Investigations to Accurately Measure the Healing and Receding Edges in Chronic Venous Leg Ulcers

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Background

The boundaries of chronic venous leg ulcers constantly change, accurately recording the extent of healing and expanding edges to determine the impact of localised treatment proves challenging. Physical tracing, standard photography and 3D imaging all capture changes in ulcer area, however without consistent leg/ulcer registration, the accuracy of localised boundary changes lack confidence e.g. ulcer area measurements will appear unchanged if one side has expanded and the other healed by a similar amount.

Objective

The primary research objective was to accurately measure the healing and receding edges of a chronic venous leg ulcer over time, so enabling direct comparison between localised treatments. Secondary considerations of system cost, ease of use, ease of analysis and accuracy of data were investigated, as strong combinations could potentially out-way the primary objective.

Methods

Four methodologies shown in Table 1 were investigated:

1. **Wound tracing via acetate sheets,**

   One sheet per visit was used to outline the ulcer boundary, orientation and anatomical features were clearly marked, then an adhesive ruler placed adjacent to the outline with patient and visit details added. The acetate was placed onto a sheet of A4 paper and photographed using a mobile device, with the capture application (Genius Scan) completing auto alignment for the A4 paper at the point of capture. Such process allowed for prompt outline digitisation without scanner contact/usage, following image transfer both acetate and paper could be destroyed to prevent storage and cross contamination. Image analysis methodology is as point 4 below.

2. **Standard photography with comprehensive leg/camera positioning,**

   A Nikon digital SLR employing a lens mounted Olympus ring flash, was set manually in a controlled environment for consistency of imaging. With camera, lighting and environment maintained; remaining variables were the ulcer, position of the patient's leg and photographer's capture position. By minimising the latter two variables through consistent note taking, changes to the former could be recorded with greater confidence.

   With all images, the photographer's position was perpendicular to the centre of the ulcer, ensuring the clearest perspective was maintained at each visit. Both patient position and that of the leg support were also documented, then replicated during each visit. The inclusion of scale tape around the limb (ideally at both ends of the ulcer) supported an ID label and facilitated perspective corrections – see image analysis methodology in point 4 below.

3. **3D capture system,**

   Capture technique, patient positioning and environmental variables were minimised to ensure the imaging system achieved maximum detail and consistency. Guiding lasers within the device assist capture perspective and tethered image processing allows rotation of images to match ulcers across a sequence of visits. Following user defined boundary selections, ulcer area, volume and depth is automatically calculated for each timepoint, e.g. Aranz Silhouette or Quantificare LifeViz systems.

4. **Standard photography utilising on-leg ulcer registration markings,**

   This methodology mirrors point 2, except for:
   - The addition of 2 semi-permanent ink (pen) registration marks in healthy skin at either side of the ulcer,
   - Two diffuse oblique flashes were positioned to minimise glare whilst retaining surface detail. Cross-polarisation could have been employed to negate all glare but this would have eliminated all surface detail – necessary for ulcer boundary selection.

Image analysis methodology, via Image-Pro Analyzer (open source packages include ImageJ) commenced with limb alignment and correcting for changes in perspective; for method 2 this latter action referenced rulers at either end of the ulcer (where possible), method 3 allows 3D image rotation to achieve alignment, for method 4 the semi-permanent markings guide image alignment. Post image alignment, the ulcer boundary is user defined for methods 2, 3 and 4, bringing them in-line with method 1. Following ulcer boundary selection, automated area selection (and volume/depth for method 3) is achieved.

Multiple images can be layered or masks overlaid from previous visits to suggest changes in the ulcer areas – subject to the accuracy of image alignment. Figure 1 demonstrates ulcer boundary alignment issues associated with method 1, with the capture to analysis steps associated with each method being summarised in table 1.

Figure 1. Top row from left; auto alignment selection during mobile capture, resultant images for Day 0 and Month 3. Bottom row, variability of image alignment options, with Day 0 shown as blue and Month 3 green.

