

Long-term Results of an Unloader Brace in Patients With Unicompartmental Knee Osteoarthritis

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abstract

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Previously, we reported a prospective study of 30 patients with unicompartmental osteoarthritis of the knee treated nonoperatively with an unloader brace and average follow-up of 2.7 years. Although the initial study suggested short-term benefit according to pain and function measures, the objective of the current study was to evaluate these same patients via telephone questionnaire to determine the status of their brace use and any surgical procedures on the affected limb. Because we noted that even at 2.7 years, some patients opted for surgical management despite good response to bracing, our hypothesis was that these patients would not opt for long-term brace wear. Twenty-four of 30 patients were available for reporting based on telephone interview; in addition, we talked with family members of 5 patients who had died. When evaluated at 2.7 years, 41% of the 30 patients were still using the brace, 35% had discontinued brace use, and 24% had undergone arthroplasty. When contacted for the follow-up survey at an average of 11.2 years, 17 (58.6%) of the 29 patients had undergone arthroplasty. The mean interval between initial evaluation and arthroplasty was 3.9 years. In addition, 7 patients had undergone arthroscopic surgery. Importantly, none of the patients were still wearing the brace. The use of an unloader brace is effective in providing short-term pain relief and improved function; however, most patients subsequently opt for total knee replacement on the symptomatic knee.

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Osteoarthritis is the most common cause of functional disability among Americans and commonly affects the weight-bearing joint of the knee.^{1,2} An estimated 6% of adults aged 30 years or older have symptomatic osteoarthritis of the knee.³ Overall, osteoarthritis affects an estimated 26.9 million adults in the United States, up from 21 million in 1990.⁴ Knee osteoarthritis has a prevalence of 16 per 100 adults ≥ 45 years.⁴ The incidence of osteoarthritis is higher when the diagnosis is made based on medical history and physical examination rather than on radiographic findings.⁵ The history and physical examination can provide useful information concerning joint-line tenderness, ligamentous instability, and malalignment.⁶ The incidence is also higher in men compared to women in younger populations, but the reverse is true in older populations.⁵ The most common malalignment of the knee is a varus deformity associated with osteoarthritis.²

The preferred treatment for early symptomatic osteoarthritis of the knee is a nonoperative regimen.⁵ These measures include education, weight loss, activity modification, muscle strengthening, oral medications, topical analgesics, intra-articular injections, orthotics, and bracing.⁶ Bracing has emerged as an effective nonsurgical approach for symptomatic relief of unicompartmental osteoarthritis of the knee.^{2,7-12} Braces for management of osteoarthritis are designed to reduce excessive loading on the damaged compartment, with the desired outcome of less pain, reduced stiffness, and improved function.

Specifically used in this study, the unloader brace is intended to apply a varus or valgus force at the knee and distract the joint space of the involved compartment during weight-bearing activities, such as walking.¹² Data have shown that the use of bracing has increased during the past 15 years. In 2002, an estimated 125,000 knee osteoarthritis braces were sold in the United States,⁸ and there are 12 compa-

nies that make more than 30 types of braces for knee osteoarthritis.¹³ Early results have been encouraging and indicate that this type of bracing provides interval pain relief and may delay the requirement for surgery in relatively young patients with symptomatic medial compartment osteoarthritis.

This article evaluates the long-term efficacy of a valgus-producing knee orthosis in providing symptomatic relief of medial compartment osteoarthritis. Previously, we reported the short-term results of a prospective study that evaluated the effectiveness of a newly designed knee brace (CounterForce Brace; Breg Inc, Vista, California) in relieving symptoms of medial compartment osteoarthritis in 30 patients.⁵ The goal of the current study is to review patients from our original study who had experienced excellent short-term success with the use of this unloading brace. Our hypothesis is that the short-term success of bracing is better than long-term results.

MATERIALS AND METHODS

This article describes our retrospective follow-up of 29 (16 men and 13 women) of the original 30 patients⁵ at a mean follow-up of 11.2 years from the inception of the original study. At the beginning of the initial study, patients completed the American Academy of Orthopaedic Surgeons arthritis questionnaire and the short-form SF-36 Health Survey (QualityMetric Inc, Lincoln, Rhode Island). All patients were symptomatic and had undergone at least 6 months (range, 6 months to 3 years) of nonoperative treatment without resolution of symptoms. Patients were fitted with a CounterForce brace and were instructed in the use of the brace. Brace use averaged 5 hours/day for the duration of the study, and braces were typically used only for work or weight-bearing activity.

Follow-up interviews were conducted with 29 available patients (17 men and 12 women) at an average of 2.7 years after study initiation (range, 2.6-3.2 years).

	Men (n=18)	Women (n=12)
Mean age, y	61.66	49.33
Mean height, cm	178.92	166.08
Mean weight, kg	94.42	77.2
Mean osteoarthritis grade	2.66	3.11

In the current study, long-term follow-up telephone interviews using a questionnaire were conducted for 24 available patients at a mean follow-up of 11.2 years (range, 10.8-12 years). For 5 patients who had died since the original study, family members were contacted and completed a follow-up questionnaire; from the time of induction into the study until the time of death at a mean of 7.9 years, none had undergone total knee replacement (TKR) (range, 6.1-11 years).

Extensive steps were taken to contact the original 30 patients. These steps included conducting Internet searches, reviewing clinical and hospital records, making inquiries into primary care physician records, searching obituaries, and contacting fellow local orthopedic clinics. The questionnaire asked about current brace use and surgical procedures post-brace use.

RESULTS

Table 1 summarizes characteristics of the original 30 patients, and Table 2 summarizes patient characteristics for the current study. Seventeen patients (58.6%) had undergone arthroplasty; the mean interval between initial evaluation when brace wear began and arthroplasty was performed was 3.9 years.

