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Thesis Abstract

It is estimated that 30 to 40 percent of adults who participate in sports experience hip pain (Langhout et al., 2019; Thorborg et al., 2017). Additionally, roughly one in four people will be diagnosed with symptomatic osteoarthritis in their lifetime (Murphy et al., 2010). Due to the hip joint's integral role in many everyday processes such as walking and bending, it is imperative that the health of the joint be maintained. While various treatments for hip pain exist currently, some patients require extra support while participating in athletic activities, even after surgical intervention such as hip arthroscopy. Current bracing methods available in the market include postoperative stabilization braces, joint unloading braces, and compression wraps (Kemker et al., 2021). However, none of these solutions contain all the desired properties for an athletic hip brace. This thesis sets out to develop a novel hip brace that can be worn during athletic activity, while still providing pain relief and alignment correction to the hip joint. The methods used to create said hip brace are outlined, and then the case study performed to investigate the brace's efficacy at meeting certain design criteria and outcome measures is discussed. The case study shows that the brace has promising results in the comfort and task initiation categories, but needs improvement in the area of hip alignment correction. In conclusion, with a few modifications in future research, the novel hip brace designed in this thesis has the potential to help millions of people get back to participating in athletic activities even after hip injury.

Chapter 1. Introduction and Background

Chapter 1 highlights the motivation for this thesis project and introduces essential background information to understand what problems this project tries to resolve. Additionally, the main objectives and goals of this project are introduced.

1.1 Motivation

It is estimated that 76 million people suffer from hip pain in the United States, with one in four people developing symptomatic osteoarthritis in their lifetime (Murphy et al., 2010). Osteoarthritis cases are expected to increase in the coming decades in correlation with an increasingly aging population (Fuchs et al., 2017). Osteoarthritis is not the only cause of hip pain, however. Most hip injuries that arise in younger patients and athletes under 50 years old are due to other causes such as impingement, muscle strains or tears, or damage to cartilage (Bowman et al., 2010). Labral tears in particular have become increasingly prevalent in athletes, specifically in those that play sports that require highly repetitive motions such as a catcher in baseball or softball (Torry et al., 2006). The labrum is a ring of cartilage that helps secure the femoral head in the hip joint, and damage to it can lead to hip instability, translation of the femoral head instead of rotation, and pain (Bowman et al., 2010).

Hip injuries not only cause pain and discomfort to the patient, but also can fundamentally change the mechanics of the hip, with one of the most common causes of hip pain being a decreased external hip adduction moment (Diamond, Allison, et al., 2018; Rutherford et al., 2018). When hip pain occurs, some patients present with increased hip adduction as the knee moves medially towards the midline. Additionally, decreased range of motion in all planes can be observed in hip injury patients, with the

restricted range of motion plane changing based on the location of the injury in the hip joint (Diamond, Allison, et al., 2018). Without prompt correction, these changes can alter gait mechanics even after the source of the pain is alleviated (Schmitt et al., 2015). Therefore, there is a great need to alleviate hip pain and restore a natural gait in patients experiencing hip pain.

Although various rehabilitative techniques exist to treat hip injuries, some patients experience residual pain after treatment and require further treatment or assistance to regain full function of their joint. In an investigation about return to sport rates after hip arthroscopy, researchers found that roughly 70.3% of high school athletes and 80.0% of collegiate athletes return to their sport after hip arthroscopy, but all of those who failed to return attributed their decision to symptoms in their previously-operated on hip (Perets et al., 2018). Additionally, 76.9% of those who did not return to sports stated that they did so to prevent secondary injuries to their hip (Perets et al., 2018). This is an indication that there is a population of athletes that would consider returning to sports if they had protective measures in place to reduce the likelihood of reinjury. Returning to sports or exercise after hip arthroscopy has been shown to improve patient outcomes and lower pain visual analog scale (VAS) scores (Hauer et al., 2002; Perets et al., 2018). In this thesis, a case study is performed to determine the efficacy of the brace in increasing the peak hip adduction moment, and alleviating pain within the hip joint during athletic activity and at rest.

1.2 Background

The hip joint is unique in that it is rarely completely unloaded, and therefore it is almost constantly under stress. Due to the hip joint’s integral role in many different

processes, it is imperative that the health of the joint is maintained. Once pain is experienced by the patient, measures must be taken to alleviate it and restore the natural mechanics of the hip. Hip joint pain and injury can severely impair an athlete's ability to perform at their maximum potential, so there is much interest in the field of sports and rehabilitation engineering to create solutions to help those injured get back to doing what they love, no matter their playing caliber.

Treatment for hip pain varies based on the cause of the pain. For less serious injuries such as a muscle strain, rest, anti-inflammatories and in some cases, physical therapy are all that is needed to resolve the hip pain. However, more serious injuries can require surgical intervention. For example, if impingement is severe, a surgeon can perform an arthroscopy and shave off the excess bone so that there is no longer impingement within the joint. Labral tears are also capable of repair in arthroscopic surgery, and depending on the severity of the tear, the surgeon can either remove, repair, or replace the damaged labrum within the hip joint. Postoperative bracing is utilized to restrict the range of motion while the structures inside the hip joint heal but is typically ceased within 2 weeks pending surgeon approval (Cvetanovich et al., 2017).

After treatment and rehabilitation under the supervision of physicians, injured athletes are eventually permitted to resume athletic activities. In some cases, athletes never return to their pre-injury gait pattern or level of joint stability (Sogbein et al., 2019). With this in mind, functional bracing options, suitable for athletic activity are essential for these populations. In the current market, there are few options for affordable, readily available athletic hip braces. Additionally, those that do exist offer minimal support and are comparable to elastic bandages. A more aggressive bracing option is to wear a

post-operative brace, such as the DonJoy VersaROM® Hip Brace (DJO Global, Lewisville, TX), but they are oftentimes far too bulky and almost completely restrict side to side movement as well as hip abduction, adduction, flexion, and extension, depending on the settings of the brace. Therefore, there is a need for a device that bridges the gap between the current market options that is compatible with athletic activity.

1.3 Objective

The goal of this project is to develop a hip brace that was designed specifically for use in athletic activity. Additionally, the second goal was to test said device's efficacy at restricting range of motion in the lateral plane, while remaining comfortable for the patient. This thesis differed from a "traditional" thesis and had workload distributions that focused more heavily on the iterative design portion of the project as detailed in CH# with less intense data driven analysis when compared to "traditional" research focused theses. Chapter 2 further expands upon types of hip injuries as well as clinical assessments of hip pain and current treatments and solutions to hip pain. In Chapter 3, how the hip brace was designed and then created is discussed. Chapter 4 describes a case study that was performed to determine the efficacy of the brace, as well as its results. Then, Chapter 5 presents the conclusion of this thesis as well as various potential future directions for this project as well as hip brace design.

Chapter 2. Literature Review

Chapter 2 consists of a review of rehabilitation from hip injuries and various techniques and devices implemented during rehabilitation. The first section outlines various types of hip injuries, while the following discusses hip pain assessments that clinicians use to diagnose and determine the severity of injuries. The third section introduces treatment options for hip injuries and the fourth section discusses devices implemented during recovery. Finally, the fifth section discusses the problem statement of this thesis.

2.1 Types of Hip Injuries

Various types of hip injuries occur, but three major hip pathologies are outlined in this section. Osteoarthritis, femoroacetabular impingement, and acetabular labral tears will be discussed.

2.1.1 Osteoarthritis

Arthritis is a large category of diseases that are associated with joint pain, swelling, and stiffness. The two most common forms of arthritis are osteoarthritis and rheumatoid arthritis (Park et al., 2018). Rheumatoid arthritis (RA) is an autoimmune disease characterized by symmetrical symptoms (for example both the left and right hands having RA), synovial inflammation, hyperplasia, and autoantibody production which leads to cartilage and bone deformation (Mcinnes & Schett, 2011). To determine whether a patient is suffering from RA or osteoarthritis, physicians can conduct a blood test to see whether a patient falls within the normal ranges for their rheumatoid factor, complete blood count, and C-reactive protein (Lespasio et al., 2018). Results that fall within the expected range mean that the patient likely is suffering from osteoarthritis,

and abnormal results generally indicate that the patient is suffering from RA or another form of arthritis that affects the immune system (Lespasio et al., 2018).

Osteoarthritis (OA) is characterized by the deterioration of the articular cartilage at the end of bones within any joint in the body and can lead to extreme joint pain (Buckwalter et al., 2004). A depiction of how osteoarthritis affects articular cartilage can be seen below in Figure 1. In the healthy joint, there is adequate space between the acetabulum (also known as the joint socket) and the femoral head, denoted by the solid green section, and the articular cartilage on the femoral head is intact. In the osteoarthritic joint, there is significantly less joint space denoted by the solid red band between the femoral head and the acetabulum. Additionally, the articular cartilage deteriorates, exposing the bone on the femoral head, leading to damage (Lespasio et al., 2018).

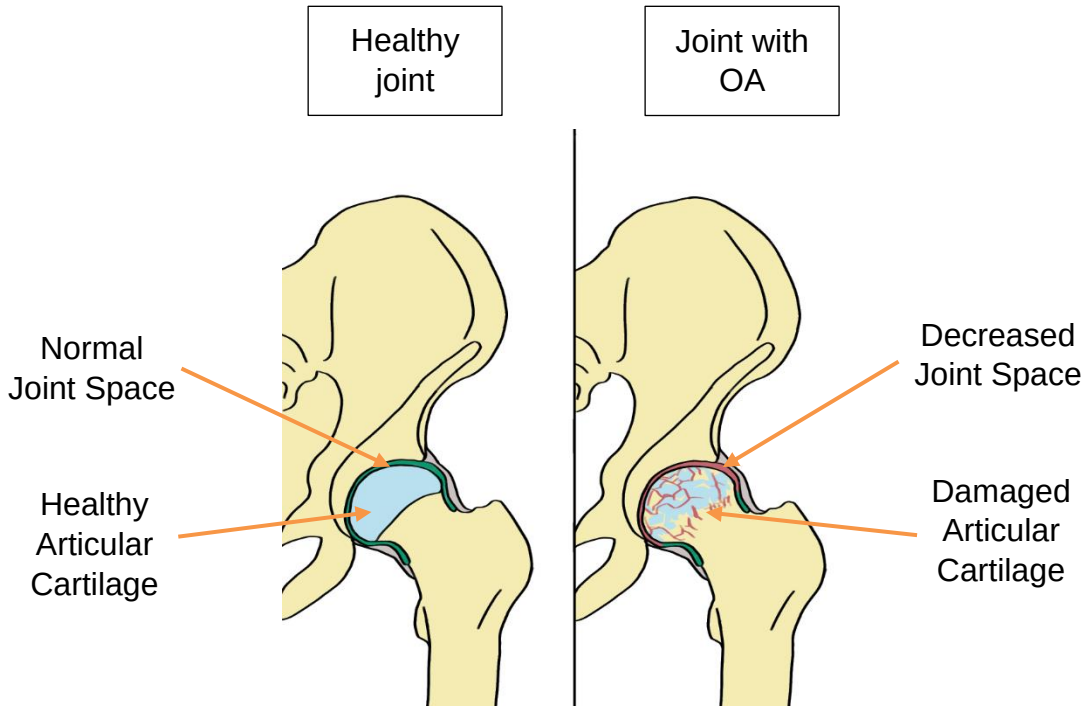


Figure 1. Healthy joint vs. joint with osteoarthritis (OA). This image depicts an unhealthy joint with decreased joint space and degenerated cartilage, and a healthy joint with undamaged structures.

One's risk for developing OA depends on a range of factors including age, gender, body mass, previous joint injury, and occupation (Zhang & Jordan, 2008). While most people who have OA are over the age of 50, some can develop the disease at an earlier age due to joint injuries or bone defects. Local risk factors such as trauma and joint dysplasia can increase an individual's likelihood of developing OA (Lespasio et al., 2018). Those assigned male at birth comprise the majority of OA patients under 50 years old, while people assigned female at birth comprise the majority of OA patients over 50 years old (Felson, 1988). Moderate intensity exercise and strength training focused on muscles surrounding high-use joints such as the knee and hip can help reduce an individual's likelihood of developing OA (Bennell & Hinman, 2005; Hunter & Eckstein, 2009). Degradation of the articular cartilage can lead to bone-on-bone contact, which is painful for the patient and harmful for bone health (Lespasio et al., 2018).

Typical symptoms of osteoarthritis include pain and stiffness that is typically worst in the morning and after prolonged periods of rest, a locking, clicking, or grinding sensation in the affected joint during movement, and decreased range of motion in all planes (Hunter et al., 2008; Lespasio et al., 2018). OA can also cause pain while performing movement. OA is diagnosed by physicians in a variety of ways. A physical examination generally occurs first, where the clinician observes the patient's gait as well as their passive and active range of motion (Hunter et al., 2008). A comparison of leg lengths and palpitation of the affected hip also occurs (Lespasio et al., 2018). Largely, osteoarthritis in the hip can be diagnosed through clinical presentation, but radiographic imaging can be valuable for diagnosis confirmation and monitoring of the progression of

OA (Murphy et al., 2010). X-ray images are the most commonly used imaging technique for OA diagnosis confirmation, but computer tomography and magnetic resonance imaging are also used in cases such as surgical planning (Lespasio et al., 2018).

