Validated 5-point photonumeric scales for the assessment of the jowls and chin

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Abstract

Objective: The objective of this investigation was to create and to examine the reproducibility and validity of 5-point photonumeric assessment scales that allow objective assessment of chin retraction and jawline sagging using a digital and a live validation.

Material and methods: Two new 5-point photonumeric scales created to assess chin projection and jawline sagging were validated by 12 experts in a digital validation and by 5 experts in a live validation setting. Intra-rater agreement and inter-rater agreement were assessed.

Results: For the digital validation, an almost perfect intra-rater (Kappa: 0.89 [95% CI: 0.86–0.91]) and almost perfect inter-rater agreement in both sessions (Kappa: 0.80 [95% CI: 0.74–0.86] and 0.80 [95% CI: 0.74–0.86]) was achieved for the Croma Chin Projection Assessment Scale. While intra-rater agreement (Kappa: 0.88 [95% CI: 0.85–0.91]) was almost perfect for the Croma Jawline Sagging Assessment Scale and inter-rater agreement being substantial in the first session (Kappa: 0.76 [95% CI: 0.71–0.81]) and almost perfect in the second session (Kappa: 0.81 [95% CI: 0.76–0.85]).
INTRODUCTION

The number of minimally invasive soft-tissue filler augmentations has experienced a spike in the last decades. Between the years 2015 and 2019, the number of injection procedures increased worldwide by 50.6% from 2.9 million to 4.3 million.1 The ease of the procedures, short downtime, and lower cost compared to surgical interventions, combined with efficient and relatively safe results can be considered as the main driving forces for the increase in number of performed procedures.2-4 Recent trends have shifted from sole amelioration of folds to sculpting the face and enhancing facial features.5-7 One of the main area of interest is enhancing the lateral view of patients by adding projection to the chin in order to harmonize the profile of the patient. A flattened and especially retruded chin can create the appearance of an unbalanced profile and create the impression of a fleeing chin.8 Not only hyaluronic acid (HA)-based fillers but also calcium hydroxylapatite (CaHA) products or surgical interventions can alter the appearance of the chin and influence the profile of a patient.9,10 Recent investigations have shown, that chin projection is an important component of facial appearance and affects the overall balance and harmony of the face.8,11 While chin retrusion is not a sign of aging but rather a genetically predisposed condition that affects patients of all age decades, the formation of jowls is considered as a sign of aging which establishes with increasing age.12-14 The formation of jowls is caused by the descent of the subcutaneous jowl fat compartment, which prolapses over the bony adhesion of the platysma.14 By injecting soft-tissue fillers along the jawline, a straight, sharp jawline can be restored and create a younger, fresher appearance of the patient.2 However, to assess the severity of chin retrusion and jawline sagging, validated scales are needed to assess the baseline state and evaluate the outcome after a minimally invasive intervention. In the literature, only two published scales are available for validated assessment of chin retrusion while furthermore only one published and validated scale for assessment of the jawline is available to the knowledge of the authors.15-17 Thus, the objective of this endeavor was to develop validated 5-point photonumeric scales, that allow a reliable, reproducible objective appraisal of chin retrusion and jawline sagging using a digital and live validation.

MATERIALS AND METHODS

2.1 Establishment of photograph database

Prior to creation of the scale and its descriptors, a professional photographer was asked to create a photograph database, which was regularly reviewed by the medical team. The database was created to depict a broad range of chin and jawline morphology. Selected subjects were photographed in a professional photograph studio by a trained photographer using a standardized protocol and 2D photographic techniques with a professional, high-resolution, digital camera. The subjects were captured in a perfectly aligned lateral view to ensure that oblique capture angles did not falsify the projection of the chin or appearance of the jowls. The background was a light to middle-hued blue to allow for facilitated post-production of the images. For consistency, images were cropped at the level of the emergence of the columella assessment scales, that allow a reliable, reproducible objective appraisal of chin retrusion and jawline sagging using a digital and live validation.
TABLE 1 Inclusion and exclusion criteria for subjects to participate in the digital and live validation

