RECELL®
Autologous Cell Harvesting Device

REDUCED MORBIDITY OF DONOR SITES HARVESTED FOR RECELL® SYSTEM COMPARED TO DONOR SITES HARVESTED FOR CONVENTIONAL AUTOGRAFTS

CASE STUDY

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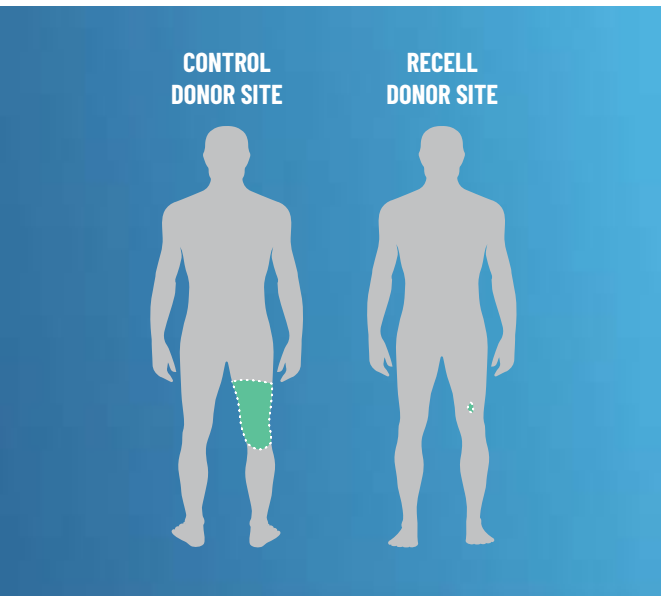
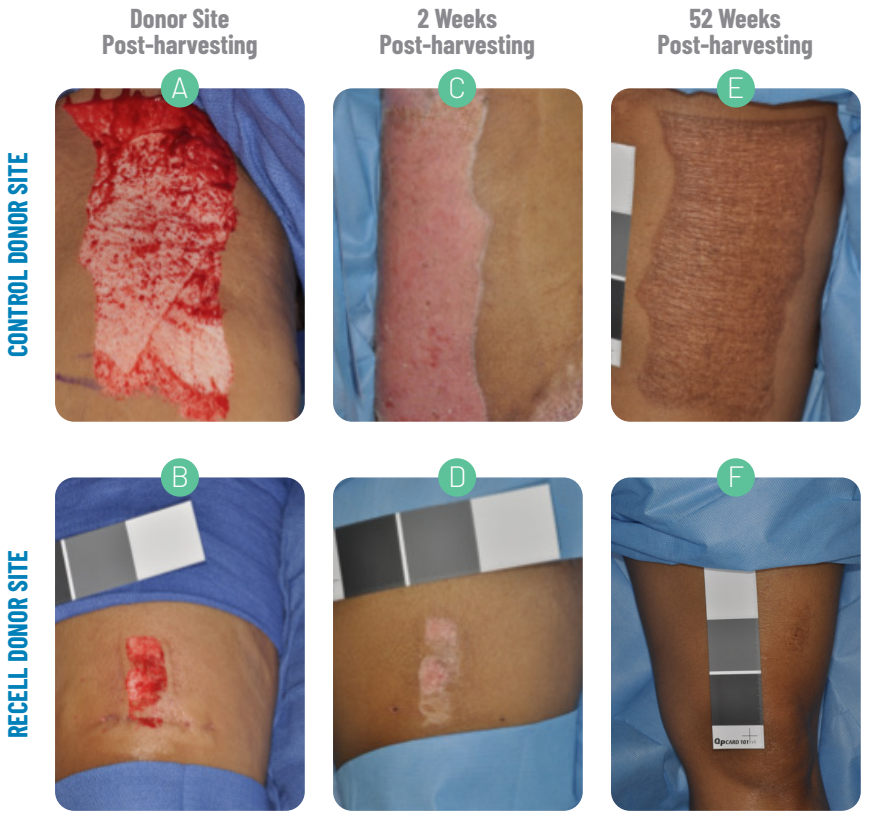
PATIENT PRESENTATION

A 51-year-old female presented with a deep partial-thickness steam burn injury. This case study focuses on healing outcomes of the donor site wounds taken for treatment with RECELL compared to meshed split-thickness skin graft.



CONCLUSION

This case study demonstrates healing outcomes of a donor site taken for RECELL treatment compared to a donor site for 2:1 meshed STSG treatment. Comparatively, less pain during the acute time frame was reported at the RECELL donor site as well as improved appearance, scar height, and vascularity at 1 year.



TREATMENT REGIMEN

This patient was treated as part of a prospective, randomized controlled trial. The burn wound was divided into two comparable sections which were randomized to receive 2:1 meshed split-thickness skin graft (STSG) or treatment with RECELL. A 0.014" deep, 147 cm^2 donor site was harvested from the left posterior thigh for 2:1 meshed autografting (Figure A) and a 0.008" deep, 4 cm^2 donor site from the left anterior thigh (Figure B) was taken to prepare Spray-On Skin™ Cells with the RECELL System. Both donor sites were dressed with Telfa™ Clear followed by Xeroform™ and bulky dressings for exudate and to provide protection to the regenerating epidermis.

CLINICAL OUTCOME

Both donor sites taken for STSG (control) and RECELL were fully healed at 2 weeks (Figures C and D). At this time, the STSG donor site was rated 84 for pain whereas the RECELL donor site was rated as a 1 (No Pain). At 52 weeks, using a visual appearance scale with a range of "Terrible" = 1 to "Exceptional" = 100, the subject rated the STSG donor site scars (Figure E) at a 46 and the RECELL donor sites at 100 or Exceptional (Figure F). The donor site used for STSG had < 2 mm scar height, pink vascularity, and normal pliability (Figure E), whereas the scar assessment for the RECELL donor site had normal vascularity and normal pliability (Figure F).

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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