

# Unloader Knee Braces for Osteoarthritis: Do Patients Actually Wear Them?

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## Abstract

**Background** Unloader braces are a nonsurgical approach for predominantly unicompartmental knee arthritis. Although noninvasive, braces are expensive and it is unclear whether clinical factors, if any, will predict regular brace use. **Questions/purposes** We asked: (1) Do patients continue to use the unloader brace more than 1 year after it is prescribed? (2) Do any clinical or radiographic factors predict continued use of the unloader brace after the first year? (3) What are the most common subjective reasons that patients give for discontinuing the brace?

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**Methods** We administered 110 surveys to all patients who were fitted for unloader knee braces for predominantly unicompartmental osteoarthritis 12 to 40 months before administration of the survey. Standardized indications and fitting protocols were used. The following parameters were tested for association with ongoing brace use: alignment, arthritis severity, compartment involved, BMI, weight, age, gender, pain and function, number of refittings, and problems with the brace. The survey response rate was 81% (89 of 110). **Results** Of the 89 responders, 28% reported regular brace use (twice per week, an hour at a time, or more); at 2 years, 25% used the brace regularly. No clinical or radiographic factors considered were associated with ongoing brace use. Patients reported lack of symptomatic relief, brace discomfort, poor fit, and skin irritation as reasons for discontinuing the brace.

**Conclusions** Surgeons and patients need to balance the benefits and absence of complications of bracing against cost and the low likelihood of ongoing use 1 year or more after the prescription of the brace.

**Level of Evidence** Level III, prognostic study. See Instructions for Authors for a complete description of levels of evidence.

## Introduction

Knee arthritis is common, underreported, and increasing in prevalence [1, 3, 4, 15]. In 2009, surgeons performed 686,000 knee arthroplasties [13]; projections going forward predict 1.52 million procedures in 2020 and 3.48 million procedures in 2030 [13]. The revision burden, likewise, continues to mount; a 600% increase in revision procedures is expected by 2030 [13]. With numbers like these, any promising nonsurgical approach deserves careful evaluation.

NSAIDs, injections, and narcotic analgesics are in common use, but each of these has disadvantages. The use of NSAIDs frequently is limited by gastrointestinal and renal side effects, especially in the elderly [19]. A recent meta-analysis investigating the benefit of injections concluded intraarticular steroid injections could provide pain relief for knee osteoarthritis up to 1 year and hyaluronate was beneficial specifically in patients who are poor surgical candidates and have mild radiographic disease [7].

Arthritis unloader braces provide a low-risk intervention for selected patients. One randomized clinical trial compared medical management, neoprene sleeves, and valgus unloader knee braces, and found improved disease-specific quality of life and function scores in patients using neoprene sleeves and in those using unloader braces, but only trends toward improvement in aggregate WOMAC<sup>TM</sup> scores compared with patients who received medical management alone [12]. In addition, patients wearing unloader knee braces had reduced pain compared with patients wearing neoprene knee sleeves in 6-minute walking and 30-second stair-climbing tests [12]. In a selected literature review on knee bracing for unicompartamental osteoarthritis, Pollo and Jackson [16] cited studies showing improvement in pain scores with brace wear, improved stride symmetry, and a decreased varus moment in valgus-braced knees. No clinical studies regarding brace compliance were available for review at the time of that report, but the authors cited compliance greater than 75% in their own clinic population. The authors concluded, "Evidence supports the clinical efficacy of bracing for managing osteoarthritis of the knee." In contrast, the 2009 the American Academy of Orthopaedic Surgeons Clinical Practice Guideline for knee arthritis concluded that the literature provided insufficient evidence to recommend for or against the use of varus- or valgus-producing unloader knee braces [18].

