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Stabilisation of sagittal split advancement osteotomies with miniplates: a prospective, multicentre study with two-year follow-up Part I. Clinical parameters

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Abstract. The principal aim of this study was to assess the postoperative stability of bilateral sagittal split osteotomies (BSSO) using two miniplates. Part I reports on the clinical results including treatment characteristics, nerve functions, TMJ function, occlusional relapse and patient satisfaction.

This prospective study evaluated a group of 222 patients who underwent a BSSO for mandibular advancement. The same treatment protocol was used at seven participating institutions at which the patients were treated. A stable occlusion without appreciable relapse was seen in 84% after 2 years of follow-up. A considerable minority (16%) had occlusal relapse. There were no clinical parameters that pointed towards a high risk for relapse except age. The mean operation age of the relapse group was 20.7 years (SD 6.7) and in the stable group 26.1 years (SD 8.2).

The function of the inferior alveolar nerve 2 years postoperatively was reported to be normal in approximately 88% of the patients, while 94% had no complaints about nerve dysaesthesia.

In approximately 56% of the patients with pre-existing TMJ-dysfunction these signs and symptoms had disappeared. Another group of patients, however, without TMJ-dysfunction preoperatively (22%) developed signs or symptoms of TMJ-dysfunction postoperatively.

The sagittal split osteotomy fixed with miniplates appeared to be a relatively safe and reliable procedure giving rise to a high degree of patient satisfaction, despite the fact that some occlusal relapse was seen.

Key words: sagittal split osteotomy; rigid fixation; miniplates; mandibular hypoplasia; occlusion; nerve dysaesthesia; patient satisfaction.

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The bilateral sagittal split osteotomy (BSSO) is widely used to advance and set the mandible back in patients with mandibular hypoplasia and hyperplasia, respectively. There are several options to stabilise the fragments but at present, internal rigid fixation either using positional screws[24,38,50] or miniplates[1,8,21,26,30,47], is most often applied. There are several studies that attest to the validity of both methods of internal fixation[5,6,18]. Few studies with a large number of patients deal with possible long-term effects, such as skeletal relapse, progressive condylar resorption (PCR), temporo mandibular joint (TMJ) dysfunction and nerve dysaesthesia to draw meaningful conclusions.

A study of Scheerlinck et al.[43] using miniplates for stabilisation of the fragments pointed to a rather high percentage of patients with skeletally stable results (90.3%), however, there were also 8/103 (=7.7%) patients who experienced considerable relapse because of PCR. Pre-existing TMJ dysfunction may play a role in the pathogenesis of PCR. It has been suggested that a stable Class I occlusion following orthognatic surgery might improve TMJ function[14,29,53]. Prospective studies, however, to validate these assumptions are lacking and firm conclusions cannot be drawn from the existing data presented in the literature.

Nerve function after BSSO also deserves further study. A relatively low incidence on persisting nerve dysaesthesia is reported by several authors[17,39,44,54] but little is known about the long-term effects of exposure and manipulation of the nerve during the sagittal split osteotomy and the capacity of recuperation afterwards[10,17,43,48,50,51,54]. Although patient adaptability and satisfaction after orthognatic surgery have been evaluated[4,8,33,45], it was thought to be useful to add this information on this large group of patients.

It is the aim of this prospective study to present the results on a large sample that underwent a BSSO for advancement of the mandible at seven different centres. Part I reports on the clinical results including treatment characteristics, nerve function, TMJ function, clinical relapse and patient satisfaction.

Table 1. Patient characteristics in relation to the participating centres

			Sex		Third molar removed		Age (years)			
Town	Country	*n*	♂	♀	−	+	Mean	SD	Min	Max
Nijmegen	The Netherlands	21	6	15	21	0	27.8	7.2	18	43
Groningen	The Netherlands	6	1	5	4	2	26.2	3.5	21	31
Chester	Great Britain	10	3	7	9	1	25.8	10.0	16	39
Köln	Germany	3	2	1	2	1	31.0	6.6	25	38
Barcelona	Spain	2	1	1	2	0	24.5	3.5	22	27
Arnhem	The Netherlands	175	39	136	107	68	24.7	8.4	13	53
Kiel	Germany	5	1	4	5	0	26.8	6.3	17	34
Total		222	53	169	150	72	25.2	8.2	13	53

Material and methods

A protocol was designed and approved by the participating centres prior to the study, including the selection of patients, the (post) surgical procedures and the post-treatment evaluation. The surgeons who participated in the study entered data preoperatively, immediate postoperatively and 3, 6 and 24 months postoperatively.

