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Peri- and postoperative complications in Le Fort I osteotomies

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ABSTRACT

This retrospective study was performed to report the peri- and postoperative complications encountered by patients who underwent Le Fort I osteotomy, as well as predictor variables affecting the risk of complications.

Patients who underwent only Le Fort I osteotomy were included in the study. Information on peri- and postoperative complications were collected from the patient data records. The effects of certain predictor variables on complication rates were also studied.

Twenty-four per cent of the patients suffered from complications, six (6.1%) of whom were reoperated. Most of the complications were minor and transient. Compared with one-piece osteotomy, segmental osteotomy was a significant risk factor predisposing patients to postoperative complications ($p = 0.04619$). Additionally, the use of patient-specific implants seemed to increase the risk of both perioperative and postoperative complications ($p = 0.0248$).

Currently, the conventional plate fixation method is the primary method in Le Fort I osteotomies. Careful patient selection, surgical planning, and selection of surgical technique seem to be the most important factors in reducing the complication risk. Special attention should be paid with segmental osteotomy surgery.

1. Introduction

Le Fort I osteotomy, a routine procedure in orthognathic surgery, can be performed to correct a wide range of dentofacial deformities, such as class II and III malocclusions, vertical and transversal maxillary problems, maxillary deficiency, and dentofacial asymmetries (Buchanan et al., 2013). Originally, osteosynthesis in Le Fort I osteotomy was performed by wire fixation. In the 1970s, miniplates were first introduced for osteosynthesis in maxillofacial traumatology, after which they were also adopted for orthognathic surgery (Nowak and Trybek, 2016). The plate fixation method has been shown to be more stable than wire osseous fixation (Larsen et al., 1989). During the last 5–10 years, custom-made, patient-specific implants (PSIs) have become a routine fixation method, especially in complex orthognathic surgeries (Gander et al., 2015; Suojanen et al., 2016). Conventional plate fixation remains the primary choice in less complex situations, especially in patients with one-jaw surgery.

Le Fort I osteotomy is generally considered very safe to perform, and the complication rate is low. Various complications reported in Le Fort I osteotomies by earlier studies are listed in Table 1.

Multiple studies reporting both perioperative and postoperative complications in Le Fort I osteotomies have been published. However, predictor variables affecting the complication rates, such as using a bone graft or the choice of the fixation method, have not been widely investigated.

The aim of this study was to report peri- and postoperative complications encountered by patients who underwent Le Fort I osteotomy, and to investigate which predictor variables have an effect on the complication rates.

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Table 1
Complications in Le Fort I osteotomies reported by earlier studies.

Complication	Incidence	Studies reporting the complication
Intraoperative hemorrhage	1%–5.25%	de Mol van Otterloo et al. (1991); Kramer et al. (2004); Ho et al. (2011); Eshghpour et al. (2018)
Postoperative hemorrhage	0%–2%	de Mol van Otterloo et al. (1991); Garg and Kaur (2014); Eshghpour et al. (2018)
Intraoperative mucosal tearing	1%–2.6%	Ho et al. (2011); Eshghpour et al. (2018)
Bad fracture	0%–1%	Ho et al. (2011); Garg and Kaur (2014); Eshghpour et al. (2018)
Postoperative infection	0.5%–2%	Kramer et al. (2004); Eshghpour et al. (2018)
Dental complications	3.2%–5%	Mesgarzadeh et al. (2010); Ho et al. (2011)
Oral fistula	3.7%–5%	de Mol van Otterloo et al. (1991); Ho et al. (2011)
Delayed healing in the osteotomy line	0.2%–4%	de Mol van Otterloo et al. (1991); Kramer et al. (2004); Ho et al. (2011)
Periodontal complications	0.8%–4%	Kramer et al. (2004); Ho et al. (2011)
Ischemic complications of the maxilla	0.2% –0.24%	de Mol van Otterloo et al. (1991); Kramer et al. (2004)
Complications related to maxillary sinus health	0.6%–0.7%	de Mol van Otterloo et al. (1991); Kramer et al. (2004)
Complications leading to removal of the fixation plates and screws	2%–9%	Ho et al. (2011); Eshghpour et al. (2018)
Complications regarding the positioning of the maxilla	0.2%–2%	Kramer et al. (2004); Ho et al. (2011)

2. Materials and methods

2.1. Subjects

Patients treated with only Le Fort I osteotomy in the Department of Oral and Maxillofacial Diseases, Head and Neck Center, Helsinki University Hospital (HUH) and the Cleft Palate and Craniofacial Center, Department of Plastic Surgery, HUH during 2006–2017 were included in the study. Patients originally operated on with a bilateral sagittal split osteotomy (BSSO) or a bimaxillary osteotomy requiring a Le Fort I osteotomy as a reoperation were also included in the study. Exclusion criteria were: 1) bimaxillary osteotomies; 2) cleft lip and/or palate; 3) patients suffering from diseases that affect the bony structure, such as Treacher Collins syndrome; 4) patients treated with a Le Fort I osteotomy because of post-traumatic malocclusion; and 5) patients who had their preoperative and/or postoperative orthodontic treatment performed privately, with no patient data records available apart from the operative report.

2.2. Methods

The clinical records of the patients were collected retrospectively from the patient data archives using Excel version 16.34 (Microsoft Co, Redmond, WA, USA). The data collected included the patient's sex, date of birth, systemic and mental diseases, medication, smoking, body mass index (BMI), earlier facial traumas, possible TMJ-related problems, radiological findings in the temporomandibular joint (TMJ), orthodontic diagnosis, growth type of the lower jaw, and clinical orthodontic findings.

