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No differences in infections between patient-specific implants and conventional mini-plates in mandibular bilateral sagittal split osteotomy — Up to 3-year follow-up

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ABSTRACT

The use of individually designed osteotomies, combined with individually manufactured osteosynthesis material, is rapidly becoming a standard for more challenging maxillofacial surgery. The benefits of patient-specific implants (PSI) in orthognathic surgery are clear in complex cases. PSIs can enhance precision and ease up the surgical protocol. We previously reported on the benefits of PSIs as reposition and fixation systems during Le Fort I osteotomy. The aim of this study was to evaluate a cohort of 28 patients, treated with bilateral sagittal split osteotomy (BSSO) and PSIs for fixation, with regard to healing for up to 3 years. A retrospective cohort of 48 patients with conventional mini-plate repositioned mandibles was also collected for statistical analysis. No statistically significant differences were found with regard to infection, soft tissue problems, or reoperations between these two groups.

1. Introduction

The use of virtual design for osteotomies and surgical movement of the jaws is rapidly becoming a common practice in orthognathic surgery. Individually manufactured surgical tools, such as drill and cutting guides as well as patient-specific implants (PSI) for osteosynthesis, will soon be available to all clinicians. As computer-aided design and manufacturing (CAD/CAM) has developed, the creation of more sophisticated and freely designed implants has become possible (Gander et al., 2015; Mazzoni et al., 2015; Suojanen et al., 2016, 2017). Most of the systems use either CAD/CAM-generated wafers or provide patient-specific saw and drill guides, together with custom-made titanium implants.

Individually manufactured implants, combined with the use of drill guides, also make wafer-free positioning of bone segments possible. This has been proven to be successful in Le Fort I osteotomy (Suojanen et al., 2017; Heufelder et al., 2017). However, in mandibular bilateral sagittal split osteotomy (BSSO) the drill guide combined with the PSI does not seem to be reliable enough to be used alone without wafer support (Suojanen et al., 2017). The use of PSIs in the mandible should, however, be considered in the most complex cases, where there is significant asymmetry in the ramus height or shape of the mandible. PSIs provided by companies are commonly manufactured either by milling from titanium monoblocks or by laser sintering from titanium powder. The individually designed implants often follow the contours of the underlying bone with high fidelity, which is beneficial, especially in the maxilla. However, the benefits of PSIs with regard to final positioning and stability during BSSO are not yet as clear (Suojanen et al., 2017). To date, no follow-up data on PSIs used in BSSO osteosynthesis exist.

In this study we report data with regard to complications, such as infection, soft tissue problems, or reoperations, during a follow-up of up to 3 years in a cohort of 28 patients treated with BSSO and PSIs. For a comparison of the postoperative complications mentioned above, a retrospective cohort of 48 patients treated with BSSO and conventional mini-plate fixation was collected.

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2. Materials and methods

In both the PSI and mini-plate groups the osteotomies were designed and performed according to Epker (1977), cutting straight through the mandibular bodies at the caudal part of the inferior mandibular border. Both mini-plates and PSIs were designed or adjusted to the lateral border of the mandibular ramus at the level of the molar root apexes. PSI drill holes were designed to avoid the roots and mandibular nerve despite only monocortical screws being used.

This cohort of PSI patients ($n = 28$) was previously reported in more detailed (Suojanen et al., 2017). Briefly, all PSI patients underwent a traditional BSSO, during which drill guides were used to predrill the holes for osteosynthesis with PSIs, using the Planmeca ProModel (Planmeca Ltd, Helsinki, Finland). The PSIs were milled from titanium alloy to a thickness of 0.8–1.0 mm and prepared for drill holes comparable to Matrix Orthognathic Gold mini-plates. Three screw holes were designed on both sides for vertical osteotomy. Monocortical non-locking 6–8 mm Synthes Orthognathic screws (diameter 1.85 mm) were used for each patient. PSIs were designed for similar location on the mandible lateral border to conventional mini-plates. Short advancements were performed with one interconnecting bridge and longer advancements with two bridges (Fig. 1).

The follow-up data for the PSI group were collected from the Helsinki University Hospital patient archives up to February 28,

