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## **Bilateral sagittal split osteotomy : risk factors for complications and predictability of the splitter-separator technique**

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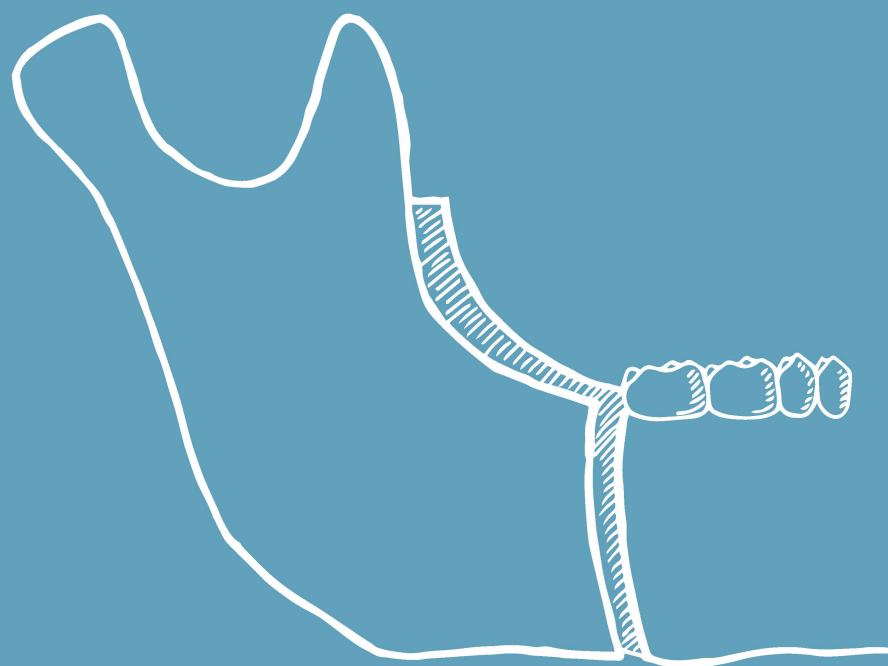


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## CHAPTER 2

# Risk factors for common complications associated with bilateral sagittal split osteotomy, a literature review and meta-analysis

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This chapter is based on the manuscript:

Verweij JP, Houppermans PNWJ, Gooris PJJ, Mensink G, van Merkesteyn JPR

Risk factors for common complications associated with bilateral sagittal split osteotomy, a literature review and meta-analysis

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## ABSTRACT

The most common complications that are associated with bilateral sagittal split osteotomy are: bad splits, postoperative infection, removal of osteosynthesis material, and neurosensory disturbances of the lower lip. Particularly in elective orthognathic surgery, it is important that surgeons inform their patients about the risk of these complications and attempt to minimise these risks. The purpose of this literature review and meta-analysis is to provide an overview of these common complications and their risk factors.

After a systematic electronic database search, 59 studies were identified and included in this review. For each complication, a pooled mean incidence was computed. Both the pooled study group and the pooled 'complication group' were analysed.

The mean incidences for bad split (2.3% per sagittal split osteotomy; SSO), postoperative infection (9.6% per patient), removal of the osteosynthesis material (11.2% per patient), and neurosensory disturbances of the lower lip (33.9% per patient) are reported. Regularly reported risk factors for complications were the patient's age, smoking habits, presence of third molars, the surgical technique and type of osteosynthesis material. This information may help the surgeon to minimise the risk of these complications and inform the patient about the risks of complications associated with bilateral sagittal split osteotomy.

## INTRODUCTION

Bilateral sagittal split osteotomy (BSSO) is an orthognathic surgical technique used to treat mandibular deformity. It was first described by Trauner and Obwegeser in 1957.<sup>1, 2</sup> Soon after its introduction, several important and widely used modifications had been suggested by Dal Pont, Hunsuck, and Epker.<sup>3-5</sup> Since then, this well-designed and valuable technique has become an important cornerstone of maxillofacial surgery. Nevertheless, it is associated with several complications, such as unfavourable fracture patterns (bad splits), postoperative infection, the need for postoperative removal of osteosynthesis material, and neurosensory disturbances (NSD) of the lower lip.<sup>6-9</sup> Because of the elective nature of BSSO, it is important to reduce the risk of complications as much as possible. Furthermore, preoperative counselling and informing the patient are considered to be of paramount importance in surgery. The surgeon therefore should know the general incidence of common complications associated with the procedure and should be aware of the possible risk factors for these complications. This allows for patient-specific counselling prior to performing BSSO and enables surgeons to evaluate their work critically and maximise the chance of success.

The aim of this review is to provide an evidence-based overview of the incidence of common complications associated with BSSO and to discuss the risk factors related to these complications. This review includes the occurrence of bad splits, postoperative infection, removal of symptomatic osteosynthesis material, and permanent neurosensory disturbances of the lower lip. The impact of common risk factors, such as the patient's age, gender, smoking habits, the presence of mandibular third molars, and concomitant procedures, were analysed and discussed. This information could help surgeons to prevent these complications.

## MATERIAL AND METHODS

*This review was registered on <http://www.crd.york.ac.uk/PROSPERO> as CRD4201502034 and conducted in accordance with the PRISMA statement.<sup>10</sup>*

### Study identification

An electronic search of Pubmed, Embase, and World of Science databases was performed. Keywords were used with their truncations and the corresponding Medical Subject Heading (MeSH) terms in various combinations. Keywords included: risk, risk factors, complication, intraoperative complications, postoperative complications, orthognathic surgery, mandibular advancement, sagittal ramus split, sagittal split osteotomy, BSSO, bad split, unfavourable fracture, lingual split pattern, lingual fracture line, infection, device removal, removal of osteosynthesis material, screws, plates, inferior alveolar nerve, neurosensory disturbances, hypoesthesia, and sensory function.

Prospective and retrospective original research papers describing clinically observed intra-operative or post-operative complications associated with BSSO (bad splits, infection, removal of osteosynthesis material, and neurosensory disturbances) were included. In vitro studies and animal studies were excluded. Letters to the editor and conference abstracts were excluded because of the lack of detail in the description of materials and methods. Non-English articles were also excluded.

