Surgical Navigation for Articular Cartilage Repair: Motivation, Development, and Validation

Thesis

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By

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Abstract

The natural history of focal cartilage defects is not entirely understood, but defect size is believed to be a critical factor in the success of surgical repair procedures. Clinical repair algorithms have identified 2 cm$^2$ as the threshold area between marrow-stimulation techniques and cartilage restoration techniques, although there is little evidence to support this threshold. Studies examining this threshold size have used circular defects, while narrow, elongated defects are more clinically relevant. Furthermore, our clinical experience suggests that two defects of approximately equal size, but oriented differently, will exhibit different repair outcomes.

We first sought to identify how cartilage defect area, location, and orientation influence subchondral bone contact within oval-shaped defects. We used cylindrical punches to create bilateral oval defects with areas between 0.73 cm$^2$ and 2.88 cm$^2$ on the femoral condyles of twelve bovine knees. Four defect groups were examined, each comprised of defects in one of two orientations, anterior-posterior or medial-lateral, on the medial or the lateral femoral condyle. We statically loaded fully-extended joints in a uniaxial testing system, while thin-film sensors recorded joint contact, and we calculated the area within the defect demonstrating subchondral bone contact. We then performed a three-way analysis of variance (ANOVA) and determined that defect area, location, and
orientation each had a significant effect on subchondral bone contact, and significant interactions were found between defect area and both location and orientation. We also determined that each defect group exhibited a different area threshold where significant contact first occurred. The findings of this study challenge current clinical algorithms that use defect area alone to dictate one cartilage surgery over another.

Cartilage defect size, location, orientation may impact the treatment of focal cartilage defects, but there are no methods to accurately measure these quantities intra-operatively. To address these limitations, we developed an image-free surgical navigation system capable of accurately measuring defect area, shape, orientation, and condyle curvature intra-operatively and arthroscopically. Hardware was also developed to provide a less-invasive means of attaching optical reference frames to bone.

We developed test methods to evaluate the accuracy and repeatability of the manual measurements and the navigation system. Seven volunteers measured the area and orientation of various shapes and the curvature of multiple surfaces, first using a common arthroscopic probe tip as a reference length, and then using the navigation system. Measurement error of the navigation system was smaller than that of manual measurements for all tasks and was less variable as well. The mean error for navigated area measurements was -0.36 ± 0.37 cm$^2$, compared to -1.13 ± 1.50 cm$^2$ for manual measurements. The mean error for navigated radius of curvature measurements was
-0.48 ± 6.07 mm, compared to 18.00 ± 42.72 mm for manual measurements. The mean error for navigated measurements of orientation was 2.69° ± 2.76°.

This navigation system will be a valuable research tool to elucidate how various defect-specific factors influence cartilage repair success. In the future, the system will allow surgeons to accurately characterize cartilage defects, with the goal of ultimately improving clinical outcomes.
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CHAPTER 1:

INTRODUCTION

1.1 Articular Cartilage Defects and Osteoarthritis Progression

The knee is arguably the most mechanically demanding of the synovial joints in humans due to the large compressive forces and complex motion between the femur and tibia. Experimental and mathematical studies of in vivo knee mechanics during various activities have revealed that forces in the knee can regularly reach 2.5 times body weight, and during physical activity these forces can be upwards of 4 times body weight (Komistek et al., 2005). Articular cartilage, the soft tissue covering the articulating ends of the distal femur and proximal tibia, provides a load bearing surface, force distribution, and a lubricated surface for articulation while experiencing virtually no wear when healthy (Setton et al., 1999).

Though articular cartilage is durable and has extremely good compressive properties, degeneration of the tissue often occurs in the form of full- or partial-thickness cartilage defects, essentially holes in the cartilage, which are considered to be the hallmark of degenerative osteoarthritis (Garnero et al., 2002). It is estimated that 32 to 37 million Americans suffer from articular cartilage defects due to osteoarthritis (Steadman,
and that 25 – 37% of people over 50 years of age suffer from osteoarthritis (Peat et al., 2001). In addition, trauma is a source of articular cartilage defects that occur most often in the knees of young and active people. Focal defects can result from high-loading and torsion impacts (Hinton et al., 2002) and often occur following injuries which shift loading patterns or cause misalignment of the tibiofemoral joint, such as ligament or meniscus tears (Mandelbaum et al., 1998; Hjelle et al., 2002).

The natural history of such focal defects is not entirely understood (Cole et al., 2009), but it is believed that these defects progress to degenerative osteoarthritis if left untreated. Progression of a defect to osteoarthritis is believed to be multi-factorial, and characteristics of the defects themselves may contribute, in addition to patient-specific factors. There are also a number of proposed mechanisms for defect progression to osteoarthritis and a significant amount of research has attempted to elucidate the source of osteoarthritis progression by investigating the mechanical influence on articular cartilage defect progression and healing response.

Biomechanical testing in animal models has provided insight into the progression of cartilage defects. Defect size has been shown to influence the potential for tissue regeneration in cartilage defects, as large defects fail to repair completely and smaller defects heal with cartilage-like tissue (Convery et al., 1972). Increased stress gradients around defect rims are one proposed cause of poor healing. Elevated contact stress gradients occur at the rim of larger defects, possible inhibiting normal repair (Brown et al., 1991).
Computational studies have predicted that the high strain and fluid flow at the articular surface generates fibrous tissue formation and inhibits chondrogenesis, causing osteoarthritis progression (Shapiro, 1993). Furthermore, finite element models have predicted greater amounts of fibrous tissue formation as the size of the defect is increased, leading to strains resulting in significant cell death (Kelly & Prendergast, 2005). Elevated axial, lateral, and shear strain in tissue adjacent to a defect suggest shear strain as a mechanism for cartilage deterioration.

Results of clinical studies have suggested that osteoarthritis should be considered as a disease to the entire osteochondral unit, rather than just to the cartilage (Henderson, 2009). Rather than being dominantly a deterioration articular cartilage, osteoarthritis could be initiated by the thickening of the subchondral bone and subsequent thinning of the overlying cartilage, which is then more susceptible to damage and further degeneration (Minas et al., 2009). Disruption of one element of the osteochondral unit may cause changes in the other (Henderson, 2009). Although a significant amount of research has elucidated possible factors leading to the progression of focal cartilage defects to osteoarthritis, the exact cause is still unknown.

1.2 Repair Techniques

A number of surgical procedures have developed that attempt to restore function and mitigate pain resulting from osteoarthritis or focal cartilage defects. Procedures range from palliative, in which pain relief is the main objective, to restorative, in which the goal is to restore function completely (Figure 1.1) (Lewis et al., 2006).
Lavage and debridement are minor arthroscopic procedures that simply remove fragmented cartilage within the joint and clean up fibrillated cartilage, respectively, which can provide effective pain relief (Gill et al., 2006; Lewis et al., 2006). These procedures provide an initial solution but are not generally pursued as long term solutions or for patients desiring an active lifestyle following the surgery (Lewis et al., 2006).

While lavage and debridement simply remove damaged cartilage from the injured knee, procedures have been developed that utilize a substitution replacement approach. The most common technique is osteochondral autograft transplantation, in which a cylindrical plug is removed from a healthy, minimally weight-bearing region of the patient knee and is then placed in the defect region where a hole of a slightly smaller
diameter has been created (Lewis et al., 2006). Osteochondral allograft transplantation is a similar procedure, in which the grafts are harvested from a cadaver knee of a comparable size to that of the patient and in a region of similar curvature. In a successful osteochondral grafting procedure, the graft will be completely integrated with the adjacent bone and cartilage.

Marrow-stimulation techniques attempt to create new cartilage to fill in a defect. The most common of these techniques is microfracture surgery (Figure 1.2), which was developed by Steadman in the 1980s (Steadman, 2001). The procedure attempts to take advantage of the pluripotency of mesenchymal stem cells (MSCs), which naturally reside within the marrow of the femur, to gradually regenerate new articular cartilage in a defect. An arthroscopic awl is used manually to create multiple holes in the bone surface (Steadman, 2001), which serves as both the source of pre-cartilage material from within the subchondral bone as well as a rough surface that leads to better adherence of this material (Gill et al., 2006). First, blood and marrow elements flow into the defect and fill it, and then mesenchymal stem cells within the marrow elements differentiate to form a reparative superclot. Finally, the repair phase is initiated and a combination of hyaline cartilage and fibrocartilage form.
Figure 1.2: Microfracture surgery procedure
Use of a curette to create a stable rim of healthy adjacent cartilage. (B) Use of an arthroscopic awl to penetrate subchondral bone and proper spacing of holes during the microfracture procedure. (C) Defect filled with marrow elements following microfracture surgery. From (Mithoefer et al., 2005).

The autologous chondrocyte implantation (ACI) procedure (Figure 1.3) is similar to microfracture surgery in that the ultimate goal is to mechanically influence cells within the defect to generate new, healthy hyaline articular cartilage. However, the two-stage surgical procedure is different than that of the single-stage microfracture surgical procedure. A cartilage biopsy is performed during the first stage, with a sample being taken from a non-weight bearing region of the knee, which is then cultured and chondrocytes isolated (Riegger-Krugh et al., 2008). The second phase occurs weeks later, during which time a periosteal flap or an artificial tissue membrane slightly larger than the size of the defect is sutured over the defect. This serves a means of containment for the chondrocytes, which are subsequently injected into the defect.
Figure 1.3: Autologous chondrocyte implantation procedure
This diagram shows explains the sequence of events in ACI, from biopsy procurement, cultivation of cells, periosteal flap procurement and suturing, and injection of cells. From (Mandelbaum et al., 1998).

1.3 Clinical Algorithms and Defect Diagnosis

Clinical algorithms have been developed to dictate which surgical procedure should be used given patient- and defect-specific characteristics. Although several factors must be considered when deciding upon the most appropriate treatment for articular cartilage defects of the knee and halt their progression, defect size is a critical element. Most current algorithms use 2 cm² as the threshold between the simpler marrow-stimulation techniques and more involved cartilage restoration techniques (W.N. Scott, 2005; Alford & Cole, 2005; Cain & Clancy, 2001; Clarke et al., 2005; Farr et al., 2004; JM. Scopp & Mandelbaum, 2004). Defects smaller than 2 cm² are generally
treated with microfracture or osteochondral autografting, while larger defects are treated with ACI or osteochondral allografting (Figure 1.4). Although this critical defect size has become widely accepted clinically, there is little biomechanical or clinical evidence to support its use.

**Figure 1.4: Clinical algorithm for focal cartilage defects on the femoral condyle**

The decision to choose ACI or osteochondral allograft over microfracture or osteochondral autograft is based primarily on defect size, with 2 cm² as the threshold (W.N. Scott, 2005). Similar clinical algorithms have been presented by others (Alford & Cole, 2005; Cain & Clancy, 2001; Clarke et al., 2005; Farr et al., 2004; JM. Scopp & Mandelbaum, 2004; W.N. Scott, 2005).

Biomechanical studies and clinicians have questioned the use of 2 cm² as a threshold area. Guettler et al. (2004) developed an experimental biomechanical model
using cadaveric knees and varied cartilage defect size, while measuring contact stress and load redistribution to adjacent cartilage in the tibiofemoral joint. Circular defects of 8 to 20 mm (in increments of 2 mm) were created and digital thin-film pressure sensors recorded contact stress during static loading. As defect diameter increased, peak contact stress remained consistent when considering defects 10 mm and larger. The authors suggested that the finding of fairly consistent peak stress values as defect size increased would have been due to cartilage deformation and recruitment of adjacent cartilage, which would decrease the peak contact stress, and suggested that a size threshold of 10 mm (0.79 cm²), based on biomechanical data, may be a useful to help guide clinical decision making.

A finite element model based on MRI data was used to investigate the effect of size and location of osteochondral defects in arthritis (Peña et al., 2007), showing that in defects larger than 1 cm² the contact stress around the rim strongly increased. It was suggested that increased compressive stress in large defects indicated a mechanical overloading effect that would lead to continued degeneration. This finding agreed with a 10 mm (0.78 cm²) threshold, based on defect rim stress, found in a biomechanical cadaver study (Guettler et al., 2004). However, this suggested threshold contradicts a recent trend to allow the use of microfracture in defects as large as 4 cm², based on studies showing good clinical outcomes (Knutsen et al., 2007).

In a study examining subchondral bone contact within circular defects in bovine knees, we found an overall threshold of 2 cm², but discovered consistently different subchondral bone contact between defects occurring on medial and lateral condyles
We noted that different sagittal plane and frontal plane radii of curvature between the medial and lateral femoral condyles and tibial plateaus may create different contact mechanics. Our study found that the largest amount of contact occurred in the lateral compartment, which exhibits the worst tibiofemoral conformity, the difference in contacting surface radii (Koo & Andriacchi, 2007). We concluded that defect location may be an important factor in clinical decision making, which may be due to the differences in curvature in the tibiofemoral joint.

Tibiofemoral conformity is dependant not only on location (i.e. medial or lateral compartment), but is also a function of direction (Koo & Andriacchi, 2007). The curvature in the frontal plane is different than that of the sagittal plane in both compartments, with the largest disparity occurring in the lateral compartment, which exhibits convex-concave conformity in the frontal plane and convex-convex conformity in the sagittal plane. The idea that the location dependency of subchondral bone contact in circular defects is due to curvature differences suggests that the orientation of non-circular defects might also contribute to subchondral bone contact trends. Since clinical experience has shown that defect shape often resembles that of an oval rather than a circle, we feel that there is a lack of data examining possible influence of shape on defect progression. The combination of complex tibiofemoral conformity and irregular, non-circular defects brings into question the use of defect area alone to dictate cartilage repair.

