Dermabond®

DERMABOND® PRINEO® Skin Closure System

Evidence Brief

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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 protection, patient comfort, and cosmesis allows healthcare practitioners to evaluate which product will provide the greatest benefits for their patients.

DERMABOND® PRINEO® Skin Closure System is an innovative skin closure device that can be used to efficiently and conveniently approximate the skin edges of surgical incisions and lacerations. DERMABOND PRINEO System redistributes tension to the surrounding healthy surface area and requires no piercing of the skin.[1] It is currently the only skin closure system that combines the benefits of a proven topical skin adhesive with a flexible, self-adhering mesh.

The performance and benefits of DERMABOND PRINEO System are supported by extensive body of published literature, including several randomized controlled trials (RCTs). This Evidence Summary includes a sample of the available studies for DERMABOND PRINEO System, and a full list of published studies supporting the DERMABOND PRINEO System and its topical skin adhesive component can be found in the bibliography section of this document.

- DERMABOND PRINEO System is supported by 4 published RCTs, with a total of 438 patients evaluated
- Additionally, the TSA component of DERMABOND PRINEO System has been extensively studied in over 40 RCTs. The complete list of RCTs related to DERMABOND® Topical Skin Adhesive can also be found in this document's bibliography

References

1. DERMABOND® PRINEO® Skin Closure System, Instructions For Use.

Case Study

Abdominoplasty Skin Closure with DERMABOND® PRINEO® Skin Closure System

Dr. Aldo Benjamin Guerra, MD, FACS, Board Certified Plastic Surgeon, Guerra Plastic Surgery Center, Scottsdale, AZ

Not real patient

Background

A 56-year-old woman with a history of recent weight loss requested cosmetic abdominal contouring. She presented 19 years after the birth of her last child. She gained 35 pounds during each of her pregnancies. More recently, she lost 20 pounds through diet and exercise. Her major complaints included dissatisfaction with the amount of loose skin and abdominal distention. Physical examination demonstrated a weakened abdominal musculature with rectus diastasis. No hernias were identified. She did show a significant amount of loose skin and moderate stretch marks. After considering her options, she elected to undergo an abdominoplasty.

Procedure

A standard abdominoplasty with rectus abdominal muscle repair was completed. To reduce the tension on the incision and advance the skin flap, progressive tension sutures were placed until the edges of Scarpa's edges were closely approximated. Closure of Scarpa's fascia was completed with #1 Coated VICRYL® (polyglactin 910) Suture. Closure of this layer dramatically reduces the tension on the incision. Deep dermal closure was performed using a running barbed suture technique on the right and left side of the incision (Figure 1).

Figure 1. Closure of Scarpa's fascia dramatically reduces tension in the closure. This prepares the tissue for the dermal closure.

This readily approximated the skin edges so the skin on either side of the incision was "kissing" the other side (Figure 2). There was little remaining tension using this technique, which is ideal to obtain an optimal result. A simple test the surgeon can perform is to gently apply pressure and observe the skin edges pull apart. When the pressure is released, the skin returns to its "kissing" position. When this occurs, there is no need to add additional sutures in the subcutaneous layer or externally. At this point, DERMABOND PRINEO System can be applied.

The mesh is applied beginning at one end of the incision while rolling it out from the device. The tape can be applied in a single motion, but a go-and-stop technique tends to reduce tension during application and minimizes skin reactions. The liquid adhesive is applied after the tape is in place (Figure 3). To reduce blood staining from the wound, it is recommended to blot (not rub) the edges of the incision, as they are vulnerable to abrasion and trauma.

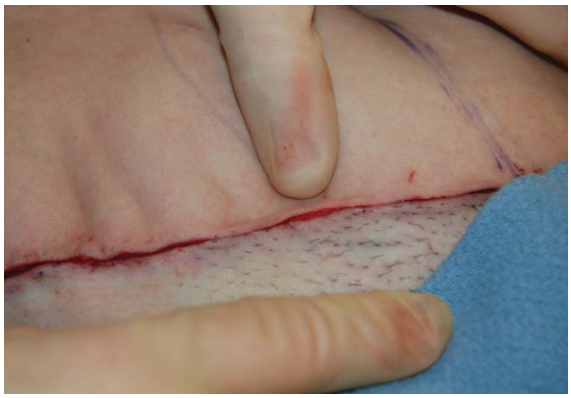


Figure 2. Once the dermal closure is performed, the skin edges appear to "kiss" and can be teased apart with gentle pressure. The skin edge readily re-approximates when the tissue is released.

