



The effects of vacuumic bracing system on the patellofemoral articulation in patients with patellofemoral pain syndrome

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A B S T R A C T

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Patellar bracing is a component of treatment of patellofemoral joint (PFJ) problems. A new vacuumic brace was designed by the researchers that act based on an external vacuuming suction. Ten patients were undertaken for the CT scan study at both 0° and 30° knee flexion immediately pre- and post-bracing. Also they examined clinically pre, post and 1 week after using the brace. Measurements of patellofemoral joint space width (PFJSW) and patellofemoral joint area (PFJA) showed that the application of the vacuumic brace is able to create a significant patellofemoral joint distraction at both knee angles. A significant reduction in visual analog scale (VAS) and increase in kujala patellofemoral score (KPS) was found in subjects after using the brace for 1 week. In conclusion, the results conveyed that application of the vacuumic brace is able to create a joint distraction and useful changes in VAS and KPS parameters.

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1. Introduction

Patellofemoral pain syndrome (PFPS) was first described by Aleman in 1928.¹ Patellofemoral pain (PFP) is one of the most common disorders affecting the lower extremities.² Although the etiology of PFP continues to be debated, abnormal patellar tracking is thought to be the primary cause.^{3,4} However, it is widely questioned by researchers, mainly due to the existence of a poor relationship between the symptoms and the mal-alignment.⁵ It is well known that the infrapatellar fat pad, subchondral bone, patellar ligament, synovial membrane and the medial and lateral retinaculum, are all supplied by rich nerve endings, which might cause pain individually or in combination with others.^{6–9} Cartilage lesions can only indirectly give rise to pain, e.g., from subchondral bone or synovial tissue because the source of pain is not the aneural damaged cartilage.¹⁰ Sanchis et al. suggest that periodic short episodes of ischemia and hyperinnervation in the lateral retinaculum are involved in the pathogenesis of PFP.^{5,6} Dye et al. suggest that PFP could be due to pathophysiologic factors, which can be characterized as loss of tissue homeostasis.^{7,8}

Currently, patellar bracing has been used in the treatment of PFP as a non-operative technique.^{11–12,13} Most of the current braces have been designed with the purpose of centralizing the patella within the trochlear groove^{14,15} or increasing the patellofemoral contact area.⁴ Although, wearing the current braces appears to be effective in reducing PFP subjectively, the underlying reason is not entirely clear. Considering the possible etiologies of PFPS, a new vacuum brace was designed with a different mechanism. This brace acts in such a manner as to pull the patella upwards into the cup using an external vacuum suction.

The therapeutic applications of vacuum cupping have very well been documented as a result of several thousand years of clinical experiences in Traditional Chinese Medicine (TCM). Cupping is a method of treatment that involves the application of a vacuum to a localized area of the skin.¹⁶ It is purported to be beneficial in treatment of many disorders.^{17,18} Employing the negative pressure of cupping on soft tissue can lead to pain relief, stretching of the skin and underlying soft tissue layers as a result of tensile stress and increasing blood circulation around the area being treated.^{18,19} According to the effects of cupping, the purpose of this preliminary study was to determine whether the new vacuum brace is able to pull up the patella into the vacuum cup and create a patellofemoral joint (PFJ) distraction and if so, whether this vacuum brace is able to create any changes in the PFP clinically.

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2. Materials and methods

2.1. Subjects

This clinical trial study was carried out in the Faculty of Rehabilitation, and Radiology Research Center at the Department of Radiology, Imam Hospital, Tehran University of Medical Sciences, Iran, from June to October 2006. Ten patients with PFPS, diagnosed by an orthopedic surgeon specialist, with a mean age of 24.3 ± 7.1 years (ranges from 17 to 40) participated in this study (8 females, 2 males). Seven out of 10 patients showed bilateral PFP and three patients had unilateral PFP. All 17 PFJs (9 right and 8 left sides) were undertaken for a computerized tomographic (CT) scan and a clinical study. This study was approved by the Ethical Committee of Tehran University of Medical Sciences (Ref. number: 260-2642). In addition, the hazards of X-rays were fully described for the patients and signed a written informed consent.

2.1.1. Inclusion criteria

(1) A subjective history consistent with the PFPS, (2) a positive result from at least two of the following clinical tests including Clarke’s sign, patellar compression test, painful palpation of the medial/lateral facets, isometric quadriceps contraction test, and squat test.

