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ORIGINAL ARTICLE

Muscle strength but not balance improves after arthroscopic biodegradable polyurethane meniscus scaffold application

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Abstract

Purpose This study aimed to assess the impact of biodegradable polyurethane meniscus scaffold implantation (BPMSI) on muscle strength and balance in comparison with the healthy contralateral knee in patients with irreparable medial meniscus defect.

Methods This observational and prospective case-cohort study was conducted with patients who had irreparable meniscal defects and underwent arthroscopic meniscus scaffold implantation. Surgeries were carried out on the medial meniscus of 16 right and 4 left knees. Visual analog scale (VAS) was used to assess the degree of pain relief. Knee Injury and Osteoarthritis Outcome Score (KOOS) and Lysholm (LYS) score were used to evaluate the functional improvement at weeks 12, 24 and 36. Concentric and eccentric quadriceps and hamstring peak torque (PT) as well as the peak torque-to-body weight (PTB) ratio, anterior–posterior, mediolateral and overall stability indexes were assessed at the same time points.

Results Twenty male patients with a mean age and body mass index of 32.2 ± 8.8 years and 26.2 ± 4.2 kg/m^2, respectively, were included in the study. The amount of pain decreased from $7.6 \pm 1.5\%$ to $2.9 \pm 1.5\%$ at postoperative week 36. Range of motion, Lysholm score and KOOS increased from $87.0^{o} \pm 9.5^{o}$ to $115.0^{o} \pm 15.1^{o}$, 30.8 ± 4.3 to 81.5 ± 5.3 and 37.4 ± 5.3 to 74.1 ± 7.2, respectively. Concentric quadriceps and hamstring peak torque values and peak torque/body weight ratios were improved in the knees that received a meniscus scaffold implant. Anterior/posterior, medial/lateral, and overall stability indexes with or without biofeedback exhibited a slight improvement, which was not statistically significant.

Conclusion BPMSI led to decreased pain and improved function at postoperative week 36. Although muscle strength almost returned to normal, balance parameters did not recover within 36 weeks after the procedure.

Keywords Meniscus · Implant · Polyurethane scaffold · Muscle strength · Balance

Introduction

Biodegradable polyurethane meniscus scaffolds (Actifit®—Orteq Sports Medicine, Wimbledon, London, UK) are arthroscopically implantable medical devices which reduce symptoms, improve function, maintain knee stability, restore biomechanics, and protect cartilage from damage after irreparable partial or total meniscus tears [1–4]. These implants are safe and effective, and they also lead to decreased pain [5–8], preserve chondral surfaces [9–13] and improve the capacity to perform daily activities [14–17]. BPMSI also supports meniscus regeneration by tissue ingrowth [18]. Failure rates of these implants were between 8 and 17.3% [15, 19]. In a study, it was reported that the patients without previous chondral injuries exhibited better outcomes [20]. There are studies demonstrating that these scaffolds have similar biomechanical properties as allografts [21, 22].

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However, MRI results and histological outcomes are conflicting in biodegradable polyurethane meniscus implants [13, 23]. A previous study demonstrated slight size reduction and morphological irregularities in second look arthroscopy [9]. Another recent meta-analysis revealed worsening of the articular cartilage [24]. Abnormal morphology and altered signal intensity in MRI were also recorded [25]. Pre-injury levels of sports participation were not provided after implantation [7]. In another study [26], the change in anterior–posterior motion was measured after BPMSI, whereas balance and muscle strength changes were not evaluated.

In this study, it was aimed to demonstrate the short-term clinical outcomes and changes in balance muscle strength and knee stability in patients undergoing meniscus implantation.

Materials and methods

This prospective and cross-sectional case-cohort study was conducted with patients who received a medial BPMSI. All participants had extensive medial meniscus defects due to a previous partial meniscectomy as well as chronic pain in the knee joint while performing daily activities.

