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Long-term skeletal effects of mandibular symphyseal distraction osteogenesis. An implant study

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SUMMARY The purpose of this study was to investigate the long-term skeletal effects of mandibular symphyseal distraction osteogenesis (MSDO) with a tooth- and bone-borne distraction device, analysed using the metallic implant method.

The study sample comprised 20 patients between 15.8 and 25 years of age, with a mean age of 20.01 ± 2.25 years at the start of treatment. In 12 subjects, titanium implants were inserted in the mandible to analyse mandibular skeletal changes in the short and long term. A custom-made intraoral, tooth- and bone-borne distractor was designed and used. After a latency period of 7 days, the distractor was activated twice daily, by a total amount of 1 mm. Postero-anterior (PA) cephalograms were obtained at the start of distraction and at the end of consolidation (94.95 ± 5.79 days after surgery) and follow-up periods (21.5 ± 4.6 months after consolidation). The data were analysed statistically using paired *t*-tests.

The mean amount of screw activation was 8.10 ± 1.68 mm. The inter-symphyseal and inter-molar implant distances and the bimolar width significantly increased during the consolidation period ($P < 0.001$) and were maintained at the end of the follow-up. On the other hand, the bicondylar width was markedly decreased ($P < 0.05$), while no significant skeletal changes were observed in bigonion and biantigonion widths, inter-ramal implant distance, or inter-ramal and implant angles at the end of the consolidation period. The long-term findings of this study indicate that MSDO provides an efficient and stable non-extraction treatment alternative, mainly by increasing the anterior mandibular skeletal and dental arches.

Introduction

Distraction osteogenesis (DO) is a biological process of new bone formation between bone segments that are gradually separated by incremental traction. The traction generates tension that stimulates new bone formation parallel to the vector of distraction (Ilizarov, 1990). During the last decade, this procedure has become a popular technique to successfully treat craniofacial skeletal dysplasias in the sagittal and vertical dimensions (McCarthy *et al.*, 1992; Molina and Ortiz Monasterio, 1995; Polley and Figueroa, 1997).

DO also has the potential to correct transverse mandibular deficiencies. Patients with mandibular transversal deficiencies, such as narrow and tapered forms as seen in hemifacial microsomia, craniosynostosis, hypoglossia–hypodactyly syndrome, or those with tooth–arch length discrepancies and/or lingually tipped teeth, would benefit from widening of the mandible by symphyseal distraction. While traditional approaches such as extractions, stripping, dental tipping or mandibular arch expansion can resolve the deficiency, treatment of transverse discrepancies with mandibular expansion or incisor protrusion has been shown to be unpredictable and could result in relapse and undesirable side-effects in the long term (Gardner and Chaconas, 1976; Betteridge, 1981; Sadowsky and Sakols, 1982; Little *et al.*, 1988; Little and Riedel, 1989; De La Cruz *et al.*, 1995; Wehrbein *et al.*, 1996; Bishara *et al.*, 1997; Blake and Bibby, 1998). On the other hand, expansion of the mandible by the principles of DO generates new bone formation in the basal mandibular bone and holds greater potential compared with previous expansion methods. Therefore, mandibular widening with DO pioneered by Guerrero (1990) would be an alternative treatment modality in subjects with transversal mandibular deficiency or crowding.

Although a number of case reports and clinical studies have been published describing the use and effects of mandibular symphyseal distraction osteogenesis (MSDO) (Guerrero, 1990; Perrott *et al.*, 1993; Guerrero *et al.*, 1997, 1999; Kewitt and Van Sickels, 1999; Del Santo *et al.*, 2000, 2002; Contasti *et al.*, 2001; Mommaerts, 2001; Orhan *et al.*, 2003a; Conley and Legan, 2003), there is still a lack of knowledge regarding the long-term effects and stability. Therefore, the aim of this study was to analyse the mandibular skeletal effects and long-term skeletal stability of MSDO, using Björk-type metallic implants.

Subjects and methods

The study sample comprised 20 patients between 15.8 and 25 years of age, with a mean age of 20.01 ± 2.25 years at the start of treatment (Table 1). In 12 subjects, titanium implants were inserted in the mandible during surgery, in order to precisely analyse the mandibular skeletal changes and long-term skeletal stability (Björk, 1968) (Table 1). In

Table 1 Age distribution of the study subjects ($n = 20$) (mean ± standard deviation).

