

# Improvement in Quality of Life with Use of an Unloader Knee Brace in Active Patients with OA: A Prospective Cohort Study

Karen K. Briggs, M.P.H., M.B.A.<sup>2</sup> Lauren M. Matheny, B.A.<sup>2</sup> J. Richard Steadman, M.D.<sup>1</sup>

<sup>1</sup>The Steadman Clinic, Steadman Philippon Research Institute, Vail, Colorado

<sup>2</sup>Clinical Research Department, Steadman Philippon Research Institute, Vail, Colorado

**Address for correspondence and reprint requests** Karen K. Briggs, M.P.H., M.B.A., Clinical Research Department, Steadman Philippon Research Institute, 181 W. Meadow Drive, Suite 1000, Vail, CO 81657 (e-mail: Karen.Briggs@sprivail.org).

J Knee Surg 2012;25:417–422.

## Abstract

The purpose of this study was to determine if short form (SF)-12 physical component would increase with unloader brace use. Patient expectations and predictors of significant improvement were determined. Our hypothesis was that patients with unloader braces will have increases in general physical health (SF-12) and function (Western Ontario and McMaster Universities Arthritis Index [WOMAC]). Patients were enrolled in institutional review board-approved prospective cohort study. They completed a self-administered questionnaire (SF-12; WOMAC, Tegner activity scale, expectations) at enrollment, 3 weeks, 6 weeks, and 6 months. In this study, 39 patients, 23 males and 16 females (average age = 61 years [range 44 to 87]), were prescribed an unloader brace. Patients had significant improvement in quality of life (SF-12) ( $p < 0.05$ ). There was significant improvement in pain, stiffness, and function (WOMAC) ( $p < 0.05$ ). Patients who reported Tegner of 3 or greater at final follow-up had significantly higher SF-12 physical component (48 vs. 37;  $p = 0.023$ ). Return to recreational sports was very important in 83% and somewhat important in 17%. Improving ability to walk was very important in 89%. Pain relief was very important in 69%, somewhat important in 17%. Of these, 39% expected most pain to be relieved and 57% expected all pain to be relieved. The most important expectations were to have confidence in knee (97% very important), avoid future knee degeneration (90% very important), and improve ability to maintain general health (93% very important). Patients demonstrated a significant decrease in pain and disability. Patients saw improvement in SF-12 physical component. Braces specifically designed to unload the degenerative compartment of the knee can be an effective treatment to decrease pain and maintain activity level to increase overall physical health.

## Keywords

- ▶ knee
- ▶ osteoarthritis
- ▶ quality of life

Osteoarthritis (OA) is a major cause of disability in the United States, currently affecting ~27 million Americans.<sup>1</sup> At age 45, OA prevalence increases greatly, and this year it is estimated that 78 million “baby boomers” will reach the age of retirement,<sup>2</sup> only increasing the amount of people who suffer from this debilitating disease.

Knee OA has been shown to cause significant pain and disability, which can lead to limitations in daily activities and a sedentary lifestyle.<sup>3–6</sup> It is estimated that 25% of people with knee OA have trouble with major activities of daily living, including walking, kneeling, and stair climbing, as well as activities in the workplace.<sup>7,8</sup> Previous studies have shown

received  
March 16, 2011  
accepted after revision  
December 28, 2011  
published online  
May 21, 2012

Copyright © 2012 by Thieme Medical Publishers, Inc., 333 Seventh Avenue, New York, NY 10001, USA.  
Tel: +1(212) 584-4662.

DOI <http://dx.doi.org/10.1055/s-0032-1313748>.  
ISSN 1538-8506.

that as limitations are placed on activities of daily living, quality of life decreases.<sup>9–12</sup> Patients who were diagnosed with OA reported significantly lower levels of quality of life; however, when physical activity was completed on a weekly basis, significant improvement in short form (SF)-12 scores were seen.<sup>13–15</sup>

As physical activity has been shown to have an effect on patients with OA, it is important for early diagnosis. Previous studies have shown that within 6 months of receiving a diagnosis of knee OA, patients made several lifestyle changes, often without the advice of a health professional and saw improvements in pain and function.<sup>16</sup> By providing treatment options early enough to patients with knee OA, patients are more able to manage the progression of OA, rather than simply tolerating it.<sup>4,17</sup>

Some surgical treatments have been developed for patients with knee OA; however, many patients do not wish to undergo surgery for various reasons. Nonsteroidal anti-inflammatory drugs (NSAIDs) have been shown to be a popular conservative treatment due to their ability to decrease pain; however, the biomechanical elements of the knee remain unchanged and the effects of long-term use unclear.<sup>17,18</sup>

