

Proceedings of the Leaders in Wound Healing conference

SerenaGroup Research Foundation, New Orleans, 17–19 April 2023

The third annual Leaders in Wound Healing conference highlighted innovations in wound healing. The event featured key opinion leaders (KOL) from across the US. The conference began with one-on-one meetings: Tides Medical shared their latest innovations with the KOLs. Board members from the four major wound care societies (American Professional Wound Care Association, Association for the Advancement of Wound Care, American College of Clinical Wound Specialists, and American College of Hyperbaric Medicines) provided an overview of their vision of the future. For the remainder of the day, industry scientists and select physicians presented the latest evidence on a wide variety of technologies and shared challenges in commercialisation.

The patient experience

Naz Wahab, MD

Hard-to-heal (chronic) wounds affect nearly 2.5% of the US population, yet little is known about this demographic.¹ To gain a better understanding of the broader population, Wahab Consulting and Research conducted a 45-question survey among 780 Americans with non-healing wounds throughout 2022. Interestingly, 96% of the respondents were <65 years. Among other results, 75.5% did not have diabetes, 50% had no comorbid medical conditions, 61% were female, 61% were white, and 67% had limb wounds. The psychosocial impact was significant, with 65% experiencing negative self-thoughts and 60% reporting adverse effects on personal relationships. Despite this, only 4% reported having seen a wound care specialist, 25% experienced difficulty paying for care, and a third of patients reported changes to their spending habits to pay for wound care. These insights call for standardised wound care protocols, reassessment of preconceived notions about affected individuals, and funding for clinical trials reflecting a broader population. For leaders in wound healing, a deeper understanding of the demographics, psychosocial and financial impacts, and access to care can help wound care specialists be better advocates for affected patients, while reducing inefficiencies and waste across the healthcare industry.

Reference

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Economics of cellular and tissue-based products for wound care (CTP aka CAMPs)

William H Tettelbach, MD

A Medicare Limited Dataset (10/01/2015–10/02/2018) was used to retrospectively analyse individuals receiving care for a lower extremity diabetic ulcer (LEDU) treated with an advanced treatment (AT) or no advanced treatment (NAT). AT was defined as high-cost cellular, acellular, matrix-like products (CAMPs)¹ reported under Current Procedural Terminology (CPT) codes 15271–15278 and the applicable Healthcare Common Procedure Coding System (HCPCS) Q-code. The analysis included major and minor amputations, emergency department (ED) visits and hospital readmissions. In addition, AT following parameters for use (FPFU) was compared with AT not FPFU. FPFU, as corroborated by the Medicare data analysis, was defined as initiating AT within 30–45 days of the first episode of care and applying AT every 7–14 days.

1. In propensity-matched Group 1 (12,676 episodes per cohort):
 - AT patients had statistically fewer minor amputations ($p=0.0367$), major amputations ($p<0.0001$), ED visits ($p<0.0001$), and readmissions ($p<0.0001$) compared with NAT patients.²
2. In propensity-matched Group 2 (1131 episodes per cohort):
 - AT FPFU patients had fewer minor amputations ($p=0.002$) than those in the AT not FPFU group.²

An expanded retrospective analysis of Medicare data files from 2015–2019 was used to generate four propensity-matched cohorts of LEDU episodes to examine cost-effectiveness. Outcomes for dehydrated human amnion/chorion membrane (dHACM) and NAT, such as amputations, and healthcare utilisation were tracked from claims codes, analysed, and used to build a hybrid economic model, combining a one-year decision tree and a four-year Markov model, analysed from the healthcare sector perspective. The budget impact was evaluated using the difference in per member per month spending following completion of the decision tree. Likewise, the cost-effectiveness was analysed before and after the Markov model at a willingness-to-pay (WTP) threshold of \$100,000 per quality adjusted life year (QALY). Episodes treated with dHACM allografts FPFU had statistically fewer amputations and healthcare utilisation. In year one, dHACM FPFU provided an additional 0.013 QALYs while saving \$3670 per patient. At a WTP of \$100,000

