Application of SUPRA® 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
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®
- 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®

<table>
<thead>
<tr>
<th>Observer</th>
<th>3 months post burn</th>
<th>6 months post burn</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular, median (range)</td>
<td>3 (2–6)</td>
<td>2.5 (1–7)</td>
</tr>
<tr>
<td>Pigmentation, median (range)</td>
<td>3 (2–7)</td>
<td>2.5 (2–8)</td>
</tr>
<tr>
<td>Thickness, median (range)</td>
<td>3 (1–6)</td>
<td>2.5 (1–4)</td>
</tr>
<tr>
<td>Relief, median (range)</td>
<td>2 (1–6)</td>
<td>2.5 (1–4)</td>
</tr>
<tr>
<td>Pliability, median (range)</td>
<td>2 (1–8)</td>
<td>2 (1–5)</td>
</tr>
<tr>
<td>Surface, median (range)</td>
<td>2 (1–7)</td>
<td>2 (1–3)</td>
</tr>
<tr>
<td>Overall opinion, median (range)</td>
<td>3 (1–7)</td>
<td>2.5 (1–5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient/parents</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain, median (range)</td>
<td>1 (1–8)</td>
<td>1 (1–2)</td>
</tr>
<tr>
<td>Itching, median (range)</td>
<td>3 (1–8)</td>
<td>2.5 (1–5)</td>
</tr>
<tr>
<td>Color, median (range)</td>
<td>6 (3–8)</td>
<td>6 (2–9)</td>
</tr>
<tr>
<td>Pliability, median (range)</td>
<td>2 (1–6)</td>
<td>2.5 (1–8)</td>
</tr>
<tr>
<td>Thickness, median (range)</td>
<td>2 (1–8)</td>
<td>3 (1–8)</td>
</tr>
<tr>
<td>Irregularity, median (range)</td>
<td>2 (1–9)</td>
<td>3 (1–8)</td>
</tr>
<tr>
<td>Overall opinion, median (range)</td>
<td>4.5 (2–9)</td>
<td>3.5 (1–7)</td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th>Patient:</th>
<th>66-year old woman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication:</td>
<td>Moist desquamation in the plantar foot due to radiation from treatment of melanoma</td>
</tr>
<tr>
<td>Cause of Burn:</td>
<td>Scalding (n=19) on the anterior trunk (n=10) and the extremities (n=17)</td>
</tr>
<tr>
<td>Treatment:</td>
<td>Debridement &amp; SUPRATHEL®</td>
</tr>
</tbody>
</table>
| Results: | - Patient reported subjective pain reduction after application of SUPRATHEL®
- 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 |

Transfer of fibroblast sheets cultured on thermoresponsive dishes with membranes

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 (NUN-CTM) coated with thermoresponsive poly(N-isopropylacrylamide) (PNIPAM) and dishes coated with thermoresponsive poly(tri(ethylene glycol) monoethyl ether methacrylate) (P(TEGMA-EE))

Results:
- For the first time, SUPRATHEL® 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 (TCPSE)
- Higher viability of re-adhered cells after transfer from SUPRATHEL® than by pipette. UpCell: $72 \pm 2.5$ vs. $58 \pm 2.2$. P(TEGMA-EE): $88 \pm 9$ vs. $24 \pm 1.1$
- Very high transfer yield (detachment yield x re-adhesion yield) for both types of dishes: UpCell ($71 \pm 3.3$), P(TEGMA-EE) ($81 \pm 2$). Value is the mean ± standard deviation
- Found that future cell transfer onto wounds using SUPRATHEL® 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 SUPRATHEL® by cell sheet transfer. Clinically, the effects were very good and the wound closed quickly.

Background

- Synthetic dressings for the treatment of partial thickness burns are a well-studied alternative to biological dressings as xenografts.  
- Suprathel®️, a polylactide-based membrane, is widely used in Europe and known for its good antimicrobial properties.  
- 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.  
- 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

- In summary, our estimates using the Tree Age Pro Healthcare®️ software showed lower hospital costs associated with Suprathel®️ 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.

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

Sigrid Blome-Eberwein MD, Patrick Pagella, RN, CNP, Deborah Boorse, RN, CNP, Hamed Amani MD
Regional Burn Center, Lehigh Valley Health Network, Allentown, Pennsylvania

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

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: 8/1/2013 – 9/30/2014
- IRB approval was obtained

Outcome Parameters
- Demographics
- Size of Burn
- Time to healing
- Pain (average)
- Failure (required removal/grafting)
- Hyperrophic scarring

Procedure
- Dermabrasion (in OR) or (rough debridement) under sedation
- Nurse with sterile supplies
- Dry dry
- Apply absorbable lactic acid membrane
- Cover with bridal veil (Demarrot®, 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
- Average age 29 years (9 weeks to 73 years)
- Average Burn size 9.5% TBSA (1-33)
- Placed in OR/BC

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)

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

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

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedation</td>
<td>$2500</td>
</tr>
<tr>
<td>Debridement</td>
<td>$2500</td>
</tr>
<tr>
<td>Change outer dressing every 3 days x5</td>
<td>$100</td>
</tr>
<tr>
<td>Gauze outer dressing</td>
<td>$20</td>
</tr>
<tr>
<td>Sedation Debridement</td>
<td>$2500</td>
</tr>
<tr>
<td>Collagen Membrane w/ Cells Cost 3/15/2015</td>
<td>$1200</td>
</tr>
<tr>
<td>Change outer dressing every 4 days</td>
<td>$100</td>
</tr>
<tr>
<td>Vaseline and gauze outer dressing</td>
<td>$20</td>
</tr>
<tr>
<td>Change outer dressing every 2 days</td>
<td>$20</td>
</tr>
<tr>
<td>Collagen Membrane W/Cells Cost 1/31/2015</td>
<td>$1500</td>
</tr>
<tr>
<td>Calcium Alginate + AG</td>
<td>$80</td>
</tr>
<tr>
<td>Change outer dressing every day x15</td>
<td>$300</td>
</tr>
<tr>
<td>Vaseline gauze 1 sheet 3x18”</td>
<td>$2.80</td>
</tr>
<tr>
<td>Pain medication (per day)</td>
<td>$2-200</td>
</tr>
<tr>
<td>Nursing time average 5 hours</td>
<td>$400</td>
</tr>
<tr>
<td>Vaseline and gauze outer dressing</td>
<td>$20</td>
</tr>
<tr>
<td>Change outer dressing every 3 days</td>
<td>$20</td>
</tr>
<tr>
<td>Collagen Membrane W/Cells Cost 1/31/2015</td>
<td>$1500</td>
</tr>
<tr>
<td>Procedure cost (sedation/anesthesia/excision)</td>
<td>$2500</td>
</tr>
<tr>
<td>Change outer dressing every 2 days</td>
<td>$20</td>
</tr>
<tr>
<td>Nursing time average 5 hours</td>
<td>$400</td>
</tr>
<tr>
<td>Calcium Alginate + AG on Donor Sites</td>
<td>$80</td>
</tr>
</tbody>
</table>

© 2016 Lehigh Valley Health Network
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 healing²
- Reduces healing time for STSG donor sites allowing for early reharvest
- ROM 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 et 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 et al., J. Wound Care 24/2015