SUPRATHEL®

Application of SUPRATHEL® in different indications

Scientific Update 04/2018

ABA 2018, Chicago

- special edition -

- Second-Degree Burn Care with a Lactic Acid Based Biodegradable Skin Substitute in 229 Pediatric and Adult Patients
- The Use of Caprolacton Dressings in Pediatric Burns - A Gold Standard?
- An Evaluation of Patients that Failed Outpatient Management but Rescued by the Use of Synthetic Lactic Acid Polymer

PMI Newsletter

THE **TEMPORARY** SECOND SKIN

PMI
The Wound Healing Company

Welcome

In this edition you will find the most recent **SUPRA**THEL® abstracts and posters from the 2018 ABA Annual Meeting in Chicago.
We are especially proud of our two expert users who received an ABA poster category award!

Dr. Eberwein from Lehigh Valley presented exciting data on Suprathel from 229 patients comparing it with other technologies:

- 97% of burn wounds in this series healed without grafting
- Pain was rated at 1.5/10 throughout – significantly superior to Transcyte
- Time to epithelialization was accelerated compared to similar wounds that received daily dressing changes and wounds that were treated with Biobrane® or allograft (12.4 days)
- No integration into wound beds was noted
- Infection rate was 3.49%

The German experts Dr. Schriek and Dr. Sinnig summarized their 10+ years of **SUPRA**THEL® usage. Key take aways based on the data from Hannover (over 1200 **SUPRA**THEL®l patients):

- **SUPRA**THEL® reduced the need for skin grafting by over 74%
- Dressing changes under general anesthesia have been reduced by 47%

We thank all presenters for their contributions to the **SUPRA**THEL® knowledge base consisting of over 160 publications, especially on when and how **SUPRA**THEL® can be used in clinical practice. We hope to see you at one of our next **SUPRA**THEL® User Workshops! Please ask your local rep or myself if you have any questions about **SUPRA**THEL®.

Thank you!

Christian Planck
Chief Operating Officer

Second-Degree Burn Care with a Lactic Acid Based Biodegradable Skin Substitute in 229 Pediatric and Adult Patients

S A Blome-Eberwein, MD, H Amani, MD, FACS, D Lozano, MD, FACS, C Gogal, BS

Journal of Burn Care & Research, Volume 39, Issue suppl_1, 9 April 2018, Pages S223
Read more

Published: 09 April 2018

Abstract

Introduction

For 2nd degree burns temporary wound coverage has been studied in the past (amniotic membrane, Biobrane®, Transcyte®, Mepithel®) to limit dressing frequency and accelerate healing. Infection and integration into the healing wounds as well as cost have been major drawbacks, final outcome reports are scarce. The ideal treatment of 2nd degree burns would 1-decrease pain, 2-limit dressing changes,3-allow assessment of healing, 4-prevent infection, 5-accelerate healing, 6-improve long term outcome, 7-save treatment cost. This biodegradable skin substitute seems to fulfill 6 out of the 7 above mentioned requirements. This study was conducted as a retrospective chart review and IRB approval was obtained.

Methods

Over 3 years 229 patients (138 pediatric) received Suprathel®, a synthetic copolymer DL-lactide membrane, to their 2nd degree burns. Wound bed preparation was achieved under anesthesia by dermabrasion. Suprathel® was applied after hemostasis. The wound bed was followed through the translucent Suprathel® and fat gauze layers. The dressing separated spontaneously after epithelialization. Information on healing time, pain, infection, demographics and long term outcome was collected.

Results

97% of burn wounds in this series healed without grafting. Infection rate was 3.49%. Time to epithelialization was accelerated compared to similar wounds that received daily dressing changes and wounds that were placed in Biobrane® or allograft (12.4 days). 10/229 wounds progressed to full thickness in small areas. No integration into wound beds was noted. Pain was rated at 1.5/10 throughout. Long term scarring was less than other treatment series (unpublished data from same authors).

Conclusions

Application of Suprathel® to 2nd degree wounds offers a simple option with potential for better outcomes and less pain. Cost was at least equivalent to current standard of care (cream dressings or other temporary skin substitutes).

Applicability of Research to Practice

Immediate.

The Use of Caprolacton Dressings in Pediatric Burns - A Gold Standard?