Bracing, however, is a conservative treatment option for patients who suffer from knee OA, but wish to remain active. Unloader braces are specifically designed to decrease the load on the degenerative compartment of the knee to improve function and decrease symptoms related to malalignment and OA.<sup>19,20</sup> A recent literature review looked at 16 studies and concluded that unloader braces are generally effective at increasing function and decreasing pain within the first few months.<sup>21</sup> Previous studies have shown a correlation between physical activity and general health (SF-12 physical component); however, this has not been documented for use of unloader braces in the OA knee.<sup>22,23</sup> The SF-12<sup>®</sup> (Quality Metric, Lincoln, RI) health-related quality of life scale is an outcome measure of general health, with two components, both physical and mental. The goal of unloader bracing in an OA patient is to maintain activity, in an overall effort to maintain general physical health. By documenting general physical health, as well as patient activity and functional levels, we are able to determine the overall benefit of specific treatments, to the patient's overall health.

The purpose of this study was to determine if the physical component of the SF-12 would improve with lateral and medial unloader brace use. In addition, we determined patient expectations and improvement in function. Our hypothesis was that patients with lateral and medial unloader braces would have increased physical health as documented by SF-12, physical component and improvement (Western Ontario and McMaster Universities Arthritis Index [WOMAC] score).<sup>24</sup>

## Methods

Patients were enrolled in an institutional review board–approved prospective cohort study. Patients were excluded if they had any arthroplasty in the knee, or moderate to severe OA in both lateral and medial knee compartments. Inclusion criteria were diagnosis of knee OA with unicompartmental

knee conditions that could benefit from load reduction to affected compartment and a minimum of a 6-month unloader brace prescription to allow for sufficient trial of the brace. Patients signed informed consent and agreed to complete all mailed questionnaires. At enrollment, 3 weeks, 6 weeks, and 6 months, patients completed a self-administered questionnaire. This questionnaire included the SF-12; the WOMAC score<sup>24</sup> (scored from 0 to 96, 0 = no disability, 96 = complete disability); and the Tegner activity scale.<sup>25</sup> In addition, all patients completed an expectation questionnaire before enrollment in the study.<sup>26</sup> There were 20 patient-expectation domains which were measured. The domains were then analyzed individually, as “very important” to “of little to no importance.”

## Statistical Analysis

The SF-12 physical component summary (PCS) and mental component summary were normally distributed at tested by the on-sample Kolmogorov-Smirnov test. Comparisons between SF-12 and WOMAC prebrace and final time point (6 months) were performed using the paired *t* test. Comparisons between independent groups were performed using the independent *t* test. We used repeated-measures analysis to determine if there was a difference between prebrace, 3-week, 6-week, and 6-month WOMAC pain and function scores. As the WOMAC scores were assessed on the same patient over time, we used repeated-measures analysis to adjust for the within-patient factors. Pearson correlation coefficient (*r*) was used for assessing associations between continuous variables.

## Results

A total of 39 patients completed this study. The average age was 61 years (range: 44 to 87). Average body mass index (BMI) was 26 (range: 20 to 37). There were 23 males and 16 females. All patients had a desire to return to recreational sports (Tegner desired activity level > 3). Thirty patients were prescribed a medial unloader brace and nine were prescribed a lateral unloader brace.

Pain relief was very important to 69% of patients and somewhat important to 17%. If patients did expect pain relief, 39% expected most of the pain to be relieved and 57% expected all pain to be relieved. The majority of patients (86%) expected knee stiffness or swelling to stop. Improving their ability to walk was considered very important in 89%. Improving their ability to go up and down stairs was considered very important in 70%. Patients considered return to recreational sports an important expectation. It was considered very important in 83% and somewhat important in 17%. The most important expectation in this group were to have confidence in their knee (97% very important), avoid future degeneration of their knee (90% very important), and improve ability to maintain general health (93% very important).

