THE EFFECT OF FUNCTIONAL KNEE BRACING ON MEDIAL COMPARTMENT OSTEOARTHRITIS

by

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ABSTRACT

The purpose of this study was to examine the clinical effects of the Patient-Ready Monarch Knee Brace (Smith and Nephew - Donjoy) in patients with medial osteoarthritis (OA) of the knee. Using a repeated measures cross over study design, ten subjects, eight male and two female, (mean values: age = 51.3 $\pm$ 8.63; weight = 185.2 $\pm$ 22.9 lbs., height = 69.5 $\pm$ 3.7 cm.) participated in the study. Subjects wore the knee brace for six weeks in each a neutral and valgus orientation with a three-week washout between trials. Clinical measurements included four functional tasks: timed figure-8-run, timed 6-stair climb, incline squat, single leg hop. Each task was measured every three weeks. In addition, subjects completed the Western Ontario McMaster University (WOMAC) osteoarthritis index daily during the fifteen weeks. The WOMAC index is an OA specific quality of life questionnaire consisting of three subscales (pain, stiffness, and physical function). Statistical significance was set a priori at $p< 0.05$. Repeated measures Analysis of Variance (ANOVA) of the figure-8-run, incline squat, and single leg hop functional tasks, measured at testing session 1,3 and 6, indicated no significant difference between the no brace, neutral and valgus brace conditions ($p>0.05$). There was a significant improvement in the time to stair climb when subjects wore a brace compared to no brace (p=. 01); however, there was no difference between valgus and neutral brace conditions (p=.21). The three subscales of the WOMAC index were analyzed separately using repeated measures ANOVA. Results indicate that the perception of pain and stiffness did not significantly change between brace conditions (p=. 43 and p=. 16 respectively). There was a significant difference between conditions found in the physical function subscale (p=. 02). Post hoc analysis indicated that subjects perceived their physical function improved when wearing a brace compared to not wearing a brace. *Conclusion:* Patients who have medial knee OA may perceive a significant improvement in performing physical tasks while wearing a knee brace. Moreover, they are able to ascend and descend stairs quicker while wearing a brace. Results must be interpreted with caution due to the small sample size used in this study.

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CHAPTER 1: Introduction

Osteoarthritis (OA), the most common chronic joint condition in the elderly, is a degenerative disorder of synovial joints characterized by focal loss of articular cartilage with reactive changes in subchondral and marginal bone, synovium and para-articular structures (Rottensten, 1996). It is second only to cardiovascular disease as contributing to overall disability among adults (Michet, 1993). The Arthritis Society of Canada estimated in 1994 that 2,930,000, or one in ten, Canadians were affected by osteoarthritis. Moreover, the knee is the most often involved weight-bearing joint afflicted with OA. It is not a systemic disease; it is a degenerative process that is localized to the articular cartilage, subchondral bone and marginal bone around a diarthroidal joint (Martin, 1994). The joint deterioration begins with fraying of the articular cartilage surface. This leads to pitting of the cartilage surfaces, hypertonic changes in the joint margins of the bone and reactive changes in the subchondral bone. The endstage of this disease is characterized by joint space narrowing, total destruction of articular cartilage leaving the eburnated subchondral bone exposed as the articulating surface and spur formation in the joint margins. Consequently, the joint capsule becomes scarred and fibrotic (Martin, 1994).

There have been two hypotheses proposed with respect to the cause of OA. 1) normal forces acting on abnormal cartilage with an inadequate healing response 2) excessive forces acting on normal cartilage (Martin, 1994; Michet, 1993). It is unknown whether it is the abnormal stress or abnormal cartilage that starts the OA process, but the biochemical changes that occur early in the condition lead to continued degradation of the cartilage and advancement of the disease.

A number of treatment options are available for patients with OA, however, many focus on the symptoms of the disease, and not the possible causes (e.g. abnormal force loading). Late stage intervention of OA usually involves surgery, in the form of wedge removal or knee replacement. To postpone this invasive intervention, treatment strategies designed for the early stages may be of benefit. Specifically, treatment designed to address the abnormal loading, such as functional varus/valgus knee bracing has been suggested. The theory behind OA knee bracing is the production of opposing forces on the segments of the involved limb. For example, in medial OA, the patient's lower limb develops a varus alignment, and the brace attempts to correct this with a valgus force to unload the medial side of the knee.

1.1 Statement of the Problem

The purpose of this study was to examine the clinical effects of valgus bracing in subjects with knee osteoarthritis. This topic was selected because there is limited information in the literature with respect to OA and bracing. The literature focuses on the biomechanical analysis of valgus knee bracing (Davidson, 1994; Greenwald, 1997; Pollo, 1995, 1997). Recently, there have been a few studies examining specific knee braces – specifically the Generation II Unloader knee brace (Horlick *et al.*, 1993;

Marsuno *et al.*, 1997, Kirkley *et al.*, 1999). Patients are interested in the role bracing can have on their level of pain and improvements in their knee function during daily activities. They are willing to try non-invasive measures to prolong the possibility of surgery. Showing that valgus knee bracing, specifically the Patient Ready Monarch knee brace, has a positive effect on both pain and function, will provide growing support that OA bracing is an effective non-surgical alternative to managing knee OA.

1.2 Hypotheses

This study will test five hypotheses:

(1) Valgus knee bracing will significantly decrease the perception of pain/stiffness and improve physical function when compared to the no-brace and neutral conditions.

(2) Wearing the valgus knee brace, will result in a significant increase in the distance hopped (and hop index) when compared to the no-brace and neutral conditions.

(3) The time to ascend/descend a set of stairs will significantly decrease while wearing the valgus knee brace when compared to the no-brace and neutral conditions.

(4) The number of incline squats performed will significantly increase while wearing the valgus knee brace when compared to the no-brace and neutral condition.

(5) The time to complete a figure-8-run will significantly decrease while wearing the valgus knee brace compared to the no-brace and neutral condition.

1.3 Limitations

A major limitation of this study is patient compliance. Wearing this brace everyday and keeping a daily record of pain and comfort relies on the dedication and support to the project on the part of the subject. As an investigator, it is important to continually encourage and stress the importance of reliable and accurate record keeping to the subjects.

Another limitation is the accuracy of collecting the data. All functional tests were measured manually which may have increased the risk for human error. For example, times to complete the stair climb and figure-8-run were measured using a manual stopwatch accurate to a 10^{th} of a second. Any factors changing the timer's focus or reaction time may have altered the accuracy of the results.

A further limitation questions whether the selected functional tests accurately reflect the functional limitations experienced by subjects with OA. This study used innovative functional tests specific to middle aged subjects with mild to moderate levels of OA. There is limited data on the reliability and validity of the selected functional tests on this population.

Finally, there is concern regarding the length of the washout period. The researcher assumed three weeks was the minimum time required for the effects of the previous brace condition to return to baseline levels. Extending the washout period any longer would have increased the study's duration. This would have further compromised patient recruitment and compliance.

CHAPTER 2: Methods

2.1 Study Protocol

A randomized, single blind, crossover design was used for this study. Subjects reported to six testing sessions, and kept a daily record of their pain and ability to function while wearing the Patient-Ready Monarch Knee Brace (Smith & Nephew - Donjoy, Carlsbad CA, U.S.A.). Each subject wore the brace for a total of twelve weeks; six weeks in each condition interrupted by a three-week washout period between each brace protocol. Specific instructions regarding the application of the brace were given to each subject; however, they were not given specifics of each brace condition. This experiment received prior approval from the University of British Columbia Committee on Human Experimentation. Written informed consent was obtained from all subjects before participating.

Table 1. Study Design Timetable

WEEKS

	0 1 2 3 4 5 6	6 7 8 9	9 10 11 12 13 14 15
GROUP 1	Condition A	W A S H	Condition B
GROUP 2	Condition B	O U T	Condition A

T_1 (week 0) T_2 (week 3) T_3 (week 6) T_4 (week 9) T_5 (week 12) T_6 (week 15)

(T = testing session)

During the first session, subjects were randomly assigned to one of the conditions (neutral vs. valgus bracing). At this time, baseline data (height, weight, age) were recorded and each subject completed a general information questionnaire on his/her condition. During this first testing session (and the 4th session), subjects performed the functional tests twice – first, in a no-brace condition and second, in the selected brace condition. In the remaining testing sessions (3, 6, 12, and 15 weeks), the subjects went through the same functional knee testing once while wearing the selected brace. Prior to starting each testing session, subjects were encouraged to warm up and stretch to prevent injury. Each testing session took approximately 30 - 60 minutes. Subjects were contacted by telephone during the first week; this was done to ensure that they were comfortable with the brace and were having no problems completing the daily questionnaire.

2.2 The Knee Brace

Subjects wore the Patient-Ready Monarch Knee Brace (Smith and Nephew-Donjoy, Carlsbad, CA, U.S.A.). This brace is an off-the-shelf pneumatic brace that applies counter pressure to the side of the knee. It redistributes the forces acting on the joint, thereby, reducing friction and pain in the knee. It is designed with two flexible cuffs (thigh and calf) within a rigid aluminum frame to allow for a better fit to the leg. Two varus/valgus hinges located above and below the knee flexion/extension hinge allow for the brace to be adjusted to fit the contour of each patient's leg. An inflatable pneumatic pad placed at the knee joint line enables the patient to customize the pain-relieving force by adjusting the amount of air pumped in. It is designed along a 3-point principle theory of a bow and arrow - when the bow is pulled back into cocking phase it generates energy and force in the opposite direction. The Monarch acts as a bow on the leg to counteract internal pressure (Smith & Nephew-Donjoy Monarch Promotional Brochure, 1996).

For this study, subjects wore the brace under two conditions. In condition A subjects wore the brace in a neutral orientation. This was achieved by adjusting the varus/valgus hinges into a neutral position and substituting a non-inflatable condyle pad in its place. In condition B, the subject wore the brace as it was designed. A valgus force was applied to the knee by way of the pneumatic airbag and minor adjustment of the varus/valgus hinges. Upon application of the brace, subjects were required to maximally inflate the airbladder with the air pump (approx. three pumps). The brace is designed to allow the patient to adjust the amount of air depending on their symptoms. However, for the purpose of keeping continuity, the subjects in this study were asked not to vary the amount of air in the bladder. To monitor each subject's exposure to the brace, he/she was asked to record time spent wearing the brace each day. They were instructed to wear the brace for a minimum of six hours/day; however, they were encouraged to wear the brace as long as possible during the day.

2.3 Subjects

Eleven subjects (9 male and 2 female) were recruited from local physicians for this study. Subjects were between the ages of 35 and 62 years, were generally healthy with mild-moderate OA and were participating in some type of recreational activity (i.e. walking, jogging, golf, roller blading, etc.). All subjects were physician diagnosed with unicompartmental medial osteoarthritis of the knee. They had a history of medial joint line pain and radiographic changes (within the last three months) showing medial compartment narrowing. Subjects were excluded from the study if they displayed any of the criteria outlined in Table 2. All subjects were asked to refrain from participating in any other treatment protocols for the duration of the study and must not have participated in any treatments at least three weeks prior to the start of this study. In addition, subjects were asked to maintain their current level of activity throughout the study period.

Table 2. Subject Exclusion Criteria

Subjects did not display any of the following:
• previous hip/knee replacement or ligament repair surgery (previous history of menisectomy or debridement okay) • any ligamentous instability of either knee • any other type of arthritis • leg length discrepancy greater that 2.0 cm • any medical condition preventing subject from performing a single leg hop, knee squats, stair climb, or figure-8 run • large varus/valgus deformity greater than 10 degrees • any condition preventing application of brace • receiving other treatments for OA (i.e. medication, over-the-counter products (e.g. Glucosamine Sulfate, aspirin, ibuprofen etc.), viscosupplementation (e.g. Synvisc, Suplasyn), physical therapy, an exercise program, or foot orthotic devices)

2.4 Functional Tasks

Subjects performed four functional tasks: the stair climb, the figure-8-run, the incline squat, and the single leg hop (for distance). The order of completing each task was randomized during each session to prevent an order bias.

Stair Climb

The stair climb required each subject to ascend and descend a set of stairs equipped with a handrail. The stair climb consisted of six steps each with a rise of 17.8 cm and a run of 27.9 cm. There was a platform at the top allowing subjects to turn around and descend the same set of stairs. Both feet were placed on the top platform before descending. Subjects began the task by standing on a line 30.5 cm from the first step with their hand on the handrail. On the command "get set…go," subjects began climbing the stairs and were timed using a stopwatch accurate to a 10^{th} of a second. Once the subject's toe crossed the line where they first started, the time (seconds) was recorded. To keep continuity between subjects, they were reminded to only climb one step at a time and to keep his/her hand in contact with the rail at all times during the ascent and descent. Practice trials were given in order to make sure the task was understood.

Figure - 8 - Run

The figure-8-run required subjects to complete one lap of the course as quick as possible. The figure-8-running course was 20 meters long with the diameter of each curve measuring 4 meters wide. Six orange cones were placed along the circumference of each curve to eliminate subjects from trying to execute shorter/tighter turns. The starting point was located 2 meters from the beginning of the straightaway. Time was measured, with a stopwatch, for each subject to complete one clockwise lap of the circuit. Subjects were given a practice trial on the circuit prior to the test.

Incline Squat

Subjects performed an assisted squat with the use of an incline-sliding bench (Total Gym, San Deigo, California). The bench consisted of a mobile body board that displaced on a track. Varying the angle of the sliding board could modify the level of resistance. The test was performed at 37.8 degrees above the horizontal. This allowed the researcher to regulate the subject's body weight - approximately 67% of the subject's freestanding weight.

Initially, goniometric measurements were taken during a single squat to 90 degrees of knee flexion. This allowed the distance limiter to be adjusted so subjects would not be able to go beyond 90 degrees during the test. To maintain position consistency, the subject's foot placement was marked on a piece of poster board secured to the foot platform. The same poster board was used for each session.

Subjects were given the opportunity to practice double leg squats to become familiar with the exercise. The testing protocol consisted of each subject completing as many knee squats as he/she could on one leg during 20 seconds. The test was performed on the non-involved leg first followed by the involved leg.

Single Leg Hop

The single-leg hop test required each subject to jump off one leg and to land on that same leg, without losing balance. Subjects were positioned with their toe behind the tape marker. The opposite leg was positioned with the knee-flexed 90 degrees and their thigh parallel to the weight-bearing leg. Their hands were placed on their hips.

A single maximal hop was executed without swinging the suspended leg or removing the hands from the hips. This eliminated movement strategies involving leg and arm swing. Subjects were encouraged to achieve a maximal horizontal distance and to land on the same foot without simultaneously touching the opposite foot down. However, once the landing foot was firmly on the ground, subjects were allowed to extend the opposite leg to avoid falling. Any jump in which the subject lost balance, or landed with two feet was discarded and the subject repeated that jump.

Each subject was given the opportunity to practice until comfortable. The testing protocol consisted of three recorded jumps on each leg starting with the non-involved leg. Subjects were allowed to rest between jumps and continued when ready. The distance hopped (centimeters) calculated from the toe marker to the heel placement was measured using a tape measure firmly secured to the floor. The subject was not informed of his/her distance, but was encouraged to jump as far as possible.