This review aimed to analyse BSSO performed according to modern surgical techniques. Therefore, articles published before 1985, using less modern techniques, were excluded. Postoperative infection and removal of hardware were investigated after BSSO with rigid fixation, using titanium osteosynthesis material. Studies that investigated other non-standard fixation techniques or that used bioresorbable fixation materials were excluded. If the operative technique was not clear, or if different orthognathic operative techniques were analysed together without identifying the BSSO-specific outcome, the paper was excluded.

In order to prevent inclusion of small, less coherent studies, the minimum number of patients for inclusion in this review was 25 subjects (50 SSOs) for assessing short-term complications (bad splits, infection, and removal of osteosynthesis material) and 50 subjects (100 SSOs) with a minimal follow-up of 1 year for assessing long-term complications (neurosensory disturbances). With regard to neurosensory disturbances, studies using subjective tests (such as questionnaires, light-touch detection, etc.) were included, as these are reported to show the highest sensitivity for detecting neurosensory disturbances. Studies using only quantitative analyses of NSD (i.e., threshold tests) were excluded.

### Data extraction

Articles that were identified through the electronic database search were first screened based on title and abstract. If the title or abstract mentioned one of the aforementioned postoperative complications associated with BSSO, the full-text article was obtained. Studies that met the inclusion criteria were analysed. The reference lists of the included studies were searched for possible additional relevant papers.

All data were recorded in an individual summary of the study and subsequently entered in a database. Demographic data of the patient groups were collected, including the number of patients, their mean age (with age range), distribution of gender, and smoking habits. Details of the surgical procedure, including the presence of mandibular third molars, the surgical technique used, and the method of fixation applied, were also noted. The incidences of different complications (bad splits, infection, removal of osteosynthesis material, and neurosensory disturbances) were recorded. Intra-operative complications (bad splits) were reported as the incidence per SSO. Postoperative complications were reported both as the incidence per SSO and the incidence per patient. When

a specific risk factor for one of the abovementioned complications was discussed in the study of interest, this was recorded in the summary of this study, and is subsequently reported in this review.

### **Quality assessment of the studies**

The methodological index for non-randomised studies (MINORS) tool was used to assess the quality of the selected studies.<sup>11</sup> Information regarding the methodological items for non-randomised studies was recorded on predesigned forms. This included the aim of the study, the method for inclusion and follow-up of patients, the protocol used for data collection, the method used for evaluation of the endpoints, the risk of bias, and the study size, including loss to follow-up. For comparative studies, the equivalence of the compared groups and statistical analyses were also evaluated. Each item was scored as 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). The maximum MINORS score was 16 points for non-comparative studies and 24 points for comparative studies.

### **Meta-analysis**

The patient groups of the included studies were analysed. A subdivision was made based on the four complications of interest (bad splits, infection, removal of osteosynthesis material, and NSD of the lower lip). Data from the study groups were pooled to compute a mean pooled incidence for each complication. A Forest plot was computed for the reported incidence of bad split per SSO, and for the incidences of infection, removal of osteosynthesis material, and NSD per patient.

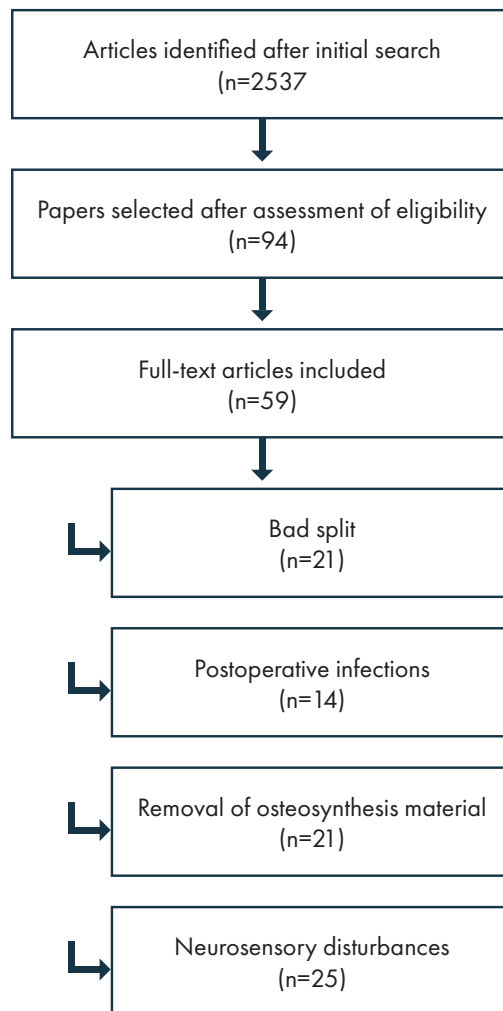
For each study group, the mean age of the patients, distribution of gender, presence of third molars, and smoking habits were reported. Surgical specifications, such as the surgical technique and the type of fixation material used, were also noted in the database when they were reported in the included studies.

The distribution of age, gender, presence of third molars, and smoking was reported for the pooled study group and for the 'complication-group' in order to facilitate a simple comparison of the distribution of possible risk factors for each complication. The individual studies and their findings regarding risk factors for complications of interest are discussed.

## **RESULTS**

### **Literature search**

The initial database search identified 2537 articles. From these papers, 2443 could be excluded based on the title or abstract. The full-texts of 94 possibly relevant articles were then obtained. Searching the reference lists of these papers revealed no additional eligible articles. After strict application of the exclusion criteria, a total of 59 articles were included for analysis in our review. These papers were then subdivided based on the four complications of interest. Ten papers described more than 1 subject of interest. A flowchart summarising the literature search for this review and the subdivision in terms of subjects of interest is shown in Figure 1.



*Figure 1: Flowchart summarising the approach followed in the literature search for studies describing risk factors for common complications after bilateral sagittal split osteotomy (BSSO). Several papers described more than one subject of interest to this study.*

### Quality assessment

A total of 15 prospective and 44 retrospective studies were included in this review. Of the 39 non-comparative studies, 8 were prospective and 31 were retrospective. Of the 20 comparative studies, 7 were prospective and 13 were retrospective.

