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Morbidity related to transmandibular distraction osteogenesis for patients with developmental deformities☆

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SUMMARY. Introduction: **The aim of this retrospective observational case series study was to determine the morbidity of transmandibular Distraction Osteogenesis (DO) using a bone-borne distraction device to adapt the surgical protocol and improve hardware design.** Patients and methods: **The treatment of 23 consecutive, non-syndromic patients who underwent transverse mandibular DO after a midline symphyseal osteotomy with the TransMandibular Distractor (TMD™) was evaluated. The follow-up period lasted at least 1 year after the end of the contention period. Treatments were analysed according to the morphological and functional Success Criteria (SC) for Craniofacial Distraction Osteogenesis (CFDO) for patients with developmental dento-facial malformations established by the steering group of European Collaboration on Cranial Facial Anomalies (EUROCRAN).** Results: **Appropriate distraction was obtained in 22 of the 23 patients. One patient had irreversible dentition damage, consisting of an inadvertent apical section. All other SC for CFDO were fulfilled 100% at 1 year follow-up. Seven patients suffered from short-term local infections during different phases of treatment. Two patients suffered subluxation of a central incisor that healed uneventfully. Local discomfort due to delayed union (in three patients) and trauma to the lower lip (one patient) were also observed.** Conclusion: **The main problems were high local infection rates and damage to an apex that required a root filling, as well as patient discomfort due to delayed union and/or the bulkiness of the TMD™ device. Based on the results of this morbidity study, modifications are recommended for both the surgical protocol and the TMD™ device hardware. © 2008 European Association for Cranio-Maxillofacial Surgery**

Keywords: **morbidity, osteogenesis, distraction, mandible, chin**

INTRODUCTION

Symphyseal transverse Distraction Osteogenesis (DO) or transmandibular DO is a successful surgical alternative to orthodontic dental compensation, removal of tooth mass by interproximal stripping, or extractions in cases of transverse anterior mandibular discrepancy (*Guerrero*, 1990; *Guerrero* et al., 1997; *Mommaerts*, 2001; *Mommaerts* et al., 2004a,b; *Mommaerts* and *Vande Vannet*, 2004; *Mommaerts* et al., 2005). Several authors have proven the efficacy of this technique in animal experiments (*Bell* et al., 1999; *El-Hakim* et al., 2004) and in small clinical series (*Weil* et al., 1997; *Kewitt* and *Van Sickels*, 1999). The distraction device itself can be tooth-borne (*Guerrero* et al., 1997; *Del Santo* et al., 2000; *Braun* et al., 2002; *Orhan* et al., 2003; *Iseri* and *Malkoc*, 2005; *Alkan* et al., 2006; *Tae* et al., 2006), bone-borne (*Guerrero* et al., 1997; *Bell* et al., 1999; *Mommaerts*, 2001; *Braun* et al., 2002; *El-Hakim* et al., 2004; *Iseri* and *Malkoc*, 2005), or a combination of both (*Uckan* et al., 2005; *Duran* et al., 2006). The activation component of the bone-borne TransMandibular Distractor (TMD™) (Surgi-tec NV, Bruges, Belgium) is positioned in the frontal buccal sulcus, behind the lower lip with the fixation arms penetrating the mucous membrane. Complications at the level of the periodontal and endodontal status of the incisors and at the Temporomandibular Joints (TMJs) have been reported in another study (*Mommaerts* et al., 2005).

The purpose of this retrospective cohort study was twofold: (1) to identify factors that cause subjective patient morbidity during symphyseal transverse DO with the TMD™ device using the morphological and functional Success Criteria (SC) for Craniofacial Distraction Osteogenesis (CFDO) established by the steering group of European Collaboration on Cranial Facial Anomalies (EUROCRAN) and (2) to suggest solutions to improve both the surgical protocol and the design of the TMD™ device hardware.

PATIENTS AND METHODS

From June 1999 until June 2004, 23 non-syndromic patients underwent transverse anterior mandibular expansion after a vertical midline symphyseal osteotomy using the bone-borne TMD™ device according to a standardised DO protocol (*Mommaerts*, 2001). Patient ages ranged from 11 to 40 years (mean: 19.5 years) at the time of surgery. There were 14 female and nine male patients. Three

☆No grants or company affiliation.