The mean distance of the three hops and a hop index value was calculated. The hop index is a generalized measurement that expresses performance of one leg relative to that on the other leg. It is not affected by differences in gender and data analysis. A value of 100 indicates that both legs are equal. The hop index is calculated as follows:

$$\frac{\text{Distance hopped involved leg}}{\text{Distance hopped non-involved leg}} \quad X\ 100$$

2.5 Western Ontario & McMaster (WOMAC) Pain Questionnaire

The WOMAC osteoarthritis index is a multidimensional self-administered instrument designed for people who have knee or hip osteoarthritis. This measure has been proven reliable (r=. 73 -. 96), valid and sufficiently sensitive to detect clinically important change (Sun *et al.*, 1997; Bellamy *et al.*, 1988; Bellamy, 1996; Bellamy *et al.*, 1992). The questionnaire is separated into three sections: pain (5 questions), stiffness (2 questions) and physical function (17 questions). Subjects were asked to complete the WOMAC osteoarthritis index (Appendix C) each day for the duration of the study. The visual analog scale (VAS) version was chosen for this study because it is slightly more responsive than the Likert scale (Bellamy, 1989). This VAS is a 100-millimeter horizontal line with the words "No Pain/Stiffness/Difficulty" on the left side and "Extreme Pain/Stiffness/Difficulty" on the right side for each respective question. Subjects were asked to place an "X" along the line that best represented the answer to each of the 24 questions. To maintain consistency, subjects were asked to complete this index each day at the same time - preferably at the end of the day. Subjects were also asked to refrain from looking at the previous day's score to prevent any potential bias from one day to the next. To analyze the data, the distance the "X" was located from the left end of the line was measured in millimeters.

2.6 Statistical Analysis

The functional tasks were all analyzed using repeated measures analysis of variance (ANOVA). Within group analysis for the WOMAC data was also analysed by repeated measures ANOVA. Post-hoc comparisons using Fisher's Least Significant Difference (LSD) procedure were used to determine individual differences between brace/no brace conditions. The level of significance (α) was set at $p<0.05$ for all comparisons. RM ANOVAs were performed using Statview statistical package - version 5.01 (1998).

CHAPTER 3: Results

3.1 *Descriptive Data*

Eleven subjects entered the study between June 1998 and January 1999. One subject dropped out because he was unable to tolerate the valgus brace. The researcher and subject both felt that there were other medical conditions present in his knee, in addition to osteoarthritis, affecting his tolerance. Therefore, ten subjects completed the study. The baseline height, weight and age are summarized in Table 3.

Table 3. Physical Characteristics of Subjects

	AGE (years)	HEIGHT (cm)	WEIGHT (kg.)
Male (n=8)			
Mean	52.25	170.44	87.16
SD	9.21	7.54	8.70
Female (n=2)			
Mean	47.50	165.50	72.27
SD	6.36	4.77	9.64

3.2 *Compliance*

The subjects' compliance wearing the knee brace in both conditions was excellent. Subjects wore the neutral brace on average 11.2 ± 2.8 hours per day and wore the valgus brace on average 10.8 ± 3.2 hours per day. Inspection of the data reveals that the brace condition selected first was usually worn for the longer period, regardless if it was the neutral or valgus alignment. This could be attributed to the early motivation and interest in participating in a study.

3.3 Testing Timeline

Subjects attended testing sessions according to the schedule outlined in Table 1 (page 6). In most cases, the timeline of 42 days in each of the brace conditions and 21 days in the washout period was adhered to (Table 4). The small variability in the numbers occurred for two reasons; first, to prevent scheduling the testing sessions on a weekend and second, to fit in with the subjects personal schedule.

Subject 5 had a two-week delay from testing session 1 until the start the study because of a blistering reaction to the felt liners on the brace. Once the blisters resolved, the felt liners were changed to a non-allergenic brand and the subject was able to re-start the study.

Table 4. Testing Timeline

	Valgus Brace	Washout	Neutral Brace
Mean (days)	42.8	22.2	42.7
S.D.	2.6	3.7	2.2

3.4 Functional tasks

The data was first analyzed for evidence of a carryover effect. This was performed by comparing the pre-brace data with day 19 of the washout data. A significant ($p<.05$) between the two values would indicate a possible carryover effect. Comparison of the pre-brace with the post-washout data using a repeated measures ANOVA revealed no evidence of a carryover effect in the stair climbing, single leg hop or figure-8-run functional tasks ($p>.05$). This suggests that it doesn't matter which brace condition the subject receives first, as it will not affect the following condition. However, analysis of the incline squat data indicated evidence of a carryover ($p<.05$). Plotting the data revealed that it was the valgus brace carrying over into the neutral brace condition. This suggests that the neutral brace data may have been skewed by the valgus brace in those subjects starting with the valgus brace first. It is also possible that the significant difference could be attributed to a learning effect by the subjects from the pre-brace to washout period. The p-values are outlined in Table 5.

Table 5. Carry-over Effect Analysis

	Stair climb	Figure-8-run	Incline Squat	Single leg hop
p-value	.783	.768	.011	.901
F (1,8)	4.07	.093	10.96	.017*

p=0.5
*F (1,7) = single leg hop because one subject had incomplete data

The functional task data were each analyzed using a repeated measure ANOVA. The final testing session data (session 3 and 6) of the two brace conditions were used for the comparison. It was assumed that both these testing sessions were a good reflection of the data. The no-brace condition was calculated as an average between the pre-brace and post washout periods. The mean data is summarized in Table 6. The results indicate that there was a significant treatment effect between brace conditions in the stair climbing ($p < .05$). However, there was not a significant difference between conditions in either the figure-8-run, incline squat, or single leg hop.

Table 6. Functional test data.

Condition	Stair climb (seconds)	Figure-8-run (seconds)	Incline Squat (number)	Single leg hop (index %)
No Brace				
Mean	4.41	10.98	14.13	80.50
S.D.	0.81	1.76	5.17	8.30
Neutral Brace				
Mean	3.92	10.80	19.30	80.92
S.D.	0.72	1.61	3.89	11.80
Valgus Brace				
Mean	4.10	11.00	18.70	80.71
S.D.	0.76	1.39	2.11	9.55

Stair climb

There was a statistical difference in the time to complete the stair climbing protocol between brace conditions ($F[2,9] = .62$; $p=.006$). A post hoc analysis, using

Fishers LSD, revealed that subjects wearing the valgus brace and the neutral brace demonstrated a significant improvement in the time to ascend/descend the set of stairs compared to the no brace (p<. 05). There was no significant difference found between the valgus and neutral conditions. Figure 1 graphically shows the means and the raw data is summarized in Table 14 (Appendix B).

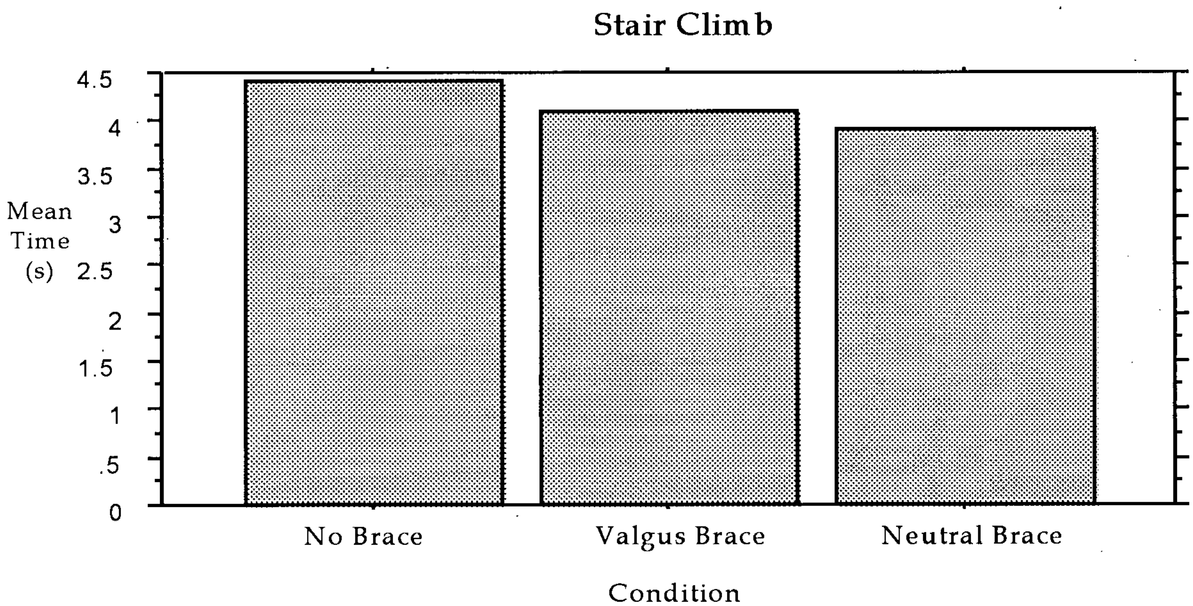

Figure 1. Comparison of the means for ascending/descending stairs.

Figure-8-run

There was no significant difference between brace conditions for the figure-8-run (F[2,9] = .49; p=. 624). A small non-significant improvement in time was noted between no brace and the first brace condition. This can be attributed to a learning effect by the subjects. More practice time would have eliminated this result. Figure 2 graphically plots the means and Table 13 (Appendix B) summarizes the individual raw data.

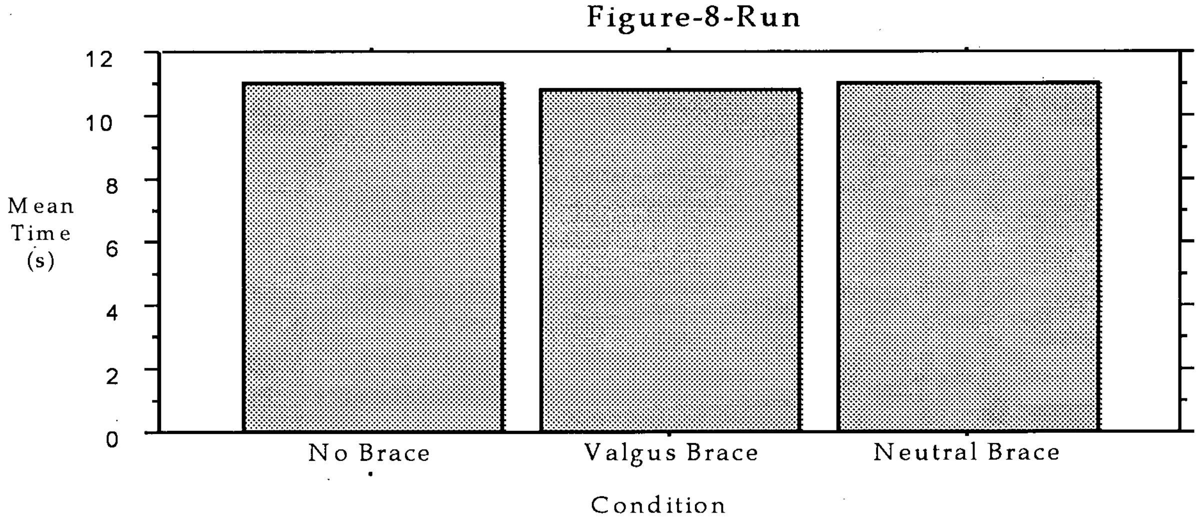

Figure 2. Comparison of the means for the figure-8-run.

Incline Squat

There was no evidence that wearing a brace improves the ability to perform incline squats. No significant difference was found between brace conditions (p>. 05). Results from this functional task must be interpreted with caution because of the evidence of a carryover effect from the valgus into the neutral condition. Figure 3 graphically depicts the mean group values for each condition while Table 15 (Appendix B) summarizes individual raw data.

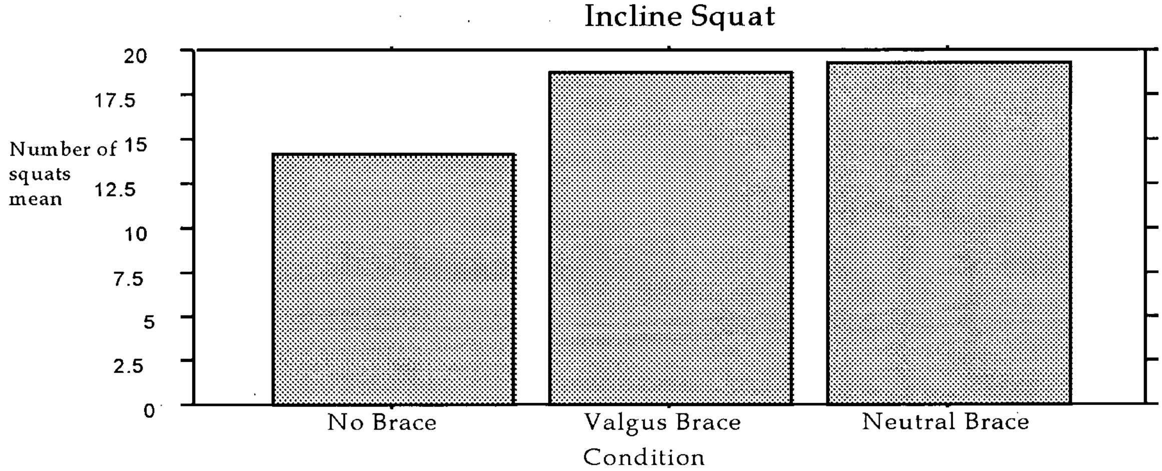

Figure 3. Comparison of the means for the incline squat.

Single Leg Hop

There was no statistical difference between brace conditions in the distance hopped (F[2,8] = .02; p= .98). Figure 4 shows single leg hop indexes mean data. Subject 10's data was excluded from analysis because it was incomplete. Therefore, the sample size for each group was unequal. Individual data can be reviewed in Table 16 (Appendix B).

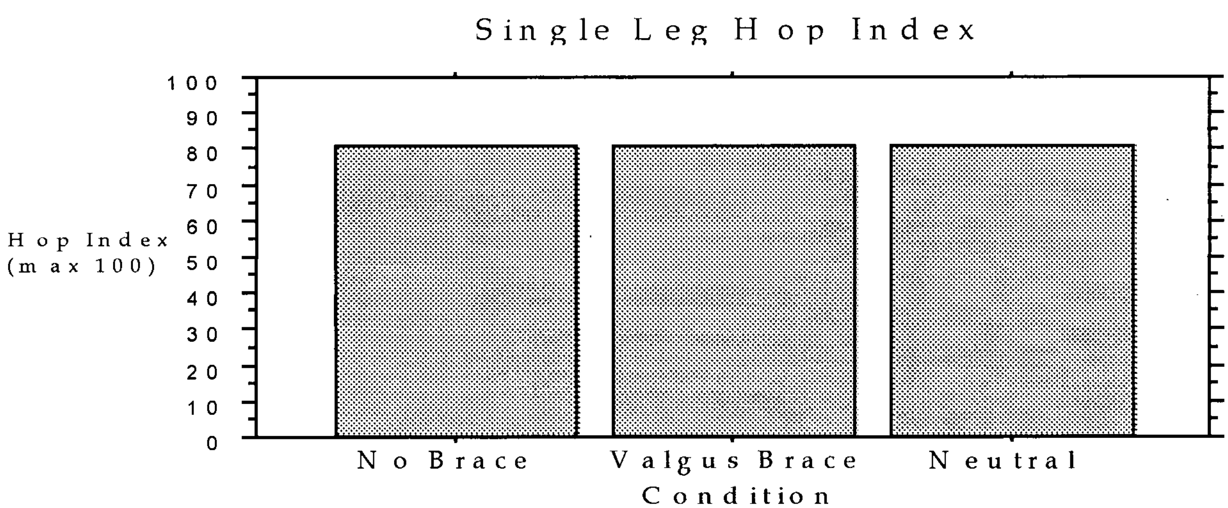

Figure 4. Comparison of the means for the single leg hop index.

3.5 WOMAC data

The WOMAC index data was analyzed using a repeated measures ANOVA The WOMAC data was analyzed for each of the subscales: 1. Pain 2. Stiffness 3. Physical function. The no brace condition data was calculated as the average between the pre brace and day 19 of the washout period. Data averaged from day 39 and 40 of each the valgus and neutral data were compared with the no brace condition. These days were selected because they were the last two days that all subjects had data. This sampling was performed because of the variable time spent in each condition and it allowed for an equal comparison. Specifically, the pre- brace condition consisted only of one session and the washout only 21 days. Ideally, the no brace period should have been consistent with the time spent in the bracing periods, however, due to time constraints this was not possible. This variability in the days can affect the overall power of the study.

