Original Article

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Comparisons of the Radiolucent Lines Between Cemented and Cementless Oxford Unicondylar Knee Arthroplasty: A Non-designer Group Report

Çimentolu ve Çimentosuz Oxford Unikondiler Diz Artroplastilerinde Radyolusent Hatların Karşılaştırılması: Tasarımcı Olmayan Bir Grup Raporu

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ABSTRACT

Objective: Aseptic loosening is one of the most important reasons for failure in unicondylar knee arthroplasty (UKA). The aim of this study was to compare early physiological and pathological radiolucent lines (RLL) between cementless and cemented UKA within a non-designer group cohort.

Methods: Two groups of patients who underwent 38 cemented UKA and 47 cementless UKA between 2012 and 2018 were compared retrospectively. In evaluating the clinical results of the patients, the Oxford Knee Score, EQ-5D-3L, EQ-VAS, and KOOS scoring were used. In the evaluation of the presence of RLLs, the tibial and femoral component interfaces were divided into regions and evaluated for RLLs.

Results: There was no statistically significant difference between the groups in terms of clinical results (p>0.05). No complete RLLs were observed in either the femoral or tibial component interfaces in any patient. Partial radiolucent regions at the tibial component interface were detected in 32 (11.3%) regions in cemented UKAs and 13 (5.7%) in cementless UKAs. The incidence of partial RLLs in the tibial component interface and the total number of radiolucent zones were higher in the cemented arthroplasties (p=0.040 and p=0.025).

Conclusion: It was determined that the excessive physiological RLLs observed in UKA had no effect on the clinical outcomes of

ÖZ

Amaç: Unikondiler diz artroplastisinde (UDA) aseptik gevşeme başarısızlığın en önemli nedenlerinden biridir. Bu çalışmanın amacı, tasarımcı olmayan bir grup kohortunda çimentosuz ve çimentolu UDA'lar arasındaki erken fizyolojik ve patolojik radyolusent hatları (RLH) karşılaştırmaktı.

Yöntemler: Bu çalışmada 2012-2018 yılları arasında 38 çimentolu UDA ve 47 çimentosuz UDA uygulanan iki hasta grubu retrospektif olarak karşılaştırıldı. Hastaların klinik sonuçlarının değerlendirilmesinde Oxford Diz Skoru, EQ-5D-3L, EQ-VAS ve KOOS skorlamaları kullanıldı. RLH'lerin varlığının değerlendirilmesinde, tibial ve femoral bileşen ara yüzleri bölgelere bölündü ve RLH'ler için değerlendirildi.

Bulgular: Klinik sonuçlar açısından gruplar arasında istatistiksel olarak anlamlı fark yoktu (p>0,05). Hiçbir hastada femoral veya tibial bileşen ara yüzlerinde tam RLH gözlenmedi. Tibial bileşen ara yüzünde parsiyel radyolusent bölgeler çimentolu UDA'larda 32 (%11,3) ve çimentosuz UDA'larda 13 (%5,7) bölgede tespit edildi. Tibial bileşen arayüzünde kısmi RLH görülme sıklığı ve toplam radyolusent bölge sayısı çimentolu artroplastilerde daha yüksekti (p=0,040 ve p=0,025).

Sonuç: Unikondiler diz artroplastisindegözlenen aşırı fizyolojik RLH'lerin hastaların klinik sonuçları üzerinde etkisi olmadığı

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the patients. The rate of physiological RLLs was significantly lower in cementless UKA than in cemented UKA.

Keywords: Unicondylar knee arthroplasty, cementless, cemented, radiolucent lines, aseptic loosening

tespit edildi. Fizyolojik RLH oranı çimentosuz UDA'da çimentolu UDA'ya göre önemli ölçüde daha düşüktü.

