Osteochondral Transplant Delivery System

Preliminary Report

Biomedical Engineering Design 200/300
Department of Biomedical Engineering
University of Wisconsin
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Abstract

There is a need for osteochondral allograft procedures to repair defects at the articular surface primarily at the lower femoral aspect. The current surgical procedures tend to use impaction, which compromises the viability of the chondrocytes within the cartilage layer. This leads to a higher failure rate in grafts because of the limited regenerative capacity of chondrocyte tissue. Thus, a design must be developed that reduces the mechanical forces exerted on the cartilage layer atop the allograft during insertion in order to obtain higher chondrocyte viability postoperatively. The design alternatives consist of a suction system used to screw a threaded graft into a recipient site with mating threads, a similar design that instead uses tines inserted into the graft to turn it into the recipient site, and a system that incorporates a threaded synthetic casing that can be turned into the recipient site. The design selected for pursuit for the remainder of the semester is the suction screw system. Current testing has shown that high strength threads can be made into bone. Further work will involve designing a method of creating a threaded plug and testing forces necessary to turn the graft into the recipient site. Modifications may be made after design testing.

Introduction

Motivation

In the United States alone, over 500,000 cartilage repair procedures are performed annually (1). Damaged articular cartilage surfaces from blunt trauma or disease induce a degenerative cascade of bone that ultimately results in osteoarthritis (Figure 1). Symptoms experienced by individuals with osteoarthritis include varying degrees of pain and loss of anatomical movement or altered function of the diseased bone. The majority of defects from osteoarthritis are treated with osteochondral grafting techniques. While this is a general approach commonly used today, it exhibits a 30% failure rate on account of its delivery method (1). Currently there is no procedure that is either consistent or reliable in allowing for the regeneration of cartilage. Consistent deterioration of bone occurs if the defect is left untreated, and because of the ineffective methods for treatment, there is a need for a novel procedure that will allow for effective treatment of osteochondral injuries.

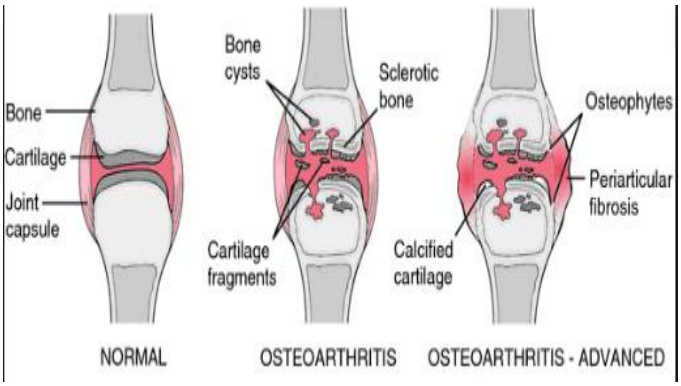

Figure 1: A diagram depicting differences between healthy bone and various cases of osteoarthritis.

Existing devices/Current Methods

Current surgical methods used for osteochondral transplants often exceed the mechanical limit for maintaining chondrocyte viability and long-term survival of the cartilaginous surface on the femoral head (4). The general procedure for an osteochondral allograft begins by placing a sizing cylinder perpendicular to the defect, a guide pin is then drilled through the cylinder into the defect. Using another cylindrical sizing device, the proper trajectory for the recipient site is viewed. A reamer is then used in conjunction with the guide pin in order to create the full size recipient site (Figure 1). Since the guide pin fits into the reamer, the trajectory depends upon the angle of insertion of the guide pin. Subsequently, measurements of depth are taken from the four quadrants of the cylindrical recipient site. A similar site to the recipient site is harvested from the donor tissue using a hollow bore reamer

or a similar cylindrical harvesting device. The plug is then sized appropriately according to depth and diameter dimensions of the recipient site using a sagittal saw. A calibrated dilator (13) or bevel of the bone in the recipient site (15) can be utilized to obtain a press fit by hand, but often impaction is required to obtain a tight fit and appropriate seating into the recipient site (13). Often times impaction is necessary to acquire a proper fit into the recipient site to allow for graft integration. This impaction often exceeds mechanical limits a portion of the chondrocyte tissue on the donor plug. This can ultimately cause associated cartilage disorders due to the lack of viable tissue. This issue is roughly associated with under 70% chondrocyte viability postoperatively (9). The graft must be flush with the articular surface (Figure 3) and if not, the surgeon must drill into the plug, remove it from the recipient site and make sizing adjustments of the recipient site or graft as necessary.

