

ORIGINAL REPORT

EFFECTS OF A SEMI-RIGID KNEE BRACE ON MOBILITY AND PAIN IN PEOPLE WITH KNEE OSTEOARTHRITIS

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Objective: Osteoarthritis is one of the most common chronic conditions leading to disability among older people (age 60+ years). Knee osteoarthritis has a significant impact on daily functioning. Pain, stiffness, reduced strength, changes in posture, and reduced knee stability may result in reduced mobility. The aim of this study is to evaluate the short- and long-term effects of conservative therapeutic use of a semi-rigid knee brace for management of patients with knee osteoarthritis, using patient-reported outcomes.

Design: Patients with osteoarthritis using a semi-rigid knee brace were asked to complete a questionnaire about the effectiveness of the brace after wearing it for 3 weeks. The primary outcome measure was mobility, assessed using an ordinal scale with and without use of the knee brace. Secondary outcome measures were pain symptoms and overall daily functioning.

Results: A total of 381 patients completed the questionnaire. The results show considerably improved mobility while using a knee brace in different mobility groups. In the group of respondents who were limited to their home environment mobility decreased by 74% while using a knee brace. In the group of respondents who were able to walk to a nearby shop mobility increased by 50%, and the group experiencing no mobility restrictions increased from 3% without using a knee brace to 13% while using a knee brace. In addition, 54% of respondents reported a reduction in pain symptoms and 62% of respondents reported an improvement in overall daily functioning while using a knee brace.

Conclusion: The results of this large-scale patient-reported outcome measure (PROM) study show that the use of a semi-rigid knee brace appears to

LAY ABSTRACT

This study of patient-reported outcome measures regarding the use of stabilizing knee braces for knee osteoarthritis provides insight into the additional care and quality of life provided by the use of these orthopaedic aids. The aims of this study are to measure the effectiveness of knee braces in daily life and to validate the efficacy of using orthopaedic medical aids. In the study, 381 patients with knee Osteoarthritis were provided with knee braces and were asked about the effectiveness of the braces 3 weeks after they first started wearing them. This large-scale study found that the use of knee braces contributed to user-mobility, reduced pain, and increased the possibility to perform daily activities. Knee braces appear to serve as a suitable support for knee joints, providing pain relief and freedom of movement, and should be considered a useful non-surgical treatment method for knee Osteoarthritis.

provide suitable joint support, offering pain relief and freedom of movement and should be considered a useful non-surgical treatment method for use in patients with knee osteoarthritis

Clinical trial: This study does not include a clinical trial.

Key words: osteoarthritis; arthritis; knee brace; orthotic device; unload.

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Osteoarthritis (OA) is one of the most common chronic conditions leading to disability among older people (age 60+ years) (1–5). Knee OA has a significant impact on daily functioning. Pain, stiffness, reduced strength, changes in posture, and reduced knee stability may cause reduced mobility (6).

Usually, a stepped care treatment plan is implemented, whereby more complex treatments, e.g. surgical interventions, are considered only when lesser complex treatments are found unsuitable. According to the Osteoarthritis Research Society International (OARSI) in the USA and the UK National Institute for Health and Care Excellence (NICE) guidelines, conservative management comprises a combination of education for self-management, exercise therapy (aerobic and strength exercise), weight management, knee braces, and pain medication. Under the Dutch national Federation of Medical Specialists (FMS) guidelines, a valgus knee brace is prescribed for patients with symptomatic medial tibiofemoral OA, where the effectiveness of other conservative management options has proven insufficient. Use of a valgus knee brace aims to delay joint replacement surgery for as long as possible, especially in relatively young and active patients (6).

Several systematic reviews have quantified the effectiveness of unloader braces in improving clinical outcomes and mechanical leverage (6–8). However, to the best of our knowledge, there is a significant research gap in perception-based studies in understanding the short- and long-term consequences of these braces on the tissues in the knee joint, including the cartilage and ligaments. Current perception-based studies are based on relatively small population sizes (9–11), and further research is needed to advance our understanding of the effects of unloader braces experienced by patients with OA.

The objective of this perception-based evaluation study is to evaluate the short- and long-term effects of a semi-rigid knee brace in patients with knee OA.

