

Teleconsultation in cosmetic clinical studies

An alternative and complement to facetoface studies

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Background :

The Covid-19 pandemic and the forced closure of clinical study centers led the Eurofins Evic study center to experiment the feasibility of conducting remote virtual clinical studies under dermatological control. Two studies were carried out by teleconsultation (in association with L'Oréal) at the subjects' homes using different tools. The objectives were to improve the quality of the images obtained in order to facilitate remote scoring by the evaluators.

Following the feedback from these two studies, it was found that the evaluators via teleconsultation had real difficulties in assessing some skin parameters on the face due to the image quality. The subjects also experienced real difficulties at home (logistics, material and connection). Without the proper tools, can tele-evaluation be used to evaluate skin parameters?

Objective :

A new study was conducted to identify and quantify the differences between face-to-face and remote assessment. In order to provide answers to:

1. Is there a difference in scoring between face-to-face and teleconsultation?
2. Can all skin parameters be scored with teleconsultation?
3. Are there tools that can be used in order to improve the scoring in teleconsultation and to get closer to real face-to-face evaluation?

Methods and Materials :

- Methodology

Two clinical experts participated in this study: the evaluator 1 who was never scored by teleconsultation and evaluator 2 who participated in two previous studies.

The study took place at the Investigational center in two dedicated rooms: one room for the subject and the face-to-face assessment and one room for the assessor and teleconsultation scoring. The screen on which the evaluators were scoring was previously calibrated and environment lights controlled.

Following a pre-study on 5 subjects, the first feedback showed the need to adapt the evaluation methodology for some parameters in order to get closer to a face-to-face evaluation. For example, parameters like pores and firmness, required either the parameterization of the tools or the intervention of the subject. In order to guide the subjects for these specific parameters it was required to create some evaluation tools.

Following these adjustments, 15 items were defined and scored with usual validated 10-point scales from 0 to 9 for each item on 23 subjects.



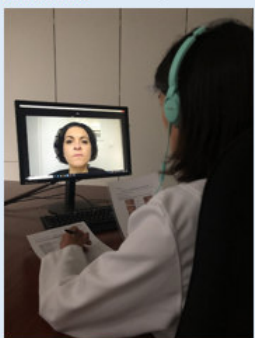
In addition to the scoring, a questionnaire was submitted to the volunteers to collect their opinion on the experience.

- Subjects

The study had a group of 23 subjects, 2 men and 21 women, aged 30 to 68 years with a Fitzpatrick phototype between II and IV with all face skin types represented. The subjects were previously acclimatized under controlled temperature and hygrometry conditions.

- Materials

The set-up of the subject should be adapted according to whether the assessment is taking place Face-to-Face or by Teleconsultation.

For the Face-to-Face assessment	For the tele-assessment	
<p>Subjects & Evaluators : An assessment table with standardized lighting using 3 neon lights (sides + top) is used. The volunteer is positioned with his or her abdomen pressed against the assessment table, arms laying on the table.</p> 	<p>SUBJECTS ROOM</p> <p>An assessment table with standardized lighting using only the upper neon light. The volunteer is positioned leaning against the back of the chair, with his arms laying on the table.</p>  <p>Camera Nikon D5200 Full HD with 18-55mm lens - Automatic mode - 24mm or 55mm (pores evaluation) lens</p> <p>Adjustable tripod according to the size of the subjects</p> <p>Key HDMI 4K</p> <p>Loudspeakers and microphone</p>	<p>EVALUATORS ROOM</p> <p>A computer with calibrated Full HD 24-inch screen 1920 x 1080 on the evaluator side Remote conferencing service of the market Headphones and microphones</p> 

- Statistical analysis (made with IBM SPSS version 28.0)