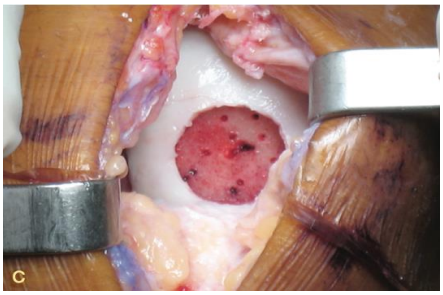

Figure 2: The recipient site for the bone graft.

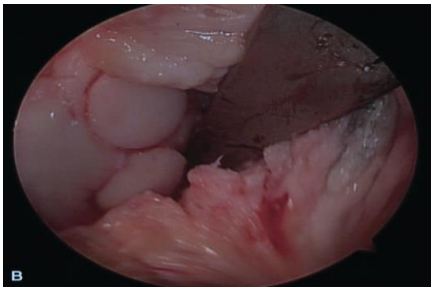

Figure 3: Multiple bone grafts after insertion into recipient sites

Problem Statement

Despite the demand for osteochondral transplants, mechanical loads applied in current methods of implantation have detrimental effects on the live chondrocytes present on the bone that replaces the defect. Healthy chondrocytes in the donor bone are required to prevent degeneration of the implanted tissue after the surgery and ultimately allow for a correction of the initial defect. Maximizing the amount of viable donor tissue during and after implantation is a crucial factor for the success of the procedure. Hence, the proposed delivery system will aim to reduce the amount of damage done to cartilage during implantation of the donor tissue and strive to increase chondrocyte viability following mechanical loading.

Background

Client Information

Dr. Brian Walczak of the Orthopedic and Rehabilitation department at the UW Hospital proposed an incentive for the design of a delivery system for osteochondral grafting procedures. Specifically, it was requested that the system either reduce or eliminate the need for impaction forces on the donor tissue during delivery into the recipient site in order to minimize potential chondrocyte damage. Furthermore the delivery system would have the ability for application in procedures with defects varying in size. These criteria to be implemented without exceeding a budget of $300.

Background Research

A large emphasis was placed on the system's ability to reduce impaction forces because, as aforementioned, current procedures used for osteochondral allografting often require the application of compressive uniaxial loads on the surface of the donor bone. This compressive force damages the healthy cartilage and can lead to complications with the transplant after the surgery. The effects of these compressive loads were observed in a study that duplicated the general procedure used in osteochondral allograft transplants with femora harvested from adult human cadavers within 72 hours after death of the donor (4). An average of 10 ± 4 impacts were required for proper insertion of the bone plug. Each impact generated an average force of 2.4 kN ± 0.9 kN and 13.3 ± 4.9 MPa of stress. While these values are expected to vary based on the size of the plug being inserted and the location of the defect, it is important to note the effects that these mechanical loads have on chondrocyte viability. After an hour of implanting the plug, there was an observed value of 21% in cell death on the superficial 500 μm layer of bone. After 48 hours, 47% of cells were reported dead at the superficial layer in addition to observed dead cells in the inner layers (4).

In another study that aimed to observe the effects of mechanical loads on chondrocyte viability, it was found that cell death can also be attributed to the role that caspase enzymes play in apoptosis (11). Cells in bone exposed to impact forces stained positive for caspase-3. This result implies that apoptosis was induced in some of these cells via a caspase-3 pathway. Furthermore, the increasing percentage of cells reported dead hours after the mechanical loads were applied indicates that the observed cell death was due in part by apoptosis as well as necrosis. The effects that compressive mechanical loads can have on bone cell viability should be considered in designing the delivery system in order to reduce the potential for inducing chondrocyte apoptotic death.

