

# Osteochondral Allograft Transplant System

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## Abstract

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Osteochondral allograft transplantation is an increasingly popular procedure performed around the world. The significant advantage of this surgery is its ability to introduce mature cartilage and subchondral bone and facilitate defect healing. However, existing systems used in this procedure are detrimental to chondrocyte viability and limit vertical graft adjustability--both are crucial for successful surgical outcomes. This report details a system that addresses both challenges by creating threads on the graft and receiving site, producing a screw-in graft. The novel system was tested by assessing the chondrocyte viability of fresh bovine cartilage after threading, or impaction sequences. The treated cartilage was immersed in a live/dead, and nuclei stain before imaging with fluorescence microscopy. The images were analyzed with ImageJ to obtain cell counts for calculating viability. Average threaded-plug viability was 97% (n=4,  $\sigma=3.3\%$ ,  $p \ll 0.001$ ) which far exceeds our post-impaction viability of 55% (n=4,  $\sigma=20.4\%$ ,  $p \ll 0.001$ ), and the success threshold of 70% viability defined by the literature. These preliminary results offer validation of this system as a possible solution to improving chondrocyte viability during an osteochondral allograft transplantation.

# Table of Contents

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Abstract.....	1
Introduction.....	4
Motivation.....	4
Existing Devices .....	4
Arthrex Osteochondral Allograft Transfer System (OATS).....	4
Zimmer Chondrofix Osteochondral Allograft System.....	5
Problem Statement.....	6
Background.....	7
Osteochondral Defect Etiology.....	7
Osteochondral Allograft Transplant Procedure .....	7
Physiology .....	7
Required Project Research .....	9
Threaded Graft Mechanical Integrity.....	9
FDA Manual Orthopedic Device Standards .....	11
Surgical Instrument Material Standards.....	11
Client Information.....	11
Design Specifications.....	11
Preliminary Designs.....	12
Recipient Site .....	12
Guide Wire Tap.....	12
Spring Loaded Thread Cutter.....	13
Combined Tap & Die: Protracted Tap .....	14
Donor Graft Site.....	14
Die.....	14
Combined Tap & Die: Retracted Tap .....	15
Guided Die .....	16
Preliminary Design Evaluation.....	17
Recipient Site & Donor Site Design Matrix .....	17
Recipient Site:.....	17
Donor Plug:.....	18
Design Matrix Criteria .....	18
Internal and External Thread Cutting Accuracy (20).....	18
Chondrocyte Viability Maintenance (20).....	19

Ease of Use (Procedure Integration) (15) .....	19
Procedure Time (15) .....	20
Serializability (10) .....	20
Safety (10).....	21
Manufacturing Time (5).....	21
Cost (5).....	22
Proposed Final Design .....	23
Development Process.....	24
Fabrication .....	24
Materials .....	24
Methods.....	24
Final Prototype.....	26
Testing .....	28
Materials .....	28
Methods.....	28
Results.....	30
Discussion.....	32
Conclusions.....	34
Works Cited .....	35
Appendix.....	36
Appendix A: Product Design Specifications .....	36
Appendix B: Thread Dimensions for Thread Shear Simulation .....	40
Appendix C: Fabrication and Testing Materials .....	41
Appendix D: Fabrication Methods.....	44
Appendix E: ImageJ Viability Assessment.....	46
Data Processing:.....	46
Raw Cell Viability Data.....	47

## Introduction

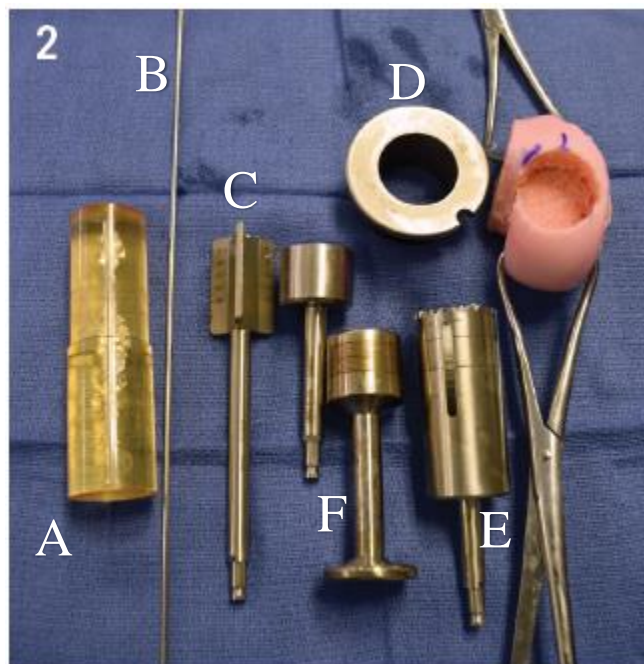
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### Motivation

Osteochondral allograft transplantation (OAT) is a surgical procedure that fuses a healthy cartilage implant from cadaveric donor tissue into the patient's cartilage lesion site. Over 200,000 OATs are performed annually, primarily on a physically active patient population under the age of 25 years old [1]. Furthermore, from 2001-2011, there was an annual 5% increase in the number of procedures performed due to the establishment of the national blood and tissue bank [2]. Despite the prevalence of this procedure, the failure rate is as high as 18% due to unsuccessful integration of the donor and recipient tissues. Nevertheless, the benefit of this procedure over total knee arthroplasty is the promising possibility of restoring full-range of motion to the patient, which is crucial to their quality of life [3]. The motivation in this project, therefore, is to improve full-graft integration and long-term integrity by protecting chondrocyte viability--the most significant factor in determining procedure success [4].

### Existing Devices

#### Arthrex Osteochondral Allograft Transfer System (OATS)

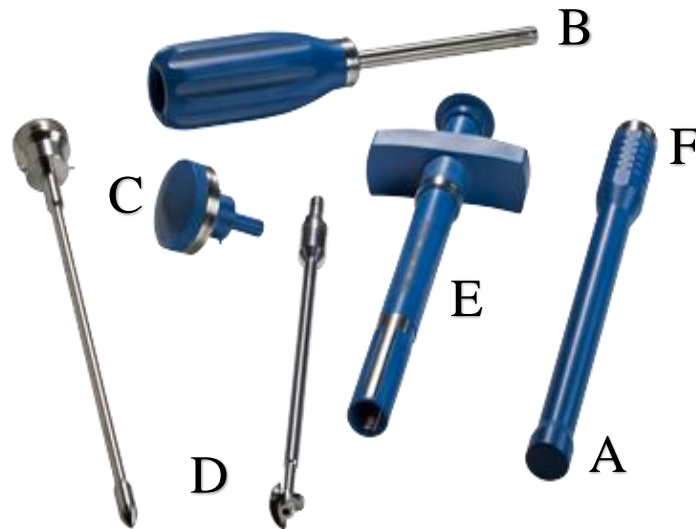


**Figure 1:** Arthrex Osteochondral Allograft System. (1A) Locating and sizing guide. (1B) Stainless steel guide wire. (1C) Cannulated reamer. (1D) Surgical hole saw guide ring. (1E) Surgical hole saw. (1F) Impacting rods.

The Arthrex Osteochondral Allograft Transfer System (OATS) uses several different tools to prepare the donor site, and harvest the graft before impacting it into the patient [5]. As shown in Figure 1, *1A* is a translucent plastic sizing guide that is used to determine how large of a graft must be placed to completely repair the defect. The surgeon places this piece over the defect to ensure that it is completely covered, selecting a larger or smaller size as needed. Once the proper size is determined, the sizing rod is held orthogonal to the surface of the defect and the guidewire (*1B*) is inserted through the hole in the center of the sizing guide, and a drill screws the guidewire through the center of the defect and into the bone. After the guidewire is positioned, the cannulated reamer (*1C*) with a diameter corresponding to the sizing guide is inserted over the guidewire to drill a receiving hole to the proper depth (typically 7-14 mm). Miscellaneous tools (*not pictured*) are used to remove loose tissue from the bottom of the hole, as well as from the cartilage surrounding this hole.

To harvest the donor plug, the cadaveric tissue is placed in a vice (*not pictured*) or another similar fixture to secure it for cutting. The shape of the condyle surrounding the prepared donor site is noted and the best geometric match on the donor tissue is selected. A surgical hole saw guide (*1D*) is held over the matched geometry of the cadaver graft and the hole saw (*1E*) is then used to cut the graft cylinder. The graft is then inserted using the impaction rod (*1F*) and a surgical hammer until it sits flush with the surface.

### Zimmer Chondrofix Osteochondral Allograft System



**Figure 2:** Zimmer Chondrofix Osteochondral Allograft System. (2A) Plastic sizing rod. (2B) Hollow punch used to align drill bit. (2C) Punch impacting cap. (2D) Drill bit corresponding to interior punch diameter. (2E) Graft insertion tool. (2F) Graft impaction rod.

The Zimmer Chondrofix Osteochondral Allograft system (Figure 2) relies on a pre-made, decellularized osteochondral plug with superficial hyaline cartilage. This eliminates the need to prepare an allograft from cadaveric tissue during surgery. The steps leading up to graft insertion are similar to the Arthrex system.

A plastic sizing (2A) rod determines the size of the graft that the surgeon will insert. A hollow punch (2B) of corresponding size is pounded into the bone over the defect while the surgeon keeps it perpendicular to the condyle surface. Depth markings on the side of the punch allow for greater control over the depth of the receiving hole. After punch insertion, the impacting handle (2C) is removed to expose a center hole that accepts a corresponding drill bit (2D) which removes the remaining bone inside the punch and leaves a perfectly sized graft receiving hole. Unlike the Arthrex system, this drilling system has a built-in depth stop allowing greater depth control, which can be challenging for surgeons. The drill bit and punch are removed and the hole depth is verified before cutting the pre-made graft to length. The graft is inserted using the insertion tool (2E), leaving it slightly proud of the surface, and the impaction tool (2F) pushes it flush with the surface. This system is designed for arthroscopic use, unlike with the Arthrex system [6].

These two systems indicate that there is little variation in methodology to OCT procedures. As a result, there is no direct competitor to a screw-in graft system. Every OCT system currently on the market relies on impaction to set the graft in place. This represents a significant gap in the market that an improved osteochondral grafting system can fill.

## Problem Statement

Treating young, active patients with chondral defects has proven to be surprisingly challenging. Normal treatment presently involves impaction of an osteochondral allograft into the prepared region of the defect. The goal of this treatment is to introduce mature hyaline cartilage and subchondral bone that will ultimately integrate with the native tissue and repair the defect. The problem facing this method is that impaction can jeopardize chondrocyte viability which directly affects the success of the procedure. In fact, failure rates are as high as 18 % [2]. The aim of this project is to ensure chondrocyte viability after grafting. This will be accomplished by developing surgical devices that allow the graft and receiving site to be threaded using a new screw system as a means of inserting the graft.

## Background

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### Osteochondral Defect Etiology

Osteochondral defects arise from any type of pathology or injury that cause the bone and articular cartilage to become separated from one another. These defects are often the result of repeated knee injuries which cause increased loading of the joint [7]. The leading concomitant knee pathology for this defect is a tear in the medial meniscus, which reduces support of the knee during loading and results in a greater articular cartilage loading [4]. Other pathologies leading to osteochondral defects include abnormal bone growth and excessive stress in the knee [7].

