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Original Research Article

Evaluation of safety and functional outcomes after rotator cuff repair using Sironix suture anchor

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ABSTRACT

Background: Arthroscopic rotator cuff repair procedures are performed to maximize clinical and functional outcomes. The surgical sector is experiencing a surge in repair surgeries involving arthroscopic repair of torn tendons using surgical implants. The study aimed to evaluate the safety and functional outcomes of rotator cuff tear repair using Sironix suture anchors.

Methods: Patients with a mean age of 53.8 years who underwent arthroscopic rotator cuff repair using a Sironix suture anchor between January 2019 and June 2022 were included in this retrospective observational study. Postoperatively, patients were assessed using the American shoulder and elbow surgeons score (ASES), level of activity using the simple shoulder test questionnaire (SST), quality of life using the shoulder pain and disability index scale (SPADI), the single assessment numerical evaluation score (SANE), and adverse events associated with study devices.

Results: Significant and clinically relevant ASES, SST, SPADI, and SANE scores were observed in all patients. The mean (SD) values of total ASES, SST, and SPADI scores were 91.6 (6.21), 94.1 (10.74), and 1.3 (2.48), respectively. The mean (SD) value of total SANE score in the affected joint was 95.8 (7.70), and the opposite side was 99.0 (3.04). No serious adverse events were reported.

Conclusions: Sironix suture anchors (CEPTRE® knotted UHMWPE suture PEEK anchor, CEPTRE® knotted UHMWPE suture PLDLA-βTCP anchor, VIPLOK® knotless PEEK anchor with titanium tip and VIPLOK® knotless PLDLA-βTCP anchor with titanium tip) have proven to be both safe and effective in repairing rotator cuff tears, enhancing shoulder function without any serious adverse effects.

Keywords: Arthroscopic cuff repair, Rotator cuff tears, Shoulder impairment, Suture anchor

INTRODUCTION

Rotator cuff tears (RCT) are the most common cause of shoulder impairment, affecting millions of individuals globally, and increasing in prevalence with age, potentially resulting in persistent pain and joint disability.[1-3] The estimated prevalence is between 20% and 30% of the general population.[4] Rotator cuff injuries can be managed conservatively with injection therapy, medications, or physiotherapy, but often result in poor functional outcomes. If conservative treatment fails, surgical intervention may be considered, and arthroscopy can improve shoulder function and facilitate a quick recovery.[5,6]

The advancement in surgical repair techniques has led to improved functional outcomes and a reduction in re-tear rates during the reattachment of the rotator cuff in RCR.[7] An arthroscopic repair is a common approach for treating rotator cuff tears, involving the use of sutures and anchors to reattach the torn tendon.[4]

In recent years, suture anchor-based fixation techniques have gained popularity due to their improved biomechanics and ease of handling.[8] The benefits of this fixation technique encompass the reduction of soft tissue damage and postoperative complications.[9] The main purpose of the suture anchor is to securely affix tissue at the appropriate location and sustain its place without experiencing excessive strain until natural healing occurs.[10] The success of an arthroscopic repair is significantly influenced by the configuration of suture anchors and the biomechanical strength of the repair construct.[11]

The increasing application of suture anchors has given rise to a variety of material-specific advantages and challenges. As a result, continuous advancements are being made to suture anchors to improve their effectiveness and safety.[12]

According to recent literature, there were no statistically significant differences in clinical and functional outcomes using knotted versus knotless suture anchor techniques for arthroscopic rotator cuff repairs. Still, there is ongoing debate concerning the most effective arthroscopic repair technique that promotes tendon-bone recovery and yields superior outcomes.[12] Given the limited data available on the use of both knotted and knotless anchors for cuff repair, this current study was designed to address this gap. Therefore, the present study was designed to evaluate the safety and functional outcomes of various types of Sironix suture anchors.

