

A comparison of cost-effectiveness of computer-assisted 2- and 3-dimensional planning techniques in orthognathic surgery

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Abstract

The aim of this randomised controlled trial was to compare the costs and benefits of computer-based 2-dimensional and 3-dimensional predictions in orthognathic surgery. Subjects aged 18–30 years with severe class III malocclusion had their treatment planned with both 2- and 3-dimensional techniques. They were randomised in a 1:1 ratio for one or other planning technique. Costs (financial, time, and dose of radiation) were compared with benefits (accuracy and health-related quality of life (HRQoL)). In total, 57 subjects (27 women and 30 men, mean (range) age 21 (18–28) years) completed the study. Comparisons showed no significant difference in total time spent, but a large advantage for the 2-dimensional technique in financial costs ($p < 0.001$); it also required a significantly lower dose of radiation ($p < 0.001$). The cost-effectiveness analysis showed a reduction in time of 0.53 minutes/HRQoL-point gained, and an increased economic cost of US\$15/HRQoL point gained for the 3-dimensional technique. It also showed that the two techniques consumed an equal amount of time, but that the 2-dimensional technique had lower financial costs, and the 3-dimensional technique a larger dose of radiation.

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Introduction

Computer-based planning has become an accessible, cheap, and efficient way to simulate the outcome of treatment in orthognathic surgery, and today planning the treatment of severe malocclusions and dentofacial deformities is based on

either 2-dimensional or 3-dimensional techniques.^{1–3} However, technical progress does not automatically favour the treatment options, and thorough clinical evaluations from several perspectives are necessary. The accuracy of the planning methods has previously been evaluated,^{4–9} and increased health-related quality of life (HRQoL) after treatment has been reported.^{10–13}

If improvement of HRQoL is facilitated by a new technique, it is interesting to evaluate if this is advocated by an increased cost. Additionally, other perspectives on costs, like time spent and biological costs (radiation dose) are interesting to evaluate.

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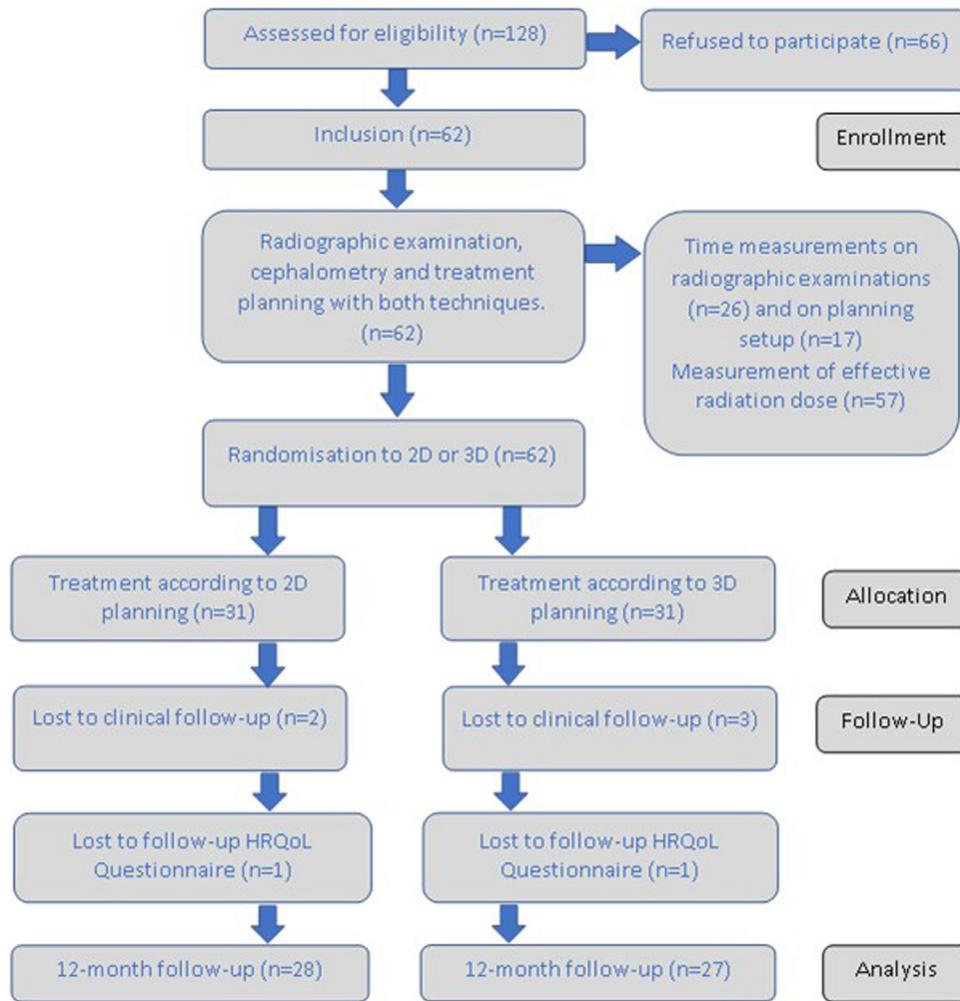


