The Application of Statistical Process Control to Cataract Surgery

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Abstract

- **Objective**: To apply statistical process control (SPC) techniques to evaluate 3 components of the phacoemulsification cataract surgery procedure.
- **Design**: Retrospective chart review.
- **Methods**: We analyzed 180 cataract surgeries performed by 6 cataract surgeons (3 “high-volume” and 3 “low-volume” surgeons). Surgical parameters evaluated were phacoemulsification time (seconds), phacoemulsification power (mJ), and surgical time (minutes). Data were analyzed using the QI Analyst software package to generate SPC run charts and histograms.
- **Results**: Our results did not reveal a statistically significant difference in mean phacoemulsification time ($P = 0.814$) or phacoemulsification power ($P = 0.115$) between high- and low-volume cataract surgeons. The difference in surgical times between high- and low-volume surgeons was statistically significant ($P < 0.001$). Visual inspection analysis of the SPC charts revealed more variability for both phacoemulsification time and power among the high-volume surgeons.
- **Conclusions**: Elements of the cataract surgery procedure can be evaluated using SPC methodology. Eye surgeons should be encouraged to use SPC charting techniques to analyze variability in ophthalmologic procedures with the ultimate goal of producing better outcomes.

Cataract surgery utilizing ultrasonic emulsification of the cataractous lens (phacoemulsification) with placement of an intraocular lens implant is the most frequently performed surgical procedure reimbursed by Medicare [1]. Quality measurement in cataract surgery has generally focused on visual function and patient quality of life [2–7]. Little research has been done on the surgical process itself. Phacoemulsification cataract surgery is generally a standardized process in which the surgeon performs the following steps: (1) preparing the eye for surgery, including antimicrobial preparation and surgical draping the operative site, (2) opening the eye through near the limbus, either through clear peripheral cornea or perilimbal sclera, (3) opening the anterior capsule of the cataractous lens, (4) ultrasonic disruption of the lens with mechanical aspiration of the lens material, (5) placement of the intraocular lens implant, and lastly (6) closure of the incision and reconstitution of the anterior chamber of the eye. The power of the intraocular lens implant is determined preoperatively based on the desired postsurgical refraction, the curvature of the cornea, and the axial length of the eye. Certain aspects of the surgical procedure are routinely documented in all operative reports or operating room records of cataract surgery. These include duration of phacoemulsification process, total energy employed in the phacoemulsification process, and total time in the operating room.

Statistical process control (SPC) is a quality control technique originally developed by Shewhart and Deming for use in evaluating quality in manufacturing [8]. The technique involves applying a specific graphical method of statistical analysis to monitor a measured process in order to track variation from desired outcomes. In any standardized process, the outcome of the process will vary from unit to unit based on process variables (eg, surgeon, assistant, accuracy of preoperative measurements, type of instruments, use of postoperative medications) and substrate variables (eg, neurologic status, wound healing, vascular supply, induced nausea and vomiting). Shewhart held that a system could not be expected to produce a “perfect” product every time due to the variability inherent in the process itself. With this inherent “common cause” variation, outcomes of a valid, “in control” process will follow the statistical rules of variability of a normal distribution. In contrast to inherent variation, “special cause” variation produces outcomes that fall outside statistical limits, indicating an “out of control” process. Statistical outliers can be traced back to a problem in the process that needs to be addressed.

A primary tool in SPC is the control chart, a graphical representation of certain descriptive statistics for specific quantitative measurements of an observed process. An SPC chart, also known as a run chart, allows visualization of...
how data vary over time. The SPC chart consists of data plotted in a time sequence with the mean and upper-control limits (UCLs) and lower-control limits (LCLs) (analogous typically to ±3 standard deviations for a normal distribution) illustrated. However, more than the mere statistics can relate, the graphic display allows one to see and intuitively understand trends in the data.

We believed that SPC charts could be an effective tool in monitoring variables in the cataract surgery procedure. We designed a pilot study to test the efficacy of SPC charts in the analysis of the cataract procedure itself. Our goal was to investigate the surgical process of phacoemulsification cataract surgery by studying variables that have the potential to be standardized, including phacoemulsification time, phacoemulsification power, and total surgical time.

