

The Learning Curve of an Absorbable Subcuticular Stapling Device in Plastic and Reconstructive Surgery

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Background: Learning curves can reflect a surgical trainee's rate of progress and competence in acquiring new skills. The INSORB subdermal staple device has been well established to facilitate decreased closure time across various surgical procedures, with similar cosmesis, healing, and consistency as those of standard subdermal sutures. This study is unique, as it demonstrated an observable learning curve with this device when used by a junior surgeon.

Methods: Sixty-six patients underwent a cosmetic procedure during the second half of 2019 under the care of a single plastic surgeon in Melbourne, Australia. This corresponded to 254 unique linear incisions. Subdermal closure was done either with interrupted 3-0 Monocryl sutures or with the INSORB device. The consultant closed the incisions on one side, with the contralateral incision closed by the assistant using the same closure method. Data were then compared retrospectively, and closure times were compared over the ensuing 6 months.

Results: Overall, consultant closure speed is 25% faster than assistant speed. When using 3-0 Monocryl, the difference is 33%, whereas the difference is reduced to 21% when using the INSORB. Furthermore, a mild learning curve could be appreciated with the assistant's use of the INSORB over the comparatively short 6-month study period.

Conclusions: In addition to improved speed, cost, outcome, and ergonomics, subdermal absorbable staples may also garner a faster learning curve than standard closure with 3-0 Monocryl. This study supported the learning curve of a surgical device as another innovative benefit and an important aspect of developing surgical technology. (*Plast Reconstr Surg Glob Open* 2022;10:e4263; doi: 10.1097/GOX.0000000000004263; Published online 25 May 2022.)

INTRODUCTION

Within plastic and reconstructive surgery, skin closure is a critical component, if not the most crucial aspect of patient satisfaction, and reflective of the treating surgeon's expertise, eye for detail, and respect for patient care. Paramount in the subspecialty of aesthetic surgery, the scar left by a procedure must be modest. Of course, it should be mentioned that scar quality also depends on various patient characteristics and operative technique. Techniques and, particularly, devices to assist with this important aspect are of moderate utility.

The INSORB absorbable subcuticular stapler (Incisive Surgical Inc., Plymouth, Minn.) is such a device, which deploys U-shaped absorbable staples into the dermal layer of tissue. A double-headed Adson forceps is used in conjunction with the stapler to ensure proper skin eversion. INSORB staples are prepared from an absorbable copolymer of polylactic acid (70%) and glycolic acid (30%) and are similar in composition to that of 3-0 Monocryl absorbable monofilament sutures (Ethicon, Somerville, N.J.) and, therefore, are an identical alternative.

This device is very familiar in our field, and the efficacy of this device is well established.¹ Within cosmetic surgery, the use of this device has been established in breast and facial rejuvenation,²⁻⁴ and within reconstructive procedures, it has been proved effective for efficient closure of donor sites.⁵ The application of this device extends to other surgical specialties mainly in obstetric, general, and orthopedic cases.^{6,7} Interestingly, the use of this device is less efficacious in vascular surgery.⁸ There are unique advantages of this device as well that have been described

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in the literature, such as decreased risk of infection in contaminated wounds.⁹

Learning curves are commonly used in statistical processes to understand the improvement of iterative procedures over time.¹⁰ Surgical learning curves have been described but more so related to the number of cases to acquire proficiency in a particular procedure.¹¹ Of course, a junior surgeon's improvement is much more complex and challenging to measure than machine learning. This is due to the main work being performed on patients, where complications are less tolerable and heavy supervision in the earlier phases of learning is vital. The idea of a surgical learning curve with a particular device, technique, or principle has not yet been determined in the broader literature.

To apply this idea further, we are in a time of rapid development of surgical technology. Such technology must go through rigorous theoretical, animal, and then human testing before being available publicly. Before this, primary key performance indicators are operative time, patient outcome, and ultimately, surgical cost. If a learning curve was demonstrable in addition to these factors, this would potentially accelerate the development of a new surgical device. The application of a learning curve to a new surgical device is relatively simple compared with that of a particular surgical procedure, such as that to learn reduction mammoplasty.

This study's initial objective was to determine whether there is a difference in total operative time with absorbable subcuticular staples compared with standard absorbable subdermal suture. However, this improvement is widely discussed in the literature, both in plastic surgery and in other surgical specialties. Almost all of these previous studies tested this device in a consultant surgeon's hands to determine the increased closure speed and a corresponding reduction in surgical cost. This study's primary objective was to investigate whether there was a considerable difference in using this device, between a senior consultant surgeon and a junior surgical assistant at the level of registrar compared with standard closure with interrupted 3-0 Monocryl.

