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THE EFFICACY OF EARLY ORTHODONTIC TREATMENT USING THE INDEX OF COMPLEXITY, OUTCOME AND NEED

by

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THE EFFICACY OF EARLY ORTHODONTIC TREATMENT USING THE INDEX OF COMPLEXITY, OUTCOME AND NEED

Abstract

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The enigma in orthodontics today is whether early phase orthodontic treatment has any effect. The present study used the ICON index to evaluate the treatment need of the first phase of two-phase orthodontic treatment with 172 treated subjects and control subjects. The same orthodontist performed treatment on all of the treated subjects. The date of birth, gender, and Angle molar classification, the type of appliance used, as well as the initial and final treatment dates for the first phase of treatment were documented. Between group differences were evaluated with paired t-tests and p-value ≤ 0.05 used to assign statistical significance. The mean initial ICON score (T0) for the treated subjects was 78.66 ± 12.91 versus 76.56 ± 10.52 for the control group. The final mean score (T1) for the treated sample

64.80 ± 17.86 versus 76.94 ± 10.55 for the control group. The mean initial age (T0) for the treated subjects was 9.90 ± 1.51 versus 8.69 ± 0.98 for the control group. The final age (T1) for the treated subjects was 13.02 ± 1.34 versus 11.89 ± 1.43 for the control subjects. Twenty of the 172 (11%) treated subjects had a post-treatment ICON score less than 43 indicating that phase two treatment for these patients would be "optional". The mean score (T0) for the "optional" group was 68.75 ± 10.87 and for the other 152 subjects was 79.96 ± 12.62. The final score (T1) for the optional phase two groups was 33.85 ± 6.37 versus 68.67 ± 14.74 for the other group. Based on these results we conclude 11% of the subjects that received a first phase of treatment would not need a second phase of orthodontic treatment to achieve an acceptable functional and esthetic result.

DEDICATION

This work is dedicated to:

GOD for allowing my dream to become a reality.

My Daddy, may he rest in peace, and my Mommy, through all of your sacrifices, I am here today. Thank you and I love you.

My best friend, Ruth, you have been with me through the many trials and tribulations. Thank you for the many days and nights, giving me that support that I needed to continue. I love you.

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INTRODUCTION

The orthodontist today is faced with the dilemma of when to start orthodontic treatment on patients. Should treatment begin when the patient is in the early mixed dentition or when the permanent dentition is completely erupted? As a neophyte to this profession, whether or not to begin early treatment on a patient can be a bit confusing. Early treatment in recent years has come under fire by the media and by people within our own profession. Ms. Clara Hemphill of the New York Times, wrote a piece entitled "Early Intervention Dentistry: Going to Work on Baby Teeth." The title of this article could entice the public to think that orthodontists are wrong for treating some patients early. In the past, most patients that received orthodontic treatment were treated in the mid to late teen years. The public could be led to believe that orthodontists are doing early treatment just for monetary gain. In addition, published studies from North Carolina, Pennsylvania and Florida that say there is little difference in the final

dental result between early treatment begun in the mixed dentition followed by a second phase of treatment to adjust the adult teeth versus treatment provided to teenagers after all the adult teeth have erupted.

Based on the results from the 1987 National Medical Expenditure Survey (NMES), and the 1996 Medical Expenditure Panel Survey (MEPS), the majority of orthodontic patients were between the ages of 12 and 18 (Manski et al. 2000). Dr. G. Thomas Kleumper of the University of Kentucky wrote, "We need to get away from the idea that early treatment is the best approach in all circumstances." The timing of early treatment should be based on the specific needs of each patient. Early orthodontic treatment is effective and desirable in certain situations. There is evidence equally compelling that such an approach is not indicated in many cases for which later, single-phase treatment is more effective. Clinicians must decide on a case-by-case basis, when to provide orthodontic treatment (Kluemper 2000). Early treatment critics, such as Dr. Lysle Johnston, cite studies that show that final results of orthodontic treatment are on average the same for children who start treatment early (ages four to

nine) compared with those who wait until all their permanent teeth come in. Advocates for early treatment say children are less rebellious than teens, and they tend to be more obedient about wearing and adjusting appliances (Parker-Pope 2000). Allan and Hodges (1968) found that the younger patients tended to be more cooperative. Weiss et al. (1977) concluded that 12-year-old and younger patients were more cooperative than older patients. Patients treated at earlier ages in the mixed-dentition are managed more easily than at older ages in the permanent dentition (Wagers 1975). Emotional and self-esteem issues may play a role in treatment decisions. Early treatment seems to help reduce psychological disturbances (Wagers 1975). Ultimately, the orthodontist will have to make the decision: whether or not to do early treatment. This thesis uses an independent needs assessment index to determine whether early orthodontic intervention reduces the complexity, and/or need for a second phase of orthodontic treatment.

LITERATURE REVIEW

Randomized Clinical Trials

Comparisons in orthodontics have generally depended on case series or observational studies (Tulloch et al. 1990). In these series or studies, the investigator is a passive observer of a technology (treatment) initiated for the purpose of patient care, and has no control over how the treatment is provided or to whom. Most often, convenience samples of patients are selected for analysis only after treatment has been started, or even after all treatment has been completed (Phillips and Tulloch 1995). Johnston et al. reported that although the serial nature of orthodontic records easily permits patients to be monitored before and after treatment, case series and observational study designs are inherently susceptible to bias, particularly those associated with selection and attrition. Due to the susceptibility bias, clinical trial methodology has been developed to minimize the chance of these biases

occurring and to provide more objective answers to the question of comparative efficacy and benefit of particular treatment procedures (Phillips and Tulloch 1995). Clinical trials can be categorized as uncontrolled, non-random controlled, or randomized controlled. As reported by Wortman and Yeaton (1987), findings from observational studies, uncontrolled and non-randomized clinical trials, are generally associated with more positive conclusions regarding the treatment effectiveness. The overall likelihood of success from a new treatment is often reported as substantially greater when such designs are used.

In randomized controlled trials (RCT), subjects are indiscriminately assigned to the treatment or control group. The control group may or may not receive treatment. The inclusion and exclusion criteria should be as inclusive as both practical and consistent with the objectives of the study. The RCT is now generally considered the strongest research design for the comparison of treatments (Phillips and Tulloch 1995). The assumption is that the random allocation of patient to treatment also randomly allocates important prognostic factors (both known and unknown) thereby

making the treatment groups as similar as possible before the initiation of the treatment protocol.

There are three randomized clinical trials that have been performed to help uncover the mysteries of early intervention for class II malocclusion. The randomized clinical trials were performed at the University of Florida, the University of Pennsylvania and the University of North Carolina. Each of the studies had different criteria for accepting the subjects into the RCT. The Florida trial included 3rd and 4th grade subjects with distocclusion fully erupted permanent first molars, not more than three permanent cuspids or bicuspids, with positive overjet and overbite. The Pennsylvania trial's inclusion criteria were bilateral distocclusion (no unilateral class II), overjet > 3 mm and Caucasian. The North Carolina trial's criteria were overjet > 7 mm, all incisors erupted, second molars not erupted, and Caucasian (Phillips and Tulloch 1995).

The North Carolina study was completed in two phases. The intent of the first phase of the trial was to assess the effect of early treatment in a broad way, addressing the questions:

> "Does early treatment affect the relationship of the maxilla to the mandible or can treatment results be accounted for by dentoalveolar changes alone; and is there a difference in the effect produced by different appliances?" (Tulloch et al. 1997) "The intent of the second phase of the clinical trial approached the more difficult question of whether--even if differential growth effects can be induced during early treatment—these effects in the end make any difference" (Tulloch et al. 1998).

The RCT was designed to cover the three phases of orthodontic treatment frequently used to treat class II malocclusion: early treatment in the mixed dentition (phase 1), comprehensive treatment in the permanent dentition (phase 2), and retention after treatment (phase 3). For phase 1 of the trial, there were a total of 166 subjects evaluated by the study. Each child was assigned to one of three groups, headgear, functional or observation only, by using gender stratified block randomization.

A combination headgear was used with a super-short outer bow and adjusted to deliver between eight and ten ounces of force to the head cap and with the neck strap force just sufficient to prevent buccal flaring of the upper molars. The functional appliance was a modified bionator with the bite taken with 4-6 mm of protrusion

and minimal vertical opening (Tulloch et al. 1997). The same research technician took the records for each of the patients.

The outcome of interest in this phase of the trial was the difference in the change in skeletal and dental relationship experienced by the two early treatment groups as compared with the observation group. The results of the first phase of the North Carolina study were that early treatment with either headgear or functional appliance therapy reduced the severity of a Class II skeletal pattern. With either approach, there is about a 75% chance of improvement in the jaw relationship. On average, headgear produces greater change in the maxilla, whereas functional appliance therapy produces greater mandibular change. There is considerable variation in the effect with both appliance systems (Tulloch et al. 1997).

There are great variations in the response to early growth modifications; sometimes the response is good and other times the response is not as favorable. As reported by Tulloch et al., if the outcomes from the clinical trial could be generalized to other mixed dentition class II populations of European origin, as

seems likely, there is about a 30% chance in untreated children of a favorable change in class II jaw relationship, approximately a 50% chance of no change, and a 15% chance that the class II condition will worsen. The headgear and the functional appliances seem to have a 70% to 80% chance of producing a favorable to highly favorable change, with the remainder having about a 20% chance of having no change or having an increase in the class II discrepancy (Tulloch et al. 1997). Some clinicians believe that early growth modification is an important part of class II treatment; for them the success rate of the appliances used in this trial may be disappointing.

For the second phase of the RCT, the patients were kept in the same treatment and control groups until the primary teeth were lost. The patients were then re-randomized (this time in blocks of eight), stratified on the basis of their phase 1 group assignment, and sent to one of four doctors for completion of treatment. Thus in phase 2 each doctor was assigned approximately equal numbers of observation only or early growth modification (headgear or functional appliance) patients. This re-randomization was undertaken to maximize the chance that

each doctor would receive approximately equal distributions of boys and girls, good and poor early-treatment responders, compliant and noncompliant children, and children with other variables that might influence treatment outcome (Tulloch et al. 1998). Of the 166 subjects used in the first phase of the RCT, only 147 were available for the second phase of the clinical trial.

Much of the "success" or "failure" of treatment that clinicians deal with on a day-to-day basis may in fact be more attributable to differences in growth and clinician proficiency than to the efficacy of a particular treatment approach (Tulloch et al. 1998). Even though the two early-treatment groups showed an increase in the proportion of patients experiencing favorable growth, the magnitude of the differential effects was small and there was much variability. So far they have been unable to identify any patient characteristics that could serve as useful predictors of treatment response (Tulloch et al. 1997). The early data from the second phase of the clinical trial suggest that the skeletal effects of early treatment on average are not maintained. The ANB differences between the

early-treatment and observation groups diminish, so that little if any difference remains after comprehensive treatment is completed (Tulloch et al. 1998). The average phase of two-treatment time was almost always shorter for the headgear and functional appliance groups than of the control patients. When the time in early treatment (approximately fifteen months) is also included, on average the two-phase treatments are longer that the single phase undertaken by the controls. The variability in skeletal growth pattern appears to be a major contributor to variability in treatment response. Differences in patient compliance, clinician proficiency, and other clinical factors also may affect treatment outcomes (Tulloch et al. 1998).

