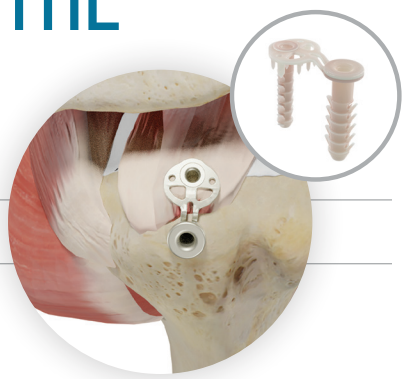
BIOMECHANICAL EVALUATION OF THE SINEFIX™ IMPLANT



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BACKGROUND

Rotator Cuff Lesions (RCL) are most commonly treated using arthroscopic techniques. However, these methods present challenges due to a flat learning curve and may not fully address the complexities of rotator cuff repair. In response to these limitations, Inovedis has developed the SINEFIX implant, designed to streamline and enhance tendon fixation procedures.

The SINEFIX implant is composed of polyether ether ketone (PEEK) and is capable of reattaching ruptured rotator cuff tendons up to 2 cm in length. It consists of two PEEK anchors and a PEEK base plate with fine pins that distribute shear stress evenly across the tendon, ensuring blood circulation. Unlike traditional fixation methods that compress the tendon, SINEFIX ensures blood flow and facilitates healing.

SINEFIX allows for a two-step attachment of the rotator cuff. The small teeth on the underside of the base plate distribute the holding force evenly across the tendon, while the lateral anchor absorbs the majority of the pull-out force. The primary goal of this repair method is to create a strong construct that withstands high pull-out forces, maintains a secure footprint, and minimizes gap formation, all of which are critical for successful healing.

HYPOTHESIS

The SINEFIX implant will demonstrate at least comparable pull-out forces and gap formation to the double-row repair (DRR) technique, which uses “all-suture” anchors, during cyclic loading.

METHODOLOGY

A total of 10 fresh sheep infraspinatus tendons were refixed using either the SINEFIX implant (Figure 1) or the DRR technique (with 2 medial and 1 lateral Y-Knot RC02N All-Suture Anchors by ConMed) (Figure 2).

Following preloading at 10 N, the tendons were subjected to cyclic loading between 10 and 62 N for 200 cycles at a frequency of 0.2 Hz. After completing the cyclic loading, the tendons were loaded to failure (Figure 3).

All tendons refixed with the SINEFIX implant (n=10) survived cyclic loading up to 62 N, with a maximum gap formation of 1.49 mm (SD 0.84). In contrast, tendons refixed with the DRR method (n=9) exhibited greater gap formation of 3.19 mm (SD 0.91) (p=0.001).

Maximum pull-out forces for SINEFIX were recorded at 215 N (SD 55) in six samples, compared to 166 N (SD 15) in four samples with DRR (p=0.084).

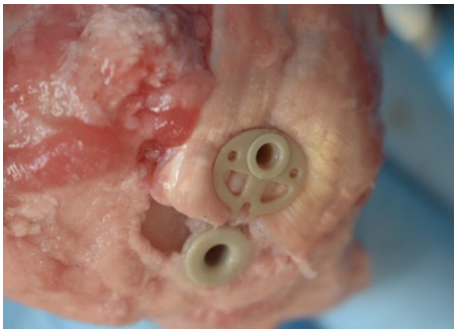


FIGURE 1
Tendon Fixed with SINEFIX

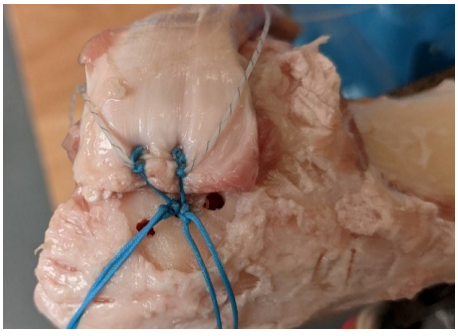


FIGURE 2
Tendon Fixed with DRR

FIGURE 3
Test Setup

Inovedis

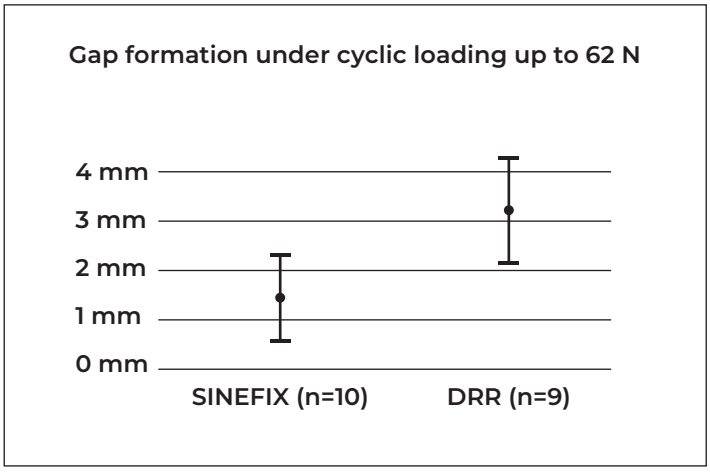
CONCLUSION

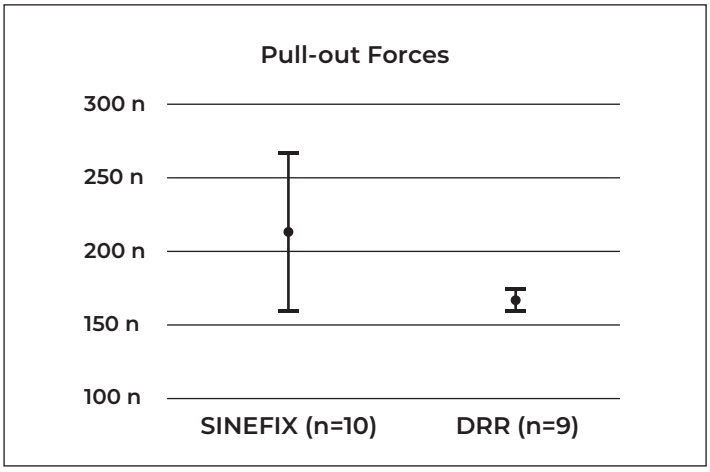
In this comparative study, the SINEFIX implant demonstrated higher pull-out forces and reduced gap formation compared to the DRR technique. However, the small sample size resulted in high standard deviations, suggesting the need for further investigation. Even with the observed variability, the SINEFIX implant's performance was consistently on par with, or better than, DRR. Future studies with larger sample sizes are required to refine these findings and further confirm the implant's advantages.

Ongoing clinical trials are currently evaluating the usability, safety, and mid-term outcomes of SINEFIX. Preliminary results are promising, but conclusive evidence of its superiority over existing devices will only be established after the planned comparison phase, which will involve more participants.

OUTLOOK

If the positive trends seen in this study are confirmed in clinical settings, and SINEFIX demonstrates superior healing properties compared to other fixation devices, it could become a valuable alternative to existing methods. The patented design of SINEFIX enables a minimally invasive, two-step procedure, potentially reducing the risk of surgical error and shortening both training time and operation duration. With FDA approval already secured in the U.S. and European trials initiated in December 2023, further biomechanical testing is underway to validate the implant's performance.





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