

15 May 2018

<https://doi.org/10.1016/j.ajem.2018.08.071>

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## Evaluation of the tensile strength and microbial barrier properties of a novel, 2-octyl-cyanoacrylate based topical skin adhesive



Topical skin adhesives (TSA) are non-invasive alternatives to suturing or stapling [1]. Cyanoacrylate-based TSA were introduced into clinical use in the late 1950s. Since then, a number of commercial butyl-based, octyl-based, and blended cyanoacrylate adhesives have become available. It has been estimated that of roughly 10 million lacerations and 100 million surgical incisions each year in the U.S., between 1 in 10 and 1 in 3 could be closed with a TSA [2]. As a result, there has been continued development of improved and less expensive TSA.

In addition to closing approximated wounds, the cyanoacrylate-based TSA also have been shown to have microbial barrier properties [3–5] as well as direct antimicrobial activity [6,7]. Thus, TSA have the potential to reduce wound infections commonly seen after wound repair. The current study was designed to compare the mechanical characteristics of Dermabond (the most commonly used TSA) and a novel 2-octyl-cyanoacrylate compounded using proprietary elasticizers and thickeners to provide unique performance characteristics of strength, flexibility and skin bonding adherence (Actabond) in an ex-vivo porcine skin strip model. We also assessed the in-vitro microbial barrier properties of Actabond.

Skin strips (10 mm × 50 mm) harvested from the back/shoulder region of domestic pigs were used to measure tensile strength ex-vivo. The strips were thawed on a hot plate set at 35 °C and the underlying fat layer was removed. The strips were cut in half widthwise and approximated with no gaps in between. The TSA (Dermabond or Actabond) were randomly applied in a single layer over the surface of the approximated strips and allowed to cure for 5 min on the hot plate. The ends of the strips were then placed within the grips of a tensiometer that measured the maximal force required to separate the wound edges. The grips were separated at a speed of 20 in./min. 20 approximated skin strips were tested for each TSA by an investigator masked to treatment allocation.

In order to test its microbial barrier function, we applied Actabond adhesive directly onto agar plates to form a polymer film. These films were then

inoculated with test solutions containing an infectious inoculum of five commonly encountered pathogens causing wound infections (Methicillin-resistant *S. aureus*, Methicillin-resistant *S. epidermidis*, *P. aeruginosa*, *E. coli*, and *E. faecium*). The microbial barrier was considered appropriate when there was no growth observed beneath the polymer film.

The mean [95% CI] tensile strength of Actabond (20.2 N [14.1–26.3]) was significantly greater than the tensile strength of Dermabond (12.5 N [8.2–16.7]); mean difference 7.7 N (95% CI, 0.6–14.8). The percentage elongation of the adhesive prior to breakage, and mode of failure (either cohesive or adhesive) was similar in skin strips approximated with Actabond or Dermabond. For all five organisms tested, no microbial growth of the challenge organism was observed for the 30 test articles after incubation for 72 h, indicating that the Actabond maintained its microbial barrier properties.

Our results demonstrate that the tensile strength of a novel topical skin adhesive, Actabond, is significantly higher than that of Dermabond. While it is likely that an adhesive with greater tensile strength would lead to a lower wound dehiscence rate in patients with repaired incisions or lacerations than one with lower tensile strength, only a randomized clinical trial would be definitive.

No studies have actually measured the mechanical forces required to separate the edges of repaired lacerations and incisions both immediately after wound closure and at later time-points. A study in human volunteers has tried to estimate the pressures within the abdominal cavity (and presumably the forces applied to the abdominal wall) during various activities. For example, an intra-abdominal pressure of approximately 130 mm Hg was measured during the act of coughing [8]. Thus, an adhesive with a tensile strength of greater than 130 mm Hg or 17 N (such as Actabond) would be unlikely to fail when subject to the forces generated by coughing.

Our study results also demonstrate that Actabond is very effective as a microbial barrier as evidenced by the 100% effectivity in preventing growth of the inoculated organisms beneath the polymer film. Prior studies have shown that other butyl- and octyl-based cyanoacrylate TSA are also very effective as microbial barriers [3–5]. Several animal studies have also shown that contaminated wounds repaired with a cyanoacrylate-based TSA have lower wound infection rates than similar wounds closed with sutures [6,7].

Our study has several notable limitations. The study was conducted ex-vivo on porcine skin strips and may not predict wound failure on actual patients. Furthermore, the clinical relevance of a 7.7 N difference in tensile strength remains unclear. In addition, tensile strength was only measured once, almost immediately after approximating the skin strips.

We conclude that Actabond is stronger than Dermabond when tested with approximated porcine skin strips. Actabond is also an effective microbial barrier to commonly encountered wound pathogens causing wound infection.

## Conflicts of interest

This study was funded by Bergen Medical, Cedar Knolls, NJ.

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17 August 2018

<https://doi.org/10.1016/j.ajem.2018.08.075>

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## Emergency physician utilization of transvaginal ultrasound after initiation of revised sterilization protocol<sup>\*</sup>



Bedside transvaginal ultrasound, performed by an Emergency Physician (EP), is an essential imaging modality in the emergency evaluation of a first trimester pregnant patient. This skill is essential in many clinical settings, where Imaging Sciences or Obstetrics departments are unavailable to perform these studies on an emergent basis. It is also designated by ACEP (American College of Emergency Physicians) to be a clinical competency required of EM (Emergency Medicine) physicians [1].

