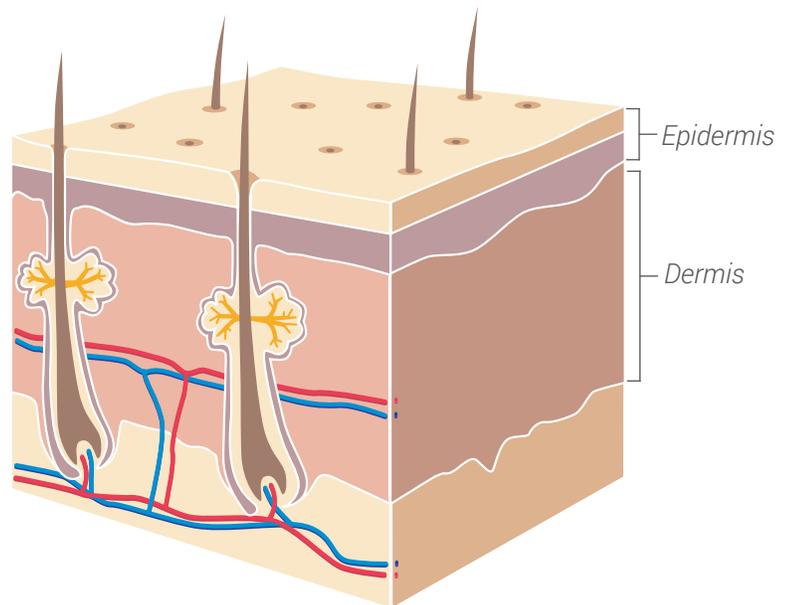


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A Noncultured
Autologous Skin
Cell Spray Graft
for the Treatment
of Burns



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Summary

- Burn injuries cause trauma and suffering, and can involve long hospital stays.
- The ReCell Autologous Cell Harvesting Device is a system that harvests, processes, and delivers an individual's own skin cells for the treatment of burns. As it does not require cell culturing in the laboratory, the procedure takes approximately 30 minutes.
- Depending on the type of burn injury, ReCell may be used alone or as an adjunct to skin grafting.
- Several randomized controlled trials have evaluated the use of ReCell for partial-thickness burns, as an adjunct to skin grafting for more severe burns, and for the treatment of donor site wounds.
- No comprehensive studies evaluating cost considerations for ReCell were identified.

Background

Burns can be a major cause of morbidity, mortality, and health care costs. According to *The Cost of Injury in Canada*, in 2010, fires and burns were responsible for 234 deaths, 982 permanent partial disabilities, 50 permanent total disabilities, 2,099 hospitalizations, and 43,684 emergency room visits.¹ In 2010, the economic burden of fires and burns in Canada totalled \$366 million.¹ A recent Ontario study estimated that the average cost to treat a patient with burns from a residential fire was \$84,678.²

Burn injuries are categorized according to their location, size, and depth. Burns on the face, hands, feet, or perineum are of greater concern, as they are more likely to result in functional or cosmetic impairment.^{3,4} Also, burns that cross major joints (e.g., knee, shoulder, hip), that encircle a body part (such as the chest area), or that are very deep are more concerning, as they may compromise circulation and respiration.^{3,5}

The size of a burn is reported as a percentage of the patient's total body surface area (TBSA).⁴ There has been a lack of consensus regarding how best to classify the depth of a burn;⁶ however, descriptive terms tend to be used most frequently.⁶ As a result, this bulletin categorizes burn depths as follows:

- **Superficial burns** — involve only the top layer of skin and typically heal without surgical treatment in three to six days (e.g., a sunburn).³
- **Superficial partial-thickness burns** — involve the top two layers of the skin and typically heal without surgical treatment in seven to 21 days (e.g., a blistering sunburn).³
- **Deep partial-thickness burns** — involve the top two layers of the skin but extend more deeply than superficial partial-thickness burns.³ Deep partial-thickness burns typically take more than 21 days to heal³ and most require surgical treatment.^{7,9}
- **Full-thickness burns** — involve all layers of the skin and surgical treatment is always required.³

