Randomised double-blind placebo-controlled study of the effect of Lactobacillus paracasei NCC 2461 on skin reactivity

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RESEARCH ARTICLE

Abstract

In recent decades, the prevalence of subjects with reactive skin has considerably increased in industrialised countries. 50% of women and 30% of men report cutaneous discomfort classified under reactive/sensitive skin. Several topical approaches have been proposed, in particular through improvement of galenic forms or protection of epidermal surface. We propose to act differently, deeply from inside the body via an innovative nutritional approach. To this purpose, Lactobacillus paracasei NCC 2461 (ST11) was selected because of its specific beneficial skin properties discovered in in vitro studies, i.e. diminution of neurogenic inflammation and promotion of the recovery of skin barrier function. We designed a randomised double-blind placebo-controlled clinical study with a two-month supplementation in two female treatment groups (n=32 per group). A capsaicin test was performed to monitor the time course of skin sensitivity. Moreover, transepidermal water loss was assessed to analyse the rate of skin barrier function recovery; dryness of the leg and roughness of the cheeks was investigated by a dermatologist as well as by self-assessment. The results of the present clinical trial show that oral supplementation with the probiotic decreases skin sensitivity and increases the rate of barrier function recovery. Thus, the data provide evidence that daily intake of ST11 could improve reactive skin condition.

Keywords: probiotic, Lactobacillus paracasei, reactive skin, barrier function

1. Introduction

The skin plays a crucial role in the protection against dehydration and chemical (e.g. pollutants, tobacco, xenobiotics), mechanical, physical (e.g. UV radiation, temperature, hygrometry) or infectious external aggression. The skin reflects the general health status and the age of the host. Although cutaneous ageing is genetically programmed, skin condition and function are also influenced by environmental factors. Indeed, lifestyle, food, climate conditions, level and number of UV exposures, free radicals, toxins, allergens, xenobiotics, and mechanical damage are all exogenous factors likely to alter skin health. Furthermore, altered hormonal or immunological status and psychological stress are endogenous factors that affect skin quality and biological functions. Under such disruptive conditions, the skin can undergo changes including immune dysfunction, inflammation, photoageing, dryness, wrinkling, dyschromia, and a variety of hyperplasia (Krutmann et al., 1996; Primavera and Berardesca, 2005).

In recent decades, the prevalence of subjects with reactive skin considerably increased in industrialised countries (Primavera and Berardesca, 2005; Willis et al., 2001). 50% of women and 30% of men report cutaneous discomfort classified under reactive/sensitive skin (Jourdain et al., 2002; Misery et al., 2005; Pons Guiraud, 2004; Seidenari et al., 1998). The main symptoms of this cutaneous discomfort are neurosensory, such as feelings of heat, burning, stinging or itching (Farage et al., 2006; Pons Guiraud, 2004; Primavera and Berardesca, 2005). On the one hand, reactive or sensitive skin is characterised by marked sensitivity to physical (heat, cold, wind) or chemical (topical product application) stimuli. During acute phases, neurogenic inflammation may be triggered by the release of pro-inflammatory neuromediators, particularly substance
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P (SP) (Schmeltz and Petersen, 2001; Steinhoff et al., 2003; Zegarska et al., 2006). On the other hand, reactive skin is also associated with impaired skin barrier function recovery. A number of studies have suggested that an impairment of skin barrier function plays a key role in the onset of sensitive skin (De Lacharrière, 2002; Misery et al., 2005; Ohta et al., 2000; Yookota et al., 2003). Decreased barrier function is reported to be responsible for enhanced penetration of potentially irritant substances. Importantly, the homeostatic hydration level of the epidermis as reflected by the rate of transepidermal water loss (TEWL) is closely related to the status of skin barrier, since disruption of skin barrier leads to an increase in TEWL (Idson, 1978; Nilsson, 1997; Pinnadoda et al., 1990).

