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Will SMILE Become the New Benchmark of Corneal Laser Refractive Surgery?

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The main focus of this special *APJO* issue is on small incision lenticule extraction (SMILE). We have articles covering the key issues related to SMILE, including its history of development, surgical techniques, astigmatic correction, evaluation of psychosocial aspects, results, retreatment, and future developments. This editorial further discusses the major advantages and drawbacks of SMILE in comparison with laser in-situ keratomileusis (LASIK) to see whether SMILE can withstand the test of time and prove to be the new benchmark of corneal laser refractive surgery in the near future.

Myopia is a major global socioeconomic burden, with a high prevalence in East Asian countries.[1] It has been shown that the prevalence is higher in urban setting than rural.[2] Although the causes of myopia are yet to be fully elucidated, both nature and nurture components have been implicated. Prevention is the best cure. One of the much talked about preventive measures in the control of myopia is using high or low concentrations of topical atropine.[3] Although concentration as low as 0.01% atropine has been suggested to be beneficial, recent studies have suggested that concentration of 0.05% to be more effective in preventing myopia progression and rebound after cessation of treatment.[4–6] Topical atropine, used along with bifocal/progressive glasses, with good photochromic lenses could prevent the unwanted side effects and improve compliance. Surgical interventions involving the posterior scleral reinforcement, although controversial, have also been attempted with positive results in preventing eyeball elongation.[7,8]

Management of stable myopia has been approved for some time, with the focus being on improving safety and speed of visual rehabilitation. Before the advent of excimer laser, automated lamellar keratectomy (ALK) was the procedure of choice for treating myopia. With the advent of excimer laser, photorefractive keratectomy (PRK) was preferred over ALK, as it negated many of the complications associated with it. Later with the advent of newer microkeratomes, ALK was combined with PRK to perform LASIK and was found to be better with respect to absence of haze and better predictability.

Femtosecond lasers (FS) were first used in 1900s and were rapidly inducted into ophthalmology for the management of refractive errors. However, the FS-LASIK is still dependent on excimer laser for tissue ablation and hence required the use of 2 platforms.[9] SMILE, a femtosecond only-based surgery, since its inception in 2009, has come a long way in the treatment of myopia and astigmatism. The flapless and potential keyhole surgery has several potential advantages compared with LASIK. Although the procedure was initially started as refractive lenticule extraction where the procedure included making of a flap, SMILE eliminated the need for flap and gained popularity rapidly.

The absence of flap makes SMILE potentially superior over LASIK because of absence of vision-threatening complications arising from flap loss, incomplete flap, traumatic flap dislocation, or significant flap striae. The intraoperative raise in intraocular pressure (IOP) during docking and active eyeball suction in SMILE has been shown to be much lower than that during FS-LASIK, which makes it more desirable in patients with glaucoma and peripheral retinal pathologies. This low IOP during suction has been attributed to the curved contact glass in the cone.[10] This also provides more comfort to the patient. As it is a single-platform surgery, there is no need to shift patients from FS to

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excimer platform as seen in LASIK, and this reduces the surgical time as well as patient anxiety. SMILE has become more and more widely accepted by surgeons and patients worldwide.[11]

SMILE has been reported to be an effective and safe procedure for the treatment of myopia and myopic astigmatism. Han et al[12] reported that SMILE provided a predictable and stable correction of moderate-to-high myopia with no significant changes of spherical equivalent (SE) occurring among postoperative follow-ups at months 1, 3, 6, and up to 4 years. SMILE is thought to be potentially more accurate than LASIK as it is not associated with the variability of environmental factors that can influence excimer stromal ablation, such as laser fluence and differences in stromal hydration.[13]

Stability of SMILE in high myopia [SE $>$ 6 diopter(D)] versus low-to-moderate myopia (SE $<$6D) was compared and was found to have significant regression in the high myopia group.[14] This may be attributed either to the epithelial changes or progression of myopia in high myopic individuals. Epithelial changes have been shown to be contributing to significant changes in refraction. Hence, there is a need for each surgeon to have their nomogram based on their initial cases especially in cases of high myopia.[15]

A systematic review and meta-analysis of 11 studies comparing SMILE with LASIK showed that there was no significant difference between the two procedures in terms of final refractive SE, the proportion of eyes losing $\geq$1 lines of corrected distance visual acuity (CDVA), or the proportion of eyes achieving an UDVA of 20/20 or better, and percentage of eyes within $\pm$1.00 Diopter of the target values.[10] Studies have shown that Higher-Order Aberrations (HOA) were found to be higher immediate postoperatively in both SMILE and LASIK, but reduced by 3 months post-SMILE as compared with post-LASIK.[16]

SMILE has its own set of disadvantages which are different from those found with LASIK. Drawbacks of the surgery include its limitation to correct astigmatism more than 5D, and the absence of an active eye-tracking mechanism to compensate for the cyclotorsion.[17] Studies have shown that there is undercorrection of cylinder especially in cases with $>$1.5D with SMILE as compared with LASIK because of the absence of eye-tracking during surgery.[18,19] However, this drawback can be minimized by manually marking the cornea before surgery in cases with high cylinder followed by manual adjustment of the cone to align with the marked axis before cutting the lenticule.[20]

The centration of the cone during docking has also been a highly debatable issue especially in people with large angle kappa. The green fixation light has been used to center the cone on the visual axis. Decentration from pupil center has not been found to cause any aberration but gross decentration from kappa intercept can cause aberrations leading to subnormal visual acuity. In cases wherein the decentration from kappa intercept is between 0.4 mm and $<$0.6 mm, it has been shown that there may be no induced aberrations; however, a decentration $>$0.6 mm may lead to visual disabilitating aberrations.[21] Hence, it is necessary to ask patients to move their eyes toward the kappa intercept before applying suction. Using a "centration chart" with pupil center as the center of the chart and marking the kappa intercept based on Pentacam or Sirius can help the surgeon in determining the location of centration during docking in cases with high angle kappa.[22]

The effective/functional optical zone has gained higher importance from surgeons recently and it has been demonstrated that the postoperative "effective/functional optical zone" is significantly larger in SMILE than in FS-LASIK based on the same diameter of optical zone.[23] It has also been noted that the effective pupil size/optic zone is less than the mesopic pupil size[24] measured and hence in patients with high myopia. Choosing an optic zone which is less than the measured mesopic pupil size by 0.2 mm has been shown to have no effect on the quality of postoperative outcome and this also helps increase the residual stromal bed and reduce the risk of postoperative ectasia.

