Disinfection

50 years of Sterillium®
50 years of trust

Most relevant studies on efficacy,
skin tolerability and compliance.

Sterillium®:
A plea for alcohol-based hand disinfection

Fifty years ago, Sterillium – the world's first marketable alcohol-based hand disinfectant – revolutionised surgical and hygienic hand disinfection: hand hygiene became more efficient and, above all, skin friendly. Since the first Sterillium batch left the factory premises in Hamburg-Stellingen, Germany in 1965, around sixty articles on the preparation have been published in scientific journals. Thus, Sterillium is the most frequently scientifically invesitgated hand disinfectant in the world.

Efficacy, skin tolerability and compliance

And this research on hand hygiene is continued unabated. A study from 2014 just proved that Sterillium possesses a skin caring effect on the skin, which is an essential aspect for the use of a hand disinfectant, because users only like to use a preparation that keeps the skin moist. Skin tolerability and efficacy are therefore the most important factors that decide on the user acceptability of hand disinfection and help to increase compliance in hand disinfection.

Enhanced hygiene quality in daily routine

On the occasion of Sterillium's fiftieth anniversary, we have looked back on the scientific highlights of the hand hygiene pioneer, and compiled a selection of the most important studies on Sterillium for you. The focus is in key hand hygiene topics: compliance, skin tolerability
and efficacy.

The publications do not only show how important hand disinfection and the selection of the right product are to healthcare facilities, but also have an impact on daily practice. All publications have one thing in common: they are a plea for alcohol-based hand disinfection. Ideally with Sterillium – as proven by the three billion applications per year.

Further study abstracts and detailed information can be found on the website of the BODE SCIENCE CENTER, the scientific centre of excellence of PAUL HARTMANN AG, at **www.bode-science-center.com.**

Your PAUL HARTMANN AG

Sterillium – efficacy and better skin tolerability in every drop for fifty years.

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Sterillium®: Guarantor of a comprehensive spectrum of activity

The antimicrobial activity is the main criterion when selecting a hand disinfectant, as nosocomial infections can only be prevented when disinfection preparations reliably inactivate the clinically relevant pathogens. In hand disinfection, alcohol is the fastest, most efficient and safest active ingredient.

By introducing alcohol as basis of a hand disinfectant fifty years ago, Sterillium made hand disinfection many times more effective. Since then, numerous studies, publications in scientific journals and expert's reports on Sterillium and even other Sterillium products have proved the formulas' fast and comprehensive antimicrobial activity.

Tested and approved

In addition to the test methods of European norms such as EN 1500 for hygienic hand disinfection and EN 12791 for surgical hand disinfection, Sterillium has demonstrated its efficiency in many individual examinations.

Mycobacterium tuberculosis, MRSA, MRGN or all 45 bacterial strains of the U.S. Food and Drug Administration (FDA): Sterillium reduces all clinically relevant bacteria and problem pathogens by more than five log_{10}steps within thirty seconds. And it also possesses reliable virucidal activity against important viruses such as HBV/HIV, influenza virus, rotavirus, adenovirus and polyoma virus.

New exposure time standards

For surgical hand disinfection in accordance with the European EN 12791 standard, the classic of hand

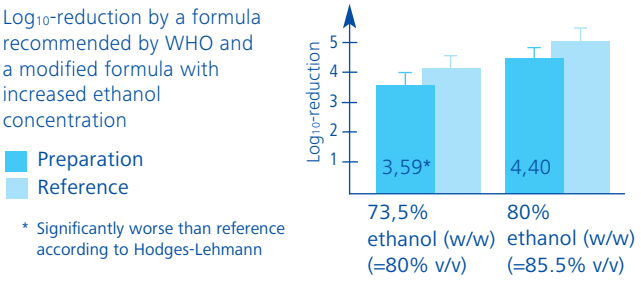
disinfection, applied for ninety seconds, achieves an activity for both the immediate effect and sustained effect (three hours after application) that is significantly better than the reference procedure applied for three minutes.

The proof of the shortened exposure time for surgical hand disinfection with Sterillium lead to a genuine change in preoperative hand antisepsis in 2005 – thousands of operating theatre teams have benefited since then. This is just one of the many standards Sterillium has set in the last decades.

Ethanol concentration in hand disinfectants

One of the commonly used active ingredients in hand disinfectants is ethanol (C_2H_5OH). For a preparation to be listed as effective for hygienic hand disinfection, it needs to fulfil the requirements for bactericidal activity in accordance with EN 1500. Also the World Health Organization (WHO) supports efficacy testing according to European standards [1].

Log_{10}-reduction by a formula recommended by WHO and a modified formula with increased ethanol concentration



Test organism: *Escherichia coli* K12; shown are mean values of 20 test subjects and standard deviation; application of preparation: 3 ml for 30 seconds.
Source: Suchomel M et al. 2012

When applying 3 ml, hand disinfectants with a relatively low ethanol concentration usually are not sufficiently active within 30 seconds (commonly recommended exposure time) [2, 3]. A study conducted with the participation of WHO demonstrated that an ethanol concentration of 73.5% w/w (=80% v/v) could not meet the efficacy requirements for hygienic hand disinfection. As soon as the ethanol concentration was increased to 80% w/w (=85.5% v/v), the preparation fulfilled the EN 1500 efficacy criteria [2]. Hence, when selecting a hand disinfectant, the ethanol concentration should be at least 80% w/w.

1. WHO (2009) WHO Guidelines on Hand Hygiene in Health Care: First Global Patient Safety Challenge Clean Care Is Safer Care. http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf (abgerufen am 20.10.2014).
2. Suchomel M et al. (2012) Testing of the World Health Organization recommended formulations in their application as hygienic hand rubs and proposals for increased efficacy. Am J Infect Control 2012, 40 (4): 328–331.
3. Kampf G, Ostermeyer C (2004) Efficacy of alcohol-based gels compared with simple hand wash and hygienic hand disinfection. J Hosp Infect 2004, 56, 13-15.

Research for infection protection. www.bode-science-center.com

BSB 100036EN_0315_1

Kramer, A. / Rudolph, P. / Kampf, G. / Pittet, D. (2002)

Limited efficacy of alcohol-based hand gels

Background

There are many gels available in healthcare facilities for the disinfection of hands. Their concentration of alcohol, however, is quite low. The aim of the study was to determine the bactericidal efficacy of ten alcohol-based hand gels and four alcohol-based rinses, including Sterillium, according to EN 1500 with 3 ml in 30 seconds which resembles current clinical practice.

Methods

Four rinses with alcohol concentrations mostly around 75 % and ten mostly ethanol-based hand gels were investigated. After a thorough handwash with non-medicated soap, hands were placed in a suspension of *E. coli* for five seconds, and allowed to air dry for 3 minutes afterwards. Pre-values were obtained from all fingertips. 3 ml of a hand gel or rub were applied for 30 seconds, or 2 x 3 ml of the reference alcohol were applied for 2 x 30 seconds (cross-over design). After the treatment of the hands, fingertips were sampled once more. Pre-values and post-values were obtained by rubbing the finger tips for one minute in nutrient broth containing validated neutralising agents followed by serial dilution. Aliquots were spread on tryptic soy agar. After incubation of the plates, the total colony counts were determined per subject and time point. All values were expressed on a $\log_{10}$ scale, the efficacy of gels and rinses was compared to the reference procedure.

Results

All ten hand gels were significantly less effective in comparison to the reference procedure (difference was between 0.7 and 2.0 $\log_{10}$ steps) and thus failed to meet the European efficacy requirements for hygienic hand disinfection. Sterillium and the other three hand rinses were not significantly less effective in comparison to the reference procedure and hence met the European efficacy requirements for hygienic hand disinfection.

Conclusions

Most alcohol-based hand gels have a rather low concentration of alcohol (≤ 70 %) and fail to meet the European efficacy requirements according to EN 1500 when tested as commonly used. These products should not be used in hospitals. Alcohol-based liquid disinfectants such as Sterillium provide much better efficacy and therefore decrease the risk of cross-transmission and nosocomial infection.

Practical relevance

Hand rinses do provide a good activity against microorganisms and should be preferred to hand gels, unless these gels contain at least 80 % (v/v) of ethanol.

