

Original Research Article

An observational retrospective study on safety and functional outcomes of arthroscopic anterior cruciate ligament reconstruction using Sironix suture button and interference screw

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ABSTRACT

Background: Anterior cruciate ligament (ACL) injury is a persistent orthopaedic condition that affects a wide spectrum of people. ACL reconstruction (ACL-R) stands out as the primary treatment option. Graft fixation with suture buttons and interference screws has proven to be a highly successful and reliable method for ACL-R. In this context, our research aims to assess the safety and functional outcomes of patients who underwent arthroscopic ACL-R using the Sironix suture button and interference screw.

Methods: This was a retrospective observational study. Patients who underwent arthroscopic ACL-R using Sironix suture button and interference screw (January 2018-March 2022) were included in the study. Functional outcomes of patients were evaluated using the international knee documentation committee (IKDC) assessment, the Tegner activity scale (TAS), the Lysholm knee scoring scale, the modified knee injury and osteoarthritis outcome score (KOOS) quality of life subscale, and the single assessment numerical evaluation (SANE) score. Adverse events, if any, were recorded.

Results: All patients achieved excellent outcome measures for IKDC, Tegner, Lysholm, KOOS, and SANE scores. The mean (SD) IKDC score was 88.76 (7.16), Tegner activity score was 5.9 (1.13), while the Lysholm score was 96.9 (6.56). The overall KOOS score was 93.7 (7.52), and the overall SANE score for the affected joint was 94.5 (7.22).

Conclusions: Arthroscopic ACL-R using Sironix implants (Helysis titanium interference screw, Helysis PLDLA+β-TCP interference screw, Infiloop fixed loop UHMWPE suture titanium button, Proloop adjustable loop UHMWPE suture Titanium button, and Titanium suture disc) demonstrated safety and good functional outcomes.

Keywords: ACL injury, ACL-R, IKDC, Interference screw, Sironix suture button

INTRODUCTION

Anterior cruciate ligament (ACL) injuries are the most common type of ligament injuries, and result in knee instability. The ACL serves as the primary internal stabilizing ligament of the knee.^{1,2} The estimated incidence of ACL tears in the general population is approximately 0.24-0.34 per 1,000 people per year.³ ACL injuries most

frequently affect people between the ages of 20 and 24.⁴ The most successful and recommended procedure for restoring knee stability and improving overall knee function is ACL-R.^{5,6}

Arthroscopic ACL-R is widely acknowledged as a highly effective procedure that consistently delivers favorable outcomes for most of the patients. It is recognized as the

preferred treatment for individuals who suffer from functional instability due to an ACL injury.⁷ ACL-R has success rates ranging from 75% to 97%. This surgical intervention can deliver exceptional results in terms of graft stability, enabling patients to return to athletic activities and mitigating functional knee instability.⁸

Although ACL-R has demonstrated success in restoring knee stability, recent research has revealed a notable occurrence of revision surgery, with revision rates ranging from 4.1% to 13%.⁹ ACL-R has predominantly centered around individual practice patterns, selection of graft type, surgical approach, and other technical aspects of the procedure.¹⁰ Selecting appropriate graft tissue is of paramount importance in this context. Graft options include autografts, allografts, and synthetic ligaments.¹¹ Hamstring and patellar tendon autografts have both proven to be successful options for graft fixation in ACL-R, traditionally secured with metallic interference screws made of materials like steel or titanium.¹²

In recent decades, substantial progress has occurred, leading to significant changes in surgical approaches.¹³ Moreover, in recent times, there has been a shift towards the use of interference screws made of bio-absorbable materials, such as poly-L-lactic acid. Bio-absorbable materials have gained popularity as they ensure appropriate graft-to-bone fixation.^{14,15} Sutures and screws are the most frequently recommended fixation devices for ACL-R. There has been a recent surge in the popularity of ultra-high molecular weight polyethylene (UHMWPE) sutures as fixation devices, offering improved knee stability.¹⁶

Suture button-based femoral cortical suspensory fixation can facilitate fast and secure graft fixation following ACL-R.¹⁷ Metallic interference screws have shown favorable clinical results with minimal complication rates.¹⁸ Interference screws made of titanium provide adequate fixation strength and facilitate rapid integration with the surrounding bone.¹⁹ The limited literature evaluating functional outcomes following ACL-R, and the wide variations in their findings, underscore the need for more research on the subject. The purpose of the current research was to assess the safety and functional outcomes following ACL-R using the Sironix suture button and interference screw.

