DEVELOPMENT AND MECHANICAL EVALUATION OF AN INNOVATIVE DEVICE FOR SOFT TISSUE REPAIR

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Introduction

Tendon injuries represent one of the most widespread soft tissues lesions. Tendon injuries may arise due to acute sport activities, traumatic lesions or because, over the years, the tissue becomes more prone to degeneration [1]. Despite the high incidence rate of this lesions, current traditional solutions as sutures threads present several drawbacks and limitations, leading to suboptimal clinical outcomes. The main causes of failure are suture's rupture, excessive scar tissue formation, and adhesions that lead to a reduction of the Range Of Motion (ROM) of the involved joints [2]. To overcome all the issues related to the use of traditional techniques, a new implantable device has been created. The innovative device concept involves a specific geometry that allows a uniform distribution of the stress field and a biocompatible and biodegradable material created ad hoc [3]. This work aims to demonstrate the correct mechanical response of the above-mentioned device.

Methods

For the mechanical evaluation of the device, numerical and experimental tests were performed on the assembly device plus tendon Figure (1). The numerical tests involved the simulation of a uniaxial tensile test, with the aim of analysing the mechanical response of the device, the distribution of the stresses on the tendon and on the surfaces of the device. The analysis was performed considering a nonlinear constitutive law for the tendon tissue and the device material.

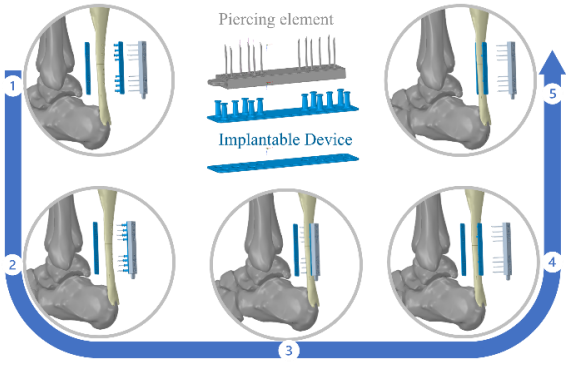

Figure 1: Implantation steps of the surgical device. 1)The two components of the implantable device and the piercing element. 2) The piercing element is placed into the implantable device component with pillars. 3) The insertion of the implantable device guided by the piercing element. 4) extraction of the piercing element once the device is completely penetrated. 5) Coupling of the two components of the implantable device.

For the experimental evaluation some uniaxial tensile tests were performed employing samples of Achilles Swine tendons, by practicing a complete laceration of the cross-sectional area of the tendon and implanting the biodegradable device.

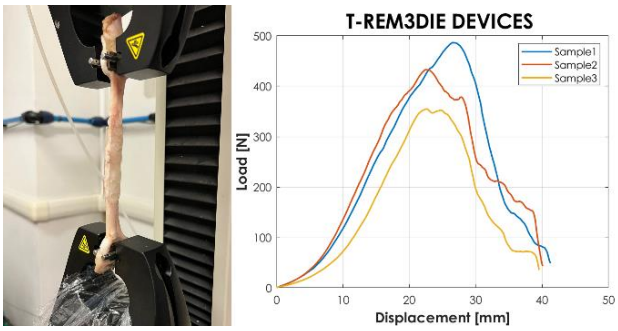

Figure 2:On the left, the tensile test of the assembly device -tendon. On the right, the load- displacement curves for the assembly.

Results

The FE models have shown a correct distribution of the stress field. The results obtained from the numerical simulations show that the implantable device plays a key role, since the highest stress concentration are all placed on the device tips and not on the tendon stumps.. The results were confirmed by the experimental uniaxial tests. Moreover, all the devices have withstood load values over 350N, i.e.higher than those developed during the execution of passive rehabilitation protocols [4].

Discussion

The experimental and numerical tests showed promising results, allowing to demonstrate the correct functioning of the implantable device. Further steps will involve the validation of the technology in a relevant environment, testing the device on cadaveric models.

References

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Acknowledgements

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