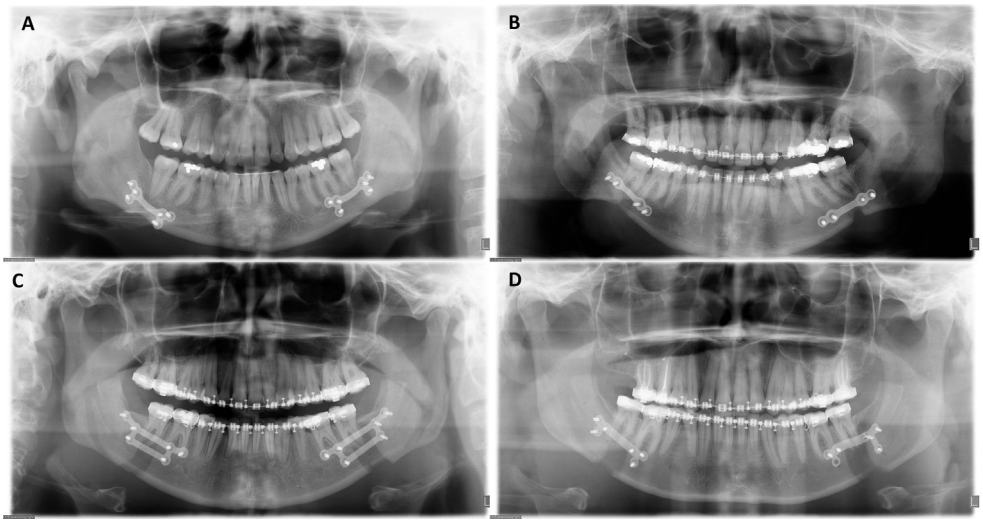

Fig. 1. Osteosynthesis with mini-plates or with PSI evaluated using orthopantomograms. In the mini-plate group osteosynthesis was performed either with non-linear (A) or linear (B) 0.8-mm-thick Synthes Orthognathic mini-plates and monocortical screws. The PSIs were designed individually for the patients and could be manufactured either as a two-bridged (C) or one bridged (D) design. All PSIs were fixed with monocortical screws in a similar way to mini-plates. D demonstrates the problem with PSI fitting when a predesigned drill whole becomes too loose for the screw: one of the left-side drill holes remained unused.

Table 1
BSSO patients operated with PSI.

Patient	Gender	Age	Diagnosis 1	Diagnosis 2	Wound problems, complications or reoperations	Follow-up (mo)
1	F	43	Deep bite	Retrognathia mnd	Wound infection left side 1 wk postop, PSI removal 4 mo	38
2	F	30	Retrognathia mnd	Anterio open bite		38
3	F	33	Retrognathia mnd	Large over jet		38
4	M	51	Retrognathia mnd	Deep bite	Wound infection left side 3 wk postop, PSI removal 6 mo	37
5	M	26	Apertognathia	Retrognathia mnd	Artrite activation 12 mo, relapse, no reoperation	36
6	M	42	Deep bite	Retrognathia mnd.	Late PSI infection right 19 mo, PSI removal	35
7	M	27	Retrognathia mnd			35
8	M	40	Deep bite	Retrognathia mnd	Late PSI infection right 7 mo, PSI removal	35
9	F	41	Deep bite	Retrognathia mnd	Reoperation 2 d due to open bite, was TMJ disc replacement	34
10	F	42	Deep bite	Large over jet		32
11	F	25	Anterior open bite	Retrognathia mnd	Open bite due to condyle resorption 21 mo postop	31
12	F	37	Deep bite	Retrognathia mnd	Wound dehiscence 10 days, resolved spontaneously	31
13	F	42	Retrognathia mnd			31
14	F	36	Retrognathia mnd	Deep bite	Wound infection right side 3 wk postop, PSI removal 6 mo	31
15	M	37	Retrognathia mnd	Anterior open bite		28
16	F	26	Retrognathia mnd			28
17	F	53	Deep bite	Retrognathia mnd		28
18	F	46	Retrognathia mnd	Deep bite	Wound infection left side 1 wk postop, PSI removal 3 mo	27
19	M	46	Deep bite	Large over jet	Wound infection right side 4 wk postop, PSI removal 3 mo	27
20	F	47	Deep bite	Retrognathia mnd	Due to subjective symptoms PSI removal 16 mo	26
21	F	38	Retrognathia mnd	Deep bite		26
22	F	29	Retrognathia mnd	Deep bite		26
23	M	25	Retrognathia mnd	Deep bite		26
24	M	54	Deep bite	Retrognathia mnd.		25
25	F	45	Retrognathia mnd	Large over jet		25
26	F	32	Retrognathia mnd	Deep bite		24
27	F	32	Retrognathia mnd	Deep bite		24
28	F	46	Retrognathia mnd	Large over jet		24

Abbreviations: F, female; M, male; mnd, mandible; wk, week; mo, month.

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2017. All PSI patients had visited the clinic within the routine protocol and there were no missing follow-up data within this scope. As a reference, a retrospective cohort of patients ($n = 48$) treated with conventional BSSO, repositioned with wafers and fixated with conventional mini-plates (DePuy Synthes Matrix Orthognathic), was also collected. This cohort was collected from the Helsinki University Hospital patient register from 1st of December 1, 2011 to 30 November 30, 2013. Patients treated with BSSO as the only operation were included in the control group.

