


ESR 2

Project title and research strand:	Development, production, and prediction of fibroin-based degradable implants. Strand 2: fibers for medical application	
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Abstract

Silk fibroin is a protein extracted from silk that exhibits excellent biocompatibility, high mechanical properties, while also being bioabsorbable, which makes it an excellent candidate as a sustainable constituent material of biomedical devices. However, the use of silk fibroin as an implantable material remains limited due to distinct challenges that are encountered during its processing phase, particularly in industrial setting where reproducibility remains an issue and it can be difficult to produce complex structures. Indeed, several methods have been proposed to fabricate silk fibroin components, among which dip-coating is particularly promising given its versatility and scalability. Using a dip-coating process, there is potential to develop new techniques to obtain stand-alone silk fibroin structures, which could be applied for different scopes in the biomedical field. However, there is a general lack of understanding of the adhesion mechanisms of silk fibroin during dip-coating. The objective of this project is therefore to address the issues that affect silk fibroin commercialization by studying the dip-coating technique for both applications as a coating and as stand-alone devices through the production of a range of tubular structures that have potential application in endoluminal settings. Furthermore, a computational model able to describe the phenomenon of enzymatic degradation to aid in the design process.

Development, Production, and Prediction of Fibroin-Based Degradable Implants

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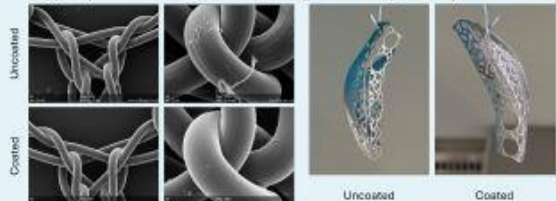
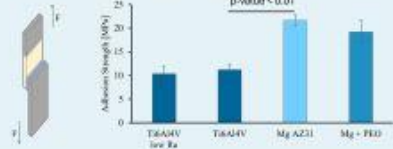
Motivation

Silk fibroin (SF) has the potential to be considered as a sustainable material [1], when it is extracted according to green chemistry as in the PureSilk[®] of Fibrothelium GmbH. However, suitable processing methods need to be found for its application in the biomedical field [2]. **Dip-coating** has the potential to be a game changer for both coatings and stand-alone devices. There is a distinct lack of knowledge regarding **adhesion strength**, and **strategies** need to be developed to coat devices with an **irregular shape**. The technique then needs to be adapted to obtain **tubular stand-alone structures** suitable for **biliary stents** [3], **oesophageal stents** [4], and **vascular grafts** [5] showing possibility of **upscaling** and **material combination**. An **enzymatic degradation computational model** is then implemented to correctly describe the behaviour of silk fibroin *in vitro* and *in vivo*.

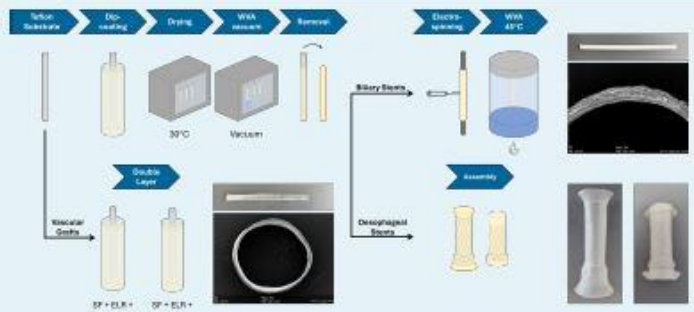
Development

The **adhesion strength** was successfully tested and **two application examples** (textile mesh and titanium mesh for guided bone regeneration) were coated.

The adhesion strength of silk fibroin is dependent on the substrate material, and not only on the surface roughness

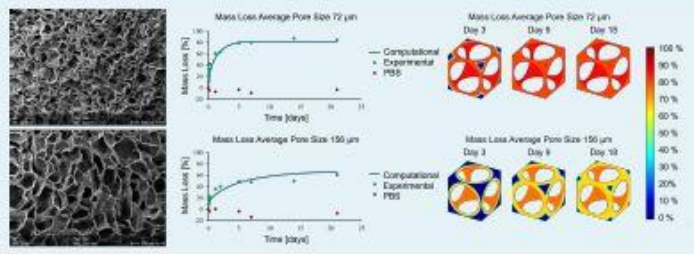


Production



- ✓ Successful **removal** and **reproducibility** of the technique platform
- ✓ Suitable **mechanical properties** for all the applications considered: biliary stents, oesophageal stents, and vascular grafts
- ✓ Successful **upscaling** in terms of dimensions
- ✓ Possible **combination** with **magnesium stent** or other biomaterials such as **ELR** (elastin-like recombinamers) in a single-step procedure

Prediction



- ✓ The model considers the **enzymatic degradation** of silk fibroin with its **surface erosion** mechanism
- ✓ The **mass loss** of experimental cases is correctly described
- ✓ The description of **in vivo degradation** literature data was successful
- ✓ **Molecular weight** and **crystalline phase** in time can be calculated

Conclusion and Outlook

The adhesion strength of silk fibroin coatings was successfully characterised with a behaviour that does **not** depend only on **mechanical interlocking** [6]. The properties of adhesion have been used to develop strategies for specific applications achieving a **barrier function** in guided bone regeneration meshes and an **open porous structure** in textile hernia meshes. The same technique was adapted to obtain stand-alone tubular structures with good results in terms of **reproducibility** and **mechanical properties**. A computational model was also realised with the possibility of the prediction of the behaviour of silk fibroin *in vitro* and *in vivo* during **enzymatic degradation**, thus helping the design of silk fibroin devices.

References

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