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Comparison between patient specific implants and conventional mini-plates in Le Fort I osteotomy with regard to infections: No differences in up to 3-year follow-up

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ABSTRACT

Individually designed osteotomies and milled or printed patient-specific osteosynthesis materials are rapidly becoming a standard in maxillofacial reconstructive surgery. The benefits of using patient-specific implants (PSIs) in orthognathic surgery are especially clear in complex cases, and for this reason they are rapidly becoming common practice. We have earlier reported the benefits related to the use of PSIs as reposition and fixation system in Le Fort I osteotomy. The aim of this study was to compare complications associated with fixation with PSIs (31 patients) versus conventional mini-plates (37 patients) in Le Fort I osteotomy. No statistically significant differences in infection, reoperations or soft tissue problems were observed between the two systems used. Interestingly, three of the 37 patients in the mini-plate group underwent reoperation due to insufficient advancement or malocclusion, whereas none of the patients in the PSI group needed reoperation. In conclusion, PSIs are reliable for use in orthognathic surgery, with no signs of infection associated complications.

1. Introduction

The use of three-dimensional (3D) design and virtual surgery is becoming a common practice in orthognathic surgery. The use of individually manufactured surgical drill and cutting guides as well as patient specific implants (PSI) for osteosynthesis is now available for all clinicians, with reasonable delivery time and expenses. The first 3D-designed implants were mere modifications of conventional mini-plates, but when the computer-aided manufacturing/computer-aided design (CAD/CAM) milling and printing techniques started to develop, more specific and freely designed implants were possible to produce (Gander et al., 2015; Mazzoni et al., 2015; Suojanen et al., 2016, 2017). Most of the commercially available systems are using CAD/CAM wafers to produce patient-specific saw and drill guides. Some systems also provide custom-made 3D-printed or milled titanium implants. Individually milled implants combined with the use of drill guides also enables wafer-free positioning of the maxilla. We have earlier demonstrated the reliable use of PSIs for wafer-free repositioning and osteosynthesis in Le Fort I osteotomy (Suojanen et al., 2016). This is supported in a recent publication by Heufelder et al., which indicates a highly accurate postoperative position of the maxilla when using PSIs in Le Fort I osteotomy (Heufelder et al., 2017). On the contrary, this is not often the case with conventional systems (Ellis, 1990). Commonly used PSIs are manufactured either by milling from titanium monoblocks or by laser sintering from titanium powder. The individually designed implants often follow the contours of the bone with high fidelity, but the implants are rather bulky and their surface is clearly

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rougher as compared to that of conventional mini-plates. This has raised questions about possible infectious problems. At present, there are no data on differences in the susceptibility to postoperative infections between mini-plates and PSIs.

In our study, 31 patients treated with Le Fort I osteotomy and PSIs were followed up for up to 3 years with regard complications associated with infections. We also collected a retrospective cohort of 37 patients treated with Le Fort I osteotomy and conventional mini-plate fixation for comparison regarding postoperative complications.

2. Materials and methods

2.1. Patients and procedures

All the patients treated with PSIs obtained implants manufactured by Planmeca ProModel system (Planmeca Ltd, Helsinki, Finland). The cohort of the PSI patients (n = 31) was formed as described earlier (Suojanen et al., 2016). The follow-up data of the 31 patients treated with PSIs was collected from Helsinki University Hospital patient archives (to February 15, 2017). All patients visited the clinic for postoperative controls according to the clinical protocol, with no follow-up data missing. For control analysis, a retrospective cohort of 37 patients treated with Le Fort I osteotomy including repositioning of the maxilla with conventional wafers and fixation with mini-plates (Gold, Matrix Orthognathic, DePuy Synthes, Oberdorf, Switzerland) was collected as well from the Helsinki University Hospital patient files from November 1, 2011, to November 30, 2013).

2.2. Statistical analysis

The collected data of demographic profile, reoperations, infections and soft tissue problems was analyzed with SPSS software version 23 (IBM Analytics from these groups). Nonparametric analysis was performed and Mann–Whitney *U* test was used. A *P* value of <0.05 was considered significant.

