AVITA MEDICAL

Healing in Every Drop.

Expedite the healing process with early point-of-care treatment using RECELL®[1]

Please see **Important Safety Information** on page 16.

RECELL®

Autografting: Essential, Yet with Limitations

Morbidities of donor site wounds[2]:

- Pain
- Itching
- Discomfort
- Risk of delaying healing
- Risk of infection
- Risk of scarring/discoloration

A REDUCTION IN THE AMOUNT OF DONOR SKIN HARVESTED CAN BENEFIT PATIENT POPULATIONS

Those at risk for healing complications[2-4]:

- Chronic co-morbidities (diabetes, cardiovascular disease, autoimmune disease, obesity, etc.)
- Substance abuse (smoking, drinking, illicit drug use)
- On certain medications (chemotheraphy, steroids, radiation, etc.)
- Elderly

Those with limited donor site availability[2,5]:

- Large surface area wounds
- Wounds covering common donor harvest areas (legs, back)
- Pediatrics

Those with specific donor site morbidity concerns impacting quality of life[2,6]:

- Cosmesis
- Pain
- Itching
- Discomfort

When it's time to graft, it's time to consider RECELL Spray-On Skin™ Cells

TESTIMONIAL

"The use of RECELL allows me to use less donor skin, allows rapid healing of the interstices of the meshed graft and spares my patients from associated complications related to delayed wound closure."

– Aesthetic and Reconstructive Surgeon

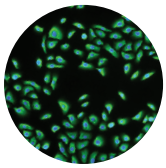
Expedite the Healing Process With Early Treatment at a Cellular Level

ACTIVE HEALING ACROSS THE ENTIRE WOUND BED

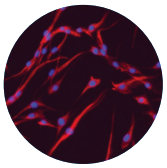
RECELL uses a small piece of the patient's skin to create a multi-phenotype suspension of Spray-On Skin Cells.[7] The application of different cell types stimulates healing and repigmentation throughout the wound bed.[8,9]

THE POWER OF MULTI-PHENOTYPE SPRAY-ON SKIN CELLS

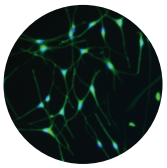
Autologous therapy at point-of-care allows for delivery of the patient's own living cells:



Keratinocytes regenerate the epidermis[10,11]



Dermal **fibroblasts** deposit new extracellular matrix proteins[10]



Melanocytes produce melanin to allow restoration of natural pigmentation[11]

RECELL TECHNOLOGY ALLOWS FOR A BROAD AND EVEN DISTRIBUTION OF SUSPENSION ACROSS THE ENTIRE WOUND BED[7,9]

RECELL Spray-On Skin Cells signal repair from within the wound[7,9,12]

Cell suspension isolated using the RECELL System contains keratinocytes, fibroblasts, and melanocytes which is delivered directly to the wound bed

Activated keratinocytes begin repopulating the wound bed

Re-epithelialization continues and fibroblast deposition of new extracellular matrix proteins occurs

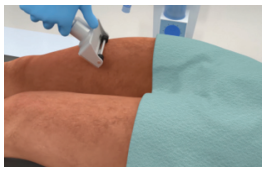
Near complete re-epithelialization with melanocyte activity

Completely healed wound

IMMEDIATE CELLULAR DELIVERY

Cost-effective point-of-care regenerative therapy in a single procedure[1,3]

Obtain

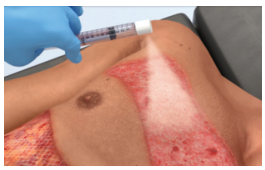


Harvest skin sample[1]
1 cm^2 donor skin treats up to 80 cm^2

Prepare

Isolate cells[1]
Non-cultured, patient-derived cells

Deliver



RECELL treatment[1]
Promotes epidermal regeneration

RECELL offers up to 80x expansion

Treating More With Less

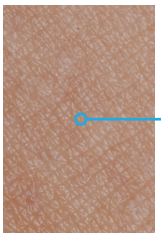
RECELL IS DESIGNED FOR DONOR SPARING, TAKING UP TO 97.5% LESS DONOR SKIN COMPARED TO CONVENTIONAL AUTOGRAFTING.[1]

97.5% average less donor skin for DPT burns[14]

32.0% average less donor skin for full-thickness burns when used in combination with autograft[15]

27.0% average less donor skin for full-thickness skin defects when used in combination with autograft[16]

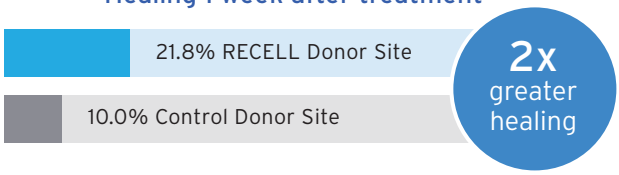
A 6 cm^2 donor site



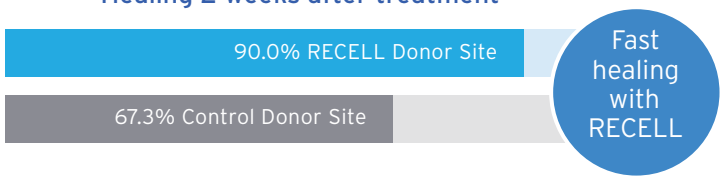
can treat an area up to **80x** its size–480 cm^2 (approximately the size of this page)

EARLIER DONOR SITE HEALING VS STANDARD OF CARE DONOR SITE[14]

Healing 1 week after treatment

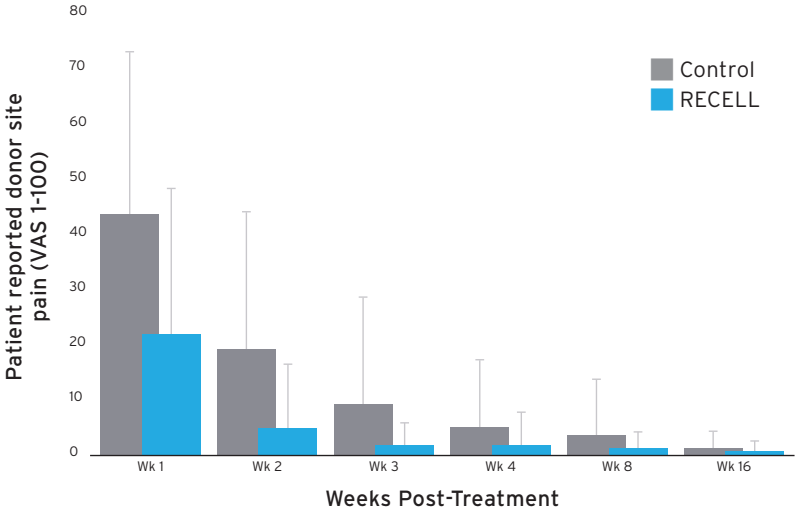


Healing 2 weeks after treatment

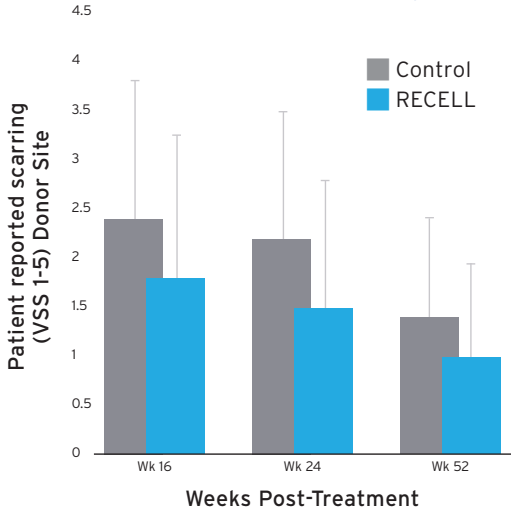


SIGNIFICANTLY REDUCED PAIN AND SCARRING AT THE DONOR SITE WITH RECELL VS CONVENTIONAL AUTOGRAFTING FOR ALL TIME POINTS[14]

