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Development of a Six Sigma Infrastructure for Cataract Surgery in Patients with Pseudoexfoliation Syndrome

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ABSTRACT

The aim of this study is to show how an eye clinic of a Turkish public hospital initiated Six Sigma principles to reduce the number of complications encountered during and after cataract surgeries in patients with pseudoexfoliation (PEX) syndrome. Data were collected for three years. To analyse the process, 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. Sources and root causes of ten types of complications were identified and reported. Experience of the refractive 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 surgery. The most frequently occurring complication was found to be posterior capsule rupture. The overall process sigma level for 3 years was measured to be 3.703. The surgical team concluded that all complications should be significantly reduced by taking the necessary preventative measures.

Keywords: Six Sigma, Ophthalmology, Cataract surgery, Pseudoexfoliation syndrome, Complications.

INTRODUCTION

Pseudoexfoliation (PEX) is an age-related illness characterized by production and progressive deposition of protein like abnormal fibrillar extracellular material in the anterior segment of the eye and conjunctiva [1]. It can briefly be defined as the deposit of white grayish PEX material on the anterior lens capsule and/ or near the pupillary margin [1]. Studies have shown that local production and deposition of PEX fibers may lead to characteristic changes of the corneal endothelium, trabecular meshwork, iris, lens, ciliary body, zonules and structures of blood-aqueous barrier [2]. These changes in the tissues of the anterior eye segment make cataract surgery potentially challenging and thus ophthalmic surgeons must be cautious of possible intraoperative and postoperative problems in managing the patient with PEX syndrome.

The awareness of the significance of PEX has increased considerably during the last ten years [2]. Studies have shown that PEX is associated with open angle glaucoma and poor pupillary dilatation [3, 4]. It has been determined that it is also a risk factor not only for the development of open-angle glaucoma, but also for angle-closure glaucoma, lens subluxation, retinal detachment, blood-aqueous barrier impairment and is correlated with an increasing number of cataract formation incidence [2]. It should be noted that cataract surgery in eyes with PEX has higher incidence of intraoperative complications like posterior capsular rupture, zonular dialysis, vitreous loss, hyphaema, residual lens matter and intraocular bleeding [5-11]. In addition, secondary cataract can be considered as another potential complication of cataract surgery in patients with PEX [12]. Postoperatively, patients have a greater risk for developing an immediate elevation of intraocular pressure and inflammation [13, 1]. Posterior capsular opacification and intraocular lens decentration are also common in patients with PEX postoperatively [14, 15, 1].

The use of Six Sigma, as a quality improvement method, can be employed in order to eliminate complications encountered during and after many ophthalmic surgeries [16]. Originally initiated by Motorola, Honeywell and General Electric [17], Six Sigma is a powerful performance improvement tool that is changing the face of modern healthcare delivery today [18]. Although it was initially introduced in manufacturing processes, Six Sigma is being implemented in diagnostic imaging processes [19-21], emergency room [22], paramedic backup [23], laboratory [24], cataract surgery [25], radiology [26], surgical site infections [27], IntraLase surgery [28], LASIK surgery [29], strabismus surgery [30], intravitreal injections [31], phacoemulsification cataract surgery [32] and stent insertion [33] as a cost-effective way to improve quality, performance and productivity [18].

A Six Sigma process produces 3.4 defective parts per million opportunities (DPMO) [34]. Being a method that eliminates errors, Six Sigma makes use of a structured methodology called DMAIC to find the main causes behind problems and to reach near perfect processes [35]. 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 [34, 18].

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

METHOD

Application of Six Sigma's DMAIC for Cataract Surgery in patients with PEX syndrome

When 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. They firstly generated a SIPOC (Supplier, Input, Process, Output and Customer) Table for the 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 surgeries performed in the eye care centre,
2. Number of complications.

Table 1. SIPOC Table for Cataract Surgery for Patients with PEX syndrome

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, surgeries were performed on 151 patients. Complications had been noted as they occurred. The surgical team identified ten 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	Posterior capsule rupture	X		X		
Type II	Zonular dialysis	X		X		
Type III	Iris retraction hooks	X		X		
Type IV	Glaucoma	X	X	X	X	X
Type V	Iridodialysis	X		X		
Type VI	IOL disclocation	X	X	X	X	X
Type VII	Retained cortex material	X	X	X		
Type VIII	Pupillar membrane		X	X	X	
Type IX	Pupillary irregularity		X	X		
Type X	Iris sphincter tears	X		X		

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 I, II and III were the three most frequently occurring complications in the cataract surgeries performed on patients with PEX syndrome (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 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”.

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 cataract surgeries performed.
B = Total number of complications occurred.

$$DPMO = B \times 1{,}000{,}000/A$$

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 [16].