Age (years)	Amount of activation (mm)	Duration of distraction (days)	Duration of consolidation (days)	Follow-up (months)
20.01 ± 2.25	8.10 ± 1.68	11.35 ± 2.18	94.95 ± 5.79	21.50 ± 4.60
19.38 ± 1.94*	7.96 ± 1.42*	11.75 ± 2.05*	96.58 ± 6.02*	22.29 ± 4.48*

*Implant cases ($n = 12$).

total, six implants were placed bilaterally in the symphyseal (anterior), lower first molar (middle) and ramal (posterior) regions of the mandible. Two pins were inserted in the symphyseal region as far down as possible on both sides of the mandibular midline, two more pins were placed bilaterally on the mandibular corpus under the first molars and finally two pins were inserted on both sides on the external aspect of the ramus at a level with the occlusal surfaces of the mandibular first molars (Björk, 1968; İşeri and Solow, 2000) (Figure 1).

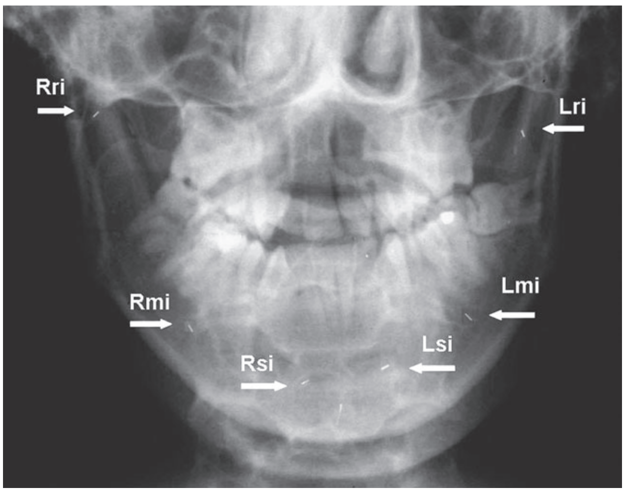

Figure 1 Segment of a postero-anterior cephalogram from a subject with mandibular bilateral symphyseal (anterior), lower first molar (middle) and ramal (posterior) implants. Lsi, left symphyseal implant; Rsi, right symphyseal implant; Lmi, left molar implant; Rmi, right molar implant; Lri, left ramal implant; Rri, right ramal implant.

The selection criteria for mandibular widening with DO included moderate to severe mandibular anterior dental crowding, transverse mandibular deficiency (narrow or V-shaped mandibular arch form), unilateral or bilateral scissor bite (Brody's syndrome) and combined maxillo-mandibular transverse deficiencies (Del Santo *et al.*, 2000; Contasti *et al.*, 2001; Conley and Legan, 2003). Eighteen patients received rapid maxillary expansion (RME) in addition to mandibular midline DO and in four of these patients surgically assisted RME was carried out. None of the patients had any systemic problems.

The patients and their parents were informed about the proposed treatment plan involving the surgical intervention, insertion of the metallic implants and conventional alternative treatment options and only volunteers were included in this study. Informed consent was obtained from each patient before the MSDO procedure and the research project was approved by the Ethical Committee of the School of Dentistry, University of Selçuk.

Appliance design

A custom-made, intraoral, rigid, tooth- and bone-borne distraction device was designed and used. The device consisted of a Hyrax screw (GAC, New York, USA) and two footplates (Strike-Liebinger, Freiburg, Germany). The distractor was positioned in front of the lower incisors at the gingival level and the opening holes of the screw were placed on the mandibular midline. The upper arms of the screw were bent in accordance with the lower anterior arch form and were fitted into the premolar brackets, which were welded to the band in a horizontal position. Footplates were

