UNIVERSITY OF CALIFORNIA, SAN DIEGO

Custom Surgical Guides for Articular Cartilage Repair

A thesis submitted in partial satisfaction of the requirements for the degree
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In

Bioengineering

by

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The Thesis of Alexander F. Szewczyk is approved and it is acceptable in quality and form for publication on microfilm and electronically:

Chair

University of California, San Diego

2018

DEDICATION

I dedicate this thesis to my family for supporting me through many challenging times in life, including graduate school. I also dedicate this thesis to Anali Ramirez and Hannah Mack for helping me survive graduate school.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

- 3D: Three-dimensional
- ABS: Acrylonitrile butadiene styrene
- ANOVA: Analysis of variance
- CAD: Computer-aided design
- CT: Computed tomography
- FDM: Fused deposition modeling
- GB: Gigabyte
- LFC: Lateral femoral condyle
- MB: Megabyte
- MFC: Medial femoral condyle
- µCT: Micro computed tomography
- MRI: Magnetic resonance imaging
- OCA: Osteochondral allograft
- SLA: Stereolithography (apparatus and 3D printing technique)
- SLS: Selective laser sintering
- STL: Stereolithography (file format)

LIST OF SYMBOLS

- d: Used as a variable to represent diameter.
- h: Used as a variable to represent height.
- θ: Theta, used as a variable to represent an angle.
- °: Degrees.
- δ: Delta, used as a variable to represent a length/displacement.
- μ: Mu, used to represent the prefix micro.

LIST OF FIGURES

LIST OF TABLES

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In addition to the members of the CTE lab, I would like to thank Dr. Koichi Masuda, Dr. William Bugbee, and Dr. Dana Covey for taking time to meet with me in the lab and participate in my study.

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ABSTRACT OF THE THESIS

Custom Surgical Guides for Articular Cartilage Repair

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Professor Robert L. Sah, Chair

Osteochondral lesions are injuries which affect the bone and articular cartilage of knee joints. Osteochondral allografts procedures are commonly used to repair damaged articular cartilage. Due to inconsistent cut angles of the recipient and donor sites, surface incongruities after an allograft procedure can lead to poor outcomes. The purpose of this project was to develop a process that would produce surface-matching surgical guides from CT scans,

which would ensure that allograft cutting tools were normal (perpendicular) to the articular cartilage when performing the procedure, therefore reducing surface incongruities.

In order to achieve this, image processing software was developed to automatically orient CT scans of femurs in a standard way, additional software was developed to produce surface normal vectors from a defect site, and CAD models of surgical guides were created, prototyped, and tested for edge offset improvements compared with unguided procedures.

CHAPTER 1: INTRODUCTION

1.1 Articular Cartilage and Osteochondral Lesions

Articular cartilage, or chondral, lesions are injuries that affect hyaline cartilage covering the subchondral bone. Physical trauma is a common cause of the lesions, although other conditions in which articular cartilage lesions occur include osteonecrosis, osteochondritis dissecans, and arthrosis. [3, 9] Cartilage lesions are a fairly common occurrence in knee injuries. Cartilage lesions have been observed in 63-66% of knee arthroscopic procedures. [2, 10, 12] Unlike chondral lesions, osteochondral lesions involve damage to the bone and there is a much greater inflammatory response due to the highly vascular subchondral bone being damaged. [14] Because cartilage is avascular and dense tissue, it has very limited ability to repair itself. [11, 14] Without treatment, articular cartilage lesions can result in pain and swelling and further damage to the joint. [14-16] Surgery is therefore necessary to treat most articular cartilage injuries.

1.2 Surgical Precision

Chondral and osteochondral lesions in joints are often repaired using osteochondral allografts, which are cylinders of bone and articular cartilage harvested from a donor. [15] It has been shown that even unstable grafts are an improvement over letting the body attempt to repair a cartilage defect on its own. [18] A study investigating the outcomes of osteochondral allografts found they had about a 67.5% survival rate (at 20 years) on surgically repairing damage to articular cartilage. [12] Another study found that there was a 63% success rate at 14 years after surgery in the allografts that were observed. [5] Those survival rates are respectable for a tissue that has extremely limited ability to repair itself, but there is room for improvement.

Osteochondral allograft procedures consist of a recipient site that has been drilled through the cartilage and bone in the area of a lesion, as well as an osteochondral core which has been harvested from a donor and inserted into the donor site. [1] The basic idea is that the damaged cartilage has simply been replaced by undamaged cartilage from a donor in a single surgery. Articular congruence, the smoothness or continuity of the articulating surface, is a critical aim for a successful allograft. [15, 16, 20] If the edge of a graft is not proud (or sunk) relative to the edge of the recipient site, then the congruence of the cartilage would be considered ideal. Poor congruence of the cartilage can lead to degeneration and failure of the graft [21], understandably so because the exposed edges of either the graft or recipient site would become a focal point for

stress during the motion of the joint. A study comparing proud (by 2 mm) and flush osteochondral autografts found that three months after the graft operation 6 of 7 flush grafts achieved a good or excellent rating while only 1 of 6 proud grafts was good or excellent. [21] The proud grafts were shown to be much more likely to experience degeneration and failure. The ability to create donor grafts and recipient sites that form right angle cylinders, as shown in **Figure 1.1**, is a significant factor in achieving articular congruence. [15] Deviation from a right angle cylinder can result in a lack of articular congruence to an extent that is dependent on the diameter of the allograft, shown in **Figure 1.2**, resulting in increased likelihood of poor congruence for grafts of larger diameters. [15]

Osteochondral allograft procedures, like other surgeries, depend on the skill of the surgeon to produce good outcomes. When a surgeon is performing a cut for an osteochondral graft, they typically do not use a guide for the cutting tool but instead use a bushing (essentially a thick sleeve) to steady the cutting tool. This means that the calculation of the normal vector from the surface of the cartilage (to which the cutting tools is aligned) is performed by the surgeon in a rough fashion using just their eyes. Reducing the possibility for human error can improve surgical results, and many other surgeries make use of custom guides to do that. An apparatus that is mounted in the femur to provide a point of reference that is unchanging relative to the femur has been used in some osteochondral autograft surgeries, although it does introduce a new injury to the femur (and surrounding tissue). [16] Customized, 3D printed surgical guides have been used

in some osteotomies with surface-matching parts of the guide that fit to the curvature of the bone. [6, 17] These guides can provide stability and an unchanging point of reference for the pieces of bone even after that cuts have been made.

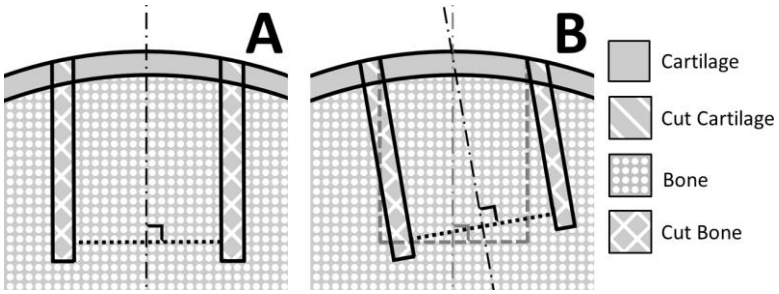


Figure 1.1: Two-dimensional cross-section diagrams illustrating the difference between the harvesting of a right-angle cylindrical osteochondral plug (A) and an osteochondral plug with an angular mismatch (B). Grey dashed lines indicate the orientation of the right-angle plug on the diagram with angular mismatch (B).

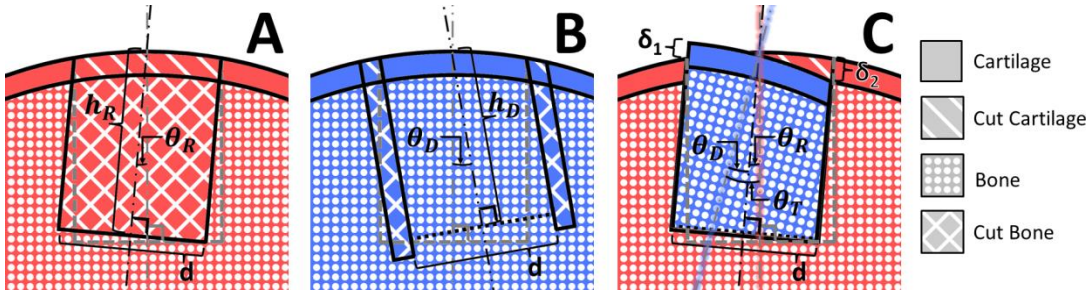


Figure 1.2: Two-dimensional diagrams of an osteochondral allograft cross-section showing the effect of angular mismatch between **(A) the recipient** and **(B) the donor** tissue of **(C) an osteochondral allograft**. Grey dashed lines in each diagram indicate the orientation of an ideal perpendicular cut (for right-angle cylinders). The grey dash-dot line and the dash-double-dot line represent the axis normal to the surface of the condyle running through the center of the ideal cut for the recipient site and donor core respectively. θ_R and θ_D are the angular deviations from a right angle cylinder for the recipient site and the donor core. δ is the resulting edge offset caused by the total angular deviation, θ_T, and the diameter, d, of the allograft. In this case, the recipient angular deviation and the donor angular deviation are in opposite directions so the total angular deviation is simply the sum of the two angles ($\theta_T = \theta_R + \theta_D$, when θ_R and θ_D are in opposite directions). The edge offset is likely to be different on either side of the graft cross-section, especially when the height of the recipient site, h_R, and the donor core, h_D, are not exactly the same.

1.3 Customized Surgical Guides

Surgical guides that match the shape of the surface upon which they rest, such as the articular cartilage and nearby bone of a femur, greatly reduce variability in picking the location and angle for performing a cut for surgical procedures. [17] By reducing variability in the location and angle of the procedures, better matching of surface curvature will be achieved between the donor tissue and the recipient. As mentioned before, such improvements in surface congruence for allograft procedures improves their outcomes.

Surface-matching surgical guides have some advantages over computer-assisted surgeries, procedures in which the computer helps navigate cuts by tracking the position of the tool. [16, 17] Computer-assisted surgeries require attaching a reference frame and registering the tracked tool by matching points on the surface of the bone to those of the computer model. Surgical guides would not require both of those, thereby requiring one fewer procedure and less time while the surgery is in progress. [17]

Stabilizing the cutting tools of an osteochondral allograft procedure to an orientation aligned with the surface normal vector by using a surgical guide should produce more consistent cuts that are closer to right angle cylinders than methods without a guide. 3D printed surgical guides have been shown to be effective in producing better outcomes for other operations [6, 17], while other surgical guides [16] have been shown to improve osteochondral graft procedures. 3D printed parts have also been used to effectively practice

surgeries without the use of biological tissue. [7] Therefore, it should be possible to make a 3D printed guide to achieve the normal vector alignment and improve the stability of the cutting tools for osteochondral allograft procedures. Given that an invasive osteochondral autograft surgical guide was able to make improvements of between 7.4° and 8° [16], the goal chosen for the less invasive 3D printed surgical guide developed as part of this project was 5° (0.35 mm edge offset for 8 mm diameter cores).

1.4 Assessing the Articular Cartilage Surface Using μCT Scans

Computed tomography (CT) scans are a common method of producing three-dimensional images of joints to evaluate injuries. While CT scans lack the contrast of an MRI to be able to identify many soft tissue injuries, they are quite effective in imaging orthopedic injuries. In addition, CT scans have the benefit of having less complex image post-processing than MRI. [22]

Typically the articular cartilage will show up on a CT scan as a moderate grey value like many other soft tissues (**Figure 1.3**). Since articular cartilage is usually around mostly other articular cartilage and bone, it is often possible to separate the articular cartilage from the rest of the scan by thresholding the pixel values in the images. To achieve images containing just the cartilage then a specific threshold range is required, going from a low value (e.g. around 30 for greyscale images) to a moderate value (e.g. around 65 for greyscale images). If the desire is to include bone, then the images can have a threshold applied with a range starting from a low value (e.g. around 30 for greyscale images) going up to the maximum value (255 for greyscale images) since bone shows up in the more bright (larger number) range of values within CT scan images.

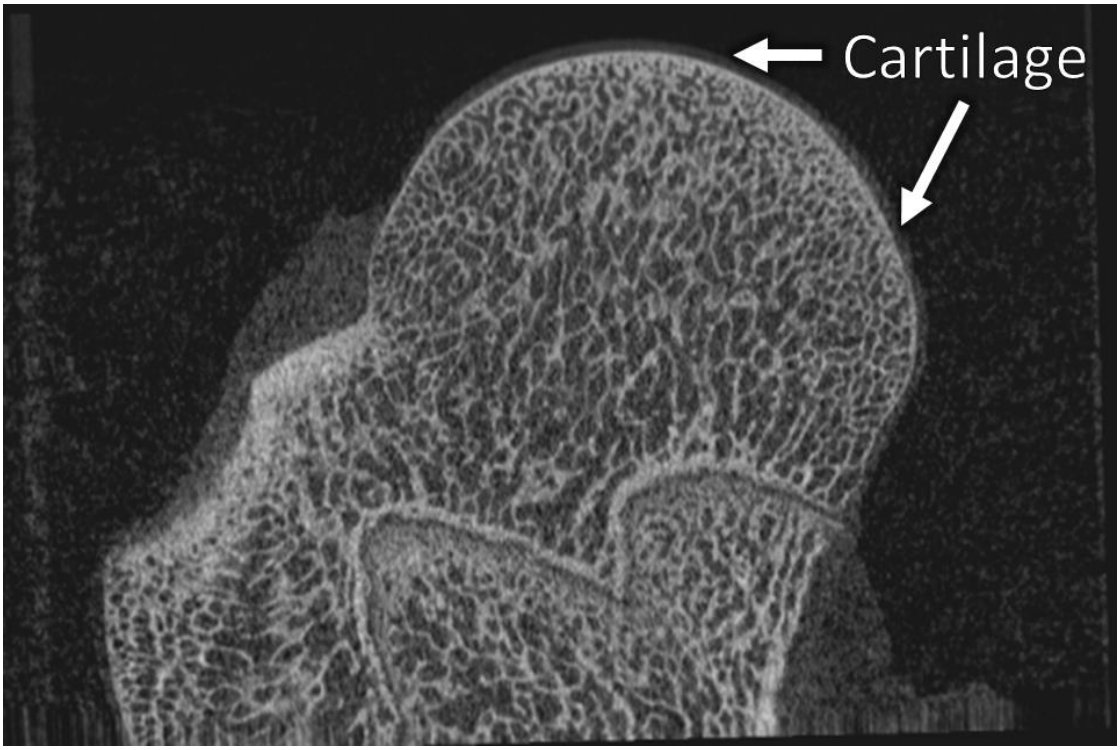


Figure 1.3: An image slice from a µCT data set of a distal goat femur that has had its contrast and brightness increased to show the cartilage more clearly. The cartilage can be seen as a moderate grey, thin layer on the surface of the condyle near the top of the image.

1.5 Distal Femur Alignment to Standardized Axes

Femoral condyles are two cartilage-covered protrusions located at the end of the distal femur. The articular cartilage covering the femoral condyles comes into contact with the articular cartilage covering the proximal tibia, the combination of which enables the low-friction articulation of the knee.

Understanding the position of the femoral condyles in 3D space is important not only to imaging but to surgical procedures. There are many methods of defining axes to landmarks on the femur. The epicondyles on the distal femur have been used to define an axis that travels roughly in the medial-lateral directions. [24] Since the shaft of the femur is mostly straight, it is useful to consider this as a central axis of the femur. Defining an axis does not fully constrain the femur in 3D space, therefore other landmarks must be used. On the distal end of the femur, the easily identifiable landmarks are the condyles and the patellar groove. Since the patellar groove can be quite subtle, such as in humans, the condyles are the clear choice for identifying the orientation of the femur. The two condyles are commonly referred to as the medial and lateral condyles based on their anatomical orientation (**Figure 1.4**). This means that the condyles are essentially aligned on a coronal plane, which separates anterior from posterior in standard biological definitions.

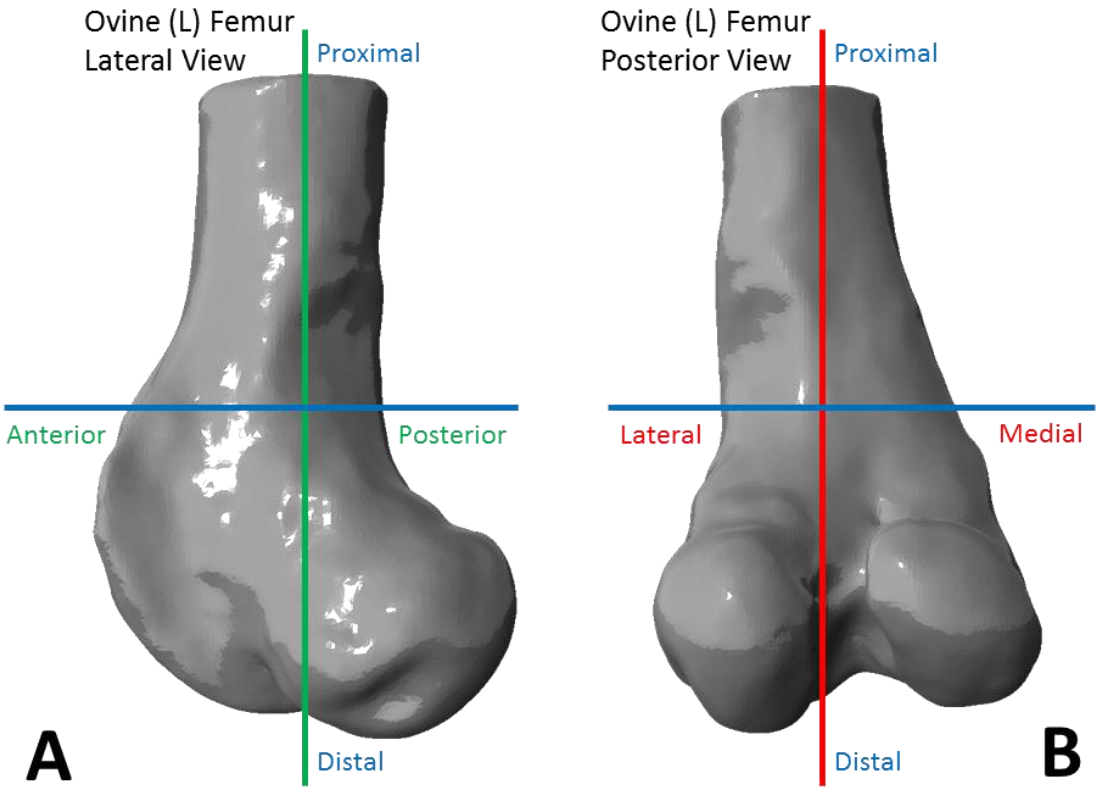


Figure 1.4: Diagrams providing anatomical descriptions of the distal femur from a lateral view (A) and a posterior view (B).

1.6 3D Printing

3D printing, a set of additive manufacturing techniques, is a useful tool for rapid prototyping and for creating parts that are difficult to manufacture by other methods. Most 3D printing involves creating a three-dimensional part by building successive two-dimensional layers. The two-dimensional layers are built using a variety of methods. Fused deposition modeling works by pushing filament through a heated extruder while the extruder, or the print bed, is moved to the location where the material is meant to be printed. Other 3D printing methods, such as stereolithography (SLA) and selective laser sintering (SLS), use lasers to create the 2D layers either by curing photopolymers or by melting powders so the particles fuse together. Each method has its unique traits but FDM printers are more common as household printers due to their generally lower cost, which is a result of not requiring an expensive laser and using relatively inexpensive materials.

There are several advantages to using 3D printing over other methods of manufacturing. 3D printers can quickly and inexpensively produce parts immediately after they are designed, while injection molding would initially take time and money to create the molds (although long term it could produce more copies of a single design). The shapes that 3D printers produce can be difficult or impossible for machining or injection molding. The use of dissolvable materials (in combination with the more common, not dissolvable, materials) can allow 3D printers to create an even larger variety of shapes that could not be machined or

molded. A spiral seashell, for example, would be extremely difficult to machine or make using molds unless it was made in more than one piece and assembled afterward. A 3D printer can make a spiral seashell in a single piece and if there are spaces within the shell that could potentially collapse while printing, the dissolvable filament could be used to support that space and be washed out once the print finishes.

1.7 Project Objectives

The purpose of this project was to achieve two major goals regarding surgical guides for osteochondral allograft procedures:

I. Design a guide for the harvest and insertion of osteochondral grafts that can be customized to the curvature of individual femoral condyles.

II. Evaluate the surgical guide for reduction of graft maximum edge offsets in osteochondral allograft procedures.

The primary study involving osteochondral allograft procedures described in this paper is being prepared for submission for publication. Szewczyk, Alexander F; Chen, Albert C; Bugbee, William D; Sah, Robert L. “Osteochondral allograft procedure cuts aided by custom surgical guides”. The thesis author was the primary investigator and author of this material.

CHAPTER 2: MATERIALS AND METHODS

2.1 Overall Project

CT scans are commonly used in medicine to produce 3D images for evaluating orthopedic conditions. Therefore, this is the starting point for obtaining the geometry required for surface-matching surgical guides to be produced. CT scans of distal femurs (or whole femurs) were chosen as the initial focus for producing these surface-matching guides in order to more easily validate the end result, concentrate the scope of the project, and because the distal femur is a common site for osteochondral allograft procedures.

In order to achieve the matched surface of the surgical guides, a 3D model of the bone in the CT scan needs to be created and a position of the procedure site must defined (relative to the 3D bone model). In order to simplify those steps, and most other uses of CT scans, automatic standard alignment of the CT scans is needed. Therefore, automatic CT scan alignment was first major goal to be accomplished on the way to completing the overall project.

The surgical guides were intended to increase the effectiveness of achieving a right-angle cylinder when performing the cuts for an osteochondral allograft procedure, for both the recipient site (right-angle cylindrical hole) and the donor core (right-angle cylindrical piece of cartilage and bone tissue). This requires that the right-angle cylinder be defined at the surgical sites. Code was

developed to produce data from CT scans that would define the position and orientation of right-angle cylinders at surgical sites.

In order for the surgical guides to be aligned with the normal vector defined from the surface of the condyle, the surgical guide CAD (computer-aided design) model needed to accept input that defined the normal vector. The guides also needed to fit snugly around two different cutting tools with different diameters, a coring bit and a guide pin. Surgical guides were designed using CAD software, and 3D printed prototypes were made.

2.2 Defining the Placement of the Surgical Guide

Based on the large amount of documentation supporting and describing Matlab as well as its prevalent use in scientific fields, Matlab was used to develop code to perform the automatic alignment of the CT scans. Using standard Matlab functions simplified some of the coding required to accomplish this project. The ‘uigetfile’ function was used to easily prompt the user to select a file to load, the ‘iminfo’ function collected the information saved within an image file so the user does not need to enter that information manually, and the ‘imread’ function imports the actual image into a variable. The ‘pcfitcylinder’ function, which was added in the 2015 version of Matlab, turned out to be extremely helpful in automatically aligning CT scans.

Despite predeveloped standard functions, developing code to automatically align CT scans is no simple task. CT scan data sets are stored as large stacks of images that, when combined, form a three-dimensional view of the scanned object. This means an entire data set can consume a lot of memory if it is loaded completely, which is most likely necessary for achieving three-dimensional alignment. For example, a particular scan of a mouse femur at a 9 micron resolution is approximately 712 Megabytes (MB). But that is only a small scan, since a mouse femur is itself quite small. A scan of only the distal portion of an ovine femur is nearly 8 Gigabytes. For comparison, at this point in time 32 Gigabytes (GB) of memory is fairly large, although likely common for computers used for CT scan processing. The distal ovine femur scan would be consuming

one quarter of the 32 GB of available memory by itself. This shows how critical it was that the image processing code was designed to make efficient use of memory.

An important strategy in efficiently using memory is to use functions with which certain pieces of data are passed into the function and other data is returned. Any variables that are set within a function are cleared automatically once the function has completed its process. If the alignment code were written instead as one long script, variables containing data would continue to consume memory until they were manually cleared.

Consecutive rotations of an image will result in the accumulation of distortions, such as in **Figure 2.1**. In order to retain as much of the original quality of the images of the CT scan as possible, the number of manipulations of the original data must be limited. Therefore, the alignment code was limited to two rotations of the original image stack: one to align the shaft of the femur with the z-axis, and another to rotate around the z-axis so the condyles are aligned.

The rotations of the CT image stack understandably require a large amount of processing power and can take a long time to complete. It was therefore important to select the best method of performing these rotations. Two standard methods were compared for speed and required computing power: the ‘imrotate’ function and the ‘tformarray’ function. Using a 712 MB data set (scan 3267) and rotations of 5 degrees around the x-axis, 10 degrees around the y-axis, and 15 degrees around the z-axis, the ‘tformarray function took almost 100

times as long as the ‘imrotate’ function. Although the ‘imrotate’ function consumed nearly twice as much processing power, the enormous difference in processing time made it a simple decision to use the ‘imrotate’ function as the primary method of rotating image stacks.