Some subjects failed to complete all questions on the WOMAC questionnaire. The primary reason being the particular question did not apply to them on that day. For example, subjects usually omitted the physical function question "Getting in/out of the bath" because they used showers. Following the WOMAC user's guide (Bellamy, 1996), missing data was scored as follows: (1) If the subject failed to complete $\geq$ two pain/stiffness, or $\geq$ four physical function questions, the subject's response was regarded as invalid and the subscale omitted for that day. (2) If subjects missed less than the above criteria, the average value for that subscale was substituted in lieu of the missing question.

Pain

The subject's perception of pain did not significantly change between brace conditions ($F[2, 9]=.892$; $p=.427$). However, visual inspection of the data reveals a small non-significant trend that the subjects' pain perception decreased while wearing a brace (Table 7).

Table 7. Mean data for pain subscale

	No Brace	Neutral Brace	Valgus Brace
Mean	121.64	92.68	86.84
S.D.	56.15	125.11	44.69

There was no significant visual difference between the valgus and neutral brace conditions. See Figure 5 for the graph of the valgus and neutral brace means.

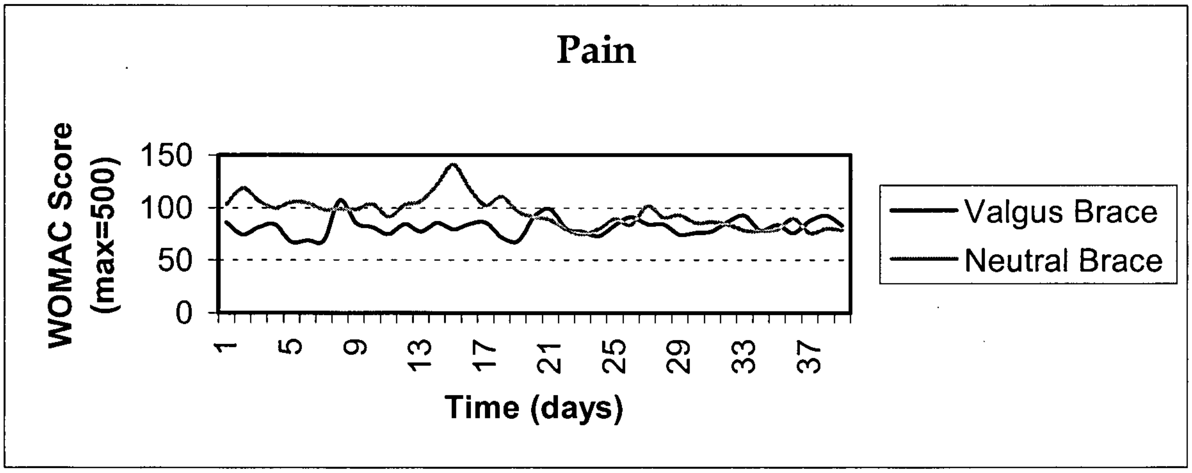

Figure 5. Plotting of the valgus and neutral brace means for pain subscale

Stiffness

Analysis of the stiffness subscale of the WOMAC index indicates no change in stiffness between brace conditions ($F[2,9]=2.06$, $p=.157$). Again, a small non-significant trend is visually observed indicating that the subjects' perception of stiffness decreased while wearing a brace.

Table 8. Mean data for stiffness subscale

	No Brace	Neutral Brace	Valgus Brace
Mean	61.93	40.27	43.82
S.D.	33.40	47.06	34.26

There was no significant visual difference between the valgus and neutral brace conditions. See Figure 6 for the graph of the valgus and neutral brace means.

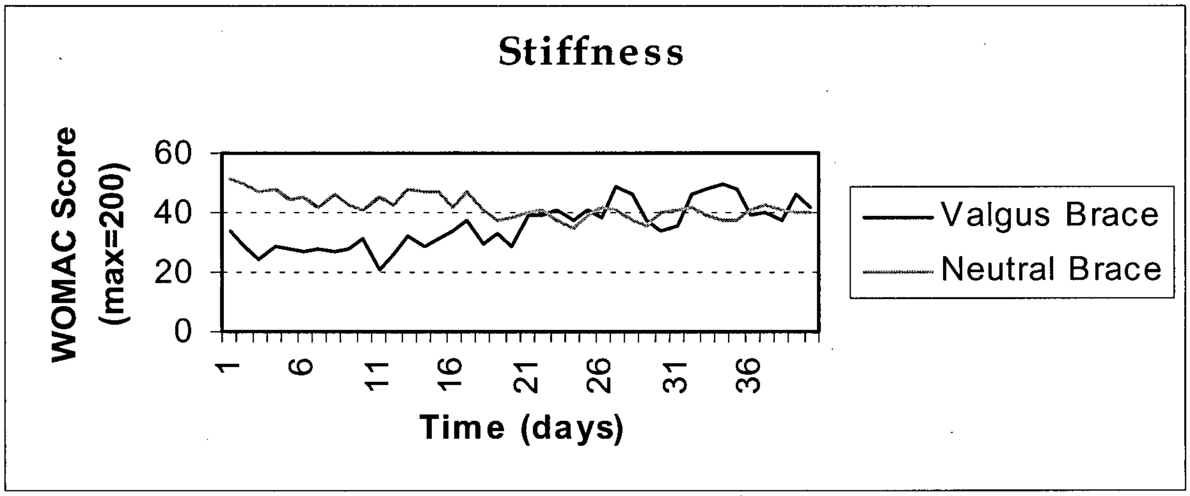

Figure 6. Plotting of the means for stiffness subscale

Physical Function

There was a significant difference between conditions in the physical function subscale ($F[2,9]=5.18$, p=. 017). A post hoc analysis, using Fishers LSD, indicates a significant improvement in the subjects' perceived physical function while wearing a brace compared to not wearing a brace (valgus: p=. 016; neutral: p=. 009). The means are outlined in Table 9.

Table 9. Mean data for physical function subscale

	No Brace	Neutral Brace	Valgus Brace
Mean	432.11	260.27	275.93
S.D.	203.55	255.96	133.27

There was no significant visual difference between the valgus and neutral brace conditions. See Figure 7 for the graph of the valgus and neutral brace means.

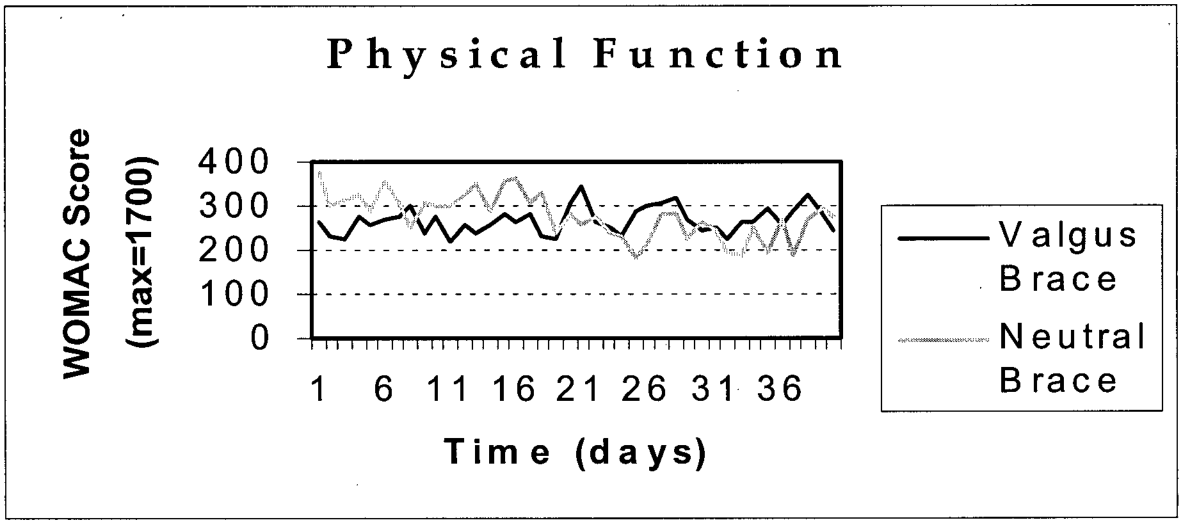

Figure 7. Plotting of the means for physical function subscale

CHAPTER 4: Discussion

Once knee osteoarthritis has progressed to the point of severe articular cartilage loss with subchondral involvement, total knee replacement is usually indicated. There are two foreseeable problems with this outcome; the health care costs associated with this type of surgery, and the increasing trend that osteoarthritis is affecting a younger age group (e.g. less than 50 years of age). For this population, total knee replacement is not recommended because the prosthesis may be subjected to greater activity demands and therefore it will likely not last the patient's expected life span. The premise behind bracing an OA knee is that it mechanically unloads the arthritic compartment to slow down further progression of the disease and provide pain relief. The current study attempted to prove that knee bracing could be a favourable treatment option for this active population.

A repeated measures crossover design was chosen for this investigation as this allows subjects to be their own controls and this helps to eliminate the inter-subject differences seen in parallel designs. This design is well suited to investigate treatments for chronic disease, as the underlying problem causing the disease can not be cured. Therefore, the effects of a treatment can be measured. However, a critical component of this design is the assumption that there is no carryover effect between the two conditions. Incorporating a washout period between treatment conditions usually eliminates this carryover effect. The crossover design has the added benefit of being cost and time effective because fewer subjects are required.

Limitations include a higher rate of dropout because of the length of the study and the possibility of a carryover effect influencing results.

Horlick and Loomer (1993), in an early clinical study on valgus bracing for knee OA, used a crossover study design. In their study, subjects were randomly assigned to different sequences of no brace, valgus brace and neutral brace conditions. Two more recent studies (Matsuno *et al.*, 1997; Kirkley *et al.*, 1999) used a prospective case series and a parallel group randomized clinical trial design. Kirkley *et al.* (1999) indicated that Horlick and Loomer's (1993) study design was inappropriate because the crossover design did not allow subject blinding and they believed an unknown carryover effect may have occurred. The possibility of a carryover effect is apparent, considering Horlick and Loomer (1993) neglected to insert a washout period between trials in their study. In this study, we corrected for both of Kirkley *et al.*'s concerns. A 3-week washout period was inserted between brace trials, and subjects were blinded as to the brace condition. The subjects were unfamiliar with the brace design and were informed that it was unknown which condition would be useful in the treatment of OA. It would have been advantageous to have the researchers also blinded however, it was impossible because of familiarity with the brace. In addition, statistical analysis of the data revealed that other than the incline squat, there was no carryover effect between brace conditions (see Table 5).

4.1 Functional Tasks

Stair Climbing

There was a significant improvement in the time to stair climb when wearing a brace versus not wearing a brace. However, no statistical difference ($p > .05$) was observed between the neutral and valgus brace conditions. Marks (1995) and Rejeski *et al.* (1995) both demonstrated very good reliability and validity for a timed stair climbing protocol. Marks (1995) calculated the reliability, using intraclass correlation coefficients, in knee OA patients for climbing 4 stairs to be $R = .82$. While Rejeski et al (1995) further substantiated this result in knee OA subjects with a 2-week reliability $R = .93$ and a 3-month reliability $R = .75$ for a 5 stair protocol. In addition, they found that stair climbing as an outcome measure has both concurrent and convergent validity. In this study, a 6-stair protocol was used because it was the closest available that corresponded to the literature. The investigator assumed that 6-stair protocol used in this study would have similar validity and reliability results to the protocols used in the literature.

It is very difficult to compare this study's results with the literature because there is so much variability with stair climbing protocols (Kirkley *et al.*, 1999; Rejeski *et al.*, 1995; Matsuno *et al.*, 1997; Marks, 1995; Lankhorst *et al.*, 1982). This variability is due, in part, because there is not one set protocol for using stair climbing as an outcome measure. One study used a knee scoring system to evaluate stair climbing and found significance with 12 OA subjects (Matsuno *et al.*, 1997). Others calculated the number of stairs climbed in a specified time frame and did not find significance with 119 OA subjects (Kirkley *et al.*, 1999).

As stated earlier, Marks (1995) used a 4-stair protocol. Although he used two less stairs than this study, the rise and run were similar. His results indicated the time to complete the task was almost twice as along as this study. This could be contributed to two factors: 1) the mean subject age (x=64.17) in his study being approximately 12 years older and 2) their condition had progressed further. Interestingly, Marks calculated a minimum change of 2.90 s was required to demonstrate a clinically significant change in 48 subjects. Although our study had a much smaller sample size, none of the subjects demonstrated more than a 2.34 s change between conditions.

Lankhorst *et al.*, (1982) measured the time required to climb eight stairs in knee OA subjects. He reported mean values of 9.1 s pre-treatment and 6.5 s post treatment. He also determined normative values for the 8-stair climb as 3.0 ±1 s Unfortunately, Lankhorst *et al.* did not indicate the mean age of their subjects, and did not specify the stair measurements to allow a thorough comparison. However, based on their limited findings and corrected for differences in stair number, this study's values are comparable. Projected values for 8-stairs would be 5.83 s pre treatment and 5.46 s with brace which is slightly faster than Lankhorst *et al's* post treatment results and slower than the expected normal values.

It is unclear why, but people with knee OA have an impaired ability to negotiate stairs (Marks, 1994,). There has been controversy as to possible reasons for this impaired ability. Andriacchi *et al.* (1982) hypothesized that at the critical angle of knee flexion during stair climbing, there is a reduction in the mechanical efficiency of the knee extensors in persons with knee OA. While Lankhorst *et al.* (1982) found no correlation between the knee extensors and stair walking time in patients with knee joint disease.

Recently, Marks (1994) found a positive correlation between pain and position sense with respect to standing and stair walking time. His results support Hurley and Newham's (1993) findings that pain and effusion associated with knee OA cause a loss or change in proprioception. Mark's results further support a study by Stauffer *et al.* (1977) who concluded that pain and impaired proprioception may cause a decrease in the functional demand on the OA knee during weight bearing therefore decreasing stair walking velocity. Research also indicates that slower stair walking speed might be the result of a wider based gait to compensate for the loss of proprioceptive feedback from the OA diseased joint. Moreover, slower velocity of stair climbing may be partly attributed to static weakness of the surrounding quadriceps muscles (Marks, 1994; Lankhorst *et al.*, 1985; Stauffer *et al.*, 1977).

Figure-8-Run

There was no difference found between brace conditions when compared against each other or the no brace condition in the figure –8- run outcome measure. The figure-8-run has been used extensively in the ACL deficient literature (Tegner *et al.,* 1986; Fonseca *et al.*, 1992). Mean values reported in the literature for uninjured subjects (younger than in this study) were 8.61 ± 0.58 s by Fonseca *et al.* (1992) and 11.99 s (for 2 laps) by Tegner *et al.* (1986). The only data available for an injured population was subjects with ACL-deficient knees. Their reported mean was 8.93 ± 0.57 s (Fonseca *et al.*, 1992). This functional task was the only test performed outside and factors such as weather and time of day may have played a factor in the results. Both are factors difficult to control for as the testing facility did not have an indoor space large enough to accommodate the circuit.

Concerns have been raised in the literature whether open kinetic chain tests, such as isolated muscle testing, are appropriate to determine an injured knee/leg's functional ability. Specifically, studies have shown that open chain testing may not be sensitive enough to correlate with closed chain activities such as walking, running etc. (Munich *et al.*, 1997; Tegner *et al.*, 1986). For example, a subject's performance in open chain muscle testing may be excellent, but his/her performance may be poor in functional everyday closed chain tasks. By relying on interpreting open chain test results there may be an inaccurate confidence in the subject's ability to function in everyday activities.

Incline Squat

The incline squat functional test provides an excellent estimate of knee OA function. Important to its acceptance as an outcome measure for OA is that it is a closed kinetic chain test that correlates well with many tasks patients with knee OA find difficult to perform (e.g. stairs, bending down, sitting etc.). It is also unique in comparison to other closed chain tests for the knee (e.g. full knee squats and hopping) in that the subject is only partial weight bearing. This allows for safe and effective testing that might otherwise be too strenuous on this population.

