3M
Cavilon™
Skin Care Solutions

EVIDENCE SUMMARY

3M™ Cavilon™ No Sting Barrier Film

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- VA VASCULAR ACCESS
- N NEGATIVE-PRESSURE WOUND THERAPY
- I INCONTINENCE-ASSOCIATED DERMATITIS
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- RA RADIATION-INDUCED SKIN INJURY

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PERFORMANCE

Clinically-supported chemistry. Powerful impact.

First to market. Only one of its kind.*

Durable

Fast-drying,[1] long-lasting, waterproof and doesn't wash off,[2] making it easy for clinicians to use.

Effective

Helps maintain a continuous protective coating, plus it's sterile** and chemically compatible with chlorhexidine gluconate (CHG),[3] making it essential for vascular access site protection.

Gentle

Alcohol-free, sting-free, fragrance-free, preservative-free and low dermatitis potential.[4]

Versatile

Helps protect skin from friction and abrasion,[4] an improvement over many creams, ointments and pastes that can increase friction at the skin surface.

Proven

Unique formulation supported by 80+ pieces of evidence.

*Of leading competitors in the market, based on disclosed ingredient information.
**Wands and wipes only.

1. 3M data on file. TEAM-MISC-05-001563, CLIN-RPT-FINAL-INV-US-05-289804 (dry time).
2. 3M data on file. CLIN-RPT-FINAL-ICH2-US-05-291160.
3. 3M data on file. TEAM-MISC-05-005732 and SPONSOR FINAL RPT-05-002049.
4. Campbell K, Woodbury MG, Whittle H, Labate T, Hoskin A. A clinical evaluation of 3M Cavilon No Sting Barrier Film. *Ostomy Wound Manage*. 2000;46(1)24-30.

Medical Adhesive-Related Skin Injury (MARSI)

The ideal way to protect skin around vascular access sites.

Skin damage from Medical Adhesive-Related Skin Injury (MARSI) at vascular access sites can be a significant problem, particularly for those with fragile skin. Although MARSI can be a prevalent and serious complication, it does not need to be an inevitable part of the patient experience. Preparation of the skin and selection of proper adhesives are the first steps to help minimize the risks of skin damage.[5]

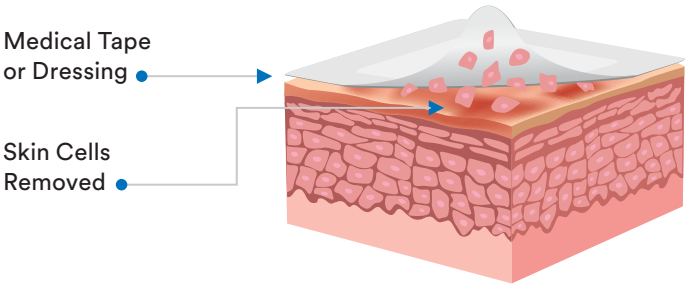
Cavilon No Sting Barrier Film works.

Cavilon No Sting Barrier Film forms a breathable, transparent, protective coating between the skin and the adhesive of the securement dressing, device or tape. When the adhesive product is changed, Cavilon No Sting Barrier Film is removed instead of skin cell layers.[6] It also protects skin from moisture, friction and shear.

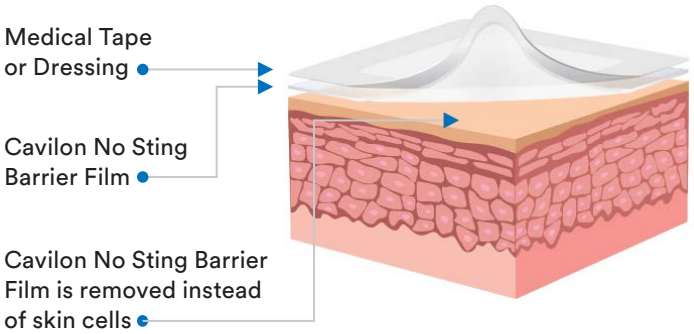
Protection from: Adhesive Products

Diagram intended for demonstration only, clinical efficacy intended to be directional.

Without Cavilon No Sting Barrier Film



With Cavilon No Sting Barrier Film



5. McNichol L, Lund C, Rosen T, Gray M. Medical adhesives and patient safety: state of the science: consensus statements for the assessment, prevention, and treatment of adhesive-related skin injuries. *J Wound Ostomy Continence Nurs*. 2013;40(4):365-380.
6. 3M data on file. CLIN-MISC-US-05-202211.

A prospective randomized trial of the effect of a soluble adhesive on the ease of dressing removal following hypospadias repair

Sanders C, Young A, McAndrew HF, Kenny SE. A prospective randomized trial of the effect of a soluble adhesive on the ease of dressing removal following hypospadias repair. *J Pediatr Urol*. 2007 Jun;3(3):209-213. doi:10.1016/j.jpurol.2006.08.006. Epub 2006 Dec 12. PMID: 18947737.

DESIGN

Prospective, unblinded, randomized controlled trial comparing dressing protocols with and without the application of Cavilon No Sting Barrier Film in pediatric patients status post (s/p) primary hypospadias repair.

METHODS

A total of 53 pediatric patients (18 mo. – 4 years) were randomized into two groups. Treatment group had Cavilon No Sting Barrier Film applied to the peri-incisional area prior to dressing application. The control group did not receive the barrier film. Both groups received the same post-operative dressing and securement device. On post-operative day seven, dressings were removed. Control group received a warm bath pre-soak to loosen the dressing. Cavilon No Sting Barrier Film group did not receive a pre-soak.

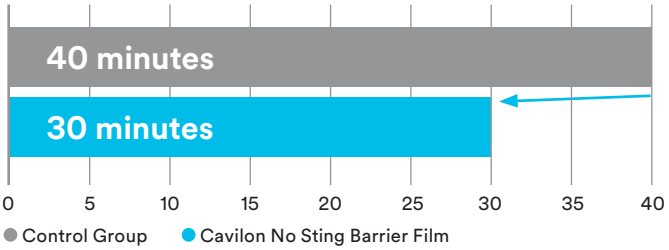
- Primary outcome measure was start time of dressing removal to completion.
- Secondary measures included the child's pain per a validated visual analogue scale (VAS) as reported by parent and nurse at four time intervals, as well as, parent state anxiety at two time intervals.

KEY FINDINGS

The incorporation of Cavilon No Sting Barrier Film into the hypospadias dressing change protocol significantly reduced dressing removal time and eliminated the need for pre-soaking in a bath, facilitating a more effective allocation of nursing time. It yielded no greater pain for the pediatric patient or parent anxiety than experienced by the control group.

RESULTS

Median dressing removal time (p=.01)



The median dressing removal time of 30 (5–86) minutes for Cavilon No Sting Barrier Film relative to 40 (17–105) minutes for control group was significantly faster (p=.01).

Applying skin barrier film for skin tear management in patients with central venous catheterization

Chen YH, Hsieh HL, Shih WM. Applying skin barrier film for skin tear management in patients with central venous catheterization. *Adv Skin Wound Care*. 2020 Nov;33(11):582-586. doi:10.1097/01.ASW.0000717208.20481.a0. PMID: 33065679.

