

# Is fixation with a U-shaped staple necessary in anterior cruciate ligament reconstruction?

Öğuzhan Pekince, Fatih Doğar

Department of Orthopaedics and Traumatology, Konya City Hospital, Konya, Türkiye

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## ABSTRACT

**Aims:** This study aimed to compare the clinical and functional outcomes of patients who underwent anterior cruciate ligament reconstruction using a quadruple hamstring autograft with and without U-shaped staple fixation and tibial tunnel BioScrew fixation.

**Methods:** Patients who underwent arthroscopic anterior cruciate ligament (ACL) reconstruction by a single surgeon between August 2020 and June 2022 were retrospectively analyzed. The time to return to sports after surgery and the evaluation of preoperative and postoperative Lysholm Knee scores, International Knee Documentation Committee (IKDC) scores, VAS scores, and thigh diameters, were conducted. Statistical analysis of the study data was performed using SPSS 29.0 (IBM InCorp, USA).

**Results:** A total of 100 patients (77% male) who underwent arthroscopic ACL reconstruction were included in the analysis. There was no significant difference in Lysholm knee scores and IKDC scores between patients undergoing fixation with or without staples. However, VAS scores were significantly lower in the non staple group.

**Conclusion:** The present study found that fixation with a staple in addition to tibial BioScrew fixation of the autograft in the tibial tunnel resulted in more pain in the patients, and there was no significant difference in clinical and functional outcomes between the staple and non staple groups.

**Keywords:** Anterior cruciate ligament, U-shaped staple, pain, VAS

## INTRODUCTION

The anterior cruciate ligament (ACL) is one of the crucial ligaments stabilizing the knee joint. The ACL, which is an extra-synovial ligament, is located in the intercondylar space, alongside the intra-synovial posterior cruciate ligament. ACL injury is the most common ligament injury in the knee, with a prevalence of approximately 1 in 3,000 in the general population. Approximately 70% of ACL injuries occur during sports activities. While conservative therapies and surgery have a place in treating ACL rupture, surgery is the primary option for young patients with a complete ACL tear who actively participate in sports activities. Aligning with the advancements in technology, arthroscopic surgery has become the most commonly preferred method for ACL reconstructions.<sup>1-3</sup>

Graft selection and graft fixation methods are among the most important factors affecting clinical and functional outcomes in anterior cruciate ligament reconstruction.

When a complete soft tissue autograft such as a hamstring tendon is used, the graft fixation method gains great importance in ACL surgeries.<sup>4,5</sup>

In addition, the length and position of the femoral and tibial tunnels also play a crucial role in determining the outcomes of ACL reconstruction.<sup>6</sup> It has been demonstrated that achieving an anatomically appropriate positioning of the graft and the femoral and tibial tunnels is crucial for successful ACL reconstruction.<sup>7</sup> However, various modern fixation systems necessitate a minimum tunnel length to anchor the graft and facilitate its successful integration securely.<sup>8</sup> Studies have demonstrated that tibial fixation in ACL reconstruction involves the utilization of various methods, such as interference screws, BioScrews, fixation with washers and screws, staples, endobuttons with suspension systems, or a combination of these techniques.<sup>9</sup>

**Corresponding Author:** Öğuzhan PEKİNCE, oguzhanpekince@hotmail.com



This study aimed to compare the clinical and functional outcomes of patients who underwent arthroscopic single-strand anterior cruciate ligament reconstruction using a quadruple hamstring autograft and the Ziploop method with Doratek lifting system, with and without staple fixation, in addition to tibial tunnel BioScrew fixation.

## METHODS

This study was approved by the Necmettin Erbakan University Non-drug and Non-medical Device Researches Ethics Committee (Date: 07.07.2023, Decision No: 2023/4427). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

We conducted a retrospective review of the medical charts of patients who underwent arthroscopic ACL reconstruction using a double-layer (four-strand) hamstring tendon graft for ACL rupture between August 2020 and June 2022.

Out of 102 patients with adequate follow-up time and complete medical records, the study included 100 patients. The study excluded patients with previous ACL surgery, a history of infection in the knee joint, inflammatory or rheumatologic conditions, severe degenerative osteoarthritis, multiple ligament injuries and graft without hamstring tendons. Two patients were excluded from the study: one with concurrent posterior cruciate ligament (PCL) rupture and another with a history of peroneus longus tendon autograft harvesting.

