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In search of a universal and objective method to assess facial aging: The new face objective photo-numerical assessment scale

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ABSTRACT

Most patients who undergo cosmetic rejuvenation treatment hope to appear younger and healthier. Although a number of scales have been put forward to assess facial aging, to date none has focused on predicting patients' age. The purpose of our study was to validate a more complete version of the face - Objective assessment scale previously developed by the authors. Since patients with a photo-damaged skin can look older than others we created a new sub-scale: the facial photo-aging scale, in order to provide a more comprehensive method for the overall assessment of facial aging.

The Rasch model was used as part of the validation process. We assigned a score to each patient based on the scales we have developed. The correlation between a patient's actual age and the obtained scores was analyzed; we also analyzed the inter-rater reliability and test-retest reliability. All the scales exceeded criteria for acceptability, reliability and validity.

The facial aging scale we have developed may prove to be a valuable tool to assess patients before and after facial rejuvenation treatment or surgery, as well as for clinical research in the field of facial skin regeneration.

1. Introduction

Aging is due to several genetic and environmental factors that, over time, lead to gradual but visible changes on the face and body. As people age, concerns about their appearance are increasingly focused on the face (Honigman and Castle, 2006). The growing acceptance of cosmetic surgery has resulted in an increase in the number of patients who seek to undergo facial rejuvenation treatments (Codner et al., 2010; Cula et al., 2013). Understanding the patient's expectations is an essential part of clinical evaluation, and the patient's satisfaction with his or her facial appearance should be a priority. Most patients who have undergone facial rejuvenation treatments feel a need to verify the treatment outcome, for example in a reduction of the signs of aging and a more youthful appearance.

Although it is possible to assess patient satisfaction, determining a person's age appears to be challenging, given that changes are considered to be subjective (Swanson, 2011; Acaster et al., 2012). An objective assessment of the signs of aging should be a first step to accurately determine a person's age and to develop a long-term, detailed plan for the necessary procedures. In clinical practice, however, this is difficult to achieve (Waaijer et al., 2012; Miyamoto et al., 2013). While evaluation scales already exist, to date none has concentrated to develop a validated method to objectively assess the effects of an anti-age treatment (Panchapakesan et al., 2013; Klassen et al., 2010).

Up to now, studies to objectively assess facial changes related to aging have encountered limitations. In addition, there is a need for an objective tool to predict outcomes for patients who undergo treatments involving a range of different facial rejuvenation techniques. The purpose of our study was to develop and measure the validity of a new tool, an objective assessment scale, to measure the severity of signs linked to aging on different parts of the face. After describing a preliminary version (La Padula et al., 2016), we now wish to improve and expand upon this scale.

2. Material and methods

This prospective study evaluated the overall aging of the face. It was based on 21 scales to obtain a score for the areas of the face that are most commonly the focus of aesthetic procedures. The study

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design was approved by our research institution's Ethics Committee.

2.1. Developing an objective assessment scale to appraise a patient's age (Table 1)

We developed scales corresponding to the upper, middle and lower parts of the face, hair density and skin quality in order to assess the severity of the signs of aging. For each degree of severity, we assigned a rating from 0 (no signs) to 3 (numerous or highly visible signs). We developed a total of 21 numerical scales and added up all scores to obtain a final figure between 0 and 63. From a patient database we randomly selected 12 groups of patients based on age. For each age group, we calculated the mean score and the standard deviation (Table 2).

2.2. Scale development

From January 2013 to May 2017, we enrolled 1,630 people, informed them about the study and conducted evaluations. Study participants were selected by four types of blinded examiners coming from different backgrounds: two groups of board certified dermatologists, one immunologist and one psychologist. Selection was based on the severity of facial changes in relation to aging so that all degrees of severity would be represented.

We included in our study 1,100 Caucasian patients (550 men and 550 women) aged 18 to 75, with skin color ranging from type I to type IV on the Fitzpatrick Scale. We applied the following exclusion criteria: prior rejuvenation surgery, treatment with botulinum toxin or a filler, facial lipoatrophy in connection with antiretroviral therapy, permanent or temporary make-up, and diseases that cause premature facial aging (Rzany et al., 2012; Lu et al., 2014; Seco-Cervera et al., 2014; Gordon et al., 2014). Two independent plastic surgeons used a high-resolution system to take two-dimensional photographs. All the patients were photographed under the same lighting conditions and in the same seated position, with the patient facing the surgeon. We created a numerical database with the 1,100 photographs. All the patients had been informed about the study objective and had given their written consent for the analysis and publication of data. The photographs were sorted into categories by 15 reviewers (6 plastic surgeons, 3 dermatologists, 2 nurses, 2 psychologists, and 2 hospital secretaries) who took part in

Table 1
Scale assessment of the facial age.

