Abstract

Since their introduction in the 1960s, surgical meshes have become the gold standard for the treatment of abdominal wall hernias and their use has subsequently expanded to the treatment of stress urinary incontinence and pelvic organ prolapse. Despite the rapid growth of surgical mesh market, the field still lacks standardisation regarding both the test setup for assessing their mechanical and morphological properties and the identification of the most suitable characteristics for reducing adverse events. As a result, recurrence rates and the frequency of other complications vary widely across the literature. This variability has recently raised concerns regarding the effectiveness and safety of these devices, particularly for urogynecological applications. Consequently, in the new Medical Device Regulation of the European Union, meshes were up classified to class III, the highest risk category for medical devices.
This doctoral dissertation aims to address the need for standardisation in the field of surgical meshes, focusing on different phases of the medical device lifecycle. The selected approach and the topics investigated are the outcome of a collaboration between Politecnico di Torino and a manufacturer of surgical meshes.

The first part presents an image analysis method for computing textile and effective porosity, the latter excluding pores in which the distance between two parallel yarns is less than 1 mm. A dedicated photographic setup for the acquisition of mesh and calibration images was developed. Subsequently, a seven-step image analysis procedure designed to improve image quality and porosity computation is introduced. To enhance usability and promote adoption from other research groups, the algorithm was implemented in a free-to-use MATLAB-based application, called *poreScanner*. The protocol was applied to 24 different meshes, with porosity values computed as the average of seven independent measurements. The coefficient of variation was calculated to validate the procedure and a usability test was carried out on the app.
The coefficient of variation was below 5% in 95% of the measurements, while a maximum value of 1.84% was reached in the usability test, confirming the robustness of the procedure.

The work then focused on studying the influence of design inputs on mechanical and morphological properties of surgical meshes. Surgical meshes are textile fabrics, usually manufactured using the knitting technology, which consists of forming yarns into loops and connecting them together to form a stable structure. Different patterning options, known as lappings, are available depending on the yarn path within the textile. The appearance of meshes can also be varied during production by adjusting the density of horizontal rows and vertical columns of stitches, referred to as courses and wales, respectively. Following production, meshes undergo post-processing treatments such as cutting, heat setting and forming, which confer the device its final shape. Among these processes, heat setting applies relatively high temperatures for a defined period while tensioning the mesh. Although this process improves handling, its effect on mechanical and morphological properties of meshes is not clear. For this reason, a factorial approach was first adopted to assess the effect of heat setting temperature and time on the stiffness and morphology of a produced lapping.

Based on the results, a combination of heat setting parameters was chosen, and the study was extended to evaluate the effect of course density on two different lappings. The mechanical characterization protocol was previously developed by our research group and includes uniaxial tensile test, ball burst test and suture retention test. Additionally, the image analysis method described above was used for morphological analysis.
The results indicate that heat setting temperature significantly influences mesh properties, with higher values reducing stiffness and thickness while increasing both porosity measures. Course density also showed a statistically significant effect on mechanical and morphological properties, with outcomes varying depending on the lapping. Overall, both parameters should be carefully considered during the design phase, as they affect device performance.

Subsequently, an electronic batch record file was developed to support the production control phase of mesh lifecycle. The file was developed in Excel, due to its flexibility to reproduce the user interface of the current paper-based records and the ease of integration with other Excel-based modules. Validation was carried out following ISO/TR 80002-2/2017, while a usability test with production personnel was also performed. Both had positive outcomes and therefore the same process will be applied to other batch records.

Finally, the activities related to the post-market phase were carried out. Specifically, a protocol for the retrieval of meta-analyses was implemented as part of the update of the State Of The Art (SOTA) file for the company's medical devices. The AMSTAR2 guideline of the GIMBE association was followed to define the appraisal method. In addition, a strategy based on the combined use of general surveys and so-called High Quality Surveys was developed to generate new clinical data. The first submitted surveys allowed to fill some gaps found in the clinical evaluation of certain medical device groups.

In conclusion, this research project underscores the importance of standardisation across the various stages of the surgical mesh lifecycle and introduces a set of methods aimed at advancing progress in this area, considering both academic and industrial perspectives. In fact, this work contributes to the development of reproducible experimental protocols, supports regulatory compliance, and promotes improved clinical outcomes for patients.