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Deployment of Six Sigma Methodology in Phacoemulsification Cataract Surgeries

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ABSTRACT: The purpose of this study is to show how a public eye care center in Turkey initiated Six Sigma principles to reduce the number of complications encountered during and after phacoemulsification cataract surgeries. To analyze the 3-year 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 ophthalmic surgeon, patient's anatomy, cooperation of patient during the surgery, sterilization and hygiene, attention of assistant surgeon, calibration of equipment and quality/chemical composition of intraocular material were identified to be Critical-to-Quality (CTQ) factors for a successful phacoemulsification cataract surgery. The most frequently occurring complication was found to be iris atrophy. The process sigma level for the process was found to be 3.958.

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

1. Introduction

Cataract is a progressive, chronic, age-related disease affecting a large number of people over the age of fifty (AAO, 2008). Its surgery is one of the most highly successful treatments in the history of medicine and ranks among the most commonly performed surgical inventions in the United States (The Eye Diseases Prevalence Research Group, 2004). Cataract removal by phacoemulsification is routine in Turkey and is the norm for cataract surgery today (Taner, 2013). Turkish private health institutions shoulders most burden for those who can afford it (Taner, 2013).

Numerous studies have documented that after cataract surgery patients rapidly recover with excellent vision and remarkably improve a patient's activities of daily living and decrease risk of injury from falls and accidents (Tinetti et al., 1988; Mangione et al., 2003).

Problems with glare, contrast sensitivity, colour perception, aberration and binocularity directly impact a patient's level of visual impairment (Lundstrom et al., 1994; Lee et al., 1997). Therefore, assessment of appropriateness is therefore of particular interest and importance. Planning and decision-making process for cataract surgery is complex and intricate, involving not only judgment about appropriate treatment and surgical techniques but also about IOL and antibiotics selection, and prevention of complications (Tobacman et al., 1996).

The natural history of cataracts is variable, unpredictable and related in some ways to its type (Schein et al., 1994). In addition, numerous potential risk factors such as diabetes mellitus, long-term topical, systemic or inhaled oral corticosteroids and prior intraocular surgery are linked with cataract development (AAO, 2008).

Although there are numerous complications reported to have occurred during and after cataract surgery such as infectious endophthalmitis, toxic anterior segment syndrome, intraoperative haemorrhage, cystoid macular edema, retinal detachment, posterior capsular or zonular rupture, loss of nuclear material into vitreous, vitreous loss, persistent corneal edema, iris abnormalities and IOL dislocation (Powe et al., 1994; Lum et al., 2000; Zaidi et al., 2007; Jaycock et al., 2009; Greenberg et al., 2011; Clark et al., 2011).

The use of Six Sigma, as a quality improvement method, can be employed in order to eliminate complications resulted during and after many ophthalmic surgeries (Taner, 2013). Originally initiated by Motorola, Honeywell and General Electric (Mehrjerdi, 2011), Six Sigma 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 (Antony and Banuelas, 2002; Antony et al., 2007; 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), IntraLase surgery (Sahbaz et al., 2014), LASIK surgery (Taner et al., 2014), strabismus surgery (Taner et al., 2014), intravitreal injections (Sahbaz et al., 2014) and stent insertion (Taner et al., 2013) as a cost-effective way to improve quality, performance and productivity.

A Six Sigma process produces 3.4 defective parts per million opportunities (DPMO) (Buck, 2001). As a method to eliminate errors, Six Sigma uses a structured methodology called DMAIC to find the main causes behind problems and to reach near perfect processes (Park and Antony, 2008). DMAIC is useful to analyse and modify complicated time-sensitive healthcare processes involving multiple specialists and treatment areas by identifying and removing root causes of errors or complications and thus minimizing healthcare process variability (Buck, 2001; Taner et al., 2007).

In this study, a Six Sigma infrastructure was developed for a public Turkish eye centre in order to improve the outcomes of their phacoemulsification cataract surgery process. In addition, sigma level of each type of complication are calculated and reported.

