

**Report on a Clinical Evaluation of the
DanMedicaSouth Ltd Treat-Eezi Bed Pad**

Ultrasound Analysis

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Trial Design

- The Treat-Eezi bed pad was evaluated on 6 Subjects in a Care Home environment over a 4 week period, in order to examine its effect on preventing pressure damage. The average age of the Subjects was 86 years, with the oldest Subject being 95 years and the youngest 70 years.
- The Waterlow Score Range was 16 – 19, with the average Waterlow Score being 17. Therefore all Subjects were in the “High Risk” category.
- Five of the Subjects had no signs of existing pressure damage prior to the use of the Bed Pad on their scapulae, spine, sacrum, buttocks or hips. One subject had a grade 2 pressure ulcer in the sacral area.

The trial design was as follows:

Visit 1

- Patients identified and consented.
- Ultrasound scan carried out on the skin of the at risk areas of pressure damage (scapulae, spine, sacrum, buttocks and hips) to establish a baseline.
- Patients were then assigned a DanMedicaSouth Treat-Eezi bed pad (Pad 4).

Visit 2

- 4 weeks after the baseline visit the at risk areas were again scanned. From the information gained from this it was possible to establish if the area had improved, deteriorated or stagnated.

Assessment:

Ultrasound Scanning:

The benefit of including ultrasound as an assessment tool is that it provides quantitative information about what is happening beneath the skin surface which is not always clinically evident (1-6).

The scanner used in this project (figure 1) operated at a frequency of 20MHz (Episcan - Longport Inc.). This frequency gives an axial resolution of 65µm.

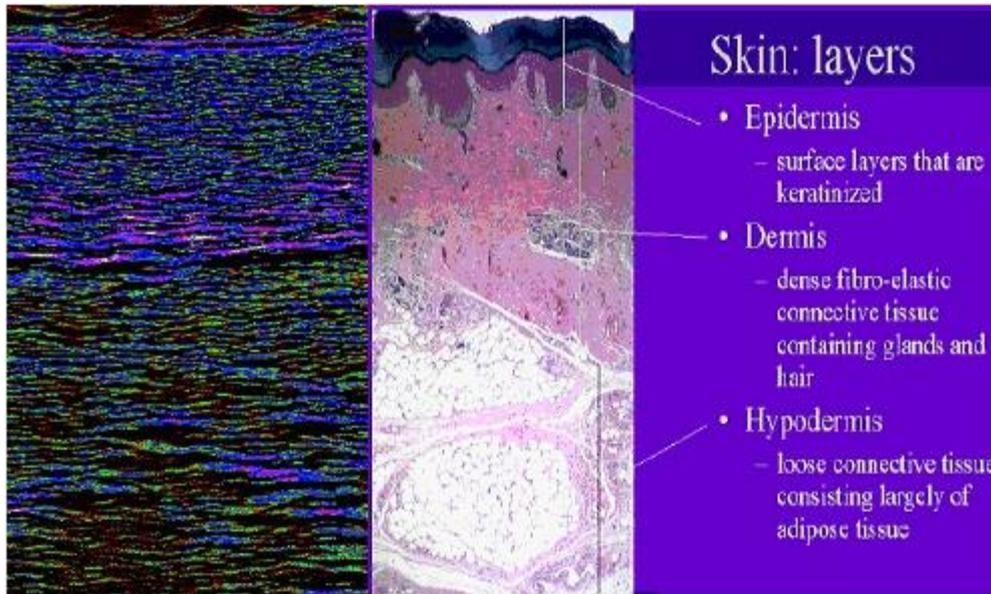
Figure 1. Ultrasound Scanner



The scanning procedure is non-invasive and the affected area was exposed and an aqueous gel applied to it and a scan then taken. Care was taken to carry out subsequent scans in the same area 4 weeks later.

In figure 2 an ultrasound scan of skin has been placed next to a labelled histological section to allow the reader to identify the different regions.

Figure 2. Scan of normal skin with adjacent histology section indicating skin layers.



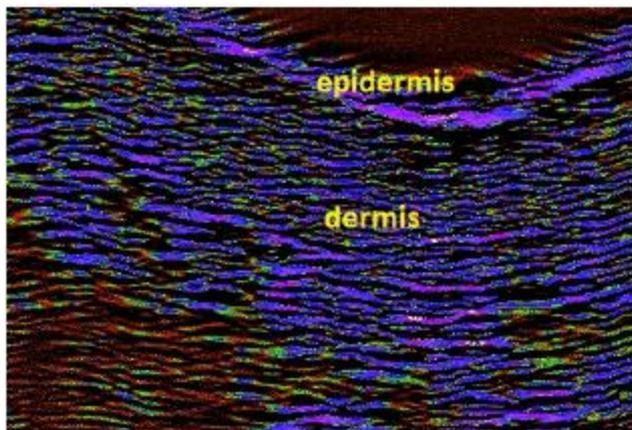
Scan Analysis

Using the scanners image analysis software it was possible to measure the amount of oedema within the dermal tissue. Each scan of the tissue was analysed using a form of pixel distribution analysis whereby pixels below certain intensity are classed as Low Echogenic Pixels (LEP). The ratio of LEP's to Total Pixel count (TP) has been shown to reflect changes in dermal water content (7, 8). Using this technique it was possible to get a quantitative assessment of the level of oedema present in the tissue.

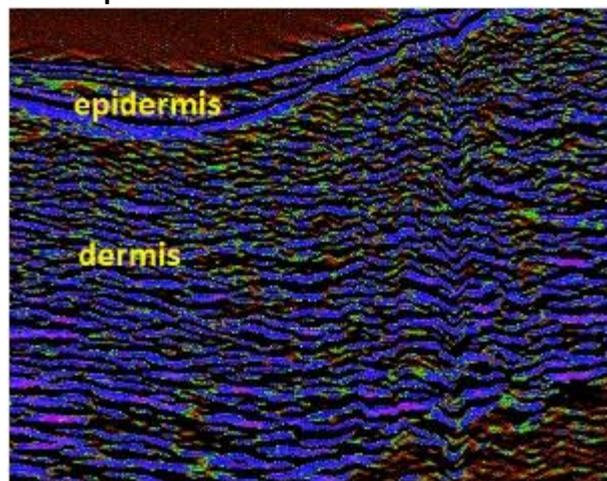
Results – BG

Figure 3. Scans comparing time 0 scans against 4 weeks for each skin location.

