

RANDOMIZED PROSPECTIVE STUDY ON THE TREATMENT OF FEMORO-PATELLAR OSTEOARTHRITIS USING BRACING

ESTUDO PROSPECTIVO RANDOMIZADO DO TRATAMENTO DA ARTROSE FÊMORO-PATELAR PELO USO DE ÓRTESE

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ABSTRACT

Objective: To compare the effect of a brace designed to stabilize the patellofemoral joint to that of a patella-shaped neoprene sleeve with patella cut out in patients with patellofemoral osteoarthritis. **Methods:** Fifty-seven patients with femoro-patellar osteoarthritis were allocated to two groups: patients with femoro-patellar functional brace and those with a neoprene knee with a patellar orifice. Both groups underwent clinical treatment of osteoarthritis and used medications daily 1 month before and up to 3 months after brace placement. They were evaluated with the WOMAC and Lequesne questionnaires and performed five times sit to stand test, Timed Up and Go test, and six minutes walk test immediately before and 1 and 3 months after brace placement. **Results:** Both groups had improved pain, stiffness, and function with no difference between groups. Drug use decreased in both groups in the first month but increased in the third month. Naproxen use was progressively higher in the control group. **Conclusion:** Both knee orthoses improved pain and function and altered drug use only in the first month. Functional knee brace provided analgesia without increased use of naproxen. **Level of Evidence IB, Randomized clinical trial**

Keywords: Osteoarthritis. Orthotic. Patellofemoral Pain Syndrome.

RESUMO

Objetivo: Comparar o efeito de uma órtese destinada a estabilizar a articulação fêmoro-patelar, em comparação com uma de neoprene com orifício para rótula, em pacientes com artrose fêmoro-patelar. **Métodos:** Cinquenta e sete pacientes com artrose fêmoro-patelar foram alocados em dois grupos conforme a joelheira que receberam: órtese funcional fêmoro-patelar e joelheira de neoprene com orifício para patela. Ambos os grupos foram orientados sobre o tratamento clínico da osteoartrite e preencherem o consumo diário de medicamentos um mês antes da colocação das órteses e até três meses depois da colocação das mesmas. Foram avaliados com o questionário de WOMAC e Lequesne e realizaram os testes de senta e levanta, Timed-up-and-go e o teste de caminhada de seis minutos, nos momentos imediatamente antes da colocação da órtese e após um e três meses. **Resultados:** Ambos os grupos melhoraram dor, rigidez e função sem diferença entre os grupos. O consumo de medicamentos diminuiu em ambos os grupos no primeiro mês, aumentando no terceiro mês. O consumo de naproxeno foi progressivamente maior no grupo controle. **Conclusão:** Ambas as joelheiras melhoraram a dor, a função e alteraram o consumo de medicamentos somente no primeiro mês. A joelheira funcional propiciou analgesia sem consumo aumentado de naproxeno. **Nível de evidência IB, Ensaio clínico randomizado.**

Descritores: Osteoartrite. Órtese. Síndrome da Dor Patelofemoral.

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INTRODUCTION

Osteoarthritis (OA) is the most common form of arthritis,¹ with the knee being the primary affected site. Although patellofemoral OA coexists with tibiofemoral OA in up to 65% of patients² and anterior knee pain is equally disabling and painful,³ most studies focus on femorotibial compartments. It has been reported that patellar alignment is correlated with the severity of symptoms and is a radiographic predictor of disease progression.^{3,4} Conservative treatments include oral non-steroidal anti-inflammatory drugs (NSAIDs) and intra-articular administration of corticosteroids

or hyaluronic acid. However, these treatments showed no curative effect on inflammation associated with this condition.⁵ The use of brace is a popular treatment for chronic knee pain because of being widely accessible and relatively inexpensive.⁶ The patellar support provided by knee braces has certain advantages compared to that by a tape, including longer equipment life, lower risk of allergic dermatitis, and similar biomechanical effects, such as increased joint contact area.⁷ Current evidence shows that variations in patellar alignment are widespread and contribute significantly to the progression and symptoms of patellofemoral

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OA; thus, it would be highly beneficial to determine whether the extent of poor alignment influences brace efficacy. To date, there is no consensus on the exact contribution and effectiveness of using knee orthoses in improving patellar alignment and pain relief. This study aimed to compare the effect of a brace designed to stabilize the femoro-patellar joint to that of a patella-shaped neoprene brace in patients with femoro-patellar osteoarthritis.

MATERIALS AND METHODS

This study was approved by the Ethics Committee for Analysis of Research Projects (CAPPesq) (number 15016/16 and Clinical Trials registration number NCT02984254). All patients signed an informed consent form after receiving a detailed explanation. This is a randomized prospective study comparing two knee braces for patellofemoral osteoarthritis (PFOA).

