RECELL®
Autologous Cell Harvesting Device

DEFINITIVE CLOSURE WITH EXCELLENT OUTCOME ACHIEVED IN A FULL-THICKNESS BURN USING RECELL® SYSTEM TREATMENT IN COMBINATION WITH DERMAL SUBSTITUTE AND MESHED AUTOGRAFT

CASE STUDY

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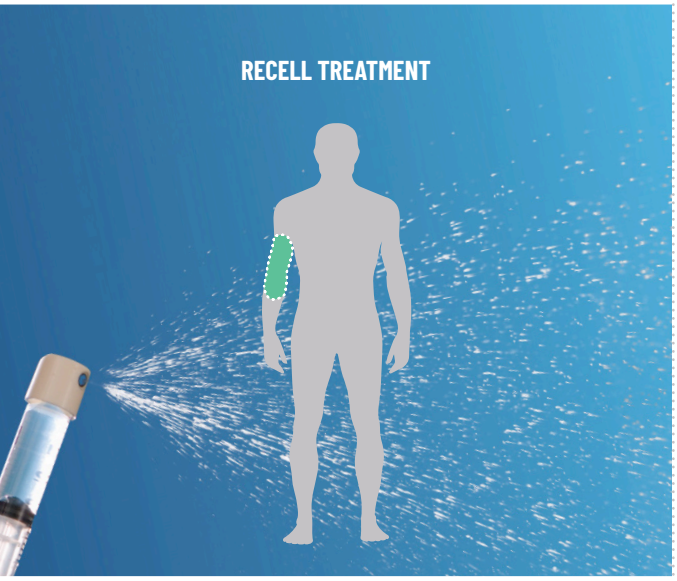
PATIENT PRESENTATION

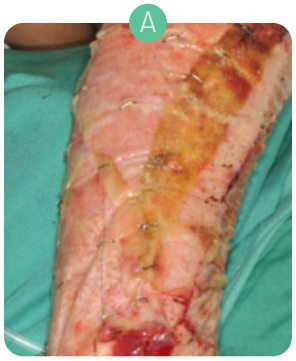
A female sustained deep-partial and full-thickness burn injuries as the result of a car explosion. Areas of injury included the face, neck, bilateral upper extremities, and bilateral lower extremities. This case study focuses on RECELL treatment of the full-thickness injury to the upper right arm using Spray-On Skin™ Cells in combination with a 3:1 meshed split-thickness skin graft (STSG).



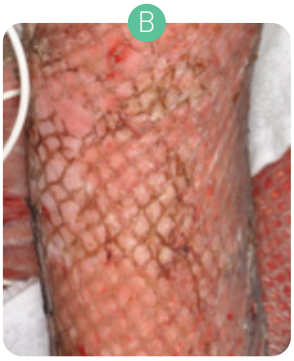
CONCLUSION

This case study demonstrates successful treatment of a full-thickness burn using RECELL in conjunction with a dermal matrix and widely meshed autograft.
This use of RECELL over highly meshed autografts reduces donor skin requirements to achieve epidermal regeneration and definitive wound closure.

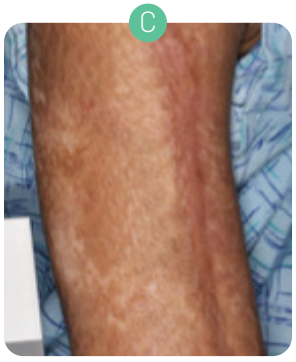
Pre-autografting



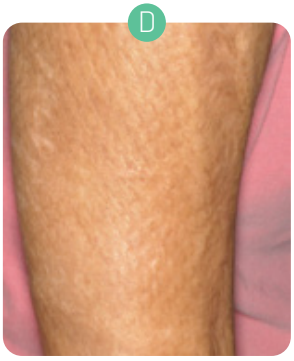
1 Week Post-treatment



3 Months Post-treatment



12 Months Post-treatment



TREATMENT REGIMEN

The patient was treated as part of a compassionate use prospective evaluation. Approximately 4 days after injury, the burn was excised using the Versajet™ System and Integra® Dermal Regenerative Template was applied. Thirteen days following Integra placement (Figure A), a 3:1 meshed STSG was applied to the forearm, and Spray-On Skin™ Cells prepared using the RECELL System were applied over the meshed graft. The treatment areas were covered with Telfa™ Clear, Xeroform™, and outer bulky dressings.

CLINICAL OUTCOME

On Day 7 post-RECELL treatment, the wound was 75% re-epithelialized (Figure B), with full re-epithelialization achieved by 1 month. Over 3 months (Figure C), color in terms of vascularity began to match the surrounding area with pigmentation and texture only being mildly mismatched. Further improvement to the skin quality was seen and results at 1 year demonstrate excellent color, texture, and pigmentation (Figure D). No long-term durability issues were reported.

For Important Safety Information, refer to back page.

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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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