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# Evaluation of safety, clinical outcomes, and patient-reported outcomes after meniscus repair using surestitch all inside meniscal repair implant: a retrospective, observational study

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## ABSTRACT

**Background:** Anterior cruciate ligament (ACL) injuries and meniscus injuries frequently co-occur, underscoring the interconnected nature of knee joint structures. Meniscus injuries, often caused by sports trauma or degenerative changes, necessitate careful management to preserve joint function and prevent complications like osteoarthritis. This retrospective observational study evaluates the safety, clinical outcomes, and patient-reported outcomes of meniscus repair using Surestitch all inside meniscal repair implant, a contemporary solution designed to optimize meniscal repair.
**Methods:** The study, approved by the institutional ethics committee, included patients aged 18-80 years who underwent meniscus repair with Surestitch between October 2020 and July 2022. Data on demographics, surgical details, and outcomes were collected from medical records and telephonic follow-ups.
**Results:** Among 36 subjects, the mean age was 36.89 years. The mean (SD) duration of follow-up was 364 days (127). There was no meniscus repair failure noted in any of the patients. Functional patient-reported outcomes assessed using international knee documentation committee (IKDC) with a score of (60.15±12.40), and Lysholm scores (77.03±14.45) demonstrated favorable results. The knee injury and osteoarthritis outcome score (KOOS) of (54.63) further indicated positive knee health across domains. There were no adverse events or reoperations.
**Conclusions:** The study demonstrated favorable safety, clinical outcomes, and patient-reported outcomes, yielding satisfactory results, and consequently establishing the safety and effectiveness of the Surestitch All inside meniscal repair implant in meniscus repair.

**Keywords:** Knee injuries, Meniscus injuries, Meniscus repair, All inside meniscus repair, Surestitch

## INTRODUCTION

Anterior cruciate ligament (ACL) injuries and meniscus injuries are both common knee injuries, often occurring in combination. The association between ACL injury and meniscus repair highlights the interconnected nature of structures within the knee joint.[1] The ACL is a ligament that helps stabilize the knee, while the meniscus (C-shaped cartilage that acts as a cushion), an essential component of the knee joint, plays a fundamental role in maintaining stability, distributing load, and facilitating smooth movement by providing lubrication. Injuries to the meniscus can occur due to various causes, including sports-related trauma, degenerative changes with age, or as a consequence of other knee injuries.[2-4]

The annual incidence of meniscal tears is significant, with a rate of 68.6 per 100,000 people. Understanding the importance of the meniscus is crucial, as it plays a vital role in bearing the tibiofemoral load. Roughly 40% to 60%

of this load is transmitted onto the menisci, and in deep knee flexion, this proportion may increase substantially, reaching up to 90%.[5,6] Unfortunately, meniscal injuries are widespread, necessitating careful management to preserve the joint function and prevent the onset of debilitating conditions such as osteoarthritis.[7] In response to this clinical challenge, recent years have witnessed a surge in interest and innovation within the realm of orthopaedics, particularly in the development of surgical techniques and implants aimed at preserving the menisci and optimizing meniscal repair outcomes.[8]

Traditionally, the approach to meniscal injuries involved meniscectomy, a procedure that removed damaged portions of the meniscus. This strategy, while providing symptomatic relief, often led to long-term consequences, including altered joint biomechanics and an increased risk of premature osteoarthritis.[9-11] However, the paradigm has shifted towards a more holistic strategy centered on meniscal repair. This transformative approach seeks to preserve and restore the meniscus, safeguarding joint functionality and mitigating long-term complications.[12] Within this context, the Surestitch All inside meniscal repair implant emerges as a focal point of investigation-a contemporary solution designed to address the challenges inherent in meniscal repair.

This manuscript undertakes a comprehensive evaluation, focusing on the safety, clinical outcomes, and patient-reported experiences associated with meniscus repair using the Surestitch implant. Our retrospective, observational study aims to illuminate the performance and efficacy of this implant in the context of diverse meniscal repair procedures.

## METHODS

### *Study design and patient selection*

Following approval by the institutional ethics committee of Sarvodaya hospital and research centre (dated: 16 November 2022), a retrospective observational study was undertaken. Patients aged 18-80 years, who underwent meniscus repair with Surestitch implant between October 2020 to July 2022 and who were able to provide written informed consent during hospital visit or verbal consent telephonically were included in the study. Patient who has suffered from traumatic injury to the operated knee after the meniscus repair surgery and who could not be contacted for attending an in clinic/telephonic follow-up visit were excluded from the study.

### *Data collection and outcomes*

The retrospective data were collected from medical records of the patients which include baseline characteristics such as sex, age, body mass index; injury details: location, mode of injury, and associated ACL injury; surgery details: number of implants used, associated surgeries, complications, and re-operations. Thereafter, all the patients were contacted and followed up telephonically to obtain functional patient-reported outcomes of meniscal repair surgery.