Source: Lancet 2002; 359: 1489-90

Comparative efficacy of alcohol-based hand disinfectants with EN 1500 reference alcohol

Active ingredients	Mean reduction factor of product	Mean reduction factor of reference alcohol*	Difference
Hand rinse (Sterillium) (w/w)			
2-propanol (45 %), 1-propanol (30 %) and mecetronium etilsulfate (0.2 %)	4.26	4.10	0.16**
Hand gels (v/v)			
Ethanol (53 %)	3.31	4.28	0.97***
Ethanol (57 %)	2.68	3.78	1.10***
[a] Ethanol (60 %)	3.07	4.12	1.05***
[b] Ethanol (60 %)	4.09	5.07	0.98***
2-propanol (60 %) plus other antiseptic ingredients	4.07	4.96	0.89***
Ethanol (62 %)	3.07	4.10	1.03***
[a] Ethanol (70 %)	2.13	4.12	1.99***
[b] Ethanol (70 %)	3.36	4.26	0.89***
1-propanol and 2-propanol (total 70 %)	3.87	4.58	0.71***
Industrial methylated spirits (70 %)	3.58	4.68	1.10***

* *Reference alcohol: 2-propanol, 60 % (v/v)*
** *(p = not significant)*
*** *(p < 0.01)*

Kampf, G. / Ostermeyer, C. / Kohlmann, T. (2008)

Bacterial population kinetics on hands during two consecutive surgical hand disinfection procedures

Background

Although clinical practice often requires to carry out two consecutive surgical procedures and thus two surgical hand disinfection procedures, the effect of the most common hand disinfectants on the bacterial density had not been studied. The study investigated the effect of two consecutively performed hand disinfection procedures with Sterillium on the resident skin flora.

Methods

The study examined Sterillium in direct comparison with an alcohol-based reference solution (n-propanol, 60 %) in accordance with EN 12791. The solutions were applied in two steps. Sterillium was rubbed in for 1.5 minutes followed by 3 hours glove wearing. The second application took 1.5 minutes, 1 minute or 30 seconds. The reference solution was always applied for 3 minutes. Four different variants were possible. The study's Latin-square design was as follows: 20 test subjects were divided into 4 groups with 5 persons each. Thus, all 4 different treatment variants could be performed with the different groups each week. For every treatment variant, the bacterial density was measured four times: directly after the first application (immediate effect), 3 hours later, directly after the second application, and another 3 hours later. During the 3-hour intervals, the test persons wore sterile single-use gloves on one hand.

Results

The first hand disinfection with the reference alcohol reduced the bacterial density by 2.87 $\log_{10}$ (immediate effect) and 2.27 $\log_{10}$ (after 3 hours). Sterillium yielded comparative values. Immediately after the second disinfection with 60 % n-propanol, the bacterial density was reduced by 0.45 $\log_{10}$. Sterillium achieved a higher immediate reduction in bacterial density: by 0.71 $\log_{10}$ (30 seconds), 0.79 $\log_{10}$ (1 minute) and 1.12 $\log_{10}$ (1.5 minutes). The differences were not significant. After another 3 hours, the bacterial density was further reduced: by 1.11 $\log_{10}$ (reference alcohol), and by 1.89 $\log_{10}$ (1 minute) and 1.67 $\log_{10}$ (1,5 minutes), 1.08 $\log_{10}$ (30 seconds) with Sterillium. There were significant differences between all four treatments ($P = 0.005$) but none of the shorter hand disinfection procedures with Sterillium were significantly less effective than the reference alcohol ($P > 0.05$).

Conclusions

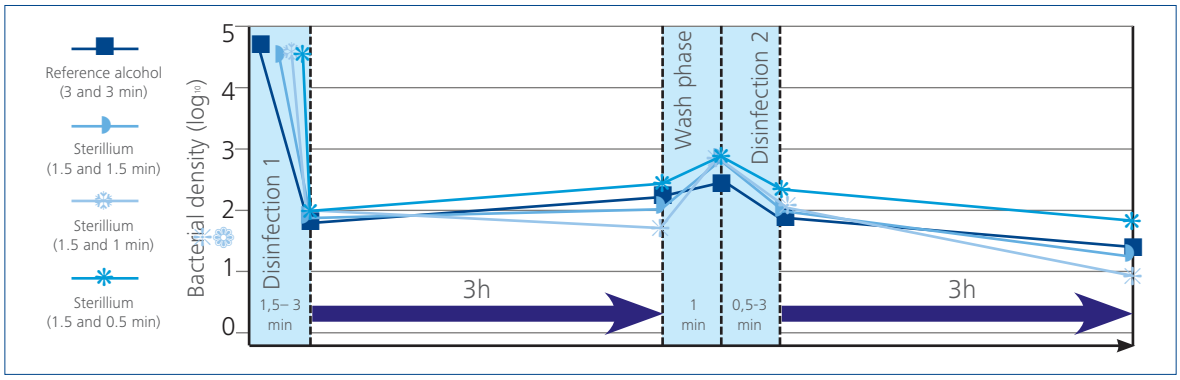
The authors conclude that the 1.5-minute surgical hand disinfection with an effective hand disinfectant keeps the resident skin flora as low as possible (irreducible minimum). This also applies to two consecutive surgical procedures.

Practical relevance

Even after 6 hours, a 1.5-minute surgical hand disinfection with Sterillium keeps the bacterial density on the hands very low.

Source: Am J Infect Control 2008; 36: 369-374

Bacterial population kinetics on hands disinfection procedures before and after (0 and 3 hours) two consecutive surgical hand disinfection procedures



Kampf, G. / Ostermeyer, C. / Heeg, P. (2005)

Surgical hand disinfection with a propanol-based hand rub: equivalence of shorter application times

Background

Around the world, surgical site infection is among the most common infections associated with health care. The decisive measure to prevent these postoperative infections is surgical hand disinfection. For the first time, this study investigated the efficacy of a propanol-based hand rub for surgical hand disinfection with application times less than three minutes.

Methods

The cross-over study examined the efficacy of Sterillium and four other hand disinfectants with different application times. For this, the 18 to 20 test subjects carried out surgical hand disinfection in accordance with EN 12791. Sterillium was applied to the hands for 3, 2, 1.5 or 1 minute(s). The application time for the reference alcohol (n-propanol, 60 %) was always 3 minutes. The four other hand disinfectants were applied for 1 minute. The fingers were rubbed in tryptic soy broth for 1 minute to determine the pre-values, immediate values and 3-hour values.

Results

The immediate effect (0-hour value) of Sterillium with application times of 3, 2 and 1.5 minutes was significantly higher than of the reference procedure with n-propanol (60 %). Rubbing the hands for 1 minute yielded a mean immediate $\log_{10}$ reduction of 1.91 (0-h value) and, however, was significantly less effective than the reference procedure (2.52; p=0.001). After 3 hours (sustained effect, 3-h value), the 1-minute disinfection with Sterillium achieved a mean $\log_{10}$ reduction of 1.81 and thus was not significantly less effective than the reference procedure (2.05; p=0.204). All other products did not sufficiently reduce the resident skin flora after 1 minute. When applied for 1.5 minutes, Sterillium was more effective than the reference procedure. Longer application times (2, 3 minutes) did not reduce the hand's microbial flora to a significantly higher extent.

Conclusions

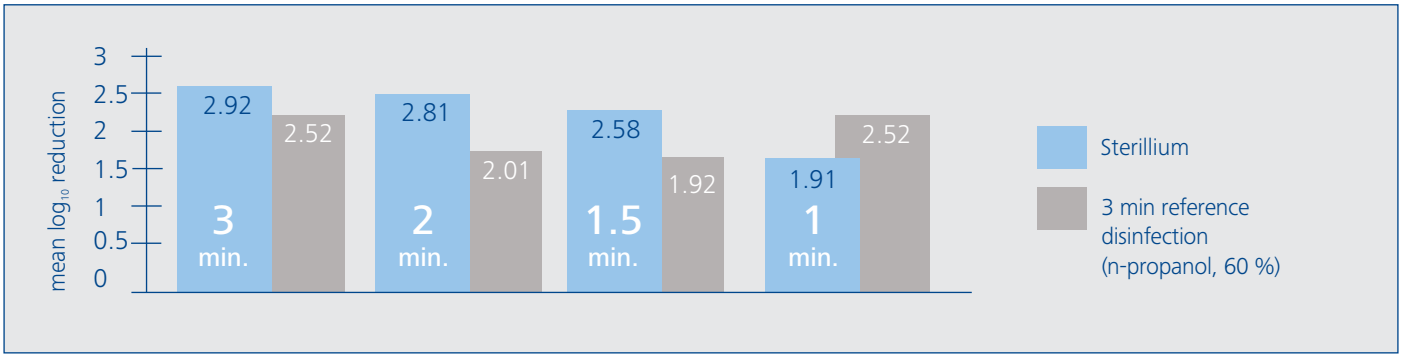
The authors emphasise that the duration of the hand disinfection itself has a considerable influence on a preparation's efficacy. The same volume of Sterillium (2 x 3 ml) did not yield a sufficient efficacy after an application time of 1 minute. When applied for 30 additional seconds, however, Sterillium's efficacy exceeded the 3- minute reference procedure.

