Rotator Cuff Refixation: A Biomechanical Evaluation of a New Implant

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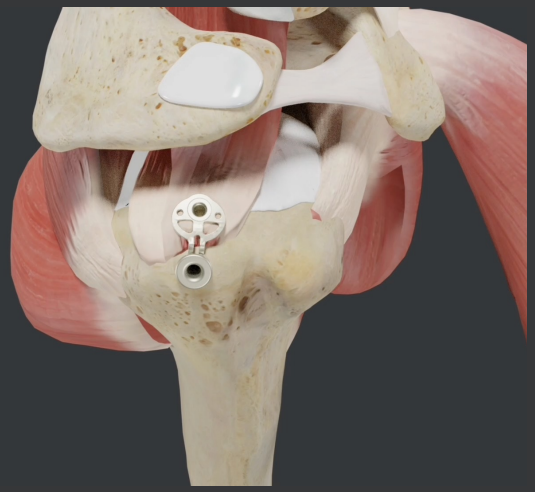
1. Background

Rotator Cuff Lesions (RCL) are primarily treated arthroscopically. This technique has a flat learning curve. Inovedis has therefore developed a new implant called SINEFIX™, which aims to simplify tendon fixation. It consists of a PEEK plate with two PEEK anchors and additional teeth that ensure the distance to the bone. The implant can be attached in two steps in such a way that the humerus and tendon are firmly connected to one another over a large area. SINEFIX™ also maintains the vitality of the tendon, improving blood circulation and thus the biological healing process.



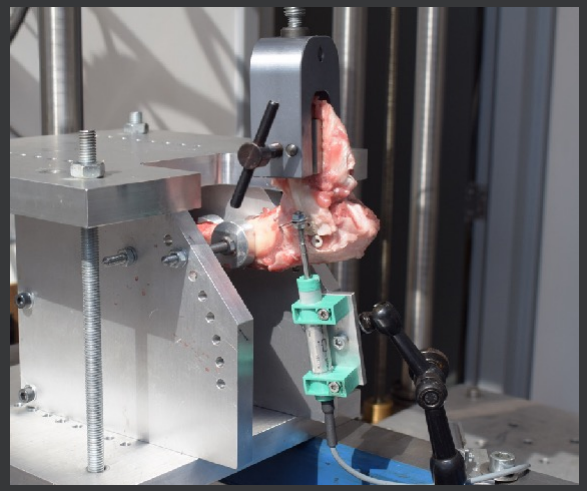
SINEFIX™, ©Inovedis GmbH

2. Hypothesis

The new implant has at least as high maximum pullout forces and gap formation as a double-row refixation (DRR) with "all-suture" anchors during cyclic loading.

3. Methodology

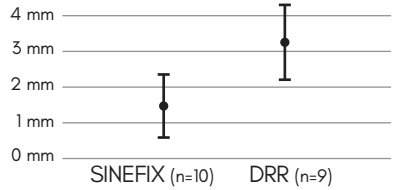
The same number (n=10) of fresh sheep infraspinatus tendons were refixed with SINEFIX™ and DRR (2x medial and 1x lateral all-suture anchor) respectively. After preloading with 10 N, the tendons were cyclically loaded with 10 to 62 N over 200 cycles at 0.2 Hz. The tendons, which were then still refixed, were loaded until they ruptured.



Test Setup, ©BAAT Medical Engineering B.V.

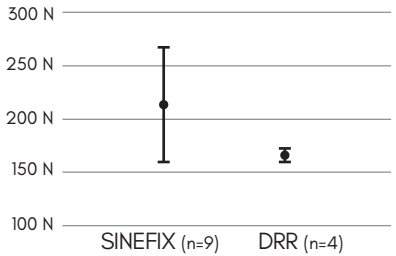
4. Results

Gap formation under cyclic loading up to 62 N



All (n=10) tendons refixed with SINEFIX™ survived cyclic loading up to 62N with a gap formation up to 1.49 millimeter (SD 0.84). In contrast, with the DRR method, one tendon remained less stable (n=9) with a gap formation of 3.19 millimeters (SD 0.91) (p=0.001).

Pullout forces:



The maximum pullout forces with SINEFIX™ (n=6) were 215N (SD 55) versus DRR (n=4) with 166N (SD 15) (p=0.084).

5. Conclusions

In a direct comparison, the new SINEFIX™ implant had higher pull-out forces and less gap formation than a DRR. Thus, the SINEFIX™ implant seems particularly suitable for older patients with porous bones. In addition, the results suggest the possibility for shorter recovery times, better chances of success and lower costs compared to the current clinical standard. However, all mentioned aspects as well as the vitality of the tendon and long-term results need to be verified in larger - and especially also clinical - studies. An in-vivo pilot study in sheep could demonstrate vital tissue under the PEEK plate.

6. Outlook

If these assumptions are confirmed in a hospital setting, SINEFIX™ takes rotator cuff refixation to a new level. This is because the patented SINEFIX™ system enables a minimally invasive procedure in fewer steps than before, reduces the risk of surgical errors and is also easier to learn. These factors save valuable time at the operating table and in training. Patients and the healthcare system as a whole would also benefit. SINEFIX™ is currently awaiting FDA approval in the U.S., and the European approval trial is starting in parallel under the leadership of Prof. Dr. Philip Kasten, a specialist in orthopedics and trauma surgery at the Orthopedic Surgery Center (OCC) in Tuebingen, Germany.

Contact us

For more information about our biomechanical evaluation please contact Prof. Dr. Philip Kasten, Orthopedic Surgery Center (OCC) Tuebingen, Germany.
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