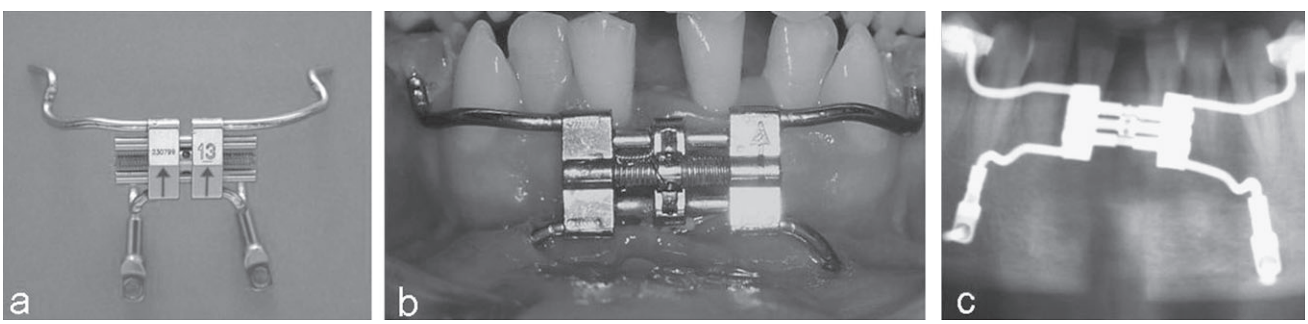

Figure 2 (a) The custom-made, intraoral, rigid, tooth- and bone-borne distractor. (b) The distractor in place, the opening procedure is completed. (c) A radiographic view of the mandibular widening.

fixed to the tip of the lower arms and adjusted according to the symphysis formation (Figure 2).

Surgical procedure

The surgical procedure was performed under local anaesthesia and intravenous sedation. An incision to a depth of 4–6 cm was made in the mandibular vestibule, through the orbicularis oris muscle. The upper arms of the device were then fixed to the first premolars, the lower arms with footplates were adjusted to the bone, and the guidance screw holes were drilled using a Lindeman bur. A vertical osteotomy was made through the symphyseal area with an oscillating saw blade, starting at the inferior border of the mandible and extending to the inter-dental space between the apices of the mandibular central incisors. Then, with a straight hand piece, the cut was continued on the labial cortical plate of the mandible until the alveolar crest was reached. The final sectioning was carried out manually with a mallet and spatula osteotome. Once the vertical osteotomy and sectioning of the mandible had been completed, the distraction device was fixed to the bone using mini plate screws and to the first premolar brackets by ligature and composite. The distractor was then carefully activated to control a complete osteotomy and then closed back to its initial position. Care was taken to ensure that the wounds were sutured in the correct tissue planes. A surgical cut was performed between the central incisors in 19 patients and between the central and lateral incisors in one patient.

Distraction protocol and orthodontic treatment

After a latency period of 7 days, the distraction device was activated by the patient twice a day, once in the morning and once in the evening, a total amount of 1 mm per day. The patients were seen regularly until the desired mandibular widening was complete. The mean amount of expansion was 8.10 ± 1.68 mm and the mean distraction time 11.35 ± 2.18 days. After the mandibular widening had been completed, the device was stabilized by a wire ligature. The mean consolidation period was 94.95 ± 5.79 days (Table 1).

Immediately after the distraction procedure, fixed appliance orthodontic treatment was initiated for the mandibular incisors and canines and tooth movement was started towards the distraction site. Dental crowding was resolved by movement of the anterior teeth into the distraction site with fixed orthodontic appliances. RME was also initiated and completed by using full coverage acrylic-bonded maxillary expansion devices in 18 subjects during the consolidation period (Memikoğlu and İşeri, 1997, 1999; Orhan *et al.*, 2003b).

Cephalometric analysis

Postero-anterior (PA) radiographs were obtained from each patient at the start of distraction, at the end of consolidation, and at follow-up periods. On the PA films, eight anatomical and six implant reference points were marked and seven linear and two angular cephalometric measurements were performed. Cephalometric landmarks are illustrated and described in Figure 3. The PA cephalometric measurements were as follows.

Implant measurements.

1. Inter-symphyseal implant distance (Lsi–Rsi) (mm): the distance between the left and right symphseal implants.
2. Inter-molar implant distance (Lmi–Rmi) (mm): the distance between the left and right molar implants.
3. Inter-ramal implant distance (Lri–Rri) (mm): the distance between the left and right ramal implants.
4. Implant angle (Lmi–Lri/Rmi–Rri) (degrees): the angle between the left and right implant lines.

