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# TITLE

Predicting Wound Healing Outcomes: A Comparative Accuracy Analysis of AI-driven Indices and Percent Area Reduction

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# Abstract

**Background:** Wounds represent a major global health and economic burden, with chronic wounds affecting millions annually and costing medical care providers over $126 billion in the US alone. Current assessment tools, such as Percent Area Reduction (PAR), are widely used but limited by subjectivity and suboptimal predictive accuracy, particularly for complex wound types. The growing integration of artificial intelligence (AI) into healthcare provides a unique opportunity to enhance wound assessment and prognostic capabilities, potentially enabling earlier and more precise interventions.

**Methods:** This retrospective study evaluated the performance of an AI-powered Healing Index (HI) in predicting delayed healing for pressure injuries, venous ulcers, diabetic foot ulcers, and arterial ulcers. Using a clinically validated dataset of 173,816 wounds collected via a digital wound care solution, we compared the HI model's predictive accuracy to PAR. The HI incorporated objective wound characteristics, such as tissue composition and exudate, to forecast healing trajectories.

**Findings:** By week 3, the HI achieved a balanced accuracy of 65%, surpassing PAR, which reached the same level only in week 4. This earlier prediction enables more timely treatment adjustments, facilitating improved outcomes and reducing healthcare costs.

**Interpretation:** The AI-powered HI demonstrates significant potential for transforming wound care by providing more accurate, objective, and earlier identification of non-healing wounds. Its integration into clinical practice could enhance resource allocation, optimise treatment strategies, and reduce the economic burden of chronic wounds. Further validation across diverse healthcare settings is warranted to ensure equitable implementation.



**Keywords:**

Wound, prediction, healing, AI, artificial intelligence, PAR


*What is already known on this topic"* - Percentage area reduction at 4 weeks is widely used to predict wound healing, but it is a single-variable measure with limited accuracy across wound types and poor applicability in routine clinical practice.

*What this study adds* - This study shows that an AI-powered HealingIndex™ (HI Model 5) predicts delayed healing more accurately and one week earlier than PAR, using only seven interpretable variables.

*How this study might affect research, practice or policy* - The findings support replacing PAR with AI-driven tools for earlier, more accurate wound assessment, with potential to improve outcomes, guide treatment decisions, and inform clinical trial endpoints.

# Introduction

Wounds are a significant global health challenge, affecting millions of people each year, with estimated costs of over $126B annually to medical care providers in the US alone[1]. Chronic wounds are also increasing in prevalence[2], likely due to aging populations and the rise of conditions like diabetes and obesity. These wounds can have a profound impact on patients' quality of life, leading to pain, disability, and prolonged hospital stays.

Given these challenges, efficient and accurate methods of monitoring healing progress are crucial. As wound care continues to evolve, digital solutions and AI-driven models offer new possibilities for improving detection, monitoring, and treatment, ultimately enhancing patient outcomes and reducing healthcare burdens. Multiple studies have highlighted the value of wound area measurements or Percentage Area Reduction (PAR) as a prognostic indicator [3,4]. In clinical practice, wound area is often measured manually using rulers, although this method is repeatedly found to produce inaccurate results and poor inter-rater reliability when compared with digital approaches[5]. Compounding this, while the general PAR threshold is a useful benchmark, it may not fully capture the complex nature of certain types of wounds, as different classes of wounds respond differently to respective treatment modalities, leading to variations in their healing pattern and trajectory[6,7]. Several studies and clinical observations have considered wounds as chronic or non-healing if the PAR threshold shows less than a 20-30% reduction in surface area after 4 weeks of receiving care[5]. Yet, the threshold for PAR may significantly differ depending on the type and category of the wound. For example, pressure injuries (PI) and diabetic foot ulcers (DFU) are both chronic wound types, however, they often exhibit distinct healing patterns and respond differently to various management strategies. This contrasts with uncomplicated simple traumatic wounds, which may heal within more predictable timeframes and respond similarly to simple treatments.

Consequently, in these circumstances, the general PAR benchmark may not accurately represent progress or be useful in guiding the clinical management plan[8,9,10]. Similarly, diabetic foot ulcers are often compounded by underlying vascular and neuropathic issues that can significantly impede the healing process[11,12,13,14]. These wound-specific factors necessitate a more nuanced and adaptive approach to assessing wound healing progress, which may contribute to the low utilization of PAR in daily clinical practice.

Nonetheless, PAR at 4-weeks is currently considered the best proxy predictor of wound healing by the US Food and Drug Administration (FDA) within clinical trials of wound products[15]. This is due to the pragmatic issues associated with waiting for complete wound healing, establishing homogenous treatment and control groups within wound patient populations to facilitate randomized controlled trials and the absence of viable alternatives. In response to these challenges, other frameworks, models, and algorithms have been explored to improve the prediction of wound healing trajectories. These include the wound status index[16], artificial intelligence (AI)-based models and predictive algorithms[14,17], and Bioelectrical Impedance Analysis (BIA)[18].

BIA is a technique that measures and tracks body composition over time and monitors the impact of a treatment plan on chronic conditions[19]. Recently, it has been introduced to monitor wound healing by measuring electrical impedance and fluid status. While it is an easy and non-invasive technique with direct algorithm, its precision is dependent on the body's hydration status and recent food intake[20]. Additionally, the accuracy of this method can be affected by wound exudate, and presence of infection[20]. Thus, single-variable approaches to predicting wound healing offer poor prognostic abilities. This is unsurprising given the many factors known to impact on healing potential[21].

In contrast, recent studies in AI technology have explored the use of predictive algorithms to forecast wound healing times and identify non-healing wounds. Image-based AI tools have been shown to analyze wound images, detecting early warnings for potential complications in research and pilot settings[22]. Similarly, several studies report that machine-learning approaches can model wound healing trajectories by identifying patterns across multiple clinical and wound-related variables[17,23,24]. One study evaluating an AI-driven analytics model for wound assessment reported improved accuracy in predicting healing trajectories compared with conventional approaches, based on longitudinal monitoring of wound characteristics[25]. In addition, AI-supported systems have been proposed as a means of assisting documentation and wound tracking, although evidence to date remains largely evaluative rather than confirmatory[24,26].

Various techniques of machine learning and classification have been used for predictive analyses in wound management, with the aim of improving clinicians' preparedness and management of patients' conditions. However, it is important to note that the success of predictive analytics depends on the quality of data and the technological infrastructure used to develop and implement predictive models [22,24,27,28]. Accordingly, the use of structured clinical data has gained prominence in wound care for evaluating and predicting wound healing progress based on various parameters, including wound characteristics, wound bed attributes, and the patients' health status. One example of this approach used in evaluating the healing progress of PIs is the Pressure Ulcer Scale for Healing (PUSH), which focuses on the assessment of wound size, exudate, and tissue type[29]. Research has indicated that the PUSH is a simple, effective, and reliable approach for detecting improvements in wound healing and guiding treatment plans [8,29,30]. However, this method still relies on subjective assessment and requires consistent training of healthcare professionals to ensure accuracy[29]. Despite these strengths, there also remains no clear evidence that it is widely used in practice.

Another example of a wound healing assessment tool in clinical practice is the Venous Leg Ulcer Wound Healing Index (VLU WHI), a comprehensive scoring system used to assess wound area size reduction, depth, tissue type, and exudate to predict wound healing progress[31]. Although limited to a single wound type, this model was validated on a large data set (VLU = 11,773) and achieved significant predictive outcomes on the validation data set. The VLU WHI was embedded within an electronic medical record and the authors noted with appropriate interventions, wounds identified to have non-healing risk were able to heal with best practice interventions. However, systematic reviews of wound healing indexes specific to VLU and diabetic foot ulcers (DFU) have reported that the existing models lack robust evidential basis and are therefore of limited clinical utility [32,33]. Taken together, these reviews indicate that in most cases the existing models aim to predict healing at 24 weeks, use heterogeneous variables and wound area is often not included within the models. This is perhaps due to the pragmatic challenges in measuring wounds manually, which remains a common assessment approach globally despite its aforementioned clinimetric limitations.

Gupta et al[17] developed a prognostic system similar to the VLU WHI concept using AI to improve subjective wound assessment data with objective data using computer vision. The model, HealingIndex™ (hereafter referred to as HI) was based on wound characteristics, including estimated wound area and tissue quantities derived from wound segmentation and tissue quantification models. In their study, the efficacy of these objective prognostic models across multiple wound types (i.e., PI, VLU, DFU, arterial ulcers) were compared to traditional clinical tools such as the PUSH and the Bates-Jensen Wound Assessment Tool (BWAT) systems. Their findings indicated that a hybrid prognostic model, referred to as HI Model 5, produced significant improvements over conventional tools, outperforming PUSH by 4% and BWAT by 7%. HI Model 5 incorporated objective data concerning wound extent and severity, with tissue composition accurately calculated using SmartTissue™, an image-based deep learning model. By integrating these objective features, the model enabled a more precise evaluation of wound progression[17].

Building on this foundation, the present study evaluated the performance of the HI model against the PAR model in predicting delayed wound healing across a range of wound types and pathologies. The HI in this study is an AI-powered tool that integrates both objective and subjective wound data including wound characteristics, such as digitally measured surface area, tissue types, exudate type, exudate amount, anatomical location of the wound and clinical setting, to generate a quantitative prognosis for wound healing. Additionally, the researchers sought to determine which wounds were expected to heal within a 12-week timeframe. Ultimately, by leveraging advanced analytics, clinicians may make more informed decisions, identifying non-healing wounds earlier which may facilitate more timely specialist intervention and identification of ineffective wound therapies. This may, in turn, reduce healthcare costs associated with chronic, non-healing wounds.

# Methods

# Research question

How does the predictive accuracy of the AI-powered Healing Index (HI) compare to Percent Area Reduction (PAR) in identifying delayed wound healing across four common chronic wound types?

## Data sources and approach

The study leveraged a clinically calibrated and validated Digital Wound Care Solution (DWCS) database, encompassing data from various healthcare settings. Data was collected from organizations that agreed to share de-identified clinical data. Research ethics exemption was provided for this analysis by Pearl Institutional Research Board (2023-0100). Using Structured Query Language (SQL), we extracted weekly wound evaluations for four wound types (PI, DFU, VLU, and AU) dated between February 2017 and April 2022. Together, these four wound types account for 38.01% of all wounds tracked using the DWCS in homehealth and skilled nursing facility settings. These evaluations were tracked over the first four weeks following the initial wound care assessment recorded in the system. Wounds were included in the analysis if they were monitored for a minimum of 12 weeks or had healed within that period. This allowed for classification into two categories: optimally healed wounds (healed within 12 weeks) or delayed healing wounds (≥12 weeks to heal).