Although no significance was found between brace conditions in this study ($p > .05$), subjects indicated that they found the task easier to complete using a brace. Compared to the normal population studied by Munich *et al.* (1997) this study's results, as expected, are lower. Caution must be used in interpreting these results for two reasons: 1) the incline squat test has not been proven reliable in an OA population and 2) the validity of this functional test has not been determined. Future research is needed in this area.

Single Leg Hop

This study did not find significance in the subjects' ability to improve their hop for distance in either brace condition. However, the results did demonstrate that subjects jumped less with their OA leg compared to their un-involved leg (mean hop index $= 83.3 \pm 9.4$). This difference may be attributed to OA subjects having unequal muscle strength between legs. Pincivero *et al.* (1997) concluded that concentric quadriceps and hamstring strength significantly contribute to the distance achieved in the single leg hop. They specifically found that hamstring muscles play a more important role during the propulsive phase, therefore enabling subjects to jump further. In patients with knee OA, muscle strength inequality has been demonstrated (Wessel, 1996). This inequality may be because these individuals favour their OA knee and are less likely to add extra stress to that side. Moreover, as the condition progresses, patients are less active and have developed compensatory actions with the non-involved leg to accomplish certain tasks. Therefore, the weakness seen in the OA leg, compounded by the subject's decreased confidence, adds up to an expected poorer result for the OA knee in the single leg hop.

There is a gap in the OA literature, using a single leg hop as an outcome measure. It is a measure more commonly used in anterior cruciate ligament (ACL) research (Kramer *et al.*, 1992; Fonseca *et al.*, 1992; Juris *et al.*, 1997; Daniel *et al.*, 1990; Tegner *et al.*, 1986). Investigators have used this measure in these studies as an indicator of leg confidence and function. In performing the single leg hop, the integrity of the joint capsule, intra-articular structures, the surrounding musculature is tested (Juris *et al.*, 1997). Juris *et al.* (1997) indicated that the single leg hop test is effective at examining the combination and interaction of motor skill and intrinsic joint stability because of its demands on motion control and force production/absorption. These are all-important variables important to also measure in subjects with knee OA. The absence of the use of this test in the OA literature may be due to the premise that the single leg hop is too "demanding" on the OA knee. This may be true if tested in subjects where OA has progressed to a point where activities of daily living are affected, but judging by the performance in this study, it is applicable in this population. As expected, the subjects were tentative when jumping without the brace yet many indicated that with application of the brace they had more confidence performing the task.

4.2 WOMAC Data

The WOMAC osteoarthritis index has the unique design in that it can be analyzed using two methods. Each subscale (1. pain 2. stiffness 3. physical function) can be analyzed separately or the three subscales can be aggregated together into a single score. For the purpose of this study, the former method was used.

Pain and Stiffness

There was no significant difference in the pain and stiffness subscales between brace conditions ($p>.05$). However, there was a slight non-significant trend indicating that wearing a brace improved the subjects' perception of pain and stiffness compared to the no brace condition. A larger sample size may have found significance in this instance.

Kirkley *et al.* (1999) estimated their sample size to be thirty-seven subjects in each group for their parallel design. They calculated this by using the standard deviation (91.06 millimeters) provided by Bellamy *et al.* (1992) for the change in pain score (baseline and post treatment). An alpha of 0.05 and a beta of 0.80 were used in the calculation. They indicated that with this sample size (37/group) a clinically important difference of 60 millimeters on the pain scale would be needed for significance.

Physical Function

There was a significant difference between brace conditions for the physical function subscale (p=. 02). Specifically, subjects' perceived that wearing a brace improved their ability to perform physical tasks better than not wearing a brace.

Kirkley *et al.* (1999) analyzed their WOMAC data using both a single aggregate score and individual subscales. The results of this study support their findings that the valgus and neutral brace improved physical function ability compared to the no brace (control) condition. Also similar was the lack of significance between the valgus and neutral (placebo) brace conditions in the stiffness and physical function subscale. For the pain and stiffness subscales, there was no significance between brace and no-brace conditions in this study. As stated earlier, this result may have been influenced by the small sample size. There was a strong trend in both subscales indicating that pain and stiffness improved while wearing a brace. Interestingly, although Kirkley *et al.* (1999) found significance in both these sections comparing no brace and bracing, they only found a significant difference between the unloader and placebo brace in the pain subscale.

A number of studies have looked at the relationship of knee OA and impaired proprioception (Sharma *et al.*, 1997; Sharma *et al.*, 1997; Hurley *et al.*, 1997; Marks, 1994). There is evidence showing proprioception is worse in subjects with knee OA compared to aged matched controls (Barrett *et al.*, 1991; Sharma *et al.*, 1997; Hurley *et al.*, 1997). However, there is a discrepancy in the literature as to what causes this impaired proprioception. Hurley *et al.* (1993) believe knee OA causes the impaired proprioception whereas Sharma *et al.* (1997) indicate that it is the impaired proprioception that may cause knee OA. Sharma *et al.* (1997) compared knee OA subjects with elderly matched controls, and further compared the OA knee with the non-involved knee of the same subject. They hypothesized that if the impaired proprioception was the result of OA then a between knee difference would be expected. Their results indicated no between knee differences; therefore, they concluded that impaired proprioception was not exclusively the result of knee OA. Hurley *et al.* (1997) compared the quadriceps sensorimotor function in knee OA subjects with control subjects. They investigated whether these changes were associated with impairment of functional performance. They concluded that the reduced quadriceps motoneurone excitability and diminished proprioceptive acuity might be due to OA subject's articular damage. Thus resulting in reduced functional performances by subjects with knee OA.

Research has demonstrated that application of an elastic bandage and/or a neoprene sleeve markedly improves proprioception in patients with knee OA (Kirkley *et al.* 1999; Marks, 1996). McNair *et al.* (1996) studied the effects of a "pseudo" knee sleeve on the proprioceptive ability of normal subjects in a dynamic tracking task. Their results showed an 11% increase in tracking ability when their subject wore a knee brace. A study by Kirkley *et al.* (1999) compared an unloader knee brace, a neoprene sleeve and standard medical treatment in patients with medial knee OA. Their findings support the hypothesis that the unloader knee brace decreases pain and improves the quality of life. However, they also demonstrated that a neoprene sleeve showed, on average, an improved quality of life and reduced pain associated with functional activities of walking and stair climbing. The authors indicated that since a sleeve offers little mechanical support, the patient's feeling of stability and reduced pain may be due to the improved joint proprioception with application of the sleeve.

The results from this study lend some support the idea that bracing improves knee proprioception. Although the functional task data showed no significance between bracing conditions, there was significant improvement over the no brace condition in stair climbing. As indicated earlier, this lack of significance may be due to the small sample size. However, based on Kirkley *et al.*'s (1999) results, it is quite possible that the significant difference from no brace to brace application but lack of significance between brace conditions occurred because of this improvement in proprioception.

4.3 Limitations

The main limitation of this study was the small sample size. Subjects were recruited from local orthopedic and sport medicine physicians. Flyers, personal correspondence and word of mouth were all used to promote this study. There are three possible reasons for the limited sample size: 1) the stringent inclusion/exclusion criteria (i.e. age, no history of ligament laxity) excluded possible participants 2) the limited time available for subject recruitment 3) the competitor's brace is produced locally and is commonly prescribed by local physicians.

Prior to the start of the study, a power analysis to estimate a sample size was performed. Means for the functional tasks provided in the literature were used to estimate the effect size. Because much of the literature on these functional tasks was based on either normal or ACL populations, it was difficult to estimate for an OA population. Based on a power of 0.8, alpha set at 0.05 and one-tailed test, a sample size of 10 was calculated. However, upon review of the new means collected in this study, an over–estimation of the effect size occurred. Another power analysis based on means derived from this study was performed. Different effect sizes ranging from zero to two and the mean differences for each functional task found in this study were plugged into the SPSS power analysis program. It is estimated that a sample size of 74 subjects is needed to give this study a .809 power to yield a significant result. This computation assumed that the population from which the sample would be drawn has a mean difference of 2.8 with a standard deviation of 4.3. The observed value would be tested against a theoretical value of 1.0.

Another limitation could be the change in weather/season over the study duration might have affected the results. Anecdotally, many OA patients' claim they can "tell the weather by how their knee is feeling. " (Harris, 1987). Although limited research has been carried out on this topic, there has been support for changes in barometric pressure and temperature increasing OA symptoms (Harris, 1987). Harris (1987) performed a quasi-experiment in which he reviewed the number of visits to doctors' offices for OA pain. The monthly figures showed an interesting distribution. There were two peaks, one in April/May and the other in September-November, in which OA patients saw their doctors office more often for pain related symptoms. He did state the results should be interpreted with caution as it was a retrospective study and the criteria for inclusion may not have been consistent. Nonetheless, seasonal related factors might have influenced the results of this study. The first five subjects started in the summer and ended in the fall/winter. The latter five subjects started in the fall and finished in the winter. The weather in the summer months in Vancouver was warmer and had much less rain than in the fall and/or winter months. If Harris' hypotheses are true, the weather may have influenced the subject's perception of pain. Further study using prospective trials are needed to determine if and what influence the weather has on pain perception in OA.

Another limitation may be the variance in the subjects' activity level over the study period. Apart from casually discussing with subjects what they had been doing, there was no formal record kept. Although subjects were asked not to increase or decrease their activity level from the start of the study, a daily/weekly activity log would have helped researchers to monitor this. Conceivably, a person's level of activity may be altered by changes in the weather and or season. People tend to be more active in the summer months when the weather is better and the days are longer. As previous stated most subjects started in one season and did not finish until the next one. An increase or decrease in their activity level may have influenced the subject's function and pain therefore biasing the results.

A further limitation may be the manual recording of the data. The times collected for the stair climbing and figure-8-run were manually recorded using a stopwatch accurate to a 10th of a second. Unfortunately, manual timing may generate a source of error due to the variability of the investigator's reaction time (Marks, 1995). Ideally, it would have been more accurate to use an electronic measuring system such as that used by other investigators (Fonseca *et al.,* 1992; Tegner *et al.,* 1986). Unfortunately, this type of equipment was not available for this study. However, it is important to note that most clinicians are not likely to have this electronic equipment either. Therefore, it may be more realistic to create norms using the easily accessible manual timing method to allow clinicians easy comparison. Moreover, good reliability has been demonstrated in the literature for manually recorded stair climbing in knee OA population (Marks, 1995; Rejeski *et al.,* 1995).

Finally, the inclusion and exclusion criteria for this study were quite stringent. However, even with such criteria, a major limitation to this study and many other OA studies, is group homogeneity. There is so much variability in the status and progression of OA, that it is very difficult to select a specific population all at the same stage with the same symptoms. It is common for someone with OA to have intense pain and functional impairment but have little joint destruction. Conversely, have someone with minor pain and functional impairment with severe joint destruction. Suggestions to decrease this variability are to have each subject assessed by the same physician and perform a magnetic resonance imaging (MRI) scan to clearly see the extent of the joint damage. However, costs associated with performing a MRI and the feasibility of each subject being assessed by the same physician was not realistic for this study. However, even with these suggestions group homogeneity may still be difficult to achieve.

4.4 Summary

The results of this study support that wearing a knee brace improves the time to ascend/descend stairs compared to not wearing a brace. Moreover, they support that subjects perceive their ability to perform physical tasks easier while wearing a brace. However, the results did not show that valgus bracing is different than neutral bracing. This lack of support may due to the small sample size. The results from this study provide valuable data for further research. It is innovative in its selection of functional outcome measures and its chosen OA population. Much of the research on knee OA has focussed on subjects over age 65 who have difficulty performing activities of daily living (ADL). Specific to this older population, the outcome measures used in the literature have primarily focussed on the ability to perform these ADL. Because knee OA is affecting a younger population, outcome measures specific to the middle-aged population and their level of deterioration are needed. Future research still needs to substantiate non-invasive treatment measures that can slow the progression of this disease and help this population remain active.

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APPENDIX A: Review Of Literature

The Normal Knee Joint

The articulating surfaces of the knee joint that are affected by OA are the condyles of the femur, the tibial plateau, and the posterior aspect of the patella. The surrounding support structures that play key roles from a mechanical and nutritional standpoint are the menisci, ligaments, joint capsule, muscles, tendons, retinacula and the synovium.

The menisci aid in stability and contribute to stress distribution during weight bearing. The ligaments also aid in stability while aligning the opposing articular surfaces throughout the knee movements. The joint capsule, muscles, tendons and retinacula all add secondary restraints to the knee joint. Moreover, the muscle and tendons further contribute to absorbing stress in the knee by being more flexible than the ligaments. Therefore, all structures contribute to an important role in approximating and stabilizing the articular surfaces throughout the range of motion of the knee (Martin, 1994).

The synovial membrane lines the knee joint and has three functions. The first is to regulate the content of the synovial fluid, the second is to remove waste products by phagocytosis, and the third, is to secrete synovial fluid and other macromolecules. It is an extremely vascular tissue that is made up of predominantly two cell types; Type A which are mainly phagocytic and Type B which are secretory and produce synovial fluid. It is this synovial fluid that covers the articular surfaces of the joint and is responsible for lubrication and nutrition of the articular cartilage (Bullough et al., 1984).

This articular cartilage is supported by underlying subchondral bone and further supported by the trabeculae which is responsible to absorb and offer support for the majority of stresses of the knee. The cartilage is composed mainly of water and helps absorb the shock through the joint. The water content is highest at birth and decreases with age. Other components of the articular cartilage are Type II collagen and proteoglycans. The collagen, secreted by the chondrocytes, provides the articular cartilage with tensile strength and stiffness by way of crosslinking its polypeptide chains in a triple helix configuration. Proteoglycans are complex hydrophilic glycoproteins that aid in creating an expansive osmotic effect and contributes to the weight bearing ability of cartilage (Martin, 1994). Specifically, water is released gradually at the articular surface when a compressive load is applied and the process reverses when the load is removed (Pinals, 1996). It is all these components, that allow the articular cartilage to have a viscoelastic nature to withstand forces up to seven times body weight (Martin, 1994).

Epidemiology & Risk Factors

Several factors have been found to either initiate or perpetuate the development of OA (Michet, 1993). Increasing age is one of the strongest determinants of this condition. This is supported by evidence of radiographic changes seen in the 40+ age group and the increasing occurrence in the elderly

(Felson, 1987). More importantly, radiographic evidence of OA was observed more frequently in the older person, irrespective of symptoms. The mechanism underlying the influence of aging is unclear. However, it appears that during aging, the joint has a decreased ability to withstand compression and this puts more stress on the subchondral bone and surrounding support structures. The articular cartilage loses water and proteoglycan concentrations, and therefore, some of its weight bearing properties (Pinals, 1996). However, OA is not merely caused by the natural aging process of cartilage. Other possible factors include cumulative biomechanical trauma to the cartilage, changes in the chondrocyte functioning or possible decline in the neuromuscular protective mechanisms about the joint.

Trauma has a variable impact on the risk of OA. A joint injury such as ligament tears, or joint fractures may lead to increased laxity or incongruity to the joint, predisposing the cartilage to extra stress. This leads to the question - does exercise increase the risk of OA? There is no evidence that recreational exercise itself increases the risk (Lane, 1995). However, there is concern that elite level athletes are at more risk due to excessive loading and greater frequency of joint injuries (Spector, 1996). Lane (1995) concluded that exercise or activities that repeatedly expose joints to high levels of impact or torsional loading appear, over time, to be associated with an increase risk. It has also been suggested that stresses placed on a joint due to repetitive occupational activities can influence the OA risk. For example, a job requiring continual knee bending may increase the prevalence. For these reasons, it has been more prevalent for men to experience OA at a younger age than women (Michet, 1993, Rottensten, 1996).

