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Comparison of postoperative skeletal stability of maxillary segments after Le Fort I osteotomy, using patient-specific implant versus mini-plate fixation

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A B S T R A C T

Background: Three-dimensionally (3D) designed osteotomies and customised osteosynthesis are rapidly becoming standard in maxillofacial reconstructive and deformity surgery. Patient-specific implants (PSIs) have been in use for a few years in orthognathic surgery as well. In Le Fort I osteotomy, wafer-free fixation of the maxillary segment can be performed by individually manufactured cutting and drill guides together with PSIs.
Aim: This retrospective study was performed to compare the postoperative skeletal stability of the maxillary segment fixed by patient-specific implants versus mini-plates after Le Fort I osteotomy.
Patients: Fifty-one patients were divided into subgroups according to the fixation method and the advancement of the sub-spinal point. The postoperative skeletal stability of the maxillary segment was evaluated from lateral cephalometric radiographs one year postoperatively.
Results: No statistically significant differences were found between the postoperative skeletal stability of the PSI and mini-plate fixed maxillae. Prospective studies, possibly with 3D fusion analysis, are warranted to confirm the results.
Conclusion: The choice between the two fixation methods does not seem to affect the postoperative skeletal stability of the maxillary segments.

1. Introduction

The use of three-dimensional (3D) design is rapidly becoming a common practise in orthognathic surgery. The benefits are clear in two-jaw surgery and in complex asymmetry cases in both planning and performing the surgery. Individually designed and manufactured surgical drill and cutting guides as well as patient-specific implants (PSI) for osteosynthesis are now available for reasonable costs and within a short space of time. The development of 3D-designed implants has been fast.

Change from crude modifications of conventional mini-plates to individualised implants became possible when computer-aided design and manufacturing (CAD/CAM), including milling and printing techniques, started to develop (Gander et al., 2015; Mazzoni et al., 2015; Suojanen et al., 2016). Individually milled implants, combined with the use of drill guides also makes wafer-free fixation of the maxillary segment possible, and ideal fitting of the osteosynthesis material is passive and tension-free. Whether this leads to better postoperative skeletal stability remains to be investigated. The use of PSIs for wafer-free fixation and osteosynthesis after Le Fort I osteotomy has proven reliable and accurate (Suojanen et al., 2016; Heufelder et al., 2017). According to the literature, the stability of the maxillary segments after Le Fort I

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osteotomy has been debated, especially in cases when the maxillary segments were moved counter-clockwise (Ohba et al., 2015). However, the treatment results with mini-plates for semi-rigid osteosynthesis have markedly improved results and stability compared to wire osteosynthesis (Larsen et al., 1989; Reyneke et al., 2007). Differences in the susceptibility to postoperative relapse in cases treated with mini-plate versus PSI fixation have not been reported.

The aim of this study was to compare the postoperative skeletal stability of the new position of the maxillary segment fixed either with PSIs or conventional mini-plates after Le Fort I osteotomy and repositioning, using clinical and cephalometric data after 9–34 months follow-up.

2. Material and methods

2.1. Patients

This retrospective study investigated the clinical and cephalometric records of 51 patients treated with Le Fort I osteotomy in Helsinki University Hospital (HUH), Helsinki, Finland. Inclusion criteria for the study were as follows: (1) Le Fort I maxillary surgery, with or without simultaneous mandibular osteotomy (bilateral sagittal split osteotomy [BSSO]); (2) availability of preoperative (T1), immediate postoperative (T2) and follow-up (T3, nine months to 34 months postoperatively) cephalometric radiographs; (3) availability of patient data records.

The patients were divided into two groups according to the method of maxillary fixation. The first study group (Group A) was a retrospective cohort of PSI-fixed maxillae that was collected between December 2013 and November 2015. This patient series was also used in our earlier studies (Suojanen et al., 2016; Suojanen et al., 2016). A few patients (patient nos 3, 4, 11 and 32 in the study by Suojanen et al., 2016, and patient nos. 3 and 11 in the study by Suojanen et al., 2018, respectively) were excluded from the present study due to lacking follow-up radiographs, and one patient (no 28 in the study published 2016 and no 18 in the study published 2018, respectively) due to a genetic disorder (Treacher Collins).

The second group (Group B) of mini-plate fixed maxillae were collected between September 2011 and November 2013. This cohort has not been published fully earlier. Part of the series (operations November 1, 2011 to November 30, 2013) was published similarly earlier as presented with the PSI group (Suojanen et al., 2018). Due to lacking follow-up radiographs, we expanded the cohort period to achieve a matching number of patients for the analysis.

More specific information about the groups is presented in Table 1. Anamnestic and clinical findings were recorded at the beginning of the treatment. Table A.1 in Appendix A presents more detailed data on patients.

All the patients were treated orthodontically with fixed appliances as part of the orthognathic surgery treatment at HUH. During postoperative orthodontics, intermaxillary elastics were used. After the postoperative orthodontics, the retention period started, and the patients wore a removable retention plate 24 h (h)/day for six to nine months and then during night time for 1.5 years. In addition, permanent retention wires were placed lingually to lower incisors and canines and often palatinally to upper incisors. During the retention period, the patients were checked at least every six months, and good stability of the occlusion and incisal inclination was detected.

Table 1
Patients.

	Group A	Group B
Number of patients	27 (16 males, 11 females)	24 (13 males, 11 females)
Mean (range) age (years)	29 (19–48)	29 (19–52)

2.2. Surgical methods

Fifty-one patients underwent Le Fort I surgery, which was performed sub-spinally with a similar surgical protocol regardless of the fixation system used. In sub-spinal osteotomy (Mommaerts et al., 1997), the bony nasal spine is separated from the maxillary segment with a saw, after which the nasal mucosa and septal cartilage are freed from the hard palate together with the bony nasal spine. When Le Fort I osteotomy is performed sub-spinally, the osteotomy line is approximately at the same level as the sub-spinal point (point A), in which case, point A is transferred together with the maxillary segment.