2.1.2. Exclusion criteria

The subjects were excluded if they showed any history of knee trauma, surgery or neurologic disorders, any evidence of meniscal or ligamentous damages, or presenting an active knee effusion.²⁰

2.2. Instrumentation

A new vacuum based patellar brace was used in this study (Fig. 1). This brace consisted of five parts (1) an elastic silicone part that attaches to a patient’s knee, (2) a rigid vacuum cup connected to the front silicone part, (3) a neoprene part with three belts for holding the silicone part on the patient’s knee, (4) a suction pump to create a negative air pressure, and finally, (5) a calibrated pressure gauge to determine the air pressure used in the system.

2.3. Measurements

2.3.1. Patellofemoral joint space width (PFJSW)

To determine the amount of displacement in PFJSW before and after bracing, six bony landmarks of the patella or femoral trochlea were used. According to the position of the patella in relationship to

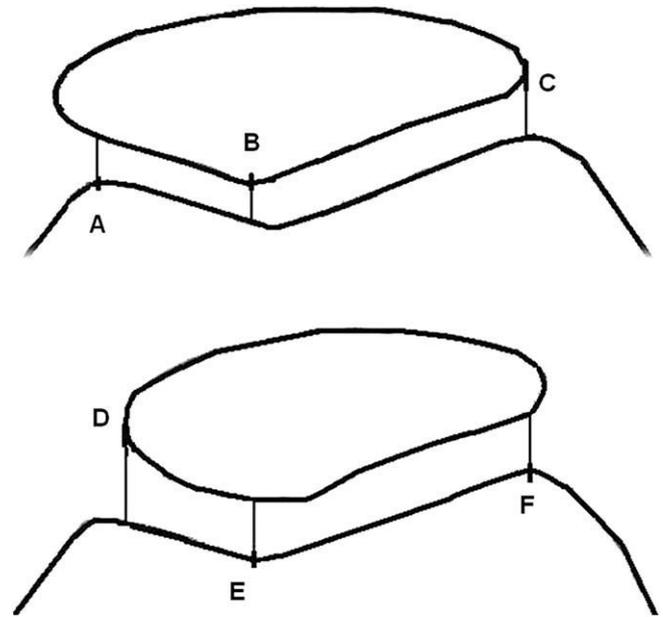


Fig. 2. Six bony landmarks of the patella (D, B and C) or femoral trochlea (A, E and F).

the femoral trochlea, we used only three landmarks among the six presumptive landmarks. These three landmarks were the best points for starting to draw the three perpendicular lines in the medial, middle and lateral parts of the PFJ. The landmarks are as follows (Fig. 2).

(E) The deepest portion of the trochlear groove; (A and F) the summits of the femoral condyles; (B) the lowest aspect of the patellar ridge; (D) the most medial border of the patella; and (C) the most lateral border of the patella. Medial PFJSW is the length of the line which connects point D to the femur or A to the patella perpendicularly. Middle PFJSW is the length of the line which connects point B to the femur or E to the patella perpendicularly. Lateral PFJSW is the length of the line which connects point C to the femur or F to the patella perpendicularly.

2.3.2. Patellofemoral joint area (PFJA)

This area was defined before and after bracing by the line tangent to the subchondral surfaces of the patella and femur using four landmarks D, A, F and C (Fig. 3).

2.3.3. Kujala patellofemoral score (KPS)

It was measured through the Kujala Score questionnaire.²¹ Each subject completed a reliable and valid questionnaire before and after the 1-week use of the brace and the functional status of the subjects were investigated.²¹

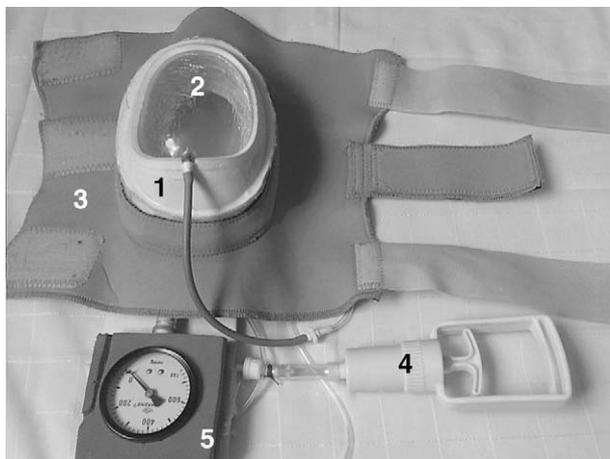


Fig. 1. The structure of different components of vacuum brace.



Fig. 3. The area of patellofemoral joint (AFCD).

