Randomized Controlled Trial Testing the Impact of High-Protection Sunscreens on Sun-Exposure Behavior

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Objective: High-protection sunscreens have been suspected to prompt people to increase sun exposure, and thus to increase skin cancer risk. We tested the influence of both the actual protection (sun protection factor [SPF]) and the information about protection (label) on sun-exposure behavior.

Design: Randomized controlled trial.


Participants: A total of 367 healthy subjects during their 1-week holiday. Outcome was assessable in 98% of them.

Intervention: Subjects were offered free sunscreens, with randomization into the following study arms: (1) SPF 40 labeled as “high protection”; (2) SPF 40 labeled as “basic protection”; and (3) SPF 12 labeled as “basic protection.” Arm 4, ie, SPF 12 labeled as “high protection,” was not implemented for ethical reasons. Subjects were not aware of the real target of the study and were blinded to the SPF value.

Main Outcome Measure: Duration of sunbathing exposure during 1 week. Secondary outcomes were occurrence of sunburns and amount of sunscreen used. Influences of SPF and label were assessed separately.

Results: Compared with the low-SPF group, the high-SPF group did not have longer sunbathing exposure (12.9±7.2 h/wk for high SPF vs 14.6±6.7 h/wk for low SPF; P=.06), experienced fewer sunburns (14% vs 24%; P=.049), and used less sunscreen (median, 30 g vs 109 g; P<.001). The label “high protection” or “basic protection” had no influence on these end points.

Conclusions: In this adult population, higher SPF had no influence on duration of sun exposure and offered better protection against sunburns. Although higher SPF may increase sun exposure duration in specific populations, this effect cannot be viewed as a universal side effect of high-SPF sunscreens.

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were not informed (1) of the existence of a randomization pro-
the study.

ie, they agreed to use exclusively the free sunscreen given by
Grande Motte, Le Grau-du-Roi) and Atlantic (Seignosse) coasts,
ning to the actual SPF and sunscreen label.

We thus designed a randomized trial to test whether high-
SPF sunscreens have an impact on the sun-exposure be-
vior in people spending family holidays. We jointly ad-
dressed the impact of the actual high protection and the
impact of the impression of being well protected.

Our objective was to test the influence on sun-exposure be-
behavior in a usual family holiday week at the seaside of (1) the
actual ability of a sunscreen to protect against UV-B, which
is linked to its SPF; and (2) the information on the protection given
by the label on the tube.

We initially designed a theoretical 2 × 2 factorial random-
ized study testing both SPF (SPF 40 vs SPF 12) and label on the
tube (“high protection” vs “basic protection”) on the duration of
sun exposure in an adult population in seaside resorts. The 4
groups were designed as follows: (1) SPF 40 sunscreen labeled as
“high protection”; (2) SPF 40 sunscreen labeled as “basic pro-
tection”; (3) SPF 12 sunscreen labeled as “basic protection”; and
(4) SPF 12 sunscreen labeled as “high protection.” The ethical
committee did not allow the implementation of group 4. We there-
fore implemented 3 randomization groups (1, 2, and 3) accord-
ing to the actual SPF and sunscreen label.

The study took place in 4 French V V F Vacances resorts
situated on the French Mediterranean (Balearic-les-Bains, La
Grande Motte, Le Grau-du-Roi) and Atlantic (Seignosse) coasts,
during 5 consecutive weeks in July and August 2001.

Adults on their day of arrival at the resort were eligible for
the study, if they considered themselves sunscreen users and
volunteered to participate in a 1-week study on “skin and sun,”

ie, they agreed to use exclusively the free sunscreen given by
the on-site investigator during 1 week, to keep this sunscreen
for their own use, and to complete a questionnaire every evening.
Exclusion criteria were a history of skin cancer, recent history
of severe sunburn, contraindication to sun exposure, known
contact dermatitis to a sunscreens agent, pregnancy or breast-
feeding, and participation of another member of the family in the
study.

