Original Article

Arthroscopic Rotator Cuff Restoration Using Sironix Suture Anchor: A Retrospective Observational Study

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Abstract

Purpose: The most effective approach to treat individuals with rotator cuff tears (RCTs) remains uncertain, but operative treatment, especially arthroscopic surgery with various suture anchors, is becoming more popular. The purpose of this study was to assess the functional outcomes in patients who underwent arthroscopic RCTs restoration using Sironix suture anchors. **Materials and Methods:** Eighty patients (36 males and 44 females) who had arthroscopic rotator cuff restoration using Sironix suture anchors were included. Postoperatively, patients were followed up and functional outcomes were evaluated using the American Shoulder and Elbow Surgeons Standardization Shoulder Assessment (ASES), level of activity using the Simple Shoulder Test (SST) questionnaire, Quality of life using the Shoulder Pain and Disability Index (SPADI) scale, and Single Assessment Numerical Evaluation (SANE) score on a scale of 0–100. Adverse events were recorded post-RCTs restoration. **Results:** The functional outcomes were presented as the mean (standard deviation [SD]) values of total ASES, SPADI, and SST scores, which were observed to be 92.6 (05.28), 01.6 (02.46), and 90.3 (14.22), respectively. The SANE mean (SD) values of the operated shoulder and the opposite shoulder were 91.8 (10.22) and 97.3 (5.68), respectively, with a $P = 0.0001$. No serious adverse events were reported and none of the subjects discontinued the study. **Conclusions:** The current study demonstrated that the functional outcomes were quite satisfactory, with good results. Therefore, Sironix shoulder implants (CEPTRE® Knotted UHMWPE Suture PEEK Anchor and CEPTRE® Knotted UHMWPE Suture Titanium Anchor) were considered safe and effective in rotator cuff restoration.

Keywords: PEEK anchor, restoration, rotator cuff tears, suture anchor, titanium anchor

Introduction

Rotator cuff tears (RCTs) are among the most common muscle injuries,[1] with a prevalence of 20% in the general population which increases with age, whereas 50% of tears are degenerative and occur in patients over 80 years. A large subset of tears occurs in the athletic population. RCTs can be classified as chronic tendinosis, partial thickness tears (articular, bursal, or intratendinous), and full-thickness tears, with or without accompanying disease.[2]

RCTs can be managed with conservative options such as physiotherapy, nonsteroidal anti-inflammatory agents, and corticosteroid injections. If conservative measures fail, surgical treatments may be offered, with open and arthroscopic techniques being standard. Common arthroscopic techniques include single-row and double-row techniques with the usage of suture anchors. There is no clear evidence of superior clinical outcomes or healing rates. Surgical intervention may be considered when nonoperative management fails.[3]

The ultimate objective of any rotator cuff restoration should be tendon healing. One of the most significant advances in arthroscopic RCT restoration has been the development of suture anchors.[4,5] Suture anchors have revolutionized orthopedic surgery by enabling faster and more efficient fixation of tendons to bones in both open and arthroscopic surgery, resulting in better clinical outcomes.[6] They offer

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increased tissue holding strength and reduced surgical time due to their ease of placement. They do not migrate in the shoulder joint and do not cause arthritic changes.[7] The suture anchor is widely accepted as the gold standard for RCT restoration.[8]

International literature suggests arthroscopic surgery using suture anchors is the best strategy for restoring rotator cuff lesions.[9,10] Recent investigations have shown that conventional suture anchors produce 90% to 95% good to outstanding results.[11]

Over the last decade, various types of anchors have been produced and anchor designs have improved to maximize their efficiency in producing a firm tendon-to-bone restoration. Because of its exceptional performance, PEEK is increasingly being employed in Arthroscopic surgery. Furthermore, Metallic anchors were the first-generation suture anchors, and titanium is commonly employed in orthopedic applications.[12] However, an ideal material should provide good fixation strength and minimal soft-tissue reaction with better functional outcomes.[13]

Therefore, the current study was undertaken to evaluate the functional outcomes in patients who underwent arthroscopic RCTs restoration using various Sironix suture anchors.