The most commonly used scale for determining the severity of OA in patients is the Kellgren and Lawrence (K&L) grade (Ball et al., 1963). The K&L grade is a scale ranging from 0 to 4, with grade 2 through 4 describing radiographic OA, or OA that can be confirmed via radiographic images. Grade 0 is associated with the absence of OA, while grade 1 is associated with doubtful joint space narrowing and marginal osteophyte (bone spur) formation on the femoral head (Lespasio et al., 2018). In grade 2 (mild OA), there is definitive joint space narrowing, slight osteophyte formation on the femoral head, and a small amount of subchondral bone thickening (subchondral sclerosis) (Kohn et al., 2016). Grade 3 outlines the symptoms of moderate OA such as significant narrowing of the joint space, small femoral head osteophyte formation, moderate subchondral sclerosis as well as cyst formation, as well as deformation of the acetabulum and femoral head (Lespasio et al., 2018). Grade 4 (severe OA) is characterized by almost complete elimination of the joint space, large osteophyte formation, definitive deformity of the femoral head and acetabulum, and marked subchondral sclerosis and cyst formation (Kohn et al., 2016). Later stage OA is also associated with reduced muscle volume of the gluteus maximus, minimus, and medius, and has been suggested to be related to the reduction in hip abduction and internal rotation strength (Zacharias et al., 2016).

2.1.1.1 Biomechanical Impact

Osteoarthritis can cause extreme pain for those who suffer from it while performing everyday tasks such as walking. While the pain associated with OA is potentially severe, it is not the only side effect of the disease. End-stage OA is associated with a lower walking velocity than asymptomatic OA patients (Eitzen et al., 2012; Queen et al., 2016). Additionally, OA can cause changes in gait, such as decrease in the sagittal plane range of motion through reduced hip extension (Eitzen et al., 2012; Kumar et al., 2015). When a person has reduced hip extension, they have a shorter stride and cannot let their leg extend very far behind their body. OA can also cause an increase in hip adduction, partially due to a decrease in hip abductor mass and strength (Zacharias et al., 2016). An increase in hip adduction causes the knee to move towards the midline of the body (towards the unaffected knee), and can cause hip and even secondary knee pain for the patient (Hall et al., 2018; Neal et al., 2019). Figure 2 depicts the potential changes in hip adduction that can occur with OA.

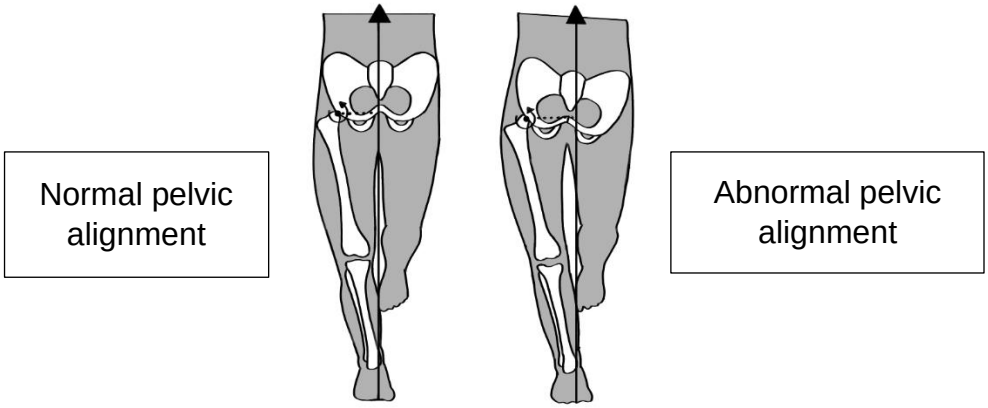


Figure 2. External hip adduction moment. This figure depicts changes within the hip joint due to an increased hip adduction angle. The external hip adduction moment is influenced by the distance between the hip joint and where the ground reaction force vector passes medial to the hip joint center.

Generally, OA is associated with a lower external hip adduction moment than control populations not experiencing OA (Hall et al., 2019). There are two main components to the external hip adduction moment— the moment arm and the ground reaction force. In Figure 2, the ground reaction force is shown by the large black arrow, while the moment arm is shown by the dashed line leading from the arrow to the hip joint. Moment is the product of the force and the distance of the moment arm (M = D x F), so increased hip adduction may increase the length of the moment arm from the ground reaction force vector, increasing the external hip adduction moment (Pohl et al., 2015).

Generally, OA is associated with a lower external hip adduction moment than control populations not experiencing OA (Hall et al., 2019). However, more severe OA often corresponds with magnified external hip adduction moment in patients with OA versus controls without OA (Wesseling et al., 2015). This is explained by the severe hip adduction position adopted by these patients, resulting in a greater lever arm when calculating external hip adduction moment (Pohl et al., 2015). compensating for the often reduced ground reaction force that is observed in patients with OA versus controls without OA (Wiik et al., 2017). This increased hip adduction can explain how sometimes a higher external hip adduction moment can be seen in patients with moderate OA versus mild OA despite similar ground reaction forces (Hall et al., 2018).

2.1.2 Femoroacetabular Impingement

Femoroacetabular impingement, also known as FAI, is a bone condition that can alter the structure and anatomy of the hip joint, leading to repetitive contact between the femoral neck and acetabular rim (Banerjee & Mclean, 2011). FAI can be both congenital

or acquired (Fadul & Carrino, 2009), and is often cited as a potential cause of other conditions such as labral tears and OA (Banerjee & Mclean, 2011). In 2003, FAI was identified as one of the leading causes of osteoarthritis (Ganz et al., 2003). Symptoms of FAI include instability within the hip joint, hip pain, a locking or clicking sensation while walking, a pain when rotating the leg with the affected hip inward, as well as a decreased ability to do activities that involve hip flexion such as sitting or squatting (Byrd, 2014; Keogh & Batt, 2008).

There are two differing kinds of bone lesions that cause FAI, CAM and pincer lesions, although they often occur together within the same joint to form mixed CAM and pincer impingement (Banerjee & Mclean, 2011). Both CAM and pincer-type lesions can be seen in Figure 3 below. CAM lesion impingement is characterized by a thickening of the femoral neck, creating a smaller femoral head neck offset, while pincer lesion impingement is characterized by increased overhang of the acetabulum (Rhee et al., 2017). Both types of FAI are associated with symptoms the symptoms listed above, as well as biomechanical changes in gait (Banerjee & Mclean, 2011). FAI can cause labral tears due to the lack of clearance between the bony structures within the hip joint, which results in the acetabular labrum getting pinched or gradually delaminated during hip flexion, leading to tears (Byrd, 2014).

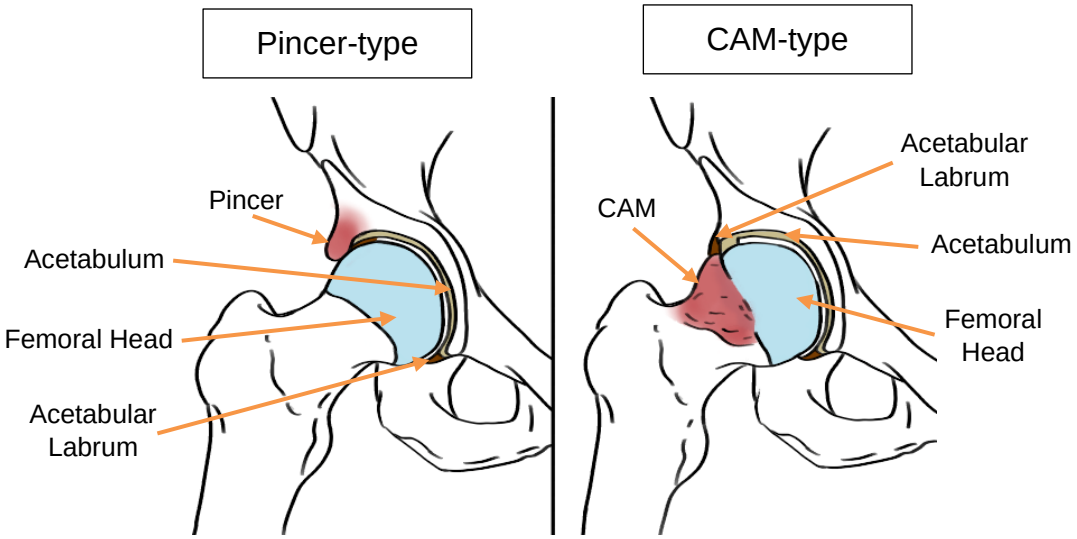


Figure 3. Pincer- and CAM-type impingement within the hip joint. Pincer-type impingement results in an overhang of the acetabulum, while CAM-type impingement is characterized by a thickening of the femoral neck.

Fewer known risk factors are associated with FAI than with osteoarthritis. Pincer lesions can be due to acetabular retroversion, which is a bone deformity that causes the superolateral acetabular rim to be angled posteriorly, thus obstructing hip flexion (Banerjee & Mclean, 2011). CAM lesions can arise from coxa vara, a non-spherical femoral head, femoral osteotomy, and poorly healed fractures of the femoral neck (Banerjee & Mclean, 2011). Increasing evidence has shown that femoral neck fractures are commonly caused through sport, which is a potential explanation why young men experience the highest risk for CAM-type impingement (Keogh & Batt, 2008).

While CAM and pincer lesions are sometimes present from birth, it is important to note that there are ways to reduce one's risk for furthering the development FAI. Implementing a pre-season screening program among athletes to determine if one is at risk of having FAI can be integral to minimizing further injury (Cakic & Patricios, 2014).

After identifying athletes that potentially have FAI, it is important to monitor and potentially limit involvement in sports that require a large amount of squatting or cutting (such as a catcher in baseball or an ice hockey player). This is one way to ensure that a malformed joint is not undergoing too much mechanical stress, which could lead to potential labral tears or a femoral neck fracture (Cakic & Patricios, 2014; Keogh & Batt, 2008).

FAI can be preliminarily diagnosed in a clinician's office with a physical examination (M. Philippon et al., 2007). In the exam, the physician will move the patient's leg in multiple different directions and induce rotation to determine where they experience pain and where the likely impingement is located (Byrd, 2014). Examples of tests done by the clinician are the log roll test, the FABER test (flexion-abduction-external rotation test), and the impingement test (Byrd, 2014; Rutherford et al., 2018). Outside of a physical examination, FAI can be diagnosed in a multitude of ways, including X-ray, computed tomogram (CT) scans, and magnetic resonance arthrography (MRA) (Banerjee & Mclean, 2011). However, the most used imaging techniques for diagnosing FAI are X-ray and MRAs, as FAI is generally accompanied by labral tears and labral tears are diagnosed via MRA (Groh & Herrera, 2009; Rhee et al., 2017).

2.1.2.1 Biomechanical Impact

FAI can affect hip biomechanics as well as related structures' biomechanics such as the trunk while performing certain movements (Diamond, Bennell, et al., 2018). While in a deep squat, in the sagittal plane there is decreased hip internal rotation as well as decreased posterior pelvic tilt in patients with FAI (Bagwell et al., 2016). Decreased range of motion in internal hip rotation has been identified as one of the leading factors

that limits performance (Bizzini et al., 2007). Additionally in the sagittal plane, patients with FAI walking up a set of stairs exhibit a significantly larger trunk forward flexion angle than those without FAI (Hammond et al., 2017). FAI has been associated with a decreased sagittal plane hip range of motion (Diamond et al., 2016). While walking across level ground, no differences in external hip adduction moment were observed between patients with and without FAI (Diamond, Bennell, et al., 2018), but the symptomatic group had abnormal hamstring and gluteus maximus activation when compared to the group without FAI (Rutherford et al., 2018).

In the frontal plane, FAI has been shown to cause up to 25% more hip adduction in patients with FAI than in the control group, with the FAI patients experiencing 5.2° more hip adduction than their counterparts (Diamond, Bennell, et al., 2018). Additionally, patients with FAI exhibit substantial lateral trunk lean towards the affected side, and most patients in a study conducted by Diamond, Bennell, et al. observed that patients tended to report pain during step ascent (Diamond, Bennell, et al., 2018).

2.1.3 Acetabular Labral Tear

Due to improvements in imaging techniques, the number of diagnosed acetabular labral tears is increasing (Groh & Herrera, 2009). Approximately 22% of patients with groin pain and 55% of patients with mechanical hip pain with no apparent or known cause have acetabular labral tears when examined further (Lewis & Sahrmann, 2006). The acetabular labrum is a ring of fibrocartilage that surrounds the acetabulum in the hip joint. The acetabular labrum's function is to provide cushioning, lubrication, and stability to the hip joint (Groh & Herrera, 2009). An acetabular labrum tear is characterized by three different types of labral lesions: fraying or tearing of the

acetabular labrum, and detachment of the labrum from the acetabular rim (J. McCarthy et al., 2003). A labral tear is shown below in Figure 4.