Fig. 1. CONSORT flow chart of the progress of the trial.

Based on previous studies of cephalometric accuracy and comparisons of HRQoL,^{1–3} we designed this trial to compare the cost-effectiveness of the two techniques.

Our hypothesis was that 3-dimensional prediction is superior to 2-dimensional for accuracy and HRQoL outcome, but that the price is longer time spent, higher financial cost, and larger dose of radiation.

Patients and methods

The study was a double-blinded randomised controlled trial with a 1:1 allocation ratio. Sixty-two consecutive subjects aged between 18 to 30 years with Angle class III occlusions and a minimum of 5 mm negative overjet were included. Subjects with systemic musculoskeletal diseases, drug abuse, poor mental status, or disease in the temporomandibular joint were excluded. Patients were randomised after completion of preoperative orthodontic treatment and before operation during the period 2011–2016. The planning technique was used for cephalometric diagnosis, decisions about treatment, and definitive planning of movements.

The 2-dimensional software that we used was Facad[®] (Ilexis AB, Linköping),¹⁴ and the 3-dimensional software was Simplant[®] (Materialise Corp).¹⁵

All treatments were planned using both the 2- and 3-dimensional techniques in the order mentioned, and before operation were divided into a control (2-dimensional) and a test (3-dimensional) group (Fig. 1). Both groups were handled similarly during treatment, except for the difference in planning technique. The surgical options involved Le Fort 1 maxillary osteotomy, segmented Le Fort 1 maxillary osteotomy, bilateral sagittal split mandibular osteotomy, vertical ramus mandibular osteotomy, and genioplasty. The endpoint of follow-up was 12 months postoperatively and included clinical examination, photographs, and radiographs.^{1,2}

Methods

The techniques were compared for time spent, financial cost, and dose of radiation. Time spent was measured on radiographic examination and preparation, and setting of

the planning software. All other sequences involved were assumed equal between the techniques. Planning decisions were made by the surgeon who would operate on the patient.

As all patients were examined and their treatment planned with both techniques, measurements of costs (time spent, financial cost, and dose of radiation) were independent of randomisation. The variables depending on the randomisation (cephalometric accuracy and HRQoL) were measured for each subject, so the costs of a technique (2- or 3-dimensional) were compared with benefits to the subject (control or test).

Radiographic examination included orthopantomography, profile, forward projection and computed tomography (CT) in the same radiology department.

A 70 kV cephalostat was used for profile projection 53 ms (16 mAs) and posteroanterior projection 84 ms (25 mAs), with a 10% variation depending on the size of the patient.

A 120 kV CT was used with 512 × 512-pixel image matrix, 0.800 mm thick slices, 0.399 mm slice increment, 0.352 mm pixel size, 196 mm median scanning distance (range 162–236 mm) and 11.3 mGy median computed tomographic dose index (range 3.6–16 mGy).

The computer used was a Hewlett-Packard® Elite Book 8730 W with an Intel® Core™ 2 Extreme processor (CPU x9100, 3.06 GHz, 2.96 GB RAM, Graphic card: Nvidia® Quadro® FX 3700M (dedicated graphic memory of 1024 MB).

