Evolution of Primary Scleral Buckling Surgery: A Modified Lean Six Sigma Technique to Improve Surgical Efficiency

by Thomas A. Ciulla, MD, MBA; Rehan M. Hussain, MD; and Justin H. Townsend, MD

INTRODUCTION

Pars plana vitrectomy (PPV) surgery has advanced tremendously in the past two decades, facilitating the migration of vitreoretinal surgery from the hospital operating room (OR) to the ambulatory surgery center (ASC); however, innovation in scleral buckling (SB) surgery has lagged behind. This has created a dichotomous paradigm with technologically advanced PPV surgery and decreasing surgical times, in contrast to technologically stagnant SB surgery and static surgical times. Consequently, it is not surprising that a recent retrospective cohort study of 31,995 eyes with primary rhegmatogenous retinal detachment (RRD) repair from 2003 to 2016 revealed that PPV has progressively become the most commonly used procedure, whereas SB utilization has declined.1 According to the 2019 ASRS Preferences and Trends Survey, when asked their surgical approach to a phakic superior RRD with a single tear, only 23% of United States retina specialists chose primary SB, whereas 33% chose primary PPV, 7% chose combined SB/PPV, and 36% chose pneumatic retinopexy.2 Soon, SB surgery could become a lost art, narrowing surgical options for patients, unless SB techniques advance with improved surgical times in ASCs while also retaining good outcomes and patient satisfaction.

There is no uncertainty that advances in vitrectomy surgical techniques have decreased the number of scleral buckles used to repair retinal detachments. The annual American Society of Retina Specialists Preferences and Trends Survey has shown declining numbers of scleral buckles used year over year. Unless scleral buckle techniques evolve, to help us keep up with external pressures such as ambulatory surgery center surgical times, this procedure may become a lost art.

I have asked Thomas A. Ciulla, MD, MBA, Rehan M. Hussain, MD, and Justin H. Townsend, MD, to discuss their interesting experience using Lean Six Sigma methodology to increase efficiency of scleral buckling surgery. They will discuss modern-day challenges that currently tip the scale against scleral buckle use and propose solutions based on each step of this procedure. Their advice, if implemented, may reduce waste and potentially provide cost savings while maintaining favorable patient outcomes.

I am certain that their insights will be very valuable for maximizing surgical outcomes in patients with retinal detachments — but enabling us to do so while respecting external challenges surrounding modern-day vitreoretinal surgery.

doi: 10.3928/23258160-20200501-02
LEAN SIX SIGMA IN RETINA SURGERY

Although surgical time is commonly monitored by hospital and ASC administrators, retina surgeons have not yet recognized prolonged surgical time as a defect in care that can be formally assessed through traditional manufacturing techniques including Lean and Six Sigma. Derived from the Toyota Production System, Lean emphasizes streamlining process by eliminating waste such as transportation, inventory, motion, waiting, over-processing, and excessive production.\(^3\) From an operations standpoint, Lean can be applied to health care, because performing surgery represents the creation of relative value units (RVUs) through multiple surgical steps.

Six Sigma, developed by Motorola in 1986 and popularized by Jack Welch’s adoption at General Electric in 1995, aims to identify and eliminate defects and to reduce variation in processes. Six Sigma is a statistically and organizationally rigorous process improvement method that follows five steps to define, measure, analyze, improve, and control a problematic process.\(^4\) Processes with poor reproducibility, wasted resources, and/or high variation are often identified as having defects.

Lean and Six Sigma have considerable overlap, hence the term “Lean Six Sigma” is being used with greater frequency. Process improvement requires aspects of both approaches to maximize positive results. Lean focuses on waste reduction, whereas Six Sigma focuses on variation reduction.\(^4\) This paper describes application of these principles to the SB procedure to limit variation and wasted steps, respectively.