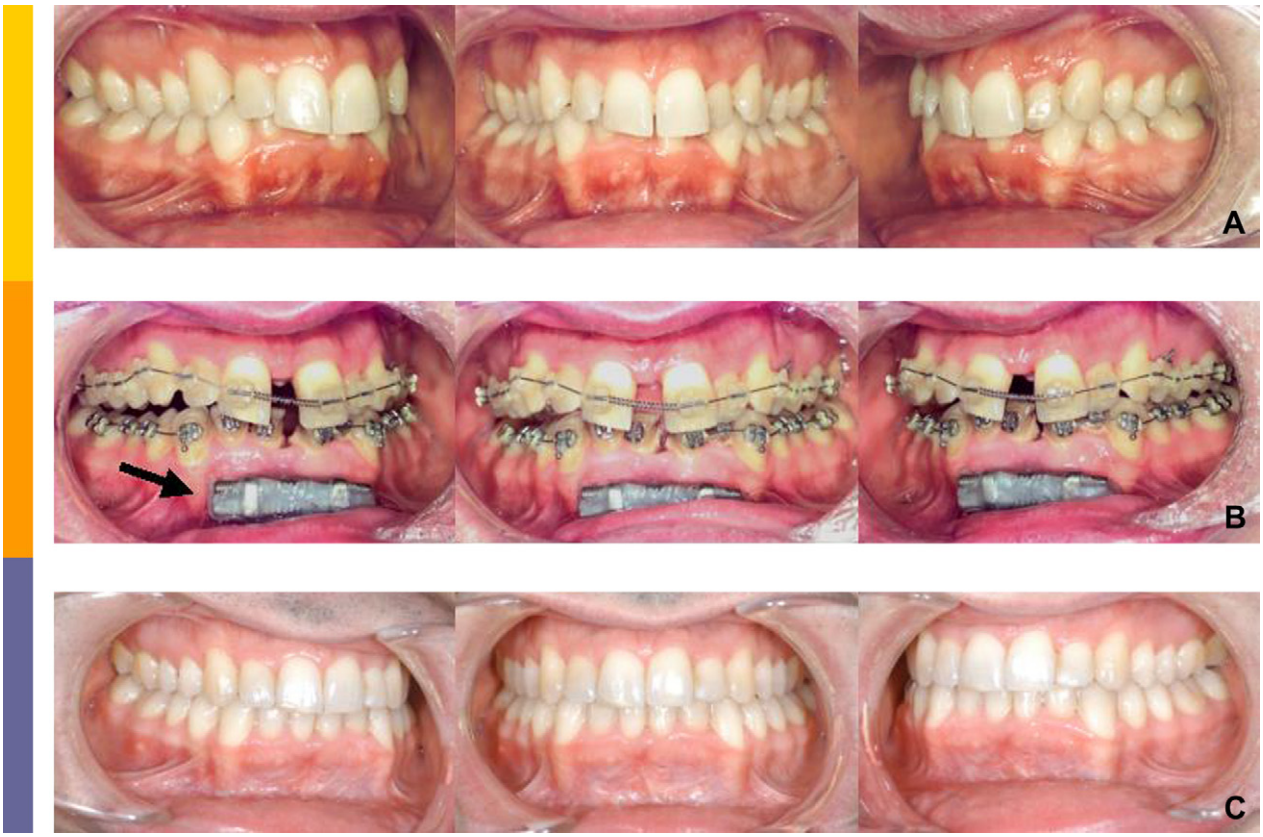

Fig. 1 – (A) Pre-treatment condition being a Class I malocclusion with upper and lower anterior crowding and aesthetically disturbing buccal corridors. A case for smile (aesthetic) enhancement by transpalatal and transmandibular osteodistraction, in combination with fixed orthodontic appliances. (B) Consolidation condition (orthodontics by N. Lammens, LDS, MSc). The TPD device on the palate is not visible. The arrow points at the TMD device. (C) After debonding.

staff surgeons performed these operations (Maurice Mommaerts 14; Johan Abeloos 8, and Calix De Clercq 1), with the assistance of different trainee surgeons and fellows. Twenty-one patients underwent simultaneous transpalatal osteodistraction using the bone-borne TransPalatal Distractor (TPD™) device (*Neyt* et al., 2002; *Mommaerts* et al., 2004a; *Mommaerts* and *Vande Vannet*, 2004 – Fig. 1).

