DERMABOND ADVANCED™ Topical Skin Adhesive

Evidence Brief

ETHICON
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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 barrier, 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 57 randomized controlled trials (RCTs). DERMABOND ADVANCED™ Adhesive has a patented, proprietary chemical formulation[1] that has been shown to provide significantly stronger 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 ADVANCED™ Adhesive or DERMABOND™ Topical Skin Adhesive. **A full list of published studies can be found in the bibliography section of this document.**

- DERMABOND ADVANCED™ Adhesive and DERMABOND™ Adhesive are supported by 57 published RCTs*†
- Total of 6,258 patients evaluated

References

1. DERMABOND ADVANCED® Topical Skin Adhesive Label. LAB-0012182 DNX12. Ethicon, Inc.

2. Singer AJ, Perry LC, Allen RL. In vivo study of wound-bursting strength and compliance of topical skin adhesives. Acad Emerg Med. 2008;15(12):1290-1294.

3. Nipshagen MD, Hage JJ, Beekman W. Use of 2-octyl-cyanoacrylate skin adhesive (Dermabond) for wound closure following reduction mammaplasty: a prospective, randomized intervention study. Plast Reconstr Surg. 2008;122:10-18.

4. Scott GR, Carson CL, Borah G. Dermabond skin closures for bilateral reduction mammaplasties:a review of 255 consecutive cases. Plast Reconstr Surg. 2007;120:1460-1465.

5. Toriumi DM, O'Grady K, Desai D, Bagal A. Use of octyl-2-cyanoacrylate for skin closure in facial plastic surgery. Plast Reconstr Surg. 1998;102:2209-2219.

6. Quinn J, Wells G, Sutcliffe T, et al. A randomized trial comparing octylcyanoacrylate tissue adhesive and sutures in the management of lacerations. JAMA. 1997;277(19):1527-1530.

*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. January 2022.

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
Orthopedic			
DERMABOND™ efficacy in total joint arthroplasty wounds	Miller	*Am J Orthop (Belle Mead NJ).* 2010;39(10):476-478.	Rates of Infection, Wound Drainage, and Dehiscence
Plastics			
Use of 2-octyl-cyanoacrylate skin adhesive (DERMABOND™) for wound closure following reduction mammaplasty: a prospective, randomized intervention study	Nipshagen	*Plast Reconstr Surg.* 2008;122(1):10-18.	Cosmesis, Patient Comfort, Satisfaction
Dermabond skin closures for bilateral reduction mammaplasties: a review of 255 consecutive cases.	Scott	*Plast Reconstr Surg.* 007;120(6):1460-1465.	Cosmesis, Patient Comfort, Satisfaction
Cardiovascular / Cardiothoracic			
Use of 2-octyl cyanoacrylate for skin closure of sternal incisions in cardiac surgery: observations of microbial barrier effects	Souza	*Curr Med ResOpin.* 2008;24(1):151-155	Length of Hospital Stay, Infection Rates
Randomized prospective study comparing conventional subcuticular skin closure with DERMABOND™ skin glue after saphenous vein harvesting	Krishnamoorthy	*Ann Thorac Surg.* 2009;88(5):1445-1449	Closure Time, Cosmetic Appearance, and Patient Satisfaction
OB-GYN			
Health and economic outcomes after OB-GYN surgery: a comparison of skin closure techniques	Murrmann	Poster presentation at 2008 Annual Clinical Meeting of The American College of Obstetricians and Gynecologists; May 3-7, 2008;	Hospital Costs, Infection Rates
ER			
A Randomized Trial Comparing Octylcyanoacrylate Tissue Adhesive and Sutures In the Management of Lacerations	Quinn	*JAMA.* 1997;277(19):1527-1530.	Cosmesis, Time, Pain
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	Internal Ethicon Study	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

Clinical Reference Article Summary: Orthopedic

DERMABOND™ efficacy in total joint arthroplasty wounds

Adam G. Miller, MD, and Michael L. Swank, MD

Source:

Am J Orthop (Belle Mead NJ). 2010;39(10):476-478.

Study Objective

The purpose of this study was to compare the efficacy of DERMABOND™ and the efficacy of surgical staples in healing high-tension, mobile surgical sites of the efficacy of TJAs.

Method

The surgery performed an unselected consecutive series of 236 primary TKAs since 2003 and 223 primary THAs since 2002, 459 cases total.

All patients underwent computer-assisted surgery at the same institution. No statistical difference in comorbidities existed between groups.

