Original Article

Investigation of Hamstring Tendon Graft Fixation for the Reconstruction of Anterior Cruciate Ligament using Interference Screw Merely or in Combination with Supplementary Staple: A Clinical Trial

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Abstract

Background: Hamstring graft tendon for anterior cruciate ligament (ACL) reconstruction is a common approach worldwide. Tibial side graft fixation to achieve appropriate stability is a serious concern, worldwide. The current study aims to compare the outcomes of mere use of interference screw for fixation of hamstring tendon graft versus the use of interference screw plus supplementary staple. **Materials and Methods:** This is a randomized clinical trial conducted on 53 patients who underwent ACL reconstruction from 2016 to 2018. The study population was randomly divided into two groups: graft fixation with interference screw only and interference screw plus supplementary staple. Postoperative recovery time, postoperative clinical examinations, and the scale of the International Knee Documentation Committee were assessed for participants and compared between two groups. **Results:** Comparison of two groups regarding demographic information, including age, gender distribution, postoperative recovery time, and body mass index, showed no statistical difference ($P > 0.05$). Postoperative Pivot test was insignificantly positive in 4 (16.7%) cases of screw interference with supplementary staple while it was positive in 3 (10.7%) cases with screw interference only approach ($P = 0.98$). IKCD index was not statistically different between two groups postoperatively ($P = 0.72$), while IKCD scores changed significantly following the surgical procedure, regardless of the type of the surgical procedure ($P < 0.001$). **Conclusion:** Use of supplementary staple beside interference screw was as successful as mere use of interference screw for fixation of hamstring tendon autologous graft of the ACL reconstruction, regarding force withstanding. The comparison of the two approaches revealed no remarkable difference.

Keywords: *Anterior cruciate ligament, anterior cruciate ligament reconstruction, bone screw, bone-patellar tendon-bone grafts, sutures*

Introduction

Reconstruction of anterior cruciate ligament (ACL) is among the most common orthopedic procedures, which could successfully restore the stability and function of the injured knee following the ligament rupture and allow the person to return to daily routine activities.[1,2]

However, the graft choice for achieving optimal reconstruction outcomes has been a great challenge worldwide; two graft options including autologous central third patellar tendon with the associated bone (bone–patellar tendon–bone) (BTB) and hamstring grafts consisting of semitendinosus and gracilis are the most popular ones.[3,4] Reports in the literature have presented equivalent success rate of these two approaches, while the use of hamstring graft leads to less morbidity and greater strength of the graft, making this approach of remarkable favor by orthopedists.[5,6]

Soft tissue only grafts without a bone plug such as the approach of hamstring tendons graft are considered as the weakest point for initial ACL reconstruction. This fact occurs due to the forces against the graft that are mostly parallel to the tibia tunnel, while the tibial metaphysis is a relatively softer bone than the femoral tunnel.[7,8]

Another remarkable point about such procedures that involve soft tissue grafts only without bone integration is the considerable required time for its integration occurrence, unlike the bone-to-bone integrations.[9]

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On the other hand, the graft fixation on the femoral tunnel provides a greater strength than tibial tunnel, a fact due to more bone mineral density at distal part of the femur. Therefore, the tibial site of fixation is the weakest point of ACL reconstruction.[10]

A notable issue to achieve successful ACL reconstruction is to perform an aggressive rehabilitation schedule, early weight-bearing, strengthening, and immediate range of motion, before bone to graft integration occurs. Therefore, prevention of any loss or failure of the graft tension should be considered through an adequate initial tibial fixation.[11,12]

Given the fact about weakness of tibial tunnel link with reconstructed ACL, a strong enough initial fixation is required to allow for aggressive rehabilitation within the time to achieve the expected the graft–bone integration.[13] Therefore, some of the scientists prefer the supplementary use of a staple added to interference screw to improve the strength of reconstructed ACL.[13] However, evidence has shown that by the use of staple, there is an increased risk of symptomatic hardware that necessitates a second revised surgery for device removal,[3] while others prefer the use of screw to make reliable strength and stiffness. These authors claim that irritating hardware sensation when the staple is used may require reoperation for its removal.[2,13]

In the current study, we have aimed to compare the outcomes of tibial fixation using either screw interference with tunnel staple fixation or only screw interference for patient who had undergone autologous hamstring tendons with a tibial fixation for ACL reconstruction.

