Performance Evaluation of an Artificial Intelligence–Based Dermoscopic Image Analysis Program for Diagnostic Support of Skin Tumors

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Objective

This study aims to evaluate the performance of a newly developed AI-based dermoscopic diagnostic support system for skin tumors.

The primary objectives are to demonstrate:

1. **non-inferiority in sensitivity** for malignant lesion detection compared with board-certified dermatologists; and
2. **superiority in specificity** for benign lesion identification compared with board-certified dermatologists.

Because the system is intended to support referral decision-making by non-dermatologist physicians, demonstrating non-inferior sensitivity and superior specificity compared with board-certified dermatologists would be clinically meaningful. Such performance could help minimize missed referrals of potentially malignant lesions while reducing unnecessary referrals of benign lesions. If these objectives are achieved, we plan to pursue regulatory approval of the system as software as a medical device (SaMD).

Methods

Study Design

- Retrospective, multicenter, observational study
- Non-interventional and non-invasive

Study Population

Eligibility

Patients with dermoscopic images acquired using the CASIO Dermatology Camera DZ-D100 are included if they meet all the following criteria:

- Skin lesions located on hair-bearing skin or palmoplantar areas and indicated for dermoscopic examination
- Lesion diameter of ≥4.0 mm and <25.0 mm
- Ulceration, crusting, bleeding, and keratinization involving <50% of the lesion area

Target Cases

- Total: 157 (Benign: 58; Malignant: 99)

Target Lesions

- **Malignant:** melanoma, basal cell carcinoma, actinic keratosis, Bowen's disease, squamous cell carcinoma, Paget's disease, and other malignant lesions
- **Benign:** melanocytic nevus, seborrheic keratosis, dermatofibroma, vascular tumors, eccrine poroma, solar lentigo, and other benign lesions
- Palmoplantar lesions are included

Study Procedures

- The study workflow is shown in Figure 1.
- Dermoscopic images with confirmed diagnoses are collected from seven institutions to construct the test dataset.
- Using the test dataset with the reference labels masked, the AI system and independent reviewers will independently determine whether referral is warranted. Their referral decisions will subsequently be compared by an independent statistical analysis organization.

Ethics / Registration

- Ethics approval obtained from the Clinical Research Ethics Review Committee of Chiba University Hospital
- Registered in the Japan Registry of Clinical Trials (jRCT1032250551)

