THE EFFECT OF A SEMI-RIGID PATELLAR TRACKING ORTHOSIS ON PATELLOFEMORAL PAIN

By

KAREN SUE BLOCH

Bachelor of Science

Western Illinois University

Macomb, Illinois

1998

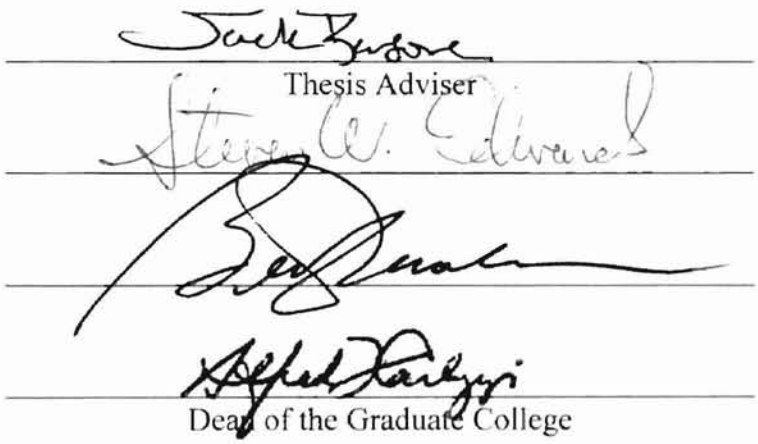
Submitted to the Faculty of the
Graduate College of the
Oklahoma State University
in partial fulfillment of
the requirements of
the Degree of
MASTER OF SCIENCE
August, 2001

THE EFFECT OF A SEMI-RIGID PATELLAR

TRACKING ORTHOSIS ON

PATELLOFEMORAL PAIN

Thesis Approved:



Thesis Adviser

Dean of the Graduate College

PREFACE

Injuries to the knee are complex due to the dynamic structures that stabilize the joint to provide stability and movement for active daily living. It has been stated that 30% of patients in the sports medicine clinics are seen for patellofemoral pain (Kowall, Kolk, Nuber, Cassi, & Stern, 1996). The high incidence of patellofemoral pain has inspired physicians to find the most ideal treatment to reduce the pain in these individuals, specifically to correct maltracking of the patella. Due to the dynamic structure of this joint, it has been a challenging task to find an effective treatment. The Breg® Patellar Tracking Orthosis was designed to help stabilize the patellofemoral joint with the intention of limiting the incidence of pain suffered by individuals with this affliction. Positive finding from this investigation could potentially shed light on conservatively treating patients with a chronic history of patellofemoral pain, and provide an avenue of immediate pain relief. This study proposed to determine the effectiveness of the Breg® Patellar Tracking Orthosis on patellar maltracking, which is a directly related to patellofemoral pain (Powers et al., 1999). The study was designed to determine if the Breg® Patellar Tracking Orthosis brace would decrease the likelihood of patellar maltracking, due to the reinforcement and re-alignment of the patella throughout knee flexion and extension. The independent variables, the Lysholms II and Knee Orthopedic Outcome Score were the subjective tests that measured the dependent variables through the pre, mid and post time-frames over the five week experimental period.

ACKNOWLEDGEMENTS

First, I wish to express my sincere appreciation to my major advisor, Dr. Jack Ransone for his guidance and patience during this process. Second, I would like to thank Dr. Ken Smith for granting me the opportunity to pursue this subject matter with the Breg Incorporation. His countless hours devoted to this topic have been the instrumental in the completion of this document. Third, I would like to extend much thanks to my other committee members Dr. Steve Edwards, who assisted me through many hours of data collection and computation, and Bert Jacobson, who also sacrificed extra time to assist me with this thesis. Fourth, thanks are conveyed to Pat Cawley for donating the Breg PTO braces and providing vital information on the protocol. Other individuals such as Tom Altena and Dr. Carey Couch assisted their time in proof reading the material, and giving encouragement along the way. Finally, I would like to thank my devoted mother and best friend, Sandra Bloch, who has been my inspiration, strength and mentor throughout my life endeavors.

This thesis is dedicated to my loving and devoted father, Gerald Bloch who passed from this earth February 15, 1998. He instilled the devotion and passion within my soul to be the best person both academically and personally.

TABLE OF CONTENTS

Chapter Page

LIST OF TABLES

LIST OF FIGURES

CHAPTER I

INTRODUCTION

Patellofemoral pain represents 30% of the injuries in both athletic and non-athletic populations as reported by sports medicine clinics (Kowall, Kolk, Nuber, Cassisi, & Stern, 1996). Pain over the anterior aspect of the knee can be attributed to multiple factors including patellofemoral maltracking (Bellemans, Cauwenberghs, Witvroum, Brys, & Victor, 1997). Powers (1998) stated that 50% of the patellofemoral pain victims have patellar maltracking due to such anomalies as femoral trochlea dysplasia, patella alta, tightness of the lateral soft tissues, or unequal activation of the vastus lateralis and vastus medialis. A primary pathologic entity relating to this pain is thought to be associated with the increased shearing and compression associated with abnormal patellar tracking (Powers, Shellock, Beering, Garrido, Goldbach, & Molnar, 1999). Despite the high number of individuals afflicted with patellofemoral pain, it is believed that with a focus of conservative treatment, such as nonsteroidal anti-inflammatory medications, stretching, McConnell taping style, bracing, and/or quadriceps strengthening, pain and functional disorder can be reduced (Muhle, Brinkmann, Skaf, Heller, & Resnick, 1999; Shellock, Mullin, Stone, Colememan, & Crues, 2000).

Proper diagnosis and treatment of patellofemoral disorders is critical in improving the long-term prognosis and preventing osteoarthritis of the patellofemoral joint (Muhle

et al., 1999). One of the most noted underlying causes of patellofemoral pain has been identified as malalignment of the patella, which may be manifested due to subluxation and tilt of the patella. This tracking dysfunction results in damage to the posterior articulating surface of the patella, as well as straining the peripatellar structures, which directly results in pain (Kowall et al., 1996). Other predisposing patellar tracking disorders include: femoral trochlea dysplasia, patella alta, tightness of the lateral soft tissues, and uneven activation of the vastus lateralis and vastus medialis (Powers et al., 1999).

One of the most common types of conservative treatments of patellofemoral pain is the use of a knee brace or sleeve (Birmingham, Kramer, Inglis, Mooney, Murray, Fowler, & Kirkly, 1998; Powers, 1998). The widespread application of a knee support device has received recognition largely because of its potential role in improving performance and decreasing injury. A variety of braces or sleeves have been implemented on individuals suffering from knee pain. However, recent studies have reverted from the traditional open-buttress neoprene sleeve, to a more specific patellar tracking orthosis. Specifically, researchers have discovered that patellar realignment braces are beneficial in the treatment of patients with various patellofemoral disorders. This brace dissipates lateral forces on the patella, maintains patellar alignment, improves patellar tracking, and prevents patellar subluxation and/or dislocation (Maenpaa & Lehto, 1997; Muhle et al., 1999). In addition, certain types of braces contain a firm plate to compress the buttress laterally providing a rigid resistance to the patella, causing the patella to track more normally and resist subluxation. Despite the variation in each brand

of knee brace, the overall goal is to decrease patellofemoral pain by reducing patellar maltracking (Powers).

Statement of the Problem

The problem of this investigation was to determine the effect of a centralized semi rigid patellar tracking orthosis on patellofemoral pain using the Lysholms II and Knee Osteoarthritis Outcome Score. The creation of a more centralized course for the patella was proposed to reduce or eliminate abnormal contact stresses, and reduces or eliminates symptoms originating from abnormal stresses, which are direct contributors of patellofemoral pain (Powers et al., 1999).

Null Hypothesis

The following hypotheses were tested at the .05 level:

There will be no significant difference in patellofemoral pain among the pre-test, mid-test and post-test of the experimental group using the semi rigid patellar tracking orthosis and the control group using the neoprene sleeve as measured by the Lysholm II scale.

There will be no significant difference in patellofemoral pain among the pre-test, mid-test and post-test of the experimental group using the semi rigid patellar tracking orthosis and the control group using the neoprene sleeve as measured by the Knee

Osteoarthritis Outcome Score investigating five sub-scales of pain, symptoms, activities of daily living, sports and recreation function, and knee related quality of life.

Delimitations

The study is delimited by the following:

1) The sample group consisted of subjects aged 18 to 45 years because the epiphyseal plates are closed, and the risk of osteoarthritis is reduced.
2) The subjects had no systemic illness with chronic use of medication as defined by those taking medication for more than two consecutive months.
3) The subjects had a history of patellofemoral pain and/or instability greater than two months duration (by symptoms and history).
4) The individuals were symptomatic with patellofemoral pain prior to and at the time of the baseline evaluation.
5) The population was targeted to active individuals experiencing pain during active daily living and functional activities.
6) The subjects were not randomly selected due to the limited number of available subjects with patellofemoral pain evidencing no exclusion criteria.

Limitations

The study is limited by the following:

1) Apparently healthy male and females with generalized patellofemoral pain were randomly assigned to the experimental group or control group, with either patellofemoral pain with instability (subluxation and/ or dislocation), malalignment with no instability, or patellofemoral pain without malalignment.
2) There was no control over the subject's decision to wear the brace during the five-week period.
3) Exercise frequency, intensity, and duration outside of the designated rehabilitation exercises were not controlled due to the lack of subject stipends for participation reward and time demand that each subject would be required to spend if asked to perform the preceding variables.
4) The population used in this investigation does not allow influence beyond an active population.

Assumptions

The following assumptions were made for this study:

1) All subjects complied by wearing the brace during active daily living throughout experimental period. The weekly phone conversation and weekly

diary monitored compliance with the braced subjects and adherence to exercise protocol.

2) Subjects answered truthfully when filling out health history forms concerning all medications taken throughout the evaluation period.
3) Perceived pain scale and pain tolerance varied between individuals.

Significance of Study

Injuries to the knee are complex due to the dynamic structures that stabilize the joint to provide stability and movement for active daily living. The high incidence of patellofemoral pain has inspired physicians to discover the most ideal treatment that reduces the pain in these individuals, and to specifically correct maltracking of the patella. Due to the dynamic structure of this joint, it has been a challenging task to find the ideal treatment. The semi rigid patellar tracking orthosis was designed to help stabilize the patellofemoral joint with the intention of limiting the incidence of pain suffered by individuals with this infliction. Positive finding from this investigation could potentially shed light on conservatively treating patients with a chronic history of patellofemoral pain, and provide an avenue of immediate pain relief. This study proposed to determine the effectiveness of the semi rigid patellar tracking orthosis on patellar maltracking, which is a directly related to patellofemoral pain (Powers et al., 1999). The study was designed to determine if the semi rigid patellar tracking orthosis brace would decrease the likelihood of patellar maltracking, due to the reinforcement and re-alignment of the patella throughout knee flexion and extension. The independent

variables, the Lysholm II and Knee Osteoarthritis Outcome Score were the subjective tests that measured the dependent variables through the pre, mid and post time frames over the five week experimental period.

Definitions

Apprehension test is an orthopedic test that places stress on the medial order of the patella. The subject will express pain and discomfort if the test is positive.

Crepitation is the crackling sound or sensation when bones are moving.

Closed Chain Exercise is the motion that occurs when the distal portion of the extremity is weight bearing or otherwise fixed (Starky & Ryan, 1996).