**Methods**

We analyzed 180 cataract surgeries performed by 6 cataract surgeons in the Department of Ophthalmology of the University of Tennessee College of Medicine–Chattanooga Unit. Surgeons who operated at the Miller Eye Center at Erlanger Medical Center in support of the ophthalmology residency were invited by letter to participate in the study. Initially, many of the surgeons were reluctant to participate if the results of the individual surgeons could possibly become known. We agreed to analyze 2 small groups of eye surgeons rather than individual ophthalmologists. A small group of high-volume surgeons would be compared with a small group of low-volume surgeons. A surgeon was considered “high volume” if he/she performed more than 6 to 8 cataract surgeries per week. A surgeon was considered “low volume” if he/she performed less than 5 cataract surgeries per week. There were 3 high-volume surgeons and 3 low-volume surgeons in the study group.

The study was performed between 1 March 2002 and 1 September 2002. For each surgeon, the first 30 cataract surgeries without intraoperative complications surgeries were evaluated. Only straightforward cataracts surgeries with intraocular lens implantation were included, excluding, for example, those patients with intraoperative vitreous loss, posterior capsular rupture, or anterior vitrectomy, eliminating the need for risk adjustment of the patient data. Surgical parameters were collected by retrospective chart review. These were phacoemulsification time (seconds), phacoemulsification power (mJ), and total surgical time (minutes). Phacoemulsification power and time are measures of how difficult the lens was to emulsify ultrasonically, with harder lenses requiring more energy and more difficult surgeries requiring more time. We did not intend to evaluate final surgical outcomes such as visual acuity or complications.

Data were entered into the QI Analyst software program (SPSS, Inc., Chicago, IL). Simple SPC charts were generated to compare the differences in phacoemulsification time, phacoemulsification power, and surgery time between high-volume and low-volume surgeons. Data were also evaluated using the Student’s t-test. The study was approved by the institutional review board of the University of Tennessee in Chattanooga.

**Results**

For the high-volume surgeons, following the SPC run chart for phacoemulsification time, the UCL was 3 minutes and 42 seconds and the LCL was reset to zero. There were 2 data points that fell above the UCL, suggesting special cause variation (Figure 1). For the low-volume surgeons, the run chart for the phacoemulsification time resulted in a UCL that was 3 minutes and 51 seconds and the LCL was reset to zero. All the data points fell between the UCL and LCL for the low-volume surgeons (Figure 1). Comparison of the histograms suggested more homogeneity among the 3 high-volume surgeons and perhaps a bimodal representation among the 3 low-volume surgeons. The mean phacoemulsification time for low-volume surgeons was 1 minute and 22 seconds (82 sec) and the mean phacoemulsification time for high-volume surgeons was 1 minute and 21 seconds (81 sec). The difference in phacoemulsification time between high- and low-volume surgeons was not statistically significant ($P = 0.814$).

Considering the SPC run charts for phacoemulsification power, the UCL and LCL for high-volume surgeons were 35.8 mJ and 4.4 mJ. There were 2 data points that were higher than the UCL, again suggesting special cause variation (Figure 2). For low-volume surgeons, the SPC run chart of the phacoemulsification power revealed an UCL of 45.1 mJ and the LCL was reset to zero. No data points fell outside the UCL for the low-volume surgeons (Figure 2). The mean phacoemulsification power for high-volume surgeons was 20.5 mJ per case with a standard deviation of 6.2 mJ. Comparison of the histograms suggests more homogeneity among the 3 high-volume surgeons and perhaps a bimodal or trimodal representation among the 3 low-volume surgeons. For the low-volume surgeons, mean phacoemulsification power was 18.5 mJ with a standard deviation of 7.5 mJ. Again, the difference in phacoemulsification power was not statistically significant ($P = 0.115$) between the high- and low-volume surgeons.

Considering the SPC run charts for the surgical time, for the high-volume surgeons the UCL was 272 minutes and the LCL was 4.4 minutes with 1 data point higher than the UCL, suggesting special cause variation (Figure 3). For the low-volume surgeons, the UCL was 66.5 minutes and the LCL was reset to zero, with no data points higher than the...
Comparison of the 2 histograms suggests an expected normal distribution of the times for both the high-volume and low-volume surgeons. The average time to perform cataract surgery for the high-volume surgeons was 15.8 minutes with a standard deviation of 4.2 minutes. The average time for low-volume surgeons was 27.9 minutes with a standard deviation of 11.1 minutes. The difference in the surgical times between high- and low-volume surgeons was statistically significant ($P < 0.001$).