At induction, all patients were given 1 g Cefazolin (Kefzol®, Eli Lilly B.V., Houten, the Netherlands) and 125 mg methylprednisolone (Solu-medrol®, Pharmacia & Upjohn, Puurs, Belgium). Disinfection of the face was performed using 0.5% aqueous chlorhexidine solution and intra-orally with hexitidine solution (Hextril®, Pfizer Pharma GmbH, Karlsruhe, Germany). A 1% lidocaine solution with epinephrine 1/80,000 (Xylocaine® 1%, NV Astra Pharmaceuticals, Brussels, Belgium) was infiltrated into the buccal sulcus mucosa.

A straight, vertical, symphyseal osteotomy design was used (*Mommaerts*, 2001 – Fig. 2). The incision into the vestibular fold was limited to 15 mm and the subperiosteal dissection of the alveolus and symphysis was limited to the width of the fixation arms of the distractor. Hence, sectioning and stripping of the mentalis muscle can be avoided. The osteotomy line was marked with a small Lindemann bur (Komet, Lemgo, Germany). The size of the TMD™ device (paediatric/adult, 12- or 20-mm distraction) was adapted to the mandibular symphysis and provisionally fixed with one osteosynthesis screw on each side of the marked osteotomy line. The symphyseal component of the osteotomy was performed

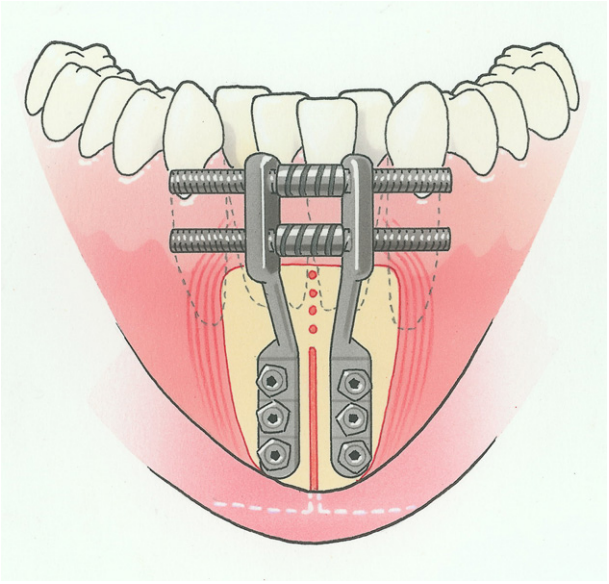

Fig. 2 – Symphyseal vertical midline osteotomy, avoiding the mentalis muscles but endangering the apices of the central incisors when these are juxtaposed.

Table 1 – Morphological and functional SC for CFDO in patients with developmental dentofacial malformations established during the EUROCRAN distraction steering group meeting of November 13, 2004 (www.eurocran.net)

1	Appropriate distraction is obtained to achieve desired morphology or function	Yes (+)/No (−)
2	Adequate occlusal relationship is achievable	Yes (+)/No (−)
3	No occurrence of pseudarthrosis	Yes (+)/No (−)
4	No severe complication arising from infection (e.g., osteomyelitis, permanent facial nerve damage)	Yes (+)/No (−)
5	No NSDs	Yes (+)/No (−)
6	No persistent pain or discomfort (e.g., TMJ problems)	Yes (+)/No (−)
7	No irreversible damage to the dentition, periodontium and/or skin	Yes (+)/No (−)
*8**	*Overall facial contour and profile improvement*	*Yes (+)/No (−)*
9	No dentoalveolar compensations	Yes (+)/No (−)
*10**	*Skeletal stability 1 year after the end of the retention period*	*Yes (+)/No (−)*

*These variables were not rated in this study.

bicortically with a disposable reciprocating saw (Aesculap AG, Tuttlingen, Germany). The buccal cortex in the apical area was cut with the fine Lindemann bur. Finally, an interdental and upper lingual osteotomy was completed with osteotomes. The TMD™ device was then fixed with one bicortical and two monocortical screws on each side of the midline symphyseal osteotomy line. When the mobility of both segments was in doubt, a limited distraction test was performed. After copious irrigation with saline solution, the incision was closed with Polyglactin 910 4-0 (Vicryl® Rapide, Ethicon, Johnson & Johnson, Dilbeek, Belgium). Care was taken to adapt the mucosa around the submerged vertical arms of the TMD™ device. The intra-oral, extra-mucosal component of the TMD™ device was covered with Utility wax (Heraeus Kulzer Inc., South Bend, USA) to protect the lower lip.