K S Schriek, M M Sinnig, MD

Journal of Burn Care & Research, Volume 39, Issue suppl_1, 9 April 2018, Pages S209,
More information

Published: 09 April 2018

Abstract

Introduction

We present our data of second degree burns in children starting 2004 and evaluated the effectiveness of our paradigm shift in the treatment of superficial and partial thickness burns in children over the period of the last 13 years: Starting with the first treated cases in our pediatric burn unit in the year 2004 up to the use of a caprolactone membrane as the goldstandard since 2010.

Methods

A retrospective study (2002 - 2017) was conducted to evaluate the use of caprolactone membranes in respect of burn depth, total body surface area (TBSA), number of dressing changes, need for skin grafting and length of hospital stay.

Results

2134 children have been treated in our institution between 2004 and (August) 2017: 1989 children had a second degree burn (2a°= 908, 2b° = 1081 patients) and 324 patients had a third degree burn. 1210 patients were treated with the caprolactone membrane. The need for skin transplantation in second degree burns dropped inversely proportional to the use of caprolactone membranes. The number of dressing changes under general anaesthesia had decreased by more than 40 percent.

Conclusions

The use of caprolactone membranes in pediatric burns provides advantages regarding the need for skin transplantation, number of dressing changes and length of hospital stay.

An Evaluation of Patients that Failed Outpatient Management but Rescued by the Use of Synthetic Lactic Acid Polymer

T Short, MD, D Johnson, BS, D Bennett, APRN, FNP

Journal of Burn Care & Research, Volume 39, Issue suppl_1, 9 April 2018, Pages S193–S194,
More information

Published: 09 April 2018

Abstract

Introduction

We implemented and participate in telemedicine for outpatient referrals from outlying and surrounding hospitals. Outside hospitals will submit photos and provide basic information about the burn injury. A staff physician then triages the pic and suggests inpatient vs outpatient management. Quality review of this process identified 5 patients that on presentation to clinic were admitted secondary to uncontrolled pain. The charts were assessed for areas of complaint, narcotic needs, previous dressings used and what treatments were implemented post intervention.

Methods

Patients were identified during a quality review for admissions on first presentation to clinic. These assessments are evaluated for assurance that things aren't missed or overlooked in our telemedicine program. When looking at this data we noted that of the 3 patients had polylactic acid synthetic polymer skin substitute applied. Once identified the charts were retrospectively reviewed for treatment course post admission. Key items identified was percent and depth of burn, narcotic usage on arrival to clinic and post procedure narcotic usage, time to discharge post intervention, standard pictures were reviewed.

Results

Review of the charts yielded the following: Pt# 1 was a 16 year old female that sustained 7% TBSA 2nd degree burn to the lower extremity.. She presented in a wheelchair taking oral narcotics at home q4h and undergoing silver sulfadiazine (SSD) twice daily. Taken to the OR 2 hrs post admission and placed in polylactic acid polymer. Her narcotic need decreased to 4 pills on POD#0 and was discharged home POD#1. Pt #2 was a 70 year old male who had polylactic acid skin substitute applied to the left leg and silicone backed foam dressings applied to the right. The patient represented 2 days later with uncontrolled pain in the right leg. He remained in the hospital for 3 additional days with only a complaint on the right. This situation led to a great controlled evaluation of pain perception as his treatments were different Pt# 3 was admitted with 20% TBSA 2nd degree scald burns. Wounds initially dressed in antibiotic ointment and gauze. He was taken to the OR and placed in polylactic acid to minimize wound care. But it was noted that he received and requested no narcotic medications in his 24 hours post operative period and was slated for discharge on POD #2

Conclusions

With such drastic changes in narcotic need, physical actitivty and ability to discharge home, this warrants a continued look at the ability of the polylactic acid synthetic polymer skin substitute to minimize pain and why. We plan to next evaluate if pain is decreased or minimized in the most painful wounds of all, donor sites.

Applicability of Research to Practice
May decrease narcotic need through minimally invasive interventions.