METHODS

During the second half of 2019, 66 patients underwent a cosmetic procedure under the senior author's care (R.B.) in Melbourne, Australia. All procedures were elective and included breast reduction, abdominoplasty, brachioplasty, back lift, buttock lift, and body lift. As such, incisions were on the breast, abdomen, arm, thigh, back, and buttock. This corresponded to 254 unique linear incisions. Patients undergoing breast reduction would have additional vertical incisions as per an anchor pattern or Wise pattern incision.¹² There was an even mix of right-sided and left-sided incisions.

The plastic surgeon would have a rotating roster of two junior surgical assistants with experience in plastic surgery. The consultant surgeon closed the incisions on one side, with the contralateral incision closed by the assistant using the same closure method. All procedures

Takeaways

Question: INSORB is already established to facilitate decreased closure time across various surgical procedures. A unique aspect of this study is that it demonstrates an observable learning curve with this device when used by a junior surgeon.

Findings: A mild learning curve could be appreciated with the assistant's use of the INSORB over the 6-month study period.

Meaning: This study supports the learning curve of a surgical device as another innovative benefit of developing surgical technology.

were performed under general anesthesia. Subdermal skin closure was performed with a standard interrupted undyed 3-0 Monocryl suture on a PS-2 needle, starting and finishing with a buried knot at each end. Subdermal staple closure was performed by a single operator in a technique described by the manufacturer's instruction manual, with skin edges opposed by the provided double Adson forceps. A further layer of continuous subcuticular closure with a running 4-0 Monocryl suture was performed in both cases. At our institution, only individuals with private medical insurance are approved for closure with the INSORB device; therefore, insurance status would determine whether a wound is closed with Monocryl or by using the described device.

The circulating nurse recorded skin closure time (in minutes), based on when the surgeon declared the incision's commencement and closure. Timing of closure began with the placement of the first deep dermal suture or dermal staple and ended when the second subcuticular layer with continuous 4-0 Monocryl was complete. Other demographic data, including age at procedure, gender, and insurance status, were also recorded. This information was then entered into a Microsoft Excel spreadsheet and analyzed retrospectively by Shaani Singhal.

Fortunately, in this study, all patients were in otherwise good medical health before the procedure, and no exclusions were necessary. This was determined at the preoperative consult and a clinic nurse assessment the week before the procedure. Comorbidities that interfere with cutaneous healing, such as active infection, long-term pharmacological steroid therapy, and immunodeficiency, would be important criteria for exclusion in these studies. No incentives or financial support were received from the manufacturers, and both closure methods are currently accepted standards of care.

This review primarily looks at closure time as a simplistic measure of this objective and was compared retrospectively. Additional follow-up data, including postoperative pain, scar quality at postoperative clinic review, wound complications, cosmesis, patient satisfaction, and overall hospital cost, were not recorded at reliable standard at intervals as per the retrospective nature of the review. These factors were, therefore, not described in this review. This study was conducted in accordance with the

National Health and Medical Research Council Ethical Considerations in Quality Assurance and Evaluation Activities (2014) guideline.¹³

RESULTS

One patient may have more than one procedure, and one procedure may have multiple incisions. Hence, results are numbered by incision. Of the 254 incisions, 240 were women, and 14 were men, with the average age being 40 (19–71) at the time of the procedure. A total of 129 incisions were closed by a consultant, and the other 125 were closed by the assistant. The INSORB was used for closure in 125 patients and standard 3-0 Monocryl in 129 patients. The primary procedures were breast reduction, abdominoplasty, back lift, brachioplasty, body lift, abdominal scar revision, and thigh reduction. These demographic data are summarized in [Tables 1](#) and [2](#).

The average incision length across the entire study was 21.1 cm (5–45), with an average closure time of 16.6 minutes (3–47), including the second subcuticular layer. This corresponds to an average speed of 1.4 cm per min for the entire study. Incisions closed with INSORB averaged 1.5 cm per min (0.6–3.7). When closed with the 3-0 Monocryl, the average speed was 1.1 cm per min (0.4–2.0). When closed by the consultant, the average speed was

1.5 cm per min (0.4–3.7). When closed by the assistant, the average speed was 1.2 cm per min (0.5–2.6). These data are shown in [Tables 3](#) and [4](#).

