

ASSESSMENT OF QUALITY OF LIFE RELATED TO CHEILITIS IN ACNE PATIENTS UNDER ISOTRETINOIN TREATMENT COMBINED WITH A REPAIRING LIP BALM LipQoL™ QUESTIONNAIRE

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INTRODUCTION

Patients suffering from moderate to severe acne can benefit from **oral isotretinoin treatment** to achieve lasting improvement in their skin condition. However, the **drying effects** of this treatment can strongly affect the lips, whose stratum corneum is five times thinner than on the rest of the face. This results in **cheilitis**, which impacts the patient's quality of life and can lead to non-compliance with medical treatment. **In this context, the use of a suitable lip balm is recommended.** The aim of this study is to **develop a scale** that allows to specifically characterize the impact of cheilitis on subjects' quality of life and serves as an objective tool to assess the **positive impact of a new repairing/healing lip balm on patient well-being in link with the clinical improvement of cheilitis.**

MATERIALS & METHODS



A 10-item questionnaire, **LipQoL™** was developed under dermatological consultancy, based on medical practice, patients shared experience and medical literature. The questions were answered in a 4-item system enabling to measure the impact: **not concerned / never (0) / a little bit (1) / frequently (2) / always (3). The maximum score is 30.** This questionnaire was then tested in a **monocentric open clinical study conducted in Brazil**, along with dermatological evaluation of **clinical signs** related to cheilitis **Isotretinoin Cheilitis Grading Scale (ICGS)**, standardized images and **functional signs (pain sensation and discomfort).**



30 subjects aged 17 to 40 years old, under isotretinoin and presenting with cheilitis at inclusion were followed for **28 days** while using a lip balm and had to fill in the cheilitis questionnaire at each time point (D0, D7 and D28). At the end of the study, the subjects and investigators were asked about the relevance of the questionnaire.

RESULTS

The LipQoL™ questionnaire was elaborated to appraise the impact of physical discomfort of cheilitis on patients' daily life as well as the socio-emotional consequences of this condition.

100% of the investigators and subjects judged the questionnaire relevant to their condition and easy to answer.

On the clinical point of view, we observed a significant decrease of the **total ICGS score** ($p < 0.001$, Wilcoxon test, figure 2) and **visual clinical scores** reaching significant decrease at D1 and **maximal decrease at D28** (**dehydration -61.0%, dryness -56%, roughness -57%, rigidity -58%**, $p < 0.001$, Wilcoxon test)

Subjects **pain sensations** decrease significantly as soon as D1 and at D28 (**-89%**, $p < 0.001$, Wilcoxon test). The **pulling sensation and the global discomfort** also decrease significantly as soon as D1 and after 28 days of use (**-85% for pulling sensation and -85% for global discomfort**, $p < 0.001$, Wilcoxon test)

The overall impact of cheilitis on the subject's quality of life assessed with the LipQoL™ questionnaire improved over the time.

The calculated **total LipQoL™ score** decrease by **-65%** and **-78%**, after 1 day and 28 days of lip balm use respectively ($p < 0.001$, Wilcoxon test). Moreover, each question score decreased statistically as soon as after 1 day of use and after 7 and 28 days (-52% to -86% depending on the question and time point, figure 1).

