

## Comparison of Different Invasive Type of Refractive Anomalies Operation



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**Abstract :** The methods of ametropia of the human eye correction are divided into invasive and non-invasive methods. Each method has its own merits and drawbacks. Each method has its limitations due to type of compensation; therefore it is difficult to make a straightforward decision. In this study is tried to compare the results of methods to find out their predictability, UCVA, safety and stability. In this work the result data of 24012 patient of different type of operation were investigated. In this work the data are gathered from different papers from 1980 till now. The data are classified on the base of the type of operation and the degree of ametropia which includes myopia, hypermetropia, and presbyopia. Gathered data are analyzed with Chi-square measure. This study shows that for the patients with hypermetropia less than 3.5 diopter the Conductive Keratoplasty (CK) and Laser Thermal Keratoplasty (LTK) have best correction results respectively. Then the results of Photorefractive Keratectomy (PRK) and Laser SubEpithelial Keratomileusis (LASEK) give same results after CK and LTK. For all range of myopia the LASEK gave the best result. The Laser in Situ Keratomileusis (LASIK) gave proper performance in moderate and higher myopia refractive anomalies. But the PRK had given better performance in low myopia refractive anomalies.

**Key words :** LASIK, LASEK, PRK, LTK, CK, DTK, RK

### Introduction

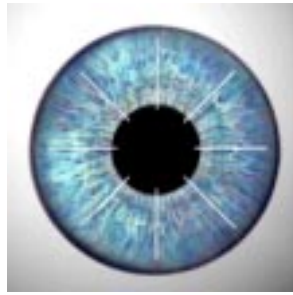
The 1997 Baltimore Eye Study showed a distribution of refractive errors that approached a normal distribution, in North America alone; 150 million potential patients are 40 or more years of age (Bower *et al.*, 2001). The methods of ametropia of the human eye correction are divided into non-invasive methods (like glasses and lens) and invasive methods which consist of:

1-Incisional method: like Radial Keratectomy (RK). In the past, RK was performed to treat patients with myopia. The

surgeon makes a number of microscopic corneal incisions in a radial or spoke-like pattern. This allows the outer cornea to relax so that the central cornea flattens (Figure 1). The new shape of the cornea is permanently retained as the cornea heals.

This procedure has declined in popularity since 1995, when the U.S. Food and Drug Administration (FDA) approved the use of the Excimer laser, and because of the superior results of the other commonly performed refractive surgeries (Katz *et al.*,

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**Figure 1 : Spoke-like pattern of RK**

1997; Koralewska-Makar and Stenevi, 1992; Charpentier *et al.*, 1998; Hamdi *et al.*, 1997).

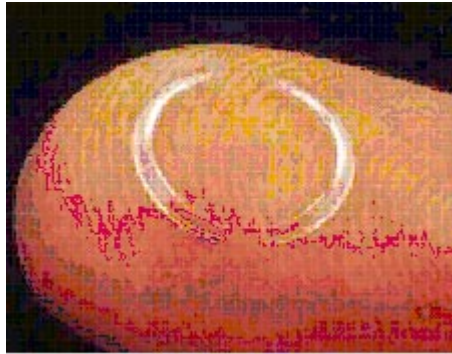
2-Ablation methods: in these methods by using Excimer lasers micro amounts of corneal tissue (due to topographic plot of patient's cornea) vaporized. The Excimer laser emits an ultraviolet beam that has sufficient energy to break intermolecular bonds within the cornea (photo ablation). Because little or no thermal damage occurs to adjacent tissue, this is often referred to as a "cool" laser beam. A computer, programmed with the patient's refraction and corneal topography, controls the laser beam to precisely remove corneal tissue (Alessio *et al.*, 2000).

The ablated part could be in the centre of cornea like myopic patients or from the peripheral part of cornea like hyperopic patients. These methods consist of Photorefractive Keratectomy (PRK) which involves the use of an Excimer laser to reshape the anterior corneal surface. Laser in Situ Keratomileusis (LASIK) which the Excimer laser is used to reshape the cornea under a corneal flap Laser SubEpithelial Keratomileusis (LASEK) which is a relatively new refractive surgical technique that purportedly combines the advantages of LASIK and PRK. Like LASIK, on the one

