



**Health Policy Advisory Committee on
Technology**

Technology Brief

**CelluTome™ Epidermal Harvesting System for the
treatment of acute or chronic wounds**

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HealthPACT
emerging health technology

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Summary of findings

The CelluTome™ Epidermal Harvesting System is a minimally invasive skin harvesting system that produces autologous epidermal skin grafts for the treatment of acute or chronic wounds. The treatment can be used in a variety of clinical locations, including inpatient, outpatient, primary care or community settings.

Current evidence on the safety and clinical effectiveness of epidermal grafting using CelluTome™ is limited to a few small case series. No comparative studies were identified and, therefore, no conclusions as to the clinical effectiveness of the Cellutome™ system can be made. Conflicts of interest were noted in four of the five studies, which reflected the manufacturer either funding the study and/or authors being manufacturer employees or consultants.

The CelluTome™ treatment is generally well tolerated by the patient. There are limited reports of subsequent infection following treatment of both acute and chronic wounds; however, the infection may have been present in the wound bed and cannot be directly attributed to the treatment.

Although CelluTome™ may have the potential to reduce clinical visits for patients with chronic wounds, and avoid hospitalisation and theatre admissions, the case-series evidence to date can only inform safety, not effectiveness. Further assessment of safety outcomes with larger populations is required. Similarly, comparative clinical evidence and cost-effectiveness analysis is required to ascertain effectiveness and clinical utility of the Cellutome™ system.

HealthPACT Advice

The management and treatment of chronic wounds represent a significant economic burden on the healthcare system, which will increase with an ageing population and the increasing prevalence of chronic disease such as diabetes. In addition, chronic wounds have a significant impact on patient quality of life. The CelluTome™ technology may represent a new and cost-effective option to assist in wound healing, improving patient outcomes and reducing contact with the health system.

However, clinical utility of the Cellutome™ technology has not, as yet, been proven. The lack of comparative evidence and long-term follow-up data does not adequately demonstrate safety, clinical or cost effectiveness of this technology. HealthPACT does not support the introduction of this technology into public practice at this time, and recommends that CelluTome™ should only be used under the auspices of a controlled clinical trial. HealthPACT recommends that the evidence on the use of CelluTome™ for wound closure be reviewed in 24 months.

Technology, Company and Licensing

Register ID	WP239
Technology name	CelluTome™ Epidermal Harvesting System
Patient indication	For the treatment of acute or chronic wounds

Description of the technology

The CelluTome™ Epidermal Harvesting System (Cellutome™) is a skin harvesting system that cuts thin sections of epidermal skin (the superficial layer of skin tissue) from a patient, to form a graft for acute or chronic wound sites. The system uses negative pressure and warmth to raise a formation of small blisters, known as epidermal microdomes, which are then harvested to form the graft. The deeper layers of the skin at the donor site (the dermis and hypodermis) remain intact.

The CelluTome™ system consists of (1) a control unit, which regulates the suction pressure and temperature for raising the microdomes; (2) a vacuum, which delivers the suction pressure and warmth to the harvester; and (3) a harvester, which provides the microdome grid and cutting mechanism. It is currently the only available technology that has fully automated the process (Figure 1).¹



Figure 1 CelluTome™ Epidermal Harvesting System (printed with permission KCI Medical Australia Pty Ltd)

The harvester is positioned at the donor site (typically the patient's inner thigh) and the vacuum unit is attached to initiate the microdome raising process. The system heats the skin to between 37°C and 41°C and applies 400–500mmHg of negative pressure. An approximate 5 x 5cm array of 128 microdomes (each approximately 1.8mm in diameter) gradually forms

over approximately 30-40 minutes. The microdomes consist of epidermal skin tissue, down to its basal layer, including basal keratinocytes.

The harvester then cuts the raised microdomes, which are captured by a 3M™ Tegaderm™ 60mm x 69mm film dressing to form a transferrable skin micrograft (Figure 2). The micrograft should ideally be applied to the recipient site within two minutes after it has been obtained.



