

**University of Alberta**

Tooth-Anchored Vs. Bone-Anchored Maxillary Expansion:  
A randomized controlled trial comparing dental and skeletal effects

by

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A thesis submitted to the Faculty of Graduate Studies and Research  
in partial fulfillment of the requirements for the degree of

Master of Science

in

Medical Sciences - Orthodontics

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Fall 2010

Edmonton, Alberta

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## **DEDICATION**

To Mom and Dad.

Thank you for caring about the happiness of your children above all else.

I hope to be as good a parent one day.

## ABSTRACT

**Aim:** To investigate the differences, if any, between tooth-anchored maxillary expansion (TME) and bone-anchored maxillary expansion (BME) in terms of the produced longitudinal dentoskeletal changes -and the stability of these changes- in adolescents with maxillary constriction.

**Methods:** Sixty two suitable subjects were randomly assigned to one of three groups: (1) TME group; (2) BME group; (3) Control group. Lateral cephalograms, posteroanterior cephalograms, and dental casts were obtained at baseline and at three post-expansion time points. Records from all time points were analyzed.

**Results:** There were no clinically significant differences between the TME and BME groups at any data collection time point. Both showed initial increases in dentoskeletal widths and dental tipping which were subsequently largely lost to relapse in the absence of retention.

**Conclusion:** There are no clinically significant differences in the dentoskeletal changes -or the stability of these changes- produced by TME and BME in adolescents with maxillary constriction.

## **ACKNOWLEDGEMENT**

I would like to give special thanks to Manuel Lagravère for designing and conducting the exceptional clinical trial from which was drawn the raw data for this thesis. To make good on a project of this proportion is nothing short of outstanding, and I am grateful for your efforts.

I would also like to thank my thesis committee members for giving prompt and useful feedback throughout this process. This was a new experience for me, and you helped make it an agreeable one.

Last but not least, thanks to the support staff and my fellow residents for making the program as smooth-running as it was enjoyable. I have been fortunate to forge bonds with truly wonderful people over the past three years, and I look forward to maintaining lifelong friendships.

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## LIST OF SYMBOLS AND ABBREVIATIONS

°	degrees
~	approximately
*	asterisk (indicates that additional information is provided in an indented paragraph just below the asterisk symbol)
$\alpha$	level of significance
$\Lambda$	Wilks' lambda
$\eta^2$	partial eta squared
$\chi^2$	chi square
ACP	American College of Physicians
ADA	anterior dental arch width
ANS	Anterior Nasal Spine
BME	bone-anchored maxillary expansion
CCTR	Cochrane Control Trials Register
CI	confidence interval
cm	centimeter(s)
CMR	Cochrane Methodology Register
DARE	Database of Abstracts of Reviews of Effectiveness
dpi	dots per inch
DSR	Database of Systematic Reviews
EBM	Evidence-Based Medicine
F	female

F(x,y)	F = F statistic; x = degrees of freedom between-groups; y = degrees of freedom within-groups
FOP	Functional Occlusal Plane
Go	Gonion
H <sub>a</sub>	alternative hypotheses
H <sub>o</sub>	null hypothesis
HTA	Health Technology Assessment
IC	inclusion criteria
ICC	intraclass correlation coefficient
ICD	intercanine distance
IMT	intermolar tip
IMW	intermolar width
kV	kilovolt(s)
Ln	Lateronasal point
M	male
mA	milliamperes
MANOVA	multivariate analysis of variance
Me	Menton
mm	millimeter(s)
MP	Mandibular Plane
Mx	Maxillaire point
N	Nasion
N/A	not applicable

N/S	not specified
NHSEED	National Health Service Economic Evaluation Database
p	probability value
PA	posteroanterior
PDA	posterior dental arch width
PNS	Posterior Nasal Spine
PP	Palatal Plane
Q	question
RM-ANOVA	repeated measures analysis of variance
RM-MANOVA	repeated measures multivariate analysis of variance
s	second(s)
S	Sella
SABME	surgically-assisted bone-anchored maxillary expansion
SATME	surgically-assisted tooth-anchored maxillary expansion
SNP	Sella-Nasion Plane
T1	time point prior to the commencement of expansion
T2	time point immediately post-expansion
T3	time point just prior to expander removal
T4	time point ~6 months after expander removal
TME	tooth-anchored maxillary expansion
Vs.	versus
Zg	Zygomatic point

**CHAPTER 1**  
**Introduction**

## 1.1 Background and Literature Review

In orthodontics, a maxillary expansion procedure is one that involves the application of transverse force to maxillary structures in an attempt to increase upper arch width and perimeter. Expansion procedures have been widely used for over half a century to help alleviate crowding and to help restore proper occlusal form and function<sup>[1,2]</sup>.

Several types of maxillary expansion appliances exist. A common design incorporates a jackscrew in the middle of the appliance, and an activation of this screw produces a transverse opening force (see Figures 1-1 and 1-2).<sup>[3]</sup>

Using this type of expander, the procedure generally follows the below sequence:

- (1) The expander is placed and secured intraorally. Sections 1.1.1 and 1.1.2 outline the current methods for securing the expander.
- (2) The expander is activated until the maxillary constriction is corrected or overcorrected; most clinicians prefer overcorrecting the constriction since some relapse is generally expected. The term ‘activated’ refers to a turning of the jackscrew\*.
- (3) The expander is left passively in place as a fixed retainer for a period of at least 3 months. The rationale for this retention period is that the propensity for relapse is very high within this time-frame.

\*Activation rates can range from rapid ( $\geq 0.5\text{mm}$  per day) to slow ( $\leq 0.25\text{mm}$  every other day). Thus, to achieve 10mm of width increase, the active expansion period would be  $\leq 20$  days with rapid activation, and  $\geq 80$  days with slow activation. It is generally thought that the final results are similar regardless of the activation rate, but that slow activation engenders a more physiologic tissue response.<sup>[4]</sup>

### 1.1.1 Tooth-anchored maxillary expansion (TME)

While the goal of maxillary expansion is generally to achieve an increase in arch width primarily via separation of the bony palatal shelves at the midpalatal

suture<sup>[5]</sup>, maxillary expanders have traditionally been anchored to teeth, in one form or another, mainly out of convenience<sup>[3, 4]</sup>. Figure 1-1 depicts a banded four-tooth-anchored maxillary expansion appliance; this is a one of the most common ways in which TME appliances are anchored to teeth. The topic of TME has been studied extensively in the literature, and the outcomes of this procedure have been submitted to rigorous scientific inquiry. Indeed, publications include two meta-analyses<sup>[6, 7]</sup> and five systematic reviews<sup>[3, 8-11]</sup>.



**Figure 1-1.** Tooth-anchored maxillary expander (courtesy of Dr. Manuel Lagravère)

While TME procedures have enjoyed widespread popularity in modern orthodontics, they have not been without problems. Several untoward side-effects associated with TME use have been reported over the years. These include opening of the bite<sup>[12]</sup>, buccal cortical bone dehiscence and recession<sup>[13]</sup>, root resorption<sup>[14]</sup>, and a propensity for relapse<sup>[2, 15]</sup>. These issues all relate to the fact that buccal crown tipping is unavoidable with traditional appliances since the expansion force is applied directly to the teeth<sup>[4]</sup>.

### **1.1.2 Bone-anchored maxillary expansion (BME)**

In the age of dental implantology, it is now possible to bypass the teeth and apply transverse force directly to the palatal shelves of the maxilla [Figure 1-2]. In theory, dental side effects would be avoided with such an approach, and early reports of surgically-assisted BME in humans were enthusiastic, the general consensus being that results showed fewer dental side effects and greater stability

than those of TME<sup>[16-30]</sup>. Until recently<sup>[31, 32]</sup>, studies on the topic of non-surgically-assisted BME were not reported in the literature.



**Figure 1-2.** Bone-anchored maxillary expander (courtesy of Dr. Manuel Lagravère)

### **1.1.3 Cephalometrics and the evaluation of changes due to expansion**

While conventional two-dimensional cephalometry will surely be antiquated by three-dimensional imaging in the future, it remains for now the most common standard for analyzing skeletal changes brought about by orthodontic interventions [Figure 1-3]. Well-designed maxillary expansion studies using lateral and posteroanterior (PA) cephalograms to measure treatment changes are numerous<sup>[12, 33-53]</sup>, and reliability of the methods has been shown<sup>[54, 55]</sup>.



**Figure 1-3.** *Left:* Lateral cephalogram / *Right:* PA cephalogram

#### **1.1.4 Dental casts and the evaluation of changes due to expansion**

The use of casts in dentistry predates cephalometric radiography by over two centuries<sup>[56]</sup> [Figure 1-4]. Well-designed maxillary expansion studies using dental casts to measure treatment changes are numerous<sup>[15, 36, 42, 45, 49, 53, 57-72]</sup>, and reliability of the methods has been shown<sup>[57, 61]</sup>.



**Figure 1-4.** Dental cast

### **1.2 Research Problem and Rationale for Inquiry**

While the literature contains claims of, amongst other things, the lower degree of dental side-effects and the superior stability of surgically-assisted BME over TME<sup>[16-30]</sup>, these are not substantiated by rigorous evidence. Furthermore, the topic of non-surgically-assisted BME has not been studied until recently<sup>[31, 32]</sup>. There is thus a need for scientifically sound investigations of the topic of BME.

### **1.3 Investigative Method**

In 2005, a randomized controlled trial designed to compare the longitudinal effects of non-surgically-assisted TME and BME was started at the *University of Alberta*. A doctoral thesis on the three-dimensional imaging findings of the study has since been completed<sup>[31]</sup>, and other raw data collected on the same subjects are analyzed in the present study; these other raw data consist of lateral cephalograms, PA cephalograms, and dental casts.

## 1.4 Study Aim and Research Questions

The aim of this study is to gain a better understanding of the differences, if any, between the longitudinal dentoskeletal changes seen in non-surgically-assisted TME, non-surgically-assisted BME, and untreated subjects (Control group). Specifically, answers to the following research questions are sought:

- Q1. Are there between-group differences in the dental and skeletal changes seen during the *expansion phase*, i.e., the time period between pre-treatment baseline measurements (T1) and the end of active expansion (T2)?
- Q2. Are there between-group differences in the dental and skeletal changes seen during the *retention phase*, i.e., the time period between the end of active expansion (T2) and the removal of the passive expansion appliance (T3)?
- Q3. Are there between-group differences in the dental and skeletal changes seen during the *settling/post-retention phase*, i.e., the time period between the removal of the passive expansion appliance (T3) and a time point ~6 months later (T4)?
- Q4. Are there between-group differences in the dental and skeletal changes seen during the entire *post-expansion phase*, i.e., the time period between the end of active expansion (T2) and a time period ~11 months later (T4)?
- Q5. Are there between-group differences in the dental and skeletal changes seen during the *pre-settling phase*, i.e., the time period between pre-treatment baseline measurements (T1) and the end of retention (T3)?
- Q6. Are there between-group differences in the dental and skeletal changes seen over the entire observation period (*overall phase*), i.e., the time period between pre-treatment baseline measurements (T1) and a time point ~12 months later (T4)?

Q1 pertains to (a) the immediate dentoskeletal changes produced by the two expansion methods, and (b) the time-matched dentoskeletal changes taking place in untreated subjects.

Q2, Q3, and Q4 pertain to (a) the stability of these immediate dentoskeletal changes during the various post-expansion phases, and (b) the time-matched dentoskeletal changes taking place in untreated subjects.

Q5 pertains to (a) the overall dentoskeletal changes produced by the two expansion methods up to the end of retention, and (b) the time-matched dentoskeletal changes taking place in untreated subjects.

Q6 pertains to the overall dentoskeletal changes produced by the two expansion methods up to the end of the observation period of the study, and (b) the time-matched dentoskeletal changes taking place in untreated subjects.

## 1.5 Hypotheses

For each of the above-listed research questions, the following null and alternative hypotheses apply.

- Q1.  $H_0$ : There are no between-group differences in the dental and skeletal changes seen during the expansion phase (T1-T2).  
 $H_a$ : There are between-group differences in the dental and skeletal changes seen during the expansion phase (T1-T2).
- Q2.  $H_0$ : There are no between-group differences in the dental and skeletal changes seen during the retention phase (T2-T3).  
 $H_a$ : There are between-group differences in the dental and skeletal changes seen during the retention phase (T2-T3).
- Q3.  $H_0$ : There are no between-group differences in the dental and skeletal changes seen during the settling/post-retention phase (T3-T4).  
 $H_a$ : There are between-group differences in the dental and skeletal changes seen during the settling/post-retention phase (T3-T4).
- Q4.  $H_0$ : There are no between-group differences in the dental and skeletal changes seen during the post-expansion phase (T2-T4).

- H<sub>a</sub>: There are between-group differences in the dental and skeletal changes seen during the post-expansion phase (T2-T4).
- Q5. H<sub>0</sub>: There are no between-group differences in the dental and skeletal changes seen during the pre-settling phase (T1-T3).
- H<sub>a</sub>: There are between-group differences in the dental and skeletal changes seen during the pre-settling phase (T1-T3).
- Q6. H<sub>0</sub>: There are no between-group differences in the dental and skeletal changes seen over the entire observation period (T1-T4).
- H<sub>a</sub>: There are between-group differences in the dental and skeletal changes seen over the entire observation period (T1-T4).

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## **CHAPTER 2**

### **Systematic Review of Bone-Anchored Maxillary Expansion**

## 2.1 INTRODUCTION

Patients with a constricted maxillary arch can have concomitant sequelae such as posterior crossbites and dental crowding; correction of the constriction can therefore be required to establish proper form and function. Since its popularization in the mid-twentieth by Haas, maxillary expansion has become a well-established and widely-accepted method for correcting maxillary arch constriction.<sup>[1, 2]</sup>

In growing patients, a tooth-anchored maxillary expansion (TME) procedure can produce long-term increases in maxillary arch width and perimeter as concluded in a systematic review of the topic<sup>[3]</sup>. In most instances, however, the goal is to achieve this increased arch width and perimeter primarily via separation of the bony palatal shelves at the midpalatal suture rather than via dental tipping<sup>[4]</sup>. Be that as it may, maxillary expansion has traditionally been carried out by applying the expansion force to the teeth, in one form or another<sup>[5]</sup>, rather than directly to the bone; because of this, the unwanted dental side-effect of buccal crown-tipping seems unavoidable regardless of appliance activation and design, i.e., fixed vs. removable<sup>[6]</sup>, tooth-borne vs. tooth-tissue-borne<sup>[7]</sup>, bonded vs. banded<sup>[8]</sup>, slow activation vs. rapid activation<sup>[9]</sup>. Even if the expansion is accomplished almost solely by separation of the midpalatal suture in the initial stages of TME in growing patients, there is nothing to prevent the maxillary halves from relapsing back to their initial position soon after beginning the expansion procedure and even throughout the retention phase, during which time the expander holds the teeth rigidly in place<sup>[10]</sup>. Indeed, a controlled radiographic study showed that in the long-term, skeletal expansion accounts for only 25% of the total expansion seen clinically when TME is performed in pre-pubertal adolescents; in the post-pubertal population, the long-term skeletal contribution to the overall gain in arch width and perimeter was found to be insignificant in the long-term<sup>[11]</sup>. More to the point, effects secondary to achievement of an increase in arch width and perimeter by dental tipping can include opening of the bite<sup>[12]</sup>, buccal cortical bone dehiscence and recession<sup>[13]</sup>, root resorption<sup>[14]</sup>, and a

propensity for relapse<sup>[15]</sup>, though there is some controversy in the literature regarding the expected long-term extent and significance of these potential side-effects<sup>[3, 16, 17]</sup>.

In non-growing patients, the capacity for sutural opening via TME is minimal to nil<sup>[11, 18]</sup>. Therefore, when TME is attempted in a non-growing patient, the dental and periodontal side-effects as well as the post-expansion instability are often reported to be greater than those already described for growing patients<sup>[19-21]</sup>. For this reason, it is generally agreed that adults requiring maxillary arch expansion must first undergo a surgical procedure prior to commencing expansion, the purpose of which is to separate the tightly interlocked palatal shelves<sup>[22, 23]</sup>; the procedure is termed surgically-assisted tooth-anchored maxillary expansion (SATME). Though considered the expansion procedure of choice in skeletally mature patients by some, others have put into question the necessity of the surgical step<sup>[24-26]</sup>. In any case, because the expansion appliance is still anchored to the teeth, studies have shown that even with surgical assistance, the resultant expansion in the long-term is due more to dental tipping than to an increase in basal bone width, and the same drawbacks as with non-surgical expansion can thus be seen<sup>[27-29]</sup>. Moreover, the pre-expansion surgery must be performed in a hospital setting and carries the same medical risks as other types of maxillary orthognathic surgeries<sup>[30]</sup>; not surprisingly then, the overall cost of a treatment involving SATME is significantly greater than one involving simple TME<sup>[31]</sup>.

The aforementioned short-comings of traditional tooth-anchored expansion -with or without surgical assistance- lead researchers to seek ways to separate the midpalatal suture other than by the application of mechanical force through the intermediary of the teeth<sup>[32]</sup>. By the mid 1980s, the advent of dental implantology lead to animal studies in which solid anchors (titanium screws, plates, and/or implants) placed directly into bone were used instead of teeth to support the maxillary expansion appliance<sup>[33, 34]</sup>. In 1999, the first report of a human treated with a bone-anchored maxillary expansion (BME) device was published<sup>[35]</sup>; in the report, the expansion procedure was preceded by a surgical

procedure to facilitate the subsequent widening of the maxilla, so it is more properly termed a surgically-assisted bone-anchored maxillary expansion (SABME). In addition to eliminating the untoward dental and periodontal side-effects seen when SATME is employed, advocates of SABME reported the following advantages: a relatively greater expansion of the anterior than the posterior region of the maxilla, allowing for greater alleviation of anterior crowding as well as the attainment of a conventional U-shaped arch form (studies show that the expansion obtained with SATME is greater posteriorly than anteriorly<sup>[20, 29]</sup>, resulting in a more V-shaped arch form); a more favorable force system since the expansion force is applied closer to the area of interest, i.e., the midpalatal suture; the possibility of beginning full fixed appliance therapy during the retention phase, thereby reducing the overall treatment time; the ability to expand the arches of patients who do not have teeth to support a tooth-anchored device; less risk in expanding the arches of patients with pre-existing periodontal disease; greater stability since the expansion is the result of a true basal bone width increase rather than dental tipping<sup>[35-49]</sup>.

So far, two meta-analyses<sup>[50, 51]</sup> and five systematic reviews<sup>[3, 5, 21, 52, 53]</sup> pertaining to TME have been published, and two systematic reviews related to SATME are in the current literature<sup>[29, 54]</sup>. However, no systematic reviews related to BME or SABME have been published to date. If the potential advantages of BME/SABME over TME/SATME are confirmed by scientific inquiry, the impact on orthodontic treatment could be important since maxillary arch constriction is a relatively common problem<sup>[55, 56]</sup>.

The objective of this systematic review is to evaluate the dental and/or skeletal changes seen at least three months after completion of active expansion using BME or SABME procedures. A three-month period was chosen since previous studies show that this is the minimum retention period that should be observed following maxillary expansion procedures<sup>[57-60]</sup>.

## 2.2 METHODS

The following electronic databases were searched for articles pertaining to the topic of this systematic review: Medline (1950 to week 5 of January 2008), Medline In-Process & Other Non-Indexed Citations (week 5 of January 2008 to week 1 of February 2008), PubMed (1950 to week 1 of February 2008), Web of Science (1900 to week 1 of February 2008), and All Evidence-Based Medicine (EBM) Reviews (up to first quarter of 2008), i.e., Cochrane Database of Systematic Reviews (DSR), American College of Physicians (ACP) Journal Club, Database of Abstracts of Reviews of Effectiveness (DARE), Cochrane Control Trials Register (CCTR), Cochrane Methodology Register (CMR), Health Technology Assessment (HTA), and National Health Service Economic Evaluation Database (NHSEED). The searches were conducted without language restrictions. The search strategies employed were discussed with a senior researcher experienced in the field of systematic reviews.

Retention and rejection of articles returned by the database searches were based on the following protocol. Initial inclusion criteria applied to the abstracts/titles: Any study or case report in which (1) maxillary expansion was accomplished by a bone- rather than a tooth-anchored appliance, and (2) subjects were human. In situations where the information contained in the title and abstract was insufficient to make a reasonable assumption as to whether these initial inclusion criteria were met, the full-length paper was retrieved and read. The full-length articles of all the references which appeared to meet the initial inclusion criteria were then retrieved and read in their entirety, and their reference sections were manually searched for any articles potentially relevant to this systematic review, but which were absent from the electronic search results. The initial inclusion criteria were then again applied to the full-length articles with the addition of a final exclusion criterion: Articles were rejected if records were not taken and evaluated at a pre-expansion time point as well as at a time point at least 3 months post-expansion. Only the articles which passed both screenings would become the subject of this systematic review. At all stages of article

selection and rejection, two researchers independently decided which articles should pass on to the next phase; any discrepancies were settled through discussion and mutual agreement.