Table 1. Cost-effectiveness of DHACM treatment in LEDUs

Cost-effectiveness results per patient			
	Year 1	Years 2–5	Years 1–5
Cost of DHACM, \$ USD	25,677	34,315	59,992
Cost of NAT, \$ USD	29,347	35,422	64,769
Cost of difference, \$ USD	(3670)	(1107)	(4777)
QALYs of DHACM	0.785	2.516	3.301
QALYs of NAT	0.772	2.481	3.252
QALY difference	0.013	0.035	0.049
ICER (\$/QALYs)	Dominant	Dominant	Dominant
NMB at \$100,000 WTP threshold, \$ USD	5004	4621	9625
Budget impact for 1 million members in Year 1, \$ USD			
Cost difference for 5980 people at risk ⁸			21,944,742
Cost difference per one million members in a health plan			21.94
Savings per member per month			1.83
DHACM—dehydrated human amnion/chorion membrane; ICER—incremental cost-effectiveness ratio; LEDU—lower extremity diabetic ulcer; NAT—no advanced treatment; NMB—net monetary benefit; QALY—quality adjusted life year; WTP—willingness to pay			

per QALY, the five-year Net Monetary Benefit was \$9625 (Table 1).³

Nonetheless, the true clinical and economic impact of CAMPs cannot be fully realised in the absence of good wound bed preparation prior to application of a CAMP. Prospectively collected data examining the quality of debridement and retrospectively analysed Medicare data examining the frequency of debridement supports routine adequate wound debridement. In patients who received debridement at intervals of seven days or less with concurrently applied dHACM, amputation rates dropped by 65% to the lowest levels identified among Medicare LEDU episodes (2.1%).⁴

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A novel offloading boot

Jason Hanft, MD

Total contact casting may be the gold standard for offloading in patients with a diabetic foot ulcer (DFU).

However, there are several factors that limit its use: expense; reimbursement; patient acceptance; the need for trained technicians; and the time required to place and remove a cast. Historically, the solution was to use fixed ankle walkers, but patients do not wear them. Why don't patients use these offloading devices? They are unsightly, bulky, uncomfortable, difficult to get on and off, and they interfere with normal daily activities. Dr. Hanft introduced a novel offloading boot, The Defender, that addresses the drawbacks of traditional offloading devices. Most importantly, The Defender effectively decreases pressure on the plantar foot. Its modern design is attractive. It is easy for patients to get on and off. Several of the KOLs at the meeting reported that patients like the boot which in turn increases adherence.

Advanced pathology solutions provide a polymerase chain reaction in bacteria detection

Richard Simman, MD

Detection of bacteria in the wound based on DNA amplification with polymerase chain reaction (PCR) is an interesting and promising technology, which will help wound care providers identify bacteria and treatment of choice in a short period of time. After obtaining a sample from the wound bed, whether from a swab or soft tissue culture, serial bacterial identifications and antibiotic sensitivity is provided within 24 hours, including yeast culture, which usually takes a few weeks to grow in culture. This is a helpful tool, especially for wound care providers without a background in infectious diseases and who may not be comfortable providing wide spectrum empiric antibiotic treatment while waiting for the final culture results.

Energy-based therapies

SANUWAVE Health Inc.

SANUWAVE Health, Inc. is an emerging leader in the development and commercialisation of energy transfer technology. SANUWAVE's ENERGY FIRST wound care portfolio includes dermaPACE and UltraMIST, both regenerative medicine, non-invasive technologies that help restore the body's natural healing processes.

dermaPACE is a non-invasive, shockwave therapy device that was shown to accelerate the healing of hard-to-heal wounds in clinical trials.¹ Shockwave therapy increases blood flow to the affected area. The device has been cleared by the US Food and Drug Administration (FDA) for the treatment of DFUs and is currently being evaluated for the treatment of other hard-to-heal wounds, including venous leg ulcers (VLUs) and pressure ulcers.

