

Computational and experimental mechanical characterization of a novel corneal implant for the treatment of keratoconus

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References (if any):

Aims / Purpose:

Current treatment options of keratoconus have several limitations. These limitations have been addressed by developing a novel nitinol GROSSO® implant, that restores the physiological curvature of the cornea by virtue of a dome-shaped design. Its minimally invasive implantation requires accurate assessment of the mechanical properties, investigated here both experimentally and computationally.

Methods:

Bending of two opposite edges of the implant is necessary for its implantation in the intracorneal pocket. Bending was conducted experimentally at 37 °C using a DMA Q800 (TA Instruments) with a thermal chamber and a cell load of 18 N to obtain force-displacement curves. A computational model of the real implant was reconstructed from microcomputed tomographic acquisitions (Phoenix v|tomo|x m, resolution: 1µm). The mechanical behaviour of the implant was modelled by implementing a superelastic constitutive law with material parameters obtained from experimental tensile tests of the nitinol, which also determined the plastic permanent deformation value. Finite element analysis of the bending simulation was performed in Abaqus (Dassault Systèmes Simulia Corp.) to obtain the bending force (BF) and assess the absence of permanent deformation.

Results:

A good agreement between the experimental (0.09 N) and computational tests (0.08 N) in terms of BF was observed. The computational simulation highlighted that the maximum principal strain value during bending was 10.8%, i.e. below the limit strain for plasticity of 12%.

Conclusions:

The GROSSO[®] implant can be safely bent during implantation with minimal effort, as the force applied does not exceed 0.1 N. The ongoing validation of the computational model will enable a cost-effective prediction of macro-scale mechanical properties and compliance with relevant standards and regulatory requirements. Additional critical scenarios and the remodeling effect imposed by the implant on corneal tissue will be the subject of future investigations.