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The Impact of Different Anterior Cruciate Ligament Status on Unicompartmental Knee Arthroplasty: Short Term Clinical and Functional Results

Unikompartmantal Diz Artroplastisine Ön Çapraz Bağ Durumunun Etkisi: Kısa Dönem Klinik ve Fonksiyonel Sonuçlar

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ABSTRACT

Purpose: Purpose of this study is to compare the short-term results of unicompartmental knee arthroplasty applied stable knees regardless of the condition of the ACL and the application of unicompartmental knee arthroplasty and ACL reconstruction combined surgery applied to ACL deficient cases with anterior instability and to identify the condition and function of the ACL for success in this surgery.

Patients and Methods: 80 out of the 105 patients who were operated in 2013-2015 and came for follow-up were included in the study and the patients were divided into four groups. The VAS pain score, KSS Score, WOMAC score, OKS questionnaires and joint range of motion measurements were conducted pre-operatively and post-operatively. One leg standing test, joint position sense measurement, and isokinetic muscle strength test were performed in post-operative controls.

Results: There was no statistically significant difference between the demographic data and follow-up of the groups (p>0.05). While there was a statistically significant difference in knee flexion between Group 2-Group 4 and Group 3-Group 4 in the pre-operative period, no difference was found in the post-operative period (p>0.05). While there was no difference among the groups, knee joint range of motion in direction of extension declined in a statistically significant way in all four groups (p<0.05). Pain felt postoperatively was the most in Group 1 and the least in Group 3. A statistically significant difference was found between Group 1 and Group 3 in the test performed with the eyes closed (p<0.05).

Conclusion: The presence of a functional anterior cruciate ligament is expected to make a positive contribution to surgical results especially in young patients with high activity expectation. Whether the patient's ACL rupture is primary or secondary and his/her activity expectation should be effective in the choice of a surgical method.

Keywords: Medial compartment osteoarthritis; unicompartmental knee arthroplasty; anterior cruciate ligament; pain; joint position sense; muscle strength.

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ÖZET

Amaç: Bu çalışmanın amacı ön çapraz bağın durumuna bakılmaksızın stabil dizde uygulanan unikompartmantal diz artroplastisi ile anterior instabilitesi ve ön çapraz bağ eksikliği olan olgularda unikompartmantal diz artroplastisi ve ön çapraz bağ rekonstrüksiyonu uygulanan hastaların kısa dönem sonuçlarını karşılaştırmak ve unikompartmantal diz artroplastisinde cerrahinin başarını arttırmak için ön çapraz bağın durumunu ve işlevini belirlemektir.

Hastalar ve Yöntem: 2013-2015 yıllarında opere edilen ve kontrole gelen 80 hasta çalışmaya dahil edildi ve hastalar dört gruba ayrıldı. Pre-operatif ve post-operatif VAS ağrı skoru, KSS Skoru, WOMAC skoru, OKS skoru ve eklem hareket açıklığı değerlendirmeleri yapıldı. Post-operatif kontrollerde tek ayak denge testi, eklem pozisyon hissi ölçümü ve izokinetik kas kuvvet testi uygulandı.

Bulgular: Grupların demografik verileri arasında istatistiksel olarak anlamlı fark yoktu (p>0,05). Grup 2-Grup 4 ve Grup 3-Grup 4 arasında pre-operatif dönemde diz fleksiyonunda istatistiksel olarak anlamlı fark bulunurken, post-operatif dönemde fark saptanmadı (p>0,05). Diz ekstansiyonu dört grupta da istatistiksel olarak anlamlı düzeyde azaldı (p<0,05). Post-operatif ağrı en fazla Grup 1'de, en az ise Grup 3'te görüldü. Gözler kapalı yapılan denge testinde Grup 1 ile Grup 3 arasında istatistiksel olarak anlamlı fark bulundu (p<0,05).

Sonuç: Özellikle aktivite beklentisi yüksek olan genç hastalarda fonksiyonel ön çapraz bağ varlığının cerrahi sonuçlara olumlu katkı sağlaması beklenmektedir. Hastanın ÖÇB yırtığının primer veya sekonder olması ile aktivite beklentisi cerrahi yöntemin seçiminde etkili olmalıdır.