## 2.3 RESULTS

The various database search strategies are presented in Table 2-1. The progression and distribution of the results obtained by following the aforementioned protocol are listed in Table 2-2.

**Table 2-1.** Database search strategy

	Search Strategy
Medline	(1) Palatal Expansion Technique/; (2) palat* expan*.mp; (3) maxil* expan*.mp; (4) bone borne.mp; (5) skelet* borne.mp; (6) bone anchor*.mp; (7) skelet* anchor*.mp; (8) implant*.mp; (9) miniscrew*.mp; (10) miniplate*.mp; (11) temporary anchorage device.mp; (12) tad.mp; (13) tads.mp; (14) 1 or 2 or 3; (15) 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13; (16) 14 and 15
Medline In-Process & Other Non-Indexed Citations	(1) Palatal Expansion Technique/; (2) palat* expan*.mp; (3) maxil* expan*.mp; (4) bone borne.mp; (5) skelet* borne.mp; (6) bone anchor*.mp; (7) skelet* anchor*.mp; (8) implant*.mp; (9) miniscrew*.mp; (10) miniplate*.mp; (11) temporary anchorage device.mp; (12) tad.mp; (13) tads.mp; (14) 1 or 2 or 3; (15) 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13; (16) 14 and 15
PubMed	(1) palatal expansion technique; (2) palat* expan*; (3) maxil* expan*; (4) bone borne; (5) skelet* borne; (6) bone anchor*; (7) skelet* anchor*; (8) implant*; (9) miniscrew*; (10) miniplate*; (11) temporary anchorage device; (12) tad; (13) tads; (14) #1 or #2 or #3; (15) #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13; (16) #14 and #15
Web of Science	(1) Topic = (palat* expan*); (2) Topic = (maxil* expan*); (3) Topic = (bone borne); (4) Topic = (skelet* borne); (5) Topic = (bone anchor*); (6) Topic = (skelet* anchor*); (7) Topic = (implant*); (8) Topic = (miniscrew*); (9) Topic = (miniplate*); (10) Topic = (temporary anchorage device); (11) Topic = (tad); (12) Topic = (tads); (13) #1 OR #2; (14) #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12; (15) #13 AND #14
All EBM Reviews	(1) palat* expan*.mp; (2) maxil* expan*.mp; (3) bone borne.mp; (4) skelet* borne.mp; (5) bone anchor*.mp; (6) skelet* anchor*.mp; (7) implant*.mp; (8) miniscrew*.mp; (9) miniplate*.mp; (10) temporary anchorage device.mp; (11) tad.mp; (12) tads.mp; (13) 1 or 2; (14) 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12; (15) 13 and 14

**Table 2-2.** Progression and distribution of results<sup>a</sup>

	Total Hits	Full Articles Collected (34 total)	Fulfilled Inclusion Criteria (14 total)	% of Total Fulfilling Inclusion Criteria	Finally Selected (3 total)	% of Total Finally Selected
Medline	60	24	11	78.6	3	100
Medline In-Process & Other Non-Indexed Citations	0	-	-	-	-	-
PubMed	261	25	12	85.7	3	100
Web of Science	161	15	5	35.7	1	33.3
All EBM Reviews	1	0	0	0	0	0

<sup>a</sup>Some articles appeared in the results of more than one database search; as such, column totals do not add up to the total number of articles retained at each stage, and percentages listed do not add up to 100.

It can be noted that the proportion of articles ultimately fulfilling the initial inclusion criteria relative to the total number of hits returned is greatest with Medline (11 of 60); the Medline Search was therefore the most specific. The Web of Science search yielded the least specific results (5 of 161), and the PubMed search was sensitive, but not particularly specific (12 of 261). No EBM reviews on the topic of BME/SABME were found.

The full-length article for thirty-four references across all the databases were collected either because (1) the title and abstract of the reference gave good reason to believe that the initial inclusion criterion would be met, or (2) the reference could not be immediately rejected based on the information provided in the title and abstract alone. Upon reading the full articles for these thirty-four references, however, only nineteen truly met the initial inclusion criteria; a manual search of the reference sections of these nineteen articles did not yield any potentially useful references that were not returned in the electronic searches.

After applying the final exclusion criterion to the nineteen selected articles, only three<sup>[39, 42, 44]</sup> remained. Fourteen<sup>[35-37, 40, 41, 43, 45-47, 49, 61-64]</sup> of the other sixteen references were rejected at this final stage because post-expansion records evaluating dental and/or skeletal changes at a time point at least 3 months post-expansion were absent. The two other articles<sup>[38, 48]</sup> were rejected because they used the same study sample as two of the finally selected articles<sup>[39, 44]</sup>; in both cases, the finally selected articles contained a more detailed data treatment, and they were retained over their sister articles for this reason.

A summary of the three finally selected studies is given in Table 2-3. A methodological checklist designed to quantitatively assess the quality of clinical trials was applied to these three studies [Table 2-4], and the results of this assessment are presented in Table 2-5. This checklist (Table 2-4) and score table (Table 2-5) were previously published in a systematic review evaluating the long-term skeletal changes produced by rapid maxillary expansion<sup>[21]</sup>.

**Table 2-3.** Finally selected articles

	Design	Sample	Procedure	Method of Evaluation
Hansen et al. [44]	Prospective, longitudinal, experimental	-12 patients (genders N/S) -Mean age: 25.3y -Age range: 17-36y	SABME with bone-anchored distractor (Dresden Distractor)	Standardized axial computed tomography (CT scan)
Gerlach et al. [39]	Prospective, longitudinal, experimental	-9 F, 1 M -Mean age: 25.8y -Age range: 12-37y	SABME with bone-anchored distractor	Plaster casts & Two-dimensional radiography
Ramieri et al. [42]	Prospective, longitudinal, experimental	-21 F, 8 M -Mean age: 26.4y -Age range: N/S	SABME with bone-anchored distractor (TPD - <u>T</u> ranspalatal <u>D</u> istractor)	Two-dimensional radiography

<sup>a</sup>N/S = Not specified

**Table 2-4. Methodological Quality Checklist for Clinical Trials<sup>a,b</sup>**

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**I. Study Design (9 √)**

- A. Objective – objective clearly formulated (√)
- B. Population – described (√)
- C. Selection criteria – clearly described (√); adequate (√)
- D. Sample Size – considered adequate (√); estimated before collection of data (√)
- E. Baseline characteristics – similar baseline characteristics (√)
- F. Timing – prospective (√)
- G. Randomization – stated (√)

**II. Study Measurements (5√)**

- H. Measurement method – appropriate to the objective (√)
- I. Blind measurement – blinding (examiner √, statistician √)
- J. Reliability – described (√), adequate level of agreement (√)

**III. Statistical Analysis (6√)**

- K. Dropouts – dropouts included in data analysis (√)
- L. Statistical analysis – appropriate for data (√); combined subgroup analysis (√)
- M. Confounders – confounders included in analysis (√)
- N. Statistical significance level – P value stated (√); confidence intervals (√)

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<sup>a</sup>Adapted from Lagravère et al. 2005 [21]

<sup>b</sup>Maximum number of check points (√) = 20

**Table 2-5. Methodological Quality Checklist Score for the three finally selected articles<sup>a</sup>**

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	Checks/ Total
Hansen et al. [44]	√	√	± -	- -	N/A	√	N/A	√	- -	√ ±	N/A	√ -	-	± √	8.5 / 17
Gerlach et al. [39]	√	±	- -	- -	N/A	√	N/A	√	- -	- -	N/A	- -	-	- -	3.5 / 17
Ramieri et al. [42]	√	±	± -	- -	N/A	√	N/A	√	- -	- -	-	- -	-	- -	4 / 18

<sup>a</sup>Scoring is as follows: “√” indicates that the criterion was satisfied, and 1 check point is awarded; “±” indicates that the criterion was partially satisfied, and a ½ check point is awarded; “-” indicates that the criterion was not satisfied, and no check point is awarded. “N/A” indicates that the criterion is not applicable to the study in question.

It can be seen that all three studies scored poorly on the Methodological Quality Checklist. A significant problem common to all studies was the small sample size.

### **2.3.1 Skeletal and dental changes in patients undergoing SABME**

In the study by Hansen et al.<sup>[44]</sup>, dental, alveolar process, and bony skull landmarks on CT scans were used to measure changes between two time points: T<sub>0</sub> (pre-expansion) and T<sub>1</sub> (3-11 months post-expansion). In the sagittal plane, there was mesial migration of skeletal and dental landmarks in both the maxilla (0.5-0.8mm) and in the mandible (0.9-2.6mm). In the vertical plane, the mandible and its teeth rotated superiorly (1.0-2.7mm) while the maxilla and its dentition remained unchanged. In the transverse plane, mean buccal-tipping of all areas of the maxillary alveolar process was statistically significant (8.01- 9.66°,  $p \leq 0.01$ ), as was that of the right maxillary premolars (4.62°,  $p \leq 0.01$ ); mean buccal-tipping of the right maxillary molars and left maxillary premolars was statistically significant (2.58-3.09°,  $p \leq 0.05$ ); mean buccal-tipping of the right maxillary molars was not significant (1.13°). The following mean transverse width increases were found: 3mm in the midpalatal suture at the height of the anterior nasal spine; 0.97mm in the midpalatal suture at the height of the posterior nasal spine; 4.24mm in the midpalatal suture at the height of *A point*; 5.55mm and 4.87mm for the alveolar processes in the premolar and molar region respectively; 6.07mm and 5.71mm for first premolar and first molar crowns respectively; 4.28 and 4.98mm for first premolar and first molar root apices respectively. From these figures, the authors calculated that, on average, 85% of the expansion at the level of the molars and 91% of the expansion at the level of the premolars was achieved skeletally. Furthermore, comparing the amount of dental buccal tipping recorded in their study with that found in studies on SATME, the authors stated that SABME produces less buccal tipping of teeth. The authors concluded that “the negative side-effects associated with tooth-borne expansion appliances, such as root resorption, attachment loss and buccal tipping of teeth, are thus prevented” by SABME.

In the study by Gerlach et al.<sup>[39]</sup>, plaster casts were made of the subjects' maxillary arches at three time points: T<sub>0</sub> (pre-expansion), T<sub>1</sub> (immediately post-expansion), T<sub>2</sub> (6 months post-expansion). At each time point, three transverse measurements were taken: intercanine distance (ICD), anterior dental arch width (ADA), and posterior dental arch width (PDA). Subjects underwent maxillary expansion until complete correction of the lateral cross-bites. Mean increases between T<sub>0</sub> and T<sub>1</sub> were as follows: ICD = 8.8mm, ADA = 8.6mm, PDA = 8.3mm. The range of variation between the width measurements taken at T<sub>1</sub> and T<sub>2</sub> were: ICD = +0.5 to -1mm, ADA = +0.5 to -1mm, PDA = -0.5 to -1mm. An undisclosed number of study participants also had panoramic and maxillary occlusal radiographs taken at roughly the same three time points. At T<sub>1</sub>, incipient ossification of the palatal suture was noted. At T<sub>2</sub>, advanced ossification was noted. In three cases, complete ossification of the midpalatal suture was verified clinically as flap surgery was required for removal of the expander. The authors concluded that with SABME, "all problems induced by forces acting upon anchorage teeth are eliminated" and "the technique for maxillary expansion [is] free of complications and relapses".

In the study by Ramieri et al.<sup>[42]</sup>, twenty-three of the twenty-nine enrolled subjects were radiographically examined at three time points: T<sub>0</sub> (pre-expansion), T<sub>1</sub> (immediately post-expansion), T<sub>2</sub> (4-6 months post-expansion). An unspecified number of study participants were also examined radiographically at T<sub>3</sub> (1 year post-expansion). The following radiographs were used: anteroposterior & lateral cephalograms, panoramic radiographs, occlusal radiographs, and periapical radiographs (of the maxillary central incisors only). At T<sub>1</sub>, all subjects had a homogeneous transparency along the entire line of the osteotomy. At T<sub>2</sub>, subjects revealed a variable amount of newly formed bone along the entire line of the osteotomy; the authors also noted that the trabeculae of forming bone were predominantly oriented parallel to the distraction pathway. Spontaneous migration of the central incisors toward the midline was also noted at this time. At T<sub>3</sub>, complete bone-healing was observed in all patients. The authors thus concluded

that SABME provided osseous enlargement that was maintained at 1 year post-expansion.

### **2.3.2 Skeletal and dental changes in patients undergoing BME**

Only one article<sup>[64]</sup> reported the use of BME. It was a case report on the use of bone screws and plates for protraction and expansion of the hypoplastic maxilla of an eleven year-old girl with hypodontia; no follow-up data was provided, however, and the article was therefore discarded at the final screening point. Proffit<sup>[60]</sup> also presented the use of BME in a case similar to that reported in the latter article, but no quantitative data was provided. Our electronic and manual searches of the literature therefore reveal that there are no publications on BME at this time which meet the criteria for inclusion in this systematic review.

## **2.4 DISCUSSION**

The tooth-anchored expanders used in TME and SATME procedures have for a long time provided clinicians with a way of increasing arch width and length in patients with maxillary constriction<sup>[1, 3, 5, 22, 23]</sup>. However, it has been shown that these increases are the result primarily of buccal crown-tipping rather than, as once thought, an increase in basal bone width through separation of the midpalatal suture<sup>[11, 19, 20, 60]</sup>. Buccal crown-tipping isn't necessarily a concern in and of itself, but its potential ancillary effects -including poor stability and negative periodontal manifestations- can be<sup>[12-15, 27-29]</sup>.

Because the above-outlined problems with traditional TME and SATME procedures are thought to be primarily the result of the expander being anchored to teeth as well as the lack of measures in place to prevent skeletal relapse, direct anchorage of the expander to the palatal shelves of the maxilla would appear, from a theoretical standpoint, to resolve both issues simultaneously seeing as no force would be placed directly on the teeth, and the bony maxillary halves would be mechanically prevented from returning back to their starting point. Other surmised advantages of bone-anchorage for maxillary expansion include: the

option of beginning full fixed therapy while the expander is still in place during the retention phase; the observation that expansion with skeletal anchorage is greater in the anterior portion of the arch; the more favorable location of force application (i.e., closer to the midpalatal suture); the ability to expand the arches of patients who cannot support a tooth-anchored expander (e.g., patients with hypodontia or periodontal disease).<sup>[35-49]</sup>

Since 1999, the use of bone-anchored expansion appliances in humans has been reported with some frequency in the literature<sup>[35-49, 61-64]</sup>; most are case reports pertaining to SABME.

After applying the inclusion and exclusion criteria to the relevant articles that were returned by our electronic database searches of studies pertaining to BME or SABME, only three were retained for full analysis in this systematic review<sup>[39, 42, 44]</sup>. As reflected by their relatively low score on the Methodological Quality Checklist (see Tables 2-4 and 2-5), however, these studies do not offer a very high level of evidence, and their results must therefore be interpreted with caution. Nevertheless, at this time, they represent the best available evidence on short-term dental and skeletal changes following SABME. It should be noted that two excellent studies<sup>[36, 37]</sup> from a methodological standpoint were excluded from this systematic review because they only evaluated the changes seen immediately post-expansion; the dental cast measurements from one of the finally selected studies<sup>[42]</sup> were also excluded from this paper for the same reason.

The results presented by Hansen et al.<sup>[44]</sup> warrant further discussion. The authors attributed the sagittal maxillary skeletal changes to the normal effect of maxillary expansion on *A point* as cited by others<sup>[20, 65]</sup>, and they attributed the sagittal maxillary dental changes to a mesial migration of the teeth toward the midline diastema created by the expansion; both explanations seem theoretically reasonable. They attributed the vertical and sagittal dental and skeletal changes seen in the mandible to a counter-clockwise autorotation of the latter made possible by the “largely skeletal expansion together with minimal dental tipping” in the maxilla; still, in the absence of maxillary skeletal or dental displacement superiorly, it is difficult to see why the mandible would undergo a counter-

clockwise autorotation. Finally, the authors attributed the higher buccal-tipping of the alveolar processes as compared to the teeth to the concurrent use of a full fixed appliance (which has an uprighting effect on the teeth) as well as a direct transfer of force to the bone; these explanations seem theoretically reasonable. As for the authors' claim that SABME produces less dental buccal tipping than SATME, the confidence intervals of the SATME studies chosen for comparison overlap with those of their own SABME study; from a clinical standpoint, this claim is thus not substantiated by their data. Moreover, it should be noted that the standard deviations are frequently larger than the mean measurements, indicating that the effect measured is not predictable even if statistically significant.

The authors of all three qualifying studies concluded that SABME produced skeletal expansion without extensive dental side-effects or relapse, and that SABME was therefore was an improved alternative to traditional SATME. These conclusions do not appear to be solidly supported by the data they obtained, however, and their study design flaws further put into question the believability of these conclusions. For instance, full fixed appliance therapy was undertaken on all study subjects prior to the completion of data collection; dental changes due to SABME are thus difficult -if not impossible- to interpret. Also noteworthy is the wide age-range of patients treated with SABME in each study (Table 2-3), the large standard deviations in measurement changes, the lack of adequate statistical analysis and powering, and small study samples. Lastly, none of the studies produced comparative data or had set controls. Many of these design flaws make it difficult to determine which effects are due to the expansion procedure itself and which are due to adjunctive dental therapy and/or normal growth & development. These flaws also make it difficult to claim any superiority of the intervention over another. Any conclusions drawn from this secondary level of evidence are thus questionable at best.

In summary, the current literature contains inadequate information to comment on the effects of BME. As for SABME, the published short-term dental and skeletal effects are thus far encouraging, but not conclusive. Existing studies on the topic lack scientific rigor, and their weaknesses have been outlined in the

preceding paragraph and in Tables 2-4 and 2-5. In order to produce more believable conclusions, long-term, comparative, controlled, adequately powered & statistically-analyzed, prospective, longitudinal, randomized, blinded studies - without any adjunctive dental treatment over the period of data collection- should ideally be undertaken. Such studies will help determine (1) the true dental & skeletal effects of BME/SABME in the long-term, and (2) the true advantages of BME/SABME -if any- over traditional TME/SATME and over unadulterated growth alone. It should be kept in mind that the use of bone-anchored expanders implies greater risk, invasiveness, and cost to the patient; scientific evidence of a clinically significant difference over lower risk, less invasive, and less costly procedures is thus needed before recommending their common use.

## 2.5 CONCLUSIONS

The following conclusions can be drawn from the results of this systematic review:

- The current literature contains only a secondary level of evidence with regards to dental and skeletal changes produced by SABME, and caution must therefore be exerted in interpreting the results;
- Short-term skeletal vertical changes produced by SABME are inconclusive;
- Short-term skeletal sagittal changes produced by SABME are inconclusive;
- In the short-term, SABME produces an increase in the transverse skeletal dimension of the maxilla;
- In the short-term, SABME produces buccal-tipping of the maxillary teeth, and it is not clear if it does so to a lesser extent than that seen with SATME;
- The current literature contains insufficient information to comment on the short-term dental and/or skeletal effects of BME.

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## **CHAPTER 3**

### **Tooth-Anchored Vs. Bone-Anchored Maxillary Expansion: A randomized controlled trial comparing dental and skeletal effects**

### 3.1 INTRODUCTION

Since its popularization in the mid-twentieth century by Haas, maxillary expansion has become a well-established and widely-accepted method for correcting maxillary arch constrictions.<sup>[1, 2]</sup>

In growing patients, a tooth-anchored maxillary expansion (TME) procedure can produce long-term increases in maxillary arch width as concluded in a systematic review of the topic<sup>[3]</sup>. In most instances, however, the goal is to achieve this increased arch width primarily via separation of the bony palatal shelves at the midpalatal suture -resulting in an increase in basal bone width- rather than via dental tipping<sup>[4]</sup>. Be that as it may, maxillary expansion has traditionally been carried out by applying the expansion force to the teeth rather than directly to the palatal shelves<sup>[5]</sup>. Because of this, unwanted dental side-effects are unavoidable, and end results are similar for all forms of TME, i.e., fixed vs. removable<sup>[6]</sup>, tooth-borne vs. tooth-tissue-borne<sup>[7]</sup>, bonded vs. banded<sup>[8]</sup>, slow activation vs. rapid activation<sup>[9]</sup>.

Furthermore, even if a separation of the midpalatal suture is seen in the initial stages of TME in growing patients, there is nothing to prevent the maxillary halves from relapsing back to their initial position soon after beginning the expansion procedure -and even throughout the retention phase-, ultimately resulting in buccal crown tipping<sup>[10]</sup>. Indeed, a controlled radiographic study showed that in the long-term, skeletal expansion accounts for only 25% of the total expansion seen clinically when TME is performed in pre-pubertal adolescents; in post-pubertal subjects, the long-term skeletal contribution to the overall gain in arch width and perimeter was found to be insignificant<sup>[11]</sup>. More to the point, effects secondary to achievement of an increase in arch width by dental tipping -rather than by true bony expansion- can include opening of the bite<sup>[12]</sup>, buccal cortical bone dehiscence and recession<sup>[13]</sup>, root resorption<sup>[14]</sup>, and a propensity for relapse<sup>[15]</sup>. There is some controversy in the literature regarding the expected long-term extent and significance of some of these potential side-effects, however<sup>[3, 16, 17]</sup>.