Various short- and long-term studies have shown that LASIK induces or aggravates dry eye of various degrees in patients because of the damage to the subbasal nerve plexus. This has been attributed to the cut made along the anterior corneal surface to create the flap. The small incision size (2–4 mm) in SMILE although theoretically reduces chances of developing dry eye, it has been seen that dry eye also develops in patients following SMILE. This has been happening more in cases where the cap thickness is set at around 100 to 130 microns than in thicker caps as the lenticule will be placed much anterior in these cases leading to more damage to subbasal nerve plexus.[25] Several comparative studies have shown that, comparing with SMILE, LASIK induces more dry eyes and takes a longer recovery time.[20,27] This has been confirmed by confocal studies showing more damage to subbasal nerves in LASIK.[19,26,27]

There have been contrasting reports on the effect of SMILE on biomechanical strength of the cornea. Although some studies show that because of the preservation of the biomechanically stronger anterior corneal stroma in SMILE and the smaller incision size, it leaves a cornea which is biomechanically stronger than that with LASIK.[28] An indirect evidence of the greater biomechanical strength following SMILE is the fact that there have been very few reports on ectasia following SMILE. This may also be attributed to the fact that the procedure is relatively new and underreporting.[29] However, some studies refute these findings and have shown that the strength of the cornea reduces equally in both SMILE and LASIK.[30] Hence, till these findings are further proven using a machine which can accurately measure biomechanics, it would be difficult to come to a definite conclusion.

Visual recovery has been found to be slower in SMILE as compared with LASIK especially in the hands of an inexperienced surgeon. This has been attributed to multiple factors such as increased surgical manipulations to remove the lenticule, the effect of FS laser, microdistortions in Bowman membrane, and saline wash after removing lenticule. With increase in experience of the surgeons who become more competent to smoothly maneuver the lenticule, lesser trauma is made to the surrounding tissues and early visual recovery can be achieved. Moreover, many surgeons now do not advocate aggressive lamellar interface washing, which was the norm initially. Mild stretching or distending the cap at the end of the surgery can reduce or prevent microdistortions of Bowman membrane and improve visual acuity.[31] Zhao et al have described a newer technique—"continuous curvilinear lenticulerrhexis"—wherein the lenticule is removed similar to that in continuous circular capsulorhexis while only separating the 0.3-mm pocket in the lenticule interface near the incision, which can facilitate lenticule extraction with minimal surgical manipulation leading to early and better visual recovery.[32] Lastly, patients have to be clearly counseled about the delayed improvement in visual acuity before undergoing surgery to avoid undue stress postoperatively.

The other drawback of SMILE is the problems faced in cases where retreatment is needed. Various treatment options such as PRK, conversion of the incision to a flap if the cap is thin, or creating a new LASIK flap if the cap is thick have been recommended but with varying levels of success and complications.[33,34] There have been studies on "redoing" SMILE for retreatment; however, this procedure is still controversial.[35]

NEWER MODIFICATIONS

Smile Xtra

Combining SMILE with corneal collagen crosslinking has been performed in cases wherein the topography is suspicious or patients with high risk such as thin corneas or biomechanically weaker corneas. Following SMILE, riboflavin is injected into the interface and UVA is administered for a fixed time following which the interface is washed with balanced salt solution. Although encouraging results have been obtained in treating high-risk patients, different treatment protocols have been used regarding the strength of riboflavin used and the intensity and duration of UVA applied.[36] Further studies with longer-term follow-ups are warranted.

Treatment of Hyperopia

There is currently no software to treat hyperopia with SMILE.[37] This is mainly because of the fact that the small cone size used may not be sufficient to produce a lenticule which is large enough to get a thinner center and a thicker periphery. There has been a study on performing hyperopic SMILE using a larger optic zone and transition zone; however, long-term data are awaited.[38] Some studies suggest that femtosecond intrastromal lenticule implantation, where a lenticule obtained from myopic donor is inserted into the lamellar space, can also help in hyperopia correction.[39]

Other Uses of SMILE Lenticule

The lenticule obtained from SMILE has been used in the management of keratoconus by inserting them into the lamellae at fixed depth followed by corneal collagen crosslinking. Good initial results have been obtained. The lenticules have also been used to seal corneal perforations.

To conclude, although SMILE is not yet a perfect refractive surgery, it does have its own advantages over LASIK and the limitations of SMILE are easily manageable. SMILE is preferred by surgeons as well as patients in countries that have started SMILE earlier, such as Hong Kong, Singapore, and China. New advancement (under evaluation) will make treating myopia of >10D and hyperopia a possibility in the near future. Moreover, newer machines with higher frequencies are being tested to reduce the surgical time and increase smoothness of the tissue after the laser ablation, thereby faster visual recovery. We are of the opinion that SMILE will overtake LASIK to become the new benchmark of corneal laser refractive surgery in the near future.

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