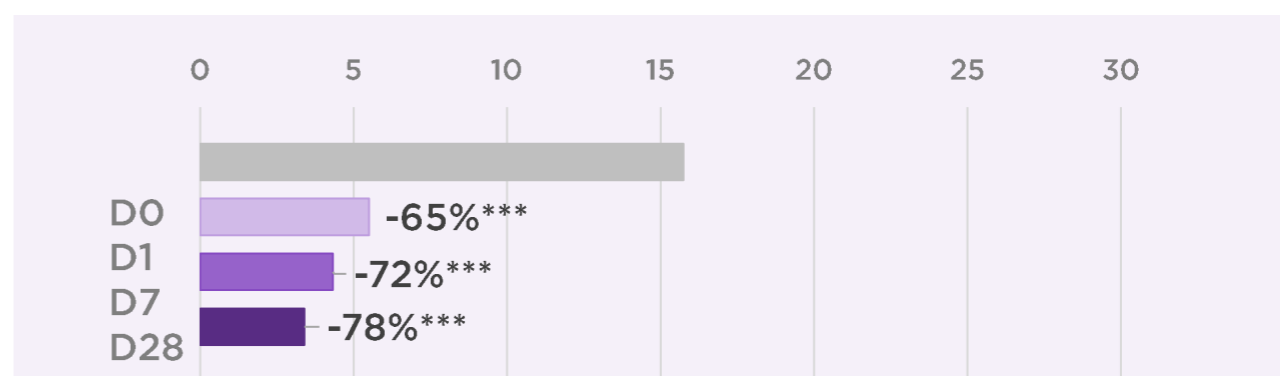


Figure 1 - Total LipQoL™ questionnaire

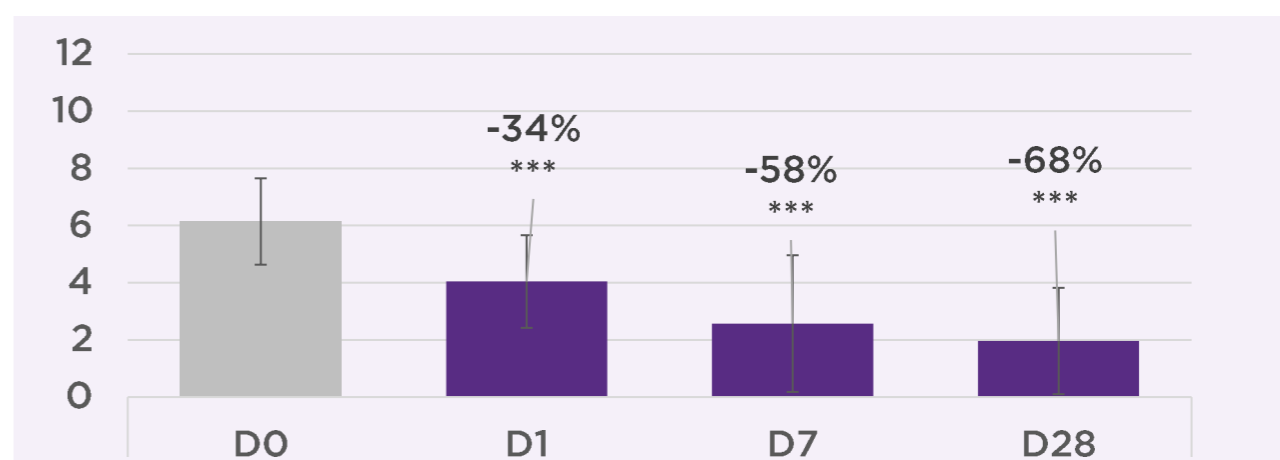


Figure 2 - Evolution of the total ICGS score during the study

Effective on cheilitis from the very first day of use

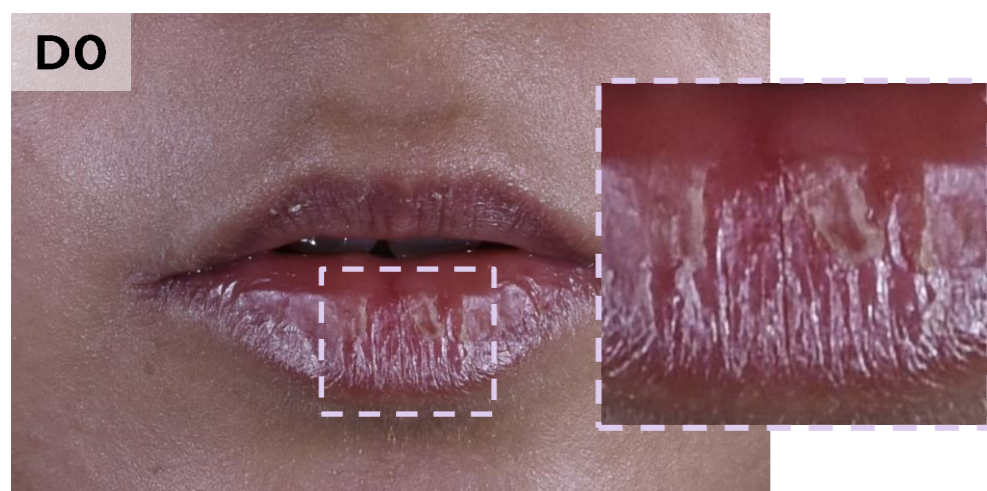


Figure 3 - Standardized picture at D0

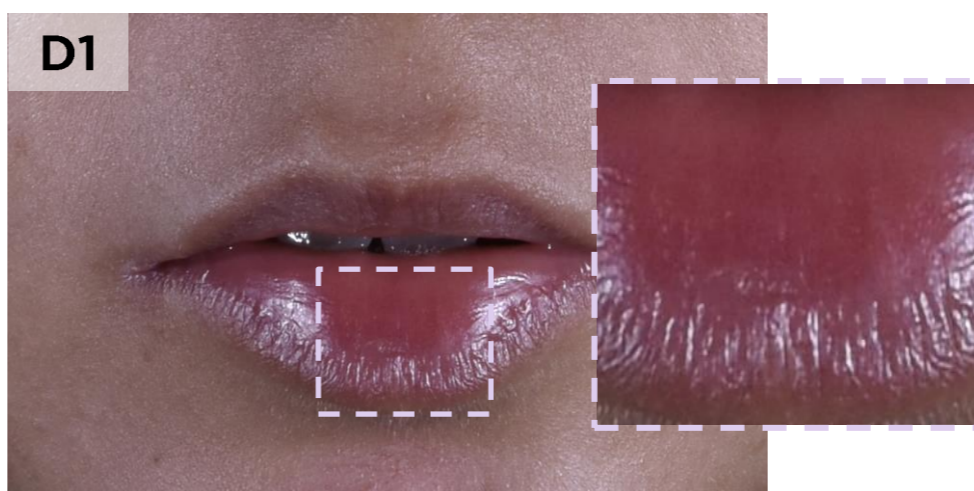


Figure 4 - Standardized picture at D1

- 55%** OF PAIN SENSATIONS AFTER 1 DAY OF USE
- 46%** OF PULLING SENSATION AFTER 1 DAY OF USE
- 39%** OF CRACKED LIP AFTER 1 DAY OF USE

CONCLUSION

This study allowed us to validate the LipQoL™ questionnaire focusing on the cheilitis induced by isotretinoin, by showing **a correlation between the clinical improvement of the cheilitis by the lip balm and the evolution of the score of this questionnaire** developed to assess the impact of cheilitis on the patient's life.

Thus, this questionnaire is therefore a useful tool for specifically address the cheilitis burden and for objectively assessing the effect of any healing or soothing lip balm on the patient's quality of life, making it easier for dermatologists to choose the right dose of isotretinoin to ensure good compliance.