

**Surgically Assisted Rapid
Maxillary Expansion;
surgical and orthodontic
aspects**

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Surgically Assisted Rapid Maxillary Expansion; surgical and orthodontic aspects

**Chirurgisch geassisteerde snelle maxillaire expansie;
chirurgische en orthodontische aspecten**

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Promotoren: Prof.dr. K.G.H. van der Wal
Prof.dr. S.E.R. Hovius

Overige leden: Prof.dr. R.J. Baatenburg de Jong
Prof.dr.ir. H.H. Weinans
Prof.dr. H. van Beek

Copromotor: Dr. E.B. Wolvius

Paranimfen: Dr. J. Koudstaal
 I.P. Leistikow

‘My philosophy, in essence, is the concept of man as a
heroic being, with his own happiness as the moral
purpose of his life, with productive achievement as his
noblest activity, and reason as his only absolute’

Objectivism, Ayn Rand, 1957

CONTENTS

Prologue and aim of the study	1
Part I General introduction	5
Chapter 1 Surgical Assisted Rapid Maxillary Expansion (SARME); a review of the literature <i>Int J Oral Maxillofac Surg 2005;34:709-714 Invited review</i>	7
Part II Fundamental studies and development	25
Chapter 2 Experience with the Transpalatal Distractor in congenital deformities <i>Mund Kiefer Gesichtschir 2006;10(5):331-334</i>	27
Chapter 3 The Rotterdam Palatal Distractor: introduction of the new bone-borne device and report of the pilot study <i>Int J Oral Maxillofac Surg 2006;35:31-35</i>	35
Chapter 4 Relapse and stability of Surgically Assisted Rapid Maxillary Expansion, an anatomic biomechanical study <i>J Oral Maxillofac Surg, DOI:10.1016, accepted</i>	47
Part III Prospective randomized patient study	59
Chapter 5 Stability, tipping and relapse of bone-borne versus tooth-borne surgically assisted rapid maxillary expansion; a prospective randomized patient trial <i>Int J Oral Maxillofac Surg, submitted</i>	61
Chapter 6 Changes in the nasal airway and speech through bone-borne versus tooth-borne surgically assisted rapid maxillary expansion; a prospective randomized patient trial <i>Rhinology, submitted</i>	81

Chapter 7	Analysis of upper facial changes through bone-borne versus tooth-borne surgically assisted rapid maxillary expansion; a prospective randomized patient trial <i>Am J Orthod Dentofacial Orthop, submitted</i>	99
Part IV	Auxiliary studies	111
Chapter 8	Distraction osteogenesis in the head and neck region <i>Anest Intensiv Med 2008;19:xx-xx</i> Adapted form the original article in Dutch <i>Ned Tijdschr Geneesk 2006;28:1557-1561</i>	113
Chapter 9	Surgical assisted rapid maxillary expansion in two cases of osteopathia striata with cranial sclerosis <i>Cleft Palate Craniofacial Journal, DOI:10.1597, accepted</i>	123
Part V	General discussion	135
Chapter 10	General discussion and conclusions	137
Chapter 11	Epilogue and future perspectives	145
Summary		149
Dutch summary	(Nederlandse samenvatting)	155
Addendum	Research protocol	161
Acknowledgement	(Dankwoord)	181
Curriculum vitae		183

Prologue and aim of the study

The scope of this thesis is to shed more light, from a number of perspectives, on surgically assisted rapid maxillary expansion (SARME). The primary questions this thesis set out to answer were; ‘is there a difference in stability between bone-borne and tooth-borne distraction?’ and ‘can a relationship be found between segmental maxillary tipping, relapse, and the mode of distraction?’ Secondary questions were; ‘what is the influence of surgically assisted rapid maxillary expansion on the nasal airway and the nasalance of speech?’ and ‘what is the effect of surgically assisted rapid maxillary expansion on the upper facial appearance?’ The thesis is divided into five Parts.

Part I consists of the general introduction, a review of the literature on SARME (*Chapter 1*). No consensus could be found regarding the surgical technique, the type of distractor used (tooth-borne or bone-borne), the existence, cause and amount of relapse, and whether or not overcorrection is necessary. Furthermore, relapse is widely recognized yet poorly explicated. A wide variety of techniques and methods to correct transverse maxillary hypoplasia is currently used without underlying scientific basis.

In order to answer the thesis questions, several different studies and experiments were launched in 2004.

The more basic studies are described in **Part II**. Initially, an evaluation of the bone-borne distractor, the Transpalatal Distractor (TPD) used by the Erasmus University Medical Center was performed (*Chapter 2*). This distractor was originally designed to be used in non-congenital deformity patients. The Craniofacial Unit of the Erasmus University Medical Center regularly treats congenital deformity patients. The conclusions of this study have led to the development of a new bone-borne distractor, the Rotterdam Palatal Distractor (RPD) which avoids the possible negative side effects and complications found with the previously used TPD distractor. Before the newly developed RPD was introduced to the market in September 2004, a pilot study was performed. The introduction of the RPD and the pilot study of its use is described in *Chapter 3*.

In order to understand the issue of tipping and some of the problems encountered in the clinical situation, an anatomic biomechanical experiment was completed. The scope of this specific experiment was the basic movement of the maxillary halves due to distraction forces applied by either a tooth-borne or a bone-borne distractor. For this study, anatomic specimens were used and the results of this experiment are described in *Chapter 4*.

Part III deals with a prospective randomized patient study. The Standing Committee on Ethical Research in Humans of the Erasmus University Medical Center approved the study by the end of 2003. The protocol of this study is found as an addendum to this thesis. The study was registered at the National Trial Register (NTR:1087). Between January 2004 and December 2007, 46 mature non-syndromal patients with transverse maxillary hypoplasia were recruited for this study. The patients all underwent SARME in order to treat the transverse maxillary hypoplasia. The patients were randomized into a bone-borne and a tooth-borne group. Stability, segmental maxillary tipping, and relapse were the primary outcome of this study, and the results are described and discussed in *Chapter 5*.

Chapter 6 deals with the secondary outcome of the prospective randomized patient study. Due to maxillary expansion, a change in the nasal airway is to be expected. Speech is not expected to change as a result of the therapy. Improved respiratory function and absence of snoring after transverse maxillary expansion is reported in the literature. Objective nasal capacity was measured using acoustic rhinometry and nasometry. Subjective changes in nasal airway were evaluated using a visual analogue scaled (VAS) patient questionnaire.

Moving supportive bony structures might influence the outer appearance of the face. These possible changes of the upper face due to transverse expansion were studied on standardized frontal photographs and results of this study are reported in *Chapter 7*.

In **Part IV**, two auxiliary subjects of interest are reported. Distraction osteogenesis is currently widely used in the field of oral and maxillofacial surgery. There is a variety of distractors for use on the different parts of the maxillofacial skeleton. The aim of *Chapter 8* is to give publicity to distraction osteogenesis in the field of oral and maxillofacial surgery and of the different types of intra- and extraoral distractors frequently used in the craniofacial region. The application of such distractors for several months, while the patient carries on normal day-to-day activities, can be a risk in case of an emergency. The anesthesiological aspects of these devices are discussed in order to minimize the risks in cases of acute medical interventions.

Chapter 9 reports on extreme transverse maxillary hypoplasia and the transverse maxillary expansion in two cases with a rare skeletal dysplasia, osteopathia striata with cranial sclerosis.

The general discussion of this thesis is described in **Part V**, *Chapter 10*, where possible answers to the thesis questions are provided. *Chapter 11*, the epilogue, discusses the

limitations of the study and questions that could not be answered as well as future perspectives.

Part I

General introduction

- Chapter 1 Surgical Assisted Rapid Maxillary Expansion (SARME);
a review of the literature
Int J Oral Maxillofac Surg 2005;34:709-714 Invited review

Chapter 1

General introduction

SURGICAL ASSISTED RAPID MAXILLARY EXPANSION (SARME); A REVIEW OF THE LITERATURE

M.J. Koudstaal¹

L.J. Poort¹

K.G.H. van der Wal¹

E.B. Wolvius¹

B. Prahl-Andersen²

A.J.M. Schulten²

¹ Department of Oral and Maxillofacial Surgery,
Erasmus University Medical Center Rotterdam

² Department of Orthodontics,
Erasmus University Medical Center Rotterdam

Published

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Abstract

Transverse maxillary hypoplasia, in adolescents and adults, is frequently seen in non-syndromal and syndromal patients including cleft patients. In skeletally matured patients, the uni- or bilateral transverse hypoplasia can be corrected by means of a surgically assisted rapid maxillary expansion. The treatment is a combination of orthodontics and surgical procedures and provides dental arch space for alignment of teeth. The procedure also causes a substantial enlargement of the maxillary apical base and of the palatal vault, providing space for the tongue for correct swallowing and thus preventing relapse. In addition, a distinct subjective improvement in nasal breathing associated with enlargement of the nasal valve towards normal values is seen with an increase of nasal volume in all compartments.

In this article we give a review on surgically-assisted rapid maxillary expansion. We conclude that there is no consensus in the searched literature regarding either the surgical technique, the type of distractor used (tooth-borne or bone-borne), the existence, cause and amount of relapse and whether or not overcorrection is necessary. A proposal for a prospective randomized patient study in order to find answers to the lacunas in knowledge regarding this treatment is done.

Introduction

The general indications for surgically assisted rapid maxillary expansion (SARME) are skeletal maturity, (extreme) transverse maxillary hypoplasia, either uni- or bilateral, anterior crowding and buccal corridors, the so called black corridors, when smiling. Furthermore the indications for SARME include any case where orthodontic maxillary expansion has failed and resistance of the sutures must be overcome. Transverse maxillary hypoplasia, in adolescents and adults, is frequently seen in non-syndromal and syndromal patients including cleft patients. In skeletally matured patients the uni- or bilateral transverse hypoplasia can be corrected by means of SARME. The treatment is a combination of orthodontics and surgical procedures and provides dental arch space for alignment of teeth. The procedure also causes a substantial enlargement of the maxillary apical base and of the palatal vault, providing space for the tongue for correct swallowing and thus preventing relapse. In addition, a distinct subjective improvement in nasal breathing associated with enlargement of the nasal valve towards normal values is seen with an increase of nasal volume in all compartments.

Transverse expansion of the maxilla was first done in 1860 by means of an orthodontic appliance. In the following decennia the orthodontic treatment evolved. The theory of distraction was first published in 1905 by Codivilla¹⁵. The combined surgical and orthodontic treatment for maxillary expansion was introduced in 1938 for skeletally matured patients. The first successful use of distraction on the femur of a significant group of patients was published in 1990²⁶. In 1999 the first bone-borne distractor was introduced⁴⁵.

Maxillary expansion by means of distraction is a nowadays widely used treatment. However, there is no consensus in the searched literature regarding the surgical technique, the type of distractor used (tooth-borne or bone-borne), the existence, cause and amount of relapse and whether or not overcorrection is necessary.

Review of the literature

A systematic search of the literature was performed (Pubmed) with special interest in the history of orthodontic and surgical treatment, the history of distraction, the different surgical techniques and relapse.

History of orthodontic treatment for maxillary constriction

Growth at the suture occurs through deposition of new bone at the sutural margin by the adjacent cellular layer. Toward the end of fetal life the cellular layers decrease in thickness, indicating that the rate of growth is slowing down, and the number of fibers in the intermediate layer uniting the capsular layers decreases. In a study of human

sutures from birth to 18 years, Latham and Burston³³ concluded that after about 2 of 3 years the sutures of the skull in general functioned primarily as sites of union of bones, but localized remodeling is a continuing process.

Cranial sutures are unified before complete eruption of the third molar. Soon after this, facial sutures close, and the sutures connecting the cranial and facial complexes are the last to close³². Regarding the facial sutures, Sicher⁶² states that the closure of sutures in human beings starts, as a rule, in the middle 30s at the posterior end of the median palatine suture but that some facial sutures, including the frontozygomatic, may remain open even in older age groups. This view is supported by Wright⁷⁴, who claimed the intermaxillary and palatine sutures to be unossified and susceptible to comparatively easy separation at as late an age as 35 years.

A conflicting view is expressed by Persson⁵², who found evidence of bony union at 17 years in the midpalatal suture. Latham and Burston³³, however, found no evidence of synostosis in the same suture by the age of 18 years. An over-all view is expressed by Scott⁶¹, who believes that, although most facial sutures appear open on the surface of old skulls, some degree of union may be present in the substance of the suture. It is obvious therefore, that the available literature is inconclusive and conflicting.

In clinical practice, skeletal correction of the transverse discrepancy via orthodontics (orthopedics) is successful until the age of approximately 14-15 years depending on the gender of the patient. After this age, orthodontic widening becomes virtually impossible and very painful^{41,50,55}. In general, it is assumed that closure of the midpalatal suture prevents this type of expansion^{41,55}.

In the first part of nineteenth century, Lefoulon^{34,35} and Talma⁶⁹ reported on maxillary expansion with a palatal or buccal C-shaped spring. A method, reserved for less severe cases, consisted of lateral thumb pressure, 'every morning and even many times daily', by the parent or the child itself. The first documented case of orthodontic correction of maxillary width discrepancies was by Angell³. He performed rapid maxillary expansion with the use of a jackscrew appliance in a 14-year-old girl. He observed that by turning the jackscrew daily, he was able to open the maxillary suture sufficiently in a period of 2 weeks. Angell³ mentions correction of maxillary width discrepancies by opening the midpalatal suture. In 1913, Schröder-Benseler⁵⁹ presented the still-popular all-wire frame with a non-spring-loaded jackscrew, the hygienic appliance. Derichsweiler¹⁶ uses bonds to the premolar and molar, which are embedded into a split acrylic base plate with an incorporated conventional orthodontic expansion screw. In 1961 Haas 'Reintroduced' rapid maxillary expansion (RME) and mentions in 1970 that the use of RME is ideally during the growth spurt^{21,23}. Reichenbach & Brückl⁵⁶ pub-

lished an excellent survey on orthodontic treatment of maxillary transverse hypoplasia in 1967.

History of surgical treatment for maxillary constriction

Once skeletal maturity has been reached, orthodontic treatment alone cannot provide a stable widening of the constricted maxilla in cases of deficiencies of more than 5 mm. In general, an orthodontist can camouflage transverse discrepancies less than 5 mm with orthopedic forces alone⁶³.

The literature mentions several problems accompanied by RME on mature patients, such as failure and or relapse and periodontal problems with the tooth-borne appliances⁵³. Timms & Vero⁷⁰ mention that 33-50% of the expansion has relapsed before stability is achieved. Others report the lack of movement of the maxillary halves; excessive tipping of the anchor teeth; buccal root resorption of the anchor teeth or even periodontal defects as the teeth are pushed through the buccal cortical plate, which lead to bony defects and gingival recession; unequal expansion and unpredictable relapse and the sensation of pain and necrosis of oral mucosa under the appliance^{45,51,63}. Bell and Starnbach^{5,7,64} report that activation of an appliance against mature sutures can lead to the sensation of pain and necrosis of oral mucosa under the appliance. These forces can also result in periodontal defects as the teeth are pushed through the buccal cortical plate, which lead to bony defects and gingival recession. These complications can be avoided by surgically releasing the osseous structures that resist the expansive forces^{5,64}. Therefore the combination of surgical and orthodontic treatment is advocated for widening of the maxilla in skeletally matured patients. Advantages of SARME include improvement of periodontal health; improved nasal air flow; elimination of the negative space, which results in less visible tooth and gingival structures upon smiling⁶⁷. There is also a cosmetic improvement of the buccal hollowing secondary to post-expansion prominence at the site of the lateral wall osteotomy^{5,64}. Tooth extractions for alignment of dental arches are often unnecessary⁶³.

Brown¹² probably first described a technique of SARME with midpalatal splitting in his textbook. Heiss²⁵ probably first inaugurated the midline splitting in the anterior maxilla for the extension of the compressed maxillary arch for orthodontic reasons. In 1961, Haas²¹ described the downward and forward movement of the maxilla that occurs during RME because of the location of the Cranio Maxillofacial sutures. He believed that the maxillary halves separated from each other rather in a tipping than in a parallel fashion due to the strength of the zygomatic buttresses²¹. Isaacson & Ingram²⁷ and Isaacson et al.²⁸ mention that historically, the midpalatal suture was thought to be the area of resistance to expansion, but the facial skeleton increases its resistance to

expansion as it ages and matures, and that the major site of resistance is not the midpalatal suture but the remaining maxillary articulations. Wertz⁷² advocated that resistance of the zygomatic arch prevents parallel opening of the midpalatal suture. In 1975, Lines³⁷ and in 1976 Bell & Epker⁵ demonstrated that the area of increased facial skeletal resistance to expansion was indeed not the midpalatal suture, but the zygomaticotemporal, zygomaticofrontal and zygomaticomaxillary sutures. Identification of these areas of resistance in the craniofacial skeleton stimulated the development of various maxillary osteotomies to expand the maxilla laterally in conjunction with orthodontic RME appliances⁴. The areas of resistance to lateral forces in the midface are the piriform aperture (anterior), the zygomatic buttress (lateral), the pterygoid junction (posterior) and the midpalatal synostosed suture (median). In the early reports all four are transected^{6,7,30,31}. In 1972 Steinhäuser⁶⁵ reports a maxillary expansion osteotomy technique without the use of distraction, a Le Fort I type of osteotomy in combination with the surgical splitting of the palate in the midline, after which a triangular uncortical iliac graft is inserted into the void created by the expansion.

More recently, with the emphasis on decreased morbidity and ambulatory surgery, fewer supports are osteotomized; the anterior, lateral and median⁴, the lateral and median⁵⁴, the anterior, posterior and lateral⁴², the anterior and lateral^{17,19}. Most reports note that surgically assisted maxillary expansion is more stable than orthodontic RME alone^{5,30,31,36}.

Glassmann et al.¹⁹, Alpern & Yurosko² and Lehmann & Haas³⁶ reported successful expansion in humans performed with a Hyrax appliance following a lateral osteotomy from the piriform rim to the pterygoid plate without palatal surgery. Their study did not consider the amount of skeletal versus dental expansion and the corresponding relapse following a retention period⁴⁶. In 1984 Glassmann et al. postulates that uniform palatal expansion can be achieved without sectioning of either palate or the pterygomaxillary fissure¹⁹.

In the year 1999, Mommaerts⁴⁵ presented the Trans Palatal Distractor (TPD), which is a bone-borne device for SARME. After surgical release of the areas of maxillary support the tooth-borne devices used for SARME cause undesired movements of the abutment teeth during expansion and retention phases that could lead to periodontal problems^{4,19,31}. Prolonged retention and overcorrection is advisable to counteract skeletal relapse^{18,29,31,54}. The TPD avoids all of these aforementioned problems, since fixation is sought in palatal bone³⁷. Recently, the Magdenburg Palatal Distractor (PD) was presented, also a bone-borne device which claims to have no relapse^{18,74}.

History of Distraction

As mentioned before SARME is a form of distraction that was applied before its biological healing principles were known. Codivilla¹⁵ was the first to describe the technique of distraction osteogenesis for the shortened femur in 1905. Ilizarov described the use of distraction osteogenesis in the field of Orthopedics to lengthen the leg bones in a large group of patients in 1990²⁶. The technique is based on a 5-day period of rest after corticotomy before the expansion starts. This gives the tissue time to form the first callus but is too short for consolidation. Four phases of new bone formation can be described. The first is a fibrovascular hematoma; between day 5 and 7 collagen fibers are formed that will arrange parallel to the distraction vector. Second, the bone formation follows the collagen fibers through intramembranous ossification; from the outside to the inside. Third, remodeling phase of the new bone. Fourth, formation of solid compact bone with the same texture as the surrounding (old) bones. When the distraction is performed too fast, the collagen fibers might lose contact and there is no in growth of new bone, providing non- or mal-union. In cases of a too slow distraction premature consolidation can occur and the requested elongation cannot be reached.

Surgical technique

Since early in the 20th century various techniques have been developed for SARME. The main considerations have opposing interests. One side is a more invasive technique with maximal mobility of the maxillary halves for correction over larger distances with less force but with more possible complications. The other side is less invasive with less possible complications but with more relapse, more periodontal problems, and unexpected fractures.

The opinions vary about the site of major resistance in transverse distraction in the midface and also about the method of releasing it. Most methods consider the zygomaticomaxillary junction the major site of resistance and perform a corticotomy through the zygomatic buttress from the piriform rim to the maxillopterygoid junction (Fig. 1).

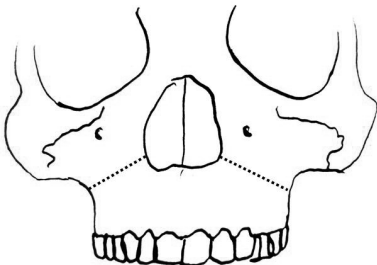


Figure 1. Schematic drawing showing the corticotomy from the piriform rim to the maxillopterygoid junction.

The midpalatal suture is historically considered the major place of resistance but this was proven to be untrue by Isaacson & Ingram²⁷, Isaacson et al.²⁸ and Kennedy et al.³⁰ (Fig. 2). Still many, but not all, release the midpalatal suture to improve mobility and to prevent deviation of the nasal septum.

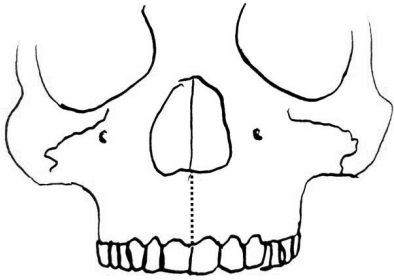


Figure 2. Schematic drawing showing the osteotomy of the midpalatal suture.

Several authors describe two paramedian palatal osteotomies from the posterior nasal spine to a point just posteriorly of the incisive canal (Fig. 3)^{9,11,57}.

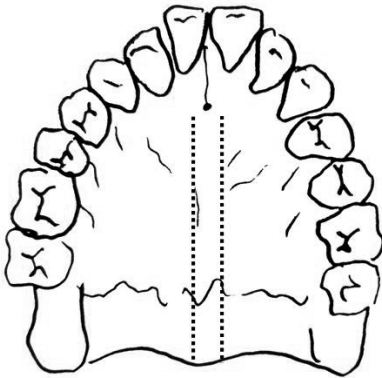


Figure 3. Schematic drawing showing the two paramedian palatal osteotomies from the posterior nasal spine to a point just posteriorly of the incisive canal.

The pterygoid plates are also a considerable site of resistance but because of the increased risk of injuring the pterygoid plexus by the osteotomy, some chose not to, without losing much mobility (Fig. 4). By not releasing the pterygoid junction, the pattern of opening of the maxillary halves is more V-shaped with the point of the V dorsally and it might be considered as an individual treatment to achieve more distraction either on the posterior or anterior level.

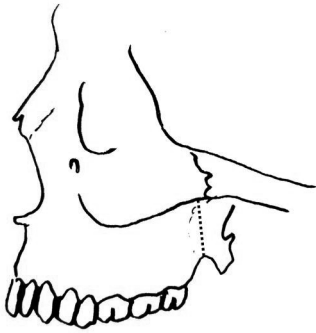


Figure 4. Schematic drawing showing the osteotomy of the pterygoid plates.

The nasal septum is often released from its palatal base to avoid shifting to either side and thereby causing changes in nasal flow (Fig. 5). A tomographic study by Schwarz showed no significant change in nasal septum position in SARME without sectioning of the nasal septum and an increase nasal airway space⁶⁰.

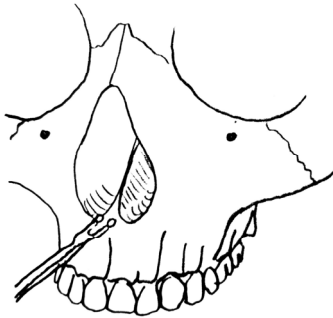


Figure 5. Schematic drawing showing the release of the nasal septum with the use of a septum osteotome.

Of the studies on SARME mentioned in international literature, the mean age of the patients undergoing SARME varied from 19 to 29 years^{4,6,8,13,19,31,46,47,49,66}. The groups studied were quite small and mostly contained not more than 20 patients. The period of retention after expansion varies from 2 to 12 months. Generally, a period of three month is used.

The amount of distraction at the canine level mentioned varies from 3.4 mm to 5.0 mm, in the first premolar region 4.7 mm to 5.9 mm and in the first molar region 3.4 mm to 8.0 mm.

SARME is considered a procedure with little risk of serious complications, however several complications are mentioned in literature varying from life threatening epistaxis to a cerebrovascular accident, skullbase fracture with reversible oculomotor nerve pareses and orbital compartment syndrome^{31,42,54}. Less serious complications reported are postoperative hemorrhage, pain, sinusitis, palatal tissue irrita-

tion/ulceration, asymmetrical expansion, nasal septum deviation, periodontal problems and relapse⁴⁰.

Relapse

In a recent study a questionnaire was sent to 2476 craniofacial and oral/maxillofacial surgeons about distraction osteogenesis. The 145 (6%) respondents treated in total 3278 craniofacial distraction cases⁴⁴. The surgeon's were asked whether they had noted relapse in any of their distraction patients. Of the 50.4% of respondents, who recognized relapse, such relapse was encountered by 64.8% of respondents in the mandible and 60.6% in the midface. Again, of the 50.4% of respondents who recognized relapse, 67.6% first encountered relapse less than 6 months after completion of distraction whereas 31.0% first encountered it more than 6 months after the completion of distraction.

The majority of surgeons (66.7%) did not routinely overcorrect during the distraction process. Several surgeons reported overcorrection only in the growing patient. Of the 42 surgeons who routinely overcorrected during distraction, the average amount of overcorrection was 3.3 mm.

Relapse, defined as the gradual recurrence over time of the abnormality for which distraction was performed, was also not included as complication but was noted by over half the respondents. Nearly equal numbers of surgeons encountered relapse in the mandible and the midface⁴⁴.

Rapid maxillary expansion has been shown to be a valuable aid in the orthodontic treatment of growing patients exhibiting transverse maxillary hypoplasia, pseudo-Class III malocclusion, and rhinologic and respiratory problems^{10,20,22,24}.

Numerous RME appliances have been widely used by the clinicians such as Haas and Hyrax-type banded or bonded appliances. However, long-term evaluation has shown a relapse tendency up to 63% in patients that were treated by these conventional appliances of maxillary expansion^{10,43,58,70-72}. Age has also been discussed as a factor in the prognosis of RME, especially regarding long-term stability. Bishara and Staley¹⁰ stated that the optimal age for expansion is before 13 to 15 years. Although it may be possible to accomplish expansion in non-growing patients, the results are neither as predictable nor as stable. Proffit⁵⁵ and McNamara and Brudon³⁹ supported this opinion by suggesting that the feasibility of palatal expansion in the late teens and early twenties is questionable. Surgically assisted RME combined with fixed orthodontic treatment has been suggested to overcome this problem⁷².

Berger et al.⁸ reported on two groups of patients using both RME and SARME with a hyrax expander. In the RME group the ages ranged from 6 to 12 years. In the

SARME group the ages ranged from 13 to 35 years. They concluded that there is no difference in the stability of SARME and RME. They mentioned relapse without quantifying the amount⁸.

In SARME alone only few studies report relapse, relapse rate varies from 5% to 25%^{4,8,45,48,67,68}. As for the stability of SARME, Pogrel et al⁵⁴ studied 12 adult patients, all of whom were still in orthodontic appliances 1 year following surgery, and found only 11.8% relapse and the maxillary first molar. Bays & Greco⁴ found, in a retrospective study of 19 adult patients who were out of appliances more than 6 months, 8.8% relapse at canines, 1% at the first premolar and 7.7% at the first maxillary molar. The mean follow-up period in this study was 2.4 years. They conclude that SARME has an excellent stability and therefore no overcorrection would be necessary. Pogrel and Bays & Greco used tooth-borne distractors. There are also several authors that mention relapse, using SARME in combination with a tooth-borne distractor, but do not quantify the amount of relapse^{12,36,46}.

Matteini & Mommaerts³⁸ and Mommaerts⁴⁵ using the TPD, and Zahl & Gerlach⁷⁴ using the PD, both bone-borne devices, find it unnecessary to over expand since they claim no relapse upon follow-up. The reason for this is the fact that the forces of the distraction are directly applied to the skeletal base⁴⁵.

Discussion

Distraction osteogenesis therapy is widely used in the field of oral and maxillofacial surgery despite the fact that there are still a lot of unanswered questions.

Concerning the surgical technique one has to look for optimal equilibrium between maximal mobility of the maxilla and minimally invasive surgery to avoid complications. The literature shows no consensus and very little study has been conducted on this subject, however, the tendency is towards minimally invasive surgery.

Relapse often is not mentioned even though it is a serious factor to consider in treatment planning. Therefore, it is remarkable that only four studies recommend over expanding 0.5 mm to 2 mm on either side^{31,36,47,54}.

Matteini & Mommaerts and Mommaerts using the TPD, and Zahl & Gerlach using the PD, both bone-borne devices, find it unnecessary to over expand since they claim no relapse upon follow-up^{38,45,74}.

Tooth tipping of 0.08 – 0.3 mm and 6.5 -7 degrees following distraction is mentioned in two studies using a tooth-borne device^{13,49}. Other studies reported tipping but did not support these findings with statistics^{36,46}. Pinto & Mommaerts using the TPD, report tipping of teeth of 8.3 degrees at the premolar area and 0.9 degrees at the

molar area (variation 10°) was reported. Interestingly, they mention that they find no relapse implying that tipping is not one of the causative factors of relapse⁵³.

Swennen et al.⁶⁷ recently published a review on craniofacial distraction discussing 109 clinical articles concluding that there is a lack of appropriate data on long-term results and relapse.

Further study will be necessary to determine possible causative factors for relapse, including dental and skeletal tipping, the length of the consolidation period, the total length distracted, and intrinsic growth disturbances leading to recurrence.

Since January 2004, a prospective randomized patient study to answer several of the above-mentioned questions was initiated at the Erasmus University Medical Center Rotterdam, the Netherlands. Included patients were randomized in two groups. The surgical technique for the corticotomy was the same in both groups and included a buccal corticotomy (anterior and lateral) and median split of the maxilla. In one group, expansion was performed using a tooth-borne device, whereas the other group was expanded using a bone-borne device. The main outcome will be the amount and possibly the difference in relapse between the two groups. Also the nasal airway resistance, aesthetics and possible complications will be studied.

Vertical and anterior movement of the maxillary halves has been described in RME^{1,14}. In cases of SARME Chung et al.¹⁴ reported anterior movement as well as vertical movement of the maxillary halves, however, without significance. In our investigation, the anterior movement of the maxillary halves will also be studied.

Besides the patient study, a biomechanical and anatomical study will be performed to find answers to the questions on tipping and as well as relapse.

Conclusion

SARME is an established and widely used technique for correcting transverse maxillary discrepancies. There is no consensus in the searched literature regarding the surgical technique, the type distractor used (tooth-borne or bone-borne), the existence, cause and amount of relapse and whether or not overcorrection is necessary. Especially relapse is widely recognized yet poorly described. A wide variety of techniques and methods to correct transverse maxillary hypoplasia is used without underlying scientific basis.