UltraMIST delivers low frequency (40kHz), nonthermal, ultrasonic energy without surface contact through a fluid medium. This creates an ultrasonic mist delivered to the wound bed. The energy continues into the depth of wound resulting in bacterial death, reduced inflammation and increased perfusion.

SANUWAVE is committed to advancing the field of wound care through ongoing research and development, and has an extensive pipeline of new products and technologies in various stages of development.

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Kerecis

Mark Suski, MD

Kerecis fish skin-derived grafts are versatile, durable and reliable. The grafts positively modulates all phases of wound healing. The rapid incorporation allows for early stage reconstruction or effective secondary intention healing. Fish skin grafts can be placed on all anatomic regions. Their naturally-occurring bacterial resistance allows for earlier application following aggressive debridement. Kerecis products can be used at all points of service, i.e., in the operating room, hospital ward, wound care centre, skilled nursing facilities, etc. It is particularly useful for complex scenarios involving exposed deep structures, including bone, tendon and hardware.

Authors' comment: Kerecis fish skin matrix is gaining in popularity and is being used by clinicians as a matrix replacement in wounds of different aetiologies and on any part of the body, with excellent outcomes.

MolecuLight

Globally, wound bacterial infection management presents a substantial human and economic challenge. Newer technologies have illuminated the extent of this challenge and reinforced the importance of objective diagnostics, and appropriate bacterial and biofilm management in wound care.

At the Leaders in Wound Healing meeting, there was discussion on how one heavily validated point-of-care diagnostic technology (MolecuLight) is addressing some of these challenges head on, including:

- Objective wound monitoring: MolecuLight can locate and track elevated bacterial loads/biofilm and wound size with an optimised, electronic medical record-integrated workflow. This eliminates the need for other cameras, and manual, inaccurate and slow measurement solutions
- Diagnostic inequality related to skin tone. Published evidence showed that standard clinical assessment underdiagnoses erythema and other signs and symptoms of wound infection in patients with dark skin tones.¹ Objective imaging of bacteria flagged patients with erythema/infection across all skin tones
- Reactive infection management. Earlier awareness and locational information on bacterial loads/biofilm enable proactive, local and targeted interventions.² The body of evidence supporting how fluorescence

imaging-informed approaches are preventing infection complications, healing wounds faster,^{3,4} and promoting more rational antibiotic use^{4–6} was discussed

- Monitoring debridement efficacy. Debridement under standard clinical practice frequently leaves behind pathogenic bacterial loads.^{7–10} Debridement treatment plans frequently change post-imaging towards a more extensive debridement procedure. Evidence for this across 200+ US facilities was discussed²
- Patient engagement and adherence. Patient survey data shows that patients were more likely to follow home care routines if educated using images, and were more likely to keep future appointments if they knew fluorescence imaging would be performed. Meeting attendees engaged in dialogue about how this has also been observed in their own clinical practice
- Patient access to diagnostic technology. Attendees discussed cost savings⁴ and a reimbursement pathway for facilities and clinicians for the MolecuLight-enabled procedure of non-contact real-time fluorescence imaging for bacterial presence, location and load.

With this multitude of benefits, many meeting attendees shared how their wound care facilities have incorporated the MolecuLight devices (i:X and DX) as standard of care (SoC). There was unanimous consensus that the devices enabled clinicians to achieve these significant benefits in terms of improved outcomes, cost savings, reduction in antimicrobial usage and reduction in adverse patient events.

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Natrox topical oxygen therapy

Windy Cole, DPM

While presenting 'The use of a topical oxygen therapy system to promote healing,' Dr. Cole shared the results of four studies that have added to the growing body of evidence supporting the use of topical oxygen therapy (TOT) as a promising therapeutic approach in wound care. The first study aimed to investigate the impact of continuous topical oxygen therapy (cTOT) on wound tissue perfusion, using a near-infrared spectroscopy (NIRS) device. In this case series, a group of five patients with hard-to-heal wounds received cTOT using NATROX O₂, all of whom displayed a weekly increase in oxygenated haemoglobin on NIRS imaging. The median baseline wound age prior to cTOT was 32 weeks, and the median baseline wound surface area was 8.95cm². The median time to wound healing using cTOT was 6.4 weeks, and all wounds healed within the 12-week study period.¹ This suggests that NATROX O₂ may be an effective therapy for improving tissue perfusion in patients with hard-to-heal wounds.