The capacity of certain probiotic strains to modulate immune functions was a rationale for using such living microorganisms to prevent and/or improve clinical outcome of allergies, particularly skin symptoms (Del Giudice et al., 2002; Niers et al., 2007; Peguet Navarro et al., 2008). Preclinical and clinical data have provided a body of evidence that specific probiotic strains including Lactobacillus paracasei NCC 2461 (ST11) could modulate immune homeostasis and/or downregulate immune-related disorders (Ibnou-Zekri et al., 2003; Von der Weid et al., 2001). Recently, the potential effect of ST11 on skin reactivity was addressed using an in vitro model in which skin organ culture was challenged with a proinflammatory neuromediator SP to mimic neurogenic inflammation. A marked and statistically significant decrease in vasodilatation, oedema, mast-cell degranulation and SP-induced TNF release was observed with ST11-conditioned medium (obtained from Caco-2 and peripheral blood mononuclear cells stimulation with ST11) compared to the control (Gueniche et al., 2010). Moreover, the ability of ST11-treated epithelial cells-conditioned medium to promote recovery and maintenance of the skin barrier function was also shown using a new ex vivo system of skin organ culture (Gueniche et al., 2010). Recently, this effect on skin barrier recovery was confirmed in vivo (Philippe et al., 2011).

In the present study, we report the results of oral supplementation with probiotic ST11 on reactive skin symptoms in human volunteers, evaluated by the following two primary outcomes: skin sensitivity and skin barrier function recovery.

2. Materials and methods

Oral supplementation

L. paracasei NCC 2461 (ST11) was obtained from the Nestlé culture collection. This strain is registered at the Pasteur culture collection under the code CNCM I-2116. Each subject was supplemented daily with a sachet containing powder of the probiotic preparation, on average $1\times10^{10}$ cfu, or a placebo (maltodextrin). The powder containing ST11 also contained a small amount of maltodextrin as a carrier.

Human volunteers and experimental design

Results from a previous clinical trial designed to assess skin sensitivity with a capsaicin test (unpublished data) suggested that a minimum of 30 subjects per group would be required to detect a statistically significant difference between treated and placebo groups with a probability of 5% type I error (two-sided test). Therefore, two groups of 32 Caucasian women volunteers with skin-type I/IV, aged 18 to 40 years, were included in the study. Selection of the subjects with sensitive skin was based on two different criteria: a validated questionnaire and a positive reaction to capsaicin at one of the 3 lowest concentrations ($3.18\times10^{-5}, 1\times10^{-4}$ or $3.17\times10^{-4}$%). In addition, all the subjects were low consumers of fermented milk products (less than 125 ml per day) and not allowed to take any commercial products containing probiotics during the study. Exclusion criteria included post-menopausal women, pregnant or breastfeeding women or women planning pregnancy during the study, recent excessive or chronic UV exposure within four weeks prior to inclusion or during the study period, and use of systemic medications that could affect inflammatory responses within two weeks prior to inclusion. Moreover, subjects with a history of intestinal surgery, vegetarian diet or having taken mineral supplements or vitamins within 3 months before enrolment were also excluded.

The double-blind placebo-controlled study was performed at the Laboratoire Dermscan (Lyon, France) in accordance with the Declaration of Helsinki and its amendment, and the Guidelines on Good Clinical Practice adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Moreover, the protocol was approved by an independent ethics committee from Centre Léon Berard (Lyon, France). Informed consent was obtained from all the subjects before starting the study. Since there is difference in skin sensitivity over different seasonal periods, the recruitment and follow-up took place from mid-August 2004 until early June 2005; the treatment period was from October until early May, during winter and spring. A two-month supplementation period was chosen to ensure optimal activity of the supplements used in the study. Indeed, based on our experience, approximately 15 days are needed for consistent probiotic gut colonisation, i.e. stable detection in faecal content, and approximately 1 month to observe a significant change in cytokines at the gut level (unpublished data). Thus, 2 months might be long enough to get activity on the skin. To ensure that the gastrointestinal tract was cleared of dietary or supplementary probiotics a washout period of 6 weeks was imposed, whereafter the volunteers were randomly divided into two groups.
of 32 subjects. The treatment randomisation list was carried out using SAS PROC Plan. The treatments were balanced by blocks of two; they had the same taste without any possibility to distinguish between them. Laboratoire Dermscan enrolled participants and assigned participants to interventions (Table 1).