Anahtar Sözcükler: Unikondiler diz artroplastisi, çimentosuz, çimentolu, radyolusent hatlar, aseptik gevşeme

Introduction

Unicompartmental knee arthroplasty (UKA), developed by Marmor (1) in the 1970s, is a successful method in the treatment of medial or lateral end-stage knee arthritis. Although unsuccessful results and high revision rates in the very first applications led to suspicion of UKA (2,3), it was again popularized following the improvements in prosthetic design and surgical techniques within the last two decades (4). However, aseptic loosening is still one of the most important reasons for failure in the modern designs (5). Radiolucent lines (RLLs) observed around the prosthesis are a strong indicator of loosening (6). However, Goodfellow et al. (7) reported that RLLs did not always indicate implant loosening and they could be classified in two groups as pathological and physiological in UKA. Pathological RLLs are generally thicker than 2 mm, increase in thickness over time, and indicate infection or loosening. Physiological RLLs are non-progressive, thinner than 2 mm, and do not indicate loosening. The differential diagnosis of pathological and physiological RLLs is difficult especially in the presence of pain. Tibial pain is usually observed in the early rehabilitation phase of patients who have undergone UKA. This condition, which is associated with increased stress in the proximal tibia, usually resolves spontaneously within the first year (8,9). This condition can be easily assessed as an aseptic loosening of the prosthesis if physiological RLLs are observed. Cementless UKA has a constructional advantage in this respect as physiological RLLs in such prostheses are considerably less than in cemented ones. A few studies have shown that cementless UKA reduces RLL incidence and revision rates (10,11). Nevertheless, the results reported by non-designer groups are quite limited (12,13).

The hypothesis of this study was that there would be no difference in clinical outcomes due to RLLs in cemented and uncemented UKA. The aim of this study was to compare early physiological and pathological RLLs in cementless UKA with cemented versions within a non-designer group cohort. With the comparison made, RLL in the groups cemented and cementless, and its effect on the clinical results of the patients were investigated.

Methods

The study was approved by the Local Ethics Committee and all procedures were applied in compliance with the Declaration of Helsinki. Written informed consent was obtained from all the study participants.

A retrospective evaluation of 37 consecutive patients (38 knees) who underwent cemented Oxford UKA for isolated anteromedial osteoarthritis between 1 November 2012 and 31 May 2018 and who had completed at least 2 years of clinical follow-up, and a cohort with cementless UKA of similar age, gender, and body mass index (41 patients, 47 knees) was made (Table 1). All the operations were performed by the senior surgeon (HA). For statistical evaluation, operation periods, clinical results, [Oxford Knee Score, Knee Injury and Osteoarthritis Outcome score (KOOS), EQ-5D-3L scores and range of motion] incidence of RLLs in tibial and femoral component interfaces and reoperation rates for any reason were evaluated and compared between the groups.

The inclusion criteria of the study were:

1. Patients were operated on according to the selection criteria of the Oxford group with a cemented or cementless Oxford UKA design (4).
2. Patients completed at least two years of follow-up of adequate radiographic and physical evaluation.

Two patients with progressive osteoarthritis in the lateral compartment in the cemented group, and one patient with an intraoperative tibial plateau fracture in the non-cemented group

Table 1. Demographic data of the patients

	Cementless (n=37)	Cemented (n=41)	p value
Age (year)	57.4 (47-74)	59.2 (47-72)	.277 (t-test)
Sex (F/M)	28:9	37:4	.156 (x^2)
Side (R/L) *	22:16	23:24	.157 (x^2)
Length (m)	1.62 (1.52-1.70)	1.63 (1.53-1.86)	.489 (t-test)
Weight (kg)	80.6 (55-112)	81.1(64-108)	.854 (t-test)
BMI (kg/m^2)	29.9 (23.3-34.5)	30.3 (23.1-40.6)	.719 (t-test)
Follow-up period (month)	25.9 (25-38)	38.1 (28-65)	<0.001(t-test)

Statistically significant values are in italic and bold
*Both knees were evaluated in patients who had undergone bilateral unicondylar arthroplasty.
F: Female, M: Male, R: Right, L: Left, BMI: Body mass index

were excluded from the study, as they were patients who missed regular follow-up appointments or whose follow-up radiographs were not of sufficient quality. Patients' age and weight, and the degenerative status of the patellofemoral joint were not accepted as contraindications.

Surgical Technique

Oxford phase 3 cemented and cementless UKA were used in all patients. Of the 38 knees in the cemented UKA group, 24 were operated under epidural anesthesia and 14 under general anesthesia, and of the 47 knees in the cementless UKA group, 32 were operated under epidural anesthesia and 15 under general anesthesia. All surgical procedures were performed under tourniquet control. The anteromedial minimally invasive technique was used as the surgical incision in all patients. Following the cleaning of osteophytes in the medial of the femoral condyle and intercondylar notch, tibia and femur cuts were made. The prostheses were placed after stability and mobility control with gap measurement and trial components, respectively. In deciding whether the prosthesis was to be applied with or without cement, the bone hardness test was applied as described by Stempin et al. (14). If there was a stability problem during the placement of the trial components following the tibial and femoral cuts, (ie, movement detected in the trial components during flexion-extension), then cemented application was preferred for such patients.

