Osteochondral Allograft Transplant System

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Abstract

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. Important design specifications include chondrocyte viability, ease of use and procedure time. In a total of six designs for threading the graft or receiving site, the guided wire tap and the guided die design achieved the highest design matrix score. Future work includes receiving client feedback on the proposed design before fabricating a prototype and testing the system.

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Introduction

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, an increase of 5% in the total number of procedures performed every year was seen between 2004-2011 due to the establishment of the national blood and tissue bank in 2006 [3]. 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 (FRM) to the patient, which is crucial to the life quality of these young patients [2]. The motivation in this project, therefore, is to improve the likelihood of graft integration by protecting chondrocyte viability--the most significant factor in determining procedure success [4].

Existing Devices

Arthrex Osteochondral Allograft Transfer System (OATS)

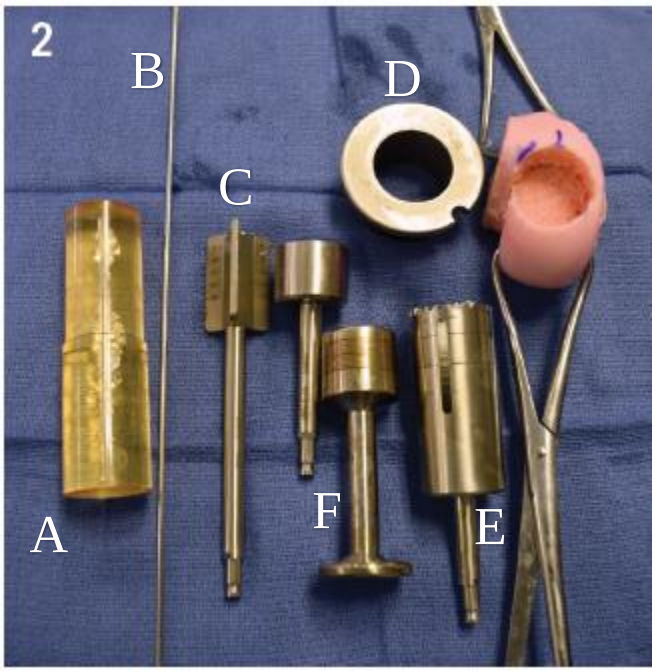


Figure 1. Arthrex Osteochondral Allograft System. (*1A*) Locating and sizing guide. (*1B*) Stainless steel guide wire. (*1C*) Cannulated reamer. (*1D*) Surgical hole saw guide ring. (*1E*) Surgical hole saw. (*1F*) Impacting rods.

The Arthrex Osteochondral Allograft Transfer System (OATS) uses several different tools to prepare the donor site, and harvest the graft plug before impacting it into the patient [6]. 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

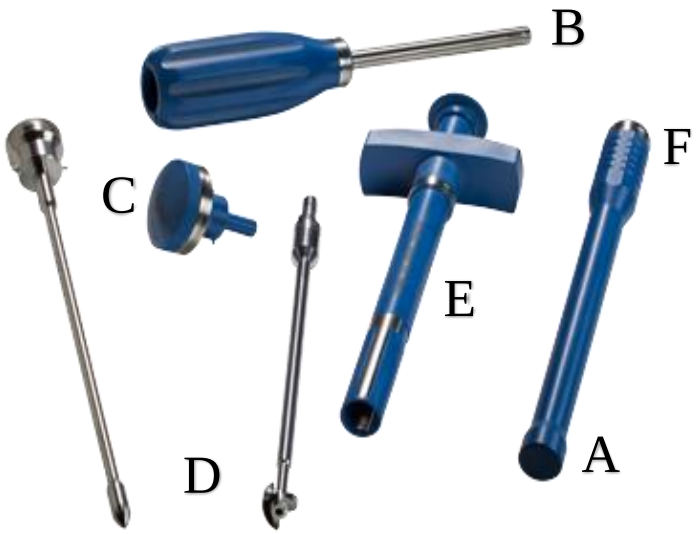


Figure 2. Zimmer Chondrofix Osteochondral Allograft System. (*2A*) Plastic sizing rod. (*2B*) Hollow punch used to align drill bit. (*2C*) Punch impacting cap. (*2D*) Drill bit corresponding to interior punch diameter. (*2E*) Graft insertion tool. (*2F*) Graft impaction rod.

