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Original Article

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A Retrospective, Observational, Multicentric Study to Assess Functional Outcomes of Anterior Cruciate Ligament Reconstruction

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Abstract

Background: Injury to anterior cruciate ligament (ACL) requires reconstruction surgery. The objective of the present study is to evaluate the functional outcomes in patients who had arthroscopic anterior cruciate ligament reconstruction (ACLR) using Sironix knee implants. ***Methods:*** 113 patients who underwent ACLR (April 2018 and July 2022) in two centers were included in this observational, retrospective, multicentric study. The primary endpoint was the International Knee Documentation Committee (IKDC) score. The secondary endpoints were Tegner Activity Scale (TAS), the Lysholm score, modified Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Single Assessment Numerical Evaluation (SANE) score. ***Results:*** The mean (SD) total IKDC score was 79.14 (8.36). The mean (SD) total TAS score was 4.5 (2.04) pre-injury and 4.2 (1.12) post-surgery with a p-value of 0.059. The mean (SD) total Lysholm scores decreased from 96.35 (6.34) pre-injury to 85.30 (10.23) post-surgery (p = 0.000). The mean (SD) total KOOS score was 86 (10.55). The mean (SD) total SANE score of patients in the operated side and the opposite side were 85.0 (8.70) and 98.3 (3.46), respectively (p-value: 0.0001). ***Conclusion:*** The study demonstrated that ACLR using Sironix knee implants resulted in good functional and patient-reported outcomes, indicating that the implants are safe and effective.

Keywords: ***anterior cruciate ligament, sports injuries, interference screw, suture button.***

Introduction

Anterior cruciate ligament (ACL), one of the cruciate ligaments in the middle of the knee, has a predominant role in knee joint stability. In cases of injury to ACL, ligament reconstruction is required to prevent knee instability and potential long-term degenerative problems [1,2].

ACL tears in athletes can occur through a combination of non-contact mechanisms and contact mechanisms. Non-contact injuries are common while the athletes are changing directions, in sports such as soccer and basketball, and contact injuries are common during direct trauma to the knee [3]. These injuries frequently result in swollen joints, decreased flexibility, muscle weakness, and reduced functional performance, and in long run leads to meniscus injuries and osteoarthritis (OA) [4].

ACL tears are generally considered to have poor healing potential and hence have a very high (40 to 100%) failure potential post-surgical repair. Hence, ACL reconstruction (ACLR) has been unanimously chosen over suture repair for ACL injuries [5].

ACLR has shown success in improving subjective and objective outcomes across all patient demographics. The procedure involves graft selection and harvesting, bone tunnel implantation, graft fixation, and postoperative therapy, all of which impact the clinical outcome [6]. ACLR involves replacing the damaged ACL with either an autograft or allograft under arthroscopic control. Arthroscopy is preferred for its benefits in reducing post-operative swelling and allowing early range of motion. Fixation methods, including metal screws and biodegradable screws, are used during surgery [7].

Arthroscopic ACLR aims to rebuild native knee mechanics and functionality. In addition, it also aims to prevent injury associated knee osteoarthritis and meniscal lesions [8]. The ACLR's success depends mainly on the type of the graft, graft fixation methods (aperture fixation or suspensory methods), and rehabilitation [9-11]. Fixed loop and adjustable loops are used for suspensory fixation, and interference screws are used for aperture fixation. Currently a combination of aperture fixation and suspensory fixation is most commonly employed in ACLR [12].

Both Interference screws and loops are available in various materials such as titanium, Polyether Ether Ketone (PEEK), and poly-L-co-DL-lactic acid-beta tricalcium phosphate (PLDLA-BTCP). In this study, a combination of interference screws and loops are used for ACLR [13].

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According to earlier research, ACLR using interference screws is the gold standard technique [14]. Both patellar tendon and hamstring autografts have been effectively used for anterior cruciate ligament rehabilitation, employing interference screws for graft fixation [11]. The fixation technique significantly impacts primary stability and initial graft healing. While transfixing screws or pins may seem stable, they can lead to intraoperative issues. Using an interference screw or metal screw alone carries a risk of graft slippage. Cortical button fixation through suture loop suspension has gained popularity among ACL orthopaedics [15].