Second-Degree Burn Care with a Lactic Acid Based Biodegradable Skin Substitute in 229 Pediatric and Adult Patients

Sigrid Blome Eberwein MD, Patrick Pagella, RN, CNP, Deborah Boorse, RN, CNP, Hamed Amani MD

Lehigh Valley Health Network Allentown, Pennsylvania

OBJECTIVES

- Evaluate 229 patient cases
- Discuss outcome measures for second degree burns
- Understand different treatment options for second degree burns
- Compare outcomes after different treatments for second degree burns
- Evaluate Cost of different treatment options for second degree burns

ABSORBABLE SYNTHETIC MEMBRANE

Positioning in the Treatment of Wounds

superficial	superficial dermal	deep dermal	dermal subcutaneous
1 - 2a⁰	2a⁰	2b⁰	3⁰

- Alginate
- Hydrofibres
- Hydrogels
- Foam dressing
- Hydrocolloids
- Film dressing

- Cadaver-based scaffolds
- Split-thickness skin grafts
- Mesh-graft transplantations
- Cultured epithelial autografts (CEA)
- Acellular grafts
- Dermal substitutes

Lactic Acid Membrane

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 – 12/31/2016
- IRB approval was obtained

OUTCOME PARAMETERS

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

PROCEDURE

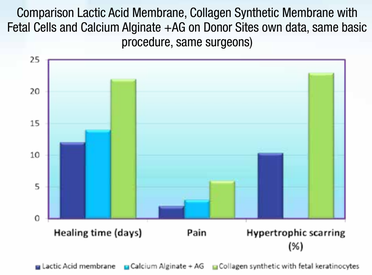
- Dermabrasion (in OR) or rough debridement (under sedation) of wound
- Rinse with sterile saline
- Dab dry
- Apply (absorbable lactic acid) membrane
- Cover with Vaseline gauze
- Cover with bridal veil (Dermanet®, N-terface® …)
- Cover with absorbent gauze
- Cover with Ace® bandage or Coban® or surgical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

RESULTS - Demographics

- 229 patients, 474 applications, for Burns
- 88 female/ 141 male
- 138 pediatric
- Average age 20 years (9 weeks to 73 years)
- Average Burn size 8.6 %TBSA (1-60.5)
- Placed in OR/BC 158/71
- 220x2nd degree, 5x3rd degree, 4x indeterminate depth

RESULTS

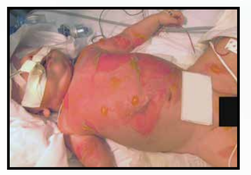
- Average time to healing - 14.2 days
  - Pediatric: 12.4 days
  - Healing time determiniation for outpatients prolonged because of link to appt.
- Average pain level throughout - 1.7/10
- Areas of infection - 3.5%
- Area of progression to FT 5/229 - 2.24%
- Some hypertrophic scarring - 12%
  - 10.1% pediatric, 14.3% adult;
  - 4.3% of BC applications vs 15.2% OR applications, probably because of deeper burns being applied in the OR



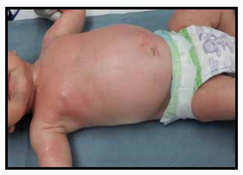
CASE STUDY

9 week old with 26% TBSA

Membrane applied 5 hours after burn after dermabrasion



Staph aureus pneumonia
Extubation day 7
Discharge home day 13



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$
- 1Nursing time average 5 hours - 400$
- Healing in 15 days - 4100$

OINTMENT DRESSINGS 3% TBSA COST

- Sedation Debridement - 2500$
- Ointment 50$ /3000$ (3 days per tube)
- Vaseline and gauze outer dressing - 20$
- Change outer dressing every day x15 - 300$
- Nursing time average 5 hours - 400$
- Healing in 15 days - 3250$/6200$ (or 3700$ without debridement when using collagenase)

LACTIC ACID ABSORBABLE MEMBRANE3% TBSA COST

- Sedation Debridement - 2500$
- Membrane -300$
- Vaseline/-Gauze outer dressing - 20$
- Change outer dressing every 3 days x5 - 100$
- Nursing time average 1 hours - 80$
- Healing in 15 days - 3000$

CONCLUSION

- Lactic Acid membrane is a competitive second degree burn treatment option
- Lactic Acid membrane treatment has a low infection/failure rate when applied onto a vital and clean wound bed
- Lactic Acid membrane coverage decreases the systemic inflammatory response and fluid loss when applied within the first 2 days post burn, especially in children
- Lactic Acid membrane coverage is patient friendly (less pain, less dressing changes)
- Lactic Acid membrane coverage of 2nd degree burn wounds is cost neutral or effective, depending on what other dressing option is used

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Lehigh Valley Health Network

The Use of Caprolactone Dressing in Pediatric Burns - A Gold Standard?