Donor Site Pain



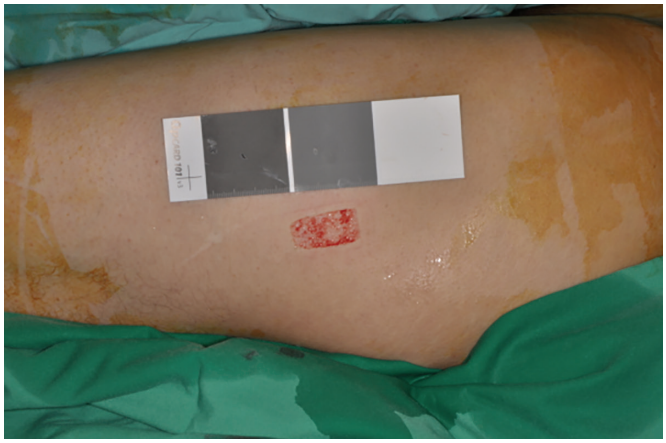
Donor Site Scarring



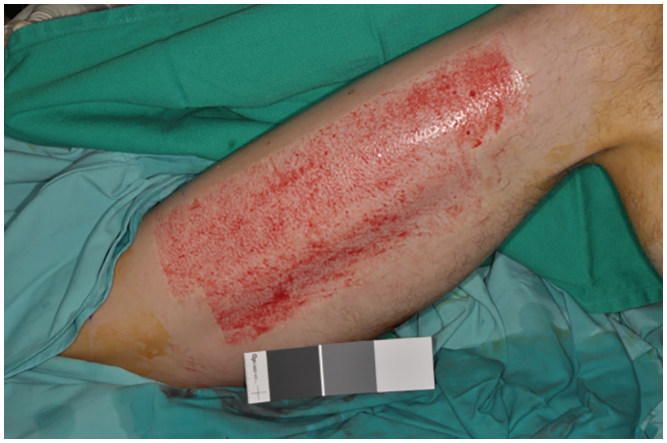
Superior Donor Site Outcomes, With Less Pain and Scarring vs Conventional Autografting

REDUCE DONOR SKIN REQUIREMENTS WITH RECELL[1]

Donor Site for Treatment of a DPT Wound With RECELL Alone



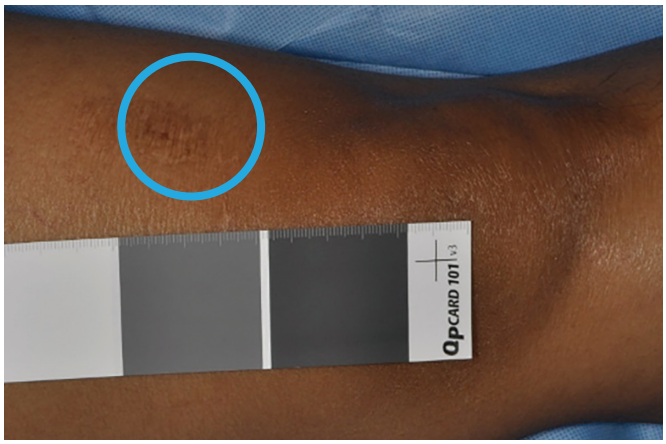
Typical Donor Site for Treatment of a DPT Burn Wound With Conventional Autografting



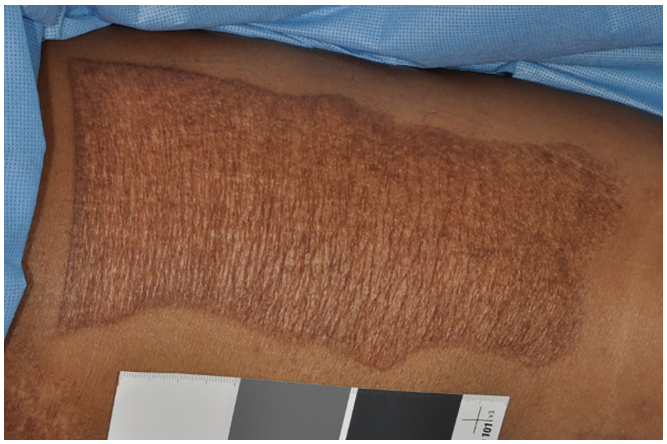
Photos courtesy of Joseph Molnar, MD, PhD and James Holmes IV, MD, FACS
Wake Forest Baptist Medical Center, Winston-Salem, NC.

MINIMIZE SCARRING AT THE DONOR SITE WITH RECELL[5]

Donor Site Harvested for RECELL Alone to Treat DPT Burn 52 Weeks Post-Harvest



Donor Site Harvested for 2:1 Autograft to Treat DPT Burn 52 Weeks Post-Harvest



Photos courtesy of Michael Feldman, MD, FACS
Virginia Commonwealth University, Richmond, VA.

Less Invasive Wound Closure

HEALING IN NONTHERMAL FULL-THICKNESS SKIN DEFECTS[16]

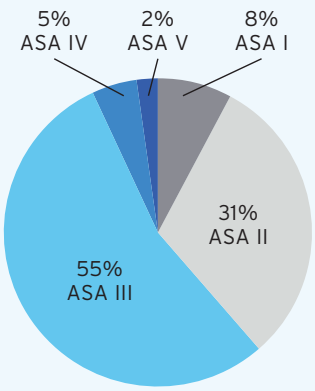
RECELL provides definitive wound closure with less donor skin for various types of patients, including those with multiple risk factors for impaired wound healing.

In a pivotal, randomized, within-subject controlled trial, conventional autografting was compared to RECELL with more widely meshed autograft.

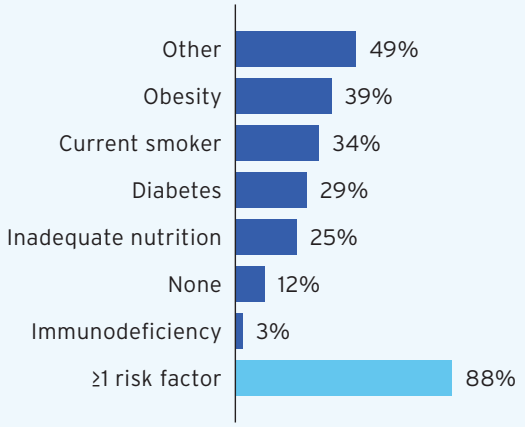
RECELL resulted in non-inferior healing outcomes with a significant reduction in donor skin requirements, saving an average of 27% less skin.

