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Outcomes with Additional Manual Lymphatic Drainage to Rehabilitation Protocol in Primary Total Knee Arthroplasty Patients: Preliminary Clinical Results

Primer Total Diz Artroplastisi Hastalarında Rehabilitasyon Protokolüne Ek Olarak Uygulanan Manuel Lenfatik Drenajının Etkileri: Klinik Ön Sonuçlar

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ABSTRACT

Objective: This study was carried out to evaluate the clinical outcomes such as pain, kinesiophobia and quality of life of additional manual lymph drainage (MLD) technique in the after total knee arthroplasty (TKA) surgery.

Methods: Twenty-one TKA patients were randomly allocated to a control group (n:10) and MLD group (n:11). Both groups received routine postoperative rehabilitation. MLD group also received MLD in the first three days after surgery. Clinical assessment was undertaken on postoperative 3rd day and at 6th week. This included knee pain using Visual Analog Scale (VAS), kinesiophobia using Tampa Kinesiophobia Scale (TKS) and quality of life using Nottingham Health Profile (NHP).
Results: VAS and TKS values of the MLD group on the 3rd day and at the 6th week were found to be significantly lower than the control group ($p<0.05$). The 6th week NHP values of the MLD group were found to be significantly lower than the control group ($p<0.05$). For all three values, within-group, and between-group according to processes the effect size of the MLD group is greater than the control group.

Conclusion: The results of the present study demonstrated that addition of MLD application to the standard rehabilitation protocol of TKA positively affected the healing process and it also improved the quality of life by reducing postoperative kinesiophobia and pain level. Adding this special technique to the rehabilitation program in TKA surgeries will provide patient satisfaction and contribute positively to the improvement in

Keywords: Total knee arthroplasty, manual lymphatic drainage, kinesiophobia, pain, quality of life

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ÖZET

Amaç: Bu çalışma total diz artroplasti (TDA) cerrahisi sonrası uygulanan manuel lenf drenajı (MLD) tekniğinin ağrı, kinezyofobi ve yaşam kalitesi üzerine olan klinik sonuçlarını değerlendirmek amacıyla yapılmıştır.

Metod: TDA cerrahisi geçiren hastalar randomize olacak şekilde kontrol grubu (n:10) ve MLD grubuna (n:11) ayrıldı. Her iki gruba standart postoperatif rehabilitasyon protokolü uygulandı. MLD grubunun rehabilitasyon protokolüne ek olarak cerrahiden sonra üç gün boyunca MLD uygulaması eklendi. Klinik değerlendirme postoperatif 3. gün ve 6. haftada yapıldı. Dizdeki ağrıyı değerlendirmesi için Vizüel Analog Skala (VAS), hareket korkusunu değerlendirmesi için Tampa Kinezyofobi Skalası (TKS) ve yaşam kalitesi değerlendirmesi için Nottingham Sağlık Profili (NSP) anketleri kullanıldı.

Bulgular: MLD grubunun 3. gün ve 6. haftadaki VAS ve TKS puanları kontrol grubuna göre anlamlı olarak düşük bulundu ($p<0,05$). Aynı şekilde, MLD grubunun 6. hafta NHP puanları kontrol grubuna göre anlamlı olarak düşük bulundu ($p<0,05$). Süreçlere göre grup içi ve gruplar arası her üç değerlendirme sonucunda elde edilen skor için de MLD grubunun etki büyüklüğü kontrol grubundan daha büyüktür.

Sonuç: Çalışmanın sonucunda, TDA cerrahilerinden sonra uygulanan standart rehabilitasyon protokolüne ek olarak MLD tekniğinin eklenmesinin iyileşme sürecini olumlu etkilediği ve ayrıca postoperatif kinezyofobi ve ağrı düzeyini azaltarak yaşam kalitesini iyileştirdiğini görüldü. TDA cerrahilerinden sonra bu özel tekniğin rehabilitasyon programına eklenmesi hasta memnuniyetini sağlayacak ve klinik sonuçların iyileşmesine olumlu katkı sağlayacaktır.

