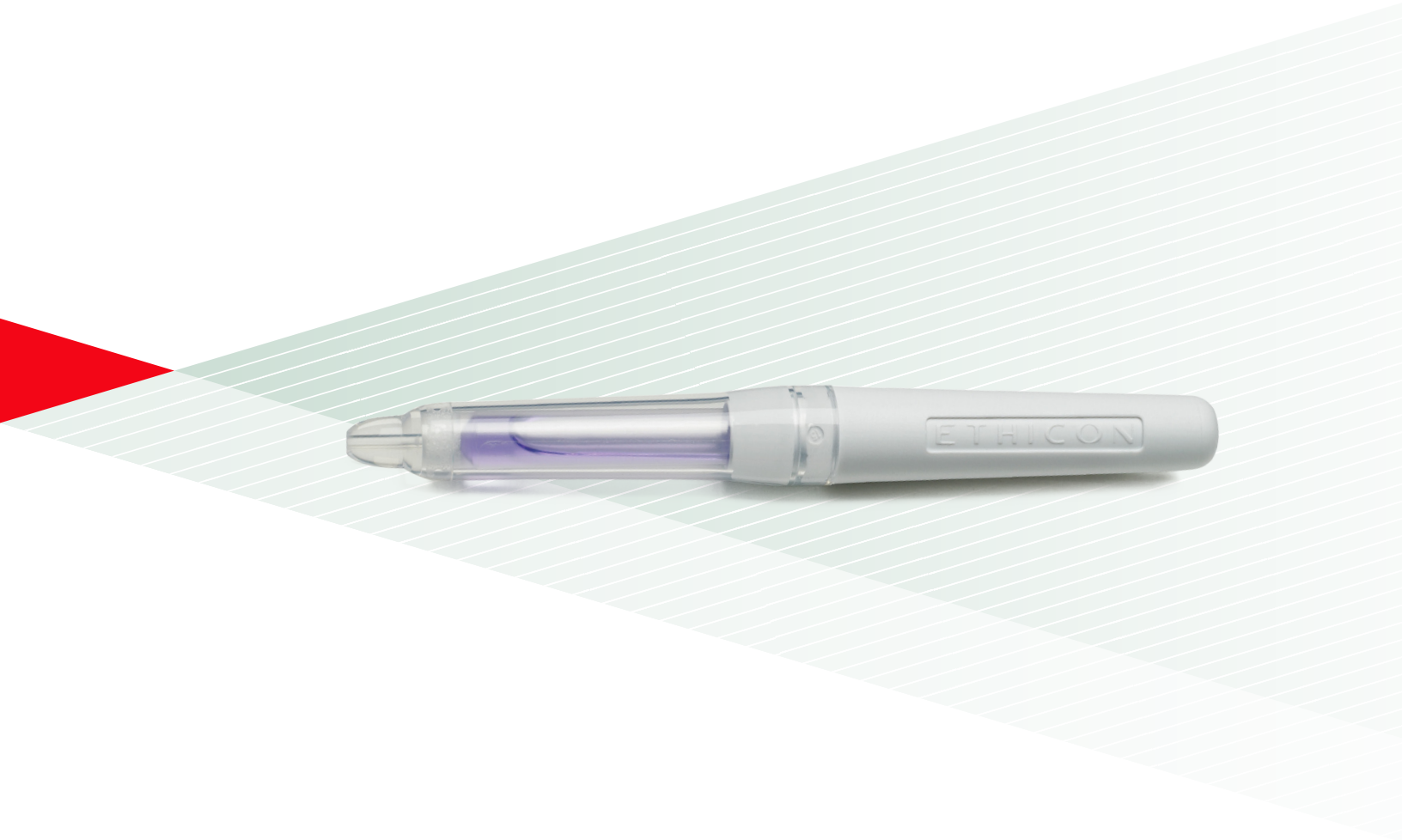
Dermabond Advanced®

DERMABOND ADVANCED®
Topical Skin Adhesive
Evidence Brief



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Shaping
the future
of surgery

Overview

As the final layer of wound closure, topical skin adhesives (TSAs) are an integral part of a successful clinical outcome. When deciding which TSA to use, clinical study information on closure strength, microbial protection, patient comfort, and cosmesis allows healthcare practitioners to evaluate which product will provide the greatest benefits for their patients.

