

Introduction

Negative Pressure Wound Therapy (NPWT) is a well-established procedure used for non-healing wounds including burn wounds, pressure ulcers and other types of combat injuries. The goal of any wound regimen is to optimize wound healing by combining basic wound care modalities including debridement, off-loading, and infection control.

Vacuum-assisted (VA)-NPWT is a useful therapeutic procedure for non-healing wounds and more recently for acute skin-grafted burn wounds, both partial thickness and grafted full thickness. The benefit of NPWT is offset by the complexity of clinical procedures and the associated costs. In addition, there has been a limited number of studies in burn patients and thus more studies need to be performed. Success with VA-NPWT is attributed to efficient removal of wound exudates, reduction in edema, and keeping the wound free from excessive infection and inflammatory mediators. It is also postulated that mechanical suction is stimulatory to blood flow and fibroblasts, promoting tissue repair.

In vacuum assisted NPWT (VA-NPW), a special sealed dressing of large cell foam (>400 µm) or gauze is connected to a pump. The sealed dressing acts as a conduit to pressure transfer and aids in the passive flow of fluid. Most commonly, negative pressures between -10 and -125 millimeters of Mercury (mm Hg) are used. Reticulated foams with micron-size open cells (100 to 5µm) exert capillary suction between 10 and 50 mm of Hg. With a multilayered foam-dressing device, a Capillary Suction Device (CSD), the suction pressure can be enhanced to about 70 mm of Hg. These negative pressures produced are within the range of suction by mechanical pumps.

In the study presented here a porcine model with excised surgical wounds was used to compare efficacies of conventional VA-NPWT (110 mm Hg negative pressure by a pump) and CSD with capillary suction of 30 mm and 70 mm Hg. This porcine model has been shown to demonstrate increase healing of full-thickness wounds using VA-NPWT.

Methods

Wound Model: Yorkshire pigs were anesthetized, surgically prepped and administered pre-emptive and post-emptive analgesics. Five full-thickness excisional wounds (3 cm sq.) were created on each side of the dorsal area of each pig sown to the fat layer using a scalpel. An autoclavable Teflon sheet was used as a guide to the size and spacing of the wounds. The wounds were photographed and covered with a standard bandage material (gauze), CSD or negative pressure foam. One side was covered with gauze or negative pressure foam while the other side was covered with CSD. The negative pressure device (extriCARE 2400, Devon Medical Products, King of Prussia, PA) consists of foam mounted on a plastic backing with a port in the center to hook to the pump using tubing. Fluid was collected when the container was approximately 1/2 full or less and returned to pump. Stockinet was placed over the bandages and around the midsection of the animal. A custom mesh jacket (Lomir Biomedical, Malone, NY) was used to protect the dressings and attach the pump. Animals were observed daily to ensure bandages were in place and to recharge the pumps. The wounds were measured on day 2 and then every 4 to 5 days thereafter. We also determined the total fluid collected by the various dressings over time. Animals were euthanized at the completion of the study and 3 mm biopsies were obtained using a punch. Wounds were measured and photographed during bandage changes or more often if they appeared to be closing rapidly. Analysis of wound sizes was performed using Fiji/Image J. All animal studies were reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) at the University of Cincinnati.

Capillary Suction Devices (CSD): CSD were produced from reticulated foams with micron-size open cells (100 to 5µm) which exerts capillary suction between 10 and 70 mm of Hg with a multilayered foam dressing. The negative pressures produced are within the range of suction by mechanical pumps. Two types of CSD were examined, CSD-30 with capillary suction of 30 mm Hg and CSD-70 (HSD) with capillary suction of 70 mm Hg. Capillary suction was measured using an ascending chromatographic technique. The maximum capillary suction height equates to the capillary suction pressure (CSP) measured in millimeters of water. For purposes of comparison, negative pressures in mm of Hg were calculated from the measured units. The densities used for conversion from millimeters of water to millimeters of Hg were 1.05 g / ml and 13.53 g / ml for blood different times or stages of wound treatment plasma and mercury, respectively.

Statistical Analysis: Wound size differences were analyzed using repeated measures ANOVA assuming capillary suction device and gauze were independent groups and days the repeated factor. The least squared means method was used to test differences between CSD and gauze at each time point post-wound. Statistics were calculated using SAS® version 9.4.

Histology: Three mm punch biopsies were obtained at the end of the studies post-euthanasia. Tissues were fixed in formalin, dehydrated, embedded in paraffin, sectioned and stained with hematoxylin and eosin (H&E).

