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ORIGINAL ARTICLE

Observational Study

Assessing clinical and patient reported outcomes of Sironix suture anchors in rotator cuff and Bankart repair surgeries

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Abstract

BACKGROUND

Rotator cuff tears and Bankart lesions significantly affect shoulder function and quality of life. Arthroscopic rotator cuff repair and Bankart repair has become the standard treatment for restoring function and reducing pain. Recent advancements include new suture anchor technologies, such as the Sironix suture anchor known for its biomechanical strength and promising outcomes. However, there are limited real-world data on its effectiveness and safety, particularly in the Indian population.

AIM

To evaluate the effectiveness and safety of Sironix suture anchors in rotator cuff and Bankart repair surgeries.

METHODS

Sixty participants underwent surgery between January 2021 and December 2022, and demographic data and postoperative outcomes were collected through retrospective reviews and telephonic interviews. Validated scales, including the PENN Shoulder Score (PSS), Disabilities of the Arm, Shoulder, and Hand (DASH) score, and Single Assessment Numeric Evaluation (SANE), were utilized for assessment.

RESULTS

Treatment with Sironix suture anchor devices, including Ceptre Knotted

UHMWPE Suture Titanium Anchor, Spyke Knotted UHMWPE Suture Peek Anchor, Stativ Knotted UHMWPE Suture Anchor, and Viplok Knotless Peek Screw Anchor with Titanium Tip, revealed no repair failures. Participants demonstrated high satisfaction and functional improvement, as evidenced by the mean Quick DASH score (32.01) and PSS (71.65) and the satisfactory SANE scores for both injured joints (74.33) and non-injured (83.67) shoulder joints.

CONCLUSION

The study yielded favorable outcomes for rotator cuff tear repair and Bankart repair. No repair failures were observed, supporting the safety and efficacy of these devices in shoulder injury management.

Key Words: Arthroscopic Bankart repair; Rotator cuff repair; Shoulder injuries; Suture anchor; Treatment outcome

Core Tip: This study assessed clinical outcomes and patient-reported outcomes after treating shoulder injuries using Sironix suture anchor devices. Treatment with Sironix suture anchor devices yielded favorable outcomes for rotator cuff tear repair and Bankart repair in terms of safety and efficacy.

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INTRODUCTION

The human shoulder boasts unparalleled mobility among joints, largely due to the intricate interplay of its structures. Central to its stability is the rotator cuff, which provides dynamic restraint through a concavity-compression mechanism [1]. Loss of rotator cuff integrity can precipitate shoulder instability, compromising function and causing significant impairment[2]. Rotator cuff repair aims to alleviate pain, restore function, and enhance shoulder strength and range of motion[3].

Arthroscopic techniques have gained prominence, offering advantages such as a reduced risk of complications and improved outcomes[4]. Traditionally, single-row repair techniques were employed, but concerns regarding the rotator cuff footprint reinstitution prompted the development of double-row or transosseous equivalent methods[5,6]. These newer techniques exhibit superior footprint restoration and biomechanical properties[7].

Shoulder stability is crucial for maintaining humeral head centrality within the glenoid fossa, with instability manifesting as dislocation or subluxation, primarily anteriorly[8-10]. Anterior shoulder dislocation frequently results in Bankart lesions, necessitating interventions to restore stability and prevent osteoarthritis[11,12]. Arthroscopic Bankart repair is a leading treatment, emphasizing the restoration of capsulolabral anatomy for optimal outcomes[13]. Rotator cuff repair is a common orthopedic procedure requiring meticulous attention to detail, including anchor selection[14,15]. While single-row, transosseous, and double-row repairs have proven efficacy, further studies are warranted to elucidate optimal techniques and implants[16]. Effective management of shoulder injuries is imperative for enhancing function and mitigating disability[17,18].

Recent data indicate a rising incidence of rotator cuff injuries worldwide, but specific prevalence rates in India are currently not available. However, anecdotal evidence suggests a growing number of cases, potentially influenced by lifestyle changes and increased participation in sports activities[19]. Additionally, comprehensive data on Bankart repair procedures in India are limited. This underscores the importance of comprehensive evaluation and tailored management strategies for shoulder injuries in the Indian population.

Orthopedic surgeons face several challenges in managing rotator cuff injuries, including achieving adequate tendon-to-bone healing, minimizing re-tear rates, and optimizing patient outcomes amidst varying tear patterns and patient characteristics[20]. Notably, the Sironix suture anchors (Healthium Medtech Ltd, Karnataka, India) have gained attention for their potential in enhancing rotator cuff repair outcomes. Preliminary data suggest favorable biomechanical properties and clinical outcomes with their use[21,22]. This study sought to fill the gap in the evidence on the effectiveness of suture anchors in rotator cuff repair and Bankart repair in patients in India. The findings provide valuable insights that can inform clinical practice and optimize patient care. This study also assessed the effectiveness and safety of interventions in treating shoulder injuries utilizing real-world postoperative data from the Indian population.