In this mini-plate group osteosynthesis was performed using the Matrix Orthognathic system (DePuy Synthes) This used 0.8-mm-thick linear or nonlinear plates with two or three screws each side, together with 1.85-mm-diameter non-locking 6–8 mm screws. The length of the plate was selected individually for each case, based on the osteotomy gap. See Fig. 1 for details.

In both groups the patients underwent similar surgical protocols, were treated pre- and postoperatively (7–10 days) with 0.12% chlorhexidine mouth rinse, and received prophylactic intravenous antimicrobial therapy, either with penicillin G, cefuroxime, or ampicillin 15–30 min prior to surgery, according to the clinic protocol. Both groups used postoperative wafers for 4 weeks and were allowed to freely mobilize their jaws postoperatively. They were advised to avoid biting and hard chewing of food for 8 weeks postoperatively.

The collected data, including demographic profile records, reoperations, infections, and soft tissue problems, were analyzed with SPSS software version 22 (IBM Analytics). Non-parametric analysis was performed and the Mann–Whitney U-test was used; a p-value of <0.05 vas considered significant.

3. Results

The demographic data for the PSI and mini-plate cohorts did not differ significantly (gender, $p = 0.705$ and age, $p = 0.579$). The PSI cohort data covered follow-up from 24 to 38 months (average 30 months) and the mini-plate cohort from 12 to 63 months (average 50 months). All PSI patients were followed at the University Hospital Clinic, without dropouts; in the control group only one of the

Table 2
BSSO patients operated with mini-plates.

Patient	Gender	Age	Diagnosis 1	Diagnosis 2	Wound problems, complications or reoperations	Follow-up (mo)
1	M	56	Deep bite	Retrognathia mnd		63
2	F	44	Deep bite	Retrognathia mnd	Swelling left side 8 mo, no clear infection, resolved spontaneously	62
3	F	19	Deep bite	Retrognathia mnd		62
4	F	45	Deep bite	Retrognathia mnd		62
5	F	21	Anterior open bite	Idiopatic condyle resorption		61
6	M	33	Deep bite	Retrognathia mnd	Plate infection left 2 mo, plate removal 4 mo	59
7	F	20	Retrognathia mnd	Juvenile oligoarthritis	Relapse, Le Fort I osteotomy 36 mo	59
8	M	49	Anterior open bite	Osteoarthritis seropositiva		58
9	F	42	Deep bite	Retrognathia mnd		58
10	F	35	Deep bite	Retrognathia mnd	Wound infection right 1 wk, resolved with amoxicillin	58
11	F	49	Deep bite	Retrognathia mnd	Wound dehiscence left 1 wk, soft tissue revision 3 mo	57
12	F	49	Retrognathia mnd	Distal bite	Plate infection right 1 mo, plate removal 3 mo	56
13	M	50	Deep bite	Retrognathia mnd	Wound infection left 2 wk, plate removal 5 mo	56
14	M	37	Deep bite	Retrognathia mnd		56
15	M	39	Deep bite	Retrognathia mnd		54
16	M	21	Anterior open bite	Retrognathia mnd	Relapse, anterior open bite 0.5 mm, no reoperations	54
17	F	42	Deep bite	Retrognathia mnd	Reoperation 2 days due to open bite, wound opening both sides 10 days	53
18	F	33	Deep bite	Retrognathia mnd	Wound infection left 2 wk, several antibiotics, revision 2 mo	53
19	M	38	Deep bite	Retrognathia mnd	Plate infection left 2 mo, plate removal 4 mo	53
20	M	39	Deep bite	Retrognathia mnd	Wound dehiscence right 1 wk, plate removal 3.5 mo	53
21	M	41	Scissor bite		Plate removal 12 mo patient request, no sight of infection	53
22	F	35	Deep bite	Retrognathia mnd		53
23	F	25	Retrognathia mnd		Wound infection 1 wk, resolved with clindamycin and metronidazole	12
24	F	31	Anterior open bite	Retrognathia mnd		52
25	F	32	Deep bite	Distal bite	Plate infection 3 wk, plate removal 5 mo	41
26	F	35	Deep bite	Retrognathia mnd	Wound infection 1 wk, resolved with amoxicillin	52
27	M	28	Retrognathia mnd	Distal bite	Wound dehiscence left 1 wk, resolved with chlorhexidine mouth rinse	51
28	F	18	Retrognathia mnd	Distal bite		51
29	F	45	Deep bite	Retrognathia mnd		49
30	F	46	Prognathia mx	Deep bite		49
31	M	51	Retrognathia mnd			48
32	F	49	Deep bite	Retrognathia mnd	Swelling left side 2 mo, no clear infection, resolved spontaneously	48
33	F	20	Anterior open bite	Retrognathia mnd	Infection 10 d, revision 2 wk, late plate infection 23 mo, plate removal	47
34	F	42	Deep bite	Retrognathia mnd	Wound infection 10 d, resolved with kefalexin	46
35	F	34	Retrognathia mnd	Anterior open bite	Osteosynthesis failure 4d, reoperated	46
36	F	39	Scissor bite	Deep bite		46
37	F	35	Deep bite	Retrognathia mnd	Wound infection both sides, plate removal 5 mo	45
38	F	45	Deep bite	Retrognathia mnd		45
39	F	23	Anterior open bite	Retrognathia mnd	Relapse 18 mo, no reoperation	45
40	F	36	Deep bite	Retrognathia mnd	Late plate infection 17 mo, plate removal	45
41	M	25	Deep bite	Retrognathia mnd		44
42	F	33	Distal bite	Deep bite		43
43	F	50	Deep bite	Retrognathia mnd		43
44	F	22	Anterior open bite	Cross bite		42
45	F	26	Deep bite	Retrognathia mnd		42
46	F	50	Deep bite	Retrognathia mnd		42
47	M	44	Deep bite	Retrognathia mnd		41
48	F	52	Deep bite	Retrognathia mnd		39