The operations were performed by four senior surgeons accompanied by junior surgeons. The differences in the results between the surgeons were not investigated in this study.

Twenty-seven patients received bone graft to the Le Fort I osteotomy line, of whom 14 belonged to Group A and 13 to Group B. Nine of the Le Fort I osteotomies were performed with segmentation of the maxillary segments into two pieces and two into three pieces. A simultaneous BSSO (Epker, 1977) was performed in 24 patients. Two patients underwent Le Fort I osteotomy and BSSO at different dates due to an open bite, one noticed immediately postoperatively and the other one during the routine postoperative control. Two patients underwent reoperation with a second Le Fort I osteotomy. One of these patients was initially treated with a bimaxillary surgery, and the open bite was noticed immediately postoperatively. The other one was initially operated with Le Fort I osteotomy and underwent reoperation due to an unsatisfactory bite immediately postoperatively. All the patients who underwent reoperation belonged to the mini-plate group (Group B). The immediate postoperative cephalometric radiograph taken after the reoperation was used as the immediate postoperative cephalometric radiograph (T2) for all the patients who underwent reoperation, because the surgical treatment was finished only after reoperation.

Group A received custom-made, 3D-designed, patient-specific fixation. The skeletal structures of the face of each patient were preoperatively imaged by computed tomography (CT) and transformed into a 3D image. The surgery and PSIs were planned virtually with a 3D program (Planmeca ProModel system, Planmeca Ltd, Helsinki, Finland). The PSIs were manufactured using computer-aided design and manufacturing (CAD/CAM) technology (Planmeca Ltd, Helsinki, Finland) according to the surgical plan. The general form of PSI was identical in all patients as presented earlier (Suojanen et al., 2016). All patients had two PSIs, where the cranial and tooth-bearing segments were interconnected with two bridging bars in zygomatic buttress and aperture piriformis areas. The PSI frame width was 2 mm and the thickness was 0.8 mm; it was milled from grade 23 titanium monoblocks. In segmented osteotomies, all segments contained at least two screw holes per side.

Group B underwent surgery with conventional wafers and a mini-plate fixation. The mini-plates (DePuy Synthes, Matrix Orthognathic, Raynham, MA, USA) were bent on-site during the surgery. L-shaped, 0.8 mm thick Matrix Orthognathic plates (DePuy Synthes, Matrix Orthognathic, Raynham, MA, USA) were placed in the zygomatic buttress and the piriform aperture. In segmented osteotomies, the segments were also bridged with 0.6 mm or 0.8 mm straight Matrix Orthognathic mini-plates with at least two screws on each side of the segment.

In both groups, monocortical Synthes Matrix Orthognathic screws 6–8 mm in length and 1.85 mm in diameter (DePuy

Synthes, Matrix Orthognathic, Raynham, MA, USA) were used primarily for plate/implant fixation. In the case of a hole failure of the primary screw, 2.1 mm emergency screws were used routinely.

Postoperative cephalometric and panoramic radiographs were taken one day postoperatively of all the patients in this study. According to the clinic's normal treatment protocol, follow-up radiographs were taken one year postoperatively, combined with the final surgical check-up. The purpose of the follow-up radiographs was to evaluate the ossification of the operation site and the stability of the correction of the malocclusion radiologically.

2.3. Cephalometric analysis

The postoperative skeletal stability of the maxillary segments was evaluated from the standardised lateral cephalometric radiographs taken with the Frankfurt plane positioned horizontally. Radiographs taken at three time points were used: preoperative (T1, on average 4.5 months prior to the surgery, range 1–26 months), immediate postoperative (T2, one day after the surgery) and follow-up radiographs (T3, on average 14.5 months postoperatively, range 9–34 months).

The cephalometric tracing was digitised using the Dolphin Imaging 11.95 Premium program (Patterson Dental Supply, Inc., Minnesota, USA) with conventional cephalometric analysis. To evaluate the amount of anteroposterior and vertical surgical transfer of the maxillary segments, the immediately postoperative radiograph was superimposed over the preoperative cephalometric radiograph (Fig. 1A). Evaluation of the skeletal stability was performed by superimposing the follow-up radiograph over the immediately postoperative radiograph (Fig. 1B). To ensure that the cephalometric points used for the measurements were placed at correct points, sella–nasion and porion–orbitale lines were first adjusted to correspond to each other in each radiograph of the particular patient.

The skeletal stability was investigated by determining the relapse of the maxillary segments using the best available skeletal and dental points. The relapse was evaluated both in anteroposterior and vertical dimensions.

The anteroposterior points used in the determination of the relapse were (1) sub-spinal point (A point); (2) posterior nasal spine (PNS); (3) upper central incisal tip (U tip); (4) the angle between sella, nasion, and A point (SNA angle). The vertical points used in the determination of the relapse were (1) U tip and (2) PNS (Fig. 2).

The U tip was used for the evaluation both in anteroposterior and vertical dimensions. Although U tip is a dental point, the inclinations of the upper incisors are decided and achieved in our treatment protocol at the preoperative orthodontic treatment and the changes of the incisor inclinations during postoperative orthodontics are very minor if any. The reliability of the U tip point was ensured by superimposing the immediately postoperative and follow-up radiographs in line with the maxillae and checking whether the inclination of the upper incisors had remained unchanged during the postoperative orthodontic treatment. The inclination of the upper incisors was shown to have remained very stable; thus, the U tip point was included in the evaluation.