**Discussion**

SPC is a method of monitoring, and ideally improving, a process through statistical analysis and observation [9–11]. Health professionals have only recently become aware of this powerful statistical application. SPC chart analysis has been used in medicine infrequently. In one example, SPC charts were used to analyze the incidence of postoperative complications in cardiac surgery; subsequent changes in practice patterns were seen that resulted in decreased complications and decreased length of stay for coronary artery bypass graft patients [12]. There have been cases reported of SPC being used to improve the quality of emergency care, clinical pediatric medicine, diabetes management, perioperative care, and an occupational health program [13–17]. Control charts have been used in health care monitoring and public health surveillance evaluating excess morbidity and mortality [1,18–21]. SPC charts have been used rarely in ophthalmology to evaluate pediatric strabismus surgery outcomes [22–24].

Our results showed that there were no statistically significant differences between mean phacoemulsification time ($P = 0.814$) and phacoemulsification power ($P = 0.115$) for high-volume and low-volume cataract surgeons. Most surgeons can understand this analysis of the mean and standard deviation obtained using the Student’s $t$ test. However, the SPC run charts revealed information that was

![Statistical process control charts for high-volume surgeons (1A) and low-volume surgeons (1B) with corresponding histograms of phacoemulsification time.](image-url)
Figure 2. Statistical process control charts for high-volume surgeons (2A) and low-volume surgeons (2B) with corresponding histograms of phacoemulsification power.

not apparent from the simple comparison of mean outcome, which is commonly used in routine surgical analysis. The SPC run charts showed normal statistical fluctuation for both the high- and low-volume surgeons. Interestingly, the high-volume surgeons’ phacoemulsification time and phacoemulsification power had lower UCLs than low-volume surgeons’ surgical parameters. However, none of the cases among the low-volume surgeons fell above their UCL. Conversely, 2 of the high-volume cases fell above the UCL for phacoemulsification time, and 2 different cases fell above the UCL for phacoemulsification power, suggesting special cause variation that would be worth investigating. It would interesting to know if these outliers perhaps were over-represented among 1 of the 3 high-volume surgeons. Also, comparison of the histograms for phacoemulsification time and phacoemulsification power between the high- and low-volume surgeons suggests more homogeneity among the 3 high-volume surgeons. Lastly, considering the SPC charts for total surgical time among the high- and low-volume surgeons, the 1 outlier for a relatively longer surgical time among the high-volume surgeons was close to the average surgical time for the low-volume surgeons. This single case was not one of the cases that manifested excessive phacoemulsification time or phacoemulsification power among the high-volume cases.

Because high-volume surgeons perform more surgeries within a given time period as compared with low-volume surgeons, they may have less variation utilizing the phacoemulsification apparatus as manifest by less variation in phacoemulsification power and phacoemulsification time in order to finish the case faster. Comparing the means alone does not suggest that there is any difference between high- and low-volume surgeons, but the SPC chart gives this additional information. Considering actual surgical time for the cataract surgery, it seems likely that a surgeon performing a greater number of surgeries during an operative “time block” would feel pressured to move the patient in and out of the operating room faster. The shorter operating room time
would definitely result in lower operating room charges. In future studies it would be interesting to determine if shorter operating time, or cases involving phacoemulsification time or phacoemulsification power that are in excess of the UCL, are associated with different rates of complications or different visual outcomes. Again with a higher volume of cases, special cause variations such as turnover time or experience of the surgical technician are perhaps minimized to achieve an “in control” process.

Conclusion
Operative parameters such as phacoemulsification time and phacoemulsification power seem to be independent of surgical volume and may be described by standard models of statistical fluctuation. However, surgical time seems to be lower with a higher volume of cases. Variation in operative parameters and varied surgical time may directly affect postoperative complications and surgical outcome as well as cost and are all worthy of further study. SPC may be a valuable method to analyze variability in many ophthalmologic procedures, with the goal of minimizing variability to achieve better outcomes. SPC could also be applied to evaluate resident surgical procedures as a means of determining surgical competency as required by the Accreditation Council for Graduate Medical Education. SPC charts could be used to evaluate uncommon but yet very serious surgical complications, such as endophthalmitis, in large insurance databases using the pyramid of investigation model [11]. Eye surgeons should be encouraged to embrace SPC charting techniques as a superior tool leading to improved outcomes through timely analysis of controlling variables and skill in detecting clinically significant changes.

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Figure 3. Statistical process control charts for high-volume surgeons (3A) and low-volume surgeons (3B) with corresponding histograms of surgical time.
References


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