THE EFFECTS OF THE GENERATION II UNLOADER EXPRESS BRACE ON MEDIAL COMPARTMENT KNEE OSTEOARTHRITIS

by

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ABSTRACT

Osteoarthritis (OA) is a disease characterized by the deterioration of cartilage, formation of osteophytes, and subchondral sclerosis. So far, there is nothing available to stop disease progression or reverse disease symptoms. Bracing has been found to be an alternative to more invasive measures to reduce symptoms in individuals with knee OA.

Twenty-one subjects (14 male, 7 female) enrolled in a twelve week repeated measures study. There were three brace conditions: no brace (control), brace in neutral (placebo) , and brace adjusted to four degrees valgus. All subjects underwent each condition in the same sequence. There was a three week washout period between the neutral and valgus brace conditions. A questionnaire, adapted from the WOMAC, was designed for this study showed good reliability ($r = 0.89$ to $r = 0.93$) for the three parameters assessed

This study found wearing the valgus brace significantly minimized the increase in pain ($p = 0.037$), difficulty in function ($p = 0.032$), and stiffness ($p = 0.021$) experienced after activity compared to wearing the neutral brace.

The results of this study suggest that the Generation II Orthotics Unloader Express is an effective treatment for those suffering mild forms of osteoarthritis.

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INTRODUCTION

Hanna (1996) recently reported that "it is expected that arthritis will become the disease of the nineties." Arthritis has been classified into atrophic arthritis and hypertrophic arthritis. Atrophic arthritis consists of rheumatoid arthritis (RA) and septic arthritis (SA) (Moskowitz 1992). This paper will focus on the hypertrophic type, osteoarthritis (OA), also known as degenerative joint disease. OA is the most common joint disorder in the world and affects many species. In fact, OA is noted to be a major source of health problems for animals. (Peyron et al. 1992) In humans, OA is known to be the single largest cause of locomotor problems. All joints of the body can be affected; however, there is a predilection for the knees, the hips, and the distal interphalangeal joints of the hand. (Buckwalter et al. 1996, Adebago 1995)

OA is further divided into primary and secondary OA. Primary OA is idiopathic in which the source of the problem, is not known. It is however known to be associated with aging. In contrast, secondary OA is when there is a known etiology or when the OA is associated with specific risk factors of joint degeneration. (Moskowitz 1992) The age group affected is also relatively younger (30-50 yrs of age). (Peyron et al. 1992) So far, therapies for OA are focussed on symptomatic relief and not on changing the

course of the disease or having a curative intent. (Fisher et al. 1993, Ivarsson et al. 1991, Ettinger et al. 1994)

EPIDEMIOLOGY

An accurate prevalence of OA is difficult to determine namely because the definition and diagnostic criteria are not consistent between studies. (Adebajo 1995) However, it is widely accepted that OA of the knee is the second most commonly affected site of OA. (Goldberg et al. 1992) Generally, most studies have found a greater prevalence in older adults and females. (Peyron et al. 1992) Salaffi (1991) reported that a study in the United States found OA as being second only to ischemic heart disease as a cause of work disability in men over 50 years of age, and accounts for more hospitalizations than the other arthritity, rheumatoid arthritis. Furthermore, another study using radiographs found that the majority of people in western populations will have OA by 65 years of age and about 80% of those over 75 years of age. (Salaffi 1991) These studies may have produced interesting findings, yet they must be interpreted carefully as the methods used across the studies varied greatly. Moreover, these findings are not specific to the knee.

PATHOLOGY AND ETIOLOGY

The knee is the largest synovial joint in the human body. The knee

can be broken down into several important anatomical structures namely the joint capsule, surrounding ligaments, articular cartilage, meniscus, and the synovial membrane. (Swartz 1994) Usually, the disease process of OA can be observed through changes of the articular cartilage and the subchondral bone. However, it is important to note that joint degeneration does not occur in a uniformly progressive sequence. Typically, the degeneration progresses slowly over many years, although it may stabilize or even improve spontaneously with at least partial restoration of the articular surface. The variation among individuals is primarily due to the differences in the rate of remodeling and repair of the knee. (Goldberg 1992)

In the early stages of the disease, there is fibrillation of the superficial layers of the articular cartilage. As the disease progresses, more of the articular surface is affected and the fibrillation occurs deeper into the cartilage. Typically, by the time the cartilage fissures have reached the subchondral bone the superficial tips of the fibrillated cartilage will have torn and have released free fragments into the joint space and the thickness of the cartilage will have decreased. In addition, enzymatic degradation of the matrix will have further decreased the cartilage surface area, which results in exposed bone. (Jackson 1992)

Furthermore, progression of OA is observed through changes to bone. Specifically, these changes include alterations of the subchondral bone, and

formation of cyst like bone cavities. Typically, alteration of the subchondral bone means an increased subchondral bone density. However, bone cysts which contain myxoid, fibrous, or cartilaginous tissue may appear before a generalized increase in bone density. Nevertheless, this leads to dense subchondral bone articulating with a similar opposing denuded bony surface. As a result, the shape of the joint may change and subsequently the joint becomes deformed and unstable. (Bullough 1992)

Frequently, the formation of osteophytes accompany the changes in articular cartilage and subchondral bone. The mechanisms underlying their formation remain unclear. Osteophytes are palpable, fibrous, cartilaginous and bony prominences that usually develop around the periphery of the joint. Furthermore, they are usually found at the cartilage-bone interface specifically known as marginal osteophytes. They also form along joint capsule insertion, and thus appropriately named capsular osteophytes. In more advanced OA bony growths protruding from the degenerating joint surface are referred to as central osteophytes. Osteophytes may cause tenderness and moreover, may restrict motion or contribute to pain with motion. (Buckwalter et al. 1996)

Changes to the synovium, surrounding ligaments and muscles are secondary to the changes in articular cartilage and subchondral bone. The

synovial membrane occasionally will develop an inflammatory reaction to the fragments of articular cartilage. The surrounding ligaments and muscle will contract abnormally to compensate the loss of stability. Subsequently, the knee joint will have a decreased range of motion and then muscle atrophy. These secondary changes contribute to symptoms such as stiffness, and weakness of the knee. (Moskowitz 1992) The rate at which this disease progresses varies among individuals. Factors affecting this rate vary from molecular factors to gross lifestyle factors. (Rejeski et al. 1994) There is no clear evidence that moderate exercise causes or accelerates OA; in fact, cyclic loading of cartilage stimulates matrix synthesis. (Peterson 1993, Goh et al. 1993) However, prolonged static loading or the absence of loading and motion causes degradation of the matrix and eventually leads to joint degeneration. Activities subjected to repetitive lifting, carrying heavy objects, an awkward work posture, and vibration have been found to accelerate the development of OA. Numerous common occupations carry these risk namely, farmers, construction workers and pneumatic drill operators. (Goldberg et al. 1992, Martin 1994) Furthermore, participation in sports, perhaps more so in competitive collision sports may also pose a threat. For example, American football frequently exposes the athlete to high levels of impact to the knee joint especially with a torn anterior cruciate Ligament (ACL) and joint instability. (Buckwalter 1996)

SIGNS AND SYMPTOMS

Diagnosis of OA is difficult because the condition is heterogeneous. Although there is an association with radiographic changes and increases in pain, some people are asymptomatic. This is perhaps due to the variability in the reporting of pain and tolerance level. Nevertheless, the most reported OA symptom is pain. Patients may also present with stiffness. (Adebajo 1995, Dekker 1993, Moskowitz 1992, Goldberg et al. 1992, Swartz 1994) Table 1 summarizes the signs and symptoms of knee OA.