Skeletal and dental measurements.

1. Bicondylar width (Lco–Rco) (mm): the distance between the most lateral points of the right and left condyles.
2. Bigonial width (Lgo–Rgo) (mm): the distance between the right and left gonial points.
3. Biantegonial width (Lag–Rag) (mm): the distance between the right and left antegonial points.
4. Bimolar width (Llm–Rlm) (mm): the distance between the most prominent lateral points on the buccal surfaces of the left and right second permanent mandibular first molars.
5. Ramal angle (Lco–Lgo/Rco–Rgo) (degrees): the angle between the left and right ramal planes.

The changes that occurred during the different stages of treatment were evaluated statistically using the paired *t*-test.

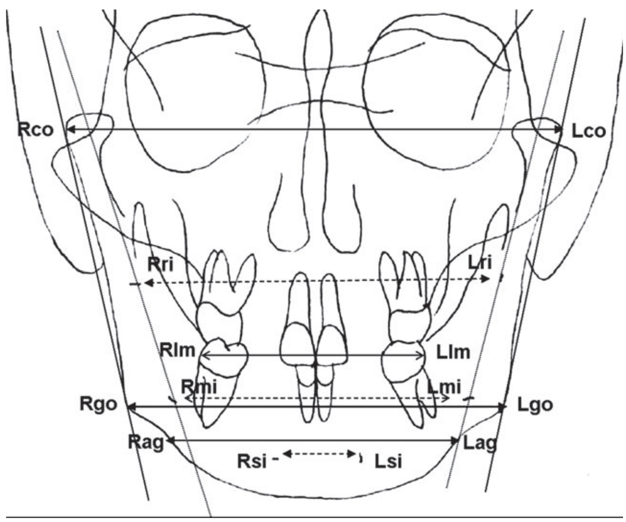

Figure 3 Reference points and measurements on postero-anterior cephalometric films. Lsi, left sympyhseal implant; Rsi, right symphyseal implant; Lmi, left molar implant; Rmi, right molar implant; Lri, left ramal implant; Rri, right ramal implant; Lco, left condyle; Rco, right condyle; Lgo, left gonion; Rgo, right gonion; Lag, left antegonion; Rag, right antegonion; Llm, left lower molar; Rlm, right lower molar.

The reliability of the measurements was examined on the records of all 20 subjects by repeating the point marking and measurement procedures within a 4 week interval. The reliability of a single measurement, computed using the formula described by Winner (1971), ranged between 0.83 and 0.99.

Results

Descriptive statistics and a comparison of the data by paired *t*-test are shown in Table 2.

There were significant increases in inter-symphyseal and inter-molar implant distances ($P < 0.001$), while no significant changes were observed in the inter-ramal implant distance or the implant angle between the start of distraction and the end of the consolidation periods. No significant changes were observed in any of the implant measurements, but the inter-symphyseal implant distance increased ($P < 0.05$) during the follow-up period. The increases in both inter-symphyseal and inter-molar implant distances were maintained (Table 2, Figure 4).

PA analysis also demonstrated that there were no significant skeletal changes in the bigonial and biantegonial widths or inter-ramal angle between the start of distraction and the end of the consolidation periods. However, there was a statically significant increase in bimolar width ($P < 0.001$), while bicondylar width was significantly decreased in the same period ($P < 0.05$). Bicondylar width was significantly increased during the follow-up period ($P < 0.05$), while no significant changes were observed in the other measurements (Table 2, Figure 5).

Discussion

MSDO has become an important treatment option for patients with mandibular hypoplasia and transversal mandibular deficiencies over the last decade. Despite the reports of success (Guerrero, 1990; Perrott *et al.*, 1993; Guerrero *et al.*, 1997, 1999; Kewitt and Van Sickels, 1999; Del Santo *et al.*, 2000, 2002; Contasti *et al.* 2001; Mommaerts, 2001; Malkoç *et al.*, 2002, 2003; Orhan *et al.* 2003a), there are still some questions that remain unanswered, especially regarding the displacement pattern of the mandible and long-term stability following MSDO.