FOCUS

VA VASCULAR ACCESS

DESIGN

A randomized study to evaluate skin strength, skin integrity, and decreased incidence of interventions to improve the skin integrity to mitigate medical adhesive-related skin injury (MARSI) in ICU patients receiving central venous catheterizations (CVCs).

METHODS

A total of 102 patients (≥ 18 years) within the ICU that underwent CVC, possessed intact skin post-CVC and provided informed consent were recruited. Study duration was from April 1, 2017 to March 31, 2018. Patients were randomized to the experimental group (Cavilon No Sting Barrier Film) or the control group (no barrier film). For both groups, CVC sites were disinfected using alcohol (75% + 10% alcoholic beta iodine). Both groups had 2" x 2" gauze dressings applied and affixed to the skin using adhesive tape. The incidence of skin tears was compared between groups.

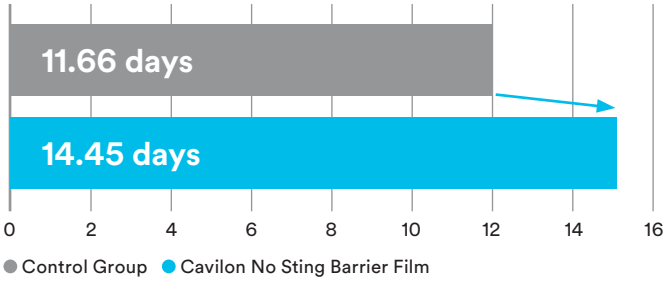
KEY FINDINGS

Application of Cavilon No Sting Barrier Film should be considered for routine care for patients undergoing central venous catheterization.

RESULTS

A total of 98 ICU patients with CVC were included in the final analysis (experimental group = 50 versus control group = 48). Both groups averaged a single dressing change per day (experimental group = 1.0 ± .02 versus control group = 1.06 ± .12).

Days without skin tear (p=.009)



The incidence of skin tears was lower in the experimental group relative to the control group (22.0% vs. 47.9%). Kaplan-Meier curve analysis demonstrated that the application of Cavilon No Sting Barrier Film prior to CVC effectively protected skin and reduced skin-tear risk (p<.01).

Effect of an acrylic terpolymer barrier film beneath transparent catheter dressings on skin integrity, risk of dressing disruption, catheter colonisation and infection

Pivkina AI, Gusarov VG, Blot SI, Zhivotneva IV, Pasko NV, Zamyatin MN. Effect of an acrylic terpolymer barrier film beneath transparent catheter dressings on skin integrity, risk of dressing disruption, catheter colonisation and infection. *Intensive Crit Care Nurs*. 2018 Jun;46:17-23. doi:10.1016/j.iccn.2017.11.002. Epub 2018 Mar 23. PMID: 29576395.

FOCUS

VA VASCULAR ACCESS

DESIGN

A single-center, open-label, randomized controlled trial evaluated the effect of applying Cavilon No Sting Barrier Film around the catheter insertion site on the frequency of dressing disruptions and skin integrity.

METHODS

A total of 60 patients (≥ 16 years) requiring central venous catheterization (CVC) for a minimum of seven days were recruited. The study occurred over a five-month period (August to December 2014).

The control group received standard transparent polyurethane CVC dressings without barrier film (n=30).

The intervention group received a chlorhexidine-impregnated transparent polyurethane CVC dressing and Cavilon No Sting Barrier Film around the CVC insertion site (n=30). Issues associated with skin integrity included: hyperemia of insertion site, skin irritation under dressing, the presence of adhesive residues, and moisture under the dressing. Patients were randomized according to interventions.

KEY FINDINGS

The application of Cavilon No Sting Barrier Film around the CVC insertion site was associated with fewer dressing disruptions and issues with skin integrity. The risk of CVC colonization or central line-associated bloodstream infection (CLABSI) was not altered by Cavilon No Sting Barrier Film application, at least not in conjunction with chlorhexidine-impregnated transparent polyurethane CVC dressings.

RESULTS

A total of 60 patients were included in the final analysis. Participating patients recorded a total of 533 catheter days.

There was a statistically significant difference in CVC dressing dwell time between groups, with the intervention group being significantly longer (2.5 days vs. 7.0 days; p<.0001).

In the control group, full dressing disruption occurred more frequently (17 [56.7%] versus 2 [6.7%]; p<.001) and at an earlier time point relative to the intervention group.

Skin integrity issues were observed more often within the control group (11 [36.7%] versus 1 [3.3%]; p=.001).

The most common issue in the control group was moisture under the dressing (6 [20.0%] versus 0 [0.0%]; p=.009).

Among secondary outcomes, no difference in CVC colonization or CLABSI were noted between groups.

Use of a barrier film (3M Cavilon No Sting Barrier Film) to reduce local skin complications around peripherally inserted central catheter lines: a randomised prospective controlled study

George M, Pal U, Guduri V, et al. Use of a barrier film (3M Cavilon No Sting Barrier Film) to reduce local skin complications around peripherally inserted central catheter lines: a randomised prospective controlled study. *WCET Journal.* 2016;36(4):8-13.

FOCUS

VA VASCULAR ACCESS

DESIGN

Randomized clinical trial evaluating Cavilon No Sting Barrier Film versus standard care in preventing against skin complications from peripherally inserted central catheters (PICC) lines.

METHODS

Observations were conducted August through December 2012. Study included 100 patients with PICC line insertions managed with standard care (gauze with medical tape) or Cavilon No Sting Barrier Film. The treatments were administered 24 hours after PICC line insertion. Clinical outcomes were assessed between two and 11 days later, depending on the patient. Patients were evaluated for maceration, rash or redness, adhesive residue transfer, and skin peeling due to adhesive trauma on a yes/no grading scale at each dressing change.

KEY FINDINGS

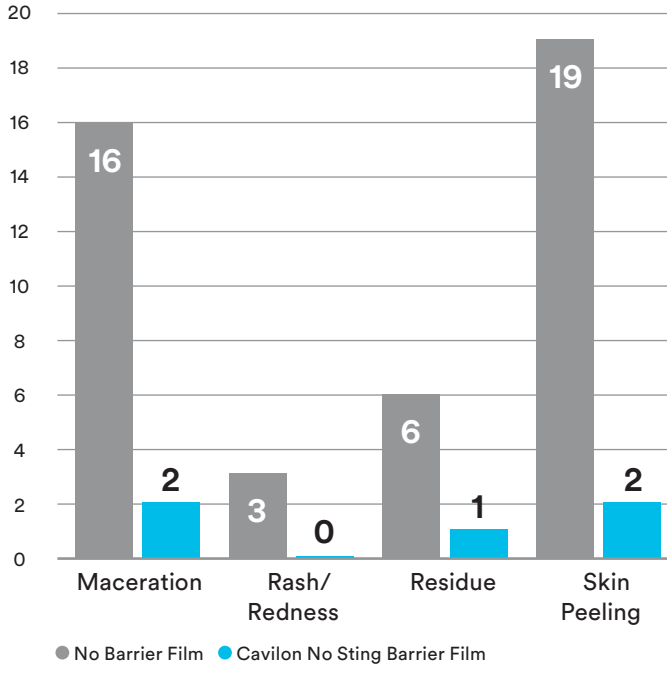
Use of Cavilon No Sting Barrier Film as a skin protectant was effective at helping to reduce MARSI complications arising from PICC line insertion.