Figure 2 CelluTome™ micrograft (printed with permission KCI Medical Australia Pty Ltd)

According to the manufacturer, there is no need for anaesthesia as the grafting process has minimal pain and donor site trauma, and therefore can be performed in inpatient, outpatient, primary care and community settings.²

Company or developer

CelluTome™ is marketed in Australia by KCI Medical Australia Pty Ltd, a subsidiary of Acelity L.P. Inc.

Reason for assessment

CelluTome™ is an innovative device that harvests healthy epidermal skin tissue with minimal damage to the donor site and may represent a convenient grafting option for patients with acute and chronic wounds. In addition, CelluTome™ may reduce the number of patients who require surgery and general anaesthetic as part of other skin grafting procedures.

Stage of development in Australia

- | | |
|--------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input checked="" type="checkbox"/> Nearly established | |

Licensing, reimbursement and other approval

The CelluTome™ Epidermal Harvesting System was registered by the TGA in June 2014, and “is intended to reproducibly cut a thin skin graft for autologous skin grafting”. CelluTome™ is classified by the United States Food and Drug Administration as a Class I device exempted from premarket notification procedures. The CelluTome™ Epidermal Harvesting System received a CE mark in April 2014.

Australian Therapeutic Goods Administration approval

- | | |
|-----------------------------------------|------------------------|
| <input checked="" type="checkbox"/> Yes | ARTG number (s) 224372 |
| <input type="checkbox"/> No | |
| <input type="checkbox"/> Not applicable | |

Technology type

Device

Technology use

Therapeutic

Patient Indication and Setting

Disease description and associated mortality and morbidity

Chronic wounds are defined as wounds that have failed to proceed through an orderly and timely repair process to produce anatomic and functional integrity, over a period of three months.³ Although chronic wounds can occur anywhere on the body, the lower legs, feet and bony prominences are most commonly affected.⁴ Approximately 70 per cent of chronic wounds are leg ulcerations caused by ischemia, secondary to diabetes mellitus, venous stasis, or pressure.^{5,6}

Chronic wounds can have a significant impact on health and well-being. Patients frequently experience chronic pain, and physical limitations such as gait changes and difficulty ambulating.^{4,7} Immobility is a prominent issue; a 1994 Australian study found 45 per cent of leg ulcer patients were housebound.⁸ Chronic wounds are also susceptible to infections, such as cellulitis, abscess formation, osteomyelitis, gangrene, and sepsis, and have the potential for malignant transformation.⁷ In Australia, more than 3,000 lower limb amputations are performed yearly due to non-healing leg or foot ulcers.⁹

Number of patients

Internationally, the actual burden of chronic wounds is unclear due to a combination of factors, including definitions of “chronic wound”, under-reporting, and inaccurate diagnostic coding.¹⁰ Additionally, those with chronic wounds are often afflicted with potentially significant comorbidities, which can diminish the presence and significance of the wound.¹¹ However, in developed countries, it is estimated that one to two per cent of the population will experience a chronic wound during their lifetime.¹²

Within Australia, it is estimated that over 433,000 people suffer from chronic wounds, however there are initiatives to improve reporting. The Australian Wound Management Innovation Cooperative Research Centre is developing an Australian Wound Registry, which is intended to provide greater prevalence and associated economic information. The Registry is a national collaboration, and includes the Commonwealth Government; State Governments of Western Australia, South Australia, Victoria, New South Wales and Queensland; academic institutions, and industry. A pilot study of the Registry was completed in May 2015.¹³ Current prevalence data for New Zealand was unable to be located.

Speciality

Skin disease, burns and wound care

Technology setting

General hospital, and Ambulatory, Community and Primary Care

Impact

Alternative and/or complementary technology

The device may represent either a complementary or substitution technology. CelluTome™ may provide an alternative to both standard chronic wound treatment of dressing and compression therapy, and contemporary skin grafting procedures.

Current technology

Standard chronic wound treatment consists of debridement, dressing, and compression therapy, except where peripheral arterial disease is present. Where effective treatment is applied early, the majority of wounds can reportedly be healed within 12 weeks. However, this can be difficult to achieve external to the acute health system, particularly where patients are required to self-fund bandage purchases.¹³

If standard treatment fails, surgical skin grafting procedures represent a second-line strategy. Skin grafts are defined by the thickness of the grafts, and include split-thickness skin grafts (STSG), full-thickness skin grafts (FTSG), and suction blister grafts.

