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Title: Bilateral sagittal split osteotomy by the splitter-separator technique: technical aspects, safety, and predictability
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Discussion and future perspectives
The aim of this thesis was to prove the safety and predictability of bilateral sagittal split osteotomy (BSSO) performed with the splitter–separator technique. This was achieved through the following analysis:

1. Systematic review of the incidence of NSD of the IAN (chapter 2)
2. Cadaveric studies of fracture patterns (chapters 5 and 6)
3. Prospective multicenter human study of the incidence of hypoesthesia of the IAN (chapter 3)
4. Retrospective controlled investigation of the stability of BSSO during adolescence (chapter 4)
5. Analysis of the incidence of bad splits (chapter 7).
Systematic review of the incidence of NSD of the IAN

The systematic review was aimed at revealing the effect of the splitting technique on the incidence of postoperative NSD. Most full-length articles identified by a specific PubMed search were excluded because of their failure to describe the splitting technique in sufficient detail or meet the inclusion criteria. When the selected articles were divided into 3 groups (no chisel use, undefined chisel use, and explicit chisel use), higher incidence of postoperative NSD was observed in the chisel group (4.1% and 18.4% vs. 37.3%). In addition, modifications with the use of chisels resulted in rather high mean incidences of NSD (12.8–32%) after BSSO. Of course, the etiology of IAN damage during surgery is multifactorial.

Medial dissection has also been described as a cause of impairment of the IAN. A few intraoperative studies showed decreased nerve function during medial dissection to identify the lingula or mandibular foramen.1-3 In these cases, however, total recovery was achieved either during surgery or within a short period thereafter. In addition, a decrease in intraoperative nerve function may result from damage to the IAN by sharp instruments.1 The intraoperative technique is likely to play an important role, especially when chisels are used along the IAN (“cortical shaving”), a view supported by other authors.4

Therefore, chiseling is considered as a risk factor for postoperative NSD, while spreading and prying are likely to be safer.5-8

Cadaveric studies of fracture patterns

A. Pig mandibles

The pilot study using 10 pig mandibles showed that prying and spreading in the revised BSSO technique and placement of the horizontal osteotomy in the concavity of the mandibular foramen lead to a predictable fracture pattern and can minimize the risk of damage to the IAN and bad splits. The technique is easy to perform and learn. Furthermore, it could lower the incidence of postoperative hypoesthesia, as suggested in earlier studies.6,8,9 The pig model allowed thorough inspection of the lingual splitting patterns after BSSO. Further, superior visibility of the mandibular foramen was achieved, compared with the degree of visualization in the clinical setting.

The pig model has been used successfully in earlier studies.10-14 because of the similarities between the pig and the human mandible, but caution is necessary when extrapolating the results. Pigs have longer mandibles and more teeth than humans. The vertical osteotomy was placed posterior to the most distal molar in the pig mandible in the pilot study, which seems to be comparable to the osteotomy site in humans. Unerupted molars were present in all the mandibles, but the fracture line
always ran downward and did not follow the follicular space of these molars. In previous clinical studies, BSSO was performed in the presence of third molars and no significant increase in the incidence of bad splits or damage to the IAN was noted when compared with BSSO after third molar removal. Further, the pig mandibular canal is larger and has a pronounced divergence at the mandibular foramen. The mandibular angle contains more cortical bone and less cancellous bone, which can influence the fracture pattern. However, in a normal split, this part of the mandible is located in the proximal segment and will not influence the fracture pattern.

The fracture lines in this study were almost optimal, running nearly perpendicular from the inferior part of the vertical osteotomy site to the inferior border and along the mandibular canal to the mandibular foramen. Many (80% of the fractures) seemed to follow the path of least resistance, probably because the separator was introduced immediately at the inferior border during the unfolding of the split, therefore avoiding the inferior bone cut described by Schoen et al. No sharp bone fragments pointed toward the mandibular canal. The reported rate of bad splits ranges from 0.5% to 5.4%, but bad splits were not observed in this study. Only one unfavorable fracture occurred during the splitting process, where the nerve was still attached to the proximal segment because the fracture line ended just anteriorly to the mandibular foramen. None of the other splits resulted in the IAN being attached to the proximal segment.

