NEGATIVE PRESSURE WOUND THERAPY IN COMPARISON TO STANDARD CARE IN TREATMENT OF IIA AND IIB BURN WOUNDS: RESULTS OF A PROSPECTIVE MONO-CENTRE RANDOMISED DOUBLE-ARM STUDY

C. Tapking[1], J. Endlein[1], J. Warszawski[2], D. Kotsougiani-Fischer[1,3], E. Gazyakan[1], G. Hundeshagen[1], C. Hirche[2], D. Trofimenko[4], T. Burkard[5], U. Kneser[1], S. Fischer[1,3]

[1]Department of Hand, Plastic and Reconstructive Surgery, Microsurgery, Burn Center, BG Unfallklinik Ludwigshafen, Heidelberg University, Ludwigshafen, Germany

[2]Department of Plastic, Hand and Reconstructive Microsurgery, Handtrauma- and Replantation Center, BG Unfallklinik Frankfurt am Main GmbH, Frankfurt/Main, Germany

[3] AESTHETIKON, private practice for plastic and aesthetic surgery, Mannheim, Heidelberg, Germany

[4] Department Clinical Regulatory Affairs (QRA-RA-C), Lohmann & Rauscher GmbH & Co. KG, Neuwied, Germany

[5] Anfomed Gmbh, Möhrendorf, Germany

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STUDY OBJECTIVES

Negative pressure wound therapy (NPWT) has become a widely used tool for the coverage and active treatment of complex wounds, including burns. However, there is only little data on how it may be superior to common wound dressings. This study compared efficacy of negative pressure wound therapy (NPWT) and a local standard of care (SoC) in treatment of second-degree burns.

This prospective, open-label, randomized monocentric study was conducted in Burn Center of Emergency Hospital Ludwigshafen (Germany) between May 2019 and November 2021.

The primary endpoint was time to achieved healing or skin grafting.
Secondary endpoints were rate of achieved healing and time to complete healing after skin graft.

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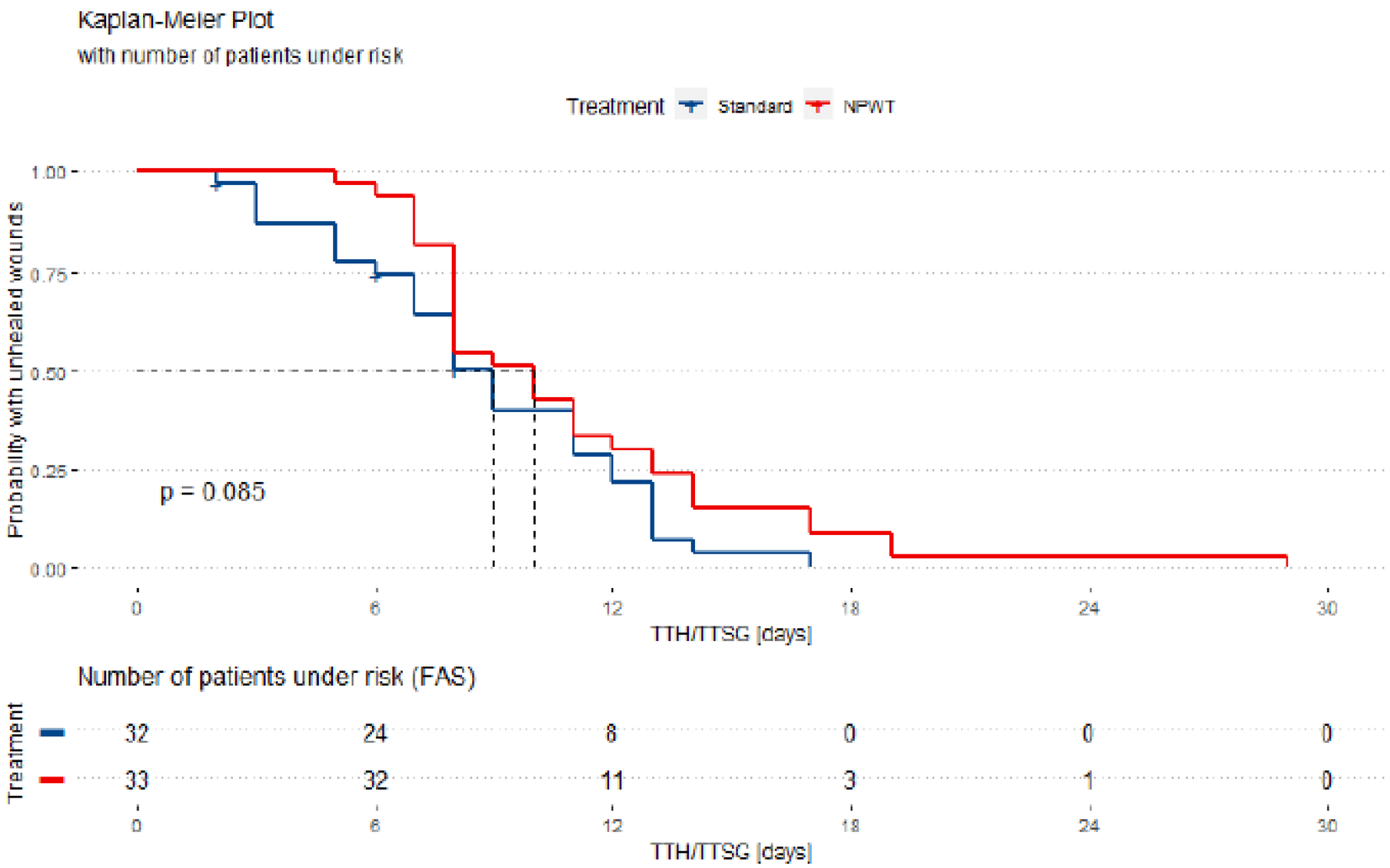
DESIGN and METHODS

