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ORIGINAL ARTICLE

Does the gap balance technique really elevate the joint line in total knee arthroplasty? A single-center, randomized study

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Dissatisfaction after total knee arthroplasty (TKA) is reported up to 20% in the literature.[1] Correct positioning of the components in TKA, providing a balanced flexion-extension gap, and restoring the joint line (JL) are among the factors affecting patient satisfaction.[1] A change of more than 4 mm in the JL may lead to impaired patellofemoral joint alignment, mid-flexion instability, and poor clinical outcomes.[2,3] Although studies on the elevation of the JL are mostly addressed in revision TKA, this issue may affect biomechanical and clinical outcomes in primary TKA.[2] In a biomechanical study, a 4-mm JL elevation resulted in poor results.[4] However, how many millimeters of change can affect clinical outcomes still remains controversial.[2,5]

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ABSTRACT

Objectives: This study aims to compare patients undergoing total knee arthroplasty (TKA) with gap balancing (GB) versus measured resection (MR) techniques in terms of joint line (JL) using radiographic measurements from both femoral and tibial sides.

Patients and methods: Between August 2019 and May 2021, a total of 107 patients who underwent TKA were included in this randomized study. The patients were divided into two groups as the GB group (n=54; 9 males, 45 females; mean age: 66.6±7.4 years; range, 51 to 81 years) and the MR group (n=53; 10 males, 43 females; mean age: 64.0±6.8 years; range, 50 to 80 years). The adductor tubercle joint line (ATJL) and the tibial tubercle joint line (TTJL) were evaluated for JL measurement. Clinical and functional evaluation was made using the range of motion of the joint, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, Knee Society Score (KSS)-Knee and Functional scores.

Results: The mean follow-up was 34.2±3.5 months in the GB group and 34.4±3.3 months in the MR group (p=0.80). The mean operation time was 119.1±14.9 min in the GB group and 118.6±17.5 min in the MR group (p=0.89). A total of 31 (57.4%) patients in the GB group had a degree of release of 3-4, while 21 (39.6%) patients in the MR group had a degree of release of 3-4 (p=0.26). The ATJL measurement was similar in the GB and MR groups, while the TTJL measurement was significantly different between the two groups (p=0.01). There was no significant correlation between the ATJL measurement and the degree of release, while there was a significant correlation between the TTJL and the degree of release (r=0.731, p<0.001).

Conclusion: While ATJL measurements in TKA showed similar results with GB and MR techniques, the amount of release may have caused the significantly higher JL elevation in the GB group in TTJL measurements. Based on these findings, we suggest that radiographic JL measurements on both the tibial and femoral sides in TKA may provide a more accurate assessment and we recommend to measure JL from the femoral side.

Keywords: Adductor tubercle, gap balancing, measured resection, tibial tubercle, total knee arthroplasty.

In the positioning of components in TKA, gap balancing (GB), in which femoral bone cuts are made according to the soft tissue balance in the coronal plane in the extension position, and measured resection (MR), in which bone cuts are made according to the transepicondylar axis and Whiteside's line without considering the soft tissue balance, can be used.[6,7] While there are many studies on the clinical outcomes of these two techniques and femoral component (FC) rotation, studies on the effect of JL are limited.[6-8] Considering the radiographic studies examining the effect of these two techniques on the JL, it can be seen that most studies performed JL measurements from the tibial side.[6,9-11] Measurements taken from the tibial side can produce variable results with soft tissue release, bone cuts, and deformity correction. In addition, as the distal femoral cut is computer-guided in navigated systems, bone cuts vary depending on the computer algorithms.[12,13]

To the best of our knowledge, there is no study in the literature which compares the conventional extension first GB technique with the MR technique for radiographic JL measurements from both the tibial and femoral sides. In the present study, our primary objective was to compare the conventional extension first GB technique with the MR technique in TKA and examine whether the GB technique caused JL elevation in TKA. The secondary objective was to investigate whether tibial measurements were associated with soft tissue release.