Patients

The sample comprised 222 Caucasian patients from seven institutions, examined at all three follow-up intervals. There were 53 males (24%) and 169 females (76%), with an age range of 13–53 years. The specific data are presented in Table 1.

All patients were accepted according to the following criteria:

- No anterior vertical open bite of more than 2 mm, as assessed from the lateral cephalometric radiograph.
- No additional osteotomies or other surgery on the facial skeleton.
- Uninterrupted dental arches.
- Pre- and postoperative orthodontic treatment with fixed appliances.

Surgical technique

A bilateral sagittal split advancement osteotomy was carried out on all patients according to Obwegeser[35,36] and as modified by Dal Pont[12]. This osteotomy was performed with or without the Hunsuck modification[23]. After advancement the desired occlusion was fixed with stainless steel intermaxillary wires with a thin interocclusal acrylic splint (wafer) in place. Stainless steel or titanium miniplates (four or six holes) were used for fixation of the fragments as described by Rubens et al.[42]. The proximal fragments were positioned with a gauze-packing instrument to guide the proximal segments into the proper posterior position in the fossa. The miniplates were bent to accommodate for a possible step and positioned passively against the bone fragments and fixed with at least two monocortical 5 or 7 mm screws on each side of the osteotomy. The intermaxillary fixation (IMF) was released, the centric occlusion was compared to the models[42], and if necessary, the plates were reapplied as above. In case of bad split the loose fragment was stabilised with an additional plate. Tight elastics, i.e., patients could hardly open the mouth, were applied to keep the mandible in the proper occlusion.

Post-surgical protocol

The tight elastics were kept in place for the first 2–5 postoperative days. At the time the first postoperative cephalogram was taken the patient had to bite properly in the splint. Loose guidance elastics were usually worn for a further period of 6 weeks that allowed the patient to open the mouth at least 15 mm. Patients were instructed, however, to keep the splint in for a period of 6 weeks, unless a stable occlusion was present, which allowed for splint removal. The patients were encouraged to open and close their mouth, but they had to maintain a soft diet for 6 weeks. Exercises to achieve the original mouth opening as quickly as possible were also allowed. Professional physiotherapy, however, to assist in achieving presurgical mouth opening was not prescribed. Patients were seen and instructed by an oral hygienist at regular intervals. Postoperative orthodontic treatment started usually after 6 weeks.

If the surgeon planned to remove plates, the protocol recommended doing this after 6 months, but this was not prescribed as being obligatory[49]. If removed it was noted whether the screws were surrounded by granulation tissue. This was denoted as inflammatory reaction. In case of clinically visible infection the plates had usually been removed sooner.

Postoperative evaluations were carried out at 3, 6 and 24 months following surgery. Identical forms were used at each time interval for clinical examination. After each examination the form was filled out and directly sent to the principal investigator (WB) in order to preclude the examiner being influenced by the previous data.

Evaluation

The treatment parameters recorded were: operating time, volume of blood loss, the use of antimicrobial prophylaxis and steroids, plate fixation and subsequent removal, reoperation and duration of orthodontic treatment. The follow-up evaluation included additional fractures (bad splits), nerve function, occlusal assessment, TMJ function, and patient satisfaction.

The following parameters involving the intraoperative location and condition of the inferior alveolar nerves were recorded:

- Located in distal segment but not seen after sagittal section.
- Located in distal segment and seen after sagittal section.
- Freeing with elevator.
- Required instrumentation to free it from the bony canal.
- Unintentionally damaged, but continuous (repaired).
- Transected (repaired).

Questioning the patient assessed the sensory function of the mental nerve. It was recorded as normal, hypersensation, anaesthesia and paraesthesia. The latter refers to any sensation that is different from normal, but not including pain or total numbness.

The occlusion was clinically classified as stable, i.e., without appreciable relapse, or a horizontal relapse of 1–3 mm or more than 3 mm, or an anterior vertical open bite, as compared to the immediate postoperative position.

