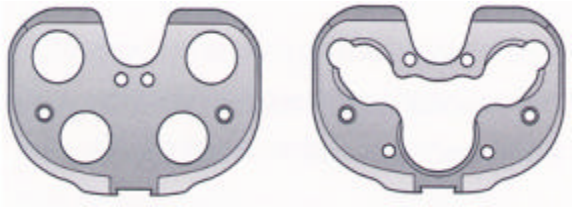


**Figure 23. Pegged and stemmed tibial sizing plates**

In order to measure the loads, load cells are employed. Load cells have to be placed in "crucial" positions, facilitating accurate measurement; that's something that the non-uniform placement of features like holes and pegs on the tibial sizing plates don't allow. For example in both plates, there are 3 or 4 large holes in order to drive drilling and 4 or 6 smaller holes to include fixating pins. On the other side, Zimmer gave the green light to modify the articular surface, as long as no existing functional properties are affected.

The idea could briefly described as a plate, made of metal, that would provide housing for the load cells, and that can be placed between the unmodified tibial sizing plate and the slightly modified articular surface part.

When assembled, the tibial plate – probe plate – articular surface assembly would look quite similar to the existing configuration (Fig. 24, 25).

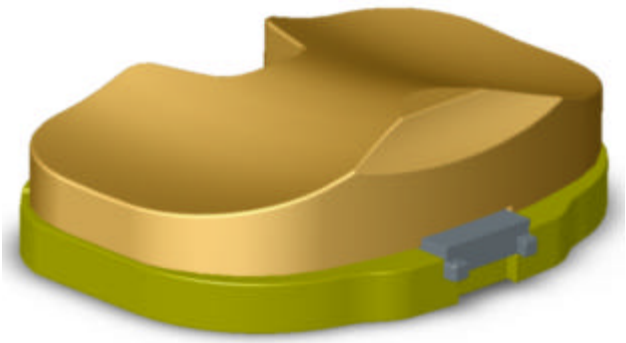


**Figure 24. Tibial plate – probe plate – articular surface assembly**

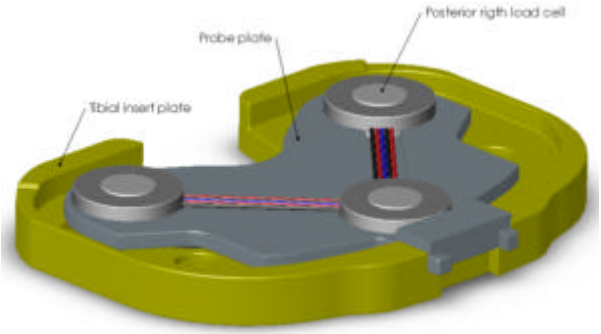



**Figure 25. Articular surface removed revealing probe plate with load cells**

The probe plate is a 2mm thick metal plate that has 3 housings (1mm deep) to support load cells. There are also 2 grooves to house cables. We selected Entran ELFM-B1 subminiature load cells. They measure 12.7mm in diameter and 3.5mm in height. On the bottom part of the probe plate, there are 2 pegs that are inserted in the two corresponding holes of the tibial sizing plate, in order to center the plate and maintain the same position no matter what the type or size of the tibial plate is (Fig. 26, 27).

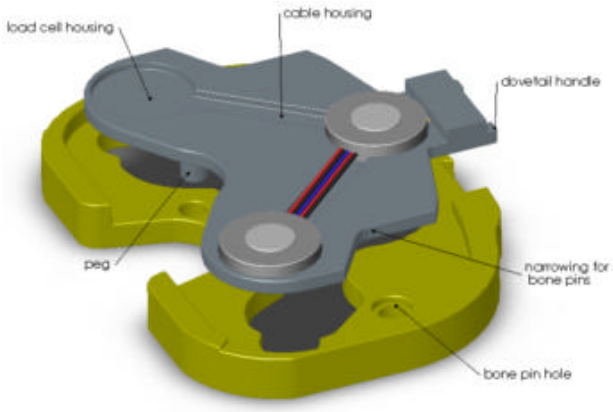



**Figure 26. Probe plate details**

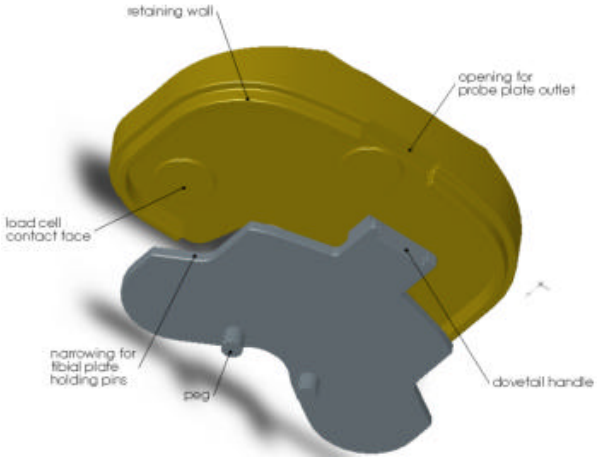



**Figure 27. Probe plate with articular surface**

In order to keep the bone pinholes functional, there are narrowings that reveal those holes. In the front part, the probe plate has an inlet for some kind of plug (to be determined). To facilitate ease of mounting, a dovetail handle is placed on the probe plate (Fig 27), which can be manipulated by the same instrument Zimmer provides.

The articular surface is slightly modified in this realization. The bottom part is currently not solid, as it comes out of the mould; the only thing to change is to add 3 slightly extruded faces, where the load cells contact the articular surface trial part, in order to avoid false reading because of any tissue or other impurities that could interfere between.

## Reading Device:

The reading device externally has handheld dimensions (fig. 28). There is a LED table that indicates the case that the current PCL evaluation falls. Two tests are required in order to fill this

table, one in flexion and the other in extension. Table 6 is suggested as a method of classification and includes 9 cases for each of which, there is a suggested treatment. For example, case TL indicates need for a thinner polyethylene component, or a smaller femoral component.


**Figure 28. The reading handheld device.**

**Table 6. The balance table**

| Flexion \ Extension | Tight | OK | Loose |
|---|---|---|---|
| Tight | TT | TO | TL |
| OK | OT | OO | OL |
| Loose | LT | LO | LL |

Below this table, a confidence meter shows how "deep" we are in the indicated LED table area. For example, in a case that the unbalance is not so great, but still the unbalance LED is on, the surgeon can identify there is no need for major changes.

The medial-lateral load indication shows if the difference between medial and lateral condyle load is within the desired range. So, the left light would go on if the left side is overloaded, the right-hand one would go on if the right-hand side is overloaded and the middle one if the distribution is within the expected range.

