

Research Paper
 Orthognathic Surgery

Three-dimensional soft tissue prediction in orthognathic surgery: a clinical comparison of Dolphin, ProPlan CMF, and probabilistic finite element modelling

P. G. M. Knoop^{1,2,3}, A. Borghi^{1,2},
 R. W. F. Breakey^{1,2}, J. Ong^{1,2},
 N. U. O. Jeelani^{1,2}, R. Bruun³,
 S. Schievano^{1,2}, D. J. Dunaway^{1,2},
 B. L. Padwa³

¹UCL Great Ormond Street Institute of Child Health, London, UK; ²Craniofacial Unit, Great Ormond Street Hospital for Children, London, UK; ³Department of Plastic and Oral Surgery, Boston Children's Hospital & Harvard School of Dental Medicine, Boston, Massachusetts, USA

P. G. M. Knoop, A. Borghi, R. W. F. Breakey, J. Ong, N. U. O. Jeelani, R. Bruun, S. Schievano, D. J. Dunaway, B. L. Padwa: *Three-dimensional soft tissue prediction in orthognathic surgery: a clinical comparison of Dolphin, ProPlan CMF, and probabilistic finite element modelling.* *Int. J. Oral Maxillofac. Surg.* 2018; xxx: xxx–xxx. © 2018 The Author(s). Published by Elsevier Ltd on behalf of International Association of Oral and Maxillofacial Surgeons. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Abstract. Three-dimensional surgical planning is used widely in orthognathic surgery. Although numerous computer programs exist, the accuracy of soft tissue prediction remains uncertain. The purpose of this study was to compare the prediction accuracy of Dolphin, ProPlan CMF, and a probabilistic finite element method (PFEM). Seven patients (mean age 18 years; five female) who had undergone Le Fort I osteotomy with preoperative and 1-year postoperative cone beam computed tomography (CBCT) were included. The three programs were used for soft tissue prediction using planned and postoperative maxillary position, and these were compared to postoperative CBCT. Accurate predictions were obtained with each program, indicated by root mean square distances: $\text{RMS}_{\text{Dolphin}} = 1.8 \pm 0.8$ mm, $\text{RMS}_{\text{ProPlan}} = 1.2 \pm 0.4$ mm, and $\text{RMS}_{\text{PFEM}} = 1.3 \pm 0.4$ mm. Dolphin utilizes a landmark-based algorithm allowing for patient-specific bone-to-soft tissue ratios, which works well for cephalometric radiographs but has limited three-dimensional accuracy, whilst ProPlan and PFEM provide better three-dimensional predictions with continuous displacements. Patient or population-specific material properties can be defined in PFEM, while no soft tissue parameters are adjustable in ProPlan. Important clinical considerations are the topological differences between predictions due to the three algorithms, the

non-negligible influence of the mismatch between planned and postoperative maxillary position, and the learning curve associated with sophisticated programs like PFEM.

Key words: soft tissue prediction; virtual surgery planning; orthognathic surgery; craniofacial surgery; Dolphin; ProPlan CMF; finite element modelling.

Accepted for publication

Introduction

Treatment planning and the prediction of procedural outcomes in orthognathic surgery have traditionally relied on manual tracing of cephalometric radiographs² and the use of well-established hard-to-soft tissue ratios³. However, in recent years, three-dimensional (3D) computer planning has gained popularity as an accurate surgical simulation in 3D that is valuable for patient communication, surgical planning, and the assessment of operative outcomes⁴⁻⁶.

Various commercial programs are available for 3D planning and soft tissue prediction, with the main difference between them being the physical model they utilize. Some are based on sparse models that require landmarking and rely on interpolation between points, whereas others use dense volumetric models, including finite element models (FEM), mass tensor models (MTM), or mass spring models (MSM)⁷. Regardless of the model, the accuracy of these 3D prediction tools remains uncertain. Some studies have shown that various prediction programs have errors of <2 mm, which is considered clinically acceptable, whilst other studies have contradicted these findings⁸⁻¹³. In addition to inaccuracies arising from the prediction algorithm, the mismatch in bone repositioning between preoperative planning and the operation itself may also cause a discrepancy between soft tissue prediction and postoperative appearance; for example, differences of 0.99 mm and 1.17 mm between the planned and actual result have been reported after Le Fort I osteotomies¹⁴ and bimaxillary procedures¹⁵, respectively.

The purpose of this study was to evaluate three different programs, two commercially available programs, i.e. Dolphin 3D (Dolphin Imaging & Management Solutions, Chatsworth, CA, USA) and ProPlan CMF (Dentsply-Sirona, York, PA, USA), and one in-house developed probabilistic finite element model (PFEM)¹⁶, and to compare the 3D surgical soft tissue predictions achieved in a group of patients who had undergone Le Fort I maxillary advancement. The specific aims were to investigate the features and limitations of

the three different 3D soft tissue prediction programs and to determine how these limitations may affect clinical utility for Le Fort I osteotomies. It was hypothesized that all three methods would provide clinically meaningful results, in line with previous findings, but that each method and its underlying physical model would have advantages and disadvantages over the other methods.

