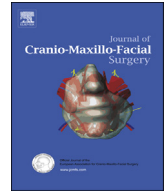




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Third-generation slotplates for orthognathic and facial corrective surgery

Brandaan G.R. Zigterman ^{a,*}, Stijn E.F. Huys ^{b,c}, Maurice Y. Mommaerts ^a

^a European Face Centre (Chair: Prof. Maurice Y. Mommaerts), Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel, Belgium

^b Department of Mechanical Engineering, Biomechanics Section, KU Leuven, Leuven, Belgium

^c R&D Officer, CADskills BVBA, Gent, Belgium

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ABSTRACT

The aim of this study was to retrospectively assess the osteosynthesis material–related morbidity rates of third-generation (3.0) slotplates, and to compare those with the previously researched second-generation (2.0) slotplates.

In the 2.0 slotplate design, there were additional tabs in line with the vertical slotted screw hole; in between these tabs, the additional locking screw was placed. In the 3.0 slotplates, these tabs were replaced by a full screw hole for the locking screw, and the 3.0 slotplates are slightly broader than the 2.0 slotplates. Osteosynthesis material–related morbidity rates after Le Fort I–type, zygoma-valgisation, and chin osteotomies were assessed in a cohort receiving 3.0 slotplates in a tertiary care centre and compared to a previously analysed cohort receiving 2.0 slotplates in the same tertiary care centre.

Medical records of 77 patients (101 surgeries) receiving 3.0 slotplates were reviewed. Plate infection and plate removal rates were low in the 3.0 slotplate group (2.6% ($p = 0.123$) and 3.9% ($p = 0.103$), respectively). No delayed union or non-union occurred in the 3.0 slotplate group. Comparing the morbidity rates with the 2.0 slotplate cohort did not yield any significant differences.

Although there was a tendency towards better outcomes with 3.0 slotplates compared to the 2.0 slotplates, the outcome differences did not reach statistical significance.

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1. Introduction

Slotplates are indicated for orthognathic and other corrective surgeries of the facial skeleton, including Le Fort I–type osteotomy, chin osteotomy, and zygoma-valgisation osteotomy (Mommaerts, 2002). The slotted holes allow the surgeon to reposition the osteotomized segment during the osteosynthesis phase by untightening one (or two) screws, without drilling new holes (i.e., the “slot principle”). This is supposed to shorten the operation time and to allow the surgeon to work with more precision. Third-generation slotplates (Surgi-Tec NV, Sint-Denijs-Westrem, Belgium) underwent design modifications based on a retrospective study in 109 patients (146 surgeries) of complications associated with second-generation slotplates (Zigterman and Mommaerts, 2017). In that study, the slot principle was

used in 20% of patients with second-generation slotplates (Zigterman and Mommaerts, 2017); however, the occurrence of one case of non-union and two cases of delayed union prompted us to suggest design modifications.

In the present study, we retrospectively analysed osteosynthesis-related morbidity rates of orthognathic and facial corrective surgeries using third-generation (3.0) slotplates in a tertiary teaching hospital and compared these rates to outcomes with second-generation (2.0) slotplates, which were inserted in previous years at the same hospital. The two generations differed in two key design aspects and placement of a locking screw became mandatory in Le Fort I–type osteotomies in the 3.0 slotplate cohort. We hypothesized that 3.0 slotplates would perform better in terms of plate breakage and delayed union or non-union, when compared with 2.0 slotplates.

* Corresponding author. European Face Centre, Universitair Ziekenhuis Brussel, Laarbeeklaan 101, 1090, Brussel, Belgium. Tel.: +32 (0)2 477 60 12.

E-mail address: Brandaan.Zigterman@uzbrussel.be (B.G.R. Zigterman).

2. Materials and methods

2.1. Design changes in the 3.0 slotplates

The 2.0 slotplates design included two additional tabs (“devil horns”) in line with the long axis of the slotted hole. These were meant to receive a locking screw to prevent movements of the plate when chewing forces acted on the vertical slots, mainly in Le Fort I–type osteotomies. Because of the (few) unstable results with 2.0 slotplates, it was decided that the tabs should be closed to form a full screw hole in the 3.0 slotplates. Placement of an additional locking screw in this screw hole became mandatory in Le Fort I–type osteotomies, fixating the plates with three screws per plate instead of two. This would lead to improved stress distribution in the lateral wall of the screw hole, increasing overall durability and rigidity of both the plate and osteotomy, because lateral forces are absorbed by a full circumference, rather than two separate tabs. Furthermore, the screw head has a larger contact surface during clamping, leading to more uniform stress distribution on top of the plate. An additional advantage is easier screw insertion.