The following signs and symptoms concerning the TMJ-function were documented:

- Clicking (left, right).
- Preauricular pain (left, right).
- TMJ dysfunction (any clicking and or pain, left, right).
- Maximal mouth opening (measured at central incisors).
- Protrusive movements (measured at the dental midline).
- Lateral excursions (measured from the dental midline).

Patient satisfaction was measured at 3, 6 and 24 months follow-up. Satisfaction with their facial appearance was rated with a 4-point scale: not satisfied, does not know, satisfied and highly satisfied. With respect to chewing capacity, patients had to choose from three options: better, same as before or worse. They were also asked whether the operation had an influence on their social life or career by choosing from three options: positive, negative or no influence. Finally, the overall satisfaction with the procedure was assessed by the question: 'would you do it all over again' with the options: yes or no.

Statistical analysis

Emphasis was given to the description of the findings in terms of means and percentages of the outcomes. Five different types of outcome were analysed using age, gender and relevant clinical parameters observed in the operative and postoperative treatment. The outcomes were:

1. Treatment findings (additional fractures, nerve position).
2. Nerve (position in fragments, function and subjective complaints).
3. TMJ (clicking, pain, max. mouth opening, excursions).
4. Occlusion (relapse, overjet, open bite).
5. Satisfaction (chewing capacity, quality of life).

Depending on the scale of measurement (dichotomous or metric) logistic or linear regression (or ANOVA) was applied, respectively. Influential parameters were quantified in terms of correlation coefficients, relative risk (RR), odds ratio (OR) or mean difference and 95% confidence intervals (95% CI).

Progression in time (before, 3, 6 and 24 months after operation) was analysed by the sign test or the paired t-test.

Due to administrative incompleteness, the total number of considered patients varies between 195 and 222. The missing values are considered to be at random.

Significance is taken at $P < 0.05$, the SAS® statistical package was used for calculations (SAS Institute Inc., Cary, NC, USA).

Results

Treatment characteristics

The mean operating time was 101 min (SD 40, median 90). A mean volume of 220 cc bloodloss was recorded (SD 123, median 200). All patients except one received anti-microbial prophylaxis (mean duration 1.4 days), 75% of the patients had steroids (mean duration 1.1. days). Impacted third molars were simultaneously removed from 60 right sides and 63 left sides in 72 patients (Table 2).

In 86% of the patients, titanium plates were used, the others had stainless steel plates. Fixation of both plates took on average 21 min operating time (SD 11, median 17.5). In four patients, one extra plate was used on the left side to secure a buccal plate fracture. In one patient, one extra plate was used on the right side. The majority of the plates (55%) were taken out within 8 months. Inflammatory reactions around the removed plates were seen in 29 sides (7% of the sides), although most of these patients had no signs or symptoms of infection.

Reoperation appeared to be necessary in five cases. In four patients readjusting of the distal fragment was done within 2 weeks. In one case reoperation took place after 11 months. All were successfully done, in that the proper planned occlusion was achieved.

According to the treatment protocol, all patients had orthodontic treatment with fixed appliances. The mean period of preoperative orthodontic treatment was 16.1 months (SD 7.4, median 14.5). The mean period of postoperative

Table 2. Relation of additional fractures during osteotomies and simultaneously removal of third molars

	Right side mandible			Left side mandible		
	Not present	Removed at operation	Total	Not present	Removed at operation	Total
No fracture	157	55	212	152	60	212
Buccal plate fracture	4	0	4	4	0	4
Lingual plate fracture	1	5	6	3	3	6
Total	162	60	222	159	63	222
Fisher's exact test		$P = 0.0085$			$P = 0.27$	

orthodontic treatment was 9.2 months (SD 5.7, median 8.0).

Additional fractures

Sagittal osteotomies without fractures occurred in 205 patients (92%). Bad splits including buccal and lingual plate fractures occurred in 20 sides (4.5% of the sides, Table 2). There were eight buccal plate fractures equally divided between left and right side. They all occurred in patients in whom no third molars were taken out at time of operation. Fractures including the condyle and/or condylar neck did not occur. The risk of a lingual plate fracture in the right mandible when third molars were simultaneously removed was significantly higher as compared to mandibles were no third molar was present. Relative risk $(RR) = 13.4$ (95% $CI = 1.8$–99, $P = 0.0085$, Fisher exact test). The RR for the left mandible $(RR = 2.5)$ was not significant ($P = 0.27$). Logistic regression showed no overall significant relation between additional fractures during osteotomy and the removal of third molars ($P = 0.23$), age ($P = 0.34$) or gender ($P = 0.48$).

