# Report on Three Porcine Proof-of-concept Studies: Comparison of a Dermatome With a Rotating Excision Ring with Conventional Dermatomes for the Harvesting of Split Skin Grafts and Excision of Necrosis

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#### ABSTRACT

**Introduction.** A new pneumatic dermatome with a circular excision blade was designed to improve a number of disadvantages of regular dermatomes. **Objective.** This study analyzes the safety and efficacy of a new dermatome (test device) for the tangential excision of necrosis and harvesting of split-thickness skin grafts (STSGs). **Materials and Methods.** Three porcine proof-of-concept studies were conducted to compare the test dermatome with conventional dermatomes (control devices) for both excision of necrosis (one study) and the harvesting of a STSG (2 studies). For the harvesting studies, donor sites and grafts were analyzed for viability, healing rate, and scar outcomes. Biomechanical tests also were performed on the donor sites. For the necrotectomy study, healing of the excised area and thickness of the excised tissues were studied. **Results.** The test device was similar to the control devices in viability of collected tissues, speed of healing, and donor site biomechanics. In 1 graft harvesting study, as well as in the excision study, uniformity of the thickness of the harvested tissues was better for the test device than for the control devices. The test device performed better than the controls on maneuverability, control of the consistency of the relationship between depth setting and actual graft thickness, device assembly, overall ease of use, depth of the debridement as intended, consistency of the debridement thickness, device accuracy, and size. **Conclusions.** The studies showed the test device, when compared with the control devices, was equal on safety. On efficacy, consistency of the excised tissues was superior for the test device, which may result in better grafts and outcomes. Several aspects related to the ease of use, particularly maneuverability, were superior as well.

#### KEY WORDS

dermatome, excision, split-thickness skin graft, STSG, consistency of thickness, necrosis, porcine, animal model

#### INDEX

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Dermatomes primarily are used for the removal of necrosis and the harvesting of a split-thickness skin graft (STSG). For tangential excision of necrosis, the most commonly used devices are the Humby knife<sup>1</sup> and Goulian Weck dermatome,<sup>2</sup> both hand-driven devices that have not changed substantially since their invention in the 1930s. Both devices also can be used to harvest STSGs, although, particularly for larger grafts, mechanical (air-driven or electric) dermatomes more commonly are used. With the latter, the thickness of the excised tissue is better controlled, and it is possible to take longer and more consistent grafts.<sup>3</sup>

The "typical" dermatome, whether mechanical or hand-driven, uses a straight blade in an oscillating fashion. The excisional direction is perpendicular to the oscillation and away from the dermatome operator. The thickness of the excision is set by using a guard plate for hand-driven dermatomes, while mechanical dermatomes usually have a depth-adjustment dial set on the side. Excision of the proper amount of necrosis without sacrificing viable layers of tissue underneath has proven difficult,<sup>4</sup> even with modern dermatomes. "Shelving" can occur due to variances in excision depth, and the "angle of attack" (the angle between the knife and skin) also influences the actual excision thickness.<sup>5</sup> Adjusting the thickness of excision during operation is very difficult because of the location of the depth-adjustment dial on the side of the device, while, when a hand-driven dermatome is used, the surgical procedure must be interrupted to install a different depth gauge.

Powered dermatomes are pushed away from the surgeon, while hand-driven dermatomes are drawn toward the operator. Hand-driven dermatomes have a steep learning curve and limited fidelity. In addition, powered dermatomes have limited fidelity and intrinsic difficulties engaging tissues; they are rarely used for (tangential) excision.

Alternatives to debridement or tangential excision of necrosis with a dermatome include noncontact, low-frequency ultrasound and hydrosurgery6,7 as well as a specific type of bromelain enzyme.8,9 These alternatives have their own peculiarities and learning curve,10-12 while pain is associated with the bromelain procedure.13 Other enzymes are significantly less successful, at least in burn care, because of the inconsistency and unreliability of their results.10-12,14 Maggot therapy is safe and very effective but relatively slow versus surgical excision<sup>15</sup> and carries a strong psychological burden.<sup>16,17</sup> Excision and debridement with different types of lasers, tested in burn care, were reasonably successful but never became common therapies.18,19

To overcome challenges associated with the ability to observe the harvest site during operation and make real-time changes in harvest depth, an easy-touse dermatome was developed. The Amalgatome SD (test device; Exsurco Medical Inc, Wakeman, OH; **Figure 1**) is a new air-powered dermatome with a circular excision blade that rotates at a high speed and has a dissection range of 180°. The handle has a 15% angle versus the blade, minimizing the need for the operator



