

# TESTING AND TREATING FOR ELEVATED PROTEASE ACTIVITY (EPA) IN WOUND CARE CLINICS IMPROVES CLINICAL OUTCOME AT NO ADDITIONAL COST

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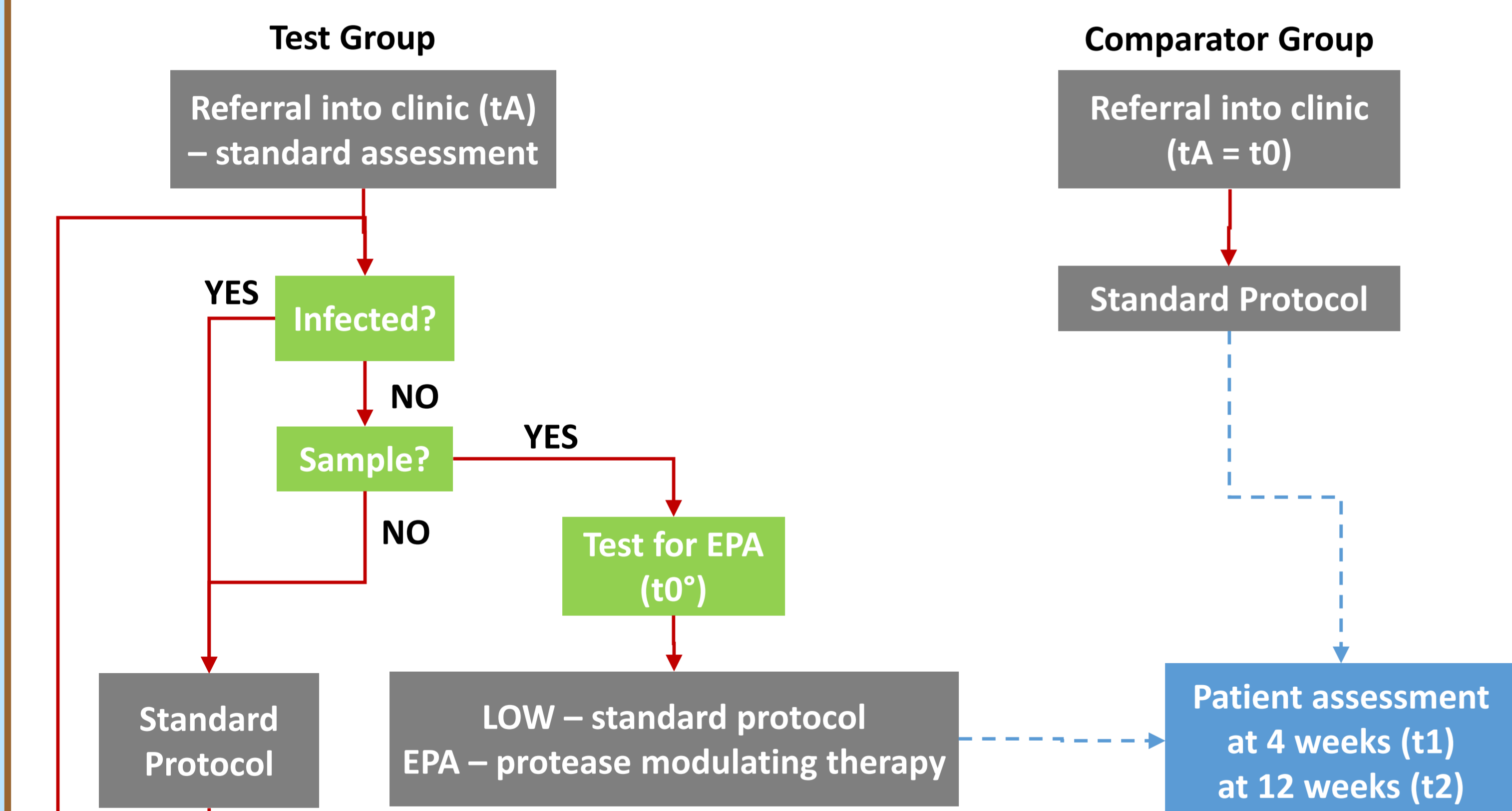
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## Introduction

