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The Use of Suprathel in the Treatment of Pediatric Burns: Retrospective Review of First Pilot Trial in a Burn Unit in the United States

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The Use of Suprathel in the Treatment of Pediatric Burns: Retrospective Review of First Pilot Trial in a Burn Unit in the United States[1]

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Introduction: This presentation discusses a trial study of the use of Suprathel in pediatric patients at the Burn Center at St. Christopher's Hospital for Children in Philadelphia. Suprathel consists of polylactide in a membrane form that adheres to the burn or donor site. It has antimicrobial properties and is pliable, allowing it to be placed in difficult to treat areas. Previous studies have demonstrated Suprathel's safety and efficacy in both adult and pediatric patients 1, 2. This trial represents the first such study done in a burn center in the United States.

Methods: Suprathel was placed on 12 patients with both superficial and deep partial thickness burns. Non severe burns were selected in order to assess the performance of the product without multiple confounding comorbidities. The patients were all pediatric patients (ages 9 months to 12 years) with burns ranging from 1-15% TBSA. The Suprathel was covered after placement with a non-adherent layer (Xeroflo or Adaptic) and an outer cover layer. The outer dressing was changed once a week and the Suprathel and non-adherent layer left in place until healing occurred.

Results: The results of the trial study on the burn wounds only were analyzed retrospectively and the data includes length of stay, rates of healing, infection rates, satisfaction rates and pain reduction/pain medication issues. The average length of stay in the Suprathel treated patients was 1.4 days (range 1-3 days). The amount of pain medication before and after placement of Suprathel decreased from 1.5 to 0.1 doses per patient. The average pain score (1-10 scale) was 1.2 at the first office visit post placement of Suprathel on the burn wound. The burns all healed within 16 days with an average healing of 9.5 days. There were no infections seen in any of the patients. Finally, the patient/parent satisfaction on a 1-4 non-validated subjective scale averaged 3.66 (range 3-4).

Conclusions: In conclusion, the Suprathel was easy to apply and manage post application. It adhered well to the wound bed, eliminating the need for daily dressing changes and wound bed disruption. This resulted in excellent healing in both partial thickness burns and donor sites with minimal pain and anxiety during dressing changes. The dressings were able to be changed every 5-7 days, allowing for less need for nursing care and costly dressing changes. Suprathel was found to be a safe and effective treatment in burns in pediatric patients.

Applicability of Research to Practice: This retrospective review of a pilot study demonstrated a safe and effective new skin substitute previously not evaluated in the United States. The product performed will and show promise for clinical use in every day practice in our Pediatric Burn Unit.

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[1] [abstract] In: Proceedings of the American Burn Association 46th Annual Meeting; 2014 March 25-28 Boston, Massachusetts, USA.p.159.

The Use of Suprathel® in the Treatment of Pediatric Burns: Results of an Initial Pilot Investigation

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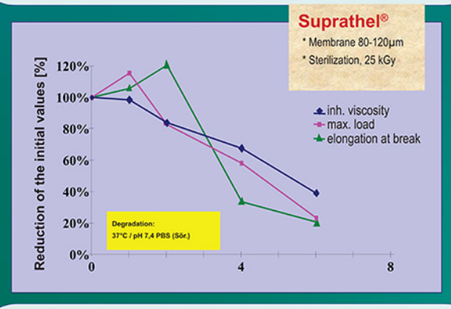
Introduction

Cost effective and timely management of pediatric burn injuries continues to be a challenging dilemma in the burn unit. Managing pain, healing time, overall comfort and cost containment proves to be a daily challenge. A new resorbable wound dressing shows promise in making this duty more bearable for the young patient and more cost effective to the institution.

Suprathel® is a fully synthetic polymer based on degradable Poly-DI-lactides. The final product is a porous membrane with a nearly symmetrical cross sectional density and an interconnected structure of multifaceted pores. This material has excellent mechanical parameters with an elongation of 250%, acidic pH, physiological adopted transepidermal water loss (TEWL) and fast metabolization by hydrolytic degradation without any human tissue irritations.

