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Minimizing Individual Learning Curves in a Mature Endoscopic Fetal Surgery Program

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Keywords
Fetal surgery · Learning curve · Training

Abstract
Introduction: Twin-to-twin transfusion syndrome affects monochorionic twin pregnancies and can result in fetal death. Endoscopic laser treatment remains a relatively infrequent procedure for this condition. This presents difficulties for maintaining proficiency and for training new personnel. ***Objective:*** The dual mentoring program at our institution allows for continuous mentoring of new providers. We hypothesize that this approach stabilizes program proficiency despite the addition of new practitioners. ***Methods:*** Query of the fetal treatment program database returned 146 cases of laser ablation between 2000 and 2019. Patient and pregnancy characteristics as well as operative time and outcomes were recorded. The learning curve-cumulative summation method and rolling averages were used to analyze outcomes. ***Results:*** Overall survival was 69%, and survival of at least 1 twin was 89%. Mean operative time was 53.6 ± 20.9 min. Overall twin survival stabilized after the first 40 cases. Rolling averages for operative time decreased from 71 to 49 min for the most recent cases. These results were not affected by the introduction of new surgeons. ***Conclusions:*** Creative mentoring can maintain stable overall program outcomes despite changes in team composition. This training approach may be applicable to other rare procedures in fetal surgery.

Introduction

Twin-to-twin transfusion syndrome (TTTS) is a condition that affects monochorionic twin pregnancies and can result in severe cardiac morbidity or death for either fetus. Severe cases are typically treated by endoscopic laser ablation of the communicating placental vessels, a process which renders the gestation functionally dichorionic. This procedure is the most commonly performed maternal-fetal operation today, and innumerable centers offer this form of therapy worldwide. In 2016, the North American Fetal Therapy Network (NAFTNet) docu-

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mented almost 1,000 pregnancies with this diagnosis; of these, >600 underwent laser ablation procedures in 30 centers – an average of 20 cases/center/year (source: NAFTNet statistics). NAFTNet includes most but not all fetal therapy centers in North America. Based on these numbers, the overall median case load per center remains fewer than 2 cases per month. Therefore, while TTTS is a well-recognized condition that affects 15–20% of all identical twin gestations, endoscopic laser treatment remains a relatively infrequent procedure. Even busy institutions may not have a large annual volume of procedures. Rare conditions such as these present difficulties both for maintaining proficiency for individual providers and centers as well as for providing opportunities for the training of new personnel.

Learning curves for new providers are an often-overlooked problem in surgery and other interventional specialties. Unlike other fields such as the airline and the manufacturing industries, [1] medicine has inconsistently studied how experience, volume, and training affect outcomes. One means of estimating the case volume needed for proficiency is the observation of the plateauing of complication rates. This has been used in orthopedic surgery, such as in a study by Kempton et al. [2], where a complication-based learning curve was used to determine proficiency in reverse shoulder arthroplasties, and in pediatric laparoscopy to determine proficiency in performing laparoscopic antireflux surgery in infants and children [3].

One robust methodology used to assess the proficiency requirements for a technique or method is the cumulative summation (CUSUM) for learning curve (LC-CUSUM). This tool calculates when a process has reached a predefined level of performance competency [4, 5]. It has been used most recently to examine the learning curve in fetal surgery for myelomeningocele, based on a systematic review of the literature [6]. A 2011 study by Papanna and colleagues [7] was the first to examine the learning curve for fetoscopic laser ablation. In this study, the authors demonstrated that the learning curve was longest for the first operator (when the procedure was introduced at their institution in 2005). It was substantially shortened for the second and later the third operator. This outcome suggests the importance of mentorship and hands-on training in attaining proficiency.

The present study was undertaken to validate the learning curve for endoscopic laser ablation at a fetal treatment center where the procedure is performed with a different approach based on collaboration between 2 specialty services and to evaluate the proficiency of the center itself, rather than the individual operators. We hypothesize that this dual mentoring program might eliminate the peaks and troughs in program proficiency that can otherwise occur during the training of new providers.

Materials and Methods

The Fetal Treatment Program of New England is a collaborative initiative between Hasbro Children's Hospital (part of Rhode Island Hospital), Women & Infants Hospital of Rhode Island (all on the same campus), and the Alpert Medical School of Brown University. It consists of more than 15 subspecialties that are led primarily by the Divisions of Maternal-Fetal Medicine (MFM) and Pediatric Surgery. The program has offered endoscopic laser ablation of placental vessels for severe TTTS since 2000. This treatment has always been performed as a strict collaboration between MFM and pediatric surgery specialists, and both specialties are always present during the procedure. In this 2-service system, at least 1 senior practitioner from either service must be present at the time of any ablation procedure until proficiency has been reached by the corresponding junior faculty member. The staggered staffing allows for continuous mentoring during which new providers are trained, while it minimizes any effect on the quality of the care provided.

