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The influence of wound measurement precision on the ability to correctly classify wounds as "likely healers" or "likely non-healers" at 4 weeks

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Objective

To determine the degree of precision required in wound measurement in order to correctly classify wounds 95% of the time as "likely healers" and "likely non-healers" at 4 weeks.

Background

A growing body of evidence suggests that the successful healing of different wound types can be predicted from early (<=4 week) wound area changes (Cardinal et al., 2009; Sheehan et al., 2003).

For example, the study by Sheehan et al. indicated that for diabetic foot ulcers a percentage reduction of about 50% at four weeks served as a useful discriminator. Those above this threshold (ie those which had decreased in size by more than 50%) were more than six times more likely to experience total healing at 12 weeks compared with those were below this threshold and had experienced smaller changes at 4 weeks (58% healed by week 12 versus 9%).

This association may help to identify individuals who may need additional wound care to enable total wound healing, and those that do not.

If a perfect wound measurement tool existed that allowed us to precisely measure the initial wound area at 0 weeks (ie, typically upon admission), and the wound area measurement at 4 weeks, then we could confidently calculate the percentage reduction at 4 weeks (as a function of these two measurements) and appropriately allocate the wounds into a likely healing group and a likely non-healing group.

By likely healing group we mean those wounds with a percentage reduction that are above a certain threshold at 4 weeks, and are likely to heal by 12 weeks; and similarly for likely non-healing group.

However, wound measurement methods are not perfect. The degree of imprecision in wound area measurements will impact the precision of the percentage reduction that is calculated at 4 weeks, and subsequently the ability to correctly allocate wounds into likely healing and likely non-healing groups. Any such mis-classification could have important treatment ramifications.

Methods

A Monte Carlo simulation approach was used to estimate the probability of correctly or incorrectly classifying the actual percentage reduction at 4 weeks using measurement methods of varying precision. A hypothetical population of 10,000 patients was modeled with one wound each. Each of these wounds had a four week percentage reduction assigned to them, in the range of 10% to 70%, chosen at random from a normal distribution (mean of 40%, standard deviation of 10%), as shown in Figure 1. This mimics a sample of individuals with a particular wound type which is likely to have a particular healing pattern. This was called the actual percentage reduction.

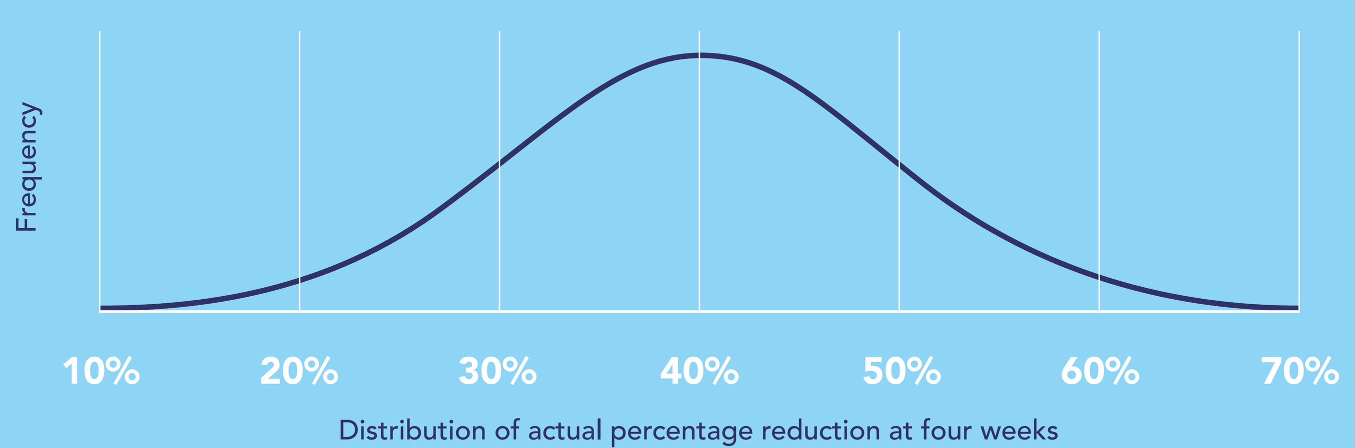

Figure 1:The distribution of actual percentage reduction at four weeks for the modelled population. Because a normal distribution is used, approximately 68% of the time the selected percentage reduction will be within the range of 30%-50%.

Next, the degree of imprecision for the wound area measurements was chosen, and for each of the 10,000 wounds the measured percentage reduction was calculated from the two measurements (0 and 4 weeks). This process was repeated for different levels of imprecision in wound area measurement of 5%, 10%, 15%, 20%, 25% and 30%.