METHODS

Between 23 September 2022, and 23 December 2022, this retrospective, single-center, observational study was conducted at Saifee Hospital, Mumbai, Maharashtra, India. The Institutional Ethics Committee assessed and approved the study protocol. The study was registered at CTRI under the reference CTRI/2022/12/048062.

Patients were eligible for inclusion if they were within the age range of 18 to 80 years, had undergone arthroscopic rotator cuff tear repair utilizing Sironix suture anchors between January 2019 and June 2022, and had provided written informed consent during an in-clinic follow-up visit or verbal consent during a telephonic follow-up visit. Patients who did not respond to calls after three attempts or were not interested in participating in the study, and patients who had a traumatic injury to the same shoulder post-rotator cuff tear restoration procedure, were excluded from the study. Participants were screened *via* telephonic visit. A total of 40 patients who met the above eligibility criteria were enrolled in the study.

For each participating patient, demographic data (age, sex, affected side), medical, radiological (MRI, X-ray), and surgical information were collected from hospital records. The primary objective was to evaluate the function of the shoulder after arthroscopic rotator cuff tear repair. The secondary endpoints were to assess the level of activity pre-injury and post-surgery, the quality of life after rotator cuff tear repair, and the adverse events associated with arthroscopic rotator cuff tear repair. Patient functional outcomes were assessed using the American shoulder and elbow surgeons standardized shoulder assessment form (ASES), the simple shoulder test (SST) questionnaire, the shoulder pain and disability index (SPADI), and the single assessment numerical evaluation (SANE) at each postoperative follow-up visit (6 months to 1 year, 1 year to 2 years, and more than 2 years). The medical dictionary for regulatory activities (MedDRA) was used to summarize adverse occurrences.

The following arthroscopic shoulder implants were used in the study: CEPTRE® knotted UHMWPE suture PEEK anchor–screw/wedge, CEPTRE® knotted UHMWPE suture PLDLA-βTCP anchor–screw/wedge, VIPLOK® knotless PEEK anchor with titanium tip, and VIPLOK® knotless PLDLA-βTCP anchor with titanium tip (Sironix division, Healthium Medtech Limited, India).

Device description

CEPTRE® knotted UHMWPE suture PEEK anchor and CEPTRE® knotted UHMWPE suture PLDLA-βTCP anchor are intended to be used for soft tissue fixation to the bone (Figures 1 and 2).

VIPLOK® knotless PEEK anchor with titanium tip and VIPLOK® knotless PLDLA-βTCP anchor with titanium tip are intended to be used for soft tissue fixation to the bone (Figures 3 and 4).

Figure 1: CEPTRE® knotted UHMWPE suture PEEK anchor.

Figure 2: CEPTRE® knotted UHMWPE suture PLDLA-βTCP anchor.

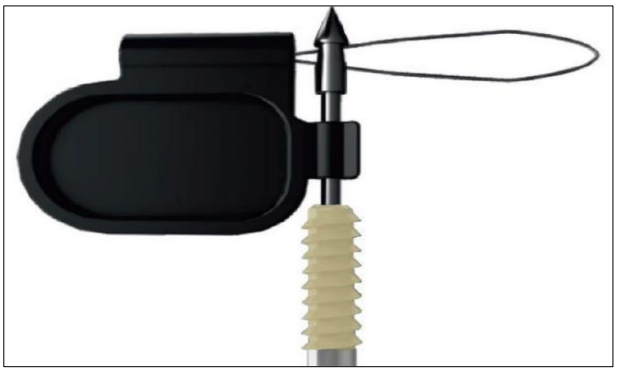

Figure 3: VIPLOK® knotless PEEK anchor with titanium tip.

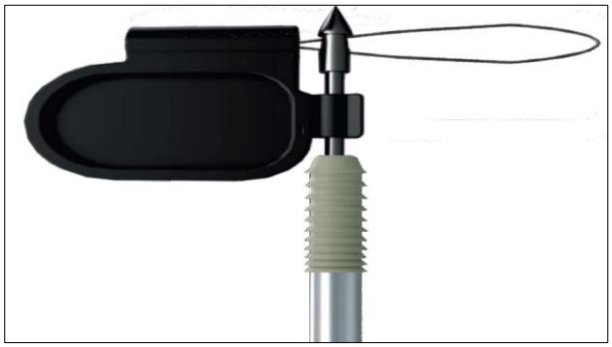

Figure 4: VIPLOK® knotless PLDLA-βTCP anchor with titanium tip.