PATIENT CHARACTERISTICS

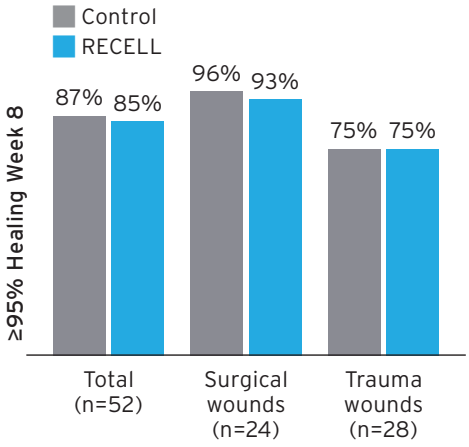
American Society of Anesthesiologists (ASA) Physical Classification Score



Risk factors for impaired healing



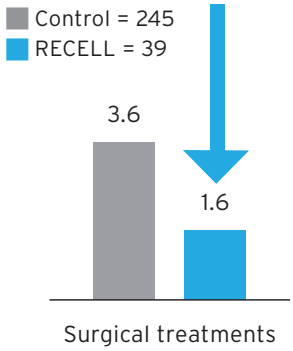
HEALING OUTCOMES



FEWER AUTOGRAFTING PROCEDURES REQUIRED FOR DEFINITIVE CLOSURE VS CONVENTIONAL AUTOGRAFT OF FULL-THICKNESS BURN WOUNDS[1,13,17]

Pediatric patients

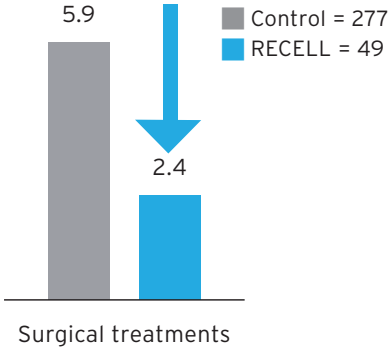
56% fewer mean autografting procedures with RECELL[1]



Consider the impact of **fewer procedures and consequently, fewer dressing changes** on the patient experience

Adults with >50% TBSA

60% fewer mean autografting procedures with RECELL[1]



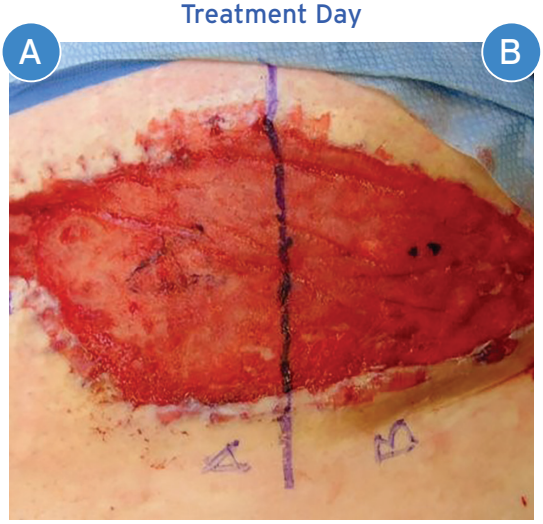
95% re-epithelialization achieved in the majority of adult and pediatric full-thickness burn injuries by week 8[1]

A 189 cm^2 Degloving Injury

SUCCESSFUL TREATMENT WITH COMPARABLE OUTCOMES USING LESS DONOR SKIN

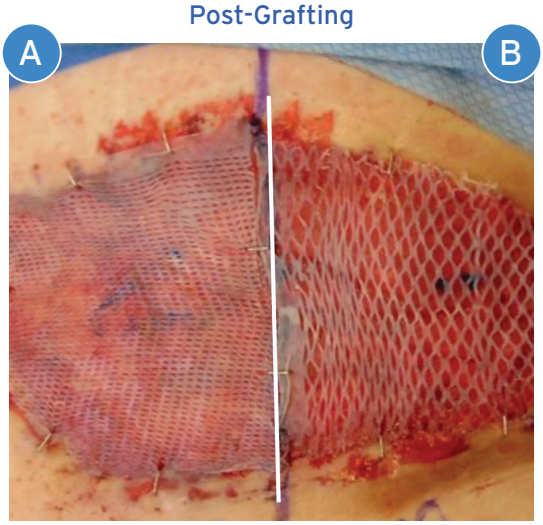
- 45 year-old male
- Degloving to abdomen
- Dermal Substitute
- RECELL+ 2:1 meshed STSG

Treatment Day



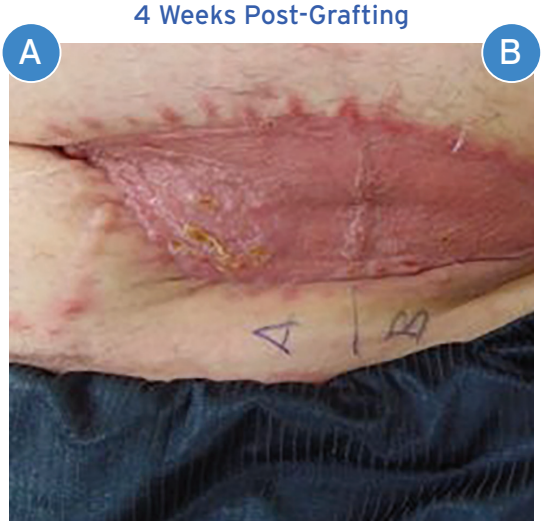
A = 1:1 STSG B = 2:1 STSG + RECELL

Post-Grafting



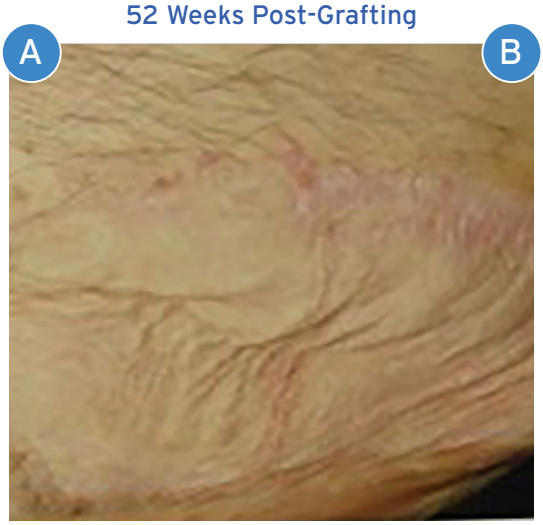
A = 1:1 STSG B = 2:1 STSG + RECELL

4 Weeks Post-Grafting



A = 1:1 STSG B = 2:1 STSG + RECELL

52 Weeks Post-Grafting



A = 1:1 STSG B = 2:1 STSG + RECELL

Case report courtesy of Neil Mashruwala, MD , FACS (Carle Foundation Hospital, Urbana, IL)

RECELL Achieved: **A 35% reduction in donor skin requirements in the treatment of a small degloving injury, compared to conventional autografting, with comparable long-term aesthetic outcomes.**