RESULTS

All 100 patients recruited were included in results.

Although the Cavilon No Sting Barrier Film-treated group had more pre-existing complications at baseline, the Cavilon No Sting Barrier Film group had fewer complications at the end of the study (5 versus 30 patients; p<0.0001).

Fewer incidences



Skin impairment associated with vascular access devices and semi-permeable transparent dressings

Hitchcock J, Anderson L, Escorcio J, et al. Skin impairment associated with vascular access devices and semi-permeable transparent dressings. Imperial College Healthcare NHS Trust. *NIVAS*. 2015. Poster Presentation.

FOCUS

VA VASCULAR ACCESS

DESIGN

An advisory panel of vascular access and tissue viability teams convened to identify types of medical adhesive-related skin injuries (MARSI) and create a peripherally inserted central catheter (PICC) algorithm including Cavilon No Sting Barrier Film as an intervention against iatrogenic skin reactions.

METHODS

The vascular access and tissue viability teams collaborated on the execution of a systematic literature review, explored anecdotal experience, and collated clinical data. The teams also evaluated cases to discern possible causes of noted adverse events to the skin. Interventions (guidelines revision, production of educational material, and dressing algorithms) were devised to manage, and/or prevent skin reactions.

KEY FINDINGS

Incorporating Cavilon No Sting Barrier Film into the PICC line algorithm to reduce the risk of MARSI during central venous access device (CVAD) dressing change helped to enhance best practice, mitigate detrimental outcomes in vascular access device securement and improve patient experience.

RESULTS

The teams identified several challenges: Incorrect application of products, assessment inconsistencies, diversity of patient population across specialty wards, and dearth of resources.

The MARSI on CVAD algorithm was devised to address skin contamination and to present resources for clinical decision making.

In search of a better central line dressing protocol in the autologous bone marrow reinfusion patient

Link D, Cutler C. In search of a better central line dressing protocol in the autologous bone marrow reinfusion patient. 3M Clinical study (1998). White Paper.

FOCUS

VA VASCULAR ACCESS

DESIGN

A randomized study to compare the effect of Cavilon No Sting Barrier Film or 3M™ Tegaderm™ Hydrocolloid Thin Dressing on skin integrity, skin colonization, laboratory-confirmed bloodstream infection, patient and nurse satisfaction, and nursing time in patients undergoing autologous bone marrow reinfusion (ABMR).

METHODS

A total of 50 patients were enrolled. Study duration was from March 1994 to December 1995. Patients were randomized to either Group I (Cavilon No Sting Barrier Film, n=21) or Group II (Tegaderm Hydrocolloid Thin Dressing, n=23). Dressing changes occurred twice weekly using 3M™ Tegaderm™ Transparent Dressing. A three-point skin integrity scale (1 = no erythema; 2 = erythema; 3 = skin breakdown) was employed to assess skin integrity, and photographs were taken to objectively enhance reliability between raters.

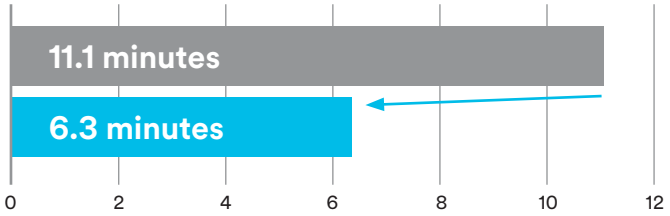
KEY FINDINGS

This study demonstrated that the dressing protocol using Cavilon No Sting Barrier Film was superior in cost analysis as well as satisfaction for both patient and nurses. The dressing protocols revealed no significant difference in mean skin integrity rating, skin colonization, or laboratory-confirmed bloodstream infection.

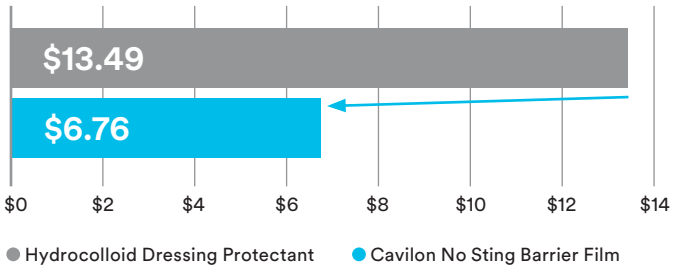
RESULTS

A total of 44 patients were included in analysis.

Nursing time



Cost per dressing change



3M™ Cavilon™ No Sting Barrier Film

6 Additional Studies

AUTHOR	TITLE
MARSI	
Hitchcock J	Medical adhesive-related skin injuries associated with vascular access
NPWT	**Using a barrier film wipe, wand, or spray is an established technique to reduce maceration and protect periwound skin during Negative-Pressure Wound Therapy.**
Driver RK	Utilizing the VeraFlo Instillation Negative Pressure Wound Therapy System with advanced care for a case study
Jerez Gonzalez JA	Catastrophic abdominal wall after repair of enterocutaneous fistula: a case study
Mangelsdorff G	Reduced anterolateral thigh flap donor-site morbidity using incisional negative pressure therapy
No Authors	Retrospective case series: Wounds treated with V.A.C. VERAFLO Therapy
Williams C	3M Cavilon No Sting Barrier Film in the protection of vulnerable skin

Moisture-Associated Skin Damage (MASD)

Excessive hydration compromises barrier function, making the epidermis more vulnerable to damage. If untreated it can result in delayed healing, increased risk of secondary infection, and patient discomfort.

First to market. Only one of its kind.

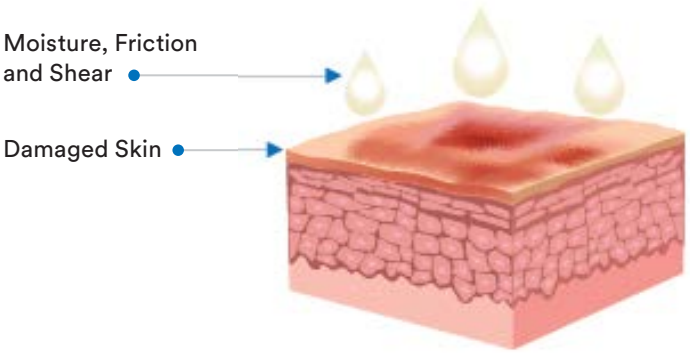
Cavilon No Sting Barrier Film is the original and only terpolymer-based alcohol-free barrier film* that helps prevent skin damage before it occurs.

Its unique formulation of polymers forms a sting-free, waterproof, protective coating that is breathable and transparent, allowing for continuous visualization and monitoring of skin. It is also flexible and conforms to the skin during movement or position changes.

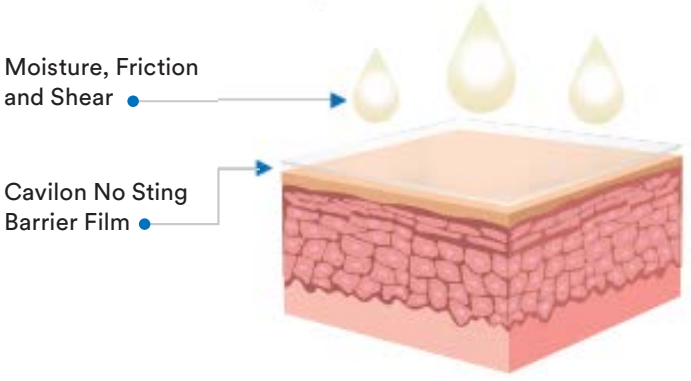
Protection from: Moisture, Friction, and Shear

Diagram intended for demonstration only, clinical efficacy intended to be directional.