Results

The basic wound appears in **Fig. 1**, while the placement of the CSD-70 and NP device appears in **Fig. 2**. The wounds at day 20 appear in **Fig. 3**. By post-wound day 20, the wounds treated with CSD-70 and NPWT were 100% closed while the wounds treated with CSD-30 and gauze were 65 and 45% closed, respectively. At the end of the study on day 30 the wounds treated with CSD-30 were 100% closed while wounds covered with gauze were only 80% closed. CSD-30 treated wounds also closed significantly faster at all-time points, **Fig. 4A**. Although the CSD-30 product was superior to gauze, it was less efficacious than the tested NPWT treated animals. As displayed in **Fig. 4B**, the time course of closure for CSD-70 versus NPWT are essentially identical. These results indicated comparable wound closure efficacies for CSD-70 and NPWT. **Fig. 4C** displays a comparison of CD-70 versus CD-30. There was no difference through the first 10 days but by day 20 the CD-70 treated wounds were closed while the CSD-30 were not completely closed. A comparison of the percentage closure for all 4 bandages appears in **Fig. 4D**. The average total fluid uptake measured in grams dry weight was similar for CSD-70 and NPWT, 36 and 38g., respectively while the values were 24g for CSD-30 and 12g for gauze (**Fig. 5A**). However, the maximum fluid uptake observed at day 2 indicated that CSD-70 and CSD 30, 24 and 14g respectively, were superior to NPWT and gauze 12 and 7g respectively (**Fig. 5B**). Although the rates of wound closure were identical for the NPWT and the CSD-70 treated animals, histological analysis indicated some differences. Histology of the biopsies at the day of closing indicated that the wounds treated with NPWT displayed very developed rete ridges (**Fig. 6A**) compared to the CSD-70 treated animals (**Fig. 6B**) which were more like untreated porcine skin. The NPWT treated wounds also displayed slightly more dermal inflammation. The epidermis of the CSD-70 treated skin was thicker than NPWT treated skin, which was more like normal pig epidermis.



Figure 1: The wound prior to treatment.