Thickness:	**50-150 µm**
Transepidermal water loss (TEWL):	**40-70 ml/m²*hour**
Porosity:	**70 - 80%**
Pore size:	**2 - 40µm (av. < 10µm)**
pH	**5.5 (initial) => 4.0 in vitro**

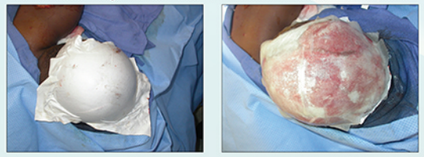


Aim

The aim of this presentation is to evaluate this new product in a pilot trial of superficial and deep partial thickness burns in pediatric patients and compare this material in a retrospective chart review of historical standard of care practice in an inpatient urban burn center. This was the first pilot study performed in a United States burn center.

Method

- All patients in the study were treated in the hospital within 48 hours of admission.
- Wounds were debrided in the BICU or in the Operating Room.
- Suprathel® is applied with at least 2 cm overlap to the wound bed and to the surrounding skin surfaces. No additional fixation is required.



- Suprathel® is then directly covered with a non-adherent gauze dressing of choice and then a secondary bolster dressing over top.
- Patients can be discharged the same day or next day – whenever pain is controlled at a tolerable level.
- Dressings are left in place for the first 5-7 days for follow up.

- Outer dressings are removed and replaced as needed to manage exudates but the non-adherent layer is left intact to the wound bed until healing is complete. This layer is trimmed as needed.
- Follow up for next 5-7 days until full healing is achieved.

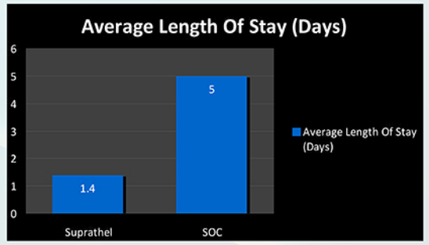
Suprathel® Pilot Study Population

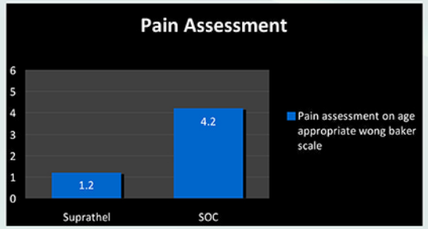
15 Patients
- 3 donor sites
- 12 partial thickness burns
- (7 superficial / 5 mixed deep)

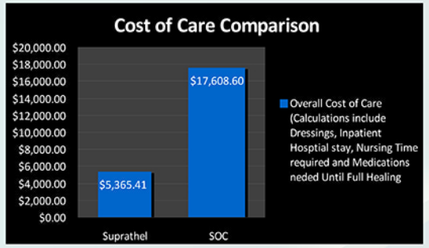
Age 3.6 years (range 10 months - 10 years)
Sex (10 female / 5 male)
Average TBSA 5.5% (range 2-14%)
Time to complete re-epithelialization: 8.4 days
Incidence of infection: 0 occurences

Results

Data was collected in a retrospective fashion and comparisons were made between Suprathel® and the historic Standard of Care (SOC). The results below demonstrate some of the useful benefits that this new wound dressing has to effectively treat mixed depth pediatric burn injuries.







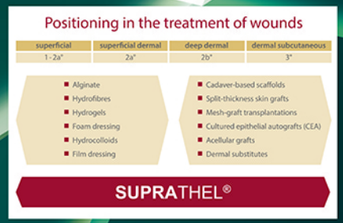
Discussion

Retrospectively, Suprathel® showed significant clinical advantages in the treatment of mixed 2nd degree burns (superficial to deep dermal). The material was easy to use and to handle, simple to manage postoperatively and facilitated rapid wound healing. In our pilot study, use of the Suprathel® served to reduce the length of time to full re-epithelization and significantly improve the rate of healing when compared to the Standard of Care data. This material was not associated with any infections nor was any additional antimicrobial barrier required. Additionally, Suprathel® showed significant cost savings in overall dressing care and management, a reduction of nursing time required, a reduction in pain measured with both subjective assessment ratings and with a decrease in overall narcotic request and usage required.

Suprathel® is a fully synthetic material with favorable characteristics when compared to other types of wound dressings. This artificial and fully bio degradeable membrane may provide for a broader range of uses across ethnic and cultural boundaries when compared to other biological materials. Due to the unique elasticity, high water vapor permeability and impermeability to bacteria, Suprathel® can be a very effective material to use to treat difficult burns and wounds.

Conclusion

Suprathel® is a very effective skin substitute material to use for partial thickness burns in children. Suprathel® should be considered a primary intervention when rapid healing, pain management, cost containment and ease of overall burn wound care is required, especially in mixed depth dermal injuries involving young children.



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