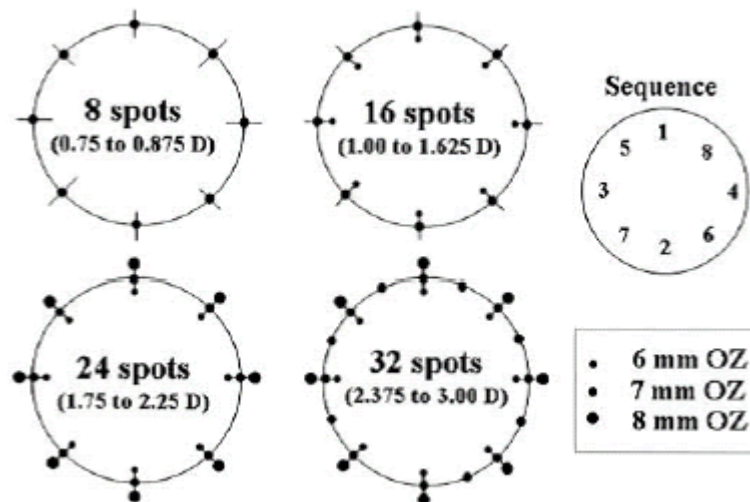
hand, it employs a "flap" and consequently has the advantages of faster visual recovery, less postoperative pain, reduced stromal haze, and faster epithelial healing than PRK (Dastjerdi and Soong, 2002; Lee *et al.*, 2001; Lee *et al.*, 2002).

3-put an Implant in the cornea: like intra corneal ring. Intacs is a non-laser procedure with FDA approval for use in patients with low amounts of myopia (-1.00 to -3.00 diopters of myopia with up to +1.00 diopters of astigmatism). The procedure involves the placement of two plastic segments within the non-seeing periphery of the cornea. These segments flatten the central cornea without removing tissue to better focus light. The segments are made of the same material that's been implanted in human eyes after cataract surgery for nearly 50 years, called PMMA (polymethylmethacrylate). Intacs have the advantage of remove ability or exchangeability for different sized segments, and maintaining a more natural corneal shape [10]. The more natural corneal shape may provide better vision than LASIK. (See figure 2)

Also this method was mixed by Lasik or PRK for patients within high myopia or high hyperopia (Jimenes-Alfararo *et al.*, 1998; Siganos and Pallikaris, 1998; Shah and Dua, 2000).



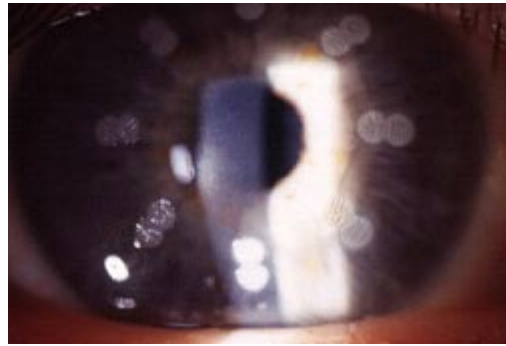
**Figure 2:**The more natural corneal shape providing better vision than LASIK.



**Figure 3:** CK pattern shows that an increasing number of spot placed for increasing level of hyperopia [18]

4-thermal methods: as we know stroma has the majority thickness of the cornea. The major constituent of the stroma is collagen fibers. These collagen fibers form lamellar sheets. Methods which used thermal characteristics of collagen fibers are called thermal methods like Conductive keratoplasty (CK) and Laser Thermal Keratoplasty (LTK)

CK is a surgical technique that delivers radio frequency (350 kHz) current directly into the corneal stroma through a Keratoplast tip inserted into the peripheral cornea at 8 to 32 treatment points. A full circle of CK spots produces a cinching effect that increases the curvature of the central cornea, thereby decreasing hyperopia [Hersh *et al.*, 1997; McDonald, 2005; McDonald *et al.*,



**Figure 4 : an eye underwent LTK**

2002; McDonald *et al.*, 2002). see figure 3

LTK procedure was FDA approved on June 30, 2000 for the temporary reduction of hyperopia from +0.75 to +2.50 diopters for patients 40 years and older with up to 0.75 diopters of astigmatism and refractive stability for the previous 6 months. It involves the strategic placement of 16 laser spots onto the peripheral cornea [Rocha *et al.*, 2003; Hill, 2003; Nano and Muzzin, 1998; Durrie *et al.*, 1994; Alió, 1997; Koch, 1997) see figure 4.

Thermal methods also involve Hyperopic thermokeratoplasty (HTK) and Diode laser thermal keratoplasty (DTK). Unfortunately thermal methods don't have any application in myopia.

Each of mentioned methods had some benefits and some complications and manipulated in special ranges. The aim of this study is to assess and compare each method.