The Pennsylvania study sought to evaluate the correlation between timing of emergence of the permanent teeth and sagittal occlusal changes in children enrolled in a prospective clinical trial of class II, division 1 treatment. The children, ages 7.2-13.3 years, met strict inclusion criteria and were assigned at random to treatment with either a headgear or a Frankel functional appliance (Ghafari 1998). There were sixty-three children used from the initial sample of eighty-four

patients. The headgear used was a straight-pull headgear with the inner bow adjusted at every visit to avoid any constriction or major expansion of the intermolar distance. There was an average of 14-16 ounces of force used per side. The functional regulator type II (FR-II) allowed the amount of initial mandibular forward positioning to be less than 5 mm and usually not more than 4 mm. Every visit the labial bow was adjusted to insure that contact with the maxillary incisors was not an obstacle to the expression of distal force to the maxillary first molars (Ghafari et al. 1998). The severity of the malocclusion was defined by the discrepancy in the cephalometric ANB measurement. Low was defined as an ANB of 4.5-6.5° and high was defined as an ANB ≥ 6.6°. Molar and canine relationships, overjet, intermolar and intercanine distances were measured from casts taken every two months, and mounted on a SAM II articulator. Cephalometric radiographs were taken annually. The emergence of a permanent tooth was scored on a scale from one to three, depending on the eruptive level of the tooth. Level one was just cutting through the gingival tissue; level three was used to

indicate a tooth had reached the occlusal table. Specifically, emergence on the second premolars (PM2) and permanent second molars (M2), the most adjacent teeth to the first molars, was evaluated as it interacted with development of the sagittal occlusion. This study found that treatment of the distocclusion was as effective in late childhood as in mid-childhood. Improvement of the molar and canine relationships was greater with the headgear and reduction of overjet was larger with the Frankel appliance. The headgear group on average had a distal effect on the maxilla and first molars, but not the maxillary incisors, whereas the Frankel appliance restrained the growth of the maxilla resulted in a retroclination of the maxillary incisors. They also reported a more forward position of the mandible and a proclination of the mandibular incisors. A significant finding of this study was the increased maxillary intercanine distance and spacing among the maxillary anterior teeth with headgear treatment. Increases in maxillary intermolar distance were related to different mechanisms. With the headgear an active force was used to expand the first molars where as with the Frankel FR expansion was achieved by removing of

cheek pressure. The larger correction of the overjet with the Frankel FR occurred because this appliance can exert a distal force on the maxillary incisors. Within each group, the emergence of PM2 and M2 did not affect the amount of progress toward class I. This indicated that the improvement from distocclusion to neutrocclusion with each appliance was not influenced by the emergence of these teeth. These findings support a one-phase treatment starting in the late mixed dentition. However, the authors recommended earlier intervention, in mid-childhood, in the presence of several developmental conditions, or when the dental and skeletal development deviate significantly in the individual patient. Timing of treatment in developing malocclusions may be most critical just before the loss of the primary second molars (considering both treatment of the occlusion and space management). This potential discrepancy in the individual patient must be incorporated in the analysis of timing and efficacy of early treatment (Ghafari 1998).

The Florida study examined the anteroposterior skeletal and dental effects that occur as a result of early treatment with the headgear/bite plane and

bionator, as well as those changes that occur after appliance removal before the second phase of full appliance therapy (Keeling et al. 1998). Children, aged 9.6 ± 0.8 years at the start of study, were randomly assigned to a control group (n = 81), bionator (n = 78), or headgear/bite plane (n = 90) treatments (Keeling et al. 1998). There were certain criteria used to choose the subjects. The severity of the class II malocclusion was rated as mild (bilateral half-cusp), moderate (one-side three quarter cusp) or severe (one side cusp). The second criterion for assignment was the need for preparatory treatment/observation (1 maxillary incisor alignment to produce an overjet equal to or greater than the molar discrepancy—only subjects assigned to treatment received this, if necessary; (2 posterior crossbite correction; (3 incisor eruption; and (4 habit cessation. The third criterion was the mandibular plane angle (MPA): low < 30°, normal 30° to 40°, and high > 40°. The fourth criterion was race, black or non-black, and the fifth criterion was the patient's sex. This criterion was applied to cases in which the mandibular plane angle was greater than 40°.

The subjects were assigned to a treatment group. After the preparatory treatment/observation, three stages of treatment were observed: class II early treatment, retention/non-retention, and follow-up. Class II treatment/observation ended when two orthodontists independently agreed during a three-month interval that a least a bilateral class I molar relation existed or two years had elapsed from the start of treatment. The retention/non-retention and follow-up were fixed at six-month intervals. The cephalograms were obtained initially, after a class I molar relationship was obtained or two years had elapsed, after an additional six months during which treated subjects were randomized to retention or non-retention and after a final six months without appliances. Calibrated examiners, blinded to group, used Johnston's analysis (Johnston 1986) to measure anteroposterior cephalometric changes. The headgear group received a cervical or high-pull headgear depending on the degree of severity of the mandibular plane angle and a flatplane maxillary acrylic anterior bite plane designed to disclude posterior teeth, along with a labial bow and molar circumferential wires. The bionator group received a

bionator to maintain the bite, with occlusal stops for maxillary and mandibular teeth (Keeling et al. 1998). For the retention/non-retention stage of the study, the subjects allocated to the retention group were told to wear the appliances every other night to bed, approximately ten hours. The subjects in the non-retention group had the appliances discontinued for this phase of the study.

The data from this study showed that facial growth is altered during both the bionator and headgear/bite plane therapies. The headgear/bite plane and bionator both enhanced mandibular growth without detectable relapse a year after the end of active treatment. Growth in the anterior direction along the occlusal plane added to the correction to the class II malocclusion. The six-month retention period had no effect on the skeletal or dental changes achieved during the early treatment phase (Keeling et al. 1998). The data showed that any relapse observed during the six-month follow-up period without appliances is clearly dental and not skeletal. All changes seen during the six-month retention and six-month follow-up periods were most likely due to group differences in tooth movement,

not skeletal structures. Therefore, retention as provided in this trial was not effective in preventing dental relapse. The authors suggested that perhaps a different method for retention might prevent dental relapse. The study's results reveal that both bionator and headgear treatments corrected class II molar relationships, reduced overjet and apical base discrepancies, and caused posterior maxillary tooth movement. The skeletal changes, largely attributable to enhanced mandibular growth in both headgear and bionator subjects, were stable a year after the end of treatment, but dental movements relapsed (Keeling et al. 1998).

Class II Treatment

In recent years, there has been a movement in orthodontics to treat class II patients in two phases. Extensive clinical experience with early treatment for class II malocclusions has shown favorable growth responses. In class II treatment, a reduction in the jaw discrepancy, a corresponding decrease in the overjet, and correction of the molar relationship is the usual description of a favorable outcome (Tulloch et al. 1997). There are many arguments for and against two-phase treatment. Livieratos and Johnston (1995) looked

at class II malocclusions treated in a two phase compared to a single-phase approach. The subjects were Caucasian, between the ages of 7-14 years, with a bilateral class II, division 1 malocclusion. The treatment plan for the subjects was initially non-extraction for the two-phase or the one-phase treatment modality. For the two-phase treatment, the bionator was used to correct the development of the facial skeleton in the first phase, followed by fixed appliances during the second phase. The single-phase treatment involved only the use of fixed appliances. There were twenty-five two-stage and twenty-eight single-stage non-extraction patients in each group. According to the authors, patients treated in two phases tended to be younger and to have more severe malocclusions. At the completion of the study, the two groups were essentially identical. The groups did not have any differences cephalometrically or on the study-models. The two groups had almost identical molar and overjet corrections, with the tooth movement serving to correct irregularity of anteroposterior dental relationships. Correction of the molar discrepancy and overjet was significantly more efficient in the single-phase

subjects. For both treatments, the source of these changes was differential jaw growth. The magnitude of which was significantly greater in the two-stage patients. This seems to be misleading, given that it took the two-stage subjects a year and a half longer to complete treatment. "One way to see a lot of growth is to treat a long time." (Livieratos and Johnston 1995) The amount of the mandibular advancement relative to the cranial base was not statistically significant in the two groups. There was no significant difference in mandibular length both in terms of annual rate and in final size. Livieratos and Johnston (1995) found that there was no difference between the two-phase and the single-phase orthodontic treatment of these subjects. The authors stated that the functional appliances were not used in the older patients and the milder class II malocclusions. The study stated the younger, extreme cases where growth adaptation may be needed are most likely to receive functional appliance therapy. The results from this study were not encouraging for advocates of the two-phase treatment approach. The authors implied that even though this data was not encouraging, clinicians would probably continue to use

functional appliances in two-phase treatment. The suggestion was made that two-phase treatment may be a practice-management issue rather than an issue of treatment efficacy.

Katzan (1998) examined the outcome of one-phase and two-phase orthodontic treatment using the Peer Assessment Rating (PAR) index. The study enrolled 200 consecutive one-phase subjects and 201 consecutive two-phase subjects selected from the private practice of a single clinician. The single-phase subjects had models evaluated at time 0 (initial) and time 2 (final). For the two-phase subjects, the models were evaluated at time 0, time 2, as well as time 1 (initial for the second phase). The results from the study found that two-phase subjects began the treatment at a younger age than the single-phase subjects. The average age for the two-phase subjects was 9.9 ± 1.5 years versus 13.2 ± 2 for the single-phase. The average two-phase subjects had more severe malocclusions than the single-phase subjects based on the PAR scores. The PAR scores for the two-phase subjects were 31.9 ± 8.6 versus the PAR score for the one-phase subjects 26.9 ± 9.2, at the initial indicating the severity of the malocclusions.

The class II subjects that were treated in two-phases, had the highest PAR scores at the beginning (mean 33.1 ± 8.2) and the end of treatment (mean 3.7 ± 3.5). After the completion of treatment the two-phase versus the one-phase subjects had approximately the same amount of correction of the malocclusion as measured by percentage reduction in PAR. Both groups finished with a percent reduction in the PAR scores below 5. Single-phase subjects with the same severity of malocclusion were treated to the same final occlusal result as the two-phase subjects, PAR for the one-phase 3.8 ± 3.2 versus the PAR for the two-phase 4.2 ± 4.5. The subjects that underwent the first phase of two-phase treatment had a reduction in the degree of malocclusion below the initial malocclusion of the single-phase subjects, 21.9 versus 26.2, respectively. The length of treatment for the two-phase subjects on average was three years longer than the single-phase subjects. This time period included a resting phase between the two phases. Most of the patients treated in two-phases possessed a class II malocclusion. The appliances that were most commonly used for the first phase of treatment were: The headgears (high-pull, combination and cervical), palatal

expanders, and the placement of brackets in a 2 x 4 configuration on the teeth. The total percent PAR score reduction for the single and two-phase subjects were statistically the same upon completion of treatment. The greater part of the correction of the malocclusion happened in the second phase of the two-phase treatment. The extraction rates for the two-phase subjects on average were lower than the one-phase subjects. The investigator concluded that orthodontists can accurately correct a severe malocclusion in one phase, having the same level of occlusion as if the malocclusion was treated in two phases.

King et al. examined how orthodontists perceive the impact of phase one on phase two needs. There were 242 class II subjects, aged 10-15, who had undergone phase one treatment or observation in a RCT. There were 85 headgear, 79 controls, and 78 bionators patients used from the Florida randomized clinical trial. For each subject, video orthodontic records, a questionnaire, a fact sheet, and a cephalometric tracing were sent to five randomly selected reviewing orthodontists blinded to subject group and study purpose (King et al. 1999). There was a significant difference among the average age

of the groups, with the control group younger at the time of the video that the bionator group. There were no differences among the groups based on gender, initial severity, or mandibular plane angle (King et al. 1999). Except for age, the samples of adolescent patients used in the study were equivalent among the treatment groups. The controls were younger than the bionator and headgear treatment groups, by an average of five or fewer months, and the treated groups contained more pretreatment and retention cases. The headgear and bionator groups did not differ significantly with respect to pre-treatment or retention age (King et al. 1999). The reviewing orthodontists were asked to assess treatment need, general approach, need for extractions, priority, difficulty and determinants. The study found that the orthodontists agreed highly on treatment need (95%) and moderately on treatment approach (84%) and extraction need (80%). They did not perceive differences in need, approach, or extractions between treated and control groups. Treated subjects were judged as less difficult and having a lower treatment priority than controls. In ranking problems that affect treatment decisions, the orthodontists ranked dental class II and skeletal

relationships more highly in control than in treated patients. (King et al. 1999). From the information gathered in this study, the orthodontists did not perceive phase one treatment for class II as preventing the need for a second phase or as offering any particular advantage with respect to preventing the need for extractions or other skeletal treatments on that second phase (King et al. 1999). Most of the orthodontists believed that early class II treatment were an effective measure in decreasing the difficulty of and the importance for phase two.

