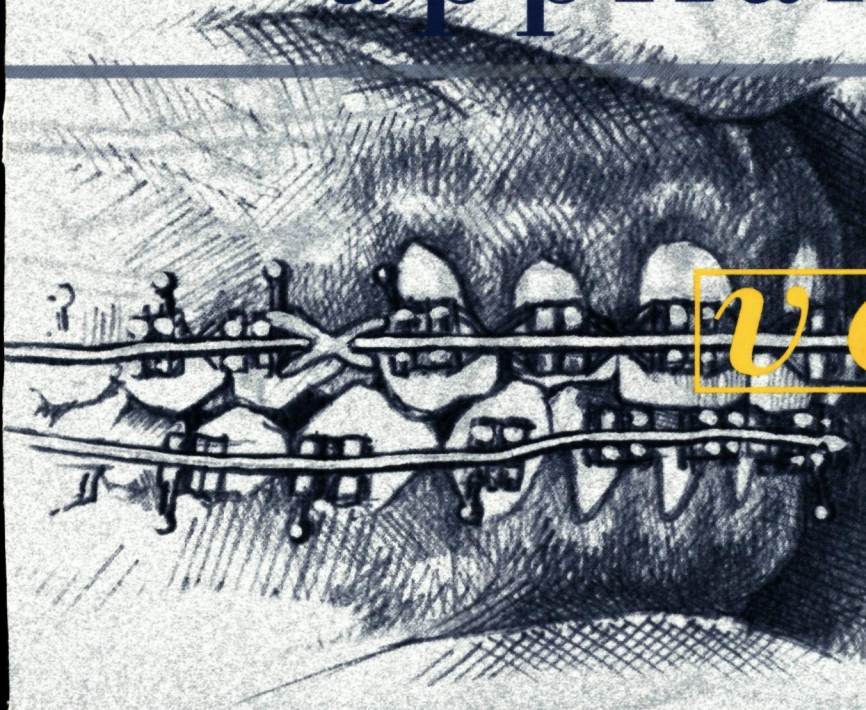
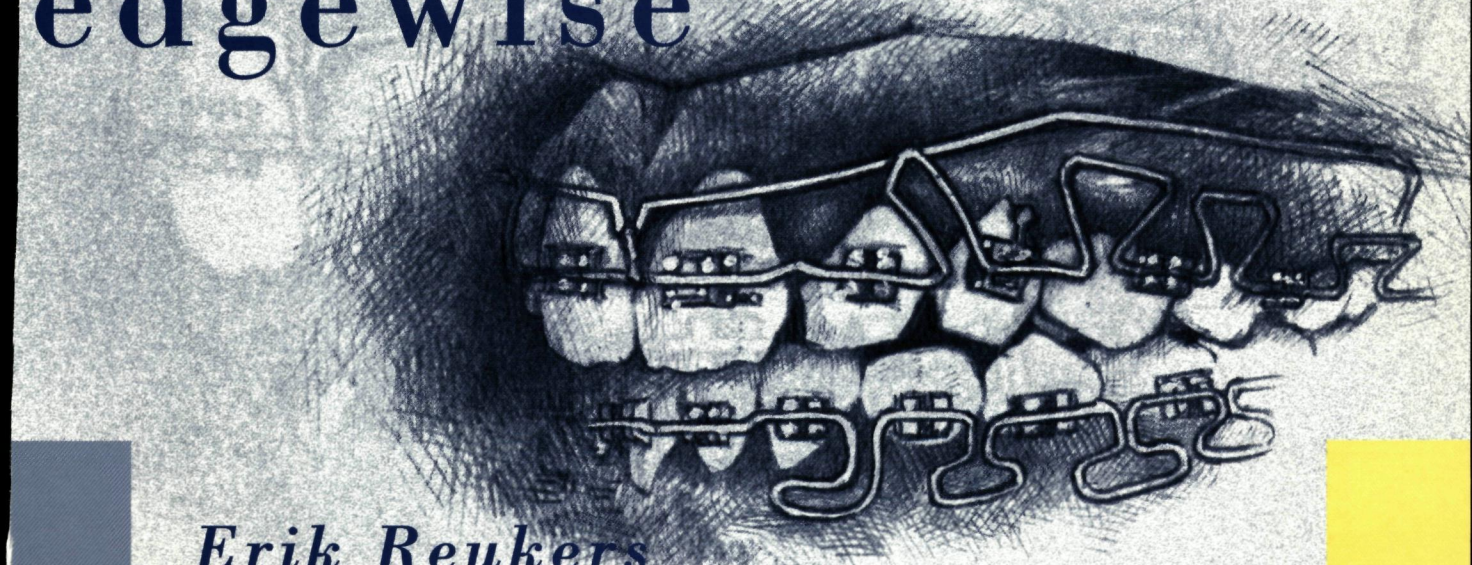
straight wire appliance



versus

conventional full edgewise



Erik Reukers

STRAIGHT WIRE APPLIANCE

VERSUS

CONVENTIONAL FULL EDGEWISE

A PROSPECTIVE CLINICAL TRIAL

Cover:
Willem te Molder
Groenlo

ISBN 90-9010942-0

Printed by Universiteitsdrukkerij Nijmegen

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A PROSPECTIVE CLINICAL TRIAL

Een wetenschappelijke proeve op het gebied van de Medische Wetenschappen

Proefschrift ter verkrijging van de graad van doctor aan de Katholieke Universiteit Nijmegen volgens besluit van het College van Decanen in het openbaar te verdedigen op donderdag 4 december 1997 des namiddags om 3.30 uur precies

door

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geboren op 31 augustus 1961 te Groenlo

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The study presented in this thesis was conducted in the Department of Orthodontics and Oral Biology (head: Prof. Dr A.M. Kuijpers-Jagtman), College of Dental Science, Medical Faculty, University of Nijmegen, the Netherlands.
The College of Dental Science participates in the Netherlands Institute for Dental Sciences (acknowledged in 1996 by the Royal Dutch Academy of Science KNAW).
This study was carried out in collaboration with the Department of Biostatistics and Epidemiology, Medical Faculty, University of Nijmegen.

Voor Carla, Floor en Gijs

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Dit onderzoek werd mede mogelijk gemaakt door:

"A"- Company

Contents

CHAPTER 1

General introduction

1.1 History of fixed appliances

Since antiquity, attempts have been made to correct the malalignment of teeth. Primitive orthodontic appliances have been found in both Greek and Etruscan materials (Corrucini and Pacciani, 1989). In the mid-eighteenth century several early types of orthodontic appliances were described. Fauchard (1746) described short flexible strips of gold or silver (bandelettes) which were tied to the teeth with waxed threads. The individually tailored platinum band was introduced in 1871, and the development of oxyphosphate cement at this time allowed such bands to be cemented Elastic traction in order to move the teeth within the arch was extensively used from 1850 but was often rejected because of the unfavorable movements of anchor teeth (Dixon 1972).

Until the early twentieth century the primary goal of orthodontic treatment was to align teeth within the arch. The correction of the interarch relationship hardly got any attention In 1907 Angle published a definition of normal occlusion in the natural dentition. He postulated that the upper molars are the key to occlusion; the upper and lower molars should be related so that the mesiobuccal cusp of the upper molar occludes in the buccal groove of the lower molar. He developed four major appliance systems capable of correcting teeth to an ideal arch form. His first system was of the so-called E-arch type. In this typical orthodontic appliance from the early 1900s, bands were placed only on molar teeth, and a heavy labial arch wire extended around the dental arch. Ligatures from the teeth to the archwire were used to bring malaligned teeth to the line of occlusion. This early appliance was capable only of tipping teeth to a new position. It was not able to precisely bring teeth into alignment. In 1912 new gold alloys allowed Angle to introduce the pin and tube technique for root movements In this technique bands with a vertical tube were placed on each tooth (except the molars). Into this tube a soldered pin from a smaller archwire was placed. Tooth movement was accomplished by repositioning the pins at each appointment. Although this appliance was theoretically capable of very precise toothmovement, it proved impractical in clinical use. Because of the complexity in constructing and adjusting the appliance only very few people were capable to master it (Proffit 1993).

As a result of the difficulties with the contemporary

appliances of that time Angle introduced the ribbon arch appliance (Proffit 1993). He modified the vertical tube of the pin and tube technique to provide a vertically positioned rectangular slot behind the tube. A ribbon arch of gold wire was placed into the slot and held with pins. The appliance was a success because it had good spring qualities and was efficient in aligning teeth. The biggest disadvantage, however, was that the ribbon archwire provided a poor control of root position.

To overcome the disadvantages of the ribbon arch, in 1928 Angle introduced the first edgewise appliance. In this appliance the archwire was inserted at a 90-degree angle to the plane of insertion of the ribbon arch. The rectangular wire was tied into a rectangular slot with wire ligatures, providing control over the teeth in all three dimensions. Tooth movement was accomplished by bending the archwire so that a force could be exerted to every single tooth (Proffit 1993).

Begg (1965) introduced a new technique for orthodontic treatment in which he retained the original ribbon arch bracket, but turned it upside down so that the bracket slot pointed gingivally rather than occlusally. The appliance allows good control of crown and root position in all three planes of space. In the final stage of treatment however it can be very difficult to precisely position the teeth. To accomplish specific movements, such as rotation, uprighting and torque, specially designed auxiliaries are used. These auxiliaries are usually attached to the bracket of a malposed tooth and its other end is hooked on a more or less straight archwire. Recently combinations of Begg and edgewise appliances have been proposed (Thompson 1988, Kesling 1989).

Positioning of teeth properly is not only influenced by the type of appliance that is used, but also by the way the brackets are positioned at the buccal surface of the teeth. In the early days, clamp bands were used which were tightened around molar teeth by screw attachments. With the advent of custom-fitted pinched bands, it was practical to place fixed attachments on more than a few teeth. Preformed steel bands came into use during the 1960s. Because these bands were anatomically correctly shaped, the brackets could be positioned more precisely to the buccal surface of the tooth.

Since the introduction of the acid-etching technique by Buonocore (1955), which enhanced the adhesion of resins to enamel,

rapid developments led to the concept of directly bonded brackets to the enamel surface. Newman (1992) reported the use of this technique in orthodontics since the late 1950s. It allowed for very precise positioning of the brackets to the buccal surface of the tooth. Bonded attachments also have no interproximal component and therefore require no separation of teeth and are less painful. They are easier than bands both to put on and remove, and they are more aesthetic because the highly visible metallic band material is eliminated. Furthermore they are less irritating to the gingiva. Another advantage of bonded attachments is that at the end of active treatment no band spaces are left. Although there are exceptions, the rule in contemporary orthodontics is that bonded brackets are almost always preferred for anterior teeth; bonds or bands may be used on premolars depending on the height of the clinical crown. Bands usually are preferred for molars.

Since mid-century, almost all orthodontic practice has relied on stainless steel or on a cobalt-chromium alloy wires with similar properties. Before that, precious metal alloys (gold) were used routinely for orthodontic purposes, primarily because nothing else would tolerate intraoral conditions (Dixon 1972). In recent years, nickel-titanium alloy wires (NiTi) were introduced into orthodontics. NiTi alloys have the unique properties of shape memory and superelasticity. Several nickel-titanium alloys with different grain structures were developed (martensitic: M-NiTi, austenitic: A-NiTi) which had their own specific advantages. The possibility of A-NiTi to produce a constant force over a long range of activation made it a particularly attractive alternative to steel wires in the initial phases of treatment when the teeth are severely malaligned (Profit 1993). In the early 1980s beta-titanium (TMA: titanium-molybdenum alloy, Ormco/Sybron) was introduced, which was primarily developed for orthodontic use (Burstone and Goldberg 1980). It offers a highly desirable combination of strength and springiness as well as reasonable good formability. It should be a good choice for auxiliary springs and for intermediate and finishing rectangular archwires (Profitt 1993).

1.2 Edgewise appliances

Orthodontic treatment usually involves three phases. First (if necessary) the sagittal relation between the upper and lower dental

arch is corrected. Consequently, the teeth in each arch are leveled and aligned and the extraction sites, if present, are closed. The third phase involves fine-tuning of the position of the teeth to optimal occlusal standards. Removable appliances and fixed appliances without rectangular slots can deal successfully with treatment requiring tipping but are not efficient for tooth translation or fine-tuning tooth position, without the use of auxiliaries. Fixed appliances with edgewise slots are most effective for those procedures because the slot permits three-dimensional control.

According to the definition of Andrews (1989) edgewise appliances can be divided into three categories: nonprogrammed, partly programmed and fully programmed appliances.

1.2.1 Nonprogrammed appliances

The Angle-designed edgewise brackets are nonprogrammed. These brackets are designed according to the same characteristics for all tooth types (figure 1.1). The base of the non-programmed bracket is perpendicular to the facio-lingual axis of its stem. Occlusogingivally and mesiodistally this base is not contoured equivalent to the curved surface of a toothcrown. The slot of the bracket runs parallel with the occlusal/incisal and cervical margin of the bracketbase and is in facio-lingual direction oriented perpendicular to its stem. The base-point-to-slot-point distance is the same for all non-programmed brackets.

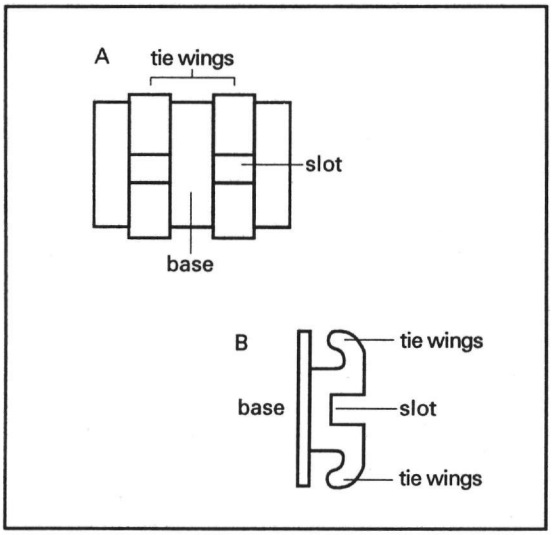


Figure 1.1
Non programmed bracket design
A. frontal view
B. lateral view

The optimal position for each individual tooth must be achieved by forming and bending the archwire. This must be done in all three planes of space. Buccolingual bends in the archwire, necessary to compensate for variations in the contour of the labial surfaces of individual teeth, are called first-order or in-out bends.

Proper mesiodistal rootpositioning requires angled bends in the archwire that are called second-order or tip bends. Proper vertical positioning can either be achieved by placing the brackets at a standard distance from the occlusal/incisal edge of the teeth or by placing bends in the archwire that are also called second-order bends. To avoid inadvertent torquing movements of properly positioned teeth or to apply torquing movements to improperly positioned teeth it is necessary to place a twist in the segments of each rectangular archwire referred to as third-order or torque bends.

1.2.2 Partly programmed appliances

A partly programmed appliance (PPA) is defined as a set of brackets designed with some built in features, but that always requires some wire bending though less than required by nonprogrammed appliances (Andrews 1989).

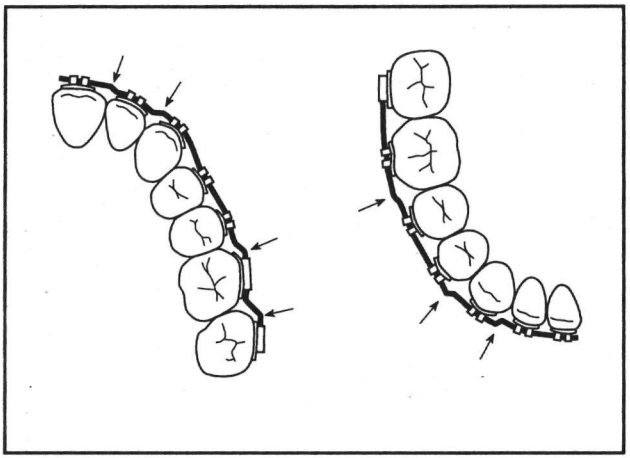
To reduce the number of archwire bends, Angle suggested in 1927 angulating the bracket on the band. Holdaway (1952) suggested bracket overangulation for teeth on either side of an extraction site. Both suggestions were made to reduce the second-order wire bends. Jarabak and Fizzel (1963) incorporated slot inclination to reduce the need for third-order archwire bends. He also recommended bracket angulation. In 1958 Stifter patented an edgewise bracket with built-in guidance into all three planes of space. His system, however, needed many separate parts and was difficult to handle which made it not very satisfactory (Andrews 1989).

By the early 1960s, there were individualized bands for each tooth type, but not adequate individualized brackets. Edgewise brackets with inclined slots were available in 5° increments from 5° to 25°. But except for the amount of inclination and, perhaps, mesiodistal size, these brackets were alike and could be used for any tooth type (Andrews 1989).

1.2.3 Fully programmed appliances

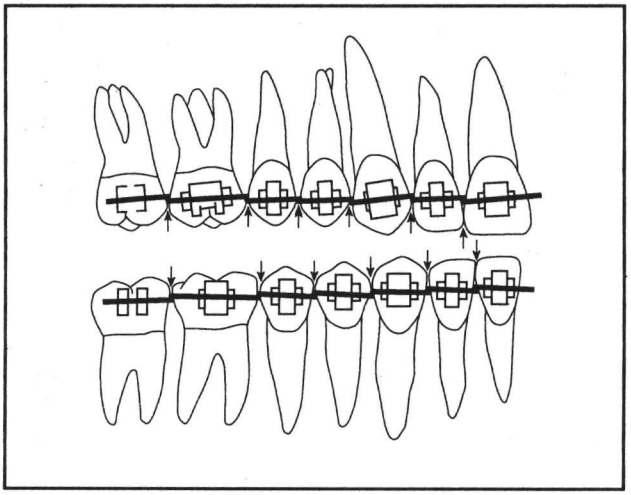
A fully programmed appliance (FPA) is defined as a set of brackets designed to guide teeth to their goal positions with unbent archwires (Andrews 1989). The FPA places the primary control of tooth position within the attachment rather than in the archwire. First-order bends (figure 1.2) are eliminated because compensation is

Figure 1.2
First order bends (marked by arrows)



built into the base of the bracket itself: a thick bracket base gives a relative inset and a thin bracket base produces a relative offset of the buccal surface of the tooth. Angulation in the bracket slot relative to the long axis of the bracket base removes the necessity for second-order bends (figure 1.3) to provide a proper angulation of the roots. Finally, the bracket slots in the FPA are inclined to compensate for the inclination of the facial surface of the tooth so that third-order bends should not be necessary.

Figure 1.3
Second order bends (marked by arrows)



The Straight-Wire Appliance (SWA) was the first fully programmed appliance. It was designed to treat only non-extraction cases with an ANB differential of less than 5° without the necessity of putting offset bends into the wire. Since then, several additional fully programmed appliances or "prescriptions" have been developed by Alexander, Gerety, Hilgers, Ricketts and Roth (Tenti 1986).

Since closing diastema after extraction of premolars produces undesired side-effects (rotation and tipping), Andrews later introduced different series and sets of brackets for different

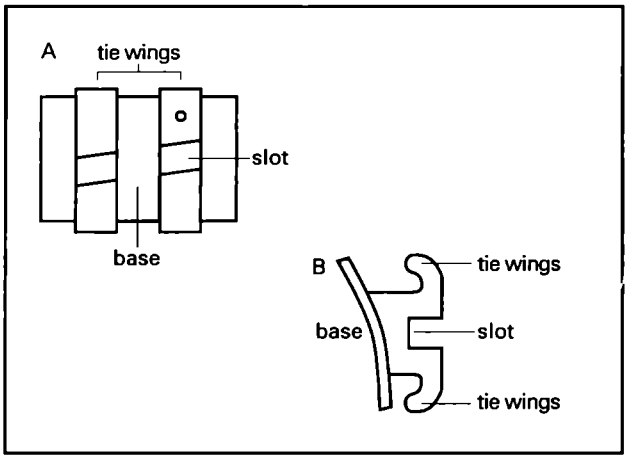


Figure 1.4
Fully programmed bracket design
A. frontal view
B. lateral view

combinations of extractions, ANB differentials and anchorage requirements. He developed a special classification of malocclusions and prescribed various bracket series (translation brackets) for treatment of each, to allow translation of teeth without the need for bending offsets and also to allow for overcorrection in view of relapse tendencies. Translation brackets were defined as fully programmed brackets for teeth that require translation after extraction for orthodontic treatment (Andrews 1989). They have all the features of standard FPA brackets plus a power arm and two additional slot-siting features: counter-mesiodistal tip and counterrotation. Maxillary molar brackets include a third feature, counter buccolingual tip. These features, along with the archwire and mesial or distal force, should provide countermoments for translation and the guidance needed for overcorrection in all three planes of space.

1.3 Review of literature on the Straight Wire Appliance

In 1972 Andrews reported on 120 casts of nontreated subjects with dentitions he considered to have optimal alignment and occlusion. His purpose was to seek data that uniquely characterized these dentitions and to establish basic standards against which deviations could be recognized and measured. Andrews referred to these standards as the Six Keys to Normal Occlusion (Andrews 1972). In later publications they are called the Six Keys to Optimal Occlusion (Andrews 1989). The six keys are: correct angulation, correct inclination, no diastemas (good contacts), no rotations, Class I interarch relationship and no or little curve of Spee.

The communality of objectives for 90% of the individuals

meant to Andrews that it should be possible to develop an efficient appliance, economical in both time and energy requirements, for achieving the Six Keys. The result was the Straight-Wire Appliance (SWA) ("A" Company, 11436 Sorrento Valley Road, San Diego, Ca 92138, USA) which was introduced to the profession in 1970.

In 1976 Andrews published a series of 3 articles in which he presented the concept, the appliance and the techniques of straight-wire treatment. He concluded that the SWA could reduce the total error potential in orthodontic treatment. Nevertheless, he admitted that the SWA is not perfect and that no appliance can ever terminate the need for the wisdom, experience and perspective of the orthodontist (Andrews 1976 a,b,c).

In that same year Roth (1976) published a "five year clinical evaluation of the Andrews SWA". He recognized, "after exclusively using the SWA for a period of almost four years" no less than 12 orthodontic advantages of the appliance: ease of wire construction; no need for inter-bracket span; ease of wire placement; less round-tripping; better control of tooth positions; better and more consistent results with shorter treatment time; patient comfort; complete space closure can be accomplished with one set of archwires; ease of ligation and less gingiva impingement because of the stepped out tie-wings; easy bracket identification; easier and more accurate bracket placement and advantage in surgical cases, especially in those cases where the jaw relationship discrepancy is such that occlusal forces are working against the ultimately desired tooth positions prior to surgical correction of the jaws. He concluded that in his hands the SWA created better and more consistent results with shorter treatment time for the patient and less chairtime for the orthodontist. He could find "no clinical disadvantages to the use of SWA". In this article Roth did not mention, however, the number of cases he treated and the use of a group of controls.

Mayerson (1977) came to comparable conclusions. He stated that it was his contention that with the use of the SWA the orthodontic corrections achieved are as good or better than those achieved by the same individual using his previous appliance, that these results can be achieved in the same time or less for the patient and in the same chairtime or less for the doctor.

In 1987 Roth published a follow-up article in which he discussed 17 years of experience with the SWA. To overcome certain

problems that he met in working with the standard SWA, namely the large number of different series and sets of brackets for different combinations of extractions, ANB differentials, and anchorage requirements, he developed the Roth prescription that was introduced in 1976. He felt that it should be possible to use primarily one prescription for most cases and to finish to an "end of appliance therapy" goal in which all tooth positions are slightly overcorrected and from which the teeth will most likely settle into non-orthodontic normal positions. Using his prescription, Roth claims to save three to six months treatment time and to gain 20% chair time reduction in cases with extraction therapy.

Bennett and Mc Laughlin produced a series of articles (Bennett and Mc Laughlin 1990 a,b, Mc Laughlin and Bennett 1989, 1991 a,b) in which they discussed the transition from standard edgewise to preadjusted appliance systems. They discussed how preadjusted (FPA) appliances can be used best in the sequential phases of most orthodontic treatment: anchorage control, leveling and aligning, overbite control, overjet reduction, space closure, and finishing. They reached the conclusion that, although very little bending is needed during the first five stages of treatment, finishing requires some wire bending in almost every case.

In 1997 the "A"-company reported about a retrospective straight-wire appliance efficiency study. Six orthodontists each evaluated 10 patients treated with the SWA and 10 treated with standard edgewise brackets. They claimed a reduction in treatment, appointment, and chair time, and an increase in office efficiency ("A"-company 1997).

Initially the advantages of the SWA were described, but later on comments were made on potential shortcomings of the system. Several authors described reasons why current fully programmed appliances would not achieve ideal tooth positions. The most frequent reason is inaccurate bracket placement (Balut et al 1992). Since the facial surface of the tooth is curved both mesiodistally and occlusogingivally, misplaced brackets in the mesiodistal plane result in rotational irregularities, whereas those in the occlusogingival plane result in inadequate torque, as well as height errors (Germane et al 1990). Brackets not aligned with the long axis of the tooth result in tip variations.

Another reason for failure is the variation in tooth structure.

Irregular facial surfaces, abnormal crown-root angulations, and unusual crown shapes require archwire variations in tip, torque, rotation and height to achieve optimum results (Dellinger 1978; Vardimon and Lambertz 1986; Germane et al 1989; Morrow 1978; Taylor 1969). Andrews (1990) has stressed, however, that the inclination of the buccal surface of the patient's teeth may vary from the average, but when that occurs, it will do so in an orderly manner throughout the arch.

Variations in the vertical and anteroposterior jaw relationships require variations in the positions of maxillary and mandibular incisors. In Class III skeletal frameworks maxillary incisors are more procumbent and mandibular more upright than in Class I skeletal frameworks; in Class II mandibular incisors are more procumbent and maxillary incisors are more upright (Root 1986). Ross et al (1990) stated that it is clear that the concept of "one appliance fits all" defies the normal biologic variation among orthodontic patients.

Tissue rebound or relapse tendencies could also cause difficulties to achieve optimum results. Overcorrection of rotations (Zachrisson 1986) and/or height, tip and torque (Roth 1985, Swain 1986) should enable the teeth to rebound to the desired situation. It is obvious, however, that it is impossible to predict the exact amount of relapse, so the amount of overcorrection which is needed can not be determined.

Finally, edgewise orthodontic appliances have mechanical deficiencies that might lead to non-optimum results. The application of a force to a tooth by an archwire away from the center of resistance of the tooth produces additional forces on the tooth (Nagerl et al 1991). This can especially be observed when an extraction diastema is closed reciprocally. Andrews (1989) anticipated on this and designed a series of antitip/antirotational brackets specifically for these problems. Another deficiency is the play between the archwire and the archwire slot. Play is required if archwires are to be inserted and removed. Unfortunately, it could cause inaccurate torque, incomplete vertical bracket-to-bracket leveling and inadequate tipping if the archwire is not bent (Creekmore and Kunik 1993). Finally, a straight wire will never become quite straight. Force diminution (= the reduction in the force produced by an archwire, deflected within its elastic limits, as it

returns to its original shape) occurs in all directions of tooth movement. Force diminution adds on to play. It is not yet clear how to control force diminution other than by bending archwires (Creekmore and Kunik 1993).

1.4 Discussion

The Straight-Wire Appliance (SWA) has had an important impact on appliance design and selection (Proffit 1993). On theoretical grounds, Andrews developed different series and sets of brackets (prescriptions) to meet with all different requirements. He made a description of these sets in his book "Straight Wire - The Concept and Appliance" (1989) but no article was published by Andrews in which treatment results have been described and scientifically evaluated. Roth (1976) recognized no less than 12 advantages after using the Andrews appliance for almost five years. It is unclear however how he reached these conclusions as no comparison was made between his treatments and a group of controls.

Because of the complexity of the original Andrews prescription, attempts were made to make a more universal prescription (Tenti 1986; Roth 1987). Roth (1987) claimed that he could save three to six months treatment time by using his prescription and that he could gain 20% chair time reduction in cases with extraction therapy. Mayerson (1977) already claimed the same advantages with the use of the Andrews prescription. Both publications, however, are of an anecdotal nature because they are not based on a sound scientific research design for comparison of two different treatments.

Based on one publication of Andrews (1972) and one publication of Roth (1976), which are discussed above, it is commercially claimed that "the Straight Wire appliance concept is built on sound scientific foundation" ("A"-company 1994). The orthodontic product catalog reports "excellent results and shorter treatment time....., positions and relationships that will compose a good, functional occlusion....., complex mechanics are no longer necessary....., minimized or eliminated wire bending and a tremendous savings in chair time". As a result of this, the efficiency of the Straight Wire treatment would increase. In 1997 the "A"-company specifies these claims with actual data from a

retrospective study in a newsletter ("A"-company 1997).

A review of the scientific literature revealed, however, that only few studies have been completed that critically evaluate the use and results of SWA. Only one article was found that made a comparison between treatment with a fully programmed appliance and a standard edgewise appliance (Kattner and Schneider, 1993). In this retrospective study a comparison was made of SWA and standard edgewise appliance treatment results on a sample of 120 orthodontically treated cases, completed by two practitioners who both used the SWA and a standard edgewise appliance. They concluded that despite using the SWA, experienced clinicians still found it difficult to achieve all of the Six Keys to Normal Occlusion. The SWA only scored significantly higher than the standard edgewise appliance for the angulation and inclination of the maxillary posterior teeth. Most of the other studies discussed the individual variation between patients regarding the anatomy of the teeth, the dental archform and the growth pattern and how this is neglected by using a preformed appliance. It is stressed that there is minor consistency in torque values when a bracket is not bonded on the most ideal position of the buccal surface of a tooth (Vardimon and Lambert 1986; Root 1986; Germane et al 1989; Elema 1994). Creekmore and Kunik (1993) discussed why the goals of individual tooth positions can not always be achieved using straight wires only. They gave five reasons why this would not be possible as mentioned in chapter 1.3.

It can be concluded from the available literature on the topic of Straight Wire that there is a lack of sound scientific data to support the advantages or disadvantages of treatment with the Straight Wire Appliance. This led to the idea to start a multipractice prospective clinical trial in which two different types of edgewise appliances will be compared.

1.5 Research goal

Aim of the study presented here is to evaluate the effects and results of orthodontic treatment with a fully programmed edgewise appliance (FPA) compared with the effects and results of treatment with a partly programmed edgewise appliance (PPA) in a randomized prospective clinical trial design.
More specific the following hypotheses will be investigated:

1. FPA translation brackets can control rotations for teeth requiring translation without auxiliaries better than PPA.
2. Treatment with an FPA requires less chairtime for the orthodontist and/or dental assistant to reach the Six Keys goals than with a PPA.
3. FPA is physically and psychologically more comfortable to the patient than is a PPA.
4. FPA will cause less rootresorption than PPA.
5. The FPA design will lead to less plaque retention and gingival irritation than a PPA.
6. A correctly prescribed and sited FPA will direct teeth to ideal tooth positions with less treatment time than will a PPA.
7. A correctly prescribed and sited FPA will lead to better treatment results than will a PPA.

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CHAPTER 2

Design, materials and methods of the clinical trial

Abstract
To evaluate the effects and treatment results of treatment with a FPA versus a PPA, a randomised multi-practice clinical trial was set up. In this trial 149 patients were orthodontically treated by 11 orthodontists. The experimental variable "type of fixed appliance" was to be investigated. The treatment option was assigned by balanced allocation. Treatment had to be carried out following clinical treatment protocols. Data had to be recorded according to the instructions. The sample description is presented.

2.1 Introduction

Until recently, clinical studies in orthodontics were generally case series studies or observational studies (Tulloch et al 1990, Johnston et al 1991). In these studies the investigator was a passive evaluator of a treatment initiated for the purpose of correcting malocclusion and had no control over how the treatment is provided or to whom. Because neither the treatment provided nor the way patients are assigned to treatment is governed by any written protocol, the treatment groups are likely to differ in some systematic way (either recognised or not) and so bias in the comparison of treatments is most likely.

Clinical trial methodology has been developed to minimise the chance of bias and to provide more objective answers to the questions of comparative efficacy and benefit of particular treatments. A clinical trial is a "method of comparing the relative merits (and shortcomings) of two or more treatments tested in human subjects" (Phillips and Tulloch 1995). The assignment of patients is controlled by a well defined protocol. The protocol also makes explicit the objective of the study, which treatments are to be applied how, when and where, and to what kind of patient. Clinical trials are always prospective studies and can be classified as (1) uncontrolled; (2) nonrandom controlled and; (3) randomised controlled. The randomised clinical trial (RCT) is now generally considered the strongest research design for the comparison of treatments. Subjects are randomly allocated to treatment and control groups. The control group may receive no treatment (observation only or placebo) or the current standard treatment (active control).

Review of the orthodontic literature in Medline for the period of 1983 until 1997 revealed 12 titles when "trial", "orthodontic*" and "randomi*" were given as keywords. Three of these titles did not really report on a randomized orthodontic clinical trial (Robertson 1983, Burden et al 1995, Keeling et al 1996,), whereas Phillips and Tulloch (1995) reviewed issues that should be addressed in planning a randomized clinical trial (RCT). Baumrind et al (1996) looked into the decisions of clinicians on whether to extract or not in a subset of samples derived from an RCT of patients with Class I and Class II malocclusions. Six studies described an RCT in orthodontics (table 2.1). Pontier et al (1990) studied the efficacy for plaque inhibition of a prebrushing rinse for orthodontic patients. Trombeli et al (1995)

evaluated plaque removal by counterrotational electric toothbrushes in orthodontic patients. Jones and Chan (1992) compared the pain and discomfort of two archwires experienced during initial aligning, whereas West et al (1995) studied the clinical effectiveness of similar archwires. Paganelli (1993) evaluated the efficacy for relief from painful symptoms originated by removable and permanent devices and the tolerability of a topical anti-inflammatory drug. Finally, Ghafari et al (1994) evaluated some effects of two different types of appliances during the correction of Class II, Division 1 malocclusions. Changes in arch width during the early treatment with either the Fränkel functional appliance or headgear were compared.

