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A Preliminary Study for Six Sigma Implementation İn Laser *in situ* Keratomileusis (LASIK) Surgeries

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ABSTRACT: The purpose of this study is to show how a private eye care center in Turkey developed a Six Sigma infrastructure to investigate the root causes of complications occuring during LASIK surgeries. To analyze the collected data, main tools of Six Sigma's Define-Measure-Analyze-Improve-Control(DMAIC) improvement cycle such as SIPOC table, Fishbone Diagram and, Failure, Mode and Effect Analysis were implemented. Experience of the refractive surgeons, type of microkeratome and hygiene of microkeratome were identified to be Critical-to-Quality (CTQ) factors for a successful LASIK surgery. The most frequent complications of LASIK surgeries were found to be dry eye syndrome, subconjunctival haemorrhage and flap edge melt. The process sigma level was found to be 3.7135.

Keywords: Six Sigma; ophthalmology; refractive surgery; complications
JEL Classifications: I120; L15

1. Introduction

Over the past two decades, there has been a fundamental revolution in the field of ophthalmology. New and better equipment, procedures and applications have emerged for the diagnosis and treatment of many ocular diseases. Daily practices have been changed because they now use new techniques and it is referred to specialists who use them. The ability to diagnose and treat many ocular diseases has improved tremendously during the past decade (Gubman, 2003).

The procedure performed by using laser technology to provide vision without eye glasses and contact lenses for patients with refractive errors such as myopia (Pallikaris and Sigonis, 1997), hyperopia and/or astigmatism (Lindstrom et al., 2000), is named refractive surgery. Its procedures are undergoing constant development and modification. For instance, in the last decade, laser in situ keratomileusis (LASIK) has essentially replaced incisional radial keratotomy (RK) as the preferred treatment for patients with myopia. Some aspects of LASIK surgery make it a unique surgical procedure necessitating a novel approach to patient selection and preoperative evaluation. Firstly, patients often request treatment of eyes that have problems for which surgery might be contraindicated. Secondly, although advice regarding the propriety of LASIK surgery must always be

individualized to each patient (age > 19)'s risk-benefit ratio. LASIK surgery is contraindicated for patients with systematic immunologic disorders, systematic collagen vascular diseases, psoriasis, diabetes mellitus, keratoconus, active corneal or ocular disease or those who are pregnant or lactating, and those who have large pupil size or thin corneas or too steep corneas or too flat corneas or deep-set eyes should be avoided due to possible severe corneal postoperative complications and wound healing problems.

According to a survey by Miller et al. (2001), patients who have had LASIK for the correction of myopia, 85% were at least very pleased with their refractive outcome and 97% said they would decide to have the procedure performed again. Factors that were found to be correlated well with patient satisfaction were postoperative improvements in uncorrected visual acuity and decreased cylindrical correction. Dissatisfaction was associated with postoperative dry eye.

In a study by Bailey et al. (2003), factors such as increasing age, flatter preoperative minimum corneal curvature, and surgical enhancement were found to be associated with decreased satisfaction and night vision symptoms after LASIK.

Solomon et al. (2009) reported that an average 95.4% of patients were satisfied with their outcome after LASIK surgery. With 16.3 million procedures performed in the world, and more than a decade of clinical studies and technological innovation, LASIK surgery is considered among the most successful refractive procedures. LASIK surgery compares more favorably with other procedures in terms of generally higher satisfaction rates.

Uncorrected refractive error accounts for half of the burden of avoidable vision impairment and a third of the global burden of avoidable blindness worldwide (Dondana and Dondana, 2006). One hundred and fifty-three 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). Under-corrected refractive error accounts for almost seventy-five % of all impaired vision in high income populations, affecting quality of life (Dondana and Dondana, 2006).

LASIK has great potential for complications. Some of these complications can be very serious; others may be inconsequential and easily avoidable (Schallhorn et al., 2006; Melki and Azar, 2001).Complications need to be diagnosed and treated early to optimize postoperative outcome. A list of common LASIK complications is given on Table 1.