Patients had a significant improvement in their quality of life as shown by the improvement in the physical component of the SF-12 ( $p < 0.05$ ). SF-12 scores are shown in **Table 1**. As expected, the patient mental component of quality of life remained unchanged. WOMAC scores are also reported

**Table 1** Average WOMAC and SF-12 Scores

	WOMAC Pain	WOMAC Stiffness	WOMAC Function	WOMAC Total	SF-12 PCS	SF-12 MCS
Prebrace	7	3	19	28	38	57
3 wk	3	1	7	10	NA	NA
6 wk	3	1	10	14	43	57
6 mo	3	2	9	12	46	58

MCS, mental component summary; NA, not applicable; PCS, physical component summary; SF, short form; WOMAC, Western Ontario and McMaster Universities Arthritis Index.

in **Table 1**. There was significant improvement in pain, stiffness, and function components of the WOMAC score ( $p < 0.05$ ). Those patients who reported a Tegner activity level of 3 or greater (recreational sports) at final follow-up had a significantly higher SF-12 physical component (48 vs. 37;  $p = 0.023$ ). Age did not correlate with any of the outcome measures. There was also no difference by gender. Similar results were seen in patients with medial or lateral unloader braces. At 6 months, 25% of patients reported a decrease in pain medication, 31% reported a decrease in over-the-counter anti-inflammatories, and 35% reported a decrease in prescription anti-inflammatories.

There were 12 patients (31%) who underwent subsequent knee surgery; 1 (3%) underwent manipulation under anesthesia and insufflation; 6 (15%) underwent arthroscopy for various pathologies including OA, meniscus and chondral damage; 2 (5%) underwent an osteotomy, one high tibial osteotomy and one distal femoral osteotomy; 3 (8%) underwent total knee arthroplasty (TKA); and 6 (15%) reported discontinuing brace use. Of these six patients, four proceeded to surgical intervention (three TKAs, one arthroscopy as described above). No complications were reported in this study.

## Discussion

This study showed that patients suffering from knee OA had significant improvement in their physical quality of life with use of an unloader brace. Following unloader bracing, patients were able to significantly decrease pain and increase function. Patients showed a desire to participate in recreational activities and maintain overall general health.

Multiple studies have shown a decrease in disability and pain following use of an unloader brace for patients suffering from OA.<sup>19,21,27-38</sup> In our study, patients demonstrated a decrease in disability following unloader brace use at all time points, compared with prebrace disability. Patients also showed a decrease in pain with brace use. Kirkley et al demonstrated decreased disability and decreases in pain with use of the unloader brace. The study did not focus on the active patients. Their study concluded that unloader braces were more effective at relieving pain and increasing function than a neoprene sleeve or no brace/sleeve at all.<sup>19</sup> However, they also noted the need to determine which patients were ideal candidates.<sup>19</sup> Brouwer et al<sup>28</sup> also showed functional

increases and decreased pain at each follow-up interval for the unloader brace group, more than the conservatively treated group.

Although previous studies have shown that patients who suffer from knee OA may benefit from physical activity; physical health following bracing is not well documented. Previous studies have shown the positive effects of physical activity, recommending that adults should participate in physical activity at least three times per week for 35 minutes to deter disability in older patients suffering from OA.<sup>39</sup> Fransen et al demonstrated the positive effects of hydrotherapy and martial arts in a randomized controlled trial. Patients had improved general health (SF-12 PCS) at 12 weeks with sustained improvement at 24 weeks.<sup>13</sup> These results are similar to those of our study, with significant improvements in physical health seen at 6 weeks and 6 months following bracing. Everard et al demonstrated the positive effects of high-demand leisure activities in older adults. Patients who participated in high-demand leisure activities, as well as instrumental and social activities, were associated with higher physical health scores. This study also identified participation in low-demand leisure activities as a risk factor for lower overall physical health. When risk factors that are modifiable are able to be identified at the beginning of functional decline, early intervention for knee OA is more likely, and it may be possible, to decrease disability.<sup>14</sup>

This study also revealed that patients expected to perform recreational activities and maintain general health following bracing. Both of these were improved when patients wore the brace. This study also showed that patients expected improvement in their ability to participate in recreational activities. It was very important for patients to avoid future degeneration of the knee and to be able to maintain their general health. Lack of knowledge of expectations can lead to inappropriate treatment, decreased patient satisfaction, and failure to return for subsequent treatment or elective surgery. By identification of patients' expectations, better clinical and surgical care may be provided, and communication between physicians and patients may improve.<sup>40</sup> Few studies have looked at patient expectations. Mancuso et al validated the expectation questionnaire for use following arthroscopy.<sup>26</sup> To date, few articles have reported findings using these patient-expectation questions.