Full weight-bearing was allowed after the removal of drains (24 h after surgery). All patients wore compression stockings as thromboembolic prophylaxis.

Clinical and Radiological Outcome Assessments

In evaluating the clinical results of the patients, the Oxford Knee score (OKS), EQ-5D-3L, EQ-VAS, and KOOS scoring were used.

The OKS is a short patient-reported outcome measure to evaluate physical function and pain developed by Dawson et al. (15), and validated by Tuğay et al. (16) for Turkish patients. KOOS is a disease-specific questionnaire that can be used to evaluate physical function in patients with knee problems (17). EQ-5D-3L score is descriptive system for health-related quality of life states in adults, consisting of the following five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression, and each domain has three severity levels (18).

To standardize the preoperative radiographs, the X-ray beam was directed from the posterior with the knees flexed at 20º-30º, as defined by Lyon-Schuss (19). Radiographs were repeated on the postoperative first day, at the end of the first month and of the following three months. In addition, axial radiography was taken in all patients preoperatively and in the postoperative 6th week. Annual follow-up examinations were made in the following period. To ensure minimal rotational variations, attention was paid to forward facing of the patella and that the tibial spines were located in the center relative to the intercondylar notch on the radiographs.

In the evaluation of the presence of RLLs, the tibial component interfaces were divided into 6 regions according to the method described by Gulati et al. (20) and these were evaluated for RLLs (Figure 1). Cemented femoral component interfaces were divided into 6 zones according to the technique described by Kalra et al. (21) (Figure 2). In the cementless arthroplasties, the same method was modified and the femoral component interface was divided into 6 regions and evaluated for RLLs.

Statistical Analysis

Data obtained in the study were analyzed statistically using SPSS for Windows v. 12.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables were tested using the Independent Samples t-test and Mann-Whitney U test. Pearson's $\chi 2$-test was used in the comparisons of categorical variables. The prevalence of radiolucency in the cemented and cementless radiographs was also examined using a $\chi 2$-test. A value of $p<0.05$ was accepted as statistically significant. To assess the interobserver reliability of categorical data, kappa coefficients were calculated using 95% confidence intervals.

Results

Evaluation was made of 37 patients treated with 38 non-cemented Oxford UKA and 41 patients with 47 cemented Oxford UKA. The mean follow-up period was 25.9 months (25-38) in the cementless group and 38.1 (28-65) months in the cemented group. The mean operation time was 39.2 minutes (36.92-41.48) in the cementless group and 51.5 minutes (47.31-53.29) in the cemented group, with a difference of 12 minutes ($p<0.001$). The mean age of the patients was 57.4 (47-74) years in the cementless group and 59.2 (47-72) years in the cemented group. The body mass index was 29.9 (23.3-34.5) in the cementless group and 30.3 (23.1-40.6) in the cemented group (Table 1).

In evaluating the clinical results of the patients; OKS, EQ-5D-3L, EQ-VAS, and KOOS scoring were used.

Figure 1. Tibial component interfaces evaluated according to the method described by Pandit et al. (22).

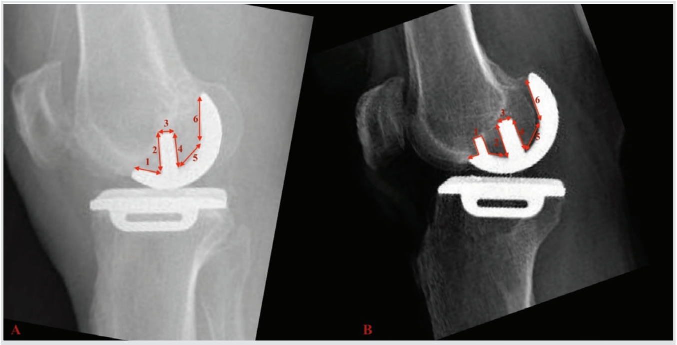

Figure 2. Femoral component interfaces evaluated according to the method described by Kalra et al. (21) (A). In cementless arthroplasties, the same method was adapted and used again (B)

There was no statistically significant difference between the groups in terms of clinical results (Table 2).