Recent literature has suggested that the prevalence of OA increases with age because of an increase in joint load caused by a decline in joint position sense and/or proprioception (Sharma *et al.*, 1997; Barrett *et al.*, 1991). Barrett *et al.*, 1991 demonstrated that knee position sense is worse in subjects with knee OA versus aged matched controls. However, the "chicken and egg" phenomenon is applied here, because researchers are not sure whether the impaired proprioception is caused by the OA or vica versa. Hurley *et al.* (1997) believe knee OA causes the impaired proprioception, whereas Sharma *et al.* (1997) have indicated that the impaired joint position sense causes the OA.

Obesity may also play a possible factor in knee OA. This is especially evident in older women due to the greater hip angle in females. It had been suggested that joint impairment, induced by the obesity, may contribute to the greater incidence; however, Michet (1993) argued that it is likely the result of increasing biomechanical stress on the joint. Studies have indicated that weight loss in the obese patient will reduce the risk of knee OA (Felson, 1992; Felson, 1994).

Structural changes seen with OA

In an osteoarthritic knee there are some key structural changes observed compared to the "normal" knee. Fissuring, erosion, softening and ulceration occur to the articular cartilage. The lesions appear first in the load bearing areas, but during progression of the condition, there is a thinning, loss of cartilage and, ultimately, subchondral bone sclerosis (Pinals, 1996). In addition, the joint space undergoes narrowing while the joint capsule thickens and the synovial tissue becomes inflamed. As weight bearing continues in this abnormal situation, the final stage is characterized by a complete breakdown of articular cartilage resulting in a bone-on-bone weightbearing situation (Martin, 1994).

It has been postulated that the progression of OA is related to the degree of imbalance between the degradation and repair of cartilage. The cartilage damage is the result of increase enzyme release from the chondrocytes into the matrix leading to increase cartilage matrix degradation (Pelletier, 1993; Pinals, 1995). This is evident in that an increase synthesis rate of enzymes such as collogenase and stromelysin is proportional to the severity of cartilage matrix lesions. Stromelysin breaks down proteoglycans and collagenase is responsible for degrading the type II collagen fibers of cartilage. The breakdown of these structures releases fragments into the synovial fluid which may act as irritants and may be partially responsible for the inflammatory changes that occur in the synovial membrane (Pelletier, 1993).

During the course of OA the synovial fluid loses its viscoelastic properties. Specifically, a component of the fluid, called hyaluronic acid, loses its viscoelasticity, which contributes to poor lubricating ability of the synovial fluid on the cartilage surface. This alters the mechanical force transmission to the cartilage, increasing the wear and tear.

Pinals and colleagues (1996) indicated that early in this destructive process there might be accompanying efforts to repair cartilage. The chondrocytes attempt to generate new cells in a very limited capacity. The proteoglycan component may also increase which leads to an increase in fibrocartilage, however, this type of cartilage has inferior mechanical properties compared to the "real" cartilage. This attempted restorative process may cause overgrowth and remodeling of the bone; one of the earliest signs may be the formation of osteophytes (Pinals, 1996). These bony changes alter the joint configuration and decrease the range of motion in response to mechanical forces between the calcified cartilage adjacent to the bone and overlying hyaline cartilage (Pinals, 1996).

Classification/Diagnosis

Diagnosis of OA is not straightforward. It is important to rule out other diseases and conditions such as neurological disorders (e.g. Parkinson's disease), referred pain as observed in neuropathies, soft tissue disorders independent of OA, arthritis of some other origin, pathological changes of adjacent bone (e.g. tumor) or mechanical injuries such as fractures. The American College of Rheumatology has set out criteria to aid in the proper classification of knee OA.

Table 10. Classification Criteria for Knee Arthritis (Altman, 1995)

American College of Rheumatology Classification Criteria
1. Knee pain (on most days of the month) 2. Crepitus 3. Morning Stiffness < 30 minutes 4. Age greater than 38 years 5. Boney enlargement of the joint

Classification is made if the patients elicit the following combinations of the above criteria: 1,2,3,4, or 1,2,5 or 1,4,5. The classification criteria are different from diagnostic criteria, as the latter is a symptom directed process.

The clinical diagnostic process consists of analysis of symptoms, laboratory findings and imaging results. A common diagnostic tool for detection of osteoarthritis is x-ray imaging. In early stages of the condition the presence of osteophytes exists. As the condition progresses, there is evidence of the joint space narrowing and/or hardening of the subchondral bone (Balint, 1996). However, as stated earlier in this paper, patients may exhibit some of these initial radiographic changes but still be asymptomatic.

Currently, laboratory findings do not play a very important role in the diagnosis of OA. Sedimentation rate, joint fluid properties and synovial fluid volume are all at, or close to, normal. However, biochemical markers such as cartilage and bone derived components, and indicators of synovial activity are under investigation, and may prove helpful in the early diagnosis of this disease (Balint, 1996).

Clinical symptoms of OA usually include pain, crepitus, swelling, and possible decrease in range of motion. Upon a knee examination, there may be some abnormal passive movements due to joint laxity as a result of ligamentous or capsular injury. A varus or valgus deformity and/or bony growths may be present depending on the affected side. These deformities originate from the gradual destruction of the articular structures such as the cartilage, synovium and subchondral bone.

The pain associated with OA is usually mechanical in nature, increasing with movement and joint loading while subsiding with rest. It is usually worse when initiating a movement. For example, getting out of a chair after sitting, or getting up out of bed after sleeping. As the condition progresses the pain is evident during extended periods of walking and movement because of the bone-on-bone grating. The cause of the pain in an individual with osteoarthritis may be complex and is not easy to explain. For example, it is not uncommon to have individuals in the advanced stages with deteriorating radiographs exhibiting minimal pain and individuals with mild OA experiencing intense pain. The pain is thought to have an articular or periarticular origin rather than the articular cartilage itself. For example, soft tissue damage such as synovial inflammation, joint capsule distention, ligament damage, muscle spasm or bursitis could be the cause of the pain. Conversely, the pain may be completely independent of this, and be related to factors unrelated to the articular events. For example, factors such as lifestyle, depression, anxiety, social reasons, job related physical stress or obesity may all influence pain perception.

Pinels and colleagues (1996) also indicated that the possible breakdown of the sensory reflex mechanisms might contribute to OA pain by allowing motion beyond the normal limits.

Pain Measurements

Pain is a response that consists of a sensory and psychological component. In the laboratory setting pain measurement usually involves the sensory components whereas in the clinical setting pain assessment predominantly involves the affective components. The literature is extensive on general pain scales available for research (Gracely, 1988; Huskisson, 1983;Melzack, 1983). Three of the more commonly used scales are the Descriptor Differential Scale, The McGill Pain Questionnaire, and the Visual Analog Scale.

The Descriptor Differential Scale (DDS) method of pain assessment, collects multiple responses minimizing response variability and scaling error (MacIntyre, 1995). The DDS measures both the sensory and affective component of pain, and was designed to randomly present twelve descriptors so as to reduce the effect of memory. It requires a 21-point scale response in relation to each descriptor as the subject is asked to rate each descriptor through a range of -10 to +10. Criticism made with respect to the DDS implies that it is sometimes difficult to rate some of the descriptors on the DDS, and subjects may find themselves attempting to make comparisons between descriptor items. For example, deciding where to put the check mark in relation to the descriptor "mild" and "very mild", or "weak" and "very weak" can be a very difficult task, especially if there is confusion interpreting the meaning of the words. This may also lead to inter-subject variability because each subject may interpret the meaning differently.

The McGill Pain Questionnaire (MPQ) provides a reliable and valid indices of pain sensitive enough to detect differences between different pain relief methods (Reading, 1983). The MPQ has 20 groups of various descriptive words that are categorized under 4 major sections: sensory, affective, evaluative and miscellaneous. Subjects are asked to indicate which word(s) in the group(s) best describes their pain and a rank value is given for each word. Criticism towards this questionnaire includes its prognostic precision, and questions have been asked with respect to its incremental validity to alternative measures. In addition, it has not been proven whether tailored abbreviated formats prove as reliable or valid (Reading, 1983).

The Visual Analog Scale (VAS) is a simple, robust, sensitive and reproducible method of measuring pain. It allows the patient to express the severity of pain in such a way that it can be given a numerical value. It is commonly used to compare pain severity in the same patient at different times and/or receiving different treatments. The VAS is a line, usually measuring 10 cm in length, in which the line represents the continuum of some experience (i.e. pain). Therefore, one end is often marked "no pain" and the opposite end is marked "severe pain". The subject is asked to put a single mark on the line that corresponds to the severity of pain. The distance measured from the end of the line represents the pain severity. Scott and Huskisson (1979) reported that there was no difference whether a vertical or horizontal line is used, however, the horizontal line is more commonly used in the literature. This scale is easy to understand and the subject is able to quickly evaluate their pain (Huskisson, 1983). It is an ideal scale to be used in crossover experiments where subjects are comparing different treatments. The main criticism is that the VAS perceives pain as a simple unitary dimension varying only in intensity (Gracely, 1988). In addition, it possibly allows the subject to remember a past response and may therefore suffer from scaling error (MacIntyre, 1995). However, although it can not be denied that previous scores may influence the subject, knowledge of previous scores may lead to greater precision and less variation in the results. Particularly during, or after, prolong treatment periods when the patient's memory of the initial state has faded (Scott & Huskisson, 1978).

There is a new trend for researchers to develop outcome questionnaires specific to conditions. For example, for knee OA, Rejeski and colleagues (1995) developed a Knee Pain Scale (KPS). They attempted to capture both the frequency and intensity of pain experienced during the patient's daily living activities. This scale is better suited for patients who display disability in their daily living activities.

Lequesne *et al.* (1987) developed indexes of severity for both knee and hip OA. In the knee index, there are three sections: pain or discomfort, maximum distance walked, activities of daily living. In the pain subscale patients answer 5 questions regarding night pain, stiffness duration, pain during walking, standing and sitting. In the second subscale subjects are asked to select the distance able to walk. The final section has the patients rate their ability in four activities of daily living. In each section the patients are awarded points based on their answer. The higher the point score the greater the disability (e.g. >14 equals extremely severe handicap and 1-4 equals mild handicap). This measure has been reported to have good inter-rater reliability and has demonstrated responsiveness in NSAID trials.

Similarly, Bellamy and colleagues (1988) developed an activity based pain subscale called the Western Ontario and McMaster University Osteoarthritis Index (WOMAC). This index separates evaluation of the knee into three categories: pain, stiffness, and physical function. Subjects answer twenty-four questions using either the Likert or Visual Analogue scaled formats. WOMAC is a valid and reliable measure that is sensitive enough to detect clinically important health status changes following an intervention (Bellamy, 1996). Reliability values of the three subscales ranged from .73 to .96 for the Visual Analogue and .75 to .97 for the Likert scaled versions (Bellamy, 1996). In a validation study done by Bellamy *et al.* (1988), each subscale of the WOMAC fulfilled conventional criteria for face, content and construct validity, reliability, responsiveness and relative efficiency. Potential limitations include its restriction to pain intensity assessment and it does not consider pain during transfer activities (i.e. getting in/out of a car).

Comparisons between the Lequesne and WOMAC indices have been addressed in the literature (Bellamy *et al.*, 1991; Sun *et al.*, 1997; Stucki *et al.*, 1998). In a double blind randomized trial comparing two NSAID medications by Bellamy *et al.* (1992), the study demonstrated the relative efficiency of the WOMAC was similar to that of the Lequesne index. Stucki *et al.* (1998) compared the German version of

WOMAC and the Lequesne in knee and hip OA patients. They concluded that the all subscales of the WOMAC were internally consistent but found only the function subscale (not the symptoms) internally consistent in the Lequesne index. Sun *et al.* (1997) in a comparative literature review of knee and hip OA outcome measures indicated that the WOMAC subscale showed relatively high levels of correlation with the Lequesne items, but indicated that the Lequesne probed different dimensions of health - specifically, the type of pain and duration of stiffness. Conversely, the WOMAC measures the severity of pain and stiffness and is more sensitive to change. The World Health Organization and the American Association for Orthopedic Surgery has recommended both the WOMAC and Lequesne indices as the primary efficacy measures in OA treatment studies (Sun *et al.*, 1997).

Treatment of OA of the Knee

The general goals in treating individuals with OA are (1) to increase function (2) to maintain current function (3) to prevent dysfunction or preserve normal function (Hicks, 1992). Treatment programs are usually tailored to the individual depending on the amount of pain and disability he/she experiences. Early intervention may consist of a physical therapy rehabilitation program. In this situation, the goal is to use modalities to aid in pain relief. Active rehabilitation, in the form of exercise and strengthening, can maintain joint range of motion and to improve mechanical stabilization of the joint. Muscles perform an important protective function in the knee by maintaining normal alignment and help in absorbing shock. If the muscles are too weak and unable to perform this function, the loading stress that is not absorbed will impact directly on the opposing articular cartilage (Tan, 1995). Research has demonstrated that effectively strengthening the muscles around the knee joint will decrease pain and increase function (Fisher, 1991; Fisher 1993).

Another early treatment intervention has been the use of non-steroidal anti-inflammatory drugs (NSAID) to help in pain relief by decreasing inflammation. However, OA is not an inflammatory disease and NSAID's are only effective if the patient has an associated inflammatory condition (Michet, 1993). A more appropriate chemical intervention is an analgesic (i.e. acetaminophen) to help in pain control. Nonetheless, the use of a medication only serves to treat the symptoms and will not delay or heal the progressively deteriorating condition.

New research has been focussing on other areas of treatments such as viscosupplementation, glucosamine sulfate and even transplanting cartilage cells developed in the laboratory setting. Viscosupplementation attempts to restore the homeostasis of the viscloelastic properties of the synovial joint. A synthetic hyaluronan derivative is injected into the joint in an attempt to act as a lubricant to provide protection of the joint surfaces. There is some evidence indicating it may stimulate the body's own production of hyaluronan, but this has not been substantiated (Balazs *et al.,* 1993). The effect of viscosupplementation does not last indefinitely. This is primarily due to the underlying problem not being resolved and the supplement breaking down and being absorbed by the body.

Glucosamine sulfate is a nutritional supplement taken orally by OA patients in an attempt to supplement and/or possibly stimulate the body's production of glycosaminoglycans in the articular cartilage (Creamer *et al.*, 1998). Research is ongoing, in that much of the evidence is anecdotal or is not methodologically sound.

Other, more invasive, treatment options include surgery; (1) debridement, (2) tibial/femoral osteotomies, (3) knee replacement. These options are not usually considered until the disease has progressed to a disabling state and all other treatment options have been exhausted.

Debridement, as the name implies, consists of debriding the knee joint of any loose bodies, rough edges, and/or bony growths in an attempt to re-align the congruity of the two joint surfaces (Goldberg, 1992). It is usually a temporary treatment option, as the joint will eventually return to pre-debridement state due to the same forces still present on the articular surfaces. This procedure is commonly performed on OA patients less than 65 to prolong the time until they require joint arthroplasty.

The goal of the osteotomy surgery is to cut a wedge out of the tibia or femur (depending which bone is creating the varus/valgus deformity) to re-align the extremity and to decrease the stress on the single degenerated compartment.

Knee arthroplasty, replacement with a synthetically manufactured joint, is usually done as the last resort. It can be either partial (replace only the affected compartment) or complete (replace the whole joint). The prognosis is good for arthroplasty, however, long-term effects are just becoming known. Generally, this type of surgery is only considered in patients over 65 as the replacement usually wears out after 10 years.

Relating to this study, a treatment option becoming more widespread in its use is knee bracing. Specifically, the use of a valgus/varus brace for medial/lateral OA, respectively. There is little in the literature with respect to bracing and OA. Much of the research focuses on knee bracing for the anterior cruciate deficient knee (Cawley *et al.*, 1991; Houston *et al.*, 1982; Kramer *et al.*, 1997). However, there are two types of knee braces, explained in the literature, for knee OA.