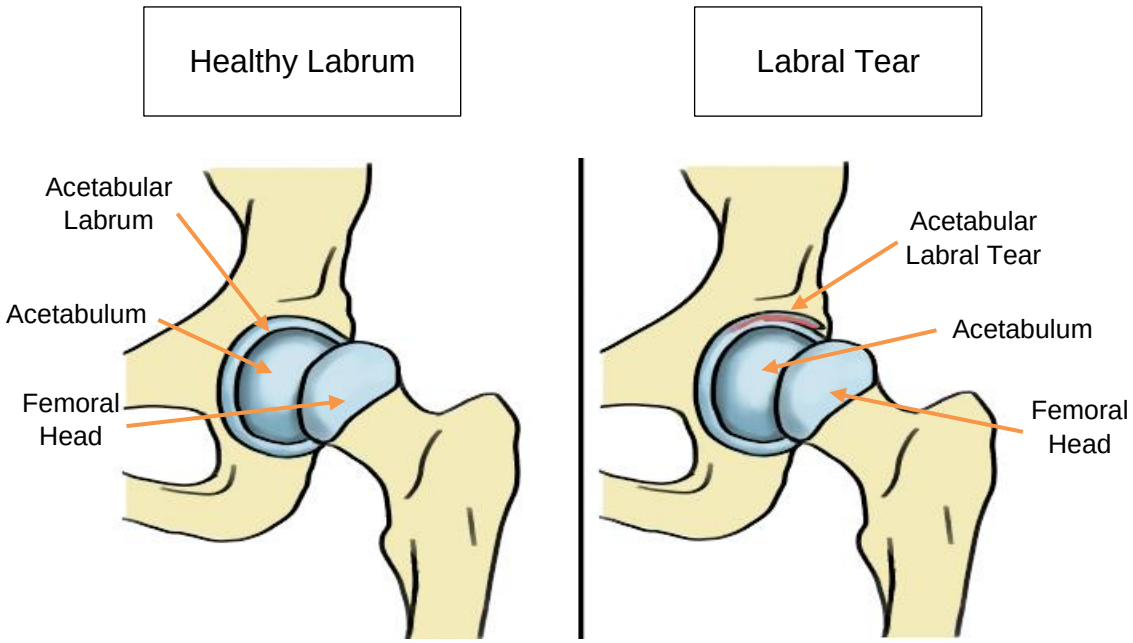


Figure 4. Acetabular labral tear. The left half of the figure shows a healthy acetabular labrum, while the right half depicts a tear within the anterior portion of the acetabular labrum.

Symptoms of a labral tear include hip and groin pain that occurs in varying locations depending on the location of the tear within the joint (Lewis & Sahrmann, 2006). The pain experienced by patients can be described as a locking, clicking, catching or snapping sensation, and some patients may feel their hip give way (Farjo et al., 1999; Groh & Herrera, 2009).

The labrum provides stability though reducing femoral head translation by creating a deeper socket, with some studies estimating that the labrum increases the acetabulum's depth by 21% (Tan et al., 2001). Surface area of the acetabulum is increased 28% by the labrum, allowing for increased distribution of load and decreased

contact stress on the articular cartilage of the femoral head (Tan et al., 2001). The labrum's role is especially important in preventing damage to the articular cartilage on the femoral head. In patients with labral tears, roughly 73% of patients with an acetabular labrum tear suffered from chondral damage, and that 94% of those patients experience the articular cartilage damage in the same area as the tear (Groh & Herrera, 2009; J. C. McCarthy et al., 2001). With a labral tear alone, an increase in contact stress between the cartilage layers is associated with a higher risk for degenerative disorders such as osteoarthritis (Altenberg, 1977; M. J. Philippon et al., 2012). Without an acetabular labrum, contact stress between the femoral and acetabular cartilage has been shown to increase by up to 92%, while lateral translation of the femoral head increases as well (Ferguson et al., 2000).

There are many different risk factors associated with acetabular labral tears. Environmental risk factors include direct trauma (such as falls, slips, or dislocations) as well as participation in sports with frequent twisting or external rotation of the hip have been shown to increase one's risk for labral tears (Binningsley, 2003; Lewis & Sahrmann, 2006). Running has also been identified as a potential cause of labral tears (Fitzgerald, 1995), but roughly 74% of labral tears have no known cause (Lewis & Sahrmann, 2006; Santori & Villar, 2000). Labral tears are more likely to occur in those assigned female at birth (J. C. McCarthy et al., 2001), and this may be partially due to a higher prevalence of hip dysplasia in that population (Bache et al., 2002). Femoroacetabular impingement is also associated with a higher risk of labral tears, as the CAM and pincer lesions can pinch, shred, and tear the labrum over time (Banerjee & Mclean, 2011; Groh & Herrera, 2009). Acetabular dysplasia is associated with a

higher risk of labral tears. The acetabular labrum is increasingly important in hip joints with acetabular dysplasia (Henak et al., 2011), a condition in which the acetabulum is abnormally shallow, resulting in an increased amount of pressure on the acetabular rim (Sharp, 1961). In hips with acetabular dysplasia, labral tears are more likely to occur due to the increased reliance on the labrum to provide joint stability instead of the acetabulum, in addition to the labrum undergoing 4 to 10 times more load transfer than in a hip with a normally-shaped acetabulum (Henak et al., 2011).

While it is difficult to prevent labral tears that are a result of bone deformities such as CAM and pincer lesions, it is possible to mitigate one's risk. Identifying femoroacetabular impingement as soon as possible and taking corrective action such as osteoplasty can return the hip joint to a natural anatomy and prevent the labrum from getting torn between the femoral head and acetabular rim (Dukas et al., 2019). Additionally, limiting repetitive external rotation can reduce one's risk for developing a labral tear (Binningsley, 2003).

To diagnose a labral tear, a patient will typically undergo a physical examination first, and if the clinician believes that they might have a labral tear, the patient undergoes a magnetic resonance arthrogram (MRA) (Lewis & Sahrmann, 2006). Initial physical tests done by a physician include an anterior hip impingement test, a FABER test, a resisted straight leg raise, a log roll test, and a FADIR test (flexion, adduction, internal, rotation test) among others (Fitzgerald, 1995; Lewis & Sahrmann, 2006; Magee, 2013; M. J. Philippon et al., 2012). If a patient presents with pain during any of these tests, the clinician may decide to proceed with the MRA to officially diagnose the labral tear. In an MRA, a radiologist injects the hip joint with gadolinium dye and the

patient then undergoes an MRI with contrast. If the dye leaks from the joint capsule, it is indicative of a labral tear (Byrd & Jones, 2004).

Labral tears are most commonly found in the anterior region of the labrum, but posterior, superior, and lateral labral tears can also occur (J. McCarthy et al., 2003). Labral tears can be classified into three stages. Stage I tears are isolated to one portion of an anatomical region (such as the anterior labrum), stage II tears are throughout an entire anatomical region, and stage III tears involve multiple anatomical regions (J. McCarthy et al., 2003).

2.1.3.1 Biomechanical Impact

Labral tears create a slight decrease in rotation range of motion, but can also negatively affect hip flexion, extension, abduction and adduction ROM (Groh & Herrera, 2009). Additionally, patients with labral tears exhibit less hip extension in the initial part of the swing phase of gait, as well as a slower walking speed than control groups (Freemyer et al., 2022). Patients with anterior labral tears may experience pain during hip extension, so a shorter gait may be observed in patients with anterior labral tears in an effort to mitigate their symptoms (Lewis et al., 2010).

2.2 Clinical Assessment of Hip Pain

In addition to the procedures outlined in section 2.1 for identifying different hip pathologies, there are several other methods that a clinician can employ to assess a patient's hip pain and function. One of the simplest ways to obtain a patient's pain level is to employ a visual analog scale (VAS) for pain, which is a scale that ranges from 0 (no pain) to 10 (the worst imaginable pain) (Hawker et al., 2011). The Harris Hip Score (HHS) is a popular survey for patients to take regarding the difficulty of certain activities,

but it does not focus on the patient's pain level and is mostly used to measure patient outcomes (Mahomed et al., 2001).

Another survey that can be used to assess a patient's pain, symptoms, and how their hip pain affects their quality of life and daily life activities is the Hip disability and osteoarthritis outcome score (HOOS) (Nilsdotter et al., 2003). The HOOS survey is a 40-question survey that is an effective tool for obtaining information about a patient's activity levels, pain during certain activities, as well as overall symptoms. Examples of questions include pain frequency, pain intensity, difficulty with long strides, difficulty pivoting, and confidence in their hip (Nilsdotter et al., 2003). This survey was used in an adapted form to obtain information regarding the clinical participant's pain level in this case study.

2.3 Types of Treatment and Rehabilitation for Hip Injuries

2.3.1 Physical Therapy

Physical therapy is the least invasive treatment of the three presented in this review. In physical therapy, patients with hip injuries perform various exercises aimed at strengthening the muscles around the hip joint as patients with chronic hip pain have been shown to have reduced hip muscle strength, particularly reduced hip abductor strength (Diamond, Allison, et al., 2018; Harris-Hayes et al., 2014). Reduced hip abductor strength is associated with an increase in hip adduction, which can impinge the hip and lead to pain (Diamond, Allison, et al., 2018; Groh & Herrera, 2009).

In physical therapy, the patient can also practice gait modifications to reduce their pain level. While gait training is unlikely to be beneficial in symptomatic FAI (Diamond et al., 2016), gait modifications such as an increase in foot pushoff may

reduce a patient's anterior hip pain by reducing the forces acting on the anterior acetabular rim, helping patients who have anterior labral tears or OA in that area (Lewis & Garibay, 2015).

It is important to note that physical therapy cannot heal labral tears or fix femoroacetabular impingement, as the labrum is avascular and incapable of repairing itself and femoroacetabular impingement requires osteoplasty to be resolved (Banerjee & Mclean, 2011; Groh & Herrera, 2009).

2.3.2 Steroid Injections

Another form of treatment for hip pain is steroid injection. Steroid injection is not suitable for every hip pathology. Steroid injections are most commonly used for osteoarthritis and to reduce swelling within the hip joint, and can be used in conjunction with physical therapy (Zhong et al., 2020). Steroid injections reduce inflammation within the hip joint and provide immediate and long-term pain relief for the patient, allowing them to participate in other treatments such as physical therapy (Zhong et al., 2020). Steroid injections are oftentimes not a long-term solution and are deemed a conservative care treatment option. They are frequently used to delay inevitable surgeries such as a hip arthroscopy or total hip replacement (Kruse, 2008).

2.3.3 Hip Arthroscopy

Hip arthroscopy is a treatment used for both FAI and labral tears (Banerjee & Mclean, 2011; J. McCarthy et al., 2003). Hip arthroscopy is a minimally invasive surgery that allows surgeons to make small incisions in order to operate within a patient's hip (Byrd, 2006). In hip arthroscopy, the affected leg is placed in traction to create increased joint space for the surgical instruments, and the surgeon inserts tools into the

intra-articular space to operate (Byrd, 2006). For FAI, the surgeon performs an osteoplasty procedure to shave away excess bone that forms the CAM and pincer lesions that lead to FAI (Banerjee & Mclean, 2011). To treat labral tears, surgeons have a variety of techniques they can employ based on the severity of the patient's tear. If the patient has a small, clean tear, they can perform a labral repair by stitching the labrum back together (M. J. Philippon et al., 2012). If the labrum is beyond repair, they can resect the destroyed tissue and reconstruct the labrum with cadaver tissue (typically a iliotibial band allograft) (White & Herzog, 2015). After hip arthroscopy, patients typically undergo physical therapy to rebuild the strength lost during recovery and to properly heal the newly formed labrum (Cvetanovich et al., 2017).

2.3.4 Total Hip Arthroplasty

Total hip arthroplasty (THA) is typically used as a treatment for late-stage osteoarthritis. In total hip arthroplasty, an artificial hip implant replaces the patient's degenerated hip joint (Lespasio et al., 2018). Typically, these implants are comprised of titanium and various polymers (Hussain et al., 2019). Various surgical techniques exist for placing the implant within the hip joint, with some entering the joint space anteriorly and others choosing to place the implant posteriorly. However, the posterior approach has been shown to have far less complications than the anterior approach with similar rates of dislocation after surgery, making it the preferred approach (Aggarwal et al., 2019). 95% of hip implants last 10 years in the body, while roughly 80% of hip implants are capable of lasting for 25 years within the body (Lespasio et al., 2018). After THA, most patients participate in physical therapy to strengthen their new hip, and after release are able to fully participate in exercise and everyday life (Freburger, 2000).

2.4 Assistive and Wearable Technology

There are various options available for patients looking to provide additional stability to the hip, but few designed specifically for the purpose of wearing during athletic activity. The main form of assistive technology specific to hip pain and stability is hip braces. Stabilizing braces such as the DonJoy VersaROM® Hip Brace (DJO Global, Lewisville, TX) seen in Figure 5 below are worn by the patient for roughly 2 weeks after surgeries such as hip arthroscopy and total hip arthroplasty. Stabilizing braces are used to prevent motion that could potentially damage the repairs done in surgery as well as aid in stabilizing the hip after a hip replacement so dislocation does not occur (Kemker et al., 2021).

Figure 5. DonJoy VersaROM Hip Brace. This brace is a stabilizing brace, which limits the range of motion while flexing, abducting, and rotating the hip.

