Comparison of Perioperative Malposition Rates of Fixed and Adjustable Suspensory Button Implants Used for Femoral Fixation During Anterior Cruciate Ligament Reconstruction

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Abstract

Aim: This study compared the malposition rates of fixed and adjustable suspensory button implants used for femoral fixation of the graft during anterior cruciate ligament (ACL) reconstruction and examined the effectiveness of intraoperative imaging in managing these complications.

Methods: This retrospective study evaluated 187 patients who underwent arthroscopic ACL reconstruction. The patients included in the study were categorized into two groups according to the type of femoral suspensory button (FSB) implant used: fixed suspensory button (FxSB) and adjustable suspensory button (ASB). Button malpositions were determined and recorded with intraoperative images in cases where fluoroscopy was used and postoperative X-ray radiographs in cases where fluoroscopy was not used. Malposition rates were compared between the two groups, and risk analysis was performed.

Results: Malposition was observed in 24 patients (12.8%). It occurred in 5 patients (5.6%) in the FxSB group and 19 patients (19.3%) in the ASB group (p=.012). ASB implants were associated with a 3.5-fold higher risk of malposition compared to FxSB implants (OR: 3.57, 95% CI: 1.36–10.1, p=.002).

Conclusions: ASB implants were linked to a significantly higher rate of button malposition than FxSB implants. Intraoperative fluoroscopy proved effective in detecting and correcting malpositions across both implant types.

Keywords: *ACL reconstruction; suspensory button implant; fluoroscopy; malposition*

1. Introduction

The technique of suspensory fixation of anterior cruciate ligament (ACL) grafts has become popular with the advent of femoral suspensory button (FSB) implants. Various problems with the previously widely used screw fixation method have led surgeons to use suspensory fixation techniques increasingly.[1-3] Two types of FSB implants are commonly used today. Fixed suspensory button (FxSB) implants are the first devices to be used. Careful calculation of the tunnel length and the appropriate implant length during surgery is very important for the survival of the reconstruction.[4,5] Adjustable suspensory button (ASB) implants are relatively newer implants and can be used without complex tunnel and implant calculations.[6,7] Many biomechanical studies have shown that FSB implants provide excellent fixation and tension in the graft tendon, as well as ease of use.[8-10] Despite these advantages, perioperative malposition is well-known to orthopedic surgeons. However, there is insufficient information on the malpositioning rates of these devices, and FxSB has only been partially addressed in a few studies.[11,12]

The most commonly reported malposition is due to excessive pulling of the button during removal from the femoral tunnel. This technical error can cause the buttons to dislodge through the iliotibial band, vastus lateralis, and even the skin, resulting in soft tissue interposition between the button and the lateral femoral cortex. If the surgeon does not recognize this condition, the button will rotate outside of the vastus lateralis or iliotibial band and not make cortical contact.[7,13] Without early intervention, ischemic

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necrosis of the intervening tissue may develop, failing to maintain proper graft tension, which is key to the success of ACL reconstruction. O'Brien et al. reported a 15.7% rate of soft tissue interposition in their study of ACL reconstruction using an FSB implant (Arthrex Tightrope RT or Mitek Rigid Loop).[14] Mae et al. (Smith & Nephew EndoButton) found this rate to be 25.2%.[15] Another important fixation failure is intra-tunnel malposition caused by the under-drawing of button implants.[16] In a study by O'Brien et al., intra-tunnel malposition was reported in 9.8% of FSB implants.[14] Suppose such complications are detected by the surgeon intraoperatively. In that case, the necessary intervention can be performed and an optimal button fit can be achieved. However, in cases that are not detected intraoperatively, it can have devastating consequences, leading to a second surgical intervention in the early period or even revision ACL reconstruction in neglected cases. In a recent study on FSB implants, Gürpınar et al. showed that soft tissue interposition of 2 mm or more between the implant and the femoral cortex negatively affects the results after ACL reconstruction.[4]

The purpose of this study was to determine the perioperative malposition rates of FxSB and ASB implants, which are now widely used for femoral fixation of the graft in ACL reconstruction, and to determine the effectiveness of intraoperative imaging in managing these complications.