The MINORS scores of the included studies were assessed. For non-comparative studies, one study scored 8 points, ten studies scored 9 points, six studies scored 10 points, fourteen studies scored 11 points, seven studies scored 12 points and one study scored 13 points. For comparative studies, one study scored 14 points, three studies scored 15 points, four studies scored 16 points, one study scored 17 points, five studies scored 18 points, three studies scored 20 points and three studies scored 21 points. The range of MINORS scores thus ranged from 8 to 13 points (out of 16 points) for non-comparative studies and from 14 to 21 points (out of 24 points) for comparative studies.

Methodological flaws included an incomplete description of the protocol used for data collection or evaluation of the outcome, absent or incomplete description of statistical methods, absence of



baseline equivalence of the groups, and loss to follow-up of more than 5% of cases. Exclusion of specific studies or a subdivision based on risk-of-bias was found to be unnecessary, as there were no important methodological flaws that would relevantly influence the analysis.

### Bad splits

Eighteen retrospective and three prospective papers describing bad splits were included. Two papers reported on the same patient group and were therefore analysed as one. The studies reported on 8225 patients that received 16359 SSOs in total. A total of 381 bad splits were reported. The pooled incidence of bad split was 2.3% per SSO (Figure 2). The reported incidences of bad split varied between 0.5% and 14.6% per SSO (Table 1).

#### Reported incidences of bad split

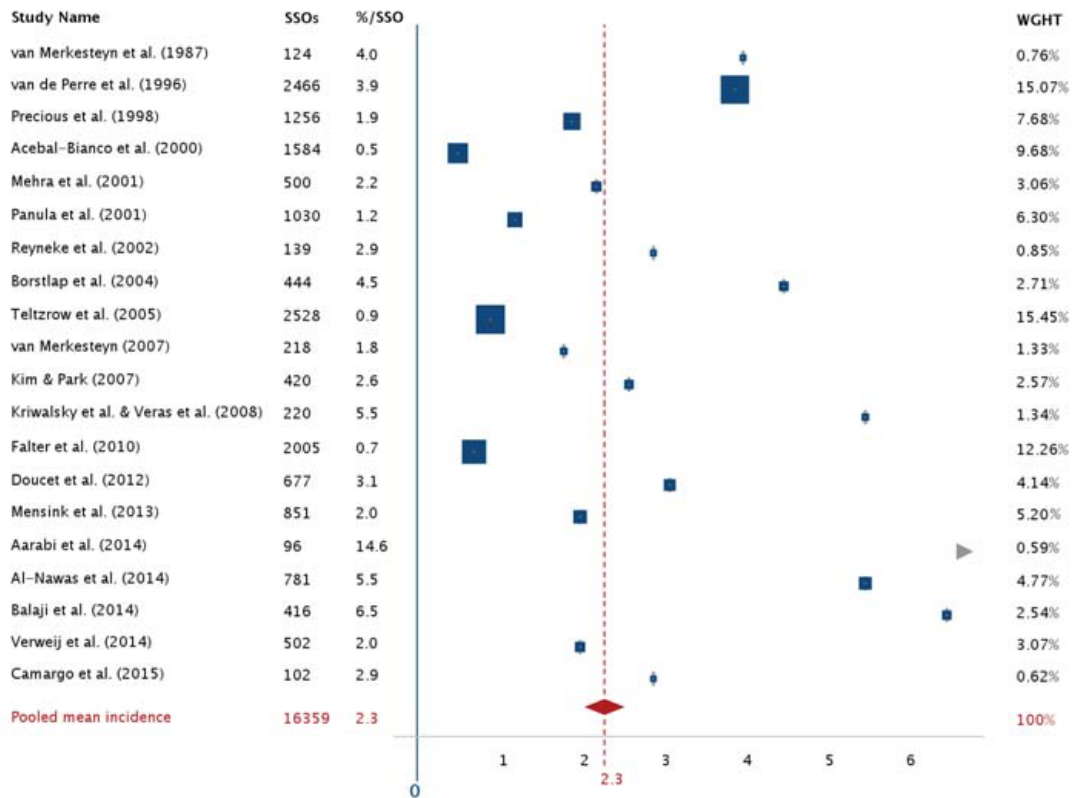


Figure 2: Forest plot for the reported incidence of bad splits per SSO.

Authors	Year	Patients	SSOs	Incidence (%/SSO)
Van Merkesteyn et al. <sup>12</sup>	1987	62	124	4.0
Van de Perre et al. <sup>13</sup>	1996	1233	2466	3.9
Precious et al. <sup>14</sup>	1998	633	1256	1.9
Acebal-Bianco et al. <sup>15</sup>	2000	802	1584	0.5
Mehra et al. <sup>16</sup>	2001	262	500	2.2
Panula et al. <sup>17</sup>	2001	515	1030	1.2
Reyneke et al. <sup>18</sup>	2002	70	139	2.9
Borstlap et al. <sup>19</sup>	2004	222	444	4.5
Teltzrow et al. <sup>20</sup>	2005	1264	2528	1.0
Van Merkesteyn et al. <sup>21</sup>	2007	109	218	1.8
Kim & Park <sup>22</sup>	2007	210	420	2.6
Kriwalsky et al. <sup>23</sup> & Veras et al. <sup>24</sup>	2008 2008	110	220	5.5
Falter et al. <sup>25</sup>	2010	1008	2005	0.7
Doucet et al. <sup>26</sup>	2012	339	677	3.1
Mensink et al. <sup>27</sup>	2013	427	851	2.0
Aarabi et al. <sup>28</sup>	2014	48	96	14.6
Al-Nawas et al. <sup>29</sup>	2014	400	781	5.5
Balaji <sup>30</sup>	2014	208	416	6.5
Verweij et al. <sup>31</sup>	2014	251	502	2.0
Camargo et al. <sup>32</sup>	2015	52	102	2.9

*Table 1: The reported incidence of bad splits during BSSO.*

The patients in the study groups consisted of 1% males and 65.9% females, with a mean age of 25.1 years (range 12.1-68.0). The relationship between gender and bad split was reported in eight articles, with 40.5% males and 59.5% females in the bad split group. The mean age of the bad split group was mentioned in nine articles, resulting in a pooled mean age of 30.3 years (SD: 6.7 years; range 15.0-61.0). The presence of third molars was mentioned in ten articles comprising 5110 SSOs. In 75 of 2172 SSOs (3.3%) involving third molars, a bad split occurred, in comparison to 72 of 2938 SSOs (2.4%) not involving third molars.