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Part II

Fundamental studies and development

Chapter 2 Experience with the Transpalatal Distractor in congenital deformities

Mund Kiefer Gesichtschir 2006;10(5):331-334

Chapter 3 The Rotterdam Palatal Distractor: introduction of the new bone-borne device and report of the pilot study

Int J Oral Maxillofac Surg 2006;35:31-35

Chapter 4 Relapse and stability of Surgical Assisted Rapid Maxillary Expansion, an anatomic biomechanical study

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Chapter 2

EXPERIENCE WITH THE TRANSPALATAL DISTRACTOR IN CONGENITAL DEFORMITIES

M.J. Koudstaal

K.G.H. van der Wal

E.B. Wolvius

Department of Oral and Maxillofacial Surgery,
Erasmus University Medical Center Rotterdam

Published

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Abstract

The transpalatal distractor is a bone-borne device that should eliminate negative orthodontic side-effects of tooth-borne devices. The literature contains reports of several possible complications of the transpalatal distractor. In this retrospective study its use was evaluated in ten patients with various congenital craniofacial anomalies, including clefts.

During placement of the transpalatal distractor it was noted that in extremely narrow maxillae the palatal bone is very thin, which makes the initial placement difficult and therefore less primary stability can be obtained. There is often a thick palatal mucosa, which makes placement of the abutment plates difficult and leaves hardly any space for the module itself. Finally, in patients with mental retardation it is difficult to exchange modules and re-fix abutment plates.

In our group of ten patients with congenital deformities a 60% complication rate was observed. The transpalatal distractor seems not to be the ideal device for use in widening the maxilla in cases with congenital deformities.

Introduction

Transverse maxillary hypoplasia is frequently seen in the presence of noncongenital and of congenital deformity. In skeletally mature patients uni- or bilateral transverse hypoplasia can be corrected by means of surgically assisted rapid maxillary expansion. The treatment is a combination of orthodontics and surgical procedures and provides space in the dental arch for lining up the teeth. The procedure also causes substantial widening of the maxillary apical base and of the palatal vault, providing space for the tongue and thus allowing correct swallowing and preventing relapse and improved nose breathing.

Traditionally, the distractors used for such expansion have been tooth-borne devices, i.e. Hyrax appliances. In 1999 the transpalatal distractor (TPD™, Surgitech, Bruges, Belgium) was developed (Fig. 1). The TPD is a bone-borne device, so that its use would avoid such negative orthodontic effects as periodontal ligament compression, buccal root resorption, fenestration of the mandibular/buccal bony cortex, tooth tipping, and orthodontic relapse during and after maxillary expansion [1, 2, 3]. The main advantage of a bone-borne device is that while high-level orthopedic force can be applied less tipping of the maxillary segments results [4].



Fig. 1 The transpalatal distractor in place in a patient with noncongenital deformity

The literature contains reports of several possible complications of the TPD in noncongenital deformities, including loosening of the module, loss of the osteosynthesis screws, and loosening of the abutment plates [4]. In addition to these complications, there are risks of damaging the roots of teeth with the abutment plate screws and of postoperative infection of the mucosa of the hard palate.

In this article experience with the TPD in a group of patients with congenital deformities is discussed.

Patients and Methods

Since August 2002 the TPD has been used in ten patients being treated for congenital deformities in the department of Oral and Maxillofacial Surgery of the Erasmus Medical Center Rotterdam. The specific syndromal conditions were frontal-nasal dysplasia (1 patient), Pfeiffer's (1 patient), Apert's (2 patients), and Saethre-Chotzen (1 patient) syndromes, and 1 patient had facial dysmorphism without a specific diagnosis. Four patients with clefts were treated: three with cleft lip, alveolus and palate (CLAP) and one with cleft lip and alveolus (CLA). The patients' characteristics are noted in Table 1.

The general indications for surgically assisted rapid maxillary expansion are (extreme) transverse maxillary hypoplasia, whether uni- or bilateral, anterior crowding, and wide buccal corridors.

All patients were admitted to the hospital for 3 days and prescribed antibiotics, and a LeFort I approach was followed while patients were under general anesthesia. The buccal corticotomies were performed by the method generally used for a LeFort I osteotomy with no disjunction of the pterygoid plate. The median osteotomy was between the central incisors. A 1-cm-wide osteotome was used to mobilize the segments. The palatal gingiva over the roots of the first or second bicuspids was infiltrated with a local anesthetic agent incorporating a vasoconstrictor in some cases, depending on which procedure had been planned for the antero-posterior expansion. An incision was made, and the mucoperiosteum was raised. Two abutment plates were adjusted subperiosteally on the palatal bone. The module was installed parallel to the occlusal plane and perpendicular to the midsagittal plane; the segments were prized apart by adjusting the wings of the module. After testing the module and examining the mobility of the maxillary segments, the operator blocked the module with a screw and secured it with a stainless steel wire to prevent aspiration. It would be possible to combine the corticotomy with extraction of teeth, such as wisdom teeth, in preparation for possible future osteotomies (e.g., LeFort I).

The latency period was 7 days in all patients, after which the distractor was activated at a rate of 1 mm/day. The patients were seen once a week in the outpatient clinic. When necessary the module was exchanged for a larger one. When the desired expansion was reached the module was blocked. At the end of a 3-month consolidation period the module and the abutment plates were removed under local anesthesia in six cases. General anesthesia was necessary for removal in four patients who are mentally retarded.

Results

Placement of the abutment plates is difficult in the presence of craniofacial deformities involving extremely narrow maxillae, because of the lack of space. In addition, most patients in this group had very thick palatal mucosa, which made subperiosteal placement even more difficult.

The desired expansion was reached in all ten patients. In six of the ten the following complications of the device were seen: loosening of the module (3 cases), loss of the osteosynthesis screws (1 case), loosening of the abutment plates (1 case). In addition, one postoperative infection of the palatal mucosa and one case of an oro-antral fistula following removal of the abutment plates were observed. The complications are listed in Table 1.

Patient no.	Age	Sex M/F	Type of congenital deformity	Distraction length	Complications encountered
1	13	M	Fronto-nasal dysplasia	8 mm	Loosening of the module
2	17	F	Apert's syndrome	10 mm	
3	13	M	Apert's syndrome	12 mm	
4	15	M	Pfeiffer's syndrome	10 mm	Loosening of abutment plate
5	13	F	Right-sided CLAP; ectodermal dysplasia	10 mm	Palatal abscess
6	18	M	Saethre-Chotzen syndrome	12 mm	
7	15	F	Facial dysmorphism; unknown diagnosis	10 mm	
8	18	M	Left-sided CLAP	9 mm	Loosening of the module
9	19	M	Left-sided CLA	5 mm	Loosening of the module
10	20	M	Left-sided CLAP	6 mm	oro-antral fistula

CLAP cleft lip alveolus and palate, CLA cleft lip and alveolus

In patients 1, 8, and 9 the module came loose during the consolidation period. These patients were treated in the outpatient clinic, where the modules were refixed.

In patient 4 one of the abutment plates and its fixation screws became detached from the palate during the distraction phase, resulting in a painful and unstable situation of the distraction module. The module had to be removed under local anesthesia, and the orthodontist was asked to place a tooth-borne distractor (Hyrax appliance). The desired expansion was subsequently reached in this patient.

Patient 5 developed a palatal abscess during the consolidation phase. The abutment plates had not loosened. The abscess was incised, and antibiotic treatment was continued until the distractor was removed.

Patient 10 was a 20-year-old man with a left-sided cleft lip, alveolus, and palate (CLAP). Previous operations he had undergone included closure of the lip and the soft palate, bone grafting with autologous bone from the chin at the alveolar cleft, and closure of the hard palate. After removal of the module there was no air passage through the palate. When the patient returned 2 weeks later, an oro-antral fistula was noted where the left abutment plate had been positioned (Fig. 2). The Valsalva test was positive. A conservative regimen was followed, and after 2 months the fistula closed spontaneously.

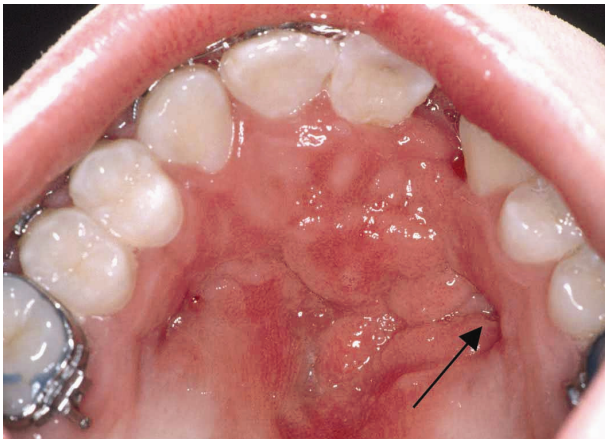


Fig. 2 Palate after removal of the TPD, with oro-antral fistula on the left side (arrow)

Discussion

Bone-borne distractors such as the TPD might avoid several of the negative orthodontic effects, such as periodontal ligament compression, buccal root resorption, fenestration of the buccal alveolar cortex, tooth tipping, and orthodontic relapse, that occur during and after maxillary expansion with tooth-borne devices, e.g., Hyrax appliances. Furthermore, in patients with congenital deformities involving extremely narrow maxillae there is frequently not enough space for placement of a tooth-borne device, and in mentally retarded patients poor oral hygiene might cause dental caries when tooth-borne devices are used.

The necessity for screw fixation when the TPD is used has several disadvantages. A burr being used in placement of the screws and/or the screws themselves might damage the underlying roots of the dentition. There is also a risk of introducing the burr or the screws into the maxillary sinus. This situation involves the risk of an oro-antral fistula after removal of the abutment plates. In a patient with a hypoplastic maxilla this risk might be increased. Careful placement and removal are advised. The

screws should preferably be positioned between the roots of the dentition rather than further cranially, as this lowers the risk of placing the screws in the maxillary sinus. It should, however, be borne in mind that this position of the abutment plates makes the vector of the distraction less favorable.

The TPD has been studied in patients with no congenital malformations and has proved successful. In the patients described here, all of whom had congenital deformities involving extremely narrow maxillae, it was found that the palatal bone was very thin, making the initial placement of the TPD difficult and thereby limiting the degree of primary stability. Also, in most cases the palatal mucosa was very thick, which made placement of the abutment plates difficult and left hardly any space for the module itself. Finally, in mentally retarded patients general anesthesia was mostly necessary before modules could be exchanged or the abutment plates re-fixed and/or removed. In recent years several new bone-borne devices for maxillary expansion have been introduced. The Rotterdam Palatal Distractor (RPD) type A is designed for extremely narrow maxillae, particularly in patients with congenital malformations [5]. This device measures 9 mm from plate to plate when closed, and 28 mm when opened to its maximum. No screws are necessary to fix the distractor to the bone. Our personal experience of using this device in patients with congenital deformity has so far been very positive.

Conclusion

The transpalatal distractor is a bone-borne device that has proved its worth in patients without congenital malformations. Several possible complications of its use have been reported. In patients with congenital deformities complications not previously reported were noted in our group of patients: palatal infection and an oro-antral fistula. In addition, owing to the often thick palatal mucosa in patients with congenital deformities, placement of the abutment plates is difficult and leaves hardly any space for the module itself. The transpalatal distractor seems not to be the ideal device for use in widening the maxilla in the presence of congenital deformities and extremely narrow maxillae.

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Chapter 3

THE ROTTERDAM PALATAL DISTRACTOR: INTRODUCTION OF THE NEW BONE-BORNE DEVICE AND REPORT OF THE PILOT STUDY

M.J. Koudstaal¹

K.G.H. van der Wal¹

E.B. Wolvius¹

A.J.M. Schulten²

¹ Department of Oral and Maxillofacial Surgery,
Erasmus University Medical Center Rotterdam

² Department of Orthodontics,
Erasmus University Medical Center Rotterdam

Published

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Abstract

Transverse maxillary hypoplasia, in adolescents and adults, is frequently seen as an acquired deformity and in congenital deformities patients and can be corrected by means of surgically assisted rapid maxillary expansion. Traditionally, the distractors for expansion are tooth-borne devices, i.e. hyrax appliances, which may have some serious disadvantages such as tooth tipping, cortical fenestration, skeletal relapse and loss of anchorage. In contrast, with bone-borne distractors most of the maxillary expansion is orthopedic and at a more mechanically desired level with less dental side effects. A new bone-borne palatal distractor has been developed. By activation the nails of the abutments plates automatically stabilizes the device and no screw fixation is necessary anymore. This new distractor is presented and the data of five acquired deformity and eight congenital deformity patients that were treated with this distractor are reported.

Introduction

Transverse maxillary hypoplasia, in adolescents and adults, is frequently seen as an acquired deformity and in congenital deformities patients including cleft patients⁷. In skeletally mature patients the uni- or bilateral transverse hypoplasia can be corrected by means of a surgically-assisted rapid maxillary expansion^{2,4}. Traditionally, the distractors for expansion are tooth-borne devices, i.e. hyrax appliances, which have some serious disadvantages: periodontal problems, like buccal root resorption and cortical fenestration, segmental tipping and anchorage-tooth tipping, loss of anchorage, dental caries in congenital patients with mental retardation and poor oral hygiene^{2,4}.

In contrast, with bone-borne distractors applied at a higher level in the palatal vault, most of the maxillary expansion is orthopedic and at a more mechanically desired level^{4,6}. In addition the forces are directly on the bone and no tooth tipping and other unwelcome side effects are to be expected. The now commercially available bone-borne distractors like the Transpalatal Distractor (TPD™) and the Magdenburg palatal distractor⁹ have to be fixed with screws on the palatal bone and have proven to be useful in acquired deformation patients. The MDO-R device (Orthognathics Ltd.) has no screw fixation, however it has a minimal width of 1.5 cm. In congenital patients with extreme narrow maxillas these devices seem to be impracticable due to difficulties with screw fixation and the devices are often too large to be placed.

A new bone-borne palatal distractor, the Rotterdam Palatal Distractor (KLS Martin, Postfach 60, D-78501 Tuttlingen, Germany) has been developed based on the mechanical properties of a car jack. By activation the nails of the abutments plates penetrate the bone and automatically stabilizes the device. No screw fixation is necessary anymore. This new distractor is presented and the data of five acquired deformity and eight congenital deformity patients that were treated with this distractor is reported.

Design of the distractor

The Rotterdam Palatal Distractor (RPD) is a bone-borne distractor made of titanium grade II based on the mechanical design of a car jack (Fig 1). The two abutment plates (5 x 12 mm) contain six nails each 2 mm long. The plates are angled-attached (65°) to the part with a joint providing rotation. The activation part exists of a small hexagonal activation rod that is positioned directly behind the maxillary central incisors.

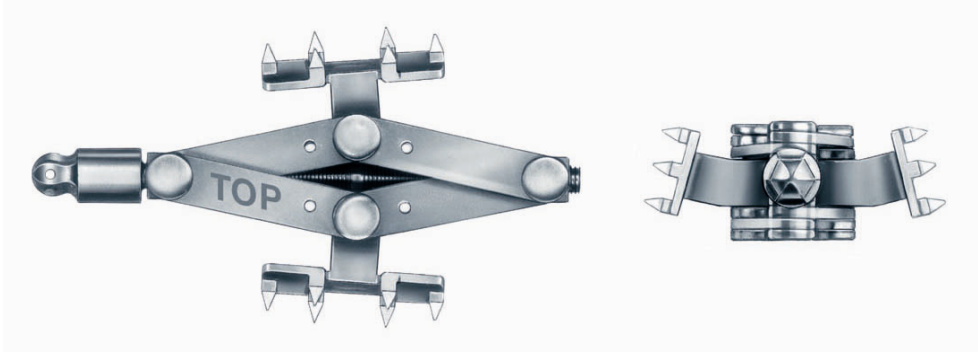


Figure 1. Design of the Rotterdam Palatal Distractor, a bone-borne distractor made of titanium grade II based on the mechanical design of a car jack. The basic part has holes to secure the device with stainless steel wires around the premolars. The two abutment plates (5 x 12 mm) contain six nails each 2 mm long. The plates are angled-attached (65°) to the part with a joint providing rotation. The activation part exists of a small hexagonal activation rod that is positioned directly behind the maxillary central incisors with a little hole at the tip of the activation part for blocking the device.

By activating the distractor the 2 mm long nails of the two abutment plates will penetrate the bone and the device is stabilized automatically. No screws are necessary to fixate the distractor to the bone. At the end of the distraction period the distractor can be blocked with a stainless steel wire. For that reason a little hole at the tip of the activation part is provided.

The RPD is available in two sizes. Type A is designed for extreme narrow maxillas particular in congenital patients. Especially in these cases there is no space for a conventional hyrax appliance or other bone-borne type distractors with necessary screw fixation. This device measures closed a distance from plate to plate of 9 mm and maximally opened 28 mm. Type B is the standard size that measures closed 12 mm distance from plate to plate and maximally opened 31 mm.

Surgical technique

The procedure is done under general anesthesia with preferable naso-endotracheal intubation. Standard corticotomies of the anterior, lateral and median bony supports of the maxilla without pterygoid disjunction are performed. The palatal gingiva of the premolars is infiltrated with local anesthesia including a vasoconstrictor. For parallel expansion the RPD is positioned with the abutment plates over the roots of the first or second premolars (Fig. 2).

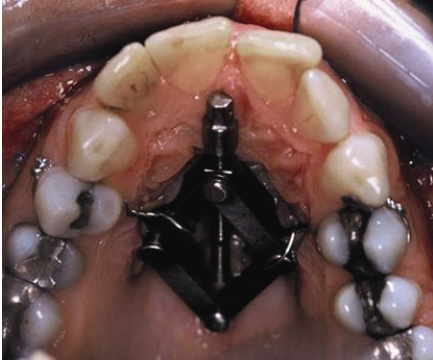


Figure 2. The distractor in place in a non-congenital deformity patient.

In cases when the expansion is needed more in the anterior or molar region the abutment plates can be positioned slightly more anterior or posterior. The activation rod is in the midline and must not interfere with the lower teeth in occlusion. The distractor is slightly activated and then removed. Thus the print of the plates is clearly visible in the mucosa. Now the palatal mucosa directly around the abutment plates is incised. The palatal mucosa slightly smaller than the abutment plate is removed. It is important to obtain local haemostasis. The RPD is placed again with the plates now on the bone. The distractor is slightly activated so the nails penetrate the bone stabilizing the distractor. Finally, the distractor is secured with stainless steel wires around the premolars on both sides to prevent aspiration or swallowing if the distractor should come loose.

The design of the RPD is based on a car jack and therefore food remnants are easily stuck in the device. Patients must be instructed to clean the device at least twice per day thoroughly and a regular visit to an oral hygienist is strongly recommended.

At the end of the consolidation period the distractor can be removed in an outpatient clinic. The palatal mucosa surrounding the distractor is infiltrated with local anesthesia including a vasoconstrictor. The stainless steel wires are removed; the distractor is deactivated and removed. The healing of the mucosa is normally complete within two weeks (Fig 3).



Figure 3. Complete healing of the mucosa after two weeks.

Distraction protocol

Due to the mechanical properties of the distractor equal activation will result in a progressively decreasing distraction length. Activation with 0.6 turn ($0.6 \times 360^\circ = 216^\circ$) at the start of the distraction will result in a distraction length of 1 mm. After 5 mm distraction, for example, 1,3 turn of 468° is necessary to achieve the same distraction length of 1 mm. In other words during the progression of the distraction period more turns are necessary to obtain the same amount of distraction per day. To come close to the 1 mm distraction rate per day a special protocol was made with four intervals. Each with an increased number of turns per day (Diagram 1). It is very important to note the opening length (amount of turns) of the distractor during the placement to know where to start in the scheme.

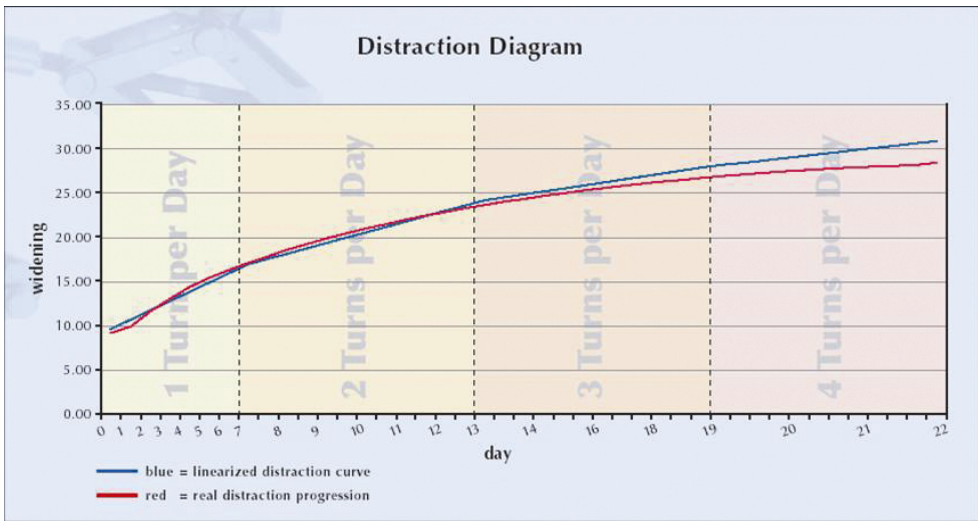


Diagram 1. Distraction diagram showing the amount of widening and the advised amounts of turns per day in four intervals. One turn being 360° . In the first week one turn will lead to 1 mm. distraction per day. In the next 6 days two turn are necessary for 1 mm. of distraction. From the 13th till the 19th day three turns per day have to be made and in the last four days four turns per day are necessary to reach the 1 mm. distraction length.

A latency period of seven days is followed by the distraction of approximately 1 mm per day with the use of a patient screwdriver or hockey-stick like. At the end of the distraction the device can be with a stainless steel wire and a retention period of 3 months is followed. Figure 4 shows an example of the clinical situation after distraction in an acquired deformity patient. During this period the orthodontist can start the treatment with the fixed appliances.



Figure 4. Clinical situation after the distraction in a non-congenital patient. (same patient as figure 2).

Pilot patient study

Between October 2003 till October 2004 we used the Rotterdam Palatal Distractor on 13 patients. Five acquired deformity and eight congenital deformity patients with transverse maxillary hypoplasia all were bilateral had anterior crowding and some had buccal corridors when smiling.

The surgical procedure and the placement of the RPD was carried out in the above mentioned way. Type A was used on the congenital deformity patients since there was not enough space for type B.

The congenital deformity patient group consisted of four patients with Apert's syndrome, one midline cleft patient, one patient with Osteopatia Striata, one with a bilateral cleft and one with Treacher Collins syndrome. These patients showed extreme forms of maxillary hypoplasia in that extent even so that the palatal mucosa from the left and right side touched in the middle. The patient's data are noted in Table 1. The amount of distraction was determined using both the amount of turns of the device, clinical and model measurements. As mentioned before oral hygiene is of utmost importance in this patient group since compliance is rather low. These patients visited the oral hygienist once a week and were asked to clean the device twice a day. One distractor related problem was encountered. In this case of a patient with Apert's syndrome the distractor slipped of the palatal mucosa on one side and ended up pushing partially against the dentition itself. Because of this complication we adjusted the earlier design of the plates that were placed at a 90° angle of the distraction force and had 18 pins on each plate. In the adjusted model the plates were placed at an angle of 65° and only six pins were positioned on each plate. This adjustment gives the distractor more grip on the palate.

In the case of the patient with the Osteopatia Striata the bone was extremely thick and hard. The distraction led to a frontal wedging of the maxillary halves with hardly any expansion in the molar region. Therefore an additional hyrax expander was placed dorsally of the RPD in the molar region. A sufficient expansion was reached.

No further complications in this patient group like loosening of the distractor, loss of the distractor, damage to the dentition or infection of the palate.

In the acquired deformity patient group the desired amount of distraction was reached in all five patients without any complications (Table 1).

Patient Number	Age	Sex M/V	Congenital/ Acquired	Type of deformity	Amount of distraction	Complications
1	16	V	Congenital	Apert's syndrome	19 mm	
2	16	M	Congenital	Apert's syndrome	10 mm	Slipping of distractor
3	12	M	Congenital	Apert's syndrome	11 mm	
4	16	M	Congenital	Apert's syndrome	12 mm	
5	15	M	Congenital	Midline Cleft	8 mm	
6	21	V	Congenital	Osteopatia Striata	15 mm	2 nd device added (Hyrax)
7	17	M	Congenital	Treacher Collins	13 mm	
8	19	M	Congenital	CLAP duplex	8 mm	
9	27	V	Acquired	TMH	6 mm	
10	16	M	Acquired	TMH	6 mm	
11	34	V	Acquired	TMH	7 mm	
12	31	V	Acquired	TMH	6 mm	
13	21	M	Acquired	TMH	7 mm	

CLAP: cleft lip alveolus and palate. TMH: transverse maxillary hypoplasia. All of the patients had a transverse maxillary hypoplasia. In the acquired deformity group there is no additional diagnosis.

Discussion

The general indications for surgically assisted rapid maxillary expansion also apply for the Rotterdam Palatal Distractor. These are (extreme) transverse maxillary hypoplasia, uni- or bilateral, anterior crowding and showing black buccal corridors upon smiling.

The treatment is an association of orthodontics and surgical procedures and provides dental arch space for lining up the teeth. The procedure also causes a substantial enlargement of the maxillary apical base and of the palatal vault, providing space for the tongue for correct swallowing and thus preventing relapse. In addition, a distinct subjective improvement in nasal breathing associated with enlargement of the nasal valve towards normal values is seen with an increase of nasal volume in all compartments^{1,8}.

The theory that bone-borne distractors apply their force at a higher, more mechanically desired level⁴⁻⁶ thereby excluding dental tipping and other unwelcome side

effects of the tooth-borne devices has not been proven in the literature so far. We have started a randomized prospective patient study to determine the relative amounts of skeletal versus dental tipping using both tooth-borne and bone-borne devices.

Because of the design of the RPD there is a relative contra-indication in cases with a class II deep bite; the distractor or the small activation rod on the palate may then interfere with the teeth of the mandible. This can be overcome by placing the RPD more distally or by wearing an occlusal splint during the distraction and consolidation period.

One absolute contra-indication is in case of a low palate seen for example in Apert's syndrome and cleft patients. The nails of the abutment plates will lose fixation and the distractor is not stable. A general contra-indication for distraction is an immune deficiency and irradiation prior to the surgery.

Due to the design and the fact that it is a one-piece-device the RPD is easily placed and activated. There is no need for dental anchorage that might cause damage to the dentition or dental tipping. Since the use of burrs and screws is not necessary there is no risk of damaging the (pre-)molar roots or causing oro-antral or oro-nasal fistula. The device easily blocked with a stainless steel wire at the end of the distraction period. Because there is no dental anchorage the distractors allow simultaneous orthodontic treatment with fixed appliances. After the consolidation period the RPD can be easily removed under local anesthesia.

For primary stabilization the RPD has to be slightly activated for approximately one turn of 360° sometimes already resulting in a minor diastema between the maxillary central incisors. One should realize that due to the mechanical principle of a car jack equal activation during the distraction period will result in a progressively decreasing distraction length. The patients have to be thoroughly instructed and should write down daily the amount of turns.

Patients with the RPD have to keep up oral hygiene and a regular visit to the oral hygienist is strongly recommended.

For the placement and adjusting the now commercially available bone-borne distractors like TPD and Magdenburg some palatal space is necessary for putting in the abutment plates and screws. The use of these screws bears the risk of damaging the roots of the dentition and for oro-antral (TPD) or oro-nasal fistulas (Magdenburg distractor). In addition, the placement and removal of these devices can be complicated. The bone-borne MDO-R requires a minimal palatal width of 1.5 mm. In congenital patients with extreme maxillary hypoplasia the conventional distractors are too large and cannot or not be optimally positioned and fixated.

In order to circumvent these problems we have developed a bone-borne palatal distractor that fixates through its expansion force without the use of screws and is easily placed and removed. The device is also available in a small size for the use on the extremely narrow maxilla in congenital deformities.

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Chapter 4

RELAPSE AND STABILITY OF SURGICALLY ASSISTED RAPID MAXILLARY EXPANSION, AN ANATOMIC BIOMECHANICAL STUDY

M.J. Koudstaal¹

J.B.J. Smeets²

G.J. Kleinrensink³

A.J.M. Schulten⁴

K.G.H. van der Wal¹

¹ Department of Oral and Maxillofacial Surgery
Erasmus University Medical Center Rotterdam

² Faculty of Human Movement Sciences
VU University Amsterdam

³ Department of Anatomy
Erasmus University Medical Center Rotterdam

⁴ Department of Orthodontics
Erasmus University Medical Center Rotterdam

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Abstract

Purpose: This anatomic biomechanical study was undertaken to gain insight into underlining mechanism of tipping of the maxillary segments during transverse expansion using tooth-borne and bone-borne distraction devices.

Materials and Methods: An anatomic biomechanical study was performed on 10 dentate human cadaver heads using tooth-borne and bone-borne distraction devices.

Results: The amount of tipping of the maxillary halves was greater in the tooth-borne group, but the difference was not significant. Four of the specimens showed an asymmetrical widening of the maxilla.

Conclusions: Segmental tipping was seen in both study groups. In this anatomic model, tooth-borne distraction led to greater segmental tipping compared with bone-borne distraction. Keep in mind, however, that this anatomic model by no means depicts a patient situation, and any extrapolation from it must be done with great care. The fact that the tooth-borne group demonstrated greater tipping might reflect the general opinion that bone-borne distraction causes less segmental angulation than tooth-borne distraction. Some tipping was seen in the bone-borne group, suggesting that overcorrection to counteract relapse will be necessary with this treatment modality.

Introduction

In patients with transverse and sagittal maxillary hypoplasia of the midface, buccal cross-bites (unilateral and bilateral), anterior and posterior crowding, dental compensation (eg, as lingual tipping of mandibular posterior teeth), and buccal corridors may be noted clinically. The aim of treating this deformity is to obtain transverse occlusal stability, resulting in stable sagittal and vertical relationships.

Orthodontic correction of the transverse discrepancy is successful until closure of the midpalatal suture at approximately 14 to 15 years of age depending on the patient's gender. Once skeletal maturity has been reached, surgically assisted rapid maxillary expansion (SARME), in combination with a corticotomy, must be performed to release the areas of bony resistance, such as the midpalatal suture, the zygomatic buttresses, and the piriform aperture. This technique includes a buccal corticotomy and a median osteotomy. It appears to be predictable and can provide sufficient expansion as well as long-term stable results. It has several advantages, including bone apposition in the osteotomy site, reduced risk of dental version or extrusion compared with regular orthopedic care, and increased periodontal stability.

Traditionally, a tooth-borne orthodontic appliance called a hyrax expander is placed preoperatively to expand the maxilla. Dental anchorage gives rise to several complications, including damage to the teeth, possible loss of anchorage, periodontal membrane compression and buccal root resorption, cortical fenestration, and anchorage-tooth tipping and segmental tipping. Advantages of the hyrax expander include its ability to be placed and removed in the orthodontic outpatient clinic without local anesthesia.

To help prevent dental complications, several bone-borne devices (distractors) have been developed. These distractors are placed directly on the palatal bone during surgery. They are claimed to avoid several of the problems associated with the Hyrax expander including damage to the teeth, periodontal membrane compression and buccal root resorption, cortical fenestration, skeletal relapse, anchorage-tooth tipping.¹⁻³ The major advantage of the bone-borne devices is that the forces are acting directly to the bone at the mechanically desired level, which prevents dental tipping and keeps segmental tipping to a minimum.⁴ Bone-borne devices have several disadvantages, including risk of damaging the roots of the dentition during placement of the devices, risk of loosening of the module or the abutment plates, and the need to remove the distractor under local anesthesia in the outpatient clinic after the consolidation period.