Because consistency is important when aligning CT scans of femurs for scientific analysis, it was important to keep alignment methods as consistent as possibly between two different types of femur CT scans that include the femoral condyles: whole femur, and distal femur. Because a distal femur scan would not include the femoral head of the proximal femur, the femoral head could not be used as an alignment landmark. The epicondyles of the distal femur, being essentially lumps on either side of the femur, are not simple to identify using code unless the femur has already been aligned. Therefore, it was not considered a good strategy to use the epicondyles in the alignment process. Instead, the primary alignment step was to use the femoral shaft to define the first axis of the femur scan. Using the ‘pcfitcylinder’ Matlab function (**Figure 2.2**) multiple times, removing outliers, and taking the average, the angles required to align the femoral shaft with the z-axis of the CT image stack (the axis running through the center of each image in the image stack) were calculated. The femur CT scan was then rotated based on the calculated angles before performing further alignment steps.

Once the femoral shaft was rotated into alignment with the z-axis of the CT image stack, the femoral condyles were used to fully define the orientation of

femur within the image stack. While some studies have defined the medial-lateral orientation of the femoral condyles by using a cylinder fit to the surfaces of the condyles [13], this code was developed differently. The medial-lateral orientation of the condyles was determined in two steps: finding the intercondylar notch and levelling the condyles flat against a coronal plane.

The purpose of finding the intercondylar notch was to provide a rough orientation of the condyles so they could be more easily located and oriented. The intercondylar notch was found by rotating z-axis image slices until the code found a notch pointing toward the edge of the image, as shown in **Figure 2.3**. Once the intercondylar notch was identified, the angle of its orientation was returned and used to rotate temporary copies of the z-axis image slices.

The image slices from the intercondylar notch identification step were then used to produce the final result in which the condyles were flat against a coronal plane. This was done by rotating the images until the condyles on either side of the notch were level, as in **Figure 2.4**. The rotation angle of this step was added to the rough rotation angle of the previous step to produce the final rotation angle for the original image stack. The code was designed to then use this angle and rotate the original image stack (after being rotated once to align the femoral shaft). At this point the code would export the aligned image stack and an STL file of the femoral condyles could be created using a standard task list in CTAn (software used for CT scan analysis and image processing).

The code to produce the position of the allograft site was designed to export two points, chosen to be named the Defect Point and the Guide Point, so that the surgical guide parts can be oriented properly with respect to the surface of the condyles. Both points lie on the normal vector calculated from a point on the surface of a condyle. In order to present the condyle surface to a user, the code imports an STL file of the femoral condyles and presents a window displaying a computer rendering of the condyle surface so the user can select a surgical site. The surgical site selected by the user becomes the Defect Point. The code then checks the area near the Defect Point and calculates a normal vector based on the position of nearby points on the condyle surface. The settings used to calculate the normal vector for the OCA study checked the nearest 100 points on the condyle surface, which for the 3D model files used means that the code checked points within about a 1.5 mm radius. The Guide Point is then defined to be along the normal vector but separated from the surface of the condyle by a certain distance, and the three pieces of data, shown in **Figure 2.5**, are exported for use by the surgical guide design.

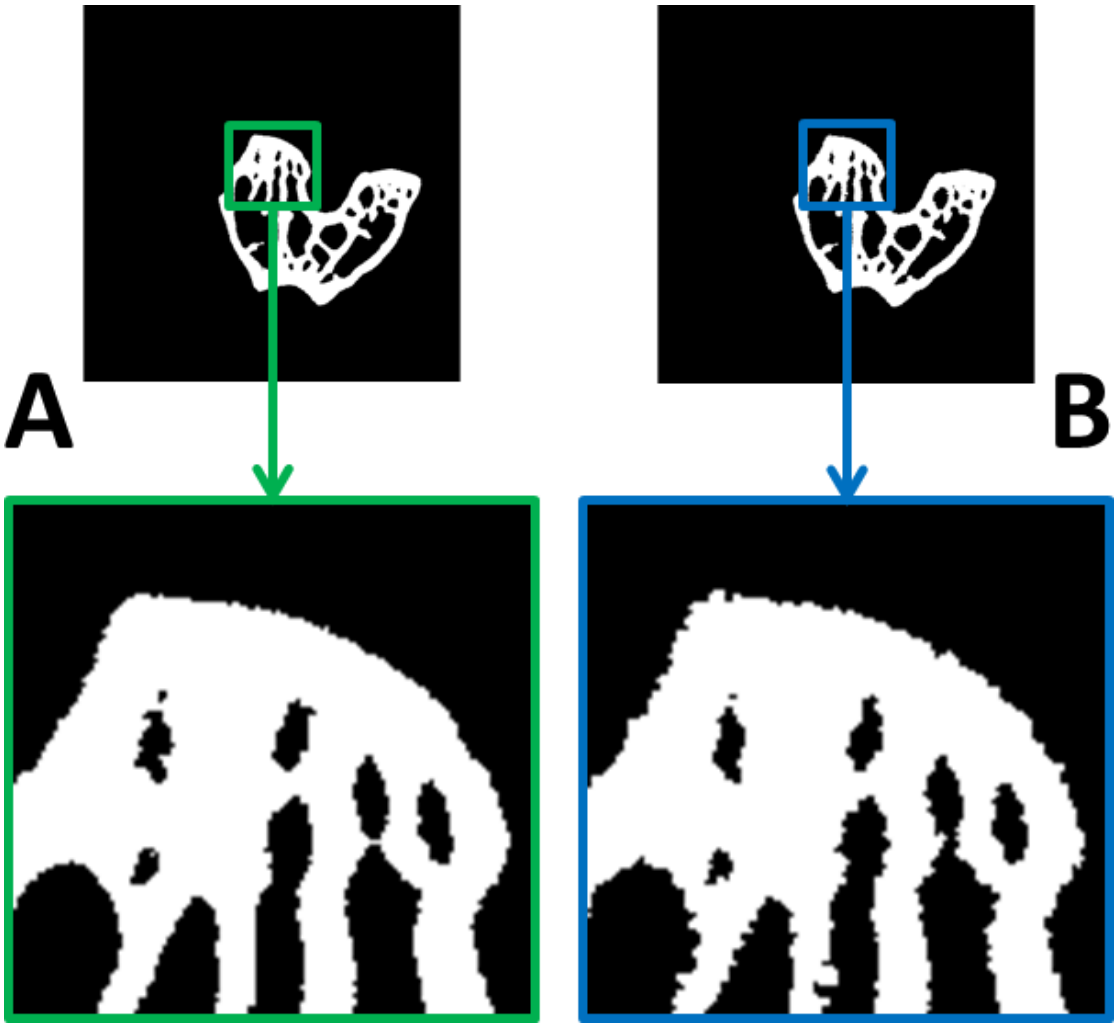


Figure 2.1: Diagrams showing a comparison between rotating an image with a single 100° rotation (A) and 10 successive 10° rotations (B).

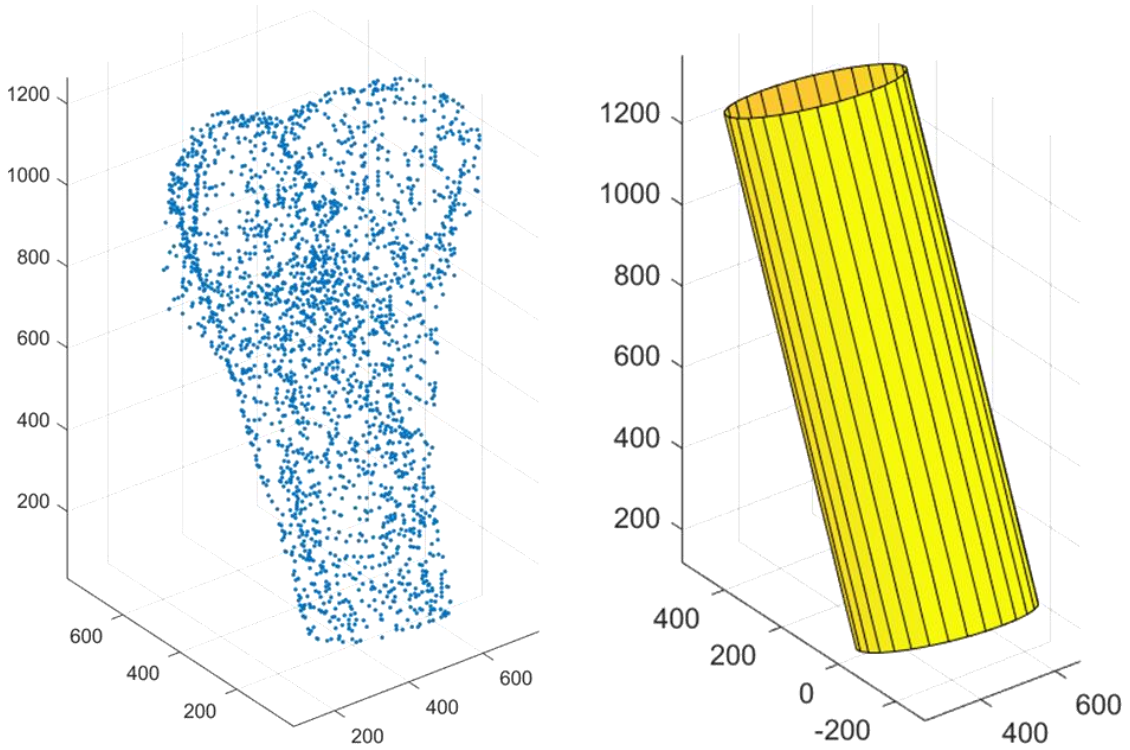


Figure 2.2. Graphical representations showing the process of fitting a cylinder to the femoral shaft of a distal femur scan. On the left is a diagram of the point cloud derived from a distal femur CT scan. On the right is the cylinder created by the pcfitcylinder Matlab function.

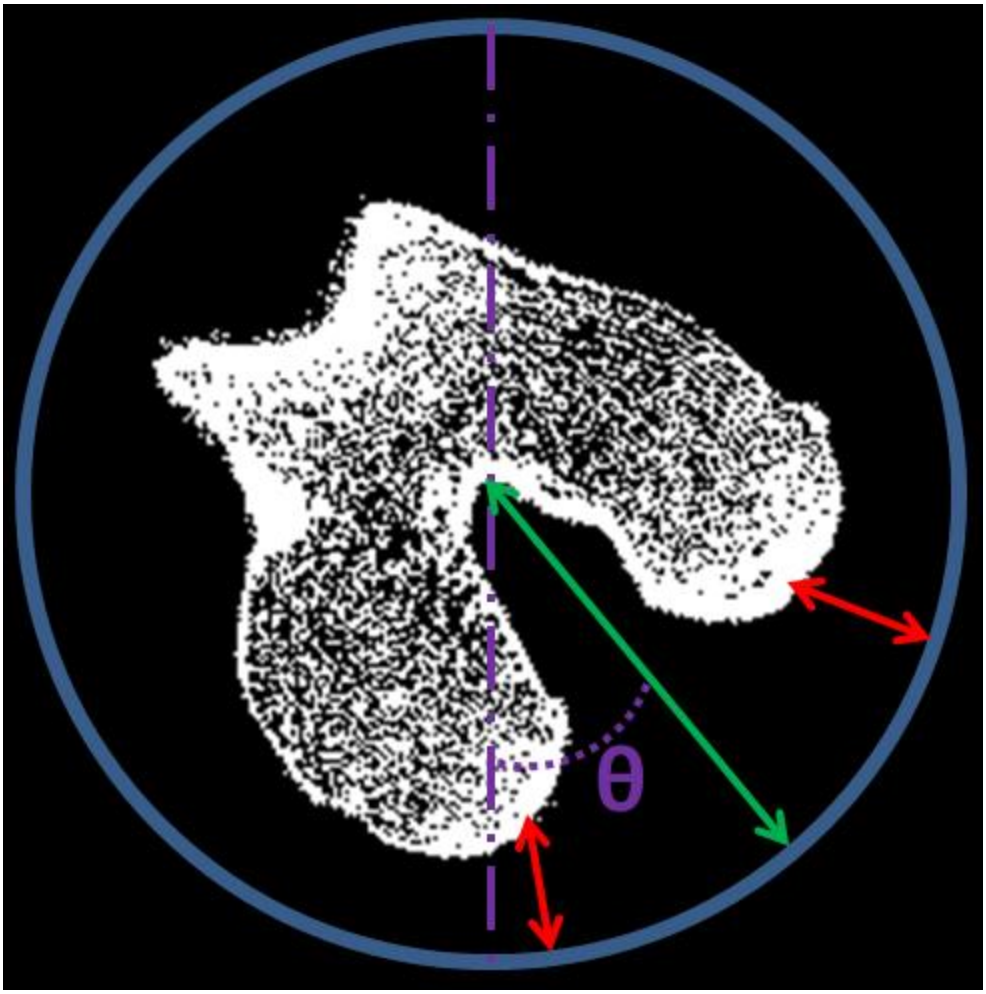


Figure 2.3. A diagram showing how the CT scan alignment code identifies the z-axis rotation of the groove between condyles.

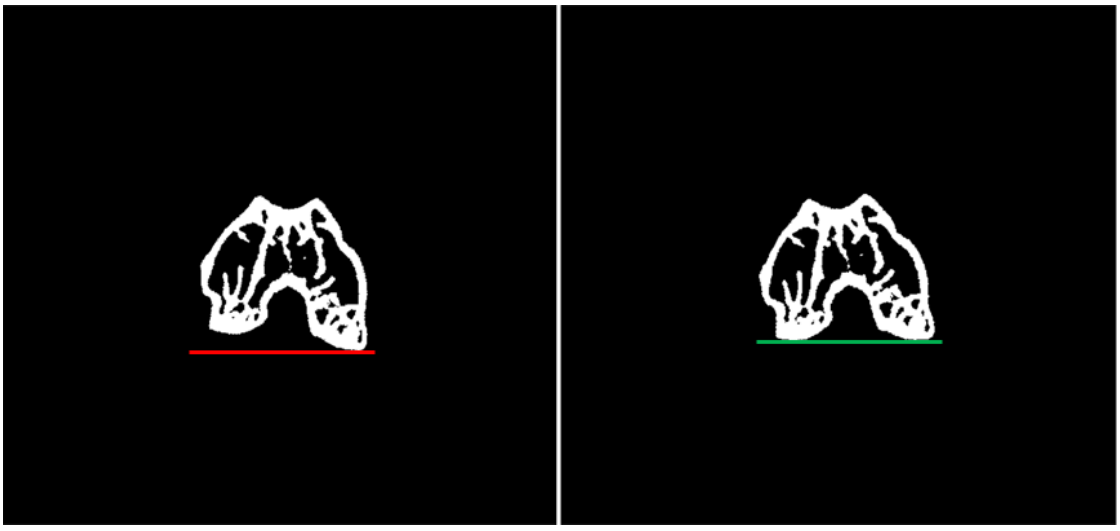


Figure 2.4. Fine tuning the alignment of the condyles with the horizontal axis of the CT images.

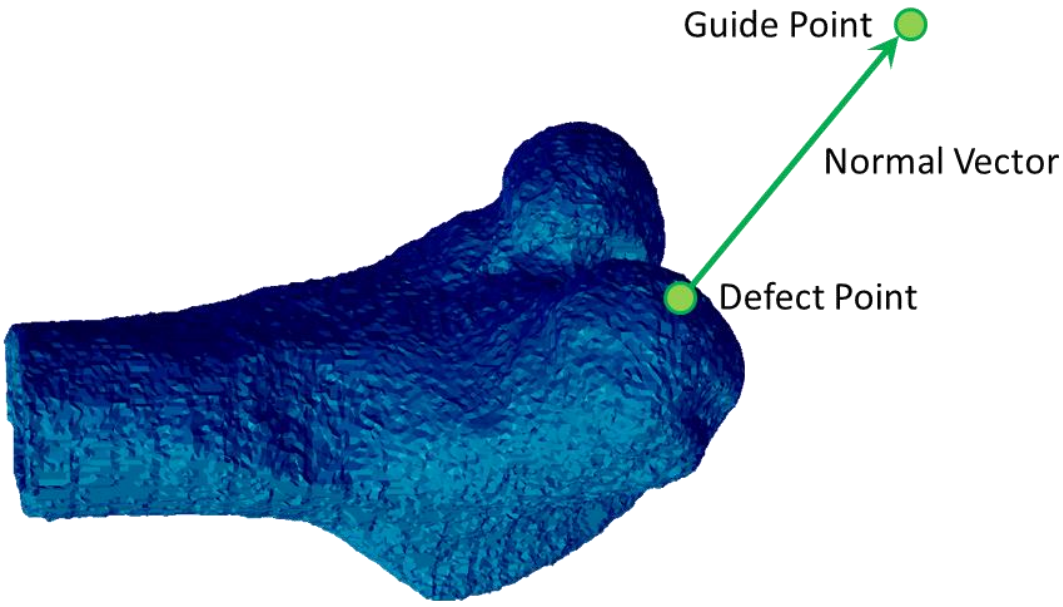


Figure 2.5. Allograft site position export code output.

2.4 Design of Allograft Surgical Guides Customized to the Curvature of Femoral Condyles

The surgical guides were designed in Autodesk Inventor. The part design begins with two 3D points defined so that they match the points exported by the allograft site position export code. These two points, named the Defect Point and the Guide Point in the same way as the allograft site position export code, provide the necessary starting point for orienting the parts in 3D space. The two 3D points were used to define a simple cylinder around which the actual surgical guide is oriented by aligning the cutting tool hole of the guide to the main axis of the cylinder.

The main part of the surgical guides was designed with the intent that the final product would be machined from stainless steel or titanium so that it would satisfy the requirements of being used in a medical setting and stand up to the forces involved in guiding a rotating cutting tool. The Arthrex AR-4081-08 workstation bushing performs a similar task (steadying the rotating cutting tool during osteochondral allografts) and is machined from stainless steel, so it is a logical example of how the final surgical guide should be manufactured. Because 3D printing is required for the customized contact surface that touches the articular cartilage of the femoral condyles, attachment points for 3D printed parts were designed into the main part of the surgical guide. Keeping the 3D printed part separate from the main part also eliminates the need to 3D print a large part in metal, which is costly and requires a lot of post-printing manual cleanup and

polishing, thus reducing cost and preparation time between imaging and the actual allograft procedure. The attachment points were designed as simple slots in order to achieve effective functionality and easy manufacturability.

The major focus for creating osteochondral allograft guides was to match the surface curvature of the condyles upon which the procedure would be performed, and the contact pieces were designed to serve that function. The contact pieces were originally designed as two simple parts that fit into the main part of the guide on opposite sides of the central tool guide hole. After a prototype was created, it was clear that additional contact with the condyle surface was needed, especially in the sagittal plane. The prototype would easily slide along the condyles in the sagittal plane as if it were the articular cartilage of the tibia. The design was updated to include four contact pieces which more completely surrounded the central tool guide hole and provided more contact surface area in the anterior-posterior directions, shown in **Figure 2.6**. The contact pieces themselves were designed basically as a rectangular extrusion and a cylinder with a spherical cap at both ends. The rectangular extrusions of the contact pieces fit into the slots of the main guide piece, and were altered to form simple snaps that would hold the contact pieces within the slots of the guide's main piece. The cylindrical part of the contact pieces is the portion that is designed to get customized for every procedure. This concept was intended to provide a large volume of the model that would accommodate the condyle

geometry which trims away the cylinder. The other benefit of the capped cylinder design is that it has no edges upon which surrounding tissue might get caught.

A critical step in creating the custom surgical guides is obtaining the 3D geometry of the femur from the CT scan. This was accomplished by running a standardized task list in CTAn on each data set. The task list performed thresholding to select for bone and cartilage, then morphological operations to clean up the images, and exported a 3D model as an STL file.

The customization of the guide's contact pieces was performed using Autodesk Meshmixer. After the contact pieces were aligned to the chosen surgical site, they were exported in that orientation as STL files. This maintained the orientation of the contact pieces relative to the condyle model. The four contact pieces were then imported into Meshmixer along with the condyle model. Using the Boolean Difference function, the condyle model was used to cut away from the contact pieces so that their overlapping volume was eliminated. This resulted in the customized surfaces on the surgical guide's contact pieces.

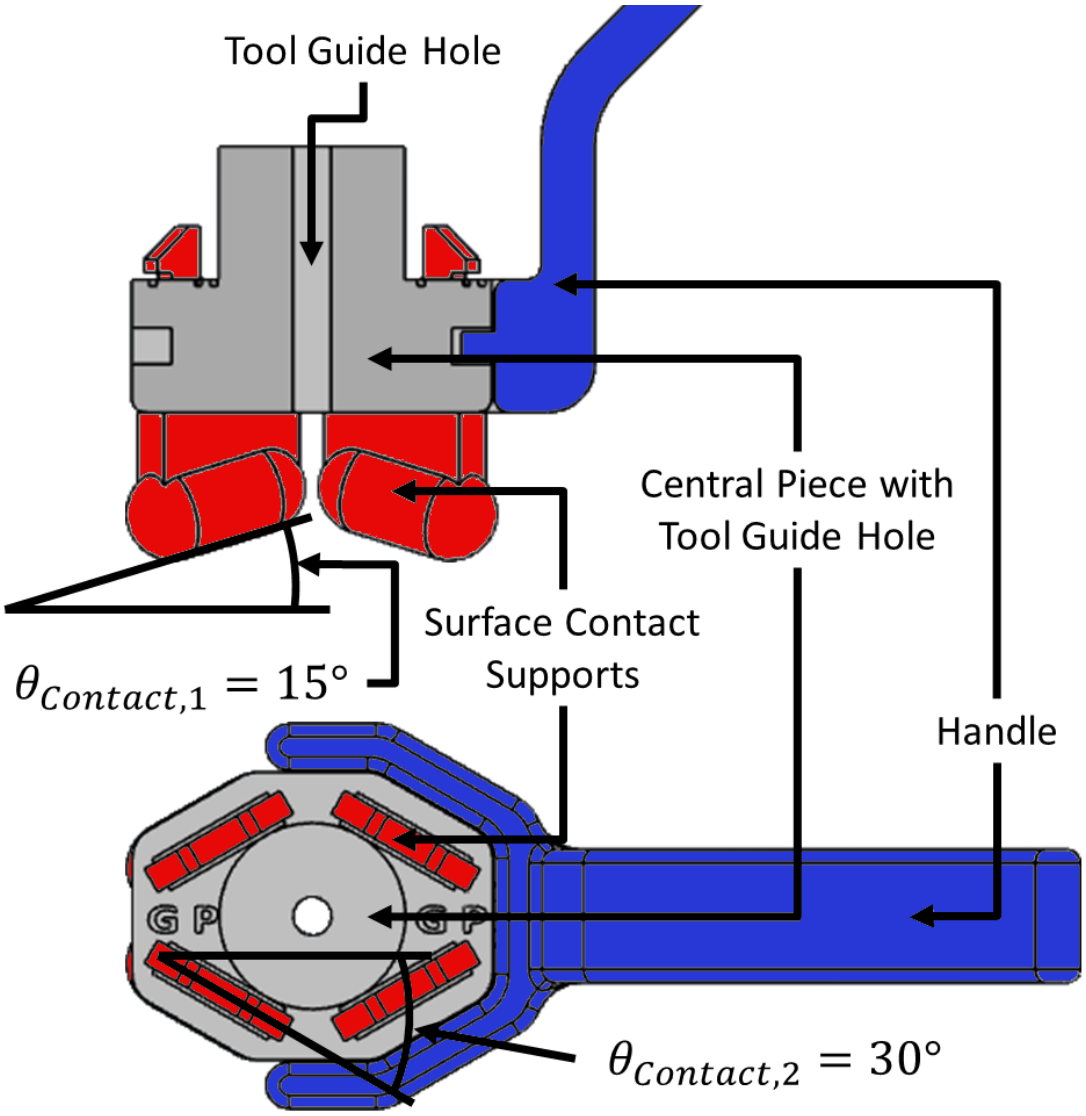


Figure 2.6. A technical illustration showing the surgical guide design, including labels for each part and angles of the contact pieces (shown as surface contact supports).

2.5 Evaluation of the Surgical Guide: Allograft Procedures

The surgical guides were tested by performing osteochondral allograft procedures on 3D printed distal femurs. Six surgeons performed eight procedures each, shown in **Table 2.1**, on two different goat knee models created from CT scan data. Each surgeon performed half of their procedures with a surgical guide and half without.