For each evaluation, wound area was calculated in square centimeters using AutoTrace™, a deep learning algorithm specifically trained and calibrated to measure wound size accurately. Additionally, the presence and distribution of tissue types (granulation, epithelial, slough, eschar, and healthy tissue) within the wound bed were assessed using SmartTissue™, an AI-powered deep learning tool designed to differentiate between tissue types [34]. Both SmartTissue and AutoTrace are semantic segmentation models utilizing a U-Net architecture optimized for running on-device at the bedside (see Ramachandram *et al.* 2022 for an in-depth description of model architectures). Clinical documentation was used for the exudate type, exudate amount, body location, and clinical setting.

The AI-powered HI models were calculated post-hoc using combinations of the following features, which were chosen using a forward-backwards selection process, whereby features whose univariate model improved predictive power relative a null model were all included in the forward pass, and subsequently removed if their omission from the full model did not significantly decrease the model AIC (see see Gupta *et al.* 2024):

- User enhanced area* vs AutoTrace™ area measurements
- Subjective tissue type analysis vs SmartTissue™
- Exudate amount (clinician documented)
- Exudate type (clinician documented)

- Edges (clinician documented)
- Location (anatomical)
- Setting (clinical)

*In user enhanced area measurements, clinicians refine the wound area margins identified using AutoTrace to adjust photogrammetry measurements documented within the DWCS.

HI scores were derived by fitting these features to a time-varying Cox Proportional Hazards (CoxPH) model and extracting a hazard score using the fitted coefficients. Model performance was evaluated using Incident/Dynamic Area Under the Curve (AUC), which acts as an extension to concordance indices allowing to calculate concordance of HI scores at different time points in the wound healing process (see Gupta *et al.* 2024 for a full description and analysis of the HI models). This comprehensive, data-driven approach ensured a thorough assessment of wound healing trajectories across multiple wound types, offering insights into the relationship between tissue composition, wound size, and healing outcomes.

## Percent Area Reduction (PAR) and HI Variations

Percent Area Reduction (PAR) was calculated using the formula (Ai-Ac)/Ai X 100, where Ai represents the wound area at the initial assessment, and Ac is the wound area at the current assessment [35]. This metric provided an indication of the percentage reduction in wound size over time. Additionally, six variations of a HI were computed for each wound evaluation. These variations incorporated different combinations of subjectively observed features (such as clinician assessments) and AI-estimated features[17].

Both PAR and the HI models serve as standalone predictors of wound healing outcomes. By establishing specific thresholds for each model, wounds will be classified as either optimally healed or delayed in healing. The HI model offers the potential for improved prediction and classification of wound healing trajectories, allowing clinicians to better tailor treatment plans based on early assessments of wound progress.

## Accuracy Metrics

To ensure stability and optimize the performance of the healing models, we implemented a K-Fold cross-validation design to derive Receiver Operating Characteristic (ROC) curves to visualize the predictive power of PAR and HI across decision thresholds. The dataset was initially split into an 80% training set and a 20% holdout set. The training set was further divided into 10 equal-sized folds for cross-validation. For each fold, we calculated ROC curves across different weeks of evaluation, wound types, and healing models to assess the predictive accuracy of PAR and HI models in predicting delayed healing.

From the ROC curves, we derived the AUC for each permutation, which provided an overall ranking of model performance across all possible decision thresholds. Additionally, ROC analysis allowed us to determine the classification threshold for each fold by calculating Youden's J ,*i.e.* the point where the difference between true positive and false negative rates was maximized, achieving an optimal balance between sensitivity and specificity.

AUC values closer to the maximum value of 1.0 indicate better performance for binary classifiers but may be misleading in cases of class imbalance. We therefore also calculated balanced accuracy scores (BAS) to address class imbalance in the dataset (i.e., a higher number of delayed healing wounds compared to those healing within 12 weeks). This metric considers both sensitivity (the ability to correctly identify healing wounds) and specificity (the ability to correctly identify non-healing wounds), giving equal weight to both, ensuring that both true positives and true negatives were equally considered, mitigating any skew in predictive accuracy due to class imbalance. Furthermore, confidence intervals were calculated on the accuracy metrics to ensure conservative estimates of model performance. No resampling techniques were applied to the training dataset to attempt to balance the dependent variable.

The mean and standard deviation of BAS was calculated for each fold to determine metric stability. Furthermore, the optimal decision threshold for each HI variation was averaged across the 10 training folds to establish an overall optimal threshold. This threshold was then applied to the holdout dataset to evaluate AUC and BAS on unseen data, with 95% confidence intervals derived by non-parametric bootstrap resampling ($B$=10,000) of the model's predictions on the held-out data.

The AUC reflects the model's overall ability to classify healing versus non-healing wounds across various thresholds, while balanced accuracy evaluates its reliability at a specific threshold. The AUC and balanced accuracy scores from these predictions are reported in the results section to provide a comprehensive evaluation of the healing models' predictive performance.

## Statistical Analysis

We conducted a repeated measure ANOVA test to compare the performance of the various healing models. In this design, subjects were defined as a combination of the wound type and the evaluation week, with the model being the sole within-subject factor. The response variable was the balanced accuracy score. This approach allowed us to assess differences in model's predictive accuracy while controlling for variability related to wound type and week of evaluation.

Following the repeated measures ANOVA, we conducted post-hoc one-tailed paired t-tests to compare the accuracy of the PAR scores model to the HI models. These t-tests were designed to test the null hypothesis that the accuracy of the HI was less than or equal to that of PAR. Given the multiple comparisons, we applied a Bonferroni correction to adjust for the six tests, setting a corrected significance threshold of alpha = 0.008.

All data processing and statistical analysis was carried out in Python 3.11. Statistical analyses relied on scikit-learn 1.5.1 and statsmodels 0.14.2.

# Patient and Public Involvement statement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

# Results

## Demographics

Our analysis incorporated a total of 173,816 wounds from 85,599 patients across 2,316 Skilled Nursing Facilities (SNF) and 132 Home Health facilities from all 50 United States and several Canadian provinces. Among the patients, 46,789 (55%) were female, 38,350 (45%) were male, and 460 patients (<1%) had no documented sex in our records. The average age of the patients was 76.3 years. The wounds consisted of 122,659 pressure injuries (70.8%), 23,451 venous wounds (13.5%), 16,578 diabetic wounds (9.6%), and 10,861 arterial wounds (6.3%). Figure one illustrates the counts of wounds included in the analysis at each evaluation week, categorized by wound type. The green bars indicate the number of wounds that healed within 12 weeks, while the yellow bars represent those that required more than 12 weeks for healing. Notably, at each time point, the dataset consistently exhibited a significantly lower count of optimally healing wounds compared to those with delayed healing, resulting in a marked imbalance. This disparity reflects a real-world bias towards delayed healing wounds being documented in HomeHealth and SNFs, and underscores the rationale for employing balanced accuracy as the primary metric for evaluation in this study.

Figure 1: Count by wound type across evaluation time points by week included in the analysis

## Predictive Accuracy of PAR Scores and Balanced Accuracy for Delayed Wound Healing by Week 4

Figure 2 demonstrates a clear relationship between the percent area reduction (PAR) classification scores and the accuracy of predicting delayed wound healing. Specifically, as PAR scores decrease to between 35-40% indicating that the wound is showing more signs of healing and reducing in size the accuracy of predicting delayed healing improves. This trend is reflected in the increasing balanced accuracy scores over time. By week 4, the balanced accuracy reaches approximately 65% across all four wound types, meaning that by this point in the wound's progression, the model is 65% more accurate in predicting which wounds are likely to experience delayed healing. This highlights the importance of the 4-week mark as a critical time for evaluating wound healing trajectories.

Figure 2: Optimal PAR Threshold and Balanced Accuracy for Predicting Delayed Healing.

## Performance Comparison: Healing Index Models vs. PAR

The repeated measures ANOVA demonstrated a significant impact of the healing model on the balanced accuracy score ($F=35.3187$, $p<0.001$). Follow-up one-tailed paired t-tests further confirmed that all variations of the HI significantly outperformed the PAR model. Among these, HI 5 yielded the highest statistical value, indicating its superior performance compared to PAR. As a result, subsequent analyses focused on HI 5 for further evaluation.

## Balanced Accuracy Scores by Week for Each Healing Model Across Wound Types

Figure 3 compares the balanced accuracy scores of PAR with the HI model 5 across four different wound types. Across the different wounds, PAR recorded the lowest mean balanced accuracy at 55.4%, which improved to a peak of 65% by week 4. In contrast, the HI model 5 had consistently outperformed PAR, demonstrating higher accuracy and greater AUC scores for each wound type analyzed throughout the weeks. Furthermore, HI model 5 was less likely to overclassify wounds as delayed healing than PAR, as evidenced by a consistently superior specificity.

## ROC curves and AUC scores for Percent Area Reduction and HealingIndex™ 5 Model

Figure 4 demonstrates a consistent increase in AUC scores for both HI model 5 and PAR over the 4-week period for pressure injuries (PI). Notably, by week 4, the AUC score for HI model 5 was 0.7 points higher than that of PAR, indicating significantly greater accuracy of the HI model in predicting delayed wound healing by this stage. This result underscores the superior predictive performance of HI model 5 compared to PAR at the 4-week mark.

Figure 4: ROC curves and AUC scores for Percent Area Reduction (black trace) and HealingIndex™ 5 (orange trace) at each time point.

### Balanced Accuracy Scores for HI model 5 compared to PAR for pressure injuries

Figure 5 illustrates the performance of HI model 5 in comparison to PAR, based on balanced accuracy scores for predicting delayed pressure ulcer healing. The horizontal dotted line indicates maximum performance of PAR to highlight the time point at which HI outperforms PAR's best performance.