Practical relevance

For surgical hand disinfection, alcohol-based preparations with a short exposure time of 1.5 minutes that has been proven to be effective offer the benefit of saving time.

Source: Journal of Hospital Infection 2005; 59: 304-310

Immediate effect of Sterillium for surgical hand disinfection with different application times (1, 1.5, 2, 3 minutes) compared with the reference surgical disinfection (3 minutes), presented as the mean reduction of the resident skin flora



Kampf, G. / Ostermeyer, C. / Heeg, P. / Paulson, D. (2006)

Evaluation of two methods of determining the efficacies of two alcohol-based hand rubs for surgical hand antisepsis

Background

Surgical disinfection is a standard procedure, which is used worldwide to prevent surgical site infections. Different studies have shown that surgical gloves are not an absolutely safe barrier against pathogens – approximately 18.6 % of surgical gloves perforate during surgical procedures. Hence, it is necessary to reduce the hand's microbial flora lastingly and effectively to prevent microorganisms from entering the surgical wound even in case the glove perforates. The study tested the efficacy of Sterillium and Sterillium Rub (product is exclusivly available in the US for surgical hand disinfection) in accordance with the European Norm (EN 12791) and the US-American Tentative Final Monograph for Healthcare Antiseptic Products (TFM).

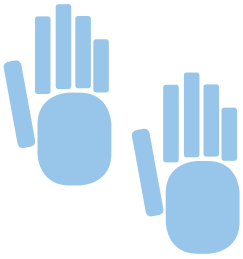
Methods

The European test method was conducted with 20 test subjects. Both hand disinfectants were tested in individual experiments and compared with the reference solution (n-propanol, 60 % v/v) in a cross-over design. The fingers were rubbed in tryptic soy broth for 1 minute to determine the baseline (pre-values). Afterwards, the hands were treated with the disinfectant or reference solution. After 1.5 (Sterillium), 2 (Sterillium Rub) or 3 minutes (reference), the immediate effect was determined on one hand, the other hand was gloved for 3 hours. After glove removal, the second post-value (3-hour value) was determined.

According to the US method, the efficacy of the two hand disinfectants was tested with 36 test subjects in a second study phase in comparison to an approved reference product. The pre-values were determined on three days within one week by the glove juice method. Both hand disinfectants were then applied and compared to the reference product. After the application times of 1.5 (Sterillium), 2 (Sterillium Rub) or 3 minutes (reference), the immediate effect and post-values were determined. For the latter, some sampling fluid was taken from the donned glove after 3 and 6 hours (glove juice method).

Results

During the TFM study phase, Sterillium's mean, immediate $\log_{10}$ reduction was 2.82 (Day 1), 3.29 (Day 2) and 3.25 (Day 5) with an application time of 1.5 minutes. 3 and 6 hours after the application of Sterillium, the bacterial count still was at least 1.57 $\log_{10}$ below baseline. The examinations according to the European standard revealed comparative results. The bacterial count remained 2.35 $\log_{10}$ (immediate effect) and 2.17 $\log_{10}$ (3-hour value) below baseline. Sterillium Rub also met the efficacy requirements of both standards with an exposure time of 2 minutes. It immediately reduced the bacterial count on both hands by 2.99 $\log_{10}$ (Day 1), 3.0 $\log_{10}$ (Day 2) and 3.43 $\log_{10}$ (Day 5) when tested following the US method. The examination in line with EN 12791 reached mean $\log_{10}$ reductions by 2.97 (immediate effect) and 2.20 (3-hour value).



Conclusions

The study demonstrates that Sterillium and Sterillium Rub fulfil the efficacy requirements of two completely different test methods. This even applies to short exposure times of 1.5 minutes with Sterillium and 2 minutes with Sterillium Rub.

Practical relevance

Sterillium meets the requirements of both European and US-American standards.

Source: Applied and Environmental Microbiology 2006; 76, 6: 3856-3861

continued on next page

Kampf, G. / Ostermeyer, C. / Heeg, P. / Paulson, D. (2006)

Evaluation of two methods of determining the efficacies of two alcohol-based hand rubs for surgical hand antisepsis

Reduction of bacterial baseline counts on fingertips by surgical hand disinfection with Sterillium Rub according to prEN 12791, compared to the 3-minute reference treatment

Sampling time	Reference treatment (60 % propan-1-ol; 3 min)		Sterillium Rub (2 min)	
	CFU* (mean ± SD)	Mean $\log_{10}$ reduction	CFU* (mean ± SD)	Mean $\log_{10}$ reduction
Baseline	4.41 ± 0.61	NA**	4.56 ± 0.63	NA**
Immediate	1.49 ± 1.05	2.92 ± 1.03	1.59 ± 1.15	2.97 ± 0.89
Baseline	4.52 ± 0.69	NA	4.45 ± 0.70	NA
3 h	2.05 ± 1.41	2.47 ± 1.25w	2.24 ± 1.18	2.20 ± 1.07

** colony-forming unit; rough estimate of the number of viable bacteria cells in a sample* ***NA, not applicable*

Reduction of bacterial baseline counts on fingertips by surgical hand disinfection with Sterillium according to prEN 12791, compared to the 3-minute reference treatment

Sampling time	Reference treatment (60 % propan-1-ol; 3 min)		Sterillium (1.5 min)	
	CFU* (mean ± SD)	Mean $\log_{10}$ reduction	CFU* (mean ± SD)	Mean $\log_{10}$ reduction
Baseline	4.55 ± 0.57	NA	4.90 ± 0.36	NA
Immediate	2.70 ± 0.89	1.86 ± 0.87	2.54 ± 0.91	2.35 ± 0.99
Baseline	4.47 ± 0.77	NA	4.91 ± 0.37	NA
3 h	2.98 ± 0.99	1.50 ± 1.26	2.74 ± 0.94	2.17 ± 1.00

** colony-forming unit* ***NA, not applicable*

Kampf, G. / Hollingsworth, A. (2003)

Validity of the four European test strains of prEN 12054 for the determination of comprehensive bacterial activity of an alcohol-based hand rub

Background

In Europe, the bactericidal activity of a hand rub is determined in a suspension test with four specific test bacteria (prEN 12054, now EN 13727). It is assumed that the four test bacteria cover the entire spectrum of clinically relevant bacterial species. Against this background, aim of the study was to determine if the four test bacteria of prEN 12054 indeed cover most of the clinically relevant bacterial species.

Methods

The following species were used: ATCC strains of *P. aeruginosa*, *E. coli*, *S. aureus* and *E. hirae*. For the suspension test, 9 ml of Sterillium were mixed with 1 ml of the inoculum. After the exposure time of 30 seconds, 1 ml of the mixture was transferred to a solution containing valid neutralising agents and mixed. After five minutes, serial dilution was performed, aliquots were transferred to tryptic soy agar, plates were incubated, and the reduction of viable counts was calculated as the difference before and after the exposure time. Four replicates were performed.

In addition, 13 Gram-positive species,18 Gram-negative species and 14 emerging pathogens were used to determine the efficacy of Sterillium in the Time Kill Test. Among them were species such as MRSA, VRE, *S. pneumoniae, A. baumannii* and *K. pneumoniae*.

For all species, except the emerging pathogens, the efficacy was determined both against an ATCC strain and a clinical isolate. 99 ml of Sterillium were supplemented with 1 ml of inoculum and stirred. After the exposure time of 30 seconds, 1 ml of the mixture were transferred to 9 ml of a solution containing valid neutralising agents and mixed. Serial dilution was performed and aliquots from selected dilution plated on appropriate types of agar. After appropriate incubation colonies were counted and the $\log_{10}$ reduction calculated.

Results

Sterillium killed all four test bacteria by > 5 $\log_{10}$ steps within 30 seconds. In the Time Kill Test, all 13 Gram-positive bacteria, all 18 Gram-negative bacteria and all 14 emerging pathogens were killed by > 5 $\log_{10}$ steps within 30 seconds. See the table below for detailed results.

Conclusions

Sterillium, a hand rub with bactericidal activity according to prEN 12054 (now: EN 13727) has comprehensive bactericidal activity including many multi-resistant species.

Practical relevance

Healthcare workers can be confident of antimicrobial efficacy of Sterillium against all the organisms examined within 30 seconds.