METHODS

Following institutional ethics committee approval, a retrospective observational study was undertaken. Patients aged 18 to 60 years, who underwent arthroscopic ACL-R between January 2018 and March 2022 at Medicover Hospitals in Hyderabad, India using the Sironix suture button and interference screw, at a high-volume tertiary care center, were recruited for the study. Patients who did not respond to calls after three attempts or were not interested in participating in the study, and patients with traumatic injury to the same knee post ACL-R were

excluded from the study. Informed consent was obtained from all patients. All patients who met the inclusion criteria were asked to complete outcome questionnaires to assess functional outcomes.

Data collection and outcomes

Comprehensive pre-operative data were collected for each patient, including demographic details [age, height, weight, body mass index (BMI), and gender], injury related information (type of injury, cause, and concurrent knee pathology), and clinical evaluation findings (from knee examination). The primary endpoint of the study was knee function following ACL-R, assessed using the IKDC assessment form. The secondary endpoints assessed were level of activity post ACL-R using the TAS and Lysholm score, the quality-of-life post ACL-R using modified KOOS quality of life (QOL) subscale, and SANE score on scale of 0-100. Adverse events, if any, were documented.

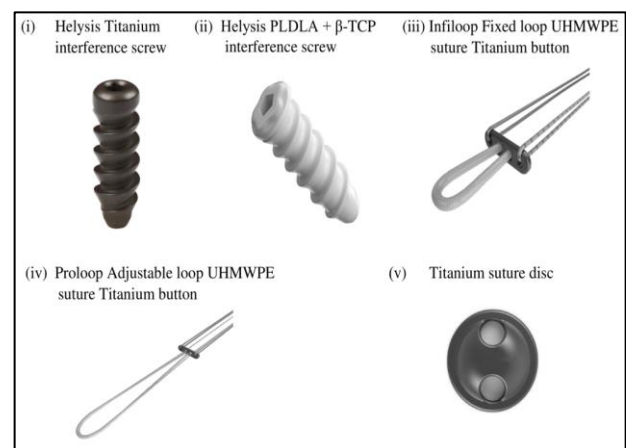


Figure 1: Study implants.

Choice of graft and implants

Semitendinosus and gracilis autograft were used in all patients. Surgery was performed using Sironix implants for graft fixation (Figure 1). Femoral side fixation was performed using the proloop adjustable loop UHMWPE suture titanium button (Sironix Division, Healthium Medtech Limited, India) or the infiloop fixed loop UHMWPE suture titanium button (Sironix Division, Healthium Medtech Limited, India), both of which were composed of two components: a variable suture loop and a metal fixation device (button). The suture portion of the fixation device is made of UHMWPE, and the fixation device (button) is made of titanium alloy. In two patients, the Helysis PLDLA + β -TCP interference screw was used for femoral fixation. The tibial fixation was performed using the Helysis titanium interference screw (Sironix Division, Healthium Medtech Limited, India) or the Helysis PLDLA + β -TCP interference screw (Sironix Division, Healthium Medtech Limited, India), which is made of PLDLA- β TCP [poly (L-co-DL lactic acid) + Beta Tricalcium phosphate]. In addition to the above implants,

for posterior cruciate ligament (PCL) injury repair, Titanium suture disc was used (Sironix Division, Healthium Medtech Limited, India).

Statistical analysis

Categorical variables were represented as percentages, while numerical variables were expressed using means and standard deviation. Statistical analysis was performed using SAS software (version 9.4).

RESULTS

Demographics and other baseline characteristics

A total of 32 patients who fulfilled the eligibility criteria were available for follow-up and were included in the study. Their mean (SD) age was 34.3 (8.37) years. Of these, 24 (75%) were male and 8 (25%) were female.

Femoral fixation was performed using Proloop adjustable loop UHMWPE suture titanium button for three patients, Infiloop fixed loop UHMWPE suture titanium button for 27 patients and Helysis PLDLA+β-TCP interference screw for two patients. The tibial fixation was performed using Helysis PLDLA+β-TCP interference screw for 19 patients, and Helysis titanium interference screw for 13 patients. Details of demographic characteristics, ACL injury and ACLR surgery are provided in Table 1.

Number of devices implanted

A total of 69 devices were implanted in 32 patients, comprising 14 Helysis titanium interference screws, 22 Helysis PLDLA + β-TCP interference screws, 28 IGnfiloop fixed loop UHMWPE suture titanium buttons, 3 proloop Adjustable loop UHMWPE suture titanium buttons and 2 titanium suture disc implants (Figure 2).

Table 1: Demographic characteristics of the study population, and details pertaining to ACL injury and ACL-R.