Table 1 Signs and Symptoms of Knee Osteoarthritis

SYMPTOMS	•Use related pain •Morning stiffness •Limited ROM (range of motion) •Feelings of knee being unstable •Functional limitations and handicap
SIGNS	•Tender spots around the joint margin •Firm swellings of the joint margin •Coarse crepitus (cracking or locking) •Restricted, painful movements •Radiographic evidence of joint space narrowing •Radiographic evidence of subchondral sclerosis •Radiographic evidence of bone cysts •Radiographic evidence of osteophytes

MANAGEMENT

Management of OA is based on the severity of pain. The patient and the physician can choose a treatment / management protocol in one of the following categories: surgical and non-surgical. Usually, the earlier the OA can be identified the better the outcome. Typically, patients with more advanced OA may be advised to consider surgical therapies. Generally, the severity of pain is used as an indicator to physicians whether surgery is needed. Persistent and severe night pain or rest pain would be a strong consideration for surgery. Often, surgery will take place when limited range of motion (ROM) is noticed. (Buckwalter 1996) Muscle atrophy may result if there is prolonged knee disuse. A common misconception of surgery that a patient may hold is that surgery restores function like that of a healthy knee. In contrast, the main purpose of surgery is to relieve pain and restore adequate function of the knee for rehabilitation therapy to take place. There are several surgical procedures that can be used depending on the severity of the disease, namely joint debridement, tidal irrigation, osteotomy, and arthroplasty. (Peyron et al. 1992) For less severe OA, tidal irrigation or joint debridement via arthroscopy may improve the mechanical function of the joint and decrease pain. However, the prognosis following these procedures remains unclear. Severely degenerated joints may require either osteotomy or arthroplasty. (Matsuno 1997) Osteotomy, specifically high tibial

osteotomy, realigns the knee joint and subsequently redistributes the load from severely degenerated regions to regions that have remaining articular cartilage. Although osteotomies have provided clinical outcomes comparable to arthroplasty, the post surgical outcomes are less predictable. Therefore, this procedure is used only when there is a stable joint, with a functional range of motion, good muscle function and some remaining cartilage. (Martin 1994) Typically, when osteotomy is not feasible arthroplasty is the alternative used. Normally, prosthetic implants made of polyethylene or metal is used in the resection and replacement of the joint. Despite relieving pain and sometimes improving motion, arthroplasty does not restore an articular surface with the mechanical properties and durability of articular cartilage. (Pollo et al. 1994) Features such as a low friction gliding surface, the ability to distribute loads across the synovial joint, and the bond between articular cartilage and bone are not duplicated by the synthetic materials. These implants have a limited lifespan and the possibility of the implant loosening results in implant failure. Despite the general positive features of surgery such as alleviating pain and restoring some functional range of motion, there are concerns. There are common surgical complications to consider such as infections, nerve and blood vessel injuries, venous thrombosis and pulmonary embolism. Hence, in most cases, non-surgical therapies should be considered first. (Barrett 1991)

Non-surgical therapies consist of drugs, education, exercise, orthotics, visco supplementation and bracing. Currently, there are three types of drugs available for the treatment of OA namely, analgesics, NSAIDS, and intrarticular corticosteroids. Among the three, analgesics and NSAIDS are more commonly used. Analgesics simply relieve pain, particularly mild to moderate joint pain. On the other hand, NSAIDS have shown to alleviate mild to moderate levels of inflammation, in joints per se, which is sometimes inadvertently associated with pain relief. Both analgesics and NSAIDS have adverse effects associated with them. Some analgesics may cause rashes, nausea, vomiting and even hepatotoxicity, whereas NSAIDS also cause adverse events, most notably gastrointestinal bleeding. In addition, kidney, liver and bone marrow function may be affected. (Bellamy 1996, Brandt 1993) A more recent form of treatment used is the injection of various forms of hyaluronic acid. The hyaluronic acid acts as a lubricant to protect the articular cartilage soft tissue surface of the knee. Non invasive supportive aids such as splints, orthotics, canes, and braces provide symptomatic relief. Generally, heel cushions have been shown to absorb impact loads, which relieve symptoms induced from walking. Canes and walking aids help to reduce joint loading and thus also help to relieve symptoms induced from walking. Heel wedges may help to counteract the effects of varus and valgus deformities; orthotic braces and

splints help to stabilize the knee joint and in some cases add a valgus stress on the knee to counter the deformity. The effectiveness of these braces have been well documented. However, these studies have focussed on the efficacy of bracing on patients with severe OA. Due to the inconsistency in investigation of functional knee braces, the effectiveness of bracing remains unclear. (Liu et al. 1995)

BRACING STUDIES

There is very little literature available on braces for mild forms of OA. The development of braces for OA relief began as early as the mid 1970s where the CARS-UBC brace was first introduced. Jawad and Goodwill (1986) introduced the TVS brace which is a modified version of the CARS-UBC brace being lighter and smaller from its predecessor but essentially using the same concept. Its design helps to stabilize a knee from moving into a deformed alignment of the knee joint which is painful. The brace is active when the knee is in extended and does not restore proper alignment by manipulation. Subsequently, the brace only relieves pain while weight bearing and not resting or night pain. There are few studies on the TVS brace. The few that are available give very little detail and only report the percentage of people who choose to continue to use the brace. (Jawad and Goodwill, 1986).

Horlick and Loomer (1993) were the first to report the efficacy of the Generation II Unloader (GII) brace designed for knee osteoarthritis. The brace is made of a rigid plastic with thigh and calf sockets and a strong polyaxial hinge to allow full flexion and extension. It restricts the knee from axial rotation in the last ten to fifteen (10-15) degrees of extension, but after fifteen (15) degrees of flexion, allows essentially full axial rotation. This brace was originally designed principally for anterior cruciate ligament deficiency. However, GII modified the brace adding a medial hinge that made it easier to provide a valgus movement to the knee. GII later added a patented ADJ hinge, which allowed better adjustment.

Most of the other studies pertaining to bracing for osteoarthritis appear to focus on how the brace affects joint loading, gait patterns and other biomechanical features. No study has investigated the efficacy of Generation II braces for mild to moderate OA. Furthermore, no one has investigated pain, function, and stiffness as a result of the individuals' sport activity. Matsuno (1997) investigated the efficacy of bracing on pain, function, and stiffness as a result of an individuals' activities however, on individuals with severe OA. However, that study investigated the efficacy of bracing on subjects with severe OA. Kirkley et al. (1999) used a parallel group, randomized clinical trial design. There were three groups in her study. One group was simply receiving standard medical treatment", the

second group wore a neoprene sleeve in addition to receiving standard medical treatment and the third group wore a custom made GII ADJ Unloader ® brace as well as receiving standard medical treatment. The groups did not cross over to other treatments and function was measured based on questions available on a combination of the WOMAC (Western Ontario and McMaster University Osteoarthritis Index) and MACTAR (McMaster-Toronto Arthritis Patient Preference Disability Questionnaire). Prior to this study, no studies had controlled trials of use of a sleeve for OA and reports of improvement as a result of wearing sleeve were merely anecdotal (Kirkley et al. 1999). Kirkley et al (1999) found significant differences, six months later, in pain and stiffness both in unloader brace and control, and neoprene sleeve and control contrast measures. Although contrast measures found no significant difference between the sleeve and brace groups, there was a strong trend towards an improvement in function. She attributed these improvements to an increase in joint proprioception, which perhaps is the best explanation to this day since numerous studies have demonstrated an increase in joint proprioception with wearing a sleeve (Kirkley et al. 1999).