Materials and methods

Patients

Seven patients (mean age 18 ± 1 years; five female, two male) who had undergone single-jaw Le Fort I maxillary advancement with vertical repositioning and an alar base cinch suture were retrospectively included in this study (Table 1). All patients were treated at Boston Children's Hospital, Boston, USA between December 2011 and January 2015 and had cone beam computed tomography (CBCT) images acquired 3 months preoperatively and 1 year postoperatively (Table 1). Patients presented with maxillary sagittal hypoplasia ($n = 7$). Five patients also had vertical hypoplasia or hyperplasia that was treated at the time of Le Fort I: anterior maxillary vertical hypoplasia ($n = 3$), anterior vertical maxillary excess ($n = 1$), and posterior vertical maxillary excess with anterior open bite ($n = 1$). All patients had preoperative and postoperative orthodontic treatment, with fixed orthodontic appliances in place during the Le Fort I osteotomy and no appliances in place during the postoperative CBCT. This study was approved by the Institutional Review Board of the Center for Applied Clinical Investigation at Boston Children's Hospital and all patients provided consent.

Surgical simulation and soft tissue prediction

Soft tissue predictions were generated retrospectively based on the preoperative CBCT, using Dolphin (version 11.95), ProPlan CMF (version 3.0.1), and PFEM¹⁶. The pipeline consists of image acquisition and processing, soft tissue prediction, and post-processing and visualization (Fig. 1). The three methods share

the image processing approach, albeit utilizing different software: DICOM files (digital imaging and communications in medicine) were imported and the head structures segmented, resulting in 3D reconstructions of bone and soft tissue, with negligible differences between the three methods. Reconstructed volumes from pre- and postoperative CBCT were aligned on the skull base using an iterative closest point (ICP) algorithm. A Le Fort I osteotomy was virtually performed according to the postoperative CBCT, followed by repositioning according to the advancement and rotation as measured on the postoperative CBCT (Table 1), with average movements of 5.8 mm sagittal advancement, 1.1 mm vertical shortening, 2.4° steepening of the occlusal plane (measured as the angle formed by the intersection of a line drawn through anterior nasal spine (ANS) and posterior nasal spine (PNS) in the midsagittal plane and the Frankfort horizontal), and 1.7 mm of rotation/jaw correction measured at the contact point of the central incisors. Finally, the soft tissue prediction resulting from each analysis was viewed and exported as a stereolithography (STL) file for comparison.

Dolphin utilizes a sparse landmark-based algorithm for soft tissue prediction and allows hard-to-soft tissue ratios to be set to account for some inter-patient variability, such as the thickness of the upper lip³. Three sets of hard-to-soft tissue ratios – default, minimum, and maximum, based on literature³ and further assessed by an orthodontist – were investigated to observe how adjusting the ratios affects the predicted soft tissue changes.

ProPlan is based on a finite difference method (FDM) – a relatively fast discretization technique that allows mathematical equations to be solved through numerical approximations – and has no manual setting for specific material properties.

PFEM is an extension of a traditional FEM: a range of soft tissue properties can be manually provided as an input, resulting in a set of potential outcomes based on uncertainties incorporated into the underlying physical model. These uncertainties

Table 1. Patient characteristics.

Patient	Sex	Ethnicity	Age (years)	Diagnosis	Planned advancement (mm)	Postoperative advancement (mm) ^a	Mismatch (mm)	Preoperative CBCT time (days)	Postoperative CBCT time (days)
1	M	Caucasian	19	MSH	4	3.0	-1.0	97	385
2	F	Caucasian	18	MSH	5	3.3	-1.7	65	422
3	M	Caucasian	18	MSH, AOB	6	5.8	-0.2	115	365
4	F	African American	16	MSH, MVH	6	5.8	-0.2	100	608
5	F	African American	17	MSH, MVH, VME	6	6.5	+0.5	134	231
6	F	Caucasian	18	MSH	7	7.3	+0.3	117	369
7	F	Caucasian	18	MSH, MVH	8.5	9.5	+1.0	92	580
Mean ± SD ^b	5 F:2 M	-	18 ± 1	-	6.1 ± 1.4	5.8 ± 2.1	0.7 ± 0.6	103 ± 22	423 ± 131

AOB, anterior open bite; CBCT, cone beam computed tomography; F, female; M, male; MSH, maxillary sagittal hypoplasia; MVH, maxillary vertical hypoplasia; SD, standard deviation; VME, vertical maxillary excess.

^aSagittal advancement measured at A-point.

^bThe mean and standard deviation are shown in the bottom row, except for the male-female distribution; the absolute mean and standard deviation are shown for the mismatch.

can be related to the soft tissue material properties themselves and/or account for a range of potential on-table adjustments of the pre-planned bone positions during surgery. Therefore, like Dolphin, the PFEM allows for patient-specific parameters and for population-specific average models to be incorporated into the prediction algorithm. A detailed description of the PFEM methodology has been published previously¹⁶. In brief, image processing was conducted in Simpleware ScanIP (Synopsis, Mountain View, CA, USA) and finite element analysis in Ansys (17.2; Ansys Inc, Canonsburg, PA, USA). An initial PFEM was performed with a range of material properties from the literature¹⁶. Then, an iterative process was carried out to optimize the material properties for this group of patients by minimizing the difference between the predicted soft tissue and the soft tissue from postoperative CBCT. The optimized population-specific material properties were as follows: soft tissue Young's modulus = 0.157 MPa (initial range 0.1–1 MPa), soft tissue Poisson's ratio = 0.465 (0.45–0.499), soft tissue viscoelastic relaxation = 75% (31–94%), and nasal cartilage Young's modulus = 1.20 MPa (0.5–5 MPa). The soft tissue prediction results from a second FEM iteration using the optimized parameters, rather than a range of material properties for each parameter, were exported for comparison with the outcomes from the commercial software analyses.

