

World Journal of *Methodology*

World J Methodol 2020 October 28; 10(1): 1-6



ORIGINAL ARTICLE**Clinical Trials Study**

- 1 Randomized clinical trial comparing skin closure with tissue adhesives *vs* subcuticular suture after robotic urogynecologic procedures

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ABOUT COVER

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INDEXING/ABSTRACTING

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RESPONSIBLE EDITORS FOR THIS ISSUE

Production Editor: Jia-Hui Li; Production Department Director: Xiang Li; Editorial Office Director: Jia-Ping Yan.

NAME OF JOURNAL

World Journal of Methodology

ISSN

ISSN 2222-0682 (online)

LAUNCH DATE

September 26, 2011

FREQUENCY

Irregular

EDITORS-IN-CHIEF

Gerhard Litscher

EDITORIAL BOARD MEMBERS

<https://www.wjnet.com/2222-0682/editorialboard.htm>

PUBLICATION DATE

October 28, 2020

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<https://www.wjnet.com/bpg/gerinfo/208>

ARTICLE PROCESSING CHARGE

<https://www.wjnet.com/bpg/gerinfo/242>

STEPS FOR SUBMITTING MANUSCRIPTS

<https://www.wjnet.com/bpg/GerInfo/239>

ONLINE SUBMISSION

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Clinical Trials Study

Randomized clinical trial comparing skin closure with tissue adhesives vs subcuticular suture after robotic urogynecologic procedures

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Author contributions: Fluellen S designed and performed the research study; Mackey K wrote manuscript; Hagglund K performed data analysis; Aslam MF designed research study.

Institutional review board statement: This study was reviewed and approved by Ascension St John Hospital Institutional Review Board, reference number 1165375.

Clinical trial registration statement: This study is registered at clinicaltrials.gov with an ID: NCT03891004.

Informed consent statement: All subjects in this study provided informed written consent prior to study enrollment.

Conflict-of-interest statement: All authors in this study do not have any conflict-of-interests.

Data sharing statement: Dataset available from the corresponding

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Abstract

BACKGROUND

Skin closure techniques during minimally-invasive gynecologic surgery is largely based on surgeon preference. The optimum technique would theoretically be safe, rapid, inexpensive, and result in good cosmetic appearance. Cyanoacrylate tissue adhesive (Dermabond) may be a comparable and safe option for port site closure as compared with subcuticular suture. In this randomized clinical trial, we hypothesized that operative time for skin closure would be less than subcuticular suture during robotic urogynecologic procedures.

AIM

To compare skin closure during robotic urogynecologic surgeries for tissue adhesives and subcuticular suture.

METHODS

Fifty female subjects > 18 years of age undergoing robotic urogynecologic procedures were randomized to have port site closure with either cyanoacrylate tissue adhesive ($n = 25$) or subcuticular suture ($n = 25$). All procedures and postoperative evaluations were performed by the same board certified Female Pelvic Medicine and Reconstructive Surgeon. Incisional closure time was recorded. Each subject was followed for 12-wk postoperatively. Incision cosmesis was evaluated using the Stony Brook Scar Evaluation Scale.

RESULTS

A total of 47 subjects (cyanoacrylate group, $n = 23$; suture group, $n = 24$) completed the 12-wk postoperative evaluation. Closure time was significantly less

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CONSORT 2010 statement: The authors confirm that the manuscript was prepared according to the CONSORT 2010 statement.

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Manuscript source: Unsolicited manuscript

Received: March 9, 2020

Peer-review started: March 9, 2020

First decision: September 21, 2020

Revised: October 6, 2020

Accepted: October 13, 2020

Article in press: October 13, 2020

Published online: October 28, 2020

P-Reviewer: Borkow G, Bramhall SR, Neri V

S-Editor: Zhang L

L-Editor: A

P-Editor: Li JH



($P < 0.0005$) using cyanoacrylate tissue adhesive (5.4 ± 2.0 min) than subcuticular suture (24.9 ± 5.6 min). Cosmesis scores were significantly higher in the cyanoacrylate tissue adhesive group than subcuticular suture ($P = 0.025$). No differences were found between bleeding, infection, or dehiscence ($P = 1.00$, $P = 0.609$, $P = 0.234$, respectively). No statistical demographical differences existed between the two study arms.

CONCLUSION

Our study supported our original hypothesis that cyanoacrylate tissue adhesive for port site closure during robotic urogynecologic procedures uses less time than with subcuticular suture. Our study also supports that tissue adhesive is comparable to cosmetic outcome while not jeopardizing rates of bleeding, infection, or dehiscence.