Materials and Methods

The current report is a randomized clinical trial with parallel design conducted on 53 patients who underwent ACL reconstruction referred to Alzahra and Kashani Hospitals, affiliated at Isfahan University of Medical Sciences, from 2016 to 2018. Figure 1 represents the consort diagram of the study.

Study population selection

Patients with an age range of 18–50 years who had ruptured ACL and underwent surgery for primary reconstruction were included.

Patients who required knee osteotomy, which presented multiple ligaments rupture (e.g., the other knee), and patients with a history of collagen vascular diseases or immunodeficiency diseases were excluded.

Isfahan University approved the study protocol of Medical Sciences Ethics Committee. Besides, this study protocol has been registered in the Iranian Registry of Clinical Trials encoded as IRCT20130311012782N28.

Then, the study protocol was explained for the patients, and they were reassured about the confidentiality of information. Therefore, all of the participants were requested to sign the written form of participation in the study.

Sample size

The desired number of the patients was achieved using the following formula, in which $z_{1-\alpha/2}$, $z_{1-\beta}$, and d were accounted for 1.96, 0.89, and 0.55, respectively.

$$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2)}{d^2} = 30 \text{ per group}$$

$\alpha = 0.05$ and $\beta = 0.20$

$\sigma_1 = 0.08$ and $\sigma_2 = 0.7$

$d = 0.55$.

Therefore, a number of 30 cases were required for each of the groups, while four ones withdrew the study as presented in the following.

The study population was nonrandomly selected through convenience sampling technique until achieving the required number of patients.

Then, the selected cases were randomly divided into two groups using Random Allocation software. In this term, each patient was provided with a specific number attributed him/her to a group of treatment, including Group A: screw interference and Group B: screw interference with a supplementary staple.

The orthopedist who performed the postoperative assessments was other than the surgeon who performed the surgical procedures, and therefore, he/she was blinded to the type of the surgery performed for the patients.

The surgical procedure and rehabilitation schedule

The surgical procedure performed for the patients was as done by Teo *et al*. using a minimally invasive arthroscopy technique.[14] All of the procedures were performed by a single surgeon to minimize the interobserver bias. Within a week after the surgical procedure to the 6th postoperative week, a routine schedule of physiotherapy as three times a week was initiated for the patients.

Outcomes

Patients' demographic information including age, gender, side of the injury, and body mass index (BMI) in addition to surgical procedure-related data including the width of utilized autologous hamstring tendon graft, meniscectomy requirement during the operation, and type of the interference (screw with/without staple) were recorded.

WClinical examinations including Lachman test, Pivot test, and ADT were performed by a single orthopedist for all of the patients before the surgical procedure and then within the interval time of 8 months.

The success of the operation was assessed using the scale of the International Knee Documentation Committee (IKDC).