### Osteochondral Allograft Transplant Procedure

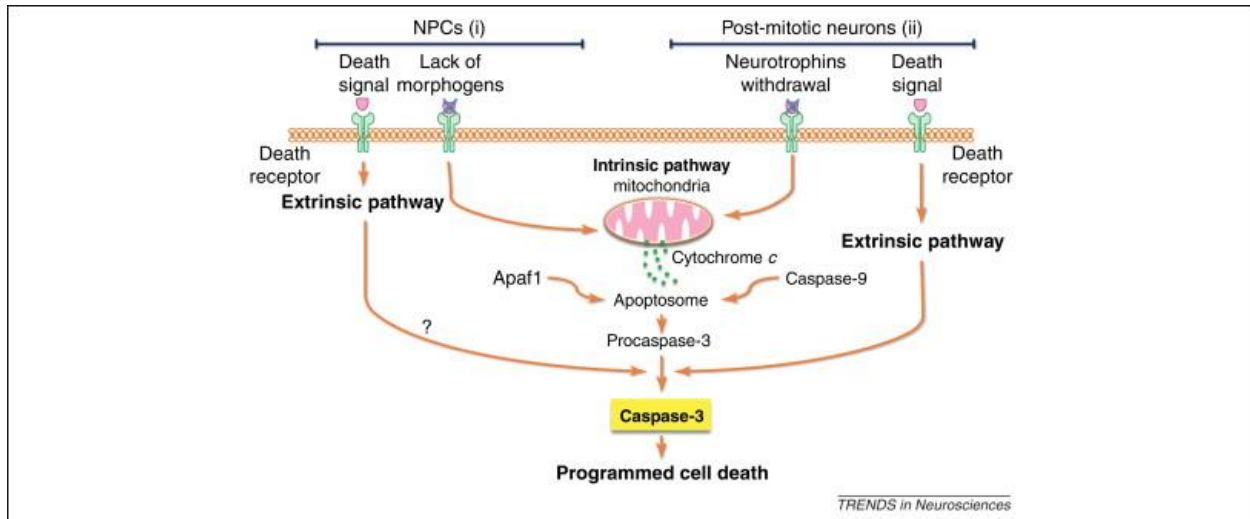
The most common surgical approach to implanting an osteochondral allograft is the dowel technique. This procedure begins by preparing the recipient site for the allograft. The focus of this preparation is to create a cylindrical void that is perpendicular to the surrounding cartilage. To ensure a perpendicular void, a guide wire is inserted orthogonal to the condyle at the defect site. A cannulated dowel reamer is passed down the guidewire and advanced to a depth of between 7 mm -14 mm, clearing a void 10 mm-25 mm in diameter.

The allograft is created from fresh cadaveric tissue, and its geometry is matched to the recipient site on the patient. To create graft plug, a surgical hole is passed through a guide ring perpendicular to the articular cartilage creating a cylindrical dowel. Then, the measurements of the recipient site depths are used to guide the surgeon as they cut the graft to a complementary length with an oscillating saw. The allograft is then positioned directly above the recipient site, and gently tapped into place such that the graft lays flush with the surrounding cartilage [8].

### Physiology

Impaction force used to press fit osteochondral allografts into place during a transplant procedure induces cell death in the superficial portion of the articular cartilage. The impaction impulse deforms mechanoreceptors in the cell. This initiates an intracellular signaling cascade ultimately activating executioner caspases triggering cellular apoptosis (Figure 3).

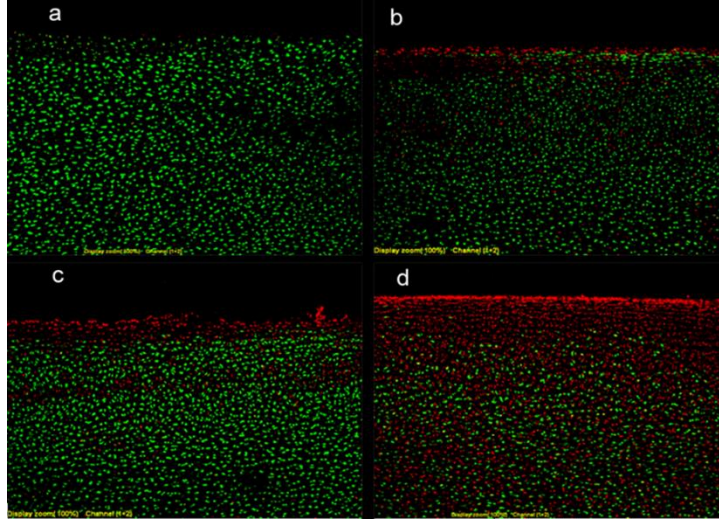




**Figure 3:** Bio-signaling pathway leading to chondrocyte death following impaction. Mechanoreceptors initiate a signal cascade ultimately activating executioner caspases and leading to apoptosis [9].

This mechanism was discovered in a study to assess the effects of impaction on chondrocyte viability during the insertion of an osteochondral allograft. In this study, two grafts were taken from the distal aspect of the femoral head of twelve femora from six individuals, and inserted via impaction into the recipient sockets of twenty-four femurs. Two other grafts were taken from each donor knee and used as control. The grafts were assessed after forty-eight hours, and the impacted grafts had an average of 47% greater cell death particularly on the superficial layer of the cartilage (Figure 4). The impacted grafts showed increased levels of caspase 3 activity which is a known enzyme involved in programmed cell death [9].

A separate study was conducted to assess the relationship between impaction force and chondrocyte viability. Since osteochondral allografts require a mechanical force for placement within the host tissue, these researchers aimed to determine what would be the optimal ratio of number of impacts to force required for implantation. They set up a study in which they struck the allograft plug with 37.5, 75, 150, and 300 N loads 74, 37, 21, and 11 times respectively. One unimpacted allograft was kept as a control. The researchers found that a direct relationship was formed between cell viability and the force to hits ratio, and that lower impulses with more hits yielded higher cell viability. Furthermore, the unimpacted control allograft had little to no cellular death [10]. This study provides further evidence supporting the hypothesis that impaction force causes cell death in osteochondral allograft transplant.



**Figure 4:** Live/dead chondrocyte cell staining following impactation at varying loads. Red indicates cell death; green indicates viable cells. (a) control (b) 75 N (c) 150 N (d) 300 N [10]

The effects of impactation on chondrocyte viability is an important medical concern for this procedure as chondrocyte viability at the time of impactation is the primary determinant of allograft success. A study was performed in canine models to assess the effects of chondrocyte viability at the time of impactation on allograft success. Subjects (n=16) received an osteochondral allograft and their cell viability was assessed at the time of impactation where viability ranged from 23-99%. Six months post-surgery, procedural success was measured compared to initial chondrocyte viability. The researchers found that no graft with an initial chondrocyte viability below 70% was successful [11]. While other factors contributed to procedural success, none were as determining as initial chondrocyte viability.

## Required Project Research

### Threaded Graft Mechanical Integrity

Given the novel method of using a threading system to secure the graft into the patient, it is critical to characterize its mechanical strengths and ensure that the graft will not unexpectedly fail. In this case, the graft is usually unsupported at the bottom of the hole—this space is left to afford the surgeon a degree of adjustment to the vertical graft placement. Consequently, the only portion of the graft supporting tibiofemoral contact forces is the thread. Given contact forces applied to the axis of the graft, the threads are most likely to experience shear-stress failure.

Shear stress at the threads can be modeled based on the applied axial compressive load, as well as the geometry of the thread. In this case, the thread shear area ( $AS_s$  in  $\text{mm}^2$ ) is related to  $LE$ , the length of engagement (mm);  $p$  the thread pitch (mm);  $D_{1max}$  the maximum minor diameter of the internal thread (mm); and  $d_{2min}$  the minimum pitch diameter of the external thread [12]. (The diameter and pitch specifications are easily gathered from a table of thread dimension standards for each given thread size [13].)

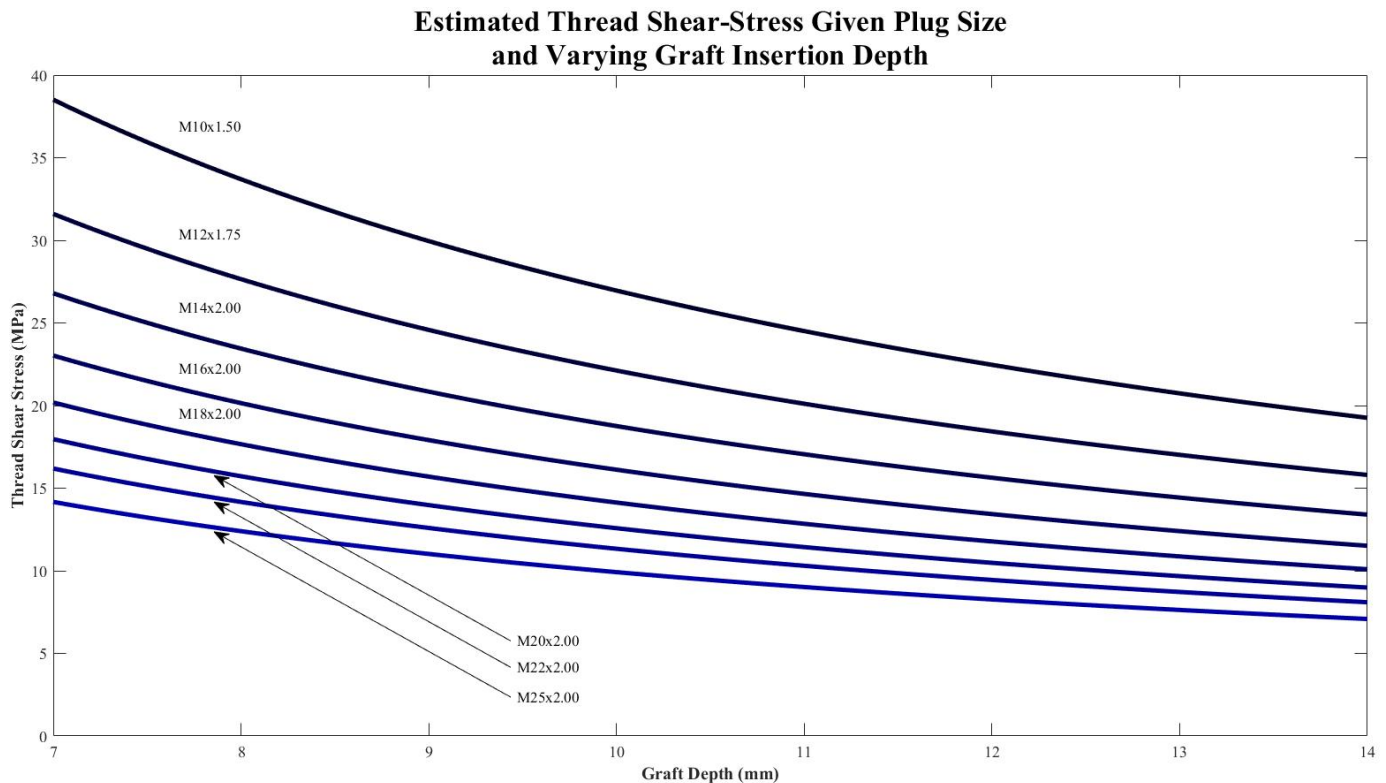
$$AS_s = \frac{\pi * LE * D_{1max}}{p} \left[ \frac{p}{2} + 0.57735(d_{2min} - D_{1max}) \right]$$

Using the following equation where  $F$  is the applied load,  $AS_s$  is the thread shear area, the shear stress  $V$  (MPa) can be calculated.

$$V = \frac{F}{AS_s}$$

The applied force  $F$  was estimated based on numerous assumptions of extreme loading circumstances. The graft was assumed to have been placed on the femoral condyle and sitting proud of the surface so that it bears the entirety of any tibiofemoral contact force. Such forces have been found to exceed 6.2 body-weights during large loading activities such as stair climbing [14]. Assuming the individual weights 150-pounds (667 N), this corresponds to a simulated tibiofemoral contact force of over 4100 N.

Given that  $F = 4100 \text{ N}$ , the shear stress  $V$  was calculated for numerous graft sizes from 10-25 mm encompassing the most common sizes of osteochondral allografts across the typical graft insertion depths (represented by the length of engagement  $LE$  in the equation). The results were plotted in Figure (5). The specific diameter parameters used for each thread size can be found in Appendix B.