Please note that there are alternative classification systems for burns that may be in use.⁶

Burns may have varying depths (e.g., some areas of partial-thickness burn and some areas of full-thickness burn). The classification of a burn may also change over time (for instance, a superficial partial-thickness burn may deepen and ultimately require surgical treatment).^{3,10,11}

Common causes of burns include hot water, steam, or contact with other hot liquids or hot objects; burns from flames; chemical burns; electrical burns; and sunburns.³

Risk factors that may influence burn severity and negatively affect healing include age (young children and the elderly because of thinner skin) and conditions that reduce peripheral blood flow or immune function (e.g., individuals with diabetes, peripheral vascular disease, or those receiving immunosuppressive therapy).⁴

Long-term consequences of burns may include the need for multiple reconstructive surgeries, decreased mobility and function of the burned area, chronic pain, prominent scars, the psychosocial impacts of scarring and altered appearance, possible post-traumatic stress disorder, and the challenges of re-entry into society.^{4,12}

While skin grafting is currently the gold standard for burns requiring surgical treatment, limitations to this approach include a potential lack of donor skin availability (depending upon the size of the burn), the possible need for multiple reconstructive surgeries (to re-harvest the same donor sites after allowing them to heal), and potentially less-than-ideal functional and cosmetic outcomes.^{13,14} The ReCell Autologous Cell Harvesting Device (Avita Medical, Valencia, California) is a new treatment option that aims to address some of these limitations.

The Technology

The ReCell Autologous Cell Harvesting Device is a cell harvesting, processing, and delivery system.^{11,15} It is noncultured, meaning that it avoids the long laboratory time — typically a number of weeks — required to culture skin autografts, which are skin grafts grown from an individual's own skin cells.¹⁶ It is also autologous, meaning that it uses the patient's own cells and thus avoids triggering an immune reaction or risking an immune rejection.¹⁵

ReCell can either be used independently to treat partial-thickness burns, or in combination with skin grafting and/or a dermal regenerative template to treat deep dermal or full-thickness burns.^{8,17} The procedure takes approximately 30 minutes and is performed by a burn surgeon trained in how to use ReCell; it does not require specialized laboratory staff.^{11,15}

When using ReCell, a small split-thickness biopsy including the epidermis and part of the dermis is obtained, up to 2 cm-by-2cm, and from 0.15 mm to 0.50 mm thick.^{8,11,15} The skin sample from the biopsy is then mixed with a proprietary enzyme solution containing trypsin that disaggregates, or separates, the cells from one another.^{7,11,15}

Once the cells are disaggregated in the processing unit, the skin sample is removed and scraped with a scalpel to create a “plume of cells,” which are added to a buffer solution.¹¹ Finally, the cells are aspirated and filtered to create a suspension called the Regenerative Epithelial Suspension.¹¹ The suspension is delivered to the burn site via a spray applicator, or it can be dripped directly onto the area of the burn.¹¹ The suspension contains all subtypes of cells (keratinocytes, papillary dermal fibroblasts, Langerhans cells and melanocytes) to optimize healing and repigmentation.^{8,15}

The expansion ratio for ReCell is 1:80, meaning that a 2 cm-by-2 cm sample of the patient's skin can cover a burn surface area up to 320 cm².^{8,15} This greatly exceeds the expansion ratios of traditional meshing techniques for skin grafts, which is of particular importance for patients with extensive burns.¹⁵

ReCell is supplied as a sterile pack, together with all of the necessary equipment and components to treat up to 320 cm² of burned skin.¹¹ If the burn surface area to be treated with ReCell exceeds 320 cm², additional packs will be needed.