The aforementioned short-comings of TME lead researchers to seek ways of separating the midpalatal suture other than by the application of mechanical force through the intermediary of the teeth<sup>[18]</sup>. By the mid 1980s, the advent of dental implantology lead to animal studies in which solid anchors (titanium screws, plates, and/or implants) placed directly into bone were used instead of teeth to support the maxillary expansion appliance<sup>[19, 20]</sup>. In 1999, the first report of a human treated with a bone-anchored maxillary expansion (BME) device was published<sup>[21]</sup>.

Many existing reports pertaining to BME indicate that width increases are more stable and that fewer dental side-effects are produced compared to TME. Unfortunately, these claims are based on either case reports or expansion procedures involving a preliminary surgery and other concurrent therapy.<sup>[21-35]</sup>

If these potential advantages of BME over TME were confirmed by sound scientific investigation, however, the impact on orthodontic treatment would be important since maxillary arch constriction is a relatively common problem<sup>[36, 37]</sup>. The topic of TME has been extensively studied and reviewed. Indeed, two meta-analyses<sup>[38, 39]</sup> and five systematic reviews<sup>[3, 5, 40-42]</sup> pertaining to the dental and skeletal effects of TME have thus far been published; conclusions are mixed. However, aside from the present ongoing study<sup>[43, 44]</sup>, there are no studies which have investigated the use of non-surgically-assisted BME. There are, however, several studies which have reported the use of BME in conjunction with surgical assistance<sup>[21-35]</sup>. Of these studies, only two<sup>[25, 30]</sup> provide quantitative data related to skeletal and/or dental measurements at the pre-expansion time point as well as at a time point at least 3 months post-expansion, which is generally considered the minimum retention period which should be observed following maxillary expansion procedures<sup>[10, 45-47]</sup>. Furthermore, both of these studies unfortunately contain design flaws which hinder the interpretability of their results. For instance, neither study was controlled to factor out changes due to normal growth (subjects in their early teens were included in these studies), and full fixed appliance therapy was undertaken on all subjects prior to the completion of data collection in both studies as well; dental and skeletal changes due to the

surgically-assisted BME are thus difficult -if not impossible- to differentiate from those induced by the full fixed appliance therapy.

From the above, it can be concluded that sound scientific evidence of the advantages of BME, with or without surgery, over TME is lacking. The aim of the present study is to gain a better understanding of the differences, if any, between the longitudinal dentoskeletal changes -and the stability of these changes- produced by TME, non-surgically-assisted BME, and unadulterated growth of adolescents with maxillary constriction. Specifically, answers to the following research questions are sought:

- Q1. Are there between-group differences in the dental and skeletal changes seen during the *expansion phase*, i.e., the time period between pre-treatment baseline measurements (T1) and the end of active expansion (T2)?
- Q2. Are there between-group differences in the dental and skeletal changes seen during the *retention phase*, i.e., the time period between the end of active expansion (T2) and the removal of the passive expansion appliance (T3)?
- Q3. Are there between-group differences in the dental and skeletal changes seen during the *settling/post-retention phase*, i.e., the time period between the removal of the passive expansion appliance (T3) and a time point ~6 months later (T4)?
- Q4. Are there between-group differences in the dental and skeletal changes seen during the entire *post-expansion phase*, i.e., the time period between the end of active expansion (T2) and a time period ~11 months later (T4)?
- Q5. Are there between-group differences in the dental and skeletal changes seen during the *pre-settling phase*, i.e., the time period between pre-treatment baseline measurements (T1) and the end of retention (T3)?
- Q6. Are there between-group differences in the dental and skeletal changes seen over the entire observation period (*overall phase*), i.e., the time period between pre-treatment baseline measurements (T1) and a time point ~12 months later (T4)?

Q1 pertains to (a) the immediate dentoskeletal changes produced by the two expansion methods, and (b) the time-matched dentoskeletal changes taking place in untreated subjects.

Q2, Q3, and Q4 pertain to (a) the stability of these immediate dentoskeletal changes during the various post-expansion phases, and (b) the time-matched dentoskeletal changes taking place in untreated subjects.

Q5 pertains to (a) the overall dentoskeletal changes produced by the two expansion methods up to the end of retention, and (b) the time-matched dentoskeletal changes taking place in untreated subjects.

Q6 pertains to the overall dentoskeletal changes produced by the two expansion methods up to the end of the observation period of the study, and (b) the time-matched dentoskeletal changes taking place in untreated subjects.

## **3.2 MATERIALS AND METHODS**

Raw data for this study was obtained from an ongoing clinical trial being conducted at the *University of Alberta*<sup>[43, 44]</sup>; as such, the steps described in sections 3.2.1 to 3.2.3 were carried out prior to the commencement of the present study. The present study was approved by the *University of Alberta Health Research Ethics Board* [Appendix A].

### **3.2.1 Sample Selection and Size**

Selection criteria were the following: Healthy, non-syndromic human adolescent subjects (11-17 years old) with maxillary constriction. Maxillary constriction was considered present when the buccal cusp of at least one maxillary posterior tooth was in an edge-to-edge relationship (or worse) with its mandibular antagonist in centric relation. All study subjects were recruited from the *University of Alberta Graduate Orthodontic Clinic* patient pool.

As many suitable subjects as possible were enrolled in the study during an 18 month recruitment window; a power analysis was not performed. In the end,

62 suitable subjects were recruited for participation in the study. Subjects were assigned a code for blinding and were then randomized to one of three groups by an independently working statistician. The randomization procedure resulted in the following: 20 subjects in the TME group; 21 subjects in the BME group; 21 subjects in the Control group.

### **3.2.2 Study Design**

Subjects in the TME group were fitted with a traditional banded four-tooth-anchored Hyrax expansion appliance (see Figure 1-1) cemented with *GC Fugii Plus* (*GC America*, Alsip, IL, USA) glass ionomer cement. Their expansion screw was turned at home twice a day (0.25mm per turn for a total activation of 0.5mm per day) until the maxillary constriction was overcorrected by ~1mm per side.

Subjects in the BME group were fitted with a *Palex II Extra-Mini Expander* (*Summit Orthodontic Services*, Munroe Falls, OH, USA) appliance which was directly anchored to the maxillary palatal bones via custom-milled stainless steel onplants (3mm thickness, 8mm diameter) secured by titanium mini screws (12mm length, 1.5mm diameter, *Straumann GBR-System* by *Straumann*, Mandover, MA, USA) (see Figure 1-2). Their expansion screw was turned at home once every other day (0.25mm per turn for a total activation of 0.125mm per day) until the maxillary constriction was overcorrected by ~1mm per side.

In both the TME and BME groups, the expander was left passively in place as a retainer for a period of ~5 months after achieving the slight overcorrection of the maxillary constriction. The expander was then removed, and the subjects were observed for an additional ~6 months (see section 3.2.3.1).

Control group subjects received no treatment for the duration of the study.

### **3.2.3 Data Collection**

All data for this study were collected between October 2005 and May 2008 on the *University of Alberta* premises.

### 3.2.3.1 Data collection timeline

The study design called for data collection at the following four time points:

T1: Pre-treatment baseline

T2\*: Immediately post-expansion

T3: Just prior to expander removal (~5 months post-expansion)

T4: ~6 months after expander removal

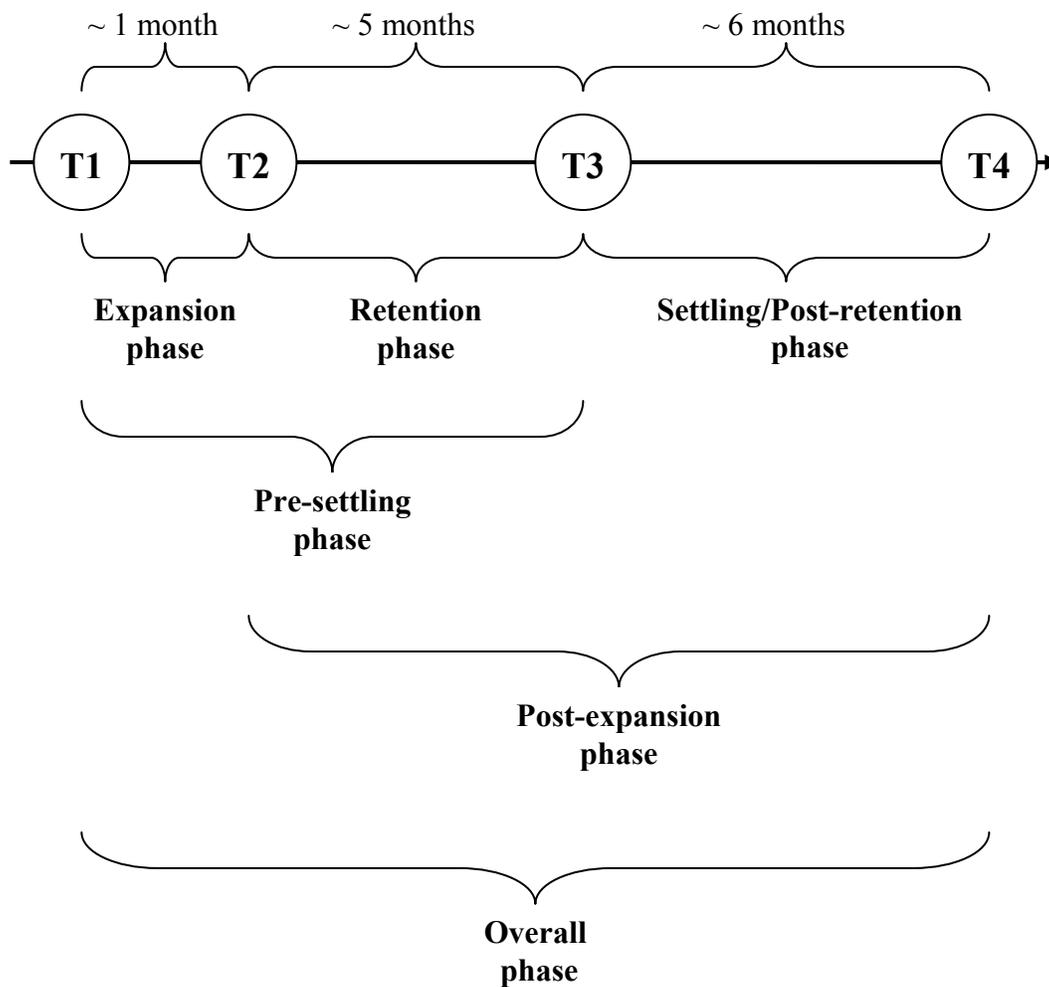
\*Control group subjects did not have records taken at T2 seeing as the expansion procedure was expected to be completed in a matter of a few weeks to a few months, and discernable changes due to growth were unlikely in this short timeframe. Thus, for analytical purposes, T1 values were also used at T2 for Control group subjects, the assumption being that the baseline values had not changed significantly in that time.

A description of the intervals between the data collection time points is provided in Table 3-1. Figure 3-1 graphically depicts the planned data collection timeline.

**Table 3-1.** Data collection time point intervals and phases of the study

Interval	Phase	Planned Duration <sup>a</sup>	Description
T1-T2	Expansion	~1 month	Time period during which the expansion screw was turned
T2-T3	Retention	~5 months	Time period during which the expander was left passively in place as a retainer
T3-T4	Settling (Post-retention)	~6 months	Time period during which neither an active or passive outside force was applied to the teeth or jaws
T2-T4	Post-expansion	~11 months	Time period after the completion of active expansion; encompasses retention and post-retention phases
T1-T3	Pre-settling	~6 months	Time period from the pre-treatment baseline to the end of retention; encompasses expansion and retention phases
T1-T4	Overall	~12 months	Time period from the pre-treatment baseline to the end of the observation period; encompasses all phases

<sup>a</sup>The actual duration of each interval per study group is provided in Table 3-2.



**Figure 3-1.** Planned data collection timeline

At each of the four data collection time points, the primary collected data consisted of a cone beam image, conventional plain film lateral and PA cephalograms, and dental casts. The plain film cephalograms and dental casts are the records of interest for the study herein; the cone beam images were analyzed in a separate thesis<sup>[44]</sup>.

### 3.2.3.2 Cephalograms

Cephalograms were taken with an *Orthoceph OC100 (Instrumentarium Imaging, Milwaukee, WI, USA)* radiographic unit. *FUGI Super-HRS 30 Film (20 X 25cm by FugiFilm, Mississauga, ON, Canada)* and regular rare earth green-light-emitting *Kodak Lanex Intensifying Screens (Kodak, Rochester, NY, USA)* were used. An automatic processor (*Kodak M35A*) was used to develop and fixate the radiographs (Developing solution: *Kodak RP X-Omat* / Fixing solution: *Kodak RP X-Omat LO*).

For lateral cephalograms, radiographic settings were generally 0.64s, 12mA, 73kV, and a soft tissue filter was used. Subjects were positioned with their midsagittal plane 60 inches from the radiographic source plane using a head positioning device consisting of bilateral ear rods and a nose support. The film cassette was positioned perpendicular to the central ray at a distance of 15cm from the midsagittal plane. This protocol ensured consistent head positioning and magnification from one exposure to the next.

For PA cephalograms, radiographic settings were generally 0.8s, 12mA, 73 kV, and a soft-tissue filter was not used. Subjects were positioned with their midcoronal plane 60 inches from the radiographic source plane using a head positioning device consisting of bilateral ear rods and a nose support. The film cassette was positioned perpendicular to the central ray at a distance of 15cm from the midcoronal plane. This protocol ensured consistent head positioning and magnification from one exposure to the next.

### 3.2.3.3 Dental casts

Impressions were taken in *Basis Type 1 Fast Set Alginate (Ormco, Orange, CA, USA)* using metal rim-lock trays (*Dentsply Caulk, Milford, DE, USA*). Impressions were poured as soon as possible using *Coecal Type III Dental Stone (GC America, Alsip, IL, USA)*. Casts were separated from the impression material and trimmed no earlier than the following day. T1 and T4 casts were generally soaped and polished; T2 and T3 casts generally were not.

### 3.2.4 Data Analysis

Each subject had each cephalogram and cast from all four time points analyzed by a single investigator.

Only two subjects had missing or unusable records. Subject 52 (TME group) failed to show for the T2 radiographic data collection appointment; as such, no radiographic records were available for this subject at T2. Subject 57 (BME group) had all records taken at all time points, but the lateral cephalogram from T3 was grossly overexposed and impossible to accurately analyze; as such, this record could not be used in the study.

#### 3.2.4.1 PA cephalograms

The purpose of this analysis was to investigate the between-group differences, if any, in skeletal width changes during each phase.

Films were scanned at 300dpi into the *Dolphin Imaging 11.0* (Dolphin, Chatsworth, CA, USA) software program using a flatbed scanner (*Epson Perfection V700 Photo* by Epson, Toronto, ON, Canada). A 100mm transparent band was placed horizontally on the scanner bed atop each radiograph as a calibration ruler for magnification correction. The following cephalometric points were digitized using a custom analysis:

- i. *Maxillaire* (Mx): Point located at the depth of the concavity of the lateral maxillary contour at the junction of the maxilla and the zygomatic buttress.

This point was chosen because the linear measurement between the right and left landmarks (inter-Mx) reflects maxillary bony width, and this is a dimension of clinical interest.

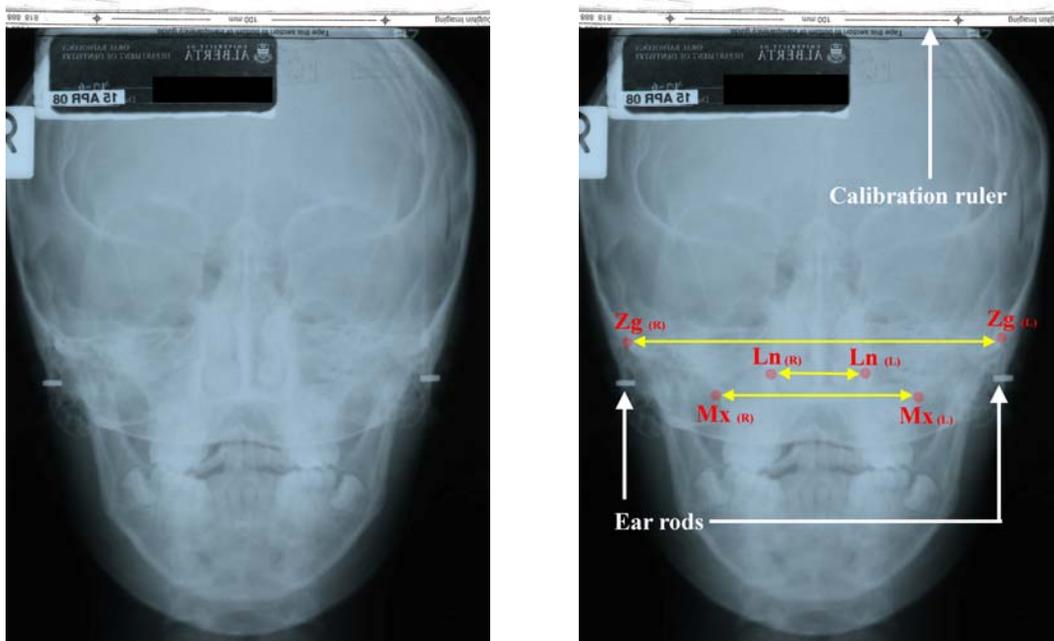
- ii. *Lateronasal* (Ln): Point located on the most lateral aspect of the nasal cavity.

This point was chosen because the linear measurement between the right and left landmarks (inter-Ln) reflects nasal cavity width, and this is a dimension of clinical interest.

iii. *Zygomatic (Zg)*: Point located on the most lateral aspect of the zygomatic arch.

This point was chosen because the linear measurement between the right and left landmarks (inter-Zg) reflects facial width, and this is a dimension of clinical interest.

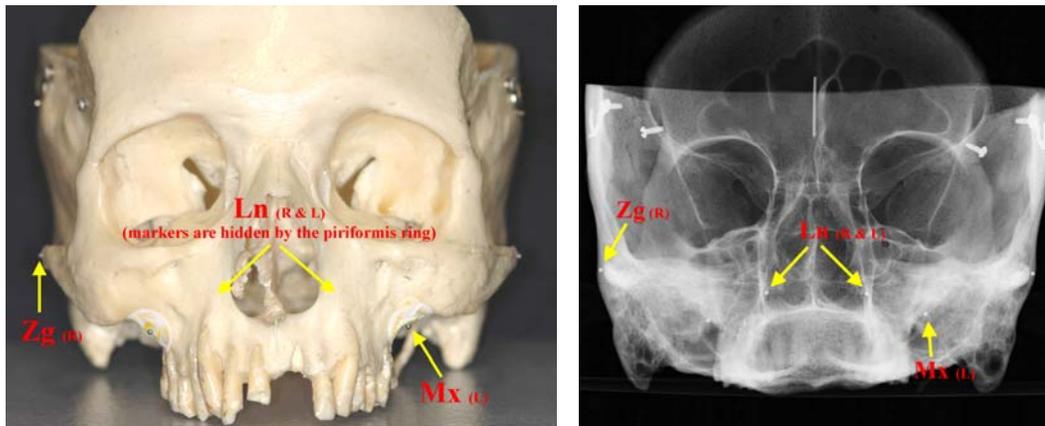
Figure 3-2 shows a scanned PA cephalogram with highlighted landmarks.



**Figure 3-2.** Left: PA cephalogram for subject 21 at T4 / Right: Same PA cephalogram with identification of landmarks

Because linear measurements are magnified on conventional plain films, a dry skull with 1.5mm metallic spheres (*Spee-D-Mark* by *The St. John Companies*, Santa Clara, CA, USA) placed on the Zg, Ln, and Mx landmarks was radiographically imaged [Figure 3-3]. The same cephalometric unit and head positioning techniques described in section 3.2.3.2 were used. Using digital calipers (*Absolute Digimatic Caliper Series 500* by *Mitutoyo*, Mississauga, ON, Canada), the distances between the markers on both the radiographic image of the dry skull and the dry skull itself were measured five times each. The average of

each distance was used to calculate a magnification factor for each measurement of interest.



**Figure 3-3.** *Left:* Dry skull with metallic markers on landmarks of interest / *Right:* Radiographic image of same dry skull and markers

The distance between the metallic spheres marking Ln could not be measured directly on the skull since the surrounding anatomical structures prevented this. However, the Ln markers were placed on the same coronal plane as the Mx markers for the radiographic exposure seen in Figure 3-3, and since the Ln markers appeared in the correct location on the film, the same magnification factor was used for the inter-Ln measurements as for the inter-Mx measurements.

