A comprehensive study of corneal tissue responses to customized surgical treatments

Chapter 10

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A case report about a 26 year old female subject who underwent refractive surgery sparked this idea of a prediction platform. All preoperative screening tests were normal for the subject and a well laid out postoperative management was followed. But the result was ectasia, diagnosed 3.5 years after the surgery. Questions soon followed from the clinics to the lab. “Why did this happen?” How do we prevent it?” AcuSimX™ was envisioned and then realized to give a predictive edge while planning a laser vision correction (LVC) or a customized collagen cross-linking (CXL) surgery so that such incidents can be prevented. In other words, it can be called a Digital Twin. A digital twin is a concept first practically defined by NASA in 2010, where a digital simulation was used to understand possible spacecraft operations.[1] The idea was that missions can be evaluated virtually on the ground and the best possible approach can be carried out in space. Similarly, we do simulations to understand the complex biomechanical responses of the human cornea and harness this knowledge to better shape the biomechanical outcome after surgery.

AcuSimX™ is introduced in this dissertation as a platform and not software. AcuSimX™ is a collection of software modules to implement any predictive simulation project in the field of ophthalmology. The platform has a 3-dimensional modelling module that can be used to create surfaces from a point cloud, e.g. creating a 3-dimensional corneal model from Pentacam HR tomographer elevation and thickness points. It also includes a module for implementing complex material property models to transform 3-dimensional structures into the mechanically functional body. AcuSimX™ incorporates mathematical equation solvers to perform finite element method (FEM) calculations using the defined bodies such as the cornea. The platform can also adjust the results using a large data AI-derived correction model, e.g. regression equations developed from AI using normative data.

For any platform to work outside the research domain a certain level of automation and simplicity is required. To this extent, the platform is encapsulated in an intuitive graphical user interface with ergonomic controls and well laid out workflow. Additionally, an internal database management module is present to keep track of the clinical data and simulation results. Most significantly, the platform has a robust input data quality control system. Patient measurement and clinical data suffer quality issues arising from an uncooperative patient (due to dry eyes, low vision etc.), instrument-related or operator related issues. Thus a robust quality control system can help in ensuring results are not affected by lower quality input data.

To the clinical community, this dissertation adds a way to use predictive surgery in clinical practice and thereby reduce the risk of ectasia after LVC procedures. Also, the treatment of keratoconus and post-LVC ectasia utilizing the promising customized CXL procedure.

The platform also provides a framework to envision future applications involving AI and FEM in the ophthalmology domain.

To society, the better prediction of possible ectasia after surgery means an increase in the accessibility of LVC procedures due to decreased false positives in screening tests. Also, increased safety due to reduced false negatives. Reduced ectasia incidence after the LVC procedure could lead to cost savings as further surgical intervention and medical care can be avoided. A well planned customized CXL procedure can increase the flattening and aid in better vision. All of which will help improve the visual acuity of the workforce, one of the most valuable natural resource of any nation.

To the scientific community, the dissertation already has accumulated a sizable normative and ectatic data set. Advanced machine learning and deep learning models which have shown great promise require a huge amount of data. A simple platform for predictive simulation would allow for large scale usage of such technology in the clinic. This would lead to more data generation, which could drive greater scientific research in the field of early diagnosis and treatment management.

Reference

1. Negri E, Fumagalli L, Macchi M. A review of the roles of digital twin in CPS-based production systems. *Procedia Manufacturing* 2017;11:939-948.