Materials and Methods

Study design and patient selection

Between January 2019 and June 2022, 80 patients had an arthroscopic RCT restoration using the Sironix Suture Anchors at Advanced Surat Traumatology and Orthopaedic Surgery Hospital, Surat, Gujarat, India. This was a retrospective observational study with ethical approval granted by the institutional ethics committee, and informed consent was obtained from all patients before participation. All eighty patients met the inclusion criteria which included patients having an arthroscopic rotator cuff restoration using the Sironix suture anchor, and patients who were 18–80 years of age. Patients who were not responding to calls after three attempts or were not interested in participating in the study and patients with traumatic injury to the same shoulder post RCTs restoration procedure were excluded from the study.

From all the study participants, baseline demographic data and other clinical characteristics were collected. The study-specific physical examinations and outcome assessments were performed at the patient's follow-up visit. The primary purpose of this study was to evaluate the function of the shoulder after arthroscopic RCTs restoration which was assessed using American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), and the secondary purpose was to assess the level of activity postsurgery using the simple shoulder test (SST) questionnaire, and quality of life after RCTs restoration using the Shoulder Pain and Disability Index (SPADI) scale, Single Assessment Numerical Evaluation (SANE) score on a scale of 0–100 and any adverse events, post-RCTs restoration.

Data collection and outcomes

Preoperative data collection included basic demographics, clinical histories, and laboratory data such as radiology including magnetic resonance imaging and X-rays were collected from hospital records. Moreover, the postsurgery follow-up was conducted either by in-clinic visit or telephonic visit and the data such as ASES, SST, SPADI, SANE, and adverse events were collected for study assessment.

Study implants

CEPTRE® Knotted UHMWPE Suture PEEK Anchor [Figure 1].

CEPTRE® Knotted UHMWPE Suture Titanium Anchor [Figure 2].

Description of devices used in the study

Both CEPTRE® Knotted UHMWPE Suture PEEK Anchor and CEPTRE® Knotted UHMWPE Suture Titanium Anchor (Sironix, Healthium Medtech Limited, Bengaluru, Karnataka, India) are intended to be used for soft-tissue fixation to the bone. PEEK Anchor is made up of polyether ether ketone, and titanium anchor is made up of titanium alloy.

Statistical analysis

To summarize the demographic data and the surgery details, descriptive statistics were employed. Data for qualitative factors were reported as percentages and data for quantitative variables were reported as mean ± standard deviation (SD). An independent *t*-test was employed to compare the mean SANE scores between the operated and normal shoulder. A significance level of $P \leq 0.05$ was considered indicative of statistical significance (SAS 9.4, SAS Institute Inc., North Carolina, USA).

Results

Eighty patients who underwent arthroscopic rotator cuff restoration using the Sironix suture anchors were evaluated for functional outcomes at postsurgery follow-ups. The average age was 59 (8.36), and BMI (kg/m^2) was 26.7 (4.88). There were 36 (45.0) men and 44 (55.0) women.

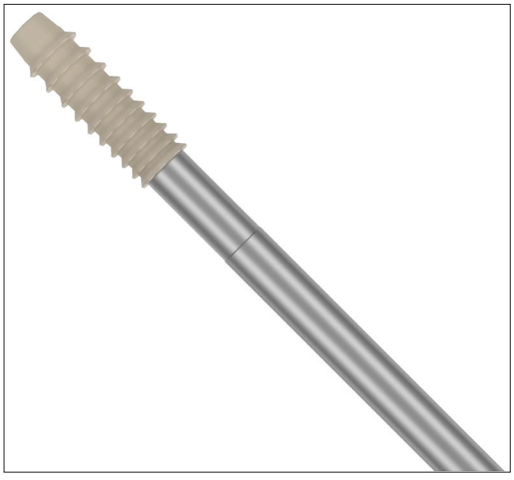

Figure 1: CEPTRE® Knotted UHMWPE Suture PEEK Anchor

Figure 2: CEPTRE® Knotted UHMWPE Suture Titanium Anchor

Among 80 patients, 76 had supraspinatus tendon tears, 4 had subscapularis tendon tears, and 17 had infraspinatus tendon tears. 71.3% of patients had right shoulder injuries, 28.7% had left shoulder injuries, and 97.5% had no injuries to their opposing shoulders [Table 1].