Osteoarthritis and Bracing

The first arthritic knee brace to be designed was the CARS-UBC brace or the slightly modified version of it called the TVS brace (Butler, 1983; Jawad *et al.*, 1986). It was designed to hold a medially or laterally unstable knee from moving into a painful position. However, this brace was only effective in patients who exhibited a small degree of varus/valgus deformity (Jawad *et al.*, 1986; Butler, 1983). The brace consisted of two plastic cuffs, with velcro closures, joined together by a flexible nylon rod, and a telescopic metal tube. A leather knee sling is joined to the cuffs by two front straps and connected behind the knee to the telescopic tube by clips. Jawad and Goodwill (1986) reported that pain reduction in patients wearing the brace either occurred in the first three days or not at all, and that 14 of 18 patients with OA who found the brace relieved their pain continued to wear the brace. There is no current literature on this knee brace, and it is assumed it is no longer in production due to its cumbersome appearance, difficult application, and patient discomfort.

The second type of knee brace used to treat OA is the varus/valgus knee brace. This brace design, first introduced in 1989, is the one referred to in the current literature (Horlick *et al.*, 1993; Pollo *et al.*, 1997; Pollo, 1995; Davidson, 1994; Greenwald, 1997; Matsuno *et al.*, 1997; Kirkley *et al.*, 1999). The premise behind this type of bracing is that it utilizes a three-point system to reduce the load across the painful compartment by shifting the load to the unaffected compartment. It basically involves applying a medial or lateral force to the center of the knee in conjunction with two opposing forces, transmitted through cuffs above and below the knee joint, to provide this unloading design.

There are many features differentiating the array of OA braces on the market. Some are custom made, while others are over-the-counter. The cuffs can be made of plastic, aluminum or composite materials, while the application of the center force can be achieved through condylar pads, inflatable air bladders or a spiral strap. In addition, brace designs differ in single vs. double upright supports, single vs. polyaxial hinge design and the ability to adjust the brace for patient comfort. A clinical comparison of the various designs has not been addressed in the literature. Pollo and colleagues (1997) did state that although the dual upright design is a more rigid brace, the materials used to manufacture the single upright design is more than rigid enough to withstand the loads it requires. Furthermore, the polyaxial hinge design will allow greater motion, similar to that of the normal knee joint.

Horlick and Loomer (1993) tested the efficacy of a valgus knee brace (Generation II, Vancouver, B.C.) in patients with medial gonarthrosis. They looked at two valgus brace designs - one with a lateral hinge and the other with a medial hinge. The medial hinged design was better accepted by the patients and resulted in more patients continuing to wear the brace after the study. Results indicated significant pain relief (from both designs) when compared to baseline. No significant changes were observed between the brace vs. unbraced radiographs. The authors concluded that valgus knee bracing is a useful treatment modality to reduce the pain associated with OA.

Matsuno and colleagues (1997) concurred with Horlick and Loomer (1993) that Generation II bracing caused significant reduction in pain relief in medial OA patients. Muscle strength and performance in the walking test and stair climb also significantly improved. Other variables, the femorotibial angle and mean angle, measured at the pre-brace and final observation period both decreased.

Kirkley *et al.* (1999) in the most recent study compared a custom valgus OA knee brace (Generation II, Richmond, BC), a neoprene sleeve and no brace (control) condition. The authors used a parallel – group, randomized clinical trial design with the following outcome measures: WOMAC osteoarthritis index, McMaster-Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR), six-minute walk and thirty-second stair climbing task. One hundred and nineteen subjects were randomized between groups and scores at baseline and six-months were analyzed. Results indicated that subjects in both brace conditions significantly improved in all outcome measures compared to the control group. There was also a significant difference between the valgus brace and neoprene sleeve in the functional tests; however, no difference was found between braces for the disease specific questionnaires.

Greenwald and colleagues (1997) studied the forces applied to the lateral side of the knee and compared the varus moment at the knee during level gait with and without the valgus knee brace. They used the Monarch Knee Brace (Smith & Nephew - Donjoy, Carlsbad, CA). They concluded that this brace significantly reduced the varus moment at 20 and 25% of the stance phase compared to the unbraced condition. Furthermore, the application of the brace resulted in a relatively constant level of valgus force being applied during the stance phase.

Pollo and colleagues (1997) measured the effect of valgus knee bracing (Generation II, Bothell, WA) on gait mechanics at the knee initially and three months after bracing treatment. They reported that the brace condition resulted in a significant reduction in the external varus moment experienced by the knee from 5% to 43% of the stance phase. Subjects showed no treatment effect when walking unbraced after three months, but showed improvement in pain and function parameters. Therefore, they felt application of the brace resulted in less varus loading to the knee.

Davidson (1994) studied how knee bracing (Generation II, Vancouver, BC) altered the alignment of the shank segment with respect to the thigh segment. The results showed that the brace did not have an effect on the thigh coronal angle, but was significant in reducing the shank coronal angle into varus at toe-off. He also reported that bracing prevented full extension during mid-stance and created significant external rotation of both the thigh axial angle throughout the stance phase and of the shank axial angle during knee flexion. However, he attributed this to the brace's helical strap design.

Functional Knee Evaluation

Functional evaluation of the knee is an important factor in the analysis of evaluating the success of a treatment option. Many OA studies observe patients performing active daily functions such as getting in and out of a chair, or walking a specified distance. Unfortunately, these types of measures may be difficult to quantify or have not been proven reliable or valid. However, there are some valid and reliable functional tests assessing knee function in OA patients. Further a number of tests that have been used more extensively in the ACL literature.

An appropriate functional assessment measurement applicable for mild OA patients is the one-legged hop test. Originally described by Daniel et al (1990), this test requires the subject to hop from and land on the same leg without losing balance. The one leg hop test has been reported as a good indicator of leg confidence and function, and has been given support by the International Knee Documentation Committee to be included in their knee test protocol (Kramer *et al.*, 1992). Most of the literature assessing the performance of the one-leg hop test is reported using patients who have experienced anterior cruciate ligament (ACL) deficiencies.

Kramer and colleagues (1992) studied the test-retest reliability of the one leg hop test using two measures - the distance hopped, and the hop index score in patients following ACL reconstruction. The results indicated an acceptable test-retest reliability of .75.

Fonseca and colleagues (1992) examined a selection of knee functional tests to assess ACL repair. The four performance tasks he reviewed were the slalom circuit, straight running, figure- 8-run and single leg hop test. He reported that the best test for distinguishing normal and ACL deficient knee was the figure of 8 test (expressed as a ratio of time obtained in the straight run test). He also concluded that this test and the hop index appear to complement each other and should be incorporated into studies evaluating functional outcomes of ACL injuries and their treatment.

Table 11. Summary of research using Single Hop Test (for distance)

Reference	Subjects	Results
Bolgla *et al.* (1997)	- 20 males/females - no lower extremity dysfunction	- Reported intraclass correlation coefficients (ICC) of .95 to .96 suggesting high level of reliability
Fonseca *et al.* (1992)	- 10 ACL deficient subjects - 10 normal controls	- both the figure of 8 run and hop index complement each other and should be used to evaluate functional outcomes of ACL injuries
Kramer *et al.* (1992)	- 22 men/16 women who had undergone ACL repair	- acceptable reliability; - ICC>0.75 for any one occasion. ICC greater if averaged over two occasions
Daniel *et al.* (1990)	- 100 normal subjects	- one leg hop for distance - serves as a objective measure of knee function

A common complaint by the osteoarthitic patient is the difficulty climbing and descending stairs. For this reason, a functional test measuring the time for subjects to ascend/descend a set of stairs is applicable. Stair climbing has been often used in the literature (Fisher, 1993; Matsuno *et al.*, 1997; Rejeski *et al.*, 1995; Houston *et al.*, 1982; Kirkley *et al.*, 1999), however, there is little information regarding reliability and validity of this functional test. Rejeski *et al.*(1995) revealed a 3-month test/re-test reliability of .75 and .87 using a 5-stair protocol at two individual testing sites, but gave no information on the validity. In addition, there is concern over the lack of general agreement with respect to a standardized test protocol for the stair climb. This includes measurements for the stair rise/run and the number of stairs involved in the test.

Table 12. Summary of research using stair climbing.

Reference	Method	Results
Rejeski *et al.* (1995)	- 148 knee OA subjects > 60 years - assessing physical activity restrictions - 5 stair protocol	- good test-retest reliability for stair climb (R=.75 and .87 for two different groups)
Fisher *et al.* (1993)	- 40 knee OA subjects - studied the effects of rehabilitation program	- significant increase inability to climb stairs after treatment
Matsuno *et al.* (1997)	- 20 knee OA subjects - Studied effect of valgus bracing - used knee scoring system to evaluate stair climbing function - number of stairs not given	- no reliability/validity data given for knee scoring system - significant improvement seen in the stair ascent/descent
Houston *et al.* (1982)	- 7 males with past ACL - each wearing a ACL knee knee brace to compare braced vs unbraced performance in tests	- stair protocol consisted of measuring vertical velocity betw. the 8th and 12th step
Kirkley *et al.* (1999)	- 119 knee OA subjects - compared GII, neoprene sleeve and no brace -stair protocol: number of stairs in 20 s	- bracing better than no bracing - valgus bracing better than neoprene in functional task grps. - no difference between brace conditions in both questionnaires

In a recent study, Munich and colleagues (1997) reviewed the test - retest reliability of an incline squat protocol. This functional test relates well to OA patients because it closely replicates the stair climbing activity as well as many other daily functions. (i.e. such as getting in/out of a chair or car or bending down to get something out of the cupboard). This test uses an incline slide board apparatus to help subjects perform a knee squat to 90 degrees. The incline feature allows a partial weight-bearing environment for the subjects (approximately 65% depending on the degree of incline) so as to minimize the stress to a painful knee or weak muscle group. The authors tested two protocols: (1) how long it would take the subject to do 50 squats and (2) how many squats the subject could perform in 20 seconds. The intraclass correlation coefficient for a one-week repeated test was .80 and .89 respectively. These results indicate acceptable test-retest reliability and the authors advocate the use of this protocol to evaluate functional ability during rehabilitation of lower extremity conditions

Summary

There is a large volume of research available with respect to knee osteoarthritis. Much of the literature focuses on an older population at the end stage of the disease process and the treatment options available at this severe stage. The information is scarce for those patients with mild to moderate OA and the treatment strategies best initiated at these stages. It is the younger OA population that we must concentrate our future research. Questions such as: How can we prevent their disease from getting worse? How can we prevent this disease? should be an area of focus.

APPENDIX B: Raw Data

Figure-8-run Data

Table 13. Time (seconds), Individual subject data

Subject	Pre-Brace	Test 1	Test 2	Test 3	Post Wash	Test 4	Test 5	Test 6
01B/A	13.00	13.81	12.22	12.72	14.34	14.32	13.00	13.38
02B/A	9.25	9.38	8.87	9.16	9.00	8.97	9.41	10.25
03A/B	13.81	12.44	11.41	11.54	11.90	11.22	11.75	12.47
04A/B	9.97	10.03	10.60	10.09	9.43	9.62	10.06	10.53
05B/A	9.00	9.31	8.50	9.37	8.84	8.81	9.53	8.88
06B/A	12.13	12.03	12.19	11.72	12.03	11.69	11.97	13.09
07A/B	9.63	9.69	10.33	9.57	9.25	9.44	9.97	9.47
08A/B	13.66	12.13	11.94	11.75	11.03	11.13	did not finish study	
09A/B	9.25	9.59	9.62	9.32	10.00	9.81	9.34	9.36
10B/A	12.19	12.91	12.25	11.81	12.50	11.59	11.19	11.41
11A/B	12.25	11.75	12.90	12.47	12.38	11.97	11.62	11.41

- A/B; B/A indicates order of crossover (A= neutral brace, B= valgus brace)
- Subject 08 withdrew from study – data not used in analysis

Stair Climb Raw Data

Table 14. Time (seconds), individual subject data

Subject	Pre-Brace	Test 1	Test 2	Test 3	Post Wash	Test 4	Test 5	Test 6
01B/A	5.91	6.34	5.59	5.85	5.85	5.47	4.97	5.22
02B/A	3.93	4.06	3.63	3.84	3.59	3.56	3.71	3.68
03A/B	6.78	4.78	3.91	4.25	4.38	3.44	3.81	3.97
04A/B	5.00	4.65	4.56	4.34	3.34	4.08	4.06	4.16
05B/A	4.32	3.84	3.38	3.31	3.25	3.31	3.41	2.97
06B/A	4.37	4.34	4.03	4.13	3.69	3.68	3.87	3.88
07A/B	3.56	3.91	3.78	3.06	3.18	2.94	3.16	3.00
08A/B	4.66	4.60	4.19	4.54	4.09	4.50	did not finish study	
09A/B	3.75	4.16	3.65	3.22	4.16	3.81	3.50	3.90
10B/A	4.98	5.03	4.63	4.31	4.25	4.37	4.03	3.94
11A/B	4.29	4.69	5.22	4.65	4.97	4.78	4.38	4.50

- A/B; B/A indicates order of crossover (A= neutral brace, B= valgus brace)
- Subject 08 withdrew from study – data not used in analysis

Incline Squat Raw Data

Table 15. Number of time in 20 s, individual subject data

Subject	Pre-Brace		Test 1		Test 2		Test 3		Post-Wash		Test 4		Test 5		Test 6	
	OA	NORM	OA	NORM	OA	NORM	OA	NORM	OA	NORM	OA	NORM	OA	NORM	OA	NORM
01B/A	9	13	14	14	14	16	13	16	9	16	14	18	9	18	11	18
02B/A	16	16	19	16	20	19	21	21	23	22	25	23	24	24	26	24
03A/B	6.5	9.5	9	15	13	15	12	18	11.5	17	15	18	14	17	14	18
04A/B	16	16	20	19	20	20	17	19	17	19	21	21	18	21	18	19
05B/A	19	18	24	23	23	23	21	20	22	22	22	22	23	23	24	26
06B/A	17	18	19	18	22	21	23	21	21	22	22	22	20	19	22	23
07A/B	16	15	18	18	21	17	21	19	20	22	23	23	21	21	22	21
08A/B	15	20	20	20	16	19	18	20	18	17	19	22	did not finish			
09A/B	9	18	15	20	7	22	12	15	8	21	12	18	4	20	5	19
10B/A	6	15	7	16	7	16	0*	16	7	17	8	19	7	18	5	17
11A/B	10	10	13	13	11	14	13	14	13	15	13	15	11	15	12	16

- A/B; B/A indicates order of crossover (A= neutral brace, B= valgus brace)
- OA = OA involved leg; NORM = uninvolved leg
- Subject 08 withdrew from study – data not used in analysis

Single Leg Hop Raw Data

Table 16. Distance (centimeters), individual subject data

Subject	Pre-Brace			Test 1			Test 2			Test 3		
	OA mean	Norm mean	H.I.	OA mean	Norm mean	H.I.	OA mean	Norm mean	H.I.	OA mean	Norm mean	H.I.
01B/A	45.80	82.67	55.40	86.33	93.73	92.10	79.20	96.57	82.01	71.67	90.53	79.17
02B/A	102.87	135.27	76.05	102.07	133.33	76.55	112.27	141.33	79.44	98.67	123.00	80.22
03A/B	71.33	97.00	73.54	58.60	91.40	64.11	62.87	87.07	72.20	56.00	83.40	67.15
04A/B	65.53	77.13	84.96	68.00	69.80	97.42	77.93	81.00	96.21	66.93	82.00	81.63
05B/A	118.33	126.47	93.57	132.80	132.30	100.38	134.00	142.83	93.82	135.33	142.00	95.31
06B/A	85.40	101.07	84.50	86.73	93.87	92.40	90.87	96.40	94.26	84.83	97.83	86.72
07A/B	112.13	123.50	90.79	106.10	120.33	88.19	124.67	139.00	89.69	134.50	147.00	91.49
08A/B	14.70	73.93	19.88	38.87	75.93	51.19	40.83	83.83	48.70	61.50	85.00	72.35
09A/B	70.83	84.83	83.50	84.50	85.33	99.03	81.50	92.50	88.11	102.67	110.17	93.19
10B/A	87.00	112.67	77.22	87.33	123.00	71.00	93.00	126.67	73.42	71*	114.00	62.28*
11A/B	90.33	98.50	91.71	90.33	101.50	88.99	80.67	104.17	77.44	77.33	103.33	74.84

