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Development of Six Sigma Infrastructure for Strabismus 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 strabismus 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. Patient's eye anatomy, experience of the anesthesiologist, experience/attention of the strabismus surgeon was identified to be Critical-to-Quality (CTQ) factors for a successful strabismus surgery. The most frequent complications of strabismus surgeries were found to be X, Y and Z. The process sigma level was found to be 3.2025.

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

1. Introduction

Strabismus, an ocular misalignment, is a failure of the two eyes to maintain proper alignment and work together as a team. It is mostly caused by abnormalities in binocular vision or by anomalies of neuromuscular control of ocular motility (Wright, 2000).

The estimated prevalence of strabismus in the general US population is from 2% to 5%, i.e. between 5 and 15 million individuals in the United States are believed to have strabismus (Roberts and Rowland, 1978; Donnelly et al., 2005; Friedman et al., 2008). Strabismus is more prevalent in people with multiple handicaps, occurring in approximately 50% of patients with Down syndrome, 44% of patients with cerebral palsy, and 90% of patients with craniofacial dysostosis such as Apert-Crouzon syndrome (Rutstein et al., 2010). Children born prematurely and of low birth weight develop a greater risk of strabismus than children born at term. The prevalence is also higher in families, which a parent or sibling has strabismus, ranging from 23% to 70% of family members (Rutstein et al., 2010). Findings show that patient satisfaction after the surgery was 9.5 on a 10-point scale (Darkow et al., 2001). In another study, overall satisfaction with the surgical outcome was rated good or very good in 85% of seventy-seven children under age six (Mruthyunjaya et al., 1996).

Normal binocular vision is needed for many occupational and avocational tasks, as well as many other activities in daily life. Symptoms such as diplopia, headaches, blurred vision, and ocular fatigue may cause individuals with intermittent strabismus who have the potential for normal binocular vision and older persons who are developing strabismus to alter their activities of daily activities (Rutstein et al., 2010). Therefore, both prompt diagnosis and treatment of strabismus are critical.

Strabismus surgery is performed to restore binocular vision, improve ocular alignment, enlarge the field of single binocular vision, alleviate abnormal head position and improve the aesthetic appearance of the strabismic patient by slackening a muscle (i.e. recession), tightening a muscle (i.e. resection), or changing the muscle's insertion site thus changing the direction of pull (i.e. transposition) (Wright, 2000; Coats and Olitsky, 2007). To achieve these goals, a rigorous preoperative assessment should be performed on all patients with strabismus, making certain that all steps of the ocular examination are addressed and not overlooked. High attention to the sensory and motor components of the examination will ensure that the correct procedure is performed and that all of the functional goals are achieved (Spaeth, 2003).

The most important problem in strabismus surgery is the inability to accurately predict the outcome of the surgery (Tripathi et al., 2003). Therefore, meticulous planning and proper surgical technique are the prerequisites when caring for the strabismus patient. While successful implementation of the surgical plan is critical for the successful management of strabismic patient, the initial step to successful surgical care is preoperative management and good surgical decision-making. Likewise, it is impossible to completely eliminate complications from strabismus surgery, but it is possible to minimize their occurrence and significance by proper prevention management. A detailed list of strabismus complications is given on Table 1. Strabismus surgery is exceptionally associated with higher incidence of nausea and vomiting, ranging between 40% and 90% (Treschan et al., 2005). This may increase hospital expenditure by prolongation of hospital stay, and management of vomiting related complications such as dehydration electrolyte disturbances, and pulmonary aspiration (Apfel et al., 1999).

In this study, a Six Sigma infrastructure in a Turkish private eye center to improve the strabismus surgery process will be developed. In addition, sigma level of each type of complication will be calculated and reported.

2. Six Sigma Methodology

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), LASIK surgery (Taner et al., 2014) 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 on strabismus surgery 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 (Antony and Banuelas, 2002; Antony et al., 2007). DMAIC is particularly useful to analyze and modify complicated time-sensitive healthcare processes involving multiple specialists and treatment areas by identifying and removing root causes of defects or errors and thus minimizing healthcare process variability (Buck, 2001; Taner et al., 2007).

3. Application of DMAIC to Strabismus 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 strabismus surgery process (Table 2).