Six Sigma as a quality management system can improve the treatment of ocular diseases (Taner et al., 2013). In this study, a Six Sigma infrastructure in a Turkish private eye center to improve the LASIK surgery process will be developed. In addition, sigma level of each type of complication will be calculated and reported.

2. Six Sigma Methodology and LASIK Surgery

Six Sigma, originally initiated by Motorola, Honeywell and General Electric (Mehrjerdi, 2011), is a powerful performance improvement tool that is changing the face of modern healthcare delivery today (Taner et al., 2007). Although it was initially introduced in manufacturing processes, it is being implemented in diagnostic imaging processes (Taner et al., 2012), emergency room (Miller et al., 2003), paramedic backup (Taner and Sezen, 2009), laboratory (Nevalainen et al., 2000), cataract surgery (Taner et al., 2013), radiology (Cherry and Seshadri, 2000), surgical site infections (Pexton and Young, 2004) and stent insertion (Taner et al., 2013) as a cost-effective way to improve quality, performance and productivity. This study is the first Six Sigma research in the literature.

As a method to eliminate variation, waste, errors and inefficiencies, Six Sigma uses a structured methodology called DMAIC to find the main causes behind problems and to reach near perfect processes. DMAIC is especially useful to analyze and modify complicated time-sensitive healthcare processes involving multiple specialists and treatment areas by identifying and removing root causes of defects (errors) and thus minimizing healthcare process variability (Buck, 2001; Taner et al., 2007).

The DMAIC is a five-step improvement cycle that aims to continuously reduce errors:

1. Define the problems of the process, clarify its scope and define its goals;
2. Measure the current performance of the process, gather and compare data, refine its problems/goals;
3. Analyze the process by identifying sources and root-causes of errors;

4. Improve the process by conducting trials to eliminate root causes, measuring results, standardizing solutions and implementing the improved processes by designing creative solutions to fix and prevent problems;
5. Control the new process by institutionalizing improvements and implementing mechanisms for ongoing monitoring in place (Park and Antony, 2008).

Table 1. Complications

Preoperative Complications*	**Microkeratome-Related Complications****	**Intraoperative Complications*****	**Vitreoretinal Complications*****
Anaesthesia, Conjunctiva, Lashes, Drape, Speculum.	Incomplete Cut, Irregular Cut, Free Flap, Perforated Lenticule, Buttonhole, Corneal Perforation Inadequate Suction, Inadequate Exposure, Corneal Epithelial Defect, Wound Dehiscence, Corneal Bleed, Thin Flaps, Decentered Flaps, Edematous Flaps.	Suction-Related Problems, Buttonhole, Flap Dislocation, Intraocular Penetration, Complete Cut (Free flap, decentered flap, superficial/too thin/irregular flap), Incomplete Cut (Under half, over ¾)	Retinal Breaks, Rhegmatogenous Retinal Detachment.
Early Postoperative Complications******	**Postoperative Complications***	**Late Postoperative Complications********	**Photoablation-Related Complications****
Overcorrection, Undercorrection, Sliding or Dislodged Flap, Loss of the Flap/Cap. Diffuse Lamellar Keratitis or the Shifting Sands of the Sahara, Infectious Keratitis, Epithelial Ingrowth, Flap edge melt, Decentred Flap, Foreign Bodies, Microstriae.	Decentred Flap, Central Island, Diffuse Lamellar Keratitis/Shifting Sands of Sahara, Epithelial Ingrowth, Infectious Keratitis, Flap Wrinkles or Striae, Keratectasia.	Induced or Iatrogenic Keratectasia, Keratitis, Night Vision Problems/ Glare/Halos, Visual Aberrations, Irregular Astigmatism, Decreased Contrast Sensitivity, Infection, Dry Eye Syndrome, Epithelial Ingrowth,	Decentration, Central Islands, Wrinkles, Interface Debris, Destruction of the Flap, Uneven Ablation.

*Dayanir and Azar,2004
**Farah and Azar, 2004; Tham and Maloney, 2000; Ghadhfan et al., 2007.
***Haw and Manche, 2008; Arevalo et al., 2000.
****Farah and Azar, 2004; Cummings and Lavery, 2001; Ambrioso and Wilson, 2001.
*****Dayanir and Azar, 2004;Cummings and Lavery, 2001; Ambrioso and Wilson, 2001; Nakano et al., 2004.

