TESTING CHRONIC WOUNDS FOR EPA. THE BENEFITS OF TESTING ALL WOUNDS, WHETHER ASSESSED AS HEALING OR NON-HEALING.

Molly Gibson[1], Thomas E Serena[2], Claire Bartle[1], Simon Bayliff[1], Jane Clark[3], Breda Cullen[1] and Louise Digby[1]
[1]WOUNDCHEK™ Laboratories, Gargrave, UK; [2]SerenaGroup, Cambridge, MA, USA; [3]Systagenix, Gatwick, UK

Objectives

- To establish the degree to which a protease test is able to identify chronic wounds that are non-healing due to elevated protease activity (EPA).
- To demonstrate the prevalence of EPA in chronic wounds of different aetiologies and durations.
- To understand how the test is being used in clinical practice, reasons for not testing all chronic wounds for EPA, and whether excluding wounds assessed as healing could be limiting the number of chronic wounds with EPA being identified.

Introduction

The WOUNDCHEK™ Protease Status is a point of care test to detect EPA in chronic wound fluid swab samples. A previous study has shown that there are no visual cues for EPA[1], and that EPA is present in wounds of different aetiologies and wound durations[2]. Therefore all chronic wounds could have EPA. In this study we explore the potential effects of limiting testing for EPA to wounds clinically assessed as non-healing.

Methods

A clinical study across 5 wound care centres in the USA (Study A) tested chronic wounds for the presence of EPA using WOUNDCHEK™ Protease Status.

All eligible patients who gave informed consent were recruited into the study, regardless of the healing status of the wound.

Wounds were classified as healing / non-healing based on the percentage reduction in wound area over a 2 to 4 week time frame prior to the protease test being carried out.

Experienced wound care clinicians were asked to classify each wound as healing / non-healing based on their clinical judgement *(N.B. having access to prior wound measurements in the patient record).*

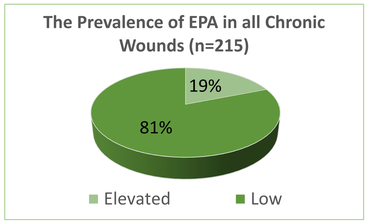
We assessed the ability of clinicians to classify a wound as healing / non healing as compared to healing status by percentage reduction in wound area.

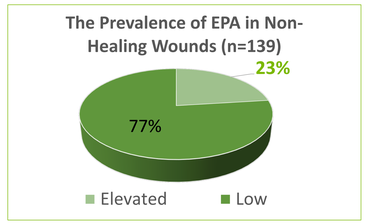
The use of percentage reduction in wound area was chosen to assess healing status as it was identified as the most commonly used outcome in controlled and comparative wound healing studies in a review by The European Wound Management Association[3]. Although the use of percentage reduction as a surrogate end point is supported by numerous research studies[4-9], it is not always used in clinical practice.

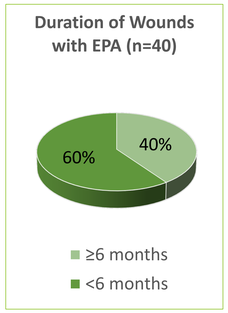
A separate study was conducted in 10 wound clinics in multiple UK (Study B) locations using WOUNDCHEK™ Protease Status in routine clinical practice. For each patient treated, clinicians recorded the use of WOUNDCHEK™ Protease Status, and where patients were not tested for EPA, they recorded their reasons for this.

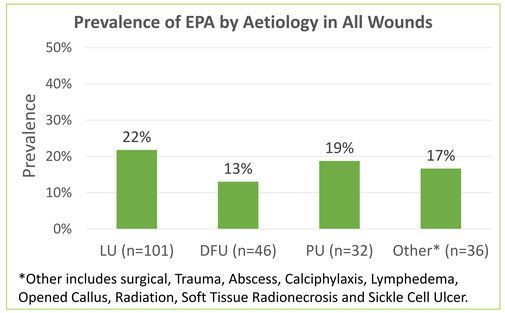
Results – Study A

WOUNDCHEK™ Protease Status results and healing data were collected for a total of 215 patients. The study confirmed that chronic wounds of different aetiologies and different durations have EPA.









