ORTHODONTIC ANCHORAGE – EVIDENCE-BASED EVALUATION OF ANCHORAGE CAPACITY AND PATIENTS’ PERCEPTIONS
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ORTHODONTIC ANCHORAGE

Evidence-based evaluation of anchorage capacity and patients’ perceptions

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To Hartmut, Andreas and Antonia

Give me a place to stand and I will move the earth”
Archimedes 287 – 212 BC
This thesis is based on the following papers, which are referred to in the text by their Roman numerals I-IV.


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ABSTRACT

Orthodontic anchorage is the ability to resist unwanted reciprocal forces and reinforcement of anchorage by supplementary appliances, in or outside the mouth, is often needed to obtain successful results. In the last 10 years, interest in appliances that use implants has been growing.

Successful orthodontic treatment demands effective methods and systematic evaluation of different treatment approaches is therefore essential. Several studies on the efficiency of various anchorage systems have been published, but a critical appraisal or interpretation of evidence that systematically considers validity, results, and relevance has not been made. Analysis of treatment modalities must also include patients’ perceptions and potential side-effects.

The overall aim of this thesis was to evaluate a new anchorage technique that incorporates osseointegration and compare it with conventional methods concerning effects on tooth movements in adolescents and their acceptance and experience of the additional surgical procedures that osseointegration involves. The following anchorage systems were analyzed: Onplant system, Orthosystem implant, headgear and transpalatal bar.

This thesis was based on four studies:

Paper I systematically reviewed the efficiency of orthodontic anchorage systems and interpreted the methodological quality of the selected studies from an evidence-based perspective. The literature search spanned January 1966 – December 2004 and was later extended to July 2007.
Paper II, a methodological study involving 60 adolescent patients, examined the validity and reliability of a new questionnaire for assessing adolescent patients’ perceptions of orthodontic treatment. The questionnaire was based on focus group interviews.

Papers III and IV were randomized controlled trials involving 120 adolescent patients in orthodontic treatment. Paper III evaluated and compared adolescent patients’ perceptions of premolar extractions and surgical placement of Onplants and Orthosystem implants. Paper IV compared anchorage capacities of the four systems.

These conclusions were drawn:

- The scientific evidence, found in the review, was too weak to evaluate the efficiency of various anchorage systems (conventional and osseointegrated) during space closure after premolar extraction, and most studies have quality problems. Future randomized controlled trials are recommended.
- The new questionnaire, developed from focus group interviews, had overall acceptable to good reliability and high face validity. It can therefore be recommended for use in the assessment of adolescents’ experiences of orthodontic treatment.
- Pain intensity after surgical placement of an Orthosystem implant was less than after Onplant installation and premolar extraction. Pain intensity after Onplant installation and premolar extractions were comparable.
- With respect to pain intensity, discomfort, and analgesic consumption, the Orthosystem implant can be recommended over the Onplant system.
- The Onplant system and the Orthosystem implant provided stable anchorage throughout the observation period. Headgear anchorage was stable during the leveling/aligning phase but anchorage loss occurred at the end of the observation period. Transpalatal bar anchorage was never sufficient at any point in the observation period.
- Headgear and the transpalatal bar can only be recommended when need for anchorage reinforcement is limited.
• For maximum anchorage and if patients’ perceptions are considered, the osseointegrated Orthosystem implant is the system of choice.
POPULÄRVETENSKAPLIG SAMMANFATTNING

När en tand utsätts för en kraft genereras alltid en motriktad (recipro) kraft av samma dimension. Ortodontisk förankring definieras som förmåga att avleda oönskade reciproka krafter och förankringsförstärkning ingår ofta som en viktig del i behandlingsplaneringen för att säkerställa att behandlingsmålet uppnås. Under den senaste 10-års-perioden har stort intresse visats för tekniker som använder benförankrad förankringsförstärkning.


Det övergripande syftet med denna avhandling var att utvärdera ny förankringsteknik, baserad på osseointegrering, och jämföra med konventionella metoder med avseende på förankringskapacitet hos en grupp ungdomar som genomgår ortodontisk behandling. Dessutom analyserades patienternas upplevelser av de tillkommande kirurgiska momenten och jämfördes med tandextraktioner.

Följande fyra förankringssystem system har analyserats: Onplant, Orthoimplantat samt extraoralt drag (EOD) och transpalatinal bar.

Avhandlingen är baserad på följande studier

Studie I var en systematisk litteraturöversikt över effektiviteten av olika förankringssystem, ur ett evidensbaserat perspektiv. I syftet för

Studie II var en metodstudie som inkluderade 60 ungdomar och där reliabiliteten och validiteten av ett nytt frågeformulär, baserat på fokusgruppintervjuer, analyserades.

Studie III och IV var randomiserade kontrollerade studier med 120 ungdomar som genomgick ortodontisk behandling. Studie III utvärderade och jämförde ungdomars upplevelser av kirurgisk insättning av två olika osseointegrerade förankringselement och premolar extraktioner. Studie IV analyserade och jämförde förankringskapaciteten för de fyra olika förankringssystemen.

Konklusioner:

- Översikten visade att det inte var möjligt att dra några evidensbaserade slutsatser om förankringsförstärkning på molarer efter premolar extraktioner. Studiernas kvalitet var mestadels låg och mera forskning behövs.
- Det nya frågeformuläret, baserat på fokusgruppintervjuer, uppvisade acceptabel till god reliabilitet och hög validitet. Det kan därför i framtiden rekommenderas när ungdomars erfarenheter av ortodontisk behandling skall utvärderas.
- Smärta efter kirurgisk insättning av Orthoimplantet var lägre än efter insättning av ett Onplant eller premolarextraktioner. Smärta efter kirurgisk insättning av ett Onplant var jämförlig med premolarextraktioner.
- Onplant och Orthoimplantat-systemet utgjorde stabil förankring under observationsperioden medan både EOD och transpalatinal bar uppvisade förankringsförluster.
- EOD och transpalatinal bar kan endast rekommenderas när begränsad förankring eftersträvas.
- Vid behov av maximal förankring och om hänsyn tas till patientens upplevelser så är det osseointegrerade Orthoimplantatet det rekommenderade förankringssystemet.
INTRODUCTION

Orthodontic anchorage

The law of Nature that underlies orthodontic tooth movement is Newton’s third law of motion (1687): For every action there is an opposite and equal reaction. This natural law guides orthodontic treatment thought in the planning of (1) what forces and moments are needed to reach treatment objectives and (2) what reactive forces need to be diverted.

In most cases anchorage is produced within the orthodontic appliance with the strategy to dissipate the reaction forces over as many teeth as possible and thereby control anchorage. Pressure in the periodontal ligaments of the anchor teeth are thereby kept to a minimum. The anchor value of each tooth can be mathematically estimated as a function of root-surface area, and magnitudes of the forces of orthodontic tooth movements can be predicted. But this principle is not always reliable since anchorage capacity is also influenced by attachment level, density and structure of the alveolar bone, periodontal reactivity, muscular activity, occlusal forces, craniofacial morphology, and friction resulting from tooth movement. The stability of biological anchorage may thus be enhanced by selectively modifying various moments and forces to alter root inclination or torque of the anchorage teeth. These techniques are effective, but they depend on the dexterity and biomechanical skills of the operator and the capability to deal with possible adverse side effects like rotation and vertical forces.
Satisfactory reinforcement of anchorage may therefore require supplementary use of extraoral units, like headgear. Headgear can be effective and is easily adjustable for dissipating adverse vertical and rotational side effects but also limited: headgear is seldom used for more than part of the day, and its metallic bow has been associated with injury in the facial area.

Another strategy is the use of intermaxillary elastics to distribute reaction forces to the opposite jaw, thereby spreading forces over a larger area of the periodontal ligament and reducing pressure on the anchor units. Risk of vertical side effects and tipping, can however limit the use of elastics as routine anchorage. Use of headgear or elastics is highly dependent on patient cooperation, which implies a risk of prolonged treatment time and jeopardizes the treatment goal if patients do not cooperate. Patient cooperation is also considered difficult to predict.

To minimize the need for compliance, various transpalatal bars and lingual arches—passive and active—have been widely used as alternatives to headgear and elastics. These bars and arches produce anchorage by blocking molars in combination with pressure from the tongue, but the literature contains little or no evidence that such anchorage reinforcement is substantial. Another appliance that is widely used as anchorage during molar distalization—the Nance holding arch—produces anchorage via an acrylic button placed on the anterior palate. But studies have demonstrated that when molars are moved distally, anchorage is lost and overjet increases. Furthermore, insufficient hygiene under the button has caused soft tissue in contact with the button to become inflamed.

All of these anchorage arrangements discussed produce acceptable to good anchorage, but none provide completely secure anchorage in all three dimensions and 100% resistance to reactive forces, in other words, absolute anchorage. So interest in appliances that use implant-based anchorage has been great.

**Skeletal anchorage**

Most dental implant research focuses on the prosthodontic use of endosseous implants, but several experimental studies and case reports indicate that osseointegrated endosseous implants are also resistant to applied orthodontic forces. Conventional dental im-

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plants require edentulous space in the dental arch and are most use-
ful when combined orthodontic and prosthodontic treatment mo-
dalities are needed.\textsuperscript{28-30} Since most orthodontic patients are adoles-
cents with complete dentitions, alternative placements and designs 
for using implantable devices to reinforce anchorage are needed. 
Such devices, when used in orthodontic treatment, are temporary 
and should be removed after treatment.

In recent years, numerous, novel ways of reinforcing anchorage 
have appeared in the literature.\textsuperscript{31-41} These new methods use a variety 
of devices temporarily anchored in bone. The devices can be located 
subperiosteally or endosteally and be fixed to bone, osseointegrated 
or non-osseointegrated. Skeletal anchorage can be loaded in two 
ways:

\begin{itemize}
  \item directly: forces needed for desired tooth movements are ap-
  plied to the skeletal device.
  \item indirectly: the teeth that act as reactive units are indirectly 
  stabilized by the skeletal device via a transpalatal arch or 
  wire.
\end{itemize}

With indirect anchorage, the stability of the anchoring teeth also de-
pends on the rigidity of the connecting unit.

\textbf{Osseointegrated anchorage systems}

Several manufacturers have modified restorative implant designs to 
produce customized orthodontic titanium fixtures such as the Fri-
alit-2 Implant system\textsuperscript{34} and the Orthosystem\textsuperscript{®} implant, which is 
most documented\textsuperscript{33,42-46} The Orthosystem implant is an endosseous 
titanium implant of screw-type with a sandblasted, large-grit, acid-
etched surface (SLA) that can be placed in the palate or the retromo-
lar area.

The Onplant\textsuperscript{™} system, designed by Block and Hoffman,\textsuperscript{31,47-49} is an 
osseointegrated anchorage system that is placed subperiosteally in 
the palate where vertical bone height is limited. The device in this 
system, the Onplant, is a titanium disc coated with a thin layer of 
hydroxyapatite to facilitate osseointegration. Surgical placement and 
removal of an Onplant involves a larger area of the palate than does 
an implant, and a second-stage surgery to uncover the Onplant is 
required. However, no drilling is involved in placement. All tempo-
rary osseointegrated anchorage devices need a healing period which
was initially set to 10-12 weeks. Recent research suggest that shorter healing period for palatal implants is possible.

Non-osseointegrated anchorage systems

Ideally, implant anchorage should be easy to insert and remove and inexpensive. This goal led to the development of orthodontic mini-implants, which can be inserted by the orthodontist and were first described in the late 1990s. Mini-implants derive from maxillogenial fixation techniques and rely on mechanical retention for anchorage, but their ends are specifically modified to engage orthodontic auxillaries. The Aarhus Anchorage System®, the Spider screw®, the Absoanchor® Micro Implant, and the IMTEC® Ortho Implant are examples of mini-implants available in different lengths and diameters for placement at various sites in both jaws. Smaller diameters make insertion between roots possible, but a sufficient diameter is more important than length for mechanical interlocking in bone. Complications lie predominately in the potential for iatrogenic root lesions and poor soft tissue response. Mini-screws have been found to extrude and tip in the direction of orthodontic loading.

In 1998 Umemori introduced an orthodontic titanium mini-plate system—the Skeletal Anchorage System (SAS)—for stable anchorage with immediate loading. Since then, other variations in mini-plate design such as the OrthoAnchor™ System (C-tube plate and Palate Plate) and the Zygoma Anchorage System have been introduced. Surgical placement of mini-plates is more invasive than of mini-implants, and infections occur, but the advantage of these plates is that they are located away from the dentition and do not interfere with tooth movements.

Most publications on osseointegrated and non-osseointegrated skeletal anchorage systems are method descriptions of new designs, case reports, or small case series, so not all aspects of these new concepts have been explored from an evidence-based viewpoint. New prospective studies with sufficient sample size that compare various anchorages systems—skeletal and conventional—are therefore needed.
Patients’ perceptions of orthodontic treatment

Successful orthodontic treatment demands effective methods, so systematic evaluations of new treatment approaches are essential. But besides analyses of the effectiveness of new treatment methods, it is necessary to explore patients’ acceptance and experiences and possible side effects, especially when the new approach involves invasive techniques.

Pain has been reported to be patients’ major concern during orthodontic treatment, and studies on adults and adolescents reveal that 95% of patients reported pain experiences during orthodontic treatment. The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.” Experiences of pain are always complex and multidimensional and have a sensory and an affective aspect expressed as intensity and discomfort.

Pain perception is subjective, and the objective strength of a pain stimulus has a limited association with the response and personal experience of pain. Perception is also influenced by several factors such as emotional, cognitive, environmental, and cultural aspects. It has been stated that elevated anxiety levels increase pain reports while high motivation for orthodontic treatment reduces pain reports.

Adolescence appears to be a sensitive time in life, which coincides with the most common age for orthodontic treatment. Furthermore, gender has been shown to be a risk factor for developing chronic pain as well as acute pain. Previous studies have shown that girls are more sensitive to pain and more likely to use analgesics than boys. Studies on adults also show that women are more likely to experience pain than men are. Studies have also pointed out that chronic and acute pain may have an impact on daily life by causing, for example, disturbed sleep and difficulties in chewing and biting foods of firm consistencies, which cause patients to change their eating habits.

Since pain is a subjective experience, self-report has been suggested to be the criterion standard for pain assessment. A common method of assessing patients’ experiences of pain, discomfort, and functional impairment during treatment is use of self-administrated
questionnaires. Two commonly used scales are the visual analogue scale (VAS) and the verbal rating scale (VRS). The VAS allows patients to indicate pain intensity precisely and maximizes personal expression\textsuperscript{68,69} while the VRS contains a list of adjectives that describe various intensities for the patient to choose between. Both scales are valid for children and adolescents.\textsuperscript{70,71}

Drawing generally applicable conclusions from self-report questionnaires requires that the reliability and validity of these subjective measurements has been determined. So it is important to analyze whether questionnaires are adequate, well understood, and easy for the patients to complete. Qualitative methods can be complementary and useful tools when orthodontic treatment—from a patient’s perspective—is explored through a questionnaire. Focus group interviews are one example of such a qualitative method, until recently, when they began to be used in medicine and dentistry, they had been predominantly used in sociological research.\textsuperscript{72,73} Few studies have however evaluated the reliability and validity of questionnaires in a young population receiving regular orthodontic treatment.\textsuperscript{73-75}

Except for third molar removal, patients’ perceptions of surgical procedures associated with orthodontic treatment have been sparsely evaluated. In 2004 Chaushu published two articles on patients’ perceptions of recovery after exposure of impacted upper canines.\textsuperscript{76,77} Nearly one-third of the adolescent patients participating in these studies reported severe pain (8-10 on a VAS from 1-10) one day after surgery, and analgesic consumption was high. Surgical placement of palatal implants was demonstrated to be well tolerated by adult patients, and they got used to the implants in about 2 weeks.\textsuperscript{78} Moreover, postoperative pain and discomfort after placement of two different mini-implants and a mini-plate have been compared and patients’ pain and discomfort was significantly reduced during mini-implant placement without mucoperiostel incision or flap surgery.\textsuperscript{79}

Extractions on orthodontic indications, most frequently premolars, are common but often a source of anxiety for the patients, so extractions can be an important factor for declining orthodontic treatment. A newly published study revealed that 17% of adolescent
patients reported severe pain (8-10 on a VAS from 1-10) 1 day after extraction while only 3% reported such pain after 2 days. Overall, few studies have been published on patients’ perceptions and experiences of surgical procedures and tooth extractions associated with orthodontic treatment.

**Evidence-based evaluation**

Evidence-based decision making is a combination of the best available scientific evidence, clinical experience, and the patients’ desire. The process begins with a clinically relevant question, followed by an efficient literature search and finally an evaluation of the evidence, applying strict rules for reliability and validity. These findings are then integrated with clinical experiences and the patient’s desire. Risks of ineffective treatment methods and of variation in treatment care and outcome are thus minimized.

The randomized controlled trial (RCT) has become the criterion standard for evaluation in an evidence-based approach and is considered to generate the highest level of evidence, followed by controlled trials, trials without controls, case series, case reports, and finally expert opinions. RCTs are considered to provide the least biased assessment of differences in effects between two or more treatment alternatives since allocation to different study groups is made randomly. This assures that known and unknown determinants of outcome are evenly distributed between groups. In a comparison between randomized trials and nonrandomized prospective studies, differences in estimated magnitude of treatment effects are common.

Anyhow, the RCT study design is not appropriate for answering all questions, and ethical issues can arise, especially if untreated controls are used. The RCT is also expensive and time consuming due to the recruitment procedures which must be considered. It is therefore important to realize that well-designed prospective and retrospective studies can also provide valuable evidence, although their results must be carefully analyzed, considering their limitations.

Much new information has become available in all fields in recent decades and orthodontic literature is no exception. As a practitioner, it can be an almost impossible assignment to deal with this new in-
formation and to classify different levels of evidence to determine the best possible treatment. Meta-analysis and systematic reviews are therefore helpful tools and have grown in importance. The meta-analysis statistically combines results from several studies to strengthen evidence for a specific question while a systematic review locates and evaluates evidence from scientific studies with outcome measures relevant for the patient, including making a comprehensive summary.

Thus, in the process of systematically assessing evidence from scientific studies to value results and clinical relevance, a critical approach can be recommended, and this also applies to evaluation of different orthodontic anchorage systems.

**Final remarks**

Anchorage is a vital part of orthodontic treatment, and several studies on various anchorage systems have been published concerning application, function, and effectiveness. But it can be difficult for practitioners to interpret the information and evidence presented in these studies because they use a variety of study designs, sample sizes, and research approaches. In view of this, and because evidence-based medicine has grown in importance, a systematic review of present knowledge is helpful.

To reach a high level of evidence, RCTs that compare anchorage capacities of osseointegrated systems with traditional anchorage systems need to be done, and since placement of units designed for osseointegration is invasive, patients’ perceptions should be explored.

A common method for assessing patients’ experiences of pain, discomfort, and functional impairment during treatment is use of self-administrated questionnaires. Generally applicable conclusions cannot be drawn from self-reported questionnaires unless the reliability and validity of these subjective measurements has been determined. So it is important to analyze whether questionnaires are adequate and well understood by the patients. Few studies have evaluated the reliability and validity of questionnaires used in young populations that receive regular orthodontic treatment.
AIMS

Paper I
In a systematic review of the literature, to:
- Determine what orthodontic anchorage systems have been evaluated in an evidence-based manner.
- Evaluate the anchorage efficiency of the systems in the selected studies.
- Analyze the methodological quality of the selected studies.

Paper II
In two groups of consecutive adolescent patients, one group to enter orthodontic treatment, and one group in active treatment:
- To evaluate the reliability and validity of a questionnaire that assessed the expectations and experiences of orthodontic treatment.

Paper III
In a group of adolescent patients undergoing orthodontic treatment:
- To evaluate and compare perceived pain intensity and discomfort following installation of two orthodontic anchoring units designed for osseointegration and premolar extraction.

Paper IV
In a group of adolescent patients undergoing orthodontic treatment:
- To evaluate and compare anchorage capacity following insertion of two osseointegrated and two conventional anchorage systems.
HYPOTHESES

**Paper I**
Despite numerous studies on various orthodontic anchorage systems, the level of evidence for anchorage capacity is low or non-existent.

**Paper II**
A questionnaire with a design based largely on focus group interviews will be reliable and valid.

**Paper III**
Differences in perceived pain intensity and discomfort between surgical installation of orthodontic anchoring units and premolar extractions will be nonsignificant.

**Paper IV**
Osseointegrated anchorage systems provide higher maxillary molar anchorage than conventional systems during leveling/aligning and space closure after maxillary premolar extractions.
MATERIALS AND METHODS

SUBJECTS
The study participants in papers II–IV were consecutively recruited from the Orthodontic Clinic in the Public Dental Service, Gävleborg County Council, Gävle, Sweden from January 2003 to March 2005. Figures 1 and 2 present flow charts of the patients in these studies.

Two groups of patients were selected for paper II: 30 consecutive patients (i.e. allocated for paper III and IV) yet to begin treatment (19 girls and 11 boys, mean age 14.6 years, SD 2.31) and 30 consecutive age-matched adolescent patients in active orthodontic treatment with fixed appliances (17 girls and 13 boys, mean age 15.1 years, SD 2.00).

Of the 168 patients invited to enter studies III and IV, 48 declined to participate. Thus, 120 patients (mean age 14.3 years, SD 1.73) were randomized to receive one of four anchorage systems; each group contained 15 girls and 15 boys. Paper III compared the two osseointegrated anchorage groups (Onplant and Orthosystem implant) with the Premolar extraction group, which comprised study patients allocated to the Headgear group and Transpalatal bar group.

All patients met these inclusion criteria: healthy, non-smoking adolescents in need of orthodontic treatment; no previous experience of orthodontic treatment; permanent dentition; no transversal discrepancies; treatment plan involving extraction of two maxillary premolars (most patients also needed two premolars in the lower jaw extracted) followed by fixed appliances in both jaws; and additional anchorage on the upper first molars considered necessary. The
study sample involved patients with large overjets and patients with crowding; need for additional anchorage varied from moderate to maximum (Figure 3). Treatment objectives for each patient were considered to be reachable with all four techniques.

The 48 patients who declined to participate comprised 26 boys and 22 girls (mean age 13.8 years, SD 1.28) and were not significantly different concerning gender and age compared to those who entered the study. The main reasons for declining were either fear of the surgical procedures or reluctance to wear headgear. After randomization but before treatment start, one patient from the Onplant anchorage group moved from the area and one patient in the Transpalatal bar group became seriously ill and dropped out of the study. These two patients were excluded because they did not start the allocated intervention. The study sample in papers III and IV thus comprised 118 patients.

Ethical considerations
The ethics committee of Uppsala University, Uppsala, Sweden, which follows the guidelines of the Declaration of Helsinki, approved the informed consent form and study protocol.

Consent and randomization
Before studies II, III, and IV, two orthodontists provided the patients and parents with oral and written information of details about the study. After written consent was obtained from the patient and parent, the patients were randomized in blocks of four into one of four anchorage groups. The randomization process per se distributes subject characteristics equally between groups, but since more girls than boys requested and received orthodontic treatment in Gävle, it was decided to stratify for gender so that each group would contain an equal number of girls and boys. The allocation sequence was computer generated by a statistician at Gävleborg County Hospital, Gävle, Sweden and concealed in envelopes until randomization.
Figure 1. Flow chart of the patients in paper II and III.
Figure 2. Flow chart of the patients in paper IV.
Figure 3a. Study patient number 16 with severe crowding in the upper jaw before treatment.

