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A Comparative Study between conventional LASIK and IntraLASIK Surgeries based on Sigma Quality Levels

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Abstract

IntraLASIK is the most recent surgery for corneal refractive surgery and has emerged as an alternative to LASIK surgery. However, IntraLASIK surgery comes at a higher cost to the patient and also requires additional investment to any eye center willing to practice it. This study identifies the complication profiles of conventional LASIK and IntraLASIK surgeries. The incidences of the complications in each surgery are individually presented in terms of sigma quality levels to contrast the efficiency. Having led to fewer complications, the process sigma level of IntraLASIK is found to be higher than the level of LASIK. This suggests that IntraLASIK is a more efficient refractive surgery than LASIK.

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Keywords: Refractive surgery, LASIK, IntraLASIK, Complications, Sigma Quality Level

1. Introduction

Untreated refractive error accounts for 50% of the burden of avoidable vision impairment and 33% of the global burden of avoidable blindness worldwide (Dondana and Dondana, 2006). 153 million people have visual impairments, or are blind due to uncorrected refractive error and the majority live in low income countries (Dondana and Dondana, 2006). Undercorrected refractive error accounts for almost 75% of all impaired vision in high income populations, affecting quality of life (Dondana and Dondana, 2006).

Over the past two decades, a progressive revolution has occurred in ophthalmological techniques. The advent of better equipment, techniques and applications has resulted in a profound improvement of many ocular treatments. Practices have improved, due to these new techniques and form part of the specialists' instruments employed daily.

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The ability to diagnose and treat many ocular diseases has improved with rapid developments evidenced in the past decade (Gubman, 2003).

Refractive surgery is the name given to the procedure which is performed using laser technology to provide vision free from eye glasses and contact lenses for patients with refractive errors such as short-sightedness (Pallikaris and Sigonis, 1997), long-sightedness and/or astigmatism (Lindstrom et al., 2000). These procedures are undergoing revised development and modification. For instance, during the last decade, conventional laser in situ keratomileusis (LASIK) has essentially replaced incisional radial keratotomy as the preferred treatment for patients with short-sightedness. In recent years, a more improved technique called IntraLase femtosecond (FS) laser assisted LASIK (IntraLASIK) has shown more accurate and safer results than the conventional LASIK surgery in creating corneal flap (Friedlaender, 2006). On the other hand, Lim et al. (2006), Zhang et al. (2011) and Chen et al. (2012) stated that IntraLASIK FS laser offered no significant benefits over conventional LASIK with microkeratomes in regards to safety and accuracy. To date, many studies compared technical properties of LASIK surgery and IntraLASIK surgery (Montes-Mico et al., 2007; Chan et al., 2008; Rosa et al., 2009; Tanna et al., 2009; Zhang et al., 2011; Xia et al., 2015).

Şahbaz et al. (2014) and Taner et al. (2014) stated that refractive surgeons are in a key position to eliminate the ophthalmologic complications and added that complications occurring throughout LASIK and IntraLASIK processes can be reduced as refractive surgeons gained experience and is trained on how to identify, minimize or eliminate the sources and root-causes of the complications. It has been reported by Coşar et al. (2013) that no significant differences in complication rates existed between LASIK surgery and IntraLASIK surgery.

2.Methods

2.1. Research Goal

In this study, the authors aim to demonstrate the success rates of LASIK surgery and IntraLASIK surgery, and the incidence of complications in detail by using sigma levels to contrast the reliability and efficiency of each separate technique and highlight any shortcomings which may result.

2.2. Sample and Data Collection

In this study, the retrospective data consisted of complications observed during and after 200 consecutive LASIK and 200 consecutive IntraLASIK surgeries performed in a Turkish private eye center between the years, 2010 and 2014.

2.3. Analyses and Results

This study identified twenty-two types of complications for LASIK surgery and eighteen types of complications for IntraLASIK surgery. For each type of complication, a severity score was assigned from 1 to 4 (Table 1). This prioritized the complications according to how serious their consequences were. Complications of LASIK and IntraLASIK surgeries were tabulated in Table 2 and Table 3, respectively.

