SUPRATHEL®

Application of SUPRATHEL® in diverse indications

2016
Publications & Posters

Partial Thickness Burns in Children

Severe Burns in the Elderly Population

Moist Desquamation from Radiation

Relocating Cell Sheets from Thermoresponsive Dishes

PMI Newsletter

THE **TEMPORARY** SECOND SKIN

PMI
The Wound Healing Company

Usability and effectiveness of SUPRATHEL® in partial thickness burns in children

A Prospective/Observational Study

Patients: Twenty-one children (median age 2.4 years; range 5 months-14 years)

TBSA: Median of 4% (range 1-18%)

Indication: Superficial partial thickness burns (57%) & deep partial thickness burns (43%)

Cause of Burn: Scalding (n=19) on the anterior trunk (n=10) and the extremities (n=17)

Treatment: Debridement with Versajet®, SUPRATHEL®

Results:

- The median number of outer layer dressing changes was three (1-13).
- The median background COMFORT-B score for patients younger than 7 years was 13.8 (10-23), while their median procedural pain score was 14.8 (13-23).
- The median re-epithelialization time was 13 days (7-29).
- The majority of (POSAS) scores were found to be in the lower third of the range and showing a favorable scar quality at six months.

Table 3 Scores on the Patient and Observer Scar Assessment Score (POSAS) for evaluation of scar formation in 21 children with partial thickness burns treated with Suprathel®

	3 months post burn	6 months post burn
Observer		
Vascular, median (range)	3 (2–6)	2.5 (1–7)
Pigmentation, median (range)	3 (2–7)	2.5 (2–8)
Thickness, median (range)	3 (1–6)	2.5 (1–4)
Relief, median (range)	2 (1–6)	2.5 (1–4)
Pliability, median (range)	2 (1–8)	2 (1–5)
Surface, median (range)	2 (1–7)	2 (1–3)
Overall opinion, median (range)	3 (1–7)	2.5 (1–5)
Patient/parents		
Pain, median (range)	1 (1–8)	1 (1–2)
Itching, median (range)	3 (1–8)	2.5 (1–5)
Color, median (range)	6 (3–8)	6 (2–9)
Pliability, median (range)	2 (1–6)	2.5 (1–8)
Thickness, median (range)	2 (1–8)	3 (1–8)
Irregularity, median (range)	2 (1–9)	3 (1–8)
Overall opinion, median (range)	4.5 (2–9)	3.5 (1–7)

Rashaan Z.M., Krijnen P., Allema J.H., Vloemans A.F., Schipper I.B. & Breederveld R.S. (2016). Usability and effectiveness of partial thickness burns in children. Eur J Trauma Emerg Surg, pg. 1-8.

SUPRATHEL®

SUPRATHEL® for severe burns in the elderly: Case report and review of the literature

A Case Report

Patient:	81-year old man
TBSA:	51% on face, upper body, lower extremities
Indication:	Superficial dermal burn wounds
Cause of Burn:	Ethyl alcohol due to accelerated combustion of garden waste
Co-morbidities:	Arterial hypertension, atrial fibrillation, congestive heart failure, 80%+ mortality rate
Treatment:	SUPRATHEL® + two layers of fatty gauze
Results:	- Minimum analgesia and sedation were needed, reducing the risk for cardiovascular issues. - Less expensive when comparing an 8 wound dressing change of SUPRATHEL® (6,450€) to a standard polyhexanide gel (7,000€). - Was discharged 69 days after injury without significant handicaps. - Feasible to use SUPRATHEL® for large scale burns in high risk patients. - Found to be crucial when treating burns in ill and elderly patients. - SUPRATHEL® remained on patient until epithelialization. - 97% epithelialization 14 days after injury.

Fig. 1:
Initial admission, burned surface on lower legs

Fig. 2
During SUPRATHEL® and fatty gauze application, right lower leg

Fischer S., Kremer T., Horter J., Schaefer A., Ziegler B., Kneser U. & Hirche C. (2016). Suprathel forvsevere burns in the elderly: case review and review of the literature. Burns, pg. 1-7.