Figure 3b. Study patient number 61 with 10mm overjet before treatment
METHODS

Paper I

To identify studies that examined orthodontic anchorage systems or applications and their effectiveness, a survey of the Medline database (Entrez Pub Med, www.ncbi.nlm.nih.gov) and the Cochrane Collaboration Oral Health Group Database of Clinical Trials (www.cochrane.org) was conducted. The search covered the period from January 1966 to December 2004 and used the Medical Subject Heading (MeSH) term “orthodontics” combined with the term “anchorage”.

The search included human studies written in English but excluded in vitro studies and articles on surgical treatment or cleft lip and palate treatment. Study design requirements were RCTs, prospective and retrospective controlled studies, and clinical trials that compared at least two anchorage applications and reported quantitative data on the effects of various anchorage devices (anchorage loss). Two reviewers independently assessed all of the articles with respect to the inclusion and exclusion criteria, and any inter-examiner conflicts were resolved by discussion to reach consensus.

Data were extracted on these items: author, year of publication, study design, material, gender and age, treatment time, anchorage unit used, ratio between anchorage loss and active movement. To document the methodological soundness of each article, quality was evaluated using a modification of the method described by Antczak et al.\(^8\) and Jadad et al.\(^7\) These eight variables were evaluated: study design (RCT = 3 points; prospective study = 1 point; retrospective study = 0 points); adequate sample size (1 point); adequate selection description (1 point); valid measurement methods (1 point); use of method error analysis (1 point); blinding in measurement (1 point); adequate statistics (1 point); no confounders included in analysis (1 point). Of the eight variables, a study could score a maximum of 10 points; study quality was categorized as low (0–5 points), medium (6–8 points), or high (9–10 points).

Several articles have been published since December 2004. So paper I was supplemented with a new survey from December 2004 to
Paper II

Development of the questionnaire

A new questionnaire was developed to assess adolescent patients’ opinions and experiences of orthodontic treatment. To ensure that the questionnaire items were relevant, four focus groups were formed: three with four age-matched adolescent patients each who had recently completed active orthodontic treatment and a fourth group with four parents of patients who had completed treatment. Two investigators conducted interviews using an open-ended interview style and collected 4 hours of audio-taped information. The participants were asked to describe why they had sought orthodontic treatment and how they had experienced the various phases of orthodontic treatment such as insertion of the fixed appliance, the first week of wearing braces, changes of arch wires, and so on. Specific questions about various anchorage systems and experiences from premolar extractions and surgical procedures, mainly exposure of impacted upper canines, were also included.

Transcripts of the audiotapes were analyzed and used when the questionnaire was being constructed. Information from the four focus groups was similar. Pain and soreness, difficulties when eating specific foods together with concern about facial appearances when wearing braces were important issues, but most patients stated that they “got used to it” and “relied strongly on the clinician’s professional judgment”. Most patients also claimed that they had made an independent decision to undergo orthodontic treatment, although mostly after advice from clinical dental staff: “they should, of course, know what is best”.

The questionnaire comprised 46 questions divided into five separate domains; the questions were based on results of the focus group interviews and on other questionnaires (Appendix, Table A).11,94,95

Questionnaire

All patients in the group that was to enter orthodontic treatment were instructed to assess all 46 questions while the 30 patients al-
ready in active treatment assessed the questions that pertained to treatment (questions 12–42, 45, and 46).

The questionnaire comprised five domains:

**Treatment motivation**: This domain contained 7 questions (1–7) assessed on a VAS with the end phrases "not at all" and "very much" or "not at all" and "completely".

**Treatment expectations**: This domain contained 4 questions (8–11) assessed on a VAS with the end phrases “not at all” and “very much”.

**Pain and discomfort from teeth, jaws, and face**: This domain contained 13 questions (12–24): 10 questions on a VAS with the end phrases “none at all” and “worst imaginable” and 1 question on a 2-point scale (yes or no) with 2 follow-up questions.

**Functional jaw impairment**: This domain, a freestanding questionnaire, has previously been used in other populations, but not for regular orthodontic patients, and contained 18 questions (25–42). Eight were related to mandibular function, 3 to psychosocial activities, and 7 to eating specific foods. Each question was assessed on a 4-point scale with the alternatives not at all, slightly, much, or extremely difficult.

**Questionnaire validity**: This domain contained 4 questions (43–46), one for each domain, assessed on a VAS with the end phrases "not at all" and "very well".

**Reliability and Validity**
In paper II, the reliability of the self-reported base-line questionnaire was determined in a test-retest study by administering the questionnaire on two separate occasions at an interval of 1–2 weeks. Reliability was tested on all individual questions and for the separate domains within the questionnaire. Internal consistency, which characterizes the homogeneity of the separate questions and expresses how well the separate questions within each domain relate, was also evaluated. Face validity was established by asking the patients if they considered the items were relevant and reflected their motivation for orthodontic treatment and their expectations and experience of orthodontic treatment.
Paper III

Surgical placement and premolar extractions

All Onplants (Nobel Biocare, Göteborg, Sweden) and Orthosystem implants (Institut Straumann AG, Basel, Switzerland) were placed according to standard surgical procedures under local anesthesia (see paper III for details). Onplants and Orthosystem implants were placed para median but close to the midline in the anterior palate at the level of the premolars. A guide stent was used to help position the Orthosystem implant. After surgical placement of the Onplants, a trimmed, vacuum-formed stent was placed over the surgical site to prevent hematoma formation and facilitate adaptation of the Onplant to the bone surface. Patients wore the stent 24 hours a day for 1 week. Orthosystem implant patients received a similar stent, which they wore 24 hours a day for 2 weeks to protect the implant from parafunctional activity from the tongue.

Fifty-one patients in the premolar extraction group had one maxillary and one mandibular premolar extracted on one occasion and maxillary and mandibular premolars on the other side extracted 1-2 weeks later. Eight patients had two premolars in the upper jaw extracted during one session. Two maxillofacial surgeons at the Maxillofacial Unit, Public Dental Service, Gävleborg County Council, Gävle, Sweden, performed the surgery and premolar extractions.

Questionnaires

The questionnaires included self-report items developed in paper II and a few questions modified for this study (Appendix, Table B,C). Patients’ perception of pain intensity and discomfort and analgesic consumption were evaluated on the first evening and 1 week after surgical placement of an Onplant or an Orthosystem implant. The premolar extraction group was evaluated on the first evening after the first two extractions and 1 week after the last premolars were extracted (Appendix, Table B). The questionnaire that was administered 1 week after the surgical interventions and premolar extraction had additional questions about daily activities and functional jaw impairment (Appendix, Table C).
All patients received orthodontic appliances based on McLaughlin, Bennett, Trevisi's straight-wire concept with a .022-inch slot size and designed for light forces. Leveling and aligning were carried out with laceback ligatures, coil springs, or both depending on the degree of crowding with this arch wire sequence: .016-inch Heat-Activated Nickel-Titanium (HANT), .018-inch stainless steel (SS), and .019 x .025-inch HANT. Spaces were closed with active tiebacks and .019 x .025-inch SS arch wires. The leveling/aligning phase was defined as the time in months from treatment start until insertion of a .019 x .025-inch SS arch wire while the space closure phase was the time in months from the end of the leveling/aligning phase until extraction spaces were closed or (in cases with planned anchorage loss) until anterior space closure with a correct Class I occlusion canine relationship was established. Two orthodontists at the Orthodontic Clinic, Gävleborg County Council, Gävle, Sweden performed the orthodontic treatments.

**Anchorage systems**

Nobel Biocare’s Onplant system is a subperiosteal implant in the shape of a 7.7-mm titanium disc. The disc is coated with a layer (75 µm) of bioactive hydroxyapatite to help osseointegration. The disc is slid through a subperiosteal tunnel into a position near the palatal midline via a surgical procedure under local anesthesia. After a healing period of 16 weeks, an abutment was connected to the Onplant under local anesthesia and a 1.3-mm SS transpalatal bar was fabricated and bonded to the maxillary first molars (Figure 4a).

The Orthosystem implant is a short titanium implant (3.3 x 4 mm) that was inserted under local anesthesia near the midline of the palate. After a healing period of 16 weeks, a 1.2-mm SS transpalatal bar was fabricated, connected to the implant, and bonded to the maxillary first molars (Figure 4b).

Headgear consisted of bands on the maxillary first molars and a short outer bow with the direction of force (400 g) corresponding to medium pull (Figure 4c). Force was checked on each visit to the clinic, and adjustments were made when necessary. Patients were instructed to wear the headgear 10–12 hours a day.
The transpalatal bar consisted of bands on the maxillary first molars with a 2.0 x 1.0-mm soldered SS bar. There was a 2-mm space between the bar and the palate (Figure 4d).

Figure 4. Occlusal view of the Onplant bar (a) and Orthosystem implant bar (b). Lateral view of the headgear anchorage (c) and occlusal view of the transpalatal bar (d).

Outcome measures
The main outcome measures that were assessed after the leveling/aligning (T1) and space closure (T2) phases were:
- Position of the maxillary first molars and distance moved
- Position of maxillary central incisors and distance moved
- Skeletal sagittal position of the maxilla
- Treatment time of each phase

Data on all patients who were randomly assigned to the four groups were analyzed on an intention-to-treat (ITT) basis. Thus, as soon as the anchorage system had been placed, all results—
regardless of outcome—were analyzed. Successful anchorage was defined as an anchorage loss of \( \leq 1 \text{ mm} \), no osseointegration failures or failures during anchorage system placement, and no dropouts after treatment start (insertion of anchorage).

**Analysis of lateral head radiographs**

Lateral head radiographs in habitual occlusion were made at baseline (T0), after completion of the leveling/aligning phase (T1), and after the space closure phase (T2). Measuring points, reference lines, and measurements used were based on those defined and described by Björk\(^9\) and Pancherz.\(^{100,101}\) Dental and skeletal changes as well as dental changes within the maxilla and mandible were determined by Pancherz SO analysis (analysis of changes in sagittal occlusion, Figure 5).

![Figure 5. SO-analysis according to Pancherz.](image)

Measurements were made by hand to the nearest 0.5 mm or 0.5 degrees. Images of bilateral structures were bisected. No correction was made for linear enlargement (10%). Changes in the various measuring points during treatment were calculated as differences in the after-minus-before positions. One orthodontist (Dr Feldmann)
made all measurements. Blinding during measurement was not possible since the four anchorage systems were easily recognizable on the lateral cephalograms.

**Statistical analysis**

Inter-rater agreement between reviewers in assessing articles with respect to inclusion and exclusion criteria and quality evaluations in paper I was assessed with the kappa statistic (Cohen’s kappa, κ). Kappa values > 0.80 were considered excellent, 0.61–0.80 good, 0.41–0.60 moderate, 0.21–0.40 fair, and ≤ 0.20 poor.102

Test-retest reliability: Test-retest reliability in paper II was assessed by the kappa statistic when the questionnaire variable was measured on an ordinal or dichotomous scale. Kappa scores were supplemented with percentage of total agreement.

When the questions were evaluated on a continuous scale or when summary scores for questionnaire domains were measured in paper II, reliability was assessed by calculating the intraclass correlation coefficient (ICC) based on a two-way mixed analysis of variance (ANOVA). This is an estimate of the precision in the data obtained by multiple measurements, relating the amount of measurement error to subject variability. An ICC above 0.75 indicates excellent reliability, between 0.4 and 0.75 fair to good reliability, and below 0.4 poor reliability.103

Internal consistency: In paper II, Cronbach’s alpha (α)104 was calculated to estimate how consistently the subjects responded to the separate questions within each domain. Alpha values 0.70 or higher were considered sufficient.

Descriptive statistics including median value, interquartile range, and range were calculated for each variable in paper III, and the arithmetic mean and standard deviation (SD) were calculated for each variable in paper IV.

Differences between groups for pain and discomfort in paper III were tested with the nonparametric Kruskal-Wallis and Mann-Whitney tests. Chi-square tests were used to determine differences between groups in functional jaw impairment, affected daily activities, and use of analgesics and, in paper IV, for success rate of anchorage capacity.
Differences in means within groups in paper IV were tested by one-way ANOVA. A repeated measure ANOVA with a Bonferroni correction was used to analyze differences between groups at T0, T1, and T2.

Differences in papers III and IV with a P value less than 5 % (P<0.05) were considered statistically significant.

In paper IV, a sample size calculation was performed and based on an alpha significance level of 0.05 and a beta of 0.1 to achieve 90 % power to detect a clinically meaningful difference of 1.5 mm (SD 1.5) in anchorage loss between the four groups. The calculation revealed that 21 patients in each group were sufficient, but to compensate for conceivable dropouts during the trial, 30 patients were enrolled in each group.

Method error: In paper IV, 20 randomly selected cephalograms were traced on two separate occasions. No significant mean differences between the two series of records were found using paired t-tests. The method error did not exceed 0.5 mm or 1.0 degree except for molar inclination where the error did not exceed 1.5 degrees.
RESULTS

Paper I

The search strategy yielded 494 articles, but only 14 articles \(^{19,106-118}\) fulfilled the inclusion/exclusion criteria. The most common reasons for exclusions were case-report or small case-series, technical presentations and articles with objectives that did not follow this review (for details see paper I). Two main anchorage situations were found, anchorage of molars during space closure after premolar extractions and anchorage in the incisor and/or premolar region during distal movement of molars.

Inter-rater agreement was excellent for inclusion/exclusion assessment and good to excellent for data extraction and judgment of the selected articles’ quality.

Anchorage effectiveness of molars during space closure

Seven studies remained for the final analysis. Two were RCTs, \(^{113,118}\) two prospective comparative “split-mouth” studies, \(^{108,109}\) and three retrospective comparative studies. \(^{106,107,114}\) Various techniques and auxiliary holding appliances were used for either active movement or anchorage. The two RCTs reported conflicting results. Usmani et al. \(^{113}\) reported no difference in anchorage loss of molars during leveling of the upper jaw with or without laceback ligatures (0.49 mm and 0.50 mm, respectively) while Irvine et al. \(^{118}\) demonstrated a significantly larger anchorage loss when laceback ligatures were used for leveling the lower jaw (0.75 mm and -0.08 mm, respectively). The other five studies \(^{106-109,114}\) revealed vast heterogeneity, and it was therefore difficult to value the efficiency of various anchorage systems.
Anchorage effectiveness during distal movement of molars
The primary concern in the seven studies was to demonstrate distal molar movement, and the secondary concern was to show anchorage loss. One study was an RCT,\textsuperscript{112} two studies were prospective comparative studies,\textsuperscript{111,115} one study was a retrospective controlled study,\textsuperscript{110} and three were retrospective comparative studies.\textsuperscript{19,116,117} A Nance or a modified Nance appliance was the main method of anchorage during the intraoral distalization procedure while the active unit varied. Anchorage loss, measured at the incisors or premolars, varied from 0.2 to 2.2 mm, and the anchorage loss/distal molar movement ratio ranged from 0.2 to 0.8.

Study quality
Research quality and methodological soundness were high in two studies,\textsuperscript{113,118} medium in three studies,\textsuperscript{19,110,112} and low in nine studies.\textsuperscript{106-109,111,114-117} The most obvious shortcomings were retrospective study design with inadequate selection description and small sample sizes, which mostly implied low power. In all studies, the methods used to detect and analyze anchorage loss and active tooth movements were valid and generally well known. But nine studies did not include a method error analysis, and only three studies used blinding in measurements. Moreover, three studies did not consider the risk of confounding factors influencing the outcome.

New literature search
In a supplementary literature search between December 2004 and July 2007, another 257 articles on orthodontic anchorage were found. Eleven\textsuperscript{119-129} studies merited final analysis, and the two main anchorage situations found in the primary search - (1) molar anchorage during space closure after premolar extraction and (2) anchorage in incisal and premolar regions during distal movement of molars - were the same in these studies.

Data of the four new articles on molar anchorage during space closure are summarized in Appendix, Table D. Three were prospective comparative “split mouth” studies\textsuperscript{120-122} and one study was retrospective.\textsuperscript{119} Seven articles on anchorage during distal movement of molars are listed in Appendix, Table E. Three studies were prospec-
tive, comparative and four were retrospective. The Nance button was still the most frequently used anchorage unit during molar distalization.

Quality assessments of the eleven articles are presented in Appendix, Table F. Five studies were of medium and six of low quality. The main weaknesses were retrospective study design, small sample sizes and inadequate selection description in combination with lack of blinding during measurement.

Skeletal anchorage
The first literature search up to December 2004 contained 149 articles (out of 494) on skeletal anchorage with various implant systems. Since most of the implant studies were technical presentations of new approaches and/or small case series, they did not qualify for the final analysis and were thus excluded. The expanded search up to July 2007 contained an additional 176 (of 257) articles, and two of them qualified for the final analysis. The prospective comparative study by Thiruvenkatachari reported absolute anchorage (i.e. anchorage loss = 0 mm) with micro-implants during canine retraction after premolar extractions in comparison with a control group without any auxiliary anchorage unit. The study comprised just 10 patients and was overall judged to be of low quality. Gelgor compared the anchorage of a transpalatal bar system and a modified Nance, both enhanced by intraosseous screws, during molar distalization. Anchorage loss for the transpalatal bar was 0.5 mm and negligible for the modified Nance (0.1 mm).

Paper II
Reliability and validity
All 60 patients filled in the questionnaire twice at an average interval of 12 days.

Reliability of the questionnaire, based on summary scores, was excellent (ICC = 0.85–0.92) for all five domains. Differences in domain reliability between the group of patients yet to enter treatment and those already in treatment were minor. But a discrepancy for the treatment motivation domain was observed between girls and boys (good and excellent, respectively).
Overall, reliability of the separate questions within each domain was good to excellent. But three questions (6, 18, and 19) had poor reliability and two questions (8 and 15) fair reliability. Figure 6a,b presents questions 18 and 19. In the functional jaw impairment domain, question 31 and 34 exhibited fair reliability and question 27, 29, and 35 moderate reliability. But these questions were considered acceptable since percent total agreement was comparable with the other questions in this domain. Internal consistency for the five separate domains varied between 0.67 and 0.87 at the first assessment and between 0.63 and 0.94 at the second assessment, which implies that consistency was sufficient for all domains.

**Figure 6a.** Plot of first and second assessment for the question 18; “Do you have pain from your molars when they are in contact?”

**Figure 6b.** Plot of first and second assessment for the question 19; “Do you have pain from your molars when they are not in contact?”
Very high scores (Md 80–94) were obtained at the VAS assessment for face validity, which indicates that the patients considered the questions to be valid, and since the questions originated from the focus group interviews, the questionnaire also had content validity.10

**Paper III**

The response rates for the questionnaires the first evening after the interventions were 97%, 93%, and 98% and after 1 week 90%, 90%, and 100% for the Onplant, the Orthosystem implant, and the Premolar extraction groups, respectively. Overall, gender differences were few.

**Pain intensity, discomfort, and analgesic consumption**

Pain intensity was significantly higher the first evening after surgical placement of an Onplant (Md=38.5, \(P=0.002\)) and after premolar extraction (Md=29, \(P=0.007\)) compared to placement of an Orthosystem implant (Md=4). One week after the interventions, pain intensity was still significantly higher in the premolar extraction group compared to the Orthosystem implant group.

Discomfort was significantly higher the first evening after surgery in the Onplant group (Md=34.5, \(P=0.04\)) than after extraction in the Premolar extraction group (Md=22). The Onplant and Orthosystem groups were comparable concerning discomfort, but the Orthosystem patients reported in an open-ended question that they had experienced drilling during surgery to be especially unpleasant. One week after the intervention, Orthosystem patients reported significantly less discomfort compared to the other two groups.

The protective stent caused more discomfort (Md=48, \(P=0.002\)) than did the actual surgery site (Md=13.5) in the Orthosystem group the first evening and in both groups 1 week after surgery.

On the first day, significantly more patients in the Onplant group than in the Premolar extraction group took analgesics (\(P=0.037\)). In the week following intervention, analgesic consumption was significantly lower in the Orthosystem group compared to the other two groups (\(P=0.004\)). After all interventions, analgesic consumption on
the first day differed depending on gender (girls consumed more than boys, \(P=0.042\)).

**Table I. Analgesic consumption on the first day and the following week after surgical placement of an Onplant, an Orthosystem implant and premolar extractions.**

<table>
<thead>
<tr>
<th></th>
<th>Onplant (A)</th>
<th>Orthosystem implant (B)</th>
<th>Premolar extraction (C)</th>
<th>Total</th>
<th>Group difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>N = 29</td>
<td>N = 30</td>
<td>N = 59</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analgesics on the first day</td>
<td>24</td>
<td>19</td>
<td>37</td>
<td>80</td>
<td>A/C: (P = 0.037)</td>
</tr>
<tr>
<td>No analgesics on the first day</td>
<td>4</td>
<td>9</td>
<td>21</td>
<td>34</td>
<td>A/B = NS</td>
</tr>
<tr>
<td>Total</td>
<td>28</td>
<td>28</td>
<td>58</td>
<td>114</td>
<td>B/C = NS</td>
</tr>
<tr>
<td>Analgesics the following week</td>
<td>19</td>
<td>9</td>
<td>39</td>
<td>67</td>
<td>A/B: (P = 0.004)</td>
</tr>
<tr>
<td>No analgesics the following week</td>
<td>7</td>
<td>18</td>
<td>20</td>
<td>45</td>
<td>B/C: (P = 0.004)</td>
</tr>
<tr>
<td>Total</td>
<td>26</td>
<td>27</td>
<td>59</td>
<td>112</td>
<td>A/C = NS</td>
</tr>
</tbody>
</table>

**NS = Not significant**

**Daily activities and functional jaw impairment**

During the first week after the intervention, the Onplant group reported disturbed sleep more often than the Premolar extraction group \((P=0.033)\). The Onplant and Orthosystem groups also reported more affected speech than the Premolar extraction group \((P<0.001)\). Differences between groups in eating specific foods were significant, with the Onplant and Orthosystem groups being more inconvenienced than the Premolar extraction group, but with no apparent pattern.

**Paper IV**

This study comprised 118 patients. Five patients dropped out from the trial, but these patients were included and analyzed on an ITT basis as failures; thus, while 118 patients were included in the analysis, only 113 completed all phases of the study (Figure 2, Table II).
Table II. Distribution of success rate concerning anchorage capacity for the Onplant group (A), Orthosystem implant group (B), head-gear group (C), and transpalatal bar group (D).

<table>
<thead>
<tr>
<th></th>
<th>Onplant (A)</th>
<th>Orthosystem implant (B)</th>
<th>Headgear (C)</th>
<th>Transpalatal bar (D)</th>
<th>Total</th>
<th>Group difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 29</td>
<td>N = 30</td>
<td>N = 30</td>
<td>N = 29</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Successful</td>
<td>24</td>
<td>28</td>
<td>14</td>
<td>8</td>
<td>74</td>
<td>A/B: NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A/C: P = .0039</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A/D: P &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>B/C,D: P &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>C/D: NS</td>
</tr>
<tr>
<td>Not successful</td>
<td>5</td>
<td>2</td>
<td>16</td>
<td>21</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>29</td>
<td>30</td>
<td>30</td>
<td>29</td>
<td>118</td>
<td></td>
</tr>
</tbody>
</table>
| Reasons for not successful | 1 no ossea-integration | 1 no ossea-integration | 16 anchorage loss > 1.0 mm | 21 anchorage loss > 1.0 mm | 74 | A/B: NS  
|                | 2 technical problems |                          |               |                      |       | A/C: P = .0039  |
|                | 1 discontinued treatment (poor oral hygiene) |                          |               |                      |       | A/D: P < 0.001  |
|                | 1 anchorage loss > 1.0 mm |                          |               |                      |       | B/C,D: P < 0.001|
|                |             |                          |               |                      |       | C/D: NS         |

NS = Not significant

Because no significant differences in pretreatment cephalometric characteristics between the four groups or between girls and boys were found, data for girls and boys were pooled and analyzed together.