Infrapatellar means below the patella.

Open Chain Exercise is the motion that occurs when the distal portion of the extremity is non-weight bearing (Starky & Ryan, 1996).

Patella alta refers to the patella having an abnormally high position relative to the joint line of the knee (Starky & Ryan, 1996).

Patellar grind test is an orthopedic test that puts the subject's knee in a flexed and extended position, and the clinician places his or her hand over the patella to feel any grinding, clicking or pain through the knee range of motion.

Patellofemoral maltracking is noted as the incongruent positions of the patella in the femoral groove (Shellock et al., 2000).

Peripatellar pertains to the surrounding area of the patella.

Retropatella refers to pain behind the patella.

Synovial plica is located in the anteromedial and anterolateral joint capsule, and is a thickened fold of tissue (Starky & Ryan, 1996).

Viscoelastic is the tissue response to loading over a period of time with changing rates of deformity (Anderson & Hall, 1995).

CHAPTER II

REVIEW OF LITERATURE

One of the most common complaints observed in the clinical setting pertains to patellofemoral pain (Arroll, Ellis-Pegler, Edwards, & Sutcliffe, 1997, Kowell et al., 1996, Powers et al., 1999). Kannus, Natri, et al. (1999) reported that 10% of all the orthopaedic visits and 20%-40% of all knee complaints are related to the patellofemoral region. Powers (1998) linked this type of patellofemoral pain to maltracking of the patella because of the abnormal shearing and compression of the patella through a range of motion.

Regarding both athletic and non-athletic populations, research has stated patellofemoral-related problems are more prevalent among females than males (Huie, Scuderi, & Scott, 1997; Kowell et al., 1996; Powers, 1998). One linking factors for this higher percentage of knee pain has been linked to a greater Q-angle in females. The ratio of patellofemoral pain incidence is nearly two to one in females vs. males, even with men out-numbering females when athletes are studied (Powers). Targeting the general population, one in four people are affected with patellofemoral pain (Powers et al., 1999; Shellock et al., 2000). Validation of the high diagnosis of patellofemoral pain has been supported by a five-year study, which demonstrated that 25% of all knees evaluated in sports injury clinics were patellofemoral pain victims (Powers et al.). It is believed that

the success rates on long-term prognosis and prevention of osteoarthritis in the patellofemoral joint will improve with proper diagnosis and treatment of patellofemoral pain (Muhle et al., 1999).

Anatomy

Huie et al. (1997) provided a detailed explanation of the patellofemoral joint anatomy. The patellofemoral joint is comprised of the articulation between the undersurface of the patella and the sulcus of the femur. The patella has an articular surface consisting of seven facets, lies within the quadriceps tendon, is the largest sesmoid bone in the body, and acts as a bony shield for both the trochlea and distal femoral condyles when the knee is in the flexed position. Furthermore, the femoral sulcus is flatter proximally than it is distally, which encourages patellar subluxation to occur laterally in early flexion of the knee. In the healthy joint, lateral subluxation is prevented by the lateral femoral condyle due to it being slightly larger than the medial femoral condyle. The fascia of the four-quadriceps muscles, which are the rectus femoris, vastus lateralis, vastus medialis, and vastus intermedius, forms the quadriceps tendon and attaches to the proximal pole of the patella. The patellar ligament connects the distal pole of the patella and the tibial tubercle (Huie et al.).

Biomechanics

Proper biomechanics of the patellofemoral joint is key to the prevention of pain. Kowall et al. (1996) stated that the most frequent cause of patellofemoral pain was malalignment, manifested as subluxation and tilt of the patella through out range of motion, causing damage to the patellar articular surface, as well as a strain on the peripatellar structures.

The functional patella acts as a mechanical fulcrum, providing leverage during leg extension by centralizing the combined forces of the quadriceps muscles (Powers, 1998; Huie et al, 1997). Powers (2000) stated vastus medialis weakness relative to vastus lateralis strength is indicative of comprised medial patellar stability. The patella is specifically adapted to bearing high compressive forces since the articular cartilage of the patella is aneural and avascular. As the knee extends through the full range of motion, compressive forces are dramatically increased. The patella sits within the intercondylar notch at full flexion (130 degrees). The greatest amount of contact that the patella makes with the distal surface of the sulcus and femoral condyles is at the proximal pole of the patella when the knee is at 90 degrees. As the degrees of motion decrease to 60 degrees, the central portion of the patella comes in contact with the femoral groove in a fairly even distribution of compressive forces. The distal pole of the patella has the greatest contact with the uppermost portion of the femoral condyles at 30 degrees. The undersurface of the patella is no longer articulating with the articular surface of the femoral condyles in full extension (0 degrees), but is proximal to it. In full knee extension, the free-floating patella has unevenly applied vector forces, which are at the most distal facets of the

patella. During normal knee motion, the greatest amount of friction and erosion of the undersurface of the patella is in positions over 80 degrees and less than 30 degrees (Powers, 2000; Huie et al.).

Etiology of Patellofemoral Pain

A number of factors have been linked to the speculated causes of patellofemoral pain. Kowall et al. (1996) reported that trauma: both acute and chronic, directly to the knee joint, osteochondritis, synovial plicae, chondromalacia, and patellofemoral malalignment are all favorable reasons for pain. Shellock et al. (2000) primarily related patellofemoral pain to the incongruent positions of the femoral groove. In addition, Huie et al. (1997) associated pain with the combination of repetitive microtrauma from overuse, and dysplastic pathomechanics. These conditions relate the overuse factors as the primary cause of pain in the healthy population. Hsieh et al. (1998) adds the relation of abnormal kinematics of the patellofemoral joint, resulting in abnormal pressure distribution, as the responsible factor of patellofemoral pain. Powers (1998) revealed that nearly half of the patellofemoral pain victims have maltracking due to femoral trochlea dysplasia, patella alta, tightness of lateral soft tissues, or unequal activation of the vastus lateralis and vastus medialis.

The lack of an established relationship between patellofemoral pain and the structures involved in the knee has been a common inquiry among physicians. Huie et al. (1997) proposes a question about the "pain" factor of the patellofemoral pain victims and the absence of nerve root endings in the undersurface of the patella and femoral sulcus.

In this excerpt, there was no proven connection of pain and the absence of nerve roots. Powers et al. (1999) and Shellock et al. (2000) agree that the articular cartilage is aneural, and have dismissed this portion of the knee as a possible source of symptoms. However, it has been proposed that abnormal patellar tracking, which increases patellofemoral joint stress and subsequent articular cartilage wear, exposes the subadjacent endplate to pressure variations that would normally be absorbed by healthy cartilage. It is this mechanical stress that is believed to stimulate receptors in the subchondral bone, and cause the pain (Powers et al.; Shellock et al.).

Overuse risk factors have been related to the patellofemoral injuries. Huie et al. (1997) state that training errors, muscle-tendon imbalance, anatomic malalignment, improper footwear, and playing surface/terrain are all pre-disposing factors relating to knee pain. Factors specifically leading to patellofemoral pain related to maltracking have been linked to the Q-angle, tightness of the lateral retinaculum, vastus medialis obliquus muscle function, vastus lateralis to vastus medialis obliquus muscle ratio, femoral anteversion, tibial tubercle position, and trochlear shape (Bellemans et al, 1997; Sandmeier, Burks, Bachus & Billings, 2000).

Patellofemoral Evaluation

Four categories of evaluation for patellofemoral pain include history, observation, palpation, and special tests (Powers et al., 1999; Huie et al., 1997):

History: Powers et al. (1999) states the sources of pain being multiple, but generally characterized as being diffuse, and arising from the anterior aspect of the knee. The onset

of pain is persistent and its progression is slow. Pain is usually activity-induced and aggravated with functions that increase patellofemoral compressive forces, such as ascending and descending stairs, inclined walking, squatting or kneeling, and prolonged sitting (Arroll et al., 1997 & Huei et al.). Rest from activity normally relieves this knee pain. The position of knee in relation to the discomfort, reoccurrence of pain, and the activity of onset can depict patellofemoral pain.

Observation: Huie et al. (1997) observed gait, especially to rule out pathology in the hip that might contribute to pain in the knee. Quadriceps atrophy and abnormal Q-angle are other observed features that can be related to patellofemoral pain. Specifically, the Q-angle (Figure 1) draws a line from the anterior superior iliac spine of the pelvis to the center of the patella. It is transected by a line from the proximal tibial tubercle throughout the center of the patella. The tendency for the patella to track laterally will increase when the angle between these lines increases (Huie et al.). This angle, which is normally greater in females, might be the factor relating to the higher incidence of patellofemoral pain in women than in men. Powers et al. (1999) also adds that the loss of motion, patellar tracking, patellar placement and a sensation of giving way or instability within the knee are other features of observation that can be processed in an evaluation.

Palpation: Tenderness along the peripatellar facets with particular attention to the lateral border are the most palpated areas of the knee. The presence of effusion can be a contributing factor of knee pain, but can also be a red flag for a more severe internal joint derangement (Huie et al., 1997).

Special tests: Powers et al. (1999) reveal a positive patellar grind test and discomfort with palpation of the medial borders of the patella. Huie et al. (1997) add the apprehension

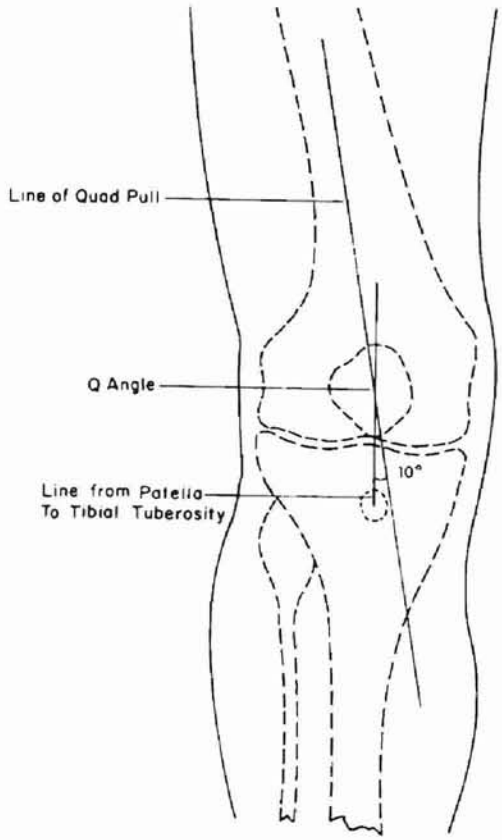


Figure 1. Q-Angle Measurement

sign, which is demonstrated by the patient tightening the quads to prevent further movement of the patella as its apex touches the lateral femoral condyles.

Diagnostic Studies

Upon completion of the initial evaluation, further diagnostic testing might be needed to complete a final diagnosis. There are four routes that can be taken. First, and most frequently used tool is the routine radiograph. Anterior-posterior (A-P), lateral, and sunrise views are normally taken to evaluate the anatomy and position of the patella (Huie, et al., 1997; Murray, Dupont, & Fulkerson, 1999). Second, the computerized

tomography can be utilized to scan cross-sectional images of the knee at every degree of flexion. Furthermore, it tracks the patella through the trochlear groove, and enables the clinician to manipulate and analyze the data with a computer (Bellemans et al., 1997; Huie et al.). Third, the MRI can be used to evaluate the soft tissues of the knee. It defines exact location, extent, and severity of tendonitis, cartilaginous, ligamentous, and osseus injuries without emitting radiation. Finally, the last resort is knee arthroscopy. Huie et al. stated this method is the best tool available today for visualizing pathology and determining the extent and classification of the injury.