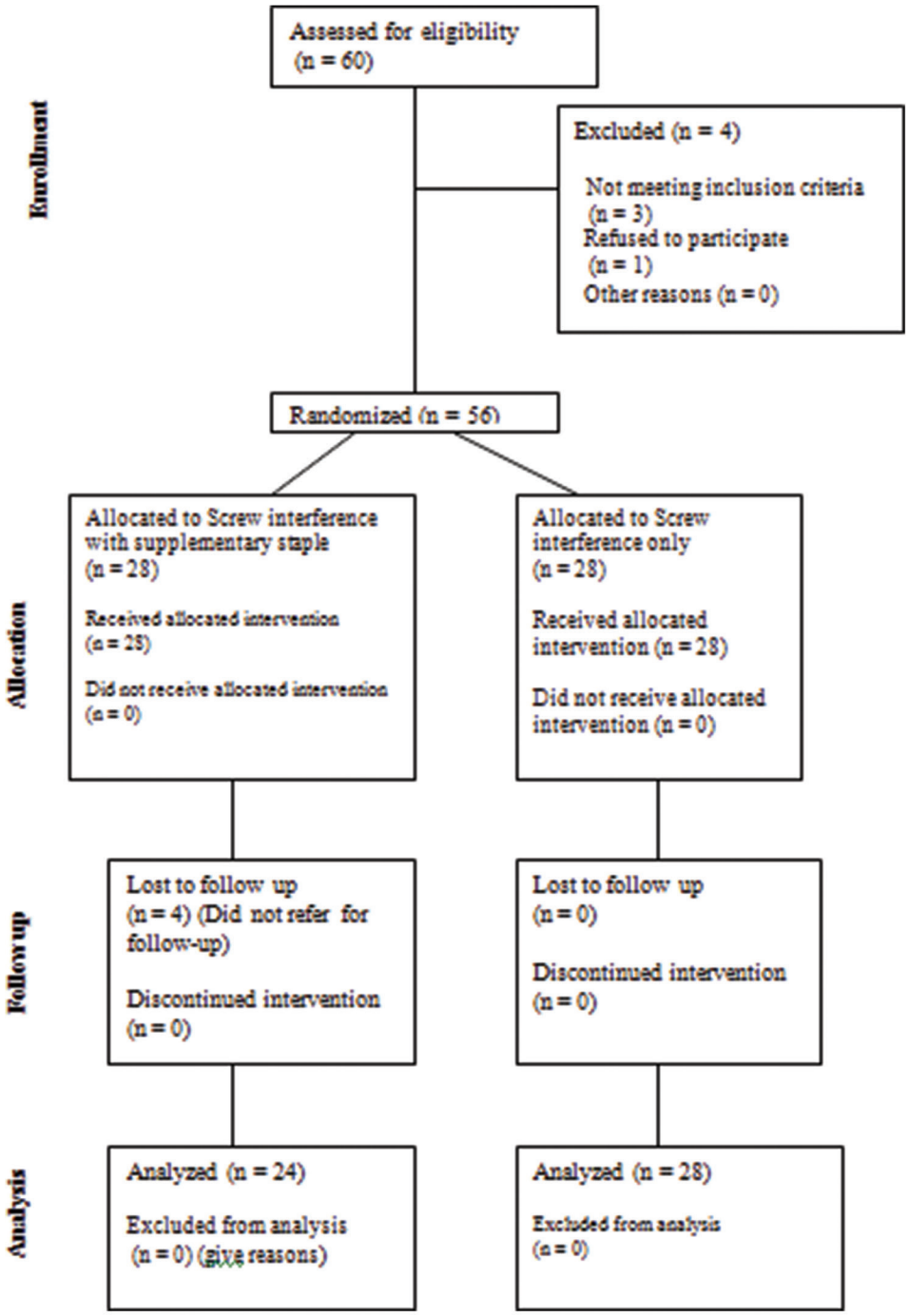

Figure 1: Consort diagram of the studied population

This scale was assessed before the surgical procedure and then within at least 8 months following the surgical procedure.[14]

The tunnel view radiography including anterior–posterior, upright, and 35° knee flexion view was taken preoperatively and at the end of the physiotherapy sessions as the follow-up study. The radiographies were performed to assess the severity of the injury and compartment degeneration.

Study analysis

Obtained data were entered into SPSS-20 (IBM; Chicago; The United States) and analyzed. Descriptive data were presented in mean and percentages, while for analytics, Chi-square test, *t*-test, and Fisher's exact test were used. $P < 0.05$ was considered statistically significant.

Results

In the current study, eligibility of 60 patients was assessed,

among which four did not meet the inclusion criteria and 56 were randomly allocated to the interventions in equal groups of screw interference with supplementary staple (n = 28) and screw interference only (n = 28). All of the operated cases in the screw interference with supplementary staple finished the study protocol, while four in the latter group lost to refer for follow-up visit [Figure 1].

