SUPRATHEL®

# Scientific Update 05/2021

## - ABA 2021 -

**The Beneficial Use of SUPRATHEL®:**

- With regard on Inflammation Response and Oxidative Stress
- On Split Thickness Skin Grafts
- In Pandemic Times
- With Suspension Epidermal Autografts

# PMI Newsletter

THE **TEMPORARY** SECOND SKIN

PMI
The Wound Healing Company

SUPRATHEL®

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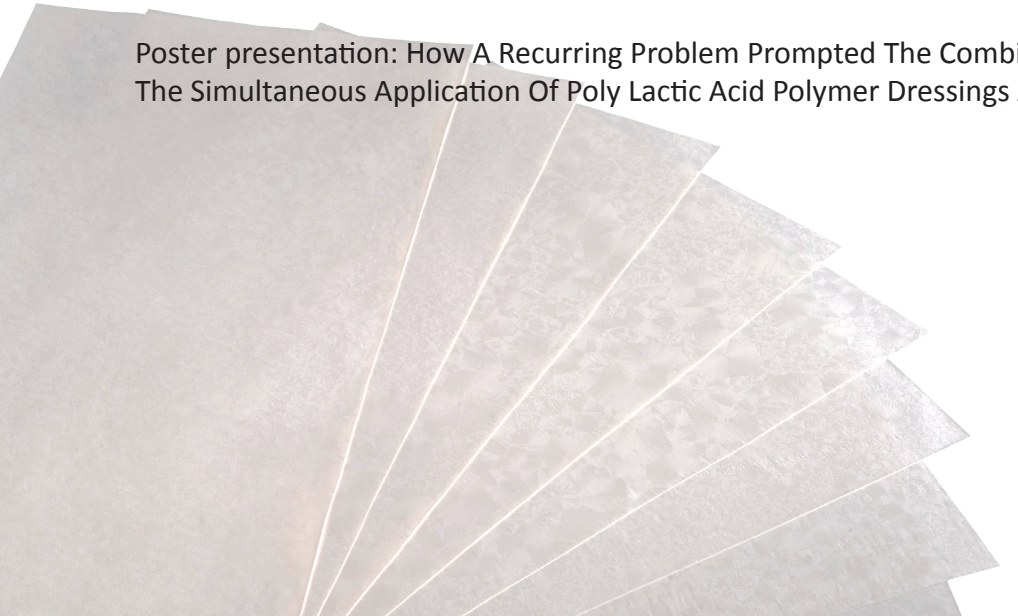

# Message from the CEO

Dear customers,

The PMI team missed seeing you in person at this year's ABA. At the same time we are looking forward to in person meetings in the coming weeks and months.

We would like to take this opportunity to thank you for your tireless work helping patients and your colleagues during this challenging pandemic. You have made many personal sacrifices in order to treat and heal your patients. Thank you!

Luckily the PMI team was able to keep all operations up and running both in the US and Germany in order to make sure that you have sufficient Suprathel supplies in your burn units: Our production, Quality Management, Customer Service, Medical and Sales Teams were operating at 100% capacity through the whole pandemic. It was our goal to come out stronger than we were before. Thanks to you as our customers and our incredible team we have accomplished this goal: Last year we doubled our Suprathel sales in the US and might triple them in 2021. Suprathel is becoming a standard in burn care.

At this year's ABA several interesting presentations and posters showed how Suprathel is both helping during the pandemic and at the same time improving outcomes.

Please get in touch with our team if you have any questions or ideas.

Stay healthy! We hope to see you in person again soon.

