Treatment outcomes and patient-reported quality of life after orthognathic surgery with computer-assisted 2- or 3-dimensional planning: A randomized double-blind active-controlled clinical trial

Martin Bengtsson,[a] Gert Wall,[a] Pernilla Larsson,[b] Jonas P. Becktor,[c] and Lars Rasmusson[d]
Lund, Linköping, Malmö, and Gothenburg, Sweden

Introduction: Thorough treatment planning is essential for a good clinical outcome in orthognathic treatment. The planning is often digital. Both 2-dimensional (2D) and 3-dimensional (3D) software options are available. The aim of this randomized 2-arm parallel double-blinded active-controlled clinical trial was to compare the outcomes of computer-based 2D and 3D planning techniques according to patient-reported health related quality of life. The hypothesis was that a 3D technique would give a better treatment outcome compared with a 2D technique. **Methods:** Orthognathic treatment for 62 subjects, aged 18 to 28 years, with severe Class III malocclusion was planned with both 2D and 3D techniques. After treatment planning but before surgery, the patients were randomly allocated via blind collection of 1 enveloped card for each subject in a 1:1 ratio to the test (3D) or the control (2D) group. Thus, the intervention was according to which planning technique was used. The primary outcome was patient-reported outcome measures. The secondary outcome was relationship between patient-reported outcome measures and cephalometric accuracy. Questionnaires on the patient's health-related quality of life (HRQoL) were distributed preoperatively and 12 months after surgical treatment. The questionnaires were coded, meaning blinding throughout the analysis. Differences between groups were tested with the Fisher permutation test. The HRQoL was also compared with measurements of cephalometric accuracy for the 2 groups. **Results:** Three subjects were lost to clinical follow-up, leaving 57 included. Of these, 55 subjects completed the questionnaires, 28 in the 2D and 27 in the 3D groups. No statistically significant difference regarding HRQoL was found between the studied planning techniques: the Oral Health Impact Profile total showed −3.69 (95% confidence interval, −19.68 to 12.30). Consistent results on HRQoL and cephalometric accuracy showed a difference between pretreatment and posttreatment that increased in both groups but to a higher level in the 3D group. A difference between pretreatment and posttreatment HRQoL was shown for both groups, indicating increased quality of life after treatment. This supports recent findings comparing 3D and 2D planning techniques. No serious harm was observed during the study. **Conclusions:** Improvements of HRQoL were shown after treatment independent of which planning technique, 2D or 3D, was used. No statistically significant difference was found between the planning techniques. **Registration:** This trial was not registered. **Protocol:** The protocol was not published before trial commencement. **Funding:** This project was supported by personal grants to Martin Bengtsson from the Scandinavian Association of Oral and Maxillofacial Surgeons (25000 SEK), the Southern Region of the Swedish Dental Association (50000 SEK), and the Swedish Association of Oral and Maxillofacial Surgeons (25000 SEK). The sponsors

[a]Department of Oral and Maxillofacial Surgery, University Hospital of Skåne, Lund, Sweden.
[b]Center of Oral Rehabilitation, Östergötland County Council, Linköping, Sweden; Department of Orofacial Pain and Jaw Function, Faculty of Odontology, Malmö University, Malmö, Sweden.
[c]Department of Oral and Maxillofacial Surgery and Oral Medicine, Faculty of Odontology, Malmö University, Malmö, Sweden.
[d]Department of Oral and Maxillofacial Surgery, Sahlgrenska Academy, Gothenburg University, Gothenburg, Sweden.

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Address correspondence to: Martin Bengtsson, Department of Oral and Maxillofacial Surgery, University Hospital of Skåne, Lund S-22185, Sweden; e-mail, martin.n.bengtsson@skane.se.
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When planning treatment of severe malocclusions and dentofacial deformities today, there are possibilities for both 2-dimensional (2D) and 3-dimensional (3D) methods.[1,2] The planning methods could be used for both determination of which treatment (orthodontic, surgical, or both) that is preferred and the extension of the surgical treatment (eg, surgery of 1 jaw or both jaws) but also planning of distances and angulations in orthodontic and surgical movements in detail.

Severe malocclusions and dentofacial deformities have since the beginning of the 20th century been corrected with both orthodontic and surgical methods.[3] Today the method of choice is often a combined treatment.

Previous studies commonly assessed the quality of planning techniques in orthognathic surgery with measurements of cephalometric accuracy.[4-11]

The patient's wish for treatment is often based on a combination of malfunction and a need for better facial and dental appearances.[12,13] There is also general knowledge that the patient's health-related quality of life (HRQoL) depends on appearance and self-esteem. An attractive face presumably contributes to a more successful life and also to the person's self-esteem.[14]

Demand for facial esthetics has increased during recent decades. A report showed a self-perceived need for orthodontic treatment by 22% of young adults.[15] These patient demands are challenging, and the significance of preoperative prediction should therefore not be underestimated. Several recent studies have reported increases of HRQoL after treatment of dentofacial deformities.[16-19] Modern social media have also been part of the change in importance of facial appearance.[20] A correction of a malocclusion should always be made to achieve the best possible facial esthetics.[21] Even with limitations in accuracy, the use of digital prediction techniques is recommendable to improve facial esthetics. To assess the limitations, the evaluation of a prediction technique should include all decision-making steps in all sequences of the treatment; this means both major treatment decisions and definite planning of distances and angulations in orthodontic and surgical movements. This also means that the accuracy of a planning technique should be measured as a result of clinical outcome after finalization of all orthodontic and surgical treatment sequences.

Measurements of patients' self-perceived HRQoL have frequently been made with patient-reported outcome measures. These are often conducted by validated questionnaires, of which many are constructed toward a specific situation, functionality, or disease.[22-27]

The accuracy of surgical treatment for severe malocclusions depends on 3 main sequences: preoperative planning, transference of planning to surgery, and surgical precision and relapse. Previous studies on 3D planning techniques have not focused on only one of these but reported accuracy as a consequence of multiple sequences.[6-11] In our study cohort, accuracy was measured as a result of 1 sequence—preoperative planning. The other sequences were equally distributed in both groups. We compared treatment outcomes of 2 planning techniques from the subjects' HRQoL perspective. Results from studies of cephalometric accuracy in this cohort have previously been published.[28,29] Based on these results, with an indication of higher accuracy for 3D planning, it was assumed that the 3D technique also could result in greater HRQoL compared with the 2D technique.

Specific objectives or hypothesis

This study was designed to investigate possible differences of HRQoL after orthognathic treatment, depending on either a 2D or a 3D planning technique. The primary objective was to compare the treatment outcomes between 2D and 3D planning techniques by measurements of the patients' self-perceived HRQoL before and 12 months after surgical treatment. The secondary objective was to compare any differences in the patient's self-perceived HRQoL outcomes with the results from cephalometric measurements of accuracy in this cohort that were previously published.[28,29]

MATERIAL AND METHODS

Trial design and any changes after trial commencement

The study was conducted as a prospective, parallel group, randomized 2-arm parallel double-blinded active-controlled clinical trial with a 1:1 allocation ratio. No changes to the study design were made after commencement.

The study was approved by the regional ethical committee in Gothenburg, Sweden (registration number