PATIENTS AND METHODS

This single-center, prospective, randomized study was conducted at Health Science University, Bursa Yüksek İhtisas Training and Research Hospital, Department of Orthopedics and Traumatology between August 2019 and May 2021. Patients with loss of function due to advanced degenerative knee osteoarthritis who accepted unilateral TKA after failure of conservative treatment and committed to follow-up for at least two years were included in the study. Exclusion criteria were as follows: inflammatory diseases, posttraumatic arthritis, lower extremity involvement due to any neurological or orthopedic disorder, and a deviation of more than 3° in mechanical axis alignment on postoperative radiographic evaluation. Randomization was performed by an independent researcher who was blind to the study protocol using a sealed envelope procedure, and TKA was performed using the other method after the first patient. Finally, a total of 107 patients who met the inclusion criteria were recruited. The patients were divided into two groups as the GB group (n=54; 9 males, 45 females; mean age: 66.6±7.4 years; range, 51 to 81 years) and the MR group (n=53; 10 males, 43 females; mean age: 64.0±6.8 years; range, 50 to 80 years). All TKAs were performed by a single experienced surgeon. Cemented, posterior stabilized fixed insert TKA (The Columbus®, TKR System Aesculap, Tuttlingen, Germany) was used in all operations. Patellar resurfacing was not performed in any case. Neither the patients included in the study nor the researchers who collected the data were familiar with the technique used in TKAs. A written informed consent was obtained from each patient. The study protocol was approved by the Bursa Yüksek İhtisas Training and Research Hospital Ethics Committee (date: 27.02.2019, no: 2019/02-08). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Surgical technique

Regional anesthesia methods were applied to all patients. The deep medial collateral ligament, menisci, and cruciate ligaments were excised by using a pneumatic tourniquet through the medial parapatellar approach. In all TKAs, starting from the tibia, a proximal tibial bone cut was made with an extramedullary guide perpendicular to the mechanical axis and with a tibial inclination not exceeding 5°. Then, a distal femur cut was made at 5° valgus to the distal articular surface with an intramedullary guide. Tibial component rotation was adjusted to 10° external rotation to the posterior condylar line in all patients. Patelloplasty, which consisted of the excision of patellar osteophytes and patellar rim cauterization, was performed in both groups. Patella eversion was avoided, and all patella were excised laterally. Hemovac® drains were not used in any case.

Gap balancing: After bone cuts of the proximal tibia and distal femur, all osteophytes were excised. Soft tissue release was performed gradually when necessary to create a symmetrical rectangle in the extension gap. The gap was evaluated by measuring medially and laterally with a gap meter. This progressive releasing consisted of *(i)* a posteromedial capsule, *(ii)* pie-crusting of the superficial MCL with a needle tip, *(iii)* semimembranosus, and *(iv)*pes anserinus tendons.[14] A 2-mm medial and lateral stretch of the extension gap after release was considered to be balanced. Then, the knee joint was flexed 90° and the estimated FC size was determined with the help of the guide of the set. In the measurements of the size in between, the larger one was started first. The posterior femoral cut site was determined by determining the flexion gap equal to the extension gap with a lamina spreader placed between the tibial cut face and the femoral notch and distracted by the same surgeon in each case. No special torquemeter or tensioner was used. Femoral cuts were completed in accordance with the FC size, equal to or at most 2-mm smaller than the extension gap and without obvious anterior notching. The first extension GB technique was applied without any soft tissue release in flexion.

Measured resection: After determining the FC size, the femoral cutting guide was used to make chamfers cut to the posterior condyles with 3° of external rotation. The trial components were, then, placed and ligament balance was checked for extension and flexion. If ligament balance was not achieved, the soft tissue releases listed above were performed as necessary, and an attempt was made to balance the medial and lateral sides.

Active in-bed exercises were started in all patients on the day of surgery, and patients were mobilized on postoperative Day 1. Range of motion exercises were performed as tolerated by the patient. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score and the Knee Society Score (KSS)-Knee and Functional scores were completed by an independent observer.

