Comparing Tissue Adhesives in Port Site Closure: A Randomized Controlled Trial

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Comparing Tissue Adhesives in Port Site Closure: A Randomized Controlled Trial

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Population: 186 adults over the age of 18 having elective laparoscopic surgery through Department of Minimally Invasive Surgery at UTHealth

Number of sites: 3

Study Duration: 2 years

Subject Duration: 2 years

Significance

Tissue adhesive has become increasingly popular in closing surgical incisions. However, side effects of different types of skin adhesive have been poorly studied. In particular, the rate of contact dermatitis associated with the use of tissue adhesive is unknown and ranges from 0-14% in the literature.[1-4] Reactions from tissue adhesive can range from minor skin irritation to permanent discoloration and scarring, leading to patient and surgeon frustration. In this randomized controlled trial, two different types of skin adhesive are being compared.

Background

2-Octylcyanoacrylate tissue adhesive (Dermabond, Ethicon) was approved by the Food and Drug Administration (FDA) in 1998.[5] Initially used for closing small lacerations, it has now become commonplace to reinforce surgical incision closure in the operating room. Competitors such as n-butyl-2-cyanoacrylate tissue adhesive (SwiftSet, Medtronic), have also entered the market. There can be a significant difference in cost between these different products.

One of the more significant complications that has been observed with the use of these skin adhesives is the development of contact dermatitis.[6] While many surgeons have anecdotal evidence favoring one tissue adhesive over another, there are no head to head trials comparing these two different types of adhesive in closing surgical incisions.

Hypothesis

In patients undergoing laparoscopic surgery, the use of SwiftSet tissue adhesive over port site incisions will have a higher rate of contact dermatitis compared to Dermabond tissue adhesive at 6 weeks post-operative.

Study Design

This is a single-center randomized controlled trial to evaluate two different methods of reinforcing surgical port site closure: 2-Octylcyanoacrylate and n-butyl-2-cyanoacrylate. The primary objective of this trial will be to assess the proportion of patients with contact dermatitis within 6 weeks post-operative. The secondary outcome will include the diameter of erythema around any skin reaction, any wound dehiscence, or surgical site infection.

Methods

Inclusion Criteria

All adult patients undergoing an elective laparoscopic or robotic abdominal surgery will be eligible.

Exclusion criteria

(1) Patients unlikely to follow-up (live out of state, unable to be reached by phone or email)
(2) Patients with a known allergy to Dermabond or SwiftSet.

Study Procedures:

Eligible patients will be approached by research staff either in clinic or in pre-operative holding for trial enrollment. Each patient will serve as their own control. Enrolled patients will have both

surgical glue types used, one on each half of their abdomen. The side for each glue will be randomly assigned by the day of the month. On odd days, Dermabond will go on the patient's left abdomen. On even days, Dermabond will go on the patient's right abdomen. If there is an odd number of incisions, the extra incision will be included on the patient's left (figure 1).

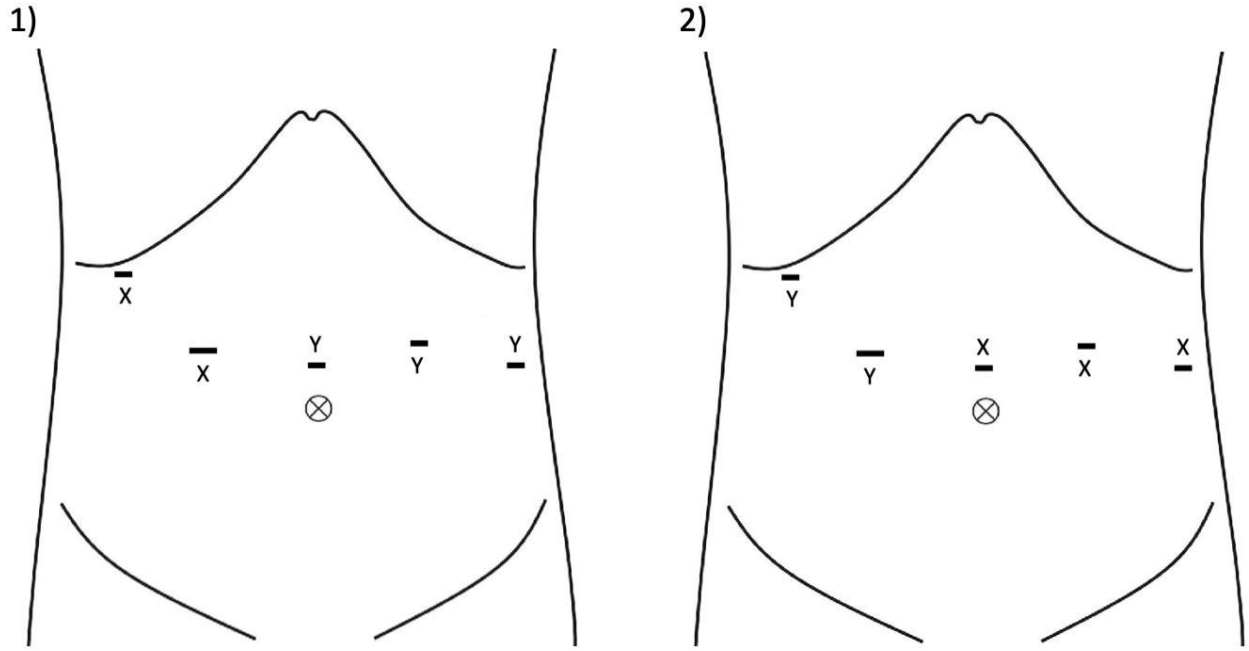

Figure 1: 1) Glue X on right and glue Y on left. 2) Glue Y on right and glue X on left

All incisions will be closed with Monocryl. Closed incisions will be covered with skin glue. For participants, there will be a required post-op visit within 6 weeks after having surgery.

