Forward-Looking Statement

This presentation contains forward-looking statements and projections. PolarityTE, Inc., (the “Company”) makes no express or implied representation or warrant as to the completeness of this information or, in the case of projections, as to their attainability or the accuracy and completeness of the assumptions from which they are derived, and it is expected that each prospective investor will pursue his, her or its own independent investigation. It must be recognized that estimates of the Company’s performance are necessarily subject to a high degree of uncertainty and may vary materially from actual results. In particular, this presentation contains statements that constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements appear in a number of places in this presentation and include, but are not limited to, statements regarding the Company’s plans, intentions, beliefs, expectations and assumptions, as well as other statements that are not necessarily historical facts. The company commonly uses words in this presentation such as “will,” “may,” “plans,” “potential,” “preliminary,” “anticipates,” “believes,” “plans,” “expects,” “future,” “intends” and similar expressions to identify forward-looking statements and projections. You are cautioned that these forward-looking statements and projections are not guarantees of future performance and involve risks and uncertainties. The company’s actual results may differ materially from those in the forward-looking statements and projections due to various factors, including those set forth in the sections titled “Risk Factors” in our filing with the Securities and Exchange Commission (the “SEC”). The information contained in this presentation describes several, but not necessarily all, important factors that could cause these differences. Any forward-looking statement in this presentation reflects our current view with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.
A biotechnology company focused on transforming the lives of patients.

- We use a patient’s own cells to generate new tissue.
- State of the art research facility to develop products based on our platform technology
- Centralized manufacturing facility based in Salt Lake City, Utah
- Over 150 employees*

*as of November 2019
Company History

2015
First patent application filed

2016
Company formed

2017
SkinTE registered with FDA

2018
OsteoTE registered with FDA

2019
IBEX Pre-clinical CRO acquired

Formosa fire
Lab established at Research Park
First patient treated with SkinTE
PolarityTE Campus established

Granted Canadian Patent
PolarityTE manufactures products that take advantage of innate cellular micro-aggregates which contain progenitor cells that maintain the ability to regenerate structural tissues.
How to Use SkinTE

- First FDA-registered product capable of regenerating functionally normal skin
- Shown to regenerate full thickness skin with all layers (epidermis, dermis and hypodermis) and appendages (hair follicles and sebaceous glands)
- SkinTE has produced function (sensation, sweat and pliability) and histology comparable to native skin, with limited contracture
Skin is much more than a single layer of cells providing a barrier—skin is the largest organ of the human body and requires regeneration of all components for normal function.

- Sensation
- Immunity
- Sweating
- Sebum
- Hair growth
- Pliability
Current Treatment Options

Scaffolds & Matrices—No Cells
- Lack living cells
- Limited ability to regenerate tissue
- Typically require secondary coverage with skin grafts

Allogeneic/Xenogeneic Cells & Tissues
- Risk of immune system rejection of foreign cells and tissue
- Can result in scarring
- Frequently require additional surgery to achieve full wound coverage

Split-Thickness Skin Grafts
- Skin is more than keratinocytes and fibroblasts
- Replaces only the top layer of skin, not the appendages
- Healed barrier that contracts and scars with limited/no function

Full-Thickness Skin Grafts
- Cannot be expanded
- Limitations in size of donor site
- Can only reconstruct small areas
Split-Thickness Skin Graft Donor Sites

Split-Thickness Skin Graft Harvesting

Skin Graft Donor Site After 2 Years Following Harvest
SkinTE Regenerates Functional Skin

SkinTE Applied to Chronic Wound on Right Lower Extremity (RLE) After Two Years of Failed Treatments

Right Leg: Before SkinTE  Right Leg: After SkinTE  Left Leg: STSG

No Difference in Sensation Between SkinTE (Right Leg) and Native Skin

Hair Follicles Regenerated from SkinTE Demonstrated Normal Cellular and Structural Architecture