## Circuit Design:

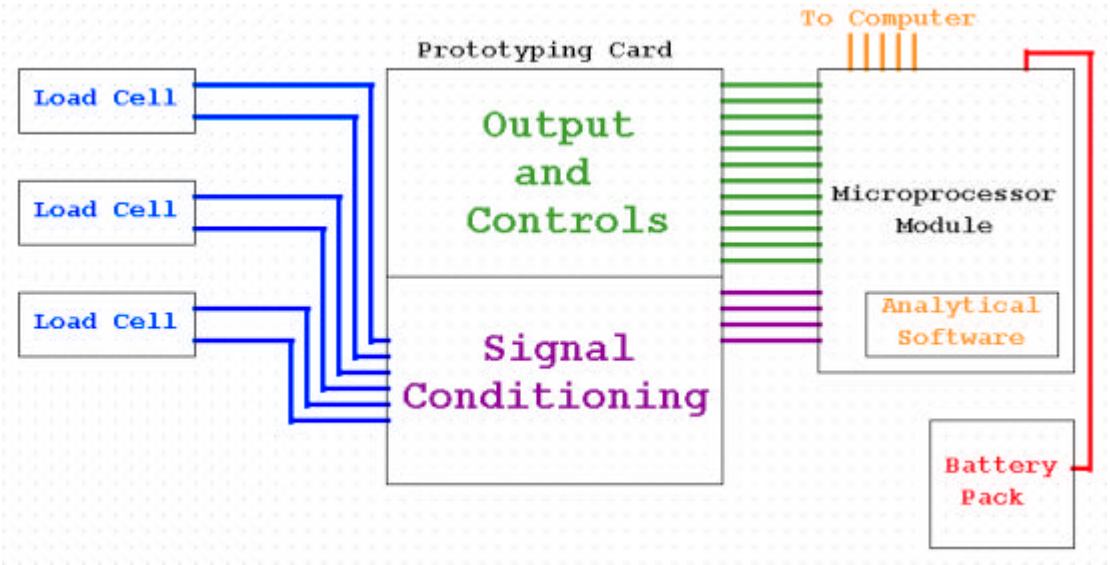



**Figure 29. Flow Chart of Circuit Design**

Figure 29 shows the flowchart of the circuit design. Briefly, the signal inputted from the load cells will be organized in the signal conditioning circuit and then sent to the microprocessor module for analysis. Analytical software in the on-board memory of the module will analyze the signals and then send the results to the output and controls circuit.

**Micro controller Module (Circuit Board).** A micro controller module will be utilized in the creation of the handheld reading device. The micro controller will be the "heart" of operations and will analyze and provide power to load cells, signal conditioning circuits, and output LEDs. The Adapt912 micro controller module offered by Technology Arts Inc. (in Canada) was chosen by our team due to the module's size, cost, ease of use, and functionality (Fig. 30). The Adapt912 has the compact dimensions of 2.25" x 3.25" and requires a DC voltage supply between 8 and 15V. As suggested, for our portable application, an 8.4V NiCd battery pack will be used to power the module. The module draws a nominal current of 50mA, which will allow the battery pack to be used to power other components of the device if needed. However, the on-board 500mA 5V regulator supplied by the module will be sufficient to power all the other components of the device.[22] See appendix F for the schematic of Adapt912.

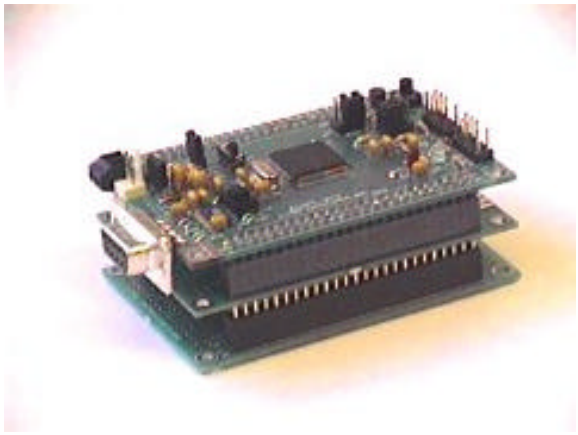


**Figure 30. Technological Arts Adapt912 Micro-controller Module (AD912B32SP) with two add-on Adapt12 prototyping cards. [22]**

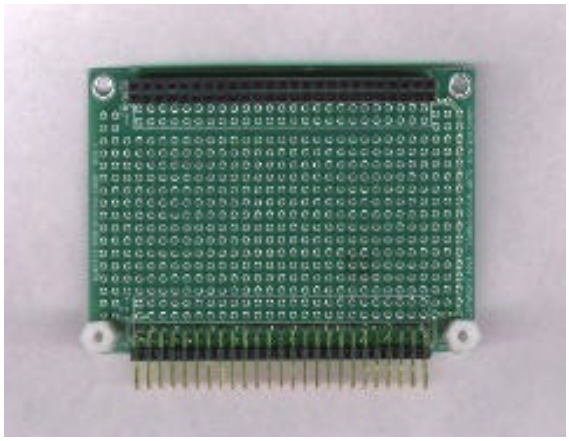


**Figure 31. Technological Arts Adapt12 prototyping card (Adapt12PRO1). [22]**

With a commercial cost of $130.00 for the starter pack (which includes a fully assembled and tested module with different connector options, ADHDR50-F adapter, standard 9-pin serial cable, and ribbon cable for BDM interface, user guide, and full schematic), the Adapt912 is very affordable for the creation of a medical device. A $15.00 Adapt12 add-on prototyping card (Fig. 31) was purchased for the placement of the signal conditioning circuit and output LEDs and switches. As seen in Figure 30, the prototyping card has the same dimensions as the Adapt912 module and does not significantly add-on to the overall size of the device, allowing the device to be portable.[22]

The ease of use of Adapt912 is illustrated by other components found on the microprocessor module. A total of 53 I/O lines, all programmable as input or output, is sufficient for the 3 input load cells, 11 output LEDs, and 3 switches the handheld reading device will utilize. An on-board 8-channel, 10-bit analog-to-digital converter will allow $2^{10}$ or 1024 steps of resolution at 5VDC. For example, at 5V input voltage, an analog 50 lb load cell will be able to measure forces in 0.049 lb (22.23 g) increments. The 32K on-board flash memory can be programmed using C, SBASIC, or assembler software languages. A supplied standard 9-pin serial cable will be used to download the force evaluation software from the computer to the module.[22]

Professor Ed Carryer, the professor for ME218(Smart Product Design, Stanford), recommended to use the Adapt912 module and has been a great aid to us in our project.

Technological Arts Website
Adapt912 Microprocessor Module: http://www.technologicalarts.com/myfiles/ad912.html
Adapt12 prototyping cards: http://www.technologicalarts.com/myfiles/ad12acc.html

**Load Cell.** Three subminiature load cells will be employed as sensors to determine the position and magnitude of tibiofemoral forces on the surface of Zimmer tibial trial inserts. Entran ELFM-B1 50 lb high stability subminiature load cells have been chosen for this purpose due to their small dimensions (Figure 32). These circular plate-like load cells are 3.2mm in height and 9.5mm in diameter (Figure 33). They employ miniature metallic foil strain sensors to guarantee high stability. With an excitation voltage of 5VDC and 350? bridge impedance, the ELFM-B1 can be powered directly through the 5V regulator that Adapt912 provides. The output voltage of ELFM-B1 is 2mV/V, which will be amplified 250 times in order to obtain an output voltage of 0.5V/V. This will allow for $2^{10}$?2 or 512 steps of resolution. The ELFM-B1 has a compensated temperature range of 60?F to 160?F and is made of stainless steel, which is appropriate for surgery room usage.