Table 4. Mental nerve function evaluated at 3, 6 and 24 months follow-up

Nerve function	3 months		6 months		24 months	
	Right % ($n = 213$)	Left % ($n = 212$)	Right % ($n = 209$)	Left % ($n = 209$)	Right % ($n = 199$)	Left % ($n = 198$)
Normal	65.2	62.7	86.1	79.4	88.9	85.4
Hypersensation	1.9	1.4	1.0	1.4	0.5	1.0
Anaesthesia	2.4	3.8	1.0	1.0	1.5	1.0
Paraesthesia	30.5	32.1	11.9	18.2	9.1	12.6
Total	100	100	100	100	100	100
Number of (ab)normal nerve function (%)						
Both nerves normal	52		75		79	
One abnormal	24		17		16	
Two abnormal	24		8		5	

Table 5. Subjective perception of sensation of lower lip and chin at 3, 6 and 24 months following surgery

Sensation lower lip	3 months		6 months		24 months	
	n	%	n	%	n	%
No complaints	178	85	192	92	184	94
Hindrance	26	12	15	7	9	5
Troublesome	6	3	1	1	2	1
Total	210	100	208	100	195	100

Nerve

During the operation special attention was paid to the inferior alveolar nerve and its relation to the bone. Nerve position during the sagittal split varied considerably as demonstrated in Table 3. Analysis of variance on the position score (left and right separately) did not show a significant correlation of this nerve position with age or gender (all $P > 0.15$). Gentle freeing or removal of bone to expose the nerve was necessary in about 37%. Unintentional damage to the nerve was seen in only five sides. In one case, the surgeon attempted to repair the damaged nerve, leading to normal sensation after 24 months. Complete transection did not occur.

Information about nerve dysaesthesia over a 2-year period is presented in Table 4. The nerve function improved considerably over this period. At 3 months postoperatively, 52% of the patients had normal function of both mental nerves. This percentage increased significantly to 75% after 6 months follow-up (paired *t*-test, $P = 0.001$) and continued to increase to 79% after 24 months ($P = 0.08$).

Logistic regression to explain altered nerve function (at 3, 6 and 24 months) showed a significant effect of age (all $P < 0.01$) and nerve position (all *P*-values around 0.05), but no effect of gender or bad splits (all $P > 0.20$). The mean age at surgery of patients with normal nerve sensation after 24 months was 24 years (SD 8) while the mean age at surgery of the patients with abnormal nerve sensation after 24 months was 31 years (SD 7). Two years after surgery the relative risk for abnormal nerve function was 1.3 (left) and 3.6 (right) for patients needing manipulation of the nerve, including freeing and or chiselling.

The subjective perception of dysaesthesia of the lower lip and chin of the patients over the 2-year time period is presented in Table 5. At 3 months postoperatively 85% of the patients reported no complaints. This percentage increased to 94% at the latest follow-up. All 11 patients with complaints had an abnormal nerve function, while 17% of the patients without complaints also had abnormal nerve function. At 24 months follow-up, there was no correlation of the subjective perceptions of dysaesthesia with age ($P = 0.10$), gender ($P = 0.50$), additional fractures ($P = 0.07$) and preoperative existence of third molars ($P = 0.45$).

Table 3. Position of the mandibular nerve at surgery ($n = 222$)

Nerve position (score)	Right %	Left %
Located in distal segment but not seen after section (0)	13	15
Located in distal segment as seen after split (1)	49	48
Required freeing with elevator (2)	17	16
Required instrumentation or burring to free from bony canal (3)	20	20
Unintentionally damaged but continuous (4)	1	1
Total	100	100

Nerves with a score = 0 are seen as normal, nerve scores 1–4 are abnormal.