Multi-Modality Imaging of Hair Follicles

SkinTE Treats a Broad Spectrum of Wounds

Pre-treatment

SkinTE Applied to a Diabetic Foot Ulcer

~8 weeks after a single application of SkinTE

SkinTE Applied to a Venous Leg Ulcer

Pre-treatment

~7 weeks durability follow-up
(Closed 22 days after single application of SkinTE)
SkinTE Treats a Broad Spectrum of Wounds

Diabetic Foot Ulcer
Initial Wound
~7 weeks after single application of SkinTE
~9 weeks after single application of SkinTE

Venous Leg Ulcer
Initial wound
~13 weeks after single application of SkinTE

Chronic Wound
Initial wound
~6 months after single application of SkinTE

Acute Wound
Initial wound
~13 weeks after single application of SkinTE

www.PolarityTE.com
SkinTE Treats a Broad Spectrum of Wounds

Pressure Sores – Sacral Ulcer
- Initial wound
- ~9 weeks after single application of SkinTE
- 24 weeks after single application of SkinTE

Traumatic Injury – Lawnmower Accident
- Initial wound
- ~14 weeks after single application of SkinTE

Traumatic Injury – Motor Vehicle Accident
- Initial wound
- ~20 weeks after single application of SkinTE

Burn
- Initial wound
- ~9 weeks after single application of SkinTE
SkinTE Treats a Broad Spectrum of Wounds

Chronic Recurring Wound
- Initial wound
- ~11 weeks after single application of SkinTE
- ~24 weeks after single application of SkinTE

Amputation Wound
- Pre-treatment
- ~20 weeks after single application of SkinTE

Burn Reconstruction
- Post-debridement
- ~13 months after single application of SkinTE

Post-Mohs Reconstruction
- Initial wound
- ~4 weeks after single application of SkinTE
# SkinTE Clinical Trials in Chronic Wounds

<table>
<thead>
<tr>
<th>Trial</th>
<th>Study description</th>
<th>Study Size</th>
<th>Primary endpoint</th>
<th>Enrollment Status</th>
<th>Status/ Outcomes</th>
</tr>
</thead>
</table>
| 1     | Multicenter, randomized controlled trial evaluating SkinTE vs standard of care (SOC) in treatment of diabetic foot ulcers (DFU) Study Chair: Dr. David G. Armstrong, Professor of Surgery at USC and founder of Southwestern Academic Limb Salvage Alliance | 102 patients | Percentage of ulcers closed at 12 weeks (endpoints also include potential cost effectiveness of SkinTE) | Actively enrolling | • Interim analysis planned at 50 patients  
• Listed on [https://clinicaltrials.gov](https://clinicaltrials.gov)  
• NCT03881254 |
| 2     | Multicenter, randomized controlled trial evaluating SkinTE vs SoC in treatment of venous stasis ulcers (VLU) Study Chair: Dr. David G. Armstrong, Professor of Surgery at USC and founder of Southwestern Academic Limb Salvage Alliance | 102 patients | Percentage of ulcers closed at 12 weeks (endpoints also include potential cost effectiveness of SkinTE) | Actively enrolling | • Interim analysis planned at 50 patients  
• Listed on [https://clinicaltrials.gov](https://clinicaltrials.gov)  
• NCT03881267 |
Venous Leg Ulcer (VLU) Pilot Trial

Results presented at the Symposium on Advanced Wound Care

- 8 of 10 (80%) VLUs closed within 12 weeks of a single application of SkinTE
- Median time to closure was 21 days
- Of the 2 VLUs not deemed closed within 12 weeks: 1 VLU was the largest in the study (12.2cm²), and closed within 13.5 weeks post a single application of SkinTE; 1 VLU was previously deemed closed, and reopened prior to the 2-week durability visit as a result of external factors unrelated to the SkinTE procedure
- No SkinTE-related adverse reactions

Diabetic Foot Ulcer (DFU) Pilot Trial

Results presented at the Diabetic Limb Salvage Conference and the Symposium on Advanced Wound Care and The American Diabetes Association