Non-osteoarthritic knee joints with an intact anterior–posterior meniscal root along with a peripheral meniscal rim were eligible and included in this study. In addition, patients with stage 3 or lower osteochondral damage according to the International Cartilage Regeneration and Joint Preservation Society (ICRS) were included. The exclusion criteria were as follows: (a) age 50 years and above (b) repairable meniscus tears, (c) concomitant widespread chondral damage in medial femoral condyle or medial tibial plateau (full thickness loss of articular cartilage with exposed bone—ICRS stage 3 and above) and arthrosis, (d) absence of peripheral meniscus tissue due to total meniscectomy, (e) meniscus defects that could not be treated with a single implant, (f) the presence of lower extremity malalignment or varus/valgus deformity (assessment with full length–weight bearing X-ray, deformity greater than 5°), (g) history of surgery in the contralateral lower extremity, and (h) history of infection or inflammatory disease in the knee joint. Patients with concomitant anterior and posterior cruciate ligament injury, lateral meniscus tear or extensive chondral defects were also treated in the same session; however, these patients (6 males and 2 females) were not included in the study. There was no intra- or postoperative complication in the patients included in the study. The study was approved by the ethics board of the university on July 16, 2014 #128. The patients were informed about the study and written consent was obtained from all patients prior to enrollment.

All patients were operated under general or spinal anesthesia by a single experienced surgeon (MB). The procedure was performed after placing a tourniquet on the lower extremity to be operated on. Routine diagnostic arthroscopy was performed on all patients. In order to enhance the fixation of the meniscal implant and improve blood flow, hand tools were used to refresh the medial meniscus wall. Then, meniscus defects were measured with an arthroscopic ruler to determine the appropriate implant size. For optimal fitting, a polyurethane-based medial meniscus implant (Actifit®, Orteq Sport Medicine) oversized by 10% was prepared [17, 23]. Both tips of the implant were marked to identify the implant surface and direction within the joint (Fig. 1). All-inside, all-inside and inside-out, and outside-in suture techniques were used for implant fixation (Fig. 2), after which an arthroscopic probe was used carefully to check stability while moving the knee in the range of 0°–90°.

Mobilization was recommended without weight bearing on the operated side during the first 6 weeks and an adjustable knee brace was used after surgery. An accelerated rehabilitation program was applied during the subsequent 6 weeks, utilizing weight bearing as much as the patient tolerated. The brace was adjusted to 0°–30°, 60°, and 90° flexion limit angles in the first 2 weeks, at week 3, and at weeks 4 to 6, respectively. Patients were able to reach maximum flexion without the use of a brace after 6 weeks.

All patients completed (a) the Visual Analogue Scale (VAS), (b) Range of Motion (ROM) Scale, (c) Lysholm (LYS) Scale and (d) Knee Injury & Osteoarthritis Outcome Score (KOOS) preoperatively and at postoperative weeks 12, 24, and 36. In addition, balance and isokinetic muscle strength measurements were also performed after the procedure. The operated extremities were compared to the non-operated extremities, which constituted the control group.

All tests were performed by a single independent observer (NO). Balance was measured using the single foot postural stability test with a balance system (Biodex, New York, USA). Balance measurements were conducted before the muscle strength tests in order to avoid muscle fatigue effect. Patients recognized their own change of location (visual feedback) in the first test, and this feature was removed in the second test (no visual feedback). In both tests, the duration of standing on one foot was 30 s, and the stability level of the device was set at 8 s (Fig. 3).

The isokinetic muscle strength protocol was applied using a dynamometer (Biodex, New York, USA) at 60°/second in two different modes to test concentric and eccentric muscle strength. All tests were performed while patients were in seated position. The trunk, thigh and tibia were stabilized with straps in order to prevent extreme joint movement (hyperflexion and hyperextension). The movement angle of the concentric test was determined to be 0°–90° and that of the eccentric test to be 20°–90° (0° corresponds to full extension). Axis of rotation of the dynamometer was aligned with the lateral