[Table 5](#) shows the question of the current study. The consultant using the INSORB would average a closure speed of 1.7 cm per minute (0.9–3.7) compared with 1.4 cm per minute (0.6–2.6) when an assistant used the same device. Similarly, the consultant using 3-0 Monocryl would average a closure speed of 1.2 cm per minute (0.4–2.0) compared with 0.9 cm per minute (0.5–1.6) when an assistant used the same closure method.

Notably, a comparison can now be made. Overall, a consultant is 25% faster than the assistant (1.5 cm/min versus 1.2 cm/min). When using 3-0 Monocryl for subdermal closure, this difference is 33% (1.2 cm/min versus 0.9 cm/min). However, when using INSORB, this difference is reduced to 21.4% (1.7 cm/min versus 1.4 cm per min). Therefore, the difference between a consultant and assistant using INSORB is much narrower than that between a consultant and assistant using 3-0 Monocryl, suggesting a shorter time to improvement.

[Figure 1](#) shows all four graphs, which are separated into individual graphs ([Figs. 2–5](#)). An attempt was to observe the improvement in rate with the number of cases over the ensuing 6 months. To appreciate a possible learning curve, the graphs using Monocryl ([Figs. 2](#) and [3](#)) show a relatively stable rate over the last 6 months. Interestingly, the graphs using INSORB ([Figs. 4](#) and [5](#)) demonstrate a slight learning curve over 6 months.

Table 1. Summary of Demographics

Parameter	No.
Total	254 (100.0%)
Age, y	40 (19–71)
Women	240 (94.5%)
Men	14 (5.5%)
Level of operator	
Consultant	129 (50.8%)
Assistant	125 (49.2%)
Closure method	
3-0 Monocryl	129 (50.8%)
INSORB	125 (49.2%)
Laterality of incision	
Right sided	123 (48.4%)
Left sided	131 (51.6%)
Procedure	
Breast reduction	90 (35.4%)
Abdominoplasty	79 (31.1%)
Back lift	30 (11.8%)
Undescribed	17 (6.7%)
Body lift	16 (6.3%)
Brachioplasty	12 (4.7%)
Thigh reduction	6 (2.4%)
Abdominal scar revision	4 (1.6%)

Table 2. Range of Incisions by Location

Location	No.	Average Length (cm)
Abdomen	83 (32.7%)	27.1 (17–40)
Horizontal breast	54 (21.3%)	19.7 (6–29)
Vertical breast	43 (16.9%)	7.0 (5–22)
Back	32 (12.6%)	22.6 (18–26)
Arm	14 (5.5%)	33.4 (25–45)
Undescribed	12 (4.7%)	20.1 (5.5–28)
Thigh	10 (3.9%)	20.7 (11–35)
Buttock	2 (0.8%)	21.5 (21–22)
Hip	2 (0.8%)	14.75 (11–18.5)
Lateral Chest	2 (0.8%)	18.5 (18–19)
Total	254 (100.0%)	21.1 (5–45)

DISCUSSION

New procedures and techniques are continually being developed, with an associated period of learning and familiarity by the operating surgeon. Each of these procedures and techniques, therefore, comes with an intrinsic learning curve. The learning curve is an important factor when taking on a new innovation and would be an interesting outcome when assessing the efficacy of new technology in addition to speed, cost, and outcome. Such a benefit is rarely discussed in the literature with regard to a device, and even less so in the promotion of such a device.

Consultant Monocryl closure was 33% faster than assistant Monocryl closure. This decreases to 21% when the INSORB is used. In addition to overall closure time, when graphed over the 6 months, one cannot ignore, however, as the trend lines for Monocryl closure in both clinicians are relatively stable, there is a slight logarithmic curve in the trend lines for INSORB closure. This result poses an additional benefit to the use of the INSORB stapling device. Also, the reduction in difference from 33% to 21% attests that experience is less of an influencer in the use of this closure method, and therefore empirically less complex. Accounting for this difference, barriers to the learning largely revolve around the concurrent use of double-headed Adson forceps to achieve adequate eversion of skin edges. Furthermore, an average closure speed improvement was observed over 6 months when an assistant used the device. The significance of this latter observation, however, is indeterminate.