MATERIALS AND METHODS

Study design and participants

The research focused on evaluating postoperative outcomes following rotator cuff tear repair or Bankart repair using Sironix suture anchor devices. The study enrolled 60 subjects aged between 18 years to 80 years who underwent either rotator cuff tear repair or Bankart repair surgery between January 2021 and December 2022. Inclusion criteria encompassed male and female patients who had either rotator cuff tear repair or Bankart repair surgery between the specified dates with at least 4 months of follow-up after surgery. Exclusion criteria included patients with traumatic shoulder injuries occurring after the surgeries mentioned above and those unwilling to attend follow-up appointments.

Sample size

This study included all patients aged between 18 years to 80 years who underwent either rotator cuff tear repair or Bankart repair surgery between January 2021 and December 2022 as per the inclusion and exclusion criteria of the study.

Intervention and data collection

Patient data encompassing demographic profiles, medical histories, surgical procedures, and postoperative outcomes were meticulously curated through comprehensive retrospective medical record reviews and structured telephonic interviews. Patient-reported outcomes were assessed using validated scales such as the PENN Shoulder Score (PSS), Quick Disabilities of the Arm, Shoulder, and Hand (DASH) score, and Single Assessment Numeric Evaluation (SANE) score.

Outcome measures

The primary endpoint was rate of repair failure, as assessed by the need for a second surgery to address shoulder issues following the initial procedure. Secondary endpoints included patient-reported outcomes using the following three surveys: PSS (a questionnaire consisting of 30 items to assess shoulder function and pain); Quick DASH (an 11-item survey to evaluate daily activities and symptoms related to shoulder function); and SANE (a single question asking patients to rate their satisfaction with shoulder function on a scale of 0 to 100). These surveys were administered to patients to evaluate their shoulder function, pain levels, and satisfaction following their surgical procedure.

Statistical analysis

The primary endpoint of this study, the repair failure rate, was described descriptively. Secondary endpoints, including patient-reported outcomes (PSS, Quick DASH, SANE), underwent descriptive statistical analysis, including counts (n), means, medians, and SDs. In addition to the descriptive statistics mentioned, the SANE scores were subjected to a two-sample t-test for comparative analysis. The adverse events were summarized descriptively along with the total count of observed events.

Ethical consideration and quality control

This study was conducted in strict adherence to established regulatory standards after obtaining approval from the institutional ethics committee. All participants provided written or verbal informed consent before being included in the study.

RESULTS

Demographic characteristics

Table 1 provides a demographic overview of the enrolled participants. The mean (SD) age was 55.45 (60.50) years. There were slightly more male patients (n = 33, 55.0%) than females (n = 27, 45.0%). The mean (SD) total duration of follow-up was 20.67 (5.98) months.

Implant details

Table 2 summarizes the types and quantities of implants used in the study, with 80% utilization of the Ceptre Knotted UHMWPE Suture Titanium Anchor. This is indicative of its widespread adoption and effectiveness. The Spyke Knotted UHMWPE Suture Peek Anchor was used in 18.3% of cases, the Viplok Knotless Peek Screw Anchor with Titanium Tip in 80% of cases, and the Stativ Knotted UHMWPE Suture Anchor in 1.7% of cases.

Repair failure rate

There was no incidence of repair failure among any of the enrolled participants.

Patient-reported outcomes

The Quick DASH score reflected a low level of disability in activities of daily living (mean Quick DASH score: 32.01 ± 10.51), while the PSS indicated a high level of shoulder function and satisfaction (mean PSS: 71.65 ± 9.94). Table 3 presents the summary of the SANE enrolled set. The mean (SD) score of the SANE questionnaire for the operated shoulder and normal shoulder was 74.33 ± 9.54 and 83.67 ± 12.65, respectively, with a P value < 0.001. Table 4 presents the subgroup

Table 1 Summary of patient demographics

Characteristics	Overall, *n* = 60
Age (year)	
mean (SD)	55.45 (60.50)
Sex	
Female	27 (45.0)
Male	33 (55.0)
Race	
Asian Indian	60 (100.0)

Data are *n* (%) unless otherwise indicated.