Without Cavilon No Sting Barrier Film



With Cavilon No Sting Barrier Film



*Of leading competitors in the market, based on disclosed ingredient information.

An economic evaluation of four skin damage prevention regimens in nursing home residents with incontinence: economics of skin damage prevention

Bliss DZ, Zehrer C, Savik K, Smith G, Hedblom E. An economic evaluation of four skin damage prevention regimens in nursing home residents with incontinence: economics of skin damage prevention. *J Wound Ostomy Continence Nurs*. 2007 Mar-Apr;34(2):143-152; discussion 152. doi:10.1097/01.WON.0000264825.03485.40. PMID: 17413828.

FOCUS

I IAD

DESIGN

Multi-site, open-label, quasi-experimental study evaluating the cost and efficacy of four skin care regimens in the incontinence-associated dermatitis (IAD) prevention care of nursing home residents.

METHODS

Study evaluated nursing home residents with incontinence (n=981) from 16 nursing homes across 15 states. The skin care regimens were characterized by the inclusion of the application of either:

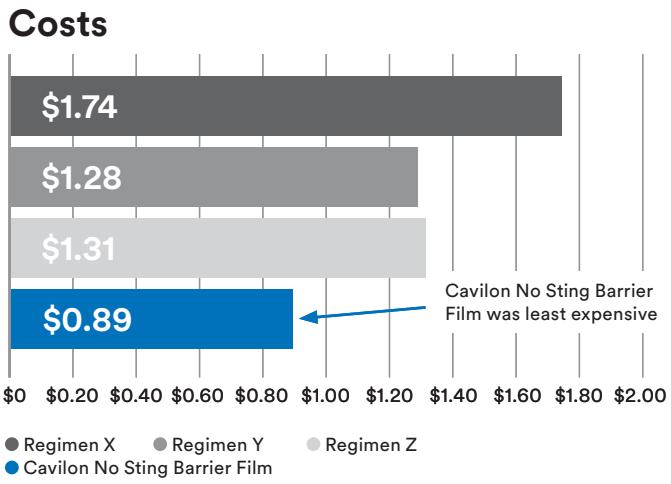
- Cavilon No Sting Barrier Film (Regimen W)
- an ointment with 43% petrolatum (Regimen X)
- an ointment with 98% petrolatum (Regimen Y)
- or a cream with 12% ZnO + 1% dimethicone (Regimen Z).

Economic data labor cost (time to complete protocol by nursing assistants) and product costs (cleanser, barrier, supplies) were calculated.

KEY FINDINGS

- The total cost to apply Cavilon No Sting Barrier Film three times weekly was significantly less than applying the product from any of the other regimens following episodes of incontinence.
- The three-time weekly application of Cavilon No Sting Barrier Film demonstrated effectiveness as a strategy to help protect the skin from breakdown associated with incontinence.

RESULTS



The regimen that included Cavilon No Sting Barrier Film was the least expensive IAD prevention protocol relative to Regimen X, Regimen Y, and Regimen Z (p<.001).

17 Additional Studies

AUTHOR	TITLE
Beeckman	Prevention and treatment of incontinence-associated dermatitis: literature review
Bernatchez SF	Reducing friction on skin at risk: the use of 3M™ Cavilon™ No Sting Barrier Film
Bonnetblanc	Periwound protection with 3M™ Cavilon™ No Sting Barrier Film for patients with chronic venous leg ulcers, a randomized multi-centre trial
Coutts	Periwound skin protection: a comparison of a new skin barrier vs. traditional therapies in wound management
Gerber	Wound protection for delicate baby and children's skin
Guest JF	Clinical and economic evidence supporting a transparent barrier film dressing in incontinence-associated dermatitis and periwound skin protection
Guest JF	Relative cost-effectiveness of a skin protectant in managing venous leg ulcers in the UK
Hampton	Film subjects win the day
Hune	Innovative strategy to prevent incontinence dermatitis
Issberner	A comparative study of the skin protectant performance of five barrier films
LaVoie	Comparison of the effectiveness of five different skin protective products
Lopez JR	Diaper rash. Local treatment with barrier products and quality of life
Mooney	Use of a non-alcohol incontinence barrier film on patients with severely compromised skin
Murray	Evaluation of routine use of an alcohol-free barrier film on patients with urinary and/or fecal incontinence
Prather P	Effectiveness of topical skin products in the treatment and prevention of incontinence-associated dermatitis: a systematic review
Zehrer	A comparison of cost and efficacy of three incontinence skin barrier products
Zimmaro Bliss	Incontinence-associated skin damage in nursing home residents: a secondary analysis of a prospective, multi-centre study

Effectiveness of association of multilayer compression therapy and periwound protection with Cavilon™ (No Sting Barrier Film) in the treatment of venous leg ulcers

Serra N, Palomar-Llatas F, Pujalte BF, et al. Effectiveness of association of multilayer compression therapy and periwound protection with Cavilon™ (No Sting Barrier Film) in the treatment of venous leg ulcers. *Gerokomos*. 2010;21(3):124-130. http://scielo.isciii.es/scielo.php?pid=S1134-928X2010000300006&script=sci_abstract&tlng=en.

FOCUS

PW PERIWOUND

DESIGN

Randomized, multicenter, controlled clinical trial of venous ulcer patients treated with multilayer compression therapy with or without Cavilon No Sting Barrier Film.

METHODS

Study recruited 98 patients (49 in the Cavilon No Sting Barrier Film group and 49 in the control group). Control group consisted of no treatment to the periwound skin. Study was conducted for up to 12 weeks or until ulcer was healed. Planimetric measurement of ulcer area was conducted on a weekly basis. Primary endpoint was ulcer size reduction.

KEY FINDINGS

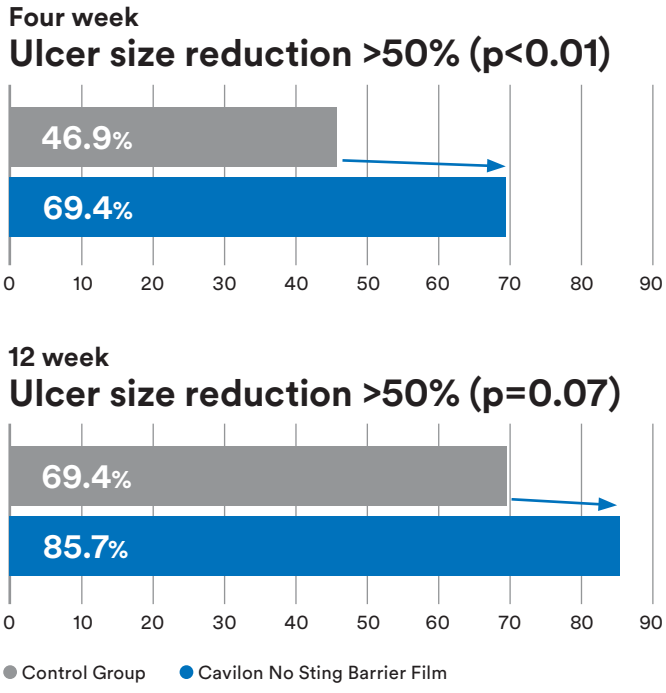
Compared to the control group, the group receiving compression therapy with Cavilon No Sting Barrier Film for periulcer skin protection had:

- More ulcers with at least 50% reduction in size at four weeks.
- A higher percent reduction in ulcer size at 12 weeks.