The THAs involved 212 posterior approaches and 11 anterior. High-viscosity DERMABOND™ and a 4-gauge Monocryl subcuticular suture were used in 250 cases (143 TKAs beginning in May 2004 and 107 THAs beginning in January 2004), and surgical staples were used in 209 controls (93 TKAs, 116 THAs) performed before the test cases.

Deep fascia and subcutaneous layers in all case and control wounds were prepared with Vicryl sutures.

All patient data were prospectively gathered in a computerized database and then retrospectively reviewed.

Variables analyzed at 2 and 6 week follow-ups included:

- Deep infection
- Superficial infection
- Stitch reaction
- Abnormal redness
- Blisters
- Drainage
- Dehiscence

Infection rates were calculated according to definitions of deep infection, débridement was required, and superficial infection, antibiotics were prescribed.

Wound closure time was determined by measuring time to closure beginning with release of the tourniquet used during TKAs.

Results

The case group consisted of 97 men and 153 women, 250 patients in total, and the control group consisted of 75 men and 134 women, 209 patients in total.

Neither group developed any deep infections. According to χ^2 analysis, the case–control difference in incidence of superficial infections at the 2 and 6 week follow-up was not statistically significant, shown in **Figure 1.**

Figure 1. Statistical Analysis[a]

	Control		Case		P[b]		
	Knee	Hip	Knee	Hip	Knee	Hip	Total
Patients							
Female	58	76	89	64	.98	.38	.52
Male	35	40	54	43	--	--	--
Mean age (y)	66	63	67	62	.48	.37	.86
Infection[c]							
Deep	0	0	0	0	--	--	--
Superficial	4	1	4	4	.53	.22	.60
Inflammation							
Dehiscence	0	2	1	2	.42	.33	.80
Abnormal redness	9	1	14	4	.98	.22	.28
Drainage	0	2	4	1	.10	.20	.36
Tape blister	0	6	0	0	--	.00	.01
Stitch reaction	2	2	0	0	.08	.05	.03
Closure Time (min)[d]	**31.4**	**NA**	**38.5**	**NA**	**.00**	**NA**	**NA**

There was no statistical significance in the inflammatory response (abnormal redness, drainage, dehiscence) between the case group and the control group.

Closure time was a mean of 7 minutes longer for case patients than for control patients.

Incidence of blisters and stitch reactions was significantly lower for cases than for controls.

Conclusion

The results of this study demonstrate that DERMABOND™ is as effective as surgical staples in high-tension TJA wound closure and appearance, with an increase of satisfaction for TJA patients when it comes to recovery (no staple removal), the ability to shower, and reduced need for wound care.

Abbreviation: NA, not applicable.

a All numbers are n, except where noted otherwise.

b Determined from χ^2 test for independence. Knee and hip *P*s reflect their respective surgeries. Total *P* reflects groups defined as all cases and all controls.

c Deep infections were defined as requiring débridement, superficial infections as requiring antibiotics.

d Total time needed to close all layers of tissue with control or case method. Not recorded for hip cases.

Clinical Reference Article Summary: Plastics

Use of 2-octyl-cyanoacrylate skin adhesive (DERMABOND™) for wound closure following reduction mammaplasty: a prospective, randomized intervention study

Martine D. Nipshagen, M.D. J. Joris Hage, M.D., Ph.D. Werner H. Beekman, M.D., Ph.D.

Source:

Plast Reconstr Surg. 2008;122(1):10-18.

Study Objective

The purpose of this study was to evaluate the use of 2-Octyl-cyanoacrylate skin adhesive (DERMABOND™) used for surgical wound closure after bilateral reduction mammaplasty by randomized unilateral use of a skin adhesive and contralateral conventional suturing to assess the possible difference in outcome between these two methods.

Method

The authors conducted a prospective, randomized, controlled clinical intervention study in which the scar characteristics after use of skin adhesive were compared with those after suture closure.

Bilateral reduction mammaplasty was performed in 50 patients. The method of closure (sutures versus skin adhesive) applied to each breast was determined randomly, using each patient as her own control.

Scars were assessed by the patient and by a blinded panel, at 1 week, 6 weeks, and 6 months after surgery, using a visual analogue scale, the modified Hollander Wound Evaluation Scale, and the Patient and Observer Scar Assessment Scale.

Results

Patients expressed an overall preference for the adhesive side as of 1 week after surgery. The panelists expressed no overall preference for either method of skin closure after 1 week however they preferred the skin adhesive closure at 6 weeks and 6 months.

