

Evaluation of a novel non-adherent antimicrobial silver alginate/CMC wound dressing in the porcine partial-thickness excisional wound model



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Introduction

The development of safe and effective wound management therapies is centrally dependent on appropriate and relevant pre-clinical evaluation. Such evaluation, prior to clinical use, offers the opportunity to both maximize therapy efficacy and minimize unwanted adverse effects.

In this study, a porcine partial-thickness exudating wound model was used to examine the performance of two absorbent silver containing dressings intended for the management of exudate in wounds that are infected or at risk of infection. The dressings evaluated were (i) an established Hydrofiber silver dressing and (ii) a novel non-adherent antimicrobial silver alginate/CMC dressing. Dressings were assessed and compared, at the macroscopic level in terms of wound exudate retention, dressing structure on exposure to exudate, adherence to wound tissues, and wound surface debris. Wound tissue, from differentially treated wounds, was also compared histologically in terms of the amount of trapped dressing debris, the tissue reaction to that debris and the level of wound tissue disruption consequent to debris entrapment.

Model & Method

Porcine exudating partial-thickness wound model

- Approval from institute ethics committee & UK Home Office.
- Female large white domestic pigs (~35 kg).
- Appropriate general anaesthesia & systemic analgesia.
- Partial-thickness (0.8mm - deep) excisional wounds (2 x 2cm), created with a dermatome (Zimmer Inc, USA).
- Dressing application after initial wounding (day 0) & days 2 & 4.
- 8 replicate wounds per treatment.
- Wounds secondarily dressed with (i) an adhesive film dressing, and (ii) a protective gauze pad.
- Dressings and wound sites assessed at days 2, 4 and 7.
- Wound sites harvested at day 7 – for histological assessment.
- Test materials prepared as individual sterile 2.5 x 2.5cm dressings.
- Hydrofiber dressing = Aquacel Ag (Convatec UK);
- Novel antimicrobial dressing = a product in development by Systagenix Wound Management Ltd.

Live Phase Assessments – Days 2, 4 & 7

- Quantitative assessment of exudate management – measured in terms of volume of free exudate aspirated from beneath film dressing.
- Semi-quantitative assessment of force required to remove dressing from wound surface using scoring system below (Table 1).
- Semi-quantitative assessment of the level of dressing debris on the wound surface. Average scores were taken from 2 independent observers. Debris was scored (following gentle cleaning) from magnified digital images of wounds.

Table 1

Score	Wound Adherence	Level of Wound Surface Debris
1	None	None visible
2	Very light	Low retention of dressing material
3	Light	Moderate retention of dressing material
4	Moderate	Extensive retention of dressing material
5	Strong	Very extensive retention of dressing material
6	Very strong	

Histological Assessments – Day 7

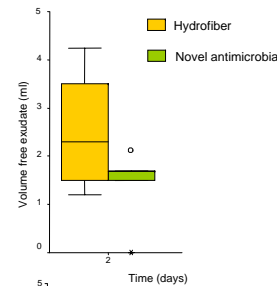
- Wound tissue was fixed, sectioned (6µm) and stained (H&E); and representative sections viewed under x100 mag. All sections were read blind by a single observer.
- The number of discrete pieces of trapped product debris and number of giant cell foreign body reactions (GC-FBRs) in each of 6 (3.14mm²) fields of view (fov) was counted and an average count per fov established.
- The impact of dressing use on wound tissue disruption was semi-quantitatively assessed using the scoring system below (Table 2):

Table 2	Wound Tissue Appearance (tissue disruption)
1	Normal (no disruption)
2	Low level disruption
3	Moderate disruption
4	Significant disruption

Results

Live Phase – Days 2, 4 & 7

All results are displayed as box-whisker plots showing median (central bar), interquartile range (box), highest and lowest values (vertical bars), extremes (*) and outliers (○). *Mann Whitney U-test

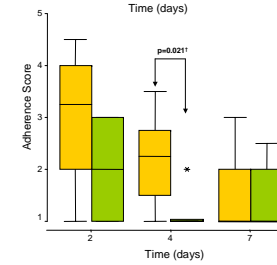


Exudate Management

- Unabsorbed exudate at day 2 only.
- A non-significant trend towards higher levels observed with Hydrofiber dressing.

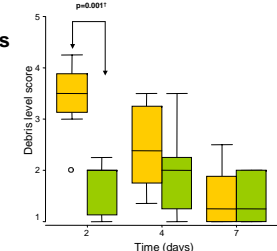
Dressing Adherence

- Higher median adherence at days 2 & 4 with Hydrofiber dressing.
- Significant at day 4 (p=0.021).
- Day 7 – low level of adherence with novel antimicrobial dressing due to dried exudate over surface of healed wound.



