

CASE STUDY

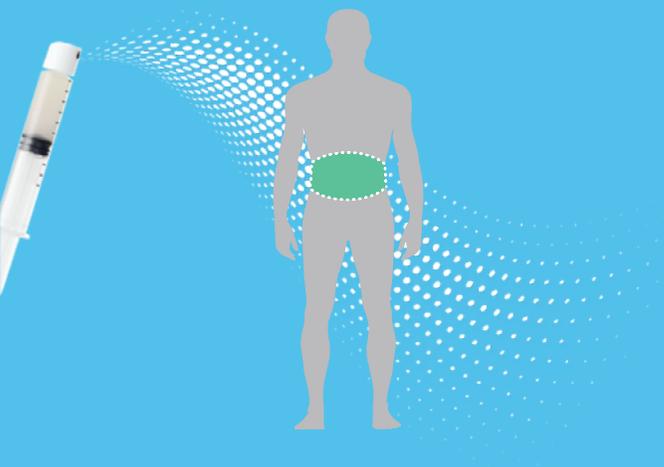
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PATIENT PRESENTATION

A 45-year-old, male, sustained a 189 cm² degloving injury caused by a seat belt during a motor vehicle collision. This case focuses on wound closure of the full-thickness injury to his abdomen.

Novosorb[®] Biodegradable Temporizing Matrix (BTM) followed by the combination of meshed split-thickness skin graft (mSTSG) and RECELL Spray-On Skin[™] Cells were applied.

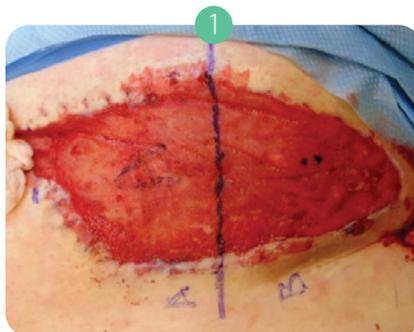
RECELL TREATMENT AREA



CONCLUSION

This case demonstrates Spray-On Skin Cells, used in combination with a 2:1 mSTSG, can be used to successfully treat a full-thickness degloving injury with comparable outcomes to a 1:1 mSTSG and less donor skin.

Grafting Day



2 Weeks Post-grafting



4 Weeks Post-grafting



52 Weeks Post-grafting



TREATMENT REGIMEN

This patient was treated as part of a prospective, randomized, controlled clinical trial. Eight weeks post injury the patient had BTM placed on the wound, then after 5 weeks the BTM was delaminated, and the wound bed was prepared with tangential excision and hydro-surgical debridement (Figure 1). The study areas were randomized. Site A (control site) received a 1:1 mSTSG alone. Site B (treatment area) received a 2:1 mSTSG with Spray-On Skin Cells prepared using the RECELL System. Both areas were covered with Telfa Clear, Xeroform and VAC dressings.

CLINICAL OUTCOME

At 2 weeks post grafting 70% of the control area A had healed and 50% of the RECELL treatment area B had healed (Figure 2). At 4 weeks post grafting, both control area A and the RECELL treatment area B were both 100% healed (Figure 3). At 52 weeks post grafting, both areas had comparable longer term outcomes (Figure 4). The use of RECELL Spray-On Skin Cells in combination with a 2:1 mSTSG reduced donor site requirements in the treatment of this degloving injury by 35% compared to the control area.



Visit RECELLsystem.com to learn more.

IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE: The RECELL Autologous Cell Harvesting Device is indicated for the treatment of thermal burn wounds and full-thickness skin defects. The RECELL Device is used by an appropriately licensed and trained healthcare professional at the patient's point of care to prepare autologous Spray-On Skin Cells for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older, or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients and full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer) in patients 15 years of age and older.

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 (Hartmann's) solution, patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.

WARNINGS: Autologous use only. Control infections on wounds prior to application of the cell suspension. Excise the necrotic tissues on wound bed prior to application of the cell suspension. 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 if packaging is damaged or expired. Choose a donor site with no evidence of cellulitis or infection and process skin immediately. A skin sample

should require between 15 and 30 minutes contact with 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 for use without meshed autograft for treatment of acute full-thickness burn wounds or full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer). The safety and effectiveness of RECELL without meshed autograft have not been established for treatment of partial-thickness burn wounds: on the hands and articulating joints $>320\text{cm}^2$, in patients with wounds totaling $>20\%$ total body surface area (TBSA). The safety and effectiveness of RECELL with autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulating joints, and in patients younger than 28 days of age (neonates). The safety and effectiveness of RECELL plus autografting have not been established for application in combination with meshed autografting on full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer): on the hands and genitalia.

SPECIAL PATIENT POPULATIONS: The safety and effectiveness of RECELL have not been established for treatment of acute thermal partial-thickness burn wounds in pediatric patients younger than 18 years of age. For complete Important Safety Information, refer to Instructions for Use.

INSTRUCTIONS FOR USE: Consult the Instructions for Use prior to using RECELL. The Instructions for Use can be located at www.RECELLsystem.com.