Table 1. Severity scores

Severity Score	4	3	2	1
Severity of Complication	Permanent harm	Temporary harm	Low harm	No harm

Table 2. Complications of LASIK surgery

Type	Complication's Name	Severity Score	Incidence Rate (%)	Sigma Level
I	Dry eye syndrome	2	62	1.19
II	Subconjunctival hemorrhage	1	85	0.46
III	Flap edge melt	4	3	3.38
IV	Photophobia	3	24	2.21
V	Epilethial ingrowth	3	1	3.83
VI	Thin flap	3	3	3.38
VII	Undercorrection	4	4	3.25
VIII	Overcorrection	4	3	3.38
IX	Epithelial erosion	2	2	3.55
X	Decentered flap	2	3.5	3.31
XI	Incomplete flap	4	2	3.55
XII	Interface debris	1	4	3.25
XIII	Buttonhole	4	1	3.83
XIV	Punctate epitheliopathy	2	1	3.83
XV	Shifting sands of the Sahara	3	1	3.83
XVI	Flap wrinkling	3	2	3.55
XVII	Small flap	3	1	3.83
XVIII	Inadequate suction	4	2.5	3.46
XIX	Tear in flap	2	1.5	3.67
XX	Sliding flap	4	0.5	4.08
XXI	Chemosis	1	7	2.98
XXII	Free flap	2	0.5	4.08

Table 3. Complications of IntraLASIK surgery

Type	Complication's Name	Severity Score	Incidence Rate (%)	Sigma Level
I	Dry eye syndrome	2	48	1.55
II	Subconjunctival hemorrhage	1	74	0.86
III	Tear in flap	2	0.5	4.08
IV	Photophobia	3	17	2.45
V	Epilethial ingrowth	3	0.5	4.08
VI	Chemosis	1	7	2.98
VII	Undercorrection	4	2	3.55
VIII	Overcorrection	4	1	3.83
IX	Sliding flap	4	1	3.83
X	Decentered flap	2	3.5	3.31
XI	Incomplete flap	4	1	3.83
XII	Interface debris	1	1	3.83
XIII	Sidecut inefficiency (use of scissors)	3	1	3.83
XIV	Punctate epitheliopathy	2	0.5	4.08
XV	Shifting sands of the Sahara	3	0.5	4.08
XVI	Flap wrinkling	3	2	3.55
XVII	Sidecut inefficiency (use of syringe)	3	1	3.83
XVIII	Suction loss	2	1	3.83

Complications such as shifting sands of the Sahara, overcorrection, undercorrection, incomplete flap, decentered flap, interface debris, dry eye syndrome, epilethial ingrowth, sliding flap, flap wrinkling and subconjunctival hemorrhage occurred with both the mechanical microkeratome and the FS laser. However, there was a significant decrease in the number of severe complications by the use of FS laser. This finding is in contradiction to Coşar et al. (2013). Many of the complications such as buttonhole, flap edge melt, thin flap, epilethial erosion, wrinkles, small flap, free flap and inadequate suction were totally eliminated by the use of the FS laser.

This study also showed that flap-related complications were reduced in IntraLASIK surgery. Shifting sands of the Sahara, subconjunctival hemorrhage, overcorrection, undercorrection, incomplete flap, tear in flap and interface debris were reduced to lower levels. On the other hand, there were no changes in the incidence rates of chemosis, flap wrinkling and decentered flap. Other complications specifically occurred by the use of the FS laser were sidecut inefficiency and suction loss.

For each type of complication, sigma level was calculated individually from the incidence rate and given in Table 2 and Table 3. Then, the overall process sigma level of each surgery was calculated by diving the total sigma levels to the number of complication types. Consequently, process sigma levels of LASIK and IntraLASIK surgeries were found to be 3.27 and 3.41, respectively.

The lowest sigma level was found for subconjunctival hemorrhage for both LASIK (0.46) and IntraLASIK (0.86) surgeries. The highest sigma level (4.08) in the IntraLASIK surgery was obtained for tear in flap, epilethial ingrowth and shifting sands of the Sahara. Similarly, punctate epitheliopathy and free flap yielded the highest levels of sigma (4.08) in LASIK surgery.

Table 4. Sources of LASIK complications

Type	Complication's Name	Source of Complication
I	Dry eye syndrome	Patient, Microkeratome
II	Subconjunctival hemorrhage	Patient, Suction-ring
III	Flap edge melt	Patient
IV	Photophobia	Patient, Laser
V	Epilethial ingrowth	Refractive surgeon, Patient
VI	Thin flap	Refractive surgeon, Patient, Microkeratome
VII	Undercorrection	Refractive surgeon, Patient, Laser
VIII	Overcorrection	Refractive surgeon, Patient, Laser
IX	Epithelial erosion	Refractive surgeon, Patient, Microkeratome
X	Decentered flap	Refractive surgeon
XI	Incomplete flap	Refractive surgeon, Patient, Microkeratome
XII	Interface debris	Refractive surgeon
XIII	Buttonhole	Refractive surgeon, Patient, Microkeratome
XIV	Punctate epitheliopathy	Patient
XV	Shifting sands of the Sahara	Nurse, Technician, Patient
XVI	Flap wrinkling	Refractive surgeon, Patient
XVII	Small flap	Refractive surgeon, Microkeratome
XVIII	Inadequate suction	Refractive surgeon, Patient, Suction-ring
XIX	Tear in flap	Refractive surgeon, Microkeratome
XX	Sliding flap	Patient
XXI	Chemosis	Suction-ring
XXII	Free flap	Refractive surgeon, Patient, Microkeratome