In preparation for the osteochondral allograft procedures, 48 goat distal femur models were prepared. Goat knee scans were chosen because they are commonly used in cartilage repair studies. [8] The goat knee models were exported as STLs after importing the CT scan images into CTAn, and thresholding for bone and cartilage. There was some manual trimming of the model using Meshmixer, to remove pieces that were not connected to the external surfaces of the distal femur model. Any parts that were still attached to the distal femur but were not part of the sample were selected and deleted, often resulting in holes in the model (never in the articular cartilage). These holes were then closed using Netfabb's default repair tool, which essentially just connects the dots between exposed vertices of triangles since an STL file is composed entirely of triangles. It was at this point that the distal femur models were used in the normal vector calculation Matlab code to produce a defect point (a point on the surface of the condyle) and a guide point (a point along the normal vector but away from the condyle surface).

In preparation for 3D printing, the condyle models had a vice attachment added, a T-shaped extrusion below the condyle model (**Figure 2.7**), to make it simple and easy to mount the models in a vice. 24 models, 12 for each CT data set, with unaltered articular cartilage surfaces were printed using a Lulzbot TAZ 4 FDM (fused deposition modeling) 3D printer. Each model was printed (**Figure 2.8**) with a 0.1 mm layer thickness and 40% rectilinear infill. An additional 24 models were printed using the same settings (and the same vice attachment) but with defect sites added to the articular cartilage surface. The defect sites were added by creating 5 mm spheres in Autodesk Inventor, oriented to each defect point (one for each condyle) that had been exported by the normal vector calculation Matlab code, and exporting the sphere as an STL. Using Meshmixer's Boolean Difference function, the sphere STLs were used to cut spherical defect sites into the distal condyle models.

The defect point and guide point, which were exported by the normal vector calculation Matlab code, were then used to align the osteochondral allograft surgical guide models. Each condyle, having its own defect point, required its own unique version of the surgical guide's contact pieces. Since the guide designed to work with the guide pin and the guide designed to handle the coring bit have contact pieces in the same position, only one alignment of the guide per condyle was necessary. The alignment, as mention previously, was performed by aligning a cylinder model to the defect point and guide point, then aligning the surgical guide to that cylinder in Autodesk Inventor (**Figure 2.9**). The

contact pieces for each condyle were exported as an STL, trimmed by the condyle model using Meshmixer, and 3D printed with a layer thickness of 0.1 mm.

Six surgeons, three experienced and three inexperienced, performed eight procedures (using the tools in **Figures 2.10, 2.11, 2.12, and 2.13**) each on the 3D printed distal goat femurs. The surgeons performed these procedures according to their given schedule which alternated the following factors: whether or not a guide is used, which scan (2 total), and which condyle (medial or lateral).

Each procedure was started by mounting the recipient femur model (the one with defect sites in the articular surface) in a vice which was clamped to a table. The vice was oriented so that the jaws close in a direction parallel to the edge of the countertop, the condyle model was mounted in the vice with the patellar groove away from the user.

In order to cut the recipient site (**Figure 2.14**), the first step was to drill the guide pin into the center of the defect which was marked with a spherical cut into the surface of the condyle. The surgeons would align the guide pin so that it was normal to the condyle surface, either using the guide pin surgical guide to orient the pin or manually. If a guide was used it was placed on the condyle and oriented until it felt stable, then the guide pin was inserted into the guide. The guide pin was drilled approximately 20 mm into the condyle. Once the guide pin had been drilled into the condyle surface, it was left in place. By sliding it over the guide pin, the reamer was then used to drill the recipient site to a depth of about

10 mm. Measurements of the recipient site depth were taken at four equally spaced points around the perimeter of the cut using the depth probe of digital Vernier calipers and recorded into a data sheet.

The donor core was harvested (**Figure 2.15**), using an 8 mm coring bit, from the same location as the recipient site on another copy of the condyle model from the same CT scan. Unlike the recipient models, the donor models did not have any cuts into the articular surface to mark the position. This was done to better mimic conditions for a real allograft procedure in which the surgeon would be able to see the position of the defect site but there would be no defects in the donor knee. Before cutting the donor core, the surgeons marked the cutting position with a marking that identified the rotational orientation of the core. They were instructed to mark it with a line starting in the center of the cut and moving straight away from the surgeon (i.e. perpendicular to the table edge), although some used different markings like T-shapes. If a surgical guide was used for a donor core harvest, the surgeon set the coring bit guide onto the condyle surface in the orientation that felt the most stable and centered in the same area as the recipient site. If no guide was used for a particular procedure then the surgeon would place a workstation bushing on the condyle and insert the coring bit into the bushing. The bushing provided stability to the cutting tool so that it would not slide out of position while cutting. The coring bit was drilled into the condyles about 20 mm deep, intentionally deeper than the recipient site so the core could be trimmed to the exact depth.

Often the cylindrical core would break from the model on its own. If it did not a surgical saw was used to cut into the side of the condyle model, approximately 20 mm below the top surface of the core, until the core was freed from the rest of the model. The surgeons used their measurements of the recipient site depth to mark the core for trimming. The cores were then placed between two half-moon blocks with the articular surface of the core pointed down. The blocks were set between the jaws of a vice and the vice was tightened until the core was held firmly in place. A surgical saw was then used to trim the donor core to match the measurements of the recipient site.

Once the recipient site and donor core were prepared, the donor core was inserted into the recipient site by hand (**Figure 2.16**). The marking on the surface of the core was used to keep the core rotation consistent with its original orientation. The core was pressed into the recipient site until it was as flush as possible. If the core could not be pushed in by hand, a tamp and a rubber mallet were used to tap the core into place.

Once all eight procedures were completed by each surgeon, measurements of the edge offset of the implanted cores were taken at eight equally spaced points around the edge of the recipient sites (**Figure 2.17**). If the edge of the donor core was recessed below the surface of the recipient, the depth was recorded as a negative number. If the edge of the donor core was proud (i.e. if the cylindrical wall of the core was exposed), the height of the core relative to the condyle surface was recorded as a positive number.

Statistical tests were performed using code in RStudio software to determine if the differences in the maximum edge offset data were statistically significant. The maximum edge offset data was initially evaluated using unpaired t-tests. Since the surgeons each performed one unguided and one guided procedure in each trial, paired t-tests were then used in order to account for the paired data. In order to determine if the surgeon's experience-level had an impact on the effect of the surgical guides on maximum edge offset, two-way ANOVA tests were performed on the data for each trial. Additionally, the depth mismatch of the grafts was evaluated using paired t-tests and two-way ANOVA tests in the same way as the maximum edge offset data.

The primary study involving osteochondral allograft procedures described in this paper is being prepared for submission for publication. Szewczyk, Alexander F; Chen, Albert C; Bugbee, William D; Sah, Robert L. "Osteochondral allograft procedure cuts aided by custom surgical guides". The thesis author was the primary investigator and author of this material.

Table 2.1. The osteochondral allograft procedure study groups were categorized by surgeon experience, and the use of a guide. 48 procedures were performed by six individuals, three without osteochondral allograft procedure experience and three experienced surgeons who have performed osteochondral allograft procedures during their career as medical doctors. The inexperienced surgeons were not medical doctors, but were graduate or medical students working in a bioengineering lab specializing in cartilage tissue engineering.

	Surgeon Experience	n	Trial 1 Guide		Trial 2 Guide		Trial 3 Guide		Trial 4 Guide	
1	-	3	-	+	-	+	-	+	-	+
2	+	3	-	+	-	+	-	+	-	+

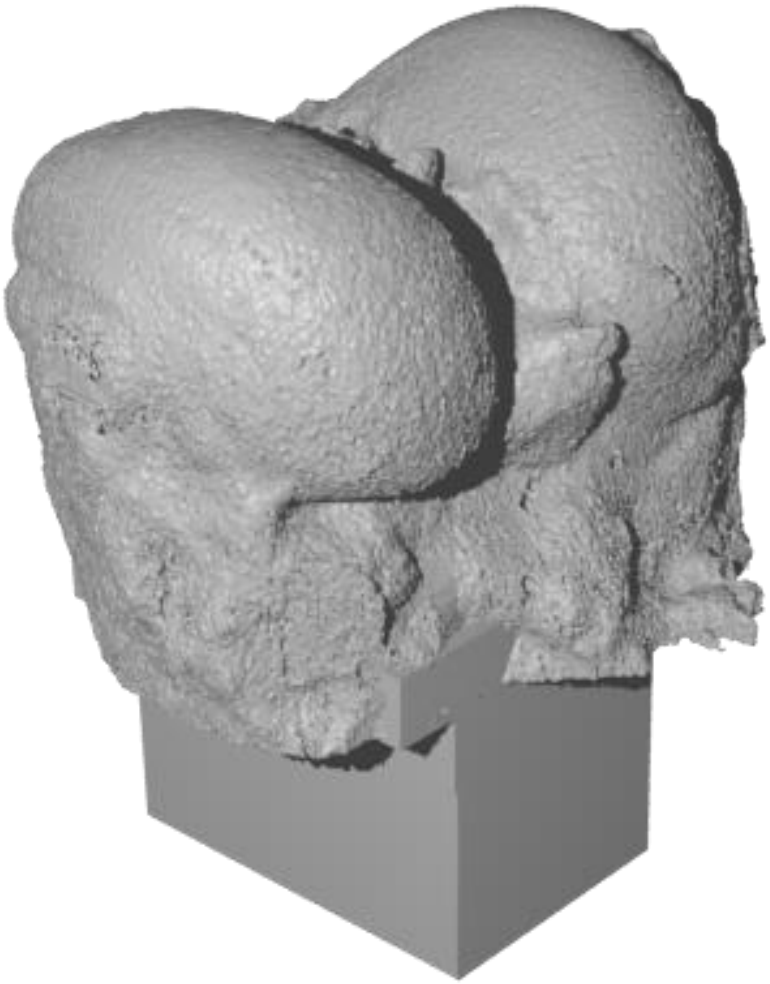


Figure 2.7. A distal goat femur computer model after attaching a T-shaped vice attachment model to the bottom.

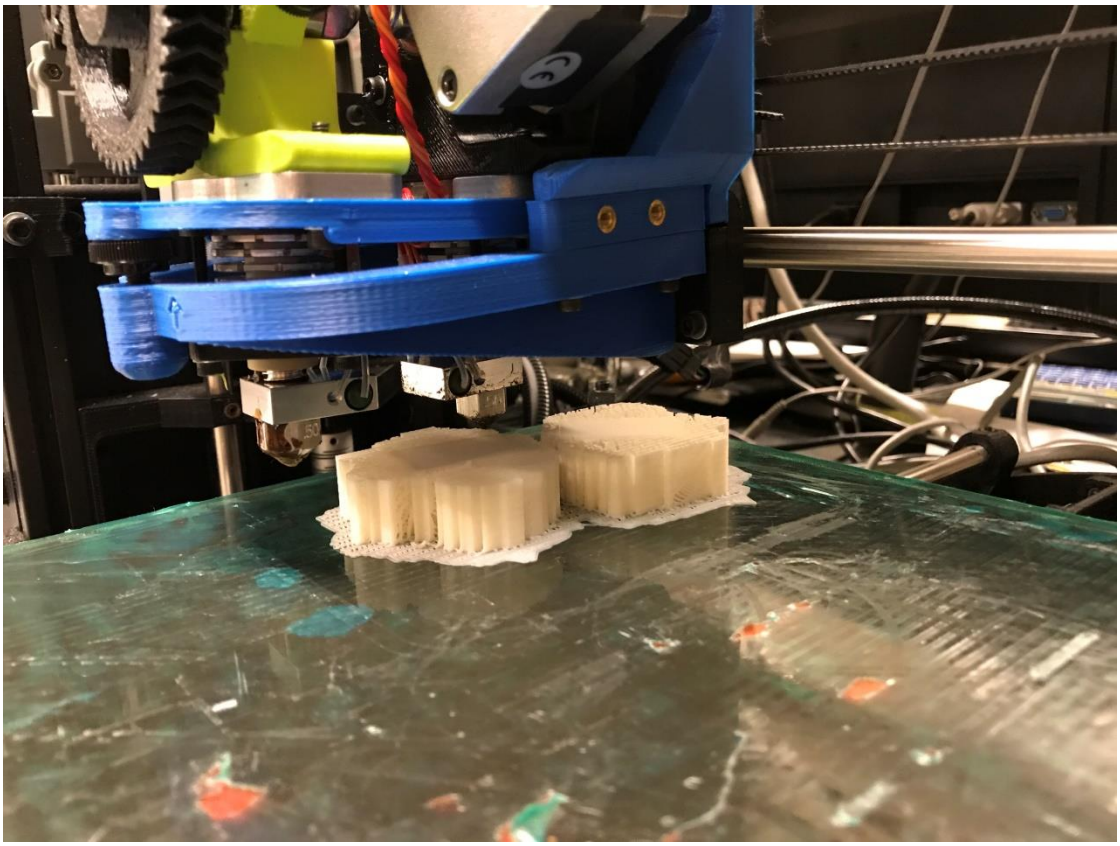


Figure 2.8. 3D printing two distal goat femur models on a Lulzbot TAZ 4 FDM 3D printer. The filament was ‘natural’ (off-white) colored ABS.

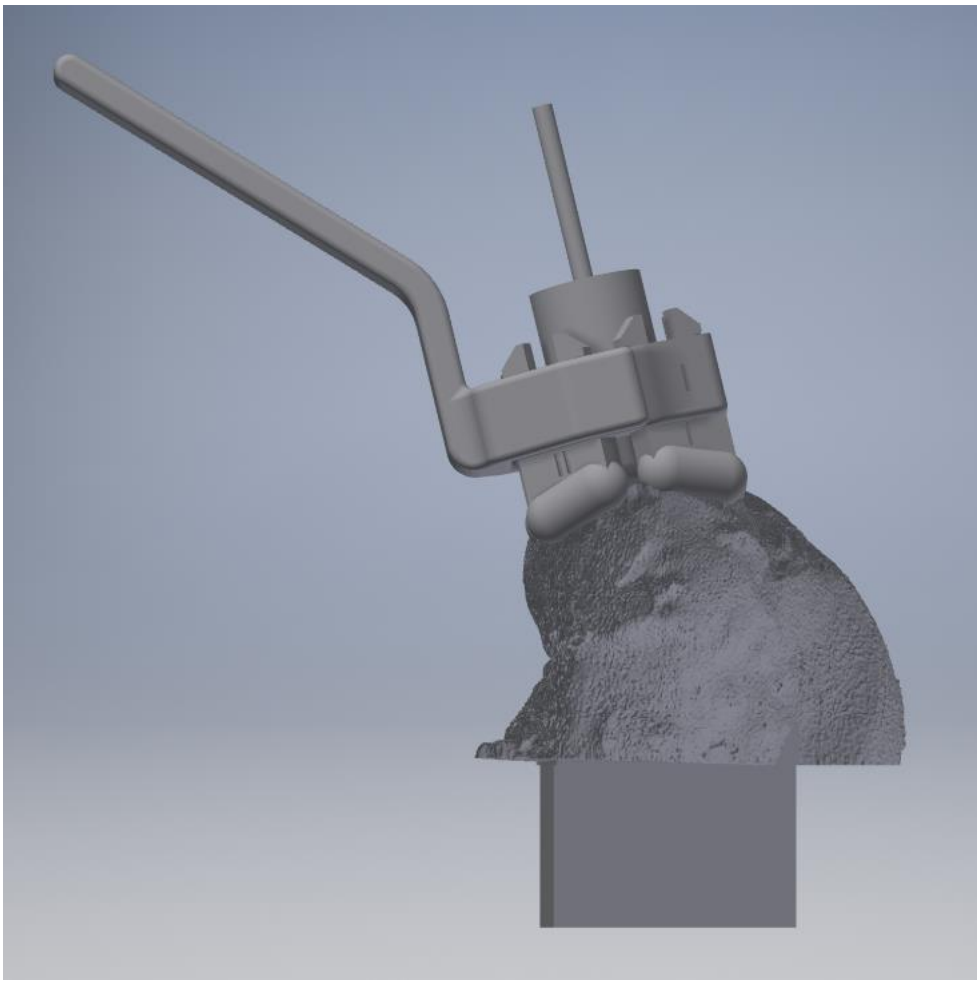


Figure 2.9. Alignment of the osteochondral allograft surgical guide to a cylinder model that has been defined by two points: the defect point and guide point. The two points were exported by Matlab code designed to calculate a normal vector from a point selected on an object's surface.

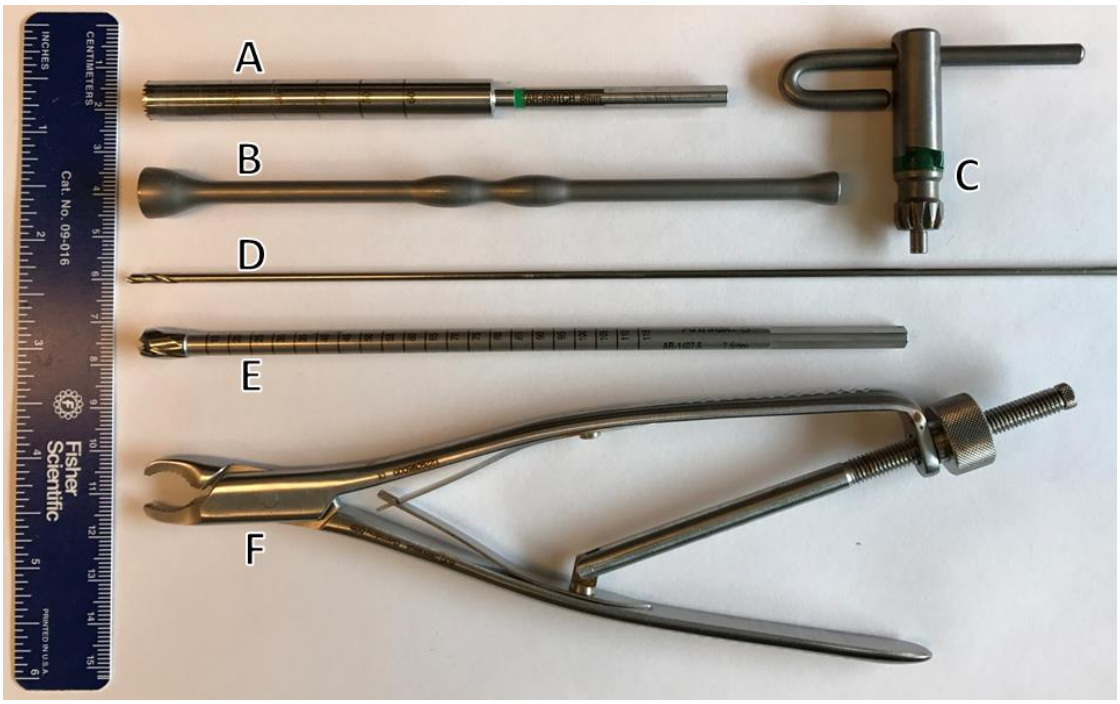


Figure 2.10. Allograft procedure tools: 8 mm coring reamer Arthrex AR-8901CR (A), two-ended tamp (B), chuck key (C), guide pin Arthrex AR-1250L (D), 8 mm cannulated headed reamer Arthrex AR-1408 (E), allograft holding forceps Arthrex AR-4076SM (F).

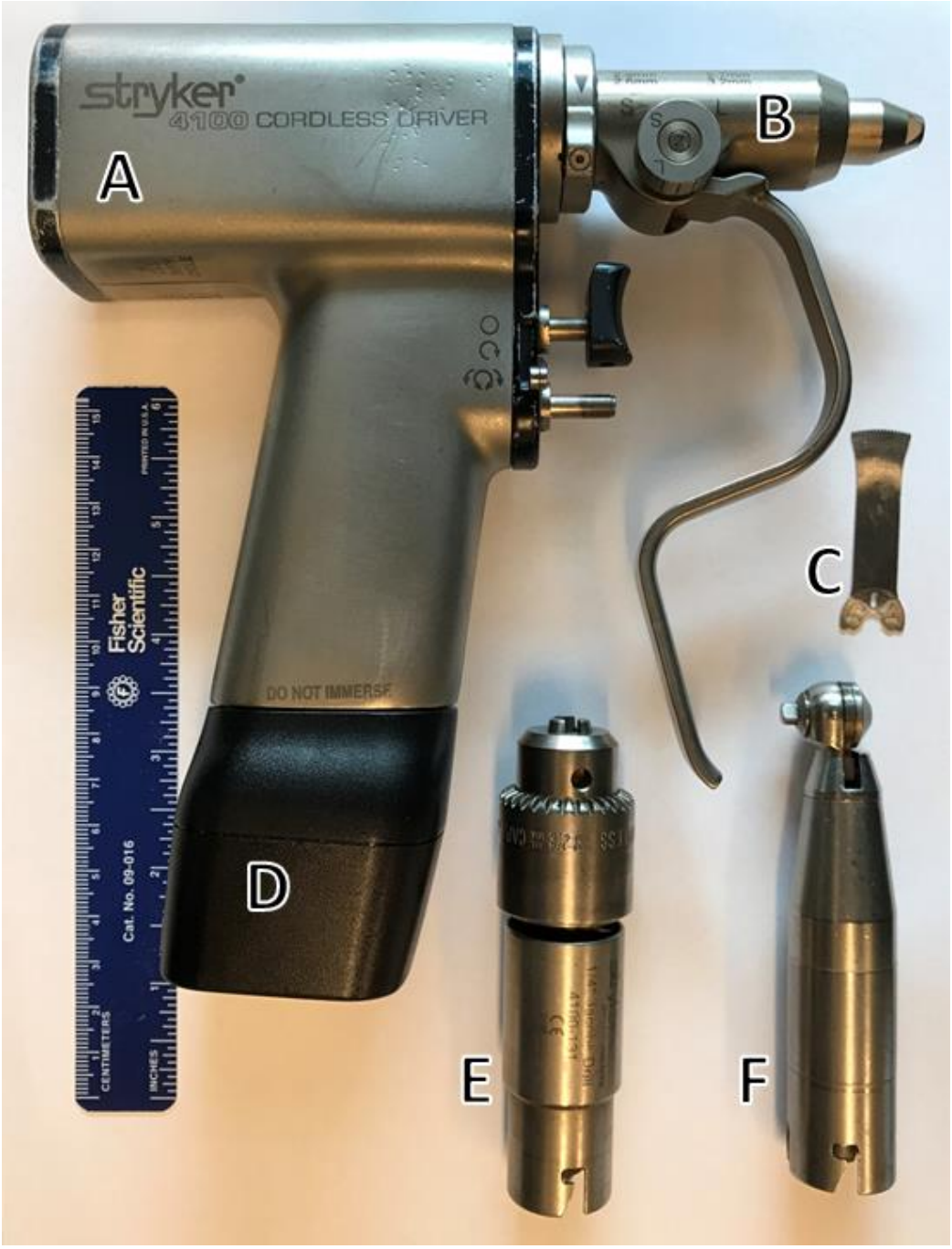


Figure 2.11. Allograft procedure driver and attachments: Stryker 4100 cordless driver (A), Stryker 4100-126 pin collet (B), Stryker 2296-3-106 surgical saw blade (C), rechargeable battery (D), Stryker 4100-131 ¼" Jacobs Drill tool holding chuck (E), Stryker 4100-400 sagittal saw attachment.