Use of a Polylactide-based Copolymer as a Temporary Skin Substitute for a Patient with Moist Desquamation Due to Radiation

A Case Report

Patient:	66-year old woman
Indication:	Moist desquamation in the plantar foot due to radiation from treatment of melanoma
Cause of Burn:	Scalding (n=19) on the anterior trunk (n=10) and the extremities (n=17)
Treatment:	Debridement & SUPRATHEL®
Results:	- Patient reported subjective pain reduction after application of **SUPRA**THEL® - Re-epithelialization 10 days after application. - Easy application for medical professionals - Reduced potential skin infections - Allows for the continuation of radiotherapy without delay, which may increase patient comfort and compliance - Can be used on difficult areas such as fingers and ears - No additional wound dressing changes are needed - Cost-effective

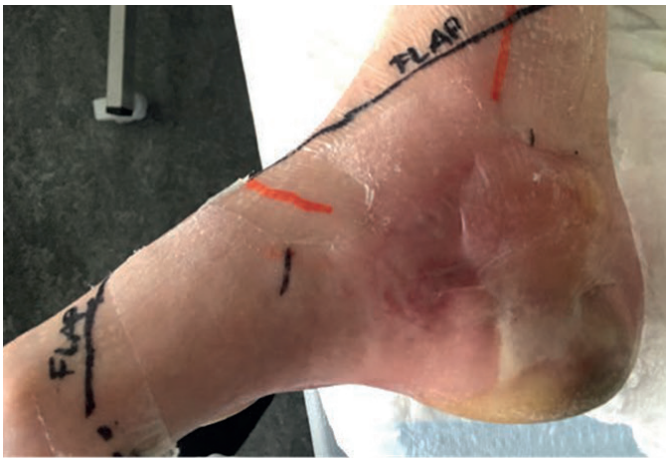


Fig 1:
A moist desquamation of the foot due to radiation

Fig 2:
10 days after debridement and application. Suprathel is completely detached and re-epithelialization can be seen

Rothenberger J., Constantinescum A., Held M., Aebersold D.M., Stolz A., Tschumi C. & Olariu R. (2016). Use of a polylactide-based copolymer as a temporary skin substitute for a patient with moist desquamation due to radiation. Wounds, 28(7): E26-E30.

