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White paper summary

Evidence-based wound surveillance

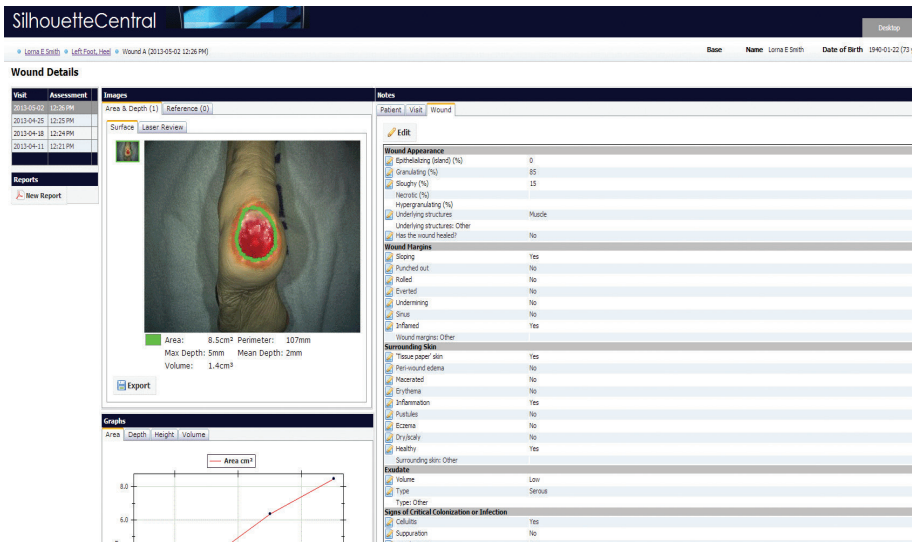
A Three-Dimensional Approach to Measuring, Imaging, and Documenting Wounds

Up to 6.5 million Americans, or 2% of the population, suffer from non-healing wounds each year[1]. The rate of chronic wounds is increasing steadily as a consequence of trends such as the ageing population and the diabetes epidemic.

Chronic wounds are complex and can lead to greater risk of mortality, longer hospital lengths of stay, amputations, and readmissions. They are also placing an increasing clinical, operational and financial burden on providers, particularly with the introduction of penalties associated with hospital-acquired pressure ulcers (HAPUs).

Therefore, providers need to put wounds under vigilant surveillance so they can quickly identify wounds that are at risk of becoming chronic or reportable and take early, effective action. Inadequate wound surveillance can lead to diagnostic errors and mismanagement, resulting in higher numbers of chronic, worsening and reportable wounds. This paper reviews the three dimensions of effective wound surveillance:

- Accurate and precise measurement and reliable healing trend data;
- High quality imaging;
- Standardized documentation.



The three dimensions of effective wound surveillance: Accurate and precise measurement and reliable healing trends; high quality imaging; and standardized documentation.

When wound specialists and multi-disciplinary teams are equipped with 3D wound surveillance, they can:

- More effectively manage wound-related risk using reliable evidence;
- Improve wound-related multi-disciplinary team communication across multiple and remote sites;
- Oversee non-specialist wound assessments to improve point-of-care practice;
- Improve patient comfort and compliance
- Make better-informed treatment decisions that enable more effective healing.

Dimension One: Measurement

Practitioners measure wounds to identify a healing trend, usually area reduction over time[2]. They rely on these trends to predict healing rates, identify factors delaying healing in a timely fashion, intervene rapidly, and provide appropriate treatment[3]. For example, a widely accepted rule of thumb used by practitioners is that reduction of diabetic foot ulcers by 53% or more in the first four weeks is a robust predictor of complete healing within 12 weeks[4]. As another example, the proportional relationship between one-dimensional perimeter and area measurements correlates to the healing progress of venous leg ulcers[5].

Unfortunately, not only are methods commonly used in clinical practice difficult to use, they are often poorly validated, and subject to serious questions in terms of accuracy and precision[6].