3. Application of Six Sigma's DMAIC to LASIK Surgery:

The eye care center decides that Six Sigma is the best way to achieve their goals. A surgical team is assembled and trained in the methodology. Committed and consistent leadership to overcome the complications is assured by this team. The surgical team firstly generates a SIPOC (Supplier, Input, Process, Output and Customer) Table for LASIK surgery process (Table 2).

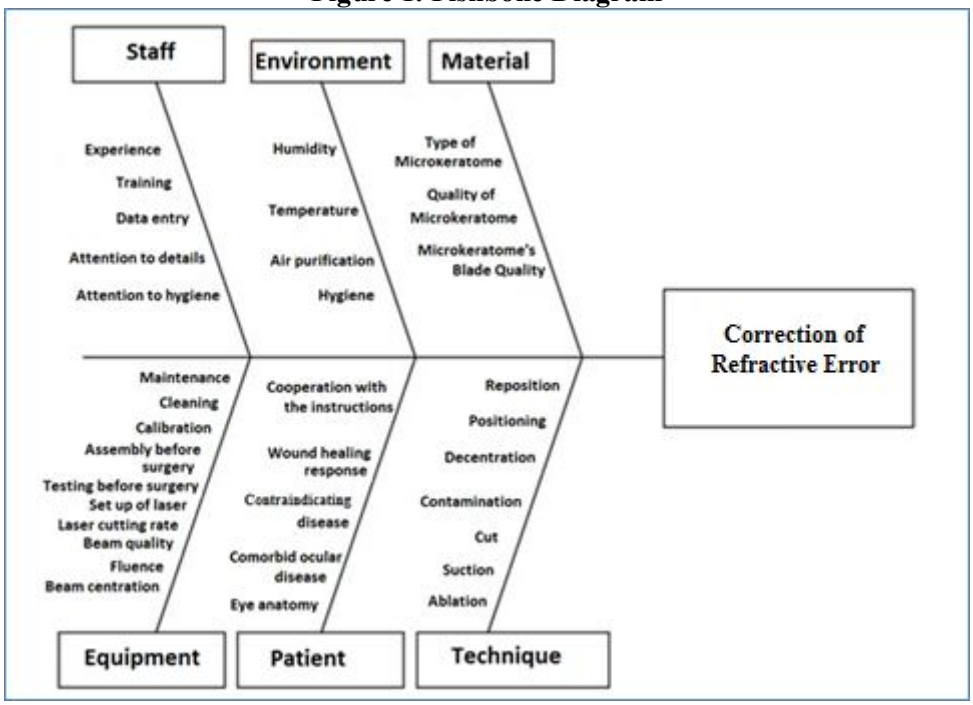
The surgical team defines the performance objective as patients with corrected refractive error after nearly perfect LASIK procedures; or as patients with "Emmetropia" after perfect LASIK procedure, i.e. no refractive error. They also define a complication as any unwanted outcome inhibiting the patient to be cured and stable. It compounds the illness and decreases the patient's quality of life or prolongs the planned hospital stay (Taner et al., 2013). To achieve the performance objective, the surgical team first determines the Critical-to-Quality (CTQ) factors by brainstorming.

The CTQ factors are those factors that may have an influence on the objective. These factors are presented in the fishbone diagram (Figure 1).

Table 2. SIPOC Table for LASIK Surgery

SUPPLIER	INPUT	PROCESS	OUTPUT	CUSTOMER
Refractive surgeon	Patient	Ocular examination (i.e. acuity testing, refraction, computerized videokeratography, wave front analysis if available, slit-lamp examination, retinal evaluation, eye dominance testing, and evaluation for monovision when appropriate, measurement of pupil size, Schirmer test)	Emmetropia	Patient
Biomedical technician	Laser	Biometric measurements, Corneal topography.	Corrected refractive error	
Nurse	Microkeratome	Evaluation by refractive surgeon		
Laser technician		Verification of patient data inserted in the computer, Insertion of the blade into the microkeratome head, Draping, Speculum, Positioning of the patient, Marking of cornea, Placement of the suction ring, The microkeratome cut, Laser ablation, Replacing the flap.		
		Discharge		