SUPRATHEL®

Transfer of fibroblast sheets cultured on thermoresponsive dishes with membranes

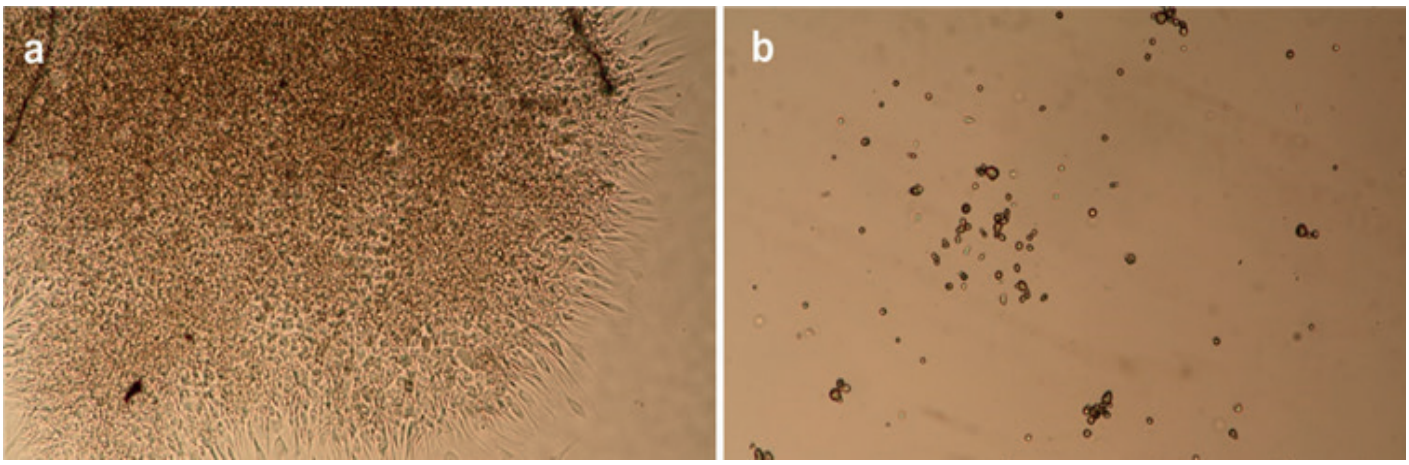
An Experimental Study

Aim of Study: To develop a procedure using membranes to transfer cells sheets to dishes coated with TRPs

Materials: Human skin fibroblasts,thermoresponsive polymer: commercial UpCell dishes (NUNC-TM) coated with thermoresponsive poly(Nisopropylacrylamide) (PNIPAM) and dishes coated with thermoresponsive poly(tri(ethylene glycol) monoethyl ether methacrylate) (P(TEGMA-EE)

Results:

- For the first time, **SUPRA**THEL® was shown that it can be a useful tool for removing a whole, undisturbed cell sheet from both UpCell and P(TEGMA-EE) dishes, and for transportation to a new plate (TCPS)
- Higher viability of re-adhered cells after transfer from SUPRATHEL® than by pipette. UpCell: 72 ± 2.5 vs. 58 ± 2.2. P(TEGMA-EE): 88 ±9 vs. 24 ± 1.1
- Very high transfer yield (detachment yield x re-adhesion yield) for both types of dishes: UpCell (71 ± 3.3), P(TEGMA-EE) (81 ± 2). Value is the mean ± standard deviation
- Found that future cell transfer onto wounds using **SUPRAT**HEL® is possible
- The wound dressing can be left in place, therefore protecting the cells from external factors ensuring proper wound healing
- No additional equipment is needed when using the thermo-responsive dishes allowing for a simplified transportation
- A patient hospitalized in the Burn Centre for Treatment was given **SUPRA**THEL® by cell sheet transfer. Clinically, the effects were very good and the wound closed quickly.



a: transferred, re-adhered cells after temperature detachment at 20 C from UpCell using SUPRATHEL

b: detached cells using dispase II at 37C and transferred by pipette (24 h after transfer)

Kawecki M., Kraut M., Klama-Baryla A., Labus W., Kitala D., Nowak M., Glik J., Sieron A., Utrata-Wesolek A., Trzebicka B., Dworak A., & Szweda D. (2016). Transfer of fibroblast sheets cultured on thermoresponsive dishes with membranes. J Mater Sci: Mater Med, Vol. 27: 111.

Biobrane® and Suprathel® as synthetic wound dressings for partial thickness burns: Comparison of cost-effectiveness in Europe

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Background

- Synthetic dressings for the treatment of partial thickness burns are a well-studied alternative to biological dressings as xeno- and homografts.[1]
- Suprathel®, a polylactide-based membrane, is widely used in Europe and known for its good antimicrobial properties.[2,3]
- Biobrane®, a semi-permeable biosynthetic wound dressing consisting of porcine collagen type I has been commonly used for the treatment of dermal burns in the US.[4]
- Costs as well as cost-effectiveness of dressings are a detrimental topic in burn care.
- Hence, we aimed to assess the cost effectiveness of Biobrane® and Suprathel® for the treatment of partial-thickness burns

Materials and Methods

This study used standard health economic techniques comparing Biobrane® and Suprathel®.

Data from three burn centers as well as recent medical literature were used to assess and define primary endpoints for the cost estimations and calculations.

As endpoints, we defined successful healing, duration of healing, infections and necessity of surgery, as well as pain and number of dressing changes. Cost specific information from the included hospitals and cost data from the German hospital quality reporting system were implemented and a decision tree model was created.