Product Design Specifications

This design must meet specific standards in order for it to be a valuable option for use in osteochondral allograft procedures. The most important criterion must be an increase in chondrocyte viability from the current 70% success rate mentioned by Cook et al., as well as the client. This will be achieved through a reduction of mechanical forces on the articular cartilage during insertion. Another criterion is that the device will not cause any chipping or fragmentation of the bone plug during the procedure by remaining under the stress limitations of trabecular bone as described in the attached PDS. These two specifications along with proper fitting of the graft into the recipient site will ensure proper graft integration into native tissue, properly maintained hyaline cartilage, lack of associated cartilage disorder, and lack of significant fissuring, fibrillation, or fibrous tissue infiltration. These should improve upon the current success rate mentioned by the client of 75-80%.

Additionally the device should be intuitive and simplistic for use in the operating room as well as being easily sterilizable. Plastic and polymeric materials used in the design will likely be disposable attachments, if necessary for incorporation, and metals will be available for multiple uses if desired by the surgeon. The device should comply with FDA standards for surgical devices. The sizing of the device will vary depending on the extent of the defect, but should be capable of creating a recipient site and a plug at mm increments ranging from 5mm-20mm. This device should also allow for easy insertion of the graft, while improving the efficiency of the procedure by reducing the current five hour procedure time and being less invasive than the current procedure. Compliance of these specifications should be made with an estimated budget of $300. For the full project design specifications see Appendix

Preliminary Designs

There are three current designs being evaluated for possible fabrication. Figures 4-6 represent the three designs in consideration. Figure 10 is a common tap and Figure 9 is a common die. Figure 7 represents the donor plug and Figure 8 represents the recipient hole, respectively.

All designs will utilize the tap and die represented in Figures 4-6. The hole and plug sizes will range from 5mm to 20mm depending on each patient's defect. Thus, tap and die sizes must match this range. Metric tap and dies will be used, sized 5M through 20M. All thread sizes will be standard pitch. The tap will be used to tap the recipient hole as in Figure 8, and the die will be used to cut threads into the donor plug as in Figure 7.

Design Alternative 1: Suction Screw

Figure 4 represents the design that utilizes suction to provide the torsional forces required to thread the donor plug into the hole. The suction force will be provided by a suction cup with diameters ranging from 5 to 20mm. Until testing is performed, it is unclear whether

the vacuum will be generated by the operator or by vacuum tubes currently in the operating rooms. Figure 4 shows the surgeon operated method, by which a handle is pulled to create the vacuum. The device will have set increments and a vacuum gauge. This will allow the operator to apply the exact force required to turn the plug. If the vacuum lines in the operating room are utilized, the vacuum hose would replace the function of the handle. The device must be suited for the correct diameter tubing, as a larger tube will provide a greater flow rate (3).

Design 2 Alternative 2: Tine Screw

The second design represented by Figure 5 uses the insertion of tines to provide the torsional force. A motor, powered by a battery or AC current will drive a central shaft. The central shaft will power the shafts for the tines. Once the device is turned on, the spinning tines will then be used to drill into the donor plug. Upon insertion, the tool will be turned by the surgeon to screw in the plug. Figure 5 shows two tines; however, up to four tines will be used if two are insufficient. The goal is to use the least amount of tines without causing them to shear. Per the client's request, the tines must be no larger than 1/16 inches in diameter.

Design Alternative 3: Synthetic Casing

The final design involves a synthetic casing composed of calcium phosphate or hydroxyapatite. A casing can be 3d printed or fabricated with the threads included. The casing can then be used as a sleeve for the donor plug, eliminating the need to cut threads into the bone plug. Threading bone has proved difficult in the lab, and this option provides a viable option to circumvent the issue. The largest downfall of this design is that it fails to address the issues of how the plug will be turned and how the plug will be inserted into the casing. Even with the synthetic casing, there still needs to be a novel tool that is capable of twisting the casing into the recipient hole. A possible option would be to design a handle into the casing that can be removed after the donor plug has been inserted. These casings will need an outer diameter ranging from 5mm-20mm, and an inner diameter that can be matched by the bone plug. If this issue is not addressed, one of the additional designs would also have to be constructed.