RESULTS

A total of 83 patients were included in analysis (42 in the Cavilon No Sting Barrier Film group and 41 in the control group).

At four weeks of treatment, ulcers treated with compression therapy in the Cavilon No Sting Barrier Film group showed a marginally greater reduction in ulcer size than the control group (56.7% vs 45.5%; p=0.087). At 12 weeks of treatment, the reduction in ulcer size was significantly greater in the Cavilon No Sting Barrier Film versus the control group (83.4% vs 71.6%; p=0.046).



The protective effects of a new preparation on wound edges

Neander KD, Hesse F. The protective effects of a new preparation on wound edges. *J Wound Care*. 2003 Nov;12(10):369-371. doi:10.12968/jowc.2003.12.10.26548

FOCUS

PW PERIWOUND

DESIGN

An intra-individual, double-blind, randomized study was performed on patients with venous stasis ulcers to compare outcomes of periwound skin protection using Cavilon No Sting Barrier Film versus control (water).

METHODS

A total of 239 patients had Cavilon No Sting Barrier Film used on one half of each wound, and water was applied to the other half. Cavilon wound halves were randomized throughout and neither patient nor clinician was aware of which was water or product. Daily erythema assessment of the periwound skin using a chromameter, 10 measurements were taken at each assessment and an average of those scores was recorded. The initial value recorded for each patient was used as baseline, and changes from this baseline were recorded as a percentage.

KEY FINDINGS

- After only two days, periwound skin protected with Cavilon No Sting Barrier Film showed reduced erythema by 99%.
- Cavilon No Sting Barrier Film demonstrated superiority over water-treated periwound skin in each of the four days of treatment.

RESULTS

A total of 227 patients were included in the analysis.

Second day of the study: erythema on the Cavilon No Sting Barrier Film-protected side of the wounds had reduced to 1%, versus 97% on the control side.

Third day: erythema had completely disappeared in 88.1% of the periwound skin protected with Cavilon No Sting Barrier Film.

Day four

100%

Total clearance of erythema (0% intensity) was observed in 100% of the periwound skin protected with Cavilon No Sting Barrier Film. Water-treated periwound skin was still at 99% intensity relative to baseline.

Comparison of two peri-wound skin protectants in venous leg ulcers: a randomised controlled trial

Cameron J, Hoffman D, Wilson J, Cherry G. Comparison of two peri-wound skin protectants in venous leg ulcers: a randomised controlled trial. *J Wound Care*. 2005 May;14(5):233-236. doi:10.12968/jowc.2005.14.5.26779

FOCUS

PW PERIWOUND

DESIGN

Randomized controlled trial comparing the efficacy and cost-effectiveness of Cavilon No Sting Barrier Film and zinc paste compound.

METHODS

A total of 36 patients with venous leg ulcers were recruited. Cavilon No Sting Barrier Film or the zinc compound were each reapplied around the peri-ulcer area at each dressing change. Clinical assessment included percentage of total healing, percentage increase in healing rate, and condition of periwound area. Cost-effectiveness was determined by cost of product, nursing time, and amount of applications. Patients were assessed six times throughout the course of the 12-week trial.

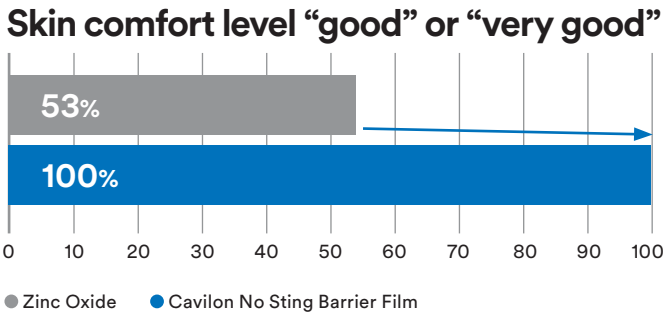
KEY FINDINGS

For patients receiving periwound skin care with Cavilon No Sting Barrier Film:

- The wound area of venous leg ulcers was reduced by 55.5% after 12 weeks.
- Time for removal and reapplication was significantly lower.
- Less pain and higher comfort of periwound skin was reported.
- 12 weeks of care were significantly more cost effective than zinc oxide paste.

RESULTS

A total of 35 patients were included in the final analysis.



At the end of the study, 100% of patients in the Cavilon No Sting Barrier Film group rated their periwound skin comfort level as “good” or “very good”, versus 53% of patients in the zinc paste group (p=0.005).

The reduction of pain reported was higher in the Cavilon No Sting Barrier Film group: 50% of patients were reported being pain-free after 12 weeks, compared to 29% for the zinc oxide group.

56% of nurses rated Cavilon No Sting Barrier Film as very easy to apply, versus 6% of nurses applying zinc oxide paste.

A liquid film-forming acrylate for peri-wound protection: a systematic review and meta-analysis (3M Cavilon No Sting Barrier Film)

Schuren J, Becker A, Sibbald RG. A liquid film-forming acrylate for peri-wound protection: a systematic review and meta-analysis (3M Cavilon No Sting Barrier Film). *Int Wound J*. 2005 Sep;2(3):230-238. doi:10.1111/j.1742-4801.2005.00131.x

FOCUS

PW PERIWOUND

DESIGN

Systematic review and meta-analysis of the clinical cost effectiveness of Cavilon No Sting Barrier Film.

METHODS

A search of electronic databases identified 49 papers with Cavilon No Sting Barrier Film as a treatment; of these, seven randomized controlled trials and two case-controlled studies were included in the systematic review.

KEY FINDINGS

- Use of Cavilon No Sting Barrier Film is associated with significantly reduced cleansing and application time than zinc oxide/petrolatum alternatives.
- Patients treated with Cavilon No Sting Barrier Film report lower pain and higher comfort than patients treated with zinc oxide/petrolatum alternatives.
- For erythema and maceration control, Cavilon No Sting Barrier Film is comparable to other methods of periwound protection, and significantly better than placebo.

RESULTS

Two studies reported cleansing time, finding a **significant advantage** to Cavilon No Sting Barrier Film over alternative treatment ($p<0.0001$). Cavilon No Sting Barrier Film also had lower application times than control ($p<0.001$).

Two studies evaluating patient pain found a significant benefit of Cavilon No Sting Barrier Film over control ($p=0.007$). One study reported higher levels of patient comfort with Cavilon No Sting Barrier Film vs. control ($p=0.04$).

Comparative study of a barrier product versus zinc oxide for the treatment of incontinent lesions

Lopez JR, Perejamo MA, Torra JE, et al. Comparative study of a barrier product versus zinc oxide for the treatment of incontinent lesions. World Union of Wound Healing Societies (WUWHS) 2004. Oral Presentation.

