MAR Orthopedics & Trauma (2024) 6:2

Observational Study

Clinical and Patient Reported Outcomes after Treatment of Rotator Cuff Tears: A Retrospective, Observational Study.

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Received: 21 May 2024

Published: 01 June 2024

DOI: https://doi.org/10.5281/zenodo.11399469

ABSTRACT

Background: *The study aimed to collect actual postoperative data from rotator cuff tear repairs performed with and without Sironix knotted and knotless suture anchors, as the postoperative results of arthroscopic Rotator Cuff Tear surgery in India are not well documented.*

Methods*: This study aimed to collect retrospective data from arthroscopic RCT surgery participants between April 2018 and June 2022, focusing on repair failure rate. Data was collected from medical records, demographics, and baseline features. Secondary goals included evaluating patient-reported outcomes using the PENN Shoulder Score, DASH, and SANSE questionnaires. Adverse device effects and occurrences related to surgery were also gathered. All participants provided their consent.*

Results: *A study involved 54 participants aged 58.7 years and 13.5 months with an average follow-up period of 4.3 months. 63% received right shoulder acromioplasty and arthroscopic cuff repair, with no failures. The overall PENN shoulder score was 94.6, and the Quick-DASH total score was 11.6. The SANE questionnaire score was 95 for patients with and without shoulder injuries, and no negative device impacts were known.*

Conclusion: *Current research devices show functional improvement and post-operative recovery without repair failures, making them a safe and practical strategy in RCT procedures, requiring further assessment through larger cohort prospective studies.*

Keywords: *Suture anchor, Rotator cuff tear, Arthroscopy, Outcomes*

Introduction

Rotator Cuff Tears (RCT) are a common condition affecting the shoulder joint, with an age-dependent increase in incidence. India, with its 1.3 billion population, represents a potential caseload of RCT tears in the millions. Globally, RC tear prevalence is approximately 40% in asymptomatic individuals and 65% in symptomatic individuals. RCT tears can lead to shoulder dysfunction and impairment, with a higher incidence in patients over 50 years and a progressive pattern in most cases.[1-4]

Arthroscopic treatment of rotator cuff tears has become a routine procedure due to the trend towards minimally invasive surgery. Arthroscopic shoulder repair has become the main treatment for rotator cuff injuries due to its advantages of small surgical trauma, low postoperative adhesion risk, low infection probability, and easy early rehabilitation after surgery. The combined use of acromioplasty and arthroscopic rotator cuff repair promotes joint function recovery and alleviates patient pain.[5-7]

However, the uptake of shoulder surgery in India has been extremely slow due to factors such as lack of patient education, lack of hospital infrastructure, and lack of shoulder-specific training. Many studies have used standardized questionnaires like PSS, Quick-DASH, and SANE scores to assess outcomes related to functionality after arthroscopic rotator cuff surgery. This study aimed to assess clinical and functional outcomes using real-world data after rotator cuff repairs.[8-12]

Device Description

The Sironix Ceptre® Knotted Ultra-High Molecular Weight Polyethylene suture (UHMWPE) Polyether Ether Ketone (PEEK) anchor is designed for soft tissue fixation to bone, offering superior repair strength when double or triple-loaded with suture(s)/tape(s). (fig 1)

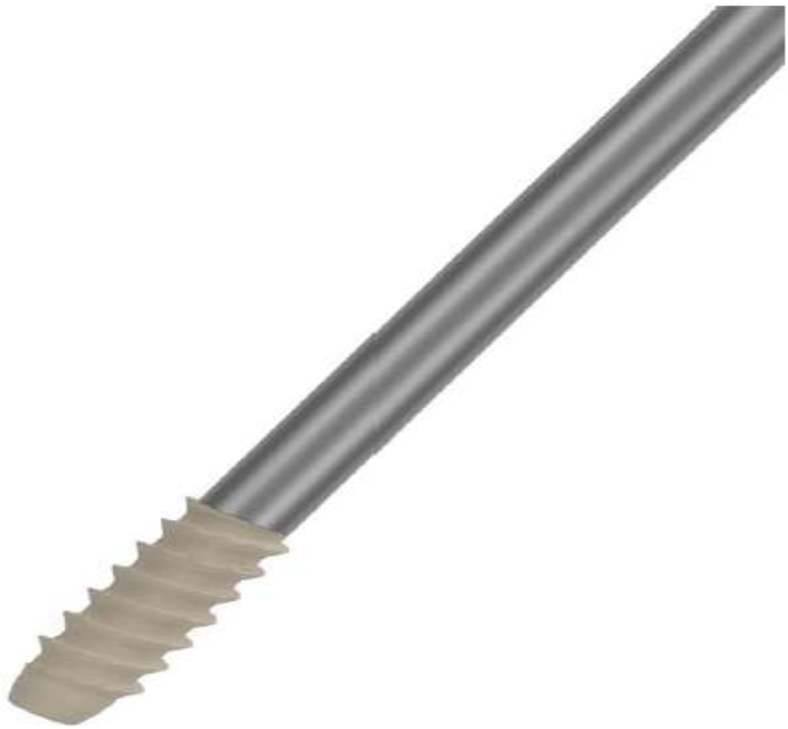

Figure 1: Ceptre® Knotted UHMWPE suture PEEK anchor.