Rulers: The standard area formula *length x width* is inaccurate, and typically over-estimates true wound area by 44%[7]. This method is also not precise, with practitioners often using different ways to calculate length and width, resulting in measurements with poor reproducibility;

Planimetry: This method involves tracing a wound onto acetate film and calculating the area. It has been estimated to have an error rate of up to 22%[8].

Digital planimetry: This involves using software to estimate the area within a user-drawn outline on a digital image, and requires a number of conditions to be met to ensure accuracy is not compromised. For instance, slightly altering the angle of the camera so it is no longer perpendicular to a wound can distort measurements by 10%[9] to 35%[10].

Geometry: Errors compound on any method that involves determining an area based on a linear measure. This not only involves rulers, but also digital planimetry.

Wound depth and volume measurement: Traditional measurement methods are extremely unreliable. For instance, wound volume measured using alginate casts produces errors of 5%-40%[11], and the Kundin method is considered to be very subjective[12].

Unreliable trends

Practitioners graph the measurements they have made over time in order to look at healing trends. Many practitioners assume that wound measurements contain a systematic (non-random) deviation from the true value – in other words, they are "uniformly inaccurate", and can therefore form a trustworthy healing trend. However, this is not the case. As wounds are measured by many assessors, the accumulation of errors tend to be more random in nature, making the resulting error bars of their measurements too wide to be clinically useful. Rating variability ranges from 16%[13] to more than 50%[14].

Lack of precision in the measurement data results in unreliable healing trends and this can affect clinical decision making. If error bars are too broad to confirm if a wound is getting smaller or larger, a facility is less able to detect and respond promptly to meaningful changes in wound size, or to provide valid evidence supporting healing outcomes.

Practitioners skilled at wound care combine their measurements with clinical judgment about the wound to assess change and make sound decisions. However, the healthcare system is moving toward higher levels of precision, demanding not just quality care, but reliable evidence of quality care.

Precise measurement is important, and inaccuracy is costly. It has been estimated that the measurement-related portion of the US healthcare budget ranges from 10%-15%, and error-related spend (re-work, quality tests, etc.,) accounts for 30%[15]. As technology developments make measurement in healthcare easier and more precise, payers can demand more accurate measurement data as a basis for reimbursement and shift the costs of inaccuracy to providers. Wound measurement is not exempt from this trend.

Dimension Two: Wound imaging

Images are useful for wound documentation. However, if the images are neither standardized nor of high quality, they add risk and introduce error to documentation. Wound photo transfer is unproductive and can cause local storage and security issues and photos are difficult to transfer to an electronic medical record (EMR). Guidelines are often complicated, and the cost of ownership of cameras can escalate.

Dimension Three: Documentation

The problems described above are compounded by the ineffective and inefficient collection and management of critical information about wounds. While there is a lot of literature about "wound management" in the context of clinical guidelines, very little has been written about the complexity of the overall wound management effort. Systemic factors include:

Risk management: With the spotlight on a potential legal case or penalty, the lack of standardization of wound documentation is exposed and there is a higher risk of an unfavorable outcome[16]. Practitioners are not necessarily adept at gathering accurate measurement data or conforming with strict documentation standards, resulting in inconsistencies that can

expose facilities to risk[17].

Multi-disciplinary team communication: It is being recognized that success in chronic wound care requires an integrated chronic disease management methodology[18] rather than a siloed approach. Many disciplines are involved in the wound care effort, often in multiple organizations. Under these circumstances, care teams need high-quality communication based on readily available wound information that is accurate, easy to access, and comprehensive.

Lack of specialist competency: There are recognized issues with the accuracy of wound assessment by non-specialized staff[19]. Wound specialists are a crucial part of the wound care system, but are typically stretched to capacity managing the wound care effort and an increasing documentation burden[20].

Litigation: Documentation is a critical success factor in pressure ulcer litigation[21]. If documentation can prove no neglect occurred, a lawsuit is less likely to proceed; however, many out-of-court settlements have been forced on providers because of a lack of evidence of care, not necessarily the absence of care itself[22].