Anahtar Kelimeler: Total diz artroplastisi, manuel lenfatik drenaj, kinezyofobi, ağrı, yaşam kalitesi

1. Introduction

In the last stage of an arthritic knee where different medical treatments applied with drugs and other than drugs are not effective, the currently accepted standard and most commonly performed treatment method is total knee arthroplasty (TKA) procedure [1]. In addition to the TKA performed with an appropriate technique, a proper and regular rehabilitation process to be applied after surgery is indispensable in order to maintain an independent life and achieve a high clinical success.

Since the TKA procedure is a comprehensive procedure which is done on bone and joints, pain that occurs afterwards is one of the most important symptoms of patients in the postoperative period [2]. While the pain that occurs before surgery causes movement avoidance behavior, it causes kinesiophobia, which is a biopsychosocial behavior along with the pain preservation behavior that occurs after surgery [3,4]. In the early postoperative period, the joint, which is expected to recover progressively with load transfer and movement, is adversely affected by kinesiophobia. While primary TKA may be effective in improving the quality of life and patient satisfaction, pain and accompanying kinesophobia that negatively affect the healing factors can negatively affect this process and cause patients not to meet their expected life standards after surgery [5].

Manual lymph drainage (MLD) which includes soft massage techniques has been observed that it is also used in a limited number of orthopedic cases [6-9]. The basis of this concept is stimulating the lymph system and increasing circulation, removing biochemical residues, reducing edema and pain, and regulating sympathetic and parasympathetic responses [10]. Postoperativel MLD is known to rapidly regulate lymphatic circulation by creating changes in interstitial fluid pressure, thus preventing even arthrofibrotic tissue that may occur after a traumatic situation, and increasing mobility by reducing edema, which is a predisposing factor for pain [11]. There are studies showing that MLD can

be used as an alternative treatment method in the early postoperative period, based on the successful results obtained in orthopedic surgery and sports traumas [7,8,12].

In the literature, the primary effect of MLD on edema and pain was examined. In addition to investigating the effectiveness of treatment on symptoms and complaints in the treatment process of diseases, it is also necessary to examine the effects of treatment on individuals' quality and independent lives within the scope of a biopsychosocial model. In this context, our hypothesis is that the addition of the MLD technique to the standard postoperative rehabilitation protocol will improve acute and mid-term postoperative pain, kinesiophobia and quality of life of patients undergoing TKA.

2. Material and Method

In this prospective randomized controlled study, twenty-two patients who underwent unilateral primary TKA with a standard surgical technique by a single experienced knee surgeon with the radiological and clinical diagnosis of gonarthrosis in the Department of Orthopedics and Traumatology at Necmettin Erbakan University Meram Medical Faculty Hospital between March 2021 and April 2021 were included in our prospective, randomized study. One patient in the control group was excluded due to deep vein thrombosis. Ethics committee permissions were obtained for the study in accordance with the Declaration of Helsinki (Decision number: 2019/2154). Additional formal written informed consent was obtained from all participants, together with their informed consents for surgery.

Patients with postoperative pulmonary thromboembolism or treatment-related complications in the past, patients with osteoarthritis secondary bone or joint infections, patients with presence of hematological disease and malignancy, major cardiac pathology, venous insufficiency, patients taking high-dose anticoagulants were excluded from the study. Patients between the ages of 40-85, who were diagnosed with stage IV gonarthrosis and planned TKA and who were evaluated before the operation and whose informed consents were obtained were included in the study.

Clinical Evaluation

The patients were evaluated clinically before surgery, on the postoperative 3rd day (acute phase) and in the 6th week (mid-term phase), as outlined in the flowchart in Figure 1.

Pain

Pain was evaluated with the Pain Visual Analogue Scale (VAS) [13]. It was explained to the patients that "0" means "no pain" and "10" means "unbearable pain" on a 10 cm horizontal line. The patients were asked to mark the pain of activity on the line with the help of a pencil. The values were calculated with the help of a ruler in centimeters.

Kinesiophobia

Tampa Kinesiophobia Scale (TKS) was used to evaluate kinesiophobia. The scale consists of 17 statements. As the score increases, the painful patient is considered to have an increase in kinesiophobia. The validity and reliability of the scale were previously reported by Yılmaz et al [14].