**Figure 5:** Plot of thread shear stress with various thread geometries varying with graft insertion depth. The simulated load comes from a 150-pound individual climbing stairs generating a tibiofemoral contact force of 4100 N.

Cortical bone, such as that present surrounding the receiving hole for an osteochondral allograft, can support a shear stress of approximately 50 MPa [15]. Given the results of the simulation in Figure 5, shear stress in the smallest graft (a 10-mm graft with an M10x1.50 thread)

at the minimum insertion of 7-mm only experiences a shear stress of 38.51 MPa—this is below the prescribed failure criterion of 50 MPa. Given the extreme, and very unlikely loading parameters described in this simulation, the contact forces acting directly on the graft will result in shear stress far below the failure stress. Ultimately, the data indicate that the graft can readily support moderate loads until the donor bone can integrate with native bone reforming a solid foundation.

### **FDA Manual Orthopedic Device Standards**

The U.S. Food and Drug administration outlines medical device regulations in CFR Title 21- Subchapter H [12.16]. There are particular exemptions to the requirement of sending premarket notifications to the FDA, provided that the device has existing characteristics of commercially distributed devices of that generic type [13.17]. In the case of intention to use a device for a different purpose than that of pre-existing devices of the same type, notification is still required. In addition, a modified device operating on a different fundamental technology requires notification of the FDA. For the purposes of manual orthopedic surgical instruments, exemptions apply in the same manner, so long as they are classified within a particular group, as well as adhere to specific limitations [14.18]. A generic device, such as a bone tap with minor modifications, would most likely necessitate little regulation, and perhaps qualify for exemption, in contrast to a novel instrument for threading donor tissue.

### **Surgical Instrument Material Standards**

Various grades of stainless steel are used in biomedical applications. Corrosion resistance is an essential aspect of any surgical instrument. The ISO (International Organization for Standardization) specifies metals commonly used to manufacture standard surgical instruments [15.19]. There are many alloys of stainless steel available, however martensitic alloys are generally chosen for surgical instruments, due to its substantial hardness. [16.20] This grade of surgical steel meets the requirements of ISO product standards, passing corrosion tests based on the methods of sterilization normally encountered by these products (i.e. autoclaving) [17.21].

### **Client Information**

Dr. Brian Walczak is a faculty member at the University of Wisconsin School of Medicine and Public Health. Dr. Walczak is an orthopedic surgeon specializing in sports medicine, pediatric sports medicine, and joint preservation. He is very experienced with the OCA procedure, and therefore proposes the mechanism of screw-in graft to address numerous shortcomings.

### **Design Specifications**

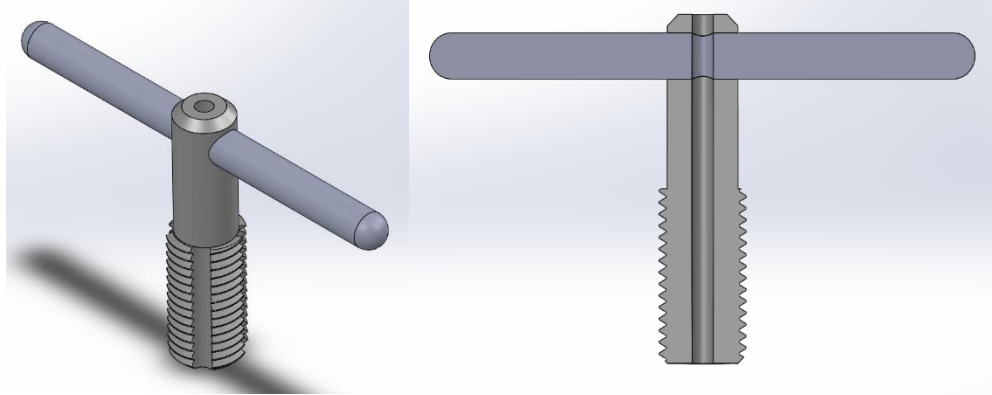
A device will be developed for orthopedic surgeons performing osteochondral allograft transplantation and allow them to thread the donor graft and corresponding recipient site. The chief aim of the system is to improve chondrocyte viability (compared to current impaction methods) which has a positive relationship with procedure success. The procedure for threading the graft and donor site should be easy for the surgeon, and should integrate with the current surgical technique. Ideally, the system will require minimum skilled input from the surgeon to prevent avoidable errors. The entire system must be easily serializable, and operable in a surgical environment. For more detailed product specifications, refer to Appendix A.

## Preliminary Designs

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### Recipient Site

#### Guide Wire Tap

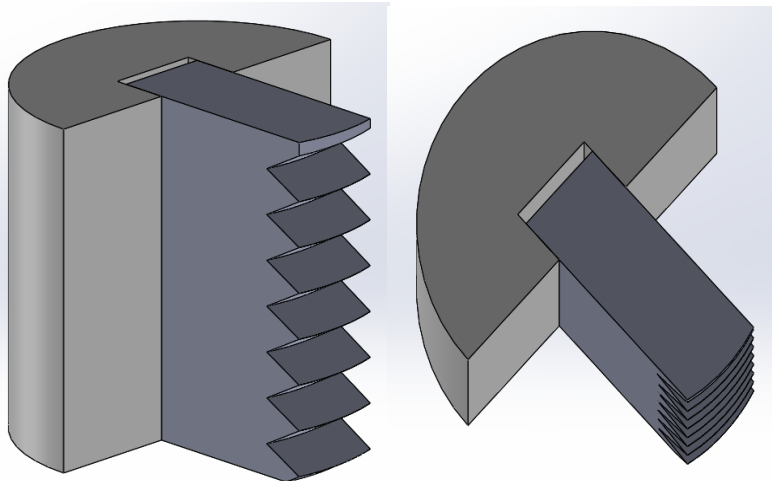


**Figure 6:** Guide Wire Tap Design. Isometric view (left) and section view (right). This design is identical in principle to a standard machine tap, but note the center hole to direct the tap along the surgical guide wire.

The Guide Wire Tap is a handheld, hand powered device to tap the recipient site. This design uses the same principle as a standard machining tap but is made from stainless steel in order to be compatible with operating room standards. The bottom of the device is threaded to the appropriate graft size to cut threads in the recipient site. The threads are sectioned into four parts with four flutes in between to catch and expel bone shavings as the device is turned. At the top is a handle for the surgeon to turn the device and, with sufficient downward force, thread the recipient site. Along the axis of the device is a hole drilled completely through for the guide wire to be inserted while it is attached to the knee.

This design has threads that provide consistent grooves along the vertical length of the recipient site. The handle allows for easy operator use because it allows for a sufficient amount of torque to be generated for cutting the bone. The guide wire hole allows for easy integration into the current procedure by utilizing the guide wire to direct the threading operation and ensure accuracy.

## Spring Loaded Thread Cutter



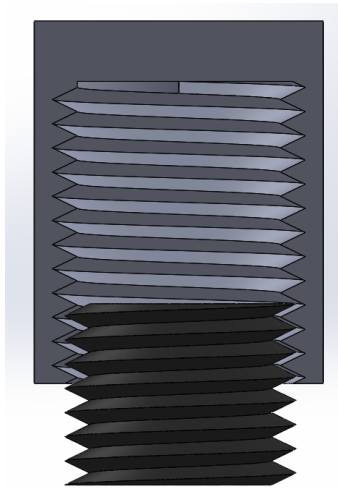
**Figure 7:** Spring Loaded Thread Cutter. Isometric view (left) and top view (right) of the spring-loaded thread cutter.

The Spring-Loaded Thread cutter consists of a half-cylinder, rectangular insert with thread cutting teeth, and a spring inserted between these two components. It is constructed of stainless steel, and maintains a radius coinciding with its recipient hole. The depth of the device exceeds that of its recipient hole, and when compressed and fit within this site, maintains pressure along the inner wall of the reamed hole. After insertion, the device is spiraled upwards, using teeth to carve threads in the recipient site.

This device is an alternative method and novel approach to threading, particularly in comparison to a standard tap. The downfalls it poses are inaccuracy and inconsistency in threading. Misalignment with donor plug threading is also a relevant concern, as it could prove difficult to produce exact thread depths with this method.



## Combined Tap & Die: Protracted Tap

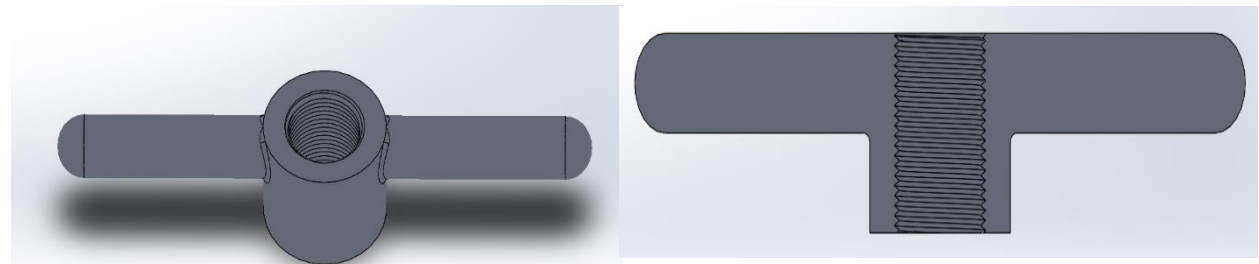


**Figure 8:** Protracted screw configuration of combined Tap and Die design.

The Combined Tap and Die Design consists of a tapping screw enclosed within a cylindrical die. Both portions are constructed of stainless steel, with coinciding threads on both components. As this single tool accomplishes both tasks of tapping the recipient site and threading the donor plug, a locking mechanism holds any particular component of the tool stationary, while the other is free to rotate. In this specific configuration, the screw is protracted by hand, and maintains a length of that required for any desired hole depth. Any pre-reamed hole can be tapped by hand.

## Donor Graft Site

### Die



**Figure 9:** Isometric view (left) and section view (right) of the die design.

The die design works on the same principle as a standard machining die used to cut external threads on metal components. Threads with the desired size and pitch are inscribed in the die and that profile is transferred to the graft as the device is screwed down onto it. The oversized graft would be screwed from the side into a larger block (in a portion of the bone that would later be removed) allowing the surgeon to easily hold the small plug while they manually align the die with graft. Slight downward pressure with turning will cut the thread profile into the graft. The handles

on the side give the surgeon a mechanical advantage, increasing the torque they can generate allowing the graft to be easily threaded. Once the die is screwed all the way to the graft mounting plate, the screwing direction is reversed, and the surgeon can remove the die. A series of dies would need to be made in various sizes to allow for multiple graft sizes.

While machine dies already exist, they are all made with rusting metals and are not compatible with a surgical environment; a custom die would need to be made from medical grade stainless steel. Furthermore, as with standard machine dies, they tend to deviate from the central axis if they are not carefully held perpendicularly to the threads. Manual alignment may be sufficient for most applications, but it is by no means has the highest likelihood of accurate threading. Nevertheless, the simplicity of this design plays a large part in its consideration.

### Combined Tap & Die: Retracted Tap

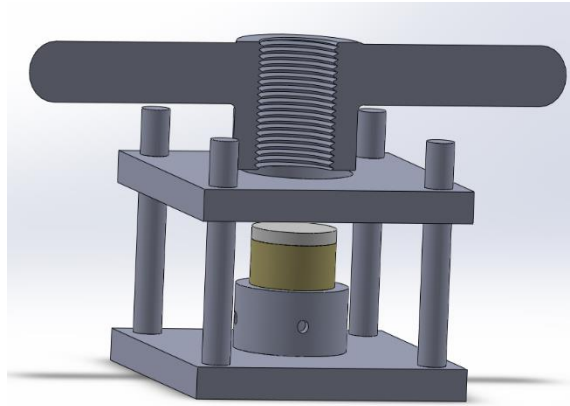


**Figure 10:** Retracted screw configuration of combined Tap and Die design.

This design uses the same principles as the aforementioned die to cut external threads on the graft. However, this is the second part of a 2-in-1 design wherein the tapping screw is retracted and locked into place exposing the die-like internal threads. An oversized bone plug would be held in a similar fixturing device as in the die design to give the surgeon a firm grasp on the plug during threading. Again, much like the die, spinning this tool with downward pressure will carve threads into the graft. Relief slots would be cut into the shell to provide an avenue for waste bone exit.