DERMABOND ADVANCED® Topical Skin Adhesive is supported by an extensive body of published literature, including 51 randomized controlled trials (RCTs). DERMABOND ADVANCED Adhesive has a patented, proprietary chemical formulation[1] that has been shown to provide superior strength versus other commercially available TSAs,[2] and also has benefits that enhance patient comfort and cosmetic outcomes.[3-6]

This Evidence Summary includes a sample of the available RCTs for DERMABOND® Topical Skin Adhesive. **A full list of published studies can be found in the bibliography section of this document.**

- DERMABOND ADVANCED Adhesive is Supported by 51 Published RCTs*†‡
- Total of 5,718 Patients Evaluated

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*DERMABOND ADVANCED Adhesive tests equivalent or superior to DERMABOND Adhesive in head-to-head testing for microbial barrier, wound-bursting strength, tensile strength, flexibility, durability, viscosity, drying time, water vapor transmission rate, water resistance, and physician satisfaction.

†Based on published literature in PubMed and SCOPUS, using only RCTs that evaluated the use of the product in a manner consistent with intended indication.
‡Based on search results in Pubmed and SciFinder databases in October 2016.

Summary of Key Studies

The publications that support the claims for DERMABOND ADVANCED® Topical Skin Adhesive are listed in the table below. A summary of each of these studies can be found on the subsequent pages.

Publication Title	Lead Author	Source	Outcome Studied
In vitro Assessment of Microbial Barrier Properties of DERMABOND® Topical Skin Adhesive	Bhende	*Surgical Infections.* 2002;3(3):251-257.	Microbial Barrier
In vitro study to determine the ability of DERMABOND ADVANCED® Topical Skin Adhesive to inhibit bacterial growth	Bhende	Data on File. Ethicon, Inc.	Inhibition of Bacteria
In Vivo Study of Wound Bursting Strength and Compliance of Topical Skin Adhesives	Singer	*Academic Emergency Medicine.* 2008;15(12):1290–1294.	Strength and Flexibility
Postoperative Outcomes Associated with Topical Skin Adhesives among Women Having Hysterectomies	Murrmann	*Surgical Infections.* 2010;11(5):441-447.	Hospitalization Costs
A Randomized Trial Comparing Octylcyanoacrylate Tissue Adhesive and Sutures in the Management of Lacerations	Quinn	*JAMA.* 1997;277(19):1527-1530.	Cosmesis, Time, Pain

Clinical Reference Article Summary

In Vitro Assessment of Microbial Barrier Properties of DERMABOND® Topical Skin Adhesive

Bhende S, Rothenburger S, Spangler D, Dito M

Source:
Surgical Infections. 2002;3(3):251-257

Study Objective

The purpose of this study was to evaluate the ability of DERMABOND Adhesive to provide an effective microbial barrier against the penetration of microorganisms in vitro.

Bacteria used in this study included:

Staphylococcus aureus

Staphylococcus epidermidis

Escherichia coli

Pseudomonas aeruginosa

Enterococcus faecium

Method

Plates containing an agar media were created in a sterile environment. The agar media contained a pH-sensitive dye designed to color when exposed to the acidic metabolic products of bacteria.

DERMABOND Adhesive was applied to the agar surface. In total, 300 single-layer films and 300 triple-layer films were examined. The surface of each film was inoculated with a 10 µL aliquot of bacteria containing at least $1x10^3$ cfu.

All test and control plates were incubated at 37°C for 72 hours. A change in color indicated a breach in the adhesive's microbial barrier.

Results

Single-layer films: 299 of the 300 samples retained their integrity as microbial barriers for 72 hours. All 300 samples maintained their microbial barrier for 48 hours.

For the triple-layer films, 299 of the 300 samples retained their integrity as microbial barriers for 72 hours.

Conclusion

The results of this study demonstrate that DERMABOND Adhesive provides a microbial barrier with 99% protection in vitro for at least 72 hours against organisms commonly responsible for SSIs, including: *Staphylococcus epidermidis, Staphylococcus aureus , Escherichia coli, Pseudomonas aeruginosa,* and *Enterococcus faecium.*

Clinical Reference Article Summary

In vitro study to determine the ability of DERMABOND ADVANCED® Topical Skin Adhesive to inhibit bacterial growth

Bhende S

Source:
Data on File. Ethicon, Inc.