Quality of Life

Quality of life was evaluated with the national version of Nottingham Health Profile (NHP). The questionnaire consists of 38 questions consisting of 6 main topics, namely, energy level, pain, physical mobility, sleep, social isolation, and emotional reactions. The total score for each subtitle is 100, and the total score is obtained by adding the scores obtained from these subtitles. A low score indicates a high quality of life. The validity and reliability was previously reported by Küçükdeveci et al. [15].

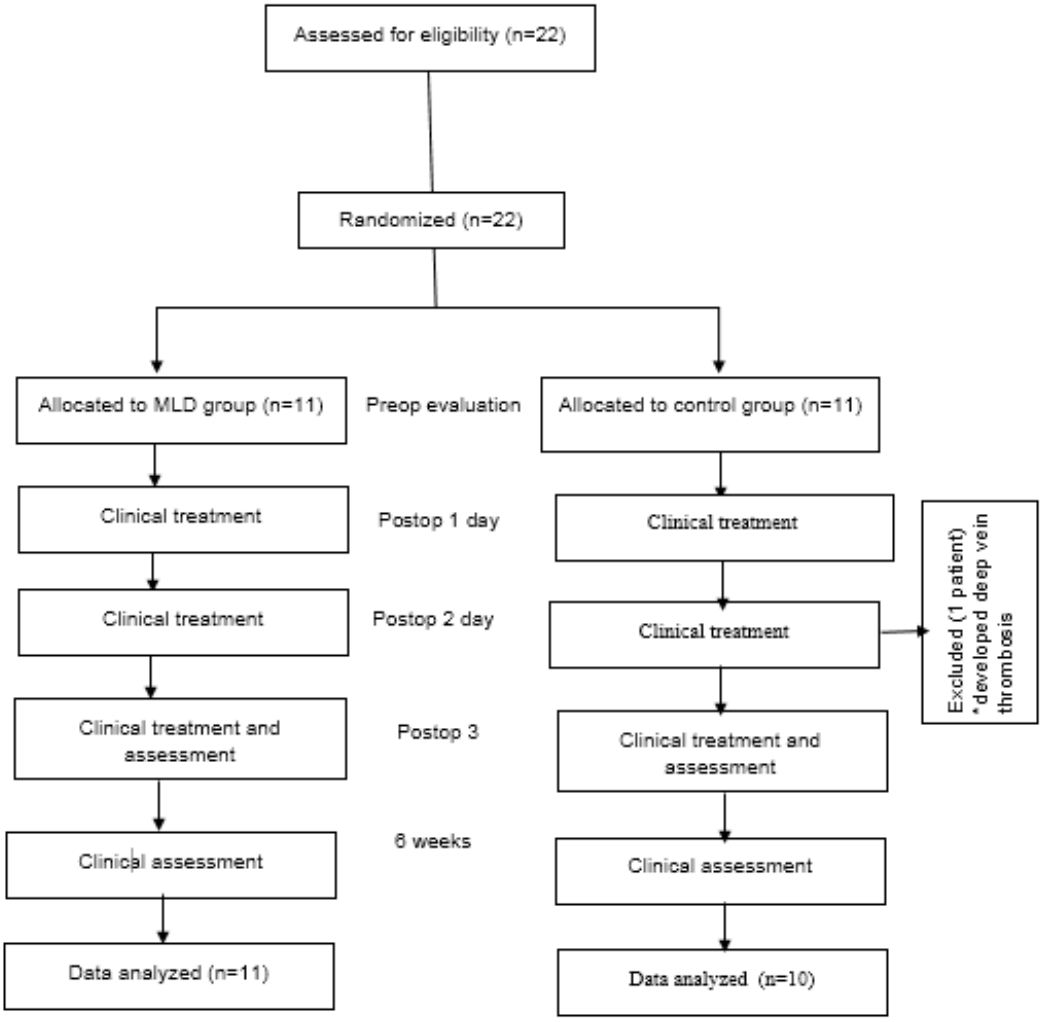

Figure 1: Flow Chart (Patient randomization and clinical treatment and assessment)

Intervention Methods

Postoperative Care and Rehabilitation Protocols

In the postoperative period were randomly divided into 2 groups. Standard rehabilitation protocol was administered to the 1st group (control group) while MLD was applied to the second group (MLD group) in addition to the standard rehabilitation protocol. From the first day after surgery (postoperative 1), 3 days of acute phase treatment was applied.

