In Silico Modeling of the GROSSO® Reshaper Corneal Implant in Trauma-Induced Corneal Biomechanical Weakening

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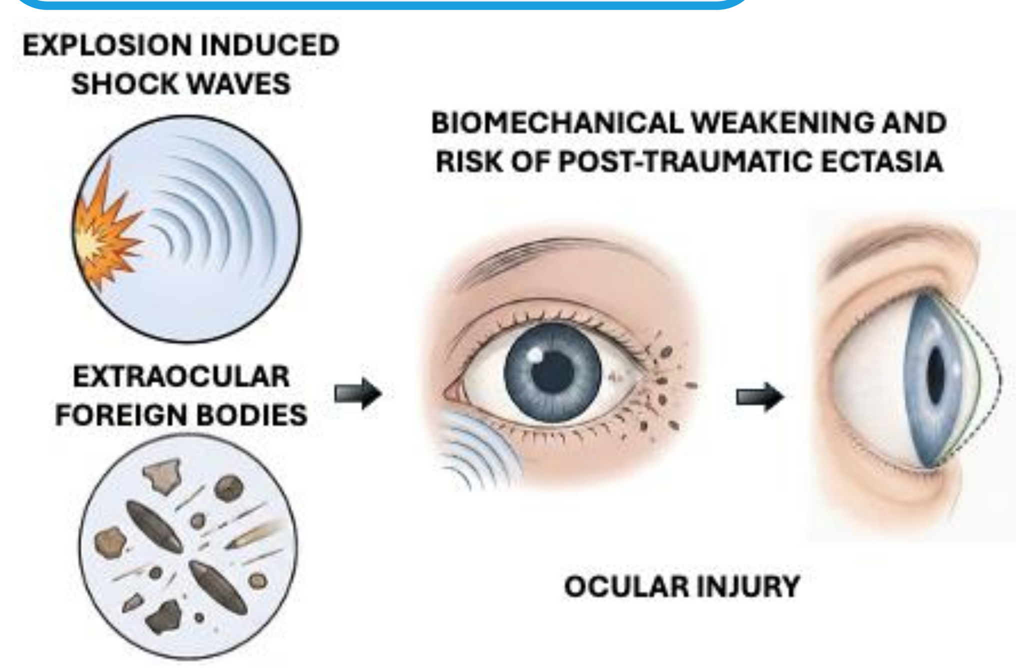
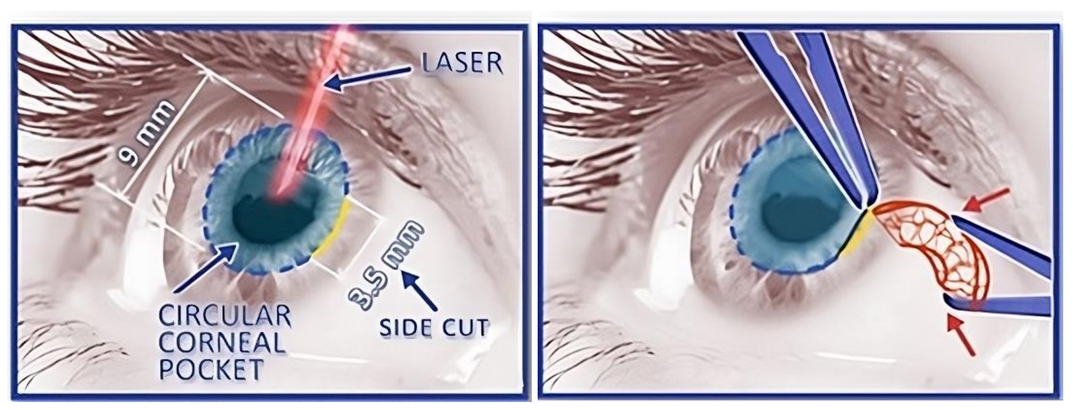
INTRODUCTION



Ocular trauma, including ***extraocular foreign bodies*** and ***blast-related contusions***, two of the leading causes of eye injuries presenting to civilian emergency departments, can compromise corneal microstructure and induce ***biomechanical weakening***, while increasing the risk of ***post-traumatic ectasia***.

RECORNEA is an Italian clinical-stage medtech VC-backed company developing minimally invasive therapeutic devices in ophthalmology. The first product developed by Recornea is ***the GROSSO® Reshaper***, the world's first nitinol intracorneal device for keratoconus.