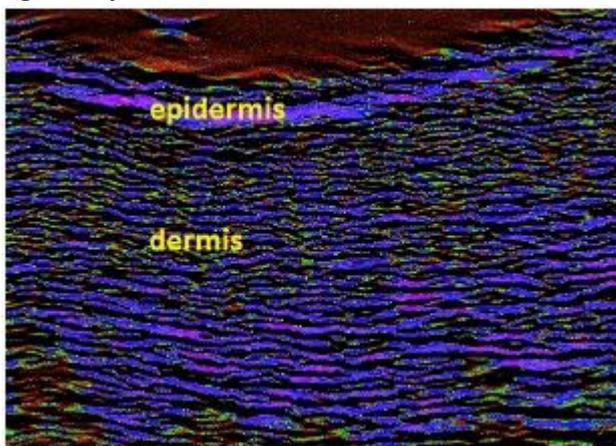
Left Scapula - Time 0



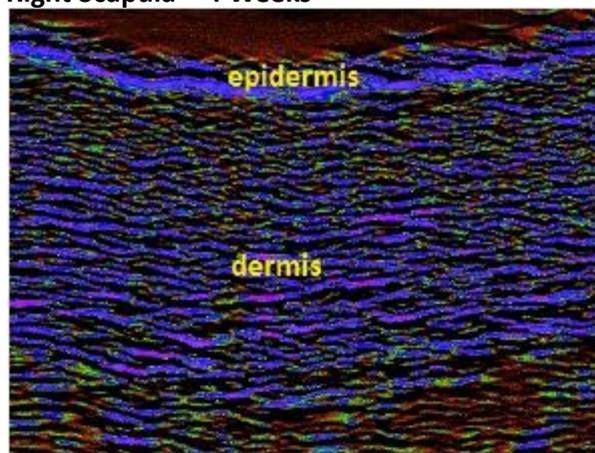
Left Scapula – 4 Weeks



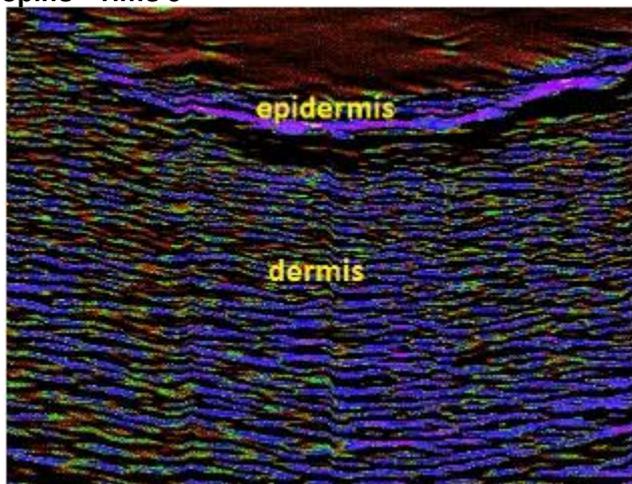
Right Scapula - Time 0



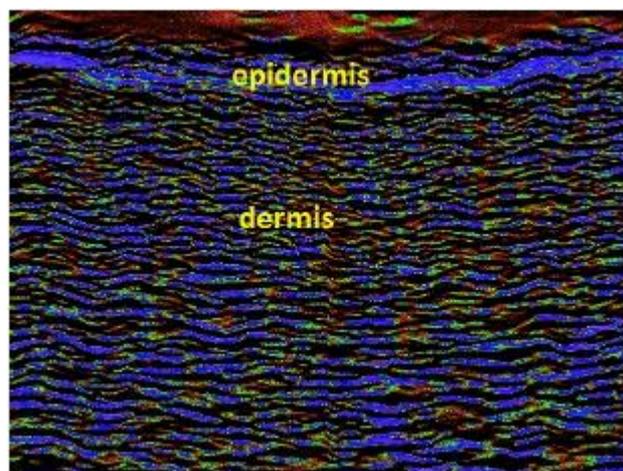
Right Scapula – 4 Weeks



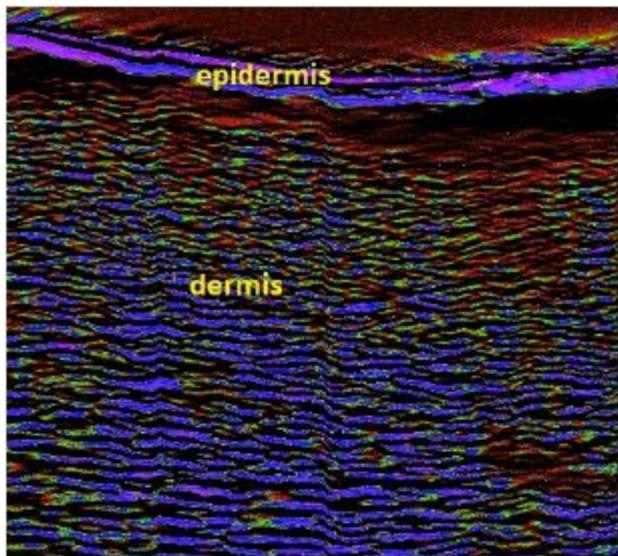
Spine - Time 0



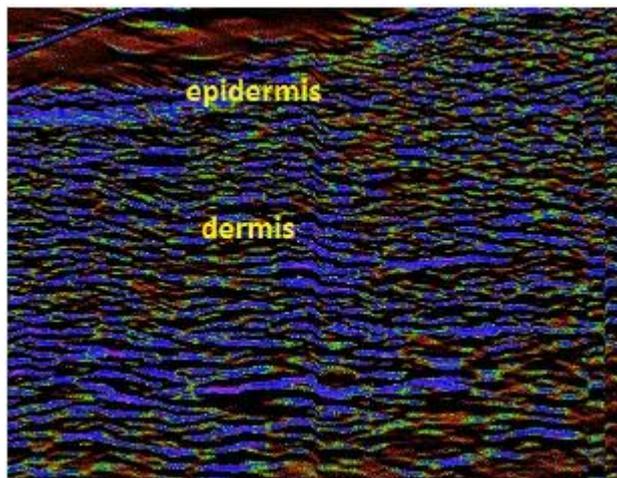
Spine – 4 Weeks



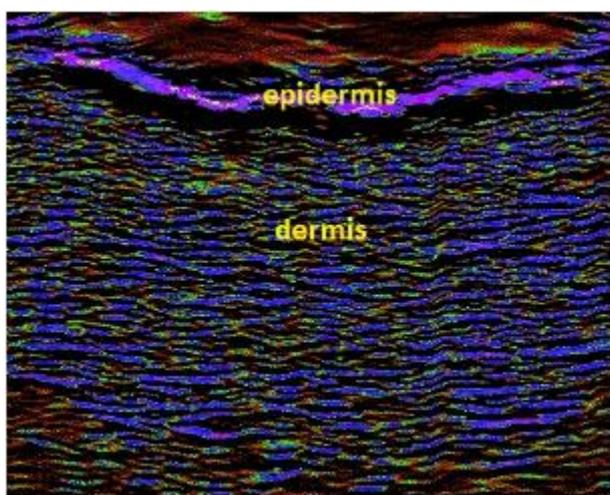
Sacrum - Time 0



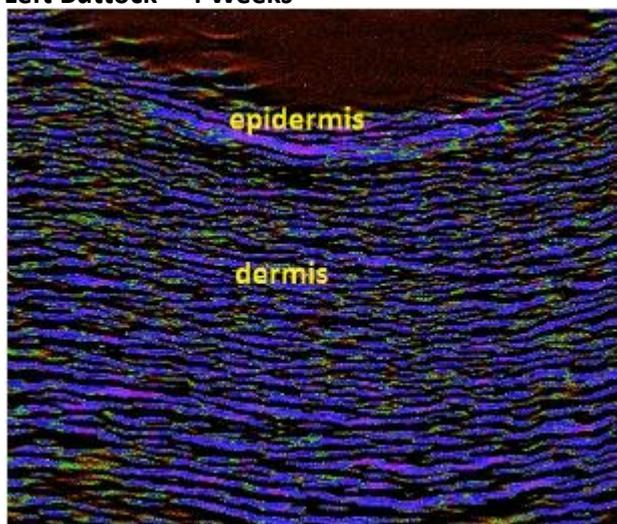
Sacrum - 4 Weeks



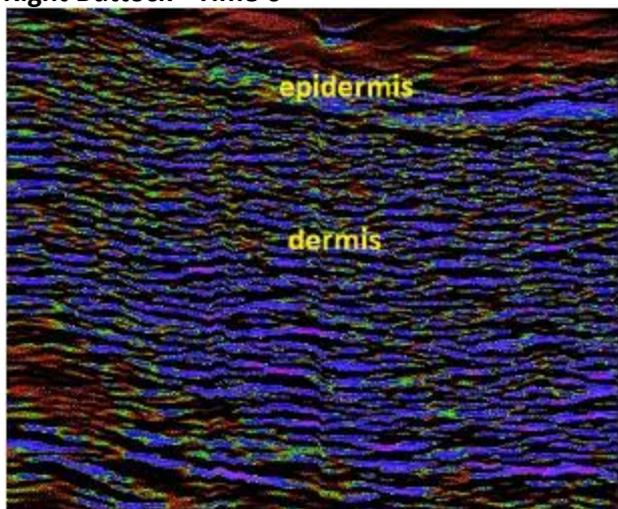
Left Buttock - Time 0



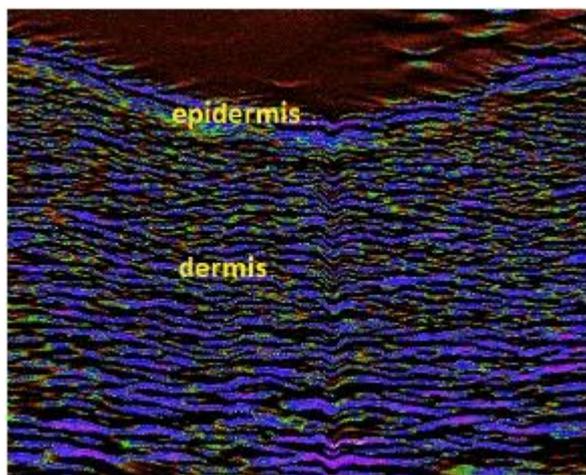
Left Buttock - 4 Weeks



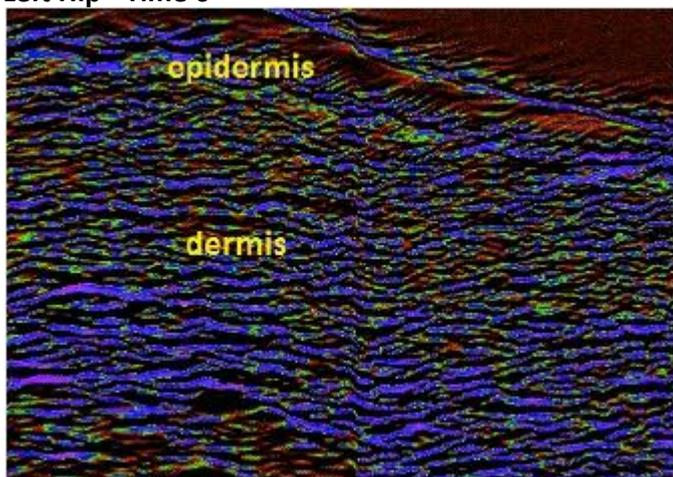