TMJ

Pre- and postoperative clinical findings concerning the TMJ function are presented in Table 6. A significant decrease over time from 39.2% to 30.6% in TMJ dysfunction (any clicking and or pain, left, right side) was observed (sign test, $P = 0.04$). This decrease is the result of disappearance of symptoms in patients

Table 6. Pre- and postoperative clinical findings in relation to TMJ

Clinical findings	Preoperative, $n = 222$	3 months postoperative, $n = 210$	6 months postoperative, $n = 208$	24 months postoperative, $n = 195$
TMJ-symptoms (%)				
Clicking	32.9	21.6	24.8	27.9
Preauricular pain	16.2	17.1	13.5	9.9
TMJ dysfunction	39.2	31.1	31.1	30.6
Distances: mean (SD) in mm				
Maximal mouth opening at central incisors	46.4 (7.1)	37.6 (6.8)	41.8 (7.6)	45.6 (6.6)
Protrusive movement in dental midline	9.7 (2.9)	5.7 (2.4)	6.5 (2.3)	7.5 (3.9)
Lateral excursions from dental midline	10.1 (3.0)	6.5 (2.5)	7.5 (2.4)	8.3 (2.4)

with pre-existing TMJ-dysfunction and appearance of these symptoms in patients who did not have pre-existing TMJ-dysfunction. After 24 months signs of TMJ-dysfunction appeared in 22% of the patients without preoperative dysfunction and remained in only 44% of the patients with preoperative TMJ-dysfunction. For clicking the decrease was not significant ($P = 0.20$). Preauricular pain reduced significantly from 16.2 to 9.9% (sign test, $P = 0.05$). There was no significant correlation found between TMJ dysfunction symptoms and age (logistic regression, all $P > 0.20$) and gender (all $P > 0.15$) at the different moments.

In the relapse group ($n = 35$, see next section) 36% of the patients had TMJ dysfunction signs and symptoms. This percentage did not change significantly after surgery.

Maximal mouth opening returned to normal postoperatively. The slight difference in opening between the preoperative and 2 years postoperative period was not significant (paired *t*-test, $P = 0.20$). Significant limitation of movement after 2 years was seen in the protrusive and lateral excursions of the mandible (paired *t*-test, both $P = 0.0001$). With regard to mouth opening and mandibular excursions, age and gender appeared not to be important factors (regression analysis, explained variance maximal 6%).

Occlusion

Table 7 presents the occlusal relapse over time. The clinical assessment of the occlusion after 3, 6 and 24 months revealed the following:

- A stable occlusion without appreciable relapse was seen in 95% of the patients at 3 months, 93% at 6 months and 84% at 24 months postoperatively.
- At 24 months, 35 patients showed relapse (relapse group); 25 patients (11%) had a horizontal relapse of 1–3 mm, whilst 10 patients (5%) had more than 3 mm horizontal relapse, as compared to the immediate postoperative position.
- Anterior vertical open bites at 24 months occurred significantly more in the relapse group (28%) compared to 1.3% in patients without occlusal relapse (chi-square test $P = 0.001$).

Logistic regression showed no significant influence of gender, maximal mouth opening, excursions, additional fractures and TMJ-dysfunction on relapse after 24 months (all $P > 0.20$). Only age was an explanatory factor. The mean operation age of the relapse group was 20.7 years (SD 6.7) and the stable occlusion group had a mean operation age of 26.1 years (SD 8.2).

Satisfaction

Patient satisfaction and chewing capacity are presented in Tables 8 and 9. Ninety-four percent of the patients were satisfied or highly satisfied. This percentage remained constant during the follow-up period, while the group ''highly satisfied'' increased with 15%. No correlation was found between patient satisfaction and age, gender or the appearance of postoperative relapse (Pearson correlation test, all $P > 0.05$).

Improvement of the chewing capacity 2 years after surgery compared to that before the operation was reported by 61% of the patients. Three patients claimed worsening.

No correlation was found between chewing capacity and age, gender, additional fractures during osteotomy, or the appearance of postoperative relapse at the three moments (Pearson correlation, all $P > 0.05$). However, the TMJ dysfunction had a significantly negative influence on chewing capacity at 3 and 6 months postoperatively (both $r = -0.26$, $P = 0.0001$).