The inclusion criteria were as follows: symptomatic PFOA knee OA, absence of axis dislocation, age ≥ 30 years, and clinical treatment for knee osteoarthritis for more than 6 months.

The diagnosis of PFOA OA was made using the clinical criteria of the ACR⁸, i.e., presence of symptoms (pain and sensitivity) in the patellofemoral compartment of the knee, associated with signs of OA according to the K&L classification,⁹ and showing no misalignment. Alignment was examined through panoramic radiography of the lower limbs, tracing the mechanical axis, from the center of the femoral head to the center of the ankle, and the femorotibial angles. Patients with involvement of the femorotibial compartment of the knee or who could not read or understand the consent form or the WOMAC questionnaire were excluded from this study.¹⁰ Patients with grade II and III or morbid obesity were also not included.

The exclusion criteria were as follows: braces used differently from what was requested; abandonment of the study; non-adaptation to the brace; skin and vascular complications due to brace use; failure to report medication use for the month between signing the consent and brace placement.

Procedure: Upon inclusion, the 60 patients were divided into three blocks and allocated to one of the two groups according to the order given by the spreadsheet 6591 created on April 12, 2017, at 8:58:36 in www.randomization.com. Thigh and leg circumferences were measured 15 cm from the center of the patella of the patients included in the study. They started to record their daily use of drugs (paracetamol, dipyrrone, naproxen or other anti-inflammatory drugs, codeine, tramadol, cyclobenzaprine, and other drugs for diabetes, hypertension, etc.). After 1 month, upon delivering the sheet with the medications used in the first month, the patients filled out the questionnaires, performed the function test, and received knee braces following the order of the draw, along with the guidelines for their use:

1. Free Knee: patellofemoral functional brace (Figure 1a) (study)
Technical characteristics: knee brace made of neoprene with upper, lower, and lateral impact absorption system.

2. Neoprene knee brace with a patellar orifice (Figure 1b) (control)
Technical characteristics: patella-shaped neoprene knee brace with lateral reinforcement.

All patients attended a half-day course on osteoarthritis and its forms of treatment based on an osteometabolic disease group educational program for patients with knee OA.¹¹

The patients answered the WOMAC and Lequesne questionnaires and performed the five-times-sit-to-stand test (FTSST), Timed Up and Go (TUG), and six-min walk (6MWT) tests.^{10,12-14}

Use of braces: The patients left the hospital with the brace(s) placed in the affected knee(s). They were instructed to use the brace for 2 h on the first day and increase by half an hour per day from the second day, up to a maximum of 12 h/day. These 12 h of use could be continuous or at intervals of not less than 4 h (from the second



Figure 1. A) Functional knee orthosis (Free Knee®, Salvapé, made of neoprene with Velcro and rubber tubes in the upper, lower, and lateral parts of the patella). B) Neoprene knee orthosis (Knee orthosis with patellar orifice, Salvapé, neoprene, and Velcro).

week) with rest of up to 2 h during the day, replacing the brace. The patients were instructed to sleep without the knee brace(s) and use them when performing physical activities, as long as activities were not performed in water.

Evaluations: The primary objective was to assess pain and stiffness, function, and drug use in the short term. To this end, follow-up evaluations were made before and 1 and 3 months after knee brace placement. Evaluations included the records of medications used daily (along with the number of hours of brace use), the WOMAC and Lequesne questionnaires, and functional evaluations. Radiography without the brace (Schuss view and profile and axial views of the patella) to measure the affected joint spaces and panoramic radiography to measure the internal and external femorotibial angles were performed before inclusion of patients. Age, years of schooling, and weight and height for BMI calculation were also obtained.

Sample calculation: "n" was calculated to obtain a statistical power of 80% and a significance level of 5%. To this end, we considered the standard deviation of the WOMAC variation in the study by Campos et al., who used a similar population of patients with knee OA from the Institute of Orthopedics and Traumatology.¹⁵ The sample size was selected so that it allowed the detection of a 5-point WOMAC variation. Considering eventual dropouts of about 10% of the patients, 26 patients per group was obtained as the recommended sample size.

Statistical analysis

Age and years of schooling were described according to groups using summary measures (means, standard deviations, medians, minimums, and maximums) and compared between groups using Student's t-test and Mann-Whitney test, respectively. Sex was described according to groups using absolute and relative frequencies, and the association was verified using Fisher's exact test.

The scores of the questionnaires were described according to the groups over the evaluation period using summary measures and compared between groups and time-points using generalized estimation equations with normal marginal distribution and identity link function. The same analyses were performed for the drugs used, assuming a negative binomial distribution with identity link function and a first-order auto-regressive correlation matrix between the evaluation periods for all the analyses. The analyses were followed by Bonferroni's multiple comparisons to determine the point at

which significant differences between the groups and evaluation periods occurred.