The orthodontic diagnosis and the initial treatment plan based on clinical examination, plaster models, intra- and extraoral photos, panoramic radiographs, and cephalometric analysis were determined by specialists in orthodontics. The growth type of the lower jaw was determined by cephalometric analysis. The cephalometric tracing was digitised using Dolphin Imaging 11.95 Premium program (Patterson Dental Supply, Inc., St. Paul, Minnesota, USA) with conventional cephalometric analysis.

The final treatment plan for each patient was made in an orthodontic–surgical meeting by senior orthodontists and senior oral and maxillofacial surgeons.

The main principles of the surgical technique were the same regardless of the fixation system used. A high horseshoe-shaped incision was made buccolabially from one first molar or second premolar to the other. The mucoperiosteal flap was elevated to identify the bony structures, the piriform aperture, and the infraorbital nerves. In the case of patient-specific implants, the cutting and drilling guides were fixed at this point to mark the osteotomy line; for factory-made and prebent miniplate techniques, the osteotomy line was outlined with a pencil. In conventional surgery planned with dental cast models, the height of the osteotomy was determined to be 23–26 mm above the buccal cusps in the molar and premolar area, and subspinally below the lower border of the piriform aperture in the anterior area. The osteotomy line was cut in all patients with a traditional saw. The walls of the sinus and the pterygoid processes were chiselled. The final splitting of the osteotomy line was performed with a piezoelectric device. In segmental osteotomies, the interdental osteotomies were performed with chisels and piezoelectric devices, and the segmentation was taken into account during the presurgical orthodontic treatment by making space between the roots in the interdental osteotomy area. Segmental osteotomies were performed in a Y-shape, with posteriorly directed horns positioned medially to the descending vessels. The downfracture of the maxilla was made manually by using forceps. The maxilla was placed in the new position using the splint and then fixed with miniplates or patient-specific implants. Possible bony interferences were first reduced. The widening of the nose was managed by measuring the width before the incision, and alar stiches were used if marked widening was observed after advancement.

Information collected about the Le Fort I osteotomy included the patient's age during the operation, the surgeon in charge, the amounts and directions of the movements of the maxilla (as reported in the operative report), the fixation method, the use of bone graft, the use of E bar in the case of segmental Le Fort I osteotomy, the time between the osteotomy and the removal of the splint, and the peri- and postoperative complications encountered by the patient. Information on the following minor complications was collected: mucosal tearings, unfavourable split, peri- and postoperative hemorrhage, perioperative nerve damage and subsequent long-term nerve function impairment, periodontal and dental complications, wound dehiscence, mild wound infections, removal of fixation plates or screws, sinus complications, and fistula. Information on the following major complications were collected: peri- and postoperative hemorrhage, severe wound infections requiring reoperations or use of intravenous antibiotics, ischemic complications, and complications with ossification of the osteotomy line. Perioperative hemorrhage was considered a complication if tamponage or clipping of the bleeding vessel was needed; minor bleedings stopped by bipolar electrocautery were not considered complications but as normal incidents during the operation. Postoperative hemorrhage was considered a complication if tamponage or other procedures were required or if a major

hematoma was noticed after the operation. Mucosal tearing was included in the complications if suturing was needed. The split was considered unfavourable if an additional, unplanned fracture was noticed during the downfracture of the maxilla. Wound infections that discharged pus and required antibiotics were considered complications. Postoperatively noticed gingival recession near the osteotomy line was considered a periodontal complication. Dental complications requiring endodontic therapy or extraction of the damaged teeth were included in the complications list, as well as cases where damage to the tooth was noticed during the operation. All situations leading to removal of a fixation plate or screw were considered complications, regardless of whether the removal was made as a result of the patient's request or was due to infection or exposure of the plate or screw. Incidences where the whole or a part of the repositioned maxilla turned necrotic following the operation were considered ischemic complications. Sinus complications requiring antibiotics were included as postoperative complications. Patients developing a palatal fistula postoperatively were also included in the complications group. A gap in the osteotomy line noticed in a postoperative radiograph, as well as a floating maxilla, were considered complications relating to ossification of the osteotomy line.

2.3. Statistical analysis

Student's *t*-test and the chi-square test were used to investigate whether there was a significant association between the incidence of complications and the age or sex of the patients. Fisher's exact test was used to assess whether the risk of a complication was affected by various predictor variables. All p-values < 0.05 were considered significant. Biostatistics experts were consulted in order to verify all of the analyses.

2.4. Ethical approval

The protocol of this retrospective study was approved by the Hospital District of Helsinki and Uusimaa (HUS/358/2018, §4). Principles outlined in the Declaration of Helsinki were followed.

3. Results

3.1. Clinical and surgical findings

Ninety-eight patients (50 males and 48 females) were included in the study. Table 2 presents the original orthodontic diagnoses of the patients. All the patients were treated orthodontically with fixed appliances as part of their orthognathic surgery treatment at HUH.

The majority of the patients (55.1%) presented an opening growth type. A total of 35.7% of the patients presented a neutral growth type, and 9.2% presented a closing growth type.

The mean treatment time for presurgical orthodontic treatment was 25.7 months (range 10.7–73.3 months). One patient was treated with a surgery-first technique. Nine patients were treated with surgically assisted rapid maxillary expansion (SARME) prior to the Le Fort I osteotomy. The mean amount of distraction achieved with surgically assisted rapid maxillary expansion between the first molars was 6 mm (range 3–9 mm).

Four senior surgeons were in charge of the operations. Because of the educational mission of our centre, nearly all osteotomies were performed at least partly by residents under the supervision of senior surgeons. The differences in the complication rates between the surgeons were not investigated in this study.

The mean age at Le Fort I osteotomy was 31 years (range 19–54 years). The operation was planned with 3D virtual planning in 29 patients (30%), of whom 11 received a patient-specific implant (Planmeca Ltd, Helsinki, Finland) and 18 received a prebent implant (DePuy Synthes, Matrix Orthognathic, Raynham, MA, USA). A CAD/CAM saw guide without predesigned drill holes was used for this 3D-designed Synthes miniplate fixation method. For other patients, conventional treatment planning with dental cast model surgery was performed; these underwent surgery with conventional wafers and factory-made miniplate fixation.