Pre- and postoperative anteroposterior (AP) and true lateral radiographs and orthopantomograms were obtained in all patients. Mechanical axis and JL measurements from both the tibial and femoral sides were obtained from pre- and postoperative radiographs. The mechanical axis was measured as the angle between the line connecting the center of the femoral head and the deepest point of the femoral notch and the line connecting the tibial crest on radiographs taken with the patient standing upright with the patella facing forward. The JL was measured on AP radiographs from the femoral side, and the adductor tubercle-JL (ATJL), as described by Hoffman et al.[15] was measured and recorded preoperatively and postoperatively (Figure 1). The JL was measured on lateral tibial radiographs as the distance from the most proximal point of the tibial tubercle to the most distal point of the femoral condyles (TTJL) (Figure 2).[3] In the preoperative measurements, 2.15 mm was added

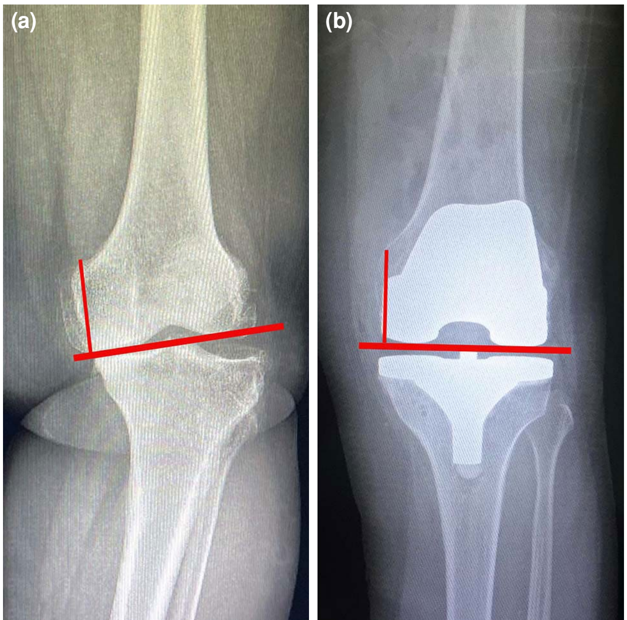

FIGURE 1. The measurement of ATJL level **(a)** preoperative ATJL level on the weight-bearing anteroposterior X-ray **(b)** postoperative ATJL level on the weight-bearing anteroposterior X-ray.
ATJL: Adductor tubercle joint line.

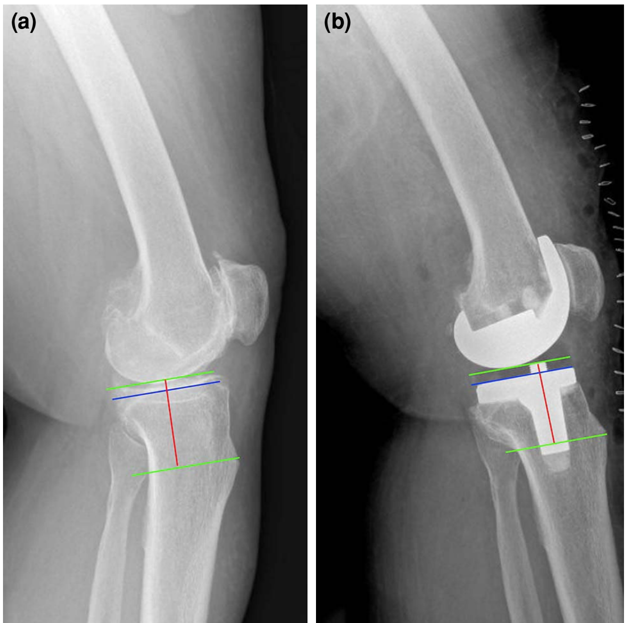

FIGURE 2. The measurement of the TTJL change in lateral X-rays. The blue is line parallel to the tibial slop. The line parallel to the blue line at the top of the tibial tuberosity (first green line). The second green line is parallel to the first green line on the femoral condyles. The amount of the joint line change is the distance between the two green lines. **(a)** Preoperative TTJL measurements on the weight-bearing lateral X-ray, **(b)** postoperative TTJL measurements on the weight-bearing antero-posterior X-ray.
TTJL: Tibial tubercle joint line.

to the preoperative measurements to eliminate the error which would occur, as the cartilage thickness was not visible on plain radiographs.[16] All radiological measurements were measured three times at different time points by two orthopedic specialists experienced in musculoskeletal radiological imaging who were blinded to the patient allocation, and the measurements were averaged.

