

Complications in bilateral mandibular distraction osteogenesis using internal devices

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Objective. We sought to evaluate the possibility of distraction osteogenesis as an alternative to conventional bilateral sagittal split osteotomy. Complications (intraoperative, intradistraction, and postdistraction) were evaluated retrospectively.

Study design. Seventy consecutive patients (40 males and 30 females, 11.2-37.3 years old; mean, 14.2 years) underwent distraction osteogenesis to lengthen the mandible. The surgical procedure was carried out with the patient under general anesthesia. After the osteotomy was performed, 2 intraoral monodirectional distraction devices were placed on the mandibular cortex in the third molar region. The rate of distraction was 1 mm/day. The different complications encountered during all phases of the distraction procedure were recorded.

Results. A total of 28 complications (40%) were recorded. In 10 patients (14.3%), the complications were technique- or device-related, or both, and occurred early in the learning period. Five patients (7.1%) had infection occur, and 3 patients (4.3%) had prolonged sensory loss in the distribution of the alveolar nerve. Severe complications occurred in 6 patients (8.6%). Rehospitalization was necessary in 5 patients (7.1%), 4 of whom (5.7% of the series) required further surgery under general anesthesia.

Conclusion. Distraction osteogenesis can be considered a safe and predictable procedure for lengthening the mandible, with a low incidence of major complications. The infection rate and the incidence of damage to the inferior alveolar nerve (2.1%) are low. Compliance of both patients and parents during the whole treatment period is of the utmost importance. (*Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2003;96:392-7)

In recent years, the use of distraction osteogenesis as a possible alternative to conventional surgery has led to several publications on the biology of the distraction process, technical aspects, indications and costs.¹⁻⁶ The controversy over whether distraction osteogenesis can be considered a justifiable alternative to bilateral sagittal split osteotomy (BSSO) is ongoing.^{3,7} It is essential to record any complications that occur during the entire period of treatment so that this technique can be evaluated as an alternative to conventional surgery.

Before Ilizarov^{1,8,9} defined the optimal criteria for the correct use of distraction osteogenesis, complications were regularly seen, and because of the high complication rate in orthopedic surgery, this technique did not have wide clinical application. Complications in bone formation (eg, malunion and premature consolidation) after

distraction osteogenesis and their prevention have been well documented by several authors.¹⁰⁻¹²

Complications can be divided into 3 groups: intraoperative, intradistraction, and postdistraction complications. The intraoperative complications concern the surgical procedure (eg, malfracturing, incomplete fracture, nerve damage, and excessive bleeding) and device-related problems (eg, fracture and unstable placement). Intradistraction complications concern those arising during distraction (eg, infection, device problems, pain, malnutrition, and premature consolidation). Postdistraction complications concern the late problems arising during the period of splinting and after removal of the distraction devices (eg, malunion, relapse, and persistent nerve damage).¹¹

The aim of this retrospective study was to record and evaluate complications of distraction osteogenesis for mandibular lengthening in a group of 70 consecutive patients, in relationship to the known results of BSSO. The results should add further to the discussion on distraction osteogenesis as an alternative to traditional osteotomy.

PATIENTS

From December 1996 to December 2001, 70 consecutive patients (40 males and 30 females 11.2-37.3 years old; mean, 14.2 years) underwent distraction osteogen-

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Received for publication Oct 3, 2002; returned for revision Nov 30, 2002; accepted for publication Jul 17, 2003.

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1079-2104/2003/\$30.00 + 0

doi:10.1016/S1079-2104(03)00472-4

esis in a more or less standardized fashion¹³ to lengthen the mandible. The mean sagittal overbite at the time of operation was 8.7 mm (5-15 mm). All patients had Angle Class II/Division 1 mandibular hypoplasia and had undergone recent orthodontic therapy. The orthodontist (K.H.B.) and the surgeon (P.v.S.) were both of the opinion that mandibular advancement surgery would eventually be necessary in all these patients. The young patients and their parents were given the choice between treatment by distraction osteogenesis while the patient was still young or BSSO at a later stage. One adult patient decided to undergo distraction osteogenesis to correct an overbite. Bilateral, intraoral, boneborne monodirectional distraction devices were used [Medicon (1x) (Tuttlingen, Germany), Martin (9x) (Tuttlingen, Germany), Howmedica-Leibinger (25x) (Freiburg, Germany), and Mondeal (35x) (Tuttlingen, Germany)]. No patient selection was made in relationship to the devices used.