**Figure 1.** Test dermatome: 2-in and 4-in versions. Note the "windows" through which excised tissues can be viewed (red arrows).

to put pressure on the dermatome. This, in turn, lowers the chance for inconsistencies and shelving in the thickness of the graft taken. The depth-limiting plate on the instrument is designed to flatten the skin as it approaches the cutting edge. The dermatome also is pulled towards the operator instead of pushed away, allowing for better control of the instrument's movement. As the depth gauge is on the top of the device, the depth setting (0.005 in-0.045 in; 0.127 mm-1.143 mm) can be changed without stopping the surgical procedure. The dermatome exists in 4- and 2-inch head assemblies; different plates/blade guards are used for width adjustment.

The instrument has been designed to overcome the major drawbacks of conventional dermatomes, primarily aiming at improving the ability to tangentially excise tissue, maneuverability, and the consistency of thickness of excised tissue. Together, this should result in potentially greater graft yield since grafts can be taken from areas that are difficult to use with conventional dermatomes, including bony prominences and contoured areas. The entire design also aims at increasing ease-of-use aspects, such as simplicity in assembling and disassembling.

To evaluate the functionality of the test device, 3 porcine proof-of-concept studies were performed to compare the test device with 3 different types of air-driven dermatomes (control devices). In the first study (Debridement 1), uniformity of excised necrotic tissue was measured while the second study (STSG 1) focused on different aspects of STSG harvesting, both with regard to the donor site as well as the grafts obtained. The third study (STSG 2) addressed different aspects of STSG harvesting and primarily looked at different facets of the donor site. The primary objective of all studies was to characterize the performance and safety of the test device in the different indications and compare with control devices. Excised tissues (burn necrosis and STSG) were tested on uniformity with regard to thickness, and viability was evaluated for STSGs. Donor site evaluation included biomechanical properties, speed of reepithelialization,

rate of contraction, the level of postoperative erythema, and pigmentation. For the visual assessment of erythema, a scale of 0 to 4 was used, with 0 representing no erythema and 4 representing severe erythema. For assessing edema, a similar scale was used, ranging from 0 (no edema) to 4 (severe, extending beyond the area of exposure). The percentage of granulation tissue and reepithelialization was judged visually by the lead investigator.

Secondary objectives in the studies Debridement 1 and STSG 1 included assessing aspects of overall ease of use, maneuverability, ease of sterilization, ease of assembly and disassembly, usage as intended, and use within attended margins. For these practical aspects, subjective ratings, ranging from poor to good, were used.

# MATERIALS AND METHODS General procedures

The primary objective of the studies was the assessment of performance and safety of the test device in excision of necrosis and graft harvesting (when compared with control devices). Secondary objectives were to asses a number of practical aspects of the devices.

All studies were conducted in accordance with US Food and Drug Administration Regulations on Good Laboratory Practices for Nonclinical Laboratory Studies CFR Title 21 Part 58 and protocols, approved by the individual institutions. The studies Debridement 1 and STSG 1 were performed by NAMSA (Brooklyn Park, Minnesota, MN). The STSG 2 study was performed following a protocol approved by the Institutional Animal Care and Use Committee at The Ohio State University (Columbus, OH). Both are Association for Assessment and Accreditation of Laboratory Animal Care International-accredited institutions.

Husbandry and basic operation protocols were similar for all studies, although each facility used its own approved standard operating procedures. All studies were prospective, nonblinded, and randomized in character.

For the Debridement 1 and STSG 1 studies, 4 female Yorkshire Cross swine were used. The animals were 3 to 4 months old and weighed about 60 kg at the date of the initial procedure. For the STSG 2 study, 4 similarly aged, female red Duroc pigs were used. Animals were verified to be in good health through a physical exam performed by testing facility veterinary care staff at the time of arrival and 2 days prior to the study procedure. Food and water were provided per testing facility's standard operating procedure. Diet was a commercially available feed from a testing facility-approved supplier.

For all studies, on the day of the procedures, animals were sedated, intubated, and prepped for procedures with an antiseptic scrub. Wounds were dressed postoperatively with a neutral, nonadherent, and separate fixation dressing. Postoperative pain was properly addressed (eg, with Novaplus Fentanyl patches; Watson Pharmaceuticals, Inc, Parsippany, NJ). Animals were recovered from anesthesia and returned to general housing. During the in-life portion of the study, animals were observed daily for overall health by animal care staff. For Debridement 1 and STSG 1, each wound and the surrounding tissues were observed, scored by a test facility veterinarian, and photographed daily.