Types of Patellofemoral Maltracking

Patellofemoral Dysplasia represents a spectrum of biomechanical abnormalities associated with anterior knee pain and patellar instability (Huie et al., 1997). The most prevalent types of patellar maltracking disorders are hypermobile patella, patellar subluxation, recurrent patellar dislocation, and acute patellar dislocation. Bellemans et al. (1997) studied patients with chronic anterior knee pain and divided them into three groups depending on their type of patellofemoral malalignment. The groups were subjects with patellar tilt, patellar subluxation, or a combination of patellar tilt and subluxation. Subluxation was defined as any lateral deviation of the patellar apex from the bisector of the femoral sulcus angle. The tilt, known as the angle of the patella formed by the line parallel to the lateral facet and the line connecting the posterior condyles, was less than eight degrees (Bellemans et al.). Each one of these terms is important in the following five-patellar tracking disorders.

Lateral Patellar Compression Syndrome: condition anticipated by activity related pain in the absence of patellar instability. Subjects complain of a dull, aching anterior knee pain that is exacerbated by prolonged sitting, stair climbing, or running. Furthermore, upon palpation there is a variable amount of superolateral or inferomedial patellar facet tenderness. The patellar tilt is from an abnormality of the lateral peripatellar retinaculum. A diminished passive medial patellar excursion is demonstrated excessively to the tight lateral soft-tissue tethering of the patella during flexion and extension. The normal treatment for this is a lateral release of tight fascia (Huie et al, 1997).

Hypermobile Patella: condition as having a more cephalad position of the patella (patella alta) with generalized ligament laxity. Pain is present with increased activity and is prone to patellar subluxation due to laxity. Treatment includes exercises designed to increase quadriceps strength and to stabilize the extensor mechanism (Powers, 1998).

Recurrent Patellar Dislocation: Huie et al. (1997) explains this injury as a recurrent lateral dislocation of the patella, which usually reduces without any interventions. This is characterized by giving away, locking, catching of the knee with recurrent effusions. Patella alta is normally present along with an increased Q-angle. The patellar apprehension sign is positive with this condition. Sandmeier et al. (2000) revealed that non-operative treatment of this condition has a failure rate as high as 40-50%.

Acute Patellar Dislocation: dislocation occurs directly after a direct blow to the medial edge of the patella, or sometimes with violent external rotational valgus injury. This mechanism of injury ruptures the patella's medial stabilizers. Symptoms of this disorder result in the patella resting in the lateral gutter with the knee locked in flexion. This injury needs immediate referral unless the dislocation is reduced (Huie et al., 1997).

Patellar Subluxation: subluxation of the patella occurs when the knee is flexed between zero and 30 degrees, and is noted as a brisk lateral deviation of the patella. The reasoning behind this is due to the strong lateral structures of the quadriceps muscles (vastus lateralis, vastus intermedius, and rectus femoris). This can occur through dynamic imbalance to vastus medialis insufficiency, which has been associated with atrophy, inhibition, and impaired motor control. The treatment is focused on the rehabilitation of the vastus medialis, and the release of the lateral structures (Huie et al., 1997; Powers, 1998). In a more recent study, Powers (2000) stated a reduction in motor unit activity of the vastus medialis muscle could be a main contributor of this condition.

Another patellofemoral pain indicator is chondromalacia (Huie et al., 1997). Often characterized by a crepitus sensation under the patella and softening of the hyaline cartilage under the patella, it has been known to cause pain in the later stages of development. There are grades of progressive degenerative changes of the patella involvement ranging from mere softening, to fissures, to "crabmeat changes", and finally the denudation of the cartilage down to the subchondral bone.

Treatment

Numerous researchers reported that conservative, nonoperative treatment of patellofemoral pain has had a highly successful rate on the recovery of knee pain (Bellemans et al., 1997; Kowall et al., 1996; Muhle et al., 1999; Powers, 1997; Shellock et al., 2000; & Worrell, Ingersoll, Bockrath-Pugliese, & Minis, 1998). The treatment programs typically include the following procedures: rest-depending on severity,

stretching of the quadriceps, hamstring, and patellar retinaculum, closed chain exercises, foot orthotics, muscle reflex training of the vastus medialis obliquus, non-steroidal anti-inflammatory therapy, cryotherapy, McConnell taping style, bracing, progressive functional rehabilitation, and aquatic therapy.

Kowall et al. (1996) firmly believes in the focus of correcting muscular imbalances between the vastus medialis and the vastus lateralis muscles, which directly relate to patellar maltracking. This was discovered through numerous electromyographical studies involving recorded muscle activity of the quadriceps for patients with pain and dislocation (Kowall et al.). Powers et al. (1999) agrees with this study and adds aggressive open chain and closed chain rehabilitation. However, exercise restriction might be implemented if an increase in pain occurs from over activity.

The initial step in the rehabilitation stage is to limit any joint stress while strengthening the quadriceps; specifically, strengthening the vastus medialis during the acute phase of patellofemoral pain (Powers, 1998). Therefore, exercises should be performed at zero to 45 degrees knee flexion. An introductory rehabilitation protocol provided by Powers and Kowell et al. (1996) includes straight leg raises, quadriceps muscle isometrics, knee extensions, wall slides, and short-arc terminal extension. Furthermore, Kowell et al. suggests using McConnell taping style throughout the exercises.

Beynnon et al. (1997) and Kowall et al. (1996) both advocate the McConnell taping style to facilitate the quadriceps and aid in the passive correction of patellar subluxation, tilt, and rotation, to decrease pain during knee motion. Both researchers stated that success is between 92-96% for pain-free range of motion. This McConnell

taping method pulls the patella medially, and anchors the patella to the midline within the femoral groove, creating the proper positioning of the patella through knee range of motion. Arroll et al. (1997) stated that this taping method was 96% effective, coupled with a quadriceps rehabilitation program.

Maenpaa et al. (1997), Muhle et al. (1999), and Kowall et al. (1996) support the idea that knee braces assist normal patellar tracking, which in turn decreases the pain associated with exercise. Patellar tracking realignment braces have proven to be beneficial in treating patients with patellofemoral joint disorders (Maenpaa et al.; Muhle et al.). Modern knee braces are intended to dissipate patellar lateral force, which assist ligament stability, improve patellar tracking, and prevent patellar subluxation or dislocation. Beynnon et al. (1997) states the effect of a functional brace on the knee is determined by the brace attachment technique, brace design parameters, the brace-limb attachment interface, and the loading environment to which the brace is exposed. Braces most commonly used are ones with an infrapatellar strap and the patella cutout sleeve with a lateral buttress pad. The use of bracing is commonly an adjunct method to the supplementation of specific strengthening techniques of the vastus medialis (Powers, 1998).

Surgery is the final resort in treatment of patellofemoral pain. Bellemans et al. (1997) stated that there are two procedures commonly used for surgical correction of patellofemoral pain. First, improvement in patellar subluxation and tilt can often occur with a lateral release. This surgery involves the release of the lateral patella retinaculum to allow normal patellar tracking throughout the trochlear groove. It has been noted to improve functional scores in patients with chronic anterior knee pain. Second, a more

complicated surgery, called an isolated anteromedial tibial tubercle transfer, is a more complex option in patellofemoral pain treatment. This procedure is intended to reduce patellar subluxation by surgically transferring pre-disposing structures that directly contribute to maltracking of the patella.

Prophylactic Brace Studies

Paluska & McKeag (2000) describe knee braces as a support worn for the painful or injured knee. This knee brace may consist of a combination of metal, foam, straps, plastic, and elastic material, made specifically to come in many designs and sizes. Many bracing companies over the past years have researched and invented individual spins on the variations of knee bracing; each of which claiming to provide the most effective support in the main goal of reducing patellofemoral pain.

The introduction of brace wear to knee pain patients allows normal joint function through activity (Greene, Hamson, Bay, & Byrce, 2000). Often focusing on the overall decrease in knee pain, the possibility of overall performance inhibition may be overlooked due to the alteration of joint mechanics with a fitted brace. Research by Greene et al. (2000) revealed wearing prescription braces as not always significantly altering the knee joint kinematics and changing force distribution characteristics during the stance phase of running in 80% of healthy subjects. Patellar tracking devices were not included in this study. However, the fact that the patellar tracking orthosis brace alters the tracking of the patella through range of motions, leads one to question the correlation of joint kinesthesis and the relationship of overall performance.

Muhle et al. (1999) studied a patellar realignment brace that consisted of a viscoelastic silicone insert with an integrated control guide design to counteract patellar subluxation or dislocation during joint motion. This brace was evaluated using a MRI to monitor patella movement. No significant change in patellar maltracking was found within the study. Recently, a study performed by Ward and Powers et al. (2001) involved the analysis of open and closed chain patellofemoral movement by kinesthetic magnetic resonance imaging. Two braces were tested, one of which being the patellar tracking orthosis. Results revealed a reduction in patellar maltracking while wearing the patellar tracking orthosis by Breg® during closed and open chain exercises.

Also, Powers et al. (1999) studied the Bauerfeind Genutrain P3 Brace. This brace did not significantly affect patellar tracking as evaluated by MRI. The only significance was found in the sulcus angle. It was suggested that future research be conducted to determine whether there is a more subtle mechanical effect on patellofemoral bracing, such as change in contact area or pressure.

Shellock et al. (2000) used the OnTrack Patellofemoral Knee Brace System (OrthoRx, Inc., San Diego, CA). This brace consists of a neoprene knee cuff, a neoprene strap, a circular adhesive patch that is placed over the patella, and a vastus medialis obliquus activator component. Results revealed the application of this specialized brace produced a centralization or improvement in position of the patella in most of the patients in their study, as shown by the kinematic MRI of the patellofemoral joint, hence counteracting the abnormal patellar position).

Patellar bracing and the McConnell taping style has shown to be effective in only the first ten degrees of knee flexion during a static MRI condition. These researchers

concluded that patellar alignment is just one factor of multiple etiologic factors, which caused patellofemoral pain (Worrell et al., 1998).

Visual Scales

Visual analog scales are implemented for research subjects to subjectively assess knee pain (Bellemans et al., 1997; Demirdjian, Petrie, Guanche, & Thomas, 1998; Hoher, Munster, Klein, Eypasch, & Tiling, 1995); Roos, Roos, Ryd, & Lohmander, 2000). Hoher et al. (1995) stated that interviews conducted with knee surgeons revealed that 85% judged the Lysholms and Cincinnati questionnaires as being acceptable for clinical use. The reliability of visual analog scales in this study for healthy individuals was r=0.86, and r=0.96 for postoperative knee patients.

Roos et al. (2000) administered a Knee Injury and Osteoarthritis Outcome Score, which is a self-administered instrument-measuring outcome of knee injury at impairment, disability, and handicap level in five subscales; including knee pain, other symptoms, function in active daily living, function in sport and recreation, and knee related quality of life. Roos (1998) stated that the content of a KOOS provides validity, and has been insured through literature search, a pilot study, and expert panel (US & Sweden) consisting of patients, orthopedic surgeons and physical therapists. Standardized answer options are given and each question was scored from zero to four points, depending on the column that the subject marks. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale. As associated with other

scales, such as the Lysholm scale, the reliability, validity, and responsiveness of individuals taking the KOOS scale, was proven just as viable.