The patient data was further divided into subgroups according to the original anteroposterior movement of the A point during the surgery:

1. Forward movement of the A point less than 2 mm, where the main purpose of the surgery was to rotate the maxillary segments vertically either clockwise or counter-clockwise to correct the malocclusion
2. Forward movement of the A point more than 2 mm

Subgroup 2 was further divided into two smaller subgroups to see whether there was a statistically significant difference in the stability, depending on the length of the forward transfer:

2.1) Forward movement of the A point 2–5 mm
2.2) Forward movement of the A point more than 5 mm

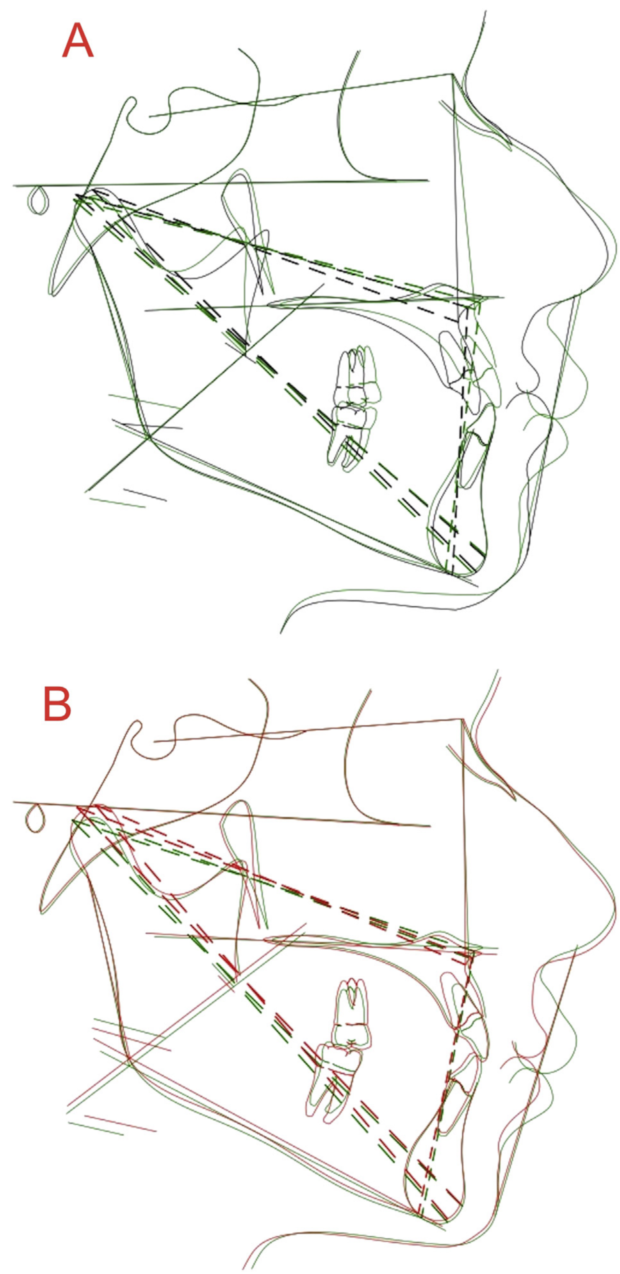

Fig. 1. Superimposition of the cephalometric radiographs: (A) preoperative (black) and immediate postoperative (green); (B) immediate postoperative (green) and follow-up (red).

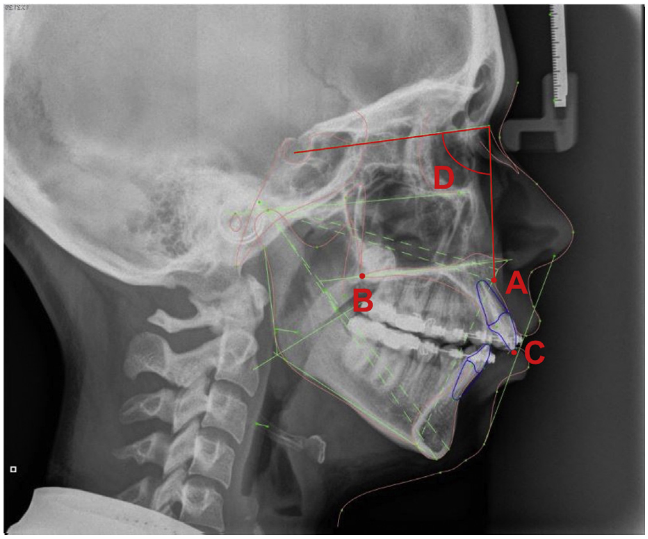

Fig. 2. Cephalometric points and lines used in the study: (A) A point; (B) PNS; (C) U tip; (D) SNA angle.

Patient data of the different subgroups is presented in Tables 2 and 3.

2.4. Statistical analysis

The *t*-test and Mann–Whitney U test were used for normally distributed and non-normally distributed variables, respectively, to examine whether the relapse of the points of interest differed significantly from each other in the two study groups (Group A and Group B). The patient data was further divided into smaller subgroups 1, 2, 2.1 and 2.2 described earlier, which were tested with the applicable *t*-test or the Mann–Whitney U test as well. Multiple testing corrections were made for all the p-values by various methods.

A further analysis was performed for the dependent variables, with the smallest p-values in the *t*-test or Mann–Whitney U tests. A regression analysis was conducted, taking into account the following independent variables: age at the operation date, sex, rheumatoid disease, smoking, open bite as a diagnosis, use of bone graft during the operation and the vertical direction of the movement of the maxillary segments during the operation. The residuals were tested and concluded homoscedastic and normally distributed.

In all statistical analyses, values of $p \leq 0.05$ were considered statistically significant.

For the statistical analysis, biostatistics experts were consulted, and all the analyses were verified by them.

2.5. Intra-rater reliability

One observer (KK) performed the cephalometric tracing. Intra-examiner reliability was assessed by digitising twice 20 randomly selected radiographs, including radiographs from all the stages. The intra-class correlation coefficient (ICC) was used to calculate the error.

2.6. Ethical permission

The protocol of the retrospective study was approved by the Hospital District of Helsinki and Uusimaa (HUS/358/2018, §4). The study does not fulfil characteristics of a medical study according to the Medical Research Act and does not need ethical permission. Principles outlined in the Declaration of Helsinki were followed.