An autologous STSG is a well-established surgical procedure, and consists of harvesting of healthy epidermis and some layers of dermis for transfer to the wound site.¹⁴ The effectiveness of STSG is dependent on a range of factors, including the location and type of wound, size of the ulcer and its duration, quality of the recipient bed, and patient comorbidities. STFG failure rates of up to 33 per cent have been previously reported,¹⁵ however successful graft take on leg ulcers of up to 90 per cent has been achieved when used in combination with systemic (low molecular weight heparin) or topical (platelet gel, vacuum-assisted closure) treatments.¹⁶ Healing times can vary, however have been reported as approximately two to four weeks in non-diabetic patients, and five to 12 weeks in diabetic patients.¹⁷ Common recipient site complications may include graft contraction, graft failure, hyper-pigmentation, itchiness and dryness of the graft, durability, and growth complications. Similarly, donor site complications include pain, pruritus, infection, skin colour alterations, scarring, and delayed healing, particularly in patients with underlying comorbidities.¹⁴

FTSG are composed of epidermis, dermis and various layers of subcutaneous tissue, and compared to SGST have better mechanical, functional and aesthetical properties, however contain increased tissue requiring revascularisation. For this reason, they are not often employed for chronic wounds with reduced blood supply, such as venous or arterial insufficiency ulcers.¹⁶

The use of suction blister grafting was first introduced in the 1960's. Within this procedure, suction is created through the use of syringes and stopcocks, or suction pumps, to raise the epidermal skin layer, which is then excised with scalpels or scissors for transplant.¹⁴ To date, its use within clinical practice has been limited due to the lack of a reliable and efficient harvesting method.¹⁸ The CelluTome™ technology is intended to automate the suction blister graft procedure within non-surgical settings, negating the need for theatre access, anaesthesia, and appropriately skilled medical specialists.

Diffusion of technology in Australia and New Zealand

According to the manufacturer, CelluTome™ is in use within public hospitals in Queensland (Princess Alexandra Hospital, Bundaberg Base Hospital, Gold Coast University Hospital), New South Wales (Royal North Shore Hospital and Westmead Public Hospital), and a single private hospital in Victoria. KCI also advised that CelluTome™ is under review by a number of other Australian medical facilities. There is no current use of this technology in New Zealand (personal communication, KCI Medical Australia Pty Ltd).

International utilisation

Country	Level of Use		
	Trials underway or completed	Limited use	Widely diffused
Austria		✓	
Canada		✓	
France		✓	
Germany		✓	
Ireland		✓	
Netherlands		✓	
South Africa		✓	
Spain		✓	
Sweden		✓	
Switzerland		✓	
Turkey		✓	
United Arab Emirates		✓	
United Kingdom		✓	
United States of America		✓	

The manufacturer states that internationally since 2014, there has been over 25,000 procedures completed, with about 17,000 anticipated in 2016 (personal communication, KCI Medical Australia Pty Ltd).

Cost infrastructure and economic consequences

A 2010-11 economic study estimated that chronic wounds placed a significant burden on the health care system in Australia.¹⁹ According to that study, the estimated total direct health care cost of chronic wounds was about US\$2.85 billion annually (approximately AUD\$2.94 billion), with large uncertainty around this estimate. At that time, this financial expenditure equated to approximately two per cent of the total national health expenditure. The direct health care costs by major type of chronic wounds for each state and Australia overall in all the hospitals from 2010-11 were modelled, and are presented in Table 1.

