

## Complex cutaneous wounds treated with autologous homologous skin construct yields neogeneration of functional full thickness skin in preclinical and clinical models

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Critical cutaneous wounds affect thousands of individuals each year. Skin requires regeneration of all components to function normally after such traumas. Current established standards of care, such as split-thickness skin grafts (STSG), do not allow for full regeneration or function of the skin and often result in incomplete healing, scarring and contraction. SkinTE™ is a novel autologous homologous skin construct (AHSC) that has the ability to regenerate full-thickness skin with associated appendages, including sweat

glands and hair follicles. AHSC treats a full spectrum of conditions of the skin in a manner that promotes and utilizes self-regeneration early in the healing process. AHSC was evaluated in both adult and pediatric patients for its ability to close complex wounds in multiple clinical settings. RAMAN spectroscopy and macro and microscopic imaging were used to analyze neo-generation of dermal appendages and AHSC shows promise for the regeneration of full-thickness hair-bearing skin. Preclinical data shows regeneration of epidermis, dermis and dermal appendages with decreased contraction and scarring. Clinical applications have shown complete healing in complex cutaneous wounds, including pigment development and appendage regeneration. Improved function, sensation, contour and superior cosmesis as compared to STSGs were also noted. We compare clinical outcomes of AHSC to the current standard of

care therapies for critical skin wounds and summarize the functional outcomes from a large case series following the application of AHSC in early clinical settings for a multitude of complex wounds. We confirmed the generation of dermal appendages with multiple imaging and observational platforms and evaluated the molecular profile of AHSC compared to native skin. Lastly, we evaluated macro-properties of AHSC including collagen content, fibril organization and appendage morphology compared to native skin. We concluded that one application of AHSC has the capacity to facilitate the regeneration of full-thickness, fully functional skin and reduces the surgical and healthcare burden for acute and chronic cutaneous wounds, acute burns, burn reconstruction, scar revision, surgical reconstruction and the replacement of skin grafts.

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