Original Article

Stand-Alone Tibial Interference Screw Fixation and Tibial Interference Screw Plus Tibial Staple Fixation Produce Comparable Outcomes After Primary Anterior Cruciate Ligament Reconstruction Using Hamstring Autografts

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Purpose: To investigate the impact of adding a metal staple alongside the interference screw in tibial side graft fixation during anterior cruciate ligament reconstruction (ACLR). **Methods:** All patients treated with autograft hamstring ACLR at our institution between January 2017 and December 2021 with a minimum 1-year follow-up were reviewed retrospectively. Patients treated with a stand-alone interference screw for tibial side fixation were compared with those treated with a combination of interference screw and staple. The primary outcome was failure of the reconstructed graft. Secondary outcomes were operative time, complication rate, and reoperation rate. **Results:** A total of 497 patients met the study's inclusion and exclusion criteria. A combination of staple and interference screw was used in 167 patients (33.6%), whereas a standalone interference screw was used in 330 patients. There was no significant difference between the 2 groups in terms of operative time, complication rate, or failure rate. The mean follow-up was 23.25 (±13.29) months. **Conclusions:** Our results demonstrate that augmenting the interference screw with a staple for tibial-side fixation in ACLR does not have a significant impact on operative time, reoperation rate, complications, or failure rates. **Level of Evidence:** Level III, retrospective cohort study.

Several options and techniques exist for anterior cruciate ligament reconstruction (ACLR), as well as graft substitutes. Among these are hamstring autografts, which demonstrate high graft strength, minimal donor-site morbidity, and require a simple harvesting technique.[1,2] However, several studies have shown a slower integration of hamstring grafts (bone-to-tendon) when compared with bone–patellar tendon–bone (bone-to-bone).[3-8]

The different techniques used for tibial-side graft fixation aim to overcome the factors contributing to graft failures on that side, such as low bone mineral density and the parallel alignment of the tunnel to the graft, which increases shear forces and compromises graft stability.[9] Some surgeons address the weaknesses of tibial-side fixations by adding supplementary graft fixation using a metal staple in conjunction with an interference screw.[10]

The purpose of this study was to investigate the impact of adding a metal staple alongside the interference screw in tibial-side graft fixation during ACLR. The hypothesis was that augmenting the interference screw with a staple would not affect the rates of failure and complications of ACLR.

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Methodology

This study was conducted with adherence to the Strengthening the Reporting of Observational Studies in Epidemiology checklist for cohort studies.[11]

Study Design and Subject Selection

This study was approved by the Medical Research Center of Hamad Medical Corporation, Protocol MRC-01-22-424. After institutional review board approval, we identified all patients who underwent ACLR between January 2017 and December 2021. The inclusion criteria were patient age greater than 18 years, primary ACLR with a hamstring autograft, femoral graft fixation using an Endobutton, and a minimum 1-year follow-up. The exclusion criteria were previous ACLR, concomitant ligamentous injury, previous knee osteotomy, symptomatic chondral injury, less than 1 year follow-up, and insufficient documentation in the medical record. Patients were included in the study regardless of whether they had a concomitant meniscal injury.

The study population was divided into 2 groups: interference screw fixation alone or interference screw fixation augmented with a staple, which was the preferred technique for one surgeon (K.P.A.) during the study period. The primary outcome was failure of ACLR, which was defined as persistent or recurrent instability, revision of ACLR, and/or ACL graft rupture on magnetic resonance imaging. The secondary outcome was complication rate, which was defined as knee pain, discomfort, graft impingement, clicking sound, staple protrusion, loose staple, pain at the staple site, kneeling pain, or reoperation to remove the staple. Data were extracted from the electronic records at our institution by 2 authors (R.Y.A. and A.R.A.).

Surgical Technique

All patients underwent standardized arthroscopic single-bundle ACLR by a senior consultant (A.J.M., F.A.A., and K.P.A.). Femoral graft fixation was done using a suspensory fixation with an Endobutton (Smith & Nephew Endoscopy, Andover, MA), and tibial-side graft fixation was done using 25-mm absorbable interference screws with/without metal staples while the knee was at 30° of flexion. The tunnel size varied from 32 to 38 mm; the size of the Endobutton was selected accordingly, securing at least 20 mm of the graft inside the tunnels.