- Patients with IIa-b degree burns of at least one extremity and a total body surface area (TBSA) of burn of 0.5 to 10% were included in this study.
- Upon debridement under sterile conditions, patients were randomly assigned to NPWT (wound dressing consisted of diaphanous drainage film that was placed directly on the wound and a bag-like film that was gloved over the extremity, pressure level was 80mmHg) or SoC (polyhexanide gel, fatty gauze and cotton wool) and received therapy until wound healed or skin grafting was possible (phase 1).
- In case surgery was necessary, a tangential necrosectomy followed by split-thickness skin graft was performed. After skin grafting all remaining patients were treated by NPWT until wound healing (phase 2).
- Time to achieved healing (defined as complete re-epithelialization of the wound when no surgery was necessary), or a time till the decision about surgery was evaluated by experienced clinicians.
- Subjective levels of pain were assessed by the patients using a visual analogue scale (VAS, 0=no pain, 10=strongest imaginable pain) at inclusion and every dressing change.
- At the end of the study, upper and lower extremity function were evaluated using the Disabilities of Arm, Shoulder and Hand Score (DASH) and the Lower Extremity Functional Score (LEFS), respectively, and scar assessment was performed using the Patient and Observer Scar Assessment Scale (POSAS).
- Quality of life was evaluated using the Short Form (36) Health Survey (SF-36).
- Additionally, the number and duration of dressing changes was evaluated.

STUDY RESULTS – MAIN ENDPOINT

- 65 patients were included in this study (33 patients in the NPWT and 32 in the SOC group) = FAS
- Both groups were similar regarding age (39.8±13.7 vs. 44.8±16.2 years, p = 0.192), total burn size (3.1 ± 2.3 vs. 3.4 ± 2.8% TBSA, p = 0.721) and treated wound size (1.9 ± 1.2 vs. 1.5 ± 0.8 % TBSA, p = 0.138).
- The most frequent mechanisms of burn in the total cohort were scalds (n=22, 36.1%) and flame burns (n=15, 24.6%).



FAS=Full analysis set; TTH=time to healing; TTSG=time to skin grafting

The median time to healing or skin grafting was 10 (8-11) days for NPWT and 9 (7-11) days for Standard therapy.

The Kaplan-Meier curve exhibited no statistically significant difference (p=0.085).

The primary endpoint was also assessed in the per protocol set (61 patients). There was non-significant difference regarding healing time (11.0±4.9 vs. 8.6±3.8, p=0.074, Wilcoxon rank-sum test).

Healing time in days was longest in the age group 51 – 70 years and the healing time was shorter in wounds with burn degree IIa with a median of 8 days in both treatment groups.

STUDY RESULTS – FURTHER ENDPOINTS

- Healing in phase 1 was achieved for 28 patients in NPWT group (84.8%) and 22 patients in SoC group (78.6%). Skin grafting was performed for all remaining patients (N=5 NPWT, N=7 SoC), all of them later achieved healing, healing time 7.8±2.6 days in NPWT vs 9.8±5.2 days in SoC group (p=0.058).
- Number of dressing changes was significantly lower in NPWT group (3.6±1.6 vs 5.7±2.6, p<0.001).
- Pain levels significantly decreased (p<0.001) in both groups (by 2.7±2.5 points in NPWT vs 2.3±3.2 in SoC group, p=0.549).
- Assessment of extremity function (DASH or LEFS), QoL (SF36) and scarring (POSAS) did not show significant differences between groups.
- No adverse events were reported during the study.