Abbreviations: F, female; M, male; mnd, mandible; wk, week; mo, month; mm, millimeter; mx, maxilla.

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48 patients dropped out after 12 months follow-up because the postoperative orthodontics were performed outside the hospital. The individual patient data, including postoperative wound and soft tissue problems, as well as reoperations, are presented in detail in Table 1 for PSI patients and in Table 2 for the conventional mini-plate patients.

Soft tissue problems were divided to three categories: wound dehiscence, early infection (0–4 weeks), and late infection (after 4 weeks). If pus was detected, or the wound problem so severe that the clinician administered antibiotic therapy, this was classified as infection. The groups did not differ statistically with regards postoperative wound problems or infections ($p = 0.248$), hardware removal ($p = 0.395$), or reoperations ($p = 0.847$). In general, both groups developed a surprisingly high number of postoperative wound problems (eight out of 28 for the PSI group and 19 out of 48 for the control group). When the data were analyzed by gender, hardware removal was significantly more common in females ($p = 0.031$), however, the number of female postoperative infections or wound problems was not significantly higher ($p = 0.485$). The reason for this difference in asymptomatic plate removal between the genders remains unclear.

4. Discussion

PSIs are an ideal way to achieve faster and more precise surgery. For advancement of the maxilla with Le Fort osteotomy their use has been proven to be accurate, even without wafers (Heufelder et al., 2017). The repositioning of bone segments in the mandible can be achieved without wafers. For condylar segment positioning both bone- and dentition-supported drill guides together with PSIs have been used (Abdel-Moniem Barakat et al., 2014; Suojanen et al., 2017). However, in our previous study the CAD/CAM drill guide system was not reliable enough to be recommended for use without wafers (Suojanen et al., 2017).

The PSIs are usually produced from titanium alloy using similar methods to those used almost a decade ago in reconstructive surgery. Some follow-up data for the use of PSIs already exist and rather high postoperative complication rates have been reported (Stoor et al., 2017). We have previously reported that PSIs lead to similar postoperative infection profiles but fewer reoperations due to a malocclusion, when compared with conventional mini-plates (Suojanen et al., 2018). However, to our knowledge, no follow-up data on the use of PSIs in BSSO exist to date.

An ideal implant is both biocompatible and antibacterial, and these properties are linked to both the chemical composition as well as the tooling of the implant. Several physical and chemical techniques and manipulations have been studied with the aim of improving surface characteristics of medical implants. The ultimate goal is to facilitate bio-integration and prevent initial bacterial adhesion at the same time (Veerachamy et al., 2014). Formation of biofilms starts from initial infection, either during surgery or later after wound problems. In both cases graft material is covered with biofilm, which leads to the clinically manifested postoperative infection. This is a four-step process, starting with initial attachment of bacteria to the implant surface, followed by multiplication and aggregation of bacteria into multilayer structures. This leads to consecutive biofilm formation, eventually resulting in detachment of planktonic bacterial cells from the biofilm community into the surrounding tissues (Arciola et al., 2015). Design of CAD/CAM implants may be a compromise between susceptibility to bacterial infection and biocompatibility, and to date very few clinical data exist on this. Infection rates in the mandible are generally higher than in the maxilla (Davis et al., 2017). Wound problems were also surprisingly common in both of our study groups.

5. Conclusions

The follow-up data in this study suggest that CAD/CAM-produced titanium PSIs do not differ in terms of their localized long-term complication profile when compared with conventional mini-plate systems after bilateral sagittal split osteotomy.

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Conflicts of interest

Authors JS, ZH, 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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