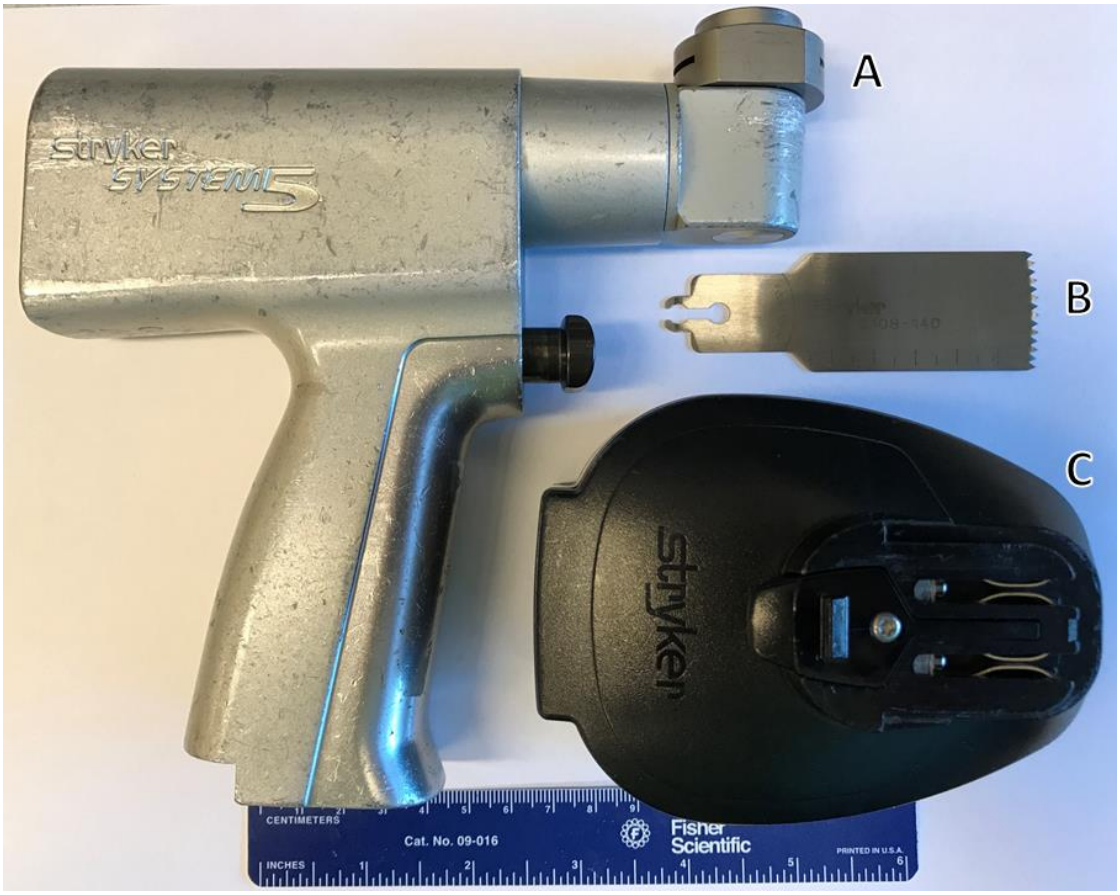


Figure 2.12. Large surgical saw for freeing the donor core from the donor condyle: Stryker System 5 surgical saw driver (A), Stryker 2108-140 surgical saw blade (B) and battery case with rechargeable battery (C).

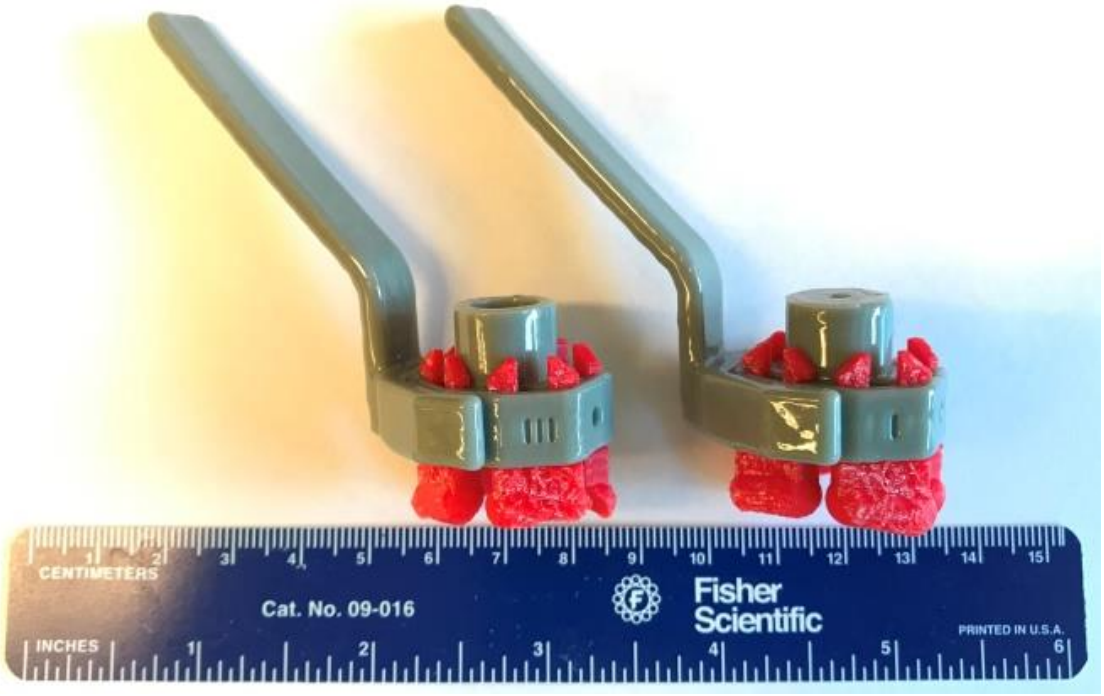


Figure 2.13. Two surgical guides for each condyle and each scan, eight in total.

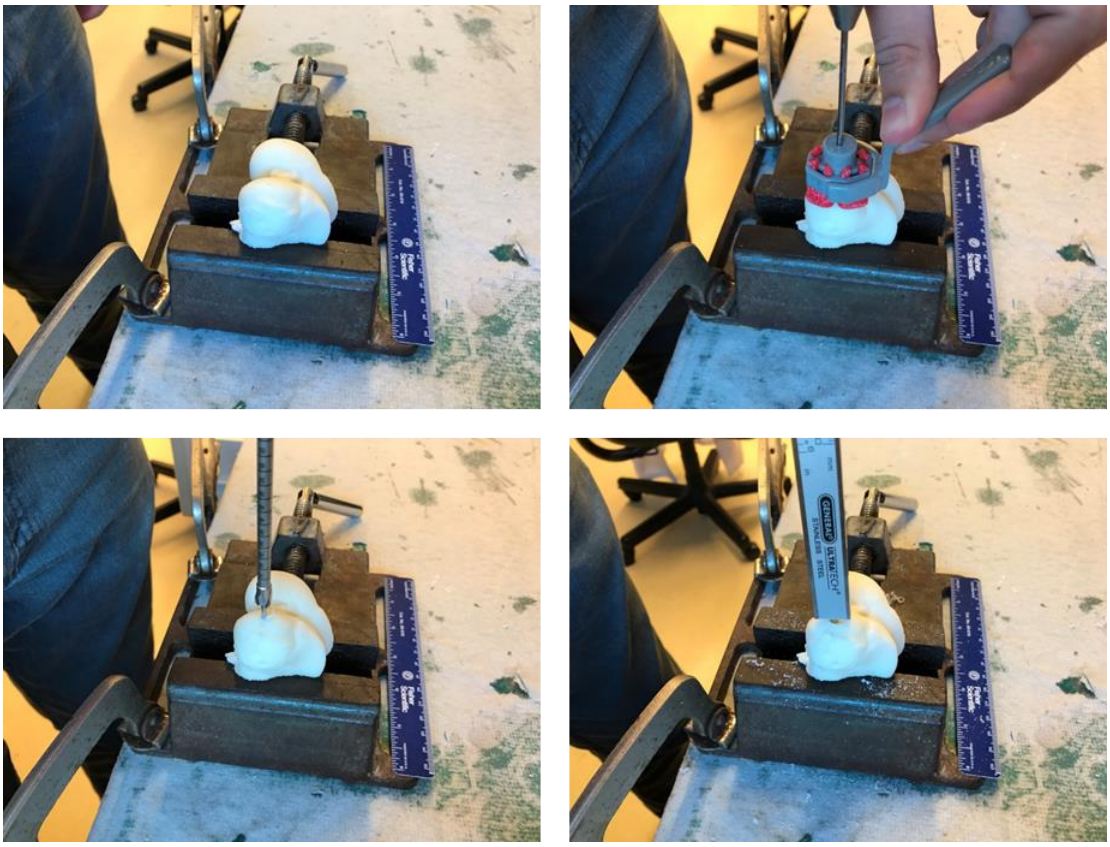


Figure 2.14. Preparing the recipient site using a surgical guide.

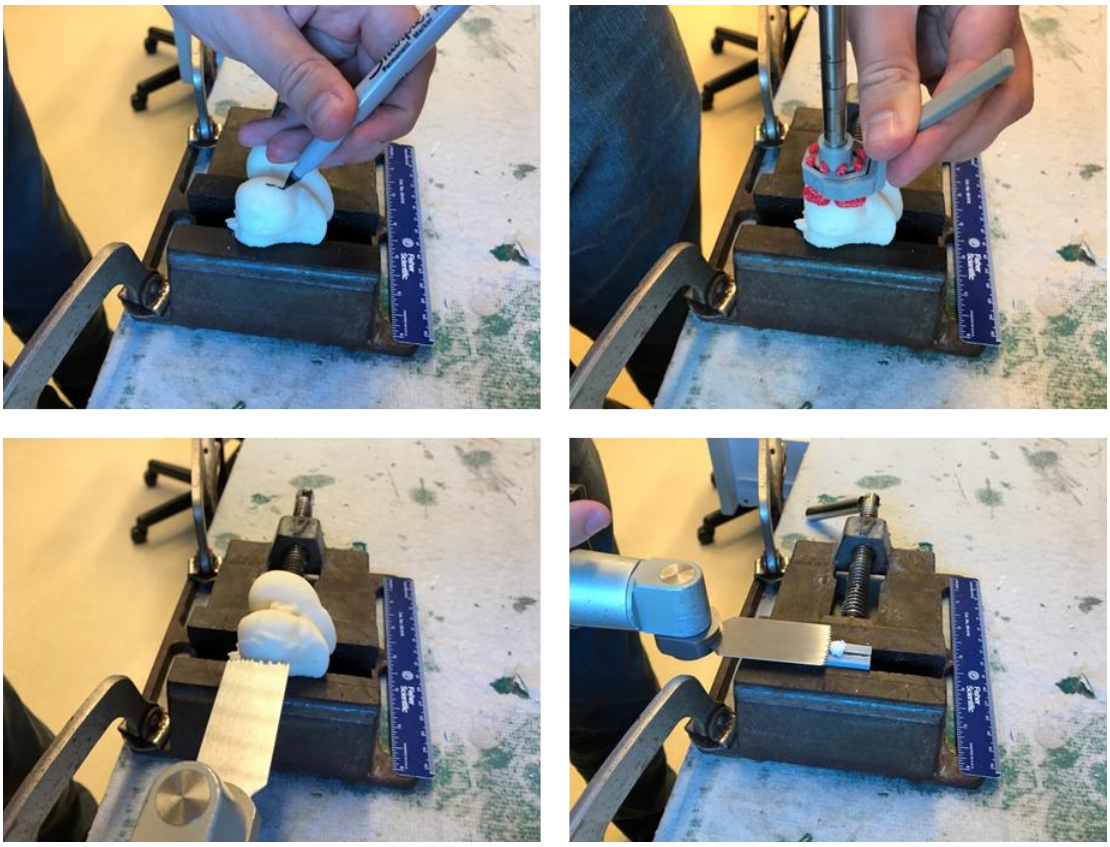


Figure 2.15. Harvesting a donor core using a surgical guide.

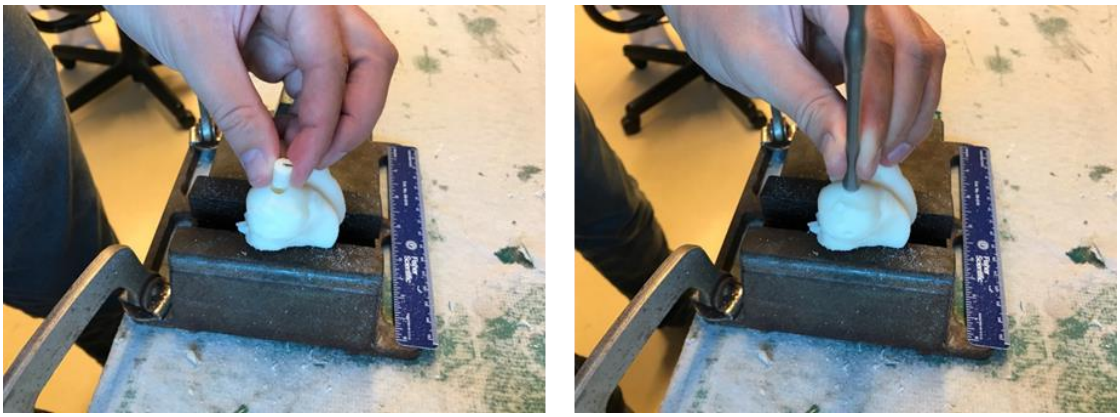


Figure 2.16. Implanting the donor core into the recipient site by hand and then tapped into place using a tamp.

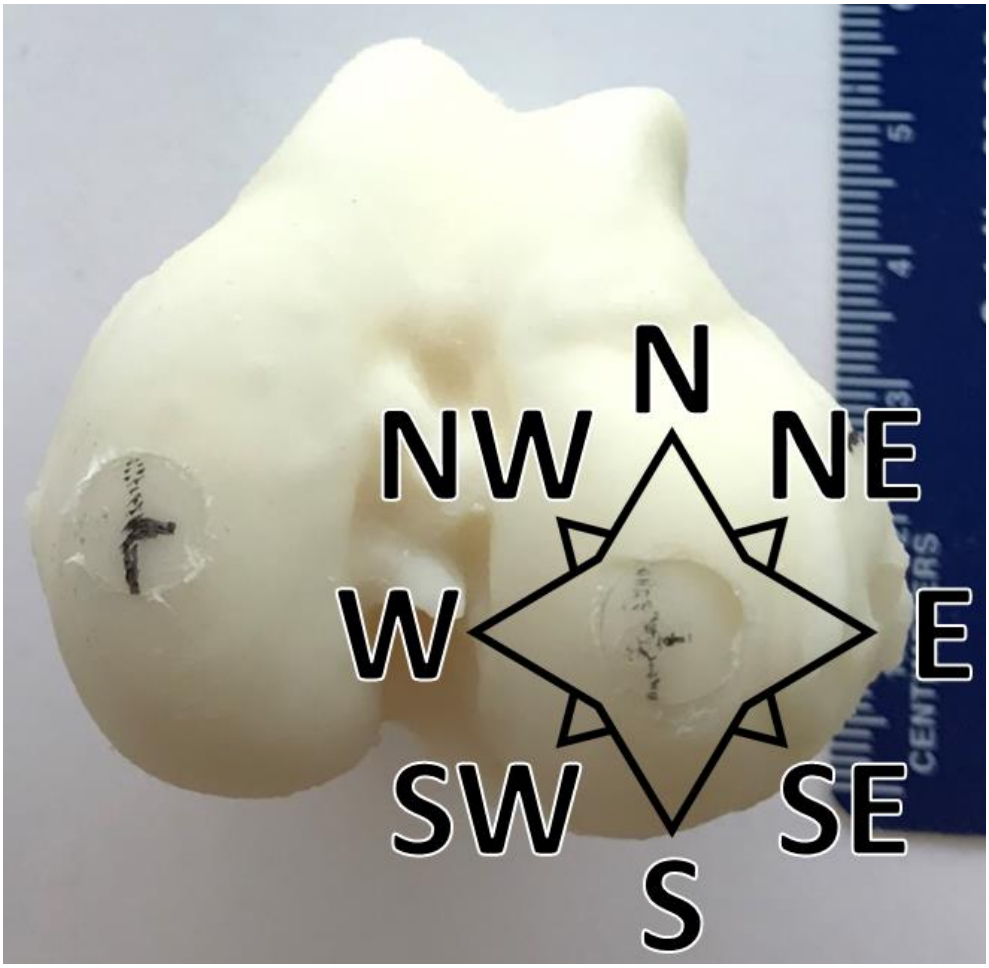


Figure 2.17. Edge offset measurements were taken for each implanted core in eight equally spaced locations around the edge of the grafts.

CHAPTER 3: RESULTS

3.1 Overall Project

An entire process for producing surface-matching surgical guides was developed and implemented beginning with a CT scan of the femur injury. The process produces the surgical guides by using CT scan alignment and allograft site position export code, entering allograft site position export points into the parameters of a CAD model, cutting the surface curvature of the femur model into the CAD models of the surgical guide contact pieces, and concludes with 3D printing the surgical guide contact pieces.

The surgical guide design was evaluated for reduction of graft maximum edge offsets in osteochondral allograft procedures. This was done in a study consisting of experienced and inexperienced surgeons performing osteochondral allograft procedures on 3D printed goat distal femurs with the surgical guides and without the surgical guides.

3.2 Evaluation of the Surgical Guide Design

Prototype surface-matching surgical guides were 3D-printed in acrylonitrile butadiene styrene (ABS), seen in **Figure 3.1**. Parts intended to be machined from stainless steel in a final product were printed in a gray color, and the surface-matching contact pieces were printed in red. The contact pieces (**Figure 3.2**) were labelled with Roman numerals 'I', 'II', 'III', or 'IV' on one the side in order to match with corresponding markings on the slots of main guide piece. The contact pieces snapped into the slots and can be replaced with other contact pieces that are customized to other CT scans.

The guide pin and coring bit slid into their respective 3D printed guides smoothly with very little wobble, about the same fit that was expected from the CAD design. The sides of the contact pieces facing downward during the 3D printing process were fairly rough, due to being printed on supports, but the Roman numeral markings could still be seen. The contact pieces snapped securely into the main guide part but the snaps showed signs of plastic deformation (whiteness in the plastic near the base of the snaps), so they would likely not be reusable. Since the contact pieces would not be reused anyway, because they are customized for a particular procedure, the plastic deformation was not a serious concern for the design.

The desired outcome for the surgical guides was that they would reduce angular mismatch by 5 degrees when compared with unguided procedures. That value was chosen based on autograft research that involved a much more

invasive surgical guide, which resulted in improvements from about 7.4 degrees to 8 degrees. [16] In order to achieve that outcome, the possible error introduced by the surgical guides must be less than the goal of 5 degrees improvement. The surgical guides were designed with a small difference in diameters between the inside of the guides' central holes and the outside of the cutting tool so that the cutting tools would easily slide into the guide. The red, purple, and blue lines in **Figure 3.3** show an exaggerated version of the rotation of the cutting tool possible due to the difference between the outer diameter of the cutting tool and the inner diameter of the surgical guide. Using the guide holes' diameter difference of 0.25 mm and the length of the guide hole of 20 mm, the angular error introduced by the gap between the cutting tool and the guide hole was calculated to be 1.43 degrees. The layer thickness of the 3D printing process, 0.1 mm, used to produce the surgical guide was assumed to be the largest possible printing error for the guides. The distance from the center of the 3D-printed surgical guide contact pieces to the rotational axis (along the shaft), or center, of the cutting tool for the surgical guide design was 8.375 mm. This was used with the layer thickness to calculate the possible error introduced by converting the 3D models into tool paths for 3D printing. The error angle produced by the layer thickness was calculated to be 0.68 degrees. The sum of both error angles was 2.11 degrees, well within the 5 degrees that was the objective. The error angle converted to an edge offset for an 8mm diameter core is calculated (shown in

Figure 3.4) to be 0.15 mm, which of course is less than the 0.35 mm edge offset calculated from the objective of 5 degrees of angle mismatch.

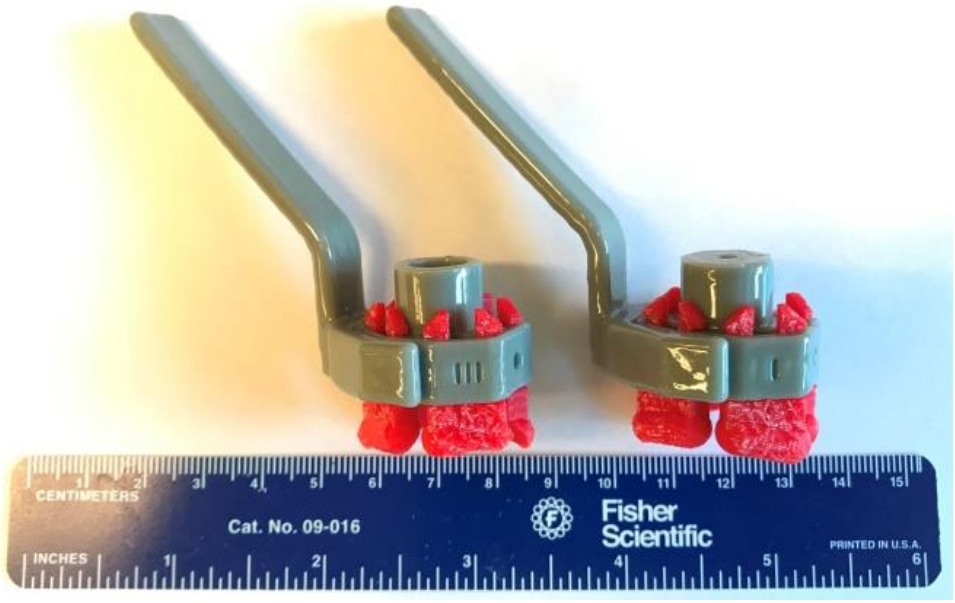


Figure 3.1. Two 3D printed surgical guide prototypes, one for each cutting tool. The contact pieces were printed in red ABS, central guide part and handle were printed in grey ABS.

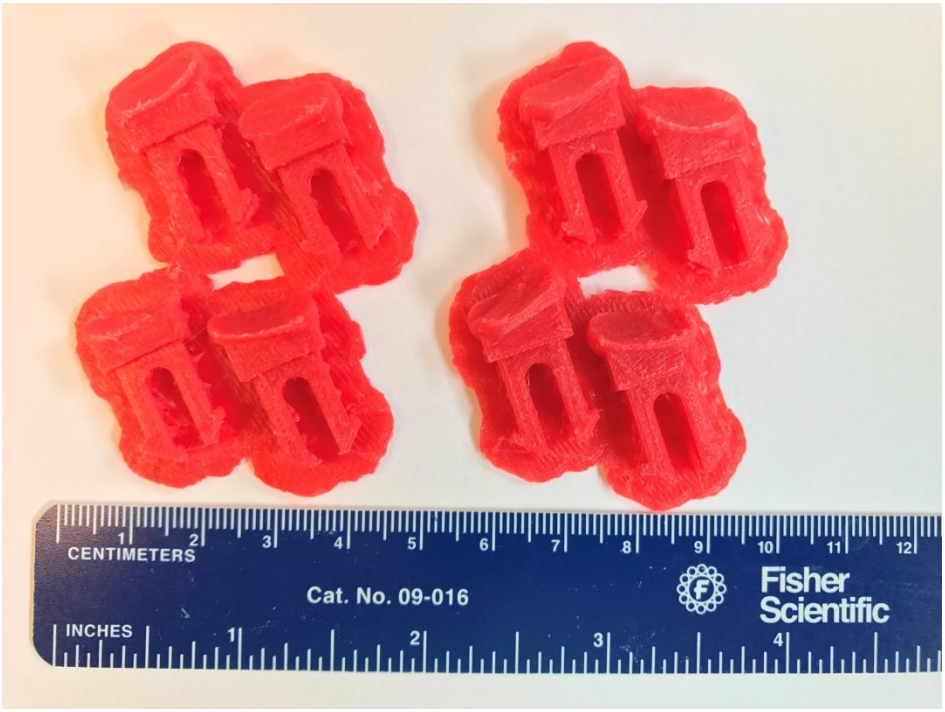


Figure 3.2. Top view (A) and side view (B) of a 3D-printed osteochondral allograft surface-matching surgical guide prototype with interchangeable surface contact pieces.