2. Materials and Methods

This study was conducted after approval by our institutional human research ethics committee. The study was conducted in accordance with the principles of the Declaration of Helsinki and written informed consent was obtained from all subjects. The records of 187 patients (133 males, 54 females; mean age: 29.5 years [SD: 1]) who underwent consecutive arthroscopic ACL reconstruction for ACL tears at two different treatment centers by a single orthopedic surgeon between June 2012 and February 2022 were retrospectively reviewed. The following criteria were sought for patients included in the study: Physical examination and radiographic determination of ACL tear, arthroscopic anatomic single tunnel ACL reconstruction, use of autogenous hamstring tendon grafts, and FSB implants for femoral fixation. Patients with revision ACL reconstruction and multiple ligament injuries were not included in this study. According to the type of FSB implant used, the patients included in the study were divided into two different groups: the FxSB implant group (Tulpar LoopFix Button, DePuy Synthes Rigidloop Endobutton Cortical System) and the ASB implant group (Tulpar LiftFix Button, DePuy Synthes Rigidloop Adjustable Cortical System).

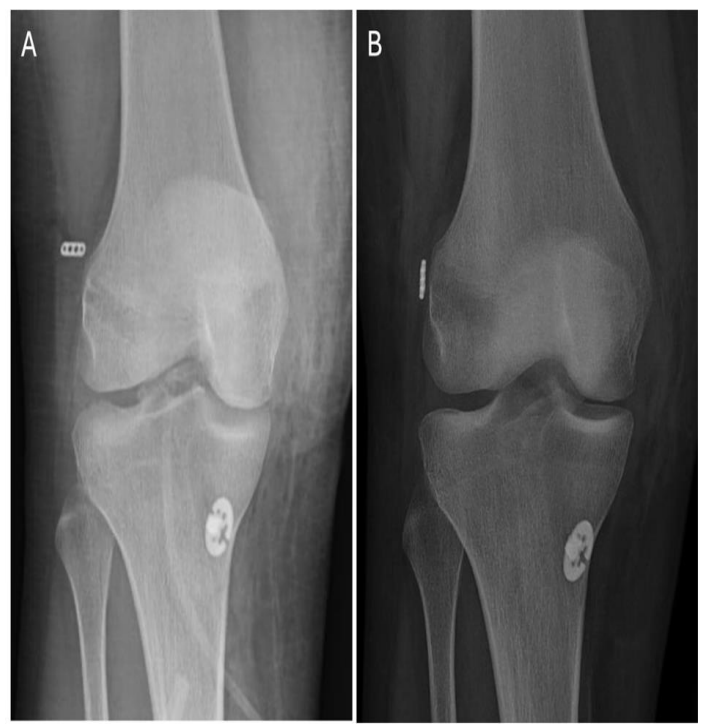
2.1. Surgical technique-Perioperative imaging methods

An autogenous hamstring graft obtained by folding the gracilis and semitendinosus tendons in two was used in all our patients. Our arthroscopic technique used the anatomic single tunnel ACL reconstruction technique described by Kim et al. in 2011.[17] Depending on the type of FSB implant used, tunnel, tendon, and implant preparation were performed according to the manufacturer's instructions. After the graft and associated suspension button were seen in the intercondylar notch, they were pulled toward the lateral femoral cortex, and the surgeon applied force to the graft from the tibial side at the point where it was felt to change as it exited the cortex. With this force, it was understood that the tendon and button implant would not return, and thus, the implant was properly positioned in the femoral cortex. In cases where C-arm fluoroscopy was used, intraoperative images were obtained at this stage, and this recorded data was analyzed. In cases where C-arm fluoroscopy was not used, radiographs obtained at the first postoperative visit were evaluated and analyzed.

