# Clinical Evaluation of 54 Patients in the UK of a Bioengineered Reactive Oxygen® Wound Gel in the Treatment and Management of Wound Infection.

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## Introduction

Reactive Oxygen® is a potent antimicrobial generated throughout the wound healing process in the form of hydrogen peroxide as part of the naturally occurring immunological response to prevent and fight infection. A honey based wound gel bioengineered to carry and deliver fast acting Reactive Oxygen® to the wound bed has been evaluated by Tissue Viability Specialists and Wound Care Practitioners to establish its efficacy and acceptability in clinical practice.

## Methods

Patients were invited to participate in a structured clinical evaluation following approval and informed consent. A total of 54 completed data sets were returned for analysis.

## Results

- 54 completed data sets were returned for analysis
- Completed by TVN (n25), Staff/DN (n20), PN (n5), not stated (n4)
- Patient ages ranged between 46-99 years with Female ratio (n35) to Male (n18), not completed (n1)
- Wound types LU (n26), PU (n10), Surgical (n5) and other (n2)
- Wound duration range six weeks to three years

### WOUND MICROBIOLOGY

- Conducted in only (n12) of the 54 participants
- (n11) microbiology results were positive demonstrating heavy growth of microorganisms and active infection
- (n42) patients received no microbiological assessment prior to antimicrobial use
- (n15) were receiving systemic antibiotics at time of the evaluation
- Subtle signs of infection or suspected biofilm data fields were completed

### PAIN

- Initiation Visual Analogue Scale (VAS) pain scores were recorded in only (n23) of the 54 participants
- Dressing change weekly pain scores were not consistently reported
- Patient comfort score was consistently reported
- Evaluations ended associated to pain revealed discrepancies between recorded pain score and recorded patient comfort

### OUTCOMES

- Where microbiology was confirmed microbes were effectively treated. Where microbiology was not confirmed positive wound response and reduction of subtle signs of infection were reported
- Actual wound measurement was not consistently documented throughout the evaluations – however correlation between wound images, recorded data regarding improved/ deteriorated status and final evaluation statements demonstrated positive healing outcomes

### END OF EVALUATION FEEDBACK

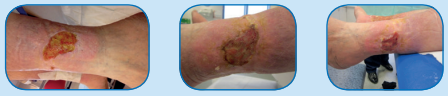
- "Excellent for treating *Pseudomonal* infections"
- Effectively treated a multi-drug resistant (MDR) *E-coli* as adjunct therapy
- Disparity reported in ease of use
- Disparity reported in pain on application/ wear time
- Odour eliminated consistently reported
- Improved wound healing and excellent healing reported
- Works quickly

## CASE 1 – *Pseudomonas aeruginosa*

Male 75 years of age suffering bilateral non healing Venous Leg Ulcers. Duration of wounds reported to be in excess of 4 years despite 'Gold Standard' compression therapy and treatment of recurrent local wound infections with cadexomer iodine and silver hyrofibre topical antimicrobials.

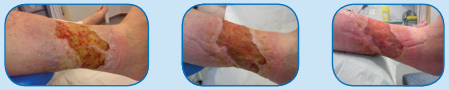
Wound microbiology obtained pre evaluation with positive result confirming *Pseudomonas* infection. Reactive Oxygen® evaluation commenced 14th September 2018 and at week 2 assessment both wounds are recorded as being improved with changes to wound bed tissue and fibrin lift. Throughout the duration of the 6 week evaluation the wound continued to improve with no deterioration recorded and the *Pseudomonas* infection resolved.

**Left lateral gaiter**



17/09/18 | 19/10/18 | 17/12/18

**Right lateral gaiter**



17/09/18 | 19/10/18 | 17/12/18

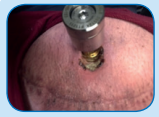
## CASE 2 – MDR *Escherichia coli (E. coli) and Staphylococcus aureus*

Male mid 30's, post traumatic Military injury resulting in above knee amputation due to recurrent osteomyelitis and deep tissue infections. This patient has undergone several surgical procedures managing and avoiding further wound infection following the introduction of topical honey and Reactive Oxygen® to his local wound care pathway.

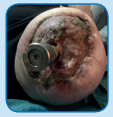
April 2018 Osseointegration, the implantation of a titanium prosthetic pin into his femur was successfully performed in Australia. Two weeks post operatively he returned to the UK displaying clinical signs of infection and *E.coli* (MDR) was confirmed at the pin base. Systemic antibiotics were already in place and topical silver spray had been used so Reactive Oxygen® was commenced locally. Wound reviews at 24 and 48 hours revealed significant improvements to clinical signs of infection and repeat microbiology 14 days later was negative to *E.coli*. Whilst in this instance topical therapy was an adjunct therapy previously utilised topical antimicrobials had not resulted in improvement.

In March 2019 a *Staphylococcus aureus* infection had been isolated following a routine refashioning of the implant stoma site procedure. Topical silver was in use but clinical signs of infection were increasing. The wound was cleaned thoroughly with a debris softening cloth and Reactive Oxygen® applied to the pin stoma and surrounding tissue.

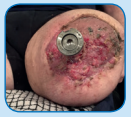
At 24 and 48 hours significant improvement was seen. Repeat microbiology 1 week following commencement of treatment confirmed eradication of the microbes. The introduction of Reactive Oxygen® again to this complex case regime has resulted in progression to complete wound healing and no further episodes of infection have been experienced.



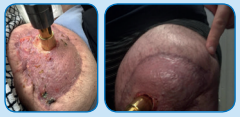
**1. 24/04/18** Episode one *E.coli* isolated at pin base



**2. 16/02/19** New post-op episode. Following refashioning procedure 12 months after Osseointegration and topical silver



**3. 21/02/19** Following 5 days Reactive Oxygen®



**4. April 2019** following scar management and lymphatic drainage

## Discussion

The purpose of this evaluation was to obtain 'real world' feedback relating to the efficacy and acceptability of Reactive Oxygen® Wound Gel. Disparity between evaluations was found in all of the data fields completed, microbiological confirmations and pathways of standard care. However, where microbiology was obtained effectiveness was found to be validated. Wound size response and reduction in the clinical signs of infection were reported and seen in the returned imagery but due to the lack of actual wound measurement within the data the true efficacy on wound healing cannot be established from this evaluation.

Many practitioners commented on the speed of response to infection, de-sloughing, and tissue regeneration ability. Many comments related to an initial de-sloughing and debriding effect improving the wound bed visually usually at the first or second dressing change. They acknowledged a slight increase in wound size initially, which is expected due to removal of devitalised tissue, but the improvement seen from weeks 2 to 6 resulted in wound size decrease. Ease of use was rated highly by the majority of evaluators with (n5) stating the honey carrier was too runny.

## Summary

This evaluation has produced some encouraging results and patient outcomes and will be used as direction for further development of new modes of delivery for bioengineered Reactive Oxygen®. A more consistent approach to clinical assessment and data collection with an agreed standard of care pathway is required through the undertaking of a formal clinical trial to establish and validate efficacy.