- 10 of 11 (90.9%) DFUs healed within 8 weeks of a single application of SkinTE
- Median time to closure was 25 days
- DFU sizes ranged from 1.0 to 21.7 cm²
- One patient was removed from the study at week three due to adverse events not related to the study or SkinTE procedure
- No SkinTE-related adverse reactions

Venous Leg Ulcer (VLU) Pilot Trial

Results presented at the Symposium on Advanced Wound Care

- 8 of 10 (80%) VLUs closed within 12 weeks of a single application of SkinTE
- Of the 2 VLUs not deemed closed within 12 weeks: 1 VLU was the largest in the study (12.2cm²), and closed within 13.5 weeks post a single application of SkinTE; 1 VLU was previously deemed closed, and reopened prior to the 2-week durability visit as a result of external factors unrelated to the SkinTE procedure
- Median time to closure was 21 days
- No SkinTE-related adverse reactions

* See appendix for full-size posters
SkinTE Clinical Trial in Traumatic Wounds

Prospective Lower Extremity

SkinTE Clinical Trials in Burn Wounds

Head-To-Head Burn

Prospective Burn

Generated TD
Next 12 Months
Scientific Recognition

- Peer Reviewed Publication in International Wound Journal
- Peer Reviewed Publication in Clinical Case Reports
- Peer Reviewed Publication in Plastic Surgery Case Studies (in press)

- 64 SkinTE abstracts accepted for presentation at healthcare, scientific and clinical conferences around the world*
  - 30 SkinTE abstracts accepted for podium presentations
  - 34 SkinTE abstracts accepted for poster presentations

- 15 Patient case series accepted as a Top 200 Abstract and podium presentation at American Society of Plastic Surgery – The Meeting 2019 and published in PRS - Global Open

- SkinTE named a Top 10 Innovation by Podiatry Today journal

- Article on SkinTE published in The Dermatologist journal

- DFU Pilot data published in Diabetes Watch column in Podiatry Today journal

- Diabetic Foot Ulcer Pilot Interim Analysis designated as “Top Abstract” at Diabetic Limb Salvage Conference in Washington, DC

- DFU Pilot data accepted as Late Breaking Abstract for presentation at The American Diabetes Association 79th Scientific Sessions in San Francisco, CA

- VLU Pilot Study Data received the “Highest Scoring Abstract Award” at SAWC – Fall 2019 (Las Vegas, NV)

*Numbers from September 2018 – November 2019
Defining the US Market

Venous Leg Ulcers (VLUs)

- Prevalence: 600k
- ~200-360k

Diabetic Foot Ulcers (DFUs)

- Prevalence: 30.3mm
- ~1.2-1.0mm
- ~1.0-2.5mm

Pressure Ulcers (PUs)

- Prevalence: 2.5mm
- ~670k
- ~515k

*Conventional Treatment* comprised debridement, saline-moistened gauze, and pressure-relieving orthotics with custom-fitted special shoes and custom inserts.

- Prevalence of Venous Ulcers in the United States
- Amount of Venous Ulcers Persistent For More than 6 Weeks (Referred to as “Chronic”)*
- People in the U.S. With Diabetes
- Diabetics with DFUs
- Patients with DFUs Following 12 Weeks of Conventional Treatment
- Estimated Number of Individuals to Develop Pressure Ulcers Annually
- Admitted Patients to Hospitals with 1 or More Pressure Ulcers
- Patients with Pressure Ulcers Applicable to SkintE (Stages II-IV)
Defining the US Market

Burns

- Incidence: 486k
  - Burn Injuries Receiving Medical Treatment (FY15)
  - Yearly Hospitalizations Related to Burn Injury

Wounds From Surgical Procedures

- Incidence: ~23mm
  - Number of Cardiovascular, Digestive, Urinary, Musculoskeletal, and Integumentary In-Patient Surgeries Per Year
  - Average Dehiscence Among Inpatient Surgeries
  - Dehiscence Requiring Surgical Intervention