STATEMENT OF PROBLEM

A more recent brace developed by Generation II Orthotics is an

adapted version of the GII ADJ Unloader ® brace with the convenience of off the shelf sizing called the GII Unloader Express ®. This brace is intended for patients with signs and symptoms of mild forms of osteoarthritis.

No study has investigated this brace.

RESEARCH QUESTION

This study proposes to investigate the clinical efficacy of the Generation II Unloader Express Brace specifically:

a) What effect does it have on the level of pain experienced in the knee?

b) What effect does it have on the level of stiffness experienced in the knee?

c) What effect does it have on function, specifically performance in subjects' respective sport activities?

Hypotheses

(a) Subjects will experience less pain wearing the valgus brace compared to the neutral and no brace conditions (valgus brace > neutral brace > no brace)

(b) Subjects will experience less stiffness following activity when wearing the valgus brace compared to the neutral brace and no brace conditions

(c) Subjects will have less difficulty in function following activity when wearing the valgus brace compared to the neutral brace and no brace conditions

METHODS

SUBJECTS

Subjects were recruited from the Allan McGavin Sports Medicine Centre in Vancouver B.C. and from Generation II orthotics. Some subjects responded to an article in a local newspaper, "The Richmond News", which made reference to this study. All subjects were diagnosed with medial compartment knee secondary OA. Diagnosis of the disease were based on standing x-rays showing joint space narrowing, sub-chondral sclerosis, and osteophyte formation. Subjects were between the ages of thirty and seventy. The exclusion criteria was similar to those used by Horlick and Loomer (1993). Subjects were not allowed to enroll in study if they had: (a) arthritides other than OA; (b) previous fracture of ipsilateral femur or tibia; (c) previous surgery to affected knee other than arthroscopy, debridement, or partial menisectomy; (d) fixed flexion deformity greater than fifteen (15) degrees; (e) flexion less than one hundred and fifteen (115) degrees; (f) leg length discrepancy greater than two (2) centimeters and; (g) skin disease or peripheral vascular disease preventing brace application; (h) not participating in another study involving the arthritic knee. All subjects were given an informed consent explaining the procedures of the study. Subjects signed the consent form to indicate that they understood the procedures and

exempted any researchers involved from any liability. Prior to this, the ethics board of the University of British Columbia in Vancouver BC approved the study. Subjects were encouraged not to take any drugs to relieve pain. Subjects were allowed to withdraw at any time during the course of the study without any reason. Subjects who dropped out were noted in the results section, but data of those who dropped out were not used in analysis.

STUDY PROTOCOL

The duration of the study for each individual was twelve weeks. There were three conditions in this study: no brace, neutral brace and valgus brace (brace adjusted to four degrees valgus). All subjects began the study in the no brace condition, followed by the neutral brace condition and finally the valgus brace condition. Between the neutral and valgus brace conditions there was a washout period. Each of the three conditions, including washout period, was three weeks in duration. In each condition, except the washout period, subjects completed a two page self-administered questionnaire (Appendix A) a minimum of twice a week. Therefore, for each condition a minimum of six questionnaires would be completed. Subjects were also asked to report any flare-ups and swelling. Subjects were given instructions to be fitted for a brace at the Generation II Orthotics Inc. head

office in Richmond, BC. Subjects were told they would have to wear two different braces sometime in this study and that the two braces would be different from each other. Subjects returned to Generation II Orthotics during the washout period to have the brace adjusted. Subjects were not compensated for travel time and related expenses. In total the subjects met with the co-investigator for five times, the initial meeting and after each of the conditions including the washout period, at the Allan McGavin Sports Medicine Centre or at a pre arranged location as long as there was space to make measurements of the knee. (see Knee Flexion Measurements)

THE KNEE BRACE

Knee braces were supplied by a local orthotics company Generation II Orthotics Inc. The functional brace used in this study was the Generation II Unloader Express Brace. This brace combines the basic design components of the GII Unloader ADJ Brace and the convenience of off the shelf sizing. The design includes helical dynamic force straps, an ADJ hinge, and semi-rigid, wrap around stabilizers. The functional brace had the hinge altered by a GII Orthotics technician to allow an application of four degrees in valgus. The non-functional brace used as the placebo was the same brace with the ADJ set at zero degrees otherwise known as the neutral brace.

INITIAL MEETING

The initial meeting was arranged via telephone and held at the Allan McGavin Sports Medicine Centre or at a pre-arranged location to accommodate the subjects' request. Subjects name, age were recorded. If at that time a scale was available, the subject would also be weighed. The subject height and weight was recorded at another time. The reason there was no strict procedure for this data is that it was just used as a representation of the subjects and not for comparison purposes. Hence, accuracy was not an issue.

Subjects' OA were confirmed by x-rays, which the subjects were told to obtain from their physicians. If the subject did not have x-rays but were diagnosed by a physician of having OA, they were given a requisition to receive anterior posterior x-rays of the affected knee. Upon confirmation of OA by x-rays the subject was notified that they were allowed to continue.

Subjects also were informed of the procedures of the study. They were given a consent form to read and to sign. They were also given twenty four questionnaires in an envelope and a schedule for meetings with the co-investigator. They were also given directions, if needed, to Generation II Orthotics to be fitted for the brace. In some cases an appointment for the brace fitting was done on behalf of the subject by the co-investigator.

After signing the consent form, subjects were asked to complete a three question questionnaire. Approximately fifteen minutes later the subjects were asked to complete a second questionnaire with the same three questions. This test retest was to establish reliability of the modified WOMAC questionnaire used in this study. Of the three questions in the test retest questionnaire the first assessed the subjects' pain level, the second question assessed the subjects' stiffness level and the third assessed the subjects' function level. The questionnaire had the same six VAS questions as the questionnaire the subjects completed throughout the study. Three questions were circled to indicate to subjects, which three of the six they were to answer. The same three questions were used in the repeat test. Subjects were told to disregard the time restriction and to assess the parameters at their current state.

KNEE FLEXION MEASUREMENTS

After the initial meeting, subjects met with the co-investigator four more times. Once at the end of the no brace condition, then at the end of the neutral brace condition, after the washout period and finally at the end of the valgus brace condition. Subjects were instructed to bring shorts or loose pants that could be rolled up above their knees. Knee flexion was measured using a goniometer with the subject instructed to lie supine with both legs

flat on the examination table. The fulcrum of the goniometer was aligned with the lateral epicondyle of the femur. The stationary arm was in line with the greater trochanter and midline of the femur and the moving arm in line with the lateral malleolus and midline of the fibula. Knee flexion was measured at the second (after the no brace condition), third (after the neutral brace condition) and fifth (after valgus brace condition) meetings only. At the second the non OA knee was measured then the affected knee was measured. At the third and fifth meetings, the non OA knee was measured, then the affected knee was measured without the brace. Then the OA knee was measured again with the brace on. The average of two measurements for each measure was recorded. In the case where the two measurements were one degree apart the higher number was recorded. The measurements were recorded in degrees.

