



Abstract Title:	Porcine Proof-of-Concept Studies: A Dermatome with a Rotating Excision Ring Compared to Conventional Dermatomes for Harvesting Split Skin Grafts and Excision of Necrosis
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Objective:	Upon completion of the lecture, attendees should be better prepared to: <ul style="list-style-type: none">• Describe proof-of-concept studies, using both objective and subjective outcomes, aimed at testing the design improvements.
Abstract:	<p>Introduction: “Standard” dermatomes have a number of practical disadvantages, whether hand driven or mechanical, and whether for removal of necrosis or the harvesting of a split thickness skin graft (STSG). These include the amount of tissue excised, that is often greater and deeper than the amount of necrotic tissue, the overall level of precision (maneuverability and, particularly, the lack of consistency relating to the thickness of the excised tissue) and "shelving"(1) . A new pneumatic dermatome uses a circular excision ring™ blade that rotates at high speed and has a dissection range of 180 degrees. This dermatome is specifically designed to increase ease of use, including maneuverability, and to obtain a better consistency on the thickness of the excised tissues.</p> <p>Methods and Results: In 3 porcine, proof-of-concept studies the dermatome (test device) was tested for safety and efficacy and compared to standard hand driven and mechanical dermatomes (controls), both for excision of deep dermal burns (1 study) and the harvesting of split thickness skin grafts (2 studies). For the split thickness skin graft studies results show that viability of the grafts was similar for both test- and control devices, as was healing time for the donor sites (measured using transepidermal water loss) as well as their biomechanical properties. With regard to healing of the excised necrosis, results were also similar between test- and control device.</p> <p>In the debridement/excision study and the one graft harvesting study in which it was measured, the focus was of studying graft thickness. The consistency of thickness of the excised tissues, measured using a calibrated microscope, was better for the test device as was the depth of the debridement as intended by the depth gauge on the dermatome(s). With regard to ease of use, the test device performed better than controls on several aspects, including maneuverability, control of the consistency of the relationship between the depth setting and the actual graft thickness, device assembly, overall ease of use, device accuracy and device size. Subjectively, the amount of blood</p>

loss during excision of necrosis was less for the test device as well. The studies also showed that the test device was equal to the control devices with regard to safety (no adverse events occurred in any of the studies).

Conclusion: In proof-of-concept studies a newly designed rotational air powered dermatome proved superior to standard dermatomes on consistency of the thickness of excised tissues, which, in the clinic, may result in better grafts and better outcomes for the recipient site as well as the donor site. The relationship between the “set depth” and actual depth of excision, as well as the maneuverability (both very important when excising tissues) were also superior for the test device, as were several aspects related to the ease of use. These results, while obtained in pig-studies, may very well translate to better clinical results in the clinic, which will have to be tested in clinical trials in humans.

References and Resources:

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Disclosure:

Michel Hermans – Consulting fee: Exsurco