Bishara et al. (1994) observed the effects of growth and orthodontic treatment on class II patients. The researchers compared sample subjects with class II molar and canine relationships to the control group, which exhibited class I molar and canine relationships. The class II subjects were Caucasian and matched on age with the control subjects. The control sample were the untreated normal subjects from the Iowa Longitudinal Facial Growth Study. There were ninety-one treated class II subjects, forty-six subjects that were treated with a non-extraction approach and forty-five subjects that

were treated with the extraction of the four first premolars.

The success of treatment depends as much on the skill of the orthodontist as on a favorable pattern of facial growth. The lack of sufficient and/or favorable growth during treatment makes it difficult to correct the skeletal mal-relationship or significantly improve the profile. The researchers evaluated lateral cephalograms and dental casts at three stages: pre-treatment, post-treatment and approximately two years after treatment. The cephalograms before treatment indicated that prior to treatment, the subjects that underwent extractions had more protrusive lips and a larger tooth size-arch discrepancy. After the treatment the lips were more retrusive in the extraction group and protrusive in the non-extraction group. The extraction subjects had straighter faces and more upright maxillary and mandibular incisor. Class II, division 1 malocclusions vary morphologically in their dentofacial relationships. Those patients responded differently to treatment and expressed their own unique individual growth patterns (Bishara et al. 1994). Prior to treatment, there were significant differences in the

dental, soft tissue and skeletal relationships between the normal control, and the class II, division 1 groups. The differences between the two groups of class II, division 1 subjects with or without extraction of first premolars were less significant. The researchers observed the groups over a five-year period and found that there were changes in the class II groups and the normal control group. The differences were the result of the combined effects of treatment and growth (Bishara et al. 1994). The results of this study indicated that, in general, orthodontic treatment which includes the use of orthopedic extra-oral forces, as well as light class II elastics, "normalizes" the skeletal relationships. Bishara et al. (1994) found that the decision to extract or not extract, as long as it is based on solid diagnostic criteria did not have detrimental effects on the profile. The clinician needs to be aware of the trends in the two-treatment modality to avoid emphasizing the unattractive profile characteristics (Bishara et al. 1994)

Opinions on Early Treatment

Early treatment in the mixed dentition allows the orthodontist to guide mal-positioned teeth into a better

position and direct the growth pattern of the skeleton. Wagers (1975) divided early phase treatment in two categories, pre-orthodontic guidance and corrective orthodontic treatment. Those patients who do not need corrective orthodontic treatment but who have malocclusions in the deciduous or mixed dentition define pre-orthodontic guidance. Orthodontic treatment can be delayed until they are in the permanent dentition. This type of patient may need space maintenance, serial extraction or habit correction. Those patients who have malocclusions in the deciduous, mixed, or permanent dentition and need immediate corrective treatment define corrective orthodontic treatment. The orthodontist has the duty to care for those early treatment patients, who begin in the mixed dentition stage, until all of the permanent teeth erupt. When the decision to begin early treatment has been made, it is best to keep the treatment as simple as possible.

The timing of any orthodontic treatment is important. Weiss and Eiser (1977) believed that:

> "prepubescent children are emotionally ripe for orthodontic therapy and, therefore, will carry out instructions more faithfully than adolescents."

Cooperation may be improved if the patient is psychologically ready for treatment. According to Proffit (2001), the gold standard for the timing of early treatment is in the very late mixed dentition. There is still some growth available to assist the treatment. During the very late mixed dentition, there are permanent teeth available for final positioning. Arguments against early phase treatment express that it is best to wait until the permanent dentition is erupted and the patient is nearing the end of the growth spurt. The timing of efficient orthodontic treatment is based on the patient's type of malocclusion. The objectives of treatment that begins before the eruption of all the permanent teeth are to: 1) correct the skeletal discrepancy between the jaws; 2) improve function and facial esthetics by allowing them to develop normally; 3) create an ideal overbite and overjet relationship; and 4) align the anterior permanent teeth (incisors) and reduce the chance of trauma to these teeth. This improves the width of the dental arches and reduces the risk for extraction of permanent teeth on normal eruption of the full permanent dentition and for surgery (in severe cases). Based on opinion and experience,

Viazis (1995) believes that unattended orthodontic problems can lead to impairments in speech, chewing, and loss or trauma of teeth (Viazis 1995). The correct timing of orthodontic treatment remains in dispute. If treatment is begun too early in the primary dentition, this can prolong treatment time over a ten-year span, sometimes requiring three phases of treatment and leading to patient burnout and parent dissatisfaction (Dugoni 1998).

Waiting until the late mixed dentition also has its disadvantages. The female patients have passed the peak velocity of their skeletal growth and strategies aimed at growth modification have reduced effectiveness. Treatment commenced when the lower second primary molars are loose can often extend over three or four years, while waiting for canines and second molars to erupt (Dugoni 1998). Treatment in the late mixed dentition only allows for one opportunity for correction. Unfortunately, the patient becomes less cooperative and the compliance level decreases. Dugoni (1998) believes treatment that begins in the permanent dentition involves more problems with compliance with teenage patients; post menarche female patients having little

growth remaining, decalcification, root resorption and ectopic eruption of teeth.

Patient Cooperation

The early phase treatment goals need to be considered when making the decision to treat the pre-adolescent. During the initial assessment of the patient, it is important to determine what is in the best interest of the patient. Patient cooperation is one of the most important factors every orthodontist must contend with when treating patients (Nanda et al. 1992). The ability to motivate a patient to comply is an essential ingredient of successful orthodontic therapy, whether therapy is initiated in the mixed or permanent dentition. Allan and Hodgson (1968) found that age was the single best predictor of patient cooperation. The younger patients tended to be more cooperative. Weiss and Eiser (1975) concluded that 12-year-old and younger patients were more cooperative than older patients. Even though the younger patients were more cooperative with treatment, they were less cooperative in keeping appointments and protecting appliances from breaking. Lewit and Virolainen (1968), reported that a patient's perception of his own

malocclusion was a better predictor of cooperation than that of the orthodontist, and that dependent adolescents regarded their parent's wishes as more important than adolescents with a low dependency on parents but a high need for peer approval who perceived peer standards as the most important. Cooperative patients show a high internal control orientation (El-Mangoury 1981), and a positive self-concept (Robinson 1975). As reported by Fox, Sergl found four personality traits differing between cooperative and uncooperative patients, those traits being aggression, masculinity, impulsiveness, and effort avoidance. Fox proposed that attitude towards orthodontics could be relevant for cooperation. Dissatisfaction in the dental appearance was found to be more common in girls than boys (Shaw 1981). Girls also tend to mature earlier than boys, and therefore, may take a more adult attitude toward the orthodontic experience (Starnbach 1974). In a study on patient cooperation, Kreit et al. (1968) found the most prominent feature of uncooperative patients was the perception of poor relations with their parents. The parent-child relationship seemed related to cooperation with treatment. The dentist should try and alleviate

conflict between parent and child with regards to orthodontic treatment. The orthodontist becomes a substitute parent while the patient is in treatment. In a young adolescent there is a strong desire for independence from parents during the same period when orthodontic treatment is being administered. The orthodontic patient does not want to be uncooperative, but he has a great desire for independence, autonomy and self-regulation (Story 1966).

Occlusal Indices

Occlusal indices are used in connection with public health orthodontic programs; their application in a series of studies has led to the conclusion that occlusal indices have a role in resource allocation and planning, promoting treatment standards, identifying prospective patients, and informed consent (Shaw et al. 1995). An index, as defined in the orthodontic context, is used to describe a rating or categorizing system that assigns a numeric score or alphanumeric label to a person's occlusion (Shaw et al. 1995). These indices can be used for diagnostic classification, epidemiological indices, treatment need (priority), and treatment outcome and treatment complexity. According

to Dr. Firestone, an orthodontic index is a set of definitions and procedures that objectively assigns a numeric score or label to a person. A good index is valid, reliable, modifiable, quantitative and quick (Firestone 2001).

The Index of Orthodontic Treatment Need (IOTN)

The Index of Orthodontic Treatment Need (IOTN) ranks the malocclusion in terms of the significance of various occlusal traits for the person's dental health and perceived esthetic impairment, with the intention of identifying those persons who would be most likely to benefit from orthodontic treatment (Shaw et al. 1995). This index has a dental health and esthetic component.

The dental component of IOTN represents an attempt at synthesis of the current evidence for the deleterious effects of malocclusion and the potential benefits of orthodontic treatment. The occlusal traits that are believed to contribute to the longevity and the satisfactory functioning of the dentition are defined and placed into five grades, with clear cut-off points between the grades. The grades range from grade one (no need for treatment) to grade five (great need for treatment). The index may be used clinically or on study

models. There are a few differences in the index when used on study models. The fundamental purpose of the index is the recognition that dental diseases are site specific, and the most severe anomaly identified is the basis for grading the person's need for treatment on dental health grounds (Shaw et al. 1995). There is no summation of the individual traits.

The esthetic component of IOTN consists of a ten-point scale, illustrated by a series of numbered photographs, which were rated for attractiveness by laypersons and selected as being equidistantly spaced through the range of scores (see Materials and Methods). A rating is allocated for overall dental attractiveness rather than specific morphologic similarity to the photographs. The value arrived at gives an indication of the patient's treatment need on the grounds of esthetic impairment, and by inference reflects the socio-psychological need for orthodontic treatment (Shaw et al. 1995). This component of the index can also be performed clinically or on the study models.

Peer Assessment Rating (PAR) Index

The Peer Assessment Rating (PAR) index was developed through a series of meetings with a group of

ten experienced orthodontists, the British Orthodontic Standards Working Party. This index was developed to assess treatment outcome. Study casts of various treated and untreated occlusions were examined and discussed until agreement was reached about the individual features that should be assessed to obtain an estimate of alignment and occlusion. A scoring system was developed and a ruler designed to allow analysis of a set of study casts in approximately two minutes (Shaw et al. 1995). There are six factors that are part of the index. Those factors are:

1. The buccal segment-mesial contact point of the first molar to the distal contact point of the canine

2. Anterior segment-the distance between the mesial contact points of the right and left canines, crowding and spacing is measured from the contact points of the occlusal plane

3. Buccal occlusion-from the canine to the most posterior molar in the vertical, transverse and anterior-posterior directions

4. Overjet-from the labial surface of the most prominent incisor

5. Overbite-amount of lower lateral coverage be the upper centrals or the amount of open bite

6. Centerline-distance of the upper midline from the lower midline

Buccal segments, anterior segments, and buccal occlusion were measured separately for upper and lower and right and left (Richmond et al. 1992). The individual scores for the components of alignment and occlusion are finally summed to calculate an overall score. A score of zero would indicate perfect alignment and occlusion while higher scores, rarely beyond 50, indicate increasing levels of irregularity. The index is applied to both the start and the end of treatment study casts, and change in the total score reflects the success of treatment in achieving overall alignment and occlusion (Shaw et al. 1995).

Index of Complexity, Outcome and Need (ICON)

The Index of Complexity, Outcome and Need was developed to assess the treatment need, complexity, treatment improvement and outcome based on international professional opinion, from nine countries, Germany, Greece, Hungary, Italy, the Netherlands, Norway, Spain, the United Kingdom, and the United States. The Index is intended for use in the context of the specialist practice, to hopefully provide the means to compare treatment thresholds in different countries and serve as a basis for quality assurance standards in orthodontics.

The international panel of ninety-seven orthodontists were solicited to judge a diverse sample of study models, 240 dental casts for assessment of treatment need and ninety-eight paired pretreatment and post-treatment cases for assessment of treatment outcome (Daniels and Richmond 2000). In the selection of the orthodontists, at least ten practitioners had a postgraduate degree. None of the examiners received compensation for participation in the study. The casts showed a wide range of objectively determined treatment need. The Index of Orthodontic Treatment Need (IOTN) was used as an objective classification of the sample. Each orthodontist was asked to examine the entire sample of the cases and indicate his/her opinion by using ordinal rating scales on the need for orthodontic treatment on dental health grounds, the need for orthodontic treatment on dental esthetic grounds, deviation from normal occlusion, treatment complexity and finally the dichotomous decision whether or not to recommend treatment (Richmond and Daniels 1998).