### **Material and Methods**

About 24013 patients were underwent refractive operation for refractive anomalies treatments were selected by authors in different articles by bellowing keywords in the Pubmed and Medline databanks:

Conductive Keratoplasty (CK), Hyperopic thermokeratoplasty (HTK),

Diode laser thermal Keratoplasty (DTK), Laser Thermal Keratoplasty (LTK), Photorefractive Keratectomy (PRK), Laser In Situ Keratomileusis (LASIK), Laser Sub Epithelial Keratomileusis (LASEK) Radial Keratotomy (RK).

For a refractive procedure there are four important indices of outcome: 1- Postoperative uncorrected visual acuity (UVCA), 2-Predictability (is an indication of the refractive accuracy and is usually reported as the percentage of eyes achieving a correction within (0.50 D or 1.00 D) of the desired refractive correction., 3-Stability which shows the interval between the surgical procedure and a stable refraction allows the determination of the earliest reasonable time when reoperation might be considered for residual refractive errors. as we know The long-term stability data for refractive surgical procedures allow accurate refractive correction with minimal risk of future large changes in refraction. And 4-Safety (is typically reported as the percentage of eyes losing two or more lines of best spectacle-corrected visual acuity (BCVA) on the Snellen chart as the result of surgical treatment.) of the procedure (Manche, 1998). And these are Criteria's for articles that we selected. Then classified the Data of

each article according to the range of operation. At last analyzed the data by SPSS software.

## Results

In CK operation 1320 patients up to  $<+4D$  ( $+0.75$  to  $+4D$ ) were evaluated during 2001 to 2006 underwent Ck operation. After the operation the mean manifest refractive spherical equivalent (MRSE) was  $0.15 \pm 0.45D$ . The Uncorrected visual acuity (UCVA) was 20/40, 20/25 and 20/20 or better in 91.89%, 75.5% and 53.9% respectively after 12 months. 1.5% of patients were lost 1 or 2 lines of BCVA and 61% and 89.6% were within  $\pm 0.5$  and  $\pm 1D$  respectively after operation (Asbell, 2001; McDonald, 2005; McDonald *et al.*, 2002; McDonald *et al.*, 2002; Lin and Manche, 2003; Naoumidi, 2006; Pallikaris *et al.*, 2005).

Studies on patients underwent LTK and HTK during 1999 to 2005 shows that there is no significant statistical difference in terms of UVCA but in these operations 0% lost of BCVA lines occurred moreover 92% and 100% of patients were within  $\pm 0.5$  and  $\pm 1D$  respectively after operation [Rehany and Landa, 2004; Rocha *et al.*, 2003; Hill, 2003; Nano and Muzzin, 1998; Durrie and Schumerv, 1994; Alió *et al.*, 1997; Koch, 1997; Papadopoulos *et al.*, 2005; Neumann *et al.*, 1991).

Concisely LTK and CK operations have the same post UCVA and percentage of patients within  $\pm 1D$  results, but in terms of safety and percentage of patients within  $\pm 0.5D$  LTK has better results than CK (P-Value $<0.005$ ).

In PRK operation 16 estropia patients up to  $-3.7D$  and  $10.7D$  Prism were evaluated during 2001 underwent PRK

operation. After the operation the MRSE was  $-0.7D$ , the UCVA was 20/40 or better in 100% eyes and 100% were within  $\pm 1D$  after operation (Nucci *et al.*, 2003).

In PRK operation 507 patients up to  $+3.5D$  ( $+0.75$  to  $+4D$ ) were evaluated during 2001 to 2005 underwent PRK operation. After the operation The UCVA was 20/40 and 20/20 or better in 88.4% and 75.7%, respectively which shows a significant statistical difference between CK and PRK (CK had better results: P-Value $<0.005$ ). Moreover, 0.2% of patients were lost 2 or more lines of BCVA and 75% and 82.8% were within  $\pm 0.5$  and  $\pm 1D$  respectively after operation [Nagy *et al.*, 2001; Jackson *et al.*, 1998; Sameh *et al.*, 2000).

In general, CK operation on hyperopic patients had better results than PRK (P-value $<0.001$ ) except the terms of Safety (P-value $<0.005$ ).LTK operation compared with CK for patients up to  $+3D$  had superiority results in all terms (P-value $<0.001$ ).