Patients' visual analogue scale scores for scar comfort and aesthetic outcome and panelists' visual analogue scale scores for aesthetic outcome were significantly better for the adhesive side at 6 weeks and 6 months ($p < 0.05$).

The modified Hollander Wound Evaluation Scale for the panel indicated a significantly more favorable overall result at the skin adhesive side at 6 weeks after surgery ($p<0.01$).

The total Patient and Observer Scar Assessment Scale score at 6 months was significantly better for the adhesive side according to the patients ($p<0.01$). The scores for the panelists indicated significantly less vascularization and less pigmentation of the scar on the breast closed with skin adhesives ($p<0.05$).

Conclusion

The results of this study demonstrate that DERMABOND™ is a sound alternative for wound closure after reduction mammaplasty.

DERMABOND™ observed significantly better aesthetic outcome and overall preference for the use of the skin adhesive over sutures, among both the patients and the panelists.

Clinical Reference Article Summary: Plastics

DERMABOND™ skin closures for bilateral reduction mammaplasties: a review of 255 consecutive cases.

Gregory R. Scott, M.D. Cynthia L. Carson, P.A.-C. Gregory L. Borah, M.D.

Source:

Plast Reconstr Surg. 2007;120(6):1460-1465.

Study Objective

The purpose of this study was to review a large series of 255 consecutive bilateral reduction mammaplasty patients to evaluate the safety and efficacy of DERMABOND™ for these procedures.

Method

A review was undertaken of 255 consecutive bilateral reduction mammaplasties performed by a single surgeon from 1999 to 2005 with DERMABOND™ used for skin closure.

This series of patients was compared with an earlier review by the same surgeon of 415 consecutive bilateral reduction mammaplasties using standard layered sutured skin closures.

Results

DERMABOND™ was associated with decreased operative times compared with the sutured closures (93 minutes compared with 118 minutes; or 20% less time).

The rates for minor wound dehiscence (1.18 percent), major wound dehiscence (0.78), hypertrophic scar revisions (2.75 percent), and cellulitis (2.75 percent) were all lower in the DERMABOND™ group, but these differences were not statistically significant. **(Figure 1)**

Patient discomfort was minimized because no sutures needed be removed after surgery and no tapes or other postoperative dressings were required beyond gauze and a surgical bra. Patients were pleased to be able to shower after their first postoperative visit (5 to 7 days)

Figure 1. Complications

	1992–1998* (%)	1999–2005† (%)	*p*‡
Delayed wound healing	21 (5.06)	15 (5.88)	0.65
Dehiscence			
Minor	12 (2.89)	3 (1.18)	0.15
Major	8 (1.93)	2 (0.78)	0.33
Hypertrophic scar revisions	19 (4.58)	7 (2.75)	0.23
Cellulitis	17 (4.10)	7 (2.75)	0.36
Total	77 (18.46)	34 (13.36)	

*n = 415 patients.
†n = 255 patients.
‡Chi-square Fisher's exact test.

Conclusion

The results of this study demonstrate DERMABOND™ is a safe and effective means of skin closure for bilateral reduction mammaplasties. Shortened operative times can lead to economic health cost savings. Patient discomfort is minimized and postoperative care is simplified.

Clinical Reference Article Summary: Cardiovascular / Cardiothoracic

Use of 2-octyl cyanoacrylate for skin closure of sternal incisions in cardiac surgery: observations of microbial barrier effects

E.C. Souza et al.

Source:

Curr Med ResOpin. 2008;24(1):151-155

Study Objective

The purpose of this study was to evaluate the impact of the use of 2-OCA (DERMABOND™ Adhesive) as an add-on measure in the closure of sternotomy incisions by comparing post-operative infection rates and lengths of hospital stay.

Method

- Retrospective, non-randomized review of a total of 1360 patients. Conducted at the largest cardiac care facility in Latin America, the Hospital Beneficiência Portuguesa, São Paulo, Brazil.
- 680 patients who received DERMABOND™ Adhesive from 2000-2004 served as test group.
- 680 patients who did not receive DERMABOND™ Adhesive from 1995-1999 served as control group.
- Suturing technique was the same for all patients.

Results

- Overall infection rate (superficial and deep) was reduced from 4.9% to 2.1%, (p = <0.001).
- Superficial infection rate decreased from 4.3% to 2.1%.
- Deep infection rate decreased from 0.6% to 0%.
- Post-operative hospital stays were reduced from median of 13 days to 9 days, (p = <0.001).