## Guided Die



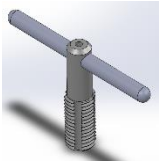
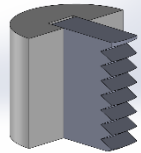
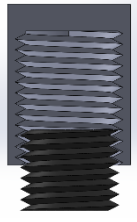
**Figure 11:** Isometric view of Guided Die design with internal view of the thread cutting die. Below the die is the uncut allograft (brown) capped with chondral tissue.

The guided die relies on a custom surgical die, much like the standalone die design, but it is augmented with a supporting platform. The platform is made of stainless steel compatible with the operating room, and it has a fixed base with a moving support. The base has a cutout to receive the graft support block. This block allows the graft to be screwed in place, and then set into the base to prevent it from spinning during the threading action. The top platform is spring loaded and provides a constant upward force against the die as it screws down over the graft. The upward force and the parallel platform combine to offer support to the die allowing for much easier tracking of the graft axis. This affords the die increased threading accuracy as it will be less likely to wander during use.

## Preliminary Design Evaluation

### Recipient Site & Donor Site Design Matrix

Recipient Site:

Design		Guide Wire Tap		Spring Guided Tap		2 in 1: Retractable Tap and Thread Design	
Criteria	Weight						
Threading Accuracy	20.00	5	20.00	2	8.00	3	12.00
Chondrocyte Viability Maintenance	20.00	4	16.00	3	12.00	3	12.00
Ease of Use	15.00	5	15.00	2	6.00	4	12.00
Procedure Time	15.00	4	12.00	3	9.00	4	12.00
Sterilizability	10.00	5	10.00	4	8.00	4	8.00
Safety	10.00	4	8.00	2	4.00	3	6.00
Manufacturing Time	5.00	4	4.00	4	4.00	3	3.00
Cost	5.00	4	4.00	4	4.00	5	5.00
<b>Total</b>	<b>100.00</b>		<b>89.00</b>		<b>55.00</b>		<b>70.00</b>

**Table 1:** Design matrix for the potential recipient site threading designs. Individual criteria scores are out of 5 and are weighted by each category. The highest possible score is 100. Red cells indicate the high score in each criteria category.

## Donor Plug:

Design		Die Design		Guided Die Design		2 in 1: Retractable Tap and Thread Design	
Criteria	Weight						
Threading Accuracy	20.00	2	8.00	5	20.00	3	12.00
Chondrocyte Viability Maintenance	20.00	3	12.00	3	12.00	3	12.00
Ease of Use	15.00	2	6.00	3	9.00	4	12.00
Procedure Time	15.00	4	12.00	4	12.00	4	12.00
Sterilizability	10.00	5	10.00	4	8.00	4	8.00
Safety	10.00	3	6.00	4	8.00	3	6.00
Manufacturing Time	5.00	4	4.00	3	3.00	3	3.00
Cost	5.00	5	5.00	4	4.00	5	5.00
<b>Total</b>	<b>100.00</b>		<b>63.00</b>		<b>76.00</b>		<b>70.00</b>

**Table 2:** Design matrix for the potential donor plug threading designs. Individual criteria scores are out of 5 and are weighted by each category. The highest possible score is 100. Red cells indicate the high score in each criteria category.

## Design Matrix Criteria

### Internal and External Thread Cutting Accuracy (20)

In osteochondral transplant procedures, the individual differences among recipient femur sites alter the length and size of the required bone plug. It is important for the product to be consistent and accurate in the bearings provided for both the threading and the taping to ensure the final assembly fulfil the requirements of a successful surgical procedure. The tools developed should integrate into similar OTS procedures despite the differences in the individual surgeon's style.

For this category, the Guide Wire Tap received the best score because when it is slid over the guidewire, the center of the threading is positioned at the center of the recipient hole at a perpendicular angle. This setup is optimal because it requires the least amount of torque to tap the hole and has the optimal angle for the donor site to rotate into. The Spring-Loaded Thread Cutter scores poorly in this category because it is variable to the speed and angle at which the operator spins it, creating varying threading depths and pitches in the donor site between procedures.

The Die design scores low in this category because its accuracy depends on the operator. The turning speed and pressure applied is inconsistent between each procedure as well as the angle of the threads compared to the axis of the graft. This would make each donor plug mesh differently with the recipient site. The Guided Die design improves upon these issues and, therefore, scores highly in this category. The upwards force of the springs underneath the top platform helps to normalize the downward pressure applied on the donor plug as it threaded. The base also secures the plug such that the donor plug is orientated at a perpendicular angle to the die.

The 2-in-1: Retractable Tap and Thread design has a mid-level score because it suffers from the same orientation issues by the operator as the Die and Spring-Loaded Thread Cutter designs but ensures complementary threading. The internal and external threads on this design mesh perfectly and will transfer this property to both the donor and recipient sites. For this reason, it scores higher than the Die, and Spring-Loaded Thread Cutter designs.

### **Chondrocyte Viability Maintenance (20)**

Chondrocytes viability is crucial because research shows that successful osteochondral transplant system require cell viability of 70% or above [11]. The problem identified in this design project needs solutions that will minimize cell death. The purpose of this screwing mechanism is to reduce mechanical impact that is typically associated with press-fitting the cartilage plug into the recipient site. Therefore, chondrocyte viability is very important in determining the success of the overall procedure.

The threading of both the donor and recipient site occurs within the bone tissue and should not affect the chondrocytes directly. However, there is an opportunity to scrape the chondrocytes away parallel to the surface being threaded or to impact the chondrocytes from the top, decreasing the total viability. Both of these scenarios could happen as a result of human error or misalignment of the tools themselves. Therefore, the Spring-Loaded Thread Cutter, both portions of the 2-in-1: Retractable Tap and Thread design, Die design, and Guided Die designs score equally well in this category. The Guide Wire Tap scores higher because the guidewire hole drilled along the axis allows for it to be placed directly in the center of the hole made for the recipient site.

### **Ease of Use (Procedure Integration) (15)**

Surgeons already have a well-established protocol for osteochondral allografts. Therefore, creating a device that could easily interface with existing procedures is ideal. This would increase surgeon comfort with the device and improve its marketability. Furthermore, a device used in the operating room must be easy to operate in order to decrease the risk for surgeon error when performing this surgery.

The Guide Wire Tap design scores well in this category because it utilizes a major component of the current procedure: the guidewire itself. The tap is the only additional component and slides over the guidewire while it is already inserted into the bone. The Spring-Loaded Thread Cutter scores poorly in this category because it is a cumbersome device to insert into the graft hole

and to spin since there are no handles on the device, meaning it requires large forces to generate small torques to carve the bone. Additionally, this device may require sufficient practice to master. The 2-in-1 design also scores well in this category for both matrices because it utilizes one tool to perform two functions, threading both the donor and recipient sites of the graft, and is therefore easier for the operator to learn and integrate. One drawback, however, is the device is complicated by the retractable tapping screw being a moving part and requiring a locking mechanism that will need to be activated and inactivated during each procedure.

The Die design scores poorly in this category because, although it is the simplest of the donor plug threading designs, the design uses guidance from the operator's eyes to properly align the threading. Given that this is a small object situated on a relatively unstable base, this task can be difficult to accomplish. The Guided Die design solves the accuracy issue by adding a more stable way to secure the graft to the base and a stability platform to ensure the threading is applied perpendicularly to the axis of the plug. This design has a more complicated setup and uses a die similar to the Die design for which points were docked, but it scored mid-tier overall.

### Procedure Time (15)

The length of the OCA procedure tends to be correlated with its overall success due to the need to maintain chondrocyte viability of the donor plug. The longer a procedure takes, which means the longer the donor graft is removed from the 37 °C storage condition to be manipulated for grafting, the lower the likelihood of a successful outcome due to diminishing chondrocyte viability [3]. Specific to osteochondral transplants, prolonged removal of the chondral tissue from *in-vivo* conditions can jeopardize cell viability. Thus, it is critical to develop a device and associated procedure that will effectively thread the graft and donor site, without a dramatic increase in procedure length. This aspect of the device is not as critical as maintaining chondrocyte viability or easily and accurately preparing and placing the graft, and it was weighted accordingly.

Each of the designs for both the recipient and donor sites are hand powered devices and will reflect similar times between each of the designs. The Guide Wire Tap, the 2-in-1: Retractable Tap and Thread, Die, and Guided Die designs all scored similarly for this reason and scored well because hand threading generally takes under five minutes to complete. The Spring-Loaded Thread Cutter scores one mark less than these designs because it requires more effort to insert the device into the recipient hole and a larger amount of force by the operator to turn the device. Both variables work to slow the procedure slightly.

### Serializability (10)

All tools used in a surgical setting must be serializable. Therefore, it is necessary that the product can be easily sterilized. Since sterilization is a common practice with surgical devices, it did not receive as high of a weight as some of the considerations that are more specific to this device.

All of the devices will be made from stainless steel so that they all possess the ability to be sterilized using an autoclave. The two designs best suited to this process are the Guide Wire Tap and the Die designs. These designs consist of only broad faces with tight outer corners that are consistent with standard machining tools. This allows for quick and thorough cleaning of the tools in addition to the autoclaving process. For this reason, the Guide Wire Tap and Die designs score extremely well in this category.

The Spring-Loaded Thread Cutter, both portions of the 2-in-1: Retractable Tap and Thread design, and Guided Die designs include moving parts, which make each become more difficult to clean all the particulate matter that pathogens could attach to and harbor in. In the Spring-Loaded Thread Cutter, this occurs in the space where the springs are located between the half cylinder and the thread cutter. In the 2-in-1: Retractable Tap and Thread design, tissue debris could potentially accumulate in the space between the internal and external threads and within the locking mechanism. The Guided Die design has space around the tubular legs which the top platform slides up and down on. The locations on all these designs are able to be fully cleaned and autoclaving will take care of the pathogens so these designs score well, but do not get perfect scores.

### **Safety (10)**

The tools must minimize risk to both the operator and the patients. For the patient, the device should perform cleanly enough to not produce damage to the area surrounding the procedure. This category was not considered to be a major factor in the design matrix because the device would be primarily a modification of current orthopedic technologies that are also subject to these guidelines. Medical devices inherently require a high level of safety and should automatically be considered with the design.

The Guide Wire Tap scores highly in this category because it is accurately applied to the recipient site and lacks the ability to cut too deep into the bone. The Spring-Loaded Thread Cutter scores poorly because of the inconsistency with which it would cut threads. The threads could vary within a single recipient site may leave pockets where bone is removed but is not filled by donor threads open to infection. Additionally, the force of the springs could cause the device to be flung out of the recipient site, impacting the surrounding tissue.

The 2-in-1: Retractable Tap and Thread received a mid-tier score for this category because having both the donor and recipient threads on one tool allows for the opportunity that tissue will be pinched between the moving parts of the device.

The Die design also scores mid-range because of the inaccuracy of the device. The varying threading of the device could result in improper meshing of the donor plug and recipient site threads, opening the potential for infections within the unoccupied space. The Guided Die design addresses consistency concerns in the threading of the donor plug so it receives a score one mark higher than the Die design. The only safety concern to the patient would be the moving parts pinching the operator and resulting in some form of contamination.