Source: Journal of Hospital Infection 2003; 55: 226–231

Wirksamkeit von Sterillium gemessen als minimale $\log_{10}$-Reduktion im Time Kill Test (Auszug):

Species	ATCC Stamm	Klinisches Isolat
Streptococcus pneumoniae	5,87	5,77
Streptococcus pyogenes	5,83	6,23
Acinetobacter baumannii	6,60	5,32*
Burkholderia cepacia	6,04	5,94
Enterobacter cloacae	7,00	5,89
Klebsiella pneumoniae	6,58	6,42
Proteus mirabilis	6,85	6,08
Salmonella typhimurium	6,23	6,54
Serratia marcescens	6,52	6,00
Mycobacterium tuberculosis	5,88	5,92 (MRE**)

* Bei einem klinischen Isolat handelte es sich um Acinetobacter calcoaceticus var. lwoffii

** MRE = multiresistenter Erreger

Kampf, G. / Steinmann, J. / Rabenau, H. (2007)

Suitability of vaccinia virus and bovine viral diarrhoea virus (BVDV) for determining activities of three commonly-used alcohol-based hand rubs against enveloped viruses

Background

So far, there is no European standard procedure available to determine the activity of a disinfectant against enveloped viruses. However, in 2004, a national test method has been published in Germany. According to this method it is possible to claim activity of a hand rub against all clinically relevant enveloped viruses including HBV, HCV and HIV, if the hand rub is effective against vaccinia virus and bovine viral diarrhoea virus (BVDV). But it has never been shown systematically, if other relevant viruses are inactivated within the same exposure time.

Methods

In order to determine the activity of three hand rubs against vaccinia virus, BVDV and four other enveloped viruses with four different types of organic load, the reduction of viral infectivity was measured according to the German DVV/RKI* guideline. The test principle is identical to EN 14476. Three hand rubs were included: Sterillium, based on 45 % isopropanol, 30 % n-propanol and 0.2 % mecetronium etilsulfate; Manusept basic, based on 80 % ethanol; and Sterillium Virugard, based on 95 % ethanol. In addition to vaccinia virus and BVDV, herpes simplex viruses (HSV) type 1 and 2 were tested along with two influenza A viruses (human and avian) at exposure times of 15, 30 and 60 seconds. Four different types of organic load were included: 10 % foetal calf serum (FCS), 0.2 % bovine serum albumin (BSA) as well as clean and dirty conditions according to EN 14476. Water served as a negative control for organic load. The activity was expressed as a $\log_{10}$ reduction of viral infectivity in appropriate cell cultures.

Results

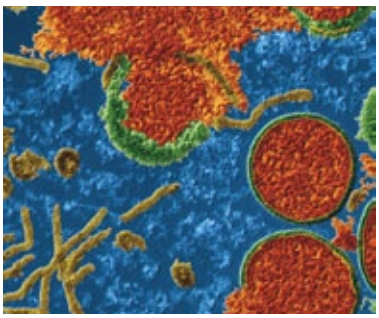
All three alcohol-based hand disinfectants reduced the infectivity of vaccinia virus and BVDV by ≥ 4 $\log_{10}$ steps within 15 seconds with or without organic load. Similar results were yielded against the other four enveloped viruses within 15 seconds, also irrespective of the type of organic load.

Conclusions

The authors found that all the types of organic load tested in these experiments barely compromised the activities of the hand rubs against various enveloped viruses. It has previously been shown that the type of organic load may impair the mean reduction of viral infectivity significantly in a test under practical conditions. Hence, it was vital to confirm activity not only against different viral species but also under varying types of organic load.

Practical relevance

A hand rub with 75 % of alcohol or more, e.g. Sterillium, which is active against vaccinia virus and BVDV, is also active against many other clinically relevant enveloped viruses.



Vaccinia virus

Source: BMC Infectious Diseases 2007; 7: 5

*German Registered Association for Combating Viral Diseases (DVV); Robert Koch-Institute (RKI)

Reduction of viral infectivity ($\log_{10}$ steps) obtained with Sterillium (based on 45 % isopropanol, 30 % n-propanol and 0.2 % mecetronium etilsulfate) against six different enveloped viruses with different types of organic load

Type of organic load**	BVDV	Vaccinia virus	HSV 1	HSV 2	Human influenza A virus	Avian influenza A virus
Reduction of viral infectivity ($\log_{10}$-steps) with a defined contact time***						
None (aqua bidest.)	≥ 4.3	≥ 6.3	≥ 4.0	≥ 4.8	≥ 4.3	≥ 5.1
10 % FCS	≥ 4.3	≥ 5.3	≥ 4.3	≥ 4.8	≥ 4.4	≥ 5.3
0.2 % BSA	≥ 4.8	≥ 5.6	≥ 4.0	≥ 5.0	≥ 4.3	≥ 5.3
"clean conditions"	≥ 4.7	≥ 5.7	≥ 4.4	≥ 4.1	≥ 4.4	≥ 5.0
"dirty conditions"	≥ 4.5	≥ 6.4	≥ 4.4	≥ 4.1	≥.4.0	≥ 5.4

*** FCS: foetal calf serum; BSA: bovine serum albumin; „clean conditions": (0.03 % bovine serum albumin); „dirty conditions": (0.3 % bovine serum albumin and 0.3 % sheep erythrocytes)*

**** one result is presented in which the $\log_{10}$ reduction was the same at all three exposure times*

Suchomel, M. / Gnant, G. / Weinlich, M. / Rotter, M. (2009)

Surgical hand disinfection using alcohol: the effects of alcohol type, mode and duration of application

Background

Due to their strong antimicrobial activity, rapid action, good skin tolerability and ease of use, alcohol-based hand rubs are recommended for surgical hand disinfection. Three hand disinfectants based on different types of alcohol were tested in accordance with the European EN 12791 standard with a shortened application time.

Methods

The study followed the specifications of EN 12791. Study series 1 and 2 were conducted with 21 test subjects - study series 3 with 20 subjects. The test persons were divided into three groups for the first two test series and into four groups during the third test series. For the first experimental series, surgical hand disinfection was performed with Sterillium (propan-2-ol 45.0 g, propan-1-ol 30.0 g, mecetronium etilsulfate 0.2 g) and a reference alcohol (n-propanol, 60 % v/v). The subjects applied as much Sterillium as necessary to keep the hands wet for 1.5 or 3 minutes. In the second test series, two other hand disinfectants (one based on propanol and one based on ethanol) were tested for their efficacy within 1.5 minutes. For the third test series, hands and forearms were rubbed with Sterillium for 1.5 and 3 minutes, respectively. The exposure time for the reference procedure was always 3 minutes – with and without application to forearms. To determine the preparations' immediate effect and 3-hour values, the test persons rubbed their fingers in tryptic soy broth for 1 minute followed by serial dilution, agar plating and incubation.

Results

With a shortened exposure time of 1.5 minutes, Sterillium fulfilled the EN 12791 efficacy requirements, also when the forearms were included. With an exposure time of 3 minutes Sterillium yielded $\log_{10}$ reductions of 3.43 ± 1.28 (immediate effect) and 2.16 ± 1.23 (3-hour-value) and thus even exceeded the efficacy of the reference procedure (immediate reduction: 2.97 ± 0.97; 3-hour value: 1.60 ± 0.97). The second hand disinfectant based on propanol also met the test requirements. The ethanol-based hand disinfectant, however, failed to achieve a sufficient efficacy within the 1.5-minute hand disinfection.

Conclusions

The authors conclude that an alcohol-based hand disinfectant containing a mixture of two highly concentrated propanol types within 1.5 minutes yields an efficacy that is at least as high as the 3-minute hand disinfection with the reference alcohol (EN 12791). The tested ethanol-based product for hand

disinfection did not fulfil the efficacy requirements within 1.5 minutes although when the alcohol concentration was equally high. The antimicrobial efficacy on the resident hand flora of alcohol-based hand disinfectants varies depending on the type of alcohol used (propan-1-ol is more effective than propan-2-ol, which is better than ethanol), the respective concentration and application time.

Practical relevance

Sterillium effectively disinfects hands and forearms within 1.5 minutes.