Limitations of this study include a patient selection bias due to the fact that the study was conducted at one referral

center. Most patients were active and highly motivated to remain active. Lack of longer term follow-up is also a limitation of this study. The study was limited to 6 months to see early changes in quality of life. This information could then be used for patient education to improve compliance and longer use. The long-term effects of the unloader brace are unknown. Tracking compliance of brace use was also limited in this study. All patients reported using the brace; however, it is unclear how much the brace was worn. Most patients were candidates for TKA and consequently were prescribed NSAIDs as that is part of standard of care for conservative treatment at this clinic. Although patients reported a decrease in medications, this study is limited by the lack of data on specific dosages. In this patient population, the mean BMI was lower, which may not be representative of a normally distributed population. Also, there were no control groups, and only one type of brace was used in this study. No control group was used because of equipoise and the ethics of clinical research.<sup>41</sup> Previous research and the senior authors own experience have demonstrated that the use of the unloader is superior to no treatment.

Overall, active patients demonstrated a significant decrease in pain and disability. Patients saw improvement in the physical component of their quality of life score. These patients had expectations to improve their ability to participate in recreational sports. Most patients improved or maintained their activity level. This led to a high patient satisfaction with the treatment option. Braces specifically designed to unload the degenerative compartment of the knee can be an effective treatment to decrease pain and maintain activity level to increase overall physical health.

#### Funding

This study was funded by Ossur of the Americas. The institute has received research support from the following: Smith & Nephew, Arthrex, Siemens, and Ossur.

#### References

- 1 U.S. Department of Commerce. Facts for Features—January 3, 2006. Available at: <http://www.census.gov>. Accessed March 2011
- 2 Roos H, Adalberth T, Dahlberg L, Lohmander LS. Osteoarthritis of the knee after injury to the anterior cruciate ligament or meniscus: the influence of time and age. *Osteoarthritis Cartilage* 1995;3(4):261–267
- 3 Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage* 2008;16(2):137–162
- 4 Altman RD. Early management of osteoarthritis. *Am J Manag Care* 2010;16(Suppl Management):S41–S47
- 5 Steadman JR, Ramappa AJ, Maxwell RB, Briggs KK. An arthroscopic treatment regimen for osteoarthritis of the knee. *Arthroscopy* 2007;23(9):948–955
- 6 Yildiz N, Topuz O, Gungen GO, Deniz S, Alkan H, Ardic F. Health-related quality of life (Nottingham Health Profile) in knee osteoarthritis: correlation with clinical variables and self-reported disability. *Rheumatol Int* 2010;30(12):1595–1600
- 7 Dillon CF, Rasch EK, Gu Q, Hirsch R. Prevalence of knee osteoarthritis in the United States: arthritis data from the Third National Health and Nutrition Examination Survey 1991–94. *J Rheumatol* 2006;33(11):2271–2279
- 8 Gignac MA, Cao X, Tang K, Beaton DE. Examination of arthritis-related workplace activity limitations and intermittent disability over four and a half years and its relationship to job modifications and outcomes. *Arthritis Care Res* 2011;63(7):953–962
- 9 Kwok WY, Vliet Vlieland TP, Rosendaal FR, Huizinga TW, Kloppenburg M. Limitations in daily activities are the major determinant of reduced health-related quality of life in patients with hand osteoarthritis. *Ann Rheum Dis* 2011;70(2):334–336
- 10 Łastowiecka E, Bugajska J, Najmiec A, Rell-Bakalarska M, Bownik I, Jedryka-Góral A. Occupational work and quality of life in osteoarthritis patients. *Rheumatol Int* 2006;27(2):131–139
- 11 Cook C, Pietrobon R, Hegedus E. Osteoarthritis and the impact on quality of life health indicators. *Rheumatol Int* 2007;27(4):315–321
- 12 Kim I, Kim HA, Seo YI, et al. Tibiofemoral osteoarthritis affects quality of life and function in elderly Koreans, with women more adversely affected than men. *BMC Musculoskelet Disord* 2010;11:129
- 13 Fransen M, Nairn L, Winstanley J, Lam P, Edmonds J. Physical activity for osteoarthritis management: a randomized controlled clinical trial evaluating hydrotherapy or Tai Chi classes. *Arthritis Rheum* 2007;57(3):407–414
- 14 Everard KM, Lach HW, Fisher EB, Baum MC. Relationship of activity and social support to the functional health of older adults. *J Gerontol B Psychol Sci Soc Sci* 2000;55(4):S208–S212
- 15 Bertheussen GF, Romundstad PR, Landmark T, Kaasa S, Dale O, Helbostad JL. Associations between physical activity and physical and mental health—a HUNT 3 study. *Med Sci Sports Exerc* 2011;43(7):1220–1228
- 16 Grindrod KA, Marra CA, Colley L, et al. After patients are diagnosed with knee osteoarthritis, what do they do? *Arthritis Care Res (Hoboken)* 2010;62(4):510–515
- 17 O'Connor JP, Lysz T. Celecoxib, NSAIDs and the skeleton. *Drugs Today (Barc)* 2008;44(9):693–709
- 18 Tallon D, Chard J, Dieppe P. Exploring the priorities of patients with osteoarthritis of the knee. *Arthritis Care Res* 2000;13(5):312–319
- 19 Kirkley A, Webster-Bogaert S, Litchfield R, et al. The effect of bracing on varus gonarthrosis. *J Bone Joint Surg Am* 1999;81(4):539–548
- 20 Pollo FE, Jackson RW. Knee bracing for unicompartmental osteoarthritis. *J Am Acad Orthop Surg* 2006;14(1):5–11
- 21 Beaudreuil J, Bendaya S, Faucher M, et al. Clinical practice guidelines for rest orthosis, knee sleeves, and unloading knee braces in knee osteoarthritis. *Joint Bone Spine* 2009;76(6):629–636
- 22 Corbacho MI, Daputo JJ. Assessing the functional status and quality of life of patients with rheumatoid arthritis. *Rev Bras Reumatol* 2010;50(1):31–43
- 23 Gandhi SK, Salmon JW, Zhao SZ, Lambert BL, Gore PR, Conrad K. Psychometric evaluation of the 12-item short-form health survey (SF-12) in osteoarthritis and rheumatoid arthritis clinical trials. *Clin Ther* 2001;23(7):1080–1098
- 24 Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15(12):1833–1840
- 25 Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. *Clin Orthop Relat Res* 1985;198(198):43–49
- 26 Mancuso CA, Sculco TP, Wickiewicz TL, et al. Patients' expectations of knee surgery. *J Bone Joint Surg Am* 2001;83-A(7):1005–1012
- 27 Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15(12):1833–1840