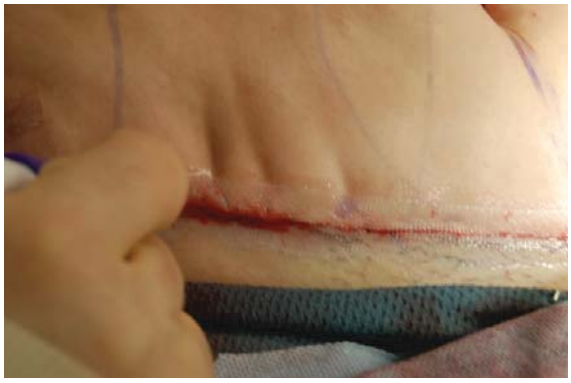
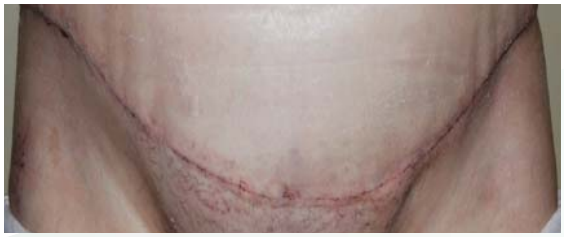


Figure 3. Blotting the wound to control oozing is better than rubbing to keep the tape from staining. The mesh tape is then applied to approximate the edges. The liquid adhesive is applied after the mesh tape is in place.

Follow-up

The patient was seen on several occasions within the first 2 weeks after surgery. She made excellent progress and her DERMABOND PRINEO System tape was removed during the 2 week visit. The wound edges were well approximated and there were no signs of infection (Figure 4).

Figure 4. Photograph taken immediately after removal of DERMABOND PRINEO System 2 weeks after surgery.



Summary of Key Studies

Publications that support the claims for DERMABOND® PRINEO® Skin Closure System 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	Procedure
Evaluation of a novel wound closure device: a multicenter randomized controlled trial	Singer	*Acad Emerg Med.* 2011;18:1060-1064.	Strength, flexibility and durability	N/A
A comparison of a new skin closure device and intradermal sutures in the closure of full-thickness surgical incisions	Richter	*Plast Reconstr Surg.* 2012;130:843-850.	Strength, flexibility, and durability; patient comfort	Abdominoplasty
Evaluation of a new skin closure device in surgical incisions associated with breast procedures	Blondeel	*Ann Plast Surg.* 2013 May 30 (ePublication ahead of print).	Strength, flexibility, and durability; patient comfort	Breast
Use of 2-octyl cyanoacrylate together with a self-adhering mesh (DERMABOND® PRINEO® Skin Closure System) for skin closure following abdominoplasty: an open, prospective, controlled, randomized, clinical study	Parvizi	*Aesthetic Plast Surg.* 2013;37:529-537.	Strength, flexibility, and durability; patient comfort; cosmesis	Abdominoplasty
Effective wound closure with a new two-component wound closure device (DERMABOND® PRINEO® Skin Closure System in excisional body-contouring surgery: experience in over 200 procedures	Huemer	*Aesthetic Plast Surg.* 2012;36:382-386.	Strength, flexibility, and durability	Body contouring
In-vitro study of DERMABOND® PRINEO® Skin Closure System's ability to kill bacteria on contact	Bhende	Data on File. Ethicon, Inc.	Inhibition of bacterial growth	N/A
In vitro evaluation of the microbial barrier properties of Dermabond ProTape*	Bhende	Data on File. Ethicon, Inc.	Microbial barrier	N/A

*Dermabond ProTape is a previous name for DERMABOND® PRINEO® Skin Closure System

Clinical Reference Article Summary

Evaluation of a Novel Wound Closure Device: A Multicenter Randomized Controlled Trial

Singer AJ, Chale S, Giardano P, et al.