Table 1 Total estimated direct health care costs (US 2012 dollar) of chronic wounds in Australia

Type of wound	Australia		Public Hospitals		Private Hospitals		Residential care	
	Cases	Costs (US\$, m)	Cases	Costs (US\$, m)	Cases	Costs (US\$, m)	Cases	Costs (US\$, m)

Type of wound	Australia		Public Hospitals		Private Hospitals		Residential care	
Pressure ulcer	357,847 ±191,868	\$1,654.6 ±1,054.2	236,295 ±129,230	\$1,127 ±718.7	111,155 ±61,000	\$529.4 ±338.2	10,397 ±1,638	\$14 ±5.2
Diabetic foot ulcer	13,355 ±3,675	\$249.7 ±127	Total hospital cases = 12,839 ± 3,534 Total hospital costs = \$238.7 ± 124				516 +141	\$11 ±3
Venous leg ulcer	49,050 ±16,332	\$802.6 ±307.5	32,055 ±10,686	\$532.9 ±208.1	15,256 ±5,069	\$252.9 ±98.6	1,739 ±577	\$17.9 ±10.3
Arterial insufficiency ulcer	4,899 ±1,634	\$143.7 ±47.5	3,206 ±1,069	\$96.6 ±32.2	1,519 ±507	\$45.8 ±15.2	174 ±58	\$1.8 ±1

Note: Financial figures presented in US 2012 dollars, and rounded to single decimal places for presentation purposes

According to Wounds Australia, a driver of these costs is where patients are required to fund the dressing themselves, many of which are unable to afford the costs. This results in a non-healing wound, and subsequent ongoing contact with outpatient, primary or community medical personnel, pharmaceutical costs for infections or pain, and repeated hospital admissions for recurring complications.¹³

According to the manufacturer of the CelluTome™ technology, the cost of the control unit and vacuum is approximately AUD\$16,000; however, price is negotiable depending on usage. At the time of writing, the Australian distributor advised of a product familiarisation scheme. The manufacturer will provide the CelluTome™ control unit and vacuum head pump system on a loan basis, and the medical facility will be required to pay for consumables only. Consumables consist of the harvester units, which cost AUD\$625 for a single-use disposable unit, and 3M™ Tegaderm™ film. Within reported studies to date (see Evidence and Policy section below), a single micrograft is used. This includes wounds that are larger in size than the graft, with successful grafts gradually expanding to cover the wound area. Training is provided by the manufacturer at no additional charge (personal communication, KCI Medical Australia Pty Ltd).

There are multiple Diagnosis Related Groups (DRG) to which this treatment could be assigned. Additionally, current Medical Benefits Schedule (MBS) items for skin grafting relate to traditional surgical procedures. The procedure could potentially be ascribed to item 10.13 (minor medical procedures) or item 40.13 (wound management) under Tier 2 Non-Admitted Services. Should the CelluTome™ technology continue to diffuse into the health sector, appropriate treatment classification and subsidies will require further consideration.

Ethical, cultural, access or religious considerations

No ethical, cultural, or religious considerations for CelluTome™ were identified. This technology could potentially improve access to chronic wound treatment, through the provision of grafting services within a range of clinical care settings.

Evidence and Policy

Safety and effectiveness

Five small case series (level IV interventional evidence) were identified for inclusion in this technology brief. An overview of studies is presented in Table 2.

Table 2 Included study characteristics

Study/location	Inclusion criteria	Exclusion criteria	Length of follow-up, number of patients and losses to follow-up	Conflicts of interest
Prakash et al 2016 ²⁰ Case series India (single centre)	Patients with complex, nonhealing wounds with healthy granulation tissue	Highly exudative wounds, signs of infection, wounds larger than 7 cm × 7 cm. Patients with poor glycemic control or unhealthy skin over the donor site.	Up to 14 weeks n=18	One of the author is a consultant for KCI, an Acelity company. Another of the authors is an Acelity employee. Acelity provided statistical support, and manuscript editing.
Bhatia 2016 ²¹ Case series USA (single centre)	Patients with complex wounds that failed with previous wound closure treatments	NR	NR n=34 One loss to follow up	The author is a consultant for KCI Medical. Acelity contributed with data collection, statistical support, and manuscript preparation.
Harach-Haram et al 2016 ²² Case series UK (multi-centre)	Patients with wounds with a clean granulating base appropriate for grafting	Infection.	Up to 20 weeks n=35 No losses to follow-up	NR
Osborne et al 2016 ¹⁸ Case series USA (single centre)	Healthy human volunteer subjects.	NR	28 days n=15 Losses to follow-up: one subject missed visit 5	Research report was funded by the manufacturer, KCI Medical, and authors are employees of KCI Medical.
Serena et al 2015 ²³ Case series Republic of Haiti (single centre)	Patients with wounds with a clean granulating base appropriate for grafting	NR	4 weeks n=15 No losses to follow-up	One of the authors is a consultant for the manufacturer, KCI Medical. KCI Medical provided editorial assistance

NR = not reported

A number of case reports were also located, which outline treatment outcomes for selected individuals²⁴⁻²⁸, however will not be expanded upon in this report.