A total of 96 devices were implanted for 80 patients, with one patient receiving three devices, 14 receiving two devices, and 65 receiving one device (64 peek screw anchors and 1 titanium screw anchor).

Postoperative functional outcome measures

Primary functional outcome

Evaluation of American Shoulder and Elbow Surgeons Assessment Score

The ASES Score was used to assess the condition of the shoulder during postsurgery periods. The total mean (SD) ASES assessment score for all 80 patients was 92.6 (5.28), the mean (SD) of pain score was 43.6 (3.00) out of 50 points, and the mean (SD) of ADL score was 49 (3.02) out of 50 points. The mean (SD) values of the total ASES score for 32 patients with a duration of 6 months to 1 year were 93.3 (3.50), for 46 patients with a duration of 1–2 years, 92 (6.28), for one patient with a duration of <6 months, 95, and for the one patient with a duration of more than 2 years, 95 [Table 2].

As shown in Figure 3, The mean pain score, ADL score, and total ASES score in 79 patients who were implanted with 95 PEEK Anchor devices were 43.5 (3.01), 48.27 (2.87), and 91.81 (5.37). The pain score, ADL score, and total ASES score in one patient who was implanted with one titanium anchor device were 45, 50, and 95.

Secondary outcomes

Assessment of shoulder pain and disability index score

SPADI score was used to assess the quality of life after RCT restoration. The overall mean (SD) value of the total SPADI score for 80 patients was 1.6 (2.46). The mean (SD) values of the total SPADI score for 32 patients with a duration of 6 months to 1 year were 1.3 (1.80), for 46 patients with a duration of 1–2 years, 1.8 (2.85), for one patient with a duration of <6 months, 3.8, and for the one patient with a duration of more than 2 years, 0 [Table 3].

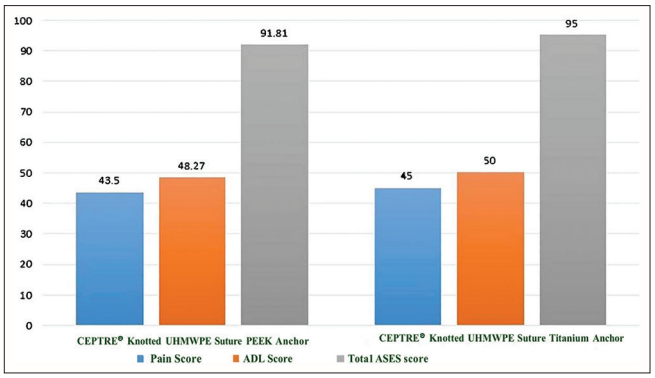

Figure 3: Graphical representation of ASES score by devices

Table 1: Baseline demographic and surgery details

Description	Values
Age (years)	
n	80
Mean±SD	59±8.36
Gender, *n* (%)	
Male	36 (45.0)
Female	44 (55.0)
Body weight (kg)	
n	79
Mean±SD	71.6±13.57
Height (cm)	
n	79
Mean±SD	164±6.61
BMI (kg/m^2)	
n	79
Mean±SD	26.7±4.88
Rotator cuff injury, *n* (%)	
Infraspinatus tendon tear	17 (21.3)
Subscapularis tendon tear	4 (5.0)
Supraspinatus tendon tear	76 (95.0)
Reason for injury, *n* (%)	
Accident	6 (7.5)
Jerk during activity	13 (16.3)
Fall	59 (73.8)
Reason not known	2 (2.4)
Which shoulder injury?, *n* (%)	
Right	57 (71.3)
Left	23 (28.7)
Condition of the opposite shoulder, *n* (%)	
No injuries	78 (97.5)
Injury present, but not operated	2 (2.5)
Number of devices implanted in patients	96*
Implant used, *n* (%)	
CEPTRE® Knotted UHMWPE Suture PEEK Anchor	95 (118.8)
CEPTRE® Knotted UHMWPE Suture Titanium Anchor	1 (1.3)

*Multiple devices implanted to same patients. *n*: Number of patients, %: Percentage of patients, SD: Standard deviation, BMI: Body mass index

Simple shoulder test questionnaire score

To assess the activity level after RCT restoration, the SST questionnaire was used. A total of 80 patients had a total mean (SD) SST score of 90.3 (14.22) after surgery [Table 4].