Source:
Academic Emergency Medicine. 2011;18:1060-1064

Study Objective

The purpose of this prospective study was to assess whether DERMABOND® PRINEO® Skin Closure System was equivalent to high-viscosity tissue adhesive (DERMABOND® Topical Skin Adhesive) after laceration repair.

Method

216 patients at 9 academic and community ERs and urgent care centers participated in this open-label randomized controlled trial. Patients were at least 1 year of age and had one or more traumatic wounds. If required, deep tissues were closed with interrupted deep dermal sutures.

Patients were randomized in a 2:1 ratio to DERMABOND PRINEO System and DERMABOND Adhesive, respectively. Wounds could be covered with a dry, non-medicated dressing.

The primary outcome was the incidence of wound edge apposition without dehiscence, or need of re-approximation at 14 ± 2 days following wound repair. Secondary outcomes included the incidence of infection at 14 and 30 days and the percentage of lacerations with an optimal cosmesis score at 30 days following surgery. Cosmesis was assessed by an investigator unaware of the device assignment using a validated 6-item wound evaluation scale where an overall score of 6 was considered optimal.

Infection was defined according to the presence of redness >3-5mm from the repaired wound, swelling, purulent discharge, pain, increased skin temperature, or fever.

The incidence and extent of local acute inflammatory reactions, including edema, erythema, pain, and local temperature were determined and used to calculate an Acute Inflammatory Response Evaluation (AIRE) score.

Results

There were no significant differences indemographic characteristics between the two groups. Most wounds were on the face and upper extremities. Deep sutures were used in 26 patients in the DERMABOND PRINEO System group and in 14 patients in the DERMABOND Adhesive group.

The incidence of successful wound closure was higher in the DERMABOND PRINEO System group than in the DERMABOND Adhesive group (86.0% vs. 78.1%, respectively).

At 30 days after surgery, the rates of wounds with optimal cosmesis scores were similar for DERMABOND PRINEO System and DERMABOND Adhesive (65.0% vs. 58.9% respectively), as were the rates of optimal AIRE scores (61.5% vs.60.3%).

Conclusion

DERMABOND® PRINEO® Skin Closure System of traumatic lacerations was shown to be equivalent to DERMABOND Adhesive with regard to complete wound edge apposition and need for reclosure due to dehiscence, as well as cosmetic appearance.

Clinical Reference Article Summary

A Comparison of a New Skin Closure Device and Intradermal Sutures in the Closure of Full-Thickness Surgical Incisions

Richter D, Stoff A, Ramakrishnan V, et al.

Source:
Plast Reconstr Surg. 2012;130:843-850

Study Objective

The purpose of this prospective study was to assess the short- and long-term outcome with regard to cosmetic and postoperative complications of plastic surgical incision closure with DERMABOND® PRINEO® Skin Closure System versus standard wound closure by intradermal suturing.

Method

In this study at 5 European centers, 77 women and 6 men (mean age of 49.8 years) underwent abdominoplasty or circumferential body lift which required skin closure of a full-thickness surgical incision of at least 20cm in length.

Incisions were divided in half, and each half was randomized to closure with either DERMABOND PRINEO System or intradermal sutures. Investigators were not blinded to the skin closure device.

Superficial fascia was closed along the entire length of the incision with interrupted suturing, relieving tension for approximation of the skin layers. The subcutaneous layer was then closed with interrupted suturing. Finally, half of the incision randomized for closure with intradermal sutures was closed first, followed by application of DERMABOND PRINEO System to the other half.

The primary outcome was complete approximation of the skin edges at 24 hours, 7 days, and 12 - 25 days after surgery.

Hollander cosmesis scale was used to grade wounds at 90 days and at 6 and 12 months postoperatively. Cosmetic outcomes were also analyzed at 6 and 12 months using the Patient and Observer Scar Assessment Scale (POSA).

