**Corneal biomechanics losses due to refractive surgery**

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**Abstract**

Recent advances, specifically the understanding in the biomechanical properties of the cornea and its responses to diseases and surgical interventions, have significantly improved the safety and surgical outcomes of corneal refractive surgery, whose popularity and demand are continue growing worldwide. However, iatrogenic keratectasia resulting from the deterioration in corneal biomechanics caused by surgical interventions, although remains rare, is still a global concern. On one hand, in-vivo biomechanical evaluation, enabled by new clinical imaging system such as Corvis ST, has decreased the number of iatrogenic keratectasia cases; on the other, new surgical modality like SMILE was introduced, theoretically offering superior biomechanical advantages to LASIK, but failed to prove such advantages clinically, creating more myths than answers. We have yet only had sound evidence that tPRK is the most preservative in term of corneal biomechanics compared to LASIK. The current in-vivo imaging methods such as ORA and Corvis ST for corneal biomechanics may have limitations that the parameters provided are all indications of the overall stiffness of the cornea but not its regionally variable intrinsic material properties. The aim of this paper is to discuss the importance of corneal biomechanical evaluation prior to refractive surgery and the current understanding in the corneal biomechanical deterioration caused by mainstream corneal refractive surgeries. Corneal refractive surgery introduces biomechanical deterioration to the cornea and may lead to severe complications such as keratectasia unless thorough risks screening and prediction is in place. Although we now have an agreement that tPRK may introduce the least deterioration, no agreement has been reached comparing SMILE and LASIK. New imaging techniques, parameters and evaluation systems may be needed to reflect the true advantages of SMILE over LASIK and/or when these advantages are significant enough to offer better prevention for severe post-surgery complications.

**Keywords**: Corneal refractive surgery, in-vivo corneal biomechanics

**Introduction**

Corneal refractive surgeries (CRS) reshape the anterior corneal surface to adjust the refractive power of the eye, enable light rays to focus on the retina and correct the various forms of refractive error. Keratectasia, although relatively rare (between 0.04 and 0.6% 1), is always considered a serious complication of CRS. 96% of keratectasia cases develop after laser-assisted in situ keratomileusis (LASIK) 1, while small incision lenticule extraction (SMILE) and other surface ablation procedures, such as laser-assisted subepithelial keratomileusis (LASEK), photorefractive keratectomy (PRK) and trans PRK (tPRK) are rarely associated with the condition. These trends and the increased demand for CRS in recent years have now made it essential to better understand the effect of various CRS procedures on corneal integrity and effectively identify patients at high risk of developing iatrogenic ectasia. A further purpose of research would be to develop less invasive CRS options with reduced biomechanical effect, such as those involving surface ablation, or solutions that integrate corneal cross-linking or use scleral contact lenses 2.

Despite a large body of research on the topic, the pathogenesis of iatrogenic ectasia is not yet fully elucidated. Ectatic cornea could have developed keratoconus or had biomechanical weakness preoperatively 3, with the loss of tissue during CRS further weakening the cornea, destabilizing its architecture, and precipitating ectasia 4. Several risk factors including abnormal topographic pattern, low residual stromal bed thickness, thin preoperative corneal thickness, young age, high refraction error correction and percent tissue altered have been identified for developing iatrogenic ectasia 5-7. This research and the current careful screening of potential candidates for refractive surgery, have led to reduced numbers of iatrogenic keratectasia cases \*\*\*\*\*refs\*\*\*\*\*.

This review looks closely at the biomechanics of the commonly used forms of CRS, the effects on corneal behavior and mechanical integrity and the current methods to estimate corneal biomechanics in vivo with a view to risk-assess individual CRS patients.