Anahtar Kelimeler: Medial kompartman osteoartriti, unikompartmantal diz artroplastisi, ön çapraz bağ, ağrı, eklem pozisyon hissi, kas kuvveti.



1. Introduction

Unicompartmental knee arthroplasty (UKA) offers a good solution for isolated medial compartment osteoarthritis (MCOA) with a better range of motion, preserving natural knee kinematics, and less bone resection [1]. For these patients, UKA gives equal or better results than total knee arthroplasty (TKA), [2]. In the last decade, UKA has become a very popular treatment choice for MCOA.

Anterior cruciate ligament (ACL) injuries are one of the most common injuries of the knee. Long term results after ACL reconstruction are very promising. Knee stability can be restored to almost normal. Patients can return to their pre-injury level of activity after ACL reconstruction [3].

MCOA in active patients with ACL deficiency is increasingly a common problem [4]. It is well known that knee kinematics changes significantly in ACL deficient knees [5,6]. MCOA in conjunction with anterior instability is very difficult to treat and TKA might be the treatment option for these patients [3]. Increased failure rates have been reported with UKA in instable knees [7].

Combination of ACL reconstruction to UKA may be a preferable option for active patients that have MCOA. It also may preserve range of motion and normal kinematics of the knee and also preserves patients' activity level. Several studies reported good results with UKA and ACL combined surgery for active patients with MCOA who have instable knees [3,8]. They concluded in their studies that UKA and ACL reconstruction combined surgery seems to be a very good option for ACL deficient instable knees [3,8]. Recent studies defend UKA alone for ACL deficient but functionally stable knees. Boissonneault et al. found similar survivorship between ACL intact and ACL deficient but stable knee

groups after five years follow-up [9]. Functional stability of ACL seems more important than anatomical intactness. There are still controversies about proprioceptive ability of the UKA performed knees with or without ACL even in stable knees.

The aim of this study is to determine the short term clinical and functional results and knee proprioception of UKAperformed in ACL intact knees, in ACL ruptured stable knees, ACL ruptured instable knees, and in ACL partial ruptured knees.

2. Material and Method

General Information

This study was approved by the ethics committee of Süleyman Demirel University, decision numbered 157 dated 2016. After local ethical committee approval, 105 patients that had undergone medial UKA in 2016-2018 were investigated at the sports medicine clinic.

Inclusion and Exclusion Criteria

Patients within the age range of 40-80 who had completed their 24 months postoperatively after unicondylar knee arthroplasty, and whose informed consent was obtained were included into the study. Patients who required revision in the surgical area, those who developed technical failure in the knee that underwent surgery, who had a patellofemoral joint arthrosis of above Kellgren Lawrence Grade 2, and who could not comply with the functional tests applied were excluded from the study.

Surgical Techniques

All surgeries were performed by a single senior expert knee surgeon (MU). Following a standard anteromedial skin incision, the medial compartment was accessed through a medial parapatellar mini arthrotomy. The anterior and medial parts of the medial meniscus were excised. Tibial and femoral osteophytes were removed. The necessary tibial and femoral incisions were made in line with the implant application guidelines (Zimmer, Warsaw, USA). Following the application of test implants, the tibial and femoral implants were fixed with the bone. A fixed insert was used as interface. The same brand of implant was applied using the same technique to all the patients included into the study.

In patients who underwent UKA and ACLR, UKA was performed with the standard technique mentioned above.

For ACL reconstruction, a four-strand hamstring tendon autograft was taken and prepared as ACL graft. The tibial tunnel was drilled by means of a guide pin, and the femoral tunnel was drilled through the femoral footprint using a free-hand technique so as to create an anatomic single tunnel. Buttons or intra-tunnel fixation materials were used for femoral fixation while bio-screws and staple U nails were used for the tibial tunnel.

Post-operative Rehabilitation

The patients started walking with weight-bearing to the pain threshold with double crutches from postoperative day one. The patients were not made to use knee braces. All patients were made to do active flexion and passive extension range of motion exercises, isometric and isotonic strength exercises aimed for thigh muscle groups, balance exercises, and given walking training as standard for 8 weeks under the supervision of a physiotherapist. Then, a home-based exercise program was maintained for 6 months.

Groups

The patients were divided into four groups as follows: ACL intact (Group 1), ACL partial rupture (Group 2), ACL total rupture (Group 3), and Combined UKA+ACL reconstruction (Group 4).