Source: Journal of Hospital Infection 2009; 71: 228-233

Immediate and 3-hour effect of the alcohol-based hand rub Sterillium after application for 1.5 and 3 minutes with inclusion of the forearms as compared with the reference disinfection according to EN 12791 and with inclusion of the forearms (modified reference)

	Length of application (min)	Forearm included	Mean (N = 20) $\log_{10}$ reduction ± SD	
			Immediate	3h
Sterillium	1.5	Yes	3.12 ± 1.46	1.98 ± 0.88**
Sterillium	3	Yes	3.88 ± 1.03*	2.64 ± 1.09
modified reference	3	Yes	2.90 ± 0.78	2.31 ± 0.87
reference	3	No	2.86 ± 0.87	2.11 ± 0.84

** Significantly (two-tailed $P < 0.05$) superior to reference.*
***Significantly ($P < 0.05$) inferior to product C (ethanol, 78.2 % w/w and biphenyl-2-ol, 0.1 %) (3min).*

Sterillium®: Role model for skin tolerability matters

Intact skin is the prerequisite for effective hand hygiene.
It is precisely the hands of caregivers, however, that are exposed to different skin-stressing influences every day. Particularly repeated handwashing or inadequate skin care jeopardise the skin's health. The consequences often are dry and rough skin that may lead to irritant contact dermatitis. This inflammatory skin disease is one of the most common occupational diseases among health care workers. Hand disinfection is better tolerated than handwashing. Many healthcare workers consider the high hygiene requirements as the cause of skin irritations. An opinion that is correct for frequent handwashing but not for alcohol-based hand disinfection. On the contrary: the development of Sterillium fifty years ago for the first time allowed skin-friendly disinfection with high quality products. Since then, around thirty dermatological, observational and clinical studies have confirmed Sterillium's skin tolerability.

Also the pharmacovigilance data, i.e. the collection and monitoring of adverse effects with pharmaceutical products that is obligatory in Germany and the EU, speak for themselves: skin irritations attributed to the use of Sterillium were only reported forty-five times in 2012 – this corresponds to one case in sixty-six million applications.

Additional skin care
Sterillium is well tolerated on the skin, but also has nurturing properties, as proved by a recent study, which measured, for example, the skin hydration, skin elasticity and the transepidermal water loss (TEWL). The intensive application of Sterillium increased the skin hydration condition and additionally improves the skin's health thanks to its moisturising substances refuting the prejudice that alcohol-based hand rub dries the skin. A fundamental finding, because the hand disinfectant's skin tolerability and the employees' skin health are the most important prerequisites that encourage healthcare workers to actually perform hand disinfection.

Even after fifty years, Sterillium's skin-friendly formula has lost none of its modernity.

RCTS, Barry (2014)

Evaluating the effect of a hand sanitiser using an exaggerated handwash method

Background

To improve the compliance in hand hygiene and to effectively prevent infections, hand disinfectants need to be effective and accepted by the users. In terms of efficacy and skin tolerability, alcohol-based hand disinfectants are considered the state of the art in hand hygiene. However, there are often concerns that frequent hand disinfection with alcohol-based products might dry the skin or disturb the skin barrier. Hence, besides possessing a reliable efficacy, hand disinfectants need to be skin friendly or even exhibit skin caring effects e.g. by moisturizing the skin.

Methods

The prospective clinical study examined the effects of Sterillium classic pure on skin of 29 healthy subjects with special emphasis concerning skin caring effects. The intention was to simulate intensive hygienic hand disinfection similar to daily clinical routine. Three ml of Sterillium classic pure were applied to the designated hand of the subject and rubbed in for 30 seconds by a technician using gloved hands and allowed to air dry for at least 40 seconds. This procedure was repeated 30 times per day during 10 treatment Days. Thus, Sterillium classic pure was applied 300 times to every subject. The second hand was not treated and served as control. Duration of the treatment phase was 12 Days.

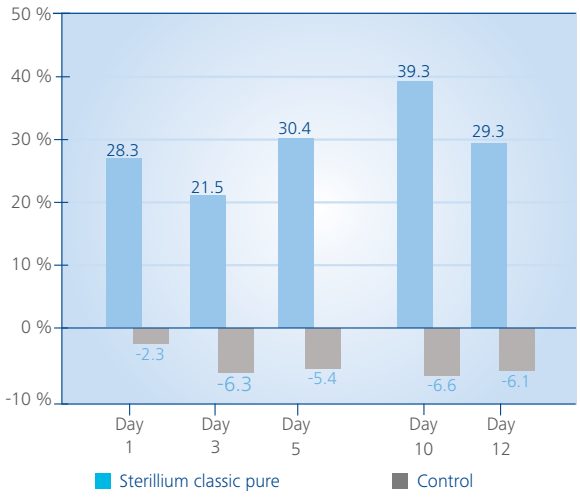
Skin moisture, skin pH, skin elasticity, desquamation index, skin texture and wrinkles, and transepidermal water loss (TEWL) were measured. The objective assessment of the skin tolerability included dryness and inflammatory skin changes by a clinical grader. The subjective skin tolerability was defined on the basis of dryness values, and the assessment of redness, and the overall condition and the feel of tension in the skin by the subjects.

Results

The increased corneometer values showed that the intensive application of Sterillium classic pure resulted in a significantly improved skin hydration on every measuring time point compared to baseline and compared to the untreated hand. At the end of the first test week, skin hydration had significantly increased by 30.4 %. On the tenth day, the increase in skin hydration was 39.3 %. The subjective perception reflected these results: at all time points, the skin dryness declined compared to the baseline (pre-value).

Conclusions

Change in skin hydration relative to baseline in % (corneometer data)



The repeated daily use of Sterillium classic pure significantly increases corneometer values, indicating an increase in skin hydration. This result was further substantiated by skin firmness data, desquamation index and subjects self-assessment of dryness. Furthermore, measurement of transepidermal water loss suggests that the skin barrier remains within the range of healthy skin. The same holds true for the measured pH-values which also remained within the range of healthy skin.

Practical relevance

Taken together, the concern that the frequent use of alcohol-based hand disinfectants may damage the skin could be dispelled for Sterillium classic pure.

As the formulations of Sterillium and Sterillium classic pure are identical except colourants and fragrance, the skin caring properties of both products are comparable.

Source: RCTS' Study No. 3295

Proske O. / Sauermann G. / Pietsch H. / Rohde B. (1995)

The skin tolerability of mecetronium etilsulfate in a hand disinfectant – a clinical study

Background

Hand disinfectant selection criteria are based, on the one hand, on the results of bacteriological examinations and, on the other hand, on the clinical skin compatibility. Especially the latter – together with the subjective user acceptance – is particularly important when it comes to compliance. The study examined the hand disinfectant Sterillium, which contains the active ingredient mecetronium etilsulfate (MES), in direct comparison with the basic Sterillium formula without MES (control group). The focus was on the question of which impact MES has on the dermatological and cosmetic properties of Sterillium.

Methods

In the double-blind study with cross-over design, Sterillium with MES and the basic Sterillium formulation without MES were investigated in fifteen test subjects over two periods of four weeks each. Both products were tested at the same time: one on the left, one on the right hand. After a five-week rest period, the products were applied to the respective other hand. During both test periods, the study participants were encouraged to use the product as often as possible on working days. At the beginning and the end of the two test cycles, the hands were examined by a specialist. This examination was complemented by questionnaires. Also the test subjects were asked to fill in standardised questionnaires to evaluate the subjective skin tolerability. Once per week, the skin's hydration was determined with a corneometer as skin capacitance as well as the skin roughness. Further skin changes were detected by means of reflectance and fluorescence spectroscopy.

Results

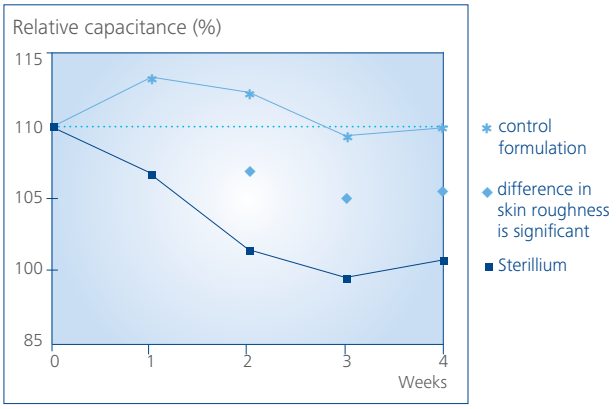
The specialist examination and the test persons' subjective assessment revealed that both test preparations were well tolerated. Two-thirds of the participants did not register any negative changes on the hands during both test periods – one third reported of positive effects of both products. The use of Sterillium with MES resulted in smoothing of the skin, which was significant compared to the control formulation at the end of the second week. Additionally, the results of reflectance spectroscopy for both preparations and the relative capacitance, which increased during the first test cycle, testify to the improvement of the skin hydration. The dryness and roughness that occurred and minimally increased during the second test phase can be attributed to weather conditions, because dry skin is more common in autumn.

Conclusions

Compared to the control preparation, MES in Sterillium has a significant roughness-minimising effect on the back of the hand and was at least equivalent in terms of the assessment criteria important for skin tolerability. In summary, the authors conclude that the good skin tolerability of Sterillium with MES is also given with regular use.