To further strengthen the plates, the arms of the connecting parts were broadened by 0.35 mm; this further stabilised the plate three-dimensionally, thereby increasing the stress-failure (S–N fatigue) curve and improving overall rigidity of the plate. This adaptation negatively influenced the ease with which the plate shape could be adjusted to precisely fit the patient’s anatomy, but this minor trade-off was considered worthwhile because it increased overall patient safety. The space between these arms was kept the same to allow placement of a micro-screw for fixation of bone grafts. The design differences between both generations are illustrated in Fig. 1.

2.2. Study population

All consecutive patients who underwent Le Fort I–type osteotomy, chin osteotomy, and/or zygoma-valgisation osteotomy using 3.0 slotplates from November 1, 2016 until January 1, 2019 were included in this study. The control group, which received 2.0 slotplates, was the test group from our previous study (Zigterman and Mommaerts, 2017). Patients who did not sign an informed consent form or did not have a form signed by a responsible person on their behalf were excluded. The only other exclusion criterion was failure to receive either a 2.0 or 3.0 slotplate. The study was approved by

the Medical Ethics Committee of the UZ Brussel (B.U.N. 143201941215).

2.3. Interventions

All patients were operated on by the same surgical team. The type of slotplate was chosen intraoperatively by the surgeon, taking into account the specific type of operation and the degree of bony displacement. The names of the plates correspond to the different sizes and shapes (Fig. 2). Diamond, Ruby and Emerald plates are used in Le Fort I–type and chin osteotomies. These three plates all consist of a horizontal and a vertical slot. The slots are connected by two struts, in between these struts there is enough space to place a mini screw for bone graft fixation. In line with the vertical slot lies the screw hole for the locking screw. The horizontal slot is fixed on the caudal segment and the vertical slot on the cranial segment. The lengths of the plates (Diamond 17 mm, Ruby 21 mm, Emerald 26 mm) are enough to allow all clinically necessary degrees of bony displacement. In many cases, a mix of different plates is used: for instance, Diamond at the piriform aperture and Ruby at the zygomatic buttress. Topaz and Amethyst plates, both with two longitudinal slots and a length of 24 mm and 30 mm respectively, are mostly used in zygoma-valgization osteotomies. The plates with two longitudinally oriented slots have a screw hole for the locking screw on both ends of the plates. All plates were fixed with two or three self-tapping screws (“Pentagon” 2.3-mm diameter; Surgi-Tec NV, Sint-Denijs-Westrem, Belgium). The third screw being the locking screw in its own specially designed screw hole. Intravenous antibiotics (1 g amoxicillin/clavulanic acid or 600 mg clindamycin) were administered intraoperatively to all patients. Patients in the 3.0 slotplate group received an additional 5 days of oral antibiotics (875/125 mg amoxicillin/clavulanic acid or 600 mg clindamycin 3 times per day) because of changes in our perioperative antibiotics protocol based on the results of a systematic review (Brignardello-Petersen et al., 2015).

Patients who underwent orthognathic surgery received guiding elastics postoperatively. These patients were also instructed to adhere to a semi-liquid diet during the first postoperative week and then a soft to soft–normal diet in the following 3 weeks.

2.4. Data collection

All data were collected retrospectively from electronic patient records. Medical images, which were available in digital format, were analysed as well. All data were collected and analysed by the principal investigator (BZ).

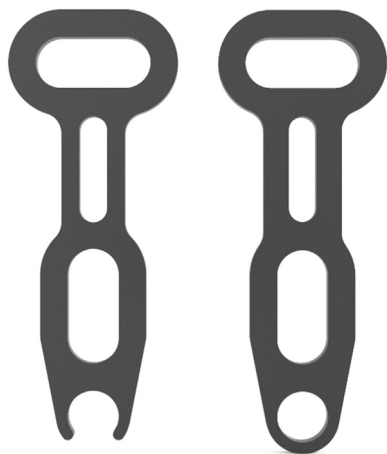


Fig. 1. Comparison in design of a 2.0 (left) and 3.0 (right) Ruby slotplate. Note the design differences: a full screw hole instead of “devil horns,” and broadened arms of the connecting parts.