2. Method: Application of Six Sigma's DMAIC for Phacoemulsification Cataract Surgery

The eye care centre decided that Six Sigma was the best way to achieve their goals. A surgical team was assembled and trained in the methodology. Committed and consistent leadership to overcome the complications was assured by this team. The surgical team firstly generated a SIPOC (Supplier, Input, Process, Output and Customer) Table for phacoemulsification cataract surgery process (Table 1). To achieve the performance objective, the surgical team first determined by brainstorming the CTQ factors, i.e. the factors that may have an influence on the objective.

The surgical team determined the metrics to measure existing process. The metrics to be chosen for a Six Sigma study were:
1. Total number of phacoemulsification cataract surgeries performed in the eye care centre,
2. Number of complications.

Table 1. SIPOC Table for Phacoemulsification Cataract Surgery

SUPPLIER	INPUT	PROCESS	OUTPUT	CUSTOMER
Ophthalmic surgeon	Intraocular lens	Ocular examination	High visual acuity	Patient
Nurse	Viscoelastic materials, Miostat, Adrenaline, BSS, Trypane blue, Intracameral lidocaine, Intracameral cefuroxime	Biometric measurements		
Assistant surgeon	Phacoemulsification equipment	Evaluation by ophthalmic surgeon		
Biomedical technician	Surgical instruments	Medical consultation and systematic examination of patient at Internal Medicine Department		
	Topical anaesthesia or sub-tenone	Preparation of the patient		
		Surgery		
		Discharge		

Data were collected for a period of three years. In this period, phacoemulsification cataract surgeries were performed on 1050 patients. Complications had been noted as they occurred. The surgical team identified sixteen types of complications and classified them as when (i.e. intraoperatively and/or postoperatively), and how soon they occur, i.e. acute, sub-acute and/or chronic (Table 4). Then, sources (Table 3) and root-causes (Table 4) of these complications are tabulated by type.

Table 2. Complications Experienced (January 2011 – December 2013)

	Complication	Intra-Operative	Post-Operative	Acute	Sub-Acute	Chronic
Type I	Damage to the IOL	X		X		
Type II	Radial tears in the anterior capsule	X		X		
Type III	Posterior capsular tear	X		X		
Type IV	Capsular tension ring implantation	X		X		
Type V	Iridodialysis	X		X		
Type VI	Zonular disinsertion	X		X		
Type VII	Retained cortex material	X	X	X	X	
Type VIII	Iridodonesis		X		X	
Type IX	Iris prolapse		X	X	X	
Type X	Pupillary irregularity		X	X	X	
Type XI	Endophthalmitis		X	X	X	X
Type XII	Intraocular pressure elevation and Glaucoma		X	X	X	X
Type XIII	Iris atrophy		X		X	X
Type XIV	Fibrin reaction		X	X	X	
Type XV	Irvine-Gass syndrome		X		X	X
Type XVI	Corneal edema and bullous keratopathy		X	X	X	X

3. Analysis

The surgical team analysed the occurrence frequency of each complication and related them with the root-causes. (Table 4 and Table 5). The analysis revealed that Type III, XII and XIII were the three most frequently occurring complications in the phacoemulsification cataract surgeries (Table 5). Then, they classified the CTQs 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 phacoemulsification cataract surgery were determined to be the experience of the ophthalmic surgeon, patient's anatomy and cooperation of patient during the surgery. The other factors, i.e. sterilization and hygiene, attention of assistant surgeon, calibration of equipment and quality/chemical composition of intraocular material were the "trivial many".

Table 3. Sources of Complications

	Ophthalmic Surgeon	Nurse	Assistant Surgeon	Patient	Equipment	Materials
Type I	X	X	X			X
Type II	X			X		
Type III	X			X	X	
Type IV	X			X		
Type V	X			X		
Type VI	X			X		
Type VII	X					
Type VIII				X		
Type IX	X			X		
Type X	X					
Type XI	X	X	X	X	X	X
Type XII	X			X		X
Type XIII	X			X		
Type XIV	X	X		X		X
Type XV				X		X
Type XVI	X			X		X