The percent agreement for the treatment decisions on individual models was unevenly spread, but 76% of the cases obtained more than 80% agreement on the need for

treatment. Treatment decisions seemed to be influenced systematically by the country of the practitioner and his customary payment method. This is likely to be a function of market economics. Professional opinion on the need for treatment appeared to be markedly divided in 24% of the cases and varied by up to 48% between individual practitioners (Richmond and Daniels 1998). The dental casts were examined and the occlusal traits were comprehensively scored. Five occlusal components were used in the Index: the assessment of dental esthetics; the presence of cross bite; analysis of upper arch crowding (or the presence of impacted teeth in either arch); buccal segment anteroposterior interdigitation; and the anterior vertical relationship. This identified similar occlusal traits to predict both dichotomous decisions. Initially, weightings for the five occlusal traits were calculated for the treatment need and outcome decisions separately, then a single set of weightings was tested based on the average of the two weightings for each occlusal trait (Daniels et al. 2000). Predictive equations were calculated for treatment need and outcome decisions. This identified similar occlusal traits to predict both dichotomous decisions. The set 'average'

weightings formed a new single index of treatment need and outcome assessment.

ICON uses the dental esthetic component of the IOTN index, for the scoring of the dental esthetic portion. The Index of Orthodontic Treatment Need (IOTN) ranks the malocclusion in terms of the significance of various occlusal traits for the person's dental health and perceived esthetic impairment, with the intention of identifying those persons who would be most likely to benefit from orthodontic treatment (Shaw et al. 1995). ICON uses the ten pictures from the IOTN index for evaluation the esthetic dental component. The dentition is compared to the illustrated scale and a global attractiveness match is obtained without attempting to closely match the malocclusion to a particular picture on the scale. The scale works best in the permanent dentition. The casts are compared to the pictures from IOTN to rate the malocclusions from one to ten. The score of one is rated as most attractive and ten is rated as least attractive. The ICON raw score from the picture rating is multiplied by a weighting of seven.

The upper arch crowding or spacing is measured with a millimeter ruler to attain a score, which is

multiplied by the weighting for the occlusal characteristic to obtained the raw scores. For example, if there were three millimeters of crowding or spacing, the number falls in the category of 2.1 to 5 mm, which gives a raw score of one. The raw score is then multiplied by the weighting of five. When scoring the cast for the crowding or spacing, the trait with the highest numerical value is used.

The presence of a crossbite anterior or posterior is the next trait to be evaluated. A crossbite is defined, for the anterior segment, as an upper incisor or canine in edge-to-edge of lingual occlusion. In the posterior, the crossbite is defined by a transverse relationship of the cusps or worse in the buccal segments (Daniels and Richmond 2000). If a crossbite is present, the raw score is one and if not, the raw score is zero. These values are derived by use of the formula that follows. The raw score is then multiplied by the weighting of five.

The anterior vertical relationship is evaluated by observing the models and determining that there is an open bite or overbite. The worse of the two traits is scored. The open bite is measured with a millimeter

ruler and the value is obtained and multiplied by the occlusal characteristic weightings to obtain the raw score. For example, if the open bite on the casts measures less than 1 mm, the raw score is one. The score is then multiplied by the weighting of four. When looking at the casts for the overbite, the amount of lower incisor coverage is evaluated. For example, if 1/3 of the lower incisor is covered, this warrants a raw score of zero. The raw score is then multiplied by the weighting of four.

The anteroposterior relationship of the buccal segment is evaluated by observing the interdigitation of the canine, premolar and molar teeth. There are three choices in obtaining this raw score. The casts must show: cusp to embrasure relationship only, class I, II or III = raw score of zero, any cusp relation up to but not including cusp to cusp = raw score of one and cusp to cusp relationship = raw score of two. Each side of the casts is scored, the values added together, and the sum is multiplied by the weighting of three.

Equation 1.

$$(\text{IOTN} \times 7) + (\text{upper crowding/spacing score} \times 5) + (\text{crossbite score} \times 5) + (\text{overbite/open bite score} \times 4) + \left[\frac{(\text{buccal right} + \text{buccal left})}{2} \times 3\right] = \text{ICON SCORE}$$

The raw scores for the specific traits are multiplied by the appropriate weightings, and summed to get the ICON score. If the ICON score is greater than 43, there is a need for treatment. This index can also be performed at the conclusion of treatment to assess treatment outcome. A post-treatment score of less that 31 means an acceptable occlusion.

The pretreatment score obtained from ICON can be used to determine the complexity of the case. The 5-point grading of treatment complexity is summarized below:

ICON complexity cut-off values

Easy	<29
Mild	29-50
Moderate	51-63
Difficult	64-77
Very difficult	>77

(Daniels and Richmond 2000)

Once treatment is complete, ICON can be used to rate the amount of improvement. The practitioners used in the study also rated the improvement on the post-

treatment models. This method was sufficient for making qualitative comparisons, but was not sufficiently sensitive to grade the degree of occlusal change. Comparing the pre-treatment assessment with the post-treatment and calculating either the overall score reduction or a percentage improvement was used to assess occlusal improvement. The pre-treatment and post-treatment score, score reduction and percentage reduction were calculated for each treated case. The mean improvement rating for each case was calculated and a number of possible expressions were tried to model the mean improvement ratings. To assess the degree of improvement, multiply by four, to find the post-treatment score; the result is subtracted from the pretreatment score. The ratings for the improvement in treatment are below:

ICON improvement ratings

Greatly improved	> -1
Substantially improved	-25 to -1
Moderately improved	-53 to -26
Minimally improved	-85 to -54
Not improved or worse	< -85

(Daniels and Richmond 2000)

Unpredictability with the ICON index

ICON is a very simple index to master and can be quickly applied to models or clinically to determine the need for treatment. The ICON index is heavily weighted on the esthetic variable. There are many different occlusal traits, such as, large overjet, open bite, or cleft lip that can affect the aesthetics of the anterior malocclusion. This variable is the most important factor in the ICON index scoring (Daniels and Richmond 2000). The ICON index was conceived to bring together different indices to develop one index for treatment complexity, outcome and treatment need. There are drawbacks with the ICON index in that its development was based on a large panel of international orthodontic opinion. Therefore the validity is dependent on the subjective opinion of the person using the index with aesthetics being the heaviest weighted variable. The ICON index is best used in the late mixed to permanent dentition, because it is more difficult to judge the aesthetics of the early to mixed dentitions (Daniels and Richmond 2000).

This study will use ICON scores to determine whether early phase treatment is beneficial to the patients and prevent the need for a second phase of treatment.

HYPOTHESES

The following are hypotheses to be tested:

1) Early treatment will convert 34% patients from needing treatment ICON $\geq$ 43 after the first phase to optional treatment for the second phase of orthodontic treatment ICON < 43.

2) Early treatment will cause the ICON scores of class II subjects to be reduced to a value < 43, therefore moving those subjects to treatment optional.

3) In the absence of orthodontic treatment, there is no change in the malocclusion.

MATERIALS AND METHODS

The study was an analytical, retrospective, longitudinal investigation of orthodontic patients who underwent two phases of treatment. The data were collected from a single provider in Norwalk, Ohio (Gary Wolf, DDS, MSD). Subjects were selected from a previous study, Outcomes Assessment of One Phase and Two Phase Orthodontic Treatment by Dr. Charissa Katzan (1998).

Subject Selection

172 subjects that underwent two-phase orthodontic treatment were selected from the previous study by Katzan (1998). These subjects were matched on age, gender and Angle molar classification. The treated subjects were compared with 172 untreated control subjects from the Bolton-Brush Growth Study.

Inclusion criteria were:

1. No syndrome patients with craniofacial anomalies
2. No surgical cases

3. No adults over the age of 18 years

4. All early treatment cases must have started treatment in the mixed dentition

No subjects were eliminated based on gender or race.

Based on the previous study, the treated subjects exhibited differing Angle classes of malocclusion and were treated with different combinations of functional appliances.

Data collected for each patient incorporated:

1. Initial age for phase one

2. Angle's molar classification

3. Appliances used for the phase one treated subjects

4. Final age for the end of phase one

Scoring the Models

The dental models of the subjects were scored using the Index of Complexity, Outcome and Need (ICON)(Daniel and Richmond 2000) by a single examiner (RMH). The examiner was self-calibrated.

ICON uses the dental esthetic component of the IOTN index, for the scoring of the dental esthetic portion. The Index of Orthodontic Treatment Need (IOTN) ranks the malocclusion in terms of the significance of various

occlusal traits for the person's dental health and perceived esthetic impairment, with the intention of identifying those persons who would be most likely to benefit from orthodontic treatment (Shaw et al. 1995). ICON uses the ten pictures from the IOTN index for evaluation the esthetic dental component. The scale works best in the permanent dentition. The casts are compared to differing pictures of malocclusions rated from one to ten. The most attractive receives a score of one and the least attractive receives a score of ten. The raw score from the picture rating was multiplied by a weighting of 7.

The upper arch crowding or spacing is measured with a millimeter ruler and then the number is compared with the table below and the raw score is obtained. For example, if there are three millimeters of crowding or spacing, the number falls under the category of 2.1-5 mm, which gives a raw score of one. The raw score is then multiplied by the weighting of five. When scoring the cast for the crowding or spacing, the trait with the highest numerical value is used. If any teeth are missing or impacted, the score of five is given for that trait.

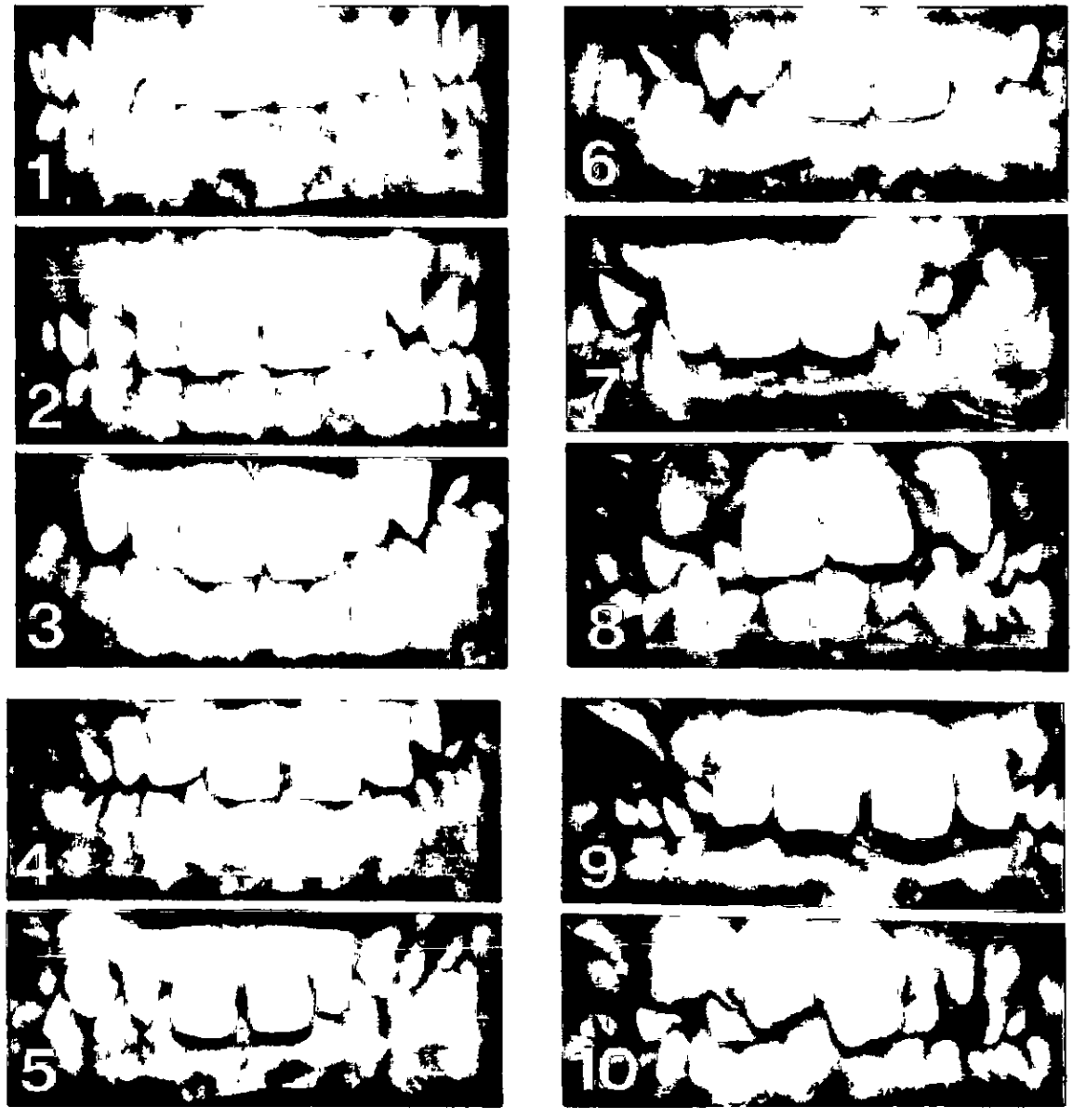


Figure 1. Photographs from IOTN used for the dental esthetics component of ICON (Daniels and Richmonds 2000)

