Long-term effect of a 1.5 minute surgical hand rub with a propanol-based product on the resident hand flora

Madam,

It has been described recently that the application of a specific propanol-based hand rub for surgical hand disinfection is equally effective according to EN 12791 in 1.5 min when compared with the traditionally recommended 3 min.1,2 More data obtained with the test method of the US Food and Drug Administration further support the scientific basis of the 1.5 min application for the hand rub.3 In EN 12791, the efficacy of a procedure for surgical hand disinfection is measured immediately and 3 h after application of the hand rub. Recent research with a 3 min application time indicates that the bacterial density on hands remains at ~1 log below baseline even after 6 h under the surgical glove.4 But it is unknown if an equivalent effect can be achieved with a 1.5 min application time with the same preparation. That is why we have measured the reduction of the resident hand bacteria for a 1.5 and 3 min application with a hand rub based on 45% (w/w) iso-propanol, 30% (w/w) n-propanol and 0.2% (w/w) mecetronium ethysulphate (Sterillium, Bode Chemie GmbH & Co. KG, Hamburg, Germany) against the 3 min reference treatment of EN 12791 (60% v/v n-propanol). Pre- and post-treatment values (0 and 1, 3, 6 h after application respectively) were obtained by rubbing the finger tips in 10 ml sampling fluid. These and their diluents, which were used for the assessment of post-treatment values, contained a mixture of 3% Tween 80 (Merck 8.22187), 3% saponin (Riedel-de-Haen, Seelze, D, 1.6109), 0.1% cysteine hydrochloride (Merck 1:02838) and 0.1% L-histidine hydrochloride (Merck 1.04351) for neutralization of possible residual bacteriostatic or bactericidal activity.5 In total, six test runs were performed at intervals of one week; 24 volunteers were randomly assigned by computer to perform one of the three disinfection procedures, including the reference procedure (three groups of eight subjects). Using the 'split-hands' model, the sampling times for the assessment of POST-values were also randomly assigned to right and left hands such that, at a time, a subject used one disinfection procedure that was evaluated at two different sampling times. After the sixth week each volunteer had tested every procedure at every pre-determined sampling time. The three disinfection procedures were tested concurrently. To guarantee balance of the sequence of tests, the three groups, three procedures and four sampling times were arranged in a quasi-Greco-Latin square under the constraint that the sampling times for POST-values were not equal for both hands. The Greco letters were interpreted as applying to the left hand; the Latin ones as applying to the right hand. In contrast to a true Greco-Latin square design, however, each subject had eventually tested every procedure at all four sampling times. As compared to the reference procedure R, the mean log reductions (RF) (±SD) assessed at t0 demonstrate the significantly (P < 0.001) higher antimicrobial efficacy of Sterillium™ (B) if used for the same application time of 180 s: 2.28 log (>0.92) and 3.21 log (>1.03) respectively. If used for 90 s, the efficacy of Sterillium™ is equivalent to that of the reference: 2.19 log (±1.42) and 2.28 log (±0.92) respectively (P > 0.1). The increase in the release of skin bacteria during the course of time from t0 over t1 and t2 to t6 is approximately parallel (Figure 1). After 6 h the microbial release is still significantly (P < 0.05) less than before disinfection by 0.74 log (A), 0.99 log (B) and 0.83 log (R). In accordance with the requirements of EN 12791, this antimicrobial effect of Sterillium™ would permit surgical hand disinfection for only 90 s, resulting in a microbial reduction that is equivalent to that of the reference disinfection even after 6 h. However, from the results of this investigation it must not be concluded that a shortened duration of application of 90 s is justified for all products listed in the respective official registers of the Austrian or German Societies for Hygiene and Microbiology certifying sufficient antimicrobial efficacy of a product, or even, generally, for all alcohol-based surgical hand antiseptics. On the contrary, the
suitability of each single product must be established by results of an evaluation according to EN 12791.

References