With size-based algorithms dominating the clinical landscape, measurement of a defect is an important and necessary task. Currently, this is accomplished either by attempting to interpret radiographic images prior to surgery, or during an arthroscopic
diagnostic examination. Both methods have shown to provide inaccurate estimates of defect size (Erggelet et al., 2008; Oakley et al., 2003; Diaz & Albright, 2008).

The nature of radiographic images, which are compilations of serial, two-dimensional cross-sectional images representing a three-dimensional body, lends well to measurements of cartilage thickness and studies have presented extremely good results in doing so (Graichen et al., 2005; Marlovits et al., 2008). However, because these images represent slices through the cross-section of a defect, the actual size and shape of a defect is difficult to ascertain. Graichen et al. (2005) observed an overestimation of the true size of artificial cartilage defects in the human knee using MRI quantification techniques. Interestingly, error in area estimates decreased from 42% in 3 mm defects to 4% in 8 mm defects, revealing a major limitation in the technology, since the area of a defect is what currently dictates cartilage repair.

In the presence of a quasi-circular defect, a measurement of the defect width can give a reasonable estimate of the defect area by simply inserting the diameter into the equation of a circle. However, we know that circular defects are rare. Furthermore, when measuring the defect width from a radiographic image, one must assume that location of the image slice corresponds with the location of the maximum width, which may not be the case. Studies have shown that three-dimensional spatial mapping models derived from MRI images can allow accurate measurement of defect size (McGibbon & Trahan, 2003), but such techniques are computationally expensive and not widely adopted clinically.
Intraoperatively, two methods are most commonly employed to take measurements arthroscopically. Both methods generally estimate the size of the defect by measuring the length and width. Using the tip of probe as a sizing tool (Figure 1.5a), surgeons can estimate the defect area by taking measurements parallel to the defect margins (Diaz & Albright, 2008; Erggelet et al., 2008; Oakley et al., 2002). There is inherent error in this method of measurement, and one study showed poor results, with 29% error in area measurements and intra-observer and inter-observer errors of ±11% and ±16%, respectively (Oakley et al., 2003). Another method of measurement makes use of graduation lines that are present on a number of arthroscopic tools (Figure 1.5b) (Erggelet et al., 2008). Although no studies have examined it, one can assume that this method would result in comparable accuracy and repeatability to that of other methods.

Figure 1.5: Current arthroscopic defect measurement techniques
(a) Arthroscopic images depicting the measurement of a cartilage defect using a probe tip of known dimension as reference. From (Jackson, 2007). (b) Arthroscopic image depicting the measurement of a cartilage defect using a graduated tool. From (Erggelet et al., 2008).
There is inherent difficulty associated with both of these measurement techniques due to limited space, the inability to maneuver a tool in the vicinity of a defect, and the challenge of defect visibility. Tool orientation must be either parallel to or perpendicular to the width being measured, which may be difficult or impossible in some situations and the tool often cannot be laid flat on cartilage surfaces, potentially leading to an additional source of error (Oakley et al., 2002). In addition, all measurements must be made while viewing the defect and tool in an arthroscopic monitor, leading to further inaccuracy. Often only a part of the cartilage surface can be viewed in a single arthroscopic image and defects on the trochlear groove provide further challenges (Oakley et al., 2003). Finally, measurement of non-circular defects can be particularly difficult. Medical textbooks have gone so far as to give the equation for the area of an ellipse based on the two axis dimensions, but concede that this leads to inaccurate estimates (Erggelet et al., 2008). Without question, area cannot be easily calculated by estimating the width of the defect alone, and performing multiple measurements by visual inspection does not necessarily ensure an accurate estimate of defect area.

1.4 Surgical Navigation Systems

The use of computers in orthopaedic surgery provides the ability to perform procedures more accurately and more repeatably. Computer assisted surgical systems can be classified as active robotic, semi-active robotic, or passive. The most common example of a passive system is the surgical navigation system, which allows for the spatial monitoring of the femur and tibia through use of an optical tracking system.
(Siston et al., 2007). Position of tools instrumented with optical reference frames can also be monitored, and presented in relation to anatomical structures (Diaz & Albright, 2008).

Most research in surgical navigation for orthopaedics has been focused on improving alignment of the components during total knee arthroplasty and total hip arthroplasty. Using navigated tools and tracking the motion of the femur and tibia during surgery allows for the real-time measurement of relative position and orientation of bones. In traditional surgery these relationships must be visually estimated by the surgeon, a task that has been shown to produce large inaccuracies and poor repeatability in alignment (Siston et al., 2007).

Although similar improvements in measurement accuracy, and subsequently in surgical outcome, would presumably be possible in the field of cartilage repair surgery, the use of surgical navigation systems to improve cartilage repair procedures has not been widely researched, with only a few studies having been published on the subject. The first study examining the use of surgical navigation for the sizing of cartilage defects (Diaz et al., 2005) used a commercially available system, OrthoPilot from Aesculap, with a dedicated cartilage defect-managing module. In performing area measurements of two defects, one circular and one comprised of three tangentially-connected circles (Figure 1.6), the authors reported an overall mean error of less than 10% for three participants, a substantial improvement to the 29% error reported using arthroscopy alone (Oakley et al., 2003).
(1) Defects labeled 1 and 2, created in sawbones for this pilot study, were measured. (2) Commercially available software used for defect measurement and data collection.

A different study using the OrthoPilot navigation system exhibited the ability to measure cartilage defect sizes of different geometries, which could then be used to prepare tissue engineering scaffolds of the proper size during ACI procedures (Angele & Fritz, 2006). Three defect shapes, a circle, a square, and a mushroom shape, were digitized with a navigated stylus and displayed as connected points on a monitor. A live arthroscopic camera image of a “transfer platform,” consisting of a sheet of paper to simulate a graft, was then placed in the background of the navigation screen. As the participant viewed his own hand in the monitor, he attempted to trace the recorded defect shape using on the sheet of paper placed in front of him using a normal pen (Figure 1.7b). Proper magnification of the arthroscopic image was achieved by overlapping four red
dots on the OrthoPilot navigation screen with four corresponding dots on the transfer platform (Figure 1.7b). The authors reported accuracies of ±1 mm when comparing defect geometry obtained with the navigated system and the exactly defined defect sizes, both of which were measured with a ruler following the experiment. The navigation system was used only as a way to map the defect outline during the tracing task, and not for any calculations or measurements.

Figure 1.7: Experimental setup of study by Angele and Fritz (2006)
(a) Drawing defect outline on paper while arthroscopic camera records. (b) OrthoPilot monitor showing digitized defect outline overlaid on arthroscopic camera image. (c) Transfer of defect shape from navigation system to sheet of paper representing ACI graft.
The major benefit of surgical navigation is that accurate measurements can be obtained using simple user inputs to a software program. During surgical navigation of total joint replacements, algorithms create anatomical coordinate systems that can be followed in real-time and used to guide surgical cuts. This can reduce error in alignment, which may reduce the chance of suboptimal outcomes (Siston et al., 2007). In similar fashion, we believe that inaccurate measurement of cartilage defect area, orientation, and location may influence repair success. In addition, results from our previous studies also suggest that the three-dimensional curvature of the femur and tibia may influence the degree of contact between exposed subchondral bone within a defect and the opposing cartilage surface, and currently measurements of such curvature is not possible. Surgical navigation technology provides the means to perform these measurements intra-operatively.

1.5 Focus of Thesis

This thesis is focused on the motivation, development, and validation of a surgical navigation system used to intra-operatively diagnose articular cartilage defects in the knee. The motivation for the system was a study in which we examined effect of defect shape, orientation, and location on subchondral bone contact during static loading of bovine tibiofemoral joints. We then developed a MATLAB-based, image-free surgical navigation system that enables a surgeon to intra-operatively measure various aspects of a defect region, namely those aspects that we found to be important from our previous work. A validation of the system was then performed. This work involves a combination...
of experimental orthopaedic biomechanics, software and user interface engineering, and mechanical design.

1.6 Significance of Research

We have presented the first experimental research examining the effect of articular cartilage defect shape on the mechanical environment in and around a defect, and found that defect area, orientation, and location may be important factors in cartilage defect healing response. Though results from our bovine study may not be directly applicable to cartilage repair in humans, they elucidate possible factors that may influence threshold areas where contact occurs, and provide the motivation for future studies.

We have also developed the only cartilage defect surgical navigation system that is not affiliated with a medical device company, and only the second such system, to our knowledge, regardless of affiliation. This is also the only system with the capability to intra-operatively and arthroscopically measure the curvature of the knee, which is an attribute of the knee that we believe is influential in defect healing. The navigation system can be used as a research tool for various purposes, namely to investigate the effect of defect size, shape, orientation, and condyle curvature on cartilage defect repair success. It also represents a first attempt at creating a diagnostic tool for clinical settings. Furthermore, by modifying a commercially available intraosseous needle, a novel method of quickly attaching reference frames to bone was developed, which allows surgical navigation tasks to be performed during arthroscopic surgeries when access to exposed
bone is limited. The software and user interface were created entirely in the MATLAB programming language, an almost universal programming language in engineering and in biomechanics research, which allows the program to be modified and adapted by others as additional features are required.

1.7 Overview of Thesis

This thesis contains five chapters. Chapter 2 exists as a self-contained journal manuscript that describes a study examining the effect of defect shape on subchondral bone contact, an extension of previous research on the effect of size on subchondral bone contact, an extension of the author’s previous research on the effect of size on subchondral bone contact. Chapter 3 presents the design and fabrication of a surgical navigation system for characterizing articular cartilage defects intra-operatively. Chapter 4 presents the results and analysis following validation testing of the device. A conclusion is presented in Chapter 5.
CHAPTER 2:
DEFECT SHAPE STUDY
SHORTCOMINGS OF A CIRCULAR MODEL FOR DICTATING ARTICULAR CARTILAGE REPAIR: EFFECTS OF DEFECT SHAPE, LOCATION, AND ORIENTATION ON SUBCHONDRAL BONE CONTACT

2.1 Abstract

Focal, full thickness articular cartilage defects are a significant cause of immobility and pain in patients. Though the natural history of such defects is not entirely understood, it is believed that defects progress to osteoarthritis by biomechanical overload of the defect rim and subchondral bone thickening. Defect-specific factors, such as defect size, condyle curvature, and location, may influence progression to osteoarthritis. Many reparative clinical solutions exist, and the accepted threshold between simpler marrow-stimulation techniques and more complex cartilage restoration techniques is a defect area of 2 cm$^2$, which is based on a circular defect model. Clinically, however, circular defects are rare and it is questionable whether a 2 cm$^2$ threshold is appropriate for treating all defect shapes. Therefore, the purpose of this study was to identify how femoral condyle cartilage defect size, location, and orientation
influences subchondral bone contact within the defect for oval-shaped defects. We also hypothesized that, for oval defects of a given orientation and location, significant subchondral bone contact would occur in defects smaller than 2 cm$^2$.

Oval-shaped defects with areas between 0.73 cm$^2$ and 2.88 cm$^2$ were created in twelve bovine femurs. Knees were statically loaded in full extension while thin-film sensors recorded joint contact. A custom MATLAB program calculated the area within the defect demonstrating subchondral bone contact.

A three-way analysis of variance (ANOVA) showed that defect area, defect location, and defect orientation each had a significant effect on subchondral bone contact ($p<0.001$ for each group) and significant interactions were found between defect area and both location and orientation. Defects oriented with the primary axis in the medial-lateral (ML) direction defects resulted in significantly higher subchondral bone contact than that of defects oriented in the anterior-posterior (AP) direction. Significantly higher subchondral bone contact occurred on the lateral condyle compared to the medial condyle, and higher contact occurred in ML defects than in AP defects, possibly due to differences in tibiofemoral conformity throughout the joint. Contact was never significantly different from zero for AP defects on the medial condyle, and thresholds for the three other groups occurred at different defect sizes. The findings of this study suggest that the use of defect area alone to dictate one cartilage surgery over another may be insufficient, and that effects of other defect factors, such as defect orientation and location, may influence clinical success.
2.2 Introduction

The natural history of traumatic, focal cartilage defects in the knee is not completely understood (Cole et al., 2009). Most clinicians agree that unrepaired, full-thickness cartilage defects progress to osteoarthritis by biomechanical overload of the defect rim with subsequent adjacent cartilage degeneration, subchondral bone changes, and opposing articular surface overload (Minas & Nehrer, 1997). Progression of a cartilage defect to osteoarthritis is multifactorial, and characteristics of the defects themselves, such as their size, location, depth, number, and geometry may contribute (Cole et al., 2009; Minas, 1999; Minas & Nehrer, 1997).

Biomechanical testing in animal models has provided insight into the progression of cartilage and osteochondral defects. Rim stress concentration can be elevated in circular defects as small as 0.03 cm² in smaller sized knees (Blevins et al., 1998; Brown et al., 1991) and in circular defects as small as 0.78 cm² in adult human knees (Guettler et al., 2004). Other studies have shown that, over time, there is an increase in defect size, with early flattening and deformation of the defect edges and collapse of the surrounding subchondral bone and osteoarthritic changes (Convery et al., 1972; Jackson et al., 2001; Lefkoe et al., 1993). Clinical studies suggest that as defect size increases, more surface area of exposed subchondral bone is pressurized and a greater area of bone undergoes sclerotic changes, possibly influencing the success of cartilage reparative techniques (Minas & Nehrer, 1997; Minas et al., 2009).