Upper face				
forehead lines at rest	no lines 0	mild lines 1	moderate lines 2	severe lines 3
forehead lines dynamics	no lines 0	mild lines 1	moderate lines 2	severe lines 3
brow positioning	very high with arch 0	high with arch 1	medium 2	low and flat 3
glabellar lines at rest	no glabellar lines 0	mild glabellar lines 1	moderate glabellar lines 2	severe glabellar lines 3
glabellar lines dynamic	no glabellar lines 0	mild glabellar lines 1	moderate glabellar lines 2	severe glabellar lines 3
crow's feet at rest	no wrinkles 0	mild wrinkles 1	moderate wrinkles 2	severe wrinkles 3
crow's feet dynamic	no wrinkles 0	mild wrinkles 1	moderate wrinkles 2	severe wrinkles 3
inferior eyelids dark circles and bags	no dark circles and bags 0	mild dark circles and bags 1	moderate dark circles and bags 2	severe dark circles and bags 3
superior eyelid skin elasticity	eyelid fold well defined 0	mild loss of skin elasticity 1	moderate loss of skin elasticity 2	severe skin redundancy 3
Mid face				
infraorbital hollow	no hollowness 0	mild hollowness 1	moderate hollowness 2	severe hollowness 3
cheek fullness	full cheek 0	mildly sunken cheek 1	moderately sunken cheek 2	severely sunken cheek 3
Lower face				
nasolabial folds	no folds 0	mild folds 1	moderate folds 2	severe folds 3
marionette lines	no lines 0	mild lines 1	moderate lines 2	severe lines 3
lip wrinkles at rest	no wrinkles 0	mild wrinkles 1	moderate wrinkles 2	severe wrinkles 3
lip wrinkles dynamic	no wrinkles 0	mild wrinkles 1	moderate wrinkles 2	severe wrinkles 3
oral commissures	no downturn 0	mild downturn 1	moderate downturn 2	severe downturn 3
jawline	no sagging 0	mild sagging 1	moderate sagging 2	severe sagging 3
neck folds	no folds 0	mild folds 1	moderate folds 2	severe folds 3
Hair and skin				
hair	high hair density 0	mild loss of hair density 1	moderate loss of hair density 2	severe loss of hair density or baldness (men) 3
skin	thick and elastic skin 0	mild loss of thickness and elasticity 1	moderate loss of thickness and elasticity 2	severe loss of thickness and elasticity 3
photo-aging	no spots 0	1–5 spots 1	6-10 spots 2	>10 spots 3

Table 2
Correspondence between total face score and patient age.

Age range	Age mean ± SD	Score range	Score mean ± SD
18–22	20,2 ± 1.2	2–6	4 ± 1.6
23–27	25 ± 1.5	4–10	7.21 ± 1.9
28–32	31 ± 1.1	12–15	13.8 ± 1.6
33–37	35 ± 1.5	22–26	24.1 ± 1.3
38–42	40 ± 0.9	27–29	28 ± 0.8
43–47	45 ± 1.3	29–33	31.1 ± 1.4
48–52	50 ± 1.7	32–34	33 ± 0.7
53–57	55 ± 1.9	32–42	37 ± 4.5
58–62	60 ± 2.2	33–44	41 ± 3.2
63–67	65 ± 2.6	42–49	44.1 ± 2.8
68–72	70 ± 2.5	51–57	54.2 ± 4.5
>72	73,5 ± 1.5	>57	57.6 ± 0.6