Several studies on brace compliance differ in terms of whether patients continue to use the unloader brace with time. One study in a Veterans Affairs population evaluated brace use in 48 men and one woman with an average age of 57 years and found 76% of patients used the brace at least once weekly at 1 year and 69% at 2 years [10]. Another study reported improvements in pain relief in patients wearing the brace longer than 8 weeks, but despite this relief, compliance with brace use at a mean of 2.7 years was only 42% [2]. That same group of patients was recontacted in a followup study; none continued to use the brace at 11 years [21]. A Cochrane review from 2005 concluded that braces have some (albeit limited) efficacy for treatment of medial compartment osteoarthritis and little long-term use [5]; an additional study in 2006 found 42% of subjects discontinued brace use within the 12-month trial period, 88% of whom discontinued the brace within the first 6 months [6]. Given the disparate findings pertaining to ongoing brace use—from 0% to 76%—we sought to look specifically at patient use (or lack of use) of

unloader braces. Patient compliance is important because of the cost of these braces; although unloader braces do not carry much risk (there is a single case reported associating pulmonary embolism and deep venous thrombosis with brace use [10]), these braces are expensive. The patient charge for one kind of brace is nearly USD 1800 at our institution. By comparison, the professional fee for a knee arthroplasty for a Medicare patient is approximately USD 1450 [9].

We therefore asked three study questions: (1) Do patients continue to use the unloader brace more than 1 year after it is prescribed? (2) Do any clinical or radiographic factors predict continued use of the unloader brace after the first year? (3) What are the most common subjective reasons that patients give for discontinuing the brace?

## Patients and Methods

Surveys were administered to all patients who underwent initial fitting for an unloader knee brace from October 2007 to June 2010. All patients initially seen for knee OA during the study period regardless of severity were offered an unloader brace (Össur Americas, Foothill Ranch, CA, USA) as part of the nonoperative approach. The indications for brace use were predominantly medial or lateral radiographic osteoarthritis, or pain clinically correlating with the most involved compartment on weightbearing radiographs. The contraindications for brace prescriptions were superficial wounds, arterial insufficiency, or severe varicosities that could result in skin at risk with regular brace wear. Weight, BMI, radiographic severity, and limb alignment (varus or valgus) were not used as contraindications to offering patients the brace as an option during this period. Patients were free to decline the brace prescription. We sent postal surveys to all 110 patients fitted for an unloader brace during the period in question; patients could actively opt out of any specific question or the study in entirety by mail, over the phone, or simply by nonresponse. Brace fitting occurred at a mean 24 months (range, 12–40 months) before the survey was mailed. The survey response rate was 81% (89 of 110). The mean age for survey responders was 63 years (SD, 9.4 years), and the mean BMI was 28 (SD, 5.6). The population was 52% male and 48% female; 59% had predominantly varus alignment and 68% had predominantly medial compartment involvement (Table 1).

The same surgeon (SSL) wrote all the brace prescriptions. All braces were fitted by the same experienced orthotist, who fits approximately 160 braces per year and has worked clinically on a referral basis with the senior investigator (SSL) since 2007. The orthotist is not associated with the referring institution or the referring surgeon in any other way. All patients were fitted using the same family of braces and the same guiding principle for proper fit: neutral alignment or the smallest amount of unloading that generated a level of

**Table 1.** Demographics of survey responders

| Variable                   | Value            |
|----------------------------|------------------|
| Age (years)*               | 63 ± 9.4 (43–83) |
| BMI*                       | 28 ± 5.6 (20–50) |
| Weight (kg) *              | 86 ± 20 (50–145) |
| Sex                        |                  |
| Male                       | 52%              |
| Female                     | 48%              |
| Radiographic alignment     |                  |
| Varus                      | 59%              |
| Valgus                     | 26%              |
| Neutral                    | 15%              |
| Most involved compartment  |                  |
| Medial                     | 68%              |
| Lateral                    | 32%              |
| Arthritis severity (1–3)** |                  |
| Medial compartment         | 2.39 ± 0.86      |
| Lateral compartment        | 1.66 ± 0.88      |
| Patellofemoral compartment | 1.26 ± 0.49      |

\* Values are expressed as mean ± SD, with range in parentheses;