After a mean latency period of 7 days (Standard Deviation [SD]: 1.5 days), the patients received proper instructions on the activation of the distraction device at a rhythm and rate of once at 0.4 mm/day. The activation period lasted on average 19 days (SD: 6.7 days). The consolidation phase lasted for 65 days on average (SD: 22.3 days). An occlusal radiograph and/or ultrasound scan was performed prior to distractor removal to ensure proper callus ossification (*Mommaerts* et al., 2004b).

Patients were seen post-operatively, 1 week after surgery, once or twice at the end of the activation period, at the end of the consolidation period, and when difficulties required intervention. The post-consolidation clinical follow-up period extended for minimum of 1 year. Patient samples were analysed according to the morphological and functional SC for CFDO for patients with developmental dentofacial malformations established during the EUROCRAN distraction steering group meeting of November 13, 2004 (Table 1).

RESULTS

The results of the rating of patient samples according to the EUROCRAN SC for CFDO are summarised in Table 2. Other clinical observations relevant to patient morbidity are also listed in this table. Appropriate distraction was obtained in 22 out of 23 patients. In all patients, an adequate occlusal relationship was achieved after 1 year of follow-up. There were no pseudarthroses. There were three cases of delayed union, for which the consolidation period was extended by 3 weeks. There were no severe complications from infection, although seven patients suffered from short-term local infections during different phases of treatment. There was one case of necrotising gingivitis, one case of local infection around an osteosynthesis screw, and five local chin infections. Two chin infections appeared as classical wound infections during the first post-operative week and five cases occurred during the contention period. The necrotising gingivitis was treated with mouth rinses that consisted of PerioGard (Colgate–Palmolive) and a 3% H_2O_2 solution. The local infection around the osteosynthesis screw was treated with Doxycycline. The chin infections were treated with drains and antibiotics (cephalosporin orally, amoxicillin–clavulanate potassium orally and IV). In one patient with infection during the retention period, the TMD™ device had to be removed prior to the end of the stabilisation period and

Table 2 – Rating of the patient samples according to the EUROCRAN SC for CFDO

Patients											Other observations
	1	2	3	4	5	6	7	8	9	10	
1	+	+	+	+	+	+	+		+		Subluxation of a central incisor (remained vital)
2	+	+	+	+	+	+	+		+		Necrotising gingivitis
3	+	+	+	+	+	+	+		+		Chin abscess and lip ulceration
4	+	+	+	+	+	+	+		+		
5	+	+	+	+	+	+	+		+		
6	+	+	+	+	+	+	+		+		
7	+	+	+	+	+	+	+		+		
8	+	+	+	+	+	+	+		+		
9	+	+	+	+	+	+	+		+		Subluxation of a central incisor (remained vital)
10	+	+	+	+	+	+	+		+		Delayed union
11	+	+	+	+	+	+	+		+		
12	+	+	+	+	+	+	+		+		
13	+	+	+	+	+	+	+		+		Chin abscess 1 month post-operatively
14	+	+	+	+	+	+	+		+		
15	+	+	+	+	+	+	+		+		
16	+	+	+	+	+	+	+		+		
17	–	+	+	+	+	+	+		+		Incomplete osteotomy
18	+	+	+	+	+	+	+		+		Local infection of a chin haematoma 3 days post-operatively
19	+	+	+	+	+	+	+		+		Delayed union
20	+	+	+	+	+	+	+		+		Delayed union
21	+	+	+	+	+	+	+		+		
22	+	+	+	+	+	+	+		+		Chin abscess 2 months post-operatively
23	+	+	+	+	+	+	–		+		Central incisor dead