Plooij et al. described 4 lingual fracture patterns on the basis of the lingual splitting scale (LSS): LSS1 or “true” Hunsuck split, LSS2 or Obwegeser split, LSS3 or split through the mandibular foramen, and LSS4 or other splitting type (i.e., bad split). Performing the Hunsuck technique, they stated that the horizontal osteotomy should be placed behind the mandibular foramen and a small curved osteotome should be used to fracture the bone behind the mandibular foramen and separate the cortices. The medial cut should be high enough to allow space for the osteotome above the mandibular foramen. In contrast, in the revised BSSO technique, this cut is extended to the concavity of the mandibular foramen, just behind the anterior border of the lingula and just above the entrance of the mandibular foramen.

Although Plooij et al. intended to perform a “true” Hunsuck split every time, only 51% of the splits were classified as LSS1; in 32% of the cases, an LSS3 pattern was obtained, as is desirable in the revised BSSO technique. They emphasize further dorsal placement of the horizontal osteotomy site, increasing the number of “true” Hunsuck splits and decreasing the number of lingual fractures through the mandibular foramen. This is in line with the findings of the pilot study. Of note, Hunsuck advised that the horizontal osteotomy should be made through the cortical bone superior to the lingula, which is not located as posterior as suggested by Plooij et al. Therefore, BSSO by the splitter–separator technique ensures a consistent fracture pattern in pig mandibles. A fracture running through the mandibular foramen and
along the mandibular canal could follow the path of least resistance. Placement of the horizontal osteotomy in the concavity of the mandibular foramen (i.e., more anteriorly) could mean less mobilization of the IAN.

**B. Human mandibles**

The human cadaveric study was conducted to evaluate the revised BSSO technique further. The hypothesis was that the lingual fracture line will run through the mylohyoid groove or mandibular canal, as the possibly weakest region of the mandible, and end in the mandibular foramen. However, the results did not prove the hypothesis. Some splits ran along the mandibular canal (35%) and/or mylohyoid groove (30%), and the concavity between the mandibular foramen and the inferior border defined a relatively consistent fracture path. However, an LSS3 split was associated with the fracture running through the mylohyoid groove. The mandibular canal or dental status showed no correlation within this limited dataset. Inferior border fractures were classified almost equally into groups 1, 2, and 3 (0 mm, 1–10 mm, and >10 mm, respectively). No buccal fracture lines occurred in group 4. These results could explain why only a few lingual fractures were associated with the mylohyoid groove or mandibular canal. Instead of running more cranially, the fracture ran through the inferior border. Furthermore, the absence of bad splits is favorable in comparison with the series of Plooij et al.\textsuperscript{15} In their study, 3% of the fractures were bad splits, in keeping with the literature. No bad split occurred in the cadaveric study, which is well below the reported rate (mean, 4.6% per patient).\textsuperscript{18}

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Comparison of the lingual fracture patterns between the human cadaveric study and the Plooij et al.\textsuperscript{15} study.</th>
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</thead>
<tbody>
<tr>
<td>Category</td>
<td>Human cadaveric study</td>
</tr>
<tr>
<td>LSS1 (“true” Hunsuck split)</td>
<td>25%</td>
</tr>
<tr>
<td>LSS2 (Obwegeser split)</td>
<td>2.5%</td>
</tr>
<tr>
<td>LSS3 (split through the mandibular foramen)</td>
<td>72.5%</td>
</tr>
<tr>
<td>LSS4 (bad split)</td>
<td>0%</td>
</tr>
</tbody>
</table>

As shown in Table 1, the frequencies of the splits differ between the Plooij et al.\textsuperscript{15} and the current studies. The more anterior split (i.e., LSS3) was common in the current study. Plooij et al. also stated that the chance of splitting the ramus according to the Hunsuck description increases from 44% to 63% when the horizontal osteotomy ends behind the anterior border of the mandibular foramen and the chance of splitting...
through the mandibular canal is significantly reduced from 43% to 11%. In the human cadaveric study, the horizontal osteotomy in the mandibular foramen resulted in 72.5% of the lingual fractures ending in the mandibular foramen, with a 6-fold higher chance when the lingual fracture ran along the mylohyoid groove. The relationship with the mandibular canal could not be explored because of the limited sample size.

