

Clinical Comparison: Amalgatome® SD vs. Conventional Dermatomes

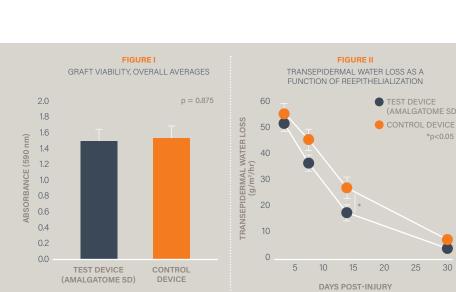
STUDY PURPOSE

To determine the efficiency and effectiveness of two types of dermatomes, three porcine proof-of-concept studies were conducted. The studies used the Exsurco Medical Amalgatome SD with a Rotating Excision Ring™ blade and conventional dermatomes to harvest split skin grafts and excision of necrosis.

HOW WE MEASURED SUCCESS

The following outcomes of the Amalgatome SD versus conventional dermatomes are reported:

- Viability of grafts (Figure I)
- Thickness of excised tissue (graft, necrosis) and consistency of thickness (calibrated microscope)
- Time to granulation and reepithelialization (Figure II)
- · Donor site properties, including erythema, color, laxity, elasticity, and stiffness (Figure III)
- Device ease of use







* Note that the graft thickness is less for

30

STUDY RESULTS





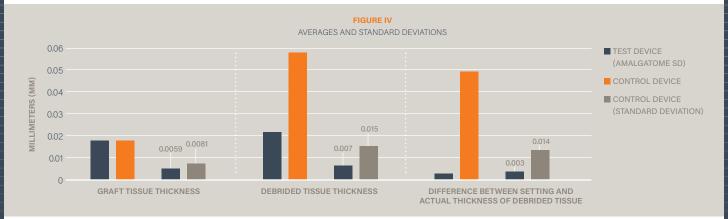
- Superior graft quality: more consistent thickness (calibrated microscope) and potentially better results for the donor and recipient site (Figure IV, standard deviations)
- More consistent thickness for excised necrosis (calibrated microscope): easier to avoid (deep) excision into viable tissue (Figure IV, standard deviations)
- A better relationship between the set depth of excision and actual depth (Figure IV, standard deviations)
- · Better ease of use with regard to:
 - Overall device size
 - Device assembly
 - Device accuracy
 - Potential less blood loss during excision of necrosis

STUDY CONCLUSION

The Exsurco Medical Amalgatome SD Skin Grafting and Wound Debridement device was superior when evaluating:

- 1. Consistency of the thickness of excised tissues (important for the wound healing process)
- 2. Maneuverability (important for the clinician)
- 3. Several facets of ease of use

The conventional dermatomes did not outperform the Amalgatome SD on any of the test parameters.



REFERENCE

Hermans, MHE. Report on three porcine proof-of-concept studies: comparing a dermatome with a rotating excision ring with conventional dermatomes for the harvesting of split skin grafts and excision of necrosis. *Complete study on file at Exsurco Medical, Inc.*



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