The questions whether the operation had an influence on social life, career or study was positively answered by approximately half of the patients. At the 3 months postoperative evaluation 10 patients claimed a negative influence. This number decreased to three patients after 2 years (Table 10). No significant correlations were found between the influence of the operation on social life career or study with age, gender, postoperative nerve disturbance, additional fractures during osteotomy or even relapse (Pearson correlation test, all $P > 0.05$), while there was a significant negative influence of TMJ dysfunction at the 3 moments ($r = -0.14$ to -0.21, all $P < 0.05$).

Knowing the procedure, about 87% of the patients ''would do it all over again'' (Table 11). This percentage remained constant during the whole follow-up period. No significant correlations were found with age, gender, postoperative nerve disturbance, additional fractures during osteotomy or relapse (Pearson correlation test, all $P > 0.05$). There was no significant correlation found with postoperative relapse.

Table 7. Occlusal relapse at 3, 6 and 24 months follow-up

	3 months	6 months	24 months
No relapse	212 (95%)	207 (93%)	187 (84%)
Relapse	10 (5%)	15 (7%)	35 (16%)
Total	222	222	222

Table 8. Patients satisfaction concerning facial appearance following surgery

Facial appearance	3 months		6 months		24 months	
	n	%	*n*	%	*n*	%
Not satisfied	3	1	9	4	10	5
Does not know	10	5	6	3	5	3
Satisfied	98	46	86	40	59	29
Highly satisfied	102	48	112	53	128	63
Total	213	100	213	100	202	100

Table 9. Patients satisfaction concerning chewing capacity after surgery compared to that before

Comparison of chewing capacity before and after surgery	3 months		6 months		24 months	
	n	%	*n*	%	*n*	%
Better	102	48	119	56	123	61
Same	90	42	86	40	76	38
Worse	21	10	8	4	3	1
Total	213	100	213	100	202	100

Table 10. Patients opinion concerning the influence of the operation on social life, career and study

Influence of the operation on social life, career and study	3 months		6 months		24 months	
	n	%	*n*	%	*n*	%
Positive	83	39	92	44	97	48
Negative	10	5	4	2	3	1
No influence	118	56	114	54	102	51
Total	211	100	210	100	202	100

Table 11. Patients satisfaction concerning the whole procedure

Knowing the procedure ''would you do it all over again''	3 months		6 months		24 months	
	n	%	*n*	%	*n*	%
No	29	14	24	11	27	13
Yes	181	86	188	89	173	87
Total	210	100	212	100	200	100

Discussion

The BSSO is currently the most widely used surgical procedure for the management of mandibular hypoplasia. Relatively few studies are available addressing aspects like stability, nerve and TMJ function and patient satisfaction[1,6,26,43,50] over a 2-year period, with enough patients to draw meaningful statistically supported conclusions. A multicentre study was thought to be necessary in order to accumulate enough patients in a reasonably short period for meaningful data collection. The large number of patients followed up in this study and the fact that all had the same type of osteotomy and were operated under similar conditions makes it acceptable to draw general conclusions. The number of patients from the various centres, unfortunately, is not well balanced. Different departments imply different operators, qualified surgeons as well as trainees. Therefore, the treatment and examination protocol was kept as simple as possible. Still, a lot of data had to be filled out by the co-operating surgeon, which led to missing data in several patients.

Some 30 years ago surgeons[32,46] started to use rigid skeletal fixation with either bicortical screws or miniplates, which allows for early postoperative mobilisation.

Although bicortical screws are probably just as effective as miniplates in stabilising the fragments there are some inherent disadvantages:

- need for (small) extra oral incisions for transbuccal placement of the screws;
- chance of rotation of the mandibular condyles due to compression of the proximal fragments;
- risk of harming the inferior alveolar nerve by placing the bicortical screws or by compressing the nerve between the bony fragments.

Yet, most surgeons tend to prefer the use of bicortical screws over miniplates[1,3,6,10,13,18,28,50,54].

It was, therefore, felt that there was a need for a prospective study of a large group of patients stabilised with miniplates and monocortical screws to gain more information on stability and other aspects concerning the procedure.

The relative high incidence of bad splits as compared to the results of Akhtar & Tuinzing[2] can probably be attributed to the fact that the operations were carried out in teaching hospitals where trainees have done most of the surgery. From the data presented it appeared that the presence of third molars did not have a correlation with the incidence of buccal plate fractures but lingual fractures on the right side were statistically more frequently seen when third molars were simultaneously removed. Overall the additional fractures did not result in a higher incidence of nerve dysaesthesia or higher incidence of skeletal relapse (see part II).