the scale validation process without being informed about the overall patient selection. The scales were printed next to a separate field where the raters typed in their findings for the relevant aesthetic facial areas. The photographs were shown at the same time and in the same office, where the reviewers worked on 15 identical computers with the same image settings. They used four degrees of severity (none, mild, moderate, severe) and, in the field next to the scales, they observed the severity of the signs of aging for each facial area for the 1,100 subjects. Each rater conducted the evaluations independently, providing a total score that was the sum of the scores of each scale. At the end of the evaluation, the subject's actual age was revealed. The raters were instructed to evaluate patients independently and to return the printed scales with their ratings. The entire process lasted two days. One month later it was repeated in order to test inter-rater reliability. Certain cropped pictures representing different aesthetic areas were selected from among the 1,100 subjects to be presented with the scales at the end of the validation process, based on the area under study, image quality and clarity. We selected photographs from the database to represent the degrees of severity of aging for the different facial areas. Next we matched the selected photographs with each of the different numerical degrees of the 21 scales (Fig. 1). We paired the photographs with the scales if at least seven reviewers had assigned the same rating to a specific aesthetic area for the same patient. In developing the scales, we adhered closely to the guidelines to develop a credible, clinically meaningful scientific tool (Hays et al., 1993; Cano and Hobart, 2008; Klassen et al., 2010; Lasch et al., 2010; Mokkink et al., 2010). Using an inductive methodological approach, all the ratings were combined to obtain the sum of the aesthetic areas (upper, middle, lower face and hair and skin quality) in order to calculate a total facial score and obtain a valid scale to predict apparent age. Descriptive statistics (mean, standard deviation) were calculated for patients' ages and scores. We used the Rasch model during the validation process. After establishing the correlation between actual age and patients' scores, we analyzed inter-rater reliability and test-retest reliability.

After describing a preliminary version of our face - objective assessment scale (La Padula et al., 2016), we developed and included a new sub-scale to enable a more complete facial evaluation: the facial photo-aging scale.

2.3. The facial photo-aging scale

Clinical changes due to actinic skin aging or dermatoheliosis affect the areas of the body that receive the most sun exposure, in particular the face.

Pigmented spots, wrinkles and spider veins are the first signs of chronic repeated exposure to the sun; the skin then becomes leathery, yellowish and drier; wrinkles deepen into creases and skin color becomes uneven, with hyperpigmented and hypopigmented spots, freckles and actinic spots (Han et al., 2014). The appearance of such spots has a very substantial impact on overall facial appearance and may therefore influence apparent age. Since new treatments are nowadays available for this condition we felt the need to create and validate a new scale: *the facial photo-aging scale.*

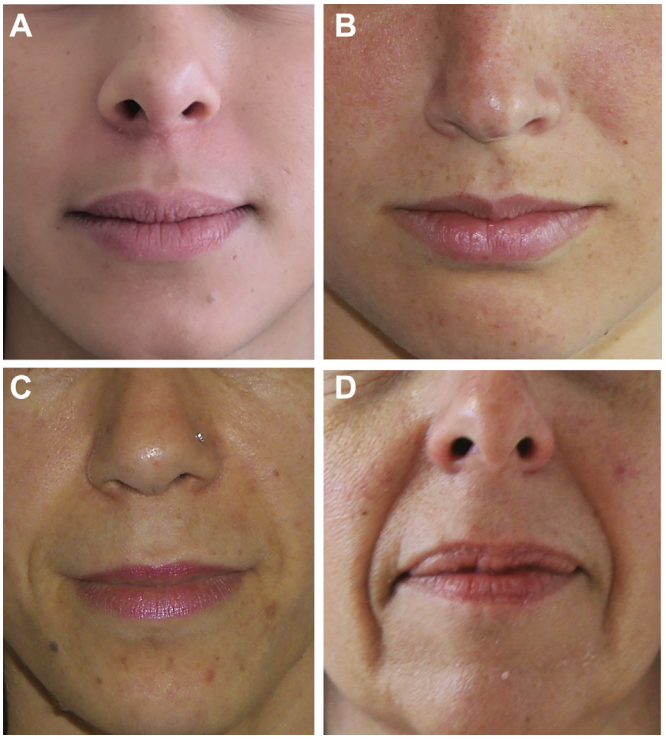

Fig. 1. Representative example of the nasolabial folds photo-numerical rating scale. Nasolabial folds: no folds (a); mild folds (b); moderate folds (c); severe folds (d).

As with the other scales, we established four degrees of severity (from no spots to >10 spots) and applied the same statistics to validate this new scale.