The KOOS was found to have high correlation when comparing it to the Lysholm scale (Roos, Roos, Ekdahl, & Lohmander, 1998). The Lysholm scale is a subjective knee evaluation questionnaire used for follow-up assessment after knee surgery or other related injuries to the knee (Demirdjian et al., 1998; Lysholms, 1982). Johnson and Smith (2000) stated that this scale is the most frequent one used, and has been adequately validated prior to use. This subjective test is a 100-point rating scale has varying categories and assigned point values assessing function through activities such as stair climbing, walking, squatting, and also symptoms such as limping, support, instability, pain, and swelling. Furthermore, this test is known to be one of the most commonly used tools for subjective postoperative assessment of patellar dislocations (Almekinders, L., & Dedmond, 2000).

CHAPTER III

METHODS AND PROCEDURES

This chapter provides a detailed description of the subjects, testing scales, braces, procedures, experimental design, and statistical analysis used to measure the perceived pain of subjects wearing a Breg® Patellar Tracking Orthosis brace or Breg® neoprene sleeve over a five-week period. The purpose of this study was to determine the effects of a centralized Breg® Patellar Tracking Orthosis on patellofemoral pain.

Subjects

Thirty-one subjects (18 males, 13 females) were selected from the general population of individuals inflicted with patellofemoral pain. These subjects, diagnosed with patellofemoral pain syndrome, were under the care of a physician. The subjects' age ranged between 18 to 45 years, which helped assure that epiphyseal growth plates were closed, and thus, bone growth complete. The inclusion criteria for this study revealed that each individual had no systemic illness with chronic use of medication, was presently symptomatic of patellofemoral pain and had a history of patellofemoral pain and/or instability greater than two months duration. Symptoms of pain and instability of the knee might have been found during the following actions: jumping, squatting, ascending

or descending stairs, crepitation during squatting, subluxation or dislocation, retropatellar pain with sustained flexion & relief on extension, snapping or pseudolocking, and stiffness and effusion (Powers, 1998).

Subject inclusion depended upon completion of an informed consent as approved by the Institutional Review Board of Oklahoma State University (Appendix A). Second, an assessment of eligibility (Appendix B) was necessary to qualify individuals for this study. Each subject had one of these three pathologies or symptoms: 1) patellofemoral pain with instability (subluxation and/or dislocation); 2) patellofemoral pain with malalignment but no instability; or 3) patellofemoral pain without malalignment.

Upon completion of the aforementioned preliminary evaluation, subjects were excluded from this research based on the following exclusion criteria: ligament deficiency or associated knee instability, meniscus tear, evidence of osteoarthritis greater than grade 2, osteochondritis dessicans, loose bodies within joint space, severe limb alignment or limb length deficits, and previous ligament reconstruction or patella realignment procedure. Subjects with one or more of these disorders were dismissed from further testing.

Each potential subject was immediately notified after completion of the physical exam if he/she qualified for the study based on the aforementioned criteria. Participants were randomly placed into an experimental group or control group. If for any reason a subject was chosen and unable to participate, another subject was selected by the methods previously described and placed into the appropriate group. Confidentiality of records was assured by placing data into a computer database along with hard copies of paperwork into a locked filing cabinet.

Test Scale

The instrumentation used in this study was the Lysholm II scale (Appendix C) and the Knee Injury and Osteoarthritis Outcome Score scale (Appendix D). The subjects completed these scales, which are subjectively perceived measurements that rate the present condition of the subject's knee pain (Demirdjian et al., 1998; Roos et al., 2000). These rating scales are designed to provide feedback that do not require physical testing; coupled with subjective measurement over the five-week trial period that was performed at home. Johnson and Smith (2000) noted the Lysholm knee scoring scale as one of the most frequently used validated measurements. Roos et al. (1998) also state that the use of the American version of the KOOS test is comparable to the Swedish version of the KOOS, which has undergone reliability, validity, and responsiveness measures in the Sweden to measure knee injury at impairment, disability, and handicap level in five subscales.

Brace/Sleeve

The Breg® Patellar Tracking Orthosis is a device designed to force the patella to track naturally through the knee range of motion and resist subluxation. The rigid plate within the brace compresses a buttress lateral to the patella providing rigid resistance, hence realigning the patella through the trochlear groove during motion. With increasing knee extension, the medial hinge increases tension in the buttress straps to provide increasing lateral compressive forces. A recent study performed by Shellock et al. (2000)

used a similar structured brace that obtained 86% correction or improvement in patellar displacement and a reduction in the symptoms of patellofemoral pain.

The Breg® neoprene sleeve is a knee support that adds diffuse compression to the knee joint (Birmingham et al., 1998). These braces are intended for non-specific knee pathology and are commonly used for swelling maintenance. Despite, the general use of this brace, Birmingham et al. stated that the use of these braces are extremely common, and are known to have a high success rate in improving subjective testing of knee pain.

Each subject was given the opportunity to obtain the new Breg® Patellar Tracking Orthosis at no cost for future use upon culmination of the study. Each subject wearing the sleeve will obtain pertinent information upon the culmination of the study concerning the brace wear.

Procedure

The subjects were chosen after the baseline evaluation was performed on Day one. Each person selected for the study filled out a card to indicate his/her location over the five-week period, along with a phone number in which he/she could be contacted. The number where the person could be reached was necessary for weekly calls to record compliance. Information from the cards was entered into a database to store the records and only obtained by the chief investigator. The cards were then appropriately discarded. An equal number of individuals in the experimental and control group were randomly selected out of the pool of 31 by the primary investigator as each subject was evaluated and approved. The testing group received the Breg® Patellar Tracking Orthosis brace,

and the control group was given a Breg® neoprene sleeve. Directions on application of each brace were reviewed at the time of distribution, while the classification of each group type was not revealed to prevent any skewing of data in the study.

To ensure optimal compliance of prophylactic wear by each subject, advice to wear the brace or sleeve as desired throughout the course of the study was administered. However, each subject was encouraged to wear the brace or sleeve as much as possible throughout daily activity to see if the brace reduced the patellofemoral pain that each subject was experiencing. Weekly phone calls to the individual's residence were made to ensure satisfaction with the brace and monitor adherence to the brace. Also, each individual completed a weekly diary (Appendix E) at the end of each week (days 7, 14, 21, 28, 35). This document monitored adherence to the brace condition along with subjective feedback.

Prescribed by the physician, a set standard rehabilitation protocol was implemented five days out of the week, one time per day. These exercises, which have been proven to assist in the conservative treatment of patellofemoral pain, focused on the restoration of normal patellar tracking by adding medial stabilization of the patella (Powers, 1998). Five exercises that involve quadriceps strength, primarily the vastus medialis (Appendix F), were to be performed with the brace or sleeve on at the time of rehabilitation. A review of these exercises was given at the time of brace distribution.

The Lysholm II and Knee Injury and Osteoarthritis Outcome Scores taken on day one (pre-testing) of brace distribution and instruction, day 18 (mid-testing), and then on day 35 (post-testing). Collection of paperwork occurred at the culmination of study, along with a final baseline evaluation that included a brief overview of their present

condition, and re-assessment of patellar alignment, patellar grind test, and apprehension test. A calendar of events was given to the individual on day one, and a reminder to fill out everything was re-enforced via phone conversation.

Design

Two groups of patients participated in this study. Each group ($\underline{n}$ = 15) with the patellar tracking orthosis brace, and ($\underline{n}$=16) of the sleeve group were composed of selected individuals with a history of patellofemoral pain and/or instability greater than two months, and either diagnosed with patellofemoral pain with instability (subluxation and/or dislocation), patellofemoral pain with malalignment but no instability, or patellofemoral pain without malalignment. At the time of testing, the subjects presented symptoms of patellofemoral pain. The first group was composed of randomly assigned subjects who represented the testing group, and wore the Breg® Patellar Tracking Orthosis brace. The second group was the control group consisting of randomly assigned subjects wearing a Breg® neoprene sleeve. Group identification was not be revealed to the subjects. Both groups wore the brace or sleeve throughout the five-week testing period. The only mandated occasion was during the quadriceps strengthening exercises that were performed once a day, five times a week. The scale scores were collected at the end of the five weeks, and the scores were compiled for the pre-test, mid-test, and post-test experimental group and control group design. This permitted comparison at the pre-test, mid-test, and post-test of the dependent variables.

Analysis of Data

On the final day of the five-week study, scores and weekly journal entries were compiled for data analysis. A 2 X 3 repeated measures analysis of variance (ANOVA) was conducted with a grouping factor at two levels (experimental group vs. control group) and a trial factor at three levels (the three measurement points in time) for the Lysholm II dependant variable scale. The dependent variables with five subscale scores from the Knee Injury and Osteoarthritis Outcome Score (KOOS) scale conducted a 2 X 3 X 5 repeated measures analysis of variance (ANOVA) was conducted with a grouping factor at two levels (experimental group vs. control group), a trial factor at three levels (the three measurement points in time), and five subscale scores within the KOOS scale. An ($p>.05$) alpha level was used for all statistical tests.

CHAPTER IV

MANUSCRIPT

Patellofemoral dysfunction is a common affliction affecting many active individuals. Approximately 30% of athletic and non-athletic patients in sports medicine clinics are seen for patellofemoral pain (Kowall, Kolk, Nuber, Cassisi, & Stern, 1996). Pain over the anterior aspect of the knee can be attributed to multiple factors including patellofemoral maltracking (Bellemans, Cauwenberghs, Witvroum, Brys, & Victor, 1997). Powers (1998) stated 50% of the patellofemoral pain victims have patellar maltracking due to femoral trochlea dysplasia, patella alta, tightness of the lateral soft tissues, or unequal activation of the vastus lateralis and vastus medialis. A primary pathologic entity relating to this pain is the increased shearing and compression associated with abnormal patellar tracking (Powers, Shellock, Beering, Garrido, Goldbach, & Molnar, 1999). Despite the high number of patellofemoral victims, it is believed that with a focus on conservative treatment, such as nonsteroidal anti-inflammatory medications, stretching, McConnell taping style, bracing, and/or quadriceps strengthening, pain and the functional disorder will reduce (Muhle, Brinkmann, Skaf, Heller, & Resnick, 1999; Shellock, Mullin, Stone, Coleman, & Crues, 2000).

Proper diagnosis and treatment of patellofemoral disorders is the critical factor in improving the long-term prognosis and preventing osteochondritis of the patellofemoral

joint (Muhle et al., 1999). One of the most noted underlying causes of patellofemoral pain has been identified as malalignment of the patella – specifically, subluxation and tilt of the patella. This tracking dysfunction has been shown to result in damage to the posterior articulating surface of the patella, as well as straining the peripatellar structures, resulting in pain (Kowall et al., 1996). Powers et al. (1999) added other predisposing patellar tracking disorders that contribute to pain, including: femoral trochlea dysplasia, patella alta, tightness of the lateral soft tissues, and uneven activation of the vastus lateralis and vastus medialis.