The suggestion of Precious et al.[40], that ''mandibular fractures may occur with greater frequency when the impacted third molar teeth have been removed at least 6 months before sagittal split osteotomy as compared with that when third molar teeth are removed concomitant with sagittal-split osteotomy'', seems to support our findings with regard to the results with buccal plate fractures. Our results are in line with those of Mehra et al.[31]. They found an incidence of 3.2% of unfavourable splits (eight) in the group patients with concomitant removal of impacted third molars of which seven fractures extended through the extraction socket in the distal segment. This is also in accordance with our results where exclusively lingual plate fractures were seen when third molars were concomitantly removed. Reyneke et al.[41], however, found all fractures in the proximal and/or distal segments (4 out of 70 patients, 137 splits) occurring in the younger age group (<20 years) with unerupted third molars present at the time of surgery.

In the present study logistic regression showed no overall significant relation between additional fractures during osteotomy and the removal of third molars or age. When using miniplates and monocortical screws to fix the fragments, lingual fractures of the distal fragment will not compromise the result. This undoubtedly is an additional advantage of this technique.

The incidence of temporary and permanent nerve dysaesthesia is similar to other findings[10,39,54]. There appeared to be a tendency towards complete recovery of sensation. Recovery appeared to be quicker in the young age group. Although 21% of patients had some form of dysaesthesia only 5% reported some hindrance (Table 5).

The data about nerve dysaesthesia, of course, lack accurate assessment using objective criteria. In the context of a multicentre study, however, this was thought to be not feasible. WESTERMARK et al.[52], however, concluded that there is a relatively good positive correlation between subjective evaluation and objective assessment of the sensory nerve function of the lower lip and chin after BSSO. It appears from the present study that patients are quite tolerant since their perception was slightly more positive than the findings of the clinicians. Nerve dysaesthesia is probably related to a number of factors.

First, the nerve is exposed over a fairly large area and thus, probably deprived from the ''vasa nervorum''. This may result in some local ischaemia with subsequent damage to the axons. This may particularly be the case when the Dal Pont modification is used since this gives rise to more exposure of the nerve. This theory is in keeping with the increased relative risk factors as found when manipulating the nerve. Second, advancement of the distal fragment causes the nerve to stretch. The nerve will, therefore, not be fully located in its bony canal. This, in conjunction with rigid fixation, may cause some damage to the nerve by impingement between bony fragments. It is hypothesised that this may be even worse when bicortical screws are used to fix the fragments[28]. TEERIJOKI-OKSA et al.[48] found decreased sensory nerve action in 4 out of 20 cases when the screws were tightened. These screws may also directly damage the nerve when drilling the holes[7,27,31,32,47]. Comparable studies using screw fixation are, however, not available. Third, as suggested by AUGUST et al.[3] and WESTERMARK et al.[51] there might also be a correlation with age. This could be explained by the decreased capacity of the axons to regenerate after damage with increasing age. The results of this study showed that a significant difference existed between the younger and the older group with regard to complete recuperation of nerve function. At 24 months, however, the subjective perception of dysaesthesia did not differ anymore.

TEERIJOKI-OKSA et al.[48], who performed intraoperative nerve conduction recording, revealed that there probably is also a possibility of damage during the operative procedure on the medial side of the mandibular ramus. These authors found a clear tendency towards more disturbed inferior alveolar nerve conduction with longer duration of these procedures.

The relatively short period of time (10 min per side) required for the placement of miniplates relates well with the time needed for other means of fixation. Inflammatory reactions around the plates and screws necessitating their removal occurred in a relatively low percentage of sides (7%). This finding is in line with the findings of MOSBAH et al.[34]. They found a removal rate of 9% for the orthognathic cases (Le Fort I osteotomy) and infection and/or wound dehiscence were the predominant causes for plate removal in spite of the routine use of prophylactic antibiotics.

In our study these inflammatory reactions were usually apparent when removing the plates after several months, although early infections occurred, necessitating early removal. In the relapse group ($n = 35$) only five sides with inflammatory reactions were seen: a relationship with postoperative relapse could not be proven.

Clinical assessment of occlusion revealed stable results without appreciable relapse in 95% of patients at 3 months and 84% at 24 months postoperatively.