2.4. The Rasch measurement theory

We used the Rasch measurement theory (RUMM2030 software) as part of the validation process of the face objective assessment scale (Wright and Masters, 1982; Andrich, 1988a,b; Andrich, 2004). This theory applies a mathematical model to examine the differences between observed and predicted responses to determine the data corresponding to a group of items. When the data match the Rasch model, the measurement theory (i.e., a scale measuring a specific construct) is supported by the data. The Rasch measurement theory analysis examines discrepancies (or matches) between observed scores (response rate per item) and the values predicted by the Rasch model, which is assessed using a series of statistical tests to examine each scale (Rasch, 1960; Andrich, 1988a,b). With this model, it is possible to assess the overall quality of the scale. We interpreted our results as follows:

2.5. Item response category

Each item of the face objective assessment scale was assigned one of four possible response categories indicating the degree of severity (none, mild, moderate, severe), which reflected an ordered

continuum that increased for the construct under study. The threshold is the location at which the probability of responding in adjacent pairs to response options is 50% (Andrich, 1988a,b). When the categories work as intended, the thresholds are ordered. By contrast, "disordered" thresholds suggest that the response categories for a given item are not working as intended, which is what occurred when the reviewers had trouble distinguishing between the different response options (Zhu et al., 1997). When the response options worked as expected, the validity of the scale was confirmed (Andrich, 1982).

2.6. Statistics for matching items

The items of a scale had to match and work together both clinically and statistically. When they did not (i.e., in the case of a mismatch), adding up the responses from the different items to obtain a total score was not meaningful.

2.7. Item location

The items define a continuum, and by looking at the items' locations on this continuum, we observed that they were evenly distributed across a reasonable range.

2.8. Internal consistency reliability

Internal consistency reveals the extent to which the individual scales of each item are in agreement and denote an underlying construct. The internal consistency of the face objective assessment scale and its dimensions were estimated using Cronbach's α coefficient, between 0 (no internal consistency) and 1 (high degree of internal consistency) (Cronbach, 1951). This is considered to be a way to gauge the scale's reliability.

2.9. Person Separation Index

This statistical reliability is comparable to Cronbach's α coefficient and quantifies the error associated with measurements in a sample. High values indicate a high degree of reliability.

2.10. Reliability and validity of the new face objective assessment scale

The facial score's validity was assessed by looking at the correlation of the scores obtained for each patient with their age using the Pearson test (r) (Alkrisat and Dee, 2014). Inter-rater reliability was analyzed to assess the reliability of the aesthetic scales (Neumann et al., 2000).

The scores that followed a normal distribution obtained for each reviewer were compared using a paired *t* test. Test-retest reliability was used to observe whether inter-rater variability could be excluded (Rieu et al., 2015).

The same examiners reassessed all the patients one month later to test the accuracy of the scores and observe any changes over time. Using a paired *t* test, we compared the initial scores to the total scores obtained one month later and their correlation with the patient's actual age following a normal distribution. We analyzed the same data using the Pearson test, considering a value of $p < 0.05$ to be significant. We also analyzed the normal distribution of the continuous variables using the Kolmogorov-Smirnov test. All the analyses were performed with PRISM, version 5 (Graph Pad, USA). Each of the authors had complete access to the database and was fully responsible for data integrity.

2.11. Validation of the new face objective assessment scale in clinical practice

To test the efficacy of the face objective assessment scale in clinical practice, we used it with 100 patients (50 men and 50 women) who had undergone a facelift performed by the same surgeon. The degree of severity of facial aging signs was assessed by each patient and by the surgeon prior to surgery and six months after surgery.

3. Results

3.1. Descriptive statistics

The participants' mean age was 45.6 ± 13.3 years (range: 18 to 76). The men-to-women ratio was 1. Women's mean age was 44.5 ± 10.4 years and men's mean age was 44.1 ± 11.6 years. The

Table 3
Overall fit to the rasch model and person separation index for each scale.