| Inclusion Criteria                                                                 | Exclusion Criteria                                                                 |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 1. Male or female, 18 years of age or older                                       | 1. Presence of infectious, inflammatory, or proliferative lesions in the face or neck area |
| 2. Healthy skin in the face and neck area which is free of diseases that could interfere with evaluation | 2. Cutaneous lesions in the face of neck area                                       |
| 3. Willingness to abstain from any aesthetic or surgical procedures in the face between the time of photographs and the live evaluation | 3. History of major reconstructive surgery, that is, split-thickness grafts or free flaps in the face or neck |
| 4. Written consent that participants might be available for live evaluation after taking the photographs | 4. History of major maxillofacial surgery in the face or neck area                   |
| 5. Written signed and dated informed consent                                         | 5. Tattoos in the face or neck area                                                   |
| 6. Capable to understand information about the investigation, including subjects’ obligations, and is willing to take part, as evidenced by signed and dated informed consent | 6. Permanent make-up in the face or neck area                                         |
| 7. Jewelry of any kind that cannot be removed in the face or neck area               | 7. Jewelry of any kind that cannot be removed in the face or neck area                |
| 8. Epilepsy                                                                         | 8. Written consent that participants might be available for live evaluation after taking the photographs |
| 9. Subjects whose participation in clinical trials is prohibited by the Austrian Medical Devices Act (eg, persons with a legal custodian appointed due to mental disability, prisoners, soldiers and other members of the armed forces, civil servants) | 9. Subjects whose participation in clinical trials is prohibited by the Austrian Medical Devices Act (eg, persons with a legal custodian appointed due to mental disability, prisoners, soldiers and other members of the armed forces, civil servants) |

2.2 Scale creation

A suitable cohort of subjects was screened from the photography database by an experienced medical team consisting of both dermatologists and plastic surgeons. A total of 112 subject photographs representing different grades of the chin projection scale and jawline sagging scale were selected to represent diversity in sex and Fitzpatrick skin type. A total of four independent physicians who are Key Opinion Leaders in the aesthetic field were asked to rate the 112 subjects during an online rating. As guidance, a representative image of a chin with ideal projection (Grade 1) and an image of a chin with very severe chin retrusion (Grade 5), which was chosen by the medical team, was given as guidance for grading of chin retrusion. Likewise, a representative image of a jawline with none sagging (Grade 1) and a jawline with very severe sagging (Grade 5) was given for assessment of jawline sagging. The raters were asked to rate the chin retrusion and the jawline sagging as either none (Grade 1), mild (Grade 2), moderate (Grade 3), severe (Grade 4), or very severe (Grade 5). Based on the mean rating, the 112 subjects were ranked and attributed with their respective average rated grade. Once the medical team received an independent rating of the chin photographs, a morphed chin projection scale was created by selecting one subject whose image is representative of general chin projection (Grade 3), and a morphed jawline sagging scale was created by selecting one subject whose image is representative of general jawline sagging (Grade 3), respectively. To create the rest of the gradings for the morphed chin projection scale, additional images were selected from the pool of images and varying degrees of severities of chin projection and jawline sagging were overlaid, respectively, onto the base under close supervision of the medical team. After morphing the scales, a photoguide was created by choosing from the pool of rated images. A total of 4 examples per grade was chosen to give an extensive reference. Moreover, descriptors were chosen by the medical team, which are given in Figures 2 and 3. The final scales contained the scale with an assessment guide, the morphed image, and the real subject images drawn from the digital photoguide.

2.3 Digital validation

For the digital validation, a total of 12 experienced dermatologists and plastic surgeons were invited. Prior to digital validation, all raters underwent an interactive online group training session led by the medical project leader of the scale development team using 5 exemplary subjects. The digital validation process involved the randomization of subject photographs that were uploaded to an encrypted online platform that was specially created for validation purposes. The medical team chose approximately equal distributions of severity gradings that were to be rated by the evaluators. For the Croma Chin Projection Assessment Scale, raters were asked to grade the severity of chin retrusion of shown subjects using the provided scale and its descriptors. For the Croma Jawline Sagging Assessment Scale, raters were asked to rate the severity of jawline sagging using the provided scale. After a 1-week interval, digital photograph evaluation was repeated with the same photographs, but with a different subject randomization sequence.

2.4 Live validation

For the live validation, a total of five raters with experience in dermatology were invited to grade the chin retrusion and jawline sagging of subjects in real life with the provided Croma Chin Projection Assessment Scale and Croma Jawline Sagging Assessment Scale. Approximately two months after their photographs were taken, subjects whose images have been used in the digital evaluation, and not in the process of scale creation, were asked to take part in two live validation sessions which were set apart one month. During the first and second live validation sessions, each physician rater evaluated all subjects. Raters were placed in separated evaluation compartments with an examination lamp and the photonumeric scale mounted and displayed for use in subject evaluation. Subjects presented themselves to each rater individually and proceeded from one rating compartment to the next in the same order until being evaluated by all five raters. Raters were instructed to avoid any discussion with subjects or other raters. The raters were instructed to switch their rooms every two hours in order to ensure randomized,
non-influenced surroundings, had regular breaks and a 1 h lunch break to avoid rater fatigue.