Table 2.1
Randomized clinical trials in orthodontics from 1983 to 1997

author(s)	title	detail
Pontier et al (1990)	Efficacy of a prebrushing rinse for orthodontic patients	finished
Jones M, Chan C (1992)	The pain and discomfort experienced during orthodontic treatment.	finished
Paganelli C (1993)	Pharmacological support during orthodontic therapy with a topical anti-inflamatory.	finished
Ghafari et al (1994)	Changes of arch width in the early treatment of Class II, division 1 malocclusions.	finished
West et al (1995)	Multiflex versus superelastic: a randomized clinical trial of the tooth alignment ability of initial archwires.	finished
Trombeli et al (1995)	Clinical evaluation of plaque removal by counterrotational electric toothbrush in orthodontic patients	finished
Baumrind S (1994)	The decision to extract: preliminary findings from a prospective clinical trial	ongoing
Keeling et al (1994)	Timing of Class II treatment: rationale, methods, and early results of an ongoing randomized clinical trial	ongoing
Tulloch et al (1994)	Early vs late treatment of Class II malocclusion: preliminary results from the UNC clinical trial.	ongoing

The twelfth study that was given by Medline was the same as the first one (Robertson 1983).

In volume 30 of the Craniofacial Growth Series (1994), entitled "Orthodontic treatment: outcome and effectiveness", besides Ghafari et al (1994), three other ongoing clinical trials are being described. Baumrind (1994) is studying the relative efficacy of extraction and non-extraction strategies in the orthodontic treatment of mild to moderately severe Class I and Class II malocclusions in adolescents and adults. Keeling et al (1994) examine issues involved in the timing of treatment for Class II malocclusion. They presented early findings as at the end of year 4 of a five-year study Finally, Tulloch et al (1994) presented preliminary results from the UNC clinical trial on early versus late treatment of Class II malocclusion

In the present study our aim was to compare the effects and results of a "new" treatment (FPA) in a group of patients with a "standard" treatment (PPA) in a control group of comparable patients The basic design was that each eligible patient was randomly assigned to receive either FPA or PPA. This randomisation was stratified for 10 criteria. Each patient that entered the trial was to be followed from the start of treatment to the end of active treatment; this required a longitudinal research design with prolective data collection. The present protocol, as will be described in this chapter, was screened on its ethical acceptability by the Committee Experimental Research on Man (CEOM) of the University of Nijmegen and confirmed by CEOM nr.1989-2440.

In this chapter the design of the trial will be discussed as well as the patient selection, the participating clinicians, the treatment protocols, the data recording, the blindness of the trial and a description of the sample The applied statistical analyses will be discussed in every separate chapter.

2.2 Trial organisation

2.2.1 Design of the trial

The patients, who entered the trial, were referred for treatment to one of the participating orthodontists during the enrolment period of the trial. The intake period lasted from April 1990 until April 1992. After the standard initial records were taken (alginate impressions, cephalogram, panoramic X-ray, extra- and intra-oral slides), a diagnosis and a treatment plan were made by the

orthodontist. After making the treatment plan and before starting treatment the patients were screened on the inclusion and exclusion criteria of this trial (table 2.2). Eligible patients were asked to enter the trial. When the treatment plan was discussed with the patient the participating orthodontist would give verbal and written information to the patient and the parents about the consequences of participating in the trial. In case the patient would decide not to participate in the trial, he/she was treated according to the treatment plan, with a fixed appliance that was normally used by the orthodontist.

Table 2.2
Patient inclusion and exclusion criteria for the trial

INCLUSION CRITERIA	EXCLUSION CRITERIA
* need for orthodontic treatment * Angle Class II malocclusion of 1/2 premolar width or more * healthy person * treatment plan includes fixed appliance	* rootresorption prior to treatment * agenesis (except third molars) * extraction caused by trauma * age > 15 years at start of treatment * extraction therapy other than first or second premolars * abnormalities or use of medication that might have an influence on tooth development, tooth form, gingival and periodontal tissue and saliva secretion

Patients who agreed to entering the trial were asked to sign a letter of consent (Appendix A). After this form was signed and had been returned to the orthodontist the treatment allocation form was filled out (Appendix B) and sent to the central trial registration for allocation of treatment i.e. PPA or FPA.

A computerprogramme was designed to assign every patient to one of the two treatment groups. Treatment allocation was balanced using 10 criteria mentioned in table 2.3 and was performed at the central trial registration. When the treatment modality was assigned, the orthodontist was informed by the secretary of the central trial registration.

Table 2.3
Balancing criteria used for treatment allocation

* Sex
  1 = girl; 2 = boy

* Type of Class II
  1 = Cl. II div. 1; 2 = Cl. II div. 2; 3 = Cl. II div. 1 subdivision;
  4 = Cl. II div. 2 subdivision

* Molar relationship (first permanent molars) Class II
  1 = 1/2 premolar width (pw); 2 = 3/4 pw; 3 = 1 pw or more

* Arch length discrepancy (see chapter 3)
  1 = spacing; 2 = crowding $0 \leq x \leq 3$ mm; 3 = crowding > 3 mm

* Overjet
  1 = $x \leq 5$ mm; 2 = $5 < x \leq 10$ mm; 3 = $x > 10$ mm

* Overbite
  1 = $x \leq 3$ mm; 2 = $x > 3$ mm

* Open bite
  1 = none; 2 = partial in the frontal region; 3 = partial in the molar/premolar region; 4 = total open bite

* Trauma
  1 = no; 2 = yes

* Extraction therapy
  1 = none; 2 = 2 premolars (first or second);
  3 = 3 or 4 premolars (first or second)

* Initial treatment
  1 = none; 2 = functional appliance; 3 = headgear;
  4 = headgear with removable appliance

According to the study protocol several records had to be taken during treatment (table 2.4). The patient follow up lasted until the end of active treatment.

Table 2.4
Data collection

SA=start of active treatment
tx=time in months from the start of the fixed appliance therapy
SR=start of retention
SR1=1st visit after SR

stage	records
SA	impressions, cephalogram (HP), orthopantomogram (OPT), intra-oral slides, extra-oral slides
t00	pocketstatus, gingival-index, plaque-index, periapical X-ray upper central incisors, chairtime
t04	gingival-index, plaque-index, patient-questionnaire, chairtime
t07	gingival-index, plaque-index, chairtime
t10	gingival-index, plaque-index, patient-questionnaire, chairtime
t13	gingival-index, plaque-index, chairtime
t16	gingival-index, plaque-index, chairtime
SR	pocketstatus, HP, OPT, intra-oral slides, extra-oral slides, periapical X-ray upper central incisors, chairtime
SR1	patient-questionnaire

2.2.2 Patients

Between April 1990 and April 1992 149 patients entered the trial: 64 male (43%) and 85 female (57%). The mean age at the start of fixed appliance therapy was 12 years and 4 months (SD 1 yr. 2 months; Range: 10 yrs. 7 months to 15 yrs. 8 months.). The number of the patients per clinician per treatment is given in table 2.5.

Table 2.5
Number of patients per practice per treatment

practice	1	2	3	4	5	6	7	8	9	10	11	total
FPA	6	6	11	8	11	6	6	5	3	4	7	73
PPA	6	9	12	7	11	3	7	5	4	5	7	76
total	12	15	23	15	22	9	13	10	7	9	14	149

2.2.3 Clinicians

In order to assess the effectiveness of the different treatments and to avoid interaction, several operators are required in a clinical trial (Mahler and Marantz 1979). In general a larger number of

operators improves the external validity of the trial results. However a small group of operators is preferred to reduce the operator effect. Since the efficacy of both FPA and PPA has been established already, the main objective of this study was to assess the effectiveness of FPA versus PPA. Therefore, a large number of operators was required.

Table 2.6
Orthodontist characteristics

orth= orthodontist
age= age of the orthodontist (in years) at the start of the trial
exp= number of years working in private orthodontic practice
cou= number of attended SWA courses between 1985 and 1989
ext= means of gathering extra information about the SWA before the start of the trial
B= books
A= articles in journals
C= attending congresses about SWA

orth	1	2	3	4	5	6	7	8	9	10	11
age	59	42	40	32	45	37	29	35	37	28	32
exp	28	13	6	4	14	8	2	8	9	1	1
cou	1	2	3	1	0	0	0	2	1	1	0
ext	BA	BAC	BA	BA	BA	BA	BA	BA	BA	BA	BA

The operators were 11 orthodontists (4 female, 7 male) working in the Netherlands. They replied positively after all 54 orthodontists who received postgraduate training at the University of Nijmegen and the staff members were asked to participate in the trial as operator. All operators were registered as specialist in orthodontics. All were trained in the standard full edgewise technique. Before starting the trial they were all trained in the SWA method since most of the operators did not have clinical experience in working with the SWA. The most important characteristics of the participating clinicians are given in table 2.6.

2.3 Treatment protocols

2.3.1 Initial treatment

Orthodontic treatment need is often not only resulting from malpositioned teeth on well proportioned jaws but also from a disproportion in the size and/or position of the jaws themselves. Before aligning the teeth within one arch it can be helpful to correct the sagittal relationship between the maxilla and the mandible (initial treatment). Prior to the fixed appliance therapy such an initial treatment was allowed. In this treatment phase, the use of the following appliances was permitted: functional appliances, headgear and removable appliances in combination with headgear.

2.3.2 Fully programmed appliance

2.3.2.1 General

When patients were assigned to the FPA therapy, the Roth appliance was used provided by "A"-Company[1]. The specifications of the prescription are mentioned in table 2.7. The size of the bracket slot was 0.022 x 0.028 inch. The brackets had to be placed at he Andrews FA-point (Andrews 1989). In non-extraction cases all premolar brackets had a mesial ball hook while the canine brackets had a distal ball hook. In extraction cases the premolar and canine brackets had a power arm instead of a ball hook.

Table 2.7
Roth prescription -Twin brackets ("A"-Company)

tooth=toothtype
ang=angulation
tor=torque
rot=rotation
**=prescription as non-extraction*

	maxillary arch						mandibular arch					
tooth	non-extraction			extraction			non-extraction			extraction		
	ang	tor	rot	ang	tor	rot	ang	tor	rot	ang	tor	rot
1	5°	12°	0°	*			2°	-1°	0°	*		
2	9°	8°	0°	*			2°	-1°	0°	*		
3	13°	-2°	4°	14°	-7°	4°	7°	-11°	2°	8°	-11°	4°
4	0°	-7°	2°	5°	-7°	4°	-1°	-17°	4°	5°	-17°	4°
5	0°	-7°	2°	-1°	-7°	4°	0°	-22°	4°	-1°	-22°	4°
6	0°	-14°	14°	*			-1°	-30°	4°	*		
7	0°	-14°	14°	*			-1°	-30°	4°	*		

In case of incorrectly placed brackets, they had to be replaced instead of bending the archwire. Bending the archwire was only allowed for the following reasons: adjusting width, adjusting shape and incorporating a (reversed) curve of Spee. Sliding mechanics were used to move teeth along the straight wire. The necessary force was supplied by grey polyurethane elastic chains (Force A®, "A" - Company).

Torque- and/or uprighting auxiliaries were not allowed. The use of rotation auxiliaries (f.i. rubber wedges) as well as intra- and intermaxillary elastics was permitted. Permitted also with the FPA therapy was the use of a cervical headgear, a high pull headgear (except a Lewis headgear with J-hooks), a palatal bar and a lipbumper in upper and/or lower jaw.

[1] "A"-Company, 11436 Sorrento Valley Road, San Diego, California 92121-1393, USA

Rinsing with a fluoride solution (0.01 - 0.05% NaF solution in water) once a day during the course of the treatment was allowed, according to the individual practice protocol.

2.3.2.2 Archwire sequence

The following archwires were allowed to be used; not all of them had to be used. The choice of the archwires is depending on the different stages of treatment. All sizes mentioned are in inches.

. initial stage (unravelling, levelling)

.. 0.016; 0.018 round Align® small, nickel titanium

.. 0.014; 0.016; 0.018 round Tru Arch® solid strand small, stainless steel

. working stage (torquing, levelling, closing)

.. 0.016 x 0.022; 0.017 x 0.025; 0.018 x 0.025; 0.019 x 0.025 rectangular Tru Arch® solid strand small, stainless steel

.. 0.017 x 0.025 rectangular Align® small, nickel-titanium

.. 0.019 x 0.025 rectangular Align® small, nickel titanium (in extraction cases)

. finishing stage (detailing, final setting of the arches)

.. 0.019 x 0.025 rectangular Tru Arch® solid strand small, stainless steel

.. 0.019 x 0.025 rectangular Align® small, nickel titanium

.. 0.021 x 0.025 rectangular Memoflex®[2] small, braided stainless steel

The orthodontist had to collect the used archwires to provide a check by the investigator for deviations in the treatment protocol.

2.3.3 Partly programmed appliance

2.3.3.1 General

When treatment allocation resulted in treatment with the PPA, standard edgewise twin brackets had to be used with an

[2] Align®, Tru Arch® and Memoflex® are registered trademarks of "A"-Company

0.018 x 0.025 inch slot. Microloc® brackets (GAC-company[3]) were recommended but not obligatory. These brackets have no built-in tip, torque and/or in/out with exception of the upper central incisor (22° torque), the upper lateral incisor (14° torque) and the upper cuspid (7° torque and 5° tip). Any other 0.018 inch slot appliance that complies with this prescription (or with less angulation and/or torque) was permitted as well.

In order to close the extraction diastema, closing loops had to be used; elastic traction along the archwire was not allowed. Also allowed were:

. intra- and intermaxillary elastics, except for closing extraction sites
. utility arches
. sectional arches
. utility springs and rotation auxiliaries (f.i. rubber wedges)
. cervical headgear
. high pull headgear (no Lewis headgear with J-hooks)
. palatal bar
. lipbumper in upper and/or lower jaw

The use of a fluoride rinse (0.01 - 0.05% NaF solution in water) once a day during the course of the treatment was allowed, according to the individual practice protocol.

2.3.3.2 Archwire sequence

The archwires mentioned, are the archwires that were allowed to be used, not all of them had to be used. The choice of the archwires is depending on the different stages of the treatment. All sizes are mentioned in inches.

.initial stage (unravelling, levelling)
.. 0.014; 0.016 round Nitinol®[4] nickel titanium
.. 0.014; 0.016 round stainless steel
.. 0.016 x 0.016 square stainless steel
. working stage (levelling, torquing, closing)
.. 0.016 x 0.016; 0.016 x 0.022; 0.017 x 0.025 rectangular stainless steel

[3] GAC International, 185 Oval Drive, Central Islip, New York 11722, USA
[4] Nitinol® is a registered trademark of #M Unitek, 2724 South Peck Road, Monrovia, California 91016, USA

. finishing stage (detailing, final setting of the arches)
.. 0.016 x 0.022; 0.017 x 0.025; 0.018 x 0.025
rectangular stainless steel

The orthodontist had to collect the used archwires to provide a check by the investigator for deviations in the treatment protocol.

2.3.4 End of active treatment

When the orthodontist had assessed that the treatment goals as described in his/her treatment plan had been achieved, the appliance was removed. For retention purposes either removable or bonded retainers could be used as well as a combination of these devices. According to the protocol of the individual orthodontic practice debonding and placement of the retainer(s) took place in one visit or two visits with a minimal time interval. The design of the retainer as well as the wearing regime were according to the protocol of the individual orthodontic practice.

2.4 Records

As soon as the treatment was allocated, the orthodontist would get a form-book from the central trial administration for that specific patient (Appendix C). During every visit one form was to be filled out and sent back to the trial-administration. In order to be able to evaluate the results of the treatment, in every stage a specific set of records was taken (table 2.4). As a reminder the composition of this set, was per visit mentioned on the form. The required records had to comply with specific standards which are discussed below.

2.4.1 Impressions

Alginate-impressions were made according to the standard impression procedures (Van der Linden en Boersma 1986). The impressions were to be filled with stone and finished as a study-model.

2.4.2 X-rays

For making a cephalogram the use of a cephalostate was required; the film had to be placed parallel to the median plane of the head. The central X-ray beam was to pass through the external auditory canal, perpendicular to the surface of the film. The Frankfurter Horizontal Plane had to be parallel to the floor. Making

up an inventory of the cephalostates as used by the participating orthodontists, showed that 10 participants used a focus-film distance of ±1.5 meters and 1 participant used a cephalostate with 4.75 meters focus-film distance. The distances that were assessed on the latter cephalograms were corrected for the focus-film distance.

A panoramic X-ray was made three times (table 2.4). This intra-oral radiograph is valuable for orthodontic evaluation at any age. The panoramic film has two significant advantages over a series of intra-oral radiographs: it yields a broader view and thus is more likely to show any pathologic lesions and supernumerary or impacted teeth, and the radiation exposure is much lower.

In order to study apical root resorption (chapter 5B), intra-oral radiographs (3 x 4 cm; Kodak Ektaspeed, Kodak Co.) of the upper central incisors were to be made using the bisecting-angle technique. The radiographs should be taken at the start and at the end of the fixed appliance therapy.

2.4.3 Extra-oral and intra-oral slides

A standard set of extra-oral slides had to be made: en face, en profile and 3/4 smiling. The standard set for the intra-oral view consisted of: occlusal view maxillary and mandibular dental arch, frontal view in maximal occlusion, lateral view in maximal occlusion, 3/4 view of the posterior region left and right in maximal occlusion. All slides were in colour. The slides had to be made at the start of active treatment and at the start of retention.

2.4.4 Pocketstatus

Both the margin of the free gingiva in relation to the cemento-enamel junction, and the depth of the gingival sulcus were to be measured utilising a calibrated periodontal probe (Hu-Friedy), in a gentle way (approximately 25 grams). Probing depth examinations were made on 6 representative sites: the first permanent molars, the first upper right incisor and the first lower left incisor. Measurements were made on the (1) distobuccal line angle, (2) mesiobuccal line angle, (3) midbuccal region of every root (one or two), (4) distolingual line angle, (5) mesiolingual line angle, and (6) midlingual region of every root (1 or 2). On both the mesial and distal aspects of the tooth, the probe should be placed as far interdentally toward the contact as possible, while maintaining

parallelism of the probe to the long axis of the tooth

All measurements were to be recorded and registered on a standard pocket graph form. The margin of the free gingiva in relation to the cemento-enamel junction (0-line) was recorded using a red line. For recording the depth of the gingival sulcus a black or blue line was used.

2.4.5 Gingival index

The tendency for bleeding had to be assessed using a periodontal probe. Both dental arches were to be divided into 3 segments: 2 segments with molars and premolars and 1 segment with incisors and cuspids. The probe was placed about 1 millimetre deep in the gingival sulcus on top of the interdental papilla. Next, the sulcus was explored 5 millimetre mesial and distal of the top of the papilla. This was carried out for every tooth. If extravasation of blood was found, the most severe bleeding in that sextant had to be scored. The applied scores were modified after Saxer et al. (1977).

0 = no bleeding within 30 seconds after probing
1 = small bleeding points occur 2 to 3 seconds after probing
2 = immediate (severe) bleeding after probing

The assessed scores had to be transferred to the relevant form (Appendix C).

2.4.6 Plaque index

In assessing the amount of plaque present the plaque index according to Silness and Löe (1964) was used. Applying this method, specifically the cervical part of the teeth is examined. Scoring was done by eye and using a probe after air drying. The possible scores were:

0 = no plaque perceptible by eye or by probing
1 = no plaque perceptible by eye but by probing the gingival margin
2 = thin layer of plaque along the gingival margin, assessable by eye
3 = considerable plaque accumulation and debris along the gingival margin

The scores were to be assessed per sextant and to be transferred to the relevant form (Appendix C).

2.4.7 Chairtime

The effective chairtime had to be recorded every visit, for the orthodontist and the auxiliaries separately. The chairtime was assessed using a stopwatch. The results had to be rounded off to entire minutes ($x < 30$ seconds downwards, $x \geq 30$ seconds upwards). Time used for protocol procedures (taking records) and for conversations with the parents were not included.
The chairtime had to be filled out on the relevant form (Appendix C).

2.4.8 Questionnaires

In order to assess the subjective experience of the patient wearing fixed appliances, the patients were asked to fill out questionnaires. Questions had to be answered concerning (dis-) comfort during treatment and oral hygiene. The questionnaires (Appendix D) had to be handed out to the patient at the start of the predetermined visit. He/she could return the completed forms at the end of the visit or the next visit.

2.5 Blindness of the trial

The comparison of treatment data may be biased if the patient and those responsible for treatment and evaluation, know which treatment has been used. While randomisation eliminates bias at the start of the clinical trial, the use of appropriate blinding techniques is essential to minimise the bias during the trial. The therapy given must ideally be concealed from both the patient and the operator/evaluator (double-blinding).

There are three potential areas in a clinical trial where blinding concerning the experimental variables is requested: blinding to patients; blinding to operators; blinding to evaluators. In our study completely blinding of the patients to the treatment variable is not possible. Patients could be aware of the presence of loops and/or auxiliary wires in the nearness of the gingiva in case of PPA treatment. To study this possible influence the perception of treatment with a fixed appliance was investigated using questionnaires and tested statistically for both treatment groups.

Given the types of treatment, blinding the operators was not possible either. The operator had to apply the assigned appliance and was aware of this experimental variable. A biasing factor could

be that the operator, who has a negative attitude to one of the treatment options, is less careful in applying this method and is thus inducing probable failures leading to a self-fulfilling prophecy.

Blinding the evaluators could be performed in all instances. The participating orthodontists sent a list of all patients participating in the trial to the trial registration centre. On this list all patients were given a code by the secretary of the registration centre. This code was written on every record that had to be evaluated (casts and radiographs) in such a way that the evaluator could not recognise name of the patient, treatment option and/or the practice were treatment took place.

The last area of possible bias to the evaluators is that the results of earlier examinations are known when later examinations are conducted. Results of interim analysis may also have an influence on the results of later evaluations. However, this may not be true for the 'blind evaluator".

In this study every possible measure has been taken to assure optimal blindness in evaluating the data collected during the trial. Blinding the orthodontists or the patients was not possible due to the nature of the treatments. It may be concluded that in orthodontics it is very difficult to conduct an ideal (double-)blind study.

2.6 Description of the sample

In table 2.8 the result of treatment allocation using the balancing criteria is given. The chi-square test showed no significant difference in the distribution of the criteria over the two treatment groups, which will be evaluated in this study.

Information about the average cephalometric values (figure 2.1) at the start of treatment (initial or fixed appliance) is depicted in table 2.9. The t-test showed no significant difference for any variable between both treatment groups. Dual measurements of the cephalograms by two observers showed correlations of 0.89 to 0.99 for the different assessements.

Table 2.8
Sample description after treatment allocation using the balancing criteria

- type of Class II: according to the classification of Angle
- molar relationship: the amount in which the first permanent molar occlusion deviates from an Angle Class I occlusion is given in premolarwidths
- arch length discrepancy: see chapter 3
- overjet: sagittal distance from the labial side of the incisal edge of the most prominent upper central incisor to the labial surface of its antagonist, measured parallel to the occlusal plane
- overbite: vertical overlap of the right lower central incisor by the right upper central incisor, measured between the incisal edges of both teeth
- open bite: absence of normal vertical contact between opposing teeth or between teeth and the opposing gingiva
- trauma: trauma to one or more teeth without (future) loss of one or more teeth

		FPA	PPA
number		73	76
gender	male	30	34
	female	43	42
type of Class II	Class II/1	58	61
	Class II/2	11	9
	Class II/1 subdivision	3	4
	Class II/2 subdivision	1	2
molar relationship	1/2 premolar width disto	29	30
	3/4 premolar width disto	16	16
	1 premolar width disto	28	30
arch length discrepancy	spacing	7	13
	crowding 0≤x≤3 mm	22	25
	crowding >3mm	44	38
overjet	x≤5 mm	27	20
	5<x≤10 mm	40	44
	x>10 mm	6	12
overbite	x≤3 mm	33	30
	x>3 mm	40	46
open bite	none	43	47
	partial: frontal region	23	19
	partial: (pre)molar region	1	1
	total open bite	6	9
trauma	no	62	63
	yes	11	13
extraction therapy	none	50	50
	2 premolars	16	14
	3 or 4 premolars	7	12
initial treatment	none	21	16
	functional appliance	19	26
	headgear	23	23
	headgear/removable plate	10	11

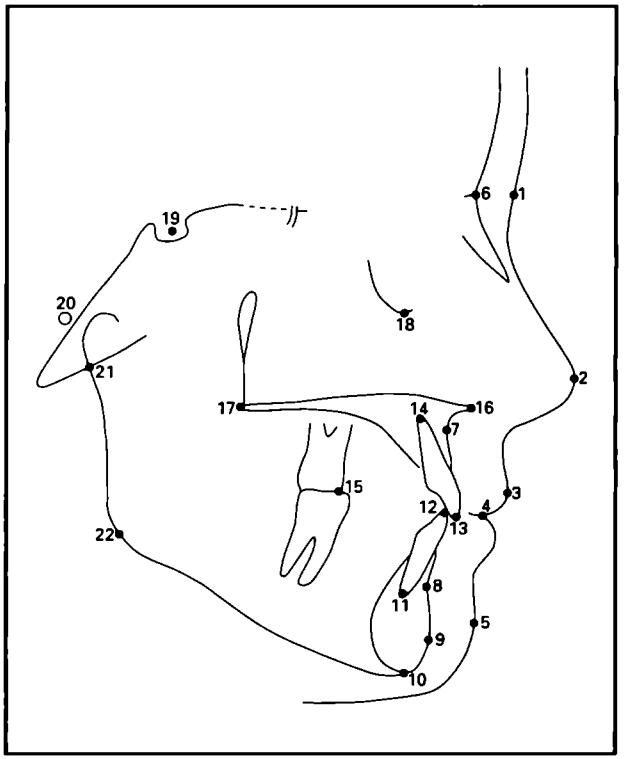

Figure 2.1
Definitions of cephalometric landmarks in the lateral cephalometric tracing.
1. sN; SKIN-NASION: crossing of the soft-tisue profile with a line from nasion, parallel to the Frankfurter horizontal plane
2. NT; NOSE TIP: the most anterior point of the soft profile of the nose, in relation to a perpendicular line to the Frankfurter horizontal plane
3. UL; UPPER LIP: the most anterior point on the profilr of the upper lip, in relation to a perpendicular line to the Frankfurter horizontal plane
4. LL; LOWER LIP: the most cranial point of the lower lip, in relation to a parallel line to the Frankfurter horizontal plane
5. sPg; SKIN-POGONION: the most anterior point of the soft tissue of the skin, in relation to a perpendicular line to the lower border of the mandible
6. N; NASION: the centre of the ventral entrance of the sutura nasofrontalis
7. POINT A: the innermost point on the contour of the premaxilla between anterior nasal spine and the incisor tooth
8. POINT B: the innermost point on the contour of the mandible between the incisor tooth and the contour of the chin
9. Pg; POGONION: the most anterior point on the contour of the chin, in relation to a perpendicular line to the lower border of the mandible
10. Me; MENTON: the most inferior point on the mandibular symphisis
11. Alci; APEX LOWER CENTRAL INCISOR: apex or centre between the most apical discernable labial and lingual contour of the most labial lower incisor
12. Ielci; INCISAL EDGE LOWER CENTRAL INCISOR: incisal edge of the most labial lower incisor
13. Ieuci; INCISAL EDGE UPPER CENTRAL INCISOR: incisal edge of the most labial upper central incisor
14. Auci; APEX UPPER CENTRAL INCISOR: : apex or centre between the most apical discernable labial and apical contour of the most labial upper incisor
15. Mp; MOLAR POINT: centre between the (overlapping) mesial cusps of the first molars
16. ANS; ANTERIOR NASAL SPINE: the most anteriorly discernable point of the nasal spine
17 PNS; POSTERIOR NASAL SPINE: the most distally discernable point of the nasal spine
18. O; ORBITALE: the lowest point on the inferior margin of the orbit
19. S; SELLA: the midpoint of the cavity of the sella turcica
20. Po; PORION: the midpoint of the upper contour of the earplug of the cephalostate
21. Art; ARTICULARE: the point of intersection of the shadow of the zygomatic arch and the posterior border of the mandibular ramus
22. Go; GONION: the centre of the inferior contour of the mandibular angle

Table 2.9
Average cephalometric values ± standard deviations at the start of treatment (initial or fixed appliance)

	FPA (n=73)	PPA (n=76)
Angles in degrees	value ± sd	value ± sd
SNA	79 ± 3	80 ± 3
SNB	75 ± 3	76 ± 3
ANB	4 ± 1	4 ± 2
SN - spinal plane	7 ± 3	7 ± 3
SN - occlusal plane	16 ± 4	15 ± 4
SN - mandibular plane	37 ± 4	36 ± 6
spinal plane - upper 1	109 ± 6	110 ± 7
occlusal plane - upper 1	52 ± 10	50 ± 10
occlusal plane - lower 1	65 ± 5	66 ± 5
mandibular plane - lower1	95 ± 5	93 ± 7
inter incisal angle	127 ± 9	126 ± 8
gonial angle	129 ± 4	130 ± 4
H-line - (N - pogonion)	15 ± 4	16 ± 4
H-line - SN	61 ± 5	61 ± 6
Distance in millimetres	value ± sd	value ± sd
tip of the nose - H-line	18 ± 5	10 ± 5
top of lower lip - occlusal plane	2 ± 3	-3 ± 3

2.7 Discussion

The randomised controlled clinical trial has become the standard experimental design for evaluation of clinical therapies. The balance procedure of assigning patients to the different treatments was a successful method for ensuring comparability between treatments. This implies that the conclusions of the study are based on an independent treatment allocation rather than on subjective clinical opinions.

The validity (internal and external) of a clinical trial depends on several aspects of the design, including the method of randomisation, the criteria for patient selection, the description of the treatment protocol (blindness and evaluation methods) and the use of appropriate analysis. In the literature many systems have been developed for clinical trials. Especially for drug trials, systems have been advocated that guarantee a high internal validity. For operative trials, some problems remain, affecting the internal validity. These

problems are related to blindness of operators and evaluators, and evaluation of protocol deviations. Due to the nature of orthodontic treatment blinding of the participating orthodontists is not possible. Every possible measure has been taken, on the other hand, to ensure optimal blindness of the evaluators. Deviations of the protocol could only be assessed by evaluating the used archwires. It was not possible to fully control the compliance to the protocol.

The external validity of the trial, and thus the relevance for the practitioner, is influenced by the selection criteria for patients, the treatment protocol applied and the representativeness of the operators. Patient characteristics can significantly vary. Control for patient characteristics was attained through strict inclusion and exclusion critria. Ideally, treatment protocols must be (almost) similar to those used by a majority of practitioners. In this study the applied protocols were derived from the Straight Wire course by Dr. R. Roth (FPA) and from the post-graduate orthodontic training at the University of Nijmegen (PPA).

To create a high external validity, we have chosen for a multi-practice clinical trial with a broad variety of practitioners. Differences in operator performance, however, occur when the outcome of a particular intervention is technique sensitive. To give in to this objection, a wide variety of operators with the same background was selected. They were all trained well and highly motivated to ensure that any potential beneficial outcome would be attained using either of the treatment techniques. The relatively short experience in treatment with the FPA is about the same for all practitioners so that this is not of major influence to the external validity. Theoretically, orthodontists can participate in a randomised clinical trial only when they truly have no preference for either treatment involved. Practically, there are no orthodontists who do not have an opinion as to what procedure works best in their hands to correct the malalignment of teeth.

The unique strength of randomised clinical trials stems from the reduction of bias in assessing treatment effects through the random allocation of subjects to both treatment groups. Thus all subjects who meet the entry criteria have the same chance of receiving either treatment. Designing an ideal double-blind randomised clinincal in orthodontics, however, is not possible for various reasons as described above.

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CHAPTER 3

The assessment of crowding and spacing: measuring or assessment by eye?

This chapter is an edited version of: Reukers HAJ, Kuijpers-Jagtman AM, van 't Hof MA. Het bepalen van crowding en spacing. Opmeten of schatten? Ned Tijdschr Tandheelk 1994;101:394-97. It is printed with kind permission of the publisher.

Abstract
Two methods for the assessment of crowding or spacing are compared (measuring and assessment by eye). On ten sets of study casts the arch length discrepancy (ALD) was assessed using both methods. The intra- and inter-observer correlations were high while the inter-observer differences were small. The time needed for the assessment of ALD when measuring is about six times as much as needed for the assessment by eye. It is concluded that both methods are well comparable and reproducible. Assessment by eye has the practical advantage that it takes considerable less time.

3.1 Introduction

One of the criteria on which the treatment allocation was balanced was the amount of crowding or spacing (table 2.3) The assessment of this value was carried out by the participating clinicians as part of the diagnosis before making a treatment plan. Several methods have been described to assess the amount of crowding/spacing (Nance, 1947; Lundström, 1964; Graber and Swain, 1985; van der Linden and Boersma, 1986; Moyers, 1988; Rakosi et al., 1993). On inquiry, however, it appeared that almost every participating orthodontists made an assessment of the crowding/spacing by eye. They claimed that they were able to determine the arch length discrepancy by eye and that this would take less time than any other method of measuring. A pilot study was carried out to compare the assessment of crowding/spacing by measuring and by assessment by eye.

3.2 Measurements of crowding and spacing

Dental casts are an indispensable source of information in diagnostics, planning and evaluation of orthodontic therapy (Graber and Swain, 1985; van der Linden and Boersma, 1986; Moyers, 1988; Rakosi and Jonas et al., 1993). Not only information about intermaxillary relations but also about intramaxillary aspects can be obtained. One of the most important assessments is the determination of the amount of "Arch Length Discrepancy" (ALD) (Nance, 1947). This is the difference between the space available for alignment of the teeth and the amount of space required to align them properly. In case of crowding the available space is too small (ALD negative) and in case of spacing too big (ALD positive).