In PRK operation 358 patients more than  $+3.5D$  were evaluated during 2001 to 2003 underwent PRK operation. After the operation the UCVA was 20/40 and 20/20 or better in 45.7% and 34.2%, respectively. 28.2% of patients were lost 2 or more lines of BCVA and 22.3% and 46% were within  $\pm 0.5$  and  $\pm 1D$  respectively after the operation [Nagy *et al.*, 2001; Jackson *et al.*, 1998; Sameh *et al.*, 2000; O'Brart *et al.*, 2005).

Our studies also illustrate that in PRK operation 968 myopic patients up to  $-3.5D$  were evaluated during 1995 to 2005 underwent PRK operation. After the operation the UCVA was 20/40 and 20/20 or better in 93.7% and 75%, respectively. 0.1% of patients were lost 2 or more lines

of BCVA. 90.8% and 97.55% also were within  $\pm 0.5$  and  $\pm 1D$  respectively after the operation (Hamdi *et al.*, 1997; Tanzer, 2004; Nucci *et al.*, 2003; Schraepen *et al.*, 2005; Rajan *et al.*, 2004)

In addition, in PRK operation 5337 patients between -3D to -6D were evaluated during 1992 to 2005 underwent PRK operation. After the operation the UCVA was 20/40 and 20/20 or better in 94% and 62%, respectively. 0.2% of patients were lost 2 or more lines of BCVA. Besides, 64.3% and 88.9% were within  $\pm 0.5$  and  $\pm 1D$  respectively after the operation [Hashemi *et al.*, 2002; Stevens *et al.*, 2002; Carpineto *et al.*, 2001; Honda *et al.*, 2004; El-Maghraby *et al.*, 1999; Tole *et al.*, 2001; Beauduin *et al.*, 2002; Waring *et al.*, 1995; Schraepen *et al.*, 2005; Shah *et al.*, 1998; Kim *et al.*, 1995; Pietila *et al.*, 2004; Hersh *et al.*, 1997; Rajan *et al.*, 2004; Schor *et al.*).

According to our studies, In PRK operation 6693 myopic patients (-6D to -10D) were evaluated during 1997 to 2005 underwent PRK operation. After the operation the UCVA was 20/40 and 20/20 or better in 91% and 42.8%, respectively. 3.8% of patients were lost 2 or more lines of BCVA. Moreover, 69.5% and 87.5% were within  $\pm 0.5$  and  $\pm 1D$  respectively after the operation. Analyzing the data shows that there is a significant statistical difference between this range of myopia and (-3D to -6D) patients (Schraepen *et al.*, 2005; Honda *et al.*, 2004; Shah *et al.*, 2002; Kim *et al.*, 1997).

Studies on 194 high myopic patients (over -10D) evaluated during 1997 to 2004 underwent PRK operation shows that after the operation the 0.67% of patients were lost

2 lines of BCVA and 38.2% were  $\pm 1D$  after the operation (Schraepen *et al.*, 2005; Pietila *et al.*, 2004; Shah *et al.*, 2002).

In LASIK operation 313 patients up to +3D were evaluated during 1998 to 2005 underwent LASIK operation. After the operation The UCVA was 20/40 and 20/20 or better in 94.4% and 45.4%, respectively. Moreover, 0.98% of patients were lost 2 or more lines of BCVA and 67.9% and 87.9% were within  $\pm 0.5$  and  $\pm 1D$  respectively after operation (Oral *et al.*, 2005; Hill, 2003; Williams, 2000; Jaycock *et al.*, 2005; Sameh *et al.*, 2000). The major problem is that we need a wide treatment area (optical zone) for obtaining the result (Jackson *et al.*, 1998).

In summary, for hyperopic patients the results are not as well as myopic patients. For low hyperopic patients (<+3D) both PRK and LASIK have the same results in terms of safety but analyzing the data shows the superiority of PRK results in terms of percentage within  $\pm 0.5$  (P-value = 0.016) and also in terms of UVCA 20/20 or better (P-value<0.001).

In LASIK operation 596 patients up to -6D were evaluated during 1999 to 2006 underwent LASIK operation. After the operation The UCVA was 20/40 and 20/20 or better in 92.3% and 74.3%, respectively. In addition, 1.4% of patients were lost 2 or more lines of BCVA and 78% were within  $\pm 0.5$  after operation (Raffati *et al.*, 2001; El-Maghraby *et al.*, 1999; Tole *et al.*, 2001).