A chronic wound with EPA (elevated protease activity) has only a 10% chance it will heal, without appropriate protease modulating intervention<sup>1</sup>. Once treated with an effective protease modulating therapy, 77% of chronic wounds with EPA have been shown to respond to treatment<sup>2</sup>. It is now possible to test chronic wounds for EPA, one of the underlying causes of non-healing, at the point of care. A pilot was carried out at a group of wound care clinics in Germany to assess the impact of testing for EPA in a 'real world' clinical setting. The GVW group of wound care clinics follows a consistent care pathway and manages all patient data in an electronic patient record system.

## Methods

Upon initiation of the pilot the group's prescribed care pathway was modified to include the testing of newly referred chronic wounds for EPA and the option to treat chronic wounds with EPA with protease modulating dressings. All clinicians employed by the group were trained on how to carry out the test\*. 107 newly referred chronic wounds were tested for EPA across 9 wound care clinics and followed up over 12 weeks (test group). The treating clinicians were free to choose treatment, taking into consideration the test result.



The data collected was analysed and compared to the equivalent data collected from an equivalent sample of 90 chronic wounds newly referred into the same 9 wound care clinics prior to initiation of the pilot, when the treating clinician did not have access to the test for EPA and treatment followed the group's prior unmodified care pathway (comparator group). The clinicians involved were also surveyed about the test.

## Clinical Results

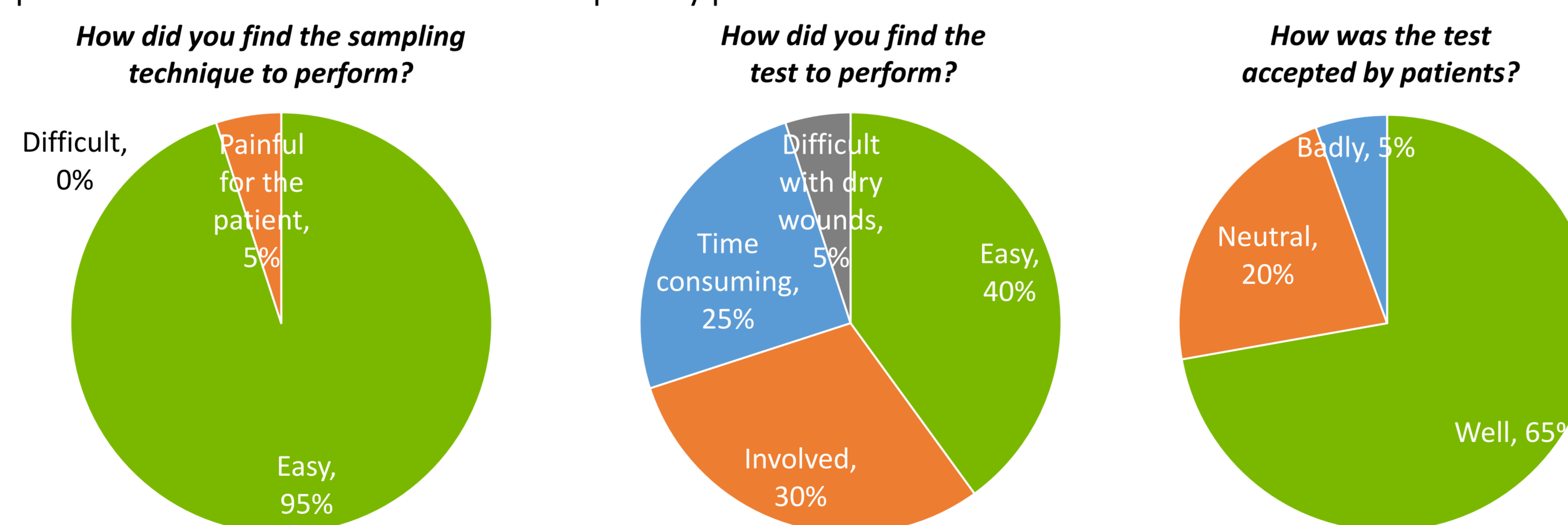
The patient and wound characteristics of both groups were compared.

