

Use of an Elastomeric Knee Brace in Patellofemoral Pain Syndrome: Short-Term Results

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Abstract

Purpose This article verifies the effectiveness of a new brace on patellofemoral pain syndrome (PFPS) in adjunct to a specifically developed rehabilitation program.

Methods Two groups of 30 patients with PFPS were prospectively and randomly allocated to a rehabilitation protocol, with (group A) or without (group B) the use of a specific brace. All the patients were assessed at 3, 6, and 12 months using the disease-specific Kujala scale and a visual analog scale (VAS) for pain; time to return to sport and patient satisfaction with the brace were also recorded.

Results Kujala scale's values showed constant and progressive improvement. The mean score at 6 months was 79.8 ± 6.8 points in group A and 76.8 ± 8.6 in group B, rising at 12 months to 80.9 ± 7.5 in group A and 78.4 ± 8.3 in group B. VAS scores significantly differed ($p < 0.05$) between the two groups at both 6 and 12 months; the score recorded at 12 months was 0.9 ± 1.3 in the brace-treated group and 1.8 ± 1.6 in the controls. The patients who used a brace showed a quicker return to sports and 75% of the patients in this group were satisfied.

Conclusion All the scores improved progressively in both groups. The most significant improvement concerned pain, showing that the brace used in this study may allow a better subjective outcome and a quicker return to sport.

Level of Evidence Level II, prospective randomized controlled trial.

Keywords

- knee joint
- patellofemoral pain syndrome
- braces
- athletes

Introduction

Anterior knee pain is currently one of the problems most frequently encountered in orthopaedic settings and one of the most difficult to manage.^{1,2} Retropatellar and peripatellar pain, clinically referred to as patellofemoral pain (PFP), is a common disorder experienced by young adult and adolescent athletes who participate in jumping, cutting, and pivoting sports.^{3–5} Prevalence of PFP seems to be higher in

females.^{6,7} This is probably due to anatomical, neuromuscular, and hormonal factors.⁸

Patellofemoral disorders may be divided into three groups: objective patellar instability, potential patellar instability, and PFP.⁹ Pain is the main symptom of potential patellar instability, which is characterized by the presence of at least one of the main factors of instability, namely, trochlear dysplasia, patella alta, and pathological tibial tuberosity-trochlear groove distance. Pain is also the main

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symptom of PFP syndrome (PFPS), in which the pain has a mainly nonpatellar origin (hip, ankle, spine, etc.).^{10,11}

In the absence of chondral lesions, conservative treatment is usually the first option for the PFPS. This approach, based on an appropriate rehabilitation program, is designed to manage pain and promote recovery of the range of motion (ROM), as well as muscle strength and proprioception.¹² Rehabilitation is often supported by the use of knee braces and foot orthoses.¹³

Knee braces have been shown to reduce pain by reducing patellofemoral pressure and increasing the contact area to allow a better distribution of the forces over the patellofemoral joint.^{2,12,14,15} Their effectiveness has been explored in several studies, with contrasting results.^{16–24}

The purpose of this study was to assess the efficacy of a new knee brace with elastomeric properties specifically developed for athletes, in adjunct to a purposed rehabilitation program, in relieving symptoms in patients affected by PFPS. The hypothesis of the study was that the knee brace has a significant effect on symptoms relief in patients affected by PFPS.

Methods

This study was designed as a prospective randomized multicenter study. Seventy patients were recruited at the Knee Surgery Unit of the G. Pini Orthopaedic Institute in Milan and at the Orthopaedic Clinic of the University Hospital of Sassari. All the patients included were informed of the randomized nature of the study, and signed a purposed informed consent. The institutional review boards approved the study and all the procedures were in accordance with the current ethical standards.

Inclusion criteria were: age between 16 and 35 years, a diagnosis of anterior knee pain due to PFPS, a Tegner score of ≥ 3 , and a body mass index (BMI) between 18 and 26. Patients with knee comorbidities, such as ligament, meniscus, or cartilage lesions, were excluded.

Patients were randomized into two groups. In group A, patients underwent a rehabilitation program combined with the use of a knee brace (Reaction Knee Brace; DJO Global, Vista, California, United States); in group B, they underwent only rehabilitation. The rehabilitation protocol was divided into different phases based on the patient's progress. The goal of the first phase was to reduce pain and swelling, to improve the balance between vastus medialis and vastus lateralis of the quadriceps muscle, to restore normal gait, and to decrease loading of the patellofemoral joint. The second phase included improvement of postural control and coordination of the lower extremity, increase of quadriceps and hip muscle strength, and restoration of good knee function. The patients were encouraged to return to sports with a suitable regular physical exercise. The third phase included functional exercises.