Figure 1. Fishbone Diagram



The surgical team determines the metrics to measure existing process. The metrics to be chosen for a Six Sigma study are:

1. Total number of LASIK performed in the eye care center,
2. Number of complications.

Data were collected for a period of 7-years. In this period, a total of 2357 LASIK surgeries were performed by a Schwind Carriazo-pendular microkeratome. Complications had been noted as they occurred. The surgical team identified twenty types of complications and classified them as how soon they had occurred, i.e. acute and/or sub-acute; and in which stage they had occurred, i.e. pre-operatively, intra-operatively or post-operatively (Table 3). Sources (Table 4) and root-causes (Table 5) of these complications are tabulated by type.

The incidence of complications depends on multiple sources (variables). Measurement variables, surgeon variables, staff variables, patient variables, suction-ring variables, microkeratome variables and laser variables must all be evaluated when attempting to assess the root-cause of a complication (Table 4 and Table 5).

The surgical team analyzed the occurrence frequency of each complication (Table 5) and related them with the root-causes on Table 4. The analysis revealed that Type I, II and III were the four most frequently occurring complications in the LASIK surgeries (Table 5). Then, they classified these root-causes as "vital few factors" and "trivial many factors" according to how frequent they caused the complications. The "vital few" factors, i.e. the factors that had the most impact on the success of LASIK surgery were determined to be the experience of the refractive surgeons, type of the microkeratome and hygiene of the microkeratome. The other factors were "trivial many".

Table 3. Complications Experienced (2006-2013)

	Complication	**Pre-Operative**	**Intra-Operative**	**Post-Operative**	**Acute**	**Sub-Acute**
Type I	Dry eye syndrome			X	X	
Type II	Subconjunctival haemorrhage		X	X	X	
Type III	Flap edge melt			X		X
Type IV	Limbal haemorrhage		X		X	
Type V	Epilethial ingrowth			X		X
Type VI	Thin flap		X		X	
Type VII	Undercorrection			X	X	X
Type VIII	Overcorrection			X	X	X
Type IX	Epithelial erosion		X	X	X	
Type X	Decentered flap		X		X	
Type XI	Incomplete flap		X		X	
Type XII	Interface debris		X		X	
Type XIII	Buttonhole		X		X	
Type XIV	Wrong insertion of patient's biometric data	X			X	
Type XV	Shifting sands of the Sahara			X	X	X
Type XVI	Wrinkles		X	X	X	
Type XVII	Small flap		X		X	
Type XVIII	Inadequate suction		X		X	
Type XIX	Free flap		X		X	
Type XX	Sliding flap			X	X	

The surgery team calculated the current Defects per One Million Opportunities (DPMO) and sigma levels (See the Appendix) for each complication type (Table 6). The process sigma level, calculated as the arithmetic average of twenty complications, was found to be 3.7135.

The highest sigma levels were obtained for Type XVII, XVIII, XIX and XX. The lowest sigma level was found to be belong to Type I. Having sigma levels much lower than 4.00, the alerting complications for LASIK were Type I and II. These are the complications whose rates need to be significantly reduced.

Table 4. Sources of Complications

	Measurement	Surgeon	Nurse/Technician	Patient	Suction-ring	Microkeratome	Laser
Type I						X	
Type II					X		
Type III				X			
Type IV					X	X	
Type V		X		X			
Type VI		X		X		X	
Type VII		X		X			X
Type VIII		X		X			X
Type IX		X		X		X	
Type X		X					
Type XI		X		X		X	
Type XII		X					
Type XIII		X		X		X	
Type XIV	X	X	X				
Type XV			X	X			
Type XVI		X		X			
Type XVII		X				X	
Type XVIII		X		X	X		
Type XIX		X		X		X	
Type XX				X			

Risk assessment of the LASIK process was done by the failure mode and effect analysis (FMEA). Utilization of the FMEA involved break down the process into individual steps: potential failure modes (i.e. complications), severity score, probability score, hazard score, criticality and detection, so that the surgery team could look at key drivers in the process based on the past experience. Complication trends and their consequences over a 7-years period had been monitored and recorded.