**Figure 32. Entran ELFM-B1 50 lb high stability subminiature load cells. [23]**

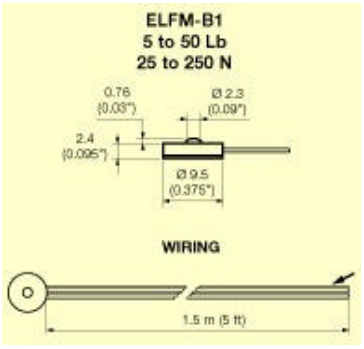



**Figure 33. Dimensions of ELFM-B1 load cells. [23]**

Entran Website
Entran ELFM-B1 load cells: http://www.entran.com/elfm.htm

**Signal Conditioning Circuit.** Signal conditioning is the transformation of an electric quantity from a sensor into a form appropriate for input into data acquisition systems. This often involves changing sensor output to a voltage, modifying the sensor's dynamic range to maximize the accuracy of the data acquisition system, removal of excess signals, and limiting the sensor's spectrum. Analog signal processing also reduces the processing load of the data acquisition system.

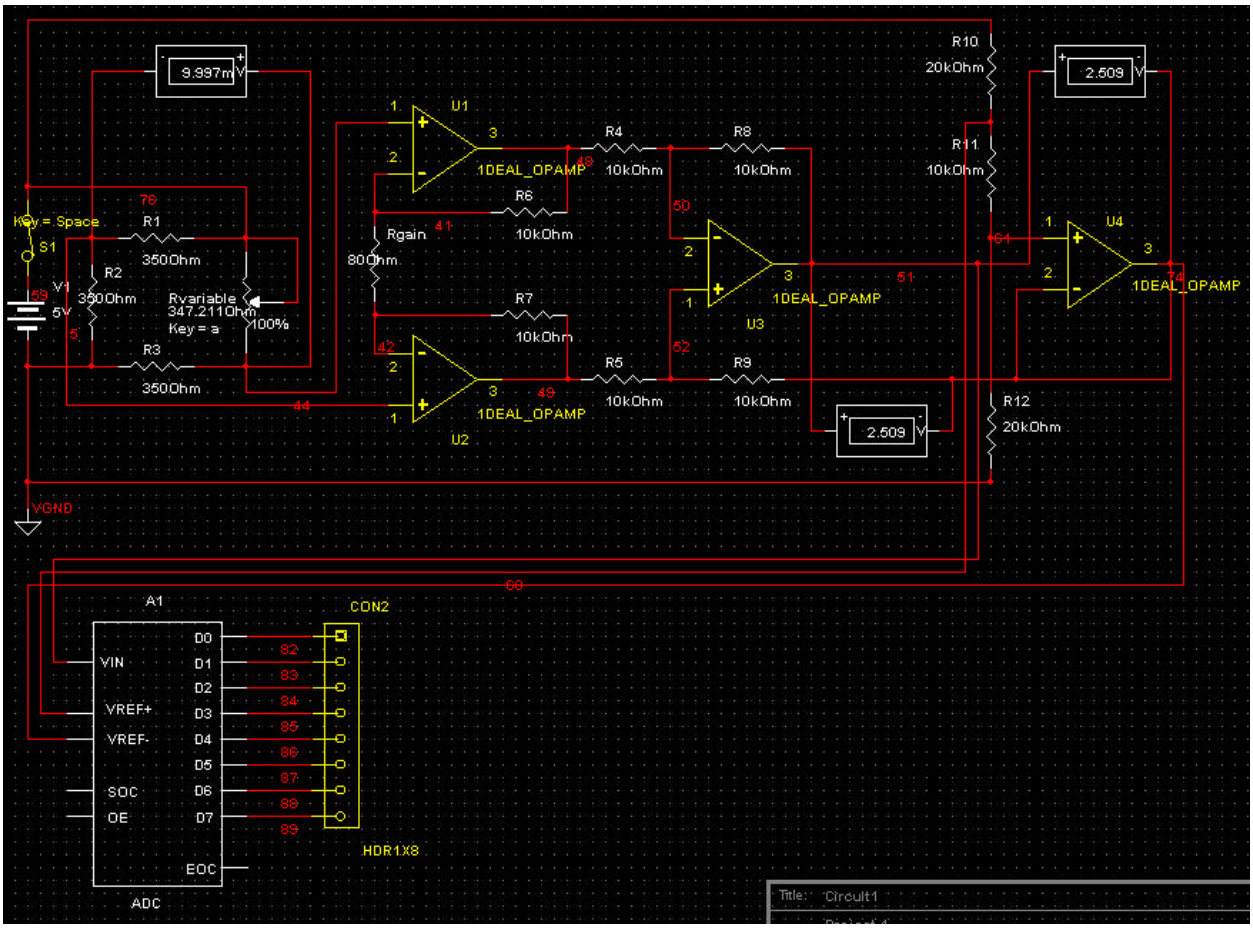



**Figure 34. Schematic of signal conditioning circuit.**

The schematic of the signal conditioning circuit which will be used to connect the ELFM-B1 load cells with the Adapt912 microcontroller module is shown in Figure 34. In order to validate the functionality of the circuit, the circuit was simulated using Electronics Workbench MultiSIM v6.20 provided by Stanford's ME282 class. An ideal instrumentation amplifier (IA) made of 3 ideal op-amps was used to amplify a 10mV (at 5V excitation) load cell output 250 times (gain) to 2.5V (Fig. 34). The overall differential gain of the IA can be calculated from the equation

$$A_{VD} = [1 + 2(R_3/R_G)](R_2/R_1)$$

where $R_1$, $R_2$, $R_3$, and $R_G$ are the values of the resistors show in Figure 35 below. The IA was utilized in our circuit design because it offers many advantages over the use of a non-inverting amplifier. The IA provides an accurate and stable finite gain, usually between 1 and 1000. Instrumentation amplifiers offer high input impedance and low output impedance.[24] They also have a extremely high common mode rejection ratio (CMRR), which is the ratio of the gain of the amplifier for differential-mode signals ($A_{VD}$) to the gain of the amplifier for common-mode signals ($A_{VC}$) or

$$CMRR = A_{VD}/A_{VC}$$

where

$$A_{VD} = V_O/(V^+ - V^-) \quad \text{and} \quad A_{VC} = 2[V_O/(V^+ + V^-)].$$

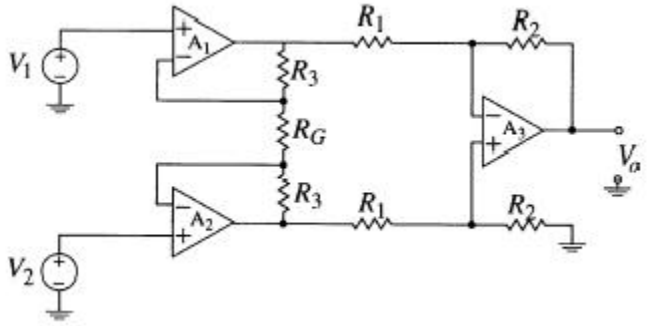



**Figure 35. Instrumentation amplifier. [24]**

Analog Devices AD620 is the commercial IA that our team chose to employ in our circuit design (Figure 36). It requires only a ?2.3V to ?18V voltage supply and 1.3mA (max) of current. This allows the AD620 to be directly powered by the 5V regulator on the Adapt912 module. Other desirable qualities of the AD620 include: (1) high accuracy of 40 ppm maximum nonlinearity, (2) low offset voltage of 50?V max, (3) low offset drift of 0.6?V/?C, (4) low noise of 0.28?V peak-to-peak, and (5) low input bias current of 1.0nA max. The gain obtained from AD620 can be programmed with a single external resistor. The value of this resistor can be calculated using the equation

$$R_G = 49.4k? /(G-1)$$

where G is the gain desired.[25]