Table 3. Comparison of Closure Device

	INSORB	3-0 Monocryl	Average/Total
Age	41 (22–71)	38 (19–66)	40 (19–71)
Men	14	0	14 (5.5%)
Women	142	98	240 (94.5%)
Incision length	22.0 (5–45)	19.8 (5–30)	21.1 (5–45)
Closure time	15.1 (3–47)	19.0 (4–47)	16.6 (3–47)
Speed (cm/min)	1.5 (0.6–3.7)	1.1 (0.4–2.0)	1.4 (0.4–3.7)
Total	156 (61.4%)	98 (38.3%)	254 (100.0%)

Table 4. Comparison of Level of Operator

	Consultant	Registrar	Average/Total
Age	40 (19–71)	40 (19–71)	40 (19–71)
Men	8	6	14 (5.5%)
Women	121	119	240 (94.5%)
Incision length	20.1 (5–42)	21.4 (5–45)	21.1 (5–45)
Closure time	14.2 (3–31)	19.1 (3–47)	16.6 (3–47)
Speed (cm/min)	1.5 (0.4–3.7)	1.2 (0.5–2.6)	1.4 (0.4–3.7)
Total	129 (50.8%)	125 (49.2%)	254 (100.0%)

Table 5. Comparison of Combinations of Closure Device and Level of Operator

	Consultant INSORB	Registrar INSORB	Consultant 3-0 Monocryl	Registrar 3-0 Monocryl	Average/Total
Age	41 (22–71)	41 (22–71)	38 (19–66)	37 (19–62)	40 (19–71)
Man	8	6	0	0	14 (5.5%)
Women	70	72	51	37	240 (94.5%)
Incision length	21.8 (5–42)	22.1 (5–45)	19.3 (5–30)	20.3 (5–30)	21.1 (5–45)
Closure time	13.2 (3–24)	17.0 (3–47)	15.7 (4–31)	22.6 (6–47)	16.6 (3–47)
Speed (cm/min)	1.7 (0.9–3.7)	1.4 (0.6–2.6)	1.2 (0.4–2.0)	0.9 (0.5–1.6)	1.4 (0.4–3.7)
Total	78	78	51	47	254 (100.0%)

An observation of this study is that consultant Monocryl closure was observed to slightly decrease with the number of cases within the study period. It is difficult to justify this discrepancy; however, one potential reason would be the bias inherent to the time of the study and the relatively short number of cases. Another reason is that the surgeon has surpassed the time needed to achieve proficiency in this method, and therefore, this 6-month snapshot rather reflects a fluctuation in closure time rather than a genuine decline in closure speed. It is actually very important to mention; however, given the role of the assistant is to assist, more difficult and complex wounds are closed by the consultant, whereas easier wounds are closed by the assistant. The difficulty of a wound closure would be an interesting input parameter.

There are a few unique aspects of this study. Faster closure speed with INSORB is well established; this study looks at the learning curve by comparing the use of the device with operators of different expertise.^{6,8,14} Importantly, this is a real-world study in that patients are selected for the closure device based on factors outside of surgeon preference. Studies in this field tend to look at a single surgeon closing all incisions with either modality to demonstrate the product's efficacy for marketability. This study considers the varying experience of the operator closing the incision and the decision to use a particular closure method based on insurance status and actual circumstance rather than randomization, which is much more realistic in clinical practice.

There are some limitations to this study. Generic limitations include the small subgroup size despite the moderate overall sample size of over 250 incisions. There is also a relatively short sample time; more extensive studies are prospective over 12 months. Moreover, the rotating roster of separate surgical assistance skews the learning curve by half and may suggest that a more substantial learning curve could be appreciated if the data were of one surgical assistant. Other ergonomic factors that could have been included are laterality of incision, the impact of operator right- or left-handedness, and the effect of a standard number of subdermal staples or sutures.

One significant limitation is the primary outcome of closure time. Choosing a primary outcome of wound complications may have been more clinically relevant, and a primary outcome of cosmesis may have been more patient-centered. Albeit, wound healing, patient satisfaction, scar quality at follow-up, and impact on hospital cost are well established and discussed in other review articles. The aim of the current study was not to reestablish such outcomes, but rather to observe the described learning curve, which should indeed be considered when developing and promoting new surgical technology.