Sincerely,

Christian Planck
Chief Executive Officer

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## Oral presentation

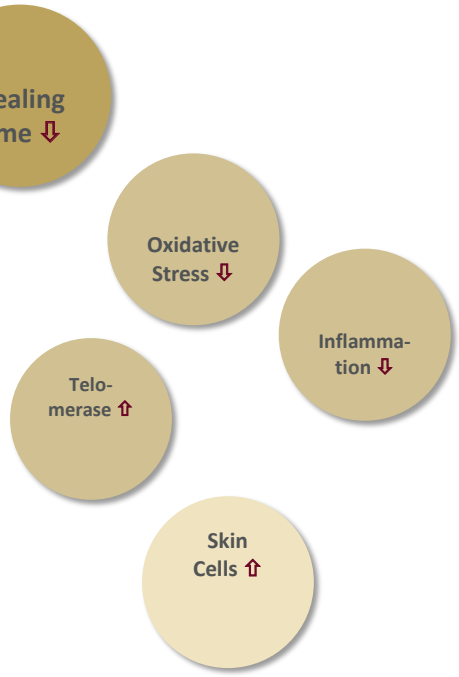
### Oxidative Stress Can Be Significantly Influenced and Reduced by Polylactide-based Membrane Dressings

**Herbert Haller[1], Mehmet Demircan[2], Kubilay Gürünlüoglu[2]**

1. HLMedConsult Austria 2. İnönü University, School of Medicine, Pediatric Burns Center, Malatya, Turkey

Dr. Herbert Haller presented the scientific studies of Dr. Demircan´s working group, showing how beneficial SUPRATHEL® can influence oxidative stress and inflammatory response systemically compared to Hydrofiber Ag dressing:

- Healing time was significantly shorter with SUPRATHEL®
- Application of SUPRATHEL® significantly reduced oxidative stress
- SUPRATHEL® application resulted in a rapid reduction of the inflammatory response (significantly decreased levels of TNF-α and IL-6 and significantly increased levels of TGF-β)
- Telomerase levels in SUPRATHEL® covered wounds were increased, what prevents telomere shortening usually caused by oxidative stress.
- Total cell count of skin cells as well as epidermal thickening was significantly increased in wounds covered with SUPRATHEL®



## 133 Oxidative Stress Can Be Significantly Influenced and Reduced by Polylactide-based Membrane Dressings

Herbert Haller, Mehmet Demircan, Kubilay Gurunluoglu,
*Linz, Oberosterreich; Inonu University, Malatya, Malatya; Inonu University, Malatya, Malatya*

**Introduction:** Oxidative stress is part of the physiological response to local thermal injuries and has systemic effects in more extensive burns, vascular hyperpermeability, burn edema, cellular damage, and functions of the heart, lung, liver, kidneys, muscles, and other organs. Free NO and OH radicals affect mitochondrial function, and lower energy delivery to other organelles releases thermal energy, leading to hypermetabolism. Antioxidant therapies have attempted to reduce the consequences of oxidative stress with limited effects; however, the effect of external dressings is unclear. This study aimed to investigate the positive effects of polylactide-based membranes (PLM) on oxidative stress and clinical outcomes in burns.

**Methods:** Herein, a prospective study assessed the correlation between oxidative stress and the severity of injuries by measuring serum malonaldehyde (MDA) and glutathione levels and the total oxidant and antioxidant capacities (TOC and TAC) among children with electrical injuries. Furthermore, a prospective randomized study evaluated the TOC and TAC, MDA, glutathione, IL-6, TNF-α, and TGF-β levels, and the ratio of telomerase positive staining in epidermal cells along the particle thickness of burns in children, when comparing polylactide dressings to Hydrofiber Ag(HFAg), autografts, and controls.

**Results:** Coherence between measured oxidative stress and injury severity was apparent herein. Application of PLMs significantly reduced oxidative stress in partial-thickness burns compared to HFAg. PLMs decreased the TOC (4,91 VS. 16,78 µmol/L, day 7) and increased the TAC (14,47 VS. 4,34 µmol/L, day 7). The healing duration was lesser than that of HFAg (13 VS. 21 d). Proinflammatory IL-6 levels were significantly lower in the PLM group and TNF-α values were significantly reduced from days 7 to 14. The anti-inflammatory levels of TGF-β was significantly elevated (days 3–21) in the PLM Group. Telomerase levels and the cell count were higher in healed skin in the PLM group.

**Conclusions:** Oxidative stress depends on injury severity and is potentially influenced by dressings. PLM mediates the regulation of oxidative stress, as evident from the TOC and TAC, and pro- and anti-inflammatory cytokines including IL-6, TNF-α, and TGF-β by PLMs might positively influence the healing duration and skin quality in burns. These results could show that oxidative stress can be significantly influenced and reduced by PLM dressings.