The model computed a point estimate for the cost-effectiveness ratio for the treatment alternatives, assuming a 15% total body surface area (TBSA) partial thickness burn. In addition, the statistical error of the model was assessed by a probabilistic sensitivity analysis (PSA).

The statistical software used was Tree Age Pro Healthcare® (TreeAge Software Inc., Williamstown, MA, USA).

Results

Figure 1. Estimated costs per dressing using Tree Age Pro Healthcare®.
P: Probability
#: Primary dressing application

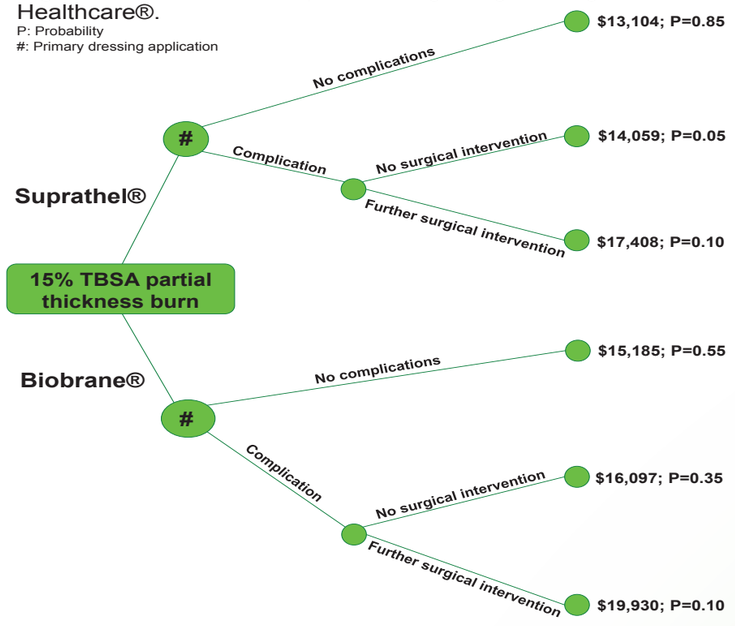

Table 1. Dressing characteristics according to the German hospital quality reporting system.

	Suprathel®	Biobrane®
Dressing costs per cm²	$0.74	$0.79
Probability of surgical intervention	5%	10%
Estimated time for dressing change	0.75 hours	1.00 hours
Probability for dressing change	30%	100%
Costs for pain medication	$79.24	$226.39
Additional care (hours)	0.75 hours	1.00 hours

- In summary, our estimates using the Tree Age Pro Healthcare® software showed lower hospital costs associated with Suprathel® when compared to Biobrane®.
- The generated model produced the calculation of costs for different paths a patient would undergo during treatment (no complication, surgical or non-surgical revision).
- The calculated treatment cost for a partial thickness burn covering 15% TBSA ranged from $13,104 - $17,408 for Suprathel® and from $15,185 - $19,930 for Biobrane®.
- Lower amounts of dressing changes, shorter application time and a reduced length of hospital stay were observed when using Suprathel®..
- Although variations of care costs and treatment patterns of different hospitals had to be considered in our model, results were comparable for all included centers.
- A one way PSA confirmed the robustness of the generated model.

Conclusions

Suprathel® can be used with high cost efficiency for the treatment of a 15% TBSA partial thickness burn. Thus it can be considered as an alternative to the commonly used skin substitute Biobrane®.

Further cost comparison analyses are warranted to compare it to various synthetic and biologic wound dressings and to validate these benefits in the US health care system.