When evaluating new technologies, one interesting source of bias is “gizmo idolatry”: the unquestioning or unfounded belief in new procedures, drugs, or devices. This misdirected enthusiasm has the potential to drive widespread acceptance of technology before superiority is documented. The novelty of a new device can bias

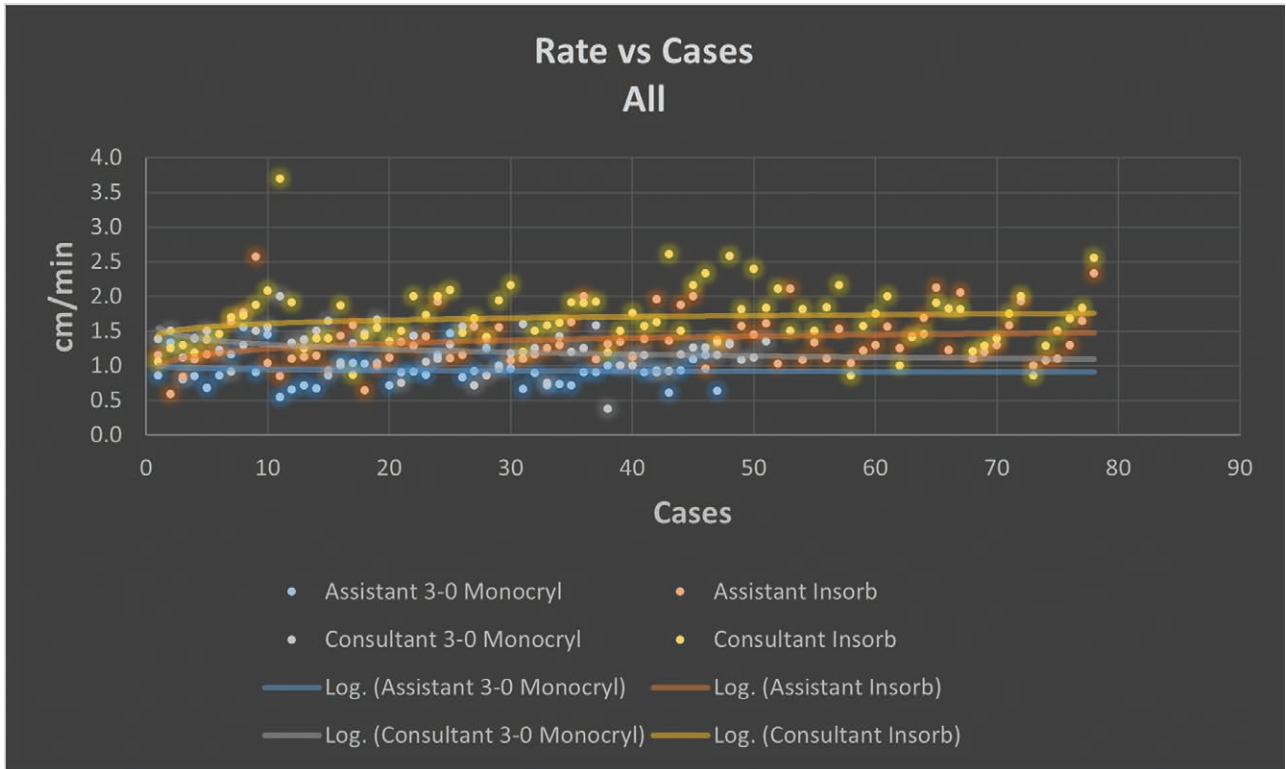


Fig. 1. Comparison of combinations of closure device and level of operator.