Key Words: Skin closure in robotic surgery; Dermabond; Cosmesis; Urogynecology; Closure time

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Core Tip: This clinical trial study is novel in its investigation of traditional vs innovative skin closure techniques with respect to closure time, cosmesis, and equivalency during urogynecologic robotic procedures. Our study demonstrated a reduction in closure time, improved cosmetic healing while not jeopardizing incidence of wound complications. This supports the use of tissue adhesive as being not only comparable, but also advantageous during closure of robotic urogynecologic procedures.

Citation: Fluellen S, Mackey K, Hagglund K, Aslam MF. Randomized clinical trial comparing skin closure with tissue adhesives vs subcuticular suture after robotic urogynecologic procedures. *World J Methodol* 2020; 10(1): 1-6

URL: <https://www.wjgnet.com/2222-0682/full/v10/i1/1.htm>

DOI: <https://dx.doi.org/10.5662/wjm.v10.i1.1>

INTRODUCTION

For many years, we have used suture, staples and adhesive tapes as methods of skin incision closure. The choice of which method to use is largely based on the surgeon's preference. Of the three methods, tissue adhesives have entered the clinical practice most recently. Although repairing surgical wounds with suture is the most common method, it is operator dependent, carries an increased risk of needle sticks to the practitioner, and requires more operating room time^[1,2]. The ideal method of incision closure should be simple, safe, rapid, inexpensive, painless, bactericidal, and result in optimal cosmetic appearance of the scar^[1]. The use of tissue adhesives offers multiple advantages such as: Barrier protection to aid in wound healing, shorter operating room time, elimination of the risk of sharps exposure *via* needle sticks, and comparable cosmesis to standard closure methods^[3].

Dermabond glue, a cyanoacrylate tissue adhesive, is a liquid monomer that forms a strong tissue bond with a protective barrier that adds strength and inhibits bacteria^[4]. It is applied as a bridge over the opposing skin edges and forms a flexible seal over the wound^[5]. The adhesive reaches maximum bonding strength within 2.5 min and is equivalent in strength to healed tissues at seven days post repair^[5]. Skin closure with tissue adhesive is more rapid than standard suture, and both wound dehiscence and infection rates are similar^[1]. Most importantly, the cosmetic appearance with tissue adhesives is similar to incisions closed with standard suture methods^[1].

The ideal scar assessment tool should be a validated, comprehensive, reliable and standardized tool^[6,6]. Recommendations in recent reviews of scar management strategies support a move to a more evidence-based approach in scar assessment and management^[7]. The Stony Brook Scar Evaluation Scale is specifically designed to assess short-term appearance of repaired lacerations or incisions^[8]. Of course, patients are

concerned about the physical appearance of scars as poorly healed scars can have major psychological effects; therefore, when deciding on closure method one needs to take into account postoperative aesthetics.

The primary outcome of the study was to compare skin closure time between suture and cyanoacrylate tissue adhesive (Dermabond) in urogynecological robotic surgeries. Therefore, if the tissue adhesive was cosmetically comparable to that of sutures that will be the reason to use tissue adhesives over traditional sutures due to saved operative time. In these surgeries, there are five to six port sites (compared to fewer port sites for traditional laparoscopic procedures), and the procedures are lengthy (average duration about 300 min as per American Society of Gynecologic Urology/American College of Obstetricians and Gynecologists committee opinion). If we can show significant time reduction for closure, that should reduce operative time and costs. To our knowledge, this is the first study of its kind to make this comparison for urogynecologic robotic procedures.

MATERIALS AND METHODS

This randomized controlled trial compared skin closure after robotic urogynecologic surgery with tissue adhesive *vs* subcuticular suture. This study is registered at clinicaltrials.gov (ID: NCT03891004). Between March 2018 and December 2018, we randomized 50 women, 25 in each group. The primary outcome, closure time, was measured in the operating room. Incision cosmesis, the secondary outcome, between the two arms was measured at the 12-wk follow up visit using the Stony Brook Scar Evaluation Scale (Table 1). For randomization, a computer randomization program was used to assign group assignments to the numbers 1 to 50. Security envelopes were numbered from 1 to 50, and a piece of paper with the group assignment was placed in a sealed, opaque envelope with the corresponding number. The study number became the patient's study ID, and the assignment within the numbered envelope became patient's group assignment.