Relapse, defined as the gradual recurrence over time of the abnormality for which distraction was performed, is widely recognized yet poorly described. There is no con-

sensus in the searched literature regarding the cause and amount of relapse and whether or not overcorrection during the distraction phase is necessary.

One factor to be considered is that some relapse will occur due to the scar tissue contraction after distraction if sufficient time is not taken for consolidation. Three months is generally accepted as sufficient time to prevent this kind of relapse.

Another factor to consider is the mode of distraction. It has been suggested that the relapse is greater when a tooth-borne device is used. An explanation for this might be the tipping of the elements due to the tooth-borne fixation of the Hyrax expander. Another contributing factor may be the tipping of the maxillary segments instead of parallel expansion due to the different position of the tooth-borne and bone-borne distractors relative to the 'center of resistance',⁵ the area where the maxillary halves are still connected to the skull after the corticotomy, the pterygoid region.

To the best of our knowledge, to date no basic anatomic study has been performed on this specific subject. This anatomic biomechanical study aimed to gain insight into the underlining mechanism of tipping of the maxillary segments after transverse expansion using tooth-borne and bone-borne distraction devices.

Material and methods

An anatomic biomechanical study was performed using 10 dentate human cadaver heads. The skulls were randomly selected into 2 groups of 5 skulls each, with 1 group using the tooth-borne distractor (Hyrax) and the other group using a bone-borne device (Rotterdam Palatal Distractor, [RPD]).⁶ All of the soft tissues were removed from the specimens, leaving only the bone intact. In the skulls of the tooth-borne group, dental casts were made, on which the Hyrax expanders were manufactured. A routine corticotomy (buccal and median osteotomy of the maxilla) was performed on each specimen, and either the Hyrax or the RPD was placed (Figs 1 and 2).

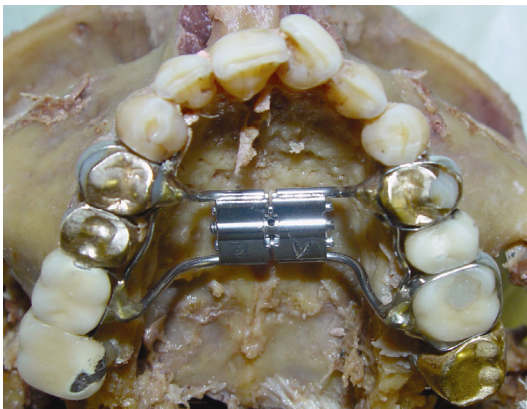


Figure 1. Photograph of the tooth-borne distractor (Hyrax) in situ on the anatomic specimen.

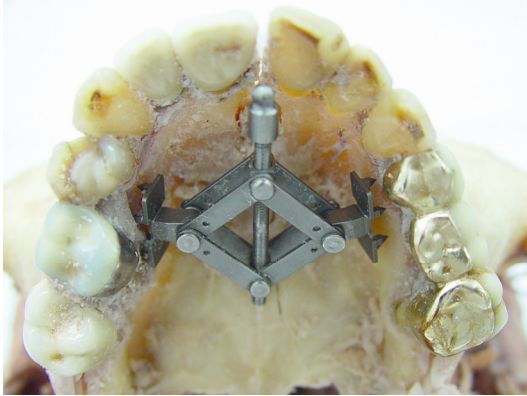


Figure 2. Photograph of the bone-borne distractor (RPD) in situ on the anatomic specimen.

The bone-borne RPD was placed as superiorly as possible. Each skull was fixed to the investigation table using a steel 4-pin anatomic specimen holder. There was no contact between the upper and the lower dentition. The same amount of distraction was acquired in both groups (1.5 cm).

During the distraction phase, the movement of the maxillary halves was registered using an opto-electronic system with active markers (Optrotrak 3020; Northern Digital Inc, Waterloo, Canada).⁷ This device uses active markers that can be placed on the object of interest and is capable of measuring movement with a resolution of >0.02 mm. Three small plastic plates were used, each with 3 markers positioned in a triangular configuration. These 3 markers made it possible to measure the displacement in distance and in angles (resolution, 0.05 degrees). The plates were connected with osteosynthesis screws to the bone. One of the plates was connected to the left maxillary half, and the other plate was connected to the right maxillary half. The third plate was connected to the frontal bone of the skull to measure any unwanted movement of the entire specimen due to manipulation. (Fig. 3a and 3b).

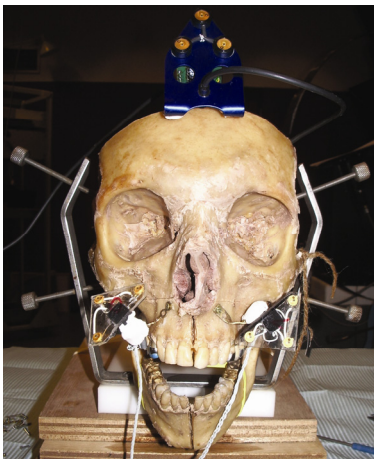


Figure 3a. Photograph of the experimental set up set up during measurement. The skull is fixed to the investigation table using a steel 4-pin anatomic specimen holder. Note the 3 sensor plates each containing 3 active markers.

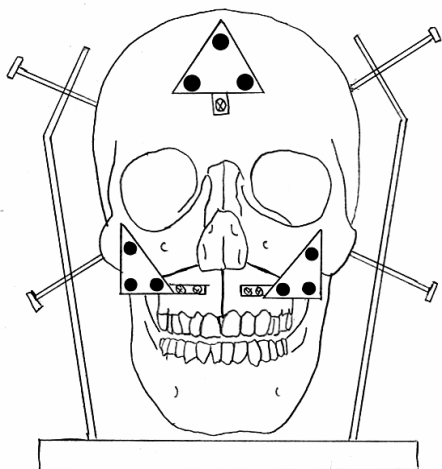


Figure 3b. Schematic drawing of the experimental set up during measurement. Note the 3 sensor plates each containing 3 active markers.

Results

The results of the angular displacements measurements are given in Table 1. Both maxillary halves have a horizontal and vertical outcome. The vertical result is the amount of rotation in the coronal plane, in other words, the amount of tipping of the maxillary half. The horizontal result is the rotation of the maxillary half in the axial plane. Table 2 shows the average vertical and horizontal rotations per group and the outcome of the statistical analysis (Student *t*-test). The outcomes of the vertical and horizontal movements in both groups were not significant. Specimen 1 and 8 and to a lesser degree, specimen 5 and 7, exhibited asymmetric widening of the maxilla.

Table 1. Results of the Optotrak measurements: vertical and horizontal angular displacement of the right and left maxillary segments (in degrees).

Specimen	Right vertical	Right horizontal	Left vertical	Left horizontal
1 Hyrax	1.70	9.02	1.32	2.78
2 Hyrax	2.97	1.76	1.06	1.86
3 Hyrax	1.69	3.01	5.30	1.04
4 Hyrax	0.69	1.64	5.96	1.82
5 Hyrax	9.46	2.54	0.91	7.93
6 RPD	1.29	1.26	0.62	2.25
7 RPD	1.98	6.64	2.41	2.48
8 RPD	9.41	10.85	1.04	2.11
9 RPD	1.00	1.13	2.10	3.98
10 RPD	1.79	2.15	2.07	0.17

Table 2. Average amount of horizontal and vertical movement in the 2 groups (n.s.: not significant).

Group	Average vertical movement (Degrees°)	Average horizontal movement (Degrees°)
Hyrax	5.42	5.73
RPD	3.32	5.54
P value; <i>t</i> -test	0.161 (n.s.)	0.785 (n.s.)

Discussion

The major advantage of the bone-borne devices is claimed to derive from the fact that the forces are acting directly to the bone at the mechanically desired level.⁴ Therefore, distraction by bone-borne devices would be expected to have a more parallel movement with less tipping of the maxillary halves compared with distraction by tooth-borne devices.

Few studies have reported relapse in SARME, relapse rate varies from 5% to 25%.^{2,4,8-11} Pogrel et al.¹² studied 12 adult patients, all of whom were still in orthodontic appliances 1 year after surgery and tooth-borne distraction, and found a relapse rate of only 11.8% at the maxillary first molar. Bays & Greco,⁸ in a retrospective study of 19 adult patients after tooth-borne distraction who were out of orthodontic appliances for longer than 6 months, found relapse rates of 8.8% at the canines, 1% at the first premolar, and 7.7% at the first maxillary molar. The mean follow-up period in that study was 2.4 years. The authors concluded that SARME has excellent stability, and thus no overcorrection is necessary. Several authors have reported relapse using SARME in combination with a tooth-borne distractor, but do not quantify the amount of relapse.¹³⁻¹⁵

As for bone-borne distraction, Matteini and Mommaerts,¹ using the Transpalatal Distractor (TPD), and Zahl & Gerlach,¹⁶ using the Palatal Distractor (PD), found overexpansion to be unnecessary because they detected no relapse on follow-up. These authors attributed the lack of relapse to the fact that the forces of the distraction are applied directly to the skeletal base.

As mentioned earlier some theorize that distraction by bone-borne devices has a more parallel movement with less tipping of the maxillary halves compared with tooth-borne devices. Thus, it is important to place the bone-borne device as superiorly as possible to achieve optimal positioning and a vector of the distraction forces relative to the 'center of resistance.' If the assumption that tipping (either dental or segmental) causes relapse is correct, then there would be no need for overcorrection if the movement of the maxillary halves would be perfectly parallel. In this study, segmental tipping occurred in both the tooth-borne and bone-borne groups, suggesting

that overcorrection is needed to counteract the tipping-related relapse regardless of the device used. The tooth-borne group showed more tipping (although not significant), reflecting the general opinion that bone-borne distraction causes less segmental angulations than tooth-borne distraction.

Keep in mind that this anatomic model by no means depicts a patient situation, and any extrapolation from it must be done with great care. The distraction in this study was performed all at once. This is in contrast with the normal clinical situation in which distraction osteogenesis is performed gradually, thereby allowing the tissues the possibility to respond to the applied forces. The anatomic specimens were not able to respond to the different stresses applied, which possibly could have influenced the outcome between the different study groups and also possibly the degree of asymmetric widening.

In several clinical cases, the expansion of the maxilla was asymmetric. In these patients, 1 maxillary half moved more than the other or even solitarily, leaving the other side stationary, leading to an asymmetric end-result. Our first impression was that the surgical mobilization was not performed evenly on both sides. In 1 case, we performed a second surgery in which both maxillary halves were again evenly mobilized; however, during the distraction phase, the same asymmetric widening occurred. An explanation for this finding could be that the different occlusal contact on each side was causing this problem. During the distraction phase of this anatomic study, asymmetric widening also occurred in 2 cases (Fig 4), specimen 1 and 8, and, to a lesser degree in specimen 5 and 7 (Table 1). The fact that asymmetric widening also occurs without influence of the occlusion casts a different light on the former explanation, making it less plausible.

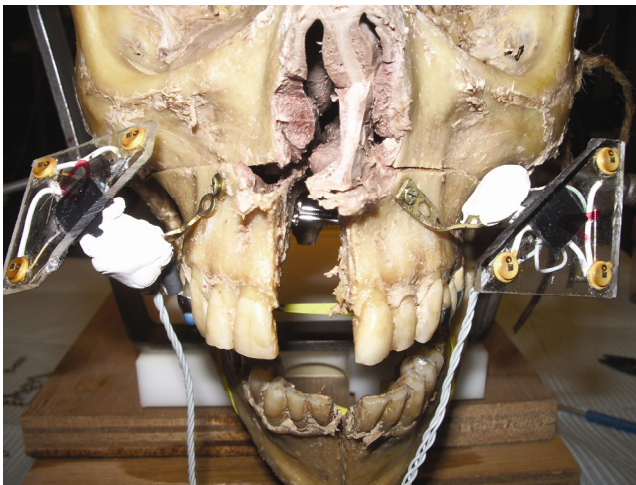


Figure 4. Photograph of the asymmetric expansion of the maxillary halves. Note that the right maxillary half has moved, whereas the left half is almost stationary.

Based on what we learned from this study, another possible explanation might be that an equilibrium exists between the resistance of both maxillary halves. After the corticotomy, the maxillary halves are connected to the skull in the pterygoid region. This area and also probably the soft tissues (muscles, ligaments) will affect the amount of resistance on each side. If the difference in resistance between the 2 sides is excessive, then only the side with the least resistance will move, leaving the other side stationary.

Segmental tipping of the maxillary halves was seen in both study groups. In this anatomic model, tooth-borne distraction led to more segmental tipping compared with bone-borne distraction. One should be aware that this anatomic model by no means depicts a patient situation, and any extrapolation from it must be done with great abstention. The fact that the tooth-borne group showed more tipping might reflect the general opinion that bone-borne distraction causes less segmental angulations as tooth-borne distraction. There is also some tipping in the bone-borne group suggesting that overcorrection to counteract relapse would be necessary with this treatment modality.

Asymmetric maxillary expansion which is seen in the clinical situation was also encountered in this study model, suggesting that an imbalance in the equilibrium of the resisting forces in the maxillary segments might be the causative factor.

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Part III

Prospective randomized patient study

- Chapter 5 Stability, tipping and relapse of bone-borne versus tooth-borne surgical assisted rapid maxillary expansion; a prospective randomized patient trial
Int J Oral Maxillofac Surg, submitted
- Chapter 6 Changes in the nasal airway and speech through bone-borne versus tooth-borne surgical assisted rapid maxillary expansion; a prospective randomized patient trial
Rhinology, submitted
- Chapter 7 Analysis of upper facial changes through bone-borne versus tooth-borne surgical assisted rapid maxillary expansion; a prospective randomized patient trial
Am J Orthod Dentofacial Orthop, submitted

Chapter 5

STABILITY, TIPPING AND RELAPSE OF BONE-BORNE VERSUS TOOTH-BORNE SURGICALLY ASSISTED RAPID MAXILLARY EXPANSION;
A PROSPECTIVE RANDOMIZED PATIENT TRIAL

M.J. Koudstaal¹

E.B. Wolvius¹

A.J.M. Schulten²

W.C.J. Hop³

K.G.H. van der Wal¹

¹ Department of Oral and Maxillofacial Surgery,
Erasmus University Medical Center Rotterdam

² Department of Orthodontics,
Erasmus University Medical Center Rotterdam

³ Department of Epidemiology and Biostatistics
Erasmus University Medical Center Rotterdam

Submitted

Int J Oral Maxillofac Surg

Abstract

Study objective: The aim of this study was to evaluate stability, tipping, and relapse after surgically assisted rapid maxillary expansion (SARME), comparing bone-borne versus tooth-borne devices, in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia.

Study design: Randomized, open-label, clinical trial (NTR:1087).

Methods: Mature non-syndromal patients with transverse maxillary hypoplasia (n=46) were recruited and randomized in a bone-borne (n=25) and a tooth-borne (n=21) group. The surgical technique for the corticotomy was the same in both groups and included a buccal corticotomy (anterior and lateral) and median split of the maxilla. In the bone-borne group, the expansion was performed using a bone-borne device, whereas in the tooth-borne group expansion occurred via a tooth-borne device. Dental study casts, lateral and postero-anterior cephalograms were taken before treatment (t1), after the distraction phase (t2) and at the 12 month follow-up (t3). Stability, segmental maxillary tipping and relapse are the primary outcome of this study.

Results: Twentythree bone-borne and 19 tooth-borne patients were analyzed. There were no significant differences between the two groups. Widening achieved was comparable at canine, premolar and molar level. The relapse was not significant and at follow up the significant increase in distance sustained. A significant increase in palatal width, at both the premolar and molar level was found within both groups. The maxilla moves slightly downward in SARME. Segmental maxillary tipping was found in both groups.

Conclusions: There is no significant difference between the two groups. In SARME, the achieved widening at dental level is stable at the 12 month follow-up. Overcorrection does not seem to be necessary. The maxilla moves slightly downward in SARME. Tipping of the maxillary segments is equal, in both bone-borne and tooth-borne SARME, and increases in the retention period. Segmental maxillary tipping does not affect relapse in SARME.

Introduction

The indications for surgically assisted rapid maxillary expansion (SARME) are skeletal maturity, (extreme) transverse maxillary hypoplasia, either uni- or bilateral and buccal corridors (black corridors), when smiling. Indications for SARME include cases where orthodontic maxillary expansion has failed and resistance of the sutures must be overcome. Transverse maxillary hypoplasia, in adolescents and adults, is frequently seen in non-syndromal and syndromal patients including cleft patients. In skeletally matured patients, the uni- or bilateral transverse hypoplasia can be corrected by means of SARME. The treatment is a combination of a surgical procedure and orthodontic treatment, and provides, by means of distraction osteogenesis, dental arch space for alignment of the dentition. Subsequently, the procedure causes a substantial enlargement of the maxillary apical base and the palatal vault, providing space for the tongue. In addition, a distinct subjective improvement in nasal breathing associated with enlargement of the nasal valve towards normal values is seen with an increase of nasal volume in all compartments.

Traditionally, a tooth-borne orthodontic appliance called a hyrax expander is placed preoperatively to expand the maxilla. Dental anchorage, however, might cause several negative and unwanted side-effects including; damage to the dentition, possible loss of anchorage, periodontal membrane compression and buccal root resorption, cortical fenestration, anchorage-tooth tipping, and maxillary segmental tipping.

To avoid these dental complications, several bone-borne devices (distractors) have been developed which are placed directly on the palatal bone during surgery. It is claimed that these distractors avoid several of the problems stated for the hyrax expander such as periodontal membrane compression and buccal root resorption, cortical fenestration, anchorage-tooth tipping, and maxillary segmental tipping, and orthodontic relapse.^{14,15,18} The major advantage of the bone-borne devices is claimed to be that the forces are applied directly to the bone at the mechanically desired level thereby avoiding both dental tipping and keeping segmental tipping to a minimum.^{14,16}

Relapse is defined as the gradual over time recurrence of the abnormality for which distraction was performed. This phenomenon is widely recognized yet poorly examined. In addition, there is no consensus in the searched literature regarding the cause and amount of relapse and whether or not overcorrection during the distraction phase is necessary.¹¹

One factor that needs to be considered is that relapse will occur due to scar tissue contraction after distraction. A consolidation period of three months is generally accepted to be sufficient to avoid most of the relapse due to scar contraction. Another factor to consider in relapse is the mode of distraction. It is suggested that the relapse

will increase when a tooth-borne device is used compared to a bone-borne distractor.¹⁸ An explanation for this might be the tipping of the elements due to the tooth-borne fixation of the expander.^{2,7} Yet another factor might be the tipping of the maxillary segments instead of parallel expansion due to the different position of the tooth-borne and bone-borne distractors relative to the 'center of resistance'.^{5,18} This 'center of resistance' is a combination of the area where the maxillary halves are still connected to the skull after the corticotomy, the pterygoid region, and the resistance of the surrounding soft tissues.

Maxillary expansion by means of distraction is currently a widely used treatment. However, there is no consensus in the searched literature regarding the surgical technique, the type of distractor (tooth-borne or bone-borne), the existence, cause and amount of relapse and whether or not overcorrection is necessary.¹¹

The aim of this prospective randomized patient study (NTR:1087) was to evaluate two conventional distraction modes, the bone-borne versus the tooth-borne distraction, in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia undergoing SARME. To our knowledge, no prospective randomized patient study comparing these two modes of distraction in SARME has been performed. The primary objective was to study the difference between the two groups considering the amount of stability, segmental maxillary tipping and relapse. The amount of displacement of the maxilla in the sagittal dimension was recorded. Occurrence of complications during the course of the study was noted. The secondary outcome of the study was the difference in nasal airway change between the two groups. Results of this outcome are published in the Otolaryngology literature given that it focuses mainly on the nasal function.

Methods

Participants

A prospective randomized open-label clinical study was performed at the Erasmus University Medical Center. The Standing Committee on Ethical Research in Humans of the Erasmus University Medical Center Rotterdam approved the study in December 2003. Patient recruitment occurred between January 2004 and December 2007, and the written consent of all patients was obtained. A sample size of 20 patients per group was feasible, with these numbers differences as great as 1 standard deviation (SD) can be detected at $\alpha=.05$. with a power of about 90%.

A random number table was used to prepare opaque sealed envelopes that were opened if a patient met the inclusion (and no exclusion) criteria and had given a writ-

ten consent to participate in the study. The patients were randomized in a bone-borne and a tooth-borne group. The inclusion criteria consisted of non-syndromal patients, age 16 or over with a transverse narrow maxillary arch (hypoplasia), which clinically showed one or more of the following situations; dental cross-bite: unilateral or bilateral; anterior and/or posterior crowding; clinical evidence of buccal corridors (when smiling). The transverse hypoplasia could not be corrected by orthodontics alone due to full skeletal maturation. In case of doubt about the skeletal maturity in patients between the ages of sixteen and eighteen, hand-wrist radiograph were taken to determine the stage of skeletal maturation using the Greulich-Pyle analysis.¹⁰ The buccal osteotomy did not interfere with the apices of the dentition and there is no risk of damage to the infra-orbital nerve. This could be determined on the pre-operative panoramic x-ray as well as on the postero-anterior cephalogram (PA-cephalogram). Exclusion criteria were syndromal patients (including cleft), patients who were not fully matured between the ages of 16 and 18, a history of radiation therapy or surgery in the area of interest and mental retardation.

Interventions

The basic surgical principle for the corticotomy was the same for both patient groups. The patient was admitted to the hospital for three days and was put on antibiotics. In general anesthesia a Le Fort I approach was followed. The buccal corticotomies were performed as usual for a Le fort I osteotomy, without pterygoid disjunction. The median osteotomy was between the central incisors. Prying motions with an osteotome resulted in mobilization of the segments. Depending on the randomized group, different distractors were placed and used for the transverse distraction osteogenesis.

In the tooth-borne study group, an orthodontic appliance called a hyrax expander was placed one week preoperatively to expand the maxilla (Hyrax CE 0297, Forestadent, Pforzheim, Germany). The hyrax consists of an expansion screw that is ideally attached to the maxillary first bicuspid and first molar.

In the bone-borne study group, two different distractors were used. Both distractors were placed at the same anatomical position on the palate and despite the difference in design, the vector of the applied forces through the devices are the same. The Transpalatal Distractor (TPD, CE 9001, Surgi-tec, Bruges, Belgium) was developed in 1999.¹⁵ The TPD module consists of a two-cylinder screw attached to abutments plates fixated to the palate with screws. During the course of this study, a new bone-borne palatal distractor was developed in the oral and maxillofacial department of the Erasmus University Medical Center. The Rotterdam Palatal Distractor (RPD, CE-0297, KLS Martin, Postfach 60, D-78501 Tuttlingen, Germany) is a bone-borne dis-

tractor made of titanium grade II based on the mechanical design of a car jack. The two abutment plates (5 x 12 mm) contain six nails, each 2 mm long. The activation part consists of a small hexagonal activation rod that is positioned directly behind the maxillary central incisors. By activating the distractor, the 2 mm long nails of the two abutment plates will penetrate the bone and the device is stabilized automatically, no screws are necessary to fixate the distractor to the bone.¹² At the end of the surgical procedure, the distractor was tested and the oral mucosa sutured.

The distraction started in both groups after a latency period of one week. The patient was instructed to activate the device at a rate of one millimeter per day until the desired expansion was obtained. At the end of distraction, there was a period of three months of consolidation (or neutral fixation). Thereafter, the device was removed in the outpatient clinic. If not already done before surgery, six weeks after the expansion, the orthodontist was able to place the fixed orthodontic appliances.

Objectives

The aim of this study was evaluate two conventional distraction modes, the bone-borne versus the tooth-borne in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia.

Null hypothesis

In skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, less tipping of the maxillary segments and increased stability in transverse dimensions at tooth and bone levels is achieved with a bone-borne device versus a tooth-borne expander, in SARME.

Outcomes

Measurements taken were dental study casts, lateral and PA-cephalograms. All measurements were done before treatment (baseline, t1), after the distraction phase (t2), and 12 months after treatment (t3). All measurements were done in the outpatient clinic. The primary outcome was the difference between the two groups comparing the amount of tipping between t1 and t2 and the difference in relapse from t2 to t3. The secondary outcome was the difference in nasal airway change between the two groups, and results are published in the Otolaryngology literature given that it focuses mainly on the nasal function.

Dental study casts

On the dental study casts, measurements were obtained according to Adkins et al. with the adaptation of the landmarks on the gingival margin of the teeth.¹ Due to the orthodontic appliances used in our study, the gingival margin was not a reliable measurement point. Landmarks used were the tip of the cusp of the canine, the tip of the buccal cusp of the first premolar and the tip of the disto-buccal cusp of the first molar to measure the arch width (Figure 1). The contact points on the mesial surface of the first molar, the mesial surface of the first premolar, and the distal surface of the central incisor were used to measure the arch perimeter (Figure 2).

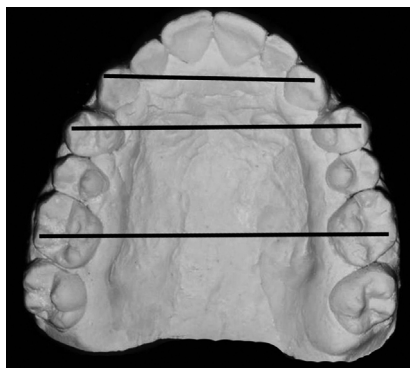


Figure 1. Landmarks for arch width measurements.



Figure 2. Landmarks for arch perimeter measurements.

An electronic digital caliper (Kraftixx®, art.0906-90) with an accuracy of 0.02mm. was used to do the actual measurements on the dental study casts. All measurements were done in millimeters (mm.).²

According to Northway et al, a digital depth measurement instrument and a fixation bridge was used to measure the depth of the palatal vault at the first premolars and molars (Figure 2).¹⁷ Similar palatal points were used by sighting on a straight line between two points on teeth on opposite sides of the arch and matching them up with palatal rugae and contours. Palatal rugae have provided valid reference points in numerous studies (Figure 3).¹⁷ The width of the palate was also recorded at a height of 5 mm occlusal to the palatal depth at t1 and t3 (Figure 4).¹⁷ These measurements were done at time intervals t1 and t3. Due to the presence of the distraction devices it was impossible to measure the palatal depth and width at t2.

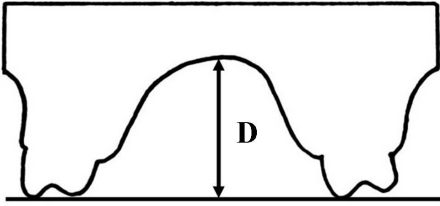


Figure 3. Measurement of the palatal vault depth measurements. D: palatal depth.

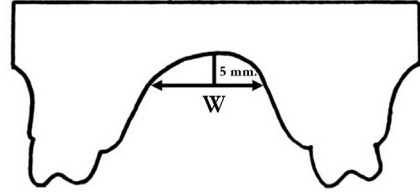


Figure 4. Measurement of the palatal vault width measurements. W: palatal width at 5 mm. occlusal to the maximal palatal depth.

Lateral cephalograms

In order to evaluate the movement of the maxilla in the sagittal plane, lateral cephalograms were traced. Angular and linear measurements recorded were SNA angle (degrees), perpendicular distance from line SN to A and from line SN to PNS (Figure 5).²¹

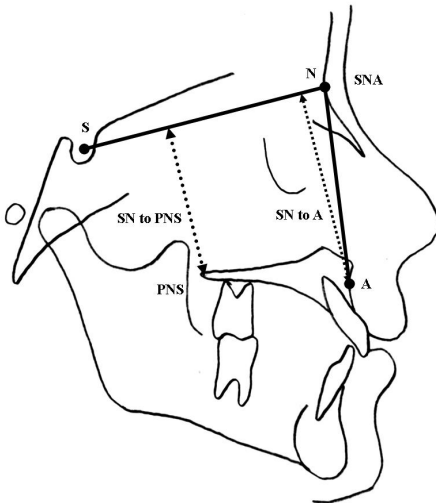


Figure 5. Lateral cephalogram measurements.

Postero-anterior cephalograms

In order to evaluate the skeletal widening of the maxilla, several linear measurements were performed on the PA-cephalogram (Figure 6). The width at the zygomatic process left and right was recorded (Z – Z) as a control measurement. Frequently, the most lateral aspect of the bony nasal cavity is taken.^{4,8,19} In our patient groups, however, the corticotomy is placed in this area, thereby introducing a possible bias if tak-

ing this measurement. To circumvent this, the most inferior point of the piriform aperture was chosen (Nc2). Width at the nasal level was measured from Nc2 left to right (Nc2 – Nc2) for evaluation of the skeletal widening of the maxillary segments at the upper level. For measuring the skeletal widening of the maxilla at the most caudal level, point Ma was taken, situated at the intersection of the molar to the alveolar process left and right (Ma – Ma).⁴

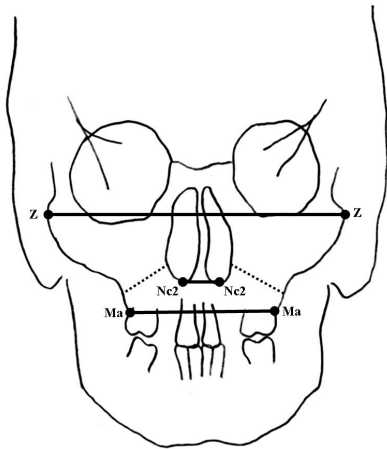


Figure 6. Postero-anterior cephalogram measurements. Dotted lines represents the position of the buccal corticotomy.

To study the amount of segmental maxillary tipping, the change in distance at the upper level (Nc2-Nc2) was subtracted from the change in distance at the caudal level (Ma – Ma). The segmental maxillary tipping due to the treatment (t1 to t2), at follow-up (t1 to t3) was evaluated.

Measurements on both the lateral and PA-cephalograms were performed using the digital dicom-data program EasyViewWeb (2005, Philips Medical Systems, Best, The Netherlands).

Statistical method

All measurements were done by the principal author. The analysis was performed using the Statistical Package of the Social Sciences (version 12.0, SPSS Inc, Chicago,IL). The unpaired student t-test was used for comparison of outcomes between groups, and the paired t-test for comparison within groups. P=0.05 (two-sided) was considered the limit of significance. Prior power calculations had led to 20 patients in each group. Correlation coefficients shown are Pearson's.

Reliability

From all three time intervals, eight models, lateral and PA-cephalograms were randomly selected to assess intra- and inter-observer agreement. Agreement was quantified by calculating intra-class correlation coefficients (ICC). For ICC values >0.9 the reliability of the measurement is generally considered to be excellent.

Results

A total of 46 patients were randomized during the study period. Of these, 42 completed the study protocol and were evaluated. Figure 7 depicts the patient flows through the study. Twentythree bone-borne and 19 tooth-borne patients were analyzed. Table 1 shows the baseline characteristics of randomized patients.