Therefore, the current study was performed in patients who had undergone arthroscopic ACLR using the Sironix suture button and/or interference screw, to assess the safety and functional outcomes.

Materials and Methods

Study design and Patient selection

113 patients who underwent ACLR (April 2018 and July 2022) in two centers were included in this observational, retrospective, multicentric study. The study aimed to assess knee function post-ACLR, activity pre-injury and post-surgery, the quality of life after ACLR, and the adverse events associated with knee arthroscopy procedures. The study was conducted in conformity with ICH-GCP (R2), ISO 14155, and CDSCO medical device regulation 2017. Patients were included as per the eligibility criteria after obtaining the patient's telephonic informed consent. This study was registered at the CTRI portal prior to the enrolment of patients into the study.

The study inclusion criteria were as follows: 18 to 60 years aged male or female patients who underwent arthroscopic ACLR using a Sironix suture button and/or interference screw; patients willing to give written informed consent to participate in the study during an in-clinic follow-up visit; or patients providing verbal consent during the telephonic follow-up visit. Patients who did not respond to calls after three attempts, patients who refused to participate in the study, and patients who had an injury and underwent re-surgery on the same knee following ACLR were excluded from the study.

Data collection and outcomes

The demographic data, clinical characteristics, and radiological investigations were obtained from the patient's hospital records. Subsequently, patients were contacted via telephone, and data collection involved asking questions through a predetermined questionnaire. The primary outcome was evaluated through the IKDC score. Secondary outcomes such as activity levels were assessed using the Tegner Activity Scale (TAS) and Lysholm scale. The Quality of life of patients was assessed using KOOS and SANE scores; any adverse events or postoperative complications were recorded and reported.

Description of Devices Used in the Study

The arthroscopy knee implants used in the current study were (i) Helysis titanium interference screw, (ii) Helysis PLDLA-BTCP interference screw, and (iii) Proloop adjustable loop UHMWPE suture titanium button for ACLR (Sironix Division; Healthium Medtech Limited, Bangalore).

Helysis titanium interference screw: The Helysis titanium interference screw is made of titanium and intended for soft tissue fixation to the bone (**Figure 1**).

Figure 1: Helysis titanium interference screw

Helysis PLDLA-BTCP interference screw: The Helysis PLDLA-BTCP interference screw is made of PLDLA - [poly (L-co-DL lactic acid) + Beta-tricalcium phosphate]. It is intended for soft tissue fixation to the bone (**Figure 2**).

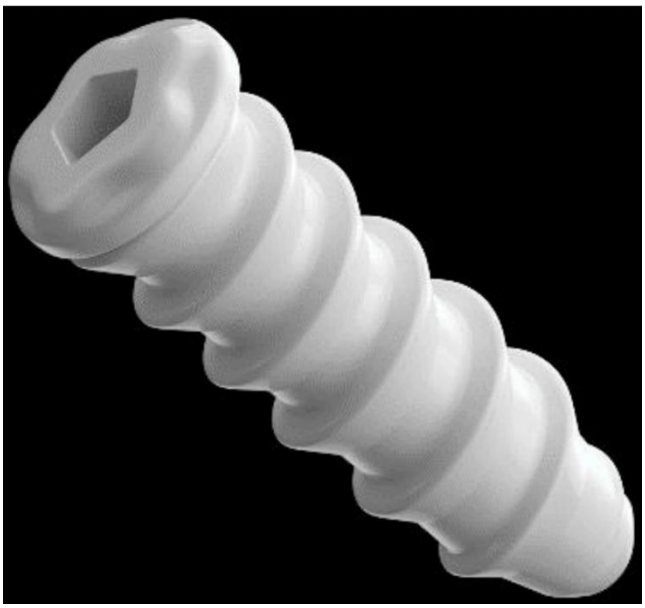

Figure 2: Helysis PLDLA-BTCP interference screw

Proloop adjustable loop UHMWPE suture titanium button: The Proloop adjustable loop UHMWPE suture titanium button is made up of a titanium button and an adjustable loop made up of UHMWPE suture. It is intended for soft tissue fixation to the bone (**Figure 3**).