Right Buttock - Time 0



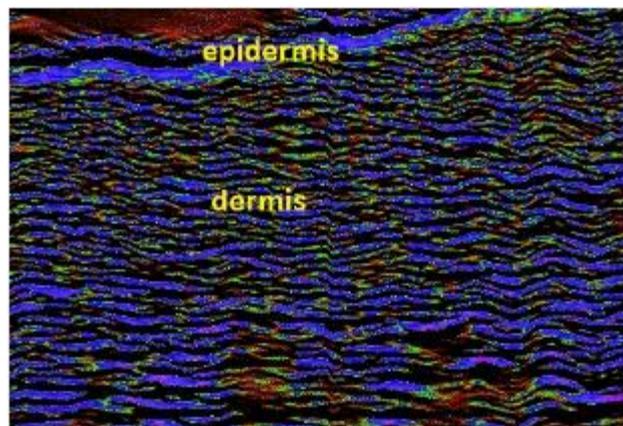
Right Buttock - 4 Weeks



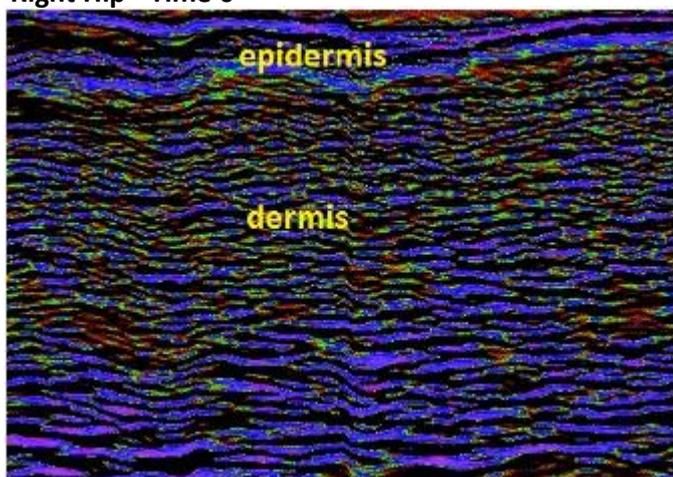
Left Hip - Time 0



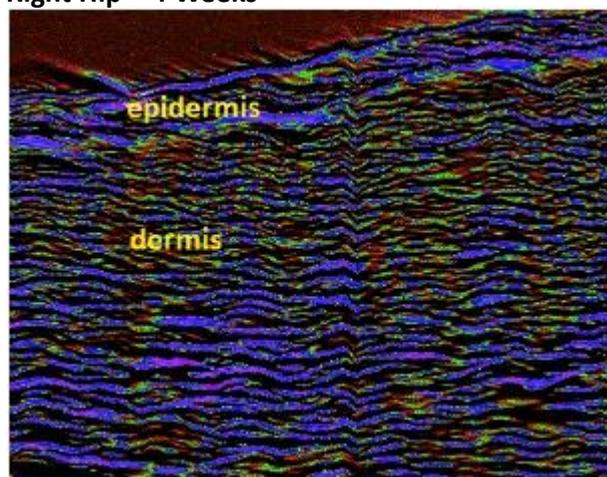
Left Hip - 4 Weeks



Right Hip - Time 0

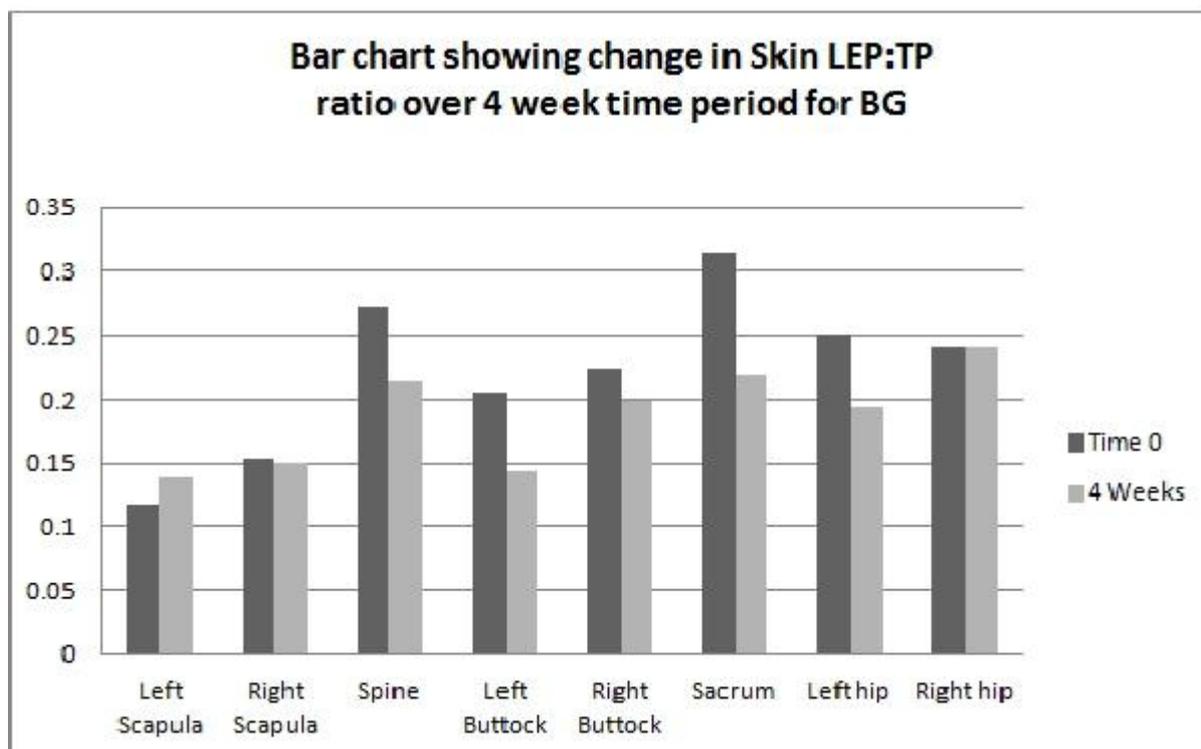


Right Hip - 4 Weeks



The scan of the time 0 sacral skin shows a very obvious elevated number of red pixels in the dermis just below the epidermis indicating the presence of oedema. The scan of the same tissue after 4 weeks shows that there is a decrease in red pixels and an increase in blue pixels which indicates a decrease in oedema. Analysis of all the scans in this subject are shown in figure 4.