The time to closure of the incisions was measured. For DERMABOND PRINEO System, timing started when the mesh applicator made contact with the skin and ended when the application of the liquid adhesive was complete. For intradermal sutures, the time started once the needle made skin contact and ended after the entire segment had been sutured and the final suture was tied and cut.

Clinical wound infection was defined as redness, swelling, purulent discharge, pain, increased skin temperature, or fever. Local inflammatory reactions were assessed using Acute Inflammatory Response Evaluation (AIRE) score.

The proportion of patients with complete approximation of their wounds was 94% for intradermal sutures vs. 89.2% for DERMABOND PRINEO System. No statistically significant difference was found between the two wound closure systems with regard to complete approximation.

The mean time to closure was 1.46 minutes vs. 6.65 minutes for DERMABOND PRINEO System and intradermal sutures, respectively. This was a statistically significant shorter mean time.

Results

Incision healing and cosmetic outcomes were similar for the two groups at 90 days and 6 and 12 months postoperatively.

There were no major differences between treatments for cosmetic outcomes as evaluated by the POSA questionnaires and photography at 6 and 12 months, with the majority of scores in the “good” category.

Some significant statistical differences were observed in the individual AIRE characteristics. Compared to DERMABOND® PRINEO® Skin Closure System, intradermal sutures showed more erythema at 24 hours, more edema and pain at 12-25 days, and more pain on day 7.

With regard to DERMABOND PRINEO System, blistering was evident at day 7 and at days 12-25 in 2 of 83 patients (2.4 %).

Conclusions

In conclusion, DERMABOND PRINEO System can be considered equivalent to intradermal sutures for full-thickness surgical incisions with regard to safety and effectiveness.

The ease and speed of DERMABOND PRINEO System application contribute to shortened operative times.

Clinical Reference Article Summary

Evaluation of a New Skin Closure Device in Surgical Incisions Associated with Breast Procedures

Blondeel PN, Richter D, Stoff A, et al.

Source:
Ann Plast Surg (ePublication). 2013

Study Objective

The purpose of this prospective study was to assess whether DERMABOND® PRINEO® Skin Closure System was equivalent to intradermal sutures for wound closure.

Method

In this prospective study at 5 European centers, 79 patients with a mean age of 38.8 years underwent elective surgery requiring symmetrical breast incisions of at east 15cm in combined length.

Superficial fascia was closed with interrupted suturing to relieve tension for approximation of skin layers. The subcutaneous tissue was closed with interrupted suturing. Each breast was then randomized to either DERMABOND PRINEO System or intradermal sutures.

The primary outcome was complete approximation of the skin edges at 24 hours, 7 days, and 12-25 days after surgery.

Hollander cosmesis scale was used to grade wounds at 90 days and at 6 and 12 months post-operatively. Cosmetic outcomes were also analyzed at 6 and 12 months using the Patient and Observer Scar Assessment Scale (POSA).

The time to closure of the incisions was measured. For DERMABOND PRINEO System timing started when the mesh applicator made contact with the skin and ended when the application of the liquid adhesive was complete. For intradermal sutures, the timing started once the needle made skin contact and ended after the entire segment had been sutured and the final suture was tied and cut.

Clinical wound infection was defined as redness, swelling, purulent discharge, pain, increased skin temperature, or fever. Local inflammatory reactions were assessed using Acute Inflammatory Response Evaluation (AIRE) score.

Results

Percentage of patients with complete approximation was the same for both devices (96.2%). There was no statistically significant difference between DERMABOND PRINEO System and intradermal sutures with regard to complete wound approximation.

The mean time to closure was 2.56 minutes for DERMABOND PRINEO System and 16.22 minutes for intradermal sutures.

Incision healing and cosmetic outcomes were similar based on the modified Hollander cosmesis scale at 90 days and 6 and 12 months postoperatively.

For all POSA characteristics, the majority of scores for both devices were in the "good" category at 6 and 12 months.

A significant difference was observed for the AIRE characteristic of edema, with intradermal sutures showing more edema than DERMABOND® PRINEO® Skin Closure System at 12-25 days post-op.

With regard to DERMABOND PRINEO System, blistering was evident at 24 hours in 2 patients (2.5%), at 7 days in 8 patients (10.3%), and 12-25 days in 2 patients (2.5%).