Wound Surface Debris

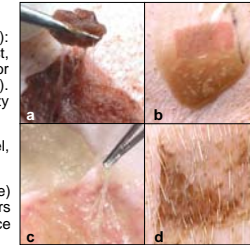
- Higher median levels of dressing debris on wound surface with Hydrofiber dressing at days 2 & 4.
- Significant at day 2 (p=0.001).



Other Characteristics

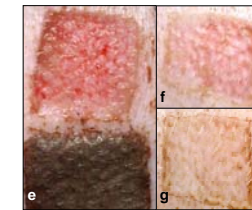
Hydrofiber Dressing:

- Day 2 (highly exudative): dressing structure was lost, forming a gel (a) or disintegrating completely (b). Difficult to remove in entirety leaving high levels of debris.
- Day 4: formed sticky gel, difficult to remove (c).
- Day 7 (minimally exudative) Hydrofiber dressing fibers dried into wound surface requiring careful removal (d).



Novel Antimicrobial Dressing:

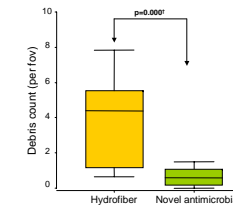
- Day 2 (highly exudative): Dressing structure retained, became hydrated, lifted off easily in entirety (e).
- Days 4 & 7: Structure retained throughout, in less hydrated conditions no adherence or fibre incorporation into wounds - enabling rapid & clean removal (f [day 4] & g [day 7]).



Histology - Day 7

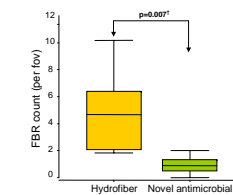
Level of Debris

- Significantly greater counts of dressing debris per fov in wounds in receipt of the Hydrofiber dressing relative to similar wounds in receipt of the novel antimicrobial dressing (p=0.000).



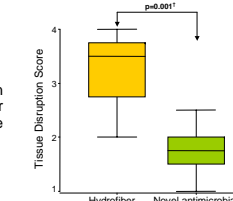
Tissue Reactions

- Significantly greater numbers of GC-FBRs (to wound embedded debris) in wounds in receipt of the Hydrofiber dressing (p=0.007).



Tissue Disruption

- Significantly higher median tissue disruption score for wounds in receipt of the Hydrofiber dressing (p=0.001).

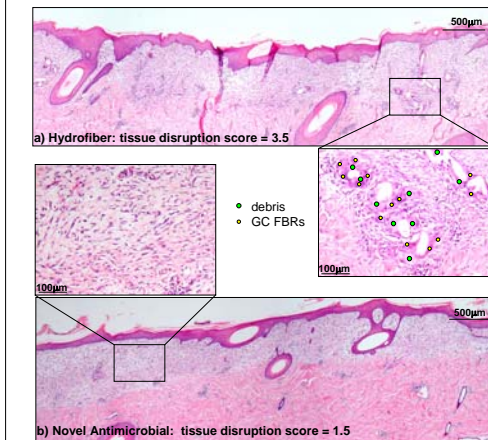


Histology Examples:

Showing representative wound tissue histology:

- a. Substantial debris entrapment, tissue reactions and wound tissue disruption following treatment with the Hydrofiber dressing.

- a. Minimal tissue debris entrapment, tissue reactions and disruption following treatment with the Novel antimicrobial dressing.



Conclusions

This study compared the performance of two absorbent silver dressings in a porcine *in vivo* model. The novel antimicrobial dressing (a silver alginate dressing combined with a non-adherent film) was found to perform favorably in this study, relative to the Hydrofiber dressing, at both the macroscopic and microscopic level.

The novel antimicrobial dressing, which was largely equivalent to the Hydrofiber dressing in terms of exudate management, exhibited lower wound surface adherence and reduced dressing debris deposition. On histological assessment, tissues from novel antimicrobial dressing treated wounds displayed reduced dressing debris entrapment, which was paralleled by reduced host reactions and reduced wound tissue disruption.

Novel Antimicrobial Dressing vs Hydrofiber Dressing		
Study Observations & Potential Clinical Benefits		
Stage	Observations	Potential Clinical Benefits
Live	Lower wound surface adherence	Reduced wound surface damage
	Lower wound surface debris	Reduced patient discomfort Reduced dressing change time
Histology	Reduced debris in wound tissues	Reduced inflammation
	Reduced foreign body reactions	Unimpeded progression of repair
	Reduced tissue disruption	

Declaration of Interest:

Cica Biomedical Ltd is an independent contract research company that specialises in wound healing research. This work was funded by Systagenix Wound Management UK.

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