An observational study evaluating the efficacy of Accel-heal® on the management of non-healing venous leg ulcers

INTRODUCTION
The study was based upon the following hypothesis:
ACCel-Heal will promote healing in venous leg ulcers (VLU) that have been clinically classified as non-healing.

The objectives of the study are:

- Assess the degree of wound healing using high-frequency ultrasound imaging, wound measuring mapping and visual assessment,
- Evaluate any changes in the levels of exudates over the study period,
- Assess patient levels over the study period,
- Evaluate the clinically acceptance of the ACCel-heal device.

BACKGROUND

WOUND HEALING AND ELECTRICAL THERAPY

- The ACCel-heal treatment involves the delivery of an electric current to the skin surface adjacent to the wound edge via two electrodes. The net effect of this current delivery is to create a flow of ions through the wound.
- Previous studies have reported beneficial effects in promoting wound healing attributed to galvanic effects, and stimulatory effects on specific cells types such as fibroblasts, in terms of replication and collagen synthesis.
- In skin to stimulating wounds, directly there is evidence that electrical stimulation has an anti-inflammatory effect and increased blood flow in the area.
- The increase in blood flow has also been associated with a reduction in edema.
- This is an important effect as edema can significantly delay wound healing, increase pain, tissue fibrosis, the formation of adhesions and decreased mobility of cells.

WOUND EVALUATION AND ASSESMENT

- High frequency ultrasound is an increasingly important diagnostic method used to image wounds.
- The introduction of high frequency 20 MHz probes has facilitated the assessment of the deeper parts of the wound, clearly detailing the three distinct tissue layer epidermis, dermis and subcutaneous tissue.
- Changes that occur during healing can be visualised providing accurate, statistical data using this non-invasive method.
- The 20 MHz transducer increases the resolution of the image covering a tissue depth of a few centimetres with an axial resolution of 60µm.

METHOD

A SIX MONTH OBSERVATIONAL STUDY

Twenty-two (n=22) subjects with chronic, non-healing venous leg ulcers (VLU) clinically managed with a standard four-layer high compression bandaging system (sub-bandages pressure 35-40mmHg at the ankle) with the additional treatment application of ACCel-heal. The follow-up wound assessment measures were used:

1. Photography
2. Ultrasound
3. Exudate levels
4. Pain
5. General observations of wound
6. Ultrasound: 20 MHz diagnostic ultrasound.

Images were acquired from three regions on the wound: Region 1 the untreated edge of the wound, Region 2, the periwound tissue and Region 3 the uninjured adjacent skin.

THE ULTRASOUND ASSESSMENT

Ultrasound images were acquired from three regions on the wound as depicted in figure 2.

**Figure 2: Areas Imaged**

Region 1: the untreated edge of the wound, Region 2, the periwound tissue and Region 3 the uninjured adjacent skin.

**Figure 1: ACCel-heal is a Class IA medical device**

Pre-programmed device that connects to two electrodes packed containing a metal conductive, medium placed either side of the wound on the intact skin a few centimetres from the wound edge.

DISCUSSION

- This observational study contained a relatively small number of subjects. However, given that the recommended therapy of compression bandaging alone had failed to promote any degree of healing in the VLU in this group of patients any improvements promoted by the addition of peripheral edema should be viewed as clinically relevant.
- The outcome measures evaluated were primarily the absolute degree of wound healing and secondary any changes in pain and edema levels over the study period.
- The study was not designed to explore the mechanism of action that the ACCel-heal promoted if the wounds did show evidence of healing. However, because ultrasound imaging was to assess the changes in the VLU during the study period data relating to changes within the wound could be extrapolated to suggest a possible mechanism of action.
- The most dramatic change is measured in the ultrasound images where the changes in the wound correlate to the ultrasound images. On each image the region of interest (8mm2) is within the wound cavity is changing dramatically in that it is losing a high level of contrast to a low level of contrast.
- The ultrasound enabled the measurement of the width of the zone of oedema collecting beneath the epidermis of the intact periwound skin.

**Figure 3: Ultrasound Images of normal skin A and wound periwound skin B**

**Figure 4: Ultrasound Image of a VLU**

**Figure 5: Baseline ultrasound Examination with corresponding wound photograph.**

**Figure 6: 10 days after ACCel-heal treatment started showing a reduction in oedema**

**Figure 7: 90 days after ACCel-heal treatment started showing a healed VLU**

The images show the wound area at time 0 is saturated with oedema, which is shown in the scans as a red/black colour. The accompanying photograph also shows this and note that the surrounding periwound tissue is also unfurled. After 10 days of treatment (figure 6) the nature of the tissue within the wound cavity is changing dramatically in that it is losing a high degree of the oedema here that was present at time 0. The tissue at 90 days has a predominance of blue areas, which are indicative of intact tissue which is comparable to that seen in normal skin (see figure 7).

CONCLUSION

- The study was based upon the hypothesis that ACCel-Heal will promote healing in venous leg ulcers (VLU) that have been previously clinically classified as non-healing. In this study ACCel-Heal proved to be an effective in stimulating non-healing VLU to heal.
- Given that the average duration of these wounds was 2.2 years the accurate and the fact that a significant proportion of these wounds responded following application of the ACCel-heal device is encouraging.

The study has a few limitations, the size of the study and the number of subjects, the type of patients included and the size of the sample. However, this is an observational study and it is not possible to get a quantitative assessment of the level of oedema present in this wound.

**Figure 8: Ultrasound Images highlighting changes in level of oedema.**

**Figure 9: Day 0**

**Figure 10: Day 10**

**Figure 11: Day 20**

**Figure 12: Day 90**

To further aid interpretation of these images it is helpful to think of all areas that are dark red/black are high in fluid, whereas areas which are blue/white tend to be occupied by more fibrous and less hydrated structures. Un-injured skin has a greater proportion of blue reflection to the red/black as shown in figure 9A.

RESULTS

- Subjects mean age was 69.2±11.4 years, 62% of subjects were female.
- The mean time of the VLU before the start of the study was 2.2±2.0 years.
- 95% of subjects VLU improved with 36% healing to closure.
- The mean number of nurse visits with ACCel-heal was 35.9 compared with a pre-treatment average of 49.
- Pain pre-commencement of ACCel-heal was a mean of 5.3 on a score of 0 (no pain) to 10 (worst pain imaginable). At the completion of the study mean pain levels had decreased to 1.6.
- Exudate levels pre-commencement of the average was 5.8 on a score of 1 (no) which had reduced to a mean of 2.8 where a score of 10 means the dressing requires changing daily due to exudates leak. This represents a drop of 51% in exudates.

REFERENCES

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