Evaluation of Invisalign Treatment Utilizing the American Board of Orthodontics Objective Grading System for Dental Casts

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In partial fulfillment for the degree of

Master of Science in Orthodontics

April 30, 2004

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## ACKNOWLEDGEMENTS

I would like to thank and acknowledge all the people who contributed to and facilitated the completion of this project.

To Dr. Larry Doyle, colleague, friend, and thesis advisor. Thank you so much for your direction and ideas for this study. Your time and efforts throughout this entire project along with your personal contribution to my orthodontic training will always be greatly appreciated.

To Dr. Dale Rhoney and Daniel Yaillen, professors and members of my thesis committee. Thank you for your helpful suggestions and use of records during this project. My personal interaction with both of you has enhanced me as a person and a clinical orthodontist.

To Dr. Rosenbarger, Dr. Kaplan, Dr. Gardner, Dr. Ensley, and Dr. Doleac, practicing orthodontists in Portland, Oregon and Salt Lake City, Utah. Thank you for time, suggestions and use of your records

To Lori Lambert, biostatistician and member of my thesis committee. Thank you for your guidance and helpful suggestions with my data analysis.

To my wife Jennifer. Thank you for your support throughout this whole journey and your brilliant suggestions. You and our newly born baby Maddox have given me the internal drive to complete this research.

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Oregon Health & Science University

2004

## ABSTRACT

The purpose of this study was to evaluate the treatment outcome of orthodontic cases treated with the Invisalign appliance using the American Board of Orthodontics (ABO) Objective Grading System (OGS) for dental casts. Private orthodontic practices in Portland, Oregon and Salt Lake City, Utah supplied 135 pre- and post-treatment models from cases treated with Invisalign. Of these, 65 met the selection criteria including: treated exclusively with Invisalign, no missing teeth (other than previous 4 bicuspid extraction), and adequate pre- and post-treatment models. Descriptive statistics and paired t-tests were computed for three groups: (1) the entire sample, (2) the Class I group, and (3) OGS scores of 30 points or less. The results revealed that 24% of the 135 cases required the use of fixed appliances or active retainers to finish the treatment. Improvement in anterior and posterior alignment accounted for 62% of the total treatment changes seen from pre- to post-treatment, which is 85% of the positive change. Interproximal spaces were effectively closed with the Invisalign appliance, which totaled 5.5% of the total treatment change. Occlusal contact deficiencies totaled 27% of the total treatment changes from pre to post treatment, which is 97% of the total negative change. All other areas in the OGS had minor changes and may not be clinically significant. This study suggests positive treatment change with the Invisalign appliance in alignment and interproximal space closure, negative treatment change in occlusal contacts and inconsistent change in all other OGS categories.

# INTRODUCTION

Adult orthodontics has become a significant portion of many orthodontic practices over the last couple of decades. Some surveys have reported that 25% of all orthodontic patients in the United States are over the age of eighteen (Gottlieb et al., 1991). In a study from 1986, adult untreated subjects were asked why they did not seek orthodontic treatment, and over 50% of the responses were related to "embarrassment associated with wearing braces" as the primary reason (Breece et al., 1986). In 1997, Align Technology (Santa Clara, California) developed a high technology, new generation orthodontic removable appliance entitled, "Invisalign". The new appliance works through a series of clear, removable aligners that resemble vacuum formed retainers. The patient wears each set of aligners for about two weeks, removing them only to eat, drink, brush, and floss. As each aligner is replaced by another, the teeth move in small increments until the final aligner is worn. At this time the teeth should have been positioned as the orthodontist had prescribed (Boyd 2000). With such a new treatment modality and increased popularity, there is a need to objectively evaluate the treatment effects of the Invisalign System.

The American Board of Orthodontics (ABO) Objective Grading System (OGS) was finalized in 1998 after numerous field tests that spanned approximately four years. The purpose of the OGS is to allow orthodontists to assess the occlusal and radiographic results of orthodontic treatment. The OGS has been suggested to be more precise than the Peer Assessment Rating (PAR) Index for discriminating minor tooth inadequacies of tooth position (Casko et al., 1998). While the PAR index evaluates the differences from pre-

and post-treatment models, the OGS was originally designed to examine the post-treatment model only.

To date, the bulk of literature on Invisalign is based on case reports and there has been no published scientific evaluation to objectively assess the effectiveness of this new treatment modality. Invisalign has been available to the orthodontic community since 1999 and more difficult cases are now being completed with this appliance. An unpublished study evaluated twenty-five of the first cases finished in the state of Oregon with Invisalign. This study looked mainly at cases that were treated for minor crowding or spacing (Robinson, 2002). The purpose of the present investigation was to evaluate the efficacy of the Invisalign system for treating a larger range of malocclusions. The treatment results were determined by measuring cases utilizing the American Board of Orthodontics Objective Grading System for dental casts.

## BACKGROUND

Significance of the Problem. A considerable portion of today's potential orthodontic patients are adults that present with incisor crowding. Despite recognizing the potential benefits of orthodontic correction, many adults are reluctant to seek treatment According to Lew, the main reasons are lack of awareness that adults can wear appliances, high cost, duration of treatment, and fear of pain (Lew, 1993). In fact, from studies of orthodontically treated adults, subjects reported that appliance discomfort was the worst aspect of orthodontic treatment (Lew, 1993; Sergl et al., 1997). The Invisalign System was introduced as a new orthodontic tool in 1997 and offers adult patients full orthodontic treatment with a removable and esthetic appliance. Studies are needed that objectively validate the objective outcome of the Invisalign System.

Adult Orthodontics. Dating back to early orthodontic history, it was thought impossible to achieve permanent occlusal change in an adult dentition (MacDowell, 1901). Today, this philosophy has obviously changed and orthodontic treatment among the adult population has become more common. The adult patient pool in some offices is estimated at more than 40% (Mathews and Kokich, 1997). These patients present a challenge to the orthodontist not only because of the multitude of dental conditions that can complicate orthodontic treatment, but also because of the high esthetic demands. Motivation and cooperation are typically higher for adults, but so are their expectations of treatment outcome, regardless of their dental condition.

Esthetic concerns are a motivating factor for many older adolescent and adults who seek treatment for malocclusion (Phillips et al., 1992). In some reports it has been shown that improvement of a patient's esthetics to enhance

psychosocial well being is often the most salient benefit of treatment (Mohlin, 1982; Tulloch et al., 1984). Studies in social psychology indicate that physical attractiveness plays a major role in social interaction and can influence the impression of an individual's social skill (Baldwin, 1980). The connection between facial attractiveness and dental appearance has been shown to be coincident (Jenny and Proshek, 1986). Another study in 1986 concluded that society has established norms for appropriate dental appearance, and extreme deviations from these norms are defined by society as unacceptable (Cons, 1986). Comprehensive orthodontic treatment is feasible for adults of all ages and correction of malocclusion makes it possible to improve the quality of periodontal and restorative treatment, in addition to providing psychosocial benefits (Buttke and Proffit, 1999).

According to the Third National Health and Nutrition Examination Survey (NHANES III) which included occlusal traits as part of the oral health component, only 43% of U.S. adults have an ideal incisor overjet of 1 to 2 mm, about 50% exhibit excessive overjet, and about 6% exhibit an anterior crossbite (Proffit et al., 1998). U.S. adults also frequently exhibit significant crowding and misalignment of maxillary and mandibular incisors, posterior crossbites and maxillary diastemata (Buttke and Proffit, 1999). Crowding is the predominant intra-arch problem in adults in the United States and Western Europe, followed by spacing, crossbites and rotated teeth. The NHANES also concluded that two-thirds to three-fourths of adults in the United States and Western Europe possess some form of malocclusion (Proffit et al., 1998). It therefore could be suggested that the adult population could benefit from orthodontic correction of certain malocclusions.

The adult population often overlooks the potential improvements that orthodontic treatment can achieve for numerous reasons. Cost, pain, discomfort, and embarrassment are just a few of a long list of reasons that potential adult orthodontic patients answered in a survey (Lew, 1993). Increased social acceptance of orthodontic therapy in adults associated with the increase in adult orthodontic patients has diminished some of the fears of embarrassment (Buttke and Proffit, 1999). The author states that it takes most adults a good deal of ego strength to seek out treatment and once treatment is initiated, the patient shows a more positive self-image than average. Dr. Proffit also believes that the demand for an invisible orthodontic appliance comes almost entirely from adults who are concerned about the reaction of others to obvious orthodontic appliances (Proffit, 2000).

Invisible Retainers. The use of full coverage retainers to orthodontically move teeth has been described as early as 1945 by Dr. H. D. Kesling who reported on the use of a flexible tooth positioning appliance that was fabricated following a series of planned diagnostic wax set up models (Kesling, 1945). Later, others contributed to the literature on the subject of minor tooth movement with full coverage retainers (Nahoum, 1964; Ponitz, 1971; McNamara et al., 1985; Sheridan et al., 1993; Rinchuse and Rinchuse, 1997). Raintree Essix (New Orleans, LA) developed an appliance for minor tooth movements with clear aligners. The appliance is modified with "divots" to create a force to push individual teeth, and "windows" are made to create space for teeth to move into. The main limitation with this technique is the movements are limited to 2-3 mm; beyond this range, another impression and new appliance is needed (Wong, 2002).

Invisalign System. Align Technology, Inc. (Santa Clara, CA) introduced the Invisalign system in 1997 as an alternative to conventional orthodontics with brackets and wires. This system uses the first three-dimensional-based digital technology for orthodontic treatment. Computer programs are used that have the capability to manipulate 3D images of individual malocclusions to produce a series of stages in which to move the teeth (Kuo et al., 2003). Stereolithographic models are constructed for each stage, which consist of precise movements of teeth approximately 0.15-0.25 mm between stages (Boyd and Vlaskalic, 2001). The clear, .030-inch thick, overlay aligners are then fabricated over the models and are packaged together and shipped to the orthodontist.

Following a thorough initial diagnosis by the clinician, polyvinylsiloxane (PVS) impressions are taken of the upper and lower dentitions along with a registration of the occlusion. The PVS impression and bite registration, appropriate radiographs, photographs, and a tentative treatment plan are all sent directly to Align Technology. The impressions are digitally scanned and Align Technology creates a virtual treatment sequence of tooth movement. Using a software program called ClinCheck, an internet based application, allows the orthodontist to simulate the proposed treatment. The clinician has the option of accepting the proposed treatment plan or requesting any needed modifications. An Align staff orthodontist reviews any revisions made. Once the clinician approves the virtual treatment, the aligners are fabricated from the stereolithic models for each stage of treatment and sent to the orthodontist for delivery to the patient.

The initial visit following the fabrication of the aligners consists of seating the first aligner and checking that it is fully seated. Each aligner is typically worn for 10-14 days before proceeding to the next set of aligners. Some patients require composite attachments bonded to particular teeth to facilitate more difficult movements such as tooth extrusion, intrusion, uprighting, extraction space closure, or alignment of severely rotated teeth. Invisalign patients are typically seen every 6 weeks to evaluate hygiene, compliance, alignment, occlusion and general treatment progress. After the final aligner is worn, a decision is made by the clinician and patient to perform any refinement to the alignment or occlusion. A new PVS impression is needed if any refinement is to be done.

The past literature on the topic of the Invisalign system has been exclusively case-report-based which can be considered weak on the hierarchy of evidence-based research (NHS Centre for Reviews and Dissemination, 2001). Align Technology has conducted a number of private and university-based clinical studies prior to commercially releasing the Invisalign system to orthodontists in 1999. Case reports in the literature are mostly from the conducted clinical trials (Womack et al., 2002; Boyd et al., 2000, 2001; and Vlaskalic and Boyd, 2001). With such a new product, little time has elapsed to carefully document its effectiveness and no published reports have examined the Invisalign system with an objective method.

Dr. Robert Boyd, Chairperson of the Department of Orthodontics at the University of the Pacific, started the first clinical trial using the Invisalign system in 1998. In April of 2000, a case report was written that included four successful cases from the trial. All patients presented were adults with mild

crowding or spacing with Class I occlusions. The paper concluded that the Invisalign system has opened up a new alternative for adult orthodontics and serves patients who may reject traditional fixed appliances (Boyd et al., 2000). In 2001, Dr. Vlaskalic, an assistant clinical professor at the University of the Pacific, and Dr. Boyd published another case report of an adult with a Class I malocclusion consisting of 4-5 mm of maxillary and mandibular crowding, 0% overbite, and an anterior crossbite of the left lateral incisor. Following the final aligners, refinement was needed to fully correct the anterior crossbite and obtain more overbite but the patient chose not to extend the treatment and said she happy was happy with the result obtained. The author explained that fixed appliances could have achieved the same or better occlusal result in arguably less time and the main advantage of the Invisalign system is clearly its esthetic, removable nature (Vlaskalic and Boyd, 2001).

Albert Owen, who used corticotomy-assisted surgery in combination with the Invisalign system to treat himself, reported an alternative, accelerated Invisalign treatment in 2001. Instead of the traditional 10-14 days per aligner, Dr. Owen changed his aligners every 3 days and the treatment took 8 weeks to correct his minor crowding (Owen, 2001).

In December of 2001, Boyd published another paper on the Invisalign system with more specific guidelines about the appliance. He emphasized that based on the results at that time, the treatment outcome is highly dependent on the clinicians experience and case selection. This is contradictory to recent advertising by Align Technology that claims, "No prior experience is necessary" and that this system is "the most significant new esthetic procedure since bleaching and almost as simple" (JADA, 2002). According to Boyd, the most

significant limitation to the appliance is the need for all permanent teeth to be fully erupted to achieve retention of the appliance and therefore, only non-growing adult patients are candidates for this appliance. He also stresses that there is no capability to incorporate basal orthopedic change with this appliance system, thus restricting the appliance to treating malocclusions that require purely dental movement. The main advantage cited for this system remained the same as reported earlier, the esthetic, hygienic, low discomfort, and removable nature of the appliance (Boyd and Vlaskalic, 2001).

An unpublished study done in 2002 as a certificate in orthodontics research project looked at the effectiveness of the Invisalign system. PAR (Peer Assessment Rating) Index changes and ABO (American Board of Orthodontics) OGS (Objective Grading System) for dental casts scores were evaluated on 25 patients treated exclusively with the Invisalign System. The mean percentage of PAR reduction for the sample was 46%, which represented a significant treatment change. Of the finished cases, 76% fell into Richmond's improved category and 72% were deemed acceptable alignment. Only the maxillary and mandibular anterior alignment showed statistically significant improvement with treatment. Only 28% of the cases passed the ABO dental cast scoring criteria (which was set at 25 in the study) and of these, 43% began treatment with a passing ABO score. The author finished by saying; "Even though this preliminary data suggests treatment success with the Invisalign System, further follow up needs to be performed due to the small sample size and the relative minor pretreatment conditions of the sample" (Robinson, 2002; OHSU).

Other clinicians have written about the frustrations with the Invisalign appliance and criticized the company for changing their views on who and what

types of problems the appliance can treat. In the spring 2002 issue of the Southern Association of Orthodontists news, Dr. DeWayne McCamish criticized the Invisalign appliance for a number of reasons that included: marketing directly to the public, a greater expense, inability to perform certain tooth movements consistently, more time needed by the doctor to treat the case and the inability to finish cases ideally. He did state that Invisalign had its place in orthodontics but the company is influencing the public to believe that the appliance can correct any malocclusion (McCamish, 2002). In the same issue, Dr. Michael Stewart, who is one of earliest Invisalign users, reported a different side of the appliance (Stewart, 2002). He stated that he experienced some major problems (Clin-Check flaws, breakage of aligners, aligners not fitting part way through treatment etc.) with Invisalign from the beginning, but like anything that is new to the profession, there is a steep learning curve and certain limitations with the appliance must be understood. He explains what he calls "Reciprocity of Application" as the following: "If our agreed treatment goals are comprehensive, the application of Invisalign may be limited. On the other hand, if our goals are limited, the application of Invisalign can be more comprehensive" (Stewart, 2002). The conclusion from both of these clinical articles is that Invisalign has a place in orthodontics but diagnosis and treatment planning still dictates the type of treatment that should be rendered to the patient. As with many of the reports in the literature, both of these articles are based solely on personal experience and lack clinical research.