Table 5. Sources of IntraLASIK Complications

Type	Complication's Name	Source of Complication
I	Dry eye syndrome	Patient, FS laser
II	Subconjunctival hemorrhage	Patient, Suction-ring
III	Tear in flap	Refractive surgeon, FS laser
IV	Photophobia	Patient, FS laser

V	Epilethial ingrowth	Refractive surgeon, Patient
VI	Chemosis	Suction-ring
VII	Undercorrection	Refractive surgeon, Patient, FS laser
VIII	Overcorrection	Refractive surgeon, Patient, FS laser
IX	Sliding flap	Patient
X	Decentered flap	Refractive surgeon
XI	Incomplete flap	Refractive surgeon, Patient, Suction-ring
XII	Interface debris	Refractive surgeon
XIII	Sidecut inefficiency (use of scissors)	FS laser
XIV	Punctate epitheliopathy	Patient
XV	Shifting sands of the Sahara	Nurse, Technician, Patient
XVI	Flap wrinkling	Refractive surgeon, Patient
XVII	Sidecut inefficiency (use of syringe)	FS laser
XVIII	Suction loss	Refractive surgeon, Patient, Suction-ring

Table 6. Root Causes of Complications in LASIK surgery

Type	Complication's Name	Experience	Calibration	Maintenance	Hygiene
I	Dry eye syndrome		x	x	
II	Subconjunctival hemorrhage	x		x	
III	Flap edge melt		n/a		
IV	Photophobia	x	x	x	
V	Epilethial ingrowth	x		x	
VI	Thin flap	x	x	x	
VII	Undercorrection	x	x	x	
VIII	Overcorrection	x	x	x	
IX	Epithelial erosion	x			
X	Decentered flap	x	x	x	
XI	Incomplete flap	x	x	x	
XII	Interface debris	x			x
XIII	Buttonhole	x	x	x	
XIV	Punctate epitheliopathy		n/a		
XV	Shifting sands of the Sahara	x			x
XVI	Flap wrinkling	x			
XVII	Small flap	x	x	x	
XVIII	Inadequate suction	x	x	x	
XIX	Tear in flap	x	x	x	
XX	Sliding flap	x			
XXI	Chemosis	x			
XXII	Free flap	x	x	x	

Table 7. Root Causes of Complications in IntraLASIK surgery

Type	Complication's Name	Experience	Calibration	Maintenance	Hygiene
I	Dry eye syndrome		x	x	
II	Subconjunctival hemorrhage	x		x	
III	Tear in flap	x	x	x	
IV	Photophobia	x	x	x	
V	Epilethial ingrowth	x		x	
VI	Chemosis	x			
VII	Undercorrection	x	x	x	
VIII	Overcorrection	x	x	x	
IX	Sliding flap	x			
X	Decentered flap	x	x	x	
XI	Incomplete flap	x	x	x	
XII	Interface debris	x			x
XIII	Sidecut inefficiency (use of scissors)		x	x	
XIV	Punctate epitheliopathy		n/a		
XV	Shifting sands of the Sahara	x			x
XVI	Flap wrinkling	x			
XVII	Sidecut inefficiency (use of syringe)		x	x	
XVIII	Suction loss	x	x	x	

Having sigma levels under 3.00, the complications of subconjunctival hemorrhage (0.46), dry eye syndrome (1.19), photophobia (2.21) and chemosis (2.98) must be significantly reduced in order to take the overall LASIK process under control. In the IntraLASIK process, incidences of these complications were decreased. However, more improvements still need to be achieved to reduce the complications of subconjunctival hemorrhage (1.55), dry eye syndrome (0.86), photophobia (2.45).

Being the refractive surgeon, patient, microkeratome, suction-ring, laser and/or FS laser, sources were identified for each complication type (Table 4; Table 5). Then, root causes of complications such as the experience, calibration, maintenance and hygiene were determined by brain-storming (Table 6; Table 7).

As demonstrated in Table 6 and Table 7; while the success of the LASIK and IntraLASIK surgeries is mainly dependent on the experience of refractive surgeon, regular maintenance and proper calibration of the equipment are also crucial. They both depend on the efficiency of on laser technician reducing any subsequent cause of risk and harm to a minimum. It is also shown that the standards of hygiene practiced with the LASIK surgery must at least be maintained if not further improved in the IntraLASIK surgery.

3.Discussion

In LASIK surgery, the refractive surgeon creates the corneal flap with a blade-based mechanical microkeratome whereas IntraLASIK involves cutting the flap with a FS laser instead of a blade (Kezirian and Stonecipher, 2004).