One of the most common types of conservative treatments of patellofemoral pain is the use of a knee brace or sleeve (Birmingham, Kramer, Inglis, Mooney, Murray, Fowler, & Kirkly, 1998; Powers, 1998). The widespread application of a knee support device has received much recognition largely because of its potential role in improving knee conditions and decreasing injury rate. A variety of braces or sleeves have been implemented on individuals suffering from knee pain. More recent studies have progressed from the traditional open-buttress neoprene sleeve to a more specific patellar tracking orthosis. Specifically, researchers have discovered that patellar realignment braces are beneficial in the treatment of patients with various patellofemoral disorders. This brace dissipates lateral forces on the patella, maintains patellar alignment, improves patellar tracking, and prevents patellar subluxation and/or dislocation (Maenpaa & Lehto, 1997; Muhle et al., 1999). In addition, certain types of braces contain a firm plate to compress the buttress laterally. This provides a rigid resistance to the patella, causing the patella to track more naturally and lowers the chance of subluxation.

The purpose of this investigation was to determine the effects of a centralized semi rigid patellar tracking orthosis on patellofemoral pain using the Lysholms II and Knee Osteoarthritis Outcome Score (KOOS). The creation of a more centralized course for the patella was proposed to reduce or eliminate abnormal contact stresses, and reduces or eliminates symptoms originating from abnormal stresses, which are direct contributors of patellofemoral pain (Powers et al., 1999).

Methods

Subjects

Thirty-one subjects (age = 23 ± 5.42 yr, ht = 70.2 ± 3.46 in, wt = 187.9 ± 38.80 lb.,) were college students experiencing knee pain, and diagnosed with patellofemoral pain while under the direction of a physician. All subjects had a history of patellofemoral pain and/or instability greater than two months duration (by symptoms and history), no systemic illness with chronic use of medication, and the age of no less than 18 years, and no greater than 45 years. The individuals reported patellofemoral pain, but were excluded from this research based on the following exclusion criteria: ligament deficiency or associated knee instability, meniscus tear, evidence of osteoarthritis greater than grade 2, osteochondritis dessicans, loose bodies within joint space, severe limb alignment or limb length deficits, and previous ligament reconstruction or patella realignment procedure.

Test Scale

The instrumentation used in this study was the Lysholm II scale and the Knee Injury and Osteoarthritis Outcome Score scale. The subjects completed these scales, which are subjectively perceived measurements that rate the present condition of the subject's knee pain (Demirdjian et al., 1998; Roos et al., 2000). These rating scales are designed to provide feedback that do not require physical testing; coupled with subjective measurement over the five-week trial period that was performed at home. Johnson and Smith (2000) noted the Lysholm knee scoring scale as one of the most frequently used validated measurements for knee pain patients. The American version of the KOOS test is comparable to the Swedish version of the KOOS, which has undergone reliability, validity, and responsiveness measures in Sweden to measure knee injury at impairment, disability, and handicap levels in five subscales (Roos et al., 1998).

Testing Procedures

Subjects (male = 18, female = 13) gave their written, informed consent to participate in these experiments after the purpose, procedures, and known risks of the tests were explained in accordance with the University Institutional Review Board. Each subject completed a physical evaluation and medical history questionnaire designed to evaluate health status, medication, and previous injury status. Participation in the study required that the subject be in apparently good health, but diagnosed and presently experiencing patellofemoral pain syndrome. Any indication of a possible health problem

that might compromise the safety of the subjects or the validity of the study excluded the individual from the present investigation. The subjects were assigned randomly to one of two experimental groups.

The subjects were chosen after the baseline evaluation was performed on day one. Each person selected for the study filled out a card to indicate his/her location over the five-week period, along with a phone number in which he/she could be contacted. The number where the person could be reached was necessary for weekly calls to record compliance. An equal number of individuals in the test and control group were randomly selected out of the pool of 31. The testing group received the Breg® Patellar Tracking Orthosis brace, and the control group was given a Breg® neoprene sleeve. Directions on application of each brace were reviewed at the time of distribution, while the classification of each group type was not revealed to prevent any skewing of data in the study.

To ensure optimal compliance of prophylactic wear by each subject, advice to wear the brace or sleeve as desired throughout the course of the study was administered. However, each subject was encouraged to wear the brace or sleeve as much as possible throughout daily activity to see if the brace reduced the patellofemoral pain that each subject was experiencing. Weekly phone calls to the individual's residence were made to ensure satisfaction and monitor adherence to the brace or sleeve. Also, each individual completed a diary at the end of each week (days 7, 14, 21, 28, 35). This document monitored adherence to the brace along with subjective feedback. The data from this diary revealed that each person wore the brace or sleeve on average 3.2 hours per day.

A set standard rehabilitation protocol was implemented five days out of the week, one time per day, with duration of 15-30 minute bouts as prescribed by a supervising physician. These exercises, which have been proven to assist in the conservative treatment of patellofemoral pain, focused on the restoration of normal patellar tracking by adding medial stabilization of the patella (Powers, 1998). These involved five exercises that focused on quadriceps strength, primarily the vastus medialis. The exercises performed are as follows; quadriceps contractions with a five second hold, straight leg raise (subject lying supine with knee fully extended, leg elevated to 45 degrees of hip flexion and a ten second hold), short arc quadriceps (knee flexed to 30 degrees with lower leg fully extended and held for a five second count), standing single leg clocks (standing in a stork stance position, and with the non-weight bearing foot touch each of the seven spots while maintaining balance and performing a mini-squat with the weight bearing knee), and forward step-ups on a six inch box. The quadriceps contraction was a set of three with 25 repetitions. The other four exercises were performed in sets of three with repetitions of ten. These exercises were to be performed with the brace or sleeve on at the time of rehabilitation. A review of these exercises was given at the time of brace distribution.

The Lysholm II and Knee Injury and Osteoarthritis Outcome Scores taken on day one (pre-testing) of brace distribution and instruction, day 18 (mid-testing), and then on day 35 (post-testing). Collection of paperwork occurred at the culmination of study, along with a final baseline evaluation that included a brief overview of their present condition, and re-assessment of patellar alignment, patellar grind test, and apprehension

test. A calendar of events was given to the participants on day one, and reminders to fill out everything were re-enforced via phone conversation.

Experimental Design and Statistical Analysis

This study was experimental in nature and followed a 2 X 3 repeated measure analysis of variance design for the Lysholm II scale, which conducted a grouping factor at two levels (experimental group vs. control group) and a trial factor at three levels (the three measurement points in time). The KOOS scale followed a 2 X 3 X 5 repeated measure analysis of variance design with a grouping factor at two levels (experimental group vs. control group), a trial factor at three levels (the three measurement points in time), and a trial factor at five levels (the five subscale scores from the KOOS).

Results

Thirty-one subjects completed the five-week trial period. There was no statistically significant difference between the Breg® patellofemoral tracking brace and the Breg® neoprene sleeve trials using the Lysholm II ($F=2.96$, $p>.05$) or KOOS scales ($F=1.77$, $p>.05$). However, there was a significant time effect for both analyses. The Lysholm II scale revealed that the brace and sleeve both displayed a significant difference over time ($F=8.93$, $p<.01$). The KOOS scale revealed similar results with significant difference using the brace and sleeve over the five-week time period

($F=16.33$, $p<.01$). There were no significant interaction effects between the Lysholm II and the KOOS scale (Appendix G).

Discussion

Due to the high percentage of patellofemoral pain patients, health professionals have searched for the most ideal conservative treatment dealing with knee pain. Numerous researchers reported that conservative, nonoperative treatment of patellofemoral pain has had a high success rate (Bellemans et al., 1997; Kowall et al., 1996; Muhle et al., 1999; Powers, 1997; Shellock, Mullin, Stone, Coleman, & Crues, 2000; & Worrell, Ingersoll, Bockrath-Pugliese, & Minis, 1998). Specifically, the patellofemoral tracking braces have been a common method to provide immediate relief of knee pain by creating a more centralized and controlled path for patellar maltracking during functional activities of daily living, sport functions and the aid in the rehabilitation process. Researchers have performed evaluations on patellofemoral braces via kinesthetic MRI, radiographs, and basic MRI views to evaluate the effect of these brace on patellofemoral joint. However, none have used subjective testing such as the Lysholm II and KOOS scale to grade the effect of the patellofemoral tracking orthosis on patellofemoral pain.

In the present study, the effects of the semi rigid patellar tracking orthosis on patellofemoral pain were examined by using the Lysholm II and KOOS scale. The results of the KOOS and Lysholm II Mean ± S.E. Measures are in Table I and II. There

was no significant ($p>.05$) difference detected by the Lysholm II or KOOS test between the patellar tracking orthosis and the knee sleeve. Both groups improved over the five-week period, which leads a reader to believe that both the brace and sleeve are effective in decreasing patellofemoral pain. Because of the small difference in results between brace and sleeve, this study proves that either option provides an avenue of treatment for patellofemoral pain victims.

TABLE I

KOOS MEAN ± S.E. MEASURES

	PRE-TEST	MID-TEST	POST-TEST
Sleeve Pain	78.7 ± 3.28	81.4 ± 3.57	84.9 ± 2.47
Symptoms	76.9 ± 3.27	79.1 ± 3.18	83.9 ± 3.45
ADL	89.5 ± 3.62	92.1 ± 3.57	94.6 ± 1.97
Sport & Rec	71.6 ± 4.46	72.8 ± 4.58	79.4 ± 4.55
Quality	63.6 ± 4.13	70.1 ± 4.71	73.6 ± 4.80
PTO Pain	67.1 ± 3.39	71.3 ± 3.69	82.4 ± 2.56
Symptoms	69.8 ± 3.38	72.3 ± 3.28	78.8 ± 3.56
ADL	76.1 ± 3.74	79.1 ± 3.69	89.5 ± 2.04
Sport & Rec	50.3 ± 4.60	59.3 ± 4.73	76.3 ± 4.70
Quality	46.3 ± 4.26	52.2 ± 4.86	62.5 ± 4.95

TABLE II

LYSHOLM II MEAN ± S.E. MEASURES

	PRE-TEST	MID-TEST	POST-TEST
SLEEVE	76.9 ± 3.64	76.9 ± 3.78	81.9 ± 3.53
PTO	59.2 ± 3.76	68.6 ± 3.91	76.7 ± 3.64

From a clinical point of view, there appears to be greater improvement overtime with the semi-rigid brace in comparison to the neoprene sleeve. For the fifteen subjects

with the brace on, the Lysholm II scale showed a seventeen unit gain between the pre and post test in comparison to the sleeve group that only had a five-unit gain. Figure 2 reveals this difference.