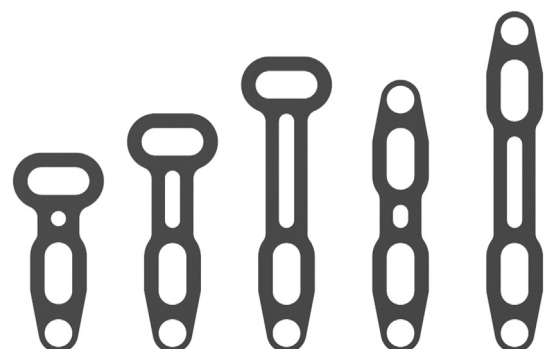


Fig. 2. Third-generation slotplates. Shown from left to right are Diamond, Ruby, Emerald, Topaz, and Amethyst slotplates.

2.5. Outcome measures

All assessed outcome measures are listed in Table 1. Infection on the osteosynthesis material was defined clinically as pain, redness, warmth, swelling, fistula formation and/or pus collection for which additional treatment was deemed necessary. Early onset was defined as <6 weeks postoperatively, late onset infection as >6 weeks postoperatively. Delayed union was defined as no bony healing at 3 or more months after surgery, and non-union was defined as no bony healing at 9 or more months postoperatively on CBCT (Verhaar and van Mourik, 2018). The presence of palpability was recorded if patients complained of feeling their plates when palpating the extra- and/or intraoral soft tissues overlying the osteosynthesis material. Tooth root injury was only verified when patients complained of toothache or tooth discoloration after the orthognathic intervention. This was assessed by pulp sensitivity testing with CO₂ and with additional dental x-rays. All patients were evaluated in our outpatient clinic at 1 week, 3 weeks, and 6 months after surgery. Patients were seen more frequently if indicated. Panoramic x-rays were obtained at 2 weeks preoperatively, as well as 1 week and 6 months postoperatively. If indicated (pain, infection, persistent swelling, higher than expected mobility, etc.), additional radiographs or cone-beam computed tomography (CBCT) scans were performed.

2.6. Statistical analysis

Descriptive statistics were used to analyse the population and morbidity rates. Fisher's exact tests were performed to compare outcomes between groups.

3. Results

3.1. Demographics

A total of 186 patients met the inclusion criteria: 77 in the 3.0 slotplate group and 109 in the 2.0 slotplate group. A total of 317 3.0 slotplates (mainly Diamond [139] and Ruby [145]) were used, and 435 2.0 slotplates were placed. Table 2 lists demographic characteristics of both groups. None of the differences between groups were statistically significant except that significantly more patients in the 3.0 subgroup were lost to follow-up in the period 3 weeks to 3 months postoperatively ($p = 0.028$).

Table 1
Outcome measures.

General:	Sex Age at surgery Type of surgery Concomitant surgeries
Surgery:	Follow-up duration Plate type(s) Protrusion or setback (mm) Anterior extrusion or intrusion (mm) Special notes about the surgery
Morbidity:	Infection (early or delayed onset) Palpability of hardware Plate removal Revision surgery Delayed union Non-union Tooth root injury Plate breakage

3.2. Morbidity

The osteosynthesis material-related morbidity rates in both groups are shown in Fig. 3.

3.3. Palpability

Although the slotplates are only 0.6 mm thick, palpability of the plates remained an issue. Six patients in the 3.0 slotplate group had palpability issues, two of whom chose removal of the plates because of this complaint. In the 2.0 slotplate group, eight patients complained of palpability of the plates, six of whom requested plate removal.

3.4. Plate removal

Plate removal was performed in three patients in the 3.0 slotplate group. Indications were palpability (two patients) and infection (one patient). The latter patient developed a low-grade infection with dehiscence 7 months postoperatively after chin osteotomy, for which partial plate removal was performed: the coronal screw and coronal half of the plate on the right side were removed. In the 2.0 slotplate group, thirteen patients underwent plate removal. The indications were infection (six), palpability (two), infection and palpability (four), and patient request (one, this patient did not feel comfortable having titanium plates in his body; however he did not have any other osteosynthesis material-related morbidity). The patients undergoing plate removal are not included in the subgroup of revisional surgery, so as not to confound the results.