2.3. Ethics considerations

The protocol of the retrospective study was approved by the Institutional Research Ethics Board 25 May 2015.

3. Results

The demographic (age and gender) data of the PSI and mini-plate cohorts did not differ statistically ($P = 0.304$ and 0.557, respectively). The PSI cohort data covered follow-up from 14 to 37 months (average 26 months) and the mini-plate cohort from 38 to 62 months (average 49 months). The individual patient data as well as postoperative wound and soft tissue problems and reoperations can be seen in detail in Table 1 for PSI patients and in Table 2 for the conventional mini-plate patients. The groups did not differ statistically based on postoperative wound problems, infections ($P = 0.500$) or plate/screw removal ($P = 0.668$). Infection and wound complications were rare in both groups. In the PSI group, one patient developed a palatal fistula and one patient was diagnosed with an early maxillary sinusitis. In the mini-plate group, one patient was diagnosed with a late maxillary sinusitis and one patient showed postoperative infection. Interestingly, three of 37

Table 1
Patient-specific implant (PSI) patients.

Patient	Gender	Age	Diagnosis 1	Diagnosis 2	Type of surgery	Augmentation	Complications in maxilla	Follow-up (mo)
1	M	25	Retrognathia mx.	Cross-bite	Le Fort I	None	Palatal fistula, reoperation 3wk	37
2	M	25	Prognatia mnd.	Retrognathia mx.	Le Fort I	None		36
3	F	23	Retroghnatia mx.		Le Fort I	None		35
5	F	44	Distal bite	Anterior open bite	Bimax	DBX		31
6	M	28	Retrognathia mx.		Le Fort I	None		31
7	F	22	Retrognathia mx.	Cross-bite	Le Fort I	DBX		29
8	M	25	Prognathia mnd.	Anterior open bite	Bimax	DBX		29
9	F	24	Retrognathia mx.	Cross-bite	Le Fort I	DBX		29
10	F	48	Retrognathia mx.	Cross-bite	Bimax	DBX	Maxillary sinuitis 2 wk postop	28
11	F	28	Retrognathiamx.	Asymmetria mnd.	Bimax	DBX		28
12	M	33	Prognathia mnd.	Asymmetria mnd.	Bimax	BioOss block		28
13	M	24	Retrognathia mx.		Le Fort I	Chronos		27
14	F	19	Retrognathia mnd.	Anterior open bite	Bimax	None		27
15	F	43	Retrognathia mx.		Lefort I	DBX	Plate removal, patient request, no infection	27
16	F	24	Anterior open bite	Retrognathia mnd.	Bimax	Human bone		26
17	F	27	Anterior open bite	Retrognathia mnd.	Bimax	None		26
18	F	37	Retrognathia mnd.	Anterior open bite	Bimax	None		26
19	F	30	Anterior open bite	Facial asymmetry	Bimax	None	Septum deviation fixed 1 wk	25
	F	45	Cross-bite		Le Fort I	None		25
21	M	25	Anterior open bite	Retrognathia mnd.	Bimax	None		25
22	M	27	Anterior open bite	Cross-bite	Bimax	None		22
23	M	21	Anterior open bite		Bimax	Human bone		22
24	F	21	Anterior open bite	Cross-bite	Bimax	None	Swelling of cheek 4 wk, left side, unknown origin	21
25	M	23	Anterior open bite	Cross-bite	Le Fort I	BioOss block		21
26	F	25	Prognathia mnd.	Retrognathia mx.	Le Fort I	BioOss block		20
27	M	37	Acromegaly	Posterior open bite	Bimax	Iliac crest		20
28	M	22	Treacher Collins	Retrognathia mnd.	Bimax + PEEK prost.	None		19
29	F	25	Retrognathia mnd.	Deep bite	Bimax	None		19
30	F	20	Anterior open bite	Retrognathia mnd.	Bimax	None	Septum deviation, rhinoplasty 16 mo	16
31	F	25	Anterior open bite	Retrognathia mnd.	Bimax	BioOss block		14

Follow-up data and complications of the patients who underwent operation with the Planmeca PSI system. Abbreviations: F, female; M, male; mx, maxilla; mnd, mandible; DBX, commercial bone matix derivate augmentation material; Chronos, commercial tricalciumphosphate augmentation material; Human bone, commercial cadaver bone from Regea Finland; BioOss block, commercial allograft augmentation material; wk, week; mo, month.

