Assessing the Clinical Performance of an Carboxymethylcellulose Gelling Fiber Dressing for Reduction of Devitalized Tissue in Exuding Wounds

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INTRODUCTION

Devitalized tissue, including necrotic and sloughy tissue impedes wound healing and increases risk of infection and other complications. This study evaluated the performance of McKesson Gelling Fiber dressing and its ability to reduce devitalized tissue during routine clinical use in wound care.

The dressing is constructed with a quilted pattern which allows ingress of viscous exudate. On contact with wound exudate, the CMC and alginate fibres form a cohesive, clear gel. This gel conforms to the wound bed, promoting moist wound healing and supporting integral and autolytic debridement by removal of non-viable tissue. The structure allows easy, intact removal and helps reduce the risk of wound trauma during dressing changes.

METHOD

This prospective, open-label, single-arm, observational study on 217 patients across nine wound-centres in South Africa was undertaken. The evaluation complied with required ethics and regulatory approvals. Adults with a moderate or heavily exuding wound from multiple aetiologies (Fig. 1), were treated with the subject dressing for up to 6 weeks. All wounds were managed using McKesson Gelling Fiber as part of routine care for up to 6 weeks. The primary outcome of the study was to assess the effectiveness of the McKesson Gelling Fiber as measured by wound progression parameters such as percentage reduction of devitalised tissue, increase in granulating and epithelial tissue, and wound size and/or depth. Additionally, the safety of the dressings was assessed as a secondary outcome. Wound bed tissue composition was assessed at baseline with regular follow up appointments using standard clinical evaluation to determine the dressings effect. Wound progression, including healing or measurable improvement, and adverse events were recorded. Statistical comparisons were performed between baseline and end-of-study assessments.

Statistical testing

Statistical analyses were performed according to the statistical analysis plan. Variables were reported as mean ± standard deviation, 1-sided 95% confidence interval (CI) (97.5% 2-sided CI), median, minimum and maximum, count or percentage. Parameter percentage reduction is calculated using the following formula: “100 – ((end visit value/baseline) x 100)”.

RESULTS

On analysis of 217 patients, baseline mean wound bed composition across all wounds consisted 5.2% necrotic and 25.2% sloughy tissue. By end of study, mean necrotic tissue fell to 0.9% demonstrating an 82.7% reduction; ($p < 0.0001$). Mean sloughy tissue decreased to 4.1% representing an 83.7% reduction; ($p < 0.0001$). Considerable reduction in devitalized tissue was observed in all wound types,(Fig 1).

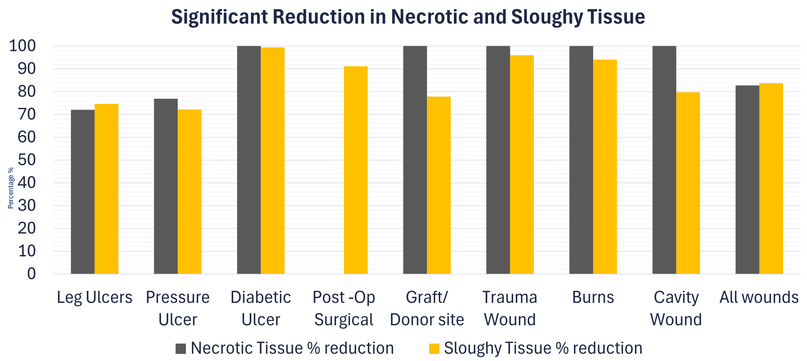


Figure 1: Percentage Reduction of Sloughy and Necrotic Tissue by wound type across 217 subjects

Patient demographics n	N=217
Male/ Female n (%)	118 (54.4) / 99 (45.6)
Age, years, mean ±SD; (range)	56.3±20.36 ;(10-99)

Figure 2: Patient Demographics

Mean necrotic tissue diminished to 0% at the end of the study in several wound types including diabetic ulcers, trauma wounds, burns, graft /donor sites and cavity wounds. Reduction of sloughy tissue exceeded 90% in diabetic ulcers, trauma wounds, first and second degree burns and post operative surgical wounds.