STANDARDIZED SCLERAL BUCKLE PROCEDURE

Although a comprehensive review of SB principals is beyond the scope of this paper, Table 1 outlines the steps of traditional SB surgery, with a step-by-step comparison to the modified Lean Six Sigma technique. Individual surgeon technique preferences such as the use of scleral belt loops versus sutures to secure the buckle, and scleral cut-down drainage versus internally visualized needle drainage, may vary from the technique described. Obviously, in many instances, a surgeon is more efficient performing a known technique compared to adapting a new technique, with the known technique resulting in lower surgical times. However, in consideration of the optimization process described herein, standardizing important steps while identifying and eliminating wasteful steps may yield improved operative times.

This standardized SB procedure is indicated for those RRDs with anterior breaks with or without lattice degeneration. However, RRDs with breaks approaching the equator or more posteriorly, proliferative vitreoretinopathy, media opacities, and other complex conditions are not suitable for this standardized SB procedure. The determination of the appropriateness of the standardized buckling procedure is completed during careful preoperative clinical assessment. This allows greater coordinated, simultaneous preparation of the surgeon and surgical staff for the planned procedure, and prevents staff downtime while the surgical plan is formed.

Standardizing the SB procedure eliminates many of the steps associated with selecting, measuring, placing, and adjusting the SB, as well as multiple examinations using indirect ophthalmoscopy. It also simplifies decision-making around drainage of subretinal fluid, anterior chamber tap, and injection of intravitreal gas. The standard SB elements include a #41 band and a #70 sleeve. A #41 band has a 3.5-mm diameter on its flat side and a 0.75-mm thickness. A #70 sleeve has a 1-mm internal diameter, which expands to accommodate the #41 band.

SURGICAL TIMES AND SINGLE OPERATION SUCCESS RATE

This technique was assessed in a retrospective fashion. Surgical times were not formally studied in a prospective fashion, because the Lean Six Sigma SB technique evolved over many years, during which time variation was gradually minimized. However, surgical times using the Lean Six Sigma approach to SB surgery were compared to peers operating in the same ASC system for the first 6 months of 2017 (all using the same scleral buckling CPT code, 67107). The average total OR times (entry to exit) were obtained from the operative record. To complete a primary SB surgery, one of the authors (TAC) averaged 54.7 minutes in total OR time, compared to a mean of 86.7 minutes (range: 59 to 138 minutes, standard deviation 23.5 minutes) for 12 other retina specialists, which is 37% less time on average.

With respect to surgical success, using the Lean Six Sigma approach to SB, 34 of 37 primary SBs resulted in anatomic success with one surgery (92% single-operation success rate) from 2015 to 2017. This success rate is similar to that reported in the literature, with single-operation success rate ranging from 84% to 91%\(^5\) to 91%\(^6\).

DISCUSSION

In a recent clinical study conducted by two of the authors, Lean Six Sigma process improvement was employed in a typical retina clinic setting to decrease patient visit time by 18%, demonstrating that this ap-
## TABLE 1

**Key Steps in Standardized Scleral Buckling Procedure Compared to Traditional Scleral Buckling Surgery With Respect to Variation Minimized and Waste Eliminated**