Capsaicin test

To monitor the time course of skin sensitivity, a capsaicin test was performed at baseline (day 1) and at the end of the supplementation period (day 57). This newly developed test is based on the threshold of capsaicin detection determined by serial application of increasing concentrations of the stimulant (Jourdain et al., 2005). Solutions were applied serially on the nasolabial sulci from the nasal ala to the corner of the mouth until the subject perceived a feeling due to capsaicin application. Five solutions with different capsaicin concentrations, i.e. $3.18 \times 10^{-5}$, $1 \times 10^{-4}$, $3.17 \times 10^{-4}$, $1 \times 10^{-3}$, and $3.16 \times 10^{-3}$%, were used. For each subject, the result was expressed from grade 1 to 5 accordingly. When no feeling was experienced, even at the highest capsaicin dose, grade 6 was given.

Determination of transepidermal water loss

TEWL was determined on day 1 and day 57 to analyse the rate of skin barrier function recovery. Briefly, dermatological tape was repeatedly applied to the skin on the lateral surface of the volunteer’s forearm. Tape stripping was repeated as much as necessary to reach a TEWL ≥15 g/cm²/h. For each challenge, TEWL was measured before, just after and at 4, 8, 24, 48, 72 and 96 h after tape stripping using an evaporimeter (Idson, 1978; Nilsson, 1997; Pinnagoda et al., 1990). To understand the differences between the two groups, the area under the curve (AUC) representing the kinetics of TEWL was evaluated. AUC was calculated by subtracting the TEWL value at the stripped area from the value at an unstripped zone.

Clinical score, self-assessment and safety

Clinical score was graded on day 1, day 29 and day 57. The dermatologist investigated the dryness of the skin at the lateral surface of the right leg at each visit. The scale ranged from 0 to 3 as follows: not dry; slight dryness (slight roughness); moderate dryness (moderate roughness, some scaling); and severe dryness (marked roughness and scaling). The dermatologist also evaluated skin roughness of the two cheeks, by touch, at each visit using the following grading scale from 0 to 4: no (surface perfectly smooth and supple); mild (slight irregularity and roughness to tangential touch); moderate (marked irregularity, rough appearance and mild induration of the skin detected by vertical touch); severe (more marked irregularity and roughness associated with induration of the skin); and extreme (very marked irregularity and major disturbance of skin marking with more marked induration). In addition, the dermatologist asked the volunteer to conduct a self-assessment of skin dryness on the legs and face using the following scale from 0 to 5: not at all; very slightly; slightly; moderately; severely; and very severely.

During each visit, the subjects were questioned by the dermatologist on safety and invited to report any adverse events in the daily diary.

Surface epidermal samples

Surface epidermal samples were collected for the biochemical follow-up of markers associated with a decrease in skin hydration. The samples were taken from the lateral surface of the right leg (moisturising factors) on day 1 and day 57 by using a turbine-type device with buffer solution circulating over the surface of the skin. All the samples were taken in the same volume of buffer from 3.14 cm² skin.

The markers were selected among some components of the natural moisturising factor (NMF) of the skin that play an important role in skin moisturisation, i.e. sodium lactate and urea. Sodium lactate has marked hygroscopic properties and urea increases moisturisation of the stratum corneum by direct action of proteins. After concentrating the samples by evaporation, the chosen NMF markers were analysed by spectrophotometry using ABX Pentra kits (product code A11A01721 and A11A01641) as described by the manufacturer (ABX Diagnostics, Montpellier, France).