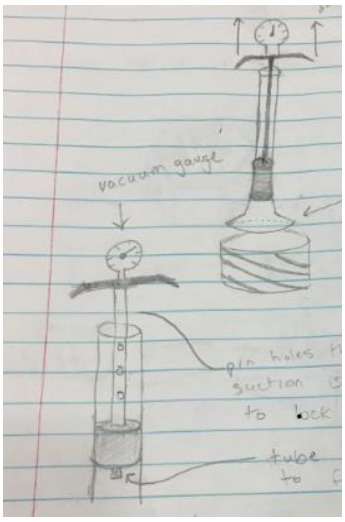

Figure 4: Suction Screw

Figure 5: Tine Screw

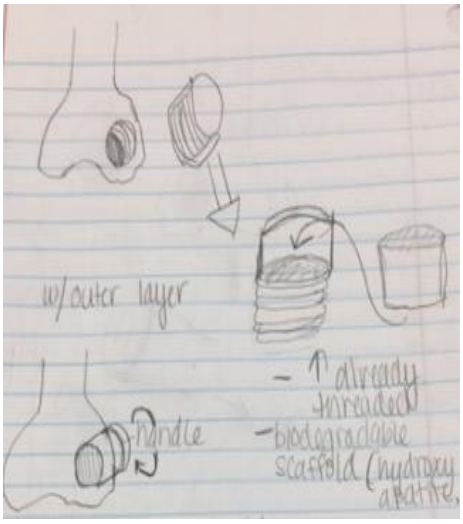

Figure 6: Synthetic Casing

Figure 7: SolidWorks design of threaded graft

Figure 8: SolidWorks design of threaded recipient site

Figure 9: Die (14)

Figure 10: Tap (14)

Preliminary Design Evaluation

Design Matrix

Criteria	Design 1: Suction Screw		Design 2: Tine Screw		Design 3: Synthetic Casing	
Potential for Chondrocyte Damage (25)	4/5	20	2/5	10	4/5	20
Procedure Length (20)	3/5	12	3/5	12	4/5	16
Ease of Use (18)	3/5	10.8	3/5	10.8	5/5	18
Sterilizability (15)	4/5	12	5/5	15	2/5	6
Adjustability (12)	5/5	12	3/5	7.2	2/5	4.8
Cost (10)	4/5	8	5/5	10	2/5	4
Total (100)		74.8		63		68.8

The criteria of the design matrix were chosen and weighted based off the criteria set in the PDS. The project's goal is to reduce damage to chondrocytes through reducing forces applied to the cartilage layer on the donor graft, which means the most important factor to consider is the potential for chondrocyte damage, weighted at 25. Since no testing has been able to be performed, they were ranked on a relative scale. Suction screw is ⅘ due to the idea of a small surface area being affected, with it being under torsion and tension, versus impaction. The Tine screw was ranked ⅖ because it requires the insertion of 2-4 tines, which cause irreversible damage to the cartilage layer. The Synthetic casing could be screwed in by hand or suction methods, and doesn't require the direct threading of the donor graft, which is why it is rated as ⅘.

Procedure length is weighted at 20 because the designs should either maintain or lower the procedure length of 5 hours. It is a very important design aspect because if the device decreases length of time spent in the operating room, it increases the safety of the patient and reduces costs. Both screw designs were ranked equivalently at ⅗ due to the necessity of threading both the graft and site of insertion, which could be lengthy. The Synthetic Casing, ⅘, could be made beforehand and would therefore decrease procedure length significantly.

Ease of use is also weighted highly at 18. There are limited resources and a time constraint, so it is crucial that the surgeon is able to easily use the design. Once again, the screw designs are ranked the same because their functionality and use is very similar in practice. Both require some manual labor to use the tap and die, which is why they are only given ⅗. Because the synthetic casing can be pre-made, the ease of use was rated as 5/5.

Sterilizability is next at 15, as all surgical tools must be sterilized before use in the operating room. The creation of the Synthetic Casing must be done in a sterile environment with sterile materials, which is more complicated than just autoclaving, leading to its ranking at ⅖. The Suction Screw was not the highest, at only ⅘ due to the use of plastic components, which are not always as easily autoclaved as steel. The Tine Screw was 5/5 because it is entirely made of metal, and therefore easily autoclaved.