\*\* modified Kellgren-Lawrence scale as follows: Grade 1, minimal to no osteophytes or joint space narrowing; Grade 2, osteophytes and/or moderate joint space narrowing (Kellgren-Lawrence Grade 1 or 2); and Grade 3, severe joint space narrowing (Kellgren-Lawrence Grade 3 or 4).

symptomatic relief that the patient found satisfactory, whichever correction was smaller. Off-the-shelf braces were used when possible; custom-fit braces were used when necessary, usually based on the size or alignment of the limb. All patients were instructed to return to the orthotist as needed for refittings without charge. All patients were offered a trial of the brace and were encouraged to return it at no cost within 30 days for any reason. Of the 110 patients who received a survey, 88 patients (80%) had been fitted for a custom-fitted unloader brace and 22 (20%) for an off-the-shelf brace.

We encouraged patients to use various nonsurgical approaches; the menu of nonoperative cotreatments we used included infrequent use of NSAIDs and nonnarcotic analgesics, a recommendation against narcotic analgesics, occasional use of intraarticular corticosteroid injections and/or viscosupplementation injections, assistive devices for ambulation when necessary, weight control, and reasonable activity modifications. In our study, we sought neutral alignment or the smallest coronal-plane correction that provided symptomatic relief. This approach is supported by the work of Ramsey et al. [17] who evaluated the mechanics of brace efficacy in 16 patients with medial compartment osteoarthritis; that group used gait analysis and compared bracing with neutral alignment to an over-correction of 4° valgus and found the smaller correction to result in better pain scores, knee function, and gait.

The survey asked about current and past brace use, knee pain, function, satisfaction with the brace, and problems related to use of the brace, such as skin irritation or knee swelling. The mailed cover letter and survey were intentionally designed to minimize bias in responses. (Appendix 1). We defined regular brace use as at least an hour a day, at least 2 days a week. Two weeks after the survey was mailed, patients who did not respond to the survey were contacted by telephone. All patients were given the option of declining to participate and could do so by telephone, by email, or by returning a postage-paid form indicating their desire to be excluded from the study.

We determined height, weight, age, BMI, and sex by chart review. We determined the severity and pattern of knee arthritis by radiographic review; arthritis severity in the most-involved compartment was one variable considered, but we also investigated the potential impact of radiographic changes in the less-involved (or uninvolved) compartments. Radiographs were independently analyzed by two reviewers (ES, DLS); discrepancies were adjudicated when necessary by a third reviewer (SSL). Arthritis severity was determined using standing AP and Rosenberg views and a patellar sunrise view. Arthritis was graded in the medial, lateral, and patellofemoral compartments using a modification of the Kellgren-Lawrence grading system [11] as follows: Grade 1, minimal to no osteophytes or joint space narrowing; Grade 2, osteophytes and/or moderate joint space narrowing (Kellgren-Lawrence Grade 1 or 2); and Grade 3, severe joint space narrowing (Kellgren-Lawrence Grade 3 or 4). Limb alignment was characterized as varus, valgus, or neutral on standing films.

Descriptive statistics of available responses and data were used for primary data explorations and comparisons. Logistic regression was used to determine whether respondent attributes (BMI, weight, age, sex, radiographic severity, limb alignment) were associated with the likelihood of using a brace for 3, 6, and 12 months. A two-tailed Fisher's exact test was used to determine whether a difference in brace use was associated with an increased maximum walking distance. We performed statistical analysis using PASW® Statistics 18 (IBM Corp, Armonk, NY, USA).