For the studies Debridement 1 and STSG 1, 28 ( $\pm$  2) days after skin harvest and necrosis excision procedures, the animals were sedated, anesthetized, and humanely euthanized. A general necropsy was performed. Wounds were evaluated visually, measured, and described and subsequently excised and preserved in 10% neutral buffered formalin for histological evaluation.

Throughout the study, 6-mm biopsies were collected. Biopsies were frozen at -20°C; cryosections were cut to be 7-µ thick, stained with hematoxylin and eosin, and imaged using Bright-field microscopy. Histological thickness measurements were taken to the nearest 1000th of an inch with a calibrated microscope. Preoperative and postoperative bloodwork included hematology (complete blood count with differential) and standard serum profile, including tests for liver and renal functions.

For the STSG 2 study, the time of humane euthanasia was 30 days post harvesting procedure.



**Figure 2.** Split-thickness skin graft study 1. (A) Procedure on day o prior to test dermatome and control use; and (B) postoperative day 21 with complete reepithelialization. No difference was noted between the test and control sites. SD: test device; C: control device



**Figure 3.** Debridement 1 study: (A) day 0, lesion post burning procedure; (B) post burn day 3, excision with test dermatome; and (C) post excision day 21 with complete reepithelialization (post burn day 24). No difference was noted between the study and control devices.

# STSG 1 study: procedure

In this study, 6 wounds (3 on the left, 3 on the right of the spine) were created in a randomized fashion using either the test or control device (Figure 2). A total of 4 pigs were used, thus creating 24 lesions. Wounds were located a minimum of 2.5 cm from the midline spine and spaced evenly down the extent of the dorsal crest. The STSGs were harvested with the 4-in head test device (rotating blade) and Humeca D8oSTS (HUMECA, Borne, Netherlands) battery-powered dermatome and Integra Padgett Electric Powered Dermatome (Integra LifeSciences, Plainsboro, NJ) (control devices, both with oscillating blades).

The donor sites were 7.0 cm to 9.5 cm x 5.0 cm to 10.0 cm x 0.018 cm to 0.025 cm. Each donor site was observed and scored on the levels of edema and erythema (range, absent to severe), the presence and percentage of granulation tissue (range, absent to overgranulation), and the level of reepithelialization (range, absent to complete reepithelialization) by a qualified veterinarian. Cover dressings were changed daily and remained in place for a duration as deemed necessary by a testing facility veterinarian. Animals were placed in jackets to prevent disruption to donor sites. Antibiotic and analgesic therapies were administered if and when necessary. At the end of the study (day 28  $[\pm 2]$ ), the animals were euthanized and tissues harvested as per the previously described procedures. At this point, biopsies were taken for histological analysis.

#### Debridement 1 study: procedure

In this study, 24 burns were created in a randomized fashion and spaced similarly to those in the STSG 1 study. Six mid- to deep-dermal burns, about 4 cm in diameter, were created using a modified validated model<sup>20</sup> with an aluminum rod heated by submersion in boiling water for about 15 to 20 minutes (**Figure 3**). The rod then was applied without pressure to the dorsum of the animal for 20 to 40 seconds. The burns were dressed with a nonadherent, absorbent bandage. Three

# **Table.** Thickness measurements (inch) of the test and control dermatomes in STSG 1 and Debridement 1 studies

#### STSG 1 STUDY: GRAFT TISSUE THICKNESS

Test	Control
0.0174	0.0174
0.0080	0.0050
0.0320	0.0350
0.0059	0.0081
	Test         0.0174         0.0080         0.0320         0.0059

#### DEBRIDEMENT 1 STUDY: THICKNESS OF EXCISED NECROSIS

	Test	Control
Avg	0.021	0.058
Min	0.008	0.020
Max	0.033	0.089
SD	0.007	0.015

#### DEBRIDEMENT 1 STUDY: DIFFERENCE BETWEEN DERMATOME SETTING AND MEASURED THICKNESS OF EXCISED TISSUE

	Test	Control	
Avg	0.003	0.049	
Min	-0.002	-0.063	
Max	0.009	-0.018	
SD	0.003	0.014	
STSG: split-thickness skin graft; Avg:			

average; Min: minimum; Max: maximum; SD: standard deviation

days after burn creation, when the lesions were clinically determined to have an appropriate amount of blistering and necrotic tissue to undergo debridement, the animals were sedated, anesthetized, and prepared for the procedures. The 2-in version of the test device was used for tangential excision and compared with the (manual) Goulian Weck Skin Graft Knife, commonly referred to as Weck Knife, as control (multiple manufacturers; eg, Teleflex Medical, Wayne, PA). The burn wounds were debrided using both the test and control devices in accordance with the instructions for use for the different dermatomes and with fixed settings. The

excised specimens of necrotic tissue were prepared for histological evaluation.

