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Research Article

Controlled Release Needles versus Swaged Needles on Subdermal Wound Closures: A Pilot Study

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Abstract

Purpose: to compare suture time and closure quality of a swaged-on needle versus a Controlled Release needle (CR) for a better wound closure to achieve efficient and cosmetically pleasing outcomes.

Methods: Eight midlevel and senior orthopaedic residents performed a seven-centimeter wound closure onporcine skin with both suture types. Closures were timed, and an image was captured on each specimen. Evaluations of images were conducted by threeboard certified orthopaedic surgery faculty on aspects of closure quality and overall pass/fail measures.

Results: Mean time to closure differed significantly by needle type: CR time was 225.7 seconds, 95% CI (205.1, 246.3), whereasswaged was 265.8 seconds, 95% CI (242.3, 289.2); p = 0.011. Interrater agreement showed no statistical difference for closure quality, except forknot visibility where the swaged-ontype had more reports of no knot visualization. Evaluations for pass/fail ratesdid not find statistical difference between needle types.

Conclusions: This study demonstrates that wound closure procedures utilizing controlled release needlesare significantly faster and provides similar outcomes. Future studies should evaluate potential cost savings using this method.

Keywords: Wound closure; Control release needle; Pop-off; Swaged-on needle

Introduction

Wound closure, a critical step for surgeons in all specialties, allows the skin to heal appropriately and provides a barrier between surgical repair and the environment. However, wound complications may occur with improper closure. For example, animal studies show that increased tension on a wound would lead to a wider scar and worse cosmesis [1]. Complications of wound closures may appear immediately or can be delayed (causing scar formation and wound necrosis, among others). Immediate complications include formation of hematomas or development of wound infection. Improper wound closure can be devastating if infection spreads to the deep operative site.

The ideal wound closure should be cost-effective, time-efficient, manageable, and achieve optimal cosmetic outcomes. Many studies have been conducted to evaluate best practices; however, the time to suture a wound is usually overlooked. If good wound closures can be done efficiently, it would lessen the surgery time thatin turn decreases morbidity related to anesthesia and surgery and lowers the cost of operations. Selection of suture material and needle type may impact quality, efficiency, and outcome for wound closures.

Polyglactin 910 suture (Vicryl Rapid, Ethicon Inc, Somerville, NJ) is commonly used to close the subdermal layer prior to final skin closure. Al-Mubarak and Al-Haddab compared types and report this suture is synthetic, multi-filamentous, braided, absorbable, and with a tensile strength of 75% at 14 days, reduced to 50% at 21 days [2]. Reported beneficial properties include good ease of handling, fair knot security, and low tissue reactivity. Although, they also state that braided sutures, in general, incur more infections than non-braided types.

Polyglactin 910 sutures are available with a controlled release (CR) needle (or "pop-off") and the commonly used swaged-on needle. The CR is needle and suture contained in one unit that may be separated by means of a light pull on the needle (held with a needle holder) of approximately 1 to 56 ounces [3,4], allowing the surgeon to tie or close the wound without a needle remaining on the end of the suture. The release of the needle is accomplished by the design of the swage withlower compression forces, allowing for easier removal of the needle [5]. One of the advantages of the CR suture over swaged-on is to allow for uninterrupted suturing. Some surgeons find that CR suture is simpler and faster than using a needled item that requires cutting of the suture after each pass. Thus, CR may reduce the time that a surgical patient must spend in the Operating Room (OR).

One school of thought supports that CR suture is more efficient, while another viewpoint posits it is too cost prohibitive compared to the common suture with the needle swaged on. To our knowledge, there is scant literature substantiating the benefit and necessity of using CR sutures over swaged on needles. Although, some studies show little difference by suture type. For example, in a study of midline incision in the knee, there was no difference in type of closure done between a simple vertical mattress and semi-subdermal suturing technique [6].

The specific aim of this pilot study wasto compare surgical wound closures, carried out on fresh porcine skin, using CR needles versus swaged on needles. Both suture time and closure quality were evaluated for each specimen. We hypothesized that procedure with CR needles wouldtake less time than swaged-onneedles but with equivalent closure quality. Results of this study wouldbe used for a larger study to further delineate the overall quality, efficiency, and potential forcost savings between these closure methods.