Table 4. Root-causes of Complications

	Experience of Ophthalmic Surgeon	Sterilization and Hygiene	Attention of Assistant Surgeon	Cooperation of Patient	Patient's Anatomy	Calibration of Equipment	Quality/ Chemical Composition of Intraocular Material
Type I	X		X				X
Type II	X			X	X		
Type III	X			X		X	
Type IV					X		
Type V	X				X		
Type VI	X				X		
Type VII	X						
Type VIII					X		
Type IX	X			X	X		
Type X	X						
Type XI	X	X		X	X	X	X
Type XII	X				X		X
Type XIII	X				X		
Type XIV		X					X
Type XV					X		X
Type XVI	X				X		X

To measure the current sigma level of a complication, surgical team calculated the current DPMO and sigma levels for each complication type (Table 5). For this, two distinct datasets are required:

A = Total number of phacoemulsification cataract surgeries performed.

B = Total number of complications occurred.

The DPMO formula is: DPMO = B x 1,000,000/A

Normal distribution underlies Six Sigma's statistical assumptions. An empirically-based 1.5 sigma shift is introduced into the calculation. A higher sigma level indicates a lower rate of complications and a more efficient process (Taner, 2013).

Table 5. Cumulative Frequency, DPMO and Sigma Levels

	Count	Frequency (%)	DPMO	Sigma Level
Type I	14	1.333	13333	3.72
Type II	6	0.571	5714	4.03
Type III	22	2.095	20952	3.53
Type IV	6	0.571	5714	4.03
Type V	1	0.095	952	4.60
Type VI	8	0.762	7619	3.93
Type VII	12	1.142	11429	3.78
Type VIII	2	0.191	1905	4.39
Type IX	7	0.666	6667	3.97
Type X	4	0.381	3810	4.17
Type XI	2	0.191	1905	4.39
Type XII	20	1.905	19048	3.20
Type XIII	30	2.857	28571	3.40
Type XIV	8	0.762	7619	3.93
Type XV	16	1.524	15238	3.66
Type XVI	1	0.095	952	4.60

The highest sigma level was obtained for Type XVI. The lowest sigma level was found to belong to Type XII. Having sigma levels lower than 4.00; Type I, III, VI, VII, IX, XII, XIII, XIV and XV needed to be significantly reduced.

The process sigma level, calculated from the arithmetic average of sigma levels of sixteen complications, was found to be 3.958.

Table 6. Severity Scores

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

4. Discussion

Risk assessment of the phacoemulsification cataract surgery was achieved 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.

Occurrence trends and consequences of complications over a 3-year period had been monitored and recorded. Surgical team prioritized the complications according to how serious their consequences were (i.e. severity score), how frequently they occurred (i.e. 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 6).

Table 7. FMEA Table

Complication Type	Hazard Analysis			Decision Tree Analysis	
	Severity Score	Probability Score	Hazard Score	Critical?	Detectable?
Type I	2	0.01333	0.02666	No	Yes
Type II	3	0.00571	0.01713	Yes	Yes
Type III	3	0.02095	0.06285	Yes	Yes
Type IV	1	0.00571	0.00571	No	Yes
Type V	3	0.00095	0.00285	Yes	Yes
Type VI	3	0.00762	0.02286	Yes	Yes
Type VII	1	0.01142	0.01142	No	Yes
Type VIII	1	0.00191	0.00191	No	Yes
Type IX	2	0.00666	0.01332	No	Yes
Type X	2	0.00381	0.00762	Yes	Yes
Type XI	4	0.00191	0.00764	Yes	Yes
Type XII	3	0.01905	0.05715	Yes	Yes
Type XIII	2	0.02857	0.05714	No	Yes
Type XIV	2	0.00762	0.01524	No	Yes
Type XV	3	0.01524	0.04572	Yes	Yes
Type XVI	4	0.00095	0.00380	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 7). Among the complications, Type III yielded the highest hazard score. Type X and Type XI were almost equally hazardous complications and so were Type XII and Type XIII. According to FMEA, Type V was the least hazardous complication.

