Enzymatic Disaggregation Is Superior to Mechanical De-Epithelialization in Preparation of Cutis Grafts for Hernia Repair: Results of the Cutis Ex-vivo Graft I Study (CutE GRAFT I)

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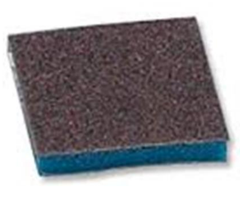
Introduction

- Hernia repairs
  - > 1 million procedures/year
  - > $10 billion/year
- Current standard of care: biologic or synthetic mesh
  - prohibitively expensive
  - can increase healthcare costs > $100,000/complication
- Cost-effective solution: autologous cutis grafts - mechanical de-epithelialization of full thickness skin graft using a Bovie scratch pad or Norsen debrider
  - physically demanding
  - time consuming
  - inconsistencies due to skin pigment - darker pigments are easier to visualize during de-epithelialization
  - risk of epidermal inclusion cysts
- Optimization: Avita Medical ReCell enzyme system for epidermal disaggregation
  - FDA approved for autologous skin cell suspensions (burn treatments)
  - faster and easier de-epithelialization
  - unknown efficacy

Hypothesis

- Pretreatment of the specimen with enzymatic disaggregation system results in higher proportions of epidermal removal as compared to mechanical debridement alone



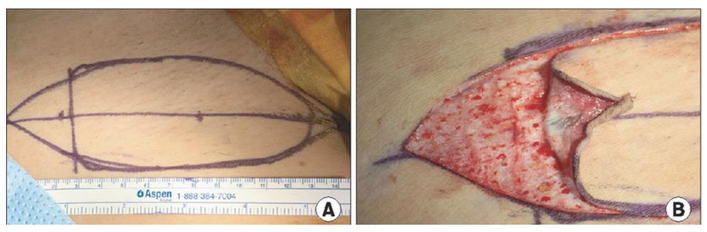
Mechanical De-epithelialization with Bovie scratch pad or Norson Debrider

VS

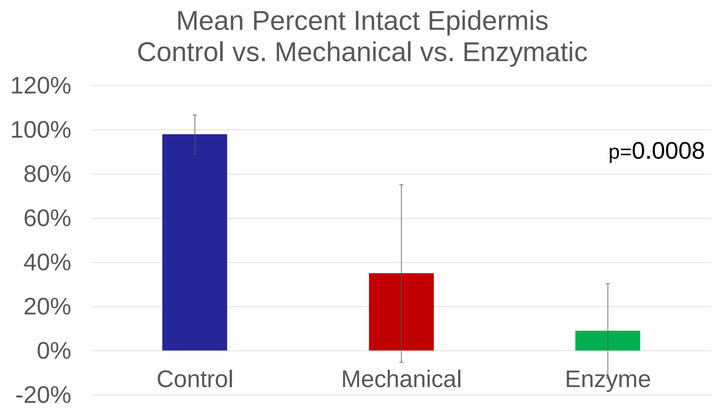
Enzymatic De-epithelialization with Avita Medical ReCell enzyme kit

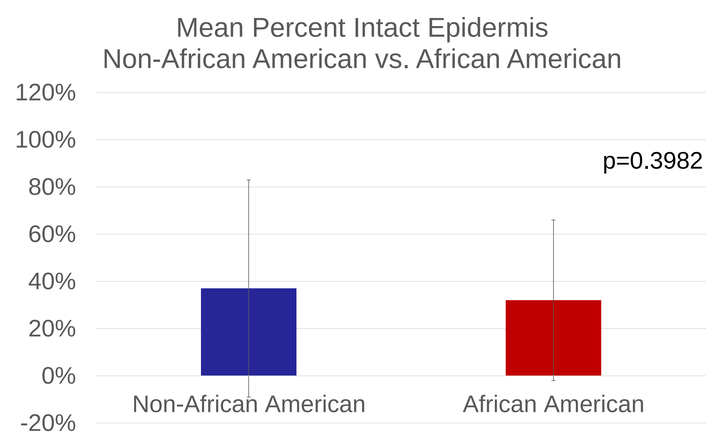
Methods

- 10 patients
- Full thickness skin specimens harvested at incision for open ventral hernia repairs or abdominal pannus for laparoscopic repairs
  - 3 pairs of 2 x 1 cm:
    - C – unprocessed control group
    - E – enzymatic de-epithelialization
      - Processed for 30-45 min
    - M – mechanical de-epithelialization
  - Two 4mm punch biopsies from each specimen
  - Histologic analysis of H&E staining measuring percentage of intact epidermis

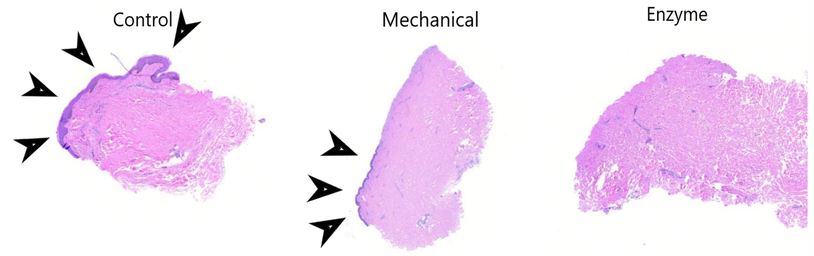


Data





Microscopic Analysis



*Arrows indicate residual epidermis

Results

- Ages 23-83 years (M=52.1+17.2)
- 60% female
- 50% African American, 40% Caucasian, and 10% Hispanic
- Time required to enzymatically process specimen ranged from 30-45 min (M 36.0 + 5.7)
- Amount of epidermis remaining from greatest to least (p=0.0008):
  - C group (50-100%, M=98%+8.7%, Mdn=100%)
  - M group (0-100%, M=35%+40%, Mdn=14%)
  - E group (0-80%, M=9%+21%, Mdn=0%)
- Within the M group, the amount of epidermis remaining was greatest in non-African American patients (0-100%, M=37%+46%, Mdn=4%) versus African American patients (0-95%, M=32%+34%, Mdn=15)
  - not statistically significant (p=0.3982)

Conclusion

- Mechanical de-epithelialization is by nature inconsistent
- Enzymatic disaggregation of the epidermis using the Avita Medical ReCell enzyme kit appears to be a viable method for the development of cutis grafts for use in hernia repairs
  - low-cost mesh alternative
  - may have the additional benefit of increased reinforcement by means of preserving the papillary dermis
- Further studies will be necessary to evaluate tensile strength of the processed tissue (CuteE GRAFT II)