Although multiple factors must be considered when deciding upon the most appropriate treatment, defect size has become the critical element (Cole et al., 2009).
Most current algorithms use 2 cm$^2$ as the threshold between the simpler marrow-stimulation techniques and more involved cartilage restoration techniques (Alford & Cole, 2005; Cain & Clancy, 2001; Clarke et al., 2005; Cole et al., 2009; Farr et al., 2004; JM. Scopp & Mandelbaum, 2004; W.N. Scott, 2005). There is, however, no evidence to show that defect area alone is the only factor that contributes to clinical success. Algorithms prescribe different treatment pathways for femoral and patellofemoral defects (Cole et al., 2009), but no distinction is made between suggested treatment paths for medial and lateral femoral condyle defects.

Previous studies examining the influence of defect size on defect healing in animals or on mechanical conditions in the knee have used circular defect models (Brockmeier et al., 2009; Brown et al., 1991; Convery et al., 1972; Guettler et al., 2004; Jackson et al., 2001; Peña et al., 2007). However, cartilage defects are generally not circular in shape, as elongated defects are more common and possibly more relevant clinically. Furthermore, our experience has been that two defects of approximately equal size, but oriented differently on the femoral condyle, will usually exhibit different repair outcomes.

To our knowledge, no research has investigated how cartilage defect shape, location, and orientation might influence contact distributions within the knee. Therefore, the purpose of this study was to identify how femoral condyle cartilage defect size, location, and orientation influence subchondral bone contact within the defect for oval-shaped defects in bovine knees. We further hypothesized that, different
combinations of orientation and location would lead to different defect size thresholds where subchondral bone contact would occur.

2.3 Methods

Twelve fresh-frozen bovine knees were obtained for this study. Specimens were received fresh from a butcher and then immediately frozen. Prior to use, they were thawed at room temperature for between 8 and 12 hours and, once thawed, all skin and subcutaneous tissue were removed. The menisci were removed at their respective anterior and posterior horn insertions, while the cruciate (ACL, PCL) and collateral (MCL, LCL) ligaments were kept intact. All remaining soft tissue was dissected free from the distal femur and proximal tibia. All specimens were carefully inspected to ensure no osteoarthritis was present, and knees with cartilage softening, fissuring, fibrillations, or full-thickness defects were excluded.

Each knee was then positioned in full extension within a fabricated stainless steel frame and locked in a uniaxial material testing system (MTS-858 Bionix Test System, Eden Prairie, Minnesota, USA) with the femur rigidly fixed to a load cell (10 kN capacity) (Figure 2.1). Eight cortices of fixation were obtained on both the distal femur and proximal tibia using four 5-mm diameter high-speed steel drill bits placed parallel to the joint line. Coronal plane alignment was adjusted as necessary to prevent any eccentric valgus or varus loading conditions.
Figure 2.1: Bovine knee positioned in full extension with sensors in place
During static loading, thin-film sensors recorded tibiofemoral contact pressure around and within the defect. We then calculated subchondral bone contact area from the contact pressure plots.

Pressure measurements were obtained with digital electronic pressure sensors (I-Scan, version 5.8x, Tekscan, Boston, Massachusetts, USA) placed between the articulating surfaces of the femoral condyles and tibial plateau (Figure 2.1). Prior to testing, the sensors were calibrated according to the manufacturer’s instructions by applying a 1,000 N load. Next, to ensure equal distribution of applied load, a zero load measurement was obtained when contact was first visualized simultaneously in the medial and lateral compartments. All knees and sensors were pre-conditioned prior to
each testing sequence procedure and zeroed prior to load testing for each individual defect size. Sensors were removed from the joint and a 1,000 N load was applied to the knee, during which time the femoral condyle contact areas were mapped using a surgical marker. These areas were bisected with use of an electronic digital caliper to locate the center of the intended defect.

To evaluate the effect of defect shape and orientation on subchondral bone contact, knees were divided into four test groups: (1) defects oriented in the medial-lateral direction (ML) on the lateral condyle, (2) defects oriented in the medial-lateral direction (ML) on the medial condyle, (3) defects oriented in the anterior-posterior direction (AP) on the lateral condyle, and (4) defects oriented in the anterior-posterior direction (AP) on the medial condyle. Defects with areas between 0.73 cm$^2$ and 2.99 cm$^2$ were created with a set of cylindrical coring punches with diameters between 6.4 mm (0.25 in) and 12.7 mm (0.5 in).
After identifying the intended defect area, the femoral fixation apparatus was removed from the MTS to allow access to the articular surface, and a 0.73 cm$^2$ defect was created with the 6.4-mm punch. To create the oval defects, two tangentially connected circular defects were first created and then an incision was made to create the defect edges parallel to the long axis. The oval defect was thus characterized by a major axis that was equal in length to twice the minor axis. The subchondral bone was not penetrated with the device. Any remaining cartilage was removed with a curette to ensure a vertical perpendicular defect rim (Figure 2.2). After creating the defect, we then re-mounted the specimen on the MTS and reinserted the Tekscan K-Scan sensors into the joint to record the contact within and around the defect. The knee was preloaded to 20 N and then loaded at a rate of 20 N/s to 1,000 N, where it was held for 30 seconds while

Figure 2.2: AP and ML oval defects
(a) Oval defect oriented in anterior-posterior (AP) direction. (b) Oval defect oriented in medial-lateral (ML) direction.
contact readings were recorded. This load was selected to approximate one quarter of the static body weight of a young cow, as the bovine specimens used in the study were believed to be not fully mature. After the load returned to zero, the specimen was unlocked from the MTS. We repeated this procedure and enlarged the defect until reaching a maximum size of 2.88 cm$^2$. A custom MATLAB program was created specifically for use in this study to calculate the area within the surgically-created defect based on the Tekscan I-SCAN software contact data (Figure 2.3).

**Figure 2.3: subchondral bone contact area plots of AP and ML defects**
(a) Contact pressure plot of AP defect demonstrating non-significant subchondral bone contact. Colors correspond to the level of contact pressure, with black representing zero contact. (b) Plot of area within AP defect demonstrating subchondral bone contact. Minimal contact was observed at one point. (c) Contact pressure plot of ML defect demonstrating significant subchondral bone contact. Colors correspond to the level of contact pressure, with black representing zero contact. (d) Plot of area within the ML defect demonstrating subchondral bone contact. Roughly one third of the defect is contacted in this case, as illustrated by the shaded region.
Following testing, we took measurements of the medial and lateral condyle radii of curvature of two bovine specimens using an optical tracking system and custom software. The average medial and lateral condyle radii of curvature in the frontal plane were 28 mm and 20 mm, respectively. The average medial and lateral condyle radii of curvature in the sagittal plane were 47 mm and 49 mm, respectively.

Statistical analysis was first performed to examine the effects defect area, orientation, and condyle location on subchondral bone contact using a three-way analysis of variance (ANOVA) model, including all main effects and two-factor interactions. For post-hoc analyses, we performed multiple one-sample t-tests with Bonferroni correction for each defect group at each defect size to determine when statistically significant contact occurred; this level of statistically significant contact revealed when contact resulting from defects at one size was consistently non-zero, such that we could declare, with 95% confidence, that the contact was not a result of pure chance or experimental error. We then considered the defect size at which significant contact occurred to be the threshold area for that defect group, provided that defects larger than the threshold area also exhibited statistically significant contact. All data analysis was performed with SPSS software, Version 16.0.1 (SPSS Inc., Chicago, IL).

2.4 Results

A three-way ANOVA showed that defect area, defect location, and defect orientation each had a significant effect on subchondral bone contact (p<0.001 for each factor). Additionally, a significant interaction was found between defect area and
location (p=0.001), indicating that the effect of defect area on subchondral bone contact for lateral defects was significantly greater than that of medial defects (Figure 2.4a. and Figure 2.4c.). The interaction between defect area and orientation was found to be significant as well (p<0.001), indicating that the effect of defect area on subchondral bone contact for ML defects was significantly greater than that of AP defects (Figure 2.4b. and Figure 2.4e.). There was not a significant interaction (p=0.237) between defect location and defect orientation, meaning that combined effects of these factors are simply additive (Figure 2.4d and Figure 2.4f.).
Figure 2.4: Profile plots of defect area, defect location, and defect orientation
(a) An interaction effect is present between defect area and location, as illustrated by the “fan” shape. (b) An interaction effect is present between defect area and orientation, as illustrated by the “fan” shape. (c) Lateral defects were had higher subchondral bone contact. The difference in slopes of the lateral and medial curves shows the interaction. (d) Lateral defects had higher subchondral bone contact, regardless of orientation. No interaction was present between defect location and orientation. (e) The interaction between defect area and orientation is apparent from the difference in slopes of the AP and ML curves. (d) ML defects had higher subchondral bone contact, regardless of location. No interaction was present between defect location and orientation.
Each defect group exhibited a different threshold area, as shown in Table 2.1 and Figure 2.5. AP defects on the medial condyle never demonstrated significant subchondral bone contact ($p>0.115$), so the threshold is larger than $2.88 \text{ cm}^2$. Contact for ML defects on the medial condyle became significant at an area of $1.61 \text{ cm}^2$ ($p=0.006$). Contact for AP defects on the lateral condyle became significant at an area of $1.14 \text{ cm}^2$ ($p=0.037$). Contact for ML defects on the lateral condyle became significant at an area of $0.73 \text{ cm}^2$ ($p<0.031$).

**Table 2.1: Threshold area of significant subchondral bone contact**

Defect threshold area was the smallest for lateral, ML defects. Significant subchondral bone contact did not occur for medial, AP defects.

<table>
<thead>
<tr>
<th>Defect Location</th>
<th>Defect Orientation</th>
<th>Threshold Area (cm$^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial Condyle</td>
<td>Anterior-Posterior (AP)</td>
<td>-</td>
</tr>
<tr>
<td>Medial Condyle</td>
<td>Medial-Lateral (ML)</td>
<td>1.61</td>
</tr>
<tr>
<td>Lateral Condyle</td>
<td>Anterior-Posterior (AP)</td>
<td>1.14</td>
</tr>
<tr>
<td>Lateral Condyle</td>
<td>Medial-Lateral (ML)</td>
<td>0.73</td>
</tr>
</tbody>
</table>
Subchondral bone contact from AP medial defects was not significantly different from zero for all defect areas. ML medial defects showed statistically significant contact in defects of $1.61 \text{ cm}^2$. AP lateral defects showed statistically significant contact in defects of $1.14 \text{ cm}^2$. ML lateral defects showed statistically significant contact in defects of $0.73 \text{ cm}^2$. Error bars represent one standard deviation.

**2.5 Discussion**

In this study, we tested the hypothesis that defect size, location, and orientation would affect subchondral bone contact in oval defects. Furthermore, we predicted that different thresholds for significant subchondral bone contact would be exhibited for each defect group. We found that defect size, location, and orientation each had a significant
effect on subchondral bone contact. An interaction effect between defect size and location was found to be significant, as an increase in defect size resulted in a larger increase in contact for lateral defects than what was observed from a similar increase in size for medial defects. Similarly, the interaction effect between defect size and orientation was significant, as an increase in defect size resulted in a larger increase in contact for ML defects than what was observed from a similar increase in size for AP defects. In addition, we found that significant contact occurred at different sizes for each of the four defect groups. Thresholds were below 2 cm² for both ML oval groups and for the lateral AP group, while significant contact did not occur in defects as large as 2.88 cm² for the medial AP group.

There are a number of limitations to our approach. The experimental loading procedure attempted to ensure equal contact between medial and lateral compartments while under static loading via visual representation on the Tekscan software and, although adjustments were made, equal distribution was never perfectly achieved. Similar to the approach of previous biomechanical studies of tibiofemoral contact in cadaver knees (Brown et al., 1991; Lefkoe et al., 1993; Nelson et al., 1988), the menisci were removed from all specimens. Though this was done to obtain usable contact readings from in and around the defects, it does not represent in vivo loading, in which the femoral cartilage may articulate with part of the meniscus as well as the tibial surface. Given these limitations, the results may be different with intact menisci and under dynamic loading conditions.
Another potential limitation of the study is the use bovine specimens rather than human cadaver knees. While there is significant interspecies variability between most articular cartilage animal models (Athanasiou et al., 1991), and the bovine stifle joint is larger than the human knee joint, similarities in condyle geometry and material properties do exist. The site-specific variation in condyle radius curvature in the human knee has been well-documented; the average radius of curvature of the lateral femoral condyle is smaller than that of the medial femoral condyle, and the sagittal plane radius of curvature differs from the frontal plane radius of curvature within each compartment (Ahmad et al., 2001; Koo & Andriacchi, 2007). We measured the bovine condyle surface curvature with an optical tracking system and custom software and discovered comparable radius magnitudes to that of human knees. Average bovine femoral condyle radius of curvature values ranged from 20 mm to 49 mm, while the range of curvatures from previous studies of human femoral condyles was found to be 21 mm to 38 mm (Ahmad et al., 2001; Koo & Andriacchi, 2007). A previous study reported bovine radius of curvatures on the order of 30 mm, which is similar to the average curvature that we measured (Raimondi & Pietrabissa, 2005). Our measurements also showed consistent differences in radii of curvature between the medial and lateral condyle and between the frontal and sagittal plane within in each compartment. In addition, bovine articular cartilage material properties (Martin, 1998) and cartilage thickness (An & Freidman, 1998; Kaab et al., 1998; Martin, 1998) are comparable to that of human articular cartilage. The similarities in condyle geometry and material properties, quantities that influence contact mechanics, between bovine and human knees suggest that similar contact trends may be seen in the
human knee, possibly leading to different subchondral bone contact thresholds based on defect location and orientation.

