
The VisuMax and SMILE

1.1. History of Intrastromal Refractive Surgery

Ever since femtosecond lasers were first introduced into refractive surgery, the ultimate goal has been to create an intrastromal lenticule that can then be removed manually in one piece, thereby circumventing the need for incremental photoablation by an excimer laser. A precursor to modern refractive lenticule extraction was first described in 1996 using a picosecond laser to generate an intrastromal lenticule that was removed manually after lifting the flap;^{1,2} however, significant manual separation was required leading to an irregular surface. The switch to using a femtosecond laser improved the precision³ and studies were performed in rabbit eyes in 1998⁴ and in partially sighted eyes in 2003;⁵ however, these initial studies were not followed up with further clinical trials.

Following the introduction of the VisuMax femtosecond laser (Carl Zeiss Meditec),⁶ the intrastromal lenticule method was reintroduced in a procedure called femtosecond lenticule extraction (FLEx). The 6-month results of the first 10 fully seeing eyes treated were first presented in 2006 and published in 2008⁷ and results of larger populations followed.^{8,9} The refractive results were similar to those observed in LASIK, but visual recovery time was longer owing to the lack of optimization of energy parameters and scan modes; further refinements have led to much-improved visual recovery times (Chapter 7.1).¹⁰

Following the successful implementation of FLEx, a new procedure called small incision lenticule extraction (SMILE) was developed: an all femtosecond laser, keyhole, flapless procedure that is in the process of revolutionizing corneal refractive surgery and realizing José Ignacio Barraquer's original concept of keratomileusis.¹¹ The SMILE procedure is gaining popularity following the results of the first prospective trials¹²⁻¹⁴ and more recent reports that have demonstrated that the visual and refractive outcomes are similar to LASIK (Table 1-1: literature review conducted March 2017).¹⁵⁻⁴⁸ The United States Food and Drug Administration (FDA) trial for spherical myopia was also completed and approved in October 2016.⁴⁴ As of October 2017, more than 1,000,000 procedures have been performed worldwide with more than 1,300 surgeons trained to perform SMILE.

In this book, we are not attempting to make a formal comparison of outcomes between SMILE and LASIK, other than to provide this summary of the published SMILE studies at the time of writing this chapter. When considering these data, it should be noted that many of these studies represent the development phases of the procedure itself and/or the learning curve of the surgeons. There are studies where SMILE was shown to be superior to LASIK, studies where LASIK achieved better outcomes than SMILE, and others where the results were similar. In our experience, we find virtually no difference in visual and refractive outcomes between SMILE and LASIK as will be demonstrated for example for low myopia in Chapter 3.4.