During the follow-up period, mobile bearing dislocation occurred in 2 patients in the cementless group in the 6th and 8th months, respectively. In the cemented group, two cases of mobile bearing dislocation occurred in the 5th and 22nd months, respectively. In all these cases, the bearings were exchanged for 1mm larger ones. In the cemented group, 2 patients underwent revised total knee arthroplasty in the 31st and 33rd months because of progressive lateral osteoarthritis. Total knee prosthesis was applied to a patient with unexplained medial tibial pain in the 28th postoperative month. No significant difference was determined between the two groups in respect of re-operation rates (p=0.461). In the survival analysis where reoperation for any reason was accepted as the last point, the cementless group had a survival rate of 94.7% at 25 months and the cemented group had a survival rate of 87% at 38 months and there was no significant difference between the groups (Figure 3).

No complete RLLs were observed in either the femoral or tibial component interfaces in any patient. The total number of partial radiolucent regions in cemented UKA was 32 (11.3%) and the most partial RLLs were found in 1.5 and 2 regions, respectively. In the cementless UKA group, the total number of partial

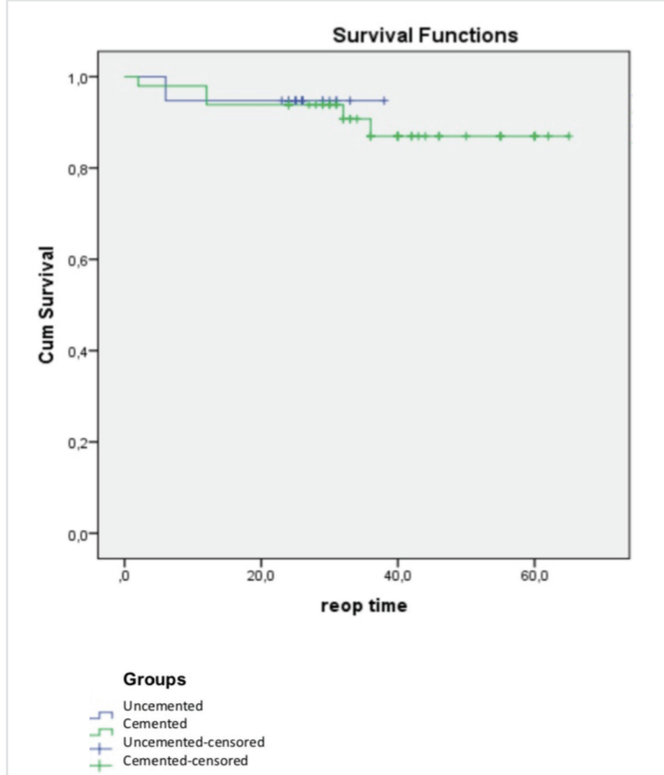

Figure 3. Kaplan-Meier curve of re-operation for any reason was determined as the last point

radiolucent regions in the tibial component interface was 13 (5.7%) and the maximum partial RLLs were observed inzones 2, 3 and 5. The incidence of partial RLLs in the tibial component interface and the total number of radiolucent zones were higher in the cemented arthroplasties (p=0.040 and p=0.025).

Considering the femoral radiolucent areas, none of the cemented and cementless UKA had complete radiolucent areas. Partial radiolucent areas were observed in 1 (2.6%) cementless UKA and in 2 (4.3%) cemented UKA cases. There was no significant difference between the groups in terms of the incidence of partial RLLs in the femoral components (Table 3).