Scale	Degrees of freedom	P	X^2	Person separation index
forehead lines at rest	15	0.16	24.3	0.88
forehead lines dynamics	20	0.56	33.8	0.90
brow positioning	20	0.41	15.3	0.89
glabellar lines at rest	20	0.15	21.7	0.90
glabellar lines dynamic	20	0.12	32.4	0.90
crow's feet at rest	16	0.74	41.7	0.90
crow's feet dynamic	16	0.23	13.3	0.90
inferior eyelids dark circles and bags	20	0.34	34.9	0.90
superior eyelid skin elasticity	16	0.15	49.5	0.90
infraorbital hollow	20	0.25	55.8	0.90
cheek fullness	20	0.16	14.8	0.90
nasolabial folds	20	0.60	33.3	0.90
marionette lines	16	0.21	54.8	0.90
lip wrinkles at rest	15	0.55	31.2	0.88
lip wrinkles dynamic	20	0.45	27.4	0.90
oral commissures	20	0.41	20.1	0.90
jawline	20	0.33	61.8	0.90
neck folds	30	0.45	44.7	0.90
hair	40	0.67	21.5	0.85
skin	41	0.70	34.8	0.84
photo-aging	40	0.69	33.7	0.86

mean score of women patients and of men patients during the first evaluation was, respectively, 30.2 ± 11.4 and 30.1 ± 12.7. During the second evaluation (one month later), the mean score was 30.3 ± 11.6 and 30.4 ± 11.6. We randomly selected 12 age groups from the database and calculated the mean score and standard deviation for each age group (Table 2).

3.2. Rasch measurement theory

The statistics corresponding to the Rasch model are presented in Table 3 (as mentioned, the data matched the model's predictions). Target values were correct and for each of the 21 scales, all items showed ordered thresholds, which indicates that the examiners were able to successfully distinguish between the four options (none, mild, moderate, severe) for each item. A non-significant Chi-square value confirmed that the 21 scales matched the Rasch model. All the scale items had a residual matching within the recommended range of −2.5 to +2.5. The Person Separation Index values were greater than or equal to 0.8 for each scale, which indicates good reliability. These results confirmed the reliability and validity of each of the 21 scales for their respective construct.

3.3. Internal consistency reliability: Cronbach's α coefficients

All the scales met acceptability, reliability and validity criteria. Scale reliability and validity were confirmed especially by Cronbach's α coefficients (≥0.90) and intra-class correlation coefficients (≥0.78). These findings indicate that the items of each scale were statistically compliant and that the scores were valid and reliable (Table 4).

3.4. Validity of the total facial score

The Pearson test score demonstrated the strong correlation between the patient's actual age and the total facial score among both men and women (Fig. 2a,b). The 12 age groups were strongly correlated with the mean age of each group (Fig. 2c). The second round of assessments confirmed these strong correlations using nearly identical correlation coefficients (Table 5).

Table 4
Cronbach's alpha and intra-class correlation coefficients.

Scale	Cronbach's Alpha	Mean Intraclass Correlation Coefficient
forehead lines at rest	0.90	0.78
forehead lines dynamics	0.96	0.78
brow positioning	0.97	0.83
glabellar lines at rest	0.92	0.79
glabellar lines dynamic	0.94	0.80
crow's feet at rest	0.98	0.88
crow's feet dynamic	0.94	0.84
inferior eyelids dark circles and bags	0.95	0.84
superior eyelid skin elasticity	0.93	0.78
infraorbital hollow	0.97	0.88
cheek fullness	0.93	0.84
nasolabial folds	0.95	0.84
marionette lines	0.94	0.84
lip wrinkles at rest	0.93	0.78
lip wrinkles dynamic	0.96	0.78
oral commissures	0.97	0.78
jawline	0.94	0.83
neck folds	0.96	0.83
hair	0.94	0.78
skin	0.96	0.78
photo-aging	0.95	0.84