#### 3.2.4.2 Lateral cephalograms

The purpose of this analysis was to investigate the between-group differences, if any, in vertical dimension changes during each phase.

Films were scanned as described in the previous section. The following points and planes were digitized using a custom analysis:

i. *Sella-Nasion plane* (SN):

Plane formed by the line connecting the two following landmarks:

- Sella (S): Center of the pituitary fossa.
- Nasion (N): Suture between the frontal and nasal bones.

This plane was chosen as a reference because of the relative ease of identification of its constituent landmarks.

ii. *Mandibular Plane (MP)*:

Plane formed by the line connecting the two following landmarks:

- Gonion (Go): Most posterior inferior point at the angle of the mandible.
- Menton (Me): Most posterior inferior point of the chin.

This plane was chosen because changes in its orientation to the reference plane (MP-SN angle) reflect changes in overall vertical dimension, and this is a change of clinical interest.

iii. *Palatal Plane (PP)*:

Plane formed by the line connecting the two following landmarks:

- Anterior Nasal Spine (ANS): Most anterior point on the nasal floor.
- Posterior Nasal Spine (PNS): Most posterior point on the hard palate.

This plane was chosen because changes in its orientation to the reference plane (PP-SN angle) reflect changes in maxillary bone position, and this could help explain the cause of changes seen in the overall vertical dimension, i.e., MP-SN.

iv. *Functional Occlusal Plane (FOP)*:

Plane best fitting the maximum intercuspation of molar and premolar teeth. This best-fit line splits the upper and lower molar occlusal contact points posteriorly, and those in the premolar region anteriorly.

This plane was chosen because changes in its orientation to the reference plane (FOP-SN angle) reflect changes in dental positions, and this could help explain the cause of changes seen in the overall vertical dimension, i.e., MP-SN.

Figure 3-4 shows a scanned lateral cephalogram with highlighted landmarks and planes.



**Figure 3-4.** *Left:* Lateral cephalogram for subject 17 at T3 / *Right:* Same lateral cephalogram with identification of landmarks

### 3.2.4.3 Dental casts

The purpose of this analysis was to investigate the between-group differences, if any, in dental width and tip changes during each phase. Dental casts were used for this purpose since anatomical superimpositions on PA cephalograms obscure the analysis of dentoalveolar structures. The following measurements were taken on the dental casts:

- i. *Intermolar width (IMW):* The distance between the mesiopalatal cusp tips of the upper first molars.

This measurement was chosen because dental width is a dimension of clinical interest. Measurements were taken directly on the dental casts using an *Electric Digital Caliper, Orthodontic Tip (OrthoPli, Philadelphia, PA, USA)*; the manufacturer reports an accuracy of 0.025mm.

- ii. *Intermolar tip (IMT):* The angle formed by the intersection of the long axes of the upper first molars.

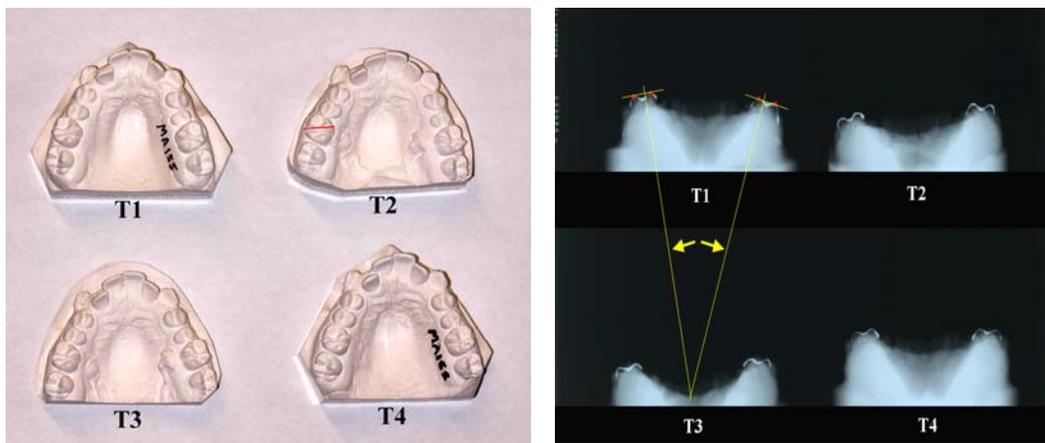
This measurement was chosen because dental tipping is a parameter of clinical interest.

To measure IMT, a technique described in a recent article was mimicked<sup>[48]</sup>. This involved painting a thin line of paste consisting of three parts water and one part *E-Z-HD Barium Sulfate Powder 98 w/w (EZ EM, Princeton,*

NJ, USA) over the mesiopalatal and distobuccal cusps of the upper first molars. The painted casts were then radiographically exposed with the cephalometric unit and materials described earlier (Radiographic settings: 0.1s, 12mA, 73kV). Up to four casts were exposed on each cephalometric film so that all time points for a given subject were captured in a single radiograph; to do this, T1 and T2 casts were placed on top of a cardboard box, and the T3 and T4 casts were placed within the box. All models were placed as close as possible to the film cassette with the midpalatal suture perpendicular to the film plane.

The radiographic images of the barium sulfate-painted casts were then scanned into *Dolphin Imaging 11.0* at 300 dpi. Using a custom analysis, points were digitized on the mesiopalatal and distobuccal cusp tips of each upper first molar; these points appeared prominently on the films because of the radiopaque barium sulfate paste painted over them. On each molar, a line was drawn through the digitized cusp tip points, and a second line was drawn perpendicular to the latter. By calculating the angle formed by the intersection of the second lines of each molar on a given cast, a rough estimate of the angle formed by their long axes could be extrapolated.

Figure 3-5 shows casts with the applied barium sulfate, the corresponding radiographic appearance, and the method of IMT measurement.



**Fig 3-5.** *Left:* Casts for subject 37 with barium sulfate painted over the mesiopalatal and distobuccal cusp tips of upper first molars (red line on T2 cast runs through the barium sulfate line) / *Right:* Radiograph of the same casts with the IMT analysis shown for the T1 cast (arrows indicate the angle of interest)

### 3.2.5 Reliability

Ten subjects at any one of the four data collection time points were randomly selected using *Microsoft Excel 2003* (Microsoft, Redmond, WA, USA) software. Each record (PA cephalogram, lateral cephalogram, dental cast, and radiographically-imaged cast) from these time points was analyzed on five occasions, each occasion separated by at least two weeks. The measurements from each analysis were statistically compared to establish intrarater reliability.

Because the same investigator analyzed all radiographs, and because interrater reliability for PA and lateral cephalograms has been reported previously<sup>[49, 50]</sup>, interrater reliability was not assessed in this study. Likewise, the dimensional accuracy of the images produced by the radiographic unit used in this study has been reported previously<sup>[51]</sup>.

### 3.2.6 Statistical Analyses

*SPSS Statistics 16.0* (SPSS, Chicago, IL, USA) software was used for all statistical analyses. The level of significance ( $\alpha$ ) for all hypothesis-testing analyses was set at 0.05.

#### 3.2.6.1 Group composition and data collection timeline

The objective of this analysis was to uncover any differences between the three study groups in terms of (1) the sex distribution of subjects in each group, (2) the age of the subjects making up the groups, (3) the data collection timeline for the groups, and/or (4) the baseline dentoskeletal measurements of the subjects making up the groups. The null hypothesis is that no between-group differences exist in either of these parameters. To test for sex distribution differences between groups, a chi square ( $\chi^2$ ) test was performed. To test all other hypotheses, one-way *multivariate analysis of variance* (MANOVA) procedures were performed, and when results suggested significant between-group differences, *Bonferroni multiple comparisons tests* were performed post-hoc to further elucidate the nature of these differences.

### 3.2.6.2 Group comparisons

Dental and skeletal changes which took place during the time intervals described in Table 3-1 provide the basis for the research questions listed at the end of section 3.1. For each of the six questions, the null hypothesis is that there are no differences in the dental and skeletal changes between the three groups (see section 1.5). The objective of the statistical analyses was to test these hypotheses.

To meet this objective, a *repeated measures multivariate analysis of variance* (RM-MANOVA) was applied to the data for each research question/hypothesis. For each analysis, the within-subjects factor was *Time* [Two levels: (1) The dentoskeletal measurements at the time point marking the end of the interval, and (2) The dentoskeletal measurements at the time point marking the beginning of the interval], and the between-subjects factor was *Group* [Three levels: TME, BME, Control].

When significant differences were found after this preliminary test, additional statistical tests were performed. First, to find out which measurements showed significant differences between the groups, each measurement was submitted to univariate testing via a *repeated measures analysis of variance* (RM-ANOVA). Then, measurements showing significant between-group differences were submitted to a one-way MANOVA on their difference scores for the time interval being tested. And finally, to find out which specific groups differed significantly in these measurements and by how much, *Bonferroni multiple comparisons tests* were applied post-hoc.

Additional information pertaining to the statistical analyses discussed above is provided in Appendix B.

### 3.2.6.3 Reliability

An *intraclass correlation coefficient* (ICC) was calculated for each measurement. The ICC was preset in *SPSS 16.0* as follows: ‘two-way mixed model’ (i.e., fixed rater, random subjects), ‘single measure reliability’, and ‘absolute agreement’.

### 3.3 RESULTS

#### 3.3.1 Group Composition and Data Collection Timeline

Table 3-2 lists the demographic and data collection timeline information for the three study groups.

**Table 3-2.** Group demographics and data collection timeline<sup>a,b</sup>

	TME group	BME group	Control group
# of subjects	20	21	21
Sex distribution	5M / 15F	8M / 13F	6M / 15F
Age at T1	166.90 (17.85)	171.38 (15.98)	153.83 (14.71)
Age at T2	169.50 (17.60)	175.82 (16.25)	153.83 (14.71)
Age at T3	174.80 (17.50)	179.23 (16.24)	159.61 (14.61)
Age at T4	180.62 (17.39)	185.42 (16.42)	165.82 (14.65)
Time span T1-T2	2.70 (1.36)	4.44 (1.35)	N/A
Time span T2-T3	5.20 (0.94)	3.40 (0.95)	5.77 (0.80)
Time span T3-T4	5.83 (0.51)	6.19 (0.84)	6.21 (1.00)
Time span T2-T4	11.03 (1.14)	9.60 (1.08)	11.99 (1.45)
Time span T1-T3	7.90 (1.2)	7.85 (1.27)	5.77 (0.80)
Time span T1-T4	13.73 (1.28)	14.06 (1.32)	11.99 (1.45)

<sup>a</sup>Mean ages and time spans are listed in months; standard deviations are in parentheses.

<sup>b</sup>The T1-T2 time span for the Control group is considered nil for analytical purposes (see section 3.2.3.1).

To check for any significant between-group differences in the sex distribution data listed in Table 3-2, a chi square test was performed. Results showed no significant between-group differences ( $\chi^2 = 0.891$ ,  $p = 0.641$ ).

To check for any significant between-group differences in the age and timeline data listed in Table 3-2, a way-one MANOVA was performed. Results showed statistically significant between-group differences [ $\Lambda = 0.176$ ,  $F(8, 112) = 19.4$ ,  $p \sim 0.000$ ], and *Bonferroni multiple comparisons tests* were thus performed. The results of these post-hoc tests are shown in Table 3-3.

**Table 3-3.** Group differences in age and data collection timeline<sup>a,b</sup>

	Mean difference (TME – BME)	Mean difference (TME – Control)	Mean difference (BME – Control)
Age at T1	-4.48, $p \sim 1$	<b>13.07</b> , $p = 0.037$	<b>17.55</b> , $p = 0.003$
Age at T2	-6.22, $p = 0.672$	<b>15.77</b> , $p = 0.009$	<b>21.99</b> , $p < 0.001$
Age at T3	-4.43, $p \sim 1$	<b>15.19</b> , $p = 0.011$	<b>19.62</b> , $p = 0.001$
Age at T4	-4.79, $p \sim 1$	<b>14.80</b> , $p = 0.014$	<b>19.60</b> , $p = 0.001$
Time span T1-T2	<b>-1.74</b> , $p < 0.001$	<b>2.70</b> , $p < 0.001$	<b>4.44</b> , $p < 0.001$
Time span T2-T3	<b>1.80</b> , $p < 0.001$	-0.57, $p = 0.138$	<b>-2.37</b> , $p < 0.001$
Time span T3-T4	-0.37, $p = 0.465$	-0.39, $p = 0.391$	-0.02, $p \sim 1$
Time span T2-T4	<b>1.43</b> , $p = 0.001$	<b>-0.96</b> , $p = 0.046$	<b>-2.39</b> , $p < 0.001$
Time span T1-T3	0.05, $p \sim 1$	<b>2.13</b> , $p < 0.001$	<b>2.07</b> , $p < 0.001$
Time span T1-T4	-0.31, $p \sim 1$	<b>1.74</b> , $p < 0.001$	<b>17.55</b> , $p = 0.003$

<sup>a</sup>Mean values are in months.

<sup>b</sup>Mean differences in bold font are statistically significant ( $0.00 < p \leq 0.05$ )

Table 3-4 lists the mean baseline (T1) value of each dental and skeletal measurement for each group.

**Table 3-4.** Mean baseline (T1) values of dental and skeletal measurements<sup>a</sup>

	Dental width (mm)	Dental tip (°)	Skeletal widths (mm)			Vertical dimension (°)		
	IMW	IMT	Inter-Ln	Inter-Mx	Inter-Zg	PP-SN	OP-SN	MP-SN
TME group	37.27 (3.33)	18.26 (8.06)	27.95 (1.54)	61.30 (3.08)	115.85 (5.69)	8.38 (3.20)	24.68 (4.26)	39.15 (6.66)
BME group	37.27 (2.98)	16.50 (9.13)	28.57 (2.14)	62.04 (3.26)	118.20 (6.08)	8.82 (3.90)	24.49 (4.96)	37.39 (6.46)
Control group	37.23 (3.84)	17.68 (9.23)	28.22 (1.60)	61.65 (3.98)	117.48 (5.75)	9.55 (3.79)	25.91 (5.82)	38.90 (7.39)

<sup>a</sup>Numbers in parentheses are standard deviations.

To check for any significant between-group differences in the baseline (T1) measurements listed in Table 3-4, a one-way MANOVA was performed. Results showed no significant between-group differences [ $\Lambda = 0.871$ ,  $F(16, 104) = 0.465$ ,  $p = 0.958$ ], and post-hoc tests were thus not indicated.

### 3.3.2 Descriptive Statistics

Table 3-5 lists the mean outcome value of each dental and skeletal measurement taken at each data collection time point for each group. Visual depictions of analogous information are provided via profile plots in Appendix C and box plots in Appendix D.

**Table 3-5. Mean outcome values at each data collection time point<sup>a,b</sup>**

		Dental width (mm)	Dental tip (°)	Skeletal widths (mm)			Vertical dimension (°)		
		IMW	IMT	Inter-Ln	Inter-Mx	Inter-Zg	PP-SN	FOP-SN	MP-SN
TME group	T1	37.27 (3.33)	18.26 (8.06)	27.95 (1.54)	61.30 (3.08)	115.85 (5.69)	8.38 (3.20)	24.68 (4.26)	39.15 (6.66)
	T2	42.76 (2.63)	29.90 (9.38)	29.21 (1.96)	62.77 (3.39)	116.59 (6.10)	7.98 (2.83)	24.57 (4.07)	39.58 (6.49)
	T3	42.33 (2.84)	25.47 (9.19)	29.35 (1.87)	63.37 (3.44)	118.35 (5.31)	8.14 (3.27)	24.81 (3.88)	39.42 (6.74)
	T4	39.91 (2.92)	19.09 (8.33)	29.36 (1.70)	63.26 (3.58)	118.54 (5.42)	8.31 (3.30)	24.84 (4.15)	39.37 (6.71)
BME group	T1	37.27 (2.98)	16.50 (9.13)	28.57 (2.14)	62.04 (3.26)	118.20 (6.08)	8.82 (3.90)	24.49 (4.96)	37.39 (6.46)
	T2	41.85 (3.13)	24.31 (10.56)	29.79 (2.12)	63.91 (2.91)	119.53 (5.63)	8.88 (3.82)	24.42 (4.89)	37.61 (6.29)
	T3	41.54 (2.89)	20.17 (10.17)	29.81 (2.09)	63.95 (2.60)	120.5 (5.37)	8.63 (3.89)	24.24 (5.20)	37.33 (6.44)
	T4	39.56 (2.93)	16.37 (8.03)	29.93 (2.06)	63.73 (2.68)	120.59 (4.70)	8.71 (3.84)	24.10 (5.04)	37.03 (6.44)
Control group	T1/2	37.23 (3.84)	17.68 (9.23)	28.22 (1.60)	61.65 (3.98)	117.48 (5.75)	9.55 (3.79)	25.91 (5.82)	38.90 (7.39)
	T3	37.05 (3.78)	16.75 (8.82)	28.63 (1.52)	62.13 (3.56)	119.23 (5.40)	9.80 (3.77)	25.76 (6.00)	38.73 (7.40)
	T4	36.98 (3.71)	16.28 (9.07)	28.87 (1.41)	62.50 (3.35)	120.31 (4.83)	9.75 (3.83)	25.54 (5.65)	38.44 (7.32)

<sup>a</sup>Numbers in parentheses are standard deviations.

<sup>b</sup>The same outcome values were used at T1 and T2 for Control group subjects (see section 3.2.3.1).

Table 3-6 lists the mean group difference scores (i.e., mean group changes) for each measurement during each data collection interval (see Table 3-1).

**Table 3-6. Mean dentoskeletal changes during each data collection interval<sup>a,b,c,d</sup>**

		IMW (mm)	IMT (°)	Inter- Ln (mm)	Inter-Mx (mm)	Inter- Zg (mm)	PP- SN (°)	FOP-SN (°)	MP- SN (°)
TME group	Expansion (T1-T2)	5.48 (1.66)	11.64 (3.81)	1.25 (1.02)	1.64 (1.03)	1.07 (1.93)	-0.05 (0.50)	0.16 (0.85)	1.07 (0.92)
	Retention (T2-T3)	-0.42 (0.43)	-4.44 (4.33)	0.19 (0.72)	0.46 (0.85)	1.55 (2.90)	-0.22 (0.43)	0.01 (0.72)	-0.85 (1.07)
	Settling (T3-T4)	-2.43 (1.24)	-6.38 (4.12)	0.01 (0.43)	-0.12 (0.43)	0.19 (1.91)	0.18 (0.50)	0.04 (0.51)	-0.06 (0.66)
	Post- expansion (T2-T4)	-2.85 (1.31)	-10.82 (5.2)	0.18 (0.69)	0.34 (0.90)	1.77 (2.08)	-0.03 (0.51)	0.02 (0.92)	-0.86 (0.92)
	Pre-settling (T1-T3)	5.06 (1.51)	7.21 (4.35)	1.40 (0.96)	2.07 (1.24)	2.50 (2.39)	-0.24 (0.60)	0.13 (0.63)	0.27 (0.63)
	Overall (T1-T4)	2.64 (1.69)	0.83 (4.47)	1.41 (0.88)	1.96 (1.18)	2.69 (2.35)	-0.07 (0.54)	0.16 (0.49)	0.22 (0.78)
BME group	Expansion (T1-T2)	4.58 (2.65)	7.81 (5.99)	1.22 (0.86)	1.87 (1.57)	1.34 (1.90)	0.06 (0.43)	-0.07 (0.59)	0.33 (0.71)
	Retention (T2-T3)	-0.31 (0.70)	-4.14 (3.93)	0.02 (0.65)	0.04 (0.68)	0.52 (1.50)	-0.06 (0.45)	-0.03 (0.67)	-0.12 (0.60)
	Settling (T3-T4)	-1.97 (1.37)	-3.80 (4.30)	0.12 (0.50)	-0.22 (0.67)	0.53 (1.34)	-0.14 (0.63)	-0.32 (0.53)	-0.46 (0.75)
	Post- expansion (T2-T4)	-2.28 (1.9)	-7.94 (6.09)	0.14 (0.64)	-0.18 (0.87)	1.05 (1.95)	-0.17 (0.49)	-0.32 (0.68)	-0.59 (0.71)
	Pre-settling (T1-T3)	4.27 (2.37)	3.67 (4.74)	1.24 (0.99)	1.92 (1.41)	1.86 (2.21)	0.03 (0.62)	-0.12 (0.74)	0.24 (0.80)
	Overall (T1-T4)	2.29 (1.78)	-0.13 (2.93)	1.36 (0.97)	1.70 (1.25)	2.39 (2.44)	-0.11 (0.59)	-0.39 (0.73)	-0.26 (0.87)
Control group	Expansion (T1-T2)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Retention (T2-T3)	-0.18 (0.41)	-0.92 (1.26)	0.41 (0.65)	0.49 (0.89)	1.75 (2.26)	0.25 (0.42)	-0.14 (0.57)	-0.17 (0.49)
	Settling (T3-T4)	-0.07 (0.25)	-0.47 (0.98)	0.24 (0.74)	0.36 (0.84)	1.08 (2.17)	-0.05 (0.43)	-0.22 (0.64)	-0.30 (0.54)
	Post- expansion (T2-T4)	-0.25 (0.49)	-1.40 (1.81)	0.65 (0.77)	0.85 (1.07)	2.83 (3.10)	0.20 (0.45)	-0.37 (0.74)	-0.46 (0.44)
	Pre-settling (T1-T3)	-0.18 (0.41)	-0.92 (1.26)	0.41 (0.65)	0.49 (0.89)	1.75 (2.26)	0.25 (0.42)	-0.14 (0.57)	-0.17 (0.49)
	Overall (T1-T4)	-0.25 (0.49)	-1.40 (1.81)	0.65 (0.77)	0.85 (1.07)	2.83 (3.10)	0.20 (0.45)	-0.37 (0.74)	-0.46 (0.44)

Footnotes related to Table 3-6:

<sup>a</sup>Numbers in parentheses are standard deviations.

