RECELL®
Autologous Cell Harvesting Device

TREATMENT OF A 5% BSA MIXED-DEPTH BURN WITH RECELL®

CASE STUDY

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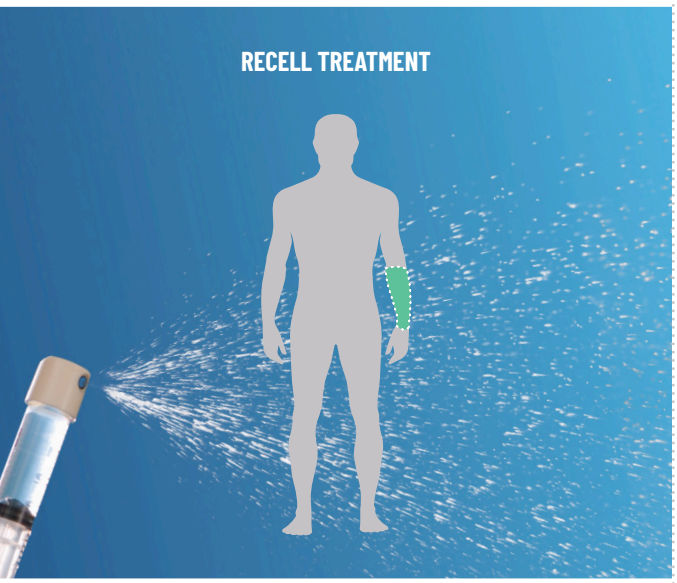
PATIENT PRESENTATION

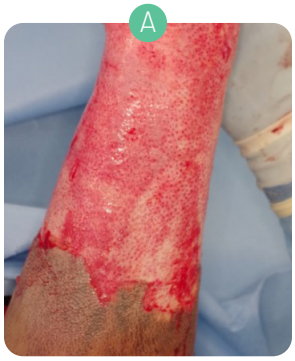
An 85-year-old female presented with a 9% total burn surface area (TBSA) mixed-depth flame burn injury to the lower left arm. This case report focuses on the treatment outcomes achieved using Spray-On Skin™ Cells in combination with a 2:1 meshed split-thickness skin graft (STSG). This case report focuses on a treatment area with the RECELL System which represents an approximately 2-3% body surface area (BSA).



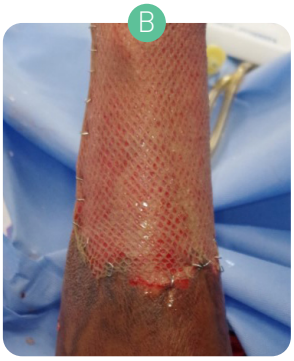
CONCLUSION

This case study of an elderly patient demonstrates successful treatment of a small, mixed-depth burn using RECELL with a meshed autograft. Use of RECELL resulted in definitive closure within 2 weeks using a small amount of donor skin. Re-pigmentation of the treatment site was evident at week 24 (Figure D). The Patient and Observer Scar Assessment Scale score (POSAS) ranked the pigmentation of the RECELL-treated area as having the same pigmentation as "normal skin."

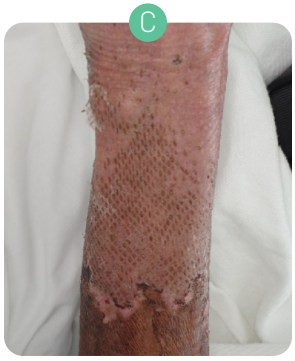
Excision A



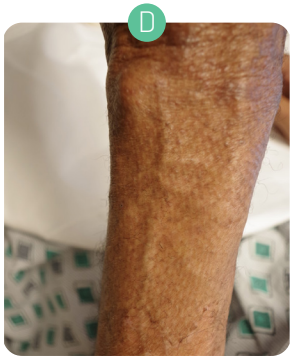
Treatment Day B



2 Weeks Post-treatment C



24 Weeks Post-treatment D



TREATMENT REGIMEN

The mixed-depth wound was excised (Figure A). The RECELL System was used to prepare Spray-On Skin Cells which were applied over a 2:1 meshed STSG (Figure B). The wound was dressed with Telfa™ Clear, followed by Xeroform™ and bulky dressings.

CLINICAL OUTCOME

By week 1 post-treatment (not pictured), the RECELL-treated area was ≥ 95% healed according to the attending physician. By week 2 post-treatment (Figure C) the wound was completely re-epithelialized. At Week 24 (Figure D), the RECELL-treated area was assessed using the Patient and Observer Scar Assessment Scale (POSAS). The observer scored the pigmentation of the RECELL-treated area as a "1," indicating the area treated with Spray-On Skin Cells had the same pigmentation as "normal skin."

For Important Safety Information, refer to back page.

RECELL®

Autologous Cell Harvesting Device

INSIDE BURN PATIENTS' SKIN CELLS ARE REGENERATIVE FORCES AT THE READY.

GIVE THEM THE SIGNAL TO MOVE.

Visit RECELLsystem.com to learn more.

IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE: The RECELL® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL® device is used by an appropriately licensed healthcare professional at the patient's point of care to prepare autologous RES® Regenerative Epidermal Suspension for direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds.

CONTRAINDICATIONS: RECELL® is contraindicated for the treatment of wounds clinically diagnosed as infected or with necrotic tissue present in the wound bed. RECELL® is contraindicated for the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate solution (Hartmann's Solution). The skin sample collection procedure specified for use of RECELL® should not be used with patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.

WARNINGS: Autologous use only. Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension. RECELL® is provided sterile and is intended for single use. Do not use RECELL® or device components if packaging is damaged, there are signs of tampering or date of use is beyond the stated expiration date. Choose a skin sample donor site that shows no evidence of surrounding cellulitis or infection. The skin sample should be processed immediately after harvesting. If a skin sample is harvested and processed according to these instructions, it should require between 15 and 30 minutes of contact with the Enzyme. Contact in excess of 60 minutes is not recommended. RECELL® Enzyme is animal derived and freedom from infectious agents cannot be guaranteed.

PRECAUTIONS: RECELL® is not intended to be used alone (i.e., without meshed autograft) for treatment of full-thickness burn wounds. The safety and effectiveness of RECELL® used alone (i.e., without meshed autograft) have not been established for treatment of partial-thickness burn wounds: on the hands and articulated joints, >320 cm2, in patients with wounds totaling >20% Total Body Surface Area (TBSA). The safety and effectiveness of RECELL® plus autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulated joints, in patients with wounds totaling >50% Total Body Surface Area (TBSA).

SPECIAL PATIENT POPULATIONS: The safety and effectiveness of RECELL® have not been established for treatment of acute thermal partial-thickness or full-thickness burn wounds in pediatric patients younger than 18 years of age.

For complete Important Safety Information, refer to Instructions for Use at RECELLSystem.com.

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