Postoperative procedures were, essentially, similar to those in the STSG 1 study as were the analysis and scoring of the wounds. At 28 ( $\pm$  2) days after the debridement procedures, the animals were sedated and humanely euthanized with an intravenous overdose of a barbiturate-based euthanasia solution. Histological specimens were taken, and a limited necropsy was performed.

# STSG 2 study: procedure

In the STSG 2 study, the test device was compared with a Zimmer Biomet Air Dermatome (Zimmer Biomet, Warsaw, IL). Wounding was performed in a randomized fashion and by a single surgeon, coauthor of this paper. The wounding protocol was separated in 2 different segments.

For an analysis on thickness uniformity, 6-mm punch biopsies at 3-cm intervals were collected from each graft harvested at different dermatome thickness settings (0.012 in–0.018 in). Biopsies were placed between 2 glass slides and measured using digital calipers.

To evaluate the total amount of skin harvested as well as the amount of usable skin (for this measurement, areas that were too thin or irregular in the clinical opinion of the lead investigator were excluded), each piece of skin was photographed, digitized, and total area measured using computerized planimetry.

Graft viability was measured using an MTT assay, as previously described,<sup>21</sup> with punch biopsies, taken about 3 cm apart down the length of the graft randomizing edge versus center collection points. Six sites from each graft (n = 6/device) were assessed with average absorbance  $\pm$ standard error of the mean (SEM) plotted. Higher absorbance indicates a higher level of cellular metabolism, which, in turn, indicates greater viability.

In the second part of the STSG 2 study, reepithelialization and donor site contraction, color (as judged visually be the lead investigator), and biomechanics were assessed on 6 different animals. A STSG measuring 2 in x 10 in was harvested on either side of the dorsum with collection device site randomized. Transepidermal water loss (TEWL; Tewameter TM 300; Courage + Khazaka electronic GmbH, Cologne, Germany) measurements were collected at 3, 7, 14, and 29 days post harvesting with 3 individual measurements per donor site collected at each time point and presented as average TEWL ± SEM. Photographs and tracings of each donor site were collected at the same time points with tracings scanned (Brother MFC-8710DW; Brother International, Bridgewater, NJ) and total donor site area assessed using ImageJ (ImageJ software; National Institutes of Health, Bethesda, MD). Donor site contraction was calculated by dividing the measured area at a given time point (Af) by the size of the initial area (Ai) multiplied by 100. Average percent of original area ± SEM was plotted for each group at each time point.

At the final time point (day 29), donor site pigmentation and erythema were assessed using a Mexameter (Courage + Khazaka electronic GmbH). The device exposes the skin to light at 3 different wavelengths (568 nm, 660 nm, and 870 nm) and calculated the quantity of light absorbed by the skin at each wavelength. The redness of the skin (erythema) and pigmentation were quantified at 3 different points along each donor site (n = 6 donor sites/device) and normalized to erythema and pigmentation of the surrounding skin (as measured for each pig). Results were plotted individually as normalized color for each pig and as an average deviation for normal for all pigs.

Biomechanics of the donor site at day 29 post harvesting were measured using a hand-held BTC-2000 (SRLI Technologies, Franklin, TN) and a torsional ballistometer (Dia-Stron, Clarksburg, NJ). The handheld device applies suction to the skin and measures the deformation of the skin in response to the suction. Skin stiffness, elasticity, and laxity (pliability) were calculated from the time-displacement curves.

#### Statistical analyses

All data from the STSG 2 study were compared using a Student's *t* test (SigmaStat v.12; Systat Software Inc, San Jose, CA), with *P* < .05 considered statistically significant.

#### RESULTS

The primary objective of these studies was to compare the test device with conventional devices on performance and safety in the harvesting of STSGs and excising necrosis, while secondary objectives included aspects of healing as well as ease of use. With regard to safety, none of the animals in any of the studies developed any adverse experiences and all remained healthy throughout the study; also, all procedures were successfully completed. There were no significant changes in any of the values in the blood tests on any of the animals during the study.

