AN EXHAUSTIVE TEST PROTOCOL FOR THE MECHANICAL CHARACTERIZATION OF SURGICAL MESHES

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Introduction

The mechanical characteristics of surgical meshes, adopted for the strengthening of herniated abdominal wall and for the treatment of pelvic floor disorders, are often burdensome to determine and compare due to the absence of specific standards or harmonized test protocols [1], [2]. In this context, it is usual to adapt International Standards, available for different scopes, in terms of (1) reduction in specimens dimension and (2) adjustment of test parameters (e.g. strain rate) [3]. The computation of mechanical parameters is also affected by the lack of specific standards which define results to report as well as data post-processing methods.
This study proposes an *in vitro* protocol for the mechanical characterization of surgical meshes. Its repeatability was tested on 14 polypropylene meshes, 3 composite meshes and 6 urogynecologic devices.

Methods

The test protocol was defined selecting three of the most performed test methods: ball burst test, uniaxial tensile test and suture retention test. All the tests are conducted under displacement-controlled conditions performing five replicas for each configuration. In uniaxial tensile test and in suture retention test, specimens are cut along the weak and strong knitting directions of each mesh. The test set up of ball burst test is adapted from ASTM D6797-15 using reduced dimensions of circular specimens and ball-burst attachment. Nonetheless, the ratio between the internal diameter of the ring clamp and the diameter of the spherical indenter, suggested by the standard, is not modified. The standardized testing rate of 300 mm/min is used for the penetration of the specimens by the indenter. The bursting strength (BS) and the corresponding membrane tension (MTmax) and dilatational strain (DSmax) are computed from the raw data. ISO 13934-1:2013 is used as reference standard for the uniaxial tensile test, although dogbone specimens are selected in order to reach a compromise between small dimensions and acceptable ruptures (beyond 5 mm from the gripped region). The test is performed at a rate of 20 mm/min. The displacement of the narrow zone is recorded through a Digital Image Correlation (DIC) system using two markers sewn on mesh locations that do not alter the motion of the yarns. Markers coordinates and raw data are used for the computation of specimens deformation and tension at rupture (SR and UTS). Moreover, from the slope of the initial portion of the strain *vs* tension curves the secant stiffness (k) is extracted. In suture retention test rectangular specimens (70 mm x 55 mm) are tested using a test configuration adapted from [3]. The specimens are clamped with the upper grip and a Assusteel® monofilament wire (0.350-0.399 mm diameter) is inserted 10 mm from the inferior edge of each specimen. The upper grip is moved vertically at a rate of 300 mm/min till rupture. The suture retention strength (SRS) is then computed from the peaks of the force-displacement raw curve according to ASTM D2261-13.

Results

The repeatability of the test methods was evaluated through a frequency analysis of the coefficient of variations (CVs) within the parameters computed on the 335 specimens tested. The CVs distributions for the different test methods (Figure 1) highlight a negligible variability among them. Median values between 0.05 and 0.14 are indeed found for the three test methods, with rare CV values over 0.25.

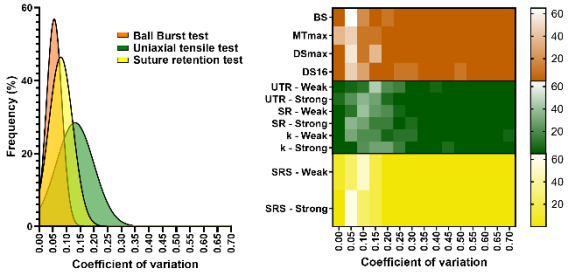

Figure 1: CVs frequency analysis. On the left, Gaussian fits on the frequency distributions for the three test methods; on the right heat map for the computed parameters.

Discussion

The proposed protocol allows a comprehensive mechanical characterization of surgical meshes, providing (1) information complementary to the in vitro basic characteristic (e.g., uniaxial strain and tension) and (2) an estimation of mesh performance under physiologic-like loads. The proposed test protocol results easily replicable for all the 23 surgical meshes. We encourage its adoption in other laboratories in order to obtain an extended and comparable dataset, and to allow the determination of the inter-subject variability assessing its repeatability among different users.

References

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