Another type of hip brace is a hip unloader brace. Hip unloader braces such as the Össur Unloader Hip Brace (Össur, Reykjavik, Iceland) are typically used with patients who have osteoarthritis to transfer body weight from the deteriorated cartilage within the hip joint to reduce pain, and can be worn without surgical intervention

(Kemker et al., 2021). One downside of the braces listed above is that they are very bulky and could potentially hurt a patient if they were used during athletic activity. Additionally, they highly restrict motion in the lateral plane that would be necessary during certain sports, such as a side-shuffle in basketball. These braces also are generally only available for purchase through a medical professional, so they can be inaccessible to those without access to care or highly expensive without a prescription. Therefore, they are not an adequate solution for patients looking for hip support while participating in athletic activities.

When conducting an online search for hip braces, one can find a variety of wraps and compression braces for sale, but rarely one that restricts range of motion, provides joint unloading, and compression throughout the hip joint area. For example, the BraceAbility Hip Flexor Compression Spica & Groin Brace (BraceAbility, Cedar Falls, IA) provides correction for hip adduction as well as compression, but no range of motion restriction (BraceAbility, 2023). While the online solutions for hip bracing tend to be below $100 and provide alignment correction as well as compression, their lack of any range of motion restriction results in a possible area of improvement.

2.5 Problem Statement

The bracing methods outlined in section 2.4 all have their own drawbacks. Heavier-duty braces such as the DonJoy VersaROM® Hip Brace and the Össur Unloader Hip Brace can restrict motion too much, potentially harm the wearer in event of a fall, and are expensive. Additionally, these braces tend to be uncomfortable for the wearer which results in noncompliance (Kemker et al., 2021). Other options that are available online tend to not provide the full range of qualities such as range of motion

restriction and alignment correction desired in a hip brace, despite them being more comfortable, affordable, and accessible than the aforementioned braces. After conducting a literature review of hip pathologies, treatments for hip injuries, and current hip braces on the market, it became apparent that there was a gap in the market that needed to be filled. Therefore, this project set out to design a hip brace that could adequately support the hip, relieve pain, provide comfort, be worn during athletic activity, and be affordable for the consumer.

Chapter 3. Hip Brace Device Design

Chapter 3 discusses the creation and development of a novel hip brace designed for athletic use. This device was created by Megan Mentzer, along with help from other members of the Breen Lab. The design was informed by input given from University of Oklahoma Athletics personnel, personal experience, and various other brace designs. This device was an iterative design, with multiple components having numerous versions before the final design was decided upon.

3.1 Methods

Chapter 3's focus is on the development of a novel hip brace for athletic use in people with a history of hip injuries such as the ones mentioned in section 2.1. First, how the design was informed will be expanded upon, and the metrics for the brace will be stated. Then, the initial prototype and iterative design process will be discussed. The final device design is detailed in section 3.2 and discussed in section 3.3. The final device was used in a case study and will be focused on in chapter 4.

3.1.1 Informed Design

To design the brace, it was important to first gather information about current bracing methods and speak with current clinicians who treat hip injuries. To begin, a literature review over the existing hip bracing methods was performed. These methods are outlined in section 2.4.

To gain information about the perspective of clinicians who are treating athletes at the University of Oklahoma, members of the Sports Medicine department within University of Oklahoma Athletics were consulted. From conversations, it became clear

that at the collegiate level, where athletes are receiving a high level of care, it would be unlikely that athletes would be cleared to return to their sport if they were still experiencing pain within their hip, or had any lack of confidence in their hip's ability to be able to perform at full capacity. Therefore, they generally only use taping or wraps to create a "girdle" or a specific type of taping orientation similar to a hip spica (Riney et al., 1995) if an athlete needs support for their hip. In addition, it was emphasized by sports medicine staff that because the hip is such a "deep" joint, it can be challenging to effectively brace the joint and control rotation while performing athletic movements. Despite the difficulties of bracing the hip joint and the likely lack of use at the collegiate or professional level of sport, the clinician was still optimistic about the device. It was determined that the device could be used in amateur sports settings rather than professional or semi-professional sports. Key information gathered was that the device should brace the hip in a similar fashion to a hip spica or girdle, to provide joint unloading and alignment correction.

After consultation with University of Oklahoma Athletics personnel and a thorough literature review, key design criteria were developed:

1. The brace must be soft enough to be worn (and potentially fallen on) during athletic use.
2. The brace must provide alignment correction to the hip and should do so by resembling a hip spica or girdle.
3. The brace should have components that restrict and/or guide movement in the lateral plane.
4. The brace must be able to be worn repeatedly.

5. The brace should cost less than $125 to make.

Following creation of these design criteria, a mock-up of the device design was created and can be seen below in Figure 6. In this figure, proposed elastic design is shown in the solid blue bands, while a proposed exoskeleton placement is shown in the green grid. Rubber adhesive to keep the brace in place on the lower thigh is shown in orange.

Figure 6. Proposed Left Hip Brace Design. This figure shows the anterior, sagittal, and posterior view of the proposed left hip brace. The solid blue lines depict the elastic, while the green grid depicts the exoskeleton and the orange line represents the adhesive.

3.1.2 Initial Prototype

Once funding was secured, the first step of creating the initial prototype was determining the structure of the shapes to be used in the exoskeleton. Various shapes were created in TinkerCAD, a free web-based computer-aided design software created by Autodesk, due to the rudimentary nature of the shapes. Three proposed shapes were created: a parallelogram, a rectangle, and a hexagon, and their designs can be seen in Figure 7 below.

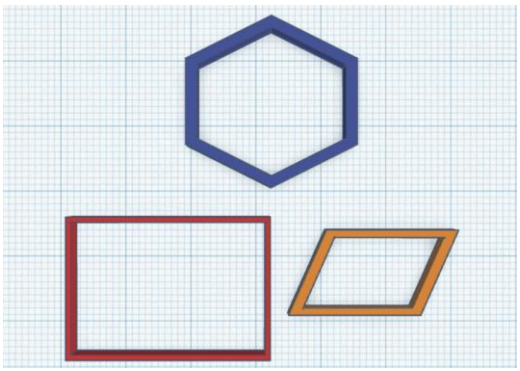


Figure 7. Initial proposed exoskeleton base shapes. A hexagon, rectangle, and parallelogram were created in TinkerCAD.

The three shapes were 3D printed in thermoplastic polyurethane (TPU) using a Prusa i3 MK3S+ fused deposition modeling 3D printer. These shapes were investigated for their stretch and resistance in various directions using manual testing, and it was determined that the parallelogram was best suited for our application, as it allowed movement in one direction and resisted movement in the perpendicular direction. Based on the orientation and placement of the parallelograms, we could modulate the allowed range of motion in certain planes. The hexagon proved to be too rigid, and the rectangle was also more rigid than the parallelogram in the x and y directions. Once we had decided upon the parallelogram for the base shape for the exoskeleton, it was then time to create parallelograms with various wall thicknesses to determine the structure needed to best balance rigidity and flexibility for this device.

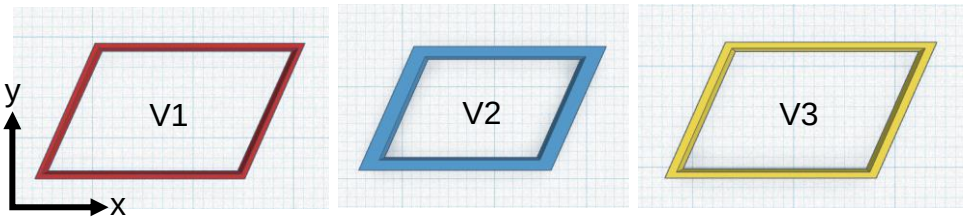


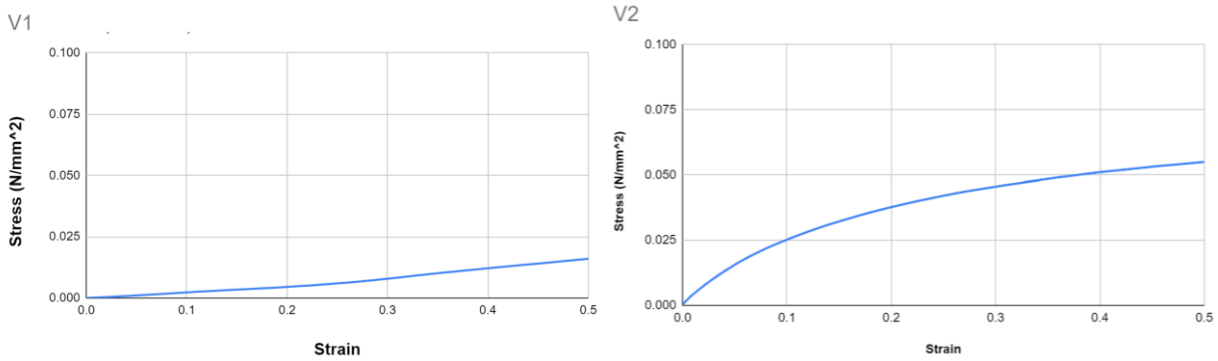
Figure 8. Various proposed parallelogram designs. Various parallelograms were created with varying wall thicknesses.

As seen in Figure 8 above, while each version of the parallelogram was created to have approximately the same overall dimensions such as length, width, and height, each version had a different wall thickness. In Table 1 below, the dimensions and wall thickness of each version are outlined.

	Length	Width	Height	Wall Thickness
V1	25.40mm	12.70mm	2.00mm	0.40mm
V2	25.40mm	12.70mm	2.00mm	1.50mm
V3	25.40mm	12.70mm	2.00mm	0.80mm

Table 1. Parallelogram version dimensions. The parallelograms had identical length, width, and height, but varied in wall thicknesses.

Three different versions of the parallelograms were printed using the Prusa i3 MK3S+ 3D printer and then were tested in a TestResources 100 Family Electromechanical Universal Test Machine (TestResources Inc., Shakopee, MN) to gain information about their tensile stress and strain. The samples were tested at 10 mm/min for a maximum of 10 minutes using the accompanying Newton software. From the exported extension and load data, stress-strain curves were created for each version of the parallelograms and compared, seen in Figure 9 below.



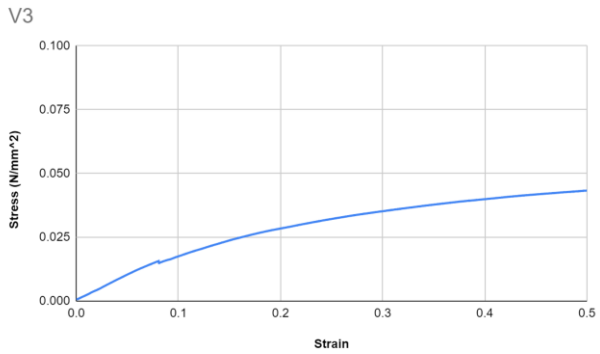


Figure 9. Stress-strain plots for three representative samples from each version of parallelogram. Version 1 experienced the lowest amount of stress at 0.015 strain, followed by version 3 then version 2.

It is expected that the participant will experience no more than 10° of hip adduction (Diamond, Bennell, et al., 2018), and through trigonometry it can be determined that said adduction corresponds to a strain value of 0.015. Each of the versions of the parallelograms are still well within their elastic region at 0.015 strain, meaning that each version would not undergo plastic deformation when implemented in the brace. Therefore, it was decided to use parallelogram version 1 in the exoskeleton to save money and materials when constructing the brace.

Once a decision had been made that version 1 of the parallelograms would be used in the exoskeleton, grids of the parallelogram were 3D printed to be put on the brace. Below in Figure 10 is the 3D model of the grid (dimensions shown in millimeters), as well as the grid after it was printed in TPU.