<table>
<thead>
<tr>
<th>Surgical Steps in Traditional Scleral Buckle Surgery</th>
<th>Surgical Step in Lean Six Sigma Scleral Buckle Surgery</th>
<th>Variation Minimized</th>
<th>Waste Eliminated</th>
</tr>
</thead>
<tbody>
<tr>
<td>The posterior pole is inspected by indirect ophthalmoscopy. Localize all holes and tears and mark each, respectively. Cryopexy is applied to the retinal break and the suspicious regions.</td>
<td>The posterior pole is inspected by indirect ophthalmoscopy. Cryopexy is applied to the retinal break and the suspicious regions.</td>
<td></td>
<td>Tears are not marked, but are treated directly, eliminating an unnecessary step.</td>
</tr>
<tr>
<td>Select style and size of buckling elements to be used. These elements are soaked in antibiotic solution prior to placement.</td>
<td>A #41 band and #70 sleeve are used routinely.</td>
<td></td>
<td>The scleral buckling elements are standardized.</td>
</tr>
<tr>
<td>Preplace mattress sutures to be used in securing buckle (5-0 nylon). Place buckle. Temporarily tie the buckle into position with the preplaced mattress sutures. Verify proper positioning of buckle over retinal breaks by indirect ophthalmoscopy.</td>
<td>The eye is then encircled with a #41 band, precut to 100 mm. It is placed under each of the four rectus muscles and secured in the superior nasal quadrant with a #70 sleeve. The band circumference is then standardized to 70 mm by tightening the band until its end-to-end overlap measures 30 mm. The excess overlapping ends are cut as they exit from the sleeve and discarded. The band is permanently secured with a 5-0 nylon mattress suture, one per quadrant. If a scleral belt-loop technique is used instead of sutures, the belt-loops are fashioned in the usual technique, positioned 3.5 mm posterior to the spiral of Tillaux in the uninvolved quadrants and 7 mm posterior in the involved quadrant(s). The band is then passed under the muscles and through the belt-loops and secured with the sleeve.</td>
<td></td>
<td>The band circumference is standardized. The mattress sutures are placed after the scleral buckle placement, simplifying and facilitating more rapid passage of the scleral buckle around the globe. The eye is not re-examined with indirect ophthalmoscopy, eliminating an unnecessary step.</td>
</tr>
</tbody>
</table>

Table continues on next page
During this process, the band is placed one band-width posterior to the Spiral of Tillaux, except in the quadrant that contains the retinal break(s), where it is placed two band-widths posterior to the Spiral of Tillaux. Retinal breaks more posterior, approaching the equator, would require more posterior placement of the scleral buckle and may not be suitable for this procedure. The band location is standardized in the anterior-posterior plane. Intraoperative examination and decision-making are minimized.

| Drain subretinal fluid if indicated. Untie temporary sutures to loosen scleral buckle. Within scleral buckle bed, scratch down sclera to suprachoroidal space with scarifier (e.g. Grieshaber #681.01, #57 Beaver blade). Make incision radially and approximately 3 mm in length. Perform drainage with a 30-gauge needle. Examine retina by indirect ophthalmoscopy. Verify buckle location and elevation over breaks. Secure buckling elements permanently. Trim buckling elements with scissors, as necessary. | If planned preoperatively or indicated during cryotherapy, the subretinal fluid is drained (generally not indicated for shallow retinal detachments, in which the break is already well apposed to the indented “buckled” eye wall). External drainage of the subretinal fluid is carried out using a 25-gauge needle on a plunger-less tuberculin syringe. The needle is passed in the scleral buckle bed under direct visualization with the indirect ophthalmoscope in the most bullous region of the retinal detachment. Drainage of subretinal fluid is standardized under direct visualization so that the needle tip is verified in the proper position and the subretinal fluid is directly observed as it is drained from the subretinal space. The scleral buckle is not repositioned, and then re-secured, eliminating unnecessary steps. Decision-making around drainage of subretinal fluid is simplified (generally not indicated for shallow retinal detachments, in which the break is already well apposed to the indented “buckled” eye wall). |

| SF₆ gas injection is standardized, restoring ocular volume after subretinal fluid drainage, and tamponading superior breaks postoperatively. Decision-making around anterior chamber tap and injection of intravitreal gas is simplified (generally not indicated when the break is already well apposed to the indented “buckled” eye wall). |