Subject	Post Wash			Test 4			Test 5			Test 6		
	OA mean	Norm mean	H.I.	OA mean	Norm mean	H.I.	OA mean	Norm mean	H.I.	OA mean	Norm mean	H.I.
01B/A	62.33	78.00	79.91	69.83	82.00	85.16	64.17	84.17	76.24	62.33	79.50	78.41
02B/A	104.50	129.17	80.90	102.50	136.17	75.27	120.50	152.67	78.93	123.33	150.67	81.86
03A/B	57.00	94.00	60.64	75.67	106.67	70.94	64.00	85.50	74.85	81.83	116.00	70.55
04A/B	69.33	89.33	77.61	70.00	75.83	92.31	60.17	74.33	80.95	59.67	75.00	79.56
05B/A	135.17	151.00	89.51	145.17	153.33	94.67	135.33	153.17	88.35	152.57	162.83	93.70
06B/A	84.50	94.00	89.89	82.33	97.00	84.88	74.17	86.67	85.57	86.33	97.00	89.00
07A/B	119.00	137.67	86.44	126.17	135.33	93.32	126.17	144.00	87.62	126.17	138.00	91.43
08A/B	69.33	98.33	70.51	*	98.50		did not finish					
09A/B	86.17	98.00	87.92	100.00	104.33	95.85	91.00	114.83	79.25	89.00	107.17	83.05
10B/A	*	121.33	*	59*	117.33	50.29*	73.00	106.67	68.44	64.5*	111.33	57.94*
11A/B	66.00	96.00	68.75	90.00	101.33	88.82	84.33	100.33	84.06	82.00	104.00	78.85

- A/B; B/A indicates order of crossover (A= neutral brace, B= valgus brace)
- OA = OA involved leg; NORM = uninvolved leg; HI = hop index
- Subject 08 withdrew from study – data not used in analysis; subject 10 unable to perform this test – data not used in analysis

WOMAC Raw Data – Pain Subscale

Table 17. Numerical score (max=500), individual raw data

01B/A	Pre Brace	243.5																					
	Valgus	251	106.5	203	190	163	129	105.5	123	148	201	176.5	129	170.5	150.5	100.5	168.5	136	159	135	221	263	173.5
	Washout	247	221	223	267.5	286.5	259	274.5	334	346	329	306	293.5	346	346.5	308	302	322.5	291	223.5			
	Neutral	257	213	315.5	295.5	337.5	322	343	346.5	333	327	344	340.5	342	388	386.5	375	343	380.5	343	343	361	326
02B/A	Pre Brace	236.5																					
	Valgus	163.8	154.4	92	183.5	104	88	70.5	69	37.5	35	55	128	39.5	83.5	156.5	216	186	86.5	88	63	179	71.5
	Washout	88	95	127	116	124	108	114	115.5	99	111	109	108	98.5	102.5	110	122	90	86.5	93.5	95	97	
	Neutral	73	71	80	67.5	91	73	82	80	71	72	71	72	62	65	70	66	62	53	62.5	62	50.5	52.5
03A/B	Pre Brace	192																					
	Valgus	61.5	55	51	46.5	49	51	*	*	85	64.5	50.5	60.5	63.5	42	55	52.5	51.5	46.5	49.5	43	49	53.5
	Washout	49	30.5	26.5	31	55	42	90	44.5	59	57	80	57	95	75	93	94.5	100	88	97	103	108.5	132
	Neutral	89	*	90	*	129.5	113	98	73	112	169	118	76.5	41	77	246.5	60	*	42	60	49	52	39.5
04A/B	Pre Brace	173.5																					
	Valgus	3.5	6.5	3	6.5	4.5	5.5	3	6	3	3	7	4.5	5	1	9.5	5.5	6	5.5	4.5	5.5	5.5	8.5
	Washout	2.5	4.5	5	1	8.5	3	2	5.5	0.5	2.5	3.5	3	2	5	5.5	5	2.5	4	4.5	4.5	4	
	Neutral	96	111.5	55	60	24	53	63	54	49.5	22.5	8	6.5	12.5	9.5	9.5	9	9	6.5	3.5	8.5	4	2.5
05B/A	Pre Brace	133.5																					
	Valgus	60.5	79.5	81	113	54	82.5	136	147	128.5	101.5	67.5	157.5	141.5	147.5	130	141.5	204.5	150.5	142.5	203.5	203.5	135
	Washout	96.5	108.5	116	106	105	135.5	121	122	129	161	120	108	110	124.5	146	157	159.5	126	98.5	98.5	109	
	Neutral	105.5	115.5	113.5	104.5	76.5	85	65	68.5	143.5	162	82	210	262.5	261.5	209.5	168.5	148.5	151	91.5	84	96	92.5
06B/A	Pre Brace	63.8																					
	Valgus	34.5	40.5	27	42	28.5	33	38	42	38	50.5	46	46.5	50.5	47.5	50.5	17.5	33	47.5	46	36.5	35	23.5
	Washout	112	95	38	110	122	59	47	66	43.5	69.5	58	62.5	46	42	45	62	47.5	44.5	33	43.5	38	
	Neutral	35.5	50.5	29	28	42.5	61.5	47.5	43	37	29	54	37.5	66.5	34	27	32	35.5	60.5	34.5	25	33	36
07A/B	Pre Brace	159																					
	Valgus	66.5	78.5	46.5	63.5	69.5	63.5	50.5	55	75	78.5	68	57.5	95.5	87	75	60	74.5	50.5	63	91	59	90
	Washout	36.5	33	56	43.5	38	32	39.5	44	59.5	57.5	47	60	56	55	73.5	70.5	76	84	75	67.5	64.5	
	Neutral	77	114.5	102.5	120.5	133	103	74	62	48.5	46.5	46	29.5	40.5	34	35	36.5	33.5	32	32	35.5	39.5	30
08B/A																							
09A/B	Pre Brace	22.5																					
	Valgus	118	87.5	148.5	103	103.5	112	71.5	51	63.5	88.5	71	65.5	19.5	41.5	29	23	29	42.5	33.5	81	90	89
	Washout	39	46	63.5	60	71	106.5	125	102	99.5	102	79.5	100	110	111.5	91	93.5	102.5	75.5	57.5	66.5	81	112.5
	Neutral	38	119.5	133	80	57	76.5	67	107	48	59.5	57.5	95.5	88.5	77.5	85	80.5	48	57.5	74.5	94.5	97.5	74.5
10B/A	Pre Brace	131.5																					
	Valgus	77.5	114.5	137.5	73.5	77	103.5	115	86.5	89.5	118	108	116	137	125.5	112	114	116.5	93.5	97.5	99.5	81.5	105
	Washout	102	107.5	101.5	113.5	114	116.5	129	111	121	136	115.5	128	120	118.5	114.5	120	115.5	138.5	146.5	170	127	
	Neutral	123.5	122.5	130.5	118.5	113.5	119.5	117.5	108	115.5	121.5	106.5	135	121.5	120	121.5	123.5	122	119.5	123.5	120	121	115
11A/B	Pre Brace	159.5																					
	Valgus	21	17	21.5	15.5	17.5	21	25	382.5	181	72	96	76	49	128	74	44	19.5	35	20	67	19.5	44
	Washout	24	23.5	19	19	21	24	24.5	40	23.5	19	19.5	20.5	23.5	26	22	22.5	81	18	88.5	23.5	18.5	
	Neutral	135	150.5	18.8	22	46.5	39	25	48	22.5	25	23.5	24.5	23.5	154.5	216	239.5	118	205.5	137	91.5	27	21.5

WOMAC Raw Data – Pain Subscale - page 2

195	149.5	166	132	123.5	158	132.5	123	186	271	247	133	197	155.5	240.5	171.5	134	141	157	167							
314	312.5	359	371.5	354	351	326.5	353	366	362	340.5	354	358.5	371	368.5	377	393.5	388	364.5	342	319						
96	40	95.5	132	134	129.5	105	95	76	61	75	77	61	105	109	116	94.5	94.5									
43	53	62	48	56.5	50	62	58.5	51	49	52	61	53.5	69.5	59	69	57.5	66									
65	80.5	96.5	63.5	48.5	60.5	58.5	*	*	*	*	*	93.5	61	55	78	91	80	77								
116	90	97.5	91	106.5	89	101.5	98	97.5	108																	
37	32	30	18.8	36	35	52	10	7	7	6.5	5.5	7.5	6.5	4.5	2	1.5	4.5	36.5								
7.5	4	3.5	2	3.5	2.5	8	6.5	7.5	6.5	8.5	4	2	5.5	6.5	10	3.5	4.5	7								
3	3	3.5	4.5	1.5	3.5	1	2.5	4	0.5	2	1	1	1.5	4.5	3	2.5	2.5	4	1							
104.5	115	132	158	191	162.5	144	133	125	170.5	184.5	185	140	97.5	101	156	109.5	107.5	108.5	103	103	110.5					
88	71	72.5	78	89.5	80	75	84	137	131.5	104	85	94.5	98.5	103	81	74	70.5	70.5	71	78.5	101					
34.5	37	55.5	87	43	38	25	27	42.5	37	53.5	30.5	39.4	30.5	29	27	42.5	25	29	34							
31.5	20	47.5	48	105	89	62	65.5	38.5	50	49	40.5	59	36.5	37	48.5	56	52	52	45.5							
64	110.5	69.5	113	96	101.5	96.5	81	61.5	63.5	111	93	64	55.5	79	75	76.5	71	74.5	56.5							
34	32	31.5	38	35	40	45.5	33	32.5	37.5	36.5	39.5	37.5	51	40	36.5	27	33.5	37	28.5							
69.5	78.5	83	81	65.5	37.5	35	75.5	49	36	29	35.5	37	30	104.5	90	80	34.5	17.5	14	22	19	19				
140.5	156																									
57.5	72.5	80	76.5	137.5	104	95	91	86.5	66.5	50	51.5	40	47	17	46	32.5	71	71	59.5							
115.5	94.5	103	121	114.5	127.5	111.5	96.5	104	122	102.5	115.5	113	120.5	124	132.5	119	105.5	113.5	94.5							
111.5	117.5	125	131	116	129	134.5	131	117.5	115.5	116.5	116	119.5	113.5	109.5	113	124	117	116.5	131	106.5	117	123	122	129	123	
20.5	19	26.3	22	23.5	25	24.5	47.5	47	17.5	19	26	92.5	98.5	25.5	68.5	79	96	45.5	174.5	49.5	76	47.5	47.5	143	75.5	45.4
26	80.5	81	24	83.5	24	75.5	25	20.5	18	24	24.5	22	98.5	16.5	22	18.5	20	20.5	20	18.5						

WOMAC Raw Data – Stiffness Subscale

Table 18. Numerical score (max=200), individual raw data

01B/A	Pre Brace	113																					
	Valgus	97	70	34.5	29.5	71.5	48	35.5	22	41	50	40	33	45	38	38.5	45	67	57	60	75	90	97
	Washout	102	86	93	100.5	97	112	130	108	143	102	118	131	143	127.5	136.5	146	148.5	137	102			
	Neutral	117	102	123	122	134	135	132	138	141	140	156.5	136.5	142	153.5	147	154	145	170	140	148	158	146
02B/A	Pre Brace	101																					
	Valgus	70	57	33	65	38	30.5	23	40	14.5	33	20	36	25	24	82	112	92	40	46	17	96	29
	Washout	62	68	71	87	87.5	90	101	96	103	92.5	116	104	95	117	100	110	104	111	109.5	96	91	
	Neutral	45	54	53	42.5	62	34	53	56	28	38	39	38	39	54	39	28	36.5	17	27	29	33	34
03A/B	Pre Brace	76.5																					
	Valgus	29	15	28	37	14	23	*	*	55	23.5	21	14	57	46	35.5	42	40	49.5	38	32	10.5	70
	Washout	14	20	11	14	14.5	30	11.5	9.5	12	2	8	0	40	32	55	63.5	50	38	69.5	62.5	57	52.5
	Neutral	43.5	*	38	*	12	12.5	3	35	14	10	8	2	2	2	54	1	*	0	0	0	2	2
04A/B	Pre Brace	166																					
	Valgus	5	4	4.5	4	4.5	4.5	4.5	4.5	5	3	2.5	3.5	4	4	6	5	4.5	5.5	6.5	4	5	4
	Washout	1	2.5	3	4	1.5	1	1.5	2	1	5	3.5	5	4	3.5	3.5	3.5	3	4.5	5.5	5.5	8	
	Neutral	79	37.5	10	39.5	5.5	14	17	33.5	31.5	10.5	2.5	4	7	4.5	5.5	5	3.5	2	1.5	2.5	1	0
05B/A	Pre Brace	48																					
	Valgus	42.5	44.5	40	56.5	59	58	83	76.5	64.5	57	34.5	41.5	42.5	37	32	40.5	76.5	34.5	72.5	47	70.5	56
	Washout	66.5	60.5	78	60.5	73	60.5	75	65	67.5	74.5	94.5	62	79.5	89	89.5	96	104.5	99.5	72.5	66.5	76.5	
	Neutral	73	74	73	95.5	66	63.5	71	67.5	83.5	93	71	122	129.5	135	107.5	90	82	80	71	73	82.5	67
06B/A	Pre Brace	17.5																					
	Valgus	15.5	16.5	17	21	12	14.5	13	16	14	18	12.5	21	25	18.5	24	12	13.5	11.5	26	15.5	25	18.5
	Washout	24	38	21	57	41.5	20	24.5	22	24.5	31.5	34	42	23.5	19	17.5	23	15	17	15	24.5	15	
	Neutral	12	21	11.5	19	12	32	20.5	14.5	10	13	29	15	35.5	10	10.5	16.5	19.5	23.5	16.5	15.5	13.5	14.5
07A/B	Pre Brace	67.5																					
	Valgus	33	35	24	41	24	36.5	18	30.5	33.5	30	29.5	36.5	41	45.	24	25	21	39.5	24.5	43	45	37.5
	Washout	19	20.5	49	32	23.5	31	17.5	25	33.5	23	24	22	42.5	37.5	24	39	25	32.5	39.5	32.5	27.5	
	Neutral	26	38.5	56.5	37	49	35.5	30	23.5	25	25	29.5	26.5	26.5	20	20	19	34.5	24	21	18.5	21.5	20.5
08B/A	(withdrew)																						
09A/B	Pre Brace	39																					
	Valgus	5.5	8.5	6	5.5	5.5	6.5	4	7.5	3.5	5.5	4.5	8	9	7	5	6	6.5	9.5	6	6.5	7.5	8
	Washout	6	9	8	7	6	7	6	7	10	9.5	8	10.5	9	7.5	8.5	5.5	7.5	9	11.5	7	7.5	9.5
	Neutral	35	6	5.5	4	6.5	30.5	11	9	8	8	27.5	11.5	12	12.5	12.5	17.5	9.5	7.5	9.5	5.5	8.5	42
10B/A	Pre Brace	73																					
	Valgus	27	35	44	27	33.5	37	57	40.5	36	83	35	52	61	54	55	46	42.5	42.5	39.5	39.5	36.5	41.5
	Washout	61.5	60	57	61.5	62.5	64.5	70	62	72	77	83	66.5	53	67.5	60	71.5	66.5	73	72	78	81	
	Neutral	70.5	78.5	75	63.5	79.5	83.5	78	73	73	64	71.5	65	79	73	70	77	78	79.5	74	75	70	70
11A/B	Pre Brace	7																					
	Valgus	10.5	7.5	8.5	6.5	18.5	9.5	10	8	10.5	7.5	10	9.5	9	11.5	9.5	10.5	8	7.5	8.5	10.5	7	31
	Washout	11.5	10	9.5	9	10	11.5	11	10	9	9.5	9	8.5	10.5	9.5	9.5	8	37	10	32.5	10	8.5	
	Neutral	8	37.5	24	10	8.5	8.5	8.5	13.5	11	8.5	10.5	11	8.5	8	8.5	8	11	6	8.5	9.5	10	9.5