Soft tissue and intra-tunnel malpositions were identified and recorded in both groups. Although the definition of soft tissue malposition is not well known, recent studies have defined it as a distance of more than 2 mm between the button and the cortex of the femur and identified it as a critical value in terms of its clinical importance.[4,18] In our study, we defined this as the critical value. In the cases where we used fluoroscopy during surgery, the malpositions were corrected by a 2 cm lateral femoral skin incision, and the optimal fit of the button to the cortex was ensured. For malpositions detected on postoperative imaging without fluoroscopy, no observation was performed in any patient, and a second early surgical procedure was performed to ensure appropriate reconstruction (Figure 1). In our study, these recorded data were analyzed and compared between groups, and risk analyses were performed using subgroup studies.

Figure 1

A: Malposition of the femoral button implant B: Image of the patient with the button implant fixed in the optimal position with a secondary surgery.



2.2. Statistical Analysis

R 4.2.3 and SPSS 22.0 versions were used for statistical analysis. The chi-square test, a non-parametric test, was applied to determine the significance level of the relationship between categorical variables. In accordance with the conditions of the cross-table created for the Chi-Square analyses, the analysis of the difference between the groups was performed using Yates' Correction and Fisher's Exact methods. The results of the tests performed on the variables in the study were evaluated at a 95% confidence interval, and $p<0.05$ was considered significant. Risk analysis was performed using binary logistic regression analysis between the groups in terms of secondary surgery. For statistical significance, $p<0.05$ was accepted, and the data are presented as odds ratio (OR) and 95% confidence interval (CI).

Table 1

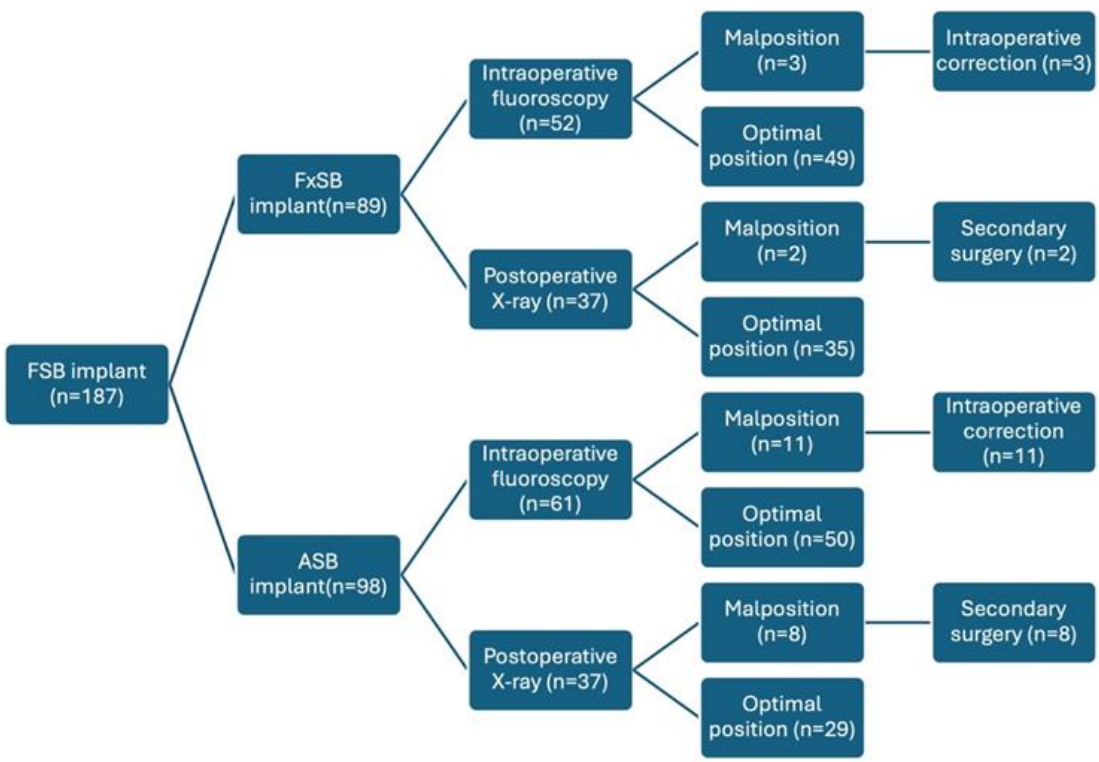
Demographic and imaging characteristics of patients