The leveling/aligning phase
Maxillary molars within the maxilla in the Onplant, Orthosystem implant, and Headgear groups were stable during leveling and alignment. In the Transpalatal bar group, the molars on average moved forward 1.0 mm. Mesial movement of the molars (anchorage loss), which occurred in the Transpalatal bar group, was significantly different compared to the other three groups (P<0.001). The amount of mesial molar tipping was small in all four groups but significantly larger in the Transpalatal bar group (mean 4.1 degrees, P<0.001).
Figure 7a-d. Maxillary dental and skeletal changes (in mm) and standard deviations (SD) contributing to alterations in the four groups during the levelling/aligning phase.

Average sagittal forward growth was 0.8–0.9 mm for the maxilla and 0.9–1.4 mm for the mandible. These changes were significant for all groups but with no differences between the four groups (Figure 7a–d).

The space closure phase
Maxillary molars in the two osseointegrated anchorage groups were stable during space closure. In the Headgear group the molars on average moved forward 1.6 mm ($P<0.001$) and in the Transpalatal bar group, anchorage loss continued and averaged another 1.0 mm ($P<0.001$). Mesial tipping of the molars during space closure was small and nonsignificant within and between the four groups.
Sagittal forward growth was 0.5–0.8 mm for the maxilla and 0.7–0.9 mm for the mandible. These changes were significant for all groups but with no differences between the four groups (Figure 8a–d).

**Figure 8a-d.** Maxillary dental and skeletal changes (in mm) and standard deviations (SD) contributing to alterations in the four groups during the space closure phase.
Total observation period

The maxillary molars were stable in the Onplant and Orthosystem groups, whereas they moved mesially in the Headgear and Transpalatal bar groups, mean 1.2 and 2.0 mm, respectively (Figure 9). The anchorage loss/incisor retraction ratio was 0.05 for the Onplant group, 0.02 for the Orthosystem group, 0.15 for the Headgear group, and 0.54 for the Transpalatal bar group (Figures 10a–d).

**Figure 9.** Maxillary upper first molar movements during leveling/aligning (T0-T1) and space closure (T1-T2) for all four groups.

Success of anchorage capacity

The Onplant and the Orthosystem implant had significantly higher success rates of anchorage than the headgear and transpalatal bar, and differences between the two osseointegrated groups and between the two conventional groups were nonsignificant (Table II). Differences in success rate between the two orthodontists who performed the treatments were also nonsignificant.

In the Headgear group 14/30 patients had successful anchorage and ten of them were girls, which was a significant difference in comparison to boys (P = 0.028). There were no difference in mean
age between patients in the Headgear group with respect to success rate.

In the Transpalatal bar group there were no differences in gender, age, pre-treatment morphology or treatment time between the patients who had successful anchorage (8/29) and those who had not.

**Treatment time**
Average treatment time for the leveling/aligning phase varied between 8.0 and 8.7 months and for the space closure phase between 8.6 and 9.7 months. Differences between the four groups were non-significant.

*Figure 10a-d. Maxillary dental and skeletal changes (in mm) and standard deviations (SD) contributing to alterations in the four groups during the total observation period.*
DISCUSSION

The overall aim of this thesis was to evaluate a new anchorage technique, relying on osseointegration, and compare it with conventional methods concerning effects on tooth movements and patients’ acceptance of the surgical procedures pertaining osseointegration. The most important findings were that the two osseointegrated anchorage systems—the Onplant system and the Orthosystem implant—provided stable anchorage during orthodontic treatment after maxillary premolar extractions and had significantly higher anchorage capacity compared to the two conventional anchorage systems—headgear and transpalatal bar. Furthermore the surgical procedures were overall well tolerated by adolescent patients and comparable or even better tolerated than premolar extractions carried out as a part of the orthodontic treatment.

Systematic review
Orthodontic anchoring technique has undergone substantial development since the mid-1990s. To date, several technical presentations, case reports, and small case series, along with several reviews, concerning application, function, and effectiveness aspects of various new anchorage systems, have been published. But it is difficult to interpret the results and evidence of these studies because of the variety of study designs, sample sizes, and research approaches used. Reviews are helpful tools for summarizing the literature on various aspects of orthodontic treatment, but reviews seldom evaluate the evidence, and so a systematic review of present knowledge
was made in connection with the clinical studies presented in this thesis.

The systematic review (paper I), including the supplementary search up to July 2007, indicated that there is undisputed agreement among orthodontists that anchorage preparation is a vital part of orthodontic treatment planning and is one of the major decisive factors for outcome success. The review also indicated that there was little evidence concerning anchorage capacity with conventional methods during space closure after premolar extractions. Even though skeletal anchorage during space closure has garnered much interest among researchers, no studies up to July 2007 reported evidence for its superiority. The overall conclusion of this systematic review was that more research on anchorage control during space closure after premolar extraction is needed. To achieve the highest level of evidence, the clinical design of the studies in this thesis were based on the criterion standard – RCT methodology.

**Development of a questionnaire**

When new techniques are introduced, it is essential to explore patients’ perceptions and acceptance of the novelty; in the field of skeletal anchorage, this is even more important since it involves additional surgery. Pain intensity and discomfort are frequently reported side effects during orthodontic treatment, and common methods for assessing these are self-reported questionnaires. Few studies have explored adolescent patients’ experiences of standard orthodontic treatment including premolar extractions and additional surgical procedures. A new questionnaire was therefore developed.

A questionnaire is an instrument that must be valid and reliable so that generalized conclusions can be drawn. Focus group interviews were therefore conducted with adolescent patients and parents of patients who recently completed active orthodontic treatment to develop relevant questions. The participants in these interviews were unanimous in selecting the areas of pain, discomfort, soreness, the necessity to alter food habits, and some esthetic considerations as being relevant. Consequently, the final questionnaire contained five domains with a total of 46 items (Table I). Although the focus groups claimed that they relied on the clinician’s professional judgment, they were convinced that they had made an independent deci-
sion to undergo treatment. This agrees with Trulsson’s experience in a qualitative study of teenagers’ decision to undergo orthodontic treatment. One weakness with the focus groups was that the participants had already completed orthodontic treatment, which may have made certain interview areas obsolete. For example, the treatment motivation and treatment expectations domains contained 11 items of general character; with more focus groups with patients from the waiting list, these domains might have been more specific about anxiety, fear of pain, and esthetic concerns before entering orthodontic treatment. Nevertheless, face validity was high, which indicated that the patients in paper II considered the questions to be relevant.

Reliability was tested in a test-retest study and was acceptable for all domains. Two obvious limitations to a test-retest analysis are demonstrated in paper II. One limitation is the difficulty in foreseeing whether circumstances between the two assessments are stable, and this can be crucial when exploring acute pain. One outlier for question 18 (Figure 6a) “Do you have pain from your molars when they are in contact?” decreased this question’s reliability (ICC) from 0.69 to 0.39 with scores of 0 at the first assessment and 43 at the second assessment (VAS). A supplementary interview regarding pain status might therefore have revealed valuable information, since a pattern of marked differences between pain and functional impairment assessments were observed for this patient.

The second limitation of a test-retest analysis is that excellent reliability (ICC, κ) in single questions is difficult to achieve in homogenous populations since reliability is a measure of how well the variable can distinguish between subjects. This was illustrated in questions about pain and functional impairment since the patients in paper II formed a homogenous group of healthy adolescents with no or few symptoms (Figures 6a, b). Considering these limitations, the results from the test-retest analysis were satisfactory.

Patients’ perceptions of surgery and premolar extraction
Patients’ experience of surgical placement of an Onplant and an Orthosystem implant were compared to experiences of premolar extractions. Orthodontic treatment in combination with premolar ex-
tractions is common, but according to many orthodontists, surgical placement of an anchorage device still involves “too much blood”. Naturally, comparing such surgical procedures with premolar extractions was valuable, especially since this had not been done earlier. Thus, it could be concluded that the Orthosystem implant was better tolerated than premolar extraction and that the Onplant was comparable to premolar extraction concerning pain intensity.

Indications for the two osseointegrated anchorage systems are the same, and both surgical procedures were simple and took only 10–15 minutes to perform. One explanation for the higher pain intensity and discomfort reported in the Onplant group is that Onplant installation involved a larger surgical area than the Orthosystem implant. This agrees with a comparative study of surgical placement of mini-screws and mini-plates where the patients complained more about pain and discomfort after procedures involving mucoperiosteal incision or flap surgery than about procedures that did not.

Reported pain intensity, discomfort and analgesic consumption following surgery and premolar extraction were relatively moderate compared to other studies, but some patients described the experiences as worst imaginable. Gender differences were few, but there was a tendency that girls experienced more pain and more often used analgesics than boys which is in agreement with other studies. Most of the patients in this thesis had excellent oral health and no or little experience of dental procedures such as cavity restoration. Beginning orthodontic treatment with surgery or premolar extractions could therefore have been frightening for some patients. Enhanced anxiety levels can influence perception of pain intensity and might explain the wide range in pain and discomfort reports.

The most optimal study design might have been to compare one surgical intervention per group, that is, one anchorage system with extraction of only one premolar. But standard clinical procedure is to extract two premolars simultaneously, and this intervention was considered to be most clinically relevant. A recently published study also confirmed that there is no significant difference in pain intensity and discomfort between extraction of one maxillary premolar and
extraction of two (one maxillary and one mandibular) premolars on the same side.

The protective stent caused greater discomfort than did the actual site of surgery, and the patients in the surgery groups also reported more difficulties with speech and eating specific foods, which presumably was an additional effect of the stent, compared to the premolar extraction group. A plausible explanation was that the semi-elastic stent caused uncontrolled forces and tension on the teeth, since many patients had severe crowding in the upper jaw. In future, an alternative design with looser contacts between the stent and the teeth is recommended. In 2006, a newly designed Orthosystem implant with a lower profile was introduced. This reduces the risk for parafunction from the tongue, and a stent will most likely no longer be required for this group. This would also eliminate risk of transference of discomfort between the surgery site and the stent.

**Anchorage success**

The overall definition of successful anchorage was anchorage loss of ≤ 1 mm, no osseointegration failures, no failures during anchorage system placement and no dropouts after treatment start. This way of analyzing anchorage capacity is perhaps most clinically relevant since dropouts and failures are also analyzed. The suggested level of sufficient anchorage can be discussed but if maximum anchorage is needed 1.0 mm is what can be clinically acceptable.

Both osseointegrated anchorage systems were connected to the maxillary first molars with a transpalatal bar (indirect anchorage), and anchorage success rate was therefore also depended on the rigidity and stability of the bar. An in vitro study on permanent deformation of transpalatal arches connected with palatal implants concluded that SS arches from 0.8 x 0.8 mm to 1.2 x 1.2 mm in size underwent deformation at a force level of 500 cN. In paper IV the connecting transpalatal bars for the Onplant and Orthosystem implant were made of spring-hard SS wires 1.3 mm in diameter and 1.2 mm in diameter, respectively and the incisors were retracted with light forces far below 500 cN. Potential deformation of the bars was therefore not considered clinically relevant. But it is important to recognize that deflection of the bar rises in proportion to in-
creased force application and that anchorage needs determine bar dimensions.\textsuperscript{137}

\textbf{The palatal midsagittal area}

Transverse maxillary growth is the result of a combination of appositional remodeling of the alveolar process and growth in the median suture. According to histological studies, although suture growth slows down proportionally with age, it continues up through adolescence.\textsuperscript{138,139} One report found nine boys aged 10–18 years to have average transverse maxillary growth of 3 mm.\textsuperscript{140}

The potential influence of palatal implants on normal transversal growth is still unclear. But a study in pigs demonstrated a reduction in transversal growth with an Orthosystem implant inserted in the palatal suture.\textsuperscript{141} Moreover, another study in pigs found restricted bone growth after insertion of rigid skeletal fixation over facial sutures.\textsuperscript{142} To avoid interference with transverse growth of the maxilla, efforts were made to insert the Onplants and the Orthosystem implants in a para median position as near the midline as possible to guarantee sufficient amounts of bone.

\textbf{The Onplant versus the Orthosystem implant}

Despite concerns about available bone volumes in the anterior palate, osseointegration success rates were equally high for the Onplant and the Orthosystem implant. Use of a guide stent, which other studies have also advocated, may have contributed to the success of the Orthosystem implant.\textsuperscript{143,144} The Onplant system appeared to be more sensitive to anatomical restrictions since two Onplants, due to narrow palates, were found in a tilted position after osseointegration and could not be used. From a clinical view, osseointegration that fails or devices that are unusable are time-consuming and expensive since alternative treatment approaches must be used.

Concerning pain intensity, discomfort, and analgesic consumption following surgical placement, patients clearly reported significantly fewer concerns related to the Orthosystem implant than the Onplant. Since the Onplant system also required an additional surgical procedure for uncovering the disc and abutment placement, advantages of the Orthosystem are obvious.
Headgear

One of the most traditionally used systems for additional anchorage is headgear. The participants of the studies in this thesis cooperated well during the leveling-aligning phase, but during space closure, the molars moved forward and an anchorage loss of 1.2 mm was found for the entire observation period. The range of molar movement was larger in the Headgear group than in the other groups, which indicated that some patients cooperated well throughout treatment and some patients did not cooperate at all.

Gender was found to be a predictor for patient compliance since more girls than boys demonstrated successful anchorage with headgear. This is in agreement with studies by Clemmer \textsuperscript{11} and Cucalon \textsuperscript{145} but conflicting to Brandao \textsuperscript{13} who found boys more compliant. Clinical trials run the risk of a Hawthorne-effect (positive bias), which means that participants are more compliant because they know they are a part of a trial. Thus, success rate might be even more discouraging in “real life” treatment. Due to the unpredictability of patient cooperation, headgear is therefore unsuitable as orthodontic anchorage when maximum anchorage is needed.

Transpalatal bar

Anchorage loss with the transpalatal bar was surprisingly large and mesial molar tipping was observed. Similar results have been presented in a few studies when canines were retracted after premolar extractions,\textsuperscript{120,146} but comparisons could not be drawn since designs and bar dimensions differed from those used in this thesis. The transpalatal bar in paper IV was a passive 1.0 x 2.0 mm soldered bar, placed 2 mm from the palatal mucosa and positioned on the mid-palatal surface of the maxillary first molars. A study of tongue pressure on the loop of a transpalatal arch during deglutition found that pressure was highest if the transpalatal bar was positioned further back, at the level of the second molar, and was placed 4–6 mm from the palatal mucosa.\textsuperscript{147} This suggests that an alternative design might have improved anchorage. But a finite element analysis of stress-related molar response to a transpalatal bar concluded that the bar decreased molar rotation, had no effect on molar tipping, and provided insufficient sagittal anchorage.\textsuperscript{17}
Anchorage loss/active movement ratio for the Transpalatal bar group in paper IV was however lower than what was found in other studies without reinforced anchorage on the molars, which indicates that the transpalatal bar had some anchoring effect, although substantially less than expected.\textsuperscript{106,113,118} Thus, use of transpalatal bars should be restricted to when need of reinforced anchorage is limited.

**Clinical implications**

An ideal anchorage device has these characteristics: can withstand orthodontic forces, does not require compliance, is simple to use and inexpensive, and yields clinically equivalent or superior results when compared with other anchorage systems. After 40 years of research, the concept of osseointegration with a bone-to-implant contact has been accepted as being sufficiently stable to withstand occlusal and orthodontic forces. This thesis had no intention of questioning this concept, but it was important to demonstrate that the benefits of osseointegration could be made use of in a clinical orthodontic situation. This thesis clearly demonstrated that the molars in the osseointegrated groups were stable during orthodontic treatment in comparison with conventional headgear and transpalatal bar groups. In an ITT approach, the success rate for osseointegrated anchorage (52/59 patients) was significantly higher than for conventional headgear (14/30 patients) and transpalatal bar (8/29 patients) systems. Osseointegrated anchorage was thus stable and superior to conventional systems.

When new treatment methods that involve surgical procedures are introduced, patients’ acceptance needs to be explored. Overall, surgical placement of the osseointegrated devices was well tolerated by the patients in this thesis, and when in place, the subsequent orthodontic treatment followed standard procedures with no need for patient cooperation. This was a huge advantage in comparison with the headgear, which is theoretically also able to produce stable anchorage.

Although costs have not been considered in this thesis, they are important issues since osseointegrated anchorage devices are more expensive to purchase than conventional devices and require surgical referrals. But for patients with crucial anchoring problems, secure anchorage is invaluable, and any possible benefits of shorter treat-
ment times—which are an advantage for patients, parents, and orthodontists—must also be taken in consideration.

Osseointegration requires a healing period of 10–12 weeks, but studies on early loading indicate that presence of intermediate fibrous tissue does not compromise the clinical stability of the implant during treatment.\textsuperscript{36,148,149} This has led to a new era of mini-implants that are easy to insert and remove, immediately loadable, and inexpensive. It should be noted that few mini-implant systems were commercially available when these studies commenced. But in future it would be interesting to compare the results of this thesis with these new non-osseointegrated mini-implant systems.

**Evidence-based evaluation**

The RCT was the study design of choice, since a high level of evidence was desirable, when anchorage capacity and patients’ perceptions were evaluated in a comparison between osseointegrated and conventional anchorage systems. The randomization process confirmed that subject characteristics were equally distributed in the four groups and withdrawals before treatment start were known. The drop-out rate after treatment start was low; the reasons for drop-out were explained and in an intension to treat (ITT) analysis the drop-outs were incorporated in the results. The allocation procedures guaranteed external validity and the results could therefore be generalized to other adolescent orthodontic patients.

The newly developed questionnaire was valid and reliable and the measurement methods on lateral cephalograms are well known and accepted. Method error analysis was performed, but blinding during measurement was not possible since the different anchorage systems were easily recognized on the cephalograms.

The results from the studies have therefore provided high levels of evidence for the conclusions presented in this thesis.
CONCLUSIONS

In the systematic review of orthodontic anchorage, it was concluded that:

- Scientific evidence was too weak to evaluate the efficiency of various anchorage systems during space closure after premolar extraction.
- Most studies had quality problems and new RCTs that compared various anchorage systems, including skeletal anchorage, were needed to obtain a high level of scientific evidence to determine the most effective system.
- Further studies should also consider patients’ acceptance of various anchoring systems.

In the methodological study concerning reliability and validity of a newly developed questionnaire that assessed motivation, expectations, and experiences of adolescents in orthodontic treatment, it was concluded that:

- The questionnaire proved to have overall good test-retest reliability, acceptable internal consistency, and high face validity.
- The questionnaire, largely designed from focus group interviews, can be recommended for exploring adolescents’ experiences of orthodontic treatment.

In the comparison of perceived pain intensity and discomfort following placement of two anchoring units designed for osseointegration and premolar extraction, it was concluded that:
• Pain intensity after surgical placement of an Orthosystem implant was less compared to both Onplant installation and premolar extraction.
• Pain intensity after surgical placement of an Onplant was comparable to premolar extraction.
• The Orthosystem implant is the anchorage of choice compared to the Onplant concerning pain intensity, discomfort, and analgesic consumption.

In the comparison of anchorage capacity between four anchorage systems—two osseointegrated and two conventional—it was concluded that:
• Stable anchorage was provided with the Onplant and the Orthosystem implant throughout the observation period.
• Headgear was stable during the leveling/aligning phase but demonstrated anchorage loss at the end of the observation period. Furthermore, patient compliance was unpredictable.
• The transpalatal bar provided insufficient anchorage throughout the observation period.
• Headgear and the transpalatal bar can only be recommended as anchorage when need for anchorage reinforcement is limited.
• If maximum anchorage is required, the Orthosystem implant is the anchorage system of choice.
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Swedish Dental Society
Faculty of Odontology, Malmö University, Sweden
REFERENCES


Table A. Questionnaire about treatment motivation, treatment expectations, pain and discomfort, functional jaw impairment and validity.

<table>
<thead>
<tr>
<th>Treatment motivation</th>
<th>End-phrases/Alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do your teeth bother you?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>2. If it was possible, how much would you like to change the appearance of your teeth?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>3. Do you think your teeth need straightening?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>4. Do you think orthodontic treatment is good for your teeth?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>5. How motivated are you to have orthodontic treatment with braces?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>6. Have you been properly informed about the orthodontic treatment?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>7. Was it your own decision to undergo orthodontic treatment?</td>
<td>Not at all/Completely</td>
</tr>
<tr>
<td>Treatment expectations</td>
<td></td>
</tr>
<tr>
<td>8. Do you think it is going to be difficult to wear braces?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>9. Are you worried about having orthodontic treatment?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>10. Are you worried about how you are going to look with braces on?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>11. Have you ever been teased about the appearance of your teeth?</td>
<td>Not at all/Very much</td>
</tr>
<tr>
<td>Pain and discomfort from teeth, jaws and face</td>
<td></td>
</tr>
<tr>
<td>12. Do you have pain in your jaws?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>13. Do you have pain in your neck?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>14. Do you have pain in your palate?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>15. Do you have pain in your tongue?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>16. Do you have pain in your incisors when they are in contact?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>17. Do you have pain in your incisors when they are not in contact?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>18. Do you have pain from your molars when they are in contact?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>19. Do you have pain from your molars when they are not in contact?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>20. Do you experience tension in your teeth?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>21. Do you experience tension in your jaws?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>22. Do you ever have a headache?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>23. If yes, is your headache sporadic, frequent or constant?</td>
<td>Sporadic/frequent/constant</td>
</tr>
<tr>
<td>24. If you answered that your headache occurs frequently or constantly, how often have you had a headache in the last 3-month period? 1-3 times a month, once or twice a week, every other day?</td>
<td>1-3 times a month/once or twice a week/every other day</td>
</tr>
</tbody>
</table>
Functional jaw impairment

If you have pain or discomfort in your teeth and jaws, how much does that effect

<table>
<thead>
<tr>
<th>Question</th>
<th>End-phrases/Alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>25. Your leisure time</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>27. Your ability to take a big bite</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>28. Your ability to chew hard food</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>29. Your ability to chew soft food</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>30. Your schoolwork</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>32. Laughing</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>33. Your ability to chew against resistance</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>34. Yawning</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
</tbody>
</table>

Eating means taking a bite, chewing, and swallowing, how difficult is it for you to eat

<table>
<thead>
<tr>
<th>Food</th>
<th>End-phrases/Alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>38. Raw carrots</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>40. Peanuts</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>41. Apples</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
<tr>
<td>42. Cake</td>
<td>Not at all/slightly/much/extremely difficult.</td>
</tr>
</tbody>
</table>

Questionnaire validity

<table>
<thead>
<tr>
<th>Question</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>43. Do you think that the questions you have answered describe</td>
<td>Not at all/Very well</td>
</tr>
<tr>
<td>what you think of your teeth?</td>
<td></td>
</tr>
<tr>
<td>44. Do you think that the questions you have answered describe</td>
<td>Not at all/Very well</td>
</tr>
<tr>
<td>how you are feeling about getting braces soon?</td>
<td></td>
</tr>
<tr>
<td>45. Do you think that the questions you have answered describe</td>
<td>Not at all/Very well</td>
</tr>
<tr>
<td>how much pain and discomfort you experience?</td>
<td></td>
</tr>
<tr>
<td>46. Do you think that the questions you have answered describe</td>
<td>Not at all/Very well</td>
</tr>
<tr>
<td>how your pain and discomfort affect you daily?</td>
<td></td>
</tr>
</tbody>
</table>

80
Table B. Questionnaire administrated the first evening after surgical placement of an Onplant/Orthosystem implant and after premolar extractions.