There is a widely accepted clinical workflow in the evaluation of the pregnant patient to confirm an intrauterine pregnancy: first, a transabdominal pelvic ultrasound (TAUS) is performed. If an intrauterine pregnancy (IUP) cannot be reliably identified, then the EM physician should move on to perform a transvaginal ultrasound. If an IUP cannot be identified transvaginally considering a quantitative beta-HCG at or above the discriminatory zone (usually 1500–2500 mIU/ml), OB is consulted. This will be referred to as the “rule-out ectopic pregnancy” process.

Achieving adequate disinfection of the transvaginal ultrasound probe is also an essential part of the Emergency Department workflow. Both the CDC and American Institute of Ultrasound in Medicine classify the transvaginal probe as “semi-critical”, meaning a device that comes in contact with mucous membranes [2,3]. The disinfection process recommended for semi-critical devices is high level disinfection (HLD), the “eradication of all organisms except bacterial spores” [2].

Previously, our institution had accomplished this disinfection process beginning with gross decontamination (removing the disposable cover and visible debris, wiping down with a clean cloth), then soaking in a 2% glutaraldehyde solution (Cidex®) for a period of 20 min.

Our emergency department recently enacted a new HLD policy on 7/1/2016 [4]. The revised protocol includes the aforementioned gross decontamination, then a disinfectant cleaning cloth, transportation of the probe in a biohazard bag to a processing area, then high level disinfection using Trophon®—an automated point-of-care machine utilizing hydrogen peroxide and a chemical indicator. After each processing cycle (7 min), the Trophon machine notifies the provider that the cycle is complete and whether or not it was successful. The results, along with the result of the chemical indicator (colorimetric pass/fail, interpretation based on a graphic displayed nearby), the patient’s medical record information sticker, the date and times of the cycle, and the cycle number, are then recorded by hand in an accompanying adjacent logbook.

<sup>\*</sup> This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

The goal of this new policy is to create a consistent disinfection process with compliant procedure documentation, to improve patient safety, and make a more effective workflow. However, the additional steps required may be perceived to impede workflow, leading ED providers to not perform the transvaginal scan, thus having a negative impact on physician and department workflow, overall cost, and patient safety. This study assessed the impact of the revised sterilization protocol on emergency physician-performed TVUS utilization rates pre- and post-protocol initiation. We also addressed the frequency of Obstetrics consultations pre- and post-protocol as some of these consultations can be obviated by successful identification of IUP by ED providers.

Study subjects were identified by manually reviewing our ED ultrasound imaging storage program, Sclmage. Subjects were all cared for at a single, large, urban and academic Emergency Department and tertiary referral center with an annual census of over 115,000. All pregnant patients who underwent pelvic ultrasounds in the ED (transvaginal or transabdominal) during the time period 6 months prior to the initiation of the policy (1/1/2016–6/30/16), and 6 months after the initiation of the policy (7/1/16–12/31/16) were included in the analysis. The patient’s MRN, age, date of service, provider (attending physician, resident physician, and/or advanced practice provider), pregnancy status, preceding transabdominal ultrasound (TAUS), whether or not an intrauterine pregnancy (IUP) was identified, whether the IUP was identified on TAUS or TVUS, OB/Gyn consultation, whether IUP was identified by OB/Gyn, and by what method (TAUS/TVUS) the IUP was identified were all recorded.

Each ultrasound study was manually reviewed by the research team (NG, TO, ME), who underwent specific study training in image interpretation and the study protocol. Charts were reviewed for demographics, lab values, documented ultrasound results, and presence or absence of OB consultation. We reviewed both the actual ultrasound clips within Sclmage, as well as the physician documentation within the electronic medical record (EMR). Any documented ultrasound interpretation was taken as final considering our intention to study the use of the sterilization procedure rather than image quality.

There were individual cases where it was determined that the provider misinterpreted the images (in most cases, an IUP was apparent on the available images, but subsequently documented as negative). For these cases, we recorded the documented interpretation used in the medical decision making, as this result drove subsequent additional imaging (for example, an unindicated TVUS) or an OB/Gyn consultation. Equivocal studies were reviewed during the Emergency Department’s weekly quality assurance process.

The study sample was characterized using descriptive statistics. To assess comparability of pre- and post-study samples, bivariate analyses were conducted. The proportion of subjects who underwent TAUS and TVUS as well as the proportion of OB consultations were quantified in the pre- and post-periods and compared using Chi-Square tests and Fisher’s Exact test as indicated. Given the exploratory nature of the study, a  $p$ -value < 0.05 was used to determine statistical significance and no adjustments were made for multiple comparisons. All data analysis was conducted in SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). 3.

## 3. Results

From January 2016 to December 2016, we reviewed charts to determine the frequency of pelvic ultrasound use, with attention to July 1st which marked the initiation of our revised sterilization protocol. During the pre-period 340 patients were evaluated for IUP, compared to 307 patients in the post-period. The ages of patients did not differ between time periods. After initiation of the revised protocol, the total number of TVUS decreased from 165 to 105 (Fig. 1). This represents an overall decrease in the rate of TVUS from 48% to 34%, a statistically significant decrease of 14% ( $p < 0.001$ ).

Additionally, there was an increase in the overall number of OB consultations without an indicated TVUS (Fig. 2). This increase in OB