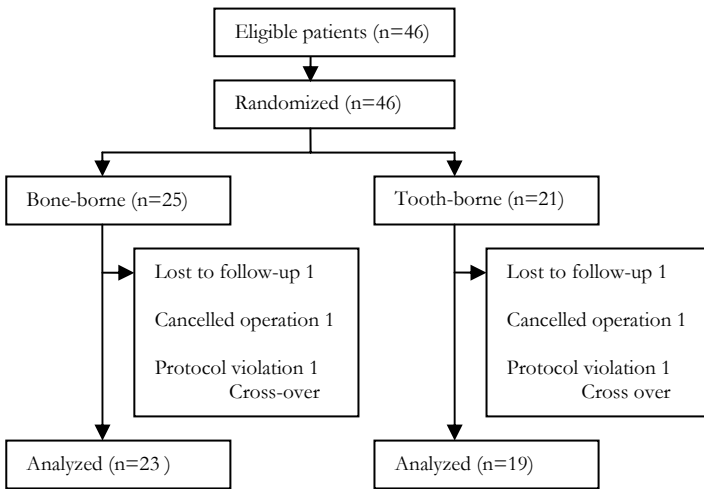


Figure 7. Flow diagram for a depiction of patient flows through the study.

Table 1. Baseline patient data.

	Bone-borne	Tooth-borne	Total
Number (%)	25 (54%)	21 (46%)	46 (100%)
Age (y)	33 (16 – 50)	25 (16 – 44)	30 (16 – 50)
Male/Female, n (%)	10/15 (40/60)	13/8 (62/38)	23/23 (50/50)

Y: years; n: number.

There were two protocol violations in patients who crossed-over between treatment modality. The statistical analysis performed, for both ‘intention-to-treat’, and ‘as-treated’, resulted in similar conclusions. Therefore, results of the ‘as treated’ analysis are presented.

The intra-class correlation coefficient (ICC) for each separate measurement both inter-, and intra-observer, was greater than 0.95 indicating that the various measurements performed are reliable.

Dental study casts

The results of the distance and arch perimeter measurements are shown in Table 2. There was a significant change in all measurements, within the groups, due to the therapy (t1-t2) and at follow up (t1-t3). There was no significance (ns) between the two groups. The widening achieved was comparable at canine, premolar and molar level, making the expansion parallel in the posterior-anterior plane. Change of the canine width, from t2 to t3 should be regarded as the result of the orthodontic alignment of the anterior dentition, using the created midline space. The relapse at premolar level was 0.1 mm. in the bone-borne group (ns). In the tooth-borne groups there was an increase of width (from t2 to t3) at the premolar level of 1.1 mm. This should also be regarded as a result of the orthodontic treatment. The relapse at the molar level was not significant in both groups (bone 0.6, tooth 0.5). The measurements for the arch perimeter showed an increase due to therapy of 7.3 mm. in the bone-borne, and 5.7 mm. in the tooth-borne group. The relapse was not significant and at follow up the significant increase in distance was sustained.

Table 2. Results of the dental study casts distance and arch perimeter measurements in millimeters (mm.).

	t1 (SD)	Mean (SD) t2 (SD)	t3 (SD)	Tx change t1-t2 (SD)	Relapse t2-t3 (SD)	Net change t1-t3 (SD)	Relapse in percentage(%) (SD)
Width at canine (mm.)							
Bone-borne	28.9 (4.2)	34.9 (5.7)	33.6 (3.6)	6.0* (3.4)	-1.3* ^{bl(0.064)} (3.2)	4.7* (3.2)	-2.4 (10.9)
Tooth-borne	31.9 (3.7)	37.8 (4.3)	35.6 (2.5)	5.9* (3.6)	-2.2* (3.8)	3.7* (3.0)	-5.1* (8.2)
Width at premolar (mm.)							
Bone-borne	35.2 (3.4)	42.2 (3.8)	42.3 (3.0)	7.0* (3.1)	-0.1 (2.5)	7.0* (3.5)	0.2 (5.9)
Tooth-borne	35.6 (3.3)	42.8 (3.2)	43.9 (3.4)	7.1* (3.5)	1.1 (2.5)	8.2* (4.1)	2.6 (5.7)
Width at molar (mm.)							
Bone-borne	47.1 (3.5)	52.3 (3.7)	51.7 (3.6)	5.2* (3.4)	-0.6 (1.5)	4.6* (3.1)	-1.1 (2.8)
Tooth-borne	47.1 (4.7)	53.9 (5.0)	53.4 (4.4)	6.8* (2.9)	-0.5 (1.8)	6.3* (3.4)	-0.7 (3.2)
Arch perimeter (mm.)							
Bone-borne	64.2 (8.9)	71.5 (8.8)	70.0 (7.2)	7.3* (3.7)	-1.3 (4.5)	6.0* (5.8)	-1.4 (6.3)
Tooth-borne	67.6 (6.8)	73.3 (7.7)	72.4 (7.1)	5.7* (3.4)	-0.9 (3.4)	4.8* (3.6)	-1.0 (4.7)

Data given are mean and standard deviation (SD) at three time points. t1: baseline; t2: at the end of distraction; t3: at the 12 month follow-up; Tx change: changes due to the treatment; Net change: change at follow-up.

*: significant within groups change, different from 0; ^{bl}: borderline significance.

The results of the palatal depth and width measurements are shown in Table 3. The loss of palatal depth at the molar level was found to be significant in the bone-borne group. A significant increase in palatal width, at both the premolar, and molar level was found within both groups. Pearson correlation analysis showed a significant ($p=0.031$) negative correlation between palatal depth and width at the molar level. Increase in width results in a decrease in depth. There were no significant differences between the two groups.

Table 3. Results of the dental study casts palatal depth and width measurements in millimeters (mm.).

	Mean (SD)		Net change
	t1 (SD)	t3 (SD)	t1-t3 (SD)
Palatal depth at premolar (mm.)			
Bone-borne	20.3 (4.6)	20.2 (4.0)	-0.1 (2.1)
Tooth-borne	19.4 (2.9)	18.7 (3.1)	-0.7 (2.1)
Palatal depth at molar (mm.)			
Bone-borne	22.7 (2.6)	22.3 (2.5)	-0.4* (0.7)
Tooth-borne	22.2 (1.9)	22.1 (1.9)	-0.1 (1.5)
Palatal width at premolar (mm.)			
Bone-borne	12.2 (4.0)	15.1 (3.5)	2.9* (2.2)
Tooth-borne	12.6 (3.9)	15.2 (3.3)	2.6* (2.9)
Palatal width at molar (mm.)			
Bone-borne	16.6 (4.7)	19.2 (4.3)	2.6* (2.5)
Tooth-borne	15.8 (3.8)	18.3 (3.2)	2.5* (2.1)

Data given are mean and standard deviation (SD) at two time points. t1: baseline; t3: at the 12 month follow-up; Net change: change at follow-up. *: significant within groups change, different from 0.

Lateral cephalograms

The results of the measurements on the lateral cephalograms are shown in Table 4. There was no significant change in the angle SNA within and between groups. The distances from SN to A, and from SN to PNS increased significantly in both groups, but no significant difference between the two groups was found.

Table 4. Results of the lateral cephalogram measurements.

	Mean (SD)		Net change
	t1 (SD)	t3 (SD)	t1-t3 (SD)
SNA (degrees °)			
Bone-borne	79.7 (4.0)	80.2 (4.3)	0.5 (1.3)
Tooth-borne	81.2 (4.9)	81.5 (5.1)	0.4 (0.8)
Distance SN to A (mm.)			
Bone-borne	61.7 (5.2)	62.4 (5.0)	0.8* (1.6)
Tooth-borne	60.3 (5.3)	61.5 (4.9)	1.2* (2.0)
Distance SN to PNS (mm.)			
Bone-borne	48.0 (4.8)	48.8 (4.7)	0.8* (1.0)
Tooth-borne	49.3 (4.2)	50.5 (4.2)	1.3* (1.7)

Data given are mean and standard deviation (SD) at two time points. t1: baseline; t3: at the 12 month follow-up; Net change: change at follow-up. *: significant within groups change, different from 0.

Postero-anterior cephalograms

The results of the distance measurements on the PA-cephalograms are shown in Table 5. The increase of the skeletal maxillary width at the upper level (Nc2–Nc2), and at the caudal level (Ma–Ma), were both significant within the groups, due to the therapy (t1-t2), and at follow up (t1-t3). Relapse, at the upper level, was found to be significant in both groups, but greater in the tooth-borne group (bone-borne 4.7%, tooth-borne 6.4%) (Figure 8). Relapse, at the caudal level, however, was found only to be significant in the bone-borne group, however, the amount of relapse was comparable (bone-borne 0.9%, tooth-borne 0.6%). No significant difference between the two groups was found.

Table 5. Results of the PA-cephalogram distance measurements in millimeters (mm.).

	Mean (SD)			Tx change	Relapse	Net change	Relapse in
	t1 (SD)	t2 (SD)	t3 (SD)	t1-t2 (SD)	t2-t3 (SD)	t1-t3 (SD)	percentage (%)
Nc2 – Nc2 (mm.)							
Bone-borne	17.8 (3.0)	20.4 (2.3)	19.2 (2.7)	2.4* (1.9)	-1.0* (0.9)	1.4* (1.7)	-4.7* (4.4)
Tooth-borne	17.0 (2.9)	19.4 (3.0)	18.1 (2.4)	2.6* (1.8)	-1.4* (1.4)	1.1* (1.3)	-6.4* (6.3)
Ma – Ma (mm.)							
Bone-borne	58.8 (4.0)	62.1 (3.8)	61.4 (3.8)	3.1* (2.4)	-0.5* (0.8)	2.76 (2.2)	-0.9* (1.3)
Tooth-borne	60.6 (5.4)	63.7 (4.9)	63.3 (4.8)	3.1* (2.0)	-0.4 (1.3)	3.0* (2.23)	-0.6 (2.0)

Data given are mean and standard deviation (SD) at three time points. t1: baseline; t2: at the end of distraction; t3: at the 12 month follow-up; Tx change: changes due to the treatment; Net change: change at follow-up. *: significant within groups change, different from 0.

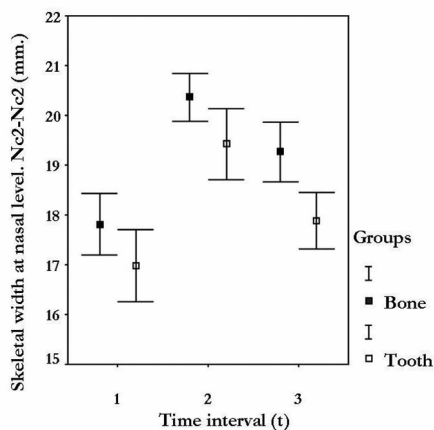


Figure 8. Error bar chart showing the measurements, on the postero-anterior cephalograms, of the upper maxillary width (Nc2 – Nc2) in millimeters (mm.). Both groups, at all three time intervals.

The results of the segmental maxillary tipping measurements on the PA-cephalograms are shown in Table 6. Tipping of the maxillary segments due to the therapy (t1-t2) was found in both groups, 0.7 (SD2.6) in the bone-borne group and 0.5 (SD2.3) in the tooth-borne group, but this was not significant. The difference between the two groups was 0.2 ($p=0.82$, 95% confidence interval -1.46 to 1.83). At follow up (t1-t3), however, the rotational movement had increased, 1.2 (SD2.1) in the bone-borne group and 1.8 (SD2.4) in the tooth-borne group, and this was significant in both groups. It should be noted that difference in the tipping between the two groups was not significant.

Table 6. Results of the segmental maxillary tipping measurements on the postero-anterior cephalograms in millimeters (mm.).

	Tx change t1-t2 (SD)	Net change t1-t3 (SD)	95% Confidence Interval (CI) for Tx change		
Bone-borne	0.7 (2.6)	1.2* (2.1)	-0.45	to	1.85
Tooth-borne	0.5 (2.3)	1.8* (2.4)	-0.71	to	1.74

To calculate the tipping change in distance at the upper level (Nc2-Nc2) was subtracted from the change in distance at the caudal level ($Ma - Ma$). Data given are mean and standard deviation (SD) of changes due to the treatment and at follow-up. t1: baseline; t2: at the end of distraction; t3: at the 12 month follow-up; Tx change: changes due to the treatment; Net change: change at follow-up. *: significant within groups change, different from 0.

Complications

During the course of the study three complications were encountered. In the tooth-borne group one patient experienced a discoloration of the right central incisor three weeks after surgery. The incisor was treated endodontically. In two patients in the bone-borne group, the expansion was asymmetric.

Discussion

The primary objective was to study the difference in the amount of stability, segmental maxillary tipping, and relapse, in bone-borne versus the tooth-borne distraction, in a group of skeletally matured non-syndromal patients, with transverse maxillary hypoplasia, undergoing SARME.

According to the literature, the major advantage of bone-borne distraction in comparison with tooth-borne distraction, is the fact that the expansion forces are acting directly to the bone at the mechanically desired level. This avoids anchorage-tooth tipping, excludes orthodontic relapse, and keeps segmental maxillary tipping to a minimum, leading to less skeletal relapse.^{14-16,18}

The measurements performed on the patients treated during this study, with either bone-borne or tooth-borne expansion, were directed towards stability at a dental and skeletal level, and at rotational movement (tipping) of the maxillary segments. It was not relevant to compare the amounts of expansion achieved, since this varied from case to case.

The reasons for the two cross-over patients were fear of one patient for a bone-borne device, and problems in the oral function (eating) with the Hyrax, in the pre-operative period in the second patient. These reasons are not expected to affect the results. Furthermore, the statistical analyses performed, 'intention-to-treat' and 'as-treated', resulted in similar differences between evaluated groups.

Most importantly, the results of this study show that there is no significant difference between the two groups. This leads to discarding the null hypothesis that, in skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, less tipping of the maxillary segments and increased stability in transverse dimensions at tooth and bone levels is achieved with a bone-borne device compared to a tooth-borne expander, in SARME.

Results of dental study casts show that there is a significant increase in maxillary width and arch perimeter, due to the therapy, which is stable over a one year period. Relapse in width at dental level, was small, between 0.5 and 0.6 mm. (0.7 and 1.1 %), which corroborates other studies, using tooth-borne expansion, after SARME.^{3,4,17} The fact that all patients underwent orthodontic treatment after the expansion probably influenced the outcome.

The Pearson correlation analysis of the palatal depth and width measurements showed a significant ($p=0.031$) negative correlation between palatal depth and width at the molar level in both groups. Increase in width results in a decrease in depth, which can be explained by the tipping movement of the maxillary segments.

In the sagittal dimension, the maxilla moved slightly downward. In SARME this downward movement of the maxilla could be explained by the direction of the lateral corticotomy. This osteotomy line is generally slanting slightly downward from the nasal aperture to the zygomatic buttress, due to the anatomic shape of the maxilla, and the need to avoid apices of the dentition. The direction of the expansion of the maxillary segments is guided by this osteotomy line, and might result in some downward movement of the maxilla besides its planned lateral movement. Similar downward displacement has been reported in patients undergoing Rapid Maxillary Expansion (RME), but an explanation is not given.^{8,9,21} When looking at tooth-borne SARME, Chung et al. found a slight forward movement of the maxilla, but no significant vertical displacement.⁶

On the PA-cephalograms, both skeletal widening and rotational movement (tipping) of the maxillary segments was studied. A rotational movement of the maxillary segments was found in both groups due to the therapy, and this movement increased during the retention period. The explanation for this lies in the amount of relapse, which was greater at the upper, compared to the caudal level. The different position on the palate of the bone-borne and tooth-borne distractors did not make a difference.

The fact that segmental maxillary tipping was present in both groups, and that it increased during the retention period, combined with the very small amount of relapse, leads to the conclusion that segmental maxillary tipping does not influence relapse in SARME, using either bone-borne or tooth-borne distraction.

Surgical or orthodontic trauma probably caused the discoloration of the central incisor in one patient. The median osteotomy is placed directly between the central incisors, and although an osteotome is used in this area, there is always a risk of trauma to the adjacent teeth. The orthodontic treatment, moving the central incisors into the distraction gap, might also have caused this trauma. No reports were found in the literature regarding damage to dentition in SARME.

The cause of the asymmetric widening of the maxillary segments, found in two patients, can not be explained by this study. Since surgery was equal in both groups, we feel that it is a coincidence that both patients were from the bone-borne group. In these two these patients one maxillary halve would move more, or even solitary leaving the other side stationary, leading to an asymmetric end-result. The first impression was that the surgical mobilization was not performed evenly on both sides and in the first case a second surgery was performed in which both maxillary halves were again evenly mobilized. However, during the distraction phase, the same asymmetric widening occurred. One explanation for this finding could be that a different occlusal con-

tact on each side was causing this problem. In the searched literature one article mentions this complication in bilateral cleft lip and palate patients, but provides no explanation.²¹ An anatomic biomechanical study that addresses this complication with SARME has recently been published.¹³ In this anatomic specimen study asymmetric widening of the maxilla was found in a laboratory situation with no influence of the occlusion. This finding casts a different light on the former possible explanation, making it less plausible. Another explanation might be that an equilibrium exists between the resistance of both maxillary halves. After the corticotomy, the maxillary halves are connected to the skull in the pterygoid region. This area and also probably the soft tissues (muscles, ligaments) will affect the amount of resistance on each side. If the difference in resistance between the two sides is excessive, then only the side with the least resistance will move, leaving the other side stationary.

Advantage of the tooth-borne expander, compared to a bone-borne distractor, is that it can be placed and removed in the orthodontic outpatient clinic, without local anesthesia. The placement of the TPD bone-borne device, during surgery, is time consuming. Furthermore, the hyrax expander is less expensive than the bone-borne devices.

The results of this study show no differences in stability, tipping and relapse, between bone-borne and tooth-borne expansion in SARME. In skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, tooth-borne SARME gives a stable clinical end result, is less invasive for the patient, and less expensive.

An indication for a bone-borne distractor (RPD) exists in congenital deformity patients with extreme narrow maxillae.¹² In these situations, a tooth-borne appliance can not be placed due to its size.

Conclusions

1. There is no significant difference between the two groups. This leads to discarding the null hypothesis that, in skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, less tipping of the maxillary segments and increased stability in transverse dimensions at tooth and bone levels is achieved with a bone-borne device versus a tooth-borne expander, in SARME.
2. In SARME, when using either a bone-borne or tooth-borne distractor, the achieved widening at dental level is stable at the 12 month year follow-up. Over-correction does not seem to be necessary.
3. The maxilla moves slightly downward in SARME.
4. Tipping of the maxillary segments is equal in both bone-borne and tooth-borne SARME, and increases in the retention period.
5. Segmental maxillary tipping does not affect relapse in SARME.

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Chapter 6

CHANGES IN THE NASAL AIRWAY AND SPEECH THROUGH BONE-BORNE VERSUS TOOTH-BORNE SURGICALLY ASSISTED RAPID MAXILLARY EXPANSION; A PROSPECTIVE RANDOMIZED PATIENT TRIAL

M.J. Koudstaal¹

E.B. Wolvius¹

S. Klootwijk²

W.C.J. Hop³

P.A van der Eerden⁴

K.G.H. van der Wal¹

¹ Department of Oral and Maxillofacial Surgery,
Erasmus University Medical Center Rotterdam

² Department of Ear, Nose and Throat
Erasmus University Medical Center Rotterdam

³ Department of Epidemiology and Biostatistics
Erasmus University Medical Center Rotterdam

⁴ Department of Ear, Nose and Throat
't Lange Land Hospital, Zoetermeer

Submitted

Rhinology

Abstract

Study objective: The aim of this study was to evaluate the effect on the nasal airway and speech, of surgically assisted rapid maxillary expansion (SARME), comparing bone-borne versus the tooth-borne devices, in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia.

Study design: Randomized, open-label, clinical trial (NTR:1087).

Methods: Mature non-syndromal patients with transverse maxillary hypoplasia (n=46) were recruited and randomized in a bone-borne device group (n=25) and a tooth-borne device group (n=21). The surgical technique for the corticotomy was the same in both groups and included a buccal corticotomy (anterior and lateral) and median split of the maxilla. In the bone-borne group, the expansion was performed using a bone-borne device, whereas in the tooth-borne group expansion was achieved using a tooth-borne device. Objective measurements were done, using acoustic rhinometry (AR) for nasal airway volume changes, and nasometry for evaluation of nasalance. Subjective evaluation was done using a visual analogue scaled (VAS) patient questionnaire. All measurements were taken before treatment (t1), after the distraction phase (t2) and at the 12 month follow-up (t3). The primary objective was to study the difference in the nasal airway measurements between the two groups. Change in the nasalance of speech was evaluated secondarily.

Results: Twentythree bone-borne and 19 tooth-borne patients were analyzed. There were no significant differences between the two groups. The average expansion of the maxilla was 6.5 mm. (standard deviation 3.2). The AR measurements showed an increase in both groups at t2 and t3, relapse was negligible. The nasometry measurements did not show any significant changes. The VAS scores showed a subjective improvement of nasal breathing capacity, and a reduction of snoring.

Conclusions: The results of this study show no differences between the two groups. All AR nasal capacity measurements increased due to SARME. The nasalance of speech is not influenced by SARME. The objective improvement of the nasal capacity is in agreement with the subjective improvement but no significant correlation was found. In both groups a subjective reduction of snoring was found.

Introduction

The general indications for surgically assisted rapid maxillary expansion (SARME) are skeletal maturity, (extreme) transverse maxillary hypoplasia, either uni- or bilateral and buccal corridors (black corridors), when smiling. Furthermore, the indications for SARME include any case where orthodontic maxillary expansion has failed and resistance of the sutures must be overcome. Transverse maxillary hypoplasia, in adolescents and adults, is frequently seen in non-syndromal and syndromal patients including cleft patients. In skeletally matured patients, the uni- or bilateral transverse hypoplasia can be corrected by means of SARME. The treatment is a combination of a surgical procedure and orthodontic treatment and provides, by means of distraction osteogenesis, dental arch space for alignment of the dentition. Subsequently, the procedure causes a substantial enlargement of the maxillary apical base and of the palatal vault, providing space for the tongue. In addition, a distinct subjective improvement in nasal breathing associated with enlargement of the nasal valve towards normal values is seen with an increase of nasal volume in all compartments ⁽¹⁻³⁾.

Traditionally, a tooth-borne orthodontic appliance called a hyrax expander is placed preoperatively to expand the maxilla. Dental anchorage, however, might cause several negative and unwanted side effects including; damage to the dentition, possible loss of anchorage, periodontal membrane compression and buccal root resorption, cortical fenestration, anchorage-tooth tipping, and maxillary segmental tipping.

To avoid these dental complications, several bone-borne devices (distractors) have been developed which are placed directly on the palatal bone during surgery. It is claimed that these distractors avoid several of the problems stated for the hyrax expander ⁽⁴⁻⁶⁾. The major advantage of the bone-borne devices is claimed to be that the forces are applied directly to the bone at the mechanically desired level thereby avoiding both dental tipping and keeping segmental tipping to a minimum ⁽⁷⁾.

Theoretically, instead of tipping the maxillary segments after tooth-borne expansion, bone-borne distraction would cause a more parallel expansion of the maxillary segments. As a result, the nasal bony structures are also expected to be widened more by bone-borne versus tooth-borne distraction leading to a superior improvement in nasal airway capacity in the bone-borne group.

In 1989, acoustic rhinometry (AR) was introduced by Hilberg ⁽⁸⁾ for measuring nasal cavities. AR provides an objective measurement of cross-sectional area and volume of the nasal cavity ⁽²⁾. The underlying principle is the analysis of acoustic pulse response that arises through impedance discontinuity inside hollow spaces ⁽⁸⁾. A pressure wave of 55 db is applied to the airway through a manufactured nosepiece adapter. Incident and reflected pressure waves are recorded during a time frame of 10 ms. Ac-

According to the Ware-Aki algorithm ^(1,10), amplitude and velocity of incident and reflected acoustic impulses can be traced back to a cross-sectional area profile of the structure that was traversed by the pressure wave ⁽⁹⁾. The accuracy of AR has been studied extensively and most of these studies report the technique to be very reliable in the anterior part of the nose up to 6 cm. ⁽¹¹⁻¹⁴⁾. It is a quick, painless, non-invasive, and reliable procedure that can be performed easily with minimal patient cooperation ^(2,14).

Several authors have researched nasal volume changes through orthodontic transverse maxillary expansion (RME) using AR ^(2,15-22). Others have reported changes in nasal airway after SARME ^(1,18,23,24).

Nasometry is a measurement instrument for objective assessment of rhinophonia. It measures nasalance, the relative sound pressure level of the nasal signal in speech, expressed as a percentage. It is able to differentiate with high sensitivity and specificity between normal nasal resonance and hypernasality ⁽²⁵⁾, which confirms its validity ⁽²⁶⁾. As mentioned earlier, nasal airway changes in anatomy, volume, and breathing capacity due to the surgery are to be expected in our patient group, however, the velopharyngeal function is not likely to be affected by the treatment. In other words, no differences are to be expected in the outcome of the nasometry measurements. The reason to perform the nasometry in this study was to evaluate if there truly are no changes in speech due to the performed surgery and the different modes of expansion.

To evaluate the subjective changes of the nasal airway due to the SARME, patients were asked to complete a questionnaire using six visual analogue scaled (VAS) questions.

The aim of this prospective randomized patient study (NTR:1087) was to evaluate two conventional distraction modes, the bone-borne versus the tooth-borne, in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia undergoing SARME. The objective of this study was to evaluate the difference in nasal airway change and differences in the nasalance of speech between the two groups, and the results will be presented here. Objective measurements were done using AR and nasometry. Subjective evaluation was done using a visual analogue scaled (VAS) patient questionnaire. Stability, segmental maxillary tipping and relapse of the two distraction modes was also assessed, and those results are published in the Oral and Maxillofacial Surgery literature given that its focus is mainly on the surgical and orthodontic aspects of the treatment.

Methods

Participants

A prospective randomized open-label clinical study was performed at the Erasmus University Medical Center. The Standing Committee on Ethical Research in Humans of the Erasmus University Medical Center Rotterdam approved the study in December 2003. Patient recruitment occurred between January 2004 and December 2007, and the written consent of all patients was obtained. A sample size of 20 patients per group was feasible, and with these numbers, differences as great as 1 standard deviation (SD) can be detected at $\alpha=.05$ with a power of about 90%.

A random number table was used to prepare opaque sealed envelopes that were opened if a patient met the inclusion (and no exclusion) criteria and had given written consent to participate in the study. The patients were randomized in a bone-borne and a tooth-borne group. The inclusion criteria consisted of non-syndromal patients, age 16 or over with a transverse narrow maxillary arch (hypoplasia), which clinically showed one or more of the following situations; dental cross-bite: unilateral or bilateral; anterior and/or posterior crowding; clinical evidence of buccal corridors (when smiling). The transverse hypoplasia could not be corrected by orthodontics alone due to full skeletal maturation. In case of doubt about the skeletal maturity in patients between the ages of sixteen and eighteen, hand-wrist radiograph were taken to determine the stage of skeletal maturation using the Greulich-Pyle analysis (27). The buccal osteotomy did not interfere with the apices of the dentition and there is no risk of damage to the infra-orbital nerve. This could be determined on the pre-operative panoramic x-ray as well as on the postero-anterior cephalogram (PA-cephalogram). Exclusion criteria were syndromal patients (including cleft patients) who were not fully matured between the ages of 16 and 18, a history of radiation therapy or surgery in the area of interest, and mental retardation.

Interventions

The basic surgical principle for the corticotomy was the same for both patient groups. The patient was admitted to the hospital for three days and was put on antibiotics. In general anesthesia a Le Fort I approach was followed. The buccal corticotomies were performed as usual for a Le fort I osteotomy, without pterygoid disjunction. The median osteotomy was between the central incisors. Prying motions with an osteotome resulted in mobilization of the segments. Figure 1 shows the positions of the osteotomies made during the corticotomy. Depending on the randomized group, different distractors were placed and used for the transverse distraction osteogenesis.

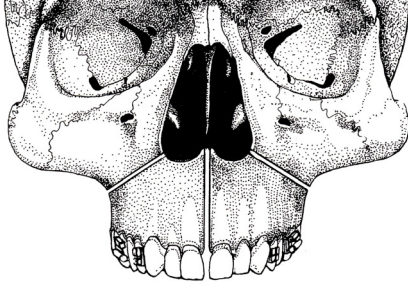


Figure 1. Schematic drawing of the positions of the osteotomies performed during a corticotomy.

In the tooth-borne group, an orthodontic appliance called a hyrax expander was placed one week preoperatively to expand the maxilla (Figure 2).

In the bone-borne group, the distractor was preoperatively placed on the palate (Figure 3) ^(5,28). At the end of the surgical procedure, the distractor was tested and the oral mucosa sutured.



Figure 2. Clinical photograph of the tooth-borne Hyrax expander in situ.

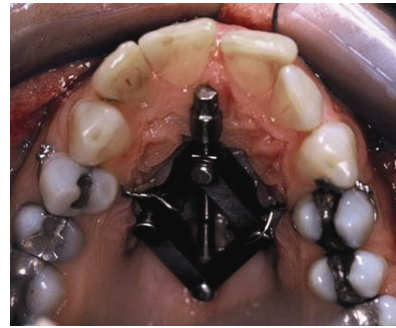


Figure 3. Clinical photograph of the bone-borne distractor in situ.

The distraction started in both groups after a latency period of one week. The patient was instructed to activate the device at a rate of one millimeter per day until the desired expansion was obtained (Figure 4). At the end of distraction, there was a period of three months of consolidation (or neutral fixation). Thereafter, the device was removed in the outpatient clinic.



Figure 4. Clinical photograph of the bone-borne distractor in situ at the end of the distraction period.

Objectives

The aim of this study was to evaluate two conventional distraction modes, the bone-borne versus the tooth-borne in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia.

Null hypothesis

In skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, more improvement in the nasal airway capacity after SARME is to be expected in the bone-borne group versus the tooth-borne group. No change in the nasalance of speech is to be expected.

Outcomes

All measurements were taken before treatment (baseline t1), after the distraction phase (t2), and at 12 months after treatment (t3). The primary outcome was the difference in nasal airway changes between the two groups. Change in speech was evaluated secondarily. Objective measurements were done using acoustic rhinometry (AR) and nasometry. Subjective evaluation was done using a visual analogue scaled (VAS) patient questionnaire.

The AR measurements were taken according to the consensus report on acoustic rhinometry and recommendations for technical specifications and standard operating procedures^(29,30). Measurements were performed by the principal author after having receiving training to use the AR device, by a specialist of the Ear, Nose, and Throat (ENT) department. The AR device used was the SRE2000 (Rhinometrics A/S, Hellerup, Denmark). All AR measurements were performed at room temperature, with standard humidity and background noise not-exceeding 60 dB. In order to exclude the influence of lining mucosal variations and to concentrate on skeletal changes, the patients were given decongestant (Xylomethazoline HCL, 0.1% PCH) and were allowed to rest for 20 minutes in order to give the decongestant time to take effect and the patient to relax. A minimum of three valuable measurements were taken on each nostril using a specially manufactured nosepiece adapter for the left and right nostril. Data registered was the anterior nasal volume, from 0 to 22 mm. (Volume 1), and the posterior nasal volume, from 22 to 54 mm. (Volume 2). The first two minimum cross-sectional areas (MCA1 and MCA2), represent respectively, the nasal valve and the head of the inferior turbinate, and their distance from the nostril.

For the nasometry, a Nasometer™ model 6200-3 (Kay Elemetrics Corp, Lincoln Park, NJ, USA) was used. All measurements were performed by a trained speech therapist under standard conditions. Data registered was the percentage of the nasal

signal in speech when pronouncing a standardized sentence for the average nasal and oral sounds; a standardized sentence with exclusively oral sounds, and a standardized sentence with exclusively nasal sounds.