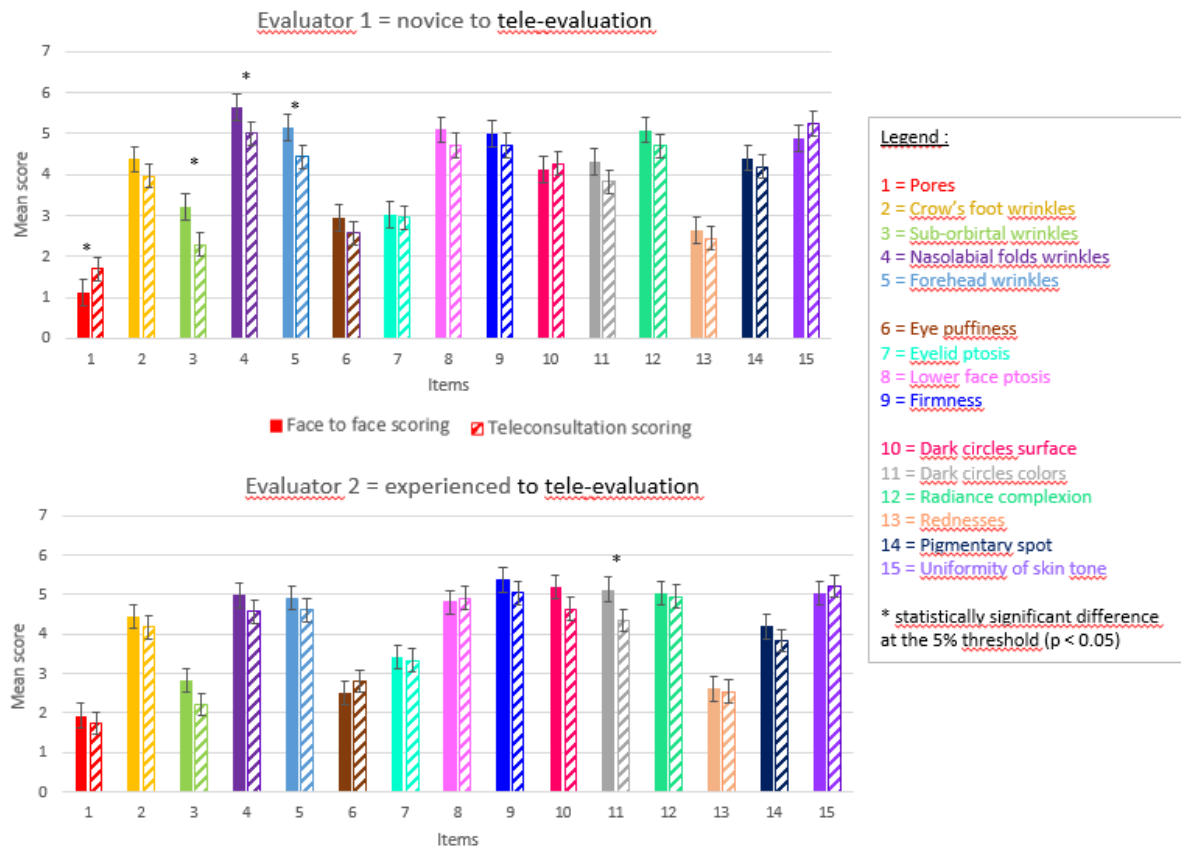
The data of each subject is collected and sorted out for each item according to the 4 conditions (Face-to-face - evaluator 1 / Tele-evaluation - evaluator 1 / face-to-face evaluator 2 / Tele-evaluation - evaluator 2).

A 2-factors ANOVA was performed with the condition defined as a fixed factor and the subjects as a random factor followed by Tukey tests. If the normality of residues was not verified (Shapiro-Wilk at the significance threshold of 1%), the ANOVA was performed on the ranks.

A Pearson correlation was also calculated between the average scores of the 2 evaluators for each item.