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## Poster presentation

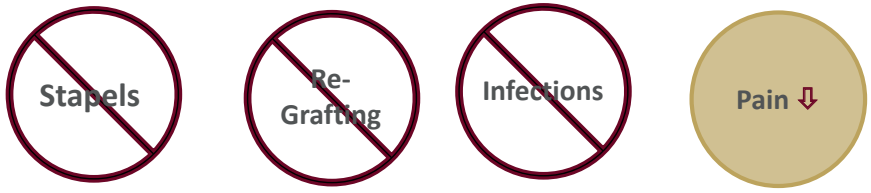
### Single surgeon experience using a Poly-Lactate based copolymer dressing to cover and secure Split Thickness Skin Grafts

**Eduardo Navarro[1], Pavel Mazirka[2], Joshua Carson[2]**

1. University of Florida College of Medicine. 2. Department of Surgery, University of Florida College of Medicine, Gainesville, Florida

Dr. Navarro presented their experience using **SUPRA**THEL® to cover split thickness skin grafts in 22 patients. The results demonstrate that **SUPRA**THEL® can function as an effective means of securing and protecting freshly applied skin graft. They described the following benefits:

- No staples were utilized
- No re-grafting required
- No unplanned readmissions
- No wound infections
- Ease of dressing changes
- Pain mitigation



# Single surgeon experience using a Poly-Lactate based copolymer dressing to cover and secure Split Thickness Skin Grafts

Eduardo Navarro[1], Pavel Mazirka MD[2], Joshua Carson MD[2].

1. University of Florida College of Medicine. 2. Department of Surgery, University of Florida College of Medicine, Gainesville, Florida.

## Introduction

With successful graft-take contingent upon postoperative wound care,[1] identifying improved dressing materials and techniques is a constant priority in burn care. An ideal wound dressing for STSG would 1) effectively secure the graft in place, 2) provide a barrier from trauma and contamination, 3) allow for efflux of wound exudate, 4) minimize complexity of dressing changes, and 5) mitigate pain associated with wound care.

A synthetic copolymer dressing that imitates body's natural epithelium has previously been shown to be efficacious as a post-operative dressing for management of skin-graft donor sites [2] It has porous structure and a high degree of plasticity that allows for adaptation to shape of wound, and reported antiseptic properties.[3,4]

We believe the benefits seen with PLM in donor sites and second degree burns can be translated to meshed grafts. Further, PLMs property of selectively adhering to unepithelialized wound bed could be used to anchor fresh graft to the wound bed.

Here we describe our experience using of intra-operatively placed PLM as a dressing for meshed STSG and its impact on skin graft survival.

PLM – Poly-Lactate Membrane
STSG – Split Thickness Skin Graft

## Methods

With formal IRB approval, Retrospective chart review of adult patients treated with a PLM over STSGs between April 2018 to March 2019 was performed.

PLM was applied intra-operatively at the attending surgeon's discretion over the entirety of the graft surface and was covered by a non-adherent inner liner of a paraffin gauze and an outer layer of dry, sterile, absorbent gauze.

The outer layer of absorbent gauze was changed daily. The PLM was left in place until absorbed, and the inner liner was allowed to fall off spontaneously.

| | n (%) |
|---|---|
| Male | 16 (72) |
| Female | 6 (28) |
| Total | 22 (100) |