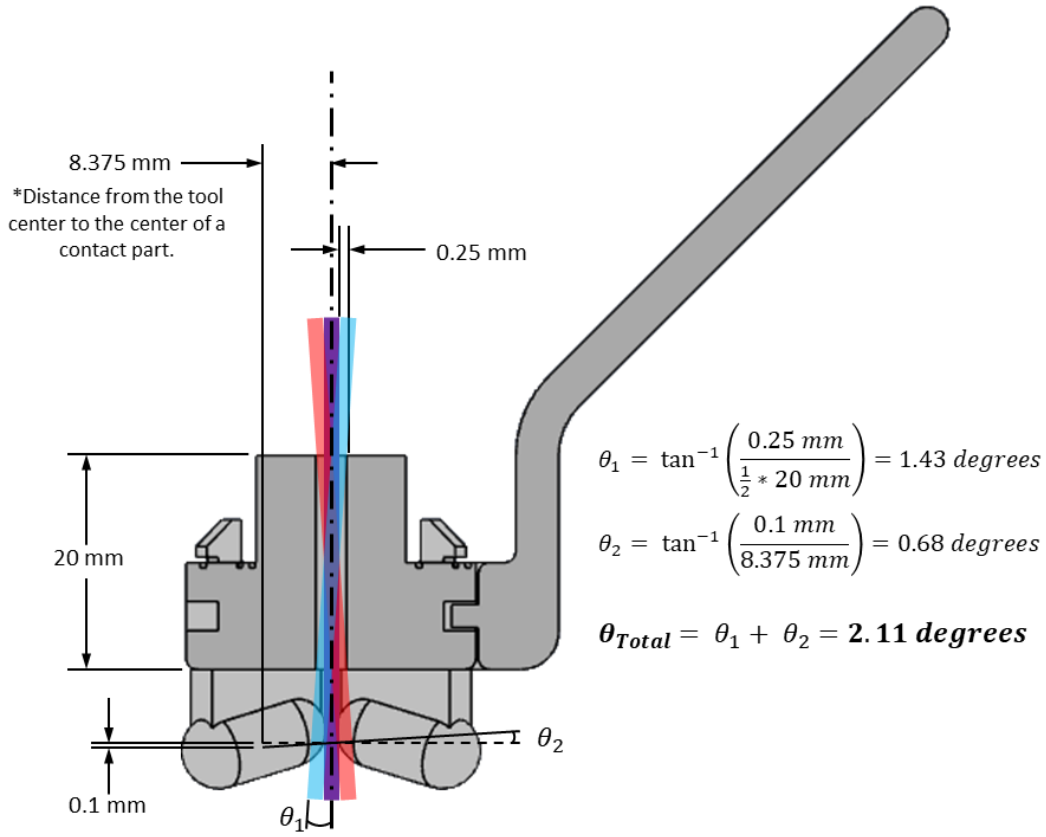
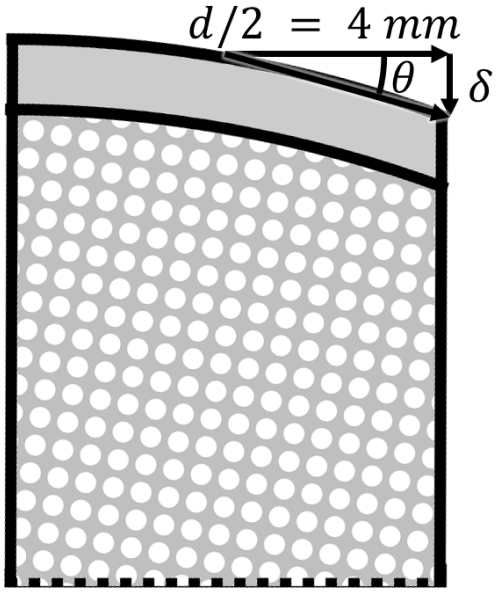


Figure 3.3. Maximum OCA guide error angle calculations. The guide was designed with a gap between the cutting tool and the guide hole of 0.25 mm. This enables the cutting tool to slide into the guide but it can also contribute to error. Simply using the tool-hole gap and the height of the guide hole of 20 mm, the error angle, θ_1, was calculated to be 1.43 degrees. The layer thickness setting of the 3D printer used to produce these guides was set to its most accurate value of 0.1 mm. Using the distance from the center of the contact pieces to the center of the guide hole, the layer thickness was used to calculate the maximum error angle, θ_2, caused by converting the 3D model into the tool paths for the 3D printer. With θ_2 being equal to 0.68 degrees, the total maximum error angle from combining these two factors was 2.11 degrees.



Maximum OCA Guide Error Angle:

$\theta = 2.11\,degrees$

Resulting OCA Guide Error Edge Displacement:

$\delta = (\tan^{-1}\theta) * 4\,mm = \mathbf{0.15\,mm}$

Figure 3.4. Converting the error angle to a displacement value. Using a simple trigonometric calculation involving the diameter, d, of the graft cylinder, the guide error in the form of edge offset was calculated to be 0.15 mm.

3.3 Qualitative Observations of the Surgical Guide Goat Condyle Procedures

The 3D printed goat distal femur models were effective test subjects for the guided and unguided osteochondral allograft procedures. The models, such as the set in **Figure 3.5**, produced easily measureable results that could be stored indefinitely and without using a freezer.

Surgeon #4 appeared to be using significantly greater force when tamping down the grafts into the recipient sites in order to get them to fit better. This likely compressed the cylindrical grafts, skewing the results for this surgeon so that the grafts had very similar maximum edge offsets regardless of the quality of the cuts.

There were instances in which the cutting tool would slip on the surface of the condyle models at the beginning of the cut. The surface of the 3D printed models is harder and provides less friction to the cutting tool than the articular cartilage of an actual biological condyle. Because the coring cuts were performed with a heavy bushing or a surgical guide to steady the cuts, this effect is likely to be similar between guided and unguided cuts. Therefore the slipping of the cutting tools is not expected to have a great impact on the data between guided and unguided cuts.

While the surgeons were initially attempting to place the surgical guides on the condyles, they mentioned that it was difficult to feel the guide fit into its place. So they switched to holding the guides at the main piece containing the

cutting tool guide hole, ignoring the handle. None of the surgeons ended up using the handles, and therefore this would not affect the data. For future designs, a handle is not recommended.

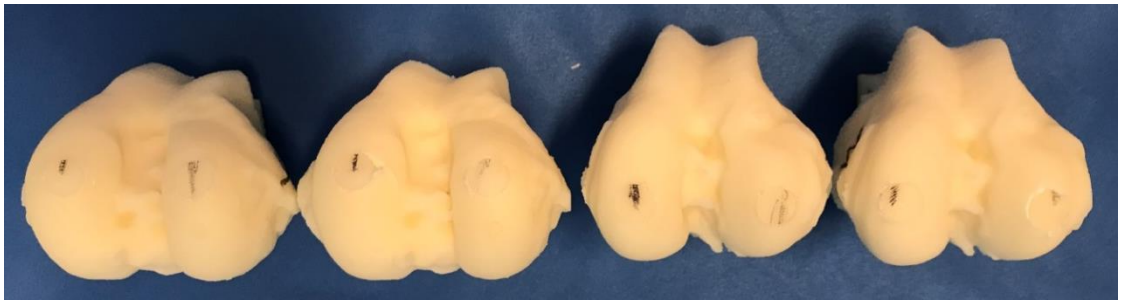


Figure 3.5. A complete set of grafts performed by one of the surgeons. Each surgeon performed procedures with and without guides, on medial and lateral condyles, and with each of those four variations repeated for a total of eight procedures.

3.4 Quantitative Results of the Surgical Guide Goat Condyle Procedures

The maximum edge offset was evaluated for each of eight procedures per surgeon by collecting the eight equally spaced measurements around the edge of the graft, subtracting the average of those measurements (**Figure 3.6**) to correct for core depth mismatch (to be evaluated separately), and selecting the measurement with the greatest magnitude. The data for maximum edge offset (**Table 3.1**) shows that the mean maximum edge offset for all surgeons in each of the four trials ranged from 0.50 mm to 0.95 mm for unguided procedures and from 0.24 mm to 0.55 mm for guided procedures. The mean maximum edge offset for all surgeons was smaller for guided procedures in each of the four trials, implying that the surgical guides generally reduced the maximum edge offsets. The standard deviation of the maximum edge offsets for all surgeons ranged from 0.20 mm to 0.47 mm for unguided procedures and from 0.08 mm to 0.32 mm for guided procedures. The standard deviation for all surgeons was smaller for guided procedures than unguided procedures in all but the fourth trial, implying that the use of the surgical guides resulted in less varied maximum edge offsets. The means of the difference between the maximum edge offset of unguided procedures and the maximum edge offset of guided procedures (**Table 3.2**) shows that the data from the first trial for all surgeons resulted in an average reduction of 0.67 mm when the surgical guide was used, well over the goal of 0.35 mm. However, the data from the subsequent trials did not achieve the goal. The smaller difference between unguided and guided procedures in the last three

trials seems largely due to better than expected (i.e. smaller) maximum edge offsets achieved for the unguided procedures, partially due to the excessive tamping of surgeon #4 as mentioned earlier. It is also possible that the unguided procedures resulted in smaller maximum edge offsets after the first trial simply because the surgeons had some practice and adjusted their technique based on how the first trial went. The maximum edge offset reduction on the first trial suggests that surgeons would more greatly benefit from the use of a surgical guide for their first osteochondral allograft procedure of the day.

Separating the maximum edge offset data into sequential series by the surgeon experience groups (**Figure 3.7**) clearly shows that the unguided first procedure resulted in larger maximum edge offsets, regardless of the surgeon's experience-level. However, the first guided procedure resulted in about the same maximum edge offset, from 0.12 mm to 0.41 mm, as other guided procedures, from 0.15 to 0.88 mm. Focusing on the maximum edge offset data for the first trial only (the first guided and the first unguided procedures) for each surgeon experience group (**Figure 3.8**) shows that the guided procedures resulted in much less maximum edge offset than the unguided procedures, regardless of surgeon experience.

In the unpaired t-tests (**Table 3.3**) the only trials to have p-values below the statistically significant threshold of 0.05 were the first and third trials (using maximum edge offset data for all surgeons). Only one trial from the paired t-test output (**Table 3.4**), the first, had a significant p-value at 0.02 (using maximum

edge offset data for all surgeons). In the first and third trials of the output from the two-way ANOVA tests (**Table 3.5**) the guide factor p-values were (similar to the unpaired t-test) statistically significant. Conversely, the surgeon experience factor never resulted in a statistically significant p-value. The interaction between the guide and surgeon experience factors was also never statistically significant.

When comparing the degree to which the grafts are proud or recessed within the recipient site (i.e. the core depth mismatch), it is important to note that the trimming of the graft and implantation process is the same whether a surgical guide has been used or not. Therefore, the degree to which the graft is proud or recessed is not indicative of the success of the surgical guides but rather a reflection of the skill and attention to detail of the surgeons. The data for the core depth mismatch magnitude (**Table 3.6**) shows that the mean depth mismatch magnitude for all surgeons in each of the four trials ranged from 0.27 mm to 0.38 mm for unguided procedures and from 0.38 mm to 0.70 mm for guided procedures. There may appear to be an impact on the depth mismatch of the grafts by the guide, however the paired t-tests (**Table 3.7**) resulted in no trials in which the effect of the guide had a significant value. This result was unsurprising given the fact that the surgical guides are not involved in trimming the graft cores to match the depth of the recipient site. The two-way ANOVA tests on the depth mismatch data (**Table 3.8**) resulted in no trials with a significant p-value for the guide factor, but the effect of surgeon experience on reducing the depth mismatch was significant in the first trial. It is difficult to determine exactly what

caused the effect of surgeon experience to be significant only on the first trial, but the mean depth mismatch for experienced surgeons seemed to increase after the first trial. It is possible that the experienced surgeons did not focus or were not careful after performing the first trial.

The primary study involving osteochondral allograft procedures described in this paper is being prepared for submission for publication. Szewczyk, Alexander F; Chen, Albert C; Bugbee, William D; Sah, Robert L. “Osteochondral allograft procedure cuts aided by custom surgical guides”. The thesis author was the primary investigator and author of this material.

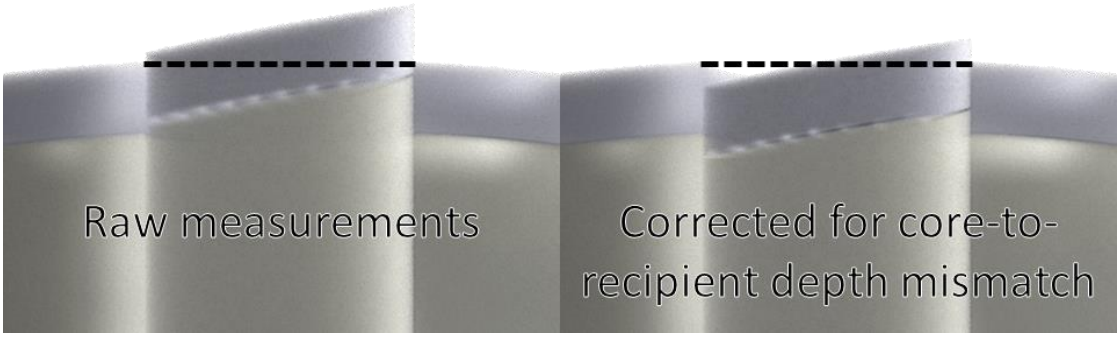


Figure 3.6. Diagrams describing how correcting for core-to-recipient depth mismatch in osteochondral allografts mathematically would look in a physical manifestation. The average edge offset is subtracted from the data to result in all cores having an average edge offset of zero. This effectively limits the edge offset measurements to reflecting only the displacement caused by angular mismatch and missing the ideal surgical site.

Table 3.1. The OCA maximum edge offset (in mm) means and standard deviations for each experience group or combined experience groups in guided and unguided trials. Three surgeons in each surgeon experience group performed four sets of osteochondral allograft procedures, and each trial set consisted of one procedure performed with a surgical guide and one procedure performed without a surgical guide. The maximum edge offsets were measured in eight equally spaced locations around the edge of the grafts using the depth probe of Vernier calipers.

Surgeon Experience	Trial 1 Guide				Trial 2 Guide				Trial 3 Guide				Trial 4 Guide			
	-		+		-		+		-		+		-		+	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
-	0.98	0.54	0.31	0.09	0.50	0.33	0.63	0.22	0.44	0.25	0.19	0.05	0.59	0.23	0.23	0.06
+	0.91	0.49	0.26	0.12	0.71	0.65	0.46	0.27	0.62	0.31	0.28	0.07	0.40	0.14	0.47	0.45
- & +	0.95	0.46	0.28	0.10	0.60	0.47	0.55	0.24	0.53	0.27	0.24	0.08	0.50	0.20	0.35	0.32

Table 3.2. Means and standard deviations of the differences in OCA maximum edge offset between procedures performed without a surgical guide and with a surgical guide, for each trial, for each surgeon experience group. The first trial resulted in the largest difference, implying that the surgical guides reduced maximum edge offsets the most for the first procedure of the day performed by a particular surgeon.

Surgeon Experience	Trial 1 Guide Difference		Trial 2 Guide Difference		Trial 3 Guide Difference		Trial 4 Guide Difference	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
-	0.68	0.54	-0.13	0.19	0.25	0.28	0.36	0.26
+	0.66	0.49	0.25	0.76	0.34	0.38	-0.07	0.59
- & +	0.67	0.58	0.06	0.64	0.30	0.33	0.15	0.54

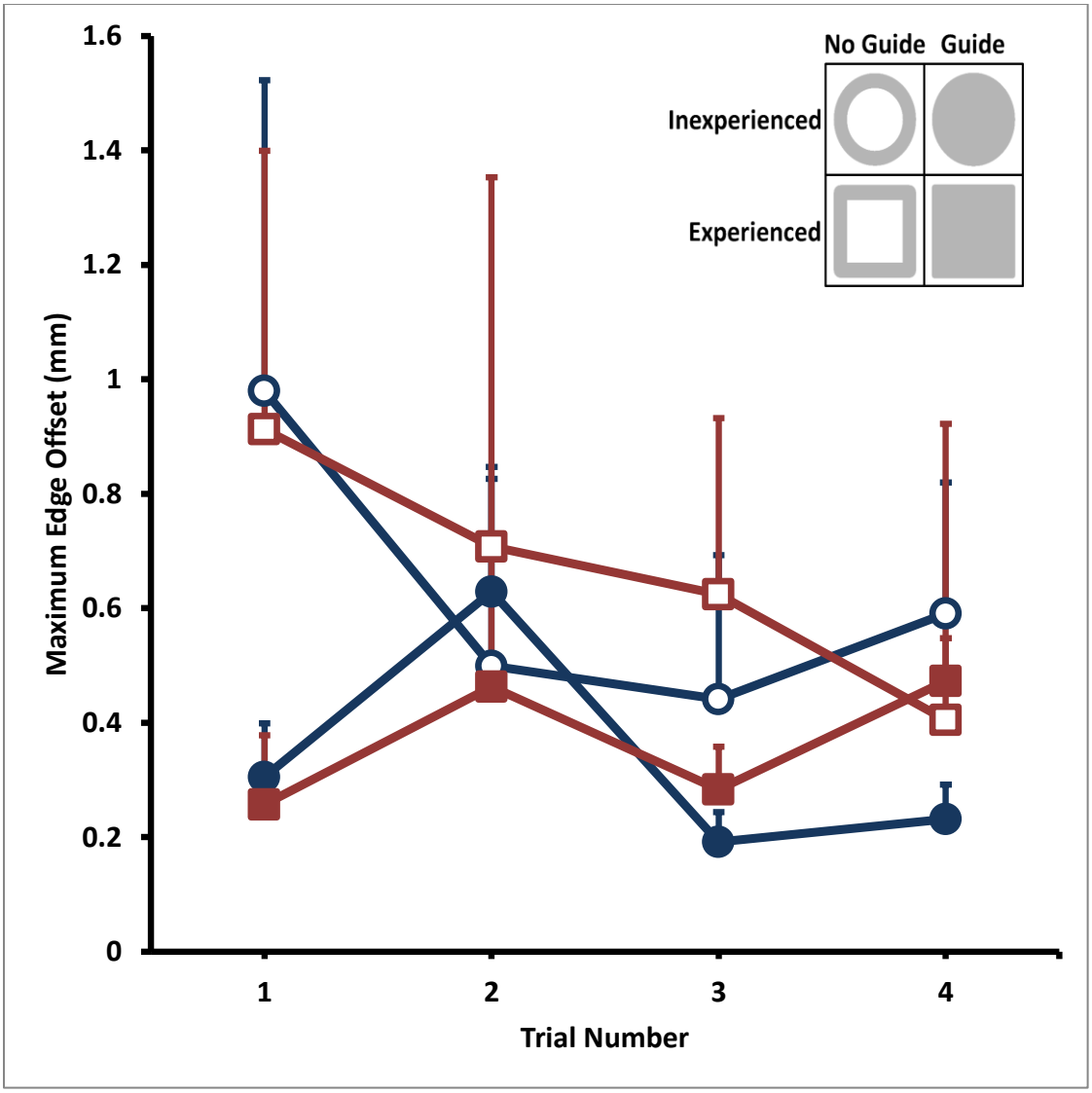


Figure 3.7. Maximum edge offset (Mean±SD) of each procedure averaged for surgeons of each experience level in order of when the procedure was performed. Blue circles represent data from the inexperienced surgeons, while red squares represents data from the experienced surgeons. Open squares or circles represent data from procedures in which no guide was used, while filled squares or circles represent data from procedures in which a guide was used. Overall a general reduction in maximum edge offset can be seen for procedures in which a surgical guide was used, but the first trial was the most affected.

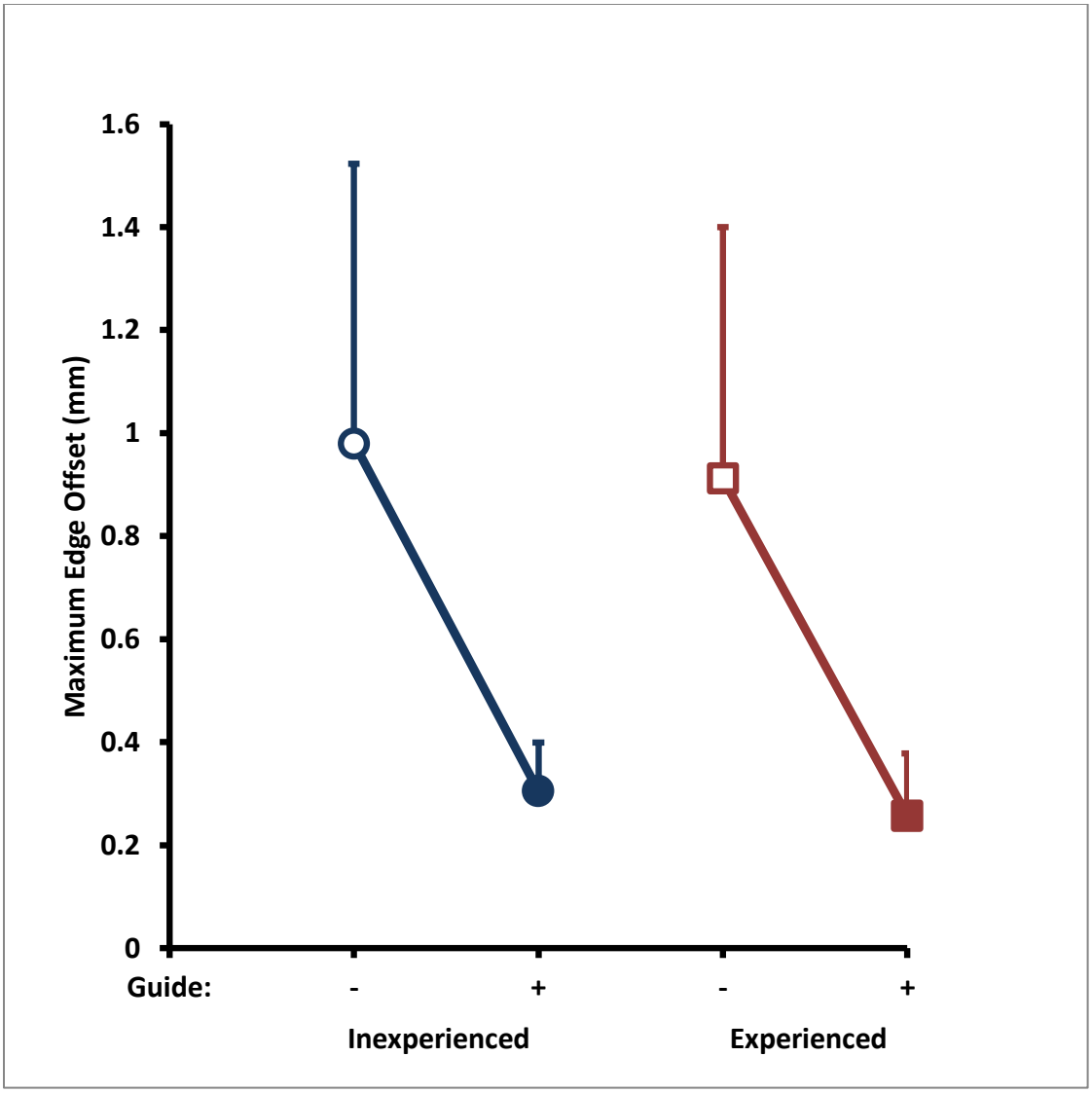


Figure 3.8. Average maximum edge offset (Mean±SD) for all surgeons in each surgeon group on their first trial. Blue circles represent data from the inexperienced surgeons, while red squares represents data from the experienced surgeons. Open squares or circles represent data from procedures in which no guide was used, while filled squares or circles represent data from procedures in which a guide was used. There is a clear reduction in maximum edge offset and less variability when the guide is used for either surgeon experience group.

Table 3.3. Effects on OCA maximum edge offset (in mm) of trial for each experience group or combined experience groups, analyzed by unpaired t-test. Three surgeons in each surgeon experience group performed four trials of osteochondral allograft procedures, and each trial consisted of one procedure performed with a surgical guide and one procedure performed without a surgical guide. The statistical results of the unpaired t-test (p-value and 95% confidence interval) are shown for each trial. The effect of the guides was significant for the first and third trials when using data from both experience groups.

Surgeon Experience	Trial 1			Trial 2			Trial 3			Trial 4		
	Effect of Guide			Effect of Guide			Effect of Guide			Effect of Guide		
	p-value	95% CI		p-value	95% CI		p-value	95% CI		p-value	95% CI	
-	0.10	-0.21	1.56	0.60	-0.76	0.50	0.17	-0.16	0.66	0.06	-0.02	0.74
+	0.09	-0.15	1.46	0.58	-0.87	1.36	0.14	-0.17	0.85	0.81	-0.82	0.69
- & +	0.01	0.23	1.10	0.79	-0.42	0.54	0.03	0.04	0.55	0.36	-0.19	0.48

Table 3.4. Effects on OCA maximum edge offset (in mm) of trial for each experience group or combined experience groups, analyzed by paired t-test. Three surgeons in each surgeon experience group performed four trials of osteochondral allograft procedures, and each trial consisted of one procedure performed with a surgical guide and one procedure performed without a surgical guide. The statistical results of the paired t-test (p-value and 95% confidence interval) are shown for each trial. The effect of the guides was significant for the first trial only using data from both experience groups.

Surgeon Experience	Trial 1			Trial 2			Trial 3			Trial 4		
	Effect of Guide			Effect of Guide			Effect of Guide			Effect of Guide		
	p-value	95% CI		p-value	95% CI		p-value	95% CI		p-value	95% CI	
-	0.16	-0.67	2.02	0.35	-0.59	0.33	0.26	-0.44	0.94	0.14	-0.29	1.01
+	0.15	-0.57	1.88	0.63	-1.65	2.14	0.26	-0.60	1.28	0.86	-1.53	1.40
- & +	0.02	0.18	1.15	0.80	-0.51	0.62	0.06	-0.02	0.61	0.48	-0.35	0.64

Table 3.5. The results of a two-way ANOVA performed on the OCA maximum edge offset measurements for each trial. Three surgeons in each surgeon experience group performed four sets of osteochondral allograft procedures. The results are shown in terms of p-values with Surgeon Experience being an independent factor but Guide being a repeated factor, along with the interaction between factors. The effect of the guides was significant for the first and third trials.