Figure 4 Graph of LEP: TP ratio for BG Skin Analysis

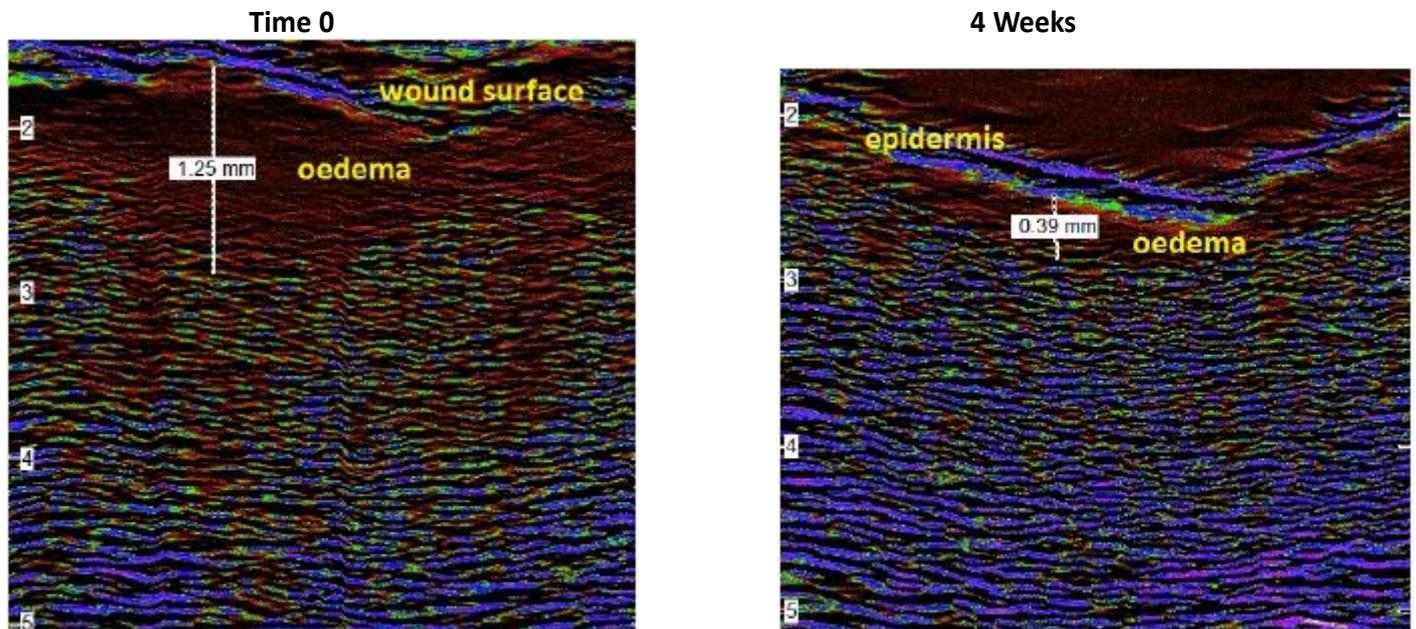


The results show that there are changes to be seen in the oedema levels in the skin of this subject when comparing time 0 with 4 weeks. Apart from a slight increase in the left scapula and no change in the right scapula all other areas have seen a decrease in oedema. This is particularly pronounced in the sacrum.

Additional data for Subject BG: Wound in Left Sacral Area

Subject BG had a grade 2 pressure ulcer in the left sacral area. This was scanned at Time 0 and then at 4 weeks. Below in figure 5 are the scans at these two time points.

Figure 5. Scans showing the grade 2 pressure ulcer at time 0 and 4 weeks



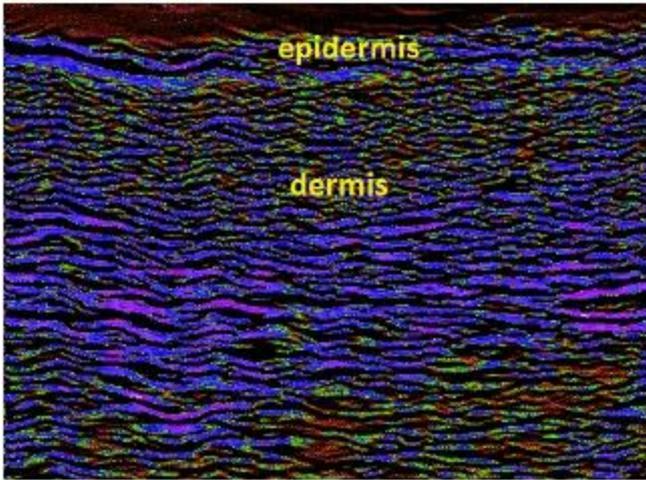
The time 0 scan shows the wound bed. From the scan it can be seen that the epidermis is not present and the main zone of oedematous wound tissue is approximately 1.25mm thick. The scan also shows that the tissue beneath this main zone is itself very oedematous.

The scan of the same area 4 weeks later shows that the epidermis has now regenerated. Note the depth of the oedema compared to the time 0 state. There has been a great reduction in oedema, which corresponds to what was noted clinically (see clinic report).

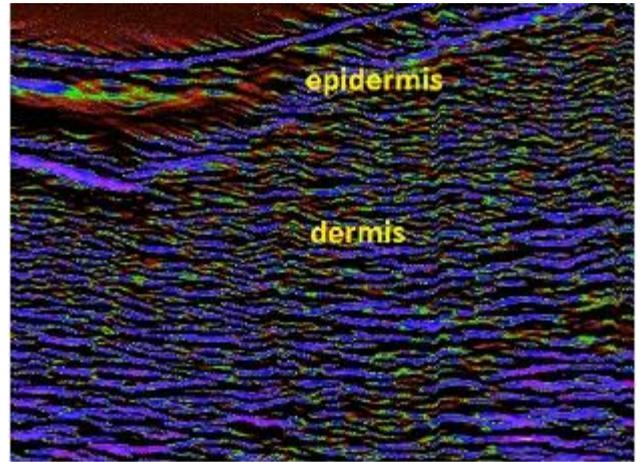
Results – CB

Figure 6. Scans comparing time 0 scans against 4 weeks for each skin location.