Table A.1 in Appendix A provides information on the transfers of the maxilla.

Sixty patients received a bone graft to the maxillary osteotomy line. Sixteen patients received autogenous bone grafts, and six patients received allogenous bone grafts. Twenty-three osteotomy lines were grafted with Bio-Oss (Geistlich Pharma, Wolhusen, Switzerland), 16 with DBX (Demineralized Bone Matrix; DePuy Synthes, West Chester, PA, USA), and one with chronOS (DePuy Synthes, West Chester, PA, USA). One of the patients received both allograft bone and DBX during the operation, and one received bone graft during both the original operation and the reoperation.

The splint was removed on average 25 days postoperatively (range 0–55 days). Seventeen splints (17.3%) were removed during the operation. The reasons for immediate splint removal were as follows: 1) accurate occlusion was achieved also without the splint (11 cases); 2) there was occlusal interference or precontact with the splint, or the splint did not fit properly and the intermaxillary fixation was made without the splint (five cases); and 3) the splint was broken during the operation (1 case).

The postoperative orthodontic treatment continued 4–6 weeks after the surgery. The mean postoperative orthodontic treatment time was approximately 9 months (range 3–30 months). 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/day for 6–9 months and then at nighttime for 1.5 years. A permanent retention wire was placed lingually from the canine to the canine to the lower jaw in all patients and palatally to the upper incisors in some patients. The patients were followed for at least 2 years after the removal of fixed permanent appliances.

3.2. Perioperative complications

Altogether, seven patients (7.1%) suffered from perioperative complications. All of the perioperative complications were considered minor and were treated immediately. No laceration of the infraorbital nerve was reported. Table 3 presents the perioperative complications and the actions taken to manage them.

3.3. Postoperative complications and reoperations

Fifteen patients (15.3%) suffered from postoperative complications. Only one of the postoperative complications — delayed

Table 2
Orthodontic diagnoses for the patients at the beginning of treatment.

	Cross bite	Maxillary retrognathia	Mandibular prognathia	Open bite	Asymmetry	Crowding	Hypodontia	Mandibular retrognathia	Deep bite
Number of patients (%)	76 (78)	69 (70)	45 (46)	28 (29)	17 (17)	14 (14)	9 (9)	6 (6)	1 (1)

Table 3
Perioperative complications.

Patient No.	Age	Sex (F/M)	Diseases	Fixation method[a]	Segmentation	Rotation[b]	Bone graft[c]	Complication and treatment
Mucosal tearing								
2	25	M	–	PSI	Two-piece	Straight	–	Tearing of the mucosa of approx. 10 mm in diameter in the border of the hard and soft palate; sutured
7	43	F	–	PSI	Two-piece	Straight	Allog. + DBX	Small mucosa tearing on the left peritonsillar area; sutured
9	45	F	–	PSI	One-piece	CW	–	Small mucosa tearing in the soft palate area behind the second upper molar on the right side; sutured
Hemorrhage								
35	23	M	–	3D	One-piece	Straight	Allog.	Bleeding from the major palatinal artery; clipped
81	33	F	–	Conv.	One-piece	Impaction only	–	Problem with hemostasis at the end of the osteotomy; nasal tamponage
Unfavourable split								
49	31	M	–	Conv.	One-piece	Straight	Bio-Oss	A fracture was noticed during the downfracture on the left side in the maxillary tuber region; piezoelectric unit used for finishing the fracture
Dental complications								
46	22	M	–	Conv.	One-piece	CW	Bio-Oss	Upper molar roots resected during the operation bilaterally

[a] PSI = patient-specific implant; 3D = three-dimensional planning and fixation by prebent miniplates; Conv. = conventional miniplates.
[b] CW = clockwise rotation of the maxilla.
[c] Autog. = autogenous bone graft from iliac crest; Allog. = allogenous bone graft.

ossification in the midline of the palatinum — was considered a major complication; others (14.2%) were considered minor. Table 4 presents the postoperative complications and the treatments. No periodontal or ischemic complications because of the Le Fort I osteotomy were observed in our study, and none of the patients suffered from long-term nerve function impairment. One patient suffered from a postoperative infection, but this did not require hospitalisation.

Six patients (6.1%) underwent reoperation, and one of the reoperated patients required further reoperation. All of the cases requiring reoperation were considered major complications. Four of the patients were treated by using conventional treatment planning and factory-made miniplate fixation, and two were treated by 3D virtual planning and prebent miniplate fixation without surgical drill guides. None of the patients had received patient-specific implants. No reoperation was performed because of infection. Table 5 presents the reoperated patients and the indications for reoperation.

Various complications are shown in Fig. 1.

3.4. Patient demographic data

No significant association was found between age and complications according to Student's t-test ($p = 0.347$). The chi-squared test revealed that the patient's sex did not affect the complication rate ($p = 0.138$).

3.5. The effect of segmental osteotomy on complications

A significant difference was noticed in the postoperative complication rate between one-piece, two-piece, and three-piece osteotomies, with segmental osteotomy being a risk factor for a postoperative complication ($p = 0.04619$). Of the 23 patients operated on with a segmental Le Fort I osteotomy, seven (30.4%) suffered from a postoperative complication, whereas only eight (10.7%) of the 75 patients operated on with a one-piece Le Fort I osteotomy suffered from a postoperative complication. Comparing one-piece osteotomies with segmental osteotomies, the perioperative complication rate and the reoperation rate were not affected by segmentation ($p = 0.6652$ and $p = 0.6229$, respectively).

