Deployment of Six Sigma Methodology in Pars Plana Vitrectomy

Ibrahim Sahbaz[1], Mehmet Tolga Taner[2,*], Huseyin Sanisoglu[3], Taner Kar[4], Gamze Kagan[5], Ebubekir Durmus[3], Meltem Tunca[3], Engin Erbas[6], Ilker Armagan[1] and Mehmet Kemal Kagan[7]

[1]*Department of Opticianry, Uskudar University, Istanbul, Turkey*

[2]*Department of Healthcare Management, Uskudar University, Istanbul, Turkey*

[3]*Department of Ophthalmology, Haydarpasa Education and Research Hospital, Istanbul, Turkey*

[4]*Department of Ophthalmology, GATA Haydarpasa Military Education Hospital, Istanbul, Turkey*

[5]*Department of Occupational Health and Safety, Uskudar University, Istanbul, Turkey*

[6]*Institute of Health Sciences, Uskudar University, Istanbul, Turkey*

[7]*Department of Diagnostic Radiology, Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital, Istanbul, Turkey*

Abstract: *Purpose*: To show how a Turkish public eye care centre in Turkey initiated Six Sigma principles to reduce the number of complications occurring during and after pars plana vitreoretctomy surgeries.

Method: Data were collected for two years. To analyse the complications among 2272 patients, main tools of Six Sigma's Define-Measure-Analyse-Improve-Control (DMAIC) improvement cycle such as SIPOC table, Fishbone Diagram and, Failure, Mode and Effect Analysis were implemented. Sources and root causes of twenty-two types of complications were identified and reported.

Results: For a successful pars plana vitrectomy procedure, experience of vitreoretinal surgeon, attention of vitreoretinal surgeon, patient's anatomy were determined to be the "critical few" factors whereas, sterilization and hygiene, amount of silicone oil and amount of gas were found to be the "trivial many" factors. The most frequently occurring complication was found to be subconjunctival haemorrhage.

Conclusion: The sigma level of the overall process was measured to be 3.8559. The surgical team concluded that twelve of the complications should be significantly reduced by taking the necessary preventive measures.

Institutional ethics committee approval has been taken due to retrospective nature of this study.

Keywords: Six Sigma, ophthalmology, pars plana vitrectomy, complications.

INTRODUCTION

In the fourty-four years since its genesis by Machemer, remarkable advances in vitrectomy have established the pars plana vitrectomy as one of the most common intraocular, vitreorenital and microsurgical technique performed in the deeper part of the eye, all of which involve removing some or all of the vitreous, i.e. internal jelly that fills the eye from the iris to the retina [1, 2]. In the early years, vitrectomy was used to restore ambulatory vision in eyes that were destined to become blind and were related to a large variety of serious complications [1]. As refinements in technique continued and safety of the procedure was established, it has become a widely used technique for the treatment of a variety of blinding disorders e.g. proliferative diabetic retinopathy, complex retinal detachment, macular hole, epiretinal membrane by removing vitreous opacities, relieving vitrorenital traction, restoring the normal anatomical relationship of the retina and retinal pigment epithelium and accessing the subretinal space [2].

As the scope of vitreoretinal surgical applications increases, so does the potential for complications [3]. Identifying complications and the risk factors associated with them may help reduce the likelihood of poor anatomic or visual results [3]. However, the rate of complications decreased as improvements in technology were introduced [1]. Surgeon skill, experience and training were also significant factors that reduced the rate of complications [1].

Nuclear sclerotic cataract development is the most common complication of pars plana vitrectomy [4]. Within two years of undergoing vitrectomy, more than 90% of phakic eyes in patient over the age of 50 years will develop visually significant nuclear sclerotic cataract [5]. Evidence suggests that vitrectomy

*Address correspondence to this author at the Department of Healthcare Management, Uskudar University, Istanbul, Turkey; Tel: 00-90-216-400-2222; Fax: 00-90-216-4741256; E-mail: mehmettolga.taner@uskudar.edu.tr

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increases the long-term risk of open-angle glaucoma by 10-20% [6]. Other complications of pars plana vitrectomy include retinal tears and detachment, subretinal perfluorocarbon liquid, retinal and vitreous incarceration, endophthalmitis, and recurrent vitreous haemorrhage [2]. Endophtalmitis after vitrectomy is rare but is more commonly found in patients with diabetes and in eyes with retained intraocular foreign bodies [7]. Table **1** lists the common complications of pars plana vitrectomy [2, 3].