THE QUESTIONNAIRE

The questionnaire used in this study was adapted from the validated Western Ontario McMaster University Arthritic Index (WOMAC). The WOMAC has two versions, one which uses a descriptive scale and the other a visual analog scale (VAS). Both versions measure three entities: pain, stiffness, and function. We adapted the basic format of the WOMAC with measurements of the three entities; pain, stiffness and function. The

visual analog scale used in this study was a ten centimeter long, horizontal line flanked by two extremity description appropriate for the parameter assessed (Appendix A). Subjects were instructed to mark an "x" on the line corresponding to intensity of the respective parameter. Assessments were measured in centimeters to the nearest tenth of a centimeter. Unlike the original WOMAC, there was only one specific activity parameter restriction for the measurement. For example, there was no measurement for pain while "Descending Stairs" and then another measurement for pain for "Ascending Stairs". Instead there was only pre and post actvity assessments for each parameter. The McGill Pain Questionnaire, Keele and Pooles Knee Scale which use descriptive measures were considered; however, after further consideration it was felt that a more sensitive scale was needed. This is primarily because the subjects had relatively mild OA and were in early stages of the disease. Similar to the WOMAC, the questionnaire addressed pain, function and stiffness. This questionnaire was unique in that it formulated the question around one issue, the subjects' chosen, sport activity. The self-assessment questionnaire was divided into three sections: section A addressed pain, section B addressed function, and section C addressed stiffness. Both sections A and B had two questions. One of the questions addressed the subjects perception of the respective parameter within fifteen minutes before activity and the other fifteen minutes

after participation in their chosen activity. In Section C, there were four questions. Again, there were two questions, similar to sections A and B, which were answered on the VAS. Unlike pain and function, stiffness was assessed within fifteen minutes after getting out of bed on the day of activity and fifteen minutes after getting out of bed the morning after activity. Stiffness is a parameter, perhaps as subjective as pain. Previous studies that have measured stiffness used the VAS as the outcome measure. However, similar to the parameter pain, there was no validated, objective outcome measure for stiffness. This study attempted to provide some visual, tangible, objective element to the sensation of stiffness. After completing the VAS for the stiffness parameter, subjects were asked to assess their knee flexion. They were instructed to imagine that while standing straight the hip is in the 12 o'clock position with the foot being at 6 o'clock and the knee is the fulcrum where the two hands (hour and minute) connect in the center of the clock. Subjects were instructed to look in the mirror to estimate what time, to the closest hour, they could flex their knee. The heel was the reference point (hour hand on a clock) as to what point one could flex the knee. For example, if the heel were to indicate 9 o'clock, one can assume the toes of the same foot would indicate somewhere between 8 and 9 o'clock. Subjects were told to assess their stiffness level on the VAS first then followed by the clock test.

VISUAL ANALOG SCALE

The Visual Analog scale (VAS) is a tool widely used to measure pain and activity. The VAS allows the subject to express the severity of pain in a way that it can be given a numerical value. (Huskisson 1983) Rojkovich et al. (1998) used the VAS to distinguish between pain experienced at rest and pain experienced when there is joint movement. (Rojkovich et al. 1998) Its limitations are also well known. There is a possibility that the subject may not understand the concept and have difficulty in using the scale. Reproduction of the line on a VAS may be variable because the photocopier may make the photocopied line longer than the original. Moreover, there is the never ending doubt about the relationship of the measurement to the true pain experience (Huskisson 1983) Recently, the use of VAS as a measurement for pain has been validated (Shearer 1996). Notwithstanding that pain is subjective and albeit an entity which is impossible to measure, there have been numerous accounts which claim to measure this entity with many assumptions and is confounded to certain restrictions. The literature agrees that although the VAS is not perfect, It offers the greatest sensitivity when cross-validated using objective measurement scales.

ACTIVITIES

Each subject participated in an activity that the subject normally participated on a regular basis, which involved knee flexion while performing the activity. The subjects were asked to participate in their respective activities at a minimum of two times a week. Subjects were instructed to perform the activity at their highest intensity and longest duration that they could bear. For example, if the activity was golf the subject should attempt to play all eighteen holes and only stop if the pain is too debilitating. The subjects were asked to refrain from performing activities at a skill level, intensity or duration more than required of the sport or that they would normally do if they had a healthy knee. For example, if the activity was skiing and the skier is a novice skier, it would be unreasonable for the subject to set his accomplishment standard as completing a black diamond run. Since it was likely that the respective athleticism of these subjects would be variable, the study aimed to measure the change in pain and change in performance rather than the absolute pain and absolute performance.

STATISTICAL ANALYSIS

Power calculations for subject number requirements were based on accepting the following variables ($\alpha_1 = 0.05$ and power ≥ 0.80). Using

Horlick and Loomer's (1993) data an effect size slightly over 1.0 is estimated. Therefore, the required number of subjects to achieve power of 0.85 is fourteen (n = 14). Pearson correlation coefficient was used to analyze the correlations in the test retest. Paired t-tests were used to detect differences between pre and post activity pain, function and stiffness levels in all three brace conditions. One Way ANOVA for repeated measures were used to detect significant differences between the three bracing conditions in regards to how subjects change in each of the three parameters, pain, function and stiffness levels, from pre to post. Pairwise comparisons were used to detect significant differences between the three possible pairs (No Brace VS Neutral Brace, No Brace VS Valgus Brace, and Neutral Brace VS Valgus Brace) in how they changed from pre to post significant differences between the bracing conditions regarding the mean change in pain, function and stiffness levels (Post Activity $_{\text{Pain, or Function, or Stiffness}}$ – Pre Activity $_{\text{Pain, or Function, or Stiffness}}$). One Way ANOVA for repeated measures were used to detect differences between the conditions in pre activity pain, function, and stiffness levels. The same analysis was also performed for post activity pain, function and stiffness levels. Pairwise comparisons were also used to detect differences between all possible pairs of conditions.

RESULTS

SUBJECTS

A total of twenty-two subjects enrolled in the study. Potential candidates for study responded to a print advertisement titled "Subjects needed" which was posted at the Allan McGavin Sports Medicine Centre. The same advertisement was also requested to be posted at several lower mainland rheumatologist and general practitioners offices. "The Richmond News", a local community paper, wrote an article about osteoarthritis and mentioned the study, which attracted over forty-five inquiries about the study. One withdrew from the study three weeks into the study for no specific reason and her data was not used for the study. Of the twenty-one subjects remaining in the study, thirteen were male and seven were female. Of the fourteen males, five had OA in the right knee, and nine in their left. Of the seven females, four had OA in their right knee and three had OA in their left knee. In total forty-five responses to various ads were received. Fifteen were not included because they were over the age limit. Five were excluded because the OA was on the lateral side and three were excluded because radiographs showed the OA was too severe (i.e. very near to bone on bone). The average age of subjects was 57.4 ± 10.9 yrs., the average height of subjects was 68.4 ± 3.5 inches, and the average weight was 173.2 ± 42 lbs. The subjects had to choose a single sport in which they were to participate throughout the study. Table 2 outlines the types of

activities chosen for this study and the number of subjects in each type.