Both HI and PAR show an increase in accuracy over time; however, HI consistently demonstrates higher accuracy than PAR. Notably, by week 3, HI model 5 achieved a >65% accuracy level (HI week 3 BAS: 0.658, 95% ci 0.650 - 0.665; PAR week 3 BAS: 0.601, 95% ci 0.594 - 0.609), while PAR only reached that level by week 4 (HI week 4 BAS: 0.695, 95% ci 0.688 - 0.702; PAR week 4 BAS: 0.651, 95% ci 0.644 - 0.658). This result implies that by week three, HI improves the accuracy in classifying chronic wounds by 9.5%, and by 6.8% at week 4. This earlier prediction of delayed healing with HI model 5 holds significant clinical implications, as clinicians can identify potential healing delays a week sooner, allowing for timely adjustments to management plans and protocols. Such early interventions may reduce time to heal, improve patient quality of life, and offer cost benefits to skilled nursing facilities (SNFs) by potentially preventing wounds from progressing to more severe stages, which are more challenging to manage.

Figure 5: Balanced Accuracy Scores (BAS) for HI Model 5 compared to PAR (dashed line).

## Discussion

An ideal wound healing prediction tool would be non-invasive, utilize objective metrics to ensure inter-rater reliability, require a minimal number of variables to improve explainability and would show high predictive accuracy early in the lifespan of the wound. These features would maximize opportunities for early intervention, minimize the risk of misinterpretation and therefore yield optimal clinical and economic benefits. The results of this retrospective analysis provide significant insights into the effectiveness of an AI model (HI Model 5) with these characteristics in predicting delayed wound healing. We examined a comprehensive dataset of 173,816 wounds tracked over the first four weeks following the initial wound care assessment recorded in the digital system from various healthcare settings that utilized the digital wound care solution. Our study indicated the HI model's ability to incorporate multiple wound characteristics, such as tissue type and exudate, enhancing its predictive capacity and accuracy by accounting for more dynamic wound features than a single variable PAR model. Our findings demonstrated the AI-powered HI model 5 outperformed the traditional PAR model consistently, achieving a balanced accuracy of 65% by week 3, one week earlier than PAR, which only attained this level by week 4.

The proactive and effective identification of delayed healing presented in this study aligns with findings from previous research, emphasizing the critical role of machine learning and AI in early prediction efforts. For example, Berezo and colleagues [36] investigated the efficacy of machine learning models in predicting healing outcomes for chronic wounds during various follow-up visits. They specifically assessed the probability of wounds healing within 4, 8, and 12 weeks post-treatment initiation[36]. Their findings indicate that machine learning algorithms can provide accurate predictions for chronic wounds at risk of delayed healing within defined timeframes. However, unlike the Berezo et al [36] model which utilized 187 covariates taken from an electronic health record system, the HI achieved accurate predictive capabilities with only seven. This has implications for the ease of implementation of HI in addition to ethical implications in relation to the interpretability of its outputs. Crucially, in the HI model, clinicians retain full control over the data input into the system. While we acknowledge that larger, routinely generated datasets can enhance model performance and highlight the strength of machine learning over traditional statistical approaches, the use of a smaller, interpretable variable set, as demonstrated in the HI model, offers distinct advantages in clinical contexts. These include greater transparency, ease of integration into diverse healthcare settings, and enhanced trust among clinicians due to the model's simplicity and user control. In resource-constrained environments especially, the ability to achieve robust predictive performance with minimal input data is a notable strength.

Wound management often employs a "step up, step down" approach, where the level of intervention adapts based on the patient's healing trajectory. In cases of delayed healing, the "step up" strategy entails enhancing care by integrating advanced therapies, like negative pressure wound therapy, growth factors, or bioengineered skin substitutes earlier in the treatment process [37,38]. Early detection is crucial for making informed treatment decisions and optimizing the use of advanced therapies. Most wound care protocols advocate for standard treatments during the initial four weeks, followed by a reevaluation to determine if advanced therapies are warranted [37,39]. However, this traditional approach may not adequately prevent wounds from developing into chronic conditions.

Our research shows that the HI model identifies delayed healing more effectively than PAR. By detecting wounds with slow healing trajectories early on, healthcare providers can implement advanced therapies promptly, thereby conserving vital resources. For instance, triggering broader screening for impairment to wound healing, initiating advanced treatments or making referrals early for further investigations and specialist intervention may decrease the number of clinic visits and hospital admissions. One study found that starting more advanced therapies sooner led to a reduction in necessary wound care visits by up to 40% [40]. This decrease not only saves time for healthcare professionals, allowing them to concentrate on critical cases or complex patients, but also enhances staff productivity. With fewer follow-up visits, healthcare facilities can improve overall workflows and reduce wait times for other patients in need of care.

Digital tools like the Healing Index (HI) offer a scalable solution for effectively monitoring large patient populations. By leveraging these tools, healthcare systems and clinicians can stratify patients based on their risk of delayed healing, optimize resource allocation, and improve care coordination. The growing significance of AI-driven tools in wound care is underscored by recent studies demonstrating their potential to enhance clinical outcomes. For instance, a 2020 study achieved a predictive accuracy with an AUC of 0.712 using patient demographics, clinical characteristics, and wound characteristics to identify wounds likely to heal within 12 weeks [48]. While their model was not directly compared to the PAR model, our findings suggest that at four weeks, it outperforms PAR (0.69) but does not achieve the predictive capability of the HI Model 5 (0.76). It should be noted that the Cho et al. model was based solely on wound and patient characteristics collected at the initial presentation, whereas the HI incorporates wound progress over the first weeks of care. Because healing trajectories are strong predictors of outcomes, this difference likely accounts for the higher accuracy observed with the HI. In this way, the two approaches address different stages of clinical decision-making: Cho et al. provides prognostic information at intake, while the HI supports prediction once early follow-up data are available. Additionally, the HI Model 5 holds a key advantage over the Cho et al [48] model, which required 21 variables, whereas HI Model 5 relies on just seven.

This simplicity makes HI Model 5 more practical for clinical implementation, as it requires minimal input from healthcare providers without necessitating advanced training or licensure. Moreover, it does not depend on detailed medical data within the electronic medical record, such as smoking status or body mass index, making it more accessible and easier to integrate into routine practice. As digital wound care solutions are further refined and tailored for specific applications, the ability to accurately predict delayed healing will further streamline wound management, improving patient outcomes and reducing healthcare costs, particularly for systems managing a high volume of chronic wound patients. Additionally, in an era of expanded movement to value-based care, new applications like HI can support improving patient outcomes, controlling costs and improving overall quality of life especially for high-risk, older adults.

A comparable model to the Healing Index (HI) was developed by Dallmann et al[49], incorporating a similar range of variables and likewise reporting that changes in wound exudate were not significant predictors of healing. Their model identified changes in wound area as the most influential factor in predicting wound outcomes. However, wound area was estimated using an assumed elliptical shape derived from manual length and width measurements, an approach that may not accurately reflect true wound morphology, particularly in irregularly shaped or undermined wounds. Although measuring area using a geometric approach could produce measurement error compared with segmentation area-by-pixel, it would be expected to reduce predictive discrimination, not increase it. Thus, the variation in AUC reported is more likely due to different cohort compositions, feature sets, definitions of outcome measures, or evaluation/validation methods discussed in article methodology, rather than 'the area estimation method' alone.

Chronic non-healing wounds impose a substantial financial burden on Medicare, with annual costs exceeding $28 billion, largely driven by the costs associated with DFU and PI [41]. Previous studies suggest that earlier initiation of advanced therapies, particularly within the first four weeks, may improve healing outcomes and reduce complications such as infection and amputation[37,39,42]. These associations have been linked, in the broader literature, to reduced treatment duration and lower healthcare utilisation[41,43,44]. However, the present study did not evaluate clinical outcomes, healthcare utilisation, or costs. Its findings are limited to the predictive accuracy and timing of the Healing Index in identifying wounds at risk of delayed healing. While prior economic analyses indicate that earlier intervention may be associated with cost reductions[37,41,45–47], these effects cannot be inferred from the current results.

Future prospective studies should explicitly test whether earlier risk stratification using predictive tools such as the Healing Index leads to measurable improvements in clinical outcomes and economic endpoints, including hospital admissions, complication rates, and overall cost of care.

## Limitations

Despite the promising findings of this research, several limitations should be considered. For example, the generalizability of findings from analysis of the DWCS database. One of the variables in the HI model was practice setting. The model was trained exclusively on data from post-acute care settings (e.g., SNF, home health). This denotes that the predictive capability shown here is most applicable for post-acute settings. Generalizability will depend on validating it in acute, ambulatory, and other settings. Furthermore, the inherent biases present in AI models trained on historical data may impact their predictive accuracy across diverse patient populations and wound care environments.

Another consideration is the class imbalance within our dataset, where delayed healing wounds outnumbered optimally healed wounds by approximately 4:1. This imbalance reflects the epidemiology of post-acute care, where a substantial portion of wounds are not expected to heal within the next 12 weeks. In these contexts, the HI model is appropriate, and clinically useful, because it flags delayed healing and directly acknowledges healing trajectories with a weaker than expected sensitivity. However, if healing trajectories are more balanced (by way of an example - outpatient clinics or surgical follow-up where almost all wounds heal in an expected period of time), the same decision thresholds may over-identify delayed healing, subsequently lowering the positive predictive validity of the decision threshold and possibly raising unnecessary alerts, recommendations or notifications. Conversely, if delayed healing was even more prevalent, then we would perhaps decrease the specificity for the HI model. This context dependence of performances conveys that when used in practice reports it depends on context; and it demonstrates the need for political recalibration, or re-validation of the model, in populations with different case-mix ratios.

Additionally, while the HI model demonstrated higher predictive accuracy than PAR in skilled nursing and home health settings, its effectiveness heavily relies on accurate image capture and quality of data entry. Variability in these methods among different users and practice setting can further complicate its application in practice. In real-world use, additional barriers may include differences in smartphone camera quality, inconsistent lighting conditions, variability in clinician training, and atypical wound presentations, all of which may undermine SmartTissue™ performance. Furthermore, unequal access to technology across healthcare organizations can limit adoption and contribute to disparities in benefit. These considerations reinforce the importance of testing this model in different clinical contexts to check for robustness and equitable implementation.

Further prospective research is needed to test the clinical and economic impacts of the HI model when deployed within clinical practice, in addition to studies of its acceptability by the diverse range of clinicians who may benefit from its use. The model would also require further testing in an expanded set of wound aetiologies to confirm its value across a broader spectrum of patients.