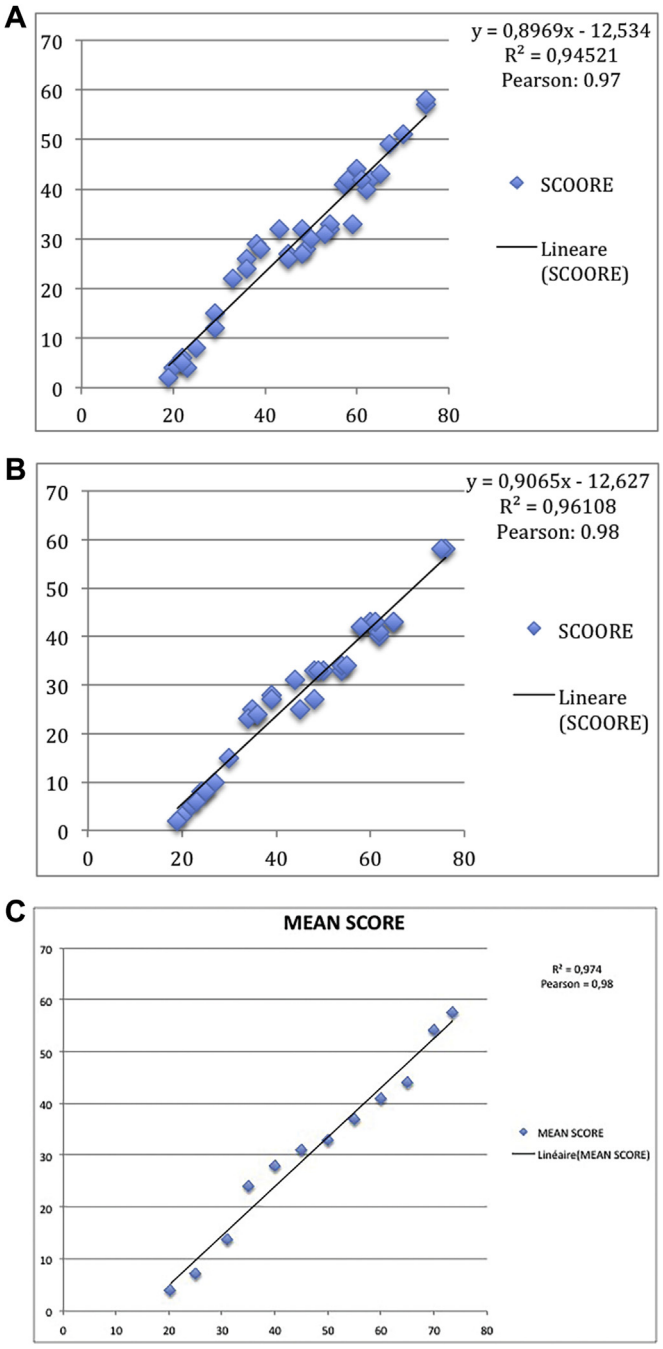

Fig. 2. A)Correlation Analysis of total face score with patients age in women (Rater 1) x: women age; y: total face score b)Correlation Analysis of total face score with patients age in men (Rater 1) x: men age; y: total face score c)Correlation analysis of the mean total facial score in the 12 age groups with the mean age of each group. x: mean age; y: mean total facial score.

3.5. Reliability of the total facial score

Inter-rater reliability: No significant difference was observed between the scores assigned by the reviewers for the female group (t test = 1.44; p = 0.15) and the male group (t test = 1.43; p = 0.16).

Test-retest reliability: All patients were reassessed one month later by the same raters. No inter-rater variation was observed for the female patient group (t test = 1.44; p = 0.16) or the male patient group (t test = 1.43; p = 0.16).

Table 5
Correlation of patients age with the total face score at first assessment and one month later; PCCV (Pearson correlation coefficient value).

Raters	PCCV females	PCCV males	PCCV females (test-retest reliability)	PCCV males (test-retest reliability)
Rater 1	0.97	0.98	0.97	0.98
Rater 2	0.97	0.98	0.97	0.98
Rater 3	0.97	0.98	0.98	0.98
Rater 4	0.97	0.97	0.98	0.98
Rater 5	0.96	0.98	0.96	0.98
Rater 6	0.98	0.98	0.98	0.98
Rater 7	0.97	0.99	0.97	0.98
Rater 8	0.98	0.98	0.98	0.98
Rater 9	0.98	0.98	0.98	0.97
Rater 10	0.97	0.98	0.97	0.98
Rater 11	0.98	0.98	0.98	0.98
Rater 12	0.98	0.97	0.98	0.97
Rater 13	0.97	0.97	0.98	0.98
Rater 14	0.98	0.98	0.98	0.98
Rater 15	0.96	0.98	0.97	0.98

3.6. The new face objective assessment scale validation in clinical practice

The physician and the 130 patients reported a significant reduction in the total score after 6 months of follow up (with a mean reduction, respectively, of 10 ± 2.7 points and 10 ± 1.7 points). Scores pre-surgery and post-surgery were significantly different ($p < 0.05$).