Accordingly, the horizontal osteotomy need not be placed dorsally to the mandibular foramen and/or cortical separation by chiseling cranially and dorsally from the mandibular foramen is unnecessary to obtain a predictable split. Moreover, with a more anterior split, less splitting is required in the sagittal plane, reducing instrumentation along the IAN, trauma to the IAN, and operative time.

The value of cadaveric studies of splitting techniques may be limited by the use of formalinized mandibles and higher frequency of edentulous mandibles than in the clinical setting. Further, in this series, only 2 hemi-mandibles contained molars, which might have influenced the fracture patterns. The increased gonial angle in older and edentate subjects is also controversial, and the IAN position could vary depending on the degree of alveolar ridge resorption. However, according to Oth et al.\textsuperscript{19}, the use of mandibles from older individuals remains a suitable option for such studies. Nonetheless, the results should be interpreted cautiously, because the degree of visualization is poorer clinically.

In conclusion, the hypothesis that the mandibular canal and/or mylohyoid groove act as the path of least resistance was only partially confirmed. Furthermore, 72.5% of the lingual fractures ended in the mandibular foramen, with a 6-fold chance of a fracture in the mandibular foramen when it ran along the mylohyoid groove. The study also showed that the revised BSSO technique does not increase the incidence of bad splits, implying its safety and predictability.

**Multicenter human study of the incidence of hypoesthesia of the IAN**

In the 2-year prospective controlled multicenter study, 2 clinics used the chisel–mallet technique and the other 2 used the splitter–separator technique to prove that the revised technique is associated with a lower rate of hypoesthesia of the IAN. The percentage of SSOs that resulted in IAN hypoesthesia after 1 year was 5.1%, and 8.9% in the 158 patients who did not undergo concomitant genioplasty. Considering that the reported rates of hypoesthesia are rarely under 10%\textsuperscript{20-24} and the mean incidences of NSD with undefined and explicit use of chisels per side are 18.4% and up to 37.3%, respectively\textsuperscript{3,25-27}, the clinical findings confirm the hypothesis of lower incidence of hypoesthesia of the IAN by the splitter-separator technique. Of note, a standardized form was provided to all the clinics to gather information before and after the operation.
Unfortunately, despite all efforts, the 2 clinics that used the chisel–mallet technique did not supply data at all or provided insufficient data, so the findings of the control group were not analyzed. However, the clinics that used the splitter–separator technique supplied sufficient data of 172 patients, with results of postoperative NSD. Therefore, the research was published as a prospective multicenter cohort study.

No association between persistent hypoesthesia at 12 months after BSSO and perioperative third molar removal was found. This observation is consistent with that of Reyneke et al. 28, who reported that although IAN recovery is slower in patients with unerupted third molars at the time of surgery, their recovery rates at 1 year are equal to those without unerupted third molars.

NSD was tested by both objective and subjective measurements, because the prevalence of hypoesthesia of the IAN varies according to the type of assessment. 29 An NSD noted by either test was recorded as a positive finding. This methodology avoids underestimation of hypoesthesia.

This study therefore showed that BSSO performed with a sagittal splitter and separators leads to fewer injuries of the IAN compared with the literature, regardless of the presence of unerupted third molars.

