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Skeletal stability after bilateral sagittal split osteotomy or distraction osteogenesis of the mandible: a randomized clinical trial

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Abstract. A randomized clinical trial was carried out to evaluate postoperative stability after mandibular advancements in non-syndromal class II patients with a bilateral sagittal split osteotomy (BSSO) or distraction osteogenesis (DO). In total 32 patients could be included in the BSSO group and 34 patients in the DO group. The BSSO was converted to a unilateral procedure for one patient, and two patients in the BSSO group were lost during follow-up. A total 63 patients could be evaluated, 29 in the BSSO group and 34 in the DO group. Advancement was comparable in the two groups (mean 7.2 mm). The mean follow-up period was 23.8 months (range 11–50 months). Lateral cephalograms were hand-traced. Horizontal relapse was measured in Y–B (mm) and SNB (°). For DO this was −0.324 mm and −0.250°, and for BSSO this was −0.448 mm and −0.259°, respectively (both not significant; NS). Vertical relapse measured in X–B was −0.074 mm for DO and −0.034 mm for BSSO (NS). The magnitude of advancement, a high mandibular plane angle, age and gender were not identified as independent risk factors for relapse. In conclusion, a BSSO and DO gave both similar stable results in advancements of the mandible up to 10 mm.

Key words: relapse; mandibular advancement; mandibular distraction osteogenesis (DO); bilateral sagittal split osteotomy (BSSO); mandibular retrognathia; RCT; complication; stability.

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The bilateral sagittal split osteotomy (BSSO) described by Trauner and Obwegeser in 1957[1] and modified by Dal Pont[2] and Hunsuck,[3] is considered the standard procedure for advancement of the mandible in skeletal class II patients. The main complications are injuries to the inferior alveolar nerve, with numbness of the lip and chin region, and relapse. Early and long-term relapse can influence the outcome of this procedure considerably. A possible explanation for early relapse is slippage of the

osteotomy segments and condylar sag. Long-term relapse can be related to changes in the morphology of the condylar head.[4] Skeletal stability has much improved since the introduction of stable internal fixation with miniplates or screws instead of wire fixation.[5]

McCarthy described the first clinical use of distraction osteogenesis (DO) in advancements of the mandible.[6] Intraoral, submerged distraction devices were later introduced, which did not require percutaneous pins and thus cutaneous scars could be prevented. Some early users of DO reported stable skeletal results after mandibular DO, although this was reported in animals[7] and primarily syndromal young children.[8–10] Because of these promising results, mainly in unilateral procedures, it was hypothesized that relapse after DO was minimal due to gradual distraction of the soft tissues[9,11] and could also be applied in less severe cases. Van Strijen et al.[12] reported stable skeletal results after DO in skeletal class II non-syndromal patients with a low mandibular plane angle, although patients with a high mandibular plane angle showed more relapse in this study.

With regard to stability, DO and BSSO have been compared in only a few studies, and no significant differences were observed.[13–17] However, all of these reports, except one, were retrospective in nature. To avoid selection bias and to balance known and unknown prognostic factors, a randomized clinical trial was performed to compare BSSO and DO for advancement of the mandible in non-syndromal class II patients. The primary outcomes were the occurrence of neurosensory disorders of the inferior alveolar nerve and postoperative skeletal stability. The results of skeletal stability are presented herein.

Patients and methods

Between March 2008 and July 2011, 66 patients were included in this prospective study. These patient cases with regard to skeletal stability have not been reported previously. The study design was a prospective randomized clinical trial. All patients were treated in the Department of Maxillofacial Surgery, Isala Clinics Zwolle, Netherlands. This department serves as a training centre for residents in oral and maxillofacial surgery. All surgical procedures were performed by a staff surgeon (JdeL, FB, or EB) and a resident.