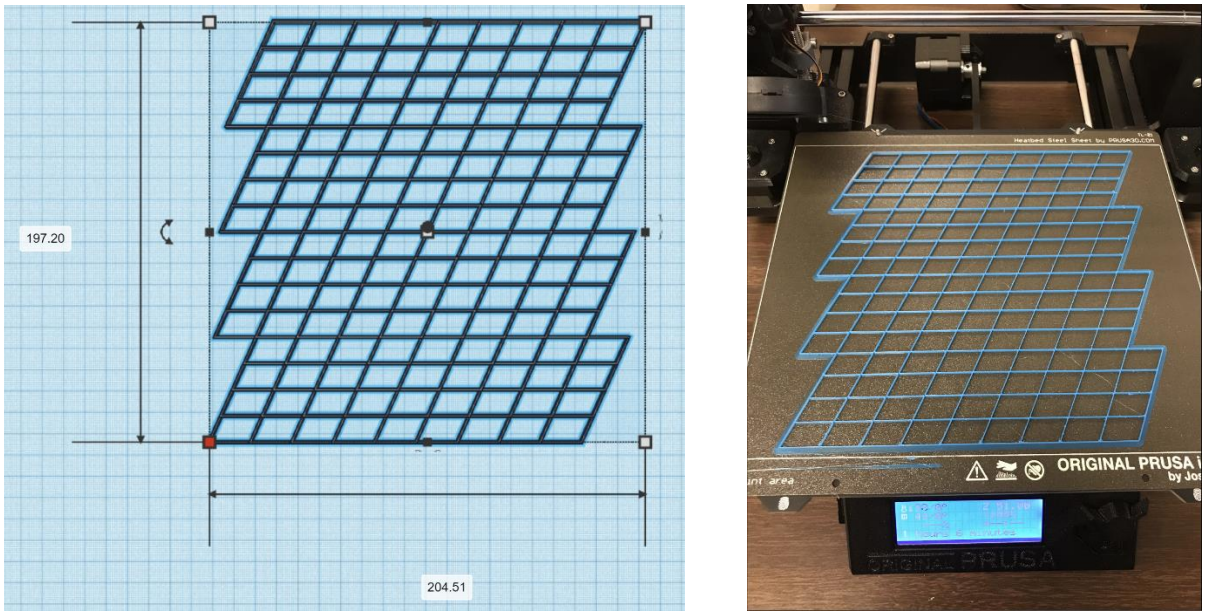


Figure 10. CAD model and 3D printed exoskeleton grid. The 3D model was 197.20mm x 204.51mm, and was then printed on a Prusa i3 MK3S+ 3D printer

The next step in fabricating the exoskeleton was assembling the components for a left hip brace. The base component of the brace, high-waisted 8.5” inseam bike shorts (Girlfriend Collective, San Francisco, CA), were placed on a mannequin to resemble a person wearing the shorts so an accurate shape of a human body could be obtained for placing on the other components. Then, a 6” wide strip of elastic was wrapped around the shorts and pinned in place for sewing to provide joint unloading and alignment correction. Additionally, a strip of rubber adhesive was placed at the bottom of the short legs on the inside of the fabric to help prevent the fabric from riding up the wearer’s legs. A Singer Heavy Duty sewing machine (Singer, La Vergne, TN) was then used to sew the components into place using a zig-zag stitch with elastic thread to allow the components to stretch with the fabric of the shorts when donned.

Once the elastic and adhesive had been sewn onto the brace, the exoskeleton was then hand-stitched onto the brace. A member of the lab then put on the brace and gave preliminary feedback regarding the tension in the elastic, and it was determined that there was too much tension across the front of the brace, which caused unwanted adduction of the left leg. To relieve this, a small cut was placed in the front piece of elastic. Figure 11 below features photos of the finished first prototype.

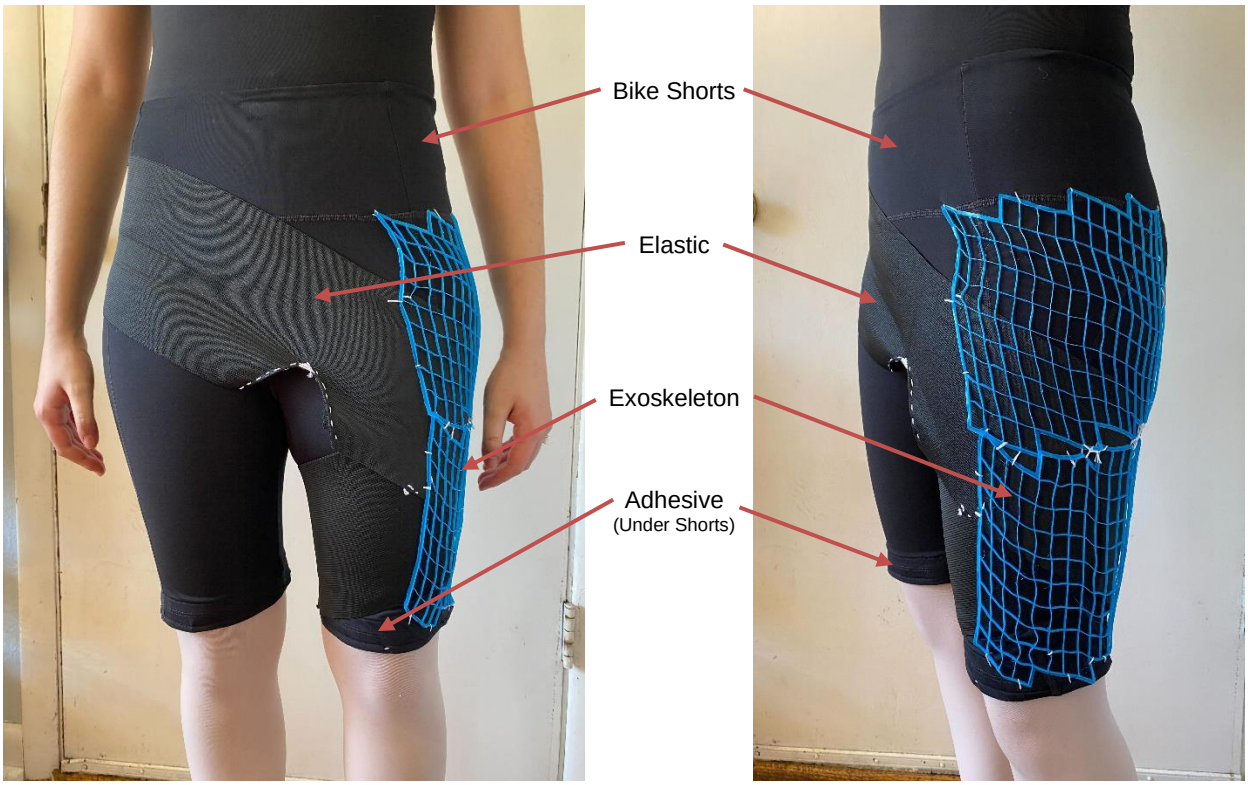


Figure 11. Completed first prototype. The elastic wraps around the left leg and then passes around the body, while the exoskeleton and adhesive are featured solely on the left leg portion of the brace.

3.2 Final Device Design

As stated in the previous section, the device has three main components. The shorts, the elastic, and the exoskeleton each serve different purposes in support of the hip joint. The compression shorts provide compression to the hip area, which has been

proven to help with inflammation and swelling, thus reducing pain (Agarwal & Juneja, 2022). The elastic provides joint unloading and corrects hip adduction, that is often the result of pain, by creating abduction to restore natural alignment to the hip (Nérot & Nicholls, 2017). While creating increased abduction will decrease the magnitude of the moment arm, it is expected that an increase in the ground reaction force will allow for a net increase in the external hip adduction moment (Samaan et al., 2017).

The elastic provides slight joint unloading through the strap that crosses underneath the buttocks of the wearer. This also potentially acts as a preventative measure, as joint unloading has been shown to slow the progression of some degenerative bone and cartilage disorders such as osteoarthritis (Schröter et al., 1999). The exoskeleton of the brace isolates control of the frontal plane while not interfering with the sagittal plane of motion. Figure 12 shows photos of the second prototype alongside the directions of the force applied by the elastic.

Figure 12. Final prototype of the brace. The direction of force applied by elastic is designated with arrows. The brace was designed for the right hip and features the elastic and exoskeleton in a mirrored orientation from figure 11.

The second and final prototype was assembled in the same way as the first, with some changes in the design. First, the second prototype was created to be worn on the right hip, as that side was the affected hip for the clinical participant. Next, a different pair of compression shorts were used for the brace. The second pair had a 10” inseam, and was made entirely from cotton whereas the first pair was made of spandex. The longer inseam was needed to prevent the brace from moving on the participant, while the change in material was due to the difficulty of sewing and assembly with spandex. Another change that was made was in the elastic. The second iteration utilized two strips of 3” wide elastic to modulate the amount of tension that was applied to different areas of the brace. As seen in the photos below, two strips of elastic were used in the main areas of joint unloading and alignment, while only one strip was used across the front of the brace. This was done to reduce the amount of adduction that could inadvertently be created by the elastic, as that was the opposite of what we wanted to achieve with the brace.

3.3 Discussion

This part of the project was focused on creating a working prototype for testing at the Center for Human Performance Measurement (CHPM). Two complete prototypes were successfully created and it was decided to use the second iteration for testing at the CHPM due to it being better suited for the case study participant.

It is expected that this device will be successful in meeting the design criteria stated in section 3.1.1. The brace is made entirely of non-metal, flexible and soft materials, making it safer to participate in athletic activity in than traditional post-operative braces in terms of injury risk if a fall were to occur. The brace also utilized

elastic to meet the second design criteria of providing alignment correction that resembled a hip spica. The device design also featured the exoskeleton placed in an orientation that helped limit the range of motion in the lateral plane, and cost $108 to make, meeting the last two design criteria. It is anticipated that future braces would cost less than the original two designs, as certain materials such as the TPU filament are bought in bulk and thus able to be used to create multiple braces.

3.3.1 Limitations

This device had many limitations to its design, as well as its manufacturing process. To start, the hip joint is underneath a large amount of tissue, making it a “deep” joint. This makes it hard to control the rotation of the femur within the joint without stiff bracing materials such as metal, but we were unwilling to compromise on using only soft materials to construct the brace out of wearer safety concerns. Another limitation of the final brace design was the decision to switch from a compressive material for the shorts to a cotton bike short. While using the cotton shorts resulted in easier construction, it reduced the amount of compression that was delivered by the shorts and thus potentially reduced the amount of pain mitigation that the shorts could have provided (Agarwal & Juneja, 2022). Another problem with brace construction was trying to sew the elastic to the shorts. The tension within the sewing machine needed to be adjusted multiple times throughout the sewing process to create the adequate amount of hold within the stitch to keep the elastic in place while still allowing it to stretch with the body and motion. Both problems, the material of the shorts and sewing the elastic, could have been solved with an increased amount of funding for this project. With more funding, we could have conducted more trial runs during construction without having to

worry about destroying the materials that we were able to order within our budget. A final limitation to the design process was trying to create a brace for a person without obtaining their measurements beforehand. Due to protocols, we had to create the brace prior to obtaining a clinical participant, so the brace was constructed using a mannequin that was a close but not a perfect match for the clinical participant's size.

3.3.2 Future Work

Once the final working prototype of the brace had been created, it was time to test it with a clinical participant in a case study. The goal of the case study was to determine whether the brace was capable of meeting biomechanical metrics that will be outlined in the next chapter, as well as comfort and pain reduction metrics. The biomechanical metrics were tested through a testing protocol that was undergone at the Center for Human Performance Measurement (CHPM), while the comfort and pain reduction metrics were tested through surveys completed at the start and completion of the biomechanical testing.

Future directions for the brace design include creating a more robust exoskeleton. A possible design change is adding a component that resembles the range of motion restriction component featured on the DonJoy VersaROM® Hip Brace, seen in Figure 5 (DJO Global, Lewisville, TX). While it would be difficult to create this part within the design constraints of using soft materials, flexible filament such as thermoplastic polyurethane (TPU) could be used to create the structure while still allowing for compression if fallen on. Another change that could be made regarding the exoskeleton is testing varying sizes of parallelograms for the exoskeleton grid. While the models used had varying wall thicknesses, all the versions were the same overall size.

By varying the length and width of the parallelograms, differing tensile properties could be observed, allowing for a more apparent best choice between the versions.

Another future direction for this project would be to expand the population that was tested. This project was limited to a single-person case study, but in order to get a larger sample size multiple braces could be fabricated to test how the materials work for individuals of varying sizes, genders, and injury states. Another potential study could involve investigating the brace's efficacy at preventing injuries in those who are predisposed to suffer from hip pain and injuries. Besides the testing that was done in the lab in this case study, more realistic testing measures could be beneficial in determining the brace's efficacy in a sport setting. For example, developing a study that has a testing protocol centered around a specific sport, such as basketball or softball, would help researchers get a more accurate picture of how the brace affects the wearer while participating in a sport.

Additionally, it would be beneficial to gain more opinions on the design of the brace. Potential participants include athletic trainers treating middle school and high school athletes, amateur adult athletes, orthopedic surgeons, and physical therapists. This expansion would allow for multiple different points of view to share their opinion on the brace design, introduce potential problems with the current design, and introduce future directions for the brace design.

Chapter 4. Hip Brace Case Study

This chapter will discuss the case study that was conducted to evaluate the brace's effect on hip mechanics, patient pain and comfort. Additionally, the results of the study will be expanded upon and key findings and limitations for this project will be highlighted. Once again, the brace consists of three main components, a pair of bike shorts, an elastic band, and a 3D-printed exoskeleton. Due to the short-term duration of this project, a case study was performed rather than a larger scale study to obtain preliminary results about the brace's efficacy. Several outcome measures were created to determine the brace's efficacy, and are outlined in the section below.

4.1 Methods

4.1.1 Participant Information

This study was performed with a single participant, a 23 year old female with a history of hip injuries in both hips. This participant was recruited through a connection in the Stephenson School of Biomedical Engineering at the University of Oklahoma. A member of the college had knowledge of this project and its goals and determined that the participant was a potential good fit for testing. After further discussion and IRB approval for human testing, we reached out to the participant and asked if she would like to participate in this case study. After consent was obtained, a review of the participant's hip-related medical history was conducted.

In 2016, the participant underwent a right hip arthroscopy procedure to repair a torn labrum as well as undergo osteoplasty on both the femur and acetabulum to fix both CAM- and pincer-type FAI. In 2018, the participant underwent the same procedure,

but on the left hip. While both hips were operated on, the left hip had its pain resolved by surgical intervention, but the right hip has experienced recurring pain since 2016. It was determined that although the patient had a history of hip pain in both hips, since the left hip was asymptomatic they would be a good fit for the study.