Fixed financial costs, including radiographic examination and software, were collected from the local radiology department and from the software manufacturers, respectively.

Time spent in the planning phase was transformed into financial costs by taking the mean salary for a Swedish Oral and Maxillofacial Surgeon and specifying it to financial cost/minute. Fixed and calculated costs together were used for comparison.

The effective dose (mSv) from the CT examination was calculated from the dose-length product with a factor 0.0019 mSv/mGycm.¹⁶ Mean values from the preoperative and 12 months' follow up examinations were calculated for each subject. Mean (SD), and median (range) were presented for the 3-dimensional radiographic technique. For 2-dimensional radiography, data were fixed and obtained from the department of radiology.

The present group had previously had the planning techniques compared from the points of view of measurements of cephalometric accuracy^{1,2} and HRQoL.³ To compare the two different cephalometric systems (2- and 3-dimensional), cephalometric comparison between the planning techniques was based on distances and angles between cephalometric markers extracted from each cephalometric analysis. The cost-effectiveness was compared by weighting the outcome in time spent and financial costs against differences in HRQoL measurements using calculations of cost/change of one point in the outcome of the Oral Health Impact Profile (OHIP), as described by Hulme et al.¹⁷

Table 1
Difference in time (minutes).

Variable	Mean (SD)	p value*
Radiographic examination (n = 26):		4.8E – 5
2-dimensional	19.75 (6.95)	
3-dimensional	9.17 (4.48)	
Setting of planning software (n = 17):		4.4E – 4
2-dimensional	14.92 (3.17)	
3-dimensional	22.72 (5.45)	
Total time consumption (radiography and planning) (n = 17):		>0.30
2-dimensional	34.13 (7.75)	
3-dimensional	32.17 (7.08)	

* Fisher's test for paired comparisons.

Calculation of sample size

The sample size was based on previous publications,^{4–9} and no specific calculation was made (because of the lack of a preliminary study and previous studies) of cephalometric accuracy and HRQoL at the time the data were collected.

Statistical analysis

Comparisons of time spent was made with Fisher's non-parametric two-tailed test for paired comparisons. Mean (SD) values were calculated.

Cost effectiveness was analysed on cost/time between treatment increments, and analysed on the ratio of cost/time and OHIP points. We used Fisher's two-tailed test for paired comparisons for cost and time/OHIP point gained. Probabilities of less than 0.05 were accepted as significant.

Results

Fifty-seven subjects aged between 18 and 28 years (mean 21 years) completed the 12-month clinical and radiological follow-up. At follow-up, the test group included 13 male and 15 female patients with a mean age of 21 years, and the control group 17 male and 12 female patients with a similar mean age (Fig. 1). The test group consisted of 15 double and 13 single jaw operations, and the control group 14 double and 15 single jaw operations.

Time spent was measured for 26 subjects with both 2- and 3-dimensional examination, and 17 subjects were compared with both planning techniques (Table 1).

Significantly less time was taken for radiographic examination for the 3-dimensional technique, and significantly less time was used on setting of the planning software for the 2-dimensional technique. A comparison of total time spent (examination + planning) showed no significant difference between the techniques.

Financial costs for radiographic examination and those calculated for surgical planning were compared between the two techniques. Economic cost/unit of time was used for translation of the time recordings into a financial comparison.

Table 2
Difference in cost (\$US), VAT excluded.

Variable	2-dimensional	3-dimensional	p value*
	Mean (SD)	Mean (SD)	
Time calculated cost	156.12 (4.24)	211.88 (7.18)	1.1E – 5
Fixed economic costs:			
Software	2588	16471	
Licence software/year	706	2941	
Radiographic examination	136	182	

Fixed costs were collected from the local radiology department and from the software manufacturers respectively. Cost calculated from time measurement (n = 17).

* Fisher's test for paired comparisons.

son (Table 2). The mean difference was US\$55.76 lower cost for the 2-dimensional technique.

There was a significant difference between the radiographic techniques ($p < 0.001$) for the radiation doses delivered (Table 3). The mean effective dose for the 3-dimensional radiographic technique compared with other radiographic examinations of the facial skeleton is shown in Table 4.