3. Results

3.1. Clinical findings

A total of 51 patients (24 males, 27 females) were included in the study. Group A (mean age 29 years, range 19–48 years) was a retrospective cohort of PSI-fixated maxillary segments and Group B (mean age 29 years, range 19–52 years) of mini-plate fixated maxillary segments. Patient-specific data on gender, age, orthodontic diagnosis, type of surgery and bone grafting are shown in Table A.1 in Appendix A. Clinical dental findings are shown in Table 4.

3.2. Cephalometric results of surgery movements

The mean forward transfer of the maxillary segments was 4.5 mm (range 0.0–10.0 mm, SD = 2) in Group A and 4.9 mm (range −1.0–10.0 mm, SD = 3.7) in Group B, respectively. The anterior impaction was on average 1.2 mm (range −2.3–5.0 mm, SD 2.1) and the posterior impaction was 1.1 mm (range −5.7–5.0 mm, SD 2.4) in Group A. For Group B, the respective values were 0.2 mm (range −7.9–3.0 mm, SD 2.4) and 0.8 mm (range −2.0–3.5 mm, SD 1.4).

3.3. Cephalometric results of stability

No statistically significant differences were found between the stability of the studied groups, that is, PSI (Group A) vs. mini-plate (Group B) fixed, when comparing the two whole groups of patients (Table 5).

No statistically significant differences were found in subgroup 1 (forward movement of the A point less than 2 mm), as shown in Table 6.

In addition, eliminating the very small forward transfers of the A point as a result of only rotating the maxillary segments (subgroup 1) and examining subgroup 2 (forward movement of the A point more than 2 mm) yielded no statistically significant differences, as shown in Table 7.

However, examining subgroups 2.1 (forward movement of the A point 2–5 mm) and 2.2 (forward movement of the A point more than 5 mm), yielded a statistically significant difference in subgroup 2.1 in the relative relapse of the U tip in the vertical

Table 2
Subgroups 1 and 2.

	Subgroup 1	Subgroup 2
Number of patients	13 (7 males, 6 females)	38 (17 males, 21 females)
Group A patients	8 (4 males, 4 females)	19 (7 males, 12 females)
Group B patients	5 (3 males, 2 females)	19 (10 males, 9 females)
Mean (range) age (years)	30 (22–48)	28 (19–52)
Mean (range) age (years) of Group A	32 (23–48)	27 (19–45)
Mean (range) age (years) of Group B	28 (22–43)	29 (19–52)

Table 3
Subgroups 2.1 and 2.2

	Subgroup 2.1	Subgroup 2.2
Number of patients	21 (7 males, 14 females)	17 (10 males, 7 females)
Group A patients	12 (4 males, 8 females)	7 (3 males, 4 females)
Group B patients	9 (3 males, 6 females)	10 (7 males, 3 females)
Mean (range) age (years)	28 (19–48)	28 (21–52)
Mean (range) age (years) of Group A	27 (19–45)	27 (21–43)
Mean (range) age (years) of Group B	28 (19–48)	29 (21–52)

Table 4
Findings of the clinical dental examination of the patients at the beginning and end of the treatment.

Preoperatively	Group A		Group B	
	Mean	Range	Mean	Range
Maximum jaw opening (mm)	48.0	30–62	50.0	40–65
Overjet (mm)	3.0	−3.0–14.0	1.0	−9.0–15.0
Overbite (mm)	−0.7	−6.0–6.0	−0.1	−4.0–3.5
Lower facial height (LAFH/TAFH) (%)	55.5	51.4–60.8	55.4	49.0–62.0
Angle between sella–nasion plane and mandibular plane (MP–SN) (°)	40.8	3.1–62.4	36.3	17.5–48.9
Angle between palatal plane and mandibular plane (PL–MP) (°)	34.4	−4.5–55.6	29.7	16.9–42.7
SNA (°)	81.1	73.6–88.7	81.4	64.4–87.5
Upper incisal inclination U1–SN (°)	105.2	91.7–122.8	105.3	93.5–124.6
Upper Incisal inclination U1–PL (°)	111.6	99.5–129.9	111.9	97.0–131.5
Lower incisal inclination L1–MP (°)	89.2	73.4–102.5	90.1	76.1–107.0
At the end of treatment	Group A		Group B	
	Mean	Range	Mean	Range
Maximum jaw opening (mm) at the beginning of retention	46.0	23–62	49.0	36–70
Overjet (mm) at the beginning of retention	2.4	1.0–5.0	2.3	0.5–4.5
Overbite (mm) at the beginning of retention	1.8	0.0–3.0	1.7	−1.0–3.0
Lower facial height (LAFH/TAFH) (%)	55.6	51.5–60.5	55.3	50.2–60.2
Angle between sella–nasion plane and mandibular plane (MP–SN) (°)	39.3	19.2–58.7	35.9	19.2–51.2
Angle between palatal plane and mandibular plane (PL–MP) (°)	32.8	6.7–53.6	27.5	17.0–41.8
SNA (°)	84.2	74.9–94.9	85.5	72.0–93.9
Upper Incisal inclination U1–SN (°)	106.3	90.4–119.2	105.5	90.5–132.4
Upper Incisal inclination U1–PL (°)	112.8	98.5–131.7	113.9	99.9–137.4
Lower Incisal inclination L1–MP (°)	86.7	72.7–105.4	88.8	75.9–103.5

Table 5
P values for the stability between Group A and Group B in anteroposterior (x) and vertical (y) dimensions.

			Absolute relapse (mm/°)	p value	Sign.	Relative relapse[a]	p value	Sign.
A point (x) (mm)	Group A	Mean	−0.64	0.95	NS	−0.40	0.51	NS
		SD	0.78			0.78		
	Group B	Mean	−0.75			−0.42		
		SD	0.73			1.03		
PNS (x) (mm)	Group A	Mean	−0.09	0.15	NS	−0.12	0.47	NS
		SD	1.18			0.98		
	Group B	Mean	−0.54			−0.02		
		SD	0.99			0.47		
U tip (x) (mm)	Group A	Mean	−0.27	0.70	NS	−0.09	0.86	NS
		SD	1.34			0.70		
	Group B	Mean	−0.22			−0.19		
		SD	1.31			1.58		
SNA (x) (°)	Group A	Mean	−0.57	0.44	NS	−0.33	0.39	NS
		SD	0.74			0.56		
	Group B	Mean	−0.75			−0.07		
		SD	0.82			0.74		
U tip (y) (mm)	Group A	Mean	1.07	0.47	NS	0.77	0.49	NS
		SD	0.95			0.90		
	Group B	Mean	0.82			0.82		
		SD	0.67			1.37		
PNS (y) (mm)	Group A	Mean	0.17	0.74	NS	−0.23	1.00	NS
		SD	0.92			0.70		
	Group B	Mean	0.11			−0.50		
		SD	0.86			2.42		

[a] Calculated as the relative change between the postoperative and follow-up situations in relation to the original transfer.

