

Delivering Accuracy, Consistency and Security for LifeNet Health



Name: LifeNet Health

Location: Virginia Beach, Virginia, USA

The Study: A Multicentre, Randomized, Controlled, Open Label Trial of DermACELL in Subjects with Chronic Wounds of the Lower Extremities

Purpose: To compare treatment with DermACELL to conventional care in diabetic foot ulcers (DFU).

Timeframe: 24 weeks

Phase: 4

Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Intervention Model: Parallel Assignment

Masking: Open Label

Primary Purpose: Treatment

About DermACELL

DermACELL is made from donated human skin. DermACELL has been processed so that cells are removed and bacteria and viruses are destroyed. This processing provides a supporting structure, an acellular dermal matrix, into which cells can migrate and initiate the wound healing process.

In the largest and most rigorous randomized control trial to date for human Advanced Dermal Matrix (ADM) products, DermACELL® AWM™ (Advanced Wound Management) demonstrated superior rates of healing and wound closure in diabetic foot ulcers.

In 2013, LifeNet Health began a 13-site interventional study of its DermACELL product with 203 patients (168 diabetic foot ulcers and 35 venous leg ulcers). DermACELL is a human decellularized regenerative tissue matrix allograft processed using proprietary MATRACELL® technology produced by LifeNet Health.

The ARANZ Medical Silhouette system was used to measure and document the treatment effects of DermACELL and conventional care in subjects with diabetic foot ulcers and a small number of venous stasis ulcers. In addition, DermACELL was compared to an active comparator, GraftJacket®, in subjects with diabetic foot ulcers.

“...we wanted to ensure that we had reliable, consistent measurements from all of our sites. Silhouette was the best system available to ensure that the wound measurements we were recording across all of our 13 sites were accurate, consistent and securely documented.”

— Kimberly Dorsch, Sr. Manager, Clinical Affairs, LifeNet Health

“The benefits of using Silhouette have been enormous for us. We have been able to accurately provide detailed measurements across all of our research sites, export the data when we needed it, and the secure database of images and measurements enables all clinicians to see how the wounds are healing without compromising patient confidentiality.”

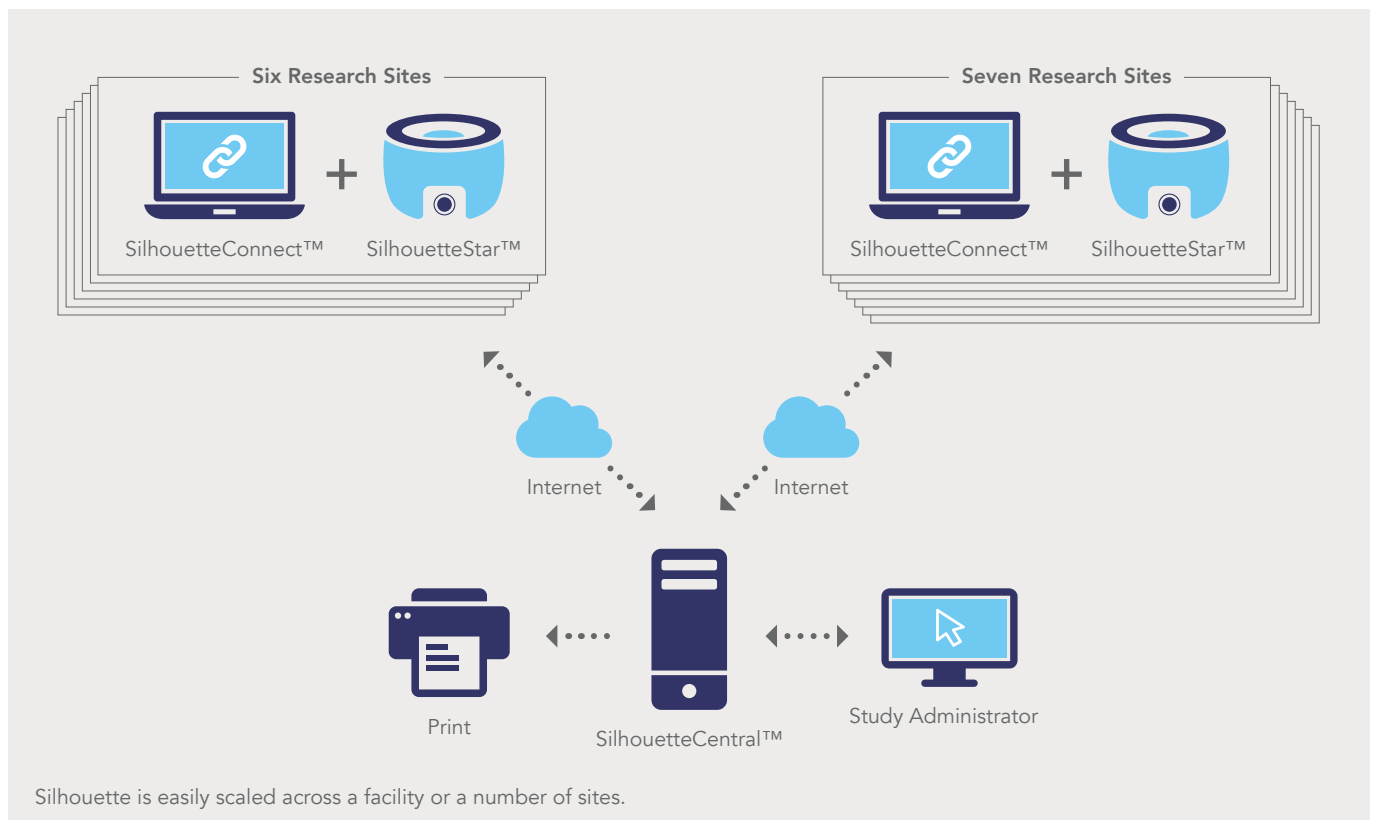
— Kimberly Dorsch, Sr. Manager, Clinical Affairs, LifeNet Health