### **Manufacturing Time (5)**

The device must be constructible within the means of tools accessible in the COE student shop. In addition, the team's ability to use such tools proficiently will determine the degree of manufacturability pertaining to the design. The materials chosen must be easy to work with while compatible with other requirements of our design.

The manufacturing time of the design is directly correlated with the intricacy of the design which can be measured by two factors: number of constituent parts and complexity of the geometry of each part. The Guide Wire Tap scores well in this category, but not perfect, because it has simple geometry that takes the shape of a standard machining tap, and only requires two constituent parts. However, there are four flutes for bone shaving extraction that need to be cut into the design with a lathe. The Spring-Loaded Thread cutter scores similarly. There are three

components to this design: half cylinder, springs, and cutting tool which are simple to fabricate but will require significantly time to assemble than the Guide Wire Tap.

The 2-in-1: Retractable Tap and Thread and Guided Die designs receive a mid-range score because they each have moving parts that need to be machined and assembled. The 2-in-1: Retractable Tap and Thread has both the internal and external threads that need to be attached through a locking mechanism. The Guided Die design requires a platform that slides up and down with the die. The addition of these moving parts complicates the geometry of the assembly resulting in these devices receiving a lower score.

Similar to the Guide Wire Tap, the Die design takes the shape of a standard machining die, meaning the manufacturing time will be relatively short. However, the internal structure of the die requires the diameter to be milled to that of the desired donor plug and flutes will need to be milled in to allow the excess bone shavings to escape. Additionally, the threading of the tap will be complicated by the fact that its threads are located on the inside surface. These factors result in the Die design receiving the same score as the Guide Wire Tap.

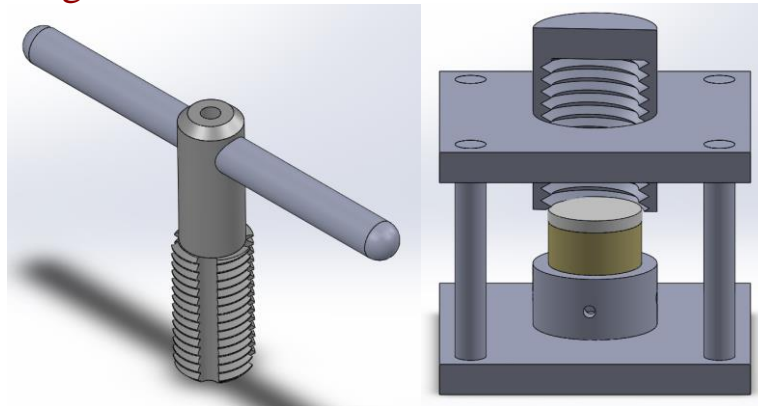
### Cost (5)

Cost does not represent a significant design constraint given that the team will only be producing a single prototype to demonstrate a *proof-of-concept*. Furthermore, this device will ultimately be used in an extremely well-funded medical field so producing an extremely inexpensive device is not of utmost concern. However, these designs may be scored for cost based on the quantity of material needed for fabrication, and compared to the precedent set by the cost of fabricating analogous devices.

The Die design, which is the simplest and most unspecialized of the designs receives a high score because it can be produced using current methods to create machining dies, resulting in it having the lowest cost. The Guided Die design and the Spring-Loaded Thread Cutter score one mark lower because they require the machining and assembling of multiple parts per each design. The Guide Wire tap scores similarly because it requires extra machining because of the guidewire hole not being standard in machining taps. The 2-in-1: Retractable Tap and Thread scores similarly high to the Die design because it combines two tools into one thus reducing the amount of material needed for fabrication. Although this design has moving parts that require extra machining and assembly, the combination of having both a tap for the recipient site and a die for the donor plug in one device brings the cost down overall compared to purchasing a tap and a die independently.



## Proposed Final Design



**Figure 12:** Guide Wire Tap used to thread the recipient site (left). The right image shows the device used to thread the donor site; it is a hybrid that utilizes the consistency of the Guided Die design and the threading mechanism of the Combined Tap & Die design.

For the threading of the recipient site, the proposed final design is the Guide Wire Tap. This design is appealing because it follows a proven method for threading internal surfaces. The ability of this tool to integrate with the guide wire that is already used in this procedure significantly increased this tool's ease of use since there is no additional set up time for this device to be implemented. This also prevents the procedure time from being significantly affected as the device can be used in a natural progression of the procedure. Furthermore, this ability to interface with the guidewire will allow this device to have the greatest accuracy in cutting threads. The interface with the guide wire will also protect the chondral tissue from gyration of the tool, which could damage the tissue. Due to the simplicity of the geometry of this design, the device is able to be easily autoclaved in line with standard medical hygiene.

The proposed final design for the external threads on the donor site is a hybrid of the Guided Die design and the external threading portion of the 2 in 1 design. As shown in *Table 2*, there is no clear winner that scored highly in both the Ease of Use category and the Thread Cutting Accuracy. The 2-in-1: Retractable Tap and Thread design clearly won in Ease of Use but fell short in the Thread Cutting Accuracy category because there was no mechanism to stabilize lateral movement of the device. The Guided Die design was marked as the most accurate of the donor plug threading designs as it does have such a stabilization mechanism, but because it used the Die design, it ranked low for ease of use. Therefore, it was decided that the best way to optimize this device was to combine the best elements of each design. The base and stability platform of the Guided Die design are taken in order to ensure the highest level of accuracy possible when threading the donor plug. The external threading system of the 2-in-1: Retractable Tap and Thread design provides an easy to use die with an additional bonus of having an ideal conformation for the Guided Die device. The length of the die is optimal for threading a variety of lengths of plugs that can be cut down afterwards using a bone saw to fit defects of varying depths.



# Development Process

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## Fabrication

### Materials

The key material constraints in this prototype were driven by the fact that they must comply with a surgical environment. Traditionally, these include 400-series martensitic stainless steels which offer excellent strength and corrosion resistance [20]. While these alloys are the standard in surgical applications, they tend to be more expensive, harder to machine, and are more challenging to locate in appropriate sizes. Given that the team was simply making a prototype to demonstrate a proof-of-concept, scrupulous adherence to these standards was not necessary. The team decided to use 300-series stainless steel alloys which are less expensive, easier to machine, and more readily available, but still offer sufficient strength and corrosion resistance. All tap, die, and guidewire components were made from stainless steel to demonstrate functionality when they are not made from traditional high-speed tool steel. The graft holding cup, as well as the die guiding plate and graft cup holding plate were made from 6061-aluminum because it was far less expensive, and made manufacturing significantly quicker than using even 300-series stainless steel. The material properties of these components are not critical to proper prototype function, so this was deemed an acceptable substitution. For a complete list of materials used, refer to Appendix C.

### Methods

The prototype consists of four primary components: the tap, die, graft holding cup, and the alignment platforms. Each was manufactured separately, while periodically checking for the necessary mutual integration between interfacing components (i.e. matching the threads between the tap and die; ensuring a slip fit between the die body and the guiding hole on the alignment platform, and between the graft holding cup and its supporting plate).

The tap was cut to rough length of 100-mm from the raw stock. It was then turned down on a lathe to 16-mm, the major diameter of the M16x2.00 thread to be cut. 30-mm of the rod was left at the 16-mm major diameter, and the remaining 70-mm was turned down to 13.5 mm which is below the minor diameter of the thread—this would allow for proper threading of the tap. An M16x2.00 die was used to cut the external threads along the 30 mm that was left at the 16-mm diameter. Next, a 0.125-inch hole was drilled through the entire length of the die to accommodate the guidewire. Both ends of the hole were countersunk, and both ends of the tap were given a slight chamfer.

At the mill, the tap was placed in a square collet block with the threaded end out. A 0.25-inch ball endmill was used to cut 4 flutes at 90 degrees to one another down the middle of the threaded portion. The tap was flipped in the collet block exposing the unthreaded end into which a 0.25-inch hole was drilled to accommodate the tap handle. Both sides were countersunk, and the tap was complete.

The tap handle was cut to 100-mm in length before being turned down to 0.375-inches in diameter. The diameter was further reduced to 0.25-inches along 70-mm of the handle to allow it

to slide into the tap-handle hole. Both ends were chamfered before taking the handle to the mill to drill the 0.125-inch guidewire hole in the middle of the handle.

The 1-inch die stock was cut to 100-mm in length before turning down to 0.95-inches. A 14-mm tap hole was drilled in the end of the die to allow the M16x2.00 tap to cut internal threads. This hole was tapped and countersunk, before both ends of the die were chamfered. At the mill, the die was placed in a collet block before a 0.25-inch ball endmill was used to flutes on opposite sides. Like with the tap, a 0.375-inch hole was drilled at the opposite end to accommodate the die handle.

The graft holding cup was cut from a 2-inch long piece of 1-inch square aluminum stock. This was oriented vertically in the mil vise and CNC was used to mill the external profile. A 0.375-inch hole was drilled all the way through (giving access to push the graft out should it become stuck). Over this hole, a 0.625-inch hole was drilled to a depth of 0.5-inches. The bottom of this hole was flattened, and the diameter enlarged using an endmill. The block was cut to final length, and holes for the bone securing pins were drilled in each of the four sides.

Both top and bottom support plates were started by squaring the aluminum stock, before using the CNC mill to cut the top half of the external profile, then flipping to mill the other half. A 0.240-inch hole was drilled in the four corners of both plates before they were reamed to 0.249-inches. This would allow for a press fit of the 0.2500-inch stainless-steel support pins. A 0.75-inch hole was drilled in the middle of both plates. This hole was progressively enlarged using the CNC mill until it allowed for a slip fit of the die body. The hole in the bottom plate was cut with a profile matching the graft holding cup and was tuned to allow for a slip fit of the cup. An arbor press was used to press the stainless-steel pins into the bottom plate before the top plate was pressed over the other end of the pins.

Full dimensioned drawings of the prototype can be found in Appendix D

## Final Prototype



**Figure 13:** Solidworks rendering of the final die in the alignment plates with the threaded graft in the graft holding cup. This image demonstrates the intended interaction between these components to successfully thread the bond graft.



**Figure 14:** The die guiding platform was made from 6061 aluminum alloy for both flat faces, and stainless steel for all four dowel pins. The top face has a circular hole coinciding with geometry of the die for consistent threading of the graft. Here, the removable graft receiving cup, also 6061 aluminum, is placed into the square cut portion of the bottom aluminum face, preventing rotation while threading. Pin fixation of the bone graft through side holes in the graft cup also performs this function.



**Figure 15:** Guide-Wire Tap (left) and die (right). The tap is constructed of 303 stainless steel. Its removable handle is inserted through a hole at the opposite end of the cutting threads. A defining feature is a hole running the entire length of its axis, allowing for insertion over the recipient-site guidewire. The tap maintains four straight flutes for removal of bone during the tapping process. The die is constructed of 304 stainless steel. Its removable handle is inserted at the opposite end of the threading portion. The threads within the cylindrical tube extend 30-mm into the tool. Two side flutes allow for removal of bone during the threading process.

## Testing

### Materials

Bovine shanks were used as a model to test our transplant delivery system because this was the only tissue that the team could get within hours of animal death which was essential for accurate testing. The anatomical structure is quite different from the femoral condyles in humans, but geometric considerations were not paramount in this testing. Osteochondral allograft surgical instrument analogs were used to harvest the allograft from the bovine tissue, and implant the tissue into a separate bovine knee. (The knee was not fresh, but it merely provided the structure for insertion—its chondrocyte viability was not assessed). These analogs included a 0.625-inch tenon plug cutter for harvesting the bone graft, and a 14-mm drill bit for drilling the receiving site.

After donor graft preparation, DMEM Cell Media was used to maintain the viability of the cartilage before and after implantation to maintain cell viability for an accurate assessment of the threading and impacting experimental variables. PBS was used to clean donor and recipient tissue since it maintains biologic osmolarity and would not harm the tissue.