Table 1. Summary of general characteristics of the subjects.

<table>
<thead>
<tr>
<th>Test products</th>
<th>Subjects (n)</th>
<th>Mean age ± SEM</th>
<th>Phototype</th>
<th>Mean height ± SEM (cm)</th>
<th>Mean weight (kg) ± SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>32</td>
<td>34±2</td>
<td>9 II, 22 III, 1 IV</td>
<td>166±0.01</td>
<td>61.6±1.5</td>
</tr>
<tr>
<td>ST11</td>
<td>32</td>
<td>31±1</td>
<td>12II, 20 III, 0 IV</td>
<td>164±0.01</td>
<td>58.8±1.9</td>
</tr>
</tbody>
</table>

1 SEM=standard error of the mean.
Collection of fresh stools and analysis of microbiota composition

Faecal samples were taken on day 1, day 29 and day 57. Volunteers’ fresh stools were collected in dry containers. 0.5 to 1 g stool was transferred into a tube containing 5 ml Ringer’s solution with 10% glycerol. Enterobacteria, lactobacilli and bifidobacteria were enumerated after culturing on semi-selective medium plates according to the method previously described (Tannock et al., 2000). The bacterial counts were expressed in log 10 cfu/g stool. The probiotic strain used in our trial was identified by PCR using primers designed to recognise ST11: ONCC2461_A: TGGACTTACGCGAGTGTGAA; and ONCC2461_B: ACTGAACCATCGTCCAGAC. Amplification conditions were the same as those previously described by Rouge et al. (2010).

Cytokine measures

Blood samples (10 ml) were drawn into dry tubes. The tubes were centrifuged at 6,000 rpm for 10 min. The sera were separated and stored at -20 °C until analysis of the selected cytokines IL-10, IL-12 and TGF-β using respective R&D kits (R&D Systems, Minneapolis, MN, USA) according to manufacturer’s recommendation.

Statistics

The study was analysed by the intention-to-treat (ITT) approach. TEWL measurements of each subject were summarised at each visit through AUC calculation using the trapezoid rule based on the difference of TEWL values between unstripped and stripped area. Then, a mixed model of variance for repeated longitudinal data was performed in an unstructured covariance pattern framework with treatment, time, and the treatment×time interaction as fixed effects. Between groups comparisons were performed using contrasts. Ordinal repeated measurement for capsaicin effects. Between groups comparisons were performed using the non-parametric Wilcoxon test. All statistical analyses have been carried out using SAS Enterprise Guide version 4.2 (SAS Institute, Cary, NC, USA) and SPSS version 17 (IBM, Armonk, NY, USA) statistical software. The two-sided significance threshold was set at 5%.

3. Results

Subjects and adverse events

Thirty two subjects were randomised in each group with a balanced age allocation (34±2 years old for the placebo group and 31±1 years old for the ST11 group). The height and weight were also well balanced between the two groups. The phototype (sun reactive skin type based on sunburn susceptibility, tanning ability and phenotypic information) was also equilibrated between the two groups (Table 1). Only two drop-outs were recorded, both in the probiotic group, due to difficulties with study planning (Figure 1). Moreover, full product intake was reported, all together reflecting a high compliance to the study protocol.

All reported adverse events (AE) were unrelated to the study products. The gastrointestinal disorders, colds and headaches occurring during the study were not considered to be related to the study products, as the percentage of occurrence was the same in both groups. Moreover, the nature and number of these events, mainly related to cold, could be considered as expected due to the season (winter) during which the study was conducted. No AE led to interruption of trial or drop-out. Overall, the products were well tolerated and perfect compliance was noticed. In addition, no major protocol deviation was noticed.