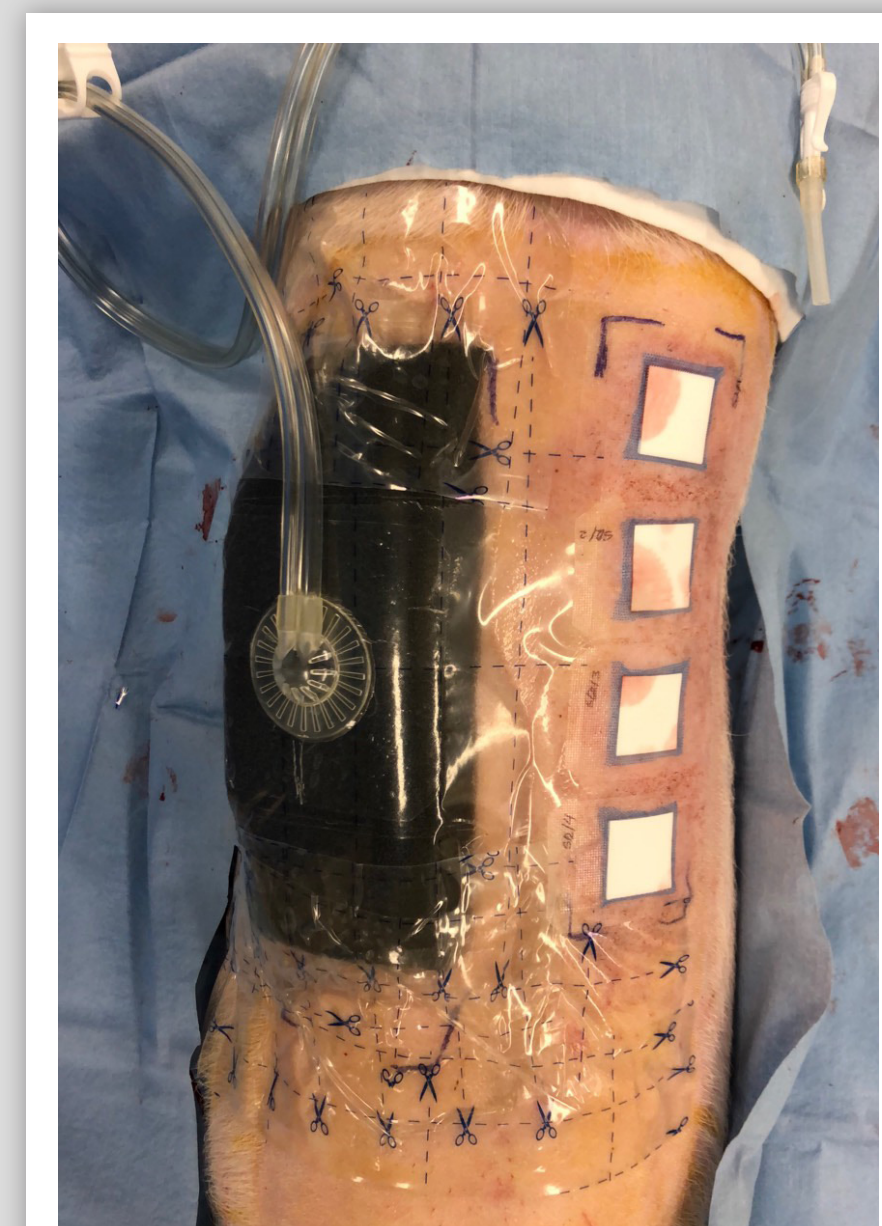


Figure 2: The dorsal side of the animal showing wounds bandaged with CSD-70 on right and the extriCARE 2400 negative pressure device on left.



Figure 3: The wounds displayed on post-surgery day 20.

Figure 4: Displays the percent wound closure for wounds treated with capillary suction device (CSD-30) versus