Results and discussion

Comparison between teleconsultation and face-to-face scoring by evaluator:



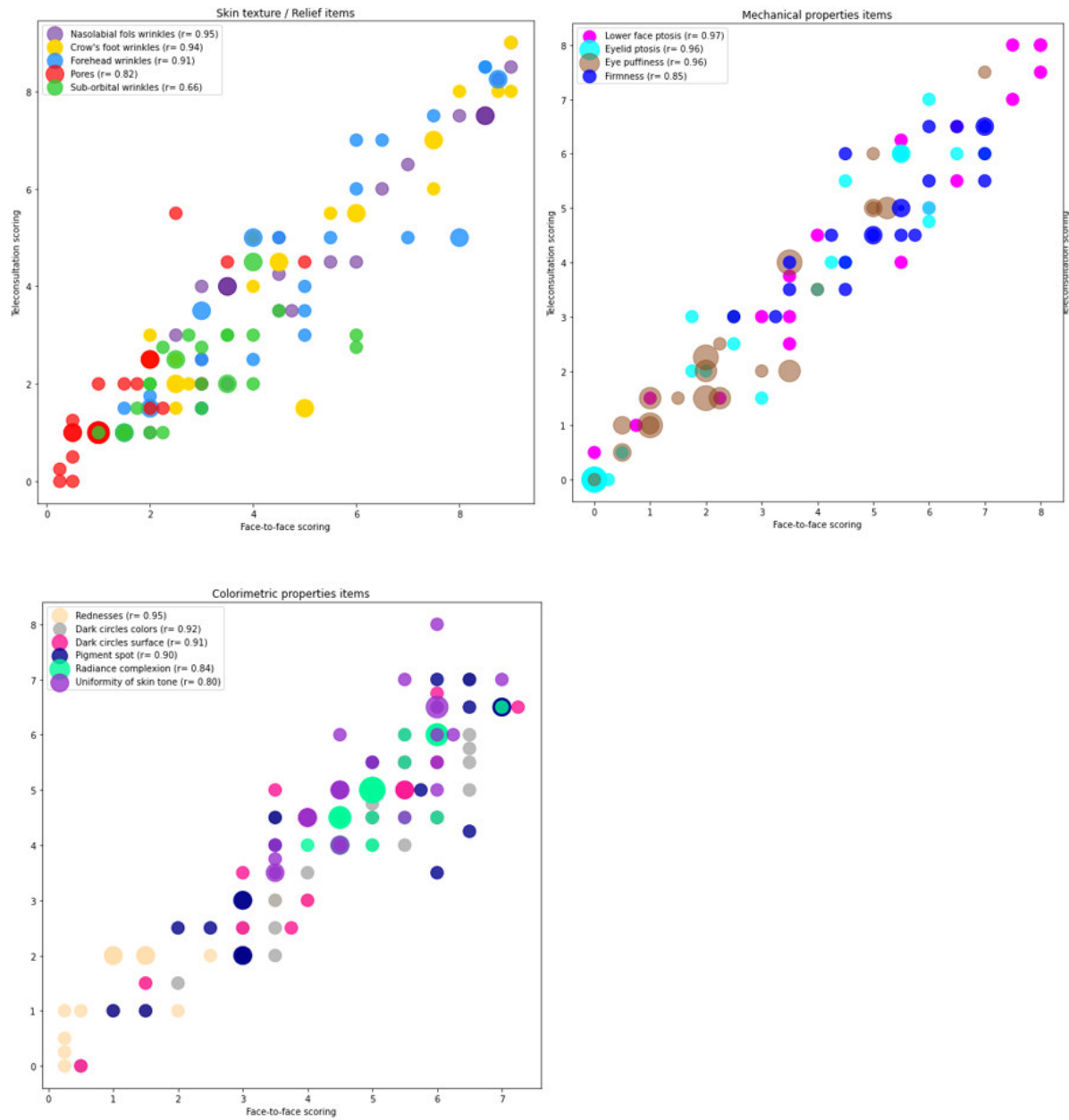
For Evaluator 1 novice to tele-evaluation, significant differences between teleconsultation and face-to-face assessment were found for 4 items related to skin texture or relief (pores and wrinkles).

