n the fall of 2002, the United States Food and Drug Administration (US FDA) granted pre-market approval to the Alcon CustomCornea platform (Alcon Laboratories Inc, Ft Worth, Texas) for wavefront-guided treatment of myopia and myopic astigmatism. This approval began a new era of customized laser vision correction in the United States, which has flourished over the past decade. Over these past 10 years, we have seen multiple platform approvals of wavefront-guided LASIK for myopia with and without astigmatism, hyperopia with and without astigmatism, and mixed astigmatism. We have also seen the approval of wavefront-optimized LASIK for the same indications, multiple femtosecond laser 510K approvals for flap creation and therapeutic corneal uses, and even femtosecond lasers for cataract surgery with approvals for corneal incisions, capsulotomies, and lens fragmentation. Although none of these approvals came easily, they have contributed significantly to the commercial use of customized ablation in refractive surgery.

One customized approval, topography-guided LASIK, is still pending after several years of enrollment and data collection, which hopefully will round out the complement of commercially approved customized ablation. Although not yet approved at the time of publishing of this supplement, topography-guided LASIK has been submitted to the US FDA for the correction of myopia and myopic astigmatism. Although not yet implemented in the United States, topography-guided LASIK and photorefractive keratectomy have been utilized in various parts of the world with notable success, which gives us hopeful anticipation for its eventual success in the United States as well.

With this introduction, we are pleased to present the following six articles for this 10-year review of commercially approved customized ablation. The first three articles cover unique applications of the most recently approved femtosecond laser, the WaveLight FS200 (Alcon Laboratories Inc). In the first article, Shetty et al1 from India show how intraoperative ocular coherence tomography can be used to accurately detect flap thickness profiles during LASIK, revealing the anatomical benefit of the FS200 in comparison to mechanical microkeratomes. In the second article, Au and Krueger2 at the Cleveland Clinic combine the FS200 with the wavefront-optimized profile of the Allegretto Wave Eye-Q laser to show that spherical aberration, which typically increases with increasing myopic correction, is maintained at its preoperative level regardless of the amount of myopia corrected. In fact, it actually significantly reduces, rather than induces, the level of spherical aberration by 0.002 μm/diopter of myopia corrected. In the third article, Yoo and Al-Ageel3 at Bascom Palmer Eye Institute show that, similar to other commercially approved femtosecond lasers, the FS200 can be used to perform customized keratoplasty to provide refractive precision to therapeutic keratoctomy applications.

Among the second group of three articles, Tan et al4 from Singapore display their experience with topography-
Figure. Decision tree for customization, based on previous investigational studies of the WaveLight Allegretto Wave Eye-Q laser.

guided LASIK by reporting their results in correcting myopia in 2051 eyes. In the fifth article, Kanellopoulos and Kahn in Athens, Greece, report the superior outcomes of bilateral hyperopic topography-guided femtosecond laser–assisted LASIK, with the WaveLight FS200 and EX500 lasers, using intrastromal cross-linking (CXL) in one eye of each patient to significantly reduce hyperopic LASIK regression after 2 years. In the sixth and final article, Lin et al6 in Vancouver, Canada, show that not only can topography-guided customized ablation be successful in normal myopic and hyperopic eyes, but in highly aberrated eyes and keratoconus with CXL as well.

So, with the recently approved WaveLight FS200 femtosecond laser for adding precision and customization to LASIK flap creation and keratoplasty, as well as the soon to be approved topography-guided customized ablation of the WaveLight Allegretto and EX500 excimer lasers, the customization we have previously enjoyed over the past decade will likely be refined and expanded upon in the next decade and beyond. Customization in refractive surgery will no longer be restricted to only wavefront-guided ablation, as it was in the early part of the past decade. Rather, we have seen internationally (Fig), and soon will see in the United States, a whole menu of customization options that will help us refine our outcomes for the future.

Finally, with 10 years of customized treatments behind us, is there a glimpse into something more beyond the category of customization that will help reach the next level in the more distant future? We believe there is, and we call it “adaptive.” Even in these articles, the precursors of adaptive corrections can be seen with the prevention of hyperopic LASIK regression and the dynamic control of keratoconus ablation stability using CXL techniques. Real adaptive corrections will add this dynamic control, not only postoperatively, but also in real-time during the procedure to optimize patient outcomes, adaptively. Dynamic, multi-dimensional eye tracking7, and newer, iterative ray tracing techniques8,9 will be among the early forms of adaptive correction, and there will likely be others. Unfortunately, we will see these new modalities internationally years before we see them in the United States. Yet, we press on with technology development and the regulatory approval process, so as to bring these new modalities step-wise to fruition. The future is bright, but it is with the memory of the past that we can view and perceive the possibilities and pathways to take. In doing so, we look back 10 years and say, “Happy Anniversary, CustomCornea,” so that we may look forward to the next 10 years and dream of the possibilities to come.

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REFERENCES