Data analysis

The postoperative CBCT and the three sets of soft tissue predictions were first compared with the preoperative surface to illustrate the differences amongst them (Fig. 2). Next, the three sets of soft tissue predictions were compared with the postoperative CBCT to assess how well the predictions described the surgical outcome.

Comparisons of surfaces were computed as the closest point distance vectors (VMTK¹⁷; The Vascular Modelling Toolkit, Bergamo, Italy) in Matlab (v2016b; MathWorks, Natick, MA, USA) and subsequently visualized in ParaView¹⁸ (Kitware, Clifton Park, NY, USA). For comparison to the postoperative CBCT, only the upper lip and paranasal regions were of interest, as these are the areas of the face mainly affected by Le Fort I maxillary advancement. The full-face surfaces were cropped with a plane created between the stomion superius (upper lip), left tragus, and right tragus, and

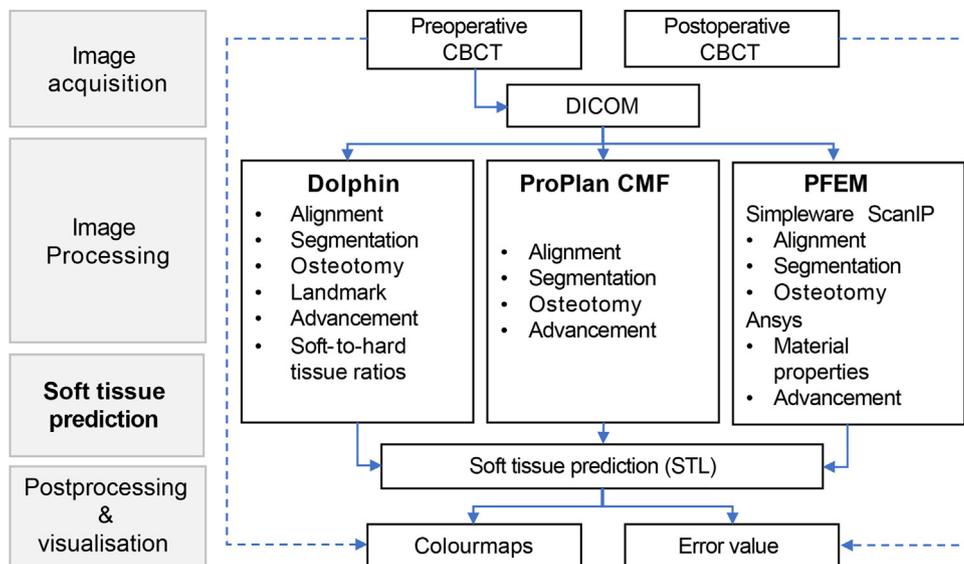


Fig. 1. Pipeline for the soft tissue prediction using the three selected methods. Note that the image processing for the three methods is identical, consisting of ICP alignment, segmentation, osteotomy, and advancement, whereas there are differences in the soft tissue prediction algorithms: Dolphin is a landmark-based method and allows patient-specific soft-to-hard tissue ratios to be set; ProPlan does not require landmarks and is, therefore, relatively straightforward; and PFEM requires two separate programs for the full process, but allows patient or population-specific material properties to be defined.

Table 2. Root mean square distance and percentage within 2 mm of the soft tissue prediction compared to the postoperative CBCT. Mismatch is the difference in maxillary position in the sagittal plane at A-point between the postoperative position and the surgical planning.

Patient	Mismatch (mm)	Dolphin		ProPlan		PFEM	
		RMS (mm)	Percentage <2 mm (%)	RMS (mm)	Percentage <2 mm (%)	RMS (mm)	Percentage <2 mm (%)
1	-1.0	1.6	93	0.9	98	0.9	98
2	-1.7	1.0	97	0.8	100	0.8	99
3	-0.2	1.9	73	1.4	86	1.5	81
4	-0.2	1.9	74	1.5	83	1.7	76
5	+0.5	1.4	89	1.1	94	1.1	91
6	+0.3	1.5	86	0.9	99	1.0	96
7	+1.0	3.4	66	1.7	78	1.8	76
Mean ± SD	0.7 ± 0.6	1.8 ± 0.8	83 ± 12	1.2 ± 0.4	91 ± 9	1.3 ± 0.4	88 ± 10

CBCT, cone beam computed tomography; PFEM, probabilistic finite element modelling; RMS, root mean square distance.

another plane between the subnasale, left tragus, and right tragus (Meshmixer; Autodesk, San Rafael, CA, USA) (Fig. 3). To describe the similarity between the soft tissue prediction and the pre- or postoperative CBCT, root mean square distances (RMS) – a measure commonly used to describe the discrepancy between two surfaces – and the percentage (P) of points between the two surfaces that are <2 mm of each other were computed using Matlab.

To investigate the effects on the soft tissue of the difference in maxillary position between the surgical plan and the actual result achieved during the operation (Table 1), another soft tissue prediction was analysed for each patient with each method using the planned advance-

ment, instead of the actual advancement performed during the procedure and assessed from the postoperative CBCT. Furthermore, for the patient with the largest difference between planned and delivered maxillary position, a range of bone displacements (0–7 mm) was tested to assess the effect on soft tissue prediction (Fig. 4).