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 (2*A*) rod determines the size of the graft that the surgeon will insert. A hollow punch (2*B*) 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 (2*C*) is removed to expose a center hole that accepts a corresponding drill bit (2*D*) 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 (2*E*), leaving it slightly proud of the surface, and the impaction tool (2*F*) pushes it flush with the surface. This system is designed for arthroscopic use, unlike with the Arthrex system [5].

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 % [3]. 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

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 zone of the articular cartilage. The impaction impulse activates mechanoreceptors in the cell initiating a cascade resulting in the activation of executioner caspases in the articular cartilage of the allograft. These caspases trigger an apoptotic response from the cells, which result in cell death (Figure 3).

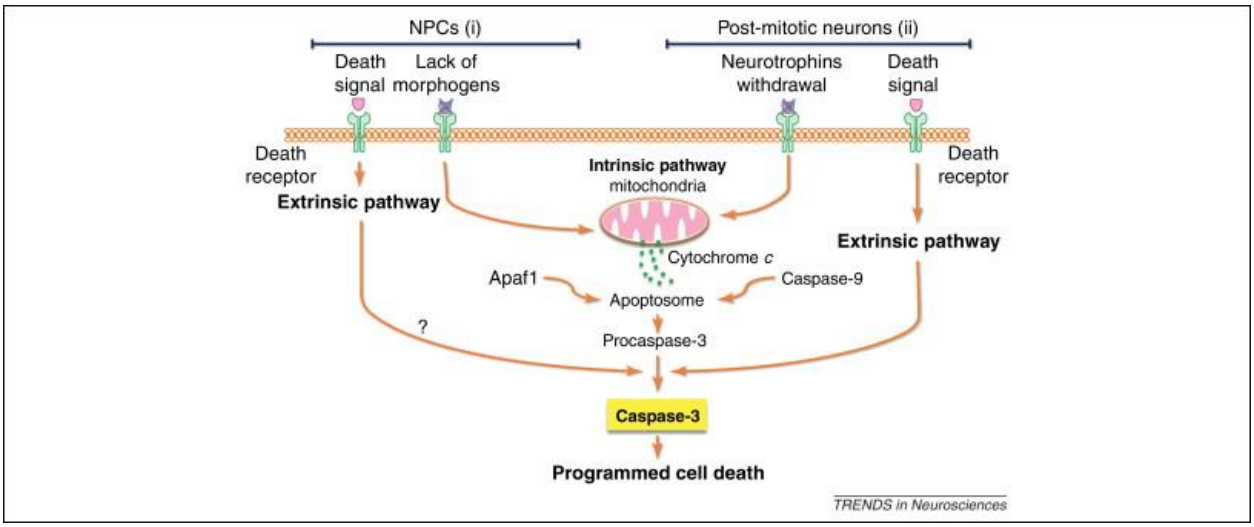


Figure 3. Biochemical pathway leading to chondrocyte death following impaction. Mechanoreceptors initiate a signal cascade ultimately activating executioner caspases and leading to apoptosis [9].

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 in order to be properly placed 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.