The Fetal Treatment Program of New England database, which is associated with the region's maternal and pediatric hospitals, was queried for patients with TTTS who underwent laser ablation from 2000 to 2019. One hundred forty-six consecutive cases were analyzed. Information collected included that regarding twin donor and recipient characteristics, particularly stage, placental location, surgical technique, and days from diagnosis to procedure. For each provider, the operative time, number of vessels lasered, intraoperative complications, and postoperative outcomes were recorded. Outcomes included fetus status at the end of case, maternal operative complications, pregnancy complications prior to discharge, and ultimate outcome of the pregnancy. Number of placental vessels lasered was not confirmed by postnatal placental analysis: as a regional referral center, we often do not deliver mothers at our institution after laser ablation, and the placenta is, therefore, not available in most cases. The operative technique, typically performed under general anesthesia in the operating room, has been described elsewhere [8–10]. Long-term morbidity has been reported as well [11].

LC-CUSUM Analysis for the First Operator

The LC-CUSUM was then used to examine operative time and outcome of survival of at least 1 fetus for each pediatric surgical provider. LC-CUSUM sequentially tests the null hypothesis "performance is unacceptable" against the alternative "performance is acceptable." A logarithmic function is used to track successive outcomes and calculate a score based on the results of individual cases. When the score reaches a predetermined limit, the performance of the provider is deemed acceptable [5]. Papanna et al. [7] used "survival of at least 1 twin" as their standard of proficiency and based this metric on a systematic review of studies on endoscopic laser ablation. We emulated their study but used the Eurofetus study outcomes: since the initial LC-CUSUM analysis reflects our early experience with laser surgery, it was important to compare it

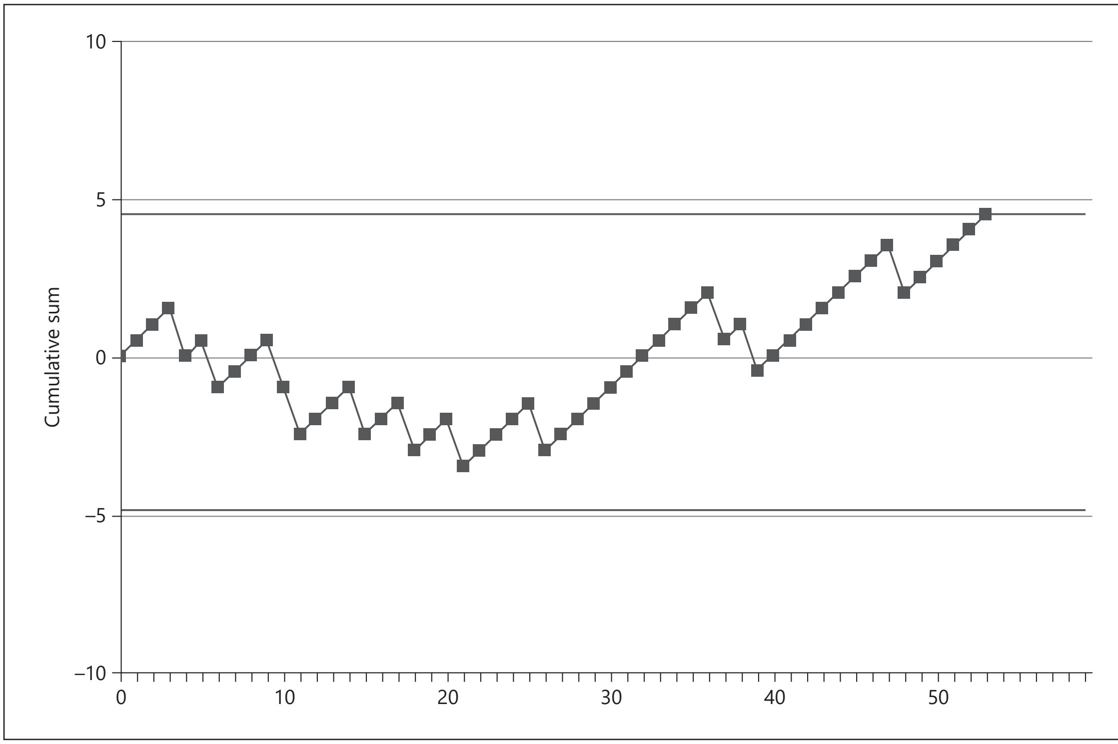

Fig. 1. LC-CUSUM for the senior operating team. The curve was calculated using standardized methods (see text for details). Solid horizontal lines are the upper and lower controls, respectively. The progression of individual data points reflects the success (upward slope) or failure (downward slope) of chronologic cases. Proficiency is said to have occurred when the graph reaches the upper control. LC-CUSUM, learning curve-cumulative summation

with the gold standard at the time. Proficiency for survival of at least 1 twin was set at 76% for all stages to reflect the outcome of the 2004 randomized controlled study [12]. The LC-CUSUM curves were then further stratified by severity (stages 1–2 and stages 3–4), as our patient distribution leans toward more severe cases than the Eurofetus study did.