METHODS

Measurement of perception-based outcomes among patients is used to evaluate health outcomes and quality of life and to provide insight into the value of patient care (12, 13). For this study, the patient-reported outcome measurement (PROM) toolbox of the Netherlands Healthcare Institute, and the Netherlands Federation of University Medical Centres (NFU) guidelines for the selection of Patient Reported Outcomes (PROs) and PROMs were used (14–16). An illness or condition often causes complaints and symptoms, such as pain, which relate to problems with daily functioning. Retrospective measurements provide insight into the effect a treatment has on a patient's perceived health in terms of their physical well-being and/or functioning. In this study, subjects were questioned about symptoms, functional status, and perceived health. The following PROs were defined to determine the effectiveness of the knee braces:

1. How has your general daily functioning changed since using your knee brace?

2. How have your pain symptoms changed since using your knee brace?
3. Please indicate how mobile you are with/without the knee brace?

Information about health prior to and after an intervention is needed to improve the effectiveness of using a knee brace. This study compared feedback from patients about function gained with and without a semi-rigid knee brace. There are no standard or target values that could be used in the study, as there are no comparable studies regarding the effectiveness of these orthopaedic aids. The PROM questions in the study were prepared based on the usual questionnaires used in orthopaedics (surgery), thus, adhering to scientifically accepted and validated PROM questions (13, 17).

Between October 2018 and December 2020, a total of 1,003 patients with OA who were provided with a knee brace (both new users and repeat users) were invited to complete a questionnaire about the effectiveness of the brace after wearing it for 3 weeks. Patients received their knee brace from a qualified certified prosthetist/orthotist (CPO) and were mostly referred to the CPO by medical doctors. The questionnaires were sent by e-mail, and patients were informed that responding to the questionnaire was voluntary. In addition, informed consent was given. The questionnaire contained questions related to pain perception and daily functioning, each with a qualitative ordinal scale (7-point scale ranging from “very deteriorated” to “improved significantly”). Using these questions, patients were encouraged to compare their pain perception and daily functioning at the time of the survey with their perceived perception and functioning 3 weeks earlier. Mobility was expressed in meters. The primary outcome measure was mobility assessed with and without using the semi-rigid knee brace. Secondary outcome measures were pain symptoms and overall daily functioning assessed with the 7-point ordinal scale. Age and sex were also documented.

Descriptive statistics were used as basic measures to describe the survey data. They consist of summary descriptions of frequency and percentage response distributions, and mode was used to measure the central tendency (18).

With a population size of 4,025 patients provided with a semi-rigid knee brace in the Netherlands during the study period and a 95% confidence level, a margin of error of 5% was calculated. This expresses the amount of random sampling error in the results of this survey.

The diagnosis of OA was confirmed by a medical doctor (MD) for all patients. The diagnosis was mostly made based on X-rays and/or magnetic resonance imaging (MRI). Patients throughout the Netherlands in various institutions, ranging from university hospitals and rehabilitation centres to nursing homes, were eligible for this study if the MD recommended use of a knee brace. Patients with OA were randomly allocated to treatment with a conventional semi-rigid knee brace (Agillium Reactive®, Ottobock, Duderstadt, Germany or Defiance®, DJO, Lewisville, TX, U.S.A (Fig. 1). Both

braces were selected for their unloading capabilities, and were supplied to the patient by a qualified CPO.

RESULTS

A total of 381 out of 1,003 patients completed the outcome study questionnaire; a response rate of 38%. All responses were analysed and included in this study as acceptable data.

Table I shows the descriptive characteristics of the study population. In total, 63% of respondents were aged 60 years or over, and 30% were aged 70 years or over. This age range also matches the greatest prevalence and incidence rates of OA, where the majority of people over 55 years of age have radiological features of OA (19). The majority of respondents (60%) in this study were women. The results are presented separately for each question in the questionnaire.

Fig. 2 shows the results regarding the change in mobility for all respondents. Mobility while using a knee brace improved considerably in different mobility groups. The mobility of respondents who were limited to their home environment reduced by 74%. The mobility of the respondents who were able to walk to a nearby shop increased by 50%, and the group experiencing mobility restrictions increased from 3% without using a knee brace to 13%

while using a knee brace. A total of 42% of respondents using a knee brace indicated that they could take a long walk again (18%) or go to the local shop (24%). 80% of mobility improvement is noted for the combined three higher mobility classes (d,e and f in Table II). Only 9% of patients were limited to their own living environment while using a knee brace.