3D methods

Recent three-dimensional electronic wound measurement methods can more accurately measure wounds, accounting for both the curvature of the body and the irregular nature of the wounds. Such methodologies not only measure area accurately and precisely, they can also measure volume, depth and perimeter[23], and generate reliable healing trends.

The Silhouette system

One such 3D-based system is the Silhouette wound imaging, measurement and documentation system.

The key components of Silhouette are:

- SilhouetteStar™ point-of-care camera and 3D capture device;
- SilhouetteConnect™ software, which creates a 3D model of the wound based on the data acquired by SilhouetteStar. It derives accurate area, perimeter, depth and volume measurements from the model, and records standardized notes;
- SilhouetteCentral™, a secure database that stores and consolidates the information obtained from the organization's SilhouetteStar + SilhouetteConnect devices, sharing data with the EMR and across one or many facilities.

Precise measurements result in reliable healing trends

Silhouette enables clinicians to capture accurate and precise measurements and derive reliable healing trends that are both statistically robust and clinically meaningful. A recent study found that any single Silhouette-derived measurement is likely to be within approximately 2% for area, 1% for perimeter, 5% for average depth and 5% for volume (95% confidence interval). Inter- and intra-rater variability is extremely low – <1% for area and perimeter, and <2% for average depth and volume. This indicates that repeated measurements over time, even by non-specialist assessors, will detect small differences as a wound changes in size and shape.

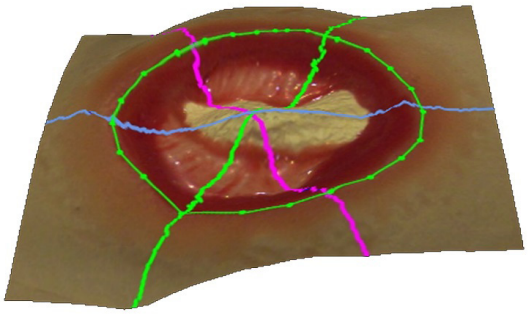
Wound imaging

Silhouette addresses typical wound image management issues, producing high quality images at the point-of-care. The SilhouetteStar device has no user-adjustable settings – the camera has its own light source, and the laser lines position the camera for optimum focus and composition. There is only one moving part – the button which captures the wound image.

Silhouette assessments are recorded directly into the patient record. Images are not stored on the camera because image data is transferred in real-time to the SilhouetteConnect software. The wound photographs and measurement information are displayed together so the practitioner, or any authorized stakeholder logged in remotely, can compare the image with healing trends and other clinical information.

Documentation

Silhouette provides reliable documentation for reimbursement, defense and audit purposes. Wound Assessment Reports combine measurements, graphs displaying the latest healing trends, images, and documentation. If SilhouetteCentral is integrated with the EMR, the wound information can also be transferred to the EMR automatically.



Behind the scenes, Silhouette creates a 3D model of the wound.

Process improvement

Silhouette improves communication between multi-disciplinary teams. Wound specialists can extend their reach using Silhouette and improve the assessment capability of non-specialists using Silhouette information for feedback and training.

Silhouette gives organizations oversight of the entire wound care effort. Clinical managers can use aggregate reporting to review important trends, key areas of focus and wound outcomes metrics.

Silhouette also offers a configurable structured workflow.

If there is an adverse event such as a suspected hospital-acquired pressure ulcer, the whole "story" of the wound is provided in one place.

Privacy, safety, data security and compliance

Silhouette supports a variety of protocols and functionality, including HL7 patient demographic information exchange, DICOM image transfer, and DICOM Encapsulated PDF report creation and transfer. Silhouette is designed to support PHI, HIPAA and Health Information Technology for Economic and Clinical Health Act (HITECH) compliance.

The Silhouette system is compliant with all major accreditation marks. Regulatory clearance includes an FDA Class 1 approval (US).

Summary

Silhouette is a long-awaited tool to significantly boost the precision of wound measurement and the reliability of healing trends, and provide a solution to the challenges of wound image and documentation management.

The Silhouette system gives providers the confidence of knowing that they offer evidence-based and accountable wound care, readying them for the accountable pay-for-performance environment.

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