Since it can be argued that twin survival (dual survival, as well as survival of at least 1 twin) depends on many factors, only one of which may be intraoperative proficiency, we analyzed the learning curve for the first operator against several other criteria, including operative time (absolute, as well as relative to the number of ablated placental vessels) and complication rates. Operative time was defined as surgical time or "skin-to-skin" (not just intrauterine time). The overall maternal complication rate was very low; therefore, it was difficult to construct CUSUM curves based on this metric. In addition, one specific change in protocol which affected anesthetic management that occurred in 2007; this adjustment further reduced the sporadic occurrence of maternal respiratory complications to zero and altered maternal outcomes [13].

For the purpose of CUSUM analysis, baseline proficiency operative time was set at within 2 standard deviations of the overall cohort's average operative time of 53 min. The Foresee CUSUM Calculator for Clinical Control was the primary program used to carry out the LC-CUSUM analysis (https://jacob.puliyel.com/foresee/). When it was determined that a surgeon had reached proficiency, a CUSUM test using QI Macros (https://www.qimacros.com/control-chart/cusum-chart/) was carried out on subsequent operative outcomes.

Table 1. Perinatal survival after endoscopic laser ablation of placental vessels for severe TTTS, by stage

	N	Dual survival	At least 1 survivor	Dual demise
Stage II	33	19 (58%)	33 (100%)	0
Stage III	91	43 (47%)	79 (87%)	12 (13%)
Stage IV	21	10 (48%)	7 (81%)	4 (19%)
Stage V	1	0	1	0

TTTS, twin-to-twin transfusion syndrome.

Institutional Maintenance of Proficiency: Rolling Averages

The staggered training model of this 2-service system requires that at least 1 senior operator (MFM or Pediatric Surgery) be present for each case. During subsequent cases, the novice operator progressively assumes more autonomy (graded responsibility). Once a novice operator has attained proficiency, they can operate

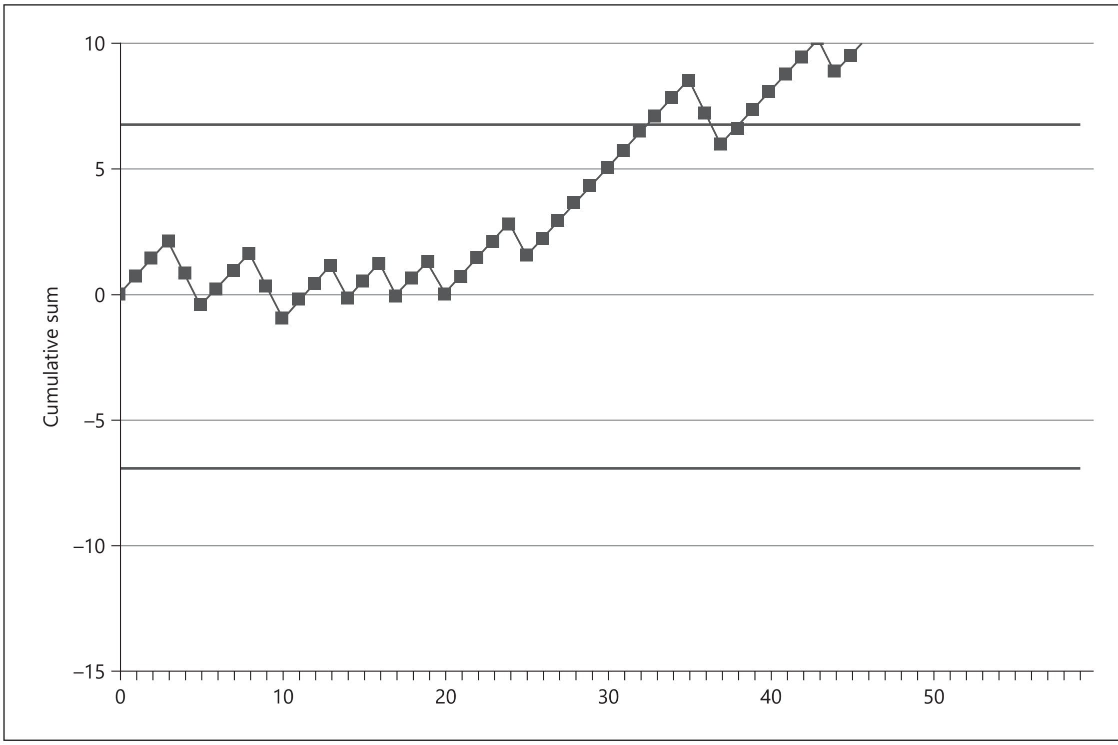

Fig. 2. LC-CUSUM for the senior operating team, advanced stage. (See text and Fig. 1 for details). LC-CUSUM, learning curve-cumulative summation.

independently (with either a novice or senior member of the other team – MFM or Pediatric Surgery). To test the hypothesis that this model safeguards the consistently proficient performance of the operating team, the rolling averages of the entire 19-year cohort for survival of at least 1 twin and for operating time were calculated. The introduction of a new pediatric surgical operator was noted along this timeline (3 surgeons over the 19-year period) to evaluate the degree of deviation from the baseline curve (i.e., evaluation of the presence or absence of a dip in team proficiency).