Our estimates, based on surgical experience and our pilot data, were that the standard (stitch) approach would take a mean of 16.0 min (standard deviation 3.0 min), compared to the tissue adhesive only, which will take a mean of 13.0 min (standard deviation 3.0 min). To show such an effect, at least 17 patients were required per group, for 80% power and $\alpha = 0.05$. To allow for attrition, we added 20% to the sample size and recruited 25 patients per group. Closure time was compared by group using the Student's *t*-test, and cosmesis scores were compared by group using the Mann-Whitney *U*-test. The median and interquartile range was reported for each group. $P < 0.05$ were considered significant. Associations between categorical variables were made with chi squared or Fisher exact test as appropriate, and again the Mann-Whitney *U* test was used for continuous variables.

Study subjects were women, ages 18 years and older, undergoing urogynecologic robotic procedures that were ultimately not converted to open cases. Women with active skin infections were excluded from the study, along with any of the procedures that were converted to a laparotomy (although none of the procedures in our study were converted to laparotomy). These procedures involved five to six port incisions which required closure at the end of the case. Women were invited to participate in the study during their preoperative visit. An explanation of the study was given, and informed consent obtained. Randomization to one of the two groups occurred at the end of the surgery so that the surgeon was aware of which closure method to use. A fellowship trained, board certified, FPMRS surgeon was the primary surgeon for every procedure.

For the tissue adhesive group, Dermabond was used. Dermabond was food and drug administration approved for skin closure in 1998. For the suture arm, only the subcuticular layer was closed. We recorded the length of time of each closure method for comparison, and had each patient follow-up at two, six and 12 wk. At the 12-wk visit the appearance of the incision was scored using the Stony Brook Scar Evaluation Scale.

Each method of closure was safe and effective; therefore, the fastest method is more ideal to cut down on operating room time and cost. The secondary outcomes that we focused on were comparing cosmesis of the incisions and patient satisfaction regarding cosmesis at the 12-wk postoperative visit. One certified registered nurse evaluated all of the patients at the 12-wk postoperative visit, and was blinded to each patient's group assignment.

Table 1 The stony brook scar evaluation scale

	Scar category	Points
Width	> 2 mm	0
	≤ 2 mm	1
	Elevated/depressed in relation to surrounding skin	0
Height	Flat	1
	Darker than surrounding skin	0
Color	Same color/lighter than surrounding skin	1
	Present	0
Hatch marks/Suture marks	Absent	1
	Poor	0
Overall appearance	Good	1

(Table reprinted from Fearmonti, 2010).

RESULTS

The study enrolled 50 patients, 25 patients in each arm, however a total of 47 patients completed their 12-wk postoperative visit ($n = 23$ in tissue adhesives group, $n = 24$ in the suture group). The primary outcome, length of time for each closure method, was significantly less ($P < 0.0005$) in the tissue adhesive group (5.415 ± 2.035 min) when compared to the suture group (24.98 ± 5.665 min). It was determined that the cosmesis score was significantly higher ($P = 0.025$) in the tissue adhesives group (median = 4.0, interquartile range = 1.0) than in the suture group (median = 3.0, interquartile range = 2.0). There was no significant difference in bleeding ($P = 1.00$), dehiscence ($P = 0.234$), infection ($P = 0.609$) or any extra wound treatment ($P = 1.00$) between the two arms.

When comparing patient demographics between the two study arms, there was no statistical differences (Table 2).

DISCUSSION

The major findings of our study showed that the length of closure time was significantly shorter in the tissue adhesive group (5.4 ± 2.0 min) than that of the suture group (24.9 ± 5.6 min). Furthermore, tissue adhesives result in a superior cosmetic appearance of the scar without increasing the risk of wound complications in robotic urogynecologic surgery. When comparing complications such as wound dehiscence, infection, bleeding and other complications requiring extra wound treatment, there was no significant difference between the two arms. In our study, none of the patient's assigned to the Dermabond arm experienced an allergic reaction or contact dermatitis. It is said that there is a female predominance of acrylate allergy, with a male/female ratio of 1:15^[9]. If an adverse reaction is noted, studies have shown to observe the wound until the product peels off spontaneously^[10]. Occasional use of systemic steroids is sometimes required for a severe allergic reaction^[10].

The Stony Brook Scar Assessment, as shown in Table 2, was the ideal scar assessment tool as it is specifically designed to assess short-term appearance of repaired lacerations or incisions^[8]. This tool assigns a score to 5 aesthetic parameters and yields a total score ranging from 0 (worst) to 5 (best). Although caution should be used with the clinical application of scar assessment tools as they are subjective and hard to standardize, cosmesis and patient's satisfaction were the main goals of the study.