4.1.2 Outcome Measures

To assess the brace's effect on hip mechanics as well as hip pain and comfortability, several metrics were chosen. These metrics are listed below:

1. The brace should increase the peak hip external adduction moment.
2. The brace should not increase the wearer's time to initiate a movement in response to a stimulus.
3. The brace must not increase the wearer's pain levels.
4. The brace must be comfortable for the wearer.
5. The brace must fit underneath a standard athletic uniform.

4.1.3 Brace Testing

At the start of the testing session at the Center for Human Performance Measurement (CHPM), the participant signed an informed consent form. Then, as the participant was being fitted with spherical reflective markers, they completed a survey about hip pain levels prior to intervention with the brace (featured in the appendix). The 3D motion capture markers were placed in a modified Helen-Hayes orientation (Collins et al., 2009), outlined below in Figure 13.

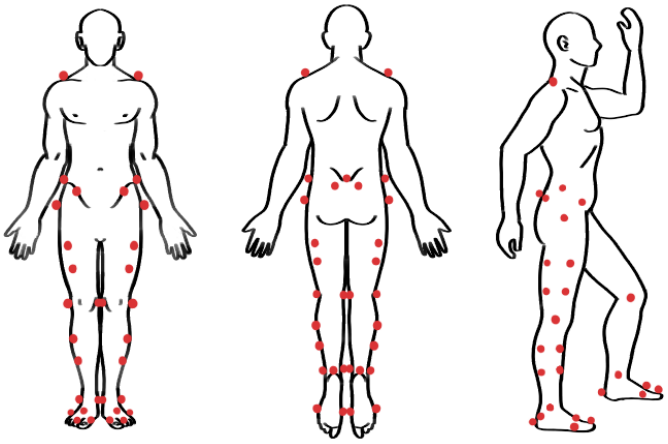


Figure 13. Modified Helen-Hayes marker set used for this study. The majority of the markers were featured on the lower half of the participant's body.

Once the participant was fitted with the markers, calibration was performed to create a 3D reference for the cameras in the motion capture system. Then, the participant underwent a five-minute walking warmup on a treadmill, set to a 0° incline and 3 MPH (seen in Figure 14).

Figure 14. Participant undergoing the second walking warm-up prior to the overground walking trials. The participant walked at 3 MPH at 0° incline for five minutes.

The participant then performed 15 overground walking trials where they walked over a grid of four 24” x 16” force plates, arranged in a 48” x 32” grid. The goal was to obtain ten trials capturing one complete walking stride with both heels completing a heel strike on a force plate. After completing the overground walking tests, the participant then underwent five repetitions of a T-test, an agility test, with 30 seconds of rest in between trials. The T-test used in this testing protocol required the participant to sprint forward for 7 meters, touch a cone, side-shuffle to the left for 3.5 meters, touch another cone, shuffle to the right for 7 meters, touch a cone, shuffle to the left 3.5 meters, touch a cone, then backpedal for 7 meters to return to the starting point. This pattern creates a T-shaped path, depicted below in Figure 15.

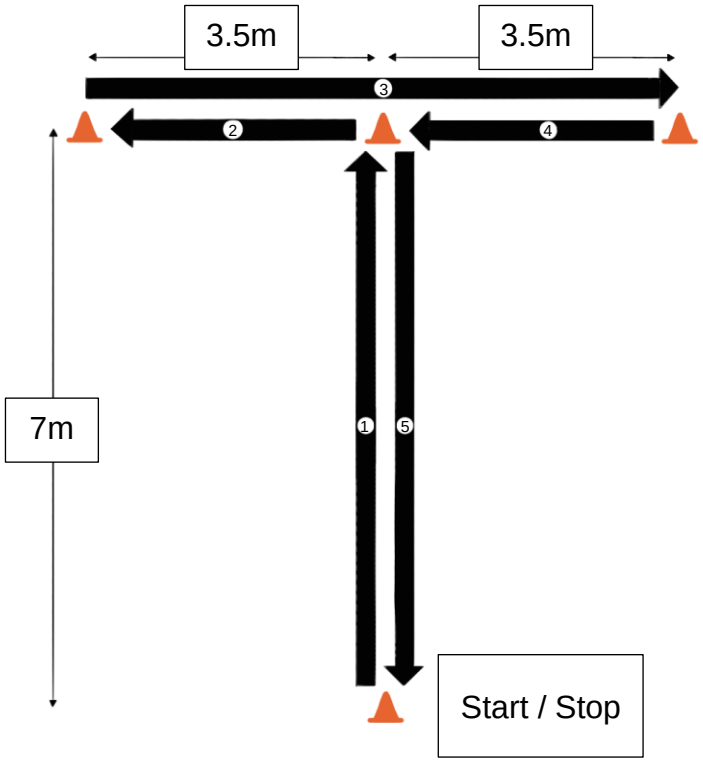


Figure 15. T-test running pattern. The participant began at the lower cone, sprinted 7m to the middle cone, shuffled left 3.5m to the cone, shuffled completely to the right for 7m, shuffled left 3.5m, and then backpedaled for 7m to the starting point.

After completing five repetitions of the T-test, the participant then had the markers removed so the brace could be donned. Once the brace was in place, the markers were refitted. The participant then repeated the protocol for the calibration, the walking warm up, the overground walking trials, and the T-test. Once they had completed this protocol, the participant completed two surveys while the markers were being removed. The first survey was the same pain survey that was taken prior to putting on the brace, while the second was a survey that obtained the participant's opinion on the comfortability of the brace (both surveys can be found in the appendix).

4.2 Results

Of the 15 walking trials that were conducted, 9 samples per condition had heel strikes for each foot and thus were able to be included in data analysis. Average peak right hip external adduction moment for the unbraced condition and braced condition are listed below in Table 2, and a graphical representation of the right frontal plane hip moment is shown in Figure 16.

Condition	Average Peak Right Hip External Adduction Moment	Standard Deviation	P Value
Non-Braced	5.137 %bwht	0.286 %bwht	0.542
Braced	5.043 %bwht	0.270 %bwht	

Table 2. Average peak right hip external adduction moment. This table illustrates no statistically significant increase in the average peak right hip external adduction moment between the unbraced and braced condition.

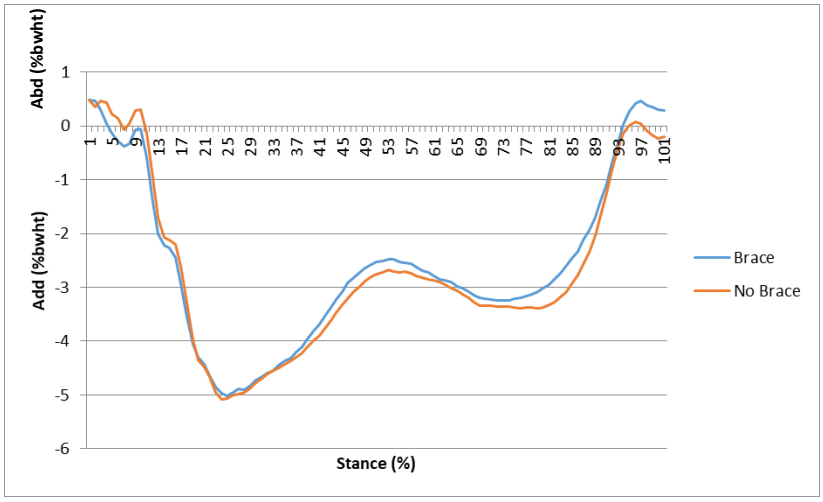


Figure 16. Right frontal plane hip moment. This figure shows no statistically significant increase in the peak right hip external adduction moment.

In addition to the right frontal plane hip moment, the right frontal plane hip angle was also measured. Average peak right hip adduction angle for the unbraced and braced conditions are listed below in Table 3, and a graphical representation of the average right frontal plane hip angle is displayed in Figure 17.

Condition	Average Peak Right Hip Adduction Angle	Standard Deviation	P Value
Non-Braced	4.905 °	0.621°	0.010
Braced	5.760 °	0.573°	

Table 3. Average peak right hip adduction angle. This table shows a statistically significant increase in the hip adduction angle from the non-braced condition to the braced condition, totaling 0.8° more of adduction while wearing the brace.

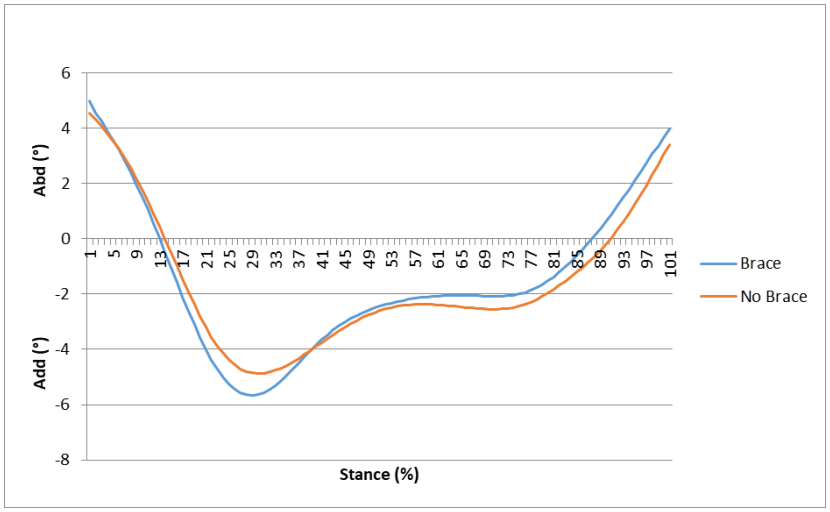


Figure 17. Average right frontal plane hip angle. There was a statistically significant increase in the hip adduction angle during the braced condition compared to the unbraced condition.

From the t-test, the participant's time to initiate a movement in response to a stimulus was measured. Each trial was timed, then the results from each condition were averaged and are listed below in Table 4.

Condition	Average T-Test Time	Standard Deviation	P Value
Non-Braced	16.6 s	0.8 s	0.477
Braced	16.2 s	0.4 s	

Table 4. Average T-test time. There was no statistically significant increase in the time taken to complete the t-test while in the braced condition compared to the unbraced condition.

The surveys regarding the participant's pain that were administered prior to testing and after the brace was tested received similar answers for both conditions. In both conditions, the participant noted that they experienced hip pain daily. The participant said that no pain was experienced while standing, and mild pain was experienced while sitting and walking on a flat surface. Additionally, it was noted that they experienced moderate pain while squatting and experienced severe pain while

running on a flat surface. The only difference in pain noted between the non-braced condition and the braced condition is that the participant experienced severe pain while twisting and turning without the brace, but only experienced moderate pain while wearing the brace and performing those movements.

In addition to pain, the surveys also gathered information regarding the difficulty of certain movements. Like the pain portion of the survey, there was little difference between the non-braced and braced conditions. For both conditions, the participant stated that they experienced no difficulty while standing, and mild difficulty while walking on a flat surface. The participant experienced moderate difficulty while twisting, turning, and squatting, and experienced severe pain while running on a flat surface. The difficulty level was different between conditions for the sitting down category—the participant found it mildly difficult to sit with the brace on, but not difficult to sit without the brace.

The comfort survey that was administered after the brace was tested yielded a neutral rating in the running and squatting category, and a comfortable rating in the walking category. Sitting, standing, and turning all received extremely comfortable ratings.

The brace measured at 3.5mm thick at its thickest section, and 1.10mm thick at its thinnest section.

4.3 Discussion

4.3.1 Key Findings

The brace failed to meet the first outcome metric, “the brace should increase the peak hip external adduction moment.” When a paired t-test was conducted, no statistically significant increase was found in the peak hip external adduction moment in the braced condition when compared to the unbraced condition (Table 2; p value = 0.542). There are three potential reasons as to why this occurred: there was a decrease in the hip adduction angle that was accompanied with an increase in the ground reaction force that resulted in similar peak hip external adduction moments; the brace failed to make any difference in the hip adduction angle or ground reaction force; or the brace increased the right hip adduction angle and was accompanied by a decrease in the ground reaction force.

When comparing the max hip adduction angle between the non-braced and braced conditions, it is apparent that a statistically significant difference occurred between the two (Table 3; p value = 0.010). The braced condition’s average peak adduction angle was 0.855° higher than the unbraced condition, indicating that the brace inadvertently caused hip adduction. This was the opposite of what the brace set out to do. It is likely that the adduction was created by the elastic band that was placed across the front of the body, running from the left hip to the right thigh. While great care was taken during brace construction to ensure that the force was applied in the desired direction and only on the areas that were specifically designated for alignment correction, it is possible that during the anchoring process the amount of force applied by that strap was inadvertently increased. Another factor that could have led to an increase in hip abduction is trunk lean, both in the frontal and sagittal plane. If the participant leaned towards the affected side, an increase in hip adduction could occur.

Since the external hip adduction moment did not significantly change while the hip adduction moment increased, it can be inferred that the ground reaction forces decreased in the braced condition compared to the non-braced trials.