According to recent Align Technology information, over 155,000 patients have either finished or are currently undergoing treatment with the Invisalign System. The company expects the range of applicability of their appliance to

expand as a result of the many clinical studies and the numerous numbers of patients currently being treated with the Invisalign system (Invisalign.com, 2004). Currently, there are a number of university-based studies being conducted on various aspects of the system. The University of the Pacific is evaluating a range of mild to severe malocclusions such as premolar extraction cases, anterior open bites, and severe rotations. The University of Florida is conducting a randomized clinical trial to study various attachment designs for extrusion, rotation, and intrusion of teeth to be used with the Invisalign system. The University of Washington is studying the effectiveness of different materials and different treatment times. Align is also working with the University of Ferrara, Italy to study the effectiveness of using a new aligner material as well as case refinements and mid-course corrections. They also plan to look at potential risk factors associated with wearing the new aligner material on oral hygiene, tooth sensitivity, root resorption, and temporomandibular joint discomfort (Invisalign.com, 2004).

Occlusal Indices. Edward H. Angle published his first classification on malocclusion in the late 1890's (Angle, 1900). His description has been widely criticized for relying on the position of the maxillary first molar in relation to the mandibular first molar and its inability to incorporate facial balance in all three dimensions (Pickering and Vig, 1975). Even so, others have found that the patient's satisfaction highly correlated with Angle's classification and it is the most widely used indicator of the prevalence of malocclusion in various populations (Katz, 1978; Houston et al., 1992).

In the 1950's, methods were used to evaluate occlusion through indices for the purpose of gathering epidemiological data on the prevalence of

malocclusions in children. The Handicapping Labio-lingual Deviations Index (HDL Index) was established in 1958 by Draker and described a malocclusion as an orthodontic handicap (Draker, 1958). Draker developed the HDL Index to be quantitative and to indicate the severity of the condition. The Index evaluates overbite, overjet, mandibular protrusion, open bite and transverse discrepancies. Any malocclusion measuring over a total of 13 mm indicated an orthodontic handicap. The main downside to this index was that equal weights were given to each of the five measurements, and an open bite of 4 mm was given the same score as an overjet of 4 mm. Also, the measurements were not mutually exclusive, as a subject could not have an open bite and an overbite. The index also indicated that a subject with an end-to-end relationship (0 mm overbite and 0 mm overjet) had no occlusal handicap; whereas a subject with a more ideal 2 mm of overjet and 2 mm of overbite would be judged to have some tendency towards an occlusal handicap. The main use of the HDL index was for identifying serious handicapping occlusions and not as an index for assessing the degree of malocclusion.

The Orthodontic Treatment Priority Index (TPI) was developed in 1967 and added up six categories of occlusal features. It then calculated a final score to distinguish persons with normal occlusion from those with varying degrees of malocclusion (Grainger, 1967). The following occlusal features were measured: overjet, overbite and open bite, tooth displacement, first molar relationship, congenitally missing teeth, and posterior cross-bite. The greatest use of the TPI was for surveys of occlusion used by the United States Public Health Service that evaluated children and adolescents between 1963 and 1970.

In 1966, the World Health Organization (WHO) came up with a list of certain requirements that were considered necessary for an index of occlusion (WHO, 1966). The first was reliability. The index should be reproducible by other examiners or by the same examiner at some other point in time. The next requirement was the index needed validity and should measure what it was intended to measure. Lastly, validity over time needed to be addressed because the index should consider the normal development of occlusion.

A method by Eismann to evaluate the effectiveness of orthodontic treatment was devised based on fifteen morphological criteria (Eismann, 1974). Each subject was assigned points for each condition registered and the points were totaled to give a score that reflected the morphological problems. The higher the amount of points scored, the more severe the condition was thought to be. This method has been highly criticized for the subjective means for assigning points.

A system designed specifically to grade orthodontic results was published in 1975 (Gottlieb, 1975). Dr. Gottlieb took a standard group of tooth relationships that were generally accepted criteria for orthodontic correction. These included:

I) Class I molar relationship
II) Class I cuspid relationship
III) Cuspal interdigitation
IV) Overbite
V) Overjet
VI) Midline
VII) Rotation
VIII) Crowding or spacing
IX) Arch Form
X) Torque and parallelism

Dr. Gottlieb assigned a specific point system to use for grading the treatment results but made note that the ten categories do not cover all aspects of a comprehensive grading system. The points assigned were as follows:

| | | |
|---|---|---|
| I) | 5 points: | condition corrected |
| II) | 4 points: | condition almost corrected |
| III) | 3 points: | condition half corrected |
| IV) | 0 points: | condition not corrected |
| V) | -1 point: | condition worsened |

The assumption with the point grading system was that each characteristic was of equal importance. A percentage achievement was obtained which related to the factors requiring correction at the beginning of treatment. Gottlieb arrived at the following interpretation of his grading system:

| | | |
|---|---|---|
| I) | 85% or better corrected: | good result |
| II) | 75-85% corrected: | satisfactory result |
| III) | 65-75% corrected: | mediocre result |
| IV) | 55-65% corrected: | poor result |
| V) | <50% corrected: | unsatisfactory result |

This method has been criticized in the literature due to the point system allotting more points for improvement compared to only minimal reduction for worsening of the condition (Otuyami and Jones, 1995). Dr. Gottlieb was also surprised to find out some of his own cases, which he felt to be his most successful, scored less than satisfactory.

All the previous indices mentioned compared pre-treatment and post-treatment records to score the treatment change achieved and the overall outcome for the correction of the malocclusion. Unfortunately, many in the literature have challenged the reliability and validity of these indices. In a

paper written by Richmond and colleagues in 1992, they mention that none of the above indices has been universally accepted (Richmond et al., 1995).

PAR (Peer Assessment Rating) Index. Ten British orthodontists developed the PAR index over a series of six meetings in 1987. The purpose of the PAR index was to design an occlusal index that was reliable, valid and be utilized to record a malocclusion at any stage of treatment. Scores are given to various occlusal characteristics that make up the malocclusion and the individual scores are totaled. The final summation represents the degree a case deviates from perfect alignment and occlusion. Therefore, a score of zero would indicate perfect alignment and occlusion, while higher scores would indicate increasing levels of occlusal irregularities (Richmond et al., 1992). The PAR index can show improvement of a malocclusion in two different ways: (1) total point reduction in the PAR score and (2) the percentage reduction in the PAR score (Richmond et al., 1992). The PAR index is made up of the following eleven criteria:

I) Upper right segment
II) Upper anterior segment
III) Upper left segment
IV) Lower right segment
V) Lower anterior segment
VI) Lower left segment
VII) Right buccal occlusion
VIII) Overjet
IX) Overbite
X) Midline
XI) Left buccal occlusion.

The difference between the pre- and post-treatment scores is indicative of the success or degree of improvement in each case. A score of 10 or less

designates an acceptable alignment and occlusion and 5 or less suggests an almost ideal occlusion. Richmond went on to say that in terms of assessment of improvement, a case is considered to be improved when there is at least a 30 percent reduction in PAR score. Great improvement is accomplished with a decrease of 22 points or more in the PAR score. If there is not at least a 30 percent reduction in the PAR score, the case is considered to be worse or no different (Richmond et al., 1992).

The initial validation of the PAR index was completed by 74 British orthodontists for the five main components. The designers established a weighting system based on statistically sampled components of the index because certain components did not seem to possess any predictive power and therefore were eliminated from the weighted PAR Index. The weighted components resulted in a statistically higher correlation with the average deviation from a normal occlusion when compared to the unweighted PAR (Richmond et al., 1992). The following weighting system was proposed:

| | | |
|---|---|---|
| I) | Upper and lower anterior segments | x 1 |
| II) | Left and right buccal occlusions | x 1 |
| III) | Overjet | x 6 |
| IV) | Overbite | x 2 |
| V) | Midline | x 4 |

Validation of the PAR index in the United States was done in 1995 by a group of eleven practicing orthodontists. The study consisted of 200 sets of models representing all types of cases, which were evaluated for treatment difficulty and the severity of the malocclusion. Multiple regression techniques revealed that the panel placed more emphasis on certain features of the malocclusion. Overjet, overbite, midline discrepancy, upper anterior alignment,

and buccal segment relationships were all criticized more extensively. The study proclaimed that the lower anterior segment crowding did not have a predictive effect and was not weighted which was contradictive to the British study. The other differences in weightings were the overbite weighting was 3 (2 in the British study), the midline weighting was 3 (4 in the British study), the overjet weighting was 5 (6 in the British study), and the buccal segment relationship weighting was 2 (1 in the British study) (Deguzman et al., 1995).

Other studies have criticized the generic weighting of the PAR index, particularly with overbite and overjet (Fox, 1993; Kerr et al., 1993; Hamdan and Rock, 1999). It has been suggested that the increased weighting of overjet can overly influence the index to such an extent that it can be excessively sensitive in any malocclusion where overjet is decreased. A reduction from 9 mm to 3 mm of overjet will reduce the PAR score by 18 points, which is only 4 points from the greatly improved group. On the other hand, overbite scoring could be too low and the correction of a deep and traumatic overbite only reduces the PAR score minimally. The results from Hamdan's study might indicate a different weighting system should be used for each type of malocclusion (Hamdan and Rock, 1999).

American Board of Orthodontics (ABO) Objective Grading System (OGS). In 1994, the American Board of Orthodontics began a process to produce an objective method to evaluate candidates for the Phase III examination. Over the following five years, the ABO developed the OGS through a series of field tests. At the 1995 ABO Phase III examination, 100 cases were selected and evaluated by measuring fifteen criteria on every dental cast and panoramic radiograph. The evaluation revealed that 85% of the discrepancies in the final results

occurred in 7 of the 15 criteria which included alignment, marginal ridges, buccolingual inclination, overjet, occlusal relationships, occlusal contacts, and root angulations (Casko et al., 1998).

At the 1996 Phase III examination, the reliability and consistency was tested. The inadequacies in the same categories were seen, but the reliability of the examiners was questioned and a recommendation was made for a measuring device to be made to make the grading system more reliable (Casko et al., 1998).

In preparation for the 1997 exam, a measuring device was fabricated and all the examiners were calibrated prior to the examination. The results were similar to prior exams and the same seven problems were identified. Interproximal contacts were added to the scoring system as well as some slight modifications to the measuring device (Casko et al., 1998).

The 1998 exam was the fourth and final field test and proved to be very successful in establishing an objective scoring system to determine the success of completed orthodontic treatment. It was determined that a score below 20 is considered passing and a score above 30 is failing. Any score between 20 and 30 falls into a gray area and the quality of records, appropriateness of the treatment plan, objectives for positioning the maxilla, mandible, maxillary dentition, mandibular dentition, and facial profile are all considered (Casko et al.,1998). The current OGS has been used for the last 5 years for the Phase III portion of the ABO examination (James, 2002).

Recent literature (Lieber et al., 2003) has examined the reliability of the ABO's scoring index. Thirty-six post-treatment models were evaluated by four different orthodontists and measured using the ABO OGS at two separate

scoring sessions four weeks apart to determine intrajudge and interjudge reliability. A subset of the study was to determine the frequency of subtraction for different aspects of the scoring index. All four judges underwent a four-stage calibration process prior to the study. The results showed that both the intrajudge and interjudge reliability were surprisingly low with correlation values of $r = 0.77$ and $r = 0.85$ respectively. Even though the correlation values were low in this study, the authors still feel that the ABO Objective Grading System is a very powerful index if clinicians understand the reliability before using the scoring index.

## MATERIALS AND METHODS

Research Purpose. To determine the effectiveness of the Invisalign System by measuring pre- and post-treatment models using the American Board of Orthodontics (ABO) Objective Grading System (OGS) for dental casts.

Research Design. 135 subjects treated using the Invisalign appliance were identified in 8 different private practices in the Portland, Oregon and Salt Lake City, Utah metropolitan areas. Of the 135 subjects identified, 65 met the following criteria that were used in this study:

1- Case was treated with Invisalign exclusively.

2- Pre- and post-treatment models with appropriate wax bite registrations were available

3- No missing teeth (Exception was if patient had previous orthodontic treatment that required four bicuspid extraction.)

4- Panoramic radiographs were not used in this study due to the low number of final panoramic radiographs taken on these patients.

All together, 70 of the 135 subjects that were initially identified were either finished using appliances other than Invisalign aligners (brackets, spring aligners, etc., 33), had missing teeth other than four bicuspids from previous orthodontic treatment (12) or had poor or missing records (25). This left 65 patients that were included in this study. (See Figure 1)

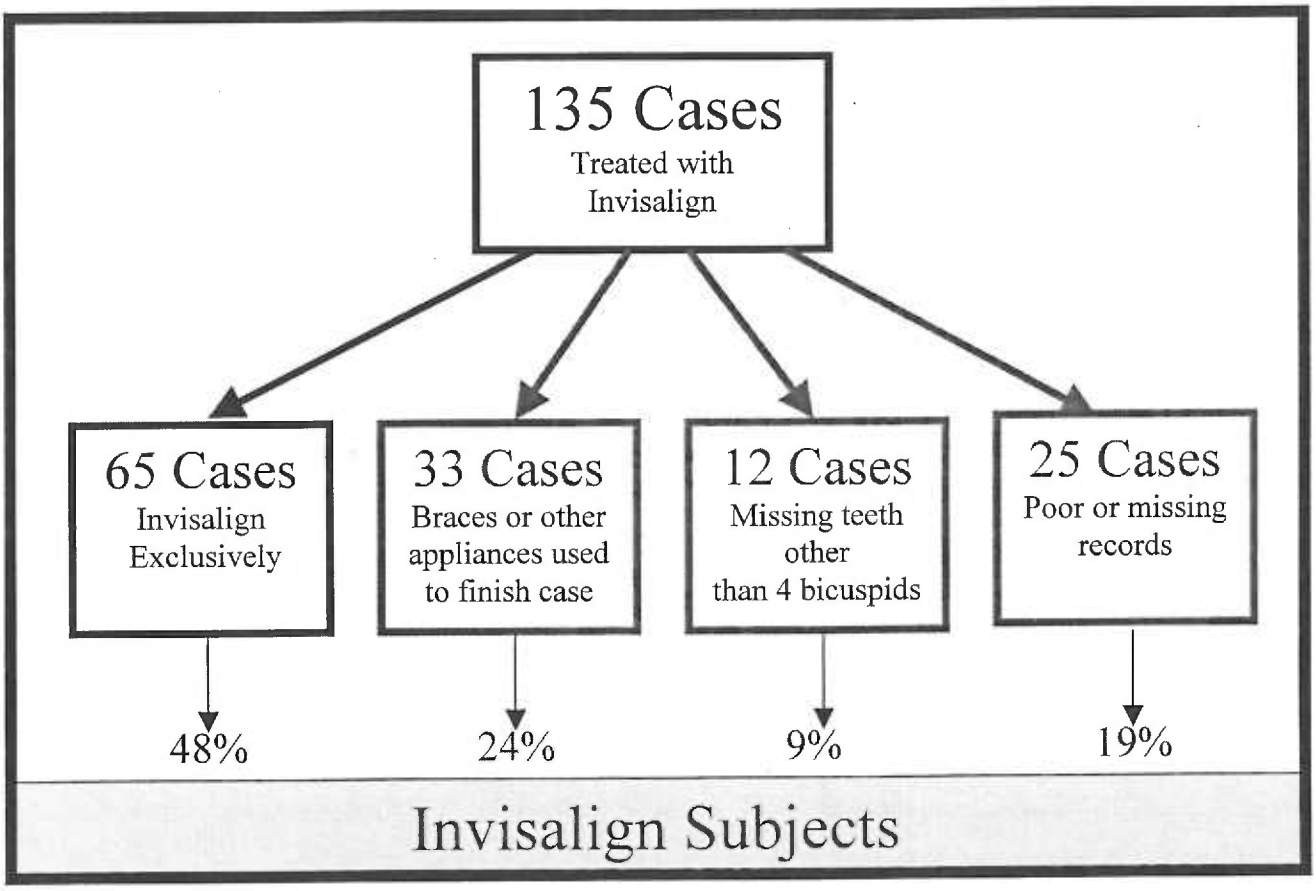


**Figure 1.** Distribution of the subject pool. 135 subjects were identified and of which 65 were treated exclusively with Invisalign, 33 used brace or other appliances, 12 had missing teeth, and 25 had poor or missing records.

PAR Index. Initially, the PAR index was considered for this study, but during the preliminary calibration period, the PAR was tested to evaluate the sensitivity of the measuring protocol. It was found that the PAR index did not evaluate small changes and discrepancies that are seen with the majority of Invisalign cases and was therefore not used in this study.