Results

From 2000 to 2019, more than 400 women with monochorionic, diamniotic twin pregnancies were referred to or diagnosed with TTTS at the Fetal Treatment Program of New England. Of these, 146 patients underwent endoscopic laser ablation of placental vessels. For the first 6 years, the same physician duo (1 MFM specialist and 1 pediatric surgeon) performed all procedures.

In 2006, a second pediatric surgeon joined the operating team. In 2018, a third pediatric surgeon was recruited and followed a similar training pathway. During the entire period, 4 additional MFM specialists were mentored as well. During the entire 19-year period, every case required the presence of at least 1 senior physician (MFM specialist or pediatric surgeon) until the trainee physician was deemed to have reached proficiency. Operative responsibility of the pediatric surgeon was graded as follows: assistant surgeon first, followed by increasing degrees of participation as primary surgeon (port insertion, intrauterine endoscopy, identification of vascular anastomoses, and laser coagulation). Surgical proficiency was evaluated by the senior physicians. Only when proficiency was deemed to be achieved could newer pediatric surgeons operate independently, and only then were they allowed to operate with an MFM trainee (staggered independence of MFM specialists and pediatric surgeons).

Of 146 patients, 33 were stage II, 91 were stage III, and 21 were stage IV. One patient was stage V preoperatively, and intervention was performed in an attempt to save the least affected twin. There were no stage I cases. Overall survival for the entire cohort was 69% and survival of at least 1 twin was seen in 89%. Survival stratification by stage is shown in Table 1. Mean operative time for the entire cohort was 53.6 ± 20.9 min. There was no statistical

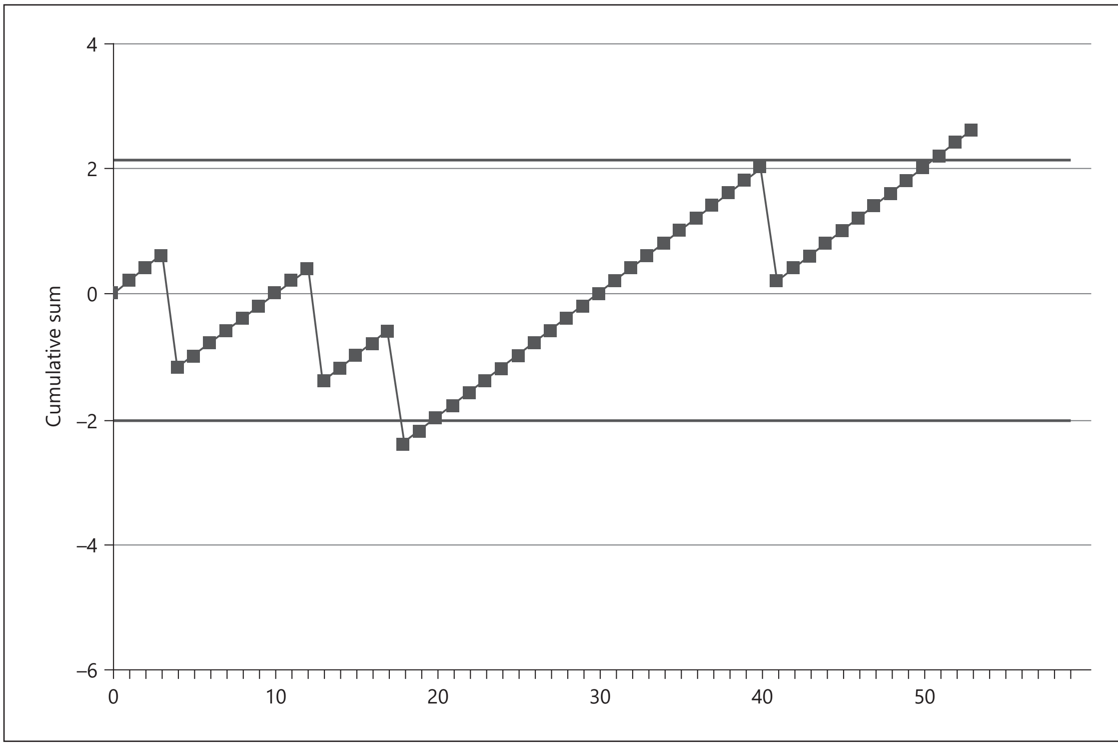

Fig. 3. LC-CUSUM for the senior operating team, operative time (see text and Fig. 1 for details). LC-CUSUM, learning curve-cumulative summation.

difference in operative time between anterior placental (58.4 min) and posterior placental (50.2 min) location ($p = 0.1$, Student's t test).