To model the imprecision of the wound area measurement, the imprecision for each wound measurement was chosen at random from a normal distribution, where the nominal level of imprecision was used to define the standard deviation of the normal distribution. For example, with the nominal imprecision level of 5%, the imprecision for any particular measurement would be chosen at random from the distribution as shown in Figure 2.

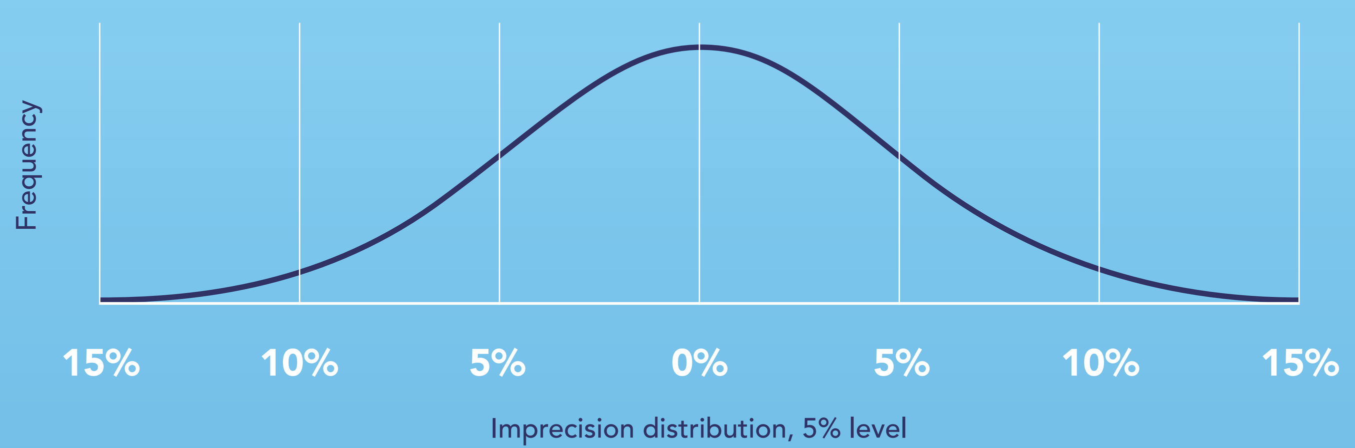

Figure 2: The distribution of individual values used to model the imprecision of the wound area measurement method, showing the case with the level of imprecision at 5%. Because a normal distribution is used, approximately 68% of the time the selected imprecision will be within the range of +/- 5%.

Finally for each of the 10,000 wounds and a particular level of wound measurement imprecision, the actual percentage reduction and the measured percentage reduction were compared with each other, and the wounds were classified as follows:

- If the actual and the measured percentage reductions were both less than or equal to 50%, then this simulation resulted in a 'correct' classification; similarly if the actual and measured percentage reductions were both above 50% then this also resulted in a 'correct' classification.
- However, if the actual percentage reduction was less than or equal to 50% and the measured percentage reduction was greater than 50%, this was considered an 'incorrect' classification; and if the actual percentage reduction was greater than 50% and the measured percentage reduction was less than or equal to 50%, this was also considered an 'incorrect' classification.

Results

Table 1 shows the results of correctly and incorrectly classified wounds as a function of the imprecision in the wound area measurement, and graphed in Figure 3.

Discussion

Given the association between 4 week percentage reduction in wound area and healing at 12-weeks, it is important to determine the role that measurement precision might play in determining the percentage reduction and therefore in accurately classifying the wounds into likely healing or likely non-healing groups.

In other words, in order to make use of this relationship, it is necessary to have a wound area method of measurement that is sufficiently precise so that the classification can be relied upon.

Level of imprecision in area measurement	Classification	
	Correct	Incorrect
5%	95.3%	4.7%
10%	86.5%	13.4%
15%	78.2%	21.7%
20%	72.7%	27.2%
25%	68.8%	31.1%
30%	65.9%	34.0%

Table 1: Rates of correct and incorrect classification as a function of the imprecision in wound area measurement.