Fig. 3 shows the results for the reduction in pain symptoms. The group wearing a knee brace showed an improvement (reduction) in pain symptoms of 54%. Of the respondents, 29% reported that their pain symptoms were reduced significantly or very significantly, while 36% experienced no change. A small difference was noted between new users and repeat users; new users showed greater improvement (61% for new users and 44% for repeat users) and less deterioration (3% for new users and 16% for repeat users).

Fig. 4 shows the results for change in overall daily functioning while using a knee brace. Sixty-two percent of respondents indicated that their general daily functioning improved after they started using a knee brace, 29% indicated that it improved significantly, and 7% very significantly. There was a small difference between the improvement in patients who started using a knee brace (new users indicate an improvement of 69%) and patients who continued the treatment with a knee brace (repeat users indicate an improvement of 60%). Nine percent of all respondents stated that their functioning deteriorated after using the knee brace.

Table II shows the mobility results for both new and repeat users with or without using a knee brace. In the low mobility class (class a – I can walk in the house (0–10 meters), a difference was reported between repeat users (39% of respondents could walk 0–10 m without using a brace, and 10% with using a brace) and new users (24% of the respondents could walk 0–10 m without using a brace, and 6% with using a brace). In addition, a difference was also noted in the highest mobility class between repeat users (class f – I no longer have a mobility restriction in terms of distance (> 5 km) - is 5% for repeat users without using a brace and 17% with using a brace) and new users (class f is 0% without using a brace and 6% with using a brace). It can be concluded that the distribution of results is skewed more towards the extreme mobility classes (low and high) for repeat users than for new users.

Table III compares a combination of mobility classes with and without a knee brace. When combining the low mobility classes, the low mobility group (class a and b combined) of users without using a knee brace is predominated by repeat users compared to new users, as 45% of respondents who are repeat users are in this lowest mobility group compared with 30% for new users. When using a knee brace, the amount of users in the low mobility group was decreased with 60% for new users and 64% for repeat users. The amount of new users in the high mobility group (class e and f combined) increased by +192% when wearing a knee



Fig. 1. Types of knee brace used in this study.

Table I. Descriptive characteristics of the study population

	Total	Female	Male
N (%)	381	227 (60)	154 (40)
Age group, years			
<30	3%	3%	2%
30–60	34%	35%	31%
60–70	33%	31%	36%
70–80	18%	16%	21%
>80	12%	15%	9%
Age mean, years	64,9	64,9	65,0
New users, %	67		
Repeat users, %	33		