### Surgical Technique and Patient Classification

Semitendinosus and gracilis tendon autografts were harvested for ACL reconstruction, and both ends were sutured using reinforced sutures. The autografts were held taut in traction with the help of the tensioners in the system, ensuring appropriate tension. The femoral tunnels were placed in an anatomically appropriate location, while the tibial tunnels were opened using a 55-degree angled tibial guide. A 25-mm long femoral tunnel of standard size was created using femoral reamers matching the diameter of the tendon graft. All patients underwent the same method for graft fixation in the femoral tunnel, using the Ziploop technique with a lifting system. However, patients were divided into two groups based on the differences in the fixation method used in the tibial tunnel. Fifty patients who underwent fixation with a staple in addition to BioScrew fixation in the tibial tunnel were classified as Group 1, while another 50 patients who underwent only BioScrew fixation in the tibial tunnel without using staple were classified as Group 2. Any additional pathologies seen in the knee joint during knee arthroscopy were noted. Postoperative complications (wound infection, hematoma, re-rupture, etc.) were recorded.

### Clinical and Radiological Evaluation

Demographic characteristics (age, gender, follow-up time, laterality and comorbidity), trauma etiology, operation time, and length of hospital stay were evaluated. Postoperative time to return to sports, daily sports activity, and change in thigh circumference were recorded. The visual analog scale (VAS), International Knee Documentation Committee (IKDC) knee evaluation score and Lysholm scores were used to evaluate the clinical and functional outcomes of the patients preoperatively and during the last follow-up visit. Patients with persistent postoperative knee joint complaints and those with a history of trauma underwent follow-up magnetic resonance imaging (MRI) to assess ACL re-rupture, graft loosening, or other potential reasons, and the results were recorded.

### Statistical Analysis

Descriptive statistics are presented as frequency (percentage) and mean  $\pm$  SD or median with minimum and maximum values. The normality of numerical variables was analyzed using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Nonparametric tests were employed for comparisons since it was observed that the scores did not adhere to a normal distribution. The Mann-Whitney U test was used to analyze two independent groups, and the Wilcoxon signed-rank test was used for paired comparisons. The relationships between categorical variables were analyzed using the Chi-square test with Monte Carlo correction. A p-value of less than 0.05 was considered statistically significant in the analyses.

## RESULTS

This study was completed by retrospectively investigating 100 out of 102 patients who underwent ACL surgery. Of the study patients, 77% were male, and the mean age was  $32.05 \pm 9.48$  (median 33; 16-51) years. The primary surgical procedure was performed by a single surgeon, and all patients underwent arthroscopic ACL reconstruction using hamstring autografts. Sixty percent of the surgeries were performed on the right knee, with meniscal repair in 18 patients (18%) and microfracture in 9 patients (9%). The most common cause of trauma was football (51%), followed by falls (42%), basketball (accounting for 5%), and kickboxing and wrestling (accounting for one patient). Of the patients, 41% had an ASA score of 1 (normal), and 53% had an ASA score of 2 (mild systemic disorder). Most patients (76%) were hospitalized for three days postoperatively. As additional procedures, two patients in Group 1 underwent closed mobilization, and one patient underwent arthroscopic graft exchange, while only two patients in Group 2 underwent superficial wound debridement procedures ([Table 1](#)).

**Table 1. Demographic and clinical characteristics of patients according to Staple Fixation**

	Group 1 n (%)	Group 2 n (%)	Total n (%)	P
Sex				
Male	38 (76)	39 (78)	77	0.813
Female	12 (24)	11 (22)	23	
Trauma				
Fall	17 (34)	25 (50)	42	0.119
Basketball	2 (4)	3 (6)	5	
Football	30 (60)	21 (42)	51	
Kick-Box	1 (2)	0 (0)	1	
Wrestling	0 (0)	1 (2)	1	
ASA				
1	27 (54)	14 (28)	41	0.028*
2	20 (40)	33 (66)	53	
3	3 (6)	3 (6)	6	
Hospitalization				
2	11 (22)	9 (18)	20	0.667
3	37 (74)	39 (78)	76	
4	2 (4)	2 (4)	4	
Surgery				
Primary	49 (98)	50 (100)	99	0.317
Revision	1 (2)	0 (0)	1	
Side				
Right	31 (62)	29 (58)	60	0.685
Left	19 (38)	21 (42)	40	
Additional processing				
No	40 (80)	32 (64)	72	0.113
Meniscal Repair	7 (14)	11 (22)	18	
Microfracture	2 (4)	7 (14)	9	
Additional Surgery				
No	45 (90)	48 (96)	93	0.668
Mobilisation	2 (4)	0 (0)	2	
Arthroscopy-intact	2 (4)	0 (0)	2	
Tunnel Grafting	1 (2)	0 (0)	1	
Debridement	0 (0)	2 (4)	2	

