A Novel Silk-Based Scaffold Patch Enhances Tendon Regeneration in a Preclinical Rotator Cuff Model

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INTRODUCTION: Rotator cuff tears remain a significant clinical challenge with high re-tear rates following conventional repair. Biological scaffolds have emerged to enhance healing, yet concerns about integration, inflammation, and durability persist. We evaluated a novel silk-based patch scaffold engineered for rotator cuff regeneration in a sheep model, focusing on integration, remodeling, and biomechanical function.

METHODS: This study was approved by the local Ethics Committee. In a delayed-repair sheep model window defects of 2 cm x 1.5 cm (length x width) have been created in the infraspinatus tendon of the left shoulder in adult female sheep and filled with a silicon spacer to prevent scaring. After 3 weeks, the defects were treated either with a silk-based scaffold (Fig. 1 and Fig. 2) or a cutis patch (Arthroflex® 3 mm, Arthrex, Inc.) during a second operation. Animals were euthanized at 6 months (n = 12) and 12 months (n = 16) post-implantation for post-explant analysis. Macroscopic inspection, micro-CT, biomechanical testing (load to failure and stiffness), and histological assessment (HE-, MSB- and picrosirius red stainings) were performed in a standardized, blinded manner. Scaffold integration and tendon regeneration were scored histologically. Biomechanical testing was performed using a Zwick tensile testing device. The contralateral healthy tendon served as reference.

RESULTS SECTION: From all animals in the study only one did not survive the intended observation period as a result of an intercurrent disease unrelated to the implantation procedure. Macroscopic evaluation showed that in all animals the defect was filled with new tissue independent of the used device. However, the thickness of the new-formed tissue in the defect area was more compareable to the surrounding tissue in the silk-based patch group. The repaired tendons showed intact, smooth tendon morphology at both time points, with no signs of inflammation near the implants. Micro-CT revealed progressive integration and mineralization remodeling from 6 to 12 months.Biomechanical testing: At 6 months, the maximum load to failure was 4187 ± 617 N in the control group, 3066 ± 421 N in the ArthroFLEX® group, and 3334 ± 197 N in the silk-based patch group. At 12 months, the respective values were 4133 ± 774 N, 3635 ± 733 N, and 4209 ± 738 N. Thus, after 12 months the silk-based patch group demonstrated maximum load values close to those of the control group, which represented the unoperated contralateral healthy shoulder. In the silk-based patch, abundant cellular ingrowth was observed throughout the porous implant in both, the 6 and 12 months group (Fig. 3). In contrast, in the ArthroFLEX® group cells were mainly restricted to the graft surface. Both materials supported the formation of tendon-like collagenous tissue on their surfaces, but the silk-based patch appeared more integrated into the defect owing to deeper cell infiltration and collagen deposition. In the silk group, collagen fibers were well aligned and frequently displayed the characteristic crimp pattern of native tendon.

DISCUSSION: This study confirms that a silk-based scaffold patch supports long-term tendon regeneration, with robust integration, outstanding biomechanical function, and histological remodeling over 12 months. The results support further preclinical and translational investigation toward clinical use.

SIGNIFICANCE/CLINICAL RELEVANCE: Rotator cuff repair continues to suffer from high failure rates, especially in large or chronic tears. A silk-based scaffold offering durable integration and biomechanical restoration could significantly improve healing outcomes and reduce revision surgeries in clinical practice.
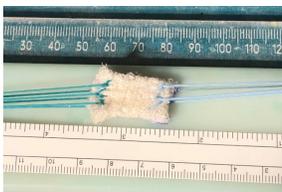
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Fig.1 Silk-fiber based scaffold before implantation

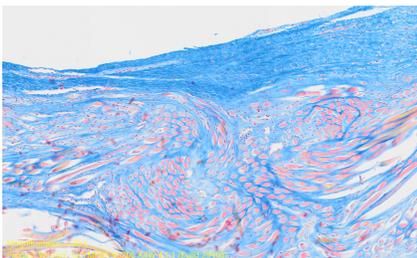Fig. 2 Silk-fiber based scaffold after implantation in tendon defect

Fig. 3 MSB staining of the cross-section of the repaired tendon 12 months after implantation of the silk-based patch shows numerous cells with dark-red stained nuclei, residual silk fibers visible in orange to light red, and newly formed tendon-like collagen highlighted in blue.