Table 1.—Protocol for Occlusal Trait Scoring (Daniels and Richmond 2000)

Component	0	1	2	3	4	5	WT
Aesthetic Component	Score 1-10 based on IOTN pictures						7
Upper arch crowding	< 2 mm	2.1-5 mm	5.1-9 mm	9.1-13 mm	13.1-17 mm	> 17 mm	5
Upper arch spacing	< 2 mm	2.1-5 mm	5.1-9 mm	> 9 mm		Impacted	5
Crossbite	No crossbite	Crossbite present					5
Incisor open bite	Complete bite	< 1 mm	1.1-2 mm	2.1-4 mm	> 4 mm		4
Incisor overbite	< 1/3 incisor covered	1/3-2/3 coverage	2/3-fully covered	Fully covered			4
Buccal segment antero-posterior	Cusp-embrasure only, Class I, II or III	Any relation, to cusp-cusp	Cusp to cusp				3

The presence of a crossbite anterior or posterior is the next trait to be evaluated. For the anterior segment a tooth in crossbite is defined as an upper incisor or canine in edge-to-edge of lingual occlusion. In the posterior, a crossbite is defined as a transverse relation of cusp to cusp or worse in the buccal segment (Daniels and Richmond 2000). If a crossbite is present the raw score is one and if not, the raw score is zero. These values are taken from Table 1 above. The raw score is then multiplied by the weighting of five. If the crossbite is present in the anterior and posterior segments, the score of one is given and the score is multiplied by the weighting of five.

The anterior vertical relationship is obtained by observing the models to determine if there is an open bite or overbite present. The worse of the two traits is scored. The open bite is measured with a millimeter ruler and the value is compared to the table above to obtain the raw score. For example, if the open bite on the casts measured less than 1 mm, the raw score is one. The score is then multiplied by the weighting of four. When looking at the casts for the overbite, the amount of lower incisor coverage is evaluated. For example, if 1/3 of the lower incisor is covered, this warrants a raw score of zero. The raw score is then multiplied by the weighting of four. The antero-posterior relationship of the buccal segment is evaluated by observing the interdigitation of premolar and molar teeth. There are three choices to obtain this raw score. The casts can show: cusp to embrasure relationship = raw score of zero; any cusp relation up to but not including cusp to cusp = raw score of one; and cusp to cusp relationship = raw score of two. Each side of the casts is scored, and the scores added together, then the sum is multiplied by the weighting of three.

Equation 1.

$$(\text{IOTN} \times 7) + (\text{upper crowding /spacing score} \times 5) + (\text{crossbite score} \times 5) + (\text{overbite/open bite score} \times 4) + \left[\frac{(\text{buccal right} + \text{buccal left})}{2} \times 3\right] = \text{ICON SCORE}$$

Once the appropriate weightings have multiplied the raw scores obtained for the specific traits, they are summed to get a total. If the total score is greater than forty-three there is a need for treatment. This index can be performed at the conclusion of treatment in the same manner as described above to assess treatment outcome. A post-treatment score of less that thirty-one means an acceptable end occlusion.

The pretreatment score obtained from ICON can be used to determine the complexity of the case. The practitioners then gave a five-point rating scale for the pretreatment complexity on the models scored. The mean complexity was then worked out for each case. The five-point grading of treatment complexity is summarized below:

ICON complexity cut-off values

Easy	<29
Mild	29-50
Moderate	51-63
Difficult	64-77
Very difficult	>77

(Daniels and Richmond 2000)

Once treatment is complete, ICON can be used to rate the amount of improvement. The practitioners used in the study also rated the improvement on the models that were used in the study. This method is sufficient for making qualitative comparisons, but is not sufficiently sensitive to grade the degree of occlusal change. To assess the occlusal improvement the pre-treatment score is compared to the post-treatment score. Either the overall score reduction or improvement can be calculated. The pre-treatment and post-treatment score, and score reduction was calculated for each treated case. The mean improvement rating for each case was calculated and a number of possible expressions were tried to model the mean improvement ratings. To assess the degree of improvement, multiply the post-treatment score by four and subtract the result from the pretreatment score. The ratings for the improvement in treatment are listed below:

ICON improvement ratings

Greatly improved	> -1
Substantially improved	-25 to -1
Moderately improved	-53 to -26
Minimally improved	-85 to -54
Not improved or worse	< -85

(Daniels and Richmond 2000)

ICON was performed on 172 treated and control subjects, evaluating the models at time zero (initial) and the models at time one (after early treatment). The subjects were divided into class I, class II and class III malocclusions. Two sets of models were scored for the two-phase patients: The beginning of the first phase of treatment (T0) and the completion of first phase/beginning of second phase of treatment (T1). The ICON index consist of scores for:

1. IOTN dental esthetic score
2. Upper crowding/spacing score
3. Crossbite score
4. Overbite/open bite score
5. Buccal segment interdigitation for the right and left

Each score was registered on a data sheet with the proper weightings for each variable of the index to provide the total score. The pictures for the IOTN were used to measure the dental esthetic variable (Daniel and Richmond 2000).

Statistical Analysis

The statistical analyses were calculated using the Statistical package for the Social Sciences (SPSS) for

Windows® software (SPSS, Inc., Chicago, IL). Means and standard deviations were calculated for all continuous variables. Two-tailed t-tests were used to compare the means of ICON at T0 and T1 for the treated and control subjects. Paired sample t-tests were also prepared for each variable of ICON for the groups that were created from the original treated sample based on the ICON score ≥ 43 (treatment need) and ICON < 43 (treatment optional). The t-tests were prepared assuming alpha ≤ 0.05. The following comparisons were computed:

1. ICON T0 vs ICON T1-treated
2. ICON T0 vs ICON T1-control
3. ICON T0 vs ICON T1-treatment need
4. ICON T0 vs ICON T1-treatment optional
5. Esthetic component T0 vs Esthetic component T1-treatment need
6. Esthetic component T0 vs Esthetic component T1-treatment optional
7. Crowding/spacing component T0 vs Crowding /spacing component T1-treatment need
8. Crowding/spacing component T0 vs Crowding /spacing component T1-treatment optional
9. Crossbite component T0 vs Crossbite component T1-treatment need

10. Crossbite component T0 vs Crossbite component T1-treatment optional

11. Anterior/vertical component T0 vs Anterior/vertical component T1-treatment need

12. Anterior/vertical component T0 vs Anterior/vertical component T1-treatment optional

13. Buccal sagittal-left component T0 vs Buccal sagittal-left component T1-treat-ment need

14. Buccal sagittal-left component T0 vs Buccal sagittal-left component T1-treat-ment optional

15. Buccal sagittal-right component T0 vs Buccal sagittal-right component T1-treat-ment need

16. Buccal sagittal-right component T0 vs Buccal sagittal-right component T1-treat-ment optional

17. Buccal sagittal-total component T0 vs Buccal sagittal-total component T1-treat-ment need

18. Buccal sagittal-total component T0 vs Buccal sagittal-total component T1-treat-ment optional

19. ICON T0 vs ICON T1-treatment need

20. ICON T0 vs ICON T1-treatment optional

21. ICON T0 and ICON T1-treated group vs ICON T0 and ICON T1-control group

The percent reductions were calculated using the formula:

$$R = \frac{T0 - T1 \times 100}{T0}$$

T0 = ICON score initial
T1 = ICON score before the second phase
R = %reduction in (T0-T1)

Intra-examiner Percent Reliability

Thirty subjects from the control sample were selected and re-scored two weeks after the original scoring with the ICON index. Intra-examiner correlation was used in the calculation of the percent reliability at T0 and T1 to test the accuracy of the examiner's use of the ICON index in scoring the models.

The intra-examiner correlation coefficient was calculated using the following equation:

$$R = \frac{MSb - MSw}{MSb + MSw}$$

R = Intraexaminer correlation coefficient
MSb = Mean square between subjects
MSw = Mean square within subjects

The reliability was calculated using the intra-examiner correlation coefficient.

Tests for Significance

The tests for significance of the difference between the T0 (initial) and T1 (before the second phase) were evaluated using a two-tailed t-test, assuming equal variances and an alpha = 0.05.

RESULTS

Demographics

The study has an analytical, retrospective design with a complete sample of 344 (n = 344), 172 treated subjects and 172 control subjects. The ICON score showed a decrease from an initial 78.66 ± 12.91 to 64.80 ± 17.68 for the treated subjects. There was a slight increase in the ICON score from 76.6 ± 10.5 to 76.9 ± 10.6 for the control subjects. 54.5% of the treated and control subjects were females and 45.5% were males. The average age of the treated subjects at T0 was 9.9 ± 1.5 and at T1 13.0 ± 1.3. The average age of the untreated subjects at T0 was 8.7 ± 1.0 and at T1 11.9 ± 1.4, as stated in Table 2.

TABLE 2.--Summary Demographics

Variables	Treated Group	Control Group
Percent female	54.5%	54.5%
Percent male	45.5%	45.5%
Age T0	9.9 ± 1.5	8.7 ± 1.0
Age T1	*13.0 ± 1.3	*11.9 ± 1.4

*Significance difference $p \leq 0.05$

The molar classifications of the treated and control subjects exhibited that class II molar relationship on the right and left was the most common, followed by class I molar, lastly followed by class III molar. This can be seen in Table 3 below:

TABLE 3.--Subjects with Class I,II,III Molar Classification

	Class I R & L	Class II R & L	Class III R & L
TREATED SUBJECTS	28	137	7
CONTROL SUBJECTS	39	128	5

Table 4 lists the subdivisions of the Angle's molar classification of the treated subjects. Those subdivisions were added to the respective molar groups to have only three groupings.

TABLE 4.--Number of Subjects with Angle's Subdivisions of Class I, II and III Molar Classification

	Class I R & L	Class II R & L	Class III R & L	Class II Subdivision R & Subdivision L	Class III Subdivision R & Subdivision L
TREATED SUBJECTS	28	117	5	20	2

ICON Scores

The cut-off for treatment need is an ICON score greater than forty-three. After the first phase of treatment, T1 (beginning of phase two), there were only twenty subjects in which the ICON score was less than forty-three. These subjects moved into the category where the second phase of orthodontic treatment would be optional. There were 152 treated subjects in whom the ICON scores were greater than forty-three. For those subjects, a second phase of orthodontic treatment would still be a needed. Table 5 shows the average initial and final ICON scores for the subject groupings.

TABLE 5.--Average ICON Scores

Subject Groups	Initial Score (T0)	Final Score (T1)
Treated subjects (172)	78.7 ± 12.9	*64.8 ± 17.9
Control subjects (172)	76.6 ± 10.5	76.9 ± 10.6

*Significance difference $p \leq 0.05$

Table 6 lists the means and standard deviations of the treated and control subjects with the variables of ICON that were measured in data collection. The averages for PAR scores were taken from Katzan's study (1998) for

the treated subjects. The table also shows the average ages of the treated and control subjects.