Good cephalometric accuracy was shown in predicting facial outcome for both techniques,^{1,2} and in the anterior maxilla, 3-dimensional had significant better cephalometric accuracy than 2-dimensional. Both techniques were less accurate in the mandible. Despite a difference in cephalometric accuracy,^{1,2} both planning techniques showed equal improvement in HRQoL after treatment.³

At baseline there was an initial difference in HRQoL between the groups, which gave rise to a comparison between groups when adjusting for baseline differences. There was a significant difference in the change between preoperative and follow-up in the OHIP oral function, 4.8 (95% CI 0.5 to 9.1) ($p = 0.028$) when baseline OHIP orofacial pain was adjusted for.

Cost-effectiveness

When measurements of time spent on radiographic examination and planning were compared with findings of HRQoL they showed a reduction in time with 0.53 minutes for every OHIP point gained by using the 3-dimensional technique (Table 5).

Comparison of financial costs for radiographic examination and calculated costs for planning with the findings of HRQoL (Table 2) showed additional planning costs of

Table 3
Effective dose in milliSievert (mSv).

Variable	2-dimensional				3-dimensional (CT)		p value*
	OPG	Frontal	Profile	Total	Mean (SD)	Median (range)	
Dose (mSv)	0.007	0.002	0.001	0.01	0.54 (0.10)	0.54 (0.32–0.83)	4.4E – 13

Mean (SD) and median (range) calculated for mean of preoperative and follow-up computed tomographic (CT) examinations (n = 57). Total = total effective dose for 2-dimensional examinations.

* Fisher's test for paired comparisons. OPG = orthopantomogram.

Table 4
Effective doses of various craniofacial radiographic systems.

Radiographic system	Effective dose (mSv)
CT full skull	1.8
CT specified orthognathic planning	0.5
Cone-beam CT*	0.05
OPG	0.007
Profile	0.001

* ²⁰CT = computed tomography, OPG = orthopantomogram.

US\$15 for every OHIP point gained using the 3-dimensional technique (Table 5).

Discussion

The hypothesis that 3- is superior to 2-dimensional planning in accuracy and outcome of HRQoL measures, but at a price of financial cost and dose of radiation, was confirmed. Adding fixed financial costs to the comparison results in an increased cost of US\$272/OHIP point gained when using 3-dimensions. Total time spent measured was equal in the two groups.

The accuracy of surgical treatment of severe malocclusions is dependent on three main stages: preoperative planning; transfer of planning to operation (surgical template); and surgical precision or relapse.

Previous studies of 3-dimensional planning have not focused on only one of these, but reported outcome as a consequence of multiple sequences.^{4–9} We designed the present trial to measure the planning sequence alone, so that it evaluates the preoperative planning phase with greater precision.

The accuracy of the outcome of treatment has been evaluated with hard tissue markers, but we know of no studies on the accuracy of soft tissue markers. When planning treatment, soft tissue simulations are an important guide to deciding about treatment, and are therefore even more important to evaluate, so a future study on this would be the next step in the evaluation of the accuracy of planning, particularly if combined with a comparison of HRQoL outcome.

A fair comparison of prediction techniques in orthognathic surgery can be made when circumstances outside the field of interest are as identical as possible. One sequence that always differs between 2- and 3-dimensions is the transfer of the planning, and there are published examples of studies that do not take such differences into account and so lack a fair comparison between 2- and 3-dimensional prediction

Table 5
Comparison of cost-effectiveness analysis between-groups (\$US).

Technique	Mean (SD)	Between-treatment increment	Mean (SD) OHIP points	Between-treatment increment	Effectiveness ratio
Time-effectiveness (m)					
2-dimensional	34.13 (7.75)	−1.96	23.62 (33.30)	3.69	−0.53(m/OHIP)
3-dimensional	32.17 (7.08)		27.31 (24.59)		
Cost-effectiveness (\$)					
2-dimensional	156 (4.24)	56	23.62 (33.30)	3.69	15(\$/OHIP)
3-dimensional	212 (7.18)		27.31 (24.59)		

OHIP = Oral Health Impact Profile.

techniques.^{16,17} We studied the prediction sequence alone, which means that both 2- and 3-dimensional planning were done with the same template fabrication technique – a moldable acrylic splint – without assistance from a digital service centre.