References

1. Wurzer P, Keil H, Branski LK, Parvizi D, Clayton RP, Finnerty CC, Herndon DN, Kamolz LP. The use of Skin Substitutes and Burn Care- A Survey. J Surg Res 2016.
2. Schwarze H, Küntscher M, Uhlig C, Hierlemann H, Prantl L, Ottomann C, Hartmann B. Suprathel, a new skin substitute, in the management of partial-thickness burn wounds: results of a clinical study. Ann Plast Surg. 2008 Feb;60(2):181-5.
3. Selig HF, Keck M, Lumenta DB, Mittlböck M, Kamolz LP. The use of a polylactide-based copolymer as a temporary skin substitute in deep dermal burns: 1-year follow-up results of a prospective clinical noninferiority trial. Wound Repair Regen 2013;21:402–9.
4. Lesher AP, Curry RH, Evans J, Smith VA, Fitzgerald MT, Cina RA, et al. Effectiveness of Biobrane for treatment of partial-thickness burns in children. J Pediatr Surg 2011;46:1759–63.

Applicability to Practice

Changes in availability of synthetic dressings are encouraging us to validate the cost-effectiveness of already well clinical studied wound dressings as Suprathel®, Biobrane® or others.

SUPRATHEL®

Results From Application of an Absorbable Synthetic Membrane to Superficial and Deep Second Degree Wounds

Results From Application of an Absorbable Synthetic Membrane to Superficial and Deep Second Degree Wounds

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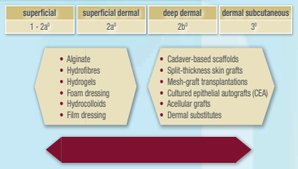
Objectives

- Understand different treatment options for second degree burns
- Compare outcomes after different treatments for second degree burns
- Discuss outcome measures for second degree burns
- Evaluate Cost of different treatment options for second degree burns

Absorbable Synthetic Membrane

Positioning in the Treatment of Wounds



Properties

Composition	Lacto-capromer, main constituent: Polylactic acid
Degradation	4 weeks (hydrolytically)
Plasticity	>200% elongation at break
Permability to water vapor	40 - 70 ml/m2 (hour approx. 1.000 - 1.700 per day
pH	5.5 (initial) => 4.0 in vitro

Study Design

- Retrospective chart review
- 2nd degree wounds (2A and 2B)
- Patient received wound debridement under sedation/anesthesia and absorbable synthetic lactic acid based membrane was placed (= standard care)
- Study period: 9/1/2013 – 9/30/2014
- IRB approval was obtained

Outcome Parameters

- Demographics
- Size of Burn
- Time to healing
- Pain (average)
- Infection
- Failure (required removal/grafting)
- Hypertrophic scarring

Procedure

- Dermabrasion (in OR) or rough debridement (under sedation) of wound
- Rinse with sterile saline
- Dab dry
- Apply (absorbable lactic acid) membrane
- Cover with bridal veil (Dermanet®, N-terface® …)
- Cover with absorbent gauze
- Cover with Ace® bandage or Coban® or surgical netting
- Change outer dressing every 1-4 days down to bridal veil
- Remove when healed

Results

Demographics

- 85 patients, 238 applications, for burns
- 34 female/51 male
- 39 pediatric
- Average age 20 years (9 weeks to 73 years)
- Average Burn size 9.5 %TBSA (1-33)
- Placed in OR/BC 79/6

Results	
Average time to healing	12.05 days
Average pain level throughout	2/10
Area of Infection	3/85 = 3.5%
Area of progression to FT	7/85 = 8.2%
Hypertrophic scarring *(27 had no later follow up pictures available, so could be as low as 5%)*	6/58 = 10.43%

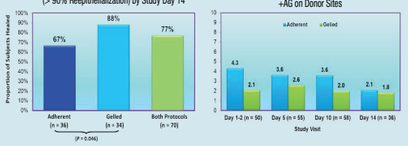
Comparison to Other Skin Substitutes

Results Retrospective/prospective Comparison Collagen Membrane with Fetal Cells vs. Ointment Treatment for Second Degree Burns (partially previously not published)