Understanding operative times and hospital costs is essential to value-based care. There is a growing body of literature describing cost-saving interventions in surgery^[11-14]. As a reference point, a cross-sectional analysis performed in California showed the mean cost of operating room time in the fiscal year of 2014 was \$36 to \$37 per minute^[15]. Therefore, it was our main goal to show that tissue adhesives can substantially decrease operative times which furthermore decreases cost. Additionally, a study by Sebesta and Bishoff (2003) showed a reduced cost and procedural time for

Table 2 Patient characteristics stratified by subcuticular skin closure and tissue adhesive closure

Demographics	Tissue adhesive <i>n</i> = 23, mean \pm SD or <i>n</i> (%)	Subcuticular suture <i>n</i> = 24, mean \pm SD or <i>n</i> (%)	<i>P</i> value
Age (yr)	58.3 \pm 9.9	56.8 \pm 13.2	0.659
Body mass index	27.9 \pm 5.8	28.7 \pm 4.6	0.60
Parity	2.6 \pm 1.5	2.5 \pm 1.2	0.954
Race			
Caucasian	19 (83)	20 (83)	1.0
Black	4 (17)	4 (17)	

cyanoacrylate tissue adhesive for laparoscopic port closures compared to subcuticular sutures^[16].

The study did have its limitations. One limitation was cost. We did not evaluate the cost difference between the two methods. However, a study comparing laparoscopic port-site closure with octylcyanoacrylate (Dermabond) tissue adhesive to be significantly less in duration, comparable in cosmetic outcome, and significantly reduced cost (\$198 United States for tissue adhesive *vs* \$497 United States for suture) than with suture^[16]. Another limitation is that we did not screen nor exclude patient's with history of pathological wound healing. Anecdotally, we did not find much difference. Of note, our closure time with tissue adhesive *vs* suture was significantly reduced (less than 50%). As compared to the pilot data discussed in the methods section, this does perhaps raise the possibility of unmindful bias. However, the closure time for tissue adhesive was still markedly reduced (5.415 \pm 2.035 min) compared to pilot data for suture closure (16 \pm 3 min).

Our study had several strengths. The first is that this study was a randomized trial and the incision assessor was blinded to the result. Next, the study was performed at a single institution; therefore, we were able to assure uniformity of care. Both the surgeon and the scar assessor were consistent throughout the study. This subsequently decreases the potential bias in wound assessment. Fourthly, the prospective approach coupled with the high follow-up rate of the patients made this study successful. Next, another strength is we had the surgeon closing the skin with both methods, which takes bias out for the time. Lastly, to the best of our knowledge, this is the first study to use the Stony Brook Scar Evaluation Scale to evaluate skin closure cosmesis in urogynecologic robotic procedures.

CONCLUSION

In summary, we aimed to assess incisional cosmesis and operative time between suture and skin adhesives. Given that there was no significant difference between wound complications, tissue adhesives have proven to be the superior closure method and results in shorter operative times and can be safely adopted.

ARTICLE HIGHLIGHTS

Research background

Skin closure method during robotic urogynecologic procedures can vary overall operative time and costs. Cyanoacrylate tissue adhesive is a potential method to reduce this as compared to subcuticular suture, and maintain incisional cosmesis while not jeopardizing wound complications.

Research motivation

A faster yet comparable method for skin closure during robotic urogynecologic procedures may significantly reduce operative time and costs while maintaining or even improving incisional cosmesis.

Research objectives

To compare skin closure *via* cyanoacrylate tissue adhesive and subcuticular suture

during robotic urogynecologic procedures.

Research methods

Fifty subjects were randomized to have port site closure with either cyanoacrylate tissue adhesive or subcuticular suture. Subjects were followed for 12-wk postoperatively to evaluate incisional cosmesis and complications.

Research results

Closure time was significantly reduced using cyanoacrylate tissue adhesive than with subcuticular suture. Cosmesis scores were greater in the cyanoacrylate tissue adhesive group. No differences in bleeding, infection, or dehiscence existed.

Research conclusions

Cyanoacrylate tissue adhesive for skin closure during robotic urogynecologic procedures reduces operative time and improves incisional cosmesis compared to subcuticular suture. Cyanoacrylate tissue adhesive is a reasonable alternative for skin closure during robotic urogynecologic procedures.

Research perspectives

The utility of tissue adhesive as reducing operative time and overall costs is a potential area of future investigation.

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