Prakash et al 2016²⁰

This study describes wound outcomes following CelluTome™ treatment for 18 patients with a mean age 54.1 years (range 32–70 years) at a community health center in India. The

patient wounds included 12 diabetic foot ulcers (66.7%), four non-diabetic foot ulcers (22.2%), one pressure ulcer (5.6%), and one venous leg ulcer (1/18, 5.6%). In 17 patients, the wounds were present for two to 180 months (mean of 36.8 months). The wound age of the other patient was unknown. Previous treatments included debridement, antibiotic therapy, standard wound care dressings, and previous STSGs.

The majority of wounds were pre-treated prior to grafting with negative pressure wound therapy, to promote healthy granulation tissue formation. Following grafting, wound re-epithelialization was monitored at each dressing change and at weekly follow-up visits for up to 14 weeks.

The majority of wounds (88.9%) healed following epidermal grafting (16/18), with a mean time to epithelialization was 3.7 ± 1.8 weeks (range 2–9 weeks). Two patients showed complications, including a non-compliant patient who removed the graft dressing under non-sterile conditions, and subsequently developed an infection that resolved with antibiotic therapy. The other patient developed hypergranulation at the wound site, requiring resection of the excessive granulation. Both patients progressed to complete healing. All donor sites healed without complications.

Bhatia 2016²¹

This study describes wound outcomes following treatment for 34 patients with a mean age of 67.1 years (range: 37–103). The patient wounds were a mixture of traumatic wounds, diabetic foot ulcers, venous stasis ulcers, pressure ulcers, and surgical wounds, located on the right arm (2.9%), left thigh (50%), and right thigh (47.1%). All wounds had been present from several weeks to over a year (mean of 95.7 days), and had failed to close despite the application of a variety of treatment methods, including autolytic debridement, hydrogels, collagenase, antimicrobial dressings, alginate dressings, collagen dressings, cellulose dressings, extracellular matrix scaffolds, collagen scaffolds, skin substitutes, and Unna boot.

Reported outcomes were 82.4% (28/34) of wounds were healed, 2.9% (1/34) wounds showed improved healing, 11.8% (4/34) of wounds did not heal, and 2.9% (1/34) were lost to follow-up. The mean epithelialisation rate at the recipient site was 7.0 weeks (range: 1–35 weeks).

Wound complications included drainage, hypergranulation, and oedema. A second graft was required in seven out of 34 patients due to complications of increased drainage and infection (n=1), hypergranulation (n=2), oedema (n=1), or re-opening of the wound (n=1).

The remaining two patients did not have any reported wound complications, therefore it is presumed that graft failure occurred. Complications were observed in five out of 27 patients that received one graft application. The wounds had complications of drainage (n=1), drainage and maceration (n=1), oedema (n=1), re-opening of the wound (n=1), and stalled healing (n=1). All donor sites healed without complications.

Harach-Haram et al 2016²²

This study describes wound healing rates, associated pain, and the appearance of donor-site healing post-harvest following use of CelluTome™ in 35 patients, with an average age of 66.1 years (range: 18 – 93 years). Patients presented with 10 acute wounds and 25 chronic wounds, with the majority of the wounds treated were located on the leg (40%) followed by the ankle (17.1%) and abdomen (14.3%). Healing rates were assessed as time taken for 50 per cent and 100 per cent reduction in wound size, as well as the time taken for the donor site to heal. Wounds were reviewed on day 7 ± 3 post-grafting, and then weekly for a minimum of six weeks or until the wound had healed. The pain score was measured using a Numerical Rating Scale, with zero being no pain and 10 being the worst pain. The donor site scar quality was evaluated using the Vancouver Scar Scale at six weeks post-graft.