Calcein AM/EthD-1 was the live/dead stain used to assess post-implantation cell viability. Hoechst stain was the nuclei stain that allowed for quantification of the total number of cells for cross comparison to the number of live and dead cells counted. 4% agarose gel was used to stabilize the cartilage samples for imaging. Agarose was employed because it can be easily shaped, and does not negatively affect the tissue.

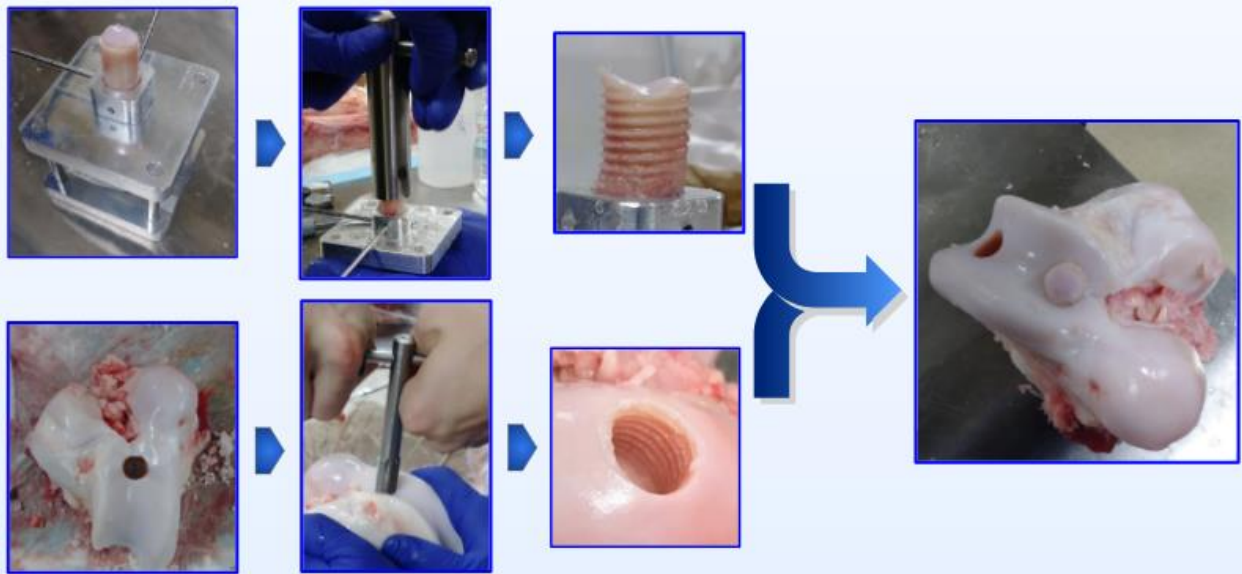
### Methods

The final testing was designed to measure the difference in chondrocyte viability between applying the impaction and the screw-in graft method. The goal was to realistically mimic the actual surgical procedure while obtaining quality samples that reflected what could be collected *in vivo*. The initial testing called for the collection of three bone plugs (control, threaded, and impacted) from the same bovine femoral condyle. However, due to unexpected change in tissue supply, only bovine shanks were available. Rather than harvesting the bone plugs from the condyles, we were only able to harvest plugs from the hock joint (tarsus) and carpus. Due the limited surface area and uniquely ununiform geometry of the joint, we were able to harvest only two plugs from each shank. The control tissue was obtained from the same feet as simple cartilage scrapings (not as full bone plugs) prior to staining. Four bone plugs were removed, threaded, and implanted using the procedure outlined in the following section. Four more bone plugs were removed and implanted via the impaction method.

To collect the samples, the superficial tissue was resected, and the stabilizing ligaments were severed allowing the tarsus joint to be completely exposed. Immediately after exposure, the cartilage was covered with a gauze pad soaked in PBS 1X and 10X DMEM cell media to maintain viability. The tenoning drill-bit was used to cut plugs 30-40 mm in length before a hacksaw was used to free the pugs from the remaining bone. The plugs were secured in the graft cup using threaded pins, and a standard machine die was used to cleanly start the threading. The threads were completed using the prototype die. The plugs were trimmed to 15-mm to prepare for insertion.

The receiving hole was prepared by using a 14-mm twist drill bit drilling to a depth of approximately 20-mm. The guidewire was inserted into the middle of the drilled hole, and the tap

was run over it, cutting threads to the bottom of the hole. The hole was cleaned of debris using PBS, and the previously threaded graft was screwed into place manually. This procedure is graphically outlined in Figure 16.



**Figure 16:** Flowchart of threading and tapping procedure. Following pin fixation of the bone plug within the supporting cup, the die inserted into the guiding platform is used to thread the donor tissue. The tap slides over the recipient site guidewire ensuring perpendicular tapping of the hole. The bone plug is then cut to a desired depth, and manually screwed into the recipient site.

The impaction sequence followed the same bone-plug collection protocol. The receiving hole was drilled to 0.625-inches to match the diameter of the tenon-plug cutter. However, there was still significant interference, so the plugs could not be fully seated. Nevertheless, the plugs were placed in the unthreaded receiving hole, and impacted with a metal hammer 20 times each using a subjectively assessed *moderately light* force; all impactions were performed by the same individual.

Thirty minutes post-implantation, samples were excised from each bone plug using a razor blade. A 1.3-1.5 mm thick cross-section of the samples was obtained by slicing each cartilage sample vertically in half. The cross-sections were stained with 2:1:5 ratio of Hoerst, Calcein AM and EthD-1 diluted in 500  $\mu$ l PBS and 500  $\mu$ l DMEM media. All samples were incubated for one hour allowing the stains to selectively bind to the live and dead cells, and cell nuclei. Following this incubation period, all samples were rinsed with DMEM cell media, then stabilized in 4% agarose gel to allow for imaging of the vertical cross-section.

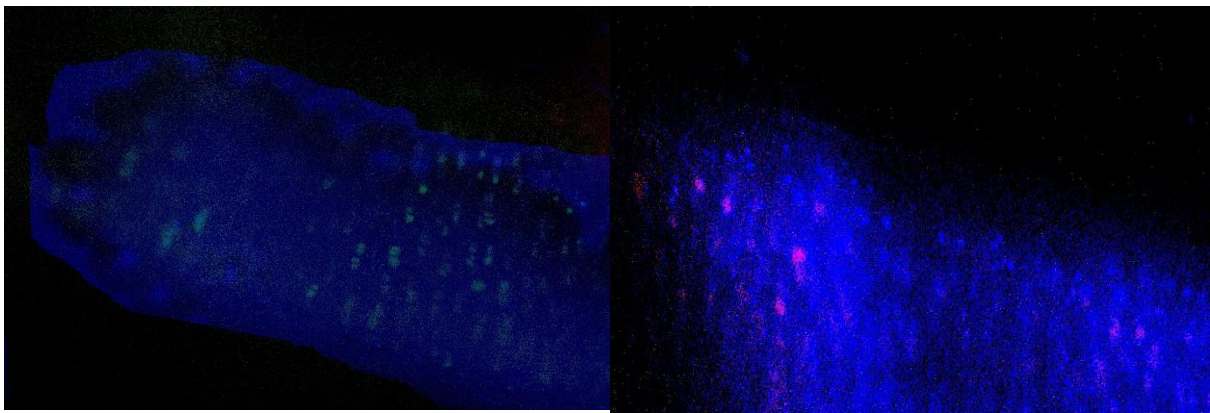
Each sample was imaged using a fluorescence microscope and Nikon Elements fluorescence microscopy software. DPIP, FTIC, and TRIC filters were applied to view each of the stains. All images were then exported to ImageJ for cell viability analysis that is further detailed in Appendix E.



## Results

Experimental Group	Threaded Plug Chondrocyte Viability	Impacted Plug Chondrocyte Viability
1	93%	61%
2	99%	61%
3	99%	48%
4	97%	51%
Mean	97%	55%
$\sigma$	3.3%	20.4%
p-value	$1.86 \times 10^{-5}$	

**Table 3:** The percent of living chondrocyte cells are recorded for each specimen as well as the averages and standard deviations. A two-variable t-test compared the viability between the two treatments and p-value recorded.



**Figure 17:** Cross-section of cartilage from a threaded plug (17a. left) and an impacted plug (17b. right). Collected on a fluorescence microscope under 10x magnification. Blue: Cell nuclei; Red: Dead Cells; Green: Live Cells

When the percentage of viable chondrocytes for the threaded bone plugs sample was compared to that of the mock impaction sample, a statistically significant difference between the two groups is observed. The mean chondrocyte viability for the threaded bone plug sample was 97% and had a standard deviation of 3.3%. The mean chondrocyte viability for the mock impaction sample was 55% and had a standard deviation of 20.4%. A two-sample t-test was performed on the data with a null hypothesis of each treatment having equal effects on chondrocyte viability. A p-value of  $1.86 \times 10^{-5}$  was obtained; this value is highly significant at the  $\alpha=0.001$  level, and we can reject the null hypothesis. (Raw data can be found in Appendix E.) Therefore, we have evidence to believe that threaded bone grafts exhibit greater chondrocyte viability than the impacted bone grafts. This can be seen in Figures 17a and 17b. Figure 17a shows a cross-section of cartilage from a threaded bone graft and Figure 17b shows a cartilage cross-section from a mock impaction plug. The number of live cells (indicated by green dots) in the threaded plug is higher

than in the impacted plug; the number of dead cells (indicated by red dots) is a smaller percentage in the threaded plug than in the impacted plug.

It should be noted that the images provided do not fully capture the amount and relative abundance of live and dead cells—in other words, qualitative observation of the images in Figure 17 does not accurately reflect the quantitative data obtained from those images. This is because the images are captured using the same exposure time in order to be processed with intensity histogram analysis in FIJI (Image-J). Additionally, the relative concentrations of cell stain (Calcein AM, EthD-1, and Hoerst) are disproportional (1:5:2). Despite that the more distinct cells can be seen in individual channels, the composite image quality is suboptimal. After a uniformed background noise is subtracted from the images, weaker cell signals can disappear visually, but can still be detected by the ImageJ software that counting these cells.



## Discussion

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The data obtained indicates that threading the donor plugs retains 40% more viable chondrocytes than the impaction method. The threading method also appears to retain 27% more viable chondrocytes than the 70% standard that has been previously linked to successful outcomes in the literature. However, this result may be affected by multiple factors. One is that the sample size is relatively small, which may produce a less representative data set than a larger sample would.

The simulated impaction method does not strictly comply with surgical procedure. In the impaction trials, the chondrocytes were impacted directly by a hammer 20 times instead of the chondrocytes being buffered by an impacting rod, and only being hit enough to force the plug into the recipient hole. Thus, our impaction trial viability may be slightly different from the true surgical viability.

Variability in the plug conditions prior to cartilage harvesting could also confound the data. For our tests, all the cow legs were taken out of the incubator at the same time. Then the excess tissue, such as the tendons, were removed. Finally, the donor plugs were removed sequentially. The result was that some samples were outside of the incubator for as much as two hours longer than others before being tested, potentially decreasing the number of viable chondrocytes in those samples.

Consistency in separating the cartilage from the subchondral bone using a razor blade proved to be challenging. The cartilage thickness ranged from 1.3-1.6 mm depending on the plug harvest location. The manual separation is suboptimal and erroneous in that it produces various thickness of the cartilage for imaging making it difficult to draw accurate quantitative comparisons between each sample. Consequently, the large variability in the total number of cells calculated from each sample is due to the inconsistent thickness of cartilage cross sections. Additionally, there was a suboptimal concentration ratio of cell stain which generated excessive background noise in the imaging. This drawback renders it difficult to draw the same conclusion qualitatively from the image as the quantitative results from ImageJ analysis. Despite the improvement made in better quantification of cells for chondrocyte viability assessment by adding nuclei staining, it also makes it more difficult to stain the cells thoroughly.