Conclusion

The results of this study demonstrate routine use of DERMABOND™ Topical Adhesive as an add-on measure to conventional sutures was associated with a significant reduction in infection rates for cardiovascular surgery patients. Following introduction of DERMABOND™ Adhesive, deep infection rates were reduced to zero and post-operative hospital stays were also significantly reduced.

Clinical Reference Article Summary: Cardiovascular / Cardiothoracic

Randomized prospective study comparing conventional subcuticular skin closure with DERMABOND™ skin glue after saphenous vein harvesting

Bhuvaneswari Krishnamoorthy, Osman Najam, Ursalan A. Khan, Paul Waterworth, James E. Fildes, Nizar Yonan

Source:

Ann Thorac Surg. 2009;88(5):1445-1449

Study Objective

The purpose of this study was to compare results of skin closure using DERMABOND™ and subcuticular sutures after coronary artery bypass grafting (CABG) in relation to cosmetic outcomes, patient satisfaction, and operative times.

Method

The study prospectively enrolled and randomized 106 patients who underwent CABG. The groups received closure with DERMABOND™ skin glue or subcuticular sutures (n=53 each) after saphenous vein harvesting using the bridging technique.

Clinical variables included:

- Incidence of wound complications
- Cosmetic results
- Patient satisfaction early and late after the operation

In the DERMABOND™ group (n=53), the wound was closed with subcutaneous sutures, skin approximated, and the skin glue applied. DERMABOND™ was applied in two layers over the edges of the skin after complete drying.

Wound closure time for the two methods was recorded. Cosmetic appearance was assessed using the Hollander, the Vancouver, and the visual analog scale.

Patient satisfaction was recorded before discharge and at week 6.

Results

There were no significant differences in the total operative time between the two groups (p=0.43).

Closure time was significantly shorter in the DERMABOND™ group (p=0.017). The median closure time in the DERMABOND™ group was 10 minutes 45 seconds compared with 13 minutes 20 seconds in the suture group.

Patients in the DERMABOND™ group also reported superior cosmetic outcome at weeks 1 ($p < 0.001$) and 6 (p=0.001) and significantly greater patient satisfaction with the scar color and visibility at 6 weeks ($p < 0.001$).

Conclusion

The results of this study demonstrate DERMABOND was shown to provide statistically significant closure time, cosmetic appearance, and patient satisfaction compared to traditional subcuticular skin sutures. This technique provides a novel method of wound closure after CABG.

*Clinical significance unknown.

Clinical Reference Article Summary: OB-GYN

Health and economic outcomes after OB-GYN surgery: a comparison of skin closure techniques

Susan G. Murrmann, Jeffrey S. Markowitz, Elane M. Gutterman, Glenn Magee

Source:

Poster presentation at 2008 Annual Clinical Meeting of The American College of Obstetricians and Gynecologists; May 3-7, 2008;

Study Objective

The purpose of this study was an assessment of outcomes comparing use of topical skin adhesives (cyanoacrylate) to conventional skin closure techniques among women undergoing OB-GYN surgery.

Method

The study utilized an administrative hospital database. Adult women who had an abdominal hysterectomy (HYS-C) or cesarean delivery (CS-C) in 2005 were aggregated into 2 cohorts.

Each cohort was further classified by method of skin closure:

- Sutures
- Staples
- Octylcyanoacrylate (OCA)
- Staples + OCA

Unadjusted and adjusted comparisons controlling for covariates were conducted on non-prophylactic antibiotic treatment after day 4, a proxy for surgical site infection, and total hospital costs. Pairwise group comparisons were performed when overall P value<0.01 (2-tailed).

Results

In total, hysterectomy distribution was 21,201 sutures, 23,441 staples, 880 OCA and 489 staples + OCA (combination).

Respective rates of infection were:

- Sutures-12.93%
- Staples-17.51%
- OCA-11.14%
- Staples + OCA-23.72%

For infection rates and costs, adjusted pairwise comparisons indicated no statistically significant difference between OCA versus sutures or staples (P>0.01), while OCA was superior to combination (P<0.001). Infection as reflected by non-prophylactic antibiotic treatment and total costs is summarized in **Figure 1.**