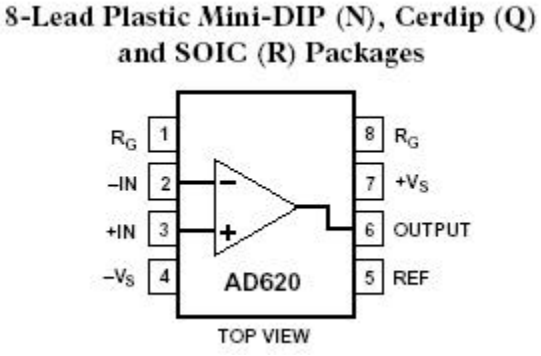



**Figure 36. Analog Devices AD620 low cost, low power instrumental amplifier. [25]**

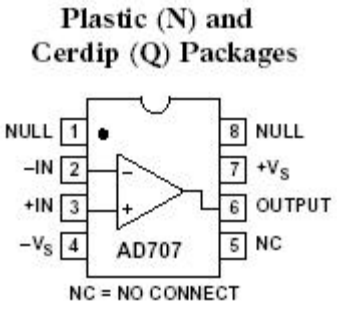



**Figure 37. Analog Devices AD707 ultralow drift op-amp. [25]**

Analog Devices AD707 is the op-amp that our team chose to use in the construction of a unity-gain buffer (Fig. 37). This buffer will isolate the instrumental amplifier by preventing it from being loaded down by the analog-to-digital converter. Unity-gain buffers usually have high input impedance and low output impedance. The AD707's 13V/?V open-loop gain, 140dB

CMRR, high DC precision, and ultralow drift makes it a good candidate for precision instrumentation applications.

Electronics Workbench Website: http://www.electronicsworkbench.com/
Analog Devices AD620 IA: http://products.analog.com/products/info.asp?product=AD620
AD705 Ultralow Drift Op-Amp: http://products.analog.com/products/info.asp?product=AD707

**Output Circuit.** As discussed in the Reading Device section, the main output of our device will be a 3 x 3 array of red LEDs, which will be used to display whether there is too much, too little, or just the right amount of tibiofemoral forces in different locations on the tibial trial implant surface. Two additional green LEDs will be used in the output circuit and will light up if there is too much tibiofemoral forces (compared to normal) on either two sides (medial or lateral) of the tibial trial insert. LEDs suitable for these tasks were found on Digi-Key Corporation website. The Fairchild Semiconductor HLMP-1700 (red), 1719 (yellow), and 1790 (green) LEDs found on the website were highly compatible with the Adapt912 module. They required only 1.8-1.9V and 2.0mA of current for operation and produce an intensity of 2.0mcd.[26] The dimensions of these LEDs are shown in Figure 38.

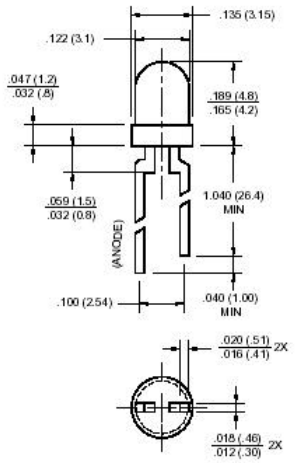



**Figure 38. HLMP-17XX low current LEDs. [26]**

One switch and two buttons will be utilized in the output circuit to control the power supply, measurement of flexion tibiofemoral forces, and measurement of extension tibiofemoral forces, respectively. The type of switch or button that will be employed is still current undecided.

Fairchild Semiconductor HLMP-17XX LEDs: http://www.fairchildsemi.com/ds/HL/HLMP-1700.pdf

## Mechanical Analysis:

In order to calibrate and validate the function of the system, we need to know how the applied load from the femoral component is transmitted to the load cells. Using finite element analysis, the distribution of loads is estimated for various loading conditions.

For the FE model MSC NASTRAN software was used; CAD geometry was imported as .igs format file. The model consists of approximately 15,000 tetrahedral elements (fig. 39).

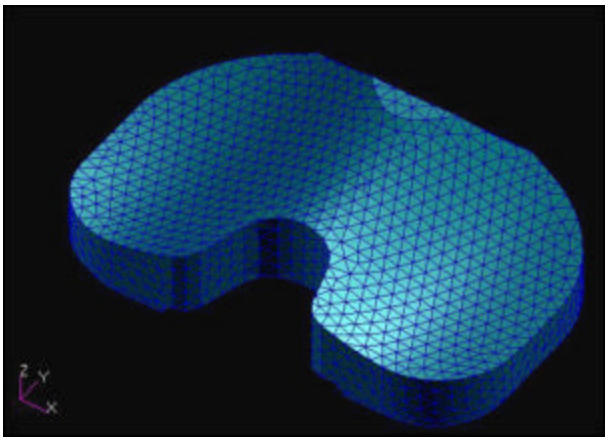


**Figure 39. The model after meshing is applied.**

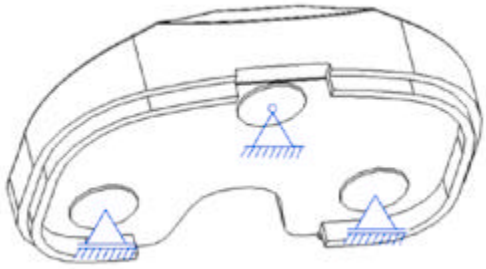


**Figure 40. Boundary conditions assumed for the FE model**

Not much attention was given to material properties since there is no interest on the intra-distribution of stresses but on the resulting contact forces. As for boundary conditions, on the posterior contact faces, spatial translation restriction is set for the Z direction, on the anterior contact face, XYZ restriction is assumed in order to have a well-defined model (fig. 40). No restriction for rotations has been assumed. The total load applied in all cases was 100 while load position and distribution was determined from Zimmer's studies using either Tekscan system or Fuji film that was placed between the surfaces, imprinting thus the trace of the load. Figure 42 shows the hypothetical load conditions fro our FE model.

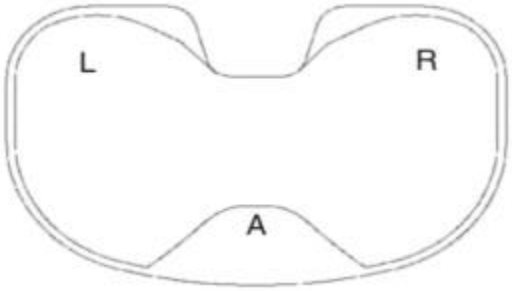



**Figure 41. Articular Surface (Top View)**

**Table 3. Load Distribution on Articular Surface with Respect to Flexion Angle**

| Load case | Total Load | Distribution Between Condyles | | Load cell | | |
|---|---|---|---|---|---|---|
| | | LC | RC | A | L | R |
| Flexion | 100 | 50 | 50 | 6 | ~47 | ~47 |
| Extension | 100 | 50 | 50 | 28 | ~36 | ~36 |
| Uneven | 100 | 60 | 40 | 22 | 46 | 32 |

A very important and interesting outcome is that stresses are not uniformly distributed on the contact faces, this has to be investigated further in order to determine its effect on the load cell output signal. This nonuniformity might be significant. Load cells are made of 4 strain gages in polar placement ($90^o$ angular distance), the orientation is very important. Alternatively, load cells that have a very small contact area can be used in order to eliminate inaccuracies.