#### STSG 1 study

Postoperative observation showed low and comparable levels of erythema and edema among the different wounds, while the development of granulation tissue was similar with regard to percentage of the wound surface and speed of development. Histologically, all lesions showed similar amounts of (minimal) fibrosis in the dermis, and signs of cellular infiltration and inflammation also were similar. All wounds showed a similar overall healing profile over time and were completely reepithelialized by the end of the study (postop day 28).

Graft thickness, measured with a calibrated microscope, was more consistent (smaller variance) for those taken with the test device than the control devices (**Table**). The test device also obtained better scores than the controls on the consistency of the relationship between the depth setting and the actual graft thickness, as well as on overall device size and maneuverability. Ratings on ease of sterilization; assembly, disassembly, and "instructions that were easy to follow"; usage of the devices as intended; ability to use the devices within the intended margin; and maneuverability were similar among the test and control devices.

#### Debridement 1 study

The objective of this study was to compare the performance and safety of 2 types of dermatomes when used for excision of



**Figure 4.** Split-thickness skin graft 2 study: graft viability (MTT assay). (A) Average for test and control devices per pig; and (B) overall averages for the test and control devices. <sup>a</sup> Statistically significant.



**Figure 5.** Split-thickness skin graft 2 study. Hematoxylin and eosin stains of 6-mm biopsies. On day 3, reepithelialization is initiated and complete at day 7. Dermal and epidermal structures are similar among control and test devices.

dermal necrosis in deep partial-thickness burns. Debridement procedures were successful for all wounds.

Erythema and edema scores were similar between the excisional wounds created by the test and control devices and relatively high immediately following debridement. The scores gradually decreased as time progressed. No differences were observed with regard to the post excision development of granulation tissue and reepithelialization. Control sites were noted to have discharge (either serous or serosanguinous) throughout the study more frequently than test sites. The average wound size (including contraction) at study end was similar for the test and control devices (3.20 cm<sup>2</sup> and 3.18<sup>2</sup> cm, respectively) with normal and complete healing.

Thickness measurements with a calibrated microscope of the excised necrotic tissues showed a narrower range of thickness than for the control (**Table**). For the test device, a higher level of accuracy and repeatability with regard to the dermatome setting as well as for the actual thickness of the excised tissue was demonstrated (**Table**).

The test device subjectively scored better on device assembly, overall ease of use, depth of the debridement as intended, consistency of the debridement thickness, the amount of blood loss (less loss of blood provided a better score), device accuracy, and device size. Test and control device received equal scores on other aspects of use, such as "instructions that were easy to follow," ease of sterilization, ease of assembly and disassembly, usage of the devices as



**Figure 6.** Split-thickness skin graft 2 study: transepidermal water loss (TEWL) as a function of reepithelialization.

Note: the graft thickness is less for the test device than for the control. <sup>a</sup> P<.05



**Figure 7.** Split-thickness skin graft 2: donor site contraction. *P*>.05: not statistically significant.



Figure 8. Split-thickness skin graft 2 study: normalized (A) erythema and (B) pigmentation per pig.

intended, ability to use the devices within the intended margin, maneuverability, and ease of device disassembly.

# STSG 2 study

For each device, there was no difference in the usable quantity of tissue (ie, no areas of graft too thin for usage). Viability, as measured by MTT,<sup>21</sup> was not significantly different between the test and control devices for all pigs except for number 6 (**Figure 4A**) with no detectable difference when all data were as collated (**Figure 4B**; P = .875). Both devices excised at similar initial depths (**Figure 5**). On day 3, reepithelialization was initiated, and it was complete at day 7. No significant differences in dermal or epidermal structure were observed between the control and test devices.

The TEWL, which directly quantifies the reestablishment of epidermal barrier function, decreased as a function of time post harvesting in both groups. At postop day 14, the donor site in the test group had a significantly lower TEWL (**Figure 6**); no significant difference was detected, however, at any other time point and donor sites from both groups reached baseline by day 29. Donor site contraction was not significantly different between the control and the test device (P > .05) (**Figure** 7).

Quantitative assessment of color in the donor sites showed the control sites tended to be more erythematic than the test device sites (**Figure 8A**), with pigment trending toward hypopigmented versus hyperpigmented as seen in the control sites (**Figure 8B**). Judging by the overall color, erythema and pigmentation were reduced significantly at donor sites harvested with the test device (**Figure 9**). Biomechanical properties of the donor sites, created with the test or control device, showed no statistically significant differences with regard to stiffness and percentage of laxity or elasticity (**Figure 10**).