Figure 1. Unadjusted and adjusted outcomes by skin closure group

Outcomes	Sutures	Staples	OCA	Staples+OCA	Overall p-value	Significant pairwise comparisons*	Overall P-value	Significant pairwise comparisons†
HYS Cohort	Percent				Unadjusted analysis		Adjusted analysis[2]	
Antibiotic non-prophylactic treatment	12.93	17.51	11.14	23.72	<0.0001	1[a], 3[a], 4[a], 5[a], 6[a]	<0.0001	1[a], 3[a], 5[a], 6[a]
	Unadjusted means							
Total costs (dollars)	$5,862	$6,965	$5,816	$9,434	<0.0001	1[a], 3[a], 4[a], 5[a], 6[a]	<0.0001	1[a], 3[a], 5[a], 6[a]
CS Cohort	Percent							
Antibiotic non-prophylactic treatment	12.83	12.76	9.50	13.97	<0.0001	2[a], 4[a]	<0.0001	2[a], 4[a]
	Unadjusted means							
Total costs (dollars)	$5,572	$5,594	$5,010	$5,949	<0.0001	2[a], 4[a], 6[a]	<0.0001	1[a], 2[a], 4[a], 6[a]

In cesarean delivery, distribution was 102,797 sutures, 50,097 staples, 2,391 OCA and 272 combination. The rates of infection were:

- Sutures-12.83%
- Staples-12.76%
- OCA-9.50%
- Staples + OCA-13.97%

Adjusted pairwise comparisons indicated a significantly lower infection rate and lower costs for OCA versus sutures, staples and combination (P<0.001).

Conclusion

For skin closure following OB-GYN surgery, OCA was comparable or lower in infection rates and hospital costs relative to sutures or staples. Combining staples with OCA offered no additional benefit over use of single techniques for outcomes assessed.

*Significant pairwise comparisons a=P < 0.001 1 sutures vs staples; 2 sutures vs OCA;
3 sutures vs staples+OCA; 4 staples vs OCA; 5 staples vs staples+OCA; 6 OCA vs staples+OCA

†Adjusted analysis controlling for demographic, clinical and hospital dimensions

Clinical Reference Article Summary: ER

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

James Quinn, George Wells, Terri Sutcliffe, Mario Jarmuske, Jennifer Maw, Ian Stiell, Peter Johns

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 3 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	50	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™ Advanced	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**

Conclusion

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.

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 1×10^3 colony-forming units (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 significance unknown.

Clinical Reference Article Summary

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

Bhende S

Source:

Internal Ethicon Study

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 colony-forming units (cfu)/0.04 ml.

A 2 cm 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 (2 cm 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 instructions.

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

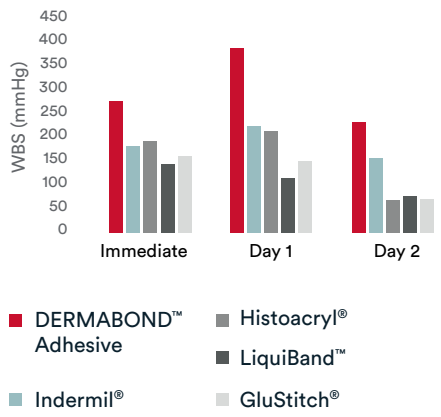
For each evaluation, 14 samples from each adhesive group were tested for wound-bursting strength, and another 14 samples were tested for flexibility.

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.

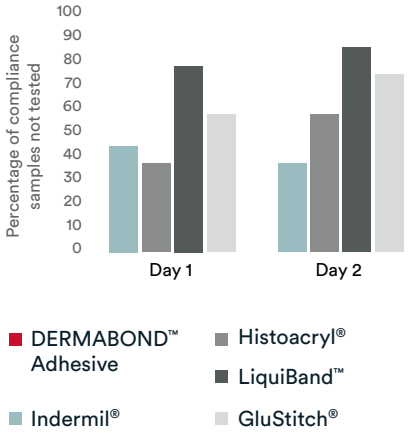
Results

Figure 1
Wound-bursting Strength



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.**

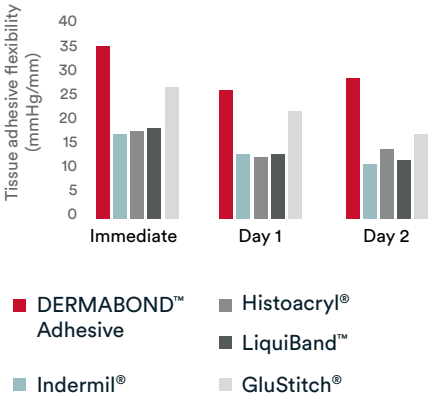
Figure 2
Percent of Samples with Visible Fractures



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 Adhesive



As seen in **Figure 3**, for the samples that maintained their integrity throughout testing, the samples in the DERMABOND™ Adhesive group consistently had the greatest flexibility. Adhesive flexibility decreased over time in all cases.

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.

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For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

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