2.5 | Statistical considerations

Sample size considerations were based on the expected width of the confidence intervals for intraclass correlation coefficients (ICC) as measures of inter-rater reliability with inter-rater reliability being the primary measure of interest. Following Bonett, the number of subjects required to achieve a certain width of the confidence intervals depends critically on the number of raters and expected ICC values. Different numbers of raters were planned for live subject validation with five raters and digital subject validation with 10 raters. A range of expected ICC values was derived from guidelines for inter-rater reliabilities by Fleiss’ kappa and using the interpretation categories of Landis & Koch (0: poor agreement; 0.0–0.20: slight agreement; 0.21–0.40: fair agreement; 0.41–0.60: moderate agreement; 0.61–0.80: substantial agreement; 0.81–1.00 almost perfect agreement). In case of digital validation with 10 different judges, a sample size of 60 subjects lead to 95% confidence intervals of widths 0.19, 0.16, and 0.13 for overall ICC values of 0.6, 0.7, and 0.8, respectively. Live subject validation carried out by 5 judges and 70 subjects lead to 95% confidence intervals of widths 0.20, 0.17, and 0.13 for overall ICC values of 0.6, 0.7, and 0.8, respectively. Inter-rater reliability (reliability between raters) and intra-rater reliability (reliability of repeated ratings) was assessed by intraclass correlation coefficient (ICC 2.1) with weighted Kappa and given as 95% CI for the digital and the live validation. A weighted Kappa coefficients of 0.00–0.19 was considered as "poor," 0.20–0.39 as "fair," 0.40–0.59 as "moderate," 0.60–0.79 as "substantial" and 0.80–1.00 as "almost perfect."

3 | RESULTS

3.1 | Subject disposition

For the digital validation of the Croma Chin Projection Scale, a total of 69 subjects (55 females, 14 males) with a mean age of 42.4 ± 12.9 years [18–68 years] were rated, while a total of 81 subjects (67 females, 14 males) with a mean age of 43.9 ± 14.1 years [18–73 years] were rated for the digital validation of the Croma Jawline Sagging Assessment Scale. For the live validation, 88 subjects (73 females, 15 males) with a mean age of 45.0 ± 14.1 years [20–73 years] were rated for both scales.

3.2 | Digital validation

For the digital validation of the Croma Chin Projection Scale, the intraclass coefficient (ICC) of the intra-rater reliability measures was on average 0.89 with a weighted Kappa of 0.89. The inter-rater reliability was 0.81 in the first session with a weighted kappa of 0.80 and 0.80 in the second session with a weighted kappa of 0.80. For the digital validation...
of the Croma Jawline Sagging Assessment Scale, intraclass coefficient (ICC) of the intra-rater reliability measures was on average 0.88 with a weighted Kappa of 0.88. The inter-rater reliability was 0.76 in the first session with a weighted kappa of 0.76 and 0.76 in the second session with a weighted kappa of 0.81. 95% CIs are given in Tables 2 and 3.

3.3 | Live validation

For the live validation of the Croma Chin Projection Scale, the intraclass coefficient (ICC) of the intra-rater reliability measures was on average 0.82 with a weighted Kappa of 0.82. The inter-rater reliability was 0.79 in the first session with a weighted kappa of 0.78 and 0.80 in the second session with a weighted kappa of 0.80. For the live validation of the Croma Jawline Sagging Assessment Scale, the intraclass coefficient (ICC) of the intra-rater reliability measures was on average 0.83 with a weighted Kappa of 0.83. The inter-rater reliability was 0.75 in the first session with a weighted kappa of 0.75 and 0.75 in the second session with a weighted kappa of 0.74. 95% CIs are given in Tables 2 and 3.

4 | DISCUSSION

The aim of this investigation was to create scales for the assessment of chin projection and jawline sagging, which were validated digitally and live. A total of twelve raters validated the scales digitally and a total of five raters validated the scales live. For the digital validation, an almost perfect intra-rater and almost perfect inter-rater agreement in both sessions were achieved for the Croma Chin Projection Scale, while intra-rater agreement was almost perfect for the Croma Jawline Sagging Assessment Scale and inter-rater agreement being substantial in the first session and almost perfect in the second session.
For the live validation, intra-rater agreement was almost perfect for both scales, while inter-rater agreement was substantial in both sessions for both scales.