The use of Six Sigma, as a quality improvement method, can improve the surgical safety, efficiency and accuracy of many ophthalmic surgeries [8]. This study addresses the complications encountered during and after the 2272 vitrectomy procedures performed and outlines the initiation of Six Sigma's DMAIC application in a public eye care centre. Sigma level of each type of complication is also calculated and reported.

Six Sigma, originally initiated by Motorola, Honeywell and General Electric [9], is a powerful performance improvement tool that is changing the face of modern healthcare delivery today [10]. Although it was initially introduced in manufacturing processes [11], it is being implemented in diagnostic imaging processes [12], emergency room [13], paramedic backup [14], laboratory [15], cataract surgery [8], radiology [16], surgical site infections [17], LASIK surgery [18], strabismus surgery [19], intravitreal injections [20], phacoemulsification cataract surgery [21], intraLase surgery [22] and stent insertion [23] as a cost-effective way to improve quality, performance and productivity. This study is the first Six Sigma research on pars plana vitrectomy 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. DMAIC is particularly useful to analyse 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 [10, 24].

Table 1: Common Complications of Pars Plana Vitrectomy

Complications of intraocular surgery in general	**Complications associated with silicone oil**	**Complications associated with intraocular gas**
Endophthalmitis	Glaucoma	Vitreous traction and irritation
Sympathetic ophthalmia	Band keratopathy	Retinal breaks
Recurrent corneal erosion	Cataract	Migration of gas
	Emulsification	Migration of air
	Perisilicone oil proliferation	
	Redetachment of the retina	
General Intraoperative Complications	**General Postoperative Complications**	**Complications commonly associated with pars plana vitrectomy**
Corneal abnormalities	Corneal abnormalities	Postoperative nuclear sclerotic cataract
Cataract formation	Cataract	Long-term risk of open-angle glaucoma
Iatrogenic retinal breaks and dialyses	Wound complications	Intraoperative or postoperative retinal break
Retinal incarceration	Intraocular fibrin deposition	Intraoperative or postoperative retinal detachment
Choroidal haemorrhage	Periretinal proliferation	Intraoperative cataract
Macular phototoxicity	Retinal detachment	Postoperative vitreous haemorrhage
Intraocular haemorrhage	Choroidal detachment	Postoperative massive fibrin exudation
Hypotony	Intraocular hypertension	Postoperative anterior segment neovascularization
Intraocular hypertension	Intraocular haemorrhage	
	Hypotony and phthisis bulbi	
	Endophthalmitis	
	Sympathetic ophthalmia	

METHODS

Application of DMAIC for Pars Plana Vitrectomy

The eye care centre decided 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 the pars plana vitrectomy process (Table **2**).

During the surgery, various microsurgical instruments are introduced into the vitreous cavity to cut or peel away scar tissue, excise blood, or apply laser treatment. Subsequent to the extraction of the vitreous from the eye, a solution or gas is placed inside the eye.

In their study, Borne et al. [25] concluded that 68% of the patients had a visual acuity of 20/40 (6/12) or better after vitrectomy. Therefore, the surgical team defined the performance objective as patients with higher visual acuity after nearly perfect pars plana vitrectomy procedures. They defined 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 [8]. 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.

DISCUSSION

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

1. Total number of pars plana vitrectomy procedures performed in the eye care centre,

2. Number of complications occurred during and/or after the procedure.

Data were collected for a period of two-years. In this period, 2272 pars plana vitrectomy procedures were performed. Complications had been noted as they occurred. The surgical team identified twenty-two types of complications and classified them as when they occur (Table **4**). Sources (Table **5**) and root-causes (Table **6**) of these complications are tabulated by type. The type, incidence and severity of complications depend on multiple factors, including the indication for surgery, the underlying ocular and systematic disease, the materials and techniques used in surgery and the degree to which the surgical objectives are meet intraoperatively. Thus, the surgery team identified the sources of complications as vitreoretinal surgeon, assistant vitreoretinal surgeon, nurse, patient and intraoperative materials. These sources are evaluated while attempting to assess the root-cause of a complication.