With the agreement of the ethical committee, participants
were not informed (1) of the existence of a randomization pro-
cess, (2) that different SPFs and labels were being tested, and
(3) of the actual objectives and outcomes, since this information
was expected to influence their behavior. An information
sheet was given containing pseudo-objectives not related to the
actual ones. After the study had been completed, participants
were fully informed by mail of the true objectives and out-
comes, and the reasons for masking were explained.

Sunscreens were especially made for this study by one of
the biggest manufacturers in France; SPF 40 and SPF 12 sun-
screens had the same components except for amount of filters
and screens. No mention of the actual SPF was made on the
label. Sunscreens had slightly different cosmetic properties on
direct comparison, SPF 12 being easier to spread.

A computer-generated randomization list, stratified by cen-
ter, with a fixed 8-length block design was drawn up by the
statistician (A. Dupuy). According to this list, the manufac-
turer prepared sealed boxes labeled with the randomization num-
ber, each containing 4 identical 150-ml sunscreen tubes. The
randomization number was also mentioned on each of the 4
tubes. The on-site investigator received the boxes ordered by
randomization number. He was unaware of the allocation un-
til the participant opened the box and was then able to ac-
knowledge only the type of label, not the actual SPF.

Participants were randomly assigned on an individual ba-
sis to 1 of the following 3 groups: (1) SPF 40 labeled as “high
protection” (referred to herein as the “high/40” group); (2) SPF
40 labeled as “basic protection” (the “basic/40” group); and (3)
SPF 12 labeled as “basic protection” (the “basic/12” group). No
mention of the actual SPF was made on the label. Each partic-
ient received 4 identical 150-ml tubes of the assigned sun-
screen. Brand-name sunscreens of intermediate SPF were given
to the rest of the family to avoid use of the tested sunscreen by
the participant’s relatives.

Participants had to complete an initial questionnaire that
included questions about their general sun-exposure behav-
ior. Every evening, they had to complete a self-administered
questionnaire describing, for every half-hour period during that
day, the type of sun exposure and body surface exposed to sun

(Figure 1). A final interview was collected at the end of the
last day.

The main outcome measure was the duration of “sunbath-
ing” defined as sun exposure while wearing a swimming suit or
equivalent. The method of calculating duration of exposure
from the questionnaire data is demonstrated in Figure 1. The
mean cumulative exposure by subject for the week was com-
pared across the randomization groups. The other outcome mea-
sures were the occurrence of sunburns (defined as “sunburn
or painful skin reddening” assessed during a structured inter-
view at the end of the last day of participation) and sunscreen
consumption, measured by weighing all the sunscreen tubes
at the end of the study. Tube weighing was done with the in-
vestigator blinded to allocation group.

To have a 90% chance of detecting as significant (at the
2-sided 5% level) a 2-hour difference during the week be-
tween 2 groups with an assumed standard deviation of 4.5 hours
and a mean duration of exposure during the week of 14 hours,
107 subjects in each group were required.

As the 2 × 2 factorial analysis could not be used, 2 separate
analyses were conducted: (1) the effect of SPF was analyzed by
comparing both groups with 2 different SPFs but featuring
the same label (the basic/40 and basic/12 groups); and (2) the
effect of label was analyzed by comparing both groups with 2
different labels but with the same SPF (the high/40 and ba-
sic/40 groups). Proportions of subjects with sunburn during
the week were compared with the χ² test and by logistic re-
gression. Sunscreen consumptions were compared by nonpara-
metric analysis of variance (Kruskal-Wallis test). All analyses
were adjusted by center and by week period (all people having

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the same weather within center and week period). Because pho-
totype (skin color and sensitivity to sun) is known to influ-
ence sunscreen consumption and sun exposure, it was also in-
cluded in the regression models. Unless otherwise specified,
the analyses were carried out on an intention-to-treat basis. Two-
sided significance tests (5% level) were used throughout. Sta-
tistical analysis was conducted with SAS software, version 8.02

**RESULTS**

Three hundred sixty-seven subjects were randomized. Eighty percent were female; their mean ± SD age was 39 ± 10
years. Eight subjects resigned just after randomization and
could not be analyzed for any outcome. Three hundred fifty-
nine subjects were followed up for at least 1 day and could
be analyzed for duration of sun exposure. Among them,
342 (95%) completed the 1-week study. A flow diagram
of the trial is presented in **Figure 2**. Baseline character-
istics in the 3 groups are presented in **Table 1**.