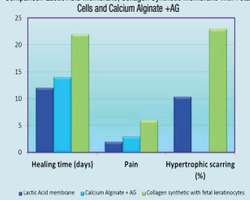
- 159 study sites
- 25 study sites were categorized as topical treatment sites
- 134 study sites were categorized as membrane treatment sites
- In the topical treatment group 32% of sites were initially identified as deep 2nd degree burns compared to 34.3% in the membrane group
- Healing time 17.2 days
- Pain average 6, larger percentage <5 in membrane group

Scarring Any Scar vs. No Scar, by Treatment Group			
Visible Scars	Topical	Operative	Overall
	%	%	n(%)
None	8 (32.0)	51 (38.1)	59 (37.1)
Any	17 (68.0)	83 (61.9)	100 (62.9)
Total	25	134	159

Healing by Study Day 14 Visit Calcium Alginate +AG on Donor Sites



Comparison Lactic Acid Membrane, Collagen Synthetic Membrane with Fetal Cells and Calcium Alginate +AG



Case Study

9 week old with 26% TBSA

Membrane applied 5 hours after burn after dermabrasion
Staph aureus pneumonia
Extubation day 7
Discharge home day 13

Cost Analysis	
1 sheet of collagen membrane with fetal cells	approx. 900$
1 sheet of lactic acid membrane	approx. 300$
1 sheet calcium alginate + AG 8x12"	28$
1 tube of collagenase ointment 90 gm	approx. 600$
1 tube of antibiotic ointment 30 gm	approx. 10$
Vaseline gauze 1 sheet 3x18"	2,80$
Cost ???	
Procedure cost (sedation/anesthesia/excision)	2500$
Material Cost (membrane/ointment/outer dressing) (per dressing change)	20 - 900$
Nursing time (1 hour per dressing change)	80$
Pain medication (per day)	2-200$
Hospital stay (per day)	2500$
Collagen Membrane With Cells Cost 3% TBSA	
Sedation Debridement	2500$
Membrane	900$
Silver and gauze outer dressing	60$
Change outer dressing every 3 days x5	300$
Nursing time average 5 hours	400$
Healing in 15 days	4100$
Ointment Dressings 3% TBSA Cost	
Sedation Debridement	2500$
Ointment (3 days per tube)	50$ /3000$
Vaseline and gauze outer dressing	20$
Change outer dressing every day x15	300$
Nursing time average 5 hours	400$
Healing in 15 days	3250$/6200$
Healing in 15 days (without debridement when using collagenase)	3700$
Lactic Acid	
Sedation Debridement	2500$
Membrane	300$
Gauze outer dressing	20$
Change outer dressing every 3 days x5	100$
Nursing time average 1 hours	80$
Healing in 15 days	3000$

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SUPRATHEL®

The temporary second skin

PMI
The Wound Healing Company

KEY BENEFITS

Significant pain relief - by up to 60%[1]

- Significantly less IV narcotic management required
- Minimally manipulative dressing changes with no anesthesia

Significant reduction of infections and inflammatory response, no biologic risk

- Synthetic, biocompatible, absorbable
- Minimizes risk of infections and inflammation, no reported allergic reactions

Faster wound healing[2]

- Reduces healing time for STSG donor sites allowing for early reharvest
- ROM can begin 2-5 days following application

Lower treatment costs[3] - by up to 69%

- One-time wound dressing, no change of SUPRATHEL® needed
- Less care and aftercare needed, shortened need for hospitalization
- Less administration of pain medication needed

Good cosmetic and functional outcomes and scar quality[4]

Literature

[1] Uhlig et al., Burns 33/2007; Schwarze at al., Am. Plast. Surgey 60/2009; Markl et al., Am Plast. Surg. 65/2010; Highton et al., Burns 39/2013
[2] Uhlig et al., Burns Nov. 33/2007; Schwarze at al., Burns Nov. 33/2007
[3] Keck et al., Burns 2012; Uhlig et al., Burns Nov. 33/2007; Highton et al., Burns 39/2013
[4] Schwarze et al., Burns Nov. 33/2007; Everett at al., J. Wound Care 24/2015

Effective. Efficient. Reliable.

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