We examined the effect on subchondral bone contact in a simple non-circular shape in only two orientations, which does not encompass all clinically observed defects. However, while irregular and nonsymmetrical defects are common, the defects used in this study may be more representative of defects observed in a clinical setting than previous in-vitro studies that have only used perfectly circular defects, (Brockmeier et al., 2009; Brown et al., 1991; Guettler et al., 2004; Jackson et al., 2001; Lefkoe et al., 1993). We believe that our study is the first to use non-circular defects in biomechanical testing of cartilage defects, and our results justify future work examining other defect geometries and orientations.

In this study, as well as in our previous study examining circular defects (Brockmeier et al., 2009), we found higher subchondral bone contact in the lateral compartment than in the medial compartment. Furthermore, there was significantly higher contact in ML defects compared to AP defects. In healthy and osteoarthritic knees in neutral alignment, pressures have been shown to be higher in the lateral than medial compartment (Agneskirchner, et al., 2007; Koo & Andriacchi, 2007; Riegger-Krugh et al., 1998). The radii of curvature between the medial and lateral femoral condyles and tibial plateaus may create different contact mechanics, which could affect contact within a defect. The disparity in contact between ML and AP defects could also be a result of differences in radii of curvature in the frontal and sagittal planes within each compartment. This finding also agrees with our clinical experience of narrow cartilage
tears oriented in the ML direction to be more deleterious, as opposed to those oriented in the AP direction. Future studies should investigate the influence of condyle curvature on subchondral bone contact and possible relationships between condyle curvature and clinical outcome.

Recent biomechanical and clinical research has brought into question the current use of 2 cm$^2$ as the threshold area for dictating focal cartilage defect repair (Guettler et al., 2004; Knutsen et al., 2004). Recent clinical studies have shown that the threshold size for determining the appropriate surgical treatment is potentially larger than 2 cm$^2$, as successful outcomes have been reported in studies evaluating microfracture surgery on defects larger than 4 cm$^2$ (Blevins et al., 1998; Gobbi et al., 2005; Knutsen et al., 2007, 2004; Steadman et al., 2003). Though clinical algorithms for management of such defects often consider patient-specific factors such as patient age, demand level, body mass index, response to previous treatment, and the presence of cofactors such as malalignment, ligament insufficiency, and meniscal deficiency (Buckwalter & Mankin, 1998; Cole & Lee, 2003; Cole et al., 2009; Minas, 1999; Minas & Nehrer, 1997; Nehrer et al., 2004), defect characteristics other than the area of a defect are not generally considered. Some algorithms prescribe different treatment pathways for femoral and patellofemoral defects (Alford & Cole, 2005; Cole et al., 2009; Lewis et al., 2006; W.N. Scott, 2005), but no distinction is made between suggested treatment paths for medial and lateral femoral condyle defects or defects of different orientations. The present study suggests that defect location (i.e. medial or lateral femoral condyle) and orientation may influence patient outcome as well. Interestingly, significant subchondral bone contact did
not occur for AP defects on the medial condyle as large as 2.88 cm², while each of the other defects reached significant contact at different points below 2 cm². Although it has yet to be investigated in a prospective, randomized fashion, the existence of multiple size thresholds based on defect location and orientation could translate to more predictable and improved clinical success of cartilage defect repair.

While surgical algorithms primarily use defect area to guide cartilage repair, our results suggest that defect location and orientation, in addition to area, influence contact within a defect. While we do not suggest that the thresholds reported in this study in a bovine knee should map directly to the human knee, we believe that the apparent dependency of subchondral bone contact on location and orientation may also be observed in human knees. Our discovery of different size thresholds based on location and orientation of a defect challenges current surgical algorithms, which use defect area as the primary factor to guide surgical decision-making. Future work, including biomechanical studies with human cadaver knees and longitudinal clinical studies evaluating patient outcomes, should determine whether patient outcomes would benefit from modifications to clinical algorithms to account for cartilage defect location and orientation.
CHAPTER 3:

DESIGN OF THE CARTILAGE DEFECT NAVIGATION SYSTEM

3.1 Introduction

The purpose of this navigation system is to provide diagnostic information related to cartilage defects and osteoarthritic knees to surgeons intra-operatively and arthroscopically. This diagnostic information, which may be important in dictating cartilage repair surgeries, has been shown to be difficult to obtain through conventional imaging techniques or arthroscopic examination (Erggelet et al., 2008; Graichen et al., 2005; Marlovits et al., 2008; Oakley et al., 2003). Through the technology employed by surgical navigation systems, we have made it possible to determine the size, shape, orientation, and location of a femoral cartilage defect, as well as information related to the curvature of the femoral condyle at the defect region.

Optical surgical navigation systems perform motion capture through the use of optical reference frames, rigidly attached to anatomical structures, and an optical tracking system located in the operating room. The optical tracking system measures the position and orientation of optical reference frames and an instrumented stylus, which is used to digitize points. In imageless navigation, which does not rely on pre-operative images to
locate anatomical landmarks, landmarks on bony structures are digitized to create anatomical coordinate systems, which relate the position and orientation of defined mechanical or anatomical axes to the optical reference frames. This provides the ability to obtain relative positions and orientations of various anatomical structures and tools (Siston et al., 2007).

An imageless optical navigation system is comprised of three subsystems: (1) the reference frames used to track anatomical structures and a stylus to digitize points for computations, (2) the software that receives data from the navigation system and converts it to usable data, and (3) the user interface with which a surgeon or researcher interacts, and which presents the usable data in graphical or numerical form. This chapter will thus be divided into sections which address each subsystem.

### 3.2 Optical Tracking System Hardware

Optical tracking systems are used in clinical settings to monitor the motion of anatomical bodies and surgical tools in space. Our system uses the Hybrid Polaris Position Sensor (NDI, Waterloo, Ontario, Canada), which is capable of measuring passive and active trackers and interfaces with the Polaris Tool Interface Unit (NDI, Waterloo, Ontario, Canada). This signal processor then communicates data to a desktop through a serial connection. The position sensor has a maximum sampling rate of 60 Hz and is capable of measuring the position of an optical marker to an accuracy of 0.350 mm RMS and with a repeatability of 0.200 mm RMS (Northern Digital, Inc., 2002).
The optical reference frames (Traxtal Inc., Toronto, Ontario, Canada) consist of three reflective spheres mounted in specific arrangements to a rigid aluminum frame, which defines a unique coordinate system for each tracker. In order to accurately measure the position of the femur and tibia during surgical navigation, rigid attachment of the trackers to bone is necessary, as bone position and orientation is continuously measured relative to fixed optical trackers. Prior systems have utilized a stem and screw configuration (Siston, 2005), in which the tracker is connected to a stainless steel stem with the use of a set screw. Rigid fixation would then be achieved by fixing a bicortical screw into the exposed patient bone during an open surgery (Siston et al., 2007). However, this method is not ideal for arthroscopic surgery since access to bone is minimal, and the less invasive nature of this type of surgery would be compromised by requiring additional incisions and screwing into bone.

We developed a novel method of fixation by utilizing a percutaneous intraosseous needle (Vidacare EZ-IO, San Antonio) as the means of bone fixation. The EZ-IO system consists of a power driver and needle that is driven through the skin and bone, with the purpose of gaining quick access to the intramedulary canal of a bone in military and hospital settings. The 15-gauge needle is made of 304 stainless steel and has a special cutting tip, capable of easily penetrating bone without damaging superficial tissue. Once driven into the bone, the inner needle and drill interface are removed, leaving the hollow needle fixed in the cortex of the bone and a threaded plastic coupling at the skin surface (Figure 3.1). Upon removal of the needle, only a small hole remains in the bone, which
has been shown to fully heal in several days and is not believed to weaken the bone or present the risk of fracture (Ong et al., 2009).

Figure 3.1: EZ-IO needle used for bone attachment

We designed a custom attachment to interface with the standard threading on the needle housing, consisting of a stainless steel Luer-lock adaptor (Vita Needle Company, Needham, MA), with a threaded hole on the outer face and fitted with a stainless steel stem (Figure 3.2 & Figure 3.4). We used a previously developed tear-drop shape interface between the stem and tracker (Maack, 2008; Siston, 2005) to minimize unwanted tracker rotation. Because tracker visibility is of great importance, multiple
angled stems were created and fitted with Luer-lock threaded couplings to enable quick replacement when necessary to improve visibility during tracker fixation (Figure 3.3).

Figure 3.2: Solid model of reference frame system

Figure 3.3: Angled stems and Luer-lock couplings for attaching reference frames
Benchtop testing of needle stability and security was performed on a cadaver knee specimen before the development of the needle-tracker adaptor. There was concern that since the needle was designed to be used in a sedentary patient’s tibia, excessive motion with the needle in place might cause rotation or loosening, compromising the measurement accuracy. The needle was driven into both the tibia and femur and a temporary method of tracker fixation was created using duct tape, as the mass of the tracker is greater than that of the needle. The knee was then ranged while tracker and needle stability was inspected. No rotation or loosening was noticed, and twisting of the percutaneous needle with the thumb and pointer finger was not possible, suggesting adequate stability.

Figure 3.4: Reference frame system using EZ-IO needle to attach to bone
In order to provide a means of digitizing anatomical points of interest, we used a passive optical three-marker linear probe (Figure 3.5) (NDI, Waterloo, Ontario, Canada). While this probe would not be suitable for arthroscopic applications due to the short and relatively thick probe tip, we declared it appropriate for initial testing. The probe is comprised of three linearly arranged reflective spheres mounted to a rigid frame and handle, and a metal probe tip secured to the frame.

![Linear probe used for digitizing points](image)

**Figure 3.5: Linear probe used for digitizing points**

After discussions with the collaborating orthopaedic surgeons, a footswitch was incorporated in the navigation system to allow hands-free input to the software during various functions, primarily for tasks requiring a large number of points to be digitized. The footswitch (Dayton, Model 5GC1) is connected to the PC though the parallel port.
connection and provides a binary signal that can be read with the appropriate software driver.

3.3 Data Processing

Data from the Polaris Tool Interface Unit is sent via parallel connection to the PC. All data processing is done in MATLAB (The Mathworks, Natick, MA), which receives the position and orientation data of all trackers that have been initialized. Communication between the PC and the Polaris unit is achieved using the `fscanf` and `fprintf` functions in MATLAB. Commands are sent using `fprintf` and data received using `fscanf`.

3.3.1 Transformation Matrices

The Polaris unit sends position and orientation information in the form of a quaternion. Preexisting MATLAB code (Siston, 2005) converts this data to a convenient 4x4 transformation matrix. The transformation matrix, denoted by $T_{local}^{global}$, is convenient a way to represent the position and orientation of a local reference frame relative to a global reference frame, and is made up of a 3x3 rotation matrix, $R_{local}^{global}$, concatenated with a vector representing the position of the origin of the body in the base reference frame, $p_{local}^{global}$. For the case of a navigation system, the global reference frame is that of the Polaris, and the tracker coordinate system is the local reference frame.
The rotation matrix can be described a number of ways, but the simplest way is by concatenating three direction cosine vectors, $\hat{u}$, $\hat{v}$, and $\hat{w}$, each representing the orientation of one axis of the tracker with respect to the Polaris coordinate system.

\[
Polaris \quad R_{\text{tracker}} = \begin{bmatrix} \hat{u} & \hat{v} & \hat{w} \end{bmatrix} = \begin{bmatrix} u_x & v_x & w_x \\ u_y & v_y & w_y \\ u_z & v_z & w_z \end{bmatrix}
\]

The position vector is made up of the coordinates of the origin of the tracker reference frame in the Polaris reference frame:

\[
Polaris \quad p_{\text{tracker}} = [x \quad y \quad z]^T
\]

### 3.3.2 Probe, Femur, and Tibia Coordinate Systems

The Polaris system tracks the position and orientation of the rigidly attached tibia and femur frames with respect to the camera reference frame. Since the information of interest is the position and orientation of the femur and tibia anatomical coordinate systems, the tip of the digitizing probe, and the cartilage defect with respect to the femur anatomical reference frame, it is necessary to obtain additional transformation matrices.
First, the location of the probe tip must be calculated with respect to the probe tracker coordinate system. This is achieved by performing a pivoting algorithm described earlier (Siston et al., 2006), and gives the vector $p_{probe\_tip}^{probe}$. An additional transformation gives the position of the probe tip in the global coordinate system, that of the Polaris system, and provides a means of locating points in the Polaris coordinate system.

$$Polaris\ p_{probe\_tip} = [Polaris\ T_{probe\_tracker}][^{probe\_tracker}\ p_{probe\_tip}]$$

By digitizing anatomical landmarks on the femur and tibia, anatomical coordinate systems of both the femur and tibia are created (Siston et al., 2006). For both coordinate systems, the positive x-direction is oriented from lateral to medial, the positive y-direction is oriented in the anterior to posterior direction, and the positive z-direction is formed orthogonal to the x-axis and y-axis, which is computed as the cross product of the vectors representing the x-axis and y-axis.
The origin of the femur coordinate system is defined as the anterolateral attachment of the posterior cruciate ligament. The z-axis of the femur is defined as the vector from the hip center to the origin, with the hip center being determined by a pivoting algorithm described earlier (Siston & Delp, 2006). A vector created by digitizing points on the medial and lateral epicondyles is then formed, and the cross product of this vector with the z-axis forms the y-axis. Finally, the cross product of the y-axis and the z-axis forms the x-axis.
The origin of the tibia coordinate system is defined as the midpoint of the tibial spines. The z-axis of the femur is defined as the vector from the ankle center to the origin, with the ankle center being defined as the midpoint of digitized points on the medial and lateral malleoli (Siston et al., 2005). A vector created by digitizing points on the medial and lateral borders of the tibial plateau is then formed, and the cross product of this vector with the z-axis forms the y-axis. Finally, the cross product of the y-axis and the z-axis forms the x-axis.