## Conclusion

To date, methods to monitor and predict wound healing outcomes have been limited by subjective metrics, single-variable predictive models, and challenges in collecting data on wound healing variables objectively. The AI-driven healing index model (HI Model 5) presented in this study provides a more efficient means of identifying delayed wound healing compared to the current standard quantitative metric Percent Area Reduction (PAR). By week three, the HI Model 5 demonstrated predictive accuracy that PAR achieved only by week four and at week two, nearly achieved parity to PAR at week 4. This early detection may enable clinicians to take proactive measures to adjust treatment plans and implement advanced therapies before complications arise. It may also compete with PAR as a proxy indicator of wound therapy efficacy in clinical studies. Additionally, recognizing healing delays sooner enables healthcare professionals to use resources more effectively and minimizes the need for extended follow-up, ultimately optimizing care for high-risk patients. As digital wound care solutions evolve, they will be crucial in enhancing wound care practices.

## Conflict of Interest

LG, HMT, SW, RDJF, JA, are all current employees of Swift Medical Inc. RG and SW are former employees of Swift Medical Inc. All other offers have no conflicts to declare.

## Author Contribution List

RF served as the guarantor for the work. LG contributed to data collection, statistical analysis, writing, and editing. HMT assisted with conceptualisation, writing, and editing, SM contributed to data collection and statistical analysis. RG supported conceptualisation, data collection, statistical analysis, and editing. SW contributed to editing, and RDFJ participated in conceptualisation, writing, and editing. MW contributed to writing and editing, and JA supported conceptualisation.

## Ethics

Research ethics exemption was provided for this analysis by Pearl Institutional Research Board (2023-0100)

## Funding -None

## Data Availability Statement

Data are available upon reasonable request. Researchers interested in access to the data set can reach out to the corresponding author via email.

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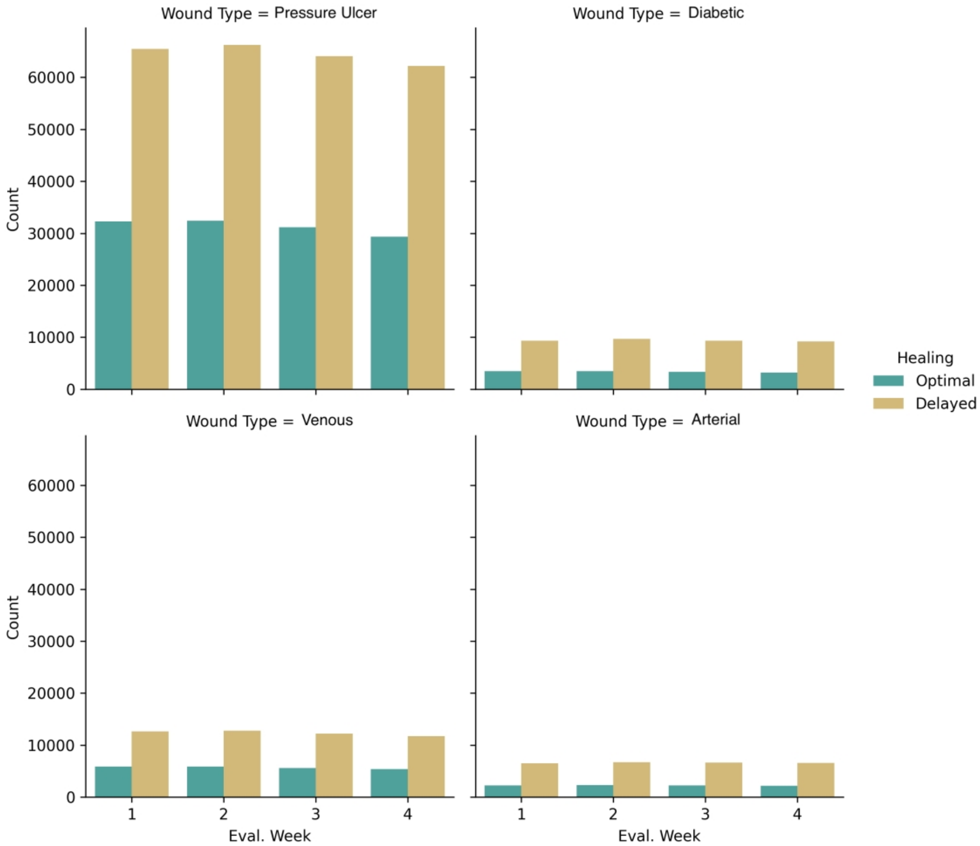


Figure 1: WoundsCount by wound type across evaluation time points by week

233x200mm (300 x 300 DPI)

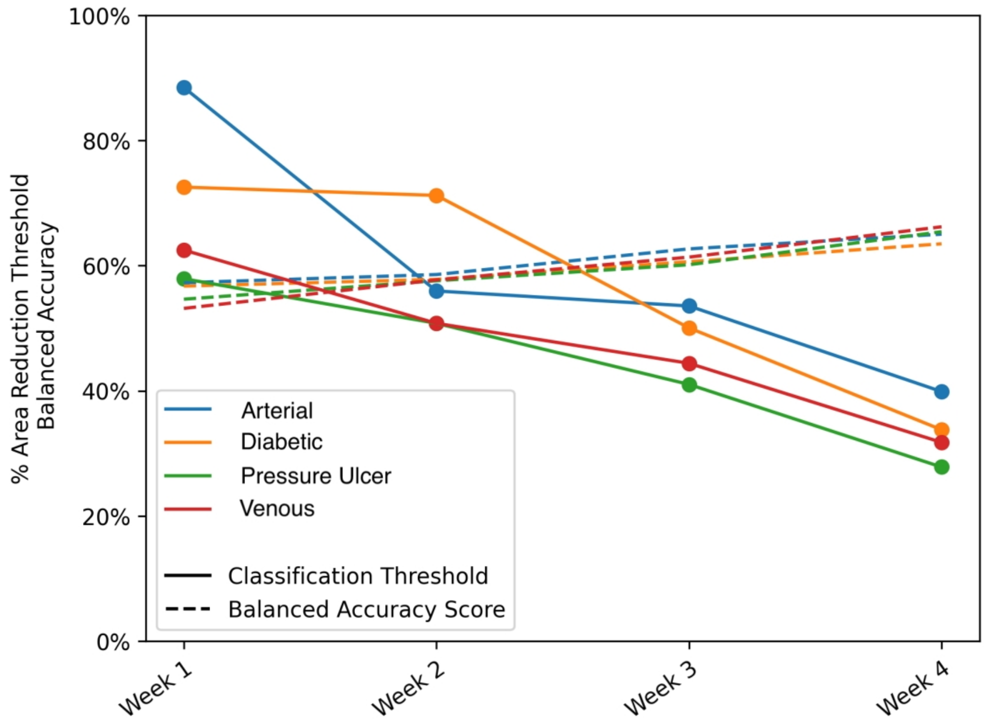


Figure 2: Optimal PAR Threshold and Balanced Accuracy for Predicting Delayed Healing

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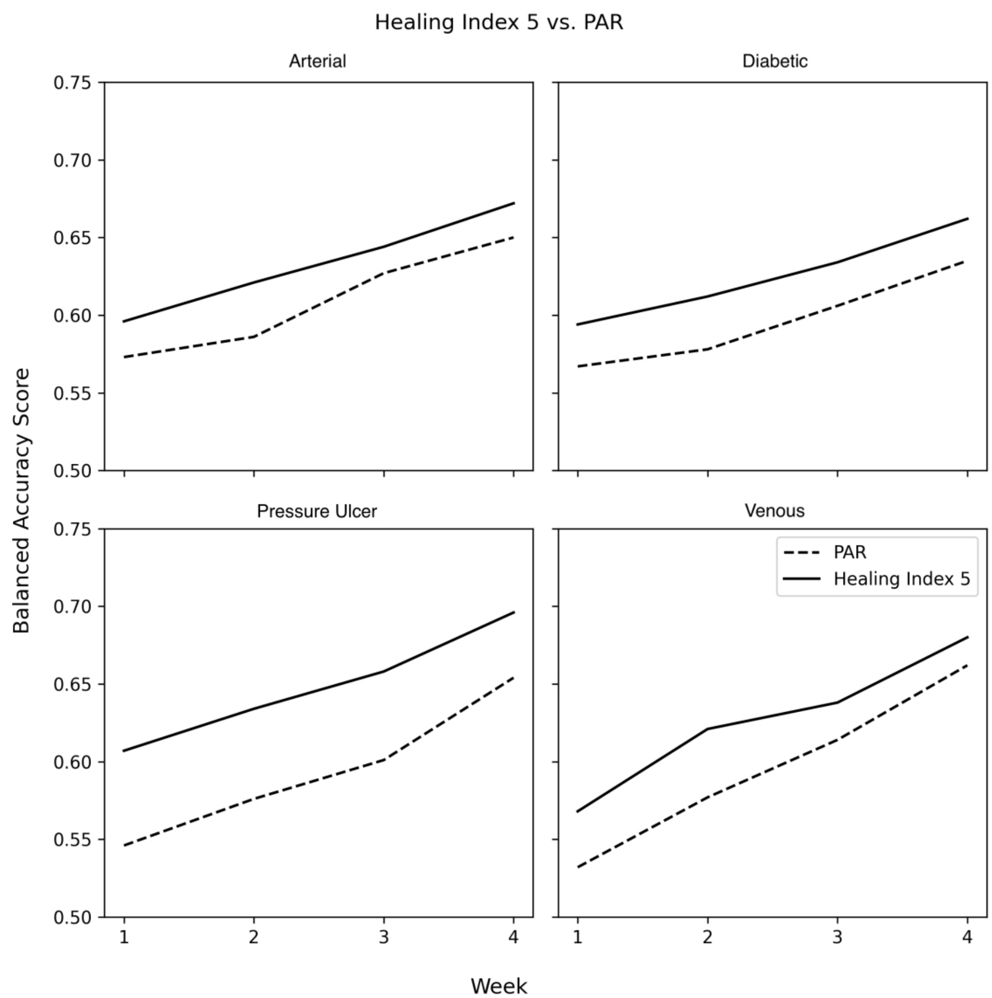


Figure 3: Balanced Accuracy Scores of each healing model for each wound type week over week

200x202mm (300 x 300 DPI)