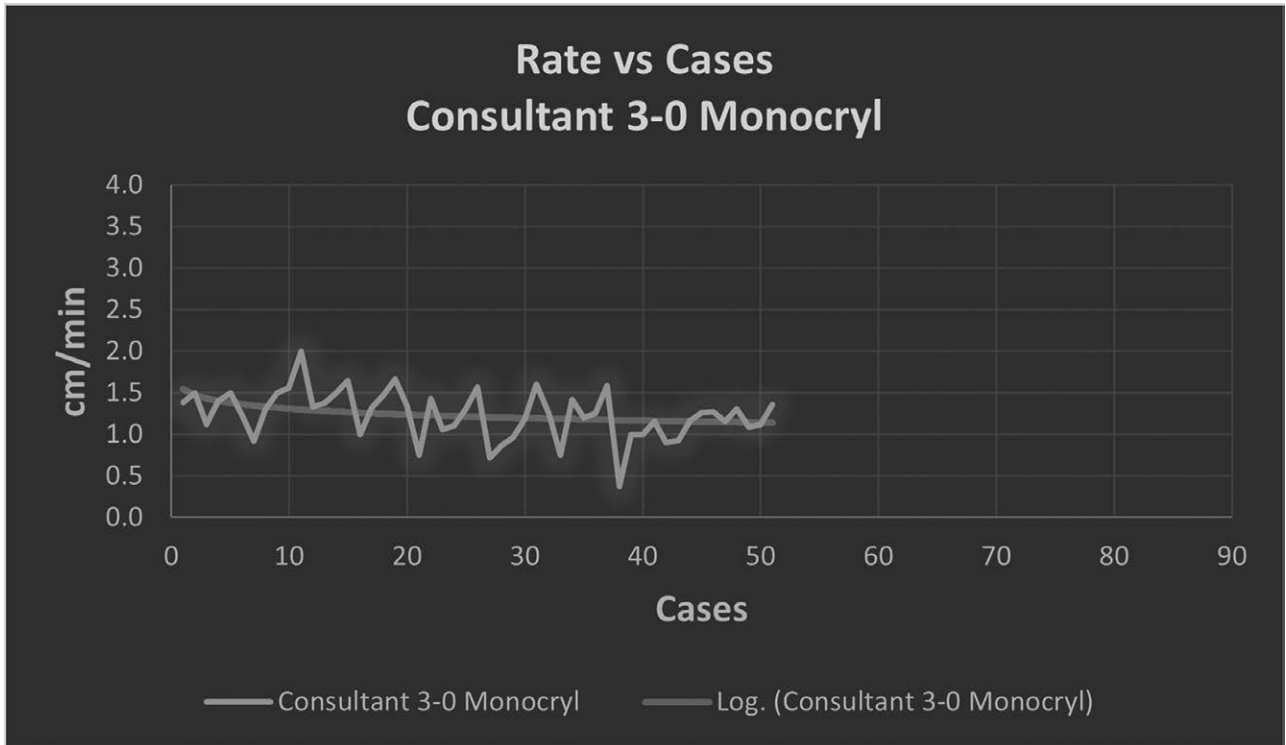


Fig. 2. Graphical representation of consultant and 3-0 Monocryl.

the surgeon either negatively (resistance to change) or positively (impressed by the novelty).¹⁵ Examples include

extensive adoption of frontal lobotomy and Swan-Ganz catheters, despite a lack of evidence of benefit.

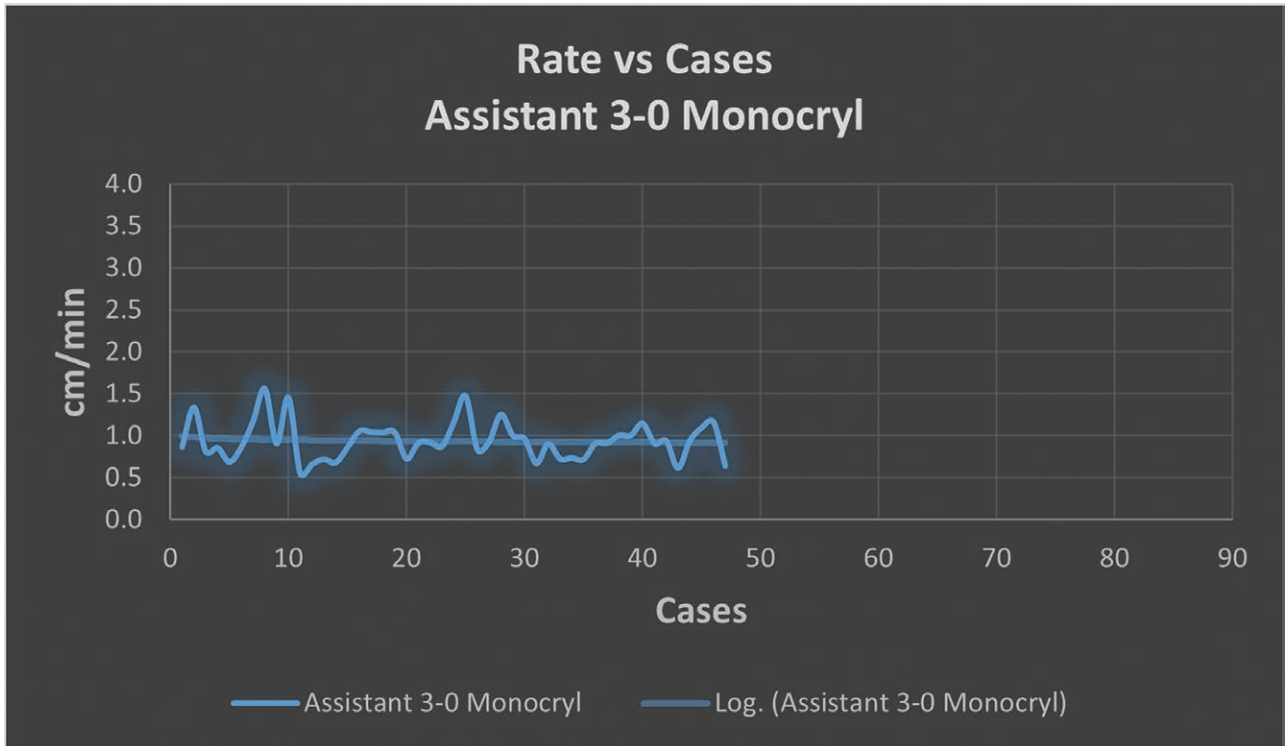


Fig. 3. Graphical representation of assistant and 3-0 Monocryl.