LC-CUSUM for the senior operating team is shown in Figure 1. Competency level for "at least 1 survivor" (ALOS, parameter used to judge proficiency by Papanna et al. [7]) was 76%, the gold standard at the time of the initial experience at the Fetal Treatment Program of New England (Eurofetus trial results published in 2004 [12]). According to that LC-CUSUM analysis, our center attained operative proficiency at 53 cases. Because of the unequal stage distribution between the Eurofetus trial and our own cohort (51% of the Eurofetus cohort was stage I or II, compared with 23% in our series), the LC-CUSUM for ALOS was also calculated for advanced stages (III–IV–V) only, with a Eurofetus-based competency level of 66% [12]. By this standard, proficiency was achieved after 32 cases in our experience (Fig. 2).

Because twin survival, in the absence of major perioperative complications, is likely multifactorial, we constructed an LC-CUSUM curve for a parameter more closely related to surgical performance: the operative time. Figure 3 shows the LC-CUSUM curve for raw operative time, using the average operative time for the entire cohort (53.6 ± 20.9 min) as baseline competency level (success) and an operative time >2 standard deviations above baseline as unacceptable (failure). Proficiency, as measured by operative time, was achieved after 40 cases in the early cohort (2 senior physicians). Operative time may be influenced by placental location since an anterior placenta may be technically more difficult. However, there was no statistically significant difference in overall operative time between anterior and posterior placenta, and LC-CUSUM analysis stratified for placental location confirmed this (results not shown). In addition, operative time may be influenced by the number of vessels to be ablated (the presence of fewer vessels may require shorter operative time). The median number of communicating placental vessels was 4, ranging between 1 and 23. Figure 4 shows the LC-CUSUM for the early cohort using Operative time/vessel number ratio, showing a similar learning curve (proficiency reached after 40 cases).

Papanna et al. [7] have already established that the learning curve is shorter for subsequent operators than for the initial operator or team. We sought to study the performance stability of the entire team through 2 chang-

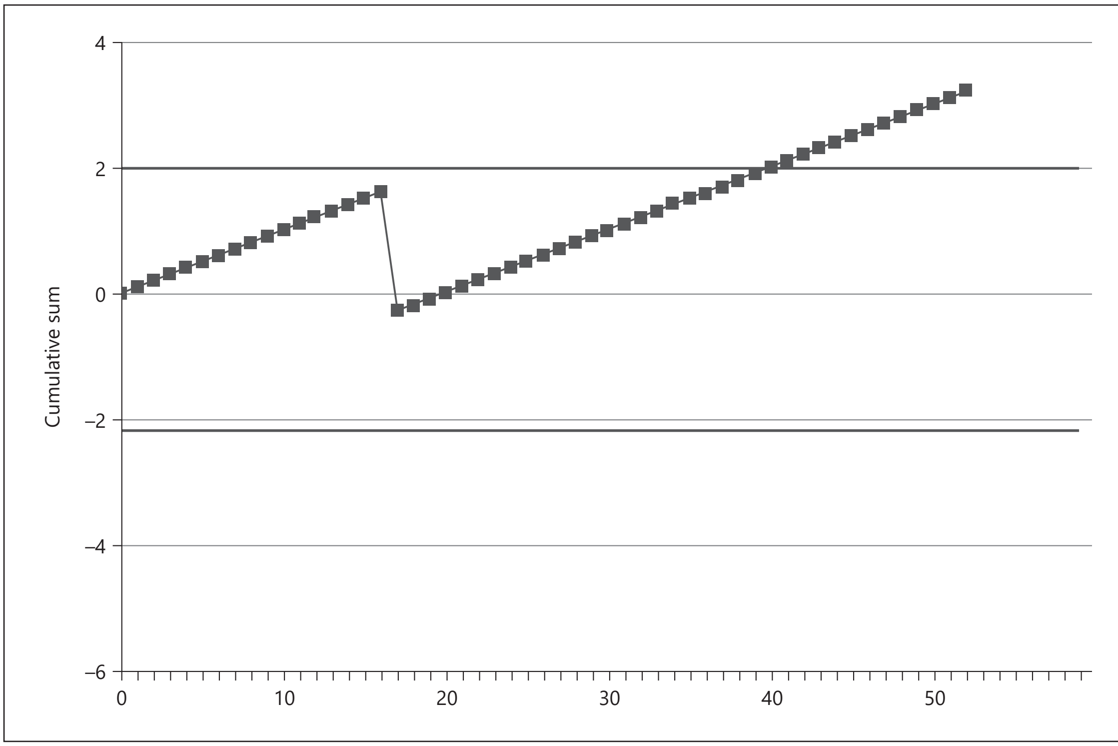

Fig. 4. LC-CUSUM for the senior operative team, operative time/vessel number ratio (see text and Fig. 1 for details). LC-CUSUM, learning curve-cumulative summation.

es in pediatric surgeons (in addition to 4 MFM specialists) during the entire 19-year period. Figure 5 shows the rolling averages for overall twin survival, showing stabilization after the first 40 cases. Average overall survival increased from 64 to 69% over the entire period.