Overall wound progression, including healing or meaningful improvement was achieved in 96.3% (209 of 217 patients), of wounds (Fig4). Clinically meaningful rates of successful improvement in the Wound progression, assessed as the change from baseline to end of follow-up. No device-related adverse events were documented.

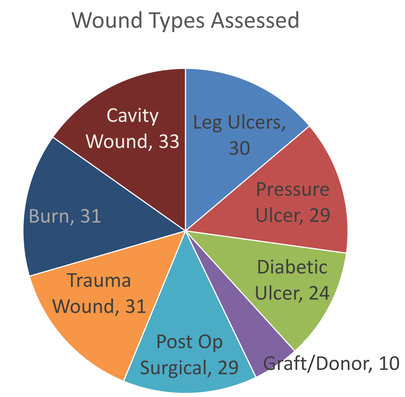


Figure 3: Wound type across 217 subjects

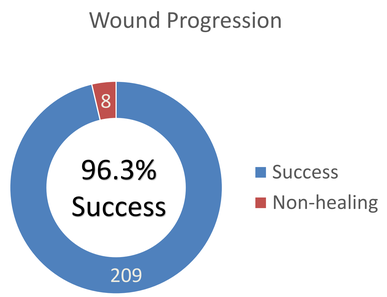
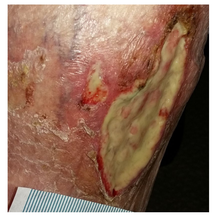


Figure 4: Wound Progression observed across 217 subjects. Successful wound progression is defined as an existing wound showing improvement through reduced size or decreased necrotic/slough tissue. Wounds that heal within 6 weeks, or no longer require the study dressing due to positive progression, are also considered successful

CASE STUDY

A 94-year-old presented with a venous leg ulcer caused by trauma with mixed aetiology and varied comorbidities.

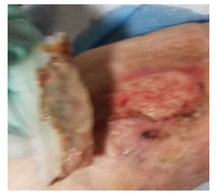


Initial Assessment

The wound measured L 6cm x W 2.5 cm x D 0.5 cm and 100% Sloughy tissue, Moderate exudate and inflamed peri wound.

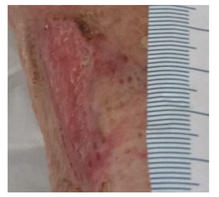
Aim: Manage Exudate and deslough the wound bed

McKesson Gelling Fiber was applied.



Day 7 and 14

Significant progress was observed and the wound decreased in size. There was a decrease in the amount of slough and noticeable residue was observed locked in the dressing. The dressing however was removed easily without damaging the wound.



Day 21

Wound progression continued. Wound size reduced to L 3.5cm x W 1.6cm x D 0.1cm. Slough largely removed and granulation tissue present with areas of epithelial tissue. Peri wound inflammation reduced, exudate low. Patient was transferred onto a foam dressing.

DISCUSSION

In this real-world clinical evaluation over a 6-week period, the use of McKesson Gelling Fiber was associated with significant reductions in both necrotic and sloughy tissue across a diverse range of wound types. The observed outcomes are consistent with effective support of integral debridement through moisture balance and gel formation. These findings along with high rates of wound progression and the absence of device related adverse events suggest the dressing was well tolerated and clinically practical. The results support consideration of the dressings to aid devitalized tissue removal as part of a broader debridement strategy in moderate-to-highly exuding wounds.

LIMITATIONS

The study was conducted without a comparative control group which limits the ability to directly compare the performance with an alternative wound dressing as standard of care . As a result, conclusions regarding relative effectiveness cannot be drawn. Also, while the study reflects real world clinical practice, variability in the different wound types and patients’ comorbidities may have influenced individual outcomes.