\*: Significant at 0.05 level according to Monte Carlo Exact Chi-Square test

Gender (p=0.813), type of trauma (p=0.119), length of hospital stay (p = 0.667), and distribution of comorbidities (p=0.369) were not significantly different between the groups. In contrast, the rate of patients with an ASA score of 1 (normal) was higher, and the rate of those with

an ASA score of 2 (mild systemic disorder) was lower in Group 1 (p=0.028). Other clinical features did not differ significantly between the groups. The ages of the patients did not differ significantly between the groups (p=0.959). Preoperative sports duration was not different between the groups, but postoperative sports duration was significantly shorter in Group 1 (p=0.011). Both preoperative and postoperative VAS scores significantly differed between the groups (p=0.001). Both scores were higher in the staple group. The median preoperative VAS score was 8 (range 5-9) in the staple group and 7 (range 5-9) in the non staple group. The median postoperative VAS score was 3 (range 1-5) in the staple group and 2 (range 1-4) in the non staple group. The Lysholm and IKDC scores did not differ significantly between the groups. Preoperative and postoperative thigh circumference values were not significantly different between the two groups (p >0.05) (Table 2).

When the preoperative and postoperative values were compared between the groups, the duration of sports after surgery showed a significant decrease in Group 1 compared to postoperative values (p= 0.001). In Group 2, the duration of sports decreased to a lesser extent after surgery (p=0.046). Preoperative and postoperative VAS scores differed significantly (p <0.001). Postoperative thigh circumference values slightly compared to preoperative values in both groups (p <0.001) (Table 3).

**Table 3. Pre-op and post-op comparisons of clinical measurements**

	Pre-op	Post-op	P
	Median±SS (Median; Min-Max)	Median±SS (Median; Min-Max)	
<b>Group 1</b>			
Spor	0.87±0.89 (1; 0-4)	0.64±0.71(0.75; 0-3)	0.001*
VAS	7.48±0.91 (8; 5-9)	3.34±0.8 (3; 1-5)	<0.001*
Thigh	51.68±4.3 (52; 38-65)	50.6±4.4 (50.5; 36-64)	<0.001*
<b>Group 2</b>			
Spor	1.14±0.9 (1; 0-4)	1.06±0.89 (1; 0-4)	0.046*
VAS	7.18±1.11 (7; 5-9)	1.76±0.85 (2; 1-4)	<0.001*
Thigh	51.98±4.48 (52; 35-61)	50.86±4.65 (51; 34-60)	<0.001*

\*: significant at 0.05 level according to Wilcoxon Signed Rank test

**Table 2. Clinical measurements of patients according to Staple fixation**

	Group 1 Median±SS (Median; Min-Max)	Group 2 Median ±SS (Median; Min-Max)	Total Median ±SS (Median; Min-Max)	P
Spor preop	0.87±0.89 (1; 0-4)	1.14±0.9 (1; 0-4)	1.01±0.9 (1; 0-4)	0.111
Spor postop	0.64±0.71(0.75; 0-3)	1.06±0.89 (1; 0-4)	0.85±0.83 (1; 0-4)	0.011*
Return to spor	4.42±4.31 (6; 0-12)	5.14±3.43 (6; 0-10)	4.78±3.89 (6; 0-12)	0.713
VAS preop	7.48±0.91 (8; 5-9)	7.18±1.11 (7; 5-9)	7.33±1.1 (8; 5-9)	0.140
VAS postop	3.34±0.8 (3; 1-5)	1.76±0.85 (2; 1-4)	2.55±1.14 (3; 1-5)	<0.001*
Lysholm	81.84±10.3 (84; 35-100)	84.94±8.25 (86; 65-100)	83.39±9.42 (85; 35-100)	0.194
IKDC	75.5±9.45 (77.5; 33-90)	78.68±7.68 (80; 60-90)	77.09±8.71 (79; 33-90)	0.054
Thigh preop	51.68±4.3 (52; 38-65)	51.98±4.48 (52; 35-61)	51.83±4.37 (52; 35-65)	0.588
Thigh postop	50.6±4.4 (50.5; 36-64)	50.86±4.65 (51; 34-60)	50.73±4.51(51; 34-64)	0.679
Age	32.02±9.53 (32; 16-51)	32.08±9.53(33; 17-51)	32.05±9.48 (33; 16-51)	0.959