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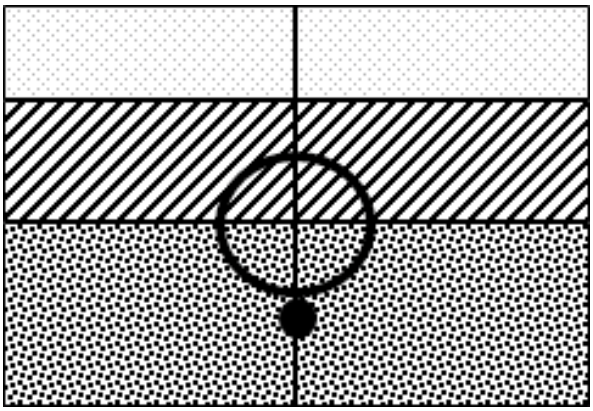
Methods

Eight orthopaedic surgery residents (four PGY-3 and four PGY-5) with wound closure experience were recruited to conduct 80 wound closures on specimens of fresh porcine skin. Three board certified orthopaedic surgery faculty were also recruited to rate the quality of wound closures on all specimens. Approval of this study design was obtained from the Institutional Review Board (IRB) at Via Christi St. Francis Hospital.

To prepare the porcine skin, a longitudinal 7 cm incisionwith 3 perpendicular reference lines was made on each specimen. In a timed event, each resident closed the wound with 2-0 polyglactin 910 CT-1 needles; five procedures were with controlled release (pop-off) needles and five were with swaged-on needles. All residents closed the incision using a simple subdermal suture fashion starting with the reference lines, proceeding fromthe proximal end of the incision to the distal end, followed by a buried knot. The subdermal closure was chosen because of its frequentuse during surgery (Figure 1). A surgical assistant was there tocut the suture after every stitch and to prepare the controlled release needle for use between stitches, to mimic OR procedures. Start and stop time for wound closure was measured and recorded on each specimen. Upon completion, a ruler was placed on the specimen for reference (minimal tension was exerted on the wound closure), and a front view pictureswere captured (Figure 2). All the captured outcome pictures were numbered for the examiners to evaluate in a blindedfashion.

To evaluate quality of the wound closure, each specimen was rated once by the three board-certified orthopaedic surgeons. Specimens were randomized prior to evaluation by the examiners. To rate closure quality, a 5-point, Likert-type scoring system that was based on criteria to evaluate medical student closures was used [7] (Table 1). Five types of evaluations were performed: 1) tissue edge approximation, 2) suture spacing, 3) suture alignment, 4) knot visibility, and 5) overall closure quality. Surgeons also provided an overall pass/fail judgement for each specimen.

Statistical analysis (IBM SPSS version 23, Chicago, IL) was performed to compare the closing outcomes by suture types. The distribution of continuous data was assessed by the Kolmogorov-Smirnov test. Results showed that data were symmetrical, bell-shaped, and did not depart significantly from the normal distribution. To evaluate mean differences the *t*-test for equality of means was conducted. Likert-type scales were summarized with frequencies and percentages. Fisher's exact test was used to compare suture types, including overall pass/fail rates. Interrater agreement was evaluated in accordance with the Guidelines for Reporting Reliability and Agreement Studies [8], Agreement for dichotomous data was measured with the Fleiss kappa and Cochran's Q; while Kendall's W and the Friedman testswere used for ordered data.To determine the extent to which the three raters agreed, the following categories were used for with the results of kappa and W: <0 poor, 0.0-0.20 slight, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 substantial, 0.81-1.0 almost perfect. A p value of less than 0.05 ($p<0.05$) was considered as statistically significant difference.



The grey dots represent the epidermis, the diagonal section represents the dermis, and the black dots represent the subcutaneous tissue.

Figure 1: Schematic representation for simple subdermal suture fashion.

