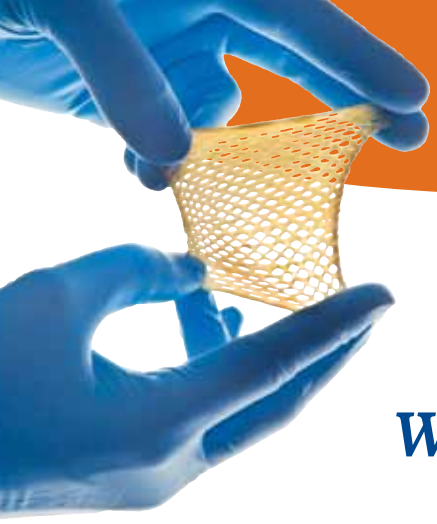


THERASKIN
Real Skin Wound Therapy

TheraSkin® The REAL Skin Wound Therapy with Living Cells

Live Cell content (per cubic mm)[1]		
	Fresh Skin*	**TheraSkin**
Total # of Live Cells at application	40,242	**39,270**
• # of Viable Replicating Cells	39,004	**25,791**
• # of Viable Apoptotic Cells	1,238	**13,479**
% of Replicating Cells compared to Fresh Skin	97%	**65.7%**
% of Viable Replicating Cells compared to **TheraSkin**	N/A	**N/A**
% of Live Cells compared to **TheraSkin**	N/A	**N/A**

*Human Skin, freshly procured, without cryopreservation

Discussion

At application, TheraSkin retains the relevant and important characteristics of healthy human skin, as illustrated in Fig. 1. TheraSkin is minimally manipulated and has live cells and a fully developed extracellular matrix with an "at ready" supply of growth factors and cytokines.

TheraSkin's living cells consist of biologically active human fibroblasts and keratinocytes. At application, these live cells are in two forms — replicative and apoptotic:

1. Replicative cells can continue to replicate. In this study, replicative cells were found to be 65.7% of all live cells.
2. Apoptotic cells are intact but are not able to replicate. In this study, apoptotic cells were found to be 34.3% of total live cells.

This study confirms that TheraSkin, in its post cryopreservation form, has a significant number of living cells at the time of application.

TheraSkin Post Cryopreservation and Fresh Human Uncyropreserved Skin Are Substantially Similar

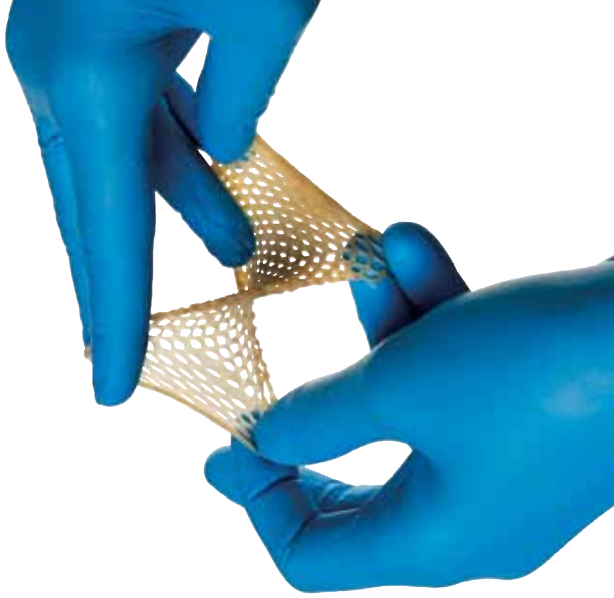
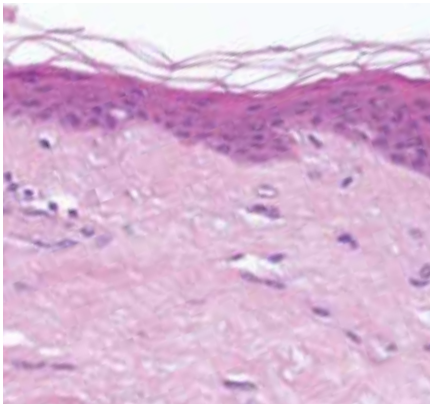
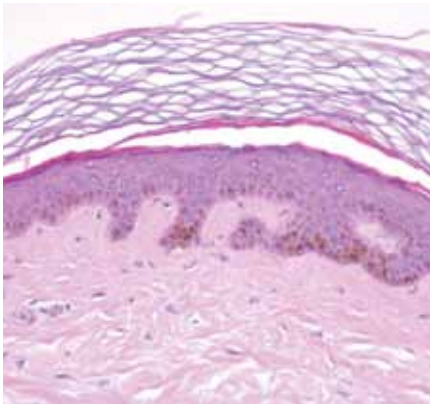


FIGURE 1



TheraSkin stained with H&E at 200x. Cell nuclei are stained dark purple/blue.

FIGURE 2



Fresh, unprocessed skin stained with H&E at 200x. Cell nuclei are stained dark purple/blue.

Study Methodology

A total of three (3) donor TheraSkin grafts, with research authorization, were assigned to this study. Three samples, each approximately 1 cm x 0.5 cm, were cut from three different regions of each TheraSkin graft. TheraSkin Instructions for Use (IFU) were followed to prepare the grafts additionally, one 1 cm x 0.5 cm piece of fresh (unprocessed) skin, with research authorization, was used as a control tissue. All histological tissue processing, staining, and evaluation procedures were performed in the LifeNet Health R&D laboratory using existing SOP. Tissues cross sections were produced in 5 µm thicknesses.

Each TheraSkin donor had three experimental slides for TUNEL staining (1 slide per sample). Histological staining for apoptosis via TdT-dUTP Nick End Labeling (TUNEL) was performed using DermaTACS®--TUNEL kit (Trevigen, Inc., Gaithersburg, MD) for skin tissue. Validity was determined by appropriate staining of positive and negative control slides.

Photographs were taken using NIH Image Pro. The cell density and number of live cells of each TheraSkin donor sample was determined quantitatively for one stained tissue section per slide utilizing the LNH SOP for computerized thresholding, using Scion Image for Windows software, version Beta 4.0.2. Volume was calculated using Scion Image for Windows software, version Beta 4.0.2, calibrating the viewed area against a micrometer, multiplied by the thickness of the tissue section (5 µm). An average cell density and number of living cells was calculated per volume, mm3, both among and within the donors.

References

1. LifeNet Health Technical Report 0262. A Quantitative Evaluation of Live Cell Content in TheraSkin Post Cryopreservation. July, 2011.

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