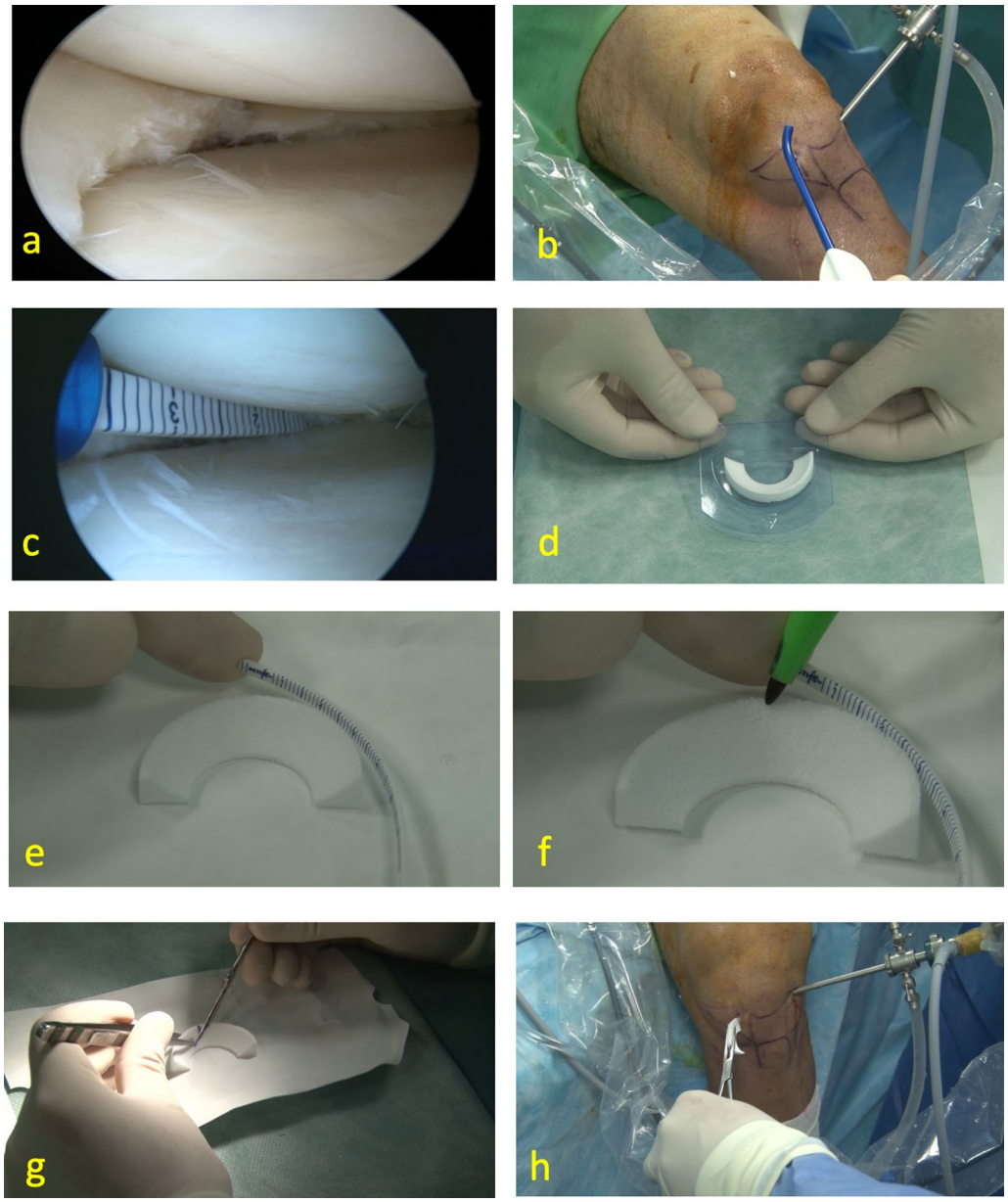

Fig. 1 Preparation steps of meniscus scaffold implantation. **a** Arthroscopic view of medial meniscus defect. **b** Arthroscopic portals and arthroscopic ruler. **c** Arthroscopic measurement of damaged meniscal area. **d** Synthetic polyurethane medial meniscus scaffold. **e** Sizing of meniscal scaffold comparing to damaged area. **f** The marking of meniscus scaffold surface. **g** The cutting of meniscus scaffold as the measured area. **h** Meniscus scaffold inserting into the knee joint with clamp

femoral condyle. After the patients completed warm-up repetitions three times, they were instructed to undertake the test at maximum concentration for five times. Verbal feedback was provided for all patients throughout the process. Muscle strength results were expressed with maximum peak torque (PT, Nm) and peak torque to body weight ratio (PT/BW, %) (Fig. 4).

Statistical analysis

Data was analyzed by repeated measures ANOVA for each dependent variable using SPSS 24.0 (Chicago, Illinois, USA) software. The Tukey post hoc analysis was employed to determine the significance of the relationships between means, when significant differences were observed. Paired