Skin sensitivity

Two measurements, on day 1 and day 57, have been carried out during the two months running period. The AUC was calculated from day 1 to day 57 to take into account the kinetics of the results. The ST11 group showed a statistically significant increase in the AUC on day 57 compared to the placebo group (P=0.035), whereas on day 1 no difference was noticed between the groups (Figure 2). This indicates a reduced sensitivity to capsaicin in the ST11 group, which is clinically relevant.

Forearm transepidermal water loss

In the placebo group, no difference in forearm TEWL between day 1 and day 57 was observed (P=0.1). In contrast, the ST11 group showed a statistically significant difference in AUC representing the TEWL between day 1 and day 57 (P=0.04) (Figure 3). Compared to the placebo group, TEWL was significantly decreased in the ST11 group when comparing day 1 to day 57 (P=0.0415), which indicates more rapid kinetics of barrier recovery in volunteers supplemented with ST11.

Clinical score and marker analysis

At each visit, the subjects were asked to make a self-assessment of skin dryness. A significant improvement (P=0.006) of face skin roughness between day 1 and day 57 was observed in volunteers given ST11 compared to the placebo group. A similar trend (P=0.08) was found for leg skin dryness. Such a trend was observed by the clinical score evaluation, but no statistical significance could be reached (Table 2). There were no differences in the markers urea and lactate between the groups at day 1. A decrease in the concentrations of urea and sodium lactate over time was only observed for the placebo-supplemented volunteers.
Effect of L. paracasei NCC 2461 on skin reactivity

Recruitment and inclusion  
\(n=64\)

Randomization (double blind)  
\(n=64\)

Allocation

ST11  
Allocated to intervention \(n=32\)  
Received allocated intervention \(n=32\)

Placebo  
Allocated to intervention \(n=32\)  
Received allocated intervention \(n=32\)

Drop-out

Analyses

Analysed  
ITT – population \(n=30\)

Analysed  
ITT – population \(n=32\)

Clinical score  
Self-assessment  
Capsaicin test  
Transepidermal water loss after repeated tape stripping  
Surface epidermal samples  
Faecal sample analyses  
Blood cytokine measures

Difficulties with study planning

n=2  
n=0

Figure 1. Flow diagram of the study of the effects of *Lactobacillus paracasei* NCC 2461 (ST11) on reactive skin. Allocation, drop-outs and analysis of the study as illustrated by the flow chart. ITT=intention-to-treat.

Figure 2. Area under curve (AUC) representing results of capsaicin sensitivity limit at day 57. Results expressed as mean±standard error of the mean.

Figure 3. Area under curve (AUC) histograms representing results of difference in transepidermal water loss (TEWL) at day 1 and day 57. The *Lactobacillus paracasei* NCC 2461 (ST11) group showed a statistically significant difference in the AUC \((P=0.04)\). Compared to the placebo group, TEWL was significantly decreased in the ST11 group when day 1 was compared to day 57 \((P=0.0415)\). Results are expressed as mean±standard error of the mean.
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Table 2. Clinical and self-assessment of face skin roughness and leg dryness.

<table>
<thead>
<tr>
<th>Group</th>
<th>Face skin roughness</th>
<th>Leg dryness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day 1</td>
<td>Day 29</td>
</tr>
<tr>
<td>Self-assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>3.44</td>
<td>2.53</td>
</tr>
<tr>
<td>ST11</td>
<td>3.34</td>
<td>2.88</td>
</tr>
<tr>
<td>Clinical assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>3.22</td>
<td>1.75</td>
</tr>
<tr>
<td>ST11</td>
<td>3.28</td>
<td>1.97</td>
</tr>
</tbody>
</table>

<sup>a</sup> Significant improvement (P=0.006) of face skin roughness observed between day 1 and day 57 in the subjects given *Lactobacillus paracasei* NCC 2461 (ST11) compared to the placebo group.

