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The suture retention test, revisited and revised

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ABSTRACT

A systematic investigation of the factors affecting the suture retention test is performed. The specimen width w and the distance a of the suture bite from the specimen free edge emerge as the most influential geometrical parameters. A conservative approach for the quantification of suture retention strength is identified, based on the use of a camera to monitor the incipient failure and detect the instant of earliest crack propagation. The corresponding critical force, called break starting strength, is extremely robust against test parameter variations and its dependence on the specimen geometry becomes negligible when $a \geq 2$ mm and $w \geq 10$ mm. Comparison of suture retention and mode I crack opening tests reveals a linear correlation between break starting strength and tearing energy. This suggests that the defect created by the needle and the load applied by the suture thread lead to a fracture mechanics problem, which dominates the initiation of failure.

1. Introduction

Sutures and staples are widely used in surgical contexts, such as in wound treatment or biomedical device implantation. Typical applications aim at closing a damage or a cut within a soft tissue by approximating its open margins, or at firmly connecting an implant to the surrounding environment in order to allow for the formation of new structures. A detailed understanding of the interaction between the suture thread (or staple) and the surrounding material is thus crucial to avoid local damage due to excessive loading.

The interaction between one suture point and the surrounding tissue is traditionally assessed by means of an *ad hoc* mechanical test aimed at quantifying the suture retention strength (SRS). This is especially popular in the cardiovascular field, where novel grafts are typically characterized based on their capability to exceed a 2.0 N threshold in terms of SRS (Billiar et al., 2001; Mine et al., 2010). The test is usually performed according to the AAMI/ISO/ANSI 7198 Standard (2016) (Fig. 1) which defines the SRS, often referred to as anastomotic strength, as “the force necessary to pull a suture from the prosthesis, or cause the wall of the prosthesis to fail”. This is generally interpreted as the peak force reached during suture pullout.

The norm only provides a vague indication of the suture type to be used for the test, which shall be “as close in size to the typical clinical instrument as possible” (ISO 7198, 2016). However, a number of different suture thread thicknesses and needle types are encountered in the clinics, often chosen based on the surgeon's experience and intended application. Thus, the norm also prescribes that the employed suture size be recorded (ISO 7198, 2016). In this context, Trostle et al. (1994) performed an investigation varying the suture bite size and observed a logarithmic enhancement in the SRS for larger holes. Mine et al. (2010) studied expanded polytetrafluoroethylene (ePTFE) grafts by using steel suture wires introduced in a previously obtained circular 0.4 mm diameter pinhole and reported a decreasing measured force when thicker wires were used. They observed different breaking patterns and proposed the existence of an early failure point for specimens displaying a circumferential tear. The corresponding force, named break starting strength (BSS), seemed to depend only moderately on the employed wire thickness. The breaking pattern appeared to be influenced by the graft fiber orientation (Mine et al., 2010). Chaparro et al. (2016) additionally reported an effect of the fibrous architecture of electrospun vascular scaffolds on the extent of specimen involvement in the suture pullout process, thus affecting the measured value of SRS.

Quite surprising for a material testing procedure, most geometrical parameters (see Fig. 1 for a schematic) remain unconstrained by the norm. Information is provided neither on the values to be adopted for the specimen width, w, which might be related to the interspace distance in sutures with multiple points (e.g. mattress type), nor for the distance of the suture bite from the clamped edge of the specimen, L_0. Though, both factors might influence the local load redistribution and bias the outcome of the test. For instance, typical suture interspace distances used for closure of abdominal incisions range between 9 and 15 mm (Campbell et al., 1989; Cooney et al., 2017; Descoux et al.,

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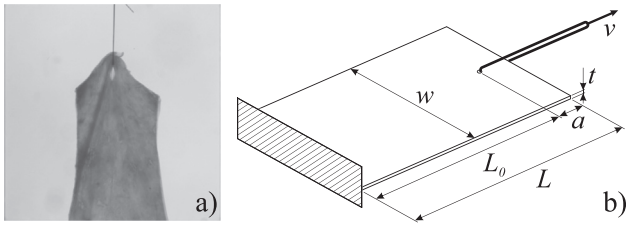

Fig. 1. Example (a) and schematic representation (b) of a specimen during suture retention strength test; the main geometrical parameters are defined.

1993), and a recent clinical trial reported reduced occurrence of incisional abdominal hernia in patients treated with smaller bites located at a closer interdistance (Deerenberg et al., 2015). Moreover, no indication is given on the relevance of the specimen thickness, *t*, nor is its role discussed. In contrast, the suture bite depth, *a*, i.e. its distance from the specimen free edge, and the pulling speed, *v*, are prescribed by the norm. The former shall amount to 2 mm and the latter shall be in the 50–200 mm/min range (ISO 7198, 2016). Suture bite depths of 10 mm are typically adopted in abdominal surgeries (Bhat, 2014). Recent work by Cooney et al. (2017) demonstrated increased values of SRS for larger values of *a* and *w* and proposed possible relations to rationalize the observed dependence. These findings indicate a clear need for a systematic investigation of the factors affecting SRS measurements and for more detailed prescriptions on the procedure to be adopted to assess a material's suitability for suturing.