Characteristics	Test Group (T) During Pilot (t0)	Comparator Group (C) Before Pilot (t0=tA)	Statistical difference? (t-Test) C/T
Mean Age	70,44 (n=107)	70,28 (n=87)	0.9339
Gender	Female (56) 52% Male (51) 48%	Female (41) 47% Male (46) 53%	0.470*
Mean Wound age (months)	36,5 (n=107)	31,3 (n=90)	0.5840
Mean Wound size	12,24 cm <sup>2</sup>	16,83 cm <sup>2</sup>	0.1922
Infection	No (100) 93,5% Yes (7) 6,5%	No (81) 90% Yes (9) 10%	0.456*
Exudate	Dry (4) 4% Moist (80) 75% Wet (17) 16% Very wet (6) 6%	Dry (11) 12% Moist (63) 70% Wet (8) 9% Very wet (8) 9%	0.053*
Wound type	PU (10) 9% DFU (13) 12% VLU (26) 24% ALU & MLU (23) 21% Surgical (27) 25% Traumatic (0) 0% Other (8) 7% Unknown (0) 0%	PU (8) 9% DFU (13) 14% VLU (21) 23% ALU & MLU (20) 22% Surgical (26) 29% Traumatic (0) 0% Other (2) 2% Unknown (0) 0%	C/T: p=0.992*

9% of the chronic wounds in the test group had EPA.

\*Pearsons chi2-Test \*Mann Whitney U-Test

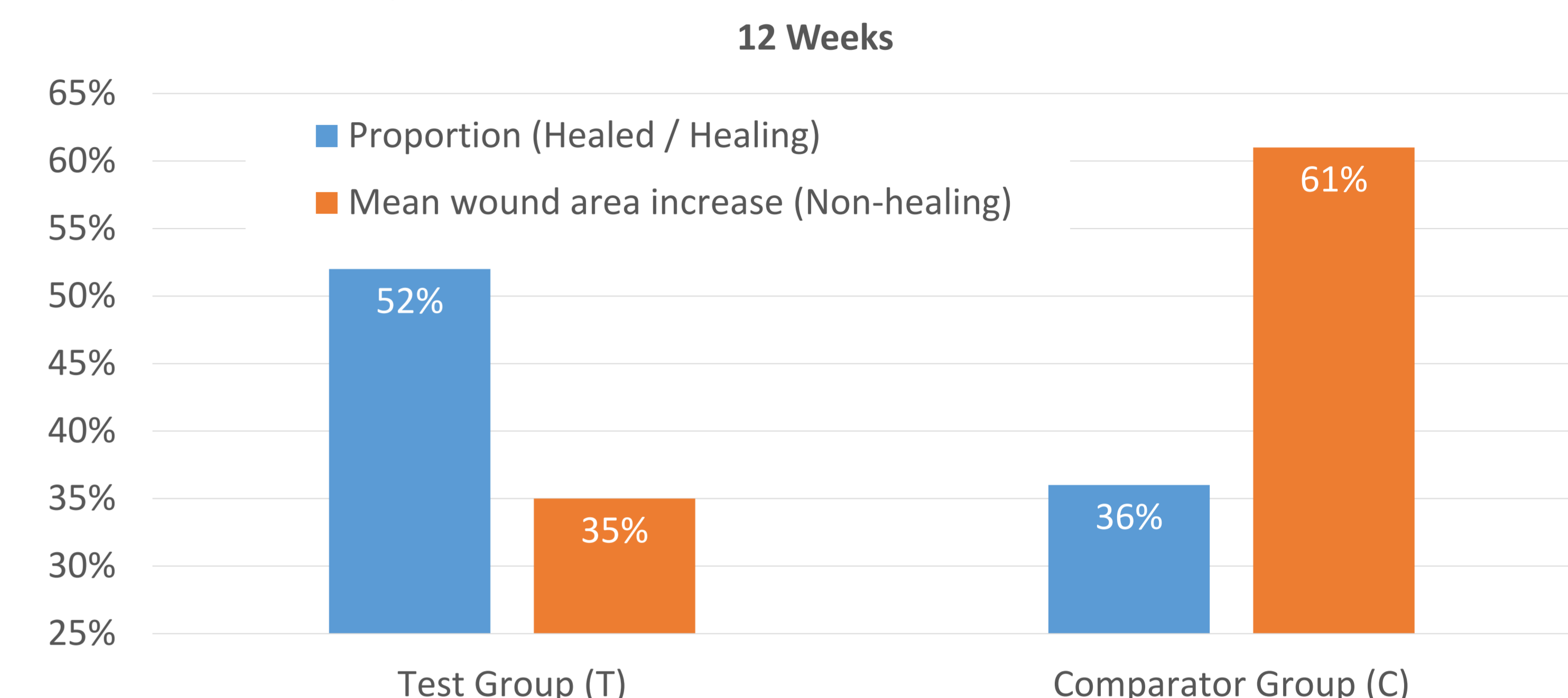
20 clinicians involved in the pilot responded to the survey, of which 95% assessed the sampling technique as easy to perform. 40% of respondents found the test easy to perform, while 30% characterised the test as 'involved'. 65% of respondents assessed the test as well accepted by patients.