The results on occlusion (Table 7) are in keeping with those reported by MCDONALD et al.[30], $36/45 = 80\%$ and SCHEERLINCK et al.[43] $39/103 = 90\%$.

Relapse may be dento-alveolar, skeletal or due to morphological changes of the condyle. This will be further addressed in part II of this series.

From the data presented (Table 6) it appears that in 56% of the patients with pre-existing TMJ dysfunction, their signs and symptoms disappeared. The use of a soft diet and guidance elastics, usually worn for a period of 6 weeks postoperatively, as well as the initially limited postoperative mouth opening and the improved occlusion may have resulted in a decrease of TMJ-dysfunction. On the other hand, 22% of patients, who had no preoperative TMD signs or symptoms ($n = 135$), developed preauricular pain or clicking postoperatively.

This explains the final figure of 30.6% as depicted in Table 6. SCHEERLINCK et al.[43] found that 12% of patients experienced aggravation of pain and dysfunction symptoms. FEINERMAN & PIECUCH[15] did not find demonstrable long-term differences between rigid and non-rigid fixation methods with respect to mandibular vertical opening, crepitance and temporomandibular joint pain.

DE KANTER [25] found in the Dutch adult population, that 18.3% of the men and 24.4% of the women reported mild or severe signs and symptoms of TMD and he concluded that only approximately 4% of the subjects, reporting signs or symptoms of TMD, intended to seek treatment. The reported percentage of patients that had signs or symptoms of TMJ dysfunction postoperatively is hardly different from these figures.

It was thought not to include muscle pain as a separate item to examine in this study because it is hard to evaluate in an objective manner in a multicentre setting. The authors admit, however, that it would have been a valuable parameter in assessing TMJ dysfunction.

Maximum mouth opening had returned to its original level in the total patient group and, therefore, could not be a prognostic sign of TMJ remodelling or resorption. Lateral and protrusive movements did not return to their original levels (Table 6), but apparently did not cause patients to complain.

The large standard deviations as shown in Table 6, are most likely due to measuring errors. Large numbers will compensate for this phenomenon and the trend seen in the postoperative period is obvious. The same trend is seen in the recuperation of movements (opening, protrusive and lateral excursions) in the total group of patients ($n = 222$) as well as in the relapse group ($n = 35$).

The mean period of postoperative orthodontic treatment was 9.2 months but this was longer in the relapse group (11.8 months). It appears that it was tried in several patients to compensate for the relapse by orthodontic treatment.

It is difficult to define satisfaction or dissatisfaction. Many physical, psychological and social aspects are involved.

Factors related to satisfaction are psychological condition, unrealistic expectations, external or hidden motives and information absorption[22]. Factors attributable to the surgeon are insufficient presurgical preparation, inability to listen empathetically, or hasty evaluation. Communication is an essential aspect. According to HAKMAN[20] postoperative satisfaction is a controversial concept not to be used.

Yet, in the present study satisfaction was repeatedly checked in a prospective manner. As 92% of patients were satisfied or highly satisfied concerning their facial appearance, this is better than one would expect based on for instance occlusal relapse or TMJ dysfunction symptoms. Analysis of patients' experiences with surgery revealed that application of internal wire fixation and IMF had a negative impact[22].

Rigid internal fixation, as used in the present study, allows patients to open their mouth soon after surgery. This might have a positive influence on overall satisfaction[37]. FINLAY et al.[16] pointed out that the most common complaint was insufficient information about arch bars and IMF.

The fact that 94% of patients had no complaints about nerve dysaesthesia is somewhat surprising, because only 79% of patients had normal sensation in both nerves (Table 4).

There appears to be a great adaptability and tolerance towards disturbance of sensibility and in general it had only a minimal influence on satisfaction[11,54].

The response to questions about complications are less dependent on the seriousness of the disorder, but more on the mental state of the person concerned and the motivation for having the correction done[20].

The results on patient satisfaction, as presented in Tables 8–11, appeared to support the results of previous studies[4,9,19,22,45].

In conclusion the clinical parameters found in this study indicate that the BSSO to correct a mandibular hypoplasia and stabilized with miniplates and monocortical screws is a relatively safe and reliable procedure, giving rise to a high degree of patient satisfaction.

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