The results of the questionnaires and function tests were illustrated in graphs showing the mean profile and respective standard errors. The analyses were performed using IBM SPSS for Windows version 20.0, and data were entered in Microsoft Excel 2003. The tests were performed with a 5% significance level.

RESULTS

The study started with 30 patients in each group. One patient in the control group and two in the study group did not attend the session for knee brace retrieval (one patient in the control group asserted that his wife did not inform him, one patient in the study group had a trip, and the other patient did not explain the reason for abandoning the study before knee brace placement). All other patients completed the study.

Table 1 shows the personal characteristics according to groups. The results showed that pain, stiffness, WOMAC and Lequesne scores, and TUG and 6MWT results evolved similarly in both groups in all study periods (Figures 2–9, Table 2), with difference only in FTSTT results between the two groups.

Table 2 shows that pain, stiffness, and WOMAC and Lequesne scores differed throughout the evaluation periods regardless of the group ($p < 0.05$). 6MWT results differed, on average, between the groups independent of the time point of evaluation ($p = 0.026$), and the time of knee brace use differed between the periods evaluated regardless of the group ($p < 0.001$).

Table 3 shows that the WOMAC domains (pain, stiffness, and function) and the WOMAC total score reduced from inclusion to the other periods ($p < 0.05$), except for stiffness, which differed only from the baseline (pre) to the third month ($p = 0.001$). The 6MWT result was, on average, higher in the control group ($p = 0.026$), and brace use was, on average, higher at 3 months than at 1 month ($p < 0.001$).

With regard to the use of drugs (Table 4) for pain control, the combination of naproxen, dipyrrone, and omeprazole or ranitidine showed a statistically significantly different mean behavior in the groups throughout the evaluation period ($p_{\text{interaction}} \leq 0.05$). The use of paracetamol, codeine, tramadol, and cyclobenzaprine showed a mean difference throughout the evaluation periods regardless of the group ($p < 0.001$). An increase in naproxen use in the first and third months, compared to the initial time point, was observed only in the control group ($p < 0.05$), and in the third month, the control group used, on average, more naproxen than the study

Table 1. Personal characteristics according to groups and results of statistical tests.

Variable	Group		Total	P-value
	Neoprene sleeve (control)	Functional brace (study)		
	(N=29)	(N=28)	(N=57)	
Age (years)				0.265
Mean SD	65.3±7.6	63±7.9	64.2±7.8	
Median (min.; max.)	65 (39. 79)	63 (41. 78)	65 (39. 79)	
Sex, n (%)				0.504**
Female	25 (86.2)	22 (78.6)	47 (82.5)	
Male	4 (13.8)	6 (21.4)	10 (17.5)	
Education (years of schooling)				0.828*
Mean SD	7.9±4.1	8.3±6.4	8.1±5.3	
Median (min.; max.)	8 (0. 16)	5 (0. 30)	7 (0. 30)	

Student's t-test; * Mann-Whitney test; ** Fisher's exact test.

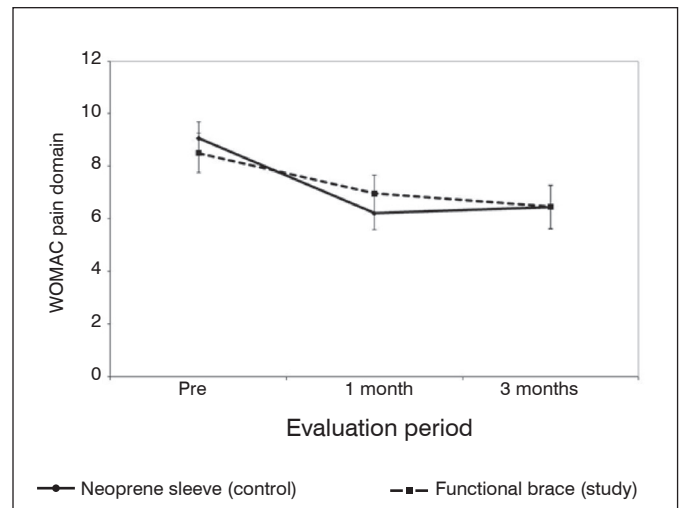


Figure 2. Mean values and respective standard errors of WOMAC pain domain by groups.

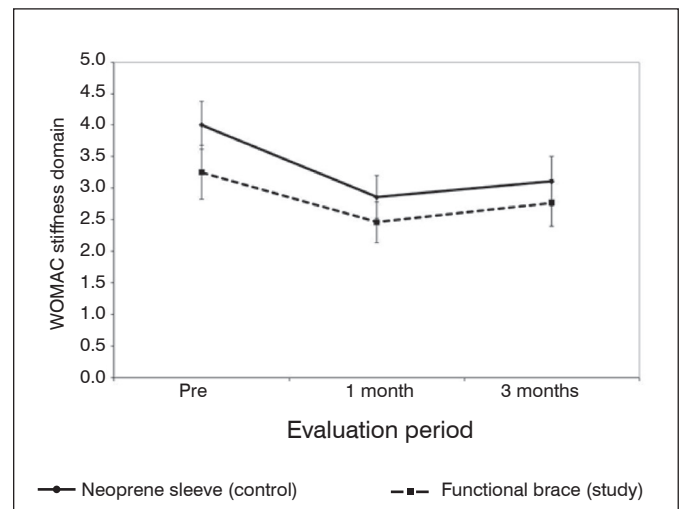


Figure 3. Mean values and respective standard errors of WOMAC stiffness domain by groups.