The Friedman test was used to verify the null hypothesis that data come from a continuous distribution with equal means for more than two groups, followed by post hoc Wilcoxon signed-rank testing for pairs within the group and Bonferroni correction – significance for three groups was set at $0.05/3 = 0.017$ – to minimize the likelihood of type I error¹⁹.

Results

The postoperative and soft tissue predictions using the different methods were compared to the preoperative CBCT scan as a baseline (Fig. 2A–E). With Dolphin, using default values for hard-to-soft tissue ratios, soft tissue displacements were localized in the upper lip area, whereas the paranasal region showed limited movement; changing these ratios had a limited effect (Fig. 2F, G). With ProPlan and PFEM, both the upper lip and paranasal region showed a more continuous displacement distribution.

A comparison between the postoperative CBCT and the soft tissue predictions based on Dolphin, ProPlan, and PFEM (patient 2, Fig. 3), showed that Dolphin

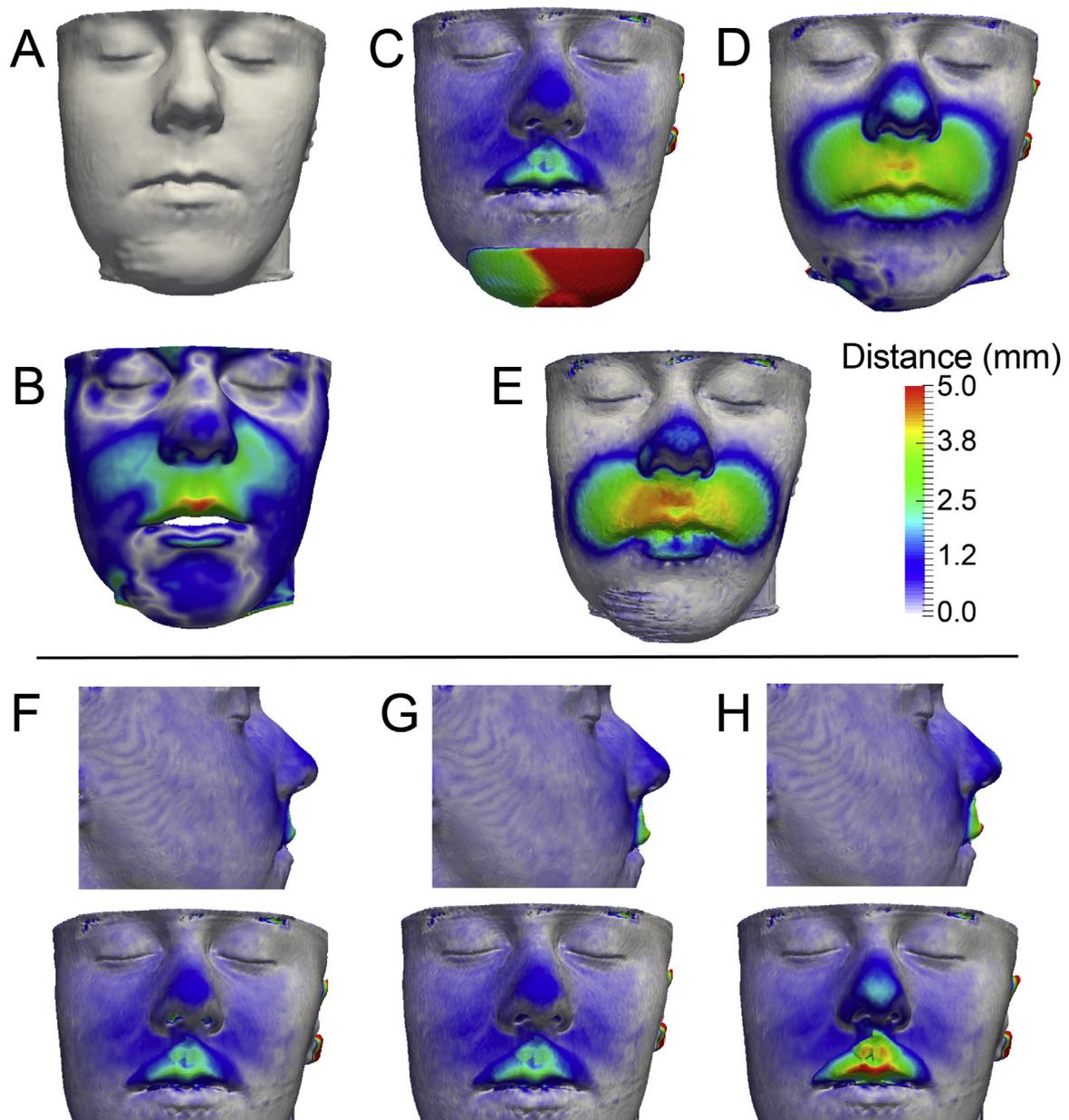


Fig. 2. Patient 2: distance colour maps relative to (A) preoperative CBCT: (B) postoperative CBCT, (C, F–H) Dolphin, (D) ProPlan, and (E) PFEM. Patient-specific hard-to-soft tissue ratios were investigated in Dolphin and the corresponding frontal and lateral views are shown for: (F) minimum ratios, (C, G) default ratios, and (H) maximum ratios. Note that in (C) the chin support of the CBCT scanner is still present; the soft tissues and support have identical grey values and Dolphin does not allow for manual tracing.