Practical relevance

Even with repeated application the special formulation of Sterillium with MES leads to good skin tolerability.



Relative skin roughness (profilometry) on the back of the hand under the influence of Sterillium with MES and the control formulation (Sterillium without MES). The data were standardised to the initial values and the means calculated.

Source: Hyg Med 1995; 20: 535-542

Kampf, G. / Muscatiello, M. (2003)

Dermal tolerance of Sterillium®, a propanol-based hand rub

Background

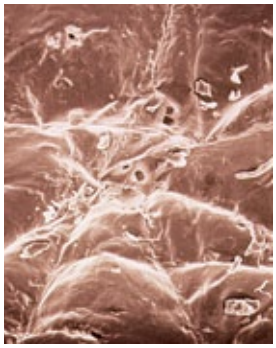
Occupational contact dermatitis is one of the main reasons for insufficient compliance in hand hygiene. Frequent handwashing with antiseptic soaps is often identified as cause of skin problems. Alcohol-based hand rubs possess better skin tolerability. However, there are often concerns that the alcohol in these products might damage the skin.

Methods

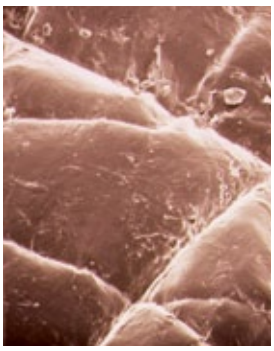
The study separated into two phases examined the skin compatibility of the hand disinfectant Sterillium. During the first three-week study period, Sterillium was applied under an occlusive patch on three predefined days per week (total of nine applications) to skin areas on the back of the test persons. The 55 test subjects removed the patch themselves 24 or 48 hours before application of the next patch. Before each application of the occlusive patch with Sterillium, the respective skin area was examined. After a two-week rest period, skin treatment was repeated on skin areas not treated before. This time, an employee removed the patch 24 hours after application. The skin areas concerned were examined for skin reactions immediately after patch removal, and 48 and 72 hours later.

Results

During the first phase, two of the 55 test subjects had a barely perceptible minimal erythema at one of nine time points. None of the remaining 53 test participants had a skin reaction at any time. During the second study period (challenge phase), none of the subjects had any skin reaction 72 hours after the application of the disinfectant.



Cracked skin



Intact skin

Conclusions

The study showed that Sterillium has no clinically relevant potential for dermal irritation and sensitisation. According to the authors, the very good skin compatibility of Sterillium can contribute to enhanced compliance in hand hygiene.

Practical relevance

Hand disinfection has no negative effect on the users' skin health provided that a product such as Sterillium is used that has proved to be gentle on the skin.

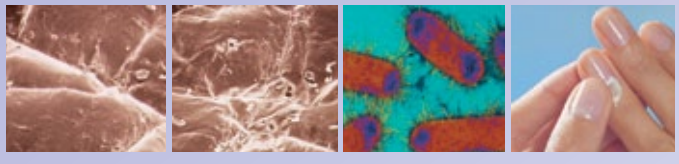
Source: Journal of Hospital Infection 2003; 55: 295-298

Proper skin protection is the most important precondition for intact skin and safe hygiene

Skin damages belong to the most frequent occupational diseases. Major risk factor: frequent work in wet environments. This for instance includes – according to dermatologists and statutory accident insurance carriers – frequent handwashing, contact with water or long wearing of gloves. Protective and regenerating products can prevent lasting skin damages. Skincare products belong to the personal protective equipment (PPE) and need to be provided by the employer and used by the employee. Professional Associations and the RKI's guideline on hand hygiene recommends:

- applying a protective W/O (water-in-oil) product before contact with aqueous solutions.
- rubbing hands with a light, quickly absorbing O/W (oil-in-water) emulsion several times a day during work.
- using moisturising W/O (water-in-oil) products before breaks, and after each shift.

Ideally, skincare products are compatible with hand disinfectants and glove materials so that skin care can be performed during work without any problems.



Repeated wet work leads to skin damages: SEM micrograph of health skin (left) and flaky skin (right).

Only intact skin provides pathogens no niches and ensures proper hand disinfection without burning sensation.

Sources:
1 Richtlinie 89/656/EWG des Rates vom 30. November 1989 über Mindestvorschriften für Sicherheit und Gesundheitsschutz bei Benutzung persönlicher Schutzausrüstungen durch Arbeitnehmer bei der Arbeit.
2 Händehygiene. Mitteilung der Kommission für Krankenhaushygiene und Infektionsprävention am Robert Koch-Institut. Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz 2000, 43:230-233.
3 BGR 197 Berufsgenossenschaftliche Regeln für Sicherheit und Gesundheit bei der Arbeit, Benutzung von Hautschutz, April 2001.
4 TRGS 401 Technische Regeln für Gefahrstoffe, Gefährdung durch Hautkontakt, Ermittlung, Beurteilung, Maßnahmen, Oktober 2006.
5 TRGS 540 Technische Regeln für Gefahrstoffe, Sensibilisierende Stoffe, Februar 2000.

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BSB100023EN_0315_1

Kampf, G. / Wigger-Alberti, W. / Wilhelm, K.P. (2006)

Do atopics tolerate alcohol-based hand rubs? A prospective, controlled, randomised double-blind clinical trial

Background

Occupational hand dermatitis is a frequently disease found among healthcare workers (HCW). An atopic constitution has been described to be associated with hand dermatitis in HCW. The dermal tolerance of hand rubs among atopic subjects, however, is unknown. Therefore, the aim of the study was to determine the dermal tolerance of five hand rubs among subjects with an atopic constitution.

Methods

Among others the following hand rubs were tested: Sterillium, Sterillium Gel and Sterillium Virugard. All hand rubs were blinded for the study. Demineralised water and 2 % sodium dodecyl sulphate served as controls. 54 subjects were recruited, half of them had an atopic predisposition with a modified Erlanger atopy score ≥ 8. In a patch test, 150 µl of the test material (product or controls) were applied on days 1, 2 and 3 to a test area on the forearm. The test material was left under semi-occlusive conditions for 3 x 23 hours. In order to evaluate tolerability, visual assessment was performed before the application on day 1, before each application on days 2, 3 and 4 as well as 48 hours (day 5) and 72 hours (day 6) after the last product application. A scale from 0 to 4 was used (0 = no apparent cutaneous involvement; 4 = very severe erythema with oedema). Mean tolerability scores were calculated for each treatment for both subject groups over days 4, 5 and 6. Skin redness was measured using a chromameter on the treatment areas in triplicate before the product application on day 1 (baseline) and during the final visit on day 6. The difference between the respective test points and baseline were taken for analysis.

Results

All hand rubs were well tolerated by both non-atopics and atopics. There was no significant difference between both groups (see table). The overall difference in skin redness was 0.15 with the negative control and 1.35 for the positive control. For the hand rubs, the difference in skin redness was in the range of the negative control (0.01 to 0.28). There was no significant difference between non-atopics and atopics.

Conclusions

The authors conclude that five commercially available alcohol-based hand rubs were all well tolerated by atopic subjects. Skin reactions and skin redness were in the same range as the negative control among non-atopics and atopics.

Practical relevance

The dermal tolerance of Sterillium is good, even among atopic subjects.

Source: Acta Derm Venereol 2006; 86: 140–143

Mean ± SD tolerability for five different alcohol-based hand rubs among atopic (n=26) and non-atopic (n=28) test subjects, controlled with demineralised water and 2 % sodium dodecyl sulphate (SDS)

	Tolerability		
Type of hand rub	Atopic subjects	Non-atopic subjects	All subjects (n = 54)
Demineralised water (negative control)	0.01 ± 0.03	0.04 ± 0.08	0.02 ± 0.07
2 % SDS (positive control)	0.15 ± 0.37	0.22 ± 0.41	0.19 ± 0.39
Sterillium	0.01 ± 0.03	0.01 ± 0.04	0.01 ± 0.04
Sterillium Gel	0.00 ± 0.00	0.01 ± 0.04	0.01 ± 0.03
Sterillium Virugard	0.01 ± 0.05	0.04 ± 0.13	0.02 ± 0.10

Hand disinfection and atopics

Especially among caregivers, contact dermatitis occurs frequently. One risk factor is atopy, i.e. an inherited predisposition which causes a tendency to develop skin irritations or allergies. A prospective, controlled, randomised double-blind study investigated the dermal tolerance to five alcohol-based hand disinfectants* among atopics and non-atopics (1).

Both atopics and non-atopics tolerated all five alcohol-based hand disinfectants well: no or only slight skin irritations occurred in comparison to the negative control (water). Conclusion: when using high-quality alcohol-based hand disinfectants on intact skin, also atopics can disinfect their hands without having skin irritations. Irritant reactions only occur on pre-damaged skin.