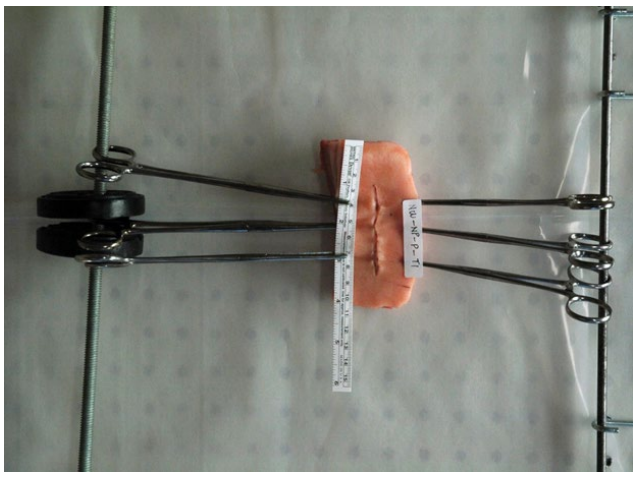


Figure 2: Image analysis of wound closure evaluation with 5 N (1 lbs) load.

Results

Data suggested that there was asignificantly less time to close the wound when using CR needles with a mean time of 225.7 seconds, 95% CI (205.1, 246.3). In comparison, an average time of 265.8 seconds, 95% CI (242.3, 289.2) was recorded for the procedures using swaged-on needles ($p = 0.011$). Table 2 shows comparisons for the five evaluations plus the pass/fail judgement by suture type. With exception of knot visibility, there were no statistically significant differences between the CR and swaged on needle. The swaged-on needle was more often reported in the "No visualization" category as compared with the CR needle 61.7% vs. 44.2%, respectively ($p = 0.003$).

Results for evaluatingwound closures were inconsistent across raters; Kendall's W ranged from 0.008 to 0.387 for CR and 0.018 to 0.289 for swaged on, indicating poor to fair agreement among raters (Table 3). Regarding pass/fail evaluation of specimens, kappa = 0.304, indicating fair agreement among raters. However, scores appeared to differ significantly for the swaged-on needles, indicating that raters differed on the number of specimens judged as passing (22 of 40 for R1 versus 35 of 40 for R3); $p < 0.001$.

Discussion

This study demonstrates that wound closures with CR needlesare significantly faster thanswaged on needles. These data provide evidence to support our future study, where we plan to examineoverall quality, efficiency, and potential for cost savingsbetween these closure methods.

When comparing the closure evaluations, there was no statistically significant difference in outcomes except for knot visibility. Given

Table 1: Five-point scoring sheet for wound closure quality.

Evaluation	1	2	3	4	5
Tissue approximation	Very poor		Competent		Excellent
Suture spacing	> 3 cm apart		2 cm apart		Within 1 cm apart
Suture alignment	> 45 degree off from incision		> 30 degrees off from incision		Perpendicular to incision
Knot visibility	Clear visualization		Partial visualization		No visualization
Overall closure quality	Very poor		Competent		Excellent
Overall, on this task, should this candidate:				Pass	Fail

Table 2: Comparison of wound closure evaluation between needle types.

	Needle type				
	Controlled Release		**Swaged-on**		
Description	**n**	**%**	**n**	**%**	**p***
Tissue approximation					0.256
Very poor	3	2.5	11	9.2	
Poor	34	28.3	32	26.7	
Competent	38	31.7	32	26.7	
Satisfactory	30	25	28	23.3	
Excellent	15	12.5	17	14.2	
Suture spacing					0.109
> 3 cm apart	0	0	3	2.5	
3 cm apart	4	3.3	0	0	
2 cm apart	31	25.8	27	22.5	
1 cm apart	58	48.3	65	54.2	
< 1 cm apart	27	22.5	25	20.8	
Suture alignment (degree off incision)					0.063
> 40 degrees	0	0	2	1.7	
> 30 degrees	2	1.7	9	7.5	
> 20 degrees	18	15	19	15.8	
> 10 degrees	55	45.8	41	34.2	
Perpendicular to incision	45	37.5	49	40.8	
Knot visibility					0.003
Clear	15	12.5	19	15.8	
Partial	52	43.3	27	22.5	
No visualization	53	44.2	74	61.7	
Overall closure quality					0.111
Very poor	4	3.3	10	8.3	
Poor	30	25	30	25	
Competent	45	37.5	34	28.3	
Satisfactory	33	27.5	29	24.2	
Excellent	8	6.7	17	14.2	
Candidate pass or fail					0.999
Pass	88	73.3	87	72.5	
Fail	32	26.7	33	27.5	

* Fisher's exact test

Table 3: Examiners agreement and reliability between needle types.