generally under-predicted the displacement of the paranasal region across the population, whilst ProPlan and PFEM over-predicted the displacement of the area above cheilion. Average root mean square distances and average percentage of points < 2 mm between the postoperative CBCT and the soft tissue predictions for all seven patients were as follows: $RMS_{Dolphin} = 1.8 \pm 0.8$ mm, $RMS_{ProPlan} = 1.2 \pm 0.4$ mm, and $RMS_{PFEM} = 1.3 \pm 0.4$ mm; $P_{Dolphin} = 83 \pm 12\%$, $P_{ProPlan} = 91 \pm 9\%$, and $P_{PFEM} = 88 \pm 10\%$ (Table 2). The

Friedman test showed significant differences amongst RMS in the groups ($\chi^2 = 10.57$, $df = 2$, $P = 0.005$), and post hoc Wilcoxon signed-rank tests with Bonferroni correction showed significantly lower RMS for ProPlan compared to Dolphin ($P = 0.016$) and for PFEM compared to Dolphin ($P = 0.016$), and no significant difference between ProPlan and PFEM ($P = 0.219$).

The mismatch in maxillary position between the surgical plan and postoperative position on the sagittal plane was investigated (Fig. 4). For each patient,

ProPlan and PFEM provided significantly different results when using the planned position compared to the actual postoperative maxillary position, although the mean differences were small: $RMS_{ProPlan,Postop} = 1.2 \pm 0.4$ mm and $RMS_{ProPlan,Plan} = 1.3 \pm 0.4$ mm ($P = 0.002$); $RMS_{PFEM,Postop} = 1.3 \pm 0.4$ mm and $RMS_{PFEM,Plan} = 1.4 \pm 0.4$ mm ($P = 0.002$). For Dolphin, there was no statistically significant difference in the mean RMS between the postoperative maxillary position and the planned position: $RMS_{Dolphin,Postop} = 1.8 \pm 0.8$ mm

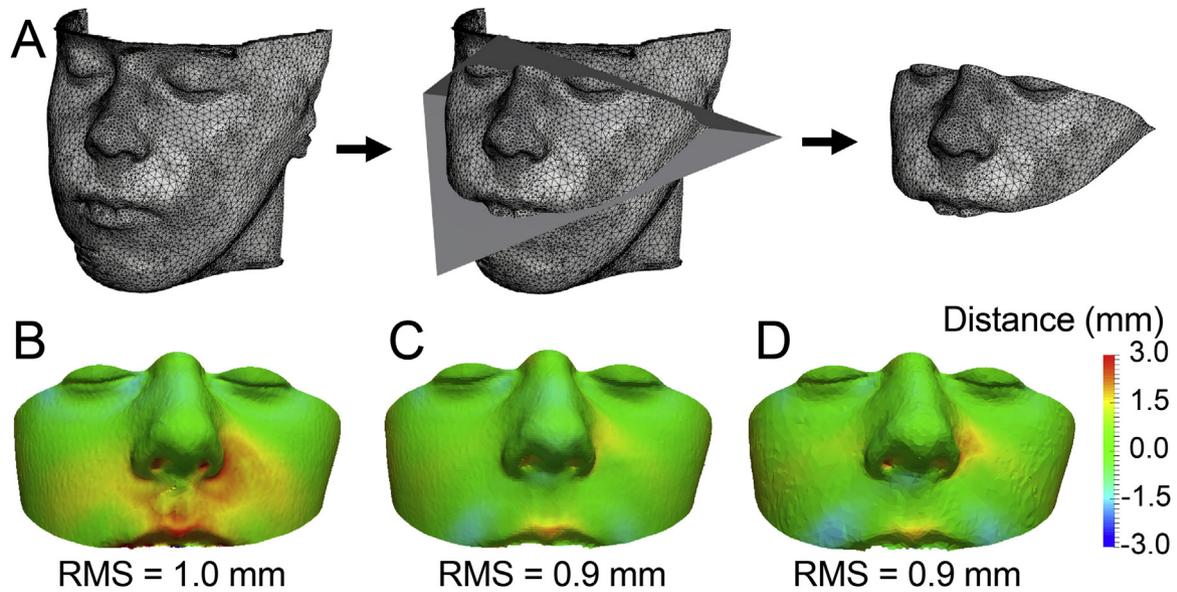


Fig. 3. (A) Cutting plane as defined by the left and right tragi, subnasale, and stomion superior. Comparison of soft tissue prediction with postoperative CBCT for (B) Dolphin, (C) ProPlan, and (D) PFEM. RMS indicates an overall accuracy for each prediction. A positive distance (red) indicates larger displacement in the postoperative CBCT and thus an under-prediction, and a negative distance (blue) indicates smaller displacement postoperatively and thus an over-prediction of the actual displacements. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