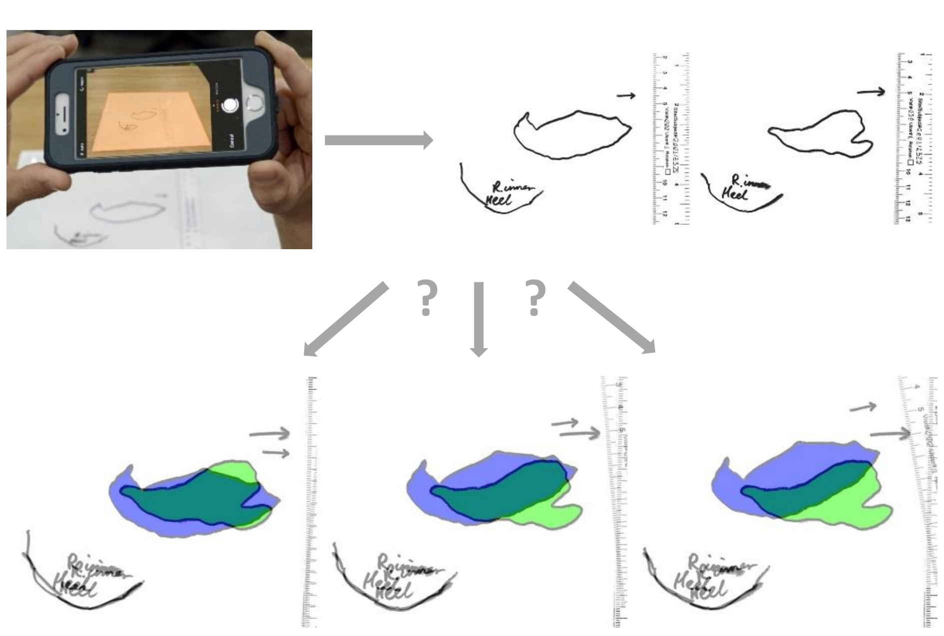


Table 1. Image path from capture to analysis:

Method 1-4				
Prep	1. Debride. 2. Position patient.	1. Debride. 2. Position patient.	1. Debride. 2. Position patient.	1. Debride. 2. Mark (or re-apply ink). 3. Position patient.
Capture	3. Trace ulcer. 4. Complete orientation markings. 5. Patient ID and ruler added. 6. Capture using phone app.	3. Patient ID and ruler added. 4. Capture.	3. Select patient from system. 4. Capture.	4. Patient ID and ruler added. 5. Capture.
Transfer	7. Transfer via secure app.	5. Place memory card in reader. 6. Copy preferred image to patient notes.	5. Delete spares images and assign to patient.	6. Place memory card in reader. 7. Copy preferred image to patient notes.
Store	8. Delete from phone/device. 9. Store in patient notes.	7. Delete original from camera.	6. Use local computer or Silhouette central back-up.	8. Delete original from camera.
Analysis	10. Open in analysis app. 11. Set calibration. 12. Run auto measurement. 13. Export measurement.	8. Open in analysis app. 9. Set calibration. 10. Select ulcer area manually. 11. Export measurement	7. Select ulcer area manually. 8. Export measurements.	9. Open in analysis application. 10. Set calibration. 11. Select ulcer area manually. 12. Overlay grid. 13. Export measures.

Results

Following test captures, outline procedures were created and ulcer images taken monthly in accordance with the above methodologies. Immediately, image consistency proved problematic in the clinic; leg and foot positioning was maintained well through precise note taking/referencing, however subtle changes in the angle of image capture introduced noticeable variability in ulcer appearance and consequently data.