Table 6
P values for the stability between Group A and Group B in subgroup 1 in anteroposterior (x) and vertical (y) dimensions.

			Absolute relapse (mm/°)	p value	Sign.	Relative relapse[a]	p value	Sign.
A point (x) (mm)	Group A	Mean	−0.64	0.83	NS	−1.03	0.83	NS
		SD	0.88			1.29		
	Group B	Mean	−0.62			−1.47		
		SD	0.62			2.07		
PNS (x) (mm)	Group A	Mean	0.25	0.22	NS	−0.07	0.44	NS
		SD	0.75			1.82		
	Group B	Mean	−0.16			0.22		
		SD	0.69			0.99		
U tip (x) (mm)	Group A	Mean	−0.24	0.72	NS	−0.13	0.13	NS
		SD	1.72			1.29		
	Group B	Mean	−0.60			−0.81		
		SD	1.40			0.21		
SNA (x) (°)	Group A	Mean	−0.60	0.71	NS	−0.83	0.28	NS
		SD	0.74			0.83		
	Group B	Mean	−0.68			0.20		
		SD	0.75			1.72		
U tip (y) (mm)	Group A	Mean	0.86	0.21	NS	0.56	1.00	NS
		SD	0.61			0.40		
	Group B	Mean	1.44			1.02		
		SD	0.96			1.53		
PNS (y) (mm)	Group A	Mean	0.56	0.09	NS	−0.21	0.62	NS
		SD	1.03			0.49		
	Group B	Mean	−0.48			−0.61		
		SD	0.79			0.56		

[a] Calculated as the relative change between the postoperative and follow-up situations in relation to the original transfer.

Table 7
P values for the stability between Group A and Group B in subgroup 2 in anteroposterior (x) and vertical (y) dimensions.

			Absolute relapse (mm/°)	p value	Sign.	Relative relapse[a]	p value	Sign.
A point (x) (mm)	Group A	Mean	−0.67	0.99	NS	−0.17	0.50	NS
		SD	0.78			0.19		
	Group B	Mean	−0.79			−0.15		
		SD	0.76			0.14		
PNS (x) (mm)	Group A	Mean	−0.28	0.58	NS	−0.06	0.68	NS
		SD	1.28			0.28		
	Group B	Mean	−0.53			−0.09		
		SD	0.93			0.20		
U tip (x) (mm)	Group A	Mean	−0.36	0.34	NS	−0.08	0.25	NS
		SD	1.26			0.24		
	Group B	Mean	−0.04			0.01		
		SD	1.16			0.27		
SNA (x) (°)	Group A	Mean	−0.58	0.50	NS	−0.14	0.91	NS
		SD	0.78			0.19		
	Group B	Mean	−0.76			−0.14		
		SD	0.86			0.13		
U tip (y) (mm)	Group A	Mean	1.19	0.12	NS	0.86	0.52	NS
		SD	1.06			1.03		
	Group B	Mean	0.64			0.66		
		SD	0.49			0.95		
PNS (y) (mm)	Group A	Mean	−0.06	0.35	NS	−0.14	0.91	NS
		SD	0.78			0.63		
	Group B	Mean	0.26			−0.73		
		SD	0.83			2.30		

[a] Calculated as the relative change between the postoperative and follow-up situations in relation to the original transfer.

dimension, taking into account the direction of the original movement of the maxillary segments in the vertical dimension ($p = 0.049$) (Table 8).

No statistically significant differences were found in subgroup 2.2, as shown in Table 9.

The stability of the U tip was further examined with linear regression analysis. According to the results, the absolute relapse of the U tip point showed a statistically significant difference in the vertical dimension in subgroup 2.1, taking into account the age of the patients during the surgery as well as the original direction of the movement of the maxillary segments ($p = 0.0094$, R^2 adjusted $= 0.326$, coefficient $= -1.20670$). Adding the open bite to the regression model, the p-value was even lower ($p = 0.00867$, coefficient $= -1.187091$) and the adjusted R^2 was a little higher (R^2 adjusted $= 0.375$). Adding any other independent variable (sex, rheumatoid disease, smoking, use of bone graft during the operation) to the model neither improved the predictive power of the model nor yielded any statistically significant effect. The models did not suffer from heteroscedasticity, but given the small sample size, it was difficult to determine whether the residuals were normally distributed; the Kolmogorov–Smirnov and Shapiro–Wilk tests indicated normally distributed residuals, but this could not be confirmed by looking at the histograms.

Table 8
P values for the stability between Group A and Group B in subgroup 2.1 in anteroposterior (x) and vertical (y) dimensions.