The analysis of the required space can be executed in various ways. When all permanent teeth have erupted, the required space can be calculated by measuring the mesiodistal width of each tooth and then adding up these widths. In the mixed dentition, the size of the unerupted teeth can be estimated with proportionality tables. There is a reasonably good correlation between the size of the erupted permanent lower incisors and the unerupted upper and lower canines and premolars. These data have been tabulated for white American children by Moyers (1973). To use these tables, the mesiodistal width of the lower incisors is measured. This value is used to predict the size of the unerupted canines and premolars. The

size of these teeth can also be calculated with the use of an X-ray. By comparing the mesiodistal width of a primary molar on the cast and on the film, for magnification can be corrected. Thus the actual width of the permanent teeth can be assessed.

The analysis of the available space can also be conducted in various ways. One way is by contouring a piece of wire to the line of occlusion from the mesial side of both first molars. When the wire is then straightened out the available space can be measured. The available space can also be measured by dividing the dental arch into straight line segments. Van der Linden and Boersma (1986) divided the arch into six segments in which the canine is considered a separate segment (figure 3.1 L). Each segment is measured individually with a sharp-pointed divider. The sum of the measured values represents the available space within a dental arch. Lundström (1964) divided the arch into six straight line segments of two teeth each (figure 3.1 R). He then compared the amount of space available and space required in each segment.

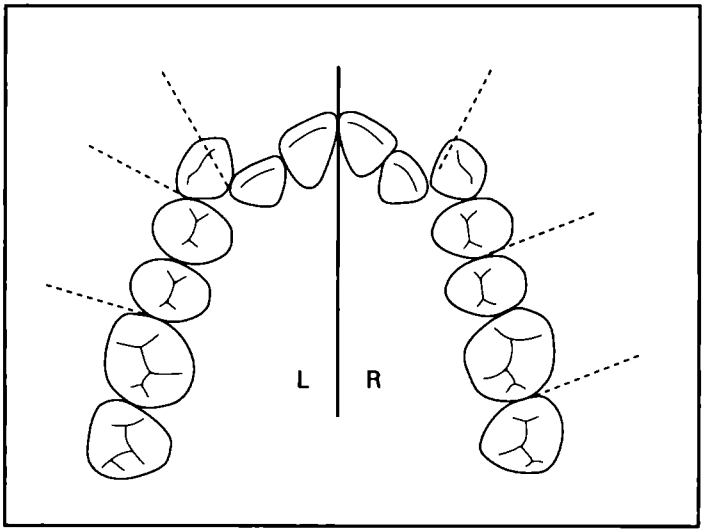

Figure 3.1
L: assessment according to Van der Linden and Boersma
R: assessment according to Lundström

Probably, in daily practice the space available and required will not always be assessed separately. The ALD will then be assessed by eye, with or without the limited use of aids. The purpose of this pilot was to compare the two main methods of assessing the amount of space within the dental arch: measuring and assessment by eye.

3.3 Materials and methods

Data selection and editing

Ten randomly selected sets of casts from patients that were to be treated orthodontically were presented to five observers in order to assess the arch length discrepancy. In all patients the primary teeth were shed and the permanent teeth were fully erupted. Crowding was present in 17 dental arches, spacing in 3 arches. Two observers were experienced orthodontists, the other three were dentists who had been in postgraduate orthodontic training for one year and a half. Both orthodontists were instructed to assess the amount of crowding or spacing in millimeters by eye in their own way. They also were asked to register the time needed to do so in minutes. After four weeks the same procedure was repeated. The three dentists were instructed to do the same; they were also instructed to conduct a space analysis according to the method of Van der Linden and Boersma (1986) (figure 3.1). In this method the required arch length (sum of the mesiodistal widths of all teeth mesial of the first permanent molars) is subtracted from the measured available arch length. The measurements were performed with Korkhaus-dividers (Seitz und Haag). The distances were pierced in a straight line on a piece of paper. The total distances were then measured with calipers (Mitutoyo 500-311). Reassessment (measuring or assessment by eye) of the complete set of models was carried out after at least four weeks.

The time required for the assessment of the arch length discrepancy of all 10 sets of casts was registered in minutes. Values up to 30 seconds were rounded down, values over 30 seconds were rounded up. The time necessary to perform an ALD analysis on the entire set of casts was divided by 10 in order to obtain the mean time for one set of casts.

Statistical methods

Systemetical differences between the two methods and between the five observers were tested by the paired t-test. Random errors were derived from the standard deviations of the difference scores. Since the difference scores contain the measurement error twice, the random error is s.d./$\sqrt{2}$ (s.d.= standard deviation of difference score). Reliability of the measurements are presented as

Pearson correlation coefficients and expressed the usefulness of the methods in the clinical context.

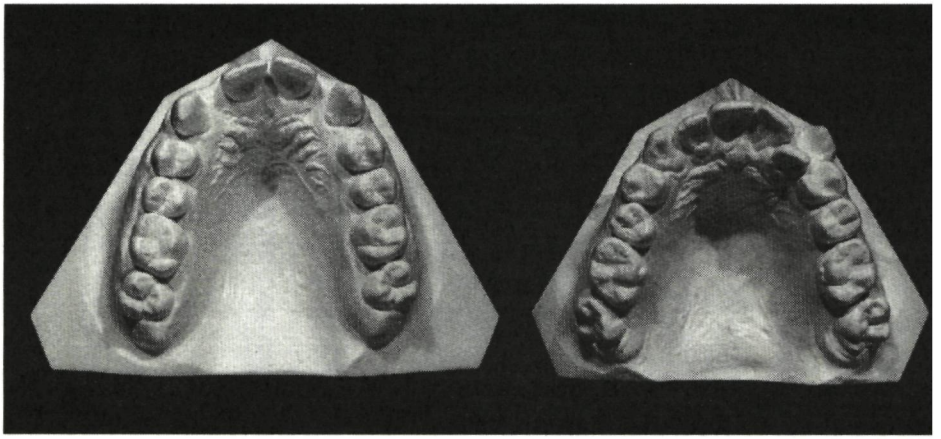

Figure 3.2
Left: model with spacing. The measured and/or estimated spacing varied between 8 and 13 mm.
Right: model with crowding. The measured and/or estimated crowding varied between 8 and 12 mm.

3.4 Results

Tables 3.1 and 3.2 show that the correlations between the different assessments are high in spite of the large differences between the extreme values per cast (table 3.3). This is due to the large inter-cast differences in ALD, varying from -11 up to 11 mm (table 3.3). There was no significant difference between the first and the second assessment by eye. The mean difference between the first and the second measurement was 1.3 mm for observer 1 ($p<0.01$) and -1.2 mm for observer 2 ($p<0.01$). The random error for measurement by eye was 1.0 mm; for measuring it was 1.2 mm. When both methods of assessment were compared per observer, it appeared that only observer 3 systematically assessed a higher arch length discrepancy by measurement than by assessment by eye (1.2 mm; $p<0.01$).

Table 3.1
Intra-observer correlations (Pearson)
n=20

OBSERVER →	1	2	3	4	5
assessment by eye	0.97	0.98	0.97	0.98	0.96
measuring	0.94	0.96	0.96		
mean assessment by eye with mean measurement	0.96	0.95	0.97		

Table 3.2
*Inter-observer correlations (Pearson) for assessment by eye and by **measuring***
n=20

OBSERVERS	1	2	3	4	5
1		0.97	0.97	0 98	0 97
2	***0.98***		0 97	0 97	0 96
3	***0.98***	***0.97***		0.98	0 97
4					0.97

Table 3 3
Extreme assessments per cast, with cast characteristics and median value in millimeters

MED= median value
EYE MIN/EYE MAX= minimum/maximum value obtained through assessment by eye
MEA MIN/MEA MAX= minimum/maximum value obtained through measuring
UP= cast of the upper arch of a set of models
LO= cast of the lower arch of a set of models

CAST ↓	CHARACTERISTIC	MED	EYE MIN	EYE MAX	MEA MIN	MEA MAX
1 UP	proposition +1+	-4.5	-4.0	-7.0	-2.5	-7.0
LO	crowding front	-3.5	-2.5	-4.0	-4.0	-5.5
2 UP	mild crowding	5 0	4.0	6.5	3 0	7.0
LO	almost ideal arch	1.5	0.5	2.0	1.0	3 0
3 UP	13 blocked out	-11.0	-10.0	-12.5	-10 0	-13 0
LO	43 blocked out	-9.5	-8.0	-12.0	-8 0	-11.0
4 UP	agenesis +2+	11.0	8.0	13.0	10.5	13 0
LO	crowding front	-5 0	-4.0	-6.0	-3 0	-5 5
5 UP	rotation +2+	-2.0	-1.0	-2.5	-2.0	-2 5
LO	square arch form	-5 5	-3 5	-9 0	-5 0	-7 5
6 UP	rotation +1+	-4 5	-3 0	-7 0	-4.5	-6.0
LO	almost ideal arch	-1.0	-0.5	-2.0	0 0	-1 5
7 UP	slight rotations	-1.0	0.0	-1.0	0 0	-2 0
LO	slight rotations	-2 5	-2 0	-3.0	-1 5	-3 0
8 UP	complex crowding	-6 0	-3 5	-8 0	-4 4	-9 0
LO	complex crowding	-8 5	-6 0	-12 0	-5 0	-10.0
9 UP	overall crowding	-6 0	-5.0	-8 0	-4.0	-7 0
LO	slight rotations	-1.0	0.0	-2 0	0.0	-2.0
10 UP	eversion front	-3.5	-1.0	-5.5	-2 0	-6.0
LO	crowding front	-4.5	-3.0	-6.0	-3 0	-6 5

The systemetical inter-observer differences, measuring minus assessment by eye (table 3.4), showed that there were few significant differences These inter-observer differences (maximally 1 2 mm) were small compared to the inter-cast differences of 22 mm (-11 to 11) and may be considered as clinically irrelevant

Table 3.4
Mean inter-observer differences (measuring minus assessment by eye), for 10 sets of casts, in millimeters (n=20)

dif= mean difference
sd= standard deviation
**p<0.05*
***p<0.01*

1-2= mean measuring values of observer 1 minus mean assessment by eye values of observer 2

OBSERVER ↓	ASSESSMENT 1		ASSESSMENT 2	
measuring minus assessment by eye	dif	sd	dif	sd
1 - 2	0.33	1.8	-0.62	1.6*
1 - 3	1.18	1.7**	-0.35	1.3
1 - 4	0.73	1.4*	-0.85	1.6*
1 - 5	0.68	2.0	-1.07	2.1*
2 - 1	-0.02	1.7	0.92	1.8*
2 - 3	0.55	1.3	1.20	1.2**
2 - 4	0.10	1.2	0.70	1.6
2 - 5	0.05	1.7	0.47	1.7
3 - 1	0.82	1.7	0.67	1.9
3 - 2	0.55	1.4	0.10	1.0
3 - 4	0.95	1.5**	0.45	1.5
3 - 5	0.90	1.9	0.23	1.4

The arch length discrepancy assessed by measuring is the result of the difference between the measurement of the required space and the available space. Both the intra- and inter-observer correlation for assessing the available space (Pearson's correlation coefficient: 0.98 - 0.99) were higher than for assessing the required space (Pearson's correlation coefficient: 0.93 - 0.96).

The mean time required for assessing the arch length discrepancy by eye was 1.6 minutes for one set of casts (one upper and one lower cast). The analysis according to van der Linden and Boersma (1986) took an average time of 8.7 minutes (table 3.5).

Table 3.5
Mean time (in minutes) necessary to perform an ALD analysis on one set of casts (assessment by eye and measuring)

OBSERVER ↓	assessment by eye	measuring
1	0.6	9.0
2	1.3	8.0
3	2.3	9.0
4	1.5	
5	2.2	
mean	1.6	8.7

3.5 Discussion

The reproducibility of the investigated methods for assessing the ALD, namely measuring and assessment by eye, was good. Assessment by eye had the advantage that it took considerably less time to perform an analysis.

These results seemed to contradict previous research regarding the agreement between analysis of the ALD by measuring and by assessment by eye (Lundström, 1964). Lundström compared the results of measurements, done according to an analysis of straight line segments, with the results of assessment by eye. He concluded that the agreement between the analyses was poor but he did not test his findings statistically. He assumed that the differences were caused by the unreliability of assessment by eye in cases of severe and complex crowding.

Several explanations can be given why the agreement between measuring and assessment by eye was better in the present pilot study than in Lundström's study. Three of the five observers made limited use of dividers. In cases of complex crowding they felt that they could get a better insight into the spatial relations in the dental arch without the time-consuming measurement of all mesiodistal widths and straight line segments. Since the correlations for assessment by eye between all observers, with or without the limited use of dividers, was very high, the use of dividers did not seem to be of decisive importance. Another factor that might influence the agreement between the analyses could be the composition of the group of casts. Lundström already assumed that assessment by eye in cases of complex crowding could lead to less agreement. The group of casts investigated contained several cases with complex crowding (table 3.3). Therefore this did not seem to be a plausible explanation. A third possible explanation for the difference in agreement could be the method used for measuring. Lundström used an analysis in which he assessed the crowding/spacing per straight line segment individually and which included the first permanent molars. In the present pilot, the method as described by van der Linden and Boersma (1986) was used in which the first permanent molars were only involved in the analysis with their mesial side.

In spite of the small mean differences between measuring and assessment by eye, between measuring mutually and between

assessment by eye mutually, there were marked differences between the extreme values per cast. The largest differences occurred in cases where it was difficult to define the dental arch-form. In these cases the extreme values determined by measuring and assessment by eye did not differ substantially (table 3.3). Obviously, assessing the available arch length is more difficult than assessing the required arch length. Several factors could be responsible for this phenomenon. No specific criteria were given for determining the dental arch form. Especially in cases of complex crowding this might lead to a different opinion about the required arch length. It is also plausible that in determining the arch form the observers already considered the limitations of the possible therapy. This phenomenon probably occurred both in measuring and assessment by eye. Another possible factor is that flattening a deepened curve of Spee takes space within the arch (Graber and Swain, 1985; Rakosi et al., 1993). If one strives for a flat curve this should be borne in mind in conducting a space analysis. In this pilot no instructions were given regarding the curve of Spee. It is possible, however, that some observers took the above into account.

In case of assessment by eye the inter-observer correlations were high (table 3.2) and the inter-observer differences were small. Taking this into consideration, long orthodontic experience does not seem to be of decisive importance in conducting a reliable assessment of the ALD by eye. Because of the magnitude of the random error and the systematic error (± 1 mm), both assessment techniques seemed to be suitable for their practical application. In most cases the ALD assessment is used to decide whether or not a tooth has to be extracted as part of an orthodontic therapy. There is no sharp dividing line between extraction and non-extraction. Therefore, a measurement error of 1 mm should probably not lead to incorrect extraction of teeth.

The main difference between measuring and assessment by eye seemed to be the time needed to conduct an analysis (table 3.5). Assessing the ALD by eye on ten pairs of casts took about 15 minutes while measuring the same casts took about one hour and a half. On average, measuring took about six times the time of assessment by eye. There was a considerable variation in the time needed to assess the ALD by eye. This was probably caused by an individually differing geometrical perception.

3.6 Conclusion

The conclusion from this pilot study is that it is very well possible to assess the ALD by eye in a reliable way. The main advantage of assessment by eye is the time needed to perform the analysis. Therefore, the evaluation of the amount of crowding or spacing, as assessed by the participating clinicians, is a valid method.

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CHAPTER 4

Duration and chairtime of orthodontic treatment using a fully programmed edgewise appliance versus a partly programmed appliance

Abstract

The duration and chairtime of treatment with fixed appliances were assessed in two series of patients with Class II malocclusions. One series had been treated according to the precepts of the Roth prescription (FPA) while the other was treated with the conventional full edgewise mechanics (PPA). The goal of this part of the study was to test whether one method would lead to reduction of treatment duration and/or chairtime relative to the other. As a result we found that the duration of both types of treatment was comparable in extraction as well as non-extraction therapy. Extraction therapy took more treatment duration than non-extraction therapy. The chairtime for orthodontists was comparable for both treatments but the chairtime for dental auxiliaries and the total chairtime was significantly more for a treatment using FPA as compared to a treatment using a PPA.

4.1 Introduction

Although there have been many attempts in the research literature to assess the effects of orthodontic treatment, the efficacy of orthodontics has not yet been systematically addressed. Treatment effect studies deal with issues of changes that are attributable to some biomechanical intervention and address questions concerning the response of the biological system to a particular technique or protocol of prescribed force application. Efficacy issues, by contrast, deal with questions that reflect on the relative utility of the outcome of clinical decisions and procedures, to both the provider and the consumer (Vig et al. 1990).

Reliable information on benefits and risks associated with treatment with SWA is not yet available. Despite, or possibly because of, this lack of objective data assertations concerning the efficacy of treatment with a fully programmed appliance are being made (Andrews 1976, Magness 1978, Roth 1987, "A"-company 1997). Subjective opinions, often strongly held, are expressed to promote the straight wire approach at the expense of others.

Two items concerning the efficacy of treatment are the duration of treatment and the time a patient spends in the chair while an orthodontic professional is working on his appliance. The literature reveals numerous statements concerning the duration of treatment for selected patients whose treatment was performed according to a specified technique. Only few studies are known that provide data assessed in a controlled clinical study. Ringenberg (1967) found that in a sample of children with Class I crowding, there were significant differences in both total treatment duration and length of active appliance therapy between those patients who had serial extraction before definitive treatment and those who did not. More recent studies are all retrospective (Vig et al. 1990; Fink and Smith 1992; Kattner and Schneider 1993; Shelton et al. 1994). Vig et al. (1990) found that differences in duration of treatment could be found when extraction and non-extraction therapy were compared. They also found significant inter-practice differences. Fink and Smith (1992) also tried to determine variables in orthodontic planning and therapy that might influence the duration of treatment. They found that the most important variable to cause differences in the duration of treatment was the extraction of premolars. Furthermore they had the impression that much of this

variation in duration might relate to differences between offices in the time spent in detailed finishing procedures. Shelton et al. (1994) compared a group of patients that was treated with Tip-Edge to a group of patients treated with standard Begg technique. They concluded that the Tip-Edge appliance may reduce treatment duration in Class I non-extraction therapy.

Andrews (1976), Roth (1976) and Magness (1978) reported that the use of the SWA reduced treatment duration in extraction cases 3 to 6 months. They did not describe a control group. The "A"-company reported an average treatment duration of 23 months for SWA treatment and 30 months for other appliances ("A"-company 1997). They found this in a retrospective study on the efficiency of the straight-wire appliance. Other than in their own newsletter, these data were not published in a scientific journal. Kattner and Schneider (1993) assessed the average duration of treatment with a Roth appliance and with a partly programmed appliance retrospectively. Their sample consisted of 120 orthodontically treated cases completed by two practitioners who used both treatments. The average treatment duration for practitioner 1 was 2 years 1 month for standard edgewise treatment and 1 year and 8 months for the Roth appliance. Practitioner 2 needed 2 years 6 months and 2 years 4 months respectively. They concluded that this decrease in treatment duration (which was not statistically tested) could be due to the gain in experience by a practitioner over time, the introduction of newer arch wires, change in the criteria used by the practitioner to discontinue treatment or to the appliance itself.

Besides duration of treatment, chairtime is another factor concerning efficacy of orthodontic treatment. Roth (1976) and Mayerson (1977) stated that one of the advantages of the SWA is less chairtime for the orthodontist. In 1987 Roth published a follow-up article in which he claimed that using a SWA one could gain 20% chairtime reduction in cases with extraction therapy. Neither Roth nor Mayerson described the use of a control group in assessing these data. The "A"-company reported in a company news letter ("A"-company 1997) that a retrospective study among six orthodontists with 120 patients showed that SWA treatment would take an average total chair time of 10 hours against 13 hours for other appliances. The number of appointments would be 20 and 26 respectively. A search of the orthodontic literature yields no previous

prospective randomized studies that analyze the time a patient spends in the chair during treatment.

The purpose of this part of the study is to compare treatment duration and chairtime in orthodontic treatment using a fully programmed edgewise appliance with orthodontic treatment using a partly programmed edgewise appliance. The influence of (non-) extraction therapy on treatment duration will be assessed. The influence on chairtime of the operators (orthodontist or auxiliary) will be evaluated.

4.2 Materials and methods

Data selection and editing

Treatment duration, beginning with the placement of the first arch wire and ending with complete bracket removal, was measured in years and months. For statistical purposes this value was transformed into a digital value according to the formula $x=n^{year}+(n^{months}+0.5)/12$. Patients that were prematurely debonded due to oral hygiene problems were excluded from evaluation. The time a patient spent in the chair while an orthodontic professional was working on the appliance was measured for the orthodontist and the auxiliary separately. Timing was conducted using a stopwatch. Values smaller than 30 seconds were to be rounded off and values equal to or larger than 30 seconds were to be rounded up to whole minutes. Only clinical actions related to the fixed appliance were included. Times needed for protocol procedures as well as oral information to the patient and/or his parents about for instance oral hygiene procedures or the progress of treatment were not recorded. The time spent on treatment planning, pre-treatment with removable appliances, debonding and retention procedures was also not included. A patient only was included for evaluation if the chairtime was recorded on every visit. If one visit was missing, the entire file was excluded for evaluation of the chairtime.

Treatment durations of 140 patients (nFPA= 69, nPPA= 71) were evaluated. From the original 149 patients 2 moved to another place and could not continue their treatment according to the protocol and 7 patients were excluded for evaluation because of premature debonding due to very poor oral hygiene

Chairtimes of 107 patients (nFPA= 48, nPPA= 59) were evaluated because 33 patients were excluded as the data set was not complete.

Statistical methods

3-Way ANOVA (practice, appliance and extraction) was applied to the treatment duration. 2-Way ANOVA (practice and appliance) was applied to the chairtime. For skewed distribution "normality" could be obtained by log-transformation. To test for differences between FPA and PPA within each individual practice a t-test was applied. An alpha level of 0.05 was used to determine the statistical significance of the applied tests.

4.3 Results

The overall mean treatment duration with fixed appliance was 1.7 years (s.d.= 0.5; minimum 0.7 years; maximum 3.2 years). Mean treatment duration with FPA was 1.8 years (s.d.= 0.4) and with PPA 1.6 years (s.d.= 0.5). ANOVA showed a significant inter-practice difference in treatment duration ($p<0.0001$). Statistically no significant difference could be assessed between the two treatment modalities. Two-way interactions between practice and appliance were significant (p= 0.04) (Table 4.1).

Table 4.1 Analysis of variance of treatment duration with practice (1-11), appliance technique (FPA or PPA) and extraction (yes/no).
*pract * appl = interaction between practice and appliance*
*appl * extr = interaction between appliance and extraction*

	practice	appliance	extraction	pract *appl	appl * extr
duration	p<0.0001	ns	p<0.0001	p=0.04	ns

Mean treatment duration in non-extraction cases was 1.6 years (s.d.= 0.4) and in extraction cases 2.0 years (s.d.= 0.4). ANOVA showed a significant effect ($p<0.0001$) for treatment duration between the non-extraction and the extraction group. Two-way interactions between extraction and appliance, however, were not significant. The interaction between practice and extraction could not be tested due to the small number of extractions per practice (lack of power). Figure 4.1 shows that in 2 practices there is a significant lower mean treatment duration (practice 5 and 6) for PPA while in 1 practice the reverse holds true (practice 9).

Figure 4.1
Mean treatment duration per treatment per practice (1-11) ± standard deviation

for number of patients per practice, see table 2.5
**p<0.005*
***p<0.001*
(t-test difference between FPA and PPA)

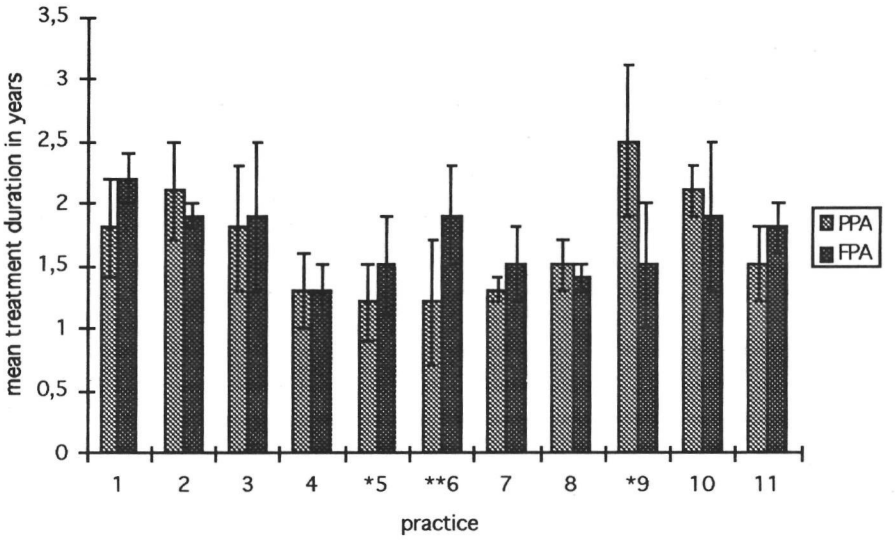
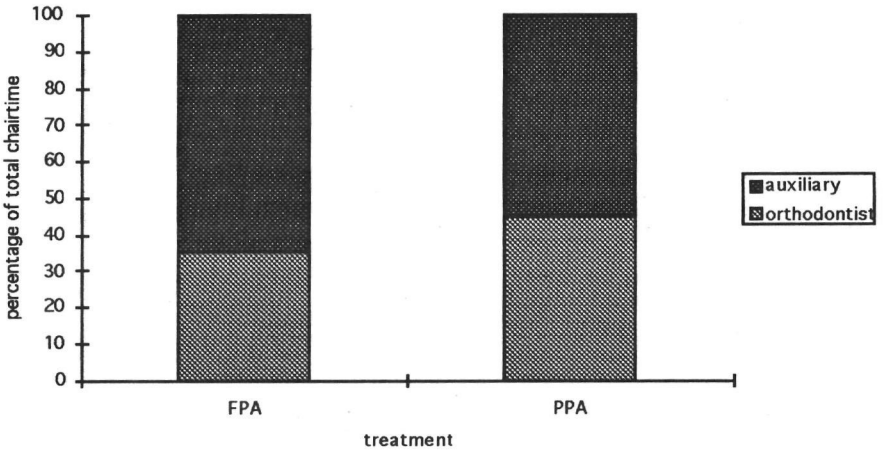


Figure 4.2 shows that in using a FPA 35% of the mean total chairtime is spent by the orthodontist and 65% by the auxiliary while in using a PPA the orthodontist spent 45% of the chairtime and the auxiliary 55%. The in terms of percentage different orthodontist involvement is significant (ANOVA, $p<0.0001$). ANOVA shows that there are highly significant inter-practice differences for the mean total chairtime ($p<0.0001$), the mean chairtime spent by the orthodontist ($p<0.0001$) and the mean chairtime spent by the auxiliary ($p<0.0001$). Comparing the chairtime for treatment using a FPA and using a PPA there is a significant difference in total mean chairtime ($p= 0.004$), no significant difference in the mean chairtime spent by the orthodontist and a highly significant difference in the mean chairtime spent by the auxiliary ($p<0.0001$). The total mean chairtime for treatment with a PPA was 12% less than with a FPA, orthodontists spent 5% less chairtime on the FPA than on the PPA and auxiliaries spent 25% less chairtime on treatment with a PPA than on treatment with a FPA. There were no significant interactions between practice and appliance with respect to chairtime.

Figure 4.2
Distribution of total chairtime between orthodontist and auxiliary per treatment modality
nFPA=48, nPPA=59



4.4 Discussion

Treatment duration

Most studies on the duration of orthodontic treatment with a fixed appliance are retrospective. They try to find factors that might influence the duration of treatment in selected cases. Several factors have been described in the literature: number of extracted premolars; number of broken appointments; pretreatment mandibular plane angle; pretreatment ANB angle; pretreatment Salzmann Index (Fink and Smith 1992); practitioner (Vig et al. 1990); treatment technique and motivation of the patient (Shelton et al. 1994) and appointment frequency (Alger 1988). In our prospective study the type of fixed appliance was allocated using balancing criteria (table 2.2). Since these criteria were well balanced over both treatment groups (table 2.7) as well as that both groups are comparable in cephalometric pretreatment values (table 2.8), we did not evaluate the influence of most of these possible factors separately on the duration of treatment with a fixed appliance. Extraction therapy was the only variable that was introduced additionally.

Fink and Smith (1992) reported that they had the impression that the time spent on detailed finishing was of major influence on the duration of treatment. The final result of detailed finishing is a

difficult factor to study objectively. It might be studied by using an index that scores the position of the teeth intra- and inter-maxillary. The Six Keys of Occlusion is one of these indices (Andrews 1989), as well as the PAR index (Shaw et al 1991) and the ITRI analysis (Haeger et al 1992). The results of both treatments as scored with these indices will be discussed in chapter 8, chapter 9 and chapter 10.

In our study no significant difference was found between the mean duration of treatment with a FPA and a PPA. The mean duration of that part of the orthodontic treatment that was done with fixed appliances in this study was 20 months: the average duration for a FPA was 21 months and for a PPA 19 months. The time used for pretreatment with removable appliances or retention was not included in the evaluation. There are no studies with which the present results on treatment duration can be fully compared. Fink and Smith (1992) included only patients treated with an edgewise appliance in a single phase (no functional and/or removable appliances). They found a mean treatment duration of 23.1 months. This result was similar to Algers (1988) mean treatment duration of 22 months for patients selected by similar criteria. Vig et al. (1990) reported a mean of 31 months for patients treated in two and three phases. Kattner and Schneider (1993) reported that in their study one practitioner used 20 months for FPA treatment and 25 months using a PPA, while the second practitioner used 28 and 30 months respectively. Shelton et al. (1994) found an average treatment duration for a group of patients treated with Tip-Edge of 12.8 months versus 20.8 months for a group treated with a conventional Begg appliance. All studies mentioned above were retrospective. Thus, the groups that were used to study the treatment duration were not balanced. Furthermore, treatment was carried out by a limited number of clinicians.

Table 4.1 shows a significant interaction between practice and appliance as related to duration of treatment. This means that in this study no overall effect could be found for treatment duration between FPA and PPA while this effect can be proven for separate practices. Figure 4.1 shows that in practice 5 and 6 treatment with the FPA significantly lasted longer while in practice 9 the reverse holds true. We could not find an explanation for these differences: the experience of the orthodontists with FPA and PPA was

comparable as well as the number of years they had been working in private orthodontic practice (table 2.5). Besides this, their groups of patients also were almost alike.

Roth (1976), Andrews (1976) and Magness (1978) claim that the use of the SWA reduces treatment duration in extraction cases 3 to 6 months. In our study this could not be confirmed. Treatment of patients who underwent extraction of premolars took longer than treatment of patients without extractions but this was not equal for both appliances. This does not mean, however, that the claims of the authors mentioned above are not valid. In our study treatment duration with a FPA was significantly less than with a PPA in one practice. This means that the authors mentioned above "in their hands" might very well be able to reduce treatment duration as claimed. Furthermore, in our study there was a discrepancy in the experience that the practitioners had in using the FPA and the PPA. All practitioners in our study were trained 4 years in using the PPA and had little experience in using the FPA (table 2.6). It is possible that after some years of experience in using the FPA differences in treatment duration can be found.

Chairtime

In the orthodontic literature no study was found with which the results of our study on chairtime can be compared. Roth (1986) claimed 20% reduction of chairtime using his appliance. He did not specify if he referred to the total chairtime (orthodontist + auxiliary) or to the orthodontist-time only. Neither did he mention whether pretreatment with functional and/or removable appliances was included. In our study treatment with the Roth appliance (FPA) resulted in a total chairtime that was 12% more than the time a patient spent in the chair when using a PPA ($p=0.004$). The orthodontists chairtime was reduced 5% using the Roth appliance (FPA) but this was not significant. Orthodontic auxiliaries on the other hand spent 25% more time on patients with the FPA than on patients with a PPA ($p<0.0001$). The chairtime that was recorded only included the time that was spent on placing and adjusting the fixed appliances. All other time consuming activities as consultation, making records, treatment planning, pretreatment with headgear or functional appliances, debonding procedures, retention phase were not included in this evaluation. Since in a treatment using a PPA the

wires have to be bent in order to get sufficient aligning and closing, it is believed that this would result in more chairtime for the patient, since bending wires would take more chairtime than placing straight preformed archwires. If in treatment with a FPA a tooth was not well aligned vertically and/or angulated, the wire was not to be bent like in a PPA treatment, but the bracket had to be replaced. In every practice bending of wires is done by the orthodontist. Placing of brackets is in some practices done by the auxiliary and in other practices by the orthodontist (chapter 2). Preparation for bracket placement (creating a dry working field and cleaning and etching of the enamel) as well as applying figure-8 steel ligatures is (nearly) always done by the auxiliary. This might explain why the auxiliaries spent more time on treatments with a FPA than on treatments using a PPA.

Since a lot of bending was not necessary anymore, it was expected that the orthodontist would reduce chairtime while working on the FPA. In our study, however, no significant reduction was seen. It is possible that the time that was spent on bending a wire in a PPA treatment was spent on careful bracket placement and replacement in a FPA treatment. Another explanation why in our study the claims regarding reduction of chairtime that were made by Roth could not be confirmed might be that all practitioners as well as their staff were relatively inexperienced is using the FPA.

4.5 Conclusion

In this part of the study treatment duration and chairtime were compared for treatment with either an FPA or a PPA. We could not find a significant reduction in treatment duration when using a FPA versus a PPA in neither non-extraction nor extraction therapy. We also could not find a significant reduction in chairtime of the orthodontist. Comparison of the chairtime for both treatment groups as used by the dental auxiliaries and of the total chairtime showed a significant longer chairtime for the treatment using a FPA.

4.6 References

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CHAPTER 5A

Assessment of apical root resorption using digital reconstruction.

This chapter is an edited version of: Reukers HAJ, Sanderink GCH, Kuijpers-Jagtman AM and van 't Hof MA: "Assessment of apical root resorption using digital reconstruction and subtraction radiography", and is accepted for publication in Dentomaxillofacial Radiology.