Table 2 Summary of implant details, *n* (%)

Implant	Overall, *n* = 60
Name	
Ceptre knotted ultra-high molecular weight polyethylene suture titanium anchor 5.5 mm (Indication used: Arthroscopic rotator cuff repair)	48 (80.0)
Spyke knotted ultra-high molecular weight polyethylene suture peek anchor 2.5 mm (Indication used: Arthroscopic Bankart repair)	11 (18.3)
Stativ knotted ultra-high molecular weight polyethylene suture anchor 1.5 mm (Indication used: Arthroscopic Bankart repair)	1 (1.7)
Viplok knotless polyether ether ketone (peek) screw anchor with titanium tip 5.5 mm (Indication used: Arthroscopic rotator cuff repair)	48 (80.0)
Number used	
Ceptre knotted ultra-high molecular weight polyethylene suture titanium anchor	
1	40 (68.3)
2	8 (11.7)
Spyke knotted ultra-high molecular weight polyethylene suture peek anchor	
2	8 (13.3)
3	3 (5.0)
Stativ knotted ultra-high molecular weight polyethylene suture anchor	
1	1 (1.7)
Viplok knotless polyether ether ketone (peek) screw anchor with titanium tip	
1	29 (48.3)
2	18 (30.0)
3	1 (1.7)

analysis based on the indication of repair surgery and duration of follow-up periods alongside the corresponding mean scores for the PSS, Quick DASH, and SANE scores.

Summary of clinical outcome

A comprehensive overview of the clinical outcomes, including key measures such as repair failure rate, duration of follow-up, and patient-reported scores, are summarized in Table 5. Each outcome measure is described briefly, along with its interpretation based on the mean scores obtained during the study period. Repair failure rate indicates the absence of repair failures observed during the study, reflecting the efficacy and reliability of the treatment approach. Duration of follow-up presents the mean total duration of follow-up, providing insights into the length of time patients were monitored post-intervention. The PSS Total Score represents the mean total PSS, reflecting patients' subjective assessment of shoulder function. The high score suggested favorable patient-reported outcomes and functional improvement. The Quick DASH Total Score reflects the mean total Quick DASH score, indicating the degree of disability

Table 3 Summary of Single Assessment Numeric Evaluation

Characteristic/Statistic	Overall, *n* = 60	*P* value
SANE score (affected joint)		< 0.001
mean (SD)	74.33 (9.54)	
SANE score (opposite side)		
mean (SD)	83.68 (12.65)	

P value by two-sample *t*-test. SANE: Single Assessment Numeric Evaluation.

Table 4 Subgroup analysis based on the indication of repair surgery and duration of follow-up with mean of PENN Shoulder Score, Quick Disabilities of the Arm, Shoulder, and Hand score, and Single Assessment Numeric Evaluation score

Subgroup	Quick-DASH score	PSS	SANE score (affected joint)	SANE score (opposite side)
Subgroup analysis based on indication of repair surgery				
Arthroscopic Bankart repair, *n* = 11	31.41 (9.31)	75.91 (6.44)	75.91 (3.75)	87.27 (9.32)
Arthroscopic rotator cuff repair, *n* = 49	32.14 (10.85)	70.69 (10.38)	73.98 (10.41)	82.86 (13.23)
Subgroup analysis based on duration of follow-up				
6 months to 1 year, *n* = 8	30.66 (4.54)	74.88 (6.75)	81.88 (7.53)	90.00 (7.07)
1 year to 2 years, *n* = 33	34.30 (12.09)	69.15 (11.67)	73.79 (10.23)	85.00 (14.42)
> 2 years, *n* = 19	28.59 (8.48)	74.63 (6.23)	72.11 (7.69)	78.68 (9.40)

Data are mean (SD). DASH: Disabilities of the Arm, Shoulder, and Hand; PSS: PENN Shoulder Score; SANE: Single Assessment Numeric Evaluation.

Table 5 Summary of clinical outcome

Outcome measure	Description	Interpretation
Repair failure rate	No repair failures observed	N/A; Successful surgeries
Adverse device effects	No adverse device effects reported	N/A; Safe device usage
Duration of follow-up	Total duration of follow-up: 20.67 (5.98) months	N/A; Provides contextual information about the timeframe of the study
Total PSS	71.65 (9.94)	High: Reflects improved shoulder function
Total Quick DASH score	32.01 (10.51)	Low: Indicates lower disability and impairment
SANE score (affected joint)	74.33 (9.54)	High: Signifies better function and less pain in the affected joint
SANE score (opposite side)	83.67 (12.65)	High: Indicates better function and less pain in the unaffected joint compared to the affected joint

Data are mean (SD). DASH: Disabilities of the Arm, Shoulder, and Hand; N/A: Not available; PSS: PENN Shoulder Score; SANE: Single Assessment Numeric Evaluation.

in daily activities. The low score suggested minimal impairment in functional activities. The SANE score (affected joint and opposite side) represents the mean SANE score for both the affected joint and the opposite side. The high score indicated favorable patient satisfaction and functional improvement in shoulder function. The interpretation of each measure provided valuable insights into the efficacy and impact of the intervention on patient outcomes, aiding in the assessment of treatment effectiveness and patient satisfaction.