Male and female patients were reported to be at similar risk of bad split.<sup>14, 19, 25-28, 30-32</sup> With regard to the influence of age on the occurrence of unfavourable fractures, reports varied.<sup>14, 25, 27, 30-32</sup> Some authors found that older age was a risk factor for bad splits.<sup>23, 26, 28</sup> Other authors, however, reported that younger patients have an increased risk for bad splits.<sup>16, 18</sup>

The presence of mandibular third molars during BSSO is the most frequently reported risk factor for bad splits.<sup>14, 16, 18, 27, 31</sup> Nevertheless, some authors found no significant association between third molars and bad splits.<sup>19, 23, 26, 32</sup> Reyneke et al.<sup>18</sup> reported age as a factor in the risk of bad splits associated with third molars. Mehra et al.<sup>16</sup> found that the risk of bad split was increased in younger patients (< 20 years) with third molars and in older patients (> 40 years) without third molars. This is in accordance with the findings by Camargo et al.<sup>32</sup>, who reported that third molars do not increase the risk of bad splits in patients aged 30 years or older. Balaji<sup>30</sup> investigated the spatial position of unerupted third molars and reported that the type of impaction, degree of third molar development, and root morphology significantly influenced the risk of bad splits. In their study, the occurrence of unfavourable fractures was reported to be more likely when third molars with a distoangular/vertical orientation or divergent roots were present.<sup>30</sup>

The surgeon's expertise has also been reported to be of importance.<sup>18</sup> Doucet et al.<sup>26</sup> reported that more bad splits occurred when BSSO was performed by residents. Borstlap et al.<sup>19</sup> considered that the relatively high incidence of bad splits in their study was due to trainees performing BSSO in a teaching hospital. Al-Nawas et al.<sup>29</sup> reported more bad splits when BSSO was performed by inexperienced surgeons, although they did not report a significant difference. Falter et al.<sup>25</sup> described that increasing expertise of surgeons had no effect, but their study protocol prescribed that third molars should be removed six months before BSSO as standard practice, making the procedure more straightforward.

Mandibular morphology has been reported to influence both the difficulty of the procedure and the risk of bad splits. Mehra et al.<sup>16</sup> reported no increased risk of bad splits relative to the occlusal plane angle or posterior mandibular height. Aarabi et al.<sup>28</sup> showed that the risk of bad splits was increased in buccolingually thinner and vertically smaller mandibles.

Some reports found that the osteotomy design influenced the risk of unfavourable fractures. An osteotomy procedure using an inferior border cut (Hunsuck modification) has been reported to result in significantly fewer bad splits than the traditional Obwegeser-Dal Pont techniques.<sup>29</sup> The use of either a splitter and separators or a mallet and chisels is reported to both result in a similar incidence of bad splits.<sup>27</sup>

### Infection

Ten retrospective and four prospective papers, describing postoperative infection after BSSO, were included in our review. All the prospective papers compared patient groups with different antibiotic treatments. The studies reported on 4123 patients in total. Postoperative infection occurred in 333 patients, and the reported incidences range from 2.0%-25.9% per patient (Table 2). The pooled incidence of postoperative infection was 9.6% per patient (Figure 3). Ten studies described infection rates per SSO. These studies described 5129 SSOs and postoperative infection occurred at 318 sites, resulting in a pooled incidence of 6.2% per SSO (range 1.0%-15.6%).

### Reported incidences of postoperative infection

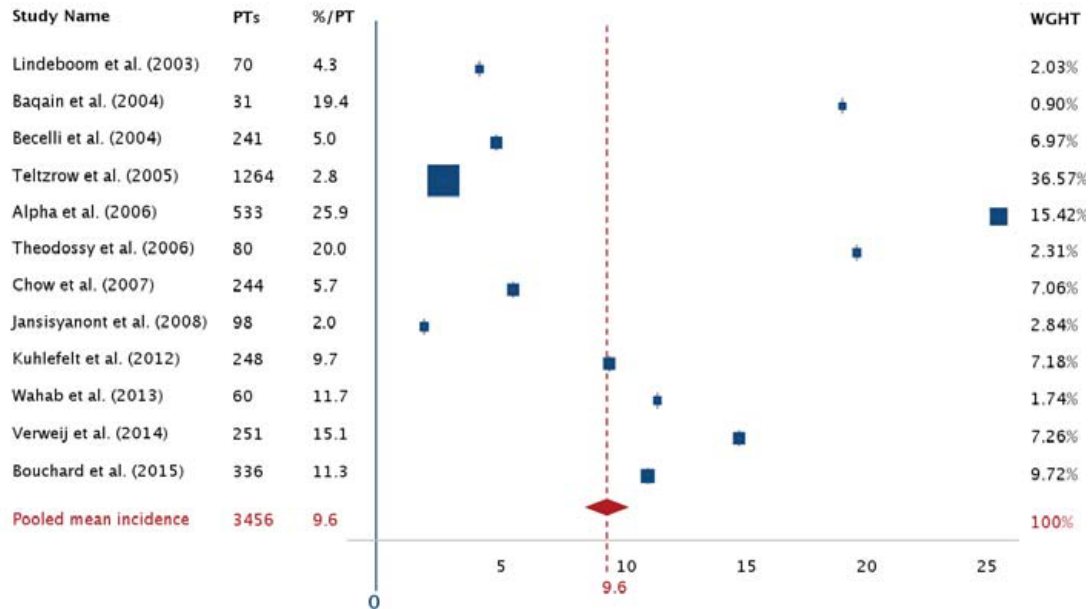


Figure 3: Forest plot for the reported incidence of postoperative infection per patient.