METHOD

The surgical procedure was carried out with the patient under general anesthesia. Perioperatively, 1 million units of phenyl penicillin was given intravenously, commencing 1 hour before the procedure and readministered every 6 hours for the first 24 hours. A mucoperiosteal flap was raised in the third molar area, and the third molar tooth germ was removed if present, as occurred in 121 of the 140 operation sites. Bone cuts were made by using a Lindeman bur (Meisinger 168/023, Hager and Meisinger GmbH, Dusseldorf, Germany) in the superior, lateral, and inferior cortex of the mandible at the selected site. Complete mobilization was accomplished by using an osteotome. The distractor was intraorally fixed into the mandibular cortex along the preoperatively planned vector by using the direction guide. Chlorhexidine mouthrinses were prescribed for daily use throughout the treatment period. A soft diet was recommended for the same period.

The latency time (ie, the time between the surgical procedure and the start of the actual distraction) was 6 days in all patients. The rate of distraction was 1 mm/day (2×0.5 mm), and the mean lengthening was 8.2 mm (range, 5-13 mm). Distraction was performed by the parents or partner after receiving appropriate instruction during the first session of distraction in the outpatient department. Patients attended the clinic every second day so that the progress of the distraction could be assessed. Removal of the distraction devices took place 3 to 9 weeks after placement (mean, 6.5 weeks) and was performed in day care with the patient under general anesthesia on an outpatient basis. Maxillomandibular elastic bands were applied as a guiding interarch force, if necessary, after completion of the

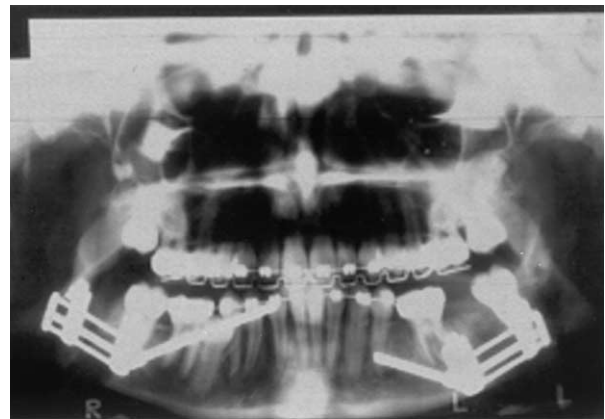


Fig 1. Incorrect left distraction site, between the first and the second molar. Note the shortening of the distraction rod to prevent a pressure sore of the lower lip.

distraction period to correct a mild open bite. Early removal of the distractors and the use of elastic band traction, according to the "floating bone" method, was performed only when it was impossible to achieve optimal occlusion through elastic band traction with the distraction devices in place.¹⁰ An orthodontic retention protocol identical to the treatment for routine (ie, non-distraction) orthodontic patients was followed. Postoperative x-rays (lateral cephalograms and orthopantomograms) were made 6 weeks, 6 months, and 12 months after distraction and evaluated by both orthodontist (K.H.B.) and surgeon (P.v.S.). The clinical notes regarding the patients were reviewed retrospectively, and all complications encountered during all phases of treatment were recorded.

Intraoperative complications

Malfracturing. In 1 patient (1 site, 0.7%), the osteotomy on one side was incorrectly placed, resulting in a distraction gap between the first and second molars and not through the alveolus of the removed third molar tooth germ. Correction of the mandibular hypoplasia was successfully achieved, with a resulting diastema between the first and second molars, necessitating prolonged orthodontic treatment. No adverse effect on the adjacent teeth was seen (Fig 1).