In the first load case, flexion condition is simulated, showing very little load in the anterior load cell. In the second case, that is extension, the anterior load cell seems to be more

loaded than before, but still less than the other two, while even distribution is observed on the posterior sensors. In the last case, an uneven distribution between the two condyles (60%, 40%) is supposed; the uneven loading results in a different force applied in the two posterior sensors. Load cells proposed for the posterior part have a maximum loading of 25lb, which seems too much for the anterior load cell that receives less loads. So, a lower capacity load cell might be used for this part in order to keep its output signal in satisfactory range. Table 6 shows the results of the contact forces, summed over each load cell contact surface for each load case.

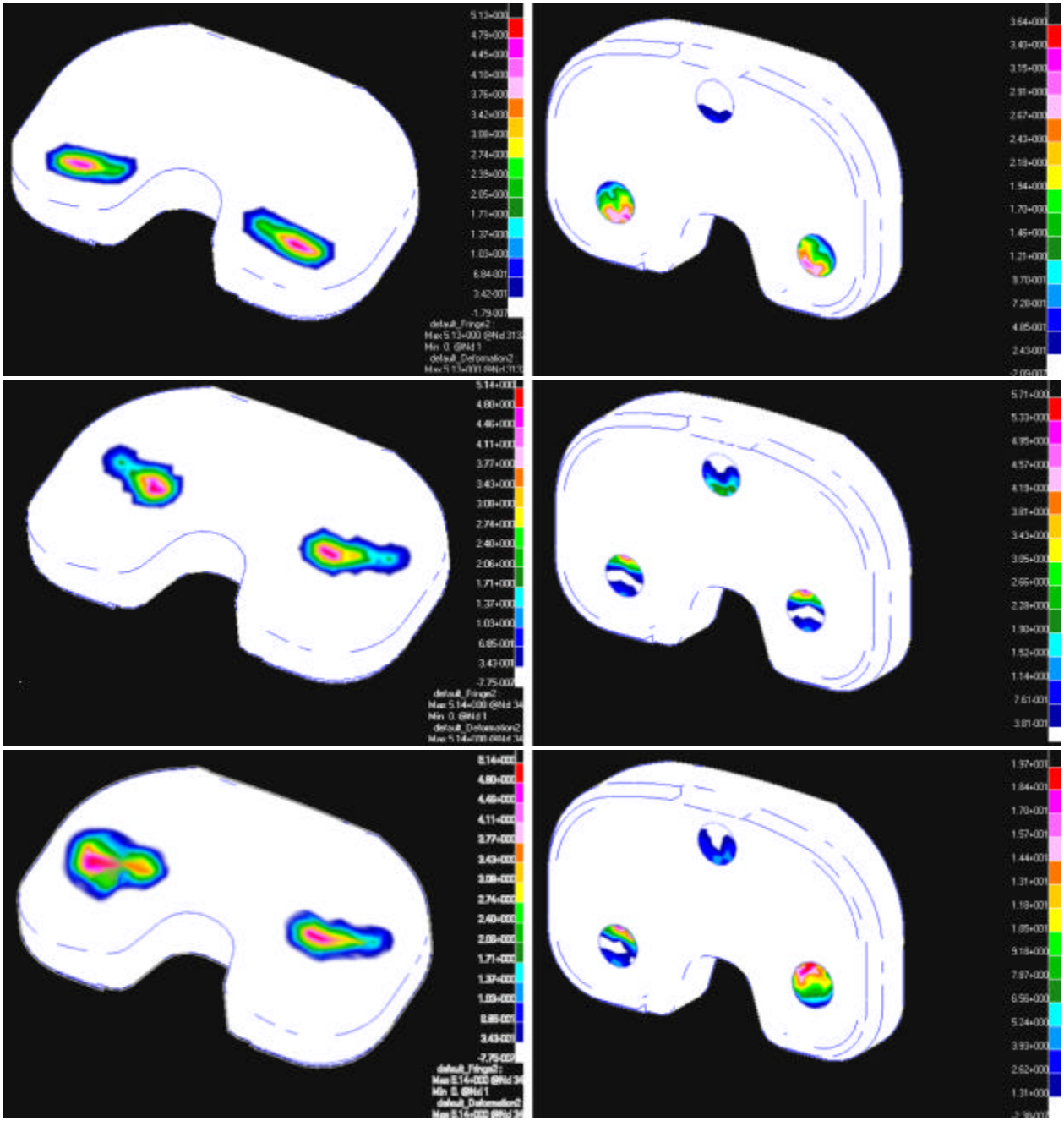
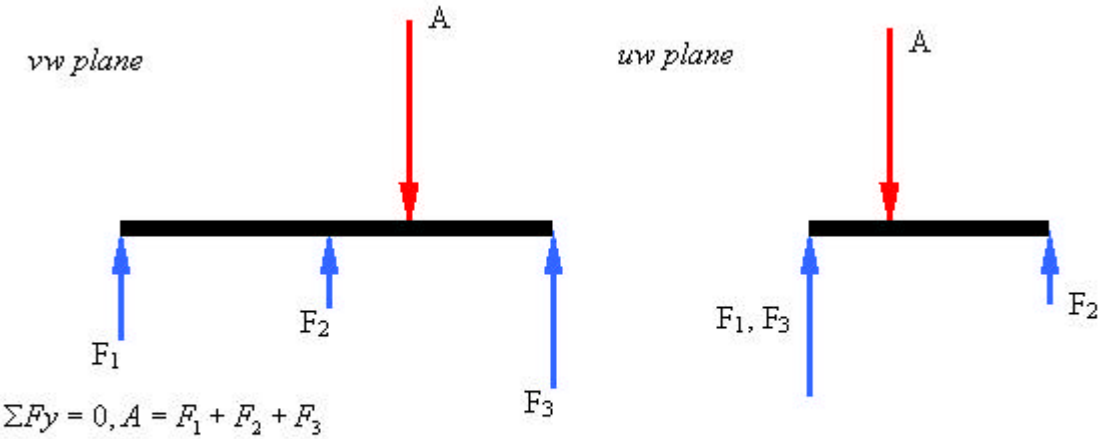


**Figure 42. The three hypothesized load cases. Left column shows the applied loads, right column shows the resulting stresses on the polyethylene-load cell contact faces. The first case simulates a 90° flexion test, the second case is simulating a full extension condition (0? flexion). The third case is an uneven (60-40) load condition in knee extension test.**