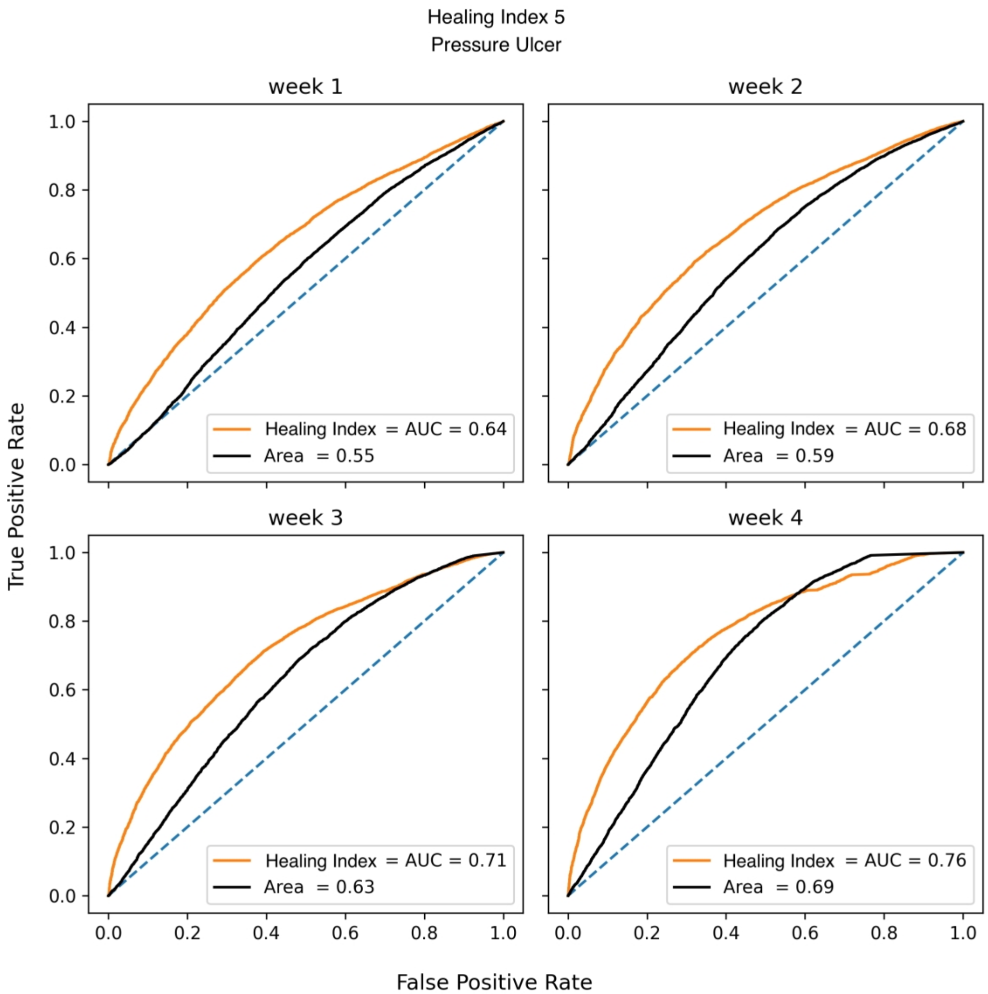


Figure 4: ROC curves and AUC scores for Percent Area Reduction (black trace) and HealingIndexTM 5 (orange trace) at each time point.

200x202mm (300 x 300 DPI)

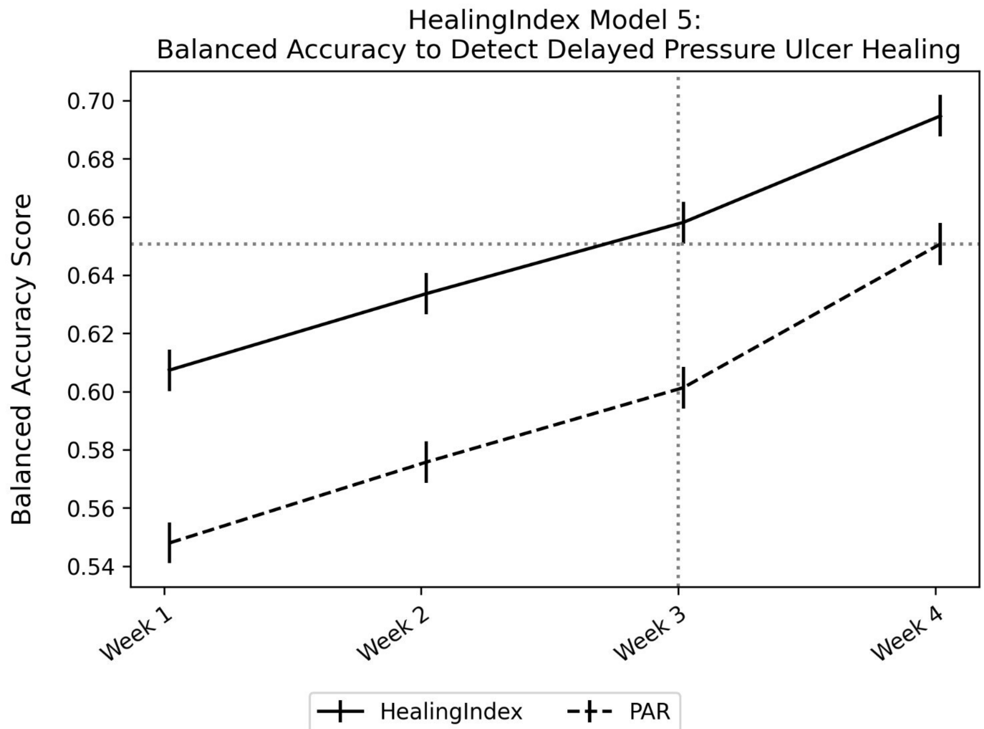


Figure 5: Balanced Accuracy Scores (BAS) for HI Model 5 compared to PAR (dashed line). The horizontal dotted line indicates maximum performance of PAR to highlight the time point at which HI outperforms PAR's best performance.

127x95mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

| | Item No. | Recommendation | Page No. |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 1 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 1 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 1-5 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 6 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 6-7 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 6-8 |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls<br>*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants | 6 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 7 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 6 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 6 – no specific controls for bias, this is acknowledged in the limitations section |

| | | | |
|---|---|---|---|
| Study size | 10 | Explain how the study size was arrived at | NA – all relevant retrospective data were included |

Continued on next page

| | | | |
|---|---|---|---|
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 7-8 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 7-8 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | NA |
| | | (*c*) Explain how missing data were addressed | NA |
| | | (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed<br>*Case-control study*—If applicable, explain how matching of cases and controls was addressed<br>*Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy | NA |
| | | (*e*) Describe any sensitivity analyses | 7-8 |
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 8 |
| | | (b) Give reasons for non-participation at each stage | NA |
| | | (c) Consider use of a flow diagram | NA |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 8 |
| | | (b) Indicate number of participants with missing data for each variable of interest | 8 |
| | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | NA |
| Outcome data | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time | 8-10 |
| | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure | NA |
| | | *Cross-sectional study*—Report numbers of outcome events or summary measures | NA |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 8-10 |
| | | (*b*) Report category boundaries when continuous variables were categorized | 8-10 |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | NA |

Continued on next page

| | | | |
|---|---|---|---|
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | NA |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 8-10 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 13 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 11-13 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 11-13 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | NA – no funding was provided |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

# TITLE

Predicting Wound Healing Outcomes: A Comparative Accuracy Analysis of AI-driven Indices and Percent Area Reduction

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# Abstract

**Background:** Wounds represent a major global health and economic burden, with chronic wounds affecting millions annually and costing medical care providers over $126 billion in the US alone. Current assessment tools, such as Percent Area Reduction (PAR), are widely used but limited by subjectivity and suboptimal predictive accuracy, particularly for complex wound types. The growing integration of artificial intelligence (AI) into healthcare provides a unique opportunity to enhance wound assessment and prognostic capabilities, potentially enabling earlier and more precise interventions.

**Methods:** This retrospective study evaluated the performance of an AI-powered Healing Index (HI) in predicting delayed healing for pressure injuries, venous ulcers, diabetic foot ulcers, and arterial ulcers. Using a clinically validated dataset of 173,816 wounds collected via a digital wound care solution, we compared the HI model's predictive accuracy to PAR. The HI incorporated objective wound characteristics, such as tissue composition and exudate, to forecast healing trajectories.

**Findings:** By week 3, the HI achieved a balanced accuracy of 65%, surpassing PAR, which reached the same level only in week 4. This earlier prediction enables more timely treatment adjustments, facilitating improved outcomes and reducing healthcare costs.

**Interpretation:** The AI-powered HI demonstrates significant potential for transforming wound care by providing more accurate, objective, and earlier identification of non-healing wounds. Its integration into clinical practice could enhance resource allocation, optimise treatment strategies, and reduce the economic burden of chronic wounds. Further validation across diverse healthcare settings is warranted to ensure equitable implementation.



**Keywords:**

Wound, prediction, healing, AI, artificial intelligence, PAR


*What is already known on this topic"* - Percentage area reduction at 4 weeks is widely used to predict wound healing, but it is a single-variable measure with limited accuracy across wound types and poor applicability in routine clinical practice.

*What this study adds* - This study shows that an AI-powered HealingIndex™ (HI Model 5) predicts delayed healing more accurately and one week earlier than PAR, using only seven interpretable variables.

*How this study might affect research, practice or policy* - The findings support replacing PAR with AI-driven tools for earlier, more accurate wound assessment, with potential to improve outcomes, guide treatment decisions, and inform clinical trial endpoints.

# Introduction

Wounds are a significant global health challenge, affecting millions of people each year, with estimated costs of over $126B annually to medical care providers in the US alone[1]. Chronic wounds are also increasing in prevalence[2], likely due to aging populations and the rise of conditions like diabetes and obesity. These wounds can have a profound impact on patients' quality of life, leading to pain, disability, and prolonged hospital stays.

Given these challenges, efficient and accurate methods of monitoring healing progress are crucial. As wound care continues to evolve, digital solutions and AI-driven models offer new possibilities for improving detection, monitoring, and treatment, ultimately enhancing patient outcomes and reducing healthcare burdens. Multiple studies have highlighted the value of wound area measurements or Percentage Area Reduction (PAR) as a prognostic indicator [3,4]. In clinical practice, wound area is often measured manually using rulers, although this method is repeatedly found to produce inaccurate results and poor inter-rater reliability when compared with digital approaches[5]. Compounding this, while the general PAR threshold is a useful benchmark, it may not fully capture the complex nature of certain types of wounds, as different classes of wounds respond differently to respective treatment modalities, leading to variations in their healing pattern and trajectory[6,7]. Several studies and clinical observations have considered wounds as chronic or non-healing if the PAR threshold shows less than a 20-30% reduction in surface area after 4 weeks of receiving care[5]. Yet, the threshold for PAR may significantly differ depending on the type and category of the wound. For example, pressure injuries (PI) and diabetic foot ulcers (DFU) are both chronic wound types, however, they often exhibit distinct healing patterns and respond differently to various management strategies. This contrasts with uncomplicated simple traumatic wounds, which may heal within more predictable timeframes and respond similarly to simple treatments.

