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Mechanical behavior of the wall of inflatable penile prosthesis for implanted penile modeling

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1. Introduction

Erectile dysfunction (ED) is a common health issue among males worldwide (Salonia et al., 2022). When pharmacological treatments, whether oral or injectable, fail to achieve an erection, healthcare professionals typically recommend treatment through inflatable penile prosthesis (IPP) (Levine et al., 2016). Currently, devices manufactured by American Medical Systems (AMS, now Boston Scientific) and Coloplast are the most widely used worldwide. These devices consist of a pair of cylinders placed under pressure within the corpus cavernosum (CC) of the penis.

Significant efforts are currently underway in modeling penile pressure to understand the erectile mechanisms involved in an implanted penis and to enhance implant design (Bose et al., 2024). However, in addition to the lack of knowledge regarding the biomechanical properties of penile tissues, the behavior of implant walls is not quantitatively well-known. This gap hampers the understanding of interactions between the implant and surrounding tissues, particularly with the tunica albuginea (TA), a fibrous connective membrane surrounding the cavernous tissue of the penis and contributing to the erection mechanism through its mechanical rigidity (Fereidoonenezhad et al., 2023). Furthermore, a better knowledge of the behavior of the implant wall in relation to the TA would help in the development of new penile prosthesis. The aim of the work reported here is to quantify the mechanical behavior of the wall of the AMS 700™ implant (Boston Scientific) under uniaxial tensile load with the aim of providing behaviors for implant numerical models. These are the first results which are compared with the mechanical behavior of TA for future work.

2. Methods

2.1 Material

An IPP with connector dysfunction was removed from a patient after use for replacement. The IPP was disinfected a first time with a bactericide shortly after collection and then stored at room temperature to be disinfected a second time before cutting (approximately 2 hours in total). For each of the 2 implant cylinders, 2 wall punches were cut respectively longitudinally and circumferentially using I-shaped die-cuts as illustrated in Figure – a. The cutting revealed the presence of 3 distinct, unrelated superimposed layers: 2 of silicone surrounding a 1 layer of fabric with 2 orthogonal “fibers orientations”. Each layer was tested independently for the 4 punches. In total, 4 fabric samples and 8 silicone samples were tested.

2.2 Tensile tests

Tensile tests were carried out using an INSTRON 8802 machine (High Wycombe, England). Each sample was marked with 2 ink dots at the extremities of the gauge length. The thicknesses of the samples were measured with a caliper. Their width was considered as equal to the die-cut geometry, i.e. 6 mm.

To prevent any slippage, the shoulder part of the samples was tightened with emery cloth. Before tightening the sample in the lower handle, an image was taken to measure its reference length between the marked dots. The sample loading was applied at a strain rate of 0.01 s⁻¹, up to 100 mm. The stretch of the samples was measured from a video recording on which the dots were tracked. The load was measured using a 250 N cell.

2.2 Mechanical behavior assessment

Nominal stress vs stretch curves were computed for the different layers; and were compared to the tensile curve obtained previously on the TA of human corpora (Luet et al., 2023). Tangent moduli in the linear parts of the curves were also compared.

3. Results and discussion

3.1 Structural Design

The three layers of each sample slid against each other, making it difficult to conduct tests involving all three layers simultaneously. The inner and outer layers were made of silicone, with thicknesses of 0.5 mm and 0.3 mm, respectively. The fabric layer had a thickness of 0.3 mm and tended to fray along the edges.

3.2 Mechanical behavior

The stress-strain curves present distinct shapes between layers (Figure – b). A circumferential fabric test resulted in premature rupture. The inner and outer silicone layers displayed linear curves and were found to have the same isotropic behavior with a linear part

modulus lower than 1 MPa (Table). Furthermore, the silicone samples did not reach failure after a deformation of approximately 600%. A greater variability was observed for the fabric layer, which exhibits an anisotropic behavior and J-shaped stress-stretch curve, similar to the typical curves of nonlinear mechanical behavior of biological fibrous membranes (Figure - b). The tangent modulus of the linear part in the circumferential direction is very low and comparable to silicone in the TA deformation zone. The tangent modulus in the longitudinal direction is greater than the TA. Thus, it seems that in the circumferential direction, the deformation of the implanted penis under inflation is mainly driven by the TA. Moreover, in term of strength, the average values of the maximum nominal stresses in the longitudinal directions were respectively equal to 28 ± 1 MPa ($n = 2$) and 7 ± 2 MPa ($n = 4$) for the fabric and the TA, respectively (Luet et al., 2024).

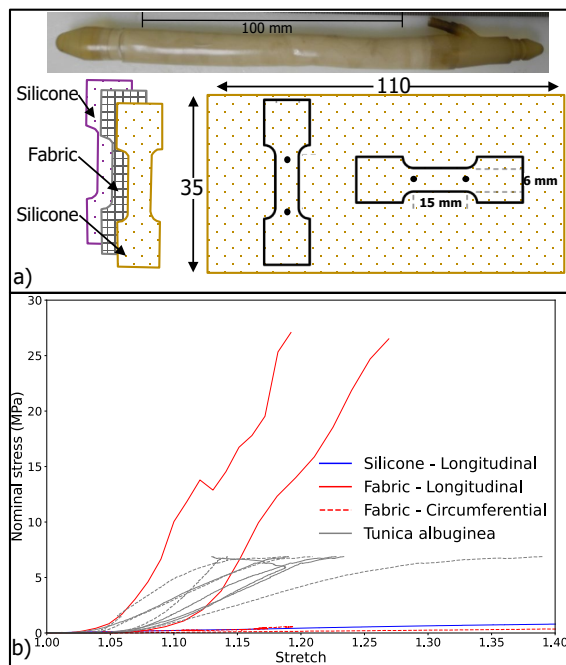


Figure. a) View of 1 cylinder of the inflatable penile prosthesis and main dimensions of samples. Three layers are obtained after cutting: silicone (yellow), fabrics (grey), silicone (purple). b) Nominal stress-stretch curves of fabric layer (red), 1 example of silicone sample (blue) compare to tunica albuginea (Luet et al., 2023)

Table. Average modulus in the linear parts of the curves (MPa)

	Silicone	Fabric	TA*
Longitudinal	0.8 ± 0.4 n=8	187 ± 13 n=2	82 ± 43 n=4
Circumferential	-	1.5 n=1	70 ± 36 n=4

* from Luet et al. (2023)

4. Conclusions

These first results represent a first step towards assessing the mechanical behavior of the wall of an inflatable penile prosthesis for modeling purposes. For the AMS 700 implant, the middle layer of anisotropic fabric plays a significant role in mechanical behavior, particularly longitudinally resembling the behavior of the tunica albuginea. Further studies involving a greater number and variety of implants (e.g., Titan, Coloplast) will be conducted under traction and other loading conditions to contribute to the development of the model of an implanted penis and enhance design and technology for novel penile prosthesis.

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