Clinical and Functional Testing

The height and body-weight measurement of the patients received for clinical follow-up and control was performed using a mechanical scale with a height rod for adults (SECA 700, Germany) after exhaling, with bare feet, in an upright position. The patients were subjected to a joint range of motion measurement (Baseline Stainless Steel Goniometer 180°, USA), [10], and to the Visual Analogue Scale (VAS) pain score [10], "Knee Society" Knee Arthroplasty Evaluation Form (KSS) Score [8], Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Score [11], and Oxford Knee Score (OKS), [8] questionnaires preoperatively and postoperatively. In addition, a 'One-Leg Standing Test' was administered postoperatively control for a maximum of 30 seconds with eyes closed and open in order to determine the functional balance status of the patients [12]. The duration the patients stood on one foot was recorded as seconds.

Proprioceptive and Isokinetic Muscle Strength Testing

Passive and active proprioception measurement was performed with an isokinetic dynamometer (HUMAC[®] NORM[™] Testing & Rehabilitation System, USA) at 30° and 75° and 1°/second angular velocity respectively in order to evaluate joint position sense [13], and isokinetic muscle strength measurement at an angular velocity of 120°/second with the concentric/concentric mode in order to evaluate muscle strength [14].

Statistical Analysis

All the data was analyzed using SPSS 22.0 package program. Descriptive statics was utilized to define the data and the Kruskal Wallis test to determine the difference independent groups. In those parameters in which a difference was found a Mann Whitney-U test with Bonferroni correction was used in order to identify between which groups the difference was. The Friedman test was used for the analysis of the difference between the preoperative-postoperative measurement values. Statistical significance was set at p<0.05 The results were given as means \pm standard deviation.

3. Results

The study was completed with 80 patients as the follow-up data of the 25 out of the 105 patients constituting the study group could not be obtained (Figure 1).

There was no statistically significant difference between the demographic data and post-operative follow-up durations of the groups (p>0.05), (Figure 1).



Figure 1: Study flow

While there was a statistically significant difference in knee flexion between Group 2-Group 4 and Group 3-Group 4 in the pre-operative period, no difference was found in the post-operative period (p>0.05). While there was no difference among the groups, knee joint range of motion in the direction of extension declined in a statistically significant way in all the four groups (p < 0.05), (Table 1).

| | Group 1 (n:32) | Group 2 (n:17) | Group 3 (n:17) | Group 4 (n:14) | p value* |
|---------------------|-------------------|-------------------|-------------------|-------------------|----------|
| Pre op flex ROM | 131.4±8.6 | 125.9±13.1 | 125.6±14.3 | 136.1±7.4 | 0.03* |
| Post op flex ROM | 128.7±10 | 127.6±11.3 | 124.1±11.7 | 124.6±14.4 | 0.6 |
| p value** | 0.4 | 0.1 | 0.4 | 0.2 | |
| Pre op extROM | 6.7±4.5 | 4.4±4.3 | 5.9±4 | 10±5.7 | 0.37 |
| Post op extROM | 0.4±1.7 | 0.9±2.6 | 0±0.1 | 0±0.1 | 0.35 |
| P value** | 0.001** | 0.007** | 0.001** | 0.001** | |

Table 1: Joint range of motion measurement values (°)

Pre op: preoperative, post op: postoperative, flex: flexion, ext.: extension, ROM: range of motion, *: Statistically significant difference in the Kruskal Wallis Test-Mann Whitney-U Test with Bonferroni correction: Group 2-Group 4 p:0.009; Group 3-Group 4 p:0.02.**: Statistically significant difference in the Friedman Test

The pain felt postoperatively was the most in Group 1 and the least in Group 3. While Group 4 had lowest post-operative KSS and WOMAC scores, Group 1 had the highest. However, the highest OKS score was obtained in Group 3. The values obtained from the questionnaires on functional knee data are summarized in Table 2.