Pars plana vitrectomy is a complex surgery performed as an outpatient fashion by an ophthalmic surgeon with special training on the technique. As new advanced technologies are being introduced, the list of indications grows longer and results improve due to the

Table 2: SIPOC Table for Pars Plana Vitrectomy

SUPPLIER	INPUT	PROCESS	OUTPUT	CUSTOMER
Vitreoretinal surgeon	Patient	Ocular examination	High Visual Acuity	Patient
Assistant Vitreoretinal surgeon	Vitrectomy Equipment	Preparative evaluation by vitreoretinal surgeon	High Vision Quality	
Nurse	Microscope	Examination of medical status and anesthetic risk		
Biomedical Technician	Endolaser	Preparation of operational plan by vitreoretinal surgeon		
	Light probe	Preparation of patient for vitreoretinal surgery		
		Sterilization of vitrectomy equipment		
		Vitreoretinal Surgery		
		Discharge		

Table 3: Indications: Pars Plana Vitrectomy Performed Per Ocular Disease

	%
Macular epiretinal membranes	33.46
Retinal detachment	28.68
Vitreous haemorrhage	18.75
Idipathic macular holes	9.19
Vitreomacular traction syndrome	2.94
IOL drop	2.20
Penetrane injury	1.83
Endophtalmitis	1.47
Premature retinopathy	0.74
Foreign object in vitreous	0.37
Chorodial mass	0.37

experience gained with each new vitroretinal technique. The surgical indications for vitrectomy procedures understudy include a wide range of conditions and are given in Table **2**.

The surgical team analysed the occurrence of each complication (Table **4**) and related them with the root-causes on Table **6**. The analysis revealed that Type I, II and III were the three most frequently occurring complications in vitrectomy (Table **7**). 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 vitrectomy were determined to be the experience of vitreoretinal surgeon, experience of vitreoretinal surgeon and patient’s anatomy. The other factors, i.e. sterilization and hygiene, amount of silicone oil, and amount of gas were “trivial many”.

A Six Sigma process produces 3.4 defective parts per million opportunities (DPMO). Normal distribution

Table 4: Complications Experienced (January 2012 – December 2013)

	Complication	Intra-Operative	Early Post-Operative	Post-Operative	Acute	Sub-Acute	Chronic
Type I	Posterior synechiae			X		X	X
Type II	Intraocular haemorrhage			X	X		
Type III	Iatrogenic retinal breaks	X			X		
Type IV	Retinal redetachment			X		X	X
Type V	Cystoid macular edema			X		X	X
Type VI	Conjunctival haemorrhage	X			X		
Type VII	Epiretinal and subretinal membrane	X				X	X
Type VIII	Glaucoma			X	X	X	X
Type IX	Hypertony		X		X		
Type X	Cataract			X	X	X	X
Type XI	Iatrogenic retinal hemorrhage	X			X		
Type XII	Hypotony		X		X		
Type XIII	Silicone oil into anterior chamber			X		X	X
Type XIV	Migration of gas into anterior chamber			X		X	X
Type XV	IOL dislocation	X		X	X	X	
Type XVI	Complete dislocation of the IOL into the vitreous cavity	X			X		
Type XVII	Posterior capsular tear	X			X		
Type XVIII	Iatrogenic retinal detachment	X			X		
Type XIX	Endophthalmitis			X	X	X	
Type XX	Escape of gas			X	X	X	
Type XXI	Expulsive haemorrhage	X			X		
Type XXII	Choroidal detachment	X			X	X	

Table 5: Sources of Complications

	Vitreoretinal Surgeon	Assistant Vitreoretinal Surgeon	Nurse	Patient	Intraoperative Materials
Type I				X	
Type II	X			X	
Type III	X				
Type IV	X			X	
Type V				X	
Type VI	X			X	
Type VII				X	
Type VIII	X			X	
Type IX	X			X	X
Type X	X				X
Type XI	X				X
Type XII	X			X	X
Type XIII	X				
Type XIV	X				
Type XV	X				X
Type XVI	X			X	
Type XVII	X			X	
Type XVIII	X				
Type XIX	X	X	X		
Type XX	X			X	
Type XXI				X	
Type XXII				X	

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 pars plana vitrectomy procedures 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.