Table 2. Clinical outcomes of the patients

	Cementless (n=37)	Cemented (n=41)	p value (MWU)
Oxford Knee score	41.1 (12-48)	40.6 (20-48)	.236
EQ-5D-3L	0.80 (0.59-1)	0.79 (0.49-1)	.625
EQ-VAS	82.8 (55-100)	82.9 (60-100)	.869
KOOS - pain	81.3 (1.67-100)	83.7 (33.3-100)	.289
KOOS - symtom	85.3 (42.8-100)	84.5 (42.8-100)	.512
KOOS - daily living	84.3 (14.7-100)	86.1 (30.8-100)	.785
KOOS - sport	67.0 (20-100)	68.7 (25.0-100)	.922
KOOS - quality of life	82.0 (25-100)	79.4 (25-100)	.245
Range of motion	112.7 (95-120)	111.4 (80-120)	.411
flexion (°)extension (°)	0.5 (0-10)	0.3 (0-10)	.793

KOOS: Knee Injury and Osteoarthritis Outcome score, EQ-5D-3L: Generic Quality of Life scale, EQ-VAS: Generic Quality of Life scale, MWU: Mann-Whitney U test

Table 3. Incidence of radiolucent lines

Tibial component			
	Cementless (n=38)	Cemented (n=47)	p value (x^2)
Total radiolucency	0 (0%)	0 (0%)	1.00
Partial RL (absent)	32 (84.2%)	29 (61.7%)	.040
Partial RL (present)	6 (15.8%)	18 (38.3%)	
Zone 1	1 (2.6%)	9 (19.1%)	.021
Zone 2	4 (10.5%)	5 (10.6%)	1.00
Zone 3	3 (7.9%)	2 (4.3%)	.652
Zone 4	2 (5.3%)	4 (8.5%)	.687
Zone 5	3 (7.9%)	7(14.9%)	.501
Zone 6	0 (0%)	2(4.3%)	.500
Sum of the zones	13 (5.7%)	32 (11.3%)	.025
Femoral component			
Total radiolucency	0 (0%)	0 (0%)	1.00
Partial RL (absent)	37 (97.4%)	45 (95.7%)	1.00
Partial RL (present)	1 (2.6%)	2 (4.3%)	
Zone 1	0 (0%)	0 (0%)	1.00
Zone 2	0 (0%)	0 (0%)	1.00
Zone 3	0 (0%)	0 (0%)	1.00
Zone 4	0 (0%)	1 (2.1%)	1.00
Zone 5	1 (2.6%)	0 (0%)	.447
Zone 6	0 (0%)	1 (2.1%)	1.00
Sum of the zones	1 (0.4%)	2 (0.7%)	.691

Statistically meaningful values are in italic and bold.
RL: Radiolucent lines

Discussion

The most important finding of this study was that physiological RLLs were statistically less common in the tibial component in cementless UKA compared to cemented UKA. In the literature, there is consensus that the incidence of femoral RLLs is very low in the cemented and cementless UKAs (22,23). In terms of tibial RLLs, there are different opinions in designer and non-designer user groups, and few publications include the results of non-designer user groups. Therefore, this report is of importance as it presents the results of a non-designer user group.

In the current study, the partial tibial radiolucency rate of 15.8% in cementless UKA was slightly higher than reported in the literature. In a designer user group, 5-year, prospective, randomized study, Pandit et al. (24) found no partial RLLs in the cementless femoral component and found a partial RLL rate of 11% in the cementless tibial component. In another study, which included a designer user group and a non-designer group, the survival of 1,000 cementless Oxford UKA was found to be 97.2% at 6 years of follow-up. No complete RLLs were observed at all, and the partial RLLs ratio on the bone-implant surface was found to be 8.9% (24). From the non-designer user group studies, Kerens et al. (13) compared cemented and cementless Oxford UKA and reported 7% partial and 0% complete RLLs in cemented UKA, and 21% partial and 0% complete RLLs in cementless UKA during a mean follow-up period of 34 months with no statistically significant difference between them. In the study of another independent center, no progressive RLLs were observed in cementless UKA, and the revision rate was found to be 0.23/100 at 5 years follow-up. Femoral RLLs were not observed at all, whereas in the tibial components of cementless UKA, RLLs were significantly fewer than in cemented UKA (22). In contrast, Bruni et al. (25) reported cementless implant survival as 74.3% at 6 years of follow-up and did not recommend the widespread use of cementless UKA because of the relationship between the high revision rates and the low bone quality. In this present study, it was seen that tibial radiolucency was more than the designer group and less than the other non-designer groups. We think that the success of UKA, which has a long and difficult learning curve, is related to the annual number of UKA case surgeries performed by the surgeon.