Table 5. Root-causes of Complications

	Maintenance Of Micro-keratome	Experience of Refractive Surgeons	Type of Micro-keratome	Cleaning of Patient's Cornea by Refractive Surgeon	Patient's Eye Anatomy
Type I	n/a	n/a	n/a	n/a	n/a
Type II	n/a	n/a	n/a	n/a	n/a
Type III		X	X		
Type IV	n/a	n/a	n/a	n/a	n/a
Type V		X			
Type VI		X	X		X
TypeVII		X			
Type VIII		X			
Type IX		X			
Type X		X			
Type XI	X		X		
Type XII				X	
Type XIII	X	X	X		
Type XIV		X			
Type XV					
Type XVI		X			
Type XVII					
Type XVIII		X			
Type XIX	n/a	n/a	n/a	n/a	n/a
Type XX					

	Cooperative Patient	Hygiene of Micro-keratome	Patient Selection	Adequate Suction	Attention of laser technician
Type I	n/a	n/a	n/a	n/a	n/a
Type II	n/a	n/a	n/a	n/a	n/a
Type III					
Type IV	n/a	n/a	n/a	n/a	n/a
Type V					
Type VI					
Type VII					
Type VIII					
Type IX					
Type X					
Type XI		X			
Type XII					
Type XIII	X	X			
Type XIV					
Type XV					X
Type XVI	X				
Type XVII			X	X	
Type XVIII					
Type XIX	n/a	n/a	n/a	n/a	n/a
Type XX	X				

Table 6. Cumulative frequency, DPMO and Sigma Levels

	Count	Frequency (%)	DPMO	Sigma Level
Type I	2357	100.00	1000000	-6.26
Type II	1308	55.49	554943	1.36
Type III	67	2.84	28426	3.40
Type IV	19	0.81	8061	3.91
Type V	11	0.47	4667	4.10
Type VI	11	0.47	4667	4.10
Type VII	11	0.47	4667	4.10
Type VIII	7	0.30	2970	4.25
Type IX	6	0.25	2546	4.30
Type X	6	0.25	2546	4.30
Type XI	5	0.21	2121	4.36
Type XII	4	0.17	1697	4.43
Type XIII	2	0.08	849	4.64
Type XIV	2	0.08	849	4.64
Type XV	2	0.08	849	4.64
Type XVI	2	0.08	849	4.64
Type XVII	1	0.04	424	4.84
Type XVIII	1	0.04	424	4.84
Type XIX	1	0.04	424	4.84
Type XX	1	0.04	424	4.84

Surgical team prioritized the complications according to how serious their consequences were (i.e. severity score), how frequently they occurred (probability score) and how easily they could be detected. Hazard analysis was employed in order to identify failure modes and their causes and effects. The surgery team determined the severity of each complication and assigned scores for them. The severity of each complication was scored from 1 to 4 (Table 7).

Table 7. Severity Scores

Severity Score	4	3	2	1
Severity of Complication	Death or permanent harm	Temporary harm	Bias	No harm

Table 8. FMEA Table

Complication Type	Hazard Analysis			Decision Tree Analysis	
	Severity Score	Probability Score	Hazard Score	Critical?	Detectable?
Type I	2	1.0000	2.0000	No	Yes
Type II	1	0.5549	0.5549	No	Yes
Type III	4	0.0284	0.1936	Yes	Yes
Type IV	2	0.0081	0.0162	No	Yes
Type V	3	0.0047	0.0141	Yes	Yes
Type VI	3	0.0047	0.0141	Yes	Yes
Type VII	3	0.0047	0.0141	Yes	Yes
Type VIII	3	0.0030	0.0090	Yes	Yes
Type IX	2	0.0025	0.0050	No	Yes
Type X	2	0.0025	0.0050	Yes	Yes
Type XI	4	0.0021	0.0084	Yes	Yes
Type XII	1	0.0017	0.0017	No	Yes
Type XIII	4	0.0008	0.0032	Yes	Yes
Type XIV	4	0.0008	0.0032	Yes	Yes
Type XV	3	0.0008	0.0024	Yes	Yes
Type XVI	3	0.0008	0.0024	Yes	Yes
Type XVII	3	0.0004	0.0012	No	Yes
Type XVIII	4	0.0004	0.0016	Yes	Yes
Type XIX	2	0.0004	0.0008	No	Yes
Type XX	4	0.0004	0.0016	Yes	Yes