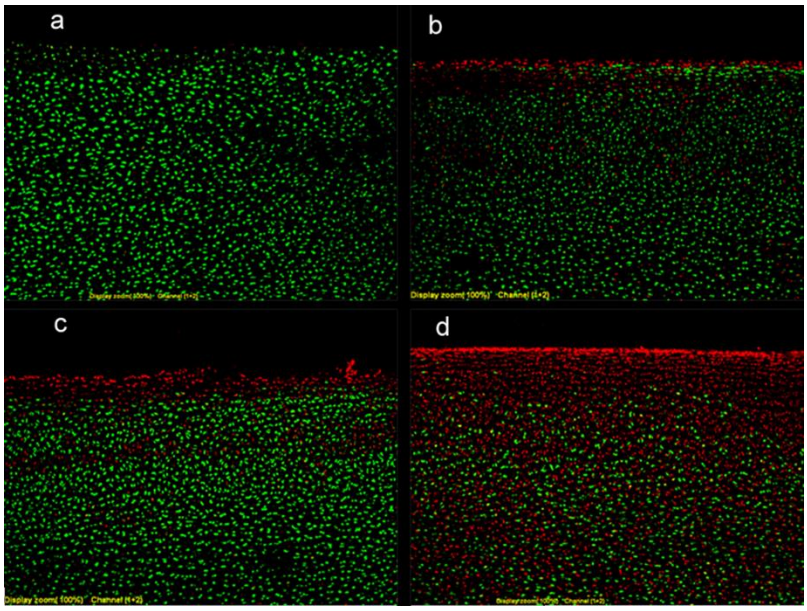


Figure 4. Live/death chondrocyte cell staining following impaction at varying loads. Red indicates cell death; green indicates viable cells. (a) control (b) 75 N (c) 150 N (d) 300 N [10]

The effects of impaction on chondrocyte viability is an important medical concern for this procedure as chondrocyte viability at the time of impaction is the number one determinant of allograft success. A study was performed in canine models to assess the effects of chondrocyte viability at the time of impaction on allograft success. Subjects (n=16) received an osteochondral allograft and their cell viability was assessed at the time of impaction 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

FDA Manual Orthopedic Device Standards

The U.S. Food and Drug administration outlines medical device regulations in CFR Title 21- Subchapter H [12]. 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]. 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]. 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]. There are many alloys of stainless steel available, however martensitic alloys are generally chosen for surgical instruments, due to its substantial hardness. [16] 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].

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 who specializes 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

Recipient Site

Guide Wire Tap

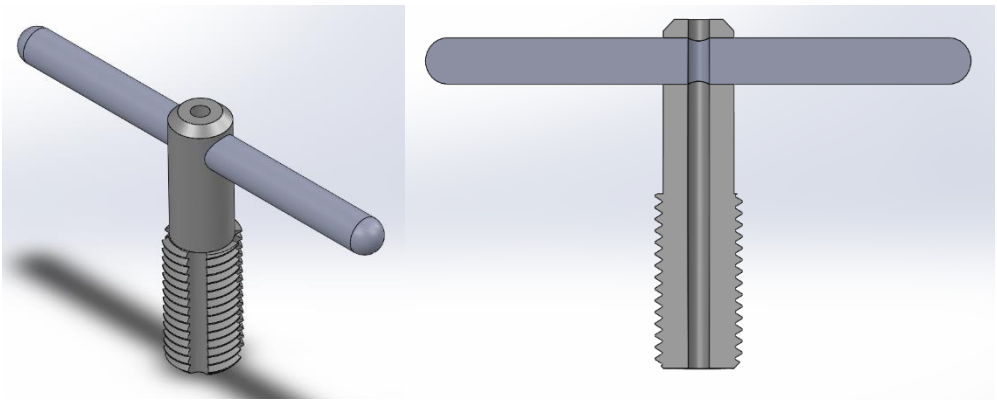


Figure 5. Guide Wire Tap Design. Isometric view (left) and section view (right). This design is identical in principle to a standard machine die, but note the center hole to direct the tap along the surgical guide wire.

