Injection Site Reaction Monitoring Reimagined: AI-Powered Detection and Inclusive Quantification

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Introduction

Injection Site Reactions (ISRs) are common adverse effects of injectable treatments, negatively impacting patient comfort, adherence, and overall treatment outcomes [1]. Timely and precise identification of these reactions is vital for effective clinical intervention and improved patient safety. The objective of this study is to leverage artificial intelligence (AI) and advanced image processing to automate the detection and evaluation of ISRs, consequently enhancing clinical monitoring capabilities and patient care.

Results

The AI model demonstrated strong performance, achieving a weighted F1 score of 0.717 and a mean IoU of 0.902 on an independent test set. It accurately detected ISRs and distinguished affected regions from healthy skin (Figure 1). Automated quantification of redness intensity (SEV signal map [2]) and lesion extent [3] provided consistent, objective measures compared with traditional manual assessments. These outputs were combined into a final ISR score, enabling longitudinal monitoring of treatment progression.

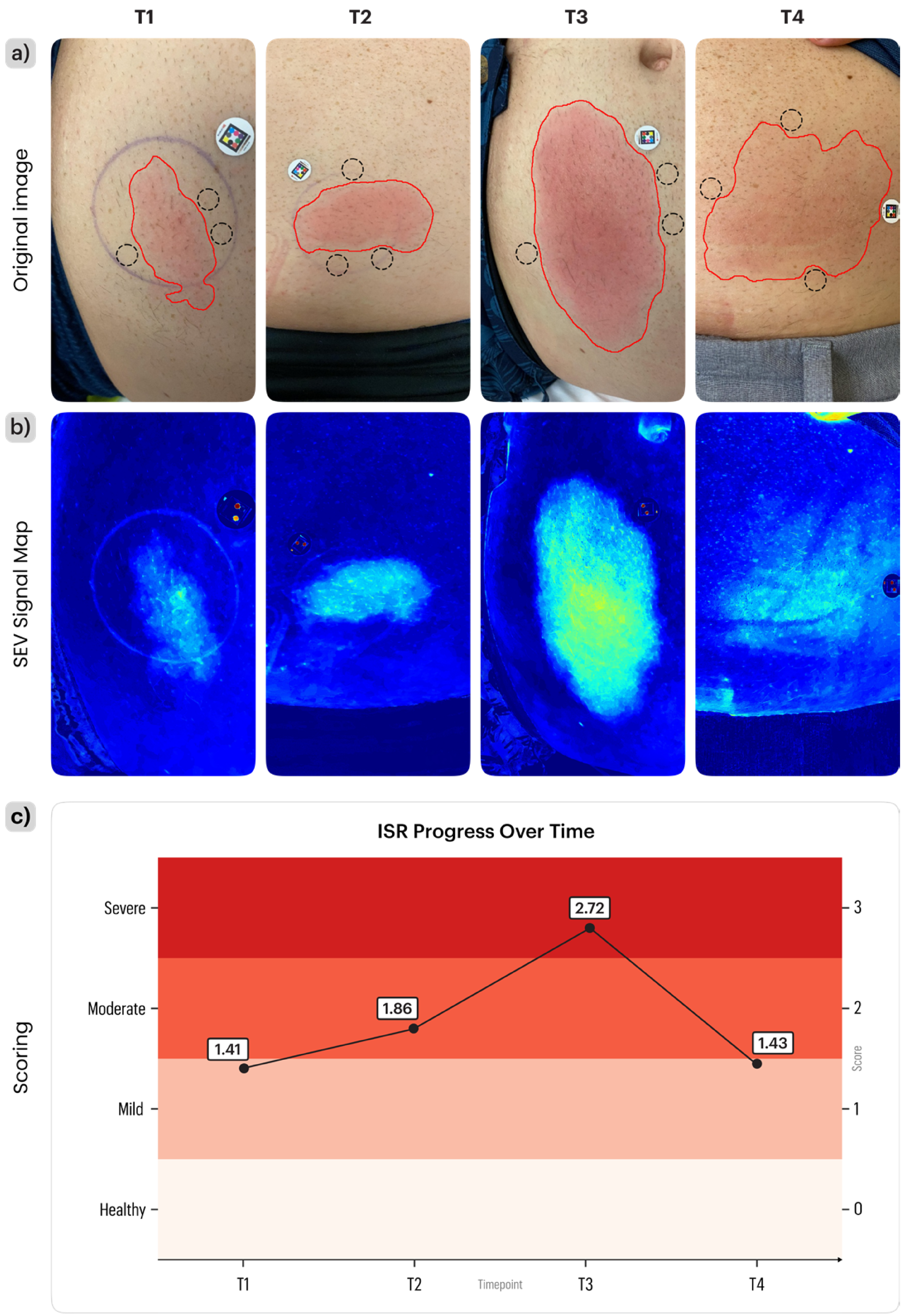

Figure 1: Advanced analysis of Injection Site Reactions:
(a) detected ISR (red), automatic creation of reference areas (black)
(b) specialised SEV signal map to highlight erythema
(c) phototype specific scoring system utilising erythema intensity and lesion extent

Intended use of the Scarletred® Vision system

Scarletred® Vision is a clinically validated and approved Software as a Medical Device (SaMD) platform for contactless monitoring and objective digital assessment of cutaneous drug effects, skin conditions, or changes in skin pigmentation. The Scarletred® Mobile App integrates the use of the Scarletred® Skin Patch, which serves as an internal reference and enables to standardize and automate the process of image documentation and measurement. The patented system is supplied online and used worldwide in pre-clinical and clinical phase I-IV studies in a broad range of indications and product biocompatibility testing.

Materials and Methods