			Absolute relapse (mm/°)	p value	Sign.	Relative relapse[a]	p value	Sign.
A point (x) (mm)	Group A	Mean	−0.83	0.15	NS	−0.22	0.30	NS
		SD	0.74			0.19		
	Group B	Mean	−0.56			−0.19		
		SD	0.47			0.16		
PNS (x) (mm)	Group A	Mean	−0.53	0.46	NS	−0.13	0.13	NS
		SD	1.10			0.29		
	Group B	Mean	−0.17			−0.06		
		SD	0.74			0.25		
U tip (x) (mm)	Group A	Mean	−0.81	0.50	NS	−0.17	0.81	NS
		SD	0.78			0.21		
	Group B	Mean	−0.32			−0.10		
		SD	0.97			0.26		
SNA (x) (°)	Group A	Mean	−0.79	0.46	NS	−0.20	0.50	NS
		SD	0.76			0.20		
	Group B	Mean	−0.49			−0.16		
		SD	0.50			0.15		
U tip (y) (mm)	Group A	Mean	1.31	0.051	NS	0.70	0.049	S
		SD	0.79			0.58		
	Group B	Mean	0.66			0.34		
		SD	0.50			0.33		
PNS (y) (mm)	Group A	Mean	−0.14	0.41	NS	−0.15	0.75	NS
		SD	0.77			0.50		
	Group B	Mean	0.40			−1.34		
		SD	1.12			3.32		

[a] Calculated as the relative change between the postoperative and follow-up situations in relation to the original transfer.

Table 9
P values for the stability between Group A and Group B in subgroup 2.2 in anteroposterior (x) and vertical (y) dimensions.

			Absolute relapse (mm/°)	p value	Sign.	Relative relapse[a]	p value	Sign.
A point (x) (mm)	Group A	Mean	−0.40	0.22	NS	−0.07	0.52	NS
		SD	0.82			0.15		
	Group B	Mean	−1.00			−0.11		
		SD	0.93			0.10		
PNS (x) (mm)	Group A	Mean	0.16	0.19	NS	0.06	0.35	NS
		SD	1.54			0.25		
	Group B	Mean	−0.85			−0.11		
		SD	1.00			0.15		
U tip (x) (mm)	Group A	Mean	0.41	0.96	NS	0.07	0.60	NS
		SD	1.60			0.22		
	Group B	Mean	0.22			0.11		
		SD	1.30			0.25		
SNA (x) (°)	Group A	Mean	−0.21	0.11	NS	−0.05	0.42	NS
		SD	0.72			0.12		
	Group B	Mean	−1.01			−0.11		
		SD	1.06			0.12		
U tip (y) (mm)	Group A	Mean	1.00	0.88	NS	1.15	0.52	NS
		SD	1.47			1.55		
	Group B	Mean	0.63			0.95		
		SD	0.51			1.23		
PNS (y) (mm)	Group A	Mean	0.09	0.96	NS	−0.13	0.42	NS
		SD	0.84			0.86		
	Group B	Mean	0.13			−0.19		
		SD	0.47			0.28		

[a] Calculated as the relative change between the postoperative and follow-up situations in relation to the original transfer.

Other models of the regression analysis showed no statistically significant differences between the stability of the maxillary segments, depending on the fixation plate used.

The intra-rater reliability was calculated to three points of interest: A point, PNS point and U tip point, both in anteroposterior (X) and vertical (Y) dimensions. The results are shown in Table 10.

4. Discussion

Three-dimensional planning and PSIs are interesting modern tools for planning, repositioning and fixation in Le Fort I osteotomy (Van Hemelen et al., 2015; Suojanen et al., 2016; Heufelder et al., 2017). According to the literature, the fitting of PSIs is accurate and the postoperative results are predictable and reliable (Heufelder et al., 2017). We demonstrated earlier that the use of PSIs may reduce the need for reoperations due to insufficient advancement of the maxillary segments immediately after surgery (Suojanen et al., 2018). In that study 0 out of 31 maxillae fixed with PSIs needed immediate reoperations due to malocclusion whereas 3 out of 37 mini-plate fixed maxillae were reoperated. However, the difference was not statistically significant. Immediate reoperation due to malocclusion almost solely relates to immediate bony relapse due to tension during osteosynthesis. It is possible that one reason for reoperation was related to mini-plate fixation. However, the effect of other reasons cannot be excluded. The small sample size of the study is also a restrictive factor when drawing

Table 10
The intra-class correlation coefficient (ICC) values for the points of interest in anteroposterior (X) and vertical (Y) dimensions to determine the intra-examiner reliability.

	ICC	
	X	Y
A point	0.98	0.965
PNS	0.984	0.991
U tip	0.999	1.000

conclusions from the study. Because the patients were reoperated shortly after the original surgery, there is no follow-up radiograph (T3) available of the original surgery. This leads to negative sampling bias in the mini-plate group.

The aim of our study was to evaluate differences in the postoperative skeletal stability between Le Fort I osteotomies fixed either by PSIs or by conventional mini-plates. To our knowledge, no similar studies on postoperative skeletal stability comparing fixation with PSIs and mini-plates have been reported earlier.

All patients in our study underwent a Le Fort I osteotomy, performed with a similar surgical protocol regardless of the fixation system used. Four senior surgeons were in charge of the operations, but this study did not investigate the differences between the surgeons.

From the initial patient data, 14 patients were excluded from the study due to lack of radiographs. The lacking radiographs were most often the follow-up radiographs, which may indicate that these were patients who did not suffer from any kind of postoperative complications or problems. Thus, the group of patients included in this study may consist of patients who had more postoperative problems or complications than the patients on average.

When analysing skeletal stability, the difficulty in comparing serial cephalometric radiographs must be remembered. During the cephalometric tracing, it was noted, for example, that the anterior nasal spine (ANS) point was difficult to trace or untraceable in many of the postoperative and follow-up radiographs due to remodelling during the surgery. Hence, this point was not used in the evaluation of the relapse.

Nine of the Le Fort I osteotomies were performed with segmentation of the maxillary segments into two pieces and two into three pieces. Because the sample size was so small, analysing the effects of segmentation on postoperative skeletal stability was not possible. Larger clinical studies are warranted for investigating the possible differences of the segmentations.

Twenty-seven patients underwent a BSSO in addition to the Le Fort I osteotomy. Earlier studies (Tate et al., 1994) have shown a statistically significant reduction in voluntary bite forces in patients treated for mandibular angle fractures. Although Tate et al. investigated patients suffering from a mandibular fracture, the clinical situation is quite similar after a BSSO performed for orthognathic reasons. Hence, a mandibular BSSO combined with a Le Fort I osteotomy can reduce the maximum bite forces postoperatively for several weeks and thus have a stabilizing effect on the maxillary segments as compared to the cases of only a maxillary Le Fort I osteotomy. However, according to our analysis, there was no statistical difference between the number of bimaxillary surgeries in Group A and Group B.