Single assessment numeric evaluation score

The SANE mean (SD) values of the operated shoulder and the opposite shoulder were 91.8 (10.22) and 97.3 (5.68), respectively, with a $P = 0.0001$ [Table 4].

Adverse events

Of the 80 patients, 10 experienced adverse effects. Eight patients experienced pain, with 5 having Grade 1 (mild) pain, 2 having Grade 2 (moderate) pain, and 1 having Grade 3 (severe) pain. Two patients experienced "musculoskeletal stiffness" and both had Grade 1 (mild) pain. There were no serious adverse events, and none of the patients were discontinued from the study.

Discussion

Arthroscopic rotator cuff repair has gained popularity due to favorable results, technical advancements, and increased patient demand for minimally invasive procedures with reduced morbidity and faster recovery.[11] With a great deal of research being done assessing procedures and results, arthroscopic rotator cuff restoration is becoming more and more common. Suture anchors are proven to be efficient in treating RCTs, according to numerous research. The principal findings of this study suggest that arthroscopic rotator cuff restoration can provide significant improvements in functions such as range of motion, stability, shoulder strength, and pain reduction with relatively low safety issues.[14] Different types of devices were in use to treat RCTs, Sironix Suture Anchor device (CEPTRE® Knotted UHMWPE Suture PEEK Anchor and CEPTRE® Knotted UHMWPE Suture Titanium Anchor) was used in this study, and functional outcomes were assessed using ASES, SPADI, SST, and SANE scores.

In the current study, over a 2-year follow-up period, the mean (SD) total ASES score was 92.6 (5.28). Similarly, a study that used the University of California at Los Angeles and ASES ratings to assess the clinical outcomes of arthroscopic rotator cuff restoration found that the ASES score after 24 months of surgery was 81.2 (20.8).[15]

A research study comparing Arthroscopic Single and Double-Row Rotator Cuff Repair by Burks *et al*. found that the mean ASES score was 85.7 for a period of 6 months to 1 year, whereas the ASES score in the current study for the same period was 93.3 (3.50), indicating superior results.[16] Furthermore, after a 2-year follow-up, the mean ASES score in a study by Carbonel *et al*. for single row and double row was 84.6 (6.1) and 85.2 (3.2), respectively.[17] However, the present study showed that the ASES score for 1–2 years was 92.0 (6.28). These findings were not significantly different when compared to our study findings. A prospective observational study conducted by Lee and Lee reported that the

Table 2: Performance outcome measure of American Shoulder and Elbow Surgeons Shoulder score

Description (mean±SD)	<6 months (*n*=1)	6 months–1 year (*n*=32)	1 year–2 years (*n*=46)	>2 years (*n*=1)	Total (*n*=80)
Pain score	45.0±	43.9±2.10	43.3±3.53	45.0±	43.6±3.00
ADL score	50.0±	49.4±2.46	48.7±3.41	50.0±	49.0±3.02
Total ASES score	95.0±	93.3±3.50	92.0±6.28	95.0±	92.6±5.28

Total ASES score: Sum of (pain score and ADL score). *n*: Number of patients, SD: Standard deviation, ADL: Activity daily living score, ASES: American Shoulder and Elbow Surgeons Shoulder score

Table 3: Summary of the Shoulder Pain And Disability Index score

Description (mean±SD)	<6 months (*n*=1)	6 months–1 year (*n*=32)	1 year–2 years (*n*=46)	>2 years (*n*=1)	Total (*n*=80)
Pain Scale score	6.0±	2.0±2.87	2.4±3.93	0.0±	2.3±3.51
Disability Scale score	2.5±	0.9±1.25	1.4±2.26	0.0±	1.2±1.91
Total score	3.8±	1.3±1.80	1.8±2.85	0.0±	1.6±2.46

n: Number of patients, SD: Standard deviation

Table 4: Subjective percentage of Simple Shoulder Test Questionnaire Score and Single Assessment Numerical Evaluation scores