	FxSB implant (n=89)	ASB Implant (n=98)	P
Sex			
• Male	63(70.8%)	70 (71.4%)	.923
• Female	26 (29.2%)	28 (28.6%)	
Side			
• Right	47	58	.626
• Left	42	40	
Average age	29.2(SD:1)	29.7(SD:1)	.681
Perioperative imaging method			
• Intraoperative fluoroscopy	52(58.4%)	61(62.2%)	.594
• Postoperative X ray	37(41.6%)	37(37.8%)	

Note: FxSB: fixed suspensory button. ASB: adjustable suspensory button.

Figure 2

Malposition results encountered in patients undergoing ACL reconstruction according to the button implant used and perioperative imaging methods.



Note: FxSB: fixed suspensory button. ASB: adjustable suspensory button.

3. Results

In our study, 89 patients (63 males, 26 females; mean age: 29.2 years) received FxSB implants, and 98 patients (70 males, 28 females; mean age: 29.7 years) received ASB implants. The number of patients who underwent intraoperative fluoroscopy was 52 (58.4%) and 61 (62.2%) in the FxSB and ASB implant groups, respectively. Intraoperative fluoroscopy was not used in 37 patients (41.6%) in the FxSB group and 37 patients (37.8%) in the ASB group. X-ray images obtained at the first postoperative visit were utilized. Demographic characteristics and perioperative imaging techniques of the patients according to the groups are presented in Table 1.

When the perioperative images of all patients included in the

study were analyzed, malposition was detected in 24 patients (12.8%) (Figure 2). When the FxSB and ASB implant groups were considered separately, the number and rates of malposition were 5 (5.6%) and 19 (19.3%), respectively. Statistically, the malposition rate was higher in the ASB implant group (p=.0123). In the regression analysis, it was determined that the risk of malposition was 3.5 times higher in the ASB implant group than in the FxSB implant group (OR: 3.57 (p=.0017) 95% CI (1.36-10.1)). When the images were analyzed in detail, it was determined that all five patients in the FxSB implant group developed soft tissue malposition, while 18 patients in the ASB group developed soft tissue malposition, and one patient developed intra-tunnel malposition.

Another important point that we examined in our study was the effect of intraoperative fluoroscopy on the identification of malpositions and subsequent optimal button positioning. Intraoperative fluoroscopy was used in three of 52 patients (5.8%) in the FxSB group and eleven of 61 patients (18%) in the ASB group and was found to be significantly higher in the ASB implant group (p=.003). Regression analysis showed that the risk of malposition was higher in the ASB implant group than in the FxSB implant group (OR: 3.66) (p=.042) 95% CI (1.01-13.4). In all of these patients, optimal positioning of the cortical buttons was achieved with intraoperative interventions without the need for a second surgical intervention. On the other hand, malposition was detected on X-ray images taken during the first visit in two (5.4%) of 37 patients in the FxSB group and in eight (21.6%) of 37 patients in the ASB group (p=.089) and optimal button positioning was achieved in all of these patients with a secondary surgical intervention in the early period. When the results of the risk analysis were analyzed, it was determined that the riskiest group in terms of secondary surgical intervention was the patients with ASB implant and no intraoperative fluoroscopy (OR: 5.4) (p=.041) 95% CI (1.0-24.5).