3.6. The effect of fixation method on complications

According to our analysis, receiving a patient-specific implant seemed to increase both the risk of a perioperative complication ($p = 0.0454$) and the risk of a postoperative complication ($p = 0.0248$) compared with the other fixation methods. Of the 11 patients who received patient-specific implants, three (27.3%) suffered from a perioperative complication and five (45.5%) from a postoperative complication. The respective values for perioperative complications were 5.6% for patients receiving prebent plates and 4.3% for patients receiving factory-made plates, and the respective values for postoperative complications were 11.1% for patients receiving prebent plates and 11.6% for patients receiving factory-made plates. The fixation method did not affect the risk of reoperation ($p = 0.645$).

The data were further analyzed to compare the patients receiving patient-specific implants with other patients to determine whether there was another predictor variable that would explain why the patient-specific implant group encountered more complications than the other groups. However, the groups did not differ significantly from one another in terms of segmentation, bone grafting, or direction of movement; hence, we could not find any explanatory connections.

Table 4
Postoperative complications and the treatments applied.

Patient No.	Age	Sex (F/M)	Diseases	Smoking	Fixation method[a]	Segmentation	Rotation[b]	Bone graft[c]	Complication and treatment given
Plate/screw removals									
7	43	F	–	No	PSI	Two-piece	Straight	Allog. + DBX	Delayed ossification in midline of the palatinum; plates removed because of patient request
20	33	F	–	No	3D	One-piece	CW	DBX	One screw removed, patient request
37	25	M	–	No	PSI	One-piece	Straight	Bio-Oss	Plates removed because of obstruction in postoperative orthodontic treatment
51	34	F	Thoracic outlet syndrome	No	Conv.	One-piece	Straight	–	One plate removed, patient's request
87	46	M	–	Yes	Conv.	Two-piece	CCW	Autog.	One plate partially exposed and the exposed part was removed postoperatively, no infection
Dental complications									
40	29	M	–	No	Conv.	Two-piece	CW	Bio-Oss	Two upper incisors necrotic postoperatively; root canal treatment
46	22	M	–	No	Conv.	One-piece	CW	Bio-Oss	Upper molar roots resected during the operation bilaterally
54	34	M	–	No	PSI	Three-piece	CW	–	One upper canine necrotic postoperatively; root canal treatment
72	22	F	–	Yes	Conv.	One-piece	Straight	–	One upper incisor and one upper canine necrotic; root canal treatment postoperatively
82	30	M	Allergy-induced asthma	No	Conv.	One-piece	Straight	DBX	One upper canine necrotic postoperatively; root canal treatment
Sinus complications									
5	48	F	Waardenburg syndrome	No	PSI	Two-piece	CW	DBX	Sinusitis; antibiotics
67	35	F	Hypothyroidism, high blood pressure	No	Conv.	One-piece	Straight	Autog.	Sinusitis; antibiotics
Delayed ossification									
7	43	F	–	No	PSI	Two-piece	Straight	Allog. + DBX	Delayed ossification in midline of the palatinum; plates removed because of patient request
73	26	F	–	Yes	3D	One-piece	Straight	DBX (+autog. In reoper.)	Maxilla mobile in postoperative control; reoperation
Wound infections									
16	28	F	Migraine, exercise-induced asthma	No	Conv.	Three-piece	Straight	–	Wound infection; antibiotics
Fistula									
2	25	M	–	No	PSI	Two-piece	Straight	–	Fistula in palatinum

[a] PSI = patient-specific implant; 3D = planning made three-dimensionally and fixation by prebent miniplates; Conv. = conventional miniplates.
[b] CW = clockwise rotation of the maxilla; CCW = counterclockwise rotation of the maxilla.
[c] Autog. = autogenous bone graft from iliac crest; Allog. = allogenous bone graft.

3.7. The effect of the amount or direction of maxillary movement on complications

The patients were divided into two groups according to the advancement of the maxilla: < 4 mm and ≥4 mm. Twenty patients (20.4%) had only a small advancement or no advancement at all, whereas the maxilla was advanced ≥ 4 mm in 78 cases (79.6%). The amount of advancement did not affect the perioperative or postoperative complication rate ($p = 1.0$ and $p = 0.729$, respectively) or the risk of reoperation ($p = 0.0974$). Moreover, when comparing the risk of complication in counterclockwise, clockwise, and straight movements, the direction of the movement was not found to affect the risk of a complication in our study group ($p = 0.664$ for perioperative complications and $p = 0.6333$ for postoperative complications, respectively, and $p = 1.0$ for reoperations).

Table 5
Reoperations.

Patient No.	Age	Sex (F/M)	Original diagnosis	Original operation	Fixation method[a]	Bone graft[b]	Reoper.[c]	Indication for reoper.	Time from original to reoper.
23	24	F	Open bite, cross bite	Le Fort I, one-piece	3D	DBX	Le Fort I	Transfer not satisfactory	10 days
29	22	M	Open bite, maxillary retrognathia	Le Fort I, one-piece	Conv.	Autog.	BSSO	Open bite	7 days
66	26	F	Cross bite, mandibular prognathia, maxillary retrognathia	Le Fort I, one-piece	Conv.	Bio-Oss	Le Fort I	Nose widened during operation	8 days
73	26	F	Cross bite, mandibular prognathia, maxillary retrognathia	Le Fort I, one-piece	3D	DBX (and autog. at reoper.)	Le Fort I	Unstable maxilla in control compression test	6 months
79	37	F	Open bite, cross bite	Le Fort I, three-piece	Conv.	(DBX at reoper.)	Le Fort I and then Bimax	Unsatisf. occlusion	2 days + 2 days
85	45	F	Open bite, cross bite	Le Fort I, three-piece	Conv.	–	BSSO	Open bite	4 days

[a] 3D = three-dimensional planning and fixation by prebent miniplates; Conv. = conventional planning and factory-made miniplates.
[b] Autog. = autogenous bone graft from iliac crest.
[c] BSSO = bilateral sagittal split osteotomy; Bimax = bimaxillary osteotomy.