Our studies shows that In LASIK operation 748 myopic patients (>-6D) were evaluated during 1997 to 2005 underwent LASIK operation. After the operation The UCVA was 20/40 and 20/20 or better in 91.7% and 60.63%, respectively and 1.2%

of patients were lost 2 or more lines of BCVA. 76.1% and 88.1% were within  $\pm 0.5$  and  $\pm 1D$  respectively after operation (Hill, 2003; Salchow *et al.*, 1998; McDonald *et al.*, 2001; Dai *et al.*, 2006; Li *et al.*, 2005).

Studies on 146 astigmatic patients up to 3D Cyl underwent LASIK during 1998 to 2005 shows that after the operation the UCVA was 20/40 and 20/20 or better in 92.3% and 68.3%, respectively. The BCVA test on 113 patients show that no one lost 2 or more lines of Snellen chart and 86% were within  $\pm 0.5D$  after the operation (Rashad, 1999; Norouzi and Rahmati-Kamel, 2003; Wiesinger-Jendritza *et al.*, 1998).

In RK operation 170 myopic patients between  $-0.75D$  to  $-10D$  was evaluated during 1997 to 1998 underwent RK operation. A 10 year follow up shows that the UCVA was 20/40 and 20/20 or better in 86.2% and 39.5%, respectively. Moreover, the BCVA test on 79 patients show that no one lost 2 or more lines of Snellen chart and 42.4% and 63.3% were within  $\pm 0.5D$  and  $\pm 1D$  respectively after the operation (Koralewska-Makar, 1992; Charpentier *et al.*, 1998; Hamdi *et al.*, 1997).

In LASEK operation 230 patients up to  $-3D$  were evaluated during 2001 to 2004 underwent LASEK operation. After the operation The UCVA was 20/40 or better in 100%. Moreover, 0.6% of patients were lost 2 or more lines of BCVA. 93.2% and 95% were within  $\pm 0.5D$  and  $\pm 1D$  after the operation respectively (Taneri *et al.*, 2004; Shah *et al.*, 2001; Azar *et al.*, 2001; Azar and Ang, 2002; Feit *et al.*, 2003).

Concisely, for low myopic patients ( $<-3D$ ) PRK and LASEK operations have the same safety but PRK had better predictability

and UVCA than LASEK and the data analyze shows that there was a significant statistical difference between the 2 operation. The P-value was  $<0.016$  and  $<0.001$ , respectively.

In LASEK operation 1444 patients between  $-3D$  to  $-7D$  were evaluated during 2001 to 2006 underwent LASEK operation. After the operation The UCVA was 20/40 and 20/20 or better in 89.9% and 74.5%, respectively. Furthermore, 0.17% of patients were lost 2 or more lines of BCVA and 81.5% and 94.12% were within  $\pm 0.5$  and  $\pm 1D$  respectively after operation (Li *et al.*, 2005; Taneri *et al.*, 2004; Azar *et al.*, 2001; Payvar and Hashemi, 2002; Gabler *et al.*, 2003; Vandorselaer *et al.*, 2003; Piechocki and McDonald, 2002; Shah *et al.*, 2001; Vinciguerra and Camesasca, 2002; Vinciguerra *et al.*, 2002; Claringbold, 2002; Lohmann *et al.*, 2002; Lee *et al.*, 2002; Lee *et al.*, 2001; Anderson *et al.*, 2002; Litwak *et al.*, 2002; Shahinian, 2002).

In summary, for myopic patients between  $-3D$  to  $-7D$  except the safety PRK had better results than LASEK (P-value $<0.001$ ).

Our studies illustrate that 711 myopic patients ( $>-7D$ ) were evaluated during 2001 to 2004 underwent LASEK operation. After the operation the UCVA was 20/40 and 20/20 or better in 97.6% and 73.8% respectively. Besides, 0.15% of patients were lost 2 or more lines of BCVA. 80.8% and 94.12% were within  $\pm 0.5$  and  $\pm 1D$  respectively after operation (Vinciguerra and Camesasca, 2002; Anderson *et al.*, 2002; Shahinian, 2004; Li *et al.*, 2005; Rouweyha *et al.*, 2002).

