

## Executive Summary

### Background

Myopia is a condition of the eye give rise to a blurred vision of a distant object. Excimer laser refractive surgery for the correction of myopia can be largely classified into LASIK and surface ablation including Photorefractive Keratectomy (PRK) and LASEK. LASIK surgery conducts ablation after forming a sliced section on the stroma and surface ablation surgery is performed without forming a corneal flap on the stroma. In Korea, Excimer laser refractive surgeries were first introduced in 1990 and their use has rapidly expanded. It is estimated that more than 100 thousand people get the correctional surgery annually. However, the precise operation status and the long term efficacy and safety of those surgeries excluding commercial purposes are not fully answered. In addition, clinical examination guidelines that suggest detailed causes that affect on the surgical results in the operations performed on Korean population are also absent.

### Objective

The present study attempts to provide objective information on the long term efficacy, safety, and stability of the surgeries and ensure the safe and effective myopia correctional surgery for the future.

## Methods

1. Through the retrospective medical chart review for patients who received refractive surgeries for myopia correction (total 2,638 patients/5,109 eyes) at six University and local hospitals between 2002 and 2004. By using the established cohort data, long term efficacy and safety of the refractive surgeries including LASIK, LASEK and PRK were evaluated .

2. Through the linkage of established cohort data and the claims data of the Health Insurance Review and Assessment service, long term safety of the refractive surgeries were evaluated.

3. After acquiring a verbal consent from the subjects of the established cohort, telephone surveys to investigate the subjective self reporting symptoms and satisfaction levels after refractive surgery were conducted.

4. Telephone surveys were performed between the ages of 18 and 45 years of age, 10,000 subjects were quota sampled proportionally to sex and regional population. Three hundred two people received surgeries more than five years ago answered the telephone survey questionnaire including self reporting symptoms and satisfaction level.

5. Systematic literature reviews were done according to the efficacy and safety of myopia correctional surgeries in Korea. A total of fifteen published articles were selected by using three overseas databases and seven domestic databases, and the clinical efficacy and safety of the refractive surgeries were evaluated.

## Results

Retrospective chart reviews from 2,638 patients (5,109 eyes) who received the refractive surgeries by using LASIK or surface ablation such as LASEK and PRK at six university and local hospitals between 2002 and 2004 were analyzed. By reviewing the surgical results three years after a selected surgery, refractive surgeries were found to be effective in visual correction by showing more than 0.5 of vision in 95% of LASIK patients and more than 97% of the patients who received the surface ablation surgeries like LASEK and PRK.

However, the myopic regression<sup>1)</sup> showing the reduction of a correctional effect at one year and three years after the surgery respectively reached 4.5% and 8% for LASIK, and 8.6% and 13.4% for the surface ablation. Several factors may contribute to myopic regression therefore, refractive power(expressed in diopters of a sphere) of the eyes before surgery, intraocular pressure and corneal thickness were observed, along with the differences caused by the selection of different surgical methods. In addition, 26 patients (34 eyes, 0.67%) required re-surgery, and keratoecasia was observed in a single case without showing any cases of losing visual acuity by the surgeries. Therefore, a complete pre-examination for the causes that could have a long term effect on the surgery should be made before the surgery.

In particular, corneal opacity was more frequently observed in the surface ablation surgeries (7.7%) than the LASIK (0.8%) surgery. However, this difference did not have effects on the final correctional visual acuity at the end of the follow up observation. Both types of

1) Myopic degeneration : Indicates the case that the refraction power 3 months after the surgery was reduced more than 10% compared to the refraction power before the surgery.  
Namely, it is defined as the refraction power more than 3 month after the surgery < (refraction power at 3month after the surgery 10% of refraction power before the surgery).

the surgeries were significantly observed in high myopia with more than -6D compared to the low myopia. Although the corneal opacity was found to occur more frequently in surface ablation surgeries than LASIK surgery, the mean corneal thickness of surface ablation surgery was 529.7um and 546.7um in LASIK surgery.

Therefore, patients who have surface ablation surgery because of a thin corneal thickness, need to be provided with cautions and explanations for possible corneal opacity before obtaining consent for the surgery.

Along with the retrospective chart review, the telephone survey results showed that for the 302 people that had refractive surgery more than 5 years ago, about 20% complained about worsening of night time discomfort and symptoms of dry eye after the surgery. Overall, refractive surgery can be seen as a relatively safe surgery, but since self-reporting symptoms as like night time discomfort and symptoms of dry eye can occur, it is important to provide an explanation for the occurrence of such symptoms and acquire consent before surgery.

## **Conclusion**

No severe complications, including loss of vision occurred after receiving the refractive surgery, but since not all refractive surgeries are expected to be effective, surgeries have to be performed after thorough pre-surgical examinations for the causes that may have an effect on the results of the surgery. It is also important to provide information about the benefit and harm including possible complications and discomfort that can appear after surgery and to acquire the patient's consent before the surgery.