\*: significant at 0.05 level according to Mann-Whitney U test

## DISCUSSION

The goals of ACL reconstruction are to prevent osteoarthritis and restore knee kinematics. The favorable result of ACL reconstruction is significantly impacted by two critical factors: rigid and stable graft fixation and anatomic positioned tunnels.<sup>10,11</sup>

Recently, significant progress has been made in ACL surgery, thanks to advancements in arthroscopic techniques and instruments. Although the studies in the literature have provided better insights into the biology, biomechanics, and pathophysiology of ACL tears, there still needs to be a standard consensus on its treatment.<sup>10,11</sup> The present study revealed that in arthroscopic ACL reconstruction using the Ziploop method with a lifting system, there were no significant differences in clinical and functional outcomes between patients undergoing fixation with a staple and those undergoing fixation without a staple, in addition to tibial BioScrew fixation of the autograft in the tibial tunnel. However, the use of staple fixation resulted in more pain for the patients.

Rigid and stable graft fixation and anatomically precise placement of the femoral and tibial tunnels are among the most critical factors influencing the successful outcome of ACL reconstruction.<sup>1,2</sup> With the increasing use of soft tissue grafts in ACL reconstruction, such as hamstring autografts, cortical suspension devices have gained popularity as a means of fixation for the femoral and tibial tunnels. Furthermore, biomechanical studies have shown that cortical suspension devices exhibit superior tensile strength and less elongation during cyclic loading when compared to interference and transfixation devices.<sup>12-14</sup>

In femoral fixation systems with suspensions, the femoral tunnel is drilled more than 6-10 mm, depending on the characteristics of the system and the surgeon's experience, to enable the implant's placement in the femoral cortex using a "flip" movement. It has been frequently reported that femoral tunnel enlargement may occur as the graft moves within the femoral tunnel. Recent femoral fixation implant designs are aimed at minimizing movement over the femoral cortical surface. In addition, improved loop materials aim to reduce the micro-movement of the graft within the tunnel. The Toggle Loc with Zip Loop (TL-ZL) system (Biomet, Warsaw, IN) is similar to the standard application of the Endobutton CL (E-CL) (Smith & Nephew, Andover, MA), while the TL-ZL is attached to the ceiling of the femoral tunnel with a mechanism similar to a graft suspensor due to improved loop formation. Thus, the objective is to fill the hole underneath the femoral tunnel ceiling.<sup>15</sup> For this reason, the Zip Loop system was used for femoral tunnel fixation as the standard of care in all patients in the present study.

Although there is currently no consensus on the appropriate length of the femoral tunnel, several studies

have suggested minimum lengths ranging from 15 mm to 30 mm.<sup>16,17</sup> Recently, adjustable-loop cortical suspension implants have been increasingly used to extend the graft length within the tunnel. These implants have effectively filled the tunnel, making the procedure technically easier to perform and eliminating the need for tedious calculations during the surgery. They also increased the graft-bone interface, providing a larger surface area for graft integration and healing. Although adjustable ring devices have theoretical advantages in promoting graft healing, recent studies have raised concerns about poor mechanical properties and the potential for elongation of adjustable rings under cyclic loading.<sup>18,19</sup> In this study, standard 25 mm long femoral tunnels were created in anatomically appropriate locations.

Stable graft fixation is required during biological union to prevent graft elongation and failure.<sup>20</sup> This is particularly required for early range of motion, weight-bearing, and the likelihood of returning to sports after ACL reconstruction.<sup>21</sup> Although studies have demonstrated higher ultimate failure loads for hamstring graft compared to bone-patellar tendon-bone (BPTB) graft, the fixation of hamstring graft to the tibial bone has often been identified as a potential cause of failure due to the weaker tibial metaphyseal bone compared to the femur.<sup>22,23</sup>

Due to the absence of gold standard material and technique for tibial fixation in ACL reconstruction using hamstring graft and the ongoing uncertainty regarding this matter, a variety of devices (such as interference screws, BioScrews, washer and screw fixation, staples, endobuttons with suspension systems, or a combination of these) are widely employed for this procedure. Consequently, this particular matter continues to be the focus of further research.<sup>24</sup> In their study, Wang et al.<sup>25</sup> investigated the safety of utilizing the Rigidfix cross-pin system through various tibial tunnels for tibial fixation in ACL reconstruction. When employing the Rigidfix cross-pin system for ACL reconstruction at the tibial fixation site, the study concluded that it is crucial to avoid placing the external opening of the tibial tunnel in the extreme posterosuperior region to prevent injuries to the medial collateral ligament (MCL) and tibial plateau cartilage (TPC).