**DURATION OF SUN EXPOSURE**

Mean ± SD duration of sunbathing exposure during the
week was 14.2 ± 7.6 hours in the high/40 group, 12.9 ± 7.2
hours in the basic/40 group, and 14.6 ± 6.7 hours in the
basic/12 group. The SPF was not associated with signifi-
cantly different durations of sunbathing during the week
\((P = .06)\), nor was it the label \((P = .13)\). Of note, the dura-
tion of exposure was higher in the basic/12 group than
in the basic/40 group. No significant overall difference
between the groups in duration of sun exposure regard-
less of clothing could be demonstrated either (**Table 2**).
Even when the analysis was performed in a “per-protocol” population (n=276; 77% of the intention-to-treat population), ie, after exclusion of the participants who declared that they had used, at least once during the week, another sunscreen than the one provided, neither the SPF nor the label significantly influenced the duration of sunbathing (P=.13 and P=.25, respectively).

SUNBURNS

The proportion of subjects who experienced sunburn during the week was higher in the low-SPF group than the high-SPF group with the same label (29 subjects [24%] in the basic/12 group vs 16 [14%]; P=.049 by χ² test). The adjusted risk for sunburn associated with a low SPF was close to significance: odds ratio, 1.96; 95% confidence interval, 0.98-3.92; P=.06. Conversely, in the 2 groups with the same SPF, the type of label was not related to the risk of sunburn: 16 subjects (14%) in the “basic protection” label group vs 18 subjects (15%) in the “high protection” label group (odds ratio, 0.91; 95% confidence interval, 0.43-1.91; P=.80).

Overall, 63 participants experienced a sunburn, and it was severe (pain during more than 2 days or blistering).

Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>High Protection, SPF 40 (n = 119)</th>
<th>Basic Protection, SPF 40 (n = 117)</th>
<th>Basic Protection, SPF 12 (n = 123)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>La Grande Motte</td>
<td>31 (26)</td>
<td>30 (26)</td>
<td>32 (26)</td>
</tr>
<tr>
<td>Balaruc-les-Bains</td>
<td>33 (28)</td>
<td>33 (28)</td>
<td>35 (28)</td>
</tr>
<tr>
<td>Grau-du-Roi</td>
<td>20 (17)</td>
<td>20 (17)</td>
<td>21 (17)</td>
</tr>
<tr>
<td>Seignosse</td>
<td>35 (29)</td>
<td>34 (29)</td>
<td>36 (28)</td>
</tr>
<tr>
<td>Female sex</td>
<td>103 (87)</td>
<td>93 (79)</td>
<td>99 (80)</td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>40</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td>Median</td>
<td>40</td>
<td>38</td>
<td>40</td>
</tr>
<tr>
<td>Range</td>
<td>18-66</td>
<td>18-78</td>
<td>18-66</td>
</tr>
<tr>
<td>Week</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>23 (19)</td>
<td>22 (19)</td>
<td>28 (23)</td>
</tr>
<tr>
<td>2</td>
<td>27 (23)</td>
<td>26 (22)</td>
<td>27 (22)</td>
</tr>
<tr>
<td>3</td>
<td>25 (21)</td>
<td>25 (21)</td>
<td>21 (17)</td>
</tr>
<tr>
<td>4</td>
<td>22 (18)</td>
<td>18 (15)</td>
<td>23 (19)</td>
</tr>
<tr>
<td>5</td>
<td>22 (18)</td>
<td>26 (22)</td>
<td>24 (20)</td>
</tr>
<tr>
<td>Family size</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>1 (1)</td>
<td>0</td>
<td>3 (2)</td>
</tr>
<tr>
<td>2 People</td>
<td>19 (16)</td>
<td>11 (9)</td>
<td>16 (13)</td>
</tr>
<tr>
<td>3 People</td>
<td>22 (18)</td>
<td>25 (21)</td>
<td>28 (23)</td>
</tr>
<tr>
<td>≥4 People</td>
<td>69 (58)</td>
<td>71 (61)</td>
<td>70 (57)</td>
</tr>
<tr>
<td>NA</td>
<td>8 (7)</td>
<td>10 (9)</td>
<td>6 (5)</td>
</tr>
<tr>
<td>Main interests during stay*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rest</td>
<td>98 (82)</td>
<td>98 (84)</td>
<td>106 (86)</td>
</tr>
<tr>
<td>Tanning</td>
<td>29 (24)</td>
<td>15 (13)</td>
<td>30 (24)</td>
</tr>
<tr>
<td>Practice sport</td>
<td>37 (31)</td>
<td>33 (28)</td>
<td>43 (35)</td>
</tr>
<tr>
<td>Enjoy sun</td>
<td>32 (27)</td>
<td>30 (26)</td>
<td>26 (21)</td>
</tr>
<tr>
<td>Tourism</td>
<td>35 (29)</td>
<td>52 (44)</td>
<td>36 (29)</td>
</tr>
<tr>
<td>Ever exposed to sun (without protection)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>94 (79)</td>
<td>98 (84)</td>
<td>96 (78)</td>
</tr>
<tr>
<td>No</td>
<td>21 (18)</td>
<td>16 (14)</td>
<td>24 (20)</td>
</tr>
<tr>
<td>NA</td>
<td>4 (3)</td>
<td>3 (3)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>If yes, frequency of tanning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always or often</td>
<td>47 (50)</td>
<td>57 (58)</td>
<td>52 (54)</td>
</tr>
<tr>
<td>Rarely or never</td>
<td>27 (29)</td>
<td>22 (22)</td>
<td>30 (31)</td>
</tr>
<tr>
<td>Unknown</td>
<td>20 (21)</td>
<td>19 (19)</td>
<td>14 (15)</td>
</tr>
<tr>
<td>If yes, frequency of burning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always or often</td>
<td>51 (54)</td>
<td>40 (41)</td>
<td>43 (45)</td>
</tr>
<tr>
<td>Rarely or never</td>
<td>30 (32)</td>
<td>39 (40)</td>
<td>40 (42)</td>
</tr>
<tr>
<td>Unknown</td>
<td>13 (14)</td>
<td>19 (19)</td>
<td>13 (14)</td>
</tr>
<tr>
<td>Phototype</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A: fair complexion; blond, red, or light brown hair</td>
<td>44 (37)</td>
<td>41 (35)</td>
<td>42 (34)</td>
</tr>
<tr>
<td>B: dark complexion; dark hair</td>
<td>59 (50)</td>
<td>56 (48)</td>
<td>60 (49)</td>
</tr>
<tr>
<td>C: neither A nor B</td>
<td>15 (13)</td>
<td>20 (17)</td>
<td>20 (16)</td>
</tr>
<tr>
<td>NA</td>
<td>1 (1)</td>
<td>0</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>

Abbreviations: NA, data not available; SPF, sun protection factor.
*Respondents could name more than 1 interest.
CALCULATION OF DERMATOLOGIC FACTORS