Similarly, rolling averages for operative time remained relatively stable throughout the study period, with a gradual decrease from 71 min early on to 49 min for the most recent cases (Fig. 6). The rolling averages for operative times for pediatric surgeons 2 and 3, respectively, are shown in Figure 7. In both cases, the operative times (once they were deemed proficient enough to operate independently) remained well within 2 standard deviations of the average operative time of 53 min and almost always below 1 standard deviation.

Discussion/Conclusions

Maintaining proficiency in the performance of procedures is important in surgery and other interventional specialties. It is a particular challenge in pediatric and fetal surgery, as these subspecialties often deal with rare conditions. The goal should be to guarantee short learning curves for new practitioners while maintaining consistent patient outcomes. In the absence of frequent exposure and simulation models, creative mentoring may bridge this gap. While this system requires that some additional manpower be deployed for each case, this investment is returned in terms of consistent patient results.

The unique partnership at the Fetal Treatment program of New England allows for a dual mentoring program that employs senior practitioners from both MFM and Pediatric Surgery. As reported here, this structure has resulted in avoidance of disruption due to the learning curves of subsequent practitioners while maintaining overall program outcomes. The introduction of new surgeons did not affect the rate of survival of at least 1 twin nor did it affect average operative time. The authors feel that this mentored training approach may be applicable to other rare procedures in fetal surgery, such as myelomeningocele repair.

The strengths of this study include the use of a comprehensive program database which provided granular data on all patients referred for evaluation for TTTS, as well as

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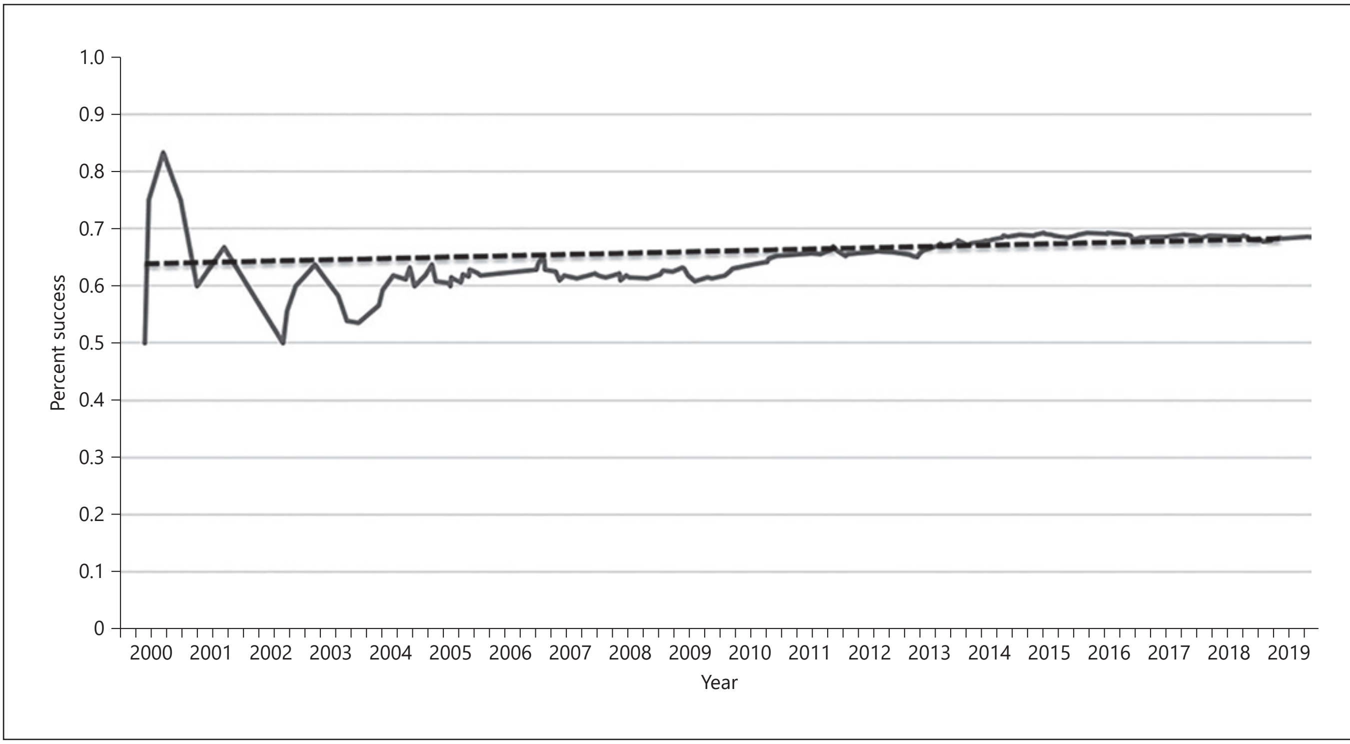

Fig. 5. Rolling averages for overall twin survival. Solid line: rolling average over a 10-case interval. Dashed line: linear progression of survival over the entire cohort.