<sup>b</sup>Difference scores for each time interval were calculated by subtracting the measurement of the earlier time point from that of the later time point. Thus, a negative value indicates a decrease in the size of the measurement during the given time interval.

<sup>c</sup>Control group difference scores were all nil during the expansion phase because the same measurement values were used at T1 and T2 (see section 3.2.3.1).

<sup>d</sup>Because of rounding off to the nearest hundredth, and because of missing values for subjects 52 and 57 at certain time points (see section 3.2.4), mean changes do not always add up perfectly between sub-phase time intervals.

Table 3-7 lists the mean percent loss of the initial IMW increase, i.e., the IMW increase achieved during the expansion phase (T1-T2), during the post-expansion phases.

**Table 3-7.** Mean percent loss of initial IMW increase (T1-T2 increase)<sup>a</sup>

		% loss of initial IMW increase
TME group	Retention (T2-T3)	7.66 %
	Settling (T3-T4)	44.34 %
	Post-expansion (T2-T4)	52.00 %
BME group	Retention (T2-T3)	6.77 %
	Settling (T3-T4)	43.01 %
	Post-expansion (T2-T4)	49.78 %

<sup>a</sup>Calculations were as follows:

(Retention phase IMW loss / Expansion phase IMW increase) X 100

(Settling phase IMW loss / Expansion phase IMW increase) X 100

(Post-expansion phase IMW loss / Expansion phase IMW increase) X 100

### 3.3.3 Group Comparisons

For all six data collection intervals (see Table 3-1), the RM-MANOVA procedure indicated that there were statistically significant between-group differences in dentoskeletal changes. Thus, for all six intervals, the eight dentoskeletal measurements were submitted to univariate testing (RM-ANOVA), and the difference scores for any measurements found to show significant between-group differences were submitted to one-way MANOVA and *Bonferroni* post-hoc testing. Detailed results for each of these statistical tests are provided in the Appendix: Expansion phase, T1-T2 (Appendix E); Retention phase, T2-T3 (Appendix F); Settling/Post-retention phase, T3-T4 (Appendix G); Post-expansion phase, T2-T4 (Appendix H); Pre-settling phase, T1-T3 (Appendix I); Overall phase, T1-T4 (Appendix J).

Table 3-8 lists the findings of the *Bonferroni* post-hoc-tests for each between-group comparison of dentoskeletal changes during each phase.

**Table 3-8.** Group differences in dentoskeletal changes<sup>a,b,c,d</sup>

		IMW (mm)	IMT (°)	Inter- Ln (mm)	Inter- Mx (mm)	Inter- Zg (mm)	PP- SN (°)	FOP- SN (°)	MP- SN (°)
Expansion (T1-T2)	TME – BME	0.90 ± 1.39	<b>3.83</b> ± <b>3.16</b>	0.03 ± 0.59	-0.23 ± 0.85	-0.27 ± 1.21	-0.10 ± 0.30	0.22 ± 0.46	<b>0.75</b> ± <b>0.52</b>
	TME – Control	<b>5.48</b> ± <b>1.39</b>	<b>11.64</b> ± <b>3.16</b>	<b>1.25</b> ± <b>0.59</b>	<b>1.64</b> ± <b>0.85</b>	1.07 ± 1.21	-0.05 ± 0.30	0.16 ± 0.46	<b>1.07</b> ± <b>0.52</b>
	BME – Control	<b>4.58</b> ± <b>1.37</b>	<b>7.81</b> ± <b>3.12</b>	<b>1.22</b> ± <b>0.58</b>	<b>1.87</b> ± <b>0.83</b>	<b>1.34</b> ± <b>1.18</b>	0.06 ± 0.29	-0.07 ± 0.45	0.33 ± 0.50
Retention (T2-T3)	TME – BME	-0.11 ± 0.41	-0.29 ± 2.65	0.18 ± 0.52	0.42 ± 0.63	1.02 ± 1.81	-0.17 ± 0.34	0.04 ± 0.52	<b>-0.73</b> ± <b>0.59</b>
	TME – Control	-0.24 ± 0.41	<b>-3.51</b> ± <b>2.65</b>	-0.22 ± 0.52	-0.03 ± 0.63	-0.20 ± 1.79	<b>-0.47</b> ± <b>0.34</b>	0.15 ± 0.51	<b>-0.68</b> ± <b>0.59</b>
	BME – Control	-0.13 ± 0.40	<b>-3.22</b> ± <b>2.61</b>	-0.39 ± 0.51	-0.44 ± 0.62	-1.21 ± 1.76	-0.30 ± 0.33	0.11 ± 0.50	0.05 ± 0.58
Settling (T3-T4)	TME – BME	-0.45 ± 0.83	-2.58 ± 2.67	-0.11 ± 0.44	0.10 ± 0.52	-0.35 ± 1.42	0.32 ± 0.41	0.35 ± 0.44	0.40 ± 0.51
	TME – Control	<b>-2.36</b> ± <b>0.83</b>	<b>-5.91</b> ± <b>2.67</b>	-0.23 ± 0.44	-0.48 ± 0.52	-0.89 ± 1.42	0.22 ± 0.40	0.26 ± 0.43	0.24 ± 0.50
	BME – Control	<b>-1.90</b> ± <b>0.82</b>	<b>-3.33</b> ± <b>2.64</b>	-0.12 ± 0.44	<b>-0.58</b> ± <b>0.51</b>	-0.54 ± 1.40	-0.09 ± 0.40	-0.09 ± 0.43	-0.16 ± 0.50
Post- expansion (T2-T4)	TME – BME	-0.56 ± 1.05	-2.87 ± 3.64	0.04 ± 0.55	0.52 ± 0.74	0.72 ± 1.90	0.14 ± 0.38	0.34 ± 0.61	-0.28 ± 0.55
	TME – Control	<b>-2.59</b> ± <b>1.05</b>	<b>-9.42</b> ± <b>3.64</b>	-0.47 ± 0.55	0.51 ± 0.74	-1.06 ± 1.90	-0.23 ± 0.38	0.39 ± 0.61	-0.40 ± 0.55
	BME – Control	<b>-2.03</b> ± <b>1.04</b>	<b>-6.55</b> ± <b>3.60</b>	-0.51 ± 0.53	<b>-1.03</b> ± <b>0.72</b>	-1.78 ± 1.86	-0.37 ± 0.37	0.05 ± 0.59	-0.12 ± 0.54
Pre- settling (T1-T3)	TME – BME	0.80 ± 1.26	<b>3.53</b> ± <b>2.91</b>	0.16 ± 0.68	0.16 ± 0.92	0.64 ± 1.76	-0.27 ± 0.43	0.24 ± 0.51	0.03 ± 0.51
	TME – Control	<b>5.25</b> ± <b>1.26</b>	<b>8.13</b> ± <b>2.91</b>	<b>0.99</b> ± <b>0.68</b>	<b>1.58</b> ± <b>0.92</b>	0.75 ± 1.76	<b>-0.49</b> ± <b>0.42</b>	0.27 ± 0.50	0.44 ± 0.50
	BME – Control	<b>4.45</b> ± <b>1.25</b>	<b>4.60</b> ± <b>2.87</b>	<b>0.83</b> ± <b>0.67</b>	<b>1.43</b> ± <b>0.91</b>	0.10 ± 1.74	-0.22 ± 0.42	0.03 ± 0.50	0.41 ± 0.50
Overall (T1-T4)	TME – BME	0.34 ± 1.11	0.95 ± 2.49	0.05 ± 0.67	0.26 ± 0.90	0.30 ± 2.04	0.04 ± 0.41	<b>0.55</b> ± <b>0.51</b>	0.46 ± 0.55
	TME – Control	<b>2.89</b> ± <b>1.11</b>	2.22 ± 2.49	<b>0.76</b> ± <b>0.67</b>	<b>1.11</b> ± <b>0.90</b>	-0.14 ± 2.04	-0.27 ± 0.41	<b>0.53</b> ± <b>0.51</b>	<b>0.68</b> ± <b>0.55</b>
	BME – Control	<b>2.55</b> ± <b>1.10</b>	1.27 ± 2.46	<b>0.71</b> ± <b>0.67</b>	0.85 ± 0.89	-0.44 ± 2.02	-0.31 ± 0.40	-0.02 ± 0.51	0.20 ± 0.55

Footnotes related to Table 3-8:

<sup>a</sup>95% CI's are provided.

<sup>b</sup>Between-group change differences were calculated by subtracting the difference score (calculated for each group as described in Footnote B of Table 3-6) of the second group from that of the first group. For example, if a given change difference on a row of 'TME - Control' is positive, this indicates that the difference score for the TME group during the given time interval for the given measurement was larger in a positive sense than that of the Control group, and vice-versa.

<sup>c</sup>Because of rounding off to the nearest hundredth, and because of missing values for subjects 52 and 57 at certain time points (see section 3.2.4), the change differences between sub-phases do not always add up perfectly and do not always exactly match the expected values based on the results listed in Table 3-6.

<sup>d</sup>Mean change differences in bold font are statistically significant ( $0.00 < p \leq 0.05$ ); see Appendices E to J for exact p-values.

### 3.3.4 Correction of Magnification

Table 3-9 lists the magnification factors for the inter-Ln, inter-Mx, and inter-Zg measurements obtained from the PA cephalograms. Throughout this paper, all listed results for these measurements are magnification-corrected.

**Table 3-9.** Magnification factors for cephalometric width measurements<sup>a</sup>

	Mean skull measurement	Mean radiographic measurement	Magnification factor
Inter-Ln	-	-	80.4 / 74 ~ 1.086
Inter-Mx	74.00 mm	80.4 mm	80.4 / 74 ~ 1.086
Inter-Zg	133.50 mm	148.7 mm	148.7 / 133.5 ~ 1.114

<sup>a</sup>The same magnification factor was used for inter-Ln as for inter-Mx (see section 3.2.4.3)

The magnification factors listed in Table 3-9 are in agreement with those reported by the manufacturer (1.08 to 1.14) and those found in other studies using the same radiographic unit<sup>[51]</sup>.

### 3.3.5 Reliability

The ICC for intrarater reliability for each of the eight dentoskeletal measurements is listed in Table 3-10.

**Table 3-10.** ICC's for the intrarater reliability of each measurement

	ICC	95% CI
IMW	0.999	[0.997 , 1.000]
IMT	0.940	[0.862 , 0.982]
Inter-Ln	0.922	[0.813 , 0.977]
Inter-Mx	0.987	[0.967 , 0.996]
Inter-Zg	0.993	[0.982 , 0.998]
PP-SN	0.954	[0.893 , 0.986]
FOP-SN	0.888	[0.756 , 0.966]
MP-SN	0.876	[0.734 , 0.962]

The ICC's for intrarater reliability listed in Table 3-10 are high for all measurements. Other lateral and PA cephalometric studies found similar ICC's for intrarater reliability<sup>[50, 52]</sup>.

## 3.4 DISCUSSION

The primary objective of this study was to gain a better understanding of the differences, if any, between the longitudinal dentoskeletal changes -and the stability of these changes- produced by TME, non-surgically-assisted BME, and unadulterated growth of adolescents with maxillary constriction. Specifically, answers to the six research questions listed at the end of section 3.1 were sought.

To achieve this objective, 62 adolescent subjects with maxillary constriction were randomly allocated to one of three study groups (TME, BME, or Control), and subjects from each group had a lateral cephalogram, a PA cephalogram, and dental casts made at four data collection time points (see section 3.2.3). These records were analyzed (see section 3.2.4), and the results of the data analysis (see section 3.3) are discussed below.

### **3.4.1 Group Composition and Data Collection Timeline**

For a comparative study to be valid, it is important to verify that (1) groups were similar at the starting point, and (2) groups were evaluated equally throughout the observation period. Thus, before listing the between-group comparative findings of the study, the groups' composition and data collection timeline were analyzed (see section 3.3.1). The objective of these analyses was to uncover any differences between the three study groups in terms of (1) the sex distribution of subjects in each group, (2) the age of the subjects making up the groups, (3) the data collection timeline for the groups, and/or (4) the baseline dentoskeletal measurements of the subjects making up the groups. Differences in these parameters could indicate that the groups were dissimilar from the start or that they were evaluated unequally over the course of the study.

Based on the chi square analysis of the sex distribution data listed in Table 3-2, the three groups could be considered homogenous from the standpoint of sex distribution ( $p = 0.641$ ).

Based on the one-way MANOVA analysis of the baseline dentoskeletal measurements listed in Table 3-4, the groups could also be considered homogenous from the standpoint of baseline dental and skeletal dimensions ( $p = 0.958$ ).

Statistically significant between-group differences were found in age and data collection timeline, however (see Table 3-3). Broadly speaking, the expansion groups (TME and BME) were more similar in these regards with each other than with the Control group.

Firstly, the Control group subjects were significantly younger than the actively treated subjects at all data collection time points. This was a consequence of the randomization process and could not have been prevented by alterations in the study design. Nevertheless, one could argue that because of this between-group age discrepancy, changes due to unadulterated growth may not have been ideally controlled.

Secondly, the data collection timeline was significantly different between all three groups. The significant differences between the TME and BME groups were expected by virtue of the differential expansion rates prescribed to the two groups (see section 3.2.2); though planned, one could argue that this discrepancy nevertheless hinders the interpretability of the TME/BME change comparisons during the data collection intervals found to be significantly different between groups. The significant T1-T2 time span difference between the expansion groups and the Control group was also expected since the Control group did not have records taken at T2, and the T1-T2 time interval was thus considered nil for this group. Conversely, differences between the expansion groups and the Control group during all other data collection intervals were due mainly to the unexpectedly long expansion times for the treated groups. At an expansion rate of 0.5mm per day, it was expected that the TME group subjects would have completed the expansion phase in an average of ~2 weeks. Likewise, at an expansion rate of 0.125mm per day, it was expected that the BME group subjects would have completed the expansion phase in an average ~2 months. However, as seen in Table 3-2, clinical reality was such that the expansion procedures took more than twice the expected time for each group; part of this could be a reflection of the fact that subjects and their guardians were responsible for activating the expansion appliance at home, and compliance levels were less than ideal in some cases. Since the original research design called for three post-expansion data collection time points separated by ~5-6 months each (T2 to T3, and T3 to T4), the total observation period for the expansion groups was extended past the originally planned 12 months. Because there were no clinical constraints on the Control group, however, subjects in this group were seen at the originally

planned intervals, i.e., ~6 months after baseline records and ~6 months after T3 records. These factors resulted in a disjointing of the data collection timeline between the actively treated groups and the untreated group. This disjointing could have been prevented by altering the data collection timeline of the Control group subjects to more closely match that of the actively treated subjects. One could argue that because of this timeline discrepancy, changes due to unadulterated growth may not have been ideally controlled.

These between-group discrepancies in age and data collection timeline were pointed out in this paper for the sake of completeness, but they are not thought to seriously hinder the interpretability of the results. Nevertheless, a discussion of a possible statistical method for accounting for these group differences can be found in the last section of Appendix B; such a statistical method was not employed in this paper, however.

### **3.4.2 Descriptive Statistics: Group Trends**

General within-group trends can be observed for each dentoskeletal measurement by studying the descriptive data (see Table 3-5 and the associated profile plots in Appendix C). The clinical significance of, and possible reasons for, any between-group differences in these trends will be discussed in section 3.4.3.

IMW increased sharply for the TME and BME groups during the expansion phase. It then dropped slightly for both groups during the retention phase. During the settling/post-retention phase, a sharp decrease was seen in both groups. IMW for the control group was fairly constant throughout the observation period, showing only a very slight but steady decrease at each time point. IMT followed the same general trend as IMW.

Inter-Ln, Inter-Mx, and Inter-Zg all followed similar trends as well. The initial (T1-T2) increases were generally sharp and then tapered off to low levels for both expansions groups (inter-Mx width in fact decreased for both expansion groups between T3 and T4), while the control group experienced moderate but steady increases throughout the study.

MP-SN showed a sharp initial increase (T1-T2) in the expansion groups, especially the TME group. This initial increase subsequently dissipated, however. MP-SN for the control group subjects was fairly constant throughout the observation period, showing only a slight but steady decrease at each time point.

FOP-SN roughly mimicked the changes seen in MP-SN, but PP-SN did not follow any predictable pattern.

### **3.4.3 Group Comparisons**

With the group disparities outlined in section 3.4.1 in mind, the findings of the between-group comparisons can be discussed. Statements regarding the clinical significance of statistically significant differences were based on whether the magnitude of the difference -using the low end of the CI as a value- would be likely to have a noticeable impact clinically. The clinical detection threshold for smile esthetic alterations has been quantified in previous studies<sup>[53-55]</sup>, and based on their findings, it is reasonable to state that width differences  $\geq 0.5\text{mm}$  and angular differences  $\geq 3^\circ$  in the present study could be argued to carry clinical significance. This being said, it would be useful to design a study aimed at quantifying the clinical detection threshold for changes in measurements commonly used in orthodontic research, as this would make the determination of clinical significance less arbitrary. For all measurements, the reliability with which their values were recorded (see section 3.3.4) should also be considered when assessing the clinical significance of statistically significant findings.

The results of the between-group comparisons of dentoskeletal measurement changes during each phase are shown in Table 3-8. Preliminary statistical tests and p-values for statistically significant change differences during each phase are in Appendices E to J.

#### **3.4.3.1 Expansion phase (T1-T2)**

The purpose of studying between-group differences during this time interval was to determine (1) whether the immediate effects of expansion differed between the TME and BME groups, and (2) whether the immediate changes

measured in each expansion group differed from the time-matched changes measured in the Control group.

The TME and BME groups showed statistically significant differences in IMT and MP-SN change. Both groups showed increases in both measurements during this phase, but the increases were greater in the TME group in both cases; the differences were not clinically significant, however.

The TME and Control groups showed statistically significant differences in IMW, IMT, inter-Ln, inter-Mx, and MP-SN changes. Since T1 and T2 values were the same for the Control group, the TME group showed greater increases in all measurements. The differences in all except the MP-SN change could be argued to carry clinical significance.

The BME and Control groups showed statistically significant differences in IMW, IMT, inter-Ln, inter-Mx, and inter-Zg changes. Since T1 and T2 values were the same for the Control group, the BME group showed greater increases in all measurements. The differences in all except the inter-Zg change could be argued to carry clinical significance.

In summary, there were several clinically significant differences in the changes which occurred during this phase. The most notable were the greater increases in IMW and IMT seen in the TME and BME groups compared to the Control group; this indicates that for both expansion methods, the increase in dental width was accompanied by an equally large increase in buccal crown tipping. The inter-Ln and inter-Mx width increases seen in the expansion groups compared to the Control group could also be argued to carry clinical significance (although to a lesser extent), and, in any case, it is clear that the arch width increase was much more the result of dental rather than skeletal movement in both groups. Other statistically significant differences were found during this phase, but they did not carry clinical significance.

#### **3.4.3.2 Retention phase (T2-T3)**

The purpose of studying between-group differences during this time interval was to determine (1) whether the stability of the immediate effects of

expansion differed between the TME and BME groups during the retention phase, and (2) whether the changes measured in each expansion group during this time period differed from the time-matched changes produced by unadulterated growth (Control group).

The TME and BME groups showed statistically significant differences in MP-SN change. Both groups showed decreases in MP-SN during this phase, but the decrease was greater in the TME group; the difference was not clinically significant, but it did nevertheless somewhat offset the greater increase in MP-SN seen in the TME group during the previous phase.

The TME and Control groups showed statistically significant differences in IMT, PP-SN, and MP-SN changes. Both groups showed decreases in IMT and MP-SN during this phase, but the decreases were greater in the TME group; the differences were not clinically significant, but they nevertheless did somewhat offset the greater increase in IMT and MP-SN seen in the TME group during the previous phase. The PP-SN decreased for the TME group and increased for the Control group during this phase; the change difference was not clinically significant, however.

The BME and Control groups showed statistically significant differences in IMT change. Both groups showed decreases in IMT during this phase, but the decrease was greater in the BME group; the difference was not clinically significant, but it nevertheless did somewhat offset the significantly greater increase in IMT that the BME group experienced during the previous phase.