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

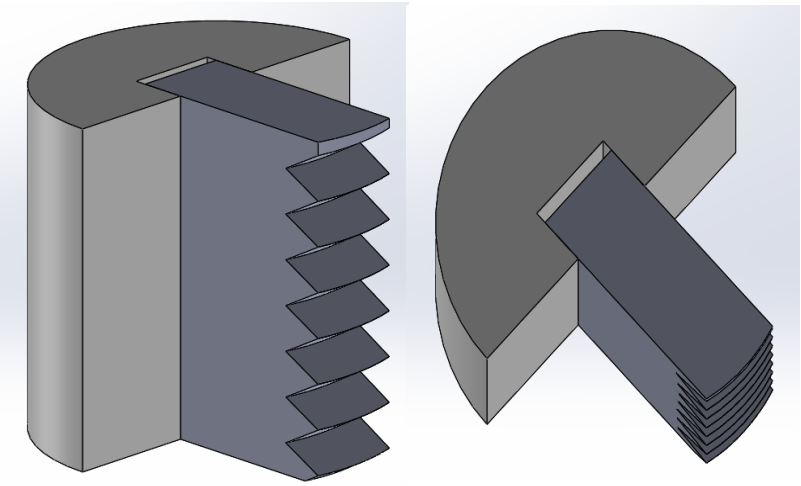


Figure 6. Spring Loaded Thread Cutter. Isometric view (left) and top view (right) of the spring-loaded thread cutter.

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

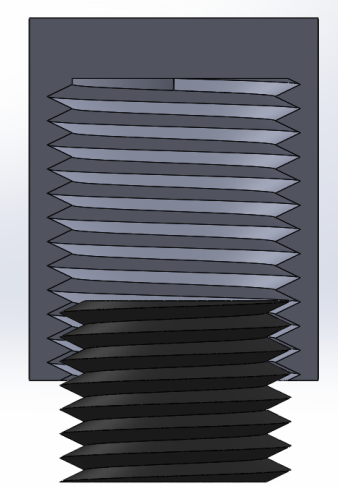


Figure 7: Protracted screw configuration of combined Tap and Die design.

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

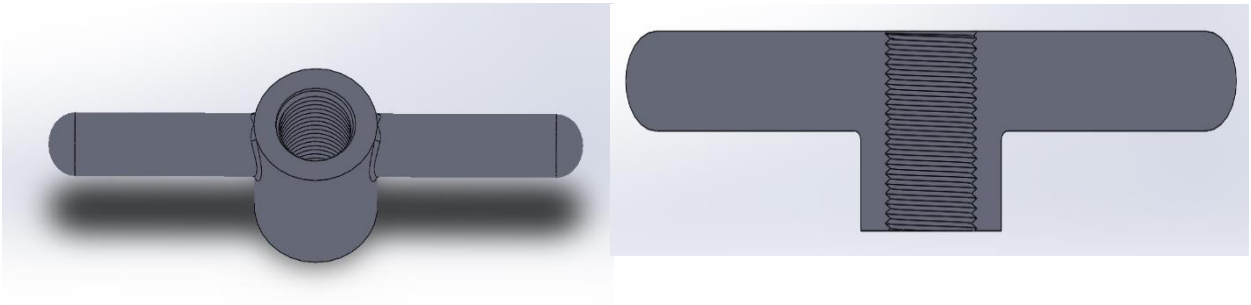


Figure 8: Isometric view (left) and section view (right) of the die design.

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 9: 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 irm 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

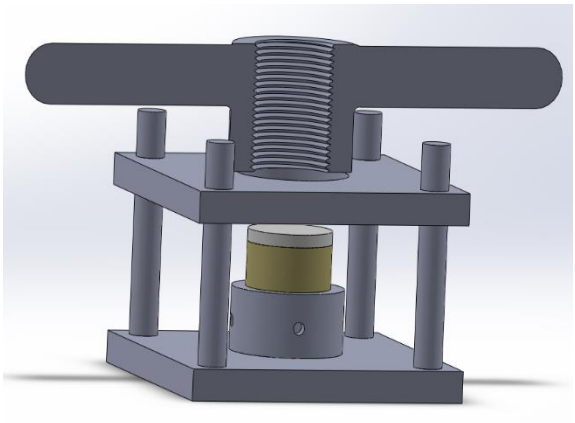


Figure 10: Isometric view of Guided Die design with internal view of the thread cutting die. Below the die is the uncut allograft (brown) capped with chondral tissue.