Table 2. Duration of Sun Exposure During the Holiday Week

<table>
<thead>
<tr>
<th>Clothing*</th>
<th>High Protection SPF 40 (n = 119)</th>
<th>Basic Protection SPF 40 (n = 117)</th>
<th>Basic Protection SPF 12 (n = 123)</th>
<th>Label Comparison (Column 1 vs Column 2)</th>
<th>SPF Comparison (Column 2 vs Column 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swimming suit (sunbathing)</td>
<td>14.2 (7.6)</td>
<td>12.9 (7.2)</td>
<td>14.6 (6.7)</td>
<td>.13</td>
<td>.06</td>
</tr>
<tr>
<td>Light clothes</td>
<td>16.1 (8.3)</td>
<td>14.4 (7.7)</td>
<td>15.9 (7.1)</td>
<td>.08</td>
<td>.10</td>
</tr>
<tr>
<td>Short clothes</td>
<td>23.2 (8.4)</td>
<td>22.3 (8.6)</td>
<td>24.2 (7.7)</td>
<td>.37</td>
<td>.06</td>
</tr>
<tr>
<td>Any clothes</td>
<td>25.2 (8.1)</td>
<td>24.5 (8.3)</td>
<td>26.1 (7.7)</td>
<td>.49</td>
<td>.14</td>
</tr>
</tbody>
</table>

Abbreviation: SPF, sun protection factor.

*The clothing possibilities are presented in Figure 1. “Swimming suit” refers to clothing types 1, 2, and 4 for women and type 1 for men. “Light clothes” refers to clothing types 1 to 4 for women and types 1 to 3 for men. “Short clothes” refers to clothing types 1 to 5 for women and types 1 to 4 for men.

This trial is the first one, to our knowledge, to assess at the same time the influence of both the actual protection (the SPF) and the information about the quality of protection (the label) on sun-exposure behavior. Although, for ethical reasons, we could not use a complete factorial design that would allow a joint analysis of these 2 factors, the power was sufficient to analyze the differences by pair groups.

Several strengths in the design should be stressed. First, the study took place in real-life conditions, and we paid close attention to not modifying the usual behavior of the participants except for the intervention. They were not only blinded to SPF but also not informed of the actual design and objectives of the study, as is allowed by French law for studies dedicated to behavior analyses. Second, stratifying by center and adjusting the analyses for the week period led to ideal conditions for comparability of the weather conditions, which are an obvious determinant of sun-exposure behavior. Third, we avoided cross-contamination between participants by including a small number of participants each week and allowing only 1 participant per family; in addition, participants’ family members were given free open-label sunscreens of intermediate SPF. Finally, on-site investigators collecting the exposure questionnaire every evening ensured high-quality follow-up of participants.

Some limitations should also be discussed. First, the sex disequilibrium in the participants had not been anticipated. As we allowed only 1 adult participant per family, the female spouse or the mother was more likely to participate than the male. Whether this bias may have selected or rejected people with more risky sun-exposure behavior is difficult to assess. Second, some cosmetic differences could be noted between the SPF 40 and the SPF 12 sunscreens, the latter being easier to spread. Therefore, although participants were blinded to SPF value and knowledge of the study objective (ie, that different SPFs were being tested), it cannot be excluded that differences observed in the amount of sunscreen used may have been a consequence of cosmetic properties, rather than a consequence of a sense of suboptimal protection with lower-SPF sunscreens. However, a participant could not compare the 2 different sunscreens directly. Moreover, SPF is intrinsically linked to cosmetic properties and, therefore, these 2 factors cannot be studied separately.

This randomized intervention study compared the effect of different sunscreens on sun-exposure behavior in resorts for family summer holidays. In this population, our findings do not support the hypothesis that a higher SPF induces a higher exposure by delaying the alarm signs, nor the hypothesis that mentioning “high protection” on the label may induce longer exposure by giving an impression of safety. In addition, this study logically confirms that the use of higher-SPF sunscreens does reduce the number of sunburns in real life. Finally, our results suggest that people tend to self-regulate their sun protection with sunscreens, by inversely adapting the amount of sunscreen to the SPF, at least when sunscreens are freely delivered.

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Because of a low tumor incidence and a very long latency period, the preventive effect of sunscreen use on melanoma cannot be directly demonstrated as it has been for squamous cell skin carcinomas.7 Some epidemiologic studies have raised suspicion about a positive association between sunscreen use and melanoma.14-16 Several questions have thus been raised about the ability of sunscreens to play a role in skin cancer prevention. Their uneven protection against the sunlight spectrum and their incorrect use in terms of quantity and modalities of application may be improved with technical advances and information. However, if more potent sunscreens systematically induce longer exposure, they may increase skin cancer risk.