ABO OGS. Alignment, marginal ridges, buccolingual inclination, occlusal relationships, occlusal contacts, overjet, and interproximal contacts were all recorded for pre- and post-treatment cases. Panoramic radiographs were not used in this study due to the low number of post-treatment

radiographs. Alignment and overjet were split into anterior and posterior to evaluate any differences seen between the two areas. The following is a specific breakdown of the different categories and the point reductions used for discrepancies measured in each section. (Examples shown in Figure 2)

I. Alignment (Anterior and Posterior)

a. 0 - .5 mm = 0 pt
b. .5 - 1 mm = 1 pt
c. > 1 mm = 2 pt

II. Marginal Ridges

a. 0 - .5 mm = 0 pt
b. .5 – 1 mm = 1 pt
c. > 1 mm = 2 pt

III. Buccolingual Inclination

a. 0 – 1 mm = 0pt
b. 1 – 2 mm = 1pt
c. >2 mm = 2pt

IV. Occlusal Contact (Posterior functional cusps)

a. In contact = 0 pt
b. >0 – 1 mm = 1 pt
c. >1 mm = 2 pt

V. Occlusal Relationships (Class I canines & posterior interdigitation)

a. 0 – 1 mm = 0 pt
b. 1 – 2 mm = 1 pt
c. > 2 mm = 2 pt

VI. Overjet (Anterior and Posterior)

a. In contact = 0 pt
b. >0 – 1 mm = 1 pt
c. > 1 mm = 2 pt

VII. Interproximal Contacts

a. < .5 mm = 0 pt
b. .5 – 1 mm = 1 pt
c. > 1 mm = 2 pt

A specific ruler designed especially for the OGS was utilized to measure each case (Figure 3). All reductions were summed up to get a final OGS score.

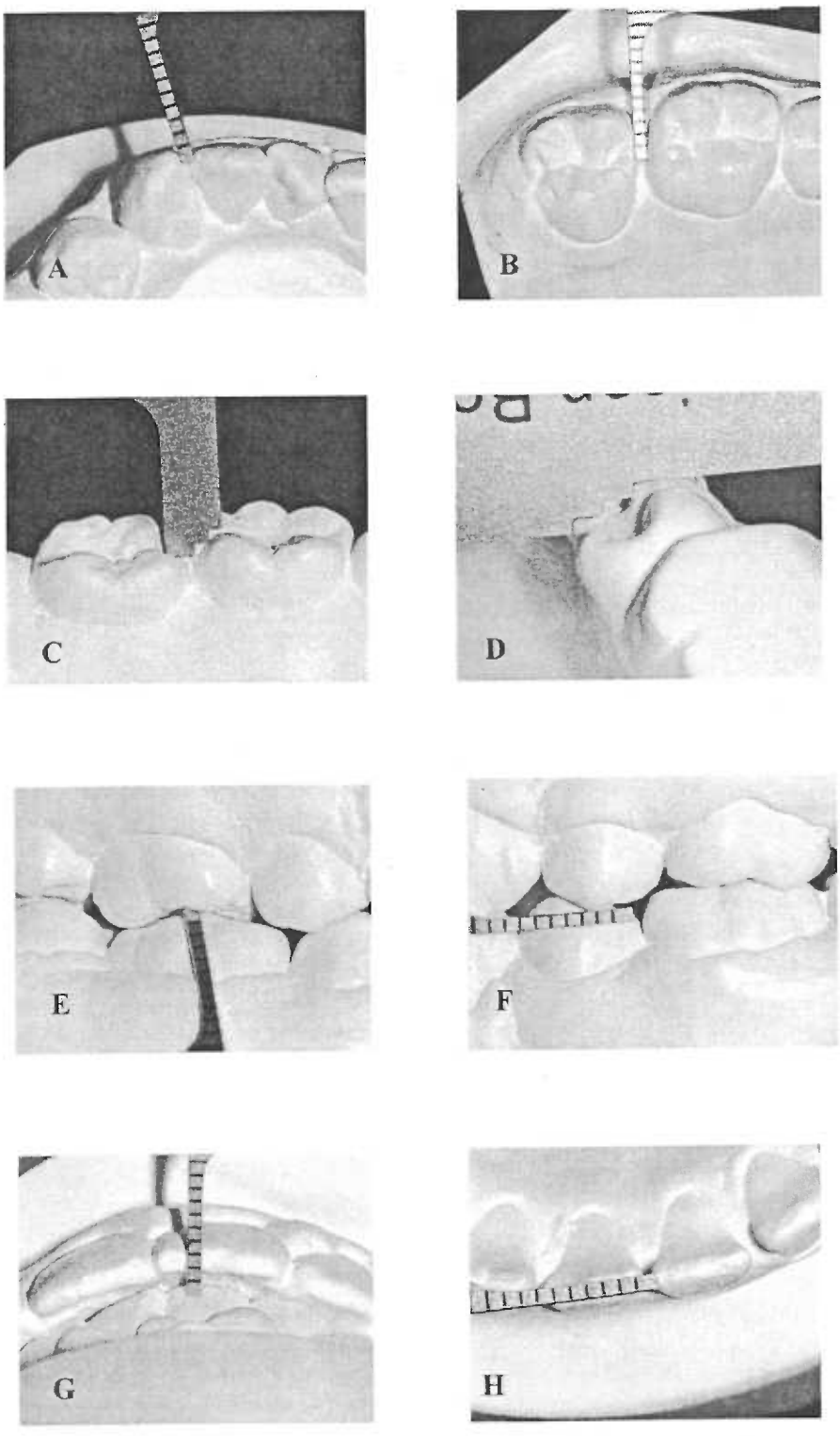


**Figure 2.** ABO OGS Grading Examples A. Anterior Alignment B. Posterior Alignment C. Marginal Ridges D. Buccolingual Inclination E. Occlusal Contacts F. Occlusal Relationships G. Overjet H. Interproximal Contacts.

The author made all OGS measurements for the entire study. Pre-treatment models were graded first and post-treatment models were scored second for each case.

The ABO has set 20 points or less to be passing, over 30 points to be failing and anything that falls in between is to be determined by the quality of the records, treatment planning and objectives of each case. This study used any case that scored 30 points or less as a passing score.

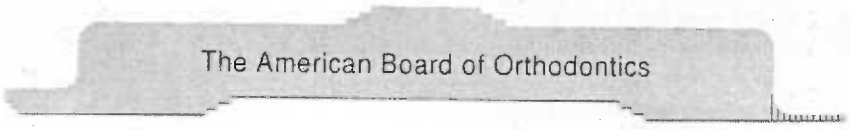


**Figure 3.** ABO measuring tool for dental casts

Error of the method. The error of method was calculated by analyzing the statistical difference between two measurements (ABO OGS) made 3 weeks apart on 10 randomly selected final study models. The error of the method was calculated using the equation:

$$S_x = \sqrt{\Sigma D^2/2N}$$

where D is the difference between duplicate measurements and N is the number of double measurements (Dahlberg, 1940). The author's error of method was calculated to be 1.56 and can be considered quite low. Spearman Rank Correlations were also calculated and the correlation coefficient ($r$) for intrajudge reliability was determined to be 0.951 (Table 1), which is considered highly reliable.

Correlations

| | | | Total OGS Score 1 | Total OGS Score 2 |
|---|---|---|---|---|
| Spearman's rho | Total OGS Score 1 | Correlation Coefficient | 1.000 | .951** |
| | | Sig. (2-tailed) | . | .000 |
| | | N | 10 | 10 |
| | Total OGS Score 2 | Correlation Coefficient | .951** | 1.000 |
| | | Sig. (2-tailed) | .000 | . |
| | | N | 10 | 10 |

**. Correlation is significant at the 0.01 level (2-tailed).

**Table 1-** Spearman Rank Correlations for intrajudge reliability

The author also used the ABO calibration models for further reliability and consistency. The calibration kit contains specific instructions to follow to make accurate readings and the specific areas to measure. The Directors of the American Board of Orthodontics have spent considerable time calibrating and grading the models that are included with the calibration kit so their results would be consistent and reliable. This information assisted the author in the calibration process giving the ability to compare the results with a "scoring key".

## STATISTICAL ANALYSIS

Statistics were calculated using SPSS version 11.5 windows based software. Descriptive statistics were calculated for (1) the entire sample, (2) the Angle Class I sample and (3) the ABO passing group. Paired t-tests were used to identify significant differences between the pre- and post-treatment groups. Wilcoxon Signed-Rank tests were also calculated to test non-normally distributed data. No differences were seen between the tests made by parametric (paired t-test) and non-parametric (Wilcoxon Signed-Rank test) procedures. Therefore, only results from the paired t-tests are reported. Paired t-tests were utilized to compare differences between pre- and post-treatment OGS scores for the three separate groups. The significance level was set at $p < 0.05$ for all tests and any p value less than this was considered to be statistically significant. Positive paired t-test values represented a reduction of OGS points from pre- to post-treatment while negative t-test values demonstrated an increase in OGS points from pre- to post-treatment.

## RESULTS

Entire Sample. Sixty-five cases qualified for this study from the 135 cases that were identified. Thirty-three cases (24%) required the use of additional appliances such as braces or active retainers to completely finish the treatment and were therefore not used in this study. The other 37 cases that were not used either had missing teeth or poor records. Individual case summaries and descriptive statistics for pre- and post-treatment scores for the 65 cases treated exclusively with the Invisalign appliance are shown in Tables 2-4. The average age of the sample was 31.1 years old and 80% (52/65) of the sample was female. The mean treatment time was 12.5 months with an average of 18 aligners for both the maxilla and mandible. The area that scored the most deductions in the pre-treatment analysis was alignment with the anterior segment receiving an average point deduction of 11.6 while the posterior segment received an average point deduction of 9.9. The area that scored the highest deductions on the post-treatment analysis was occlusal contacts with an average point deduction of 10.3. Overall, the average pre-treatment OGS score was 47.0 with a range from 14 to 85 and the average post-treatment OGS score was 36.4 with a range from 6 to 74 points lost.

Mean changes between pre- and post-treatment scores are listed with the paired t-test in Table 5. Statistically significant positive t-test values between pre- and post-treatment OGS scores were seen with anterior alignment, posterior alignment, total alignment, buccolingual inclination, anterior overjet,

**Descriptive Statistics for all Patients**

| | N | Range | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|---|
| Age | 65 | 49.00 | 12.00 | 61.00 | 31.1077 | 12.48640 |
| Treatment Duration | 65 | 21.00 | 6.00 | 27.00 | 12.5077 | 4.16129 |
| Number of Upper Aligners | 65 | 42.00 | 5.00 | 47.00 | 17.9231 | 7.33636 |
| Number of Lower Aligners | 65 | 34.00 | 6.00 | 40.00 | 17.6615 | 6.91528 |
| Valid N (listwise) | 65 | | | | | |

**Descriptive Statistics for all Patients**

| | N | Range | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|---|
| Pre-Treatment Anterior Alignment | 65 | 15.00 | 2.00 | 17.00 | 11.6000 | 3.86600 |
| Pre-Treatment Posterior Alignment | 65 | 22.00 | 1.00 | 23.00 | 9.9385 | 5.34695 |
| Pre-Treatment Total Alignment | 65 | 33.00 | 5.00 | 38.00 | 21.5385 | 7.01355 |
| Pre-Treatment Marginal Ridges | 65 | 11.00 | .00 | 11.00 | 3.3385 | 2.78544 |
| Pre-Treatment Buccolingual Inclination | 65 | 13.00 | .00 | 13.00 | 4.7538 | 2.82860 |
| Pre-Treatment Occlusal Contacts | 65 | 30.00 | .00 | 30.00 | 4.0462 | 5.52673 |
| Pre-Treatment Occlusal Relationships | 65 | 20.00 | .00 | 20.00 | 5.2462 | 6.44597 |
| Pre-Treatment Anterior Overjet | 65 | 12.00 | .00 | 12.00 | 5.7077 | 3.56512 |
| Pre-Treatment Posterior Overjet | 65 | 12.00 | .00 | 12.00 | 1.0615 | 2.12041 |
| Pre-Treatment Total Overjet | 65 | 16.00 | .00 | 16.00 | 6.7692 | 3.84370 |
| Pre-Treatment Interproximal Contacts | 65 | 25.00 | .00 | 25.00 | 1.3231 | 3.89354 |
| Pre-Treatment Total OGS Score | 65 | 71.00 | 14.00 | 85.00 | 47.0154 | 16.47203 |
| Post-Treatment Anterior Alignment | 65 | 7.00 | .00 | 7.00 | 1.5385 | 1.66843 |
| Post-Treatment Posterior Alignment | 65 | 23.00 | .00 | 23.00 | 5.4923 | 4.37722 |
| Post-Treatment Total Alignment | 65 | 26.00 | .00 | 26.00 | 7.0308 | 5.09893 |
| Post-Treatment Marginal Ridges | 65 | 9.00 | .00 | 9.00 | 3.1538 | 2.44458 |
| Post-Treatment Buccolingual Inclination | 65 | 11.00 | .00 | 11.00 | 4.1231 | 2.55262 |
| Post-Treatment Occlusal Contacts | 65 | 27.00 | .00 | 27.00 | 10.2615 | 6.37690 |
| Post-Treatment Occlusal Relationships | 65 | 20.00 | .00 | 20.00 | 5.4154 | 6.47324 |
| Post-Treatment Anterior Overjet | 65 | 12.00 | .00 | 12.00 | 4.8615 | 3.92459 |
| Post-Treatment Posterior Overjet | 65 | 10.00 | .00 | 10.00 | 1.5846 | 2.31768 |
| Post-Treatment Total Overjet | 65 | 18.00 | .00 | 18.00 | 6.4462 | 4.59630 |
| Post-Treatment Interproximal Contacts | 65 | 1.00 | .00 | 1.00 | .0308 | .17404 |
| Post-Treatment Total OGS Score | 65 | 68.00 | 6.00 | 74.00 | 36.4462 | 16.01077 |
| Valid N (listwise) | 65 | | | | | |