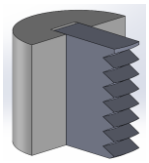
The guided die relies on a custom surgical die, much like the standalone die design, but it is augmented with a supporting platform. The platform is made of stainless steel compatible with the operating room, and it has a fixed base with a moving support. The base has a cutout to receive the graft support 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

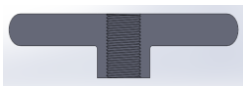
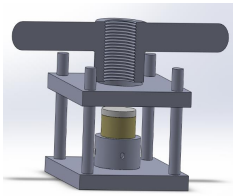
Recipient Site:

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.

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
Total	**100.00**		**89.00**		**55.00**		**70.00**

Donor Plug:

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.

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
Total	**100.00**		**63.00**		**76.00**		**70.00**

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 [2]. 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 is able to 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, the gunk 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 complexity of the design. The Guide Wire Tap scores well in this category, but not perfect, because it is a simple design that takes the shape of a standard machining tap. 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 well. The half cylinder, springs, and cutting tool of this design are simple to make but will require some time to assemble.

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 to the assembly factor result in these devices having 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.

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. 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

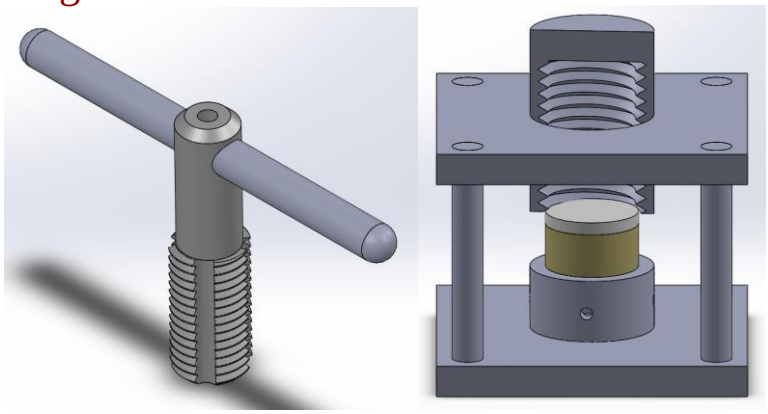


Figure 11. Guide Wire Tap used to thread the recipient site (left). The right image shows the device used to thread the donor site; it is a hybrid that utilizes the consistency of the Guided Die design and the threading mechanism of the Combined Tap & Die design.

For the threading of the recipient site, the proposed final design is the Guide Wire Tap. This design was chosen because it follows a proven method for threading internal surfaces.

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. The Guided Die design was marked as the most accurate of the donor plug threading designs, but because it used the Die design die, 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.

Future Work

After finalizing the design concept with Dr. Walczak, the team will move forward with refining design specific specifications, including precisely defining dimensions of the tap and die components. Thread profiles between the two components must match, the depth of the relief grooves in the tap and die must be large enough to accommodate waste bone, medically appropriate materials must be selected, and a specific manufacturing plan must be outlined. After the final design details are described, the prototypes can be manufactured.

Once the team has functional prototypes for both the die and tap components, testing can begin. Initial testing will use bovine tissue to evaluate only the mechanical aspects of the project. This testing is to verify that the grafts can be easily screwed in by hand, that the components can easily cut threads in the graft and donor site, and that they don't cause overt damage to the articular cartilage. After successfully cutting threads in the bovine tissue, cell viability can be assessed using fresh porcine tissue Since viable porcine tissue will likely be in short supply, initial testing with bovine tissue will provide the team with valuable experience using the device so that the viable porcine tissue is not wasted with procedural error. Live/dead staining of the porcine chondrocytes will allow the team to compare cartilage viability with the bone screw to impaction data provided by the client.

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Appendix

PDS

Osteochondral Graft Tapping System

Preliminary Product Design Specifications

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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. 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 reminder 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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