Currently under clinical investigation, no serious adverse events are reported. Potential indications extend to secondary corneal ectasias, post-keratoplasty astigmatism and higher-order aberrations, and as a dual use also for ***corneal deformation after war-related traumas in civilians and military.***



The GROSSO® Reshaper – minimally invasive surgical procedure

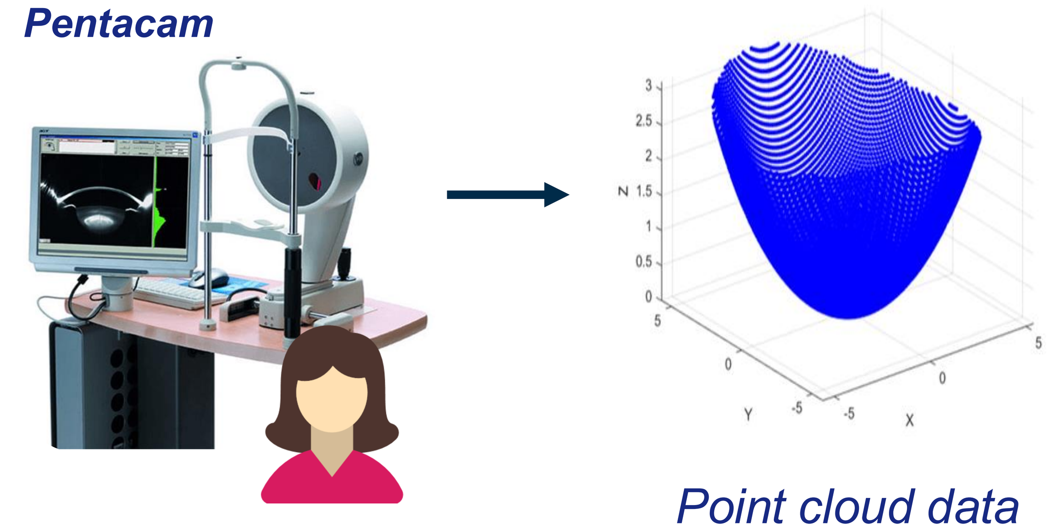
The device implantation involves a ***minimally invasive surgical procedure*** where an intracorneal pocket is created by a femtosecond laser and the device is bent and placed inside the pocket.

A ***patient-specific numerical framework*** has been developed in Abaqus Standard and validated for simulating the GROSSO® Reshaper implantation in an ectatic cornea as tool to predict and quantify corneal remodeling in weakened corneas.