In a previous study, Del Santo *et al.* (2000) pointed out the importance of future prospective longitudinal studies to evaluate distraction and post-distraction changes and recommended the use of metallic bone markers to precisely measure the amount of distraction in the anterior region. The present investigation was a prospective longitudinal study including the records of some patients with bilateral metallic implants in the mandible. A major source of random error in a cephalometric investigation is usually the identification of landmarks. However, when correctly inserted in the endosteal bone, metallic markers remain permanently stationary (Björk, 1968; Björk and Skieller, 1983; İşeri and Solow, 2000), so this type of error was markedly reduced using the metallic implant method, due to the availability of inserted sets of titanium metallic implants in 12 subjects. Therefore, Björk-type metallic implants were used to determine the skeletal widening effect of MSDO on the mandibular structures. Furthermore, the metallic implant method also helped to provide reliable knowledge regarding the long-term stability of MSDO.

PA analysis indicated that the greatest widening effect was found in the symphyseal region and gradually decreased from the anterior to the posterior direction on the sagittal plane. The width of the mandibular bone at the symphyseal region increased significantly, with the ramal and gonial regions of the mandible showing minimal displacement, while the inter-condylar width was slightly decreased and then increased again to its original distance. Therefore, the two halves of the mandible were separated in a non-parallel wedge-shape manner and the widening

Table 2 Comparison of the implant, skeletal and dental postero-anterior cephalometric measurements (mean ± standard deviation).

	Start of treatment (T1)	End of consolidation (T2)	Follow-up (T3)	Ranked ANOVA	*t*-test		
					T1–T2	T2–T3	T1–T3
Implant measurements (*n* = 12)							
Inter-symphyseal implant distance	12.18 ± 3.39	18.67 ± 3.37	17.95 ± 3.85	0.001	***	*	***
Inter-molar implant distance	58.33 ± 4.64	62.25 ± 4.65	62.43 ± 4.82	0.001	***		***
Inter-ramal implant distance	84.18 ± 5.34	84.46 ± 5.35	83.93 ± 5.29	ns			
Implant angle	37.93 ± 11.19	37.36 ± 11.21	37.13 ± 11.82	ns			
Skeletal and dental measurements (*n* = 20)							
Bicondylar width	122.19 ± 6.76	121.55 ± 6.61	122.05 ± 6.90	0.05	*	*	
Bigonial width	99.95 ± 6.67	99.74 ± 6.39	99.72 ± 6.26	ns			
Biantegonial width	86.65 ± 5.55	86.86 ± 4.95	86.45 ± 5.42	ns			
Bimolar width	66.95 ± 4.38	67.73 ± 4.34	67.83 ± 3.96	0.001	***		**
Ramal angle	24.25 ± 6.69	23.88 ± 5.92	23.95 ± 5.39	ns			

*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$; ns, not significant.

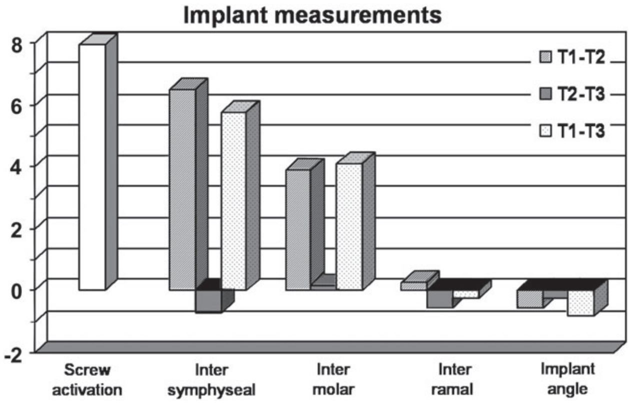

Figure 4 Changes in implant measurements.