With these coordinate systems defined, additional coordinate systems can be determined by creating a transformation matrix of the desired local coordinate system with respect to a tracker. Since the tracker is rigidly fixed to the object of interest (the femur, tibia, or probe tip), the position and orientation do not change and the transformation matrix is valid for all points in space.

\[
Polaris \ T_{femur} = \begin{bmatrix} Polaris \ T_{femur \ tracker} & [femur \ tracker \ T_{femur}] \end{bmatrix}
\]

\[
Polaris \ T_{tibia} = \begin{bmatrix} Polaris \ T_{tibia \ tracker} & [tibia \ tracker \ T_{tibia}] \end{bmatrix}
\]

\[
Polaris \ T_{probe \ tip} = \begin{bmatrix} Polaris \ T_{probe \ tracker} & [probe \ tracker \ T_{probe \ tip}] \end{bmatrix}
\]

The transformation matrices above are all written as the position and orientation of a local object with respect to the same global system, the Polaris position sensor reference frame. Therefore, additional transformations can be computed to give local coordinate system position and orientation with respect to a different local system, such as the probe tip with respect to the femur anatomical coordinate system, \( f_{emur} \ T_{probe \ tip} \).
or the tibia anatomical coordinate system with respect to the femur coordinate system, \( T_{tibia}^{femur} \), which can be used to report knee kinematics.

\[
T_{\text{probe tip}}^{femur} = \left( T_{\text{Polaris}}^{femur} \right) \left( T_{\text{probe tip}}^{Polaris} \right)
\]

\[
= \left( T_{\text{Polaris}}^{femur} \right)^{-1} \left( T_{\text{probe tip}}^{Polaris} \right)
\]

\[
T_{tibia}^{femur} = \left( T_{\text{Polaris}}^{femur} \right) \left( T_{tibia}^{Polaris} \right) = \left( T_{\text{Polaris}}^{femur} \right)^{-1} \left( T_{tibia}^{Polaris} \right)
\]

### 3.3.3 Defect Coordinate System

An additional coordinate system is defined for calculations pertaining to the evaluation of a cartilage defect on the femoral condyle. Points are first digitized on the femoral surface along the rim of the defect. Although these points are in 3D space, calculations of the area, width, length, and orientation are made simpler by assuming the defect rim to be planar. The z-axis of the defect coordinate system is defined as a unit vector normal to the calculated best-fit plane to the points on the defect rim. The x-axis and y-axis are then defined by the in-plane unit vectors along the major and minor axes of a best-fit ellipse to the set of points.

To accomplish this, a previously written MATLAB program, `lsplane` (Smith, 2002a), is first used to determine the plane estimated by the set of digitized points. The program uses singular value decomposition to minimize the orthogonal distances from the set of points to the plane (Smith, 2002a). The origin of defect space was taken to be the centroid of the set of points representing the rim of the defect, projected onto the best-
fit plane. Then, the unit vector normal to the plane is defined as the z-axis of the defect coordinate system, choosing the direction in which the z-component is positive rather than negative so that the z-axis points in the same superior-inferior sense as the femoral z-axis.

![Figure 3.7: Definition of z-axis of defect coordinate system](image)

The x-axis and y-axis are then defined by fitting a 2-D ellipse to the set of digitized points. In order to accomplish this, a transformation of the set of points is first
performed place the points in the femoral coordinate system and such that the z-component of each point in the set is close to zero. The transformation matrix is created by aligning a temporary defect coordinate system to the femoral coordinate system. The temporary defect coordinate system uses the unit normal to the best-fit plane as the z-axis, a unit vector from origin to the point with the smallest orthogonal residual to the best-fit plane as the temporary y-axis, and the cross product of the temporary y-axis and z-axis as the temporary x-axis. This transformation allows the z-component of the set of points to be ignored, since this is simply the residuals of set of points from the best-fit plane calculation, now leaving the points as a set in 2-D.

A method is then adopted to determine the best-fit ellipse (Fitzgibbon et al., 1999a), which uses an optimization routine to minimize the distances from the digitized points to a curve defined by the equation of an ellipse in 2-D. The optimization problem uses the equation for a conic as the objective function, where the coefficients $a$, $b$, $c$, $d$, $e$, and $f$ define a unique conic section, and $x$ and $y$ are the independent orthogonal variables (Eberly, 2008):

$$F(\bar{a}, \bar{x}) = ax^2 + bxy + cy^2 + dx + ey + f = 0$$

An additional equality constraint is enforced that specifies a unique ellipse:

$$4ac - b^2 = 1$$
A MATLAB program, *fitellipse* (Fitzgibbon et al., 1999b), was modified to solve this optimization problem and output the orientation of the major axis of the ellipse. The unit vector of this axis defines the new x-axis of the defect. The new y-axis of the defect coordinate system is defined by the cross product of the z-axis and the x-axis. In this convention, a narrow defect on the distal end of the femoral condyle, oriented with the long axis medial to lateral, will have a coordinate system that closely aligns with the femur coordinate system.

![Diagram of defect coordinate system](image)

*Figure 3.8: Definition of x-axis and y-axis of defect coordinate system*
3.3.4 Quantifying Defects

To better approximate the shape of a defect, we fit a cubic spline curve to the points representing the defect border using the MATLAB `spline` function. Using a spline helps to eliminate the loss of area that would occur using a linear interpolation between data points. Defect area is calculated using a built-in MATLAB function, `polyarea`, which determines the area of the polygon with vertices created by the spline function. This calculation is performed on the points in 2-D defect space, and is a 2-D estimation of the area.

Defect orientation is always taken as the angle between the x-axis of the defect coordinate system and the x-axis of the femur coordinate system. As has been described (Eberly, 2008), the components of the vector representing the orientation of an ellipse are

Figure 3.9: Definition of cartilage defect coordinate system
determined by the coefficients of the equation of the ellipse, \(ax^2 + bxy + cy^2 + dx + ey + f = 0\), and the orientation can be calculated as:

\[
\theta = \frac{1}{2} \tan^{-1}\left(\frac{-2b}{a - c}\right)
\]

where \(\theta\) is taken as the counterclockwise angle from the x-axis in the xy-plane. Further calculations are performed to present the orientation as the absolute angle between the x-axis of the defect (the major axis of the best-fit ellipse) and the x-axis of the femur. In this convention, a defect oriented with the longer axis precisely along the medial-lateral direction of the femur is defined as having an orientation of 0°, and one oriented precisely along the anterior-posterior direction is defined as having an orientation of 90°. Orientation is always a number between 0° and 180°, and defects oriented at 0° and 180° are indistinguishable.

The degree of elongation of a defect is explained by the ratio of the major and minor axes of the best-fit ellipse.

\[
elongation = \frac{R_{\text{major}}}{R_{\text{minor}}}
\]

Therefore, for a perfectly circular defect, the major and minor axes are equal and the elongation is 1.
Two additional measurements of interest are the medial-lateral and anterior-posterior width of the defect, for which a MATLAB program, `defectwidth`, was written. With the defect oriented in the femur coordinate system, in which the medial-lateral and anterior-posterior directions are equivalent to the x-axis and y-axis, this program superimposes a fine grid over the defect region and uses a built-in MATLAB function, `inpolygon`, to determine whether or not each node of the grid is inside the polygon created by the cubic spline. The defect width is then determined by multiplying the interval distance between each node by the number of intervals spanning the defect.

The defect area, orientation, elongation, medial-lateral width, and anterior-posterior width are saved and reported in the graphical user interface.

### 3.3.5 Condyle Curvature

An additional primary function of the navigation system is to determine the condyle curvature in the region of a cartilage defect. The curvature of the human knee has previously been described by four radii, the frontal and sagittal radii in the lateral compartment and the frontal and sagittal in the medial compartment (Koo & Andriacchi, 2007). Additionally, the femoral condyle curvature in the sagittal plane has been approximated by fitting a cylinder to the surface (Eckhoff et al., 2001). We chose to use this notion to approximate the curvature at the defect region, in both the sagittal and frontal planes.

To obtain estimates of the curvature in the frontal plane, we first use the stylus to digitize points on the surface of the condyle. To prevent introducing error that might
occur if the entire condyle were to be digitized, points are digitized in a rectangular region around the defect, attempting to capture the curvature in the plane of interest and avoiding the curvature in the orthogonal plane.

A previously written MATLAB program, \texttt{lscylinder} (Smith, 2002b), is then used to determine the equation of the cylinder that provides the least-squares fit to the digitized points. This program, which uses a Gauss-Newton routine as the optimization method, requires initial guesses for the cylinder axis, a point on the cylinder axis, and the cylinder radius.

For the frontal cylinder, the cylinder axis initial guess is formed by taking the cross product of two vectors. The first is the normal vector to the best-fit plane to the digitized points, as this vector will be approximately normal to the condyle surface at that location. Because the frontal cylinder axis will be approximately orthogonal to the x-axis, the second vector is taken as the unit vector in the direction of the x-axis. The initial guess for the point on the cylinder axis is the centroid of the digitized points, and the radius guess is 15 mm (Koo & Andriacchi, 2007).

The sagittal cylinder initial guesses for the point on the cylinder and the radius are the same as that of the frontal cylinder. However, the cylinder axis guess is calculated as the cross product of the normal to the best-fit plane and the unit vector collinear with the y-axis, as the sagittal cylinder will be approximately orthogonal to this vector.

If convergence does not occur with the initial calculation, the initial radius guess is increased by 10 mm until convergence occurs. If convergence does not occur after 10 attempts, new points must be digitized and the procedure must be repeated.
3.3.6 Knee Kinematics

A final function of the navigation system is the recording of knee kinematics, specifically the flexion/extension, varus/valgus, and internal/external rotation angles of the knee. In addition to these angular displacements, linear displacements between the origins of the femur and tibia are calculated. All angular and translational displacements are taken from the transformation matrix $f_{\text{femur}} T_{\text{tibia}}$ as was previously described (Grood & Suntay, 1983).

3.4 User Interface

One of the goals of this research was to develop a surgical navigation system that would not only provide accurate, repeatable geometric data to characterize a femoral cartilage defect region, but one that could also be implemented in a clinical setting. Some of the challenges posed toward the adoption of surgical navigation systems are the added operative time required, the added cost involved, and the learning curve that sometimes exists. These issues were considered during the development of this system, most notably during the graphical user interface (GUI) development. In addition, during each stage of development, surgeon feedback was solicited.

The navigation system user interface was created in the MATLAB GUIDE graphical user interface development environment (The Mathworks, Version 7.2, Natick, MA), which provides a set of tools for creating GUIs. MATLAB was chosen as over other graphical programming languages for its versatility and the ability of customization.
The GUI, which was created with the GUIDE Layout Editor and is a FIG-file, is operated by code in an accompanying M-file that calls functions based on user input.

### 3.4.1 GUI Layout

The GUI layout consists of five panels, each of which serves a specific purpose (Figure 3.10).

![GUI layout diagram](image)

**Figure 3.10: Graphical user interface layout**

The Information Panel, which stretches almost the entire width of the upper portion of the GUI, provides the location of the program title, “Cartilage Defect
Navigation System”, along with the test identifier (which is entered prior to data collection), and the date. No interaction with this panel takes place.

Along the width of the bottom is the Status Panel, which provides status information to the user and prompts input when necessary. No interaction with this panel takes place.

In the upper right corner is the Visibility Panel, which contains three indicators, labeled *Probe*, *Femur*, and *Tibia*, that constantly change colors based on the associated tracker visibility.

![Tracker visibility panel](image)

**Figure 3.11: Tracker visibility panel**
The image on the left shows a situation where the probe is not visible but the femur and tibia trackers are visible. All trackers were visible in the image on the right.

The Functions Panel, along the right side of the GUI, has two regions. The upper region is the location of Operations buttons that are sequentially used from top to bottom during a data collection session, and the lower Utilities section provides functions that can be used at any point during data collection. The Operations buttons serve as the
means of navigating the GUI, from initialization to the reporting of data that has been collected. This process is described in detail in a later section.

The Utilities buttons can be used at any point in the process of data collection. First, an Export button is available, which allows the user to export to file any data that has been stored from a previous step. This includes any patient information, registration information, or diagnostic data collected. When the Export button is pressed, a dialog appears and presents a list of data that is stored. The user selects the data to be exported and an Excel file is created containing the selected data. The Capture button saves the current GUI screen as an image and prompts the user to give a file identifier for the image. An Options button opens an additional window, in which the user can specify a new save location and choose to use a preexisting registration file.

Finally, the large central panel is the Main Panel, which changes to different subpanels based on the data collection stage and displays the majority of the user interface content. Further detail about each subpanel is given in a later section.