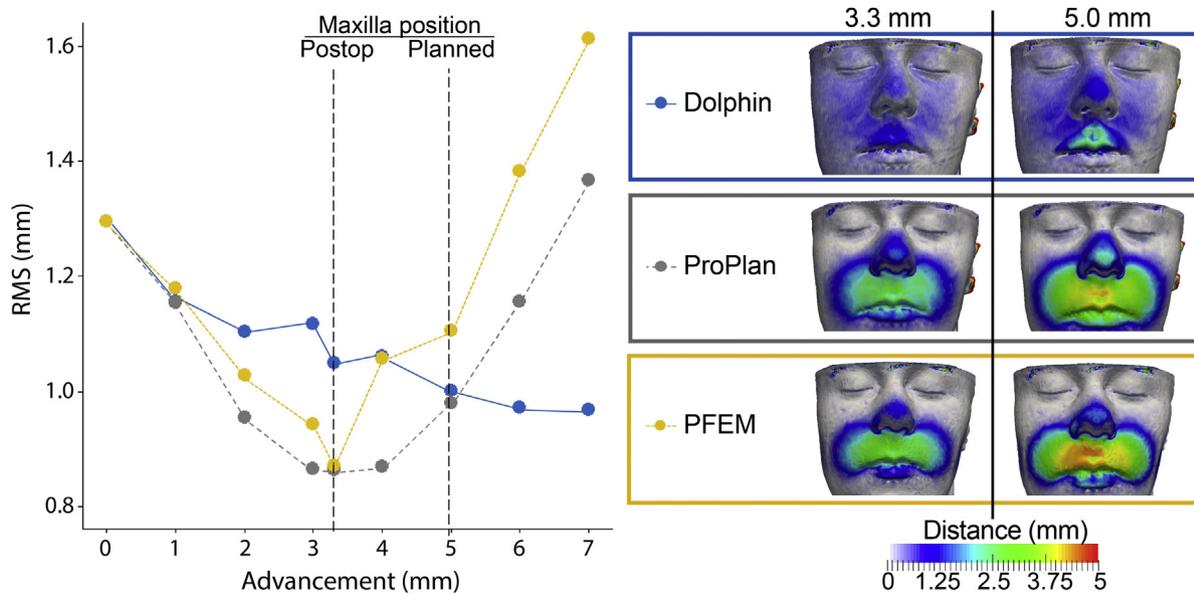


Fig. 4. Patient 2: graph showing a range of advancements from 0 mm (preoperative) to 7 mm; RMS indicates the difference between the soft tissue prediction and the postoperative soft tissues from CBCT. Planned maxillary position was 5 mm and postoperative maxillary position was 3.3 mm at A-point. Soft tissue predictions based on the postoperative maxillary position correspond to the lowest RMS for PFEM and ProPlan, whilst soft tissue predictions at 7 mm correspond to the lowest RMS for Dolphin. The colour maps illustrate how the predicted soft tissue changes as compared to the preoperative CBCT.

and $RMS_{Dolphin,Plan} = 1.8 \pm 0.9$ mm ($P = 0.812$).

As laid out in the methodology, Dolphin allows for patient-specific hard-to-soft tissue ratios, which may improve the prediction accuracy. These ratios may substantially improve the lateral (two-dimensional (2D)) view, but have a limited

effect on the 3D prediction as seen in the frontal view (Fig. 2F, G).

Discussion

The aim of this study was to compare 3D soft tissue predictions made with Dolphin, ProPlan, and PFEM to reconstructed soft tissue

surfaces from the postoperative CBCT. Strict inclusion criteria were used to minimize variation in the cohort by only including patients who had CBCT scans taken 3 months preoperatively and 1 year postoperatively (as swelling can be present for up to 6–12 months postoperatively²⁰), who had received an isolated Le Fort I osteotomy,

and who had no orthodontic appliances in place at the long-term follow-up.

The error between the soft tissue prediction and postoperative CBCT showed good results for all three methods, with statistically significant better results for ProPlan and PFEM compared to Dolphin; yet it is important to consider how these predictions differ topologically. This study showed that Dolphin predicts changes mainly on the 2D midline and in the upper lip, while it under-predicts soft tissue movements in the paranasal region due to the sparse landmark-based morphing algorithm. In contrast, predictions with ProPlan and PFEM show continuous displacements in the upper lip and paranasal region.

Based on these findings, PFEM and ProPlan equally provide accurate soft tissue prediction and could be useful at the time of preoperative patient communication. ProPlan, due to its nature of commercial ad hoc software, is designed to be user-friendly and intuitive for the clinician. PFEM is a numerical methodology that could be implemented in any finite element modelling package, but requires good knowledge of the underlying numerical algorithm; furthermore, it allows the creation of a range of predicted outcomes based on patient-specific or population-based parameters as well as uncertainty in surgical bone advancement¹⁶, which may improve patient communication and properly inform on the range of possible outcomes.

Clinically, RMS from soft tissue predictions using the planned position may be more relevant than those based on the postoperative maxillary position, e.g. preoperatively for patient communication. It is essential to consider that the accuracy of the soft tissue prediction depends on two factors: the (in) accuracy of the prediction models themselves and the mismatch between surgical planning and actual surgical movements. The mismatch in the sagittal plane was relatively small in the cohort presented here (mean absolute difference = 0.6 ± 0.5 mm, Table 2), yet a small but non-negligible increase in RMS was observed when using the planned maxillary positions. For ProPlan and PFEM, the soft tissue predictions were statistically significant in terms of accuracy when the true postoperative maxillary position was used. For ProPlan and PFEM, the accuracy of the soft tissue prediction improved significantly when the true postoperative maxillary position was used. For Dolphin, there was no significant difference between the planned and postoperative maxilla position in part due to the spread of the mismatch in the cohort (Table 2) and in part due to limitations of the landmark-based

prediction algorithm (Figure 4) - which becomes more inaccurate with large advancements (e.g. patient 7, RMS = 3.4 mm, Table 2). The limitations of Dolphin occur with large planned advancements (8.5 mm) where the actual postoperative advancement is even larger than planned (9.5 mm). Under these circumstances, the Dolphin algorithm becomes inaccurate due to its sparse architecture.

