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“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)”

Introduction Biologic or synthetic mesh reinforcement is the current standard of care for abdominal hernia repairs but remains prohibitively expensive and can increase healthcare costs by over 100,000 USD per complication. The use of autologous cutis grafts (full thickness skin grafts with the epidermis removed) are a cost-effective solution. However, the process of mechanical de-epithelialization can be physically demanding, time consuming, and result in discrepancies between patients due to differences in skin pigment, with darker pigments being easier to de-epithelialize. To facilitate this process, we proposed the use of enzymatic disaggregation. In this study, we compare the effectiveness of mechanical de-epithelialization (M), enzymatic de-epithelialization (E), and our unprocessed control group (C). We hypothesized that pretreatment of the specimen with enzymatic disaggregation system would result in lower percentages of intact epidermis as compared to mechanical debridement alone.

Methods After obtaining IRB approval, this prospective controlled trial included 10 patients with hernias. Full thickness skin grafts were harvested from either the area of incision for open ventral hernia repairs or from the lower abdominal pannus for laparoscopic repairs. Three 2x1cm samples were excised from the graft. The C group was unprocessed. The E group was prepared using the ReCell enzyme (Avita Medical), a proprietary enzyme kit used for disaggregating epidermis for use in skin grafting. The M group was de-epithelialized per our standard protocol using either Bovie scratch pads to remove the epidermis like sandpaper or a Norson debrider. Two punch biopsies were taken from each specimen and visualized using H&E stain to determine the percentage of intact epidermis.

Results Patient ages ranged from 23 to 83 years ($M=52.1\pm 17.2$) and 60% of the volunteers were female. Of the included participants, 50% were African American, 40% were Caucasian, and 10% were Hispanic. The time required to process specimens in the E group ranged from 30 to 45 minutes ($M 36.0 \pm 5.7$). The amount of epidermis remaining was greatest in the C group (50-100%, $M=98\%\pm 8.7\%$, $Mdn=100\%$), followed by the M group (0-100%, $M=35\%\pm 40\%$, $Mdn=14\%$), and the E group (0-80%, $M=9\%\pm 21\%$, $Mdn=0\%$). Two tailed t-test revealed a p value of 0.0008. Within the M group, the amount of epidermis remaining was less in African American patients (0-95%, $M=32\%\pm 34\%$, $Mdn=15$) versus non-African American patients (0-100%, $M=37\%\pm 46\%$, $Mdn=4\%$) but this finding was not statistically significant.

Discussion Mechanical de-epithelialization is by nature inconsistent which may be supported by the finding of lower percentages of intact epidermis in darker pigmented specimens. Furthermore, enzymatic disaggregation of the epidermis appears to be a viable method for development of cutis grafts as a low-cost mesh alternative and may have the additional benefit of increased reinforcement in hernia repairs by means of preserving the papillary dermis. Further studies will be necessary to evaluate tensile strength of the processed tissue.