SINEFIX AS A SOLUTION FOR CURRENT PROBLEMS IN ROTATOR CUFF REPAIR

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INTRODUCTION

The refixation of tendons to the bone presents a significant mechanical challenge. Tendon sutures must be capable of withstanding substantial pull-out forces and must possess sufficient resilience to absorb everyday mechanical loads, thereby preventing rerupture during the healing phase. Rotator cuff repair, in particular, exemplifies this difficulty, with rerupture rates varying widely. Young, healthy patients with small tears experience rerupture rates around 20%, while older patients with massive tears face rates as high as 94% [1]. This variability underscores the critical need for robust and durable tendon-bone fixation techniques to ensure successful healing.

CURRENT PROBLEMS

The high failure rate of rotator cuff repairs can be attributed to the fact that surgical techniques fail to restore the resilience mechanisms of the tendon and that fixation with suture anchors creates stress concentrations on the sutures [2]. Current double-row suture bridge repair techniques exert pressure on the tendon over a fairly large proportion (78%) of the bone footprint, but the force from the muscle to the bone is primarily transferred through the medial anchor points, resulting in punctual stress peaks [2]. This results in a failure at the musculotendinous junction and therefore in a failure of the rotator cuff repair [4].

Furthermore, the use of suture bridge techniques can lead to strangulation of the tendon by exerting to much punctual pressure on the tendon [5]. This results in impaired microvascular circulation [3], which leads to necrosis of the tendon [4]. However, the aim should be to prevent the naturally poor microvascular circulation of the tendon from deteriorating further in order to avoid these problems.

Despite the use of various fixation techniques designed to enhance fixation, there tends to be little improvement in success rates or a significant reduction in rerupture rates. This leads to the conclusion that healing is not improved by increased fixation, but rather by keeping the fixation forces as low as possible and distributing the force or load evenly over as large an area as possible, thereby creating the largest possible contact surface between tendon and bone.

HOW SINEFIX ADDRESSES THESE PROBLEMS

The SINEFIX implant allows for precise control of the optimal (low) compression pressure without causing strangulation, thereby maintaining the blood flow essential for tendon healing.

Its structured underside prevents tendon pull-out and ensures sufficient tensile strength.

FIGURE 1
SINEFIX Implant

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The implant secures the tendon to bone over a surface area almost recreating the perfect footprint of the tendon, making sure pressure is distributed evenly over the tendon and ensuring good blood circulation.

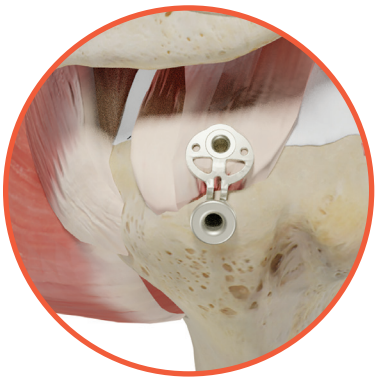

FIGURE 2
Rotator Cuff Fixed with SINEFIX

Traditional suture anchor techniques are technically complex and time-consuming due to numerous procedural steps. In contrast, SINEFIX is designed to be a simpler, more effective surgical technique with no suture management or knot tying steps. The technique appears to be easier and quicker for surgeons to learn and should minimize complications due to technical errors. The anticipated reduced surgery time and the implant's design are expected to improve outcome quality and increase patient satisfaction. These improvements may contribute to significant cost reductions. The implant is optimized for minimally invasive procedures.

The SINEFIX system's novel approach of refixating the tendon over a surface area represents a significant innovation in the field.

DISCUSSION / CONCLUSION

Overall, SINEFIX appears to address many of the challenges associated with rotator cuff repair while offering a simpler surgical technique compared to traditional suture anchor methods. SINEFIX aligns with several key points emphasized in the literature that suggest improved outcomes, including enhanced footprint restoration, more even load distribution, and preservation of microvascular circulation.

It is essential to validate these claims through clinical experience. The clinical results we are currently generating look very promising. However, how much healing and clinical outcome is improved can only be assessed with a larger number of long-term results.

REFERENCES

1. Park JY, Lee JH, Oh KS, Chung SW, Choi Y, Yoon WY, Kim DW. Rotator cuff retear after repair surgery: comparison between experienced and inexperienced surgeons. Clin Shoulder Elb. 2021 Sep;24(3):135-140. doi: 10.5397/cise.2021.00073. Epub 2021 Sep 1. PMID: 34488293; PMCID: PMC8423529.
2. Linderman SW, Golman M, Gardner TR, Birman V, Levine WN, Genin GM, Thomopoulos S. Enhanced tendon-to-bone repair through adhesive films. Acta Biomater. 2018 Apr 1;70:165-176. doi: 10.1016/j.actbio.2018.01.032. Epub 2018 Feb 8. PMID: 29427745; PMCID: PMC5871607.
3. Christoforetti JJ, Krupp RJ, Singleton SB, Kissenberth MJ, Cook C, Hawkins RJ. Arthroscopic suture bridge transosseus equivalent fixation of rotator cuff tendon preserves intratendinous blood flow at the time of initial fixation. J Shoulder Elbow Surg. 2012 Apr;21(4):523-30. doi: 10.1016/j.jse.2011.02.012. Epub 2011 May 18. PMID: 21596587.
4. Cho NS, Lee BG, Rhee YG. Arthroscopic rotator cuff repair using a suture bridge technique: is the repair integrity actually maintained? Am J Sports Med. 2011 Oct;39(10):2108-16. doi: 10.1177/0363546510397171. Epub 2011 Feb 24. PMID: 21350064.
5. Park JS, McGarry MH, Campbell ST, Seo HJ, Lee YS, Kim SH, Lee TQ, Oh JH. The optimum tension for bridging sutures in transosseous-equivalent rotator cuff repair: a cadaveric biomechanical study. Am J Sports Med. 2015 Sep;43(9):2118-25. doi: 10.1177/0363546515590596. Epub 2015 Jul 6. PMID: 26150589.

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MTG-WP-20240910 Rev A