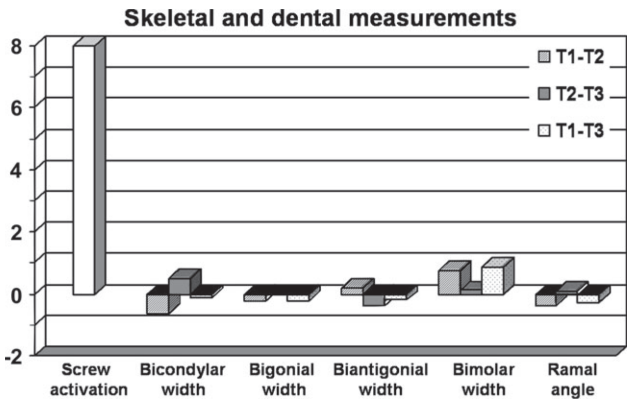

Figure 5 Changes in skeletal and dental measurements.

effect gradually decreased from symphysis to ramus, without almost any change around the ramus and gonial regions. These results are in conflict with the findings of Del Santo *et al.* (2000), who reported that a considerable widening effect was created using tooth-borne distraction devices, not only in the symphysis area, but also in the posterior structures.

Viewed frontally, both implant and skeletal measurements indicated that bone displacement was achieved almost in a parallel manner and no significant changes were observed in the inter-ramal or implant angles during the distraction or follow-up periods. In previous experimental (Hollis *et al.*, 1998; Bell *et al.*, 1999) and clinical (Guerrero *et al.*, 1997, 1999; Del Santo *et al.*, 2000) studies, disproportional displacement patterns resulting in a larger gap in the dentoalveolar area than in the basal area have been demonstrated with tooth-borne distraction devices. On the other hand, bone-borne or tooth- and bone-borne expansion devices have a greater potential for proportional movement than tooth-borne devices, and more stable results can be expected (Hollis *et al.*, 1998). Therefore, the widening effect differences between the present and previous studies in the sagittal and vertical dimensions might be related to the different designs of the distraction devices, as well as different points of force application.

No significant changes were observed during the follow-up period in the skeletal, dental or implant measurements, except for inter-symphyseal implant distance and bicondylar width ($P < 0.05$). However, mandibular skeletal widening achieved by MSDO was stable at the end of the 2 year follow-up period (Table 2, Figures 4, 5). This finding is supported by the results of a previous study where it was reported that transverse skeletal changes were stable 1.3 years after MSDO surgery (Del Santo *et al.*, 2000).

An important benefit of DO is the gradual distraction effect, not only on the skeletal structures, but also on the associated soft tissues, such as the muscles of mastication, subcutaneous tissue, and skin. This soft tissue expansion has been associated with minimal, if any, evidence of skeletal relapse. This is in fact in contrast with the predictable relapse associated with the traditional orthodontic and surgical methods (Grayson and Santiago, 1999). According to the long-term follow-up findings, relapse after 8–12 mm mandibular widening with DO would be minimal or non-existent, if an adequate distraction protocol and bony consolidation period is used. A consolidation period of at least 3 months is indicated for mandibular widening, with the exact time based on radiographic visualization of cortical bone in the distraction regenerate. From a clinical point of view, it is important to determine when the regenerated bone is sufficiently strong for the distraction device to be removed to allow unrestrained functional loading of the distracted complex. Although the appropriate duration of the consolidation period can be approximated by the distraction–consolidation index of limb lengthening, this index may not be valid in cranial bone distraction (Smith *et al.*, 1999). The results of the present study suggest that a consolidation period of approximately 3 months seems to be sufficient to prevent post-distraction relapse following mandibular widening.

Intraoral distraction devices have important advantages, such as greater patient acceptance and more time for bony consolidation, than external distraction devices (Chin and Toth, 1996). Therefore, the concept of DO for mandibular expansion is thought to be promising and feasible for clinical practice. The advent of DO in the craniofacial region has enabled the rules of not violating the inter-canine width or lower arch form to be discussed. According to the results of the present study, it does not seem likely that the mineralized symphyseal regenerative tissue will collapse at a later stage. However, the long-term stability of dentoalveolar changes in MSDO subjects should also be verified in future investigations.

Conclusion

The long-term findings of this study, based on metallic implant analysis, indicated that MSDO using a tooth- and bone-borne distraction device is an effective and stable non-extraction treatment alternative in subjects with transverse mandibular deficiency and/or mandibular anterior dental crowding, mainly by increasing the anterior mandibular skeletal and dental arch widths. However, long-term studies are still necessary, especially regarding the stability of dentoalveolar structures in MSDO cases.

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