### 3.4.2 Initialization and Registration

The user interface requires a user to complete sequential steps, so that errors might be prevented and to provide continuity to the process. When the program opens, the user must initialize the system, as the Initialize button is the only active button in the upper region of the Function Panel (Figure 3.10). Following initialization, the visibility indicators become active and tracking begins (Figure 3.12). From this point, the user can move ahead to the next stage, entering the patient information, diagnostic information
regarding the defect, and the test identifier in the Patient Information Panel (Figure 3.12). The user cannot proceed to the next stage until the Save button is pressed, as some of the information in this stage is required for later computations.

![Cartilage Defect Navigation System](image)

**Figure 3.12: Patient information screen**

After the Save button is pressed, the Register button becomes active, allowing the user to proceed to this stage. This stage is critical because data collected here influences the data collection so registration. Therefore, registration is a sequential, scripted process with specific instructions to the user to mitigate procedural error. In addition, descriptions of the action to be performed and an image of that action are provided. As a form of feedback, an indicator light is situated next to the name of the registration task.
being performed. When the task is begun, the indicator light is yellow, and becomes green when the task is successfully completed. If the task was not completed because a tracker was not visible, the indicator light turns red for an instant and then yellow again, signifying that the task is still in progress.

The registration sequence is includes previously described tasks (Siston et al., 2006) of pivoting of the probe and hip (Figure 3.13), and digitizing of the necessary anatomical landmarks (Figure 3.14), which provide data to create the probe tip offset and the femur and tibia coordinate systems. When registration is completed, functions are called that calculate transformation matrices of these coordinate systems. The system is then prepared to collect data and the Collect button becomes active.

![Registration sequence](image)

**Figure 3.13: Pivoting of the probe and hip during registration**
Pivoting of probe for calculation of the probe tip location, (2) Pivoting of femur for calculation of femoral head center, used to create femur ACS z-axis
Figure 3.14: Digitizing femur and tibia anatomical landmarks during registration
(3) PCL anterolateral attachment creates femur ACS origin, (4) Medial and lateral epicondyles form the femur ACS x-axis, (5) Midpoint of tibial spines creates tibia ACS origin, (6) Medial and lateral contours form the tibia ACS x-axis, (7) Center of ankle creates vector from origin, forming tibia ACS z-axis
3.4.3 Data Collection

The Data Collection Panel provides the functional environment for the user to perform measurements and also acts as a visual aid during data collection (Figure 3.15). It was designed to provide feedback to the user during data collection and to provide the capability to correct errors, such as an unintended point being digitized. Three plots provide two-dimensional graphical images of the measurement task being performed, with views of the front, transverse, and sagittal planes. The buttons to the right of the sagittal plane view are used to begin and end various tasks. Additionally, the current task and a description of the proper measurement technique are provided in the center area.

Figure 3.15: Data collection screen during defect tracing
To the right is a status indicator light that provides feedback to the user during data collection. When the program is idle the indicator is gray, and then turns to yellow when one of the five function buttons is selected. During tasks that require digitizing of points, the footswitch is used to activate the probe and collect a point. Therefore, when the footswitch is pressed and a point is successfully collected, the indicator turns green for an instant and then returns to yellow. In addition, a counter below the indicator light increases consecutively as points are added. In the case that a point was not successfully collected when the footswitch is depressed, due to the lack of visibility of a tracker, the indicator light becomes red for an instant and then returns to yellow, as the system is waiting for input.

![Status Indicators](image)

**Figure 3.16: Lights indicating system status for feedback during digitizing**

Yellow light indicates system is looking for footswitch input, green light indicates point(s) were successfully digitized, red light indicates a tracker was not visible when the footswitch was depressed, and a point was not collected.

If an undesired point is digitized during data collection, the Delete Last Point button provides a way for the user to erase only the previously collected point from the
data set. Furthermore, a button labeled Delete All Points erases the entire set of points that was last collected.

3.4.3.1 **Measure Distance**

The Measure Distance button provides a method for direct measurement of the distance between two points. When the button is pressed, a prompt appears asking for an identifier for the task. After the task is named, two points should be digitized and the distance is presented, in component form and also as a total distance (Figure 3.17). The data is also stored so that it can be exported.

![Figure 3.17: Distance measurement screen](image)

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3.4.3.2 **Trace Defect**

The Trace Defect button activates the probe and footswitch to enable the tracing of a defect rim for calculations. The indicator light provides feedback for the user, blinking green for an instant upon successful point digitizing and turning red for an instant if unsuccessful. The counter also increases as points are added. When the task is ended, data is stored so that it can be exported and for later calculations.

3.4.3.3 **Frontal and Sagittal Radius**

The Frontal Radius and Sagittal Radius Buttons (Figure 3.18 & Figure 3.19) operate the same way, activating the probe and footswitch to enable the tracing of a defect rim for quantification. The indicator light provides feedback for the user, turning green for an instant upon successful point digitizing and turning red for an instant if unsuccessful. The counter also increases as points are added. When the task is ended, data is stored so that it can be exported and for later calculations.
Figure 3.18: Frontal curvature measurement screen

Figure 3.19: Sagittal curvature measurement screen
3.4.3.4 Knee Kinematics

A final function is the ability to display and record knee kinematics (Figure 3.20). Again, when the Kinematics button is pressed, the indicator light becomes yellow, signifying that user input is expected. Knee kinematics will be displayed and recording begun when the footswitch is depressed and the system stops recording when the footswitch is released. When the task is ended, data is stored so that it can be exported.

Figure 3.20: Knee kinematics screen
3.4.4 Data Presentation

Following data collection, results are presented both numerically and graphically in the Report screen (Figure 3.21). In the upper left region, important numerical values are given in the Statistics column, including defect area, defect medial-lateral width, defect anterior-posterior width, defect elongation ratio, orientation, and the frontal and sagittal radius values.

The defect outline is depicted graphically in two-dimensions in a plot in the lower left region. The digitized points are shown projected onto the xy-plane of the defect coordinate system (the best-fit plane created from the digitized points), so that a two-dimensional image is possible. Then, these planar points are transformed into the femur coordinate system to depict the orientation of the defect, and an arrow shows the x-axis (or primary axis) of the defect. Therefore, the angle between the defect and femur x-axes in the plot is equal to the orientation value reported in the Statistics column.
Following a request from a collaborating orthopaedic surgeon, an interactive measurement tool was included, which allows the user to measure a two-dimensional distance in the plot (Figure 3.22). After two points are digitized in the plot using the mouse, the total distance, medial-lateral distance, and anterior-posterior distances are reported.

Two additional plots are included on the right side of the panel showing the relative radii of the fontal and sagittal planes, as well as the points collected. These plots are three-dimensional and can be rotated with the mouse to view the best-fit cylinder and data points.

Figure 3.21: Data report screen
Figure 3.22: Interactive plot measurement tool

(1) & (2) Points are digitized with the mouse to measure any distance in the plot. (3) The total distance, medial-lateral distance, and anterior-posterior distance are then displayed.
CHAPTER 4:

SYSTEM VALIDATION

The motivation for developing a cartilage defect navigation system was the documented inability of surgeons to adequately characterize a cartilage defect region, in addition to our belief that the accurate measurement of the region is necessary for choosing appropriate clinical solutions. We feel that the use of this navigation system could provide useful information in long term studies evaluating the effects of various characteristics on clinical success. Prior to implementing the navigation system in a clinical setting, a validation of the system was necessary. The system validation was intended to evaluate the performance of the cartilage defect navigation system, both in terms of measurement accuracy and repeatability, as well as the reliability of the system from a user interface perspective. We also sought to compare navigated measurements with those performed manually, since that is the currently accepted method of arthroscopic defect measurement. Measurements were performed on two-dimensional shapes machined into a polycarbonate plate, curved surfaces machined in plastic blocks, and simulated defects machined into a plastic Sawbones knee.
4.1 Methods

We first developed a test setup for participants to perform measurements of two-dimensional shapes of known geometry. The shapes consisted of: (1) circular shapes with areas from 0.25 cm$^2$ to 10 cm$^2$, elliptical shapes oriented from 0° to 90°, and irregularly shaped defects with areas from 3.53 cm$^2$ to 7.08 cm$^2$. A solid model was created in SolidWorks and shapes were then machined to a depth of 0.125” on the surface of a 12” x 12” x 0.375” polycarbonate plate using a CNC milling process.

Figure 4.1: System validation test setup
Test setup included a polycarbonate plate with shapes machined to a depth of 1/8” and ABS plastic blocks with cylindrical faces of various radii. The stylus on the left side of the picture was used to digitize the shape outlines and the curvature of the block. The user interface is shown in the monitor in the background.
Additionally, a test setup was developed to evaluate the accuracy and repeatability of the condyle curvature measurement. Two blocks of ABS plastic were machined to each have five faces of known curvature, with one block simulating frontal curvature and one simulating sagittal curvature (Figure 4.1). The blocks were also designed in SolidWorks and machined using a CNC milling process.

The test protocol evaluated a number of criteria, and was completed by seven participants. To determine the accuracy and repeatability of current measurement techniques, participants first attempted to measure the shapes manually. Using a common 5mm arthroscopic probe tip as a reference length for all measurements (Figure 4.2), participants estimated the area of 11 shapes, including four circles, four ellipses rotated to different orientations, and three irregular shapes. Participants were also asked to estimate the radius of curvature of five block faces representing condyles, and were given the length of the entire probe, 200 mm, as an additional reference. Finally, the participants attempted to measure the areas of five simulated defect that were created on the femoral condyles and trochlear groove of the Sawbones knee (Figure 4.3).
Figure 4.2: Measuring simulated defects with a 5mm arthroscopic probe tip
Subjects estimated the area of 11 shapes using the probe tip as a reference length.

Figure 4.3: Sawbones knee with simulated defects used for validation testing
Five defects were created on the femoral condyle in the following locations: (1) trochlear groove, (2) anterior medial condyle, (3) posterior medial condyle, (4) anterior lateral condyle, (5) posterior lateral condyle.
Validation of the navigation system involved three measurement tasks. First, participants used the stylus to digitize the borders of the 11 simulated planar defects. We gave instructions to digitize points such that a curve connecting the points would adequately characterize the defect shape, but no minimum number of points was given. Next, we asked the participants to digitize each of the five frontal curvatures and five sagittal cylinders, again giving instructions to collect enough points to characterize the curvature. Finally, we attached a reference frame to a Sawbones knee that with five defects and using the stylus digitized the necessary landmarks to create the anatomical coordinate system of the femur. We asked the participants to grasp the plastic knee, flexed to approximately 90°, while holding the stylus with the other hand. We then instructed the patients to diagnose each of the five defect regions, first digitizing the edge of the defect and then digitizing the frontal and sagittal curvatures. Regions that best characterized the curvatures near each defect region were identified and marked prior to testing, as most participants were unfamiliar with the concept of femoral condyle curvature. Participants performed one measurement of each shape or surface.

To obtain “true” reference measurements for each of the defects, we digitally scanned the defect shapes along with a 2.54 cm (1”) reference line that was created beside each shape. After importing the image into MATLAB, we used the interactive plot function `ginput` to digitize point along the traced defect border until a closed shape was created. We then calculated the enclosed area using the built-in MATLAB function `polyarea`, and used the endpoints of the 2.54 cm reference line to convert from pixels.
to cm². This was done three times and the average of the three areas was used as the reference value.

In order to determine the actual radii of curvature of the machined blocks, we traced the block curvature onto a piece of paper and then digitally scanned the paper, again with a 2.54 cm reference line. After importing the image into MATLAB, we then used geometrical relationships of three points on the circumference of a circle to determine the center (Bourke, 1990). We could then calculate the radius as the average of the distances from the center to three points on the circumference. This was done three times and the average of the three radii was used as the reference value.

After detecting unequal variances, we used parametric Wilcoxon rank sum tests to test for significant differences in the mean measurement error of navigated and manual measurements. We tested for differences in overall measurement error, circular shape measurement error, irregular shape measurement error, and surface radius measurement error between navigated and manual measurements. We also used Wilcoxon paired rank sum tests to test for significant differences in the mean errors of circular and irregular shapes, to test for differences in the measurement accuracy of different shapes. We used the Kruskal-Wallis parametric test to evaluate differences in mean error of navigated measurements of shapes with different areas, to evaluate the capability of the navigation system to measure shapes of various sizes. We then performed a one-way analysis of variance (ANOVA) to determine significant differences in measurement error of ellipses with different orientations. As a final evaluation of the reliability and repeatability of the
navigation system, a subset of measurements was analyzed for inter- and intra-class correlation (ICC) coefficients.

4.2 Results

Navigated measurements resulted in smaller errors than manual measurements for all defect shapes, with overall mean and standard deviation of -0.36 ± 0.37 cm² for navigated measurements and -1.13 ± 1.50 cm² for manual measurements (p<0.001). The variance in error was also significantly smaller for navigated measurements than manual measurements (p<0.001). All mean error measurements were negative, indicating that underestimates of area were common for both measurement methods.
Figure 4.4: Box plot of overall measurement error for simulated defects
Horizontal lines across each box represent median error and the upper and lower edges of each box represent the upper and lower quartiles of the data. The error bars represent the range of the data that lies within 1.5 times the interquartile range; markers show outliers.