To simplify this procedure we need to come up with a simpler model, making rational assumptions and using static equilibrium. In order to estimate the position as well as the magnitude of the two applied forces, one from the medial condyle and one from the lateral, we first calculate a net force, resulting from these two. In this analysis coronal and sagital views are examined. Suppose coronal plane is vw plane while sagital is uw plane:




$$\Sigma Fy = 0, A = F_1 + F_2 + F_3$$

$$\Sigma M_o = 0, F_1 a - F_3 a - Ax = 0$$

$$So, \boxed{x = \frac{(F_1 - F_3)a}{F_1 + F_2 + F_3}}$$

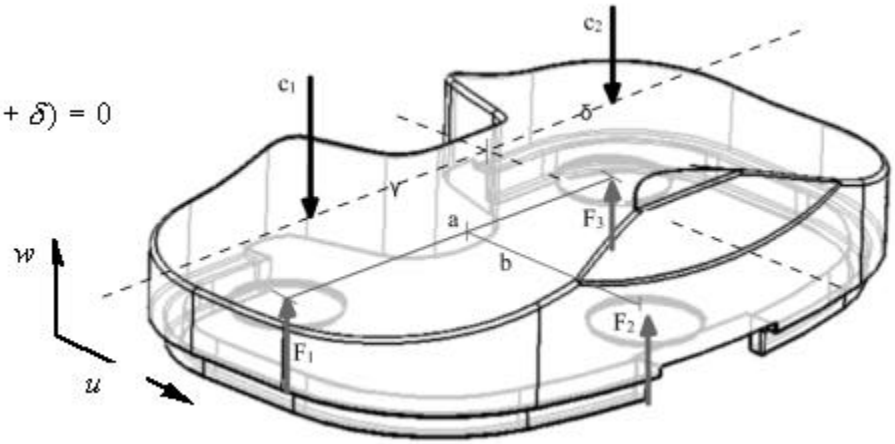
$$\Sigma M_o = 0, \quad F_2\, b - yA = 0$$

$$So, y = \frac{F_2\, b}{F_1 + F_2 + F_3}$$

$$c_1 + c_2 = A$$

$$\Sigma M_1 = 0, (\gamma + x)A - c_2(\gamma + \delta) = 0$$

$$\boxed{So, c_2 = \frac{(\gamma + x)A}{\gamma + \delta} \qquad and, c_1 = \frac{(\delta - x)A}{\gamma + \delta}}$$




Position of the net force is calculated: x, y (x is measured from the symmetry line, from the middle of the component). Then assuming that the two contact points lie on a line parallel to the coronal plane we can precisely calculate $C_1$ and $C_2$, their position on the v direction will be the same found for the net force A. This is a valuable piece of information since femoral rollback also is a way to determine PCL tension. In this analysis, a is the distance between the two posterior load cells, b is the distance between the anterior load cell and the two posterior, ? is the distance between the tibio-femoral medial contact point and the axial symmetry line of the articular surface, and d is the corresponding distance for the lateral point. Distances a, b come from our design, ?, d come from studies showing where the contact point is (Zimmer).

## Microprocessor Programming:

The signal from the load cells is read and averaged over a predefined duration giving 3 values (variables), L, M, A that correspond to loads $F_3$, $F_1$, $F_2$ respectively (calibration between voltage drop and load will be performed). The right/left switch is adjusted according to the knee that is under inspection giving a value to the variable Knee = RT or LT; for example, the default is right knee and if Knee = LT, then M swaps values with L. The surgeon presses either the flexion or the extension measurement button EX / FL.

Using the formula found above for $C_1$, $C_2$, y we can classify the examined case. First, summation of $C_1$, $C_2$ occurs. A threshold $T_1$ as well as a tolerance c has been predefined for this measurement. So, according to the outcome of the comparison $T_1$-c < $C_1$ + $C_2$ < $T_1$ + c, for both extension and flexion tests, a first clue can be identified and power thus the corresponding LED. At the same time, ratio $C_1/C_2$ is calculated and depending on the comparison with another threshold $T_2$ ? tolerance d the lateral/medial load unbalance indicator is powered. Optionally, ABS ($S_{Ci}$ – ? $_1$) is calculated showing the confidence of the measurement. Another feature that has been estimated is the femoral rollback. So, if $y_e$ were the contact line distance in the extension measurement and $y_f$ is the contact line distance in the flexion measurement, ABS($y_e$-$y_f$) can be calculated; this is the femoral roll back. This measurement can also be represented in the reading device, using for example a series of LEDs: the number of LEDs powered on will be proportional to the roll back.

# VI Project Plan

## *Overview*

With the completion of the final design, the next step in the project plan is to construct a functional prototype of the PCL evaluation device. This milestone needs to be completed as soon as possible to allow for reliability and validation testing. Accuracy and repeatability testing will be done in conjuncture with the testing of the device in cadavers. Using cadavers, the relation between PCL tension or femoral rollback and tibiofemoral forces can be scientifically determined. Slight modifications will be made to the final prototype, as needed, to improve its functionality. The final deliverable to Zimmer Inc. will be a functioning prototype, which has undergone testing, validation, and revision.

## *Deliverables*

Specific deliverables, as specified by Zimmer PCL, include a functioning prototype that has undergone preliminary testing, validation, and revision. The prototype will be further evaluated and tested by Zimmer Inc. for safety, marketability, manufacturability, and other factors. If successful, the device will be incorporated into Zimmer's TKA NexGen? prosthesis kit to make the prosthesis more attractive to orthopaedic surgeons and patients. An alternative method to market our device will be to sell the device separately.

Again, the invention of a portable device to evaluate the potential success of TKAs will bring more scientific validity into the procedure. The device will also aid less experienced orthopaedic surgeons in performing a successful TKA. A decrease in the premature failure of Zimmer NexGen prosthesis will make the prosthesis very attractive to consumers of all ages.

## *Methodology*

Methods and resources which will be used to produce the deliverables are as follows:
(Please refer to the timeline for details)

**Background**

1. Lane Medical Library- good source for finding research papers from the literature review, books on the anatomy and physiology of PCL, and books on TKA
2. eJournals (Lane Medical Library Website)- good source for finding research papers from the literature review

**Design Considerations**

1. Zimmer Inc.- used Zimmer's presentation and conference meetings to clarify problem definition
2. Delphion IP Patent Website
3. WWW Search for Benchmarking

**Design Process**

1. Procedure for Brainstorming: preliminary designs ? evaluation of designs using Pugh analysis ? feedback from Zimmer Inc. ? modify and finalize design
2. FEA- used to investigate the load distribution of insert probe CAD model
3. CAD model of Insert Probe Design (see FEA)
4. Basic Circuit Handouts- used to create the signal conditioning and output/controls circuit
5. MultiSIM 6.20 Software- used to simulate the signal conditioning circuit in order to validate it's functionality

**Prototyping**

1. Zimmer Inc.- will aid us in the prototyping of probe metal plate
2. Electronic Instruments- will aid us in the creation and testing of the circuit

**Validation**

1. Stanford Medical School- medical school anatomy classes will be a resource for knee-joint cadavers
2. Mechanical Testing Machines- perform accuracy and repeatability tests

## *Reliability and Validation*

A testing protocol will be developed to ensure that the device satisfactorily meets reliability requirements. First of all, we need to validate how accurate the probe plate with load cells measures the applied contact force. We did not yet establish accuracy threshold. However, the accuracy of 5 to 10 % within real value is acceptable for our device. Secondly, we also should verify how probe plate generates repeatable results for the same applied contact force. The null hypothesis of no significant difference between results can be established. Then, the significance level of 5 % or 10 % can be used whether the null hypothesis will be rejected or not. Those testing can be conducted using general compression tester such as Instron universal testing system or tekscan system in Zimmer.