**Table 2a & b**- Descriptive statistics for the entire sample

**Pre-Treatment Case Summaries for all Patients** [a]

| | Patient Number | Pre-Treatment Total Alignment | Pre-Treatment Marginal Ridges | Pre-Treatment Buccolingual Inclination | Pre-Treatment Occlusal Contacts | Pre-Treatment Occlusal Relationships | Pre-Treatment Total Overjet | Pre-Treatment Interproximal Contacts | Pre-Treatment Total OGS Score |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 R | 18.00 | .00 | 12.00 | 7.00 | .00 | 4.00 | .00 | 41.00 |
| 2 | 2 R | 16.00 | 11.00 | 2.00 | 4.00 | 6.00 | 10.00 | 25.00 | 76.00 |
| 3 | 3 R | 23.00 | 8.00 | 5.00 | 7.00 | .00 | 7.00 | .00 | 50.00 |
| 4 | 4 R | 5.00 | 2.00 | 5.00 | .00 | 3.00 | .00 | 3.00 | 18.00 |
| 5 | 5 R | 10.00 | 4.00 | 5.00 | 1.00 | 8.00 | 4.00 | .00 | 32.00 |
| 6 | 6 R | 21.00 | 8.00 | 8.00 | 2.00 | 1.00 | 9.00 | 1.00 | 50.00 |
| 7 | 7 R | 23.00 | 3.00 | 1.00 | .00 | 6.00 | 9.00 | .00 | 42.00 |
| 8 | 8 R | 30.00 | 2.00 | .00 | 2.00 | 5.00 | 8.00 | .00 | 47.00 |
| 9 | 9 R | 19.00 | 6.00 | 2.00 | .00 | .00 | 7.00 | .00 | 34.00 |
| 10 | 10R | 30.00 | 5.00 | 6.00 | 5.00 | 20.00 | 12.00 | .00 | 78.00 |
| 11 | 11R | 26.00 | 6.00 | 6.00 | .00 | 20.00 | 10.00 | .00 | 68.00 |
| 12 | 12R | 25.00 | 9.00 | 8.00 | 8.00 | 8.00 | 7.00 | .00 | 65.00 |
| 13 | 13R | 23.00 | 2.00 | 6.00 | .00 | 20.00 | 12.00 | .00 | 63.00 |
| 14 | 14R | 22.00 | 3.00 | 5.00 | .00 | 5.00 | 4.00 | 10.00 | 49.00 |
| 15 | 15R | 26.00 | 3.00 | 7.00 | 1.00 | 10.00 | 11.00 | 1.00 | 59.00 |
| 16 | 16R | 29.00 | 5.00 | 5.00 | 3.00 | .00 | 4.00 | .00 | 46.00 |
| 17 | 17R | 27.00 | 2.00 | 11.00 | 6.00 | .00 | 3.00 | .00 | 49.00 |
| 18 | 18R | 38.00 | .00 | 1.00 | 30.00 | .00 | 16.00 | .00 | 85.00 |
| 19 | 19R | 22.00 | 3.00 | 1.00 | .00 | .00 | .00 | 4.00 | 30.00 |
| 20 | 20R | 17.00 | 4.00 | 5.00 | 5.00 | 2.00 | 4.00 | .00 | 37.00 |
| 21 | 21R | 34.00 | 6.00 | 4.00 | 2.00 | 5.00 | 5.00 | 4.00 | 60.00 |
| 22 | 22R | 34.00 | 2.00 | 7.00 | 2.00 | 1.00 | 10.00 | .00 | 56.00 |
| 23 | 23R | 12.00 | .00 | 5.00 | 17.00 | 3.00 | 12.00 | .00 | 49.00 |
| 24 | 24R | 30.00 | .00 | 5.00 | 1.00 | 3.00 | 6.00 | .00 | 45.00 |
| 25 | 25R | 25.00 | 8.00 | 6.00 | 8.00 | 12.00 | 7.00 | .00 | 66.00 |
| 26 | 26R | 27.00 | 9.00 | 7.00 | 20.00 | 8.00 | 11.00 | .00 | 82.00 |
| 27 | 27R | 18.00 | 1.00 | 8.00 | 1.00 | .00 | 5.00 | 3.00 | 36.00 |
| 28 | 28R | 28.00 | 1.00 | 1.00 | .00 | 6.00 | 2.00 | .00 | 37.00 |
| 29 | 1Rh | 16.00 | 6.00 | 5.00 | 13.00 | .00 | 5.00 | .00 | 45.00 |
| 30 | 2Rh | 11.00 | .00 | 3.00 | .00 | .00 | 7.00 | .00 | 21.00 |
| 31 | 3Rh | 21.00 | .00 | 1.00 | 3.00 | 2.00 | 3.00 | .00 | 30.00 |
| 32 | 4Rh | 19.00 | 7.00 | 5.00 | .00 | 18.00 | 12.00 | .00 | 61.00 |
| 33 | 5Rh | 18.00 | 5.00 | 8.00 | 2.00 | 20.00 | 12.00 | .00 | 65.00 |
| 34 | 6Rh | 19.00 | 1.00 | 4.00 | .00 | .00 | 6.00 | .00 | 30.00 |
| 35 | 7Rh | 9.00 | 3.00 | 5.00 | .00 | 2.00 | 6.00 | .00 | 25.00 |
| 36 | 8Rh | 20.00 | 4.00 | 4.00 | .00 | 3.00 | 9.00 | 2.00 | 42.00 |
| 37 | 9Rh | 26.00 | 3.00 | 4.00 | 2.00 | 2.00 | 13.00 | .00 | 50.00 |
| 38 | 10Rh | 13.00 | 2.00 | 4.00 | 1.00 | 5.00 | 10.00 | .00 | 35.00 |
| 39 | 11Rh | 22.00 | 1.00 | 1.00 | .00 | 7.00 | 1.00 | 1.00 | 33.00 |
| 40 | 1D | 25.00 | 4.00 | 3.00 | 4.00 | 6.00 | 4.00 | 4.00 | 50.00 |
| 41 | 2D | 26.00 | 2.00 | 7.00 | 9.00 | 5.00 | 8.00 | .00 | 57.00 |
| 42 | 1G | 23.00 | .00 | 4.00 | 4.00 | 16.00 | 12.00 | .00 | 59.00 |
| 43 | 2G | 29.00 | 1.00 | 1.00 | 2.00 | .00 | 5.00 | .00 | 38.00 |
| 44 | 3G | 21.00 | 5.00 | 2.00 | 4.00 | 10.00 | .00 | .00 | 42.00 |
| 45 | 4G | 13.00 | 1.00 | 2.00 | .00 | 2.00 | 3.00 | 2.00 | 23.00 |
| 46 | 5G | 21.00 | 3.00 | 1.00 | 5.00 | .00 | 6.00 | .00 | 36.00 |
| 47 | 6G | 31.00 | 5.00 | 3.00 | .00 | 20.00 | 12.00 | .00 | 71.00 |
| 48 | 1Y | 24.00 | 3.00 | 4.00 | 6.00 | 20.00 | 12.00 | .00 | 71.00 |
| 49 | 2Y | 26.00 | 1.00 | 8.00 | 9.00 | .00 | 5.00 | .00 | 49.00 |
| 50 | 3Y | 5.00 | 4.00 | 2.00 | 1.00 | .00 | 1.00 | 14.00 | 27.00 |
| 51 | 4Y | 20.00 | .00 | 2.00 | 5.00 | 11.00 | 9.00 | .00 | 47.00 |
| 52 | 5Y | 22.00 | 1.00 | 2.00 | 4.00 | 6.00 | 4.00 | .00 | 39.00 |
| 53 | 6Y | 17.00 | 2.00 | 6.00 | 2.00 | 2.00 | 6.00 | .00 | 35.00 |
| 54 | 7Y | 21.00 | 3.00 | 6.00 | 5.00 | .00 | 12.00 | .00 | 47.00 |
| 55 | 8Y | 29.00 | 2.00 | 5.00 | 4.00 | 18.00 | 5.00 | .00 | 63.00 |
| 56 | 1K | 20.00 | 2.00 | 4.00 | 4.00 | .00 | 10.00 | .00 | 40.00 |
| 57 | 2K | 27.00 | 7.00 | 6.00 | 8.00 | .00 | 5.00 | .00 | 53.00 |
| 58 | 3K | 20.00 | .00 | 2.00 | 3.00 | .00 | 4.00 | .00 | 29.00 |
| 59 | 4K | 31.00 | 10.00 | 13.00 | 19.00 | 3.00 | 7.00 | 1.00 | 84.00 |
| 60 | 5K | 20.00 | 3.00 | 7.00 | 3.00 | .00 | 2.00 | 2.00 | 37.00 |
| 61 | 6K | 13.00 | 3.00 | 11.00 | 1.00 | 1.00 | .00 | .00 | 29.00 |
| 62 | 7K | 10.00 | .00 | 3.00 | .00 | 3.00 | 9.00 | 9.00 | 34.00 |
| 63 | 8K | 9.00 | .00 | 4.00 | .00 | .00 | 1.00 | .00 | 14.00 |
| 64 | 1V | 22.00 | 5.00 | 5.00 | 6.00 | .00 | 7.00 | .00 | 46.00 |
| 65 | 1E | 23.00 | 4.00 | 8.00 | .00 | 6.00 | 8.00 | .00 | 49.00 |
| Total N | 65 | 65 | 65 | 65 | 65 | 65 | 65 | 65 | 65 |

a

**Table 3.** Pre-treatment case summaries for the entire sample

**Post-Treatment Case Summaries for all Patients** [a]

| | Patient Number | Post-Treatment Total Alignment | Post-Treatment Marginal Ridges | Post-Treatment Buccolingual Inclination | Post-Treatment Occlusal Contacts | Post-Treatment Occlusal Relationships | Post-Treatment Total Overjet | Post-Treatment Interproximal Contacts | Post-Treatment Total OGS Score |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 R | 6.00 | .00 | 11.00 | 7.00 | .00 | 4.00 | .00 | 26.00 |
| 2 | 2 R | 7.00 | 1.00 | 3.00 | 4.00 | 4.00 | 10.00 | 1.00 | 30.00 |
| 3 | 3 R | 8.00 | 6.00 | 4.00 | 7.00 | 2.00 | 2.00 | .00 | 29.00 |
| 4 | 4 R | 1.00 | 2.00 | 3.00 | 8.00 | 4.00 | 1.00 | .00 | 20.00 |
| 5 | 5 R | .00 | 5.00 | 6.00 | 4.00 | 6.00 | 6.00 | .00 | 29.00 |
| 6 | 6 R | 10.00 | 8.00 | 6.00 | 10.00 | 4.00 | 2.00 | .00 | 43.00 |
| 7 | 7 R | 6.00 | 4.00 | 1.00 | 7.00 | 5.00 | 5.00 | .00 | 28.00 |
| 8 | 8 R | 10.00 | 1.00 | 2.00 | 14.00 | 3.00 | 9.00 | .00 | 33.00 |
| 9 | 9 R | 3.00 | 3.00 | 2.00 | 4.00 | .00 | 5.00 | .00 | 17.00 |
| 10 | 10R | 14.00 | 5.00 | 7.00 | 10.00 | 20.00 | 12.00 | .00 | 68.00 |
| 11 | 11R | 7.00 | 7.00 | 7.00 | 4.00 | 20.00 | 12.00 | .00 | 57.00 |
| 12 | 12R | 6.00 | 6.00 | 7.00 | 17.00 | 5.00 | 8.00 | .00 | 49.00 |
| 13 | 13R | 8.00 | 2.00 | 5.00 | 12.00 | 20.00 | 12.00 | .00 | 59.00 |
| 14 | 14R | 7.00 | 4.00 | 4.00 | 5.00 | 11.00 | 4.00 | .00 | 35.00 |
| 15 | 15R | 11.00 | 4.00 | 3.00 | 8.00 | 10.00 | 17.00 | .00 | 53.00 |
| 16 | 16R | 8.00 | 4.00 | 4.00 | 21.00 | .00 | 8.00 | .00 | 45.00 |
| 17 | 17R | 9.00 | 2.00 | 10.00 | 13.00 | .00 | 2.00 | .00 | 36.00 |
| 18 | 18R | 26.00 | 2.00 | 3.00 | 27.00 | .00 | 16.00 | .00 | 74.00 |
| 19 | 19R | 4.00 | 3.00 | 1.00 | 6.00 | .00 | 5.00 | .00 | 19.00 |
| 20 | 20R | 2.00 | 4.00 | 5.00 | 14.00 | 2.00 | 1.00 | .00 | 28.00 |
| 21 | 21R | 5.00 | 7.00 | 6.00 | 19.00 | .00 | 4.00 | .00 | 41.00 |
| 22 | 22R | 16.00 | 3.00 | 6.00 | 3.00 | 1.00 | 7.00 | .00 | 36.00 |
| 23 | 23R | 1.00 | .00 | 4.00 | 16.00 | 3.00 | 10.00 | .00 | 34.00 |
| 24 | 24R | 7.00 | .00 | 5.00 | 17.00 | .00 | 3.00 | .00 | 32.00 |
| 25 | 25R | 4.00 | 9.00 | 5.00 | 12.00 | 6.00 | 6.00 | .00 | 42.00 |
| 26 | 26R | 10.00 | 7.00 | 5.00 | 19.00 | 2.00 | 1.00 | .00 | 44.00 |
| 27 | 27R | 6.00 | 1.00 | 9.00 | 2.00 | .00 | .00 | .00 | 18.00 |
| 28 | 28R | 10.00 | 2.00 | 1.00 | 9.00 | 4.00 | 16.00 | .00 | 42.00 |
| 29 | 1Rh | 4.00 | 6.00 | 3.00 | 11.00 | 1.00 | 5.00 | .00 | 30.00 |
| 30 | 2Rh | .00 | .00 | 3.00 | 11.00 | .00 | 5.00 | .00 | 19.00 |
| 31 | 3Rh | 1.00 | .00 | 1.00 | 11.00 | 2.00 | 2.00 | .00 | 17.00 |
| 32 | 4Rh | 6.00 | 7.00 | 3.00 | 5.00 | 20.00 | 16.00 | .00 | 59.00 |
| 33 | 5Rh | 8.00 | 5.00 | 8.00 | 19.00 | 20.00 | 12.00 | .00 | 72.00 |
| 34 | 6Rh | 4.00 | 1.00 | 2.00 | .00 | 2.00 | 5.00 | .00 | 14.00 |
| 35 | 7Rh | 4.00 | 3.00 | 5.00 | 2.00 | 5.00 | 2.00 | .00 | 21.00 |
| 36 | 8Rh | 3.00 | 3.00 | 1.00 | 3.00 | 6.00 | 11.00 | .00 | 27.00 |
| 37 | 9Rh | 6.00 | 1.00 | 4.00 | 8.00 | 7.00 | 15.00 | .00 | 41.00 |
| 38 | 10Rh | 9.00 | 1.00 | 3.00 | 8.00 | 5.00 | 7.00 | .00 | 33.00 |
| 39 | 11Rh | 8.00 | 3.00 | 1.00 | 2.00 | 7.00 | 2.00 | .00 | 23.00 |
| 40 | 1D | 9.00 | 5.00 | 3.00 | 14.00 | 7.00 | 8.00 | .00 | 46.00 |
| 41 | 2D | 7.00 | 4.00 | 7.00 | 22.00 | 5.00 | 2.00 | .00 | 47.00 |
| 42 | 1G | 5.00 | .00 | 4.00 | 15.00 | 16.00 | 12.00 | .00 | 52.00 |
| 43 | 2G | 11.00 | 1.00 | 1.00 | 8.00 | .00 | 2.00 | .00 | 23.00 |
| 44 | 3G | 11.00 | 5.00 | 2.00 | 12.00 | 8.00 | 7.00 | .00 | 45.00 |
| 45 | 4G | 4.00 | 1.00 | 3.00 | 2.00 | 2.00 | 7.00 | .00 | 19.00 |
| 46 | 5G | 4.00 | 3.00 | 1.00 | 3.00 | .00 | 6.00 | .00 | 17.00 |
| 47 | 6G | 14.00 | 4.00 | 3.00 | 3.00 | 20.00 | 12.00 | .00 | 56.00 |
| 48 | 1Y | 9.00 | 3.00 | 1.00 | 17.00 | 20.00 | 12.00 | .00 | 62.00 |
| 49 | 2Y | 7.00 | 3.00 | 3.00 | 26.00 | 2.00 | 5.00 | .00 | 46.00 |
| 50 | 3Y | 2.00 | 4.00 | 3.00 | 8.00 | .00 | 5.00 | 1.00 | 23.00 |
| 51 | 4Y | 7.00 | .00 | .00 | 8.00 | 11.00 | 7.00 | .00 | 33.00 |
| 52 | 5Y | 5.00 | .00 | 2.00 | 12.00 | 5.00 | 2.00 | .00 | 26.00 |
| 53 | 6Y | 3.00 | 1.00 | 3.00 | 12.00 | 8.00 | 5.00 | .00 | 32.00 |
| 54 | 7Y | 7.00 | 9.00 | 4.00 | 17.00 | .00 | 12.00 | .00 | 49.00 |
| 55 | 8Y | 12.00 | 4.00 | 5.00 | 15.00 | 20.00 | 10.00 | .00 | 66.00 |
| 56 | 1K | 13.00 | 2.00 | 4.00 | 10.00 | .00 | 9.00 | .00 | 38.00 |
| 57 | 2K | 14.00 | 5.00 | 7.00 | 7.00 | 3.00 | 5.00 | .00 | 41.00 |
| 58 | 3K | 3.00 | .00 | 1.00 | 4.00 | 1.00 | 5.00 | .00 | 14.00 |
| 59 | 4K | 26.00 | 8.00 | 10.00 | 20.00 | 1.00 | 3.00 | .00 | 69.00 |
| 60 | 5K | .00 | 3.00 | 7.00 | 21.00 | .00 | .00 | .00 | 31.00 |
| 61 | 6K | 5.00 | 2.00 | 9.00 | 10.00 | 2.00 | 3.00 | .00 | 31.00 |
| 62 | 7K | 2.00 | 1.00 | 1.00 | 8.00 | 3.00 | .00 | .00 | 15.00 |
| 63 | 8K | .00 | .00 | 4.00 | 2.00 | .00 | .00 | .00 | 6.00 |
| 64 | 1V | 3.00 | 3.00 | 5.00 | 8.00 | .00 | 3.00 | .00 | 22.00 |
| 65 | 1E | 9.00 | 2.00 | 6.00 | 4.00 | 11.00 | 5.00 | .00 | 37.00 |
| Total N | 65 | 65 | 65 | 65 | 65 | 65 | 65 | 65 | 65 |

a.

**Table 4.** Post-treatment case summaries for the entire sample

interproximal contacts, and total OGS score. Statistically significant negative t-test values between pre- and post-treatment OGS scores were seen with occlusal contacts and posterior overjet. No statistically significant t-test values were seen in marginal ridges, occlusal relationships, and total overjet.

The largest mean change was seen in alignment, which had a mean positive change of 14.5 points with 10.1 points coming from anterior alignment change, and 4.4 points from posterior alignment change. All three categories (anterior, posterior and overall) of alignment had statistically significant positive changes from pre- to post-treatment with a significance level of $p < .005$.

Buccolingual inclination showed a statistically significant difference, but the mean change was only a reduction of 0.63 points. This amount of change between pre- and post-treatment in the OGS score may not be clinically significant.

Anterior overjet was similar to buccolingual inclination with a small decrease in mean score but a statistically significant change. With the sensitivity of the OGS, a 0.85 point change in this category may not be clinically significant.