Table 1. Demographics of the reviewed population

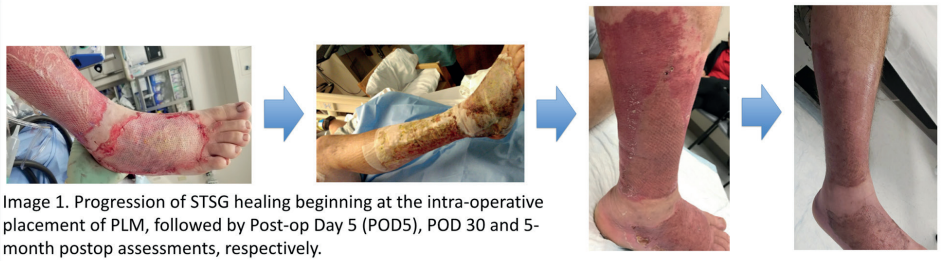


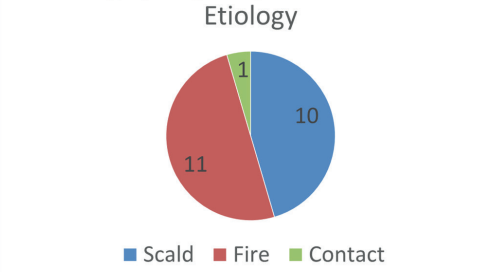
Image 1. Progression of STSG healing beginning at the intra-operative placement of PLM, followed by Post-op Day 5 (POD5), POD 30 and 5-month postop assessments, respectively.

## Results

Twenty-two patients were treated with PLM over STSG (Table 1). Follow up ranged from 21 days to 232 days postoperatively, with five patients lost to follow up during post-op clinic visits (table 3). 14 patients had complete graft take and 3 patients were noted to have minimal graft loss that healed without further intervention. There were zero readmissions, and no patients were diagnosed with an infection of their STSG site. Three patients were treated with postoperative antibiotics, two of whom received antibiotic therapy for reasons not related to wounds while the third patient was treated with antibiotics empirically for wound concerns that were later deemed unfounded on examination and the antibiotic treatment was discontinued (table 4). Anecdotally, patients and members of the care team expressed satisfaction with the ease of dressing changes and the pain mitigating effects.

| | Mean | Range |
|---|---|---|
| Age | 42.22 | (20-73 years) |
| Length of Stay | 9.45 | (24-28 days) |
| TBSA % | 9.42 | (2-40%) |
| Area Treated | 363.95 cm2 | (100-830 cm2) |

Table 2. Mean age, length of stay, Total Body Surface Area of burn and area treated.




Graph 1. Underlying mechanism of thermal injury in reviewed population.

| Total | | N (22) |
|---|---|---|
| Graft take at discharge | | 22 |
| Graft healing on follow up | | 17 |
| | Lost to follow up | 5 |
| Re-grafting | | 0 |
| Readmissions | | 0 |
| Graft loss | | 0 |
| | "Minimal" but healed | 3 |

Table 3. Outcomes of STSG healing in the reviewed population

| Total | | N (22) |
|---|---|---|
| Infection | | 0 |
| Post-op antibiotics | | 3 |
| | Infection ruled out | 1 |
| | Unrelated | 2 |

Table 4. Need for antibiotic therapy in the reviewed population

## Discussion

Our results demonstrate that a PLM can function as an effective means of securing and protecting freshly applied skin graft. PLM also allows wound examination without removal of dressing.

While this retrospective review is not designed to fully capture low-probability complications, the lack of infection or clinically significant graft failure is at least promising enough to justify further, more formalized clinical study of this technique. Also, though patient and provider feedback was positive, we did not have a mechanism to formally capture and quantify this perceived benefit.

As in most retrospective review, loss to follow up is a notable weakness in our results.

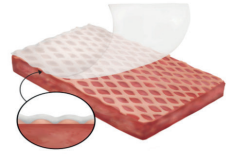


Image 2. Anchoring action of Suprathel® to Dermis over STSG.

Image 3. Shows formation of interstices (arrow). PLMs property of selectively adhering to unepithelialized wound bed could be used to anchor fresh graft to the wound bed.

## Conclusion

Our results demonstrate that a PLM can function as an effective means of securing and protecting freshly applied skin graft.

While clearly a reasonable clinical option now, prospective randomized clinical trials would be valuable to further establish and quantify the advantages of this approach.