**Corneal biomechanics and its imaging**

The corneal stroma, the main load carrying layer of the cornea, consists of more than 200 lamellae of regularly arranged collagen fibrils in the central region 9. The lamella number and their interweaving increase towards the periphery, providing the cornea with a delicate and complex balance between its stiffness and the loads it is subjected to such as the intraocular pressure (IOP) and the eyelid pressure \*\*\*\*\*refs\*\*\*\*\* 1. With the disruption of the collagen network caused by CRS, resulting from the loss of tissue due to ablation and the separation of the flap and cap (in LASIK and SMILE, respectively), this balance may be compromised. As a result, IOP-related stresses may cause the cornea to thin, bulge and become progressively conical 10. These geometrical changes, which signify the development of iatrogenic keratectasia, have made tomography devices essential to detect the condition through their elevation, thickness and curvature maps 11. In cases with advanced or moderate tomographic distortion, these maps can clearly point at the existence of keratectasia and its location. However, in mild cases, let alone sub-clinical cases, tomography measurements may not provide conclusive evidence 12, 13. In these cases, monitoring corneal biomechanics, whose deterioration is thought to take place earlier than tomographic distortion, could hold the key to early detection of the condition 8. This is one of the reasons for the in-vivo corneal biomechanical evaluation becoming a trending topic among researchers and refractive surgeons 14-16. This interest resulted in the development of biomechanics measurement devices 17, 18 including, first, the Ocular Response Analyser (ORA; Reichert Ophthalmic Instruments, NY, USA), followed by the Dynamic Schiempflug Tonometer Corvis ST (OCULUS, Wetzlar, Germany), Brillouin microscopy 19, optical coherence elastography (OCE) 20 and high-frequency ultrasound (HFU) 21, 22.

**Biomechanics measurement techniques**

The ORA provides two cornea biomechanics metrics; namely corneal hysteresis (CH) and corneal resistance factor (CRF) 23. While CH is thought to be associated with the tissue’s viscoelasticity, CRF is considered a measure of its immediate stiffness or resistance to deformation under load 24. However, despite the biomechanical origins of the two parameters, and the biomechanical causes of keratectasia, CH and CRF had had a limited role in detecting the condition or risk-profiling patients, due to a considerable overlap in values between those that developed keratectasia and normal subjects 25, 26.

Similar to ORA, Corvis ST is also a noncontact tonometer, but it is different in that it monitors corneal deformation along the principal horizontal meridian under a collimated air puff. Through analysis of the deformation profile, the Corvis ST provides various dynamic corneal response (DCR) measures of cornea’s overall stiffness including the Stiffness Parameter (SP), Integrated inverse radius (IIR), deflection amplitude (DA), deflection amplitude ratio at 1 or 2mm away from apex (DARatio1mm, DARatio2mm) and Corvis biomechanical index-laser vision correction (CBI-LVC) – all of which were used to detect corneal softening in keratoconus 27, 28. Among these parameters, SP-A1 demonstrated the strongest correlation with the cornea’s overall stiffness, and underwent consistent reductions with keratoconic progression 29, 30. Second in line is the IIR, the integrated sum of the values of inverse concave radius from first to second applanations, which showed high sensitivity and specificity in keratoconus detection studies 31. Third, the DA is defined as the maximum deflection of corneal apex under the air pressure. It was successful in differentiating ectasia patients from those with healthy corneas, and its ability to detect the condition was improved after compensating for IOP changes 32. Further, along with the IIR, the DARatio2mm was least influenced by IOP and the parameter with the strongest correlation with the central corneal thickness (CCT) 33, and the potential to differentiate ectasia and normal eyes 34. Finally, the CBI-LVC, which combines several DCR parameters through logistic regression, was highly sensitive and specific in distinguishing stable from ectatic post-CRS eyes 35.

In addition to ORA and Corvis ST, currently the only clinically available devices to provide in-vivo corneal biomechanical measures, other technologies based on lower-magnitude or non- perturbation techniques such as Brillouin scattering, OCE and HFU are under development. These techniques, which are not yet widely available for clinical use, have strong potential to improve our understanding of the biomechanical effects of CRS surgeries and enable more accurate risk screening of CRS patients 17, 18.

**Biomechanical effects of CRS**

Despite the rare occurrence of iatrogenic keratectasia, the fact that it develops in previously healthy and stable corneas has led to much interest in the biomechanical losses caused by various refractive surgeries, which evidently were behind the mechanical instability observed in the affected eyes. Much of that interest took the form of clinical studies that utilised the biomechanical metrics provided by the ORA and Corvis ST.

Cao et al studied the effect of FS-LASIK and SMILE using values of DARatio2mm and IIR measured before and after surgery 36. Even though the FS-LASIK group showed slightly higher values for both parameters up to 3 months post-surgery, indicating higher reductions in stiffness, the differences were not significant. Similarly, Khamar et al did not observe significant differences between the same two procedures, considering both DARatio2mm and IIR, in addition to SP at first applanation (SP-A1), in a contralateral study with up to 1 month follow-up 37.