	Factor	p-value
Trial 1	Guide	0.01
	Surgeon experience	0.78
	Guide:Surgeon experience	0.97
Trial 2	Guide	0.80
	Surgeon experience	0.93
	Guide:Surgeon experience	0.44
Trial 3	Guide	0.03
	Surgeon experience	0.25
	Guide:Surgeon experience	0.71
Trial 4	Guide	0.39
	Surgeon experience	0.87
	Guide:Surgeon experience	0.20

Table 3.6. The results of a three-way ANOVA performed on the OCA maximum edge offset measurements for each trial. Three surgeons in each surgeon experience group performed four sets of osteochondral allograft procedures. The results are shown in terms of p-values with Surgeon Experience being an independent factor but Guide and Trial being repeated factors, along with the interaction between factors. The guide factor is the only p-value below the threshold of 0.05, however it is possible that the trial factor and the interaction between the guide and trial factors would be significant if more data was acquired.

Factor	p-value
Guide	0.003
Surgeon experience	0.73
Trial	0.07
Guide:Surgeon experience	0.98
Guide:Trial	0.11
Surgeon experience:Trial	0.65
Guide:Surgeon experience:Trial	0.36

Table 3.7. The OCA depth mismatch magnitude (in mm) means and standard deviations for each experience group or combined experience groups in guided and unguided trials. Three surgeons in each surgeon experience group performed four trials of osteochondral allograft procedures, and each trial consisted of one procedure performed with a surgical guide and one procedure performed without a surgical guide.

Surgeon Experience	Trial 1 Guide				Trial 2 Guide				Trial 3 Guide				Trial 4 Guide			
	-		+		-		+		-		+		-		+	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
-	0.54	0.26	0.56	0.42	0.47	0.40	0.63	0.74	0.41	0.47	0.46	0.24	0.33	0.40	0.43	0.20
+	0.10	0.12	0.21	0.10	0.12	0.08	0.14	0.11	0.17	0.12	0.68	0.84	0.21	0.22	0.97	1.20
- & +	0.32	0.30	0.38	0.33	0.30	0.32	0.38	0.54	0.29	0.33	0.57	0.56	0.27	0.29	0.70	0.82

Table 3.8. Effects on OCA depth mismatch magnitude (in mm) of trial for each experience group or combined experience groups, analyzed by paired t-test. Three surgeons in each surgeon experience group performed four trials of osteochondral allograft procedures, and each trial consisted of one procedure performed with a surgical guide and one procedure performed without a surgical guide. The statistical results of paired t-test (p-value and 95% confidence interval) are shown for each trial. No statistical significance for the effect of the surgical guides on depth mismatch was achieved in any trial.

Surgeon Experience	Trial 1			Trial 2			Trial 3			Trial 4		
	Effect of Guide			Effect of Guide			Effect of Guide			Effect of Guide		
	p-value	95% CI		p-value	95% CI		p-value	95% CI		p-value	95% CI	
-	0.86	-0.41	0.37	0.82	-2.67	2.37	0.88	-1.31	1.21	0.53	-0.70	0.49
+	0.35	-0.47	0.26	0.90	-0.48	0.45	0.44	-2.88	1.84	0.41	-3.91	2.40
- & +	0.35	-0.21	0.09	0.77	-0.77	0.61	0.38	-1.05	0.48	0.29	-1.37	0.50

Table 3.9. The results of a two-way ANOVA performed on the OCA depth mismatch magnitude measurements for each trial. Three surgeons in each surgeon experience group performed four sets of osteochondral allograft procedures. The effect of the guide on depth mismatch was never significant, however the effect of surgeon experience was significant for the first trial.

	Factor	p-value
Trial 1	Guide	0.70
	Surgeon experience	0.03
	Guide:Surgeon experience	0.78
Trial 2	Guide	0.74
	Surgeon experience	0.13
	Guide:Surgeon experience	0.79
Trial 3	Guide	0.35
	Surgeon experience	0.98
	Guide:Surgeon experience	0.44
Trial 4	Guide	0.28
	Surgeon experience	0.60
	Guide:Surgeon experience	0.41

CHAPTER 4: DISCUSSION

4.1 Summary

Over the course of this project, a method for producing surface-matching surgical guides for osteochondral allografts was successfully developed. The process automatically aligns a femur CT scan to a standard orientation, exports data defining a normal vector on the surface of a condyle, aligns osteochondral allograft surgical guides to that normal vector, customizes the surgical guide so it matches the curvature of the condyle, and produces a 3D printed surgical guide that reduces maximum edge offset in osteochondral allograft procedures.

The objective of the osteochondral allograft procedure study was to determine the effectiveness of 3D printed surface-matching surgical guides in reducing the maximum edge offset, by 0.35 mm, around the perimeter of implanted cylindrical grafts from osteochondral allograft procedures. The surgical guides were able to produce a statistically significant reduction in the maximum edge offset of the grafts, but mostly on the first trial. There was no statistically significant improvement for graft core depth mismatch magnitude due to the surgical guides but since the guides were not used when trimming the cores, no improvement was expected.

In order to improve the existing method of performing osteochondral allograft surgeries, the surgical guides used in this study utilize computer calculation of the normal vector from the cartilage surface at the surgical site,

significantly reducing the involvement and potential impact of human judgement. The surgical guides maintain the role of the bushings in stabilizing the cutting tools while adding the effect of establishing the normal vector from the surgical site on the femoral condyle surface.

While evaluating the surgical guides, there were some factors that affected the study. There was one surgeon in the study whose excessive tamping seems to have reduced the effect of the surgical guides for their procedures, by reducing maximum edge offset and depth mismatch for their unguided procedures. This seems to have directly impacted the data, but it also implies that the surgical guides may have performed better than the data suggests. Surgeons repeatedly commented that they would like to be able to see the cutting tools touching the surface of the condyle, but the surgical guides did not allow them to see the cutting site. The lack of sight may have caused surgeons to slightly miss the defect site with the guide pin, resulting in a recipient site that would not exactly match the surface of the donor core. Additionally, the guides seemed to slide a little on the surface of the condyle, partially because the ABS plastic is low in friction but also because the curvature of the femoral condyles changes only subtly in the articulating direction (i.e. in the sagittal plane running through the center of the condyle). The small mass of the surgical guide prototypes (9.10 to 9.47 grams), compared to the workstation bushing (280 grams), logically would not provide as much stability with inertia alone. Making the guide larger and from a more dense material may have improved the stability

of the guide. 3D printed models of goat distal femurs were produced and used for osteochondral allograft procedures to test out 3D printed surface-matching surgical guides. This provided an effective method of testing the surgical guides with results that can be stored for long periods of time without being frozen, unlike biological tissue. However, this also means that the data could change a bit when the guides are applied to biological tissue, since surgical guides may perform differently on biological tissue than on the 3D printed plastic. The 3D printed models are effective in deciding whether or not the guides improve the procedure and if there are improvements to be made in the surgical guide design, but the degree to which the guides improve the procedure is logically less reliable for 3D printed models than for biological tissue (unless the 3D printed models are better able to mimic biological tissue).

The surgical guides did improve the osteochondral allograft cuts by improving the alignment of the cutting tools. The surgical guides would greatly improve the quality of the cuts performed during osteochondral allograft procedures and would do so without introducing any new injuries such as in the apparatus mentioned earlier. [16] A study investigating data from a number of patients reaching nearly 10% of the U.S. population found a combined (open and arthroscopic) 57,282 osteochondral allograft procedures. [19] Barring significant advancement in automated surgical tools (or until that occurs); these surgical guides could become part of the standard procedure for increasingly popular [23] osteochondral allograft surgeries and improve the outcomes of the grafts for

thousands of future patients. Further research will be required to determine the potential impact of the improved graft congruency *in vivo*, especially long term since many studies see a difference in graft survival over 20 years. [12]

4.2 Future Directions

This project could be taken further in a few directions, starting with the surgical guide production process. The process could be developed until it is completely automated from CT scan to allograft site position export, or even through surgical guide contact part customization. It could even include automatic cartilage defect detection, as well as topographic matching of donor and recipient sites similar to what has been done for autografts. [4] The CT processing code could also be expanded to enable the process to work on more than just distal femurs.

The surgical guide design could be changed to increase stability by increasing the contact surface area, possibly by utilizing the articular surface of both condyles. The code could also be updated to identify stable landmarks with which the guide would make contact. In order to improve the ease of use of the surgical guides, one side of the guide could be open to allow visual verification of the surgical site.

In addition to alterations to the surgical guide design, some changes to the testing procedure would be beneficial. In order to reduce the variability in tamping force applied, the procedure instructions could be changed to state that a tamp and rubber mallet should not be used.

The primary study involving osteochondral allograft procedures described in this paper is being prepared for submission for publication. Szewczyk,

Alexander F; Chen, Albert C; Bugbee, William D; Sah, Robert L. “Osteochondral allograft procedure cuts aided by custom surgical guides”. The thesis author was the primary investigator and author of this material.

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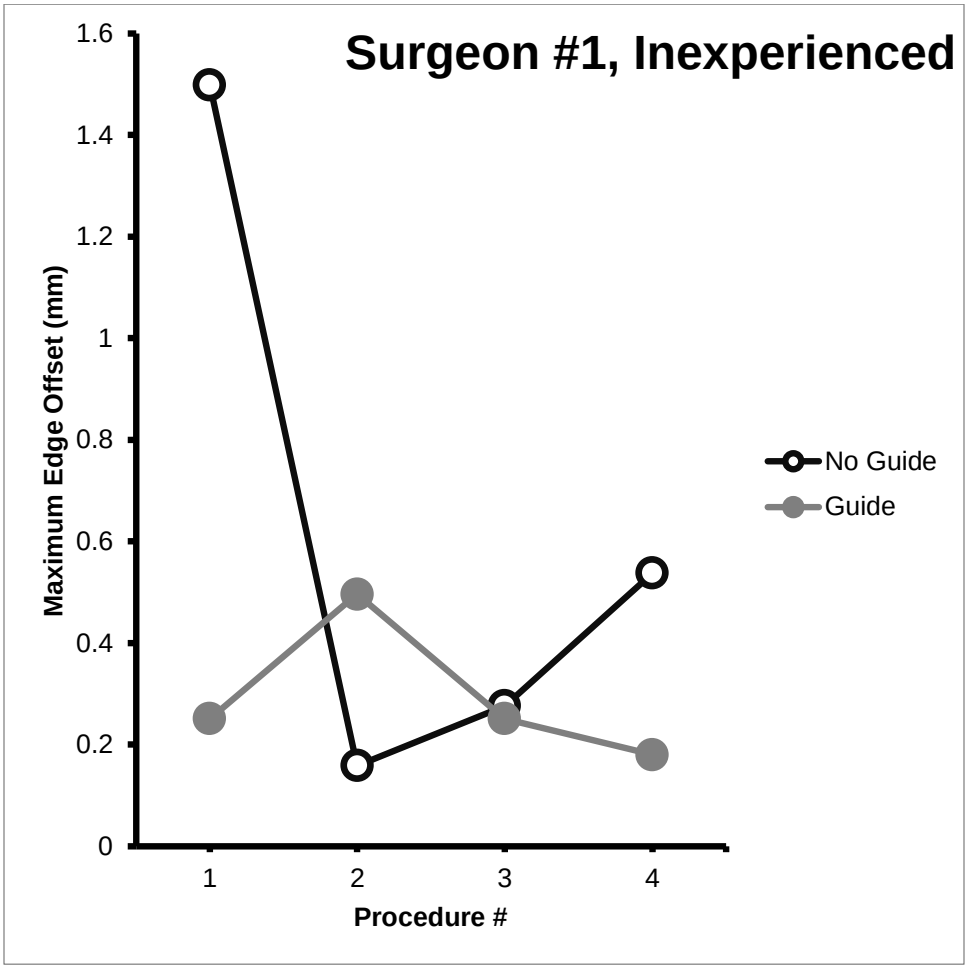
A.1. Maximum edge offset data (mm).

Surgeon #	Experience	Trial 1		Trial 2		Trial 3		Trial 4			Mean		SD	
		Guide		Guide		Guide		Guide			Guide		Guide	
		-	+	-	+	-	+	-	+		-	+	-	+
1	Inexperienced	1.50	0.25	0.16	0.50	0.28	0.25	0.54	0.18		0.62	0.29	0.61	0.14
2	Inexperienced	1.03	0.41	0.53	0.51	0.73	0.17	0.39	0.30		0.67	0.35	0.27	0.15
3	Inexperienced	0.42	0.25	0.81	0.88	0.32	0.15	0.84	0.22		0.60	0.38	0.27	0.34
4	Experienced	0.42	0.31	0.41	0.77	0.31	0.34	0.52	0.21		0.41	0.41	0.08	0.25
5	Experienced	0.93	0.12	0.27	0.28	0.92	0.20	0.46	0.21		0.64	0.20	0.34	0.07
6	Experienced	1.39	0.34	1.45	0.34	0.64	0.31	0.24	0.99		0.93	0.50	0.59	0.33
	Mean, Inexperienced	0.98	0.31	0.50	0.63	0.44	0.19	0.59	0.23					
	SD, Inexperienced	0.54	0.09	0.33	0.22	0.25	0.05	0.23	0.06					
	Mean, Experienced	0.91	0.26	0.71	0.46	0.62	0.28	0.40	0.47					
	SD, Experienced	0.49	0.12	0.65	0.27	0.31	0.07	0.14	0.45					
	Mean	0.95	0.28	0.60	0.55	0.53	0.24	0.50	0.35					
	SD	0.46	0.10	0.47	0.24	0.27	0.08	0.20	0.32					

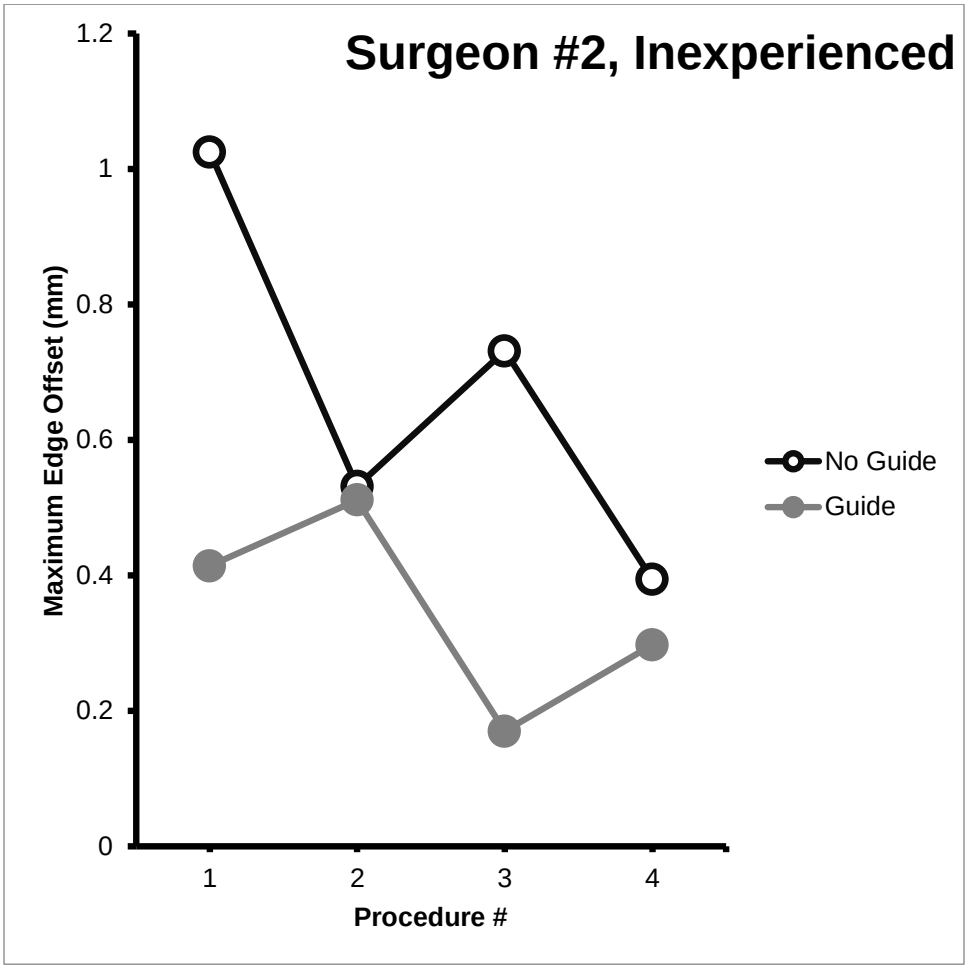
A.2. Graft depth mismatch magnitude data (mm).

Surgeon #	Experience	Trial 1		Trial 2		Trial 3		Trial 4			Mean		SD	
		Guide		Guide		Guide		Guide			Guide		Guide	
		-	+	-	+	-	+	-	+		-	+	-	+
1	Inexperienced	0.82	1.00	0.17	1.47	0.92	0.57	0.78	0.65		0.67	0.92	0.34	0.41
2	Inexperienced	0.49	0.50	0.32	0.10	0.00	0.62	0.16	0.26		0.24	0.37	0.21	0.23
3	Inexperienced	0.31	0.17	0.92	0.30	0.30	0.18	0.04	0.39		0.39	0.26	0.37	0.10
4	Experienced	0.06	0.10	0.17	0.04	0.22	0.04	0.45	0.13		0.22	0.08	0.16	0.04
5	Experienced	0.24	0.24	0.17	0.12	0.25	0.38	0.01	0.43		0.17	0.29	0.11	0.14
6	Experienced	0.01	0.28	0.03	0.26	0.03	1.63	0.18	2.34		0.06	1.13	0.08	1.03
	Mean, Inexperienced	0.54	0.56	0.47	0.63	0.41	0.46	0.33	0.43					
	SD, Inexperienced	0.26	0.42	0.40	0.74	0.47	0.24	0.40	0.20					
	Mean, Experienced	0.10	0.21	0.12	0.14	0.17	0.68	0.21	0.97					
	SD, Experienced	0.12	0.10	0.08	0.11	0.12	0.84	0.22	1.20					
	Mean	0.32	0.38	0.30	0.38	0.29	0.57	0.27	0.70					
	SD	0.30	0.33	0.32	0.54	0.33	0.56	0.29	0.82					

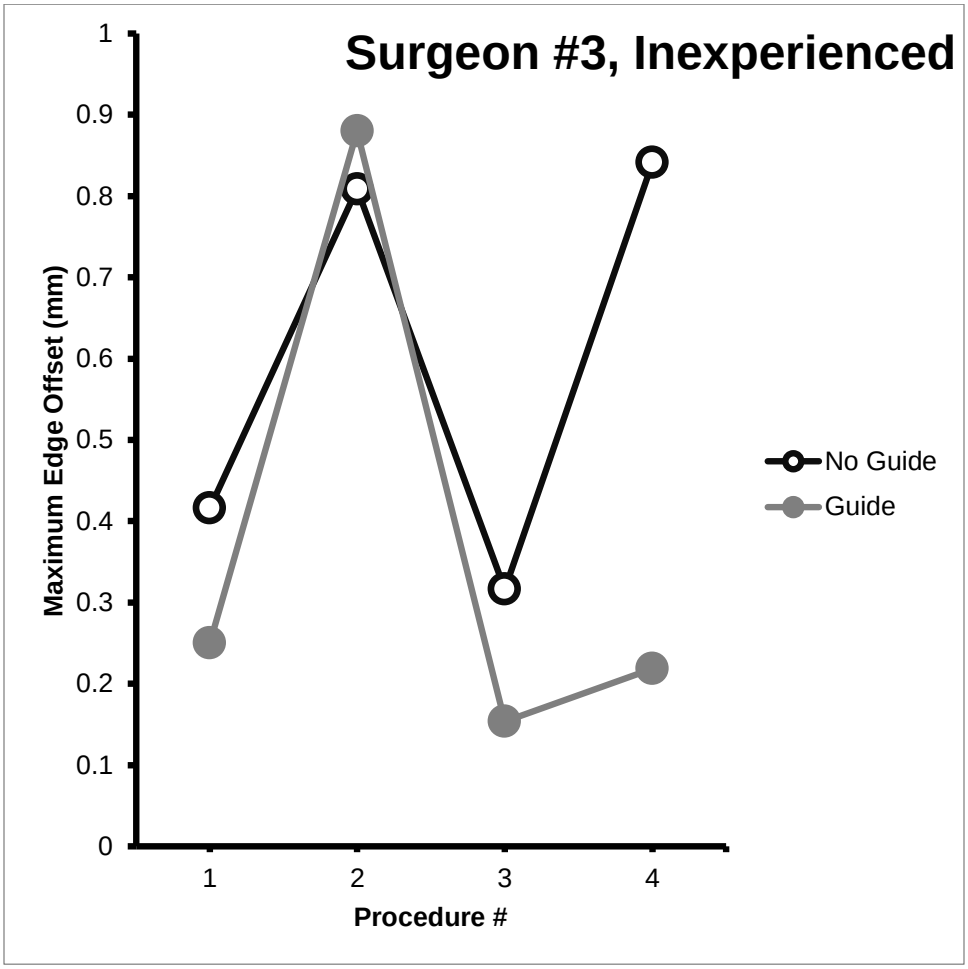
A.3. Maximum edge offset measurements (mm) for OCA procedures performed by surgeon #1, an inexperienced surgeon.



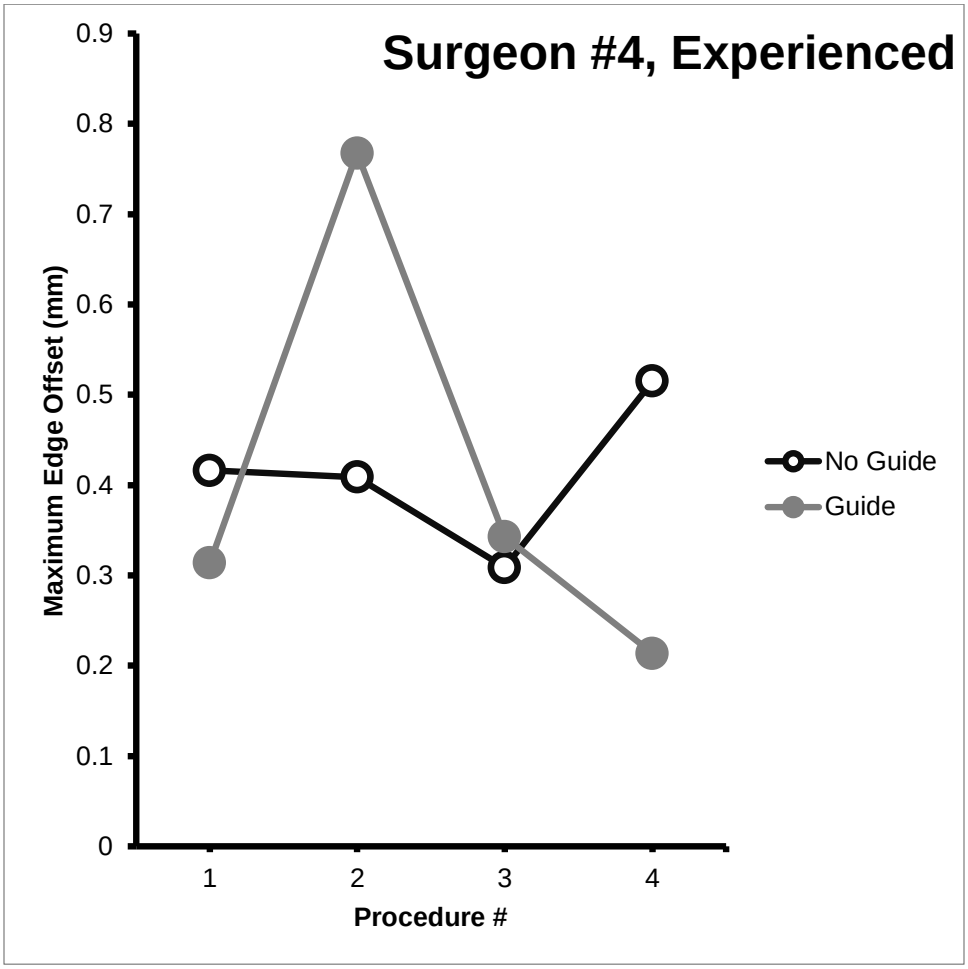
A.4. Maximum edge offset measurements (mm) for OCA procedures performed by surgeon #2, an inexperienced surgeon.