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## Poster presentation

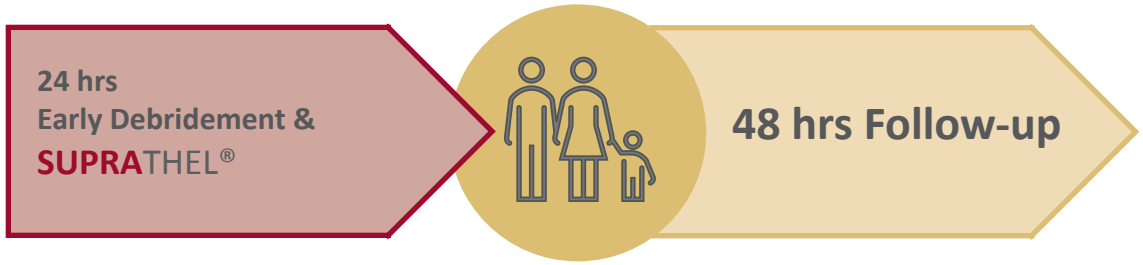
### Burns In The Time of COVID: How The Use of a Poly Lactic Polymer Skin Substitute Helped a Combined Adult/ Pediatrics Burn Unit Change Clinical Practice During The Coronavirus Lockdown

**Tracee Short**

Baton Rouge General Hospital, Baton Rouge, Louisiana, United States

Dr. Short reports the benefits of using **SUPRA**THEL® in children in times of Coronavirus Pandemic. This allowed for a discharge within 24 hours and return to clinic in 48 hours after early debridement. The chart review of 10 peds patients demonstrated:

- Scarless healing of deep wounds that were thought to require excision
- No delays in wound healing
- Only one return admission and ER visit
- Happy parents being able to care for their children at home



# Burns in the Time of COVID:
## How The Use of a Poly Lactic Acid Polymer Skin Substitute Helped a Combined Adult/Pediatrics Burn Unit Change Clinical Practice During The Coronavirus Lockdown

Baton Rouge General

*Dr. Tracee Short, MD*

## Background

In 2020, the Coronavirus pandemic abruptly changed everything about daily life. Even as a verified burn center, there was nothing that could have prepared us for a statewide stay-at-home order nor the hospital lockdown that would come with the coronavirus pandemic.

Nationwide hospital lockdowns started to prohibit the visitation of ill patients by their family members and loved ones. This was especially challenging for parents of ill or injured children. New hospital policy restricted parent visitations, thus heightening the desire to discharge quickly, which shifted our usual practice.

During March-July 2020, our hospital was forced to enforce strict visitation policies. For pediatric burn patients, this meant no visitors and no parent swap outs during the day. This resulted in early debridements, often at the bedside, and application of a polylactic acid polymer substitute to allow for quick discharge times, often within 24 hours of presentation with a 48 hour outpatient follow up.

## Material & Methods

- Chart review of 10 pediatric patients who were admitted to the Burn Unit during the Coronavirus pandemic
- These patients were treated with early debridement and early application of a polylactic acid polymer skin substitute. They were than discharged earlier than they would have been in pre-COVID times
- All patients had stable vitals and appropriate UOP at time of discharge
- Studied any resulting readmissions, ER visits, delays in wound healing, and delays in OR time (if applicable)

| Patient | Burn TBSA | Burn degree and location | Dressing | Clinical notes |
|---|---|---|---|---|
| 5 YO male | 10.5% | 2nd and 3rd to RLE | PLAP* | Length of stay: 4 days |
| 14 month old male | 3% | 2nd to feet | SFD** | Healed at 18 days |
| 5 YO male | 3% | 2nd to trunk | SFD | Length of stay: 1 day<br>Healed at 6 days |
| 9 YO female | 8% | 2nd to buttocks, trunk, B/L LE | PLAP | Healed at 16 days |
| 3 YO male | 11% | Mixed 2nd to trunk | PLAP | Length of stay: 1 day<br>Healed at 11 days |
| 4 YO female | 10% | 2nd | | Length of stay: 2 days<br>Lost to follow up |
| 11 YO male | 5% | 2nd to thighs and genitals | SFD | Healed at 8 days (telehealth visit) |
| 8 YO male | 10% | 2nd and 3rd to trunk and RUE | PLAP | Length of stay: 1 day<br>Required STSG at post-burn day 14<br>Healed at 20 days |
| 8 YO male | 4% | 2nd and 3rd LLE | PLAP | Required STSG at post-burn day 14.<br>Healed at 20 days |
| 16 month old male | 14% | 2nd trunk and RUE | PLAP | Length of stay: 4 days<br>Returned to ER day after discharge for soiled dressings.<br>Healed at 16 days. |