Through practical testing of the 4 methods, the following limitations became apparent:

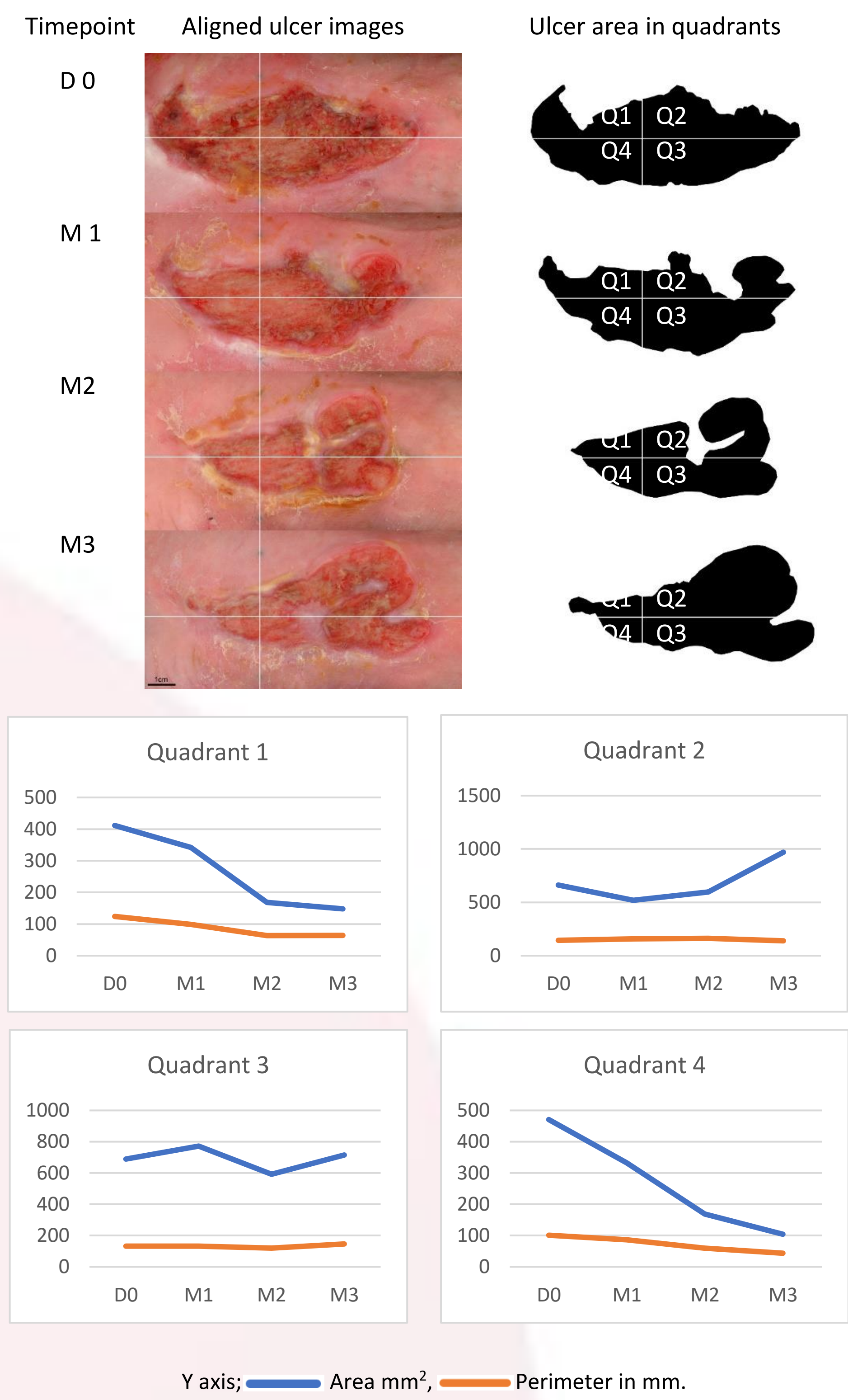
1. The acetate sheets proved problematic when tracing from complex curved surfaces and again when identifying the registration mark(s) for image alignment/analysis. They did however provide a surface plan from the 3D ulcer, unlike the other methodologies which only offered a 2D perspective within any single image.
2. Standard photography in conjunction with comprehensive leg/camera positioning suffered from the lack of clear registration marks for post capture alignment. Unlike acetate, photographer capture perspective changed between visits, so eroding data confidence and image consistency. Figure 2 demonstrates the best fit achieved for visually aligned images from both method 2 and 3.
3. The 3D imaging system negates the issue of capture perspective by allowing ulcer/leg alignment of images post capture, the lack of external registration marks, meant that data was reliant on boundary comparisons with those of earlier images.
4. The expanded 2D photography produced the clearest images (due to oblique diffuse flashes) and resulted in clearly aligned image sequences. The problems experienced by the standard photography and acetate methodologies of alignment were negated, in addition the inclusion of the fixed registration marks allowed the viewer to visually quantify the changing boundaries within the quadrants of each image.