Abstract

Apical root resorption is usually diagnosed using a radiographic difference measurement on longitudinal intra-oral radiographs. An alternative method is described to standardise both radiographs by digitally correcting for different projection angles and tooth displacement due to orthodontic therapy. The aim of this study was to assess in vitro the accuracy of a mathematical computer-based reconstruction of two images that are not taken with the same recording geometry. The method is also applied in vivo on upper central incisors that were treated orthodontically.

In vitro, a golden standard for root resorption was developed from 10 extracted upper central incisors using callipers. Radiographs made under five different projections were reconstructed by two observers. The calculated percentage loss of length was compared to the golden standard. Upper central incisors (n=82) of 61 patients were radiographically evaluated for the prevalence and degree of apical root resorption after orthodontic fixed appliance therapy. After mathematical reconstruction the relative amount of reduction was calculated.

In vitro, the inter-observer error was 1.8%. The 95% confidence intervals for the difference with the golden standard are small. The in vivo duplicate measurement error was 2.2% and the correlation between duplicate measurements was 0.94. The mean degree of loss of tooth length was 7.8% (s.d. 6.9). The prevalence of root resorption corresponds well with existing literature.

It was concluded that digital reconstruction is a reliable method to correct for different projection angles and orthodontic movement in longitudinal dental radiographs.

5A.1 Introduction

Apical root resorption is a common finding after orthodontic treatment. In most patients root resorption is minimal and of no significant clinical importance (Kaley and Phillips 1991). Root resorption can be diagnosed radiographically and histologically. Histological studies report a high incidence of root resorption whereas clinical radiographic studies reveal a more varied incidence (Brezniak and Wasserstein 1993a,b). Furthermore, radiographic studies deal only with apical root resorption; buccal and lingual resorption are less perceptible on intra-oral radiographs (Dermaut and Demunck 1986).

Usually, diagnosis of apical root resorption is based on a radiographic difference measurement. Measurements can be executed in several ways. qualitative, quantitative and semi-quantitative. In a qualitative measurement the prevalence of root resorption can be assessed (dichotome assessment) but not the (relative) amount of lost tooth substance. In a semi-quantitative measurement, usually, the radiographs are compared with a predetermined ordinal scale (Levander and Malmgren 1988). The assessed scores then give an indication of the amount of root resorption. In a quantitative measurement the length of a tooth is measured on a radiograph before and after treatment so that the actual amount of resorption can be calculated after correction for projection enlargement has taken place. If correction for projection enlargement is not possible, the relative amount of resorption can be expressed as a percentage of the actual length. This can be defined as a semi-quantitative measurement as well.

Evaluator bias is a factor when interpreting conventional radiographs. It has been reported that lack of agreement in radiographic interpretation exists between evaluators (Petrowski et al 1996). There are even large discrepancies in the analysis of a single evaluator with himself at different time periods (Goldman et al 1974). Variability has been attributed to bias resulting from prior knowledge of clinical information, variation in film density, equivocal radiographic findings resulting in an increased rate of false negative and false positive diagnosis and observer education, training and experience. The use of computer aided image analysis procedures may be helpful in increasing the reproducibility of the radiographic interpretation.

Diagnosis of apical root resorption in orthodontically treated patients being examined over a period of time using non-standardised radiographs can be misleading. Variations can occur in the projection of the teeth on the film which complicates the interpretation of the apical region. Digital subtraction radiography may be able to solve this problem. Normally, success of the subtraction method is dependent on imaging reproducibility. Reproducibility is dependent on projection, radiographic density, and contrast. It has been shown by Ruttiman et al (1986) that differences in film density and contrast, within certain limits, can be corrected. Lack of reproducibility in positioning the patient used to be the greatest obstacle in the application of the subtraction technique. Occlusal stents are used to standardise the position of the source to the film and cephalostats are used to eliminate the rotations of the patient that are not controllable by the occlusal stent. For the consequences of orthodontic movement no mechanical device to preserve the imaging geometry is available. Dunn et al (1993) have shown that application of a mathematical technique to digital images of radiographs can be used within certain limits to establish correspondence between pairs of clinical images taken at different projection angles (up to 16 degrees angular disparity). Orthodontic movement causes angulation of one or more single teeth in relation to a radiograph. As a consequence, it should be possible with this technique to establish corresponding images of orthodontically moved single teeth.

In the literature no study has been reported in which apical root resorption in vivo has been assessed using mathematical reconstruction for different projection angles and digital subtraction radiography. The purpose of this study is to assess the reliability of semi-quantitatively measuring apical root resorption in vitro after mathematical reconstruction of the images and using digital subtraction for evaluation of the mathematical reconstruction. In vivo, the prevalence and degree of apical root resorption will be assessed using this technique on upper central incisors after orthodontic treatment in a selected sample of patients.

5A.2 Materials and methods

Data selection and editing
In vitro

For this part of the study 10 extracted permanent upper central incisors were used. The length of every tooth was measured using vernier callipers (Mitutuyo 505-633). Single radiographs were taken using a Siemens Sidexis intra-oral digital CCD system. The long axis of the teeth was placed parallel to the long axis of the CCD. Then, in 8 of the incisors apical root resorption was simulated using a bur. The length of every tooth was measured again with the same callipers. Of every single tooth another 5 radiographs were taken using the same CCD. The first picture was taken the same way as before "resorption", in the second picture the incisor was rotated around its long axis for 10 degrees, in the third picture the long axis of the tooth was angulated 15 degrees to the long axis of the CCD, in the fourth picture the long axis of the tooth was inclined (tipped) 15 degrees to the horizontal with its incisal edge touching the CCD while in the fifth picture this inclination was 25 degrees.

The image processing was done using the Windows based Emago/Advanced v.2.20 software package (Oral Diagnostic Systems, Amsterdam, the Netherlands). This package includes the required features (1) gamma correction to match the density distribution of an image to a reference image to improve subtraction, (2) geometric reconstruction to standardise projection geometry for digital subtraction and (3) linear, logarithmic and colour versions of digital subtraction radiography. For each tooth the images were displayed side by side on a SVGA monitor (1024x768 pixels). Gamma correction was carried out. Two evaluators noted, independently, by pointing with a mouse, 4 feature points (e.g. recognisable anatomical landmarks such as approximo-incisal angle, typical irregularity in the root canal, cemento-enamel junction, etc.) in the initial image of the tooth to be evaluated. The points were selected so, that the matching points could easily be selected on the second radiograph as well. Furthermore, the points had to be located as far from each other as possible. Next the corresponding locations in the second image ("after treatment") were identified. This procedure was repeated for each of the 50 radiographs. Emago used the reconstruction algorithm described by Dunn et al (1993) to

identify co-ordinates of each pixel of the first image in the second image. The second image was reconstructed and subtracted from the initial image using linear subtraction. The resulting subtraction image was evaluated. If there were (almost) no root- and crown structures discernible anymore (figure 1D and 2D) the construction of the reconstructed image was considered successful. If, on the other hand, root structures and/or the dental crown were still separately distinguishable, the subtraction was considered failing due to a non-optimal reconstructed image. The evaluators were allowed to carry out one retry to get a better fit between the original and the reconstructed image.

After successful reconstruction the tooth lengths could be measured from the geometric centre of the incisal edge to the midpoint of the apex using the measuring device in Emago Advanced. With this device the tooth length is presented as the number of pixels between both determined points. The percentage loss of tooth length was calculated as ((L1-L2)/L1)*100 (L1= tooth length before treatment; L2= tooth length at the end of fixed appliance therapy). The same formula was used to calculate the resorption as assessed using the callipers. This result would serve as a golden standard.

In vivo

Intra-oral radiographs of maxillary incisors made at the start of orthodontic treatment and at removal of the fixed appliance were available from 61 patients (29 boys and 32 girls). The sample was selected from a group of orthodontic patients who participated in a multi-practice clinical trial (Reukers and Kuijpers-Jagtman 1996). The radiographs were included in the evaluation if on a longitudinal set of radiographs at least one of the upper central incisors could be evaluated. Teeth were excluded from evaluation when the apex could not be detected due to cone-cutting, when the image of the apex was heavily distorted because of malpositioning of the filmholder or poor use of the bisecting-angle technique or when a tooth was endodontically treated. Radiographs also were excluded when the apices could not be evaluated due to failures in exposure of the film or film processing failures. Thus, 82 upper central incisors entered the evaluation. All radiographs were made using the bisecting-angle technique. E-speed film (Eastman Kodak Inc.,

Rochester, NY, USA) was used.

The radiographs were converted to digital images using a Kodak, Professional PCD Imaging Workstation and stored on Kodak Photo CD master disk. Corel Photo CD Lab (Corel Corp, USA) was used to convert the Photo CD images to a 8 bit .BMP format with a resolution of 256x384 pixels. The image processing was done using the method as described above, by one of the observers.

To determine the duplicate error and reliability of the method in vivo, 13 radiographs were evaluated once more after one day.

Statistical methods

In vitro

A paired t-test was performed to test for differences between both observers. Reproducibility was studied by means of the inter-observer error. The differences between the mean values of all 5 assessments and the golden standard were calculated for both observers to study systematic errors (t-test). The 95% confidence intervals (CI) for the difference with the golden standard were calculated.

In vivo

To check for the absence of unwanted learning influences during measurement a paired t-test was executed on the duplicate assessments. The duplicate error was calculated on $\sqrt{\sum d^2/2n}$ where d is the difference between duplicate determinations and n is the number of radiographs. The reliability of the measurements was expressed by the correlation between both duplicate assessments.

A root was considered resorbed if the calculated percentage loss of tooth length was at least two times the calculated duplicate error leading to an estimate of the prevalence of rootresorption on patient level. The mean degree of loss of tooth length was calculated. If both central incisors could be evaluated, their mean score was determined so that one score per patient entered the calculation as mean degree of loss of tooth length.

5A.3 Results

In vitro

The paired t-test showed no significant difference between both observers (t=0.6). The inter-observer error is 1.8%. The mean golden standard is 10.45% resorption (range 0% - 26.6%). The confidence intervals for the difference with the golden standard for the five separate projections is given in table 5A.1. Observer A carried out one retry to get a better fit between the original and the reconstructed image in 12 of the 50 reconstructions (24%), while observer B retried once in 9 reconstructions (18%).

Table 5A.1
Confidence intervals for the difference with the golden standard in percentages.
n=10 per assessment
diff ± sd = mean difference between the values as assessed digitally by either observer A or B and the golden standard ± the standard deviation
95% CI = 95% confidence interval
straight = long axis of the tooth placed parallel to the long axis of the CCD

assessment	observer A		observer B		A+B combined
	diff ± sd	95% CI	diff ± sd	95% CI	95% CI comb.
straight	-0.63 ± 0.23	-1.2 to -0.1	-0.66 ± 0.27	-1.3 to -0.1	-1.3 to -0.1
10° rotation	-0.37 ± 0.55	-1.6 to 0.9	-0.48 ± 1.06	-2.9 to 1.9	-2.2 to 1.4
15° angulation	0.30 ± 0.62	-1.1 to 1.7	-0.12 ± 0.72	-1.7 to 1.5	-1.4 to 1.6
15° inclination	-1.46 ± 0.50	-3.6 to -0.3	-1.64 ± 0.56	-2.9 to -0.4	-3.2 to -0.4
25° inclination	-0.43 ± 0.86	-2.4 to 1.5	-0.83 ± 0.70	-2.4 to 0.8	-2.4 to 1.3

In vivo

No tooth had to be excluded due to non-optimal reconstruction. The results of the duplicate assessments are given in table 5A.2. The paired t-test showed no significant systematic error (t=1.4). The calculated duplicate error of the relative loss of total tooth length is 2.2%. The correlation between the first and second assessment is 0.94 (p=0.01). The prevalence of root resorption (i.e. loss of tooth length >4.4%) in this orthodontically treated group of patients is 66%. Of all of the evaluated upper central incisors 63% showed rootresorption. The mean degree of loss of tooth length of upper central incisors is 7.8% (standard deviation = 6.9). Figure 5A.2 shows a reconstructed image of the left upper central incisor in a patient with obvious apical root resorption.

Table 5A.2
Duplicate assessment values (n=13), representing the percentage of loss of overall tooth length.

	assessment 1	assessment 2	difference
mean	8.2	7.0	1.2
standard deviation	8.5	7.3	3.0

Figure 5A.1
Clinical example of the construction of a reconstructed image of the left upper central incisor.
A. Pre-treatment radiograph of upper central incisors
B. Post-treatment radiograph of upper central incisors
C. Reconstructed post-treatment radiograph of tooth 21
D. Difference image of radiograph A minus C. Note that almost no root structure of tooth 21 is discernible anymore; this means that the reconstruction of image B into image A has been successful. Tooth length of tooth 21 in A is 318 pixels, in C 307 pixels. The length reduction of 3.5% is less than two times the duplicate error and thus considered not clinically significant.

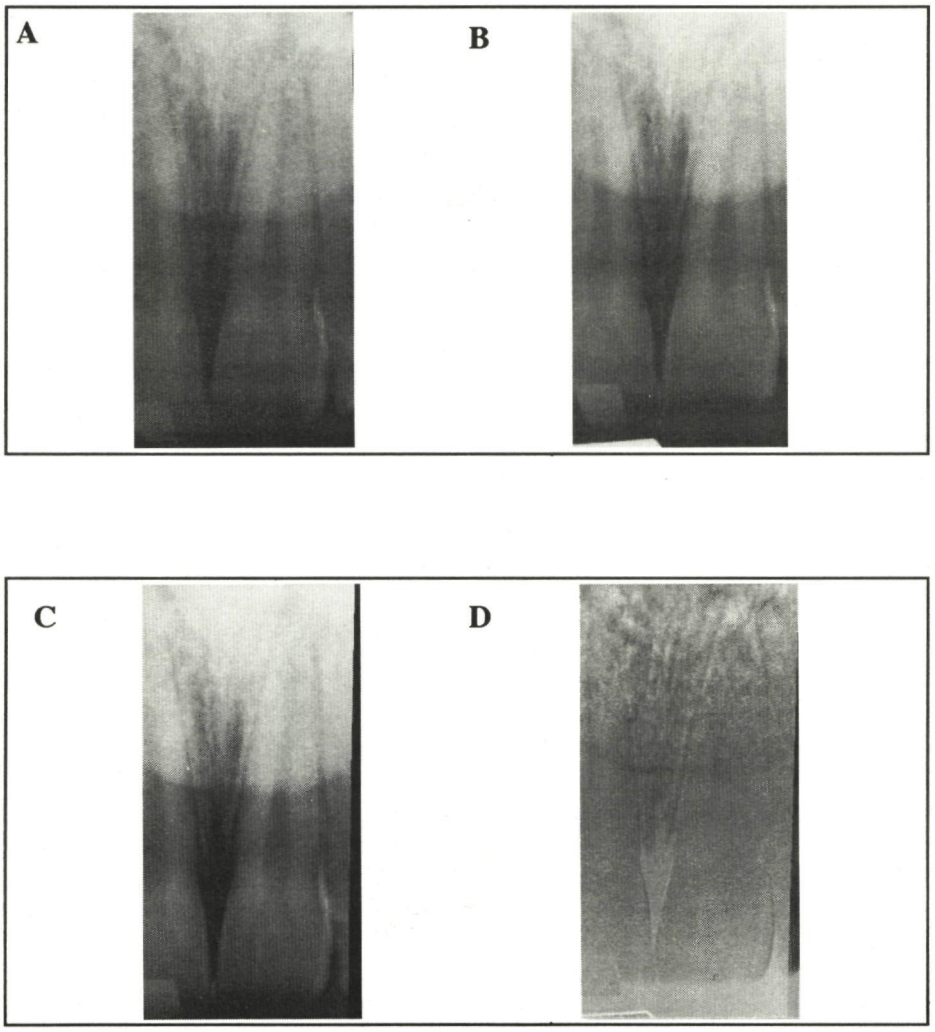
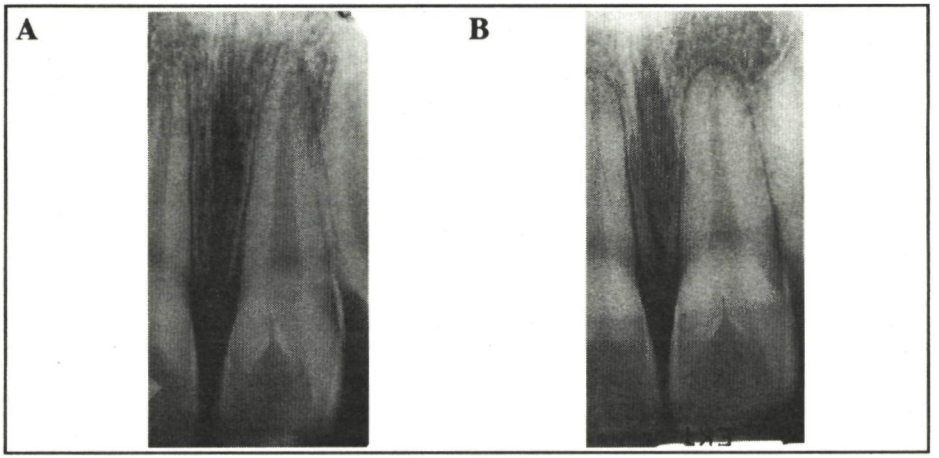
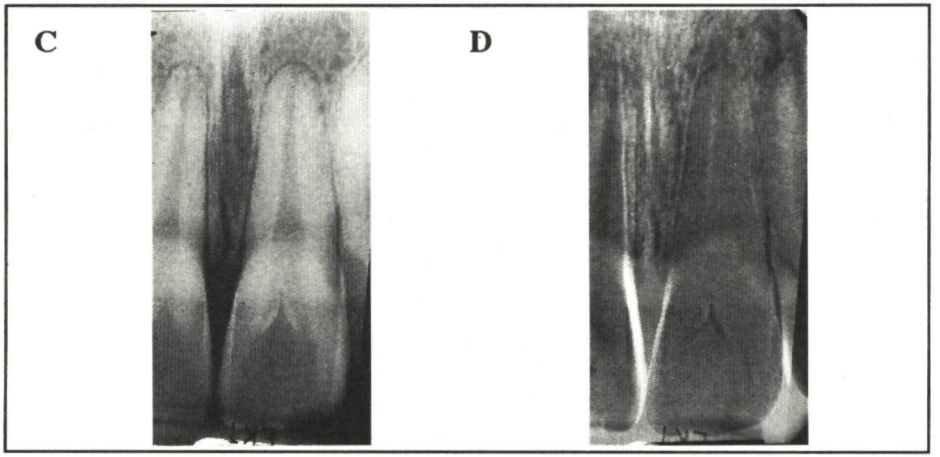


Figure 5A.2
Example of a patient with obvious apical root resorption.
A. Pre-treatment radiograph
B. Post-treatment radiograph
C. The 21 is corrected for projection and orthodontic movement
D. In the difference image (A-C) few root structures are distinguishable. The original length of the 21 is 301 pixels (A) and the reconstructed length after orthodontic treatment 254 pixels (C) resulting in a relative loss of tooth length of 15.6%.





5A.4 Discussion

In this study apical root resorption of maxillary incisors after fixed appliance therapy was evaluated radiographically using digital image reconstruction. The reconstruction was evaluated using subtraction radiography.

The 95% CI for the difference with the golden standard is

rather small for each projection that was simulated. These small intervals indicate that this in vitro study is sufficiently powerful to study the influence of different simulated projection errors on the reconstruction of post-treatment radiographs of single upper central incisors. This means that if a tooth is orthodontically moved within certain limits (10° rotation, 15° angulation or 25° inclination) or if the central X-ray beam varies within these limits this method is reliable.

The result of the duplicate error assessment in the in vivo part of the study indicates a rather small duplicate error (2.2%). It must be emphasised, however, that this is a measure of the "technical" error of the method, i.e. digitally producing reconstructed images and measuring the number of pixels in a row after reconstructing and evaluating a selection of the radiographs twice. For a total duplicate error assessment it would have been necessary to make 2 different radiographs, instead of one, each time. Mainly because of ethical considerations (i.e. unnecessary double exposure to potentially harmful X-rays) this was rejected. In a previous study, however, Dunn et al (1993) made double exposures from volunteers. They showed that the mathematical technique as implemented in the Emago/Advanced software that we applied, can be used to establish correspondence between pairs of clinical images taken at different projection angles and to produce reconstructed images comparable with images taken with occlusal stents.

Sampling the analogue image onto a larger matrix would benefit the spatial resolution of the digital image. Theoretically, this would result in more accurate measurements. On the other hand it would lead to a situation where it would not be possible anymore to display the pre- and post-treatment image on one computer screen anymore. This would probably negatively influence the accuracy in identifying feature points needed to reconstruct the images.

A major obstacle in the use of digital subtraction in orthodontics used to be geometric reproducibility. Although it is possible to preserve the imaging geometry using mechanical devices (stents, cephalostats), it has not yet been possible to correct for the essential feature of orthodontics: tooth movement. Dunn and van der Stelt (1992) have shown that invariants on a radiographic image can be used to describe the relationship of pairs of images with angular disparity of up to 16 degrees. In a follow-up study Dunn et

al (1993) showed that this invariant based registration procedure can be used to establish correspondence between pairs of clinical images taken at different projection angles. In our study we have shown that this invariant based procedure is well applicable in single teeth that are orthodontically moved within certain limits. Identification of invariants on orthodontically moved teeth is not always simple. In the in vitro part of this study both observers made one retry in 24% and 18% of the cases, respectively. In all of these cases the second subtraction was deemed good enough. The main problem (in vivo) was to find reliable landmarks that have sufficient distance between each other especially when the incisal edge of an incisor is not completely depicted on both radiographs while the apex is.

The result of the reconstruction was evaluated using digital subtraction of the (original) first image and the (reconstructed) second image. In an ideal case with no root resorption, as a result, a tooth should be visible as one unpatterned structure. Setting a criterium for success or failure of the reconstruction after subtraction is arbitrary and subjective. As the main criterium for success we considered a good fit of the crown structure together with the cervical one third part of the root. These are the structures that do normally not change in form during orthodontic treatment. If these structures were still separately visible, reconstruction was considered failing. Minor irregularities (e.g. figure 5A.2D: pulp canal still slightly visible) were permitted for a successful reconstruction. Visibility of the periodontal ligament (PDL) after reconstruction was not considered as a failure since the PDL is widened due to orthodontic movement. In spite of this arbitrary and subjective element in the evaluation of the subtracted images, the correlation between the first and second assessment was 0.94 ($p=0.01$).

The absolute amount of resorption could not be calculated in the in vivo part of the study because we had no reference to determine the enlargement factor. The relative amount of resorption was measured from the overall length and was 7.8%. This value is not comparable to a calculation of the relative amount of resorption as made by Dermaut and De Munck (1986). They calculated the relative resorption (18%) from the cemento-enamel junction to the apex. This calculation automatically leads to a higher relative degree of loss of length when the absolute amount of resorption is equal. If our calculation is corrected for the difference between root length and

overall tooth length (mean over-all length 24 mm; mean root length 12.4 mm (Sicher and DuBrul 1970)) the relative root resorption would be 15.2%. Converted to absolute figures this would be about 1.9 mm loss of root-/tooth-length. This is in accordance with most other studies on the amount of root resorption on upper central incisors after orthodontic fixed appliance therapy (Brezniak and Wasserstein 1993a).

The prevalence of apical root resorption as found in this study is also in accordance with the findings in the literature. Reported apical root resorption on orthodontically treated maxillary incisors ranges from 39 to 99.08% of the patients involved and from 34 to 92.6% of the treated teeth (Brezniak and Wasserstein 1993a). In our study this was 65.6% and 63.4% respectively. As was also found in the study of Remington et al (1989), the present investigation demonstrates that few cases show extreme root shortening during orthodontic fixed appliance therapy. Only 2 out of the 82 evaluated incisors showed loss of tooth length of more than 25% while in the mentioned study 4 out of 200 central upper incisors showed resorption of more than one third of the root.

5A.5 Conclusion

This study suggests that the application of digital reconstruction to radiographs of orthodontically treated central upper incisors can render a good diagnostic performance in detecting the prevalence and relative degree of apical root resorption. The applied method is reliable and shows a small duplicate measurement error. The prevalence and degree of root resorption in a selected group of patients were comparable with other findings in the literature. Future studies should explore the possibilities to correct for magnification of the images so that the absolute amount of apical root resorption can be assessed using this method.

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CHAPTER 5B

Apical root resorption during orthodontic treatment with a fully programmed appliance versus a partly programmed appliance

This chapter is an edited version of: Reukers HAJ, Sanderink GCH, Kuijpers-Jagtman AM and van 't Hof MA: "Radiographic evaluation of apical root resorption in a randomized clinical trial with two different types of edgewise appliances.", and is accepted for publication in Journal of Orofacial Orthopedics.

Abstract

The prevalence and degree of apical root resorption after treatment with a fully programmed edgewise appliance (FPA; n=32) and a partly programmed edgewise appliance (PPA; n=29) in a randomized multipractice clinical trial were compared radiographically. Radiographs of the maxillary incisors were made before and after active treatment with fixed appliances using the bisecting angle technique. To correct for different projecting angles the pairs of radiographs were digitally reconstructed. The degree and prevalence of root resorption were assessed. The mean amount of loss of tooth length was 8.2% for the patients treated with FPA and 7.5% for the patients treated with PPA. No statistically significant differences could be assessed between both groups at the end of active treatment. The mean prevalence of apical root resorption was 75% for the patients treated with FPA and 55% for the patients treated with PPA. Statistical evaluation showed no significant differences. We concluded that the prevalence and degree of root resorption is independent of the appliances as used in this study.

5B.1 Introduction

Apical root resorption is a common finding after orthodontic treatment (Deshields 1969, Reitan 1974, Ryhg 1977, Linge and Linge 1991, Hendrix et al 1994). In most patients root resorption is minimal and of no significant clinical importance (Kaley and Phillips 1991). Maxillary incisors appear to be the most frequently and severely affected, although incidence of this pathologic response may also be seen in other areas of the dentition (Deshields 1969). Histological studies report a high incidence whereas clinical radiographic studies reveal a more varied incidence (Brezniak and Wasserstein 1993a,b).

In an exhaustive review Brezniak and Wasserstein (1993a,b) pointed out that a variety of conditions may be related to root resorption. Risk factors that might contribute to external root resorption include individual predisposing factors as involvement of genetic predisposition and health (Massler and Malone 1954, Newman 1975), sex of the patient (Phillips 1955, Kjaer 1995), deviating root form (Kjaer 1995), traumatized teeth with signs of root resorption before orthodontic treatment (Malmgren et al 1982, Linge and Linge 1991), adverse habits (Odenrick and Brattstrom 1985, Linge and Linge 1991), age of the patient and stage of root formation at onset of treatment (Rosenberg 1972, Reitan 1974), time of treatment with rectangular archwires and/or Class II elastics (Linge and Linge 1991), overjet (Linge and Linge 1991), hormonal imbalance (Goldie and King 1984), the type of orthodontic appliances used (Linge and Linge 1991), the type of tooth movement (Dermaut and DeMunck 1986, Goldin 1989), the applied forces (Reitan 1964) and treatment duration (Reitan 1974, McFadden et al 1989, Linge and Linge 1991).

It might be possible that a straight wire appliance (SWA) causes less jiggling and roundtripping and therefore less root resorption as compared to the standard full edgewise technique. It has also been reported by Andrews (1976), Roth (1976) and Magness (1978) that the use of SWA has reduced treatment time 3 to 6 months and this could result also in reduced apical root resorption.

Prospective studies that compare apical root resorption as caused by two different types of edgewise appliances are rare. Kaley and Phillips (1991) studied factors related to root resorption in 200 patients that had received comprehensive orthodontic treatment with

the .022" slot Roth appliance. They reported severe resorption of both maxillary incisors in 3% of the patients and of other teeth in less than 1% of the patients. Comparing the patients with severe resorption with randomly selected controls it was shown that approximation of the maxillary incisor roots against the lingual cortical plate, maxillary surgery and root torque are risk indicators for resorption related to treatment with an edgewise appliance. Alexander (1996) evaluated differences in the extent of root resorption between continuous arch and sectional mechanics using a combination of .018" and .022" slot Roth appliances in a prospective study. Both treatment groups exhibited the same levels of resorption.

A prospective randomized clinical trial was designed to compare the effects and treatment results of treatment with a fully programmed edgewise appliance (FPA) with treatment with a partly programmed edgewise appliance (PPA). The purpose of a part of this study that is presented here is to compare the prevalence and degree of apical root resorption after orthodontic treatment with a fully programmed edgewise appliance (FPA) and with a partly programmed edgewise appliance (PPA) in a randomized multi-practice trial.

5B.2 Materials and methods

Data selection and editing

149 Class II patients entered the trial. They were referred for treatment to one of the 11 participating orthodontists during the intake period of the trial. Intra-oral radiographs of maxillary incisors before orthodontic treatment and at removal of the fixed appliance were evaluated. The radiographs were included in the evaluation if on a longitudinal set of radiographs at least one of the upper central incisors could be evaluated. Teeth were excluded from evaluation when the apex could not be detected due to cone-cutting, when the image of the apex was heavily distorted because of malpositioning of the filmholder or poor use of the bisecting angle technique and when a tooth was endodontically treated. Radiographs also were excluded when the apices could not be evaluated due to failures in exposure of the film or film processing failures. From the original 149 patients 2 moved to another place and could not continue their

treatment according to the protocol, 7 patients were excluded for evaluation because of premature debonding due to poor oral hygiene and 79 patients were excluded because their radiographs were not of a quality sufficient to evaluate. Scores of 61 patients (nFPA=32, nPPA=29) with 82 upper central incisors (nFPA=43, nPPA=39) were evaluated. This selection will, however, not introduce a selection bias in the comparison of FPA versus PPA.

To correct for different projection angles that are a consequence of the bisecting-angle technique, the radiographs were digitally processed according to the method as described by Reukers et al (1997).

After reconstruction of the digital images, the (relative) tooth lengths could be measured as the number of pixels on the screen. The percentage loss of tooth length was calculated as (L1-L2)/L1*100 (L1 = tooth length before treatment; L2 = tooth length at the end of fixed appliance therapy). To determine the systematic error, the duplicate error and reliability of the method, 13 randomly selected radiographs were evaluated twice with an interval of one day.

Statistical methods

To check for systematic differences in the duplicate assessments a paired t-test was executed. The duplicate error was calculated using $\sqrt{\sum d^2/2n}$ where d is the difference between duplicate determinations and n is the number of radiographs. The reliability of the measurements was determined by assessing the correlation between both duplicate assessments.

The mean degree of loss of tooth length was calculated on patient level. If both central incisors could be evaluated, their mean score was determined so that one score per patient entered the calculation. The skewed distribution could be transformed to normality by taking the square root. The comparison of FPA with PPA was done using ANOVA. Breznıak and Wasserstein (1993a,b) made clear that no uniformity of influencing factors exists. Therefore the only covariable entered in the ANOVA is chosen to be the orthodontic practice due to the multicentre aspect of the trial. In order to quantify the difference in mean resorption between both treatment types the 95% confidence interval (CI) was calculated.

The prevalence of root resorption was determined. A root was considered resorbed if the calculated percentage loss of tooth

length was at least two times the calculated duplicate error. Statistical comparisons were made using the chi-square test. The 95% CI for the difference in mean prevalence of resorption between both treatment types was calculated.

An alpha level of 0.05 was used to determine the statistical significance of the applied tests.

5B.3 Results

The results of the duplicate assessments are given in table 5B.1. The paired t-test showed no significant systematic error (t=1.4). The calculated duplicate error was 2.2%. The correlation between the first and second assessment was 0.94 (p=0.01).

Table 5B.1
Duplicate assessment values of the degree of resorption, represented by the percentage of loss of overall tooth length (n=13).

	assessment 1	assessment 2	difference
mean	8.2 ± 8.5	7.0 ± 7.3	1.2 ± 3.0

The over-all mean degree of loss of tooth length was 7.8%±6.9. For patients treated with FPA this was 8.2%±6.4 and for patients treated with PPA 7.5%±7.6 (table 5B.2).

Table 5B.2
Prevalence and degree of apical root resorption in upper central incisors using fully programmed or partly programmed edgewise appliances
- prevalence of root resorption is derived from the number of patients with root resorption divided by the number of patients examined)
- degree of root resorption is derived from the calculated percentage loss of overall tooth length

	FPA (n=32)	PPA (n=29)	significance
prevalence	75%	55%	ns
degree	8.2 ± 6.4	7.5 ± 7.6	ns

ANOVA did not reveal any significant difference between influence of treatment type (p=0.4) and individual orthodontic practice (p=0.2) on the mean degree of root resorption. The 95% CI for the difference in mean resorption between both treatment types ranged from -2.8% to 4.3%.

The overall mean prevalence of patients with loss of tooth length (e.g. more than 2 x duplicate error) was 65.6%, for patients treated with FPA 75% and for patients treated with PPA 55% (table 5B.2). Chi square testing showed no significant differences (p=0.1). The 95% CI for the difference in mean prevalence of resorption between both treatment types ranged from -4% to 44%.

5B.4 Discussion

In this study apical root resorption of maxillary central incisors after two different types of fixed appliance therapy was evaluated. The pre- and post-treatment radiographs were taken with a non standardized bisecting angle technique. This technique was chosen for radiographic examination because of the multi-practice design of the trial. Almost all participating orthodontists used a short cone X-ray tube for solo radiographs in the frontal region. It was not possible to arrange long cone tubes for this trial only. For this reason a digital geometrical reconstruction technique was applied to the post-treatment radiographs so that they could be compared quantitatively with the pre-treatment radiographs (Reukers et al 1997). The result of the duplicate error assessment of this new technique indicates a rather small duplicate error (2.2%). It must be emphasized, however, that this is a measure of the "technical" error of the method, i.e. digitally producing reconstructed images and measuring the number of pixels in a row after reconstructing and evaluating a selection of the radiographs twice. In a previous study (Reukers et al 1997) the accuracy of this method has been assessed using a golden standard. It proved to be sufficiently accurate and precise to evaluate apical root resorption on non standardized radiographs.