Atopics bear a higher risk of developing contact dermatitis.

1 Kampf G, Wigger-Alberti W, Wilhelm KP. Do atopics tolerate alcohol-based hand rubs? A prospective, controlled, randomized double-blind clinical trial. Acta Derm Venereol 2006; 86:140-143.

* The products tested included Sterillium, Sterillium Gel and Sterillium Virugard

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BSB100037EN_0315_1

Kramer, A. / Berning, T. / Kampf, G. (2002)

Clinical double-blind trial on the dermaltolerance and user acceptability of six alcohol-based hand disinfectants for hygienic and disinfection

Background

The dermal tolerance of alcohol-based hand rubs and the perception of the emollient effect are relevant factors for a good compliance in hand hygiene. But comparative data between hand rubs are rare. Aim of the study was to determine the objective dermal tolerance of Sterillium and five other hand rubs and the subjective perception of their smell, speed of drying, emollient effect and skin dryness after application.

Methods

The six hand rubs were investigated in a clinical double-blind trial involving 17 participants, divided into two groups. The first group consisted of 10 subjects without any experience in using hand rubs. They used each hand rub for seven days. On day one, it was used 20 times, on days two to seven, it was used 5 times per day. Objective measurements such as TEWL were done as baseline before the first application and on days two and seven at least three hours after the last application of test agent. Subjective assessments were performed at the end of days one and seven. The second group consisted of seven workers of a virology laboratory and used each hand rub twice in two-week blocks. Transepidermal water loss, superficial sebum content, skin pH and skin hydration were measured before and after the seven-day application of the products. The subjective assessments were performed after the first contact with each preparation, and at the end of each two-week block. Apart from Sterillium, six other hand rubs were investigated in a clinical double-blind trial. In order to assess user acceptability, smell, speed of drying, emollient effect and skin dryness, all six hand rubs were evaluated using a five point scale.

Results

All tested objective parameters did not change significantly with each of the hand rubs. Significant differences were mainly seen for the subjective assessment of the smell and the emollient effect within group one. The best scores for the emollient effect were seen with Sterillium. In group two, significant differences were mainly seen regarding the emollient effect and the skin dryness after application. The best scores were found with Sterillium.

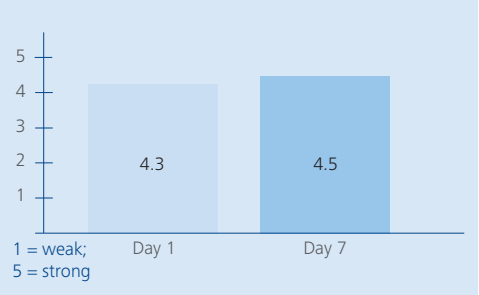
Conclusions

The objective measurement of the dermal tolerance is equally good for various hand rubs but the user may well perceive significant differences mainly in the emollient effect. This finding is relevant in order to understand changes in compliance in hand hygiene. The subjective perception of the emollient effect of Sterillium is superior.

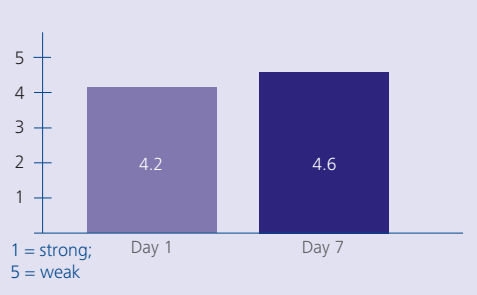
Practical relevance

Because of the perception of the emollient effect Sterillium is comfortable in use for healthcare workers.

Source: Journal of Hospital Infection 2002; 51: 114-120



Sterillium is superior in the emollient effect within the subjective assessment (group 1). The higher the value the better the perceived skincare effect.



The self-assessed dryness after the application of Sterillium (group 1). The higher the value the lower the perceived dryness.

Girard et al. (2006)

Tolerance and acceptability of fourteen surgical and hygienic alcohol-based hand rubs

Background
When selecting a hand disinfectant, the following factors require particular attention: health, safety and costs. Infection control practitioners need to choose a product that possesses the required efficacy and a good skin tolerability. At the same time, the product should enjoy high user acceptance, be easy to use and cost effective. A high user acceptance is very much determined by the hand disinfectant's skin tolerability.

Methods
The study examined the tolerability and user acceptance of fourteen different hand disinfectants with proved efficacy. The five-month study had four three-week phases. The participating hospitals routinely used two hand disinfectants: Sterillium for surgical hand disinfection and a second product for hygienic hand disinfection. Most hand disinfectants were tested twice: eight of them were compared to the surgical hand disinfection with sterillium and ten of them to the routine product used for hygienic hand disinfection.

The four study periods were separated by two-week intervals during which the customary product for surgical (Sterillium) and hygienic hand disinfection was used again. A total of four operating theatre teams and twelve wards at different clinics participated in the study. Before and after each test period, skin dryness and irritation was examined. User acceptance and ease of use (e.g. smell and rub-in characteristics) and whether a switch to the new product was desired was determined by means of a questionnaire at the end of every study period.

Results
The data showed that Sterillium was better tolerated than the tested preparations. Only for two other products the difference was not significant. Just two test persons (7.7 %) showed skin reactions when applying Sterillium. The evaluation of the questionnaires additionally revealed that the employees wanted to continue using Sterillium for surgical hand disinfection.

Users' assessment of surgical hand rubs

	Sterillium	Sterillium Gel
Good viscosity	80.8 %	76.5 %
Pleasant texture	96.2 %	64.7 %
Pleasant/neutral fragrance	80.8 %	82.4 %
Intolerance	7.7 %	41.2 %

Conclusions
The authors conclude that the acceptance of Sterillium is high in the respective hospitals. They emphasise that the user acceptance plays a central role when selecting a suitable hand disinfectant.

Practical relevance
When choosing a hand disinfectant, the employees' acceptance should be considered. The acceptance can, for example, be determined by the skin tolerability and subjective factors such as smell and rub-in characteristics.

Source: Journal of Hospital Infection 2006; 63: 281-288

Sterillium®: Paving the way for more compliance

Good compliance with hand hygiene protocols is a central element of infection control. The reason: protection against nosocomial infections can only be ensured when healthcare workers perform hand disinfection correctly and when indicated. For caregivers to adhere to hygiene protocols, compliance, however, needs to be simple. Since its development, Sterillium has strongly contributed to the simplification of hand disinfection and thus the improvement of compliance.

Simplification of working processes

This already began with Sterillium's launch in 1965. At that time, during ward rounds and patient care, hands were – if at all – washed with a rather skin-damaging, less effective solution. Sterillium superseded this less effective, time-consuming and skin-stressing procedure. Its high alcohol concentration ensured a reliable, fast activity, and the skin caring substances made for good skin tolerability. This way, Sterillium facilitated hygiene and, at the same time, lowered the hurdle of carrying out necessary hand disinfection procedures regularly and correctly.

The many studies demonstrate that Sterillium has also brought forward hand hygiene compliance during the following decades. Scientific investigations prove that the introduction of Sterillium, supported by further measures, could increase the staff's compliance in hygienic hand disinfection [1, 2]. A true success that, to a large extent, is attributed to the product's very good skin tolerability and the associated increased user acceptance.

In 2008, a study initiated another important advancement in compliance with the "researcher product" Sterillium: it showed that the responsible rub-in method with users applying the preparation with their individual technique achieves much better results in coverage than the previously recommended six-step method according to EN 1500 [3]. This also made daily hand disinfection much easier and has sustainably promoted employees' compliance.

Training and better availability

Last but not least, intensive and regular training is important to assure the staff's level of hand hygiene knowledge. Likewise beneficial is the installation of wall dispensers at the point of care and the use of pocket bottles – they ensure the availability of the hand disinfectant when needed. Conclusion: employing certain targeted measures can increase the compliance in the healthcare setting and improve the protection against nosocomial infection [4].

Sources:
[1] Maury, E. et al. Availability of an alcohol solutioncan improve hand disinfection compliance in an intensivecare unit. Am. J. Respir. Crit. Care Med., 2000; 162: 324-7.

[2] Girard, R. et al. Better compliance and better tolerance in relation to a well-conducted introduction to rub-in hand disinfection. Journal of Hospital Infection, 2001; 47: 131-137.

[3] Kampf, G. et al. Einfluss der Einreibetechnik auf die benötigte Einreibezeit und die Benetzung der Hand bei der hygienischen Händedesinfektion. Hyg Med 2009; 34: 24–31.