3.5. Infection

Only two patients (2.6%) developed infection of the osteosynthesis material in the 3.0 slotplate group. Both patients had a low-grade, late-onset infection. In one, the infection occurred 7 months after genioplasty and was treated with partial plate removal (as noted above). In the other patient, the infection occurred 8 months after Le Fort I-type osteotomy and was treated with only disinfectant mouth rinses; the patient declined plate removal. Infections were more common in the 2.0 slotplate group, occurring in a total of 10 patients (9.2%). Of these, five patients developed an early-onset (<6 weeks postoperatively) infection, seven patients developed a late-onset infections, and two patients experienced both early- and late-onset infections.

3.6. Revision surgery

One patient in the 3.0 slotplate group required revision surgery. At 2 days postoperatively; the patient decided that extrusion of the chin segment was insufficient. During reoperation, using only local anaesthesia, the slot principle was applied: the locking screw was removed from both plates, and the screw in the slot was loosened and refastened after caudal repositioning of the chin segment.

Two patients in the 2.0 slotplate group required revision surgery because of the osteosynthesis material. In one patient, an excessively mobile upper jaw after "trimaxillary" surgery was stabilized 2 weeks postoperatively by fastening the screws and replacing one paranasal plate (Ruby type, fixed twice with three screws). The other patient was a 32-year-old woman who underwent a sliding genioplasty (2-mm protrusion and midline correction, fixated with two Diamond plates using two screws each). One of the screws pierced the root of the left lower canine, resulting in a periapical

Table 2
Group characteristics.

Parameter	2.0 Slotplates (n = 109)	3.0 Slotplates (n = 77)	p Value ^a
Age, yr			
Mean (SD)	27.21 (11.63)	26.05 (12.97)	
Median	24	21	
Range	14–57	15–68	
Sex			p = 1
Female	65 (59.6%)	46 (59.7%)	
Male	55 (40.4%)	31 (40.3%)	
Surgery			
Le Fort I–type osteotomy	81 (74.3%)	60 (77.9%)	p = 0.602
Chin osteotomy	55 (50.5%)	38 (49.3%)	p = 1
Zygoma-valgisation osteotomy (bilateral)	9 (8.6%)	3 (3.9%)	p = 0.369
Unilateral zygoma-valgisation osteotomy	1 (0.9%)	0	p = 1
Follow up			
>6 mo	91 (83.5%)	67 (87.0%)	p = 0.540
3–6 mo	18 (16.5%)	6 (7.8%)	p = 0.119
3 wk–3 mo	0	4 (5.2%)	p = 0.028

2.0 = second-generation, 3.0 = third-generation, SD = standard deviation.

^a p Value according to Fisher exact test.