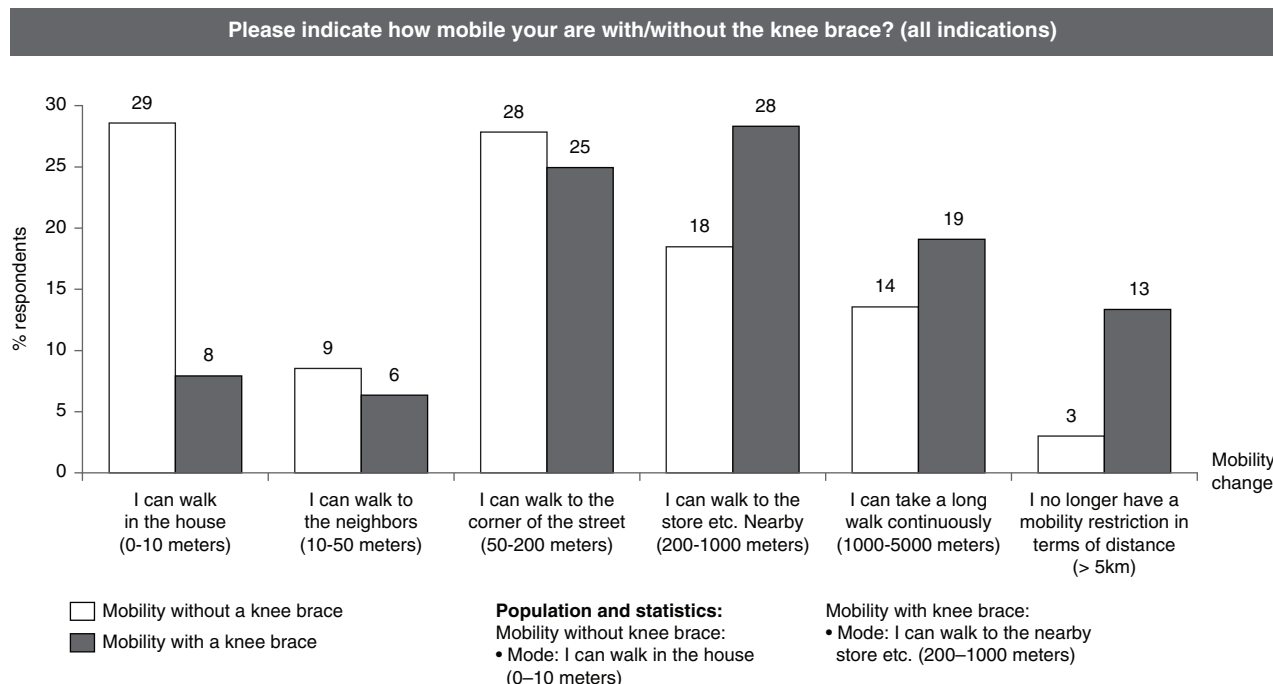


Fig. 2. Results for the question: “Please indicate how mobile you are with/without the knee brace?” (OA indication)

Table II. Results of question: “Please indicate how mobile you are with/without the knee brace?” (split between new and repeat users)

Mobility classes	(a) I can walk in the house (0–10 meters)	(b) I can walk to the neighbors (10–50 meters)	(c) I can walk to the corner of the street (50–200 meters)	(d) I can walk to the store etc. Nearby (200–1000 meters)	(e) I can take a long walk continuously (1000–5000 meters)	(f) I no longer have a mobility restriction in terms of distance (>5 km)
All users						
Mobility without a knee brace	34%	6%	30%	12%	15%	3%
Mobility with a knee brace	9%	6%	30%	24%	18%	13%
New users						
Mobility without a knee brace	24%	6%	29%	29%	12%	0%
Mobility with a knee brace	6%	6%	29%	24%	29%	6%
Repeat users						
Mobility without a knee brace	39%	6%	30%	4%	16%	5%
Mobility with a knee brace	10%	6%	30%	24%	13%	17%

brace (35% of the new users indicated to be in the high mobility group when using a knee brace, compared to 12% when not using a knee brace). For repeat users the amount of users in the high mobility group was increased by +43%, comparing the amount of repeat users while use a knee brace (30%) with the amount of repeat users without using a knee brace (21%) in the same mobility group.

DISCUSSION

This study measured the short- and long-term effects of use of a semi-rigid knee brace in patients with knee OA, using a perception-based evaluation. The results showed that 62% of all respondents indicated an improvement in daily functioning after starting using a knee brace. In a previous study comparing a braced patient group with a control group, in which patients received only conservative management without knee bracing, the patient group

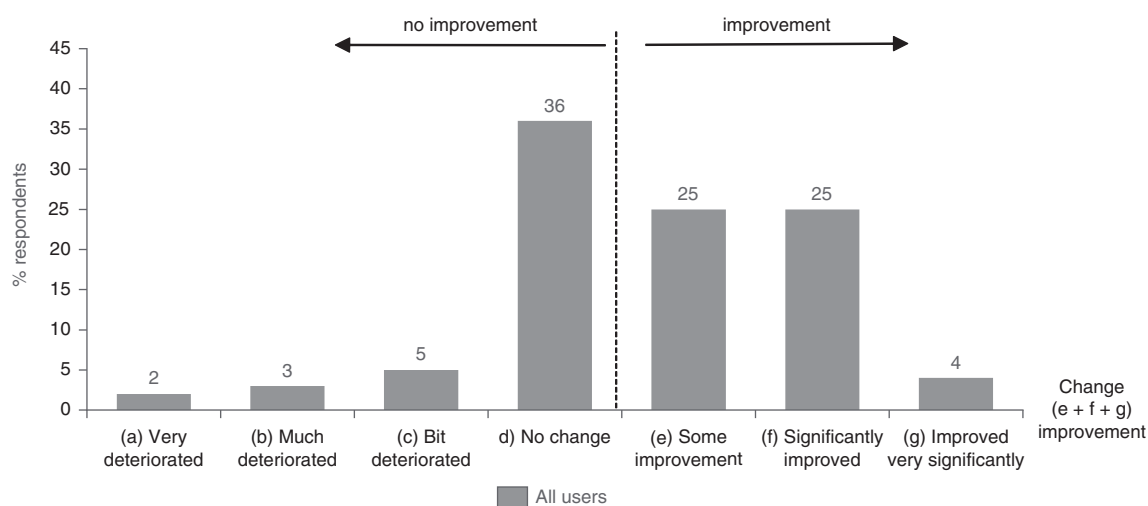
reported an improvement of 50% improvement in mobility, whereas the control group reported an improvement of 36% (20). Our study supports the findings that knee bracing improves daily functioning; we note an even higher improvement for patients using a knee brace based on a larger population (62%).