Consequently, in these circumstances, the general PAR benchmark may not accurately represent progress or be useful in guiding the clinical management plan[8,9,10]. Similarly, diabetic foot ulcers are often compounded by underlying vascular and neuropathic issues that can significantly impede the healing process[11,12,13,14]. These wound-specific factors necessitate a more nuanced and adaptive approach to assessing wound healing progress, which may contribute to the low utilization of PAR in daily clinical practice.

Nonetheless, PAR at 4-weeks is currently considered the best proxy predictor of wound healing by the US Food and Drug Administration (FDA) within clinical trials of wound products[15]. This is due to the pragmatic issues associated with waiting for complete wound healing, establishing homogenous treatment and control groups within wound patient populations to facilitate randomized controlled trials and the absence of viable alternatives. In response to these challenges, other frameworks, models, and algorithms have been explored to improve the prediction of wound healing trajectories. These include the wound status index[16], artificial intelligence (AI)-based models and predictive algorithms[14,17], and Bioelectrical Impedance Analysis (BIA)[18].

BIA is a technique that measures and tracks body composition over time and monitors the impact of a treatment plan on chronic conditions[19]. Recently, it has been introduced to monitor wound healing by measuring electrical impedance and fluid status. While it is an easy and non-invasive technique with direct algorithm, its precision is dependent on the body's hydration status and recent food intake[20]. Additionally, the accuracy of this method can be affected by wound exudate, and presence of infection[20]. Thus, single-variable approaches to predicting wound healing offer poor prognostic abilities. This is unsurprising given the many factors known to impact on healing potential[21].

In contrast, recent studies ~~advancements~~ in AI technology have explored ~~enabled~~ the use of predictive algorithms to forecast wound healing times and identify non-healing wounds. Image-based AI tools have been shown to ~~can now~~ analyze wound images, ~~with precision,~~ detecting early warnings for potential complications in research and pilot settings[22]. Similarly, several studies report that machine-learning approaches can model wound healing trajectories by identifying patterns across multiple clinical and wound-related variables~~Moreover, AI algorithms can predict wound healing trajectory based on patterns identified across multiple variables~~[17,23,24]. One~~A~~ study evaluating an ~~investigated the impact of~~ AI-driven analytics model for wound assessment reported improved accuracy in predicting healing trajectories compared with conventional approaches, based on longitudinal monitoring of wound characteristics~~on predicting wound healing outcomes found that the AI model was able to monitor wound characteristics and identify patterns in wound progress, significantly improving the accuracy of predicting wound healing trajectory compared to traditional methods~~[25]. In addition, ~~Furthermore,~~ AI-supported~~based~~ systems~~olutions~~ have been proposed as a means of assisting documentation and wound tracking, although evidence to date remains largely evaluative rather than confirmatory~~the potential to automate documentation, leading to improved workflow efficiency, reduced documentation errors, and enhanced tracking of wound progress~~[24,26].

Various techniques of machine learning and classification have been used for predictive analyses in wound management, with the aim of improving clinicians' preparedness and management of patients' conditions. However, it is important to note that the success of predictive analytics depends on the quality of data and the technological infrastructure used to develop and implement predictive models [22,24,27,28]. Accordingly, the use of structured clinical data has gained prominence in wound care for evaluating and predicting wound healing progress based on various parameters, including wound characteristics, wound bed attributes, and the patients' health status. One example of this approach used in evaluating the healing progress of PIs is the Pressure Ulcer Scale for Healing (PUSH), which focuses on the assessment of wound size, exudate, and tissue type[29]. Research has indicated that the PUSH is a simple, effective, and reliable approach for detecting improvements in wound healing and guiding treatment plans

[8,29,30]. However, this method still relies on subjective assessment and requires consistent training of healthcare professionals to ensure accuracy[29]. Despite these strengths, there also remains no clear evidence that it is widely used in practice.

Another example of a wound healing assessment tool in clinical practice is the Venous Leg Ulcer Wound Healing Index (VLU WHI), a comprehensive scoring system used to assess wound area size reduction, depth, tissue type, and exudate to predict wound healing progress[31]. Although limited to a single wound type, this model was validated on a large data set (VLU = 11,773) and achieved significant predictive outcomes on the validation data set. The VLU WHI was embedded within an electronic medical record and the authors noted with appropriate interventions, wounds identified to have non-healing risk were able to heal with best practice interventions. However, systematic reviews of wound healing indexes specific to VLU and diabetic foot ulcers (DFU) have reported that the existing models lack robust evidential basis and are therefore of limited clinical utility [32,33]. Taken together, these reviews indicate that in most cases the existing models aim to predict healing at 24 weeks, use heterogeneous variables and wound area is often not included within the models. This is perhaps due to the pragmatic challenges in measuring wounds manually, which remains a common assessment approach globally despite its aforementioned clinimetric limitations.

Gupta et al[17] developed a prognostic system similar to the VLU WHI concept using AI to improve subjective wound assessment data with objective data using computer vision. The model, HealingIndex™ (hereafter referred to as HI) was based on wound characteristics, including estimated wound area and tissue quantities derived from wound segmentation and tissue quantification models. In their study, the efficacy of these objective prognostic models across multiple wound types (i.e., PI, VLU, DFU, arterial ulcers) were compared to traditional clinical tools such as the PUSH and the Bates-Jensen Wound Assessment Tool (BWAT) systems. Their findings indicated that a hybrid prognostic model, referred to as HI Model 5, produced significant improvements over conventional tools, outperforming PUSH by 4% and BWAT by 7%. HI Model 5 incorporated objective data concerning wound extent and severity, with tissue composition accurately calculated using SmartTissue™, an image-based deep learning model. By integrating these objective features, the model enabled a more precise evaluation of wound progression[17].

Building on this foundation, the present study evaluated the performance of the HI model against the PAR model in predicting delayed wound healing across a range of wound types and pathologies. The HI in this study is an AI-powered tool that integrates both objective and subjective wound data including wound characteristics, such as digitally measured surface area, tissue types, exudate type, exudate amount, anatomical location of the wound and clinical setting, to generate a quantitative prognosis for wound healing. Additionally, the researchers sought to determine which wounds were expected to heal within a 12-week timeframe. Ultimately, by leveraging advanced analytics, clinicians may make more informed decisions, identifying non-healing wounds earlier which may facilitate more timely specialist intervention and identification of ineffective wound therapies. This may, in turn, reduce healthcare costs associated with chronic, non-healing wounds.

# Methods

# Research question

How does the predictive accuracy of the AI-powered Healing Index (HI) compare to Percent Area Reduction (PAR) in identifying delayed wound healing across four common chronic wound types?

## Data sources and approach

The study leveraged a clinically calibrated and validated Digital Wound Care Solution (DWCS) database, encompassing data from various healthcare settings. Data was collected from organizations that agreed to share de-identified clinical data. Research ethics exemption was provided for this analysis by Pearl Institutional Research Board (2023-0100). Using Structured Query Language (SQL), we extracted weekly wound evaluations for four wound types (PI, DFU, VLU, and AU) dated between February 2017 and April 2022. Together, these four wound types account for 38.01% of all wounds tracked using the DWCS in homehealth and skilled nursing facility settings. These evaluations were tracked over the first four weeks following the initial wound care assessment recorded in the system. Wounds were included in the analysis if they were monitored for a minimum of 12 weeks or had healed within that period. This allowed for classification into two categories: optimally healed wounds (healed within 12 weeks) or delayed healing wounds (≥12 weeks to heal).

For each evaluation, wound area was calculated in square centimeters using AutoTrace™, a deep learning algorithm specifically trained and calibrated to measure wound size accurately. Additionally, the presence and distribution of tissue types (granulation, epithelial, slough, eschar, and healthy tissue) within the wound bed were assessed using SmartTissue™, an AI-powered deep learning tool designed to differentiate between tissue types [34]. Both SmartTissue and AutoTrace are semantic segmentation models utilizing a U-Net architecture optimized for running on-device at the bedside (see Ramachandram *et al.* 2022 for an in-depth description of model architectures). Clinical documentation was used for the exudate type, exudate amount, body location, and clinical setting.

The AI-powered HI models were calculated post-hoc using combinations of the following features, which were chosen using a forward-backwards selection process, whereby features whose univariate model improved predictive power relative a null model were all included in the forward pass, and subsequently removed if their omission from the full model did not significantly decrease the model AIC (see see Gupta *et al.* 2024):

- User enhanced area* vs AutoTrace™ area measurements
- Subjective tissue type analysis vs SmartTissue™
- Exudate amount (clinician documented)
- Exudate type (clinician documented)
- Edges (clinician documented)
- Location (anatomical)
- Setting (clinical)

*In user enhanced area measurements, clinicians refine the wound area margins identified using AutoTrace to adjust photogrammetry measurements documented within the DWCS.

HI scores were derived by fitting these features to a time-varying Cox Proportional Hazards (CoxPH) model and extracting a hazard score using the fitted coefficients. Model performance was evaluated using Incident/Dynamic Area Under the Curve (AUC), which acts as an extension to concordance indices allowing to calculate concordance of HI scores at different time points in the wound healing process (see Gupta *et al.* 2024 for a full description and analysis of the HI models). This comprehensive, data-driven approach ensured a thorough assessment of wound healing trajectories across multiple wound types, offering insights into the relationship between tissue composition, wound size, and healing outcomes.

## Percent Area Reduction (PAR) and HI Variations

Percent Area Reduction (PAR) was calculated using the formula (Ai-Ac)/Ai X 100, where Ai represents the wound area at the initial assessment, and Ac is the wound area at the current assessment [35]. This metric provided an indication of the percentage reduction in wound size over time. Additionally, six variations of a HI were computed for each wound evaluation. These variations incorporated different combinations of subjectively observed features (such as clinician assessments) and AI-estimated features[17].