<table>
<thead>
<tr>
<th>Questions</th>
<th>End-phrases / Alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did you have pain during the injection of the anesthetic?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>2. Did you have pain during surgery/extraction?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>3. Do you have pain from the surgery site/extraction site right now?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>4. Did you have discomfort during the injection of the anesthetic?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>5. Did you have discomfort during surgery/extraction?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>6. Do you have discomfort from the surgery site/extraction site right now?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>7. Do you have discomfort from the stent that protects the surgery site?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>8. Did you experience any part of the surgery/extraction as particularly unpleasant?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>9. If yes, which part did you experience as particularly unpleasant?</td>
<td>Open-ended</td>
</tr>
<tr>
<td>11. Have you taken analgesics for pain?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>12. If yes, what kind of analgesic did you use?</td>
<td>Open-ended</td>
</tr>
</tbody>
</table>
Table C. Questionnaire administrated one week after surgical placement of an Onplant/Orthosystem implant and after premolar extractions.

<table>
<thead>
<tr>
<th>Questions</th>
<th>End-phrases/Alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you have pain from the surgery site/extraction site right now?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>2. Do you have discomfort from the surgery site/extraction site right now?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>3. Do you have discomfort from the stent that protects the surgery site?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>4. Do you have discomfort from the screw?</td>
<td>Not at all/Worst imaginable</td>
</tr>
<tr>
<td>5. Have you taken analgesics for pain this last week?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>6. If yes, what kind of analgesic did you use?</td>
<td>Open-ended</td>
</tr>
<tr>
<td>7. Did you stay at home from school the last week because of pain from the surgery/extraction sites?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>8. If yes, how many days did you stay home from school?</td>
<td>Open-ended</td>
</tr>
<tr>
<td>9. Did you refrain from your leisure activities the last week because of pain from the surgery/extraction sites?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>10. If yes, what activity did you refrain from?</td>
<td>Open-ended</td>
</tr>
<tr>
<td>11. Has your sleep been disturbed in the last week because of pain from the surgery/extraction sites?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>12-29. Domain Functional jaw impairment from Table A</td>
<td>Not at all/slightly/much/extremely difficult</td>
</tr>
</tbody>
</table>
Table D. Summarized data of four new studies concerning anchorage loss during space closure after premolar extraction

<table>
<thead>
<tr>
<th>Author</th>
<th>Study design</th>
<th>Material</th>
<th>Treatment time</th>
<th>Active unit/Anchorage unit</th>
<th>Outcome measurements</th>
<th>Ratio (Anchorage loss/active movement)</th>
<th>Authors conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urias (2005)</td>
<td>Retrospective comparative</td>
<td>I: 13 girls, 7 boys</td>
<td>I: 3.8 years</td>
<td>Active unit.</td>
<td>Cephalometric analysis of mandibular molar position before and after treatment</td>
<td>I: 0.33 (0.46 mm/1.39 mm) II: 0.37 (0.45 mm/1.23 mm)</td>
<td>Active movement not declared. Anchorage loss: I: 3.1 mm II: 4.0 mm. No significant difference in anchorage loss between groups.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(12.9 years ± 3.1)</td>
<td></td>
<td>I: Bioprogressive technique</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>II: 12 girls, 8 boys</td>
<td>II: 3.3 years</td>
<td>II: Straight wire technique</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>(15.9 years ± 6.8)</td>
<td></td>
<td>Anchorage:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>I: Utility arch for cortical anchorage</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>II: Second molars or lingual arch</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>I: 3.8 years</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>II: 3.3 years</td>
<td></td>
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</tr>
<tr>
<td>Bokas (2006)</td>
<td>Prospective comparative</td>
<td>I, II: 6 girls, 6 boys</td>
<td>I, II: 28 days</td>
<td>Active unit:</td>
<td>Analysis of maxillary molar and canine position on study casts</td>
<td>I: 0.47 (1.93 mm/4.07 mm) II: 0.42 (0.70 mm/1.67 mm)</td>
<td>No significant difference in anchorage loss between groups.</td>
</tr>
<tr>
<td></td>
<td>“split mouth”</td>
<td>(13-14.5 years)</td>
<td></td>
<td>I: Ni-Ti springs</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>II: Elastomeric chains</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Anchorage unit:</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>I, I I: Passive transpalatal bars</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thiruvnenkatchari</td>
<td>Prospective comparative</td>
<td>I. II: 7 women, 3 men</td>
<td>I, II: 4-6 months</td>
<td>Active unit:</td>
<td>Cephalometric analysis of upper and lower molar position before and after canine retraction</td>
<td>I: 0mm II: 1.6 mm on maxillary first molars and 1.7 mm on mandibular first molars. No mesial movement of molars on the implant side.</td>
<td></td>
</tr>
<tr>
<td>(2006)</td>
<td>“split mouth”</td>
<td>(18-25 years)</td>
<td></td>
<td>I: Ni-Ti springs</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Anchorage:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>I: Micro-implants</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>II: No auxiliary anchorage unit present</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sueri (2006)</td>
<td>Prospective comparative</td>
<td>I, II: 12 girls, 3 boys</td>
<td>I, II: 2.5 months</td>
<td>Active unit:</td>
<td>Cephalometric analysis of maxillary molar and canine position</td>
<td>I: 0.47 (1.93 mm/4.07 mm) II: 0.42 (0.70 mm/1.67 mm)</td>
<td>Less canine and molar movement was found for the lace-back group.</td>
</tr>
<tr>
<td></td>
<td>“split mouth”</td>
<td>(12-18 years)</td>
<td></td>
<td>I: Ni-Ti springs</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>II: Lace-backs</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Anchorage:</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>I, I I: No auxiliary anchorage unit present</td>
<td></td>
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</tbody>
</table>
Table E. Summarized data of seven new studies concerning anchorage loss during molar distalization

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Study design</th>
<th>Material</th>
<th>Treatment time</th>
<th>Active unit/Anchorage unit</th>
<th>Outcome measurements</th>
<th>Ratio Anchorage loss/active movement</th>
<th>Authors conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bondemark (2005)</td>
<td>Retrospective comparative</td>
<td>I: 14 girls, 6 boys 14.7 years, SD 1.09  II: 15 girls, 5 boys 15.0 years, SD 0.99</td>
<td>I,II: Unknown</td>
<td>I: Ni-Ti coils/Nance appliance  II: Ni-Ti Coils/Fixed bite plane</td>
<td>Cephalometric analysis of maxillary incisor and first molar position</td>
<td>I: 1.12 (1.9 mm/1.7 mm)  II: 0.78 (1.4 mm/1.8 mm)</td>
<td>No significant difference in anchorage loss between the two groups</td>
</tr>
<tr>
<td>Chiu (2005)</td>
<td>Retrospective Comparative</td>
<td>I: 19 girls, 13 boys 12.3 years, SD 1.33  II: 19 girls, 13 boys 12.5 years, SD 1.08</td>
<td>I: 10 months  II: 7 months</td>
<td>I: Coil springs/Distal jet II: TMA springs/Pendulum appliance</td>
<td>Cephalometric analysis of maxillary incisor and first molar position</td>
<td>I: 1.32 (3.7 mm/2.8 mm)  II: 0.18 (1.1 mm/0.1 mm)</td>
<td>Significantly less anchorage loss in group II</td>
</tr>
<tr>
<td>Kinzinger (2005)</td>
<td>Prospective Comparative</td>
<td>I: 10 individuals, 9.9 years  II: 10 individuals, 11.6 years  III: 10 individuals 12.8 years</td>
<td>I: 24.9 weeks  II: 17.8 weeks  III: 23.8 weeks</td>
<td>I: Modified Pendulum/ Nance appliance, deciduous molars  II: Modified Pendulum/ Nance appliance, deciduous molars and premolars  III: Modified Pendulum/ Nance appliance, premolars</td>
<td>Cephalometric analysis of maxillary incisor and first molar position</td>
<td>I: 0.63 (2.75 mm/4.38 mm)  II: 0.44 (1.65 mm/3.78 mm)  III: 0.39 (1.75mm/4.48mm)</td>
<td>Both deciduous molars and premolars are suitable for anchorage</td>
</tr>
<tr>
<td>Ferguson (2005)</td>
<td>Retrospective Comparative</td>
<td>I: 14 girls, 11 boys, 12.5 years  II: 12 girls, 13 boys, 11.5 years  III: 17 girls, 13 boys, 13.3 years</td>
<td>I: 31.5 weeks  II: 41.6 weeks  III: 30.9 weeks</td>
<td>I: Coil springs/Distal jet II: Greenfield molar distalizing appliance/ Modified Nance  III: Sagittal/headgear appliance/Removable retainer</td>
<td>Cephalometric analysis of maxillary molar and premolar position</td>
<td>I: 0.29 (1.0 mm/3.4 mm)  II: 0.74 (2.9 mm/3.9 mm)  III: 1.0 (2.1 mm/2.1 mm)</td>
<td>Anchorage loss was comparable among all three appliances</td>
</tr>
<tr>
<td>Kinzinger (2006)</td>
<td>Prospective Comparative</td>
<td>I: 10 individuals, 9.8 years</td>
<td>I: 23.1 weeks</td>
<td>I: IV: Modified Pendulum/Nance appliance</td>
<td>Cephalometric analysis of maxillary incisor and first molar position</td>
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<tr>
<td></td>
<td>II: 10 individuals, 10.6 years</td>
<td>II: 22.2 weeks</td>
<td>II: 15.5 weeks</td>
<td>Four different dentition stages in the supporting area</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>III: 4 individuals 10.3 years</td>
<td>III: 19.6 weeks</td>
<td>III: 0.32 (1.20 mm/3.75 mm)</td>
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<tr>
<td></td>
<td>IV: 5 individuals 12.1 years</td>
<td>IV: 0.17 (0.61 mm/3.56 mm)</td>
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<td></td>
<td></td>
<td></td>
<td>III: 0.38 (1.33 mm/3.50 mm)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>IV: 0.31 (1.20 mm/3.90 mm)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>During the transition from deciduous to permanent teeth in the supporting area this modified Pendulum is not recommended</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Karlsson (2006)</th>
<th>Retrospective comparative</th>
<th>I: 10 girls and 10 boys, 11.4 years</th>
<th>I: 5.2 months</th>
<th>I, II: Ni-Ti coil appliance/Nance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Second molars not erupted</td>
<td>II: 6.5 months</td>
<td>II: 0.27 (0.8mm/3.0mm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>II: 10 girls and 10 boys, 14.6 years</td>
<td>Second molars erupted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>II: 6.5 months</td>
<td>II: 0.82 (1.8mm/2.2mm)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Distal movement of maxillary first molars is more effective and with less anchorage loss before eruption of second molars</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gelgor (2007)</th>
<th>Prospective comparative</th>
<th>I: 8 girls, 12 boys, (11.6-15.1 years)</th>
<th>I: 4.6 months</th>
<th>I: Sectional arch with Ni-Ti coils/Intraosseous screw</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>II: 11 girls, 9 boys, 12.3-15.4 years</td>
<td>II: 5.4 months</td>
<td>II: Keles distalizer/Intraosseous screw and modified Nance</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>II: 0.13 (0.52mm/3.95mm)</td>
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<td></td>
<td></td>
<td></td>
<td>II: 0.03 (0.10mm/3.88mm)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Anchorage loss for group II was negligible</td>
<td></td>
</tr>
</tbody>
</table>
Table F. Quality evaluation of eleven new studies

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>Selection Description</th>
<th>Valid Measurement Methods</th>
<th>Method Error Analysis</th>
<th>Blinding in Measurements</th>
<th>Adequate Statistic Provided</th>
<th>Confounding factors</th>
<th>Judged Quality Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urias (2005)</td>
<td>Retrospective comparative</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes Different anchorage in group II.</td>
<td>Low (5)</td>
</tr>
<tr>
<td>Bondemark (2005)</td>
<td>Retrospective comparative</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Medium (7)</td>
</tr>
<tr>
<td>Chiu (2005)</td>
<td>Retrospective comparative</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Medium (6)</td>
</tr>
<tr>
<td>Kinzinger (2005)</td>
<td>Prospective comparative</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low (5)</td>
</tr>
<tr>
<td>Ferguson (2005)</td>
<td>Retrospective comparative</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low (5)</td>
</tr>
<tr>
<td>Bokas (2006)</td>
<td>Prospective comparative “split mouth”</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Medium (6)</td>
</tr>
<tr>
<td>Thiruvenkatachari (2006)</td>
<td>Prospective comparative “split mouth”</td>
<td>Inadequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low (5)</td>
</tr>
<tr>
<td>Sueri (2006)</td>
<td>Prospective comparative “split mouth”</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low (4)</td>
</tr>
<tr>
<td>Kinzinger (2006)</td>
<td>Prospective comparative</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low (5)</td>
</tr>
<tr>
<td>Karlsson (2006)</td>
<td>Retrospective comparative</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Medium (6)</td>
</tr>
<tr>
<td>Gelgor (2007)</td>
<td>Prospective comparative</td>
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<td>Inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Medium (6)</td>
</tr>
</tbody>
</table>

0-5 = Low quality, 6-8 = medium quality, 9-10 = high quality.
### Table F.

#### Quality evaluation of eleven new studies

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>Method of Selection</th>
<th>Description</th>
<th>Measures</th>
<th>Valint Error</th>
<th>Quality</th>
<th>Confounders</th>
<th>Provided Fact</th>
<th>Judged Quality</th>
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<tbody>
<tr>
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<td>Retrospective</td>
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<td>Y</td>
<td>Yes</td>
<td>Low (5)</td>
</tr>
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<td>Adequate</td>
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<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Medium (7)</td>
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<td>Chiu</td>
<td>2005</td>
<td>Retrospective</td>
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<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Medium (6)</td>
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<tr>
<td>Kinzinger</td>
<td>2005</td>
<td>Prospective</td>
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<td></td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Low (5)</td>
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<tr>
<td>Ferguson</td>
<td>2005</td>
<td>Retrospective</td>
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<td>Inadequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Low (5)</td>
</tr>
<tr>
<td>Bokas</td>
<td>2006</td>
<td>Prospective</td>
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<td></td>
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<td>Inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Medium (6)</td>
</tr>
<tr>
<td>Thiruvanekatachari</td>
<td>2006</td>
<td>Prospective</td>
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<td>Inadequate</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low (5)</td>
</tr>
<tr>
<td>Sueri</td>
<td>2006</td>
<td>Prospective</td>
<td></td>
<td></td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
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<td>Low (4)</td>
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<td>Kinzinger</td>
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<td>Prospective</td>
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<td>Inadequate</td>
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<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Low (5)</td>
</tr>
<tr>
<td>Karlsson</td>
<td>2006</td>
<td>Retrospective</td>
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<td></td>
<td>Adequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Medium (6)</td>
</tr>
<tr>
<td>Gelgor</td>
<td>2007</td>
<td>Prospective</td>
<td></td>
<td></td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Medium (6)</td>
</tr>
</tbody>
</table>

0-5 = Low quality, 6-8 = medium quality, 9-10 = high quality.
Orthodontic Anchorage: A Systematic Review
Ingalill Feldmann\(^a\); L. Bondemark\(^b\)

**Abstract:** The aim of this systematic review was to examine, in an evidence-based way, what kind of orthodontic anchorage systems/applications are evaluated and their effectiveness. A literature survey from the Pub Med and Cochrane databases covering the period from January 1966 to December 2004 was performed. Randomized controlled trials (RCT), prospective and retrospective controlled studies, and clinical trials comparing at least two anchorage situations were included. Two reviewers selected and extracted the data independently and also assessed the quality of the retrieved studies. The search strategy resulted in 494 articles, of which 14 met the inclusion criteria. Two main anchorage situations were identified: anchorage of molars during space closure after premolar extractions and anchorage loss in the incisor or premolar region (or both) during molar distalization. Because of contradictory results and the vast heterogeneity in study methods, the scientific evidence was too weak to evaluate anchorage efficiency during space closure. Intraoral molar distalization leads to anchorage loss in various amounts depending on the choice of distalization unit. Most of the studies had serious problems with small sample size, confounding factors, lack of method error analysis, and no blinding in measurements. To obtain reliable scientific evidence, controlled RCT’s with sufficient sample sizes are needed to determine which anchorage system is the most effective in the respective anchorage situation. Further studies should also consider patient acceptance and cost analysis as well as implants as anchorage. (Angle Orthod 2006;76:493–501.)

**Key Words:** Orthodontic anchorage; Systematic review

**INTRODUCTION**

During orthodontic treatment the teeth are exposed to forces and moments, and these acting forces always generate reciprocal forces of the same magnitude but opposite in direction. To avoid unwanted tooth movements and maintain treatment success, these reciprocal forces must be diverted. Orthodontic anchorage, defined as the ability to resist these unwanted reactive tooth movements, can be provided by other teeth, by the palate, head, or neck, or implants in bone.\(^1\)\(^–\)\(^10\)

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To date, several studies have been published concerning different anchorage systems from the aspect of application, function, or effectiveness. However, it can be difficult for the practitioner to interpret the results and evidence presented in these studies because a variety of study designs, sample sizes, and research approaches exists. In view of this, and because evidence-based medicine has grown in importance,\(^1\)\(^1\) a systematic review of the present knowledge seems desirable. Systematic reviews aim to locate, appraise, and synthesize the evidence from scientific clinical studies to provide informative answers to scientific questions by including a comprehensive summary of the available evidence.\(^1\)\(^2\) This systematic review was undertaken to answer the following questions:

- What kind of orthodontic anchorage systems/applications are evaluated in an evidence-based manner, and how effective is the anchorage produced?
- Furthermore, a quality analysis of the methodological soundness of the selected studies was performed in this review.

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TABLE 1. Exclusion Criteria and Number of Excluded Articles in This Systematic Review

<table>
<thead>
<tr>
<th>Exclusion Criteria</th>
<th>Number of Excluded Articles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal studies</td>
<td>65</td>
</tr>
<tr>
<td>Review articles and letters</td>
<td>27</td>
</tr>
<tr>
<td>Case reports and case series</td>
<td>153</td>
</tr>
<tr>
<td>Do not follow the objective of this review</td>
<td>92</td>
</tr>
<tr>
<td>Technical presentation of an anchorage system</td>
<td>93</td>
</tr>
<tr>
<td>In vitro studies</td>
<td>25</td>
</tr>
<tr>
<td>Surgical treatment or cleft lip and palate treatment (or both)</td>
<td>16</td>
</tr>
<tr>
<td>Papers written in a language other than English</td>
<td>9</td>
</tr>
<tr>
<td>Total number</td>
<td>480</td>
</tr>
</tbody>
</table>

MATERIALS AND METHODS

Search strategy

The strategy for undertaking this systematic review was mainly influenced by the National Health Service, NHS, Center for Reviews and Dissemination. To identify all the studies that examined orthodontic anchorage systems and their effectiveness, a literature survey was done by applying the Medline database (Entrez Pub Med, www.ncbi.nlm.nih.gov) and the Cochrane Collaboration Oral Health Group Database of Clinical Trials (www.cochrane.org). The survey covered the period from January 1966 to December 2004 and used the Mesh term (Medical Subject Heading) “orthodontics” and was crossed with a combination of the following term “anchorage.”

Selection criteria

Human studies written in English were included. Randomized controlled trials (RCT), prospective and retrospective controlled studies, and clinical trials comparing at least two anchorage applications reporting quantitative data on the effects of different anchorage devices were selected. Case series, case reports, abstract papers, review articles, animal and in vitro studies, letters, and papers describing surgical procedures and cleft lip or palate treatment (or both) were not considered. All the exclusion criteria and the number of excluded articles are listed in detail in Table 1. The reference lists of the retrieved articles were also checked for additional studies. Two reviewers (Drs Feldmann and Bondemark) independently assessed all the articles with respect to the inclusion and exclusion criteria, and the Kappa score measuring the level of agreement was 0.94 (very good). Any interexaminer conflicts were resolved by discussion to reach consensus.

Data collection and analysis

Data were extracted on the following items: author, year of publication, study design, material, sex and age, treatment time, anchorage unit used, ratio between anchorage loss and active movement. In addition, to document the methodological soundness of each article, a quality evaluation modified by the methods described by Antczak et al and Jadad et al was performed with respect to preestablished characteristics. The following eight variables were evaluated: study design (RCT = 3 points; prospective study = 1 point; retrospective study = 0 point); adequate sample size = 1 point; adequate selection description = 1 point; valid measurement methods = 1 point; use of method error analysis = 1 point; blinding in measurement = 1 point; adequate statistics provided = 1 point; confounders included in analysis = 1 point. In sum, of the eight variables, a study could maximally score 10 points and a study was categorized as low (0–5 points), medium (6–8 points), or high (9 or 10 points). The data extraction and quality scoring from each article were assessed independently by two evaluators (Drs Feldmann and Bondemark) and without blinding. Interexaminer conflicts were resolved by discussion of each article to reach a consensus. The Kappa scores measuring levels of agreement between the two reviewers are shown in Table 2.

RESULTS

The search strategy resulted in 494 articles. All these articles were analyzed according to the inclu-
ORTHODONTIC ANCHORAGE

The effectiveness of anchorage of molars during space closure

Summarized data of the seven studies are listed in Table 3. Two studies were RCT,\textsuperscript{16,19} one a prospective split-mouth randomization study,\textsuperscript{17} one a prospective split-mouth comparative study,\textsuperscript{25} and three were retrospective comparative studies.\textsuperscript{16,17,25} Various techniques and auxiliary holding appliances were used for either active movement or anchorage (Table 3).

Using RCT methodology, Usmani et al\textsuperscript{24} showed no difference in anchorage loss of molars during leveling in the upper jaw with or without laceback ligatures. Irvine et al,\textsuperscript{29} on the other hand, demonstrated a significant larger anchorage loss when laceback ligatures were used for leveling in the lower jaw.

In a split-mouth randomized study, Lotzof et al\textsuperscript{18} compared two bracket systems (Tip-Edge and A-Company straight wire) and found no significant difference between the two systems. Baker et al\textsuperscript{16} found significant less anchorage loss with an edgewise technique using an auxiliary holding appliance compared with the Begg technique used with the differential force concept. However, according to the ratio anchorage loss/active movement, the difference between the groups was small. Hart et al\textsuperscript{27} demonstrated possibilities to alter anchorage control with a differential moment technique according to the type of malocclusion and degree of crowding. They found that anchorage loss was significantly lower in cases with maximum anchorage need.

Dincer and Iscan\textsuperscript{18} focused on space closure using a Gjessing retractor vs a reverse closing loop and found that the Gjessing retractor produced significantly less anchorage loss and also a shorter treatment time.

Geron et al\textsuperscript{25} examined the relative contribution of five different factors to anchorage loss: extraction site (first vs second premolar), mechanics (labial vs lingual), age (growing vs nongrowing), crowding, and overjet. The authors concluded that anchorage loss is a multifactorial response where mechanics and crowding are considered to be primary factors. Significant less anchorage loss was found with the lingual appliance compared with labial appliances, and the initial crowding was inversely correlated to anchorage loss. Because active movement was not declared, the ratio anchorage loss/active movement was not possible to calculate.

The effectiveness of anchorage during distal movement of molars

The summarized data of the seven studies are listed in Table 4. The primary concern in all these studies was to demonstrate distal molar movement and secondarily to show anchorage loss. One study was an RCT,\textsuperscript{23} two studies were prospective comparative studies,\textsuperscript{22,29} one was a retrospective controlled study,\textsuperscript{20} and three were retrospective comparative studies.\textsuperscript{21,27,28}

In one study,\textsuperscript{27} molar distalization was performed in the mandible, whereas in all other studies it was in the maxilla.

Mostly a Nance or a modified Nance appliance served as an anchorage unit during the intraoral distalization procedure, and different active units were used for molar movements (Table 4). The anchorage loss measured at the incisors or premolars varied from 0.2 to 2.2 mm, and the ratio anchorage loss/distal molar movement ranged from 0.2 to 0.8 mm.