The mean age and mean BMI of the study population were 30.58 ± 6.38 years and 27.12 ± 4.02 kg/m^2, with a predominance of the male gender, with 66.03% of the distribution. Most of the study population presented right-sided involvement of ACL (67.9%).

Comparison of two groups regarding demographic information including age, gender distribution, postoperative recovery time, time of postoperative follow-up visit, and BMI showed no statistical differences ($P > 0.05$). Postoperative ADT and Lachman test were negative for both of the groups, while Pivot test was positive in 4 (16.7%) cases of screw interference with supplementary staple and in 3 (10.7%) cases with screw interference the only approach. Comparison of the two groups revealed no statistical difference ($P = 0.98$). Table 1 represents the mentioned information in details.

The clinical knee examinations, including Lachman, Pivot, and ADTs, have been examined before the surgical procedure and then compared with the assessments performed following it. Table 2 demonstrates the status of these tests before and after the procedure. Based on the findings of Table 2, both groups represented a significant improvement in functional examinations, following whether the screw interference only or in combination with a staple ($P < 0.05$). Postoperative comparison of two groups regarding Pivot test positivity revealed no remarkable difference between those treated with the screw interference with a supplementary staple and those who were merely treated with screw interference approach ($P = 0.98$).

IKCD index assessments are demonstrated in Table 3. Based on Table 3, two groups were not statistically different before the surgical procedures ($P = 0.69$). Besides, comparison of two groups, postoperatively, showed no statistical difference ($P = 0.72$), while IKCD scores changed significantly following the surgical procedure regardless of the type of the surgical procedure ($P < 0.001$).

Discussion

Although hamstring autograft has become of great interest for the reconstruction of ACL, a notifying concern about its inability to tolerate the initial postoperative forces of rehabilitation made scientists to raise novel approaches.[10,15]

The primary principals of this study were to compare the outcomes of the interference screw only versus interference screw with supplementary staple among the patients who had undergone ACL reconstruction using hamstring tendon autograft. As we conducted our study on two groups of the patients similar in age, gender distribution, BMI, and the side of injured ACL, the probable role of these factors on the conclusion of our study was eliminated. Postoperative examination of two groups showed no statistical differences regarding clinical laxity tests of Pivot shift, Lachman, and ADT. Besides, patients' subjective declarations of IKDC score were not statistically different between the two groups. In general, we found no remarkable benefit of supplementary staple use beside interference screw.

Table 1: Comparison of demographics and postoperative examination tests between two groups of study population

Variable	Screw interference with supplementary staple (n=24)	Screw interference only (n=28)	P	Test
Gender* (male/female)	15 (62.5)/9 (37.5)	20 (71.4)/8 (28.6)	0.19	Chi-square
Age**	31.81±6.37	29.83±6.33	0.22	T-test
Body mass index**	27.13±3.88	27.10±4.22	0.97	T-test
Involved side* (right/left)	16 (66.7)/8 (33.3)	20 (71.4)/8 (28.6)	0.29	T-test
Postoperative recovery time**	6.53±2.01	7.23±1.43	0.12	T-test
Postoperative follow-up time (month)**	2.20±9.80	2.36±10.30	0.40	T-test

*n (%), **Mean±SD. SD: Standard deviation

Table 2: Comparison of clinical examinations of the knee before the surgical procedure and after that considering the type of the surgery

Variable	Group	Before, n (%)	After, n (%)	P*
Lachman	Screw interference with a supplementary staple (+/−)	24 (100)/0 (0)	0 (0)/24 (100)	<0.001
	Screw interference only (+/−)	28 (100)/0 (0)	0 (0)/28 (100)	<0.001
Pivot	Screw interference with supplementary staple (+/−)	24 (100)/0 (0)	4 (16.7)/20 (83.3)	<0.001
	Screw interference only (+/−)	28 (100)/0 (0)	3 (10.7)/25 (89.3)	<0.001
Anterior drawer test	Screw interference with supplementary staple (+/−)	24 (100)/0 (0)	0 (0)/24 (100)	<0.001
	Screw interference only (+/−)	28 (100)/0 (0)	0 (0)/28 (100)	<0.001