For inclusion, patients had to be non-syndromal and have a hypoplastic mandible and a skeletal class II relation. They all required advancement of the mandible to obtain a skeletal class I relation. Advancement of the mandible by DO or BSSO was the only mandibular procedure executed. If indicated, a Le Fort I osteotomy was performed simultaneously. However, the assessment of relapse was correlated to the cranial base on lateral cephalograms. Patients aged >35 years and those who had undergone previous mandibular surgery were excluded. Patients were informed of the purpose of the study and all patients and/or their parents provided informed consent for participation. Patients were assigned randomly to either the BSSO or the distraction procedure (DO) (Fig. 1). Randomization was done with a randomly generated list (http://www.randomization.com) with a fixed block size of 20. No stratification was used for randomization. One person, who was not involved in the study, prepared closed envelopes (numbered 1–80) containing the allocated surgery. After informed consent was obtained, the patient was present when the surgeon opened the envelope containing the assigned type of surgery; envelopes were opened consecutively, in number order. This study was approved by the hospital medical ethics committee.

One of the primary outcomes assessed was skeletal stability after DO or BSSO. The assessment of relapse was done radiographically. Lateral cephalometric radiographs were taken preoperatively, postoperatively, or in the DO group directly post-distraction, and at ≥11 months postoperatively. The mean follow-up was 23.8 months (range 11–50 months). An X–Y cranial base coordinate system was constructed on the lateral cephalograms. The sella–nasion line represented the *x*-axis. A line perpendicular to the *x*-axis at sella represented the *y*-axis (Y). Mandibular point B was used to evaluate relapse. The following measurements were made: sella–nasion–mandibular point B (SNB), sella–nasion–mandibular plane (SN–MP), X–B, and Y–B (Fig. 2; previously published by Baas et al. in 2012[13] and Vos et al. in 2009[16]). Superimposition of the radiographs was performed using the 'manual geometric superimposition' method,[18] and they were hand-traced. Vertical relapse was represented by X–B and horizontal relapse by Y–B and SNB.

The surgical procedure

Surgery was performed under general anaesthesia for the patients in both groups. Preoperatively, 2 g cefazolin and 0.5 mg/kg dexamethasone were given intravenously. Another dosage of 10 mg dexamethasone was given at 8 and 16 h postoperative.

BSSO

The bilateral sagittal split advancement osteotomy was carried out according to the procedure of Trauner and Obwegeser,[1] modified by Dal Pont[2] and Hunsuck.[3] The inferior alveolar nerve was identified at the medial aspect of the ramus. The osteotomy cut was made with a Lindemann bur

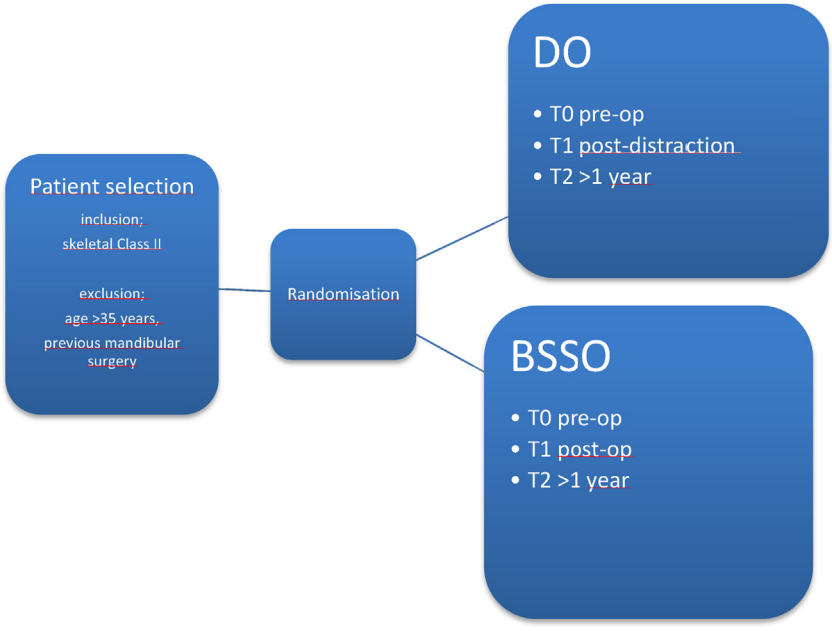

Fig. 1. Study design — randomized clinical trial.