WOMAC Raw Data - Stiffness Subscale - page 2

103.5	95	47	54	89	103.5	82	57	93	117	123	109	95	61.5	67	50	65	82	65	63							
134	129	162	165	134	114	120	131	131	141.5	126	124.5	120	146	159	157	147	160.5	147.5	122	141.5						
46	43	48	66	77.5	70	41	53	59.5	61	79	59	63	67	89.5	71	110	82									
41	36	39	39.5	57	45	48	50.5	50	51	47	50	43	54	52	54	52	50.5									
70	77	88.5	57	63.5	60	58.5	*	*	*	*	*	109	76.5	53	45	86	85	67								
53.5	58	69.5	84	54	72	70	63	52	64.5																	
3.5	4	3	0	0	0	0	1.5	2	16	0	2.5	0.5	1.5	0.5	0.5	1.5	0	21.5								
7	3	3	3	3	3.5	4.5	3.5	3	4.5	4	5	3.5	4.5	3	6	4.5	6	5								
0.5	0.5	2	1	0	1	0	1.5	0.5	2	1.5	1	0.5	0	1.5	0.5	0.5	3	*	1							
66	46	67	71.5	99	87.5	67	72.5	48	65	100	119	84	56.5	52	65.5	51	50.5	53	61	54.5	61.5					
55.5	55.5	57	72.5	75	69	64.5	70.5	88.5	91	77	70	71.5	73	82	69	59	61	64.5	56.5	65	87.5					
26	26.5	36	37.5	31	30.5	15	23.5	29	26	31	14	19	16.5	14.5	13	17	9	17	12.5							
12.5	17	13	16	23.5	25	22	24	17	15.5	19.5	11	19	14	15.5	15	22	17.5	18.5	18							
32	24	48.5	24	55	35.5	42.5	35.5	28	72.5	34.5	77	30.5	28.5	44	42.5	46	32.5	39	30							
23.5	19	22.5	30	19	24.5	20.5	33	25	21	27.5	22.5	24.5	26.5	31.5	29.5	22	29	26	20							
7	6	5	4	5	7	6	7	7	3.5	6	6	11.5	10.5	8	7.5	7.5	5.5	5.5	6	6	5.5	6				
8	12																									
12	10	10.5	8.5	10.5	7.5	6.5	9	7.5	7	9	7	6	10	6.5	8	9.5	10.5	9	7.5							
41	41.5	55	55.5	56.5	57	46	44	44.5	54.5	44	51.5	47.5	56	57.5	60	61.5	54.5	48.5	55.5							
77	72	73	79.5	80.5	69.5	71	73.5	75	67.5	71.5	72.5	74	72	71.5	69	77.5	64.5	77	82.5	72.5	75	66.5	77.5	76.5	76	
9.5	8	9.5	9.5	8.5	10	9	8	7.5	7.5	9	8.5	19.5	9	11	9	10	10.5	11	9	8.5	10.5	9	9	11	10.5	7
9	9	11	9	8.5	11.5	9.5	9	9	8	10.5	10	9.5	8.5	7	11	9.5	8	8	9.5	10						

WOMAC Raw Data – Physical Function Subscale

Table 19. Numerical score (max=1700), individual raw data

01B/A	Pre Brace	679																					
	Valgus	542	284.3	*	*	531.9	472.4	475.5	394.2	*	495.3	*	303.7	283.9	421.3	336.8	370.8	302.8	358.6	309.7	664.1	678.4	464.8
	Washout	515	509	*	592.3	668	603	814	701	637	704	643.6	652.8	685.8	820.9	711.7	760	*	882	*			
	Neutral	*	*	*	662.4	*	685.7	738.4	*	721.3	675.2	793.3	796.7	808.6	*	803.5	1037	814.9	960.5	*	746.9	800.1	942.3
02B/A	Pre Brace	778																					
	Valgus	*	*	251	577.4	416.5	420.8	303.9	304.4	*	*	175.1	578.5	253.9	265.1	624.2	727.8	604.6	272	302.3	217.8	717.2	316.2
	Washout	334	313	352	331	372	395	384	362	395	386	419.2	424.5	497.8	419.2	418.1	438	501.5	478	454.5	414	456	
	Neutral	318.8	284.2	308.7	342.7	379.3	332.6	299.1	292.7	284.8	324.6	281	287.5	315.6	241.2	240.7	223.1	225.8	183.8	185.9	216.8	221	217.8
03A/B	Pre Brace	810.5																					
	Valgus	270.8	168.3	138.8	*	168.8	258.7	*	*	219.1	223.4	169.4	177.3	185.8	157.3	*	168.8	176.1	*	169.4	*	*	*
	Washout	*	*	*	*	204	194	186	219	245	222	316.9	*	*	*	404.3	360	327.5	376	460.1	478	443	358
	Neutral	606.5	*	631	*	536	507.5	471.5	473	467	440.3	483.9	260.7	317.3	373.5	550.8	*	*	253.4	336.6	273.6	215.7	178.5
04A/B	Pre Brace	463.8																					
	Valgus	10.5	12.5	8.5	13	20	12	12	11	9.5	6.5	8	5	9	15	14	13	14.5	15.5	13	17	17	15
	Washout	10	19	8	9.5	9	7.5	10.5	13	10	9	8.5	10	10.4	16.5	7	6.5	4.5	10.5	7	16	9.5	
	Neutral	386	273	124	133	82	151	150.5	82	103.5	51.5	48	38.5	57.5	43.5	32	27.5	19.5	14	13.5	17	11.5	7.5
05B/A	Pre Brace	360.5																					
	Valgus	391	438.5	441.5	515.5	313.5	339.5	602.5	546	374	319.5	338.5	368	419.5	483	463	407	639.5	404	507.5	652	612.5	414.5
	Washout	370	382	337	347	416	347	355	355	390	443	358	366.5	364.5	411.5	448.5	493	529.5	450	316	330	331	
	Neutral	359	357.5	350.5	375	316.5	294	289	353	414.5	460.5	297.5	726	842.5	858.5	720	560	518	493	383.5	368.5	353	385.5
06B/A	Pre Brace	264																					
	Valgus	191.5	238.5	138.7	114	140.8	120.2	170.6	164.9	160.9	179.1	195.5	126.9	157.8	137.1	162.6	91.7	202.5	123.5	178	140.3	92.4	129.1
	Washout	239	235	216	367.1	308	198	270	269	218	181	222.1	217.8	175.1	179.1	143.4	186	226.7	217	125.4	260	171	
	Neutral	146.9	204	115.4	125.8	128.1	247.6	159.4	127	120	93.5	196.6	174.5	227.2	93.5	97.5	149.3	141.3	162	124.8	143	131.5	111.1
07A/B	Pre Brace	682.1																					
	Valgus	399.5	343.7	235.7	342.7	331.5	327.3	244.4	224.4	325.1	355.9	341.6	281.6	372.9	332	309.7	236.3	273.1	269.7	252.9	346.9	260.3	364
	Washout	140	189	316	214.1	225	213	184	276	289	334	175.7	193.4	309.7	254.5	261.9	326	351.9	370	333.6	326	326	
	Neutral	380.4	392.1	548.3	527	502.2	514.3	250.8	244.9	278.4	302.3	216.2	234.3	246.5	210.4	210.9	168.4	184.9	215.2	195.5	195	158.8	177.4
08B/A	(withdrew)																						
09A/B	Pre Brace	172.5																					
	Valgus	241.5	228	388.5	310	295	314.5	262	217	179	216.5	184	216.5	164.5	180.5	147	144	161.5	211.5	163	281	374	268.5
	Washout	186	184	183	215.5	204	280	272	271	270	301	276	308.5	328	283.5	271.5	276	325.5	290	241.5	245	292	293
	Neutral	302.5	264	228.5	260	229	281	268	248	225.5	226	242	282	254.5	243	247.5	233	232	241	243.5	273	218.5	265.5
10B/A	Pre Brace	516.5																					
	Valgus	241	291.5	338.5	284	267.5	336.5	304	335.5	324.5	510.5	354.5	379	396.5	349.5	345	356.5	339	320	273.5	291	287	301
	Washout	322	327	331	335	312	359	362	302	363	387	353.5	341.5	328.5	350.5	354.5	357	356	389	459.5	545	406	
	Neutral	381.5	364.5	356	351	331	327	321.5	313.5	369.5	349	380	342.5	331.5	340.5	329	370	349	306	339.5	337.5	319	350
11A/B	Pre Brace	494																					
	Valgus	77	72.3	88.7	63.8	65.9	82.9	90.3	516.4	285.8	169.5	177	138.7	107.8	249.9	123.3	109	100.4	90.8	74.4	134.4	71.2	102
	Washout	86.1	84.5	79.7	79.7	90.8	87.1	79.7	95.6	78.6	72.3	74.4	65.3	82.9	71.2	73.8	75	150.3	77.6	141.8	78.5	87.1	
	Neutral	473.5	269.5	161.5	122.7	74.5	214	95.5	111.5	86	77.5	83	92.5	71.5	171.6	324.5	492.5	295.4	456.9	320.9	236.4	148.8	93

WOMAC Raw Data – Physical Function Subscale - page 2

464.1	*	421.8	410.1	431.8	445.7	469.9	393.7	428.4	*	*	*	461.3	*	445.7	437.1	423.9	*	380.9	427.1							
684.8|	701.5	*	*	712.9	811.8	*	876	724.2	*	*	851.1	*	1020	*	861.9	917.4	920.8	960.5	874.4	756.5						
362.3	293.3	386.2	431.9	490.3	451.6	355.2	296.4	338.4	320.9	331.5	338.9	367.6	405.9	429.8	417	411.2	371.9									
216.2	206.7	221.5	239.1	256.1	205.5	248.6	252.3	221	245.4	260.8	253.9	252.3	251.8	279.4	254.5	258.2	247.6									
179.1	318.1	241.6	262.4	241	251.4	264.7	*	*	*	*	*	447.5	278.1	234.4	391.6	401.8	356.43	351.16								
363.9	381	455	357	390	340.6	387	342	385	347.3																	
156.4	124.7	109.9|	*	95.3	136	221.5	56.8	43.1	51	51	50.4	86.8	68	31.6	*	*	*	*								
26.5	10	13	11.5	16.5|	16.5	15	18.5	19.5	18	26	29.5	12.5	23.5	20	29.5	22	25.5	29.5								
7	9.5	12.5	14	8	12	4.5	8.5	14.5	7.5	3	6.5	5	5	10.5	5.5	10.5	4.5	12.5	8.5							
395.5	356.5|	447.5	548	708	578.5	548	479	331.5	365	477.5	674	511.5	333	473.5	602	352.5	355.5	364.5	329.5	360	379					
313.5	302.5	274	338	320|	319.5	328.5	365.5	458	401	374	348.5	385.5	362.5	419	323	315.5	316	276	290	326.5	387.5					
135.43	146.3	215.3	268.6	180.2	199.8	134.3	115	172.1	209.7	227.4	109.9	160.3	166.4	134.8	143.9	146.2	109.9	108.2	130.9							
135.4	108.9	116.9	130.2	338.9	323	185.4	192.7	119	158.8	189.7	163.9	191.9	127.5	127.5	131.2	304.4	152.5	170.5	196.1							
325.7	336.3	321.9	470.3	377.4	391.6	339.5	323	365.5	351.3	481.1	370.3	268.3	358.6	330.4	406.9	375.1	353.3	307.1	301.8							
196	221.5|	200.8	251.3	264.6	244.9	269.3	224.7	227.4	272	225.8	243.8	215.7	227.8	227.4	212	220.4	214.1	179.6	213.6							
248.5	230.5	255	205.5	191	184	154.5	187	180.5	150.5	164	170	177	179	378.5	286.5	211	175	131	135.5	131.5	141.5	152				
372.5	365																									
221.5	204.5	236	238.5	289.5	299	254.5	243	228.5	223	214	207	177	173	175.5	239	185	212	197	220							
308.5	319.5	311.5	335	335.5	349	298.5	296.5	311.5	329.5	312	308	311.5	355	345.5	373.5	358	301	259	281.5							
327	339	333	342	355	355.5	345.5	314	309	306.5	308.5	296	334	302	342.5	303	341	324.5	290	284.5	295.5	308.5	312	306	332	345	
82.3	80.2	*	83.4	76.5	*	81.3	99.3	91.4	68	67.4	81.3	191.8	200.8	86.6	149.8	140.8	156	105	357.5	99.3	141.8	107.3	105	209	138	105.2
92	123	145	127	162.6	95	177.4	91.5	79.7	68.5	81.3	82.9	83.4	152.5	69.6	74.9	82.9	78.1	64.8	66.9	68						

Section A

INSTRUCTIONS TO PATIENTS

The following questions concern the amount of pain you have experienced due to arthritis in your study joint(s). For each situation please enter the amount of pain experienced in the last 48 hours. (Please mark your answers with an "X".)

QUESTION: How much pain do you have?

1. Walking on a flat surface.

No Pain |————————————————| Extreme Pain

2. Going up or down stairs.

No Pain |————————————————| Extreme Pain

3. At night while in bed.

No Pain |————————————————| Extreme Pain

4. Sitting or lying.

No Pain |————————————————| Extreme Pain

5. Standing upright.

No Pain |————————————————| Extreme Pain

PAIN1	______
PAIN2	______
PAIN3	______
PAIN4	______
PAIN5	______

Section B

INSTRUCTIONS TO PATIENTS

The following questions concern the amount of joint stiffness (not pain) you have experienced in the last 48 hours in your study joint(s). Stiffness is a sensation of restriction or slowness in the ease with which you move your joints. (Please mark your answers with an "X".)

6. How **severe** is your stiffness **after first awakening** in the morning?

No Stiffness |————————————————| Extreme Stiffness

7. How **severe** is your stiffness after sitting, lying or resting **later in the day**?

No Stiffness |————————————————| Extreme Stiffness

STIFF6	______
STIFF7	______

Section C

INSTRUCTIONS TO PATIENTS

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours due to arthritis in your study joint(s). (Please mark your answers with an "X".)

QUESTION: What degree of difficulty do you have?

8. Descending stairs.

No Difficulty |————————————————| Extreme Difficulty

PFTN8 ______

9. Ascending stairs.

No Difficulty |————————————————| Extreme Difficulty

PFTN9 ______

10. Rising from sitting.

No Difficulty |————————————————| Extreme Difficulty

PFTN10 ______

11. Standing.

No Difficulty |————————————————| Extreme Difficulty

PFTN11 ______

12. Bending to floor.

No Difficulty |————————————————| Extreme Difficulty

PFTN12 ______

13. Walking on flat.

No Difficulty |————————————————| Extreme Difficulty

PFTN13 ______

14. Getting in/out of car.

No Difficulty |————————————————| Extreme Difficulty

PFTN14 ______

15. Going shopping.

No Difficulty |————————————————| Extreme Difficulty

PFTN15 ______

16. Putting on socks/stockings.

No Difficulty ——— Extreme Difficulty

17. Rising from bed.

No Difficulty ——— Extreme Difficulty

18. Taking off socks/stockings.

No Difficulty ——— Extreme Difficulty

19. Lying in bed.

No Difficulty ——— Extreme Difficulty

20. Getting in/out of bath.

No Difficulty ——— Extreme Difficulty

21. Sitting.

No Difficulty ——— Extreme Difficulty

22. Getting on/off toilet.

No Difficulty ——— Extreme Difficulty

23. Heavy domestic duties.

No Difficulty ——— Extreme Difficulty

24. Light domestic duties.

No Difficulty ——— Extreme Difficulty

PFTN16 ____

PFTN17 ____

PFTN18 ____

PFTN19 ____

PFTN20 ____

PFTN21 ____

PFTN22 ____

PFTN23 ____

PFTN24 ____

THANK YOU FOR COMPLETING THE QUESTIONNAIRE