PENETRATION OF MEDICAL GRADE PAPERS BY AIRBORNE BACTERIAL SPORES

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The prime function of the package of a 'single-use' sterile medical device is to provide a barrier to the ingress of micro-organisms during storage, handling, transport, etc. Paper is commonly used as part or whole of the package for such devices. Currently in the United Kingdom there is no agreed test method for evaluating the impenetrability of paper *to micro-organisms*. Clearly, the design of a test of impenetrability in respect of airborne micro-organisms will be determined, to a large extent, by the way in which experimental variables influence penetration. Amongst these are variables associated with the paper itself, the microbial challenge and the test procedure. The present report describes measurements of penetration of a microbial challenge presented to the paper at various concentrations and different flow rates, while keeping other recognised variables under strict control.

All test samples were preconditioned by exposure to air of 50 ± 2% relative humidity at 23 ± 1°C for a period in excess of 4 hours (BS 3431 1973). Penetration was measured over a circular area of test paper of 78.5cm^2. The microbial challenge to the paper was a dispersion of endospores of *Bacillus subtilis* var. *niger* at a given concentration between 1 x 10^3 and 1 x 10^6 spores dm^{-3} of air. The relative humidity of the dispersion was held around 50% at a test temperature of 23 ± 1.5°C. For a given paper sample, the dispersion of spores was drawn across the sample at a predetermined flow rate in the range of 1.3 to 13 ml min^{-1} cm^{-2} paper sample and estimates made of spore concentrations upstream and downstream of the sample. These estimates were used to determine the extent of penetration (P) by a particular challenge traversing the test sample at a fixed rate, as follows:

$$\frac{\text{spore concentration downstream of the paper sample}}{\text{spore concentration upstream of the paper sample}} \times 100 = \%\ \text{penetration (P)}$$

The general findings are: a) over the test range of flow rates, % penetration (P) is an inverse function of flow rate (V), b) a plot of ln P *vs* ln V is linear with a negative slope $-\kappa$ (Fig. 1), κ taking values of 0.6, 1.2 and 1.8 for three

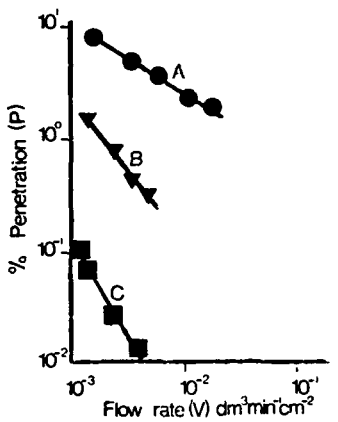

Fig. 1. Curves relating ln P and ln V for three different types of medical grade paper (microbial challenge ~1 x 10^6 spores dm^{-3}).

different paper types, and c) penetration shows a small but significant dependency on challenge concentration, κ increasing with decreasing concentration. This early work suggests that, provided test conditions are appropriately standardised, the constant κ may be used as a quantitative measure of the effectiveness of different paper types as barriers to airborne micro-organisms.

0022-3573/81/120077P-01$02.50/0