For patients who had undergone arthroplasty, mean initial Kellgren-Lawrence osteoarthritis grade was 3.47 (3.5 for women and 3.44 for men) and mean

Table 2		
Characteristics of 29 Patients at Mean Follow-up of 11.2 Years		
	Men (n=16)	Women (n=13)
Mean age, y	72.69	63.85
Mean height, cm	180.67	165.68
Mean weight, kg	96.22	74.77
Mean osteoarthritis grade	3.00	3.15

initial body mass index (BMI) was 29.1 kg/m² (28.6 for women and 29.6 for men). For patients who had not undergone arthroplasty, mean initial osteoarthritis grade was 2.0 (2.25 for women and 2.0 for men) and mean initial BMI was 27.3 (23.8 for women and 32.0 for men). There was a statistically significant difference in osteoarthritis grades for patients who had undergone arthroplasty versus patients who had not ($P \leq .05$). Table 3 summarizes the results of the long-term follow-up survey.

DISCUSSION

Bracing can provide symptomatic relief from medial compartment osteoarthritis of the knee. Commercially available braces include compression knee sleeves, supportive knee braces, and unloading braces. The unloading knee brace relieves pain during activity via a varus or valgus force that distracts the involved compartment, thus increasing joint space.¹² Others have also shown that for patients with symptomatic osteoarthritis, an orthosis designed to reduce loading in the medial compartment of the knee can provide short-term symptomatic relief.^{8,14,15}

Komistek et al⁹ performed a gait analysis study involving 15 patients using unloading braces. Fluoroscopy showed the brace achieved condylar separation of the medial tibiofemoral joint space in 12 of the 15 patients, who all reported de-

Table 3						
Characteristics and Outcomes at Mean Follow-up of 11.2 Years						
Patient No./ Sex/Age, y	Weight, lb	Height, in	BMI	Surgery	Date	Osteoarthritis Grade
9/M/85	190	67	29.8	Right TKR	July 2005	3
16/M/87	190	69	28.1	Left TKR	Aug 2001	4
25/M/74	230	72	31.2	Right TKR	Jul 1998	4
5/M/80	210	72	28.5	Left TKR	Sep 1997	4
26/M/85	230	72	31.2	Left TKR	Oct 1999	3
31/M/63	238	76	29.0	Right TKR	Jan 2005	2
34/M/81	193	71	26.9	Right TKR	Jan 2001	3
33/M/77	215	72	29.2	Right TKR	Apr 2004	4
35/M/60	240	74	30.8	Right TKR	Feb 2003	4
32/M/59	200	68	30.4	Scope		1
30/M/67	180	68	27.4	Scope		2
28/M/62	226	71	31.5	Scope		1
15/M/66	290	72	39.3	None		3
22/M/68	175	71	24.4	None		2
37/M/70	205	68	31.2	None		4
23/M/79	182	75	22.7	None		4
24/F/73	170	63	30.1	Left TKR	Jul 1998	2
19/F/52	160	62	29.3	Right TKR	Nov 1998	4
11/F/78	160	67	25.1	Left TKR	Dec 1997	3
10/F/45	130	65	21.6	Left TKR	May 1999	4
29/F/67	185	62	33.8	Right TKR	May 2001	4
7/F/60	245	64	42.0	Left TKR	Jul 2006	4
13/F/65	185	71	25.8	Right TKR	Nov 2008	3
3/F/78	134	63	23.7	Left TKR	Oct 2002	4
6/F/63	165	70	23.7	Scope		2
12/F/60	127	65	21.1	Scope		2
18/F/61	163	66	26.3	Scope		4
21/F/72	164	66	26.5	Scope		4
20/F/56	155	64	26.6	None		1

Abbreviations: BMI, body mass index; Scope, arthroscopy; TKR, total knee replacement.

creased symptoms. The authors noted that obesity and a poorly fitted brace were associated with failure to achieve relief of symptoms.⁹

We found that 58.6% of patients who used a brace subsequently underwent TKR. The data from our previous study indicate that for patients with symptom-

atic unicompartmental osteoarthritis, an orthosis designed to reduce loading in the medial compartment of the knee can provide short-term symptomatic relief. Patients using this brace uniformly reported increased function and pain relief, as well as decreased stiffness and swelling after physical activity.⁵

At long-term follow-up (mean, 11.2 years after initial evaluation), none of the 29 patients available for this follow-up study were still using the brace and 58.6% (n=17) of patients had undergone TKR. There were no statistically significant demographic differences between those requiring TKR and those not requiring TKR. Patients who had undergone arthroplasty had a mean osteoarthritis grade of 3.47, whereas patients who had not undergone arthroplasty had a mean initial osteoarthritis grade of 2.0. All patients who underwent arthroplasty reported that brace use had been effective in temporarily relieving pain.

This long-term report is not without limitations. Unlike our previously reported short-term results, this study is retrospective in nature. However, the placebo effect of treatment and study participation would not be as strong in this study. In addition, 5 patients had died, although it was reported by family that none of these patients had TKR before their deaths. One patient was lost to follow-up despite intensive searches such as contacting the medical records department of local hospitals as well as local sheriff departments, which helped to identify the deaths.

It also was difficult to establish reason for brace discontinuation or further surgery that could have been secondary to decreased efficacy or simply tiring of brace wear. In addition, we cannot comment on indications or results for the 7 patients who subsequently had arthroscopic treatment. We therefore are considering undertaking a prospective randomized long-term study of bracing versus nonbracing for patients with medial compartment arthritis who do not desire TKR. ©

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