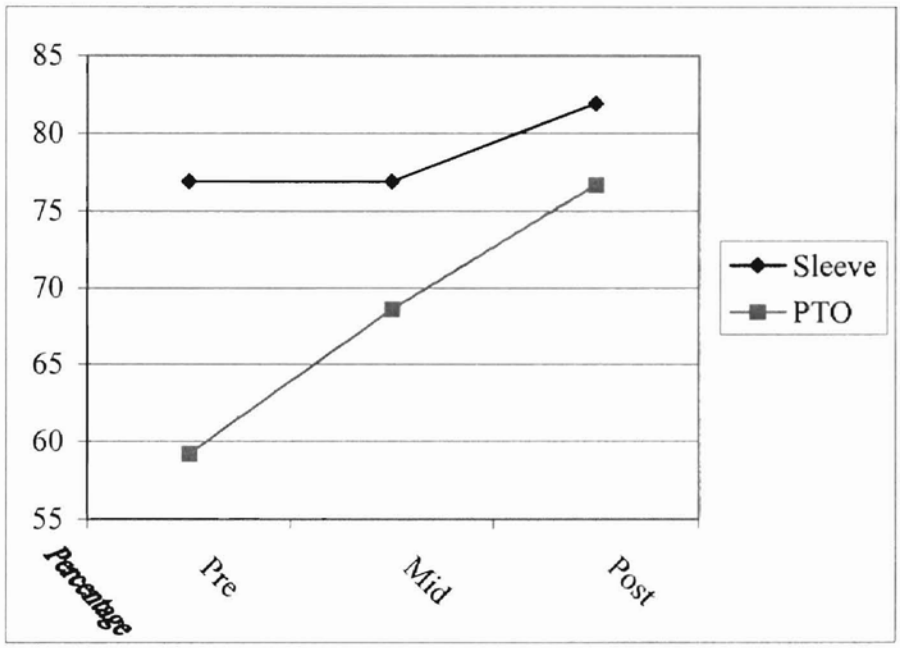


Figure 2. Lysholm II Scale Gain Score Results.

The improvement in symptoms and function over time of both the brace and sleeve groups in this study can be contributed to many factors. These forms of treatment have been proven to provide warmth to soft tissues, improve sensory feedback, and alter soft tissue tensions; each of which playing a psychological role in the rehabilitation process of patellofemoral pain victims (Cawley, 1991; Cawley, 1988; France, Cawley, & Paulos, 1990; Shellock et al., 2000). It can be speculated that both the control and experimental group in this study could have been influenced by the psychological factor due to the increased compression, warmth and neurosensory feedback mechanism from

the neoprene. This can explain why over a five-week period, patellofemoral pain can be significantly reduced with the application of either a knee brace or sleeve.

Another aspect of this study that might have contributed to the overall subjective decrease in patellofemoral pain is the rehabilitation exercises. The exercises were originally administered to make the subject wear the brace or sleeve for at least 15 to 30 minutes a day, but they have been documented to play a beneficial role in conservative treatment of patellofemoral pain by strengthening the quadriceps muscles – which in turn assist with patellar tracking. This could have been another factor leading to the contribution of subjective improvement over the base five-week period of the brace and sleeve group.

The following recommendations for future research are made: 1) using a longer treatment period to increase validity over time, 2) using larger group size with a true control group that does not wear a brace or sleeve, 3) using MRI's as a special testing procedure in conjunction with a physical examination to better identify patients with subtle anatomic changes during knee range of motion, 4) open the study to the general population including the non-athletic individuals, and 5) monitor activity 24 hours a day and mandate use of brace or sleeve at that time. Other factors within this study that can be analyzed in comparison with patellofemoral pain are Q-angle, quadriceps circumference and body mass index among the sample. Each of these factors can be analyzed to determine if there is any correlation in the predisposing factors that can contribute to patellofemoral pain.

CHAPTER V

CONCLUSIONS, APPLICATIONS, RECOMMENDATIONS

The high percentage of individuals reporting with patellofemoral pain has inspired medical affiliations to discover the quickest and most efficient way of treating knee injuries. The proposed effects of patellar tracking braces are numerous: patellar tracking braces create a more centralized course for the patella; reduces or eliminates abnormal contact stresses; and reduces or eliminates symptoms originating from abnormal stresses – which are direct contributors of patellofemoral pain (Powers et al., 1999). Powers is one of many researchers constantly pursuing studies to determine the validity of patellar tracking orthosis on patellofemoral pain.

Although most of the brace studies reviewed in this study have not indicated the use of a specific subjective testing such as the Lysholm II and KOOS to measure knee pain and function, a recent study performed by Ward and Powers et al. (2001) tested the Breg® patellar tracking orthosis through kinematic resonance imaging. The imaging was performed to analyze the biomechanics of the patellofemoral joint during active non-weight bearing knee extensions and single limb support squat from zero degrees to 30 degrees of knee flexion in comparison to the unbraced, Bauerfind Genutrain braced, and Breg® braced subjects. The use of kinematic magnetic resonance imaging specifically tested the position and angles of the patella through range of motion to observe the

effectiveness of the braces through the patella tracking. The preliminary clinical results were determined by using a repeated measure analysis of variance. It indicated that the kinematic data presented that the patellar tracking orthosis can effectively alter patellar tracking under both open chain and weight bearing conditions; therefore, being an effective modality for the treatment of patellofemoral pain (Ward & Powers et al.).

This study proposed to determine the effectiveness of the semi rigid patellar tracking orthosis on patellar maltracking, and directly relating it to patellofemoral pain by using the KOOS and Lysholm II subjective scale without using magnetic resonance imaging. This study was designed to determine if the semi rigid patellar tracking orthosis brace would decrease the likelihood of patellar maltracking, due to the reinforcement and re-alignment of the patella throughout knee flexion and extension.

The hypotheses that were tested at the .05 levels, are as follows: there will be no significant difference in patellofemoral pain between the pre-test and post-test of the experimental group using the semi rigid patellar tracking orthosis and the control group using the neoprene sleeve as measured by the Lysholm II and KOOS scale.

Recognizing that caution should be observed in generalizing from this study's results, it was concluded that neither of the two scales revealed a significant change at the 5% level. There was no statistically significant difference between the semi rigid patellofemoral tracking brace and the neoprene sleeve trials using the Lysholm II ($F=2.96$, $p>.05$) or KOOS scales ($F=1.77$, $p>.05$). However, there was a significant time effect for both analysis; KOOS ($F=16.33$, $p<.01$) and Lysholm II ($F=8.93$, $p<.01$).

Future research needs to be performed on patellofemoral pain patients to adequately assess the function of the patellar tracking orthosis in comparison to the

sleeve with knee pain. The knee sleeve has been noted to have a positive affect on the general population by providing support that adds compression to the knee joint (Birmingham et al., 1998). These braces are intended for non-specific knee pathology and are commonly used for swelling maintenance. Remarking upon the general use of this brace, Birmingham et al. stated that the application of these braces are extremely common, and are known to have a high success rate in subjective testing of patients with knee pain. The possibility that a psychological factor plays a role in the sleeve use might be a future research concern that might skew the data if using it as a control variable (Cawley et al., 1991).

Many of the previous studies used specific testing such as the use of tomographs and kinesthetic magnetic imaging as a source to determine the significance of the patellar tracking orthosis on patellofemoral pain, without testing subjectively. Also, validity will increase if a larger sample group number, a true control group, and a longer period treatment time to subjectively test the individuals with patellofemoral pain were performed. Using both specific testing coupled with subjective testing and a physical examination is most likely to fully analyze an individual's condition and study outcome.

Since no other studies have revealed subjective testing especially for patellofemoral pain directly involved with patellar maltracking, it can be speculated that the Lysholm II and KOOS tests might not be sensitive to patellofemoral pain in comparison with the normal indication of postoperative knee testing and in patients with osteoarthritis. The possibility of finding a more sensitive knee pain scale directly related to patellar tracking might be an option to improve the evaluation of subjective patellofemoral knee pain in future studies.

Recommendation for future research are as follows: offering the study to the non-athletic setting, monitoring subject activity 24-hours a day, mandating brace or sleeve use at all times, and having the subjects base his or her subjective perception of pain while the subject is wearing the brace or sleeve. Other factors that might play present predisposing factors of patellofemoral pain are q-angle, body mass index, and quadriceps circumference of the subjects.

REFERENCES

Almekinders, L., & Dedmond, B. (2000). Outcomes of the operatively treated knee dislocation. Clinics in Sports Medicine, 19(3), 503-518.

Anderson, M., & Hall, S. (1995). Sports Injury Management. Pennsylvania: Williams & Wilkins.

Arroll, B., Ellis-Pegler, E., Edwards, A., & Sutcliffe, G. (1997). Patellofemoral pain syndrome: a critical review of the clinical trials on nonoperative therapy. The American Journal of Sports Medicine, 25(2), 207-213.

Bellemans, J., Cauwenberghs, F., Witvroum, E., Brys, P., & Victor, J. (1997). Anteromedial tibial tubercle transfer in patients with chronic anterior knee pain and a subluxation-type patellar malalignment. The American Journal of Sports Medicine, 25(3), 375-382.

Beynnon, B., Johnson, R., Fleming, F., Peura, G., Renstrom, P., Nichols, C., & Pope, M. (1997). The effect of functional knee bracing on the anterior cruciate ligament in the weightbearing and nonweightbearing knee. The American Journal of Sports Medicine, 24(3), 353-360.

Birmingham, T., Kramer, J., Inglis, J., Mooney, C., Murray, L., Fowler, P., & Kirkly, S. (1998). Effect of neoprene sleeve on knee joint position sense during sitting open kinetic chain and supine closed kinetic chain tests. The American Journal of Sports Medicine, 26(4), 562-566.

Cawley, P. (1991). Knee Bracing. Knee Ligament Rehabilitation, Engle RP (ed), 213-219.

Cawley, P. (1988). Functional knee bracing for skiing. A review of factors affecting brace choice. Top Acute Care Trauma Rehabilitation, 3, 73-71.

Chan, K., Qin, L., Li, C., Hung, L., Tang, C., & Rolf, C. (2000). Removal of the lateral or medial third of patellar tendon alters the patellofemoral contact pressure and area: an in vitro experimental study in dogs. Clinical Biomechanics, 15, 695-701.

Demirdjian, A., Petrie, S., Guanche, C., and Thomas, K. (1998). The Outcomes of Two Knee Scoring Questionnaires in a Normal Population. The American Journal of Sports Medicine, 26(1), 46-52.

France, E., Cawley, P., & Paulos, L. (1990). Choosing functional knee braces. Clinics in Sports Medicine, 9(4), 743-750.

Greene, D., Hamson, K., Bay, R., & Bryce, C. (2000). Effects of protective knee bracing on speed and agility. The American Journal of Sports Medicine, 28(4), 453-459.

Hoher, J., Munster, A., Klein, J., Eypasel, E., & Tiling, T. (1995). Validation and application of a subjective knee questionnaire. Knee Surgery, Sports Traumatology, Arthroscopy, 3(1), 26-33.

Huie, G., Scuderi, G., & Scott, N. (1997). High-tech exercise and anterior knee pain. Physician Assistant, 21(3), 101-113.

Hsieh, Y., Draganich, L., Ho, S., & Reider, B. (1998). The effects of removal and reconstruction of the anterior cruciate ligament on patellofemoral kinematics. The American Journal of Sports Medicine, 26(2), 201-209.

Johnson, D., & Smith, R. (2000). Outcome measurement in the ACL deficient knee-what's the score? Knee, 8(1), 51-57.

Kannus, P., Natri, A., Paakkala, T., & Jarvinen, M. (1999). An outcome study of chronic patellofemoral pain syndrome. Seven-year follow-up of patients in randomized, controlled trial. Journal of Bone and Joint Surgery, 81(3), 355-363.

Kowall, M., Kolk, G., Nuber, G., Cassisi, J., & Stern, S. (1996). Patellar taping in the treatment of patellofemoral pain: a prospective randomized study. The American Journal of Sports Medicine, 24(1), 61-67.

Lysholm, J. (1982). Evaluation of knee ligament surgery results with special emphasis on use of a scoring scale. American Journal of Sports Medicine, 10(3), 150-54.