We detected a significant differences in measurement error of circular shapes (p=0.0146), as the mean error for navigated measurements was -0.18 ± 0.29 cm² compared to -0.90 ± 1.00 cm² for manual measurements (Figure 4.5). We also found a significant differences in measurement error of irregular shapes (p<0.001), as the mean error for navigated measurements was -0.59 ± 0.53 cm² compared to -2.65 ± 2.28 cm² for manual measurements (Figure 4.5).
Figure 4.5: Box plot of circular and irregular shape measurement error
Horizontal lines across each box represent median error and the upper and lower edges of each box represent the upper and lower quartiles of the data. The error bars represent the range of the data that lies within 1.5 times the interquartile range; markers show outliers.

Additionally, the error associated with circular shapes, regardless of measurement method, was significantly smaller than that of irregular shapes (p<0.001). The error associated with circular shapes was smaller than that of irregular shapes when considering navigated measurements (p=0.003) or manual measurements (p<0.001) individually. Navigated measurements of irregular shapes exhibited a 0.39 cm² increase in mean error compared to circular measurements. This relative increase is more pronounced for manual measurements, for which mean error of irregular shapes was 1.84 cm² higher than that of circular measurements.
The mean error for navigated measurements of artificial defects in Sawbones was 
-0.39 ± 0.22 cm². These values were smaller than the mean and standard deviation in 
error for manual measurements, -0.48 ± 0.33 cm², although this difference was not 
statistically significant (p=0.2798).

![Box plot of measurement error for artificial femoral defects](image)

**Figure 4.6: Box plot of measurement error for artificial femoral defects**
Horizontal lines across each box represent median error and the upper and lower edges of each box represent the upper and lower quartiles of the data. The error bars represent the range of the data that lies within 1.5 times the interquartile range; markers show outliers.

There were significant differences in mean error based on nominal area for 
navigated measurements of circular shapes (p=0.0249) (Figure 4.7). Mean error
increased as the nominal area being measured increased. We did not find differences in error for groups of irregular shapes based on nominal area (p=0.2128) (Figure 4.8).

**Figure 4.7: Box plot of area measurement error for circular shapes**
Horizontal lines across each box represent median error and the upper and lower edges of each box represent the upper and lower quartiles of the data. The error bars represent the range of the data that lies within 1.5 times the interquartile range; markers show outliers.
Figure 4.8: Box plot of area measurement error for irregular shapes
Horizontal lines across each box represent median error and the upper and lower edges of each box represent the upper and lower quartiles of the data. The error bars represent the total range of the data that lies within 1.5 times the interquartile range.

The mean error for ellipse orientation measurements was $2.69^\circ \pm 2.76^\circ$ (Figure 4.9). There was no significant difference in the mean errors with regard to orientation angle ($p=0.99$).
Figure 4.9: Box plot of orientation measurement error for elliptical shapes
Horizontal lines across each box represent median error and the upper and lower edges of each box represent the upper and lower quartiles of the data. The error bars represent the total range of the data that lies within 1.5 times the interquartile range.

We found no statistically significant difference when comparing the error in measurements of radius of curvature for navigated and manual measurements (p=0.3783). However, the mean error and standard deviation for navigated measurements was just -0.48 ± 6.07 mm, compared to 18.00 ± 42.72 mm for manual measurements (Figure 4.10).
Figure 4.10: Box plot of radius of curvature measurement error
Horizontal lines across each box represent median error and the upper and lower edges of each box represent the upper and lower quartiles of the data. The error bars represent the range of the data that lies within 1.5 times the interquartile range; markers show outliers.

We evaluated the intra-observer reliability of the system using a subset of three measurements: (1) an irregular shape with a nominal area of 3.53 cm$^2$, (2) the frontal plane curvature of a surface with a nominal radius of 60°, and (3) the sagittal plane curvature of a surface with a nominal radius of 15°. One subject performed the three measurements five times over a period of three days, resulting in an intra-class correlation coefficient of 0.996. We also evaluated the inter-class repeatability of the system by comparing the same subset of measurements taken by seven different subjects, and found an inter-class correlation of 0.998.
While no reference value was obtained for the frontal and sagittal curvature in the region of defects on the Sawbones knee, we analyzed the navigated measurements to evaluate variability and relative magnitude of measurements from the five femoral locations. Among frontal curvature measurements the range of standard deviations was 1.67 mm to 4.42 mm, and the largest variability resulted from anterolateral and anteromedial curvature measurements. We found a range of standard deviations from 0.99 mm to 7.79 mm for sagittal curvature measurements, also with the largest variability in measurements of anterolateral and anteromedial curvature.

Figure 4.11: Box plot of frontal curvature measurements from a Styrofoam knee
Horizontal lines across each box represent median error and the upper and lower edges of each box represent the upper and lower quartiles of the data. The error bars represent the range of the data that lies within 1.5 times the interquartile range; markers show outliers.
Figure 4.12: Box plot of sagittal curvature measurements from a Styrofoam knee
Horizontal lines across each box represent median error and the upper and lower edges of each box represent the upper and lower quartiles of the data. The error bars represent the range of the data that lies within 1.5 times the interquartile range; markers show outliers.
4.3 Discussion

In this study, we tested the hypothesis that defect size, location, and orientation would affect subchondral bone contact in oval defects. Furthermore, we predicted that different thresholds for significant subchondral bone contact would be exhibited for each defect group. We found that defect size, location, and orientation each had a significant effect on subchondral bone contact. An interaction effect between defect size and location was found to be significant, as an increase in defect size resulted in a larger increase in contact for lateral defects than what was observed from a similar increase in size for medial defects. Similarly, the interaction effect between defect size and orientation was significant, as an increase in defect size resulted in a larger increase in contact for ML defects than what was observed from a similar increase in size for AP defects. In addition, we found that significant contact occurred at different sizes for each of the four defect groups. Thresholds were below 2 cm$^2$ for both ML oval groups and for the lateral AP group, while significant contact did not occur in defects as large as 2.88 cm$^2$ for the medial AP group.

There are a number of limitations to our approach. The experimental loading procedure attempted to ensure equal contact between medial and lateral compartments while under static loading via visual representation on the Tekscan software and, although adjustments were made, equal distribution was never perfectly achieved. Similar to the approach of previous biomechanical studies of tibiofemoral contact in cadaver knees (Brown et al., 1991; Lefkoe et al., 1993; Nelson et al., 1988), the menisci were removed from all specimens. Though this was done to obtain usable contact
readings from in and around the defects, it does not represent in vivo loading, in which the femoral cartilage may articulate with part of the meniscus as well as the tibial surface. Given these limitations, the results may be different with intact menisci and under dynamic loading conditions.

Another potential limitation of the study is the use of bovine specimens rather than human cadaver knees. While there is significant interspecies variability between most articular cartilage animal models (Athanasiou et al., 1991), and the bovine stifle joint is larger than the human knee joint, similarities in condyle geometry and material properties do exist. The site-specific variation in condyle radius curvature in the human knee has been well-documented; the average radius of curvature of the lateral femoral condyle is smaller than that of the medial femoral condyle, and the sagittal plane radius of curvature differs from the frontal plane radius of curvature within each compartment (Ahmad et al., 2001; Koo & Andriacchi, 2007). We measured the bovine condyle surface curvature with an optical tracking system and custom software and discovered comparable radius magnitudes to that of human knees. Average bovine femoral condyle radius of curvature values ranged from 20 mm to 49 mm, while the range of curvatures from previous studies of human femoral condyles was found to be 21 mm to 38 mm. (Ahmad et al., 2001; Koo & Andriacchi, 2007). A previous study reported bovine radius of curvatures on the order of 30 mm, which is similar to the average curvature that we measured (Raimondi & Pietrabissa, 2005). Our measurements also showed consistent differences in radii of curvature between the medial and lateral condyle and between the frontal and sagittal plane within in each compartment. In addition, bovine articular cartilage material
properties (Martin, 1998) and cartilage thickness (An & Freidman, 1998; Kaab et al., 1998; Martin, 1998) are comparable to that of human articular cartilage. The similarities in condyle geometry and material properties, quantities that influence contact mechanics, between bovine and human knees suggest that similar contact trends may be seen in the human knee, possibly leading to different subchondral bone contact thresholds based on defect location and orientation.

We examined the effect on subchondral bone contact in a simple non-circular shape in only two orientations, which does not encompass all clinically observed defects. However, while irregular and nonsymmetrical defects are common, the defects used in this study may be more representative of defects observed in a clinical setting than previous in-vitro studies that have only used perfectly circular defects, (Brockmeier et al., 2009; Brown et al., 1991; Guettler et al., 2004; Jackson et al., 2001; Lefkoe et al., 1993). We believe that our study is the first to use non-circular defects in biomechanical testing of cartilage defects, and our results justify future work examining other defect geometries and orientations.

In this study, as well as in our previous study examining circular defects (Brockmeier et al., 2009), we found higher subchondral bone contact in the lateral compartment than in the medial compartment. Furthermore, there was significantly higher contact in ML defects compared to AP defects. In healthy and osteoarthritic knees in neutral alignment, pressures have been shown to be higher in the lateral than medial compartment (Agneskirchner, et al., 2007; Koo & Andriacchi, 2007; Riegger-Krugh et al., 1998). The radii of curvature between the medial and lateral femoral condyles and
tibial plateaus may create different contact mechanics, which could affect contact within a defect. The disparity in contact between ML and AP defects could also be a result of differences in radii of curvature in the frontal and sagittal planes within each compartment. This finding also agrees with our clinical experience of narrow cartilage tears oriented in the ML direction to be more deleterious, as opposed to those oriented in the AP direction. Future studies should investigate the influence of condyle curvature on subchondral bone contact and possible relationships between condyle curvature and clinical outcome.

Recent biomechanical and clinical research has brought into question the current use of 2 cm² as the threshold area for dictating focal cartilage defect repair (Guettler et al., 2004; Knutsen et al., 2004). Recent clinical studies have shown that the threshold size for determining the appropriate surgical treatment is potentially larger than 2 cm², as successful outcomes have been reported in studies evaluating microfracture surgery on defects larger than 4 cm² (Blevins et al., 1998; Gobbi et al., 2005; Knutsen et al., 2007, 2004; Steadman et al., 2003). Though clinical algorithms for management of such defects often consider patient-specific factors such as patient age, demand level, body mass index, response to previous treatment, and the presence of cofactors such as malalignment, ligament insufficiency, and meniscal deficiency (Buckwalter & Mankin, 1998; Cole & Lee, 2003; Cole et al., 2009; Minas, 1999; Minas & Nehrer, 1997; Nehrer et al., 2004), defect characteristics other than the area of a defect are not generally considered. Some algorithms prescribe different treatment pathways for femoral and patellofemoral defects (Alford & Cole, 2005; Cole et al., 2009; Lewis et al., 2006; W.N.
Scott, 2005), but no distinction is made between suggested treatment paths for medial and lateral femoral condyle defects or defects of different orientations. The present study suggests that defect location (i.e. medial or lateral femoral condyle) and orientation may influence patient outcome as well. Interestingly, significant subchondral bone contact did not occur for AP defects on the medial condyle as large as 2.88 cm², while each of the other defects reached significant contact at different points below 2 cm². Although it has yet to be investigated in a prospective, randomized fashion, the existence of multiple size thresholds based on defect location and orientation could translate to more predictable and improved clinical success of cartilage defect repair.

While surgical algorithms primarily use defect area to guide cartilage repair, our results suggest that defect location and orientation, in addition to area, influence contact within a defect. While we do not suggest that the thresholds reported in this study in a bovine knee should map directly to the human knee, we believe that the apparent dependency of subchondral bone contact on location and orientation may also be observed in human knees. Our discovery of different size thresholds based location and orientation of a defect challenges current surgical algorithms, which use defect area as the primary factor to guide surgical decision-making. Future work, including biomechanical studies with human cadaver knees and longitudinal clinical studies evaluating patient outcomes, should determine whether patient outcomes would benefit from modifications to clinical algorithms to account for cartilage defect location and orientation.
CHAPTER 5:

CONCLUSION

It is commonly believed that progression of a focal cartilage defect is greatly influenced by defect size, and thus defect area is a key component in guiding surgical decisions in the presence of a focal defect (Cole et al., 2009). Although progression to osteoarthritis is not totally understood, it has been proposed that changes to both the cartilage and the underlying subchondral bone may cause deterioration due to altered loading patterns of the tibiofemoral joint (Minas et al., 2009). We previously showed that defect location may be an important factor, as subchondral bone contact was significantly different in the medial and lateral compartments during static loading of circular defects (Brockmeier et al., 2009). The difference in condyle shape between the medial and lateral compartments was suggested as a possible cause of this disparity in subchondral bone contact. Geometrical differences also exist in the medial-lateral and anterior-posterior directions on both condyles (Koo & Andriacchi, 2007). Because cartilage defects are often non-circular and irregular in shape, it is possible that irregularly shaped femoral cartilage defects located on non-spherical condyles might lead to different loading conditions for defects of varying size, shape, and location.
Furthermore, current arthroscopic methods of defect measurement are lacking in accuracy and repeatability (Oakley et al., 2003, 2002), and are restricted to measurements of area alone, as defect shape and condyle curvature have not been considered to be critical measures. While freehand measurements of circular defects may provide reasonable estimates of defect size, there are limitations in the measurement of irregularly shaped defects, even with the use of imaging techniques such as MRI and CT (Graichen et al., 2005).

