

Bacterial Barrier Characteristics of TIELLE* to the Proposed CEN Test Method (prEN 13726-5.2:2002)

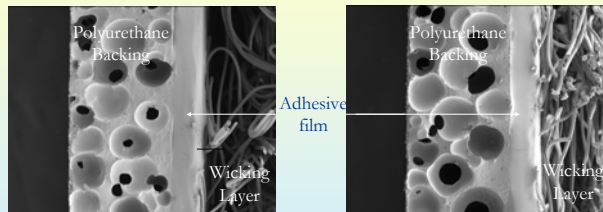
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Introduction

A protocol has been proposed by the European Committee for Standardisation (CEN) to assess the bacterial barrier properties of primary wound care dressings. The method was designed to simulate the wet conditions frequently encountered by dressings when in contact with a wound. This protocol was used to evaluate the ability of TIELLE* dressings to act as a bacterial barrier over a 7-day test period.

TIELLE* dressings were also examined by scanning electron microscopy. The micrographs revealed a continuous 70-150µm layer of adhesive which provides the barrier to the penetration of bacteria.

SEM cross-section of TIELLE* dressings prior to and following immersion in fluid over 7 days



Prior to Saturation

After 7 Days Saturation

Experimental evidence shows that an extended period of saturation does not dissolve the adhesive film and its integrity remains intact

Schematic Methodology

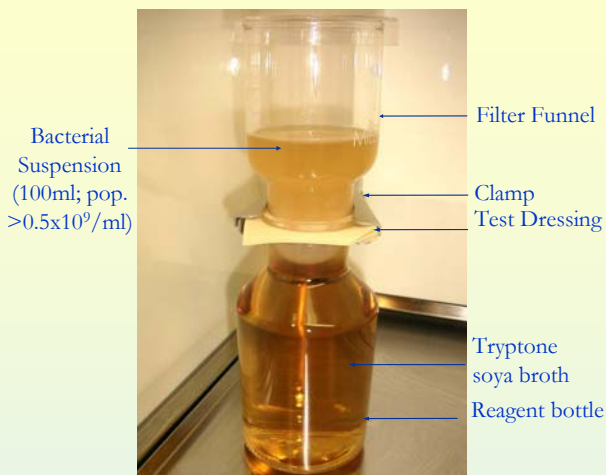
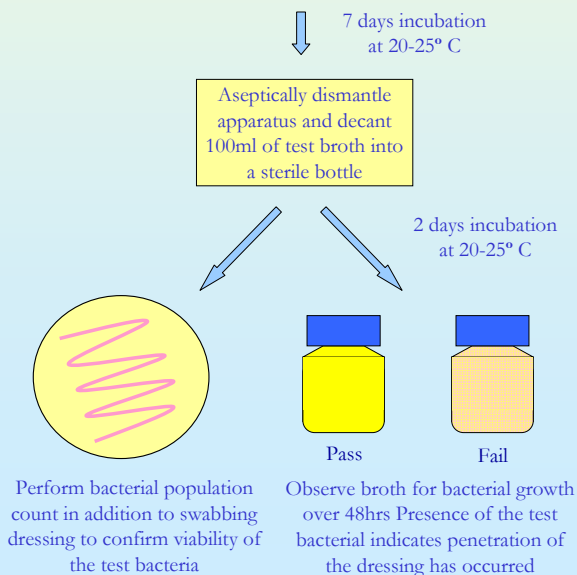


Fig. 3 Bacterial Barrier Test Apparatus



Results

Dressing	Replicate 1	Replicate 2	Replicate 3
Tielle External Layer	-	-	-
Tielle Wound Contact Layer	-	-	-

Key: + : indicates colonies of *Serratia marcescens* were present in the broth following incubation (7+2 days)
- : indicates colonies of *Serratia marcescens* were not present in the broth following incubation (7+2 days)

Average Bacterial Population prior to testing: 1.855x10⁹cfu/ml

Average Bacterial Population following testing: 1.680x10⁹cfu/ml

Acceptance Criteria (for all replicates)

No colonies of *Serratia marcescens* are present in the broth

Bacterial Pop. > 0.5x10⁹cfu/ml

Conclusions

The results of this study strongly indicate that using the proposed CEN test method TIELLE* dressings act as a bacterial barrier for the recommended wear time of up to 7 days, when challenged with a suspension of the highly motile anaerobic bacterium *Serratia marcescens*. The bacterial suspension contained approx 1.8 x10⁹ cells/ml, a level substantially greater than that encountered in heavily colonised/infected wound fluid.

In addition, following a 7-day immersion period in deionised water the adhesive layer of TIELLE* remained intact, confirming that the bacterial barrier properties of TIELLE* dressing are not compromised when the dressing is wet or saturated.

From the information available from randomised multi-centre clinical trials^{1,2} no cases of infection were reported when TIELLE* dressings were used. These results indicate that TIELLE* dressings also provide a bacterial barrier under clinical conditions.

1. Thomas S. *et al.* A comparison of two dressings on the management of chronic wounds. Journal of Wound Care Vol. 6, No. 3, Sept. 1997
2. Collier J. A moist, odour-free environment. A multi-centred clinical trial of a foamed gel and hydrocolloid dressing. Professional Nurse. Sept 1992; 804-807.