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Research Paper

Experimental study of the mechanical behavior of an explanted mesh: The influence of healing

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ARTICLE INFO

Article history:
Received 30 May 2016
Received in revised form
22 July 2016
Accepted 27 July 2016
Available online 10 August 2016

Keywords:
Mechanical characterization
Experimental protocol
Mesh
Soft tissue
Biological composite
Healing influence

ABSTRACT

To better understand the in vivo mechanical behavior of synthetic mesh implants, we designed a specific experimental protocol for the mechanical characterization of explanted mesh under uniaxial tension. The implantation of a mesh leads to the development of scar tissue and the formation of a new composite made of native tissue, a mesh implant and scar tissues. This study focused on three points: determining the minimum representative size of mesh implants required for mechanical test samples, highlighting the influence of healing, and defining the healing time required to ensure stabilized mechanical properties.

First, we determined the minimum representative size of mesh implants for the mechanical characterization with a study on a synthetic composite made of mesh and an elastomeric matrix mimicking the biological tissues. The size of the samples tested was gradually decreased. The downsizing process was stopped, when the mechanical properties of the composite were not preserved under uniaxial tension. It led to a sample representative size 3 cm long and 2 cm wide between the grips.

Then an animal study was conducted on Wistar rats divided into eight groups. One group was set as control, consisting of the healthy abdominal wall. The other seven groups underwent surgery as follows: one placebo (i.e., without mesh placement), and six with a mesh installation on the abdominal wall and healing time. The rats were sacrificed after different healing times ranging from 1 to 5 months. We observed the influence of healing and healing time on the mechanical response under uniaxial tension of the new composite formed by scar, native tissue, and textile.

It seems that 2 months are required to ensure the stabilization of the mechanical properties of the implanted mesh. We were not able to tell the control group (native

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http://dx.doi.org/10.1016/j.jmbbm.2016.07.033

abdominal wall) from the placebo group (native and scar tissue). This protocol was tested on two different prostheses after 3 months of healing. With this protocol, we were able to differentiate one mesh from another after host integration.

1. Introduction

With around one-third of women suffering from pelvic prolapse (Swift et al., 2005; Hendrix et al., 2002), this pathology has become a major public health issue. In extreme stages of this disorder, patients have to go through surgery reconstruction, including the use of a synthetic prosthesis. Inspired by meshes used in hernia repair, surgeons began to use synthetic meshes in the late 1990s (Debodinance et al., 2006). Synthetic meshes present better performance with respect to the use of the native or biological tissues (Bot-Robin et al., 2011). However, follow-up studies (Abed et al., 2011) still show numerous cases of complications (dyspareunia, mesh exposure or retraction, chronic pain, etc.) leading in the worst cases to the removal of the mesh.

Meshes were initially developed for hernia repair implants. These implants were designed with respect to the role it had to supply in the abdominal wall. One study conducted by Gabriel et al. (2011) showed that fascia tissues from the abdominal wall are four to ten times more rigid than vaginal wall tissues. A few studies suggest (Feola et al., 2013a; Röhrnbauer and Mazza, 2013) that a mismatch between the mechanical characteristics of the mesh and the native tissue might be one of the reasons for the poor host integration in the case of pelvic surgery.

Since the US FDA recommendation (U.S. Food and Drug Administration, 2011) and the removal of some pelvic organ prolapse (POP) meshes from the market, the trend in the urogynecological implant industry favors lightweight, wide-pore meshes with very poor assessment. To determine the relevance of synthetic implants, industry is increasingly seeking to characterize the mechanical accuracy of implants. Many studies focused their interest on the mechanical properties of the dry textile prosthesis (Edwards et al., 2013; Feola et al., 2013b; Jones et al., 2009; Krause et al., 2008). The term “dry textile” refers to any textile before implantation, in contrast to explanted meshes that includes biological tissues. The mechanical characterization of a dry mesh may not be representative of its in vivo behavior (Röhrnbauer and Mazza, 2013). When the mesh is implanted, it is colonized by tissues. Therefore, the mechanical properties of native tissues and colonized textile need to be determined rather than dry textile and scar tissue because they do not exist separately.

The surgical treatment of genital prolapse affects the mechanical behavior of the native tissues: a synthetic prosthesis is implanted on the vaginal wall and scar tissue grows around it. A new composite, constituted of textile, scar tissue and native tissue, replaces the native tissue. Due to healing (Bellón et al., 1995c), this composite, including native and scar tissues as well as textile, varies over time before stabilization, and healing time might be a critical parameter when an explanted mesh is tested.

The mechanical characterization of the implant has to take into account the integration process of the implant and the scarring process in the surrounding area, i.e., the healing impact on tissues and textile. Since a study on dry textile lacks information on the in vivo behavior, this research focused on the characterization of the mechanical properties for a mesh once implanted and healed. The dry prosthesis must be optimized with respect to the native tissue it will support while knowing how the healing process will affect its mechanical behavior.

Even if the mechanical characterization protocol for human soft tissue is well documented in the literature (Ettema et al., 1998; Rubod et al., 2007), composites made up of tissues and implants are insufficiently known. To fully characterize these composites and how implantation impairs the mechanical properties of native tissues, it was necessary to establish a new experimental protocol able to identify the relevant mechanical features. The present study aims at developing a new testing protocol for the characterization of a composite material made of textile and biological tissues. To set up such a protocol, an animal study on rats was conducted. In the first step, characterization technics were adapted to the size of the animal considered. Next, the healing time before explantation was studied to achieve the stabilized healed mechanical properties of the composite. Finally, the impact of a mesh implantation was studied with respect to the healing process which was also expected to affect the mechanical properties of native tissues.

2. Material and methods

2.1. *Mechanical testing and modeling*

The mechanical features are characterized using a uniaxial tension test at a constant displacement rate of 5 mm/min, which induces an average strain rate of $3 \times 10^{-3}\ s^{-1}$. Biological soft tissues display a viscous mechanical behavior (Rubod et al., 2008; Pena et al., 2010). This displacement rate is chosen low and constant to avoid affecting the results with any observable viscoelastic phenomenon. This testing protocol for biological tissue was used and validated previously for testing ewe and human connective tissues (Rubod et al., 2007).

We designed a transportable testing machine (BIOTENS shown in Fig. 1) to directly characterize the mechanical features of the biological sample when harvested in a medical environment.

The sample is clamped in the grips (Fig. 1b). Forces were measured with a 100-N load-cell (sensitivity 0.02 N). Displacement was recorded from an internal sensor of the motor (Acquisition frequency 8 Hz; precision 0.05 mm). Stress and