Table 1. Errors and Complications in Strabismus Surgeries

Preoperative Management Errors in Decision-Making****	Preoperative Measurement Errors****	Intraoperative Complications*,**	Corneal Complications****
Field of single vision, Monocular diplopia, Nystagmus and strabismus in patients with a compensatory head posture, Restrictive strabismus, Paralytic strabismus, Torsional strabismus, Misdiagnosis of apparent duction abnormalities (apparent duction deficits, pseudo oblique overaction).	Primary position measurement errors, Krimsky and Hirschberg tests, Prism measurement errors (improper prism position, addition of stacked prisms, addition of prisms held in front of both eyes), Spectacle-induced measurement errors (large refractive errors, unrecognized prism), duction limitation errors, Poor fixations, poor cooperation.	Surgery to the wrong muscle, Globe perforation, Haemorrhage/Bleeding, Detached muscle, Wrong site surgery, Slipped muscle, Lost muscle, Torn muscle.	Dellen, Corneal abrasions, Corneal ulcer, Filamentary keratitis, Reduced endothelial cell count, Corneal toxicity.
			Complications related to Anesthesia***
			Malignant hyperthermia, Bradycardia.
Scleral Complications****	Anterior Segment Complications**	Intraocular Complications**	Nonocular Complications**
Grey spot, Scleral ridge, Scleral dellen, Scleritis, Agyrosis.	Iris atrophy, Corectopia, Poorly reactive pupil.	Perforation of the sclera, Hyphema, Cataract.	Oculocardiac reflex, Malignant hyperthermia, Nasal secretions, Nausea.
Early Postoperative Complications*	Postoperative Complications**	Late Postoperative Complications*	Conjunctival Complications****
Immediate undercorrection, Immediate overcorrection, The slipped muscle, Anterior segment ischaemia, Prolapsed Tenon's capsule, Inclusion of plica semilunaris in conjunctival closure, Conjuctival inclusion cyst, Diplopia, Postoperative infection (conjuctivitis, orbital cellulitis, endophthalmitis), Suture granuloma, Dellen.	Overcorrections, Undercorrections, Orbital cellulitis, Anterior segment ischemia, Conjuctival cysts, Tenon's capsule prolapse, Eyelid changes, Dellen, Haemorrhage, Scarring and ahesions, Refractive changes, Persistent diplopia, Discomfort and pain. Neusea and vomiting.	Inferior oblique adherence syndrome, Late re-operation.	Inadvertent advancement of the plica semilunaris conjunctivae, Limbal incision closure tips, Retraction and colling, Chemosis, Pyogenic granuloma, Prolapse of Tenon's fascia, Eplithelial inclusion cyst, Sudoriferous cyst, Subconjunctival abscess, Conjunctival adhesions, Primary amyloidosis, Subconjunctival foreign bodies, Subconjunctival buttonholes.

* MacEwen and Gregson (2003)
**Larson et al. (2003)
***Pfeifer and Scott (2002)
****Coats and Olitsky (2007)

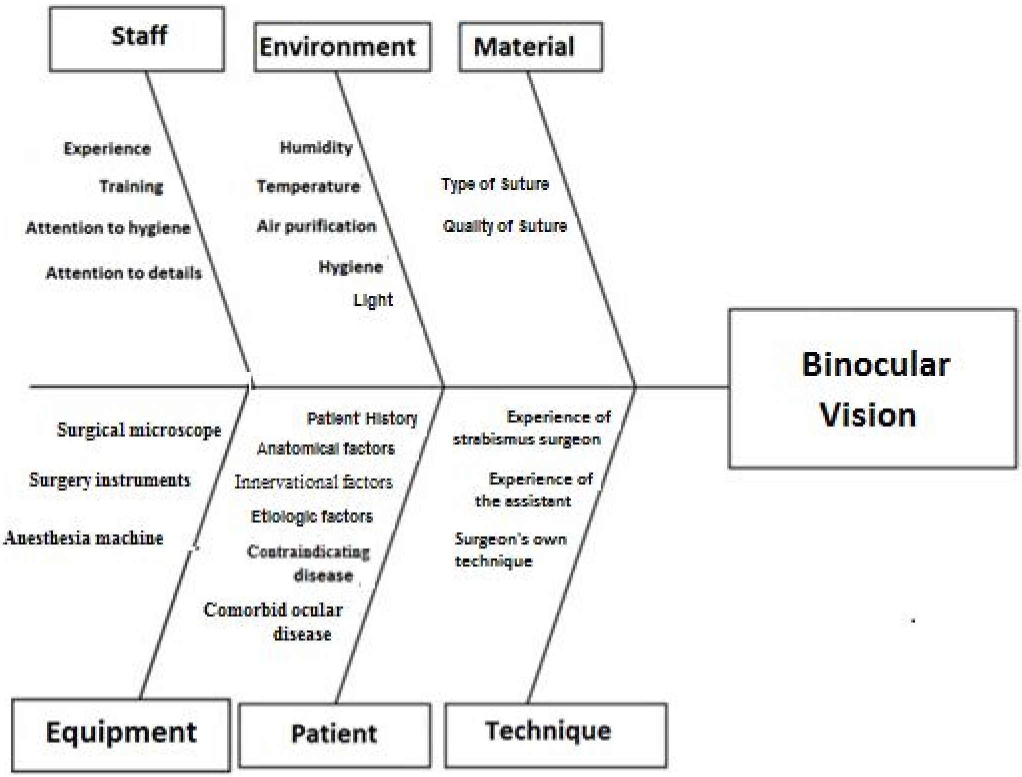
The surgical team defines the performance objective as patients with normal/single binocular function, visual alignment and normal visual acuity in each eye and improved fusion, after nearly perfect strabismus procedures; or as patients with "Orthophoria" after perfect strabismus procedure, i.e. absolute parallelism of the visual axes. 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 Strabismus Surgery