RESORBABLE SKIN SUBSTITUTE (Suprathel ®)

Copolymer of
- **ε-Caprolactone**
- Polylactide
- Trimethylen Carbonate

Features:
Pain reduction
Good wound assessment
Painfree detachement after reepithelialization
No allergic reaction

Lactate reduces the pH level:
Proteases are inhibited
Acidification has an antiseptic effect and inhibits the growth of bacteria

Lactate stimulizes the wound healing process:
Stimulization of angiogenesis
Stimulization of fibroblast migration
Supports collagen synthesis

DATA SOURCE

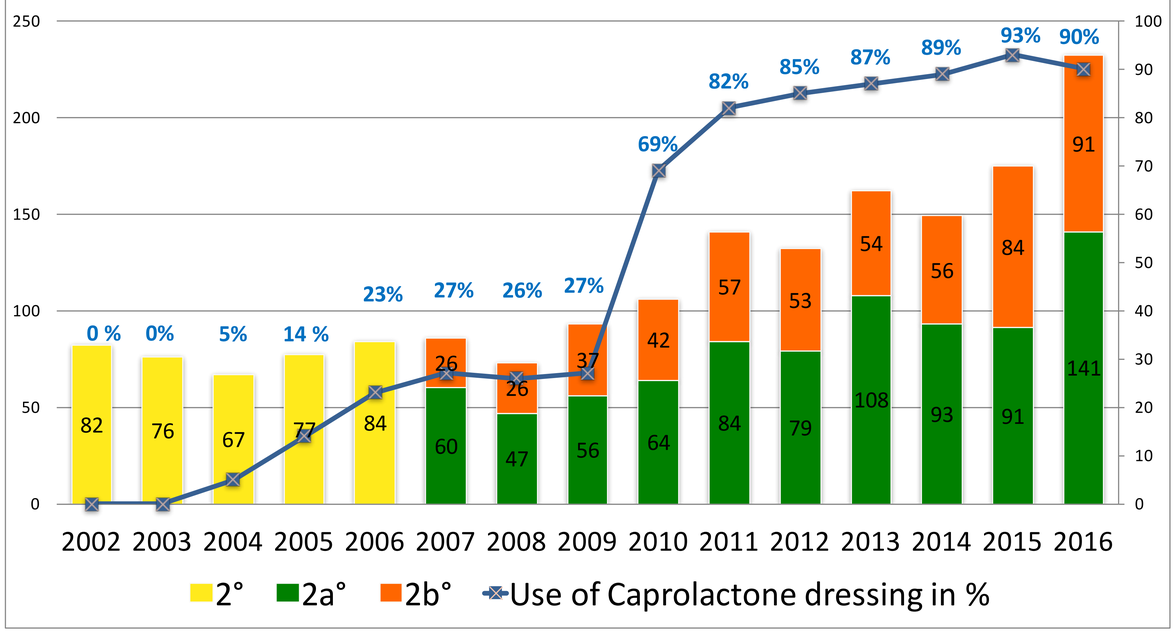
The retrospective study (2002 - 2016) was conducted to evaluate the use of Caprolactone Dressing (Suprathel®) in second degree burns in respect of the need of skin grafting and the number of dressing changes under general anesthesia

2134 pediatric burns have been treated in our institution between 2002 and 2016:

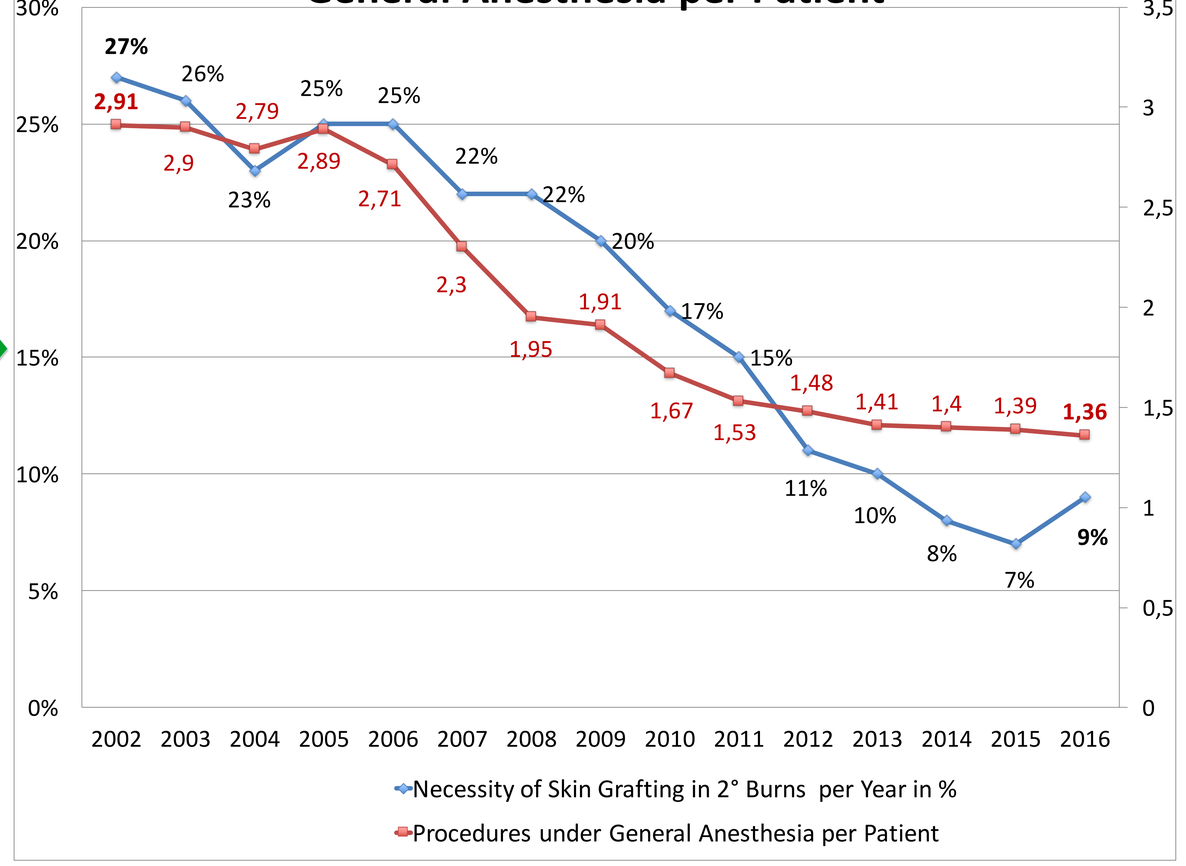
→ 1735 children had a second degree burn

→ 1063 patients were treated with a Caprolactone Dressing (Suprathel®)

Pediatric Second Degree Burns treated in our Institution between 2002-2016



Necessity of Skin Grafting and Procedures under General Anesthesia per Patient



CONCLUSION

With over 90 % of the second degree burns treated with the Caprolactone Dressing in our institution, it has become our gold standard. The increase in usage of Caprolactone Dressing from 0% in 2002 to 90 % in 2016 provided significant advantages:

The need of skin grafting in second degree burns was reduced by 74% (20ppts) during the last 14 years.
The number of dressing changes under general anesthesia was reduced by 47%.

TAKE HOME MESSAGE

The Caprolactone Dressing can be a gold standard in second degree burns. It offers significant medical benefits to patients while reducing the workload in the burn unit.

Katharina Schriek MD, Mechthild Sinnig MD
Pediatric Burn Center, Departement of Pediatric Surgery, Hannover, Germany
schriek@hka.de

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 without anesthesia

Low rate of infections and inflammatory response, no biologic risk

- Synthetic, biocompatible, absorbable
- No reported allergic reactions, only few cases with infections and inflammation

Fast wound healing[2]

- Improved early epithelization
- Early mobilization 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 60/2008; 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 38/2012; 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.

PolyMedics Innovations GmbH
Heerweg 15 D
73770 Denkendorf I Germany

Phone +49 (0)711 719 500-0
Fax +49 (0)711 719 500-10
E-mail info@suprathel.de

Polymedics Innovations Inc.
8681 Highway 92, Suite 308,
Woodstock, GA 30189

Phone +1 646 6042771
Fax +1 646 3503129
E-mail info@suprathel.com

Imprint: PolyMedics Innovations GmbH
Heerweg 15 D I 70773 Denkendorf
www.polymedics.de

Design PolyMedics Innovations
CEO Prof. Dr. Heinrich Planck

Responsible of the redaction
Christian Planck

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