Analysing the data, the results of postoperative skeletal stability revealed that relapse may seem exceptionally large when only a small transfer of the maxillary segments in the anteroposterior dimension was performed. These are usually cases in which the main purpose of the surgery was to rotate the maxillary segments vertically either clockwise or counter-clockwise to correct malocclusion. In these cases, the A point was only moved minimally in the anteroposterior dimension as a result of the rotational movement of the maxillary segments. For the limited accuracy of the cephalometric tracing as well as for the remodelling and resorption of the bone, relapse may seem as large as 100% or even more in these situations. This is due to remodelling of the sub-spinal area already during surgery to ensure that there will not be any interference between the septum and the floor of the nasal cavity leading to septum deviation, especially in counter-clockwise repositioning of the maxillary segments. For this reason, the A point was only used in the evaluation of the relapse in the anteroposterior dimension. Similar difficulties in identifying ANS and A points have been reported by earlier investigators (Venkategowda et al., 2017). The rationale and the effect of sub-spinal osteotomy on soft-tissue changes in the nasal area were analysed earlier (Mommaerts et al., 2000) but to our knowledge no comparative analysis of conventional Le Fort I osteotomy exists. However, because the nasal spine is surgically separated from the maxillary segment, and sometimes even partly resected during the impaction, it is possible that the remodelling of this area may vary considerably from one patient to another.

With regard to the postoperative skeletal stability of the maxillae, no statistically significant difference was found between the PSI or mini-plate fixed maxillae when examining the whole group of patients. A statistically significant difference was found in the relative relapse of the U tip in the vertical dimension in subgroup 2.1. The result suggests better stability for the mini-plate fixed maxillae than for the PSI fixed maxillae with small advancements. However, after multiple testing correction, this p-value was also greater than 0.05; thus, no reliable conclusions could be derived on the basis of the analysis. Interestingly, the same statistically significant difference was not found in the relative relapse of the U tip in the vertical dimension in subgroup 2.2, that is, the forward movement of the A point more than 5 mm. Neither did the whole subgroup 2 (forward movement of the A point more than 2 mm) show statistically significant difference in the relapse of the U tip in the vertical dimension. Because subgroup 2 consisted of only 38 patients, of whom 21 belonged to subgroup 2.1 and 17 to subgroup 2.2, these divergent findings are most likely due to small sample size, and more investigations are needed to confirm the findings.

The stability of the U tip was further examined with linear regression analysis. According to the results, the absolute relapse of the U tip point showed statistically significant difference in the vertical dimension in subgroup 2.1. However, when taking into account the small sample size of only 12 patients in Group A and nine patients in Group B, only directional conclusions about the better stability of the mini-plate fixed maxillae can be drawn, based on this study, and further investigations are needed to confirm this preliminary result. It is also possible for patients with mini-plate surgery with bony interference or plate tension (and susceptibility to relapse) postoperatively to need early reoperations, which may distort the findings.

The intra-rater reliability was calculated to three points of interest: A point, PNS point and U tip point, both in anteroposterior (X) and vertical (Y) dimensions. The intra-class correlation values were in general excellent, the vertical A point being the weakest (ICC = 0.965). This result was already predicted at an early stage of the study, because the curve of the anterior maxilla may be very broad, thus causing large variations in determining the position of the A point in the vertical dimension. Also, it must be noted that all patients were operated on with a sub-spinal Le Fort I osteotomy, in which the nasal spine was also separated from the maxillary segments; this causes some remodelling during the healing period, which may to some extent also affect the reliability of the A point determination in cephalometric radiographs. This may also affect the interpretation, especially in small advancements. For this reason, the A point was only used in the determination of relapse in the anteroposterior direction. Other values of ICC showed excellent accuracy.

5. Conclusions

According to the results, the choice between the two fixation methods did not seem to affect the postoperative skeletal stability of the maxillae. Although a statistically significant difference was found in the vertical stability of the U tip in one of the subgroups, U tip is a dental point and does not directly correlate to the skeletal stability. For this reason, future prospective studies are warranted to confirm the results. For example, 3D imaging and 3D fusion analysis of different time points (T1, T2, T3) would be advantageous and would allow analysis of 3D spatial changes.

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Appendix A. Table A.1. Patient characteristics.