2.3.4. Visual analog scale (VAS)

It has been shown to be reliable and valid for the measurement of pain intensity.²² A 10-cm horizontal line marked “no pain” on the left and “unbearable pain” on the right was used before and immediately after the application of vacuum brace and also after one week of using the brace. Each subject made a mark on the VAS line, which corresponded to the perceived level of pain. The distance from the left end of the VAS line to the subject’s mark was measured (cm) and recorded as the VAS score.

2.4. Imaging techniques

In contrast to the well known limitations in assessing PFJ, particularly in the first 20°–30° of knee flexion using the conventional axial radiographs, computed tomography (CT) allows accurate evaluation of the patellar position at any degree of knee flexion.^{23,24} In this study, an X-Vision CT scanner (Toshiba, Medical Systems, Tokyo, Japan) was used to determine the geometry of the PFJ. Scanning was performed at 120 KV, 230 mAs and the section thickness of 5 mm by using a standard image reconstruction algorithm. Transaxial mid-patellar CT Images were taken at 0° and 30° knee flexion. In the first position, patella could move easily and in the second position, patella gradually begins to engage with the trochlea at 20°–30° of knee flexion. Images were obtained in static position under two conditions: (1) without the vacuum brace, and (2) with the vacuum brace. A non-metal device was used for positioning of the knee in 0° and 30° knee flexion (Fig. 4).

2.5. Experimental procedure

The subjects were examined statically in the supine position at two angles of knee flexion (0° and 30°) under two conditions: with and without the vacuum brace. A CT scan image of the tested knee was taken after each implementation. All images were taken by the same CT scan equipment, all at the mid-patellar level. Positioning of the tested knee in 0° and 30° was accomplished statically using a non-metal device, while the untested knee was positioned in full flexion outside of the radiation field. Some foot, ankle and thigh straps were used to stabilize the subjects’ lower extremities.

When the vacuum brace was used, the brace was placed on the knee in such a manner that the patella was able to move freely under the vacuum cup. Since the rigid cup, which was connected to the silicone part, was made from transparent isinglass, the inside of the vacuum cup was clearly visible. For putting the center of the vacuum cup just above the center of patella, the central point of the

patella on the skin was marked by a pen to be able to superimpose the center of the cup and the marked point of the patella during fastening the brace straps. Then, a negative pressure of exactly 70 mmHg was applied by use of a suction pump. It should be mentioned that although a negative pressure of around 100 mmHg is the safety vacuum limit of skin,²⁵ a negative pressure of 70 mmHg was applied in this study for additional safety consideration. The patient was encouraged to relax the muscles around the knee joints during the test. For CT scan imaging, all measurements on the medial, middle and lateral PFJSW (mm), and PFJA (mm²) were performed in a workstation by one investigator.

To assess the VAS and KPS after 1 week use of the vacuum brace, the patients were asked to use the brace twice a day (2 h each time) in a long sitting position with a small pillow under the knee (about 20° knee flexion). Then, based on the patients’ level of bearing a negative pressure of 40–70 mmHg was applied to the brace when the brace used.

2.6. Reliability of the measuring method

To have repeatable data, all CT images were observed by one expert technician and all the measurements were carried out by him. Three subjects with PFPS were randomly selected and the images of their six PFJs (right and left) at 0° and 30° knee flexion with and without the vacuum brace were measured on the same day and two days later. The coefficients of correlation (CC) between the two measurements were used to assess the intra-observer reliability. The CC values obtained between 0.92 and 0.99 for the images convinced the researchers that the measurement technique was reliable enough to extend the study to more subjects.

2.7. Statistical analysis

A Shapiro–Wilk test was performed to analyze the distribution of the data. It showed that the data was normally distributed and satisfied the researchers to use parametric data analyses.

A paired sample *t*-test was used to compare the differences between the braced and no braced conditions. This analysis was also applied for PFJA and PFJSW at 0° and 30° knee flexion. All statistical analyses were performed using SPSS statistical software version 15 and the significant level was set on 0.05.