Incomplete fracturing. In 1 patient (1 site, 0.7%), osteotomy of the lingual cortex was not successful. This became apparent postoperatively because hardly any movement of the segment occurred during distraction (Fig 2). Additional mobilization and replacement of the rod, broken as a result of the excessive forces applied in attempting distraction, was necessary. To prevent this complication, the corticotomy procedure that was originally performed that resulted in a green-

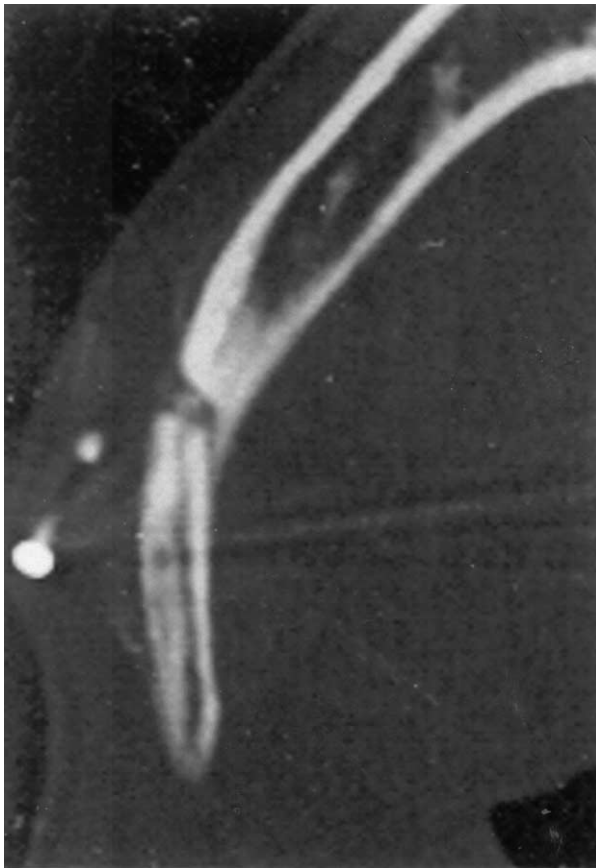


Fig 2. Incomplete mobilization of the lingual cortex at the distraction site.

stick fracture was not used—instead, full osteotomy of the distraction site was performed. This not only facilitates distraction but concomitantly reduces pain during distraction and prevents interference with the vector of distraction. To test good mobility and the correct vector of distraction, the distraction device was tested over the desired range at the end of the procedure.

Device-related problems during the procedure. In 1 patient (1 site, 0.7%), the device did not function correctly when tested after placement, limiting the forward movement of the mandible, necessitating replacement and repositioning. Fortunately, this defect was detected during the procedure and not postoperatively.

In 1 patient, a titanium screw was lost in the soft tissues while manipulating the distraction device and could not be found. A radiograph revealed that the screw was lying in the pterygomandibular sling on the lower border of the mandible. No attempt to recover this foreign body was, or has been, undertaken in this patient.

Bleeding. No excessive bleeding occurred during the osteotomy, placement, or removal of the distraction



Fig 3. Device-related problem: fracture of the distraction rod.

devices, as was also reported by Swennen et al¹⁴ in their review article on distraction complications.

Intradistraction complications

Infection. In 4 patients (4 sites, 2.9%), postoperative infection developed after placement of the distraction device. Local irrigation, improved oral hygiene, and the administration of antibiotics were sufficient to control the infection in all patients. No adverse effects or bone healing materialized.

Device-related problems. In 4 patients (4 sites, 2.9%), the distraction rod broke during the active distraction period. In all these patients, the same distraction devices had been used (Howmedica Leibinger: Vazques-Diner intraoral distraction device; Fig 3). This necessitated a second surgical procedure, with the patient under general anesthesia, to replace the device. The pressure of the distraction rod created lower lip injuries (ie, pressure sores) in 4 patients (6 sites, 4.3%). The lesions healed uneventfully after the rods had been shortened.