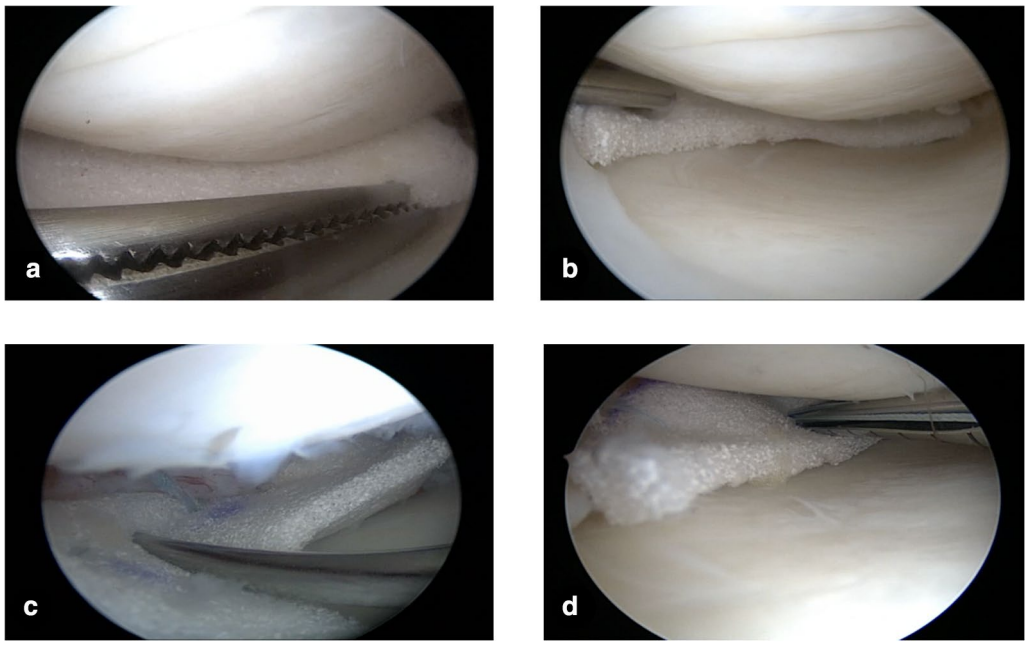

Fig. 2 Arthroscopic treatment steps of meniscus scaffold implantation. **a** Meniscal scaffold inserting into the knee joint with clamp. **b** Meniscus scaffold was placed in the defect area with the arthroscopic probe. **c** Meniscus scaffold was fixed with the inside-out meniscus suturation technique (central part of meniscus scaffold). **d** Meniscus scaffold was fixed with the all-inside meniscus suturation technique (posterior part of meniscus scaffold)

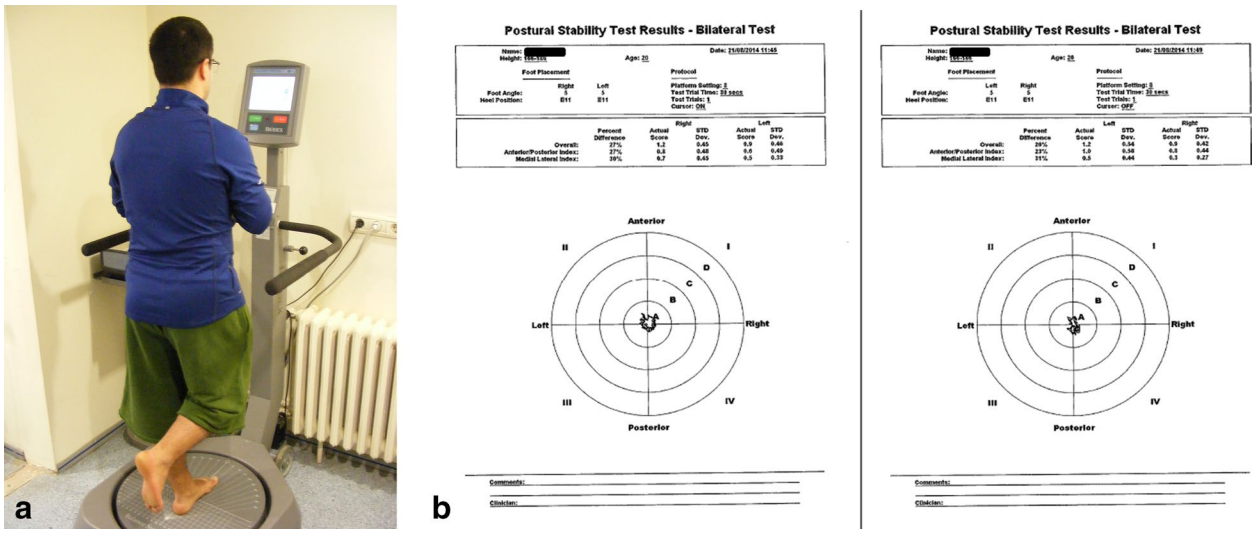

Fig. 3 Single-foot postural stability test for balance (**a**) and scheme of results (**b**)

t test was used to evaluate the differences between operated and non-operated extremities in terms of PT values. $P < 0.05$ was considered statistically significant. A post hoc power analysis was conducted. The statistical software G*Power (Erdfelder, Faul, Germany, 2014) was used for power analyses. Based on the results of ANOVA, an effect size of 0.88 ($\alpha = 0.05$), a sample size of 16 patients and a power of 0.88 were calculated.