Interproximal contacts also showed a statistically significant change from pre- to post-treatment with an average reduction of 1.3 points. Looking only at the 16 cases exhibiting deductions in pre-treatment interproximal contacts, the total deduction for these cases was 86 points with a mean average of a 5.4 point deduction. The post-treatment deductions for interproximal contacts with the same 16 cases had a total of 2 points with a mean average of 0.125 points, which proved to be statistically significant as well.

The overall OGS treatment change from pre-treatment to post-treatment was significant at a level of $p < 0.001$, with an overall positive mean change of 10.6 points. Alignment change contributed a reduction of 14.5 points to the total OGS score and therefore between the rest of the categories there was a negative overall change of 3.9 points in the OGS score. Therefore, the change in alignment accounted for 62% of the total change and 85% of the total positive change in the OGS score. (See Figures 4-7)

**Paired Samples Test for all Patients**

| | | Paired Differences | | | | | t | df | Sig. (2-tailed) |
|---|---|---|---|---|---|---|---|---|---|
| | | Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference Lower | Upper | | | |
| Pair 1 | Pre-Treatment Anterior Alignment - Post-Treatment Anterior Alignment | 10.06154 | 3.63953 | .45143 | 9.15971 | 10.96337 | 22.288 | 64 | .000 |
| Pair 2 | Pre-Treatment Posterior Alignment - Post-Treatment Posterior Alignment | 4.44615 | 3.29787 | .40905 | 3.62898 | 5.26333 | 10.869 | 64 | .000 |
| Pair 3 | Pre-Treatment Total Alignment - Post-Treatment Total Alignment | 14.50769 | 5.02532 | .62331 | 13.26248 | 15.75291 | 23.275 | 64 | .000 |
| Pair 4 | Pre-Treatment Marginal Ridges - Post-Treatment Marginal Ridges | .18462 | 1.86993 | .23194 | -.27873 | .64796 | .796 | 64 | .429 |
| Pair 5 | Pre-Treatment Buccolingual Inclination - Post-Treatment Buccolingual Inclination | .63077 | 1.40945 | .17482 | .28153 | .98001 | 3.608 | 64 | .001 |
| Pair 6 | Pre-Treatment Occlusal Contacts - Post-Treatment Occlusal Contacts | -6.21538 | 5.33412 | .66162 | -7.53712 | -4.89365 | -9.394 | 64 | .000 |
| Pair 7 | Pre-Treatment Occlusal Relationships - Post-Treatment Occlusal Relationships | -.16923 | 2.27465 | .28214 | -.73286 | .39440 | -.600 | 64 | .551 |
| Pair 8 | Pre-Treatment Anterior Overjet - Post-Treatment Anterior Overjet | .84615 | 3.12365 | .38744 | .07215 | 1.62016 | 2.184 | 64 | .033 |
| Pair 9 | Pre-Treatment Posterior Overjet - Post-Treatment Posterior Overjet | -.52308 | 2.03951 | .25297 | -1.02844 | -.01771 | -2.068 | 64 | .043 |
| Pair 10 | Pre-Treatment Total Overjet - Post-Treatment Total Overjet | .32308 | 3.79188 | .47033 | -.61651 | 1.26266 | .687 | 64 | .495 |
| Pair 11 | Pre-Treatment Interproximal Contacts - Post-Treatment Interproximal Contacts | 1.29231 | 3.74885 | .46499 | .36339 | 2.22123 | 2.779 | 64 | .007 |
| Pair 12 | Pre-Treatment Total OGS Score - Post-Treatment Total OGS Score | 10.56923 | 9.19913 | 1.14101 | 8.28980 | 12.84866 | 9.263 | 64 | .000 |

**Table 5.** Paired t-tests for the entire sample

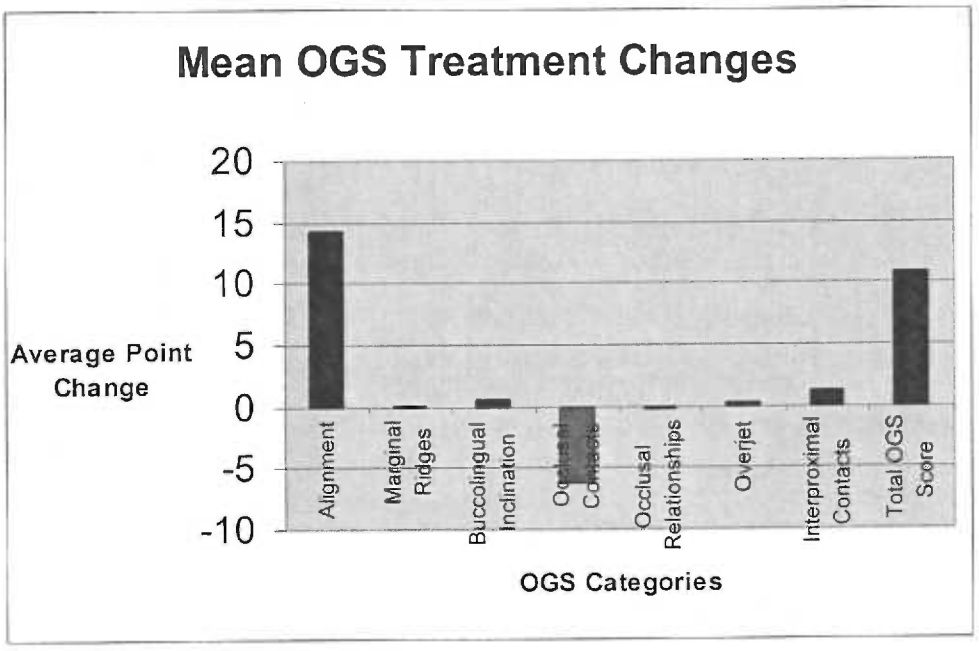


**Figure 4** Mean OGS Point Changes from Pre to Post Treatment. Alignment 14.5 points, Marginal Ridges 0.19 points, Buccolingual Inclination 0.63 points, Occlusal Contacts –6.2 points, Occlusal Relationships –0.17 points, Overjet 0.32 points, Total OGS score 10.6 points.

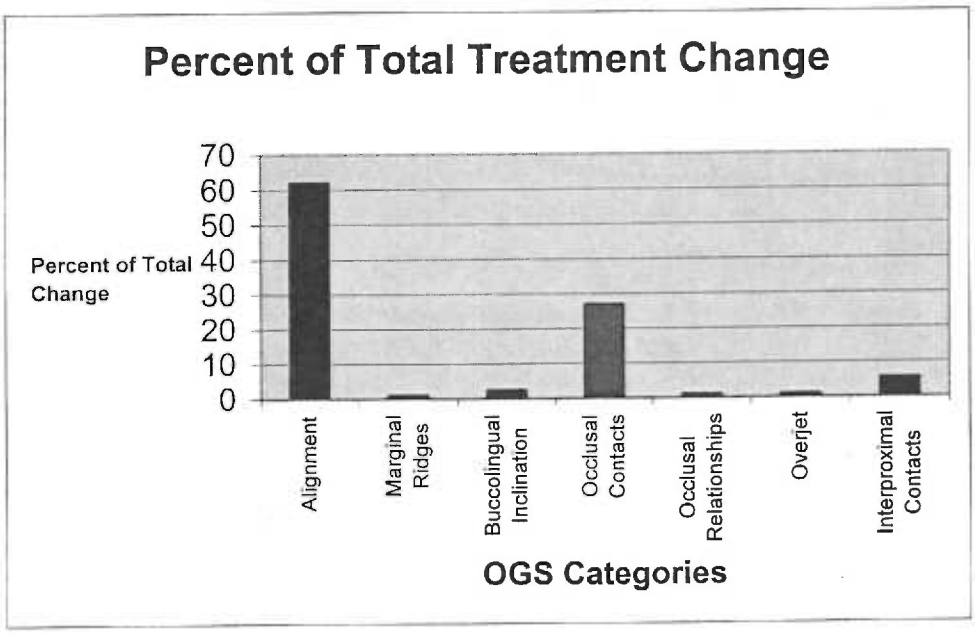


**Figure 5.** Percentage of Total Treatment Change. Alignment 62%, Marginal Ridges 1%, Buccolingual Inclination 2.5%, Occlusal Contacts 27%, Occlusal Relationships 1%, Overjet 1%, Interproximal Contacts 5.5%

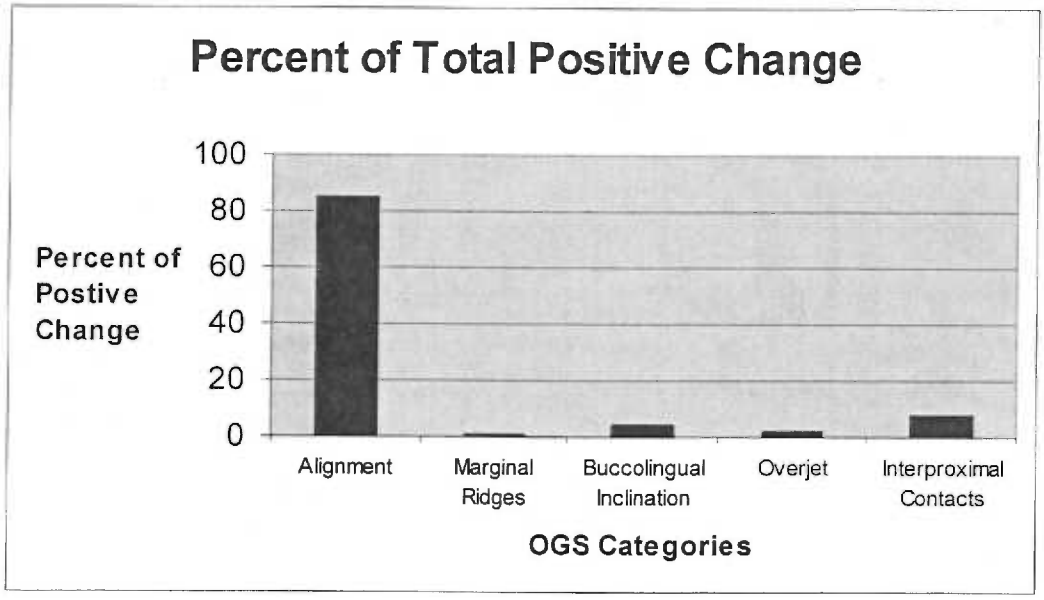


**Figure 6.** Percent of Total Positive Change. Alignment 85%, Marginal Ridges 1%, Buccolingual Inclination 4%, Overjet 2%, Interproximal Contacts 8%.

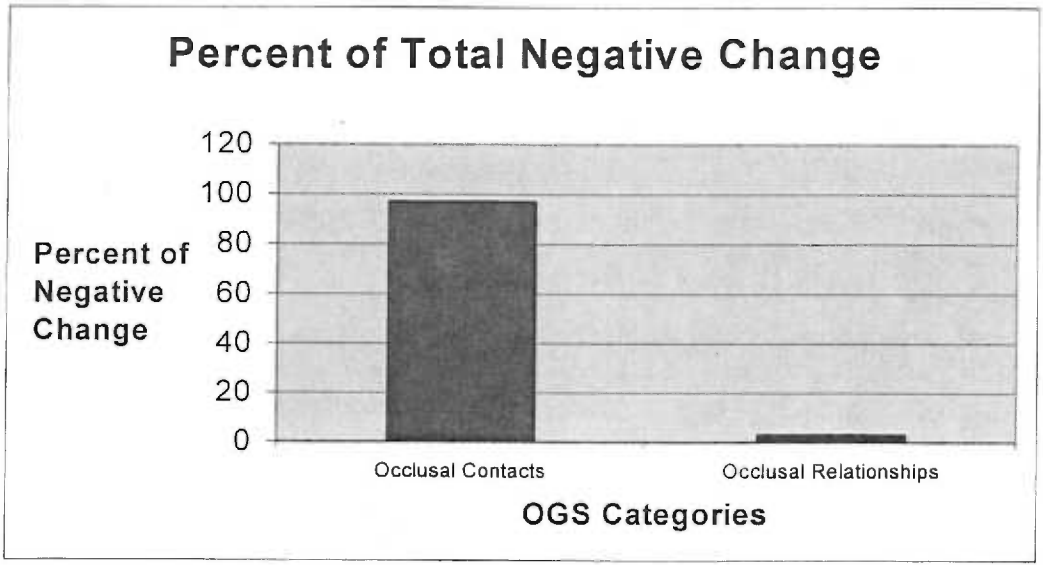


**Figure 7.** Percent of Total Negative Change. Occlusal Contacts 97%, Occlusal Relationships 3%.

The most significant treatment change in a negative direction was seen in the occlusal contact category. The mean negative change in the OGS score for this section was 6.2 points, which is 27% of the total change between pre- and post-treatment and 97% of the total negative change (Figures 4-7). Only 1 case (Subject #34) had a post-treatment score with no deductions in occlusal contacts, but this case also had no deductions to begin with. Seventeen other cases began with no deductions in occlusal contacts, but all of these cases had point deductions made from pre- to post-treatment in this category. Thus, all cases except for one had some form of posterior open bite or occlusal contact deficiency after completing Invisalign treatment.

The second statistically significant negative change identified was in posterior overjet. The mean negative treatment change was an increase of 0.52 points with a significance level of $p < 0.05$. Once again, even though this change was in a negative direction, it may not be clinically significant due to the small amount of total change.

The last three categories showed no significant change from pre- to post-treatment. They were marginal ridges, occlusal relationships and total overjet. The mean change in the marginal ridge category was slightly positive with positive change of 0.18 points. Each case was random in this section with some cases exhibiting improvement, some getting worse and some staying the same. Occlusal relationships were similar to marginal ridge changes in that some improved, some got worse and some stayed the same. The mean change was slightly negative with an average increase in OGS score of 0.17 points. The last category that showed no significant difference was total overjet with a positive mean change of 0.32 points. With the anterior component of overjet

having a slightly positive significant change and the posterior component having a slightly negative significant change, it is evident that the total overjet change was insignificant.

Class I Patients. Forty-three of the 65 patients had a Class I malocclusion before beginning treatment with Invisalign. Case summaries and descriptive statistics for these patients are shown in Tables 6-8. The mean treatment time for these patients was 11.3 months, which was 1.2 months less than the entire sample. The mean pre-treatment OGS score for the Class I patients was 41.5 points which was 5.5 points less than the total sample and the mean post-treatment OGS score was 30.9 points which is also 5.5 points less than the entire sample.

**Descriptive Statistics for Class I Patients**

| | N | Range | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|---|
| Age | 43 | 48.00 | 13.00 | 61.00 | 31.3023 | 12.87030 |
| Treatment Duration | 43 | 12.00 | 6.00 | 18.00 | 11.2558 | 3.33162 |
| Number of Upper Aligners | 43 | 22.00 | 5.00 | 27.00 | 16.7442 | 5.17362 |
| Number of Lower Aligners | 43 | 25.00 | 6.00 | 31.00 | 17.1163 | 5.69966 |
| Valid N (listwise) | 43 | | | | | |

**Table 6a.** Descriptive statistics for the Class I sample

Paired t-tests were performed to identify any differences with the Class I group from pre- to post-treatment (Table 9). The major difference was seen in occlusal relationships, which had a statistically significant negative change. The mean negative increase in OGS score was 0.72 points, which was significant at $p < 0.05$. Once again, even though this figure is statistically significant, it may not be clinically significant. The fact that this category had a negative change indicates that the Invisalign appliance may not improve and possibly worsens the occlusal relationships.