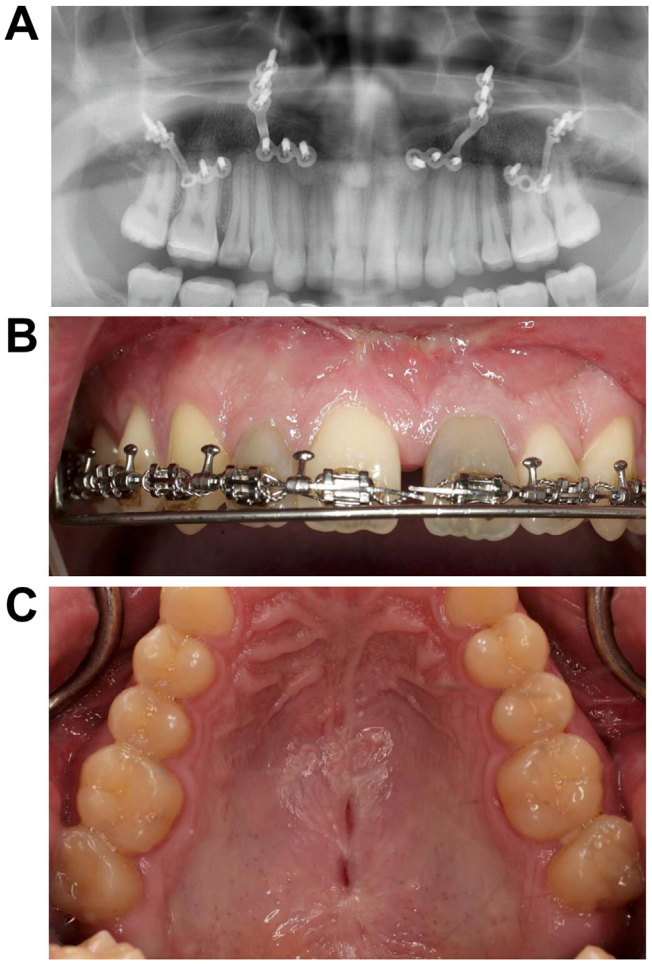

Fig. 1. a) First upper molar roots resected during the Le Fort I osteotomy. b) Two upper incisors necrotic with discoloration. c) Fistula in the palatinum.

3.8. The effect of bone grafts on complications

Receiving a bone graft did not affect the complication rates ($p = 1.0$ for perioperative complications, $p = 0.7766$ for postoperative complications, and $p = 0.4001$ for reoperations) according to Fisher's exact test. Of the 60 patients who received bone grafts, four had perioperative complications, and ten had postoperative complications. Five patients receiving a bone graft required a reoperation. Three of the 38 patients not receiving a bone graft suffered from a perioperative complication, five from postoperative complications, and one required a reoperation.

3.9. The effect of growth type on complications

No significant differences in the complication rates were found between the neutral, closing, or opening jaw relationships ($p = 0.592$ for perioperative complications, $p = 0.1042$ for postoperative complications, and $p = 1.0$ for reoperations).

4. Discussion

In our study, the complication rates were 7.1% for perioperative complications, 15.3% for postoperative complications, and 6.1% for reoperations. According to earlier reports, the perioperative complication rates ranged from 6.4% (Kramer et al., 2004) to 7.0% (Eshghpour et al., 2018). However, although *Kramer* et al. reported intra- and perioperative complications, they also included complications such as nonunion of the osteotomy gap and malposition of the maxilla in their evaluation, whereas in our study these were considered to be postoperative complications or complications requiring reoperation. Postoperative complication rates reported in earlier studies varied greatly (1.8–27%) (Haas Junior et al., 2017; Zaroni et al., 2019; Kramer et al., 2004; Garg and Kaur, 2014; Eshghpour et al., 2018). One factor affecting the complication rates is whether the centre performing the osteotomies is an educational centre or not; experienced surgeons may encounter fewer complications than surgeons with less experience. Our centre has an educational mission, and nearly all osteotomies were performed at least partly by residents under the supervision of more experienced surgeons. Other factors found when comparing the complication rates with those of earlier studies were the differences in the diagnostic criteria used to determine which incidents were considered complications, as well as the above-mentioned differences in categorizing the complications as perioperative or postoperative. Our aim was to collect comprehensive information about complications in Le Fort I osteotomies; hence, we have reported every unexpected incident requiring intervention during surgery and every unfavourable postoperative situation. Most of the complications encountered by our patients were mild and transient. However, despite the mild and temporary nature of the complications in our study, preoperative information regarding possible risks should be emphasized and indications for orthognathic surgery should be weighed against the possible complication risks (Hillerup, 2020). Surgeons and orthodontists should also pay attention to patient information regarding the expected results, as the patients may have unrealistic expectations about the treatment outcome (Engelmann et al., 2020).

4.1. Perioperative complications

In an earlier study of segmental Le Fort I osteotomies (Ho et al., 2010), oronasal communication was encountered by 6% of the patients; in our study, mucosal tearing occurred in 8.7% of the segmental osteotomies and in 1.3% of the one-piece osteotomies. All mucosal tearing complications in our study were encountered by patients who had received patient-specific implants, thus the patient-specific implant seemed to increase the risk of a perioperative complication. The patient-specific implant is the newest of the fixation methods and may thus predispose to complications, as the technique requires practice. All mucosal tearings occurred during the first 14 months after the technique was put into operation at our centre in November 2013. Since then, we have improved the shape and design of the cutting guides for more limited mucosal access, which supposedly reduces the risk for wound problems. In an earlier study reporting the use of the patient-specific implants at our centre (Suojanen et al., 2016), the patient-specific implant was found to be a precise tool for maxillary repositioning. However, further follow-up is needed to evaluate the risks of patient-specific implants.