FOCUS

PW PERIWOUND

DESIGN

A multi-center, prospective, randomized study to evaluate skin condition (area and extent of erythema and denudation) following application of Cavilon No Sting Barrier Film or zinc oxide (ZnO) as a protective barrier intervention for incontinence-associated dermatitis (IAD).

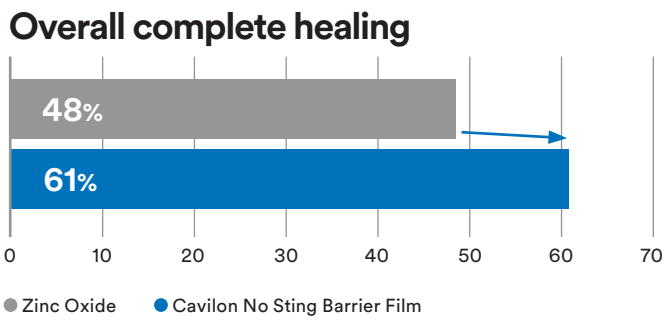
METHODS

A total of 50 patients identified for inclusion in the study were followed for four weeks. Patients were randomized according to intervention to either Group I (Cavilon No Sting Barrier Film) or Group II (zinc oxide). Descriptive statistics were used to evaluate lesions on a scale of 0–12, a score >6 indicating a severe condition, below a 6 deemed as a moderate condition.

KEY FINDINGS

This study demonstrated that Cavilon No Sting Barrier Film was effective among a higher proportion of the cohort that were scored with severe IAD.

RESULTS



Within the group receiving Cavilon No Sting Barrier Film, complete healing was reported in 50% of patients relative to 18% in the group receiving zinc oxide.

Comparing cost per use of 3M Cavilon No Sting Barrier Film with zinc oxide oil in incontinent patients

Baatenburg de Jong H, Admiraal H. Comparing cost per use of 3M Cavilon No Sting Barrier Film with zinc oxide oil in incontinent patients. *J Wound Care*. 2004 Oct;13(9):398-400. doi:10.12968/jowc.2004.13.9.27264. PMID: 15517755.

FOCUS

PW PERIWOUND

DESIGN

A single-center, prospective, randomized study to evaluate skin condition, prevention of skin (perianal/perineum/buttocks) breakdown and the total cost of treatment following use of either Cavilon No Sting Barrier Film or zinc oxide (ZnO) oil as an intervention for patients with incontinence.

METHODS

A total of 40 patients (≥ 18 years) with skin damage resulting from incontinence were recruited. Skin condition was assessed on a scale ranging from 0 (healthy, intact) to 12 (severely damaged). Patients were randomized according to intervention (zinc oxide oil or Cavilon No Sting Barrier Film). Patients were treated for 14 days. Frequency of Cavilon No Sting Barrier Film application was contingent upon skin score and number of diaper changes. Zinc oxide oil was administered per nursing home protocol. Time to wash affected areas and types of materials (incontinence pad and diaper change) were documented. A cost-effectiveness ratio was calculated to evaluate the interventions.

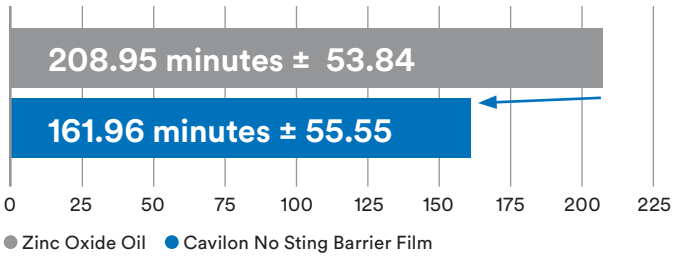
KEY FINDINGS

- Cavilon No Sting Barrier Film and zinc oxide oil facilitated improved skin condition after 14 days.
- Cavilon No Sting Barrier Film was more cost-effective as product was applied less frequently and helped reduce total nursing time.

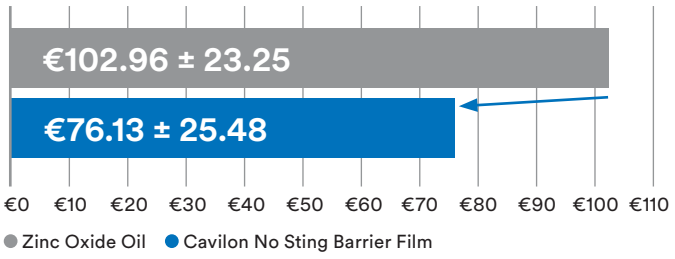
RESULTS

A total of 39 patients were included in the final analysis. Patients in both groups noted improvement in total skin damage scores, but scores were significantly better in the Cavilon No Sting Barrier Film group (p=.04).