Complete wound healing was achieved in 22 patients (62.9%), comprising seven of ten acute wound patients, and 15 of 22 chronic wound patients. Of the healed patients, 17 (77.3%) healed within six weeks, four (18.2%) healed within 8 weeks, and the remainder healed within 20 weeks. The mean time for 50 per cent and 100 per cent reduction in wound size was 3.31 ± 2.33 weeks and 5.91 ± 3.48 weeks, respectively. There was no significant difference observed in healing times between acute wounds and chronic wounds.

Four other patients achieved 50 per cent reduction, but subsequently either no change or minimal change was observed. No improvement in wound size was seen in two other patients with chronic wounds; however, the wound bed was noted to be more active with granulation tissue.

There were seven graft failures due to infection. The authors noted this was likely due to inadequate wound bed preparation and recommended wound assessment with a preoperative swab prior to the CelluTome™ treatment. No other complications were experienced by the patients.

The mean pain score during graft harvest was 1.42 ± 0.95, with a donor site mean healing time of 5.49 ± 1.48 days. At six weeks, the donor site Vancouver Scar Scale was zero for all patients.

Osborne et al 2016¹⁸

The intention of this study was not to treat chronic wounds, however to examine graft viability, associated pain from device use, and the appearance of donor-site healing post-harvest from a single application of CelluTome™. The study population consisted of 15 healthy human volunteers with a mean age of 51.9 years (range: 42-70 years). Epidermal skin grafts were obtained from the inner thigh, and subjected to fluorescence-based cell viability assay staining and image analysis. Pain assessment was obtained from subjects using the Wong-Baker FACES Pain Rating Scale during device operation, immediately following micrograft harvesting, and at seven days post-harvest. Donor-site appearance was

assessed immediately post-harvest, and at 7, 14, and 28 days post-harvest by a clinician utilising a skin appearance scale and dermal response score.

The population for viability assessment was 12 subjects. Graft viability was defined as the presence of green fluorescence within the micrograft, which is indicative of active cell metabolism. Of the 12 subjects assessed, 10 demonstrated 100 per cent epidermal micrograft viability. For all 12 subjects, there was 99.5 per cent average viability of epidermal micrografts with a standard deviation of 1.2 per cent.

The remaining three grafts were examined for secreted growth factors and published as a separate study.²⁹ Outcomes included epidermal micrografts formed at the dermal/epidermal junction that retained their original keratinocyte structure. Viable basal cells actively secreted key growth factors important for modulating wound healing responses.

At one minute following device initiation, the mean recorded pain was 0.1 on the Wong-Baker FACES pain rating scale of 0 (no hurt) to 5 (hurts worst). At 10 minutes and during harvesting, mean recorded pain was 1.0 (hurts a little bit). At 20 minutes, subjects reported the highest mean pain score of 1.3. Immediately after harvesting, the mean recorded pain was 1.0, and all subjects reported pain scores of 0 seven days after harvesting.

Immediately following harvesting, a mean dermal response score of 1.7, corresponding to minimal erythema (barely perceptible) and definite erythema (readily visible), was observed in all 15 subjects. At 7 days after harvesting, mean dermal score was 0.8, between minimal erythema and no evidence of irritation. At 14 days after harvesting, mean dermal response score was 0.5, and 76 per cent to 100 per cent of donor site skin had similar appearance to surrounding skin. At 28 days after harvesting, the mean dermal response score was 0.1.

Serena et al 2015²³

This small case series describes the effect of CelluTome™ treatment in seven patients, with an average age of 45.6 years (range: 19 – 76 years). All patients had wounds located on the lower extremities, with mean wound duration of 26.4 months. All subjects were treated in an outpatient clinic and reviewed at weekly clinics over the following four weeks.

Six out of seven subjects demonstrated decreased wound size at four weeks. One single patient failed to demonstrate improvement in a thigh wound of two years duration, which was attributed to an inability to adequately secure the graft.