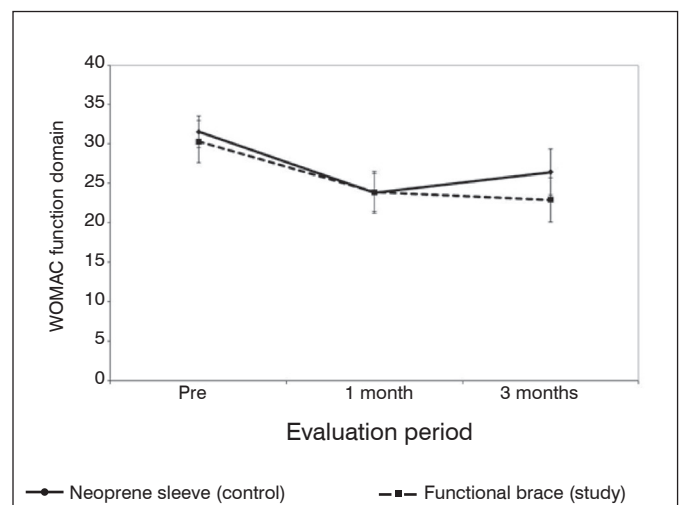


Figure 4. Mean values and respective standard errors of WOMAC function domain by groups.

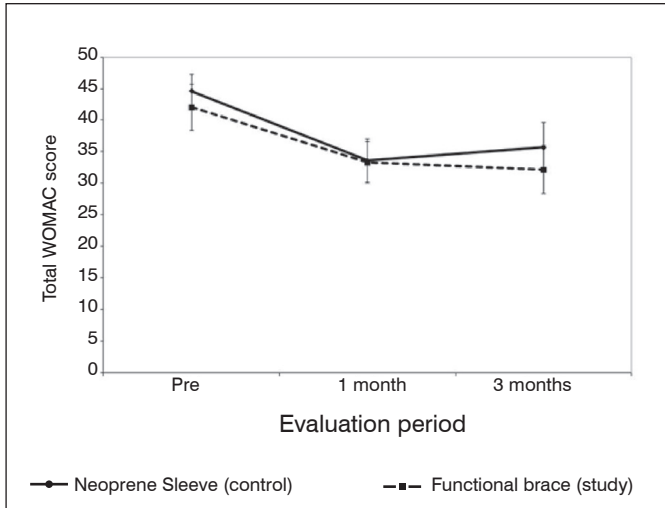


Figure 5. Mean values and respective standard errors of total WOMAC score by groups.

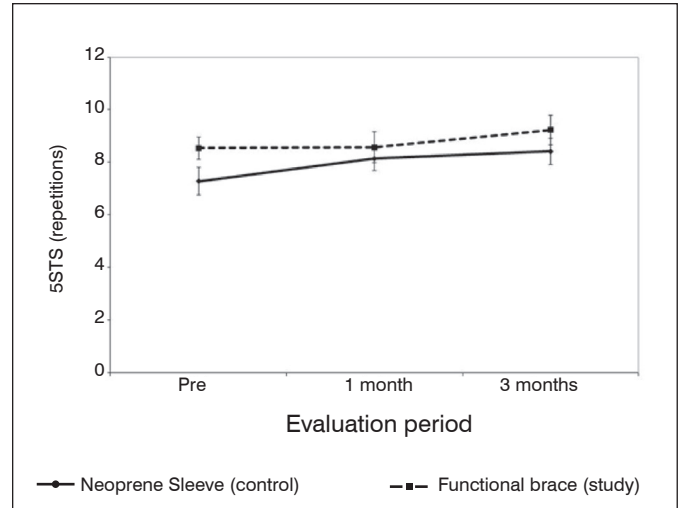


Figure 8. Mean values and respective standard errors of 5STS by groups.