Gained mobility

The results of this study support the findings of a 2012 PROM study by Briggs et al. (7), which showed a significant improvement in quality of life using a 12-item Short Form health

survey (SF-12) ($p < 0.05$) and pain, stiffness, and function using Western Ontario and McMaster Universities Arthritis Index (WOMAC) ($p < 0.05$) while using a brace, based on a study of 39 patients. The larger population size in the current study strengthens these findings; braces, specifically designed to unload the degenerative

How have your pain symptoms changed since using your knee brace?

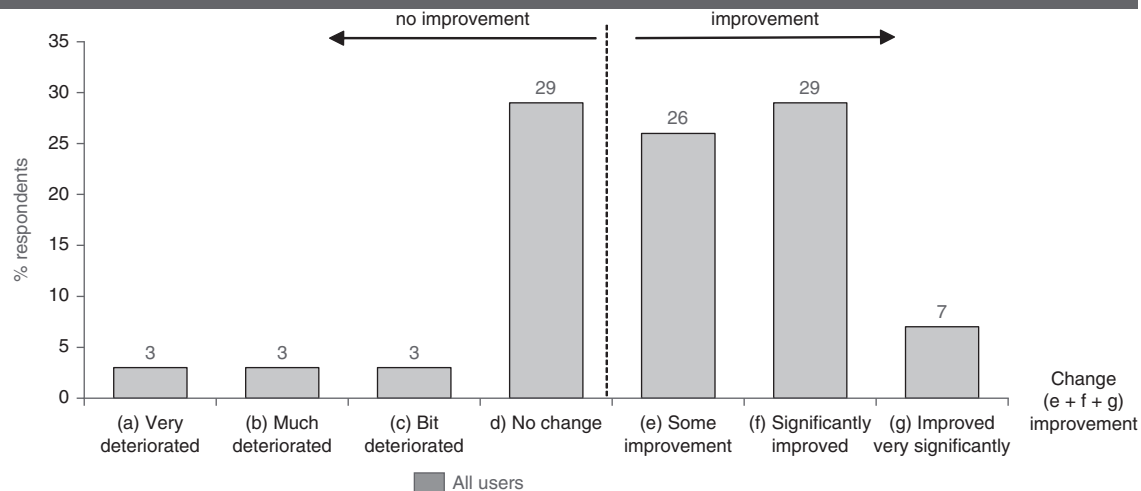


All users	2%	3%	5%	36%	25%	25%	4%	54%
New users	1%	1%	1%	36%	30%	25%	6%	61%
Repeat users	4%	4%	8%	40%	15%	26%	3%	44%

Note: (a) + (b) + (c) + (d) + (e) + (f) + (g) = 100%

Fig. 3. Results for the question: "How have your pain symptoms changed since using your knee brace?"

How has your overall daily functioning changed since using your knee brace?



All users	3%	3%	3%	29%	26%	29%	7%	62%
New users	2%	2%	2%	25%	39%	24%	6%	69%
Repeat users	3%	3%	3%	31%	22%	31%	7%	60%

Note: (a) + (b) + (c) + (d) + (e) + (f) + (g) = 100%

Fig. 4. Results for the question: "How has your overall daily functioning changed since using your knee brace?"

compartment of the knee, can be an effective treatment to decrease pain and maintain activity level.

This study builds on earlier perception-based studies in specifying the improved quality of life in gained mobility among mobility classes (21, 22). Whilst using a knee brace, 55% of respondents indicated that their mobility was improved; they could take a long walk again (24% of respondents),

go to the local shop (18% of respondents), or no longer experienced any mobility restrictions (13% of respondents). The use of the knee brace increased mobility by 83% in these 3 groups combined. Furthermore, a 69% reduction in patients limited to their own living environment was found when comparing the group using a knee brace (8% of respondents) with the group not using a knee brace (29% of respondents).