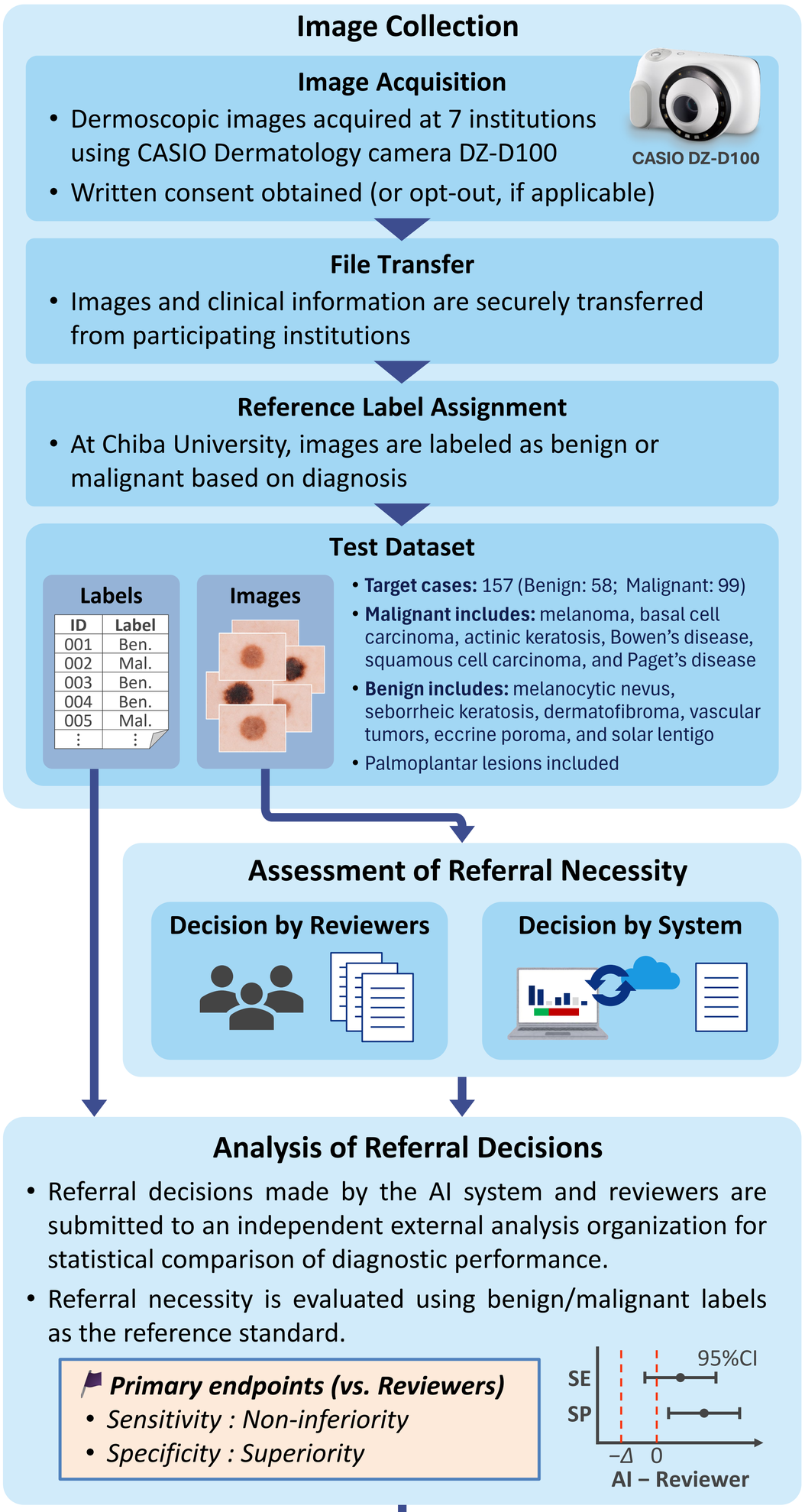

Figure 1: Study Procedures

Current Status

- Study enrollment has been initiated, and data collection is ongoing as of July 2026.
- Diagnostic performance results are not yet available.

Future Perspective

This multicenter study aims to evaluate the diagnostic performance of an AI-based dermoscopic image analysis system for skin lesions. If the predefined performance targets are achieved, the system could support referral decisions by non-dermatologist physicians, reduce missed referrals of malignant lesions and unnecessary referrals of benign lesions, and facilitate regulatory approval as software as a medical device (SaMD).

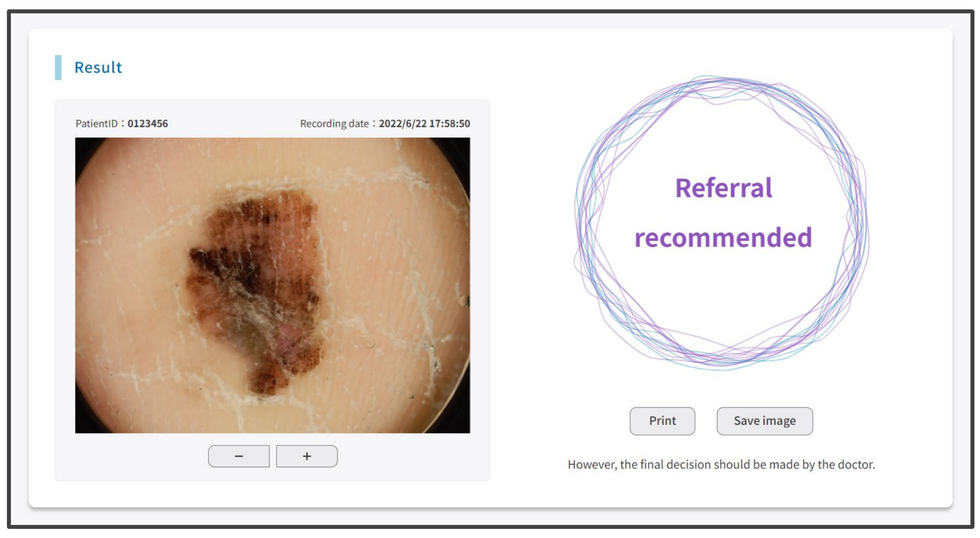

Figure 2: User interface of the AI system under development (*for conceptual purposes only*)

Acknowledgments

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