TABLE 6.--Means and Standard Deviations for Treated and Control Subjects

	Treated Subjects n = 172		Control Subjects n = 172	
	Means and Standard Deviations		Means and Standard Deviations	
Variables	T0	T1	T0	T1
Age	9.9 ± 1.5	*13.0 ± 1.3	8.7 ± 1.0	*11.9 ± 1.4
Par	31.7 ± 9.1	22.5 ± 9.5	N/A	N/A
Aesthetic Component	8.0 ± 1.2	*6.4 ± 1.9	7.8 ± 0.8	7.8 ± 0.9
Crowding/ Spacing	1.1 ± 1.0	1.1 ± 1.2	1.0 ± 1.3	1.0 ± 1.1
Crossbite	0.5 ± 0.5	*0.4 ± 0.5	0.2 ± 0.4	0.2 ± 0.4
Anterior Vertical	1.3 ± 0.8	*1.0 ± 0.7	1.6 ± 0.9	*1.8 ± 0.9
Buccal Sagittal-Left	1.6 ± 0.5	1.5 ± 0.6	1.6 ± 0.5	1.5 ± 0.5
Buccal Sagittal-Right	1.7 ± 0.5	*1.5 ± 0.6	1.6 ± 0.5	1.6 ± 0.5
Buccal Sagittal Total	3.2 ± 0.8	*3.0 ± 0.9	3.59 ± 4.46	3.1 ± 0.8
ICON	78.7 ± 12.9	*64.8 ± 17.9	76.6 ± 10.5	76.9 ± 10.6

*Significance difference $p \leq 0.05$

ICON Complexity

The complexity levels range from easy to very difficult. Based on the pre-treatment ICON score, T0 (initial) the majority of the treated subjects have very difficult (ICON score > 77) malocclusions to treat. Table 7 shows the complexity levels of malocclusion.

Table 7.--Levels of Complexity

Complexity Levels	% Of the Treated Subjects n=172
Easy < 29	(n = 0) 0%
Mild 29-50	(n = 1) 0.6%
Moderate 51-63	(n = 17) 9.9%
Difficult 64-77	(n = 56) 32.6%
Very difficult >77	(n = 98) 57.0%

The original treatment group was subdivided into two sample groups based on the ICON score at T1. Table 8 lists the means and standard deviations of the different variables observed in the groups.

TABLE 8.--Means and Standard Deviations for Subsets of the Original Treated Sample

	Treatment Optional n = 20		Treatment Needed n = 152	
	Mean and Standard Deviations		Mean and Standard Deviations	
Variables	T0	T1	T0	T1
Age	10.3 ± 1.6	*13.1 ± 1.1	9.9 ± 1.5	*13.0 ± 1.4
Par	29.2 ± 8.8	*17.9 ± 9.1	32.1 ± 9.1	*23.1 ± 9.4
Aesthetic Component	7.01 ± 1.2	*3.2 ± 1.0	8.1 ± 1.2	*6.8 ± 1.6
Crowding/ Spacing	0.7 ± 0.6	*0.2 ± 0.5	1.2 ± 1.0	1.3 ± 1.2
Crossbite	0.4 ± 0.5	*0.1 ± 0.3	0.49 ± 0.50	*0.4 ± 0.5
Anterior Vertical	1.4 ± 0.8	*0.7 ± 0.5	1.3 ± 0.8	*1.0 ± 0.7
Buccal Sagittal-Left	1.3 ± 0.5	1.1 ± 0.7	1.6 ± 0.5	1.5 ± 0.6
Buccal Sagittal-Right	1.6 ± 0.6	1.4 ± 0.7	1.7 ± 0.5	*1.5 ± 0.6
Buccal Sagittal Total	2.9 ± 0.9	2.5 ± 1.0	3.3 ± 0.8	*3.0 ± 0.9
ICON	68.8 ± 10.9	*33.9 ± 6.4	80.0 ± 12.6	*68.9 ± 14.6

*Significance difference $p \leq 0.05$

ICON Improvement

The ICON improvement rating is found by the formula:

ICON Improvement = Pre-treatment score - (post-treatment score)4

The improvement rating was carried out for the treatment groups ICON < 43 (second phase-optional) and

ICON > 43 (second phase-needed). Table 9 shows the percentage of the improvement in the ICON scores.

TABLE 9.--ICON Improvement Ratings

ICON Improvement Ratings	Treatment Optional n = 20	Treatment Needed n = 152
Greatly improved (> -1)	(n = 0) 0%	(n = 0) 0%
Substantially improved (-25 to -1)	(n = 2) 10%	(n = 0) 0%
Moderately improved (-53 to -26)	(n = 4) 20%	(n = 0) 0%
Minimally improved (-85 to -54)	(n = 9) 45%	(n = 0) 0%
Not improved or worse (< -85)	(n = 5) 25%	(n = 152) 100%

Appliances

There were numerous appliances used in the first phase of the two-phase orthodontic treatment. Table 9 indicates the different appliances used in the original treatment sample (172), the treatment sample with final score > 43 (152) and the treatment sample with final score < 43 (20).

Table 10.--Total Appliances Used in Each Treatment Group

Treatment Groups	Original treated subjects (n = 172)	Treatment Needed (n = 152)	Treatment Optional (n = 20)
Expanders	91	82	9
2 X 4	28	24	4
Class II appliances	28	26	2
Arch length holding appliance	24	21	3
Cervical Headgear	23	20	3
Combi-headgear	12	7	5
PHPHG	9	9	0
Anterior bite plane	9	9	0
Lower Schwartz	7	6	1
Protraction facemask	4	4	0
Posterior bite block	4	4	0
Serial extraction	2	2	0
Quad helix w/ tongue crib	1	1	0
Frankel IV	1	1	0
Extraction of supernumerary tooth	1	1	0
Hawley w/finger springs	1	1	0
Total Appliances	245	218	27

There were three out of sixteen appliances used in the first phase of treatment that had an impact in the lowering of the ICON score below forty-three. Based on the formula:

$$\frac{\text{Appliance \# x 100}}{\text{Total Appliance \#}} = \text{percentage score}$$

For each of the appliances, the formula was applied and the percentage score was evaluated. The treatment subjects with the ICON score < forty-three showed greater percentage score than the original treatment group of 172 subjects, for three of the appliances used in the first phase. The 2 X 4, the arch length appliances and the combination headgear use by the clinician had the greatest effect in reducing the ICON score. The combination headgear had the highest percent score.

Class II Appliance Comparisons

As mentioned previously, there were different appliances used for early treatment. The subjects that used class II appliances were evaluated to uncover any differences in the level of significance from the original treatment group. The class II appliances were: the bionator, frankel II and twin block. Table 11 shows

the mean and standard deviations of class II appliance group.

Table 11.--Class II Appliance Group Means and Standard Deviations

	Class II Treatment Appliance Group (n = 28)	
	Mean and standard deviations	
Variables	T0	T1
Age	9.7 ± 1.6	*13.0 ± 1.5
ICON		
Aesthetic Component	8.5 ± 1.3	*6.3 ± 2.0
Crowding/ Spacing	1.0 ± 0.8	0.9 ± 1.2
Crossbite	0.3 ± 0.5	0.3 ± 0.5
Anterior Vertical	1.8 ± 0.8	*0.9 ± 0.6
Buccal Sagittal-Left	1.6 ± 0.5	1.5 ± 0.6
Buccal Sagittal-Right	1.6 ± 0.5	1.4 ± 0.6
Buccal Sagittal Total	3.1 ± 0.8	2.8 ± 0.9
ICON	82.4 ± 13.2	*62.6 ± 19.0

*Significance difference $p \leq 0.05$

Percent Reliability

Intra-examiner correlation reliability for 30 double determination with the T1 (before the second phase) resulted in $r^2 = 0.53$. The r-value indicates moderate intra-examiner reliability.

DISCUSSION

Early treatment continues to come under fire in the media and orthodontic arena. There are advocates and challengers to the idea that early treatment is a necessity. The purpose of this study was to determine the efficacy of early phase treatment using the ICON index. The initial age at the beginning of treatment, the final age (the age beginning the second phase), and the change in the ICON score that converted subjects from a treatment need to treatment optional was recorded.

In the absence of treatment, there is no statistical significance in change in the malocclusion that occurs over time. The ICON score at T0 exhibited only a slight increase, which was negligible at T1. The study illustrates that no control subjects are needed for studies conducted using ICON. According to the study, the clinician can wait to treat the malocclusion, and the objective score for complexity and need remains the same. The study coincides with previous early treatment studies, for instance, the North Carolina study (Tulloch

et al. 1998) stated the information from the study suggested that failures or success from early treatment might be due to differences in growth and compliance. Therefore, waiting to begin treatment may be the better choice for patient care. The Pennsylvania study (Ghafari 1998) stated that the timing of the development of the malocclusion is more significant, just prior to the exfoliation of the deciduous primary second molars. Therefore, the timing of treatment is an important decision that the clinician must face in determining the proper treatment plan.

The malocclusion develops and essentially remains the same as the patient matures. Based on Katzan's study (1998), the one-phase subjects in the study were on average older than the two-phase subjects. An acceptable functional occlusion was established for the one-phase subjects just as well as the subjects that underwent two-phases of orthodontic treatment. Katzan reported that most of the correction occurred in the second phase of the two-phase treatment. This finding helps support the present study that the malocclusion can be treated at a later age in one-phase versus treated in two-phases at an earlier age. Orthodontists are needed to make changes in

the dental and skeletal structures. In the first phase of treatment, correction of the skeletal structures is an important goal. Katzan (1998) found this to be true. The residual dental corrections were the goal of the second phase and it was comparable to the one phase group. This supports the data found in the present study that in view of the fact that the malocclusion remains the same as the patient matures, treatment can be performed at a later age in one-phase of treatment.

Early treatment results in a statically significant decrease in ICON. The decrease in the ICON score is due to the heavily weighted esthetic score. The present study evaluated only the first phase of treatment versus Katzan's study where the subjects evaluated underwent one-phase and two-phase treatment. For those patients that were converted from a treatment needed to treatment optional level of complexity, statistically significant variables were: esthetics, crowding and spacing, presence of crossbite, the anterior vertical relationship, and the ICON score. For the subjects that remained in the treatment needed level of complexity, the statistically significant variables were: the presence of crossbite, the anterior vertical relationship, the

buccal sagittal relationship on the right side of the arch, the total buccal sagittal relationship, and the ICON score. The type of Angle classification in Katzan's study dictated the PAR score. In the present study, the Angle classification was not as important in dictating the ICON score. Katzan reported that the class I molar classification had the lowest initial and final PAR score. In this study, it is true that the class II molar classification was the most numerous, the treated and control subjects were matched on age, gender and molar classification. The control subjects' mean initial and final ages were lower than the treated subjects, based on the statistical testing. The change in ICON was not significant to corrupt the results in the treated sample. The differences in the ages are not statistically significant. The PAR score for the class II molar relationship in Katzan's study had the highest initial and final scores. O'Brien (1995) stated that the patients that initially had a higher PAR score demonstrated a greater enhancement in the occlusion. The suggestion was made that a possible bias for those patients may influence the change in the PAR score. In the present study, early treatment reduced only 7% of the

class II subjects so that the ICON score became a value lower than forty-three, which would move them into the treatment optional category. There are many different variables that could have caused the reduction in ICON and PAR, but further investigation is needed to discover which variables had the greater effect.

Early Treatment Success

The evaluation of the success of treatment using the ICON index is based on the cut off score of 31. Of the twenty subjects that were converted from a treatment need to a treatment optional, only 45% (9) of them actually could be considered an acceptable finish even though the second phase of treatment became optional. Richmond and Daniels (1998 a, b) stated that ICON has a lesser amount of predictability of the treatment outcome than the treatment need. With this in mind, can we say that ICON can predict the outcome value of the first phase of two-phase treatment so that the second phase becomes optional?

Complexity of the Malocclusion

The ICON index was performed on the models of the two subjects groups at T0 and T1. The raw score was obtained for the different variables of ICON and

multiplied by a weighted score to ascertain the pre- and post-ICON score. The pre-ICON score was used in the determination of the treated subjects' malocclusion complexity. The 56.98% of the treated subjects had very difficult malocclusions. Of the very difficult cases, 73.47% of the 56.98% of the cases were class II malocclusions. This is in accord with Livieratos and Johnston (1995), as well as Katzan (1998) documentation that the more difficult class II malocclusions receive early treatment. 32.56% of the treated subjects have a difficult level of complexity with 62.50% of this group having a class II malocclusion. Of the moderate level of complexity, there were only 9.88% of the treated subjects that received early treatment, but over half of that group, 58.80% was class II malocclusions. The early treatments provided by the clinician were in cases with difficult to very difficult levels of complexity with class II malocclusions.