gauze (**A**), capillary suction device (CSD-70) versus vacuum assisted negative pressure wound therapy (NP) (**B**), high and low pressure capillary suction devices (**C**) and a graphic of all devices together (**D**). The asterisk * indicates significance at p<0.01.

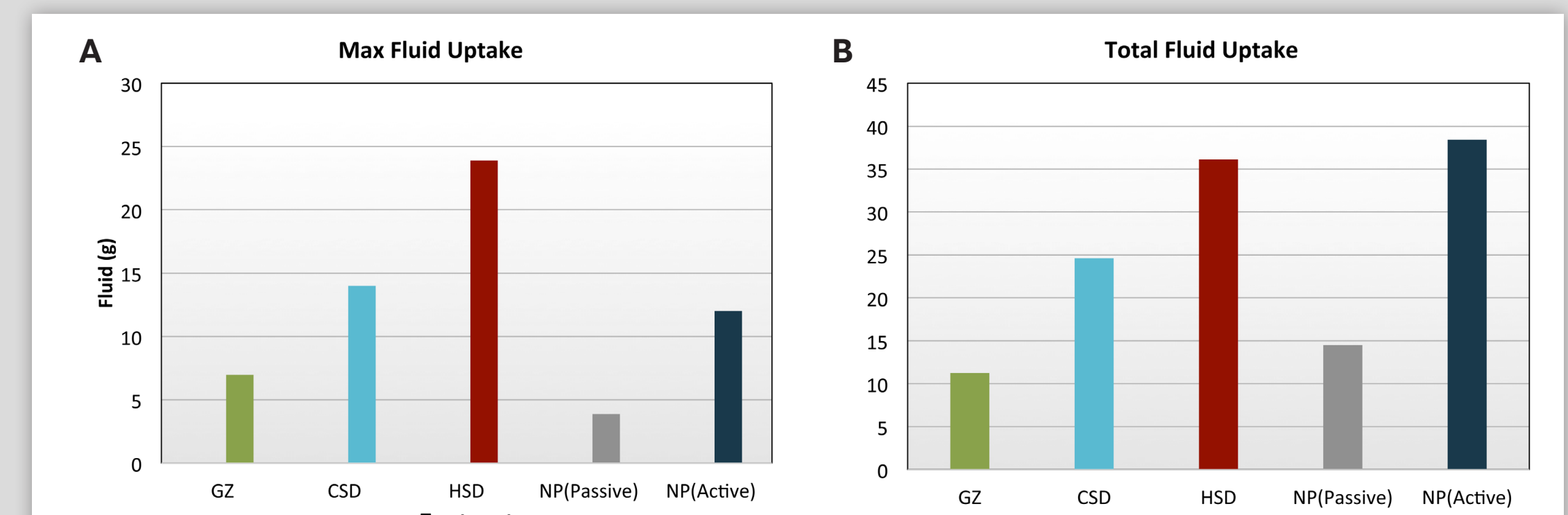
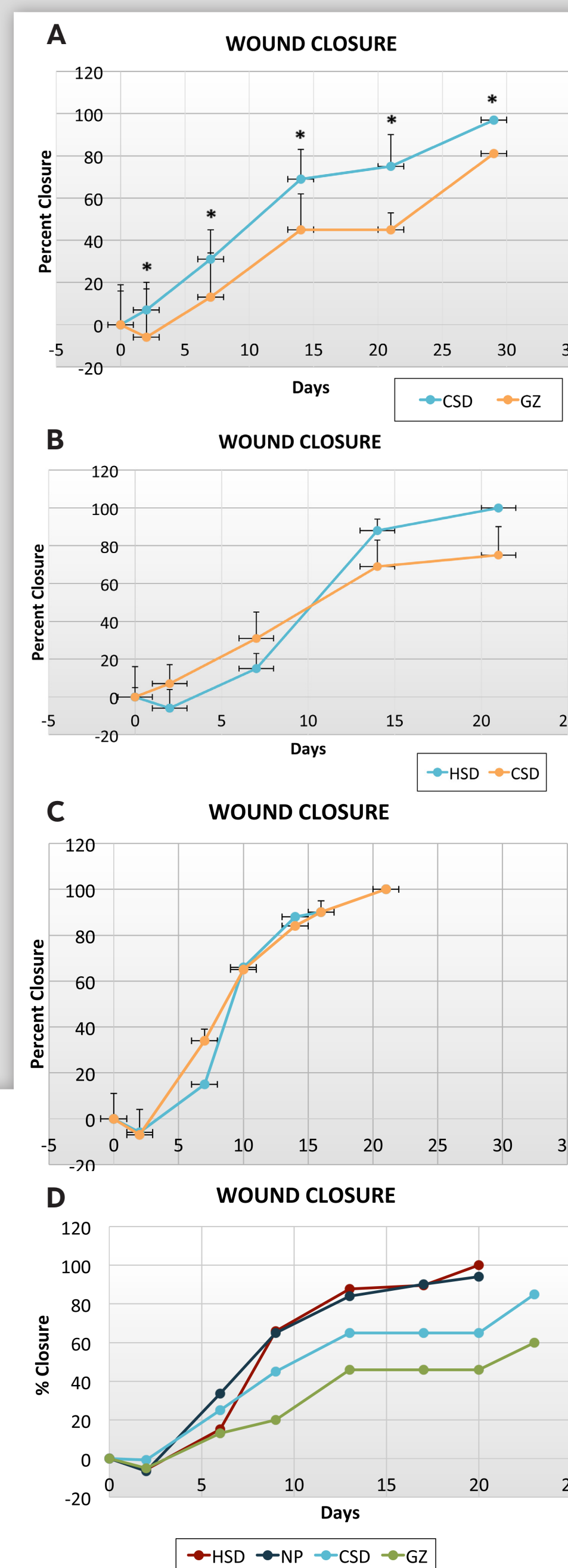