DISCUSSION

This study focused on assessing the clinical outcomes, patient-reported outcomes, and safety after arthroscopic rotator cuff repair and Bankart repair surgeries using Sironix suture anchor devices. Commencing with meticulous screening and eligibility confirmation, the study collected responses regarding clinical outcomes and patient-reported outcomes, ensuring stringent privacy and confidentiality protocols. The primary endpoint of this investigation, aimed at evaluating repair failure, yielded promising results, with no instances of failure observed in the current study cohort.

In contrast, a separate study[23] exploring re-tear rates after rotator cuff surgery revealed varying failure rates: 15% at 3 months follow-up; 21% at 3-6 months; 16% at 6-12 months; and 21% at 12-24 months. There was a subsequent decrease to 16% in follow-ups exceeding 24 months. These findings underscore the multifaceted nature of patient-related and non-patient-related factors influencing surgical outcomes. Additionally, a comparative study examining the efficacy of knotless *vs* conventional knot-tying suture bridge techniques in managing full-thickness rotator cuff tears demonstrated the absence of failures with the knotless technique, further emphasizing its potential as a viable alternative in surgical interventions.

The mean (SD) total PSS among all participants in the present study was 71.65 (± 9.94). This aligns closely with findings from a retrospective investigation[24] evaluating the clinical outcomes of arthroscopic repair for massive rotator cuff tears over at least 5 years of follow-up. In that study, patients with both partial and full coverage rotator cuff tears exhibited an average PSS of 75.8.

The mean (SD) total Quick DASH score was 32.01 (± 10.51) in the current study. These findings align with those observed in a study[25] investigating arthroscopic treatment of rotator cuff rupture in patients aged over 60 years, demonstrating a significant reduction in the Quick DASH score from 52.5 before surgery to 11.0 at final follow-up. Similarly, the Quick DASH score in another study[26] reported an improvement from 36.1 to 14.1.

The mean (SD) SANE score was 74.33 (± 9.54) for the injured shoulder and 83.67 (± 12.65) for the non-injured shoulder. A retrospective study involving 44 patients (33 males, 11 females) demonstrated an enhancement in the SANE score from 63.1 (preoperatively) to 85.1 (postoperatively)[27]. Certainly, the study did not document any untoward effects or mortalities attributable to the medical devices employed among the enrolled cohort.

There was a trifecta of limitations to this study: A modest sample size; its retrospective design; and the conspicuous absence of baseline preoperative assessments. Another noteworthy limitation pertained to the oversight of variables such as the chronicity of tears, which might have introduced confounding elements into the outcomes. Additionally, the lack of postoperative imaging data pertaining to rotator cuff repairs warrants consideration. Factors such as the level of surgeon experience or any patient adherence issues with postoperative rehabilitation may also impact outcomes. This lacuna underscores the potential for future investigations to delve deeper into this domain, preferably through meticulously crafted, prospective, randomized trials. Such endeavors hold promise for shedding light on the comparative postoperative enhancements in relation to preoperative scores and repair failure rates, thereby enriching the orthopedic literature.

CONCLUSION

The study evaluated clinical outcomes and patient-reported outcomes following shoulder injury treatment with Sironix suture anchor devices. Utilizing the Ceptre Knotted UHMWPE Suture Titanium Anchor, Spyke Knotted UHMWPE Suture Peek Anchor, Stativ Knotted UHMWPE Suture Anchor, and Viplok Knotless Peek Screw Anchor with Titanium Tip, our findings indicated that the Sironix suture anchors demonstrated a high success rate, supporting their use in rotator cuff and Bankart repairs. Further investigations into long-term outcomes could establish these devices as a preferred choice for improving shoulder function.

FOOTNOTES

Author contributions: Kumar PV, Sugath S, Mohan V, Moharana AK, Angrish S, and TS D contributed to the conception and design of the study, preparation of the materials, collection and analysis of the data, and review and approval of the final manuscript.

Institutional review board statement: This study was approved by Institutional Research and Ethics Committee Aster Medcity, Kochi on 23rd June 2023 with approval identifier AM/EC/325-3023.

Informed consent statement: Informed consent was obtained from all patients prior to participation.

Conflict-of-interest statement: Moharana AK, Angrish S, and TS D are employees of Healthium Medtech Limited, India, who are manufacturers of Sironix shoulder implants. Kumar V, Sugath S, and Mohan V declare no conflicts of interest.

Data sharing statement: Statistical code and dataset available from the corresponding author at deepak.ts@healthiummedtech.com. Participants gave informed consent for presenting anonymized data.

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