We also consider testing with cadaver knee in order to simulate real loading condition. The contact point and load distribution will be changed depending upon flexion angle. We need to set up a testing protocol to show what specific position and activity is required to ensure correct result. For that purpose, cadaver knee or plastic knee model is required. We can also compare measurements with finite element analysis results, already created to evaluate load distribution of the modified articular surface trial.

## *Major hurdles*

Many difficulties will be encountered in the prototyping of our medical device. Some of these difficulties include:

(1) supplying the correct amount of power to each component of our circuit,
(2) machining of Zimmer PE tibial insert to be compatible with the load cells,
(3) prototyping of the "insert probe" plate through machining, and
(4) programming the software which will analyze the signals inputted from load cells.

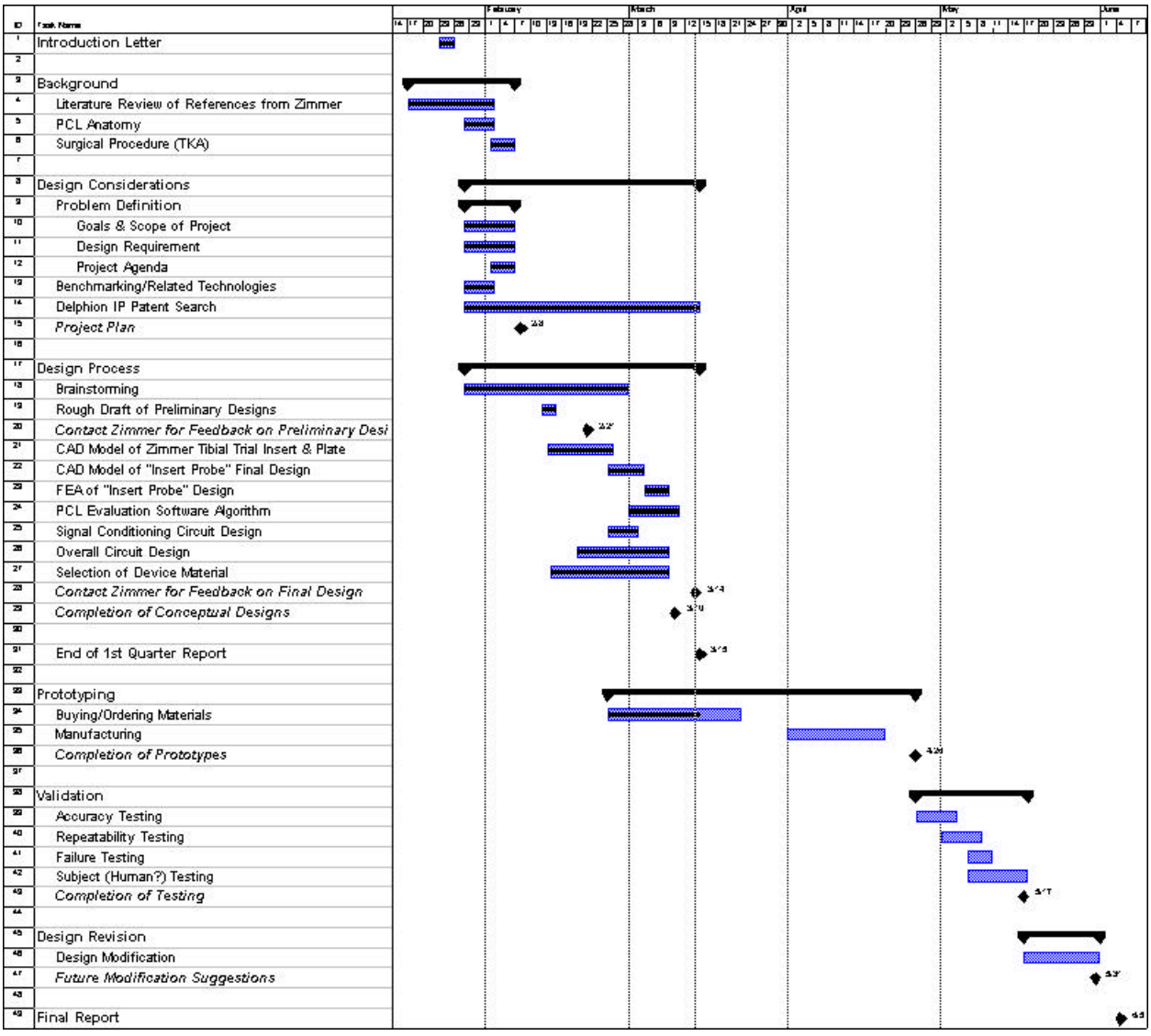
The difficulties which are the most important to attack are the creation of the "insert probe" and making the circuit functional. A functional circuit will allow us to determine the stability of the load cell output and will also allow for the validation of the device through compression and cadaver experiments. The "insert probe" must be created in order for us to test if the evaluation software can correctly determine the position and magnitude of a contact force.

In order to reduce the amount of time needed for prototyping, we have already requested Zimmer Inc. to aid us in the modification of the PE tibial insert and the prototyping of the "probe plate". Due to tremendous help from Professor Carryer, the circuit should be relatively simple to assemble. However, if circuit problems do arise, the Zimmer PCL Team will attempt to seek help from EE (electric engineering) professors and facilities.

Currently, the Zimmer PCL Team has no fallback plans. However, we will attempt to create our prototype early in spring quarter. This will allow us to adjust or replace problematic portions of our design.

## *Timeline*

**Table 4. Timeline of Completed Milestones (Winter Quarter) and Plans for Next Quarter**




By the end of Winter Quarter, the Zimmer PCL Team has completed the final design of our PCL evaluation device. To arrive at this stage, we started off with researching the background of this project by reading and evaluating the literature review given to us by Zimmer (Appendix C), by

discovering the PCL anatomy and physiology through medical books, and by learning the procedure of TKA through documentary TKA videos. This process was completed in 16 days.

Defining the problem and searching for related technologies that are patented or currently in the market was our next focus. The Delphion IP patent search has taken a considerable amount of time due to the large amount and difficulty of reading patents related to our project. Meanwhile, the design process was initialized through the brainstorm and the development of preliminary designs. On Feb. 21, we contacted Zimmer for feedback on these designs. Zimmer was really enthusiastic in our "load cell on bottom of tibial insert" design. We followed up on this design by developing two more load cell mounting methods (see Preliminary Designs section). Due to certain advantages of the "insert probe" design, we decided to use this method of load cell implementation for our device. FEA was done on a CAD model of the insert probe design to provide initial validation for our design.

At the same time, other members of our group worked to design the circuit needed to produce the "electronic load cell measurement device". With the help of Professor Carryer, whom teaches the ME218 series (Smart Products Design), components of the device were chosen by March 8. Each component for the circuit was ordered as soon as possible so that the prototyping process can begin smooth.