The versatile knotless anchor, made of PEEK, is preloaded on an inserter assembly and can take multiple sutures/tapes from the tip eyelets, available in wedge and screw designs. **(Fig. 2)**

Figure 2: Viplok® Knotless PEEK anchor

Materials and Methods

Study Design

This study aimed to assess the clinical and patient-reported outcomes of rotator cuff tear treatment. Patients who underwent rotator cuff tear surgery using suture anchors between April 2018 and June 2022 were surveyed via telephonic interviews. The primary outcome was repair failure rate, which was determined by enquiring about the need for a second repair procedure. Secondary outcomes were obtained using the PENN Shoulder Score (PSS), Quick-DASH (Disabilities of Arm, Shoulder, and Hand) Score, and Single

Assessment Numeric Evaluation score (SANE). Adverse device effects, surgery-related adverse events, and medication details were also gathered via telephonic interviews.

The clinical investigation was conducted in accordance with various regulations, including ICH GCP E6 R2 2016, GCP, New Drugs and Clinical Trials 2019, MDR17 & Amendment Rules, Declaration of Helsinki, and ISO 14155-2020, with the CTRI registration number CTRI/2022/11/047427.

The study included patients aged 18-80 years, who had surgery with Sironix suture anchor devices, had at least 6 months of follow-up, and provided written or verbal informed consent. Patients with other serious shoulder injuries or who were not willing to attend follow-up were excluded. The study included patients who were willing to provide written or verbal informed consent, and those who were diagnosed with other shoulder injuries.

Interpretation of Scores: The PENN shoulder score is a self-report scale measuring pain, satisfaction, and function based on a 10-point numeric rating scale. It aims to indicate high function, low pain, and high satisfaction with shoulder function. The Quick DASH questionnaire measures an individual's ability to complete tasks, absorb forces, and severity of symptoms using a 5-point likert scale. The Sane score evaluates a patient's sense of functional improvement on a scale of 0% to 100%, with 100% being normal. These tools are used to assess the shoulder's function after rotator cuff repair.

Statistical Methods

This study summarized demographic measurements, medical history, and surgery details, with the primary endpoint of repair failure rate. Secondary endpoints included patient reported outcomes like Penn Shoulder score, Quick DASH, and SANE. Adverse device effects were reported as the number and percentage of adverse events and the number of events.

Results

The study screened 55 subjects, with 54 being eligible based on inclusion/exclusion criteria. Figure 3 summarizes patient disposition.

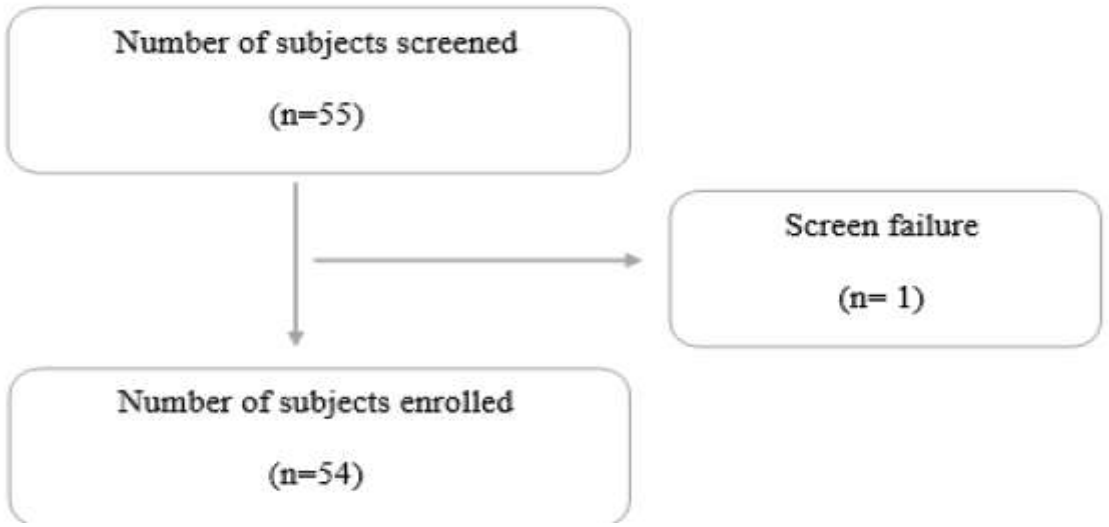

Figure 3: Disposition of subjects

The study analyzed the demographics and surgery details of 54 patients, with a mean age of 58.7 years and a majority of females (57.4%) and males (42.6%). The majority (63%) underwent arthroscopic cuff repair with acromioplasty of the right shoulder, followed by 25.9% with arthroscopic cuff repair with acromioplasty of the left shoulder. The mean follow-up duration was 13.5 months. Out of 54 patients, 95.4% received Ceptre® knotted UHMWPE suture PEEK anchors, while 48.1% received Viplok® knotless PEEK anchors. Fig 4