The absolute amount of resorption could not be calculated because we had no reference to determine the enlargement factor. The relative amount of resorption was measured from the over-all tooth length and was 7.8% for both groups together. This value is not comparable to a calculation of the relative amount of resorption as made by Dermaut and De Munck (1986). They calculated the relative resorption (18%) from the cemento-enamel junction to the apex. This calculation automatically leads to a higher relative degree of loss of length when the absolute amount of resorption is equal. If our calculation is corrected for the difference between root length and overall tooth length (mean overall tooth length 24 mm; mean root length 12.4 mm (Sicher and DuBrul 1970)) the relative root resorption would be 15.2%. Converted to absolute figures this would be about 1.9 mm loss of root-/tooth-length. This is in accordance with most other studies on the amount of root resorption on upper central incisors after orthodontic fixed appliance therapy (Brezniak and Wasserstein 1993a).

Alexander (1996) studied differences in the extent of root resorption between continuous arch and sectional arch mechanics in a group of 56 patients presenting with Class I malocclusions and anterior crowding requiring the extraction of four first premolars. All patients were treated with a programmed Roth prescription type appliance with .018" slot size and .022" slot size in the remainder of the dentition. Radiographic evaluation of the anterior teeth showed that both treatment groups exhibited the same levels of resorption. Both the study of Alexander and our study suggest that apical root resorption may be due to individual variation and not to round tripping of teeth so often assumed.

As was also found in the study of Remington et al (1989), the present investigation demonstrates that few cases show extreme root shortening during orthodontic fixed appliance therapy. Only 2 of the 82 evaluated incisors showed loss of tooth length of more than 25% while in the mentioned study 4 out of 200 central upper incisors showed resorption of more than one third of the root. Kaley and Phillips (1991) studied a group of patients that were treated in almost the same manner as our FPA group using the same appliance. They found that 3% of the patients showed blunting of the roots of the maxillary incisors beyond one-fourth of the root length after treatment as assessed on panoramic X-rays.

The 95% CI for the difference in mean resorption between both treatment types ranges from -2.8% to 4.3%. This small interval indicates that this trial is sufficiently powerful to study the influence of different types of orthodontic treatment on the degree of apical root resorption, despite the circumstance that less than half of the patients that started the trial could be evaluated for this specific part of the trial.

In this study 65.6% of the patients showed more or less loss of root length of the central maxillary incisors after treatment with fixed appliances. This frequency is comparable in both fully programmed- and partly programmed-cases. The prevalence of apical root resorption as found in this study is comparable to the findings in the literature. Reported apical root resorption on orthodontically treated maxillary incisors, ranges from 39 to 99.08% of the patients involved (Brezniak and Wasserstein 1993a). The 95% CI for the difference in mean prevalence of resorption between both treatment types in our study, however, ranges from -4% to 44%. This

means that the number of patients as evaluated after treatment is not sufficient to study the influence of different types of orthodontic treatment on the prevalence of apical root resorption in a powerful way. Initially this would not be the case but due to protocol violation two of the participating orthodontists did not make apical radiographs of the upper frontal region. Enhancing the power of the study by using the OPT radiographs was rejected because of the poor imaging quality in the frontal region.

5B.5 Conclusion

From the findings of this study it can be concluded that the degree of root resorption is independent of the appliance used i.e. FPA versus PPA even though they achieve correction of the malocclusion by different means. It is more likely that root resorption is a function of individual susceptibility than a result of appliance design.

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CHAPTER 6

Discomfort during orthodontic treatment with a fully programmed appliance versus a partly programmed appliance

Abstract
Patients undergoing orthodontic treatment can experience treatment related discomfort. Discomfort can vary in degree and symptoms. This variety could, among other reasons, be explained by the type of appliance that is used. In a randomized multi-practice clinical trial the perception of orthodontic treatment was compared between treatment with a fully programmed edgewise appliance (FPA) and a partly programmed edgewise appliance (PPA). At 3 different treatment stages the 149 patients that entered the trial were asked to fill in a questionnaire that was designed to investigate their perception of orthodontic treatment. By using factor analysis the data-set was reduced to 2 main factors: physical and psychological discomfort. ANOVA showed no significant differences for these factors between both treatment modalities or between the participating orthodontic practices. At the end of treatment patients of both groups were about equally satisfied about the treatment result. No significant differences in patient satisfaction could be assessed between both treatments or between the participating orthodontists.

6.1 Introduction

Patients undergoing orthodontic treatment report different types of discomfort. Discomfort shows itself in a variety of symptoms such as pain, difficulty in mastication and/or speech, hypermobility of teeth, soreness of the oral soft tissues, headache, poor maintenance of oral hygiene and altered facial appearance. The level of discomfort caused by orthodontic appliances has a wide range of individual response, reflecting the subjectivity of the pain response (Lew 1993). Generally, the amount of discomfort (e.g. pain) peaks at 24 hours after insertion of either orthodontic separators or arch wires, but decreases to baseline levels by 7 days (Ngan et al 1989). The perception of general pain intensity, analgesic consumption, pain when eating and the influence of discomfort on daily life are greater in girls than in boys. Patients younger than 13 years report pain less frequently than older patients and the highest frequency of pain was found in the group of 13 to 16 year old. Furthermore, the pain intensity would not differ among the age groups (Scheurer et al 1996). Light forces are reported to be the key to minimizing pain as a concomitant of orthodontic treatment (Proffit 1993). Kaneko et al (1990) found no significant difference in the pain experience caused by either a stainless steel or a nickel titanium initial archwire. A varying degree of discomfort might also be explained by the type of appliance that is used. Roth (1976) suggested that the use of a Straight Wire Appliance would lead to much less discomfort for the patient as compared to the use of a conventional full edgewise appliance. He suggested that this was due to less jiggling and roundtripping. Furthermore it might be expected that treatment with straight archwires without loops would lead to less discomfort regarding soreness of the oral tissues, the maintenance of oral hygiene, mastication of firm food and facial appearance.

A survey to study the satisfaction of Dutch orthodontically treated patients (DMO/Lagendijk 1993) showed an overall satisfaction concerning orthodontic treatment by orthodontists of 8.2 on a scale from 0 to 10.

A search of the orthodontic literature yields no previous studies that compare discomfort as caused by two different types of edgewise appliances. The purpose of the present study is to compare the perception of discomfort due to orthodontic treatment

with a fully programmed appliance (FPA) and a partly programmed appliance (PPA) in two groups of patients.

6.2 Materials and methods

Data selection and editing

According to the trial protocol (chapter 2) a questionnaire designed to investigate patients' perception of orthodontic treatment (appendix D) was posed 3 times during the course of treatment with either FPA or PPA. At the 4th visit after placement of the brackets, at the 10th visit after placement of the brackets and at the day the fixed appliance was to be removed, the inquiry forms were given to all patients that entered the trial (n=149). The patients were asked to answer the questions and to return the forms before making a new appointment.

The questionnaires were a compilation of 33 questions. Question 1-17 were designed to assess whether both treatment groups were, initially, comparable in terms of expectations and mentality for treatment. Question 18-22 and 25-27 were designed to investigate various ways of discomfort as can be experienced during orthodontic treatment. Question 23, 24 and 28 inquired about the eating pattern during treatment, whereas question 29-32 asked about oral hygiene procedures. Finally, question 33 might be informative about patient satisfaction.

Statistical methods

Questions 1-17 were submitted to the t-test in order to compare both treatment groups. Factor analysis was applied for data reduction on questions concerning discomfort (question 18-32). A factor was used in further analysis if Cronbachs $\alpha > 0.6$. Differences between FPA and PPA for relevant factors and relevant items were tested by 2-way ANOVA (treatment and orthodontist).

An alpha level of 0.05 was used to determine the statistical significance of the applied tests.

6.3 Results.

The first questionnaire was returned by 142 patients (response rate 95.3%; nFPA=71, nPPA=71) ; the second

questionnaire by 122 patients (response rate 81.8 %; nFPA=62, nPPA=60) and the third by 121 patients (response rate 81.2%; nFPA=58, nPPA=63).

None of the questions 1-17 were found to be different for FPA versus PPA. By factor analysis two main factors could be extracted from the remaining questions. Combining question 22, 26 and 27 (table 6.1) resulted in a factor we called "physical discomfort". Combining question 18, 19 and 20 (table 6.2) resulted in a factor we called "psychological discomfort". The reliability coefficient of the scales was 0.63 and 0.78 respectively (Cronbachs alpha). ANOVA showed no significant differences between PPA and FPA for both factors in either of the questionnaires at the three different moments they were given. The questions that were not included in a relevant factor were considered to be failing and therefore they were not used for further evaluation in this chapter.

Table 6.1
Factor "physical discomfort" (n=385)

question	
22	Does your appliance cause pain?
26	Does the appliance press upon your toothgums?
27	Does the appliance prod your toothgums ?
	Cronbachs alpha = 0.63

Table 6.2
Factor "psychological discomfort" (n=385)

question	
18	Did you or didn't you feel annoyed about wearing an orthodontic appliance?
19	How do you think about your appliance?
20	How do you think others think about your appliance?
	Cronbachs alpha = 0.78

The mean patient satisfaction (question 33) at the end of active treatment was 1.3 (s.d. 0.5) on a scale of 1 (very satisfied) to 4 (very unsatisfied). ANOVA showed no significant differences between both treatment groups or between the participating orthodontic practices.

6.4 Discussion

In this chapter the perception of orthodontic treatment as experienced by patients during two different types of fixed appliance therapy was evaluated using questionnaires.

Patients were treated with either a fully programmed appliance or a partly programmed appliance (parallel-group design). To obtain more accurate information about the difference between FPA and PPA a split mouth design or a cross-over study would be preferable since wearing an orthodontic appliance will nearly always cause discomfort to the patient. Due to the nature of orthodontic treatment, however, a split mouth design is almost impossible to apply. A solution for this problem could be an upper/lower jaw split design. It is very difficult, however, for a patient to distinguish precisely which jaw gives discomfort. Furthermore the type of discomfort and pain in the upper and lower jaw can differ because of anatomical differences. Therefore such a design is not very reliable. In a cross-over design it would be necessary to remove one appliance and rebond the other appliance at about halfway through the treatment. Such a study design is restricted by ethical considerations. It is not only very time consuming and causing extreme discomfort to the patient, but also potentially harmful to the enamel of the teeth involved. Furthermore, it would interfere with the testing of the other hypotheses of the entire clinical trial.

To explore the structure of the questionnaire and reduce the data-set, we employed factor analysis. Factor analysis is a correlational technique used to identify factors that can be used to replace interrelated variables (in this case questionnaire questions). Results of factor analysis of the questions indicated a multi-factor structure, with the two largest factors accounting for 36.7% of the variance in the entire data set. Remaining factors accounted for small portions of the total variance and were largely non-interpretable. For the two factors assessment of internal consistencies yielded Cronbachs alpha values of 0.78 (psychological discomfort) and 0.62 (physical discomfort).

In the literature there are very few studies to which this one can be compared. Most studies deal only with pain resulting from orthodontic treatment (Ngan et al 1989, Ngan et al 1994, Kaneko et al 1990, Scheurer et al 1996). They show that most patients more or

less suffer pain following placement of an archwire or a separator. Scheurer et al (1996) showed that 4 hours after insertion of an 0.016 inch nickel-titanium archwire 64.7% of the patients reported pain, increasing to 94% of the patients after 24 hours. This score gradually decreased to 25.5% after 7 days. Kaneko et al. (1990) found no significant difference in the pain experience between four kinds of archwires: 0.0175" braided wire, 0.012" stainless steel wire, 0.016" and 0.016" x 0.022" nickel titanium alloy wire, while Jones and Chan (1992) found the same for two kinds of archwire (0.014" nickel titanium alloy wire and 0.015" multiflex steel wire). Wires of this kind were also used in this trial; the nickel titanium alloy wires only in FPA treatment. No difference was found in our study either.

Lew (1993) also studied the discomfort, experienced by Asian adults while undergoing orthodontic treatment, using questionnaires. Pain from teeth was experienced by 91% of the patients. He found that discomfort with respect to oral soft tissues and teeth was transient and did not exceed 7 days. The results in our study suggest that discomfort is experienced irrespective to the type of fixed appliance that is used. Furthermore, the application of loops in the archwire does not seem to be extra annoying to the patient who undergoes orthodontic therapy with a fixed appliance. It must be stressed, however, that no patient really has been able to compare both appliances but probably any kind of orthodontic appliance will be uncomfortable to some extent.

The mean patient satisfaction at the end of treatment (question 33) was high. There was no significant difference between both treatment modalities or between the participating orthodontists. This question was answered immediately after the appliance was removed. Normally, a high satisfaction rate can be expected then because of the relief that all the discomfort is over. Secondly, most patients will not be totally honest about how they really feel because "they do not want to let the doctor down". Furthermore, if front teeth are well or better aligned than at the start of treatment, most patients are happy with the result irrespective to the situation in the posterior region. In a survey to study the satisfaction of Dutch orthodontically treated patients (DMO/Lagendijk 1993) a similar question was asked more than one year after the orthodontic treatment was finished. Satisfaction concerning orthodontic treatment by orthodontists then scored 8.2 on

a scale from 0 to 10.

6.5 Conclusion

In this study no differences were found for physical and psychological discomfort resulting from orthodontic treatment with a partly programmed and a fully programmed fixed appliance.

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CHAPTER 7

Effects of fully programmed and partly programmed edgewise appliances on clinical periodontal parameters

Abstract

The most commonly observed effect of orthodontic treatment on periodontal health is gingival enlargement that occurs soon after placement of a fixed appliance. In this chapter the effects of orthodontic treatment on the surrounding gingiva using either a fully programmed edgewise appliance (FPA) or a partly programmed edgewise appliance (PPA) were compared. Assessment of the pocket depth was carried out at the day the fixed appliances were inserted and at the first visit after their removal. The Community Periodontal Index of Treatment Needs (CPITN) classification was used for further evaluation. Assessment of the Plaque Index (PI) and the modified Gingival Index (mGI) was carried out at visit 1, 4, 7, 10, 13, 16 and at the day of removal of the fixed appliance. ANOVA analysis for the mean CPITN scores with treatment modality as a covariable showed no significant differences (nFPA=66, nPPA=70). The pre- and post-treatment CPITN score did not significantly differ between both appliances. No significant differences were found between both treatment groups for neither mGI (nFPA=70, nPPA=72) nor PI (nFPA=70, nPPA=71). No significant interaction between "treatment modality" and "orthodontist" could be assessed. It was concluded that an FPA and a PPA have the same effect on the patients' periodontium. A supposed less deteriorating effect due to the design and use of the FPA could not be confirmed.

7.1 Introduction

Clinical studies have indicated that orthodontic treatment with fixed appliances may cause iatrogenic damage to hard and soft tissues of the oral cavity. Enamel may be damaged during bracket removal as well as due to decalcification; roots may show resorption (chapter 5B). Mucosa can be damaged by wires that stick into the tissue; periodontal health may be affected (Zachrisson and Zachrisson 1972, Zachrisson and Alnaes 1973, Zachrisson 1976).

The effect of orthodontic treatment on periodontal health has been investigated by several researchers. The most commonly observed effect is gingival enlargement that occurs soon after placement of a fixed appliance. Alexander (1991) suggests that this phenomenon explains the increase in probing depth found during treatment but that it is not associated with any loss of attachment. This enlargement is found to be greatest interproximally and around posterior rather than anterior teeth (Zachrisson and Zachrisson 1972). Generally this enlargement resolves within 48 hours once the appliance has been removed (Alexander 1991). Most authors conclude that overall gingival changes produced by appliances are transient with no permanent damage to the periodontal tissues (Rateitschak 1968, Atack et al 1996).

The level of oral hygiene during treatment has a direct bearing on periodontal health (Rateitschak et al 1968, Kloehn and Pfeifer 1974). Appliances seem to encourage the development of gingivitis. Since plaque is the major etiologic factor in the development of gingivitis it may be that appliances per se influence the plaque population. It is possible that the "plaque retentive" properties of an appliance and/or the inability of the patients to adequately clean their teeth around it contributes to the development of gingival inflammation. The degree of gingival inflammation could be dependent of the appliance design. Furthermore it might be considered that treatment with straight wires could facilitate oral hygiene measures and eliminate direct gingival irritation as compared to archwires with loops.

The purpose of this part of the study is to compare the effects of orthodontic treatment on the surrounding gingiva using a fully programmed edgewise appliance (FPA) with orthodontic treatment using a partly programmed edgewise appliance (PPA).

7.2 Materials and methods

Periodontal examinations

149 Patients entered the trial. The trial protocol has been described in chapter 2. Assessment of the pocket depth was carried out at the day the fixed appliances were inserted, before placement of the brackets and at the first visit after their removal (nFPA= 66, nPPA= 70). Probing depth examinations were made on the buccal surfaces of 6 representative sites: the first permanent molars (4 measurements per tooth), the first upper right incisor and the first lower left incisor (3 measurements per tooth). Pocket depth was defined as the distance from the gingival margin to the bottom of the clinical pocket and was measured with a Hu-Friedy periodontal probe. All probing measurements were rounded to the nearest millimetre. For every tooth the highest measurement was used for a selection (pocketdepth) of the Community Periodontal Index of Treatment Needs (CPITN) classification: scores ≤2mm= 0, scores >2 but ≤4mm= 1 and scores >4mm= 2 (Ainamo et al 1982).

Assessment of the Plaque Index (PI) (Silness and Löe 1964) and the modified Gingival Index (mGI) (Saxer et al 1977) were carried out at visit 1, 4, 7, 10, 13, 16 and at the day of removal of the fixed appliance (PI nFPA= 70, nPPA= 71; mGI nFPA= 70, nPPA= 72). The procedure is described in chapter 2. Data from the questionnaire as described in chapter 6 (Appendix D) were used to assess the number and type of oral hygiene aids as used by the patients (question 32: What do you use to brush your teeth and your appliance?), as well as the frequency and duration of toothbrushing (question 29: How many times each day do you brush your teeth now that you wear an appliance?; question 30: How long do you brush your teeth now that you wear an appliance?)

Statistical methods

Probing depth (values/patient = 6; occasions = 2), PI (values/patient = ±20; occasions = 7) and mGI (values/patient = ±20; occasions = 7) comprise numerous amounts of data. In order to analyse the data in an efficient way, data reduction was applied in the following way:

A. for probing depth (2 occasions).

Per occasion reliability coefficients on probing depth were

calculated over the 6 index teeth (Cronbachs alpha). The mean value from the first occasion was used as baseline probing depth and the mean value of the assessment after removal of the appliances were used as the final values for further analysis (ANOVA).
B. for PI and mGI (7 occasions).

Firstly, the mean values per sextant (per patient per occasion) were calculated. Secondly, for the initial sextant values (visit 1) the reliability coefficient (Cronbachs alpha) was calculated and the mean score of the 6 sextants was used as baseline value in further analysis (ANOVA). For the 6 follow-up occasions, the sextant values (36 values/patient) Cronbachs alpha was calculated and the mean score of all available follow-up sextant values was used as treatment value in further analysis (ANOVA).

The mean number of oral hygiene aids, number of brushing moments and duration of toothbrushing was calculated (questionnaire appendix D; question 32, 29 and 30) and differences were tested using the t-test. Chi-square was used to determine whether there was any significant difference in type of oral hygiene aids as a function of treatment modality.

An alpha level of 0.05 was used to determine the statistical significance of the applied tests.

7.3 Results

The reliability coefficient for the probing depth measurements is 0.79 at the start of treatment and 0.85 at the first visit after removal of the fixed appliances. The reliability coefficients for the mGI and PI scores are 0.86 and 0.81 respectively at the start of treatment and 0.95 for both scores for the mean of the follow-up values.

The mean CPITN scores for FPA and PPA are given in figure 7.1. Post-treatment, no recession of the margin of the free gingiva was found in the patients that were evaluated. ANOVA analysis for the mean CPITN scores with treatment modality as a covariable showed no significant differences. The changes of the CPITN score did not significantly differ between both appliances.

The baseline values (visit 1) were not statistically different between both treatment groups (mGI p=0.11; PI p=0.45). ANOVA for the mean PI and mGI scores during treatment is given in table 7.1. No significant differences were found between both treatment

groups for neither mGI (p=0.61) nor PI (p=0.11). Therefore, the mean mGI and PI scores for FPA and PPA together are shown per visit in figure 7.2. Significant differences could be assessed between the participating orthodontists (mGI p=0.03; PI p<0.001). No significant interaction between "treatment modality" and "orthodontist" was found.

Figure 7.1
Mean CPITN scores ± standard deviations
(nFPA=66, nPPA=70)

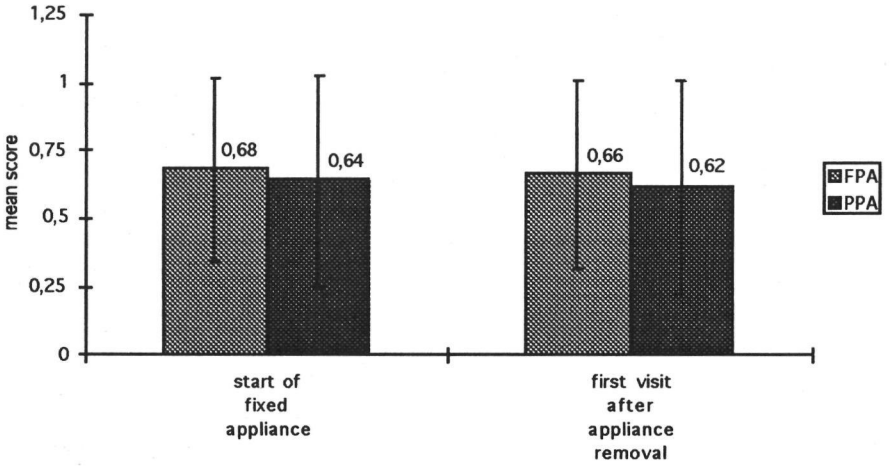
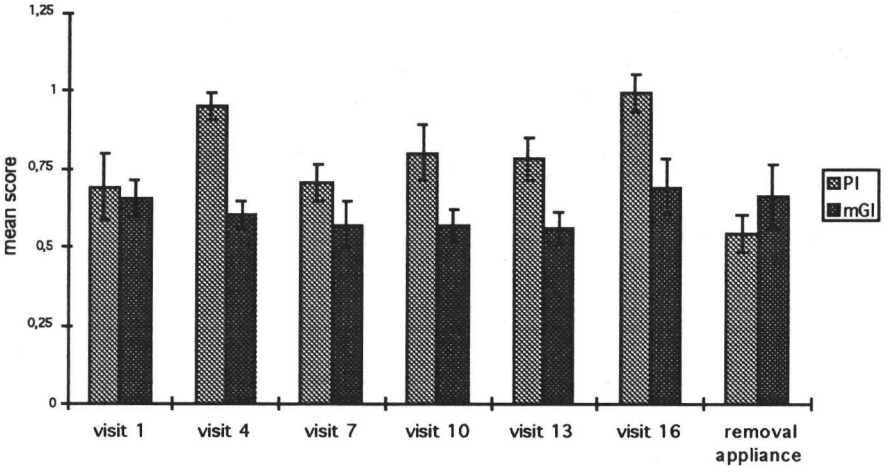


Figure 7.2
Mean PI and mGI scores per visit ± standard deviations
(PI nFPA=70, nPPA=71; mGI nFPA=70, nPPA=72)



The mean number of different oral hygiene aids per treatment type is given in table 7 2 The percentage of patients that used different oral hygiene aids is given in figure 7 3. No significant difference in the mean number of used oral hygiene aids between FPA and PPA could be determined on either of the 3 moments the questionnaire was given. Neither could statistically significant differences be assessed between both treatment groups for frequency and duration of toothbrushing (table 7.3). Chi-square testing showed no significant difference in type of oral hygiene aids as a function of treatment modality (p-value ranges between 0.06 and 1 for the different aids in the different questionnaires).

Table 7 1
ANOVA analysis of the mean mGI and PI scores of all visits except visit 1 which is used as the baseline

	mGI	PI
treatment modality	p=0 61	p=0 11
orthodontist	p=0.03	p<0 0001
interaction	p=0 11	p=0.32

Table 7 2
Mean number of oral hygiene aids (±standard deviation) per questionnaire and according to treatment (question 32)

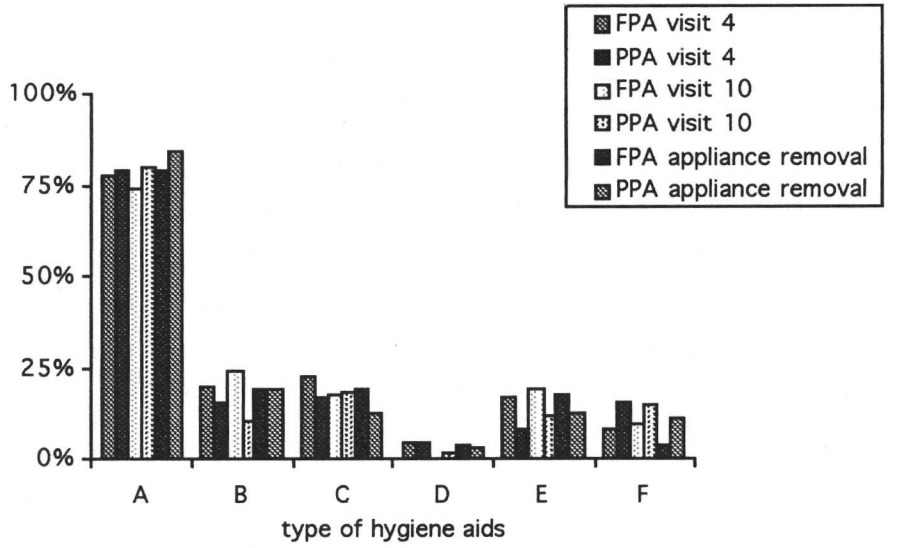
questionnaire	FPA	PPA	significance
visit 4 (n=142)	1.4±0.6	1.3±0.5	ns
visit 10 (n=122)	1.4±0.6	1.3±0.5	ns
removal appliance (n=121)	1 4±0.7	1 4±0.7	ns

Table 7 3
p-Values after t-testing between FPA and PPA for question 29, 30 and 32 at visit 4, 10 and appliance removal

	visit 4 n=142	visit 10 n=122	appliance removal n=121
question 29	0 07	0.07	0 6
question 30	0.6	0.2	0.5
question 32	0 3	0.4	0 9

Figure 7.3
Percentage of patients that used different oral hygiene aids per questionnaire and treatment modality
A=regular toothbrush; B=special toothbrush; C=mono tufted brush; D=mouthwash; E=toothpicks; F=other

visit 4: nFPA=71, nPPA=71
visit 10: nFPA=62, nPPA=60
appl. rem.: nFPA=58, nPPA=63



7.4 Discussion

In this study the periodontal health was compared for two groups of patients during orthodontic treatment with either FPA or PPA. Standard epidemiological methods were mainly chosen so that comparisons to the general population can be made (Tulloch et al 1994). The mGI and PI have shown to be very useful instruments to evaluate oral hygiene (Löe and Silness 1963, Silness and Löe 1964, Saxer et al 1977). The CPITN was selected for two reasons. Firstly, in an adolescent dentition erupting teeth would lead to biased pocket depths. The patients evaluated in this study all had already fully erupted permanent first molars and incisors which are the index teeth in the CPITN. Secondly, in adolescents it is very unusual to find loss of attachment around other teeth if the first permanent molars and/or permanent incisors are not affected (Ainamo et al 1984). Therefore, in this study, it is not necessary to measure pocketdepths in teeth other than the index teeth. The lingual/palatal surfaces were not included in the evaluation because the inter-examiner error for these sites is increased (Glavind and Löe 1967). The assessed reliability coefficients were sufficient for mGI, PI and probing depths. A limitation of the multi-practice aspect of this study is that the measurements of clinical parameters were made by several operators (orthodontists, auxiliaries). Their familiarity with

the aims of the study made "blind" measurements impossible (chapter 2.5).

In the reliability model that we used (Cronbachs alpha) each sextant value is seen as an estimate for the general value. Reliability expresses the correlation coefficient of the mean sextant value with the general value. A high reliability expresses a high degree of reproducibility within the mouth of a patient. Therefore it is not absolutely necessary to organise duplicate measurements. Practically, it is even very difficult to assess valid duplicate measurements of the mGI, since bleeding of the gingiva can not be reproduced identically.

Comparison of the pocketdepths with other studies is difficult if not impossible since in the orthodontic literature so far no study can be found in which (a part of the) the CPITN was used. Boyd and Baumrind (1992) reported pocket depths on either banded or bonded first permanent molars in adolescents who were treated orthodontically. Pre-treatment mean pocket depth on the upper and lower molars was 2.72 and 2.55 mm respectively, during treatment 3.41 and 2.99 mm and post-treatment 3.31 and 2.73 mm respectively. In our study both permanent molars and incisors were evaluated. It might then be expected that the mean pocketdepth is less than the mean pocketdepth of molars only. In our study the mean CPITN score at the start of treatment was 0.68 and 0.64 for FPA and PPA and 0.67 and 0.62 respectively the first visit after removal of the appliance. Since generally the gingiva enlargement resolves within 48 hours once the appliance is removed (Alexander 1991), this is a logical outcome. A little decrease in the mean CPITN score in the post-treatment assessment can be explained by the patients who had had pre-treatment with removable and/or functional appliances. As a consequence of wearing these appliances, they will probably have had a little increase in CPITN score at the beginning of the fixed appliance therapy.

Gingival bleeding was measured using the modified Gingival Index after Saxer et al (1977). This index is a 3-point scale in contrast to the original 4-point GI-scale according to Löe and Silness (1963). This partly explains why our values seem to be not in accordance (i.e. are lower) with other studies (table 7.4). The mean PI values are more in accordance with the values in the same literature but still rather low. After correction for the baseline level

(visit 1) no statistically significant differences could be found between both treatment groups for either the mGI or the PI (table 7.2). Significant differences could be assessed, however, between the separate orthodontic practices. On the other hand, we did not find significant interaction between treatment modality and orthodontic practice. This means that although there are significant differences between different practices in oral hygiene levels, these differences can not be explained by the way FPA or PPA is used by any of the participating orthodontists. The fact that every individual practice gave its own information on oral hygiene measures to their patients, on the other hand, might well explain this difference.

Table 7.4
Comparison of Gingival Index and Plaque Index values of recent literature with values of this study. If values of more months were given, the mean value was calculated.

Author	Gingival Index			Plaque Index		
	pre	during	post	pre	during	post
Boyd and Baumrind (1992)	0.82	1.9	0.87	0.84	1.2	0.66
Boyd and Chun (1994)	-	1.2	-	-	1.06	-
White (1996)	-	1.7	-	-	0.95	-
This study	0.65	0.61	-	0.69	0.78	-

Treatment with an FPA was expected to lead to lower values of the used periodontal parameters. In this study this hypothesis could be rejected. A possible explanation could be that patients wearing PPA used more and/or different oral hygiene aids in order to compensate for more difficult cleaning of the dentition due to the appliance. It might also be expected that they would brush their teeth more frequently and/or longer. Table 7.3 and 7.4 and figure 7.3, however, clearly demonstrate that this is not the case. Both treatment groups use a comparable number and type of oral hygiene aids. Furthermore both groups clean their dentition equally frequent and for the same length of time.

Andrews (1989) claimed that because of the design of the FPA brackets (more lateral extension of gingival tiewings) gingival impingement would be eliminated thus leading to facilitated oral hygiene. This special design, however, was only applied to posterior brackets. In this study we did not itemise the GI and PI values in anterior and posterior segments. By doing so it is possible that some

significant differences might be found.

7.5 Conclusion

In conclusion it can be stated that an FPA and a PPA have the same effect on the periodontal parameters. A supposed less deteriorating effect on the patients' periodontium due to the design and use of the FPA could not be confirmed.

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CHAPTER 8

Effectiveness of a fully programmed versus a partly programmed edgewise appliance evaluated with the PAR Index

Abstract

To compare the effectiveness of a fully programmed appliance (FPA) to a partly programmed appliance (PPA) 149 patients were orthodontically treated in a randomised multi-practice (n=11) clinical trial. Study models of 134 patients (nFPA=67, nPPA=67) were evaluated using the weighted PAR index. The mean pre-treatment PAR score was 28.7 ± 8.7 and 30.6 ± 9.4 respectively while the mean post-treatment PAR score was 4.0 ± 3.5 and 4.2 ± 2.8 respectively. The mean percentage PAR score reduction for FPA treatment was 84.8% and for PPA treatment 85.2%. Evaluation of the different PAR components did not show differences between both therapies. ANOVA showed no appliance effect. There were significant differences between the participating orthodontists for the post-treatment scores ($p=0.02$) and percentage reduction ($p=0.01$). No interaction was found between appliance and orthodontist. It was concluded that equally adequate treatment results can be achieved with a fully programmed and a partly programmed fixed appliance therapy. Treatment result, however, is dependent of the orthodontist.

8.1 Introduction

One of the main difficulties in assessing the outcome of orthodontic treatment is the measurement of treatment success. The goal of orthodontic treatment can be summed up as the creation of the best possible occlusal relationships within the framework of acceptable facial esthetics and stability of the occlusal result (Proffit 1993). Trying to achieve an ideal occlusion based on the anatomy of the teeth has been described as an ideal goal but a therapeutic impossibility (Graber 1985). Andrews developed the Six keys of occlusion as an occlusal goal (Andrews 1972). Achieving all these keys has been shown to be very difficult in the majority of cases (Kattner and Schneider 1993). It is also doubtful that such outstanding results reflect better dental health (Shaw et al 1980).

Several orthodontic indices have been developed that can assess the severity of malocclusion as well as the outcome of orthodontic treatment (Salzman 1968, Summers 1971, Haeger 1989, Shaw et al 1991). The goal of many of these indices is to assess (mal-)occlusion in a large sample. They apply a score to each feature of the (mal-)occlusion to which often a weighting is then added.