Table 2
Mini-plate patients.

Patient	Gender	Age	Diagnosis 1	Diagnosis 2	Type of Surgery	Augmentation	Complications in maxilla	Follow-up (mo)
1	M	23	Retrognathia mx.	Prognathia mnd.	Le Fort I	Iliac crest		62
2	F	19	Prognathia mnd.	Retrognathia mx.	Le Fort I	Iliac crest		61
3	M	45	Deep bite	Retrognathia mnd.	Bimax	Iliac crest	Wound infection right, 10 d	61
5	F	20	Anterior open bite		Bimax			59
6	M	37	Retrognathia mnd.	Anterior open bite	Bimax			58
7	M	27	Retrognathia mx.	Prognathia mnd.	Le Fort I	Iliac crest		58
8	M	52	Prognathia mnd.	Retrognathia mx.	Le Fort I	Iliac crest		57
9	F	28	Retrognathia mx.	Prognathia mnd.	Le Fort I, 3-piece			56
10	M	23	Anterior open bite	Preognathia mnd.	Le Fort I			53
11	M	29	Retrognathia mx.	Prognathia mnd.	Le Fort I	Iliac crest		53
12	M	50	Retrognathia mnd.	Deep bite	Bimax	DBX		53
13	M	23	Retrognathia mx.	Cross-bite	Le Fort I	DBX		51
14	M	28	Anterior open bite	Retrognathia mx.	Bimax			51
15	F	33	Retrognathia mx.	Cross-bite	Le Fort I		Removal of screw 14 mo, patient request, no infection	50
16	F	52	Retrognathia mx.	Cross-bite	Le Fort I, 2-piece	Iliac crest		50
17	F	24	Anterior open bite		Le Fort I			49
18	F	24	Anterior open bite	Cross-bite	Le Fort I		Reoperation 3wk due to insufficient advancement	49
19	F	22	Anterior open bite	Retrognathia mx.	Le Fort I			49
20	F	25	Anterior open bite	Retrognathia mnd.	Bimax		Reoperation 3wk due to open bite	49
21	M	28	Retrognathia mx.	Prognathia mnd.	Le Fort I			48
22	M	23	Retrognathia mnd.	Anterior open bite	Bimax			47
23	F	49	Prognathia mnd.		Le Fort I			47
24	F	42	Cross-bite	Prognathia mnd.	Le Fort I, 2 piece			47
25	M	24	Cross-bite	Retrognathia mx.	Le Fort I	Iliac crest		47
26	M	24	Anterior open bite	Retrognathia mx.	Le Fort I	Iliac crest	Reoperation 2 wk due to open bite	47
27	F	22	Juvenile oligoarthritis	Teeth crowding	Le Fort I			46
28	M	45	Retrognathia mx.	Prognathia mnd.	Bimax	Iliac crest	Relapse 2 mo, modification of molar occlusal surfases	45
29	F	21	Prognathia mnd.	Cross-bite	Le Fort I	Human bone		44
30	F	30	Anterior open bite	Polyarthritis	Bimax		Plate removal, pain of unknown origin, no infection	44
31	M	27	Prognathia mnd.	Retrognathia mx.	Le Fort I	Human bone		43
32	M	26	Anterior open bite	Retrognathia mx.	Le Fort I		Sinusitis right side, 39 mo postop	43
33	F	27	Anterior open bite	Teeth crowding	Le Fort I			41
34	M	23	Retrognathia mx.	Anterior open bite	Le Fort I	Human bone		39
35	F	26	Retrognathia mx.	Hypodontia	Le Fort I			38
36	F	22	Anterior open bite		Bimax			38
37	M	42	Deep bite	Retrognathia mnd.	Bimax	Iliac crest		38

Followup data and complications of the patients operated with mini-plates. Abbreviations are: F, female; M, male; mx, maxilla; mnd, mandible; DBX, commercial bone matix derivate augmentation material; Chronos, commercial tricalciumphosphate augmentation material; BioOss block, commercial allograft augmentation material; Human bone, Commercial cadaver bone from Regea Finland; d, day; wk, week; mo, month.

patients in the mini-plate group were reoperated within 3 weeks due to insufficient advancement of the maxilla, whereas in the PSI group there was no reoperations needed. However, this difference in reoperations was not statistically significant ($P = 0.108$).