Table 2. Subjects' Activities

Activity	Number of Subjects choosing Activity
Circuit Training	4
Curling	1
Cycling	3
Golf	1
Running	9
Tennis	3

VALIDATING THE QUESTIONNAIRE

This study used a questionnaire specifically created for this study by modifying a validated, reliable WOMAC questionnaire. The results from the test retest questionnaire showed a significant correlation for each of the three parameters of interest; in pain ($r = 0.89$, $p < 0.01$), in function ($r = 0.91$, $p < 0.01$), and in stiffness ($r = 0.93$, $p < 0.01$). The results suggest the questionnaire is reliable.

QUESTIONNAIRE DATA

The three parameters of interest were PAIN, FUNCTION and STIFFNESS. The mean pre and mean post levels of the three parameters in each brace condition are outlined in Table 3.

Table 3. Mean Pre and Post Levels (cm) in the Three Parameters in Each Brace Condition

Parameter	Brace Condition	Pre Activity Mean	S.D.	Post Activity Mean	S.D.
Pain					
	No Brace	2.69	1.91	4.24	2.11
	Neutral	2.48	1.65	3.12	1.54
	Valgus	2.31	1.54	2.51	1.56
Function					
	No Brace	2.69	1.89	3.93	1.89
	Neutral	2.45	1.79	3.10	1.91
	Valgus	2.22	1.56	2.34	1.65
Stiffness					
	No Brace	2.82	2.18	3.35	2.26
	Neutral	2.46	1.87	2.88	2.02
	Valgus	2.48	1.69	2.44	1.78

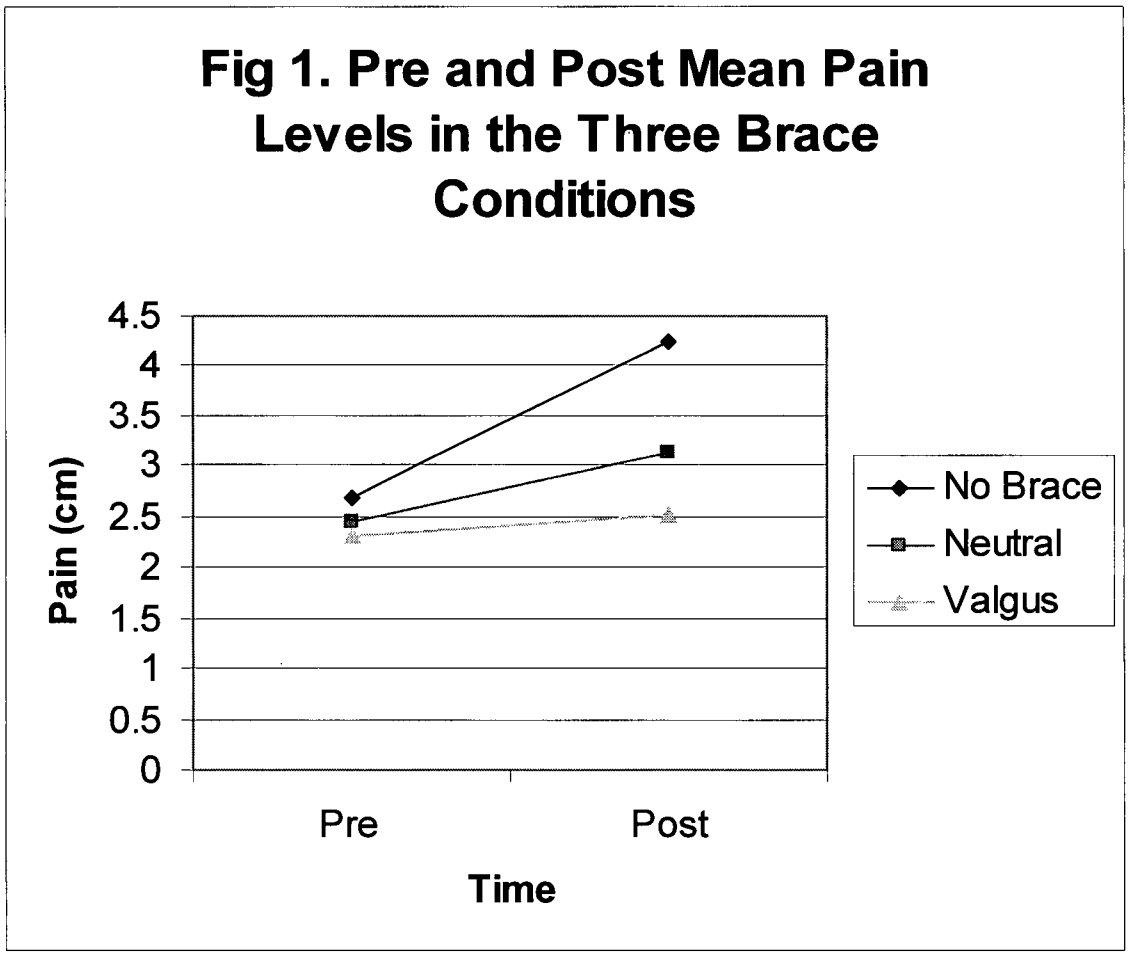
PAIN

In the no brace condition there was a significant increase in the mean post activity pain levels compared to pre activity pain levels ($t(20) = 4.712$; $p < 0.01$). There was also a significant increase in the mean post activity pain levels compared to mean pre activity levels in the neutral brace ($t(20) = 2.438$; $p = 0.024$). However, there was no significant difference found between the pre and post activity mean pain levels in the valgus brace ($t(20) = 0.900$; $p = 0.379$). These results suggest that during valgus bracing, the subjects did not experience a significant increase in pain after activity.

There was a significant difference between the brace conditions in the mean change in pain levels ($F[2,40] = 21.711$; $p < 0.001$). Pairwise comparisons revealed that the mean change in pain levels in subjects with brace in neutral was significantly less compared to the same subjects with no brace ($p < 0.001$). Likewise, the mean change in pain levels in subjects with the valgus brace was significantly less than the mean change in pain levels in the same subjects with no brace ($p < 0.001$). Moreover, the mean change in pain levels in subjects with the valgus brace was significantly less than the same subjects with the neutral brace ($p = 0.037$)

There was no significant difference between the bracing conditions in pre activity pain levels ($F[2,40] = 1.323$; $p = 0.278$). However, there was a significant difference between the bracing conditions in post activity pain

levels ($F[2,40] = 23.150$; $p < 0.001$). Pairwise comparisons reveal that the post activity, mean pain levels when wearing either brace (neutral or valgus) was significantly lower compared to wearing no brace ($p < 0.001$). Moreover, the mean post activity pain level in subjects when wearing the valgus brace was significantly lower compared to the mean post activity pain level in the same subjects wearing the neutral brace ($p = 0.028$).