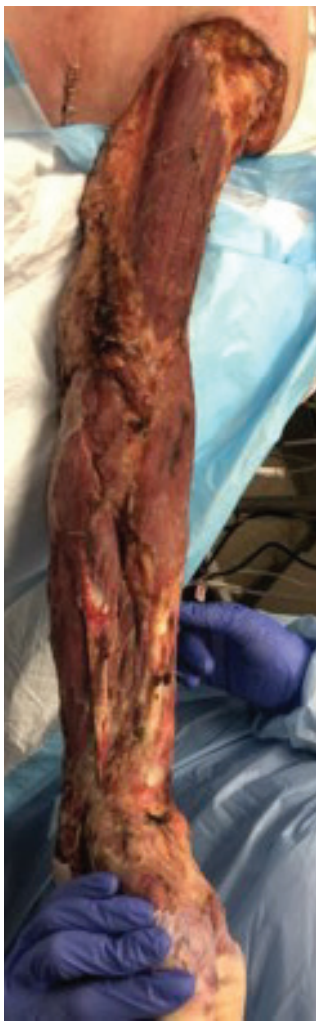
Wound Caused by Necrotizing Fasciitis

PATIENT WAS 94% HEALED 14 DAYS POST-RECELL TREATMENT

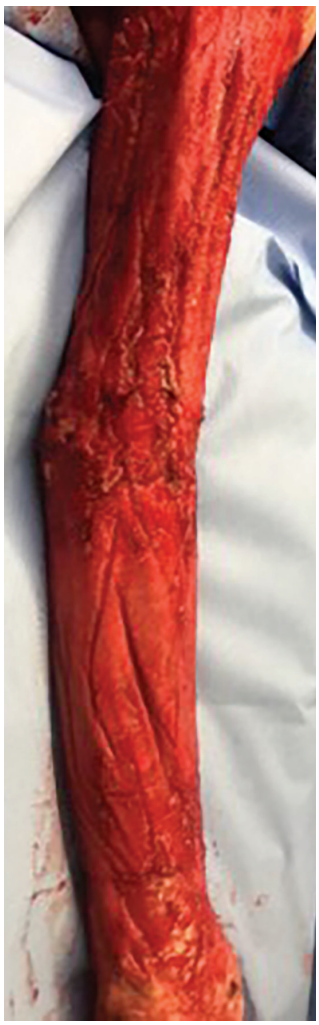
Patient presented with worsening pain in left arm due to necrotizing fasciitis infection. Excision of the infection required skin grafting.

- 67-year-old male
- Necrotizing fasciities–upper left arm
- Dermal substitute
- RECELL+ meshed 3:1 STSG

Post-Excision

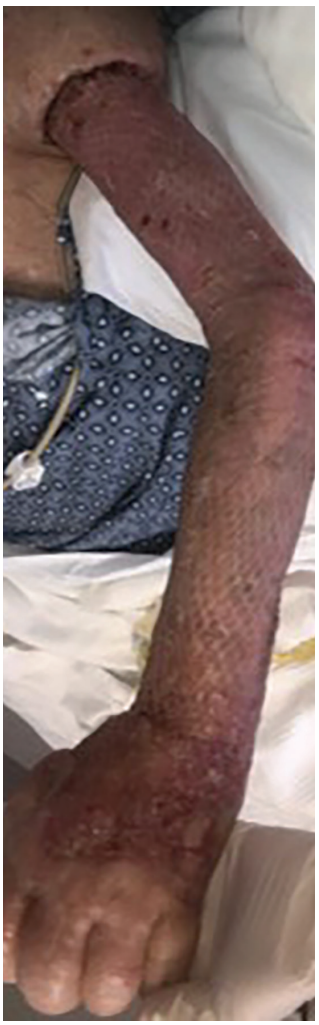


Prior to Grafting



Application of Meshed STSG and RECELL

14 Days Post-Treatment



Case report courtesy of Joe Olivi, MD, FACTS, Trauma and Burns Surgeon

RECELL Achieved: **Post-op day 14 patient was 94% healed and the hyperpigmentation was starting to fade. At one month post-op patient exhibited good range of motion with improving function of the arm. The results were described as excellent by the treating physician.**

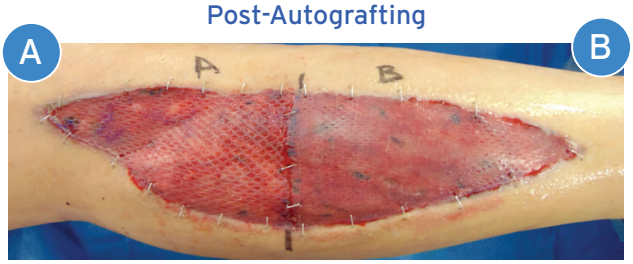
Full-Thickness Fasciotomy

RECELL USE IN PATIENT WITH A SURGICAL WOUND IN LOWER EXTREMITY

- 55-year-old male
- RECELL + 2:1 meshed STSG
- Negative pressure wound therapy

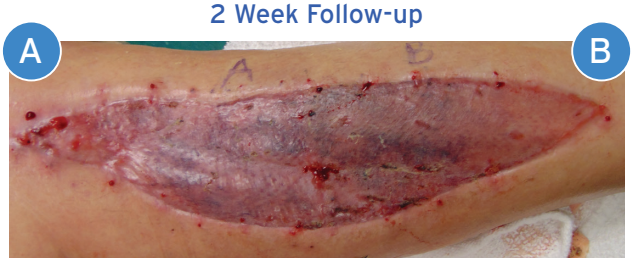
Post-Wound Bed Prep

Post-Autografting



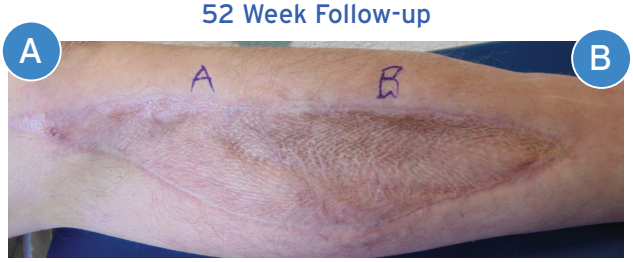
A = 2:1 mSTSG + RECELL B = 1:1 mSTSG

2 Week Follow-up



A = 2:1 mSTSG + RECELL B = 1:1 mSTSG

52 Week Follow-up



A = 2:1 mSTSG + RECELL B = 1:1 mSTSG

Photos courtesy of Derek Bell, MD (University of Rochester Medical Center, Rochester, NY)

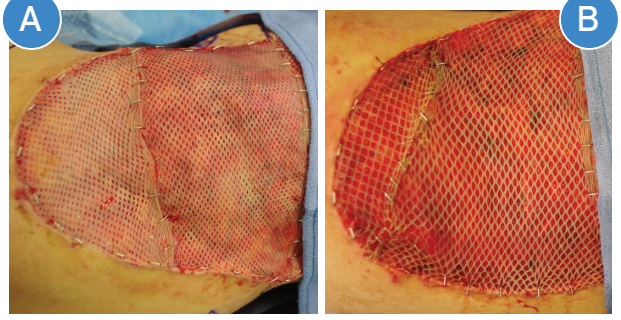
RECELL Achieved: **Wound closure by week 2 without compromise to aesthetic outcomes.**

Full-Thickness Crush Injury

EFFECTIVE TREATMENT OF A CRUSH INJURY USING RECELL + MORE WIDELY MESHED AUTOGRAFT

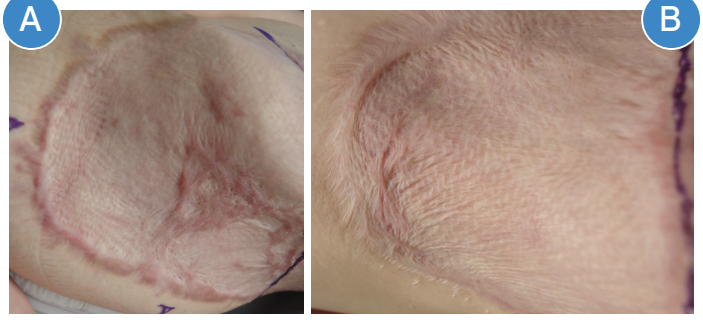
- 16-year-old female
- RECELL + 2:1 meshed STSG

Post-Autografting



A = 1:1 mSTSG B = 2:1 mSTSG + RECELL

52 Week Follow-up



A = 1:1 mSTSG B = 2:1 mSTSG + RECELL

Photos courtesy of Herbert Phelan, MD (University Medical Center New Orleans)