- 28 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(8):777-783
- 29 Chew KT, Lew HL, Date E, Fredericson M. Current evidence and clinical applications of therapeutic knee braces. *Am J Phys Med Rehabil* 2007;86(8):678-686
- 30 Draganich L, Reider B, Rimington T, Piotrowski G, Mallik K, Nasson S. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. *J Bone Joint Surg Am* 2006;88(12):2645-2652
- 31 Draper ER, Cable JM, Sanchez-Ballester J, Hunt N, Robinson JR, Strachan RK. Improvement in function after valgus bracing of the knee. An analysis of gait symmetry. *J Bone Joint Surg Br* 2000; 82(7):1001-1005
- 32 Felson DT, Goggins J, Niu J, Zhang Y, Hunter DJ. The effect of body weight on progression of knee osteoarthritis is dependent on alignment. *Arthritis Rheum* 2004;50(12):3904-3909
- 33 Finger S, Paulos LE. Clinical and biomechanical evaluation of the unloading brace. *J Knee Surg* 2002;15(3):155-158, discussion 159
- 34 Pollo FE, Otis JC, Backus SI, Warren RF, Wickiewicz TL. Reduction of medial compartment loads with valgus bracing of the osteoarthritic knee. *Am J Sports Med* 2002;30(3):414-421
- 35 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(11): 2398-2407
- 36 Richards JD, Sanchez-Ballester J, Jones RK, Darke N, Livingstone BN. A comparison of knee braces during walking for the treatment of osteoarthritis of the medial compartment of the knee. *J Bone Joint Surg Br* 2005;87(7):937-939
- 37 Self BP, Greenwald RM, Pflaster DS. A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. *Arthritis Care Res* 2000;13(4):191-197
- 38 Sharma L, Song J, Felson DT, Cahue S, Shamiyeh E, Dunlop DD. The role of knee alignment in disease progression and functional decline in knee osteoarthritis. *JAMA* 2001;286(2):188-195 Erratum in: *JAMA*. 2001;286:792
- 39 Rejeski WJ, Brawley LR, Ettinger W, Morgan T, Thompson C. Compliance to exercise therapy in older participants with knee osteoarthritis: implications for treating disability. *Med Sci Sports Exerc* 1997;29(8):977-985
- 40 Uhlmann RF, Inui TS, Carter WB. Patient requests and expectations. Definitions and clinical applications. *Med Care* 1984;22(7): 681-685
- 41 Freedman B. Equipoise and the ethics of clinical research. *N Engl J Med* 1987;317(3):141-145