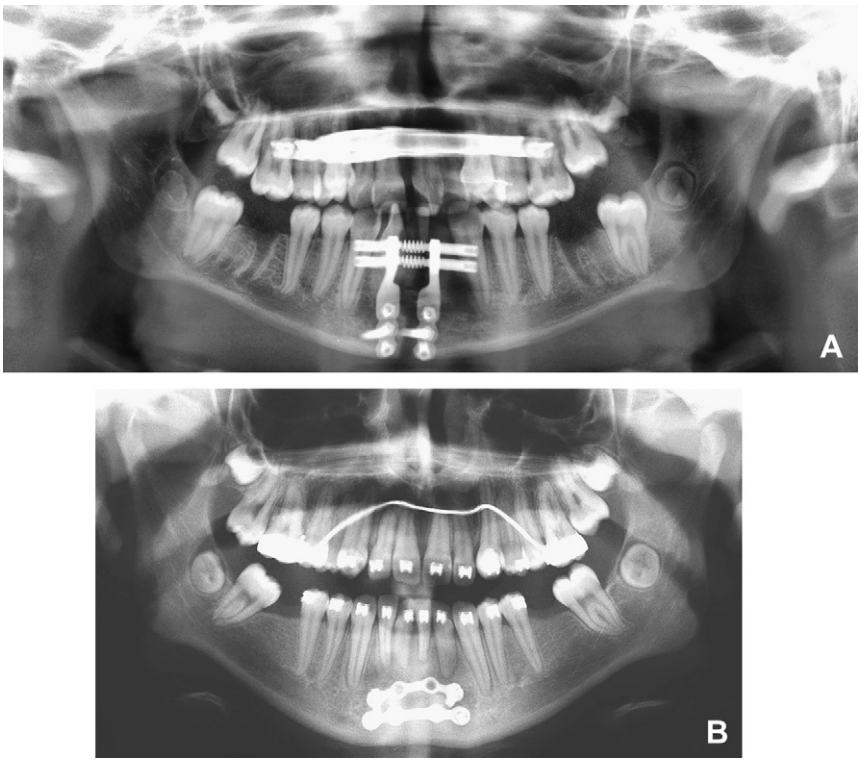

Fig. 3 – Orthopantomograms of a TPD + TMD case: (A) Two days after distractor activation. The mandibular osteotomy is of step-design and the upper limb is mesial to the left lower canine, in order to avoid the apices of the double rowed incisors. (B) Orthopantomogram (OPG) 15 months post-operatively. The TMD has been removed after the active distraction phase and replaced by osteosynthesis plates.

replaced by plate osteosynthesis (Fig. 3). In all other patients, the TMD™ device remained in place until the end of the consolidation period. There were no permanent neurosensory disturbances (NSDs). Abnormal teeth sensitivity was investigated in another study (*Mommaerts* et al., 2005). None of the patients had persistent pain or discomfort; however, local discomfort due to delayed union (three patients) and trauma to the lower lip (one patient) were observed. All devices could be adapted to not interfere with the occlusion, even for deep bites. In a few patients, the fullness of the lower lip, caused by the volume of the distractor device, created a temporary aesthetic problem. One patient suffered initially from pain in the TMJ, which resolved with physiotherapy. Two patients had irreversible damage to the dentition; in one patient, a central incisor died due to a contusion while in another patient, an iatrogenic apical resection occurred. Two other patients initially had subluxation of a central incisor that healed uneventfully. There was no dentoalveolar compensation. One patient suffered from a post-operative haematoma in the floor of the mouth. She was admitted to the mid-care unit for closer observation. Surgical re-intervention was not necessary and the haematoma resolved spontaneously.

DISCUSSION

Initially, SC for CFDO were proposed by *Swennen* et al. (2001) based on the results of a systematic review of the literature. During the evaluation process of the results of the EUROCRAN distraction study (*Kuijpers-Jagtman* and *Wijdeveld*, 2005), it became obvious that these initial SC for CFDO needed certain modifications. During the EUROCRAN distraction steering group meeting of November 13, 2004, morphological and functional SC for CFDO were developed for patients with both congenital and developmental dentofacial malformations. The latter criteria (Table 1) were used in this retrospective cohort study to evaluate patient morbidity during symphyseal transverse DO with the bone-borne TMD™ device. Two criteria ("Overall facial contour and profile improvement" and "Skeletal stability 1 year after the end of the retention period") will be analysed by EUROCRAN. The results of this study showed that at 1 year of follow-up, six of the eight SC for CFDO had been fulfilled 100%. As far as the other two SC are concerned, appropriate distraction was obtained in 21 of 23 patients; one patient had irreversible damage to the dentition. All other SC for CFDO had been fulfilled 100% at 1 year follow-up.

Although the EUROCRAN SC for CFDO were valuable for rating the long-term success of the surgical procedure (1 year follow-up), these criteria could not identify the factors that caused subjective patient morbidity during the initial distraction (period).