Referencing a second dataset, Dr. Cole discussed the 2021 randomised controlled trial (RCT) that compared the healing effects of using SoC to treat non-healing DFUs with the effects of using NATROX O₂ therapy plus SoC. At the 12-week study's completion, patients in the NATROX O₂ plus SoC group experienced a 71% higher healing rate and an average of 73% greater reduction in wound size compared with those receiving SoC alone.²

In addition to improved healing, there were two more studies shared which showcased the efficacy of NATROX O₂ with regards to durability and pain relief. Dr. Cole revealed in the third study, a follow-up study to the RCT, that 85% of the NATROX O₂ plus SoC group remained healed at one year compared with 60% of the group who received SoC alone.³ The fourth study presented showed the effects NATROX O₂ had on painful leg ulcers, where 76% of participants reported substantial and rapid pain reduction, and 69% were able to stop the use of their prescribed opioids.⁴

NATROX O₂ is the flagship product of NATROX Wound Care, a global medical technology company that specialises in developing innovative wound care solutions. The NATROX O₂ system is designed to improve wound healing by directly delivering a continuous flow of oxygen, an element required in all stages of wound healing.⁵

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Progenacare: synthetic matrix

Keratin is a crucial component of skin biology, providing strength to epidermal cells and creating a protective layer over the skin. Keratin also plays an important role in skin wound healing by regulating the inflammatory, proliferative and regenerative phases of healing. As such, this protein has been investigated in recent years as a material to assist in the healing of acute and, in particular, hard-to-heal wounds. A human keratin matrix (HKM) product was shown to heal wounds at a greater rate than other advanced wound care products in a db/db diabetic mouse model. This enhanced healing rate was shown to persist for up to two weeks with a single application of HKM. Physical contact with HKM showed an upregulation of keratinocyte expression of epidermal growth factor (EGF), insulin-like growth factor 1 (IGF1), angiogenin and vascular endothelial growth factor (VEGF), as well as dermal fibroblast expression of transforming growth factor beta 1 (TGFB1). Furthermore, HKM was shown to reduce the protease activity of matrix metalloproteinase 9 (MMP9), which may contribute to both its degradation resistance and its efficacy in wound healing.

ProgenaCare Global, LLC, makers of ProgenaMatrix, the first FDA 510(k) cleared human keratin matrix for wound healing, aims to bring highly effective wound care to everyone in a financially sustainable way. In several preliminary case series, ProgenaMatrix was shown to promote closure of previously hard-to-heal DFUs, VLU, and hard-to-heal wounds of other aetiologies. ProgenaCare Global is also partnering with makers of innovative anti-biofilm and offloading technologies to support the care of multiple wound types throughout their treatment course.

Sustainability of CAMPs: regulations, pricing and evidence requirements

Jennie Feight, Director, Health Policy, MiMedx

Skin substitutes, recently categorised as CAMPs, are used in wounds that have stalled in the healing process as per best practice among consensus experts.^{1–3} First in class CAMPs brought to market under 510K or PHS 361 regulations should show efficacy in order to be granted reimbursement—an appropriate but costly requirement of the initial manufacturer. All follow-on products require no evidence of efficacy, providing market price advantages to products with less rigor, and cost-conscious procurers can be in a race to the bottom. Noncompliance with Average Sales Price (ASP) reporting for CAMPs in the US resulted in >\$400 million USD in expenditure on 68 CAMPs product codes in just one quarter of 2022 alone (Fig 1). Feedback from the Office of the Inspector General encouraged the Centers for Medicare & Medicaid Services (CMS) to curtail runaway

pricing and CMS has proposed bundling the cost of the CAMP into the payment for the patient's visit.