Statistical analysis

A power analysis was conducted with type 1 error set at 0.05 (α=0.05) and the type 2 error at 0.20 (80% power). A minimum sample size of 27 knees was needed to detect a significant difference between the two groups.

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Continuous data were expressed in mean ± standard deviation or median (25th-75th percentile), while categorical data were expressed in number and frequency. The Kolmogorov-Smirnov test was used to determine whether quantitative variables were normally distributed. Independent groups were compared using the independent samples t-test for normally distributed variables and the Mann-Whitney U test for non-normally distributed variables. The chi-square analysis was used to examine the relationship between qualitative variables. Both inter- and intra-rater reliability was estimated using the intraclass correlation coefficients (ICC) based on a mean rating (k=2), absolute agreement, and two-way random effects. All ICC estimates were greater than 0.8. The assessment of the relationship between ATJL, TTJL, and the degree of relaxation was performed with the Pearson correlation analysis. A p value of <0.05 was considered statistically significant.

RESULTS

The mean follow-up was 34.2±3.5 months in the GB group and 34.4±3.3 months in the MR group (p=0.80). The mean operation time was 119.1±14.9 min in the GB group and 118.6±17.5 min in the MR group (p=0.89). A total of 31 (57.4%) patients in the GB group had a degree of release of 3-4, while 21 (39.6%) patients in the MR group had a degree of release of 3-4 (p=0.26). There was no statistically significant difference in the overall clinical characteristics and demographic data of the patients between the groups (p>0.05) (Table I).

Table II shows the statistics and comparison results of clinical scores and clinical findings of GB and MR groups. No significant difference was found between the groups in terms of clinical scores. Pre- and post-operative range of motion,

TABLE I
Demographic data and general characteristics between groups

	GB group (n=54)			MR group (n=53)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			66.6±7.4			64.0±6.8	0.06
Sex							
Male	9	16.67		10	18.87		0.77
Female	45	83.33		43	81.13		
Operation side							
Right	20	37.04		25	47.17		0.29
Left	34	62.96		28	52.83		
Body mass index (kg/m^2)			30.45±4.06			31.55±3.02	0.12
Follow-up time (month)			29.26±3.55			29.43±3.39	0.80
Operation time (min)			119.09±14.92			118.66±17.58	0.89
Soft tissue release							
Step 1	4	7.41		8	11.21		0.26
Step 2	19	35.19		24	40.19		
Step 3	25	46.30		16	38.32		
Step 4	6	11.11		5	10.28		

GB: Gap balancing; MR: Measured resection; SD: Standard deviation.

TABLE II
Comparison of clinical scores between groups

	GB group (n=54)	MR group (n=53)	
	Mean±SD	Mean±SD	*p*
Preoperative flexion (degree)	113.33±11.07	110.09±10.12	0.12
Postoperative flexion (degree)	120.93±10.51	120.57±10.08	0.86
Preoperative flexion contracture (degree)	4.81±3.07	5.57±3.20	0.22
Postoperative flexion contracture (degree)	3.43±3.20	3.58±2.48	0.77
WOMAC preoperative	59.39±7.89	61.66±8.27	0.15
WOMAC postoperative	12.63±2.08	12.17±2.32	0.28
KSS knee score preoperative	48.87±10.28	47.40±10.66	0.47
KSS knee score postoperative	92.22±2.53	92.40±2.92	0.74
KSS function score preoperative	50.37±9.80	49.43±9.59	0.62
KSS function score postoperative	91.85±4.79	91.42±5.04	0.65

GB: Gap balancing; MR: Measured resection; SD: Standard deviation; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; KSS: Knee Society Score.

TABLE III
Radiographic comparisons between groups

	GB group (n=54)	MR group (n=53)	
	Mean±SD	Mean±SD	*p*
Preoperative alignment (degree)	11.67±4.29	11.85±4.07	0.82
Postoperative alignment (degree)	0.09±1.55	–0.19±1.62	0.36
ATJL (mm)	1.10±0.65	1.15±0.61	0.69
TTJL (mm)	2.47±0.51	2.14±0.75	0.01

GB: Gap balancing; MR: Measured resection; SD: Standard deviation; ATJL: Adductor tubercle-joint line; TTJL: Tibial tubercle-joint line.

Womac, KSS knee and function scores were similar between groups.

