Superior exudate management with antimicrobial effect

A new gelling fiber dressing and the in vitro performance

Thomas Ricco Ølholm Larsen[1], Henrik Fallesen[1], Joana Micaela Duarte Pinto[1]
1. Coloplast A/S, Humlebæk, Denmark

Introduction

Modern antimicrobial wound dressing technologies are highly efficient in killing bacteria while also ensuring effective exudate management. The wound healing process requires controlled exudate levels.[1] Ineffective exudate management can lead to exudate pooling, which increases the risk of infection and maceration of the periwound skin.[1,2] High bacteria load may lead to inflammation and delayed healing[3]. Infected wounds may lead to severe complications[4]. Gelling fibers are often used to treat moderate to highly exuding wounds, including cavity wounds,[2,5,6] where effective management of exudate is key to promote optimal wound healing outcomes.[1,6] Sustained release of Ag (silver) is important for long term, broad spectrum antimicrobial activity[7]. The combination of technical performance and antimicrobial efficacy, are must-have elements when addressing wound healing outcomes.

This study evaluates the performance of a new gelling fiber A* with a comparator gelling fiber B# by analyzing key performance parameters such as: absorption under pressure, surface shrinkage, wet strength. It also evaluates antibacterial performance and microbial barrier testing. The performance tests methods presented are internally developed and validated Coloplast test methods. Antimicrobial performance (modified AATCC 100-2019) and microbial barrier testing are both FDA recommended tests.

Methods

Absorption under pressure measures the absorptive capacity of a wound dressing when exposed to a pressure of 40 mmHg (compression therapy simulation). The test method consists of a punched-out sample of the dressing being placed on a porous glass filter plate in a petri dish with a weight on top. Test fluid (solution A: salt water with an ionic composition comparable to wound exudate) is added, and the sample is allowed to absorb the test fluid through the glass filter plate for 90 minutes at room temperature. Finally, the weight gain of the sample is measured and reported in g/cm2.

Surface shrinkage upon wetting measures the surface shrinkage of a dressing upon saturation with test fluid (solution A). The test was carried out by letting the sample (5x5 cm) absorb excess fluid (30 minutes, 37°C) then re-measuring the sample length and width after saturation and excess fluid removal (Figure 1).

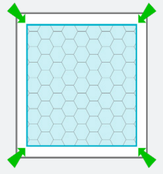

Figure 1: Illustration of surface shrinkage upon wetting test

Wet strength in weakest direction measures tensile strength of gelling fiber wound dressings when wet. The test is conducted by wetting the middle part of the dressing sample (20mm x 70mm) with solution A. The dry ends of the sample are fixated by the clamps of a tensile test machine, which pulls the sample apart by stretching at a fixed speed of 100 mm/min. Data is given in N/20 mm (Figure 2).

Figure 2: Illustration of wet strength in weakest direction test

Antimicrobial performance (AATCC TM100-2019) measures the antimicrobial performance of wound dressings on microbial numbers inside the dressing. Dressings are aseptically prepared by adding simulated wound fluid to '80 % minus 1 mL' of their absorption capacity. The microbial suspensions (1 mL) is added, following incubation with microorganisms for 24 hours at 35 °C. Log reductions are calculated based on t=0 enumeration of microbial numbers. Antimicrobial performance is defined as a reduction in microbial numbers greater than 4 log10 units.

The following organisms were tested:

- Enterococcous faecalis
- Staphylococcus aureus
- Streptococcus pyogenes
- Escherichia coli
- Klebsiella pneumoniae
- Pseudomonas aeruginosa
- Meyerozyma guilliermondii
- Cladosporium allicinum

Microbial Barrier Testing measures the ability of wound dressings to prevent the penetration of viable microorganisms from the outside of the dressing into the wound. The test runs by exposing dressing samples saturated with simulated wound fluid (7 days at 35 °C), to a microbial inoculum of 10^6 CFU per dressing sample and investigate if the microorganisms can penetrate the wetted dressing. The test was performed against 6 microbial strains including motile bacteria, a yeast and one mould.

\+ Coloplast data on file 12/20, [95% CI: 31%-41%], [p<0.0001].
++ Coloplast data on file 12/20, [95% CI: 58%-61%], [p<0.0001].
+++ Coloplast data on file 12/20, [95% CI: 174%-232%], [p<0.0001].

Results

For all technical tests, the mean and SD (Standard Deviation) were based on testing of several dressing samples (n specified in the results section). Technical performance results are presented as mean ± SD.

	Gelling Fiber A*	Gelling Fiber B#
Absorption under pressure (g/cm2)	0.18 ± 0.015 (n=30)	0.13 ± 0.007 (n=20)
Surface shrinkage (%)	13.8 ± 1.1 (n=30)	34.4± 1.9 (n=24)
Wet strength (N/20 mm)	10.1± 1.8 (n=30)	3.3± 0.7 (n=35)

Regarding antimicrobial testing, the observed log reductions demonstrate that the A* product has antimicrobial activity towards both bacteria and fungi with log reductions greater than 4 for all tested microorganisms. Similar performance was observed for gelling fiber B#.

On microbial barrier testing, the observed growth patterns support the conclusion that both A* and B# have microbial barrier properties.

A* Biatain® Fiber Ag (Coloplast)
B# Aquacel ® Ag Advantage (Convatec)

References:
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Based on bench test data. May not be indicative of clinical performance. Performance and experience may vary. Prior to use, refer to product labelling for complete product instructions for use, contraindications, warnings and precautions.

Discussion

Regarding the technical performance, gelling fiber A* had an absorption under pressure capacity 36%+ above the comparator B#. Gelling fiber A* mean absorption under pressure is significantly higher, p<0.0001, which is a critical factor when performing compression therapy to reduce the risk of wound maceration and promote healthy wound edges. In respect to surface shrinkage upon wetting, gelling fiber A* shrinks 60%++ less in contrast to gelling fiber B#. Gelling fiber A* mean surface shrinkage is significantly lower, p<0.0001. Minimal shrinkage reduces the risk of gap formation and exudate pooling. On wet strength in weakest direction, gelling fiber A* accomplished a 203%+++ more wet strength compared with gelling fiber B# in weakest direction. The mean retention capacity of gelling fiber A* is significantly higher, p<0.0001. The tensile strength of gelling fiber A* ensures one-piece removal with minimal risk of leaving residues behind - another essential feature to decrease the risk of infection. The new gelling fiber A* performed equal to the comparator B# on antimicrobial activity and microbial barrier proprieties.

Conclusion

To conclude, the new gelling fiber A* combines high technical performance with antimicrobial properties. The effective exudate management and minimal shrinkage, reduces exudate pooling and may lead to a reduction in the risk of infection and maceration. These features provide healthcare professionals with effective tools for delivering excellent patient care.

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