Description	Duration				
	<6 months (*n*=1)	6 months–1 year (*n*=32)	1 year–2 years (*n*=46)	>2 years (*n*=1)	Total (*n*=80)
SSTQ score	66.6±	91.1±13.21	90.0±14.82	100±	90.3±14.22
SANE score					
Operated shoulder	80.0±	93.3±9.65	90.8±10.58	100±	91.8±10.22
Opposite shoulder	100±	97.2±6.34	97.3±5.34	100±	97.3±5.68
P	0	0.0607	0.0006	0	0.0001

n: Number of patients, SD standard deviation, SANE: Single Assessment Numeric Evaluation, SSTQ: Simple Shoulder Test Questionnaire

mean and SD of the ASES score for 6 months after RCT surgery was 79.1 (7.3). In contrast, our study results demonstrated that the ASES score for 6 months to 1 year was 93.3 (3.50), which was significant.[18]

In a prospective observational study, Lee and Lee reported that the mean (SD) of the SST score 6 months after rotator cuff restoration was 62.5 (13).[18] The current study found that the SST scores between 6 months and a year were 91.1 (13.21), which is highly significant. The mean percentage of total SST score in the current study was 90.3 (14.22). Conversely, Berglund *et al*. reported that after 2 years of follow-up, the SST score improved to 72.1%.[19]

The SPADI score is a combination of two indices, i.e., pain and disability. The mean (SD) of the total SPADI score was 1.6 (2.46). The mean pain score was 2.3 (3.51) and the mean disability score was 1.2 (1.91). In a study by Polacek and Nyegaard, the postoperative mean SPADI score was found to be 9.7 (12.3). The mean (SD) pain score was 9.3 (15.0), and the mean (SD) disability score was 9.9 (11.2) at 1-year follow-up.[20]

In the current study, the mean (SD) SANE score at 6-month to 1-year follow-up was 93.3 (9.65). These findings are consistent with those of Burks *et al*., who reported that the SANE score after a 1-year follow-up was 90.4 (15.9).[16] However, in this study, the SANE value of the operated shoulder was statistically significant than the nonoperated opposite shoulder. This significant difference in the SANE scores between the operated and the nonoperated opposite shoulder is not an uncommon finding. Patients may perceive a difference in function between the two shoulders, even if the surgical outcome is deemed successful.[21]

A retrospective study by Panchal *et al*. (2023) assessing safety, efficacy, and functional outcomes post-rotator cuff repair found no postsurgery complications.[22] Similarly, in the current study, no serious adverse events were noted in any of the patients and no patients were discontinued from the study. In contrast, two different investigations by Kim *et al*., and Park *et al*. reported re-tear rates of 6.1% and 18.5%, respectively.[10,23]

Limitations

There were a few drawbacks to the study, including as a retrospective observational study, more prospective studies, particularly randomized controlled trials, should be conducted to offer better evidence. However, long-term follow-up data which are generated in this study in a real-world setting adds value. In addition, considering the observation that this study results have shown a significant correlation in terms of ASES score, SST score, SPADI score, and SANE score with the already published literature, it validates the current study findings.

Conclusions

The current study demonstrated that the functional outcomes were quite satisfactory, with good results as evidenced by ASES, SST, SPADI, and SANE scores. Furthermore, the results of this study revealed a substantial correlation between ASES, SST, SPADI, and SANE scores and previously published literature. Therefore, based on the performance and safety outcomes, it can be concluded that the Sironix shoulder implants (CEPTRE® Knotted UHMWPE Suture PEEK Anchor and CEPTRE® Knotted UHMWPE Suture Titanium Anchor) are regarded as safe and effective in rotator cuff restoration surgery.

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Conflicts of interest

There are no conflicts of interest.

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