The objective of the study was to evaluate the clinical outcomes after meniscus repair with Surestitch implant using meniscus repair failure rate (assessed by the incidence of reoperation due to meniscal repair failure); to evaluate the patient reported outcomes using IKDC score, Lysholm score and KOOS; and to evaluate the safety by assessing any device specific or surgery related adverse events.

### *Study implant*

Surestitch all inside meniscal repair implant: This consists of two PEEK non-absorbable implants, pre-tied with USP #2-0 non-absorbable UHMWPE suture and preloaded into a needle delivery system (Figure 1).

### *Statistical analysis*

Categorical variables were represented as percentages, while numerical variables were expressed using means and standard deviation (R software).

## RESULTS

In this retrospective study, a total of 36 subjects were enrolled, who had undergone meniscus repair with the Surestitch implant between October 2020 and July 2022, meeting the specified study criteria. The demographic information and surgical details of the patients are comprehensively presented in Table 1.

The mean age of the participants was 36.89±13.39 years. The study population consisted of 27 (75%) female patients and 9 (25%) male patients. Among the 36 subjects, 20 (55.56%) had injuries on the right knee, while 16 (44.44%) experienced injuries on the left knee. The primary cause of meniscal injury was trauma in 25 patients (69.44%), and the remaining 11 patients were not aware of the reason for meniscus injury. The mean (SD) duration of follow-up was 364 days (127).

The meniscal repair surgeries in this study were conducted utilizing the Surestitch implant. A total of 87 implants were employed across the cohort of 36 patients. Remarkably, among the subjects, 28 (77.77%) were identified to have concomitant ACL injury, as indicated in Table 1. This observation underscores the prevalence of coexisting conditions and highlights the potential association between meniscal injuries and ACL involvement in the study population.

### *Primary outcome*

There was no incidence of reoperation due to meniscal repair failure postoperatively.

***Secondary outcomes***

*Functional patient-reported outcomes: IKDC and Lysholm score assessment*

The overall mean (SD) IKDC score for all study subjects was 60.15 (12.40), reflecting the functional outcomes of the participants. Additionally, the mean (SD) Lysholm score was 77.03 (14.45), providing insight into the overall knee function and stability in the studied cohort (Table 2).

*Functional patient-reported outcomes: KOOS assessment*

The KOOS score assessment revealed comprehensive insights into the participant's knee health across multiple domains. The average scores for pain, symptoms, activities of daily living (ADL), sports and recreation function, and knee-related quality of life (QOL) were 57.87 (11.68), 51.49 (14.57), 51.47 (12.59), 51.53 (23.15), and 61.28 (13.08), respectively. The overall average KOOS score was 54.63 (Figure 2).

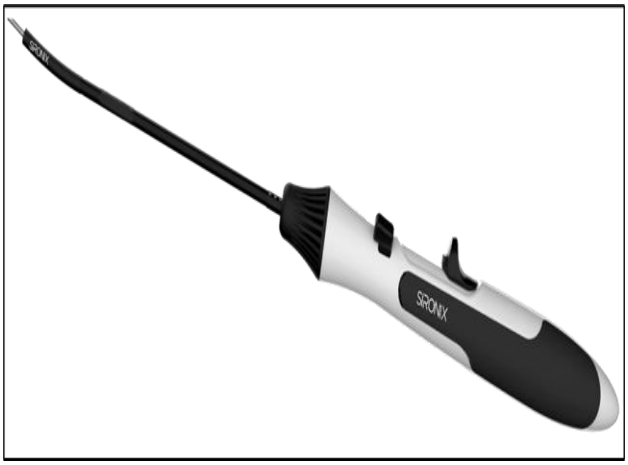


**Figure 1: Surestitch all inside meniscal repair implant.**

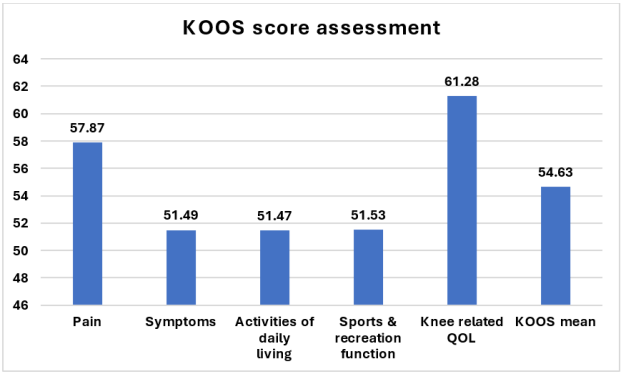


**Figure 2: KOOS assessment score.**

***Adverse event***

Among the 36 patients included in the study, no adverse events were reported.