Study Objective

The purpose of this study was to demonstrate that DERMABOND ADVANCED Adhesive inhibits gram-positive bacteria and gram-negative bacteria in vitro.

Bacteria evaluated in this study:

Methicillin-resistant *Staphylococcus aureus* (MRSA)

Methicillin-resistant *Staphylococcus epidermidis* (MRSE)

Escherichia coli

Method

Cultures of each organism were grown under sterile conditions for 18-24 hours at 35-37°C. Before being used in the experiment, each culture was diluted to achieve an approximate bacteria count of 10^5 cfu/0.04 ml.

A 2cm diameter circle was drawn on the bottom of a sterile agar plate. In the center of this circle, 0.04 ml of the diluted inoculum was placed on the surface of the agar.

After allowing the inoculum to dry, the adhesive material was applied to the inoculated surface area, making sure to cover the area beyond the marked circle.

After 10 minutes of contact time between the adhesive and the inoculated area, the adhesive's polymerized film was removed from the surface of the agar, and the plates were incubated at 37°C for up to 48 hours.

In total, 210 samples (70 samples per organism) were evaluated. The samples were examined for bacterial growth at 24 and 48 hours. Any growth originating beneath the area of adhesive application was recorded as a positive test.

Results

After 48 hours, the test plates exhibited colony counts ranging from 0 – 59 cfu, indicating significant inhibition of the bacteria.

Each inoculated plate was declared a success if a minimum of 99.9% inhibition of the initial inoculum load was observed. For all bacteria evaluated (MRSA, MRSE, *E. coli*), contact with the adhesive led to a 99.9% inhibition in bacteria load from the initial inoculum.

Conclusion

In this in vitro study, DERMABOND ADVANCED Adhesive was shown to demonstrate inhibition of gram-positive bacteria (MRSA, MRSE) and gram-negative bacteria (*E. coli*).*

*Clinical significance is unknown.

Clinical Reference Article Summary

In Vivo Study of Wound Bursting Strength and Compliance of Topical Skin Adhesives

Singer AJ, Perry LC, Allen Jr. RL

Source:
Academic Emergency Medicine. 2008;15(12):1290–1294

Study Objective

The purpose of this study was to evaluate the wound-bursting strength and flexibility of five topical skin adhesives during the two day period after wound closure.

The following adhesives were evaluated in the study:

DERMABOND® Topical Skin Adhesive

INDERMIL® Tissue Adhesive

Histoacryl® Topical Skin Adhesive

LiquiBand® Topical Skin Adhesive

GluStitch®

Method

Using a template for incision length and location, two symmetric incisions (2cm long each) were created over the dorsolateral flank area of 210 anesthetized, male Sprague-Dawley rats.

After achieving hemostasis and manually approximating the skin edges, a randomized computer algorithm was used to select an adhesive to close the incision. All adhesives were applied according to manufacturer's instructions.

The adhesives were evaluated three times during the study – immediately after closure, 1 day after closure, and 2 days after closure.

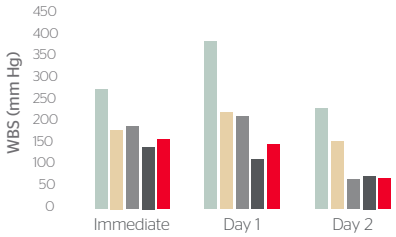
For each evaluation, 14 samples from each adhesive group were tested for wound-bursting strength, and another 14 samples were tested for flexibility.

To test for wound-bursting strength, a vacuum chamber was placed over each sample and negative pressure was applied, stressing the wound in 3 dimensions. The pressure (mmHg) needed to cause wound failure was recorded.

To test for flexibility, a vacuum chamber was placed over the sample and negative pressure was applied to the wound while a laser measured the vertical deformation of the skin (μm). Energy absorption (mmHg x mm) was calculated to quantify the adhesives' flexibility.