Results

Twenty patients older than 20 years who satisfied the inclusion criteria were included in this study. The mean age and body mass index of the patients were 32.2 ± 8.8 years and 26.2 ± 4.2 kg/m^2, respectively. All patients underwent

medial meniscus implantation, i.e., 16 patients on the right knee and 4 patients on the left knee (Table 1).

Pain decreased from 7.6 ± 1.5% to 2.9 ± 1.5% at postoperative week 36. ROM, LYS score and KOOS improved from 87.0° ± 9.5° to 115.0° ± 15.1°, 30.8 ± 4.3–81.5 ± 5.3 and 37.4 ± 5.3–74.1 ± 7.2, respectively during the same time period (Table 2). Throughout patient follow-up, there was a statistically significant change in all parameters ($p < 0.05$). There was no failure was observed in the 36-week follow-up of patients.

Of the 16 patients who were operated on the right knee, 14 had right leg dominance and 2 had left leg dominance, and of the 4 patients who were operated on the left knee, 3 had left leg dominance and 1 had right leg dominance. In cases which the dominant extremity was not the same as the operated extremity, there was no statistically significant difference between the two extremities in terms of the pain level, ROM and clinical scores ($p > 0.05$).

Concentric quadriceps (QPT) and hamstring (HPT) peak torque values and peak torque/body weight (QPTB and HPTB) ratios of the knees that were implanted with a meniscus scaffold exhibited improvement between weeks 12, 24 and 36 ($p < 0.05$). Eccentric QPT, HPT, and HPTB also exhibited a statistically significant improvement within the same time interval. However, such an improvement was not observed in eccentric QPTB (Table 3). Anterior/posterior, medial/lateral, and overall stability indexes with or without biofeedback were similar between the operated and non-operated extremities (Table 4).

Comparison of the operated and non-operated extremities showed that concentric and eccentric QPT values as well as QPTB ratios almost returned to normal within 36 weeks after surgery in the operated extremities (Tables 5, 6, 7, 8). In addition, concentric HPT values, HPTB ratios and eccentric HPTB ratios of the operated extremities almost returned to normal within 24 weeks postoperatively, whereas eccentric HPT values recovered within 36 weeks, when compared to the non-operated extremities (Tables 5, 6, 7, 8).

Discussion

The most important finding of this study was that BPMSI led to decreased pain, improved range of motion and function at postoperative weeks 24–36. In addition, we observed that muscle strength had recovered during the follow-up periods, whereas a similar improvement was not observed in terms of stability.

In a study by Efe et al. conducted with 10 patients who had medial meniscus defects and underwent BPMSI, it was observed that KOOS and VAS scores were significantly improved within a 6-month follow-up [5]. According to another study by Schuttler et al. conducted in 2015, KOOS and VAS scores were significantly improved within a 2-year follow-up in 18 patients who had medial meniscus defects [12]. Moreover, Condello et al. conducted a study in 2019 and observed significant improvement in KOOS, IKDC and LYS scores in comparison with the preoperative period within a minimum 1-year follow-up in patients who underwent BPMS implantation [27]. The clinical scores we obtained in this 36-month follow-up study in patients with medial meniscus defects undergoing BPMS implantation were similar to the results reported in the literature.