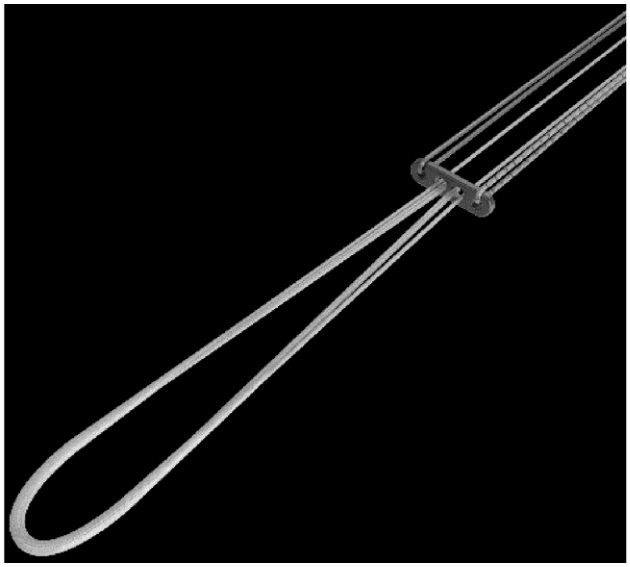

Figure 3: Proloop adjustable loop UHMWPE suture titanium button

Statistical Analysis

Descriptive statistics were employed to summarize demographic data and surgery details. Qualitative factors were presented as percentages, while quantitative variables were expressed as mean ± standard deviation. The comparison of pre-injury and post-surgery TAS and Lysholm scores was performed using a paired t-test. An independent t-test was utilized to compare the mean SANE scores between the knee's operated and normal sides. Statistical significance was defined at a significance level of $p \leq 0.05$ (SAS 9.4).

Results

One hundred and thirteen patients completed the final follow-up, whose mean (SD) age was 31.7 (8.36) years. Out of 113 patients, 87 (77%) were male and 26 (23%) were female; the mean (SD) BMI (kg/m2) was 23.4 (1.70). All patients had Grade 3 knee (ACL) injuries, of whom 64 had a right knee injury and 49 had a left knee injury. Most injuries resulted from accidents 80 (70.8%) and remaining were due to falls 33 (29.2%). Meniscal tears were identified in 79 (69.9%) patients. Posterior cruciate ligament (PCL) injury or associated injury was presented in 5 (4.4%) of 113 patients. Other baseline parameters are listed in Table 1.

A total of 228 devices were surgically implanted, encompassing 2 Helysis Titanium Interference screws, 112 Helysis PLDLA-BTCP interference screws, and 112 Proloop Adjustable loop UHMWPE Suture Titanium Buttons, distributed among 113 patients (**Table 1**).

Outcome Measures

Primary outcome: Subjective knee function

International Knee Documentation Committee (IKDC) Score

The IKDC questionnaire was used to assess subjective knee function following ACL surgery, resulting in a mean (SD) total IKDC score of 79.14 (8.36) (**Table 2**).

IKDC assessment by device

Proloop Adjustable loop UHMWPE Suture Titanium Button and Helysis PLDLA-BTCP interference screw for femoral and tibial fixation was used in 112 patients who had a mean (SD) total IKDC score as 79.15 (8.32). The IKDC score of one patient who received a Helysis titanium interference screw on both sides was 78.16.

Secondary outcomes

Tegner Activity Scale (TAS)

TAS is a standardized scale, and it was used to assess the level of activity before the injury and after the surgery. The mean (SD) total TAS score before the injury was 4.5 (2.04) and after the surgery at the time of follow-up was 4.2 (1.12), respectively with a p-value of 0.059 (**Table 3**).

Lysholm score

The Lysholm scale was employed to assess the patient's knee-specific symptoms, encompassing mechanical locking, instability, pain, swelling, as well as challenges in stair climbing and squatting. The mean (SD) total Lysholm score at pre-injury and post-surgery was 96.35 (6.34), and 85.30 (10.23), respectively (p-value of 0.000) (**Table 3**).

KOOS (QOL) Subscale score

KOOS (QOL) subscale was used to assess the quality of life. The total mean (SD) value of the KOOS score of 113 patients was 86.0 (10.55) (**Table 3**).

SANE Score

The total SANE mean (SD) values of 113 patients in the operated side and the opposite side were 85.0 (8.70) and 98.3 (3.46), respectively, with a p-value of 0.0001 (**Table 3**).