The subjective changes of the nasal airway due to SARME were evaluated using a questionnaire with five visual analogue scaled (VAS; scale 0 to 10) questions. The questions asked were; first: are you able to breathe through your nose during rest (0: not at all; 10 completely); second: are you able to breathe through your nose during normal daily activities (shopping, walking) (0: not at all; 10 completely); third: are you able to breathe through your nose during exercise (0: not at all; 10 completely); fourth: do you snore (0: never; 10; always); fifth: do you wake up at night to catch your breath (0: never; 10; always). The sixth question was an overall assessment of the change of the subjective change in nasal capacity due to the therapy and at follow-up. This question had a VAS from -10 to +10. Where -10 was a 100% worsening and +10 a 100% improvement of the nasal capacity.

All measurements were taken in the outpatient clinic of the departments of oral and maxillofacial surgery and ENT.

Statistical methods

The analysis was performed using the Statistical Package of the Social Sciences (version 12.0, SPSS Inc, Chicago,IL). The unpaired student t-test was used for comparison of outcomes between groups, and the paired t-test for comparison within groups. $P=0.05$ (two-sided) was considered the limit of significance. Prior power calculations had led to 20 patients in each group. Correlation coefficients shown are Spearman's (r_s).

Results

A total of 46 patients were randomized during the study period. Of these, 42 completed the study protocol and were evaluated. Figure 5 depicts the patient flows through the study. Twentythree bone-borne and 19 tooth-borne patients were analyzed. Table 1 shows the baseline characteristics of the randomized patients. The average expansion of the maxilla was 6.5 mm. (standard deviation (SD) 3.2).

There were two protocol violations in patients who crossed-over between treatment modality. The statistical analysis performed for both 'intention-to-treat' and 'as-treated' resulted in similar conclusions. Therefore, results of the 'as treated' analysis are presented.

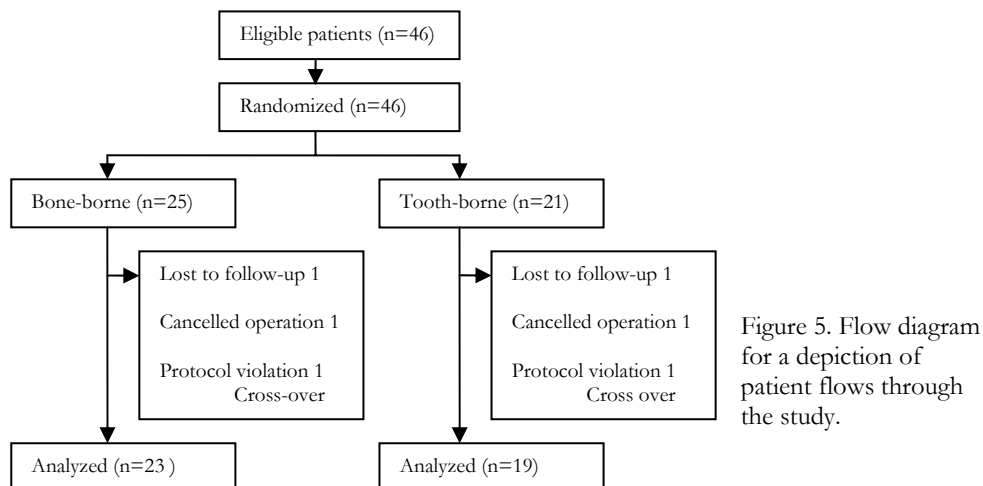


Figure 5. Flow diagram for a depiction of patient flows through the study.

Table 1. Baseline patient data.

	Bone-borne	Tooth-borne	Total
Number (%)	25 (54%)	21 (46%)	46 (100%)
Age (y)	33 (16 – 50)	25 (16 – 44)	30 (16 – 50)
Male/Female, n (%)	10/15 (40/60)	13/8 (62/38)	23/23 (50/50)

Y: years; n: number.

Acoustic Rhinometry (AR)

The results of the AR measurements are shown in Table 2. The distances for the MCA1 and MCA2 were respectively 5.8 and 22 mm.

Table 2. Results of the acoustic rhinometry (AR) measurements.

	t1 (SD)	Mean (SD) t2 (SD)	t3 (SD)	Tx change t1-t2 (SD)	Relapse t2-t3 (SD)	Net change t1-t3 (SD)
MCA1 (cm2)						
Bone-borne	1.37 (0.19)	1.57 (0.27)	1.54 (0.25)	0.21* (0.21)	-0.03 (0.22)	0.18* (0.19)
Tooth-borne	1.57 (0.35)	1.67 (0.29)	1.64 (0.32)	0.11 (0.28)	-0.03 (0.22)	0.08 (0.28)
MCA2 (cm2)						
Bone-borne	1.14 (0.30)	1.34 (0.33)	1.33 (0.42)	0.22* (0.32)	-0.01 (0.42)	0.21* (0.34)
Tooth-borne	1.24 (0.37)	1.53 (0.27)	1.64 (0.42)	0.28* (0.26)	0.11 (0.41)	0.38* (0.47)
Volume 1 (cm3)						
Bone-borne	3.74 (0.60)	4.10 (0.55)	4.08 (0.61)	0.38* (0.34)	-0.02 (0.41)	0.36* (0.51)
Tooth-borne	4.02 (0.65)	4.56 (0.60)	4.56 (0.65)	0.53* (0.53)	-0.01 (0.49)	0.48* (0.62)
Volume 2 (cm3)						
Bone-borne	10.93 (3.65)	12.82 (2.92)	13.17 (4.27)	2.09* (3.33)	0.36 (4.46)	2.45* (4.43)
Tooth-borne	10.93 (3.14)	12.39 (3.58)	15.99 (7.50)	1.61* (2.86)	3.69* (7.18)	5.11* (6.76)

Data given are mean and standard deviation (SD) at three time points. t1: baseline; t2: at the end of distraction; t3: at the 12 month follow-up; Tx change: changes due to the treatment; Net change: change at follow-up. *: significant within groups change, different from 0.

MCA1 showed a significant increase in the bone-borne group, due to the therapy (t1-t2), and at follow up (t1-t3). Relapse was not significant. In the tooth-borne group, the increase of MCA1 was not significant. MCA2 showed a significant increase in both groups, due to the therapy (t1-t2), and at follow up (t1-t3). Relapse was not significant. The differences between the two groups was not significant.

Nasal volume 1 measurements (0-22 mm.) showed a significant change within the groups due to the therapy (t1-t2), and at follow up (t1-t3). Relapse of the nasal volume 1 was very small in both groups and not significant. The differences between the two groups was not significant. Nasal volume 2 measurements (22-54 mm.) showed a significant increase within the groups due to the therapy (t1-t2), and at follow up (t1-t3). Between t2 and t3 there was an increase in volume in both groups (bone-borne 0.36 cm³ and tooth-borne 3.69 cm³) which was significant in the tooth-borne group. The differences between the two groups was not significant.

Nasometry

The results of the nasometry measurements are shown in Table 3. The nasometry measurements did not show any significant changes (both within and between groups) due to the treatment.

Table 3. Results of the nasometry measurements.

	t1 (SD)	Mean (SD) t2 (SD)	t3 (SD)	Tx change t1-t2 (SD)	Relapse t2-t3 (SD)	Net change t1-t3 (SD)
Average nasal and oral sounds (%)						
Bone-borne	33.75 (6.85)	32.94 (6.84)	34.03 (5.59)	0.29 (4.54)	0.74 (6.25)	0.37 (4.96)
Tooth-borne	32.59 (7.91)	33.47 (7.56)	33.99 (9.27)	0.34 (8.74)	1.56 (5.92)	2.49 (10.24)
Exclusively oral sounds (%)						
Bone-borne	15.36 (8.01)	14.47 (7.43)	13.93 (7.18)	0.90 (6.54)	-1.12 (6.96)	-0.21 (4.81)
Tooth-borne	14.21 (9.26)	14.28 (9.11)	12.64 (4.98)	-1.08 (9.85)	-0.41 (8.88)	-0.44 (6.88)
Exclusively nasal sounds (%)						
Bone-borne	52.97 (6.99)	52.11 (7.94)	53.31 (6.10)	-0.93 (6.94)	1.01 (7.48)	-0.31 (4.90)
Tooth-borne	50.82 (8.53)	53.24 (7.96)	55.22 (8.7)	1.50 (11.92)	2.13 (4.28)	3.62 (11.24)

Data given are mean and standard deviation (SD) at three time points. t1: baseline; t2: at the end of distraction; t3: at the 12 month follow-up; Tx change: changes due to the treatment; Net change: change at follow-up.

Visual analogue scale (VAS)

The results of the VAS scored questionnaire are shown in Table 4. Questions 1, 2 and 3 all showed (borderline) significant changes towards improvement of breathing through the nose, during rest, normal daily activity, and exercise.

Questions 4 addressed the presence and amount of snoring. There was a significant reduction of snoring in the bone-borne group. However, there was no significant

change between the two groups. Question 5 concerning the presence of sleep disturbance due to difficulty of breathing through the nose, showed hardly any presence initially (bone-borne 0.7 and tooth-borne 0.5), and did not show significant changes both within and between groups.

Table 4. Results of the VAS questionnaire answers regarding nasal airway capacity.

	t1 (SD)	Mean (SD) t2 (SD)	t3 (SD)	Tx change t1-t2 (SD)	Net change t1-t3 (SD)
Question 1 (nasal breathing capacity during rest)					
Bone-borne	7.7 (2.4)	9.2 (1.3)	8.9 (1.5)	1.9* (1.8)	1.6* (2.2)
Tooth-borne	7.3 (2.8)	8.9 (1.8)	8.9 (1.4)	1.4* (2.0)	1.1* (2.1)
Question 2 (nasal breathing capacity during normal daily activity)					
Bone-borne	7.8 (2.6)	9.1 (1.8)	8.7 (1.7)	1.4* (2.0)	1.0* ^{bl(0.055)} (2.4)
Tooth-borne	7.1 (3.1)	8.8 (1.9)	8.9 (1.6)	1.6* (2.0)	1.5* (2.2)
Question 3 (nasal breathing capacity during exercise)					
Bone-borne	6.9 (3.0)	8.6 (1.9)	8.3 (2.2)	1.6* (1.8)	1.4* (2.8)
Tooth-borne	6.4 (3.5)	7.5 (2.8)	8.3 (2.5)	1.2* ^{bl(0.055)} (2.4)	1.7* (2.5)
Question 4 (presence of snoring)					
Bone-borne	4.1 (3.3)	1.5 (2.1)	1.6 (2.3)	-2.1* (3.4)	-0.9 (3.2)
Tooth-borne	3.0 (3.3)	2.4 (2.6)	2.2 (2.3)	-1.7 (3.9)	-1.3 (3.5)
Question 5 (presence of sleep disturbance due to shortage of breath)					
Bone-borne	0.7 (1.4)	0.4 (0.8)	0.2 (0.2)	-0.4 (1.8)	-0.6 (1.6)
Tooth-borne	0.5 (0.9)	0.5 (0.8)	0.5 (0.9)	-0.1 (0.8)	-0.0 (0.9)
Question 6 (overall patients assessment of change in nasal breathing capacity)					
Bone-borne		4.1* (4.0)	3.6* (3.2)		
Tooth-borne		2.1* (4.3)	2.5* (3.1)		

Data given are mean and standard deviation (SD) at three time points. For questions 1,2,3 and 6 high score represent a favorable outcome. For questions 4 and 5 high scores represent an unfavorable outcome. t1: baseline; t2: at the end of distraction; t3: at the 12 month follow-up; Tx change: changes due to the treatment; Net change: change at follow-up. *: significant within groups change, different from 0; bl: borderline significance.

In question 6, patients were asked to score the overall changes of the nasal capacity due to the treatment (t2) and at follow-up (t3). There was a significant improvement in both groups, at t2 (bone-borne 4.1 (SD4.0) and tooth-borne 2.1 (SD4.3), and at t3 (bone-borne 3.6 (SD3.2) and tooth-borne 2.5 (SD3.1)). Spearman's correlation analysis was done between the overall subjective improvement (question 6) at t3, and the objective improvement of all nasal capacity measurements done by AR (MCA1, MCA2, volume 1 and volume 2). None of the correlations were significant (all $r_s < 0.24$; $p > 0.14$).

Discussion

The aim of this study was to evaluate the effect on the nasal airway and speech, of surgically assisted rapid maxillary expansion (SARME), comparing bone-borne versus the tooth-borne devices, in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia.

SARME causes a widening of the maxilla, and is associated with enlargement of the nasal valve and an increase of the anterior and posterior nasal volumes ⁽¹⁻³⁾. The main difference between the two modes of distraction (bone-borne versus tooth-borne), is the position on the palate, relative to the 'center of resistance' ⁽³¹⁾. This would, theoretically, cause a more parallel expansion of the maxillary segments in the case of bone-borne distraction. As a result, the nasal bony structures are also expected to be widened more, by bone-borne versus tooth-borne distraction, leading to a superior improvement in nasal airway capacity in the bone-borne group.

The reasons for the two cross-over patients were fear of one patient for a bone-borne device, and problems in the oral function (eating) with the Hyrax, in the pre-operative period in the second patient. In our view these reasons are not expected to affect the results. Furthermore, the statistical analyses performed, 'intention-to-treat' and 'as-treated', resulted in similar differences between evaluated groups.

The results of this study showed no differences between the two groups. This leads to discarding the null hypothesis that, in skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, more improvement in the nasal airway capacity after SARME, is to be expected in the bone-borne group, compared to the tooth-borne group.

The results of the AR measurements showed an increase of the MCA1 and MCA2 in both groups due to the treatment, and at follow-up. However, the MCA1 increase for the tooth-borne group was not significant. It is possible that the different position on the maxilla of the bone-borne distractor compared to the tooth-borne distractor provides more opening of the minimal anterior nasal area (MCA1). However, no differences between the two groups was found.

Nasal volume 1 and 2 both showed an increase due to the therapy, and at follow up. Relapse of the nasal volume 1 was negligible. Between t2 and t3 there was an increase in volume in both groups which was significant in the tooth-borne group. Besides the possible, still present swelling of the nasal mucosa as a result of the surgery in the posterior nasal area, regardless of the administration of Xylomethazoline, we could not explain this increase.

The increase in nasal capacity found in this study is consistent with other reports (1,18,23,24). The follow-up time in these studies varied from 4 to 12 months, and only in the study done by Berretin-Felix et al.(24), measurements were taken at different time intervals after the treatment. They concluded that there was an increase in nasal patency, however, the effect did not persist over time in most patients. This is contrary to this study, where an increase in nasal capacity is found both after treatment, and at follow-up.

The reason to perform the nasometry in this study group of non-syndromal patients, was to evaluate if there truly are no changes in speech due to the performed surgery and the different modes of expansion. A second reason was the fact that SARME is also used in patients with congenital deformities, with narrow transverse maxillae who already experience hypernasal speech (for example cleft patients). For these patients an increase in the hypernasality due to the treatment would be an adverse effect. The nasometry measurements did not show any change due to the treatment and at follow-up. Therefore, the null hypothesis regarding speech that, no change in the nasalance of speech is to be expected, is confirmed.

The results of the VAS scored questionnaire showed improvement of breathing through the nose, during rest, normal daily activity, and exercise due to the therapy and at follow-up. Both groups reported an overall improvement at follow-up. The subjective improvement of the nasal capacity is in agreement with the objective improvement found by the AR measurements but no significant correlation was found.

Snoring is caused by vibration of the uvula and the soft palate. This leads to an increased respiratory effort and collapse of the upper respiratory airway, which may result in obstructive sleep apnea (OSA) (32). The nose appears to be the preferred route of breathing during sleep (32). A transverse compression of the maxilla leads to partial obstruction of the upper airway and can cause snoring and OSA, as a result of pathologic changes in airflow velocity and resistance (32-34).

There are many publications on orthodontic transverse maxillary expansion (RME) and its effect on snoring and OSA. It is generally concluded that RME reduces or even resolves OSA problems, and that it may be an effective treatment (32,35-38).

Only two reports were found on OSA and SARME, they advocate SARME as an effective treatment, providing a profound improvement of the OSA problem (39,40). It needs mentioning that the number of patients studied was small, one (39) and six (40) respectively.

In both groups there was a subjective reduction of snoring, which was significant in the bone-borne group. Objective measurements (polysomnography), were not per-

formed in this study. For future study on the relation between SARME and its effect on OSA related problems, polysomnography should be taken into account.

Conclusions

1. The results of this study show no differences between the two groups, leading to discarding the null hypothesis that, in skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, more improvement in the nasal airway capacity after SARME, is to be expected in the bone-borne group, compared to the tooth-borne group.
2. All AR nasal capacity measurements increased in both groups due to the treatment and at follow-up, and relapse was negligible.
3. The nasalance of speech is not influenced by both bone-borne and tooth-borne SARME.
4. The objective improvement of the nasal capacity, found by the AR measurements, is in agreement with the subjective improvement, found in the VAS scaled questionnaire but no significant correlation was found.
5. In both groups a subjective reduction of snoring was found.

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Chapter 7

ANALYSIS OF FACIAL CHANGES THROUGH BONE-BORNE VERSUS TOOTH-BORNE SURGICALLY ASSISTED RAPID MAXILLARY EXPANSION; A PROSPECTIVE RANDOMIZED PATIENT TRIAL

M.J. Koudstaal¹

E.B. Wolvius¹

W.C.J. Hop²

K.G.H. van der Wal¹

¹ Department of Oral and Maxillofacial Surgery,
Erasmus University Medical Center Rotterdam

² Department of Epidemiology and Biostatistics
Erasmus University Medical Center Rotterdam

Submitted

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Abstract

Study objective: The aim of this study was to evaluate the facial changes in surgically assisted rapid maxillary expansion (SARME), comparing bone-borne versus tooth-borne devices, in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia.

Study design: Randomized, open-label, clinical trial (NTR:1087).

Methods: Mature non-syndromal patients with transverse maxillary hypoplasia (n=46) were recruited and randomized in a bone-borne device group (n=25) and a tooth-borne device group (n=21). The surgical technique for the corticotomy was similar in all patients and included a buccal corticotomy (anterior and lateral) and median split of the maxilla. Three measurements of the upper face were taken from standardized frontal photographs at three intervals of treatment: before treatment (t1), after the distraction phase (t2), and at the 12 month follow-up (t3). The primary objective was to study the difference in facial changes between the two groups.

Results: Twentythree bone-borne and 19 tooth-borne patients were analyzed. The average expansion of the maxilla was 6.5 mm. (standard deviation 3.2). A small, albeit significant increase of the nose and mouth width was found within both groups. The upper lip length did not change due to the treatment. For all three measurements performed, no significant differences could be found between the two groups.

Conclusions: There are no significant differences in changes in facial dimensions, between bone-borne versus tooth-borne expansion, in SARME. The nose and mouth width increased slightly. The upper lip length did not change.

Introduction

The general indications for surgically assisted rapid maxillary expansion (SARME) are skeletal maturity, (extreme) transverse maxillary hypoplasia, either uni- or bilateral and buccal corridors (black corridors), when smiling. Furthermore, the indications for SARME include any case where orthodontic maxillary expansion has failed and resistance of the sutures must be overcome. Transverse maxillary hypoplasia, in adolescents and adults, is frequently seen in non-syndromal and syndromal patients including cleft patients. In skeletally matured patients, the uni- or bilateral transverse hypoplasia can be corrected by means of SARME. The treatment is a combination of a surgical procedure and orthodontic treatment and provides, by means of distraction osteogenesis, dental arch space for alignment of the dentition. Subsequently, the procedure causes a substantial enlargement of the maxillary apical base and of the palatal vault, providing space for the tongue. In addition, a distinct subjective improvement in nasal breathing associated with enlargement of the nasal valve towards normal values is seen with an increase of nasal volume in all compartments.¹⁻³

Traditionally, a tooth-borne orthodontic appliance called a hyrax expander is placed preoperatively to expand the maxilla. Dental anchorage, however, might cause several negative and unwanted side effects including; damage to the dentition, possible loss of anchorage, periodontal membrane compression and buccal root resorption, cortical fenestration, anchorage-tooth tipping, and maxillary segmental tipping.

To avoid these dental complications, several bone-borne devices (distractors) have been developed which are placed directly on the palatal bone during surgery. It is claimed that these distractors avoid several of the problems stated for the hyrax expander⁴⁻⁶. The major advantage of the bone-borne devices is claimed to be that the forces are applied directly to the bone at the mechanically desired level thereby avoiding both dental tipping and keeping segmental tipping to a minimum.⁷

Theoretically, instead of tipping the maxillary segments after tooth-borne expansion, bone-borne distraction would cause a more parallel expansion of the maxillary segments. As a result, the nasal bony structures are also expected to be widened more by bone-borne versus tooth-borne distraction leading to a superior widening of the width of the nose in the bone-borne group.

Many articles have been written on the skeletal, dental and nasal airway changes through SARME. Most of the studies examining the soft tissue effects have been done on lateral cephalograms.⁸ The inability of cephalometric techniques to quantify soft tissue differences, especially from the frontal view, led to the development of other methods for soft tissue analysis; stereophotogrammetry,⁹ morphanalysis¹⁰ and mesh grid analysis.^{11,12} The cost and complexity of these techniques makes them im-

practical for general clinical use.⁸ It must be noted that stereophotogrammetry is currently widely studied and used in research settings.¹³⁻¹⁶

To our knowledge, only one article describes the facial changes associated with maxillary expansion with the use of serial frontal photographs.⁸

The aim of this prospective randomized patient study (NTR:1087) was to evaluate the changes in facial dimensions of a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia, undergoing SARME with two different modes of distraction, bone-borne versus tooth-borne. The primary objective was to study the difference between the two groups considering the amount of upper facial changes measured on standardized frontal photographs. Stability, segmental maxillary tipping and relapse of the two distraction modes was also assessed, and those results are published in the Oral and Maxillofacial Surgery literature. Difference in nasal airway change between the two groups was studied secondarily, and the results of this outcome are published in the Otolaryngology literature given that it focuses mainly on the nasal function.

Methods

Participants

A prospective randomized open-label clinical study was performed at the Erasmus University Medical Center. The Standing Committee on Ethical Research in Humans of the Erasmus University Medical Center Rotterdam approved the study in December 2003. Patient recruitment occurred between January 2004 and December 2007, and the written consent of all patients was obtained. A sample size of 20 patients per group was feasible, and with these numbers, differences as great as 1 standard deviation (SD) can be detected at $\alpha=.05$ with a power of about 90%.

A random number table was used to prepare opaque sealed envelopes that were opened if a patient met the inclusion (and no exclusion) criteria and had given written consent to participate in the study. The patients were randomized in a bone-borne and a tooth-borne group. The inclusion criteria consisted of non-syndromal patients, age 16 or over with a transverse narrow maxillary arch (hypoplasia), which clinically showed one or more of the following situations; dental cross-bite: unilateral or bilateral; anterior and/or posterior crowding; clinical evidence of buccal corridors (when smiling). The transverse hypoplasia could not be corrected by orthodontics alone due to full skeletal maturation. In case of doubt about the skeletal maturity in patients between the ages of sixteen and eighteen, hand-wrist radiograph were taken to determine the stage of skeletal maturation using the Greulich-Pyle analysis.¹⁷ The buccal osteot-

omy did not interfere with the apices of the dentition and there is no risk of damage to the infra-orbital nerve. This could be determined on the pre-operative panoramic x-ray as well as on the postero-anterior cephalogram (PA-cephalogram). Exclusion criteria were syndromal patients (including cleft patients) who were not fully matured between the ages of 16 and 18, a history of radiation therapy or surgery in the area of interest, and mental retardation.

Interventions

The basic surgical principle for the corticotomy was the same for both patient groups. The patient was admitted to the hospital for three days and was put on antibiotics. In general anesthesia a Le Fort I approach was followed. The buccal corticotomies were performed as usual for a Le fort I osteotomy, without pterygoid disjunction. The median osteotomy was between the central incisors. Prying motions with an osteotome resulted in mobilization of the segments. Figure 1 shows the positions of the osteotomies made during the corticotomy.

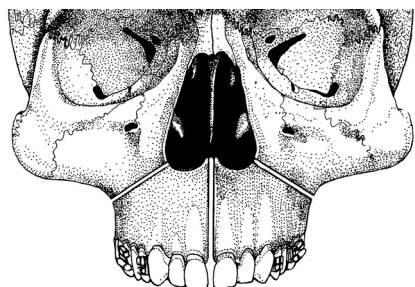


Figure 1. Schematic drawing of the positions of the osteotomies performed during a corticotomy.

Depending on the randomized group, different distractors were placed and used for the transverse distraction osteogenesis.

In the tooth-borne group, an orthodontic appliance called a hyrax expander was placed one week preoperatively to expand the maxilla.

In the bone-borne group, the distractor was preoperatively placed on the palate.^{5,18} At the end of the surgical procedure, the distractor was tested and the oral mucosa sutured.

The distraction started in both groups after a latency period of one week. The patient was instructed to activate the device at a rate of one millimeter per day until the desired expansion was obtained. At the end of distraction, there was a period of three months of consolidation (or neutral fixation). Thereafter, the device was removed in the outpatient clinic.

Objectives

The aim of this study was to evaluate two conventional distraction modes, the bone-borne versus the tooth-borne in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia.

Null hypothesis

In skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, more widening of the width of the nose after SARME is to be expected in the bone-borne group versus the tooth-borne group.

Outcomes

A Nikon d100 (Nikon Corp. Tokyo, Japan) camera standardized at 0.9 meter with a 60 mm lens (Medical Nikkor/330 ASA) was used. Frontal photographs were obtained with the subject's head in natural head position at three stages: before treatment (t1), after the distraction phase (t2), which was six weeks post surgery when the swelling of the surgery would have resolved, and at the 12 month follow-up (t3). The photographs were taken in the outpatient clinic.

All three photographs of every patient were standardized using the patients true interpupillary distance.¹⁹ An electronic digital caliper (Kraftixx®, art.0906-90) with an accuracy of 0.02mm. was used to do the actual measurements. Since some of the patients underwent simultaneous midline distraction of the mandible and this study was focused on the maxillary transverse expansion, the measurements were solely aimed at the upper part of the face. The distances for three measurements were obtained (Table 1 and Figure 2).

Table 1. Photographic measurements performed.

Landmark	Measurement
Nose width	Distance between right and left alare
Mouth width	Distance between the angle of the mouth right and left
Upper lip length	Subnasale to stomion

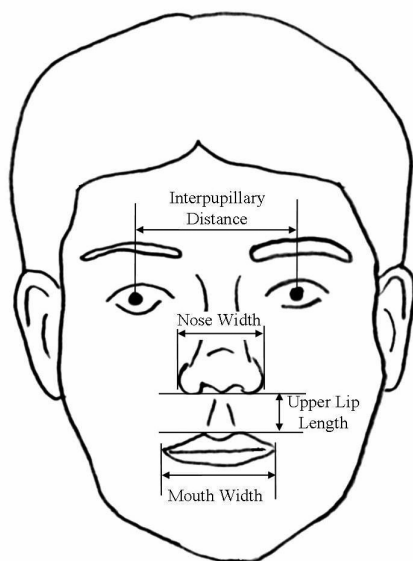


Figure 2. Schematic drawing of the measurements performed.

Statistical analysis

The analysis was performed using the Statistical Package of the Social Sciences (version 12.0, SPSS Inc, Chicago, IL). The unpaired student t-test was used for comparison of outcomes between groups, and the paired t-test for comparison within groups. $P=0.05$ (two-sided) was considered the limit of significance. Prior power calculations had led to 20 patients in each group.

Reliability

From all three time intervals, eight photographs were randomly selected to assess intra- and inter-observer agreement. Agreement was quantified by calculating intra-class correlation coefficients (ICC). For ICC values >0.9 the reliability of the measurement is generally considered to be excellent.

Results

A total of 46 patients were randomized during the study period. Of these, 42 completed the study protocol and were evaluated. Figure 3 depicts the patient flows through the study. Twentythree bone-borne and 19 tooth-borne patients were analyzed. Table 2 shows the baseline characteristics of randomized patients. The average expansion of the maxilla was 6.5 mm. (standard deviation (SD) 3.2).

There were two protocol violations in patients who crossed-over between treatment modality. The statistical analysis performed for both ‘intention-to-treat’ and ‘as-treated’ resulted in similar conclusions. Therefore, results of the ‘as treated’ analysis are presented.

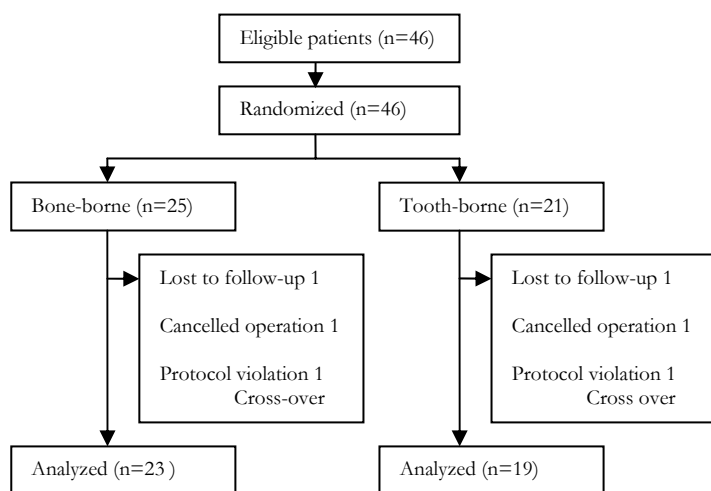


Figure 3. Flow diagram for a depiction of patient flows through the study.

Table 2. Baseline patient data.

	Bone-borne	Tooth-borne	Total
Number (%)	25 (54%)	21 (46%)	46 (100%)
Age (y)	33 (16 – 50)	25 (16 – 44)	30 (16 – 50)
Male/Female, n (%)	10/15 (40/60)	13/8 (62/38)	23/23 (50/50)

Y: years; n: number.

The intra-class correlation coefficient (ICC) for each separate measurement both inter-, and intra-observer, was greater than 0.99 indicating that the various measurements performed are reliable.

Table 3 shows the results of the facial measurements. The nose and mouth width showed a slight, though significant, increase due to the treatment (t2) and at follow-up (t3). There were no significant differences between the two groups. The upper lip length showed no significant changes within or between the groups.

Table 3. Results of the facial measurements in millimeters (mm.).

	t1 (SD)	Mean (SD) t2 (SD)	t3 (SD)	Tx change t1-t2 (SD)	Relapse t2-t3 (SD)	Net change t1-t3 (SD)	Relapse in percentage (%) (SD)
Nose width							
Bone-borne	33.7 (2.8)	36.0 (2.3)	35.3 (2.4)	2.1* (2.1)	-0.7 (1.8)	1.5* (1.5)	-1.7 (5.3)
Tooth-borne	35.9 (2.8)	38.5 (3.7)	37.2 (2.4)	2.6* (2.7)	-1.3* (2.3)	1.2* (1.5)	-3.1* (5.1)
Mouth width							
Bone-borne	47.2 (3.7)	48.3 (4.1)	48.6 (3.1)	1.5* (2.8)	-0.0 (2.3)	1.3* (2.5)	0.2 (4.5)
Tooth-borne	48.9 (3.8)	50.5 (3.5)	50.2 (3.5)	1.5* (2.6)	-0.4 (1.9)	1.2* (2.3)	-0.7 (3.7)
Upper lip length							
Bone-borne	22.5 (2.7)	23.5 (2.7)	23.0 (2.9)	0.7 (1.9)	-0.1 (1.4)	0.5 (1.9)	-0.3 (5.8)
Tooth-borne	23.8 (3.0)	24.2 (3.4)	24.5 (2.9)	0.5 (2.1)	0.24 (1.7)	0.7 (2.0)	1.4 (6.7)

Data given are mean and standard deviation (SD) at three time points. t1: baseline; t2: at the end of distraction; t3: at the 12 month follow-up; Tx change: changes due to the treatment; Net change: change at follow-up. *: significant within groups change, different from 0.