Harvesting the hamstring graft was done using a 5-cm longitudinal skin incision, started 3 fingers distal to the knee articular surface and 2 cm medial to the tibial tubercle. Gracilis and semitendinosus tendons were harvested with a closed tendon stripper. The grafts were prepared into strands ranging from 2 to7, depending on the size of the harvested graft.

Table 1. Demographic Characteristics of Participants

Variable	Subgroup	Frequency (n = 497)	Percentage (%)
Sex	Male	494	99.4
	Female	3	0.6
Laterality	Right	290	58.4
	Left	207	41.6
Mechanism	Sport	236	93.3
	Nonsport	17	6.7
Associated injuries	Yes	244	49.1
	No	253	50.9
Graft size	Two strands	1	0.2
	Three strands	10	2.0
	Four strands	34	6.8
	Five strands	382	76.9
	Six strands	69	13.9
	Seven strands	1	0.2
Staple	Yes	167	33.6
	No	330	66.4
Complications	Yes	125	25.2
	No	372	74.8
Failure	Yes	17	3.4
	No	480	96.5

	Mean	SD	Range
Age, y	30.41	7.15	15-55
BMI	28.31	17.93	18-45.89
Operative time, h	1.19	0.33	1-2.5
Follow-up, mo	23.25	13.287	12-72
Injury to surgery time, mo	23.18	33.59	0.25-180
Graft size, mm	8.86	0.80	7-10.5
Time to failure from surgery, mo	25.28	18.09	8-84

BMI, body mass index; SD, standard deviation.

After cycling 20 times then knee flexion to 30°, the tibial side graft was fixed with a bioabsorbable screw over a guidewire. Finally, one of our surgeons routinely added an 8-mm staple at the distal end of the graft as a standard practice for all his ACL cases.[12,13]

Rehabilitation Protocol

Operations for all patients were done at the daycare units, and patients were discharged home the same day. Physical therapy was started after surgery (3 sessions per week). Rehabilitation protocol included weight-bearing with axillary crutches after surgery. Knee braces were used for all the patients until suture removal. During the first 6 weeks, rehabilitation was focused on full range of motion knee and quadriceps—hamstring muscle strengthening. However, return to sport was allowed 6 months' postsurgery.

Data Analysis

Categorical variables are presented as counts and percentages, whereas continuous variables are

Table 2. Differences Between No-Staple and Staple Groups

Variable	Subgroup	No Staple (n = 330)	Staple (n = 167)	*P* Value
Sex	Female	2 (0.6)	1 (0.6)	.992
	Male	328 (99.4)	166 (99.4)	
Laterality	Right	186 (56.4)	104 (62.3)	.207
	Left	144 (43.6)	63 (37.7)	
Mechanism	Sport	157 (47.5)	79 (47.3)	.255
	Right	9 (2.7)	8 (4.8)	
Associated injuries	Yes	155 (47.0)	89 (53.3)	.183
	No	175 (53.0)	78 (46.7)	
Graft number	Two strands	0 (0.0)	1 (0.6)	.000*
	Three strands	9 (2.7)	1 (0.6)	
	Four strands	30 (9.1)	4 (2.4)	
	Five strands	223 (67.6)	159 (95.2)	
	Six strands	67 (20.3)	2 (1.2)	
	Seven strands	1 (0.3)	0 (0.0)	
Complications	Yes	80 (24.2)	45 (26.9)	.512
	No	250 (75.8)	122 (22.1)	
Failure	Yes	13 (3.9)	4 (2.4)	.371
	No	317 (96.1)	163 (97.6)	
Age, y		30.30 ± 7.24	30.61 ± 6.99	.651
BMI		27.76 ± 4.20	29.38 ± 30.30	.344
Follow-up time, mo		23.66 ± 13.69	22.42 ± 12.46	.325
Operative time, h		1.17 ± 0.31	1.23 ± 0.35	.068
Injury to surgery time, mo		22.57 ± 32.15	24.33 ± 36.27	.592
Graft size		8.85 ± 0.62	8.90 ± 1.07	.568
Time to failure from surgery, mo.		27.20 ±20.52	19.50 ± 5.75	.480

BMI, body mass index.
*$P < .05$.

interpreted as mean, standard deviation, and range. The difference in the characteristics and the outcomes of the patients who operated with and without staples was done using the χ^2 test and *t*-test for categorical and continuous variables, respectively. Any test with a *P* value .05 was considered significant. The data analysis was done using IBM-SPSS, version 25 (IBM Corp, Armonk, NY).