For Evaluator 2 experienced to tele-evaluation, significant differences between teleconsultation and face-to-face assessment were found for only 1 item related to skin color (dark circles color)

These results highlight the fact that, overall, the scoring carried out by teleconsultation and face-to-face are fairly comparable, but that the training of the evaluator in these conditions is primordial in the practice of teleconsultation scoring.

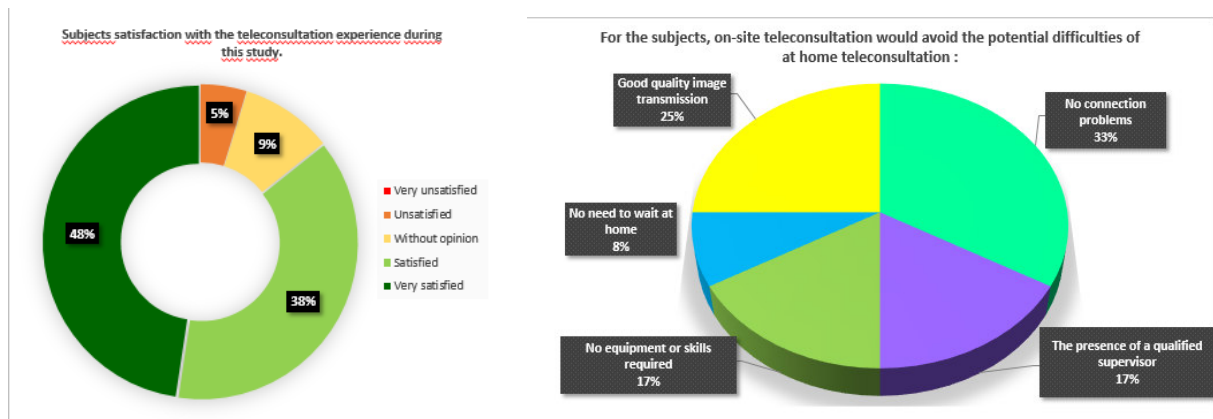
Global correlation between teleconsultation and face-to-face scoring:

Average scores of face-to-face evaluations in respect to tele-evaluation



It is highlighted here that when all evaluators are taken together, the evaluation methods are strongly correlated (correlation coefficient (r) between 0.66 and 0.96).

Subjects opinion about their on-site teleconsultation experience:



Regarding their experience during the study, the subjects showed a very high satisfaction rate (86%), specifically regarding their feeling of well-being and understanding of the study process. However, subjects claimed that on-site teleconsultation would be easier due to the presence of a supervisor.

Conclusion

From a material point of view, the light reflection parameter still needs to be improved in order to increase the correlation coefficient on the texture and relief parameters. Tests will be carried out with a polarizing filter on the camera lens.

This study shows that it is quite possible to carry out qualitative distance clinical studies. The quality of the evaluations depends on the training of the evaluators in a teleconsultation evaluation and on the implementation of specific tools. In the same way as for the face-to-face scoring, a tele-evaluation training process will be set up for the evaluators.

These results allow us to consider carrying out multicenter studies with the same trained evaluators or with multiple assessors as soon as the centers are equipped with the adapted material (easy to set up) in order to be able to offer studies with subjects from different regions and countries. The second advantage is to be able to work with experts outside the center and benefit from experts with specialties not present in our study centers.

The limitations of this type of study lie in the possible assessment area. It is well suited for facial evaluation but seems more difficult to use in studies for the evaluation of products for the body.

These results also allow us to consider the fourth phase of the prospective study, which is the qualitative home consultation and the development of mobile tools to control the positioning, the light and the web connection of the subject.

Keywords: Teleconsultation; Clinical test; Cosmetics

Conflict of interest: NONE