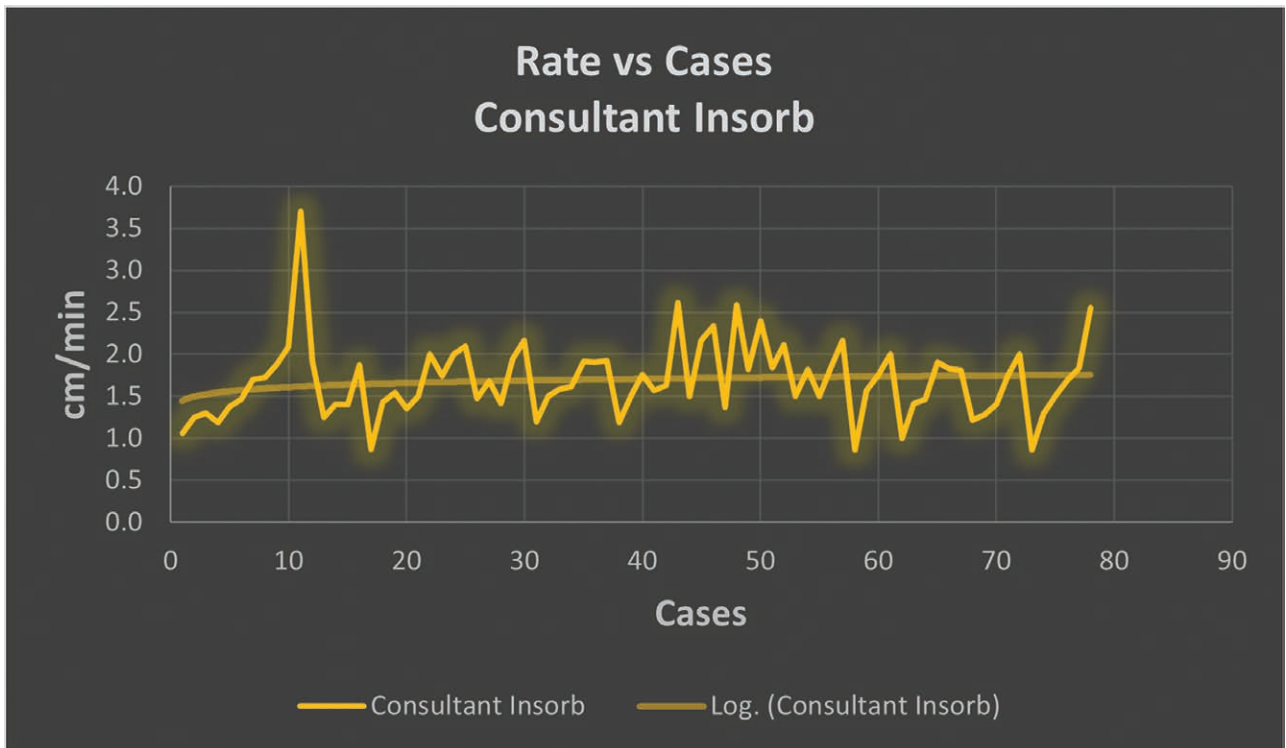


Fig. 4. Graphical representation of consultant and INSORB.

The importance of the study is not so much that their learning curve is faster with the device, but at least observable. This means that, when developing new surgical

technology, the ability to understand and use the device in an adequate time period forms an important component toward its development. One may wonder about the