CONCLUSION

- The study showed that NPWT* treatment for local burns is safe. The healing time (time to decision for surgical treatment being necessary) was longer in wounds treated with NPWT compared to standard treatment in the first phase, and shorter in the second phase of the study (after surgical necrosectomy and split-thickness skin grafting), however, the difference was not statistically significant in both cases (p=0.074 and p=0.058).
- Fewer dressing changes were required in the NPWT group, and lower pain level was observed. This may be an advantage for the patients psychologically and for the caretakers economically and logistically, as it makes burn treatment feasible in an outpatient setting.
- The groups were not different in terms of frequency of surgery, quality of life or scarring.

*Used materials were Suprasorb® CNP Drainage Film (diaphanous drainage film), Suprasorb® CNP EasyDress (bag-like airtight film), and Suprasorb® CNP P3 Therapy Unit (NPWT pump).

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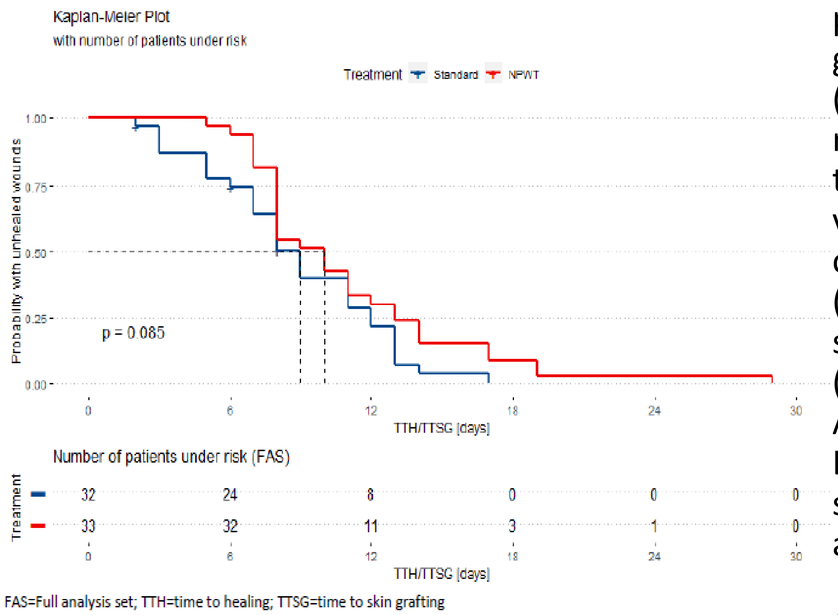
Aim: This study compared efficacy of negative pressure wound therapy (NPWT) and a local standard of care (SoC) in treatment of second-degree burns. The primary endpoint was time to achieved healing or skin grafting, secondary endpoints were rate of achieved healing and time to complete healing after skin graft.

Method: Patients were randomly assigned to NPWT* or SoC** and received therapy until wound healed or skin grafting was possible (phase 1). After skin grafting remaining patients were treated by NPWT until wound healing (phase 2).

Results / Discussion: 65 patients were included in this study (33 NPWT vs 32 SOC). Both groups were similar regarding age (39.8±13.7 vs 44.8±16.2 years, p=0.192), total burn size (3.1±2.3 vs 3.4±2.8% TBSA, p=0.721) and treated wound size (1.9±1.2 vs 1.5±0.8% TBSA, p=0.138). The most frequent mechanisms of burn in the total cohort were scalds (n=22, 36.1%) and flame burns (n=15, 24.6%).



FAS=Full analysis set; TTH=time to healing; TTSG=time to skin grafting

The median time to healing or skin grafting was 10 (8-11) days for NPWT and 9 (7-11) days for SoC, the difference was not statistically significant (p=0.085).

The primary endpoint was confirmed in the per protocol set (61 patients). Non-significant difference regarding healing time (11.0±4.9 vs. 8.6±3.8, p=0.074) was observed. Healing in phase 1 was achieved for 28 patients in NPWT group (84.8%) and 22 patients in SoC group (78.6%). Skin grafting was performed for all remaining patients (N=5 NPWT, N=7 SoC), all of them later achieved healing (7.8±2.6 days NPWT vs 9.8±5.2 SoC, p=0.058). Number of dressing changes was significantly lower in NPWT group (3.6±1.6 vs 5.7±2.6, p<0.001). Pain levels significantly decreased (p<0.001) in both groups (2.7±2.5 points NPWT vs 2.3±3.2 SoC, p=0.549). Assessment of extremity function (DASH or LEFS), QoL (SF36) and scarring (POSAS) did not show significant differences between groups. No adverse events were reported during the study.

Conclusion: The study showed that NPWT* treatment for local burns is safe. No statistically significant difference in the healing time was observed between groups. Fewer dressing changes, required by NPWT, may become a psychological advantage for the patients and economical / logistical advantage for the caretakers.

Research grant from Lohmann & Rauscher GmbH & Co. KG, Neuwied, Germany

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