**Descriptive Statistics for Class I Patients**

| | N | Range | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|---|
| Pre-Treatment Anterior Alignment | 43 | 14.00 | 3.00 | 17.00 | 11.2326 | 3.86583 |
| Pre-Treatment Posterior Alignment | 43 | 22.00 | 1.00 | 23.00 | 9.5349 | 5.86900 |
| Pre-Treatment Total Alignment | 43 | 33.00 | 5.00 | 38.00 | 20.7674 | 7.59962 |
| Pre-Treatment Marginal Ridges | 43 | 10.00 | .00 | 10.00 | 2.8140 | 2.54723 |
| Pre-Treatment Buccolingual Inclination | 43 | 12.00 | 1.00 | 13.00 | 4.9535 | 3.06247 |
| Pre-Treatment Occlusal Contacts | 43 | 30.00 | .00 | 30.00 | 4.3256 | 5.97104 |
| Pre-Treatment Occlusal Relationships | 43 | 7.00 | .00 | 7.00 | 1.6279 | 2.12719 |
| Pre-Treatment Anterior Overjet | 43 | 12.00 | .00 | 12.00 | 4.5814 | 2.83038 |
| Pre-Treatment Posterior Overjet | 43 | 12.00 | .00 | 12.00 | 1.0930 | 2.27632 |
| Pre-Treatment Total Overjet | 43 | 16.00 | .00 | 16.00 | 5.6744 | 3.58383 |
| Pre-Treatment Interproximal Contacts | 43 | 14.00 | .00 | 14.00 | 1.3488 | 2.99113 |
| Pre-Treatment Total OGS Score | 43 | 71.00 | 14.00 | 85.00 | 41.5116 | 14.55756 |
| Post-Treatment Anterior Alignment | 43 | 6.00 | .00 | 6.00 | 1.4651 | 1.50157 |
| Post-Treatment Posterior Alignment | 43 | 23.00 | .00 | 23.00 | 5.0465 | 4.87439 |
| Post-Treatment Total Alignment | 43 | 26.00 | .00 | 26.00 | 6.5116 | 5.73366 |
| Post-Treatment Marginal Ridges | 43 | 9.00 | .00 | 9.00 | 2.7907 | 2.37605 |
| Post-Treatment Buccolingual Inclination | 43 | 10.00 | 1.00 | 11.00 | 4.3256 | 2.66119 |
| Post-Treatment Occlusal Contacts | 43 | 27.00 | .00 | 27.00 | 10.2791 | 6.92245 |
| Post-Treatment Occlusal Relationships | 43 | 11.00 | .00 | 11.00 | 2.3488 | 3.01491 |
| Post-Treatment Anterior Overjet | 43 | 12.00 | .00 | 12.00 | 3.2093 | 2.85822 |
| Post-Treatment Posterior Overjet | 43 | 9.00 | .00 | 9.00 | 1.3721 | 2.02394 |
| Post-Treatment Total Overjet | 43 | 16.00 | .00 | 16.00 | 4.5814 | 3.65951 |
| Post-Treatment Interproximal Contacts | 43 | 1.00 | .00 | 1.00 | .0233 | .15250 |
| Post-Treatment Total OGS Score | 43 | 68.00 | 6.00 | 74.00 | 30.9302 | 14.08376 |
| Valid N (listwise) | 43 | | | | | |

**Table 6b.** Descriptive statistics for the Class I sample

Pre-Treatment Case Summaries for Class I Patients [a]

| | Patient Number | Pre-Treatment Total Alignment | Pre-Treatment Marginal Ridges | Pre-Treatment Buccolingual Inclination | Pre-Treatment Occlusal Contacts | Pre-Treatment Occlusal Relationships | Pre-Treatment Total Overjet | Pre-Treatment Interproximal Contacts | Pre-Treatment Total OGS Score |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 R | 18.00 | .00 | 12.00 | 7.00 | .00 | 4.00 | .00 | 41.00 |
| 2 | 3 R | 23.00 | 8.00 | 5.00 | 7.00 | .00 | 7.00 | .00 | 50.00 |
| 3 | 4 R | 5.00 | 2.00 | 5.00 | .00 | 3.00 | .00 | 3.00 | 18.00 |
| 4 | 6 R | 21.00 | 8.00 | 8.00 | 2.00 | 1.00 | 9.00 | 1.00 | 50.00 |
| 5 | 9 R | 19.00 | 6.00 | 2.00 | .00 | .00 | 7.00 | .00 | 34.00 |
| 6 | 14R | 22.00 | 3.00 | 5.00 | .00 | 5.00 | 4.00 | 10.00 | 49.00 |
| 7 | 16R | 29.00 | 5.00 | 5.00 | 3.00 | .00 | 4.00 | .00 | 46.00 |
| 8 | 17R | 27.00 | 2.00 | 11.00 | 6.00 | .00 | 3.00 | .00 | 49.00 |
| 9 | 18R | 38.00 | .00 | 1.00 | 30.00 | .00 | 16.00 | .00 | 85.00 |
| 10 | 19R | 22.00 | 3.00 | 1.00 | .00 | .00 | .00 | 4.00 | 30.00 |
| 11 | 20R | 17.00 | 4.00 | 5.00 | 5.00 | 2.00 | 4.00 | .00 | 37.00 |
| 12 | 21R | 34.00 | 6.00 | 4.00 | 2.00 | 5.00 | 5.00 | 4.00 | 60.00 |
| 13 | 22R | 34.00 | 2.00 | 7.00 | 2.00 | 1.00 | 10.00 | .00 | 56.00 |
| 14 | 23R | 12.00 | .00 | 5.00 | 17.00 | 3.00 | 12.00 | .00 | 49.00 |
| 15 | 24R | 30.00 | .00 | 5.00 | 1.00 | 3.00 | 6.00 | .00 | 45.00 |
| 16 | 27R | 18.00 | 1.00 | 8.00 | 1.00 | .00 | 5.00 | 3.00 | 36.00 |
| 17 | 1Rh | 16.00 | 6.00 | 5.00 | 13.00 | .00 | 5.00 | .00 | 45.00 |
| 18 | 2Rh | 11.00 | .00 | 3.00 | .00 | .00 | 7.00 | .00 | 21.00 |
| 19 | 3Rh | 21.00 | .00 | 1.00 | 3.00 | 2.00 | 3.00 | .00 | 30.00 |
| 20 | 6Rh | 19.00 | 1.00 | 4.00 | .00 | .00 | 6.00 | .00 | 30.00 |
| 21 | 7Rh | 9.00 | 3.00 | 5.00 | .00 | 2.00 | 6.00 | .00 | 25.00 |
| 22 | 9Rh | 26.00 | 3.00 | 4.00 | 2.00 | 2.00 | 13.00 | .00 | 50.00 |
| 23 | 11Rh | 22.00 | 1.00 | 1.00 | .00 | 7.00 | 1.00 | 1.00 | 33.00 |
| 24 | 1D | 25.00 | 4.00 | 3.00 | 4.00 | 6.00 | 4.00 | 4.00 | 50.00 |
| 25 | 2D | 26.00 | 2.00 | 7.00 | 9.00 | 5.00 | 8.00 | .00 | 57.00 |
| 26 | 2G | 29.00 | 1.00 | 1.00 | 2.00 | .00 | 5.00 | .00 | 38.00 |
| 27 | 4G | 13.00 | 1.00 | 2.00 | .00 | 2.00 | 3.00 | 2.00 | 23.00 |
| 28 | 5G | 21.00 | 3.00 | 1.00 | 5.00 | .00 | 6.00 | .00 | 36.00 |
| 29 | 2Y | 26.00 | 1.00 | 8.00 | 9.00 | .00 | 5.00 | .00 | 49.00 |
| 30 | 3Y | 5.00 | 4.00 | 2.00 | 1.00 | .00 | 1.00 | 14.00 | 27.00 |
| 31 | 5Y | 22.00 | 1.00 | 2.00 | 4.00 | 6.00 | 4.00 | .00 | 39.00 |
| 32 | 6Y | 17.00 | 2.00 | 6.00 | 2.00 | 2.00 | 6.00 | .00 | 35.00 |
| 33 | 7Y | 21.00 | 3.00 | 6.00 | 5.00 | .00 | 12.00 | .00 | 47.00 |
| 34 | 1K | 20.00 | 2.00 | 4.00 | 4.00 | .00 | 10.00 | .00 | 40.00 |
| 35 | 2K | 27.00 | 7.00 | 6.00 | 8.00 | .00 | 5.00 | .00 | 53.00 |
| 36 | 3K | 20.00 | .00 | 2.00 | 3.00 | .00 | 4.00 | .00 | 29.00 |
| 37 | 4K | 31.00 | 10.00 | 13.00 | 19.00 | 3.00 | 7.00 | 1.00 | 84.00 |
| 38 | 5K | 20.00 | 3.00 | 7.00 | 3.00 | .00 | 2.00 | 2.00 | 37.00 |
| 39 | 6K | 13.00 | 3.00 | 11.00 | 1.00 | 1.00 | .00 | .00 | 29.00 |
| 40 | 7K | 10.00 | .00 | 3.00 | .00 | 3.00 | 9.00 | 9.00 | 34.00 |
| 41 | 8K | 9.00 | .00 | 4.00 | .00 | .00 | 1.00 | .00 | 14.00 |
| 42 | 1V | 22.00 | 6.00 | 5.00 | 6.00 | .00 | 7.00 | .00 | 46.00 |
| 43 | 1E | 23.00 | 4.00 | 8.00 | .00 | 6.00 | 8.00 | .00 | 49.00 |
| Total N | | 43 | 43 | 43 | 43 | 43 | 43 | 43 | 43 |

a.

**Table 7.** Pre-treatment case summaries for the Class I sample

Post-Treatment Case Summaries for Class I Patients [a]

| | Patient Number | Post-Treatment Total Alignment | Post-Treatment Marginal Ridges | Post-Treatment Buccolingual Inclination | Post-Treatment Occlusal Contacts | Post-Treatment Occlusal Relationships | Post-Treatment Total Overjet | Post-Treatment Interproximal Contacts | Post-Treatment Total OGS Score |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 R | 6.00 | .00 | 11.00 | 7.00 | .00 | 4.00 | .00 | 26.00 |
| 2 | 3 R | 8.00 | 6.00 | 4.00 | 7.00 | 2.00 | 2.00 | .00 | 29.00 |
| 3 | 4 R | 1.00 | 2.00 | 3.00 | 8.00 | 4.00 | 1.00 | .00 | 20.00 |
| 4 | 6 R | 10.00 | 8.00 | 6.00 | 10.00 | 4.00 | 2.00 | .00 | 43.00 |
| 5 | 9 R | 3.00 | 3.00 | 2.00 | 4.00 | .00 | 5.00 | .00 | 17.00 |
| 6 | 14R | 7.00 | 4.00 | 4.00 | 5.00 | 11.00 | 4.00 | .00 | 35.00 |
| 7 | 16R | 8.00 | 4.00 | 4.00 | 21.00 | .00 | 8.00 | .00 | 45.00 |
| 8 | 17R | 9.00 | 2.00 | 10.00 | 13.00 | .00 | 2.00 | .00 | 36.00 |
| 9 | 18R | 26.00 | 2.00 | 3.00 | 27.00 | .00 | 16.00 | .00 | 74.00 |
| 10 | 19R | 4.00 | 3.00 | 1.00 | 6.00 | .00 | 5.00 | .00 | 19.00 |
| 11 | 20R | 2.00 | 4.00 | 5.00 | 14.00 | 2.00 | 1.00 | .00 | 28.00 |
| 12 | 21R | 5.00 | 7.00 | 6.00 | 19.00 | .00 | 4.00 | .00 | 41.00 |
| 13 | 22R | 16.00 | 3.00 | 6.00 | 3.00 | 1.00 | 7.00 | .00 | 36.00 |
| 14 | 23R | 1.00 | .00 | 4.00 | 16.00 | 3.00 | 10.00 | .00 | 34.00 |
| 15 | 24R | 7.00 | .00 | 5.00 | 17.00 | .00 | 3.00 | .00 | 32.00 |
| 16 | 27R | 6.00 | 1.00 | 9.00 | 2.00 | .00 | .00 | .00 | 18.00 |
| 17 | 1Rh | 4.00 | 6.00 | 3.00 | 11.00 | 1.00 | 5.00 | .00 | 30.00 |
| 18 | 2Rh | .00 | .00 | 3.00 | 11.00 | .00 | 5.00 | .00 | 19.00 |
| 19 | 3Rh | 1.00 | .00 | 1.00 | 11.00 | 2.00 | 2.00 | .00 | 17.00 |
| 20 | 6Rh | 4.00 | 1.00 | 2.00 | .00 | 2.00 | 5.00 | .00 | 14.00 |
| 21 | 7Rh | 4.00 | 3.00 | 5.00 | 2.00 | 5.00 | 2.00 | .00 | 21.00 |
| 22 | 9Rh | 6.00 | 1.00 | 4.00 | 8.00 | 7.00 | 15.00 | .00 | 41.00 |
| 23 | 11Rh | 8.00 | 3.00 | 1.00 | 2.00 | 7.00 | 2.00 | .00 | 23.00 |
| 24 | 1D | 9.00 | 5.00 | 3.00 | 14.00 | 7.00 | 8.00 | .00 | 46.00 |
| 25 | 2D | 7.00 | 4.00 | 7.00 | 22.00 | 5.00 | 2.00 | .00 | 47.00 |
| 26 | 2G | 11.00 | 1.00 | 1.00 | 8.00 | .00 | 2.00 | .00 | 23.00 |
| 27 | 4G | 4.00 | 1.00 | 3.00 | 2.00 | 2.00 | 7.00 | .00 | 19.00 |
| 28 | 5G | 4.00 | 3.00 | 1.00 | 3.00 | .00 | 6.00 | .00 | 17.00 |
| 29 | 2Y | 7.00 | 3.00 | 3.00 | 26.00 | 2.00 | 5.00 | .00 | 46.00 |
| 30 | 3Y | 2.00 | 4.00 | 3.00 | 8.00 | .00 | 5.00 | 1.00 | 23.00 |
| 31 | 5Y | 5.00 | .00 | 2.00 | 12.00 | 5.00 | 2.00 | .00 | 26.00 |
| 32 | 6Y | 3.00 | 1.00 | 3.00 | 12.00 | 8.00 | 5.00 | .00 | 32.00 |
| 33 | 7Y | 7.00 | 9.00 | 4.00 | 17.00 | .00 | 12.00 | .00 | 49.00 |
| 34 | 1K | 13.00 | 2.00 | 4.00 | 10.00 | .00 | 9.00 | .00 | 38.00 |
| 35 | 2K | 14.00 | 5.00 | 7.00 | 7.00 | 3.00 | 5.00 | .00 | 41.00 |
| 36 | 3K | 3.00 | .00 | 1.00 | 4.00 | 1.00 | 5.00 | .00 | 14.00 |
| 37 | 4K | 26.00 | 8.00 | 10.00 | 20.00 | 1.00 | 3.00 | .00 | 69.00 |
| 38 | 5K | .00 | 3.00 | 7.00 | 21.00 | .00 | .00 | .00 | 31.00 |
| 39 | 6K | 5.00 | 2.00 | 9.00 | 10.00 | 2.00 | 3.00 | .00 | 31.00 |
| 40 | 7K | 2.00 | 1.00 | 1.00 | 8.00 | 3.00 | .00 | .00 | 15.00 |
| 41 | 8K | .00 | .00 | 4.00 | 2.00 | .00 | .00 | .00 | 6.00 |
| 42 | 1V | 3.00 | 3.00 | 5.00 | 8.00 | .00 | 3.00 | .00 | 22.00 |
| 43 | 1E | 9.00 | 2.00 | 6.00 | 4.00 | 11.00 | 5.00 | .00 | 37.00 |
| Total | N | 43 | 43 | 43 | 43 | 43 | 43 | 43 | 43 |

a.

**Table 8.** Post-treatment case summaries for the Class I sample

Paired Samples Test for Class I Patients

| | | Paired Differences | | | | | t | df | Sig. (2-tailed) |
|---|---|---|---|---|---|---|---|---|---|
| | | Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference Lower | Upper | | | |
| Pair 1 | Pre-Treatment Anterior Alignment - Post-Treatment Anterior Alignment | 9.76744 | 3.73425 | .56947 | 8.61821 | 10.91667 | 17.152 | 42 | .000 |
| Pair 2 | Pre-Treatment Posterior Alignment - Post-Treatment Posterior Alignment | 4.48837 | 3.57486 | .54516 | 3.38819 | 5.58855 | 8.233 | 42 | .000 |
| Pair 3 | Pre-Treatment Total Alignment - Post-Treatment Total Alignment | 14.25581 | 5.42522 | .82734 | 12.58618 | 15.92545 | 17.231 | 42 | .000 |
| Pair 4 | Pre-Treatment Marginal Ridges - Post-Treatment Marginal Ridges | .02326 | 1.53512 | .23410 | -.44918 | .49570 | .099 | 42 | .921 |
| Pair 5 | Pre-Treatment Buccolingual Inclination - Post-Treatment Buccolingual Inclination | .62791 | 1.36318 | .20788 | .20838 | 1.04743 | 3.020 | 42 | .004 |
| Pair 6 | Pre-Treatment Occlusal Contacts - Post-Treatment Occlusal Contacts | -5.95349 | 5.80621 | .88544 | -7.74038 | -4.16660 | -6.724 | 42 | .000 |
| Pair 7 | Pre-Treatment Occlusal Relationships - Post-Treatment Occlusal Relationships | -.72093 | 2.08539 | .31802 | -1.36272 | -.07914 | -2.267 | 42 | .029 |
| Pair 8 | Pre-Treatment Anterior Overjet - Post-Treatment Anterior Overjet | 1.37209 | 2.92789 | .44650 | .47102 | 2.27316 | 3.073 | 42 | .004 |
| Pair 9 | Pre-Treatment Posterior Overjet - Post-Treatment Posterior Overjet | -.27907 | 1.57851 | .24072 | -.76486 | .20672 | -1.159 | 42 | .253 |
| Pair 10 | Pre-Treatment Total Overjet - Post-Treatment Total Overjet | 1.09302 | 3.04579 | .46448 | .15567 | 2.03038 | 2.353 | 42 | .023 |
| Pair 11 | Pre-Treatment Interproximal Contacts - Post-Treatment Interproximal Contacts | 1.32558 | 2.89269 | .44113 | .43534 | 2.21582 | 3.005 | 42 | .004 |
| Pair 12 | Pre-Treatment Total OGS Score - Post-Treatment Total OGS Score | 10.58140 | 6.76205 | 1.03120 | 8.50034 | 12.66245 | 10.261 | 42 | .000 |

**Table 9.** Paired t-tests for Class I patients

The other two differences seen were in posterior and overall overjet. Posterior overjet showed no significant difference with the Class I group and was different from the entire sample, which had a significant negative change. The total overjet category had a statistically significant positive change in this subgroup and the entire sample had no difference. Because these minor changes are small, the clinical relevance is once again questionable.