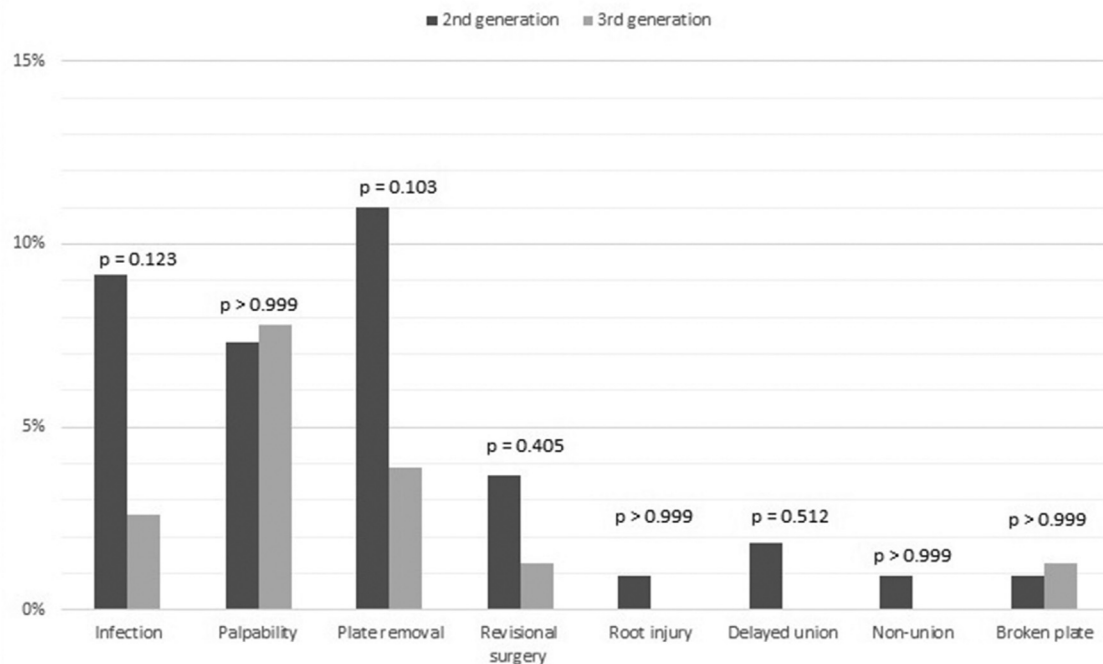


Fig. 3. Morbidity rates of second-generation vs third-generation plates. None of the between-group differences were statistically significant.

infection and subsequent pathologic symphyseal fracture. Three months postoperatively, the osteosynthesis material was removed; the genioplasty site was completely healed, but the symphyseal fracture required stabilization with two Modus Mandible 2.0 Trauma plates (Medartis, Basel, Switzerland). Another two patients required revision surgery because of delayed union, as described below.

3.7. Delayed union and non-union

No delayed union or non-union was observed in the 3.0 slotplate group. In the 2.0 slotplate group, two cases of delayed union or non-

union were reported, both following Le Fort I–type osteotomies. Delayed union occurred in a 34-year-old woman who underwent “trimaxillary” surgery with paranasal onlays. The upper jaw translated 4 mm anteriorly, with an anterior intrusion of 4 mm, and was fixed with two Diamond and two Ruby plates (two screws per plate). Five months after the initial surgery, revision was indicated because of a mobile upper jaw: the Ruby plate at the right aperture was found to be broken and was replaced with a meshplate (Surgi-Tec NV, Sint-Denijs-Westrem, Belgium). Four months later, the patient again presented with a mobile upper jaw, and repeat revision surgery was performed using bone grafts from the superior iliac crest. All existing osteosynthesis plates were removed and

replaced with Medartis Modus Mandible 2.0 Trauma plates (Medartis, Basel, Switzerland), resulting in good bone healing.

The non-union case was a 40-year-old man who underwent Le Fort I-type osteotomy with 8-mm protrusion and 4-mm anterior extrusion and fixation with four Ruby plates (two screws per plate). Although bony contact was limited, no bone grafts were used, and locking screws also were not used. Six months postoperatively, the upper jaw was still mobile. Revision surgery was performed, consisting of tightening loose screws in both zygomatic buttress plates and the left piriform aperture frame plate, placement of an extra Ruby plate on the left side, and replacement of the broken right piriform aperture frame Ruby plate. At 11 months after the revision surgery, the upper jaw remained slightly mobile. However, the patient had no complaints, so a conservative treatment was chosen for this non-union.

3.8. Tooth root injury

No patients in the 3.0 slotplate group had tooth root injuries. One patient in the 2.0 group had, as described earlier in the section Revision surgery.

3.9. Broken plates

One plate break occurred in each group. In the 3.0 slotplate group, there was radiographic evidence of a broken Ruby plate at 4 months after chin osteotomy in a 66-year-old woman. In this case, there was a stable result, and plate removal was deemed unnecessary. The broken plate in the 2.0 slotplate group occurred in the patient with delayed union after Le Fort I-type osteotomy (as described above).