Quality of the studies

A quality analysis of the 14 studies involved is summarized in Table 5. The research quality and methodological soundness were high in two studies,\textsuperscript{24,29} medium in three studies,\textsuperscript{20,21,23} and low in nine studies.\textsuperscript{16–19,22,25–28} The most obvious shortcomings were retrospective study design with inadequate selection description and small sample sizes implying low power.

In all studies, the methods used to detect and analyze the anchorage loss and active tooth movements were valid and generally well known. However, nine studies\textsuperscript{16,19,22–26} did not include a method error analysis, and only three\textsuperscript{21,22,24} studies used blinding in measurements. Moreover, three studies\textsuperscript{16,17,25} did not consider the risk for confounding factors (Table 5).

A majority of the studies used adequate statistical methods, but in one study,\textsuperscript{21} nonparametric tests were used on interval level data. The choice of statistical methods was generally not explained.

DISCUSSION

Initially, three main anchorage situations were identified (1) anchorage of molars during space closure after premolar extractions, (2) anchorage loss in...
TABLE 3. Summarized Data of Seven Studies Concerning Anchorage Loss During Space Closure After Premolar Extraction

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Study Design</th>
<th>Material Size, Sex, Age</th>
<th>Treatment Time</th>
<th>Active Unit/Anchorage Unit</th>
<th>Outcome Measurements</th>
<th>Ratio (Anchorage Loss/Active Movement)</th>
<th>Authors Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baker (1972)</td>
<td>Retrospective comparative</td>
<td>Sex and age unknown</td>
<td>Unknown</td>
<td>Active unit: Not specified in detail</td>
<td>Cephalometric analysis of upper molar and incisor position before and after treatment</td>
<td>I: 0.33 (1.5/4.5 mm) II: 0.38 (2.7/7.71 mm)</td>
<td>Significantly less anchorage loss with edgewise technique using auxiliary holding appliances</td>
</tr>
<tr>
<td>Hart et al (1992)</td>
<td>Retrospective comparative</td>
<td>17 females (10.5–41.4 y) and 13 male (8.4–15.0 y)</td>
<td>1.6–7.7 y</td>
<td>Active unit: Space-closure with power chain</td>
<td>Cephalometric analysis of upper molar and incisor position before and after treatment</td>
<td>IA: 0.11 (0.6/5.4 mm) IB: 1.71 (3.25/1.9 mm) IIA: 0.04 (0.28/6.8 mm) IIB: 0.41 (2.3/5.6 mm)</td>
<td>Differential moment concept as anchorage can achieve different control according to type of malocclusion and degree of crowding.</td>
</tr>
<tr>
<td>Dincer and Iscan (1994)</td>
<td>Prospective comparative “split mouth”</td>
<td>Sex unknown</td>
<td>I: 7.8 mo II: 6.3 mo III: 7.8 mo IV: 6.0 mo</td>
<td>Active unit: I, III: Reverse closing loop II, IV: Gjessing retraction arch Anchorage: No auxiliary anchorage unit present</td>
<td>Cephalometric analysis of molar and canine position before and after canine retraction</td>
<td>I: 0.63 (2.5/4.0 mm) II: 0.34 (1.6/4.7 mm) III: 0.48 (1.3/2.7 mm) IV: 0.32 (1.3/4.1 mm)</td>
<td>Significantly less anchorage loss and treatment time with the Gjessing retractor</td>
</tr>
<tr>
<td>Lotzof et al (1996)</td>
<td>Prospective “Split mouth randomization”</td>
<td>Seven females 13 y Five males 14 y</td>
<td>I: 10.7 wk II: 11.7 wk</td>
<td>Active unit: Canine retraction with elastic chains Anchorage: No auxiliary anchorage unit present</td>
<td>Analysis of upper molar and canine position measured on study casts before and after canine retraction</td>
<td>I: 0.30 (1.75/7.7 mm) II: 0.41 (2.35/6.6 mm)</td>
<td>No significant difference in anchorage loss between the two types of bracket systems</td>
</tr>
<tr>
<td>Usmani et al (2002)</td>
<td>Randomized controlled clinical trial</td>
<td>13 males and 22 females (13.7 y ± 1.8)</td>
<td>Unknown</td>
<td>Active unit: I: Levelling with laceback ligatures II: Levelling without laceback ligatures</td>
<td>Analysis of upper molar and incisor position measured on study casts before and after levelling</td>
<td>I: 0.98 (0.49/0.5 mm) II: −1.38 (0.5/−0.36 mm)</td>
<td>No significant difference in anchorage loss with or without lacebacks</td>
</tr>
</tbody>
</table>

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TABLE 3. Continued

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Study Design</th>
<th>Material Size, Sex, Age</th>
<th>Treatment Time</th>
<th>Active Unit/Anchorage Unit</th>
<th>Outcome Measurements</th>
<th>Ratio (Anchorage Loss/Active Movement)</th>
<th>Authors Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geron et al (2003)</td>
<td>Retrospective comparative</td>
<td>I: 12 individuals (24.8 y ± 5.6)</td>
<td>Unknown</td>
<td>Active unit: I, II: Space closure with elastic chains III, IV: Space closure with sliding mechanics and Bull-loops Anchorage: I, II: Class II elastics and bonding of second molars III, IV: Headgear and Class II elastics</td>
<td>Analysis of upper molar position from measurements on cephalograms before and after treatment</td>
<td>Active movement not declared Anchorage loss: I = 1.8 mm II = 2.4 mm III = 3.0 mm IV = 3.5 mm Significantly less anchorage loss with the lingual appliance. Initial crowding was indirectly correlated to anchorage loss</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>II: 13 individuals (24.4 y ± 6)</td>
<td>Nongrowing subjects, maxillary first premolar extraction, lingual appliance</td>
<td>Active unit: I, II: Space closure with elastic chains III, IV: Space closure with sliding mechanics and Bull-loops Anchorage: I, II: Class II elastics and bonding of second molars III, IV: Headgear and Class II elastics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>III: 20 individuals (20.1 y ± 5.4)</td>
<td>Nongrowing subjects, maxillary second premolar extraction, lingual appliance</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>IV: 42 individuals (12.6 y ± 2)</td>
<td>Growing subjects, maxillary first premolar extraction, labial appliance</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irvine et al (2004)</td>
<td>Randomized controlled clinical trial</td>
<td>62 individuals 13.7 y randomized into two groups</td>
<td>I, II: 6 mo</td>
<td>Active unit: I: Levelling with laceback ligature II: Levelling without laceback ligature Anchorage: I, II: No auxiliary anchorage unit present</td>
<td>Cephalometric analysis of molar and incisor position before and after leveling</td>
<td>T: 1.41 (0.75/0.53 mm) II: −0.18 (−0.08/0.44 mm) Significantly larger anchorage loss with lacebacks</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>I: 18 females, 12 males</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>II: 18 females, 14 males</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The effectiveness of anchorage of molars during space closure

The seven studies\textsuperscript{16–19,24,25,29} showed a vast heterogeneity, which means that it was difficult to combine data and draw any consistent conclusions from these studies. For example, two RCT studies\textsuperscript{24,29} examined anchorage loss with or without laceback ligatures but the results were contradictory, ie, no significant difference in anchorage loss with or without laceback ligatures\textsuperscript{24} vs less anchorage loss without ligatures.\textsuperscript{29} Conceivable explanations for the difference in results were forces on different anchorage teeth (maxillary vs mandibular molars), sample size discrepancy, and different
### TABLE 4. Summarized Data of Seven Studies Concerning Anchorage Loss During Molar Distalization

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Study Design</th>
<th>Material/Size, Sex, Age</th>
<th>Treatment Time/Observation Time</th>
<th>Distalizing Unit/Anchorage</th>
<th>Outcome Measurements</th>
<th>Outcome Ratio</th>
<th>Authors Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferro et al (2000)</td>
<td>Retrospective</td>
<td>I: 43 females, 67 males 10 y II: 52 females, 48 males 10 y</td>
<td>I: 12 mo (6–18) II: 13 mo</td>
<td>I: Cetlin plate and cervical headgear/Cetlin plate II: Untreated control group</td>
<td>Cephalometric analysis of upper incisor and first molar position</td>
<td>I: 1.02 (2.3/2.2 mm) II: 1.09 (1.5/1.4 mm)</td>
<td>The Cetlin method is reliable for molar distalization but 81% of the cases show Anchorage loss</td>
</tr>
<tr>
<td>Bondemark (2000)</td>
<td>Retrospective</td>
<td>I: 21 females 14.4 y II: 21 females 13.9 y</td>
<td>I: 6.5 mo II: 5.8 mo</td>
<td>I: NITI-coils/Nance appliance II: Magnets/Nance appliance</td>
<td>Cephalometric analysis of upper incisor and first molar position</td>
<td>I: 0.6 (1.5/2.5 mm) II: 0.69 (1.9/2.6 mm)</td>
<td>No significant difference in anchorage loss between the two groups</td>
</tr>
<tr>
<td>Kinzinger et al (2000)</td>
<td>Prospective</td>
<td>29 females and 21 males 11.2 y: I: 24 individuals with deciduous molars as anchorage II: 26 individuals with premolars as anchorage</td>
<td>I: 23 wk II: 21.9 wk</td>
<td>I, II: Modified pendulum/Nance appliance</td>
<td>Cephalometric analysis of upper incisor and first molar position</td>
<td>I: 0.83 (1.0/2.9 mm) II: 0.40 (1.1/2.8 mm)</td>
<td>No significant difference in anchorage loss when deciduous or permanent premolars served as an anchor for the modified Pendulum</td>
</tr>
<tr>
<td>Paul et al (2002)</td>
<td>Randomized</td>
<td>16 females and seven males I: 12 individuals 13.5 y II: 11 individuals 14.8 y</td>
<td>I, II: 6 mo</td>
<td>I: Upper removable appliance II: Jones jig/Nance appliance</td>
<td>Analysis of upper premolar and first molar position measured on study casts</td>
<td>I: 0.14 (0.18/1.3 mm) II: 0.15 (0.18/1.7 mm)</td>
<td>No significant difference in anchorage loss between the two groups</td>
</tr>
<tr>
<td>Kinzinger et al (2003)</td>
<td>Prospective</td>
<td>I: Four females, six males 9.5 y (mixed dentition) II: seven females, three males 12.3 y (permanent dentition)</td>
<td>I, II: 20 wk</td>
<td>I, II: Pendulum in the maxilla and lingual arch in the mandible/ Nance appliance and lingual arch appliance</td>
<td>Cephalometric analysis of incisor and first molar position</td>
<td>I: 0.28 (1.1/4.0 mm) II: 0.55 (1.6/2.9 mm)</td>
<td>No significant difference in anchorage loss between the two groups</td>
</tr>
<tr>
<td>Kinzinger et al (2004)</td>
<td>Retrospective</td>
<td>25 females, 11 males 12.4 y Were divided into three groups I: 18 individuals Second molar not erupted II: 15 individuals Second molar erupted III: 3 individuals Third molar germectomy completed</td>
<td>I: 18.4 wk II: 25.5 wk III: 24 wk</td>
<td>Pendulum/Modified Nance appliance</td>
<td>Cephalometric analysis of upper incisor and first molar position</td>
<td>I: 0.30 (1.0/3.1 mm) II: 0.31 (1.0/3.2 mm) III: 0.83 (2.2/7.7 mm)</td>
<td>The best time to start therapy with a pendulum appliance is before the eruption of second molars. No significant differences are shown</td>
</tr>
<tr>
<td>Kinzinger et al (2004)</td>
<td>Retrospective</td>
<td>I: seven individuals 14.3 y II: seven individuals 12.3 y III: six individuals 12.2 y</td>
<td>I: 12.5 wk II: 14.5 wk III: 22.6 wk</td>
<td>Linguar arch appliance/ I: Linguar arch appliance II: Linguar arch with sectional archwire III: Linguar arch with sectional archwire and lip bumper</td>
<td>Analysis of lower incisor and first molar position measured on study casts</td>
<td>I: 0.79 (2.6/3.3 mm) II: 0.21 (0.7/3.3 mm) III: 0.21 (0.7/3.3 mm)</td>
<td>Significantly less anchorage loss in group II and III</td>
</tr>
</tbody>
</table>
### TABLE 5. Quality Evaluation of the 14 Involved Studies

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>Selection Description</th>
<th>Valid Measurement Methods</th>
<th>Method Error Analysis</th>
<th>Blinding in Measurements</th>
<th>Adequate Statistical Provided</th>
<th>Confounding Factors</th>
<th>Judged Quality Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baker (1972)</td>
<td>Retrospective comparative</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes, different anchorage auxiliaries used in group</td>
<td>Low</td>
</tr>
<tr>
<td>Hart et al (1992)</td>
<td>Retrospective comparative</td>
<td>Inadequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes, range between pre-treatment and post-treatment cephalograms extremely long</td>
<td>Low</td>
</tr>
<tr>
<td>Dincer and Iscan (1994)</td>
<td>Prospective comparative &quot;split mouth&quot;</td>
<td>Inadequate</td>
<td>Partly inadequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low</td>
</tr>
<tr>
<td>Lotzof et al (1996)</td>
<td>Prospective comparative with a split-mouth randomization</td>
<td>Inadequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low</td>
</tr>
<tr>
<td>Perro et al (2000)</td>
<td>Prospective controlled</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Medium</td>
</tr>
<tr>
<td>Bondemark (2000)</td>
<td>Retrospective comparative</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Medium</td>
</tr>
<tr>
<td>Kinzinger et al (2000)</td>
<td>Prospective comparative</td>
<td>Adequate</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Uncertain</td>
<td>No</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Paul et al (2002)</td>
<td>Randomized controlled clinical trial</td>
<td>Inadequate</td>
<td>Partly inadequate</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Medium</td>
</tr>
<tr>
<td>Usmani et al (2002)</td>
<td>Randomized controlled clinical trial</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>High</td>
</tr>
<tr>
<td>Geron et al (2003)</td>
<td>Retrospective comparative</td>
<td>Partly inadequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes, different anchorage in different techniques</td>
<td>Low</td>
</tr>
<tr>
<td>Kinzinger et al (2003)</td>
<td>Prospective comparative</td>
<td>Inadequate</td>
<td>Partly inadequate</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low</td>
</tr>
<tr>
<td>Kinzinger et al (2004)</td>
<td>Prospective comparative</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low</td>
</tr>
<tr>
<td>Kinzinger et al (2004)</td>
<td>Prospective comparative</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Low</td>
</tr>
<tr>
<td>Irvine et al (2004)</td>
<td>Randomized controlled clinical trial</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>High</td>
</tr>
</tbody>
</table>

Measurement methods. Irvine et al\(^{29}\) performed the measurements on lateral cephalograms, whereas Usmani et al\(^{24}\) used study casts. It has been claimed that measurements on study casts and cephalograms are not comparable.\(^{22,23}\)

The five other studies,\(^{16–19,25}\) all had unique questions and aims and although the ratio of anchorage loss and active tooth movement was possible to calculate in four of these studies, the inconsistency in the methods made comparisons invalid. It is obvious that further studies are needed regarding the effectiveness of anchorage as well as which modality is the most effective during space closure.

### The effectiveness of anchorage during distal movement of molars

When first maxillary molars are moved distally, different opinions exist concerning the influence of second molars on both the active tooth movement and the
anchorage loss. Several authors have stated that distal movement of the first maxillary molars is dependent on the stage of eruption of the second maxillary molar, whereas other studies have shown that the second molars have limited effect. It can be pointed out that only five of the seven retrieved articles declared the eruption status of the second molars.

Only one study used an untreated control group, and, during the observation period of 13 months, maxillary growth effects with anterior displacement of molars and incisors were demonstrated. It is important to recognize that most of the retrieved articles in this review concerned growing patients, which means that the anchorage can also be influenced by growth effects. Therefore, it seems important to use matched control groups when the effectiveness of anchorage is analyzed.

Quality analysis

Several methods and scales to incorporate quality into systematic reviews have been proposed and have since been extensively applied to various RCTs in medicine. However, many items were clearly not applicable, for example, placebo appearance/taste, patient blinded, or observer blind to treatment. Instead, the quality of the articles was judged as low, medium, or high according to a scoring system on the basis of the characteristics given in Table 5.

Many of the studies had serious defects, and according to the criteria used, the majority of the articles were judged to be of low quality. The most serious shortcomings were retrospective study design in combination with small sample size and inadequate selection description. Problems of confounding variables, lack of method error analysis, and the absence of blinding in measurements were other examples of shortcomings. Furthermore, the choice of statistical methods was not explained.

In all studies, the methods to detect and analyze anchorage loss were valid and well known. However, different measurement methods were used to analyze the anchorage, which caused difficulties in comparing the results of the studies.

From a methodological point of view, it was notable that only three of the 14 studies declared the use of blinding in measurements. It is known that nonrandomized trials or RCT without blinding design are more likely to show the advantage an innovation has over a standard treatment method. This implies that the measurements can be affected by the researcher.

In one study, the statistical methods used were judged as uncertain, which might have influenced the outcome reliability of the study.

A randomized clinical trial is our most powerful tool to evaluate therapy, and the quality of the trial significantly affects the validity of the conclusions. Three RCT studies were identified in this systematic review, and two of them were judged to have high quality. These two studies had the same objective, evaluation of anchorage loss (mesial movement of molars) with or without laceback ligatures, but unfortunately the findings were conflicting and no conclusions could be drawn.

In the future, there is need for additional, well-controlled RCTs concerning the effectiveness of different anchorage systems including implant systems and also for assessing costs and side effects of the interventions.

CONCLUSIONS

- Two main anchorage situations were identified: (1) anchorage loss of molars during space closure after premolar extractions and (2) anchorage loss in the incisor or premolar region (or both) during distal movement of molars.
- A third anchorage category using different implants was identified, but so far only case reports and small case-series have been published, and these studies were therefore excluded in this systematic review.
- The scientific evidence was too weak to evaluate the efficiency of different anchorage systems during space closure because a vast heterogeneity of the studies existed.
- Intraoral molar distalization leads to anchorage loss in the incisor or premolar region (or both) in various amounts depending on choice of distalization unit.
- Most of the studies have serious problems with small sample size, confounding variables, lack of method error analysis, and no blinding in measurements. No evidence-based conclusions were therefore possible to draw from these studies.
- To obtain reliable scientific evidence, additional RCT's with sufficient sample size are needed to determine which anchorage system (including implants) is the most effective. Further studies should also consider patient acceptance and compliance as well as cost analysis.

ACKNOWLEDGMENTS

We wish to express our sincere thanks to statistician Hans Högbäck for valuable assistance in evaluating the statistical analysis. This study was supported by grants provided by the Centre for Research and Development, Uppsala University/County Council of Gävleborg, Sweden, and the Swedish Dental Society.

REFERENCES

ORTHODONTIC ANCHORAGE

Reliability of a Questionnaire Assessing Experiences of Adolescents in Orthodontic Treatment

Ingalill Feldmann; Thomas List; Mike T. John; L. Bondemark

ABSTRACT
Objective: To evaluate the reliability of a questionnaire that assessed the expectations and experiences of adolescent patients about orthodontic treatment.

Materials and Methods: The study included two groups of patients: 30 consecutive patients (19 girls and 11 boys, mean age 14.6 years, SD 2.3 years) naïve to orthodontic treatment, and 30 consecutive adolescent patients (17 girls and 13 boys, mean age 15.1 years, SD 2.0 years) in active orthodontic treatment with fixed appliances in both jaws. A questionnaire comprising 46 items was developed, based upon focus group interviews and previous established questionnaires. The questionnaire covered the following domains: Treatment motivation; treatment expectations; pain and discomfort from teeth, jaws, and face; functional jaw impairment; and questionnaire validity. Internal consistency as well as temporal stability with the test-retest method was investigated.

Results: A majority of the questions exhibited acceptable test-retest reliability, and composite scores yielded excellent reliability for all domains. Internal consistency was acceptable and good face validity was found for all domains.

Conclusion: The questionnaire can be recommended for use in the assessment of expectations and experiences of orthodontic treatment.

KEY WORDS: Adolescents; Orthodontic treatment; Questionnaire; Reliability

INTRODUCTION
For orthodontic treatment to be successful, treatment methods must be effective, require minimal compliance, and cause minimal pain and discomfort. Current orthodontic techniques must therefore continuously be refined and new techniques developed and systematically evaluated. Besides analyzing the effectiveness of a new treatment method, it is also necessary to investigate how well patients accept the method and whether they experience any side effects. Common methods for assessing patients’ experiences of pain and functional impairment during treatment are the use of self-administrated questionnaires that incorporate different scales such as the visual analogue scale (VAS) and the verbal rating scale (VRS). Previous research on patients’ experiences during orthodontic treatment has observed that pain and discomfort are reported mainly in the first week after insertion of an orthodontic appliance. However, other studies have reported pain periodically throughout orthodontic treatment. The degree of pain and discomfort can be explained not only by force application and different types of appliances but also by emotional, cognitive, and environmental factors, including culture, gender, and age. It has been shown that previous memories of pain or fear of pain aggravate the experience of discomfort related to orthodontic treatment, whereas patients with a high personal perception of the severity of their malocclusion exhibit high compliance and low pain and discomfort.

For generally applicable conclusions to be drawn, the reliability and validity of clinical and subjective measurements must first be determined.
Few studies have evaluated the reliability and validity of questionnaires in a young population receiving regular orthodontic treatment, and therefore it is important to analyze whether questionnaires are adequate, well understood, and easy to complete by this patient group. For this purpose, qualitative methods can be complementary and useful tools when orthodontic treatment is explored from a patient’s perspective through a questionnaire. Focus group interviews are an example of a qualitative method that has been predominantly used in sociological research but recently also in medicine and dentistry.

It was hypothesized that a questionnaire whose design was largely based on focus group interviews was reliable and valid. Thus, the aim of the study was to evaluate the reliability and validity of a questionnaire that assessed the expectations and experiences of orthodontic treatment in adolescents.

MATERIALS AND METHODS

Subjects

The study included two groups of patients: 30 consecutive patients (19 girls and 11 boys, mean age 14.6 years, SD 2.3) who were to enter orthodontic treatment and 30 consecutive adolescent patients (17 girls and 13 boys, mean age 15.1 years, SD 2.0) in active orthodontic treatment with fixed appliances at the Orthodontic Clinic in Gävle, Sweden. The ethics committee of Uppsala University, Sweden, approved the protocol and the informed consent form, according to the guidelines of the Declaration of Helsinki. The patients and their parents signed an informed written consent.

Design

The investigation consisted of a self-reported questionnaire, divided into five separate domains, concerning the motivation of adolescent patients to undergo orthodontic treatment and their expectations and experiences of orthodontic treatment. The questionnaires were completed twice at a 1- to 2-week interval, and two investigators were available to explain the questions and to check the questionnaires for completeness and legibility. About 10–15 minutes were needed to complete the questionnaire.

One form of reliability of a questionnaire is the characterization of temporal stability, and the most common approach is to administer the questionnaire on two separate occasions separated by an adequate time interval so that the measured circumstances are stable. This approach is called test-retest reliability. Reliability of a questionnaire can be assessed for single questions or for summary scores for the complete questionnaire or its separate domains. When summary scores are measured, it is important to consider a second aspect of reliability, namely internal consistency. This characterizes the homogeneity of the questionnaire items, measuring one underlying construction, and expresses how well the separate questions within each part relate. Because this questionnaire was divided into separate domains, internal consistency was also evaluated.

Reliability based on summary scores for each domain was also tested separately for girls and boys and for patients yet to undergo treatment and those already in treatment.

Face validity was established by asking the patients whether the items in the questionnaire were relevant and reflected their motivation for orthodontic treatment and their expectations and experience of orthodontic treatment.