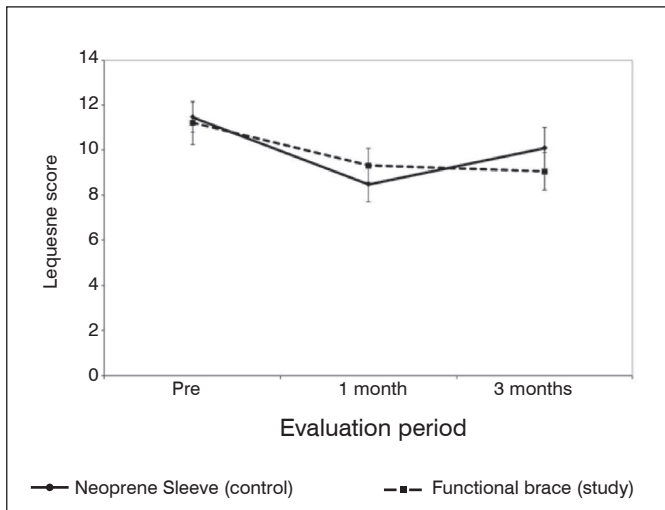


Figure 6. Mean values and respective standard errors of Lequesne scores by groups.

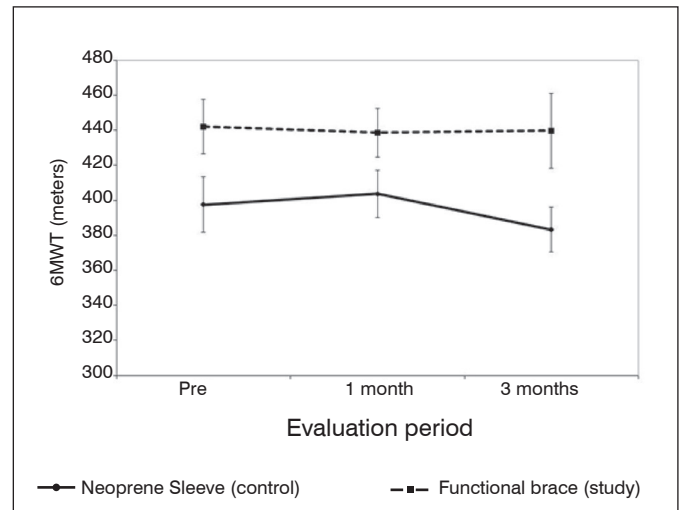


Figure 9. Mean values and respective standard errors of 6MWT by groups.

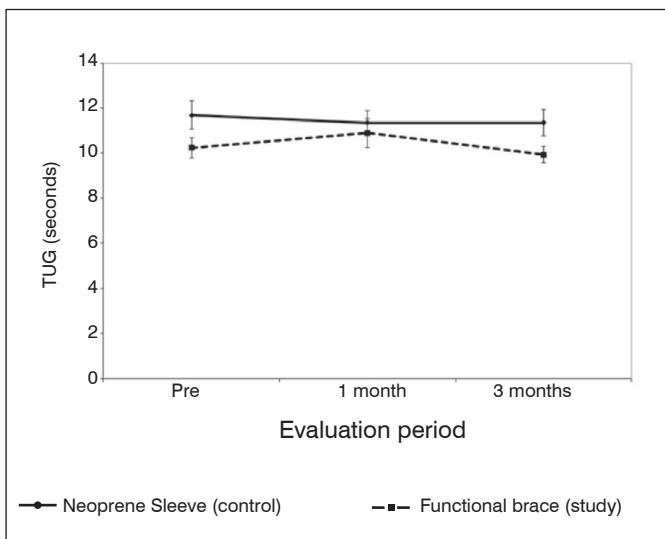


Figure 7. Mean values and respective standard errors of TUG by groups.

group ($p=0.011$) (Table 5). The use of dipyron decreased in the first month and increased in the third month in the study group ($p=0.002$ and $p=0.001$ respectively), and in the first month, the control group used, on average, more dipyron than the study group ($p=0.001$, Tables 4 and 5). The use of paracetamol and codeine increased on average in the third month, regardless of the group ($p<0.05$). Both groups used codeine, but some patients in the control group used tramadol instead of codeine (the study group did not use tramadol). The use of tramadol (only in the control group) decreased in the first month compared to that at pre ($p=0.047$) and increased in the third month, differing from pre and first month ($p=0.002$ and $p<0.001$, respectively). The variation in the use of codeine and tramadol was similar over time and between groups. The use of cyclobenzaprine was lower at the first month than at other periods, regardless of the group ($p<0.05$). The use of omeprazole or ranitidine increased in the third month in the control group ($p<0.05$) and decreased from pre to the first month in the study group ($p = 0.001$), following naproxen use (Tables 4 and 5).

Table 2. BMI, WOMAC domains, and total WOMAC score, and function tests according to groups and evaluation periods and results of comparative tests.

