Application of SUPRA\text{\textregistered}HEL\textsuperscript{\textregistered} 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
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 SUPRATHEL® usage. Key take aways based on the data from Hannover (over 1200 SUPRATHEL®l patients):

- SUPRATHEL® 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 SUPRATHEL® knowledge base consisting of over 160 publications, especially on when and how SUPRATHEL® can be used in clinical practice. We hope to see you at one of our next SUPRATHEL® User Workshops! Please ask your local rep or myself if you have any questions about SUPRATHEL®.

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

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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

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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

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

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
- Average time to healing - 14.2 days
  - Pediatric: 12.4 days
  - Healing time determination for outpatients prolonged because of link to apt.
  - 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

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

RESORBABLE SKIN SUBSTITUTE (Suprathel®)

Copolymer of
- ε-Caprolactone
- Polylactide
- Trimethylene Carbonate

Features:
- Pain reduction
- Good wound assessment
- Painfree detachment 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 stimulates the wound healing process:
Stimulation of angiogenesis
Stimulation 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®)

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%.

Necessity of Skin Grafting and Procedures under General Anesthesia per Patient

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, Department of Pediatric Surgery, Hannover, Germany
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 healing²
- Improved early epithelization
- Early mobilization can begin 2-5 days following application

Lower treatment costs³ - 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 quality⁴

Literature
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 33/2007; Highton et al., Burns 39/2013
⁴ Schwarze et al., Burns Nov. 33/2007; Everett at al., J. Wound Care 24/2015