The study findings are in line with and complement those of a previous pilot study on the same cohort⁸. In that study, Dolphin 3D was accurate to within a 2-mm threshold for certain landmarks on the 2D midline, but to a lesser extent for lateral points. An overall mean error of 2.9 mm was reported, with most of the error originating from the lateral facial points. The mean error at the midline was 1.7 mm and at the nasolabial angle was 8°, which was clinically important. The two main reasons for these errors were reported as (1) an image registration error due to overlying 3D photographs onto CBCT volumes, and (2) the Dolphin landmark-based morphing algorithm.

Almukhtar et al.²¹ described the movements associated with Le Fort I surgery, including anterior and lateral expansion around the upper lip and nose, as well as superior movement of the alar curvature and columella, and minimal changes in the cheeks. They also noted widening of the nose, anterior displacement of the nostrils, and upward movement of the nasal tip, while the subnasale and alar base showed minimal changes. They found that Maxilim (Medicim – Medical Image Computing, Mechelen, Belgium) produced clinically acceptable soft tissue predictions; however, they noted that all regions except for the upper lip were under-predicted in patients who had undergone an operation for the correction of facial asymmetry⁹. Nadjimi et al.¹⁰ compared predicted soft tissue profiles using Dolphin and Maxilim in 2D in a cohort that had Le Fort I and bilateral split osteotomies. They found a significant correlation between the position of postoperative landmarks and the predictions. Liebrechts et al.¹³ concluded that, while Maxilim was clinically accurate, patients should be informed about the shortcomings of the prediction algorithm. Many other studies have investigated the error in soft tissue prediction; however, comparing these different publications is challenging due to the variability in inclusion criteria, procedure type, and methodology. Olate et al.²² remarked that many studies have suffered from selection bias, a weak study design, and confounders, and that there is therefore insufficient data as yet that can be applied to determine soft-to-hard tissue ratios in 3D.

Some limitations of this study must be noted. Only seven patients were retrospectively included, due to the strict inclusion criteria to minimize intra-cohort variability; a larger sample size would be desirable for a prospective follow-up study to verify the findings from this study. The cohort had orthodontic appliances in place during preoperative CBCT and not during postoperative CBCT, which might have introduced a small error. Furthermore, the surface distances were computed by looking at the closest-point difference without any point-to-point correspondence, which may have led to an underestimation of the errors, especially in the coronal plane¹⁴. A-point was used to assess the postoperative position of the maxilla, which does not fully capture the movements of the osteotomized bone segment in 3D, although the small mean differences in RMS between using the planned position and the postoperative position suggest the influence of bone position on overall RMS is limited. No standardized method exists for evaluating the postoperative maxillary position; however, a semi-automated method has been described recently¹⁵. Another limitation is that the area of the face assessed between the two tragi, subnasale, and stomion superior also includes lateral parts of the face that are minimally affected by Le Fort I advancement; this may have reduced the overall RMS value and improved the percentage of points <2 mm. However, this area is defined by four landmarks only and fittingly captures the region of interest (Fig. 3). Lastly, the positions of the mandible and lower lip were not considered in this analysis on single-jaw procedures, although a change in mandible position due to autorotation or an open mouth in the CBCT (Fig. 2B) will influence the accuracy of the soft tissue simulation in the face outside of the region of interest as defined above.

In conclusion, this comparison shows that clinically useful 3D predictions can be obtained with each method when considering the overall RMS and the percentage of surface points of the 3D prediction that are accurate within 2 mm. However, it is crucial to be aware of the underlying physical prediction model and the resulting topological soft tissue prediction, as well as the small but non-negligible influence of the mismatch between the planned and postoperative maxillary position.

Funding

This research was supported by Great Ormond Street Hospital Children's Charity through a FaceValue programme grant

(number 508857), the Engineering and Physical Sciences Research Council award (EP/N02124X/1), and the UCL Bogue Fellowship. This work was undertaken at GOSH/ICH, UCLH/UCL which received a proportion of funding from the United Kingdom Department of Health NIHR Biomedical Research Centre funding scheme. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health. The authors declare no involvement of the study sponsors in the study design, data collection, analysis and interpretation of the data, writing of the manuscript, or decision to submit the manuscript for publication.

Competing interests

The authors declare no conflict of interest.

Ethical approval

Ethical approval was given by the Institutional Review Board of the Center for Applied Clinical Investigation at Boston Children's Hospital (#00019505).

Patient consent

Not required.

Author contributions

PGMK, AB, and SS designed the study, contributed to the data analysis and interpretation, and drafted the manuscript. BLP performed the operations, provided the imaging data, contributed to the study design and data interpretation, and critically revised the manuscript. RB, RWFB, JO, NUOJ, and DJD contributed to the study design and data interpretation, and critically revised the manuscript. All authors approved the manuscript for submission.

Acknowledgements. The authors would like to thank Khalid El Ghouf for his support with the data acquisition.