Level of Improvement

The ICON score post treatment can be used to determine the amount of improvement provided in treatment. Of the treated subjects that remained in the treatment need category, 100% of the subjects either

remained the same or became worse. Of the converted subjects only 11% could be considered substantially improved, which disproves the idea that early treatment will convert 34% of the patients from needing treatment ICON ≥ forty-three after the first phase to optional treatment for the second phase of orthodontic treatment ICON ≤ forty-three. The majority of the subjects were in the category of minimally improved, and even though the subjects moved to the treatment optional, 25% of those subjects were considered to have not improved or to have become worse. The explanation for the percentage that remained the same or became worse could be that the subjects' ICON score at (T1) was very close to the treatment need cut-off score of 43. Since the differences in the difficult and very difficult levels of complexity may not be able to be determined, the use of the complexity rating to determine the treatment success may not be as valid as expected (Richmond and Daniels 1998b).

Appliances

There are many different appliances that are used in early treatment. The effectiveness of which appliances have the best result in affecting the treatment outcome

in early treatment remains to be discovered. There were multiple appliances used on the treated subjects for the first phase of the two-phase treatment. The rapid palatal expander was the most commonly used appliance. However, the 2 x 4, the arch length appliances and the combination headgear were the most effective appliances. The combination headgear had the greatest effect in the conversion from treatment need to treatment optional. As in Katzan's study, these appliances were the most commonly used for treatment. This fact may be due in part to good patient compliance or stringent criteria used in choosing the patients to receive the combination headgear therapy.

Error in the Study

The ICON index is best used in the late mixed to permanent dentition, because it is more difficult to judge the esthetics in the early to mixed dentitions are (Daniels and Richmond 2000). The evaluator was self-calibrated, due to the inability to be calibrated before or during the progress of the research. There was a difference in the matching of the angle molar classification with the treated and control subjects. This did not have any effect in the statistical

significance. The ICON scores for the controls were not statistically significant.

SUMMARY AND CONCLUSIONS

The treatment need and outcome of two-phases of orthodontic therapy was assessed using the ICON index. 172 subjects were selected from the private practice of a single practitioner, Dr. Gary Wolf, of Norwalk, Ohio. The 172 subjects used for the control group was selected from the Bolton-Brush Growth Study. The models of each group of subjects were scored at (T0) initial-before treatment and (T1) final before the initiation of the second phase by a single investigator. The subjects' chronological age, gender and molar classification, and the appliances used was abstracted from the patient's chart, percent complexity and percent improvement was calculated from T0 and T1 ICON score.

The study revealed the following results:

1) In the absence of treatment, ICON does not change.

2) Early treatment results in a statically significant decrease in ICON.

3) 11% of the treated subjects were converted from a treatment needed to a treatment optional complexity level.

4) The complexity of the malocclusions of the treated subjects ranged from difficult to very difficult.

5) Only 10% of the converted subjects could be considered to have a substantial improvement.

6) The most common appliance for early phase treatment was the rapid palatal expander, but the most effective appliance was the combination headgear.

It can be concluded that early phase treatment does not prevent the need for the second phase. The ICON index may not be sensitive enough to determine the amount of improvement to yield the degree of treatment success. The practitioner would be doing a great disservice to the patient if he says that the second phase would not be necessary after the first phase of the two-phase orthodontic treatment. The ICON index only converted 11% of the treated subjects from a treatment need to a treatment optional level of difficulty.

APPENDIX. Condensed version of thesis

COVER LETTER

January 19, 2002

Dr. David L. Turpin, Editor-in-Chief
American Journal of Orthodontics
And Dentofacial Orthopedics
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Dear Sir:

The manuscript is being submitted for review for publication. The original authors are Rachel M. Hamilton, DDS, Mark G. Hans, DDS, MSD, Gary R. Wolf, DDS, MSD, J. Martin Palomo, DDS, MSD and Seth B. Canion, DDS, MSD. The manuscript was completed as partial requirement for the Master of S cience Degree in Dentistry from Case Western Reserve University, School of Dentistry, Department of Orthodontics.

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Sincerely,

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The final manuscript has been seen and approved by all of the authors. The undersigned authors transfer all copyright ownership of the manuscript "The Efficacy of Early Treatment using the Index for Complexity, Outcome and Need" to the American Association of Orthodontists in the event the work is published. The undersigned author warrants that the article is original, does not infringe upon any copyright or other proprietary right of any third party, is not under consideration by another journal, has not been previously published, and includes any product that may derive from the published journal, whether print or electronic media. We sign for and accept responsibility for releasing this material.

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THE EFFICACY OF EARLY ORTHODONTIC TREATMENT USING THE INDEX OF COMPLEXITY, OUTCOME AND NEED

By

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THE EFFICACY OF EARLY ORTHODONTIC TREATMENT USING THE INDEX OF COMPLEXITY, OUTCOME AND NEED

Abstract

The retrospective, analytical study used the Index of Complexity, Outcome and Need to evaluate first phase of two-phase orthodontic treatment with 172 treated subjects and control subjects. Between group differences were evaluated with paired t-tests and p-value ≤ 0.05 used to assign statistical significance. The mean initial ICON score (T0) for the treated subjects was 78.66 ± 12.91 versus 76.56 ± 10.52 for the control group. The final mean score (T1) for the treated sample was 64.80 ± 17.86 versus 76.94 ± 10.55 for the control group. Twenty of the 172 (11%) treated subjects had a post-treatment ICON score less than 43 indicating that phase two treatment for these patients would be "optional". This group was tested to determine the mean score (T0) for the "optional" group was 68.75 ± 10.87 and for the other 152 subjects was 79.96 ± 12.62. The final score (T1) for the subset was 33.85 ± 6.37 versus 68.67 ± 14.74, respectively. Based on these results we conclude 11% of the subjects that received a first phase of treatment would not need a second phase of orthodontic treatment to achieve an acceptable functional and esthetic result. As well as, ICON score does not change in the absence of treatment.

INTRODUCTION

The Orthodontist today is faced with the dilemma of when to start orthodontic treatment on patients. Should treatment begin when the patient is in the early mixed dentition or when the permanent dentition is completely erupted? As a neophyte to this profession, whether or not to begin early treatment on a patient can be a bit confusing. Early treatment in recent years has come under fire by the media and by people within our own profession. Ms. Clara Hemphill of the New York Times, wrote a piece entitled "Early Intervention Dentistry: Going to Work on Baby Teeth" the title of this article could entice the public into thinking that Orthodontists are wrong for treating some patients early. In the past, most patients received orthodontic treatment in the mid to late teen years. The public could be led to believe that all orthodontists are doing early treatment just for monetary gain.

Published studies from North Carolina, Pennsylvania and Florida that say there is little difference in the final dental result between early treatment begun in the mixed dentition followed by a second phase of treatment to adjust the permanent teeth versus treatment provided to teenagers after all the permanent teeth have erupted. Dr. G. Thomas Kleumper of the University of Kentucky wrote, "We need to get away from the idea that early treatment is the best approach in all circumstances." The timing of early treatment should be based on the specific needs of each patient. Early orthodontic treatment is effective and desirable in certain situations. There is evidence equally compelling that such an approach is not indicated in many cases for which later, single-phase treatment is more effective. Dr. Livieratos and Johnston

cite studies that show that final results of orthodontic treatment are on average the same for children who start treatment early (ages four to nine) compared with those who wait until all their permanent teeth erupt. Advocates for early treatment say children are less rebellious than teens, and they tend to be more obedient about wearing and adjusting appliances (Parker-Pope, 2000). Patients treated at earlier ages in the mixed-dentition are managed more easily than at older ages in the permanent dentition (Wagers, 1975). Emotional and self-esteem issues may play a role in treatment decisions. Early treatment seems to help reduce psychological disturbances (Wagers, 1975). Clinicians must decide on a case-by-case basis, when to provide orthodontic treatment (Kluemper, 2000). Ultimately, the orthodontist will have to make the decision: whether or not to do early treatment. This study uses an independent needs assessment index to determine whether early orthodontic intervention reduces the complexity, and/or need for a second phase of orthodontic treatment.

MATERIALS AND METHODS

The study was an analytical, retrospective, longitudinal investigation of orthodontic patients who underwent two phases of treatment. The data were collected from a single provider in Norwalk, Ohio (Gary Wolf, DDS, MSD). Subjects were selected from a previous study, Outcomes Assessment of One Phase and Two Phase Orthodontic Treatment by Dr. Charissa Katzan (1998).

Subject Selection

One hundred and seventy-two subjects that underwent two-phase orthodontic treatment were selected from the previous study by Katzan (1998). These subjects were matched on age, gender and Angle molar classification. The treated subjects were compared with 172 untreated control subjects from the Bolton-Brush Growth Study.

Inclusion criteria were:

1. No syndrome patients with craniofacial anomalies
2. No surgical case
3. No adults over the age of 18 years
4. All early treatment cases must have started treatment in the mixed dentition

Based on the previous study, the treated subjects exhibited differing Angle classes of malocclusion and were treated with different combinations of functional appliances.

Data collected for each patient incorporated:

1. Initial age for phase one
2. Angle's molar classification
3. Appliances used for the phase one treated subjects
4. Final age for the end of phase one

Scoring the Models

The dental models of the subjects were scored using the Index of Complexity, Outcome and Need (ICON) (Daniel and Richmond, 2000) by a single examiner. The examiner was self-calibrated.

To assess the occlusal improvement the pre-treatment score is compared to the post-treatment score. Either the overall score reduction or improvement can be calculated with ICON. The pre-treatment and post-treatment score, and score reduction was calculated for each treated case.

ICON was performed on 172 treated and control subjects, evaluating the models at time 0 (initial) and the models at time one (after early treatment). The subjects were divided into class I, class II and class III malocclusions. Two sets of models were scored for the two-phase patients: the beginning of the first phase of treatment (T0) and the completion of first phase/beginning of second phase of treatment (T1). The ICON index consist of scores for:

1. IOTN dental esthetic score
2. Upper crowding/spacing score
3. Crossbite score
4. Overbite/open bite score
5. Buccal segment interdigitation for the right and left

Each score was registered on a data sheet with the proper weightings for each variable of the index to provide the total score.

Statistical Analysis

The statistical analyses were calculated using the Statistical package for the Social Sciences (SPSS) for Windows® software (SPSS, Inc., Chicago, IL). Means and standard deviations were calculated for all continuous variables. Two-tailed t-tests were used to compare the means of ICON at T0 and T1 for the treated and control subjects. Paired sample t-tests were also prepared for each variable of ICON for the groups that were created from the original treated sample based on the ICON score ≥ 43 (treatment need) and ICON < 43 (treatment optional). The t-tests were prepared assuming alpha ≤ 0.05.

RESULTS

Demographics

The study has an analytical, retrospective design with a complete sample of 344 subjects, with 172 treated and control subjects. The ICON score showed a decrease from an initial 78.66 ± 12.91 to 64.80 ± 17.68 for the treated subjects. There was a slight increase in the ICON score from 76.6 ± 10.5 to 76.9 ± 10.6 for the control subjects. Fifty-four point five percent of the treated and control subjects were females and 45.5% were males. The average age of the treated subjects at T0 was 9.9 ± 1.5 and at T1 13.0 ± 1.3. The average age of the untreated subjects at T0 was 8.7 ± 1.0 and at T1 11.9 ± 1.4, as stated in Table 1.

Table 2 lists the means and standard deviations of the treated and control subjects with the variables of ICON that were measured in data collection. The table also shows the average ages of the treated and control subjects.

The original treatment group was subdivided into two sample groups based on the ICON score at T1. Table 3 lists the means and standard deviations of the different variables observed in the groups.