Patient no.	Group	Sub-group	Sex (F/M)	Age (y)	Orthodontic diagnosis	Type of surgery	One-piece/segment	Movement of maxilla	Bone graft
1	A	1	M	25.4	Open bite, cross bite, maxillary retrognathia	Le Fort I	Two-piece	Straight	No
2	A	2.1	M	25.6	Cross bite, mandibular prognathia, maxillary retrognathia, asymmetry	Le Fort I	One-piece	Straight	No
3	A	1	F	44.2	Open bite, mandibular retrognathia	Bimaxillary	One-piece	CCW	DBX to maxillae
4	A	2.2	M	28.3	Cross bite, maxillary retrognathia, asymmetry	Le Fort I	One-piece	Straight	No
5	A	2.1	F	22.3	Open bite, mandibular retrognathia, asymmetry, crowding	Bimaxillary	One-piece	Straight	DBX to maxillae and mandible
6	A	2.2	M	25.0	Open bite, cross bite, mandibular prognathia, asymmetry	Bimaxillary	Two-piece	CW	DBX to maxillae
7	A	2.2	F	24.3	Cross bite, maxillary retrognathia	Le Fort I	One-piece	Straight	DBX
8	A	1	F	48.5	Cross bite, maxillary retrognathia, asymmetry, crowding	Le Fort I	Two-piece	Straight	DBX
9	A	1	M	33.2	Cross bite, mandibular prognathia, asymmetry	Bimaxillary	Two-piece	Straight	BioOss
10	A	2.1	M	24.4	Mandibular prognathia, maxillary retrognathia, hypodontia	Le Fort I	One-piece	Straight	Chronos
11	A	2.1	F	19.4	Open bite, mandibular retrognathia	Bimaxillary	One-piece	Straight	No
12	A	2.2	F	43.3	Cross bite, maxillary retrognathia, asymmetry	Le Fort I	Two-piece	Straight	Human bone and DBX
13	A	1	F	23.6	Open bite, mandibular retrognathia	Bimaxillary	One-piece	CCW	Human bone
14	A	2.2	F	27.1	Open bite, mandibular retrognathia	Bimaxillary	One-piece	CCW	No
15	A	2.1	F	37.0	Open bite, mandibular retrognathia	Bimaxillary	One-piece	Straight	BonAlive to mandible
16	A	2.1	F	29.7	Open bite, asymmetry	Bimaxillary	One-piece	Straight	No
17	A	2.1	F	45.6	Cross bite, maxillary retrognathia	Le Fort I	One-piece	CW	No
18	A	1	M	27.3	Open bite, cross bite	Bimaxillary	Two-piece	CW	No
19	A	2.2	M	21.4	Open bite, mandibular prognathia	Bimaxillary	One-piece	CW	Human bone to maxillae
20	A	2.1	F	21.4	Open bite, cross bite	Bimaxillary	One-piece	CCW	No
21	A	2.1	M	23.9	Open bite, cross bite, crowding	Le Fort I	One-piece	CW	BioOss
22	A	2.2	F	25.3	Mandibular prognathia, maxillary retrognathia	Le Fort I	One-piece	CW	BioOss
23	A	2.1	M	37.4	Acromegaly, open bite, cross bite, mandibular macrognathia, asymmetry	Bimaxillary	One-piece	Straight	Iliac crest to maxillae

(*continued*)

Patient no.	Group	Sub-group	Sex (F/M)	Age (y)	Orthodontic diagnosis	Type of surgery	One-piece/segment	Movement of maxilla	Bone graft
24	A	2.1	F	25.9	Cross bite, deep bite, mandibular retrognathia	Bimaxillary	Two-piece	Straight	BonAlive to mandible
25	A	2.1	F	20.4	Open bite, mandibular retrognathia	Bimaxillary	One-piece	CCW	No
26	A	1	F	25.3	Open bite, cross bite, maxillary retrognathia, mandibular retrognathia, crowding	Bimaxillary	Two-piece	CCW	BonAlive to mandible
27	A	1	M	25.2	Open bite, hypodontia	Bimaxillary	Three-piece	Straight	BioOss to mandible
28	B	2.2	M	25.8	Open bite, cross bite, mandibular prognathia, maxillary retrognathia, hypodontia	Bimaxillary	One-piece	Straight	Iliac crest to maxillae
29	B	2.2	M	24.0	Cross bite, mandibular prognathia, maxillary retrognathia	Le Fort I	Two-piece	CCW	Iliac crest
30	B	2.1	F	19.6	Open bite, crowding	Bimaxillary	One-piece	Straight	BonAlive to mandible
31	B	2.1	M	36.9	Open bite, cross bite, mandibular retrognathia	Bimaxillary	One-piece	CCW	BonAlive to mandible
32	B	2.2	M	27.0	Cross bite, mandibular prognathia, maxillary retrognathia, crowding	Le Fort I	One-piece	Straight	Iliac crest
33	B	2.2	M	52.0	Acromegaly, open bite, cross bite, mandibular macrognathia, asymmetry	Le Fort I	One-piece	CCW	Iliac crest
34	B	2.2	F	28.1	Cross bite, mandibular prognathia, maxillary retrognathia	Le Fort I	Three-piece	Straight	No
35	B	2.2	F	23.1	Cross bite, maxillary retrognathia, asymmetry, crowding	Le Fort I	One-piece	CW	DBX
36	B	2.1	F	33.5	Cross bite, mandibular prognathia, maxillary retrognathia	Le Fort I	One-piece	CW	DBX
37	B	2.1	F	24.4	Open bite, mandibular retrognathia	Bimaxillary	One-piece	Straight	BonAlive to mandible
38	B	1	F	24.6	Open bite, cross bite	Le Fort I	One-piece	CW	DBX
39	B	2.2	M	27.1	Cross bite, mandibular prognathia, maxillary retrognathia, asymmetry, crowding	Le Fort I	One-piece	Straight	Iliac crest
40	B	1	M	22.2	Open bite, mandibular retrognathia	Bimaxillary	One-piece	CCW	No
41	B	2.1	F	48.7	Cross bite, mandibular prognathia	Le Fort I	One-piece	Straight	No
42	B	2.2	M	22.9	Open bite, maxillary retrognathia	Bimaxillary	One-piece	Straight	Iliac crest
43	B	2.1	F	21.8	Open bite, mandibular retrognathia, crowding	Bimaxillary	One-piece	CW	No
44	B	2.2	M	45.1	Cross bite, mandibular prognathia, maxillary retrognathia	Bimaxillary	One-piece	CW	Iliac crest
45	B	2.2	F	21.3	Cross bite, mandibular prognathia	Le Fort I	One-piece	Straight	Human bone
46	B	1	M	26.1	Open bite, maxillary retrognathia, crowding	Le Fort I	One-piece	Straight	No
47	B	1	F	26.9	Open bite, cross bite, crowding	Le Fort I	One-piece	CW	No
48	B	2.1	M	23.1	Open bite, cross bite, maxillary retrognathia	Le Fort I	One-piece	Straight	Human bone
49	B	2.1	M	26.3	Cross bite, mandibular prognathia, maxillary retrognathia, hypodontia	Le Fort I	One-piece	Straight	No
50	B	2.1	F	22.9	Open bite, mandibular retrognathia, crowding	Bimaxillary	One-piece	CCW	No
51	B	1	M	43.6	Deep bite	Bimaxillary	One-piece	Straight	Iliac crest to maxillae

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