Although a rehabilitation program was provided for the patients who underwent arthroscopic BPMSI, quadriceps and hamstring muscles were weaker in the operated extremities in comparison with the non-operated extremities at week 12. According to the literature, while prolonged muscle weakness is commonly observed in arthroscopic knee surgeries, it is expected to return to normal

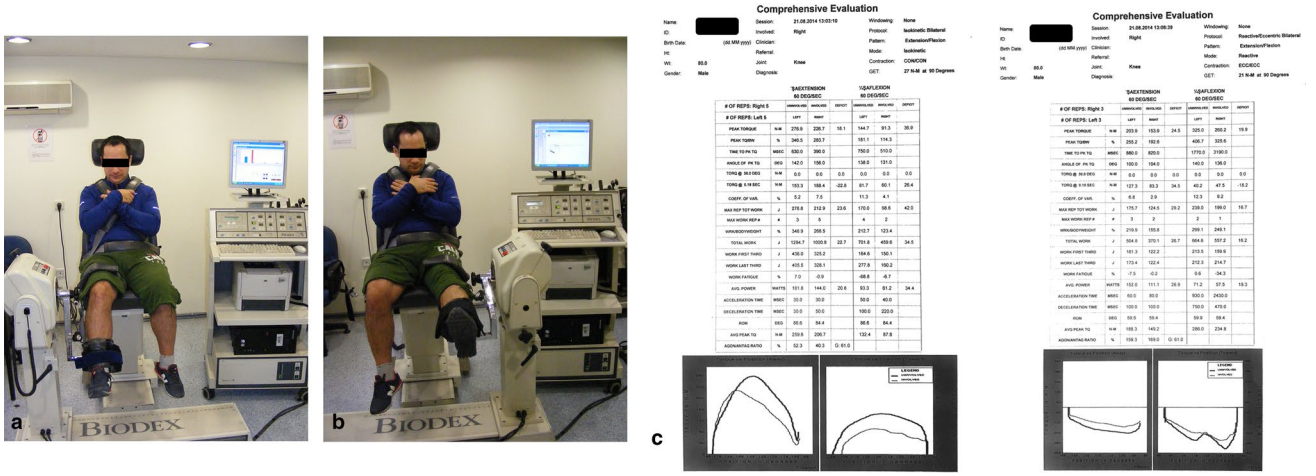

Fig. 4 The isokinetic muscle strength test unoperated side (**a**) operated side (**b**) and scheme of results (**c**)

Table 1 Study population

Study population	
Number of patients	20
Mean age at surgery	32.2 ± 8.8
Side right/left	16/4
Dominant leg side right/left	18/2
BMI	26.2 ± 4.2

within approximately 8–12 weeks after a suitable rehabilitation program [28, 29]. In the young–middle-aged patient population, partial meniscectomy leads to muscle weakness, loss of proprioception and chronic pain in the knee joint in the mid- and long term. According to the literature, clinical success of meniscus implantation (collagen or polyurethane) is very high in the short term and mid-term in these patient groups [25, 30]. Considering the literature, we observed that the rehabilitation programs for muscle strength were started after weeks 12–16 in patients undergoing meniscus treatment procedures such as BPMSI [31, 32]. Long-term follow-up studies conducted with patients undergoing arthroscopic partial meniscectomy have also shown that loss of muscle strength in the operated knee could persist for up to 1 year as compared to the intact knee despite rehabilitation support [33]. Previous studies have also shown that muscle weakness persisting for a year or longer accelerates the progression of knee osteoarthritis in the long term [34, 35]. We believe that prolonged muscle weakness depends on the duration and extent of the surgical procedure, and our patients could reach normal muscle strength functions within 24–36 weeks as a result of the accelerated rehabilitation protocol.

In a study by Karahan et al. conducted in 2010, two groups including a group that underwent partial meniscectomy and another group that had healthy knee joints were followed up for 2 years, and it was shown that proprioception was significantly reduced in the meniscectomy group [36]. In another study conducted in 2012 by Malliou et al., it was shown that the patients who underwent arthroscopic partial meniscectomy exhibited significant reduction in proprioception and muscle function in the operated lower extremity as compared to the other extremity throughout a 1- to 2-year follow-up [37]. In this study, single-foot postural stability test was used to measure all balance parameters including anterior/posterior, medial/

Table 2 Visual analog pain scale (VAS), range of motion (ROM), Lysholm (LSY), and knee injury and osteoarthritis (KOOS) scores (average ± standard deviation)