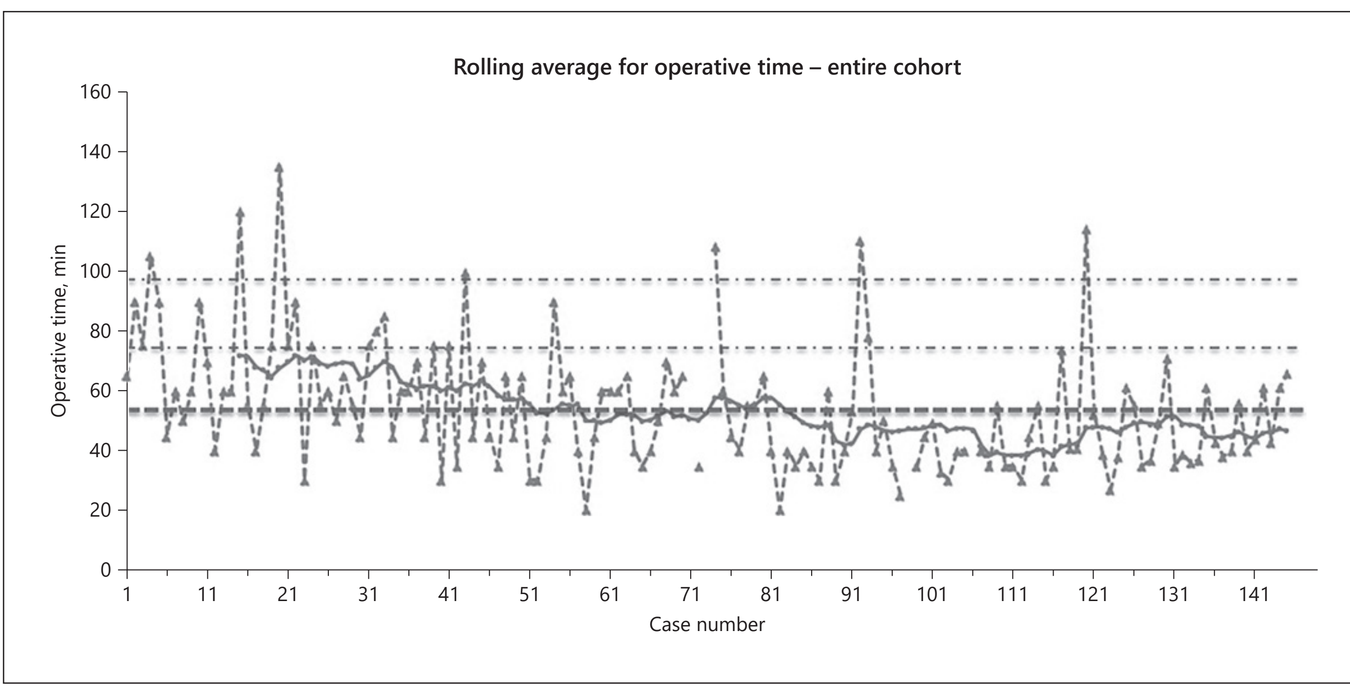

Fig. 6. Rolling averages for operative time. Dotted line: actual operative time for each case. Solid line: rolling average over a 10-case interval. The dashed horizontal line is the average operative time for the entire cohort (53.6 min). The 2 dash-dotted lines represent 1 and 2 standard deviations above the mean, respectively.