Nerve damage. Of the 70 patients (140 sites), 23 patients (33 sites, 23.6%) had altered sensation in the distribution of the mental nerve when tested with sharp and blunt stimuli after distraction. Only 2 patients (3 sites, 2.1%) still had hypoesthesia 12 months after the removal of the distraction devices. All the other patients had fully recovered.

One patient reported disturbed sensibility of the lingual nerve directly after the procedure but had recovered a few weeks after the procedure.

Compliance problems. The importance of compliance was explained extensively to both the patients and their parents, but 4 patients did not comply with instructions, especially in the wearing of supporting elastic bands. This resulted in a tendency toward open bite after the removal of the distraction devices.

One patient (1.4%) did not allow the parents to activate the distractors twice a day, which resulted in premature consolidation of the osteotomy site. One patient (1.4%) refused to eat at home after the placement of the devices. This refusal or incapability to eat necessitated rehospitalization for forced feeding. After this, treatment continued uneventfully.

Postdistractor complications

Malunion. Malunion did not occur in any patient. Solid bone formation was observed on radiographs of all patients. No periodontal problems were recorded or observed during a clinical assessment that included probing.

Infection. In 1 patient (1 site, 0.7%), infection was observed after removal of the distraction device; nevertheless, antibiotics were sufficient to control it.

Condylar effects. Noticeable condylar changes were observed on the radiographs of 3 patients (4.3%). In 1 patient, a young boy, the changes were severe and consistent with bilateral condylar resorption. Two other patients (female) exhibited mild unilateral condylar changes. In both these latter patients, strong transverse elastic band traction had to be instituted for prolonged periods to effect dental occlusion.

DISCUSSION

Complications in relation to distraction osteogenesis are more or less similar to those encountered with BSSO.¹⁵ Swennen et al,¹⁴ in their review of 109 articles on distraction osteogenesis, noted 86 complications occurring in 311 patients (27.7%) who had undergone mandibular lengthening. In our study of 70 patients undergoing distraction osteogenesis, a total of 28 complications (40%) were recorded (Table). Most of these complications could be considered mild and could be corrected through noninvasive methods. Fifty percent of them were device-related mechanical problems or local infections. Most of the aforementioned mechanical problems in our group of patients occurred in the first 20 patients during the steepest part of the learning curve and with the same type of distraction device (Howmedica-Leibinger). At that time (1996-1997), when distraction osteogenesis for this indication was still in its infancy, this was the only boneborne intraoral distraction device available to us. The change from corticotomy to full osteotomy and the use of other, stronger types of distraction devices with screw—not pin—fixation enabled us to eliminate most of the device-related complications and also facilitated the placement of the devices. In our group, this “full fracture” of the mandible appeared to be essential to prevent distraction failure, to avert achieving an incorrect

Table. Complications in 70 patients treated for mandibular lengthening

| Complications | No. | Features |
|----------------------------|-----|--|
| Incomplete fracture | 1 | Incomplete lingual mobilization |
| Device-related problems | 10 | 4 times, pressure of the distraction rod on the lower lip 1 time, lost screw 5 times, number of distraction rods |
| Infection | 5 | 4 times, after the placement of distraction devices 1 time, after the removal of distraction devices |
| Disturbance of sensibility | 3 | Persisting 1 y after distraction |
| Compliance | 6 | 4 times, inconsequent wearing of elastic band traction 1 time, premature consolidation 1 time, refusing to eat |
| Condylar problems | 3 | Uncertain whether they are related to distraction |
| Total | 28 | |

vector of distraction, and to thwart the pain caused by distraction.