## Results

Only 25 (28%) of the 89 patients continued to use the brace regularly more than 1 year after brace fitting (Table 2); mean followup for these patients was 24 months (range, 13–40 months). Of the 40 patients receiving a brace more than 2 years before the survey, 10 (25%) reported continued regular brace use. Of the 14 patients receiving a brace more than 3 years before the survey, three (21%) reported

**Table 2.** Brace use through time (months since brace fitting)

| Months since fitting | Number of surveys completed | Number of braces in use |
|----------------------|-----------------------------|-------------------------|
| > 12                 | 89                          | 25 (28%)                |
| > 24                 | 40                          | 10 (25%)                |
| > 36                 | 14                          | 3 (21%)                 |

**Table 3.** Association of use longer than 1 year with improved walking range

| Walking range improved greater than twice the range without the brace? | Number of patients          |          | p value |
|--|-----------------------------|----------|---------|
|  | Brace used at least 1 year? |          |         |
|  | No                          | Yes      |         |
| No   | 23 (68%)                    | 7 (24%)  | < 0.001 |
| Yes  | 2 (5.8%)                    | 22 (76%) |         |

Nine patients reported not having used their brace enough to comment; remaining surveys (26) submitted with this question omitted.

continued regular brace use. Nine of 89 patients (10%) who did not meet our definition of regular brace users reported more occasional brace use (once per week, an hour at a time). Most patients did not use their braces much, if at all, beyond the 1-month trial period: of the patients who discontinued use of the brace at less than a year, 26% reported never having used the brace regularly, and 39% did so for less than 3 months. In aggregate, then, 65% of the patients fitted for braces did not use them even for 3 months.

None of the potential predictor variables we analyzed (BMI, weight, age, sex, radiographic severity, limb alignment) were associated with brace use or discontinuation. Several subjective parameters from the survey were associated with brace use. Patients who described at least a considerable improvement in walking range (defined as more than twice the walking range than without the brace) were more likely ( $p < 0.001$ ) to continue to use the brace beyond 1 year. By contrast, patients who enjoyed smaller subjective improvements in function (less than doubling of walking range) were more likely to discontinue brace use before 1 year (Table 3).

Patients cited numerous subjective factors that led to brace discontinuation. Those who did not wear the brace for 1 year were more likely to describe difficulties with the brace than patients who continued to use the brace. Problems patients reported in the survey included skin irritation/swelling, poor fit, lack of symptomatic relief, difficulty donning/doffing brace, difficulty wearing with clothing, and heaviness/bulkiness of brace (Table 4). All patients were invited to return to have the brace readjusted as many times as needed at no charge; interestingly, of the patients who required two or more fittings, only 23% (three of 13)

**Table 4.** Self-reported aspects of brace that prevented greater use

| Brace aspect   | Number of patients          |              |
|--|-----------------------------|--------------|
|  | Brace used at least 1 year? |              |
|  | No (n = 42)                 | Yes (n = 20) |
| The brace causes skin irritation or swelling   | 17 (40%)                    | 4 (20%)      |
| The brace does not fit well enough or was too uncomfortable  | 25 (60%)                    | 2 (10%)      |
| The brace does not help my symptoms enough to make it worth wearing                                    | 21 (50%)                    | 2 (10%)      |
| The brace is hard to put on/take off   | 7 (17%)                     | 0            |
| The brace is too hard to wear with the clothes that I wanted to wear for the activities I wanted to do | 13 (31%)                    | 6 (30%)      |
| The brace is too heavy or too bulky  | 14 (33%)                    | 4 (20%)      |

Remaining surveys (27) submitted with this question omitted.

used the brace for a full year. By contrast, of the patients who needed the brace readjusted only once or not at all, 43% (26 of 60) used the brace for a full year. This suggests some patients may be easier to fit than others; however, we were unable to identify any factors associated with a patient who would find the brace helpful.

**Discussion**

Unloader braces are a possible nonsurgical approach for predominantly unicompartmental knee arthritis. Although noninvasive, braces are expensive, and little is known about which clinical factors, if any, are associated with regular, ongoing brace use. We therefore asked three study questions: (1) Do patients continue to use the unloader brace more than 1 year after it is prescribed? (2) Are there clinical or radiographic factors that predict continued use of the unloader brace after the first year? (3) What are the most common subjective reasons that patients give for discontinuing the brace?