Economic evaluation

No economic studies on the use of CelluTome™ were identified. The Harach-Haram et al 2016²² study briefly compared standard care wound dressing costs with the CelluTome™ intervention and subsequent care, and estimated that the intervention resulted in dressing costs of less than 10 per cent compared to the mean standard care. However, further

economic analysis is required to demonstrate if CelluTome™ represents a cost-effective alternative to other wound healing procedures and products. Relevant considerations include the cost of the CelluTome™ technology, compared to costs of standard care including surgery, differences in rates of success or complications that affecting the level of contact with the health system, and quality of life improvement costs.

Ongoing research

A total of five clinical trials on CelluTome™ were identified from a search of ClinicalTrials.gov and the Australian and New Zealand Clinical Trials Registry (Table 3). Three of the registered trials are recruiting, whilst two are not. Three are randomised controlled trials, one is a prospective/retrospective longitudinal study, and one is a case series. There are no clinical trials reportedly underway in Australia or New Zealand.

Table 3 Registered CelluTome™ clinical trial characteristics

Study Location	Design Single or multicentre	Number of patients	Intervention	Primary outcomes	Trial status (Estimated completion date)
NCT02148302 United States of America, Bahamas	Randomised Controlled Trial Multicentre	194	CelluTome™ and standard of care vs. standard of care alone	Safety and effectiveness	Recruiting (May 2016)
NCT02670837 United States of America	Case series Single centre	40	CelluTome™ treatment of lesions in persons with Epidermolysis Bullosa	Percentage of grafts successfully treated	Not yet recruiting (May 2016)
NCT02492048 United States of America	Longitudinal Case Series Multicentre	40	CelluTome™ treatment (prospective) vs. Split Thickness Skin Graft Harvest (retrospective)	Healing time	Recruiting (August 2017)
NCT02535481 United Kingdom	Randomised Controlled Trial Multi-centre	44	CelluTome™ treatment vs. Split Thickness Skin Graft Harvest	Wound and donor site healing time	Recruiting (August 2017)
NCT02150863 United States of America	Randomised Controlled Trial Single centre	30	Pre-skin cancer carbon dioxide laser resurfacing vs. carbon dioxide resurfacing plus epidermal skin graft vs. control.	Safety/Efficacy	Not yet recruiting (June 2017)

Other issues

At the time of writing, two further studies were identified that utilised this technology. The first study describes a small case series of patients (n=5) who underwent keloid excision.³⁰ Subsequent to excision, a staged reconstructive approach was undertaken using dermal regeneration substrate and the CelluTome™ technology. Over a mean follow-up of 48.8

weeks, complete wound epithelialisation was achieved at an average of 5.5 weeks with no reported infections, cellulitis or long-term pruritus or pain. All reconstructed defects were aesthetically acceptable and remained flat without significant widening.

The second case report describes the use of the CelluTome™ technology to treat two small areas (25mm and 12mm) of graft failure in a burns patient, with complete epithelialisation at four weeks without complication.³¹ These publications raise the possibility that this technology may have additional applications in plastic and reconstructive surgery.

Conflicts of interest were identified in four of the five studies. In Prakash et al (2016)²⁰, the lead author is a consultant for the manufacturer (KCI, an Acelyty company), and one other author is an employee of KCI. Acelyty also provided statistical support and assistance with preparation and editing of the manuscript.

In Bhatia (2016)²¹, the author disclosed a consultancy from KCI, and statistical support and manuscript preparation assistance from Acelyty.

In Osborne et al 2016¹⁸, the authors disclosed that the research reported was funded by the KCI, and the authors are employees of KCI.

With regards to Serena et al 2015²³, one of the authors is a consultant for the manufacturer, KCI Medical, has received research grants from Acelyty, is a member of the speakers' bureau for Acelyty, and has received payment for development of educational presentations from Acelyty. Another author disclosed that the study location (Bernard Mevs Hospital) was a past recipient of grant monies from the former MoMelan Technologies, which was the former holder of the epidermal harvesting technology (and was acquired by KCI in 2012).

Number of studies included

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the [HealthPACT web site](#).

Total number of studies: 5

Total number of Level IV studies: 5

Search criteria to be used (MeSH terms)

1. Epidermal harvest*
2. Epidermal graft*

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