ICON Scores

The cut-off for treatment need is an ICON score greater than 43. After the first phase of treatment, T1 (beginning of phase two), there were only 20 subjects in which the ICON score was less than 43. These subjects moved into the category where the second phase of orthodontic treatment would be optional. There were 152 treated subjects in whom the ICON scores were greater than 43. For those subjects, a second phase of orthodontic treatment would still be a needed.

Appliances

There were numerous appliances used in the first phase of the two-phase orthodontic treatment. Table 4 indicates the different appliances used in the original treatment sample (172), the treatment sample with final score > 43 (152) and the treatment sample with final score < 43 (20).

There were 3 out of 16 appliances used in the first phase of treatment that had an impact in the lowering of the ICON score below 43. Based on the formula:

$$\frac{\text{Appliance \# x 100}}{\text{Total Appliance \#}} = \text{percentage score}$$

For each of the appliances, the formula was applied and the percentage score was evaluated. The treatment subjects with the ICON score < 43 showed greater percentage score than the original treatment group of 172 subjects, for three of the appliances used in the first phase. The 2 X 4, the arch length appliances and the

combination headgear use by the clinician had the greatest effect in reducing the ICON score. The combination headgear had the highest percent score.

Class II Appliance Comparisons

As mentioned previously, there were different appliances used for early treatment. The subjects that were class II appliances were used, were evaluated to uncover any differences in the level of significance fro the original treatment group. The class II appliances were: the bionator, frankel II and twin block. Table 5 shows the mean and standard deviations of class II appliance group.

Percent Reliability

Intra-examiner correlation reliability for 30 double determination with the T1 (before the second phase) resulted in $r^2 = 0.53$. The r-value indicates moderate intra-examiner reliability.

DISCUSSION

There are advocates and challengers to the idea that early treatment is a necessity. The study discovered that in the absence of treatment, there is no statistical significance in change in the malocclusion that occurs over time. The ICON score at T0 exhibited only a slight increase, which was negligible at T1. The study illustrates that no control subjects are needed for studies conducted using ICON. According to the study, the clinician can wait to treat the malocclusion, and the objective score for complexity and need remains the same. The study coincides with previous early treatment studies; the North Carolina study (Tulloch et al, 1998) stated waiting to begin treatment might be the better choice for patient care. The Pennsylvania study

(Ghafari, 1998) stated that the timing of the development of the malocclusion is more significant, just prior to the exfoliation of the deciduous primary second molars. Therefore, the timing of treatment is an important decision that the clinician must face in determining the proper treatment plan.

Early treatment results in a statically significant decrease in ICON. The decreased in the ICON score is due to the heavily weighted esthetic score. The study evaluated the first phase of two-phase orthodontic treatment. Those subjects that were converted from a treatment needed to treatment optional level of complexity, statistically significant variables were: esthetics, crowding and spacing, presence of crossbite, the anterior vertical relationship and the ICON score. For the subjects that remained in the treatment need level of complexity, the statistically significant variables were: the presence of crossbite, the anterior vertical relationship, the buccal sagittal relationship on the right side of the arch, the total buccal sagittal relationship, and the ICON score.

In the present study, the Angle classification was not important in dictating the ICON score. The control subjects' mean initial and final ages was lower than the treated subjects, based on the statistical testing, the change in ICON was not significant to corrupt the results in the treated sample. The differences in the ages are not statistically significant. In the present study, early treatment reduced only 7% of the class II subjects so that the ICON score became a value lower than 43, which would move them into the treatment optional category.

Early Treatment Success

The evaluation of the success of treatment, using the ICON index is based on the cut off score of 31. Of the 20 subjects that were converted from a treatment need to a treatment option, only 45% (9) of them actually could be considered an acceptable finish even though the second phase of treatment became optional. Richmond and Daniels (1998 a, b) stated that ICON has a lesser amount of predictability of the treatment outcome, than the treatment need. With this in mind, can we say, that ICON can predict the outcome value of the first phase of two-phase treatment so that the second phase becomes optional?

Complexity of the Malocclusion

The ICON index was performed on the models of the two subjects groups at T0 and T1. The raw score was obtained for the different variables of ICON and multiplied by a weighted score to ascertain the pre-treatment and post-treatment ICON score. The pre-treatment ICON score was used in the determination of the treated subjects' malocclusion complexity. The 56.98% of the treated subjects had very difficult malocclusions. Of these very difficult cases, 73.47% of the cases were class II malocclusions. This is in accord with Livieratos and Johnston (1995), as well as Katzan (1998) documentation that the more difficult class II malocclusions receive early treatment. Thirty two point five six percent of the treated subjects have a difficult level of complexity with 62.50% of this group having a class II malocclusion. The early treatments provided by the clinician were to cases with difficult to very difficult levels of complexity with class II malocclusions.

Level of Improvement

The ICON score post treatment can be used to determine the amount of improvement provided in treatment. The treated subjects that remained in the treatment need category, 100% of the subjects either remained the same or became worse. Of the converted subjects only 10% could be considered substantially improved, which disproves that early treatment will convert 34% of the patients from needing treatment ICON $\geq$ 43 after the first phase to optional treatment for the second phase of orthodontic treatment ICON $\leq$ 43. The explanation for the percentage that remained the same or became worse, could be that the subjects ICON score at (T1) were very close to the treatment need cut-off score of 43. The use of the complexity rating to determine the treatment success may not be as valid as expected (Richmond and Daniels, 1998b).

Appliances

There are many different appliances that are used in early treatment. The effectiveness of which appliances have the best result in affecting the treatment outcome in early treatment remains to be discovered. There were multiple appliances used on the treated subjects for the first phase of the two-phase treatment. The rapid palatal expander was the most commonly used appliance. However, the 2 x 4, the arch length appliances and the combination headgear were the most effective appliances. The combination headgear had the greatest effect in the conversion from treatment need to treatment option. This fact may be due in part to good patient

compliance or stringent criteria used in choosing the patients to receive the combination headgear therapy.

Error in the study

The ICON index is best used in the late mixed to permanent dentition, because the early to mixed dentitions are more difficult to judge the aesthetics (Daniels and Richmond, 2000). The evaluator was self-calibrated, due to the inability to be calibrated in before or during the progress of the research. There was a difference in the matching of the angle molar classification with the treated and control subjects. This did not have any effect in the statistical significance. The ICON scores for the controls were not statistically significant.

It can be concluded that early phase treatment does not prevent the need for the second phase. The ICON index may not be sensitive enough to determine the amount of improvement to yield the degree of treatment success. The practitioner would be doing a great disservice to the patient if he says that the second phase would not be necessary after the first phase of the two-phase orthodontic treatment. The ICON index only converted 11% of the treated subjects from a treatment need to a treatment optional level of difficulty.

CONCLUSIONS

The study revealed the following results:

1. In the absence of treatment, ICON does not change.

2. Early treatment results in a statically significant decrease in ICON.

3. 11% of the treated subjects were converted from a treatment needed to a treatment optional complexity level.

4. The complexity of the malocclusions of the treated subjects ranged from difficult to very difficult.

5. Only 10% of the converted subjects could be considered to have a substantial improvement.

6. The most common appliance for early phase treatment was the rapid palatal expander, but the most effective appliance was the combination headgear.

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LIST OF TABLES

TABLE 1.—Description of the Samples

Variables	Treated Group	Control Group
Percent female	54.5%	54.5%
Percent male	45.5%	45.5%
Age T0	9.9 ± 1.5	8.7 ± 1.0
Age T1	*13.0 ± 1.3	11.9 ± 1.4
Class I	28	39
Class II	137	128
Class III	7	5

*Significance difference $p \leq 0.05$

TABLE 2.--The Means and Standard Deviations of the Treated and Control subjects

	Treated subjects n = 172		Control Subjects n = 172	
	Means and Standard Deviations		Means and Standard Deviations	
Variables	T0	T1	T0	T1
Age	9.9 ± 1.5	*13.0 ± 1.3	8.7 ± 1.0	*11.9 ± 1.4
ICON				
Aesthetic Component	8.0 ± 1.2	*6.4 ± 1.9	7.8 ± 0.8	7.8 ± 0.9
Crowding/ Spacing	1.1 ± 1.0	1.1 ± 1.2	1.0 ± 1.3	1.0 ± 1.1
Crossbite	0.5 ± 0.5	*0.4 ± 0.5	0.2 ± 0.4	0.2 ± 0.4
Anterior Vertical	1.3 ± 0.8	*1.0 ± 0.7	1.6 ± 0.9	*1.8 ± 0.9
Buccal Sagittal-Left	1.6 ± 0.5	1.5 ± 0.6	1.6 ± 0.5	1.5 ± 0.5
Buccal Sagittal-Right	1.7 ± 0.5	*1.5 ± 0.6	1.6 ± 0.5	1.6 ± 0.5
Buccal Sagittal Total	3.2 ± 0.8	*3.0 ± 0.9	3.59 ± 4.46	3.1 ± 0.8
ICON total	78.7 ± 12.9	*64.8 ± 17.9	76.6 ± 10.5	76.9 ± 10.6

*Significance difference $p \leq 0.05$

TABLE 3.--Means and Standard Deviations of the Subsets of the Original Treated Sample

	Treatment Optional n = 20		Treatment Needed n = 152	
	Mean and standard deviations		Mean and standard deviations	
Variables	T0	T1	T0	T1
Age	10.3 ± 1.6	*13.1 ± 1.1	9.9 ± 1.5	*13.0 ± 1.4
ICON				
Aesthetic Component	7.01 ± 1.2	*3.2 ± 1.0	8.1 ± 1.2	*6.8 ± 1.6
Crowding/ Spacing	0.7 ± 0.6	*0.2 ± 0.5	1.2 ± 1.0	1.3 ± 1.2
Crossbite	0.4 ± 0.5	*0.1 ± 0.3	0.49 ± 0.50	*0.4 ± 0.5
Anterior Vertical	1.4 ± 0.8	*0.7 ± 0.5	1.3 ± 0.8	*1.0 ± 0.7
Buccal Sagittal-Left	1.3 ± 0.5	1.1 ± 0.7	1.6 ± 0.5	1.5 ± 0.6
Buccal Sagittal-Right	1.6 ± 0.6	1.4 ± 0.7	1.7 ± 0.5	*1.5 ± 0.6
Buccal Sagittal Total	2.9 ± 0.9	2.5 ± 1.0	3.3 ± 0.8	*3.0 ± 0.9
ICON total	68.8 ± 10.9	*33.9 ± 6.4	80.0 ± 12.6	*68.9 ± 14.6

*Significance difference $p \leq 0.05$

Table 4.--Total Appliances Used in Each Treatment Group

Treatment Groups	Original treated subjects (n = 172)	Treatment Needed (n = 152)	Treatment Optional (n = 20)
Expanders	91	82	9
2 X 4	28	24	4
Class II appliances	28	26	2
Arch length holding appliance	24	21	3
Cervical Headgear	23	20	3
Combi-headgear	12	7	5
PHPHG	9	9	0
Anterior bite plane	9	9	0
Lower Schwartz	7	6	1
Protraction facemask	4	4	0
Posterior bite block	4	4	0
Serial extraction	2	2	0
Quad helix w/ tongue crib	1	1	0
Frankel IV	1	1	0
Extraction of supernumerary tooth	1	1	0
Hawley w/finger springs	1	1	0
Total Appliances	245	218	27

Table 5.--Class II Appliance Group Means and Standard Deviations

	Class II Treatment Appliance Group (n = 28)	
	Mean and standard deviations	
Variables	T0	T1
Age	9.7 ± 1.6	*13.0 ± 1.5
ICON		
Aesthetic Component	8.5 ± 1.3	*6.3 ± 2.0
Crowding/ Spacing	1.0 ± 0.8	0.9 ± 1.2
Crossbite	0.3 ± 0.5	0.3 ± 0.5
Anterior Vertical	1.8 ± 0.8	*0.9 ± 0.6
Buccal Sagittal-Left	1.6 ± 0.5	1.5 ± 0.6
Buccal Sagittal-Right	1.6 ± 0.5	1.4 ± 0.6
Buccal Sagittal Total	3.1 ± 0.8	2.8 ± 0.9
ICON	82.4 ± 13.2	*62.6 ± 19.0

*Significance difference $p \leq 0.05$

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