The brace succeeded in meeting the second outcome metric, “the brace should not increase the wearer’s time to initiate a movement in response to a stimulus.” A paired t-test was conducted with the time data gathered during the timed T-test, and no statistically significant difference was found between the values (Table 4; p value = 0.4766). Therefore, the brace did not significantly increase the time between the stimulus and when the participant initiated movement. This metric was important to test because since the brace is designed to be worn during athletic activity, there is a desire to not slow the wearer’s reaction time out of safety concerns. While the 0.4 second difference between the two conditions’ averages was not statistically significant, that amount of time can be game-changing when competing in athletic events. Four tenths of a second can be the difference between a runner being called safe or out at first base in baseball, and so this slight increase in speed must not be overlooked.

The brace succeeded in meeting the third outcome metric, “the brace must not increase the wearer’s pain levels.” Little difference was observed in the pain survey responses between the non-braced condition and the braced condition, with the only improvement in pain being a single point difference in the twisting and turning category. While any improvement in the participant’s pain levels is a positive note, the result was not what was expected. It is hypothesized that the reason that there was largely no difference in the participant’s pain level was that the participant took the non-braced condition survey prior to undergoing any testing whatsoever, and then took the braced

condition pain survey after undergoing both testing conditions. It is possible that the pain of undergoing the testing without the brace affected the results of the braced condition pain survey, as the participant voiced that they felt pain and discomfort while testing without the brace. While the second brace prototype was easier to construct, it should be noted that the first brace prototype's base material was more compressive and likely would have been more comfortable and potentially provided more pain relief and lowered the scores of the braced condition pain survey, as compression has been shown to relieve pain (Agarwal & Juneja, 2022).

The brace passed the fourth outcome metric, "the brace must be comfortable for the wearer." The brace received scored neutral, comfortable, or extremely comfortable in all categories of the comfort scale. Additionally, it caused only a single point increase from not difficult to mildly difficult while sitting down without the brace versus with the brace on, and the brace did not change the difficulty of any of the 5 other tasks listed in the survey. The increase in difficulty while sitting was likely due to the participant feeling all of the components of the brace bunch together, whereas when they stand, walk, or run, the components are in their specified place, spread apart. Additionally, when the wearer sits down, there is more compression felt around the lower torso that can be jarring when first experienced. It is anticipated that after more familiarization visits with the brace that there will be no increase in difficulty of sitting.

The brace passed the fifth outcome metric, "the brace must fit underneath a standard athletic uniform." It is assumed that since the brace is 3.5mm thick at its thickest section, that it can easily fit underneath a standard athletic uniform such as a basketball jersey and shorts, or a softball jersey and pants. This allows the wearer to

protect the brace from potentially getting damaged if they were to fall while wearing it, but also provides the wearer with more stability and support to the hip. Since the hip joint is covered by many muscles, ligaments, and other tissues, it is important to have the hip brace as close to the skin as possible to reduce the amount of internal rotation that occurs.

4.3.2 Limitations

Limitations of this study included only having one participant available for testing. Ideally, to test the brace it would be worn and tested by multiple individuals of varying sexes, ages, hip pathologies, and body sizes. This would provide a more accurate view of the efficacy of the brace rather than relying on one person and a single hip pathology. It is important to note that due to a need for future iterations of the design and the limited case-based assessment of the device, the next steps for this project do not include distributing this brace for use in the general population.

As mentioned in section 4.3.1, one limitation to the study design was when the surveys were administered. In the study's current format, the responses gathered for the braced condition have the potential to be influenced by the pain and fatigue felt from performing both the non-braced and braced trials. To limit the influence of those sections, one change that could be made to the study design is separating the data collection into two sessions, at least a week apart to allow the body to recover. At the first session, the participant can complete the non-braced portion of the study and then fill out the non-braced pain survey. At the second session, the participant can complete the braced portion of the study, followed by the braced pain survey and comfort survey.

Redesigning the survey in this manner would potentially create more distinction between the data, and also produce more valid results.

4.3.3 Conclusion

In conclusion, the brace succeeded in meeting four of the five outcome metrics. Arguably, the most important metric was the one that was not successful, but it is hypothesized that there is a relatively simple solution to the problem. By eliminating the elastic strap that crosses the body anteriorly from the left hip to the right thigh, inadvertent hip adduction is removed and the abduction that is provided by the rest of the elastic is capable of adjusting the hip joint.

Regardless of the failure to meet the first outcome metric, the brace is considered a success based on its completion of the remaining four outcome metrics. The brace did not increase the time it took the wearer to initiate movement, it did not increase their pain levels, it was comfortable for the participant to wear, and it fit underneath standard athletic uniforms.

Chapter 5. Future Directions and Conclusion

In this chapter, future directions for this study will be discussed, and the conclusions drawn from this study will be reiterated.

5.1 Future Directions

This study has many different opportunities for future directions. On the design side, alterations to the exoskeleton and elastic pattern can be explored to create better range of motion control as well as properly create hip abduction. Refinement of the exoskeleton should occur to better limit the wearer's range of motion in the lateral plane, which has the potential to lower hip pain. The exoskeleton parallelogram versions tested in the current project (Chapter 3) were seen to provide comparable levels of resistance to strain for expected patient movement. It is also unknown how the exoskeleton would respond the rates of load typical of human movement. To refine the exoskeleton design, it would be beneficial for testing to occur with various sizes and arrangements of parallelograms, as each of the versions that were tested in this study had approximately the same length and width. Another way that the exoskeleton could be refined is by testing various materials besides TPU. It is hypothesized that using different 3D printing filaments and altering the size and orientation of the exoskeleton may provide varying resistance within strain ranges for expected patient movement. All future testing of exoskeleton components should be completed at strain rates typical of athletic movement.

Refining the elastic is another future direction that must occur. This refinement must occur due to the observed increase in the right hip adduction angle during the

braced condition (see Table 3). It could be improved in two ways, removing the anterior portion of the brace or adjusting its position in relation to the hip joint are two potential solutions. Removing the anterior elastic strap that crosses across the lower stomach from the left hip to the right thigh would increase the amount of hip abduction that is created by the brace through removing any accidental forces that could be introduced during construction that would lead to hip adduction. Additionally, raising the location of the anterior strap so that it passes across the hip joint center or above it rather than below it, as in the current design, is another way to decrease the amount of inadvertent hip adduction that is created by said piece of elastic.

Once the elastic and exoskeleton have been refined, a future direction for this study is to create multiple prototypes that each feature one component of the complete prototype, so that assessment of the components are isolated. Therefore, it would be possible to determine which components are contributing the most correction to the hip joint during movement.

There are also many future directions that could be taken regarding the patient use study's design and structure. For example, having the participant come in on multiple days rather than performing both the unbraced and braced trial in the same day has the potential to produce more reliable results that are not influenced by trials previously done that day. Additionally, changing when the participant takes the pain surveys to taking the respective survey after each trial has been completed has the potential to standardize the patient's exhaustive and pain state when taking the survey. It is also would be beneficial to review the content of the surveys, expand and model them further after existing hip pain and function surveys such as the HHS or HOOS

survey. Analyzing variables such as the ground reaction forces as well as the lateral and sagittal trunk angle would also be helpful in determining the cause of changes within the external hip adduction moment, as they can affect the moment in addition to hip adduction.

5.2 Conclusion

To conclude, this thesis met the goal of developing and testing a novel hip brace designed for athletic use. This brace was designed to bridge a gap among existing market solutions, and while the hip brace is far from finished, this project served as a good starting point for future students interested in developing orthotic medical devices while at the University of Oklahoma. This case study sets the foundation for further investigation into the hip brace, and hopefully it will be expanded to include a larger sample size to obtain more representative and robust data regarding the brace's efficacy. As stated in section 5.1, the next steps that should be taken by researchers include minor brace redesigns as well as a review of the study's methods and surveys. Once further development of the design and testing methods are complete, it is expected that the hip brace will help reduce pain and improve patient outcomes during athletic activity, allowing people to stay active and continue doing activities they love despite a history of hip injuries.

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Appendix

IRB Research Protocol

IRB Number: 15538
IRB Approval Date: 03/22/2023

RESEARCH PROTOCOL

Title of Project: Hip Joint Brace for Improved Patient Outcomes During Athletic Activity

Principal Investigator: Sarah Breen; PhD; Biomedical Engineering

Abstract
It is estimated that 76 million people suffer from hip pain in the United States, with one in four people developing symptomatic osteoarthritis in their lifetime (Murphy et al., 2010). Hip injuries cause pain and discomfort but can also fundamentally change the biomechanics of the hip, with one of the most common causes of hip pain being a decreased external hip adduction moment (Diamond et al., 2018). Treatment for less serious injuries, includes rest, anti-inflammatories and in some cases, physical therapy are all that is needed to resolve the hip pain. For severe injuries, surgery may be performed. After treatment and rehabilitation under the supervision of physicians, injured athletes may resume athletic activities, but significant numbers of patients never return to their pre-injury gait pattern or level of joint stability (Sogbein et al., 2019). In the current market, there are few options for affordable, readily available hip braces to support athletic reintroduction. Additionally, those that do exist may be too bulky or offer minimal support. Therefore, there is a need for a device that bridges the gap between the current market options that is compatible with athletic activity. The purpose of this study is to examine the acute effects of a newly designed hip brace on biomechanical variables, hip pain, athletic task performance. It is hypothesized that wearing the hip brace leads to acute improvements in hip mechanics (increased hip adduction moment when compared to the no brace condition) and decreases in pain without compromising comfort or performance.

A. Specific Aims

It is hypothesized that wearing the novel hip brace leads to acute improvements in [1] hip mechanics (increased hip adduction moment when compared to the no brace condition) and [2] decreases in pain [3] without decrements in performance.

It is hypothesized that the comfort scores for the novel hip brace will be satisfactory or greater.

This project is a small-scale feasibility study to established if a soft non-invasive brace of this nature is comfortable and if it can provide acute improvements in hip pain without compromising athletic agility performance. This information can be used to inform future

long-term investigations where the measured changes in hip join mechanics can be optimized to serve as rehabilitation training exposures for long-term use.

B. Background and Significance

It is estimated that 76 million people suffer from hip pain in the United States, with one in four people developing symptomatic osteoarthritis in their lifetime (Murphy et al., 2010). Most hip injuries that arise in younger patients under 50 years old are due to causes such as impingement, muscle strains or tears, and labral tears (Bowman et al., 2010). Hip injuries cause pain and discomfort and fundamentally change gait mechanics, with one of the most common causes of hip pain being a decreased external hip adduction moment (Diamond et al., 2018). After treatment and rehabilitation, injured individuals may resume athletic activities, but significant numbers of patients never return to their pre-injury gait pattern or level of joint stability (Sogbein et al., 2019).

In the current market, there are few options for affordable, readily available hip braces to support athletic reintroduction. Additionally, those that do exist may be too bulky or offer minimal support. Therefore, there is a need for a device that bridges the gap between the current market options that is compatible with athletic activity. The purpose of this study is to examine the acute effects of a newly designed hip brace on biomechanical variables, hip pain, athletic task performance.

This project is a small-scale feasibility study to established if a soft non-invasive brace of this nature is comfortable and if it can provide acute improvements in hip pain without compromising athletic agility performance. This information can be used to inform future long-term investigations where the measured changes in hip join mechanics can be optimized to serve as rehabilitation training exposures for long-term use.

Dr Breen & Dr Shih have both conducted several studies in clinical populations examining gait mechanics and the impact of new and novel rehabilitation devices. They are experienced in the data collection, analysis and interpretation techniques required for this project.

C. Preliminary Studies/Progress Report

Dr Breen has conducted several studies in clinical populations examining gait mechanics and the impact of rehabilitation devices:

Mylle, I., Perrin, O. D., Rebensburg, A. J., Ruprecht, C., Vanwelsenaers, L., Spranger, K., ... & **Breen, S.** (2018). The Effect Of A Novel Rehabilitation Device On Muscle Activation During Gait In Persons With Multiple Sclerosis. International Society of Biomechanics in Sport Conference Proceedings, 36(1), (pp. 166-170).

Rebensburg, A. J., Perrin, O. D., Mylle, I., Ruprecht, C., Vanwelsenaers, L., Spranger, K., ... & **Breen, S.** (2018). The Effect Of A Novel Rehabilitation Program On Walking Performance In Persons With Multiple Sclerosis. International Society of Biomechanics in Sport Conference Proceedings, 36(1), (pp. 915-919).

Perrin, O. D., Rebensburg, A. J., **Breen, S.,** Ruprecht, C., Jensen, R. L., Spranger, K., ... & Mylle, I. (2018). Changes In Gait And Coordination Variability In Persons With Multiple Sclerosis Following A Rehabilitation Program. International Society of

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Clarke S.B., Deighton K, Newman C, Nicholson G, Gallagher L, Boos CJ, et al. (2018) Changes in balance and joint position sense during a 12-day high altitude trek: The British Services Dhaulagiri medical research expedition. PLoS ONE 13(1): e0190919.

Clarke, S. B., Kenny, I. C., & Harrison, A. J. (2015). Dynamic knee joint mechanics after anterior cruciate ligament reconstruction. Medicine and science in sports and exercise, 47(1), 120-127.