The proposed benefits of ReCell include the ability to cover a greater surface area of burned skin with decreased donor site requirements, faster healing of widely meshed skin grafts (with ReCell used adjunctively), improved healing of more superficial burns without the need for skin grafting (with ReCell used independently), potentially decreased hospital lengths of stay, superior scar and cosmetic outcomes, and potential health economic benefits.^{15,18}

Availability

The ReCell Autologous Cell Harvesting Device is commercially available in Europe, Australia, and China,¹⁴ but it is not currently licensed by Health Canada. The manufacturer expects it may be commercially available in Canada within one to two years (Heidi Cameron, Avita Medical, Valencia, CA: personal communication, 2017 Jun 17).

In September 2017, Avita Medical submitted a premarket application to the FDA and it is currently under review.¹⁴ Currently in the US, adult and pediatric patients who meet certain criteria are eligible to be treated with ReCell through compassionate use under the investigational device exemption.¹⁹⁻²¹

Cost

In the UK, the cost of one ReCell pack is £950.¹¹ Canadian and US prices are not currently available.

Who Might Benefit?

ReCell is proposed as a potential treatment for three categories of burns:

- **Patients with superficial partial-thickness burns who would otherwise be initially treated by conservative measures** (i.e., dressings and observation, with the possible need for delayed surgical reconstruction if the burn does not show signs of healing after about 10 days).²² In these cases, which are considered “borderline indications” for grafting, the early application of ReCell may improve wound healing and thus reduce the need for delayed surgical reconstruction.²²⁻²⁴
- **Patients with deep partial-thickness requiring acute surgical treatment.** In these cases, ReCell is being investigated for independent use as a replacement to the gold standard (split-thickness skin grafting [STSG] or meshed split-thickness skin grafting [MSTSG]).⁷⁻⁹
- **Patients with full-thickness burns requiring surgical treatment.** In these cases, ReCell is being investigated as an adjunct to skin grafting.¹⁷

Patients whose burns cover a very large surface area where there is insufficient donor skin may benefit from the ReCell technology because of its ability to help cover a greater surface area of burned skin compared with traditional skin grafting techniques alone.¹⁵

ReCell is also being investigated for the treatment of donor site wounds.²⁵

Current Practice

The first step in the management of severe burns is the stabilization of the patient as per the advanced trauma life support guidelines.⁴ The patient's vital signs (airway, breathing, circulation) and level of consciousness need to be assessed, in addition to assessing for inhalation injury if the cause of the burn was a fire.⁴

The guidelines also recommend providing appropriate pain management and IV fluid resuscitation as needed, as severe burns can cause dehydration.⁴ If the patient's burn is circumferential (i.e., if it encircles a body part such as an arm, leg, the chest, or neck, etc.) or if the patient develops burn-induced compartment syndrome (when pressure in muscle compartments builds to the point that it impairs circulation and function), escharotomy (surgical incision to relieve pressure from dead and contracted tissue) or fasciotomy (a deeper surgical incision than escharotomy) must be performed.^{4,5}

The location, size, and depth of the burn must be assessed in order to determine the treatment requirements.⁴ The two general categories of treatment are conservative management and acute surgical management.

Conservative management is generally indicated for superficial and superficial partial-thickness burns, which often heal on their own.¹¹ Conservative management consists of dressings and topical antimicrobial agents to prevent infection, as well as appropriate pain management.¹⁰ Observation is also important, as the burn can sometimes worsen in the days following the initial injury or fail to heal properly. In such cases, delayed surgical treatment with skin grafting may be needed.¹¹

Deep partial-thickness burns, as well as burns with full-thickness components, typically require acute surgical treatment.^{4,11} Surgical reconstruction of burns involves excision (removal of dead skin) followed by skin grafting (where donor skin from elsewhere on the patient's body is harvested and transplanted to cover the area of the burn).²⁶ Either split-thickness (including the epidermis and part of the dermis) and/or full-thickness (including both the dermis and epidermis) skin grafting can be used, depending upon the nature and location of the burn, as well as the availability of donor skin.²⁶