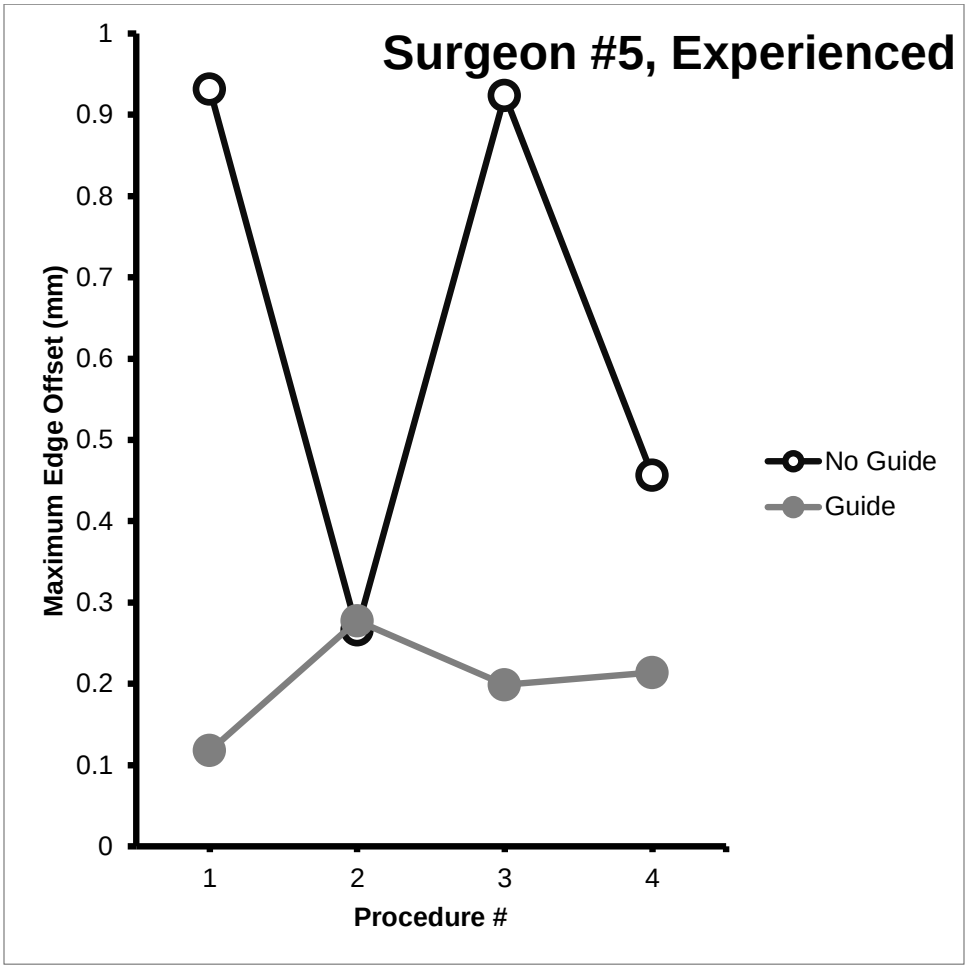
A.5. Maximum edge offset measurements (mm) for OCA procedures performed by surgeon #3, an inexperienced surgeon.



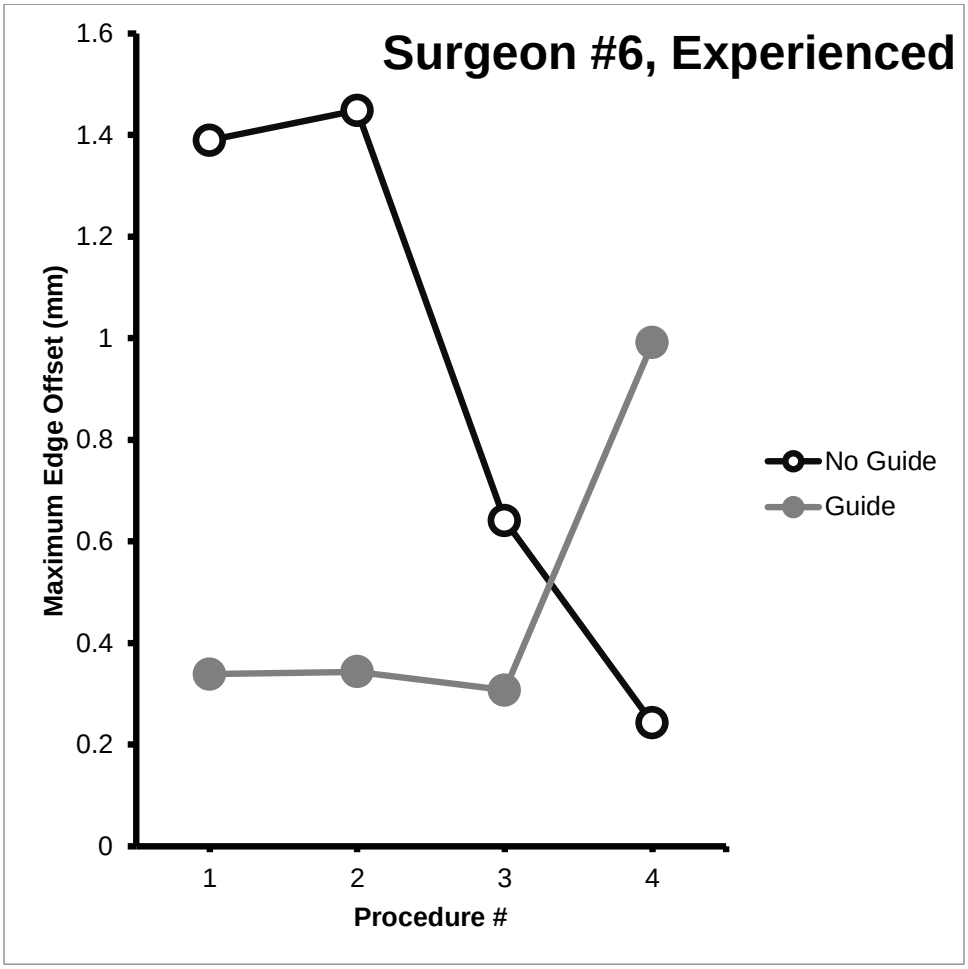
A.6. Maximum edge offset measurements (mm) for OCA procedures performed by surgeon #4, an experienced surgeon.



A.7. Maximum edge offset measurements (mm) for OCA procedures performed by surgeon #5, an experienced surgeon.



A.8. Maximum edge offset measurements (mm) for OCA procedures performed by surgeon #6, an experienced surgeon.



A.9. Statistical calculation R code and output for maximum edge offset trials.

```
> EdgeOffsetTrial1=read.csv("AFS2017-02_Trial 1_Edge Offset Data Trials From
        Femur Allograft Cuts With Surface-Matching Guides_20180124_v01.csv")
> EdgeOffsetTrial2=read.csv("AFS2017-02_Trial 2_Edge Offset Data Trials From
        Femur Allograft Cuts With Surface-Matching Guides_20180124_v01.csv")
> EdgeOffsetTrial3=read.csv("AFS2017-02_Trial 3_Edge Offset Data Trials From
        Femur Allograft Cuts With Surface-Matching Guides_20180124_v01.csv")
> EdgeOffsetTrial4=read.csv("AFS2017-02_Trial 4_Edge Offset Data Trials From
        Femur Allograft Cuts With Surface-Matching Guides_20180124_v01.csv")
> with(EdgeOffsetTrial1,t.test(Maximum.Edge.Offset~Guide,var.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 3.4423, df = 10, p-value = 0.006307
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 0.2347062 1.0961271
sample estimates:
 mean in group No mean in group Yes
       0.9462500        0.2808333

>
        with(EdgeOffsetTrial1,t.test(Maximum.Edge.Offset~Guide,var.equal=TRU
        E,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 3.5092, df = 5, p-value = 0.01711
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 0.177984 1.152849
sample estimates:
mean of the differences
           0.6654167

>
        with(EdgeOffsetTrial1,t.test(Maximum.Edge.Offset~Surgeon.Experience,v
        ar.equal=TRUE))
```

```
        Two Sample t-test

data:  Maximum.Edge.Offset by Surgeon.Experience
t = -0.20311, df = 10, p-value = 0.8431
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.6932658  0.5774325
sample estimates:
  mean in group Experienced mean in group Inexperienced
                  0.5845833                   0.6425000

> with(EdgeOffsetTrial2,t.test(Maximum.Edge.Offset~Guide,var.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 0.26824, df = 10, p-value = 0.794
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.4216542  0.5370708
sample estimates:
 mean in group No mean in group Yes
        0.6037500         0.5460417

>
        with(EdgeOffsetTrial2,t.test(Maximum.Edge.Offset~Guide,var.equal=TRU
        E,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 0.26256, df = 5, p-value = 0.8034
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.5072847  0.6227014
sample estimates:
mean of the differences
           0.05770833

>
        with(EdgeOffsetTrial2,t.test(Maximum.Edge.Offset~Surgeon.Experience,v
        ar.equal=TRUE))
```

```
        Two Sample t-test

data:  Maximum.Edge.Offset by Surgeon.Experience
t = 0.097501, df = 10, p-value = 0.9243
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.4598138  0.5018971
sample estimates:
  mean in group Experienced mean in group Inexperienced
                  0.5854167                   0.5643750

> with(EdgeOffsetTrial3,t.test(Maximum.Edge.Offset~Guide,var.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 2.5728, df = 10, p-value = 0.02776
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 0.03960499 0.55164501
sample estimates:
 mean in group No mean in group Yes
       0.5329167         0.2372917

>
        with(EdgeOffsetTrial3,t.test(Maximum.Edge.Offset~Guide,var.equal=TRU
        E,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 2.3983, df = 5, p-value = 0.06175
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.02123544  0.61248544
sample estimates:
mean of the differences
              0.295625

>
        with(EdgeOffsetTrial3,t.test(Maximum.Edge.Offset~Surgeon.Experience,v
        ar.equal=TRUE))

        Two Sample t-test
```

```
data:  Maximum.Edge.Offset by Surgeon.Experience
t = 0.96941, df = 10, p-value = 0.3552
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.1782653  0.4528486
sample estimates:
  mean in group Experienced mean in group Inexperienced
                  0.4537500                   0.3164583

> with(EdgeOffsetTrial4,t.test(Maximum.Edge.Offset~Guide,var.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 0.95421, df = 10, p-value = 0.3625
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.1938633  0.4842799
sample estimates:
 mean in group No mean in group Yes
       0.4977083         0.3525000

>
        with(EdgeOffsetTrial4,t.test(Maximum.Edge.Offset~Guide,var.equal=TRU
        E,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 0.7555, df = 5, p-value = 0.484
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.3488626  0.6392793
sample estimates:
mean of the differences
             0.1452083

>
        with(EdgeOffsetTrial4,t.test(Maximum.Edge.Offset~Surgeon.Experience,v
        ar.equal=TRUE))

        Two Sample t-test
```

```
data:  Maximum.Edge.Offset by Surgeon.Experience
t = 0.17195, df = 10, p-value = 0.8669
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.3263577  0.3809410
sample estimates:
  mean in group Experienced mean in group Inexperienced
                  0.4387500                   0.4114583
> dfEdgeOffTrial1=data.frame(EdgeOffsetTrial1,row.names = NULL)
>
        dfEdgeOffTrial1.NoGuide=dfEdgeOffTrial1[with(dfEdgeOffTrial1,which(dfE
        dgeOffTrial1$Guide=="No")),]
>
        dfEdgeOffTrial1.Guide=dfEdgeOffTrial1[with(dfEdgeOffTrial1,which(dfEdg
        eOffTrial1$Guide=="Yes")),]
>
        dfEdgeOffTrial1.Experienced=dfEdgeOffTrial1[with(dfEdgeOffTrial1,which(
        dfEdgeOffTrial1$Surgeon.Experience=="Experienced")),]
>
        dfEdgeOffTrial1.Inexperienced=dfEdgeOffTrial1[with(dfEdgeOffTrial1,whic
        h(dfEdgeOffTrial1$Surgeon.Experience=="Inexperienced")),]
>
        dfEdgeOffTrial1.NoGuide.Exp=dfEdgeOffTrial1.NoGuide[with(dfEdgeOffTr
        ial1.NoGuide,which(dfEdgeOffTrial1.NoGuide$Surgeon.Experience=="Ex
        perienced")),]
>
        dfEdgeOffTrial1.NoGuide.Inexp=dfEdgeOffTrial1.NoGuide[with(dfEdgeOff
        Trial1.NoGuide,which(dfEdgeOffTrial1.NoGuide$Surgeon.Experience=="I
        nexperienced")),]
>
        dfEdgeOffTrial1.Guide.Exp=dfEdgeOffTrial1.Guide[with(dfEdgeOffTrial1.G
        uide,which(dfEdgeOffTrial1.Guide$Surgeon.Experience=="Experienced"))
        ,]
>
        dfEdgeOffTrial1.Guide.Inexp=dfEdgeOffTrial1.Guide[with(dfEdgeOffTrial1.
        Guide,which(dfEdgeOffTrial1.Guide$Surgeon.Experience=="Inexperience
        d")),]
>
        with(dfEdgeOffTrial1.Inexperienced,t.test(Maximum.Edge.Offset~Guide,va
        r.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
```

```
t = 2.1228, df = 4, p-value = 0.101
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.2078639  1.5578639
sample estimates:
 mean in group No mean in group Yes
           0.980            0.305

>
         with(dfEdgeOffTrial1.Experienced,t.test(Maximum.Edge.Offset~Guide,var.
         equal=TRUE))

         Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 2.2629, df = 4, p-value = 0.08641
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.1488453  1.4605119
sample estimates:
 mean in group No mean in group Yes
       0.9125000        0.2566667

>
         with(dfEdgeOffTrial1.Inexperienced,t.test(Maximum.Edge.Offset~Guide,va
         r.equal=TRUE,paired=TRUE))

         Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 2.1514, df = 2, p-value = 0.1644
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.6749716  2.0249716
sample estimates:
mean of the differences
                 0.675

>
         with(dfEdgeOffTrial1.Experienced,t.test(Maximum.Edge.Offset~Guide,var.
         equal=TRUE,paired=TRUE))

         Paired t-test
```

```
data:  Maximum.Edge.Offset by Guide
t = 2.3009, df = 2, p-value = 0.1481
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.5705734  1.8822401
sample estimates:
mean of the differences
            0.6558333

>
         Result.EdgeOffTrial1=lm(Maximum.Edge.Offset~Guide+Surgeon.Experien
         ce,data=dfEdgeOffTrial1)
> anova(Result.EdgeOffTrial1)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                 Df  Sum Sq Mean Sq F value   Pr(>F)
Guide             1 1.32834 1.32834 10.7612 0.009523 **
Surgeon.Experience  1 0.01006 0.01006  0.0815 0.781706
Residuals           9 1.11094 0.12344
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> summary(Result.EdgeOffTrial1)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide + Surgeon.Experience,
    data = dfEdgeOffTrial1)

Residuals:
     Min       1Q   Median       3Q      Max
-0.55896 -0.07844  0.03187  0.09115  0.52354

Coefficients:
                                Estimate Std. Error t value Pr(>|t|)
(Intercept)                      0.91729    0.17567   5.222 0.000548 ***
GuideYes                        -0.66542    0.20284  -3.280 0.009523 **
Surgeon.ExperienceInexperienced  0.05792    0.20284   0.286 0.781706
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.3513 on 9 degrees of freedom
Multiple R-squared:  0.5464,         Adjusted R-squared:  0.4456
F-statistic: 5.421 on 2 and 9 DF,  p-value: 0.0285
```

```
>
        Result.EdgeOffTrial1.2=lm(Maximum.Edge.Offset~Guide*Surgeon.Experi
        ence,data=dfEdgeOffTrial1)
> anova(Result.EdgeOffTrial1.2)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                    Df  Sum Sq Mean Sq F value  Pr(>F)
Guide                1 1.32834 1.32834  9.5679 0.01482 *
Surgeon.Experience   1 0.01006 0.01006  0.0725 0.79457
Guide:Surgeon.Experience  1 0.00028 0.00028  0.0020 0.96556
Residuals            8 1.11067 0.13883
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> summary(Result.EdgeOffTrial1.2)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide * Surgeon.Experience,
    data = dfEdgeOffTrial1)

Residuals:
     Min       1Q   Median       3Q      Max
-0.56375 -0.07604  0.03187  0.08875  0.51875

Coefficients:
                                    Estimate Std. Error t value Pr(>|t|)
(Intercept)                          0.91250    0.21512   4.242  0.00283 **
GuideYes                            -0.65583    0.30423  -2.156  0.06321 .
Surgeon.ExperienceInexperienced      0.06750    0.30423   0.222  0.82997
GuideYes:Surgeon.ExperienceInexperienced -0.01917    0.43025  -0.045
        0.96556
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.3726 on 8 degrees of freedom
Multiple R-squared:  0.5465,         Adjusted R-squared:  0.3765
F-statistic: 3.214 on 3 and 8 DF,  p-value: 0.08293

> library(car)
> Anova(Result.EdgeOffTrial1.2,type="II")
Anova Table (Type II tests)

Response: Maximum.Edge.Offset
                     Sum Sq Df F value  Pr(>F)
```

```
Guide                  1.32834  1  9.5679 0.01482 *
Surgeon.Experience     0.01006  1  0.0725 0.79457
Guide:Surgeon.Experience 0.00028  1  0.0020 0.96556
Residuals              1.11067  8
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> Anova(Result.EdgeOffTrial1.2,type="III")
Anova Table (Type III tests)

Response: Maximum.Edge.Offset
                     Sum Sq Df F value   Pr(>F)
(Intercept)            2.49797  1 17.9926 0.002831 **
Guide                  0.64518  1  4.6471 0.063210 .
Surgeon.Experience     0.00683  1  0.0492 0.829973
Guide:Surgeon.Experience 0.00028  1  0.0020 0.965559
Residuals              1.11067  8
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> dfEdgeOffTrial2=data.frame(EdgeOffsetTrial2,row.names = NULL)
>
        dfEdgeOffTrial2.NoGuide=dfEdgeOffTrial2[with(dfEdgeOffTrial2,which(dfE
        dgeOffTrial2$Guide=="No")),]
>
        dfEdgeOffTrial2.Guide=dfEdgeOffTrial2[with(dfEdgeOffTrial2,which(dfEdg
        eOffTrial2$Guide=="Yes")),]
>
        dfEdgeOffTrial2.Experienced=dfEdgeOffTrial2[with(dfEdgeOffTrial2,which(
        dfEdgeOffTrial2$Surgeon.Experience=="Experienced")),]
>
        dfEdgeOffTrial2.Inexperienced=dfEdgeOffTrial2[with(dfEdgeOffTrial2,whic
        h(dfEdgeOffTrial2$Surgeon.Experience=="Inexperienced")),]
>
        dfEdgeOffTrial2.NoGuide.Exp=dfEdgeOffTrial2.NoGuide[with(dfEdgeOffTr
        ial2.NoGuide,which(dfEdgeOffTrial2.NoGuide$Surgeon.Experience=="Ex
        perienced")),]
>
        dfEdgeOffTrial2.NoGuide.Inexp=dfEdgeOffTrial2.NoGuide[with(dfEdgeOff
        Trial2.NoGuide,which(dfEdgeOffTrial2.NoGuide$Surgeon.Experience=="I
        nexperienced")),]
>
        dfEdgeOffTrial2.Guide.Exp=dfEdgeOffTrial2.Guide[with(dfEdgeOffTrial2.G
        uide,which(dfEdgeOffTrial2.Guide$Surgeon.Experience=="Experienced"))
        ,]
```

```
>
        dfEdgeOffTrial2.Guide.Inexp=dfEdgeOffTrial2.Guide[with(dfEdgeOffTrial2.
        Guide,which(dfEdgeOffTrial2.Guide$Surgeon.Experience=="Inexperience
        d")),]
>
        with(dfEdgeOffTrial2.Inexperienced,t.test(Maximum.Edge.Offset~Guide,va
        r.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = -0.57264, df = 4, p-value = 0.5975
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.7578648  0.4986981
sample estimates:
 mean in group No mean in group Yes
       0.4995833         0.6291667

>
        with(dfEdgeOffTrial2.Experienced,t.test(Maximum.Edge.Offset~Guide,var.
        equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 0.60785, df = 4, p-value = 0.5761
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.8740803  1.3640803
sample estimates:
 mean in group No mean in group Yes
       0.7079167         0.4629167

>
        with(dfEdgeOffTrial2.Inexperienced,t.test(Maximum.Edge.Offset~Guide,va
        r.equal=TRUE,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = -1.2083, df = 2, p-value = 0.3504
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
```

```
 -0.5910158  0.3318491
sample estimates:
mean of the differences
          -0.1295833

>
        with(dfEdgeOffTrial2.Experienced,t.test(Maximum.Edge.Offset~Guide,var.
        equal=TRUE,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 0.55487, df = 2, p-value = 0.6348
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -1.65482  2.14482
sample estimates:
mean of the differences
               0.245

>
        Result.EdgeOffTrial2=lm(Maximum.Edge.Offset~Guide+Surgeon.Experien
        ce,data=dfEdgeOffTrial2)
> anova(Result.EdgeOffTrial2)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                Df  Sum Sq  Mean Sq F value Pr(>F)
Guide            1 0.00999 0.009991  0.0648 0.8048
Surgeon.Experience  1 0.00133 0.001328  0.0086 0.9281
Residuals        9 1.38723 0.154137
> summary(Result.EdgeOffTrial2)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide + Surgeon.Experience,
   data = dfEdgeOffTrial2)

Residuals:
     Min       1Q   Median       3Q      Max
-0.43448 -0.22938 -0.05063  0.21208  0.83448

Coefficients:
                        Estimate Std. Error t value Pr(>|t|)
(Intercept)                0.61427    0.19630   3.129   0.0121 *
```

```
GuideYes                     -0.05771    0.22667  -0.255   0.8048
Surgeon.ExperienceInexperienced -0.02104    0.22667  -0.093   0.9281
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.3926 on 9 degrees of freedom
Multiple R-squared:  0.008093,     Adjusted R-squared:  -0.2123
F-statistic: 0.03672 on 2 and 9 DF,  p-value: 0.9641

>
        Result.EdgeOffTrial2.2=lm(Maximum.Edge.Offset~Guide*Surgeon.Experi
        ence,data=dfEdgeOffTrial2)
> anova(Result.EdgeOffTrial2.2)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                   Df  Sum Sq  Mean Sq F value Pr(>F)
Guide                1 0.00999 0.009991  0.0623 0.8091
Surgeon.Experience       1 0.00133 0.001328  0.0083 0.9297
Guide:Surgeon.Experience  1 0.10523 0.105235  0.6567 0.4412
Residuals                8 1.28200 0.160250
> summary(Result.EdgeOffTrial2.2)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide * Surgeon.Experience,
   data = dfEdgeOffTrial2)

Residuals:
   Min      1Q  Median      3Q     Max
-0.4417 -0.2139 -0.1185  0.2643  0.7408

Coefficients:
                                 Estimate Std. Error t value Pr(>|t|)
(Intercept)                        0.7079     0.2311   3.063   0.0155 *
GuideYes                          -0.2450     0.3269  -0.750   0.4750
Surgeon.ExperienceInexperienced          -0.2083     0.3269  -0.637   0.5417
GuideYes:Surgeon.ExperienceInexperienced   0.3746     0.4622   0.810   0.4412
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.4003 on 8 degrees of freedom
Multiple R-squared:  0.08334,       Adjusted R-squared:  -0.2604
F-statistic: 0.2424 on 3 and 8 DF,  p-value: 0.8644
```

```
> Anova(Result.EdgeOffTrial2.2,type="II")
Anova Table (Type II tests)

Response: Maximum.Edge.Offset
                    Sum Sq Df F value Pr(>F)
Guide                0.00999  1  0.0623 0.8091
Surgeon.Experience   0.00133  1  0.0083 0.9297
Guide:Surgeon.Experience 0.10523  1  0.6567 0.4412
Residuals            1.28200  8
> Anova(Result.EdgeOffTrial2.2,type="III")
Anova Table (Type III tests)

Response: Maximum.Edge.Offset
                    Sum Sq Df F value  Pr(>F)
(Intercept)          1.50344  1  9.3818 0.01551 *
Guide                0.09004  1  0.5619 0.47498
Surgeon.Experience   0.06510  1  0.4063 0.54168
Guide:Surgeon.Experience 0.10523  1  0.6567 0.44117
Residuals            1.28200  8
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> dfEdgeOffTrial3=data.frame(EdgeOffsetTrial3,row.names = NULL)
>
    dfEdgeOffTrial3.NoGuide=dfEdgeOffTrial3[with(dfEdgeOffTrial3,which(dfE
    dgeOffTrial3$Guide=="No")),]
>
    dfEdgeOffTrial3.Guide=dfEdgeOffTrial3[with(dfEdgeOffTrial3,which(dfEdg
    eOffTrial3$Guide=="Yes")),]
>
    dfEdgeOffTrial3.Experienced=dfEdgeOffTrial3[with(dfEdgeOffTrial3,which(
    dfEdgeOffTrial3$Surgeon.Experience=="Experienced")),]
>
    dfEdgeOffTrial3.Inexperienced=dfEdgeOffTrial3[with(dfEdgeOffTrial3,whic
    h(dfEdgeOffTrial3$Surgeon.Experience=="Inexperienced")),]
>
    dfEdgeOffTrial3.NoGuide.Exp=dfEdgeOffTrial3.NoGuide[with(dfEdgeOffTr
    ial3.NoGuide,which(dfEdgeOffTrial3.NoGuide$Surgeon.Experience=="Ex
    perienced")),]
>
    dfEdgeOffTrial3.NoGuide.Inexp=dfEdgeOffTrial3.NoGuide[with(dfEdgeOff
    Trial3.NoGuide,which(dfEdgeOffTrial3.NoGuide$Surgeon.Experience=="I
    nexperienced")),]
>
    dfEdgeOffTrial3.Guide.Exp=dfEdgeOffTrial3.Guide[with(dfEdgeOffTrial3.G
```

```
        uide,which(dfEdgeOffTrial3.Guide$Surgeon.Experience=="Experienced"))
        ,]
>
        dfEdgeOffTrial3.Guide.Inexp=dfEdgeOffTrial3.Guide[with(dfEdgeOffTrial3.
        Guide,which(dfEdgeOffTrial3.Guide$Surgeon.Experience=="Inexperience
        d")),]
>
        with(dfEdgeOffTrial3.Inexperienced,t.test(Maximum.Edge.Offset~Guide,va
        r.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 1.6801, df = 4, p-value = 0.1682
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.1628649  0.6620315
sample estimates:
 mean in group No mean in group Yes
       0.4412500         0.1916667

>
        with(dfEdgeOffTrial3.Experienced,t.test(Maximum.Edge.Offset~Guide,var.
        equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 1.8678, df = 4, p-value = 0.1352
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.1662125  0.8495458
sample estimates:
 mean in group No mean in group Yes
       0.6245833         0.2829167

>
        with(dfEdgeOffTrial3.Inexperienced,t.test(Maximum.Edge.Offset~Guide,va
        r.equal=TRUE,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 1.552, df = 2, p-value = 0.2608
```

```
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.4423221  0.9414888
sample estimates:
mean of the differences
            0.2495833

>
        with(dfEdgeOffTrial3.Experienced,t.test(Maximum.Edge.Offset~Guide,var.
        equal=TRUE,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 1.5596, df = 2, p-value = 0.2592
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.600907  1.284240
sample estimates:
mean of the differences
            0.3416667

>
        Result.EdgeOffTrial3=lm(Maximum.Edge.Offset~Guide+Surgeon.Experien
        ce,data=dfEdgeOffTrial3)
> anova(Result.EdgeOffTrial3)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                 Df  Sum Sq  Mean Sq F value  Pr(>F)
Guide             1 0.26218 0.262182  6.9496 0.02708 *
Surgeon.Experience  1 0.05655 0.056547  1.4989 0.25192
Residuals           9 0.33953 0.037726
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> summary(Result.EdgeOffTrial3)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide + Surgeon.Experience,
    data = dfEdgeOffTrial3)

Residuals:
     Min       1Q   Median       3Q      Max
-0.29281 -0.11740  0.00146  0.05042  0.32219
```

```
Coefficients:
                                Estimate Std. Error t value Pr(>|t|)
(Intercept)                      0.60156    0.09712   6.194  0.00016 ***
GuideYes                        -0.29563    0.11214  -2.636  0.02708 *
Surgeon.ExperienceInexperienced -0.13729    0.11214  -1.224  0.25192
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.1942 on 9 degrees of freedom
Multiple R-squared:  0.4842,         Adjusted R-squared:  0.3696
F-statistic: 4.224 on 2 and 9 DF,  p-value: 0.05084

>
        Result.EdgeOffTrial3.2=lm(Maximum.Edge.Offset~Guide*Surgeon.Experi
        ence,data=dfEdgeOffTrial3)
> anova(Result.EdgeOffTrial3.2)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                    Df  Sum Sq  Mean Sq F value  Pr(>F)
Guide                1 0.26218 0.262182  6.2954 0.03642 *
Surgeon.Experience   1 0.05655 0.056547  1.3578 0.27749
Guide:Surgeon.Experience  1 0.00636 0.006360  0.1527 0.70617
Residuals            8 0.33317 0.041647
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> summary(Result.EdgeOffTrial3.2)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide * Surgeon.Experience,
   data = dfEdgeOffTrial3)

Residuals:
     Min       1Q   Median       3Q      Max
-0.31583 -0.09438 -0.00250  0.05958  0.29917

Coefficients:
                                        Estimate Std. Error t value Pr(>|t|)
(Intercept)                              0.62458    0.11782   5.301 0.000727 ***
GuideYes                                -0.34167    0.16663  -2.050 0.074452 .
Surgeon.ExperienceInexperienced         -0.18333    0.16663  -1.100 0.303221
GuideYes:Surgeon.ExperienceInexperienced  0.09208    0.23565   0.391
        0.706168
```

```
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.2041 on 8 degrees of freedom
Multiple R-squared:  0.4939,         Adjusted R-squared:  0.3041
F-statistic: 2.602 on 3 and 8 DF,  p-value: 0.1243

> Anova(Result.EdgeOffTrial3.2,type="II")
Anova Table (Type II tests)

Response: Maximum.Edge.Offset
                     Sum Sq Df F value  Pr(>F)
Guide                 0.26218  1  6.2954 0.03642 *
Surgeon.Experience    0.05655  1  1.3578 0.27749
Guide:Surgeon.Experience 0.00636  1  0.1527 0.70617
Residuals             0.33317  8
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> Anova(Result.EdgeOffTrial3.2,type="III")
Anova Table (Type III tests)

Response: Maximum.Edge.Offset
                     Sum Sq Df F value    Pr(>F)
(Intercept)           1.17031  1 28.1009 0.0007275 ***
Guide                 0.17510  1  4.2045 0.0744518 .
Surgeon.Experience    0.05042  1  1.2106 0.3032205
Guide:Surgeon.Experience 0.00636  1  0.1527 0.7061681
Residuals             0.33317  8
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> dfEdgeOffTrial4=data.frame(EdgeOffsetTrial4,row.names = NULL)
>
        dfEdgeOffTrial4.NoGuide=dfEdgeOffTrial4[with(dfEdgeOffTrial4,which(dfE
        dgeOffTrial4$Guide=="No")),]
>
        dfEdgeOffTrial4.Guide=dfEdgeOffTrial4[with(dfEdgeOffTrial4,which(dfEdg
        eOffTrial4$Guide=="Yes")),]
>
        dfEdgeOffTrial4.Experienced=dfEdgeOffTrial4[with(dfEdgeOffTrial4,which(
        dfEdgeOffTrial4$Surgeon.Experience=="Experienced")),]
>
        dfEdgeOffTrial4.Inexperienced=dfEdgeOffTrial4[with(dfEdgeOffTrial4,whic
        h(dfEdgeOffTrial4$Surgeon.Experience=="Inexperienced")),]
```

```
>
        dfEdgeOffTrial4.NoGuide.Exp=dfEdgeOffTrial4.NoGuide[with(dfEdgeOffTr
        ial4.NoGuide,which(dfEdgeOffTrial4.NoGuide$Surgeon.Experience=="Ex
        perienced")),]
>
        dfEdgeOffTrial4.NoGuide.Inexp=dfEdgeOffTrial4.NoGuide[with(dfEdgeOff
        Trial4.NoGuide,which(dfEdgeOffTrial4.NoGuide$Surgeon.Experience=="I
        nexperienced")),]
>
        dfEdgeOffTrial4.Guide.Exp=dfEdgeOffTrial4.Guide[with(dfEdgeOffTrial4.G
        uide,which(dfEdgeOffTrial4.Guide$Surgeon.Experience=="Experienced"))
        ,]
>
        dfEdgeOffTrial4.Guide.Inexp=dfEdgeOffTrial4.Guide[with(dfEdgeOffTrial4.
        Guide,which(dfEdgeOffTrial4.Guide$Surgeon.Experience=="Inexperience
        d")),]
>
        with(dfEdgeOffTrial4.Inexperienced,t.test(Maximum.Edge.Offset~Guide,va
        r.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 2.6309, df = 4, p-value = 0.05813
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.01984654  0.73734654
sample estimates:
 mean in group No mean in group Yes
       0.5908333         0.2320833

>
        with(dfEdgeOffTrial4.Experienced,t.test(Maximum.Edge.Offset~Guide,var.
        equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = -0.25116, df = 4, p-value = 0.8141
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.8237241  0.6870574
sample estimates:
 mean in group No mean in group Yes
```

```
      0.4045833        0.4729167

>
        with(dfEdgeOffTrial4.Inexperienced,t.test(Maximum.Edge.Offset~Guide,va
        r.equal=TRUE,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 2.3615, df = 2, p-value = 0.1421
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.2948943  1.0123943
sample estimates:
mean of the differences
            0.35875

>
        with(dfEdgeOffTrial4.Experienced,t.test(Maximum.Edge.Offset~Guide,var.
        equal=TRUE,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = -0.20061, df = 2, p-value = 0.8596
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -1.533949  1.397283
sample estimates:
mean of the differences
         -0.06833333

>
        Result.EdgeOffTrial4=lm(Maximum.Edge.Offset~Guide+Surgeon.Experien
        ce,data=dfEdgeOffTrial4)
> anova(Result.EdgeOffTrial4)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                Df  Sum Sq  Mean Sq F value Pr(>F)
Guide            1 0.06326 0.063256  0.8221 0.3882
Surgeon.Experience  1 0.00223 0.002235  0.0290 0.8685
Residuals        9 0.69250 0.076945
> summary(Result.EdgeOffTrial4)
```

```
Call:
lm(formula = Maximum.Edge.Offset ~ Guide + Surgeon.Experience,
    data = dfEdgeOffTrial4)

Residuals:
     Min       1Q   Median       3Q      Max
-0.26885 -0.15240 -0.07271  0.01609  0.62510

Coefficients:
                              Estimate Std. Error t value Pr(>|t|)
(Intercept)                    0.51135    0.13869   3.687  0.00502 **
GuideYes                      -0.14521    0.16015  -0.907  0.38820
Surgeon.ExperienceInexperienced -0.02729    0.16015  -0.170  0.86846
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.2774 on 9 degrees of freedom
Multiple R-squared:  0.0864,        Adjusted R-squared:  -0.1166
F-statistic: 0.4256 on 2 and 9 DF,  p-value: 0.6659

>
        Result.EdgeOffTrial4.2=lm(Maximum.Edge.Offset~Guide*Surgeon.Experi
        ence,data=dfEdgeOffTrial4)
> anova(Result.EdgeOffTrial4.2)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                    Df  Sum Sq  Mean Sq F value Pr(>F)
Guide                1 0.06326 0.063256  0.9107 0.3679
Surgeon.Experience   1 0.00223 0.002235  0.0322 0.8621
Guide:Surgeon.Experience  1 0.13680 0.136800  1.9694 0.1981
Residuals            8 0.55570 0.069463
> summary(Result.EdgeOffTrial4.2)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide * Surgeon.Experience,
    data = dfEdgeOffTrial4)

Residuals:
     Min       1Q   Median       3Q      Max
-0.25917 -0.17083 -0.03271  0.07667  0.51833

Coefficients:
```

```
                                  Estimate Std. Error t value Pr(>|t|)
(Intercept)                        0.40458    0.15217   2.659   0.0289 *
GuideYes                           0.06833    0.21519   0.318   0.7590
Surgeon.ExperienceInexperienced    0.18625    0.21519   0.865   0.4120
GuideYes:Surgeon.ExperienceInexperienced -0.42708    0.30433  -1.403
        0.1981
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.2636 on 8 degrees of freedom
Multiple R-squared:  0.2669,        Adjusted R-squared:  -0.008043
F-statistic: 0.9707 on 3 and 8 DF,  p-value: 0.4527

> Anova(Result.EdgeOffTrial4.2,type="II")
Anova Table (Type II tests)

Response: Maximum.Edge.Offset
                   Sum Sq Df F value Pr(>F)
Guide              0.06326  1  0.9107 0.3679
Surgeon.Experience 0.00223  1  0.0322 0.8621
Guide:Surgeon.Experience 0.13680  1  1.9694 0.1981
Residuals          0.55570  8
> Anova(Result.EdgeOffTrial4.2,type="III")
Anova Table (Type III tests)

Response: Maximum.Edge.Offset
                   Sum Sq Df F value  Pr(>F)
(Intercept)        0.49106  1  7.0695 0.02886 *
Guide              0.00700  1  0.1008 0.75896
Surgeon.Experience 0.05203  1  0.7491 0.41197
Guide:Surgeon.Experience 0.13680  1  1.9694 0.19811
Residuals          0.55570  8
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
```