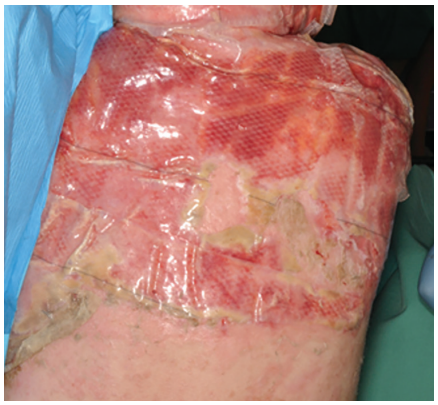
RECELL Achieved: **Wound closure with 26% donor skin reduction.**

Pediatric Full-Thickness Burns

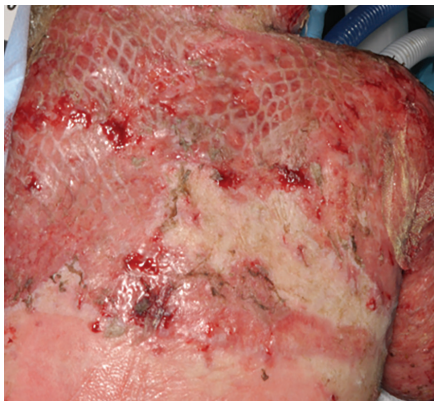
POSITIVE LONG-TERM OUTCOMES IN PEDIATRIC PATIENT

- 15-month-old female
- 58% TBSA, FT Posterior torso
- Dermal substitute
- RECELL + 3:1 meshed STSG

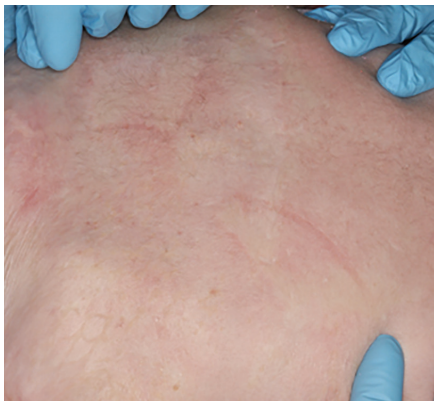
Treatment Day – Prior to Wound Bed Preparation



7 Days Post-RECELL >90% Re-Epithelialized



12 Months Post-RECELL



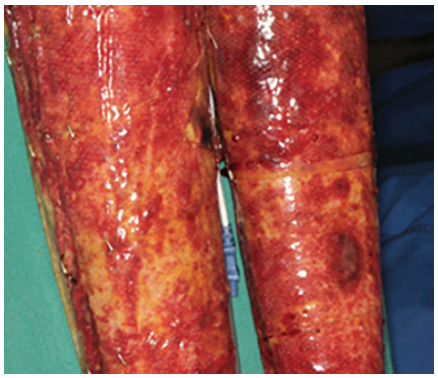
Case report courtesy of Jeffrey Carter (MD, University Medical Center, New Orleans, LA); Joseph Molnar, MD, PhD and James Holmes IV, MD, FACS (Wake Forest Baptist Medical Center, Winston-Salem, NC)

RECELL Achieved: **>95% wound closure within 28 days and positive long-term outcomes**

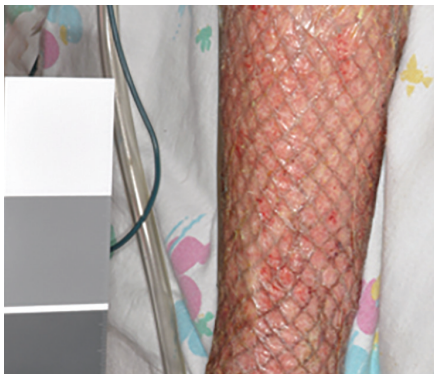
POSITIVE LONG-TERM OUTCOMES IN A LARGE BURN

- 12-year-old female
- 62% TBSA, FT Bilateral legs
- Dermal substitute
- RECELL + 4:1 meshed STSG

Treatment Day – Prior to Wound Bed Preparation



7 Days Post-RECELL 75% Re-Epithelialized



12 Months Post-RECELL

Case report courtesy of Jeffrey Carter, MD (University Medical Center, New Orleans, LA); Joseph Molnar, MD, PhD and James Holmes IV, MD, FACS (Wake Forest Baptist Medical Center, Winston-Salem, NC)

Length of stay: 28 days

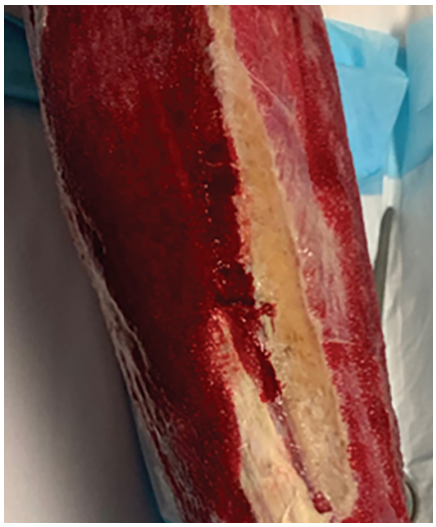
RECELL Achieved: **Complete definitive wound closure of a 62% TBSA burn within 28 days and positive long-term outcomes.**

Adult Full-Thickness Burns

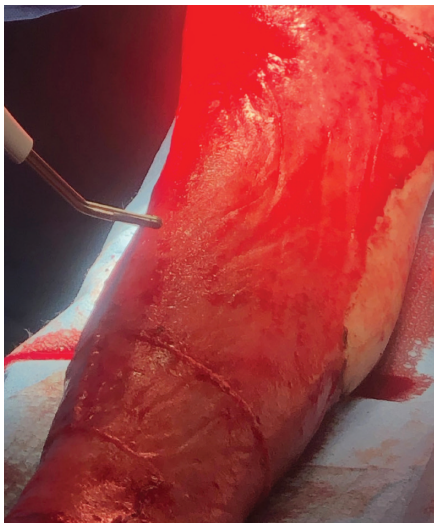
RECELL USE IN AN ELDERLY PATIENT WITH EXPOSED TIBIA AND TENDON

- 73-year-old male
- ~20% BSA, FT, Leg
- Dermal substitute
- RECELL + 3:1 meshed STSG

Excision Prior to Dermal Substitute Application



Wound Bed Preparation Prior to Grafting and RECELL Application



12 Months Post-RECELL

Effective in challenging cases

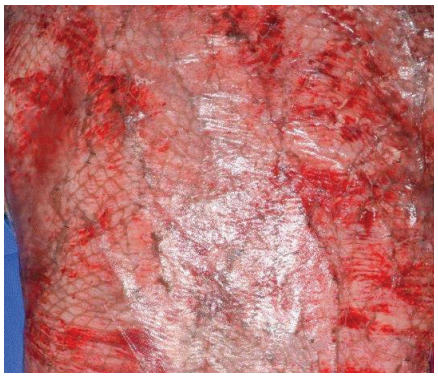
Case report courtesy of Joe Olivi, MD (Northwest Arkansas Medical Center; Bentonville, AK)

RECELL Achieved: **Wound closure in a challenging case with bone and tendon exposed.**