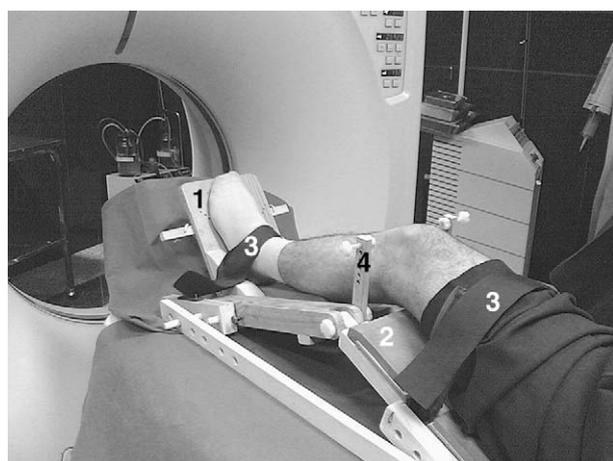


Fig. 4. The structure of different components of non-metal device. (1) A movable foot and leg support. (2) A fixed thigh support. (3) Two belt for fixing the foot, leg and thigh during the tests. (4) Two pieces of wood.

Table 1

Paired sample *t*-test results for comparisons of two conditions (no bracing and bracing) at each angle of 0° and 30°.

Pair	Paired differences			P value
	95% confidence interval of the difference			
	Mean	Lower	Upper	
1 Medial. No Vacuum Brace 0 Vacuum Brace 0	-2.777	-4.064	-1.575	<0.0001
2 Middle. No Vacuum Brace 0 Vacuum Brace 0	-2.489	-3.256	-1.722	<0.0001
3 Lateral. No Vacuum Brace 0 Vacuum Brace 0°	-2.353	-3.195	-1.511	<0.0001
4 Medial. No Vacuum Brace 30 Vacuum Brace 30°	-1.487	-2.531	-0.443	<0.008
5 Middle. No Vacuum Brace 30 Vacuum Brace 30	-0.677	-1.089	-0.265	<0.003
6 Lateral. No Vacuum Brace 30 Vacuum Brace 30°	-0.239	-0.734	0.255	<0.320
7 Area. No Vacuum Brace 0 Vacuumm Brace 0	-131.829	-172.454	-91.204	<0.0001
8 Area. No Vacuum Brace 30 Vacuumm Brace 30	-38.453	-60.319	-16.587	<0.002

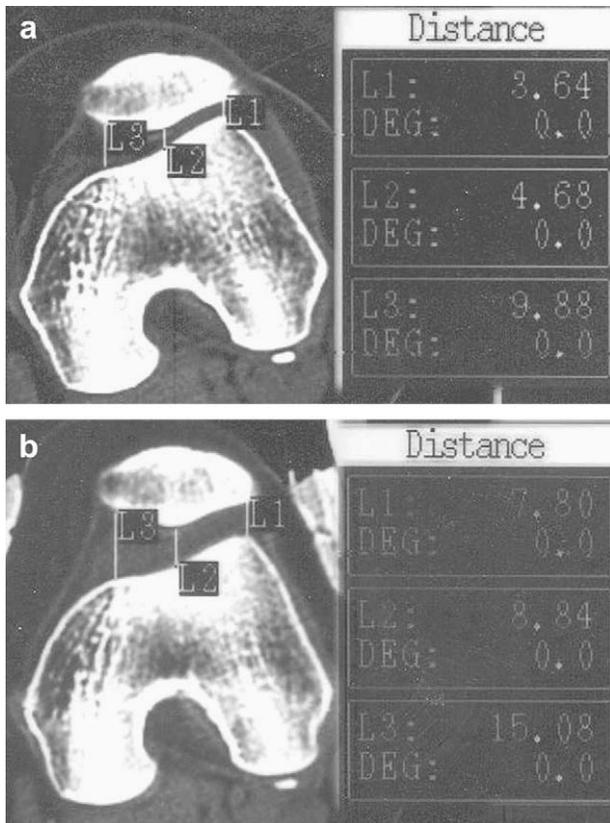


Fig. 5. Medial (L3), middle (L2), and lateral (L1) patellofemoral joint space width before bracing (a), and after bracing (b).

3. Results

A paired sample *t*-test revealed that the vacuum brace resulted in significant increase in the medial, middle and lateral PFJSW at 0° (all sites $P < 0.0001$) and 30° medial ($P < 0.008$), middle ($P < 0.003$) except for lateral PFJSW at 30° knee flexion ($P = 0.32$) and also increase in PFJA at both 0° and 30° knee flexion ($P < 0.0001$ and $P < 0.002$, respectively) of braced condition when compared to the no braced condition (Table 1). In confirm to these results, a visible increase in PFJSW and PFJA at 0° knee flexion was demonstrated in Figs. 5 and 6.