Lundin, O. & Styf, J. (1998). Intramuscular Pressure in the Leg and Thigh Related to Tensile Strap Force During Knee Brace Wear. The American Journal of Sports Medicine, 26(4), 567-570.

Maenpaa, H., & Lehto, M. (1997). Patellar dislocation: the long-term results of nonoperative management in 100 patients. The American Journal of Sports Medicine, 25(2), 213-218.

Muhle, C., Brinkmann, G., Skaf, A., Heller, M., & Resnick, D. (1999). Effect of a patellar realignment brace on patients with patellar subluxation and dislocation. The American Journal of Sports Medicine, 27(3), 350-353.

Murray, T., Dupont, J., & Fulkerson, J. (1999). Axial and lateral radiographs in evaluating patellofemoral malalignment. The American Journal of Sports Medicine, 27(5), 580-588.

Paluska, S. & McKeag, D. (2000). Knee Bracing: Current Evidence and Clinical Recommendations for Their Use. American Family Physician, 61(2), 411-418.

Powers, C. (2000). Patellar Kinematics, Part I: The influence of vastus muscle activity in subjects with and without patellofemoral pain. Physical Therapy, 80(10), 956-964.

Powers, C. (1998). Rehabilitation of Patellofemoral Joint Disorders: A Critical Review. Journal of Orthopaedic Sports Physical Therapy, 23(5), 345-353.

Powers, C., Shellock, F., Beering, T., Garrido, D., Goldbach, R. & Molnar, T. (1999). Effect of bracing on patellar kinematics in patients with patellofemoral joint pain. Medicine & Science in Sports & Exercise, 31(12), 1714-1720.

Roos, E. (1998). A User's guide to: Knee injury and Osteoarthritis Outcome Score (KOOS). 1-7.

Roos, E., Roos, H., Ekdahl, C., & Lohmande, L. (1998). Knee injury and osteoarthritis outcome score (KOOS)—validation of a Swedish version. Scandinavian Journal of Medicine and Science in Sports, 8(6), 439-448.

Roos, E., Roos, H., Ryd, L., & Lohmander, L. (2000). Substantial disability three months after arthroscopic partial meniscectomy: A prospective study of patient-relevant outcomes. Arthroscopy, 16(6), 619-626.

Sandmeier, R., Burks, R., Bachus, K., & Billings, A. (2000). The effect of reconstruction of the medial patellofemoral ligament on patellar tracking. The American Journal of Sports Medicine, 28(3), 345-349.

Shellock, F., Mullin, M., Stone, K., Coleman, M., & Crues, J. (2000). Kinematic magnetic resonance imaging of the effect of bracing on patellar position: qualitative assessment using an extremity magnetic resonance system. Journal of Athletic Training, 35(1), 44-49.

Starky, C., & Ryan, J. (1996). Evaluation of Orthopedic and Athletic Injuries. Pennsylvania: F. A. Davis Company.

Ward, S., & Powers, C. (2001). Preliminary review of Stanford Kinematic MRI PTO investigation. Manuscript submitted for publication.

Witvrouw, E., Lysens, R., Bellemans, J., Cambier, D., & Vanderstraeten, G. (2000). Intrinsic risk factors for the development of anterior knee pain in an athletic population. The American Journal of Sports Medicine, 28(4), 480-503.

Worrell, T., Ingersoll, C., Bockrath-Pugliese, K., & Minis, P. (1998). Effect of patellar taping and bracing on patellar position as determined by MRI in patients with patellofemoral pain. Journal of Athletic Training, 33(1), 16-20.

APPENDIX A

INFORMED CONSENT

OSU INSTITUTIONAL REVIEW BOARD
CONSENT FORM GUIDELINE

The Effect of the Breg® Patellar Tracking Orthosis on Patellofemoral Pain.

I, _____, voluntarily agree to participate in this investigation directed by Dr. Jack Ransone and Karen Bloch at Oklahoma State University. I know that while these individuals will supervise the research study, other professionals who work with them may assist or act on their behalf. I understand that at all times during the research, I will be under the supervision of the principal investigator, Karen Bloch. I understand that the problem of this study is to determine the effects of a centralized Breg® Patellar Tracking orthosis (Breg Incorporation, Vista, CA) on patellofemoral pain.

PROCEDURES

The procedures that I voluntarily agree to take part include:

1) A physician will perform a baseline screening evaluation.
2) A Lysholms II and Knee Injury and Osteoarthritis Outcome Score Scale will be administered to measure patellofemoral pain.
3) Each subject will do the five rehabilitation exercises one time a day, five times a week. The duration of the exercises is 15 to 30 minutes.
4) A release of pertinent demographic information will occur for weekly adherence calls.
5) Weekly diaries need to be completed.

Screening and Study Assignment

On the first occasion, the researchers will explain to me the problem of the study and I will have the opportunity to ask my questions about the study. In this study, I will be assured that my participation is completely voluntary. I am also aware that I need to provide thorough information about my medical history during the baseline evaluation. I will ensure that no surgery was performed on the injured knee, I am in no chronic use of medication, or that I have any other medical condition that might prevent me from joining the research study. The screening also includes a specific evaluation by the physician to assess gait, quadriceps measurement, q-angle, and the position of the patella with specific pathology evaluation tests. X-rays are optional depending on the discretion of the physician. Upon completion of the baseline evaluation, I will complete two subjective tests called Lysholms II and Knee Injury and Osteoarthritis Outcome Score Scale. Next, I will be given detailed instructions on the proper application of brace or sleeve and exercises that I will need to perform five times a week, one time a day. Trained personnel will explain the applications and tests to me. I will be given a calendar and will be asked to come to the study site on a designated time and day upon the culmination of study. I will expect to hear from the principal investigator once a week to monitor my compliance with the brace

Duration of Participation
In this study, I will wear the brace or sleeve at my own discretion over the three-week period. The only mandated time is during my exercise session, which lasts 15 to 30 minutes five time a week, one time a day.

Measures Made During the Study
My quadriceps circumference six inches above the superior pole of my patella, q-angle, patellar compression test, apprehension test, patellartracking, patellar placement, Lysholms II and Knee Injury and Osteoarthritis Outcome Score Scale will be measured at the beginning and end of the study.

Costs
There will be no cost to me for the use of the brace or sleeve. I understand that all additional costs will be my responsibility. Travel and transportation costs such as bus or taxi fares, gasoline, and mileage to and from the study site will by my responsibility.

If I develop health problems during the study related to the brace or sleeve, research project physician at no cost will see me. It will be my responsibility to seek additional health-related advice/follow-up examinations. The development of health problems may be a reason for me to be removed from the study.

Risks
There are no known risks associated with participation in the research activities or with the brace or sleeve.

Benefits of Participation
Subjects will receive valuable information about the status of their patellofemoral biomechanics. It is hoped that this research will help in finding a new treatment for patellofemoral pain. In addition, each subject is eligible at not cost to keep the brace or sleeve upon culmination of the study.

Compensation and Injury
If research-related injury occurs, medical treatment for the injury will be my responsibility for any cost that may occur. It is clear to me, that no compensation will be available.

Subject's Assurances

I understand that my participation in this study is voluntary:
1. I may withdraw from the study at any time without penalty or loss of benefits as explained in the two previous sections (Benefits of Participation and Compensation and Injury);
2. I may be removed from the study for medical reasons or non-compliance to the study protocol;

3. My treatment by and relations with the physicians and organizations involved in this research study will not be affected now or in the future if I decide not to participate, or if I start the study and decide later to withdraw; and
4. I have not given up any of my legal rights or released any individual or institution from liability for negligence.

I understand that I may ask questions and request information about this research project at any time. By signing this consent I acknowledge that I have been afforded the necessary opportunities to pose any questions which I may have and that they have been answered to my satisfaction. The medical terms used have been explained to me and I understand them. Dr. Ransone and Karen Bloch will be available to answer questions. Dr. Ransone may be reached in his office by calling 405-744-9439 and Karen Bloch at 405-747-6359.

I understand that no guarantees are given with regard to my participation in this project. Specifically, I understand that there are no known risks of injury, as set forth above. I agree that in the event of an injury or an adverse reaction, that I hereby consent to any and all appropriate emergency medical care can be given to me in the response to my condition.

I understand that participation is voluntary, that there is no penalty for refusal to participate, and that I am free to withdraw my consent and participation in this project at any time without penalty after notifying the project director. I may contact Dr. Jack Ransone at 405-744-9439 or Karen Bloch at 405-747-6359. I may also contact Sharon Bacher, IRB Executive Secretary, 203 Whitehurst, Oklahoma State University, Stillwater, OK 74078; telephone (405) 744-5700.

I have read this consent document and fully understand the consent form. I will sign it freely and voluntarily. A copy has been given to me.

Research Participant: _____ Date: _____

Witness: _____ Date: _____

I certify that I have personally explained all elements of this form to the subject before requesting the subject to sign it.

Project Director: _____ Date: _____

APPENDIX B

BASELINE EXAMINATION

Baseline Examination

Note: If both knees involved, describe both. Note which knee to be braced?

Subject ID: _____ **Involved (Braced Knee):** _____

1. **History (condensed)** _____

2. **Gait:** _____

	Left	Right
3. Patellar Location:		
4. Patellar Compression Test:		
5. Apprehension Test:		
6. Q-Angle:		
7. Quad Circumference: (6" above superior pole)		

8. **Radiographic Findings:** _____

8a. Congruence Angles:		
8b. Lateral Patellofemoral Angle:		
8c. Patellar tilt Angle:		
8d. Trochlear Groove Depth:		
8e. Patellar Depth:		

9. **Body Mass Index:** _____

Other Comments: _____

APPENDIX C

LYSHOLM II SCALE

Lysholm II Scale

Subject ID: **Test Interval 1 2 3 4**

Please circle the answer in each box which best describes your current condition.