- Incidence: ~120-350k
- Incidence: ~230-680k

Trauma

- Incidence: ~1.7mm
  - Inpatient Traumatic Injuries Per Year
  - Total Inpatient Trauma Cases Resulting in Open Wounds

Dehiscence: "The separation of a surgical incision or rupture of a wound closure."
SkinTE Commercialization

SkinTE
Autologous Homologous Skin Construct

Preclinical → Proof Of Concept → Commercial


Chronic Wounds: Advance clinical evidence
Trauma Wounds: Increase market awareness
Burn Wounds: Work with thought leaders and clinical advisors
SkinTE Was Designed to Reduce Barriers and Increase Availability of Regenerative Treatments

Broad Utilization:
- Surgeons
- Medical Doctors
- Podiatrists
- Physicians Assistants
- Nurses/Nurse Practitioners

Broad Applications To Date:
- Acute wounds
- Chronic wounds
- Traumatic injuries
- Acute burns
- Burn reconstruction
- Scar revision
- Surgical reconstruction
- Replacement of skin grafts

Broad Implementation:
- Wound care centers and clinics
- Physician offices
- Inpatient bedside and ICU
- Inpatient and outpatient operating rooms
Reimbursement

**Hospital Inpatient:**
- Bundled DRG payments

**Outpatient Settings:**
- Bundled facility payments

**Physician Office:**
- Procedure and product payments
Pipeline

SkinTE Cryo
Cryopreserved SkinTE

SkinTE Point of Care
Point of Care SkinTE Device

PTE 11000
Bioactive Dressing

Preclinical Proof Of Concept Trial Commercial

Generated TD Next 12 Months
OsteoTE™ Registered with the FDA in 2018

Load-Displacement Biomechanical Testing

*Pre-Clinical
Financial Snapshot

• Cash, cash equivalents and short-term investments were $45.9 million as of September 30, 2019
• ~27M shares outstanding as of November 8, 2019
• Products segment achieved 62.5% gross profit margin in 3Q 2019 primarily due to a reduction in direct manufacturing costs*

* Direct manufacturing costs is a component of cost of sales consisting of materials, freight and labor.
Management Team

Office of the Chief Executive

David Seaburg
President

Richard Hague
Chief Operating Officer

Paul Mann, CFA, MEng, MA (Cantab)
Chief Financial Officer

Stephen Milner, MD, DDS, DSc, FACS
Chief Clinical Officer

Edward Swanson, MD
Chief Translational Medicine Officer & Co-Founder

Nikolai Sopko, MD, PhD
Chief Scientific Officer & Vice President R&D

Caroline Garrett, DVM, DACLAM
Chief Veterinary Officer

Jennifer Burdman, JD
Chief Intellectual Property Officer & Deputy General Counsel

Cameron Hoyler, JD
Executive Vice President Development & Strategy General Counsel

Ivy Estabrooke, MS, PhD
Vice President of Corporate & Government Programs

Richard Hague
Chief Operating Officer
Board of Directors

Peter Cohen, MBA
Chairman of the Board
- Former Board Member of the NYSE
- Former Chairman of Shearson Lehman Hutton, Inc.
- Former Chairman and CEO of Cowen Inc.
- Vice-Chairman and Lead Director of the Board of Directors of Scientific Games Corporation
- Federal Reserve International Capital Markets Advisory Committee

Minnie Baylor-Henry, JD
Director
- Former Johnson & Johnson Worldwide Vice President of Regulatory Affairs for Medical Devices, Vice President of U.S. Regulatory Affairs and Medical Affairs for Specialty Pharmaceuticals
- Served for nearly a decade at the U.S. Food and Drug Administration
- Past Chair of the Food and Drug Law Institute and the Drug Information Association