Documenting the Study

The Silhouette system used by LifeNet included the SilhouetteStar imaging devices and software, which uses a non-invasive laser technology to provide 3D measurements of the wounds. The Silhouette system also includes the SilhouetteCentral database to analyse and securely store the images and information captured throughout the study.

LifeNet Health chose Silhouette as their preferred wound imaging, measurement and records system for their DermACELL study because it enabled them

to provide consistency across all of their trial sites, no matter who was doing the recording. Kimberly Dorsch, Sr. Manager, Clinical Affairs from LifeNet Health says, “Each clinician has his/her own way of measuring wounds. This added an unwanted variable and challenge to a successful study execution. For this study we wanted to ensure that we had reliable, consistent measurements from all sites. Silhouette was the best system available to ensure that the wound measurements we were recording across all of our 13 sites were accurate, consistent and securely documented.”





Treatment with DermACELL AWM



Healed at Week 12

The Benefits

Ms Dorsch says, "The benefits of using Silhouette have been enormous for us. We have been able to accurately provide detailed measurements across all of our research sites, export the data when we needed it, and the secure database of images and measurements enables all clinicians to see how the wounds are healing without compromising patient confidentiality."

The system's ease of use was also key to the success of the study. "The investigators found it easy to use the Silhouette system, and the training and support provided by ARANZ Medical was outstanding," said Ms Dorsch.

The Results

This study demonstrated superior healing rates for DermACELL over conventional wound care.

At the 12 weeks post-procedure primary endpoint, the one application DermACELL subjects demonstrated a significantly greater proportion of completely closed wounds than subjects who received conventional care (65.0% vs. 41.1%; $p= 0.0242$). Furthermore, at the

final 24 week post-procedure endpoint, a significantly greater healed ulcer rate was observed for one application DermACELL subjects compared to those receiving conventional care (89.7% vs. 67.3%; $p= 0.0130$).

DermACELL AWM is now available through an exclusive agreement with Novadaq Technologies, Inc. The product has been implanted over 10,000 times since its inception.

About LifeNet Health

LifeNet Health is a non-profit global leader in regenerative medicine. It is the world's largest provider of bio-implants and organs for transplantation whose mission is saving lives and restoring health by advancing the field of tissue engineering. Their tissue grafts are clinically proven in more applications than any other allograft bio-implant provider, making them the world's most trusted provider of transplant solutions, from new innovations in tissue grafts and technologies, to regenerative medicine and cellular therapies.

About Silhouette

Silhouette is an easy-to-use wound surveillance system that supports accountable, evidence-based, and standardized assessment of wounds.

The system includes an imaging device that precisely and consistently measures the area, depth and volume of wounds and their healing progress, and software to store and manage wound informatics. It enables wound assessment activity to be monitored, providing wound information that is available instantly to key stakeholders.

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