The results of these and other studies have cast doubt on the claim that the SMILE procedure brought about considerable biomechanical advantages over the most-commonly used FS-LASIK 38-45. The maintenance of the anterior stroma’s continuity in SMILE (apart from a small incision), was found in mathematical and numerical simulation studies, and even in experimental studies involving ex-vivo tissue, to lead to reduced biomechanical losses compared to FS-LASIK and also PRK 46-48. This superior behaviour was not evidenced in clinical studies 49, 50, possibly because of difficulties in controlling confounding factors such as corneal thickness, intraocular pressure, surgical variables and time of the clinical examinations. In these studies, the reported trends were contradictory and failed to lead to clear conclusions.

Examples include a study by Guo et al, who carried out a meta-analysis comparing the *in vivo* corneal biomechanical changes after SMILE, LASIK and PRK 49. In studies using CH and CRF parameters from ORA, they observed that SMILE introduced similar corneal biomechanical deterioration compared to PRK, but less than LASIK~~, with both CH and CRF being higher after PRK in comparison with SMILE, but the differences were not statistically significant~~. The same meta-analysis also reported a few studies using parameters from Corvis ST, namely applanation time, deflection length and amplitude of first, and second applanations and the highest concavity, but no obvious differences were observed among the three procedures \*\*\*\*\*refs\*\*\*\*\*. Another systematic review by Raevdal et al. compared SMILE with flap-based surgeries (the papers included only used CH and CRF measures as no study using Corvis ST parameters was eligible for inclusion), and found no statistically significant difference between the procedures 50. Both systematic reviews indicated that the number of randomised clinical trials was still insufficient and highlighted a risk of serious bias in other studies whose results may be less conclusive due to the presence of confounding factors.

Despite the inconsistencies reported above, the literature points at tPRK for being the procedure with the least effect on corneal biomechanics, and FS-LASIK being at the other extreme, with SMILE presenting intermediate values. A further observation relates to the biomechanical losses being larger in high myopia patients compared to those with low or moderate myopia 47, 51-54. This is expected as higher degrees of myopia correction would demand more tissue removal and hence introduce larger reductions in corneal biomechanics.

Another secondary observation reveals an overall softening trend over a 6 month follow-up period that adds to that confirmed in the immediate stages 55. The continuous changes of biomechanical parameters over time (albeit significantly smaller than the short-term losses) and asynchronization of these changes in different corneal regions are thought to be related to the wound healing process after surgery, and may be the cause of the continuous shape changes after surgery as reported by Bao et al 56.

Corneas after CRS are thinner and weaker than normal and are classified as abnormal by most DCR parameters, which make them unable to distinguish between KC and postrefractive surgery. CBI-LVC was designed to separate post-CRS keratectasia and patients who remained stable after CRS, and was validated by a multicenter clinical study with a large dataset 35.

**Summary:**

Corneal biomechanics is a subject of tremendous interest in the clinical research of post-CRS keratectasia 57. The corneal instability that develops with this condition leads to irregular astigmatism and serious visual impairment, which can be triggered even by small tissue alterations induced by the surgical procedures if the cornea had previously been soft 58, but may also be initiated in normal, healthy corneas that underwent large enough alterations 6, 7. Existing tools, which have been used in most of the in-vivo clinical studies reviewed, rely on parameters provided by ORA and Corvis ST as metrics of the cornea’s biomechanical response. There are also several novel tools, such as the Brillouin optical microscopy, optical coherence elastography, and high-frequency ultrasound, which are non-perturbatory and have the potential to resolve in-vivo corneal biomechanical properties in 3D. These tools however are still under development and not widely available for clinical use 59.

The combination of flap tissue separation and tissue ablation make the tissue loss in LASIK, and the subsequent biomechanics deterioration, much larger than in tPRK where only ablation takes place. Numerical modelling and clinical in-vivo studies have both confirmed this observation in most of the research reviewed herein, where the majority of studies reported significant differences in LASIK compared with PRK 60 61. In SMILE, the flap is replaced by a cap that maintains some continuity of the anterior stromal tissue. However, the tissue continuity is not perfect, as it is affected by the incisions (needed to remove the lenticule) and the loss of support on the posterior side. For these reasons, SMILE reportedly introduced intermediate stiffness losses in the cornea, larger than those presented by tPRK.

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