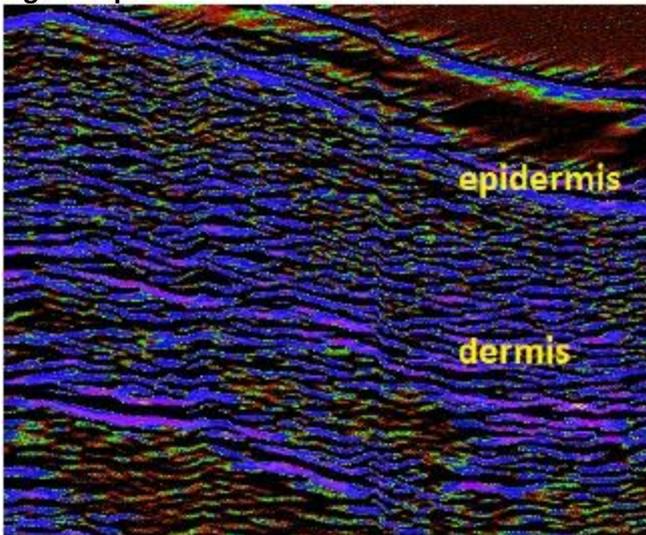
Left Scapula - Time 0



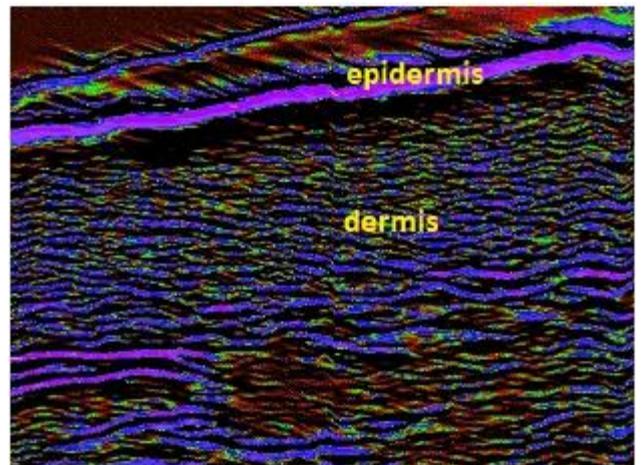
Left Scapula – 4 Weeks



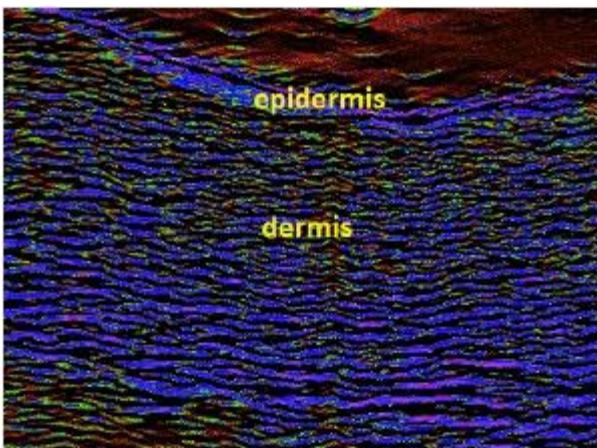
Right Scapula - Time 0



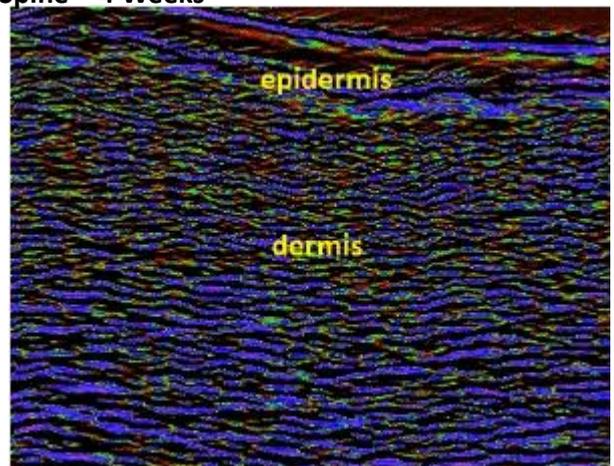
Right Scapula – 4 Weeks



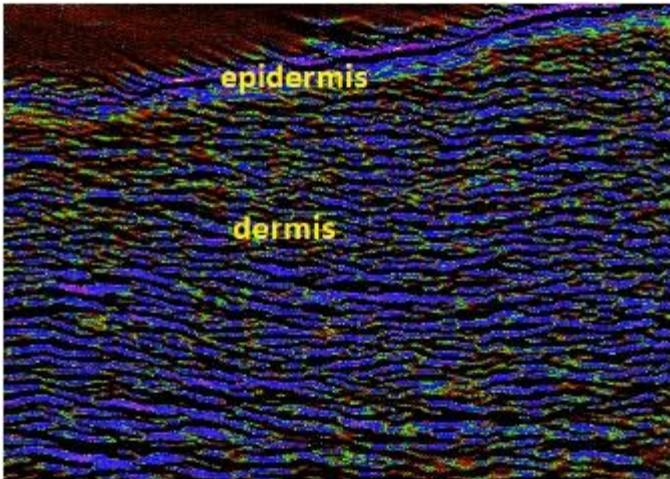
Spine - Time 0



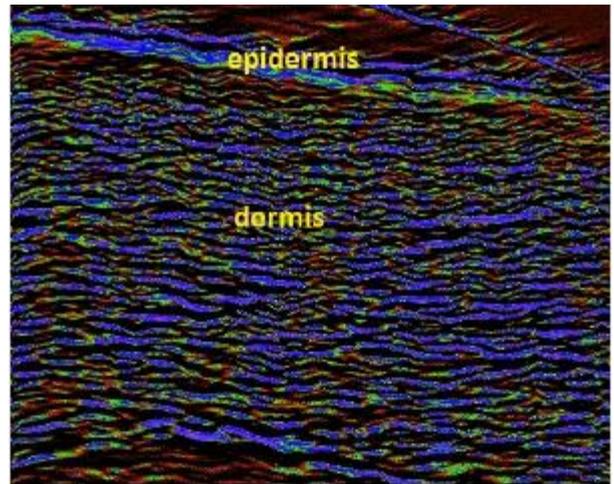
Spine – 4 Weeks



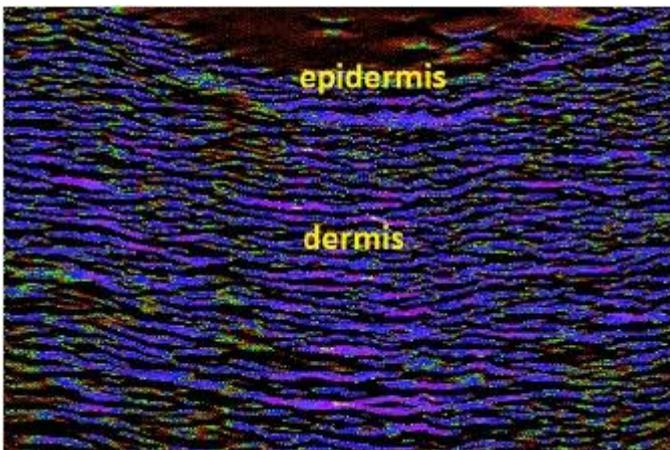
Sacrum - Time 0



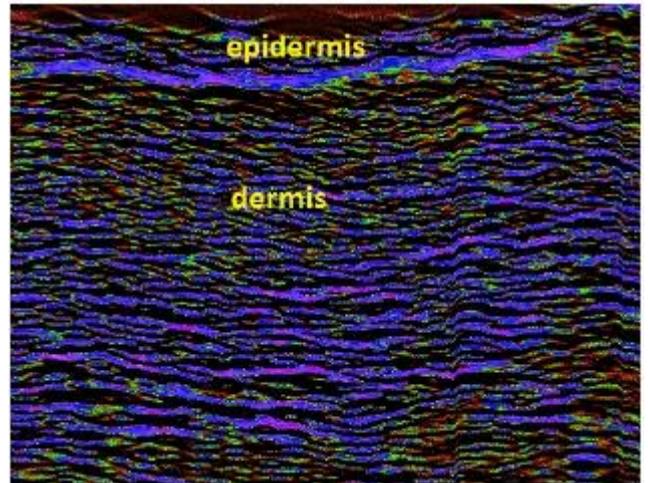
Sacrum - 4 Weeks



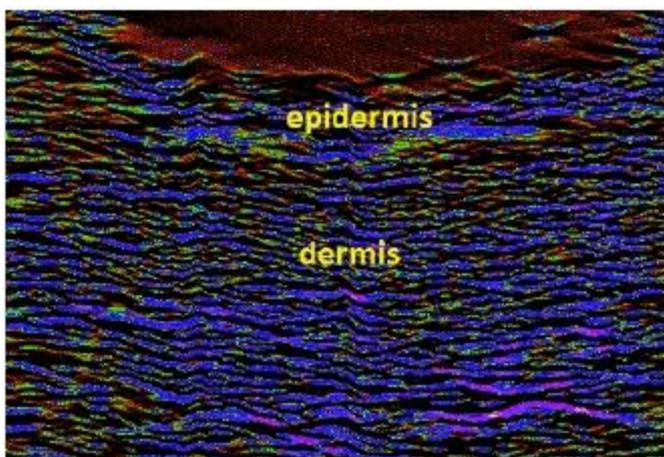
Left Buttock - Time 0



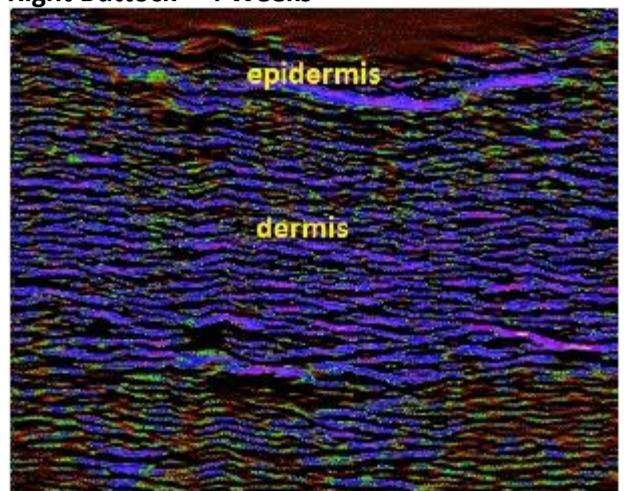
Left Buttock - 4 Weeks



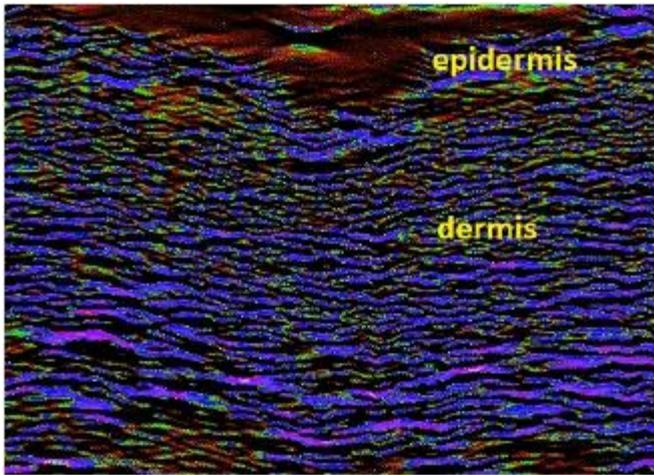
Right Buttock - Time 0



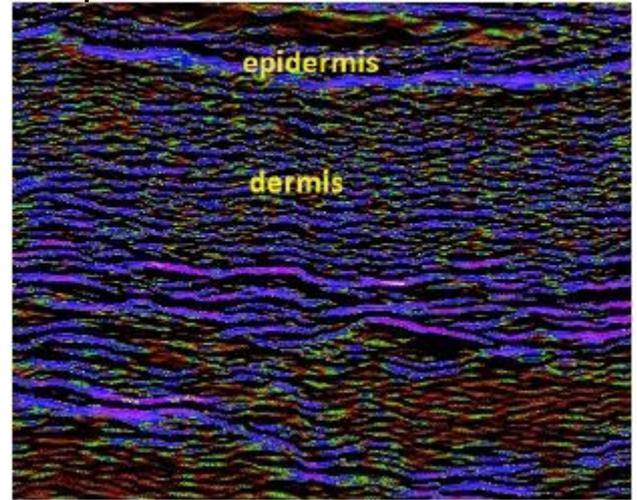
Right Buttock - 4 Weeks



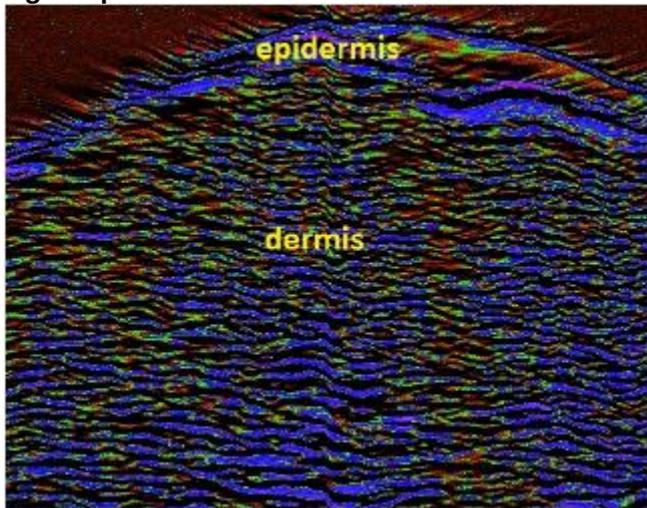
Left Hip - Time 0



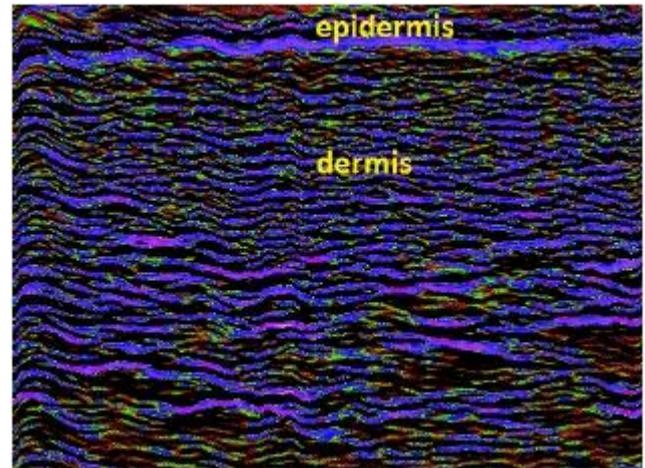