Zimmer PCL Team's first task next quarter is the construction of a functional prototype. This prototype must be completed by April 19 to leave sufficient time for testing and validation. Zimmer Inc. has agreed to aid us with the prototyping of the insert probe. Accuracy and repeatability testing will be done in conjuncture with the testing of the device in cadavers. Testing on human subject can occur only after the failure and safety testing have been completed. All through the validation period, the design of our prototype will be slightly modified, if needed.

## *Individual responsibilities of team members*

The Zimmer PCL Team was divided into two subteams:

(1) two people to design and machine the Zimmer PE trial insert and "insert probe" plate and
(2) two people to design, construct, and test the circuit needed to analyze load cell signals.

Eric Bean currently works for a biomedical device startup company and brings with him broad-based real-world experience necessary for successful product development. His specific tasks include Delphion IP patent search, FDA regulatory consideration, prototyping, and time management.

Kai Jair has phenomenal organizational and project management skills. He is in charge of defining the anatomical/physiological aspects of the project, designing and constructing the circuit needed for signal analysis, and creation and maintenance of Zimmer PCL Team Website.

Lampros Kourtis has worked on numerous medical device design projects. He is responsible for designing/CAD modeling the Zimmer PE tibial insert and "insert probe" plate, running a FEA on the CAD models, prototyping, and programming the software needed for signal analysis.

Choongsoo Shin is experienced in the creation of electronic circuits and the utilization of micro-sensors. He is in charge of constructing and testing of the circuit needed for signal analysis, generation of methods for reliability and validation testing, and evaluation of current design(s).

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# VIII Appendices

***Appendix A) Presentation Slides***

***Appendix B) Expenses***

***Appendix C) Summary of Literature Review***

***Appendix D) Patent Search Information***

***Appendix E) Design Sketches of Insert Probe***

***Appendix F) Specifications of Circuit Components***

***Appendix G) Checklists from Executive Committees***

***Appendix H) Other Information***

## *Appendix A) Presentation slides*

## *Appendix B) Expenses*

**Table 5. Expenditure to Date**

| Date | Description of Purchase | Cost | Remaining Budget |
|---|---|---|---|
| 1/07/02 | Beginning of Quarter | ----- | $5000 |
| 1/21/02 | PRL Shop Licenses for 3 | $510 | $4490 |
| 2/22/02 | Adapt912B32SP + Prototyping Card Addon | $155 | $4335 |
| 2/25/02 | Delphion IP Website Membership | $75 | $4260 |
| 2/28/02 | Low Current/Voltage LEDs | $26 | $4234 |
| 3/05/02 | Entran ELFM-B3 Subminiature Load Cell | $447 | $3787 |

**Table 6. Projected Expenditures for Next Quarter**

| Date | Description of Purchase | Cost | Remaining Budget |
|---|---|---|---|
| 01/07 | Beginning of Quarter | ----- | $5000 |
| 01/21 | PRL Shop Licenses for 3 | $510 | $4490 |
| 02/22 | Adapt912B32SP + Prototyping Card Addon | $155 | $4335 |
| 02/25 | Delphion IP Website Membership | $75 | $4260 |
| 02/28 | Low Current/Voltage LEDs | $26 | $4234 |
| 03/05 | Load Cell | $447 | $3787 |
| Spring Quarter | 3 more load cells | $1300 | $2487 |
| Spring Quarter | Misc. Prototyping Materials | $1000 | $1487 |
| Spring Quarter | Business Trip (x4 persons) | $1200 | $287 |
| Budget Margin | | | $287 |

## *Appendix C) Summary of Literature Review*

## *Appendix D) Patent Search Information*

## *Appendix E) Design Sketches of Insert Probe*

## *Appendix F) Specifications of Circuit Components*

## *Appendix G) Checklists from Executive Committees*

**Regulatory and Standards Checklist**

Checklist for Zimmer PCL project. Answers are shown in blue.
(this checklist provided by Regulatory Standards Executive Committee)

### *1. What is your project?*

Please briefly describe the project you are working on:
To design and prototype a PCL tension evaluator for Total Knee Arthroplasty.

Please describe potential solutions that you are considering for your project:
1. Direct: device fits between the tibiofemoral gap and grasps PCL to measure tenstion.
2. Indirect: device uses pressure sensors at artificial articular surface to measure pressure/force and calculate PCL tension.

List and briefly describe any potential solutions that have biological or chemical components.
None

List and briefly describe any solutions that emit radiation.
None

### *2. Project Scope*

List which solutions involve developing a completely new device.
both

List solutions reusing a known technology, approach, or process.
none

Are any solutions based on other devices?
1) Other devices exist to evaluate PCL and ACL integrity but they are quite large and more involved than we seek. 2) Other devices exist that are used to align the knee during ACL reconstruction that grasp the PCL through the tibiofemoral gap. Our device would add on that functionality to also measure tension.

If so which devices?
1) KT 1000
2) Tension Isometer TI-1000 MedMetric

Were the device(s) developed before 1976?

No

How are they similar?

1) the KT 1000 evaluates knee integrity by measuring displacement of the tibia with respect to the femur. We may do something similar, but at a smaller level
2) the TI-1000 just grasps the PCL, we want to graps the PCL and then measure tension.

Does your solution pose any new risks?

No.

Utilize any new technologies?

Possible load/cells pressure sensors.

Are any of your solutions used with other devices or treatments?

No

If so, what devices or treatments?

Are they life critical?

No

### *3. Safety*

Does you project pose any dangers to patients, physicians, or others?

Not if used correctly

If so, how?

Is it life threatening?

### *4. Sponsor recommendations*

What classification does your sponsor want your group to aim for?

Unsure, need to find out.

What premarket approval process do they envision for your project?

Unsure

### *5. Assuming your project is a device:*

This last section of the checklist is intended to help start your project's FDA identification/ classification process and to document your progress. In order to guide you through this process, this document utilizes the FDA website's device advisor (see step 1). Note: at various points

along the process the website offers more information to help you answer questions; these questions/links are not in this checklist.

Steps:

1) Open http://www.fda.gov/cdrh/devadvice/31.html
2) Does the product emit radiation? Yes / No
3) Does Your Product Meet the Definition of a Medical Device? Yes / No
4) Do you know the class of your device?
    a. If yes jump to 5
    b. If no:
        i. Read section on "How to determine Classification"
        ii. Use the Classification Database or the Device Panels (circle which you used)
5) Record the following information:

Device: PCL Tension Evlauator fits into Template for Clinical Use

Medical Specialty: Orthopedic

Product Code: 21 CFR 888

Device Class: Class I

510(k) exempt?: yes

Regulation Number (7 digit): 888.4800

**Device Description :**

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[**CITE**: **21CFR888.4800**]

[Page 475-476]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 888--ORTHOPEDIC DEVICES--Table of Contents

Subpart E--Surgical Devices

Sec. 888.**4800** Template for clinical use.

(a) Identification. A template for clinical use is a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.

[[Page 476]]

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

6) Which are required: Exempt
(circle which apply – known from the above classification)

7) The next steps in the regulatory process depend greatly on your specific project. See the regulatory team for guidance if you are uncertain of your next steps.

## *Appendix H) Other information*

**Materials Needed for Next Quarter:**

1. Voltmeter
2. Power Supply
3. Electrical Wires
4. BNC Connectors
5. Compression Mechanical Testing Machine