By 2010, over 50% of the conventional LASIK procedures in the United States were replaced with the FS laser (Bryar et al., 2013). In Turkey, private hospitals appear to use the IntraLASIK technique predominantly, whereas the LASIK technique is still preferred in state hospitals at the present time due to cost by the majority of potential patients.

A study continued between 1988 and 2008 measured patient satisfaction following LASIK surgery. High satisfaction rates, i.e. 95.3% and 96.3% were found for shortsighted and longsighted patients, respectively (Salomao and Wilson, 2010). Similarly, Miller et al. (2001) found that 85% of the shortsighted patients were at least very pleased with their refractive outcome and added that dissatisfaction was associated with postoperative dry eye.

Salomao et al. (2009) determined that eyes with FS flaps had a lower incidence of LASIK-associated dry eye and required less treatment for the disorder. On the other hand, Golas and Manche (2011) found that there appeared to be no statistically significant difference in self-reported dry eye symptoms between the conventional LASIK group and the IntraLASIK group.

In this study, the authors compared the incidence rates of dry eye syndrome experienced after the LASIK and IntraLASIK surgeries and found that there was a 14% improvement in the incidence of dry eye syndrome by the use of FS laser. This finding is in contradiction to Golas and Manche (2011).

In agreement with the study of Moshirfar et al. (2010), this study confirmed that IntraLASIK surgery greatly reduced the flap-related complications.

In this study, the incidences of complications in LASIK surgery and IntraLASIK surgery are individually demonstrated in detail and measured in terms of sigma levels to contrast the efficiency. The process sigma level of IntraLASIK is found to be higher than the level of LASIK. This suggests that IntraLASIK is a more efficient refractive surgery than LASIK. Thus, the increased accuracy of the FS laser over mechanical microkeratome was confirmed by this study. This finding is in contradiction to Lim et al. (2006), Zhang et al. (2011) and Chen et al. (2012).

The Six Sigma Methodology as a quality improvement framework has been gaining increasing attention and acceptance in health care industry (Taner et al., 2007). It has the potential to produce clinically significant improvement for surgical patients (Mason et al., 2015). It can provide a scientific and statistical basis for quality assessment for all processes through measurement of sigma levels. Moreover, success, performance, efficiency and reliability in health care processes can be reported as a sigma level (Goh and Xie, 2004).

A sigma level of the process measures how much a process varies from perfection, based on the number of defects per million opportunities. A performance level of Six Sigma equates to 3.4 defects per million opportunities, where sigma is a statistical metric of the amount of variation around the process average (Antony and Coronado, 2002). A higher sigma level is associated with a lower number of complications and a more efficient process. The average sigma level for most processes is 3-sigma (Antony and Coronado, 2002). Any performance under this level identifies a process that calls for significant improvement (Taner et al., 2013).

Health care organizations usually make use of percentages or magnitude indices to report the reliability of performance. In this study, the authors propose the use of sigma levels as a reliability index in surgical processes. Measuring surgical complications in terms of sigma levels can allow performance of similar processes to be compared throughout a spectrum of surgeries using the same metric, independently of the process to be measured. The ability to calibrate processes using sigma levels can help hospital administrators, biostatisticians and refractive surgeons to make comparison between processes, techniques, and/or equipment, and set targets in terms of improvements in the sigma value (Lighter, 2010).

Conclusion

In this study, the authors used sigma quality level as a metric to measure the incidence levels of complications occurring in LASIK and IntraLASIK surgeries. The following points merit consideration:

The IntraLASIK surgery resulted in less number of complications. In addition, it minimized the flap-related complications. On the other hand, the LASIK surgery resulted in more severe complications as the refractive surgeon had additional factors of safety to deal with. The IntraLASIK surgery required a shorter term to recover and results in better vision. While the LASIK surgery was the cheaper of the both methods, the recovery period was longer and resolution rate was not as good as the LASIK surgery. Unlike the IntraLASIK surgery which required less visits for checking and a more direct technique to establish success, multiple follow-up examinations were required in LASIK due to the wide range and high incidence of complications.

The vast majority of evidence in this study pointed to the IntraLASIK surgery being the more efficient of the two techniques. While the IntraLASIK surgery undoubtedly improved the chances of success, all methods would have their own inherent dangers. A profound advantage of the IntraLASIK surgery was the impressive reduction of complications resulting in permanent harm. The success of the IntraLASIK surgery brought additional responsibility on all members of the surgical team. All members part-taking in the surgery contributed to the efficiency and inherent dangers of a successful outcome. Because of the FS laser efficiency all personnel members were required to be more vigilant as observers and quicker to respond whenever a potentially harmful situation results.

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