First application of genetically modified, live-cell, pig skin to a human wound

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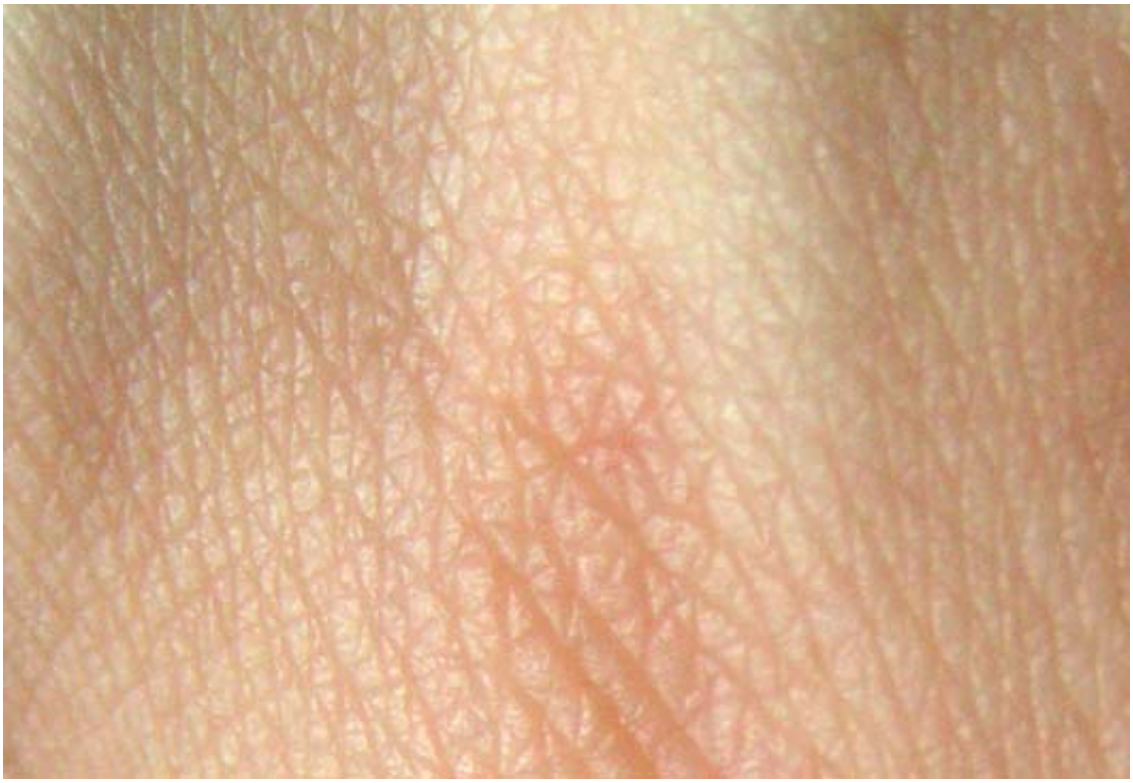

Human skin structure. Credit: Wikipedia

Burn specialists at Massachusetts General Hospital (MGH) announced today they have successfully used live-cell, genetically engineered pig skin (xenograft) for the temporary closure of a burn wound. Through an FDA-cleared phase one clinical trial led by surgeon Jeremy Goverman, MD, of the MGH Sumner Redstone Burn Service, this procedure marks

the first-time pig tissue derived from an animal with gene edits has been transplanted directly onto a human wound.

Human cadaveric skin—or allografts—obtained from national skin banks is a standard of care for deep second and third-degree burns to temporarily close massive burn wounds. Cadaveric skin, as with other organs, is often subject to national shortages, expensive and requires strictly regulated tissue banks for processing. The cadaveric skin allows time for the patient to stabilize and protects the underlying wound while the patient awaits permanent closure with their own skin.

To address these issues, MGH collaborated with Boston-based XenoTherapeutics, which designed and implemented the safety protocols for the special live pig tissue graft, known as xenoskin. The genetic modifications of these particular swine—developed in the 1990's at MGH by David Sachs, MD—removes a gene specific to pigs and not present in humans, allowing the pig skin to appear less foreign to the human immune system.

During the procedure, a 5-by-5-centimeter piece of genetically engineered pig skin was placed on the recipient's burn wound after it had been cleared of necrotic tissue. The pig skin graft was placed next to a much larger piece of cadaveric skin and both were secured with surgical staples and gauze bandages. Five days later, surgeons removed the temporary cadaveric skin and xenograft. Both skin grafts were adherent to the underlying wound bed and appeared indistinguishable from each other. No adverse events were further observed or reported and the wound was then treated further with a skin graft harvested from the patient's own thigh. Healing has progressed as anticipated and the patient will soon return to work.

Analysis from the trial's Safety Review Committee—an independent board required by MGH to ensure patient safety—as well as results

generated by an independent, accredited laboratory registered with the FDA, show no transmission of porcine endogenous retroviruses, or PERVs, which have always posed a theoretical road block for the transplantation of pig tissues or organs transplanted into human recipients.

"It is not the trial itself that is so mind-boggling and intriguing to me; rather, it's what this trial represents," says Goverman. "This small step we took today, represents a massive number of hours spanning decades of research in a multitude of fields including transplantation biology, immunology and genetic engineering. Additionally, rapid advancements in gene-editing technology open a vast new avenue for genetically modifying pig skin that isn't rejected, representing the next chapter in standards of care for burn and transplant patients alike."

"We have taken a small but unprecedented step in bringing xenotransplantation from theory to therapy, one that we hope will advance this promising field of medicine and benefit patients around the world," said Paul Holzer, CEO of XenoTherapeutics. "Our sincerest thanks go to Dr. Goverman, the surgeons, nursing staff and clinical trial coordinators at MGH for their collective help in achieving these initial and very encouraging results."

Provided by Massachusetts General Hospital