Questionnaire

To create relevant questions, a qualitative method for assessing patients’ opinions about orthodontic treatment was initiated. Interviews from three focus groups with orthodontic patients who had recently completed active orthodontic treatment and one group with parents of adolescent patients in retention resulted in 4 hours of audiorecorded information. The interviews were conducted by two investigators using an open-ended interview style. The participants were asked to describe why they had sought orthodontic treatment and how they had experienced the treatment process. Transcripts were made from the audio-tapes and the results were analyzed and used as a basis when the questionnaires were constructed. Thus, the final questionnaire comprised 46 questions influenced by the focus group interviews and partly by other established questionnaires.

The questionnaire covered the following domains (Table 1): treatment motivation; treatment expectations; pain and discomfort from teeth, jaws, and face; functional jaw impairment; and questionnaire validity.

Treatement motivation. This domain contained seven questions assessed on a VAS with the end phrases...
Table 2. Reliability of the Domain “Treatment Motivation”

<table>
<thead>
<tr>
<th>Question</th>
<th>ICC</th>
<th>95% Confidence Interval of the ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do your teeth bother you?</td>
<td>.83</td>
<td>.63 to .90</td>
</tr>
<tr>
<td>2. If it was possible, how much would you like to change the appearance of your teeth?</td>
<td>.65</td>
<td>.38 to .82</td>
</tr>
<tr>
<td>3. Do you think your teeth need straightening?</td>
<td>.70</td>
<td>.45 to .84</td>
</tr>
<tr>
<td>4. Do you think orthodontic treatment is good for your teeth?</td>
<td>.82</td>
<td>.65 to .91</td>
</tr>
<tr>
<td>5. How motivated are you to have orthodontic treatment with braces?</td>
<td>.62</td>
<td>.34 to .80</td>
</tr>
<tr>
<td>6. Have you been properly informed about the orthodontic treatment?</td>
<td>.27</td>
<td>-- .09 to .57</td>
</tr>
<tr>
<td>7. Was it your own decision to undergo orthodontic treatment?</td>
<td>.79</td>
<td>.60 to .89</td>
</tr>
</tbody>
</table>

* ICC indicates intraclass correlation coefficient.

Table 3. Reliability of the Domain “Treatment Expectations”

<table>
<thead>
<tr>
<th>Question</th>
<th>ICC</th>
<th>95% Confidence Interval of the ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Do you think it is going to be difficult to wear braces?</td>
<td>.57</td>
<td>.27-.77</td>
</tr>
<tr>
<td>9. Are you worried about having orthodontic treatment?</td>
<td>.70</td>
<td>.46-.85</td>
</tr>
<tr>
<td>10. Are you worried about how you are going to look with braces on?</td>
<td>.88</td>
<td>.77-.94</td>
</tr>
<tr>
<td>11. Have you ever been teased about the appearance of your teeth?</td>
<td>.86</td>
<td>.73-.93</td>
</tr>
</tbody>
</table>

* ICC indicates intraclass correlation coefficient.

Table 4. Reliability of the Domain “Pain and Discomfort From the Teeth, Jaws, and Face”

<table>
<thead>
<tr>
<th>Question</th>
<th>ICC</th>
<th>95% Confidence Interval of the ICC</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Do you have pain in your jaws?</td>
<td>.67</td>
<td>.50 to .79</td>
<td></td>
</tr>
<tr>
<td>13. Do you have pain in your neck?</td>
<td>.85</td>
<td>.76 to .91</td>
<td></td>
</tr>
<tr>
<td>14. Do you have pain in your palate?</td>
<td>.67</td>
<td>.50 to .79</td>
<td></td>
</tr>
<tr>
<td>15. Do you have pain in your tongue?</td>
<td>.55</td>
<td>.35 to .71</td>
<td></td>
</tr>
<tr>
<td>16. Do you have pain in your incisors when they are in contact?</td>
<td>.74</td>
<td>.60 to .84</td>
<td></td>
</tr>
<tr>
<td>17. Do you have pain in your incisors when they are not in contact?</td>
<td>.63</td>
<td>.44 to .76</td>
<td></td>
</tr>
<tr>
<td>18. Do you have pain from your molars when they are in contact?</td>
<td>.39</td>
<td>.15 to .58</td>
<td></td>
</tr>
<tr>
<td>19. Do you have pain from your molars when they are not in contact?</td>
<td>.21</td>
<td>.04 to .44</td>
<td></td>
</tr>
<tr>
<td>20. Do you experience tension in your teeth?</td>
<td>.66</td>
<td>.48 to .78</td>
<td></td>
</tr>
<tr>
<td>21. Do you experience tension in your jaws?</td>
<td>.63</td>
<td>.44 to .76</td>
<td></td>
</tr>
<tr>
<td>22. Do you ever have a headache?</td>
<td>.85</td>
<td>95</td>
<td></td>
</tr>
<tr>
<td>23. If yes, is your headache sporadic, frequent, or constant?</td>
<td>.78</td>
<td>93</td>
<td></td>
</tr>
<tr>
<td>24. If you answered that your headache occurs frequently or constantly, how often have you had a headache in the last 3-month period? (1–3 times a month, once or twice a week, every other day?)</td>
<td>.60</td>
<td>92</td>
<td></td>
</tr>
</tbody>
</table>

* ICC indicates intraclass correlation coefficient; %, percentage of total agreement between first and second assessments.
Table 5. Reliability of the Domain "Functional Jaw Impairment"a

<table>
<thead>
<tr>
<th>Question</th>
<th>κ</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you have pain or discomfort in your teeth and jaws, how much does that affect?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. Your leisure time</td>
<td>.93</td>
<td>98</td>
</tr>
<tr>
<td>26. Your speech</td>
<td>.70</td>
<td>93</td>
</tr>
<tr>
<td>27. Your ability to take a big bite</td>
<td>.58</td>
<td>80</td>
</tr>
<tr>
<td>28. Your ability to chew hard food</td>
<td>.71</td>
<td>80</td>
</tr>
<tr>
<td>29. Your ability to chew soft food</td>
<td>.52</td>
<td>90</td>
</tr>
<tr>
<td>30. Your schoolwork</td>
<td>.76</td>
<td>95</td>
</tr>
<tr>
<td>31. Drinking</td>
<td>.30</td>
<td>93</td>
</tr>
<tr>
<td>32. Laughing</td>
<td>.65</td>
<td>85</td>
</tr>
<tr>
<td>33. Your ability to chew against resistance</td>
<td>.75</td>
<td>85</td>
</tr>
<tr>
<td>34. Yawning</td>
<td>.40</td>
<td>92</td>
</tr>
<tr>
<td>35. Kissing</td>
<td>.48</td>
<td>96</td>
</tr>
</tbody>
</table>

Eating means taking a bite, chewing, and swallowing. How difficult is it for you to eat?

<table>
<thead>
<tr>
<th>Question</th>
<th>ICC</th>
<th>95% Confidence Interval of the ICC</th>
<th>Md 1</th>
<th>Md 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>36. Crispbread</td>
<td>.85</td>
<td>.38–.81</td>
<td>90</td>
<td>93</td>
</tr>
<tr>
<td>37. Meat</td>
<td>.65</td>
<td>.30–.78</td>
<td>87</td>
<td>80</td>
</tr>
<tr>
<td>38. Raw carrots</td>
<td>.79</td>
<td>.52–.80</td>
<td>87</td>
<td>89</td>
</tr>
<tr>
<td>39. Roll</td>
<td>.87</td>
<td>.52–.80</td>
<td>87</td>
<td>89</td>
</tr>
<tr>
<td>40. Peanuts</td>
<td>.78</td>
<td>.52–.80</td>
<td>87</td>
<td>89</td>
</tr>
<tr>
<td>41. Apples</td>
<td>.77</td>
<td>.52–.80</td>
<td>87</td>
<td>89</td>
</tr>
<tr>
<td>42. Cake</td>
<td>.85</td>
<td>.52–.80</td>
<td>87</td>
<td>89</td>
</tr>
</tbody>
</table>

* ICC indicates Cohen’s kappa; %, percentage of total agreement between first and second assessments.

Table 7. Reliability of the Summary Scores for the Domains in the Questionnaire

<table>
<thead>
<tr>
<th>Domain</th>
<th>ICC</th>
<th>95% Confidence Interval of the ICC</th>
<th>α1</th>
<th>α2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment motivation</td>
<td>.85</td>
<td>.70–.92</td>
<td>.70</td>
<td>.63</td>
</tr>
<tr>
<td>Treatment expectations</td>
<td>.89</td>
<td>.78–.94</td>
<td>.68</td>
<td>.85</td>
</tr>
<tr>
<td>Pain and discomfort from teeth, jaws and face</td>
<td>.87</td>
<td>.78–.92</td>
<td>.67</td>
<td>.75</td>
</tr>
<tr>
<td>Functional jaw impairment</td>
<td>.89</td>
<td>.82–.93</td>
<td>.87</td>
<td>.88</td>
</tr>
<tr>
<td>Questionnaire validity</td>
<td>.92</td>
<td>.87–.95</td>
<td>.84</td>
<td>.94</td>
</tr>
</tbody>
</table>

* ICC indicates intraclass correlation coefficient; α1, Cronbach’s alpha measured at first assessment; and α2, Cronbach’s alpha at second assessment.

The kappa statistic (Cohen’s kappa, κ) was computed to assess reliability when the questionnaire variable was measured on an ordinal or dichotomous scale. Kappa values above .80 were considered excellent, .61–.80 good, .41–.60 moderate, .21–.40 fair, and .20 and below poor.20 Kappa adjusts for the likelihood of agreement by chance. Chance agreement is high when patients can be expected to be free from symptoms. Percentage of total agreement was therefore computed for the questions measured on an ordinal or dichotomous scale.

Internal consistency. Cronbach’s alpha (α) was calculated in order to estimate how consistently the subjects responded to the separate questions within each domain. Alpha values of .70 or higher were considered to be sufficient.21

RESULTS

All 60 patients filled in the questionnaire twice at an average interval of 12 days, so there were no dropouts.

Test-Retest Reliability

The reliability of the questionnaire, based on summary scores from each subject, was excellent (ICC = .84–.92) for all five domains (Table 7). There were only small differences in domain reliability between the group of patients yet to enter treatment and those already in treatment. However, a discrepancy for the domain “treatment motivation” was observed between girls and boys. The calculated reliability was good for
the girls (ICC = .68) and excellent for the boys (ICC = .88).

Tables 2 through 6 present the reliability of the separate questions within each domain. ICC ranged between .21 and .88 and kappa ranged between .30 and .93. Overall, a good to excellent reliability was found. However questions 6, 18, and 19 showed poor reliability and questions 8 and 15 presented fair reliability.

In the domain “functional jaw impairment” questions 31 and 34 exhibited fair reliability (κ = .30 and .40) and questions 27, 29, and 35 exhibited moderate reliability (κ = .58, .52, and .48). These questions were, however, considered acceptable because percentage of total agreement was comparable with the other questions in this domain (Table 5).

Internal Consistency

Internal consistencies for the separate domains were α = .67-.87 at the first assessment and .63-.94 at the second (Table 7), which implies that internal consistency was sufficient for all five domains. The difference between the two assessments illustrated the sampling variability.

Face Validity

The fifth domain contained four questions, one for each questionnaire domain, wherein the patients were asked whether they considered the questions to be relevant. Very high scores (80-94) were obtained at the VAS assessment (0-100) for face validity. See Table 6.

DISCUSSION

Reliability and validity of a questionnaire is the decisive factor for evaluating its precision and the criterion for drawing generalized conclusions. We have here investigated two types of reliability, temporal stability and internal consistency. The most important findings were that a new questionnaire concerning motivation, expectations, and experiences of orthodontic treatment in adolescents had good to excellent reliability with the test-retest method and that the questions within each questionnaire domain had acceptable consistency. Good face validity was ensured by asking patients in the retention phase (focus groups) about developing the new questionnaire and by asking the patients whether they considered the questions to be relevant. The stated hypothesis was thus confirmed, that is, that a questionnaire designed largely from focus group interviews exhibited reliable and valid values. This means that adequate and applicable questions, easily understood by adolescents, could be constructed with the help of focus group interviews. Furthermore, the gender and age distribution in the study was similar to that in other studies of adolescents undergoing orthodontic treatment, and the results were therefore considered to be representative for these individuals.

Two types of assessment scales were used: the VRS and the VAS. Both are common methods for assessing pain and functional impairment in children and are considered to be reliable and valid methods. In this questionnaire, both separate questions and composite scores for each domain were evaluated. It was therefore important that acceptable and sufficient consistency be ensured within each domain. Cronbach’s alpha was high for the domains “functional jaw impairment” and “questionnaire validity” (α = .84-.94) and lower, but acceptable for the domains “treatment motivation,” “treatment expectations,” and “pain and discomfort from teeth, jaws, and face” (α = .63-.85). An increased number of items within these three domains would probably have improved consistency and homogeneity, but because it was important that the patients be able to assess the questionnaire relatively quickly, the number of items was restricted.

Test-retest reliability based on summary scores was excellent for all five questionnaire domains in this study (ICC = .84-.92). The domains “treatment motivation” and “treatment expectations” were assessed only by the 30 subjects yet to undergo orthodontic treatment. A probable cause for the difference in reliability for the domain “treatment motivation” between boys (excellent) and girls (good) could therefore be the small sample size.

The reliability of the domain “functional jaw impairment” was excellent (ICC = .92), which is in agreement with Stegenga, who used the scale with patients with temporomandibular disorders. The reliability found by Marcusson, however, who used the scale on adult cleft lip and palate patients, was lower (ICC = .67). To our knowledge, this scale has not been used on ordinary orthodontic patients before.

It is important to bear in mind that when questionnaire reliability is based on composite scores, one loses the opportunity to analyze details in individual questions; therefore, reliability was also tested on all individual questions. The test-retest reliability of the individual questions was acceptable overall. High reliability is, however, difficult to achieve in homogeneous populations because reliability is a measure of how well the variable can distinguish between subjects. Because the subjects in our study formed a very homogenous group of healthy adolescents with no or few symptoms, this phenomenon was illustrated in a few individual questions.

To increase the range of the two domains on potential inconveniences (“pain and discomfort” and “functional jaw impairment”), it was essential that the ques-
Figure 1. Plot of difference against mean for question 6, “Have you been properly informed about the orthodontic treatment?” at first and second assessment. ICC = .27; mean difference, 4.4; 95% limits of agreement, −14.6 to 23.4.

Figure 2. Plot of difference against mean for question 18, “Do you have pain from your molars when they are in contact?” at first and second assessment. ICC = .39; mean difference, −0.5; 95% limits of agreement, −14.1 to 13.1.

Table 8. Question 31, “If you have pain or discomfort from your teeth and jaws, how much does that affect drinking?” (κ = 0.30)

<table>
<thead>
<tr>
<th></th>
<th>Not at All</th>
<th>Slightly</th>
<th>Much</th>
<th>Extremely</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>First assessment</td>
<td>55</td>
<td>3</td>
<td>—</td>
<td>—</td>
<td>58</td>
</tr>
<tr>
<td>Not at all</td>
<td>56</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>60</td>
</tr>
</tbody>
</table>

*κ* indicates Cohen’s kappa.

Three individual questions (6, 18, and 19) in this study had poor reliability, and four questions (8, 15, 31, and 34) had fair reliability. The question “Have you been properly informed about the orthodontic treatment?” had an ICC of .27 (Figure 1). It is known from other studies that pretreatment information is an important factor for future compliance and for pain and discomfort experiences, but because our subjects systematically scored lower at the second assessment, the reliability of this question is poor and the question will not be used in further studies. However, the poor reliability was probably an effect of an incorrect assumption that the circumstances between the assessments were stable.

It can also be stressed that the two other questions with poor reliability (18 and 19), “Do you have pain from your molars when they are in contact?” (ICC = .39) and “Do you have pain from your molars when they are not in contact?” (ICC = .21) demonstrated the problem with homogeneous data sets. These two questions could also easily be mixed up or difficult to understand, especially for patients with no previous orthodontic experience. In Figure 2, one outlier (21.5; 43) in a population with little variability decreased the ICC value from .69 to .39.

Moreover, questions 31 and 34, “If you have pain and discomfort from your teeth and jaws, how much does that affect drinking?” and “If you have pain and discomfort from your teeth and jaws, how much does that affect yawning?” had kappa values of .30 and .40, that is, fair reliability. Percentage agreements for the repeated assessments were, however, 93% and 92%, which indicates that these questions are acceptable and the discrepancy with the magnitude of the kappa statistics occurred because most subjects did not experience any difficulties (Table 8).

To ensure the legitimacy of the questionnaire, a fifth domain was added, “questionnaire validity,” which contained four questions about whether the items in the respective domains of the questionnaire reflected the subjects’ opinions regarding expectations and experience of orthodontic treatment. These four questions exhibited high median values (average 89) on the VAS, which confirms that the questions were applicable and relevant.

This questionnaire was developed for a detailed scientific study of patients’ experience of new orthodontic technique from decision for treatment to outcome satisfaction. It was therefore essential to establish that the questions were reliable and valid. The focus group interviews explored different aspects of treatment ex-
RELIABILITY OF A QUESTIONNAIRE

experiences, and to ensure that the questions asked were valid, all these aspects had to be considered. For everyday clinical use, this questionnaire is somewhat extensive, but shortening the questionnaire by select-

ing a few questions is not advisable because consis-
tency and validity can then no longer be guaranteed. However, because all questionnaire domains had ex-
cellent reliability and acceptable consistency, the do-
mains could easily be used separately as “short ver-
sions.” For example, questions 1–5 and 7–11 could be used before treatment in order to establish patients’ motivation and interest. Applicable questions from the domain “pain and discomfort from the teeth, jaws, and face” could be used during orthodontic treatment to study appliance acceptance, and the fourth domain, “functional jaw impairment,” could be used to study long-term effects during orthodontic treatment.

CONCLUSIONS

• A vast majority of the questions in each domain ex-
hibited acceptable test-retest reliability, and compos-
ite scores yielded good to excellent reliability for all domains. Internal consistency within each question-
naire domain was acceptable. Good face validity was found for the domains.

• The questionnaire, which was largely designed from focus group interviews, can be recommended for use in the assessment of orthodontic treatment.

ACKNOWLEDGMENTS

We wish to express our sincere thanks to Professor Arne Halling for having inspired us to use focus group interviews. This study was supported with grants by The Centre for Research and Development, Uppsala University/County Council of Gäv-
leborg, Sweden, and the Swedish Dental Society.

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Pain Intensity and Discomfort Following Surgical Placement of Orthodontic Anchoring Units and Premolar Extraction

A Randomized Controlled Trial

Ingalill Feldmanna; Thomas Listb; Hartmut Feldmannc; Lars Bondemarkd

ABSTRACT

Objective: To evaluate and compare perceived pain intensity and discomfort between the placement of two different orthodontic anchoring units designed for osseointegration and premolar extraction in adolescent patients.

Materials and Methods: A total of 120 adolescent patients (60 girls and 60 boys) were recruited and randomized into three groups. Group A underwent installation of an onplant, group B installation of an Orthosystem implant, and group C premolar extraction. Pain intensity and discomfort, analgesic consumption, limitations in daily activities, and functional jaw impairment were evaluated the first evening and one week after the intervention.

Results: Pain intensity following surgical installation of an onplant was comparable to the pain intensity experienced after premolar extraction, but there was significantly less pain after surgical installation of an Orthosystem implant compared to installation of an onplant ($P = .002$) or premolar extraction ($P = .007$). The protective, vacuum-formed stent caused great discomfort, even more discomfort than the surgical sites following installation of the onplant or the Orthosystem implant.

Conclusion: The Orthosystem implant was better tolerated than the onplant in terms of pain intensity, discomfort, and analgesic consumption and was, therefore, the anchorage system of choice in a short-term perspective.

KEY WORDS: Adolescents; Orthodontics; Pain; Randomized trial; Skeletal anchorage

INTRODUCTION

Successful orthodontic treatment requires effective treatment methods, and continuous technique development. Systematic evaluations of these new treatment approaches are essential. Besides analyses of the effectiveness of new treatment methods, it is also necessary to explore patients’ acceptance and experiences and possible side effects, especially if the new approach involves invasive techniques.

Pain intensity and discomfort are side effects during orthodontic treatment, and it has been reported that every tenth patient drops out in the course of treatment due to pain experiences. Pain has been defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Experiences of pain are always subjective and contain both the sensory as well as the affective aspect expressed as intensity and discomfort. A common method for assessing patients’ experiences of pain intensity and discomfort during treatment is the use of different scales such as the visual analog scale (VAS), which has been found to be reliable.

In recent years, a variety of skeletal fixation methods have been used to provide orthodontic anchorage. These fixation methods, usually palatal implants, are well tolerated by adults. However, to our knowledge, no studies on the pain and discomfort related to skeletal anchoring devices in adolescents have been published. Moreover, no comparison of surgical proce-
dure for skeletal anchoring methods with ordinary premolar extraction concerning perceived pain and discomfort has been reported in the literature.

It was hypothesized that there will be no difference in perceived pain intensity and discomfort between surgical installation of orthodontic anchoring units and premolar extraction. The aim of this study was to evaluate and compare perceived pain intensity and discomfort following installation of two different orthodontic anchoring units designed for osseointegration and premolar extraction in adolescent patients.

**MATERIALS AND METHODS**

**Subjects and Study Design**

A total of 120 patients from the Orthodontic clinic at the Public Dental Service, Gävleborg County Council, Gävle, Sweden were recruited to the study. All patients met the following inclusion criteria: adolescents in need of orthodontic treatment, permanent dentition, no previous experience of orthodontic treatment, treatment plan involving extraction of two upper premolars (in most cases, also two premolars in the lower jaw) followed by fixed appliances in both jaws and additional anchorage on the upper first molars considered necessary.

The ethics committee of Uppsala University, Uppsala, Sweden approved the informed consent form and protocol, and all patients at the orthodontic clinic who met the inclusion criteria were invited to enter the trial. The orthodontist provided the patient and parent with both oral and written information on details about the study. After written consent was obtained from the patient and parent, the patient was randomized in blocks and stratified by gender into one of three groups: onplant anchorage (group A), Orthosystem implant anchorage (group B), and premolar extraction (group C). Later, ie, after the trial period of this study, conventional anchorage was inserted in group C patients.

Group A comprised 15 boys and 15 girls (mean age 14.0 years, SD 1.6), group B 15 boys and 15 girls (mean age 14.6 years, SD 2.0), and group C 30 boys and 30 girls (mean age 14.2 years, SD 1.7). The patients in groups A and B were evaluated on the first evening and one week after installation of the onplant and the Orthosystem implant, respectively. Group C was evaluated on the first evening and one week after the last premolar extraction appointment. The patients were instructed on how to complete the questionnaire and asked to bring it to the clinic at the follow-up visit. About 5–10 minutes were needed to complete the questionnaire.

**Outcome Measures**

The assessment included self-report questions from a previous study where reliability and face validity were found to be acceptable. In addition, a few questions modified for this study were included.