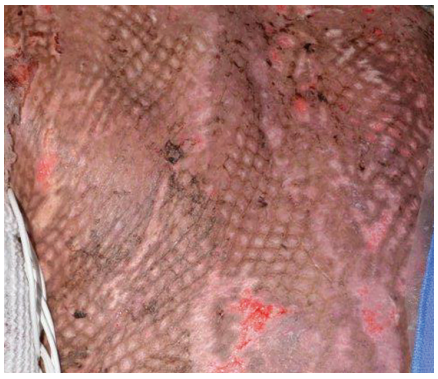
CONSIDER RECELL ON CHALLENGING AREAS FOR FAST HEALING

- 29-year-old male
- 18% BSA, FT, Back
- RECELL + 4:1 meshed STSG

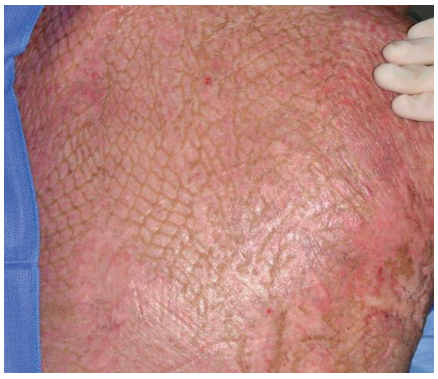
Treatment Day



7 Days Post-RECELL



2 Months Post-RECELL



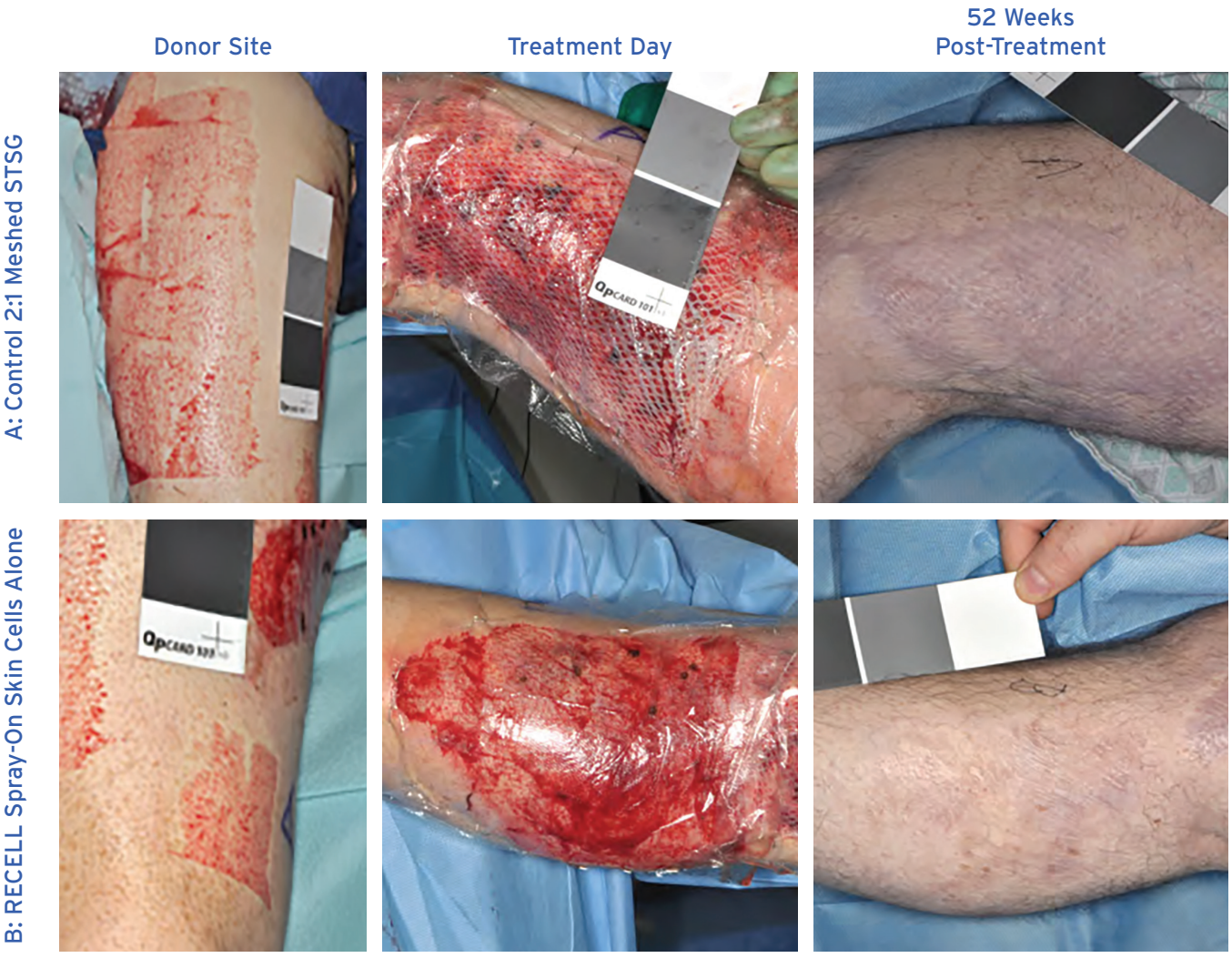
Case report courtesy of Booker King, MD (US Army Institute of Surgical Research Burn Center, San Antonio, TX)

RECELL Achieved: **Matched surrounding vascularity and pigment at 2 months with mildly mismatched texture to surrounding skin. >95% re-epithelialization achieved at week 4.**

Deep Partial-Thickness Burn

PATIENT RANKED THEIR RECELL TREATMENT SITE SUPERIOR AT 52-WEEKS WITH A 97% REDUCTION OF DONOR SKIN REQUIRED COMPARED TO CONVENTIONAL AUTOGRAFTING

- 43-year-old female
- Partial-thickness burn to bilateral legs
- A: 2:1 Meshed STSG / B: RECELL alone



Case report courtesy of Kevin Foster, MD, MBA, FACS (Arizona Burn Center - Valleywise Health)

At 1-week, on a pain scale of 0 - 100 with 100 being most severe, the subject scored the RECELL donor site as a 14 vs STSG donor site pain score at 33.

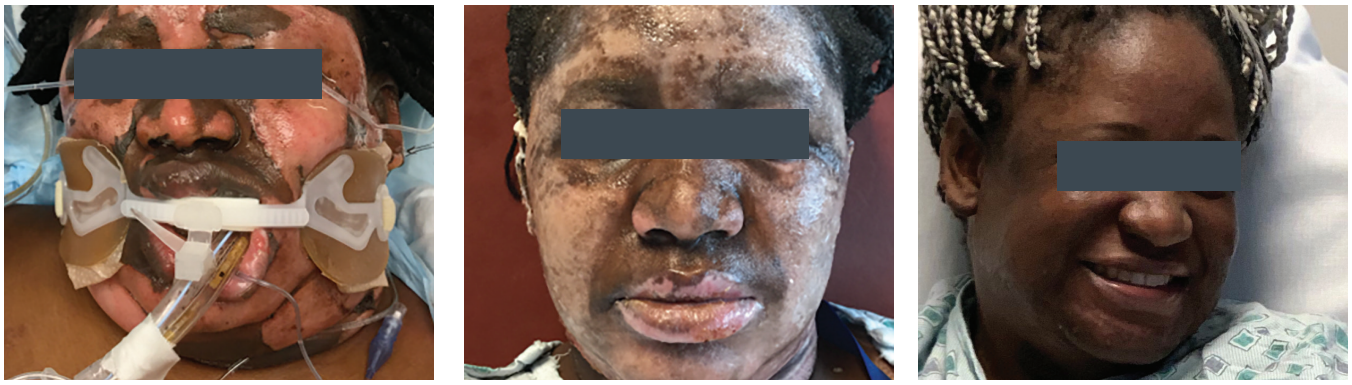
RECELL Achieved: **Effective treatment of deep partial-thickness burn with reduced donor skin, less donor site pain, and superior treatment site appearance.**