4. Discussion

The development of 3.0 slotplates was based on two key design changes to the 2.0 slotplates—a full screw hole for the “locking” screws (with obligatory placement of a third “locking” screw in Le Fort I-type osteotomies) and broadening of the two-armed connecting part in the plate—to improve firmness of the plates. These design changes could explain the differences in delayed union and non-union rates between groups, although these differences were not statistically significant. A systematic review of orthognathic surgery complications found a non-union rate of 4.55% after orthognathic surgery (Jedrzejewski et al., 2015). The exact type of orthognathic surgery was not specified in this systematic review, and thus a direct comparison with our results is not possible; nevertheless, the absence of delayed union or non-union in our 3.0 slotplate group is a good result.

Infections were more frequent in the 2.0 slotplate group than in the 3.0 slotplate group. This may be at least partly explained by a change in perioperative prophylactic antibiotic use. According to the systematic review by Brignardello-Petersen et al., long-term antibiotic prophylaxis decreases the risk of surgical site infection after orthognathic surgery, when compared with short-term antibiotic prophylaxis (Brignardello-Petersen et al., 2015). In their review, “long-term” was defined as antibiotics administered before, during, and longer than 1 day after surgery. This protocol was implemented just before the start of our 3.0 slotplate series, so the 3.0 group received long-term prophylactic antibiotics (up to 5 days postoperatively), whereas the 2.0 slotplate group received only a single dose of antibiotics less than 30 min before surgery. Our surgical site infection rates were comparable to those of recently published data (Frischia et al., 2017; Olate et al., 2018).

There could be no comparisons between the different types of plates (i.e., Ruby versus Diamond plates) because many patients

had both Ruby and Diamond plates placed in their upper jaw. These plates are essentially the same, differing only in length.

To the best of our knowledge, no research has been published on other adjustable osteosynthesis plate systems for the included surgeries (Le Fort I-type osteotomies, zygoma valgization osteotomies and chin osteotomies). One technical note from 1994 mentions osteosynthesis plates with slotted holes that can be used for both mandibular and maxillary osteotomies (Hill, 1994). There have been reports on adjustable osteosynthesis plates for sagittal split osteotomies (Baek and Lee, 2010; Ghang et al., 2013; Larson et al., 2017; Veyssiere et al., 2018). Sagittal split osteotomy of the mandible is not included in this review because the 3.0 slotplates are not used in this type of surgery. Comparison between these adjustable plate systems and the 3.0 slotplates is therefore not feasible.

In the days of intermaxillary fixation and wire osteosynthesis, the focus of research into methods of osteosynthesis was on prevention of relapse. Contemporary (semi-)rigid osteosynthesis methods and overcorrection remove the attention from relapse in orthognathic surgery. Key determinants of success in orthognathic surgery are now the final profile correction and neutral occlusion. As such, measuring sagittal or vertical relapse using cephalograms is less relevant in the study of stabilizing technique. The ongoing study did not include cephalometry on preoperative and 1-year postoperative follow-up cephalograms. This may be considered a drawback. However, setting up a clinical study with an experimental group (slotplates 3.0) and a control group (a more commonly used osteosynthesis system) would involve a high number of patients, hardly achievable in one centre. This was not the intention of the authors.

Patient-specific implant (PSI) osteosynthesis plates are popular in modern orthognathic surgery (Arcas et al., 2018; Hanafy et al., 2019; Heufelder et al., 2017; Kim et al., 2019; Kotaniemi et al., 2019; Li et al., 2017; Lin et al., 2018; Suojanen et al., 2016). Reported advantages of PSI plates include increased predictability of outcomes, less invasive procedures, and shorter operation times (Arcas et al., 2018; Hanafy et al., 2019; Heufelder et al., 2017; Kim et al., 2019; Li et al., 2017; Suojanen et al., 2016; Van den Bempt et al., 2018). However, this strategy relies solely on presurgical virtual 3D planning, without considering difficulties that may arise during surgery, necessitating deviation from the original plan. With PSI osteosynthesis plates, the position of the bony segments cannot be adjusted intra-operatively according to individual differences in lip-to-incisor ratios or to improve interdigitation of the dental cusps. Furthermore, it is unclear who is responsible for the preoperative 3D planning in studies of PSI osteosynthesis plates: is it the surgeon, the clinical engineer, or possibly the trainee? Preoperative 3D planning gives the operator false assurance that everything will proceed exactly according to the provided plan; however, it does not discharge the surgeon from being responsible for the final surgical result. Reported accuracy of PSI plates (definitive position compared to the virtual planned position) is good, ranging from 0.0 to 2.02 mm, with maximal overcorrection of 1.74 mm and maximal undercorrection of -2.02 mm (Hanafy et al., 2019; Heufelder et al., 2017; Kim et al., 2019). However, what is the advantage of a fairly (?) accurate repositioning when the segment is guided to a wrong position and cannot be adjusted? Maxillary impaction is often related to smile aesthetics; occlusal cant and midline can be determined with virtual design software, but average lip-to-incisor ratios vary between 28% and 100% (Olate et al., 2016). If one considers the standard deviations, it is obvious that the planned vertical position of the maxilla often requires alteration intraoperatively, which has consequences for the position of the mandible and the necessity or magnitude of chin advancement osteotomy.