*McNemar t-test

Table 3: Comparison of the International Knee Documentation Committee scale between two groups of the study population

Surgical technique	*n*	Mean±SD		*P**	*P** Difference means
		Before	After		
Screw interference with supplementary staple	24	59.67±19.83	79.47±14.41	<0.001	0.80
Screw interference only	28	61.57±16.98	80.70±12.82	<0.001	
*P***		Investigation of Hamstring Tendon Graft Fixation for the Reconstruction of Anterior Cruciate Ligament using Interference Screw Merely or in Combination with Supplementary Staple: A Clinical Trial	0.72		

*Paired *t*-test, **t*-test. SD: Standard deviation

Reports in the literature have presented acceptable outcomes of eccentric interference screw fixation through the ACL reconstruction using hamstring tendon, regarding the stability of reconstructed ligament for withstanding against the forces,[8,16] while some more recent studies have presented that the use of supplementary staple beside screw has remarkable beneficial in comparison to the mere use of the screws.[13,17] This theory is still a great matter of research as further evaluations showed that even if the use of staple would provide better stability against forces, this device may pose considerable complications such as pain and reoperation requirement.[1,14]

Teo *et al*. conducted a similar study as they evaluated their patients with similar means including Lachman and Pivot tests, and IKCD, and presented consistent outcomes as they found no difference between the mere interference screw and interference screw plus staple, neither in clinical examinations nor through subjective IKCD assessments. The superiority of their study was its longer duration of follow-up than us, which presented staple-related complications, including postoperative pain due to kneeling and reoperation requirement for device removal.[14]

Hill *et al*. performed another study on females who underwent ACL reconstruction with autograft of hamstring tendon using whether interference screw fixation or in combination with a supplementary staple. Although, in a similar declaration to us, they presented no significant difference between two groups regarding postoperative IKCD, they declared that treated patients with supplementary staple plus metal screws presented notably reduced laxity of their knee through clinical Lachman examinations as compared to the mere use of metal screws. They interpreted that the density of proximal tibial metaphysic bone may have decreased, following the injury and further manipulations.[13]

Bauer *et al*. also compared the outcomes of screw interference only or in combination with staple. Although they assessed the benefits of the methods based on the cross-sectional area of the reconstructed ligament, yield load, failure point on 10 mm and device failure, similar to our outcomes, they found no superiority for the staple use added to screw interference.[18]

Although we have not found any failure in our study, our patients were approximately followed only for a year while most of the studies have presented that the ultimate tendon to bone integration would occur within 2 years following the reconstruction procedure.[2] Nevertheless, there are reports representing shorter time required for achieving the desired integration as Pinczewski *et al*. represented that only 15 weeks is required to achieve the expected microscopic and macroscopic hamstring autograft–bone interface.[19] On the other hand, animal models have demonstrated that signs of tendon-to-bone integration can be detected within 4 months.[20] These findings were confirmed by Pinczewski *et al*. who presented both microscopic and macroscopic hamstring tendon autograft integration within 15 postoperative weeks.[19] The other study by Rodeo *et al*. presented the biological interface of bone to the reconstructed tendon within 8 weeks of the operation.[21] Therefore, it seems that our study protocol for postoperative follow-up was adequately presented by other authors as well.[22]

Of limitations of our study is not to assess the procedure-related complications, while the symptoms due to kneeling have made the theory on the selection of patients for staple use added to interference screw. Because pain experience poses significant bothersome to the patient, it poses a burden of secondary surgery procedure for its removal.[14]

Conclusion

Use of supplementary staple beside interference screw was as successful as mere use of interference screw for fixation of hamstring tendon autologous graft of ACL reconstruction regarding force withstanding. Comparison of two approaches revealed no remarkable difference.

Limitations

The most significant limitation of the current study is its little number of studied populations. Therefore, further studies with larger sample populations are recommended.

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Conflicts of interest

There are no conflicts of interest.

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