Stability of BSSO during adolescence

While correcting skeletal class II malocclusion, stability of the surgical procedure is important. In the retrospective controlled study to evaluate relapse in adolescents and adults (control) with the revised BSSO technique for mandibular advancement, only 10.9% of the adolescents showed relapse. The higher relapse rates in previous studies 30-32 could be explained by the different surgical technique, namely mandibular advancement with wire fixation, which is a less-stable method 33. The control group showed a relapse rate of 16.4% after 1 year. The reported 1-year relapse rates of mandibular advancement by BSSO in adults are inconsistent: from 20–30% at B point 34-36 to only 1% 37 or even anterior movement. 38

Although not significant, relapse occurred less frequently in the adolescent group. The apparent difference could be explained by the fact that any relapse would be partly compensated by postoperative mandibular growth, implying that young age could prevent relapse. The higher number of Le Fort I procedures (and further mandibular advancement) in the control group could also explain the difference in relapse rates. 39 The influence of the mandibular plane angle on relapse has been shown in several studies 40,41, but no relationship was detected between the preoperative mandibular plane angle and the horizontal relapse following surgery.

In a series of adult patients, less-stable outcomes were obtained after greater mandibular advancement. 34 Although the retrospective study included a relatively
small number of patients and involved less mandibular advancement, its results indicate that the revised BSSO technique is a stable procedure during adolescence for patients who require “normal” advancement of the mandible.

Analysis of the incidence of bad splits

The rate of bad splits during SSO ranges from 0.5% to 5.4%.\textsuperscript{7,42} Therefore, the rate of 4.5% during the splitter–separator BSSO technique in the prospective study is within the reported range. In the retrospective study of all patients treated with the revised BSSO technique at the Leiden University Medical Center, the rate of bad splits was 2% (17 of 851 SSOs in 427 patients), which is consistent with the average reported in the literature (2%). Therefore, the revised technique does not raise the risk of bad splits when compared with chiselling.

The exact combination of factors that result in a bad split is unknown. Older patients have an increased risk of bad split.\textsuperscript{43} However, no relationship between age and bad splits was found in the retrospective study. Further, no association with patient gender and surgeon’s experience has been reported, consistent with the present findings.\textsuperscript{44-46} Third molar removal before BSSO is controversial. Some have suggested that if third molars need to be removed, extraction should be performed at least 6 months before orthognathic surgery.\textsuperscript{6,44,47,48} Others have advised removal of third molars simultaneously with orthognathic surgery to reduce complications such as hypoesthesia.\textsuperscript{7,49,50} In the present patients, significantly more bad splits during BSSO occurred among those who underwent simultaneous removal of third molars. In our clinic, most third molars that were present during the last 5 years preoperatively were removed at the time of BSSO because separate removal was considered to increase the risk of damage to the IAN (when a relationship with the IAN exists) and be inconvenient for the patient (1 combined procedure instead of several procedures). One would expect bad splits to occur more often during BSSO by less-experienced surgeons such as residents. However, no such differences were found between senior staff members and residents, probably because the latter were closely supervised during BSSO and corrected when necessary. Therefore, the splitter–separator technique does not raise the risk of bad splits compared with the use of chisels, but a slight increase is possible when third molars are present during BSSO.

Conclusion

BSSO with the use of splitters and separators is a safe and predictable technique, resulting in lower rates of NSD of the IAN than the chisel–mallet technique, and providing a consistent splitting pattern without increasing the rate of bad splits.
Furthermore the results show that a BSSO performed during adolescence is a relatively stable procedure which does not show more relapse than a young adult group.

**Future perspectives**

An important feature in BSSO is control of the lingual fracture. A randomized controlled study with CBCT to compare the conventional and the revised techniques would reveal the determinants of the fracture pattern. With greater accessibility to CBCT in different maxillofacial surgery departments in the Netherlands, this comparison should be easier to perform in a multicenter design.

A controlled cadaveric study would show the differences between both techniques and elucidate the influence of differently placed cuts on the lingual fracture pattern in both the techniques. This assessment could also be achieved in the clinical setting, where the use of instruments such as a piezotome could enable easier and more controlled fracturing of the mandible.

Finally, the different sequelae related to concomitant removal of third molars should be explored.


DISCUSSION AND FUTURE PERSPECTIVES