OGS Scores of 30 points or less. The passing score for this study was set at a score of 30 points or less and a total of 24 out the total 65 patients had post-treatment OGS scores in this range. The case summaries and descriptive statistics for this subgroup are shown in Tables 10-12. Most of the means for this group were relatively lower which was expected. The major differences between the 30 points or less group and the entire sample were seen in pre- and post-treatment posterior alignment, occlusal contacts and total OGS scores. The means for posterior alignment in both pre- and post-treatment were between 3 and 4 points less in this group and, but had similar amounts of change from pre- to post-treatment. Pre-treatment occlusal contact deductions were slightly lower (1.6 points) in this group but in the post-treatment category, occlusal contacts scored 4 points less in this section compared with the entire sample. Occlusal contacts still scored an average of 6 points in this group, which accounted for 29% of the total OGS score. This figure is very similar to Robinson's investigation that found the occlusal contact score accounted for 27% of the post-treatment ABO score and is also consistent with the other 2 groups in this study.

**Descriptive Statistics for OGS Scores of 30 Points or less**

| | N | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|
| Age | 24 | 14.00 | 57.00 | 34.0833 | 11.91607 |
| Treatment Duration | 24 | 6.00 | 16.00 | 10.9167 | 2.97696 |
| Number of Upper Aligners | 24 | 5.00 | 25.00 | 16.0000 | 4.96072 |
| Number of Lower Aligners | 24 | 7.00 | 28.00 | 16.7500 | 5.55017 |
| Valid N (listwise) | 24 | | | | |

**Table 10a-** Descriptive statistics for OGS scores of 30 points or less

**Descriptive Statistics for OGS Scores of 30 points or less**

| | N | Range | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|---|
| Pre-Treatment Anterior Alignment | 24 | 13.00 | 3.00 | 16.00 | 11.2083 | 3.74142 |
| Pre-Treatment Posterior Alignment | 24 | 13.00 | 1.00 | 14.00 | 5.7917 | 3.57502 |
| Pre-Treatment Total Alignment | 24 | 24.00 | 5.00 | 29.00 | 17.0000 | 6.39973 |
| Pre-Treatment Marginal Ridges | 24 | 8.00 | .00 | 8.00 | 2.3333 | 2.23931 |
| Pre-Treatment Buccolingual Inclination | 24 | 11.00 | 1.00 | 12.00 | 3.5000 | 2.60434 |
| Pre-Treatment Occlusal Contacts | 24 | 7.00 | .00 | 7.00 | 1.8750 | 2.47268 |
| Pre-Treatment Occlusal Relationships | 24 | 8.00 | .00 | 8.00 | 1.8333 | 2.53097 |
| Pre-Treatment Anterior Overjet | 24 | 9.00 | .00 | 9.00 | 4.2083 | 2.65361 |
| Pre-Treatment Posterior Overjet | 24 | 6.00 | .00 | 6.00 | .4583 | 1.28466 |
| Pre-Treatment Total Overjet | 24 | 9.00 | .00 | 9.00 | 4.6667 | 2.76101 |
| Pre-Treatment Interproximal Contacts | 24 | 14.00 | .00 | 14.00 | 1.5833 | 3.36112 |
| Pre-Treatment Total OGS Score | 24 | 36.00 | 14.00 | 50.00 | 32.7917 | 8.73264 |
| Post-Treatment Anterior Alignment | 24 | 4.00 | .00 | 4.00 | .9583 | 1.12208 |
| Post-Treatment Posterior Alignment | 24 | 9.00 | .00 | 9.00 | 2.7917 | 2.41335 |
| Post-Treatment Total Alignment | 24 | 11.00 | .00 | 11.00 | 3.7500 | 2.75444 |
| Post-Treatment Marginal Ridges | 24 | 6.00 | .00 | 6.00 | 2.1250 | 1.77697 |
| Post-Treatment Buccolingual Inclination | 24 | 10.00 | 1.00 | 11.00 | 3.1667 | 2.64849 |
| Post-Treatment Occlusal Contacts | 24 | 14.00 | .00 | 14.00 | 5.9583 | 3.72394 |
| Post-Treatment Occlusal Relationships | 24 | 7.00 | .00 | 7.00 | 2.1667 | 2.37133 |
| Post-Treatment Anterior Overjet | 24 | 7.00 | .00 | 7.00 | 2.7917 | 2.24537 |
| Post-Treatment Posterior Overjet | 24 | 5.00 | .00 | 5.00 | .7917 | 1.28466 |
| Post-Treatment Total Overjet | 24 | 11.00 | .00 | 11.00 | 3.5833 | 2.63615 |
| Post-Treatment Interproximal Contacts | 24 | 1.00 | .00 | 1.00 | .0417 | .20412 |
| Post-Treatment Total OGS Score | 24 | 23.00 | 6.00 | 29.00 | 20.8333 | 5.72308 |
| Valid N (listwise) | 24 | | | | | |

**Table 10b.** Descriptive statistics for OGS scores of 30 points or less

The range for pre-treatment OGS scores in the 30 points or less group varied from 14 to 50 points with a mean of 32.8 and the post-treatment OGS scores ranged from 6 to 29 points with a mean of 20.8. The total OGS score also differed greatly from the entire sample with the pre-treatment group

averaging 14 less points and the post-treatment group averaging nearly 16 points less. Once again, the main changes seen in this group were similar to the entire sample with the majority of reduction in OGS score coming from alignment changes and the increase in score stemming from occlusal contact deficiencies. The mean positive change in the OGS score from the alignment category was a reduction of 13.3 points and the mean negative change coming from occlusal contacts was an increase of 4.0 points. The overall mean change in the OGS score was 12.0 points in this group, which was 1.5 points more than the change in score of the entire sample.

**Pre-Treatment Case Summaries for OGS Scores of 30 points or less**

| | Patient Number | Pre-Treatment Total Alignment | Pre-Treatment Marginal Ridges | Pre-Treatment Buccolingual Inclination | Pre-Treatment Occlusal Contacts | Pre-Treatment Occlusal Relationships | Pre-Treatment Total Overjet | Pre-Treatment Interproximal Contacts | Pre-Treatment Total OGS Score |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 R | 18.00 | .00 | 12.00 | 7.00 | .00 | 4.00 | .00 | 41.00 |
| 2 | 3 R | 23.00 | 8.00 | 5.00 | 7.00 | .00 | 7.00 | .00 | 50.00 |
| 3 | 4 R | 5.00 | 2.00 | 5.00 | .00 | 3.00 | .00 | 3.00 | 18.00 |
| 4 | 5 R | 10.00 | 4.00 | 5.00 | 1.00 | 8.00 | 4.00 | .00 | 32.00 |
| 5 | 7 R | 23.00 | 3.00 | 1.00 | .00 | 6.00 | 9.00 | .00 | 42.00 |
| 6 | 9 R | 19.00 | 6.00 | 2.00 | .00 | .00 | 7.00 | .00 | 34.00 |
| 7 | 19R | 22.00 | 3.00 | 1.00 | .00 | .00 | .00 | 4.00 | 30.00 |
| 8 | 20R | 17.00 | 4.00 | 5.00 | 5.00 | 2.00 | 4.00 | .00 | 37.00 |
| 9 | 27R | 18.00 | 1.00 | 8.00 | 1.00 | .00 | 5.00 | 3.00 | 36.00 |
| 10 | 2Rh | 11.00 | .00 | 3.00 | .00 | .00 | 7.00 | .00 | 21.00 |
| 11 | 3Rh | 21.00 | .00 | 1.00 | 3.00 | 2.00 | 3.00 | .00 | 30.00 |
| 12 | 6Rh | 19.00 | 1.00 | 4.00 | .00 | .00 | 6.00 | .00 | 30.00 |
| 13 | 7Rh | 9.00 | 3.00 | 5.00 | .00 | 2.00 | 6.00 | .00 | 25.00 |
| 14 | 8Rh | 20.00 | 4.00 | 4.00 | .00 | 3.00 | 9.00 | 2.00 | 42.00 |
| 15 | 11Rh | 22.00 | 1.00 | 1.00 | .00 | 7.00 | 1.00 | 1.00 | 33.00 |
| 16 | 2G | 29.00 | 1.00 | 1.00 | 2.00 | .00 | 5.00 | .00 | 38.00 |
| 17 | 4G | 13.00 | 1.00 | 2.00 | .00 | 2.00 | 3.00 | 2.00 | 23.00 |
| 18 | 5G | 21.00 | 3.00 | 1.00 | 5.00 | .00 | 6.00 | .00 | 36.00 |
| 19 | 3Y | 5.00 | 4.00 | 2.00 | 1.00 | .00 | 1.00 | 14.00 | 27.00 |
| 20 | 5Y | 22.00 | 1.00 | 2.00 | 4.00 | 6.00 | 4.00 | .00 | 39.00 |
| 21 | 3K | 20.00 | .00 | 2.00 | 3.00 | .00 | 4.00 | .00 | 29.00 |
| 22 | 7K | 10.00 | .00 | 3.00 | .00 | 3.00 | 9.00 | 9.00 | 34.00 |
| 23 | 8K | 9.00 | .00 | 4.00 | .00 | .00 | 1.00 | .00 | 14.00 |
| 24 | 1V | 22.00 | 6.00 | 5.00 | 6.00 | .00 | 7.00 | .00 | 46.00 |
| Total N | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 |

a.

**Table 11.** Pre-treatment case summaries for OGS scores of 30 points or less

**Post-Treatment Case Summaries for OGS scores 30 points or less**

| | Patient Number | Post-Treatment Total Alignment | Post-Treatment Marginal Ridges | Post-Treatment Buccolingual Inclination | Post-Treatment Occlusal Contacts | Post-Treatment Occlusal Relationships | Post-Treatment Total Overjet | Post-Treatment Interproximal Contacts | Post-Treatment Total OGS Score |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 R | 6.00 | .00 | 11.00 | 7.00 | .00 | 4.00 | .00 | 26.00 |
| 2 | 3 R | 8.00 | 6.00 | 4.00 | 7.00 | 2.00 | 2.00 | .00 | 29.00 |
| 3 | 4 R | 1.00 | 2.00 | 3.00 | 8.00 | 4.00 | 1.00 | .00 | 20.00 |
| 4 | 5 R | .00 | 5.00 | 6.00 | 4.00 | 6.00 | 6.00 | .00 | 29.00 |
| 5 | 7 R | 6.00 | 4.00 | 1.00 | 7.00 | 5.00 | 5.00 | .00 | 28.00 |
| 6 | 9 R | 3.00 | 3.00 | 2.00 | 4.00 | .00 | 5.00 | .00 | 17.00 |
| 7 | 19R | 4.00 | 3.00 | 1.00 | 6.00 | .00 | 5.00 | .00 | 19.00 |
| 8 | 20R | 2.00 | 4.00 | 5.00 | 14.00 | 2.00 | 1.00 | .00 | 28.00 |
| 9 | 27R | 6.00 | 1.00 | 9.00 | 2.00 | .00 | .00 | .00 | 18.00 |
| 10 | 2Rh | .00 | .00 | 3.00 | 11.00 | .00 | 5.00 | .00 | 19.00 |
| 11 | 3Rh | 1.00 | .00 | 1.00 | 11.00 | 2.00 | 2.00 | .00 | 17.00 |
| 12 | 6Rh | 4.00 | 1.00 | 2.00 | .00 | 2.00 | 5.00 | .00 | 14.00 |
| 13 | 7Rh | 4.00 | 3.00 | 5.00 | 2.00 | 5.00 | 2.00 | .00 | 21.00 |
| 14 | 8Rh | 3.00 | 3.00 | 1.00 | 3.00 | 6.00 | 11.00 | .00 | 27.00 |
| 15 | 11Rh | 8.00 | 3.00 | 1.00 | 2.00 | 7.00 | 2.00 | .00 | 23.00 |
| 16 | 2G | 11.00 | 1.00 | 1.00 | 8.00 | .00 | 2.00 | .00 | 23.00 |
| 17 | 4G | 4.00 | 1.00 | 3.00 | 2.00 | 2.00 | 7.00 | .00 | 19.00 |
| 18 | 5G | 4.00 | 3.00 | 1.00 | 3.00 | .00 | 6.00 | .00 | 17.00 |
| 19 | 3Y | 2.00 | 4.00 | 3.00 | 8.00 | .00 | 5.00 | 1.00 | 23.00 |
| 20 | 5Y | 5.00 | .00 | 2.00 | 12.00 | 5.00 | 2.00 | .00 | 26.00 |
| 21 | 3K | 3.00 | .00 | 1.00 | 4.00 | 1.00 | 5.00 | .00 | 14.00 |
| 22 | 7K | 2.00 | 1.00 | 1.00 | 8.00 | 3.00 | .00 | .00 | 15.00 |
| 23 | 8K | .00 | .00 | 4.00 | 2.00 | .00 | .00 | .00 | 6.00 |
| 24 | 1V | 3.00 | 3.00 | 5.00 | 8.00 | .00 | 3.00 | .00 | 22.00 |
| Total N | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 |

a.

**Table 12**. Post-treatment case summaries for OGS scores of 30 points or less

Paired t-tests revealed very similar significance results when compared with the entire sample (Table 13). Small differences when compared with the entire sample were seen in buccolingual inclination and posterior overjet, but both were very small changes and probably not significant. One small difference was seen with interproximal contacts, which had a mean positive change of 1.5 points while the whole sample only had an average positive change of 1.3 points. Two cases (3Y and 7K) in this group accounted for a total reduction of 22 total points from pre- to post-treatment and 16 of the 24 cases did not present with interproximal deductions in OGS score. Of the 24 cases finishing with a passing OGS score, 10 (42%) began with a passing score. This figure is fairly similar to a smaller past study by Robinson in 2002 (passing

score was set at 25), which had 3 out of 7 (43%) of the cases with pre-treatment passing scores before treatment with the Invisalign appliance.

**Paired Samples Test for OGS scores of 30 points or less**

| | | Paired Differences | | | | | t | df | Sig. (2-tailed) |
|---|---|---|---|---|---|---|---|---|---|
| | | Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference Lower | Upper | | | |
| Pair 1 | Pre-Treatment Anterior Alignment - Post-Treatment Anterior Alignment | 10.25000 | 3.35248 | .68432 | 8.83437 | 11.66563 | 14.978 | 23 | .000 |
| Pair 2 | Pre-Treatment Posterior Alignment - Post-Treatment Posterior Alignment | 3.00000 | 2.48474 | .50719 | 1.95079 | 4.04921 | 5.915 | 23 | .000 |
| Pair 3 | Pre-Treatment Total Alignment - Post-Treatment Total Alignment | 13.25000 | 4.90120 | 1.00045 | 11.18041 | 15.31959 | 13.244 | 23 | .000 |
| Pair 4 | Pre-Treatment Marginal Ridges - Post-Treatment Marginal Ridges | .20833 | 1.14129 | .23296 | -.27359 | .69026 | .894 | 23 | .380 |
| Pair 5 | Pre-Treatment Buccolingual Inclination - Post-Treatment Buccolingual Inclination | .33333 | 1.04950 | .21423 | -.10983 | .77650 | 1.556 | 23 | .133 |
| Pair 6 | Pre-Treatment Occlusal Contacts - Post-Treatment Occlusal Contacts | -4.08333 | 3.53758 | .72211 | -5.57712 | -2.58954 | -5.655 | 23 | .000 |
| Pair 7 | Pre-Treatment Occlusal Relationships - Post-Treatment Occlusal Relationships | -.33333 | 1.16718 | .23825 | -.82619 | .15953 | -1.399 | 23 | .175 |
| Pair 8 | Pre-Treatment Anterior Overjet - Post-Treatment Anterior Overjet | 1.41667 | 3.11960 | .63679 | .09938 | 2.73396 | 2.225 | 23 | .036 |
| Pair 9 | Pre-Treatment Posterior Overjet - Post-Treatment Posterior Overjet | -.33333 | 1.16718 | .23825 | -.82619 | .15953 | -1.399 | 23 | .175 |
| Pair 10 | Pre-Treatment Total Overjet - Post-Treatment Total Overjet | 1.08333 | 3.30897 | .67544 | -.31392 | 2.48059 | 1.604 | 23 | .122 |
| Pair 11 | Pre-Treatment Interproximal Contacts - Post-Treatment Interproximal Contacts | 1.54167 | 3.20298 | .65380 | .18917 | 2.89416 | 2.358 | 23 | .027 |
| Pair 12 | Pre-Treatment Total OGS Score - Post-Treatment Total OGS Score | 11.95833 | 6.72749 | 1.37324 | 9.11757 | 14.79910 | 8.708 | 23 | .000 |

**Table 13.** Paired t-tests for OGS scores of 30 points or less

## DISCUSSION

Adult orthodontics makes up a considerable percentage of most orthodontic practices and many of these patients are seeking treatment using Invisalign. Align Technology began marketing directly to the public via television advertisements before any objective research concerning treatment results was done. The sole purpose of the current study was to retrospectively and objectively investigate cases treated with the Invisalign appliance by measuring models with the Objective Grading System for dental casts designed by the American Board of Orthodontics.

