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 test device than for control

\[ 0.0 \quad 0.2 \quad 0.4 \quad 0.6 \quad 0.8 \quad 1.0 \quad 1.2 \quad 1.4 \quad 1.6 \quad 1.8 \quad 2.0 \]

\[ 0 \quad 10 \quad 20 \quad 30 \quad 40 \quad 50 \quad 60 \]

\[ 0.94 \quad 0.96 \quad 0.98 \quad 1.0 \quad 1.02 \quad 1.04 \quad 1.06 \quad 1.08 \quad 1.10 \quad 1.12 \quad 1.14 \quad 1.16 \]

\[ 5 \quad 10 \quad 15 \quad 20 \quad 25 \quad 30 \]
STUDY RESULTS
The results of the animal study demonstrated that the Amalgatome® SD provided:

- 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.