All the patients were assessed before treatment and again at 3, 6, and 12 months afterwards, using a specifically designed instrument for scoring patellofemoral disorders (Kujala scale)²⁵ and a pain visual analog scale (VAS). In

addition, time to return to sport and subjective patient satisfaction at the end of treatment were also recorded.

A 2×4 univariate analysis of variance (ANOVA) explored the effect of the brace versus no braced conditions over the different time points using the baseline as a covariate for the Kujala score and pain VAS. Time effect, group effect, and time per group interaction were explored by the use of repeated measure ANOVA. Significance was set at p -value of < 0.05 .

Results

Following the exclusion of 10 patients who were lost during the study or at follow-up, data analysis included 60 patients (all nonprofessional athletes) (**Fig. 1**). These comprised of 47 females and 13 males, with a mean age of 20 ± 4 years (range, 16–30 years) and a mean BMI of 23 (range, 18–26). The two groups did not show significant differences for age, gender, and BMI. **Table 1** shows the descriptive statistics for group A (knee brace used in combination with a rehabilitation program) and group B (rehabilitation alone) at the different time points.

The mean Kujala score showed a constant and progressive improvement over the follow-up period. The mean score at 6 months was 79.8 ± 6.8 points (range, 66–95) in group A and 76.8 ± 8.6 points (range, 60–95) in group B, rising at 12 months to 80.9 ± 7.5 points (range, 70–100) in group A and 78.4 ± 8.3 points (range, 67–100) in group B.

Successive reductions were observed in the mean VAS score, which fell from a common value of 5.9 ± 1.9 points (range, 3–9) in both groups at baseline, to 1.4 ± 1.5 (range, 0–7) in group A and 3 ± 1.6 (range, 0–6) in group B at 6 months, and then to 0.9 ± 1.3 points (range, 0–5) in group A and 1.8 ± 1.6 (range, 0–5) in group B at 12 months (**Fig. 2**).

At 6 months, 42 of the 60 patients returned to sports; 24 of these were from group A and 14 from group B. Of the patients that used the brace, 75% declared that they were satisfied or very satisfied with it.

The mean Kujala score showed no significant differences between the two groups but did show significant differences between time points ($p < 0.001$). Further post hoc pairwise comparison testing showed significant differences between all time points showing continuous improvement in both groups up to 12 months (**Table 2**).

Significantly lower mean pain VAS was seen in group A ($p < 0.001$) and between time points ($p < 0.001$). In addition, a significant interaction between the two factors was also seen ($p < 0.001$), and the repeated measures ANOVA performed separately on the two groups showed significant differences between all time points for both groups (**Table 3**).

Discussion

The best therapeutic approach to anterior knee pain is conservative treatment consisting of the use of nonsteroidal anti-inflammatory drugs for short periods of time, together with targeted rehabilitation programs and the application of