The surgical team calculated the current Defects per One Million Opportunities (DPMO) and sigma levels for each complication type (Table **7**). The process sigma level, calculated as the arithmetic average of twenty-two complications, was found to be 3.8559.

The highest sigma level was obtained for Type XXII. The lowest sigma level was found to be of Type VI. Having sigma levels lower than 4.00, the complications of Type I, II, III, IV, V, VI, VII, VIII, IX, X, XI and XII need to be reduced.

Risk assessment of the pars plana vitrectomy 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.

Complication trends and their consequences over a two-year period had been monitored and recorded. Surgical team prioritized the complications according to

Table 6: Root-Causes of Complications

	Experience of Vitreoretinal surgeon	Attention of Vitreoretinal surgeon	Sterilization And Hygiene	Patient's Anatomy	Amount of Intraocular Gas	Amount of Silicone Oil
Type I				X		
Type II	X	X		X		
Type III	X	X				
Type IV	X	X		X		
Type V				X		
Type VI	X	X		X		
Type VII				X		
Type VIII	X	X		X		
Type IX	X	X		X	X	X
Type X	X	X			X	X
Type XI	X	X			X	X
Type XII	X	X		X	X	X
Type XIII	X	X				
Type XIV	X	X				
Type XV	X	X			X	X
Type XVI	X	X		X		
Type XVII	X	X		X		
Type XVIII	X	X				
Type XIX	X	X	X			
Type XX	X	X		X		
Type XXI				X		
Type XXII				X		

Table 7: Cumulative Frequency, DPMO and Sigma Levels

	Count	Frequency (%)	DPMO	Sigma Level
Type I	119	5.24	52377	3.12
Type II	113	4.97	49736	3.15
Type III	105	4.62	46215	3.18
Type IV	69	3.04	30370	3.38
Type V	64	2.82	28169	3.41
Type VI	687	30.24	302377	2.02
Type VII	45	1.98	19806	3.56
Type VIII	44	1.94	19366	3.57
Type IX	38	1.67	16725	3.63
Type X	21	0.92	9243	3.86
Type XI	17	0.75	7482	3.93
Type XII	15	0.66	6602	3.98
Type XIII	12	0.53	5282	4.06
Type XIV	11	0.48	4842	4.09
Type XV	7	0.31	3081	4.24
Type XVI	4	0.18	1761	4.42
Type XVII	4	0.18	1761	4.42
Type XVIII	4	0.18	1761	4.42
Type XIX	4	0.18	1761	4.42
Type XX	3	0.13	1320	4.51
Type XXI	2	0.08	880	4.63
Type XXII	1	0.04	440	4.83

Table 8: FMEA Table

Complication Type	Hazard Analysis			Decision Tree Analysis	
	Severity Score	Probability Score	Hazard Score	Critical?	Detectable?
Type I	1	0.0524	0.0524	No	Yes
Type II	3	0.0497	0.1491	Yes	Yes
Type III	3	0.0462	0.1386	Yes	Yes
Type IV	4	0.0304	0.1216	Yes	Yes
Type V	2	0.0282	0.0564	Yes	Yes
Type VI	1	0.3024	0.3024	No	Yes
Type VII	3	0.0198	0.0594	Yes	Yes
Type VIII	2	0.0194	0.0388	No	Yes
Type IX	2	0.0167	0.0334	No	Yes
Type X	3	0.0092	0.0276	No	Yes
Type XI	2	0.0075	0.0150	No	Yes
Type XII	2	0.0066	0.0132	No	Yes
Type XIII	2	0.0053	0.0106	No	Yes
Type XIV	2	0.0048	0.0096	No	Yes
Type XV	2	0.0031	0.0062	No	Yes
Type XVI	2	0.0018	0.0036	Yes	Yes
Type XVII	2	0.0018	0.0036	No	Yes
Type XVIII	3	0.0018	0.0054	Yes	Yes
Type XIX	4	0.0018	0.0072	Yes	Yes
Type XX	2	0.0013	0.0026	Yes	Yes
Type XXI	4	0.0008	0.0032	Yes	Yes
Type XXII	2	0.0004	0.0008	Yes	Yes