Conclusion

DERMABOND PRINEO System is a useful alternative for wound closure in breast procedures in terms of effectiveness and time to close incisions as well as safety.

DERMABOND PRINEO can be considered equivalent to intradermal sutures for full-thickness surgical incisions with regard to safety and effectiveness.

Clinical Reference Article Summary

Use of 2-Octyl Cyanoacrylate Together with a Self-Adhering Mesh (DERMABOND® PRINEO® Skin Closure System) for Skin Closure Following Abdominoplasty: An Open, Prospective, Controlled, Randomized Clinical Study

Parvizi D, Friedl H, Schintler MV, et al.

Source:
Aesthetic Plast Surg. 2013;37(3):529-537

Study Objective

The purpose of this study was to assess whether DERMABOND PRINEO System is an effective alternative in terms of cost and cosmetic outcomes to conventional suturing for wound closure after abdominoplasty.

Method

Fifty-two women and 8 men between the ages of 21 and 65 years participated in this study conducted in Austria.

Following abdominal dermolipectomy and closure of subcutaneous fat, wound edges were approximated with interrupted, buried, resorbable intradermal sutures (2-0 Coated VICRYL® (polyglactin 910) Suture). Sutures were buried at 0.5-1.0cm intervals to achieve even tension along wound edges.

Patients were prospectively randomized using a computer algorithm into two groups - DERMABOND PRINEO System, and sutures combined with adhesive strips.

The primary outcome was the cost of wound closure. The cost analysis was based on the material costs for sutures and DERMABOND PRINEO System, as well as total operating time for each group.

A secondary outcome measured was clinical outcome within the two groups.

A panel of 3 plastic surgeons and 3 plastic surgeon residents assessed wounds and scars. The Hollander cosmesis scale was used to grade wound cosmesis at 2 weeks after surgery. At 6 weeks patients were examined for infection, inflammation, and dehiscence.

Abdominal scar appearance was assessed at 6 and 12 month using the Vancouver scar scale. Also at 12 months, patients self-answered the Patient Scar Assessment Scale on a scale of 1 (no disorder) to 10 (extreme discomfort).

Results

Mean total operating time was shorter for DERMABOND PRINEO System than for sutures (148.8 minutes vs. 161.9 minutes, respectively). The mean price difference in the operative time per patient was $134.79 in favor of DERMABOND PRINEO System.

Also, significantly more pain was associated with the removal of sutures than of DERMABOND PRINEO System, based on the Visual Analog Scale for Pain (VAS) (Table 1).

Table 1: Mean patient VAS

Suture group (SD)	DERMABOND PRINEO group (SD)
1.90 (0.29)	0.43 (0.09)*

0=no pain, 10=worst pain possible; *p<0.001

Good or excellent aesthetic appearance was noted in 56 of the 60 patients at 6 weeks. Delayed healing was observed in the other 4 patients (Table 2).

Table 2: Complications

Compication	Suture (%)	DERMABOND PRINEO (%)
Infection	1 (3.33)	2 (6.66)
Hematoma	1 (3.33)	1 (3.33)
Delayed healing	3 (10.0)	1 (3.33)
Total	**5 (16.66)**	**4 (13.32)**

At 6 and 12 months, overall mean scores for scar appearance were significantly better for DERMABOND® PRINEO® Skin Closure System. Patients also noted at 12 months significantly less pain, thickness, and irregularity with DERMABOND PRINEO System than with conventional sutures.

Conclusions

The use of DERMABOND PRINEO System decreases operative time and cost.

DERMABOND PRINEO System is a safe and effective substitute for superficial skin closure with good cosmetic results, no increase in wound complications, and enhanced postoperative patient comfort.

Key Reference Article Summary

In-vitro study of DERMABOND® PRINEO® Skin Closure System's ability to kill bacteria on contact

Bhende S, et al.

Source:
Data on file. Ethicon, Inc.

Study Objective

The purpose of this in vitro study was to demonstrate the ability of DERMABOND PRINEO System to inhibit bacteria on contact.

