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The role of morphology in surgical mesh performance: experimental and computational insights

Abstract

Polypropylene surgical meshes are currently the most commonly implanted devices for treating abdominal hernias and pelvic floor disorders, conditions whose incidence has significantly increased over the past decades. However, despite the introduction of polypropylene surgical meshes in 1958, the lack of standardization in both mesh design and testing protocols has resulted in significant variability among commercially available products. As a consequence, the absence of universally accepted design standards may have contributed to recurrence rates that remain as high as 26.5% in hernia repair. Traditionally, the design of new devices has relied on trial-and-error approaches rather than analytical methods. On the contrary, a comprehensive understanding of how the knitted pattern's structure influences implant performance would benefit all stakeholders in hernia surgery, including surgeons, patients as well as manufacturers. The here presented research is driven by the need to systematically investigate the interplay between the morphological and mechanical characteristics of PP surgical meshes. The intent is to develop a framework that assists all the stakeholders involved in providing evidence-based treatment for patients. In particular, the work focuses on a combined approach that uses in vitro, in silico, and analytical methods to elucidate and quantify the relationship between the morphology and mechanical behavior of these textile devices.

In this perspective, the project starts developing an exhaustive test protocol for the mechanical characterization of synthetic surgical meshes. The test protocol is composed of three quasi-static test methods: (1) ball burst test, (2) uniaxial tensile test, and (3) suture retention test. For each test, post-processing procedures are proposed to compute relevant mechanical parameters from the raw data. The mechanical parameters were selected to ensure both meaningful device comparisons and information applicable to physiological conditions. The proposed test protocol was applied on 14 polypropylene meshes, 3 composite meshes, and 6 urogynecologic devices to verify its universal applicability towards meshes of different types and produced by various manufacturers, and its repeatability in terms of coefficient of variation. The test protocol resulted easily applicable to all the tested surgical meshes with intra-subject variability characterized by a coefficient of variations settled around 0.05. Its use within other laboratories could allow the determination of the inter-subject variability, assessing its repeatability among users of alternative universal testing machines.

Subsequently, a morphological investigation was conducted on the previously characterized meshes to assess the correlation between their knitted pattern and their mechanical behavior, identifying the most crucial morphological parameters able to support the design of new meshes. In this regard, morphological parameters related to pore size, shape, and orientation were computed based on high-resolution images using the poreScanner app, developed within the research group, and the

Matlab Image Processing toolbox. Additional parameters, such as weight and thickness, were measured through high-precision instruments. Multivariate regression models were implemented, each using one to five morphological parameters as independent variables and one of the twelve mechanical parameters as dependent variable. A leave-one-out (LOO) validation algorithm was then employed to estimate the models performance, robustness, and accuracy for potential future predictions. Promising results demonstrate a quantifiable relationship between pores characteristics and mechanical behavior with good coefficients of determination obtained by all the 12 regression models.

Finally, numerical models combining macroscale and mesoscale models were developed for lightweight and standard weight meshes. The macroscale approach treats the mesh as a homogeneous material with an anisotropic hyperelastic formulation, replicating the method currently adopted in the literature. However, given the strong correlation between morphology and mechanical behavior as highlighted in previous investigations, different methods for defining fibers orientation and fibers dispersions were investigated and compared in the context of defining the anisotropic material. In contrast, a mesoscale model, which incorporates detailed morphological reconstruction using isotropic material definitions, was developed to embed the anisotropic behavior in the geometry rather than in the constitutive model. A linear elastic and two isotropic hyperelastic material formulations were implemented and optimized for mesoscale models. Interestingly, despite using isotropic materials definitions, the porous surfaces replicating pores shape and orientation were able to capture the anisotropic behavior. A validation based on the replication of the ball burst test was adopted for both approaches. The meshes with lower error values after the optimization process showed the best performance in the validation process. Additionally, the best mesoscale and macroscale simulations obtained similar performances even in the validation process.

At present, the design of new devices relies on trial-and-error approaches rather than analytical methods. Conversely, the dissertation presented here provides a comprehensive and consistent framework to raise awareness about the strong interplay between morphology and the performance of these medical devices. In this regard, pores shape and dimensions should be considered throughout all phases, from design to surgery day, taking into account the loading conditions the device will withstand in vivo. By addressing these aspects, it would be possible to enhance clinical outcomes, potentially reducing post-surgical complications and improving tissue integration. Building upon this foundation, the methodologies developed in this work hold promise for further advancing personalized mesh design and selection by integrating patient-specific anatomical and biomechanical data. Such an approach could support surgical planning and clinical decision-making, ultimately leading to more tailored treatments and improved patient outcomes.