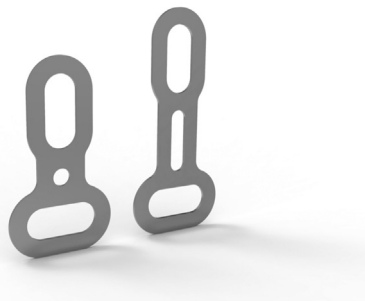


Fig. 4. Slotplates for chin osteotomies. Note the absence of a hole for the locking screw.

Slotplates adhere to the opposite principle. The surgeries are prepared by analogue, mixed analogue–digital, or fully digital workflow to evaluate the expected results on the soft tissue level and for the fabrication of the intermediate and definitive wafers. These preparations are used to guide the surgeon, but it is still necessary to intraoperatively evaluate the lip-to-incisor distance during Le Fort I–type osteotomies, the chin height and projection during chin osteotomies, and the malar projection during zygoma-valgisation osteotomies. The surgeon evaluates the results at the soft tissue level “live” during surgery, without relying solely on the virtual 3D planning. Slotplates allow for further adjustments of lip-to-incisor distance, chin height, and zygoma projection during the osteosynthesis phase of surgery, and by applying the slot principle, it is not even necessary to completely remove the screws and re-drill another screw hole. The operator can also opt for intraoperative control (midline check, occlusal plane, degree of yaw) using intraoperative cone-beam CT with 3D reconstruction. This control option makes intraoperative navigation and PSI osteosynthesis plating obsolete.

Furthermore, slotplates allow the surgery to proceed in a minimally invasive manner with little degloving (resulting in less swelling, fewer postoperative complaints, and faster healing), in contrast to the use of cutting guides or bulky PSI plates, which require more space and thus more degloving. In our practice, osteosynthesis plates are not routinely removed; but if deemed necessary, slotplates can be removed in a minimally invasive manner using only local anaesthesia.

Not for all but for most PSI osteosynthesis plates a sub-spinal Le Fort I–type osteotomy is impossible, in which alar base widening is at risk (Hanafy et al., 2019; Heufelder et al., 2017; Kotaniemi et al., 2019; Mommaerts et al., 1997). In some concepts of PSI plates, the plates need to be rigid because they are used not only for osteosynthesis but as a positioning guide as well (Arcas et al., 2018; Heufelder et al., 2017; Li et al., 2017). This rigidity, at least theoretically, increases the risk of impaired bone healing by increasing stress shielding (Chung, 2018).

The patient who developed a root injury after sliding genioplasty prompted us to request the company to develop a specific slotplate for chin osteotomies: a slotplate without a hole for a locking screw, because the locking screw is not necessary for fixation in these osteotomies due to the low forces on the bone segment. This specific chin slotplate should allow for a more safe procedure, while still allowing for the slot principle to be applied. Fig. 4 illustrates the specific slotplates for chin osteotomies.

5. Conclusion

In this retrospective analysis, the osteosynthesis material–related morbidity rates of third-generation slotplates were compared to those of second-generation slotplates. The present patient series

cannot demonstrate that the 3.0 slotplates perform better or worse than the 2.0 slotplates in the included outcome variables. However, there was a tendency towards better morbidity outcomes with 3.0 slotplates: notably, less necessity for plate removal, and absence of delayed union or non-union. The philosophy behind slotplates for orthognathic surgery differs considerably from that of PSI osteosynthesis plates.

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Declaration of competing interest

The authors have no conflicts of interest to disclose.

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