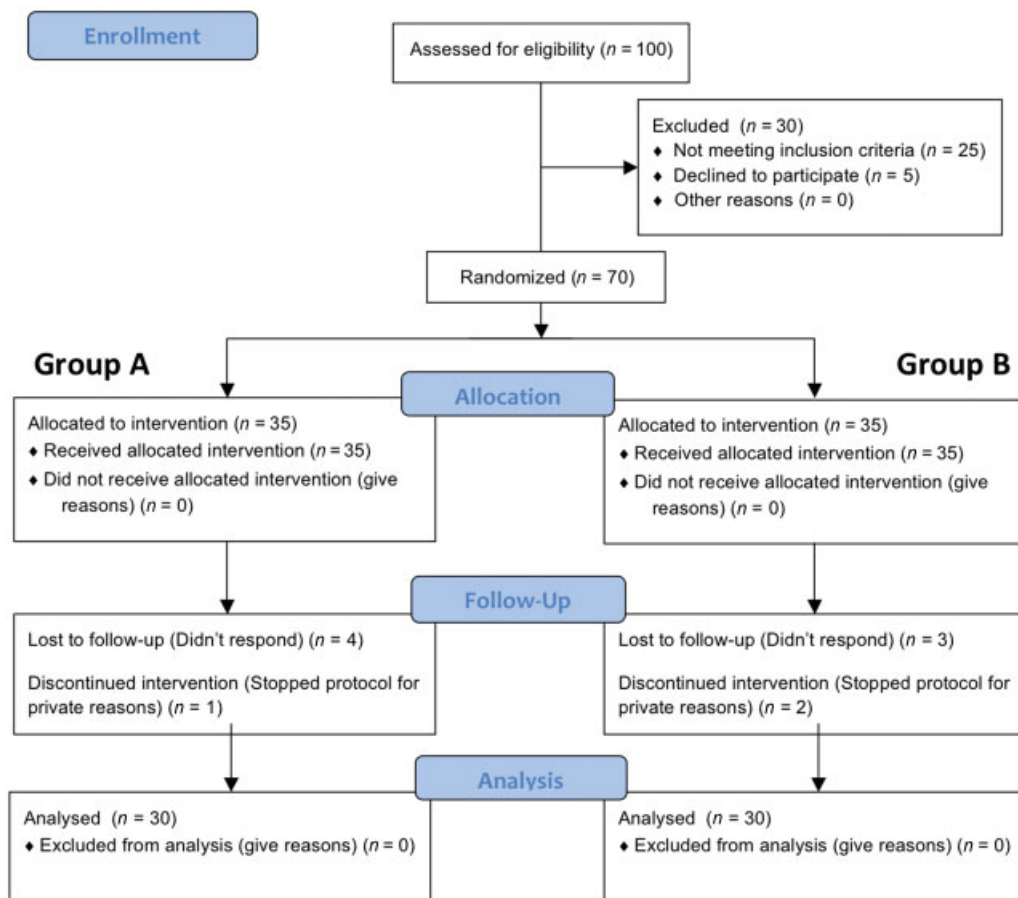


Fig. 1 Flow diagram of patients throughout the course of the study.

forces to restore medial alignment of the patella.¹¹ The latter objective is mainly achieved through the use of taping and knee braces.¹² The precise mechanism by which either of these solutions may be effective is not entirely known. The knee braces traditionally available on the market are mostly designed and constructed to apply an external, medially directed force that, in theory, counteracts the “maltracking” that tends to result in lateralization of the patella. Published

literature on the use of such braces is conflicting.²³ Draper et al,¹⁹ in a magnetic resonance imaging study on females with PFP, demonstrated that a brace applying a medial load to the patella can reduce lateral translation of the patella and

Table 1 Descriptive statistics for group A (knee brace used in combination with a rehabilitation program) and group B (rehabilitation alone)

Groups	Time interval	Kujala score, mean (SD)	VAS score, mean (SD)
Group A	Baseline	74.3 (7.1)	6.0 (1.9)
	3 months	77.1 (7.9)	2.9 (1.9)
	6 months	79.8 (6.9)	1.4 (1.6)
	12 months	80.9 (7.5)	0.9 (1.4)
Group B	Baseline	70.4 (7.2)	5.9 (1.6)
	3 months	74.7 (8.1)	3.7 (1.5)
	6 months	76.9 (8.6)	3.0 (1.5)
	12 months	78.4 (8.3)	1.8 (1.7)

Abbreviations: SD, standard deviation; VAS, visual analog scale.

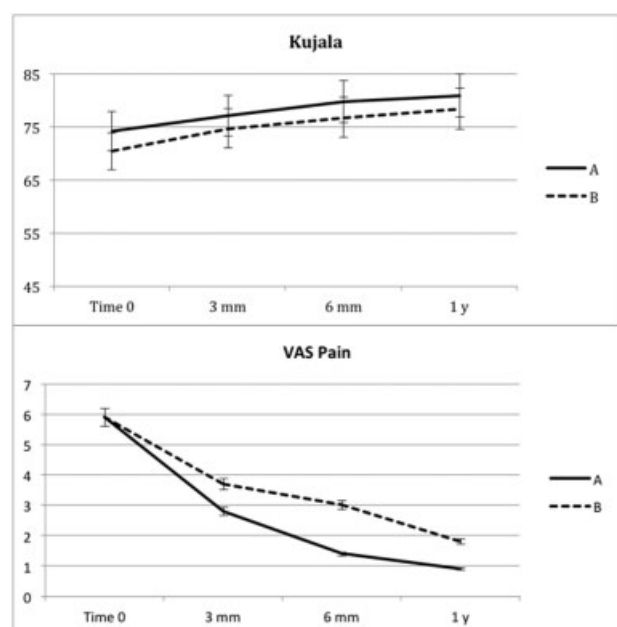


Fig. 2 Line diagrams of outcomes throughout the course of the study.