Adverse events

All 113 patients didn't report any adverse events. None of the patients discontinued the study. Based on the patients' safety profile, it was observed that Sironix knee implant devices were safe with no adverse effects.

Table 1: Demographic and other characteristics

Demographics	**N = 113**
Age (years), mean ± SD	31.7(8.36)
Sex, n (%)	
Male	87 (77.0)
Female	26 (23.0)
ACL Surgery details	
Right	64 (56.6)
Left	49 (43.4)
Reason for injury	
Accident	80 (70.8)
Fall	33 (29.2)
Associated meniscal tears	
Yes	79 (69.9)
No	34 (30.1)

Any PCL injury or associated injury	
No	108 (95.6)
Yes	5 (4.4)
No of devices implanted in patients	
Mean (SD)	2.0 (0.26)
Implants used for femoral fixation	
Proloop adjustable loop UHMWPE suture titanium button	112 (99.1)
Helysis titanium interference screw	1 (0.9)
Implants used for tibial fixation	
Helysis PLDLA-BTCP interference screw	112 (99.1)
Helysis titanium interference screw	1 (0.9)
For PCL tear, a Proloop adjustable loop UHMWPE suture titanium button was used on femoral side and Helysis PLDLA-BTCP interference screw was used on Tibial side	1(0.9)
*N: Number of patients, %: percentage of patients, SD: Standard deviation,	

Table 2: Summary of IKDC assessment by duration

Description	Less than 6 months (N=6)	6 months to 1 year (N=27)	1 year to 2 years (N=54)	More than 2 years (N=26)	Total (N=113)
IKDC Score	83.52(5.71)	80.50(7.95)	79.14(8.16)	76.70(9.32)	79.14(8.36)
IKDC: International Knee Documentation Committee					

Table 3: Summary of Secondary outcome scores by Duration

Scale	Less than 6 months (N=6)	6 months to 1 year (N=27)	1 year to 2 years (N=54)	More than 2 years (N=26)	Total (N=113)
TAS Score					
Pre-injury	4.8 (1.83)	5.1 (2.27)	4.5 (2.01)	3.8 (1.78)	4.5 (2.04)
Post-surgery	4.5 (0.55)	4.5 (1.01)	4.2 (1.11)	3.9 (1.29)	4.2 (1.12)
p-value	0.611	0.041	0.256	0.764	0.059
Lysholm Score					
Pre-injury	97.16 (3.60)	98.11 (3.30)	96.07 (6.78)	94.92 (7.92)	96.35 (6.34)
Post-surgery	91.16 (5.71)	88.92 (8.40)	84.29 (9.62)	82.26 (12.55)	85.30 (10.23)
p-value	0.103	0.000	0.000	0.000	0.000
KOOS Score (QOL)					
	84.3± 9.89	87.3± 9.35	86.1±11.04	84.9±11.21	86.0±10.55
SANE Score					
Operated side	88.3 (6.83)	86.1 (7.38)	84.4 (8.83)	84.5 (10.14)	85.0 (8.70)
Opposite side	98.3 (4.08)	98.1 (3.71).	98.1 (3.54).	98.7 (3.02).	98.3 (3.46)
p-value	0.0117	0.0001	0.0001	0.0001	0.0001
*N: Number of patients, SD: standard deviation, TAS: Tegner Activity Scale, KOOS: The Knee injury and Osteoarthritis Outcome Score, SANE: Single Assessment Numerical Evaluation					

Discussion

ACLR is conducted with the aim of reinstating stability and functionality to the knee. Multiple implants are available for the fixation in ACLR, and the current fixation devices that have been commonly employed have been suture buttons and interference screws, which have aided in an enhanced post-operative rehabilitation program. Some studies have demonstrated that suture buttons and interference screws can be helpful in the healing process of ACL injuries.

After ACLR, the most vulnerable aspect of the graft is typically its tibial attachment site. Interference screws are utilized to create a sturdy structure that promotes the healing and integration of the graft with the bone [16]. Titanium interference screws offer several benefits, including their ability to create a robust fixation and their excellent compatibility with the body. They can be used in MRI imaging and are generally more cost-effective than bioabsorbable screws [17].

The present retrospective observational study demonstrated good results in terms of assessed safety outcomes as well as functional outcomes.