Our study has some limitations. First, our study is subject to recall bias in terms of the subjective elements of the survey, as it required patients to recall the reasons for discontinued use of a brace that was prescribed anywhere from 6 to 38 months before. However, the survey should provide reasonably accurate appraisal of how many patients continued to use the brace and, for those who did not continue use, approximately when they discontinued its use. Second, we were unable to measure femorotibial angle on available weightbearing radiographs; hip-to-ankle

radiographs were not available for all patients, as we are the referral center for five states, and patients come with outside radiographs taken with variable techniques. However, all patients had weightbearing views, and we were able to classify the patients according to broad classifications of alignment (varus, neutral, and valgus), and the Kellgren-Lawrence scale provided an established and generally accepted approach for grading osteoarthritis severity [11]. Third, we had no control or comparison group. This limitation would be more important in a study on brace efficacy; it is less critical in an “open label” study on brace compliance. We believe that there is a placebo effect at work here; patients knew they were receiving an intervention, and they had agreed to it. The 1-year compliance rate of 28% effect was considered; one surgical trial resulted in a placebo-related improvement of 37% in patients with angina pectoris [8], and an even larger subset of patients reported a response to sham arthroscopic surgery [14].

Our finding of only approximately one in four patients continuing to use the brace regularly for more than a year may represent a best-case scenario, for the brace, in that we used only one experienced orthotist who communicated regularly with the prescribing surgeon, gave all patients a no-charge 1-month trial with the brace, invited the patients to have free refittings as needed, and permitted cotreatments (including joint injections and nonnarcotic analgesics) as desired by the patients. We surmise patients who declined to participate in the survey were more likely to be unhappy with the brace treatment, as there are data to suggest health states of nonresponders are lower than those of responders in survey studies [20], again emphasizing, if anything, our results represented a best-case estimate of success with the unloader brace. Other studies have varied in terms of reported compliance rates with time. One followup survey of patients previously prescribed braces reported that 41% of 30 patients were using the brace at 2.7 years, where use was defined as an average of 5 hours per day for work or weightbearing activity [2]; when those

patients (n = 29) were resurveyed at an average of 11.2 years followup, none were using the brace [21]. Another study, in a population of military veterans, found 76% of patients were still using the brace at least once a week after a year [10]. It is difficult to account for the variation among the studies. Our study used a stricter definition of brace use (twice a week, compared with once a week) than the others, and perhaps access-to-care issues associated with the managed-care population accounted for the high estimate in the Veterans Affairs study; our patients generally were commercially insured or insured through Medicare. Perhaps patients in our study believed they had more treatment choices and shorter waiting times for care than patients in a Veterans Affairs system, making them more likely to self-discontinue brace use; however, this explanation is speculative. In any case, the study in veterans [10] offered the highest estimate of ongoing use that we found in the literature.

We were unable to identify any patient or radiographic factors, such as sex, age, BMI, limb alignment, or arthritis severity that predicted use or discontinued use of the brace. Our patient population is in many ways similar to other populations studied in the brace literature in terms of age, BMI, and radiographic arthritis severity (Table 5). Our sample size of patients prescribed braces is larger than samples in the other published studies on the subject. The study by Giori [10], like ours, concluded that continued brace use was not associated with weight, BMI, or the primary compartment affected by osteoarthritis, although Giori did find that patients younger than 50 years had better brace compliance than patients older than 65 years. Brouwer et al. [6] claimed a nonsignificant trend toward better patient function and pain relief with unloader braces in younger patients. It is possible, therefore, that differences in the patient population studied—in this instance, age—may affect compliance with brace use, but the data are far from conclusive on this point.