| | Group 1 (n:32) | Group 2 (n:17) | Group 3 (n:17) | Group 4 (n:14) | p value* |
|-----------------------------------|-------------------------------|---------------------|-------------------------------|------------------------------|----------------------|
| Pre op VAS | 7.4±1.2 | 7.6±1.6 | 7.5±1.5 | 8±0.8 | 0.5 |
| Post op VAS | 0.2±0.4 | 0.4±0.5 | 0.6±0.5 | 0.4±0.6 | 0.03* |
| p value** | 0.001** | 0.001** | 0.001** | 0.001** | |
| Pre op KSS knee/ KSS function | 49.4±7/ 57.7±8.8 | 49±4/ 52.4±9.2 | 47.6±8.5/ 57.9±9.8 | 49.3±3.2/ 54.3±6.5 | 0.4/ 0.09 |
| Post op KSS knee/ KSS function | 98.5±2.6 / 99.7±1.8 | 96.8±3.1/ 98.1±4 | 96.2±3.6 / 98.2±3.9 | 94.9±4.9/ 97.1±4.7 | 0.01*/ 0.1 |
| p value** | 0.001**/ 0.001** | 0.001**/ 0.001** | 0.001**/ 0.001** | 0.001**/ 0.001** | |
| Pre op WOMAC | 48.5±2.2 | 50±4.2 | 47±0 | 50±0 | 0.5 |
| Post op WOMAC | 98.8±1.7 | 96.8±2.4 | 97.2±3 | 96.3±4.5 | 0.003* |
| p value** | 0.008** | 0.007** | 0.008** | 0.007** | |
| Pre op OKS | 13.3±3.2 | 12.4±3.6 | 12.6±3.3 | 12.4±2.7 | 0.6 |
| Post op OKS | 47.4±0.9 | 46.1±1.2 | 49.2±13.2 | 46.2±2.1 | 0.002* |
| p value** | 0.001** | 0.001** | 0.001** | 0.001** | |

Table 2: Functional knee data

Pre op: pre-operative, post op: post-operative, VAS: Visual Analog Scale, KSS:KneeSocietyscores, WOMAC: Western OntarioandMcMasterUniversitiesosteoarthritisindex, OKS:Oxford kneescores. *: Statistically significant difference in the Kruskal Wallis Test-Mann Whitney-U Test with Bonferroni correction: **Post op VAS score**Group 1-Group 3 p:0.003; **Post op KSS knee score** Group 1-Group 3 p:0.02, Group 1-Group 4 p:0.004; **Post op WOMACscore**Group 1-Group 2 p:0.001, Group 1-Group 3 p:0.009; Group 1-Group 4 p:0.02;**Post op OKSscore**Group 1-Group 2 p:0.001, Group 1-Group 3 p:0.005, Group 1-Group 4 p:0.02. **: Statistically significant difference in the Friedman Test.

A statistically significant difference was found between Group 1 and Group 3 in the test performed with the eyes closed (p:0.002). Although the measurements made with the eyes open were also in favour of Group 1, no statistically significant difference was found. There was no difference between the groups in terms of joint position sense (Table 3).

| | Group 1 (n:32) | Group 2 (n:17) | Group 3 (n:17) | Group 4 (n:14) | p value* |
|--------------------------|-------------------|-------------------|-------------------|-------------------|-------------|
| Balance- eyes open (s) | 16.4±10.1 | 14.5±11 | 9.5±8.2 | 14.9±9.2 | 0.2 |
| Balance- eyes closed (s) | 5.5±3.6 | 5.4±4.5 | 2.5±1.4 | 3.7±2.7 | 0.02* |
| Active 30° prop AES | 5.6±3 | 6.8±4 | 6.1±2.8 | 7.9±5.8 | 0.6 |
| Active 75° prop AES | 5.7±5.5 | 5.1±3.4 | 5.5±3.1 | 6.7±7.2 | 0.8 |
| Passive 30° prop AES | 6±3.3 | 6.9±5.7 | 5.1±2.3 | 6.1±3 | 0.8 |
| Passive 75° prop AES | 5.7±3.2 | 5.8±4 | 7±3.4 | 8.9±7.1 | 0.3 |

| Table 3: Functional balance and | joint position sense measurement | values |
|---------------------------------|----------------------------------|--------|
|---------------------------------|----------------------------------|--------|

Prop:proprioception, AES: Absoluteerrorscore,s:second. *: Statistically significant difference in the Kruskal Wallis Test-Mann Whitney-U Test with Bonferroni correction:Group 1-Group 3 p: 0.002.