In the acute phase after surgery, in accordance with the hospital protocol in all patients; Compression, cold application and elevation were provided by wearing “Cryo / Cuff” cooler and antiembolizing compression stockings (~15 mmHg). Continuous passive motion (CPM) in accordance with the standard protocol was added to the treatment as 45° on the postoperative 1st day, 60° on the postoperative 2nd day, and a 90° or higher angle on the postoperative 3rd day at the edge of the pain for 45 minutes in both groups.

In the standard rehabilitation protocol for after surgery, 3 sets of exercises were applied as 10 repetitions. The treatment was initiated for the patients with tolerable coughing and deep breathing exercises. Active dorsi-plantar flexion of the ankle, isometric contraction for the quadriceps, hamstrings and gluteus maximus, for the knee in the supine position on the bed; active heel shift exercises, straight leg raising and standing knee and hip flexion, active hamstring curling, and self-hamstring stretching were performed. After the exercise, the morning treatment protocol was completed with a walker at a tolerable distance. The patient was given assignment in the form of walking and repetition of morning exercises at a tolerable level at least twice during the day. In

addition to the standard rehabilitation protocol in the MLD group, MLD (to include the entire lower extremity undergoing TKA surgery) was added. The MLD technique was applied by the physiotherapist who was the first author to have an certificate (Foeldi College, Germany).

MLD was launched with simple neck application. Back-up treatment was applied for the abdominal area. Ventral drainage was applied to the lower extremity in accordance with the surgery of the patient. According to clinical experience, considering the surgical dissection site and the involvement of the ventro-medial bundle, the number of drainage was repeated here.

The patient was discharged after his pain reached a level that was responsive to oral analgesics after achieving hemodynamic stability. The exercises applied in the acute phase were also given to the patients as a home program.

The study is not a double-blind study. The fact that the surgeon and the physiotherapist are the same for each patient ensured standardization in the study.

Statistical Analysis

Both groups were evaluated just before surgery. According to the results of the evaluation, bias was blinded in the groups by applying stratified randomization. Groups stratified according to activity pain, body mass index (BMI) and age criteria were randomly divided into 2 groups. The main structure of the study is an experiment with 2 independent groups and 3 repetitions. For this reason, the appropriate method in power analysis is Repeated Measures Design. TKS values used for post power analysis. As a result of the power analysis performed using the G* power (G* power, Ver.3.0.10, Universität Kiel, Germany) program; with 90% power and 5% margin of error, a total of at least 12 samples were found sufficient (n1:6; n2:6).

Pain, kinesiophobia and quality of life values were compared within and between groups. While "Independent Sample-t" test (t-table value) was used to compare the measurement values of two independent groups which have normal distribution; "Mann Whitney U" test (Z-table value) statistics were used to compare two independent groups that did not have normal distribution. The "Repeated Measures" test (F-table value) was used to compare the measurement values of three or more dependent groups with normal distribution within the groups. "Friedman Chi-square" (χ^2-table value) statistics were used to compare three or more dependent groups that did not have a normal distribution. Bonferroni test was applied to determine which group caused the significant difference. In order to determine the effectiveness of the treatment, the effect size in the double groups was calculated with "Cohen-d" and in the triple groups with "eta square" values. The effect size value was evaluated as small for <0.10, medium for <0.25 and large for <0.40 [16].

3. Results

The patients who were evaluated before the operation were evaluated after the acute phase evaluation and they were discharged. They are re-evaluated after 6 weeks. Twenty-two (MLD:11, Control:11) patients participated in the study. One patient in the control group was excluded due to deep vein thrombosis. Patients' demographic and physical characteristics are shown in Table 1.

Table 1: Patients' demographic and physical characteristics.