(from 4.72 to 2.87 mg/kg for urea and from 13 to 6.45 mg/kg for lactate). In contrast, these markers remained unchanged throughout the study in the subjects taking ST11 (from 3.71 to 3.34 mg/kg for urea and from 7.11 to 7.82 mg/kg for lactate).

**Cytokine analysis**

The concentrations of IL-10 and IL-12 were below the limit of detection (10-20 pg/ml, respectively) as set by the kit. For TGF-β, no difference between the groups was observed at baseline. In the ST11 group, the serum concentration of TGF-β increased progressively with values peaking at day 29, whereafter the levels declined corresponding to the kinetic of reactive skin progression in the study; the levels of TGF-β were significantly higher at day 29 compared to day 1 (P=0.02) (47.0 pg/ml at day 1 and 62.0 pg/ml at day 29) (Figure 4). No significant difference over time was observed for the placebo group. Comparing the ST11 and placebo group, no significant difference existed between day 1 and day 29 (P=0.08).

**Microbiota analysis**

The amount of stool collected was not recorded, however, the quantities of bacterial components of the microbiota were measured per g stool. Three species of commensal bacteria were quantified in the faeces to evaluate the impact of ST11 on the microbiota. A significant increase in lactobacilli counts was found after 29 days in the ST11-supplemented group compared to the placebo group whereas no difference was observed for enterobacteria and bifidobacteria at any time (Table 3). This level remained high at day 57 compared to the placebo group.

ST11 was not detected in the stools of the subjects supplemented with the placebo. At day 1, subjects supplemented with ST11 were negative for ST11, but the probiotic was detected in almost 70% of the stools of the subjects during the supplementation period. The counts were 6.07±0.1 and 6.2±0.1 log<sub>10</sub> cfu/g stool on day 29 and day 57, respectively.

Table 3. Number of lactobacilli (log 10 cfu/g faeces).

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 1</th>
<th>Day 29</th>
<th>Day 57</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>5.26±1.28</td>
<td>5.48±1.18</td>
<td>5.03±1.36</td>
</tr>
<tr>
<td>ST11</td>
<td>5.62±1.40</td>
<td>6.36±1.10&lt;sup&gt;a&lt;/sup&gt;</td>
<td>6.43±1.18&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> Significant increase in lactobacilli counts in the *Lactobacillus paracasei* NCC 2461 (ST11) group compared to the placebo group (P<0.05).

![Figure 4. Serum concentration of TGF-β expressed as mean ng/ml ± standard error of the mean.](image-url)
4. Discussion

The results show that ST11 has a positive effect on the two primary outcomes, namely skin sensitivity and skin barrier function recovery, and on key associated physiological parameters evaluated as secondary outcomes. Volunteers supplemented with ST11 showed a slight but significant decrease in skin sensitivity to capsaicin over the treatment period. Three potential mechanisms may underlie the effect of the probiotic on skin sensitivity: (1) direct action through inhibition of the release of the neuromediators involved in sensitivity reaction; (2) decrease in neurogenic inflammation, which is frequently associated with sensitive skin symptoms; and/or (3) positive effect on skin barrier function (Gueniche et al., 2010; Philippe et al., 2011; Thurin and Baumann, 2003).

After repeated tape stripping, barrier function recovery measured as diminished TEWL was significantly faster in the subjects supplemented with ST11 compared to the placebo group. This effect is of particular interest with regard to the impairment of barrier function that occurs with skin ageing, in certain inflammatory diseases (e.g., atopic dermatitis) or in daily routine due to washing with detergents or exposure to environmental factors (UV radiation, pollutants, ozone, high temperature, air-conditioning, low humidity, etc.), psychological stress or dietary deficiencies (Choi et al., 2005; Mac-Mary et al., 2004).