One of the advantages of STSG is that the donor site typically heals well because of the shallower depth of the wound compared to full-thickness skin grafting.²⁶ As a result, donor sites can be re-harvested if multiple reconstructive surgeries are needed for burns that cover a very large area.²⁶

The advantages of full-thickness skin graft (FTSG) include an improved cosmetic appearance and reduced contracture, or tightening of the skin, as compared with STSG because the dermal aspects of the skin are preserved.²⁶ However, FTSG tends to be reserved for cosmetically or functionally sensitive areas such as the face or hands, whereas STSG is typically the mainstay of treatment.²⁶

One of the challenges for burns that cover a very large TBSA is insufficient donor skin.²⁶ Expansion techniques such as meshing have been developed to address this limitation. Meshing involves perforating the donor skin multiple times, and stretching the skin from 1.5 to 9 times its original size (i.e., with an expansion ratio of 1:1.5 to 1:9).^{11,13,26} While meshing and other expansion techniques have helped to cover larger surface areas of burned skin, limitations of meshing include a fishnet appearance of the scar due to the mechanism of healing and a heightened chance of infection.^{11,13} As a result, non-expanded sheet grafts are preferable for areas of high cosmetic importance such as the face.²⁶

Burn surgeons may use a number of other reconstructive techniques; for example, dermal regenerative templates such as Integra²⁷ (Integra LifeSciences Corporation, Plainsboro Township, New Jersey).²⁶ These can help in the management of severe burns by facilitating regeneration of the dermis.²⁶ Allografts (such as cadaver skin) or xenografts (skin from animals) may also be used to temporarily cover burns until treatment with autografts is possible.⁴

Methods

Please note that these bulletins are not systematic reviews and do not involve a detailed critical appraisal, evidence assessment, or include recommendations for or against a particular technology.

Literature Search

A limited literature search was conducted using the following bibliographic databases: MEDLINE, PubMed, PubMed Central, Embase, the Cochrane Library (2017, Issue 10), and Scopus. Conference abstracts were retrieved through a search of the Embase database limited to the last two years. Grey literature was identified by searching relevant sections of the *Grey Matters* checklist (<https://www.cadth.ca/grey-matters>). No filters were applied to limit the retrieval by study type. The search was limited to English language documents published between January 1, 2012 and October 24, 2017. Regular alerts updated the search until project completion; citations retrieved before January 8th, 2018 were incorporated into the analysis.

Study Selection

One author screened the literature search results and reviewed the full text of all potentially relevant studies. Studies were considered for inclusion if the intervention included ReCell technology.

Peer Review

Two clinical experts reviewed a draft version of this bulletin. The manufacturer, Avita Medical, was invited to review the content of this bulletin.

The Evidence

Six studies^{7,8,22,25,28,29} and five conference abstracts^{9,17,19,23,24} were identified that evaluated ReCell for the treatment of burns. ReCell has been studied for four indications in burn patients (summarized in Table 1). The indications represent a continuum of burn severities but have been divided into categories based on the different standards of treatment.

Table 1: Potential Indications for the ReCell Autologous Cell Harvesting Device

Population	Intervention	Comparator(s)	Outcomes
Patients with superficial partial-thickness burns ^{19,22-24}	Early use of ReCell (applied 24 to 48 hours after the burn)	Standard of Care: Conservative management initially (i.e., dressings, observation), with potential delayed surgical reconstruction	<ul style="list-style-type: none"> • Need for delayed surgical reconstruction • Donor site morbidity • Speed of healing • Overall functional/cosmetic scar outcomes • Pain • Number of dressing changes and analgesic use • Cost • Itching
Patients with deeper partial-thickness burns ⁷⁻⁹	ReCell (used independently)	Standard of Care: STSG or MSTSG	<ul style="list-style-type: none"> • Non-inferiority of healing with ReCell versus the gold standard STSG or MSTSG • Graft take rate • Donor site requirements • Overall functional/cosmetic scar outcomes • Donor site healing • Pain and medication use • Adverse effects
Patients with severe burns and aspects of full-thickness burn ^{17,19}	ReCell (used as an adjunct to skin grafting, with a minimum 3:1 expansion ratio)	Standard of Care: Skin grafting alone	<ul style="list-style-type: none"> • Non-inferiority of healing with ReCell + skin grafting versus the gold standard (skin grafting alone) • Donor site requirements • Overall scar outcomes including cosmetic appearance • Episodes of graft loss or infection • Hospital length of stay
Treatment of donor site wound(s) following skin grafting ²⁵	ReCell	Standard of Care: Conservative management (i.e., dressings, observation)	<ul style="list-style-type: none"> • Donor site rate of re-epithelialization • Donor site pain • Donor site itching

