# DEVELOPMENT OF A NOVEL NITINOL CORNEAL IMPLANT FOR THE TREATMENT OF KERATOCONUS

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## Introduction

Keratoconus (KC) is a progressive corneal ectatic disorder that causes stromal thinning and collagen weakening, resulting in a cone-like protrusion of the cornea and significant loss of vision and quality of life. Current treatment options suffer from major limitations [1]. Contact lenses and spectacles are only effective in early KC stage. Reductive laser corrective surgery is of limited use as KC corneas are thinner than healthy ones. Corneal transplant is invasive and expensive. Ring-shaped implants offer scarce remodelling support to the cornea leading to poorly predictable clinical results. The GROSSO® implant is the world's first Nitinol corneal implant aiming at remodelling the whole cornea by virtue of a dome-shaped design.

Here, we assess experimentally and computationally the mechanical performance of the GROSSO® implant in two potentially critical situations. The first situation consists in a 90° bending of two opposite edges of the implant occurring in its minimally invasive implantation in the patient's intracorneal pocket. The second one is a vertical crushing of the device to test its strength and provide information on possible impacts occurring in daily use. Moreover, a thermal colouring process of the Nitinol through heat-treatment is being developed to obtained coloured implants matching the iris colour of patients and minimise the visibility of the implant.

## Methods

The computational model of the GROSSO® implant was reconstructed from micro-computed tomographic acquisitions (Phoenix v|tome|x m, resolution: 1 µm) of the actual GROSSO® implant. The mechanical behavior of the Nitinol alloy was modelled by implementing a super-elastic constitutive law with non-linear material parameters obtained from experimental tensile tests, which also determined pseudoelastic behaviour and the strain value at which permanent plastic deformation occurs. Finite element analysis of the bending and crushing tests were performed in Abaqus (Dassault Systèmes Simulia Corp.) to obtain the reaction force (RF) exerted by the device, its maximum principal stress and maximum principal strain, verifying the absence of permanent deformations.

Heat treatment in an inert atmosphere at specific temperatures was used to control the thickness of the oxide layer and thus the interference color.

## Results

The maximum principal strain reached by the filigree connectors of the device in the bending simulation is 6.9% (Fig. 1A), while the maximum principal stress is 620 MPa, and the RF is 0.19 N. The crushing simulation indicated a maximum principal stress value of 519 MPa, a maximum strain value of 3.8% and an RF of 0.71 N. The developed computational tool is currently being validated through experimental replication of the bending and crushing simulations. Preliminary experimental results on the bending of the device confirmed the order of magnitude of the RF. Thermal treatments show promising color changes on polished Nitinol discs (Fig. 1B).

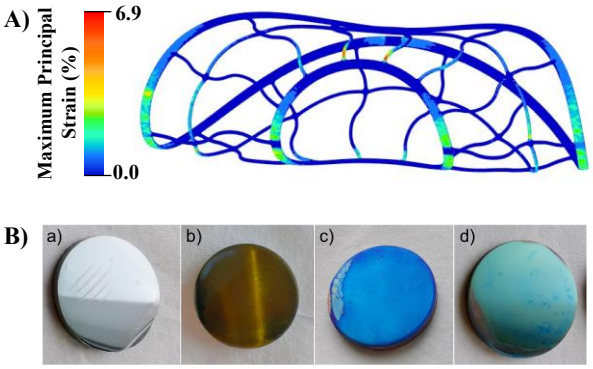


*Figure 1. A: Maximum Principal Strain reached by the implant during bending. B: Polished Ø25 mm nitinol disks (56.0 wt% Ni, $A_f$ = -14.1°C) a) as-polished, b) after heat-treatment at 400°C, c) 450°C and d) 500°C.*

## Discussion

The GROSSO® implant is expected to offer mechanical stability without any risk of permanent deformation either during implantation or during daily use. These results appear promising in view of providing a predictable clinical outcome to KC patients. The developed computational tool allows exploring different device designs, cost-effectively predicting the mechanical properties at the macroscale, and the compliance to relevant standards or regulatory requirements. Moreover, the established anodization process allows achieving colour specificity to match the most common colours of the human iris. As next steps, surface modifications induced by the anodization process will be characterized. Moreover, the interaction between the device and corneal tissues will be modelled by digitally generating KC corneal anatomies to evaluate the anatomical fitting and the reshaping effect.

## References

1. Atalay et al, Ther Adv Ophthalmol, 13: 1-13, 2021.

## Acknowledgements

Horizon 2020 project HUMANeye (GA 878719) is acknowledged.