Repigmentation With Deep-Partial Thickness Burns

PIGMENTATION CLOSELY MATCHED SURROUNDING SKIN

- 31-year-old female
- 11% TBSA, DPT, Face
- Allograft trialed and failed prior
- RECELL alone

Treatment Day | 9 Days | 12 Months



Case report courtesy of Jeffrey Carter, MD (University Medical Center; New Orleans, LA)

RECELL Achieved: **Repigmentation with transfer of the patient's own melanocytes.**

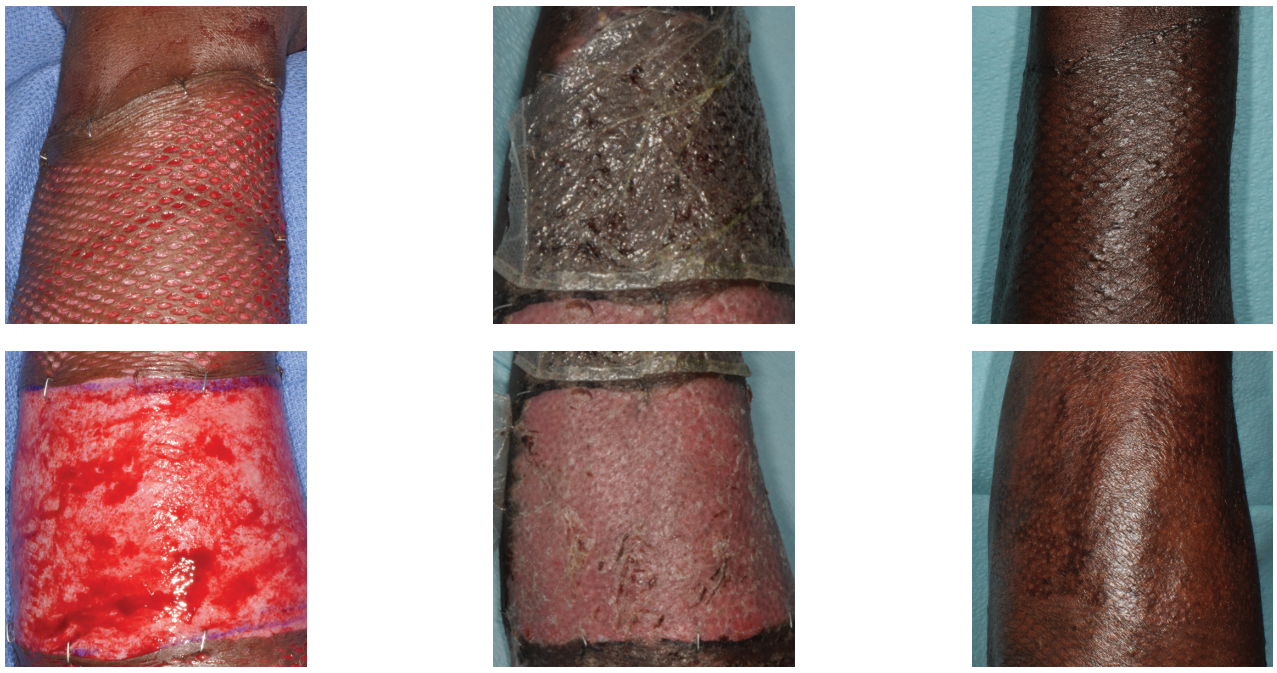
SMALL DONOR SITE REQUIREMENT WITH IMPROVED PIGMENTATION AND SCAR HEIGHT ACCORDING TO THE VANCOUVER SCAR SCALE

- 48-year-old male
- 2% TBSA, DPT, Forearm
- RECELL alone vs Control with 2:1 meshed STSG

Treatment Day | 2 Weeks Post-Treatment | 16 Weeks Post-Treatment

Control 2:1 Meshed STSG

RECELL

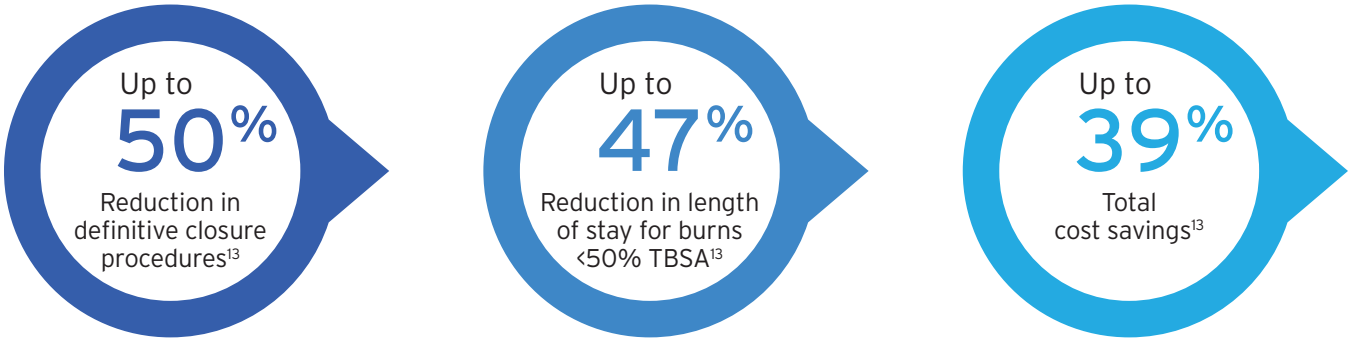


Case report courtesy of David Smith, MD (University of South Florida, Tampa, FL)

RECELL Achieved: **Reduced donor skin requirements compared to autografting, and an excellent cosmetic result with no meshed pattern observed.**

Clinical Benefits of RECELL Can Lead to Cost Savings[13]

REDUCED DONOR SKIN REQUIREMENTS CAN RESULT IN FEWER SURGICAL PROCEDURES FOR DEFINITIVE CLOSURE, DECREASED LENGTH OF STAY, AND REDUCED RESOURCE USE, TRANSLATING TO POTENTIAL COST SAVINGS.[13,17,18,19]



Results may vary for individual institutions.

RECELL Use Translates to Reduced Costs

A burn center perspective cost effectiveness model of the acute burn care pathway known as Burn Effectiveness Cost-Outcomes Nexus (BEACON) utilized data from real-world use, clinical trials and physician surveys to estimate cost-effectiveness (single patient) and burn center budget impact (population of patients) from a hospital perspective on RECELL vs Standard of Care (SOC) for definitive closure of severe burns. Below is a sample cost-savings scenario.[13]

200
Acute Thermal Burn Patients

94
RECELL Eligible Patients

Patient Distribution	Key Costs
• 40 Full-thickness/Mixed • 54 Deep partial-thickness • 106 Superficial-thickness	• $7,500 RECELL (per device) • $6,795 Burn bed cost (per day) • $3,720 OR cost (per hour)

Projected Overall RECELL Savings

$5,132,413 (19.8%) Net Savings (after RECELL costs)