In summary, there were few statistically significant -and no clinically significant- differences in the dentoskeletal changes that occurred between the groups during the retention phase. Thus, though a statistically significant amount of relapse was observed during this phase, the retention protocol was largely successful in preventing the loss of the clinically significant dental and skeletal width gains that were achieved during the expansion phase in the expansion group subjects. Indeed, only ~7% of the initial IMW increase was lost during this phase in both expansion groups (see Table 3-7).

### **3.4.3.3 Settling/Post-retention phase (T3-T4)**

The purpose of studying between-group differences during this time interval was to determine (1) whether post-retention stability differed between the TME and BME groups, and (2) whether the changes measured in each expansion group during this time period differed from the time-matched changes produced by unadulterated growth (Control group).

The TME and BME groups did not show any statistically significant differences in any measurement changes during this phase.

The TME and Control groups showed statistically significant differences in IMW and IMT changes. Both groups showed decreases in both measurements during this phase, but the decreases were greater in the TME group in both cases. Both change differences carried clinical significance and also considerably offset the clinically significant greater increases in IMW and IMT that were seen in the TME group during the expansion phase (T1-T2).

The BME and Control groups showed statistically significant differences in IMW, IMT and inter-Mx change. Both groups showed decreases in IMW and IMT during this phase, but the decreases were greater in the BME group in both cases. The IMW change difference carried clinical significance while the IMT change difference did not; nevertheless, both acted to offset the clinically significant greater increases in IMW and IMT that were seen in the BME group during the expansion phase (T1-T2). The inter-Mx width decreased for the BME group and increased for the Control group during this phase; the change difference was not clinically significant, but it nevertheless did somewhat offset the clinically significant greater increase in inter-Mx width that was seen in the BME group during the expansion phase (T1-T2).

In summary, when compared to the Control group, both the TME and BME groups experienced clinically significant decreases in IMW during the settling/post-retention phase. Other statistically significant differences with varying degrees of clinical significance were also found, and all tended to offset the initial increases that were seen during the expansion phase in the actively treated groups. These results suggest that in the absence of retention, the initial

width gains tend to relapse regardless of the type of expansion procedure that is employed. Indeed, the IMW losses during this phase represent ~44% of the initial IMW increase seen in both expansion groups (see Table 3-7).

#### **3.4.3.4 Post-expansion phase (T2-T4)**

The purpose of studying between-group differences during this time interval was to determine (1) whether the overall post-expansion stability differed between the TME and BME groups, and (2) whether the changes measured in each expansion group during this time period differed from the time-matched changes produced by unadulterated growth (Control group).

The TME and BME groups did not show any statistically significant differences in any measurement changes during this phase.

The TME and Control groups showed statistically significant differences in IMW and IMT changes. Both groups showed decreases in both measurements during this phase, but the decreases were greater in the TME group in both cases. Both change differences carried clinical significance and also considerably offset the clinically significant greater increases in IMW and IMT that were seen in the TME group during the expansion phase (T1-T2).

The BME and Control groups showed statistically significant differences in IMW, IMT and inter-Mx change. Both groups showed decreases in IMW and IMT measurements during this phase, but the decreases were greater in the TME group in both cases. Both change differences carried clinical significance and also considerably offset the clinically significant greater increases in IMW and IMT that were seen in the BME group during the expansion phase (T1-T2). The inter-Mx width decreased for the BME group and increased for the Control group during this phase. The resulting change difference was still too small to be considered clinically significant, but it nevertheless somewhat offset the clinically significant greater increase in inter-Mx width that the BME group experienced during the expansion phase (T1-T2).

In summary, the differences found during this phase were similar to those found during the settling/post-retention phase (T3-T4). This is not surprising since

the post-expansion phase encompasses the retention (T2-T3) and settling/post-retention phases, and few between-group change differences occurred during the retention phase. Nevertheless, small but statistically significant relapse tendencies were seen during the retention phase, and when added on to the larger relapse changes seen during the settling phase, the overall post-expansion phase shows even greater relapses in the actively treated groups compared to the untreated group. Indeed, both IMW and IMT showed clinically significant greater decreases in the expansion groups compared to the Control group during this phase. The total loss of initial IMW increase in both expansion groups during this phase was ~51% (see Table 3-7).

#### **3.4.3.5 Pre-settling phase (T1-T3)**

The purpose of studying between-group differences during this time interval was to determine (1) whether the overall pre-settling changes differed between the TME and BME groups, and (2) whether the changes measured in each expansion group during this time period differed from the time-matched changes produced by unadulterated growth (Control group).

The TME and BME groups showed statistically significant differences in IMT change. Both groups showed increases in IMT during this phase, but the increase was greater in the TME group; the difference was too small to be considered clinically significant, however.

The TME and Control groups showed statistically significant differences in IMW, IMT, inter-Ln, inter-Mx, and PP-SN changes. Both the IMW and IMT increased for the TME group and decreased for the Control group during this phase; the resultant change differences were clinically significant in both cases. Both groups showed increases in inter-Ln and inter-Mx during this phase, but the increases were greater in the TME group in both cases; the inter-Ln difference was not large enough on the low end of the CI to be considered clinically significant, but the inter-Mx difference could be argued to carry clinical significance. PP-SN decreased for the TME group and increased for the Control

group during this phase; the resultant change difference was not clinically significant, however.

The BME and Control groups showed statistically significant differences in IMW, IMT, inter-Ln, and inter-Mx changes. Both the IMW and IMT increased for the BME group and decreased for the Control group during this phase; the resultant change difference was clinically significant for IMW, but not for IMT. Both groups showed increases in inter-Ln and inter-Mx during this phase, but only the inter-Mx change difference could be argued to carry clinical significance.

In summary, the differences found during this phase were similar to those found during the expansion phase (T1-T2). This is not surprising since the pre-settling phase encompasses the expansion and retention (T2-T3) phases, and few between-group change differences occurred during the retention phase. Nevertheless, small but statistically significant relapse tendencies were seen during the retention phase, and these made the magnitude of the between-group differences slightly smaller during this phase than during the expansion phase.

#### **3.4.3.6 Overall (T1-T4)**

The purpose of studying between-group differences during this time interval was to determine (1) whether the overall changes differed between the TME and BME groups, and (2) whether the changes measured in each expansion group during this time period differed from the time-matched changes produced by unadulterated growth (Control group).

The TME and BME groups showed statistically significant differences in FOP-SN change. FOP-SN increased for the TME group and decreased for the BME group during this phase; the change difference was not clinically significant, however.

The TME and Control groups showed statistically significant differences in IMW, inter-Ln, inter-Mx, FOP-SN, and MP-SN changes. IMW, FOP-SN, and MP-SN increased for the TME group and decreased for the Control group during this phase; the change difference was clinically significant only for IMW, however. Both groups showed increases in inter-Ln and inter-Mx during this

phase, but the increases were greater in the TME group in both cases; neither change difference was clinically significant, however.

The BME and Control groups showed statistically significant differences in IMW and inter-Ln changes. IMW increased for the BME group and decreased for the Control group during this phase; the change difference was clinically significant. Both groups showed increases in inter-Ln during this phase, but the increase was greater in the BME group; the change difference was not clinically significant, however.

In summary, overall, the only clinically significant difference was the greater increase in IMW seen in the expansion groups compared to the Control group: these were  $2.89 \pm 1.11\text{mm}$  (95% CI) for the TME group and  $2.55 \pm 1.10\text{mm}$  (95% CI) for the BME group. All other clinically significant greater width increases initially seen in the actively treated groups were thus subsequently lost to relapse. Had data collection continued past T4, it is possible that the remaining modest -but clinically significant- IMW change differences would also have eventually dissipated in the absence of retention.

#### **3.4.4 Summary of Findings and Clinical Recommendations**

Though intuitively obvious, data from this study confirmed that maxillary expansion procedures, whether tooth- or bone-anchored, produced immediate dental and skeletal width changes that showed clinically significant greater increases than those produced by unadulterated growth. These initial width increases were accompanied by clinically significant dental tipping increases in both expansion groups as well; regardless of the expansion method then, arch width increases came largely at the expense of buccal crown tipping rather than increases in skeletal width. While all increases were relatively well maintained during the retention phase, they relapsed quickly once retention was discontinued. Indeed, the increase in dental width for both expansion groups was the only measurement that retained a clinically significant greater increase than that of the Control group over the entire length of the study; all the significantly greater initial increases in skeletal widths were ultimately lost to relapse, i.e., neither

expansion procedure ultimately produced a clinically significant increase in skeletal width measurements greater than that produced by unadulterated growth. This being said, it would be interesting to know if the significant IMW difference was maintained indefinitely past the observation period of this study, or if it too would eventually fade completely. Findings of this study also support the current view that the initial increase in vertical dimension brought about by maxillary expansion procedures is only transitory in nature<sup>[16]</sup>; it was not clear from the analyses whether this change in vertical dimension was brought about by skeletal (PP-SN) or dental (FOP-SN) changes, but it is reasonable to assume that plunging of the upper molar palatal cusps occurred as a consequence of the large amount of molar tipping seen initially, and this resulted in a temporary opening of the bite.

This study did not show any clinically significant differences in the dentoskeletal changes -or the stability of these changes- between the two expansion procedures during any phase of the study. Considering the increased risk, cost, and complexity of the BME procedure, the findings of this study cannot support its routine use over the simpler, cheaper, and less invasive TME procedure. In any case, it would appear that a long-term retention protocol is required if maintenance of the transverse correction achieved at the end of active expansion is desired; in the absence of retention, this study suggest that ~51% of the initial IMW increase will be lost within ~6 months regardless of the expansion technique employed (see Table 3-7).

#### **3.4.5 Possible Sources of Error**

During raw data collection, possible sources of error were:

- Incorrect or inconsistent patient positioning for cephalograms;
- Incorrect radiographic exposure settings;
- Distortion of dental impression material<sup>[56]</sup>;
- Incorrect or inaccurate pouring of dental impressions;
- Wear, abrasion, breakage, or distortion of dental casts<sup>[57]</sup>.

During data analysis, possible sources of error were:

- Incorrect radiographic landmark identification;

- Incorrect magnification calibration of cephalograms;
- Incorrect direct measurements on dental casts;
- Subjects undergoing tooth wear or restorative procedures between data collection time points.

The intrarater reliability tests help address some of these potential issues (see section 3.3.4), but even high reliability scores do not safeguard against intrinsically flawed or inconsistently recorded data.

### **3.4.6 Comparison with Past Findings**

As mentioned previously, the subjects in this study have previously had volumetric data analyzed at the same time points as the study herein<sup>[44]</sup> (see section 1.3). The primary investigator of this volumetric study reported the IMW, inter-Mx, and IMT change differences for the expansion (T1-T2), pre-settling (T1-T3), and overall (T1-T4) phases. From these values, changes which took place during the three other phases analyzed in the present study can be extrapolated. Data for direct comparison of the findings from two different methods of measurement, i.e., casts and cephalograms versus volumetric imaging, are thus available for three dentoskeletal measurements.

Table 3-11 lists the mean changes measured in the volumetric study.

**Table 3-11.** Mean dentoskeletal changes measured during each data collection interval in the volumetric study<sup>[44]</sup>

		IMW (mm)	IMT (°)	Inter-Mx (mm)
TME group	Expansion (T1-T2)	5.51	18.36	1.83
	Retention (T2-T3)	0.32	-4.95	-0.14
	Settling (T3-T4)	-1.59	-3.92	-0.87
	Post-expansion (T2-T4)	-1.27	-8.87	-1.01
	Pre-settling (T1-T3)	5.83	13.41	1.69
	Overall (T1-T4)	4.24	9.49	0.82
BME group	Expansion (T1-T2)	5.36	17.25	1.30
	Retention (T2-T3)	0.39	-0.48	-0.31
	Settling (T3-T4)	-1.72	-7.19	-0.37
	Post-expansion (T2-T4)	-1.33	-7.67	-0.74
	Pre-settling (T1-T3)	5.75	16.77	0.99
	Overall (T1-T4)	4.03	9.58	0.62
Control group	Expansion (T1-T2)	N/A	N/A	N/A
	Retention (T2-T3)	-0.07	-2.19	0.63
	Settling (T3-T4)	0.09	1.56	-0.81
	Post-expansion (T2-T4)	0.02	-0.63	-0.18
	Pre-settling (T1-T3)	-0.07	-2.19	0.63
	Overall (T1-T4)	0.02	-0.63	-0.18

The results shown in Table 3-11 (volumetric study) easily lend themselves to comparison with those of Table 3-6 (cast and cephalogram study). It can be seen that there are several differences in the magnitude of the measured dentoskeletal changes reported by the two methods, but the general trends are largely similar, and the main conclusions drawn in both studies are thus concordant as well. Dissimilarities in the magnitude of the measurement changes reported by the two methods can be explained by differences in the procedures used to measure the dentoskeletal parameters. For instance, in the volumetric study, IMW was measured as the distance between first molar pulp chambers, whereas in the present study, cusp tips were used. Moreover, in the volumetric study, IMT was measured using points located on tooth apices and within pulp chambers, whereas in the present study, cusp tips were again used. Along the same lines, the Mx points used in the volumetric study were extrapolated from the location of tooth apices relative to the surrounding alveolar bone, whereas in the present study, radiographic morphological appearance was used. Finally, inter-Mx measurements in this study had corrective magnification factors applied to them, whereas magnification correction was not necessary in the volumetric study.

Aside from the work just discussed, no other scientifically sound study has been published on non-surgically-assisted BME. However, several well-designed studies have investigated the dentoskeletal effects of TME using, as in this study, cephalograms and dental casts. It is nevertheless difficult to compare findings because of differences in such factors as subject age, appliance design, appliance activation, amount of expansion/overexpansion, retention protocol, and method of measurement, but with this in mind, several studies still provide useful data for comparison.

A meta-analysis was conducted by Shiffman and Tuncay<sup>[38]</sup> to assess the stability of IMW increases achieved with TME procedures. For the analysis, six studies<sup>[6, 8, 58-61]</sup> were ultimately selected from an initial pool of 5000 based on predetermined selection criteria. These were: Sample size  $\geq 10$ ; Pre- and post-expansion maxillary IMW measurements reported; Mixed or permanent dentition

only; Clear explanation of retention protocol; No confounding factors such as syndromes or concurrent therapy. All finally selected studies used serial dental casts to assess changes. Mean results were the following: IMW increase immediately after expansion = 6.00mm; Remaining IMW increase at the end of retention period ( $\geq 3$ months) = 4.89mm (18.5% loss); Remaining IMW increase at  $\geq 3$ months post-retention = 3.88mm (35.5% loss). These findings are similar to those of this study. The somewhat higher rate of relapse reported in the meta-analysis during the retention period may be due to differences in the duration of retention and the type of appliance used for retention. Conversely, the lower rate of relapse reported in the post-expansion period may be due to the younger average age of subjects at the beginning of treatment (10.8 years) and/or the fact that several subjects received subsequent treatment such as full fixed appliance therapy before post-retention measurements were recorded.

Another meta-analysis on the topic of TME was performed by Lagravère et al<sup>[39]</sup>, the objective being an assessment of the immediate dentoskeletal changes produced by the procedure. For the analysis, fourteen studies<sup>[6, 8, 12, 62-72]</sup> were ultimately selected from an initial pool of 337 based on predetermined selection criteria. These were: Immediate dental and/or skeletal changes reported; No concurrent therapy during the expansion procedure. All finally selected studies used casts and/or cephalograms to assess dentoskeletal changes. Mean results were the following: IMW increase = 6.74mm; IMT increase = 3.10°; inter-Ln width increase = 2.14mm; inter-Mx width increase = 1.88mm; PP-SN increase = 0.30°; MP-SN increase = 1.97°. Immediate changes in IMW, inter-Ln, inter-Mx, PP-SN, and MP-SN were similar in magnitude to those found in this study. All of these changes except for PP-SN were also found to be statistically significant in both the meta-analysis and the study herein. However, the immediate IMT changes reported in the meta-analysis were smaller than those found in this study, and they were not found to be clinically significant in the former but were in the latter. A possible reason for this discrepancy is the lack of uniformity in the methods used to measure IMT change amongst the studies selected for the meta-analysis: some used PA cephalograms while others used casts. Anatomical

superimpositions on PA cephalograms obscure the analysis of dentoalveolar structures, so this method may yield less valid results, and the studies using casts did not use the same technique as in the present study. Despite the non-significant IMT changes found in the meta-analysis, however, the authors concluded, as in this study, that the significant increase in IMW was more the result of dental tipping than true skeletal expansion.

There are also five systematic reviews pertaining to TME<sup>[3, 5, 17, 40-42]</sup>. One relates only to treatments performed in the primary and early mixed dentition<sup>[40]</sup>, so comparisons with this study are not appropriate. Another aims to compare different methods of crossbite resolution with one another<sup>[5]</sup>, so its results do not easily lend themselves to a comparison with those of this study either. The systematic review of the dental and skeletal changes seen in slow maxillary expansion<sup>[42]</sup> deals with subject matter pertinent to this study, but none of the studies examined in the review were methodologically sound. The two remaining systematic reviews<sup>[3, 41]</sup> warrant a closer look, however.

The first systematic review<sup>[3]</sup> pertains to long-term dental arch changes seen after TME. Inclusion criteria were: Controlled clinical trial; Dental measurement from casts and/or cephalograms; No surgical treatment concurrent with the expansion procedure. Exclusion criteria were: Lack of a control group; Unreported measurement error; Long-term data not provided. Four studies<sup>[11, 73-75]</sup> met all criteria. The authors concluded that, based on the two studies which used casts to take dental measurements<sup>[73, 74]</sup>, TME produced clinically significant long-term (5-6 years post-treatment) increases in IMW when compared to unadulterated growth, the magnitude of the difference being 3.7-4.8mm. This difference is greater than that found at the end of the observation period in this study. Several important factors may play a role in this discrepancy: (1) The retention protocol used in both studies was unclear and/or varied significantly from subject to subject, and the retention period may have been significantly longer than in this study; (2) All post-expansion data collection time points in both studies were after the full fixed appliance therapy which immediately followed the expansion procedure -it is thus impossible to separate the differences

stemming from the expansion procedure from those stemming from the full fixed therapy; (3) Expander activation was greater in both studies than in this study. Both studies also reported long-term IMT changes, but these were only discussed briefly in the systematic review. However, the same problem arises when trying to compare these results to those of this study, i.e., records were not taken until after fixed appliance therapy, and this may have significantly altered the results of the expansion procedure itself. It is nevertheless interesting to note that McNamara et al<sup>[74]</sup> found a decrease in IMT after expansion and fixed appliance therapy, but yet the width measurements taken at the occlusal and cervical levels of the molars would suggest buccal crown tipping. There were thus either significant errors in the measurements or reporting of these measurements, or significant cusp wear artificially altered the measurement of IMT between data collection time points. Either way, this discrepancy in findings was discussed in neither the original article nor the systematic review.

The second relevant systematic review<sup>[41]</sup> pertains to the long-term skeletal changes seen after TME. Inclusion criteria were: Measurements taken on cephalograms; No surgical or other treatment concurrent with the expansion procedure. Exclusion criteria were: Lack of a control group; Unreported measurement error; Long-term data not provided; Unconventional cephalometric analysis. Three studies<sup>[11, 17, 75]</sup> met all criteria. The authors concluded that (1) In prepubertal adolescents, ~25% of IMW increase is the result of a true skeletal width increase, while in postpubertal adolescents, the skeletal contribution is insignificant; (2) TME does not produce significant vertical changes. With regards to vertical changes, the results of this study are in agreement. However, a direct comparison of the results of this study with the first statement is not possible since subjects were not grouped by developmental age for the analyses. As a blanket statement though, it can be said that the skeletal contribution to the clinically significant overall IMW increase of the expansion groups in this study was not clinically significant (see section 3.4.3.6). It would nevertheless be interesting to run an analysis with subjects in this study classified by developmental stage -this could be the object of a subsequent study.

Longitudinal dentoskeletal changes occurring in untreated adolescents have previously been reported in cephalometric and cast analyses as well. In a study by Edwards et al<sup>[76]</sup>, PA cephalograms taken yearly from 10 to 18 years of age on 24 subjects enrolled in the *Iowa Facial Growth Study* were analyzed. Results were similar to those found in this study, i.e., facial skeletal widths show a small but steady increase in size during the adolescent years. In a study by Carter and McNamara<sup>[77]</sup>, serial dental casts from 53 untreated subjects enrolled in the *University of Michigan Elementary and Secondary School Growth Study* were analyzed. Casts were made at three time points: (1) After exfoliation of all deciduous teeth and closure of leeway space (Mean age = 13.9 years); (2) Around the end of puberty (Mean age = 16.9 years); (3) At adult recall (Mean age = 48.2 years). The results were again similar to those reported in this study, i.e., IMW shows a small but steady decrease over time. IMT was not measured in the study, but since the findings of the first study<sup>[76]</sup> show that skeletal widths increase over time and findings of the second study<sup>[77]</sup> show that dental widths decrease over time, it is reasonable to assume that a concomitant decrease in IMT occurs, and this would also be in agreement with the findings of the present study.