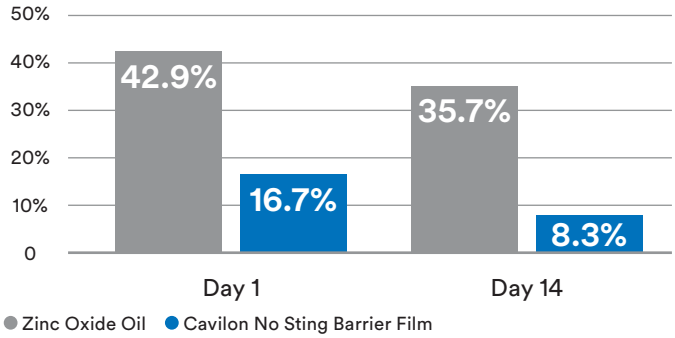
Mean (± SD) total nursing time

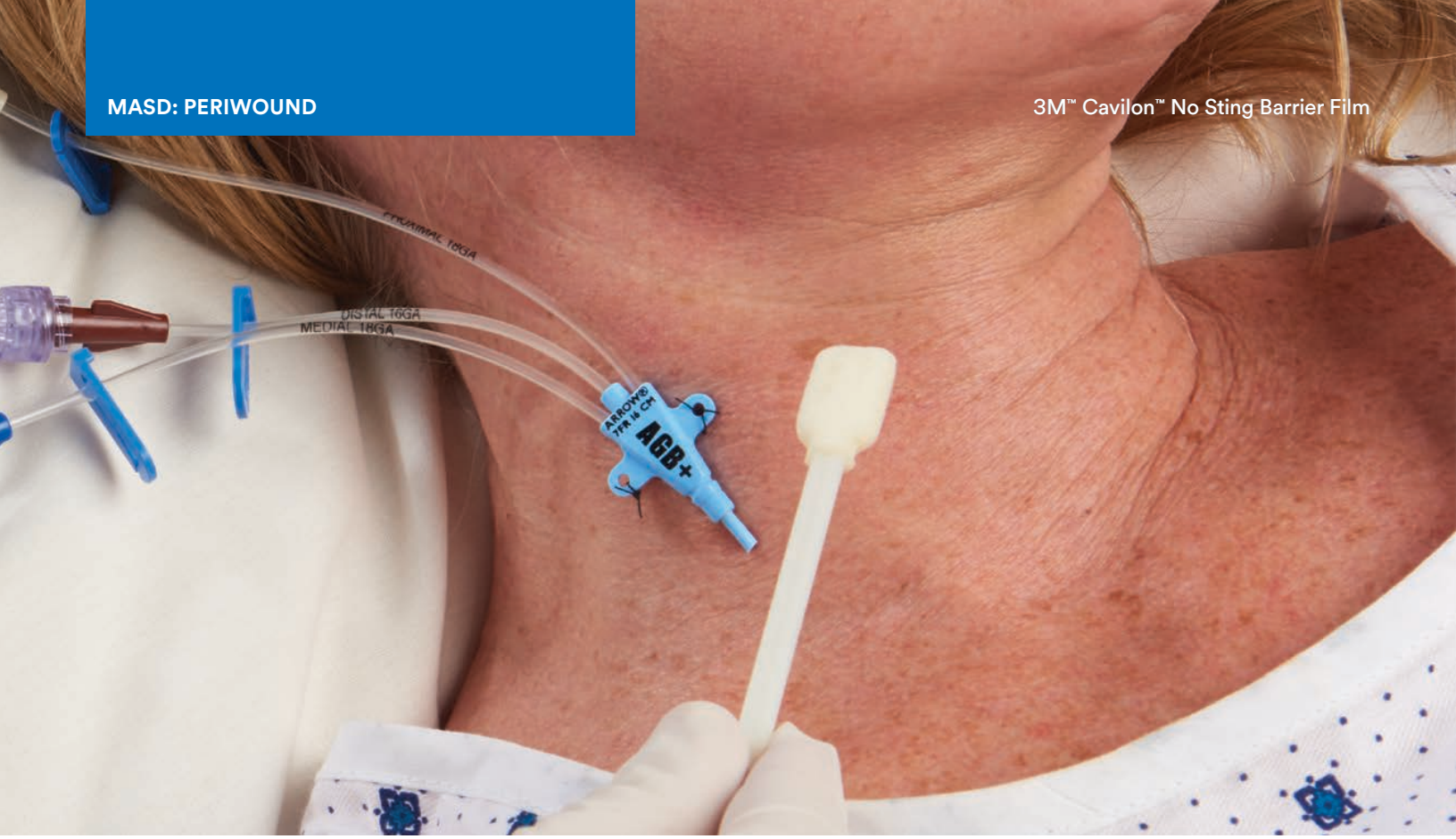


Mean total costs



Severity of skin denudation





9 Additional Studies

AUTHOR	TITLE
Bär	Ulcer edge protection with a polymer protective film
Bracelert	Clinical experience with an alcohol-free skin protectant 3M Cavilon™ No Sting Barrier Film
Campbell	The use of liquid film to treat severe incontinent dermatitis: case reports
Chan A	The use of a No Sting Barrier Film treatment protocol compared to routine clinical care for the treatment of stage 1 and 2 pressure injuries in long-term care
Garcia	3M Cavilon No Sting Barrier Film: an evaluation of periwounds prone to maceration
Gómez T	*In vivo* evaluation using confocal microscopy of protective effect of No Sting Barrier Film 3M Cavilon on periwound skin
Gonzalez	The use of 3M Cavilon No Sting Barrier Film to prevent maceration in pressure ulcers treated with an adhesive hydrocolloid dressing
Guest JF	Relative cost-effectiveness of a skin protectant in managing venous leg ulcers in the UK
Lazaro-Martinez JL	Reducing skin maceration in exudative diabetic foot ulcers

Randomized, paired comparison of No Sting Barrier Film versus sorbolene cream (10% glycerine) skin care during postmastectomy irradiation

Graham P, Browne L, Capp A, et al. Randomized, paired comparison of No Sting Barrier Film versus sorbolene cream (10% glycerine) skin care during postmastectomy irradiation. *Int J Radiat Oncol Biol Phys*. 2004 Jan 1;58(1):241-246. doi:10.1016/s0360-3016(03)01431-7. PMID: 14697444.

FOCUS

RA **RADIATION-INDUCED SKIN INJURY**

DESIGN

Randomized comparative study evaluating the effect of Cavilon No Sting Barrier Film on moist desquamation rate versus sorbolene cream (10% glycerine).

METHODS

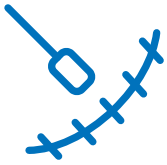
Postmastectomy patients (n=61) with a mean age of 58 years. Postmastectomy chest wall was partitioned along the mid-clavicle line into medial and lateral regions. The areas were randomized to receive either Cavilon No Sting Barrier Film or sorbolene cream. Cavilon No Sting Barrier Film was applied twice (medial) or three times (lateral) weekly. Whereas, sorbolene was applied twice daily, and once on radiotherapy (RT) days. Products were used from RT commencement until two weeks post-RT completion. Skin was assessed by physicians using Radiation Therapy Oncology Group (RTOG) acute skin scores which were then compared to the Wilcoxon signed-rank test and was assessed by patients for pain and pruritus.

KEY FINDINGS

Cavilon No Sting Barrier Film helped to facilitate the reduction and frequency of moist desquamation induced by RT.

RESULTS

A total of 48 patients were included in the analysis.



Pruritis reduction reported

Pruritis scores were significantly reduced in areas where Cavilon No Sting Barrier Film (p=.017) was applied.

RTOG skin scores to evaluate skin toxicity were 8.4 for Cavilon No Sting Barrier Film vs. 9.6 for sorbolene, respectively (p=.002). The rates of moist desquamation were 33% for Cavilon No Sting Barrier Film vs. 48% for sorbolene, respectively (p=.049).

Randomized control trial of 3M™ Cavilon™ No Sting Barrier Film for the prevention of radiation dermatitis in patients with nasopharyngeal carcinoma

Chang L. Randomized control trial of 3M™ Cavilon™ No Sting Barrier Film for the prevention of radiation dermatitis in patients with nasopharyngeal carcinoma. Presented at: Third Congress of the World Union of Wound Healing Societies; June 2008; Toronto, Canada.

FOCUS

RA **RADIATION-INDUCED SKIN INJURY**

DESIGN

Randomized clinical trial evaluating efficacy of Cavilon No Sting Barrier Film compared to control in preventing radiation dermatitis.

METHODS

Study recruited 42 nasopharyngeal cancer patients with Cavilon No Sting Barrier Film applied to one side of the treatment field. The opposite, uncovered side was used as control. Radiation Therapy Oncology Group (RTOG) scores and measurement of the skin reaction area were collected before and after radiation treatment. Subjective patient feelings including pain, burning sensation and pruritus were also captured.

KEY FINDINGS

Cavilon No Sting Barrier Film provided a protective skin barrier, which was shown to help reduce skin breakdown during radiation therapy and reduce the incidence of radiation dermatitis of grade two or higher.

RESULTS

A total of 27 patients were included in analysis.

Skin reaction in the areas treated with Cavilon No Sting Barrier Film were **significantly smaller** compared to control at weeks six ($p=0.01$) and seven ($p=0.01$) of radiation therapy. At week seven, RTOG scores were lower for treatment areas treated with Cavilon No Sting Barrier Film versus control ($p<0.05$).

Pain scores and burning sensation reported by patients were slightly lower in the Cavilon No Sting Barrier Film-protected areas compared with control-treated areas at week seven, although this difference was not significant.