The main problem during symphyseal transverse DO with the bone-borne TMD™ device appears to be high local infection rates and patient discomfort due to delayed union. High infection rates warrant further analysis. Because earlier studies in our unit did not reveal a relationship between the surgeon and the infection rate in orthognathic surgery in general (*Acebal-Blanco* et al.,

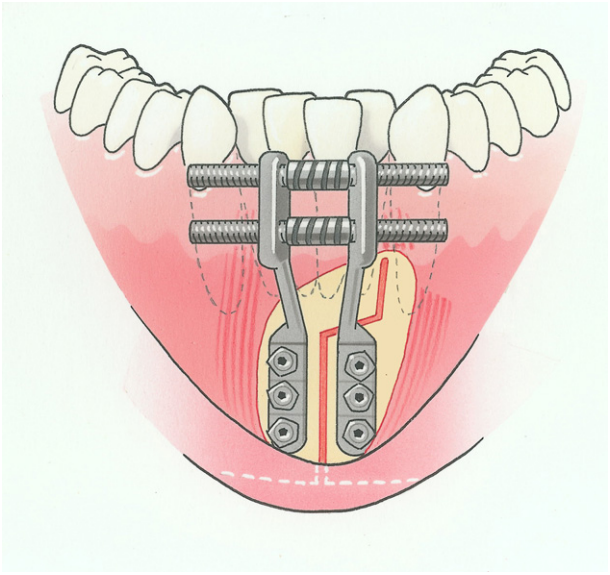

Fig. 4 – Step osteotomy in the symphysis. The alveolus between the canine and lateral incisor is often much wider than between the central incisors. The mentalis muscle at the site of the osteotomy has to be reconstructed. One vertical arm of the device is at the level of the osteotomy, hence possibly jeopardising callus formation in the case of descending infection.

2000; *Spaey* et al., 2005), it is likely that other causes are responsible. The two immediate post-operative local infections may be due to difficult wound closure, which is not easy to achieve in a watertight fashion. Miniturisation of the fixation arms may help, as well as a purse-string suture around the fixation arms that penetrate the oral mucosa. The application of fibrin glue (Tissucol®, Baxter Healthcare Corporation, Deerfield, Ireland) both in and over the wound, is an alternative means to prevent soiling with saliva and was begun immediately after the analysis of this study. Another plausible reason for the high infection rates could have been residual bone dust lingual to the symphyseal osteotomy. Hence, opening the osteotomy gap and carefully rinsing the lingual side have since become routine. The three infections that occurred during the consolidation period were probably due to a persistent entry port and/or difficulty in maintaining normal oral hygiene in the presence of the TMD™ device. In order to prevent these late local infections, the device could be removed at the end of the distraction period and replaced by titanium or resorbable osteosynthesis plates. In two patients, the distractor was removed earlier and replaced with two titanium osteosynthesis plates (Synthes NV, Brussels, Belgium) using local anaesthesia as is conventionally done for the removal of the TMD™ device. We admit that a theoretical drawback is the temporary limitation of the buccal blood supply to the immature distraction regenerate. An experimental animal study should be interesting to investigate this issue in particular.

According to the EUROCRAN SC for CFDO, two patients had irreversible damage to the dentition during the symphyseal distraction procedure. To cope with the proximity of the apices of the lower central incisors and potential iatrogenic trauma to these teeth in certain patients where a vertical midline symphyseal osteotomy is performed, *Mussa* and *Smith* (2003) suggested creating a diastema pre-operatively using orthodontics. However, since severe crowding is the primary indication for symphyseal widening, non-extraction orthodontic widening is difficult. In one patient in this study, an iatrogenic apical resection of a central lower incisor occurred during the symphyseal osteotomy. This accident led to a modification of the vertical, straight, midline osteotomy into a step osteotomy design. In cases of severe dental crowding on the midline, we currently prefer to place the interdental osteotomy at a site where there is a natural diastema at the apical level, which is frequently between the canine and lateral incisor. To prevent deviation of the chin, a vertical osteotomy is performed in the midline to 5 mm below the apices of the incisors. The two vertical osteotomy lines are then connected with an oblique subapical osteotomy (Fig. 4).

In this study, only one patient complained of TMJ pain, which resolved with physiotherapy. Hence, the TMD™ device appears to accommodate the small condylar rotations in the fossa that occur during symphyseal DO (*Mommaerts* et al., 2005).

CONCLUSION

Chin abscesses, patient discomfort, and apical trauma were the most important drawbacks of symphyseal expansion with TMD after midline osteotomy.

Two adaptations to the surgical technique may be considered. One is to close the wound around the device arms with a purse-string suture and to apply fibrin glue to seal the ‘‘porte d’entrée’’, thus minimising the number of infections. The other is to prefer a step osteotomy in order to avoid an inadvertent apical resection of a central incisor. As for recommended hardware alterations, one may think of reducing the intra-oral volume of the distractor and to protect the lip reliably from irregularities with silicon caps on the horizontal arms of the device.

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