*PLAP: Polylactic Acid Polymer
**SFD: Silver Foam Dressing

## Results

- Chart review indicated one return admission out of the 10 patients
  - *Readmission cause: planned split thickness skin graft*
- One dressing related ER visits reported
- No delays in wound healing reported
- No applicable increase in OR time
- Post-treatment satisfaction surveys showed that parents were happy and relieved to be able to care for their children at home vs. inpatient (due to the risk of COVID exposure)
- No discomfort about early discharge was reported by the nursing staff

## Conclusions

Like many aspects of medicine, COVID has made us reexamine how we care for burns in the inpatient setting. Given the increased COVID exposure in the hospital setting, we wanted to see if we could achieve comparable treatment outcomes by decreasing inpatient stay and optimizing outpatient therapy.

Optimizing outpatient therapy via early debridement and application of a poly lactic acid polymer skin substitute also illustrates the ability of large wounds, initially thought to possibly require surgical excision, to heal without hypertrophic scarring.

Our institution will consider the early practice of debridement and lactic acid polymer application, even when the restrictions are eased. Because of the success of this treatment protocol, we have also been forced to reevaluate how much we are skin grafting and reexamine what can heal on its own.

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## Poster presentation

### How A Recurring Problem Prompted The Combination Of Technologies: Our Institutional Experience With The Simultaneous Application Of Poly Lactic Acid Polymer Dressings After Application Of Suspension Epidermal Autografts

**Tracee Short**

Baton Rouge General Hospital, Baton Rouge, Louisiana, United States

Dr. Short is about to investigate the simultaneous use of suspension epidermal autografts and **SUPRA**THEL®, as it turned out that the dressing included in the kit is not suitable. The preliminary results indicated:

- Patients were able to be discharged sooner
- The wound care is more streamlined
- No areas of graft loss
- Immobility was not required for successful take

Suspension epidermal autografts

\+ SUPRATHEL® =

*LOS = Lenght of (hospital) stay

# How A Recurring Problem Prompted The Combination Of Technologies:

## Our Institutional Experience With The Simultaneous Application Of Poly Lactic Acid Polymer Dressings After Application Of Suspension Epidermal Autografts

*Dr. Tracee Short*

*Baton Rouge General Regional Burn Unit*

## Background

Our institution has utilized the suspension epidermal autograft solution since the first application with FDA compassionate use protocol. We have since used this commercially available technology for the management of deep partial thickness and full thickness burn wounds.

There is a non-adherent dressing in the commercially available kits to cover the suspension in a semi-porous fashion. We often would have beautifully dressed extremities and trunks only to find that in positions of function the non-adherent layer would pop through the intact staples.

We then investigated the source of this discrepancy and found the non-elastic property of the dressing the likely culprit. We then began the process to determine an alternative dressing that could work more efficiently.

## Material & Methods

- In an effort to determine if the institutional standard of care could be benefitted by this patient based observation, the charts of patients that underwent simultaneous application of the epidermal autograft suspension and the poly lactic acid polymer dressing were interrogated.
- The data was identified by the institutional tissue tracker. Once the patient was identified, the chart was then reviewed to determine the desired data points.
- We evaluated the charts of patients that were recorded as utilizing the suspension epidermal autograft as well as the poly lactic acid polymer skin substitute (identified by billing codes).
- The charts were then evaluated to determine if there were any deviations from our expected outcomes using the suspension alone.

## Results

- Our preliminary results indicate that the patients were able to discharge sooner when using the combination of suspension epidermal autograft and poly lactic acid polymer dressing.
- The wound care associated with the polymer skin substitute is more streamlined.
- No areas of graft loss
- In two instances, the combination remained in place longer than compared to the standard dressing.
  - The wound was healed beneath but the skin substitute remained adhered.
- Immobility was not required for successful take.

## Conclusion

The simultaneous use of suspension epidermal autografts and poly lactic acid skin substitutes has become common place for our institution.

A quick review as a QI project has resulted in the desire to delve further into comparative data points. A formal retrospective review of the charts will be undertaken for a case series of about 20 patients.

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