Adjustability of the design was chosen as a criteria, weight 12, because not all of the grafts are of the same size. The Suction Screw was given 5/5 because one can have a set of different sizes and choose accordingly. The Tine Screw was ⅘ because the tines would have to be the same size for all grafts, causing relatively more damage to smaller grafts than larger ones. The Synthetic Casing was ranked ⅖ because the difficulty by which that design can be adjusted is the highest. A unique casing would need to be made for each person, and modifications of the dimensions of the casing during the procedure would be difficult.

The last category is cost, cost was given a low weight as any reasonable cost increase for long term success of surgery would be justifiable. The budget is $300 for the creation of the design. The Tine Screw was ranked 5/5 because it would use existing tools to test and finalize the design, with very low total costs to the team. The Suction Screw is similar at ⅘, but if adjustments must be made, or new supplies bought, then it incurs more general testing costs. The Synthetic Casing was ranked lowest at ⅖ because the costs of buying the necessary material, and not having the materials be reusable would cause the design to cost the most.

Proposed Final Design

The proposed final design is the Suction Screw (Figure 4). As can be seen in the design matrix, it has the highest score of the three designs. It is the most viable option to be able to create, test, and be successful based on the criteria above. Seeing as the most important aspect is chondrocyte viability, the Suction Screw is a great choice with which to move forward because it can be adjusted with different suction and twisting forces to ultimately create a balance that will limit chondrocyte death. The necessary materials are readily available and can be tested easily in the shop. It is easily sterilizable, with most materials already used in surgical practice, and the plastic components being available at surgical standards. More testing will determine ease of us and potential aspects on which to improve.

Fabrication/Development Process

Materials

Bone graft material

Materials considered for the osteochondral graft included hydroxyapatite, autologous bone and allograft bone. Hydroxyapatite is a synthetic bone material found in normal bone that is commonly used for bone grafts due to its high biocompatibility (12). However, hydroxyapatite does not come with a cartilage layer and work would need to be done to introduce an intact cartilage layer to the area of defect. This would severely complicate the procedure and result in the use of hydroxyapatite along with either autologous or allograft bone.

Autologous bone is bone taken from a donor site on the patient and allows for high biocompatibility and no adverse immunological effects. Autologous bone is limited by the amount of bone that can be extracted as well as the type of bone as it may not be the exact density of bone as that of a femoral head.

Allograft bone is bone taken from a separate human donor with the cartilaginous layer intact, a greater amount of available bone and bone from the same region of the body. Issues with allografting procedure arise from immunological complications and difficulties preserving the donor bone while maintaining chondrocyte viability.

Allograft bone was chosen as it allowed for the most bone available for transplant as excess bone would be required for threading the bone graft.

Torque Inducing Material

Materials considered for the screwing mechanism of the bone graft included a two headed tine screwdriver, suction cups, and a suction delivery system using a vacuum. The tine screwdriver was considered due to its simplicity and ease of use as well as potential for generating torsional force. However, implementation of holes for a tine screwdriver damage the cartilaginous layer and kill the chondrocyte tissue in the area where the cartilage is punctured. This is detrimental to chondrocyte viability and long term survival of the graft.

Suction cups were considered due to the amount of force they can generate without deeply affecting the surface layer on which they act. While suction cups generate large forces these forces are usually perpendicular to the contact surface of the suction cup as compared to parallel to the contact surface. Furthermore, suction cups are known to slide when dragged across the surface on which they are connected instead of generating shear forces on the surface. This is a problem as a suction cup would spin in place instead of generating torsional forces on the bone plug when twisted.

A vacuum assisted suction system functions similarly to a suction cup, however instead of attaching directly to a surface and sticking by a difference in air pressure the vacuum is constantly creating this air pressure difference and allowing for a stronger contact surface. This

should increased strength contact surface should allow for the generation of torsional forces and screwing of the plug.

The vacuum assisted suction system was chosen as it decreased the likelihood of chondrocyte damage while being a plausible delivery system for screwing in the bone plug.