7X Savings for every dollar spent on RECELL

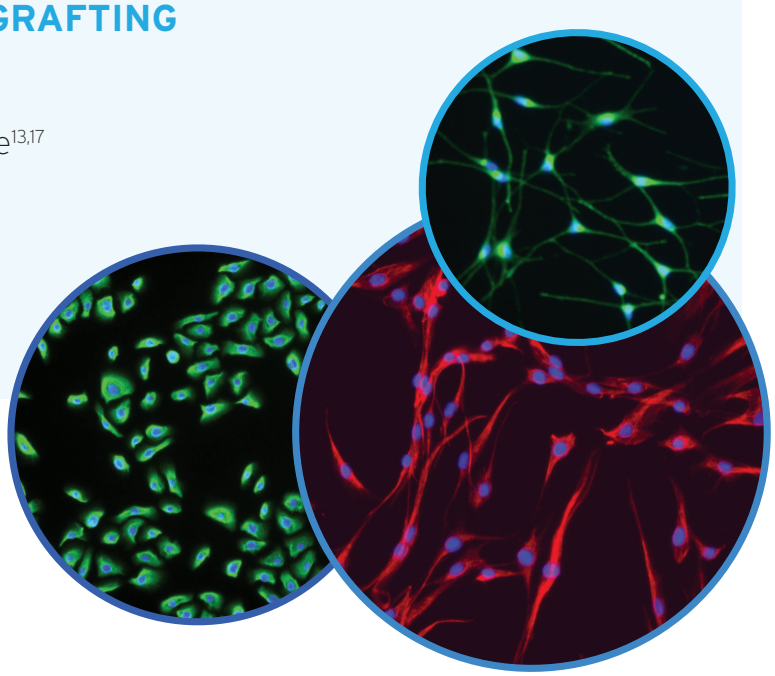
$54,600	$1.00: $7.28
Average Savings per RECELL Patient	RECELL Costs: Net Savings (Estimated savings per $1 spent on RECELL)

Cost savings with RECELL have been validated and peer-reviewed[13]

RECELL Provides Benefits Beyond Closure® Versus Traditional Skin Grafting

RECELL PROVIDES BENEFITS BEYOND CLOSURE® VERSUS TRADITIONAL SKIN GRAFTING

- Significantly less donor skin needed[1]
- Fewer procedures for definitive closure[13,17]
- Reduction in length of stay for burns <50% TBSA[13,18,19]
- Reduced scarring and pain at the RECELL harvested donor site[14]



RECELL is Backed by Robust Clinical Evidence

PUBLISHED

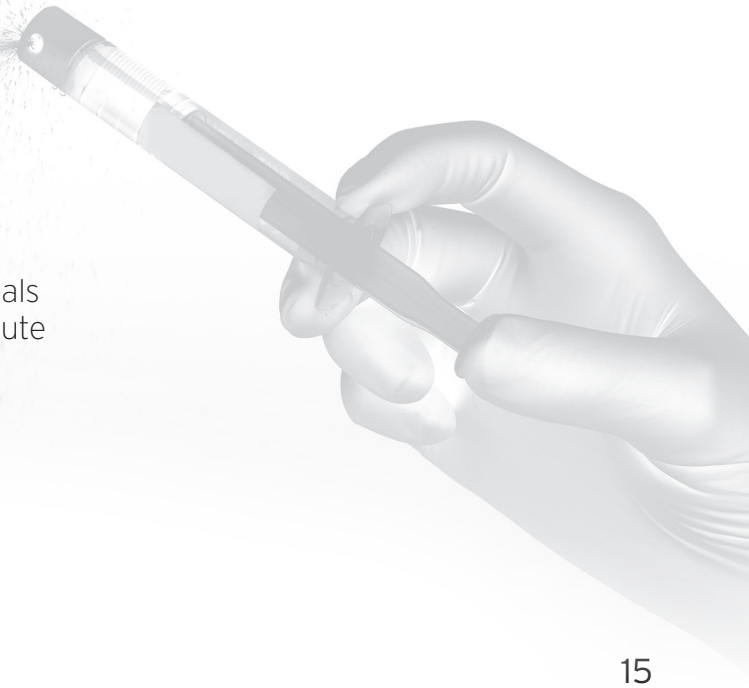
Over 70 publications[20]

PATIENTS

Thousands of patients treated

CLINICAL TRIALS

Three multi-center, randomized, controlled clinical trials in the United States of over 195 total patients with acute burn wounds or full-thickness skin defects[1]



IMPORTANT SAFETY INFORMATION

INTENDED USE/INDICATIONS:

RECELL is intended to be used to disaggregate cells from a patient's split-thickness skin sample and to collect these cells for reintroduction to the patient. The cells can be used for autologous application to the prepared wound bed as determined by the physician such as for the treatment of burns, or other acute wounds.

CONTRAINDICATIONS:

The device is contraindicated for the treatment of: patients with wounds clinically infected or with necrotic tissue present in the wound bed, patients with a known hypersensitivity to trypsin or compound sodium lactate solution, and patients with a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.

WARNINGS:

Autologous use only. The Regenerative Epithelial Suspension produced with RECELL should only be applied to the patient from whom the original skin sample was taken. RECELL is provided to the healthcare professional sterile and is intended for single use. Do not reuse, freeze or re-sterilize device components. Do not use RECELL or device components if packaging is damaged or there are signs of tampering. Do not use RECELL or device components if the date of use is beyond the stated expiration date on the packaging. RECELL components should be handled using aseptic technique. If a skin sample is harvested and processed according to these instructions, it should only require between 15 and 30 minutes of contact with the Enzyme. Contact in excess of 60 minutes is not recommended. Contaminated materials and waste must be disposed of using appropriate biohazard waste receptacles. The separation Enzyme is derived from animal tissue and, although strict controls have been implemented in the manufacturing process to minimize the risk of pathogen contamination, a small risk of contamination exists and absolute freedom from infectious agents cannot be guaranteed. The RECELL processing unit is internally powered by four non-replaceable AA batteries. The device should not be used in the presence of flammable materials and must not be incinerated on disposal.

PRECAUTIONS

Protective eyewear and other protective clothing should be worn. For optimum cell viability, the skin sample should be processed immediately after harvesting. The RECELL family of devices are for single use only. Do not reuse, freeze or re-sterilize any items within the device. Do not use the device if there is evidence of container tampering or damage.

REFERENCES: 1. Instructions for Use. RECELL® Autologous Cell Harvesting Device. **2.** Asuku M et al. *Burns*. 2021;47(7):1525-1546. **3.** Beyene RT et al. *Surg Clin North Am*. 2020;100(4):695-705. **4.** Guo S et al. *J Dent Res*. 2010;89(3):219- 229. **5.** Mathias E et al. *Medicines (Basel)*. 2017;4(4):91. Published 2017 Dec 11. **6.** Rotatori RM et al. *Burns*. 2019;45(5):1066-1074. **7.** Wood et al. *Burns*. 2012;38 (1):44-51. **8.** Navarro et al. *J Burn Care Rehabil*. 2001;22:41-6. **9.** Navarro et al. *J Burn Care Rehabil*. 2000;21:513-8. **10.** Freedberg I et al. *J Invest Dermatol* 116:633-640, 2001. **11.** Hirobe T. *Dermatol Sin*. 2014;32(4):200-204. **12.** Trim JT, Quick A. *J of Wound Technology*. 2015; 27:20-24. **13.** Kowal et al. *Adv Ther*. 2019;36(7):1715-1729. **14.** Holmes JH et al. *J Burn Care Res*. 2018;39(5):694-702. **15.** Holmes et al. *Burns*. 2019;45(4):772-782. **16.** Henry et al. *J Trauma and Acute Care Surgery*. 96(1):p 85-93, January 2024. **17.** Foster K et al. Presented at the American Burn Association 2018 Annual Meeting, April 2018. **18.** Carter et al. *Adv Ther*. 2022;39(11):5191-5202. **19.** Carson et al. *Burns*. 2023;S0305-4179(22)00299-6. **20.** Data on File.

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