Left Hip - 4 Weeks



Right Hip - Time 0

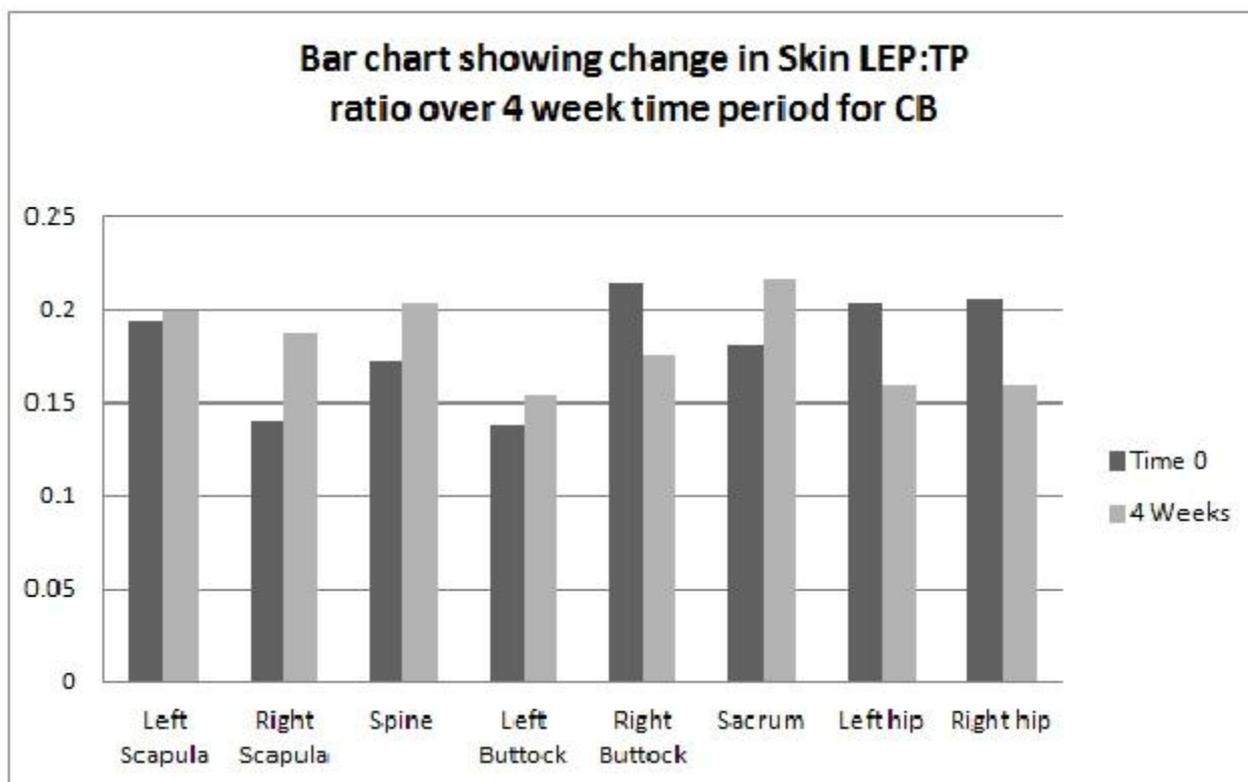


Right Hip - 4 Weeks



The scans indicate a mixture of results, some areas have improved and others have gained more oedema over the 4 weeks. Analysis of all the scans for this subject is shown in figure 7.

Figure 7 Graph of LEP: TP ratio for CB Skin Analysis

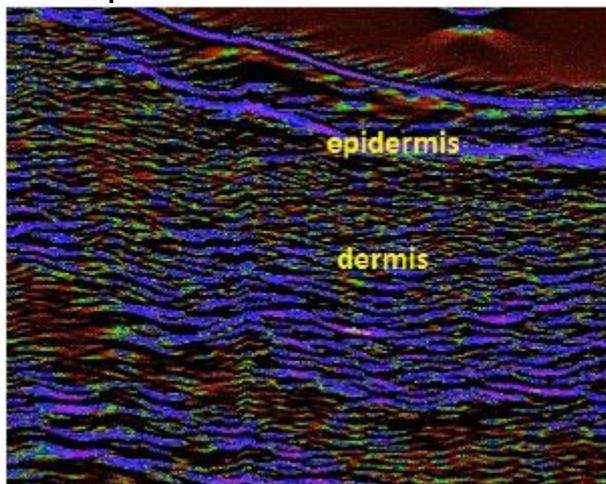


The results show that there are changes to be seen in the oedema levels in the skin of this subject when comparing time 0 with 4 weeks. Left scapula has not changed significantly. Right scapula, spine, left buttock and sacrum have seen an increase in oedema. Right buttock, left and right hip have seen a decrease in oedema.

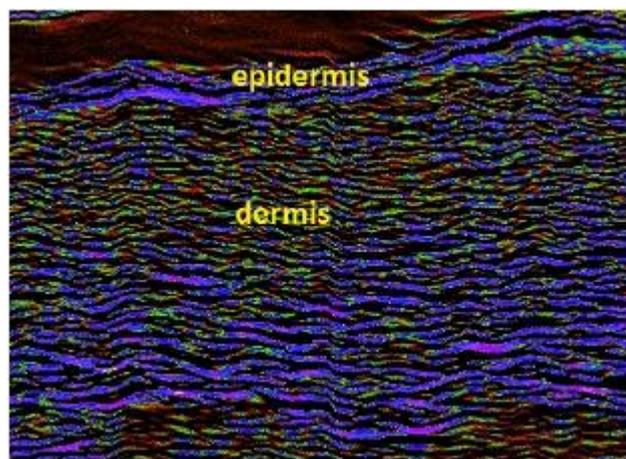
Results – DB

Figure 8. Scans comparing time 0 scans against 4 weeks for each skin location.