Concisely, for myopic patients between ( $-6D$  to  $-10D$ ) in all the terms LASEK had better results than PRK. The data analyzing

<b>Total (%)</b>	<b>6.1</b>	<b>9.2</b>	<b>6.3</b>	<b>12.7</b>
<b>Small Flap (%)</b>	<b>NM</b>	<b>NM</b>	<b>0.47</b>	<b>0.43</b>
<b>Free caps (%)</b>	<b>NM</b>	<b>1</b>	<b>0.94</b>	<b>NM</b>
<b>Glare (%)</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>0.43</b>
<b>Haze (%)</b>	<b>NM</b>	<b>0</b>	<b>NM</b>	<b>0.43</b>
<b>Dry eye (%)</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>6.1</b>
<b>Infectious Keratitis(%)</b>	<b>NM</b>	<b>0.1</b>	<b>0.1</b>	<b>0.29</b>
<b>DLK<sup>1</sup> (%)</b>	<b>NM</b>	<b>3.2</b>	<b>0.2</b>	<b>NM</b>
<b>Epithelial ingrowth (%)</b>	<b>NM</b>	<b>2.2</b>	<b>2.1</b>	<b>1.17</b>
<b>Flap folds (%)</b>	<b>1.5</b>	<b>1.1</b>	<b>0.28</b>	<b>NM</b>
<b>Incomplete flap (%)</b>	<b>1.2</b>	<b>0.3</b>	<b>0.75</b>	<b>NM</b>
<b>BCVA loss 2 lines</b>	<b>1.6</b>	<b>0</b>	<b>4.7</b>	<b>0.73</b>
<b>Displaced flap (%)</b>	<b>1.2</b>	<b>2</b>	<b>1.1</b>	<b>2.04</b>
<b>Button holed Flap(%)</b>	<b>0.3</b>	<b>0.2</b>	<b>0.56</b>	<b>0.43</b>
<b>Irregular flap (%)</b>	<b>NM</b>	<b>0.9</b>	<b>0.09</b>	<b>NM</b>
<b>Thin flap (%)</b>	<b>0.3</b>	<b>0.49</b>	<b>0.75</b>	<b>0.73</b>

**Table 1 : The incidence of LASIK flap complications from studies with more than 1000 eyes**



shows that there was a significant statistical difference between the 2 operation (P-value < 0.05).

According to our studies, In LASEK operation 108 hyperopic patients (+2D to -5D) were evaluated during 2002 to 2003 underwent LASEK operation. After the operation the MRSE was  $0.32 \pm 0.99D$  and the UCVA was 20/40 and 20/20 or better in 91% and 89%, respectively (Atrata and Rehurek, 2003). No patient was lost 2 or more lines of BCVA which had a significant statistical difference between LASEK and CK (P-value < 0.001) but there is no significant statistical difference between LASEK results and PRK results.

As we know in the LASIK complication, flap complications are in the majority. Gimbel H.V. *et al.* (1998) (Gimbel *et al.*, 1998), Lin RT *et al.* (1999) (Lin and Maloney, 1999), Stulting *et al.* (1999) (Stulting *et al.*, 1999) and Lui M.M. *et al.* (2003) (Lui *et al.*, 2003) studies show the incidence of LASIK flap complications from studies with more than 1000 eyes underwent LASIK which these data obtained.

### **PRK VS LASIK**

Unlike PRK, the incidence of Corneal Haze and Scar reduced in LASIK (Helmy *et al.*, 1996; Guell and Muller, 1996).

Reduction of more than 1 line of snellen charts may occur in up to 8% of eyes underwent the LASIK operation, this phenomenon may due to irregular astigmatism, progressive myopia, epithelium ingrowths or other complications (Lindstrom *et al.*, 1997; Marinho *et al.*, 1996; Salah *et al.*, 1995; Pallikaris and Siganos, 1994; Hersh *et al.*, 2000).

LASIK operation is repeatable. PRK may be a safe procedure to perform in corneas previously treated with LASIK surgery (Shaikh *et al.*, 2005).

LASIK operation had more serious potential complications, more difficult to perform patients than PRK operation and also is more costly (Manche *et al.*, 1998).

In LASIK operation we have rapid visual patient's rehabilitation and minimal pain or discomfort after the operation. And we have more predictability with high levels of myopia (Manche *et al.*, 1998; McDonald *et al.*, 1999; Wang *et al.*, 1997; Loewenstein *et al.*, 1997; Alió *et al.*, 1998).

In general, LASEK has the least amount of postoperative pain than the two other operations (PRK and LASIK) (Atrata and Rehurek, 2003).

### **Conclusion**

For hyperopic patients up to +3.5D thermal methods like CK and LTK have the best outcomes and LASEK and PRK both have the same results and stand in the next places.

For myopic patients in all levels, LASEK have the best outcomes and PRK have considerable results in low level of myopia. On the other hand, LASIK have noticeable outcomes in moderate myopia and high levels of myopia.

According to these results, the necessity of manipulating the CK and the LTK methods for hyperopic patients treat becomes important.

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