Other perioperative complications in our study included hemorrhage (2.0%, compared with 1.1% reported by Kramer et al., 2004 and 5.25% by Eshghpour et al., 2018), unfavourable split (1.0%, compared with 0.87% reported by Eshghpour et al., 2018 and 1.2% by Ho et al., 2010), and dental complications (1.0%, compared with 1.2% reported by Ho et al., 2010). One way to reduce perioperative hemorrhage is the choice of the surgical device with which the osteotomy is performed. Piezoelectric devices may significantly reduce blood loss during the operation (Spinelli et al., 2014). In our study, the osteotomy line was cut in all patients using a traditional saw. Dental complications leading to resection of the molar roots could be avoided by planning the osteotomy three-dimensionally.

4.2. Postoperative complications

The prevalence of postoperative complications in segmental Le Fort I osteotomies has been reported to range from 1.8% to 27% (*Haas Junior* et al., *2017*; *Zaroni* et al., 2019), whereas conventional Le Fort I osteotomy has been reported to have a complication rate of 4%–11.7% (*Kramer* et al., 2004; *Garg and Kaur, 2014*; *Eshghpour* et al., 2018; *Zaroni* et al., 2019). Anatomical irregularities, as well as segmental Le Fort I osteotomy, have been reported to enhance the risk and extent of complications (*Kramer* et al., 2004). Our study subjects did not include patients with orofacial clefts or those suffering from diseases that affect the bony structure. According to our analysis, segmentation enhanced the risk for postoperative complications: complications occurred in 30.4% of segmental osteotomies versus 10.7% of one-piece osteotomies; however, the types of postoperative complication varied from one patient to another, and we could not find any specific type of complication that would be typical for segmental osteotomies. Segmental osteotomy is performed for various purposes, such as widening the maxillary arch or correcting an asymmetric occlusal plane of the maxilla. For maxillary transverse deficiency, SARME is an alternative for segmentation; however, earlier studies have shown rather high complication rates of 21.97–52.25% (Carvalho et al., 2020; Smeets et al., 2020) for SARME procedures.

Nocini et al. (2016) studied the correlation between clinical sinusitis and Le Fort I osteotomy. They discovered that Le Fort I osteotomy can affect paranasal sinus health in terms of sinus volume decrease, morphological alterations, and radiologically detectable inflammatory processes affecting the paranasal sinuses. However, according to other earlier studies (Pereira-Filho et al., 2011; Valstar et al., 2013), performing a Le Fort I osteotomy does not exacerbate the subjective sinus-related complaints patients have before the surgery. Our study showed an incidence of maxillary sinusitis as a postoperative complication of 2.0%; however, postoperative sinusitis was only assessed in terms of subjective symptoms. Although radiological or endoscopic evaluation of sinus health pre- and postoperatively could provide valuable information about existing or manifesting inflammatory processes and their predictable variables, this was not possible with our retrospective patient data. Moreover, Valstar et al. (2013) suggested that CT scan findings correlate poorly with the symptoms of sinusitis.

Maxillary movement type, as well as the amount of advancement, has been reported to show a significant correlation with complications. Osteotomies with large anterior movements of the maxilla of 9 mm or more have been shown to enhance the risk of ischemic complications (Kramer et al., 2004), while maxillary setback with impaction has a higher risk for complications than other movement types, followed by isolated maxillary advancement, and then by other movement types (Eshghpour et al., 2018). Our study investigated the association between the prevalence of the complications and the direction of movement of the maxilla. No significant differences in complication rates were found between osteotomies with no rotation, osteotomies with clockwise rotation, or osteotomies with counterclockwise rotation. None of our patients had a maxillary setback, which can at least partly explain the differences in the results between our study and that by Eshghpour et al. (2018). The amount of advancement did not significantly affect the prevalence of the complications, although we categorized the advancements to <4 mm and ≥ 4 mm, so the results are not directly comparable with those reported by Kramer et al. (2004).

Mesgarzadeh et al. (2010) investigated the effects of Le Fort I osteotomy on maxillary incisors and canines and discovered that 3.2% of the teeth required root canal treatment, compared with approximately 1.0% in our study. Planning the osteotomy three-dimensionally may decrease the risk of dental complications, since the 3D techniques take into account the location of the roots.

The fixation plates may have to be removed postoperatively for various reasons, such as infection, tenderness and pain, sinusitis, temperature sensitivity, palpability of plate, plate exposure, or patient request without complaints (Schmidt et al., 1998; Haraji et al., 2009; Little et al., 2015; Verweij et al., 2016). The plate removal rate has been reported to be between 2.0% and 24.6% (Ho et al., 2010; Falter et al., 2011; Verweij et al., 2016). In our study, the plate removal rate was 5.1%.

Interestingly, using patient-specific implants seemed to increase the risk of a postoperative complication. We further analyzed the patient groups but did not find any predisposing factors in the patient-specific implant group that would explain the result. In addition, compared with other fixation methods, none of the complication types was overrepresented in the patient-specific implant group. According to our earlier study (Suojanen et al., 2018), which compared postoperative complication rates between patients receiving a patient-specific implant and patients receiving conventional miniplates, the patient-specific implant did not increase the risk of a complication compared with conventional miniplates. One possible reason for the higher complication rate in the patient-specific implant group is that the technique is relatively new and requires practice. Three of the five postoperative complications encountered by the patients in the patient-specific implant group occurred during the first year after the patient-specific implant technique had been put into operation in November 2013. Another possible reason for an increased risk of complications is the fact that the patient-specific implant requires more stripping of the periosteum, and may therefore predispose to complications. In addition, the small sample size of the patient-specific implant group — only 11 patients — has to be taken into account when drawing conclusions from the study. Our earlier study (Suojanen et al., 2018) consisted of a larger group of patients receiving a patient-specific implant, and no difference in complication rates was noticed between the fixation methods.