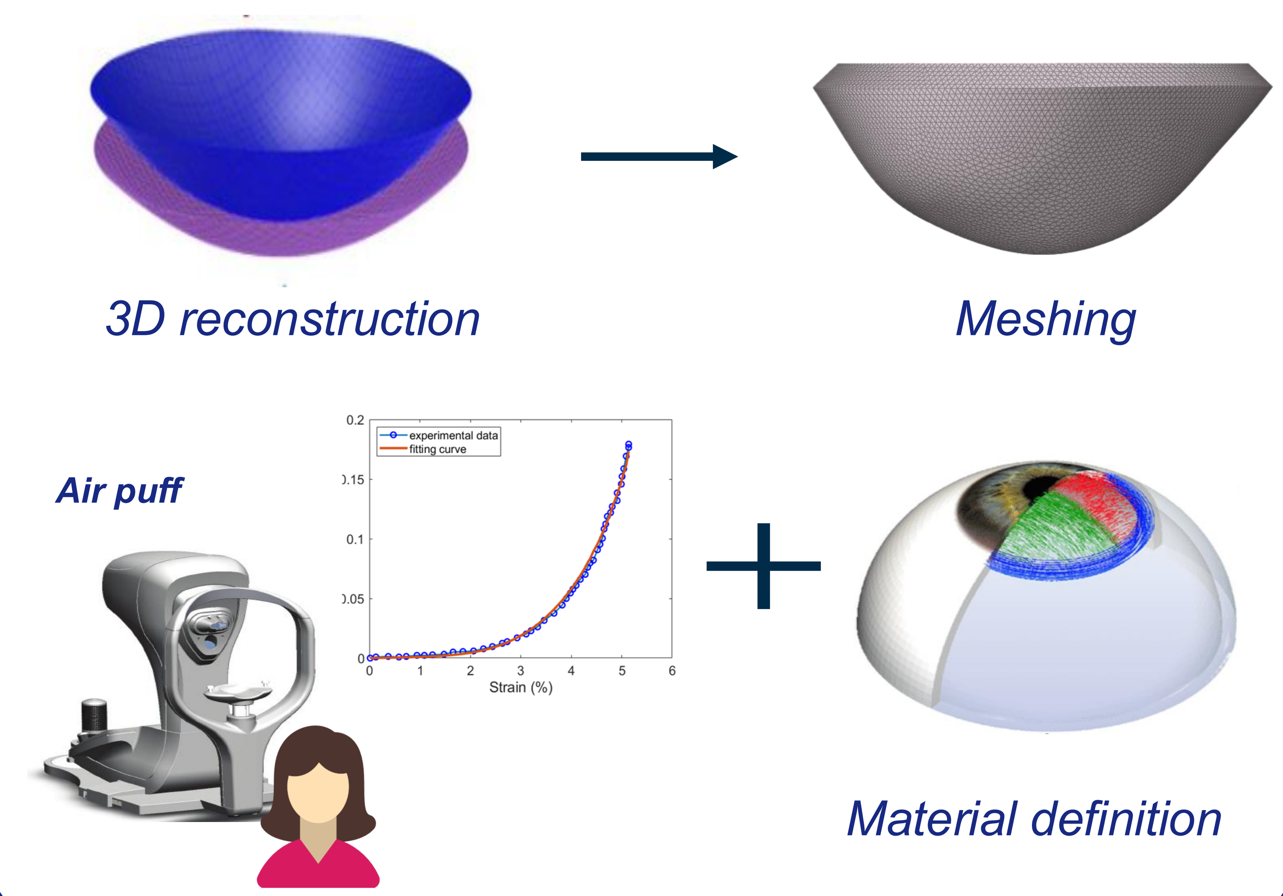
METHODS & RESULTS

3D models of an ectatic cornea, reconstructed from *in vivo* data, and of the GROSSO® Reshaper were developed. The corneal tissue was modeled using a ***hyperelastic constitutive law***, while the implant was modeled using a superelastic formulation.

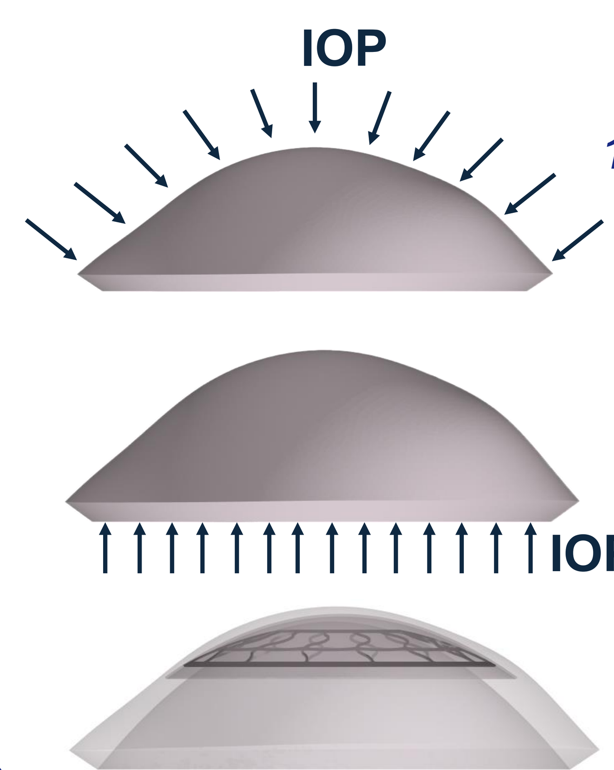
1. Data acquisition



2. Finite element model



3. Boundary conditions



A ***zero-pressure algorithm*** was applied to estimate the stress-free corneal configuration, followed by physiological re-pressurization and virtual implantation within an intracorneal pocket.

Refractive powers were calculated for both the *experimentally measured* post-implantation anterior corneal surface and the *numerically simulated* post-implantation configuration. The resulting percentage errors, which are all at most 6% (Table 1), confirm the reliability of the implantation simulation framework.

	K1 (D)	K2 (D)	Kmean (D)
EXPERIMENTAL (POST OP)	53.6	54.7	54.2
NUMERICAL (POST OP)	50.5	52.0	51.2
ERROR	6%	5%	6%

Table 1 – Comparison of the experimental and numerical refractive powers.

CONCLUSIONS

This computational framework provides a **potential decision-support tool to quantify corneal remodeling**, optimize implant design, and enhance surgical planning, with the ultimate goal of **improving visual outcomes and accelerating return to duty for both patients, civilians and people in the military.**

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