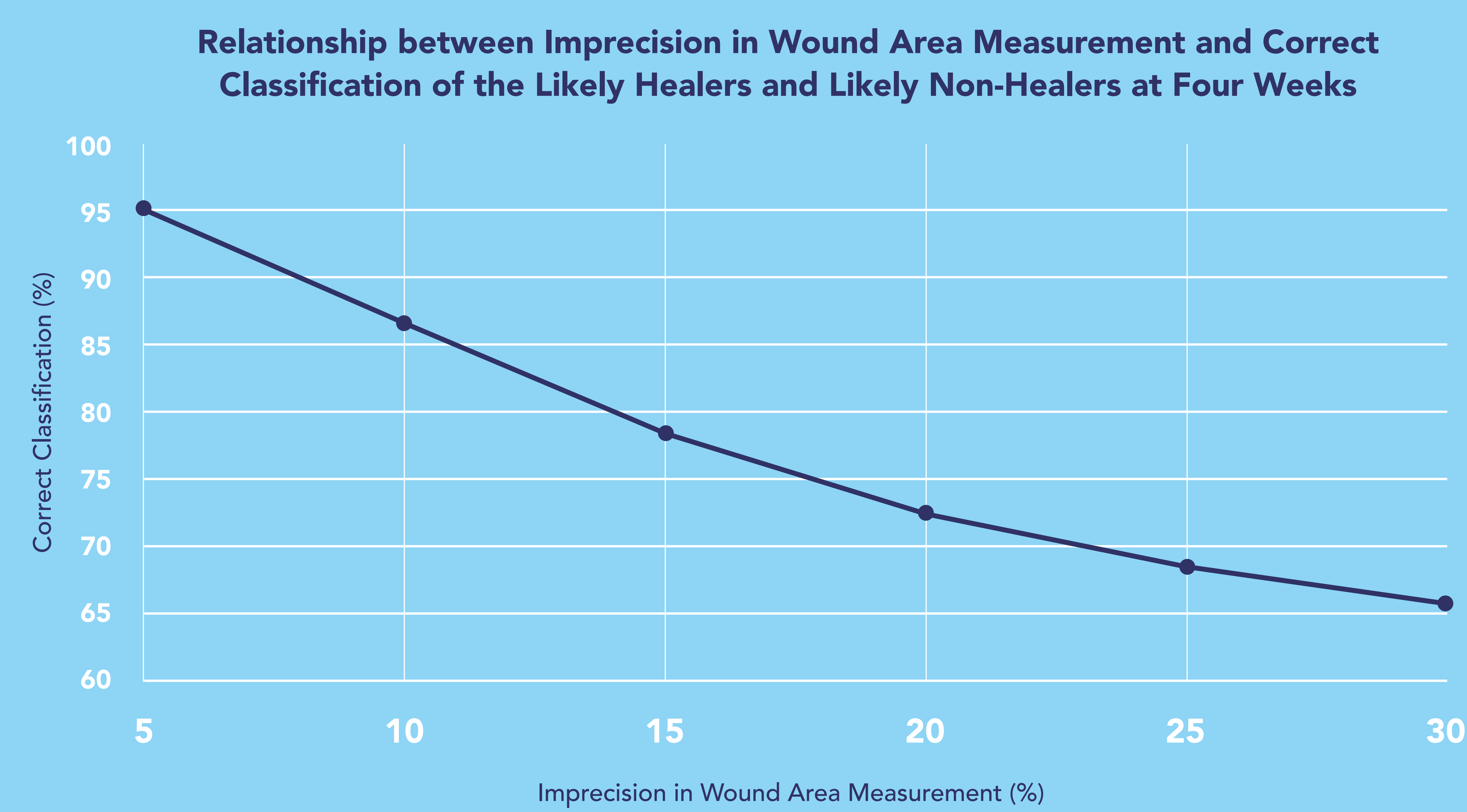

Figure 3: Graphical representation of the relationship between the imprecision in wound area measurement and the correct classification of likely healers and likely non-healers at four weeks.

In recent years there has been a move towards using emerging technologies to more accurately and precisely measure wound area (Romanelli et al). As these instruments are convenient and easy to use, they are likely to become increasingly widespread as the method of choice for wound measurement.

Given this scenario it is of particular importance to determine firstly, the precision of any measurement method and secondly, what precision is necessary in order to accurately predict total wound healing.

In terms of the latter requirement, for our modeled population, it is necessary to have a wound area measurement device that has an imprecision of 5% or less in order to correctly classify a wound 95% of the time.

Note that the results here are dependent upon how we model the healing of our population. The four week healing was assumed to be normally distributed, with a mean healing of 40%, and standard deviation of 10%. Future work will involve testing this assumption and re-running the analysis with other healing models.

Conclusion

The precision of the measurement method used to assess a wound plays an important role in assessing wound status. For the modeled population, it is necessary to maintain the imprecision to 5% or less (ie precision of 95% or better) in wound measurement in order to correctly classify wounds 95% of the time as "likely healers" or "likely non-healers" at 4 weeks.

References

Cardinal, M, Eisenbud, D, Armstrong, D. Wound shape geometry measurements correlate to eventual wound healing. Wound Repair Regen. 2009 (17)173–178.

Romanelli, M. MD, PhD, Dini, V. MD, Bertone, M. NT, Brilli, C. RN: Measuring Wound Outcomes. Wounds. 2007;19(11):294-298.

Sheehan P, Jones P, Caselli A, Giurini JM, Veves A. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. Diabetes Care. 2003 Jun;26(6):1879-82.