One of the non-device-related complications is damage to the infraalveolar nerve, which is also one of the most-documented complications of BSSO. Hypoesthesia and anesthesia have been reported in relation to BSSO in 9% to 85% of patients.¹⁶ Publications concerning craniofacial distraction osteogenesis reveal a wide spectrum of variability of neurologic disturbances varying from no clinical effect to permanent neurosensory deficits in 27% to 52% of patients.¹⁷ In our group undergoing distraction osteogenesis, the incidence of postoperative neuropathy, which was initially 23.6%, was reduced to 2.1% after 12 months. The increased mobilization and testing of the distraction device over its full length during the surgical procedure, performed to detect incomplete osteotomy, compromise the mandibular nerve. Nevertheless, this does not appear to be significantly correlated with the incidence of nerve damage.¹⁸⁻²⁰ The temporary dysfunction of the lingual nerve observed in 1 patient was most likely instigated through the use of the osteotome to complete the osteotomy on the lingual side of the mandible.

Condylar changes after distraction osteogenesis were seen in 3 patients. In the case of the young boy with bilateral condylar resorption, it is questionable whether this was attributable to distraction osteogenesis or to the fact that congenital predisposition or a moped accident played a significant role. This case has been extensively reported.²¹ In 2 other patients, both females, signs of unilateral condylar resorption were observed. The prolonged application of strong (perhaps too strong) elastic

band traction to correct occlusion may have been responsible for the changes in these 2 patients.²² It is known that compressive forces during distraction appear to induce a minimal amount of condylar flattening.²³ Good presurgical orthodontic treatment permits docking of the teeth in correct occlusion after distraction has ended and is of the utmost importance.²⁴ In a recent publication, Walker³ revealed that distraction osteogenesis for mandibular lengthening is indicated for adult patients with internal derangements, degenerative joint disease, and both presurgical and postsurgical condylar resorption. Nonetheless, whether distraction osteogenesis can prevent progressive condylar resorption is open to debate. This will remain unanswered until prospective trials are performed.

Vector control is an integral part of treatment with distraction osteogenesis. It represents the biggest difference in concept compared with traditional osteotomies for mandibular elongation. A tendency toward an open bite is not uncommon during the distraction process and can, in most patients, be controlled with light elastic band traction. Occasionally, an open bite cannot be controlled by this method. Early removal of the distractors and subsequent maxillomandibular elastic band traction lead to molding and consolidation of the regenerated bone, positioning the distal fragment correctly. No additional invasive measures are necessary, and no adverse results of the treatment have been encountered. For these reasons, additional elastic band traction and early removal of the distractors is not considered to be a complication, but rather a possible part of this treatment.^{10,25}

We are not aware of any literature regarding the rate of infection when intraoral distraction devices have been used. The infection rate associated with distraction osteogenesis in general is reported as varying between 5% and 30%.¹² However, these complications are mainly related to the application of external distraction devices. Infection is nevertheless mentioned as the most common complication during alveolar distraction.²⁶ Our incidence of local infection as a result of the procedure or arising during the active distraction period (2.9%) and seen when the devices were removed (0.7%) are thus relatively low. Notwithstanding that bacterial contamination is possible during the weeks of distraction and consolidation, the preventive administration of antibiotics during both the placement and the removal of the devices, along with good oral hygiene, appear to be sufficient to reduce the infection rate to an acceptable level.

Malunion is seldom reported.¹⁴ We discovered no evidence of malunion or pseudoarthrosis, either clinically or radiographically, in our series. A 1-mm/day rate of distraction (2 × 0.5 mm) and a 5- to 7-day

latency seem to be generally accepted as the gold standards in the field of craniofacial distraction osteogenesis.

Lack of patient compliance can result in major problems, some of which are difficult to solve, and which may lead to disappointing results and possible further surgery. Extensive pretreatment information should be provided to prevent unpleasant and disappointing results for patient and surgeon.

CONCLUSIONS

This review of 70 patients with Angle Class II/Division 1 malocclusion treated by means of distraction osteogenesis to lengthen the mandible reveals that the procedure is safe, has a low incidence of complications, and has a predictable outcome. Patient compliance during the entire treatment period is essential, and thus careful patient selection is of utmost importance. If there is any doubt about the probable compliance of either patient or parent when planning distraction treatment, one should consider alternative options to prevent disappointment for all concerned.

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