Not surprisingly, patients in our study who reported substantial improvement in comfortable walking range

**Table 5.** Comparison of published populations undergoing unloader bracing

| Study               | Sample size (number of patients) | Age (years) | BMI   | Arthritis severity | Brace compliance | Followup (years) |
|---------------------|----------------------------------|-------------|-------|--------------------|------------------|------------------|
| Giori [10]          | 46                               | 57          | 32    | 2.96               | 76%, 68%, & 61%  | 1, 2, & 3        |
| Kirkley et al. [12] | 41                               | 59          | ≤ 35* | 3.39               | NA               | 0.5              |
| Brouwer et al. [6]  | 60                               | 59          | 28    | NA                 | 58%              | 1                |
| Barnes et al. [2]   | 30                               | 57          | 29    | 2.84               | 41%              | 2.7              |
| Wilson et al. [21]  | 29                               | 66          | 29    | 3.06               | 0%               | 11.2             |
| Current study       | 89                               | 63          | 28    | 2.88**             | 28%, 24%, & 21%  | 1, 2, & 3        |

\* Average BMI not listed; however, BMI > 35 was an exclusion criteria for this study; \*\* arthritis severity of current data was obtained using a modified Kellgren-Lawrence grade as described and normalized here to a 4-point scale for comparison.



(doubling of that range or more) and fewer difficulties with the brace, such as skin irritation or difficulties using the brace with clothing, were more likely to continue using the brace. Brouwer et al. also noted cited lack of effect (15/25), skin irritation (2/25), and poor fit (2/25) as reasons for discontinuation of brace use before 12 months [6].

Our results may serve as hypothesis-generating pilot data for a prospective trial to evaluate clinical- and/or cost-efficacy of unloader braces. Insofar as these braces are expensive, we believe that such a study is warranted; charges to patients' insurance for the braces used in this study were USD 849 for an off-the-shelf single-hinge unloader knee brace, and USD 1780 for a custom single-

hinge unloader knee brace. We now counsel our patients who are considering use of an unloader brace that the likelihood they will still be using the brace is approximately one in four. We continue to offer the unloader brace as part of a comprehensive approach to nonsurgical treatment of patients whose arthritis pattern is predominantly unicompartmental; however, our findings make us less sanguine that the brace will serve as a durable intervention, and we are candid with our patients about the relatively low likelihood that a brace, once fitted, will remain in service beyond the first year of use.

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## Appendix 1. Study Information Letter Survey



Dear           (patient's name)          ,

We invite you to participate in a research survey for the Department of Orthopaedics at the University of Washington. The survey is about the use of knee braces for arthritis.

We ask for your participation because our records show that have been prescribed and fitted for an unloader knee brace in the past. Your experiences with this brace are very important to us; the information we learn from you can affect the treatment of other patients with arthritis like yours. We want to see if and how patients with arthritis use, or do not use, unloader knee braces after they've been prescribed. Your participation is voluntary. Whether or not you agree to be in this study will not affect your future health care in any way. You may skip any question.

This simple survey should take no more than 5 or 10 minutes of your time. The type of question we will ask is: On average, over the last month, how often do/did you wear the brace? If for some reason you do not want to participate, please let us know. You can call us, return the page at the end of the survey, or send an email to Leslie Meyer at meyerla@u.washington.edu, and we will not contact you again about the survey. In appreciation for your time, we will mail you a \$5 Starbucks gift card after your survey has been completed by mail or phone.

All of your answers below will be kept confidential and your name and other identifying information will be separated from the research data itself. The link connecting your name to your survey answers will be stored in a separate, secured location until July, 2016. Then we will destroy the link. If the results of this study are published or presented, we will not use your name. Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

For your convenience, we have provided a self-addressed, postage-paid envelope to mail back the completed survey. We will also call you in a few weeks, at which time you may complete the survey by phone if you prefer.

Thank you very much for your consideration!

**Appendix 1** continued

Study number: XXXXXX

Please tell us about yourself:

Age: \_\_\_\_\_

Gender (circle): Male Female

Which knee is involved?(circle): Right Left Both Knees

Where is your knee pain?(circle):

Inside of knee, Outside of knee, Entire knee

Please answer the following questions as best as you can.