Authors	SSOs	Incidence (%/SSO)	Patients	Incidence (%/patient)
Bouwman et al. <sup>33</sup>	1334	1.12	667	-
Lindeboom et al. <sup>34</sup>	140	2.14	70	4.29
Baqain et al. <sup>35</sup>	62	9.68	31	19.35
Becelli et al. <sup>36</sup>	482	2.49	241	4.98
Spaey et al. <sup>37</sup>	1067	4.40	-	-
Teltzrow et al. <sup>20</sup>	-	-	1264	2.77
Alpha et al. <sup>38</sup>	1066	15.01	533	25.89
Theodossy et al. <sup>39</sup>	160	15.63	80	20.00
Chow et al. <sup>40</sup>	-	-	244	5.74
Jansisyanont et al. <sup>41</sup>	196	1.02	98	2.04
Kuhlefeld et al. <sup>42</sup>	-	-	248	9.68
Wahab et al. <sup>43</sup>	120	5.83	60	11.67
Verweij et al. <sup>31</sup>	502	8.17	251	15.14
Bouchard et al. <sup>44</sup>	-	-	336	11.31

Table 2: The reported incidence of infection after BSSO.

The patients in the study groups consisted of 33.4% males and 66.6% females with a mean age of 26.0 years (range 13.0-68.0 years). Five studies reported on the relationship between infection and gender, with 35.2% males and 64.8% females in the patient groups that experienced postoperative infection. The mean age of the patients with postoperative infection was mentioned in 3 studies, showing a mean age in the infection group of 29.7 years (range 14.6-51.0 years).

Three studies investigated the influence of smoking on postoperative infection in 71 smokers and 878 non-smokers. The incidence of infection after BSSO was 32.4% per patient in the smokers group and 19.3% in the non-smokers group.

Six studies reported on the influence of mandibular third molar removal during BSSO on infection. Of the 421 sites involving a third molar, 49 sites developed postoperative infection (11.6% per SSO), and of the 1730 sites without a third molar, 208 sites developed postoperative infection (12.0% per SSO).

Male and female patients were generally reported to have the same risk of postoperative infection.<sup>31, 34, 35, 38-40, 42, 44</sup> Younger and older patients also exhibit similar infection rates in most articles.<sup>31, 34, 38, 40, 42</sup> Bouchard et al.<sup>44</sup> and Theodossy et al.<sup>39</sup> however reported more infections with increasing age. Alpha et al.<sup>38</sup> reported that the intra-operative removal of third molars can influence the risk of postoperative infection, but most authors found no increased risk of infection when mandibular third molars were removed during surgery.<sup>31, 39, 44</sup>

Several authors reported that smokers have an increased risk of postoperative infection after oral surgery, as compared to non-smokers.<sup>38, 42, 44</sup> Systemic conditions, such as diabetes, were also reported to increase the risk of infection and to delay wound healing.<sup>38</sup>

Procedures in the mandible were found to result in a greater risk of postoperative infection as compared to other maxillofacial procedures.<sup>37, 42, 43</sup> The supero-anterior part of the buccal cortex is reported to be at risk for sequestration after BSSO, due to the poor blood supply of this area.<sup>33, 36</sup> Moreover, the use of a drain has been reported to increase the risk of infection.<sup>37</sup>

A total surgical time of more than 3 hours has been found to be a risk factor for infection in one study.<sup>39</sup> However, other clinical studies did not find a significant association between surgical time and infection.<sup>34, 35, 40, 42</sup>

### **Removal of osteosynthesis material**

Eleven studies described removal of osteosynthesis material, due to symptoms, after BSSO (Table 3). All studies were retrospective, except for 1 prospective study, which compared titanium and bioresorbable plate fixation. Of this prospective paper, only the results related to titanium fixation were included in our study. The studies reported on a total of 2809 patients. Removal of osteosynthesis material was necessary in 240 patients and the incidence ranged from 0.0% to 25.8% per patient (Table 3). The pooled incidence of removal of osteosynthesis removal was 11.2% per patient (Figure 4). Seven studies described removal of osteosynthesis material per SSO. The pooled incidence of removal of osteosynthesis material was 5.1% per site (range 0.0%-18.3%), as it was required for 200 of 3928 sites.

#### Reported incidences of removal of osteosynthesis material

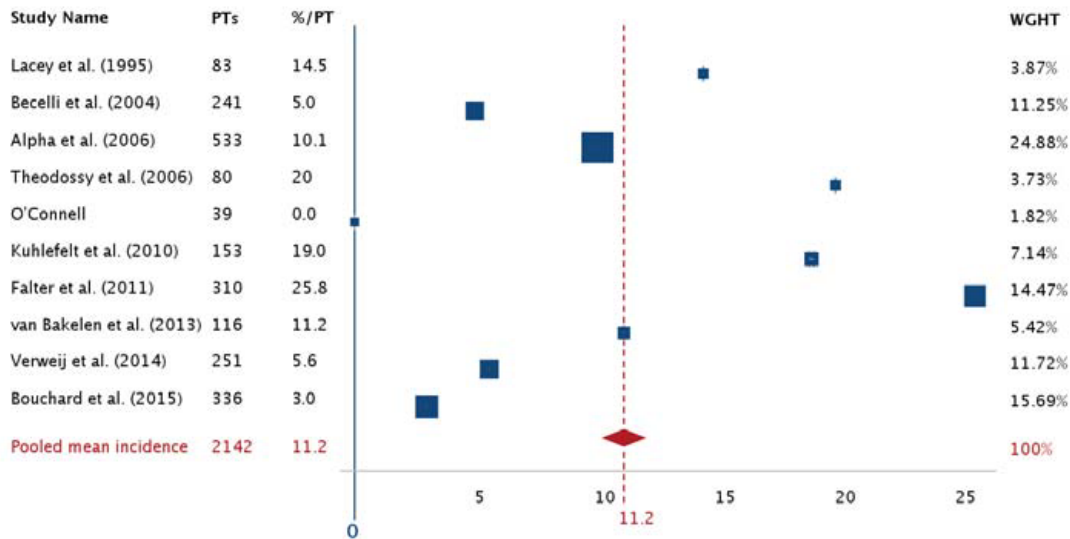


Figure 4: Forest plot for the reported incidence of removal of osteosynthesis material per patient.