**Table 1: Patient demographics and surgical details.**

| Demographics | N (%) |
|---|---|
| **N** | 36 |
| **Age (in years)** | 36.89±13.39 |
| **Gender** | |
| Male | 9 (25) |
| Female | 27 (75) |
| Body mass index (kg/m$^2$) | 26.58±4.38 |
| **Knee injury** | |
| Left side | 16 (44.44) |
| Right side | 20 (55.56) |
| **Reason of meniscus injury** | |
| Trauma | 25 (69.44) |
| Not aware of reason for meniscus injury (Presented with symptoms such as pain, swelling, and locking of the knee) | 11 (30.56) |
| **Number of Surestitch device used** | |
| Total number of Surestitch implants used in 36 patients | 87 |
| Mean number of Surestitch implants used in 36 patients | 2.42 |
| **Associated anterior cruciate ligament injury** | |
| Yes | 28 (77.77) |
| No | 8 (22.22) |
| **Type of graft used for ACL reconstruction** | |
| Quadruple semi-T graft | 28 (100) |
| **Implant used for femoral and tibial fixation in subjects with associated ligament injury** | |
| Suspensory implantation for both tibial and femoral fixation | 28 (100) |
| **Secondary fixation used in subjects with associated ligament injury** | |
| Internal bracing with tape and secondary fixation with Viplok knotless peek wedge anchor with peek tip (Sironix-Healthium Medtech) | 17 (60.72) |
| Internal bracing with tape and secondary fixation with knotless peek anchor (Smith and Nephew) | 11 (39.28) |

**Table 2: IKDC and Lysholm score.**

| Score | Mean±SD |
|---|---|
| **IKDC score** | 60.15±12.40 |
| **Lysholm score** | 77.03±14.45 |

## DISCUSSION

Meniscus repair is a pivotal aspect of orthopedic care, addressing the intricate challenge of restoring function and mitigating symptoms associated with meniscal injuries. As a result, effective repair techniques are crucial for restoring optimal knee health and preventing long-term complications. Our study delves into the evaluation of safety, clinical outcomes, and patient-reported outcomes following meniscus repair using the Surestitch implant.

According to findings in the MARS cohort, which reported a meniscal repair failure rate of 8.6% (17/197) at 2 years follow up, and in line with a retrospective study by Ronnblad et al where 22.5% (207/918) of patients necessitated surgical meniscal resection for a failed repair at 3 years.[13,14] The current study observed no occurrence of re-surgery attributed to failure in meniscus repair among the study participants indicating a potential positive impact associated with the utilization of the Surestitch implant in the subjects.

In a prospective study, Kim et al reported a mean (SD) IKDC score of 59.6±9.8 and Lysholm score of 68.5±13.5, reflecting moderate knee impairment.[15] In another prospective study, Chodavarapu et al showed a mean (SD) Lysholm score of 58.70±4.45 at 2-year follow-up.[16] In current study, the mean (SD) IKDC score was 60.15±12.40, closely aligning with Kim et al and Chodavarpu et al while the Lysholm score significantly improved to 77.0314.45, suggesting a more favorable functional patient-reported outcome. This suggests potential advancements in functional recovery within our study cohort, emphasizing potential refinements in treatment strategies or patient care for improved knee injury outcomes. However, the overall mean IKDC score is comparatively lower. The reason being most of the patients marked light (walking, housework, or yard work) to moderate physical work (or jogging) as their highest level of activity. The non-involvement of recruited patients in any kind of sports activity or heavy physical work resulted in low IKDC scores.

In the KOOS score assessment reported by Ebrahimi et al participants exhibited a mean score for pain of 57.17, other symptoms 60.71, ADL 61.44, sport and recreation 26.80, knee-related quality of life (QOL) 35, and a total KOOS score of 53.76.[17] In our study, we observed slight variations with mean scores for pain at 57.87, symptoms 51.49, ADL 51.47, sport and recreation 51.53, QOL 61.28, and a total KOOS score of 54.63.

The observed safety profile, as evidenced by the absence of major complications or adverse events, suggests that the use of this implant is associated with a favorable safety profile.

### *Limitations*

While our study contributes valuable insights, it is essential to acknowledge its limitations. The retrospective, observational nature of the study design introduces inherent biases and limits the establishment of causal relationships. Additionally, the absence of a control group and the potential for selection bias should be considered when interpreting the results. Future research endeavours should include prospective, randomized controlled trials with larger sample size to further validate the safety and efficacy of the Surestitch implant. Long-term follow-up assessments will be crucial in determining the durability of the repair and its sustained impact on patient outcomes.

## CONCLUSION

In conclusion, our study demonstrated favorable safety, clinical outcomes, and patient-reported outcomes, delivering satisfactory results and thereby confirming the safety and effectiveness of the Surestitch all inside meniscal repair implant in meniscus repair. These conclusions are drawn from the assessment of functional score evaluations, and other study parameters, collectively affirming the implant's reliability in promoting successful outcomes in meniscal repair procedures.

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*Conflict of interest: Authors Ashok Kumar Moharana, Sachin Angrish, Deepak T.S., Cismitha Sharol Pinto are employees of Healthium Medtech Limited, India, who are manufacturers of Surestitch All Inside Meniscal Repair Implant*
*Ethical approval: The study was approved by the Institutional Ethics Committee of Sarvodaya Hospital & Research Centre*

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