4. Discussion

Three-dimensional planning and the use of PSI is an interesting tool for faster and more precise outcomes when advancing the maxilla by Le Fort I osteotomy (Van Hemelen et al., 2015; Heufelder et al., 2017). The first 3D designed and produced osteosynthesis material were merely conventional mini-plates modified on top of stereolithography models. Only a few years ago, when laser sintering and CAD/CAM milling techniques started to develop, were the first true PSIs for orthognathic surgery were produced (Mazzoni et al., 2015; Gander et al., 2015). However, already a decade ago the first laser sintering–produced titanium alloy PSIs were used in reconstructive surgery. Only limited follow-up data exist, which indicate a rather high postoperative infection rate (Stoor et al., 2017). However, in large reconstructions with PSIs, there is a greater risk of wound dehiscence, and thus microvascular grafts are frequently used in addition to the PSIs. These patients often also undergo postoperative radiotherapy, further increasing the risk of infection. For this reason, the susceptibility to infections of PSIs used in orthognathic surgery cannot be compared to the susceptibility to infections of PSIs used for large reconstructions in tumor surgery.

To our knowledge, there is at present no literature available on complications associated with infections of PSIs in orthognathic surgery.

An ideal implant is both osseointegrative and antibacterial. These two properties are mediated by chemical composition and surface morphology of the implant. Over the years, various physical and chemical techniques and manipulations have been studied in order to improve surface characteristics of medical implants and to facilitate bio-integration and prevent initial bacterial adhesion, ultimately leading to biofilm and infection (Veerachamy et al., 2014). Generally speaking, biofilm formation starting from initial infection of the graft material and leading to the clinically manifested postoperative infection is a four-step process starting with (1) initial attachment of bacterial cells to the implant surface (contamination/infection of the implant), followed by (2) multiplication and aggregation of bacteria into multilayer structures with consecutive (3) biofilm formation and (4) detachment of planctonic bacterial cells from the biofilm community to the surrounding tissues (Arciola et al., 2015).

In both of our study groups, all patients were treated with a similar surgical protocol and perioperative intravenous antimicrobial therapy with either cefuroxime or ampicillin. The infection

rates in the maxilla are in general low as compared to those in the mandible (Davis et al., 2017). Our study showed similarly low infection rates in both groups.

In the mini-plate group, three out of 37 patients underwent reoperation due to insufficient advancement or malposition of the maxilla, whereas none of the PSI patients underwent reoperation. Possible reasons for this include insufficient mobilization of the maxilla, possible interference at the osteotomy site, and incorrect seating of the condylar head into the glenoidal fossa during osteosynthesis.

When using PSIs, the condylar position is preoperatively determined, and the PSIs are accordingly manufactured with the maxilla, and thus in the right postoperative position achievable without wafers (Suojanen et al., 2016).

However, the difference in the infection rate between the PSI and mini-plate group were not statistically significant in our study.

5. Conclusions

Our present follow-up data suggest that CAD/CAM-produced titanium PSIs do not differ in their local long-term complication profile as compared to conventional mini-plate systems used in Le Fort I osteotomy, with no signs of infection-associated complications. Larger studies are, however, needed for analyzing the further possible beneficial effects of the use of PSIs, including the number of reoperations needed and stability of the outcomes compared to those achieved with the use of conventional mini-plates.

Conflicts of interest

The authors JS, JL and PS have participated in congresses where attendance fees were in part or in total supported by DePuy-Synthes or KLS-Martin.

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