<table>
<thead>
<tr>
<th>Table 1. Self-Reported Questions Concerning Pain and Discomfort, Analgesic Consumption, and Daily Activities Assessed the First Evening and One Week After Surgery/Extractions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain and discomfort</strong></td>
</tr>
<tr>
<td>1. Did you have pain during the injection of the anesthetic?</td>
</tr>
<tr>
<td>2. Did you have pain during surgery/extraction?</td>
</tr>
<tr>
<td>3. Do you have pain from the surgery site/extraction site right now?</td>
</tr>
<tr>
<td>4. Did you have discomfort during the injection of the anesthetic?</td>
</tr>
<tr>
<td>5. Did you have discomfort during surgery/extraction?</td>
</tr>
<tr>
<td>6. Do you have discomfort from the surgery site/extraction site right now?</td>
</tr>
<tr>
<td>7. Do you have discomfort from the stent that protects the surgery site?</td>
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<tr>
<td>8. Do you have discomfort from the screw?</td>
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<tr>
<td>9. Did you experience any part of the surgery/extraction as particularly unpleasant?</td>
</tr>
<tr>
<td>10. If yes, which part did you experience as particularly unpleasant?</td>
</tr>
<tr>
<td><strong>Analgesic consumption</strong></td>
</tr>
<tr>
<td>11. Have you taken analgesics for pain?</td>
</tr>
<tr>
<td>12. If yes, what kind of analgesic did you use?</td>
</tr>
<tr>
<td><strong>Daily activities</strong></td>
</tr>
<tr>
<td>13. Did you stay at home from school the last week because of the pain from the surgery/extraction sites?</td>
</tr>
<tr>
<td>14. If yes, how many days did you stay home from school?</td>
</tr>
<tr>
<td>15. Did you refrain from your leisure activities the last week because of pain from the surgery/extraction site?</td>
</tr>
<tr>
<td>16. If yes, what activity did you refrain from?</td>
</tr>
<tr>
<td>17. Has your sleep been disturbed in the last week because of pain from the surgery/extraction sites?</td>
</tr>
</tbody>
</table>

**Pain and Discomfort, Analgesic Consumption, and Daily Activities**

All questions are presented in Table 1. Questions 1–8 concerning pain and discomfort were graded on a VAS with the end phrases “no pain” and “worst pain imaginable” or “no discomfort” and “worst discomfort imaginable.” Question 9 had a binary response (yes/no) and question 10 was open with space for written comments.

Question 11 about analgesic consumption had a binary response (yes/no) with an open-ended follow-up question 12. Questions 13, 15, and 17 concerning daily activities had binary responses (yes/no); questions 14 and 16 were open-ended.
Jaw Function Impairment
The scale included 18 items related to jaw function; eight were related to mandibular function, three to psychosocial activities, and seven to eating specific foods. Each item was assessed on a 4-point scale with options not at all, slightly, much, or extremely difficult.13

Surgical Procedures and Premolar Extraction
Installations of the onplant and the Orthosystem implant and premolar extraction were carried out by two experienced maxillofacial surgeons at the Maxillofacial Unit, Gävleborg County Council, Gävle, Sweden.

Local Anesthesia
Identical local anesthetic procedures were conducted prior to installment of the onplant and the Orthosystem implant, ie, a local anesthetic was injected bilaterally in the palate (1.8 mL of 20 mg/mL lidocaine with 12.5 μg/mL epinephrine). Prior to premolar extraction, the patient received a buccal and lingual infiltration of local anesthetic (20 mg/mL lidocaine with 12.5 μg/mL epinephrine) with an initial dose of 1.8 mL in the maxilla and 2.5 mL in the mandible.

Onplant
The patients were given a standard preoperative antibiotic prophylaxis (2 g amoxicillin, orally). Via a paramarginal incision, a tunnel was prepared under the palatal mucosa and extended slightly over the palatal midline (Figure 1a). The onplant—a subperiosteal implant (diameter 7.7 mm; Nobel Biocare, Göteborg, Sweden)—was slid through the tunnel into a position corresponding to the second premolar and as close to the midline as possible.

After two sutures were placed at the incision (Figure 1b), the patient received a Viscogel trimmed (Dentsply, York, Pa), vacuum-formed stent to protect the surgery site, prevent hematoma formation, and facilitate the adaptation of the onplant onto the bone surface (Figure 2).

Orthosystem Implant
The patients were given a standard preoperative antibiotic prophylaxis (2 g amoxicillin, orally). The Orthosystem implant (diameter 3.3 mm, length 4 mm; Institut Straumann AG, Basel, Switzerland) was placed in the midline of the anterior maxilla, at the approximate level of the first premolar. After the mucosa was punched (Figure 3a), a specially designed bur created an implant site, and the implant was installed with finger force (Figure 3b). The patient received a vacuum-formed stent to protect the implant from parafunctional activity of the tongue (Figure 2).

Figure 1. (a) Onplant placement; (b) onplant in place and the incision closed with sutures.

Figure 2. Vacuum-formed protective stent used for both onplant and Orthosystem implant.
Premolar Extraction

On the first occasion, 51 patients had one maxillary and one mandibular premolar extracted on the same side and eight patients had two maxillary premolars extracted. At a second session, the maxillary and mandibular premolars on the other side were extracted in the 51 patients.

Post-operative Care

All patients and their guardians received thorough postoperative information, including a recommendation to use nonprescription analgesics at their own discretion.

Stent

The Essix stents (thickness 1 mm; Raintree Essix, Los Angeles, Calif) were constructed by two orthodontic technicians, and efforts had been made to manufacture the stents as identically as possible for both groups (Figure 2). Patients in group A wore the stent 24 hours a day for one week; patients in group B wore the stent 24 hours a day for two weeks.

Statistical Analysis

Median value, interquartile range, and range were calculated for each variable. Differences between groups were tested with the nonparametric Kruskal-Wallis and Mann-Whitney test for pain and discomfort. Chi-square tests were used to determine differences between groups in functional jaw impairment, affected daily activities, and use of analgesics. Differences with a $P$ value less than 5% ($P < .05$) were considered statistically significant.

RESULTS

Of the 120 randomized patients, 118 completed the trial: one girl in group A (onplant) moved, and one boy in group C (premolar extraction) was unable to participate. The response rate for the questions ranged from 90% to 100%.

Pain Intensity

Pain intensity related to the surgical installation of an onplant or an Orthosystem implant and to premolar extraction is presented in Figure 4. The first evening after the intervention, groups A ($P < .002$) and C ($P < .007$) had significantly more pain intensity compared to group B. The difference in pain intensity between onplant installation and premolar extraction was non-significant.

One week after the interventions, pain intensity was still significantly higher in group C compared to group B, which had undergone installation of an Orthosystem implant ($P < .001$). Differences between groups A and B were nonsignificant.

Discomfort

Discomfort related to the surgical installation of an onplant or an Orthosystem implant and to premolar extraction is presented in Figure 5. Group A experienced significantly more discomfort on the first evening compared to group C ($P = .040$). No significant differences were found between groups A (onplant) and B (Orthosystem) or between groups B and C (premolar extraction).

One week after the intervention, group B exhibited significantly less discomfort than group A ($P = .005$) and group C ($P = .021$). However, group B replied more often that they had experienced a particular part of the intervention as especially unpleasant compared to groups A (difference nonsignificant) and C ($P = .047$). The main complaint in group B was associated with drilling during surgery. The complaints during onplant surgery and premolar extraction were few.

Discomfort caused by the protective vacuum-formed stent compared to discomfort from the actual surgery

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Figure 4. Median values, interquartile ranges, and ranges concerning pain intensity related to surgical installation of an onplant, surgical installation of an Orthosystem implant, and premolar extraction.

Figure 5. Median values, interquartile ranges, and ranges concerning discomfort related to surgical installation of an onplant, surgical installation of an Orthosystem implant, and premolar extraction.

site is presented in Figure 6. The first evening after surgery, the stent caused more discomfort than did the onplant and Orthosystem implant surgery sites; however, the difference was only significant in group B ($P = .020$). One week after intervention, both groups still reported significantly more discomfort from the stent than from the surgery sites ($P < .001$).

**Analgesics**

In group A (onplant), significantly more patients had taken analgesics compared to the patients in group C ($P = .037$) on the first day. In the week following the intervention, analgesic consumption was significantly lower in group B than in groups A and C ($P = .004$). Acetaminophen (paracetamol), ibuprofen, and aspirin were the most commonly used analgesics.

**Daily Activities**

Staying home from school and refraining from leisure-time activities occurred in a few cases, but the differences between the three groups were nonsignificant. The patients in group A (onplant), however, reported disturbed sleep more often than did group C ($P = .033$).

**Functional Jaw Impairment**

There were no significant differences in jaw impairment, based on summary scores of the 18 items, between groups A (median 22, range 17–57), B (median 21, range 19–33), and C (median 20, range 15–46). When the items on the scale were analyzed individually, speech was found to be significantly more affect-
Figure 6. Median values, interquartile ranges, and ranges for discomfort following surgical installation of an onplant, surgical installation of an Orthosystem implant, and the corresponding stents.

Gender Differences

Gender differences were few. Girls consumed more analgesics the day following the intervention ($P = .042$) and reported a higher intensity of pain one week after surgery or extraction ($P = .039$). Girls also complained more about chewing against resistance ($P = .046$) and eating specific foods such as crispbread ($P = .032$) and apples ($P = .039$).

DISCUSSION

The most important finding of this study was that the Orthosystem implant was tolerated better than the onplant concerning pain intensity, discomfort, and analgesic consumption. Pain intensity after surgical installation of an onplant was comparable to pain after premolar extraction, and in this respect, the initial hypothesis, that there was no difference in perceived pain intensity between installation of orthodontic anchoring units designed for osseointegration and premolar extraction, was confirmed. Furthermore, the protective stent caused greater discomfort than did the actual site of surgery.

This study evaluates experienced pain related to a surgical intervention in a short-term perspective. The most common method of evaluating acute pain is to analyze the intensity and discomfort of the experience. The scale most commonly used to assess this experience is VAS. There is considerable evidence that this scale is reliable and valid among adults and adolescents. Reliability and validity of a question are important criteria for drawing generalized conclusions. The majority of the questions were taken from a questionnaire that had been used in a previous study where reliability and face validity were evaluated and found to be good to excellent. The age distribution in this study was also similar to that in other studies of adolescents undergoing orthodontic treatment with fixed appliances. In addition, selection bias was avoided since consecutive patients were randomized into three groups.

In this study, no major gender differences in experiences of pain intensity and discomfort were found. Although a few studies have reported that girls report more pain and discomfort than boys, correlations between gender and perception of pain and discomfort during orthodontic treatment are sparse in the literature. Nevertheless, in this study, differences in gender distribution should not have influenced the results since the trial was randomized.

In this study, pain intensity and discomfort following surgical installation of an onplant or an Orthosystem implant were compared. The indications for these anchorage systems are the same and both surgical procedures were simple and took only about 10–15 minutes to perform. One explanation of the higher pain intensity and discomfort reported by the onplant group is that the onplant installation involved a larger area of the palate than the Orthosystem implant.

The patients in groups A and B were all given a vacuum-formed stent directly after the surgical proce-
dure: in group A (onplant) to protect the surgery site, prevent hematoma formation, and facilitate the adaptation of the onplant onto the bone surface; and in group B to protect the short implant from parafunctional activity of the tongue. It was surprising that the stent caused such great discomfort, even more discomfort than was caused by the actual site of surgery (Figure 6). A plausible explanation was that many of the patients had severe crowding and the semi-elastic stent may have initiated uncontrolled forces and tensions on the teeth. An alternative design of the stent, with a different form of retention, can therefore be recommended in the future.

Moreover, it was found that groups A and B, who had received an onplant or an Orthosystem implant, were significantly more inconvenienced than group C when talking and eating specific foods. Additional discomfort from the protective stent, which groups A and B wore 24 hours a day, was probably an aggravating factor in this aspect.

Median values for pain intensity and discomfort following surgery and premolar extraction were comparatively moderate, but some patients described it as the worst imaginable. Perception of pain intensity is subjective and influenced by many other factors such as anxiety levels and motivational attitude.\textsuperscript{1,2} Since the oral health of the majority of the patients in this study was excellent, they had no or little experience of ordinary dental care, which could have contributed to the range in pain intensity and discomfort.

In orthodontic treatment of crowding or overjet, premolar extraction followed by orthodontic appliances is a common treatment strategy. It was, therefore, valuable to compare surgical procedures for skeletal anchoring methods with ordinary premolar extraction. Such a comparison has never been performed. The most optimal study design would have been to compare one surgical intervention per group, ie, one anchorage system with extraction of only one premolar. However, the standard clinical procedure is to extract two premolars simultaneously, and it was therefore decided to use this intervention as the most clinically relevant comparison.

The use of analgesics on the first day after surgery or premolar extraction was 70\%, which is higher than on the first day after insertion of orthodontic fixed appliances,\textsuperscript{16,18} but considerably lower than after third molar surgery.\textsuperscript{23}

CONCLUSIONS

- Pain intensity after surgical installation of an Orthosystem implant was less than after installation of an onplant or premolar extraction.
- Pain intensity after surgical installation of an onplant was comparable to pain after premolar extraction.
- In terms of pain intensity, discomfort, and analgesic consumption, the Orthosystem implant is the anchorage system of choice compared to the onplant in a short-term perspective.
- The protective, vacuum-formed stent caused great discomfort, even more than discomfort was caused by the surgical site after installation of an onplant or an Orthosystem implant.

ACKNOWLEDGMENTS

We thank Drs Tomas Strandkvist and Lena Zettergren-Wijk for valuable assistance in the clinical procedures, and statistician Hans Högborg for his support in the statistical analysis. The study was supported by the Centre for Research and Development, Uppsala University, Gävleborg County Council, Gävle, Sweden, and the Swedish Dental Society.

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Anchorage Capacity of Osseointegrated and Conventional Anchorage Systems - A randomized Controlled Trial

Ingallill Feldmann*; Lars Bondemark†

ABSTRACT

Aim: To evaluate and compare the orthodontic anchorage capacity following insertion of four different anchorage systems during leveling/aligning and space closure after maxillary premolar extractions.

Materials and Methods: One hundred and twenty patients (60 girls and 60 boys; mean age 14.3 years, SD 1.73) were consecutively recruited and randomized into four different anchorage systems; Onplant, Orthosystem implant, headgear and transpalatal bar. The main outcome measures were cephalometric analysis of maxillary first molar and incisor movement, sagittal growth changes of the maxilla, and treatment time. The results were also analyzed on an intention-to-treat basis.

Results: Maxillary molars were stable during the leveling/aligning in the Onplant, Orthosystem implant and headgear groups whereas the transpalatal bar group demonstrated anchorage loss, (mean 1.0 mm, P<0.001). During the space closure phase the molars were still stable in the Onplant and Orthosystem groups whereas the headgear and transpalatal bar groups demonstrated anchorage loss, (mean 1.6 mm and 1.0 mm respectively, P<0.001). Thus, the Onplant and Orthosystem implant had significantly higher success of anchorage than the headgear and transpalatal bar. Compared to the Orthosystem implant there were more technical problems with the Onplant.

Conclusion: If maximum anchorage is required the Orthosystem implant is the system of choice.

INTRODUCTION

Anchorage, defined as the ability to resist unwanted reactive tooth movements, can be provided within the orthodontic appliance, but in the majority of cases additional anchorage is required. This additional anchorage has traditionally been provided by adding resistant units, such as headgear or intermaxillary elastics, resulting in distribution of the reaction forces and reduction of the pressure on the anchor units. Nevertheless, it must be recognized that the use of headgear or elastics is dependent on patient cooperation, implying risk of prolonged treatment time and jeopardized treatment objectives if the patient does not cooperate.

Thus, in order to minimize the need for patient compliance intraoral Nance holding arches or different transpalatal bars have often been used as alternatives. These appliances present acceptable anchorage but none of them provides a completely secure anchorage in all three dimensions. Therefore, appliances that use osseointegrated implants are of interest.

Several experimental studies and case reports indicate that osseointegrated implants are resistant to orthodontic force application. However, the implants require available bone without the presence of vital structures at the implant sites, such as erupted or non-erupted teeth, the nasal and sinus cavities. Several authors have reported the anterior palate, retromolar area and zygoma as the most suitable areas for short temporary implants. If the amount of bone is not sufficient for endosseous implant placement the Onplant is suggested to be a good alternative. The Onplant is a subperiosteal implant in shape of a 7.7 mm titanium alloy disc coated with a layer (75 µm) of bioactive hydroxyapatite.

Osseointegrated anchorage devices cannot be loaded until osseointegration has been established, normally 3 to 4 months, and therefore miniscrews or miniplates permitting direct loading after insertion have been developed. Miniscrews require a minor and quick insertion procedure but with the
disadvantage of not being stable in all three dimensions.  

Although, anchorage preparation is a vital part of orthodontic treatment planning there are few studies in the literature that evaluate and compare different anchorage systems. Two recently performed systematic reviews concluded a need for additional randomized clinical trials (RCTs) concerning the effectiveness of different anchorage systems and that questions concerning optimal force systems, surgical techniques and placement, and healing times remain for implant systems. 18,19

Consequently, using RCT methodology, the aim of this study was to evaluate and compare the anchorage capacity following insertion of two osseointegrated (Onplant and Orthosystem implant) and two conventional anchorage systems (headgear and transpalatal bar). It was hypothesized that the osseointegrated systems provided higher capacity of maxillary molar anchorage than the conventional systems during leveling/aligning and space closure after maxillary premolar extractions.

MATERIALS AND METHODS

Subjects and study design

The patients were consecutively recruited from the Orthodontic Clinic at the Public Dental Service, Gävleborg County Council, Gävle, Sweden from January 2003 to March 2005. All patients met the following inclusion criteria: healthy, non-smoking adolescents in need of orthodontic treatment; no previous experience of orthodontic treatment; permanent dentition; no transversal discrepancies; treatment plan involving extraction of two maxillary premolars (in most cases, also two premolars in the lower jaw) followed by fixed appliances in both jaws; and additional anchorage on the upper first molars considered necessary. The study sample involved both patients with large overjets and patients with crowding and the need for additional anchorage varied from moderate to maximum. However, treatment objectives for each patient were considered to be reachable with all four techniques.

The ethics committee of Uppsala University, Uppsala, Sweden, which follows the guidelines of the Declaration of Helsinki, approved the informed consent form and protocol. All patients who met the inclusion criteria were invited to enter the trial. Two orthodontists provided the patient and parent with both oral and written information of details about the study. After written consent was obtained from the patient and parent, the patients were randomized in blocks of four and stratified by gender into one of four groups: Onplant anchorage (group A), Orthosystem implant anchorage (group B), headgear anchorage (group C) and transpalatal bar anchorage (group D). The allocation sequence was computer generated by a statistician at Gävleborg County Hospital, Sweden and concealed in envelopes until randomization.

All patients were treated according a standard straight-wire concept20 with a .022-inch slot size and designed for light forces. The arch-wire sequence was: .016-inch Heat-Activated Nickel-Titanium (HANT), .018-inch stainless steel (SS), .019 x .025-inch HANT and finally .019 x .025-inch SS. Leveling and aligning was achieved with lace-back ligatures and/or coil-springs depending on the degree of crowding and space closure was carried out with active tie-backs. Two orthodontists at the Orthodontic Clinic, Gävleborg County Council, Gävle, Sweden performed the orthodontic treatments.

The main outcome measures to be assessed in the trial during the leveling/aligning and space closure were:

- Position and movement of the maxillary first molars
- Position and movement of maxillary central incisors
- Skeletal sagittal position of the maxilla
- Treatment time of the leveling/aligning and space closure phase

The leveling/aligning phase was defined as the time in months from treatment start until the insertion of a .019 x .025-inch stainless steel space-closure archwire whereas the space closure phase was the time in months from the end of the leveling/aligning phase until extraction spaces were closed or (in cases with planned anchorage loss) until anterior space closure with a correct Class I occlusion canine relationship was established.

The Onplant anchorage

The Onplant (Nobel Biocare, Gothenburg, Sweden) is a subperiostial implant in shape of a 7.7 mm titanium disc. The disc is coated with a layer (75 μm) of bioactive hydroxyapatite to facilitate osseointegration. The disc is slid through a subperiostial tunnel into a position near the palatal midline via a surgical procedure under local anesthesia. After a healing period of 16 weeks an abutment was connected to the Onplant under local anesthesia, and then a 1.3 mm stainless steel transpalatal bar was fabricated and bonded to the maxillary first molars (Figure 1a).
The Orthosystem implant anchorage
The Orthosystem implant (Institut Straumann AG, Basel, Switzerland) is a short titanium implant (3.3x4.0 mm) which was inserted in the palate near the midline through a surgical procedure under local anesthesia. After a healing period of 16 weeks a 1.2 mm stainless steel transpalatal bar was fabricated, connected to the implant and bonded to the maxillary first molars (Figure 1b).

The headgear anchorage
The headgear anchorage consisted of bands on the maxillary first molars and a short outer bow with the force direction corresponding medium pull. The force of 400 g was checked at each visit (every sixth week) at the clinic and adjustments were carried out when necessary. The patients were instructed to wear the headgear 10-12 hours/day. (Figure 1c).

The transpalatal bar anchorage
The transpalatal bar anchorage appliance consisted of bands on the maxillary first molars with a soldered stainless steel bar 2.0 x 1.0 mm. The bar was relieved 2 mm from the palate (Figure 1d).

Data collection
The time in months to achieve maxillary arch leveling/aligning and space closure was registered. Lateral head radiographs in habitual occlusion were obtained at the start (T0), after completion of the leveling/aligning phase (T1), and after the space closure phase (T2). The measuring points, reference lines and measurements used were based on those defined and described by Björk and Pancherz. Dental and skeletal changes as well as dental changes within the maxilla and mandible were obtained by Pancherz SO analysis (analysis of changes in sagittal occlusion). Measurements were made by hand to the nearest 0.5 mm or 0.5 degrees. Images of bilateral structure were bisected. No correction was made for linear enlargement (10%). Changes in the different measuring points during the treatment were calculated as the difference in the after-minus-before position and one orthodontist (Dr Feldmann) performed all measurements. Blinding during measurement was not possible since the four different anchorage systems were easily recognized on the lateral cephalograms.

Data on all patients who were randomly assigned to the four groups were analyzed on an intention-to-treat (ITT) basis. In this analysis patients who withdrew between randomization and allocated intervention were not included since the evaluation of anchorage success could only be performed after the insertion of the
anchorage system. Thus, as soon as the anchorage system was inserted, the results were analyzed regardless of the outcome. Successful anchorage was defined as an anchorage loss of \( \leq 1 \text{mm} \), no failures of osseointegration or failures during anchorage system placement, and no drop-outs after the treatment start.

**Statistical analysis**
A sample size calculation was performed, and, based on an alpha significance level of 0.05 and a beta of 0.1 to achieve 90% power to detect a clinically meaningful difference of 1.5 mm (SD 1.5) in anchorage loss between the four groups. The sample size calculation revealed that 21 patients in each group were sufficient, but to compensate for conceivable dropouts during the trial, it was determined to enroll 30 patients in each group.

The arithmetic mean and standard deviation (SD) were calculated for each variable. Differences in means within groups were tested by one-way analysis of variance (ANOVA). A repeated measure ANOVA with a Bonferroni correction was used to analyze differences between groups at T0, T1 and T2. Chi-square tests were used to determine differences between groups in success rate of anchorage. Differences with P-values less than 5% (P<0.05) were considered statistically significant.

**Error of the method**
Twenty randomly selected cephalograms were traced on two separate occasions. No significant mean differences between the two series of records were found by using paired t-tests. The method error\(^{23}\) did not exceed 0.5 mm and 1.0 degree except for molar inclination where the error did not exceed 1.5 degrees.

**RESULTS**
A total of 168 patients were invited to enter the study but 48 declined to participate. The main reasons for declining participation were either fear for the surgical procedures or reluctance to wear a headgear. These 48 patients comprised 26 boys and 22 girls (mean age 13.8 years, SD 1.28) and were not significantly different considering gender and age as those who entered the study (mean age 14.3 years, SD 1.73). Thus, 120 patients were randomized into four groups; Group A comprised 15 boys and 15 girls (mean age 14.0 years, SD 1.53), group B 15 boys and 15 girls (mean age 14.6 years, SD 1.99), group C 15 boys and 15 girls (mean age 14.0 years, SD 1.72) and group D 15 boys and 15 girls (mean age 14.4 years, SD 1.65). After randomization but before treatment start one patient from group A (Onplant anchorage) moved from the area and one patient in group D (transpalatal bar anchorage) became seriously ill and dropped out of the study (Fig 2). These 2 patients were excluded because they did not start the allocated intervention.