For this device to ultimately be used in an orthopedic setting, further testing of the threading effectiveness compared to the current method must be performed. To become the new standard surgical technique, the threading system must consistently outperform impaction. If not, the replacement of a well understood and practiced method with a new method, even if it integrates well into the current procedure, will require a relearning period for the surgeons that will ultimately result in unnecessary procedural failures and possible injuries or infections to the patient.

To perform an analysis of the effectiveness of the threading technique, more testing on tissue will be required. The testing the team performed focused primarily on bovine ankles. Bovine tissue is not generally regarded as a good analog for human tissue, especially regarding geometry in this case. Therefore, better human analogs (like porcine tissue), should be tested on before this device proceeds to human cadaver tissues and ultimately human clinical trials. These tests should be performed on knee tissues, which is the primary location for allograft transplants thus providing the best representation of the efficacy of this design.

Additionally, the final design will increase the length of the transplant procedure by adding the additional steps of threading both the donor plug and the recipient site. Although the scale of which is unknown for this procedure, patients will be more likely to develop an infection at the site of the surgical opening as increased procedural time has been linked to increased infection

rates in surgical settings [22]. This risk can be reduced by preparing the graft prior to opening the patient, although the effect of early preparation on chondrocyte viability should be tested before such a recommendation can be made.

## Conclusions

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The existing surgical system of bone graft impaction for repair of chondral defects falls short within two crucial determinants of overall surgical success. The force required for impaction is detrimental to chondrocyte cell viability, and vertical graft adjustment is highly limited by such methods. The design carried forward addresses each of these core dilemmas by tapping the recipient site through alignment with the existing guidewire, threading the donor graft within a plug receiving platform, and manually screwing in the plug to avoid any impactful force upon the graft cartilage. Following assessment of differences in chondrocyte viability when comparing the method of impaction to a screw-in graft, there was a significant reduction in cell death. While improvement in cell viability is evident, there are many aspects of this approach to the surgery that require further research and attention.

Regarding integrating the screw-in method, the prototype should be tested in conjunction with the current surgical system, used by the client, to address any incompatibilities in work-flow and the resulting changes in procedure duration. Furthermore, one of the greatest challenges moving forward will be the assessment of geometric constraints affecting flush graft insertion. Any minute malalignment of geometry between the donor graft threads and receiving site inhibits proper screw-insertion. A high level of consistency in threaded grafts must be achieved to demonstrate success with this method.

Numerous prototype modifications can be made to improve the efficacy, and ease of use for this system. Modifications include incorporation of a starter tap and starter die with tapered threads to aid in the initial processes of tapping the recipient site, and threading the donor graft. The first few turns with either tool proved much more difficult than anticipated, and in the case of threading, the team must avoid stripping any initial threads from the donor tissue. An initiating tap and die would avert such rigorous cutting, thus easing the start of each process. Similarly, utilizing longer handles for the tap and die would provide greater torque, also easing the process of cutting.

Integrating a graft receiving cup, capable of an adjusting bottom support, would improve the prototype in two different ways. Primarily, it would allow for varying graft depths to be placed within the cup. Also, as the threaded graft remains within the cup following use of the die, one could adjust its height before cutting the graft to the correct depth. Furthermore, a method of fixing the graft platform to the table would eliminate the need to manually prevent its rotation during the threading process. A simple clamp could be incorporated to secure the device to a table during use.

In the realm of tissue testing, the team would like to develop a revised staining protocol to more reliably stain dead cells. Also, access to cell imaging through a confocal laser microscope would improve tissue penetration, in comparison to the use of a fluorescent microscope. Likewise, a more quantitatively consistent method of cartilage removal will standardize the cross section of imaged tissue.

Despite numerous shortcomings in testing execution, tissue availability, and prototype function, the initial results are extremely promising. There is a highly significant reduction in chondrocyte death with the screw-in bone plug compared to the impaction method. These results are sufficient to warrant future work into developing this into a viable surgical alternative to traditional impaction.

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## Appendix

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### Appendix A: Product Design Specifications

# Osteochondral Graft Tapping System

## Product Design Specifications

**Team:** Alex Teague  
Josiah Wolf  
Grace Li  
David Fiflis  
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**Function:** Osteochondral allografts are used to repair chondral defects in young, active patients. The currently accepted practice involves cutting the graft from cadaveric tissue, then using impaction to drive the graft into a low clearance receiving hole drilled over the defect on the patient's articular cartilage. The large stresses associated with graft placement often lead to decreases in grafted chondrocyte viability, and negatively affect procedure outcomes [1]. To increase the number of successful procedures, Dr. Walczak envisions a screw-in graft that bypasses the need for damaging impacts. Thus, we are to design a system that will allow the graft and recipient site to be tapped, and allow the graft to be easily screwed into place.

### Client Requirements

1. The grafted plug must be removable from the recipient site so the depth of the graft can be adjusted.
2. After graft preparation and insertion, chondrocyte viability must be consistently greater than 70%, which is the accepted threshold for procedure success [1].
3. The entire system must be sterilized before use in surgery.
4. The system must be quick to use, and easy to learn so as not to drastically alter the current surgical practice.

### Design Requirements

#### 1. Physical and Operational Characteristics

##### a. Performance Requirements

- i. Threading the graft and receiving site should not damage the articular cartilage
  1. It should not gouge, scratch, or result in mechanical alterations to the native, or grafted cartilage.
  2. It should not result in significant chondrocyte death after use.
- ii. The threading must be easily executed so as to minimize the risk of damaging the graft tissue.

- iii. During the procedure, the graft should be easy to insert or remove allowing the surgeon to adjust the graft depth.
- iv. The system must reliably cut threads that are perpendicular to the central axis of the reamed hole or cylindrical graft to ensure proper alignment.
- v. The graft threading system must accurately cut tight-fitting threads that so that the graft will not loosen post-operatively.

**b. Safety**

- i. The delivery system should not increase the chances of postoperative complications, including (but not limited to) infection, tissue death, or graft dislocation.
- ii. Long term, the graft must not lead to an associated cartilage disorder, significant fissuring or fibrous tissue infiltration, or improper tissue integration.

**c. Accuracy and Reliability**

- i. The device should have a success rate that exceeds that of current procedures (>82% success) [2].
- ii. The device should also allow for successful graft integration into the recipient site. meaning that the procedure should be able to maintain at least 70% chondrocyte viability prior to implantation

**d. Life in Service**

- i. Non-disposable components must be serializable to allow for repeated use
- ii. Life of device materials will vary depending on chosen stainless steel alloy.

**e. Shelf Life**

- i. Capable of storage at room temperature.
- ii. Must be compliant with hospital regulations of storage.
- iii. Shelf life is not likely to present as a significant design consideration.

**f. Operating Environment**

- i. Method of implantation must not compromise sterility of the device or surgical field.
- ii. Must function with range of operating room temperatures, in addition to *in vivo* conditions.
- iii. All components must withstand tension, compression, rotation, and torsional forces exerted upon them during use.
- iv. Must be usable in concurrence with all other orthopedic tools and materials.

**g. Ergonomics**

- i. The device must be designed for comfortable handheld use by the orthopedic surgeon during the procedure.
- ii. Device should be easily adjusted for different sized defects and bone grafts
- iii. During use, the device should not require significant manual guidance (i.e. the device should be self-guiding to prevent surgeon errors).

**h. Size**

- i. Tools will be appropriately sized for handheld usage by orthopedic surgeons

- ii. Bone graft sizes must range between 10 mm - 25 mm in diameter and 7mm - 14 mm deep. The prototype will make a graft that is 15mm in diameter, but should be designed in such a way that future iterations can be made in various sizes (i.e. 10 mm, 15 mm, 20 mm, 25 mm).

**i. Weight**

- i. Since the device will be hand-held, its ultimate weight should not be so heavy that it is cumbersome, or fatigues the surgeon during use, ‘

**j. Materials**

- i. All materials must pass ISO regulations to corrosion resistance and excessive wear from use.
- ii. Tools involved in the procedure must possess the ability to be sterilized or disposed.

**k. Aesthetics**

- i. Aesthetics will serve as a secondary initiative to the function of the final product.

**2. Production Characteristics**

**a. Quantity**

- i. One prototype capable of properly preparing the graft.
  - 1. The prototype can have more than one component.

**b. Components**

- i. The final product should consist of a tap, die, and a bone screwdriver and possibly vices to hold the graft during preparation.
- ii. Components may be eliminated if testing deems them unnecessary.

**3. Miscellaneous**

**a. Standards and Specifications**

- i. The final product must comply with the FDA standard for manual surgical instruments as stated by CFR 21 - Subchapter H - Medical Devices [3]

**b. Customer**

- i. Orthopedic surgeons implanting an osteochondral allograft

**c. Patient Related Concerns**

- i. Decreasing chondrocytes cell viability leads to diminished graft integrity.
- ii. Unwanted debris and fragments of the graft may be released into the synovial fluid environment and cause other complications.

**d. Current Systems**

- i. Arthrex Osteochondral Allograft Transfer System (OATS). This system is the prototypical system used in osteochondral transplant procedures (and is also most similar to the system Dr. Walczak uses). It uses the sizing guide, guide wire, and cannulating reamer to size, locate, and ream the chondral defect. The allograft is prepared using the hole saw which is guided by a manually held ring. The impaction rods force the graft into the receiving hole [4].



- ii. Zimmer Chondrofix Osteochondral Allograft. This system uses a hollow punch hammered into the bone to guide the drill bit during receiving site preparation. There is no need to prepare an allograft since it comes with a pre-made, decellularized allograft that fits precisely in the hole created by the punch and drill bit. The graft is inserted the majority of the way using the insertion tool, and is pounded in the remainder of the way using an impaction rod [5].
- iii. There are no direct competitors, only current systems in use today. All of these systems however, rely on impaction to set the graft in place.

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**Appendix B: Thread Dimensions for Thread Shear Simulation**

<b>Thread Size</b>	$p$	$D_{1max}$	$d_{2min}$
M10X1.50	1.5	8.676	8.862
M12X1.75	1.75	10.441	10.68
M14X2.00	2	12.21	12.5
M16X2.00	2	14.21	14.5

M18X2.01	2	16.21	16.5
M20X2.01	2	18.21	18.5
M22X2.02	2	20.21	20.5
M25X2.00	2	23.21	23.49

**Table 4:** Table indicates the dimension values used to calculate the thread shear stress area in Figure 5.  $p$  is the thread pitch;  $D_{I_{max}}$  is the maximum minor diameter of the internal thread (mm); and  $d_{2_{min}}$  the minimum pitch diameter of the external thread [12].