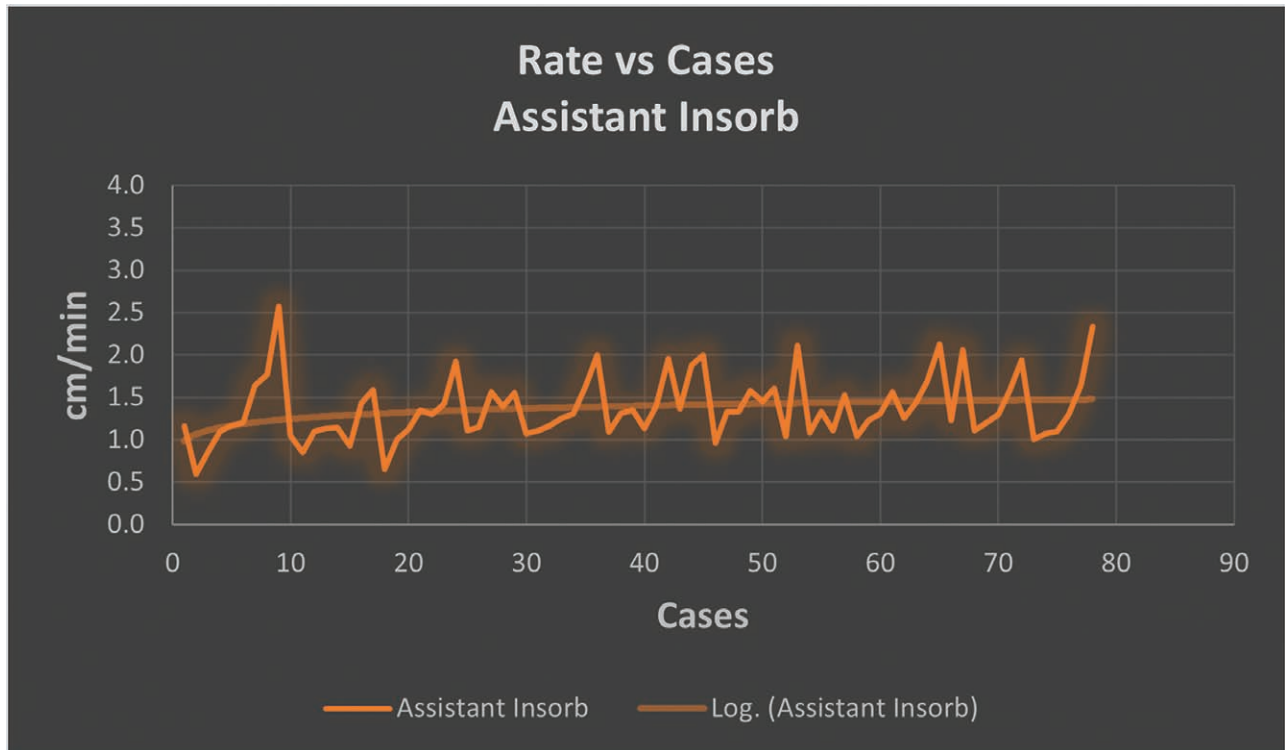


Fig. 5. Graphical representation of assistant and INSORB.

impact of a dedicated training course for the device would have on the curvature of the learning curve for this and other devices. Furthermore, one last aspect of this study is that a comparison was not made between wound closure time and the overall surgical operating time. Of course, a minute saved in operating time in comparison with a procedure that takes several hours may not be significant. This comparison is not made, as the closure time is relative to wound length, yet wound length is largely irrespective of operative time. Some procedures may take quite some time yet have small wounds such as major laparoscopic procedures, in which gains in wound closure time are less significant. Conversely, some procedures may be relatively faster yet have larger wounds, and therefore, wound closure has a larger effect on operative time. Our cohort falls into the latter, given that the procedures do not involve structures deeper than the fascia. A dedicated review of operating times can be used to supplement these data in other specialties for future studies; however, given the retrospective nature of the current study, these data are not available or measured.

Finally, it is essential to mention that with experience, there is also an understanding of when not to use the proposed surgical technology. Correct placement of the staple in the dermal layer requires adequate dermal layer thickness, and contraindications for treatment with INSORB staples are related to cutaneous thickness and quality. For example, skin with stretch marks that are too thin for sufficient binding would benefit from the placement of standard sutures instead of staples. Those with skin thinning, such as

the elderly or chronic corticosteroid users, are not appropriate candidates for this device. As subsequent generations of this device emerge, technical improvements will accommodate differences in skin thickness across various incisions and procedures on different body regions. These refinements can translate into improvements in closure time, post-operative recovery, patient satisfaction, and cosmesis.

CONCLUSIONS

This study evaluates the closure speed of the INSORB stapling device when comparing its use between a consultant and the assistant. A difference was observed in the overall rate of closure with the use of this device compared with standard 3-0 Monocryl subdermal closure. Interestingly, it suggests a measurable learning curve that could be observed with such a device. This unique aspect, as primary outcome when developing a new surgical technology, is indeed valid and will contribute greatly to our field.

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