A dataset comprising 2178 clinical images from 117 subjects with skin phototypes I to V undergoing injectable therapies was collected using Scarletred®Vision app, together with a calibration skin patch to ensure consistent and standardised image acquisition.
A convolutional neural network (CNN) was fine-tuned on the ISR dataset to automatically detect and segment ISR regions, leveraging transfer learning to adapt to the specific characteristics of injection site reactions. In addition, reference areas of unaffected skin were also identified to serve as controls for comparison, enabling more consistent and objective evaluation. Data exploration revealed the need for tailored quantification across different phototypes. To address this challenge, the fine-tuned model was integrated with a scoring system utilising advanced image processing techniques to capture critical ISR features, including redness intensity and lesion extent, thereby providing an inclusive overall status across all skin types.

Dataset & Performance	
Subjects	117
Clinical images	2,178
Skin phototypes	I-V
Injection Type	Single-injection
Weighted F1 score	0.717
Mean IoU	0.902

Table 1: Overview of the study dataset and AI model performance.

Enhanced Clinical Monitoring and Patient Care

Integration of the AI-enhanced imaging approach into the Scarletred® Mobile App enables remote, patient-driven documentation, proactive monitoring, and timely clinical intervention, thereby strengthening clinical management and patient safety. This approach empowers patients to participate actively in their own treatment by documenting reactions in real time, reducing reliance on clinic visits and subjective recall.
For clinicians, automated quantification provides consistent, objective data that can be seamlessly integrated into existing workflows, improving comparability across sites and over time. Lesion size is reported in millimetres, allowing changes to be assessed easily and enhancing clinical interpretability, while ensuring comparability across sites and studies.
By employing a process tailored to the detected skin phototype, the system ensures reliable performance across diverse populations, supports inclusive digital health solutions and actionable insights into both short-term reactions and long-term progression (Figure 2).