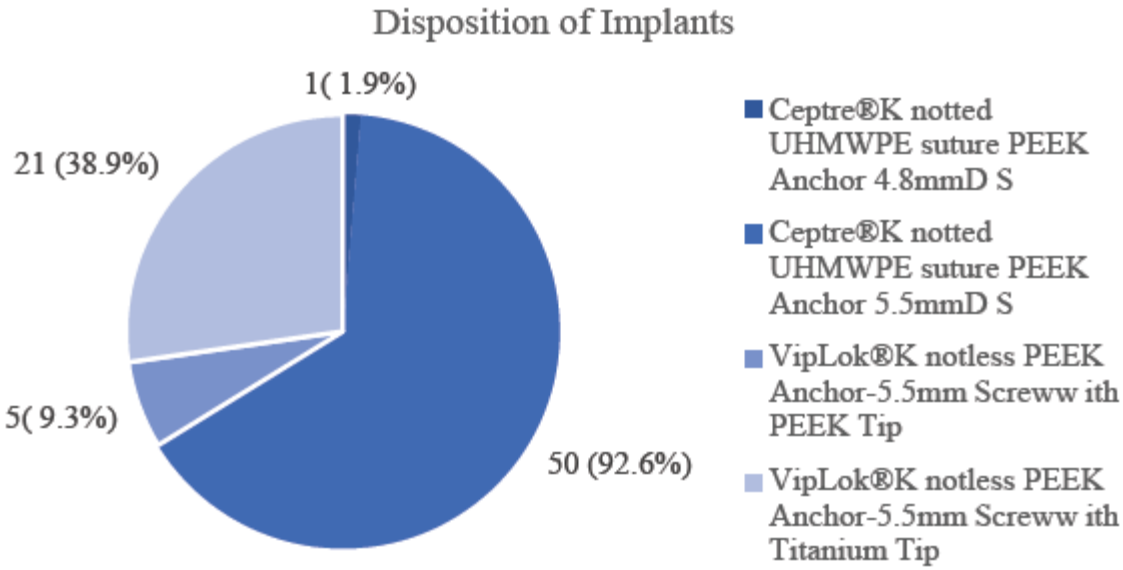

Figure 4: Disposition of Implants

This study found no repair failures in patients with shoulder injuries. The mean total PENN shoulder score was 94.6, with pain, satisfaction, and function scores of 28.5, 9.2, and 56.8, respectively. The mean Quick-DASH score was 11.6, with 1.24 being the highest score recorded for any individual question. The mean SANE questionnaire score for both injured and non-injured shoulders was 95, with no repair failures observed.

Discussion

This study aimed to evaluate clinical and functional outcomes of arthroscopic cuff repair with acromioplasty of the right shoulder. The majority of patients (57.4%) had gone through arthroscopic cuff repair with acromioplasty. Suture anchor materials with PEEK were introduced as a new material, offering biological inertness and radiolucency. The study collected data from RCT surgeries with both knotted and knotless anchors made up of PEEK material. Out of 54 enrolled patients, 51 (94.4%) received Ceptre® knotted UHMWPE suture anchors, and 26 (48.1%) received Viplok® knotless PEEK suture anchors. [13-17] No repair failures were observed in this study, indicating good recovery with suture anchors. The most notable finding was overall excellent functional outcome scores regardless of the type of rotator cuff tear. The total mean PSS score was 94.6 out of 100, demonstrating highly satisfactory outcomes. Quick-DASH scores reflected improvement in day-to-day functions post-surgery, with considerable scores reported. [18-20]

The mean SANE score of 95 (± 6.7) signified excellent functional improvement in comparison to the injured shoulder. Similar improvements were reported in a study involving elderly patients with arthroscopic repair of traumatic rotator cuff tears. There was no significant difference found in PSS, quick-DASH, and SANE scores with regard to the type of suture anchor used and duration of follow-up.[21] Repair failures are associated with risk factors like age, other comorbidities, tear size, bone mineral density, and amount of retraction. Future research could contribute to the orthopaedic literature with well-designed, prospective, randomized trials to assess precise outcomes.[22]

Conclusion

The study demonstrates that current devices in RCT surgeries are safe and effective in promoting post-operative recovery without repair failures and achieving functional improvement, despite some limitations,

thereby proving reliable in improving shoulder pain and function.

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