

# Enhanced silver dressing versus dialkylcarbamoyl chloride-coated dressing in venous leg ulcers: a blinded re-assessment of randomized controlled trial findings

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## Introduction

- Venous leg ulcers (VLUs) are hard-to-heal wounds that pose a significant burden to patients and healthcare systems worldwide
- CISEB\* is a carboxymethylcellulose fibre dressing containing ionic silver (antimicrobial), ethylenediaminetetraacetic acid (metal chelating agent), and benzethonium chloride (surfactant), designed to address the challenges of patients with hard-to-heal wounds
- Another dialkylcarbamoyl chloride-coated dressing (DACC<sup>†</sup>) acts by attracting and immobilising microorganisms (bacteriostatic) via hydrophobic interactions
- A multicentre randomized controlled trial (RCT) conducted across 20 sites demonstrated that CISEB\* achieved a significantly higher rate of complete wound closure at 12 weeks compared to DACC (74.8% vs. 55.6%; p<0.0031)<sup>1</sup>
  - Fewer adverse events were observed with CISEB (5.0%) compared with DACC (17.6%)<sup>1</sup>

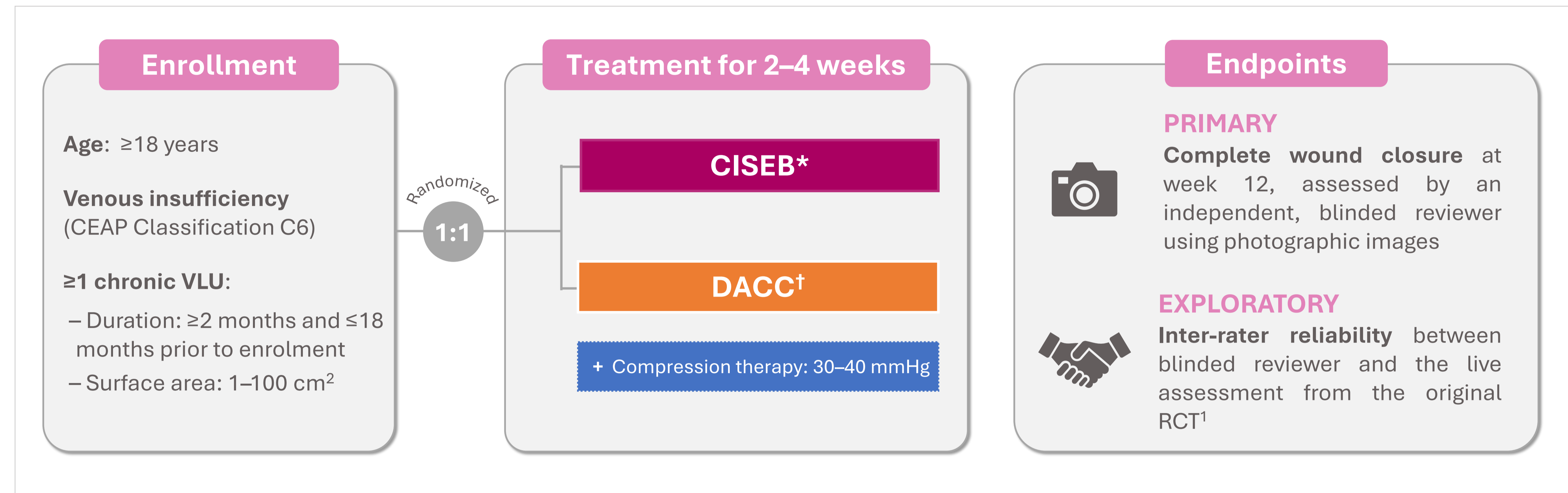
### Objective

To validate the original RCT<sup>1</sup> findings via blinded photographic re-assessment of wound closure at 12 weeks

## Methods

- Eligible patients were randomized 1:1 to receive either CISEB\* or DACC<sup>†</sup> in accordance with their instructions for use (Figure 1)
- Patients were treated with therapeutic compression at 30–40 mmHg and the study dressing for a minimum of 2 and up to 4 weeks (Figure 1)
  - At week 2, continuation of the study dressing or transition to long-term management with the standard of care was at the discretion of the investigator
  - VLUs that did not heal within 4 weeks were managed with the standard of care for up to 12 weeks, or until the wound had healed or the dressing was no longer clinically indicated

Figure 1. Study Design



## Results

Figure 2. Complete Wound Closure at Week 12 (Blinded Photographic Re-Assessment)