4. Discussion

In this study, we found that ASB implants resulted in a significantly higher rate of malposition in ACL reconstruction compared to FxSB implants. We also observed that the use of intraoperative fluoroscopy in both implant groups reduced the likelihood of revision surgery. In particular, patients in the ASB group without intraoperative fluoroscopy had the highest rate of secondary surgery. To our knowledge, this is one of the few studies comparing fixed and adjustable suspensory button implants in terms of perioperative fixation failure. Additionally, we believe our evaluation of intraoperative fluoroscopy contributes valuable data to the current literature.

Correct button placement is important with FSB implants because proper graft fixation and implant positioning are critical to maintaining graft tension.[19-21] There is no clear information in the literature regarding misplacement rates of FSB implants. Incorrectly positioned button implants have been shown to cause postoperative pain, button migration, and even revision ACL reconstruction.[8,18,22-24] The study by Simonian et al. is one of the first studies to address button malpositioning and soft tissue interposition with FSB implants.[5] In their cadaveric study, they found that the vastus lateralis and iliotibial band can be positioned between the endobuttons (Acufex Microsurgical Inc, Mansfield, MA) and the femoral cortex, which can lead to ACL reconstruction failure. With the widespread use of FSB implants, case series related to malposition have begun to be reported. The first of these is by Mae et al.[15] They reported that they used the FxSB implant (EndoButtons (Smith & Nephew Endoscopy) in their anatomic double tunnel ACL reconstruction study and found a 25.2% rate of soft tissue malposition. Büyükkuşçu et al. used the FxSB implant (Rigidloop™ cortical fixation system, DePuy Synthes) in their series of anatomic single tunnel ACL reconstruction and reported a malposition rate of 37.6%.[25] In our study, the malposition rate was 5.6% in our group of cases in which we used the FxSB implant. There may be several reasons for this low rate. First, Mae et al. accepted the minimum distance between the femoral cortex and the button implant as 1 mm for malposition and performed a double tunnel ACL reconstruction instead of a single tunnel. Similarly, Büyükkuşçu et al. accepted this distance as 1 mm. Another reason may be the failure to follow the manufacturer's technical recommendations for femoral tunnel preparation, which is especially important when using FxSB implants. Mae et al. stated in their report that they used a different technique for tunnel preparation. Büyükkuşçu et al. did not provide any information about the manufacturer's technique in their report. In our study, femoral tunnel preparation was performed according to the manufacturer's technical recommendations. One of the most recent studies on FxSB implants was performed by Gürpınar et al. (EndoButtons (Smith & Nephew Endoscopy, Andover, MA), and in their study consisting of 156 patients, they characterized soft tissue interposition over 2 mm as malposition and stated that it is clinically associated with poor functional outcome. This rate was reported to be 5.2% in their series and was found to be compatible with the results of our study.[4]

ASB implants are relatively new devices, and there are not enough studies on malposition rates. In a study by Balldin et al. using ASB implants (Arthrex Tightrope RT) and not using fluoroscopy, they found a 10% rate of soft tissue interposition (>2 mm) on postoperative X-ray images but did not mention intra-tunnel malposition.[18] O'Brien et al., using intraoperative fluoroscopy, reported a 25.5% malposition rate, of which 15.7% was soft tissue interposition, and 9.8% was intra-tunnel malposition.[14] In our study, 19.3% malposition was detected in the group in which we used ASB implants, 18.4% of which were soft tissue interposition, and 1% of FxSB had intra-tunnel malposition. None of the previous studies have compared the malposition rates of FxSB and ASB implants. The most important data we obtained in our study is that this rate is related to the type of implant. It is clearly seen that FxSB implants result in much less malposition than ASB implants. We attribute this to the importance of tunnel-implant length matching during femoral tunnel preparation when using FxSB implants. The surgeon has to follow the technical details recommended by the manufacturer to optimize this match, thus reducing the margin of error.[21,26-28] On the contrary, when preparing the femoral tunnel in ASB implants, both the tunnel length and the implant length are completely up to the surgeon's option.[7,29-31] Therefore, we believe that the higher malposition rate observed with ASB implants in our study may be attributed to the greater surgical variability in tunnel and implant length selection. The absence of a standardized matching guide or fixed reference points may increase the margin for error.