Discussion

Aim of the study was to evaluate the changes in facial dimensions of a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia, undergoing SARME with two different modes of distraction, bone-borne versus tooth-borne.

SARME causes a widening of the maxilla, and is associated with enlargement of the nasal valve and an increase of the anterior and posterior nasal volumes.¹⁻³ The main difference between the two modes of distraction (bone-borne versus tooth-borne), is the position on the palate, relative to the ‘center of resistance’.²⁰ This would, theoretically, cause a more parallel expansion of the maxillary segments in the case of bone-borne distraction. As a result, the nasal bony structures are also expected to be widened more, by bone-borne versus tooth-borne distraction, leading to a superior widening of the width of the nose in the bone-borne group.

The reasons for the two cross-over patients were fear of one patient for a bone-borne device, and problems in the oral function (eating) with the Hyrax, in the pre-operative period in the second patient. In our view these reasons are not expected to affect the results. Furthermore, the statistical analyses performed, ‘intention-to-treat’ and ‘as-treated’, resulted in similar differences between evaluated groups.

Berger et al. demonstrated that measurements on standardized frontal facial photographs is a reliable technique.⁸ The results of the intra- and inter-observer reliability ICC measurements done in this study are in accordance with this finding.

The results of this study showed no differences between the two groups. This leads to discarding the null hypothesis that, in skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, more widening of the width of the nose after

SARME, is to be expected in the bone-borne group, compared to the tooth-borne group.

A small, albeit, significant increase of nose width was found both due to the treatment (t2), and at follow-up (t3) within both groups. The upper lip length did not change due to the treatment. These results are consistent with findings of Berger et al.⁸ The width of the mouth was not studied by Berger et al.⁸ In the present study, a significant increase of the mouth width was found due to the treatment (t2), and at the 12 month follow-up (t3). For all the three measurements performed, no significant differences were found between the two groups.

In present research, changes in the upper facial appearance were studied using standardized photographs. As has been discussed, this is a reliable but rather old-fashioned technique and it provides no information on the three dimensional changes that might occur. Three-dimensional stereophotogrammetry is now becoming more and more available and we suggest the use of these techniques for future studies.¹³⁻¹⁶

It is, however, important to mention that no matter how extensive or precise the information on actual physical changes of outer appearance of a patient is, it does not convey how a patient experiences the changes in his or her appearance due to the surgery. It would be interesting to research the data on the actual physical changes versus how these changes are experienced by the patient. Only then conclusions could be drawn about the changes from an esthetical point of view.

Conclusions

1. The results of this study show no differences between the two groups, leading to discarding the null hypothesis that, in skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, more widening of the width of the nose after SARME, is to be expected in the bone-borne group, compared to the tooth-borne group.
2. The nose and mouth width increased slightly, due to the treatment.
3. The upper lip length did not change.

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Part IV

Auxiliary studies

Chapter 8 Distraction osteogenesis in the head and neck region

Anest Intensiv Med 2008;19:xx-xx,

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Ned Tijdschr Geneesk 2006;28:1557-1561

Chapter 9 Surgical assisted rapid maxillary expansion in two cases
of osteopathia striata with cranial sclerosis

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Chapter 8

DISTRACTION OSTEOGENESIS IN THE HEAD AND NECK REGION

M.J. Koudstaal¹

J. Ruprecht²

K.G.H. van der Wal¹

¹ Department of Oral and Maxillofacial Surgery,
Erasmus University Medical Center Rotterdam

² Department of Anesthesiology,
Erasmus University Medical Center Rotterdam

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Abstract

Distraction osteogenesis is a treatment often used in orthopedics and plastic surgery, but more frequently so in maxillofacial surgery. There is a variety of distractors available for use on the different parts of the maxillofacial skeleton. The aim of this article is to give publicity to distraction osteogenesis in the field of oral and maxillofacial surgery and to the different types of intra- and extraoral distractors frequently used in the head and neck region. The application of such distractors for several months while the patient carries on everyday life is potentially hazardous in case of an emergency. The anesthesiological aspects of these devices will be discussed in order to minimize the risks in cases of acute medical interventions.

Introduction

Distraction osteogenesis (DO) was first described by Codivilla in 1905¹. The first publication on the use of DO in a group of patients was written by the orthopedic surgeon Ilizarov in 1990². The theory of DO consists of the administration of gradual forces on a bone segment after it has been osteomized. These forces are exercised by means of a distractor. A distractor is a device that is in contact with both bony segments and is equipped with a mechanism that can drive the two bony segments apart by means of an activation part. Between the two bony segments new trabecular bone growth occurs that is subsequently turned into bone with a normal mineralized architecture. The end result of the treatment is lengthening of the osteomized bone. When the desired lengthening has been reached the distractor is kept in situ for 6-12 weeks to allow the new bone to adjust to the new stable situation.

DO is used in orthopedic surgery, plastic surgery, and in oral and maxillofacial surgery. For DO there are different indications. For the regular movement of bone parts a normal osteotomy will suffice. However, when the bone has to be moved over a greater distance, distraction will sometimes be the solution. In these situations the bone is gradually moved and this allows also the soft tissues (ligaments, vessels, nerves, muscles, and sometimes the scar tissues) to stretch gradually, the so-called "histiogenesis". If there is a shortage of bone in case of a normal osteotomy, the situation can be resolved by using an autologous bone transplant. DO has the advantage that there is no need for a donor site to increase the amount of bone.

There are several different distractors for the use on different areas of the facial skeleton. They vary in function, size, and the site where they are used.

The aim of this article is to increase the knowledge on DO in the head and neck region and the various different distraction devices. The specific indications and therapies for the individual cases will not be discussed.

Attention will be given to the fact that these distractors remain in situ for several months while the patient carries on everyday life. This leads to a risk when the patient has to be treated for an emergency, for example in case of an accident, a facial abscess or bleeding in the mouth or throat. The general practitioner or the anesthesiologist is then confronted with an unfamiliar situation. The anesthesiological considerations on distractors in the head and neck region will be discussed.

The distractors

DO is used in the field of oral and maxillofacial surgery to lengthen or to move a bone over a certain distance, which would not be possible with a regular osteotomy. Many different distractors are available for a range of different treatment modalities. De-

pending on the intended result distractors can be placed intra- and extraorally. The authors realize it is impossible to discuss every available distractor, but the most widely used types of distractors and their normal anatomic locations will be reviewed.

Extraoral distractors are connected to the bone segments transcutaneously or through the opening of the mouth. In most cases the actual moving parts of the distractors are located externally and are connected to the bone with transcutaneous pins. (Fig 1). These distractors are used to lengthen the mandible in cases of hypoplasia. The advantage of these devices is the fact that they are easily placed, activated, aimed, and removed. The disadvantage is the unaesthetic scar the transcutaneous pins will cause during the distraction.



Figure 1. An example of a standard extraoral distractor for lengthening the mandible.

A second type of extraoral distractor is the Rigid External Distractor (RED). The RED is used to move the maxilla at the LeFort I, II, and III level. These devices are fixed to the bone of the skull with a facial frame and pins. Through a titanium frame that is located in front of the patient's face, the device has a connection with the bone segments that need to be displaced (Fig 2).

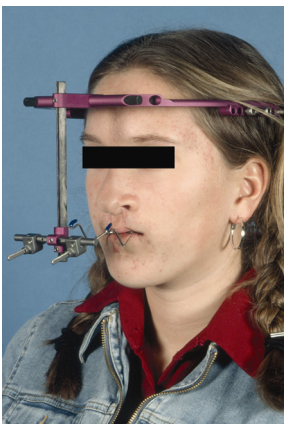


Figure 2. The Rigid External Distractor (RED) system in situ on a patient with a bilateral cleft-lip-alveolus and palate for advancing the hypoplastic maxilla.

Along with the extraoral devices, intraoral devices are also used. They are designed for a variety of therapies ranging from lengthening the mandible, widening the maxilla, or heightening the alveolar process of the mandible or maxilla for dental implant placement. The advantages of the internal device is that there is no extraoral scarring and no need for placement on the outside of the head of the patient, thereby making them more comfortable in daily life. The disadvantages are that they are more troublesome to place, aim, and remove.

There are different distractors that are located on the palate for widening the maxilla. The Hyrax expander is the oldest and most widely used tooth-borne device that is placed by the orthodontist. There are also several bone-borne devices that are placed by the surgeon during the operation. Some are fixed to the palate with screws. The Transpalatal Distractor (TPD) was developed in 1999 and is placed on the palate by screw fixation³. The Rotterdam Palatal Distractor (RPD), a bone-borne device without screw fixation was engineered in 2004 (Fig 3).



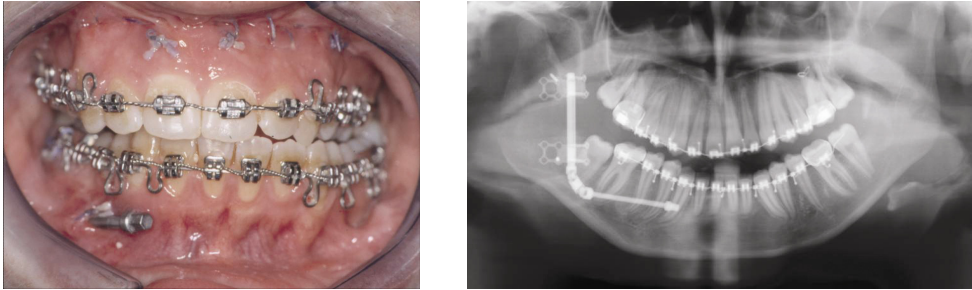
Figure 3. The Rotterdam Palatal Distractor (RPD), a bone-borne distractor for widening the narrow maxilla.

There is also a range of devices available for widening the narrow mandible. One of these is also a kind of tooth-borne Hyrax expander that is placed lingually. The different bone-borne distractors are all buccally positioned with the activation part on the inside of the lower lip. To illustrate an example the Trans Mandibular Distractor is chosen (TMD) (Fig 4).



Figure 4. Trans Mandibular Distractor (TMD), a bone-borne distractor for widening the narrow mandible.

There are several standard and custom build distractors available for lengthening the different regions of the mandible. These are placed submucosally and only their activation part sticks out in the oral orifice through the mucosa. (Figs 5a and 5b). These types of distractors are used in cases of uni- or bilateral mandibular hypoplasia.



Figures 5a and 5b. Submucosally positioned intraoral distractor.

To complete our list of mandibular distractors the custom-build devices for lengthening the mandible in the sagittal direction in newborns should be mentioned. The indication for this therapy is a compromised airway in children with extreme micrognathia. An example is the Treacher Collins syndrome, an autosomal dominant deformity. The malformation is mainly limited to the face and is usually bilateral and symmetric. There is an underdevelopment of the mandible (micrognathia) which can lead to breathing and feeding difficulties. By moving the frontal part of the mandible anteriorly, the base of the tongue is also moved forward and this facilitates the breathing. In most of these cases, the tracheostoma can be removed and/or the hospital stay at the intensive care with or without ventilation can be shortened (Fig 6).



Figure 6. Specific intraoral distractor on a patient with the Treacher Collins syndrome.

In the area of implantology, distractors are used to solve the problem of the shortage of bone in the alveolar process of the maxilla or mandible. An advantage of this therapy is the presence of histiogenesis. The distraction is directed in a vertical dimension thereby heightening the level of the alveolar process to facilitate the placement of dental implants.

Anesthesiological aspects

Some intra- and extraoral distractors can complicate access to the larynx and trachea. In one of our elective surgery cases, the intubation was difficult due to the fact that the distractor on the palate of the patient was obstructing the insertion of the laryngoscope. We advise the anesthesiologists to check the access of the larynx before administering the hypnotic and relaxant and also before the extubation at the end of the procedure. When reintubation is expected to be very difficult one should consider delaying the extubation and should follow the guidelines for rigid intermaxillary fixation.

More complicated are the emergency cases when ventilation of the patient with the facial mask may prove impossible or when intubation or placement of a laryngeal mask is difficult or not feasible. The situation certainly becomes very dangerous when facial trauma occurs to patients wearing distractors. When distractors inhibit proper oxygenation, the distractors should be removed immediately and all parts of the device carefully collected.

When it is not possible to quickly remove the distractor, the alternatives for intubation are fiberoptic intubation or the use of the light wand (“Trachlight”). One should be prepared to perform an emergency tracheotomy. Such emergencies may seem rare but are potentially life threatening. This is why they deserve the attention of emergency medical personnel and anesthesiologists.

Discussion

In the field of the oral and maxillofacial surgery, distraction osteogenesis is increasingly used in recent years. For several indication areas, where there used to be no treatment, or the treatment consisted of extensive surgery or transplantation of autologous bone, distraction is currently used. For all these different indications, there is a variety of distractors available and every year new devices are developed.

Most of these distractors barely interfere with the patient’s day-to-day activities. Some types, however, do interfere with the patient’s life for several months. In addition, the presence of the distractor itself might bear a risk for the patient. If these patients are in need of emergency medical assistance during this period and the patient

needs intubation, the device itself can lead to unexpected and unwelcome surprises for the treating physicians. In the searched literature (Pubmed, Cochrane library), no studies were found that discuss this risk. In most situations the distractors do not interfere with the access of the airway. A number of distractors, however, do pose a risk in cases of an emergency intubation. Especially the RED (Fig 2) and the mandibular distractors in the newborns (Fig 6) lead to reasonable impairment of the accessibility of the mouth and oropharynx. In these cases the distractor most likely needs to be removed to make access and intubation possible. It is therefore necessary that the patient and their families are properly informed about what to do in case of emergency, and especially about how to remove the device. Some of the other devices can inhibit the use of the laryngoscope, especially the ones that are positioned in the palate. The intra- and extraoral distractors that are used to lengthen the mandible, in combination with the performed osteotomy lead to a compromised mouth opening. This impairment will no longer be present after the administration of muscle relaxants.

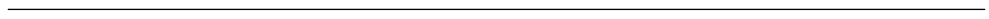
It should also be noted that many of the patients on whom distraction osteogenesis is performed suffer from craniofacial anomalies which are often accompanied by impaired mouth opening. Intubation of such patients is complicated even more by the presence of a distractor.

Conclusion

Distraction osteogenesis is a therapy used in the oral and maxillofacial surgery for correction of anomalies of the craniofacial skeleton. In addition to the advantages of DO, this treatment also induces several risks. The patient carries the device for several months, and might be in need of elective or emergency medical treatment, for example in cases of a trauma, an abscess, or bleeding. In some cases the distractors should be removed to make intubation possible. When removal of the distractor is impossible while the patient is in respiratory distress, an emergency tracheotomy must be performed. Well-informed medical personnel, familiar with the presence and the potential risks of the distractors, will be able to handle such acute medical care scenarios better.

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Chapter 9

SURGICAL ASSISTED RAPID MAXILLARY EXPANSION IN TWO CASES OF OSTEOPATHIA STRIATA WITH CRANIAL SCLEROSIS

M.J. Koudstaal¹

E.B. Wolvius¹

E.M. Ongkosuwito²

K.G.H. van der Wal¹

¹ Department of Oral and Maxillofacial Surgery,
Erasmus University Medical Center Rotterdam

² Department of Orthodontics,
Erasmus University Medical Center Rotterdam

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Abstract

Osteopathia striata with cranial sclerosis (OS-CS) is a rare skeletal dysplasia characterized by linear striations of the long bones, osteosclerosis of the cranium, and extra-skeletal anomalies. Osteosclerosis of the cranial and facial bones can lead to disfigurement and to disability due to the pressure on the cranial nerves. We report two cases of OS-CS where surgically assisted rapid maxillary expansion was performed for widening the extreme narrow maxilla. One should be aware of the disease related problems and the possible complications that might occur with this type of patients.

Introduction

Osteopathia striata with cranial sclerosis (OS-CS) is a rare skeletal dysplasia characterized by linear striations of the long bones, osteosclerosis of the cranium, and extra-skeletal anomalies (Ward et al., 2004). It was first described by the Dutch radiologist Voorhoeve in 1924. Approximately 45 individuals have been reported in the literature (Gorlin et al., 2001).

Radionuclear studies suggest an active metabolic process (De Keyser et al., 1983; Gay et al., 1994). The long bones and iliac wings appear combed with fine, uniform, linear striation, giving rise to the name osteopathia striata. These same striations may be present in the ribs. Osteopathia striata occurs as a usual feature of focal dermal hypoplasia. Cleft palate or bifid uvula is seen in 40% of the OS-CS patients (Jones and Mulcahy, 1968; Franklyn and Wilkinson, 1978; Cortina et al., 1981; Clement et al., 1982; Robinow and Unger, 1984; Piechowiak et al., 1986; Kornreich et al., 1988; Konig et al., 1996; Pellegrino et al., 1997; Lazar et al., 1999; Behninger and Rott, 2000). Spina bifida occulta in the lumbar region is common. Some patients have scoliosis (Horan and Beighton, 1978). Ventricular or atrial septal defects, pulmonic stenosis, postaxial polydactyly, transient cardiac murmurs, syndactyly between the fourth and fifth toes, duodenal web, cystic kidneys, micropenis, omphalocele and malrotation of the gut have also been described (Gorlin et al., 2001). Dental problems such as microdontia, unerupted teeth and abbreviated roots are related to the deformity (Bloor, 1954; Franklyn and Wilkinson, 1978; Piechowiak et al., 1986; Daley et al., 1996).

We report two cases of OS-CS with an extreme narrow maxilla where surgically assisted rapid maxillary expansion (SARME) was performed using a Rotterdam Palatal Distractor (RPD) (Koudstaal et al., 2006).

Case reports

Case 1: a 21 year old female with OS-CS and a cleft palate was referred from a private orthodontic practice. The medical history included closure of the hard palate at the age of one, pulmonal hypertension, conductive hearing loss and a refractory eye disorder. The patient was examined for endocrine disorders but the results came out negative. On general clinical examination there was a large head with a skull circumference of 59.5 cm. (+2.5 standard deviation), hypertelorism, open bite, long philtrum and a broad dorsum of the nose (Fig 1). There was a class I occlusion with a bilateral crossbite. The maxilla was extreme narrow with a high palate (Fig 2). The upper lateral incisors and the four second premolars were congenitally missing. The dental development was late and the upper first premolars were impacted. The molar roots were all relatively short.



Figure 1. The facial appearance of case 1 patient (with permission).



Figure 2. Clinical photograph showing the extreme narrow maxillary arch and high palate.

SARME with the use of the RPD was planned because of the extreme narrow maxilla. The preoperative computed tomography (CT) scans showed the typical cranial anomalies (Fig 3). Oro-endotracheal intubation was performed since it was impossible to perform a naso-endotracheal intubation due to the extreme narrow nasal space. The oral position of the tube complicated the procedure. Standard corticotomies of the anterior, lateral and medial bony supports were performed. The procedure was difficult due to the very hard and dense bone structure. Mobilization of the maxillary segments was time-consuming. After the corticotomy the RPD was placed in the area of the first premolar. The left second deciduous molars were removed during surgery, the right during the distraction phase. After testing, the distractor was secured to the premolars using stainless steel wires. The patient received both antibiotics and steroids during and in the first days after surgery. The patient was released from the hospital the day after the operation. After 1 week gradual distraction was started. Because of our experience with the dense bone during the operation and the fact that the patient had an operatively corrected cleft palate we used a distraction rate of 0.5 mm. per day.

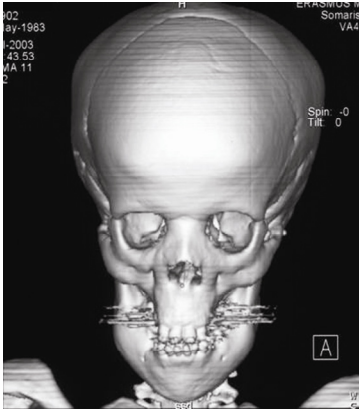


Figure 3. Three dimensional CT scan showing the frontal bossing and the extreme narrow maxilla.

During the following routinely check-ups it was noted that the maxilla expanded in a V-shaped fashion, with most of the expansion occurring in the incisor area. At the same time a dehiscence developed at the alveolar process between the central incisors. To make the distraction of the maxillary segments more parallel, an additional hyrax expander was placed on the second molars with good result (Fig 4).

After 4 weeks the required expansion was reached and after a consolidation period of 3 months the distractor was removed. One month later an augmentation was performed using chin bone to close the defect in the alveolar process between the central incisors. Figure 5 shows the clinical result after the augmentation.

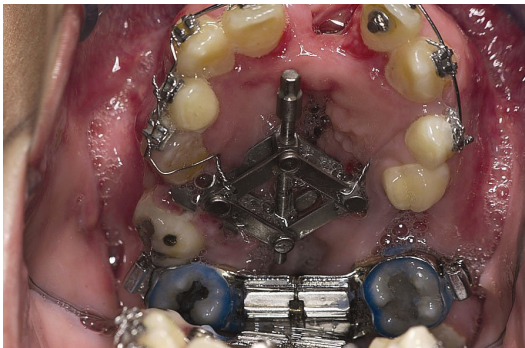


Figure 4. Clinical photograph showing both the Rotterdam Palatal Distractor and the hyrax appliance in situ.



Figure 5. Clinical photograph of the maxillary arch showing the end result after removal of the distractors and augmentation of the defect in the alveolar process between the central incisors.

The orthodontist started the realignment of the dentition. The orthodontic treatment was complicated by a shortage of vertical height in the posterior region. Since there was little to no movement after months of treatment orthodontic implants were placed. However, even with the use of the implants no dental movement was possible in the posterior region. After complaints of the patient that she did not improve, and since orthodontic treatment did not accomplish enough intrusion of posterior molars, a decision was made to extract premolars and molars and to correct the vertical height of the hypertrophic alveolar process in the posterior regions and place a fixed partial denture for an optimal dental function in a later stage. The closure of the central diastema (11 mm) took almost 1 year and 4 months. Two partial dentures were placed. (Figs 6 and 7)



Figure 6. The clinical end result without partial dentures



Figure 7. The clinical end result with partial dentures

Case 2: a 17 year old female known with OS-CS and a cleft palate presented with a medical history that included closure of the hard palate, reduction of the frontal bossing and surgery for pylorostenosis. The patient was examined for endocrine disorders but the results came out negative. On general clinical examination there was a large head, hypertelorism, open bite, long philtrum and a broad dorsum of the nose (Fig 8).

There was a class I occlusion with a bilateral crossbite. The maxilla was extreme narrow with a high palate (Fig 9). The preoperative CT scan showed dense maxillary bone without nasal sinuses (Fig 10). There was impaction of both upper cuspids. Standard corticotomies of the anterior, lateral, and medial bony supports were performed. The upper cuspids were ligated perioperatively. The RPD was placed in the area of the second premolar and the first molar. After testing, the distractor was secured to the premolars using stainless steel wires.



Figure 8. The facial appearance of case 2 (with permission).



Figure 9. Clinical photograph showing the extreme narrow maxillary arch and high palate.

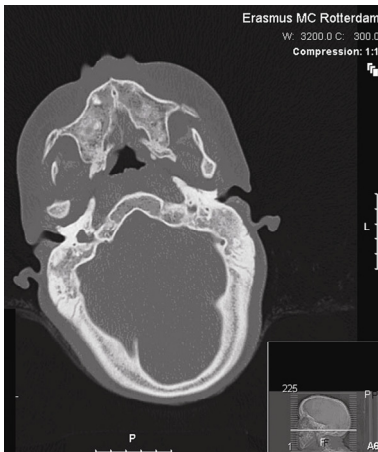


Figure 10. Section of the CT scan showing the absence of the maxillary sinuses.

The patient received both antibiotics and steroids during and in the first days after surgery. The patient was released from the hospital the day after the operation. Gradual distraction was started after one week at a rate of 0.5 mm. per day. The required expansion was reached after 3 weeks (Fig 11) and after a consolidation period of 3 months the distractor was removed. At present, orthodontic treatment is being performed. In Figure 12 the state of the maxillary arch after one year of treatment is shown.

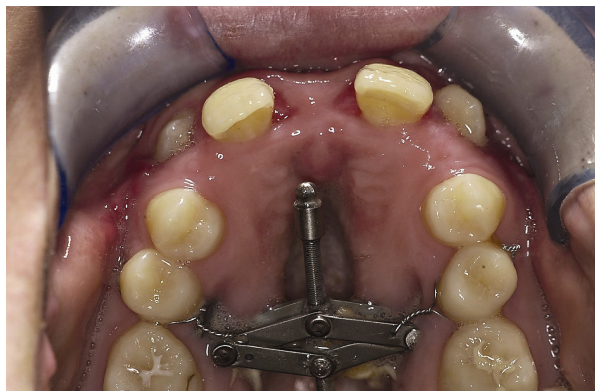


Figure 11. Clinical photograph of the maxillary arch showing the end result after distraction with the Rotterdam Palatal Distractor in place.

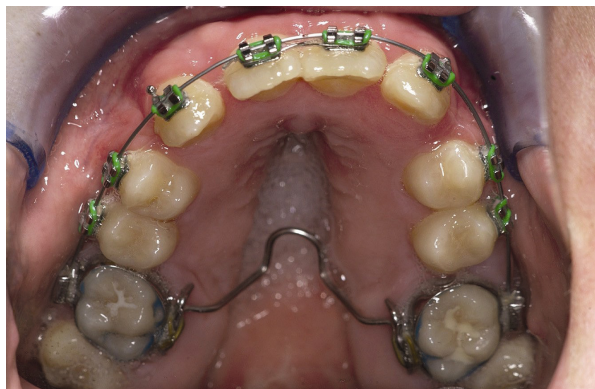


Figure 12. Clinical photograph of the maxillary arch after 1 year of orthodontic treatment.

Discussion

OS-CS is a rare skeletal dysplasia characterized by linear striations of the long bones, osteosclerosis of the cranium, and extra-skeletal anomalies (Ward et al., 2004).

There is some evidence for genetic heterogeneity of OS-CS, and most authors have favored autosomal dominant inheritance for this disorder with poor documentation for male-to-male transmission. Others, however, favor X-linked dominant inheritance (Pellegrino et al., 1997; Bueno et al., 1998; Behninger and Rott, 2000; Gorlin et al., 2001; Viot et al., 2002). There is a 2.5:1 female sex predilection (Gay et al., 1994).

Intrafamilial variation in expression may complicate genetic counseling (Clement et al., 1982; Savarirayan et al., 1997).

Osteosclerosis of the cranial and facial bones can lead to disfigurement and to disability (e.g., deafness) due to the pressure on the cranial nerves. The cranium is usually biparietally enlarged which is often evident at birth but frequently is mildly progressive. The face appears squared. Nasal obstruction may be evident in infancy (Bloor, 1954; Franklyn and Wilkinson, 1978; Horan and Beighton, 1978; Paling et al., 1981). There is frontal bossing, the nasal bridge is broad, and the eyes appear wide set (Robinow and Unger, 1984). Ankylosis of the temporomandibular joints has been reported (Behninger and Rott, 2000). Hearing loss is present in almost 50% of the cases and often involves the low frequencies (Gay et al., 1994; Konig et al., 1996; Savarirayan et al., 1997). Some of the patients experience facial palsy and other cranial nerves may also be involved (De Keyser et al., 1983; Kornreich et al., 1988; Clementi et al., 1993; Gay et al., 1994; Konig et al., 1996). With respect to causation of the palsy, some advocate the narrowing of the foramina (De Keyser et al., 1983), while others suggest that vascular compromise is the causal factor (Konig et al., 1996). Mild or moderate mental retardation occurs in 20% of cases (Jones and Mulcahy, 1968; Franklyn and Wilkinson, 1978; Horan and Breighton, 1978; Paling et al., 1981; Konig et al., 1996; Savarirayan et al., 1997; Behninger and Rott, 2000).

Radiographically, there is sclerosis and hyperostosis of the cranial vault and a marked increase in density of the cranial base, either progressive in childhood (Bloor, 1954; Robinow and Unger, 1984; Konig et al., 1996) or stationary in adulthood (Franklyn and Wilkinson, 1978). The sinuses may be obscured, as in the currently described cases, and the mastoid air cells diminished.

The indication for SARME in cases of OS-CS is a narrow maxilla which inhibits a good oral function, where orthodontic treatment alone will not lead to a satisfactory result or consumes too much time for the patient to comply with.

In patients with OS-CS the maxillary bone is very hard, making the standard corticotomy a difficult procedure. The surgeon has to schedule sufficient time for the operation since the density of the bone makes adequate mobilization of the maxillary segments time-consuming.

Regarding the distraction rate one must consider that the dense structure of the bone in this disease might show slower osteogenesis. This is why we performed the distraction at a slower rate of 0,5 mm/day instead of the usual 1 mm/day. Moreover, both patients had a cleft palate that had been surgically corrected being a second reason for a slower distraction rate. Nonetheless a dehiscence developed at the alveolar process between the central incisors in case 1. The V-shaped fashion in which the

maxilla expanded, caused most of the expansion to occur in the incisor area. This led to a higher distraction rate in the anterior area and was, in our opinion, the cause of the defect. In order to make the distraction of the maxillary segments more parallel a second distractor was placed. In case 2 we did not encounter this problem.

As reported in case 1, orthodontic treatment was very difficult. The extreme density of the bone in this disease makes movement and realignment of the dentition very difficult, despite the use of bony anchorage with ortho-implants. The vertical growth pattern of these patients might further complicate the treatment. In our first patient we were unpleasantly surprised by this phenomenon and had to change the treatment plan drastically. In both cases orthodontic tooth movement is possible, but consumes time. Therefore extensive orthodontic treatment should be avoided.

When planning the treatment for patients with OS-CS one should be aware of the disease related problems and the possible complications that might occur. The correction of an extreme narrow maxilla in OS-CS with a combined surgical-orthodontic treatment approach is a challenge for the craniofacial team. Due to the typical extremely dense bony architecture the possibilities are limited.

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Part V

General discussion

Chapter 10 General discussion and conclusions

Chapter 11 Epilogue and future perspectives



Chapter 10

GENERAL DISCUSSION AND CONCLUSIONS

The central questions at the beginning of this study were ‘is there a difference in stability between bone-borne and tooth-borne distraction?’, and ‘can a relationship be found between segmental maxillary tipping, relapse, and the mode of distraction?’ Secondary questions were; ‘what is the influence of surgically assisted rapid maxillary expansion (SARME) on the nasal airway and the nasalance of speech?’, and ‘what is the effect of surgically assisted rapid maxillary expansion on the upper facial appearance?’. All questions will be discussed separately, and answers to these questions are provided with the knowledge gathered in the study.

‘Is there a difference in stability between bone-borne and tooth-borne distraction?’