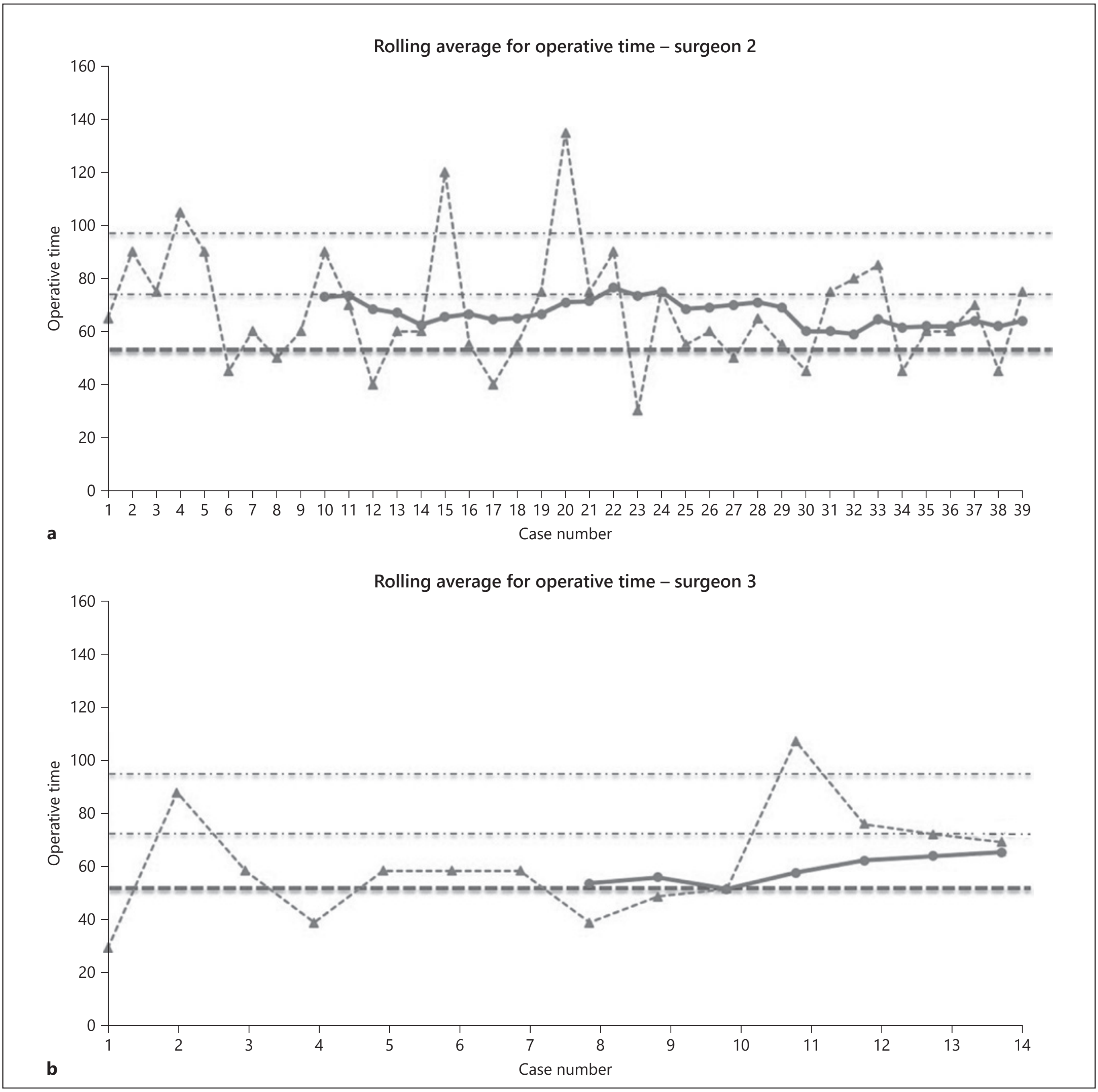

Fig. 7. Rolling averages for operative time, surgeons 2 (**a**) and 3 (**b**). Dotted line: actual operative time for each case. Solid line: rolling average over a 10-case interval. The 2 dash-dotted lines represent 1 and 2 standard deviations above the mean, respectively.

the inclusion of all consecutive laser ablation cases for analysis. We used survival of at least 1 twin, overall survival, operative time, and number of vessels lasered as surrogates for proficiency; we elected not to use accuracy and completeness of laser therapy based by placental analysis because of a substantial number of missing data (as a regional reference center, many of our patients deliver elsewhere and placentas are often not made available). The reproducibility of survival and operative time data may have rendered placental data superfluous as well.

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The weaknesses include the relatively low annual frequency of cases performed, which limits overall statistical analyses of outcomes other than twin survival and operative time. However, this factor is fundamental to the purpose of performing this study and is common across institutions.

Examining a 2-decade experience also introduces the question of consistency. The results of the Eurofetus study [12], which were reported in 2004, have been updated by most centers worldwide. Survival of at least 1 twin was 76% in 2004; by 2010, the average survival of at least 1 twin in a systematic review was 81% [14]. Today, most centers report a higher survival rate still (including ours, at 89%). This represents the "global" learning curve, which may be due to multiple factors, including a fine-tuning of the surgical approach and the operative indications as well as a better understanding of the disease. For our center, this is represented in Figure 5, which shows a gradual increase in survival over 20 years. However, the goal of this study was not to show improvements over 2 decades, but the consistency of results from year to year and from operator to operator. In that sense, it was appropriate to utilize 2004 data as a benchmark for our center's initial learning curve.

As the field of fetal surgery looks to the future, collaboration and cooperation between services involved in the care of pregnant patients and their offspring are essential to the growth of the field and the training of future practitioners. The Fetal Treatment Program of New England has supported collegial collaboration from its inception and views these partnerships as the key to the maintenance of strong outcomes for our program now and in the future.

Statement of Ethics

The research was conducted in accordance with the World Medical Association Declaration of Helsinki. The study was approved by the Institutional Review Boards of Rhode Island Hospital (Hasbro Children's Hospital) and Women & Infants Hospital of Rhode Island. Institutional Review Board approval at Rhode Island Hospital/Hasbro Children's Hospital was obtained (Approval #1469634-1). No written or verbal patient consent was required due to the retrospective nature of the study.

Conflict of Interest Statement

The authors do not have conflicts of interests to declare.

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The authors did not receive any funding.

Author Contributions

A.C.: study concept, collection of data, calculations of CUSUM and rolling averages, and manuscript preparation. E.J.R.: study concept and manuscript preparation and review. D.W.S.: study concept, collection of data, Institutional Review Board submission, and manuscript review. S.R.C.: study concept and manuscript review. F.I.L.: study concept, statistical assistance, manuscript preparation, and manuscript revision.

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