Figure 5: Panel **A** displays the max fluid in dry wt. collected at any one time point for the wounds using gauze, capillary suction device (CSD-30), high pressure capillary suction device (CSD-70), negative pressure passive (no vacuum on device, NP passive), and standard vacuum assisted negative pressure device (NP active). Panel **B** displays the total fluid collected from the devices in panel **A**.

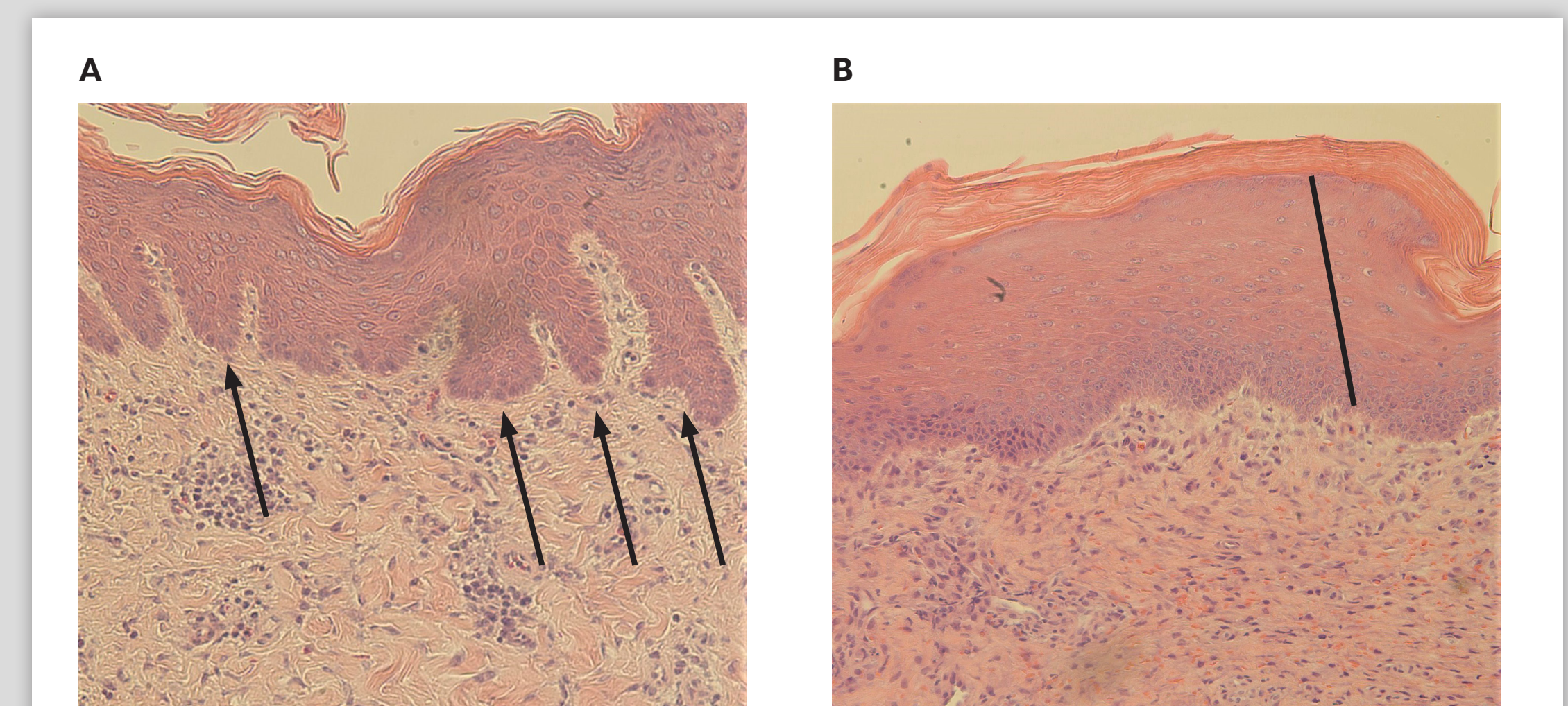


Figure 6: The histology of wound tissue on day 20 (100% closed) from a vacuum assisted negative pressure device (**A**) and capillary suction device (**B**) (CSD-70). The arrow point to representative examples of prominent rete ridges and the bar indicated the thick epidermis.

Discussion

The data presented indicated that CSD, especially CSD-70, produced wound healing results similar to conventional VA-NPWT in a porcine model. The time to complete wound closure was identical and CSD also removed more exudate, especially at early time points, than VA-NPWT. Rather than having to change the foam pad and empty a container as with VA-NPWT, CSD only required the change of a bandage. Drainage of exudates is important to remove inflammatory mediators and tissue degrading proteases, while also increasing concentrations of epithelizing and tissue growth promoting growth factors. Histological analysis indicated a few differences in the healed wounds at 20 days. The NPWT treated tissue displayed very prominent rete ridges compared to the CSD-70 treated tissue. It is possible this is due to the higher vacuum pressure with NPWT compared to CSD-70, 110 mm Hg versus 70 mm Hg respectively. The slightly increased inflammation in the NPWT animals may also be related to the difference in vacuum pressure. The CSD-70 wounds had a thicker epidermis than the NPWT wounds. This may indicate that CSD-70 wounds may be slightly more immature or hypertrophic than the NPWT wounds which appeared to be mature.

Although not universally accepted, NPWT has been shown to be advantageous for several types of traumatic wounds which are seen by military as well as civilian physicians. Major criticism of NPWT include the cost, patient non-compliance problems, and preventing loss of vacuum with mobile patients. Other investigators have suggested that the timing of applying NPWT can determine the success of the technique. Thus, there is a need of an economical, convenient, compact method of providing NPWT therapy which will promote patient compliance and for the military could be used where pumps and/or batteries are not available. The CSD meets these criteria. It is economical to produce, is lightweight which allows for easy packing, does not impair patient mobility, produces negative pressure in the range of conventional VA-NPWT and improves the removal of exudates.

Conclusions

These data indicated comparable wound closure efficacies for CSD-70 capillary suction and NPWT. The CSD product with 30 mm Hg suction was superior to gauze, but less efficacious than NPWT or CSD-70 protocol. The study results provide impetus for further research on the use of high suction CSD for replacement of pump mediated NPWT and the moderate suction CSD for preventing progression of high-risk wounds to an ulcerous stage. CSD may be an alternative to NPWT. CSD provides a significant cost and weight advantage to the patient, as well as increased mobility.

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