The part of the prospective randomized patient study that deals with this question is described in *Chapter 5*. In this study executed between January 2004 and December 2007, 46 mature non-syndromal patients with transverse maxillary hypoplasia were randomized into a bone-borne and a tooth-borne group. The surgical technique was the same in both groups and included a buccal corticotomy (anterior and lateral), and median split of the maxilla without pterygoid disjunction. In the bone-borne group, the expansion was performed using a bone-borne device, whereas in the tooth-borne group expansion occurred with a tooth-borne device. After the expansion, there was a retention period of three months before the distractor was removed. Measurements were taken before treatment, after the expansion and at the 12 month follow-up. To assess the stability of the treatment dental study casts were analyzed.

The results of the study showed that widening of the dental arch was achieved at canine, premolar and molar level in comparable amounts, making the expansion parallel. At the 12 month follow-up, relapse was not significant and the increase in width was sustained. Most importantly, this study showed no significant differences in stability between bone-borne and tooth-borne distraction. In addition, stability at the 12 month follow-up is satisfactory and overcorrection does not seem to be necessary.

‘Can a relationship be found between segmental maxillary tipping, relapse, and the mode of distraction?’

Stability of SARME is influenced by the amount of relapse in the post-expansion period. Literature suggests that the relapse will increase when a tooth-borne device is used versus a bone-borne distractor.¹⁻³ The suggested explanation for this is the tipping of the maxillary segments instead of parallel expansion due to the different position of the tooth-borne and bone-borne distractors relative to the ‘center of resistance’.^{3,4} This ‘center of resistance’ is a combination of the area where the maxillary

halves are still connected to the skull after the corticotomy, the pterygoid region, and the resistance of the surrounding soft tissues.⁴

An anatomic biomechanical study was executed to shed more light on the basic movement mechanism of tipping of the maxillary segments during transverse expansion using either a tooth-borne or bone-borne distraction device. Ten dentate human cadaver heads were used for this study and the results are described in *Chapter 4*.

The results of this study showed that there is segmental maxillary tipping in both groups and that the amount of tipping was larger in the tooth-borne group. However, this difference was not statistically significant. It is concluded that the fact that the tooth-borne group showed more tipping might substantiate the general opinion that bone-borne distraction causes less segmental angulations than tooth-borne distraction.

In *Chapter 5*, the amount of segmental maxillary tipping was studied in the clinical situation. Dental study casts and postero-anterior cephalograms were analyzed in the prospective randomized patient study.

Results showed that tipping of the maxillary segments is present and equal in both bone-borne and tooth-borne SARME, and increases in the retention period. This increase during the retention period is explained by the skeletal relapse of the maxilla at the nasal level. This fact, combined with the negligible amount of relapse at the dental level, led to the conclusion that segmental maxillary tipping does not influence relapse in SARME and that there is no difference between bone-borne and tooth-borne distraction.

It needs mentioning that research of tipping of the maxillary segments by using standard two-dimensional radiographs and dental study casts has its limitations and that three-dimensional imaging would certainly make research on segmental tipping more reliable.

‘What is the influence of surgically assisted rapid maxillary expansion on the nasal airway and the nasalance of speech?’

SARME causes a widening of the maxilla, and is associated with enlargement of the nasal valve and an increase of the anterior and posterior nasal volumes.⁵⁻⁷ The main difference between the two modes of distraction (bone-borne versus tooth-borne) is the position on the palate, relative to the ‘center of resistance’. This would, theoretically, cause a more parallel expansion of the maxillary segments in the case of bone-borne distraction. As a result, the nasal bony structures are also expected to be widened more, leading to a superior improvement in nasal airway capacity in the bone-borne group.

However, the results of the study on the segmental maxillary tipping (*Chapter 5*) showed no difference between the two groups. If the amount of tipping is equal in both groups, the results of the study regarding the nasal airway should also show no difference between the two groups.

The part of the prospective randomized patient study that deals with the nasal airway changes is reported in *Chapter 6*. Acoustic rhinometry (AR) provides an objective measurement of cross-sectional area and volume of the nasal cavity.^{5,8} The AR measurements showed an increase in both groups after the expansion and at the 12 months follow-up. As expected, there were no significant differences between the two groups.

Nasometry is a measurement instrument for objective assessment of rhinophonia.⁹ It measures nasalance, the relative sound pressure level of the nasal signal in speech. Nasal airway changes due to the surgery are found in the patient groups, however, the velo-pharyngeal function is not likely to be affected by the treatment. In other words, no differences are expected in the outcome of the nasometry measurements. One reason for performing the nasometry measurements in this study group of non-syndromal patients was the fact that SARME is also used in patients with congenital deformities with narrow transverse maxillae who already experience hypernasal speech (for example cleft patients). For these patients, an increase in the hypernasality due to the treatment would be an adverse effect. The results of the nasometry measurements did not show any change due to the treatment and at follow-up. Therefore, the hypothesis that no change in speech is to be expected, is confirmed.

To evaluate the subjective changes of the nasal airway due to the SARME, patients were asked to complete a questionnaire using six visual analogue scaled (VAS) questions. The results of the survey showed a subjective improvement of nasal breathing capacity. The objective improvement is in agreement with the subjective improvement of the nasal capacity.

In both groups a subjective reduction of snoring was found. Snoring is caused by vibration of the uvula and the soft palate. This leads to an increased respiratory effort and collapse of the upper respiratory airway, which may result in obstructive sleep apnea (OSA).¹⁰ The nose appears to be the preferred route of breathing during sleep.¹⁰ Transverse compression of the maxilla leads to partial obstruction of the upper airway and can cause snoring and OSA as a result of pathologic changes in airflow velocity and resistance.¹⁰⁻¹² Several publications advocate SARME as an effective treatment, providing a profound improvement of the OSA problem.^{13,14} Objective measurement (polysomnography) was not performed in this study. For future study on the relationship between SARME and its effect on OSA-related problems, polysomnography should be taken into account.

‘What is the effect of surgically assisted rapid maxillary expansion on the upper facial appearance?’

Chapter 7, discusses the part of the prospective randomized patient trial that focuses on the changes of upper facial dimension due to SARME. Measurements of the upper face were taken from standardized frontal photographs. A small, albeit significant increase of the nose and mouth width was found within both groups. The upper lip length did not change due to the treatment. No significant differences were found between the two groups.

Measurements on standardized frontal photographs is a reliable yet rather old-fashioned technique and it provides no information on the three-dimensional changes that might occur. Other methods for soft tissue analysis include stereophotogrammetry,¹⁵ morphanalysis,¹⁶ and mesh grid analysis.^{17,18} The cost and complexity of these techniques makes them impractical for general clinical use.¹⁹ It must be noted that stereophotogrammetry is currently widely studied and used in research settings, and may become available for clinical use in the near future.²⁰⁻²²

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Chapter 11

EPILOGUE AND FUTURE PERSPECTIVES

This chapter discusses the limitations of the study and questions that could not be answered in this thesis as well as future perspectives.

As has been discussed throughout this thesis (*Chapters 1-6*), tipping of the maxillary segments is an interesting subject in SARME as it might influence the occurrence and amount of relapse of the therapy. *Chapter 10* discusses the limitations of research on tipping of the maxillary segments by using standard two-dimensional radiographs and dental study casts. Three-dimensional imaging would certainly make research on segmental tipping more reliable. Conventional CT scans, however, expose the patient to a fair amount of radiation and exposing this patient group was not justified. Recent innovations have produced the Cone Beam CT scan which is now available for clinical practice. The major advantage of the Cone Beam CT scan is the radiation dose, which is reported to be approximately 80% less than a conventional spiral CT scan, and equivalent to a full-mouth periapical radiographic exposure.^{1,2} We suggest the use of the Cone Beam CT for future study into the subject of segmental maxillary tipping.

Saving storage room for orthodontic practices is still the main focus of the providers of digital dental casts and its software. Developments in the field of these 'Digimodels' are rapidly progressing and becoming more and more reliable and economical. The software to analyze the digital dental casts, both for orthodontic practice and oral and maxillofacial surgery, are still rather basic, but might become useful in future studies.

The psychological and emotional influence of medical treatment on patients is increasingly becoming a point of interest to healthcare professionals. The surgical treatment of SARME, the distraction phase, and the fact that the distractor stays in situ for several months before it is removed, will have an influence on the patient's 'quality of life.' In *Chapter 6*, some subjective information was gathered on the topic of nasal airway changes, however, this did not take any of the affects of the treatment itself into consideration. For future research we recommend a 'quality of life' study on this treatment modality.

Transverse maxillary hypoplasia leads to partial obstruction of the upper airway and can cause snoring and obstructive sleep apnea (OSA), as a result of pathologic changes in airflow velocity and resistance. The effect of SARME on OSA has been the aim of several studies and is discussed in *Chapters 6 and 10*. For future study on the

relationship between SARME and its effect on OSA related problems, polysomnography should be taken into account.

In *Chapter 7*, changes in the upper facial appearance were studied using standardized photographs. As has been discussed, this is a reliable but rather old-fashioned technique and it provides no information on the three-dimensional changes that might occur. Three-dimensional and four-dimensional (including movement measurements in time) photography is currently studied and might be available for future study of this patient group.

However, no matter how extensive or precise the information on actual physical changes of the outer appearance of a patient is, it does not convey how a patient experiences the changes in his or her appearance due to the treatment. It would be interesting to research the data on the actual physical changes versus how these changes are experienced by the patient. Only then conclusions could be drawn about the changes from an esthetical point of view.

As mentioned in *Chapter 7*, almost half of the patients studied underwent simultaneous midline mandibular distraction. The data on the mandibular expansion was also gathered during the course of this study. However, the results still have to be analyzed and will be published in the near future. Midline mandibular distraction alone and in combination with SARME (bimaxillary expansion) is an interesting and not yet widely described subject.

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Summary

This thesis is a study of several aspects of surgically assisted rapid maxillary expansion (SARME) and is divided into five Parts.

The questions this thesis set out to answer were; ‘is there a difference in stability between bone-borne and tooth-borne distraction?’, ‘can a relationship be found between segmental maxillary tipping, relapse, and the mode of distraction?’, ‘what is the influence of surgically assisted rapid maxillary expansion on the nasal airway and the nasalance of speech?’, and ‘what is the effect of surgically assisted rapid maxillary expansion on the upper facial appearance?’

Part I is the general introduction.

In *Chapter 1* a literature review of SARME is provided. Transverse maxillary hypoplasia, in adolescents and adults, is frequently seen in non-syndromal and syndromal patients including cleft patients. In skeletally matured patients, the uni- or bilateral transverse hypoplasia can be corrected by means of SARME. The treatment is a combination of a surgical procedure and orthodontic treatment and provides, by means of distraction osteogenesis, dental arch space for alignment of the dentition. The procedure also causes a substantial enlargement of the maxillary apical base and of the palatal vault, providing space for the tongue for correct swallowing. In addition, a distinct subjective improvement in nasal breathing associated with enlargement of the nasal valve towards normal values is seen with an increase of nasal volume in all compartments.

No consensus could be found in the literature regarding either the surgical technique, the type of distractor used (tooth-borne or bone-borne), the existence, cause and amount of relapse, and whether or not overcorrection is necessary.

In order to answer the thesis questions, several different studies and experiments were launched in 2004.

Part II consists of the fundamental studies and developments.

Chapter 2 describes the first of three fundamental studies performed. This chapter discusses the evaluation of a bone-borne distractor, the Transpalatal Distractor (TPD) that was used by the Erasmus University Medical Center.

Traditionally, the distractors for expansion are tooth-borne devices, i.e. hyrax appliances, which may have some undesirable side effects such as tooth tipping, dental relapse, cortical fenestration, loss of anchorage, and segmental maxillary tipping. In comparison, when using bone-borne distractors, most of the maxillary expansion is orthopedic and at a more mechanically desired level with less dental side effects. The TPD is a bone-borne device that should eliminate negative orthodontic side effects of

tooth-borne devices. The literature contains reports of several possible complications of the TPD. In this retrospective study, TPD use was evaluated in ten patients with various congenital craniofacial anomalies, including clefts.

During placement of the TPD, it was noted that in extremely narrow maxillae, the palatal bone is very thin, which makes the initial placement difficult and therefore less primary stability can be achieved. There often is a thick palatal mucosa, especially in Apert syndrome, which makes placement of the abutment plates difficult and leaves little, if any, space for the module itself. Finally, in patients with mental retardation it is difficult to exchange the modules and re-fix the abutment plates in the outpatient clinic.

In our group of ten patients with congenital deformities, a 60% complication rate was observed. The TPD does not seem to be the ideal device for use in widening the maxilla in cases with congenital deformities.

The conclusion of the above-mentioned study led to the development of a new bone-borne distractor, the Rotterdam Palatal Distractor (RPD). After a pilot study in which the device was tested, it was brought on the market in September 2004. Results of this second fundamental study are described in *Chapter 3*.

By activation, the nails of the abutment plates automatically stabilize the RPD and screw fixation is no longer necessary. The major advantages, however, are the fact that the RPD fits in extreme narrow maxillae and the fact that there is no need for changing the module. This new RPD is presented and data of five acquired deformity and eight congenital deformity patients that were treated with this distractor is reported.

The third fundamental study that was performed was an experiment testing the biomechanics of transverse maxillary expansion in anatomic specimens; this is described in *Chapter 4*. The aim of this anatomic biomechanical study was to shed more light on the mechanism of tipping of the maxillary segments during transverse expansion using either a bone-borne or tooth-borne distraction device. The study was performed on ten dentate human cadaver heads. These ten specimens were divided into two groups, a bone-borne device group and a tooth-borne device group. Results showed that segmental maxillary tipping was present in both groups, but the amount of tipping of the maxillary segments was larger in the tooth-borne group. However, this was not significant.

In conclusion, the fact that the tooth-borne group showed more segmental maxillary tipping might reflect the general opinion that bone-borne distraction causes less skeletal tipping than tooth-borne distraction and that relapse due to this tipping might be less in bone-borne SARME. However, both groups show segmental maxillary tipping suggesting that overcorrection to counteract relapse would be necessary in both

bone-borne and tooth-borne SARME. One should be aware that this anatomic model by no means depicts an actual patient situation, and any extrapolation from it must be done with great care.

Part III deals with different aspects of a prospective randomized patient trial that was executed. Between January 2004 and December 2007, 46 mature non-syndromal patients with transverse maxillary hypoplasia were recruited for this study. The patients all underwent SARME in order to treat the transverse maxillary hypoplasia. The patients were randomized into a bone-borne ($n=25$) and a tooth-borne group ($n=21$). The surgical technique was the same in both groups and included a buccal corticotomy (anterior and lateral) and median split of the maxilla, without pterygoid disjunction. In the bone-borne group, the expansion was performed using a bone-borne device, whereas in the tooth-borne group expansion occurred via a tooth-borne device. After the expansion, there was a retention period of three months before the distractor was removed. Measurements were taken before treatment, after the expansion and at the 12 month follow-up. Twentythree bone-borne and 19 tooth-borne patients were available for analysis.

The results of this prospective randomized patient trial are described in three different chapters.

In *Chapter 5* stability, segmental maxillary tipping, and relapse of bone-borne versus tooth-borne distraction was investigated. There were no significant differences between the two groups. Widening achieved was comparable at canine, premolar and molar level. The relapse was not significant and at follow up the increase in distance was sustained. A significant increase in palatal width, at both the premolar and molar level was found within both groups. The maxilla moves slightly downward. Segmental maxillary tipping was found in both groups. It is concluded that there is no significant difference between the two groups. In SARME, the achieved widening at the dental level is stable at the 12 month follow-up, therefore overcorrection does not seem to be necessary. Tipping of the maxillary segments is equal, in both bone-borne and tooth-borne SARME, as are increases of tipping in the retention period. Therefore, segmental maxillary tipping does not affect relapse in SARME.

Chapter 6 presents the results of the influence of SARME on the nasal airway and the nasalance of speech. Acoustic rhinometry was used to provide an objective measurement of cross-sectional area and volume of the nasal cavity. Nasometry is a measurement instrument for objective assessment of rhinophonia. It measures nasalance, the relative sound pressure level of the nasal signal in speech. Subjective changes in nasal airway were evaluated using a visual analogue scaled (VAS) patient questionnaire.

There were no significant differences between the two groups. The acoustic rhinometry measurements showed an increase of the nasal capacity in both groups after the expansion and at follow-up. Relapse was negligible. The nasometry measurements did not show any significant changes. The VAS scores showed a subjective improvement of nasal breathing capacity, and a reduction of snoring. It is concluded that there are no differences between the two groups. All nasal capacity measurements increased due to SARME. The nasalance of speech is not influenced by SARME. The objective improvement of the nasal capacity is in agreement with the subjective improvement.

In *Chapter 7*, the results of changes in the upper facial appearance due to SARME are reported. Measurements of the upper face were taken from standardized frontal photographs. A small, albeit significant increase of the nose and mouth width was found within both groups. The upper lip length did not change due to the treatment. For the three measurements performed, no significant differences could be found between the two groups.

Part IV presents two auxiliary studies that have to be regarded as supporting information completing the whole context of the thesis.

Chapter 8 provides a general overview of distraction osteogenesis in the field of oral and maxillofacial surgery. Distraction osteogenesis is a treatment which is often used in orthopedics and plastic surgery but additionally more frequently so in maxillofacial surgery. A variety of distractors are available for use on the different parts of the maxillofacial skeleton. The aim of this article is to emphasize distraction osteogenesis in the field of oral and maxillofacial surgery and different types of intra- and extraoral distractors frequently used in the head and neck region. The application of such distractors for several months while the patient carries on everyday life can cause a risk in case of an emergency. The anesthesiological aspects of these devices are reported in order to minimize the risks in cases of acute medical interventions.

The second auxiliary study reports on SARME in two cases with a rare skeletal dysplasia namely osteopathia striata with cranial sclerosis, which is discussed in *Chapter 9*.

Osteopathia striata with cranial sclerosis is characterized by linear striations of the long bones, osteosclerosis of the cranium, and extra-skeletal anomalies. Osteosclerosis of cranial and facial bones can lead to disfigurement and to disability due to pressure on the cranial nerves. Disease-related problems, consisting of extremely dense bone and therefore difficult and time-consuming surgery and distraction as well as possible complications that might occur with this type of treatment in these patients is reported.

Part IV of this thesis contains the general discussion in *Chapter 10* and the epilogue and future perspectives in *Chapter 11*.

In *Chapter 10*, the discussion is focused on the answers to the thesis questions.

‘Is there a difference in stability between bone-borne and tooth-borne distraction?’

There is no difference in stability between bone-borne and tooth-borne distraction, and stability at the 12 month follow-up is satisfactory.

‘Can a relationship be found between segmental maxillary tipping, relapse, and the mode of distraction?’

The results of the anatomic biomechanical study that was reported in *Chapter 4* are discussed with the clinical results described in *Chapter 5*. It is concluded that segmental maxillary tipping is present and equal in both bone-borne and tooth-borne SARME, and that it does not influence relapse.

‘What is the influence of surgically assisted rapid maxillary expansion on the nasal airway and the nasalance of speech?’

SARME induces an objective increase of the nasal capacity. The objective improvement is in agreement with the subjective improvement of the nasal capacity. There is no change in the nasalance of speech due to SARME.

‘What is the effect of surgically assisted rapid maxillary expansion on the upper facial appearance?’

A small increase of the nose and mouth width was found within both groups. The upper lip length did not change due to the treatment.

Chapter 11 discusses the limitations of the study and questions that could not be answered in this thesis as well as future perspectives. The topics discussed address future possibilities for research: the use the Cone Beam CT scan for three-dimensional imaging of segmental maxillary tipping; the use of digital dental casts; ‘quality of life’ study; the use of polysomnography to study the relationship between SARME and obstructive sleep apnea (OSA); a study of the transverse mandibular distraction and the combination of this with SARME (bimaxillary expansion); three- and four-dimensional imaging (stereophotogrammetry) of the face, and evaluation of how these changes are experienced by the patient.

Dutch summary

NEDERLANDSE SAMENVATTING

Transversale maxillaire hypoplasie in adolescenten en volwassenen komt voor bij non-syndromale en syndromale patiënten, met inbegrip van schisis patiënten. In skeletaal volgroeide patiënten, kan een uni- of bilaterale transversale hypoplasie gecorrigeerd worden met behulp van chirurgisch geassisteerde snelle maxillaire expansie (SARME). Deze behandeling is een combinatie van chirurgie en orthodontie en biedt ruimte in de maxillaire boog om de gebits-elementen orthodontisch correct op te stellen. Daarnaast veroorzaakt de behandeling een substantiële vergroting van de maxillaire apicale basis en van de palatinale boog, wat ruimte geeft aan de tong voor een goede slikbeweging. Bijkomstig gunstig effect is de subjectieve verbetering van het ademen door de neus, als gevolg van de vergroting van de smalste doorgang in de neus (nasale klep) en de inhoud van de neusholte.

Dit proefschrift heeft verscheidene aspecten van SARME als onderwerp, en bestaat uit vijf delen.

In **Deel I**, *Hoofdstuk 1* wordt een literatuur studie beschreven betreffende SARME ter evaluatie van de huidige kennis op dit gebied. Conclusie hiervan was dat er geen consensus bestaat betreffende de chirurgische techniek, het type distractor (tand- of bot- gedragen), het voorkomen, de oorzaak en de hoeveelheid van relaps. Of overcorrectie tijdens de verbreding, om voor de te verwachten relaps te corrigeren, noodzakelijk is, is niet bekend.

Deze conclusie leidde tot de basale vragen die gesteld werden voor dit proefschrift. Deze vragen waren; 'Is er een verschil in stabiliteit tussen bot- en tand-gedragen distractie?', 'Bestaat er een relatie tussen segmentale maxillaire tipping, relaps en de methode van distractie?', 'Wat is de invloed van SARME op de nasale luchtweg en de nasaliteit van spraak?' en 'Wat is het effect van SARME op de weke delen van het gezicht?'

In **Deel II** worden de fundamentele studies en de ontwikkeling van een bot-gedragen distractor besproken. *Hoofdstuk 2* gaat over de evaluatie van een bot-gedragen distractor die gebruikt werd in het Erasmus Universitair Medisch Centrum.

De 'transpalatal distractor' (TPD) is een bot-gedragen distractor die de negatieve orthodontische neveneffecten van tand-gedragen distractoren zou voorkomen. In de literatuur worden verschillende mogelijke complicaties besproken van de TPD. In de uitgevoerde retrospectieve studie, werd het gebruik van de TPD geëvalueerd bij tien patiënten met verschillende congenitale craniofaciale afwijkingen, met inbegrip van schisis.

Gedurende het plaatsen van de TPD werd geconstateerd dat bij patiënten met een extreem smalle maxilla het palatinale bot erg dun is, wat het plaatsen van de distractor

bemoelijkte, met beperkte initiële stabiliteit als gevolg. Voorts was er bij veel patiënten sprake van dikke palatinale mucosa, met name in het Apert syndroom, welke het plaatsnemen van de 'abutment' platen bemoeilijkte en waardoor er nagenoeg geen was voor de module zelf. Als laatste bleek bij patiënten met mentale retardatie het poliklinisch wisselen van de modules en 'abutment' platen moeizaam.

In totaal werden in de groep van tien patiënten met congenitale afwijkingen in 60% van de gevallen complicaties gevonden. Geconcludeerd werd dat de TPD niet het ideale apparaat is voor het verbreden van de maxilla in patiënten met congenitale afwijkingen.

Bovengenoemde studie leidde tot de ontwikkeling van een nieuwe bot-gedragen distractor, de Rotterdam Palatal Distractor (RPD). Nadat een 'pilot-studie' was verricht om de nieuwe distractor te testen werd de RPD op de markt gebracht in september 2004. De ontwikkeling van de RPD en de resultaten van de 'pilot-studie' worden beschreven in *Hoofdstuk 3*.

Bij het RPD apparaat stabiliseren de 'abutment' platen zich automatisch door de aanwezige pin fixatie, waardoor fixatie met behulp van schroeven niet nodig is. De grootste voordelen van de RPD zijn echter dat het apparaat toepasbaar is in extreem smalle maxillae en niet verwisseld hoeft te worden tijdens de distractie fase.

De derde basale studie die gedaan werd betrof een experiment over de biomechanica van SARME in anatomische specimen en is beschreven in *Hoofdstuk 4*. Het doel van deze studie was om meer duidelijkheid te krijgen over het mechanisme van tipping van de maxillaire segmenten gedurende SARME middels bot- en tand-gedragen distractie. Een anatomische biomechanische studie werd verricht op tien humane betande kadavers gebruik makend van bot-gedragen en tand-gedragen distractoren. De tien kadavers werden verdeeld in een bot-gedragen distractie groep en een tand-gedragen distractie groep. Resultaten lieten zien dat tipping van de maxillaire segmenten optrad in beide groepen, maar dat deze groter was in de tand-gedragen groep, dit verschil was echter niet significant.

Concluderend werd gesteld dat het feit dat de tand-gedragen distractie groep meer segmentale maxillaire tipping liet de algemene opinie zou kunnen reflecteren dat bot-gedragen distractie minder skeletale tipping veroorzaakt dan tand-gedragen distractie, en dat de relaps veroorzaakt door deze tipping in de bot-gedragen groep minder zou kunnen zijn. Segmentale maxillaire tipping wordt echter in beide studie groepen gezien, wat suggereert dat over-correctie om de relaps tegen te gaan noodzakelijk zou kunnen zijn in zowel bot- als tand-gedragen SARME. Opgemerkt wordt dat men zich bewust moet zijn van het feit dat dit anatomische model geen weerspiegeling is van de

werkelijkheid, en dat extrapolatie naar de klinische patiënten situatie met terughoudendheid moet worden gedaan.

Deel III van dit proefschrift bestaat uit de *Hoofdstukken 5,6 en 7* waarin de resultaten worden gerapporteerd van de prospectieve gerandomiseerde patiënten studie die werd verricht tussen 2004 en 2008. Tussen januari 2004 en december 2007, werden 46 volwassen non-syndromale patiënten met transversale maxillaire hypoplasie geïncludeerd in de studie. De patiënten werden gerandomiseerd in een bot-gedragen, en een tand-gedragen groep. Alle patiënten ondergingen SARME als behandeling van de transversale maxillaire hypoplasie. Na de expansie was er een retentie periode van drie maanden waarna de distractor werd verwijderd. Metingen werden verricht voor behandeling (t1), na de expansie (t2) en na 12 maanden follow-up (t3). Er waren 23 bot-gedragen en 19 tand-gedragen patiënten beschikbaar voor evaluatie.

In *Hoofdstuk 5* wordt de stabiliteit, segmentale maxillaire tipping en relaps van tand-gedragen versus bot-gedragen distractie besproken. Er was geen significant verschil tussen beide groepen. De mate van verbreding bij de hoektand, de premolaar en de molaar was vergelijkbaar. Relaps was niet significant en bij follow-up werd de bereikte breedte van de behandeling behouden. Een significante verbreding van de palatinale breedte bij de premolaar en de molaar werd in beide groepen gevonden. De maxilla bewoog door de SARME minimaal naar caudaal. Segmentale maxillaire tipping werd in beide groepen gezien. Geconcludeerd wordt dat er geen verschil bestaat tussen beide studie groepen. SARME geeft een stabiel dentaal eindresultaat na 12 maanden. Over-correctie lijkt niet nodig te zijn. Tipping van de maxillaire segmenten is gelijk in beide groepen en neemt toe in de retentie periode. Segmentale maxillaire tipping heeft geen invloed op de relaps van SARME.

Hoofdstuk 6 geeft de resultaten weer van de invloed van SARME op de nasale luchtweg en de nasaliteit van spraak. Akoestische rhinometrie werd gebruikt als een objectief instrument om de oppervlakte van doorsnedes en het volume van de neusholte te meten. Nasometrie is een instrument dat de relatieve hoeveelheid van de nasale geluidsgolf (nasaliteit) van spraak meet. Subjectieve veranderingen in de ademhaling door de neus werden geëvalueerd met behulp van een vragenlijst op basis van een visuele analoge schaal (VAS). Er waren geen significante verschillen tussen de studie groepen. De akoestische rhinometrie liet een toename zien van het volume van de neusholte na de distractie fase (t2) en na 12 maanden (t3), de relaps was verwaarloosbaar. De nasometrie metingen lieten geen veranderingen zien van de nasaliteit door de behandeling. De VAS score gaf een subjectieve verbetering aan van de ademhaling door de neus. Er wordt geconcludeerd dat er geen verschil bestaat tussen bot-

gedragen en tand-gedragen distractie. De nasale capaciteit neemt door de behandeling toe. De mate van nasaliteit in spraak verandert niet door SARME. De objectieve vergroting van de nasale capaciteit is in overeenstemming met de subjectieve verbetering van de ademhaling door de neus. In beide groepen wordt een subjectieve vermindering van snurken gevonden.

Hoofdstuk 7 laat de resultaten zien van de gevolgen van SARME op de weke delen van het gezicht. Metingen werden verricht op gestandaardiseerde frontale digitale foto's. Een kleine maar significante toename van de neus- en mondbreedte werd gevonden in beide groepen. De lengte van de bovenlip veranderde niet. Er werden geen verschillen gevonden tussen beide studie groepen.

In **Deel IV** worden twee studies gepresenteerd die aanvullend zijn bij het onderwerp SARME, om zo de context van dit proefschrift te verbreden. *Hoofdstuk 8* geeft een overzicht van distractie osteogenese in het gebied van Mondziekten, Kaak- en Aangezichtschirurgie.

Distractie osteogenese is een therapie die gebruikt wordt in de orthopedie, plastische- en maxillofaciale chirurgie. Er bestaat een brede variëteit aan distractoren die op verschillende delen van het maxillofaciale skelet gebruikt kunnen worden. Doel van deze studie was bekendheid te geven aan distractie osteogenese in het craniofaciale gebied en aan de verschillende typen intra- en extraorale distractoren. Het gebruik van distractoren, die voor enkele maanden bij patiënten worden aangebracht, terwijl de patiënt doorgaat met de dagelijkse bezigheden, draagt een risico met zich mee in geval van een ongeluk of anderszins medisch spoedgeval. De anesthesiologische aspecten van deze apparaten worden besproken om hiermee de risico's in medische noodgevallen te minimaliseren.

De tweede aanvullende studie, *Hoofdstuk 9*, rapporteert het gebruik van SARME bij twee patiënten met een zeldzame skeletale dysplasie, osteopathia striata met craniale sclerose.

Osteopathia striata met craniale sclerose wordt gekarakteriseerd door lineaire striaties van de lange beenderen, osteosclerose van de schedel en extra-skeletale anomalieën. Osteosclerose van de schedel en de faciale botten kan leiden tot misvormingen en disfunctie door druk op de hersenzenuwen. De ziektegerelateerde problemen, bestaande uit extreem compact bot en daardoor moeizame en tijdrovende chirurgie en distractie, en mogelijke complicaties die kunnen optreden bij SARME bij deze groep patiënten wordt besproken.

Deel V van dit proefschrift bestaat uit de algemene discussie en conclusies in *Hoofdstuk 10* en de epiloog met toekomstperspectieven in *Hoofdstuk 11*.

In *Hoofdstuk 10*, wordt de discussie gericht op het beantwoorden van de in het voorwoord gestelde vragen.

‘Is er een verschil in stabiliteit tussen bot- en tand-gedragen distractie?’

Er is geen verschil in stabiliteit tussen bot-gedragen en tand-gedragen distractie en de stabiliteit na 12 maanden is groot.

‘Bestaat er een relatie tussen segmentale maxillaire tipping, relaps en de methode van distractie?’