Bone grafting has been shown to promote healing of Le Fort I osteotomies, and has not been shown to increase the risk of complications significantly (Alyahya and Swennen, 2019). In our patient data, 60 patients received a bone graft to the osteotomy line. Sixteen patients received autogenous bone grafts, and six patients received allogenous bone grafts. Other patients received synthetic bone substitutes. The complication rate did not differ between patients receiving a bone graft and those not receiving a bone graft.

Nerve function impairment can significantly lower the quality of life. Neurosensory disturbances, including pain and loss of neural function, have been reported to be the most frequent reason for indemnity claims in Denmark (Hillerup, 2020). None of the patients in our study suffered from long-term nerve function impairment. Lower-jaw surgeries may be more prone to nerve injuries than maxillary osteotomies. Permanent nerve injury has been reported to be very rare in sole Le Fort I osteotomies compared with other orthognathic surgeries (Friscia et al., 2017).

4.3. Reoperations

Six patients required a reoperation, of whom one required a second reoperation. None of these patients had originally received a patient-specific implant as a fixation method. This finding is in line with our earlier study (Suojanen et al., 2018), according to which the use of a patient-specific implant may decrease the need for reoperations. Three of the patients requiring a reoperation suffered from an open or unsatisfactory bite postoperatively, and all of them were reoperated via a mandibular osteotomy. The reasons for requiring reoperation can be diverse, not only as a result of Le

Fort I osteotomy itself, but also because of the positioning of the condyles during the operation.

4.4. Miscellaneous

This paper did not investigate postoperative stability after Le Fort I osteotomy. Our previous study reported differences in postoperative skeletal stability between patient-specific implants and conventional miniplate fixation methods (Kotaniemi et al., 2019).

5. Conclusion

The complications encountered by the patients in this study were generally mild, but the complication rate was rather high and a wide range of complications was reported. This must be noted when informing the patients preoperatively. Careful patient selection, surgical planning, and selection of surgical technique seem to be the most important factors for reducing complication risk. Special attention should be paid to these in segmental osteotomy surgery. Prospective studies are warranted to confirm the effects of patient-specific implants on complication risks.

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Table A.1
Transfer of the maxilla according to the surgery records

Patient No.	Segmentation	Fixation method	Transfer
1	One-piece	Conventional	8.5 mm advance
2	Two-piece	PSI	4.5 mm advance; 7 mm widening
3	One-piece	PSI	7.5 mm advance; 1.5 mm up at the anterior teeth; 0.5 mm up at the posterior teeth
4	One-piece	PSI	7 mm advance
5	Two-piece	PSI	4.4 mm advance; 2 mm down at the anterior teeth; widening
6	One-piece	PSI	4 mm advance
7	Two-piece	PSI	6 mm advance; 3.5 mm widening
8	One-piece	3D	9 mm advance; 3 mm whole up; 1 mm rotation to the left
9	One-piece	PSI	4 mm advance; 2 mm down at the anterior teeth
10	One-piece	PSI	6.7 mm advance; 2.2 mm up at the anterior teeth; 3.4 mm up at the posterior teeth; 2.7 mm rotation to the right
11	Two-piece	Conventional	7.5 mm advance; 3 mm up at the anterior teeth; 2 mm up at the posterior teeth; 5 mm narrowing
12	Two-piece	Conventional	7 mm advance; 0.8 mm down at the anterior teeth; 3 mm widening
13	One-piece	3D	10 mm advance
14	One-piece	Conventional	8.5 mm advance; 2 mm up at the anterior teeth; 1 mm rotation to the left
15	Two-piece	Conventional	4 mm down at the left posterior teeth; 5 mm widening
16	Three-piece	Conventional	4 mm advance; 1.5 mm whole up; 2 mm rotation to the left; 4 mm narrowing
17	One-piece	Conventional	5 mm advance; 2.5 mm up at the posterior teeth
18	One-piece	Conventional	6 mm advance; 3 mm rotation to the left
19	One-piece	3D	6.9 mm advance; 2 mm down at the anterior teeth
20	One-piece	3D	7 mm advance; 2 mm up at the posterior teeth
21	Two-piece	3D	6 mm advance; 1 mm rotation to the left; 4 mm widening
22	One-piece	3D	3 mm advance; 4 mm whole up; 1 mm rotation to the left
23	One-piece	3D	1 mm setback; 3.5 mm up at the posterior teeth
24	Three-piece	3D	6 mm advance; 1 mm up at the anterior teeth; 2.5 mm up at the posterior teeth; 3.5 mm widening
25	One-piece	3D	10 mm advance; 5 mm rotation to the left
26	One-piece	3D	7 mm advance; 1 mm rotation to the right
27	Two-piece	3D	1 mm advance; 2 mm down at the left posterior teeth
28	One-piece	Conventional	6 mm advance; 3 mm down at the anterior teeth; 2 mm down at the posterior teeth
29	One-piece	Conventional	6 mm advance
30	One-piece	3D	2.7 mm advance; 1 mm up at the posterior teeth; 1.3 mm rotation to the left
31	One-piece	3D	7 mm advance
32	One-piece	Conventional	6 mm advance; 2 mm up at the anterior teeth; 1.5 mm rotation to the left
33	One-piece	3D	3 mm whole up
34	One-piece	3D	3 mm up at the posterior teeth; 2.5 mm rotation to the left
35	One-piece	3D	10 mm advance
36	One-piece	3D	6 mm advance
37	One-piece	PSI	5 mm advance; 1 mm rotation to the right
38	Two-piece	Conventional	5 mm advance; 1.5 mm up at the anterior teeth; 4 mm up at the posterior teeth; 5 mm widening
39	One-piece	Conventional	4.5 mm advance; 2 mm down at the anterior teeth; 4 mm down at the posterior teeth; 2 mm rotation to the right
40	Two-piece	Conventional	7 mm advance; 2 mm up at the posterior teeth; 5 mm widening
41	One-piece	Conventional	6 mm advance; 1 mm whole up; 3 mm rotation to the left
42	One-piece	Conventional	5 mm advance; 1 mm up at the anterior teeth; 3 mm up at the posterior teeth; 2 mm rotation to the left
43	One-piece	Conventional	7 mm advance; 1.5 mm up at the anterior teeth; 0.5 mm down at the posterior teeth; 2 mm rotation to the left
44	One-piece	Conventional	7 mm advance; 1.5 mm up at the anterior teeth; 4.5 mm up at the posterior teeth; 1 mm rotation to the left
45	One-piece	Conventional	5 mm advance
46	One-piece	Conventional	7 mm advance; 2.5 mm down at the anterior teeth
47	One-piece	Conventional	5 mm advance
48	One-piece	Conventional	5 mm advance; 2 mm rotation to the right
49	One-piece	Conventional	6 mm advance; 1 mm rotation to the left
50	One-piece	Conventional	5 mm advance; 2 mm whole up; 1 mm rotation to the left
51	One-piece	Conventional	5 mm advance; 1.5 mm whole up
52	One-piece	Conventional	8 mm advance
53	One-piece	Conventional	5 mm advance