Statistical analysis

Descriptive statistics were utilized to summarize the demographic data. The data were reported in the form of percentages for qualitative variables and in terms of the mean and standard deviation for quantitative variables. The SST score was analyzed using descriptive statistics at pre-injury and post-surgery using paired t-test/Wilcoxon test based on normality with 95% confidence interval.

RESULTS

Among the 40 patients, the average age of the patients was 53.8 (16.0) years, comprising 21 male patients and 19 female patients. The average body mass index (BMI) (kg/m^2) was 26.2 (5.99), and the average height (cm) was 163 (7.85). Demographic, clinical characteristics, and surgery details of patients are provided in Table 1. Among 40 patients, 19 had a grade-1 injury, 18 had a grade-2 injury, and 2 had a grade-3 injury. 77.5% of patients were injured on the right shoulder, and 22.5% were injured on the left shoulder. The leading cause of injury was recognized as falls in 37 patients, while 2 patients had accidents, and only 1 patient had been experiencing persistent pain over the last few months (Table 1).

The post-surgery functional outcomes were depicted in the preceding Table 2.

Table 1: Baseline demographic and clinical characteristics.

Variables	N=40
Gender, N (%)	
Male	21 (52.5)
Female	19 (47.5)
Age (years)	53.8 (16.0)
Body weight (kg)	69.1 (13.56)
Which shoulder injury?	
Right	31 (77.5)
Left	09 (22.5)
Rotator cuff injury*	
Grade-1	19 (47.5)
Grade-2	18 (45.0)
Grade-3	02 (05.0)
Reason for injury	
Accident	02 (05.0)
Patient feels pain from last few months	01 (02.5)
Fall	37 (92.5)
No of patients implanted with the device	40
No of devices implanted in patients	51
CEPTRE® knotted UHMWPE suture PEEK anchor – screw	19 (47.5)
CEPTRE® knotted UHMWPE suture PEEK anchor – wedge	3 (7.5)
CEPTRE® knotted UHMWPE suture PLDLA- βTCP anchor – screw	1 (2.50)
CEPTRE® knotted UHMWPE suture PLDLA- βTCP anchor – wedge	3 (7.5)
VIPLOK® knotless PEEK anchor with titanium tip	14 (35)
VIPLOK® knotless PLDLA- βTCP anchor with titanium tip	11 (27.5)

N: Number of patients, *one patients grade of rotator cuff injury was not available

American shoulder and elbow surgeons standardized shoulder assessment (ASES) score

The mean (SD) of the total ASES score of 40 patients was 91.6 (6.21). The mean (SD) of the total pain score was 43.3 (3.68), and the mean (SD) of the total ADL score was 48.4 (2.95) (Table 2).

Shoulder pain and disability index (SPADI) score

Among the 40 patients, the mean (SD) of the total SPADI score, pain score, and disability score were 1.3 (2.48), 2.1 (4.43), and 0.8 (1.46), respectively (Table 2).

Single assessment numerical evaluation (SANE) score

Out of 40 patients, the mean (SD) of the total SANE score in the affected joint and the opposite side were 95.8 (7.70) and 99.0 (3.04), respectively (Table 2).

Simple shoulder test questionnaire

Of 40 patients, the mean (SD) percentage of Simple shoulder test questionnaire (SST) pre-injury and post-surgery were 86.0 (12.46) and 94.1 (10.74), respectively, with a p value of 0.000 demonstrating a significant improvement in the patients' activity level following the surgery (Table 2).