	MLD (n=11) X±SD	**Control (n=10) X±SD**
Gender (F/M)	6/5	4/6
Age (year)	64.73±6.21	72.5±7.57
Weight (kg)	84.09±19.38	84.10±10.52
Height (cm)	160.18±14.82	164.10±5.04
BMI (kg/m^2)	32.54±6.21	31.88±4.62

X: mean, SD: standard deviation, BMI: body mass index, F: female, M: male

Pain Measurement Results

No significant difference was found between the groups in terms of preoperative VAS values (p>0.05) A significant difference was found between the groups in terms of VAS values on the 3rd day and in the 6th week (p<0.05). A significant difference was found in the MLD group in terms of VAS values according to the processes (χ^2=21.535; p=0.000). There was a significant difference between pre-surgery values and 3rd day and 6th week values. VAS values on the 3rd day and in the 6th week were found to be significantly higher than pre-surgery values. Likewise, a significant difference was detected between the 3rd day and in the 6th week. VAS values on the 3rd day were significantly higher than the 6th week (Table 2).

A significant difference was found in the control group in terms of VAS values according to the processes (χ^2=16,167; p=0,000). A significant difference was found between pre-surgery values and the 3rd day and the 6th week values. VAS values at the 6th week were found to be significantly lower than pre-surgery and on the 3rd day. It was determined that the effect size of the MLD group was higher than the control group (Table 2).

Table 2: Comparison of VAS scores by process within-group and between-groups

VAS	MLD (n=11)		Control (n=10)		Statistical analysis
	X±SD	Median [IQR]	X±SD	Median [IQR]	
Preoperative	10.00±0.00	10.0 [0.0]	9.60±0.84	10.0 [1.0]	Z=-1.522 p=0.128
3rd day	6.09±1.75	6.0 [3.0]	8.40±1.27	8.0 [2.0]	Z=-2.769 **p=0.006**
6th week	3.09±1.70	3.0 [4.0]	5.60±1.71	5.5 [3.0]	Z=-2.686 **p=0.007**
Analysis	χ^2=21.535 **p=0.000**		χ^2=16.167 **p=0.000**		
Difference	**[0-3,6] [3-6]**		**[0,3-6]**		
f	(3.104)		(1.835)		

X: mean, SD: standard deviation, Z: Mann Whitney U test, χ^2 : Friedman Chi-square, p <0.005, *f* :effect size

Kinesiophobia Measurement Results

No significant difference was found in terms of preoperative TKS values according to the groups (p>0.05). A significant difference was found between the groups in terms of TKS values on the 3rd day and in the 6th week (p <0.05). TKS values of the MLD group on the 3rd day and in the 6th week were found to be significantly lower than the control group (Table 3).

A significant difference was found in terms of TKS values according to the processes in the MLD group (F=10.077; p=0.001). A significant difference was found between pre-surgery values and the 3rd day and in the 6th week. Tampa values before surgery and on the 3rd day were found to be significantly higher than in the 6th week (Table 3).

There was no significant difference in TKS values according to the processes in the control group (p> 0.05). According to the processes within the groups, it was determined that the effect size of the MLD group was higher than the control group (Table 3).

Table 3: Comparison of Tampa scores by process within-group and between-groups

Tampa	MLD (n=11)		Control (n=10)		Statistical analysis *
	X±SD	**Median [IQR]**	**X±SD**	**Median [IQR]**	
Preoperative	46.36±7.88	45.0 [8.0]	46.10±8.74	48.0 [13.0]	t=0.073 p=0.943
3rd day	42.27±4.52	42.0 [10.0]	48.10±6.94	48.0 [12.0]	t=-2.303 **p=0.033**
6th week	35.00±6.66	37.0 [8.0]	47.60±6.93	44.0 [13.0]	Z=-3.426 **p=0.001**
Analysis	F=10.077 **p=0.001**		χ^2=0.974 p=0.614		
Difference	**[0,3-6]**				
f	(0.502)		(0.023)		

X: mean, SD: standard deviation, F: Repeated Measures, χ^2: Friedman Chi-square, p <0.005, *f* :effect size

Quality of Life Measurement Results

There was no significant difference between the groups in terms of pre-operative NHP values and 3rd day NHP values (p>0.05). A significant difference was found between the groups in terms of 6th week NHP values (t=-6,538; p=0,000). The 6th week NHP values of the MLD group were found to be significantly lower than the control group (Table 4).