A limitation of the Croma Chin Projection Scale is the lack of 3-dimensional appreciation of the chin. Chin projection was assessed in the lateral view only; however, an aesthetic appearance of the chin is not only determined by the projection of the chin in the lateral view, but rather by the 3-dimensional appearance including the frontal view. A strength of the Croma Chin Projection Scale is the defined descriptors, which might have contributed to the strong intra-rater and inter-rater agreement. Moreover, both scales were validated digitally and live, which has not been performed in previously published scales assessing the projection of the chin. A total of twelve experts validated the scale in the digital sessions, while five experts validated the Croma Chin Projection Scale in the live run, which is equivalent to the number of raters that validated already available scales for assessment of the chin. A limitation of the Croma Jawline Sagging Assessment Scale is the fact that only sagging of the jowls, that is, the subcutaneous jowl fat pad was taken into consideration. Especially with higher body mass index the formation of additional jowl deformation posterior to the subcutaneous jowl fat pad, that is, descent of the superficial middle cheek fat compartment can disturb the appearance of the jawline. The sole published scale for assessment of the jowls was validated digitally only, which highlights the rigorous validation standards of the Croma Jawline Sagging Assessment Scale, which was validated digitally and live. Moreover, subjects of different ethnicities and with different Fitzpatrick Skin Types were assessed to allow for cross-ethnicity assessment. Another strength of both validated scales is the combination of morphed images and the additional photograph guide, which provides real patient images with rated grades for better comprehension and application of the scale grades. Comparing the intra-observer agreement the Croma Chin Projection Scale was validated with a comparable to marginally better intra-rater and inter-rater agreement then previously published scales by Moradi et al. and Sykes et al. The inter-rater and intra-rater agreement of the Croma Jawline Sagging Assessment Scale was also comparable to the Kappa values reported by Narins et al. who reported an inter-rater kappa of 0.74 and 0.71 for the first and second session, respectively, while an intra-rater reliability of 0.80 was reported for the intra-rater reliability (compared to an inter-rater reliability of 0.75 and 0.74 for the first and second session and an intra-rater reliability of 0.83 of the Croma Jawline Sagging Assessment Scale). While Sykes et al. focused on the projection of the chin in relation to the labiomentalsulcus and the lower vermilion border, the descriptors of the Croma Chin Projection Scale considered the chin projection in relation to the soft-tissue pogonion, the lower vermilion border, and the labiomentalsulcus, as these three landmarks were considered as the most prominent of the chin in the lateral view.

Rating the outcome of aesthetic interventions is now, as before, a challenging endeavor, as personal liking and subjective perception, as well as unpleasant, locally remote facial features might influence the overall rating of a condition. 3-Dimensional surface imaging has been

| Session | Croma Chin Projection Scale | ICC | Kappa [95% CI] | Croma Jawline Sagging Assessment Scale | ICC | Kappa [95% CI] |
|---------|-----------------------------|-----|----------------|---------------------------------------|-----|----------------|
| Digital Validation | Inter-rater | 0.81 [95% CI: 0.76–0.85] | 0.76 [95% CI: 0.70–0.81] | | | |
| | Intra-rater | 0.76 [95% CI: 0.70–0.81] | 0.70 [95% CI: 0.64–0.76] | | | |
| Live Validation | Inter-rater | 0.79 [95% CI: 0.72–0.84] | 0.75 [95% CI: 0.69–0.81] | | | |
| | Intra-rater | 0.75 [95% CI: 0.69–0.81] | 0.70 [95% CI: 0.64–0.76] | | | |
shown to be a valuable tool to quantify volumetric changes after injection of soft-tissue fillers; however, they do not allow to draw conclusions on the amelioration of a condition as chin retrusion. Thus, the use of validated scales to grade a condition is of utmost importance in the planning phase of a treatment and to critically evaluate the outcome of an intervention in both the clinical and the research setting.

5 | CONCLUSION

The created scales to assess chin projection and jawline sagging have been shown to provide substantial to almost perfect agreement in the digital and live validation and can thus be considered helpful tools to assess chin projection and jawline sagging in the clinical and research setting for patients that seek amelioration of chin retrusion and sagging of the jawline.

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ETHICAL APPROVAL

Dr. Pavicic is a consultant and speaker for Merz Aesthetics, Advanced Aesthetic Technologies, J&J, BTL, and Quantificare and has performed clinical studies and research work for Merz Aesthetics, LG, AAT, and Croma Pharma. Dr. Fabi is an investigator and consultant for Abbvie, Merz, Galderma, Revance, and Croma Pharma. Dr. Frank is an consultant for Croma Pharma. The authors received financial compensation for the validation of the scale. This study required no ethical approval. The data are available from the authors upon reasonable request.

CONFLICT OF INTEREST

None of the other authors listed have any commercial associations or financial disclosures that might pose or create a conflict of interest with the methods applied or the results presented in this article.

AUTHOR CONTRIBUTIONS

R.P., V.P. M.C., J.B.G., C.A.H, T.P., D.S.M., S.S., H.K., S.G.F., D.D., A.S., and K.F. performed the research. R.P., K.F., and V.P. designed the research study. S.C., S.A.K., and K.F. analyzed the data. R.P., S.C., and K.F. wrote the paper.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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