In recent years several studies have been conducted in which the effectiveness of orthodontic treatment has been assessed using the PAR Index (Richmond and Andrews 1993, O'Brien et al. 1995). This index is a specifically developed measure of occlusal change and it is applied to the patient's pre-treatment and post-treatment study casts. Scores are allocated in respect to the alignment of the upper and lower dentition (including impactions), buccal segment relationship, overjet, overbite and midline discrepancy. The greater the PAR score, the more severe the malocclusion, and therefore a change in PAR scores reflects the occlusal changes and alignment after treatment. The success of treatment as regards dento-occlusal change is expressed as the percentage change in the PAR score (Shaw et al. 1991). In developing this index, a validation study was carried out among British orthodontists. Weightings were calculated and applied to the components of PAR resulting in the PAR Index scores reflecting contemporary British orthodontic opinion (Richmond et al. 1992). DeGuzman et al. (1995) calculated weightings for the PAR index that reflect contemporary American orthodontic opinion.

The purpose of this part of the study is to compare the change in weighted PAR scores in orthodontic treatment using a

fully programmed edgewise appliance with orthodontic treatment using a partly programmed edgewise appliance.

8.2 Materials and methods

Data selection and editing

149 Class II patients entered the trial. They were referred for treatment to one of the 11 participating orthodontists during the intake period of the trial. The experimental design of the study has been described in chapter 2. Of each patient pre-treatment and post-treatment dental casts were made. After the study models were blinded, the following scores were recorded from these models for each patient: pre-treatment PAR score; post-treatment PAR score and percentage PAR score change. The observer was not involved with the treatment of the participating patients. Scores of 134 patients (nFPA=67, nPPA=67) were evaluated. From the original 149 patients 2 moved to another place and could not continue their treatment according to the protocol, 7 patients were excluded for evaluation because of premature debonding due to poor oral hygiene and 6 patients were excluded because study models were missing.

To assess the reliability of the PAR scores a random selection of the study models (n=10) was scored by another experienced PAR observer. Inter-observer agreement was assessed by paired t-test.

Statistical methods

ANOVA was used to determine the influence of treatment type and individual orthodontic practice on the mean post-treatment PAR score and on the mean percentage PAR score reduction. Two-way interactions between the main sources of variation were tested. "Normality" could be obtained by log-transformation.

Differences between both treatment types for the six components of the (post-treatment) PAR score were tested. Since "normality" could not be obtained, the dataset was dichotomised: score 0 (meaning component is perfect) = 0 and score >0 = 1 (meaning component is not perfect). In this situation the Chi-square test was performed.

An alpha level of 0.05 was used to determine the statistical significance of the applied tests.

8.3 Results

Error of the method

Paired t-test showed a systematic observer effect on the weighted pre-treatment PAR scores of 3±3.2 ($p<0.02$). No inter-observer difference could be found for the weighted post-treatment scores, so the error of the method was considered to be acceptable.

Post-treatment results

Table 8.1 shows the means and standard deviations of the weighted PAR Index scores before and after treatment as well as the percentage reduction in PAR score.

Table 8.1
Descriptive statistics for the outcome variables (means with standard deviations in parentheses)

	n patients	pre-treatment PAR	post-treatment PAR	% change
FPA	67	28.7 (8.7)	4.0 (3.5)	84.8 (15.2)
PPA	67	30.6 (9.4)	4.2 (2.8)	85.2 (9.7)

Table 8.2
P-values resulting from the analysis of variance of PAR scores
ns=not significant

PAR score	appliance	orthodontist	interaction
pre-treatment	ns	ns	ns
post-treatment	ns	p=0.02	ns
% change	ns	p=0.01	ns

Table 8.3
Percentage of perfect scores (score=0) of the different components of the PAR index
ns=not significant

	FPA (n=67)	PPA (n=67)	significance
maxillary front	76	73	ns
mandibular front	78	85	ns
occlusion	0	0	ns
overjet	84	84	ns
overbite	96	93	ns
centreline	97	94	ns

Analysis of variance showed a significant inter-orthodontist difference in post-treatment PAR scores (p=0.02) and in percentage reduction (p=0.01). Statistically no difference could be assessed between the two treatment modalities. Table 8.2 shows that two-way interactions between orthodontist and type of appliance were

not significant.

Table 8.3 shows the result of cross-tabulating the dichotomised post-treatment PAR score components. Chi-square testing showed no significant differences between both treatment groups.

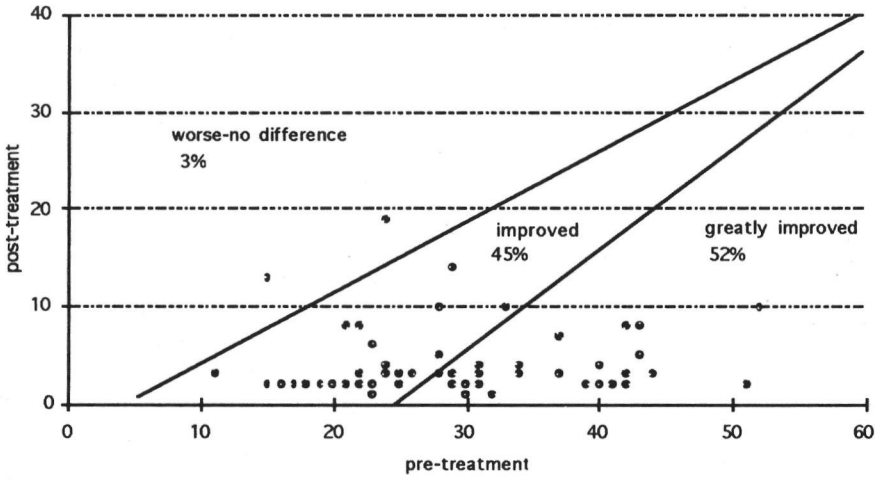


Figure 8.1a
FPA; pre-treatment PAR versus post-treatment PAR

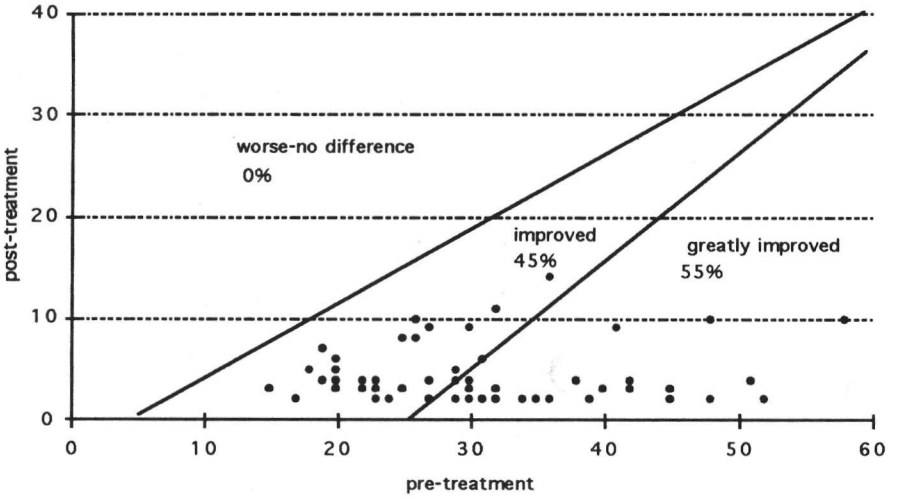


Figure 8.1b
PPA; pre-treatment PAR versus post-treatment PAR

The nomograms (figure 8.1a and 8.1b) show that in treatment with an FPA 52% of the patients were greatly improved (i.e. the PAR score dropped by at least 22 points), 45% were improved and 3% became worse or showed no difference (i.e. they failed to achieve a 30% drop in PAR score). Of the patients treated with a PPA 55% were greatly improved, 45% were improved and no patients became worse or showed no difference.

8.4 Discussion

Most studies on the effectiveness of orthodontic treatment are retrospective. No study has been published yet that compares the effectiveness of different treatment modalities with fixed appliances in a prospective controlled trial.

To measure treatment outcome the PAR Index was used. The interobserver reliability of the post-treatment PAR score in this study was good as no significant differences were found. A significant difference was found in the assessment of the pre-treatment score of 3 points between both observers (p=0.02). Turbill et al. (1994) reported a significant difference of the percentage reduction between double assessments (p=0.016). They concluded that although this is a statistically significant difference, it is not clinically significant. The same holds true for the difference in our study.

In our study both treatment groups showed a considerable percentage reduction in PAR score of about 85%. Roth (1976) claimed that use of the Andrews Straight Wire Appliance (SWA) would lead to better and more consistent results with shorter treatment duration. However, Kattner and Schneider (1993) retrospectively studied a sample of 120 orthodontically treated cases, completed by two orthodontists who both used the SWA and a standard edgewise appliance. They concluded that despite using the SWA, experienced clinicians still found it difficult to achieve all of the Six Keys to Normal Occlusion. In our study there also is no significant difference in treatment result nor in treatment duration (chapter 4). Analysis of variance showed that treatment results were significantly orthodontist dependent (p=0.02). This means that there is a subjective influence on the treatment result caused by the judgement of the orthodontist who decides when treatment can be finished. This will probably not be affected by the type of appliance.

Figure 8.2
Comparison of percentage PAR change of this study with other studies

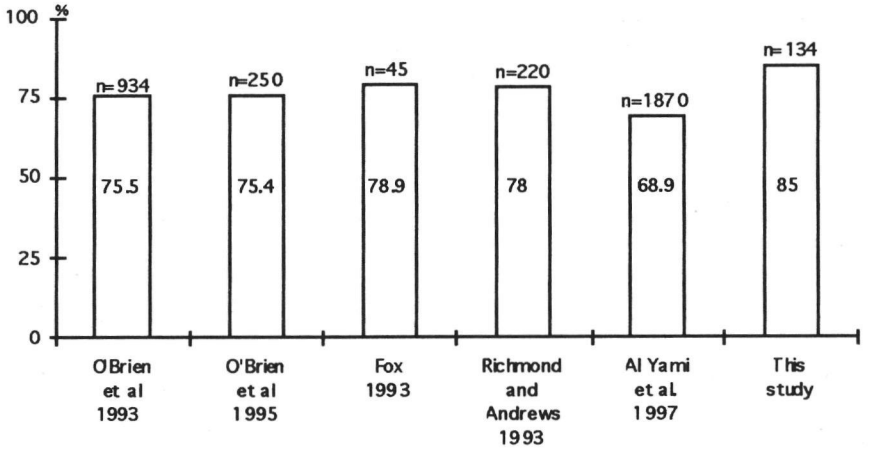
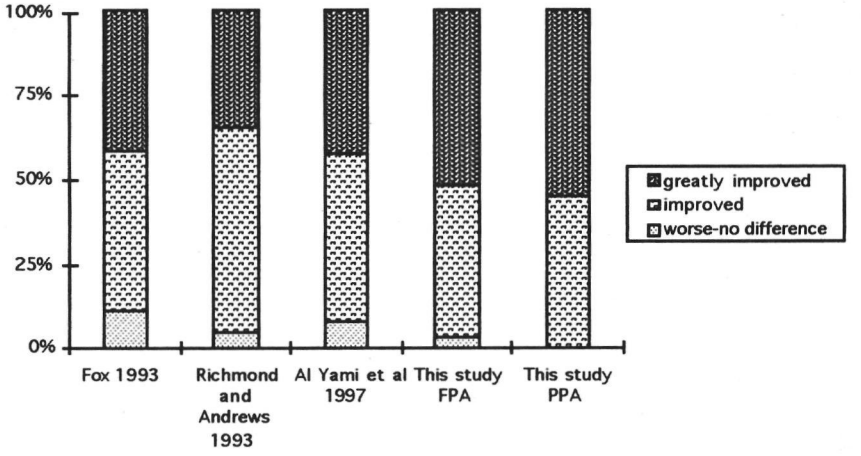


Figure 8.3
Comparison of nomogram values of this study with other studies



A comparison of the percentage PAR change and of the nomogram values in our study with other studies is given in figure 8.2 and figure 8.3 respectively. O'Brien et al. (1993) reported in a retrospective study of 1630 patients who were treated with all types of appliances in different hospitals a reduction of 67%. They reported considerable variation in treatment outcome between operator groups. In the subgroup (n=934) that was treated with full

upper and lower fixed appliances in both arches they assessed a reduction in PAR score of 75.5%. In a study with a group of 250 Class II division 1 patients O'Brien et al. (1995) found a total sample reduction of 75.4%. In that study the patients were treated by graduate students under direct supervision. Al Yami et al (1997) retrospectively studied the records of 1870 patients that were treated at the Department of Orthodontics and Oral Biology of the University of Nijmegen (The Netherlands). They reported a mean percentage improvement of 68.9%; 42.6% of the sample was greatly improved, 49.1% was improved and 8.3% was not improved or became worse. They did not specify how the patients were treated. Fox (1993) examined 92 patients, that were treated by one starting orthodontist, retrospectively. He found that 41% of the patients were greatly improved, 47% improved and that 11% showed no improvement or got worse (figure 8.3). In the group that was treated with full upper and lower fixed appliances (n=45) he achieved a percentage PAR change of 78.9% (figure 8.2). Probably the overall treatment result in our sample can best be compared to the findings of the study of Richmond and Andrews (1993) who evaluated retrospectively orthodontic treatment standards in Norway for a sample of 220 patients treated by 6 different orthodontists. All patients were treated with fixed appliances. On average, the malocclusion was reduced by 78% (figure 8.2). They found that 34% of the patients were greatly improved, 61% improved and that 5% showed no improvement or got worse (figure 8.3). In their conclusion they stated that the Norwegian orthodontists are producing a high standard of orthodontic treatment. Consequently, it might be fair to say that the same holds true for Dutch orthodontists despite the fact that the participating orthodontists in our study knew that their treatments were to be evaluated once the end of active treatment was reached.

In this study pre-treatment and post-treatment models were compared. The validity of the study may be increased further if pre-treatment and post-retention models are compared. Roth (1993) has made comments on the study of Kattner and Schneider (1993) stating that it is not appropriate to study occlusal contacts in study models made immediately after appliance removal. He stated that the Roth appliance was designed to put the teeth in an overcorrected position at appliance removal, from which they have the best chance

to settle in optimal occlusion. He did not make clear why a dentition treated with an FPA should settle in an other or more predictable way than after a PPA therapy.

Since the PAR Index is an occlusal index that measures the severity of dental malocclusion only, it will be necessary to apply further analyses to the treatment groups in order to achieve a more complete insight into the treatment results. The results of these analyses will be described in the next chapters.

8.5 Conclusion

In conclusion it can be stated that equally adequate treatment results as measured with the PAR Index can be achieved with a partly programmed and a fully programmed fixed appliance therapy. The standard of the final treatment result, however, is dependent of the orthodontist.

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CHAPTER 9

Effectiveness of rotation control in extraction cases treated with a fully programmed versus a partly programmed edgewise appliance using the ITRI

Abstract
In extraction brackets of a fully programmed appliance (FPA) counterrotation and counterangulation features are built in into the brackets when teeth need translation after extraction. In this chapter rotation control in orthodontic treatment using either a fully programmed edgewise appliance or a partly programmed edgewise appliance (PPA) was compared. Evaluation of the tooth positions was carried out by assessing the posterior intra-arch ITRI (= Ideal Tooth Relationship Index) score after anatomic contactpoint analysis. Evaluation of rotation control was carried out for 49 patients (nFPA=23, nPPA=26). The percentage ideal toothrelationships was 50.6% ±23.8 for an FPA treatment and 47.8% ±23.3 for a PPA treatment. No significant statistical differences between FPA and PPA after closure of extraction diastemas could be assessed. It was concluded that the hypothesis that FPA translation brackets can control rotations for teeth requiring translation without auxiliaries better than PPA brackets could not be confirmed by this study.

9.1 Introduction

Translation of teeth is often needed during orthodontic treatment. This is most obvious when teeth are extracted. In that case neighboring teeth have to be moved to close the diastema. Preferably, this is a bodily movement or translation (uniform motion of a body in a straight line). Because of the location of a bracket on the crown's face a real translation of teeth is difficult to achieve. The bracket is located occlusally to the tooth's horizontal center of resistance, so application of a mesial or distal force will cause angulation (tipping) around the horizontal center of rotation. The bracket is also located laterally to the vertical axis through the center of resistance. Because of this a mesial or distal force will cause rotation around the vertical center of rotation (Andrews 1989).

To overcome this tipping and rotation in orthodontic treatment with a partly programmed appliance (PPA) first-order and second-order wire bends are usually needed. The first-order bends are counterrotational and the second-order bends counterangulational. In a fully programmed appliance (FPA) counterrotation and counterangulation features are built in into the brackets (table 2.7). Usually, slot rotation and extended mesiodistal slot length provide counterrotation, whereas slot angulation, extended mesiodistal slot length and a power arm provide counterangulation. Brackets with these features are referred to as translation brackets (Andrews 1989).

Application of translation brackets in case of extraction would lead to less jiggling and roundtripping since the teeth would be moved in a straight vector (Roth 1976). One might even conclude that this could lead to better treatment results because the side-effects of space closure are practically eliminated.

The purpose of this part of the study is to compare the rotation control for teeth requiring translation after extraction in orthodontic treatment using a fully programmed edgewise appliance with orthodontic treatment using a partly programmed edgewise appliance. Evaluation of the tooth position is carried out by assessing the posterior intra-arch ITRI (= Ideal Tooth Relationship Index) score after anatomic contactpoint analysis.

9.2 Materials and methods

Data selection and editing

Evaluation of rotation control was carried out for 49 patients (table 9.1). Treatment was carried out using the bracket prescription as described in table 2.7. Of each patient post-treatment dental casts were made immediately after removal of the fixed appliance. After the study models were blinded, an anatomical contactpoint analysis was executed using the OPTOCOM (Schols et al 1988). For this analysis the mesial and distal anatomical contactpoints of the first molar, first or second premolar, cuspid and lateral incisor were assessed. Both contactpoints of one tooth were connected with each other with a straight line (figure 9.1). Contacts between the adjacent teeth were recorded as "present" when the distance between the neighboring anatomical contactpoints was 0 mm, or "absent" when this distance was >0 mm deviating from the arch form. Furthermore, since proximal spacing without rotation can be considered as correct rotation control, in this study open proximal contacts with teeth in good alignment were considered "present". Vertical contactpoint discrepancies are not taken into account using this method.

Table 9.1
Description of the sample

type of extractions	FPA	PPA
2 premolars (upper)	16	14
3 or 4 premolars (upper and lower)	7	12

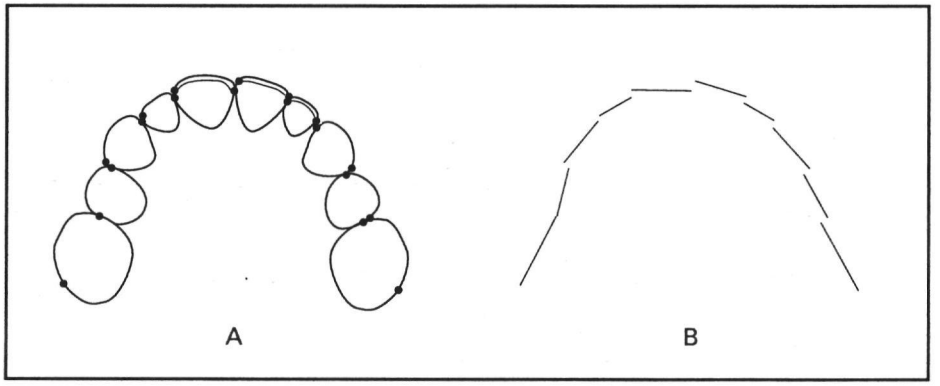

Figure 9.1
Anatomical contact point analysis on a maxillary study model
A. the mesial and distal contactpoints are indicated with a black dot
B. the mesial and distal contactpoints are connected with each other

Statistical methods

To investigate reproducibility of the analysis, dual measurements of the contact point analysis were made on a sample of 14 dental casts allowing 2 months between both measurements. To check for differences a paired t-test was applied. The intra-examiner correlation between both measurements was assessed for the ITRI analysis.

The index score (ITRI) is based on the ratio of actual to potential ideal contactpoints (n ideal contact points/n potential ideal contactpoints*100) (Haeger et al 1992). To test for differences between both treatment groups the t-test was carried out. A paired t-test was applied to test for differences between upper and lower jaws.

An alpha level of 0.05 was used to determine the statistical significance of the applied tests.

9.3 Results

No significant differences where found when the dual measurements were compared (p=0.54). The intra-examiner correlation for the ITRI analysis between both measurements is 0.74.

The mean posttreatment value for the ITRI percentage scores are provided in table 9.2. The percentage ideal toothrelationships was 50.6% ±23.8 for an FPA treatment and 47.8% ±23.3 for a PPA treatment. There were no significant differences between the FPA and PPA posttreatment scores. Also no significant differences could be assessed between the maxilla and the mandible (n=19; p=0.43) in patients were extraction was performed in both dental arches.

Table 9.2
Post-treatment posterior intra-arch ITRI scores ± standard deviation for both treatment options and p-values of the applied t-test
maxilla + mandible= mean value of patients by whom premolars were extracted in both arches
ns=not significant

	n	FPA	PPA	p-value
maxilla + mandible	19	50.6 ± 23.8	47.8 ± 23.3	0.30 (ns)
maxilla	30	50.0 ± 24.1	40.4 ± 21.7	0.14 (ns)
mandible	19	52.4 ± 24.4	63.9 ± 18.6	0.26 (ns)

9.4 Discussion

Orthodontic outcomes can be evaluated by a number of parameters. In chapter 8 this was done using the PAR Index. To evaluate specific intra-arch relationships after closure of extraction

spaces, however, this index is insufficient. Schols et al (1988) developed a so called anatomic contactpoint analysis to evaluate changes in tooth positions during adolescence. The teeth in this analysis were depicted as the connecting line between the mesial and distal anatomic contactpoint. Ideally, these lines should be connected with each other so that they form a continuous dental arch. The reproducibility of the contactpoint analysis with the OPTOCOM is sufficient in this study. Schols et al (1988) already proved that the contactpoint analysis using the OPTOCOM is highly reproducible. Schneider (University of Illinois at Chicago) formulated the Ideal Tooth Relationship Index (ITRI) as a refinement of the methodology of Hellman (1921). Haeger (1989) first reported about this index. It was reported that for the overall index, intra-examiner correlations were 0.94 and 0.93 for two examiners and that their inter-examiner correlation was 0.84. The intra-examiner correlation for the ITRI analysis in this study is 0.74. The difference can be explained because we used the contactpoint analysis to assess whether contactpoints were ideally fitting. This method is more sensitive than assessing an ideal tooth relationship by eye.

Basically, the index score is based on the ratio of actual to potential ideal inter- and intra-arch contacts or relationships (Haeger et al 1992). In this study we only used a limited part of the index: posterior intra-arch contactpoints of teeth adjacent to an extractionsite. Haeger et al (1992) reported in a group of 92 treated patients with mixed malocclusions a 47.4% posterior intra-arch score immediately after debonding. This percentage increased to 54.5% 4 years later. In a group of 10 untreated good-to-ideal occlusions this score was 33.3%. Tahir et al (1997) evaluated 90 American Board of Orthodontics cases treated by 9 practitioners. They reached a mean posterior intra-arch post-treatment score of 56.3%. They also made an assessment on 147 naturally occurring good-to-excellent occlusions as collected by L.F. Andrews. In this sample the mean posterior intra-arch score was 25.3%. It was concluded that orthodontic treatment could lead to better ITRI scores than good-to-excellent nontreated occlusions. The results from our study support this conclusion.

The lack of a significant difference between FPA and PPA may not be surprising. As one of the main objectives of orthodontic treatment is the establishment of proper or ideal occlusal

relationships, it can be assumed that each practitioner tried to achieve this ideal result, regardless of the appliance. In chapter 8 we have already shown that both treatment modalities are equally effective when the treatment result is evaluated using the PAR index. We also concluded that the final treatment result is dependent of the orthodontist. Significant differences for the ITRI analysis can therefore be expected when the results of the different practitioners would be evaluated (Kattner and Schneider 1993). The number of patients per practitioner that needed extraction, however, was too small for sufficiently powerful statistical evaluation.

Comparison of the results in this study with the posterior intra-arch percentages as found by Kattner and Schneider (1993) show that our percentages are a little lower. This can be explained by the fact that Kattner and Schneider scored "absent" ideal contact when the irregularity was more than 0.5 mm. Thus, in their study, a part of the overcorrections was included as "present" ideal intra-arch tooth relationships. In our study, overcorrections, that could be considered appropriate treatment objectives (Roth, 1987), were included as "absent". Since it was not possible to determine if proximal spacing in areas of recent band removal were due solely to the band thickness or were actual dental spacings, all open contacts were treated as absent ideal anatomical contactpoints as well. The index can be made less stringent by allowing "near perfect" results to be counted. This would decrease, however, the objectivity of the ITRI.

9.5 Conclusion

In this part of the study the hypothesis that FPA translation brackets can control rotations for teeth requiring translation without auxiliaries better than PPA brackets was investigated. ITRI analysis showed no significant statistical differences between FPA and PPA after closure of extraction diastemas.

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CHAPTER 10

Effectiveness of a fully programmed versus a partly programmed edgewise appliance assessed with the Six Keys Analysis

Abstract

To compare the effectiveness of a fully programmed appliance (FPA) to a partly programmed appliance (PPA) study models (nFPA=67, nPPA=67) were evaluated using the Six Keys Analysis, and cephalometric measurements (nFPA=55, nPPA=57) were performed. The results of the Six Keys Analysis showed that the angulation of the maxillary anterior teeth was better with the FPA. In no single patient all six keys were present together. When the models were divided into a non-extraction (n=85) and an extraction group (n=49) the non-extraction group scored better on mandibular anterior inclination, rotation, tight contacts and AP molar relationship but worse on mandibular posterior inclination. The results of the cephalometric analysis showed no significant differences between FPA and PPA. When divided into a non-extraction (n=74) and an extraction group (n=38) the extraction group showed a higher angle between the occlusal plane and the upper central incisor. For both the Six Keys Analysis and the cephalometric measurements no interaction could be assessed between extraction and type of appliance. It was concluded that equally adequate treatment results can be achieved with a fully programmed and a partly programmed fixed appliance therapy.

10.1 Introduction

In the early seventies Andrews (1972) described six characteristics that were consistently present in a collection of 120 casts of naturally optimal occlusion. He referred to these qualities as the Six Keys to Normal Occlusion. In later writings they are called the Six Keys to Optimal Occlusion (Andrews 1989). The recognition that extensive similarities prevail in the morphology of normal tooth types and in their positions when they are optimally occluded, lead Andrews to the concept of programming tooth guidance into the bracket rather than into the archwire. This resulted in the Straight Wire Appliance ("A" Company, San Diego, Calif., USA) According to the definition of Andrews (1989) it is a fully programmed appliance (FPA).

The Straight-Wire Appliance (SWA) was the first fully programmed appliance. It was designed to treat only non-extraction cases with an ANB differential of less than 5° without the necessity of putting offset bends into the wire. Since then, several additional fully programmed appliances or "prescriptions" have been developed by Alexander, Gerety, Hilgers, Ricketts and Roth (Tenti 1986). Since closing diastema after extraction of premolars produces undesired side-effects (rotation and tipping), Andrews later introduced different brackets for extractions (translation brackets) Translation brackets were defined as fully programmed brackets for teeth that require translation after extraction for orthodontic treatment (Andrews 1989). They have all features of standard FPA brackets plus a power arm and two additional slot-siting features counter-mesiodistal tip and counterrotation.

Andrews stated that his keys to optimal occlusion would provide objective treatment goals for orthodontic treatment which would create an occlusion which had the characteristics of a non-treated case with an optimal occlusion. Uhde (1980) implemented the Six Key analysis in a study on long-term stability of the static occlusion after orthodontic treatment. He observed no relationship between the degree of treatment perfection achieved at the end of treatment, based on the six keys to optimal occlusion, and the stability of the occlusion twelve years after treatment. Kattner and Schneider (1993) retrospectively compared FPA and PPA treatment results of 120 orthodontically treated cases completed by two practitioners. The results of the Six Keys Analysis showed that the

angulation and inclination of the maxillary posterior teeth were better with the FPA. Furthermore, they found that no single case achieved all six keys.

A problem, however, when evaluating the inclination of the incisors is that the Six Keys Analysis is based on the crowns' facial axis, whereas most cephalometric analyses deal with the inclination of the long axis of the central incisors. Andrews recognized that the tooth axis and the facial crown axis are not parallel. In an unpublished study, however, he assessed that there was a predictable relationship between the two axes (Andrews 1989).

In the previous chapters of this thesis an attempt has been made to evaluate the claimed advantages of the use of an FPA over the use of a partly programmed appliance (PPA) from different points of view using different assessments. The purpose of this chapter was to compare the treatment results of FPA (Roth prescription) cases with those treated with a PPA using Andrews' Six Keys Analysis.

In addition, post-treatment inclination of the maxillary and mandibular incisors were compared radiographically between FPA and PPA as well.

10.2 Materials and methods

149 Class II patients entered the trial. They were referred for treatment to one of the 11 participating orthodontists during the intake period of the trial. The experimental design of the study has been described in chapter 2. Of each patient post-treatment dental casts and lateral cephalograms were made on the same day the fixed appliances were removed. After the study models were blinded, the treatment results were evaluated using Andrews' Six Keys to Normal Occlusion.

Study model measurements

The method used for evaluation of Andrews' keys of normal occlusion was similar to that used by Andrews (1989) for key 2 to 6 and by Uhde (1980) for key 1:

- Key 1: ***anteroposterior relationship of the maxillary first molar to the mandibular first molar***

This key was considered present if three criteria were met on both left and right side of the arch: (1) the first molar

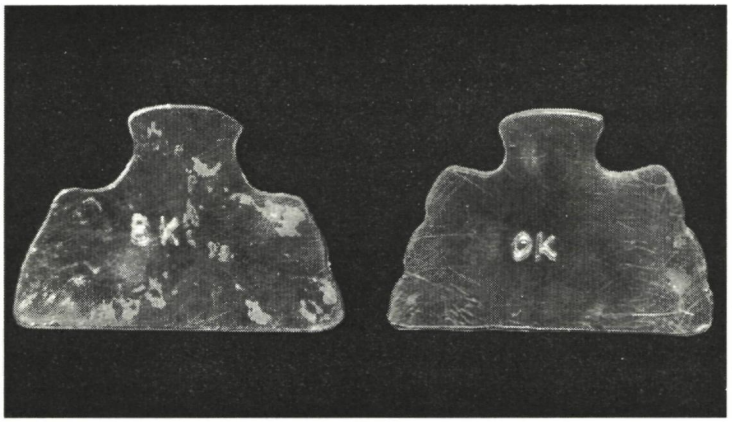


Figure 10.1 A
Plastic templates
left: maxillary template
right: mandibular template

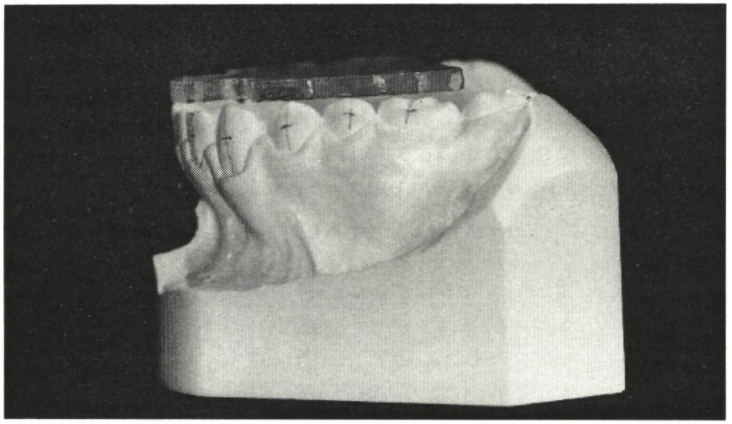


Figure 10.1 B
Position of the template on the mandibular arch to establish the lower occlusal plane

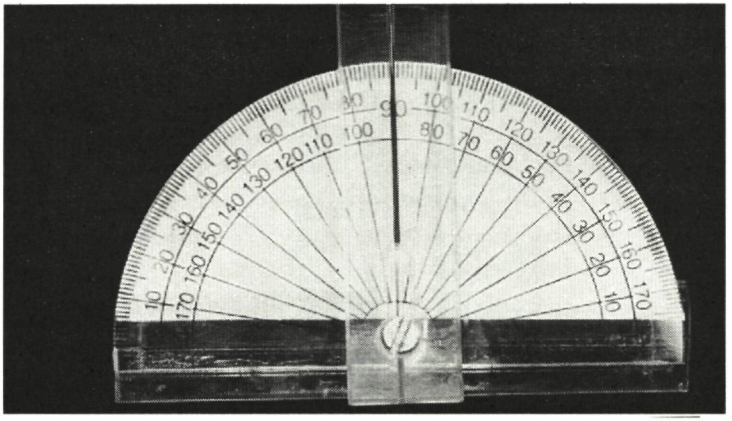


Figure 10.2
Protractor with adjustable read out arm

relationship was Angle's Class I, (2) the mesiolingual cusp of the upper first molar seated in the central fossa of the lower first molar, (3) the distal surface of the distal marginal ridge of the upper first permanent molar was in contact with the mesial surface of the marginal ridge of the lower second molar. Key 1 was also considered to be present if the first two criteria were met and the distal marginal ridge of the upper first permanent molar was well related anteroposteriorly but not actually contacting the marginal ridge of the lower second molar. Reported values are the percentage of casts meeting these specifications (Uhde 1980).