## Appendix C: Fabrication and Testing Materials

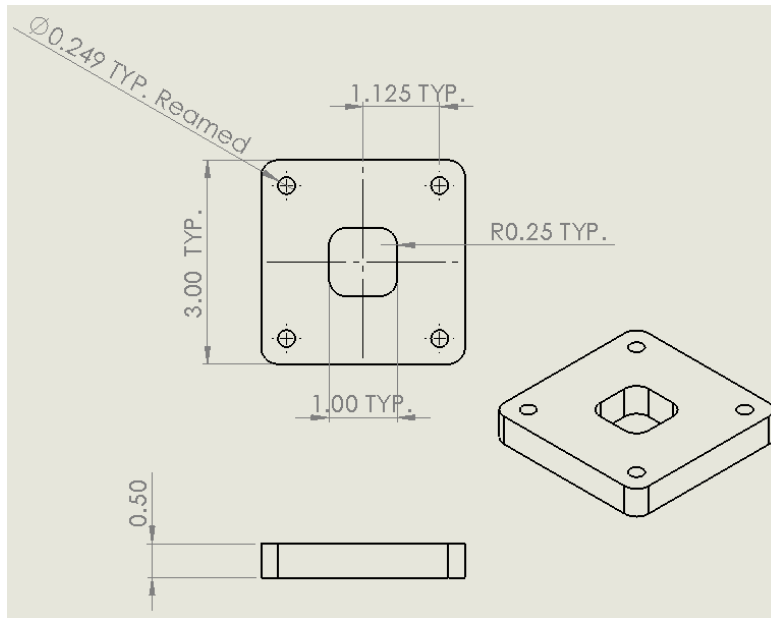
Use	Product	Part Number	Supplier	Quantity	Unit Price	Total Price
Threaded Tap	Rod,SS,303,3/4 In Dia x 1 Ft L	2EWZ5	Grainger	1	\$9.80	\$9.80
Tap/Die Handle	Rod Stock,SS,1 ft. L,3/8 in. dia.	48KU26	Grainger	1	\$4.05	\$4.05
Die Tube	Rod,SS,304,1 In Dia x 1 Ft L	2EXG5	Grainger	1	\$17.15	\$17.15
Die Support Platforms	Aluminum Flat Stock, 6061 Alloy, 0.500" Thick, 12" L X 3" W, Corrosion Resistant	2EZJ3	Grainger	1	\$9.75	\$9.75
Die Platform Support Rods	1/4X2-1/2 416 SS DOWEL PINS	88231915	MSC	5	\$2.63	\$13.14
Graft Cup	Aluminum Square Stock, 6061 Alloy, 1.000" Thick, 12" L X 1" W, Corrosion Resistant	2EZV9	Grainger	1	\$6.75	\$6.75

Guide Wire	Rod Stock,SS,1 ft. L,1/8 in. dia.	48KU23	Grainger	2	\$1.12	\$2.24
Recipient Site Guide Tube	1 Ft Welded For Plumbing, HVAC And Automotive Stainless Steel Tubing, 1/2" Outside Dia., 0.440" Inside Dia	48KV02	Grainger	1	\$6.90	\$6.90
Recipient Site Drill Bit	Brad Point Drill Bit,HSS,7/16" x 5-1/2"	19TH11	Grainger	1	\$7.60	\$7.60
Graft Plug Cutter	Tennon Plug Drill Bit,Steel,5/8"x5-1/2"	29EH39	Grainger	1	\$45.86	\$45.86
Testing Tissue	Bovine Knuckles	N/A	Conscious Carnivore	6	\$7.21	\$43.27
Viable Tissue	Bovine Shank, donated by owners	N/A	Johnson's Sausage	4	\$0.00	\$0.00
Tap and tap handle	M16X2.00	N/A	Student Shop	1	\$0.00	\$0.00
Die and die handle	M16X2.00	N/A	Student Shop	1	\$0.00	\$0.00
Drill bit	14 mm standard drill bit	N/A	Student Shop	1	\$0.00	\$0.00
Drill	Standard drill	N/A	Alex's lab	1	\$0.00	\$0.00
Hammer	Standard claw hammer	N/A	Alex's lab	1	\$0.00	\$0.00
Bone Saw	Standard bone saw	N/A	Grace's Lab	1	\$0.00	\$0.00
DMEM Cell Media	Maintains tissue viability	N/A	BME lab		\$0.00	\$0.00

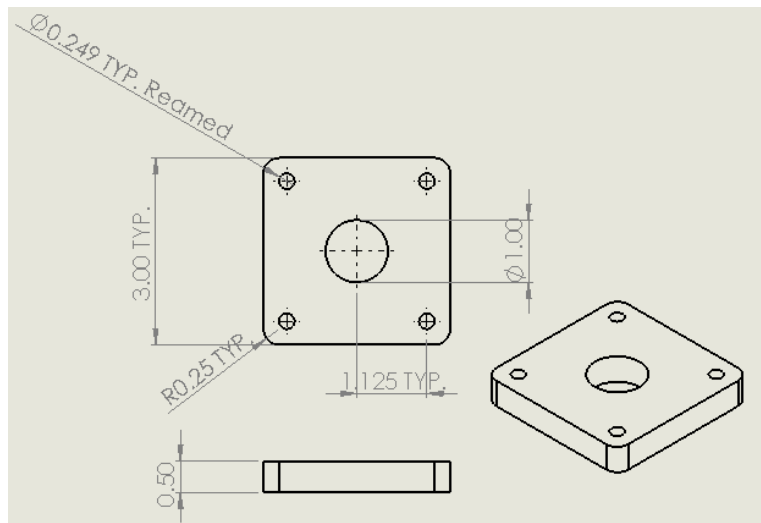
PBS	Used as biologically neutral tissue wash	N/A	BME lab		\$0.00	\$0.00
Calcein AM/EthD-1	Live/Dead fluorescent stain	N/A	Dr. Walczak		\$0.00	\$0.00
Hoechst Stain	Nuclei fluorescent stain	N/A	Grace's Lab		\$0.00	\$0.00
4% Agarose Gel	Solid gel used for stabilization of samples on fluorescent microscope slides	N/A	Grace's Lab		\$0.00	\$0.00

**Table 5:** Complete list of all materials used to make the prototype and perform testing. Total project cost was \$166.51.

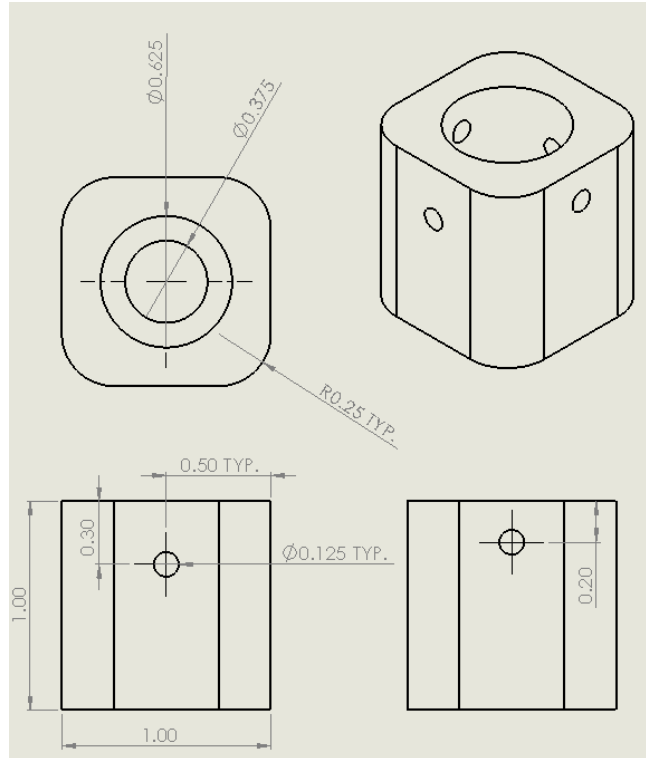
## Appendix D: Fabrication Methods



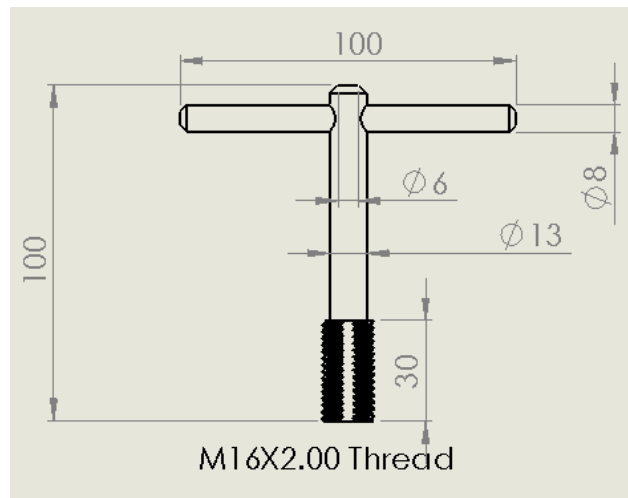
**Figure 18:** Dimensioned drawing of the graft cup holding plate. This plate lies on the bottom of the alignment fixture, and is connected to the top plate by 4 press-fit stainless-steel pins in each corner. This plate is made from 6061 aluminum plate. Dimensions are in inches.



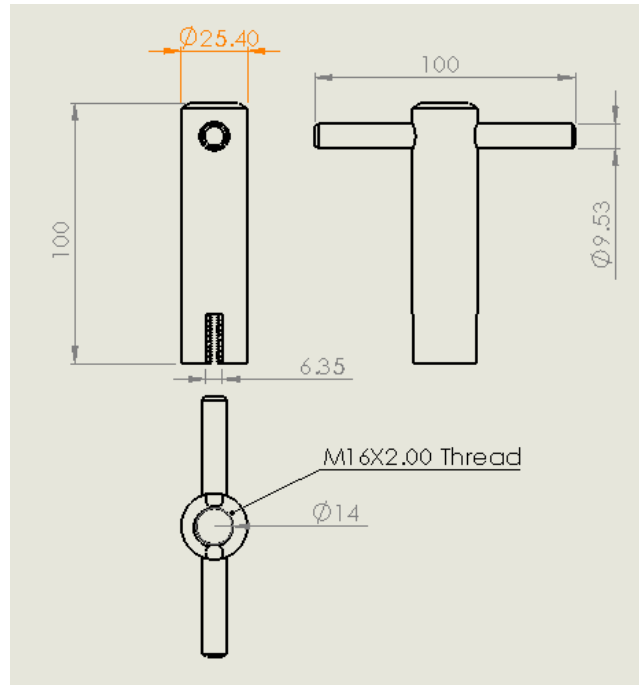
**Figure 19:** Dimensioned drawing of the die alignment plate. This plate lies on the top of the alignment fixture, and is connected to the bottom plate by 4 press-fit stainless-steel pins in each corner. This plate is made from 6061 aluminum plate. Dimensions are in inches.



**Figure 19:** Bone graft holding cup dimensioned drawing. The cup is designed to hold the 16-mm bone plug securely while threading. Threaded pins run through the holes keep the plug from pinning in the fixture. The cup is made from 6061 aluminum. Dimensions are in inches.



**Figure 20:** Guidewire tap dimensioned drawing. The tap takes advantage of the guidewire with a 6-mm hole down the entire shaft allowing the tap to slide over the wire to thread the receiving site. The tap is made from 303 stainless-steel. All dimensions are in millimeters.



**Figure 21:** Bone graft die dimensioned drawing. Internal threads allow the die to cut external threads on the bone graft when guided by the alignment fixture. The die is made from 304 stainless-steel. All dimensions are in millimeters.

## Appendix E: ImageJ Viability Assessment

### Data Processing:

#### Program: Fiji

- 1) Open .tif image
- 2) Change to 8 bit
- 3) Subtract background
  - a) 50.0 pixels
  - b) Sliding paraboloid.
  - c) Preview
  - d) Disable smoothing
    - i) Process all 3 images
- 4) Rectangle tool
  - a) Select the whole lumen
- 5) Analyze
  - a) Plot Histogram
    - i) Get the mean from each lumen images (nuclei, live (green), dead (red))

#### Data Analysis:

$$\% \text{ live cells} = \text{Mean of live (Calcein AM)} / \text{mean nuclei}$$

## Raw Cell Viability Data

		Total Cells DAPI	Dead Cells TRIC	Live Cells FITC
Group 1	Control	205	2	203
	Impacted	58	22	36
	Threaded	174	13	161
Group 2	Control	99	14	85
	Impacted	58	22	36
	Threaded	178	1	177
Group 3	Control	157	130	121
	Impacted	257	133	124
	Threaded	180	3	177
Group 4	Control	299	12	287
	Impacted	345	170	175
	Threaded	186	5	181

**Table 6:** Raw chondrocyte cell counts for each image modality. The values for the total number of cells, total number of live cells, and total number of dead cells for each condition were used to determine a measure of cell viability. The values were collected using the ImageJ protocol outlined above.