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 (4 = Permanent harm; 3 = Temporary harm; 2 = Bias; 1 = 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 VI yielded the highest hazard score. Being greater than 0.1, Type II, III and IV were also complications with high hazard scores. The results showed that Type XVI and Type XVII were equally hazardous complications. According to FMEA, Type XXII was the least hazardous complication.

Corrective Action Plan

The surgical team developed preventive measures for each type of complication in order to bring the overall pars plana vitrectomy process under control. They implemented the following corrective action plan to reduce and/or eliminate other complications (Table **9**).

RESULTS

This study investigated the pars plana vitrectomy complications, their types, their sigma levels in current practice and the CTQ factors affecting the process. Twenty-two types of complications were identified. Intraoperative complications occurred with higher frequency than post-operative complications. The sigma level of the overall process was measured and found to be 3.8559.

Table 9: Preventive Measures Per Complication Type

	Preventive Measures
Type I	-Administer subconjuctival dexamethasone injection. -Dilate the pupil of the eye
Type II	-Train the vitreoretinal surgeon. -Provide systematic and haematologic check-up of the patient. -Administer preoperative anti-VEGF.
Type III	-Train the vitreoretinal surgeon. -If necessary purchase a vitrectomy equipment of higher quality and technological capability.
Type IV	-Train the vitreoretinal surgeon. -Plan the surgery carefully and correctly.
Type V	-Keep away from the vascular areas. -Administer intraoperatively triamcinolone.
Type VI	-Keep away from the vascular areas.
Type VII	-Peel the epiretinal and subretinal membrane.
Type VIII	-Be careful about the amount of gas and silicone oil to be administered. -Be careful about the concentration of gas to be administered.
Type IX	- Be careful about the amount of gas and silicone oil to be administered. -Make sure that no viscoelastic material is left in the anterior chamber.
Type X	-Make no contact with the lens during the surgery. -Make sure that the patient is correctly postured.
Type XI	-Train the vitreoretinal surgeon.
Type XII	-Be careful about the amount of gas and silicone oil to be administered. -Prevent the escape of gas and silicone oil. -If necessary, suture the surgical site.
Type XIII	-Make sure that the patient is correctly postured. -Be careful about the amount of silicone oil to be administered.
Type XIV	-Make sure that the patient is correctly postured. -Be careful about the amount of silicone oil to be administered.
Type XV	-Train the vitreoretinal surgeon.
Type XVI	-Train the vitreoretinal surgeon.
Type XVII	-Train the vitreoretinal surgeon.
Type XVIII	-Train the vitreoretinal surgeon.
Type XIX	-Sterilize the operating room, equipment and instruments. -Clean the patient's eye and its surrounding. -Make sure the surgical team obeys all the sterilization rules.
Type XX	-Carefully check the surgical site and if necessary suture it.
Type XXI	Unknown mechanism.
Type XXII	-Avoid hypotony. -Make sure that the infusion cannula is correctly positioned.

The experience of vitreoretinal surgeon, attention of vitreoretinal surgeon, patient's anatomy, sterilization and hygiene, amount of silicone oil and amount of gas were identified to be the factors affecting the success of pars plana vitrectomy procedures. Surgeon skill, experience and training were also significant factors that reduced the rate of complications. To increase the surgical success rate, it is concluded that twelve complications (out of twenty-two), which had sigma levels smaller than 4.00, should be significantly reduced by taking the necessary preventive measures presented in Table **9**.

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