Not surprisingly, planning took longer with the 3-dimensional technique, because time-consuming steps for that technique involve a more advanced system of cephalometry, heavier data files, and a segmentation process with an added dimension.

Perhaps more surprisingly, a radiographic 2-dimensional technique, which is less complex than a 3-dimensional one, was more time-consuming. Logistic movements between the radiographic machines (panoramic, profile, and anteroposterior view) in two dimensions might explain this. However, this is how the examinations are usually made, and the trial therefore represents the settings seen in most centres for orthognathic surgery.

Adding examination and planning time into a comparison of total time taken erases the separate time differences. Using a service centre during the prediction phase will probably erase the difference in planning time, resulting in an advantage for the 3-dimensional technique. This has been shown in previous studies.^{18,19}

If we reduce the number of examinations, we also reduce the amount of time taken and so the cost decreases. This motivates a technique that combines high quality, a low dose of radiation, and a minimal number of examinations or – as Xia et al put it – to be “faster, cheaper and (have a) better outcome”.²⁰ This might be available after further development of the cone-beam CT technique with a reduced dose of radiation and better imaging of the soft tissues, or combining cone-beam CT with 3-dimensional photography.²¹ Combining a dose of radiation comparable with the 2-dimensional technique with an imaging quality acceptable for full 3-dimensional prediction, will probably make the present comparisons of doses of radiation, measured on CT, outdated, but this will not be until future techniques have been evaluated clinically. As in other studies on the dose for radiographic examination, an effective dose was used for comparison.²² The measured doses were in accordance to other studies.²³

Comparison of investment and outcome in a clinical setting is commonly used for a cost-effectiveness analysis.^{24,25} In the present comparison, differences in cost were weighted against the differences in HRQoL. Recently, a cost-effective analysis of HRQoL in the oral region used both EuroQol (EQ-5D)²⁶ and OHIP¹⁷ for the same purpose as we did in the present study; however, EQ-5D may not be sensitive enough to detect changes in the oral region.

To account for the fact that no significant difference was found in total time spent (Table 1), the cost-effectiveness analysis is affected, where every OHIP point gained also gains 0.53 minutes in time spent. The 2-dimensional technique cost less overall when we combined fixed radiographic examination costs and calculated planning time costs (Table 2) because of a higher fixed radiographic cost for the 3-dimensional technique. This affects the cost-effectiveness analysis (Table 5), where every OHIP point gained showed an increased cost of US\$15 when the 3-dimensional technique was used. Adding fixed software costs also results in an increased cost of US\$272/OHIP point gained when the 3-dimensional technique is used.

Recently, free open-source software for 3-dimensional planning in orthognathic treatment has been made available.²⁷ The implementation of such programs fundamentally changes the perspective of investment. However, it is not yet clear what level of prediction of quality is given by free open-source software.

Using service centres often comes with an additional time service of digital template fabrication, but also with an additional financial cost.²⁰ Meanwhile, 2-dimensional planning always requires a template fabricated by a dental technician. However, as a result of global differences in the training of dental technicians, a generalisation of such a comparison is complicated so, based on the present results, everybody should compare the techniques in relation to their local clinical conditions.

The differences in the cost-effectiveness analysis showed a small advantage in time spent for the 3-dimensional technique, but a significant advantage for the 2-dimensional technique in financial costs. Taking the initial software investment into the comparison leads to even greater differences in financial costs. However, this difference will decrease when the number of patients being treated increases.

Conclusions

Our results have shown equal total time consumption for the techniques, while the 2-dimensional technique showed an overall lower financial cost and the 3-dimensional technique a larger dose of radiation. Cost effectiveness analysis based on the small differences in outcome from cephalometric measurements and HRQoL, showed an advantage in time spent for the 3-dimensional technique, while the 2-dimensional technique cost less.

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Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients' permission

The study was approved by the regional ethical committee in Gothenburg, Sweden (registration number 011-11) and followed the principles of the Declaration of Helsinki. Informed written consent was signed and obtained from all subjects.

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