De resultaten van de anatomische biomechanische studie uit *Hoofdstuk 4* worden besproken met de resultaten uit de klinische patiënten studie uit *Hoofdstuk 5*. Geconcludeerd wordt dat segmentale maxillaire tipping geen invloed heeft op de relaps van SARME en dat er geen verschil wordt gevonden tussen de bot-gedragen en tand-gedragen distractie methode.

‘Wat is de invloed van SARME op de nasale luchtweg en de nasaliteit van spraak?’

SARME veroorzaakt een objectieve toename van de nasale capaciteit. De objectieve vergroting van de nasale capaciteit is in overeenstemming met de subjectieve verbetering. Er treedt geen verandering op in de nasaliteit van spraak door SARME.

‘Wat is het effect van SARME op de weken delen van het gezicht?’

Een kleine toename van de breedte van de neus en mond wordt gevonden in beide studie groepen. De lengte van de bovenlip verandert niet door SARME.

In *Hoofdstuk 11* worden de beperkingen van de studie en toekomstperspectieven besproken. De onderwerpen die aan bod komen hebben betrekking op verschillende mogelijkheden voor toekomstig onderzoek; gebruik van de Cone Beam CT scan voor 3-dimensionale beeldvorming; het gebruik van digitale gebitsmodellen; een ‘kwaliteit van leven’ studie; het gebruik van polysomnographie om de relatie tussen SARME en het obstructief slaap apnoe syndroom te verduidelijken; studie naar transversale mandibulaire verbreding en de combinatie hiervan met SARME (bimaxillaire verbreding); 3-, en 4-dimensionale beeldvorming van veranderingen van het gezicht (stereofotogrammetrie), en de evaluatie van hoe deze veranderingen door de patiënt ervaren worden.

Addendum

RESEARCH PROTOCOL

M.J. Koudstaal¹

K.G.H. van der Wal¹

E.B. Wolvius¹

A.J.M. Schulten²

W.C.J. Hop³

¹ Department of Oral and Maxillofacial Surgery,
Erasmus University Medical Center Rotterdam

² Department of Orthodontics,
Erasmus University Medical Center Rotterdam

³ Department of Biostatistics,
Erasmus University Medical Center Rotterdam

Approved by the Medical Ethical Committee Rotterdam

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Introduction

In patients with transverse and sagittal maxillary hypoplasia of the midface, buccal cross bites (unilateral and bilateral), anterior and posterior crowding, dental compensation such as lingual tipping of mandibular posterior teeth, and buccal corridors can be noticed clinically. Orthodontic correction of the transverse discrepancy is successful until closure of the midpalatal suture at approximately 14-15 years of age depending on the gender of the patient (Profitt, 2000, Melsen, 1975). Once skeletal maturity has been reached, Surgically Assisted Rapid Maxillary Expansion (SARME) in combination with a corticotomy must be performed in order to release the areas of bony resistance such as the midpalatal suture, the zygomatic buttresses, and the piriform aperture. This technique includes a buccal corticotomy and a median osteotomy, a sufficient amount of expansion as well as long-term stable results can be obtained. There are several advantages; bone apposition in the osteotomy sites, reduced risk of dental version or extrusion compared to regular orthopaedic care, and increased periodontal stability. Finally, transverse occlusal stability results in stable sagittal and vertical relationships.

Traditionally, a tooth-borne orthodontic appliance called a hyrax expander is placed preoperatively to expand the maxilla (Figure 1, Hyrax CE 0297, Forestadent, Pforzheim, Germany). It is suggested that dental anchorage gives rise to several complications; damage to the teeth, possible loss of anchorage, periodontal membrane compression and buccal root resorption, cortical fenestration, skeletal relapse, anchorage-tooth tipping, and segmental tipping instead of parallel expansion (Profitt, 2000, Mommaerts, 1999). Advantages of the hyrax expander are the fact that it can be placed and removed in the orthodontic outpatient clinic without local anesthesia. Furthermore, the hyrax expander is less expensive than the bone-borne devices.



Figure 1. Hyrax expander in situ

To avoid the dental complications a bone-borne device, the Transpalatal Distractor (TPD, CE 9001, Surgi-tec, Bruges, Belgium) was developed in 1999 (Mommaerts, 1999). The TPD module (Figure 2) is claimed to avoid several of the problems mentioned for the hyrax expander (Mommaerts, 1999). The major advantages of the TPD are claimed to be that the forces are acting directly to the bone at the mechanically desired level and that orthodontic alignment can start soon after the expansion (Mommaerts, 1999). However, the TPD has several disadvantages. First, the TPD modules have to be exchanged during the distraction phase, which can be done in an outpatient clinic without local anesthesia. Second, there is a possible risk of loosening the module and the abutment plates. To avoid swallowing or inhalation, the modules are anchored to a tooth with sutures. Third, after the consolidation period, the module and the abutment plates have to be removed under local anesthesia in the outpatient clinic (this takes approximately ten minutes) (Neyt et al., 2002).



Figure 2. TPD in situ.

During the course of this study a new bone-borne palatal distractor was developed in the department of Oral and Maxillofacial Surgery of the Erasmus University Medical Center Rotterdam, the Netherlands. The Rotterdam Palatal Distractor (RPD, CE-0297, KLS Martin, Postfach 60, D-78501 Tuttlingen, Germany) has the shape of a car-jack (Figure 3). By activation, the nails of the abutments plates automatically stabilizes the device and no screw fixation is necessary (Figure 4). In patients who were randomized in the bone-borne group, the distraction was performed with this new, less invasive distractor.

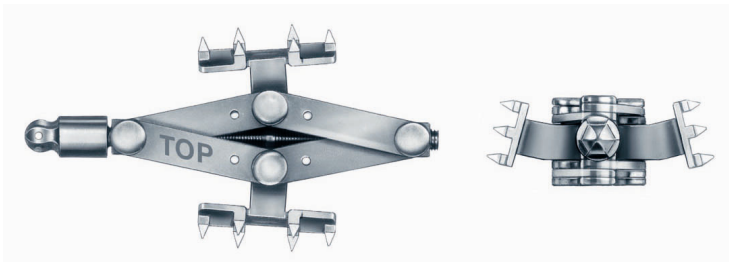


Figure 3. Design of the RPD.



Figure 4. RPD in situ before and after distraction.

Biomechanical aspects of the distractors

Tooth-borne

1) Hyrax expander. The hyrax consists of an expansion screw that is ideally attached to the maxillary first bicuspid and first molar. One turn equals a 0.25 millimeter expansion. Activation will be executed by the patient.

Bone-Borne

1) TPD device. The TPD module consists of a two-cylinder screw attached to abutments plates fixated to the palate by screws. One turn of the module equals a 0.33 millimeter expansion. Activation will be executed by the patient.

2) RPD device. The Rotterdam Palatal Distractor is a bone-borne distractor made of titanium grade II based on the mechanical design of a car jack. The two abutment plates (5 x 12 mm) contain six nails which are 2 mm long each. The plates are angled-attached (65°) to the part with a joint providing rotation. The activation part consists of a small hexagonal activation rod that is positioned directly behind the maxillary central incisors. By activating the distractor, the 2 mm long nails of the two abutment plates will penetrate the bone and the device is stabilized automatically. No screws are necessary to fixate the distractor to the bone. At the end of the distraction period the distractor can be blocked with a stainless steel (SS) wire. For that reason a little hole at the tip of the activation part is provided.

Due to the mechanical properties of the distractor, equal activation will result in a progressively decreasing distraction length. Activation with 0.6 turn ($0.6 \times 360^{\circ} = 216^{\circ}$) at the start of the distraction will result in a distraction length of 1 mm. After 5 mm distraction, for example, 1,3 turn of 468° is necessary to achieve the same distrac-

tion length of 1 mm. In other words, during the progression of the distraction period more turns are necessary to obtain the same amount of distraction per day. To come close to the 1 mm distraction rate per day a special protocol was made with four intervals. Each with an increased number of turns per day (Diagram 1). It is very important to note the opening length (amount of turns) of the distractor during the placement to know where to start in the scheme. Activation will be executed by the patient.

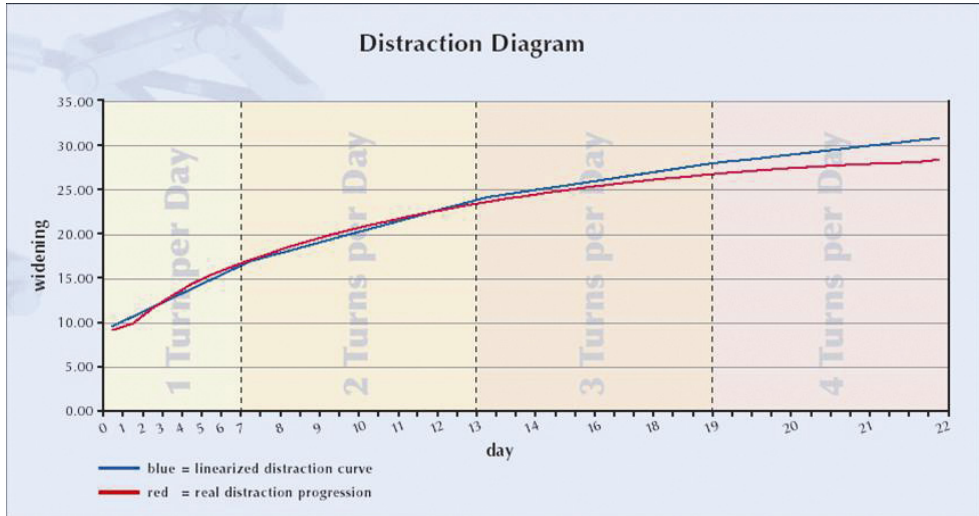


Diagram 1. Amount of widening per turn for the RPD.

Aim of the study

The aim of this study is to evaluate two conventional distraction modes, the tooth-borne versus the bone-borne in a group of skeletally matured non-syndromal patients with transverse maxillary hypoplasia.

Hypothesis

In skeletally matured, non-syndromal patients with transverse maxillary hypoplasia, increased stability in transverse dimensions at tooth and bone levels, less dental complications, and a better end-result is achieved with a bone-borne device when compared to a tooth-borne expander.

Indication

Transverse narrow maxillary arch (hypoplasia)

Quantification of the narrow maxillary arch

Dental: Minimally a transverse end-to-end relation in the molar region in a normalized sagittal skeletal and dental relation (class I canine and molar relation) as viewed on dental casts.

Skeletal: J-point analysis exceeding 22 mm as measured on PA-Cephalograms as described by Ricketts (Athanasίου and van der Meij, 1995, *Ricketts, RMO*).

Inclusion criteria

Non-syndromal patients.

Clinically the patients can show one or more of the following situations;

Dental cross-bite: unilateral or bilateral

Anterior and/or posterior crowding

Clinical evidence of buccal corridors (when smiling).

Patients are sixteen years of age and older.

The transverse hypoplasia can not be corrected by orthodontics alone due to full skeletal maturation. In case of doubt about the skeletal maturity in patients between the age of sixteen and eighteen, hand-wrist radiograph will be taken to determine the stage of skeletal maturation using the Greulich-Pyle analysis (Harris et al., 1980).

Skeletal transverse discrepancy present measured on the PA-cephalogram (Athanasίου and van der Meij, 1995).

The buccal osteotomy does not interfere with the apices of the dentition and there is no risk for damage to the infra-orbital nerve. This can be determined on the pre-operative panoramic x-ray as well as on the PA Cephalogram.

Exclusion criteria

Syndromal patients (including cleft).

Under sixteen years of age.

Patients skeletally not fully matured (Greulich-Pyle analysis) between the age of sixteen and eighteen.

History of radiation therapy in the area of interest.

Mental retardation.

Randomization

The patients are randomized in either the tooth-borne or bone-borne group by Dr. Ir. W.C.J. Hop of the department of Biostatistics of the Erasmus Medical Center Rotterdam.

Surgical technique

The basic principle for the corticotomy is the same for both patient groups.

The patients are admitted to the hospital for three days and they are put on antibiotics. In general anaesthesia a LeFort I approach is followed. The buccal corticotomies are performed as usual for a LeFort I osteotomy. The median osteotomy is between the central incisors. Prying motions with an osteotome carries out mobilization of the segments. Figure 5 shows the positions of the osteotomies made during the corticotomy.

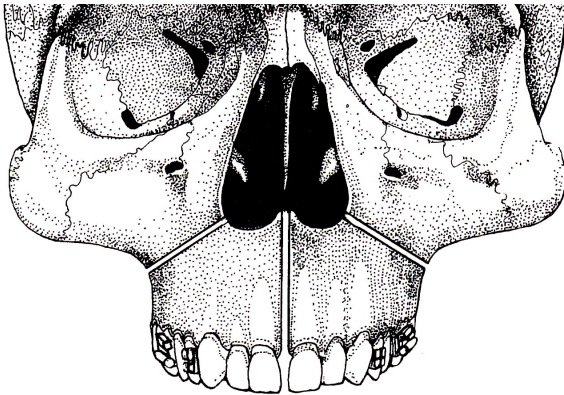


Figure 5. The positions of the osteotomies made during the corticotomy.

In the tooth-borne group, mobility of the maxillary segments is tested by opening and closing of the device. If the Hyrax is functioning well and the maxillary segments are mobile, the oral mucosa will be sutured and the operation is finished.

In the bone-borne group, in case of the TPD, after mobilizing the maxilla the operation continues with anaesthetic infiltration of the palatal gingiva over the roots of the second bicuspids. An incision is made and the mucoperiosteum is raised. Two

abutment plates are adjusted subperiosteally on the palatal bone. The module is installed parallel to the occlusal plane and perpendicular to the midsagittal plane at the premolar region, thereby prying the segments and adjusting the wings of the module. After testing the module and examining the mobility of the maxillary segments, the module is secured with a blocking screw as well as with a SS-wire to prevent aspiration. If the distractor is functioning well and the maxillary segments are mobile, the oral mucosa will be sutured and the operation is finished.

In the bone-borne group, in case of the RPD, after mobilizing the maxilla the operation continues with anesthetic infiltration of the palatal gingiva over the roots of the second bicuspid, the mucoperiosteum is removed at the site where the abutment plates will be positioned. By activating the distractor the 2 mm long nails of the two abutment plates will penetrate the bone and the device is stabilized automatically. After testing the module and examining the mobility of the maxillary segments, the module is secured with a SS-wire to prevent aspiration. If the distractor is functioning well and the maxillary segments are mobile, the oral mucosa will be sutured and the operation is finished.

The corticotomies can be combined with removal of teeth, like wisdom teeth in preparation of possible future osteotomies (e.g. LeFort I).

Distraction protocol

The distraction starts for both groups after a latency period of one week. In case of the TPD module, the blocking screw is removed. The patient is instructed to activate the device at a rate of 1 millimeter per day until the desired expansion is obtained. The desired expansion will be calculated in advance by the medical team by means of the dental casts and PA cephalogram analysis. If necessary the TPD module will be exchanged for a larger module. At the end of distraction, there will be a period of three months of consolidation (or neutral fixation).

Removal of the distraction device

Control of the distraction gap and in growth of bone in the area between the two maxillary segments is done with occlusal films. Figure 6 shows the gap directly after the end of expansion. Figure 7 shows the deposition of bone in the gap two months after the end of expansion. The occlusal films will demonstrate bone in growth resulting in increased radiopacity. The distraction device will be removed three months after the expansion. This can be done in an outpatient clinic by either the surgeon or the orthodontist.

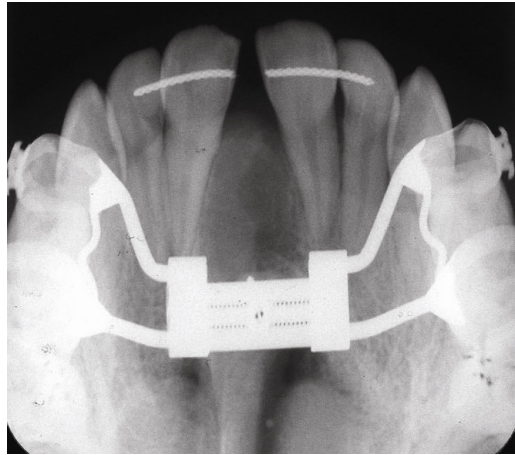
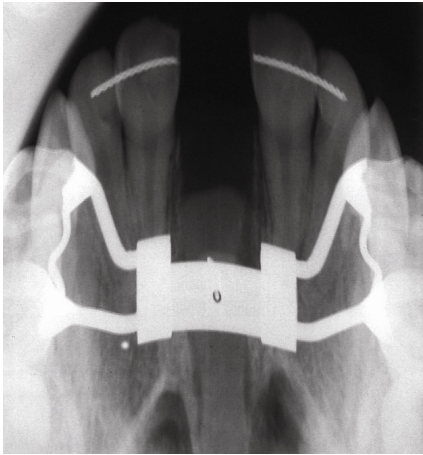


Figure 6. Occlusal film at end of distraction. Figure 7. Occlusal film at 2 months.

Placement of the fixed orthodontic appliances

If not already done before surgery, six weeks after the expansion, the orthodontist places the fixed orthodontic appliances.

Aspects of the study

All measurements will be performed before and at marked intervals after the expansion as described later in the protocol.

Relapse of the maxilla in transverse dimension

The expanded maxilla will have some relapse after the distraction. It is suggested that the relapse will be greater when a tooth-borne device is used. An explanation for this might be the tipping of the elements due to the tooth-borne fixation of the Hyrax expander. Another aspect might be the tipping of the maxillary segments during the expansion due to the different position of the two distractors relative to the center of resistance.

Cephalometric analysis will be performed on PA cephalograms (Figures 8 and 9). The amount of skeletal displacement and tipping of both segments of the separated maxilla is determined on the cephalogram analysis (Athanasίου and van der Meij, 1995).



Figure 8. PA-cephalogram

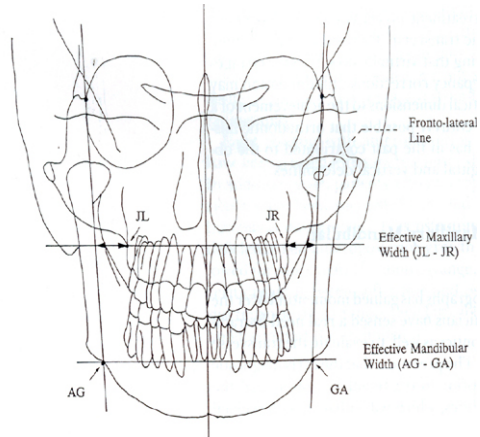


Figure 9. Cephalometric analysis

Dental casts will be taken from the patient's maxilla (Figure 10), study and will include the following analyses.



Figure 10. Example of dental study cast.

Landmark analysis.

Specific landmarks will be assigned on the casts and changes in these landmarks will be measured (Figure 11) (Pinto et al., 2001). This will show the actual displacement of the elements after the expansion. Furthermore, these landmarks will give an insight in the relapse after the distraction.

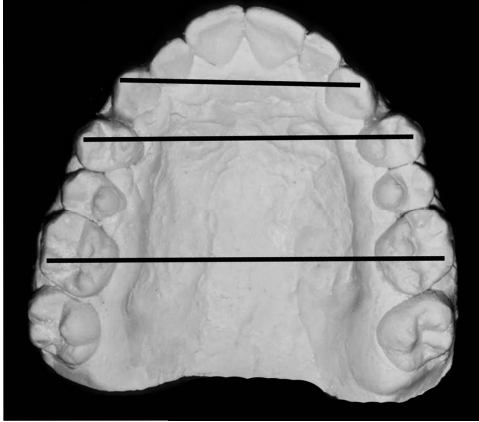


Figure 11. Landmarks for distance measurements.

Arch perimeter.

The dental arch will be measured on the casts. A change of this arch gives insight in the widening of the dental arch caused by the distraction (Figure 12) (Adkins et al., 1990).

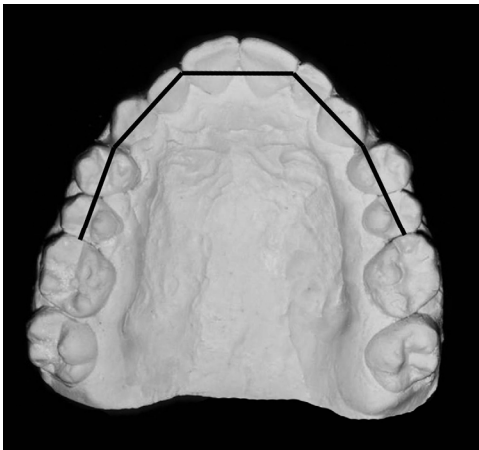


Figure 12. Landmarks for arch perimeter measurements.

Displacement of the maxilla in sagittal dimension

Lateral cephalograms will be taken to measure the position and displacement of the maxilla throughout the treatment. Several authors have reported on the fact that the maxilla moves anteriorly during transverse expansion. Lateral cephalometric analysis will be performed on the lateral cephalograms (Figures 13 and 14) (Samit and Orange, 1989).



Figure 13. Lateral cephalogram.

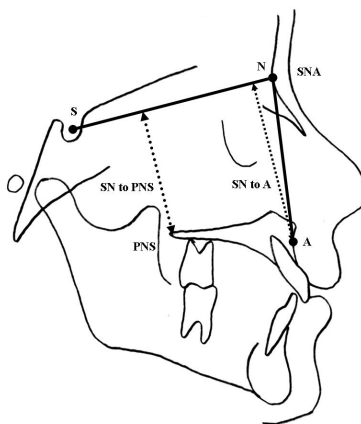


Figure 14. Cephalometric analysis.

Vitality of the dentition

Anesthesia, surgery, placement of the distractor, and the distractor itself may damage the teeth or the apices causing devitalization of the teeth involved. Therefore, a vitality test will be performed in every patient throughout the study. The vitality itself will be tested by means of faradic current.

A panoramic x-ray will be taken to evaluate possible damage to the dentition. As mentioned earlier, the pre-operative panoramic x-ray will also be necessary to determine the position of the buccal osteotomy in order to avoid surgical damage to the apices.

Photography

Before and after the distraction, standardized photographs will be taken of each patient from several angles. These photographs will be analyzed according to the method of Berger et al., 1999 (Figure 15).

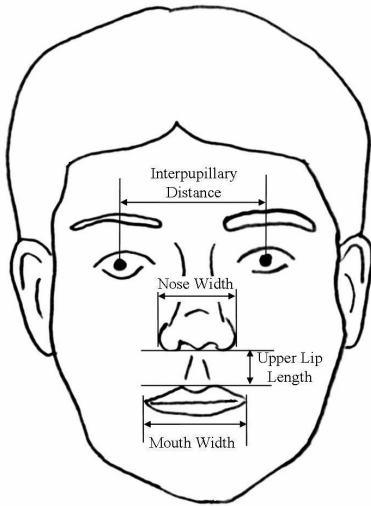


Figure 15. Measurements performed on standardized frontal photographs.

Nasal capacity / nasalance of speech measurements and subjective improvement of nasal breathing.

The nasal valve enlarges and the nasal volume has been recorded to increase with the expansion of the maxilla (Wriedt et al., 2001, Houser et al., 2002, Bressmann et al., 2000). This is expected to improve breathing through the nose. To evaluate the objective and subjective improvements the following investigations which do not carry any medical risk for the patients (Wriedt et al., 2000, Houser et al., 2002, Bressmann et al., 2000) will be performed.

Acoustic rhinometry is an echographic technique to measure the volume and capacity of the nose (Figure 16) (Wriedt et al., 2000).

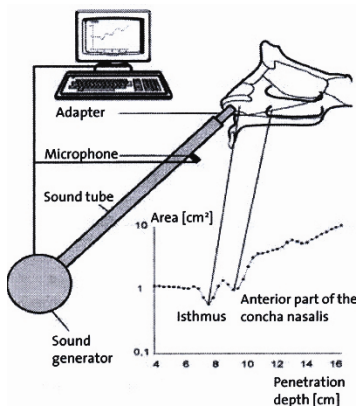


Figure 16. Acoustic rhinometry.

Nasometry is a technique that measures nasalalance. The “nasometer™ Model 6200-3 IBM PC version” is a system that is capable of measuring the proportion of the nasal energy in speech from separate measurements of nasal and oral sound pressure level (Figure 17) (Bressmann et al., 2000).

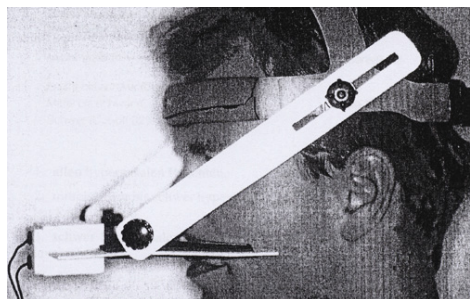


Figure 17. Nasometry measurements.

Patients will be asked to answer several questions about possible changes in nasal breathing using a Visual Analogue Scale (VAS). The use of the VAS in nasal breathing function has been validated by several studies (Simola et al., 1997, Fairley et al., 1993, Taylor et al., 2000). The questions are directed towards breathing during rest, normal daily activities, and sports, and the presence of snoring, sleep disturbance as well as an overall assessment (Attachment 1).

Complications

During the study, all possible complications concerning either the used operation technique, the distraction devices, the measurement techniques and the patients health will be recorded.

Measurements schedule (Attachment 2):

Most of the measurements are normally performed on patients before and after their surgery (Standard Orthognathic Protocol). The measurements that will be performed for study purposes only are in *Italic*. The conclusion of the study is at 12 months. The necessity of the measurements taken at 36 months are debatable and depend on the 12 month results.

Pre-operative:

- 1) Intra- and extra oral photographs
- 2) X-Rays Lateral cephalogram
PA cephalogram
Panoramic
Occlusal
(Hand-wrist film, if there is doubt about the skeletal maturity)
- 3) Vitality teeth
- 4) Dental casts
- 5) *Acoustic rhinometry*
- 6) *Nasometry*
- 7) *VAS score nasal capacity*

Post-operative:

- 1) Occlusal

Post-distraction

- 1) Intra- and extra oral photographs
- 2) X-Rays Lateral cephalogram
PA cephalogram
Panoramic
Occlusal
- 3) Vitality teeth
- 4) Dental casts
- 5) *Acoustic rhinometry*
- 6) *Nasometry*
- 7) *VAS score nasal capacity*

6 weeks post-distraction:

- 1) Placement of fixed orthodontic appliances
- 2) Occlusal

- 12 weeks post-distraction:
- 1) Occlusal
 - 2) Hyrax or TPD removal
 - 3) Placement of transpalatal bar
- 12 months post-distraction:
- 1) Intra- and extra oral photographs
 - 2) X-Rays PA cephalogram
 Panoramic
 Occlusal
 - 3) Vitality teeth
 - 4) Dental casts
 - 5) *Acoustic rhinometry*
 - 6) *Nasometry*
 - 7) *VAS score nasal capacity*
- 36 months post-distraction:
- 1) Intra- and extra oral photographs
 - 2) X-Rays PA cephalogram
 Panoramic
 Occlusal
 - 3) Vitality teeth
 - 4) Dental casts
 - 5) *Acoustic rhinometry*
 - 6) *Nasometry*
 - 7) *VAS score nasal capacity*

Statistical analysis

The statistical analysis will be performed with the assistance of Dr. Ir. W.C.J. Hop of the department of Biostatistics of the Erasmus Medical Center Rotterdam.

The displacement after the expansion will be measured at the selected landmarks (Figure 11) from the dental casts. The maximum value of these displacements will be the primary outcome for this study. The changes between the two treatment groups will be analyzed using the unpaired student t-test. The outcome at 12 months will be the primary outcome of this study. The same method will be used to compare changes in arch perimeters, the change in the amount of tipping and changes from the baseline of the nasal volume / flow measurements including VAS-score and facial changes. The incidence of complications, including whether or not devitalization of the teeth occur, will be evaluated.

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Attachment 1 (Translated from Dutch)

1) Are you able to breathe through your nose during rest?

Not at all Completely

2) Are you able to breathe through your nose during normal daily activities (walking, shopping)?

Not at all Completely

3) Are you able to breathe through your nose during exercise?

Not at all Completely

4) Do you snore?

Never Always

5) Do you wake up at night to catch your breath?

Never Always

Question 6 (after treatment)

6) Did the breathing through your nose; stay the same, worsen, or improve due to the treatment?

- No difference
- Worsened, to what extend?

No change extreme worsening

- Improved, to what extend?

No change extreme improvement

Attachment 2

SURGICALLY ASSISTED RAPID MAXILLARY EXPANSION

TOOTH-BORNE/BONE-BORNE

Pre-operative Date

Photographs intra/extra oral	
Lateral Cephalogram	
PA Cephalogram	
Panoramic	
Occlusal	
Vitality of teeth	
Dental casts	
Acoustic rhinometry	
Nasometry	
VAS score nasal air passage	

Operation date Date

Post-operation pre-distraction Date

Occlusal Date

Post-distraction Date

Photographs intra/extra oral	
Lateral Cephalogram	
PA Cephalogram	
Panoramic	
Occlusal	
Vitality of teeth	
Dental casts	
Acoustic rhinometry	
Nasometry	
VAS score nasal air passage	

6 weeks fixed ortho appliances Date

Occlusal Date

12 weeks distractor removal Date

Occlusal Date

12 months post distraction Date

Photographs intra/extra oral	
PA Cephalogram	
Panoramic	
Occlusal	
Vitality of teeth	
Dental casts	
Acoustic rhinometry	
Nasometry	
VAS score nasal air passage	

36 months post distraction Date

Photographs intra/extra oral	
PA Cephalogram	
Panoramic	
Occlusal	
Vitality of teeth	
Dental casts	
Acoustic rhinometry	
Nasometry	
VAS score nasal air passage	

Acknowledgement

Dankwoord

I would like to express my deepest gratitude to all who have helped bring this thesis to a successful conclusion.

My sincere appreciation goes out to the patients who have cooperated with the prospective study, they have sacrificed their time and energy to improve the treatment of future patients.

Een proefschrift is het werk van velen en zodoende wil ik allen, die op enigerlei wijze hebben bijgedragen tot de totstandkoming van dit proefschrift, van harte mijn dank betuigen.

Mijn dank gaat eveneens uit naar de patiënten die hebben meegewerkt aan de prospectieve studie, omdat zij bereid zijn geweest hun tijd en energie op te offeren voor een mogelijke betere behandeling van toekomstige patiënten.

Curriculum vitae

Maarten Jan Koudstaal werd geboren op 24 augustus 1975 in Asikuma, Ghana. Na het behalen van zijn Atheneum-diploma aan het Revis Lyceum te Doorn studeerde hij van 1993 tot 2001 geneeskunde aan de Universiteit van Utrecht waar hij op 25 mei 2001 zijn artsen diploma behaalde. Vervolgens was hij werkzaam op de afdeling Mondziekten, Kaakchirurgie en Bijzondere Tandheelkunde in het Erasmus Universitair Medisch Centrum te Rotterdam onder leiding van Prof.dr. Karel G.H. van der Wal. In 2002 werd de afdeling officieel erkent als opleidingcentrum en startte zijn opleiding tot specialist in de Mondziekten, Kaak- en Aangezichtschirurgie welke in juni 2008 afgerond zal worden. Het perifere deel van de opleiding werd in 2005 gevolgd in het St. Elisabeth Ziekenhuis in Tilburg onder leiding van Jan P.O. Scheerlinck. Sinds september 2005 studeert hij tandheelkunde aan de Radboud Universiteit Nijmegen en behaalt zijn tandartsen diploma in juli 2008.