- Key 2: ***crown angulation***

All crown angulations were related to the occlusal plane. Andrews established the occlusal plane on each model by placing a 2 mm thick plastic plate (figure 10.1) over the occlusal surface contacting the most prominent cusp tip of the second molars and the incisal edges of the central incisors with recessed areas for the canines. Since the second permanent molars were occasionally unerupted in this sample, only first molars were used. The crown angulation relative to the occlusal plane was measured using a protractor with an adjustable read out arm (figure 10.2). The base of the protractor was positioned on the plastic plate, which represents the occlusal plane and the read out arm was adjusted to parallel the long axis of the crown (figure 10.3). The long axis of the incisor was defined as the mid-developmental ridge, and the long axis of the molar crown was defined as the vertical developmental groove on the buccal surface. If the angulation of the long axis varied more than plus or minus 2° from the optimal for that tooth type (figure 10.4), it was considered incorrect. Reported values are the percentage of teeth demonstrating the correct relationship.

- Key 3: ***crown inclination***

The inclinations of the crowns were also related to the occlusal plane. The angle was evaluated by employing the plastic plate representing the occlusal plane and the protractor placed on the plastic plate with the read out arm adjusted to represent a line tangent to the labial or buccal surface of the crown being evaluated (figure 10.5). If the inclination of the long axis varied more than plus or minus 2° from the optimal for that tooth type, it was considered incorrect. Reported values are the percentage of teeth demonstrating the correct relationship.

Figure 10.3
Measurement of angulation of lower anterior teeth

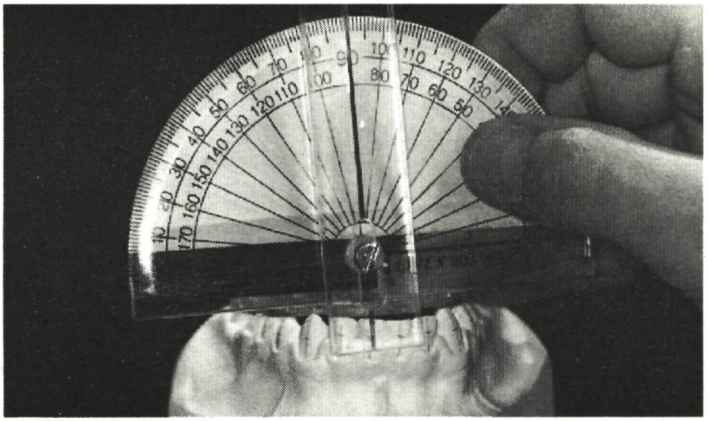


Figure 10.4
Crown angulation (A and B) and inclination (C and D) values

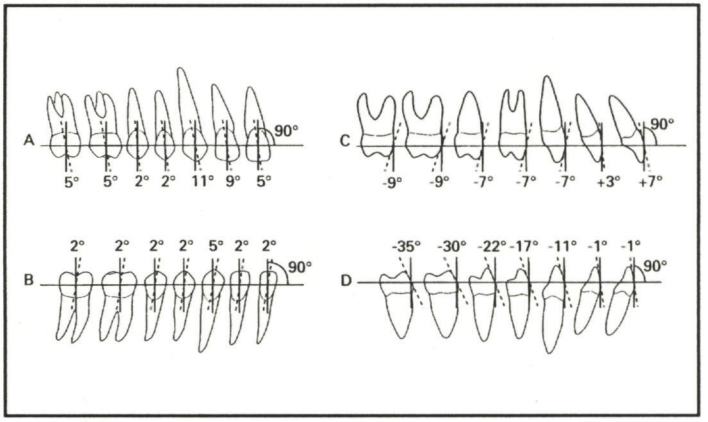
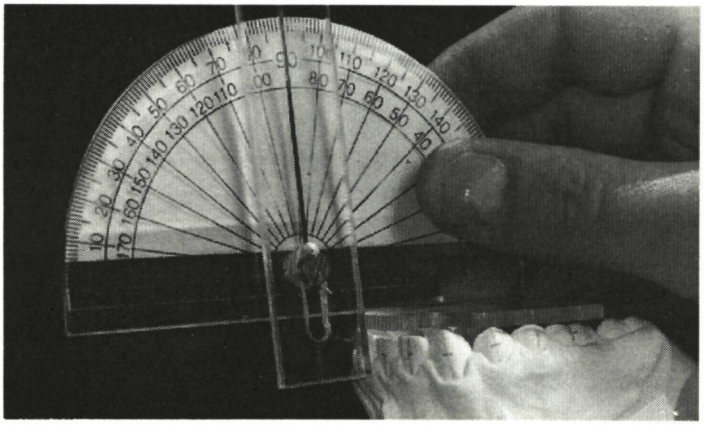


Figure 10.5
Measurement of inclination of the lower anterior teeth



- Key 4: ***rotations***

If a line connecting the contact points of a crown varied more than 2° from parallel to a line representing the arch form, the tooth was rotated (figure 10.6). Rotations are best observed from the occlusal perspective. Reported values are the percentage of teeth demonstrating the correct relationship.

- Key 5: ***tight contacts***

If any interproximal space was observed then a tight contact was considered absent (figure 10.7). Spaces that were considered to be resultant band spaces at the end of treatment, since study models were to be taken immediately following appliance removal, were ignored as well as spaces that could be related to tooth size discrepancy. Reported values are the percentage of interproximal contacts demonstrating the correct relationship.

- Key 6: ***curve of Spee***

The curve of Spee was evaluated by placing the plastic plate on the occlusal plane of the mandibular arch using the incisal edges of the lower incisors and the most prominent cusp tip of the first molar. The distance of the cusp tips of the lower dentition to the lower border of the plastic plate was then measured using a Boley gauge with sharpened points. Any model with any cusp tip in excess of 2.5 mm to the lower border of the plastic plate was categorized as having a deep curve of Spee and the key absent. Reported values are the percentage of casts meeting Andrews' (1989) specifications.

To assess the intra-observer reproducibility of the Six Keys Analysis dual measurements were made on a sample of ten sets of dental casts with a time interval of one month by the same observer.

Cephalometric measurements

After the lateral cephalograms were blinded the following angular measurements were performed (figure 10.8): (1) spinal plane to upper incisor, (2) occlusal plane to upper incisor, (3) occlusal plane to lower incisor, (4) mandibular plane to lower incisor and (5) interincisal angle. Definitions of cephalometric landmarks in the lateral cephalometric tracings and the inter-observer measurement-remeasurement correlations have been described in chapter 2.

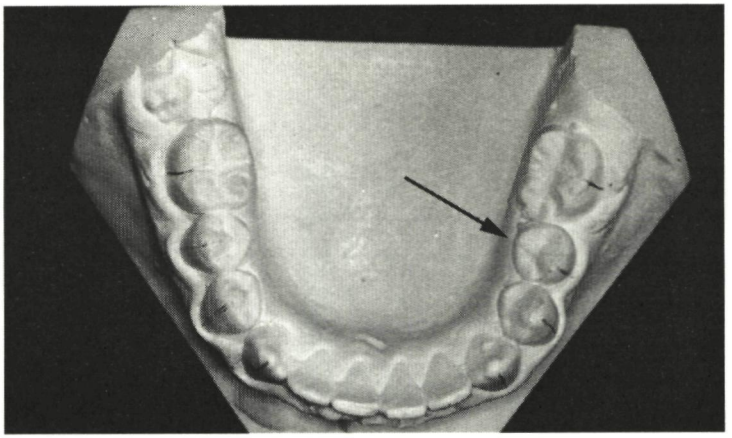


Figure 10.6
Undesired rotations (arrow)

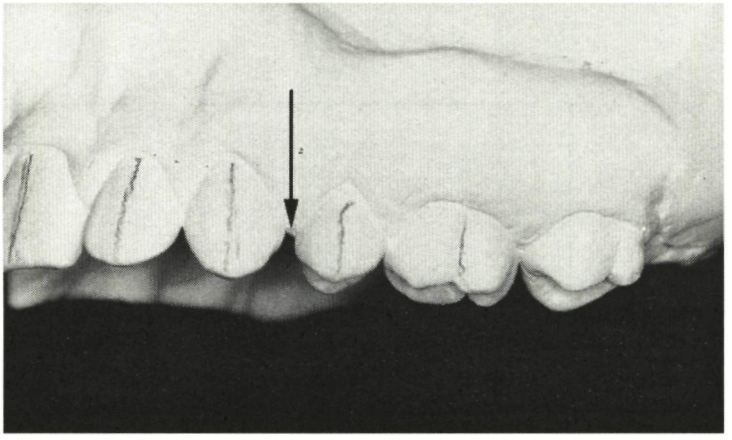


Figure 10.7
Absence of tight contact (arrow)

Patients

Scores of 134 patients (table 10.1) were evaluated with the Six Keys Analysis. The observer was not involved with the treatment of the participating patients. From the original 149 patients 2 moved to another place and could not continue their treatment according to the protocol, 7 patients were excluded for evaluation because of premature debonding due to poor oral hygiene and 6 patients were excluded because study models were missing. Cephalograms of 112 patients (table 10.1) were evaluated. Additional to the patients who moved or were debonded prematurely, in the cephalometrical evaluation 28 patients were excluded because the post-treatment

cephalograms were missing due to protocol violation. The size of the finishing arch wires for each of the practitioners and for each of the two appliances is given in table 10.2. In the collected FPA finishing archwires of 5 patients (7%) first order wire bends had been placed to create sufficient offset for the first permanent molars.

Table 10.1 Description of the sample

	nFPA	nPPA
Six Keys analysis		
extraction	23	26
non-extraction	44	41
Cephalometrical evaluation		
extraction	19	19
non-extraction	36	38

Figure 10.8 Cephalometric landmarks (legend see figure 2.1)

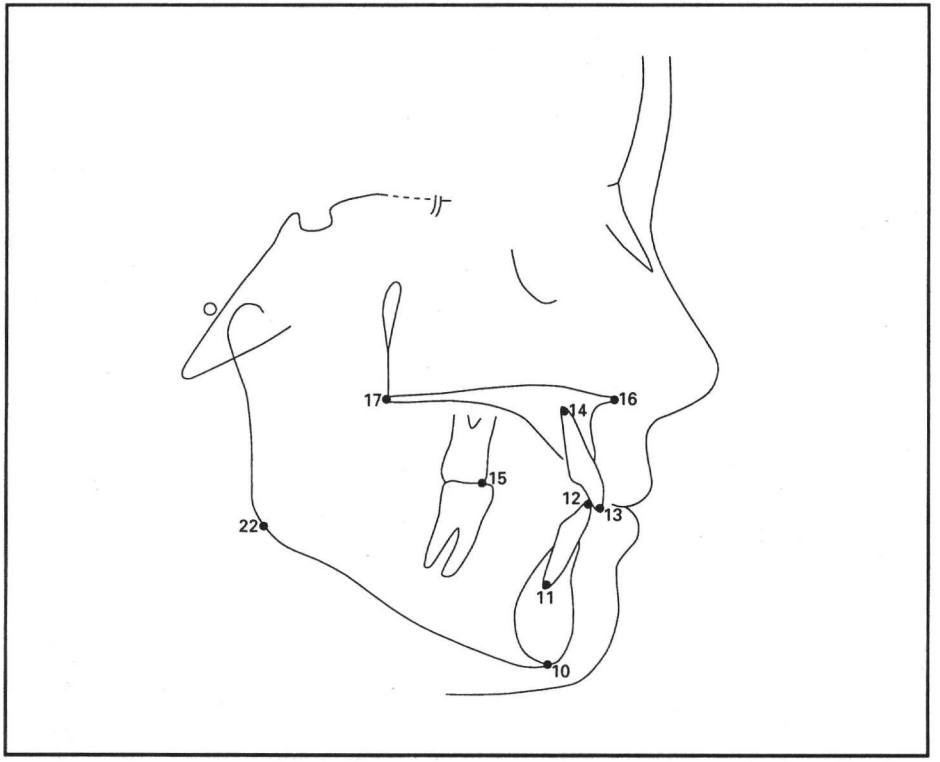


Table 10.2
Distribution of finishing arch wire sizes per orthodontist (1-11) and per appliance (FPA and PPA)
FPA (.022)= fully programmed appliance with an 0.022 inch slot size
PPA (.018)= partly programmed appliance with an 0.018 inch slot size

orthodontist	FPA (.022)	PPA (.018)
1	.017 x .025	.016 x .022
2	.021 x .025	.016 x .022
3	.017 x .025	.016 x .022
4	.017 x .025	.016 x .022
5	.018 x .025	.016 x .022
6	.018 x .025	.016 x .022
7	.019 x .025	.016 x .022
8	.018 x .025	.016 x .022
9	.019 x .025	.016 x .022
10	.018 x .025	.016 x .022
11	.018 x .025	.016 x .022

Statistical methods

The mean scores and standard deviations for angulation, inclination, rotations and contacts were calculated. A 3-way-ANOVA analysis was used to determine the influence of individual orthodontic practice, treatment type and extraction therapy. Interactions between treatment type and extraction therapy were tested. AP molar and curve of Spee were analyzed using the Chi-square analysis. The main research question comprises six different hypotheses (Six Keys) concerning the difference between FPA and PPA. These hypotheses will be tested on a nominal α=0.05 level. For angulation and inclination (each involving 7 tests) Bonferroni correction will be applied i.e. the actual α=0.007 (0.05/7). In principle the same procedure will be followed for orthodontist and extraction influences. Since 2 searches are involved (orthodontist and extraction), the nominal α will be divided by 2 i.e. inclination and angulation will be tested at α=0.0035 and the 4 other keys at α=0.025.

The mean cephalometric angles were calculated. Differences were tested using t-tests. Two-way interactions between appliance and extraction therapy were tested. An alpha level of 0.05 was used to determine the statistical significance of the applied tests.

10.3 Results

The duplicate error of the Six Keys Analysis and the

correlation between the first and second assessment are given in table 10.3. For the assessment of the maxillary inclination the duplicate error is the largest (14%, other assessments <10%), and the correlation is moderate (0.68) whereas all other assessments show a substantial to (almost) perfect correlation (0.78 - 1).

Table 10.3
Six Keys Analysis reproducibility

variable	n	duplicate error	correlation r
angulation			
maxilla	10	9.8%	0.82
mandible	10	9.8%	0.78
inclination			
maxilla	10	14.0%	0.68
mandible	10	6.0%	0.97
rotations	10	2.6%	0.86
contacts	10	1.4%	0.99
curve of Spee	10	0%	1

The results of the Six Keys Analysis are shown in table 10.4. Statistically significant differences between the participating orthodontists were found for the variables: (1) angulation of the combined maxillary anterior and posterior teeth and (2) rotations.

Statistically significant differences between FPA and PPA were found for the following variables: (1) angulation of the maxillary anterior teeth, (2) angulation of the combined maxillary anterior and posterior teeth and (3) angulation of the combined maxillary and mandibular teeth. The FPA scored higher for each of these variables.

Statistically significant differences between the non-extraction and extraction group were found for the variables: (1) inclination of the mandibular posterior teeth, (2) contacts and (3) AP molar relationship. The non-extraction group scored higher for all of these variables except for the inclination of the mandibular posterior teeth.

Out of 17 interactions (see 17 lines in table 10.4) that were tested between appliance and extraction, only one significant interaction could be assessed. From this we conclude that interaction does not play a role.

Using the variables assessed in the Six Keys Analysis the percentage of casts was calculated achieving each of the six keys

(table 10.5). No single case achieved all six keys.

Table 10.6 presents the results of the lateral cephalograms. No statistically significant differences could be assessed between FPA and PPA. The angle between the occlusal plane and the maxillary incisor was significantly larger in the extraction therapy group as compared with the non-extraction therapy group. No significant interactions could be assessed.

10.4 Discussion

Most studies on the effectiveness of orthodontic treatment are retrospective. No study has been published yet that compares the effectiveness of different treatment modalities with fixed appliances in a prospective controlled trial. In our study we used a randomized prospective clinical trial design. The balance procedure of assigning patients to the different treatments ensured comparability between patient groups. This implies that the conclusions of this study are based on an independent treatment allocation rather than on subjective clinical opinions.

To measure treatment outcome the Six Keys Analysis and cephalographic measurements were used. The duplicate error of most assessments was acceptable as well as the correlation between dual measurements (table 10.3 and chapter 2). The only moderate duplicate error and correlation was found for the assessment of inclination of maxillary teeth in the Six Keys Analysis.

The SWA was introduced as a tool in achieving the six keys to optimal occlusion. Andrews (1972) described the six keys after studying 120 naturally optimal occlusions. He did not describe the composition of this group of models regarding age, sex, development, race etc. It is obvious, however, that only dentitions with the permanent second molars fully erupted were included. This implies that most of the naturally optimal occlusions were in a later developmental stage than the patients that were treated in this study. Furthermore, many of the patients that were treated did not yet have (fully) erupted permanent second molars by the time the fixed appliance was removed. Schols and Van der Linden (1988) described changes that occur in the dentition between 12 and 22 years of age in males and females. Among other things, they

	Orthodontist			Appliance			Extraction			pooled sd
	Max	Min	sign	FPA n=67	PPA n=67	sign	non-extr n=85.	≥ 2 extr n=49	sign	
angulation										
maxilla										
anterior	71.7	39.4	p=0.03	63.9	50.5	**p<0.0001**	58.0	55.8	ns	18.8
posterior	69.0	44.3	p=0.04	61.5	55.6	ns	58.2	58.8	ns	22.4
combined	68.4	41.6	**p=0.003**	63.1	52.7	**p<0.0001**	58.1	57.2	ns	15.1
mandible										
anterior	75.1	55.4	ns	69.0	63.6	ns	66.2	66.2	ns	21.2
posterior	72.5	43.1	ns	59.9	62.4	ns	58.3	66.3	ns	22.5
combined	70.6	49.4	ns	64.3	62.7	ns	62.4	65.7	ns	16.2
combined	67.9	49.6	p=0.004	63.7	57.7	**p=0.006**	59.8	62.4	ns	11.1
inclination										
maxilla										
anterior	58.8	37.3	ns	44.8	49.1	ns	45.6	49.4	ns	31.9
posterior	57.8	19.9	ns	37.8	38.2	ns	39.9	34.9	ns	32.3
combined	51.2	34.3	ns	41.1	44.2	ns	42.5	43.1	ns	24.1
mandible										
anterior	66.1	19.2	p=0.03	47.4	47.8	ns	52.8	38.2	p=0.01	29.1
posterior	64.4	37.0	ns	46.0	54.4	ns	41.3	66.0	**p<0.0001**	28.6
combined	66.5	34.4	p=0.02	46.7	50.8	ns	47.0	52.0	ns	21.2
combined	54.5	37.4	ns	43.9	47.4	ns	44.8	47.3	ns	16.5
rotations	98.8	87.3	**p=0.009**	94.5	95.7	ns	96.0	93.6	p=0.04	5.7
contacts	98.7	92.6	ns	95.9	96.3	ns	98.0	94.5	**p=0.007**	4.9
AP molar (χ^2)	38.5	0	ns	20.0	23.2	ns	28.2	10.2	**p=0.01**	
curve of Spee	deep curve was present in 5 out of 134 cases: no statistical analysis possible									

*Table 10.4 (opposing page) Six Keys Analysis, ANOVA posttreatment results p-values not corrected for Bonferroni are given; significant effects after Bonferroni correction are printed in **bold and underlined***
max = maximum mean value over 11 participating orthodontists
min = minimum mean value over 11 participating orthodontists
non-extr = non-extraction group of patients
≥2 extr = group of patients in which 2 to 4 premolars were extracted
pooled sd = standard deviation of all values together that are depicted in the row in the table left of the sd
sign = significance
ns = not significant

conclude that the interincisal angle increases for both sexes as well as the interdigitation. Most probably, Andrews 120 naturally optimal occlusions had already undergone these changes. Therefore, it can be assumed that the design of the SWA is based on mature tooth positions.

In our study no patient achieved all six keys. Uhde (1980) described 7 out of 67 cases with all keys present at the end of full banded edgewise treatment. His measurement of the angulation and inclination, however, was a modification of Andrews' specifications which lead to better scores. Andrews reported on his analysis of 314 dental casts submitted to the American Board of Orthodontics for candidate board certification (White 1990). Only 3 of the 314 casts achieved all six keys. Kattner and Schneider (1993), who retrospectively compared FPA and PPA treatment results of 120 patients, also found no single case achieving all six keys. Table 10.5 compares the findings of Kattner and Schneider (1993) and Andrews (White 1990) with those of this study. Overall, in this study, the percentage of cases meeting the requirements of each individual key were more often close to Andrews than to Kattner and Schneider. The only clearly different value is for key 2 (inclination). The relatively low percentage of cases with an ideal inclination according to the Six Keys Analysis might be explained by the fact that hardly any of the participating orthodontists ended with full-sized arch wires in the finishing stage (table 10.2). In chapter 2.3.2.2 the protocol for archwire sequence in FPA treatment is described. It is stated that not all of the suggested wires had to be used. From table 10.2 it can be concluded that all but one participating orthodontist refrained from filling up the bracket slot with the finishing stage archwire. They used the working stage archwires as finishing stage archwires as well. Strictly, this is not a protocol violation but this treatment strategy is not fully according to the precepts of the straight wire treatment philosophy. Roth (1993) stated that using his appliance "...not filling the slots....will preclude anyone from achieving ideal occlusion". Since the Roth prescription has built in into the appliance "...overcorrection in all planes of space as an end of appliance therapy tooth positioning goal!", the teeth have to settle into optimal conclusion (Roth 1993). Therefore, differences in treatment results, if present, can only be measured after the teeth have had the chance to settle into optimal occlusion. It is, however,

Table 10.5
Percentage of casts with keys present
** Posterior limit of the occlusal plane =first molars*
*** Posterior limit of the occlusal plane =second molars*

variable	this study* n=134	White (1990)** n=314	Kattner and Schneider (1993)* n=120
key 1: AP molar relationship	22%	20%	13%
key 2: angulation	4%	9%	<1%
key 3: inclination	3%	22%	10%
key 4: rotations	41%	33%	19%
key 5: contacts	51%	57%	31%
key 6: curve of Spee	96%	44%	100%

Table 10.6
Descriptive statistics of the lateral cephalograms. The mean angle ± standard deviation are given
+1 = upper central incisor
-1 = lower central incisor
sign = significance
ns = not significant
non-extr = non- extraction group
extr = group of patients in which 2 to 4 premolars were extracted

	appliance			extraction		
	FPA n=55	PPA n=57	sign	non-extr n=74	extr n=38	sign
spinal plane to +1	109 ± 7	111 ± 7	ns	111 ± 7	108 ± 6	ns
occlusal plane to +1	59 ± 6	58 ± 5	ns	58 ± 5	61 ± 6	p=0.03
occlusal plane to -1	62 ± 7	63 ± 7	ns	62 ± 7	64 ± 6	ns
mandibular plane to -1	102 ± 10	99 ± 12	ns	101 ± 10	101 ± 12	ns
+1 to -1	119 ± 11	119 ± 11	ns	118 ± 10	119 ± 12	ns

doubtful why teeth treated with a full sized archwire in an FPA would settle better than teeth treated with an FPA without fully filling up the bracket slot or with a PPA.

The posttreatment angulation of maxillary anterior teeth was found to be better for FPA than for PPA. This was also found when the angulation for maxillary anterior and posterior teeth were combined as well as when maxillary and mandibular tooth angulation were examined as a combined variable. The strongly significant difference in one arch segment (maxillary anterior teeth), however, has influenced the findings for combined variables. Kattner and Schneider (1993) found the same phenomenon in their study

with maxillary posterior angulation as a very strong difference. They also found appliance differences for the inclination of the maxillary posterior teeth. In this study we could not assess them.

In chapter 8 the results of treatment with either an FPA or a PPA were compared using the PAR index. No differences were found between both therapies for neither the PAR index nor for the different components of the PAR index. Using that index upper and lower labial segment alignment can be evaluated but not the inclination and angulation of these teeth. This is a limitation of the PAR index that does not go for the six keys analysis. The six keys analysis, in this study, shows a major difference between the results of both therapies regarding the upper labial segment. This difference would not have been found using the PAR index only. Therefore, the six keys analysis is a useful addition to the PAR index in evaluating orthodontic treatment results.

The reported values of Kattner and Schneider (1993) for inclination are much higher than the values as reported in this study The combined score for inclination in their study ranges from 80.6 to 84.8% whereas in this study the values ranges from 37.4 to 54.5% (table 10.4). Two possible explanations can be given for this difference. Firstly, in this study filling up the bracket slot with full-sized arch wires was not done by nearly all of the participating orthodontists (table 10.2) whereas this was more routinely carried out by the orthodontists in the other study. Secondly, Kattner and Schneider obviously applied the specifications for the assessment of inclinations according to Uhde (1980) and not according to Andrews (1989). In Andrews' specifications inclination is considered absent when the recorded value differs more than plus or minus 2° from the optimal for that tooth type. In Uhde's specifications it was sufficient when the inclination of, for instance, the maxillary incisors was positive or of the mandibular posterior segment was negative. Excessive or too little positive inclination was not used as a criterion for rejection of this variable. Kattner and Schneider recognized that actual measurements would be needed. In our study these actual measurements were made, probably resulting in lower values for inclination.

Dividing the treated group in non-extraction and extraction patients showed some significant differences in the Six Keys Analysis. Firstly, the inclination of the mandibular posterior

segments differed; the extraction group showed higher values. It could be expected that the anterior segment would show lower values because incisors tend to tip back when an extraction diastema is closed without fully filling up the bracket slot with full-sized arch wires. This difference, however was not significant after Bonferroni correction. On the other hand, there is no reasonable explanation why the values in the posterior segment are higher in the extraction group. Secondly, contacts and AP molar are significantly better in the non-extraction group than in the extraction group. No interaction could be assessed between appliance and extraction indicating that creation of tight contacts and a good antero-posterior molar relationship are independent of the type of fixed appliance that is used.

The most prevalent key present in the occlusion at the end of treatment was key 6, curve of Spee. In this study a flat or mild curve of Spee was present in 96% of the cases. Uhde (1980) reported a flat or mild curve in 91% of the cases, Kattner and Schneider (1993) 100% and Andrews (White 1990) 44%. It is unclear why in the sample as studied by Andrews so many cases were considered to have a deepened curve of Spee especially when it is considered that Andrews tolerates 2.5 mm depth of curve, whereas Uhde tolerates not more than 1.5 mm.

Cephalometrically, the angle between the occlusal plane and the maxillary incisor was bigger in the extraction group (61°) than in the non-extraction group (58°). In the Six Keys Analysis this would correspond with the maxillary anterior inclination. In the latter analysis, however, a non-significant difference (after Bonferroni correction) was found for the mandibular anterior inclination; this key is more present in the non-extraction group (52.8%) than in the extraction group (38.2%). It is possible that the relation as was assessed by Andrews in his unpublished work (Andrews 1989) between the long axis of the tooth and the long axis of the clinical crown is not correct. This might lead to different results when an assessment of the clinical crown axis (Six Keys Analysis) is compared to an assessment of the tooth axis (cephalograms).

Since no interaction was found between the variables appliance and extraction for the cephalograms, this means that the more upright (tipped back) position of the upper incisors in the extraction group can not be explained by the appliance used. This is

somewhat surprising considering the fact that in most cases the play between the size of the wire and the size of the slot is bigger in the FPA group than in the PPA group (table 10.2).

10.5 Conclusion

In conclusion it can be stated that equally adequate treatment results can be achieved with a fully programmed and a partly programmed fixed appliance therapy when they are evaluated using the Six Keys Analysis. FPA therapy only scores better on "artistic positioning" (angulation) of the maxillary incisors. Differences in treatment result may occur when extraction and non-extraction therapies are compared, but these differences can not be explained by the appliance that was used. Cephalometrically, no differences in anterior tooth position could be assessed between both appliances. The inclination of the upper incisors was negatively influenced in case of extraction, but this could not be explained by the appliance that was used. Not filling up the bracket slot with full-size arch wires seems to have less impact on treatment results than can theoretically be expected.

10.6 References

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CHAPTER 11

General discussion

11.1 Introduction

Most studies on the effectiveness of orthodontic treatment are retrospective. No study has been published yet that compares the effectiveness of different treatment modalities with fixed appliances in a prospective controlled trial. The results in clinical papers are largely uninterpretable due to numerous and obvious biases (Johnston 1994). The best information on whether a given treatment does more good than harm to patients with a given disorder results from a randomized clinical trial (RCT) in which patients with the given disorder are allocated randomly to receive either the given therapy or a conventional therapy and then followed for clinically relevant outcomes of their disease and its treatment (Sackett 1994).

The purpose of our study was to evaluate the effects and results of orthodontic treatment of patients with a Class II malocclusion with a fully programmed edgewise appliance (FPA) compared with the effects and results of treatment with a partly programmed edgewise appliance (PPA) in a randomized prospective clinical trial design.

11.2 Trial design

One of the most important goals of clinical orthodontic research is to identify and isolate the effects of treatment per se. Non-randomized studies do not in fact measure and report treatment effects, but they rather measure changes observed during treatment that may or may not be caused by treatment itself. The value of the RCT lies in its ability to minimize biases both known and unknown. Randomization is generally considered ethically appropriate if there is true uncertainty as to which procedure is in the best interest of the subject (Baumrind 1994). In the literature no prospective randomized study could be found that compared treatment effects of an FPA and a PPA. A retrospective study showed almost no difference (Kattner and Schneider 1993). Therefore, it was appropriate to start an RCT to compare the treatment effects of orthodontic treatment with an FPA and a PPA.

In a controlled clinical study, the research design usually includes the participation of a specially trained and exceptionally well-qualified clinician working on a selected group of patients often in an academical clinic. This clinical setting is very different from that of a busy general orthodontic practice, and it is not considered

cost-effective and realistic for affordable orthodontic care to change the average clinical setting to that of the controlled academical clinical trial. Data from laboratory studies are even further divorced from clinical practice. As a consequence, the results from controlled academical clinical and laboratory studies can not always be extrapolated to real-life orthodontics (Mjör and Wilson 1997). It is important that orthodontic research investigates problems that are recognized and understood by clinicians. In this study, the assessement of efficiency of FPA versus PPA treatment in daily practice was more important than the assessment of maximal efficiency of both treatment options. Therefore, a ***multi-centre*** clinical trial was set up. In chapter 2 we have described that all orthodontists involved had a comparable orthodontic educational background. They treated the patients that were involved in this study in their own private practice. By choosing for a multi-centre design, the clinical relevance of the results is more apparent than if this research would have been conducted by one or two orthodontists in an academic setting.

RCT's, however, are expensive, labor-intensive and time-consuming for the operators. Furthermore, specifically orthodontic trials have a long timespan due to the nature of orthodontic treatment. As a consequence, there is a chance that the results of an RCT are outrunned by time. This study was started in April 1990 and the fixed appliances of the last patient were removed in January 1996. Since this study was started several new appliance designs have been presented by various manufacturers. In all these different prescriptions and designs one feature, however, remains unaltered, in this case the fully programmed bracket slot. This means that tip, torque and in/out have been built in but (surprisingly) these values vary for every single manufacturer (Proffit 1993). Nevertheless, the results from this study are still valid. Furthermore, treatment strategy has altered with regard to wire bending and finishing (Bennett and McLaughlin 1993). Nowadays, minor wire bending (first and second order bends) in the finishing stage is considered necessary in many cases to obtain a perfect result. It is also recommended to use a thin final archwire with vertical elastics in the posterior region in order to obtain socking in of the (pre-)molars. Therefore, strictly no wire bending, as was prescribed in our protocol, is not considered the best choice for finishing an FPA therapy

nowadays. It is questionable if, today, anyone in general orthodontic practice will treat his/her patients strictly with no wire bending.

11.3 Hypotheses

In chapter 1 seven hypotheses have been formulated that were to be investigated in this study They will be discussed successively.

1. FPA translation brackets can control rotations for teeth requiring translation without auxiliaries better than a PPA.

This hypothesis could not be confirmed by this study. The evaluation of rotations was done by using the ITRI. It was the first time that (a part of) this index was used for this purpose. Normally, the ITRI analysis consists of 62 potential contacts in a non-extraction case or 50 potential contacts in a four premolar extraction case. In this study only posterior intra-arch contacts were recorded in the dental arch were extraction had taken place. This means that in a four premolar extraction case the maximum number of contacts that we evaluated was 12 per patient. The partial ITRI seems to be a useful tool in evaluating rotations after bodily movement of teeth into extraction diastema.

2. Treatment with an FPA requires less chairtime for the orthodontist and/or dental assistant to reach the Six Keys goals than with a PPA.

It was concluded that the chairtime for orthodontists was comparable for both treatments but the chairtime for dental auxiliaries and the total chairtime was significantly more for a treatment using FPA as compared to a treatment using a PPA.

As laid down in the protocol (chapter 2), no wire bending was allowed for FPA treatment. This means that even for minor adjustments the bracket(s) had to be replaced. In every day orthodontic practice, treatment with an FPA normally is not strictly with straight wires; now and then bends are made in the archwire This means that for minor corrections brackets do not have to be replaced like in our protocol. This has a direct influence on the chairtime; replacing a bracket takes a lot more time than bending a (finishing) archwire. Most probably, therefore, the statistically significant difference in chairtime in favor of the PPA treatment is not clinically relevant. It might be possible that this difference would be in favor of FPA treatment if minor bends were allowed in the protocol, which is more in agreement with every day clinical practice.

3. FPA is physically and psychologically more comfortable to the patient than is a PPA.

No significant differences between both treatment modalities or between the participating orthodontic practices were found regarding physical or psychological discomfort. Significantly more patients with an FPA than patients with a PPA felt that they were not sufficiently able to clean their teeth and appliance. At the end of treatment patients of both groups were about equally satisfied about the treatment result. No significant differences in patient satisfaction could be assessed between both treatments or between the participating orthodontists.

Physical and psychological discomfort are very subjective sensations that are experienced by the patient. Therefore, they are difficult to measure. The only statistical difference that could be found is probably not clinically relevant. The quality of the questionaires was assessed by evaluation of the "internal consistency". In using this method, attitudes are studied by more than one question. By assessing the mutual correlation between these questions, an indication can be aquired about the specific attitude. It must be considered, however, that internal consistency does not per se mean that a questionnaire is valid. Socially desirable answers may lead to high internal consistency but low validity.

