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Early Radiologic and Clinical Outcomes after Arthroscopic Rotator Cuff Repair Augmented with Demineralized Bone Fiber Implant

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FDA Status Cleared

Summary

This study aimed to present the early radiological and clinical outcomes after arthroscopic rotator cuff repair augmented with demineralized bone fiber implant at the footprint.

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Abstract

Introduction

Healing after rotator cuff repair is always a challenge, especially in massive, retracted rotator cuff tears. Re-tear rate after repair of these tears can be as high as 94%. Even in smaller rotator cuff tears, tendon-to-bone healing has always been a weak link and can be a source of failure after rotator cuff repair. This study aimed to present the early radiological and clinical outcomes after arthroscopic rotator cuff repair augmented with demineralized bone fiber implant (Enfix RC, Enfix TAC, Tetrous Inc, Los Angeles, CA) at the footprint.

Methods

This was a retrospective review of patients who underwent arthroscopic rotator cuff repair, augmented with Enfix RCTM or Enfix TACTM from July 2023 to February 2024 performed by two senior shoulder surgeons. A control group who had no augmentation was then selected from the surgical database by matching to the augmented group in age, sex, and tear configuration. VAS, ASES, Constant Score, and active range of motion (ROM) were collected preoperatively and at 6 months postoperatively. Noncontrast MRI was obtained preoperatively for rotator cuff tear evaluation and at 6 months postoperatively for assessment of healing and enthesis.

Results

A total of 16 patients in each group were included in the study. Majority of the patients had at least 2-tendon tears (81%) with Patte 2 to 3 retraction. Repeat MRI at 6 months showed complete healing in 100% of patients with available scans. Majority in the augmented group had Sugaya type 2 repair integrity (61%), while 31% had type 3 and 8% had type 1, with mean tendon thickness of 4.7 mm. The control group had higher percentage of Sugaya type 3 (47%), while Sugaya type 2 was at 53%, with mean tendon thickness of 4.3mm. At 6-month follow-up, all patients in the augmented group showed improvement in VAS (preop 5, postop 1), ASES (preop 44, postop 89), Constant Score (preop 50, postop 74), with all improvements reaching the minimal clinically important differences (MCID). Active ROM (degrees) also improved in all planes: forward flexion (preop 118, postop 173), abduction (preop 104, postop 167), external rotation in adduction (preop 33, postop 63), and internal rotation in abduction (preop 35, postop 70). These were all comparable with the control group. No retears or reoperations were noted in both groups.

Conclusion

Early clinical and radiological outcomes of augmenting rotator cuff repairs demonstrate promising results, with noted improvement in tendon thickness and quality. Clinical outcomes of these patients showed similar results as the ones without augmentation. Longer follow-up and a larger patient cohort are necessary to evaluate the long-term effects and advantages of the demineralized bone fiber implant on tendon healing and clinical outcomes after rotator cuff repair.

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