ASES assessment by devices

A total of 51 devices were implanted in 40 patients, of which 19 Ceptre PEEK screw anchor devices achieved a mean score of 91.8 (6.13), while 3 Ceptre PEEK wedge anchor devices achieved a mean score of 95.0 (0.00). One Ceptre PLDLA-βTCP screw anchor device achieved a mean score of 70.0, while three Ceptre PLDLA-βTCP wedge anchor devices achieved a mean score of 86.7 (0.00). 11 Viplok knotless βTCP screw anchors with titanium tip devices achieved a mean score of 91.4 (5.21). 14 Viplok Knotless PEEK screw anchors with titanium tip devices achieved a mean score of 93.7 (2.94) (Figure 5).

Adverse events

Among the 40 patients, two experienced grade 3 (severe) pain. No serious adverse events (neither life-threatening nor death) were noted in any of the patients. Furthermore, none of the participants withdrew from the study.

Table 2: Summary of post-surgery functional outcomes.

Outcome	Postoperative			
	6 months to 1 year (N=12)	1 year to 2 years (N=11)	More than 2 years (N=17)	Total (N=40)
American shoulder and elbow surgeons assessments (ASES)				
Pain score	44.6±1.44	43.6±2. 34	42.1±5.02	43.3±3.68
ADL score	49.6±1.44	48.0±3.19	47.7±3.42	48.4±2.95
Total ASES score	94.2±2.89	91.6±4.54	89.8±8.18	91.6±6.21
Shoulder pain and disability index (SPADI)				
Pain score	0.3±1.15	2.0±3.22	3.3±6.04	2.1±4.43
Disability score	0.1±0.36	1.0±1.23	1.2±1.90	0.8±1.46
Total score	0.2±0.67	1.4±1.88	2.0±3.33	1.3±2.48
Single assessment numeric evaluation (SANE)				
Affected joint	98.7±2.99	96.9±4.59	92.9±10.47	95.8±7.70
Opposite side	99.2±2.89	100±0.00	98.2±3.93	99.0±3.04
Simple shoulder test score				
Pre-injury	89.5±9.52	87.8±12.58	82.3±13.82	86.0±12.46
Post-surgery	98.6±4.82	96.2±6.87	89.7±14.03	94.1±10.74
P value	0.003	0.067	0.051	0.000

N: Number of patients, Data are presented as mean±standard deviation

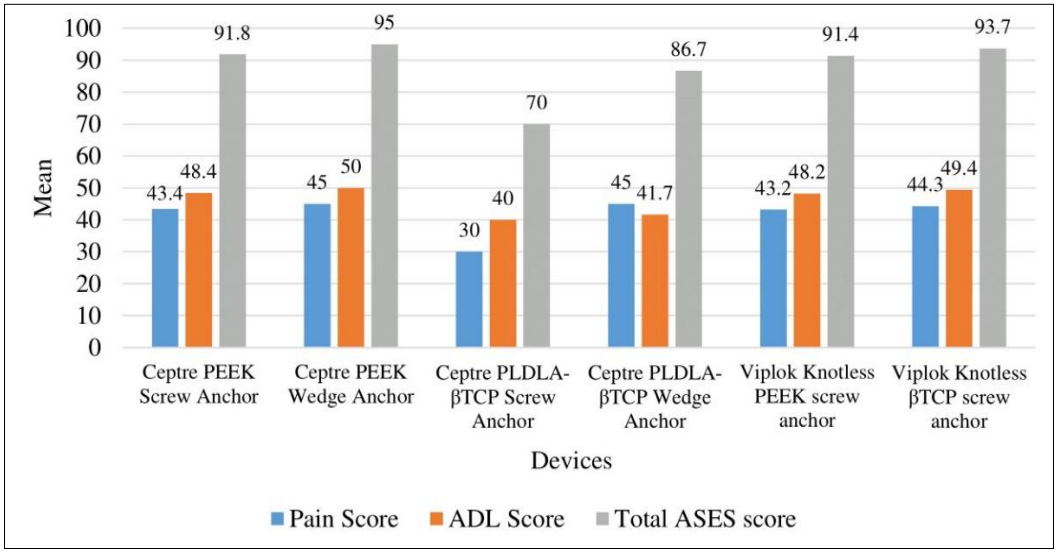

Figure 5: Graphical representation of ASES score by devices.