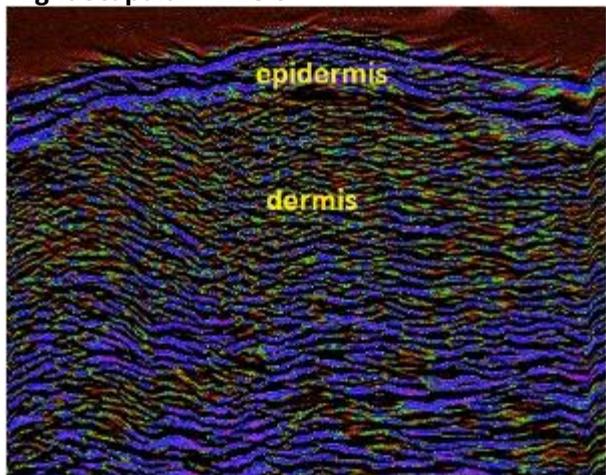
Left Scapula - Time 0



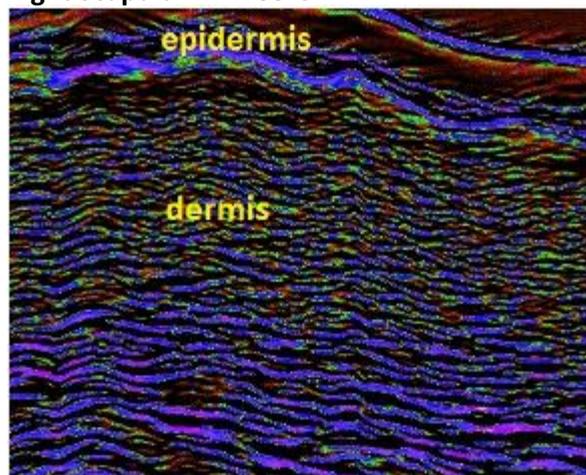
Left Scapula – 4 Weeks



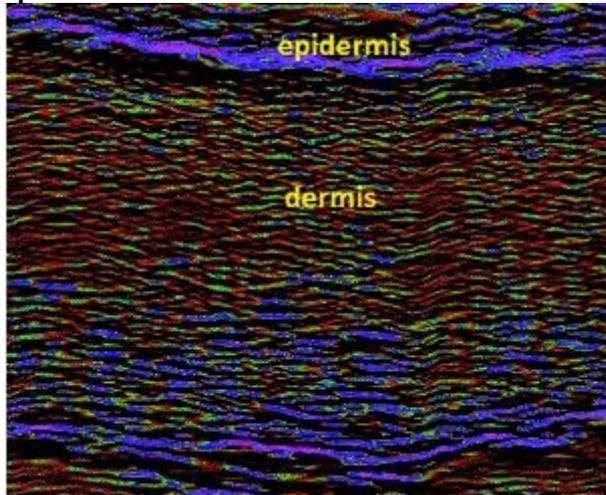
Right Scapula - Time 0



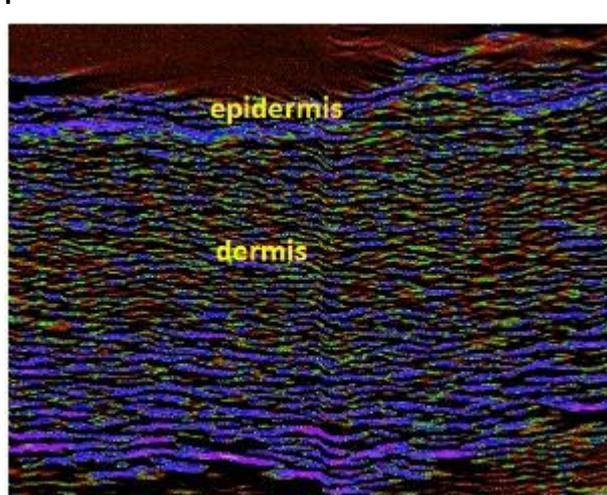
Right Scapula – 4 Weeks



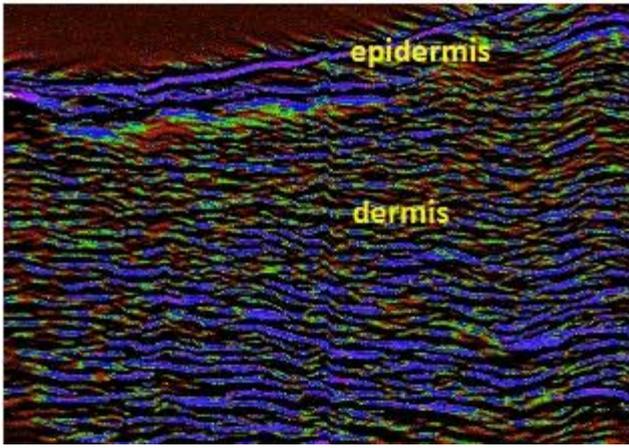
Spine - Time 0



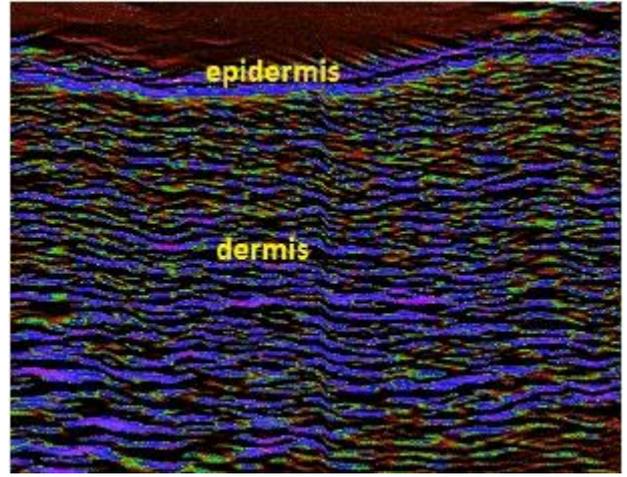
Spine – 4 Weeks



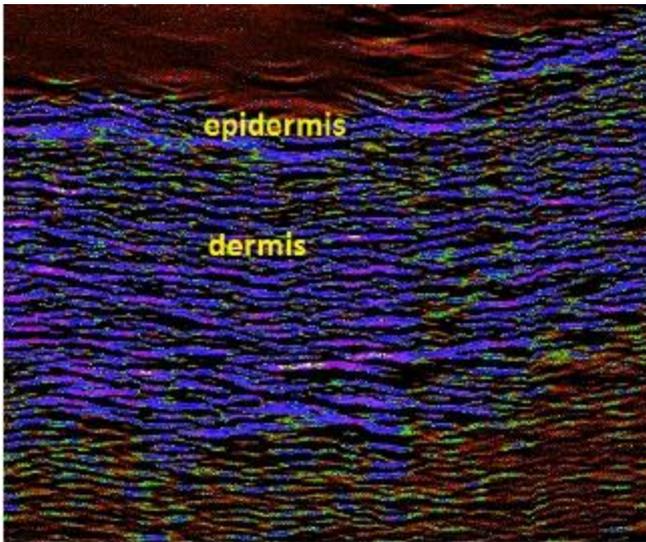
Sacrum - Time 0



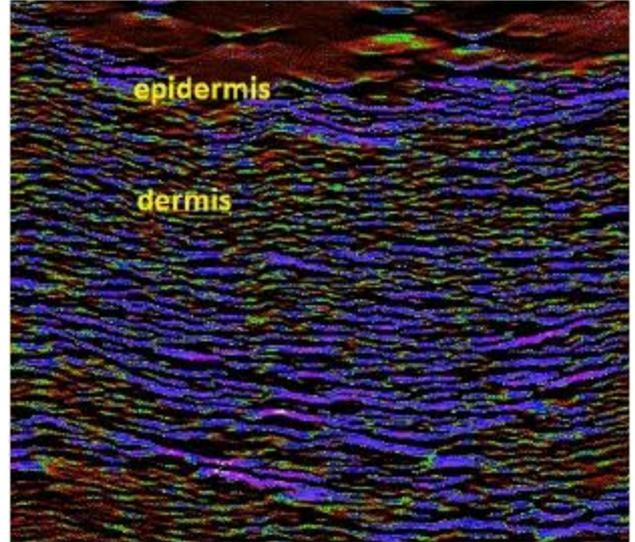
Sacrum - 4 Weeks



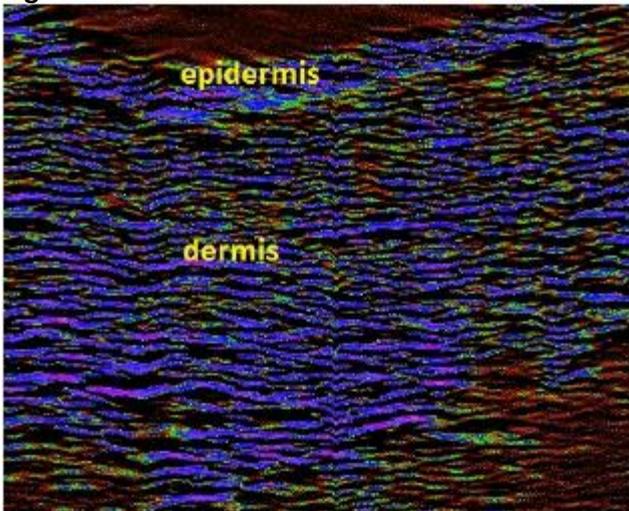
Left Buttock - Time 0



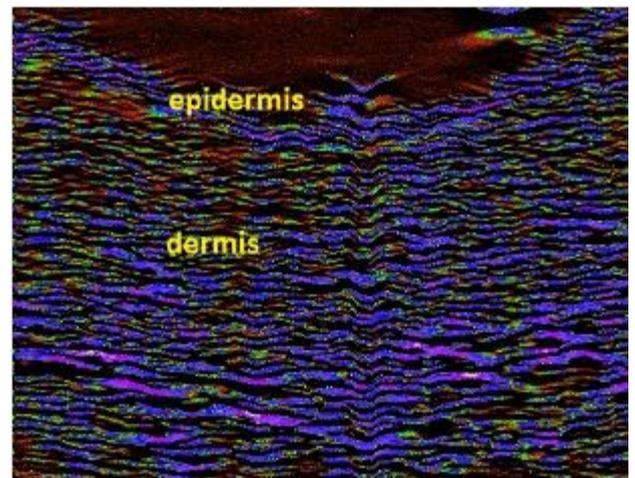
Left Buttock - 4 Weeks



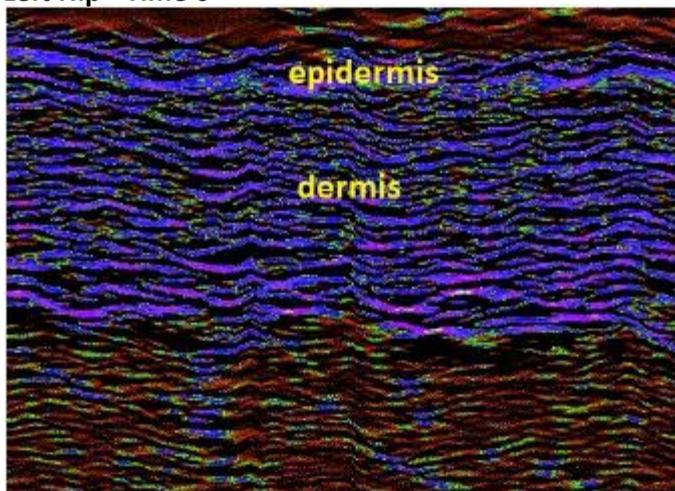
Right Buttock - Time 0



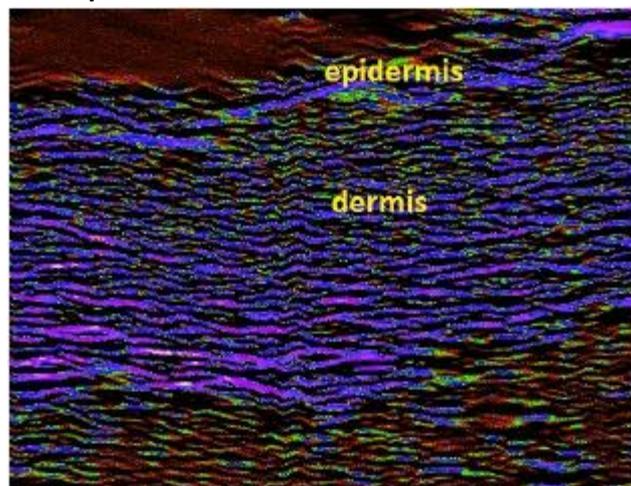
Right Buttock - 4 Weeks