Table III. Mobility improvement for low and high mobility classes combined

Low mobility classes	Mobility without knee brace			Mobility with knee brace			*Change %
	(a) 0–10 m	(b) 10–50 m	(a+b) Total	(c) 0–10 m	(d) 10–50 m	(c+d) Total	
All users	34%	6%	39%	9%	6%	15%	-62
New users	24%	6%	30%	6%	6%	12%	-60
Repeat users	39%	6%	45%	10%	6%	16%	-64
High mobility classes	(e) 1–5 km	(f) No restriction	(e+f) Total	(g) 1–5 km	(h) No restriction	(g+h) Total	%
All users	15%	3%	17%	18%	13%	31%	82
New users	12%	0%	12%	29%	6%	35%	192
Repeat users	16%	5%	21%	13%	17%	30%	43

*Change in mobility is expressed as % of the population

In the scope of this study, the authors are not aware of any previous research into the effect of knee bracing in different mobility classes.

Pain reduction

This study found that pain symptoms were reduced when using a knee brace. This finding is supported by previous studies, in which Briggs et al. reported a significant improvement in pain and function (7). They have also shown that most knee braces users (69%) found pain relief to be a very important reason to continue using the brace. This is supported by Kiel & Kaiser, showing that knee bracing resulted in a broader medial joint space when walking (23), while the medial joint space is presented as a major contributor to perceived pain symptoms.

The results of this study particularize the reduction in pain obtained with knee braces to an improvement in self-reported pain symptoms of 54% of respondents after using a knee brace. Thirty percent of the respondents reported that their pain symptoms changed significantly to very significantly. Briggs et al. have also shown that it is thought that the reduced pain experienced contributes to increased confidence in the knee and consequently improves the patient's ability to maintain their general health (7).

Course of mobility limitations over time

The mobility level of patients in the mobility range greater than 50 m was high, with, on average, 85% of respondents indicating a high level of mobility when using the knee brace. When comparing new users (88%) with repeat users (84%), no significant difference was found. These results support the findings of Van Dijk et al. and Pisters et al., who showed that limitations in activities were fairly stable during the first 3 years of follow-up (24, 25).

However, the self-reported limitation in mobility when not using a knee brace was reported to be higher for the repeat users in the current study; Only 24% of new users reported a highly limited mobility level (only being able to move within their living environment), compared with 39% of repeat users. Self-reported mobility gain for patients with a knee brace who were in the mobility range greater than 50 m was shown to improve in 26% of new users and 53% of repeat users. These results support the

findings of Holla et al. (26), showing that activity limitations decreased slightly after 2 years of follow-up.

Study limitations

Perception-based methods assess pain, function, and quality of life, which are the qualitative markers of disease progression. The quality of these methods depends on the disease condition, mood, physical activities, and ultimately the score provided by patients. Although these methods are well accepted by clinicians, it is not possible to use them to quantify morphological and biomechanical changes in the soft tissue regions. Therefore, one should be cautious about making assumptions regarding the predictive value of long- and short-term effects based on the overall physical activity of the subject.

Many patients compensate for knee instability by increasing muscle activation (co-contraction) around their knee joint. This provides a stable feeling, but also has a progressive effect on knee OA due to the increased pressure on the knee joint. Wearing a stabilizing rigid knee brace ensures a reduction in muscle co-contraction and pain (27). With a reported pain reduction of 54%, it is possible that users wearing knee braces in this study used less co-contraction, which might indicate reduced progression of knee OA. Further research is needed to confirm this finding.

The use of pain medications was not assessed in this study, and the use of analgesics could have influenced the results. Although it is expected that only a few patients use pain medication when using knee braces, further research should include this information to investigate the overall reduction in pain. In addition, 9% of patients did not experience any improvements when using a knee brace, or even experienced deterioration. While several factors, such as correct knee brace fitting, over-compensation of muscles, or additional injuries, could play a role in this, further research is required to understand these outcomes.

CONCLUSION

This large-scale PROM study of the effectiveness of use of semi-rigid knee braces in patients with knee OA shows that use of a brace contributes to general daily functioning, reduces pain, and increases the possibility

to perform daily activities. For patients with OA, reduced pain enables increased mobility away from the home environment, resulting in a more active life and increased quality of life. Use of a knee brace appears to provide suitable joint support, offering pain relief and freedom of mobility.

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