We have presented the results of a study evaluating the effect of defect size, orientation, and location on subchondral bone contact during static loading of bovine knees. The results of this study then motivated the development a surgical navigation system dedicated to the measurement of articular cartilage defects in the knee, including size, shape, orientation, and condyle curvature. We then characterized the accuracy and variability of navigated and manual measurements of simulated cartilage defects and femoral condyles, and showed smaller error and variability associated with navigated measurements.
5.1 Contributions

The main contributions of the research presented in this thesis are:

**Investigation of defect-specific factors contributing to subchondral bone contact.**
Accepted clinical algorithms for treating focal cartilage defects use defect area as the primary factor to decide on appropriate repair strategies. Although the natural history of focal cartilage defects is not entirely understood, subchondral bone changes may influence defect progression to osteoarthritis. We showed that cartilage defect area, location, and orientation affect the amount of subchondral bone contact within a defect for oval-shaped defects in a bovine model. We also determined the defect area threshold at which subchondral bone contact was consistently high enough to confidently declare it different from zero. Each of the four combinations of defect location and orientation exhibited a different area threshold.

**Creation of an image-free surgical navigation system dedicated to cartilage repair.**
A number of orthopaedic surgical navigation systems exist, both for research use and in clinical practice. We developed the only cartilage defect navigation system that is not affiliated with a medical device company. Our system is also the only one that measures defect orientation and condyle curvature. The navigation system was created using MATLAB, a common programming package that allows for the addition of features as necessary. We also devised a novel non-invasive method of fixing reference frames to bone, a necessity for the use of surgical navigation in arthroscopic surgery.
Comparison of navigated and manual measurement error in sizing cartilage defects.

Measurement of a cartilage defect area by visual inspection has been shown lack accuracy and repeatability. As part of the validation study of the defect navigation system, we investigated the error associated with manual measurements of simulated defect and condyle curvature. Our results confirm the inaccuracy and poor repeatability of manual measurements and demonstrate significant improvements when sizing a defect region with the use of our navigation system. Measurements performed using the navigation system were more accurate and more repeatable, regardless of shape. We also exhibited the ability to perform accurate measurement of condyle curvature using the navigation system, a task that presented challenges when conducted by visual inspection.
5.2 Additional Applications

This thesis presents the development of a surgical navigation system that provides the opportunity to further investigate defect- and joint-specific factors affecting clinical outcome in cartilage repair.

Influence of tibiofemoral conformity on subchondral bone contact. Results of two previous studies investigating defect-specific factors affecting subchondral bone contact have led us to hypothesize that tibiofemoral conformity, the difference in radii of the femur and tibia, at the location of a defect may play a role in dictating contact mechanics. Although higher subchondral bone contact has been found in regions that have poor tibiofemoral conformity, we have been unable to quantify this measure. We now have a system that can accurately measure condyle curvature, which can be implemented in human and animal cadaver studies similar to our previous work. This will enable us to directly investigate the impact of condyle curvature on subchondral bone contact during joint loading.

Interaction effects of defect shape, orientation, and condyle curvature on subchondral bone contact. Our previous work investigating the effects defect shape, orientation, and location on subchondral bone contact revealed significant interactions among these factors. Oval-shaped defects oriented in the medial-lateral direction located on the lateral condyle led to significantly higher contact than anterior-posterior defects on the same condyle and medial-lateral defects on the medial condyle. Again, we suspect
that these phenomena are due to a combination of orientation, shape, and tibiofemoral conformity, but have been unable to provide evidence to support this hypothesis. We now have a system to accurately characterize each of these factors.

A parametric study would allow us to determine how combinations these factors affect subchondral bone contact in cadaver knees. In addition, we have limited our investigation of defect shape and orientation to simple, repeatable shapes oriented in the medial-lateral and anterior-posterior directions, as measurement of shape and orientation has not been possible. We can now investigate multiple shapes and orientations to reveal possible thresholds beyond which point subchondral bone contact becomes significant.

**Investigation of shape, orientation, and curvature on defect healing in animals.**

Previous studies have investigated how defect area affects the ability of cartilage defects to spontaneously heal in live animals. These studies have been important in establishing defect area as a crucial element to clinical outcome. However, the inability to accurately measure other factor has limited out knowledge of how these factors might also influence outcome, so that defect area is currently the only factor included in clinical algorithms for defect repair.

A study investigating the healing response of fully characterized defects could provide important data to either confirm or contradict the use of defect area alone to prescribe different cartilage repair surgeries. In live animals, we could surgically create various defects of known area, shape, and orientation located on condyles of known radius of curvature, allowing spontaneous healing to occur. Additionally, we could
perform various cartilage repair procedures on live animals with fully characterized defects and investigate association between outcomes and defect factors.

**Implementation of custom reference frame attachment to other navigation systems.**

We chose to avoid the use of bicortical screws for attaching reference frames to bone because of complications that can occur and to maintain the less-invasive nature of arthroscopic surgery. Although no formal testing of the device has been performed, the needle-stem attachment that we developed does not require open access to bones because the needle is applied percutaneously, and most likely would prevent complications that can occur with the use of bicortical screws (Bonutti et al., 2008; Ong et al., 2009). However, we believe that the main advantage of this attachment method is the rapid means of tracker fixation that could be implemented in other surgical navigation systems and surgeries. One of the challenges to the adoption of navigated surgeries is the additional time required to prepare a system and patient, and any means of time-saving could be beneficial. The adoption of our novel fixation method to other types of navigated surgeries in orthopaedics could improve intraoperative times.
5.3 Future Work

Future work will include further development of the navigation system and implementation in an orthopaedic practice.

**Creation of an image-based surgical navigation for defect identification.** After cartilage repair surgeries, the least invasive means of follow-up examination is accomplished with the use of radiographic imaging. Post-operative follow-up is an important step in the rehabilitation procedure, as knowledge of the state of a repaired defect is crucial. While arthroscopic examinations are very effective in locating and identifying cartilage defects, visualizing cartilage defects with MRI and CT poses difficulties. Implementation of image-based capabilities in our system could provide a solution to this problem. During surgery, the location of the defect in the femur coordinate system could be stored. By performing a registration of the femur anatomical coordinate system with the coordinate system of a post-operative MRI, the location of a defect could be identified in the image. Whereas the location of a defect in multiple radiographic images taken during subsequent clinical visits may be different, a defect is stationary in the femur coordinate system since it is based on anatomical landmarks. Transforming the defect location into image space would facilitate defect identification for imaging procedures occurring at different time periods.

**Three-dimensional visualization defect contact during articulation.** While arthroscopy is the gold standard for identifying and examining a cartilage defect in the
knee, the extreme magnification of intra-articular structures and the “aquarium effect” that occurs (Strobel, 2002) lead to difficulties in visualizing tibiofemoral kinematics and contact near a defect. Furthermore, visualization of defect contact during articulation of the femur on the tibia is difficult due to the limited field of view of the arthroscope in the knee.

Almost every patient that is a candidate for cartilage repair receives a pre-operative diagnostic MRI, and methods to create three-dimensional models of bones from derived from radiographic images have been developed. This provides the opportunity to improve visualization of tibiofemoral interaction near a defect. We would first create a three-dimensional solid model of the knee using pre-operative MRI data. During a diagnostic examination, the location, shape, and orientation of the defect in the femur coordinate system could be stored and, following a registration of the femur anatomical coordinate system to the coordinate system of the three-dimensional model space, a representation of the defect could be transformed onto the femur model. During surgery, position and orientation data from the navigation system could be used as an input to a three-dimensional model to visualize contact and articulation at the defect site during normal flexion and extension.

**Longitudinal clinical studies of articular cartilage progression to osteoarthritis.** The association between focal cartilage defect and the progression of osteoarthritis is not fully understood, and, for that reason, is the subject of large number of biomechanical and clinical studies. The majority of patient with symptomatic focal defect undergo
arthroscopic diagnostic examinations before any surgical action is taken. Unfortunately, revision surgeries are often required after the failure of one procedure and, over time, degenerative osteoarthritis often results. Implementation of our navigation system in an orthopaedic practice would allow repeated observation and measurement of cartilage defects as progression occurs. The ability of the system to accurately characterize the defect and affected condyle would allow longitudinal tracking on a large scale, as cartilage defect repair is very common. Information gained from such a study could help elucidate factors that are associated with failed repair and, conversely, with successful surgeries, to provide better clinical algorithms that are based on historical outcomes.

**Application to surgical cartilage repair procedures.** The shape of a defect is also of interest for surgeries that require tissue-engineered scaffold to be placed in the defect, wither as cartilage replacement or for protection of young, regenerating cartilage. For example, the autologous chondrocyte implantation (ACI) procedure makes use of a collagen membrane to cover implanted cells within a defect, both for protection and to seal the defect. Defect shape could be digitized during an arthroscopic diagnostic examination and a template prepared for creating a membrane just larger than the defect.

Another application for which the navigation system could improve surgery is during osteochondral auto/allograft preparation and implantation. One of the critical elements of the procedure is the harvesting of an auto/allograft with similar curvature to that of the defect site, as the best outcomes occur when the native and implanted cartilage surfaces become integrated. A proud or recessed auto/allograft can be problematic. The
accurate measurement of condyle curvature provided by our system would enable improved matching of surface curvatures.

Placement of the auto/allograft in the recipient site is equally critical, as misaligning a graft can result in increased contact pressure both on the graft cartilage surface and on the opposing surface. A tool could be developed to ensure that the alignment of implant grafts is perpendicular to the condyle surface, using the navigation system to determine the normal surface vector.
5.4 Summary

Clinical and biomechanical research has made great strides to improve the diagnosis and repair of focal cartilage defects, and yet a number of important questions remain unanswered. We have yet to fully identify the factors which influence cartilage repair success, and therefore the current clinical algorithms for such surgeries are not based on solid evidence and often lead to failed repairs. The relatively low success and predictability of cartilage repair surgeries indicates that current research methods may be inadequate.

The goal of this thesis is to introduce research methods, utilizing surgical navigation, to investigate defect-specific factors that may influence clinical success, but have not been studied previously. In other areas of orthopaedics, surgical navigation systems have permitted the exploration of new concepts to improve surgical procedures and, ultimately, to identify sources that might improve outcome. The use of surgical navigation systems can provide a medium for the synthesis of biomechanics and clinical research that I believe is necessary to fully reveal the causes of surgical outcome, successful or otherwise. By applying the capabilities provided by surgical navigation to the field of cartilage repair, we believe we can improve cartilage defect diagnosis, better characterize cartilage defects, improve the performance of current procedures, and develop new procedures that would otherwise not be possible.
References


Appendix A:
Validation Test Protocol
Cartilage Defect Navigation System Validation

This validation testing aims to evaluate the key functions of the Cartilage Defect Navigation System, namely the ability to quantify a cartilage defect region. This includes the measurement of:

a. any arbitrary distance within the Polaris measurement volume
b. the total area of a simulated cartilage defect
c. the maximum width of a simulated cartilage defect, with width being defined as the distance across the defect in the medial-lateral direction
d. the maximum length of a simulated cartilage defect, with length being defined as the distance across the defect in the anterior-posterior direction
e. the orientation of a simulated cartilage defect, with orientation defined as the angle between the principal axis of the defect and the medial-lateral axis
f. the radius of curvature of a three-dimensional curved surface

Instructions for digitizing points:

a. The tip of the probe should be placed on the base and up against the wall of the simulated defect.
b. Place the probe tip in the desired location, press the footswitch until it clicks, and then release.
c. Both the probe tracker and the femur tracker must be visible or the point will not be collected. If the point was successfully collected, you will see a green indicator light. If one of the trackers was not visible, you will see a red indicator light, meaning the point was not taken. If the footswitch was not activated, nothing will happen, as the system did not receive any input, and the indicator light will remain yellow.

Validation Procedure

Part 1 – manual measurement

1) Using the provided measurement tool, perform and record all measurements in the box labeled “Part 1 – manual measurements” of Validation Tables.xls.
Navigation system preparation

1.) Open DefectNav.fig on the desktop
2.) Initialize system
3.) Enter your test identification number and the appropriate data
4.) Perform registration, using the points marked on the validation plate and the following instructions:
   a. HC is hip center
   b. KC is knee center
   c. Digitize medial and lateral epicondyles according to the labels
   d. For the tibia registration, points can be taken anywhere, as they are not used in calculations

Part 2 – Navigation system – defect measurement

1.) Begin collecting data
2.) The order of simulated defect measurement is provided in Validation Tables.xls
3.) Trace the first defect with the probe, attempting to digitize points as close together as possible around the rim of the base of the defect.
4.) When digitizing has completed, view the Report to ensure that defect shape data was collected.
5.) If data collection was successful, export the data, selecting only area, orientation, mlwidth, and apwidth.
6.) In the filename, include both the shape name and your ID (such as ‘C1_participant1.xls’).
7.) Repeat steps 6-9 for the rest of the shapes.

Part 3 – Navigation system – curvature measurement

1.) Select the appropriate function button depending on the block currently being used.
2.) Digitize points on the first surface of the curvature block, making sure that the block does not shift or rotate. Take between 20 and 30 points for each surface, and attempt to use a different number of points for each surface.
3.) When digitizing has completed, view the Report to ensure that the correct radius data was collected.
4.) If data collection was successful, export the data, selecting only the radius value that was just collected.
5.) In the filename, include both the shape name and your ID (such as ‘h_participant1.xls’).
6.) Repeat steps 6-9 for the rest of the shapes.
Appendix B:
Reference Frame Attachment Part Drawings
Figure B.1: Straight tracker post part drawing
Figure B.2: 45° tracker post part drawing
Figure B.3: 90° tracker post part drawing
Figure B.4: Needle housing coupler part drawing
Figure B.5: Custom reference frame attachment assembly