4. Discussion

As the body ages it changes considerably, and people's concerns about their appearance are increasingly focused on the face, which can have a negative psychosocial impact (Honigman and Castle, 2006). Fear of aging and body image concerns are predictive factors of social motivation to undergo cosmetic surgery. After facial rejuvenation treatment, patients feel a need to assess how much more youthful they appear. Several authors have developed tools to evaluate apparent age reduction following aesthetic treatment ((Rzany et al., 2012; Kosowski et al., 2009; Chauhan et al., 2012). 37–40). For instance, Panchapakesan et al. (2013) developed the FACE-Q Aging Appraisal Scale, which provides a global assessment of the patient's perception of facial aging. They also designed the patient-perceived age visual analogous scale (FACE-Q VAS), which consists of a single item to compare patients' actual age to how old they think they look. The authors consider that these scales make it possible to obtain accurate assessments among patients who have undergone aesthetic facial procedures. To evaluate a patient's satisfaction with an aesthetic facial treatment, we believe it is essential to take into account how old they think they look. However, their perception cannot be considered scientifically acceptable or clinically meaningful, since it is based on the viewpoint of a single individual. Swanson (2011) studied the apparent age reduction following facial rejuvenation procedures by showing photographs taken before and after surgery to independent members of the public who were asked to rate apparent age. As the authors mentioned, this study was limited insofar as it used only frontal facial photographs.

For an overall facial assessment, in 2012, Rzany et al. (2012) presented the Merz scale. However, no scale has focused on evaluating skin and hair. In our study, the skin quality and hair density scales could represent a valuable source of additional information and play a decisive role when a global facial analysis must be performed.

Although many measurement tools exist, there is a need for a valid, reliable system to predict patient age. To meet this need, our team has developed a tool based on scores from different scales, with the help of a simple, comprehensive and rapid method that could be used in clinical practice.

The impact of photo-aging prompted us to add a new scale (photo-aging scale) to enrich the comprehensive assessment of signs linked to overall facial aging.

The new face objective assessment scale was developed for research purposes and for clinical practice, in order to measure the effects after any facial rejuvenation procedure. Our findings resulted in satisfactory intra-rater and inter-rater reliability, which was in fact nearly perfect in terms of inter-rater values. In addition, intra-rater reliability was very stable. The period of one month between the two assessments was also beneficial because it decreased memory-related bias and reproduced conditions that closely resemble those of actual medical practice, when doctors re-assess their patients. The high degree of consistency in inter-rater reliability among the reviewers indicates that the overall facial assessment scale could be an appropriate tool to obtain a comprehensive and objective assessment of facial age. Moreover, the close match between the total facial score and the patient's age makes it a useful tool for the evaluation of patient apparent age. A pattern emerged from the preliminary validation of the face objective assessment scale in clinical practice: the more effective the facial rejuvenation treatment, the lower the score, the milder the signs of aging, and the more youthful the patient appeared. The physician, the patients themselves and another member of the medical team could assign a score for the patient before and after treatment, and this score could be included in the patient's record along with data and photographs.

At a time when anti-aging medicine is thriving, this scale could provide a valuable tool to assess the efficacy of rejuvenation treatments. In clinical practice, it has been established previously that taking into account the patient's experience seems to improve the doctor/patient relationship as well as health care and health outcomes (Marshall et al., 2006; Valderas et al., 2008). With this in mind, the new face objective assessment scale could be a useful indicator for clinical research, with the potential to help guide future surgical innovations during clinical trials. It would offer a means to advance comparative research in facial rejuvenation treatments, including in regenerative medicine.

Our study nonetheless has limitations. First, the study participants were exclusively Caucasian patients. Future studies could examine the use of our scales among black and Asian patients. Second, a bias may have been introduced during patient enrollment. Further studies are needed to confirm our results and establish the face objective assessment scale as a universally accepted tool for the evaluation of facial aging.

5. Conclusion

We believe the new face objective assessment scale represents a useful tool for both research and clinical practice. It provides an additional, easy-to-use tool that may be valuable both to obtain a complete initial assessment and during follow up of patients who have undergone facial rejuvenation treatment.

Compliance with ethical standards

All procedures in the study involving human participants have been performed in accordance with the ethical standards of institutional and/or national research committees and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Disclosure

The authors declare that they have no financial interests including support or grants related to the context of this article.

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Author contribution to the content:
First author: Study design/writing and data collection, Statistics.
Second author: Statistics.
Third author: Statistics, Data collection.
Last author: Study approval.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcms.2019.03.014.

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