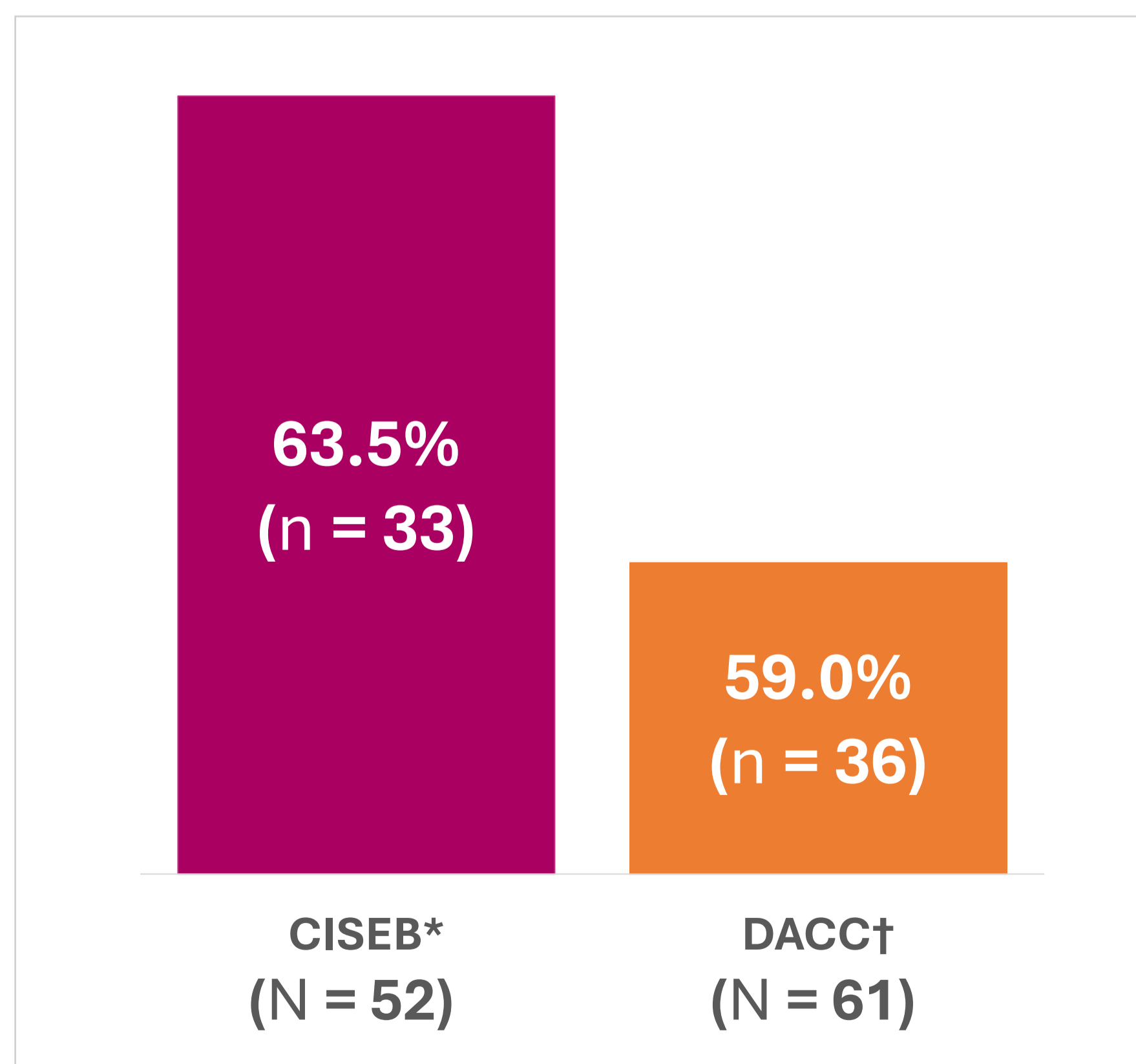


Figure 3. Inter-rater Reliability

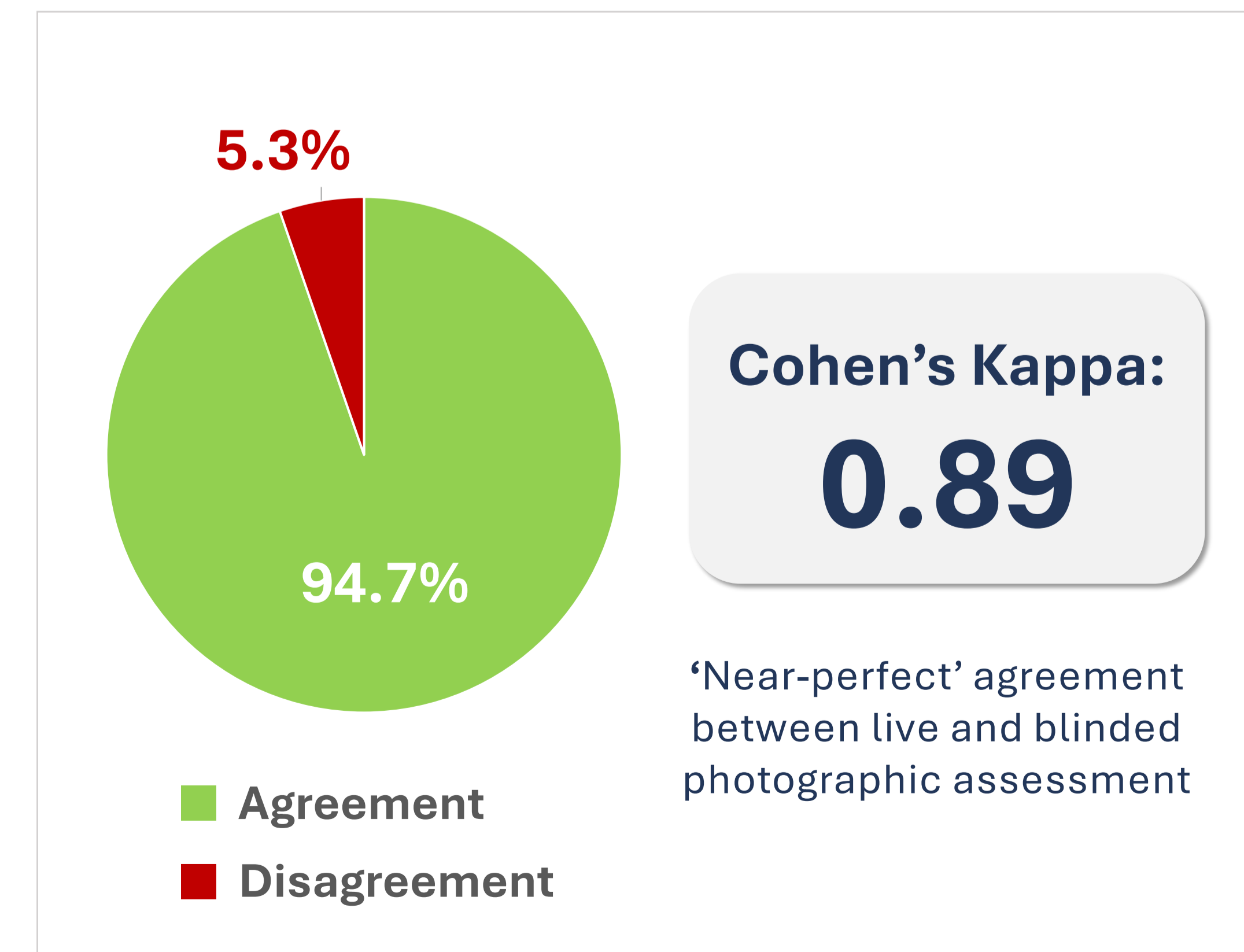


Table 1. Tipping Point Analysis: Probability of Retaining Superiority

Disagreement rate	Probability of superiority
5.3%	98%
11.1%	92.4%

- Using the disagreement rate (5.3%) to enumerate all plausible reclassification scenarios, a tipping point analysis confirmed a 98% probability that CISEB\* would retain its superiority if outcomes were reclassified based on the blinded assessment (Table 1)
- When modelling a more conservative reclassification scenario using the upper bound of the 95% CI for the disagreement rate (11.1%), the probability of superiority remained high (92.4%)

## Discussion

- This blinded re-assessment of wound closure outcomes in the CISEB versus DACC<sup>†</sup> RCT<sup>1</sup> provides critical insights into the reliability of photographic evaluation in wound care
- A high level of agreement between live and photographic (blinded) assessments of wound closure status was observed
- Photographic assessment may offer a more standardized and reproducible approach to wound evaluation, especially in multicenter trials where consistency across sites is critical

### Conclusion

Blinded photographic assessment of complete wound closure from the RCT confirmed that CISEB\* improves healing wound closure rates in VLUs compared with DACC<sup>†</sup>, validating previous findings

### References:

1. Beraldo S et al. J Wound Care 2025;34(3):170-178.  
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