Characteristics of the clinical evidence are summarized for the four indications that follow. Please note that the aim is to provide an overview of the available evidence. A formal synthesis of study findings is not presented.

ReCell Versus Conservative Management for Patients With Superficial Partial-Thickness Burns

The first potential indication for ReCell is for patients with superficial partial-thickness burns who would typically be initially treated by conservative measures. These patients are considered a "borderline indication" for grafting.²² The intent of the studies was to determine if the early use of ReCell (applied 24 to 48 hours after the burn) could reduce the need for delayed surgical reconstruction and improve overall outcomes.²² One pilot study²² and three conference abstracts^{19,23,24} have reported on the use of ReCell for this indication.

The small, single-centre, randomized controlled pilot study evaluated the treatment of pediatric scald injuries (> 2% TBSA) at a burn centre in Western Australia (n = 13).²² The study compared the use of BIOBRANE synthetic wound dressing with or without ReCell to the standard of care (INTRASITE, ACTICOAT, and DuoDERM dressings applied every two to three days).²² The primary end point was whether or not early intervention with BIOBRANE with or without ReCell reduced the incidence of surgery at day 10. Secondary outcomes of interest included the rate of healing, scar appearance, pain, number of dressing changes and analgesic use, and costs.

The first conference abstract reported on a single-centre prospective observational study that evaluated the impact of the early management of pediatric scald injuries (> 5% TBSA) at a burn unit in Yorkshire, England (n = 40).²³ Patients were divided into three treatment arms based upon the severity of their burn at presentation: the first group of patients received BIOBRANE only (n = 20), the second group received BIOBRANE plus ReCell (n = 13), and the third group received skin grafting (n = 7). Outcomes included the total number of skin grafting procedures, the time to wound healing, donor site morbidity, functional and aesthetic outcomes, dressing and analgesic requirements, and cost.

The second study, reported in two conference abstracts, described a UK retrospective analysis of consecutive cases of pediatric scald injuries treated with five different modalities at the Pinderfields Hospital Burns Centre (n = 100).^{19,24} The treatments included the standard of care dressings and observation (n = 34), BIOBRANE only (n = 21), BIOBRANE plus ReCell (n = 8), ReCell only (n = 4), and immediate STSG compared with delayed STSG

(n = 33).²⁴ The end points of interest included scar appearance, pigmentation, and itching.

ReCell Versus Split-Thickness Skin Grafting for Patients With Deep Partial-Thickness Burns

Another potential indication for ReCell is as a replacement for standard treatment (i.e., intended for independent use) for deep partial-thickness burns requiring acute surgical treatment. Two published studies^{7,8} and one recent conference abstract⁹ have evaluated the use of ReCell for this indication.

The first study, published in 2015, was a preliminary single-centre prospective observational study at a US burn centre. It compared the ReCell-only treatment to MSTSG for patients with deep partial-thickness burns covering 4% to 25% TBSA and requiring acute surgical treatment (n = 10).⁸ A "within-subject" control design was used, and both the intervention and control procedures were performed on each patient (on two separate areas of burned skin) for direct comparison. The primary end point was the graft take rate. Secondary end points included pigmentation, pain, and overall scar quality.