The present study investigates the role of several test parameters for silicone elastomers (SE) and soft biological membranes (SBM). The outcome is rationalized by means of finite element (FE) modeling. This suggests the existence of a “region of trust” for the values of *a* and *w*, whereby the test results become roughly independent of the specimen geometry. An early failure point, akin to that proposed by Mine et al. (2010), is identified for all the tested specimens and shown to provide a preferable metric for suture retention tests. Finally, the measured critical force is related to the fracture properties of the tested materials, characterized by their tearing energy obtained from mode I crack opening tests, as typically applied to elastomers (Rivlin and Thomas, 1953) and soft tissues (Taylor et al., 2012).

2. Materials and methods

2.1. Materials

2.1.1. Sutures

Products were obtained from different manufacturers: vetsuture® (vetsuture, Noévia SAS, Paris, France), B. Braun (B. Braun Melsungen AG, Melsungen, Germany), YAVO Sp. (Przedsibiorstwo YAVO Sp. z o.o., Bechatów, Poland), and Medtronic Covidien (Medtronic Covidien, Zurich, Switzerland). When not specifically indicated otherwise, 5-0 polypropylene nonabsorbable sutures were employed. The influence of thread thickness was studied by comparing 3-0, 5-0, 6-0, and 8-0 sutures; the respective gauge ranges according to the U.S. Pharmacopeia (2005) are reported in Table 1. Each suture was inserted into the specimen by means of the corresponding needle provided by the manufacturer.

Table 1
Thread gauges for nonabsorbable and synthetic absorbable sutures according to the U.S. Pharmacopeia (2005).

U.S. Pharmacopeia suture size	Thread gauge range [mm]
8–0	0.040–0.049
6–0	0.070–0.099
5–0	0.100–0.149
3–0	0.200–0.249

2.1.2. Elastomer samples

Four SE were considered: two types of PDMS (Sylgard 184 and 186, both with a 10:1 mixing ratio of base polymer to crosslinker; Dow Corning, Midland, MI, USA) and two types of RTV (RTV 4528, Bluestar Silicones, Lyon, France, and SMI G/G 0.020″, Specialty Manufacturing Inc., Saginaw, MI, USA). The production method for the first three is described elsewhere (Bernardi et al., 2017b). Thickness control and homogeneity were ensured by using two 150 × 150 mm^2 custom-made glass plates, kept apart by Teflon spacers of prescribed thickness; clips were used to hold the two plates against each other throughout the curing time indicated in (Bernardi et al., 2017b). After curing, the plates were separated and the elastomer sheets were gently lifted; specimens of the desired size were obtained by means of a surgical scalpel. SMI was acquired as material sheets of controlled thickness, which were then cut to the desired dimensions.

2.1.3. Soft biological membrane samples

The following materials were tested: human amnion, bovine Glisson's capsule, and porcine pericardium. Amnion specimens were obtained from fresh fetal membranes collected from patients who underwent elective caesarean sections between 37 and 39 gestational weeks. Patients were recruited with informed written consent using a protocol approved by the Ethical Committee of the District of Zurich (Stv22/2006 and Stv07/07). Immediately after collection, the amnion was gently separated from the chorion and stored in physiological saline solution (9 g/l NaCl) until the moment of testing, which occurred few hours after delivery. Porcine hearts and portions of bovine livers (approximate size: 120 × 120 mm^2; extracted close to the hepatic artery) were obtained from a local abattoir after animal euthanasia and inspection by a veterinarian. The Glisson's capsule was detached from the parenchyma with the help of a small bubble of physiological saline solution inserted between them via a syringe, as described in by Brunon et al. (2010) and Bircher et al. (2016). The pericardium was incised and then carefully lifted from the underlying myocardium by means of tweezers.

2.2. Mechanical testing

All the experiments were performed using a displacement-controlled, custom-built setup entailing two horizontal hydraulic actuators (MTS Systems, Eden Prairie, MN, USA) with 100 N load cells calibrated for a force range of 20 N and custom-made clamps (sandpaper was used to improve grip), and a CCD camera (Pike F-100B; Allied Vision Technologies GmbH, Stadtroda, Germany) with a 0.25× telecentric lens (NT55-349; Edmund Optics GmbH, Karlsruhe, Germany) providing a field of view of 30 × 30 mm^2 with a 1000 × 1000 pixel size.

2.2.1. Suture retention tests

Suture retention tests were performed on rectangular specimens clamped at the edge located opposite to the suture. The thread was passed through the material by means of the provided needle, then into the hole of a suture holder connected to one of the clamps, and finally closed into a loop by means of multiple knots (Fig. 2a). The specimen had free length *L* and width *w*. The suture bite was centered with respect to the specimen width and its distance from the clamp was $L_0 = L - a$ (Fig. 1b). The values of the geometrical parameters were varied throughout the study. Unless otherwise stated, the following dimensions were adopted (reference geometry): $a = 2$ mm; $w = 10.8$ mm; $L = 20$ mm; $t = 0.5$ mm.

The suture loop was first pulled at a rate of 0.2 mm/s until a prescribed force threshold was reached, while the specimen was held fixed. Once the suture wire was taut, a pulling rate $v = 1$ mm/s was applied by moving both clamps until final specimen failure, characterized by suture pullout. The specimen was monitored by the camera throughout testing and the instant of first crack propagation from the suture bite was identified from the recorded series of images. BSS was determined