Both PAR and the HI models serve as standalone predictors of wound healing outcomes. By establishing specific thresholds for each model, wounds will be classified as either optimally healed or delayed in healing. The HI model offers the potential for improved prediction and classification of wound healing trajectories, allowing clinicians to better tailor treatment plans based on early assessments of wound progress.

## Accuracy Metrics

To ensure stability and optimize the performance of the healing models, we implemented a K-Fold cross-validation design to derive Receiver Operating Characteristic (ROC) curves to visualize the predictive power of PAR and HI across decision thresholds. The dataset was initially split into an 80% training set and a 20% holdout set. The training set was further divided into 10 equal-sized folds for cross-validation. For each fold, we calculated ROC curves across different weeks of evaluation, wound types, and healing models to assess the predictive accuracy of PAR and HI models in predicting delayed healing.

From the ROC curves, we derived the AUC for each permutation, which provided an overall ranking of model performance across all possible decision thresholds. Additionally, ROC analysis allowed us to determine the classification threshold for each fold by calculating Youden's J ,*i.e.* the point where the difference between true positive and false negative rates was maximized, achieving an optimal balance between sensitivity and specificity.

AUC values closer to the maximum value of 1.0 indicate better performance for binary classifiers but may be misleading in cases of class imbalance. We therefore also calculated balanced accuracy scores (BAS) to address class imbalance in the dataset (i.e., a higher number of delayed healing wounds compared to those healing within 12 weeks). This metric considers both sensitivity (the ability to correctly identify healing wounds) and specificity (the ability to correctly identify non-healing wounds), giving equal weight to both, ensuring that both true positives and true negatives were equally considered, mitigating any skew in predictive accuracy due to class imbalance. Furthermore, confidence intervals were calculated on the accuracy metrics to ensure conservative estimates of model performance. No resampling techniques were applied to the training dataset to attempt to balance the dependent variable.

The mean and standard deviation of BAS was calculated for each fold to determine metric stability. Furthermore, the optimal decision threshold for each HI variation was averaged across the 10 training folds to establish an overall optimal threshold. This threshold was then applied to the holdout dataset to evaluate AUC and BAS on unseen data, with 95% confidence intervals derived by non-parametric bootstrap resampling ($B$=10,000) of the model's predictions on the held-out data.

The AUC reflects the model's overall ability to classify healing versus non-healing wounds across various thresholds, while balanced accuracy evaluates its reliability at a specific threshold. The AUC and balanced accuracy scores from these predictions are reported in the results section to provide a comprehensive evaluation of the healing models' predictive performance.

### Statistical Analysis

We conducted a repeated measure ANOVA test to compare the performance of the various healing models. In this design, subjects were defined as a combination of the wound type and the evaluation week, with the model being the sole within-subject factor. The response variable was the balanced accuracy score. This approach allowed us to assess differences in model's predictive accuracy while controlling for variability related to wound type and week of evaluation.

Following the repeated measures ANOVA, we conducted post-hoc one-tailed paired t-tests to compare the accuracy of the PAR scores model to the HI models. These t-tests were designed to test the null hypothesis that the accuracy of the HI was less than or equal to that of PAR. Given the multiple comparisons, we applied a Bonferroni correction to adjust for the six tests, setting a corrected significance threshold of alpha = 0.008.

All data processing and statistical analysis was carried out in Python 3.11. Statistical analyses relied on scikit-learn 1.5.1 and statsmodels 0.14.2.

## Patient and Public Involvement statement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

## Results

### Demographics

Our analysis incorporated a total of 173,816 wounds from 85,599 patients across 2,316 Skilled Nursing Facilities (SNF) and 132 Home Health facilities from all 50 United States and several Canadian provinces. Among the patients, 46,789 (55%) were female, 38,350 (45%) were male, and 460 patients (<1%) had no documented sex in our records. The average age of the patients was 76.3 years. The wounds consisted of 122,659 pressure injuries (70.8%), 23,451 venous wounds (13.5%), 16,578 diabetic wounds (9.6%), and 10,861 arterial wounds (6.3%). Figure one illustrates the counts of wounds included in the analysis at each evaluation week, categorized by wound type. The green bars indicate the number of wounds that healed within 12 weeks, while the yellow bars represent those that required more than 12 weeks for healing. Notably, at each time point, the dataset consistently exhibited a significantly lower count of optimally healing wounds compared to those with delayed healing, resulting in a marked imbalance. This disparity reflects a real-world bias towards delayed healing wounds being documented in HomeHealth and SNFs, and underscores the rationale for employing balanced accuracy as the primary metric for evaluation in this study.

Figure 1: Count by wound type across evaluation time points by week included in the analysis

## Predictive Accuracy of PAR Scores and Balanced Accuracy for Delayed Wound Healing by Week 4

Figure 2 demonstrates a clear relationship between the percent area reduction (PAR) classification scores and the accuracy of predicting delayed wound healing. Specifically, as PAR scores decrease to between 35-40% indicating that the wound is showing more signs of healing and reducing in size the accuracy of predicting delayed healing improves. This trend is reflected in the increasing balanced accuracy scores over time. By week 4, the balanced accuracy reaches approximately 65% across all four wound types, meaning that by this point in the wound's progression, the model is 65% more accurate in predicting which wounds are likely to experience delayed healing. This highlights the importance of the 4-week mark as a critical time for evaluating wound healing trajectories.

Figure 2: Optimal PAR Threshold and Balanced Accuracy for Predicting Delayed Healing.

## Performance Comparison: Healing Index Models vs. PAR

The repeated measures ANOVA demonstrated a significant impact of the healing model on the balanced accuracy score ($F=35.3187$, $p<0.001$). Follow-up one-tailed paired t-tests further confirmed that all variations of the HI significantly outperformed the PAR model. Among these, HI 5 yielded the highest statistical value, indicating its superior performance compared to PAR. As a result, subsequent analyses focused on HI 5 for further evaluation.

## Balanced Accuracy Scores by Week for Each Healing Model Across Wound Types

Figure 3 compares the balanced accuracy scores of PAR with the HI model 5 across four different wound types. Across the different wounds, PAR recorded the lowest mean balanced accuracy at 55.4%, which improved to a peak of 65% by week 4. In contrast, the HI model 5 had consistently outperformed PAR, demonstrating higher accuracy and greater AUC scores for each wound type analyzed throughout the weeks. Furthermore, HI model 5 was less likely to overclassify wounds as delayed healing than PAR, as evidenced by a consistently superior specificity.

## ROC curves and AUC scores for Percent Area Reduction and HealingIndex™ 5 Model

Figure 4 demonstrates a consistent increase in AUC scores for both HI model 5 and PAR over the 4-week period for pressure injuries (PI). Notably, by week 4, the AUC score for HI model 5 was 0.7 points higher than that of PAR, indicating significantly greater accuracy of the HI model in predicting delayed wound healing by this stage. This result underscores the superior predictive performance of HI model 5 compared to PAR at the 4-week mark.

Figure 4: ROC curves and AUC scores for Percent Area Reduction (black trace) and HealingIndex™ 5 (orange trace) at each time point.

## Balanced Accuracy Scores for HI model 5 compared to PAR for pressure injuries

Figure 5 illustrates the performance of HI model 5 in comparison to PAR, based on balanced accuracy scores for predicting delayed pressure ulcer healing. The horizontal dotted line indicates maximum performance of PAR to highlight the time point at which HI outperforms PAR's best performance.

Both HI and PAR show an increase in accuracy over time; however, HI consistently demonstrates higher accuracy than PAR. Notably, by week 3, HI model 5 achieved a >65% accuracy level (HI week 3 BAS: 0.658, 95% ci 0.650 - 0.665; PAR week 3 BAS: 0.601, 95% ci 0.594 - 0.609), while PAR only reached that level by week 4 (HI week 4 BAS: 0.695, 95% ci 0.688 - 0.702; PAR week 4 BAS: 0.651, 95% ci 0.644 - 0.658). This result implies that by week three, HI improves the accuracy in classifying chronic wounds by 9.5%, and by 6.8% at week 4. This earlier prediction of delayed healing with HI model 5 holds significant clinical implications, as clinicians can identify potential healing delays a week sooner, allowing for timely adjustments to management plans and protocols. Such early interventions may reduce time to heal, improve patient quality of life, and offer cost benefits to skilled nursing facilities (SNFs) by potentially preventing wounds from progressing to more severe stages, which are more challenging to manage.

Figure 5: Balanced Accuracy Scores (BAS) for HI Model 5 compared to PAR (dashed line).

# Discussion

An ideal wound healing prediction tool would be non-invasive, utilize objective metrics to ensure inter-rater reliability, require a minimal number of variables to improve explainability and would show high predictive accuracy early in the lifespan of the wound. These features would maximize opportunities for early intervention, minimize the risk of misinterpretation and therefore yield optimal clinical and economic benefits. The results of this retrospective analysis provide significant insights into the effectiveness of an AI model (HI Model 5) with these characteristics in predicting delayed wound healing. We examined a comprehensive dataset of 173,816 wounds tracked over the first four weeks following the initial wound care assessment recorded in the digital system from various healthcare settings that utilized the digital wound care solution. Our study indicated the HI model's ability to incorporate multiple wound characteristics, such as tissue type and exudate, enhancing its predictive capacity and accuracy by accounting for more dynamic wound features than a single variable PAR model. Our findings demonstrated the AI-powered HI model 5 outperformed the traditional PAR model consistently, achieving a balanced accuracy of 65% by week 3, one week earlier than PAR, which only attained this level by week 4.

The proactive and effective identification of delayed healing presented in this study aligns with findings from previous research, emphasizing the critical role of machine learning and AI in early prediction efforts. For example, Berezo and colleagues [36] investigated the efficacy of machine learning models in predicting healing outcomes for chronic wounds during various follow-up visits. They specifically assessed the probability of wounds healing within 4, 8, and 12 weeks post-treatment initiation[36]. Their findings indicate that machine learning algorithms can provide accurate predictions for chronic wounds at risk of delayed healing within defined timeframes. However, unlike the Berezo et al [36] model which utilized 187 covariates taken from an electronic health record system, the HI achieved accurate predictive capabilities with only seven. This has implications for the ease of implementation of HI in addition to ethical implications in relation to the interpretability of its outputs. Crucially, in the HI model, clinicians retain full control over the data input into the system. While we acknowledge that larger, routinely generated datasets can enhance model performance and highlight the strength of machine learning over traditional statistical approaches, the use of a smaller, interpretable variable set, as demonstrated in the HI model, offers distinct advantages in clinical contexts. These include greater transparency, ease of integration into diverse healthcare settings, and enhanced trust among clinicians due to the model's simplicity and user control. In resource-constrained environments especially, the ability to achieve robust predictive performance with minimal input data is a notable strength.