#### DISCUSSION

Necrotectomy and harvesting STSGs are common procedures in the management of many different types of wounds, including burns. For debridement (necrotectomy), hand-driven dermatomes are most commonly used, though low-frequency ultrasound and hydrosurgery devices have gained popularity.<sup>6,7</sup> Split-thickness skin grafts are harvested using hand-driven or mechanical dermatomes. The proof-ofconcept studies described herein were aimed at comparing a new type of dermatome with the "standard ones."

Overall results of the STSG trials showed equivalent performance between the test and control dermatomes on a number of clinical and practical aspects. The speed of healing of the donor sites was similar among the different types of dermatomes (both studies) with no substantial difference in visual observation via histology or via TEWL measurements. Overall graft viability was similar in the STSG 2 study as was overall usability of the harvested grafts. On postop day 29, donor site contraction and biomechanical properties (laxity, elasticity, and stiffness) also were similar between test and control groups. Erythema and pigmentation were significantly greater when the site was harvested by a conventional dermatome. It should be noted, though, that both pigmentation and erythema of donor sites change over a prolonged period.22 Thus, the color of the donor sites may return to normal values as the tissue continues to heal and remodel.

In the Debridement 1 and STSG 1 studies, on STSG harvesting and excision of necrosis, respectively, thickness measurements with a calibrated microscope showed better consistency within the test-dermatome-excised tissues. Wound healing-related observations (eg, postoperative erythema and edema) showed similar results. The percentages of development



**Figure 9.** Split-thickness skin graft 2 study: donor site color as function of device. *P*>.05: not statistically significant.



**Figure 10.** Split-thickness skin graft 2 study: donor site biomechanical properties of (A) percentage of laxity and elasticity; and (B) stiffness.

P>.05: Not statistically significant.

of both granulation tissue and epithelium, as well as the speed of reepithelialization, were also equal both in debrided wounds and donor sites. In the Debridement 1 study, the use of the test device was subjectively observed to result in less blood loss than when excision was performed with the control device. Histologically, there were no significant differences with regard to aspects of inflammation, fibrosis, or healing.

In the STSG 1 study, the test device reached better scores than the control

devices on ease-of-device assembly, overall ease of use, depth of the debridement as intended by the setting on the depth gauge, consistency of the debridement thickness, maneuverability, and device size.

In the Debridement 1 study, the test device subjectively scored better on the ease-of-device assembly, overall ease of use, depth of the debridement as it was intended by the setting on the depth gauge, consistency of the excised tissues, device accuracy, and device size. In neither the STSG 1 nor Debridement 1 study did the control devices score better on any of the ease-of-use aspects.

## LIMITATIONS

The studies described here are small in size. More importantly, although pig skin resembles human skin to a large extent, results in a porcine study can only be extrapolated to the human situation to a limited extent. The studies were different in their configuration, but this was done to measure different aspects of STSG harvesting, excision of necrosis, and subsequent aspects of wound healing and quality of the excised tissues.

The results of these studies, however, are uniform and consistent: the test device performed at least equally well on most study aspects when compared with control devices with regard to excision of necrosis and harvesting of a STSG, while the microscopically measured thickness of the test-device-excised tissue was more uniform.

## CONCLUSIONS

The test dermatome, with a high-speed rotating excision ring, was compared in 3 porcine studies with conventional, mechanical or manual dermatomes for the excision of necrosis after a burn injury and for the harvesting of STSGs. The test dermatome performance was equal to the control dermatomes on all aspects studied in the 3 trials with respect to overall healing, including viability of the harvested grafts, time to complete reepithelialization, and biomechanical properties of the donor sites. Although there were statistically significant differences on the level of pigmentation on postop day 30, this time point is too early to draw long-term conclusions on that aspect of the results. The test device scored better on consistency of the thickness of the excised tissues, as measured using a calibrated microscope, which is probably the most important aspect of using a dermatome since this may result in better grafts as well as better outcomes for the recipient wound bed site and the donor site.

The test device also scored better on several aspects of usability, including,

particularly, maneuverability, which is yet another important aspect of dermatome usage. While these results were obtained in porcine studies, they indicate some essential improvements over the standard devices used for harvesting STSGs and for the excision of necrosis. Human studies will have to be performed to test for the same parameters.

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