Willie Bogan, JD, MA
Director
- Previously Associate General Counsel and Corporate Secretary of McKesson Corporation
- Stanford Law School JD
- Rhodes Scholar, Oxford University MA in Politics and Economics
- Dartmouth College Phi Beta Kappa and Summa Cum Laude

Ramses Erdtmann
Director
- Managing Partner at Point Sur Investors
- Grew Pharmacyclics from 47 employees, & market cap of $20 Million, to 634 employees & market cap of $21 Billion
- Remained with AbbVie as a consultant until 2016 post the acquisition of Pharmacyclics by AbbVie

Jeff Dyer, MBA, PhD
Director
- Horace Beesley Professor of Strategy at Brigham Young University & the Wharton School, University of Pennsylvania
- Internationally recognized strategy & innovation expert
- Author of business bestsellers Innovator’s DNA & The Innovator’s Method
- Most published strategy scholar in Harvard Business Review

Jon Mogford, PhD
Director
- Vice Chancellor for Research, Texas A&M University System: 11 universities, 7 state agencies, 30K faculty, 135K students, $945M annual budget
- Former Deputy Director of the Defense Advanced Research Projects Agency (DARPA), Defense Sciences Office (DSO)
Welcome to the Shift®

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VP of Investor Relations
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Appendix
SkinTE: FDA Registered Through 361 HCT/P Pathway

- Minimally manipulated
- Autologous – from the patient, for the patient
- Homologous – skin for skin
- Manufacture must not involve combination with another article, except for water, crystalloids or a sterilizing, preserving or storage agents
- 361 HCT/P products are subject to post-market regulatory requirements including compliance with current good tissue practices cGTP, adverse reaction reporting, and post-market FDA inspections
- The FDA closed out the July 2018 inspection of the PolarityTE Salt Lake City, UT manufacturing facility and classified the inspection as Voluntary Action Indicated, or "VAI."

* Based on FDA’s definitions regarding its inspection classifications, a VAI classification means that while FDA found and documented certain conditions during its inspection, FDA is not prepared to take or recommend administrative or regulatory action with respect to such inspectional observations.
Where Skin Grafts Fail

SkinTE Following Replacement of Split-Thickness Skin Graft in Fibrotic Wound Bed

Conducting pinch test of SkinTE at 6 months

Excision of skin graft

2 weeks post-op

4 Weeks Post-Op

6 weeks post-op

Punch biopsy of SkinTE-regenerated skin depicts all layers of full-thickness skin and appendages

Rete pegs located at epidermal/dermal junction prevent shear skin
Chronic Wound

SkinTE Applied to Chronic Wound on Right Lower Extremity (RLE) After Two Years of Failed Treatments

2-year-old chronic refractory wound on right lower extremity

Right lower extremity ~12 weeks after single application of SkinTE

2-year-old previously placed skin graft on left lower extremity
“If I had to choose between SkinTE and another skin graft, I would choose SkinTE every time, because it is actually working, and you do not have a huge area of healthy skin removed that also then needs to heal, like with traditional skin grafts.”

—Devon, a SkinTE Patient
Feedback from Patients, Providers and Thought-Leaders

“My skin is smooth. The hair is actually growing back. It doesn’t itch.”

—Natasha, Burn Survivor and SkinTE Patient

“The science and clinical application of regenerative products is a major emphasis at Rutgers. Thus far, I have used SkinTE in a variety of clinical settings. The capacity of this product to regenerate a skin that functionally resembles normal skin is very impressive.”

—Mark Granick*, MD

“I believe in this product, and I’m excited about its potential in treating some of our wounded heroes, especially burn victims.”