Variable	Group						P _{Group}	P _{Period}	P _{Interaction}
	Neoprene sleeve (control)			Functional brace (study)					
	Pre	1 month	3 months	Pre	1 month	3 months			
BMI							0.329	0.427	0.270
Mean SD	29.5±3.2	29.4±2.8	29.2±2.7	28.5±3.8	28.3±3.7	28.3±4.3			
Median (min.. max.)	30 (20.7. 35.4)	30 (23.4. 34.7)	29 (23.6. 34.2)	29.1 (20.3. 35.2)	28.7 (20.2. 34.5)	27.6 (19.5. 36.2)			
WOMAC pain domain							0.935	<0.001	0.272
Mean SD	9.1±3.3	6.2±3.5	6.4±4.4	8.5±4	7±3.7	6.5±4.2			
Median (min.. max.)	10 (3. 13)	6 (0. 15)	7 (0. 20)	7.5 (2. 20)	7 (1. 14)	6 (1. 14)			
WOMAC stiffness domain							0.223	0.001	0.769
Mean SD	4±2	2.9±1.8	3.1±2.1	3.3±2.3	2.5±1.7	2.8±1.9			
Median (min.. max.)	4 (0. 8)	3 (0. 6)	3 (0. 7)	4 (0. 8)	3 (0. 5)	3 (0. 7)			
WOMAC function domain							0.575	<0.001	0.364
Mean SD	31.6±10.7	23.8±14.4	26.4±15.5	30.3±14.3	23.9±12.8	22.9±14.2			
Median (min.. max.)	34 (8. 49)	25 (0. 52)	26.5 (0. 67)	30.5 (2. 68)	22.5 (2. 54)	20.5 (0. 49)			
Total WOMAC score							0.581	<0.001	0.540
Mean SD	44.6±14.1	33.6±18.3	35.7±20.9	42±19.5	33.3±17.3	32.2±19.4			
Median (min.. max.)	48 (13. 69)	38 (0. 68)	36 (0. 94)	41.5 (4. 96)	33.5 (3. 73)	28.5 (1. 68)			
Lequesne score							0.891	<0.001	0.106
Mean SD	11.5±3.6	8.5±4.2	10.1±4.9	11.2±5	9.3±4	9.1±4.3			
Median (min.. max.)	12.5 (3.5. 17.5)	10 (1. 15.5)	10.5 (0. 22.5)	11.3 (0. 21)	9.3 (1. 16)	10 (0. 16.5)			
TUG (seconds)							0.163	0.504	0.146
Mean SD	11.7±3.4	11.4±2.9	11.4±3.1	10.2±2.4	10.9±3.4	9.9±1.8			
Median (min.. max.)	10.5 (7.8. 20.8)	10.7 (6.8. 19.6)	10.6 (7.8. 19.9)	9.8 (6.5. 16.6)	10.5 (6.6. 24.9)	9.9 (6.7. 13.3)			
FTSTS (repetitions)							0.202	0.164	0.359
Mean SD	7.3±2.8	8.1±2.5	8.4±2.6	8.5±2.3	8.6±3.2	9.2±2.9			
Median (min.. max.)	8 (0. 13)	8 (2. 12)	9 (0. 13)	8 (4. 15)	8.5 (0. 16)	9.5 (5. 17)			
6MWT (meters)							0.026	0.599	0.333
Mean SD	397.4±84.9	403.7±72.6	383.3±68.5	442.1±81.3	438.6±71.7	439.7±108.9			
Median (min.. max.)	419 (223. 517)	415 (224. 486)	398.5 (210. 480)	439 (250. 633)	450 (295. 676)	439 (233. 700)			
Use of knee brace (hours)							0.208	<0.001	0.900
Mean SD		127.2±107.2	270±240.7		191.5±145.6	325±292.2			
Median (min.. max.)		115 (0. 351.5)	257 (0. 828)		147 (0. 429)	259 (6. 924)			

EEG with normal distribution and identity link function

Table 3. Results of comparisons between WOMAC domains and total WOMAC score, Lequesne score, and use of knee brace between the evaluation periods and the 6MWT score between the groups.

Variable	Comparison		Mean difference	Standard error	gf	P-value	CI (95%)	
							Lower	Upper
Pain	Pre and	1 month	2.20	0.44	1	<0.001	1.15	3.25
	Pre and	3 months	2.28	0.57	1	<0.001	0.93	3.64
	1 month and	3 months	0.08	0.45	1	>0.999	-0.99	1.16
Stiffness	Pre and	1 month	0.96	0.26	1	0.001	0.34	1.58
	Pre and	3 months	0.68	0.32	1	0.107	-0.09	1.45
	1 month and	3 months	-0.29	0.26	1	0.834	-0.92	0.35
Function	Pre and	1 month	7.08	1.43	1	<0.001	3.66	10.49
	Pre and	3 months	6.09	1.88	1	0.004	1.59	10.60
	1 month and	3 months	-0.98	1.46	1	>0.999	-4.48	2.51
Total WOMAC score	Pre and	1 month	9.88	1.84	1	<0.001	5.47	14.28
	Pre and	3 months	9.19	2.44	1	0.001	3.34	15.03
	1 month and	3 months	-0.69	1.88	1	>0.999	-5.20	3.82
Lequesne score	Pre and	1 month	2.44	0.46	1	<0.001	1.33	3.55
	Pre and	3 months	1.71	0.61	1	0.015	0.25	3.17
	1 month and	3 months	-0.73	0.48	1	0.379	-1.86	0.41
6MWT (meters)	Control and	Study	-43.17	19.41	1	0.026	-81.22	-5.12
Use of knee brace (hours)	1 month and	3 months	-137.03	27.53	1	<0.001	-190.99	-83.07

Bonferroni's multiple comparisons

Table 4. Use of drugs according to groups and evaluation periods and results of comparative tests.