A significant difference was found in the MLD group in terms of NHP values according to the processes (F=46.687; p=0.000). There was a significant difference between pre-operative values and 3rd day and 6th week values. Preoperative NHP values were found to be significantly higher than the 3rd day and 6th week values. Likewise, a significant difference was detected between the 3rd day and the 6th week. The NHP values on the 3rd day were found to be significantly higher than the 6th week values (Table 4).

A significant difference was found in the control group in terms of NHP values according to the processes (F=10.614; p=0.001). There was a significant difference between pre-operative values and 3rd day and 6th week values. Pre-operative NHP values were found to be significantly higher than the 3rd day and 6th week. According to the processes within the groups, it was determined that the effect size of the MLD group was higher than the control group (Table 4).

Table 4: Comparison of NHP scores by process within-group and between-groups

NHP	MLD (n=11)		Control (n=10)		Statistical analysis *
	X±SD	Median [IQR]	X±SD	Median [IQR]	
Preoperative	387.00±72.58	377.0 [148.0]	394.25±113.31	391.2 [194.9]	t=-0.176 p=0.862
3rd day	258.36±77.79	254.0 [116.0]	319.72±108.03	315.0 [198.0]	t=-1.504 p=0.149
6th week	110.36±50.20	99.0 [80.0]	287.27±72.78	266.0 [114.7]	t=-6.538 **p=0.000**
Analysis	F=46.687 **p=0.000** **[0-3,6] [3-6]**		F=10.614 **p=0.001** **[0-3,6]**		
f	(0.824)		(0.541)		

X: mean, SD: standard deviation, F: Repeated Measures, χ^2: Friedman Chi-square, p <0.005, *f* :effect size

Although it was observed that the scores of the sub-parameters of NSP, such as energy level, pain, physical mobility, sleep, social isolation, and emotional reactions, decreased before surgery and in the acute phase, no significant difference was found (p> 0.05). While there was an improvement depending on the processes for both groups, the significant meaning between the groups was observed only in the 6th week (p <0.05).

4. Discussion and Conclusion

The most important result of the study is that the clinical results in the MLD group showed greater improvement in the evaluations made after active treatment period and home rehabilitation in patients who participated in the study by applying primary TKA. In the MLD group and control group, pain in the acute phase decreased by 39% and 12%, and in the mid-term phase by 69% and 41%, respectively. While MLD application in the mid-term phase decreased kinesiophobia by 23%, no improvement was observed in kinesiophobia in the control group. While the effectiveness of MLD application in increasing the quality of life was approximately nearly 2 times more effective in the acute phase compared to the control group, its effectiveness in the mid-term phase increased to 71%.

In the clinical outcomes obtained from hospital follow-up of 30 TKA patients, Pichonnaz et al. reported that the perceived movement pain level of 5.14 ± 2.57 points immediately after treatment decreased by 35% on the 7th day and 75% on the 3rd month [7]. Ebert et al. have achieved a 61% reduction in pain in the acute phase with 1.79 ± 1.29 points and a 67% reduction rate in the 6th week with 1.50 ± 1.10 points in 41 knee patients who underwent TKA with MLD in addition to the standard protocol until hospital discharge. However, with this improvement in pain, unlike our study, they did not obtain significant clinical differences between the groups [6]. In a recent study conducted where the specific interaction of MLD and pain was examined after TKA surgeries, they reported that pain significantly decreased in the MLD group at the end of the 10th day, but this was similar to the control group [17].

In our study, it was revealed that MLD application reduced pain by 3.91 cm in the acute phase, and standard application by 1.2 cm. Minimal clinically important difference was shown to be 2.26 cm in patients with TKA for the acute phase [18]. In this case, it is seen that the application of MLD brought it to the desired level clinically in the acute phase.