Francis, P., and Ledingham, J., and **Clarke, S. B.,** and Collins, D. J., and Jakeman, P., (2016) A comparison of stride length and lower extremity kinematics during barefoot and shod running in well trained distance runners. Journal of Sports Science and Medicine. 15, 417-423 ISSN 1303-2968

D. Research Design and Methods (What, When, How, Where)

The current study will be a case study involving two participants.

Hip Brace Design

The hip brace consists of three main components: compression shorts as the base, elastic bands for guided abduction, joint unloading, and support, as well as a 3D printed semiflexible exoskeleton will be used to brace an unstable hip joint providing moderate range of motion restriction.

This custom designed hip brace is soft non-invasive device that poses limited risk to participants. The brace pictured below is composed of a tight fitting clothing layer which has supplementary compressive bandage, and 3D printed lattice layer. Through device design and usability analysis the device has offered pressure and joint assistance similar to that of commonly employed athletic taping. The device will be labelled with the manufacturer's information, relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings and precautions.

Figure 1. Proposed Left Hip Brace Design. This figure shows the anterior, sagittal, and posterior view of the proposed left hip brace.

Experimental Set-Up

Biomechanical data will be collected at the Center for Human Performance Measurement (CHPM) Core Facility at the University of Oklahoma Health Sciences Center in Oklahoma City, OK. Three in-floor AMTI force plates will be used to collect kinetic data at a sampling frequency of 1,000 Hz. The CHPM utilizes a 12 camera set-up to collect kinematic data with Qualysis™, cameras will be set to a sampling rate of 250 Hz. Markers placed on the participant must be within the view of at least two cameras at once to maintain tracking. To establish a right-handed coordinate system, a rigid L-shaped frame with four markers will be placed near the force plates. To establish scale, a rod with three markers of a known distance apart will be used for calibration of the system to the person getting measured.

Experimental Procedures

Participants will be engaged in this research for two sessions, one familiarization session in Gallogly Hall, Norman Campus, and one test session at the Center for Human Performance Measurement (CHPM) OUHSC (OU Health Science Center) Campus. The first session will be a ~ 30-minute familiarization session at Gallogly Hall, in which participants will try on the brace and perform the agility tests measured during the second visit to become comfortable with them.

One week later, participants will visit the CHPM. There, they will have their mass and height measured and recorded. Prior to beginning biomechanical testing, participants will have 39 retroreflective markers placed on their pelvis and lower extremities following a modified version of the Helen Hayes marker set, consisting of a combination of clusters and single markers.

Firstly, participants will complete a standardized 5-minute warm-up of walking on a TrackMaster treadmill (TMX428CP, Full Vision Inc., Newton, KS) at a rate of 3.0 mph and 0% incline. Participants will then be instructed to stand in a neutral position, with their arms across their chest, so that one static trial can be used to align each participant with the laboratory coordinate system, as well as serve as a reference point for the data to be collected. Participants will then be instructed to perform 10 overground walking trials without the brace. Their motion will be captured, and they will walk over three embedded AMTI force platforms. Following the walking trials participants will perform five repetitions of a T-test, an athletic agility task (Munro & Herrington, 2011) without the brace. This task involves forward, and lateral movement and performance will be measured as completion time. Participant pain will then be measured on a self-reported scale (Nilsdotter et al., 2003).

Participants will then be issued and fitted with a custom designed hip brace, and conduct the warmup, walking trials and agility test again, while wearing the brace. Following completion of the agility test participants will repeat the pain scale. Patient comfort will also be measured on a self-reported scale of 0-10, 0 being the most uncomfortable brace imaginable to 10 being the most comfortable brace imaginable (Hanspal et al., 2003).

The following tests and procedures will take place at CHPM only:

- Height and mass measurements
- Hip pain survey
- Walking trials
- T-test agility test
- Brace comfort survey

Data Analysis

Visual 3D (v. 6.0, C-Motion, Germantown, MD) will be used to analyze the kinematic and kinetic gait data gathered at the CHPM, to compare hip adduction moment between conditions.

E. Inclusion / Exclusion Criteria

1. Inclusion criteria for the current study are as follows: recruited participants for the case study must be between the ages of 18 and 40, and moderately active for at least one year. Additionally, the participants must have undergone hip surgery and have continued to experience hip pain within 12 months of involvement in the current study.
2. Exclusion criteria for the current study are as follows: Any individual who is unable to perform walk 10 m or t-test unassisted. Any individual under 18 years of age or over 40 years of age. Any individual who is pregnant. Any individual who is not released for activity by their surgeon.
3. Participants have the right to withdraw from the study at any time and they will be removed from the study if they chose to do so. Other early termination criteria, includes the occurrence of pregnancy, a change in their ability to perform a 10 m walk or t-test task unassisted.

F. Gender/Minority/Pediatric Inclusion for Research

This is a small case study recruiting participants by direct contact. The participant population will not be a diverse pool that represents the population of individuals in Oklahoma or the US that demonstrate hip pain. As a pilot feasibility study we will expand recruitment to ensure the participant pool or larger future studies is representative of the patient population.

G. Recruitment and Enrollment

1. Describe the plans for recruitment.
    a. Participants will be recruited by direct contact within researchers contact pool of peers, colleagues, and past students.
2. Describe the consent procedures to be followed.
    a. All participants will complete an informed consent prior to participation
3. Describe the location where consent is most likely to take place.
    a. Familiarization and consent will take place in Gallogly Hall, U Norman campus.
    b. Testing will take place in OUHSC Center for Human Performance Measurement (CHPM) Core Facility at the University of Oklahoma Health Sciences Center in Oklahoma City, OK.
4. Describe provisions for recruiting non-English speaking participants.
    a. Non-English-speaking participants will not be recruited
5. Describe measures to decrease participant coercion
    a. Participants will be given ample time to review consent
    b. Participants will provide consent to a qualified research assistant to ensure no coercion power dynamic is present

H. Risks and Benefits

1. Describe risks and assess their likelihood and severity.
    a. Risks and side effects related to the brace we are studying include

irritation or chafing from the hip brace.

2. Risks and side effects related to the physical assessments we are conducting include tripping, falling, stumbling, and delayed onset muscle soreness because of completing the agility tests.
3. Describe procedures for protecting against or minimizing potential risks.
    a. All tasks will be clearly explained and demonstrated to participants. All experimental areas will be clear of trip hazards and will be optimally lit.
4. Discuss why risks are reasonable in relation to benefits.

The risk associated with this research are very minimal and no more than is associated with completing regular activities of daily living.

I. Statistical Methods

A One-Way ANOVA will be performed using SPSS (v. 24, IBM Corporation, Armonk, NY) to compare biomechanical data between conditions. This data will be assessed on a case study basis which each participant trial acting as a data point replicate.

Pain and comfort scales will be compared between conditions to gain insight into meaningful changes in pain and how comfort compares to industry standards for hip braces.

J. Data and Safety Monitoring Plan

Privacy and Confidentiality have been addressed in the Privacy and Confidentiality Section of the IRB application.

K. Literature Cited

Murphy, L. B., Helmick, C. G., Schwartz, T. A., Renner, J. B., Tudor, G., Koch, G. G., Dragomir, A. D., Kalsbeek, W. D., Luta, G., & Jordan, J. M. (2010). One in four people may develop symptomatic hip osteoarthritis in his or her lifetime. *Osteoarthritis and Cartilage, 18*(11), 1372–1379. https://doi.org/10.1016/j.joca.2010.08.005

Diamond, L. E., Allison, K., Dobson, F., & Hall, M. (2018). Hip joint moments during walking in people with hip osteoarthritis: A systematic review and meta-analysis. *Osteoarthritis and Cartilage, 26*(11), 1415–1424. https://doi.org/10.1016/j.joca.2018.03.011

Sogbein, O. A., Shah, A., Kay, J., Memon, M., Simunovic, N., Belzile, E. L., & Ayeni, O. R. (2019). Predictors of Outcomes After Hip Arthroscopic Surgery for Femoroacetabular Impingement: A Systematic Review. *Orthopaedic Journal of Sports Medicine, 7*(6), 232596711984898. https://doi.org/10.1177/2325967119848982

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IRB Outcome Letter

The UNIVERSITY of OKLAHOMA

Institutional Review Board for the Protection of Human Subjects

Initial Submission – Board Approval

Date:	March 22, 2023	**IRB #:**	15538
To:	Sarah Breen	**Meeting Date:**	03/20/2023
		Approval Date:	03/22/2023
		Expiration Date:	02/29/2024
Study Title:	Hip Joint Brace For Improved Patient Outcomes During Athletic Activity		
Study Status:	Active - Open - Expedited | Check-In Req		

The University of Oklahoma Health Sciences Center's Institutional Review Board (IRB) reviewed the above-referenced research study at its regularly scheduled meeting and requested specific changes to the submission. On behalf of the IRB, I have verified that the specific changes requested by the convened IRB have been made and I grant final approval for this study.

Approval for this research is limited to the activities described in the approved protocol and application. In accordance with this approval, specific conditions for the conduct of this research are listed below, and informed consent from participants must be obtained as indicated.

Risk/Benefit Assessment: Research not involving greater than minimal risk.

Informed Consent Determination:
Informed consent and research privacy authorization must be obtained using the currently approved, stamped forms. You must retain all original, signed forms.

Continuing Review Determination:
As part of this approval, annual continuing review is not required. However, this research is still subject to annual monitoring. You must promptly submit an Annual Check-In Form to the IRB upon notification, approximately 30 days prior to the check-in due date indicated above.

Principal Investigator Responsibilities:

- Conduct the research study in a manner consistent with the requirements of the IRB and federal regulations at 45 CFR 46 and/or 21 CFR 50 and 56.
- Request approval from the IRB prior to implementing any/all modifications.
- Promptly report to the IRB any harm experienced by a participant that is both unanticipated and related per IRB Policy.
- Maintain accurate and complete study records for evaluation by the HRPP quality improvement program and if applicable, inspection by regulatory agencies and/or the study sponsor.

The following are also required if applicable to this research study:

- You may *not begin your study* until the contract through Office of Research Administration (ORA) is finalized and signed as per OUHSC Institutional policy.
- If this study involves external sites requiring a reliance agreement for OUHSC to serve as IRB of record, submit a modification to add each non-OU site and non-OU collaborator to the application after a reliance agreement has been finalized.

Study documents approved or accepted with this submission are listed below. If you have questions about this correspondence, contact the IRB at 405-271-2045 or irb@ouhsc.edu.

Sincerely,

Gene Hallford, PhD, Chair
Institutional Review Board

Study documents associated with this submission:

Study Document			
Title	Version #	Version Date	Outcome
HIPAA 1 authorization form	Version 1.0	02/27/2023	Approved
Mentzer_CITI_Training	Version 2.0	01/27/2023	Noted
PainScale-Survey	Version 1.0	01/27/2023	Approved
ComfortScale-Survey	Version 1.0	01/27/2023	Approved
Protocol	Version 1.2	01/27/2023	Approved

Study Consent Form			
Title	Version #	Version Date	Outcome
InformedConsent_Breen-Menter_01-27-23	Version 1.2	01/27/2023	Approved

Information for Industry Sponsors: the columns titled Version Number and Version Date are specific to the electronic submission system (iRIS) and should not to be confused with information included in the Document and/or Consent title(s).

Surveys

Adapted HOOS (Nilsdotter et al., 2003) Pain Survey: (Pre-Braced Condition)

Please mark your selection with an X.

How often is your hip painful?

Never	Monthly	Weekly	Daily	Always

What amount of hip pain have you experienced in the last week during the following activities?

Activity	None	Mild	Moderate	Severe	Extreme
Walking on a flat surface					
Running on a flat surface					
Sitting down					
Standing					
Twisting / Turning					
Bending down to touch the floor (squatting)					

For each of the following activities please indicate the degree of difficulty you have experienced in the last week due to your hip.

Activity	None	Mild	Moderate	Severe	Extreme
Walking on a flat surface					
Running on a flat surface					
Sitting down					
Standing					
Twisting / Turning					
Bending down to touch the floor (squatting)					

Adapted HOOS (Nilsdotter et al., 2003) Pain Survey: (Braced Condition)

Please mark your selection with an X.

How often is your hip painful?

Never	Monthly	Weekly	Daily	Always

What amount of hip pain have you experienced in the last week during the following activities?

Activity	None	Mild	Moderate	Severe	Extreme
Walking on a flat surface					
Running on a flat surface					
Sitting down					
Standing					
Twisting / Turning					
Bending down to touch the floor (squatting)					

For each of the following activities please indicate the degree of difficulty you have experienced in the last week due to your hip.

Activity	None	Mild	Moderate	Severe	Extreme
Walking on a flat surface					
Running on a flat surface					
Sitting down					
Standing					
Twisting / Turning					
Bending down to touch the floor (squatting)					

Comfort Survey (Braced Condition)

Please use the following scale (Joshi et al., 2015) to rate how comfortable the brace is:

1 = extremely comfortable
3 = neutral
5 = extremely uncomfortable

What is your comfort level while standing?	
What is your comfort level while sitting?	
What is your comfort level while walking?	
What is your comfort level while running?	
What is your comfort level while turning?	
What is your comfort level while squatting?	

Appendix Works Cited

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