Authors	Type of fixation	SSOs	Incidence (%/SSO)	Patients	Incidence (%/patient)
Bouwman et al. <sup>33</sup>	S	1334	1.5	667	-
Lacey et al. <sup>45</sup>	S	-	-	83	14.5
Becelli et al. <sup>36</sup>	S	482	2.5	241	5.0
Alpha et al. <sup>38</sup>	P	1066	6.6	533	10.1
Theodossy et al. <sup>39</sup>	P	160	15.6	80	20.0
O'Connell et al. <sup>46</sup>	P	78	0.0	39	0.0
Kuhlefeld et al. <sup>47</sup>	P	306	18.3	153	19.0
Falter et al. <sup>48</sup>	P	-	-	310	25.8
Van Bakelen et al. <sup>49</sup>	P	-	-	116	11.2
Verweij et al. <sup>50</sup>	S	502	3.4	251	5.8
Bouchard et al. <sup>44</sup>	S	-	-	336	3.0

Table 3: The reported incidence of removal of osteosynthesis material after BSSO.  
S = Bicortical screw fixation, P = Miniplate fixation

The patients in the study group consisted of 32.6% males and 67.4% females, with a mean age of 27.3 years (range 13.0-68.0 years). Three studies reported on removal of osteosynthesis material and gender, with 31.6% males and 68.4% females in the group in which osteosynthesis material needed to be removed. Five studies reported on the relationship between age and removal of osteosynthesis, and found that the group in which osteosynthesis material needed to be removed had a mean age of 29.7 years (range 15.0-65.0 years).

With regard to the smoking habits of the patients, 3 studies reported that removal of osteosynthesis material was necessary in 15 of 40 smokers (37.5%) compared to 30 of 193 non-smokers (15.5%); thus, smokers more frequently required removal of osteosynthesis material. In the five studies that described the presence of third molars during BSSO, removal of osteosynthesis material was performed at 23 of 342 sites (6.7%) with third molars present during surgery and 84 of 634 sites (13.3%) without third molars during surgery. In five studies, miniplates were used as fixation material, and in six studies, bicortical screws were used. Removal of osteosynthesis material was necessary in 192 of 1225 patients (15.7%) with miniplate fixation and in 68 of 1578 patients (4.3%) with screw fixation.

Gender was not reported as a significant factor in removal of osteosynthesis material in most previous studies, although Falter et al.<sup>48</sup> did report an increased rate of plate removal for non-infectious symptoms in women.<sup>38, 44, 47, 50</sup> Most studies reported no effect of increased age of the patient, although Theodossy et al.<sup>39</sup> and Bouchard et al.<sup>44</sup> reported that removal of osteosynthesis material was more frequently required in older patients.<sup>47, 48, 50</sup> Lacey et al.<sup>45</sup> reported a higher rate of infected screws after third molar removal during BSSO and described exposed hardware in the socket as a possible reason for this. Other studies found no significant correlation between the presence of mandibular third molars during BSSO and removal of osteosynthesis material.<sup>39, 44, 50</sup>

Risk factors for postoperative infection, such as smoking, have been reported to increase the need for removal of osteosynthesis material.<sup>47</sup> Placing the fixation near the inferior border of the mandible has been reported to prevent hardware removal, because of infectious symptoms, because of a poor blood supply to the supero-anterior part of the buccal cortex.<sup>33, 36, 38</sup> The removal rates for monocortical miniplates and bicortical screws were markedly different.<sup>50</sup> No randomised studies comparing the removal rates after plate- or screw-fixation during BSSO were found.

### **Neurosensory disturbance**

Sixteen retrospective and nine prospective papers reported subjective assessment if NSD of the inferior alveolar nerve persisting at least one year after BSSO and were included in our study. Two papers described the same patient group and were analysed as one. The studies reported on 3230 patients and 5408 SSOs in total. The reported incidences of NSD are described in Table 4. The pooled mean incidence of NSD was 33.9% per patient (range 0.0%-71.0%) and 21.7% per SSO (range 0.0%-48.8%). Figure 5 shows the Forest plot with the pooled mean incidence of permanent NSD per patient.

### Reported incidences of NSD

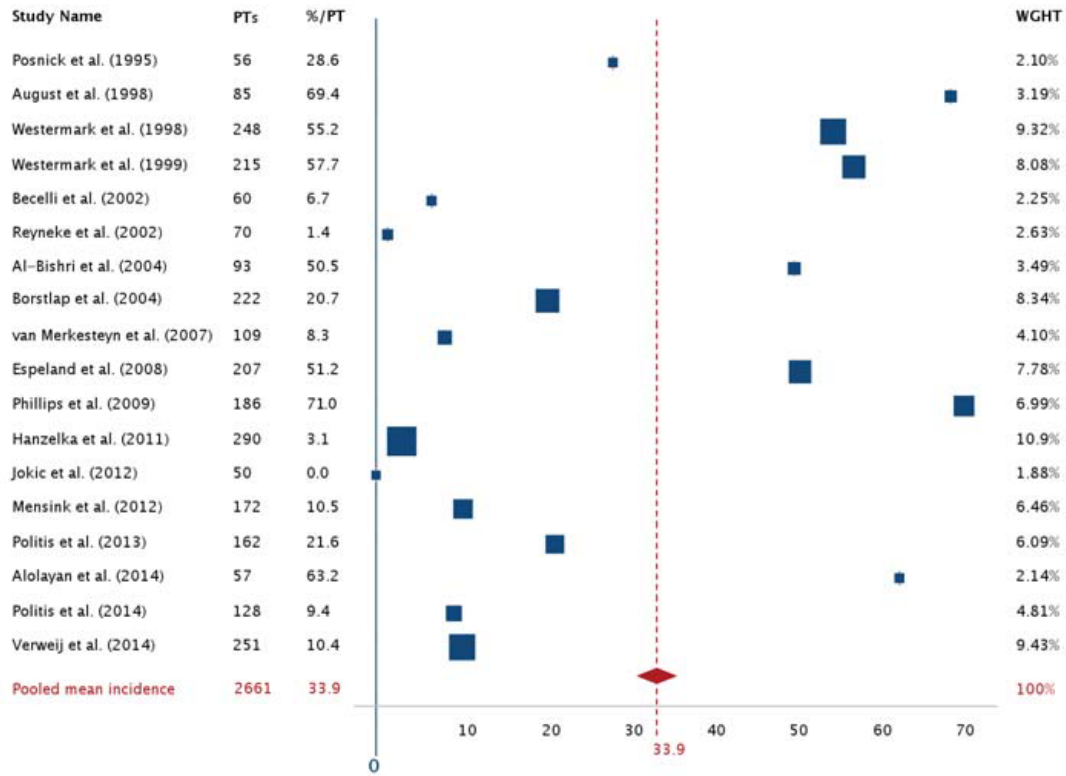


Figure 5: Forest plot for the reported incidence of permanent neurosensory disturbance (NSD) per patient.