Methods

Testing of the delivery system was done using cow femurs, acquired from Conscious Carnivore butchery. Two cow femurs were acquired with intact cartilage layers on their medial and lateral condyle. A hole of approximately 20mm depth was drilled into the lateral condyle using a size Q drill bit, as seen in Figure 11. Next, a size 10/1.5 tap was used to thread the hole (Figure 12). To simulate taking a plug from a separate piece, and to gain more leverage, a piece of approximately 15 x 10 x 5 cm was taken off of the medial condyle using a hand saw (Figure 13). Using osteochondral autografting tools (Figure 14), a plug of about 10mm in diameter and 15mm in height was taken from the removed bone. This was attempted 3 times before a suitable plug could be obtained. The difficulty was attributed to a combination of inexperience using the autografting tools, as well as the difference in composition and mechanical properties between human and cow bone (8). Using a size 10/1.5 die, the plug was attempted to be threaded, however this also proved to be exceedingly difficult as the plug's length did not allow for enough twisting using only hands.

Figure 11:
Hand drill used, size Q

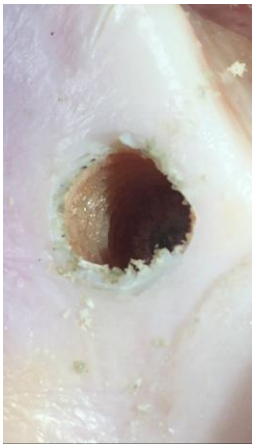

Figure 12:
Threaded hole

Figure 13:
Autograft tools

Figure 14:
Hand Saw

Results

Current testing has demonstrated the possibility of threading a recipient site in bone, however threading a bone plug must still be established. Data has not been acquired as the delivery system must be set up and values must be determined for the torsional force as well as

the induced tension by the vacuum. Once these values are acquired they will be tested on live chondrocytes to determine their effect on the chondrocyte viability.

Conclusion

An osteochondral transplant can be an effective way of treating knee defects through the use of donor tissue with viable chondrocytes. The current technique that relies on the use of impaction to insert this donor graft decreases the success rate of the surgery due to its detrimental effect on chondrocyte viability. The proposed solution to this problem is the use of a suction method that screws in the donor plug. This entails the threading of the donor graft and site of insertion using a tap and die. The graft would then be screwed in using a vacuum-suction cup, which will hopefully decrease the forces exerted on the cartilage layer on the graft to increase total chondrocyte viability, in which the ultimate goal is to increase the success rate if the procedure.

Current testing shows that it is possible to create a threaded recipient site with little problems. The retrieval of a donor graft of similar size is already done in current procedures, so any difficulty of retrieving the donor graft during testing is due to other factors. What needs to be done in immediate testing is use of other tap/die/drill sizes so as to create a perfect matching for plug and donor site. The other immediate goal is to create a better donor graft through a more practiced use of the autografting tools. In creating a better graft, it will hopefully be possible to thread, and then insert into the site using a suction cup.

Once initial testing proves that a tap and die method is possible, further testing will be done on the forces used to screw the graft in. Future work beyond that will be to use any data collected and transfer it into the lab with live chondrocytes to test for viability under the torsional forces exerted on them.

If testing shows that threading of the donor graft is too difficult without further damage of the articular cartilage, then further research on creating a synthetic casing will be necessary. Also, if the suction-screw design proves to not provide enough torsional force, the tine screw design will need to be implemented and further designed upon.

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Appendix

Appendix 1: Product Design Specifications

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Date: October 6, 2016

Function: Osteochondral allografting is a common procedure performed on patients that require replacement of diseased bone. Current methods of implantation require the application of mechanical forces that have a detrimental effect on the live chondrocytes present on the implant. Maximizing the amount of viable tissue during and after the surgery is a crucial factor for the success of the procedure. Hence, the client requests a delivery system that will reduce the amount of mechanical forces required to securely place the implant into the donor site.