In the current study, the rate of partial RLLs of 38.3% determined in the cemented group was found to be in accordance with the literature. Gulati et al. (20) reported this rate as 32% at the end of a 5-year follow-up period and Pandit et al. (22) reported 43% after a 1-year follow-up. In this present study and the similar studies about RLLs in UKA in the literature, the majority of patients who underwent cemented UKA were patients with insufficient bone quality. In our opinion, we see that cemented UKA applied to patients whose trabecular structure is not tight enough in the bone hardness test cannot complete the deficiency caused by insufficient bone quality.

When the distribution of the radiolucent line according to each zone was examined, physiological RLLs were mostly observed in zones 2 (10.5%), 3 (7.9%) and 5 (7.9%) in cementless tibial components, and in zones 1 (19.1%), 5 (14.9%) and 2 (10.6%) in the cemented tibial components, respectively. Similar to the current study, when Kleeblad et al. (26) analyzed RLLs according to zones, all tibial radiolucencies were observed in zones 1 and 5. In the current study, the total number of partial radiolucent regions was 13 (5.7%) in cementless UKAs and 32 (11.3%) in cemented UKAs. This difference was statistically significant (0.025). No complete RLLs were observed in any UKAs when both cemented and cementless prostheses were considered. In cemented UKAs, the incidence of partial RLLs and the total number of radiolucent regions in the tibial component interface were higher. However, the excess physiological line observed in cemented UKAs was not reflected in the clinical results of the patients, and no statistically significant difference was found between the groups when the postoperative OKS, EQ-5D-3L, EQ-VAS and KOOS scores were compared.

When the duration of surgery of the patients was evaluated, it was seen to be 12 minutes shorter in the cementless group. The time taken for the diagnostic arthroscopy in 32 patients was not included in the arthroplasty operative time. The shorter operative time in cementless UKA is expected when bone cement hardening time is taken into consideration in cemented UKA. The insert dislocation that is observed in a patient with a cemented UKA is because the excess cement has not been cleaned well at the posterior of the tibial component and the insert is dislocated in the third month postoperatively due to impingement. When a minimally invasive surgical technique is used, the view of the surgical field may be minimal. This can lead to problems in noticing and cleaning the cement residues at the posterior of the components, especially if a cemented femoral component is used and this may lead to problems such as pain, impingement, and insert dislocation in the postoperative period (27). Therefore, this can be stated as a further advantage of a cementless UKA.

Clarius et al. (28) reported that pulsed lavage significantly reduced the incidence of RLLs in cemented fixations. Panzram et al. (23) reported lower RLL incidence in cemented UKAs with this device but no significant difference was determined in comparison with the cementless UKAs. In the current study, jet lavage was applied to every patient and a significantly lower number of radiolucent regions was detected in the cementless group (15.8% vs 38.3%).

Study Limitations

This study had several limitations, primarily that it was a retrospective study. Second, this was a case series performed by a single surgeon with extensive surgical experience (more than 250 cases) and might not be reproducible in other centers. Another limitation was the relatively small number of cases and shorter follow-up time of the cementless group compared with the cemented group. Despite these limitations, the major strength of this study was that it was one of the few comparative studies that examined RLLs in cemented and non-cemented UKAs as a non-designer user group. The study also included the clinical results of two different fixation methods.

Conclusion

The most important finding of this study was that the rate of physiological RLLs was significantly lower in cementless UKAs than in cemented UKAs, and the presence of RLLs had no effect on clinical outcomes. This result supports the views of the designer group. This study is also important in terms of reflecting the results of a non-designer group as there are few studies in literature with comparative results of non-designer groups. Nevertheless, there is a need for larger patient series and longer follow-up results to examine the clinical safety and efficacy of cementless implants.

Ethics

Ethics Committee Approval: The study was approved by Ankara Dışkapı Yıldırım Beyazıt Research and Training Hospital Institutional Review Board (protocol no: 56/29, date: 12.11.2018). The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Informed Consent: Written informed consent obtained from all patients.

Peer-review: Externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: H.A., Concept: H.A., H.A.A, M.A., K.B., H.B.Ç., Design: H.A., H.A.A, M.A., K.B., H.B.Ç., Data Collection or Processing: H.A., H.A.A, M.A., K.B., H.B.Ç., Analysis or Interpretation: H.A., H.A.A, M.A., K.B., H.B.Ç., Literature Search: H.A., H.B.Ç., H.A.A., Writing: H.A., H.B.Ç., H.A.A.

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