For each complication type, the hazard score was calculated by multiplying the severity score with the probability score. Consequently, an FMEA table was drawn (Table 8). Among the complications, Type I yielded the highest hazard score. Type V, VI and VII were equally hazardous complications. Likewise, the pairs of Type IX and X; Type XIII and XIV; Type XV and XVI; Type XVIII and XX yielded the same hazard score. According to FMEA, Type XIX was the least hazardous complication.

The surgery team developed preventive measures for each type of complication in order to bring the overall LASIK process under control. They implemented the following corrective action plan to reduce and/or eliminate complications. Firstly, they underlined that proper laser room environment was critical for the surgical success of LASIK. Surgical success requires proper cleaning, assembly and testing of the microkeratome and accurate calibration and setup of the laser. To ensure that each surgical team member is responsible for every aspect of the process, each member carries out multiple checks along the way. Appropriate humidity, temperature, and air purification must be present in the laser room at all times. The laser should be turned on and calibrated in accordance with the manufacturer's recommendations. The laser cutting rate, fluence and beam quality must meet acceptable operation standards. The microkeratome should be assembled and tested before use. The manufacturer's recommended laser setup should be followed, and laser calibration by fluence testing should be implemented as usual.

The surgical team suggested that complications related directly to the excimer laser were largely preventable if the laser was working properly and its beam centration, fluence and beam quality were evaluated critically prior to surgery. The excimer laser should be routinely calibrated and evaluated pertaining to its energy fluence and beam quality. In addition, the proper fluence can avoid overcorrections and undercorrections, and high beam quality can prevent an irregular ablation with associated irregular astigmatism and visual side effects.

The surgical team decided to counsel all patients before surgery to be co-operative with intraoperative/postoperative instructions of refractive surgeon. In addition, they suggested the refractive surgeons appropriately trained to gain more experience on the use of the microkeratome, adequate use of suction-ring, and proper cleaning of cornea to avoid contamination in the lamellar interface. They decided that the microkeratome must be periodically calibrated. Regular and proper maintenance to the mictokeratome should be provided. The use of appropriate type of microkeratome and a blade with higher quality is also planned.

4. Conclusions

Although LASIK surgeries have gained acceptance and wider application, complications are still encountered in the eye care centers. There is still limited progress in understanding the basic mechanisms underlying the complications such as Type I, II, IV and IX.

As the number of choices grows for both patient and surgeon, it has become increasingly important for the refractive surgeon to have a solid understanding of the surgical methods that were available. The analysis showed that the majority of LASIK complications in the eye care centre had occurred intraoperatively. Postoperative complications were almost always related to events that had occurred during surgery. Many complications were related to the learning curve associated with microkeratome use. These complication rates can be reduced as the surgical team gains experience.

Although it is not possible to completely eliminate LASIK complications; identifying their sources, root-causes and careful attention to details can prevent the vast majority of them. Therefore, implementing Six Sigma for the prevention and management of these complications can significantly minimize their occurrence. If the DMAIC tools are employed, robust outcomes will be achievable.

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Appendix

A Six Sigma process produces 3.4 defective parts per million opportunities (DPMO). Normal distribution underlies Six Sigma's statistical assumptions. An empirically-based 1.5 sigma shift is introduced into the calculation. To calculate the DPMO, two distinct datasets are required:

A =Total number of LASIK surgeries performed.

B = Total number of complications occurred.

DPMO = B x 1,000,000/A

The higher level of sigma after the initiation of Six Sigma indicates a lower rate of complications and a more efficient process.