A.10. Statistical calculation R code and output for maximum edge offset combined trials.

```
> EdgeOffsetData=read.csv("AFS2017-02_Edge Offset Data From Femur
        Allograft Cuts With Surface-Matching Guides_20180121_v01.csv",
        header=T)
> with(EdgeOffsetData,t.test(Maximum.Edge.Offset~Guide,var.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Guide
t = 3.155, df = 46, p-value = 0.002829
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 0.1053350 0.4766442
sample estimates:
 mean in group No mean in group Yes
       0.6451562         0.3541667

>
        with(EdgeOffsetData,t.test(Maximum.Edge.Offset~Guide,var.equal=TRUE
        ,paired=TRUE))

        Paired t-test

data:  Maximum.Edge.Offset by Guide
t = 2.9455, df = 23, p-value = 0.00726
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 0.08662493 0.49535424
sample estimates:
mean of the differences
           0.2909896

>
        with(EdgeOffsetData,t.test(Maximum.Edge.Offset~Surgeon.Experience,va
        r.equal=TRUE))

        Two Sample t-test

data:  Maximum.Edge.Offset by Surgeon.Experience
t = 0.3142, df = 46, p-value = 0.7548
```

```
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.1726118  0.2364660
sample estimates:
  mean in group Experienced mean in group Inexperienced
                  0.5156250                   0.4836979

>
          with(EdgeOffsetData,t.test(Maximum.Edge.Offset~Surgeon.Experience,va
          r.equal=TRUE,paired=TRUE))

          Paired t-test

data:  Maximum.Edge.Offset by Surgeon.Experience
t = 0.36147, df = 23, p-value = 0.721
alternative hypothesis: true difference in means is not equal to 0
95 percent confidence interval:
 -0.1507872  0.2146414
sample estimates:
mean of the differences
             0.03192708

>
          Result.EdgeOffset=lm(Maximum.Edge.Offset~Guide+Surgeon.Experience
          ,data=EdgeOffsetData)
> anova(Result.EdgeOffset)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                 Df Sum Sq Mean Sq F value    Pr(>F)
Guide             1 1.0161 1.01610  9.7628 0.003114 **
Surgeon.Experience  1 0.0122 0.01223  0.1175 0.733329
Residuals          45 4.6836 0.10408
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> summary(Result.EdgeOffset)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide + Surgeon.Experience,
    data = EdgeOffsetData)

Residuals:
     Min       1Q   Median       3Q      Max
-0.47044 -0.18956 -0.08758  0.16180  0.86956
```

```
Coefficients:
                                Estimate Std. Error t value Pr(>|t|)
(Intercept)                      0.66112    0.08065   8.197 1.78e-10 ***
GuideYes                        -0.29099    0.09313  -3.125  0.00311 **
Surgeon.ExperienceInexperienced -0.03193    0.09313  -0.343  0.73333
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.3226 on 45 degrees of freedom
Multiple R-squared:   0.18, Adjusted R-squared:  0.1436
F-statistic:  4.94 on 2 and 45 DF,  p-value: 0.01149

>
        Result.EdgeOffset.2=lm(Maximum.Edge.Offset~Guide*Surgeon.Experienc
        e,data=EdgeOffsetData)
> anova(Result.EdgeOffset.2)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                    Df Sum Sq Mean Sq F value   Pr(>F)
Guide                1 1.0161 1.01610  9.5460 0.003468 **
Surgeon.Experience   1 0.0122 0.01223  0.1149 0.736227
Guide:Surgeon.Experience  1 0.0001 0.00008  0.0007 0.978505
Residuals           44 4.6835 0.10644
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> summary(Result.EdgeOffset.2)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide * Surgeon.Experience,
   data = EdgeOffsetData)

Residuals:
    Min      1Q  Median      3Q     Max
-0.46917 -0.19083 -0.08885  0.16052  0.87083

Coefficients:
                                          Estimate Std. Error t value Pr(>|t|)
(Intercept)                               0.662396   0.094182   7.033 1.02e-08 ***
GuideYes                                 -0.293542   0.133193  -2.204   0.0328 *
Surgeon.ExperienceInexperienced          -0.034479   0.133193  -0.259   0.7969
GuideYes:Surgeon.ExperienceInexperienced  0.005104   0.188364   0.027
        0.9785
```

```
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.3263 on 44 degrees of freedom
Multiple R-squared:   0.18, Adjusted R-squared:  0.1241
F-statistic: 3.221 on 3 and 44 DF,  p-value: 0.03162

>
        Result.EdgeOffset.3=lm(Maximum.Edge.Offset~Guide*Surgeon.Experienc
        e*Procedure..,data=EdgeOffsetData)
> anova(Result.EdgeOffset.3)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                              Df Sum Sq Mean Sq F value   Pr(>F)
Guide                          1 1.0161 1.01610 10.2298 0.002703 **
Surgeon.Experience             1 0.0122 0.01223  0.1231 0.727486
Procedure..                    1 0.3421 0.34211  3.4442 0.070850 .
Guide:Surgeon.Experience       1 0.0001 0.00008  0.0008 0.977761
Guide:Procedure..              1 0.2624 0.26243  2.6421 0.111920
Surgeon.Experience:Procedure..        1 0.0207 0.02074  0.2088 0.650150
Guide:Surgeon.Experience:Procedure..  1 0.0851 0.08508  0.8566 0.360255
Residuals                     40 3.9731 0.09933
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> summary(Result.EdgeOffset.3)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide * Surgeon.Experience *
    Procedure.., data = EdgeOffsetData)

Residuals:
     Min       1Q   Median       3Q      Max
-0.53046 -0.18698 -0.03698  0.12065  0.70600

Coefficients:
                                          Estimate Std. Error t value Pr(>|t|)
(Intercept)                                1.06417    0.22285   4.775 2.42e-05 ***
GuideYes                                  -0.81250    0.31516  -2.578   0.0137 *
Surgeon.ExperienceInexperienced                  -0.12979    0.31516  -0.412
        0.6827
Procedure..                               -0.16071    0.08137  -1.975   0.0552 .
GuideYes:Surgeon.ExperienceInexperienced          0.38167    0.44571   0.856
        0.3969
```

```
GuideYes:Procedure..                          0.20758    0.11508   1.804   0.0788 .
Surgeon.ExperienceInexperienced:Procedure..   0.03813    0.11508   0.331
        0.7422
GuideYes:Surgeon.ExperienceInexperienced:Procedure.. -0.15063    0.16275  -
        0.926   0.3603
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.3152 on 40 degrees of freedom
Multiple R-squared:  0.3044,        Adjusted R-squared:  0.1827
F-statistic: 2.501 on 7 and 40 DF,  p-value: 0.03138

> library(car)
> Anova(Result.EdgeOffset.3,type="II")
Anova Table (Type II tests)

Response: Maximum.Edge.Offset
                          Sum Sq Df F value   Pr(>F)
Guide                      1.0161  1 10.2298 0.002703 **
Surgeon.Experience         0.0122  1  0.1231 0.727486
Procedure..                0.3421  1  3.4442 0.070850 .
Guide:Surgeon.Experience   0.0001  1  0.0008 0.977761
Guide:Procedure..          0.2624  1  2.6421 0.111920
Surgeon.Experience:Procedure..      0.0207  1  0.2088 0.650150
Guide:Surgeon.Experience:Procedure.. 0.0851  1  0.8566 0.360255
Residuals                  3.9731 40
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> Anova(Result.EdgeOffset.3,type="III")
Anova Table (Type III tests)

Response: Maximum.Edge.Offset
                          Sum Sq Df F value    Pr(>F)
(Intercept)                2.2649  1 22.8023 2.417e-05 ***
Guide                      0.6602  1  6.6462   0.01373 *
Surgeon.Experience         0.0168  1  0.1696   0.68267
Procedure..                0.3874  1  3.9003   0.05521 .
Guide:Surgeon.Experience   0.0728  1  0.7333   0.39692
Guide:Procedure..          0.3232  1  3.2537   0.07880 .
Surgeon.Experience:Procedure..      0.0109  1  0.1098   0.74216
Guide:Surgeon.Experience:Procedure.. 0.0851  1  0.8566   0.36025
Residuals                  3.9731 40
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
```

```
> dfEdgeOffsetData=data.frame(EdgeOffsetData,row.names=NULL)
>
        dfEdgeOffsetData.Proc1AND2=dfEdgeOffsetData[with(dfEdgeOffsetData,
        which(dfEdgeOffsetData$Procedure..=="1"|dfEdgeOffsetData$Procedure..
        =="2")),]
>
        Result.EdgeOffset.4=lm(Maximum.Edge.Offset~Guide*Surgeon.Experienc
        e*Procedure..,data=dfEdgeOffsetData.Proc1AND2)
> anova(Result.EdgeOffset.4)
Analysis of Variance Table

Response: Maximum.Edge.Offset
                            Df  Sum Sq Mean Sq F value  Pr(>F)
Guide                        1 0.78436 0.78436  5.2451 0.03593 *
Surgeon.Experience           1 0.00204 0.00204  0.0136 0.90848
Procedure..                  1 0.00896 0.00896  0.0599 0.80973
Guide:Surgeon.Experience     1 0.04737 0.04737  0.3168 0.58136
Guide:Procedure..            1 0.55396 0.55396  3.7044 0.07224 .
Surgeon.Experience:Procedure..       1 0.00935 0.00935  0.0625 0.80572
Guide:Surgeon.Experience:Procedure..  1 0.05814 0.05814  0.3888 0.54173
Residuals                   16 2.39266 0.14954
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> summary(Result.EdgeOffset.4)

Call:
lm(formula = Maximum.Edge.Offset ~ Guide * Surgeon.Experience *
    Procedure.., data = dfEdgeOffsetData.Proc1AND2)

Residuals:
    Min      1Q  Median      3Q     Max
-0.5637 -0.1507 -0.0175  0.1443  0.7408

Coefficients:
                                                Estimate Std. Error t value Pr(>|t|)
(Intercept)                                       1.1171     0.4992   2.238   0.0398 *
GuideYes                                         -1.0667     0.7060  -1.511   0.1503
Surgeon.ExperienceInexperienced                   0.3433     0.7060   0.486
        0.6334
Procedure..                                      -0.2046     0.3157  -0.648   0.5262
GuideYes:Surgeon.ExperienceInexperienced         -0.4129     0.9985  -0.414
        0.6847
GuideYes:Procedure..                              0.4108     0.4465   0.920   0.3712
```

```
Surgeon.ExperienceInexperienced:Procedure..          -0.2758     0.4465  -0.618
        0.5454
GuideYes:Surgeon.ExperienceInexperienced:Procedure..   0.3938     0.6315
        0.624   0.5417
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1

Residual standard error: 0.3867 on 16 degrees of freedom
Multiple R-squared:  0.3796,         Adjusted R-squared:  0.1082
F-statistic: 1.399 on 7 and 16 DF,  p-value: 0.2721

> library(car)
> Anova(Result.EdgeOffset.4,type="II")
Anova Table (Type II tests)

Response: Maximum.Edge.Offset
                            Sum Sq Df F value  Pr(>F)
Guide                       0.78436  1  5.2451 0.03593 *
Surgeon.Experience                0.00204  1  0.0136 0.90848
Procedure..                 0.00896  1  0.0599 0.80973
Guide:Surgeon.Experience          0.04737  1  0.3168 0.58136
Guide:Procedure..                 0.55396  1  3.7044 0.07224 .
Surgeon.Experience:Procedure..       0.00935  1  0.0625 0.80572
Guide:Surgeon.Experience:Procedure.. 0.05814  1  0.3888 0.54173
Residuals                   2.39266 16
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
> Anova(Result.EdgeOffset.4,type="III")
Anova Table (Type III tests)

Response: Maximum.Edge.Offset
                            Sum Sq Df F value  Pr(>F)
(Intercept)                 0.74873  1  5.0068 0.03983 *
Guide                       0.34133  1  2.2825 0.15033
Surgeon.Experience                0.03536  1  0.2365 0.63335
Procedure..                 0.06278  1  0.4198 0.52621
Guide:Surgeon.Experience          0.02558  1  0.1710 0.68469
Guide:Procedure..                 0.12659  1  0.8465 0.37121
Surgeon.Experience:Procedure..       0.05706  1  0.3816 0.54545
Guide:Surgeon.Experience:Procedure.. 0.05814  1  0.3888 0.54173
Residuals                   2.39266 16
---
Signif. codes:  0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1
```