Bundling CAMPs will likely have the greatest impact on larger complex wounds, driving patients out of poor socioeconomic locations to costly inpatient hospital admissions, or to no treatment at all if providers are not offered sufficient reimbursement. The existing payment model needs revision to ensure adequate patient access and sufficient reimbursement.

Patients need providers and regulators to ensure that the system provides quality healthcare while observing cost-effective principles. Reimbursement practices need to acknowledge appropriate usage of CAMPs among other price control mechanisms. All stakeholders including patients bear the impact of the suggested regulation changes.

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Convatec: InnovaMatrix

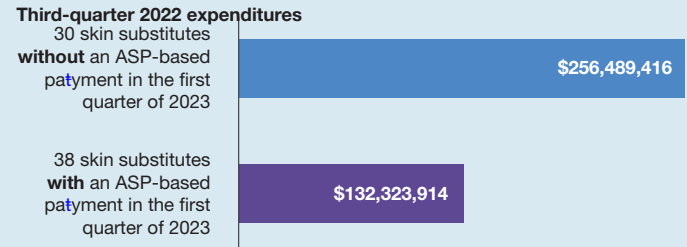
Chris Sabitino, PhD, Head of Research and Development, Triad (now Convatec)

Convatec's Advanced Tissue Technologies, formerly Triad Life Sciences, focuses on regenerative medicine and developing biologically-derived innovative products to address unmet clinical needs in surgical wounds, hard-to-heal wounds and burns. Regenerative medicine and biologically-derived therapies are frequently used to treat hard-to-heal wounds, which affect about 8.2 million Medicare patients each year in the US, according to Advances in Wound Care's May 2021 publication 'Human wound and its burden: updated 2020 compendium of estimates'. Founded in 2017, Triad Life Sciences, based in Memphis, US, was acquired in 2022 by Convatec Group Plc.

For more information about InnovaMatrix products, visit www.triadls.com and follow on LinkedIn ConvatecWound, on Twitter @ConvatecWoundUS and on Facebook @ConvatecInc.

Authors' comment: Clinical trials on Convatec's innovative porcine placental-derived extracellular matrix are underway. It was too early to discuss these at this year's Leaders meeting.

Fig 1. 30 skin substitutes (CAMPs) for which manufacturers did not report ASPs (blue bar) represented a disproportionate share of payments compared with 38 CAMP codes (purple bar).⁴ CAMPs—cellular, acellular, matrix-like products; ASP—average sales price



Wound cleansing: Urgo

Debashish Chakravarthy, PhD

Wound cleansing is understood to be an integral part of wound hygiene, and proactive wound cleansing is recommended on a frequent basis. In this context, the nature and chemistry of the cleanser used is expected to affect the health of the wound bed and the course of wound healing. An ideal cleanser has documented evidence on the removal of necrotic and microbiological debris from the wound, but without cytotoxicity associated with the cleanser. Newer technologies avoid the use of surfactants that can disturb cell walls.

There is also much in published literature on the importance of controlling the pH of the wound bed in a mildly acidic range because a low pH creates a hostile environment for pathogens. In this context, use of cytotoxic and highly alkaline products are to be avoided, particularly in a wound cleanser which is meant to be used repeatedly, sometimes more than once a day in some situations.

Vashe Wound Solution, marketed by Urgo Medical North America, contains the broad spectrum and highly effective antimicrobial preservative hypochlorous acid. Vashe has a pH that is always between 3.5–5.5 during storage and use over its entire shelf life. This tight pH range allows the hypochlorous acid to remain pure without contamination with hypochlorite which is associated with higher pH for chlorine-based cleansers. Much published evidence exists on the clinical benefit that can be expected when Vashe is used as directed. The product has no known contraindications and is safe for use on patients of all ages based on published clinical evidence.¹ **JWC**

Reference

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Thomas E Serena, MD; Richard Simman, MD; Naz Wahab, MD; Windy Cole, DPM