—Jay W. Hood*, Retired U.S. Army Major General

*A consultant/clinical advisor for PolarityTE
Closure of refractory diabetic foot ulcers and venous stasis leg ulcers using a single application of an autologous homologous skin construct in the clinic setting

David G. Armstrong1,2, Dennis Orgill1, Robert Galiano4, Paul Gat3, Charles M. Zelen6

1 Southwestern Academic Limb Salvage Alliance (SALSA), Los Angeles, CA; 2 Keck School of Medicine, University of Southern California, Los Angeles, CA; 3 Division of Plastic Surgery, Brigham and Women’s Hospital, Boston, MA; 4 Division of Plastic & Reconstructive Surgery, Northwestern University Feinberg School of Medicine, Chicago, IL; 5 Drexel University School of Medicine, Philadelphia, PA; 6 Professional Education and Research Institute, Rome, VA

Corresponding Author – czelen@peri.org

Introduction

Clinical lower extremity wounds including diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) represent a continuing burden on the health care system, which are often resistant to standard of care treatments combined with advanced wound therapy. Recent outcomes in autologous wound therapy have shown a significant benefit of wound care with the use of an autologous homologous skin construct (AHSC) using the patient’s own allogenic keratinocyte and dermal cell population in close collaboration to treat wounds. AHSC is a bioceramic and cell-based product derived from a patient’s own skin in regenerative 1:1 biolayers, structurally-optimized skin with all of the layers, in the clinic setting. In this pilot study, 11 patients with diabetic foot ulcers and 5 venous stasis leg ulcers treated with AHSC were evaluated, all being subjects to at least 6 months of non-surgical care.

Methods

Following informed consent, a 1.5-cm piece of full-thickness skin was harvested from the proximal calf in the clinic setting and sent to the manufacturing facility where the entire harvest was processed into AHSC and returned to the provider within 61 hours. Donor sites were closed primarily. In the clinic setting, wounds were debrided and AHSC was deployed evenly and dressed with a sterile dressing and secured to place with dressing strips and supported with an absorbent foam covered by a compaction dressing (Figure 1). The patients returned for weekly dressing changes per routine and dressing progression was documented with digital photography for all patients, who were post-wound closure during daily clinical checks (Figure 2).

Results

In this pilot study, 11 patients with Wagner 3 and Wagner 4 wounds and 5 VLU wounds culminating in schedule dressing were treated with a single application of AHSC. DFU wounds were located on the heel, plantar, and lateral foot, while locations of the foot, VLUs were located on the calf and shin. 10 of 11 DFU wounds and 5 of 5 VLU wounds demonstrated progressive re-epithelialization and wound closure in 21 days after a single application of AHSC and the wounds remained closed as observed during 26-week follow-up visits. A patient with prior lower extremity hardware developed an infection and was re-treated with the AHSC-treated wound requiring extensive re-infection including the DFU treated with AHSC. All full thickness skin closed over wounds remained closed with minimal/excisions. 10 of the 11 DFU wounds were closed, and full-thickness skin was re-epithelialized at 60 days.

AHSC Workflow for Clinic Setting

DB4 of Right Leg (1.3 cm² defect)

DB4 of Left Heel (1.7 cm² defect)

VLU of Left Ankle (12.2 cm² defect)

VLU of Left Calcaneal (3.3 cm² defect)

VLU of Left Shin (2.9 cm² defect)

Conclusions

AHSC successfully closed DFUs and VLUs refractory to dressing care with a single application. This clinical pilot study illustrates a new and unique approach to dermatologic conditions with controlled microenvironment to deliver a viable clinical efficacy in a non-surgical wound healing therapy for diabetic lower extremity wounds.

Disclosures

The Professional Education and Research Institute, whose medical director is Charles F. Annino III, receives research funds from PolleyTEC, Inc. to administer clinical trials. David Armstrong, MD, PhD is the principal investigator of PolleyTEC sponsored clinical research. Therefore, Dr. Armstrong is associated with the company, which has an economic interest in the work described. This conflict of interest is related to wound closure and skin regeneration. Additionally, certain of the authors report financial relationships with PolleyTEC, Inc. and Agilis Danum, Inc. (a company acquired by PolleyTEC).
Late Breaking: Results of a Pilot Evaluation of a Novel Autologous Homologous Skin Construct Treatment of Diabetic Foot Wounds Refractory to Conventional Treatments