The overall decline of the cutaneous moisturising factors normally occurs in the winter period and contributes to the impairment of barrier function integrity (Batt and Fairhurst, 1986; Tronnier, 1981). These markers remained unchanged throughout the study in the ST11 group and correlated with the increase in barrier function recovery rate reported above. This argues towards a beneficial effect of the probiotic on the maintenance of skin moisturising factor concentrations over the autumn and winter period, thus contributing to reinforced skin homeostasis.

The mechanisms underlying immune modulation by probiotics partly involve the regulation of composition and/or metabolic activity of the intestinal microbiota. However, a direct interaction between probiotics and/or one of their fractions with the gut mucosa-associated immune system has also been suggested (Uhlig and Powrie, 2003). It is currently postulated that, subsequent to the interaction between probiotics and the intestinal epithelium, the associated immune cells are activated resulting in a release of immune mediators, such as cytokines, into the blood stream. This may contribute to reinforcing or restoring skin homeostasis. Cytokines are involved in modulating the growth and differentiation of keratinocytes via paracrine and/or autocrine pathways, thus orchestrating the metabolic responses necessary for skin barrier regeneration (Marionnet, et al., 2003; Nickoloff and Naidu, 1994). Among the cytokines, TGF-β appears to play a significant role in maintaining skin integrity (Hashimoto et al., 2000; Pasonen-Seppanen et al., 2003; Wilke et al., 1988). Interestingly, we observed that subjects supplemented with ST11 showed significantly higher levels of circulating TGF-β at day 29 compared to the control group. These results are in line with previous data indicating that ST11 and/or a fraction of the probiotic is able to induce, ex vivo, the growth of a population of CD4+ T-cells very close to regulator T-cells, which are only weakly proliferative and secrete high levels of TGF-β and IL10 (Von der Weid et al., 2001). Moreover, in vitro studies have shown that ST11 is able to inhibit neurogenic inflammation in a skin model and contribute to strengthening barrier function in an EPISKIN® model (Gueniche et al., 2010).

Analysis of stool samples showed that ST11 was present in almost 70% of the samples from the group taking the probiotic during the treatment phase. However, no direct relation could be made with the amount of ST11 found in stool and the magnitude of response of the subjects. After stopping treatment, the number of positive samples markedly decreased (data not shown), and 1 week after stopping, ST11 was only found in 10% of the subjects with mean counts of 5.01±0.1 log_{10} cfu/g stool for the positive stools. This confirms the transient ability of the probiotic to persist in the intestine. Administration of ST11 did not result in major detectable changes in the microbiota composition. New methodologies, such as 16sRNA profiling or pyrosequencing, would have been more appropriate to draw a conclusion on this matter. Lactobacilli counts were significantly increased but this very likely relates, at least in part, to the presence of ST11 rather than solely to a specific impact on endogenous lactobacilli.

The results of this study demonstrate that the probiotic ST11, taken by the oral route, has a beneficial effect on reactive skin, i.e. decrease in skin sensitivity, increase in the rate of barrier function recovery, and maintenance of moisturising factor concentrations (urea and sodium lactate) in the skin. These findings support the idea to further develop a probiotic-based nutritional approach for the treatment and/or prevention of the symptoms related to reactive skin.

Acknowledgements

The authors would like to thank Dr. F. Rochat for scientific advice. Specific primers for the detection of the NCC2461 probiotic were developed and provided by Dr. B. Berger, Nestlé Research Center, Switzerland. The authors are grateful to Dr. S. Chartier, Dr. C. Noize-Pin, Dr. Yvette Weltert and Dr. F. Boujdjema from Laboratoire Dermscan for their support and contribution to the study.
Conflict of interest

The authors have no financial support or relationships that may pose conflict of interest by disclosing at the time of submission, or any financial arrangements with a company whose product figures prominently in the submitted manuscript or with a company making a competing product. However, A. Gueniche, P. Bastien, I. Castiel-Higounenc, L. Breton are employed by L'Oreal and D. Philippe, G. Reuteler, S. Blum and J. Benyacoub are employed by Nestlé.

References