Authors	SSOs	Incidence (%/SSO)	Patients	Incidence (%/patient)
Scheerlinck et al. <sup>51</sup>	206	17.0	103	-
Posnick et al. <sup>52</sup>	112	18.8	56	28.6
August et al. <sup>53</sup>	-	-	85	69.4
Westermarck et al. <sup>54</sup> & Westermarck et al. <sup>55</sup>	496	40.3	248	55.2
Westermarck et al. <sup>56</sup>	430	40.5	215	57.7
Becelli et al. <sup>57</sup>	120	5.0	60	6.7
Reyneke et al. <sup>18</sup>	-	-	70	1.4
Bothur et al. <sup>58</sup>	160	48.8	80	-
Al-Bishri et al. <sup>59</sup>	185	36.8	93	50.5
Borstlap et al. <sup>19</sup>	444	13.1	222	20.7
Nesari et al. <sup>60</sup>	136	31.6	68	-
Van Merkesteyn et al. <sup>21</sup>	218	4.1	109	8.3
Espeland et al. <sup>61</sup>	-	-	207	51.2
Phillips et al. <sup>62</sup>	-	-	186	71.0
D'Agostino et al. <sup>63</sup>	100	48.0	50	-
Hanzelka et al. <sup>64</sup>	-	-	290	3.1
Jokic et al. <sup>65</sup>	100	0.0	50	0.0
Mensink et al. <sup>66</sup>	344	5.8	172	10.5
Bruckmoser et al. <sup>67</sup>	206	22.8	103	-
Gilles et al. <sup>68</sup>	102	2.0	51	-
Politis et al. <sup>69</sup>	324	15.1	162	21.6
Alolayan et al. <sup>70</sup>	-	-	57	63.2
Politis et al. <sup>71</sup>	-	-	128	9.4
Verweij et al. <sup>31</sup>	502	5.4	251	10.4

*Table 4: The reported incidences of permanent NSD after BSSO.*

The patients in the study groups consisted of 33.6% males and 66.4% females, with a mean age of 26.8 years (range 12.6-72.4 years). The patient characteristic that was reported most often as an important predictor of NSD is increasing age.<sup>19, 31, 53, 54, 56, 58, 60-62, 66-70</sup> The risk of permanent NSD after BSSO has been reported to increase with approximately 5% per year.<sup>66, 69</sup> Patients over 30 years of age have been described as being vulnerable to nerve damage and subsequent permanent NSD.<sup>56, 60</sup> These older patients have also been reported to experience an increased burden due to NSD, and were subsequently found to be less satisfied after BSSO.<sup>53, 61, 62, 72</sup> Bothur et al.<sup>58</sup> and Bruckmoser et al.<sup>67</sup> reported female patients were at greater risk for NSD. In most studies, however, the patient's gender was found to have no significant influence on the risk of NSD.<sup>18, 31, 54, 56, 59, 60, 62, 65, 66, 69, 70</sup> Third molar removal during surgery has been reported to increase the difficulty of the sagittal split, but not the risk of NSD.<sup>18, 31, 53, 66</sup> Intra-operative complications, such as a bad split or bleeding have not been reported as a cause of NSD.<sup>19, 31, 53, 58</sup>

Some authors reported no influence of nerve manipulation during surgery.<sup>18, 53, 64</sup> Several other authors however reported that nerve encounters during the split does increase the risk of NSD.<sup>19, 31, 55, 60, 66, 67, 71</sup> The risk of NSD was reported to be increased particularly when the nerve had to be released from the lateral segment.<sup>31, 60, 66, 71</sup> Several authors propose using sagittal splitters or ultrasonic osteotomes to minimise the chance of iatrogenic nerve damage.<sup>31, 66, 68</sup>

Some studies have described less NSD after setback surgery.<sup>21, 63, 65</sup> However, other studies found no difference between patients with a class II or class III malocclusion.<sup>31, 59, 64, 67, 69</sup> Large advancements/setbacks (> 7 mm) have been reported to increase the risk of NSD by increasing the difficulty of the procedure or the vulnerability of the patient by stretching the nerve.<sup>55, 73</sup> Additional procedures in the upper jaw (i.e. Le Fort I osteotomy) have not been reported to influence the risk of NSD after BSSO. Several authors reported that genioplasty combined with BSSO increased the incidence of NSD.<sup>21, 31, 52, 55, 66, 69</sup> Others did not find a significant increase of NSD due to genioplasty.<sup>53, 58, 59, 62, 67</sup> Rigid fixation with either bicortical position screws or monocortical miniplates has been reported to result in a similar incidence of NSD with either technique.<sup>53, 58, 60, 67</sup>

## DISCUSSION

This systematic literature review and meta-analysis aimed to provide a mean complication rate that summarises the current literature regarding the most common complications associated with BSSO, such as bad splits; postoperative infection; removal of osteosynthesis material; and NSD of the lower lip.

### **Bad splits**

Soon after the development of the BSSO technique, bad splits were described as a common intra-operative complication.<sup>6-8, 12, 74-76</sup> There is, however, still no consensus in the literature about what incidence of this complication is considered acceptable and which risk factors increase the risk of unfavourable fractures. We found a mean pooled incidence of 2.3% per SSO by analysing the literature.

In their review, Chrcanovic et al.<sup>77</sup> reported an incidence of bad splits ranging between 0.21% and 22.72% per patient. The lowest incidence of bad splits in their review was reported in a letter to the editor, without description of study design or methods.<sup>78</sup> The highest incidence of bad splits was reported in papers published before 1980, which used traditional Obwegeser techniques.<sup>7, 74</sup> In the current review, we have attempted to estimate a more contemporary, representative mean incidence of bad splits per SSO. Although the incidence of bad splits per patient is not reported consistently, bilateral bad splits are relatively rare, so that the incidence per patient can be assumed to be approximately double the incidence per SSO.

