RECELL®
Autologous Cell Harvesting Device

Cost-Effectiveness of the Use of Autologous Cell Harvesting Device (ACHD) Compared to Standard of Care (SOC) for Treatment of Severe Burns in the United States

This study demonstrates that autologous skin cell suspension (RECELL) reduces costs associated with the current treatment of severe burns.

Health Economic Model Demonstrated:

- RECELL use generates $26,600-$34,100 in projected savings per patient compared to SOC
- Burn centers using RECELL save 14% to 17% annually on costs
- RECELL is cost-saving or cost-neutral for FT/mixed depth and DPT burns of 10%, 20%, 30%, 40% and greater TBSA and reduces length of stay vs SOC

Kowal S, Kruger E, Bilir P, Holmes JH, Hickerson W, Foster K, Nystrom S, Sparks J, Iyer N, Bush K, Quick A. Cost-effectiveness of the use of autologous cell harvesting device compared to standard of care for treatment of severe burns in the United States. *Adv Ther.* 2019. doi:10.1007/s12325-019-00961-2.

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STUDY OVERVIEW

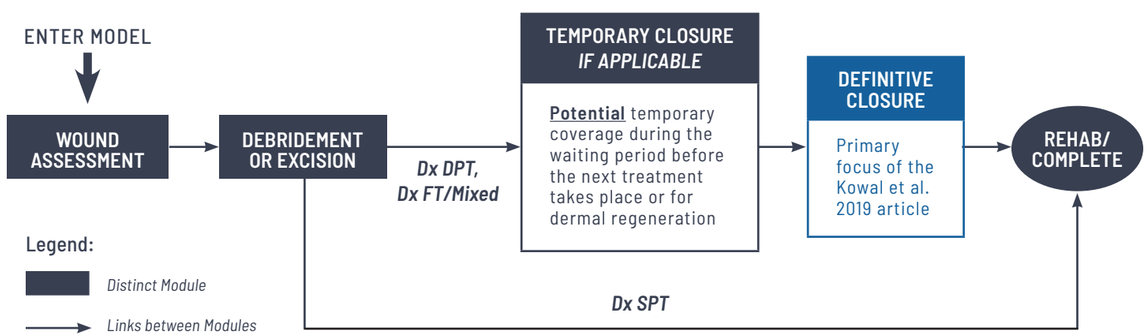
This study evaluated RECELL impact on length of stay (LOS), number and duration of definitive closure procedures, inpatient resource use and estimated burn center cost impact for severe burn treatment.

The study utilized the BEACON health economic (HE) model of the acute burn care pathway with 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 ACHD/ASCS (RECELL System) vs Standard of Care (SOC) in the Definitive Closure Phase of care for severe burns.

This study was sponsored by Biological Advanced Research and Development Authority (BARDA).

Advances in Therapy is an international, peer-reviewed journal dedicated to the publication of high-quality clinical (all phases), observational, real-world, and health outcomes research around the discovery, development, and use of therapeutics and interventions (including devices) across all therapeutic areas. Peer review included health economists to validate the model and study findings.

BURN CARE TREATMENT PATHWAY



Acronyms: Dx: diagnose; DPT: deep partial-thickness; FT: full-thickness; SPT: superficial partial-thickness

Important Safety Information

For direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds.

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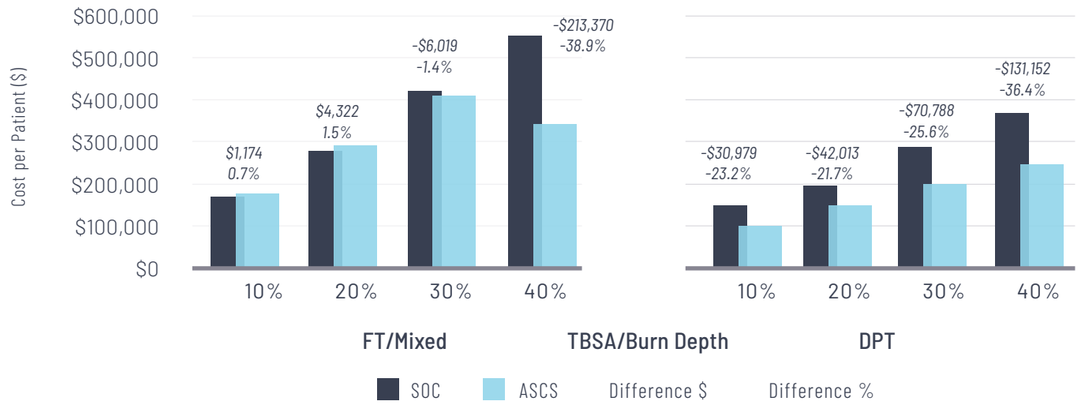
RESULTS

COST-EFFECTIVENESS RESULTS BY DEPTH AND TBSA



BUDGET IMPACT MODEL RESULTS (FOR TYPICAL 200 PATIENT BURN CENTER)

Costs by category	Conservative approximation scenario			NBR-based national average scenario		
	SOC	RECELL	Difference $ (%)	SOC	RECELL	Difference $ (%)
Wound assessment	$481,550	$481,550	$0 (0%)	$482,821	$482,821	$0 (0%)
Debridement/excision	$2,141,040	$2,141,040	$0 (0%)	$2,142,983	$2,142,983	$0 (0%)
Definitive closure	$4,496,118	$3,895,555	-$600,562 (-13.4%)	$6,047,354	$3,936,108	-$2,111,246 (-34.9%)
Rehabilitation	$995,604	$772,729	-$222,875 (-22.4%)	$996,079	$773,201	-$222,877 (-22.4%)
LOS	$29,153,546	$24,665,265	-$4,488,281 (-15.4%)	$29,220,479	$24,736,277	-$4,484,202 (-15.3%)
Other*	$547,355	$547,355	$0 (0%)	$547,213	$547,213	$0 (0%)
Total costs	$37,815,213	$32,503,495	-$5,311,718 (-14%)	$39,436,928	$32,618,602	-$6,818,326 (-17.3%)
Average cost per patient	$189,076	$162,517	-$26,559 (-14%)	$197,185	$163,093	-$34,092 (-17.3%)

**Other includes costs for anesthesia and escharotomy.*
Note: Results may differ in phases outside of definitive closure because of randomization in the Monte Carlo simulation

SUMMARY

REDUCES TREATMENT COSTS

- Saves burn center 14%-17.3% annually
- Reduces LOS compared to SOC

COST SAVINGS

- Cost-effective across all burn sizes and depths
- Greater savings seen in larger FT/Mixed and DPT burns

KEY SAVINGS DRIVERS

- Reduced LOS
- Reduced number and length of procedures
- Reduced donor site size
- Lower donor site wound care and rehabilitation needs

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Please contact
your AVITA Medical representative or our customer service helpline at 833-GO-AVITA with any questions

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 Regenerative Epidermal Suspension (RES™) 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, 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. 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 full-thickness burn wounds. 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 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 articulated joints, in patients with wounds totaling >50% 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.

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