References

- Dvortsin DP, Sandham A, Pruijm GJ, Dijkstra PU. A comparison of the reproducibility of manual tracing and on-screen digitization for

Address:

Paul Knoops
UCL Great Ormond Street Institute of Child Health
London

- cephalometric profile variables. *Eur J Orthod* 2008;**30**:586–91.
- Moragas JSM, Van Cauteren W, Mommaerts MY. A systematic review on soft-to-hard tissue ratios in orthognathic surgery part I: maxillary repositioning osteotomy. *J Craniomaxillofac Surg* 2014;**42**:1341–51.
- Xia JJ, Shevchenko L, Gateno J, Teichgraber JF, Taylor TD, Lasky RE, English JD, Kau CH, McGrory KR. Outcome study of computer-aided surgical simulation in the treatment of patients with craniomaxillofacial deformities. *J Oral Maxillofac Surg* 2011;**69**:2014–24.
- Centenero SAH, Hernandez-Alfaro F. 3D planning in orthognathic surgery: CAD/CAM surgical splints and prediction of the soft and hard tissues results—our experience in 16 cases. *J Craniomaxillofac Surg* 2014;**40**:162–8.
- Mazzoni S, Bianchi A, Schiariti G, Badiali G, Marchetti C. Computer-aided design and computer-aided manufacturing cutting guides and customized titanium plates are useful in upper maxilla waferless repositioning. *J Oral Maxillofac Surg* 2015;**73**:701–7.
- Mollemans W, Schutyser F, Nadjimi N, Maes F, Suetens P. Predicting soft tissue deformations for a maxillofacial surgery planning system: from computational strategies to a complete clinical validation. *Med Imag Anal* 2007;**11**:282–301.
- Resnick CM, Dang RR, Glick SJ, Padwa BL. Accuracy of three-dimensional soft tissue prediction for Le Fort I osteotomy using Dolphin 3D software: a pilot study. *Int J Oral Maxillofac Surg* 2017;**46**:289–95.
- Mundluru T, Almukhtar A, Ju X, Ayoub A. The accuracy of three-dimensional prediction of soft tissue changes following the surgical correction of facial asymmetry: an innovative concept. *Int J Oral Maxillofac Surg* 2017;**46**:1517–24.
- Nadjimi N, Tehranchi A, Azami N, Saedi B, Mollemans W. Comparison of soft-tissue profiles in Le Fort I osteotomy patients with Dolphin and Maxilim softwares. *Am J Orthod Dentofacial Orthop* 2013;**144**:654–62.
- Marchetti C, Bianchi A, Muyldermans L, Di Martino M, Lancellotti L, Sarti A. Validation of new soft tissue software in orthognathic surgery planning. *Int J Oral Maxillofac Surg* 2011;**40**:26–32.
- Terzic A, Combesure C, Scolozzi P. Accuracy of computational soft tissue predictions in orthognathic surgery from three-dimensional photographs 6 months after completion of surgery: a preliminary study of 13 patients. *Aesthetic Plast Surg* 2014;**38**:184–91.
- Liebrechts J, Xi T, Timmermans M, de Koning M, Berge S, Hoppenreijts T, Maal T. Accuracy of three-dimensional soft tissue simulation in bimaxillary osteotomies. *J Craniomaxillofac Surg* 2015;**43**:329–35.
- Badiali G, Roncarì A, Bianchi A, Taddei F, Marchetti C, Schileo E. Navigation in orthognathic surgery: 3D accuracy. *Facial Plast Surg* 2015;**31**:463–73.
- Baan F, Liebrechts J, Xi T, Schreurs R, de Koning M, Berge S, Maal T. A new 3D tool for assessing the accuracy of bimaxillary surgery: the OrthoGnathicAnalyser. *PLoS One* 2016;**11**:e01479625. <http://dx.doi.org/10.1371/journal.pone.0149625>.
- Knoops PGM, Borghi A, Ruggiero F, Badiali G, Bianchi A, Marchetti C, Rodriguez-Florez N, Breakey RWF, Jeelani NUO, Dunaway DJ, Schievano S. A novel soft tissue methodology for orthognathic surgery based on probabilistic finite element modelling. *PLoS One* 2018;**13**:e0197209.
- Antiga L, Piccinelli M, Botti L, Ene-Iordache B, Remuzzi A, Steinman DA. An image-based modelling framework for patient-specific computational hemodynamics. *Med Biol Eng Comput* 2008;**46**:1097–112.
- Ahrens J, Brname>Geveci, ParaView: an end-user tool for large data visualization. In: Hansen C, Johnson C, editors. *The visualization handbook*. Amsterdam: Elsevier; 2005.
- Armstrong RA. When to use the Bonferroni correction. *Ophthalmic Physiol Opt* 2014;**34**:502–8.
- Van der Vlis M, Dentino KM, Vervloet B, Padwa BL. Postoperative swelling after orthognathic surgery: a prospective volumetric analysis. *J Oral Maxillofac Surg* 2014;**72**:2241–7.
- Almukhtar A, Ayoub A, Khambay B, McDonald J, Ju X. State-of-the-art three-dimensional analysis of soft tissue changes following Le Fort I maxillary advancement. *Br J Oral Maxillofac Surg* 2016;**54**:812–7.
- Olate S, Zaror C, Mommaerts MY. A systematic review on soft-to-hard tissue ratios in orthognathic surgery part IV: 3D analysis—is there evidence? *J Craniomaxillofac Surg* 2017;**45**:1278–86.

Address:

Paul Knoops
UCL Great Ormond Street Institute of Child Health
London
UK and Craniofacial Unit
Great Ormond Street Hospital for Children
30 Guilford Street
London WC1N 1EH
UK
Tel.: +44 2097052733
E-mail: paul.knoops.14@ucl.ac.uk

Tel.: +44 2097052733

E-mail: paul.knoops.14@ucl.ac.uk