No difference was found between the groups in isokinetic muscle strength parameters (Table 4).

| | Group 1 (n:32) | Group 2 (n:17) | Group 3 (n:17) | Group 4 (n:14) | p value* |
|--------------------|-------------------|-------------------|-------------------|-------------------|-------------|
| Ext PT @120°/s | 51.5±19.9 | 45.1±23.2 | 43.8±17.9 | 47.9±27.3 | 0.5 |
| Ext PT/BW @120°/s | 60.3±19.1 | 51.5±21.3 | 52.8±24.1 | 51.8±25.3 | 0.2 |
| Flex PT @120°/s | 27.8±13.8 | 23.8±11.1 | 21.3±12.1 | 27±15.4 | 0.3 |
| Flex PT/BW @120°/s | 33.2±16.2 | 27.8±11.9 | 26.5±16.4 | 29±14.7 | 0.3 |

Table 4: Isokinetic muscle strength values (Nm)

Flex: flexion, ext.: extension, PT: peak torque, BW: body weight, s:second. *: theKruskal Wallis test

4. Discussion and Conclusion

In this study, a significant recovery was seen in all the cases, who underwent UKA, in comparison to the pre-operative period. When the patients were grouped based on the condition of anterior cruciate ligament, however, no difference was found between the groups in their joint range of motion, and muscle strength and proprioception measurement values in their post-operative controls. On the other hand, while the patients with the highest pain score in the post-operative period were the ones whose anterior cruciate ligament was totally ruptured, the patients with the lowest sense of pain were the ones with an intact anterior cruciate ligament. In terms of their knee questionnaire results, the group with the highest KSS and WOMAC scores was that of the patients with intact anterior cruciate ligament while the group with the lowest scores was that of those who had undergone combined surgery.

While no statistically significant difference was found between the groups in the with-open-eyes-part of the One-Leg Standing Test, in which functional balance is evaluated, the group of patients with totally ruptured anterior cruciate ligament had the poorest results in the second part of the test where visual inputs were blocked (with eyes closed).

This study design is the first one in the literature to investigate the impact of anterior cruciate ligament in MCOA cases and evaluate many knee functions together. According to our results, a totally ruptured anterior cruciate ligament was found to have an impact on pain and balance in particular, with the reconstruction of the ligament contributing to preventing losses in these parameters. When it is taken into consideration that the post-operative well-being of the group of patients with totally ruptured anterior cruciate ligament has reached a perfect level in terms of their joint range of motion, functional knee questionnaire scores, muscle strength values and proprioception measurement values, the difference in balance and pain is thought to stem from the fact that the anterior cruciate ligament cannot adequately function because it is totally ruptured.

The indication of unicondylar knee arthroplasty is well-defined for patients with MCOA. That the joint range of motion, walking pattern, quadriceps functions, and knee kinematics in particular can be regained at a close-to-complete level and that less bone resection is made causes this surgery to be preferred frequently [15,16]. However, there is no consensus yet on the treatment of patients who have anterior instability along with medial compartment osteoarthritis [3,17]. It is known that the instability in the knee most commonly stems from insufficient anterior cruciate ligament functions and that this problem of stabilization can be eliminated with the reconstruction of this ligament [3]. The main reason instability is among the contraindications identified for UKA is because instability increases the risk of prosthesis failure. Combined anterior cruciate ligament reconstruction and unicompartmental arthroplasty surgery has made it possible to reduce this risk in selected patients and no revision requirement emerged during a follow-up period of 53 months [3]. In a study in which the follow-up data of patients who underwent combined surgery was published, the pre-operative total KSS score of 77 (knee score: 38.4 points, functional score: 38.7) rose to 166 points (knee score: 83.2 points, functional score: 82.7) at the end of a follow-up period of 50 months in average and no difference was found between genders in terms of scores [3]. In another study in which the 2.5-year data of patients who underwent unicondylar knee arthroplasty with an intact anterior cruciate ligament and those who underwent a combined surgery were compared, one patient in the combined surgery group needed revision to a total knee replacement because of infection. There was failure or revision induced by combined surgery [8]. Knee joint flexion and extension range of motion measurement values improved in a statistically significant way in both groups. Flexion improved from 115-117° preoperatively to 130° post-operatively. Extension contracture regressed from 2.4-2.8° to 0.9-1.3° postoperatively. These values, presented by Pandit et al., were found to be consonant with the result of our study. The OKS score of combined surgery patients which was 29 pre-operatively reached 46 post-operatively, with their KKS score improving from 55 pre-operatively to 99 post-operatively. In the anterior cruciate ligament intact groups, these values rose from 26 to 43 and 55 to 94 respectively. The post-operative OKS and objective KSS scores were found to be higher in a statistically significant way in the combined surgery patients. There was no difference between the groups in their functional KSS scores [8]. There was no significant difference between the KSS scores of the groups in our study, either.