In the light of the literature reviews and the results of our clinical research; the level of pain perceived by patients with different orthopedic surgery history appears to have been affected positively from manual lymph drainage, regardless of whether it is significant or not. The cause of this condition is thought to be related to free nerve endings terminating in the skin. Soft stimulation applied to the skin may increase the touch input while closing the pain pathways. The secondary possible response is the superficial relaxation and warming provided by soft stimulation have an effect on the autonomic nervous system and activates the parasympathetic system [19].

Kinesiophobia caused by the fear of pain is very effective on both pre-operative and postoperative recovery in TKA patients. Therefore, it is one of the clinical outcomes that should be evaluated and treated in the early period. Filardo et al. showed in their study of 101 patients that kinesiophobia is an inevitable consequence and emphasized that kinesiophobia can be reduced with regular exercise [20]. The same result is also available in other studies in the literature [5,21], and it was stated that the acute and chronic phase results of surgery were negatively affected by kinesiophobia. Kinesiophobia treatment is possible with therapeutic exercise prescriptions. However, how feasible is the exercise prescription for a psychological factor originating from pain and already based on fear of starting exercise? It is clearly seen that the reduction of this factor, which has the capacity to affect the success of the surgery in all processes, depends on the answer to this question.

In the group in which the standard protocol was applied in our study, the kinesiophobia in the preoperative period increased in the early periods and could not regress to the previous score. The applied MLD has started to reduce kinesiophobia in the acute phase and caused decrease in the mid-term phase. In other words, this factor, which is predicted to improve with exercise response, was made possible to prepare for exercise with MLD. Decreased kinesiophobia in acute phase may have prevented the formation of "pain memory" [22,23], which is also psychologically based, and made the patient ready for action. The reason for this situation is that MLD, which is a painless and soft massage, inactivates the pain-avoidance behavior of the sympathetic system, which is inhibited by the sense of touch. We think that the inhibition of pain by touch may support the feeling of confidence in the patient and prevent the formation of pain memory.

One of the desired results for patients in TKA surgeries is the increase in quality of life. However, no matter how successful the surgery is, sometimes patients cannot reach the parameters in the healthy population. Yıldız et al. reported from a study of 140 people that patients who underwent surgery decreased parameters of energy level, pain, physical mobility, sleep, social isolation, and emotional reaction after treatment compared to healthy people [24]. In this case, patients should have their pre-operative conditions that determine the quality of life standards. In our study, two groups whose energy level, pain, physical mobility, sleep, social isolation, emotional reaction scores did not differ before surgery were followed according to the processes and as a result, a significant difference was observed between the groups in these sub-parameters at the 6th week. Ebert et al. whose study design and protocols are similar to ours and it has been shown that the quality of life, which is one of the sub-parameters of this questionnaire, increases with time. However, no significant difference was found between the two groups [6]. It has been shown in some studies in the literature that MLD increases the quality of life after oncological surgeries [25], but there is not enough data to investigate the quality of life after MLD application in orthopedic surgeries.

Nevertheless, the reduction in pain and kinesiophobia after MLD can improve the quality of life indirectly. While painless movement increases the level of physical activity, it will prevent social isolation and reduce emotional reactions. An improvement in the quality of life can be observed by providing an active life with pain memory that is prevented from occurring in the acute phase.

As a limitation, although the duration of follow-up is relatively short regarding surgical terminology, this time period is accepted as mid-term in rehabilitation literature. In this respect, the present study investigated the clinical effects of additional MLD after the same surgery in both groups, not the effects of surgery. Importantly, this pilot study demonstrated the preliminary results of our ongoing larger clinical study, which has included higher number of patients with longer follow-up period.

In conclusion, it was observed that adding MLD positively affected the healing process and increased the quality of life in the acute and mid-term phase by reducing the kinesiophobia and pain levels after surgery. Adding this special technique to the rehabilitation program in TKA surgeries will provide patient satisfaction and contribute positively to the improvement in clinical outcomes. As far as we have examined, our study is the first study conducted for this, biopsychosocial model purpose in the

relevant literature. Therefore, although the current clinical results an important initial study in this context; it will be able to shed light on the relevant studies to be carried out from now on. It will be able to make ameliorative contributions to increase the quality of life of patients after surgery.

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