- 1.) On average, over the last month, how often do/did you wear the brace?
  - a. Never
  - b. Once a week or less
  - c. Two to six days per week, for an hour or more
  - d. Daily, for an hour or more
  
- 2.) If you answered "never" to the previous question, how long did you use your brace for, before stopping its use? (We define "use" as at least an hour a day, at least two days per week)
  - a. I never used it that much
  - b. I used it for less than 3 months
  - c. I used it for 3 to 6 months
  - d. I used it for 6 months to a year
  - e. I used it for one year or more
  
- 3.) Did you previously or do you currently wear the brace because pain limits your ability to walk on level ground?
  - a. Yes (please go to question 4)
  - b. No

If no, please indicate why do/did you use it, and then please skip question #4.

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- 4.) Please describe how the brace changed your ability to walk.
  - a. The brace improves/did improve my comfortable walking range a little bit (up to 50%)
  - b. The brace improves/did improve my comfortable walking range moderately (more than 50%, but less than twice my range without it)
  - c. The brace improves/did improve my comfortable walking range considerably (with the brace, I could walk more than twice as far than I could without it, but still I was not unlimited in my walking)
  - d. With the brace, I could/can now walk any distance without limitation from knee pain
  - e. I don't currently/never did wear the brace enough to comment

**Appendix 1** continued

- 5.) Have you had your knee replaced, or do you have definite plans to do so (e.g. a surgical date)?
- Yes
  - No (if no, please skip question #6)
- 6.) If you've had your knee replaced or have plans to do so, how many months were/will be between receiving your brace and total knee surgery?
- 6-12 months
  - Less than 6 months,
  - 1-2 years,
  - 2 years or more
- 7.) Which, if any, activities were/are easier while wearing the brace? (Please circle as many as apply)
- Household activities
  - General shopping and errands outside of the house
  - Walking, hiking, other forms of exercise
  - Other (list): \_\_\_\_\_
  - None
- 8.) Does anything prevent you from wearing the brace more often?
- Yes
  - No (if no, please skip question #9)
- 9.) If any factors prevent you from wearing the brace more often, circle as many as apply.
- The brace is too heavy or too bulky
  - The brace is hard to put on / take off
  - The brace causes skin irritation or swelling
  - The brace is too hard to wear with the clothes that I wanted to wear for the activities I wanted to do
  - The brace does not fit well enough or was too uncomfortable
  - The brace caused a blood clot
  - The brace does not help my symptoms enough to make it worth wearing
  - Other (please list): \_\_\_\_\_
- 10.) If the brace did not fit well, how many times after the first fitting of the brace did you return to the brace specialist to get it re-fitted?
- I did not try to get the brace re-fitted
  - Once
  - Twice
  - More than twice
- 11.) Would you (or have you) recommended the brace to a friend with knee arthritis?
- Yes
  - No
- 12.) Looking back, would you choose to undergo treatment with the brace again?
- Yes
  - No



**Appendix 1** continued

- 13.) Do you use any of the following to treat your knee arthritis (circle all that apply).
- Over the counter medications
  - prescription arthritis medication: naproxen, celebrex, etc
  - Corticosteroid knee injections
  - Synvisc, Suparts, Orthovisc or other viscosupplementation knee injections,
  - cane or walking stick
  - narcotic pain killers (vicoden, oxycodone, etc)
  - Other (please list): \_\_\_\_\_
- 14.) Is there anything else you would like to tell us about your experience with the brace? If so, please use the space below to do so.

Thank you for your participation in this study!

**Unloader Brace Study**

I would prefer not to participate in this study. I understand that my medical care will not be affected regardless of whether I participate or not.

Thank you for your consideration.