The present study results were superior to the previously conducted study by Lind M *et al*. (2020),[18] who reported that the IKDC score after one year of follow-up was 73.7 (1.9). However, in this study, at time-points between 6 months and 1 year of follow-up, the mean (SD) IKDC score was 80.50 (7.95).

In a study conducted by Shervegar *et al*., the TAS was observed to be 5.44 (1.51) and 4.26 (1.99) respectively during pre-injury and post-surgery period, and the mean post-operative Lysholm score was found to be 84.42 (13.24) [19]. These results well-correlated with the current study findings, i.e., the overall mean TAS was 4.5 (2.04) and 4.2 (1.12), respectively during pre-injury and post-surgery periods, and the Lysholm score was 85.30. The statistically non-significant difference noted between the TAS indicates that post-surgery, subjects could resume to pre-injury activity levels.

Lee T.J *et al*. (2020),[20] performed a study and reported an average Lysholm score of 82.5 (14.5) after two years of ACL surgery. A study by Nwachukwu B.U *et al*. (2021) noted the mean Lysholm score of the patients at 2-year follow-up was 89.8 (10.6) [21]. Similarly, in the present study, the mean (SD) of the Total Lysholm score at more than 2 years of follow-up was found to be

82.26 (12.55), indicating that the current study findings were comparable with the earlier findings. Likewise, three additional studies conducted by Shrestha R *et al*. (2021),[22] Ettinger M *et al*. (2016),[23] and Chodavarapu *et al*. (2017) [24] demonstrated favorable Lysholm scores ranging from 84 to 91 at the two-year follow-up period.

Though the post-surgery Lysholm scores were in accordance with the published literature, the functional levels couldn't reach the pre-injury scores, which is similar to a study published by A. Gabr *et al*.[25] A study by Hill G. N *et al*. (2013) demonstrated that one year after ACLR, a mean (SD) KOOS (Quality of Life) score of 78.1 (20.2) was achieved [26]. In the current study, in 1 year to 2 years of duration, the mean (SD) of the KOOS score was observed to be 86.1 (11.04).

In a ACLR study which included 172 patients, by Douoguih WA *et al*. (2020), the mean (SD) SANE score of the affected region was 83.0 (12.9) [6]. In a previous study that included 33 patients who underwent ACLR surgery, the mean SANE score of the operated joint was 81 (11), [27] in line with the current study. The total mean SANE score of patients in the operated side and opposite side was 85.0 (8.70) and 98.3 (3.46), respectively with a significant p-value. This significant difference in the SANE scores between the operated and the unaffected opposite knees is a common finding post-ACLR. Patients may perceive a difference in function between the two knees, even if the surgical outcome is deemed successful. This emphasizes the importance of comprehensive preoperative counselling to manage patient expectations post ACLR [25].

A study conducted by Sharma et.al (2023) [28] stated that there was no incidence of re-injuries in any of the patients during the follow-up, which was in line with the current study findings.

Limitations

This study is not without limitations. Post-operative rehabilitation has a potential role in patient recovery and functional outcomes, whereas considering it is a retrospective study, the rehabilitation factor could not be considered. More randomized prospective studies should be conducted to offer better evidence. However, data in this study undoubtedly adds value, considering that the current study findings have a substantial co-relationship in terms of the assessed orthopedic scores with the available literature.

Conclusion

The study findings revealed a good functional outcome and significant improvement in activity levels to near pre-injury activity levels as indicated by Tegner activity scale, which indicated a positive knee status and function, signifying the success of ACLR. Moreover, there was a substantial enhancement in the quality of life for patients, with no reported adverse events. Based on these functional and patient-reported outcomes (IKDC, Lysholm, TAS, KOOS and SANE), it can be concluded that the utilization of Sironix knee implants (Proloop adjustable loop UHMWPE suture titanium button, Helysis PLDLA-BTCP interference screw, and Helysis titanium interference screw) is a safe and effective approach in arthroscopic ACLR surgery.

Declarations

Conflicts of interest

Authors Ashok Kumar Moharana, Sachin Angrish and Deepak TS are employees of Healthium Medtech Limited, India, who are manufacturers of Sironix knee implants. Authors K Vijayaraj and V Rathika declare no conflict of interest.

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