In terms of VAS, before the application of vacuum brace, the mean VAS score for the patients was 4.8 ± 2.2 out of a possible 10. Immediately after the bracing, no significant reduction in pain level

was observed when compared to the no braced condition (mean 4.7 ± 2.1 ; $P = 0.54$). However, after 1-week use of the brace, *t*-test showed a significant reduction in pain level when compared to the no braced condition (2.7 ± 2.1 ; $P < 0.0001$) (Fig. 7).

Regarding the KPS, before applying the vacuum brace, the mean score was 72.8 ± 8.1 out of a possible 100. After 1 week of using the brace, there was significant increase in the mean KPS score when compared to the no braced condition (79 ± 6.4 ; $P < 0.001$) (Fig. 8).

4. Discussion

The results of the present study demonstrated a significant increase in PFJSW following bracing except for lateral PFJSW at 30° knee flexion. This exception could be the result of outward pulling force of tightened lateral retinaculum acting on the Patella^{26,27} which is associated with pushing the patella directly down towards the trochlear groove of the femur due to knee flexion. The patella begins to engage in trochlea at 30° knee flexion.²⁸ Besides, this result could be particularly due to insufficiency or wasting in the vastus medialis oblique muscle^{29,30} which probably has occurred gradually during the activity of daily living. These causes could likely lead to malposition of the patella to be fixed during the CT in static position.

Regarding the significant increase in most sites of PFJSW at 0° and 30° knee flexion, one can expect an increased PFJA following the bracing. This increase could occur as a result of separation between the chondral surfaces of the patella and the trochlea of the femur in the whole areas following application of a negative pressure. Due to the fact that this is the first report providing CT scan objective data on PFJSW and PFJA in patients with PFPS by using a vacuum brace, we were unable to find any studies in the literature to compare their results to the results of this study.

Previous studies showed that the PFP could be managed by patellar bracing.^{4,11} For instance, Powers et al. reported a significant decreased pain, measured by VAS, following use of patellar bracing. They believed that this pain alleviation is probably due to shifting the contact area and/or the force from more sensitive to less sensitive areas.⁴ They studied pain only immediately after the bracing, while the current study measured pain both immediately and after one week using the vacuum brace.

In the current study, no significant pain reduction was found immediately after the bracing. This might be due to the tensile stresses on the soft tissues and irritation of the mechanoreceptors as a result of vacuum suction. However, after 1 week using the brace in resting position, significant pain reduction was reported by the subjects. Although the exact mechanism of pain alleviation could not be found from this study, authors only suggest that

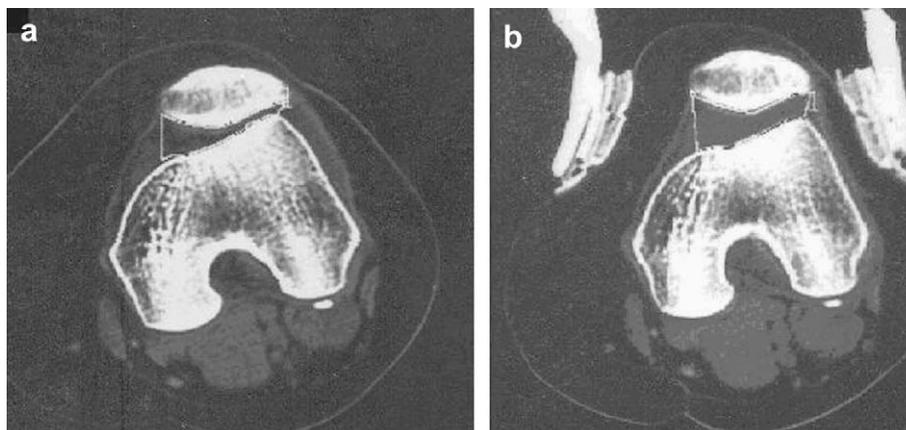


Fig. 6. Area of the patellofemoral joint before bracing (a), and after bracing (b).