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		
Type IV	X			X		X
Type V	X			X		
Type VI	X			X		
Type VII	X			X		
Type VIII	X	X		X		X
Type IX	X					
Type 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	X	X	
Type II	X			X	X		

Type III	X				X		
Type IV	X				X		X
Type V	X			X	X		
Type VI	X				X		
Type VII	X				X		
Type VIII	X	X					X
Type IX	X			X	X		
Type X	X				X		

Table 5. Cumulative Frequency, DPMO and Sigma Levels

	Count	Frequency (%)	DPMO	Sigma Level
Type I	17	11.258	112583	2.71
Type II	4	2.649	26490	3.44
Type III	4	2.649	26490	3.44
Type IV	3	1.986	19868	3.56
Type V	1	6.623	6623	3.98
Type VI	1	6.623	6623	3.98
Type VII	1	6.623	6623	3.98
Type VIII	1	6.623	6623	3.98
Type IX	1	6.623	6623	3.98
Type X	1	6.623	6623	3.98

The highest sigma level was obtained for Type V, VI, VII, VIII, IX and X. The lowest sigma level was found to belong to Type I. Having sigma levels lower than 4.00; all complications needed to be significantly reduced.

The process sigma level, calculated from the arithmetic average of sigma levels of ten complications, was found to be 3.703.

Table 6. Severity Scores

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

DISCUSSION

Risk assessment of the 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	4	0.1125	0.4500	Yes	Yes
Type II	3	0.0264	0.0792	Yes	Yes
Type III	1	0.0264	0.0264	No	Yes
Type IV	2	0.0198	0.0396	Yes	Yes
Type V	3	0.0066	0.0198	Yes	Yes
Type VI	4	0.0066	0.0264	Yes	Yes
Type VII	1	0.0066	0.0066	No	Yes
Type VIII	1	0.0066	0.0066	No	Yes
Type IX	2	0.0066	0.0132	No	Yes
Type X	2	0.0066	0.0132	No	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 I yielded the highest hazard score. Type III and Type VI were almost equally hazardous complications and so were Type IX and Type X. According to FMEA, Type VII and VIII were the least hazardous complications by yielding likewise the same hazard scores.

Corrective Action Plan

PEX syndrome presents challenges that need careful preoperative planning and intraoperative care to ensure safe surgery and a successful postoperative outcome. Thus, the surgical team developed preventive measures for each type of complication in order to bring the overall surgery process under control (See the Appendix). By brainstorming on the mechanisms underlying the complications, they implemented the following corrective action plan to reduce and/or eliminate other complications.

CONCLUSION

In this study, authors found that ten types of complications were encountered in the eye care centre while performing cataract surgeries in patients with PEX syndrome. 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 process sigma level of the overall process (i.e. cataract surgeries made in 3-years) was measured to be 3.703.

It is found that experience of ophthalmic surgeons, patient's anatomy and materials are the vital few CTQ factors that have the most impact on the success of surgeries. Many complications were related to the learning curve associated with the 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 equipment are also essential.

To conclude, the risks associated with cataract surgery in the PEX eyes can be minimized by taking the necessary preventative measures with appropriate preoperative, intraoperative and postoperative care.

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APPENDIX

Preventative Measure(s) per Complication Type

	Preventative Measure (s)
Type I	- Train the ophthalmic surgeons. - Preoperatively carefully examine patients. - Provide regular maintenance and calibration of the phacoemulsification equipment. - Be more careful for small pupils and hard nuclei. - Do not use high parametric values. - Take preventative measures to provide good and sufficient mydriasis.
Type II	- Train the ophthalmic surgeons. - Preoperatively carefully examine patients. - Use minimum power during the surgery both manually and by the phacoemulsification equipment. - Take preventative measures to provide good and sufficient mydriasis. - Carefully inspect the anatomy of the capsule and zonules.
Type III	-Make sure to use small pupils that do not have sufficient mydriasis.
Type IV	- Make sure that there is no viscoelastic substance left in the site and it is viscoelastically clean. - Carefully remove the OVD at the time of surgery, control of intraocular bleeding, and the use of intraoperative and postoperative antiglaucomatous agents. - Postoperatively administer pilocarpine gel; topical beta blockers; apraclonidine; and topical, intravenous, or oral carbonic anhydrase inhibitors - Be careful of chronic IOP elevation that may be caused by corticosteroid use, retained lens (particularly nuclear) material, chronic inflammation, peripheral anterior synechiae formation, endophthalmitis, and ciliary block. The correct diagnosis of the underlying cause is required to provide the appropriate therapy.
Type V	- Train the ophthalmic surgeons. - Preoperatively carefully examine patients. - Use minimum power during the surgery both manually and by the equipment.
Type VI	- Use a lens with high optics for patients with IOL disclocation. -In early stages, perform capsulotomy by YAG laser
Type VII	- Do not to be aggressive nor attempt to vacuum clean. - Make sure that the surgeon remains concentrated and be attentive to details throughout the surgery. - Do not try to clear the very last bit of cortex remaining.
Type VIII	- Make sure that there is minimum intervention to iris. - Use heparin-coated special IOLs postoperatively to inhibit fibrin reaction.
Type IX	- Sufficiently clean the vitreous in the anterior chamber by anterior vitrectomy.
Type X	-Be careful during hydrodissection and phacoemulsification of the lens nucleus and introduction of mechanical stretching devices to pull on the sphincter margin.