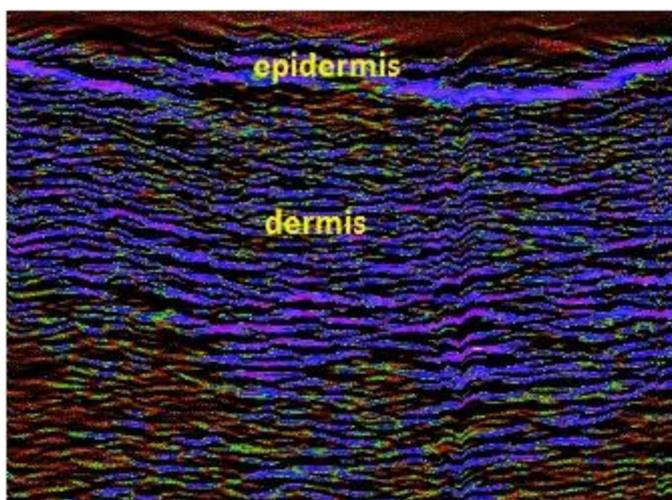
Left Hip - Time 0



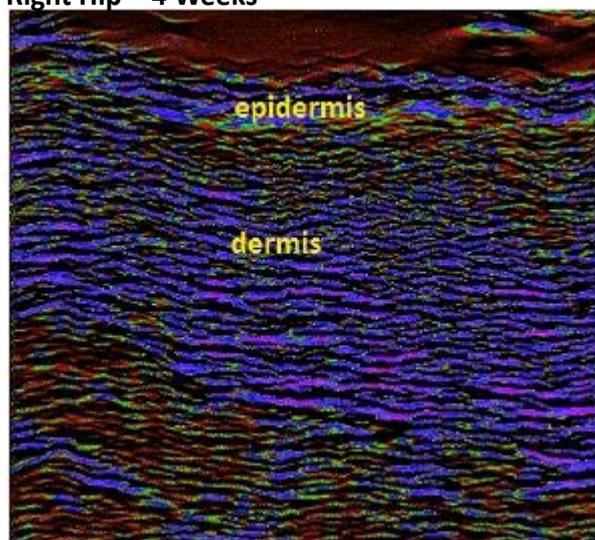
Left Hip - 4 Weeks



Right Hip - Time 0

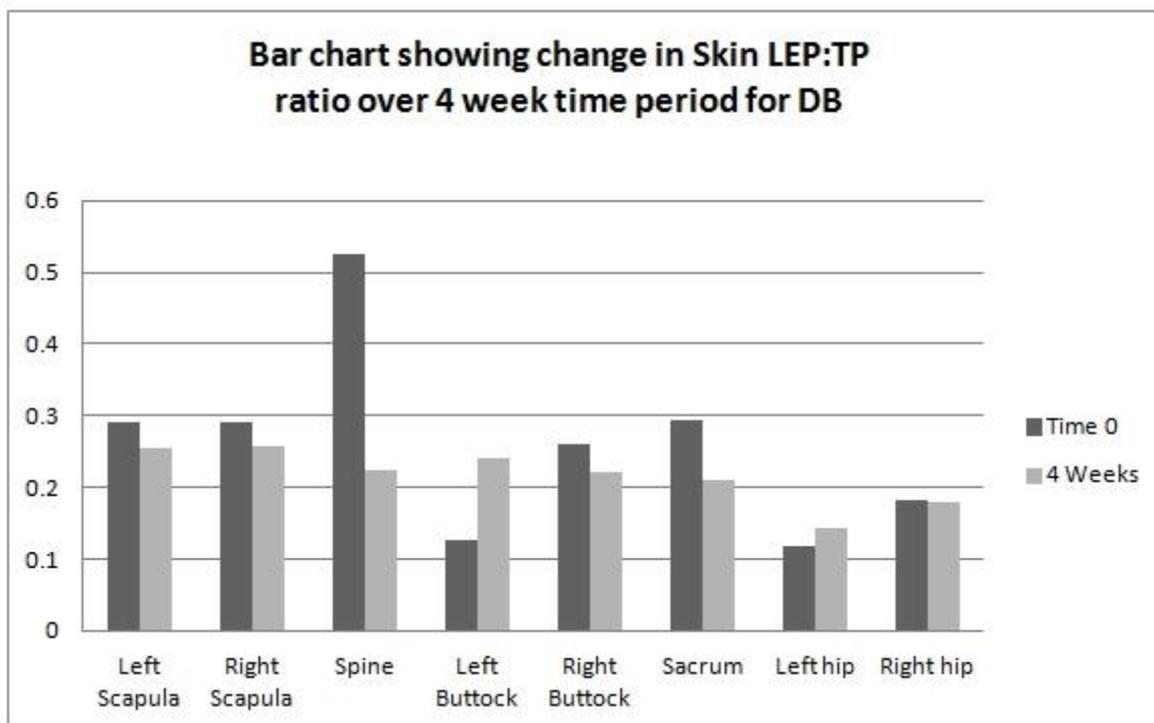


Right Hip - 4 Weeks



The scans indicate a mixture of results, some areas have improved and others have gained more oedema over the 4 weeks. Analysis of all the scans for this subject is shown in figure 9.

Figure 9 Graph of LEP: TP ratio for DB Skin Analysis



The results show that there are changes to be seen in the oedema levels in the skin of this subject when comparing time 0 with 4 weeks. Left and right scapulae, spine, right buttock and sacrum show a decrease in oedema over 4 weeks. The right hip has not changed significantly. The left buttock and left hip show an increase in oedema.