Outcomes

The primary outcome of this trial will be the proportion of patients with contact dermatitis within 6 weeks post-operative. A trained surgical clinician blinded to the treatment arms will collect outcomes at all follow up clinic visits in the first 6 weeks post-operative. Any skin reaction will be documented with photographs.

Secondary outcome will include the diameter of erythema around any skin reaction, or any wound dehiscence or surgical site infection during the 6 weeks of follow-up.

Statistics

Sample Size

The true rate of contact dermatitis is unknown but ranges from 2 to 14% in the literature. Using pooled values from the literature, we will use expected dermatitis rates of 2.2% vs 6.8%.[1-3] Using McNemar's test comparing two correlated proportions, alpha=0.05, beta=0.20, correlation coefficient 0.5, a sample size of 186 is needed.

Data Analysis
Categorical outcomes will be analyzed using McNemar's chi square. Continuous outcomes will be assessed using a paired student's t-test.

Ethics

Department approval through the McGovern Surgical Department will also be sought through a departmental review of the protocol. The consent process will take place during a patient's consultation visit or in pre-op prior to the patient's surgery. The study coordinator will approach the patient about the study privately and discuss the study and go over the study objectives, benefits and risk of participating in the study. Patients will be given printed copies of the informed consent pages to review and decide whether they would like to participate. If they decide to participate they will sign the informed consent and be given a copy for their records.

Data Handling

Privacy is important and patient's participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed. The health information that we may use or disclose for this research includes all information in a patient's medical record to include but no limited to: basic demographic information (e.g. age, gender, race/ethnicity), previous medical/surgical history, laboratory/imaging results, and information related to surgery. Research study data will be sent to the sponsor of this research study Memorial Herman Supply Chain. The data that will be sent to the sponsor will not include the patient's name but may include initials, date of birth, date of study visits, and date of study procedures. Research study data may also be sent to the research collaborators at other Universities. The data that will be shared will not include name but may include initials, date of birth, date of study visits, and date of study procedures.

Individual data will be stored with the patient's electronic medical records. Aggregate data will be stored in a data dictionary electronically where each patient will be identified by a patient numbered.

Safety Monitoring

The safety of all subject will be closely monitored by the PI. Prior to the study, study patients will be given the co-investigators number and told to call in the event they experience any adverse outcomes to the surgery or post-operative care. Given that this study is measuring adverse outcomes to the skin glue used at port-site closer, documentation will be done as described in outcomes. Evaluation of these events will be done in the clinical setting at patient's post-operative visits. While we do not anticipate any life-threatening adverse events to occur in this study, there is a remote change that such an event could occur. In the even one does happen, patients are instructed to go to their nearest Emergency Room and call the study co-investigator.

Limitations

(1) Failure to blind the treating clinicians- It is not possible to blind treating physicians. However, outcome assessors will be blinded to treatment.

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(2) Loss to follow up- A large majority of our patients are undergoing bariatric surgery. As such, they have frequent, close post-operative follow up. We anticipate a low rate of loss to follow up.

(3) Failure to achieve intended sample size- We anticipate accruing our target sample size will be easily feasible; however, we have several other sites with MIST surgeons that can be included if more patients are needed.

References

1. Nigro LC, Parkerson J, Nunley J, Blanchet N. Should We Stick with Surgical Glues? The Incidence of Dermatitis after 2-Octyl Cyanoacrylate Exposure in 102 Consecutive Breast Cases. *Plast Reconstr Surg.* 2020;145(1):32-37.
2. Nakagawa S, Uda H, Sarukawa S, et al. Contact Dermatitis Caused by Dermabond Advanced Use. *Plast Reconstr Surg Glob Open.* 2018;6(9):e1841.
3. Park YH, Choi JS, Choi JW, Kim HJ. Incidence and risk factor of allergic contact dermatitis to 2-octyl cyanoacrylate and n-butyl cyanoacrylate topical skin adhesives. *Sci Rep.* 2021;11(1):23762.
4. So SP, Yoon JY, Kim JW. Postoperative contact dermatitis caused by skin adhesives used in orthopedic surgery: Incidence, characteristics, and difference from surgical site infection. *Medicine (Baltimore).* 2021;100(20):e26053.
5. Switzer EF, Dinsmore RC, North JH, Jr. Subcuticular closure versus Dermabond: a prospective randomized trial. *Am Surg.* 2003;69(5):434-436.
6. Cook KA, White AA, Shaw DW. Patch Testing Ingredients of Dermabond and Other Cyanoacrylate-Containing Adhesives. *Dermatitis.* 2019;30(5):314-322.