Bacteria included in this study included:

Methicillin-resistant *Staphylococcus epidermidis* (MRSE)

Escherichia coli Methicillin-resistant

Staphylococcus aureus (MRSA)

Method

Cultures were grown in sterile trypticase soy broth for 18-24 hours at 35-37°C and then diluted to an approximate count of 10^4-10^5 colony-forming units (CFUs) per 0.04ml. The initial inoculum counts determined by standard plate count are shown in the table below.

Organism	Initial Inoculum Count (CFUs/0.04ml)
MRSA	1.14×10^5
MRSE	2.88×10^4
E. coli	4.43×10^5

Plates containing sterile trypticase soy agar were inoculated with diluted inoculum (0.04ml) applied within a rectangular area on the plate bottom. For the test plates, DERMABOND PRINEO System was applied on the inoculated surface and allowed to polymerize. After 10 minutes, films were removed and plates were incubated for up to 48 hours at 35-37°C. Seventy polymerized films were evaluated per challenge organism (MRSE, MRSA, and *E. coli*) for a total of 210 films.

Inoculum controls were prepared by applying diluted inoculum only to the plate. Media controls were prepared to check the media for sterility. Negative control plates were prepared by applying only DERMABOND PRINEO System to the sterile agar.

Test and control plates were incubated for up to 48 hours and observed for growth at 24 and 48 hours. Only growth originating from beneath the area of DERMABOND PRINEO System application was recorded as positive.

Results

After 24 and 48 hours of incubation, the inoculum counts ranged from 0 to 210 CFUs. This was a reduction of at least 99.95% from the initial inoculum count and was observed on all 210 test plates.

MRSA and MRSE were the most sensitive of the 3 challenge bacteria in this study. All 70 plates challenged with *E. coli* had CFUs ranging from 35-210 CFUs, and the colonies present had distinct patterns of CFUs growing along the mesh fiber lines.

Inoculum control plates showed dense growth and were impossible to count. There was no evidence of growth on media controls or on the negative control plates.

Thus, all 3 challenge bacteria (gram-positive and gram-negative) passed all of the success criteria set up to test the ability of DERMABOND® PRINEO® Skin Closure Systemto inhibit MRSA, MRSE, and *E. coli* on contact.

Conclusion

In this in vitro study, DERMABOND PRINEO System was shown to inhibit MRSA, MRSE, and *E. coli* on contact.

The proportion of minimum 99.9% bacterial inhibition was at least 98.58% with 95% confidence.

Key Reference Article Summary

In vitro Evaluation of the Microbial Barrier Properties of Dermabond ProTape*

Bhende S, et al.

Source:
Data on file. Ethicon, Inc.

Study Objective

The purpose of this in vitro study was to demonstrate that DERMABOND® PRINEO® Skin Closure System is an effective barrier against the penetration of microorganisms.

Bacteria used in this study included:

Staphylococcus aureus

Staphylococcus epidermidis

Escherichia coli

Pseudomonas aeruginosa

Enterococcus faecium

Method

Cultures were grown in sterile trypticase soy broth for 16-24 hours at 35-37°C. One 100-fold dilution of each organism was made with sterile saline. 10µL of the inoculum, one organism species per film, was used to inoculate the surface of each polymerized DERMABOND PRINEO System film. The initial number of organisms applied to each film is shown in Table 1.

Table 1: Inoculum Counts

Organism	CFUs*/test (10 ul)
P. aeruginosa	1.28×10^5
E. coli	1.38×10^5
E. faecium	4.90×10^4
S. aureus	1.41×10^5
S. epidermidis	8.10×10^4

*CFU = Colony Forming Unit

DERMABOND PRINEO System films were prepared on sanitized polyethylene sheet surfaces. The mesh tape component of DERMABOND PRINEO System was secured to the polyethylene sheet surface. The adhesive component of DERMABOND PRINEO System was then applied to the mesh tape. One vial of the adhesive was uniformly applied per 60cm of mesh tape. After polymerizing, films were aseptically cut and placed on the D/E neutralizing agar plate surface. Agar media containing pH sensitive dye was used, which changes color in the presence of acidic microbial metabolic products. A total of 60 films per challenge organism were used for a total of 300 films.