Variable	Group						p _{Group}	p _{Period}	p _{Interaction}
	Neoprene sleeve (control)			Functional brace (study)					
	Pre	1 month	3 months	Pre	1 month	3 months			
Naproxen							0.004	<0.001	<0.001
Mean SD	0.8±2.3	2.1±8.7	7.5±28.9	1.7±5	1.1±4.3	2.2±7			
Median (min.. max.)	0 (0. 9)	0 (0. 46)	0 (0. 154)	0 (0. 21)	0 (0. 19)	0 (0. 31)			
Dipyrone							0.073	0.018	0.002
Mean SD	5.7±14.7	8.6±20.8	10.3±22	7.4±23.4	1.7±6.8	8.5±20.9			
Median (min.. max.)	0 (0. 73)	0 (0. 86)	0 (0. 84)	0 (0. 122)	0 (0. 35)	0 (0. 78)			
Paracetamol							0.946	<0.001	0.225
Mean SD	12±22.1	10.9±21.2	25.2±47.5	10.4±21.6	13.4±23.9	23.7±59			
Median (min.. max.)	1 (0. 93)	0 (0. 78)	1 (0. 195)	0 (0. 102)	0 (0. 80)	0 (0. 276)			
Codeine							0.152	<0.001	0.695
Mean SD	7.3±18.7	6.2±15.2	18.6±41.7	9.8±21.6	9.8±20.7	25.8±46.7			
Median (min.. max.)	0 (0. 81)	0 (0. 57)	0 (0. 172)	0 (0. 102)	0 (0. 76)	1.5 (0. 189)			
Tramadol							#	<0.001	#
Mean SD	1.4±7.2	0.7±2.5	3.6±9.6	0±0	0±0	0±0			
Median (min.. max.)	0 (0. 38)	0 (0. 13)	0 (0. 36)	0 (0. 0)	0 (0. 0)	0 (0. 0)			
Cyclobenzaprine							0.102	<0.001	0.577
Mean SD	4.5±13	2.1±6.8	6.8±16.6	7.6±18.1	4.6±12.7	7.3±19.6			
Median (min.. max.)	0 (0. 61)	0 (0. 26)	0 (0. 63)	0 (0. 61)	0 (0. 54)	0 (0. 77)			
Omeprazole or ranitidine							0.275	<0.001	<0.001
Mean SD	6.4±14	9.7±16.8	17±26.3	12.9±33.6	4.8±20.4	7.5±17.6			
Median (min.. max.)	0 (0. 61)	0 (0. 52)	0 (0. 82)	0 (0. 147)	0 (0. 105)	0 (0. 68)			
Cortisone							#	0.133	#
Mean SD	0±0	0.1±0.4	0.3±1.2	0.1±0.8	0±0	0±0			
Median (min.. max.)	0 (0. 0)	0 (0. 2)	0 (0. 5)	0 (0. 4)	0 (0. 0)	0 (0. 0)			

EEG with negative binomial distribution and identity link function. #, unable to calculate

Table 5. Results of the multiple comparisons of the drugs that showed differences between groups or periods.

