ASSESSING CHRONIC NON HEALING WOUNDS FOR ELEVATED PROTEASE ACTIVITY

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Introduction

A chronic wound is a wound that fails to progress through a normal, orderly, timely sequence of repair and where co morbidities interfere with the normal healing process[1]. Chronic wounds are 'stuck' in the inflammatory state and elevated protease activity (EPA) could play a role in their inability to follow a normal healing process. The presence of EPA creates an environment that is detrimental to wound healing. A recent clinical trial showed chronic wounds with EPA have a 90% probability of not healing without appropriate intervention and 28% of non-healing wounds have EPA[2].

The primary objective of this study was to assess chronic non-healing wounds for the presence of EPA. An additional objective was to gain clinical feedback on the practicalities of implementing WOUNDCHEK™ Protease Status as part of routine wound assessment process for chronic non-healing wounds into clinical practice.

WOUNDCHEK™ Protease Status

WOUNDCHEK™ Protease Status is an *in vitro,* visually read, immunochromatographic test for the qualitative assessment of human neutrophil-derived inflammatory protease activity directly from wound fluid swab samples taken from chronic wounds.

This simple, rapid point of care (POC) test takes 15 minutes per sample to complete.The test helps clinicians establish within minutes which wounds may benefit from a protease modulating therapy, ensuring appropriate and targeted use of these therapies.

Methodology

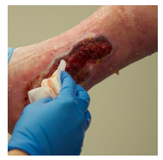
This study was carried out across 2 clinical areas within Wiltshire, a leg ulcer clinic and a vascular clinic. The Serena's Technique of collecting wound fluid was utilised, all wounds tested were deemed to be chronic , non-healing wounds and included venous leg ulcers, pressure ulcers, diabetic foot ulcers and chronic non-healing surgical wounds. All corrective measures had been implemented to facilitate healing prior to testing, wounds had failed to progress as expected.

A total of 29 swabs were taken, however 3 were invalid (these invalid results were deemed to be part of the learning curve associated with any new procedure) therefore the prevalence is based on 26 swabs and the clinical feedback is based on 29 clinical evaluations.

Method: Specimen collection

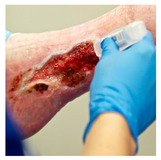
Using a sterile swab provided in the kit, collect the wound fluid sample by swabbing the surface of the wound using the following procedure (Serena's technique):

1. Prior to swabbing, cleanse the wound with sterile saline to remove all loose debris, remains of therapeutic agents (e.g. enzymatic debriders, gels, dressings, etc.) and necrotic tissue. Do not perform sharp wound debridement prior to sample collection.



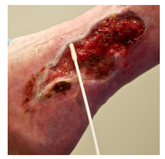
2. Ensure that complete hemostasis has been achieved before obtaining the specimen.

3. Moisten wound area to be swabbed with a addtional drops of saline (until the wound glistens). The amount of saline needed will depend on how dry the wound is. Care should be taken not to flood the wound with excessive saline.

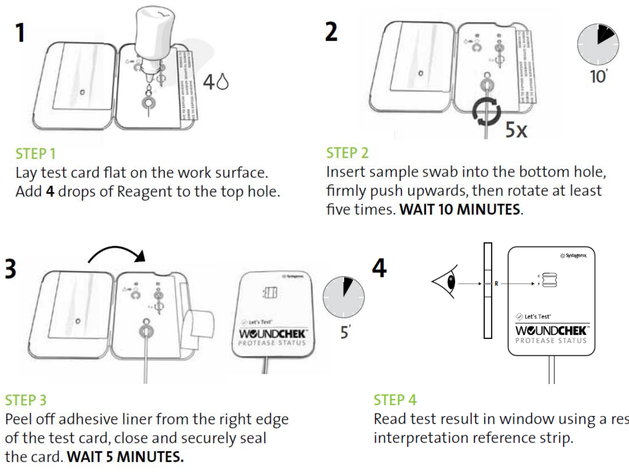


4. Avoid swabbing areas that contain blood, necrotic material, thick slough or fibrinous tissue. Test results may be affected by the presence of blood in the sample.

5. Press the head of the swab flat against the base of the wound and gently roll it back and forth several times while applying pressure. Continue rolling the swab head until fully coated and discoloured by wound fluid.



Method: How to test



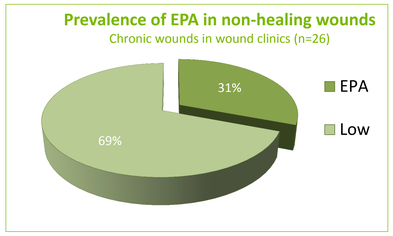
STEP 1
Lay test card flat on the work surface. Add **4** drops of Reagent to the top hole.