A single-centre randomized controlled trial, published in 2007, compared ReCell to STSG for the treatment of partial-thickness to deep partial-thickness burns at a burns centre in Italy (n = 82).⁷ The primary end points were time-to-complete re-epithelialization (both for the recipient sites and the donor sites), as well as the aesthetic and functional quality of healing (i.e., pigmentation, joint contractures). Secondary end points included adverse effects, postoperative pain and medication use, donor skin requirements, and the length of time to complete the procedure.

A 2017 conference presentation described a multi-centre, randomized controlled trial that compared ReCell to MSTSG with a 2:1 expansion ratio for the treatment of deep partial-thickness burn injuries (n = 101).⁹ The primary end points were non-inferiority of the ReCell procedure for recipient site healing and a decrease in donor site morbidity. Secondary end points included recipient site scar outcomes and overall donor site outcomes (i.e., rate of healing, pain, and cosmetic and scar appearance).

ReCell as an Adjunct Treatment for Patients With Severe Burns, With Full-Thickness Components

For severe burns with full-thickness components, ReCell is indicated as an adjunct treatment (i.e., it is not intended for independent use).¹⁷ ReCell has been used in patients with severe burns covering very large surface areas, through compassionate

use access. It was also used in one multi-centre, randomized controlled trial evaluating the use of ReCell as an adjunct to skin grafting for the treatment of full-thickness burns.^{17,19}

A 2016 conference presentation reported on a series of US patients treated with ReCell through compassionate use access (n = 16).¹⁹ The compassionate use study includes adult patients with a burn TBSA > 40%, pediatric patients with a burn TBSA > 30%, and small children with a burn TBSA > 20% and poor donor site options. The study reported on episodes of infection or graft loss, hospital length of stay compared to matched historical controls, and cosmetic appearance (e.g., reduced meshed pattern and reduced contracture).

Other researchers have also reported on the use of ReCell through compassionate use,^{19,20} and 55 compassionate use case reports were recently submitted to the FDA as part of the premarket application.¹⁴

Another 2017 conference presentation described a small (n = 30), multi-centre, randomized controlled trial evaluating the use of ReCell as an adjunct to skin grafting for the treatment of full-thickness burns.¹⁷ Skin grafting with a 3:1 expansion ratio plus ReCell to fill in the interstices was compared to skin grafting alone with a 2:1 expansion ratio. The end points of interest included donor site requirements, non-inferiority of healing, and scar outcomes.

ReCell Versus Conservative Management for the Treatment of Donor Site Wounds

ReCell is also being considered for the treatment of donor site wounds, which are typically treated with conservative management.²⁵ A single-centre, randomized, single-blind trial published in 2017 evaluated the effect of ReCell on donor site wounds at a hospital in China (n = 106).²⁵ The intervention consisted of ReCell plus a hydrocolloid dressing, and the control group received only the hydrocolloid dressing. The primary end point was the donor site rate of re-epithelialization. Secondary end points included pain and itching of donor sites, as measured on a visual analogue scale.

Hospital Length of Stay

Two studies have considered the impact of ReCell on hospital length of stay in patients with burns of varying severity.^{28,29} Both studies were retrospective analyses of patient data from the burns centre at Royal Perth Hospital in Western Australia from 2004 to 2011.^{28,29} One study assessed the relationship between acute burn surgery duration and “poorer outcomes.”²⁸ The second study examined whether the infection rate for acute burn patients

was associated with the type of skin replacement surgery. Both studies considered the same surgery types (ReCell alone, ReCell plus STSG, STSG alone, and Cell Spray [an aerosol culture of keratinocyte skin cells] plus STSG) and evaluated their impact on length of stay as one of the end points of interest.^{28,29} In both cases, STSG was used as the control.^{28,29}

Cost Evaluations

No formal and validated studies including cost considerations for ReCell have been published to date.^{11,21} There is a small amount of basic cost data from one small pilot study²² (n = 13) and one conference abstract²³ (n = 40), both of which considered cost reduction as a secondary end point in the treatment of pediatric scald injuries with ReCell.