Results

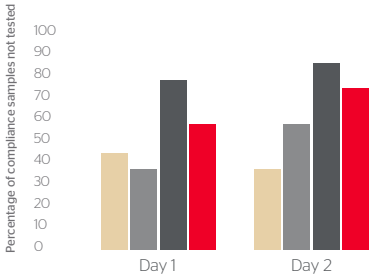
Figure 1
Wound-bursting Strength



DERMABOND® Adhesive
Histoacryl®
Indermil®
LiquiBand™
GluStitch®

In total, 210 measurements were taken on 210 incisions (5 adhesives, 3 time points, 14 samples per time point). Results are shown in **Figure 1**.

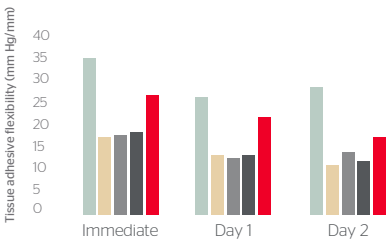
Figure 2
Percent of Samples with Visible Fractures



With the exception of the samples in the DERMABOND® Topical Skin Adhesive group, measurements could not be taken on all samples in an adhesive group because, in some samples, the adhesive's inflexibility had caused the adhesive to fracture during testing.

As shown in **Figure 2**, the percent of samples in an adhesive group experiencing fractures ranged from 36% to 86%.

Figure 3
Flexibility of Five Topical Skin Adhesives



As seen in **Figure 3**, for the samples that maintained their integrity through the testing, the samples in the DERMABOND Adhesive group consistently had the greatest flexibility. Additionally, across all adhesive groups, the adhesive's flexibility decreased over time.

Conclusion

The results of this study demonstrate that DERMABOND Adhesive was significantly stronger and more flexible than the other adhesives evaluated in the study.*

*This study was funded in full or in part by an educational grant from Ethicon, Inc.

Clinical Reference Article Summary

Postoperative Outcomes Associated with Topical Skin Adhesives among Women Having Hysterectomies

Murrmann SG, Markowitz JS, Gutterman EM, Magee G

Source:
Surgical Infections. 2010;11(5):441-447

Study Objective

The purpose of this study was to evaluate the clinical and economic outcomes associated with use of a topical skin adhesive (TSA) versus traditional methods for skin closure following total abdominal hysterectomy.

Method

The study utilized Premier, Inc.'s Perspective™ Comparative Database, which is a large, administrative database containing clinical and economic data from all patient discharge records at more than 400 US hospitals.

Any patient in the database who was discharged from a hospital in 2005 following a total abdominal hysterectomy was included in the study.

The subjects were classified into one of four treatment groups based on the clinical method used to close the surgical incision:

• Sutures • Staples • TSA • Staples and TSA

While the study was open to all commercially available TSAs, at the time of the study the only TSA used on patients in the database was DERMABOND® Topical Skin Adhesive. Thus, the TSA group only had patients treated with DERMABOND Adhesive.

All treatment groups were assessed on three continuous outcomes: length of inpatient stay, total inpatient cost, and days of antibiotic treatment. Length of stay and inpatient cost was available directly from the database; antibiotic treatment days were estimated using the last date when at dose of antibiotic was administered.

Results

In total, 46,011 patients were included in the study. The method of wound closure for these patients is summarized in **Figure 1**:

Due to the large sample size, there were no statistically significant differences in the clinical, demographic, or hospital characteristics of the four treatment groups.

Figure 1
Distribution of Skin Closure Method

Skin Closure Method Evaluated in Study	# of Patients (n)
Sutures	21,201
Staples	23,441
TSA	880
Staples and TSA	489
All Methods	**46,011**

Length of Stay (LOS) and Total Costs

A summary of mean LOS and total hospitalization costs is shown in **Figure 2**.

While the difference in total costs between suture and TSA groups did not meet the significance requirement for this study ($p \leq 0.01$), the difference suggests lower total costs for the TSA group ($p=0.039$).

Figure 2
LOS and Total Costs by Closure Method

Skin Closure Method Evaluated in Study	Mean LOS (days)	Mean Total Hospitalization Costs
Sutures	3.9	$5,862
Staples	4.5	$6,965
TSA	3.7	$5,816
Staples and TSA	5.2	$9,434

Conclusions

The results of this study demonstrate that the clinical and economic outcomes were consistently worse when staples were used to close an incision compared with use of suture or TSA alone.