4. FPA will cause less rootresorption than PPA.

The evaluation of apical root resorption showed no difference between both appliances. Although many treatment factors have been related to this phenomenon, the presence of jiggling movements or round tripping have anecdotally been stated as a cause for resorption without any hard evidence. Straight wire therapy would eliminate jiggling and round tripping, thus reducing apical root resorption. In this study we did not evaluate jiggling and roundtripping, because to study these undesirable side effects, records (alginate impressions and/or standardized photos) would be necessary at every visit. This is very difficult to arrange in a multi centre clinical trial in a non-academic setting. Alexander (1996) studied levels of root resorption associated with continous arch and sectional arch mechanics. The second technique produces more jiggling and roundtripping than the first. He concluded that both treatment groups exhibited the same levels of resorption indicating that the side effect of treatment may be due to individual variation

and not to the round tripping of teeth. This is in accordance with our findings.

5. The FPA design will lead to less plaque retention and gingival irritation than a PPA.

It was concluded that an FPA and a PPA have the same effect on the periodontal parameters. A supposed less deteriorating effect on the patients' periodontium due to the design and use of the FPA could not be confirmed.

The clinical periodontal parameters were assessed mostly by the same person in the different participating practices. Since no inter-observer agreement was assessed for the different periodontal evaluation criteria (the internal consistency was assessed), it is difficult to weigh the significance of the conclusions. It is very well possible that substantial differences might be present in the way that these data were collected despite the fact that all practices received the same instructions. As stated before, sufficient internal consistency can go together with low validity. Therefore, pertinent judgements concerning this hypothesis may not be made.

6. A correctly prescribed and sited FPA will direct teeth to ideal tooth positions with less treatment time than will a PPA.

We found that the treatment time of both types of treatment was comparable in extraction as well as non-extraction therapy.

Especially for extraction therapy, Roth (1976) was very specific about the reduction of treatment time: 3 to 6 months. He explained this by the movement of teeth in direct vector lines. However, a well designed and constructed closing loop only needs to be activated about once every 4 weeks without taking out the archwire, delivering a continuous, controlled force. Elastomeric chains, on the other hand, as were used in FPA treatment to close spaces, produce rapidly decaying interrupted forces (Proffit 1993). Samuels et al (1993) made a comparison of the rate of space closure using a nickel-titanium spring and an elastic module. Nickel-titanium springs are frequently used for space closure in orthodontic practices last years. They found that the rate of space closure was greater and more consistent with the nickel-titanium closed coil springs than with the elastic modules, in both arches. They suggested that a low constant force, as offered by the nickel-titanium spring may be more biologically acceptable than the intermittent high force delivery of the elastic modules. The latter

undergo force degradation of approximately 50% after 4 weeks with consequent loss of action. Pilon et al (1996), however, have shown that there is no direct relation between the rate of space closure and the force that is applied to the teeth.

7. A correctly prescribed and sited FPA will lead to better treatment results than will a PPA.

The treatment results were assessed using the PAR index and the Six Keys Analysis. Evaluation of the PAR index and its different components did not show statistically significant differences between both therapies. There were significant differences between the participating orthodontists. Using the Six Keys Analysis we found significant better results for the FPA for the maxillary anterior angulation. Here as well, there were significant differences between the participating orthodontists. This might lead to two different conclusions. The first one is that an FPA and a PPA therapy are equally effective in correcting a malocclusion. The second conclusion is that the most important factor in the correction of malocclusion is not the appliance that is used but the person who is handling it. To quote Roth (1993): "The Straight Wire is nothing more than a "tool". One can make beautiful furniture with simple tools or sophisticated tools. One can also turn out junk with each."

11.4 Additional studies

Two additional studies have been conducted for this trial. In the first one a comparison was made between two different methods to determine the arch length discrepancy (ALD) in a dental arch. No specific instructions were given to the participating orthodontists about how to assess the difference between the space available for alignment of the teeth and the amount of space required to align them properly when making a treatment plan. Drawing up an inventory before the intake of patients had started showed that this part of the diagnosis was conducted by each of the operators in one of two possible manners: measuring or assessment by eye. Since one of the criteria on which the treatment allocation was balanced was the amount of crowding or spacing, it was advisable to know if there are any differences between both methods regarding reliability and reproducibility. Otherwise, one standardized method would have had to be recommended. Both methods, however, were valid and reproducible.

The second additional study was conducted for another reason. Initially, the participating orthodontists were asked to adhere a thin metal plate of 4 x 4 mm centrally on the labial surface of one central upper incisor when the obligatory solo radiograph was made (table 2.4). By applying the same plate on both pre- and post-treatment radiographs, for magnification could be corrected. Unfortunately, when the radiographs were returned to the trial administration at the end of treatment, evaluation showed that in many instances placement of the metal plate was forgotten. Furthermore, in many cases, the radiographs were of poor quality probably resulting from the lack of standardization. Since evaluation of apical root resorption was not possible anymore using the correction for magnification by the metal plates, an other method had to be found. Conventional semi-quantitative assessment of apical root resorption is a rather course instrument because it is difficult to compare the X-rays from the start of treatment with those from the end of treatment because of considerable varieties in projection. Using a digital reconstruction technique as is described in this study, it is possible to correct for these projection diversities (within certain limits) and conduct a rather precise assessment of the (relative) amount of apical root resorption. The method that we developed can be helpful for retrospective studies of apical root resorption on non-standardized X-rays. In prospective studies this method can give very precise information about the actual amount of apical root resorption when X-rays are standardized with a known reference projected on the film as well.

11.5 Future research

In this study the final measurements are nearly all made on the day that he appliances were removed. This means that the end of appliance results are described. Roth (1993) claims that in the Roth prescription over-correction is built in as a basis for socking in to ideal tooth positions. Future research should evaluate the treatment results after the retention period. It can be assessed then if an FPA provides a better basis for an ideal occlusion after socking in than a PPA. Furthermore, in future trials a comparison of treatment efficiency could be made between different pre-adjusted appliances. In other words: is it necessary to have so many different prescriptions while every manufacturer claims that his presription

will lead to the best treatment result?

11.6 General conclusion

To sum up, it may be stated that none of the hypotheses can be confirmed fully by this study. If there are any significant differences, PPA treatment is better off than FPA treatment (chairtime, toothbrushing) except for maxillary anterior angulation. Furthermore, in several evaluations significant differences were found between the participating orthodontists.

The bottom line is that it is possible to treat cases well or poorly with either appliance. The Straight Wire Appliance is nothing more than a "tool" (Roth 1993).

11.7 References

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Summary

In this thesis the effects and results of orthodontic treatment with a fully programmed edgewise appliance (FPA) are compared with the effects and results of treatment with a partly programmed edgewise appliance (PPA).

The general introduction in **Chapter 1** presents a short historical overview of orthodontic fixed appliance treatment and a description of the different edgewise appliances. A review of the literature on the Straight Wire Appliance is given. The main objectives of the study are presented as seven hypotheses that are to be tested.

Chapter 2 gives information about the design of the prospective randomized clinical trial. Patient selection, the participating orthodontists, treatment protocols and the data collection are discussed. A group of 149 Angle Class II patients were selected for this study. The experimental variable "type of fixed appliance" was assigned by balanced allocation. The group of patients is described using the 10 balancing criteria for treatment allocation. Furthermore, some cephalometric characteristics of the sample are described.

Chapter 3 describes the results of a pilot study. It was studied whether it is possible to assess reliably crowding or spacing for an orthodontic diagnosis by eye instead of by measuring. It shows that assessment by eye and measurement results are well comparable and reproducible. Assessment by eye has the practical advantage that it takes considerable less time.

The duration of treatment and the chairtime of both the orthodontist and his/her auxiliaries are described and analyzed in **chapter 4**. The treatment duration is, as assessed for the entire sample, not significantly different for both types of appliance. This goes for both extraction and non-extraction therapy. Within the single practices there are significant differences but these can not be explained by the type of appliance. The chairtimes for the orthodontists are comparable for both treatment types, but the auxiliaries spend more time on FPA treatment. Furthermore, the total chairtime for FPA treatment is significantly longer than for PPA treatment.

Chapter 5 consists of two parts. In the first part the results are described of a pilot study. In vitro and in vivo, the reliability is assessed of a new digital technique that is able to correct the solo radiographs from the begin and the end of treatment for different projections and orthodontic movement. It is concluded that this method is reliable to assess the prevalence and degree of apical root resorption on non standardized solo radiographs. In the second part of this chapter this technique is used to assess the prevalence and degree of apical root resorption on the central upper incisors of the patients in the sample of this study. The occurrence and the extent of apical root resorption are independent of the type of fixed appliance that is used.

Chapter 6 deals with discomfort as experienced by patients that are treated with fixed appliances. Two types of discomfort were deduced from the questionnaires that were filled in by the patients: psychological and physical. For both the degree was not dependent of the type of fixed appliance or the practice in which the treatment was conducted. The same goes for the satisfaction with the treatment result.

In **chapter 7** the influence of fixed appliance treatment on periodontal parameters is described. Gingivitis is a commonly observed phenomenon that frequently occurs after placement of fixed appliances. The FPA design is considered to have a less unfavorable influence on the gingiva. The amount of dental plaque, the tendency for bleeding of the gingiva after probing and the pocketdepths were assessed at different points in time. Evaluation of the different assessments shows that the variable "type of fixed appliance" does not have an influence on any one of them.

In **chapter 8** the treatment results as assessed with the PAR index are described. Both the reduction in PAR score and the post-treatment PAR score show no significant differences for both treatment options. There are, however, significant differences within the different practices. No interaction could be assessed between the type of fixed appliance and the orthodontist with respect to the reduction in PAR score or the post-treatment PAR score.

Movement of teeth after extraction may cause undesired rotations. In **chapter 9** it is tested whether an FPA treatment can prevent these rotations better than a PPA treatment. This is assessed by using (a part of) the ITRI (= Ideal Tooth Relationship Index). It

shows that no confirmation can be given that an FPA treatment can prevent these rotations in a better way than a PPA treatment.

In **chapter 10** the treatment results are described using the Six Keys Analysis. Also, a limited number of cephalometric values are assessed. First, a description of the Six Keys Analysis is given. Evaluation shows that FPA treatment results in a significantly better angulation of the upper front ("artistic positioning") than PPA treatment. There are no further significant differences between both treatment options. Comparison between the non-extraction and the extraction therapy group shows that the non-extraction group scores better on the inclination of the lower front, rotations and AP molar relationship but worse on inclination of the lower (pre-)molars. No interaction between type of fixed appliance and (non-) extraction therapy could be assessed. Evaluation of the cephalometric values only shows a significant difference between the non-extraction and the extraction therapy group: the angle between the upper incisor and the occlusal plane is larger in the extraction group.

Finally, in **chapter 11** a general discussion is given. The results of the different hypotheses are discussed and suggestions for further study are given. The most important conclusion of this study is that a good or a bad treatment result is not primarily set by the appliance that is used but by the person that handles the appliance.

Samenvatting

In dit proefschrift worden de behandelingseffecten en resultaten van orthodontische behandeling met volledig geprogrammeerde vaste apparatuur (FPA) vergeleken met de behandelingseffecten en resultaten van behandeling met gedeeltelijk geprogrammeerde vaste apparatuur (PPA).

De algemene inleiding in **hoofdstuk 1** geeft een kort historisch overzicht van orthodontische behandeling met vaste apparatuur. De verschillende soorten vaste apparatuur worden besproken. Een literatuuroverzicht wordt gegeven omtrent de Straight Wire Appliance. De hoofddoelstellingen van dit proefschrift worden weergegeven aan de hand van zeven hypotheses, die zullen worden getest.

Hoofdstuk 2 geeft informatie over de opzet van het prospectieve gerandomiseerde klinische onderzoek. Patiëntenselectie, de behandelende orthodontisten, behandelprotocollen en de wijze van dataverzameling worden besproken. Een groep van 149 Angle klasse II patiënten werd geselecteerd voor deze studie. De experimentele variabele "type vaste apparatuur" werd via gebalanceerde loting toegewezen. De patiëntenpopulatie wordt beschreven aan de hand van de 10 balanceercriteria voor behandelingstoewijzing. Tevens worden enkele cephalometrische kenmerken van beide behandelingsgroepen gepresenteerd.

Hoofdstuk 3 geeft de resultaten van een pilotstudie. Hierin werd nagegaan in hoeverre het mogelijk is om ten bate van de orthodontische diagnose de hoeveelheid crowding dan wel spacing in een tandboog betrouwbaar te schatten in plaats van te meten. Het blijkt dat schatten en meten goed vergelijkbaar zijn qua resultaat en reproduceerbaar zijn. Het praktische voordeel van schatten is dat het aanzienlijk minder tijd kost.

De behandelduur en de behandeltijden aan de stoel voor zowel de orthodontist en zijn/haar hulpkrachten zijn beschreven en geanalyseerd in **hoofdstuk 4**. De behandelduur is, over de gehele onderzoeksgroep gemeten, voor beide typen apparatuur niet significant verschillend. Dit geldt voor zowel extractie- als voor non-extractietherapie. Binnen de praktijken treden wel verschillen op

welke niet kunnen worden verklaard uit het gebruikte type apparatuur. De stoeltijden voor de orthodontisten zijn voor beide typen apparatuur vergelijkbaar, echter de hulpkrachten besteden meer tijd aan de FPA. Ook de totale stoeltijd is voor de FPA behandeling significant langer dan voor de PPA.

Hoofdstuk 5 bestaat uit twee gedeelten. In het eerste deel zijn de resultaten van een pilotstudie beschreven waarin de betrouwbaarheid van een nieuwe digitale techniek, waarmee de solo-opnamen van het begin en het einde van de behandeling ten opzichte van elkaar kunnen worden gecorrigeerd ten aanzien van verschillen in inschietrichting en orthodontische verplaatsing, in vitro en in vivo werd bepaald. Geconcludeerd wordt dat deze methode betrouwbaar is om prevalentie en mate van apicale wortelresorptie te bepalen aan de hand van niet gestandaardiseerde solo-opnamen. In het tweede deel van dit hoofdstuk worden met behulp van digitale reconstructie in de onderzoeksgroep de prevalentie en mate van apicale wortelresorptie van centrale bovenincisieven bepaald. Voorkomen en ernst van apicale resorptie blijken onafhankelijk te zijn van het type vaste apparatuur dat wordt gebruikt.

Hoofdstuk 6 handelt over de mate van ongemak zoals die door patiënten wordt ervaren ten gevolge van behandeling met vaste apparatuur. Aan de hand van vragenlijsten, zoals die door de patiënten werden ingevuld, werden twee soorten ongemak gedestilleerd: psychisch en fysiek. Van beide bleek de mate niet af te hangen van de soort vaste apparatuur of de praktijk waarin de behandeling werd uitgevoerd. Ditzelfde geldt voor de mate van tevredenheid met het bereikte behandelresultaat.

In **hoofdstuk 7** wordt de invloed van vaste apparatuur behandeling op de verschillende parodontale parameters beschreven. Ontsteking van de gingiva is een algemeen waarneembaar beeld dat vrijwel altijd in meer of mindere mate optreedt na het plaatsen van vaste apparatuur. Het FPA ontwerp zou hierop een minder ongunstige invloed hebben. De hoeveelheid tandplaque, bloedingsneiging van de gingiva na sonderen en pocketdiepten werden bepaald op meerdere tijdstippen. Evaluatie van de verschillende bepalingen laat zien dat de variabele "type vaste apparatuur" hierop geen invloed heeft.

In **hoofdstuk 8** worden de behandelingsresultaten beschreven aan de hand van de PAR-index. De reductie in PAR score ten

gevolge van de behandeling alsmede de PAR score aan het begin van de retentieperiode laat geen significant verschil zien tussen beide behandelingen. Er zijn wel verschillen aan te tonen tussen de verschillende orthodontisten. Er is echter geen interactie tussen type vaste apparatuur en orthodontist.

Door het verplaatsen van gebitselementen na extractie kunnen o.a. ongewenste rotaties optreden. In **hoofdstuk 9** wordt onderzocht of een FPA behandeling deze rotaties beter kan voorkomen dan een PPA behandeling. Dit wordt bepaald met behulp van de (partiële) ITRI (= Ideal Tooth Relationship Index). Hieruit blijkt dat niet kan worden aangetoond dat een FPA behandeling deze rotaties beter kan voorkomen dan een PPA behandeling.

In **hoofdstuk 10** worden de behandelingsresultaten beschreven aan de hand van de Six Keys Analysis. Tevens worden een beperkt aantal cephalometrische waarden beschreven voor en na behandeling. De resultaten laten zien dat met behulp van FPA behandeling de angulatie van het bovenfront ("artistic positioning") significant beter is dan met een PPA behandeling. Verder zijn er echter geen significante verschillen tussen de beide types vaste apparatuur. Na vergelijking van de extractie met de non-extractie groep blijkt dat de non-extractie groep beter scoort qua inclinatie van het onderfront, rotaties en sagittale molaarrelatie maar slechter qua inclinatie van de onder (pre-)molaren. Er is geen interactie tussen type vaste apparatuur en (non-)extractie therapie. De cephalometrische evaluatie laat alleen verschil zien tussen de extractie en de non-extractie groep: de inclinatie van de bovenincisief t.o.v. het occlusievlak is groter in de extractie groep.

Tot slot volgt in **hoofdstuk 11** een algemene beschouwing. De resultaten van de verschillende hypotheses worden bediscussieerd en suggesties worden gedaan voor toekomstig onderzoek. De belangrijkste conclusie van dit onderzoek is dat een goed of slecht behandelingsresultaat niet primair wordt bepaald door de gebruikte apparatuur maar door diegene die de apparatuur toepast.

APPENDICES

Appendix A

Toestemmingsinformatie betreffend klinisch onderzoek naar twee soorten vaste apparatuur.

De orthodontist heeft het behandelplan met je besproken en hieruit blijkt dat hij je tanden recht gaat zetten met een vaste beugel.

Nu zijn er in de orthodontie verschillende soorten vaste beugels, waarmee je de tanden keurig netjes naast elkaar kunt zetten. Net zoals er verschillende soorten tandenborstels zijn waarmee je allemaal je tanden goed kunt poetsen. Alleen zul je met de ene bijvoorbeeld wat makkelijker poetsen dan met de andere.

Wij (de vakgroep Orthodontie van de Katholieke Universiteit Nijmegen) willen die twee soorten vaste apparatuur, die wereldwijd het meest worden toeqepast, met elkaar vergelijken. We willen onderzoeken of er een verschil is in de behandeling met beide soorten vaste beugels o.a. met betrekking tot duur van de behandeling, het poetsen, last van de beugel en eindresultaat.

Je orthodontist werkt met beide soorten vaste beugels en is bereid aan het onderzoek mee te doen. De vraag is of jij ook bereid bent aan het onderzoek mee te doen.

Deelnemen aan het onderzoek betekent voor jou, in vergelijking met andere kinderen die niet meedoen:
1. dat er bij het begin van de behandeling een röntgenfoto van je boventanden wordt gemaakt en aan het eind van de behandeling (na ongeveer 2 jaar) weer.
2. dat er af en toe een extra gebitsafdruk genomen wordt om vast te leggen hoe de behandeling vordert. Je moet dus een paar keer meer 'happen' dan andere kinderen.
3. dat je bij sommige controles wat meer tijd kwijt bent, omdat er in het kader van het onderzoek extra metingen moeten worden verricht, bijvoorbeeld met betrekking tot het poetsen. Deze metingen moeten op speciale formulieren genoteerd worden en dat kost tijd.

Mocht je halverwege de behandeling besluiten niet meer aan het onderzoek te willen deelnemen, dan heeft dat geen gevolgen voor het verdere verloop van je behandeling.

Indien je mee wil doen aan het onderzoek en ook je ouders/verzorgers hier geen bezwaar tegen hebben, is het van belang dat je dat schriftelijk laat weten door ondertekening van bijgaand formulier.

Naam:.....

Naam
ouder/verzorger:.....

Hiermee verklaren wij geen bezwaar te hebben tegen deelname aan het onderzoek naar vaste apparatuur. Wij zijn bereid gedurende de studie regelmatig op controle te komen en de gewenste metingen te laten verrichten.
Wij hebben de uitgereikte toestemmingsinformatie gelezen en begrepen en zijn op de hoogte van het doel van het onderzoek en de aard van de behandeling.

Plaats ..... Datum .....

Handtekening
patient.....

Handtekening
ouder/verzorger.....

Verklaring van geen bezwaar afgegeven door de Medisch Ethische Commissie, Faculteit der Geneeskunde en Tandheelkunde/Sint Radboud Ziekenhuis, Katholieke Universiteit Nijmegen, d.d. 03-10-1989 (CEOM-Nr: 1989-2440)

Appendix B
Treatment allocation form

Name of patient:..... Studynumber
Patient number:..... Date of birth

Registration date

* Sex
1= girl; 2 = boy

* Type of Class II
1 = Cl. II div. 1; 2 = Cl. II div. 2; 3 = Cl. II div. 1 subdivision;
4 = Cl. II div. 2 subdivision

* Molar relationship (first permanent molars) Class II
1 = 1/2 premolar width (pw); 2 = 3/4 pw; 3 = 1 pw or more

* Arch length discrepancy (see chapter 3.1)
1 = spacing; 2 = crowding $0 \leq x \leq 3$ mm; 3 = crowding > 3 mm

* Overjet
1 = $x \leq 5$ mm; 2 = $5 < x \leq 10$ mm; 3 = $x > 10$ mm

* Overbite
1 = $x \leq 3$ mm; 2 = $x > 3$ mm

* Open bite
1 = none; 2 = partial in the frontal region; 3 = partial in the molar/premolar region; 4 = total open bite

* Trauma
1 = no; 2 = yes

* Extraction therapy
1 = none; 2 = 2 premolars (first or second);
3 = 3 or 4 premolars (first or second)

* Initial treatment
1 = none; 2 = functional appliance; 3 = headgear;
4 = headgear with removable appliance

Treatment allocation 1=PPA; 2=FPA

Appendix C
Data form

Number of visit ☐

Name of patient:..... Studynumber ☐

Registration date ☐

☐ solo front ☐ intra-oral slides ☐ impressions ☐ pocketstatus

GI

0 = no bleeding
1 = small bleeding points
2 = immediate bleeding

☐☐☐

☐☐☐

PI

0 = no plaque
1 = no plaque by eye but by probing
2 = thin visible layer
3 = thick layer

☐☐☐

☐☐☐

CIPTN score
(to be filled in by trial administration)

☐☐☐

☐☐☐

Effective chairtime

auxiliary ☐

orthodontist ☐

Details:

The questions in this questionnaire are only related to your fixed braces and not to the facebow and/or elastics.

You can answer the questions by marking the figure that fits you best. Only one answer is possible, unless otherwise is stated.

If you have any question or additional remark about your braces, please use the backside of this form.

Good luck with filling in!

1. Were you yourself satisfied or unsatisfied about the position of your teeth?
1= very satisfied ;2= satisfied;3= unsatisfied;4= very unsatisfied
2. Were your parents/guardians satisfied or unsatisfied about the position of your teeth?
1= very satisfied;2= satisfied;3= unsatisfied;4= very unsatisfied
3. Were you teased because of your teeth?
1= always; 2= often; 3= sometimes; 4= never
4. Did you feel that your upper teeth were positioned too far forward?
1= yes; 2= no
5. Did you feel that your lower teeth were positioned too far forward?
1= yes; 2= no
6. Did you feel that your upper teeth were too far apart from each other?
1= yes; 2= no
7. Did you feel that your lower teeth were too far apart from each other?
1= yes; 2= no
8. Did you feel that your upper teeth were too much overlapping each other?
1= yes; 2= no
9. Did you feel that your lower teeth were too much overlapping each other?
1= yes; 2= no
10. Did you suffer from the position of your teeth while chewing?
1= very much; 2= much;3= little; 4= no
11. Did you suffer from the position of your teeth while biting off?
1= very much;2= much; 3= little; 4= no
12. Did you suffer from the position of your teeth while speaking?
1= very much; 2= much; 3= little; 4= no
13. Did you suffer from the position of your teeth while brushing them?
1= very much;2= much;3= little; 4= no
14. Did you suffer from the position of your teeth while closing your lips?
1= very much; 2= much; 3= little; 4= no

15. How many times each day did you brush your teeth when you did not have an orthodontic appliance?
1= 0 times; 2= 1 time; 3= 2 times; 4= 3 times or more
16. How long did you brush your teeth?
1= less than 3 minutes; 2= more than 5 minutes; 3= about 3 minutes
17. Who took the decision to be treated orthodontically?
1= you yourself; 2= your parents; 3= your dentist; 4= someone else:.....
18. Did you or didn't you feel annoyed about wearing an orthodontic appliance?
1= very annoyed; 2= annoyed;3= little annoyed;4= not annoyed
19. How do you think about your appliance?
1= very ugly; 2= ugly; 3= not ugly; 4= beautiful
20. How do you think others think about your appliance?
1= very ugly; 2= ugly; 3= not ugly; 4= beautiful
21. Is your appliance time consuming to you (monthly visits, adjusting etc.?)
1= yes; 2= no
22. Does your appliance cause pain?
1= yes; 2= no
23. Are you allowed to eat everything with your appliance?
1= yes; 2= no
24. Can you eat everything with your appliance?
1= yes; 2= no
25. Are you teased because of your appliance?
1= always; 2= often;3= sometimes; 4= never
26. Does the appliance press upon your toothgums?
1= always;2= often; 3= sometimes; 4= never
27. Does the appliance prod your toothgums?
1= always; 2= often; 3= sometimes; 4= never
28. Does food attach to your appliance?
1= always; 2= often; 3= sometimes; 4= never
29. How many times each day do you brush your teeth now that you wear an appliance?
1= 0 times; 2= 1 time; 3= 2 times; 4= 3 times or more
30. How long do you brush your teeth now that you wear an appliance?
1= less than 3 minutes; 2= about 3 minutes; 3= more than 5 minutes

31. Do you feel that you can clean your teeth and your appliance in a sufficient way?
1= yes; 2= no
32. What do you use to brush your teeth and your appliance (more than 1 answer is possible)
1= regular toothbrush;2= special toothbrush; 2= mono tufted brush; 4= mouthwash; 5= toothpicks; 6= something else:.....
(only visit 10 and removal appliance) 33. Are you satisfied with the treatment result (so far)?
1= very satisfied;2= satisfied;3= unsatisfied;4= very unsatisfied

DANKWOORD

Dit proefschrift zou niet tot stand zijn gekomen zonder de hulp van vele mensen. Dit geldt in de eerste plaats voor de 149 jongens en meisjes die, ook wanneer ze er een keer geen zin in hadden, extra afdrukken, foto's, pocket statussen, plaque indexen enzovoorts lieten maken voor iemand die ze verder niet kennen. Graag wil ik iedereen van harte bedanken voor zijn/haar inzet. Enkele mensen wil graag met name noemen.

Prof. dr A.M. Kuijpers-Jagtman, beste Anne-Marie. Jouw inzet en begeleiding zijn onmisbaar geweest voor het afronden van dit onderzoek en de rapportage hierover. Ik heb diep respect voor jouw wijze van werken. Bedankt voor een prettige en soepele samenwerking.
Dr M.A. van 't Hof, beste Martin. 1, 2, 5, 10 en 11; met veel plezier denk ik aan dit rijtje terug en ik zal me die nog lang kunnen heugen. Jouw statistische inbreng heeft het peil van dit proefschrift significant positief beinvloed.
Prof. dr F.P.G.M. van der Linden, Prof. dr H. Boersma. Hartelijk dank dat U mij de mogelijkheid hebt geboden om bij U in opleiding te komen. Uw warme en kritische belangstelling voor dit onderzoek heb ik als stimulerend ervaren.
Drs. W.J.D.M. van Beers, Drs. V.M.F. Borstlap, Drs. R.L.M. van Kerkoerle, Drs. S.T. Kusters, Drs. W.J. Lijten, Dr J.K. Noverraz-Maertens, Drs. R.R.M. Noverraz, Dr J.G.J.H. Schols en Drs. H.J.W. Wassenberg; Beste Wilma, Veronique, Rob, Stefan, Willem-Jan, Johanna, René, Jan en Hein. Wat is een multi-center clinical trial zonder toegewijde centers? Ik wil jullie en jullie medewerkers hartelijk bedanken voor de manier waarop jullie, tussen alle drukke bedrijven door, alle data hebben verzameld voor dit onderzoek.
Drs. S.M. Geurts, beste Sabine. Zonder jouw doorzettingsvermogen was dit onderzoek nooit van de grond gekomen. Bedankt voor het opzetten van de trial.
Dr G.C.H. Sanderink, beste Gerard. Jouw enthousiasme en geheel belangeloze medewerking bij het digitaal bepalen van wortelresorptie vond ik uitermate prettig. Bedankt voor je hulp en goede adviezen.
Mw. A. Prischmann, beste Anja. Bedankt voor het mooie

fotomateriaal.
Dhr. L.J.H. Hofman, beste Louis. Met zijn tweeën is het zoveel prettiger om door Medline te struinen. Bedankt voor je hulp bij het verzamelen van de literatuur.
Dhr. S.J.A.M. Nottet, beste Servaas. Bedankt voor je meetprogramma's en het bewaken van de procedures.
Mr J. Willems, beste Han. Bedankt voor het kritisch doorlezen van het manuscript. Om fouten te halen uit een tekst waar je zelf niets van begrijpt vergt heldenmoed.
Dr T.S. Leenstra, Drs. E.J. van Leeuwen en Drs. C. Prahl, beste Thomas, Eric en Charlotte. De vier jaren dat wij lief en leed hebben gedeeld op "de jongenskamer" waren eindeloos. Regelmatig denk ik met veel plezier terug aan die tijd.
Alle medewerkers van de vakgroep Orthodontie wil ik bedanken voor de prettige sfeer waarin ik mijn gang heb kunnen gaan om dit onderzoek af te maken.
Lieve Carla. Jouw steun was onmisbaar. Bedankt!

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CURRICULUM VITAE

Erik Reukers werd op 31 augustus 1961 geboren te Groenlo. In 1979 behaalde hij het VWO diploma aan de R.K. Scholengemeenschap "Marianum" te Groenlo. Na één jaar aan de opleiding voor mondhygiënisten te hebben gestudeerd, begon hij in 1980 met de studie tandheelkunde aan de Katholieke Universiteit te Nijmegen. In oktober 1985 behaalde hij het tandarts-examen. Na een korte carrière als jeugdtandarts bij de Stichting Jeugdtandverzorging Noord-Oost Noord-Brabant (1985-1987) en enkele maanden als assistent in Duitsland (Dinslaken), ging hij eind 1987 werken in de praktijk van tandarts van Dijke te Hengelo (Gld). In 1988 nam hij deze praktijk over. Naast de werkzaamheden als algemeen-practicus besteedde hij een halve dag per week als volontair-onderzoeker in samenwerking met Dr P.J.J.M. Plasmans. Van 1991 tot 1995 volgde hij de opleiding tot specialist in de dento-maxillaire orthopaedie aan de Katholieke Universiteit te Nijmegen (opleiders: Prof. Dr F.P.G.M. van der Linden en Prof. Dr A.M. Kuijpers-Jagtman). Tijdens deze opleiding werd met de vervaardiging van deze dissertatie begonnen. Sinds eind 1995 is hij gevestigd als orthodontist te Zutphen in associatie met Drs. J.H. Bakker en Dr G.J. Pruim.
Erik Reukers is getrouwd met Carla van Herpen. Zij zijn de ouders van Floor en Gijs.

STELLINGEN

behorend bij het proefschrift

STRAIGHT WIRE APPLIANCE
VERSUS
CONVENTIONAL FULL EDGEWISE

A PROSPECTIVE CLINICAL TRIAL

Erik Reukers

4 december 1997

1 Op het oog bepalen van de hoeveelheid crowding en spacing heeft als praktisch voordeel dat dit ruim 5 keer zo weinig tijd kost als de methode volgens van der Linden en Boersma terwijl de nauwkeurigheid vergelijkbaar is *(dit proefschrift)*.

2 Behandeling met partieel geprogrammeerde vaste apparatuur dan wel met volledig geprogrammeerde vaste apparatuur heeft geen invloed op de duur van de orthodontische behandeling *(dit proefschrift)*.

3 Prevalentie en ernst van apicale wortelresorptie van centrale bovenincisieven zijn niet afhankelijk van behandeling met partieel geprogrammeerde dan wel volledig geprogrammeerde vaste apparatuur *(dit proefschrift)*.

4 Het uiteindelijke resultaat van een orthodontische behandeling wordt meer bepaald door de orthodontist die de behandeling uitvoert dan door het type edgewise vaste apparatuur waarmee de behandeling wordt uitgevoerd *(dit proefschrift)*.

5 Het gebruik van volledig geprogrammeerde brackets leidt tot meer consistente artistic positioning dan het gebruik van partieel geprogrammeerde brackets *(dit proefschrift)*.

6 Het sluiten van extractiediastemen op ronde bogen in een edgewise appliance getuigt van onvoldoende inzicht in de mogelijkheden van een rechthoekig bracketslot.

7. De potentieel allergene componenten in composiet in ogenschouw nemend is de tandheelkundige professie momenteel bezig een tijdbom van grotere omvang te leggen dan in de afgelopen honderd jaar is gebeurd met het gebruik van amalgaam.

8. Afgaande op hoe wij met deze wereld en met elkaar omspringen, is de naam mens***dom*** bijzonder toepasselijk.

9. De zogenaamde "opvoedkundige tik" om ongewenst gedrag van kinderen te corrigeren bestaat niet. Hij wordt slechts zo genoemd om de opvoedkundige onmacht van diegene die hem uitdeelt te verbloemen.

10. De Nederlandse gezondheidszorg gaat een stuk minder kosten als alle medische Tv-programma's worden afgeschaft.

11. Iedere scheidsrechter fluit goed, sommige alleen op het verkeerde moment.