Wound management often employs a "step up, step down" approach, where the level of intervention adapts based on the patient's healing trajectory. In cases of delayed healing, the "step up" strategy entails enhancing care by integrating advanced therapies, like negative pressure wound therapy, growth factors, or bioengineered skin substitutes earlier in the treatment process [37,38]. Early detection is crucial for making informed treatment decisions and optimizing the use of advanced therapies. Most wound care protocols advocate for standard treatments during the initial four weeks, followed by a reevaluation to determine if advanced therapies are warranted [37,39]. However, this traditional approach may not adequately prevent wounds from developing into chronic conditions.

Our research shows that the HI model identifies delayed healing more effectively than PAR. By detecting wounds with slow healing trajectories early on, healthcare providers can implement advanced therapies promptly, thereby conserving vital resources. For instance, triggering broader screening for impairment to wound healing, initiating advanced treatments or making referrals early for further investigations and specialist intervention may decrease the number of clinic visits and hospital admissions. One study found that starting more advanced therapies sooner led to a reduction in necessary wound care visits by up to 40% [40]. This decrease not only saves time for healthcare professionals, allowing them to concentrate on critical cases or complex patients, but also enhances staff productivity. With fewer follow-up visits, healthcare facilities can improve overall workflows and reduce wait times for other patients in need of care.

Digital tools like the Healing Index (HI) offer a scalable solution for effectively monitoring large patient populations. By leveraging these tools, healthcare systems and clinicians can stratify patients based on their risk of delayed healing, optimize resource allocation, and improve care coordination. The growing significance of AI-driven tools in wound care is underscored by recent studies demonstrating their potential to enhance clinical outcomes. For instance, a 2020 study achieved a predictive accuracy with an AUC of 0.712 using patient demographics, clinical characteristics, and wound characteristics to identify wounds likely to heal within 12 weeks [48]. While their model was not directly compared to the PAR model, our findings suggest that at four weeks, it outperforms PAR (0.69) but does not achieve the predictive capability of the HI Model 5 (0.76). It should be noted that the Cho et al. model was based solely on wound and patient characteristics collected at the initial presentation, whereas the HI incorporates wound progress over the first weeks of care. Because healing trajectories are strong predictors of outcomes, this difference likely accounts for the higher accuracy observed with the HI. In this way, the two approaches address different stages of clinical decision-making: Cho et al. provides prognostic information at intake, while the HI supports prediction once early follow-up data are available. Additionally, the HI Model 5 holds a key advantage over the Cho et al [48] model, which required 21 variables, whereas HI Model 5 relies on just seven.

This simplicity makes HI Model 5 more practical for clinical implementation, as it requires minimal input from healthcare providers without necessitating advanced training or licensure. Moreover, it does not depend on detailed medical data within the electronic medical record, such as smoking status or body mass index, making it more accessible and easier to integrate into routine practice. As digital wound care solutions are further refined and tailored for specific applications, the ability to accurately predict delayed healing will further streamline wound management, improving patient outcomes and reducing healthcare costs, particularly for systems managing a high volume of chronic wound patients. Additionally, in an era of expanded movement to value-based care, new applications like HI can support improving patient outcomes, controlling costs and improving overall quality of life especially for high-risk, older adults.

A comparable model to the Healing Index (HI) was developed by Dallmann et al[49], incorporating a similar range of variables and likewise reporting that changes in wound exudate were not significant predictors of healing. Their model identified changes in wound area as the most influential factor in predicting wound outcomes. However, wound area was estimated using an assumed elliptical shape derived from manual length and width measurements, an approach that may not accurately reflect true wound morphology, particularly in irregularly shaped or undermined wounds.  Although measuring area using a geometric approach could produce measurement error compared with segmentation area-by-pixel, it would be expected to reduce predictive discrimination, not increase it. Thus, the variation in AUC reported is more likely due to different cohort compositions, feature sets, definitions of outcome measures, or evaluation/validation methods discussed in article methodology, rather than 'the area estimation method' alone.

Chronic non-healing wounds impose a substantial financial burden on Medicare, with annual costs exceeding $28 billion, largely driven by~~particularly due to~~ the costs ~~high treatment expenses~~ associated with DFU and PI [41]. ~~Evidence suggests that initiating advanced therapies before the four-week mark can significantly enhance healing outcomes, especially for chronic wounds [37,39,42]. Early intervention has been shown to reduce healing time by up to 30%, potentially leading to cost savings of approximately $6,000 to $8,000 per patient [41,43,44].~~

~~Moreover, timely application of advanced wound therapies can mitigate complications such as infections and amputations, thereby reducing the need for more aggressive and costly interventions [37,45]. Driver et al [46] estimate that preventing these complications through early intervention can yield healthcare savings of $20,000 to $40,000 per patient. For instance, the treatment cost for an infected DFU ranges from $23,000 to $51,000; however, prompt wound management strategies can significantly lower hospital admission rates and the need for surgical procedures, ultimately driving substantial cost reductions [44,47]. Additionally, minimizing hospital readmissions and reducing the length of stays in long-term care facilities could generate annual savings of $3.5 billion to $4.5 billion across the U.S. healthcare system [41]. Whilst we have not directly evaluated the economic impacts of the HI model in this study, the existing literature indicates the potential economic impacts of early intervention in wound care. Further research on AI models for wound healing prediction in clinical contexts should aim to include economic outcomes to further develop this evidence.~~

Previous studies suggest that earlier initiation of advanced therapies, particularly within the first four weeks, may improve healing outcomes and reduce complications such as infection and amputation[37,39,42]. These associations have been linked, in the broader literature, to reduced treatment duration and lower healthcare utilisation[41,43,44]. However, the present study did not evaluate clinical outcomes, healthcare utilisation, or costs. Its findings are limited to the predictive accuracy and timing of the Healing Index in identifying wounds at risk of delayed healing. While prior economic analyses indicate that earlier intervention may be associated with cost reductions[37,41,45–47], these effects cannot be inferred from the current results.

Future prospective studies should explicitly test whether earlier risk stratification using predictive tools such as the Healing Index leads to measurable improvements in clinical outcomes and economic endpoints, including hospital admissions, complication rates, and overall cost of care.

## Limitations

Despite the promising findings of this research, several limitations should be considered. For example, the generalizability of findings from analysis of the DWCS database. One of the variables in the HI model was practice setting. The model was trained exclusively on data from post-acute care settings (e.g., SNF, home health). This denotes that the predictive capability shown here is most applicable for post-acute settings. Generalizability will depend on validating it in acute, ambulatory, and other settings. Furthermore, the inherent biases present in AI models trained on historical data may impact their predictive accuracy across diverse patient populations and wound care environments.

Another consideration is the class imbalance within our dataset, where delayed healing wounds outnumbered optimally healed wounds by approximately 4:1. This imbalance reflects the epidemiology of post-acute care, where a substantial portion of wounds are not expected to heal within the next 12 weeks. In these contexts, the HI model is appropriate, and clinically useful, because it flags delayed healing and directly acknowledges healing trajectories with a weaker than expected sensitivity. However, if healing trajectories are more balanced (by way of an example - outpatient clinics or surgical follow-up where almost all wounds heal in an expected period of time), the same decision thresholds may over-identify delayed healing, subsequently lowering the positive predictive validity of the decision threshold and possibly raising unnecessary alerts, recommendations or notifications. Conversely, if delayed healing was even more prevalent, then we would perhaps decrease the specificity for the HI model. This context dependence of performances conveys that when used in practice reports it depends on context; and it demonstrates the need for political recalibration, or re-validation of the model, in populations with different case-mix ratios.

Additionally, while the HI model demonstrated higher predictive accuracy than PAR in skilled nursing and home health settings, its effectiveness heavily relies on accurate image capture and quality of data entry. Variability in these methods among different users and practice setting can further complicate its application in practice. In real-world use, additional barriers may include differences in smartphone camera quality, inconsistent lighting conditions, variability in clinician training, and atypical wound presentations, all of which may undermine SmartTissue™ performance. Furthermore, unequal access to technology across healthcare organizations can limit adoption and contribute to disparities in benefit. These considerations reinforce the importance of testing this model in different clinical contexts to check for robustness and equitable implementation.

Further prospective research is needed to test the clinical and economic impacts of the HI model when deployed within clinical practice, in addition to studies of its acceptability by the diverse range of clinicians who may benefit from its use. The model would also require further testing in an expanded set of wound aetiologies to confirm its value across a broader spectrum of patients.

# Conclusion

To date, methods to monitor and predict wound healing outcomes have been limited by subjective metrics, single-variable predictive models, and challenges in collecting data on wound healing variables objectively. The AI-driven healing index model (HI Model 5) presented in this study provides a more efficient means of identifying delayed wound healing compared to the current standard quantitative metric Percent Area Reduction (PAR). By week three, the HI Model 5 demonstrated predictive accuracy that PAR achieved only by week four and at week two, nearly achieved parity to PAR at week 4. This early detection may enable clinicians to take proactive measures to adjust treatment plans and implement advanced therapies before complications arise. It may also compete with PAR as a proxy indicator of wound therapy efficacy in clinical studies. Additionally, recognizing healing delays sooner enables healthcare professionals to use resources more effectively and minimizes the need for extended follow-up, ultimately optimizing care for high-risk patients. As digital wound care solutions evolve, they will be crucial in enhancing wound care practices.

# Conflict of Interest

LG, HMT, SW, RDJF, JA, are all current employees of Swift Medical Inc. RG and SW are former employees of Swift Medical Inc. All other offers have no conflicts to declare.

# Author Contribution List

RF served as the guarantor for the work. LG contributed to data collection, statistical analysis, writing, and editing. HMT assisted with conceptualisation, writing, and editing, SM contributed to data collection and statistical analysis. RG supported conceptualisation, data collection, statistical analysis, and editing. SW contributed to editing, and RDFJ participated in

conceptualisation, writing, and editing. MW contributed to writing and editing, and JA supported conceptualisation.

## Ethics

Research ethics exemption was provided for this analysis by Pearl Institutional Research Board (2023-0100)

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## Data Availability Statement

Data are available upon reasonable request

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