We found that the presence of third molars is regularly reported as a risk factor for bad splits, possibly in combination with the patient's age.<sup>18, 26</sup> The spatial positioning of the third molar and experience of the surgeon might also play a role in this association.<sup>30</sup> It is plausible that the presence of third molars could increase the difficulty of the procedure, and therefore the risk of bad splits, particularly for less experienced surgeons.<sup>79</sup>

Apart from patient-related risk factors, the occurrence of bad splits during BSSO probably depends first and foremost on the execution of the BSSO technique by the surgeon. Plooij et al.<sup>80</sup>, Muto et al.<sup>81</sup>, and Song et al.<sup>82</sup> showed that a horizontal and vertical bone cut in the osteotomy design and incomplete osteotomies can influence the lingual fracture pattern and therefore predispose to bad splits.

### **Infection**

Postoperative infection is a common complication after any form of surgery. We report a mean pooled incidence of infection of 9.6% per patient. Smoking was reported as an important risk factor for infection.

In their Cochrane systematic review regarding the use of antibiotics in relation to orthognathic surgery, Brignardello-Petersen et al.<sup>83</sup> concluded that long-term antibiotic prophylaxis (before/ during surgery and more than 1 day after surgery) probably decreases the risk of infection at the surgical site, and the information provided was insufficient to show whether any specific antibiotic was better than another. Therefore, it could be advisable to use long-term antibiotic prophylaxis, particularly in patients undergoing a surgical procedure that exceeds 3 hours and in patients who smoke. The exact preferred amount and type of prophylactic antibiotic to use exceeds the scope of this review.

Furthermore, possible precautions can be taken to prevent infection. Patients should be encouraged to stop smoking.<sup>42</sup> Additionally, the occurrence of infection could possibly be further reduced by specific surgical precautions, such as using fibrin glue in the wound, instead of a drain.<sup>37</sup> When postoperative infection does occur, it is practically always effectively treated using a regiment of amoxicillin-clavulanate or clindamycin.<sup>83</sup>

### **Removal of osteosynthesis material**

The introduction of rigid fixation for BSSO has been an important development for this type of orthognathic surgery and has almost completely eliminated the need for intermaxillary fixation after BSSO.<sup>84-86</sup> Removal of the titanium osteosynthesis material after BSSO can nevertheless be indicated because of the presence of several symptoms. We found a mean pooled incidence for removal of such material of 11.2% per patient.

When postoperative infection is present at the surgical site, it often requires removal of the hardware. Smoking is an important risk factor for removal of osteosynthesis material, based on infection. A thin layer of soft tissue covering the hardware could be more prone to result in wound dehiscence with subsequent infection. However, removal of osteosynthesis material can also be necessary because of subjective discomfort, palpability of the plates, or breakage of the material. There is thus some overlap between hardware removal and infection, but removal of osteosynthesis material is identified as a separate complication, requiring an additional surgical procedure.

After a comparison of studies reported in the literature, we found that removal of bicortical screws (4.3%) was necessary markedly less often than removal of titanium miniplates (15.7%). Possible explanations for this finding could be the fact that the design, size, and morphology of implanted material influences the risk of material-related infection or other complaints.<sup>50</sup> Miniplates, with monocortical screws, present much more 'foreign body material' than bicortical screws. This

enlarges the area for bacterial colonisation, which increases susceptibility of infection.<sup>87</sup> The size and position of miniplates also increase the chance that the material will be palpable, or other subjective complaints, which are indications for hardware removal. Based on the literature, we would therefore advise the use of bicortical screws to stabilise mandibular segments. If miniplates are used, it may be advisable to place the hardware closer to the caudal mandibular border to minimise the risk of complaints or wound healing problems.<sup>38</sup>

### **Neurosensory disturbance**

If any type of altered sensation is present one year after BSSO, it is considered permanent. These permanent NSD of the lower lip are probably the most important complication associated with BSSO. Many different subjective and objective tests are used in neurosensory examination.<sup>88</sup> In their literature review, Agbaje et al.<sup>89</sup> concluded that this lack of standardised assessment procedures results in a wide variation in the reported incidence of inferior alveolar nerve injury. The wide range of methods used also complicates the comparison between studies. Because this review aimed to provide a patient-focused approach to complications associated with BSSO, only studies reporting subjectively assessed NSD were included. We found a mean pooled incidence of 33.9% NSD per patient.

In their literature review, Ow et al.<sup>90</sup> reported persistent subjective IAN disturbance in 27.8% of cases, based on 14 articles, which is similar to our mean pooled incidence. Colella et al.<sup>91</sup> reviewed seven studies, in which both objective and subjective neurosensory tests were used. They found an objective incidence of permanent NSD in 12.8% and a subjective incidence of 23.8%.<sup>91</sup> Subjective assessment of NSD should thus be part of postoperative examination in order not to underestimate the incidence of neurosensory disturbances.

Based on the literature, age is probably the most important patient-related risk factor for NSD. Other characteristics of patients with NSD were unfortunately rarely mentioned in the previous papers, making further characterisation of the NSD group difficult. Some important factors could nevertheless help the surgeon in an attempt to prevent NSD after BSSO. Manipulation of the nerve during the surgical procedure generally increases the risk of NSD and should therefore be prevented.<sup>71</sup> In their review, Mensink et al.<sup>92</sup> investigated the risk of nerve damage due to the use of chisels along the buccal cortex and found higher reported rates of NSD after BSSO was performed with chisels instead of splitters and separators. Furthermore, after a successful sagittal split, it is advised that sharp bony spicules and trabeculae on the inside of the mandibular segments are carefully removed to prevent puncturing of the nerve during fixation. When fixating the proximal and distal mandibular segment, pressure that can crush the nerve should also be prevented.<sup>93</sup> These factors, combined with careful handling of the nerve by the surgeon during surgery, could help the surgeon minimise the risk of NSD as much as possible.

## **CONCLUSION**

In conclusion, this systematic literature review and meta-analysis provides an overview of important common complications associated with BSSO. Pooled mean incidences were computed for bad splits (2.3% per SSO), postoperative infection (9.6% per patient), removal of osteosynthesis material (11.2% per patient), and NSDs of the lower lip (33.9% per patient). Regularly reported risk factors for complications are the patient's age, smoking habits, presence of third molars, the surgical technique and the type of osteosynthesis material.

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