In summary, aside from the volumetric analysis of the same sample analysed in this study, there are no existing studies that provide data for comparison with (1) the BME group, or (2) the findings from all the phases analyzed in this study. Several studies evaluated immediate changes and long-term stability of TME, however, and results were mainly similar to those found in this study. Where differences existed, there were plausible reasons for explaining the discrepancies. Dentoskeletal changes found in this study's Control group were similar to those reported in other studies of untreated subjects.

### 3.5 CONCLUSIONS

With the limitations of this study in mind (see sections 3.4.1 and 3.4.5), the following inferences and recommendations can be made with regards to TME and BME in adolescent patients with maxillary constriction:

1. Expansion phase (T1-T2) dentoskeletal changes:
  - No clinically significant change differences between TME and BME.
  - Both expansion methods show clinically significant dentoskeletal width and dental tipping increases compared to unadulterated growth.
2. Retention phase (T2-T3) dentoskeletal changes:
  - No clinically significant change differences between any of the groups; fixed retention is thus successful in preventing relapse of initial increases.
3. Settling/Post-retention phase (T3-T4) dentoskeletal changes:
  - No clinically significant differences between TME and BME.
  - Both expansion methods show clinically significant decreases in dentoskeletal widths and dental tipping compared to unadulterated growth; clinically significant relapse thus occurs once retention is discontinued.
4. Post-expansion phase (T2-T4) dentoskeletal changes:
  - Findings are very similar to those of the settling/post-retention phase since few change differences take place during the retention phase.
5. Pre-settling phase (T1-T3) dentoskeletal changes:
  - Findings are very similar to those of the expansion phase since few change differences take place during the retention phase.
6. Overall (T1-T4) dentoskeletal changes:
  - No clinically significant change differences between TME and BME.
  - Both expansion methods show clinically significant increases in dental width compared to unadulterated growth, but there are no differences in overall skeletal change differences with or without expansion. It should be kept in mind that the last data collection time point was only ~6 months post-expansion, so long-term changes could still occur in the continued absence of retention, i.e., even dental width changes may ultimately be the same with or without expansion if retention is discontinued.
7. Summary:
  - Dentoskeletal changes seen in TME and BME are similar throughout the expansion and post-expansion periods.

- Though both methods of expansion produce significantly greater initial dentoskeletal width increases compared to unadulterated growth, these gains are accompanied by significant dental tipping and tend to be lost quickly in the absence of retention in both groups. Only the greater initial IMW increase seen in TME and BME over unadulterated growth is maintained at ~6 months post-retention.

#### 8. Clinical recommendations:

- Since the study did not show BME to offer any advantages over TME, the routine preferential use of BME cannot be recommended, especially in light of the greater cost, complexity, and invasiveness of the latter.
- Regardless of the method of expansion employed, long-term retention is recommended if the initial width increases are to be maintained.

It can also be concluded that the findings of this study are largely congruent with those of past studies, including the volumetric study performed on the same sample as in this study<sup>[44]</sup>. Volumetric imaging has been shown to produce accurate and reliable measurement results<sup>[78-80]</sup>, and with its ever-increasing availability and advantages over traditional plain film radiography -such as the absence of radiographic magnification, the less critical head-positioning requirements, and the ability to capture the entire skull and dentition in all dimensions with a single exposure-, it appears to provide an improved way of gathering data for orthodontic studies.

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**CHAPTER 4**  
**General Discussion and Conclusions**

## 4.1 Synthesis

Patients with a constricted maxillary arch can have concomitant sequelae such as posterior crossbites and dental crowding. Correction of the constriction can be required to establish proper form and function. For over a half century, TME procedures have been an accepted and frequently used way of treating maxillary constrictions<sup>[1,2]</sup>.

TME procedures have not been without problems, however. Several untoward side-effects associated with TME have been reported over the years. These include opening of the bite<sup>[3]</sup>, buccal cortical bone dehiscence and recession<sup>[4]</sup>, root resorption<sup>[5]</sup>, and a propensity for relapse<sup>[2, 6]</sup>. These issues all relate to the fact that buccal crown tipping is unavoidable with traditional appliances since the expansion force is applied directly to the teeth<sup>[7]</sup>.

In the age of dental implantology, it is now possible to bypass the teeth and apply forces directly to the palatal shelves of the maxilla. In theory, dental side effects would be avoided with such an approach, and early reports of surgically-assisted BME use in humans were enthusiastic, the general consensus being that this procedure provided more stable results than TME<sup>[8-22]</sup>.

However, in a systematic review of the topic of BME conducted in 2008 (see Chapter 2), no scientifically sound studies were found in the literature to support any claims of the benefits of non-surgically-assisted BME over TME. As this review was being conducted, a randomized controlled trial designed to compare the longitudinal effects of non-surgically-assisted TME and BME was concurrently underway at the *University of Alberta*, and a doctoral thesis on the three-dimensional imaging findings of the study has since been completed<sup>[23]</sup>.

The primary objective of the study herein was to gain a better understanding of the differences, if any, between the longitudinal dentoskeletal changes seen in TME, BME, and untreated subjects by way of an analysis of the cephalograms and dental casts which were taken at strategic time points over the course of the parent study<sup>[23]</sup>.

## 4.2 Strengths and Weaknesses

The major strength of this study was the controlled, randomized, longitudinal design of the parent study<sup>[23]</sup> from which the raw data was obtained. Such a design makes causal inferences permissible. Nevertheless, even an appropriate randomization process does not guarantee the formation of groups which are homogenous in all respects, and this fact was exemplified by the significant between-group age discrepancies discussed in section 3.4.1.

The study's main drawback was in the nature of the records which were analyzed: (1) Cephalograms are two-dimensional representations of three-dimensional objects, and they are thus prone to measurement errors due to superimposition of structures and distortion<sup>[24]</sup>. Also, for reproducible results, subject positioning is critical, and even small inconsistencies can lead to error<sup>[25]</sup>. (2) Dental casts are prone to wear, chipping, breakage, and dimensional instability<sup>[26]</sup>. (3) Normal tooth wear as well as routine dental procedures (e.g., restorations) performed on the subjects of a longitudinal study can also artificially influence the measurements obtained from radiographic and cast data. Reliability tests were performed for all measurements in the study, but even very high measurement reliabilities do not safeguard against intrinsically flawed or inconsistently recorded data. Another drawback was that subjects and their guardians were responsible for activating the expansion appliance at home, and compliance levels were less than ideal in some cases; this was probably an important reason for the unexpectedly long expansion periods for both expansion groups.

Finally, during the subject recruitment process, no attempt was made to distinguish (1) transverse skeletal problems from dental ones, or (2) true maxillary constrictions from relative constrictions, i.e., clinically apparent constrictions due to anteroposterior jaw discrepancies rather than transverse problems. It is reasonable to assume that subjects would respond differently based on the cause of their clinically apparent crossbite, and no attempt was made to account for this in this study.

### 4.3 Findings and Conclusions

This study found no evidence of any difference between the dentoskeletal effects seen in TME and BME at any time during or after the expansion procedure in a sample of adolescents with maxillary constriction. The initial large increase in dental width produced by both expansion methods came largely at the expense of buccal molar tipping, and in the absence of fixed retention, equally significant relapse occurred in both groups. This was somewhat surprising, but reports of similar findings have emerged in the literature<sup>[27]</sup>.

A possible explanation is that the limiting factor in achieving a true separation of the palatal shelves lies not in the location of transverse force application, but rather in the attachment of the maxilla to surrounding bones such as the palatine and sphenoid bones posteriorly, and the frontal, ethmoid, nasal, lacrimal, vomer, and zygomatic bones superiorly and laterally. Should this be the case, then any method not involving a surgical separation of the maxilla from its neighboring bones may ultimately lead to similar results.

### 4.4 Future Research

There remains a wealth of unanalyzed raw data from the parent study<sup>[23]</sup>, and interesting research opportunities abound.

For instance, hand-wrist radiographs were taken at each data collection time point, and they can be used to classify subjects by skeletal maturity rather than chronological age. A discriminant analysis could then be run to see if results differ based on skeletal maturation. Similarly, subjects could be classified based on the cervical vertebral analysis obtained from lateral cephalograms, and an analogous analysis could be run independently or in conjunction with the former. These would be useful analyses since subjects of the same chronological age are not necessarily of the same developmental age<sup>[7]</sup>; this is especially true between sexes, and there was a much larger number of female subjects than male subjects

in this study (see Table 3-2). Indeed, an investigation of this topic is currently underway at the *University of Alberta*.

Subjects could also be grouped by such characteristics as facial type, cause of maxillary constriction, and degree of maxillary constriction, and the influence of these traits on clinical outcomes could be assessed.

Using the clinical photos taken at each data collection time point, a visual assessment of changes in facial appearance and periodontal condition between the three groups is also possible. Moreover, a review of the progress notes in subjects' charts could shed light on the types and frequency of complications encountered with each expansion method.

A thesis on airway changes induced by maxillary expansion has been completed<sup>[28]</sup>, and a study comparing these findings with volumetric measurements obtained via the available three-dimensional images could be intriguing as well.

Although three-dimensional image analysis will likely be the method of choice for measuring all dentoskeletal changes in future studies because of its advantages over traditional methods (see section 3.5), there remain several measurements which could be taken on the dental casts and cephalograms. For instance, possible between-group change differences in maxillary intercanine widths, lower arch widths, overbite, overjet, and anteroposterior dentoskeletal relationships could be investigated. The dental casts could also be scanned and analyzed electronically; this may allow useful manipulations which are not possible with direct measurements, and the *University of Alberta* is equipped with a *Faro Arm (Faro Technologies, Lake Mary, FL, USA)* that could be used for this purpose.

Finally, regardless of the research topic, it is important to quantify the magnitude of change which is considered clinically significant. Because there are currently no such norms for most measurements, the determination of clinical significance in study discussions has heretofore been somewhat arbitrary in many cases. As such, a study designed to measure the threshold of clinical significance

for measurements commonly used to compare groups in orthodontic studies would be a valuable contribution to the profession as well.

At any rate, there are current works in progress at the *University of Alberta* to design a new bone-anchored expansion device which researchers hope will provide more desirable outcomes<sup>[27]</sup>. It thus appears that there will not be a shortage of new findings and advances on this topic in the coming years.

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## APPENDIX

# APPENDIX A

## Ethical Approval Forms

### Health Research Ethics Board

308 Campus Tower  
University of Alberta, Edmonton, AB T6G 1K8  
p. 780.492.9724 (Biomedical Panel)  
p. 780.492.0302 (Health Panel)  
p. 780.492.0459  
p. 780.492.0839  
f. 780.492.7808

### ETHICS APPROVAL FORM - DELEGATED REVIEW

Date: June 4, 2009  
Principal Investigator: Paul Major  
Study ID: Pro00006809  
Study Title: **Tooth-Anchored Vs. Bone-Anchored Maxillary Expansion.** A controlled, randomized study comparing dental and skeletal effects

Thank you for submitting the above study to the Health Research Ethics Board (Biomedical Panel). Your application, which involves the use of anonymized data collected in another study, has been reviewed and approved on behalf of the committee.

The ethics approval is valid until May 19, 2010. A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. You will receive electronic reminders at 60, 30, 15 and 1 day(s) prior to the expiry date. If you do not renew on or before that date, you will have to re-submit an ethics application.

For studies where investigators must obtain informed consent, signed copies of the consent form must be retained, as should all study related documents, so as to be available to the HREB on request. They should be kept for the duration of the project and for at least seven years following its completion.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of research. We assume that appropriate approval from your department is in place.

Sincerely,

J. Stephen Bamforth, MD  
Associate Chair, Health Research Ethics Board (Biomedical Panel)

*Note: This correspondence includes an electronic signature (validation and approval via an online system).*



## Health Research Ethics Board

308 Campus Tower  
University of Alberta, Edmonton, AB T6G 1K8  
p. 780.492.9724 (Biomedical Panel)  
p. 780.492.0302 (Health Panel)  
p. 780.492.0459  
p. 780.492.0639  
f. 780.492.9429

### Notification Re-approval

Date: April 22, 2010

Principal Investigator: Paul Major

Renewal ID: Pro00006809\_REN1

Study ID: Pro00006809

#### **Tooth-Anchored Vs. Bone-Anchored Maxillary Expansion**

Study Title: A controlled, randomized study comparing dental and skeletal effects

Approval Expiry Date: May 18, 2011

Thank you for returning the request for re-approval of this study. The Health Research Ethics Board (Biomedical Panel) has reviewed the file on this project for which all documentation is currently up-to-date. The research has been found to be acceptable within the limitations of human experimentation.

#### **Specific Comments**

The expiration date for this approval is noted above. A renewal report or closure report must be submitted next year prior to the expiry of this approval. You will receive electronic reminders at 45, 30, 15 and 1 day(s) prior to the expiry date. If you do not renew on or before that date, you will have to submit a new ethics application.

For studies where investigators must obtain informed consent, signed copies of the consent form must be retained, as should all study related documents, so as to be available to the HREB on request. They should be kept for the duration of the project and for at least seven years following its completion. In the case of clinical trials approved under Division 5 of the Food and Drug regulations of Health Canada, study records must be retained for 25 years.

Sincerely,

S.K.M. Kimber, MD, FRCPC  
Chair, Health Research Ethics Board (Biomedical Panel)

*Note: This correspondence includes an electronic signature (validation and approval via an online system).*



## **APPENDIX B**

### **Additional information pertaining to the statistical analyses employed**

#### **Parametric model assumptions**

For a statistical analysis to yield trustworthy results, certain assumptions pertaining to the data must be met. For repeated-measures multivariate analyses, these are: normality, sphericity, equal variance, and linearity.

Multivariate normality testing was limited to an assessment of the outcome box plots of interest, the difference score box plots, the bivariate plots of each outcome pair, and the normal Q-Q plot of each outcome variable. An overall visual inspection did not reveal any gross violations of normality in the univariate and bivariate dimensions. Furthermore, since this test is quite robust against reasonable departures from normality -especially when groups are fairly large and equal in size such as in this study-, the presence of moderately skewed distributions was not considered an obstacle to using this parametric method. As for sphericity, Mauchly's test was not applicable since only two time points were compared in each analysis. Based on Box's M, there was a violation of the homogeneity of the variance-covariance matrices across groups for certain comparisons. However, Levene's tests of univariate equality of variance across groups showed that nearly all outcome variables in each of the six analyses met this assumption. Furthermore, Box's M test is well-known to be overly sensitive, and it has been stated that if the number of experimental units in each group is approximately equal (as they are in this study), then Box's test may be ignored. For these reasons, the significant findings of Box's M test were not a concern. Finally, the linearity assumption was met based on a visual inspection of the bivariate plots of the outcome variables. All of the repeated-measures multivariate assumptions can thus be considered to have been fulfilled.

#### **Non-parametric testing**

Even though parametric assumptions appeared to be met, the non-parametric Kruskal-Wallis analysis was carried out to test each of the six research

hypotheses. The yielded p-values were all similar to those returned by the parametric tests (see section 3.3). Therefore, any violations of the parametric model assumptions do not appear to have had a major effect on the test conclusions, and the more detailed results provided by the parametric tests can be considered trustworthy.

### **Post-hoc tests**

The Bonferroni procedures were chosen for post-hoc multiple comparisons because equal variance was assumed and comparisons were not planned.

### **Outlier examination strategy**

A potential problem for all analyses was the presence of possible outliers, because the RM-MANOVA tests are not resistant to the latter. To test the effect of these possible outliers on the study results, the following outlier examination strategy was employed: all analyses were rerun with the potential outliers removed, and the results were compared to those obtained with the outliers present. Since the p-values were similar with and without the outliers in all cases, it could be concluded that the presence of the potential outliers did not have a major influence on the main results, and the analyses which included the potential outliers were thus reported.

### **Accounting for differential expansion amounts**

Subjects in this study were not each expanded by an equal amount, but rather by the amount necessary to resolve their individual crossbite. If it was found that TME and BME group subjects were expanded, on average, by a significantly different amount, it would be necessary to account for this difference during group comparisons of all other measures. However, this was not the case (see Table 3-8), so adding an extra level of complexity to the statistical analyses was not necessary.

### **Analysis of covariance**

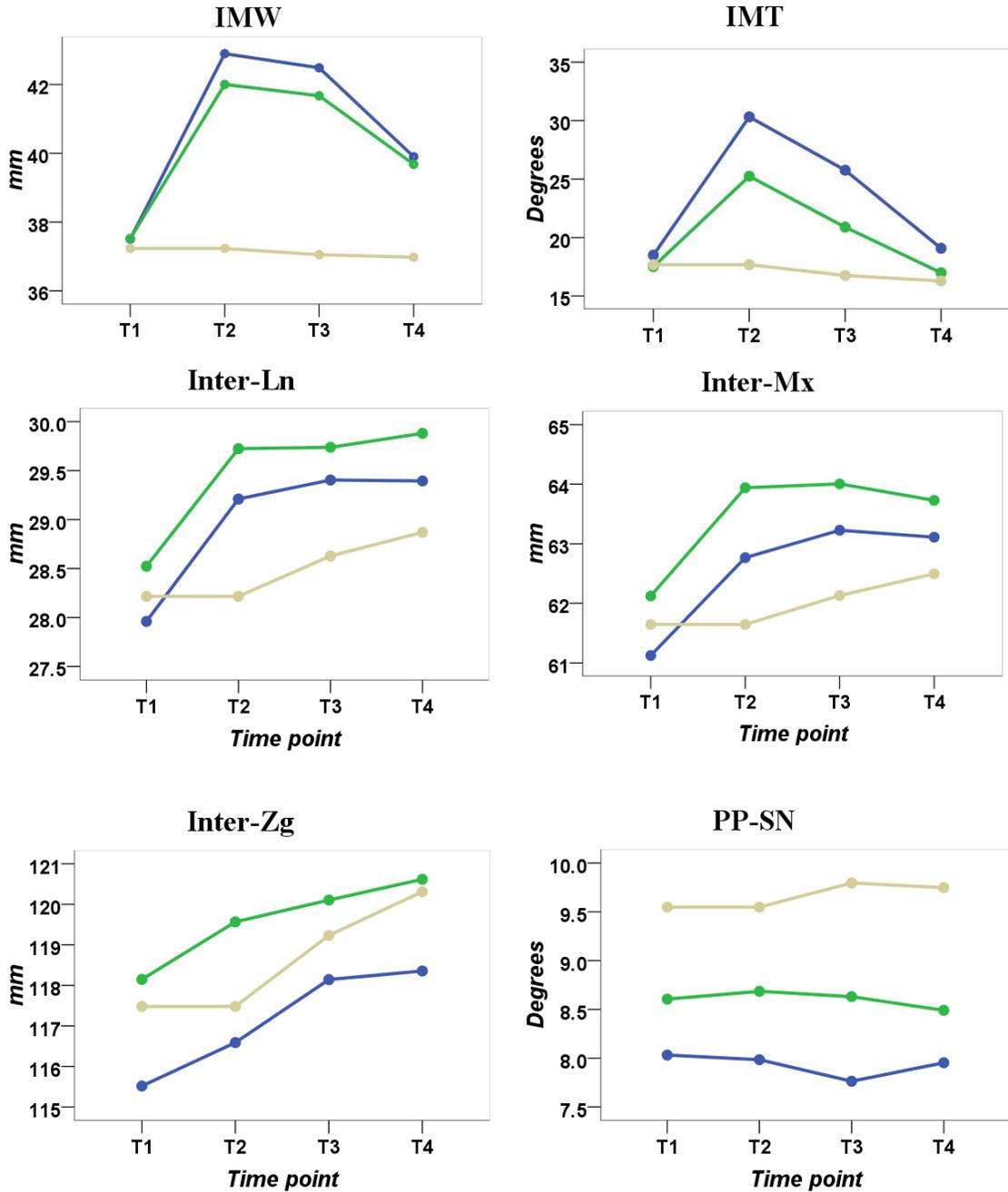
Even with randomization, group subjects are sometimes dissimilar from the start of a study in the parameters to be compared over the course of the study. In such cases, accounting for baseline differences via a statistical method such as an analysis of covariance may be indicated. However, it was shown that the groups in this study were homogenous at baseline (T1) from the standpoint their dentoskeletal measurements of interest (see Table 3-4 and paragraph immediately below it); thus, an analysis of covariance was not warranted.