FUNCTION

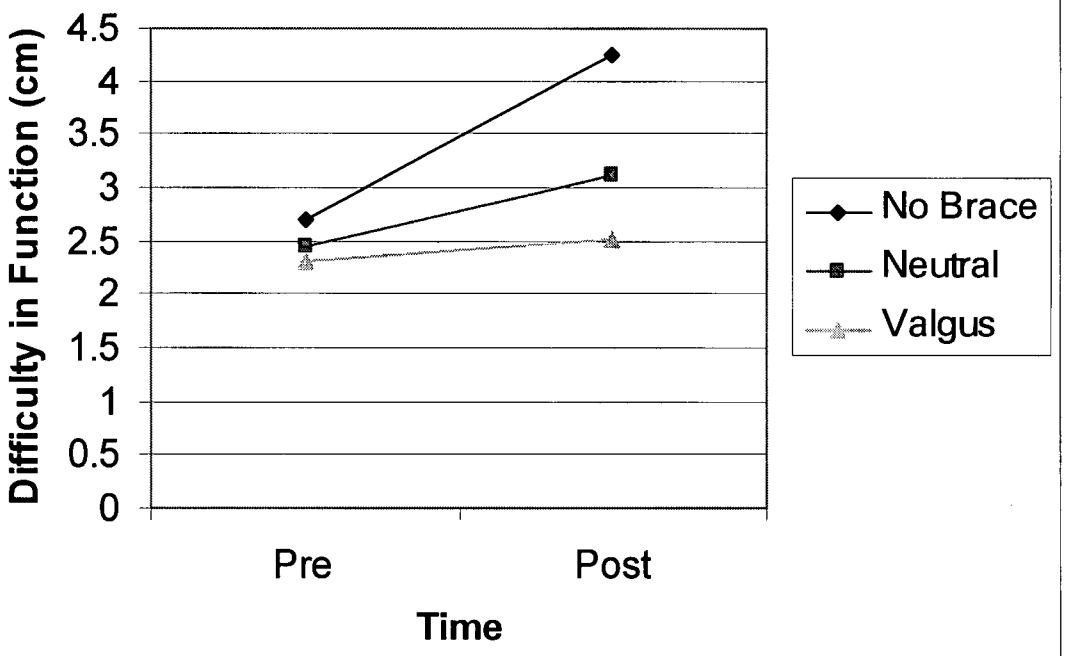
There was a significant difference between the mean pre activity and mean post activity function levels ($t(20) = 3.881$; $p = 0.01$) in the no brace condition. There was also a significant difference found in the neutral brace condition ($t(20) = 2.304$; $p = 0.032$). However, in the valgus brace condition no significant difference was found ($t(20) = 0.724$; $p = 0.477$). These results suggest that with no brace and with a brace in neutral, subjects experienced a significant increase in difficulty in function following activity. However, with the valgus brace, their difficulty in function did not change significantly after activity.

There was a significant difference between the conditions in the mean change in function levels ($F[2,40] = 11.178$; $p < 0.001$). Pairwise comparison reveal the mean change in function levels in subjects with the neutral brace was significantly less compared to the same subjects with no brace ($p = 0.011$). Likewise, the mean change in function levels in subjects with the valgus brace was significantly less compared to the mean change in function levels in the same subjects with no brace ($p < 0.001$). Moreover, the mean change in function levels in subjects with the valgus brace was significantly less compared to subjects with the neutral brace ($p = 0.032$).

There was no significant difference between the bracing conditions in pre activity function levels ($F[2,40] = 1.989$; $p = 0.150$). However, there

was a significant difference between the bracing conditions in Post Activity Function Levels. ($F[2,40] = 16.409$; $p < 0.001$). Pairwise comparison reveal that the post activity, mean difficulty in function levels when wearing either brace, neutral or valgus, was significantly lower than wearing no brace ($p < 0.01$). Furthermore, subjects' difficulty in function with valgus brace was significantly lower compared to the neutral brace ($p = 0.013$).

Fig 2. Pre and Post Mean Difficulty in Function Levels in the Three Braces



STIFFNESS

There was a significant increase in the mean post activity stiffness levels compared the mean pre activity stiffness levels in the no brace condition ($t(20) = 2.709$; $p = 0.013$). A significant increase was also present in the mean post activity stiffness levels compared to the mean pre activity stiffness levels in the neutral brace condition ($t(20) = 2.270$; $p = 0.034$). However, no significant difference was found in the valgus brace condition ($t(20) = -0.341$; $p = 0.737$). Furthermore, visual inspection of the data reveal mean post activity stiffness levels are actually slightly lower than the mean pre activity stiffness levels.

A significant difference between the conditions in the mean change was detected in stiffness levels ($F[2,40] = 5.175$; $p = 0.01$). However, pairwise comparisons reveal that mean change in stiffness levels with the neutral brace was not significantly less when compared to the mean change in stiffness levels with no brace ($p = 0.569$). Conversely, the mean change in stiffness levels in subjects with the valgus brace was significantly less compared to the mean change in stiffness levels in the same subjects with no brace ($p = 0.007$). Moreover, the mean change in stiffness levels in subjects with the valgus brace was significantly lower compared to the mean change in stiffness levels in the same subjects with the neutral brace ($p = 0.021$).

There was no significant difference between the bracing conditions in

pre activity stiffness levels (F [2,40] =1.909; p =0.162). However, there was a significant difference between the bracing conditions in post activity stiffness levels (F [2,40] =8.022; p =0.001). Pairwise comparisons detected no significant difference, but a strong trend towards significance, between subjects with the neutral brace and the same subjects with no brace in post activity stiffness levels (p =0.063). However, the mean post activity stiffness level was significantly lower in subjects with the valgus brace compared to the same subjects with no brace (p =0.002). Moreover, they were significantly lower compared to the same subjects in the neutral brace (p =0.022).

Fig 3. Pre and Post Mean Stiffness Levels in the Three Braces

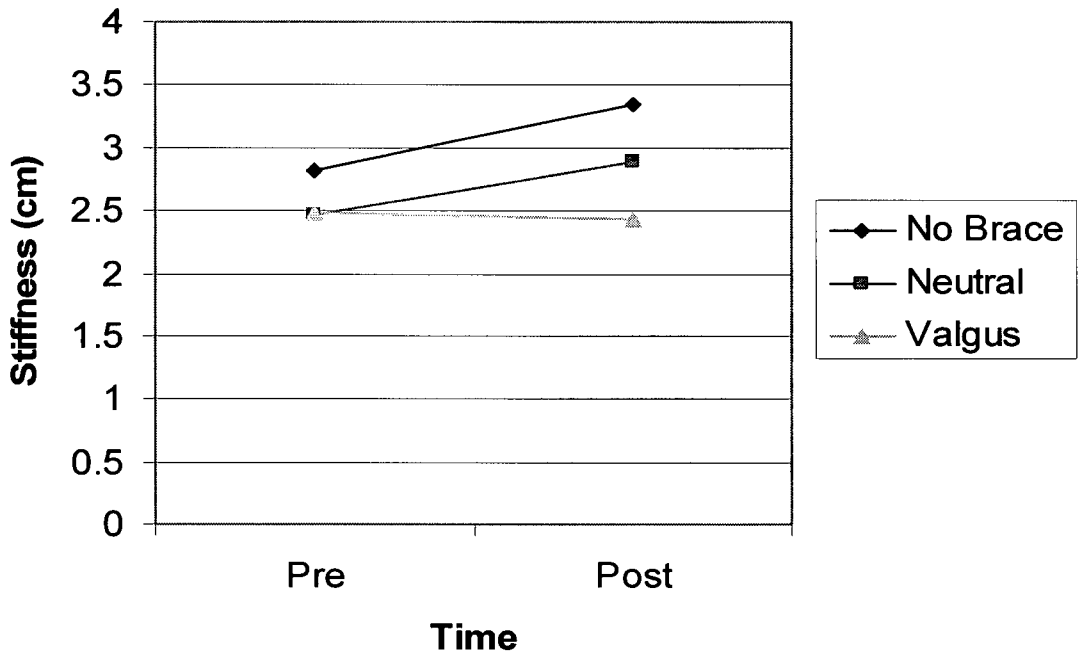


Table 4. Differences in Mean Change (cm) from Pre to Post Activity Between the Three Brace Conditions