	Pre-op.	Week 12	Week 24	Week 36	*F*	Hottelling's trace	*p*
VAS	7.6 ± 1.5	5.8 ± 1.3	4.1 ± 1.5	2.9 ± 1.5	58.3	25	0.001*
ROM	87° ± 9.5°	93.5° ± 9.5°	107.5° ± 12.8°	115° ± 15.1°	13.8	5.9	0.005*
LSY score	30.8 ± 4.3	43.3 ± 4.6	69.5 ± 4.5	81.5 ± 5.3	827.2	354.5	0.001*
KOOS pain	39.1 ± 4.8	47 ± 5.4	61.2 ± 5.6	76.0 ± 7.7	251.3	107.7	0.000*
KOOS stability	33.6 ± 5.6	42.5 ± 5.4	55.6 ± 9.2	73.1 ± 12.6	81.9	35.1	0.000*
KOOS daily living activities	45.4 ± 6.3	55.4 ± 6.5	66.7 ± 9.2	80.1 ± 8.9	384.1	164.6	0.000*
KOOS sports and recreational activities	22 ± 5.4	31 ± 5.7	47.5 ± 6.4	62.5 ± 8.6	87.7	37.6	0.000*
KOOS quality of life	25.6 ± 6.2	37 ± 3.8	51.2 ± 3.6	62.4 ± 5.9	44.7	19.1	0.000*
KOOS total	37.4 ± 5.3	45.2 ± 4.1	62.2 ± 7	74.1 ± 7.2	72.4	31	0.000*

*$p < 0.05$ statistically significant difference between times

Table 3 Concentric and eccentric isokinetics quadriceps (QPT) and hamstring peak torque (HPT), and peak torque/body weight (PTB) (Newton-meter/Nm) values (average ± standard deviation)

Nm	Week 12	Week 24	Week 36	*F*	Hottelling's trace	*p*
Concentric QPT	116.6 ± 50.1	127.6 ± 47.5	164.9 ± 53.4	24.0	6.8	0.001*
Concentric QPTB	146.3 ± 58.6	206.7 ± 59.3	206.7 ± 59.3	31.7	9.1	0.001*
Concentric HPT	78.1 ± 59.1	92.6 ± 56.4	112.9 ± 49.1	10.2	2.9	0.005**
Concentric HPTB	106.5 ± 101.0	129.5 ± 95.1	149.5 ± 88.3	10.2	2.9	0.001*
Eccentric QPT	134.8 ± 32.0	145 ± 29.8	173.4 ± 32	48.6	13.9	0.001*
Eccentric QPTB	176.9 ± 55.4	196.8 ± 63.7	207.0 ± 39.9	2.2	0.6	0.177
Eccentric HPT	149.6 ± 59.5	159.2 ± 60.1	211.6 ± 56.9	252.3	72.1	0.001*
Eccentric HPTB	198.3 ± 65.7	215.5 ± 64.9	267.0 ± 61.0	19.1	5.5	0.001*

*$p < 0.05$ statistically significant difference between times

Table 4 Stability index of the operated and non-operated extremities (average ± standard deviation)

	Week 12	Week 24	Week 36	*F*	Hottelling's trace	*p*
Operated extremities						
Biofeedback on						
Overall stability index	1.3 ± 0.7	1.5 ± 0.6	1.8 ± 0.6	0.66	0.19	0.937
A/P stability index	1.1 ± 0.7	1.2 ± 0.6	1.5 ± 0.6	0.325	0.93	0.733
M/L stability index	0.9 ± 0.4	1.1 ± 0.2	1.2 ± 0.2	3.29	0.82	0.091
Biofeedback off						
Overall stability index	1.8 ± 0.7	2.0 ± 0.6	2.2 ± 0.5	0.041	0.988	0.960
A/P stability index	1.5 ± 0.5	1.7 ± 0.5	2.1 ± 0.4	0.772	0.221	0.498
M/L stability index	0.9 ± 0.6	1.1 ± 0.6	1.4 ± 0.5	1.1	0.314	0.384
Non-operated extremities						
Biofeedback on						
Overall stability index	1.3 ± 0.4	1.5 ± 0.4	1.7 ± 0.4	0.00	20.3	1
A/P stability index	0.9 ± 0.5	1.2 ± 0.5	1.4 ± 0.5	0.64	76.2	0.443
M/L stability index	0.9 ± 0.3	1.1 ± 0.3	1.3 ± 0.3	3.4	0.85	0.088
Biofeedback off						
Overall stability index	1.7 ± 0.7	1.9 ± 0.7	2.2 ± 0.6	0.83	7.8	0.780
A/P stability index	1.3 ± 0.7	1.5 ± 0.7	1.8 ± 0.8	2.1	14	0.182
M/L stability index	1 ± 0.7	1.2 ± 0.7	1.5 ± 0.7	2.7	13.8	0.137

