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PRESS RELEASE



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FEMTOSECOND LENTICULE EXTRACTION (FLEx): A NEW ALTERNATIVE TO LASIK

LASIK is currently the most popular form of vision correction surgery in Singapore and worldwide. The Singapore National Eye Centre (SNEC) now offers patients a new alternative to conventional LASIK - Femtosecond Lenticule Extraction (FLEx) – an evolution of laser refractive surgery.

What is FLEx, and how does it differ from conventional bladeless LASIK?

LASIK involves two separate stages. Firstly, a corneal flap is made, either with a mechanical blade (microkeratome LASIK), or with a femtosecond surgical laser (bladeless LASIK). Secondly, an excimer laser is used to laser away corneal tissue to the required shape to treat the myopia, hyperopia or astigmatism, and the flap is then replaced. Nowadays, more and more patients are opting for the newer two-laser (femtosecond and excimer laser) combination treatment, i.e. bladeless LASIK.

FLEx, which stands for Femtosecond Lenticule Extraction, is a new alternative to conventional bladeless LASIK – in this procedure the entire treatment is performed with just one laser, the VisuMax Femtosecond Laser from Carl Zeiss Meditec, an advanced new generation femtosecond lasers developed for corneal surgery. Femtosecond lasers are more precise than excimer lasers, and this enables innovative laser treatments beyond the limits of excimer laser technologies.

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The VisuMax Laser also has significant advantages over other femtosecond lasers in that it provides a more gentle treatment which results in less discomfort during surgery (which SNEC has recently proven in clinical trials), and only uses about a quarter of the total laser energy on the cornea, as compared to other femtosecond lasers due to its laser focusing beam. As a result, FLEx treatment is only possible with this highly precise femtosecond laser – currently no other femtosecond lasers are able to perform FLEx surgery.

In FLEx surgery, the VisuMax laser is able to cut a lens-shaped layer (a lenticule) from within the cornea. The lens is simply removed either through a LASIK type flap, or can be removed through a small keyhole incision, all performed at the same sitting and with the one laser. The shape of the lenticule is accurately calculated to exactly match the patient's degree of myopia or astigmatism, so then when it is removed, the patient should have no more myopia or astigmatism. Being a single-stage procedure, treatment time is more than halved, as compared to bladeless LASIK. Approximately over a thousand FLEx procedures have been performed to date, in Europe and Asia, and studies there suggest that FLEx provides for greater accuracy than conventional LASIK, especially for higher degrees of myopia.

FLEx - Advantages and Benefits to Patients

The advantages and benefits of FLEx to patients compared to LASIK are:

- 1. FLEx appears to be more accurate than LASIK for higher degrees of myopia, (e.g. from 500 to 1,000 degrees).
- 2. FLEx is faster to perform than LASIK only one laser is used.
- 3. A full LASIK-type corneal flap may not be necessary in a modified procedure known as SMILE (Small Incision Lenticule Extraction). Instead of a full LASIK flap being created a much smaller keyhole incision is made through which the lenticule can be extracted with a smaller wound. Due to the smaller wound, SMILE results in a stronger eye, less immediate postoperative discomfort and tearing and the potential for less dry eye problems as compared to LASIK. Reducing these side-effects and complications, normally associated with LASIK, may make SMILE a potentially safer option.

FLEx compared with Bladeless LASIK

SNEC's Singlasik Refractive Surgery Service has performed FLEx on 34 cases since March 2010 and preliminary results appear positive and encouraging. When results of our FLEx cases were compared to the most recent results of bladeless LASIK in a comparable group of patients (treating up to 1000 degrees of myopia), although both treatments provided excellent results, we found that FLEx surgery was slightly more accurate and predictable – for eyes with higher degrees of myopia, i.e., between 500 and 1000 degrees, 100% of FLEx cases were within 50 degrees of the intended treatment as compared to 85.8% in the LASIK group. Although our results with both bladeless LASIK and FLEx showed overall excellent results, it seems that our early results agree with other FLEx studies in suggesting that FLEx appears to be that much more accurate and predictable as compared to even the latest results with bladeless LASIK, especially in the higher degrees of myopia treatment. However, we acknowledge that more cases will continue to allow us to assess and confirm these highly encouraging results.

New Research Focus at SERI: Can FLEx and SMILE actually be a Reversible Procedure?

Like all other laser refractive procedures using excimer lasers, LASIK is not reversible, as the excimer laser ablates or vaporizes away corneal tissue permanently. However, in FLEx and SMILE, the femtosecond laser accurately cuts away an intact lenticule of corneal tissue – this tissue is *not* vaporized away. Researchers at SERI came up with the idea of making FLEx and SMILE *potentially reversible* (which makes it safer than LASIK). Instead of discarding this lenticule, they developed the concept and technique of cryopreserving (freezing in liquid nitrogen) and storing the lenticule for the patient, for potential future use, a process which is currently being patented. For instance, when presbyopia ("lau hua") eventually occurs years later, a patient who previously had FLEx, could conceivably opt to have the lenticule reimplanted into his cornea, without modification, so as to restore some myopia to counteract presbyopia (myopia represents "minus" power, while presbyopia represents "plus" power). To restore good near vision without the need for reading glasses.

This ongoing research is currently part of SERI's TCR (Translational Clinical Research)

Flagship Program, funded by the National Research Foundation (NRF) and administered by

the National Medical Research Council (NMRC), in collaboration with industry partner Carl

Zeiss Meditec, and SERI researchers hope to soon prove reversibility of FLEx and SMILE in

animal trials later this year.

In summary, FLEx surgery appears to be a good new treatment on the horizon which may

have some significant advantages over LASIK today, and our studies appear to further

improve on our already highly satisfactory results which we are obtaining with bladeless

LASIK. SNEC and SERI will continue to evaluate the potential reversibility of FLEx in our

ongoing translational clinical research program, and also further develop keyhole SMILE

surgery, which may provide even more benefits to our patients who seek clearer and better

vision.

FLEx procedure at SNEC

FLEx is now available at SNEC. The cost per eye is between \$2,300 and \$2,500 and this

includes postoperative care.

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