Limp	**None**	**5**
	Slight or periodic	**3**
	Severe and constant	**0**
Support	**None**	**5**
	Stick or crutch needed	**2**
	Weightbearing impossible	**0**
Locking	**None**	**15**
	None, but catching sensation present	**10**
	Occasional	**6**
	Frequent	**2**
	At examination	**0**
Stairs	**No Problem**	**10**
	Slight problem	**6**
	One step at a time	**3**
	Impossible	**0**
Instability	**Never**	**25**
	Rarely during athletic activities	**20**
	Frequently during athletic activities	**15**
	Occasionally during daily activities	**5**
	Every step	**0**
Pain	**None**	**25**
	Inconstant & slight during strenuous activities	**20**
	Marked during or after walking more than 2Km	**10**
	Marked during or after walking less than 2Km	**5**
	Constant	**0**
Swelling	**None**	**10**
	After strenuous activities	**6**
	After ordinary activities	**3**
	Constant	**0**
Squatting	**No problem**	**5**
	Slight problem	**4**
	Not beyond 90° knee flexion	**2**
	Impossible	**0**

APPENDIX D

KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE

Knee Injury and Osteoarthritis Outcome Score

Subject ID:_____ **Test Interval: 1 2 3**

Please mark the box at the right of each question which best describes your current condition

PAIN	Never	Monthly	Weekly	Daily	Always
P1: How often is your knee painful?	☐	☐	☐	☐	☐
What degree of pain have you experienced in the last week when...	**None**	**Mild**	**Moderate**	**Severe**	**Extreme**
P2: twisting or pivoting on your knee	☐	☐	☐	☐	☐
P3: straightening your knee	☐	☐	☐	☐	☐
P4: bending your knee fully	☐	☐	☐	☐	☐
P5: walking on a flat surface	☐	☐	☐	☐	☐
P6: going up or down stairs	☐	☐	☐	☐	☐
P7: at night while in bed	☐	☐	☐	☐	☐
P8: sitting or lying down	☐	☐	☐	☐	☐
P9: standing upright	☐	☐	☐	☐	☐

SYMPTOMS	None	Mild	Moderate	Severe	Extreme
Sym1: How severe is your knee stiffness after waking in the morning?	☐	☐	☐	☐	☐
Sym2: How severe is your knee stiffness after sitting, lying, or resting later in the day?	☐	☐	☐	☐	☐
	Never	**Rarely**	**Sometimes**	**Often**	**Always**
Sym3: Do you have swelling in your knee?	☐	☐	☐	☐	☐
Sym4: Do you feel grinding, hear clicking, or any other type of noise when your knee moves?	☐	☐	☐	☐	☐
Sym5: Does your knee catch or hang up when moving?	☐	☐	☐	☐	☐
	Always	**Often**	**Sometimes**	**Rarely**	**Never**
Sym6: Can you straighten your knee fully?	☐	☐	☐	☐	☐
Sym7: Can you bend your knee fully?	☐	☐	☐	☐	☐

ACTIVITIES OF DAILY LIVING					
What difficulty have you experienced in the last week...	**None**	**Mild**	**Moderate**	**Severe**	**Extreme**
A1: descending stairs	☐	☐	☐	☐	☐
A2: ascending stairs	☐	☐	☐	☐	☐
A3: rising from sitting	☐	☐	☐	☐	☐
A4: standing	☐	☐	☐	☐	☐
A5: bending to pick up an object from the floor	☐	☐	☐	☐	☐
A6: walking on a flat surface	☐	☐	☐	☐	☐
A7: getting in or out of a car	☐	☐	☐	☐	☐
A8: going shopping	☐	☐	☐	☐	☐
A9: putting on socks/stockings	☐	☐	☐	☐	☐
A10: rising from bed	☐	☐	☐	☐	☐
A11: taking off socks/stockings	☐	☐	☐	☐	☐
A12: lying in bed, turning over, maintaining knee position	☐	☐	☐	☐	☐
A13: getting in/out bath	☐	☐	☐	☐	☐
A14: sitting	☐	☐	☐	☐	☐
A15: get on/off toilet	☐	☐	☐	☐	☐
A16: heavy domestic chores (scrubbing floors, shoveling snow, etc.)	☐	☐	☐	☐	☐
A17: light domestic duties (cooking, housework, etc.)	☐	☐	☐	☐	☐

SPORTS AND RECREATION FUNCTION					
What difficulty have you experienced the last week...	**None**	**Mild**	**Moderate**	**Severe**	**Extreme**
Sp1: squatting	☐	☐	☐	☐	☐
Sp2: running	☐	☐	☐	☐	☐
Sp3: jumping	☐	☐	☐	☐	☐
Sp4: turning/twisting on your knee	☐	☐	☐	☐	☐
Sp5: kneeling	☐	☐	☐	☐	☐

KNEE RELATED QUALITY OF LIFE	Never	Monthly	Weekly	Daily	Always
Q1: How often are you aware of your knee problem?	☐	☐	☐	☐	☐
	Not At All	**Mildly**	**Moderate**	**Severely**	**Totally**
Q2: How have you modified your lifestyle to avoid potentially damaging or painful activities to your knee?	☐	☐	☐	☐	☐
	Not At All	**Mildly**	**Moderate**	**Severely**	**Extremely**
Q3. How troubled are you with your lack of confidence in your knee?	☐	☐	☐	☐	☐
	None	**Mild**	**Moderate**	**Severe**	**Extreme**
Q4: In general, how much difficulty do you have with your knee?	☐	☐	☐	☐	☐

APPENDIX E

PATELLAR TRACKING ORTHOSIS
SUBJECTS WEEKLY DIARY

Patellar Tracking Orthosis
Subjects Weekly Diary

Subject ID:_____ (Please Circle the appropriate week) **Week 1 2 3 4**

To mark the scale, place a slash across the scale at the appropriate point as shown

1. Do you have less pain this week while using the brace? - Yes No

2. If you answered yes to the above question, please mark the scale at the right to indicate how much less pain you used. - - - - - - - - - - - - -
   No Reduction ——— 100% Reduction

3. Did you use less pain medication this week while using the brace? - - - - - - - - - - - - - - - - - - - Yes No

4. If you answered yes to the above question, please mark the scale to the right to indicate how much less medication you used. - - - - - - - - - -
   No Reduction ——— 100% Reduction

5. Did using the brace reduce your episodes on instability or giving away this week? - - - - - - - - - - Yes No

6. If you answered yes to the above question, please mark the scale to the right to indicate how much the brace reduced your instability. - - - - - - -
   No Reduction ——— 100% Reduction

7. Was your overall activity level increased due to using the brace this week? - - - - - - - - - - - - - - Yes No

8. If you answered yes to the above question, please mark the scale to the right to indicate how much your activity level increased. - - - - - - - - -
   No Reduction ——— 100% Reduction

9. Did wearing the brace help you to participate in sports this week? - - - - - - - - - - - - - - - - - - Yes No

10. If you answered yes to the above question, please mark the scale to the right to indicate how much more activity you were in sports this week. -
    No Reduction ——— 100% Reduction

11. Did wearing the brace help you perform daily activities or work this week? - - - - - - - - - - - - - - Yes No

12. If you answered yes to the above question, please mark the scale at the right to indicate how much the brace helped with work and daily activities. -
    No Reduction ——— 100% Reduction

13. Do you think using this brace improved the quality of your life this week? - - - - - - - - - - - - - - Yes No

14. If you answered yes to the above question, please mark the scale at the right to indicate how much the brace improved the quality of your life this week. -
    No Reduction ——— 100% Reduction

15. Did you use the brace this week for: (Mark all that apply) Sports Work Daily Activities All of these

16. Approximately how many hours per day did you use the brace this week? _____

Comments: _____

APPENDIX F

WEEKLY EXERCISES

Weekly Exercises: Five times a week, one time each day.

- 3 sets of 25 quadriceps contractions with a 5 second hold

  Position of the subject is sitting up with hip flexed to 90 degrees, and injured leg extended. The knee should be extended. The subject is to contract the quadriceps isometrically, causing the patella to glide toward the subject, and then hold for 5 seconds. Some cues are to dorsiflex the ankle, and push the knee joint line flat onto the table while making the muscle contraction.

- 3 x 10 short arc quad sets

  Position the subject sitting up with a rolled towel under the injured knee for support in flexion. With the knee flexed to approximately 30 degrees, instruct the subject o point toe in and then extend lower leg into full knee extension with ankle dorsiflexed, and then hold a quadriceps contraction for 5 seconds. After the 5 second hold, then the leg is lowered to the table.

- 3 x 10 straight-leg raise

  Position the subject lying supine with injured knee extended. With a quadriceps contraction, the leg is elevated to 45 degrees of hip flexion while keeping the knee extended. Hold the leg in that position for a 10-second count and then lower it.

- 3 x 10 standing single leg clocks

  The subject is in a standing position. Standing on one leg with hips in an even position, the subject is to touch 7 spots with the unsupported (uninjured) leg on the floor surrounding the individual while maintaining balance and mini-squats on the injured knee. The spots are in a clock formation around the athlete.

- 3 x 10 forward step-ups on a 6-inch box.

  The subject is standing in front of a 6-inch box or step. With hips even, the injured leg plants foot onto elevated area and then the body is lifted. In a smooth motion, the body is lowered without pushing off with trailing leg.

APPENDIX G

TABLES DEPICTING THE KOOS AND LYSHOLM II SCALES

TABLE III

KOOS STATISTICAL DATA

Source	SS	df	MS	F
Group	12950.6	1	12950.6	8.03[b]
Error	46749.6	29	1612.1	
Time	10754.4	2	5377.2	16.33[b]
Time X Group	1655.2	2	827.6	2.51
Error	19100.2	58	329.3	
Test	35018.0	4	8754.5	41.21[b]
Te X Group	1196.6	4	299.1	1.41
Error	24643.7	116	212.4	
Time X Te	860.8	8	107.6	2.58[a]
TimeXTeXG	859.0	8	73.6	1.77
Total	163,458.6	464		

[a] $p<.05$

[b] $p<.01$

TABLE IV

LYSHOLM II STATISTICAL DATA

Source	SS	df	MS	F
Group	2504.7	1	2504.7	5.99[a]
Error	12134.4	29	418.4	
Time	1982.3	2	991.1	8.93[b]
Group X Time	656.7	2	328.4	2.96
Error	6435.0	58	110.9	
Total	23,713.1	92		

[a] $p<.05$

[b] $p<.05$

APPENDIX H

INSTITUTIONAL REVIEW BOARD APPROVAL FORM

Oklahoma State University
Institutional Review Board

Protocol Expires: 11/26/2001

Date : Monday, November 27, 2000 IRB Application No ED0156

Proposal Title: THE EFFECT OF THE BREG PATELLAR TRACKING ORTHOSIS ON PATELLOFEMORAL

Principal Investigator(s) :

Karen Bloch
1924 W. State Lane
Stillwater, OK 74074

Jack Ransone
429 Willard
Stillwater, OK 74078

Reviewed and Processed as: Expedited

Approval Status Recommended by Reviewer(s) Approved

Signature .

Carol Olson, Director of University Research Compliance

Monday, November 27, 2000
Date

Approvals are valid for one calendar year, after which time a request for continuation must be submitted. Any modifications to the research project approved by the IRB must be submitted for approval with the advisor's signature. The IRB office MUST be notified in writing when a project is complete. Approved projects are subject to monitoring by the IRB. Expedited and exempt projects may be reviewed by the full Institutional Review Board.

VITA 2

Karen Sue Bloch

Candidate for the Degree of

Master of Science

Thesis: THE EFFECT OF A SEMI-RIGID PATELLAR TRACKING ORTHOSIS ON PATELLOFEMORAL PAIN

Major Field: Health, Physical Education, and Leisure

Bibliographical:

Personal Data: Born in Decatur, Illinois, March 8, 1975, the daughter of Gerald and Sandra Bloch.

Education: Graduated from Argenta-Oreana High School, Argenta, Illinois in May 1993; received Bachelor of Science degree in Physical Education with an emphasis in athletic training from Western Illinois University, Macomb, Illinois in December 1998. Completed the requirements for the Master of Science Degree with a major in Health, Physical Education, and Leisure at Oklahoma State University in August 2001.

Experience: A Certified and Licensed Athletic Trainer in the State of Oklahoma, presently employed as a graduate assistant athletic trainer at Oklahoma State University (1999-present). Other experiences include full-time assistant athletic trainer at University of Minnesota in 1999 and head athletic trainer for the Florida Wahoos Professional Softball team in 2000.

Professional Memberships: National Athletic Trainers' Association and Oklahoma Athletic Trainers' Association.

Certifications: National Athletic Trainers' Association Board of Certification, Cardiorespiratory and First Aid Certification.