Table A.1 (*continued*)

Patient No.	Segmentation	Fixation method	Transfer
54	Three-piece	PSI	3 mm up at the anterior teeth; 5 mm up at the posterior teeth
55	One-piece	Conventional	3 mm advance
56	Two-piece	Conventional	4 mm advance; 3 mm widening
57	One-piece	Conventional	6 mm advance; 2 mm whole up
58	One-piece	Conventional	3 mm advance; 1 mm up at the posterior teeth
59	One-piece	Conventional	10 mm advance; 3 mm up at the posterior teeth
60	Two-piece	Conventional	6 mm advance; 2 mm up at the anterior teeth; narrowing
61	One-piece	Conventional	5 mm advance; 1 mm up at the anterior teeth
62	One-piece	Conventional	10 mm advance; 4 mm whole up
63	One-piece	Conventional	5 mm advance; 1.5 mm up at the anterior teeth; 1 mm rotation to the right
64	One-piece	Conventional	5 mm advance; 2 mm rotation to the left
65	One-piece	Conventional	5 mm advance
66	One-piece	Conventional	8.5 mm advance; 1 mm up at the anterior teeth; whole down 3 mm at the reoperation
67	One-piece	Conventional	5.5 mm advance; 2 mm whole up
68	One-piece	Conventional	6 mm advance; 1 mm rotation to the left
69	One-piece	PSI	5 mm advance; 2 mm whole up
70	One-piece	Conventional	5 mm advance; 1 mm rotation to the left
71	One-piece	Conventional	6 mm advance; 3 mm whole up; 4 mm rotation to the left
72	One-piece	Conventional	6 mm advance; 2 mm whole up
73	One-piece	3D	10 mm advance
74	One-piece	Conventional	3.5 mm advance; 3 mm up at the posterior teeth; 1 mm rotation to the right
75	Three-piece	Conventional	9 mm advance; 2 mm down at the posterior teeth; 7 mm widening
76	One-piece	Conventional	6 mm whole up
77	One-piece	Conventional	6 mm advance; 3 mm up at the posterior teeth; 1 mm rotation to the left
78	One-piece	Conventional	2 mm advance; 1.5 mm up at the anterior teeth; 4 mm up at the posterior teeth
79	Three-piece	Conventional	3 mm advance; 3 mm whole up; 4 mm widening
80	One-piece	Conventional	6 mm advance; 1 mm rotation to the left
81	One-piece	Conventional	4.5 mm whole up; 1.5 mm rotation to the right
82	One-piece	Conventional	5 mm advance; 1.5 mm rotation to the left
83	One-piece	Conventional	5 mm advance; 1 mm rotation to the right
84	Two-piece	Conventional	3 mm advance; 3 mm up at the posterior teeth; 5 mm widening
85	Three-piece	Conventional	3 mm advance; 3 mm down at the anterior teeth; 4 mm up at the posterior teeth; 1 mm rotation to the left
86	Two-piece	Conventional	2 mm up at the anterior teeth; 1.5 mm rotation to the left; 3 mm widening
87	Two-piece	Conventional	2.5 mm advance; 0.6 mm down at the posterior teeth; 1.5 mm rotation to the right; 9 mm widening
88	One-piece	Conventional	5 mm advance; 1 mm rotation to the right
89	One-piece	Conventional	7 mm advance; 2 mm rotation to the right
90	Three-piece	Conventional	3 mm advance; 2 mm up at the anterior teeth; 5 mm down at the posterior teeth; 5 mm widening
91	One-piece	Conventional	4 mm advance; 3.5 mm rotation to the left
92	One-piece	Conventional	5 mm advance; 1 mm up at the anterior teeth; 2 mm up at the posterior teeth; 1.5 mm rotation to the left
93	One-piece	Conventional	5 mm advance; 2 mm up at the anterior teeth; 3 mm up at the posterior teeth
94	Two-piece	Conventional	6.5 mm advance; 4 mm up at the anterior teeth; 1 mm up at the posterior teeth; 1 mm rotation to the left; 3 mm narrowing
95	One-piece	Conventional	5 mm advance
96	One-piece	Conventional	6 mm advance; 1 mm rotation to the right
97	One-piece	Conventional	5.5 mm advance
98	One-piece	Conventional	5 mm advance; 2 mm whole up

Declaration of competing interest

None.

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