A/P stability index (anterior/posterior stability index), M/L stability index (medio/lateral stability index)

Table 5 Concentric peak torque values of the operated and non-operated quadriceps and hamstring muscles (average ± standard deviation)

	Quadriceps				Hamstring			
	Operated	Non-operated	*T* value	*p*	Operated	Non-operated	*T* value	*p*
Concentric peak torque (Nm)								
Week 12	116.6 ± 50.1	170.9 ± 49.9	− 5.508	0.001*	78.1 ± 59.1	102 ± 44.1	− 2.59	0.032*
Week 24	127.6 ± 47.5	168.8 ± 51.6	− 4.576	0.002*	92.6 ± 56.4	100.5 ± 44.4	− 1.479	0.177
Week 36	164.9 ± 53.4	172.1 ± 50.4	− 1.145	0.285	112.9 ± 49.1	92.1 ± 9.1	1.528	0.165

*$p < 0.05$ statistically significant difference between times

Table 6 Concentric peak torque/body weight ratios of the operated and non-operated quadriceps and hamstring muscles (average ± standard deviation)

	Quadriceps				Hamstring			
	Operated	Non-operated	*T* value	*p*	Operated	Non-operated	*T* value	*p*
Concentric peak torque/body weight (%)								
Week 12	146.3 ± 58.6	214.8 ± 54	− 5.856	0.000*	106.5 ± 101	140.3 ± 77.8	− 2.792	0.023*
Week 24	164.5 ± 48.8	218.2 ± 51.2	− 4.271	0.003*	129.5 ± 95.1	133.9 ± 76.4	− 0.547	0.599
Week 36	206.6 ± 59.3	215.6 ± 53.5	− 1.064	0.318	149.5 ± 88.3	119.2 ± 28.1	1.406	0.197

*$p < 0.05$ statistically significant difference between times

Table 7 Eccentric peak torque values of the operated and non-operated quadriceps and hamstring muscles (average ± standard deviation)

	Quadriceps				Hamstring			
	Operated	Non-Operated	*T* value	*P*	Operated	Non-Operated	*T* value	*P*
Eccentric peak torque (Nm)								
Week 12	134.8 ± 32	165.1 ± 26.7	− 3.916	0.004*	149.6 ± 59.5	221.8 ± 75.8	− 4.422	0.002*
Week 24	145 ± 29.8	174.8 ± 26.6	− 4.192	0.003*	159.2 ± 60.1	230.9 ± 74.2	− 4.366	0.002*
Week 36	173.4 ± 32	184.8 ± 28.1	− 1.541	0.162	211.6 ± 56.9	244.5 ± 74.1	− 1.908	0.093

*$p < 0.05$ statistically significant difference between times

Table 8 Eccentric peak torque/body weight ratios of the operated and non-operated quadriceps and hamstring muscles (average ± standard deviation)

	Quadriceps				Hamstring			
	Operated	Non-operated	*T* value	*p*	Operated	Non-operated	*T* value	*p*
Eccentric peak torque/body weight (%)								
Week 12	176.9 ± 55.4	209.3 ± 45.6	− 3.217	0.012*	198.3 ± 65.7	261.8 ± 83.5	− 2.471	0.039*
Week 24	196.8 ± 63.8	213.6 ± 52.1	− 0.997	0.348	215.5 ± 64.9	259.5 ± 89.6	− 1.433	0.190
Week 36	207 ± 39.9	219.2 ± 36.7	− 1.471	0.180	267 ± 61	302.7 ± 70.2	− 1.829	0.105

*$p < 0.05$ statistically significant difference between times

lateral and overall stability and a slight improvement was observed with or without feedback throughout all follow-up periods. However, the mentioned changes were not statistically significant. This shows that meniscus scaffold application had a lower impact on joint proprioception and that the patients could achieve normal balance function within a shorter period of time as a result of a suitable rehabilitation program.

The major limitations of this study were the lack of joint congruity and proprioceptive measurements. However, it was planned to include these measurements in addition to quantitative magnetic resonance imaging parameters in the follow-up at postoperative year two. Moreover, the effect of gender difference could not be evaluated since all of the subjects were male.

Conclusion

It was concluded that BPMSI was effective in decreasing pain and improving function. Moreover, muscle strength was significantly improved after surgery, although balance was not. Therefore, the said surgery can be a safe and effective biological treatment for such patients. Further large-scale and long-term prospective studies are necessary to clarify our findings.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standards All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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