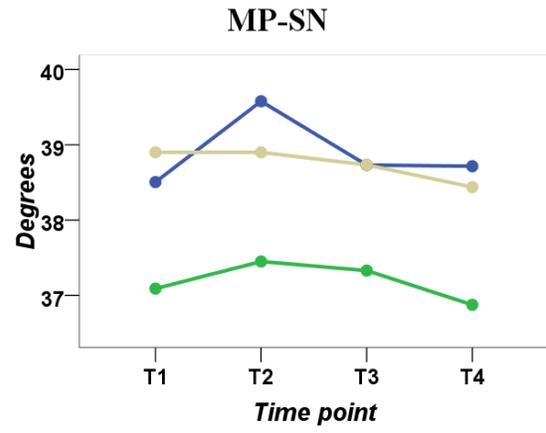
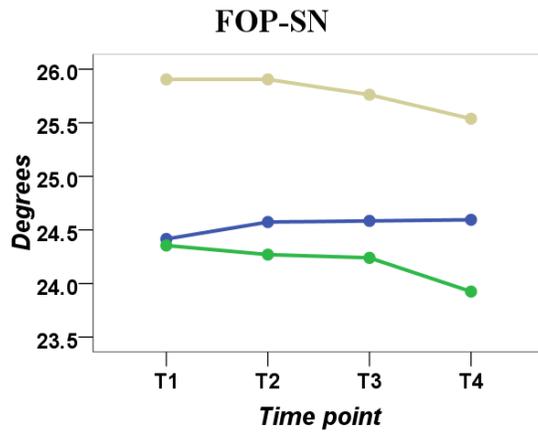
While the baseline between-group dentoskeletal characteristics were shown to be homogenous, however, it was found that between-group mean age and data collection time spans were not. An analysis of covariance could be useful in evaluating whether the data collection time span differences had a significant impact on the results, but such an analysis is not intuitively understood and was thus avoided in this paper.

## APPENDIX C

**Profile plots of the mean outcome value of each dentoskeletal measurement taken at each data collection time point for each group**

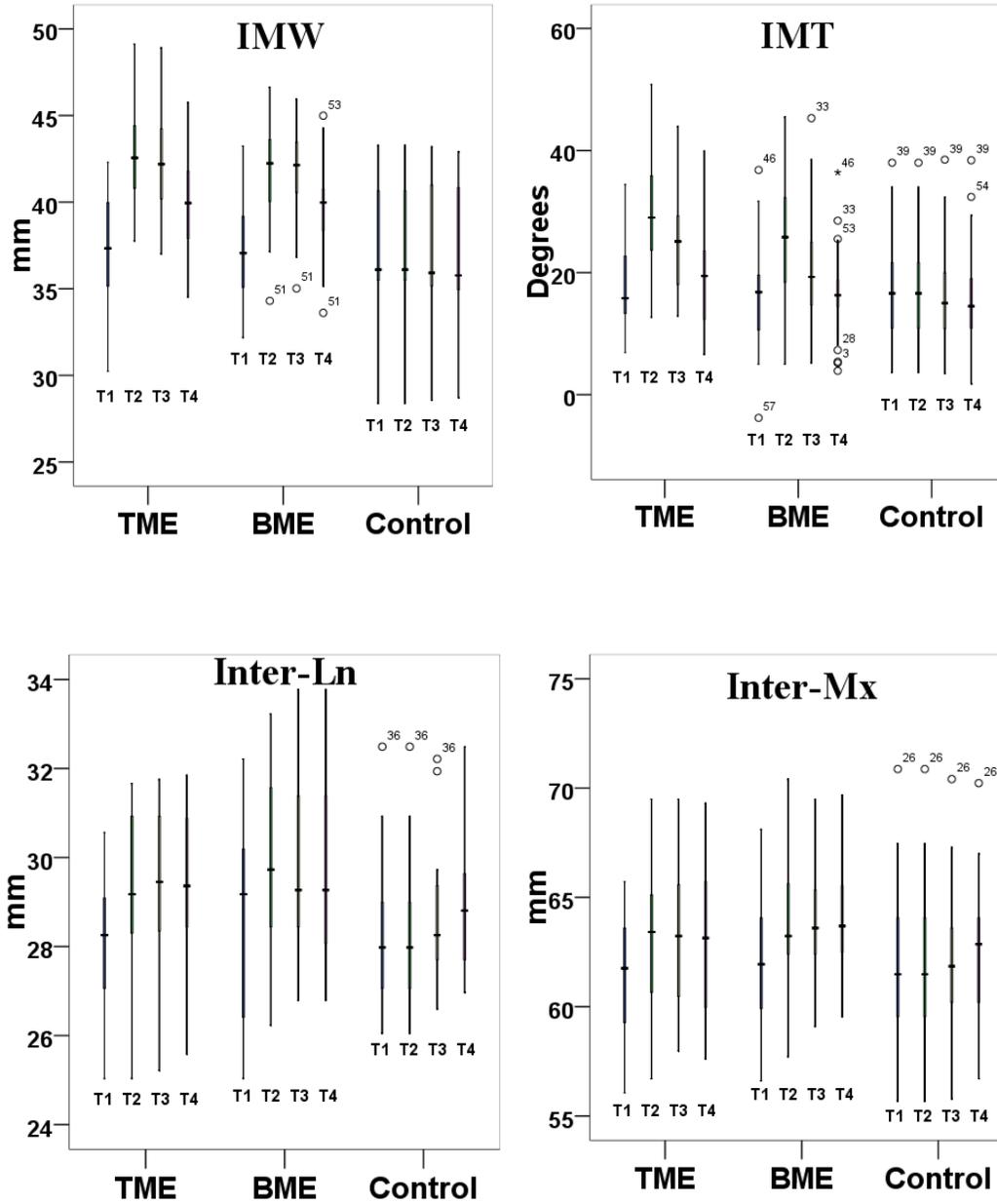
■ TME group  
■ BME group  
■ Control group

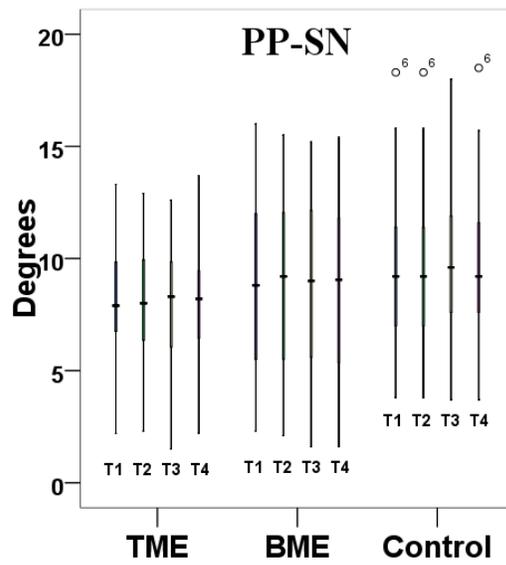
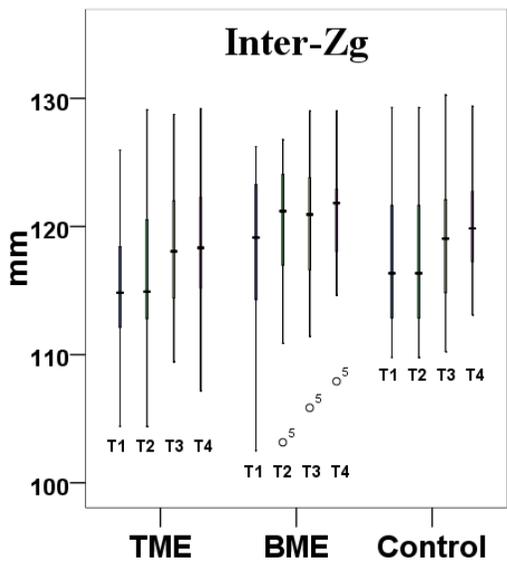
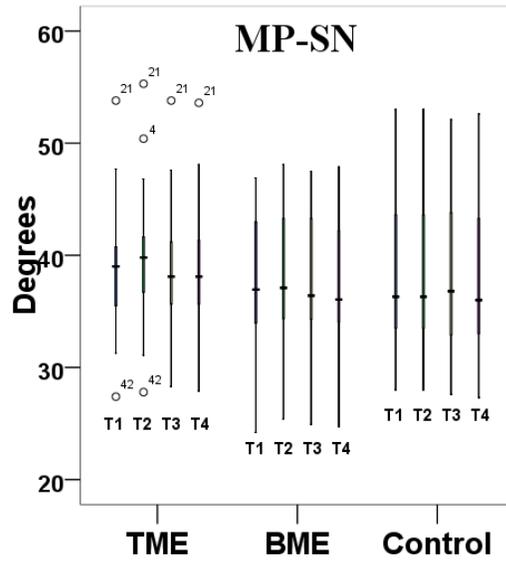
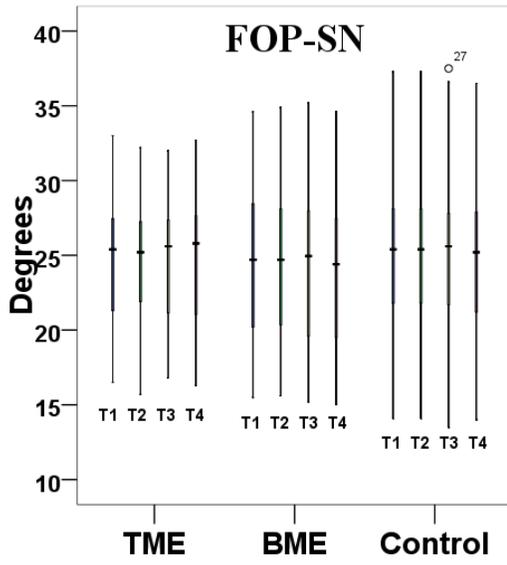




## APPENDIX D

**Box plots of the mean outcome value of each dentoskeletal measurement taken at each data collection time point for each group**





## APPENDIX E

### Expansion phase (T1-T2):

#### Detailed results of the statistical analyses performed to investigate for between-group differences in dentoskeletal measurement changes

The RM-MANOVA procedure indicated that statistically significant between-group differences in dentoskeletal changes took place during this phase [ $\Lambda=0.199$ ,  $F(16, 102) = 7.930$ ,  $p \sim 0.000$ ]. All eight dentoskeletal measurements were thus submitted to univariate testing (RM-ANOVA), and the results are listed in the table below.

RM-ANOVA results for all measurements, T1-T2 interval<sup>a</sup>

	p-value	$\eta^2$
IMW	< <b>0.001</b>	0.647
IMT	< <b>0.001</b>	0.599
Inter-Ln	< <b>0.001</b>	0.386
Inter-Mx	< <b>0.001</b>	0.388
Inter-Zg	<b>0.017</b>	0.131
PP-SN	0.684	0.013
FOP-SN	0.471	0.026
MP-SN	< <b>0.001</b>	0.319

<sup>a</sup>  $\eta^2$  = partial eta squared, i.e., the proportion of the total variability attributable to group membership.

The above table shows that there were statistically significant between-group differences in the IMW, IMT, inter-Ln, inter-Mx, inter-Zg, and MP-SN changes during this phase. Furthermore, the amount of variability in these measurement changes that was attributable to group membership ran as high as ~65% for IMW and as low as ~13% for inter-Zg.

To further elucidate the nature of the between-group differences during this phase, the difference scores were submitted to one-way MANOVA and

*Bonferroni* post-hoc testing; the results are shown in Table 3-8, and the p-values for measurements showing statistically significant between-group differences are shown in the table below.

T1-T2 measurement changes showing statistically significant between-group differences

		p-value
TME – BME	IMT ( ° )	0.009
	MP-SN ( ° )	0.002
TME – Control	IMW (mm)	< 0.001
	IMT ( ° )	< 0.001
	Inter-Ln (mm)	< 0.001
	Inter-Mx (mm)	< 0.001
	MP-SN ( ° )	< 0.001
BME – Control	IMW (mm)	< 0.001
	IMT ( ° )	< 0.001
	Inter-Ln (mm)	< 0.001
	Inter-Mx (mm)	< 0.001
	Inter-Zg (mm)	0.021

## APPENDIX F

### Retention phase (T2-T3):

#### Detailed results of the statistical analyses performed to investigate for between-group differences in dentoskeletal measurement changes

The RM-MANOVA procedure indicated that statistically significant between-group differences in dentoskeletal changes took place during this phase [ $\Lambda = 0.449$ ,  $F(16, 100) = 3.077$ ,  $p \sim 0.000$ ]. All eight dentoskeletal measurements were thus submitted to univariate testing (RM-ANOVA), and the results are listed in the table below.

RM-ANOVA results for all measurements, T2-T3 interval

	p-value	$\eta^2$
IMW	0.393	0.032
IMT	<b>0.002</b>	0.203
Inter-Ln	0.175	0.059
Inter-Mx	0.195	0.056
Inter-Zg	0.204	0.054
PP-SN	<b>0.004</b>	0.176
FOP-SN	0.742	0.010
MP-SN	<b>0.005</b>	0.167

The above table shows that there were statistically significant between-group differences in the IMT, PP-SN, and MP-SN changes during this phase. Furthermore, the amount of variability in these measurement changes that was attributable to group membership ran as high as ~20% for IMT and as low as ~17% for MP-SN.

To further elucidate the nature of the between-group differences during this phase, the difference scores were submitted to one-way MANOVA and *Bonferroni* post-hoc testing; the results are shown in Table 3-8, and the p-values

for measurements showing statistically significant between-group differences are shown in the table below.

T2-T3 measurement changes showing statistically significant between-group differences

		p-value
TME – BME	MP-SN ( ° )	0.011
TME – Control	IMT ( ° )	0.004
	PP-SN ( ° )	0.003
	MP-SN ( ° )	0.017
BME – Control	IMT ( ° )	0.007

## APPENDIX G

### Settling/Post-retention phase (T3-T4):

#### Detailed results of the statistical analyses performed to investigate for between-group differences in dentoskeletal measurement changes

The RM-MANOVA procedure indicated that statistically significant between-group differences in dentoskeletal changes took place during this phase [ $\Lambda = 0.344$ ,  $F(16, 102) = 4.495$ ,  $p \sim 0.000$ ]. All eight dentoskeletal measurements were thus submitted to univariate testing (RM-ANOVA), and the results are listed in the table below.

RM-ANOVA results for all measurements, T3-T4 interval

	p-value	$\eta^2$
IMW	< <b>0.001</b>	0.489
IMT	< <b>0.001</b>	0.339
Inter-Ln	0.455	0.027
Inter-Mx	<b>0.008</b>	0.153
Inter-Zg	0.306	0.040
PP-SN	0.157	0.062
FOP-SN	0.134	0.067
MP-SN	0.159	0.061

The above table shows that there were statistically significant between-group differences in the IMW, IMT, and inter-Mx changes during this phase. Furthermore, the amount of variability in these measurement changes that was attributable to group membership ran as high as ~49% for IMW and as low as ~17% for inter-Mx.

To further elucidate the nature of the between-group differences during this phase, the difference scores were submitted to one-way MANOVA and *Bonferroni* post-hoc testing; the results are shown in Table 3-8, and the p-values

for measurements showing statistically significant between-group differences are shown in the table below.

T3-T4 measurement changes showing statistically significant between-group differences

		p-value
TME – Control	IMW (mm)	< 0.001
	IMT ( ° )	< 0.001
BME – Control	IMW (mm)	< 0.001
	IMT ( ° )	0.009
	Inter-Mx (mm)	0.020

## APPENDIX H

### Post-expansion phase (T2-T4):

#### Detailed results of the statistical analyses performed to investigate for between-group differences in dentoskeletal measurement changes

The RM-MANOVA procedure indicated that statistically significant between-group differences in dentoskeletal changes took place during this phase [ $\Lambda = 0.347$ ,  $F(16, 102) = 4.443$ ,  $p \sim 0.000$ ]. All eight dentoskeletal measurements were thus submitted to univariate testing (RM-ANOVA), and the results are listed in the table below.

RM-ANOVA results for all measurements, T2-T4 interval

	p-value	$\eta^2$
IMW	< <b>0.001</b>	0.448
IMT	< <b>0.001</b>	0.448
Inter-Ln	<b>0.040</b>	0.105
Inter-Mx	<b>0.004</b>	0.173
Inter-Zg	0.068	0.089
PP-SN	0.053	0.097
FOP-SN	0.245	0.047
MP-SN	0.198	0.054

The above table shows that there were statistically significant between-group differences in the IMW, IMT, inter-Ln and inter-Mx changes during this phase. Furthermore, the amount of variability in these measurement changes that was attributable to group membership ran as high as ~45% for both IMW and IWT, and as low as ~10% for inter-Ln.

To further elucidate the nature of the between-group differences during this phase, the difference scores were submitted to one-way MANOVA and *Bonferroni* post-hoc testing; the results are shown in Table 3-8, and the p-values

for measurements showing statistically significant between-group differences are shown in the table below.

T2-T4 measurement changes showing statistically significant between-group differences

		p-value
TME – Control	IMW (mm)	< 0.001
	IMT ( ° )	< 0.001
BME – Control	IMW (mm)	< 0.001
	IMT ( ° )	< 0.001
	Inter-Mx (mm)	0.003

The above table shows that the post-hoc tests did not reveal any statistically significant differences between the groups for the inter-Ln width change even though the preliminary univariate tests (RM-ANOVA) in the first table suggested that there were. This discrepancy occurred because the p-values obtained from the preliminary univariate tests do not account for the artificially inflated level of confidence; the true p-values are thus higher than those reported in the first table.

## APPENDIX I

### Pre-settling phase (T1-T3):

#### Detailed results of the statistical analyses performed to investigate for between-group differences in dentoskeletal measurement changes

The RM-MANOVA procedure indicated that statistically significant between-group differences in dentoskeletal changes took place during this phase [ $\Lambda = 0.254$ ,  $F(16, 102) = 6.282$ ,  $p \sim 0.000$ ]. All eight dentoskeletal measurements were thus submitted to univariate testing (RM-ANOVA), and the results are listed in the table below.

RM-ANOVA results for all measurements, T1-T3 interval

	p-value	$\eta^2$
IMW	< <b>0.001</b>	0.680
IMT	< <b>0.001</b>	0.458
Inter-Ln	<b>0.002</b>	0.200
Inter-Mx	< <b>0.001</b>	0.269
Inter-Zg	0.565	0.020
PP-SN	<b>0.023</b>	0.122
FOP-SN	0.359	0.035
MP-SN	0.063	0.091

The above table shows that there were statistically significant between-group differences in the IMW, IMT, inter-Ln, inter-Mx, and PP-SN changes during this phase. The amount of variability in these measurement changes that was attributable to group membership ran as high as ~68% for IMW and IWT, and as low as ~12% for PP-SN.

To further elucidate the nature of the between-group differences during this phase, the difference scores were submitted to one-way MANOVA and *Bonferroni* post-hoc testing; the results are shown in Table 3-8, and the p-values

for measurements showing statistically significant between-group differences are shown in the table below.

T1-T3 measurement changes showing statistically significant between-group differences

		p-value
TME – BME	IMT ( ° )	0.006
TME – Control	IMW (mm)	< 0.001
	IMT ( ° )	< 0.001
	Inter-Ln (mm)	0.002
	Inter-Mx (mm)	< 0.001
	PP-SN ( ° )	0.019
BME – Control	IMW (mm)	< 0.001
	IMT ( ° )	0.001
	Inter-Ln (mm)	0.015
	Inter-Mx (mm)	0.001

## APPENDIX J

### Overall phase (T1-T4):

#### Detailed results of the statistical analyses performed to investigate for between-group differences in dentoskeletal measurement changes

The RM-MANOVA procedure indicated that statistically significant between-group differences in dentoskeletal changes took place during this phase [ $\Lambda = 0.364$ ,  $F(16, 104) = 4.272$ ,  $p \sim 0.000$ ]. All eight dentoskeletal measurements were thus submitted to univariate testing (RM-ANOVA), and the results are listed in the table below.

**Table 3-18.** RM-ANOVA results for all measurements, T1-T4 interval

	p-value	$\eta^2$
IMW	< <b>0.001</b>	0.457
IMT	0.096	0.076
Inter-Ln	<b>0.011</b>	0.142
Inter-Mx	<b>0.009</b>	0.147
Inter-Zg	0.861	0.005
PP-SN	0.133	0.066
FOP-SN	<b>0.017</b>	0.130
MP-SN	<b>0.012</b>	0.139

The above table shows that there were statistically significant between-group differences in the IMW, inter-Ln, inter-Mx, FOP-SN, and MP-SN changes during this phase. Furthermore, the amount of variability in these measurement changes that was attributable to group membership ran as high as ~46% for IMW and as low as ~14% for the four others.

To further elucidate the nature of the between-group differences during this phase, the difference scores were submitted to one-way MANOVA and *Bonferroni* post-hoc testing; the results are shown in Table 3-8, and the p-values

for measurements showing statistically significant between-group differences are shown in the table below.

T1-T4 measurement changes showing statistically significant between-group differences

		p-value
TME – BME	FOP-SN ( ° )	0.033
TME – Control	IMW (mm)	< 0.001
	Inter-Ln (mm)	0.022
	Inter-Mx (mm)	0.011
	FOP-SN ( ° )	0.033
	MP-SN ( ° )	0.011
BME – Control	IMW (mm)	< 0.001
	Inter-Ln (mm)	0.033