Another contribution of our study is the demonstration that the use of intraoperative fluoroscopy is a useful method to prevent possible secondary surgery by intraoperatively identifying inappropriate button positioning in ACL reconstructions using FSB devices. A standardized method for confirming proper button implant positioning has not yet been defined. Some clinicians have emphasized that the use of fluoroscopy may be useful, while others have advocated proper button positioning by direct visualization through an arthroscopic or lateral femoral skin incision. Arthur et al. compared the malposition rates of these three techniques on postoperative radiographs.[32] They reported that no malposition occurred with intraoperative fluoroscopy or open skin incision visualization, whereas direct arthroscopic visualization resulted in a 4.6% malposition rate (p< .05). Each technique has advantages and disad-

vantages. Ensuring proper button positioning with arthroscopic visualization is technically difficult and increases operative time.[13,33-35] Positioning through an open skin incision requires a larger incision and again increases the surgical time.[36,37] Intraoperative fluoroscopy appears to be a useful method of visualizing proper button positioning without the need for an additional incision and without significantly increasing operative time.[18,32] Balldin et al. reported a significant difference in button positioning between the intraoperative fluoroscopy group and the non-intraoperative group and stated that intraoperative fluoroscopy is a reliable method to detect and prevent malpositioning.[18] In our study, 14 malpositions were identified and corrected intraoperatively among 113 patients with fluoroscopy, preventing any need for revision surgery. Conversely, 10 of 74 patients in the non-fluoroscopy group required early reoperation due to unrecognized malposition. The reoperation rate was significantly higher in this group ($p < .05$), supporting the value of fluoroscopy as a preventive tool.

This study has several limitations. First, our ability to provide information, which is typical of a retrospective study, is limited to what is documented in the medical records. Therefore, we could not provide more details about the surgical techniques used, especially in patients who underwent a second surgery. Second, although our sample size seems adequate, it is relatively small. Finally, the experience of orthopedic surgeons may have changed between 2012 and 2022, which may have affected the results. Our study also has some strengths. In particular, the fact that it includes a control group and that a single orthopedic surgeon performed the surgeries is the strongest feature that distinguishes it from other studies. In addition, following the technical recommendations of the implant manufacturers during surgery is another important feature that effectively standardizes the results.

5. Conclusion

ASB implants were linked to a significantly higher rate of button malposition than FxSB implants. Intraoperative fluoroscopy proved effective in detecting and correcting malpositions across both implant types. This also reduces the likelihood of patients having to undergo a second operation. Especially in patients undergoing ACL reconstruction with the ASB implant and in whom intraoperative fluoroscopy is not accessible, it seems appropriate to perform additional control methods to ensure proper button positioning during surgery due to the high malposition rate and the possibility of needing a second surgery. We believe that our study should be supported by a larger sample size and different comparison groups.

Statement of ethics

The study was conducted in accordance with the tenets of the Declaration of Helsinki and approved by the Ethics Committee of Dr. Abdurrahman Yurtaslan Oncology Training and Research Hospital (number: 2024-09/113).

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Conflict of interest statement

The authors declare that they have no conflict of interest.

Author contributions

Conceptualization, EA, IK.; Data curation, EA, IK, HET.; Investigation, EA, IK, HET, RB, YK.; Methodology, EA. and IK.; Project administration, EA.; Resources, EA, IK, HET, RB, YK.; Writing – original draft, EA, YK.,.; Writing – review & editing, EA, IK, HET, RB, YK.

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