Description	N (%)
Age (in years)	
N	32
Mean (SD)	34.3 (8.37)
Gender	
Male	24 (75.0)
Female	8.0 (25.0)
Body weight (kg)	72.8 (8.57)
Height (cm)	169.6 (7.59)
BMI (kg/m ²)	25.5 (3.05)
Knee (ACL) injury	
Grade-3 injury	32 (100)
PCL injury	
Yes	3 (9.34)
No	29 (90.6)
Reason for injury	
Accident	3 (9.38)
Fall	25 (78.13)
Twisting injury	4 (12.50)
Side of knee injury	
Left	13 (40.63)
Right	19 (59.38)
Contralateral knee injury	
No	32 (100.0)
Yes	0 (00.0)
Type of graft used	
Semitendinosus tendon-Gracilis (STG) autograft	32 (100.0)
Implant for femoral fixation	
Proloop adjustable loop UHMWPE suture titanium button	3 (9.38)
Infiloop fixed loop UHMWPE suture titanium button	27 (84.38)
Helysis PLDLA + β-TCP interference screw	2 (6.25)
Implant used for tibial fixation	
Helysis PLDLA + β-TCP interference screw	19 (59.38)
Helysis titanium interference screw	13 (40.63)
Implants used for PCL injury repair	
Infiloop fixed loop UHMWPE suture titanium button + Helysis PLDLA + β-TCP interference screw + titanium suture disc	1 (3.13)

Continued.

Description	N (%)
Helysis titanium interference screw + titanium suture disc	1 (3.13)
Medial collateral ligament repair done with metal anchor 5 mm	1 (3.13)

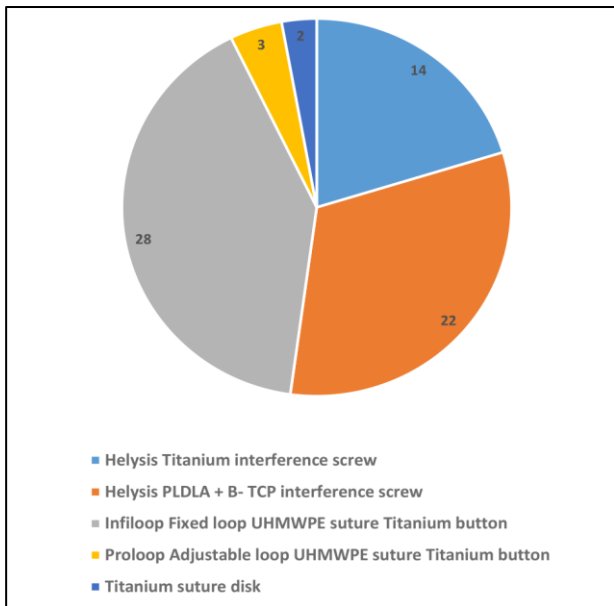


Figure 2: Implanted devices.

Assessment of functional outcomes

Primary functional outcome

Evaluation of IKDC assessment score: The overall mean (SD) value of the IKDC assessment score of 32 patients was 88.76 (7.16) (Table 2).

IKDC assessment by device: Mean (SD) IKDC assessment scores, among patients who underwent ACL-R using Helysis PLDLA+β-TCP interference screw, Helysis titanium interference screw, Infiloop fixed loop UHMWPE suture titanium button, proloop adjustable loop UHMWPE suture titanium button, and titanium suture disc

implants 90.4 (3.54), 86.0 (9.77), 88.9 (7.49), 91.6 (3.69), and 90.8 (4.88), respectively (Figure 3).

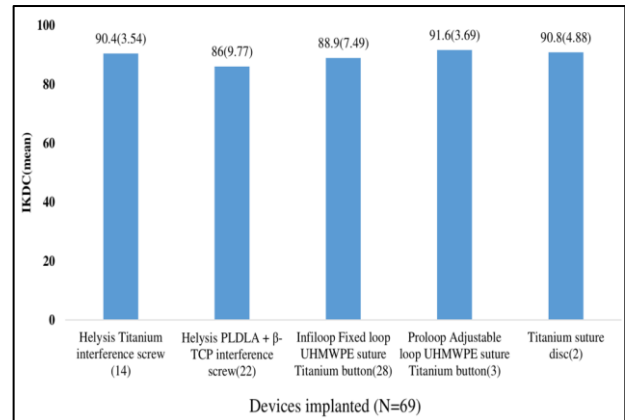


Figure 3: Analysis of IKDC assessment by device.

Secondary outcomes

Assessment of TAS and Lysholm score: The overall mean (SD) value of the total TAS was 5.9 (1.13). The overall mean (SD) value of the total Lysholm score was 96.9 (6.56) (Table 3).

Assessment of KOOS and SANE scores: The overall mean (SD) value of the KOOS score (QOL) was 93.7 (7.52). The overall mean (SD) value of the SANE score for the affected joint was 94.5 (7.22) (Table 4).

Adverse events

Out of the 32 patients included in the study, none reported any adverse events, and there were no instances where patient participation in the study had to be discontinued.

Table 2: Summary and analysis of IKDC assessment by duration following surgery.