SUPPLIER	INPUT	PROCESS	OUTPUT	CUSTOMER
Strabismus surgeon	Patient	The patient history, i.e. probable time of onset of strabismus, nature of the onset (sudden or gradual), frequency of deviation (constant or intermittent), change in size or frequency of the deviation, whether the strabismus is unilateral or alternating, presence or absence of diplopia and other visual symptoms or signs, presence or absence of any compensatory head posture, history of neurologic, systemic, or developmental disorders, family history of strabismus, and previous treatment, if any, and the type and results of such treatment.	Binocular function	Patient
Assistant (Nurse)	Surgery microscope	Interpretation and analysis of the examination results and overall evaluation	Orthophoria	
Anesthesiologist	Absorbable Suture	Anesthesia	Ocular alignment	
	Light	Position the patient's head	Visual acuity	
	Anesthesia machine	Open the conjunctiva and find the muscle	Fusion	
	Surgery instruments	Recession/Resection/Transposition		
		Conjunctival closure		
		Patient awake		
		Discharge		

Although the exact root-cause cannot always be determined with reasonable certainty, strabismus is generally attributable to refractive, sensory or organic, anatomic or motor, or innervational causes. Any of these factors alone can result in strabismus; however, strabismus may also be the resultant of multiple factors, which, occurring solely might not cause the disorder. For some individuals, strabismus can even result in permanent vision loss. During the evaluation phase before the surgery starts, the surgeon should take into account the age of the patient at the onset of strabismus, current age of the patient, overall health status of the patient, patient's developmental level and anticipated compliance with surgery, concerns of the patient and/or parents, symptoms and signs of visual discomfort, visual demands of the patient, comitancy of the deviation, size and frequency of the strabismus, presence or absence of fusion, and presence or absence of amblyopia.

Figure 1. Fishbone Diagram



The surgical team determined the following metrics to measure the existing strabismus surgery process:

1. Total number of strabismus surgeries performed in the eye care center,
2. Number of preoperative, intraoperative and postoperative complications occurred.

Data were collected for a period of 7-years. In this period, a total of 473 strabismus surgeries were performed. Complications had been noted as they occurred. 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).

Table 3. Complications Experienced (2006-2013)

	Complication	Pre-Operative	Intra-Operative	Post-Operative	Acute	Sub-Acute
Type I	Haemorrhage			X		X
Type II	Neusea and vomiting			X	X	
Type III	Undercorrection			X	X	
Type IV	No change in vertical strabismus degree			X		X
Type V	Bleeding		X		X	
Type VI	Slipped muscle		X		X	
Type VII	Partial scleral damage		X		X	
Type VIII	Orbital fat penetration		X		X	
Type IX	Wrong site surgery		X		X	
Type X	Overcorrection			X	X	
Type XI	Surgery to the wrong muscle		X		X	
Type XII	Corneal abrasions		X		X	
Type XIII	Lost muscle		X		X	
Type XIV	Wrong type of intervention to the muscle		X		X	
Type XV	Prolapsed Tenon's capsule			X		X
Type XVI	Apnea		X		X	

Sources (Table 4) and root-causes (Table 5) of these complications are tabulated by type. The incidence of complications depends on multiple sources (variables). Surgeon variables, assistant variables, anesthesiologist variables, patient variables, suture variables and anesthetic drug 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 three most frequently occurring complications in the strabismus 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 strabismus surgery were determined to be the patient's eye anatomy, experience of the anesthesiologist, experience/attention of the strabismus surgeon. The other factors were "trivial many".