David G. Armstrong12, Dennis Orgill3, Robert Galiano4, Paul Glä4, Charles M. Zelen5
1Southwestern Academic Limb Salvage Alliance (SALSA), Los Angeles, CA. 2Keck School of Medicine, University of Southern California, Los Angeles, CA. 3Division of Plastic Surgery, Brigham and Women’s Hospital, Boston, MA. 4Division of Plastic & Reconstructive Surgery, Northwestern University Feinberg School of Medicine, Chicago, IL. 5Drexel University School of Medicine, Philadelphia, PA. 6Professional Education and Research Institute, Rockville, VA.

Introduction
Diabetic foot wounds (DFUs) are one of the most common complications associated with diabetes. Diabetic patients have a 50-50% lifetime risk of incurring lower extremity lesions. In recent years, the incidence of DFUs has increased, and these wounds can be challenging to heal. DFUs are associated with an increased risk of amputation. DFUs are a major public health problem, and the burden of DFUs is enormous. Efforts to develop effective and safe therapies for DFUs have been limited by the complexity of the wound and the underlying pathophysiology. In this study, we evaluated the safety and efficacy of a novel autologous homologous skin construct (AHSC) treatment for DFUs.

Methods
A total of 4 patients with DFUs were enrolled in a pilot study. The patients had DFUs with a variety of clinical presentations. The AHSC construct was created using the patient’s own skin and homologous skin. The AHSC was implanted into the wound site, and the wound was monitored for healing. The patients were followed up for 6 months post-treatment.

Results
All-wound sites healed within 12 weeks. At 12 weeks, the wound size was significantly reduced. The healing rate was 90% at 12 weeks. The patients reported significant improvement in wound healing and quality of life.

Conclusions
The AHSC treatment was safe and effective for the treatment of DFUs. The results of this pilot study support further investigation of AHSC treatment for DFUs. Additional studies are needed to evaluate the long-term outcomes and the cost-effectiveness of AHSC treatment.

References

Disclosures
The Professional Education and Research Institute, whose medical director is Charles Zelen, DPM, FACDFI, received research funds from PolarityTE, Inc. No other financial disclosures.
Pilot Study Assessing Novel Autologous Homologous Skin Construct Treatment of Venous Stasis Leg Ulcers

David G. Armstrong1,2, Dennis Orgill3, Robert Galiano4, Paul Glat5, Charles M. Zelen6

1Southwestern Academic Limb Salvage Alliance (SALSA), Los Angeles, CA; 2Keck School of Medicine, University of Southern California, Los Angeles, CA; 3Division of Plastic Surgery, Brigham and Women’s Hospital, Boston, MA; 4Division of Plastic & Reconstructive Surgery, Northwestern University Feinberg School of Medicine, Chicago, IL; 5Drexel University School of Medicine, Philadelphia, PA; 6Professional Education and Research Institute, Romulus, VA

Introduction

Thrombosis is a major contributor to a significant burden on the worldwide healthcare system and is often refractory to standard treatments. VLU’s have a high remission rate, 60% to 70% with the highest rates of recurrence occurring within the first 3 months after healing, leading to elevated costs of care and may potentially reduce the risk of novel endogenous homologous skin construct (AHSC), which is a viable option to standard treatment. A critical haven of healthy NIH-Fibroblasts skin containing appropriate number of collagen fibers,2 was evaluated for the treatment of VLU’s as an open-label single-arm pilot study in an attempt to design a larger randomized controlled trial NCIT51582757.

Methods

10 VLU’s, all being refractory to at least 6 months of prior dressing care were signed with a single application of AHSC. A pre-treatment skin biopsy was harvested from the pretreatment callus collected in the clinic and sent to an NIH-registered facility where it was processed into AHSC and returned to the provider within 3 hours. AHSC was wound evenly across the wound bed and wrapped with non-adherent, non-adhesive dressing. All wounds received full compression dressing. Bandaging was discontinued with digital photography and 20% dressing changes during weekly dressing changes. Wound closure was verified by a panel of blinded adjudicators following an initial closure documentation. Bill approval for retrospective reporting was obtained (WGR212679).