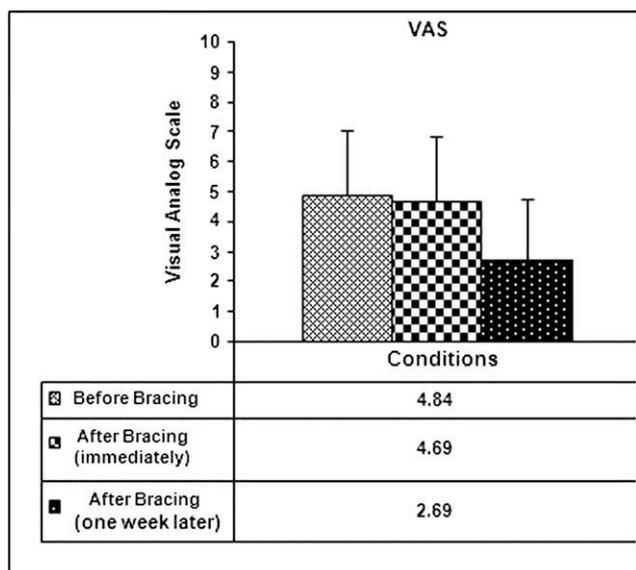


Fig. 7. Comparison of visual analog scale (VAS) among three conditions (before bracing, immediately after bracing and one week after bracing). No statistically significant differences were noted between before bracing and immediately after bracing ($P = 0.54$), but 1 week after bracing was significantly less than before bracing ($P < 0.0001$). Error bars indicate 1 SD.

sensory receptor adaptation to the tensile stresses after several usage and joint distraction could theoretically affect on pain reduction following frequently use of vacuum brace. Of course, further research will be necessary to test this hypothesis.

It is reported that subchondral bone or synovial membrane,¹⁰ patellar mal-alignment due to soft tissues tightness,^{26,27} and periodic short episodes of ischemia in the lateral retinaculum^{5,6} may be involved in the pathogenesis of PFP. Regarding the results of this study (PFJ distraction due to vacuum brace) and therapeutic effects of cupping (such as stretching of the skin and underlying soft tissue layers,^{16,31} increasing blood circulation around the area being treated^{18,19} and bringing out the toxins trapped deep in the soft tissue layers to the body surface¹⁶), logically the authors only suggest that using a vacuum brace can result in some positive

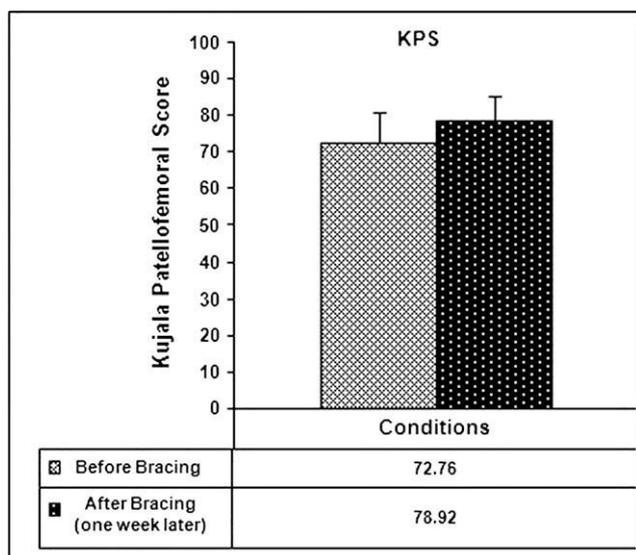


Fig. 8. Comparison of kujala patellofemoral scale (KPS) between two conditions (before bracing and 1 week after bracing). One week after bracing was significantly greater than before bracing ($P < 0.001$). Error bars indicate 1 SD.

effects on the soft tissues which may be the cause of PFP. However, this also needs to be proved by some more research.

Although the current study supported a higher mean score of 6.16 for the KPS following 1-week use of the vacuum brace, but Crossley et al. has reported that a minimum clinically significant change of between 8 and 10 points in the KPS is required to detect an improvement.³² According to this statement, we could not maintain any functional improvement for patients significantly. We suppose that this is mainly due to the short period using the vacuum brace as well as having no therapeutic exercise protocol simultaneously with using the brace. This is supported by some other researchers who recommended using the patellofemoral braces in conjunction with a comprehensive knee rehabilitation program.^{33,34}

One of the limitations in our study was that the subjects were tested only in a nonweight-bearing position with their thigh muscle relaxed. Regarding to this statement, the effects demonstrated in this report would not be expected to be maintained with the quadriceps contracted. Lack of scientific research about using vacuum suction in the joint disorders, no control group, little sample size and no follow-up examination were the other limitations. Additionally, a 2D measure was used with the CT scan and perspective error cannot be ruled out.

The authors suggest that the results of this study might be extended to patients with other patellofemoral joint problems, especially in patients with patellofemoral osteoarthritis or those who need cartilage unloading such as chondromalacia and post surgical conditions and those who have undergone cartilage procedures.

5. Conclusion

The results of this study conveyed that application of the vacuum brace is able to pull up the patella into the vacuum cup and create a patellofemoral joint distraction and useful changes in VAS parameter.

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