DISCUSSION

Arthroscopy has become the method of choice for rotator cuff repair surgery as a result of advancements in instrumentation and surgeon preference.[8] Arthroscopic rotator cuff tear repair with suture anchors is a proven treatment method and is technically more demanding due to its consistent results.[13-15]

The results of this observational study confirmed the hypothesis that the Sironix suture anchor implants were safe and effective for rotator cuff repair with excellent functional outcomes. In this study, there was an improvement in the post-operative ASES, SPADI, SST, and SANE scores.

In the present study, the mean (SD) of the total ASES score for a follow-up of 6 months to 1 year was 94.2 (2.89). This result closely resembled the findings of Bushnell et al, whose study indicated an average (SD) ASES score of 94.3 (11.6) over a 1-year follow-up.[16] Similarly, Jacob et al observed a mean (SD) ASES score of 88.3 (4.3) after a 6-month follow-up.[17] Meanwhile, Assunção et al evaluated 143 patients who underwent arthroscopic rotator cuff repair and found a mean (SD) ASES score of 81.2 (20.8) at the 24-month post-operative mark, whereas the present study noted an ASES score of 91.6 (4.54) between 1 year and 2 years.[18] In another study by Kim et al, 69 patients were randomly assigned into two groups based on the type of suture anchors used for rotator cuff repair, and the mean (SD) ASES score at the 2-year follow-up was 89.2 (8.5).[19] The current study results indicated superior ASES scores compared to those reported in the aforementioned studies.

The present study results demonstrated lower SPADI scores, indicating greater improvement in functional outcomes for patients after surgery. Consistent findings were documented in the study conducted by Carr et al, which enrolled 273 patients.[20]

Lee et al conducted a study and reported that the mean percentage of the total SST score for a follow-up of 6 months was 62.5.[13,21] In contrast, the current study demonstrated that SST scores from 6 months to 1 year were 98.6% (4.82). Furthermore, a study by Kurowicki et al examined 627 patients, evaluating outcomes at 3 months, 6 months, 1 year, and 2 years of follow-up, showing an 82% improvement in the SST score.[22] Another study, led by Berglund et al, followed 301 patients meeting the inclusion criteria for 2 years, resulting in a maximal improvement of 72.1% in the SST score.[23] Conversely, the present study indicated that the mean percentage of the SST score for 1 to 2 years of follow-up post-surgery was 96.2 (6.87).

Additionally, in a study by Kurowicki et al, the average SANE score post-operatively for 1-year follow-up was 82.3 with a standard deviation of 23.4.[22] In the present study, the average SANE score was 96.9, with a standard deviation of 4.59. Upon comparison, the SST and SANE scores reported in the literature were comparatively lower than those observed in the current study.

Limitations

There were a few limitations to the current study, notably its retrospective study design and small sample size. Therefore, more prospective studies, including randomized controlled trials, should be performed to provide better understanding and stronger evidence. However, the long-term follow-up data in this study, which is generated in a real-world setting, definitely adds value.

CONCLUSION

Arthroscopic rotator cuff repair with the Sironix suture anchors demonstrated a significant improvement in functional outcomes. Additionally, the study results showed that there were no serious adverse events. Therefore, based on the device`s performance and safety outcomes, it can be concluded that Sironix suture anchors (CEPTRE® knotted UHMWPE suture PEEK anchor, CEPTRE® knotted UHMWPE suture PLDLA-βTCP anchor, VIPLOK® knotless PEEK anchor with titanium tip and VIPLOK® knotless PLDLA-βTCP anchor with titanium tip) offer a viable option for a successful surgical procedure in rotator cuff repair surgery.

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