Results

Patients' Characteristics

The total number of the included patients was 497, 99.4% of whom were male (n = 494). The mean age was 30.41 (± 7.2) years. Right-sided ACL injury was found in 58.4% of the patients. Most injuries were related to sports (93.3%), and associated injuries were present in 49.1% of the participants. The mean follow-up was 23.25 (±13.29) months. The characteristics of the included studies are summarized in Table 1.

Descriptive Data

Out of the 497 patients, a combination of staples and interference screw was used in 167 patients (33.6%), whereas the rest were fixed using standalone interference screws. Overall, the majority of the grafts were 5-stranded (76.9%), and there was a greater number of 5-strands used in the no-staple group compared with that in the staple group; 223 and 159, respectively ($P = 0.000$).

Outcome Data

The mean operative time in the interference screw—alone group and staple groups was 1.17 (± 0.31) hours and 1.23 (± 0.35) hours, respectively ($P = .068$). There was no significant difference between the no-staple and staple groups regarding the rate of postoperative complications, 24.2% and 26.9%, respectively ($P = .512$). Failure occurred in 3.4% of the patients, in the interference screw—alone group 13 cases; 3,9% failure and 4 cases; 2,4% failure in the staple group, with no significant difference between the 2 groups ($P = .371$). The mean reconstruction-to-failure time was 27.20 ± 20.52 months and 19.50 ± 5.75 months in the no-staple group and staple group, respectively ($P = .480$). Table 2 demonstrates the differences between the no-staple and staple groups.

Discussion

The most important finding of this study was that there was no advantage to adding a tibial staple in patients who underwent primary ACLR with a hamstring autograft. There were no statistically significant differences between the staple and no-staple groups in terms of operative time, complication rates, and reoperation rates.

Teo et al.[13] conducted a comparative analysis of the previously mentioned options for tibial-side graft fixation in primary hamstring autologous ACLR. The outcomes did not show any significant differences with the addition of a staple, despite the arthrometer outcome. Furthermore, no significant differences were found in clinical laxity during physical examinations, including the Lachman test, anterior drawer test, and pivot shift test. However, there were significant differences reported in subjective patient outcomes such as kneeling pain and discomfort, which led to an increased need for a second surgery to remove the symptomatic staple. It is worth noting that our study included a much larger number of patients, approximately 500, compared with the 64 patients in the study of Teo et al. In addition, all surgeries in our study were performed by 3 experienced consultants, ensuring standardized surgical techniques including graft preparation, fixation of the femoral ends of the graft, and rehabilitation follow-up protocols, which minimized technique variability.

Some literature has shown favorable outcomes with standalone interference screw fixation for tibial-side graft fixation, considering graft stability and laxity understanding forces and rehabilitation techniques. Conversely, other literature has demonstrated benefits with the use of supplementary staple fixation in addition to the interference screw.[14,15] Bauer et al.[16] conducted a biomechanical study on porcine tibia, comparing the 2 fixation methods (interference screw alone vs interference screw plus staple). They analyzed the cross-sectional area, 10-mm failure points, and stiffness of 36 porcine knees divided into 2 groups, and found no significant differences between the groups.

As a result, the conflicting literature calls for further research on this topic. The addition of a supplementary metal staple to the interference screw in tibial side graft fixation may theoretically provide beneficial results in terms of graft stability and strength against distracting forces. However, these benefits need to be weighed against potential negative outcomes such as symptomatic hardware, kneeling pain, and the need for secondary surgical treatment to remove the staple.[10,13,16-19]

Lastly, our study did not find any significant differences between the 2 fixation methods in terms of failure rate, revision rate, instability, or subjective patient outcomes. However, 8 patients in the staple fixation group reported kneeling pain, particularly during prayer time. In addition, 2 patients in the same group required secondary surgery for staple removal.

Limitations

There are several limitations to consider in this study. First, the retrospective design of the study may have introduced selection bias. Second, the patient's clinical evaluation and assessment were conducted by the operating surgeon, which could introduce reporting bias. Furthermore, the subjective nature of the assessment may influence the interpretation of the results. In addition, the study population predominantly consisted of male patients due to the demographic profile of Qatar, where young men constitute the majority of the population. Moreover, a single technique, autologous hamstring ACL reconstruction, was used. This could limit the generalizability of the results to other populations or surgical approaches.

Conclusions

Our results demonstrate that augmenting the interference screw with a staple for tibial-side fixation in ACLR does not have a significant impact on operative time, reoperation rate, complications, or failure rates.

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