Table 2 Pairwise comparisons of time points for Kujala scores

Group A + B	Mean differences	p-Value	95% CI of difference	
Baseline vs. 3 mo	-3.25	< 0.001	-4.72	-1.78
Baseline vs. 6 mo	-5.75	< 0.001	-7.22	-4.28
Baseline vs. 12 mo	-7.32	< 0.001	-8.75	-5.89
3 vs. 6 mo	-2.50	0.001	-4.01	-0.99
3 vs. 12 mo	-4.07	< 0.001	-5.54	-2.60
6 vs. 12 mo	-1.57	0.036	-3.04	-0.10

Abbreviation: CI, confidence interval.

lateral tilt more effectively than a functional bandage can. Powers et al¹³ found improvement of pain and better activation of the quadriceps during ascending and descending stairs when using bracing. Further effects on knee joint biomechanics were studied by Selfe et al,^{22,26} who demonstrated improved coronal plane and torsional control of the knee during eccentric quadriceps contractions in subjects with soft knee braces. Thijs et al²⁴ and Callaghan et al¹⁶ reported proprioceptive effects and increased motor neuron activity; the latter detected modulation of the supplementary motor area, the cingulate motor area, and other neural areas of the brain during a proprioception knee motor task performed with and without bracing and patellar taping, respectively. In addition, D'Hondt et al¹⁸ and Crossley et al¹⁷ performed meta-analyses that highlighted better outcomes in patients using knee braces, namely, reduced pain, improved function, and a lower patellofemoral congruence angle. However, these papers also underlined the poor quality of studies in this setting, also drawing attention to

publications with limited level of evidence.²⁷ Conflicting results may also be attributable to variations in orthosis/brace designs used.

The knee brace used in this study implements an active approach that, in addition to controlling the vertical movement of the patella, ensures return of the kinetic energy accumulated during the specific sport-related flexion movement, thus lessening its impact forces. The brace features an anterior web-like structure made up of elastomeric bands that act like an elastic exoskeleton and, through elongation of the extensible components, attenuate the forces of impact on the joint, thus ensuring maintenance of proprioceptive contact throughout the entire ROM. The effect of web-like structure has been shown to improve knee stability during different sport-related motor tasks in healthy subjects, which has implications to the management of individuals with knee instability.^{20,28} Furthermore, during sports activities, the web-like structure claims to distribute the forces exerted more evenly on the patellofemoral joint and extensor mechanism.

The results of our study seem to indicate that this brace may be a useful aid in the treatment of anterior knee pain in amateur athletes, speeding up their return to sport and allowing better pain management.

Our results showed that the most significant improvement concerned pain, which was reduced by mean of over 5 VAS points, with a significant difference ($p < 0.05$) between the two groups in favor of the group who received knee bracing. We observed a progressive and significant improvement of all scores across all the time points in both the groups on VAS and Kujala scales. Moreover, 24 out of 30 patients in the group who received knee bracing returned to sport at 6 months, as opposed to only 14 of those who received the rehabilitation program only. This demonstrated that the rehabilitation program appears to be more effective when combined with the use of brace. Furthermore, 75% of the patients with brace were satisfied with the treatment, thus confirming the good level of compliance with the use of brace.

Our study has several limitations. No comparison was made with other types of brace; the sample of patients studied was small and they practiced different types of sport. All of these factors could potentially have biased our results.

In conclusion, the results of this study showed that the Reaction Knee Brace may be an effective adjunct to reducing pain in individuals with anterior knee pain and for speeding up their return to sport. As with taping,²⁹ the mechanisms by which these benefits are obtained remain unclear; they could be linked to a redistribution of stress forces, increased proprioceptive inputs, and increased neuromuscular control, which may be facilitated by the web-like structure of the knee brace and then may produce better quadriceps activation and greater control over the execution of sports exercises. Further biomechanical and clinical studies are needed to investigate more in-depth the mechanisms underlying the effectiveness of such devices and their role in rehabilitation.

Table 3 Pairwise comparisons of time points for VAS scores

Group A	Mean differences	p-Value	95% CI of difference	
Baseline vs. 3 mo	3.30	< 0.001	2.81	3.80
Baseline vs. 6 mo	4.61	< 0.001	4.01	5.20
Baseline vs. 12 mo	5.30	< 0.001	4.49	6.12
3 vs. 6 mo	1.30	0.001	0.63	1.97
3 vs. 12 mo	2.00	< 0.001	1.19	2.81
6 vs. 12 mo	0.70	0.006	0.22	1.17
Group B				
Baseline vs. 3 mo	2.16	< 0.001	1.79	2.53
Baseline vs. 6 mo	2.84	< 0.001	2.49	3.19
Baseline vs. 12 mo	4.20	< 0.001	3.80	4.60
3 vs. 6 mo	0.68	0.001	0.31	1.05
3 vs. 12 mo	2.04	< 0.001	1.62	2.46
6 vs. 12 mo	1.36	< 0.001	0.92	1.80

Abbreviations: CI, confidence interval; VAS, visual analog scale.

Conflict of Interest
None.

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