Client Requirements:

- Budget: $300
- Donor tissue must be placed into donor site with minimal exertion of forces from surgeon
- Must securely fit into donor site while maximizing tissue viability during and after the procedure
- Delivery system must only require the use of sterile tools available in a surgery room, or must be made to to fit surgical standards

Design Requirements:

- *Performance Requirements:*
    - Application of bone graft should result in approximately >70% viability of chondrocytes on donor graft
    - Procedure must be simple enough to be done in operating room, within the time period of a surgery that takes about 5 hours
    - Bone graft and vice must be held to lie perpendicular so screws on bone graft remain straight
    - Device must be capable of decreasing the force used to insert the bone graft
    - Forces exerted on the bone by the device should not cause any bone chipping, or fragmentation
- *Safety:*

    - Device should be biocompatible and should not increase chances of infection, increase chances of graft dislocation, decrease chances of surgical success, or create complications post-op.
    - Our device has failed if, postoperatively, the graft does not exhibit proper integration into the native tissue, if the hyaline cartilage is not properly maintained, if an associated cartilage disorder develops, or if significant fissuring, fibrillation, or fibrous tissue infiltration occurs (9)
- *Accuracy and Reliability:*
    - The device should have a success rate that exceeds that of current devices (20-25% failure)
    - The device should also allow for successful graft implantation, meaning it makes the procedure able to maintain >70% chondrocyte viability, with no greater risk for post-op complications than what already exists (9)
- *Life in Service*:
    - The device should be mostly reusable, and inherently sterilizable. Length of time to be determined with materials chosen
    - If plastic or biodegradable materials are included in the design, then these components may be one-use only
- *Shelf Life:*
    - The device should be capable of storage at room temperature for 9 months unless sterility is compromised before then. No corrosion should be observed on the device during its life of service and must be compliant with hospital regulations
- *Operating Environment:*
    - Product has to be sterile while in use
    - Should operate in temperatures typical of an operating room (20-23 C), with humidity of 20-60%
    - All pieces will have to withstand the forces exerted on them during operation (tension, rotational, shear, and compression).
    - Must be able to be used in conjunction with other orthopedic tools, including supports, water, bone glue...etc.
    - Must be able to be operated by an orthopedic surgeon
- *Ergonomics:*
    - Device should be able to be used easily by surgeon without damage during operation. Forces placed on the cancellous bone of the graft should not exceed

6.6 MPa from torsional stress, 3-20 MPa in tension, and 1.5-50 in compression (reference). Since, cortical bone is much stronger, considerations are not necessary because limitations will be imposed by cancellous bone. Limitations of stresses placed on chondrocytes will be determined by further testing with the stress limit correlated to chondrocyte viability. Ideally mechanical forces should approximately allow for greater than 70% viability.

- *Size:*
    - Device will be sized appropriately based on the size of the defect.
    - Range of 5mm-20mm diameter for threading device
    - Depth of at least 10 mm
- *Weight:*
    - Device should weigh 5 lbs or less to be able to be comfortably hand-operated
- *Materials:*
    - Materials should comply with medical standards set out by the FDA
    - Reusable materials must be sterilizable
- *Aesthetics, Appearance, and Finish:*
    - No color or aesthetics
    - Function over form

Production Characteristics:

- *Quantity:*
    - 1 final product, preferably multiple prototypes for testing
- *Target Product Cost:*
    - TBD
- *Standards and Specifications:*
    - Device should be to FDA standards for surgical devices

Characteristics:

- Device should consist of a tap, die, and a bone screwdriver and vices
- Must be made of surgery-grade material
- Various devices to stabilize tools will be necessary
- *Patient-related concerns:*
    - Completed bone graft must not cause pain
    - Allergies, immune response hemocompatibility, and biocompatibility
    - Device should not release unwanted fragments of bone

- Required surgery with device should not be more invasive than current procedures

- *Customer:*
  - Orthopedic surgeons implanting an osteochondral graft

Appendix 2: Materials and Expenses

Item	Supplier	Cost	Description	Notes
Cow Knuckles	Conscious Carnivore	$37.03	Cow Knuckles to model the medial and lateral condyl's of the femur	Determine possibilities of design ideas as well as forces generated on cartilage and difficulties of working with bone
Hand Drill and drill bits	Student Shop	$0	Drill used to test on cow femurs to test threading capabilities of the bone	Multiple drill bits used with sized tap/die sets.
Taps and Dies	Student Shop	$0	Tap/Dies used to thread drilled hole and reamed donor graft	
Hand Saw	Student Shop	$0	Used to remove section of cow knuckle for purpose of reaming a donor graft	
Autograft Tool Set	The Client	$0	Use of reamers to remove donor graft from cow knuckle	