Table III shows the comparison results of the radiological characteristics of the GB and MR groups. The ATJL measurement was similar in the GB and MR groups, while the TTJL measurement was significantly different between the two groups (p=0.01). The Pearson correlation analysis revealed no significant correlation between the ATJL measurement and the degree of release, while there was a significant correlation between the TTJL and the degree of release (r=0.731, p<0.001).

DISCUSSION

In the present study, we compared patients who underwent TKA with GB versus MR techniques in terms of JL using radiographic measurements from both femoral and tibial sides. The main finding of this study is that the effects of GB and MR methods used in FC rotation on JL produced similar results after measurements from the ATJL (femoral side), while different results were observed when evaluating the TTJL (tibial side).[17] When the relationship between TTJL measurements and the degree of release was evaluated, a significant relationship was found. A total of 31 (57.4%) patients in the GB group had a degree of release of 3-4, while 21 (39.6%) patients in the MR group had a degree of release of 3-4. We believe that reasons such as the degree of deformity and the amount of release may affect the JL measurements from the tibial side, and making measurements from the femoral side, such as AT, may give more accurate results in JL evaluation. However, although there was a difference between TTJL measurements in both groups, both techniques produced similar clinical results.

There are many studies in the literature comparing GB and MR techniques clinically and radiologically in TKA.[6,7,9,11,13,18-20] In the studies evaluating the effects of both techniques on the JL, the majority of studies reported that the GB technique elevated the JL, as well as studies showing that the results were similar.[9-11,13,18] In their randomized-controlled study, Babazadeh et al.[13] reported that the GB technique using navigation caused JL elevation. They attributed this to the excessive bone cuts made by the navigated computer algorithms in the GB technique to achieve interval symmetry. However, in this study, the authors did not evaluate the JL radiologically. The JL was assessed by calculating the mean value of the bone cut records of the navigated system in the condyles and calculating the difference between this value and the implanted prosthesis thickness. We believe that this measurement may lead to erroneous results, as there is no radiological verification and there may be differences in bone defects depending on the degree of deformity. It has also been reported that there is a weak correlation between intraoperative measurements of navigated systems and postoperative radiographic measurements while evaluating JL.[21] Tigani et al.[9] did not measure ATJL radiologically in their study comparing navigated GB and MR techniques, but measured TTJL similar to our study and found that the GB group had more JL elevation. In the aforementioned study, the authors found a mean of 4.1±2.3-mm elevation in the GB group and 3.0±2.3-mm elevation in the MR group. In our study, the mean TTJL elevation was 2.47±0.51 mm in the GB group and 2.14±0.75 mm in the MR group. We attribute this difference to the fact that preoperative cartilage thickness was not taken into account in that study. Similarly, Lee et al.[11] measured TTJL and fibular head from AP radiographs in their study comparing GB and MR techniques using the navigated system and found more JL elevation in the GB group. However, in this study, bone cuts were made according to the algorithms of the navigated system and bone cuts were made 2 to 4 mm more than the distal femur in knees with flexion contracture. It is well known that these factors may have an effect on JL radiological assessment.[22]

In their retrospective study comparing TKA applications with GB, MR, and hybrid methods, Hao et al.[10] measured the TTJL. They found that patients in the GB group had more JL elevation compared to patients in the MR and hybrid groups. However, no measurement was made from the femoral side in this study. In their meta-analysis comparing GB and MR techniques, Migliorini et al.[6] found that the GB group performed more JL elevation. Huang et al.[7] also found similar results in their meta-analysis. However, considering the studies included in this meta-analysis, all of them were performed with navigated systems, and only the tibial side measurements were taken in the studies which included radiographic evaluation.