Boissonneault et al. found that cases with pre-UKA ACL deficiency had lower KSS scores. However, the OKS, KSS, and Tegner scores of the ACL deficient cases suggested no statistically significant difference from those of the ACL intact group in their follow-up of 1 and 5 years [9]. The OKS, objective KSS and functional KSS scores of the ACL deficient group and ACL intact groups are 43-43, 85-85 and 90-100 at post-operative year 1 and 43-44, 85-85 and 100-73 at post-operative year 5 respectively [9]. These researchers emphasized that "an intact anterior cruciate ligament in not necessarily needed for the success of UKA surgery [9,18].

The WOMAC questionnaire is used in studies that examine osteoarthritis cases because it presents disease-specific evaluation results [11]. Krishnan and Randle reported that the 9 patients they operated with combined surgery had improved OKS, KSS and WOMAC scores and an increased joint range of motion at the end of two years in comparison to the pre-operative period [19]. It was stated that unicondylarknee arthroplasty can be performed with success as an alternative to arthroscopic debridement, anterior cruciate ligament construction only, high tibial osteotomy with or without ACL reconstruction and total knee replacement especially in young cases with isolated unicompartment osteoarthritis and concomitant instability of the knee [17,19].

The data obtained from cadaver studies on the effects of combined surgery are also found to be consonant with the results of case-based study results. In a study conducted by Çıtak et al., while there was a difference in lateral compartment translation of ACL-intact/UKA knee and ACL-deficient/UKA knee specimens, no difference was found between the ACL-intact and the ACL reconstruction groups. The researchers emphasized that ACL reconstruction can restore kinematics in the UKA knee to magnitudes similar to those of cases with an intact ACL [20]. The data obtained as a result of biomechanical studies suggest that the anterior cruciate ligament must be functional so that the success of surgery can be maintained in the long-term [21,22].

That the anterior cruciate ligament has sensorial characteristics shows that deficits in this ligament can cause various functional losses. For this reason, such other parameters as proprioception, balance and strength, which are needed in daily life, should also be examined if one is to make a complete evaluation of knee functions [13]. There is no statistically significant difference between the isokinetic muscle strength, joint position sense, and duration of standing in balance with eyes open of the groups in the current study. Joint position sense, which is one of the components of proprioception, is rather associated with the sensors in the muscle [13]. That the muscle strength restoration of the groups was ensured is believed to have caused us to obtain similar results in joint position sense with no statistically significant difference. Balance measurement, on the other hand, is a method which enables the evaluation of postural stability and sway [12]. That the duration of one-leg standing test with eyes closed of the cases in the ACL total rupture group is lower in a statistically significant way shows the importance of the anterior cruciate ligament in stability.

That proprioception, balance and strength measurements were not performed pre-operatively and that no device was used in measurement of dynamic proprioception (postural sway), in which mainly the ligaments play an active role, are among the limitations of our study. Despite all its limitations, this study presents comprehensive data both with the design of the groups and the difference of the functional evaluations performed.

Identifying the best treatment option for MCOA cases with knee instability is still a controversial issue. However, the most appropriate treatment option can be identified based on the patient's level of activity and whether the ACL deficiency is primary or secondary [8,17]. Cases with osteoarthritis developing after a primary anterior cruciate ligament are young individuals who have high activity expectation. Combined surgery can be preferred for this group of cases. On the other hand, if an agerelated degenerative anterior cruciate ligament rupture develops in an osteoarthritis patient and if the patient does not have anterior instability, UKA alone also gives successful results in this group alone.

Declaration of Ethical Code

In this study, we undertake that all the rules required to be followed within the scope of the "Higher Education Institutions Scientific Research and Publication Ethics Directive" are complied with, and that none of the actions stated under the heading "Actions Against Scientific Research and Publication Ethics" are not carried out.

*This study was approved by the ethics committee of Süleyman Demirel University, decision numbered 157 dated 2016.

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