The surgical team developed preventative measures for each type of complication in order to bring the overall phacoemulsification cataract surgery process under control (Table 8). By brainstorming on the mechanisms underlying the complications, they implemented the following corrective action plan to reduce and/or eliminate other complications.

Table 8. Preventative Measure(s) per Complication Type

	Preventative Measure (s)
Type I	-Train the ophthalmic surgeons, assistant surgeons and nurses. -Use IOLs with high quality.
Type II	-Train the ophthalmic surgeons. -Advise the patients to be cooperative during the surgery.
Type III	-Train the ophthalmic surgeons. -Provide regular maintenance and calibration of the phacoemulsification equipment. -Be careful for small pupils, hard nuclei, or pseudoexfoliation syndrome.
Type IV	-Implant capsular tension ring to patients with history of trauma who may have zonular dialysis; patients with pseudoexfoliation; hard cataracts with large nuclei; patients with larger axial length; and patients with posterior subcapsular cataracts. The necessity of implantation may be minimised by using minimal power during the surgery.
Type V	-Train the ophthalmic surgeons. - Preoperatively carefully examine patients. -Use minimal power during the surgery.
Type VI	-Train the ophthalmic surgeons. -Make careful evaluation before surgery. -Use minimal power during the surgery. -Careful inspection of the anatomy of the capsule and zonules.
Type VII	-The surgeons should remain concentrated on proceeding with skill and attention to every detail to the end stages of the operation. -Do not to be aggressive nor attempt to vacuum clean. -Do not attempt to clear the very last bit of cortex remaining as this could lead to accidental rupture of the posterior capsule.
Type VIII	No preventative measure undertaken.
Type IX	-If the anterior chamber is entered too posteriorly and interferes with the easy

	introduction of instruments into the eye, make sure to suture the incision and move to another location. -If there is an acute increase of intraocular pressure accompanied by choroidal effusion or haemorrhage, make an attempt to identify the cause and lower the intraocular pressure. -Examine the fundus to ascertain whether a choroidal effusion or haemorrhage exists. In such a case, aspiration of vitreous can be helpful.
Type X	-Make minimum contact with the iris during the surgery. -Sufficiently clean the vitreous in the anterior chamber by anterior vitrectomy.
Type XI	-Sterilize the operating room, equipment and instruments. -Scrub the lids with povidone 5% just prior to surgery.
Type XII	-Remove the ophthalmic viscosurgical device carefully at the time of surgery. -Control intraocular bleeding during the surgery. -Use of intraoperative and postoperative anti-glaucomatous agents.
Type XIII	-Make minimum contact with the iris during the surgery.
Type XIV	-Analyse all medications and fluids used during surgery, as well as completely review the operating room and sterilization protocols.
Type XV	-Make minimum contact with the iris during the surgery. -Protect carefully the posterior capsule during the surgery.
Type XVI	-Examine the patient carefully prior to surgeryfor evidence of Fuchs' dystrophy or other conditions that produce a low endothelial cell count. -Be careful about the intraoperative mechanical endothelial trauma. -Keep the excessive postoperative inflammation under control by administering corticosteroids. -Keep intraocular pressure under control during the surgery by anti-glaucoma treatment.

5. Conclusion

In this study, the authors determined sixteen types of complications encountered during and after phacoemulsification cataract surgeries. The analysis showed that these complications had equally occurred both intraoperatively and postoperatively. Postoperative complications were almost always related to events that had occurred during surgery.

The authors found that experience of ophthalmic surgeons, patient's anatomy and materials were the vital few CTQ factors that have the most impact on the success of phacoemulsification surgeries. Many complications were related to the learning curve associated with phacoemulsification equipment use. These complication rates were reduced as ophthalmic surgeons gained experience and was trained on how to identify, minimize or eliminate the sources and root-causes of the complications. Sterilization of the operating room, equipment and instruments as well as the regular maintenance and calibration of the phacoemulsification equipment were also essential.

The process sigma level of the overall process (i.e. phacoemulsification cataract surgeries made in 3-years) was measured to be 3.958. Nine of the more frequently occurring complications (out of sixteen) needed to be reduced by taking the necessary preventative measures.

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