Furthermore, Maciąg et al.[23] compared JL change with ATJL measurement in a retrospective cohort-matched analysis study comparing the GB technique with the conventional MR technique using tensioners and found that JL change was higher in the GB group than in the MR group (GB −2.6±4.1, MR −0.7±4.8). However, this study did not include measurements of the tibial side. In addition, the rate of patients with a JL change of more than 2 mm (GB=10:91 *vs.* MR=26:98, p=0.028) was higher in the MR group. Considering these values, the high standard deviation value in this study suggests that homogeneity between groups cannot be achieved. Moreover, this study was retrospective and excluded patients with flexion contracture less than 15° and patients with varus deformity more than 15°. We believe that our study is more valuable, as it is a prospective study, and the standard deviation in JL measurements is less. Hu et al.[20] performed ATJL measurement in their retrospective study comparing patients who underwent GB with a spacer and those who underwent the traditional MR technique. They reported that the effect of both groups on the JL was similar, consistent with our study. In another study evaluating ATJL measurement, patients who underwent GB with flexion first balancing technique were compared with patients who underwent MR, and contrary to all these studies, JL elevation was found to be significantly higher in the MR group.[24] However, this technique differs from ours in that the flexion area is stabilized first, and then the extension cuts are made.

In the current study, the distal femoral cut was made in the same way in both groups and, then, the champers cuts for the flexion gap were made accordingly after the extension gap was balanced first with the GB technique with a lamina spreader. Since the distal femoral cut was made in the same way in both groups and no additional procedure was performed. In addition, in the GB group, more releases are applied to achieve soft-tissue balance while stabilizing the range of motion. After all these releases, the measurements taken from the tibial side can be related to the amount of release. When we divided the patients according to our own classification system, there was no statistically significant difference between the groups, however, the total number of patients with release Grades 3 (semimembranosus) and 4 (pes anserinus) was 31/54 (57.4%) in the GB group and 21/53 (39.6%) in the MR group. We believe that one of the factors that may have contributed to the higher TTJL measurements in the GB group might be these releases. When the relationship between the degree of release and TTJL was evaluated by regression analysis, the finding of a significant relationship between TTJL and the degree of release supports this idea (r:0.731, p<0.001). Yagishita et al.[25] reported an increase in flexion-extension gaps from 0.3 mm to 3.8 mm with progressive medial soft tissue release while maintaining soft tissue balance in varus knees. Since the JL after TKA is the line formed by the FC and the tibial insert, we believe that measurements from the tibial side may be affected by medial soft tissue release, and measurements from the femoral side may provide more accurate results.

It has been demonstrated that JL elevation can cause patellofemoral pain, mid-flexion instability, and poor clinical scores.[24] However, different values such as 4 mm, 5 mm, and 8 mm have been reported for JL change affecting the clinic.[3,12,26,27] In this study, the clinical scores were similar in both groups. This result may be due to the fact that there were no cases with >4 mm JL elevation in both groups.

Nevertheless, this study has several limitations. First, the minimum follow-up time was relatively short (24 months). Although this was sufficient to evaluate the change in JL, which was our primary outcome, it can only be considered a short time for clinical evaluation. Second, although there was no significant difference in preoperative alignment between the groups, differences in bone defects due to the degree of deformity may cause difficulties in radiographic evaluation. However, intra- and inter-reliabilities above 0.8 in radiographic evaluation suggest that radiographic measurement errors are minimal. Studies in the literature reporting that the GB technique causes JL elevation are mostly studies using radiographic measurements from the tibial side or navigation systems. As there are no studies measuring the effect of the conventional GB technique on the JL from both the tibial and femoral sides, we obtained findings by measuring from both sides which is one of the strengths of this study.

In conclusion, while evaluating the effect of conventional extension first GB and MR techniques on the JL, our study showed no significant difference in JL elevation in the femoral side, whereas JL elevation was observed when measurements were taken from the tibial side. Based on these findings, we suggest that JL measurements on the tibial side may be misleading due to certain discrepancies in the balance of ligament. For JL radiographs, combined femoral and tibial measurements may provide more accurate results. Although both GB and MR techniques show a slight elevation of the JL, there are no studies which show that these small amounts of JL elevation have a clinical impact in primary TKA. Therefore, we believe that both techniques can be safely preferred in primary TKA, provided that they are used properly without concern for the JL. Further multi-center, larger-scale, long-term, prospective, randomized-controlled studies are warranted to establish more reliable conclusions on this subject.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, design, materials, writing the article: Ö.A., A.Ö.; Control/supervision, aritical review: A.Ö.; Data collection and/or processing, literature review: A.Ç., H.Ş., N.Ç.; Analysis and/or interpretation: N.Ç., Y.A.; References and fundings: Y.A., A.Ç., H.Ş.

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