Variables	6 months to 1 year, (n=4)	1 year to 2 years, (n=4)	More than 2 years, (n=24)	Total, (n=32)
IKDC score	89.66 (5.71)	92.82 (1.45)	87.93 (7.80)	88.76 (7.16)

Table 3: Summary of TAS and Lysholm score.

Variables	6 months to 1 year, (n=4)	1 year to 2 years, (n=4)	More than 2 years, (n=24)	Total, (n=32)
TAS scale	6.0 (0.82)	5.5 (0.58)	6.0 (1.25)	5.9 (1.13)
Lysholm score	98.8 (2.50)	99.5 (0.58)	96.2 (7.41)	96.9 (6.56)

Table 4: Summary and analysis of KOOS score and SANE score by duration.

Variables	6 months to 1 year, (n=4)	1 year to 2 years, (n=4)	More than 2 years, (n=24)	Total, (n=32)
KOOS score (QOL)	97.0 (6.00)	95.5 (3.00)	92.8 (8.19)	93.7 (7.52)
SANE score of affected joints of interest	97.5 (5.00)	96.3 (4.79)	93.8 (7.84)	94.5 (7.22)

DISCUSSION

Arthroscopic ACL-R continues to be the preferred treatment for knees with ACL deficiency, as most non-surgical approaches have yielded outcomes that are deemed functionally unacceptable.²⁰

The primary goal of ACL-R is to restore stability and function to the knee joint after an ACL tear.²¹

Over the follow-up of two years, both in-clinic and via telephonic follow-ups, the study has diligently employed the primary and secondary endpoints to measure the outcomes, as outlined by the IKDC score, Tegner scale (TAS), Lysholm score, KOOS with a keen emphasis on the quality-of-life sub-scale, SANE, and any adverse events.

These measures have been utilized to gauge the effectiveness and safety of the Sironix suture button and interference screw.

In a study conducted by Shervegar et al following ACL-R surgery, a mean (SD) IKDC subjective score of 75.6 (17.36) was observed.²⁰ Another study by Ra et al reported a mean (SD) IKDC score of 89.8 (9.9) for a 12-month follow-up.²² In contrast, the current study findings indicate superior results with a mean (SD) IKDC score of 92.82 (1.45).

Cheng-Yao et al found that the mean Lysholm score at one-year follow-up was 82.4 (7.8), while the score at two years' follow-up was 93.1 (8.5).²³ In contrast, the results of the present study demonstrate a deviation from these earlier findings. It was found that the mean (SD) Lysholm scores at both the one-year and two-year follow-ups were higher, at 99.5 (0.58) and 96.2 (7.41), respectively.

According to the research conducted by Muller et al the mean (SD) KOOS score was 77.6 (19.7) after more than two years of follow-up.²⁴ The KOOS score for the same follow-up period was much higher in the current study's findings, with a mean (SD) score of 92.8 (8.19), demonstrating a substantial difference.

In a study conducted by Chen et al the mean (SD) TAS score for patients who underwent single-bundle ACL-R at more than two years of follow-up was 6.59 (0.51).²⁵ Comparable results were found in the current study, where the mean (SD) TAS score was 6.0 (1.25).

Douoguih et al conducted a retrospective study on patients who underwent ACL repair with suture augmentation to evaluate outcomes and patient satisfaction and demonstrated the mean (SD) SANE score was 83.0 (12.9).²⁶ According to the current study, the mean (SD) SANE score was 94.5 (7.22), which was highly significant compared to the early findings.

Strengths and limitations

This study has a few limitations that should be acknowledged. Firstly, given its retrospective nature, there is a need for more prospective research, including randomized controlled trials, to strengthen the quality of the evidence. Secondly, there was a relatively small sample size. However, it is worth noting that the long-term follow-up data collected in a real-world setting does contribute valuable insights. Additionally, it is important to highlight that the results of this study have shown correlation with the existing literature in terms of the IKDC score, SANE score, Lysholm score, TAS, and KOOS quality of life score, which serves to validate the findings of the current study.

CONCLUSION

The study results demonstrate a significant functional status after ACL-R as evidenced by the IKDC score, SANE score, Lysholm score, TAS, and KOOS QOL score. Therefore, the utilization of the Sironix suture button (Infiloop fixed loop UHMWPE suture titanium button and Proloop adjustable loop UHMWPE suture titanium button) and interference screw (Helysis titanium interference screw and Helysis PLDLA + β -TCP interference screw) appears to be a safe and viable option while performing arthroscopic ACL-R.

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Conflict of interest: Sunil Apsingi is a consultant to Healthium Medtech Limited. Ashok Kumar Moharana, Sachin Angrish, and Deepak T. S are full time employees

of Healthium Medtech Limited. Other Authors declares no conflict of interest.

Ethical approval: The study was approved by the Institutional Ethics Committee

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