*Other includes surgical, Trauma, Abscess, Calciphylaxis, Lymphedema, Opened Callus, Radiation, Soft Tissue Radionecrosis and Sickle Cell Ulcer.

WOUNDCHEK™ Protease Status was able to identify wounds that were non-healing due to elevated protease activity with a high positive predictive value (PPV) with regard to non-healing status.

		WOUNDCHEK™ Protease Status	
		Elevated (E↑)	Low (L ↓)
Clinical Healing Status (based on wound area)	Non-Healing	32	107
	Healing	8	68
Total		40	175

Positive Predictive Value: 80% (32/40, 95% CI = 65.1 - 89.4%)

There was a poor correlation between the clinical assessment of healing status and the healing status as calculated by percentage reduction in wound area.

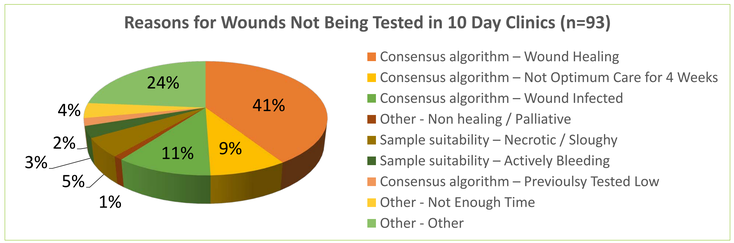
		Wound Area		Total
		H	NH	
Clinician Opinion	H	55	83	138
	NH	21	56	77
Total		76	139	215

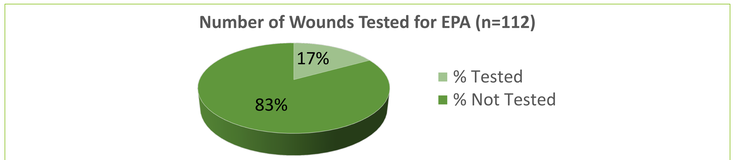
- Overall % disagreement between clinician opinion and wound area:
  - ((83+21)/215)*100 = **48%.**
- % of wounds assessed as healing by clinician that were non-healing according to wound area:
  - (83/139)*100 = **60%**

Results – Study B

Results from the study indicate that most clinicians are limiting testing for EPA to chronic wounds clinically assessed as non-healing. The most common reason for a wound not being tested was that the clinician assessed them as healing wounds (41%, 38/93).

Of all patient wounds treated, **34%** (38/112) were assessed as healing and therefore not tested.





Discussion

These studies showed that in clinical practice, clinicians are limiting the use of the WOUNDCHEK™ Protease Status test based on a clinical assessment of whether they are in a healing or non healing trajectory.
However, we have also shown that clinician's opinion does not always correlate with healing status determined based on percentage reduction in wound area, and that many wounds which have been assessed as "healing" by a clinician were in fact non-healing, and a proportion of these actually had EPA. This research suggests that limiting testing for EPA to wounds clinically assessed as non-healing may lead to patients with non-healing wounds due to EPA not being tested and therefore not being identified for targeted protease modulating treatment.

Conclusions

According to the data gathered in these studies:
60% of the **34%** of wounds treated but not tested because the wound was assessed as healing, could in fact be non-healing → **20 in every 100 wounds.**
Of these, **23%** could have EPA → **5 in every 100 wounds.**
This indicates that for every 100 chronic wounds treated, 5 wounds with EPA could remain un-detected based on the observed clinical practice.
WOUNDCHEK™ Protease Status has a high **PPV (80%)** with regard to non-healing status, so could help identify chronic wounds that are non healing due to EPA, even where the wound is clinically assessed as healing.

References

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WOUNDCHEK™ Protease Status is not currently cleared by FDA for sale within the US market.

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