Following practical experience, the clinical team were asked to rank the perceived accuracy of the healing / receding edges from outlines obtained via each capture method. In relation to this criterion alone, the Primary Objective column within Table 2 summarises the combined ranking scores for data confidence from the clinical team.

Figure 2. (L-R) Day 0, Month 3 and combined images with outline analysis from capture method 2.

The combined image (right) within Figure 2 demonstrates -through shadowing of the ankle boundary- that ankle position has altered between visits, which in turn reduces confidence in data if comparing the impact of localised treatments. For capture methods 2 and 3, such changes in the ankle result from a combination of uncontrollable variables; minor changes in leg and camera positioning, in addition to physical changes with the leg, such as swelling or compression. By contrast the introduction of markings adjacent to the ulcer -via capture method 4- allows for accurate image adjustment to minimise such variables – as shown in Figure 3.

Figure 3. Images aligned via registration marks and data achievable through capture method 4.



During practical testing, the clinical team were asked to consider and rank the secondary objectives, as strong combinations could potentially cancel out the primary objective. Table 2 summarises the secondary considerations; system cost, ease of use and ease of analysis, the scores were combined into a secondary ranking for each modality. The ranking scores for the primary and secondary objectives were then combined to provide an overall perspective between the methodologies investigated.

Table 2. Summary of primary and secondary clinical rankings, where favoured scored 3, suitable scored 2, 1 for tolerable and 0 if not acceptable.

Capture method	system cost	ease of capture	ease of analysis	Total secondary score	Secondary objective ranking	Primary objective ranking	Total primary/ secondary ranking
1. Acetate tracing	3	2	3	8	3	1	**4**
2. Basic photography	2	2	1	5	1	2	**3**
3. 3D capture	1	3	2	6	2	2	**4**
4. Photo. c/w ink markings	2	2	2	6	2	3	**5**

Conclusion

Ulcer image positioning was achieved via two perpendicular semi-permanent ink markings (beyond the mid-ulcer boundary), these also acted to identify the treatment areas for consistent application and analysis. Following a positive (upper leg) skin test, the markings were applied without disrupting skin structure but required re-application approximately every 2 months – investigating the number and application of registration marks was beyond scope.

Accurate measurements of the healing and receding ulcer edges could be achieved via both 2D and (implied) 3D image capture, providing on patient registration marks remained throughout. Neither acetate tracing, basic photography or 3D imaging was practical for this specific application without the inclusion of registration markings, due to the variability of capture and lack of reference points for treatment demarcation and analysis alignment.

Whether assessing changing ulcer boundaries, or similar mobile skin conditions/wounds, the range of scores in Table 2 suggests that early evaluation of the capture methods available, would prove beneficial in securing the clearest endpoint data. Whether the system cost is acceptable, or whether the addition of such registration marks is ethically acceptable, is a separate risks/benefits discussion in relation to the local requirements and proposed study outcomes.