[4] Kampf, G. et al. Händehygiene zur Prävention nosokomialer Infektionen. Dtsch Arztebl Int 2009; 106(40): 649-55.

Better compliance through good skin compatibility

Introducing Sterillium to a medical intensive care unit (MICU) as alternative to washing increased compliance with hand disinfection by almost 20 per cent. These results were attributed to Sterillium's good skin tolerability, even with repeated application.

Source: Maury E, et al. Availability of an alcohol solutioncan improve hand disinfection compliance in an intensivecare unit. Am. J. Respir. Crit. Care Med., 2000, 162: 324-7.

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BSB100027EN_0315_1

Girard, R. / Amazian, K. / Fabry, J. (2001)

Better compliance and better tolerance in relation to a well-conducted introduction to rub-in hand disinfection

Background

Hand disinfection is considered the most important measure to control nosocomial infection, yet compliance of healthcare workers is often inadequate. There are many reasons: high workload, lack of resources, or problems with the hand disinfection's tolerability. In addition, there are considerable differences between different occupational groups or clinical fields regarding hygiene practices. And different countries, e.g. France, recommend both antiseptic handwashing and alcohol-based rubs.

Methods

The study of Girard et al. addressed the issue of whether the introduction of an alcohol-based rub, Sterillium, in combination with other measures can increase the compliance. Furthermore, the two-phase study investigated which effect the application of Sterillium has on the skin condition of the health care workers. Between the two phases, the wards were equipped with dispensers for Sterillium, the staff was trained and specific guidelines on hand disinfection were defined.

The 20-week study was conducted in four wards of a French hospital. None of the wards had used alcohol-based rubs for hand disinfection before. During the first study phase, existing hand disinfection protocols were not changed, the alcohol-based hand disinfection rub was not available until the second phase. In both phases, compliance rates and further data on the quality of hand disinfection were measured, including the assessment of appropriate (adapted) hand disinfection procedures, properly performed (correct) procedures, and appropriate and properly performed procedures. For this, each member of the nursing staff was observed for 90 minutes while conducting several consecutive activities. In addition, skin hydration was determined with a corneometer, and dryness and irritation scores were investigated.

Results

During the first study phase, the average compliance rate was 62.2 %, which increased to 66.5 % in the second phase. In Ward 1, the compliance rose significantly from 52.6 % to 71.4 % ($p = 0.03$). Hand hygiene quality improved, too. The number of adapted procedures improved from 66.8 % to 84.3 %, the number of correct procedures from 11.1 % to 28.9 % ($p<10^6$ for both), and the rate of adapted and correct hand hygiene measures from 6.0 % to 17.8 % ($p<10^8$). The skin condition improved significantly as well. Clinical dryness scores decreased from 1.08 to 0.66 ($p<10^2$), irritation scores from 0.85 to 0.24 ($p<10^5$). The introduction of Sterillium led to the increase in the frequency of hand hygiene measures performed and improved the quality. In addition, this was linked to a better skin condition.

Conclusions

The authors concluded that the hand disinfection with an alcohol-based hand rub – supported by training, installation of dispensers and guidelines on hand hygiene – is suitable to reasonably change existing hygiene routines and improve the hand hygiene compliance. This was particularly reflected in Ward 1, as all healthcare workers had attended the information training.

Practical relevance

The use of alcohol-based rub-in products, e.g. Sterillium, combined with training and the availability of products, results in better compliance and contributes to better skin tolerability of hand disinfection.

Source: Journal of Hospital Infection 2001; 47: 131-137

continued on next page

Girard, R. / Amazian, K. / Fabry, J. (2001)

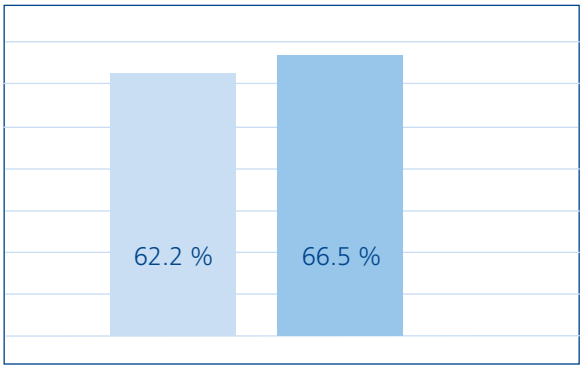
Better compliance and better tolerance in relation to a well-conducted introduction to rub-in hand disinfection

Adaption and quality of procedures by period

Criteria	First period	Second period	p*
Procedures carried out	382	280	
Adapted procedures**	225 (66.8 %)	236 (84.3 %)	$< 10^{-5}$
Correct procedures***	42 (11.1 %)	81 (28.3 %)	$< 10^{-6}$
Expected procedures	614	421	
Adapted and correct procedures	37 (6.0 %)	75 (17.8 %)	$< 10^{-8}$

* *Mantel Haenzel X^2 test*
** *procedure was appropriate for the clinical situation*
*** *procedure was performed correctly irrespective of its appropriateness*

Average compliance rates



Compliance before introduction of Sterillium

Compliance after introduction of Sterillium

Compliance: consider the employees' acceptance when selecting products.

In its hand hygiene guideline, the Robert Koch-Institute (RKI) emphasises the link between protecting skin and preventing infections: "Skin care on hands and forearms is an occupational duty, as even smallest cracks or microtraumas serve as potential reservoir for pathogens and uncared-for skin cannot be disinfected reliably." (1) For strongly promoting compliance, do not only consider efficacy data and moderate prices, but also the personnel's acceptance when selecting products. Gentle hand disinfectants and excellently fitting gloves have a share in higher acceptance and increased compliance, too. And compliance in turn is an essential measure for fighting nosocomial infections.

1 Empfehlungen Händehygiene. Mitteilung der Kommission für Krankenhaushygiene und Infektionsprävention am Robert Koch-Institut. Bundesgesundheitsblatt – Gesundheits-forschung – Gesundheitsschutz, 2000, 43: 230-233.

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Maury, E. et al. (2000)

Availability of an alcohol solution can improve hand disinfection compliance in an intensive care unit

Background
The employees' compliance in hand hygiene is often insufficient, independent of guidelines and recommendations. One of the reasons may be time constraints, especially when hand hygiene is performed as antimicrobial handwashing. Going to the washbasin, opening and closing the tap, drying the hands, etc. takes approximately one minute. A hand disinfection with alcohol-based rubs is faster and more effective. The French study by Maury et al. investigated whether the availability of an alcohol-based preparation (Sterillium) increases compliance in hand disinfection in a medical intensive care unit.

Methods
The study was conducted in a 14-bed medical intensive care unit during two consecutive five-week periods and included 53 employees. Hand hygiene comprised both handwashing and hand disinfection with Sterillium. Indications for hand hygiene were clearly defined: personal reasons; treatment of patients with and without exposure to body fluids. During the first period (P1), hand hygiene could only be performed with soap; during the second period (P2), there additionally was Sterillium as an alcohol-based hand disinfectant available. Performance of hand hygiene measures was determined by direct observation. In addition, participating healthcare workers received an anonymous questionnaire to rate their personal perception of Sterillium. After four months, compliance was assessed again.

Results
The average compliance rate during P1 was 42.4 %, and increased to 60.9 % during P2. Nursing staff improved from 45.3 % to 66.9 %; senior physicians from 37.2 % to 55.5 %; and residents from 46.9 % to 59.1 %. After four months, the compliance was still higher than in P1 (51.3 % vs. 42.4 %), but lower than during P2 (51.3 % vs. 60.9 %). The difference was significant.

Conclusions
The study demonstrates a positive and lasting effect of the alcohol-based rub Sterillium on hand hygiene compliance. Senior staff and residents achieved the highest rates of increase. This group also preferred using Sterillium. In this respect, the authors also recommend using pocket bottles that allow hand disinfection to be carried out when indicated despite high mobility.

Practical relevance
Compliance with hand disinfection is higher, if the preparation is available where it is actually needed.

Source: American Journal of Respiratory and Critical Care Medicine 2000, 162: 324–327

Distribution of use of handwashing and alcohol rubbing during study phase 2 according to healthcare worker categories and handwashing category

Professional group or indication for hand hygiene	Global Compliance	Opportunities during which washing was performed	Opportunities during which rubbing was performed
Paramedical staff	66.9 %	32.9 %	34 %
Physicians	55.5 %	13.2 %	42.3 %
Residents	59.1 %	14.6 %	44.5 %
Personal gestures	49.2 %	12.9 %	36.3 %
Care without exposure to body fluids	63.4 %	18.9 %	44.5 %
Care with exposure to body fluids	61.3 %	35 %	26.3 %

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