Your Name (Please Print): \_\_\_\_\_

Study Number: XXXXXX

**References**

- Altman RD. Overview of osteoarthritis. *Am J Med.* 1987;83:65–69.
- Barnes CL, Cawley PW, Hederman B. Effect of CounterForce brace on symptomatic relief in a group of patients with symptomatic unicompartmental osteoarthritis: a prospective 2-year investigation. *Am J Orthop (Belle Mead NJ).* 2002;31:396–401.
- Bijlsma JW, Berenbaum F, Lafeber FP. Osteoarthritis: an update with relevance for clinical practice. *Lancet.* 2011;377:2115–2126.
- Blagojevic M, Jinks C, Jeffery A, Jordan KP. Risk factors for onset of osteoarthritis of the knee in older adults: a systematic review and meta-analysis. *Osteoarthritis Cartilage.* 2010;18:24–33.
- Brouwer RW, Jakma TS, Verhagen AP, Verhaar JA, Bierma-Zeinstra SM. Braces and orthoses for treating osteoarthritis of the knee. *Cochrane Database Syst Rev.* 2005;1:CD004020.
- Brouwer RW, van Raaij TM, Verhaar JA, Coene LN, Bierma-Zeinstra SM. Brace treatment for osteoarthritis of the knee: a prospective randomized multi-centre trial. *Osteoarthritis Cartilage.* 2006;14:777–783.
- Cheng OT, Souzdamnitski D, Vrooman B, Cheng J. Evidence-based knee injections for the management of arthritis. *Pain Med.* 2012;13:740–753.
- Dimond EG, Kittle CF, Crockett JE. Evaluation of internal mammary artery ligation and sham procedure in angina pectoris. *Circulation.* 1958;18:712–713.
- Foran JR, Sheth NP, Ward SR, Della Valle CJ, Levine BR, Sporer SM, Paprosky WG. Patient perception of physician reimbursement in elective total hip and knee arthroplasty. *J Arthroplasty.* 2012;27:703–709.
- Giori N. Load-shifting brace treatment for osteoarthritis of the knee: a minimum 2½ year follow-up study. *J Rehabil Res Dev.* 2004;41:187–194.
- Kellgren JH, Lawrence JS. Radiological assessment of osteoarthritis. *Ann Rheum Dis.* 1957;16:494–502.
- Kirkley A, Webster-Bogaert S, Litchfield R, Amendola A, MacDonald S, McCalden R, Fowler P. The effect of bracing on varus gonarthrosis. *J Bone Joint Surg Am.* 1999;81:539–548.
- Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone Joint Surg Am.* 2007;89:780–785.
- Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med.* 2002;347:81–88.
- Niu J, Zhang YQ, Torner J, Nevitt M, Lewis CE, Aliabadi P, Sack B, Clancy M, Sharma L, Felson DT. Is obesity a risk factor for progressive radiographic knee osteoarthritis? *Arthritis Rheum.* 2009;61:329–335.
- Pollo FE, Jackson RW. Knee bracing for unicompartmental osteoarthritis. *J Am Acad Orthop Surg.* 2006;14:5–11.
- Ramsey DK, Briem K, Axe MJ, Snyder-Mackler L. A mechanical theory for the effectiveness of bracing for medial compartment osteoarthritis of the knee. *J Bone Joint Surg Am.* 2007;89:2398–2407.

18. Richmond J, Hunter D, Irrgang J, Jones MH, Levy B, Marx R, Snyder-Mackler L, Watters WC 3rd, Haralson RH 3rd, Turkelson CM, Wies JL, Boyer KM, Anderson S, St Andre J, Sluka P, McGowan R; American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee (nonarthroplasty). *J Am Acad Orthop Surg*. 2009;17:591–600.
19. Rosneck J, Higuera C, Tadross N, Krebs V, Barsoum W. Managing knee osteoarthritis before and after arthroplasty. *Cleve Clin J Med*. 2007;74:663–671.
20. Suominen S, Koskenvuo K, Sillanmäki L, Vahtera J, Korkeila K, Kivimäki M, Mattila KJ, Virtanen P, Sumanen M, Rautava P, Koskenvuo M. Non-response in a nationwide follow-up postal survey in Finland: a register-based mortality analysis of respondents and non-respondents of the Health and Social Support (HeSSup) Study. *BMJ Open*. 2012;2:e000657.
21. Wilson B, Rankin H, Barnes CL. Long-term results of an unloader brace in patients with unicompartmental knee osteoarthritis. *Orthopedics*. 2011;34:e334–e337.