Safety

No adverse events have been reported with the use of ReCell in managing patients with complex burns.^{7-9,11,17,19,22-25}

Concurrent Developments

The CellMist System that includes the CellMist Solution and SkinGun device (RenovaCare, New York, NY) is also an autologous skin cell spray grafting system.³⁰ With the CellMist/SkinGun system, the cells, after being collected via a biopsy, must be cultured briefly in a laboratory prior to use.^{30,31} The total procedural time with the CellMist/SkinGun is 90 minutes.^{30,31} The CellMist/SkinGun technology offers an electronically controlled spraying device that is designed to help preserve the integrity of the cells’ structure and function during application to the site of the burn.^{30,31} This may reduce the loss of viable cells.¹⁶ One published study of CellMist/SkinGun describes its use in six patients with different types of burns.³² Another recently published study of CellMist/SkinGun describes its use in 44 patients, and modifications made to the protocol to optimize the procedure, the expansion ratio, and the effective delivery of cells to the burn site.³³ Both of these studies will be used to inform planning for future clinical trials of this technology.^{32,33}

The SkinTE (PolarityTE, Salt Lake City, Utah) is a skin regeneration technology that is also in clinical development.³⁴ The SkinTE system has a unique mechanism of action.³⁴ A sample of the patient’s skin is obtained via a biopsy and the cells are then imprinted using a 3-D system in the laboratory.³⁵ The 3-D regenerated cell construct is then reapplied to the injured area of skin.³⁵ This may make it possible to regenerate and expand all layers of human skin (including the epidermis and dermis, and hair follicles).³⁵

Epicel (Vericel, Cambridge, Massachusetts) is another technology that uses cultured epithelial autografts.^{36,37} It differs from ReCell in that laboratory culturing is required, and it is also considered a xenotransplantation product — one that involves members of different species — because the manufacturing process involves mice cells.³⁶ It is indicated for use in patients with deep dermal or full-thickness burns (covering > 30% TBSA).³⁶ Epicel has been available for use in the US since 2007 under a Humanitarian Device Exemption, and it has been utilized in Canada under compassionate use regulations.^{37,38}

In addition to ReCell, Avita Medical has two other autologous skin cell technologies for wound and skin indications.¹⁵ ReGenerCell is intended as an adjunct to conventional treatments for chronic wounds including venous leg ulcers, diabetic foot ulcers, and complex hard-to-heal wounds. ReNovaCell is intended for repigmentation of scars (including burn scars), sun-damaged skin, and skin lesions associated with vitiligo and piebaldism.¹⁵

Implementation Issues

Additional costs involved in using ReCell include the device costs, as well as potential training costs for clinicians.⁸

ReCell is proposed to be a relatively easy-to-use and quick (approximately 30 minute) procedure that does not require laboratory staff expertise but rather can be performed by burn surgeons trained in how to use ReCell.¹⁵

ReCell is being investigated for a number of different indications in burn treatment. It will be important to clarify the appropriate indications for using ReCell based on the clinical evidence.

Final Remarks

ReCell may offer particular benefit to patients with burns that cover a very large TBSA because of the decreased donor site requirements.¹⁵ Studies that evaluate the impact of decreased donor site requirements on patient outcomes may help to clarify ReCell's role in this patient population.

The evidence to date has investigated the use of ReCell for several indications:

- when used independently for the treatment of partial-thickness burns⁷⁻⁹
- when used as an adjunct to skin grafting for the treatment of more severe burns with full-thickness components¹⁷
- when used to promote faster healing of donor site wounds.²⁵

Comprehensive and validated studies including cost considerations may assist in understanding the impact of ReCell on health care costs and its overall value to the health system.^{11,21}

The manufacturer has planned two further multi-centre, randomized controlled trials to evaluate the use of ReCell for superficial partial-thickness burns in pediatric patients.³⁹

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