Variable	Group/period	Comparison		Mean difference	Standard error	gf	p	CI (95%)	
								Lower	Upper
Naproxen	Control	Pre and	1 month	-1.28	0.49	1	0.131	-2.70	0.15
		Pre and	3 months	-6.66	1.49	1	<0.001	-11.03	-2.28
		1 month and	3 months	-5.38	1.47	1	0.004	-9.68	-1.08
	Study	Pre and	1 month	0.57	0.46	1	>0.999	-0.77	1.91
		Pre and	3 months	-0.50	0.64	1	>0.999	-2.37	1.37
		1 month and	3 months	-1.07	0.53	1	0.674	-2.64	0.50
	Pre	Control and	Study	-0.89	0.47	1	0.866	-2.26	0.48
	1 month	Control and	Study	0.96	0.56	1	>0.999	-0.68	2.60
3 months	Control and	Study	5.27	1.56	1	0.011	0.68	9.86	
Dipyrone	Control	Pre and	1 month	-2.96	1.95	1	>0.999	-8.69	2.76
		Pre and	3 months	-4.69	2.31	1	0.638	-11.47	2.10
		1 month and	3 months	-1.72	2.49	1	>0.999	-9.04	5.59
	Study	Pre and	1 month	5.71	1.51	1	0.002	1.29	10.14
		Pre and	3 months	-1.11	2.26	1	>0.999	-7.73	5.51
		1 month and	3 months	-6.82	1.71	1	0.001	-11.85	-1.80
	Pre	Control and	Study	-1.77	1.89	1	>0.999	-7.33	3.78
	1 month	Control and	Study	6.91	1.74	1	0.001	1.80	12.01
3 months	Control and	Study	1.81	2.64	1	>0.999	-5.93	9.55	
Paracetamol	Both groups	Pre and	1 month	-0.93	1.39	1	>0.999	-4.26	2.40
		Pre and	3 months	-13.25	3.02	1	<0.001	-20.47	-6.02
		1 month and	3 months	-12.32	2.58	1	<0.001	-18.50	-6.13
Codeine	Both groups	Pre and	1 month	0.60	1.02	1	>0.999	-1.84	3.04
		Pre and	3 months	-13.60	2.80	1	<0.001	-20.30	-6.91
		1 month and	3 months	-14.21	2.49	1	<0.001	-20.17	-8.25
Tramadol	Both groups	Pre and	1 month	0.36	0.15	1	0.047	0.00	0.72
		Pre and	3 months	-1.13	0.33	1	0.002	-1.91	-0.35
		1 month and	3 months	-1.49	0.29	1	<0.001	-2.18	-0.80
Cyclobenzaprine	Both groups	Pre and	1 month	2.44	0.88	1	0.017	0.33	4.56
		Pre and	3 months	-1.03	1.27	1	>0.999	-4.06	2.00
		1 month and	3 months	-3.47	0.97	1	0.001	-5.80	-1.14
Omeprazole or ranitidine	Control	Pre and	1 month	-3.28	1.34	1	0.215	-7.20	0.65
		Pre and	3 months	-10.55	2.83	1	0.003	-18.85	-2.25
		1 month and	3 months	-7.28	2.33	1	0.027	-14.11	-0.44
	Study	Pre and	1 month	8.11	1.96	1	0.001	2.35	13.86
		Pre and	3 months	5.43	2.21	1	0.210	-1.06	11.91
		1 month and	3 months	-2.68	1.07	1	0.184	-5.82	0.46
	Pre	Control and	Study	-6.51	2.84	1	0.328	-14.85	1.82
	1 month	Control and	Study	4.87	2.14	1	0.342	-1.41	11.15
3 months	Control and	Study	9.47	3.58	1	0.122	-1.03	19.96	

Bonferroni's multiple comparisons

DISCUSSION

Patellofemoral OA is a common condition; however, there is little consensus about nonsurgical approaches to its treatment.^{6,16,17} In our study, there was no significant improvement of one group over the other. Previous studies on the efficacy of treatment with patellofemoral braces have reported varied results.^{6,16,18} However, the use of brace is still a common conservative treatment option as it is a noninvasive and low-cost intervention that is widely available, and therefore, it is in the public interest to evaluate its reliability and therapeutic limitations. Since patellar alignment is an important factor in the progression and development of the symptoms of PFOA, a treatment approach that addresses patellar alignment would be logical and of theoretical benefit.^{3,4} Although patellar malalignment has been positively associated with progression of PFOA OA,^{4,18} poor alignment alone may be insufficient to cause pain,^{19,20} and correction of poor alignment does not necessarily reduce the symptoms.^{19,20} The current understanding of the etiology of pain resulting from patellar malalignment is incomplete.^{19,20}

In this study, both groups showed improvement during treatment targeting pain and function, which shows the importance of targeted nonsurgical intervention, such as exercise, education, and the use of knee brace. In the 3-month assessment, although pain was reported to be lower, there was an increase in the use of drugs in both groups. Specifically, the control group showed progressively increased use of naproxen, and consequently the use of gastric protectors, while reporting lesser pain, better function, and using knee braces for a relatively shorter time than the study group. This may indicate a relative superiority of the functional knee brace, with patients using it for more hours and using fewer drugs. Despite

the information provided on diet and daily exercises necessary to complement the treatment, the program was not supervised regarding these variables of clinical treatment. Thus, adherence to the unsupervised program is unknown. Considering that OA is a chronic disease, our results indicate the need for studies with an extended duration of supervised treatment or additional means to ensure adherence to an unsupervised program.

Another limitation of our study is the lack of measurement of improvement in patellar positioning and patellar tilt to assess whether there is real improvement in patellar alignment with the use of knee brace, especially during movement.

CONCLUSION

Both knee braces improved pain and function and altered the use of drugs only in the first month. The functional knee brace provided analgesia without the increased use of naproxen.

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