Abstract

Tendons are biological structures that connect muscles to bones through a specific structure called the enthesis. Tendons enable the transmission of active forces generated by the muscles to the bones, allowing joint motion. It is therefore evident that they play a crucial role in daily activities. Tendon injuries are very common in young adults and generally affect hand tendons, Achilles tendons, and rotator cuff tendons. Despite advancements in technology, tendon repair remains a challenge, as the current methods predominantly rely on traditional sutures. However, traditional suture techniques for tendon repair often result in suboptimal outcomes due to inherent drawbacks in the suture threads' functioning principles.
In the last decade, various alternatives to suture techniques have been proposed to address these issues, but none have shown significant advantages over traditional suturing.

The focus of this thesis is the development of an innovative technology for tendon repair, T-REMEDIE (Tendon Repair Medical Device). This device is a biodegradable and biocompatible implantable device applied to the two tendon stumps with the support of an applicator, T-RESAP (Tendon Repair Surgical Applicator), which enables faster and easier application. Both technologies developed during this work have been patented and are currently in the nationalization phase.

This work outlines the steps involved in the design and validation of a medical device, starting with market research and market validation. The development of the devices has focused on two areas: hand tendons and Achilles tendons. The different configurations of the implantable device disclosed in the patents have been adapted for use with Achilles and hand tendons. Through a comprehensive literature review, design requirements were established in terms of mechanical behaviour, dimensions, and anatomical considerations.

One of the core values of the implantable device is its biodegradability. To address this need, research was conducted on currently available biodegradable medical-grade materials already in use on the market. The mechanical response and degradation time requirements of the material were adjusted according to the body area, as the loads developed vary based on the tendons' functions.

Following a literature analysis and consultation with an expert company in the field of biodegradable polymers, a polymeric blend material was chosen for the Achilles tendon device, designed specifically for this purpose. Structural, mechanical, thermal, and biodegradability characterization of this blend material was necessary. For the hand tendons device, a traditional

polymeric material already available on the market was deemed most suitable, requiring no additional characterization.

The technology's design was an iterative process involving geometry design, numerical analysis using Finite Element Analysis software, prototyping through additive manufacturing techniques such as stereolithography 3D printing, setup of the implantation protocol, and analysis of the mechanical response. All these steps were performed using prototypes manufactured with the resin that best matched the mechanical properties of the previously identified polymeric materials.

Once the final prototype was obtained, the Achilles device was manufactured by injection moulding, which required slight geometry modifications to meet the technology's requirements. The applicator was manufactured by CNC in stainless steel. The final step of validating the devices and their applicator involved animal lab and cadaver lab testing for the Achilles tendon device, while the device for hand tendons was evaluated only through cadaver lab testing in its prototype version manufactured by SLA 3D printing.