STEP 2
Insert sample swab into the bottom hole, firmly push upwards, then rotate at least five times. **WAIT 10 MINUTES**.

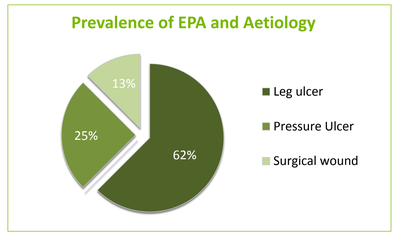
STEP 3
Peel off adhesive liner from the right edge of the test card, close and securely seal the card. **WAIT 5 MINUTES.**

STEP 4
Read test result in window using a result interpretation reference strip.

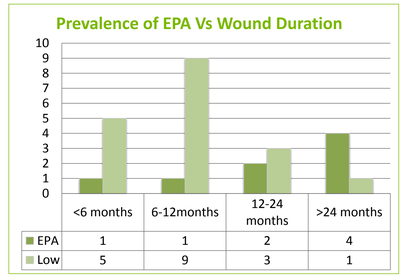
Key Results

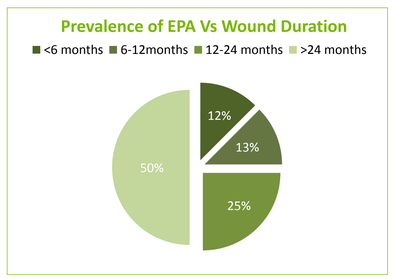


The prevalence identied during this study seems to verify previouslyreported prevalence of 28% in chronic non healing wounds.



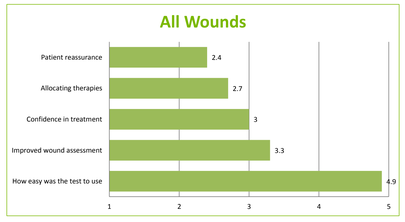
100% of all pressure ulcers tested (n=2) had EPA whilst 100% of all diabetic foot ulcer tested (n=3) were low. These results are likely to have been skewed due to the low numbers of each wound type tested.

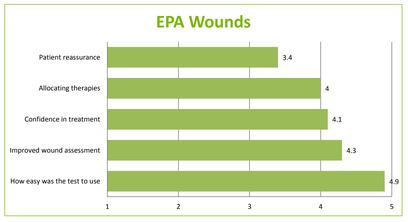




Wounds of any duration can have EPA. Whilst the most common length of duration of the wounds tested during this study was 6-12months, this was not reflected in the prevalence of EPA, with 50% of all EPA wounds being present for longer than 24 months. A recent NHS document; AQP venous leg ulcer implementation pack[3] suggested that 50% of venous leg ulcer had been present for longer than 12 months, however this study highlighted that 75% of all wounds identified with EPA had been present for longer than 12 months.

Clinical Feedback





Clinical staff scored 5 different elements on a simple scale from 1-5, with 5 being the highest ranking. There was agreement across all wound types that WOUNDCHEK™ Protease Status was easy to use, however when it came to improving wound assessment, confidence in treatment, allocating therapies and patient reassurance greater rankings were given for those patient identified with EPA.

Discussion and Conclusion

This pilot study has confirmed a prevalence of 31% of non-healing wound have EPA. Furthermore this study gives the tissue viability service in Wiltshire a clearer understanding of the prevalence of EPA across different wound aetiologies and wound duration. There were some inconsistencies in the clinical feedback; however this was very dependent on the result of WOUNDCHEK™ Protease Status test. The value of the test was perceived as much higher in the presence of EPA. It would be interesting to repeat this process following implementation of the test as part of the routine wound assessments for chronic non-healing wounds, in conjunction with the development of clear pathways for low results and next steps.

In conclusion, WOUNDCHEK™ Protease Status was a simple test to implement in normal clinical practice and if utilised appropriately can offer real clinical value.

References

1. Lazarus GS, Cooper DM, Knighton DR et al. Definitions and guidelines of wounds and evaluation of healing. *Arch Dermato* 1994;130(4):489-493
2. Serena T. et al. Protease activity levels associated with healing status of chronic wounds. Poster, Wounds UK 2011.
3. Extension of Choice of any Qualified Provider Venous Leg Ulcer & Wound Healing Implementation Pack, NHS 2012.