At 4 weeks, although there was no statistically significant difference in healing rates between the two groups, the average wound area reduction of the healing wounds in the test group was significantly greater (-73%) than that of the healing wounds in the comparator group (-56%) (p=0.000).

## Clinical Results (cont.)

At 12 weeks the proportion of wounds healed / healing in the test group (52%, 56/107) was significantly higher than that of the comparator group (36%, 32/90) (p=0.034, Pearsons chi2-Test). Further, the average change in wound area of the non-healing wounds at 12 weeks was worse in the comparator group (+61%) versus the test group (+35%).



## Economic Results

The difference in material costs between the test group and the comparator group amounts to €219/wound at a cost of only €35 for the test itself, which amounts to €2,044 material savings per EPA wound identified.

Observation	Test Group During Pilot	Comparator Group Before Pilot
Cost of care over 12 weeks (only materials)	Ø 1,146€	Ø 1,365€
Material costs	Σ 122,658€	Σ 118,778€

This far exceeds the prior estimations of the cost savings potential based on a published economic model for venous leg ulcers in the UK, which estimated a total savings, including nursing time, of £1,906 per wound with EPA identified<sup>3</sup>.

## Discussion / Conclusions

Experts agree that specific diagnostic tests for use in wounds have the potential to revolutionise their treatment and will help to improve standards of wound care and aid the cost-effective use of limited resources<sup>4</sup>. This pilot demonstrated that in a 'real world' clinical setting, targeted treatment with protease modulating therapies, guided by a test for EPA carried out upon initial referral into the clinic, can have a significant impact on clinical outcomes at 12 weeks, at no additional material cost to the clinic. It has been estimated that dressing costs only account for 16% of the total cost of care for leg ulcers in Germany<sup>5</sup>, indicating that the true economic impact of a 'test and treat' care pathway could include significant cost savings over time.

## References

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3. Nherera L. et al. Quantifying the economic value of diagnostics in wound care in the UK. Presented at EWMA 2013
4. World Union of Wound Healing Societies (WUWHS). Principles of best practice: Diagnostics and wounds. A consensus document. London: MEP Ltd, 2008
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\*WOUNDCHEK™ Protease Status (Woundchek Laboratories) - Not for Sale in the US.