The hypothesis of longer exposures being induced by potent sunscreens has been substantiated by the results of 2 randomized controlled trials in students.21,22 We did not reproduce such results in our study. Although the difference in duration of sunbathing according to SPF may be viewed, in our study, as close to significance rather than nonsignificant (P = .06), it must be noted that the duration of sun exposure was lower in the high-SPF group, ie, inverse to the effect previously demonstrated. Compared with previous studies, methodologic differences in the design across these trials can be considered minor. Consecutive days were considered in this study vs scattered days during the whole summer in the previous trials; the duration of sun exposure was indirectly calculated in this study, whereas it was directly monitored by the participants in the previous trials. It is unlikely that these differences fully account for these discrepant results. Because this study included 1 times more participants than previous studies, it cannot be argued that a difference was left undetected because of a lack of power. The matter of population selection may be the most relevant explanation for the discrepancies in results. A group composed of young students, analyzed in previous studies, may have different behavior regarding sunscreen use than a group mainly composed of women in a family holiday setting. Young people are known to have riskier behavior and may tend to expose themselves up to the limit, even when the limit is pushed forward by high-SPF sunscreens. Conversely, in other populations, exposure duration may be more a matter of personal decision than a consequence of sunscreen characteristics. Whatever the interpretation of the discrepant results across studies, the global conclusion is that high SPF does not automatically induce longer exposure, although it may be true in specific subgroups.

In a skin cancer prevention strategy, behavioral measures (clothes, hat, and avoiding sun) must be preferred to sunscreens. However, for many societal reasons that we are not able to change rapidly, sunscreens will be used by most people as the predominant sun protection. From this pragmatic point of view, we must advise the population on how to make the best choice and the best use of sunscreens. This study highlights that the information about the quality of protection mentioned on the tube label does not seem to have, per se, important consequences in terms of quantity of sunscreen used and duration of sun exposure. However, the actual protection, represented by the SPF, does influence behavior. The SPF value, even masked, was a determinant of the amount of sunscreen applied. This link between SPF and amount of sunscreen used may be a consequence of an adaptive process: suboptimal protection given by lower-SPF sunscreen may be compensated for by using a greater amount of low-SPF sunscreen; alternatively, difficulties in getting an expected tan may be compensated for by using a smaller amount of high-SPF sunscreen. However, as the lower-SPF group did experience more sunburns than the higher-SPF group, this process should be considered nonoptimal for low-SPF sunscreens. Although better protection against UV-B provided by high SPF is not at all a direct proof of better protection against skin cancer, the overall data show that high-SPF sunscreens should be preferred to low-SPF ones.

Acknowledging that, although they represent suboptimal protection, sunscreens will be used by the population, future areas of research should focus on the different influences that sunscreen characteristics may have on sun behavior in different sociological groups, and on the best ways to improve intrinsic protective properties of sunscreens against the carcinogenic effect of UV light. While further data are awaited, public health recommendations should stress wearing clothing and hats and limiting midday exposures, but should not be reluctant to promote high-SPF rather than low-SPF sunscreens.

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REFERENCES


News and Notes

The Third Certifying Examination in Dermatopathology (Diploma in Dermatopathology) will be held in Frankfurt/Main, Germany, on December 10, 2005, organized by the International Board of Dermatopathology under the auspices of the International Committee for Dermatopathology (www.icdpath.org). Participating societies: International Society of Dermatopathology, European Society for Dermatopathology, and Ibero-Latin American Society of Dermatopathology. For further information, contact Helmut Kerl, MD, Department of Dermatology, Medical University Graz, Auenbruggerplatz 8, 8036 Graz, Austria (phone: 43-316-385-2538; fax: 43-316-385-3424; e-mail: helmut.kerl@meduni-graz.at), or Gunter Burg, MD, Department of Dermatology, University Hospital Zurich, Gloriastrasse 31, 8091 Zurich, Switzerland (phone: +41-1-255-2550; fax: +41-1-255-4403; e-mail: burg@derm.unizh.ch).