Table 4. Sources of Complications

	Strabismus Surgeon	Assistant	Anesthesiologist	Patient	Suture	Anesthetic Drug
Type I				X		
Type II			X			X
Type III	X			X		
Type IV				X		
Type V				X		
Type VI	X					
Type VII	X				X	
Type VIII	X			X		
Type IX	X					
Type X	X			X		
Type XI	X					
Type XII	X	X				
Type XIII	X	X				
Type XIV	X					
Type XV	X				X	
Type XVI			X			X

Table 5. Root-causes of Complications

	Attention of the Strabismus Surgeon	Attention of the Assistant	Experience of the Strabismus Surgeon	Experience of the Anesthesiologist	Type / Quality of Suture	Patient's Eye Anatomy
Type I						X
Type II				X		
Type III			X			X
Type IV						X
Type V						X
Type VI	X		X			
Type VII	X		X		X	
Type VIII	X		X			X
Type IX	X		X			
Type X			X			X
Type XI	X		X			
Type XII	X	X	X			
Type XIII	X	X	X			
Type XIV	X		X			
Type XV	X				X	
Type XVI				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 3.2025.

The highest sigma levels were obtained for Type XVI, XV, XIV and XIII. The lowest sigma level was found to be belong to Type I. Having sigma levels much lower than 4.00, the alerting complications for strabismus were Type I, II and III. These are the complications whose rates need to be significantly reduced.

Risk assessment of the strabismus 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.

Table 6. Cumulative frequency, DPMO and Sigma Levels

	Count	Frequency (%)	DPMO	Sigma Level
Type I	473	100.00	1000000	-6.35
Type II	137	28.96	289641	2.05
Type III	23	4.86	48626	3.16
Type IV	7	1.48	14799	3.68
Type V	7	1.48	14799	3.68
Type VI	6	1.27	12685	3.74
Type VII	4	0.85	8457	3.89
Type VIII	3	0.63	6342	3.99
Type IX	3	0.63	6342	3.99
Type X	3	0.63	6342	3.99
Type XI	3	0.63	6342	3.99
Type XII	3	0.63	6342	3.99
Type XIII	1	0.21	2114	4.36
Type XIV	1	0.21	2114	4.36
Type XV	1	0.21	2114	4.36
Type XVI	1	0.21	2114	4.36

Complication trends and their consequences over a 7-years 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 (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

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 VIII, IX and X were equally hazardous complications. Likewise, Type XIII, XIV and XVI yielded the same hazard score. According to FMEA, Type XV was the least hazardous complication.

The surgery team developed preventive measures for each type of complication in order to bring the overall strabismus process under control. They implemented the following corrective action plan to reduce and/or eliminate complications. The surgical team decided to use higher quality absorbable spatula needle sutures and started to purchase them from a different manufacturer. They also started to use a better magnifier.

Table 8. FMEA Table

Complication Type	Hazard Analysis			Decision Tree Analysis	
	Severity Score	Probability Score	Hazard Score	Critical?	Detectable?
Type I	1	1.0000	1.0000	No	Yes
Type II	1	0.2896	0.2896	No	Yes
Type III	4	0.0486	0.1944	Yes	Yes
Type IV	4	0.0148	0.0592	Yes	Yes
Type V	2	0.0148	0.0296	No	Yes
Type VI	4	0.0127	0.0508	Yes	Yes
Type VII	3	0.0085	0.0255	No	Yes
Type VIII	4	0.0063	0.0252	Yes	Yes
Type IX	4	0.0063	0.0252	Yes	Yes
Type X	4	0.0063	0.0252	Yes	Yes
Type XI	3	0.0063	0.0189	Yes	Yes
Type XII	1	0.0063	0.0063	No	Yes
Type XIII	4	0.0021	0.0084	Yes	Yes
Type XIV	4	0.0021	0.0084	Yes	Yes
Type XV	2	0.0021	0.0042	No	Yes
Type XVI	4	0.0021	0.0084	Yes	Yes

To eliminate or minimize the Type III, VI, VII, VIII, IX, X, XI, XII, XIII, XIV and XV complications, the strabismus surgeons were trained on recession, resection and transposition. Likewise, the anesthesiologists were given training on the kinds and dosage of anesthetics to be used in order to get decreased post-operative complications of nausea, vomiting and apnea. The anesthesiologists were also trained on cauterization, deep anesthesia and how to use eye drops to treat patients with haematological disorders.

4. Conclusions

Although the first strabismus surgery dates back to the middle of the eighteenth century, it still is still known as one of the most complicated therapeutic approaches in the ophthalmic world. The analysis showed that majority of the complications were related to anesthesia and procedure, and added that the patient's eye anatomy, experience of the anesthesiologist, experience/attention of the strabismus surgeon were the critical success factors in strabismus surgery. Most frequent complication was haemorrhage.

Even today, there are still limitations in the planned strabismus surgeries such as patient's tolerance to the attendant anesthetics and unusual eye anatomy. Although it is not possible to completely eliminate the related complications rooted from these two limitations; identifying the root-causes of experience-related and suture-related complications 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 strabismus surgeries performed.

B = Total number of complications occurred.

The DPMO formula is:

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.