PARAMETER	CONDITION	DIFFERENCE IN MEAN CHANGE (cm)	SIGNIFICANCE
PAIN			
	Neutral VS No Brace	0.91	$p<0.001$
	Valgus VS No Brace	1.35	$p<0.001$
	Valgus VS Neutral	0.44	$p=0.037$
FUNCTION			
	Neutral VS No Brace	0.59	$p=0.011$
	Valgus VS No Brace	1.12	$p<0.001$
	Valgus VS Neutral	0.53	$p=0.032$
STIFFNESS			
	Neutral VS No Brace	0.11	$p=0.569$
	Valgus VS No Brace	0.57	$p=0.007$
	Valgus VS Neutral	0.46	$p=0.021$

KNEE FLEXION MEASUREMENTS

There was no significant change in knee flexion in the unaffected knee across the three measurements ($F[2,19]=0.265$; $p>0.05$). Similarly, there was no significant change in knee flexion measurements in the OA knee across the three measurements ($F[2,19]= 0.246$; $p>0.05$).

There was no significant difference in change in knee flexion measurements (brace on – without brac e) between the neutral and valgus brace. i.e. (neutral brace on – without br ace) VS (valgus brace on – without brace) ($t(20)=0.318$; $P>0.05$)

THE CLOCK TEST

In the no brace condition, there was no significant difference between the day of activity and the day after activity assessments ($t(20) = 1.993$; $p = 0.06$). However, there was a trend towards significance. However, there were no significant differences in either brace conditions, neutral or valgus, between the day of activity and the day after activity assessments of the foot position on the clock ($t(20) = 0.224$; $p > 0.05$) and ($t(20) = -0.660$; $p > 0.05$) respectively.

DISCUSSION

The subjects who enrolled in this study were active individuals who were generally free of illnesses. They shared a common disease called medial compartment osteoarthritis of the knee. Another commonality is that their symptoms of OA are triggered by participating in a sport activity. These subjects were diagnosed with early OA based on the Kellegren Lawrence scale. They were basically able to carry out their activities of daily living. Specific activities, namely sport activities would cause these subjects to experience pain, and stiffness and difficulty in function. In the unusual event that flare up occurred, NSAIDS would be taken. Otherwise no medication was taken by any of these subjects. Several subjects did indicate that they were taking Glucosamine and Chondroitin Sulfate. This study was designed to determine whether an off the shelf brace designed by a local orthotics company would curtail the problems these subjects were experiencing.

The study used a repeated measures design. The purpose of the "no brace condition" was to allow subjects to be their own control. Moreover, in each condition, subjects assessed the three parameters pre and post activity. Pre and post measurements allows the study to establish a baseline (pre) each time an assessment is made on the effect (post). In each parameter, the study found that pre activity parameter levels were not significantly different across the three brace conditions. Moreover, the post

significantly different across the three brace conditions. Moreover, the post activity parameter levels were significantly different across the three brace conditions. This shows that the activity chosen by the subject creates an effect on the three parameters. How it manifested depended on the brace condition. The concern of a carry over effect was addressed by the insertion of a three week washout period between the neutral and valgus brace conditions. A cross over design as in Horlick and Loomer (1986) and a parallel design similar to the one used in Kirkley et al (1999) were considered. Using a cross over design would have eliminated any order effect. The order effect would be a concern if the subject's responses were dependent on the preceding condition. There would also be a concern if there were assessments made on multiple conditions in one testing session. However, the subjects were essentially blinded to the order of the two brace conditions (neutral and valgus). Furthermore, in this study only one condition was assessed at a time. Moreover, there are associated problems with the above designs such as requiring larger number of subjects for sufficient statistical power and having to match subjects to address inter-subject differences. Using this repeated measures design in which each subject underwent the three conditions in the same sequence, we were able to have sufficient statistical power in the analyses.

THE QUESTIONNAIRE DESIGN

The investigator thought it was an important part of our methodology to design our own questionnaire. In fact, in literature it is a common practice to design questionnaires and testing protocols to examine certain parameters. The WOMAC is a commonly used, reliable outcome measure. However, we felt that a questionnaire needed to be specifically tailored for mild to moderate OA sufferers.

In the literature there have been numerous studies where the investigator chose to create questionnaires to address specific populations. This is the case with Knee Pain Scale, developed by Rejeski et al. (1995) and the outcome measure used by Matsuno et al. (1997) called the "Japan Orthapaedic Associations' knee scoring system". In both cases, the outcome measure was designed for a population suffering from severe OA. The investigators of the present study chose to design their own questionnaire simply because they felt that the questionnaires in literature would not be appropriate to their sample population. Since the use of this questionnaire has not been used in any other study the validity has not been established. However, it can be concluded from the results of our test retest of three questions that the questions in this study are reliable. ($r = 0.89$-0.93). Typically, the time between the test and retest should be large enough to avoid fatigue, learning and memory effects. Conversely, the time should be short enough to avoid genuine changes in the measured variable. We chose to have both the test and the retest within one session because

we felt that it was near impossible to keep the measured variable (i.e. pain) constant over time. Moreover, we do not believe there would be a memory effect because these subjects completed the first test without being aware that there was a retest to take place twenty minutes later.

This study found that participation in the subjects' respective sport activity does result in an increase in the levels of symptoms, namely pain ($p < 0.01$), difficulty in function ($p = 0.01$), and stiffness ($p = 0.013$). These increases in these symptoms would be representative of what the subjects experienced prior to enrollment in this study. While wearing the neutral brace, subjects also experienced significant increases from pre activity levels in pain ($p = 0.024$), difficulty in function ($p = 0.032$) and in stiffness ($p = 0.03$). Only by wearing a valgus brace were subjects able to experience no significant increase from pre activity levels in pain ($p = 0.379$), difficulty in function ($p = 0.477$), and stiffness ($p = 0.737$).

Despite these findings, wearing a brace even in neutral was still better than not wearing a brace at all in respects to pain ($p < 0.001$), and difficulty in function ($p = 0.011$). Moreover, with respects to all three parameters, pain ($p = 0.037$), function ($p = 0.032$), and stiffness ($p = 0.021$), we found a significant difference between the valgus and neutral brace conditions.

Kirkley et al. (1999) compared, in a parallel study, the GII custom Unloader ADJ to a control group and to a placebo sleeve. Similar to the present study they investigated the effects of bracing on pain, function and stiffness. The study reported significant differences between the groups.