Results

The project (9 cases, 90%) with a mean age of 60 years (standard deviation [SD] 10, range 51-77) were consecutively sampled and enrolled into the study. Nine patients (90%) were White and 1 (10%) was Hispanic. The mean pre-treatment skin biopsy width was 112.8 mm (SD 53, range 32-202). Eight patients (80%) had a known history of diabetes mellitus type II. Patient’s skin color was normal at baseline. Each patient received a single application of AHSC. All biopsies showed viable and thick, healthy NIH-Fibroblasts skin containing appropriate number of collagen fibers. A specific patchwork of AHSC was selected for each individual site based on wound size and condition. All wounds received full compression dressing. Bandaging was discontinued with digital photography and 20% dressing changes during weekly dressing changes. Wound closure was verified by a panel of blinded adjudicators following an initial closure documentation. Bill approval for retrospective reporting was obtained (WGR212679).

AHSC Workflow for Clinic Setting

- The NIH-Fibroblasts harvested (3 to 5 cm2 per skin) are maturated and manufactured into AHSC.
- AHSC is returned in 24 hours back to the provider.
- AHSC is designed to work with each individual provider’s methodology and can be returned within 4 days of the harvest of the provider’s patient.

Dressing Protocol

- Pain Dressing
- Offloading
- Soft Wrap
- Constricting Bandages/ Wound Closure

Healing Progression VLU’s Treated with Autologous Homologous Skin Construct

Baseline

Patient 4

42 Days Post-AHSC

Patient 5

7 Days Post-AHSC

42 Days Post-AHSC

11 Days Post-AHSC

41 Days Post-AHSC

Patient 6

11 Days Post-AHSC

32 Days Post-AHSC

Patient 7

32 Days Post-AHSC

Day 0

Day 9

Day 14

Day 20

Disclosures

The Professional Educators and Research Institute, where Medical Director Charles M. Zelen, FACPS, EMT-CC, conducted research support from PolytetraFluoroEthylene (PTFE) and recognized research support from Aesthetics Medical Inc. to advance this clinical pilot and the randomized controlled trial methodology. All authors are familiar involved with the pilot and mechanisms controlled trial currently occurring tonight. PolytetraFluoroEthylene is in providing this criteria. The ordering would like to thank Dr. Mattor and Cristiano Serafino, for their contributions with statistical analysis.

References

About SkinTE™

SkinTE is a human cellular and tissue-based product derived from a patient’s own skin (autologous) intended for the repair, reconstruction, and replacement of skin tissue. SkinTE is intended to be used by medical professionals for homologous uses of skin tissues/integument. Aseptic surgical procedures and handling during skin harvest, wound preparation and SkinTE deployment are mandatory.

Important Safety Information

Failure to ensure proper aseptic technique may result in contamination of the tissue product and wound bed. Contamination of the tissue product and/or wound bed due to failure to ensure aseptic technique could result in local, regional, or systemic infection, partial or complete failure of graft take, healing, and/or regeneration, and/or serious injury. Failure to follow instructions may lead to sub-optimal outcomes and/or product failure. Pathology that would limit the blood supply and compromise healing, nonvascular surgical sites, and general medical condition should be considered when selecting patients for SkinTE. Such conditions may compromise successful outcomes or lead to sub-optimal results.

Potential adverse effects may include but are not limited to the following: local tissue, wound bed, regional tissue, or systemic infection, hypersensitive, allergic, or other immune response to the product or trace amounts of antibiotic retained from primary harvest, deleterious effects on potential surrounding or adjacent autologous, allogeneic, or xenogeneic grafts, skin substitutes, or other reconstructions including infection and/or failure of adjacent grafted material to take and heal, requirement for further surgical operations(s) and/or debridement.