![Figure 2. The flow chart of patients in the trial. The reasons for declining to participate and dropouts during the trial are declared in the text.](image-url)

After the healing period one Onplant and one Orthosystem implant were still instable (no osseointegration) and therefore removed. Another two Onplants were tilted (although osseointegrated) and impressions for the bars were therefore not possible to perform. A fifth patient with the Onplant anchorage dropped out of the study during space closure phase due to poor oral hygiene. These 5 patients were included and analyzed on an ITT basis as failures, and thus, a total of 118 patients were included in this analysis and 113 completed the total observation period. (Fig 2, Table I).

The pretreatment cephalometric records are summarized in Table II and no significant differences were found between the four groups.
Table I. Distribution of success rate concerning anchorage capacity for the Onplant group (A), Orthosystem implant group (B), headgear group (C), and transpalatal bar group (D).

<table>
<thead>
<tr>
<th></th>
<th>Onplant (A)</th>
<th>Orthosystem implant (B)</th>
<th>Headgear (C)</th>
<th>Transpalatal bar (D)</th>
<th>Total</th>
<th>Group difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>29</td>
<td>30</td>
<td>30</td>
<td>29</td>
<td></td>
<td>A/B: NS</td>
</tr>
<tr>
<td>Successful</td>
<td>24</td>
<td>28</td>
<td>14</td>
<td>8</td>
<td>74</td>
<td>A/C: P = 0.0039</td>
</tr>
<tr>
<td>Not successful</td>
<td>5</td>
<td>2</td>
<td>16</td>
<td>21</td>
<td>44</td>
<td>B/C; D: P &lt; 0.001</td>
</tr>
<tr>
<td>Total</td>
<td>29</td>
<td>30</td>
<td>30</td>
<td>29</td>
<td>118</td>
<td>C/D: NS</td>
</tr>
</tbody>
</table>

Reasons for not successful:
1 no osseointegration
2 technical problems
1 discontinued treatment (poor oral hygiene)
1 anchorage loss $> 1.0$ mm

Table II. Pretreatment cephalometric records for the Onplant group (A), Orthosystem implant group (B), headgear group (C) and transpalatal bar group (D).

<table>
<thead>
<tr>
<th></th>
<th>Group A n = 30</th>
<th>Group B n = 30</th>
<th>Group C n = 30</th>
<th>Group D n = 30</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sagittal variables (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxillary base, A-OLp</td>
<td>81.0</td>
<td>4.81</td>
<td>80.9</td>
<td>4.32</td>
<td>80.1</td>
</tr>
<tr>
<td>Mandibular base, P-OLp</td>
<td>81.8</td>
<td>5.80</td>
<td>82.0</td>
<td>6.69</td>
<td>79.6</td>
</tr>
<tr>
<td>Maxillary molar, Ms-OLp</td>
<td>57.9</td>
<td>4.55</td>
<td>57.6</td>
<td>4.79</td>
<td>56.7</td>
</tr>
<tr>
<td>Maxillary incisor, Is-OLp</td>
<td>89.5</td>
<td>5.87</td>
<td>89.3</td>
<td>5.22</td>
<td>89.7</td>
</tr>
<tr>
<td>Mandibular molar, M-OLp</td>
<td>58.6</td>
<td>5.38</td>
<td>58.0</td>
<td>6.21</td>
<td>56.8</td>
</tr>
<tr>
<td>Mandibular incisor, I-OLp</td>
<td>83.1</td>
<td>6.14</td>
<td>82.7</td>
<td>5.88</td>
<td>83.0</td>
</tr>
<tr>
<td>Overjet, Is-OLp minus I-OLp</td>
<td>6.4</td>
<td>1.91</td>
<td>6.7</td>
<td>2.63</td>
<td>6.7</td>
</tr>
<tr>
<td>Molar relation, Ms-OLp minus Mi-OLp</td>
<td>-0.7</td>
<td>2.40</td>
<td>-0.3</td>
<td>2.27</td>
<td>-0.2</td>
</tr>
</tbody>
</table>

Sagittal variables (*)
Maxillary first molar inclination (Ms/NL) | 78.9 | 4.40 | 81.4 | 3.52 | 78.7 | 3.50 | 79.9 | 4.77 | NS
Maxillary incisor inclination (I/Ls/NL) | 112.7 | 5.06 | 114.9 | 7.11 | 115.3 | 6.97 | 114.5 | 6.99 | NS
Mandibular incisor inclination (I/Li/NL) | 91.4 | 5.73 | 91.6 | 6.90 | 93.5 | 7.74 | 91.3 | 7.10 | NS

Sagittal jaw relationship (*)
SNA | 81.3 | 3.28 | 80.6 | 4.01 | 82.7 | 2.62 | 82.3 | 3.80 | NS
SNB | 76.9 | 3.58 | 76.7 | 4.33 | 78.1 | 3.15 | 77.4 | 3.21 | NS
ANB | 4.3 | 2.00 | 3.9 | 2.13 | 4.6 | 1.57 | 4.9 | 2.15 | NS

Vertical jaw relationship (*)
NL/NSL | 7.0 | 4.09 | 7.6 | 4.34 | 6.1 | 2.57 | 6.3 | 3.21 | NS
ML/NSL | 36.3 | 5.22 | 35.6 | 7.07 | 35.5 | 4.69 | 36.0 | 5.87 | NS
NL/ML | 29.3 | 5.00 | 28.0 | 5.42 | 29.3 | 5.22 | 29.6 | 6.00 | NS

NS = Not significant
The leveling/aligning phase (T0-T1)

Dental changes

Maxillary molars were stable within the maxilla in the Onplant, Orthosystem implant and headgear group. In the transpalatal bar group the molars on average moved forward 1.0 mm (P<0.001) (Table III). The mesial movement of the molars (anchorage loss) found in the transpalatal bar group was significant different compared to the other three groups. The amount of mesial molar tipping was small in all four groups but significantly larger in the transpalatal bar group (mean 4.1 degrees, P<0.001) (Table III).

During the leveling/aligning phase the maxillary incisors were retracted within the maxilla 1.5-2.0 mm and the overjet was reduced 0.7-1.5 mm with no significant differences between the four groups (Table III).

Skeletal changes

The average sagittal forward growth was 0.8-0.9 mm for the maxilla and 0.9-1.4 mm for the mandible. These changes were significant for all groups but with no differences between the four groups. Small and non significant vertical jaw changes were found (Table III).

Table III. The leveling/aligning phase (T0-T1). Changes in cephalometric variables within and between the four anchorage groups (Onplant, group A; Orthosystem implant, group B; Headgear, group C; Transpalatal bar, group D).

<table>
<thead>
<tr>
<th>Skeletal sagittal variables (mm)</th>
<th>Group A n = 26</th>
<th>Group B n = 29</th>
<th>Group C n = 30</th>
<th>Group D n = 29</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary base, A-OLp</td>
<td>0.8***</td>
<td>0.77</td>
<td>0.9***</td>
<td>0.92</td>
<td>0.8***</td>
</tr>
<tr>
<td>Mandibular base, Pg-OLp</td>
<td>1.4***</td>
<td>0.99</td>
<td>0.9**</td>
<td>1.57</td>
<td>1.3***</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dental sagittal variables within the maxilla and mandible</th>
<th>Group A n = 26</th>
<th>Group B n = 29</th>
<th>Group C n = 30</th>
<th>Group D n = 29</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary molar, Ms-OLp - A-OLp</td>
<td>0.1</td>
<td>0.42</td>
<td>0.1</td>
<td>0.42</td>
<td>-0.4</td>
</tr>
<tr>
<td>Maxillary incisor, Is-OLp - A-OLp</td>
<td>-1.7***</td>
<td>1.75</td>
<td>-1.9***</td>
<td>2.25</td>
<td>-2.0***</td>
</tr>
<tr>
<td>Mandibular molar, Mi-OLp - Pg-OLp</td>
<td>0.7*</td>
<td>0.95</td>
<td>0.7**</td>
<td>1.12</td>
<td>0.9***</td>
</tr>
<tr>
<td>Mandibular incisor, II-OLp - Pg-OLp</td>
<td>-0.9**</td>
<td>1.56</td>
<td>-0.4</td>
<td>1.51</td>
<td>-1.3***</td>
</tr>
<tr>
<td>Overjet, Is-OLp - II-OLp</td>
<td>-0.8</td>
<td>2.13</td>
<td>-1.5**</td>
<td>2.71</td>
<td>-0.7</td>
</tr>
<tr>
<td>Molar relation, Ms-OLp - Mi-OLp</td>
<td>-0.6</td>
<td>1.09</td>
<td>-0.9**</td>
<td>1.20</td>
<td>-1.3***</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sagittal variables (*)</th>
<th>Group A n = 26</th>
<th>Group B n = 29</th>
<th>Group C n = 30</th>
<th>Group D n = 29</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary first molar inclination (Ms/NL)</td>
<td>0.7</td>
<td>1.69</td>
<td>0.5</td>
<td>1.65</td>
<td>1.0</td>
</tr>
<tr>
<td>Maxillary incisor inclination (Is/NL)</td>
<td>-2.9</td>
<td>5.33</td>
<td>-2.3</td>
<td>6.71</td>
<td>-4.6***</td>
</tr>
<tr>
<td>Mandibular incisor inclination (II/ML)</td>
<td>-1.4</td>
<td>3.94</td>
<td>-1.3</td>
<td>3.07</td>
<td>-2.3**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sagittal jaw relationship (*)</th>
<th>Group A n = 26</th>
<th>Group B n = 29</th>
<th>Group C n = 30</th>
<th>Group D n = 29</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNA</td>
<td>0.0</td>
<td>0.50</td>
<td>0.1</td>
<td>0.72</td>
<td>-0.4*</td>
</tr>
<tr>
<td>SNB</td>
<td>0.3</td>
<td>0.42</td>
<td>0.1</td>
<td>0.74</td>
<td>-0.4</td>
</tr>
<tr>
<td>ANB</td>
<td>-0.3</td>
<td>0.53</td>
<td>0.0</td>
<td>0.73</td>
<td>-0.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vertical jaw relationship (*)</th>
<th>Group A n = 26</th>
<th>Group B n = 29</th>
<th>Group C n = 30</th>
<th>Group D n = 29</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>NL/NSL</td>
<td>0.1</td>
<td>1.38</td>
<td>-0.3</td>
<td>1.05</td>
<td>0.3</td>
</tr>
<tr>
<td>ML/NSL</td>
<td>-0.3</td>
<td>0.92</td>
<td>-0.2</td>
<td>1.34</td>
<td>0.0</td>
</tr>
<tr>
<td>NL/ML</td>
<td>-0.4</td>
<td>1.37</td>
<td>0.1</td>
<td>1.44</td>
<td>-0.3</td>
</tr>
</tbody>
</table>

NS indicates not significant, * P<0.05, ** P<0.01, ***P<0.001
The space closure phase (T1-T2)

Dental changes

Maxillary molars in the two osseointegrated anchorage groups (A and B) were stable within the maxilla during space closure (Table IV). In the headgear group (C) the molars on average moved forward 1.6 mm (P<0.001) and in the transpalatal bar group the anchorage loss continued with another 1.0 mm (P<0.001). The anchorage loss in group C and D were thus significantly larger compared to group A and B (Table IV). Mesial tipping of the molars during space closure was small and not statistically significant within or between the four groups.

The maxillary incisors were retracted within the maxilla 1.8-2.8 mm (P<0.001) and the overjet was reduced 2.0-3.1 mm (P<0.001) with no significant difference between the four groups (Table IV).

Skeletal changes

The sagittal forward growth was 0.5-0.8 mm for the maxilla and 0.7-0.9 mm for the mandible. These changes were significant for all groups but with no differences between the four groups. Small and non significant vertical jaw changes were found (Table IV).

Table IV. The space closure phase (T1-T2). Changes in cephalometric variables within and between the four anchorage groups (Onplant, group A; Orthosystem implant, group B; Headgear, group C; Transpalatal bar, group D).

<table>
<thead>
<tr>
<th>Skeletal sagittal variables (mm)</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Group D</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary base, A-OLp</td>
<td>0.8***</td>
<td>0.7***</td>
<td>0.85</td>
<td>0.71</td>
<td>0.7*** 0.62</td>
</tr>
<tr>
<td>Mandibular base, Pg-OLp</td>
<td>0.8**</td>
<td>0.9***</td>
<td>0.85</td>
<td>0.7**</td>
<td>0.86    0.9*** 1.27</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dental sagittal variables within the maxilla and mandible</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Group D</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary molar, Ms-OLp - A-OLp</td>
<td>0.0</td>
<td>0.1</td>
<td>0.74</td>
<td>1.6***</td>
<td>1.59    1.0*** 0.96</td>
</tr>
<tr>
<td>Maxillary incisor, Is-OLp - A-OLp</td>
<td>-2.2***</td>
<td>2.25</td>
<td>-2.8***</td>
<td>2.36</td>
<td>2.32    -1.8*** 1.64</td>
</tr>
<tr>
<td>Mandibular molar, Mi-OLp - Pg-OLp</td>
<td>0.9***</td>
<td>1.14</td>
<td>0.6*</td>
<td>0.97</td>
<td>0.99    0.9** 1.25</td>
</tr>
<tr>
<td>Mandibular incisor, II-OLp - Pg-OLp</td>
<td>0.5</td>
<td>2.31</td>
<td>0.1</td>
<td>2.10</td>
<td>0.3     2.31   0.2</td>
</tr>
<tr>
<td>Overjet, Is-OLp - II-OLp</td>
<td>-2.8***</td>
<td>1.68</td>
<td>-2.9***</td>
<td>2.89</td>
<td>-3.1*** 2.40   -2.0*** 1.81</td>
</tr>
<tr>
<td>Molar relation, Ms-OLp - Mi-OLp</td>
<td>-0.9**</td>
<td>1.17</td>
<td>-0.5</td>
<td>1.33</td>
<td>0.7*    1.33   0.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sagittal variables (*)</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Group D</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary first molar inclination (Ms/NL)</td>
<td>-0.2</td>
<td>1.36</td>
<td>0.7</td>
<td>1.55</td>
<td>0.8     2.38    0.7</td>
</tr>
<tr>
<td>Maxillary incisor inclination (IIs/NL)</td>
<td>-1.7</td>
<td>4.57</td>
<td>-3.0**</td>
<td>4.62</td>
<td>-1.9    4.91    -1.1</td>
</tr>
<tr>
<td>Mandibular incisor inclination (ILI/ML)</td>
<td>-1.7</td>
<td>4.62</td>
<td>1.9</td>
<td>4.60</td>
<td>-1.6    4.85    -1.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sagittal jaw relationship (*)</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Group D</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNA</td>
<td>-0.1</td>
<td>0.47</td>
<td>-0.4</td>
<td>0.82</td>
<td>-0.3   1.04    -0.4</td>
</tr>
<tr>
<td>SNB</td>
<td>0.0</td>
<td>0.58</td>
<td>-0.1</td>
<td>0.79</td>
<td>0.0    1.11    0.0</td>
</tr>
<tr>
<td>ANB</td>
<td>0.0</td>
<td>0.52</td>
<td>-0.3*</td>
<td>0.56</td>
<td>-0.3   0.90    -0.4*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vertical jaw relationship (*)</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Group D</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>NL/NSL</td>
<td>0.3</td>
<td>1.38</td>
<td>0.3</td>
<td>0.98</td>
<td>0.2    1.25    -0.1</td>
</tr>
<tr>
<td>ML/NSL</td>
<td>0.0</td>
<td>1.14</td>
<td>0.2</td>
<td>1.27</td>
<td>0.1    1.44    0.5</td>
</tr>
<tr>
<td>NL/ML</td>
<td>-0.2</td>
<td>1.50</td>
<td>-0.1</td>
<td>1.29</td>
<td>-0.1  1.41    0.6</td>
</tr>
</tbody>
</table>

NS indicates not significant, * P<0.05, ** P<0.01, ***P<0.001
Total observation period (T0-T2)
The maxillary molars were stable in the Onplant and Orthosystem groups, whereas they moved mesially in the headgear and transpalatal groups, mean 1.2 and 2.0 mm, respectively (Figure 3). The ratio anchorage loss and incisor retraction was for the Onplant group 0.05, the Orthosystem group 0.02, the headgear group 0.15 and the transpalatal bar group 0.54.

In this trial 118 patients started the orthodontic treatment. Considering the ITT concept, estimations of the anchorage capacity as successful or not successful were made at the end of the observation period. The Onplant and Orthosystem implant had significantly higher success rate of anchorage than the headgear and transpalatal bar and with no difference between the two osseointegrated groups (Table I).

Treatment time
The average treatment time for the leveling/aligning phase varied between 8.0 and 8.7 months and for the space closure phase between 8.6 and 9.7 months. No significant differences between the four groups were found.

Figure 3 a-d. Maxillary dental and skeletal changes (in mm) and standard deviations (SD) contributing to alterations in the four groups during the total observation period (T0-T2), i.e. during the leveling/aligning and space closure phase. *** = P < 0.001.

DISCUSSION
The most important finding in this study was that the two osseointegrated anchorage systems, Onplant and Orthosystem implant, provided stable anchorage during orthodontic treatment after maxillary premolar extractions and had significantly higher anchorage capacity compared to the two conventional anchorage systems, headgear and transpalatal bar. Thus, our opening hypothesis was confirmed.

In the last decade there has been an increase of interest for different implant systems. This study is however the only one that has used RCT methodology for comparison of two different osseointegrated palatal anchorage systems during orthodontic treatment after upper premolar extractions and it was therefore not possible to make comparisons with previous studies. Nevertheless, Wehrbein found, in a small case series, an anchorage loss between 0.7 and 1.1 mm with the Orthosystem implant during space-closure after premolar extractions. Conceivably, the cause of anchorage loss was deformation of the bar, which was significantly weaker compared to the bar used in this study.

Indications for using Onplant and Orthosystem implants as anchorage are mainly the same and...
it would therefore be of interest to compare this concept with non-osseointegrated mini-implant systems. It can be pointed out, that few mini-implant systems were commercially available when this trial was commenced. However, a study where mini-implants are compared to Orthosystem implants will soon be started.

It has been suggested that the palatal midsagittal area has relatively low vertical bone high, and complete ossification of the suture is rare before 23 years of age\textsuperscript{27} which would theoretically benefit the Onplant compared to the Orthoimplant when treating adolescents. In this study there was no difference in osseointegration success-rate between the two systems. One of 30 Orthoimplants and one of 29 Onplants failed to osseointegrate during the healing period and were therefore removed before the orthodontic treatment. Furthermore, due to narrow high palates another two Onplants became tilted during osseointegration and thereby technically not possible to use in a bar system and thus removed before treatment. The Onplant system therefore appeared to be more sensitive for anatomic restrictions. These failures must be considered when effectiveness and costs of different anchorage system is discussed. In addition, the Orthosystem implant was superior to the Onplant due to fewer surgical interventions (no abutment placement) and recent results from a RCT have revealed less pain and discomfort related to an Orthosystem implant placement compared to the installation of an Onplant.\textsuperscript{28}

However, once osseointegrated, the Onplants and Orthosystem implants remained stable during treatment, and therefore, as described earlier proved to well withstand orthodontic forces.\textsuperscript{11,13}

One of the most traditionally used systems for additional anchorage is the headgear and since many studies have demonstrated the distalizing capacity\textsuperscript{29,30} it should of course also be adequate as anchorage. The most pronounced disadvantage with the headgear is the unpredictable patient cooperation. The results revealed that the patients cooperated well during the leveling/aligning phase, since the molars were stable. During the space closure phase the molars moved forward and considering the total observation period, an anchorage loss of 1.2 mm was demonstrated. However, the range was larger in this group which means that there were patients who cooperated well during the total observation period and there were patients who did not cooperate at all.

A less pronounced forward growth of the maxilla could have been expected in the headgear group but this was not evident. Instead, a similar amount of forward growth of the maxilla was found in all four groups and this was a consequence of normal growth. In this study the headgear was designed with a short outer bow and medium pull. The intention was to hold the maxillary first molars in position and if a distalizing movement occurred, the molars would move mainly bodily resulting in minimal bite-opening.

The transpalatal bar which theoretically produces anchorage by blocking the upper first molars with a stable bar in concordance with pressure from the tongue demonstrated a surprisingly large anchorage loss along with a mesial molar tipping. Similar results have been presented in other studies\textsuperscript{31,32} with transpalatal bars when canines were retracted after premolar extractions. However, the appliance design and measurement methods were different from this study and the results were therefore not comparable.

From a clinical view, the intention to treat approach is of great importance. It is vital to recognize that 1 of 30 Orthosystem implant patients and 3 of 29 Onplant patients never started the tooth movements due to technical problems or that osseointegration was not achieved. An alternative treatment approach for these patients was therefore required implying additional costs and prolonged treatment time. Another 2 patients, one in the Onplant and one in Orthosystem implant group were judged as failures due to insufficient anchorage (anchorage loss more than 1 mm). Finally, one patient discontinued treatment. Thus, 7 of 59 patients with osseointegrated anchorage provided unsuccessful anchorage, but this was still significant fewer compared to the conventional systems where unsuccessful anchorage was produced in 16 of 30 headgear and 21 of 29 transpalatal bar patients (Table I). The definition of insufficient anchorage, i.e. anchorage loss of more than 1.0 mm can of course be discussed. However, if maximum anchorage is needed the anchorage system must be reliable, and then, in our opinion an anchorage loss of maximum 1.0 mm is what can be clinically accepted.

The patients in this study had different degrees of crowding and overjet, different treatment objectives concerning molar relation and different degree of need for additional anchorage (medium to maximum). They represented a typical panorama of patients with the common treatment strategy of maxillary premolar extractions followed by orthodontic treatment and the results can therefore in this matter be generalized. Due to randomization into four different groups patient characteristics were equally distributed (Table II). Through a precise and detailed study-protocol all patients were treated as equally as possible during
the leveling/aligning and space-closure phase with one exception, the anchorage systems were different. The results after space closure phase revealed that overjet was sufficiently reduced in all four groups. Molar relation however, was only corrected accordingly to the treatment objectives in the two osseointegrated groups. This means that after completion of the space closure phase each patient was treated individually to reach its specific treatment goal. Thus, for the osseointegrated groups, the bars were removed and the molars were in some patients allowed to move forward to achieve a correct sagittal occlusion. On the other hand, in the headgear and transpalatal bar group where there has been anchorage loss, Class II elastics were inserted to make it possible to obtain a normal occlusion. These facts were the reasons why the observation period in this study was ended after the space closure phase. A follow-up study after completion of the orthodontic treatment, including a cost-effectiveness analysis, will however be presented later.

In a scientific study it is important that the study sample is not biased and that the characteristics of the withdrawal subjects are known. Moreover, since the patients were randomized, selection bias was avoided and the drop-out rate after treatment start was low and these individuals did not differ from the study subjects. It can be mentioned that 48 patients who met the inclusion criteria declined to participate in the study. The most common reason for declining participation in the study was fear for the additional surgical procedure with the Onplant and Orthosystem anchorage. But since the majority of the patients in this study had excellent oral health with no or little experience of ordinary dental care this was not an unexpected phenomenon. The other main reason for declining participation was anticipation against wearing a headgear. Nevertheless, both aspects for declining participation are important to remember during orthodontic treatment planning.

CONCLUSIONS

- Stable anchorage was provided with the Onplant and Orthosystem implant throughout the observation period.
- The headgear anchorage was stable during the leveling/aligning phase but demonstrated anchorage loss at the end of the observation period.
- The transpalatal bar provided insufficient anchorage throughout the observation period.
- If maximum anchorage is required the Orthosystem implant is the anchorage system of choice

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