Specifically, significant improvements were found using the brace or the sleeve compared to the control group (no brace). However, only an improvement in the pain subscale was found between the sleeve and brace group. She contributed the insignificant finding to the fact that both the brace group and placebo group had better joint proprioception than the control group. A possible contribution to their insignificant finding is a combination of the use of an inappropriate questionnaire and study design. If we used the WOMAC on the present study's sample, we can also speculate that there would be no improvements simply because the sample did not have issues with activities of daily living. There is a possibility that there were not enough descriptives (i.e. difficulty lying in bed, and difficulty with heavy domestic duties) which the subject could improve on. For example, of the seventeen descriptives in the function section of the WOMAC there is a possibility that the three groups did not differ in fifteen of them, leaving only two to produce a difference. Furthermore, Kirkley et al. (1999) used a parallel design. A parallel design requires matching subjects. In the case where the outcome measures are subjective (i.e. the VAS) matching may not address inter-subject variation. The decision to use a parallel design stemmed from Kirkley's criticism of Horlick and Loomer's study (1986) that there was a possible carry over effect. We feel however, that simple changes such as the ones recommended by Horlick and Loomer, such as the addition of a washout period, would have been better than switching to another design altogether. This is demonstrated by Pollo et al.

(2002) who reported improvements in function by using repeated measures analysis.

This study attempted to establish an objective measure to assess stiffness. In Section C of the questionnaire, in addition to the VAS assessment the subjects were instructed to assess their leg position (see Methods). Our results show that there was a significant difference in the subject's perception to stiffness across the three brace conditions. However, we were not able to detect a significant change in foot position across the three brace conditions. These findings suggest that a significant change in the subject's perception of stiffness may not be reflected in an objective, visual measure.

The present study has introduced several novelties. First, the questionnaire used in this study was unique to the study. We felt that an outcome measure tailored to the sample population assessed is more appropriate. There is no validated outcome measure tailored for mild to moderate OA sufferers. Subsequently, we had to use a non validated outcome measure. Secondly, there was also the addition of time restriction for assessment i.e. within fifteen minutes before and after activity, with the exception for stiffness where it was fifteen minutes after getting out of bed on the day and the day after activity. In outcome measures such as the WOMAC it instructs subjects to make assessments consistently at a set time during day throughout the study. Therefore, one could speculate that a person making an assessment, at the end of the day (i.e. about how well

they got out of their car in the morning) could be influenced by all the experiences they had in between. Pre and post measurements allow us to assess an improvement possibility in each parameter. In previous studies using the WOMAC, one only assumes that there was a possibility for improvement in all the descriptive parameters within each sub-scale, which is particularly difficult in the function sub-scale.

ASSUMPTIONS AND LIMITATIONS

In our attempt to control for when the subject made assessments, we also restricted our ability to assess pain, difficulty in function and stiffness symptoms at other times of the day. For example, two subjects, one on two different occasions, the other on two occasions, reported in their journals that they experienced pain later in the day.

The present study had a sample population with an age range of thirty-two (32) years of age to seventy-two (72) years of age. We do not feel that this age difference had a significant effect on the subject's assessment of the braces due to the time limit of the study. However, we would assume that the thirty two year old would inherently have a higher muscle mass and greater muscle tone than the seventy two year old. Hence a longer course of rehabilitation the bracing would be more efficacious in the younger subjects due to increased joint stability from muscle strengthening.

The Generation II Unloader Express at its neutral position re-aligns the tibio femoral angle to zero degrees, whereas the custom made Unloader ADJ

at its neutral setting aligns to the natural deformity of the tibio femoral angle. Therefore, when subjects wore the brace at the neutral setting, they may have experienced a different force depending on their deformity alignment. This study did not account for this variability. In addition, even at the neutral setting the dynamic force strap (DFS) has been demonstrated to significantly reduce the medial compartment force by eight percent (8%) (Pollo et al. 2002). Pollo (2002) suggested that patients may experience symptomatic pain relief in the neutral brace due to the reduced load on the affected compartment caused by the DFS. This may also explain why we found significantly lower increases in all three parameters with the neutral brace compared to the no brace condition.

Although we were able to establish reliability of our outcome measure, we did not use a validated outcome measure.

REMARKS ABOUT BRACE

Subjects, in general were quite happy about the brace. All but one subject thought the brace helped them overall. Two subjects commented that the sleeve within the brace would be better if it was adjustable or custom fit. Some had sleeve material "bunch up" behind the knee, and some felt it was causing them to sweat more. Three commented that brace was bulky and one reported that occasionally the medial hinge would scrape the medial side of the contralateral knee. One subject commented that the ends of the straps could be less abrasive.

CONCLUSION

The findings of this study demonstrated that the Generation II Unloader Express Brace has positive effects for all three parameters. Clearly, this brace should be considered as part of a treatment protocol which has an exercise rehabilitation component. Exercises should aim to promote weight loss, strengthen the muscles around the knee to increase stability, and improve proprioception of the knee joint. Non knee joint weight bearing, cardiovascular exercises (i.e. stationary bike) and closed kinetic chain exercises (i.e. drop squats) are commonly used to achieve this goal.

There are issues that could be addressed to enhance patient compliance. The alternative choice for patients suffering OA is a customize brace. This study has also shown that it remains a challenge to measure objective changes in perception outcomes measures with changes in physical movements (ROM and Knee Flexion).

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APPENDIX A

Subject ID# _____ Date of Record:_____

Instructions To Patients

Section A: The following questions concern the amount of pain you have experienced due to arthritis in your affected knee. For each situation please enter the amount of pain experienced (Please mark your answers with an "X")

Question 1: How much pain do you have within fifteen minutes before participation in your chosen activity?

No Pain |_____| Extreme Pain

Question 2: How much pain do you have during to within fifteen minutes after participation in your chosen activity?

No Pain |_____| Extreme Pain

Section B: The following questions concern your physical function. By this we mean your ability to move around and to look after yourself

Question 3: What degree of difficulty do you have within fifteen minutes before participation in your chosen activity?

No Difficulty |_____| Extreme Difficulty

Question 4: What degree of difficulty do you have during to within fifteen minutes after participation in your chosen activity?

No Difficulty |_____| Extreme Difficulty

Subject ID# _____ Date of Record:_____

Section C: The following questions concern the amount of joint stiffness (not pain) you have experienced. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints. (Please mark your answers with an "X")

Question 5 (a): How severe is your stiffness within fifteen minutes after you get out of bed on the day of participation in your chosen activity?

No Stiffness |_____| Extreme Stiffness

Question 5 (b): While standing, what time to the closest hour does your lower leg indicate when you bend at the knee within fifteen minutes after you get out of bed on the day of participation in your chosen activity? Please circle your answer

6pm 7pm 8pm 9pm 10pm 11pm 12am

Question 6 (a): How severe is your stiffness during to within fifteen minutes after you get out of bed on the day after participation in you chosen activity?

No Stiffness |_____| Extreme Stiffness

Question 6 (b): While standing, what time to the closest hour does your lower leg indicate when you bend at the knee within fifteen minutes after you get out of bed on the day after participation in your chosen activity? Please circle your answer.

6pm 7pm 8pm 9pm 10pm 11pm 12am