Clinical Validation of Digital Wound Management as an Efficient Tool for Assessing and Monitoring True Wound Depth

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INTRODUCTION

Objective:

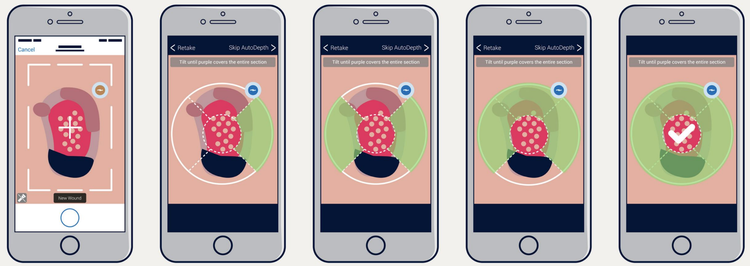
- To devise better non-invasive methods to accurately and reliably measure wound dimensions, particularly depth.

Background:

- More than 6.5 million Americans deal with chronic wounds such as pressure injuries, diabetic foot ulcers, and leg ulcers
- Current standard method for measuring wound depth is prone to significant error, as high as 75% in total, incurred at several points through the process. It is also potentially painful to the patient, requiring the clinician to place a cotton swab into the wound, probe for the deepest point, mark the deepest point on the swab with a finger, and then measure the swab against a ruler (3)
- To measure 3-dimensional properties of wounds including depth, researchers have used approaches such as dental paste (5) and plaster (6) to produce a cast followed by its measurement (7). These approaches are:
  - unlikely to find widespread adoption in real-world settings due to contamination risking infection and physical contact, which can cause patient discomfort or pain, and potentially exacerbate the wound
  - time-intensive and require resources that are not available across the care continuum
- Other methods exist through the use of external technology such as 3D wound measurement (3DWM) cameras attached to tablets and Laser Assisted Wound Measurement (LAWM) devices. Specific challenges with these include:
  - Additional technology expense and, in some cases, requiring attachment to a computer
  - Training and logistical burden in managing additional physical attachments

- **Swift Medical's AutoDepth feature provides an automated, non-contact method for measurement of depth using the everyday smartphone**

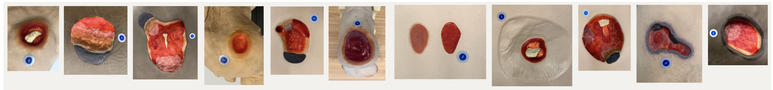
METHODOLOGY



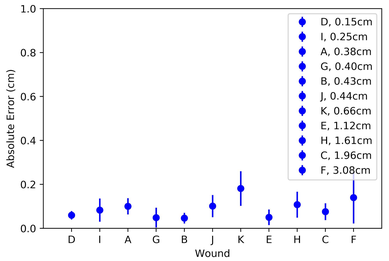
- The wound is captured by scanning the phone over all sides of the wound in order for AutoDepth to construct a computer-generated model of its topography
- AutoDepth then analyzes the topography and measures the wound at tens of thousands of points simultaneously
- A reference surface is constructed above the wound, based on the automatically or manually defined wound margin and surrounding tissue surface, and the distance from that reference surface to the wound bed is used to find the deepest visible point within the wound
- This maximum depth is reported as part of the wound assessment

RESULTS

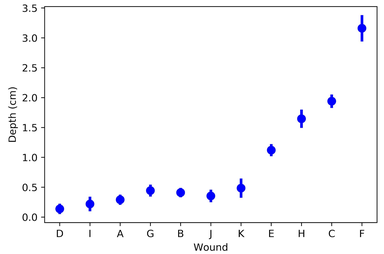
AutoDepth has been clinically validated using a standardised set of calibrated "test" wounds (11 wounds, 29 raters), and real patient wounds in representative, real-world clinical conditions (10 wounds, 2 technologies, 3 raters).



The test wounds were used to provide a measure of the reliability, repeatability, and accuracy, against known wound dimensions. The 29 raters each measured the 11 wound models three times. Validated ground truth was obtained using a Creaform HandySCAN 700 handheld laser scanner to determine the true maximum depth measurement for each wound model, with a surface accuracy of 0.05 mm. Standard conditions for AutoDepth measurement included the use of an iPhone X or iPhone XS device, held approximately 15 cm (6 inches) away from the wound. All wounds were captured under typical indoor exam room lighting conditions, with illumination between 318 to 525 lux.



Mean Absolute Error (± 1SD) per wound arranged according to increasing wound size



Mean depth (± 1SD) measurements across subjects per wound

- The intra-rater reliability measured using absolute intraclass correlation coefficient over 29 subjects was 0.99
- The inter-rater reliability measured using absolute intraclass correlation coefficient was 0.99

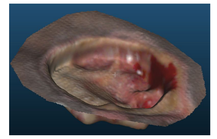
DISCUSSION

- From this analysis we conclude that AutoDepth is accurate, precise, and reliable both for individual users themselves and within a group of individuals, given training with the function
- AutoDepth strengthens the wound assessment toolkit, enabling accurate, precise, and reliable measurement of wound depth using only a smartphone
- AutoDepth has high accuracy, with a resolution of better than 2 mm, and often better than 1mm
- Measurements take just a few seconds and are available immediately at the bedside, with all computation on the device and no network connection required
- Clinicians no longer have to wait for uploads, and the technology works entirely off-line
- Depth measurement through a smartphone now renders additional camera hardware unnecessary and eliminates the need to purchase additional costly medical imaging devices
- Leveraging industry-best technology, contact-less depth measurements can be made, thereby eliminating the risk of contact-related contamination and infection, as well as potential patient discomfort and pain

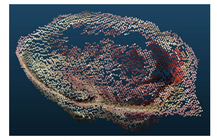
- **In summary, AutoDepth performs highly accurate and reliable measurements and provides a high-value alternative to wound depth measurement as compared to current industry standards**

On real wounds the clinical utility, accuracy, and repeatability was compared against state of the art laser scanner technology. Validated ground truth was obtained using an Artec LEO handheld laser scanner with surface accuracy of 0.1 mm.

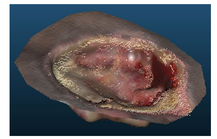
AutoDepth was used to generate a wound topography model, which was then automatically aligned with the laser scan using a fixed-scale iterative closest point approach. Absolute deviation between the AutoDepth model and the high resolution laser scan was measured for each point on the surface.



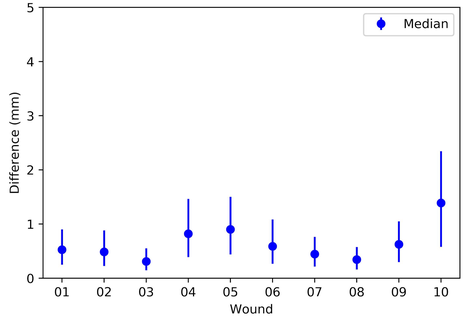
Laser-scan of wound



AutoDepth reconstruction



Scans aligned and superimposed



Mean difference across all surface points per wound

The average surface point deviation across all wounds is less than a millimeter (~0.8 mm), demonstrating the accuracy of AutoDepth's measurement when compared against the current standard. In all but one case, the 75th percentile points were below 1.6 mm, and in half the cases below 1 mm, making it highly likely for the system to detect clinically significant change in depth between assessments.

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