The clinical outcomes resulting from the use of DERMABOND Adhesive to close wounds were at least as good as the outcomes resulting from the use of suture to close wounds.

Additionally, there is evidence that the total costs of hospitalization for total hysterectomy patients may be less when the incision is closed with DERMABOND Adhesive versus sutures or staples.*

*This study was funded in full or in part by an educational grant from Ethicon, Inc.

Clinical Reference Article Summary

A Randomized Trial Comparing Octylcyanoacrylate Tissue Adhesive and Sutures In the Management of Lacerations

Quinn J, Wells G, Sutcliffe T, Jarmuske M, Maw J, Stiell I, Johns P

Source:
JAMA. 1997;277(19):1527-1530

Study Objective

The purpose of this study was to assess whether using DERMABOND® Topical Skin Adhesive for laceration repair is an effective alternative to suturing.

Method

Patients with non-mucosal facial lacerations as well as certain extremity and torso lacerations, but not on hands, feet or joints, were eligible for this study.

Using a computer algorithm, patients were prospectively segregated into facial and non-facial groups and randomized into two groups – DERMABOND Adhesive and sutures.

In the suture group, lacerations were anesthetized and cleaned, as needed, before repair with a 5-0 or 6-0 monofilament suture. A dressing was applied for at least 48 hours.

In the DERMABOND Adhesive group, lacerations were cleaned with chlorhexidene, and hemostasis was achieved using pressure or topical 1:1000 epinephrine. The wound edges were manually approximated and the adhesive was applied to the surface of the skin, covering the wound edges. The wound was held in place for 30 seconds. No dressing was applied.

The primary outcome was the cosmetic appearance of the scar, evaluated by a blinded plastic surgeon using a photograph of the wound taken three months after closure.

On two occasions, the surgeon examined the photograph and provided a cosmesis score based on a validated 100-mm visual analog scale, ranging from "best scar" to "worst scar."

Additionally, time of procedure, patient pain, and wound complications (i.e., dehiscence, infection) were recorded. Time of procedure was evaluated from start of wound care to complete closure; patient pain and wound complications were recorded on a previously validated scale.

Wound complication was initially evaluated at 3-5 days for facial and at 10-14 days for torso and extremity lacerations. A second assessment occurred 3 months after closure.

Results

In total, 130 patients with 136 lacerations were included in the study. As summarized in **Figure 1**, an equal number of lacerations (68 per group) were randomized to the suture and DERMABOND Adhesive groups.

Figure 1
Patient Retention During Study

	DERMABOND Adhesive	Suture
Randomized	68	68
Initial follow-up	53	53
3 month follow-up	55	50
Withdrawn Lost to follow-up No Photographs	1 12 5	1 17 2
Completed Study	**50**	**48**

As shown in **Figure 2**, there was no significant difference in the blinded, 3-month cosmetic score of the DERMABOND® Topical Skin Adhesive group compared with the suture group. Similarly, there was no significant difference in wound complications between the suture group and the DERMABOND Adhesive group. Statistically significant differences were seen for patient pain and procedure time.

Figure 2
Summary of Observed Clinical Outcomes

	DERMABOND Adhesive	Suture	(p) Value
Mean Cosmetic Score (mm)	67	68	0.65
% Optimal Wound Scores (initial eval)	80%	82%	0.80
% Optimal Wound Scores (3 month eval)	72%	75%	0.74
Mean Pain Scores (mm)	**7.2**	**18.0**	**<0.001**
Mean Time of Procedure (min)	**3.6**	**12.4**	**<0.001**

Conclusions

The results of this study demonstrate that DERMABOND Adhesive produces cosmetic results similar to suturing on certain types of lacerations.

Additionally, lacerations closed with DERMABOND Adhesive were associated with shorter procedure time and less patient pain than lacerations closed with sutures.*

*This study was funded in full or in part by an educational grant from Ethicon, Inc.

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Bibliography

Listed below are all of the currently published RCTs that have evaluated the use of DERMABOND® Topical Skin Adhesive in an application consistent with the indication in the product's label (e.g. skin closure). Studies that evaluated the use of DERMABOND Adhesive for purposes inconsistent with the intended indication were excluded from the bibliography.

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