	CR (mean ranking)			Friedman		Swaged on (mean ranking)			Friedman	
Rater	**R1**	**R2**	**R3**	**p**	**Kendall's W**	**R1**	**R2**	**R3**	**p**	**Kendall's W**
Alignment	2.11	1.59	2.30	<0.001	0.210	1.73	1.80	2.48	<0.001	0.227
Knot visibility	2.00	1.94	2.06	0.732	0.008	1.68	1.94	2.39	<0.001	0.270
Overall closure	2.04	2.15	1.81	0.137	0.050	1.65	1.84	2.51	<0.001	0.289
Spacing	1.84	2.58	1.59	<0.001	0.387	2.08	2.05	1.88	0.485	0.018
Tissue approx.	2.09	2.21	1.70	0.008	0.122	1.65	2.05	2.30	0.001	0.176
Candidate										
Pass	26	34	28	0.056*	0.304**	22	30	35	<0.001*	0.304**
Fail	14	6	12			18	10	5		

CR: Controlled release (pop off)

*Cochran's Q test: Ho: No difference across graders; significant difference for $p < 0.05$.

**Fleiss Kappa (rater agreement): <0 poor, 0.0-0.20 slight, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 substantial, 0.81-1.0 almost perfect.

Friedman test: Ho: Related scores are from same population; significant difference for $p < 0.05$

Kendall's W: Ho: Inter-rater correlation is zero (no agreement across raters); ranges from 0-1; where 1 refers to complete agreement.

that suture tails can obscure knots before they are cut, this could have led to this difference. Results also showed inconsistencies in inter-examineragreementwhen evaluating wound closures. This finding may be due to the evaluation was based on images rather than in person. Another possible explanation may be due to the inexperience of residents for surgical procedures performed on fresh porcine skin. (In a post-hoc analysis, the pass rate was lower for PGY-3's as compared to PGY-5's; 65% vs. 92.5%, respectively.)

Regardless, with increasing medical costs, providers and hospitals are looking for cost-saving opportunities and methods to promoteefficiencies. Costs of operating roomresult from many factors, including procedure time, delays in room turnover, patient transport, presence of resident trainees, and anesthesia staffing delays [9-11]. When asked to compare many types of sutures, orthopedic surgeons reported that almostall suture and needle types appeared clinically acceptable [5,12]. Given this acceptance, it is prudent to consider a closure technique that increases speed without sacrificing quality of wound closure.

Limitations of this study included having smaller cohorts of closures from mid-level and senior residents and using porcine skin. However, as a feasibility study, the current sample size was estimated to provide useful information with reasonable material expense. Another limitation was the lack of retest reliability. At this stage of the study, we elected not to overburden surgeons with duplicate ratings per image. Instead, we were more interested in evaluating the extent to which multiple residents could perform the procedure consistently. We were, however, cognizant that grading 80 images was time consuming and exhausting. Therefore, we conducted two rating sessions per surgeon, with 40 images each, in an attempt to minimize fatigue. Finally, results may be limited because observations were made on images, rather than in person. To reduce potential variability inherent with images, we captured each image with the same camera and in similar conditions for lighting, room temperature, and time from completion of wound closure.

This feasibility study informs direct future inquiry. Study design recommendations include conducting a power analysis to help identify the best mix for number of surgical wound closures to number of surgeon raters and number of ratings per closure. Another consideration is to conduct a formal cost benefit analysis that would provide insight on cost savings attributed to each suture type. Patient outcomes, perhaps including healing time and complication rates, should also be assessed. It may also be beneficial to perform the experiment on cadavers, rather than porcine skin, to see if the study replicates in a more realistic tissue.

To our knowledge the technical ability of residents to close a wound in acost-effective and time-efficient manner has not be published in the literature. Skillslike these may become more important to residencyprograms that are trying to train competent surgeonsin an environment full of restriction and standardization.Studies related to how to train and evaluate residents, are likely to follow. Studies could also develop a novel and inexpensive bench top model that could potentially be used as a practice model for the orthopaedic intern residents, and could also be used as an evaluation tool for training programs to facilitate proficiency in wound closure technique.

Conclusion

This study demonstrates that wound closure with a controlled release needle is significantly faster than a swaged-on needle suture type, with minimal difference in closure quality. A larger trial to determine cost effectiveness maybe beneficial to further delineate the cost savings associated with an increased speed of wound closure with the controlled release needle.

Acknowledgement and Conflict of Interest Statement

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