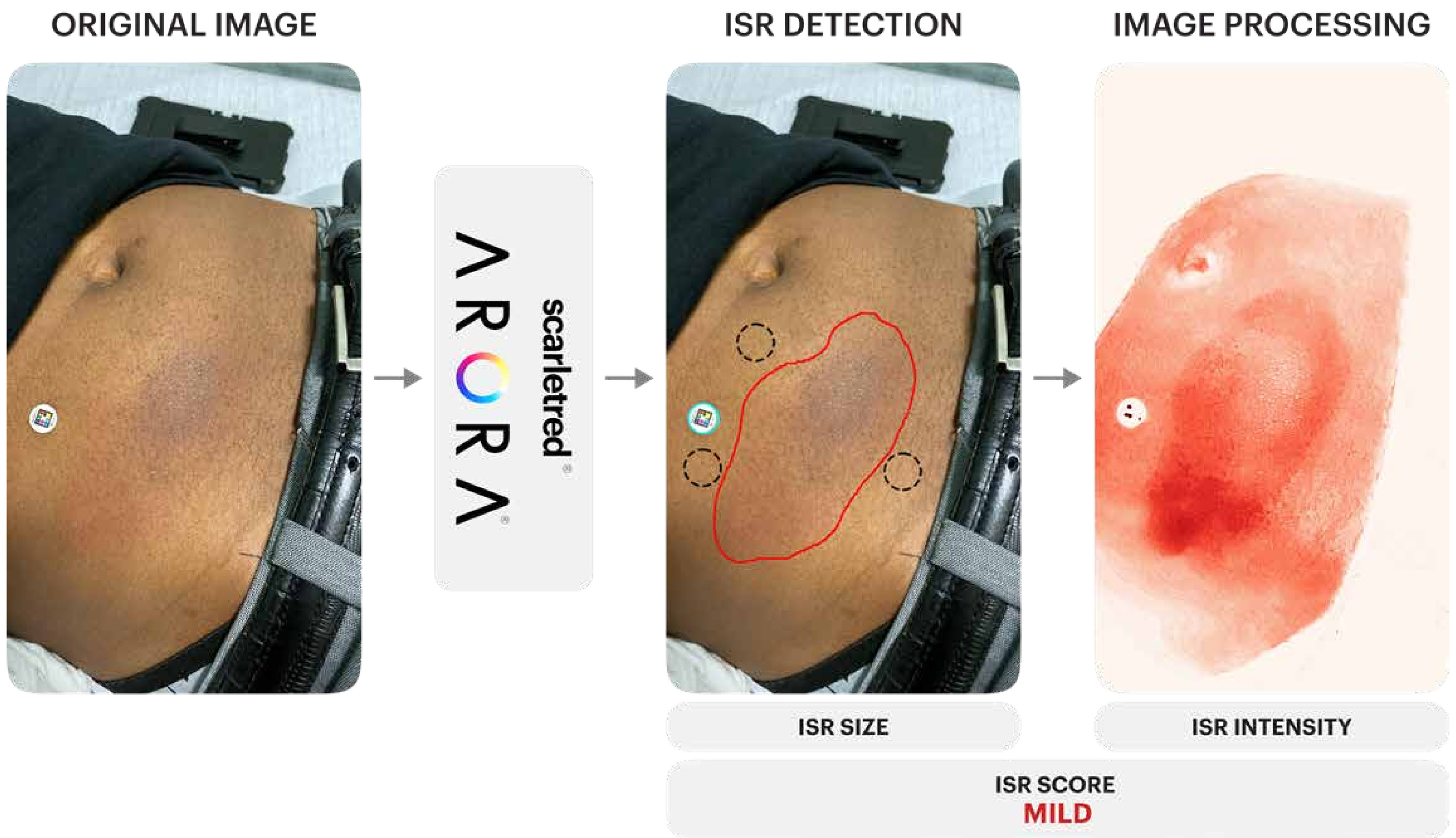

Figure 2: Pipeline for automatic ISR detection and scoring for high phototype subject. Segmentation is performed using a custom CNN, after which ISR size and intensity are jointly evaluated to derive the final score.

Key Takeaways

- AI automatically detects and segments injection site reactions.
- Objective quantification combines erythema intensity and lesion extent.
- Phototype-specific scoring enables inclusive assessment across skin types.
- Longitudinal ISR scoring enables objective treatment monitoring.
- Supports remote, standardised assessment in clinical studies.

References:
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