If indicated, an intravitreal injection of pure SF₆ gas (up to 0.5 mL), is carried out at the pars plana using a 30-gauge needle on a tuberculin syringe (generally not indicated when the break is already well apposed to the indented “buckled” eye wall; preferred for superior pathology, infrequently for inferior causative breaks). If drainage of subretinal fluid was not carried out, then anterior chamber tap is performed first to lower intraocular pressure and volume prior to SF₆ gas injection. If drainage of subretinal fluid was carried out, anterior chamber tap is not necessary; a sufficient amount of SF₆ gas (up to 0.5 mL) is injected to restore the intraocular volume and pressure. The eye is rotated slightly so that the injection is carried out slowly in the upper-most quadrant, injecting into the gas bubble to minimize “fish eggs.” If more gas than 0.5 mL is required to restore the intraocular volume, then filtered air is also injected in the same fashion to restore the intraocular volume and pressure.
approach has the potential to yield meaningful aggregate improvement in health care. Several reports have applied Lean Six Sigma principles to demonstrate statistically significant improvements in OR efficiency by reducing surgery start time delays, OR turnover times, and throughput times (from patient entry to exit of the OR). Lean Six Sigma techniques have also been demonstrated to reduce the surgical complication rate for gastrointestinal procedures and cataract surgery. This current report describes such an approach to process improvement for retina surgery. Standardizing SB surgery and eliminating unnecessary steps can limit variation and waste, respectively. Furthermore, limiting variations in surgical time can reduce the ripple effects of delays and improve overall facility function.

This report is limited, however, in that it does not present a formal prospective process improvement study, and is also limited by its retrospective nature, lack of definitive controls, and lack of information on the RRDs or SB techniques for each surgeon operating in the ASC system. For example, among the peer surgeons in the ASC system, there was a wide range of mean times to complete primary SB (range: 59 to 138 minutes), suggesting a high degree of variation in their techniques. Despite these limitations, standardizing the SB procedure demonstrably standardizes key steps and eliminates many of the wasted steps associated with selecting, measuring, placing, adjusting the scleral buckle, and multiple examinations using indirect ophthalmoscopy. It also simplifies decision making around drainage of subretinal fluid, anterior chamber tap, and injection of intravitreal gas. These process improvements lead to measurable benefits, including enhanced patient flow through the OR, as well as lower cost per case and increased revenue potential per surgeon and/or OR, given the ability to perform more surgery in a fixed amount of time. Specifically, whereas the single SB operation success rate compares favorably to that reported in the literature, the average total OR time was 37% less than the mean of 12 other retina surgeons operating in the same ASC system. According to a recent report, OR time in a California ASC costs a mean of $36 per minute. Applying this cost to the current report, in which the mean time to completion for scleral buckling was 32.5 minutes faster than the mean of other surgeons in the same ASC system, the health care system would save approximately $1,170 per procedure. If similar approaches were implemented across entire institutions, the benefits aggregate even further.

Additionally, the ability to complete the procedure more quickly with favorable outcomes can potentially result in less total intraoperative discomfort and/or anesthetic, and less postoperative inflammation. Furthermore, standardized procedures facilitate familiarity among staff, who can prepare and assist at a higher level. This results in a virtuous cycle, which could further reduce surgical time, facilitating completion of surgery under conscious sedation and local anesthesia, potentially further minimizing discomfort, and facilitating rapid postoperative recovery.

In summary, reducing waste and variation in SB surgery by standardizing it as described here can reduce surgical time while maintaining favorable outcomes, with potential for cost savings. Further utilization and study of Lean Six Sigma in the OR setting is warranted.

REFERENCES


**Disclosures:** Dr. Ciulla currently has an employment relationship with, and equity ownership in, Clearside Biomedical. He previously had an employment relationship with, and equity ownership in, Ophthotech Corporation and Spark Therapeutics. This work was undertaken in his role as Volunteer Clinical Professor at Indiana University School of Medicine and does not reflect any views or opinions of these corporations or management. Dr. Hariprasad is a consultant or on the speakers bureau for Allergan, Novartis, Graybug, EyePoint, Alimera Sciences, Spark, and Regeneron. Dr. Hussain has served on an advisory board for Alimera Sciences. Dr. Townsend has received speaker fees from Bausch + Lomb.

The authors gratefully acknowledge Dr. Donald L. Wilson, founder of Midwest Eye Institute and quintessential mentor, who originally taught standardization of scleral buckle circumference.