In another study, tibial fixation with an interference screw demonstrated superior biomechanical properties in cyclic loading tests compared to the suspension button and tape locking screw. The ultimate failure loads did not differ between the groups, and no significant difference was found in biomechanics between the suspension button and tape-locking locking screw fixation devices.<sup>26</sup> In addition to these factors, determining the preferred tibial fixation structure remains challenging due to limitations in clinical trials, such as variability in the reporting of outcomes and the use of various surgical

techniques. Clinical studies comparing various tibial fixation methods have shown no difference in clinical outcomes.<sup>27</sup>

In a study by Chadwick et al.<sup>28</sup> the Lysholm score was reported to be 94.5 after ACL reconstruction using a hamstring tendon graft and the Endobutton-CL technique. In a study conducted by Cansever et al.<sup>29</sup> the mean Lysholm score was 92.5 in the Endobutton-CL group and 94 in the Ziploop with Elevator System group. In a study conducted by Peter et al.<sup>30</sup> using the Endobutton-CL, it was reported that, in the first postoperative year, 6 out of 46 patients received A scores, 30 received B scores, and 9 received C scores in the IKDC evaluation. The study results demonstrated that the outcomes were favorable compared to the preoperative clinical status. Gobbi<sup>31</sup> utilized IKDC scoring in his study and reported that he found A-B scores in 72 patients, C scores in 7 patients, and D scores in 1 out of 80 patients after 36 months. In the study conducted by Cansever et al.<sup>29</sup> it was observed that a total of 24 (96%) patients scored A or B in both the Endobutton-CL group and the Ziploop with Lifting System group, and no patients scored D. The results were comparable in both groups. Furthermore, in the study conducted by Çınar et al.<sup>32</sup> no significant difference was found between the RigidFix and Endobutton groups postoperatively. Similarly, in the study by Mayr et al.<sup>33</sup> comparing BioScrew and suspension implants with tibia and femoral tunnel fixation in ACL reconstruction, no significant difference was detected in terms of knee function outcomes (Lysholm and IKDC scores).<sup>33</sup> In our study, the Lysholm and IKDC scores were not significantly different between the groups, which are consistent with the findings in the literature.

In the clinical study by Lai et al.<sup>34</sup> 4 out of 34 patients in the adjustable suspensory devices and interference screw (ASIS) group experienced anterior knee pain, while 11 of 32 patients in the cortical screw post along with the interference screw (CSIS) group experienced anterior knee pain at least one year after the operation. Although the risk of experiencing anterior knee pain (VAS=3) was lower in the adjustable suspensory devices and interference screw (ASIS) group, no significant difference was observed between the groups. In addition, other studies have also reported anterior knee pain due to the use of cortical screw posts in hybrid tibial fixation.<sup>35,36</sup> In the present study, the VAS score was lower in Group 1 than in Group 2, and there was a significant difference in the postoperative VAS scores of patients in Group 1 compared to preoperative values.

As limitations of this study, more meaningful results could have been obtained by including 3D computed tomography and magnetic resonance imaging as radiological evaluations to assess tibial tunnel widening in addition to the clinical and functional outcomes.

## CONCLUSION

In line with the existing literature, the findings of this study indicate that ACL reconstruction utilizing hamstring tendon autograft and the Ziploop technique with a lifting system is an effective and reliable method, offering the advantage of avoiding the complexity of tunnel size calculation and yielding favorable functional outcomes. In addition, autograft fixation in the tibial tunnel using a staple, in addition to tibial BioScrew fixation, caused more pain in patients, and there was no significant difference in clinical and functional outcomes between the groups undergoing reconstruction with and without staple fixation.

## ETHICAL DECLARATIONS

### Ethics Committee Approval

This study was approved by the Necmettin Erbakan University Non-drug and Non-medical Device Researches Ethics Committee (Date: 07.07.2023, Decision No: 2023/4427).

### Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

### Referee Evaluation Process

Externally peer reviewed.

### Conflict of Interest Statement

The authors have no conflicts of interest to declare.

### Financial Disclosure

The authors declared that this study has received no financial support.

### Author Contributions

All the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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