A NEW ANTI-BIOFILM HYDROFIBER® DRESSING – A CLINICAL STUDY[1*]

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Introduction

Biofilm in wounds is now considered a causative factor in wound chronicity, deterioration and infection.[2] Studies have demonstrated that at least 60% of all chronic wounds contain biofilm[3] and that biofilm can delay healing.[4] Failure to clinically address this problem has serious implications both for patient health and well-being, as well as increasing overall financial costs and health care resources.[5] Multi-modal strategies to address wound biofilm have been proposed.[6,7] However, for the dressing component of the protocol of care, there are a lack of evidence-supported options.

Aim

This study assesses the safety and performance of a new CE-Marked anti-biofilm Hydrofiber® dressing, **AQUACEL® Ag+**, in wounds exhibiting clinical signs of infection (Fig 1).

Figure 1. Five classic signs of wound infection

1. **Pain between two dressing changes**
2. **Peri-ulcer skin erythema/inflammation**
3. **Oedema**
4. **Malodour (foul odour)**
5. **Heavy exudate**

Figure 2. Baseline demographics

Demographics and baseline data (%)	Clinically Infected (n=10)	Colonised (n=32)
Gender		
Male	60	31
Female	40	69
Ulcer status		
Recurrent ulcer	60	53
New ulcer	40	47
Superficial	None	34
Shallow	80	63
Deep	20	3
Ulcer condition		
Improving	20	31
No progress	20	41
Deteriorating	60	28

Method

A prospective, multi-centre, non-comparative study, financially supported by ConvaTec, to evaluate the safety and performance of AQUACEL® Ag+ dressing on chronic venous leg ulcers (VLU). Forty two patients with a VLU exhibiting at least 3 of the 5 classic clinical signs of infection (Fig 2) were treated with AQUACEL® Ag+ dressing for 4 weeks followed by 4 weeks with a non-antimicrobial Hydrofiber® dressing (AQUACEL®). Adverse events, patient pain at dressing change and dressing comfort were recorded. Wound assessment included:

- Clinical signs of infection
- Wound improvement/size reduction
- Wound healing

Results

The safety profile of AQUACEL® Ag+ dressing was similar to that of a standard silver Hydrofiber® dressing previously studied (AQUACEL® Ag). Mean pain ratings decreased from baseline and over duration of use. Comfort levels on application were scored as excellent and as acceptable on removal. For wounds with 3-4 clinical signs of infection, progress was similar for all antimicrobial dressing regimes, with all study groups showing improvement (Fig 3).

For AQUACEL® Ag+ dressing, a sub-group of clinically infected wounds (n=10; 5 clinical signs) was identified. All wounds showed considerable improvement and resolution of infection, but 90% of the infection sub-group demonstrated a ≥40% reduction in ulcer area (Fig 5) compared to 69% in the non-infected sub-group.

Figure 3. Wound progression with AQUACEL® Ag+ dressing

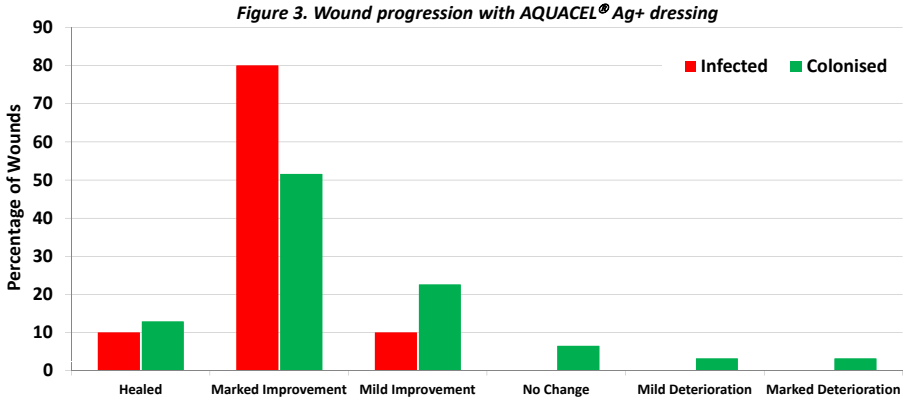
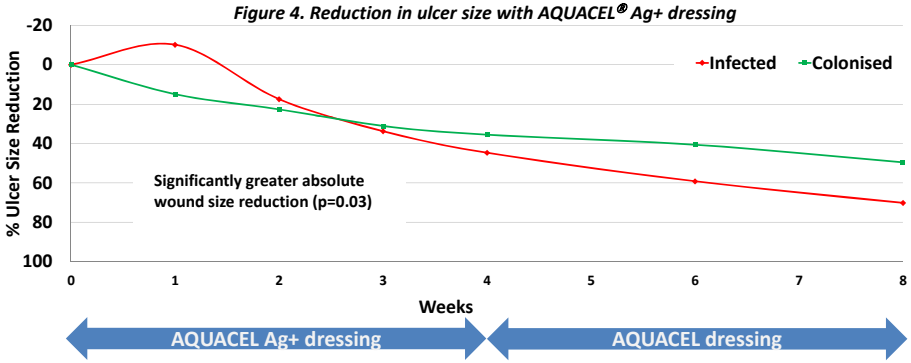


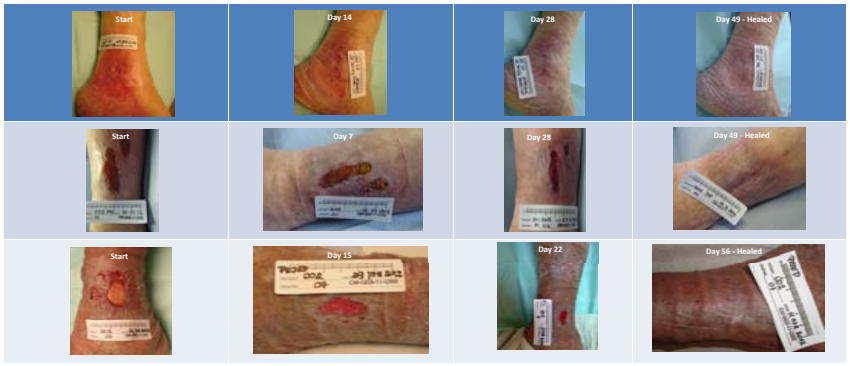
Figure 4. Reduction in ulcer size with AQUACEL® Ag+ dressing



Conclusion

The new AQUACEL® Ag+ dressing has a satisfactory safety profile. Only one subject discontinued from the study due to a non-related serious adverse event, 5 subjects' ulcers healed (12.9%; mean time to healing 47 days; Fig 5), and the remainder of subjects completed the study. Progression towards healing was observed throughout the study period from baseline to the final visit at week 8. From the limited data it is possible to suggest that AQUACEL® Ag+ dressing was beneficial when treating wounds where bacteria are a significant problem.

Figure 5. Wound healing with AQUACEL® Ag+ dressing



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