5 Additional Studies

AUTHOR	TITLE
Herst PM	Protecting the radiation-damaged skin from friction: a mini review
Kumar S	Management of skin toxicity during radiation therapy: a review of the evidence
Lam AC	Phase III randomized pair comparison of a barrier film vs. standard skin care in preventing radiation dermatitis in post-lumpectomy patients with breast cancer receiving adjuvant radiation therapy
Peskova	Some uses of 3M Cavilon No Sting Barrier Film for the prevention of postradiation dermatitis in the head and neck region
Shaw SZ	Cavilon No Sting Barrier Film or topical corticosteroid (mometasone furoate) for protection against radiation dermatitis: a clinical trial

Performance

Alcohol-free skin barriers are important.

Protecting skin from adhesive products, moisture, friction and shear is a critical part of patient/resident care and helps reduce the risk of skin breakdown from common, preventable skin injuries like MARSI and MASD.

A clear advantage over traditional skin barriers.

There might be many skin barrier options available, but not all barriers are created equal. Some still contain alcohol and can cause pain on application. Others wipe away or wash off. And still others don't hold up to moisture, leaving skin vulnerable. Featuring 3M's unique polymer chemistry, Cavilon No Sting Barrier Film offers clear advantages:

A comparison of the durability of four barrier film products over a 72 hour period on human volunteers

Houser T, Zerweck C, Grove G. A comparison of the durability of four barrier film products over a 72 hour period on human volunteers. Poster at Clinical Symposium for Advances in Skin and Wound Care (CSASWC), Orlando, Florida; 2010.

DESIGN

A randomized study comparing Cavilon No Sting Barrier Film as a skin protectant relative to three skin barrier test products.

METHODS

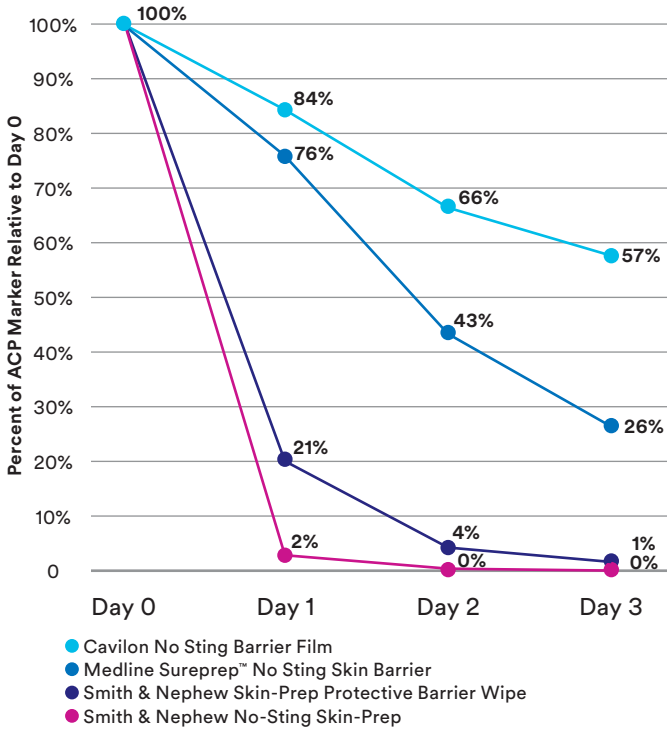
A total of 18 healthy adult volunteers were enrolled. A total of 16 test sites were identified on the dorsal surface of volunteers. Eight test sites (5 cm x 5 cm) were demarcated on the right and left sides of the back. Test sites were grouped into four quadrants. Activated Carbon Powder (ACP) was applied to each test site. Test products were randomized within each quadrant. Per the randomization schedule, skin barrier products were applied (two coats) over the test sites. ACP staining was monitored daily using digital photography and computer-assisted image analysis. Measurements of ACP staining occurred over a period of three days (72 hours). Barrier durability was determined by the amount of staining that remained (percent of ACP relative to Day Zero).

KEY FINDINGS

This study demonstrated that Cavilon No Sting Barrier Film provided significantly better protection and durability compared to three competitor skin barrier test products at least 72 hours post-application.

RESULTS

Durability of barrier films over 72 hours



Cavilon No Sting Barrier Film was more resistant to wash-off and wear-off than Medline Sureprep™ No Sting Skin Barrier, Smith & Nephew No-Sting Skin-Prep and Smith & Nephew Skin-Prep Protective Barrier Wipes on Days One, Two and Three (p<.0001).

A clinical evaluation of 3M No Sting Barrier Film

Campbell K, Woodbury MG, Whittle H, Labate T, Hoskin A. A clinical evaluation of 3M No Sting Barrier Film. *Ostomy Wound Manage*. 2000;46(1):24-30. PMID: 10732633.

DESIGN

An observational, non-comparative study to evaluate the effect of Cavilon No Sting Barrier Film as a skin protectant in incontinence-induced erythema, wound/fistula drainage, the duration of dressing adhesive or male external condom urinary catheters, and skin stripping.

METHODS

A total of 33 patients (mean age = of 69 ± 21 years) from geriatric rehabilitation (n=24) and spinal cord injury units (n=9) were enrolled. Cavilon No Sting Barrier Film was applied. Product was evaluated for seven to 10 days. Nursing staff evaluated skin for erythema, maceration, and skin stripping and also assessed the duration of dressing adhesion.

KEY FINDINGS

Cavilon No Sting Barrier Film was effective as a skin protectant. Product was easy to apply, and no adverse events were reported.

RESULTS

100%

of at-risk patients (n=21) experienced no skin stripping with the use of Cavilon No Sting Barrier Film as a skin protectant.

Erythema was reduced in 96% of at-risk patients (24/25).

Maceration was prevented in 94% of at-risk patients (17/18).

The duration of dressing adhesion or condom catheter was longer in 90% (9/10) of patients.

7 Additional Studies

AUTHOR	TITLE
Bale S	The benefits of implementing a new skin care protocol in nursing homes
Garcia	Effectiveness of 3M Cavilon No Sting Barrier Film for preventing skin damage: a systematic review
Garrick V	A multidisciplinary team model of caring for patients with perianal Crohn's disease incorporating a literature review, topical therapy and personal practice
Grove	A motorized sliding sled apparatus for measuring the coefficient of friction of human skin *in vivo*
Hampton	The nursing care of common raw and bleeding conditions
Williams	3M Cavilon No Sting Barrier Film in the protection of vulnerable skin
Zehrer	Assessment of diaper-clogging potential of petrolatum moisture barriers

Ordering Information

Cavilon No Sting Barrier Film

Supported by over 80 pieces of evidence, more than any other moisture barrier or barrier film, Cavilon No Sting Barrier Film is ideal for the routine protection of periwound skin in low risk patients (e.g., intact skin and low levels of exudate/moisture).

Cat. No.	Size	Items/ Box	Boxes/ Case	HCPCS Code
3343	1.0 mL wand	25	4	A6250
3344	1.0 mL wipe	30	4	A6250
3345	3.0 mL wand	25	4	A6250
3346	28.0 mL spray bottle	12	1	A6250

For more information, contact your 3M Health Care Sales Representative, call the 3M Health Care Customer Helpline at **1-800-228-3957** or visit **3M.com/Cavilon**.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

3M Company
2510 Conway Ave.
St. Paul, MN 55144 USA

Phone 1-800-228-3957
Web 3M.com/Medical

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