*Dermabond ProTape is a previous name for DERMABOND® PRINEO® Skin Closure System

Positive controls were prepared by introducing six-1mm holes in the DERMABOND® PRINEO® Skin Closure System film using a dissecting needle. Negative control plates were prepared by incubating DERMABOND PRINEO System films on D/E neutralizing agar plate.

Test and control plates were incubated for 72 hours at 35-37°C and plates were observed for growth and color change every 24 hours during the incubation period.

Penetration through the DERMABOND PRINEO System film and subsequent growth beneath the film was indicated by a color change from purple to yellow.

Results

As shown in Table 2, all of the 300 films evaluated retained their integrity as microbial barriers for 72 hours as measured by visual observation. No color change or bacterial overgrowth was noted in any of the 300 samples.

Table 2: Number of Test Articles

Maintaining Microbial Barrier Properties

Organism	24h	48h	72h
P. aeruginosa	60	60	60
E. coli	60	60	60
E. faecium	60	60	60
S. aureus	60	60	60
S. epidermidis	60	60	60

All positive controls were positive, as evidenced by dramatic color change from purple to yellow at 24, 48, and 72 hours. All negative controls remained purple.

Conclusion

In this in vitro study, DERMABOND PRINEO System provided a barrier to microbial penetration with 95% confidence of 99% efficacy for 72 hours.

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

*Dermabond ProTape is a previous name for DERMABOND® PRINEO® Skin Closure System

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Listed below are the RCTs and observational studies for DERMABOND® PRINEO® Skin Closure System

Blondeel PN, Richter D, Stoff A, Exner K, Jernbeck J, Ramakrishnan V. Evaluation of a New Skin Closure Device in Surgical Incisions Associated With Breast Procedures. *Ann Plast Surg.* 2013;e-publication ahead of print.

De Cock E, van Nooten F, Mueller K, Tan R. Changing the surgical wound closure management pathway: Time and supplies wtih PRINEO™ vs. standard of care for abdominoplasty surgery in Germany. Paper presented at: International Society for Pharmaocoeconomics and Outcomes Research, 11th Annual European Congress, 2008; Athens, Greece.

De Cock E, Van Nooten F, Raluy M, Muller K, Fabre J, Hargreaves J. Changing the surgical wound closure management pathway: Time and supplies with PRINEOnull vs. standard of care for breast reconstruction surgery. *Value in Health.* 2009;12(7):A294.

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Huemer GM, Schmidt M, Helml GH, Shafighi M, Dunst-Huemer KM. Effective wound closure with a new two-component wound closure device (Prineo) in excisional body-contouring surgery: experience in over 200 procedures. *Aesthetic Plast Surg.* 2012;36(2):382-386.

Loonen MPJ, Depoorter MAM. Dermabond Protape (Prineo) for Wound Closure in Plastic Surgery. *Modern Plastic Surgery.* 2012;2(2):20-23.

Parvizi D, Friedl H, Schintler MV, et al. Use of 2-octyl cyanoacrylate together with a selfadhering mesh (Dermabond Prineo) for skin closure following abdominoplasty: an open, prospective, controlled, randomized, clinical study. *Aesthetic Plast Surg.* 2013;37(3):529-537.

Richter D, Stoff A, Ramakrishnan V, Exner K, Jernbeck J, Blondeel PN. A comparison of a new skin closure device and intradermal sutures in the closure of full-thickness surgical incisions. *Plast Reconstr Surg.* 2012;130(4):843-850.

van Nooten F, De Cock E, Fagre J, Tan R. Comparing time and supplies usage associated with a new skin closure device vs. standard of care wound closure for abdominoplasty surgery in The Netherlands. Paper presented at: International Society for Pharmaocoeconomics and Outcomes Research, 11th Annual European Congress, 2008; Athens, Greece.

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.

Amin M, Glynn F, Timon C. Randomized trial of tissue adhesive vs staples in thyroidectomy integrating patient satisfaction and Manchester score. *Otolaryngol Head Neck Surg.* 2009;140(5):703-8.

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