The ABO designed the OGS to evaluate post-treatment models and panoramic radiographs. The present study evaluated both pre- and post-treatment models utilizing the OGS for dental casts and did not include panoramic radiographs due to the low number of post-treatment radiographs available. Because the majority of cases treated with the Invisalign appliance in this study involved minimal tooth movement, the OGS was used for both pre- and post-treatment evaluation of the dental casts. This scoring system is very sensitive to minor changes and was therefore the best choice of indices for assessing the effectiveness of the Invisalign appliance. The main problem may be seen when the differences between pre- and post-treatment scores are statistically significant but small in change. The clinical significance in these situations can therefore be questioned. For the larger changes such as alignment and occlusal contacts, these differences may be clinically significant and may be the main treatment changes produced by the Invisalign appliance.

This study identified 135 cases from 8 different orthodontic offices in the Portland, Oregon and Salt Lake City, Utah metropolitan areas. Of the 135 cases identified, only 65 met the criteria to be included in the study. The most interesting finding was the high percentage of patients that required the use of fixed appliances or spring aligners to completely finish the treatment. Thirty-three of the 135 cases (24%) that were identified used an appliance other than Invisalign to completely finish to the orthodontist's standards. These numbers are lower than those reported in a recent study from the University of Washington where 36 of 51 patients did not finish treatment with Invisalign alone (Bollen et al., 2003, Clements et al., 2003). Their sample was different from the present study in that the criteria for the Washington subjects required a high PAR index score and therefore the high number of cases not completing treatment with Invisalign would be more likely. The study from the University of Washington also used a different aligner material than the current material used by Align Technology. The statistics from the University of Washington study reiterate the importance of case selection with regard to the amount of change that may be possible with the Invisalign appliance. This concept is similar to Boyd's comments and ideas about the need to fully understand the appliance and limitations as well as having a learning curve associated with using Invisalign (Boyd, 2000). Align Technology's marketing statements of "no prior experience needed" and "the most significant new esthetic procedure since bleaching and almost as simple" contradict the statistics found in the present study.

Improvement in alignment has been demonstrated in all the case reports on patients treated with Invisalign. In this study, it was the most significant

treatment change seen with an average reduction of 14.5 points from pre- to post-treatment. One weakness of this study is seen when using the ABO OGS for scoring pre-treatment alignment with discrepancies larger than 1 mm between contact points. The OGS designates a 2 point deduction for anything over 1 mm for alignment so whether there is a 3 mm or a 1 mm discrepancy between contact points, the score is still 2 points for both. While the 3 mm discrepancy at pre treatment receives a 2 point deduction, it will need a 2.5 mm or better alignment change to have no points deducted. The 1 mm discrepancy will only need a .5 mm or better change to receive no deductions. Once again, the OGS was designed for post-treatment grading and therefore comparing pre and post-treatment changes needs to be evaluated with an understanding of the grading system. Overall, the post-treatment average alignment score was 1.5 points in the anterior segment and 5.5 points in the posterior segment with an overall average of 7 points. The total average reduction in anterior alignment was 10.1 points and 4.4 points for posterior alignment and an overall reduction of 14.5 points. Therefore, this study showed the most significant treatment change was in anterior alignment, which was from the mesial of one canine to the mesial of the other canine in both upper and lower arches. Posterior alignment showed some improvement from pre- to post-treatment, but not to the extent as was found with the anterior component.

The other major significant change was seen in occlusal contacts where the scores were reflected in a negative direction. The mean average deduction in OGS score for post treatment occlusal contacts was 10.2 points, which was an increase of nearly 6 points from pre- to post-treatment. The OGS is very sensitive to minor discrepancies in this category with 1 point being deducted for

any posterior open contact up to 1 mm and 2 points for any opening over 1 mm. Only 1 case exhibited zero deductions in post-treatment occlusal contacts and all others had some form of posterior open occlusion after completing Invisalign treatment. This is a very important finding when considering the type of retention protocol that should be used following treatment. Many orthodontists use the final aligners as retainers or make a new vacuum-formed overlay, which will tend to hold the posterior occlusion open and not allow the teeth to settle. It appears that the posterior teeth have a tendency to intrude during Invisalign treatment because of continuous aligner and this author recommends using retention protocols that allow for posterior settling such as bonded or wraparound retainers (Sauget et al., 1997). The majority of post-treatment records were taken following the use of the last stage of aligners and posterior settling was not complete. Whether or not posterior settling occurs and to what extent following Invisalign treatment would need to be addressed in a retention study with a similar sample of patients.

Small changes were seen between pre- and post-treatment in all other areas besides alignment and occlusal contacts. Due to the small amount of change observed, the clinical relevance may be insignificant. Most of the cases in these categories were very inconsistent in treatment change with some cases showing improvement, some having no change, and others getting worse. The predictability of attempting to improve, for example, marginal ridge discrepancies or buccolingual inclination utilizing the Invisalign appliance, may prove to be frustrating according to this study.

The Class I and the 30 points or less groups presented similar findings when compared to the entire sample. Small changes were seen, but the main

differences were in overall OGS scores of pre- and post-treatment. The Class I and 30 points or less were all relatively lower in all categories when compared with the entire sample, which was expected. One interesting finding in the Class I group was the statistically significant negative change in occlusal relationships. The change observed was small, but with the change being in a negative direction, it indicated the Invisalign appliance may have a side effect of making the occlusal relationships worse and it may truly be an intra-arch appliance. The ABO OGS is also quite sensitive to change in occlusal relationships with any discrepancy in posterior intercuspation over 1 mm being a 1 point deduction and anything over 2 mm denoting a 2 point deduction. Because the changes observed were small, the likelihood that these changes in a negative direction will settle back to their original positions needs to be addressed in a retention study.

The ABO OGS was first used to grade case reports in 1999 and the ABO encourages the use of the grading system "at any time to determine if one is producing 'board quality' results" (Casko, J. et al.). A study conducted by Yang-Powers and colleagues evaluated the differences between finished cases from orthodontic residents (University group) and ABO board-certified orthodontists (ABO group) using traditional orthodontics with brackets and arch wires. The results from the study reported the average post-treatment OGS score for the university group was 45.5 points lost and the ABO group averaged 33.9 points deducted. The university group only had 20% of the completed cases with 30 points or less while the ABO group had 47% of the their cases with deductions of 30 points or less. The present study had 37% of the finished cases with 30 points or less, but 41% (10/24) already had scores of 30 points or less. The

samples for this study were quite different from the present study. The Yang-Powers and colleagues sample was much more diverse with the complexity of cases ranging from transverse discrepancies to Class II extraction cases (Yang-Powers et al.). Even with the differences between the samples, the post-treatment OGS scores from the present Invisalign sample are similar, (Entire sample 36.4, Class I group 30.9) which indicates cases treated with the Invisalign appliance are finishing with similar results as traditional orthodontics.

Future research of the Invisalign appliance may include areas of retention and relapse. One major difference seen between Invisalign and traditional orthodontics is the order that alignment takes place. When bands, brackets and arch wires are used, the initial goal is to attain alignment and leveling during the first stage of treatment and the alignment is retained in place for the following 9 – 12 months. Cases treated with the Invisalign appliance differ in that alignment may not be completed until the final aligner is placed and possibly even require refinement to completely attain full alignment. Therefore, cases treated with traditional orthodontics have essentially been in "alignment retention" during the last year of treatment whereas cases treated with Invisalign do not begin retention of the alignment until the completion of the last aligner. Early histological studies on retention in the late 50's demonstrated stretched gingival fibers on derotated teeth up to 232 days following alignment (Reitan, 1959). This alone could be the basis for future research of the Invisalign appliance with a focus on retention, post retention, and relapse.

Some limitations of the current study include the use of the ABO OGS to evaluate pre-treatment models. A preliminary study with 10 randomized models using the PAR index revealed difficulty detecting small changes in any category other than alignment, which agreed with Robinson's study (Robinson, 2002; OHSU). Taking the OGS out of its original context and using the scoring system to evaluate pre-treatment models was done to get an idea about tooth alignment and occlusion when the cases were started. The scoring system was not modified to increase sensitivity to pre-treatment conditions. The initial design of this study was to grade post-treatment scores only and the pre-treatment scoring was done to try to quantify the change due to treatment. One must have an understanding of the point system designated by the ABO to be able to comprehend the changes observed and to what extent. Also, the criteria of the sample made it difficult to find pre- and post-treatment models as well as panoramic radiographs for cases treated exclusively with Invisalign.

Another limitation of the study was the intrajudge reliability. During the preliminary study, 10 sets of pre- and post-treatment models were measured 2 weeks apart using the OGS. The correlation coefficient (r) for the author was 0.951, which is much higher than a recent study by Lieber and colleagues who reported 0.77 for intrajudge and 0.85 for interjudge reliability. The author spent many hours prior to the study calibrating with the ABO calibration kit and this may explain the difference between the results of the two studies. The final limitation of the study may lie in the OGS for dental casts and its inability to evaluate periodontal health, root resorption and functional occlusion. Also, this study was directed at being objective and did not take in consideration patient satisfaction, which may be equally as important.

## CONCLUSIONS

The current study was an objective investigation of the Invisalign system. Align technology has been marketing the new system since 1998, but other than a few case reports, little has been documented in the literature on the efficacy of this new treatment modality. The present investigation examined pre- and post-treatment models utilizing the American Board of Orthodontics Objective Grading System for Dental Casts to objectively evaluate the Invisalign system. The following points summarize the findings from this study:

1) 24% of the cases that were started with Invisalign required the use of fixed appliances or spring aligners to complete treatment.
2) Improvement in anterior and posterior alignment accounted for 62% of the total treatment changes, which is 85% of the total positive treatment change.
3) Occlusal contact changes accounted for 27% of the total treatment changes, which is 97% of the total negative treatment change.
4) Interproximal spaces were effectively closed with the Invisalign appliance.
5) The Class I cases had an average post-treatment OGS score of 30.9, which was only 1 point higher than the score for passing set in this study.
6) 37% (24 out of 65) of the post-treatment cases scored 30 points or lower and 34% (9 out of 24) of these cases began treatment with a ABO score of 30 points or less.

7) All other categories had small changes in positive and negative directions, and were inconsistent with regard to direction. Due to the small change, they may not be clinically significant.

The data suggests significant improvement in alignment and inadequacies in occlusal contacts with the Invisalign system. Further research is needed in order to further validate the current study.

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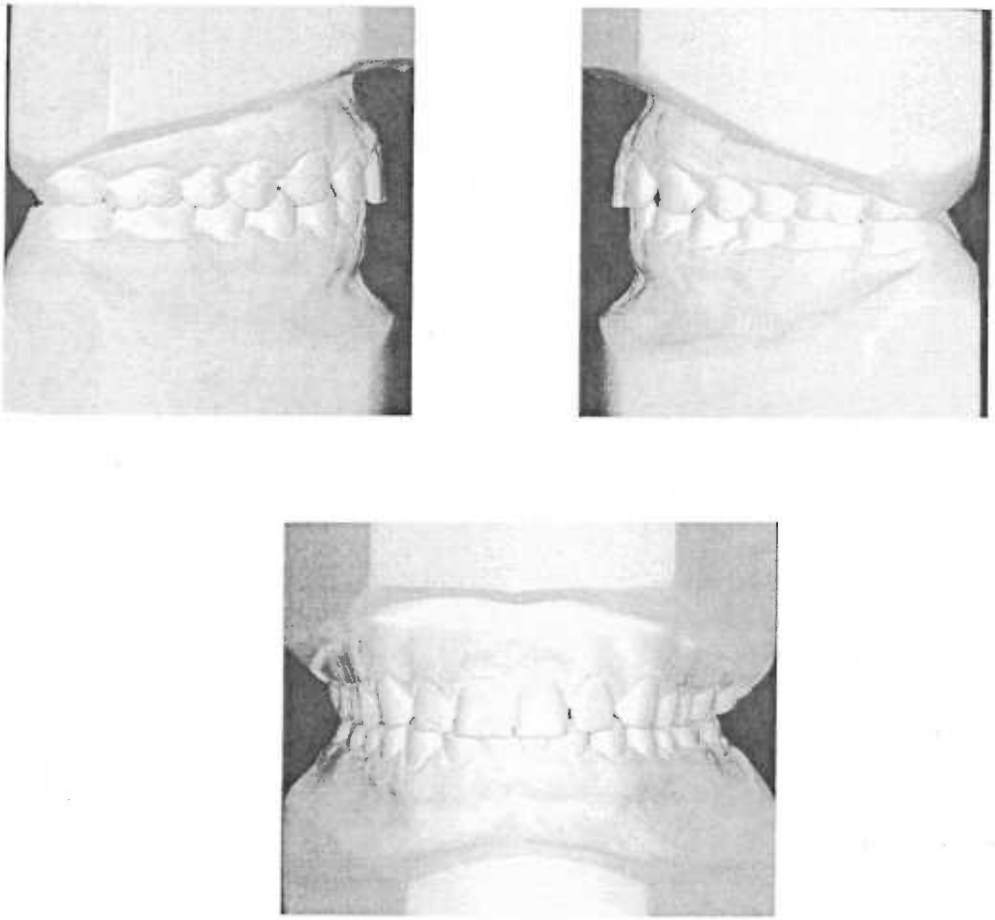
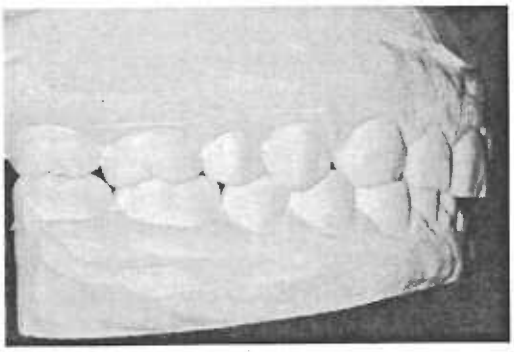
## APPENDIX

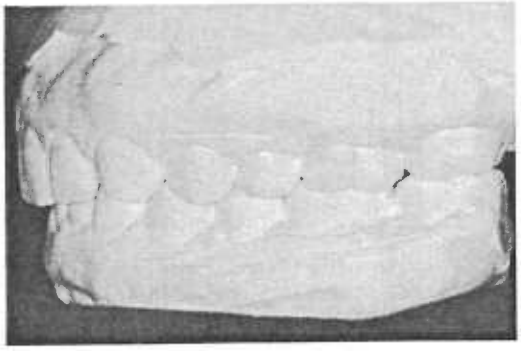
CASE 1- 3Y- ABO pre-treatment score= 27

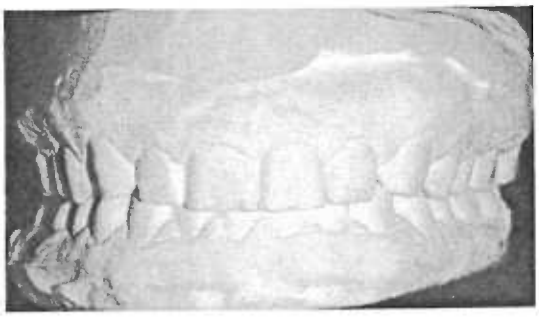


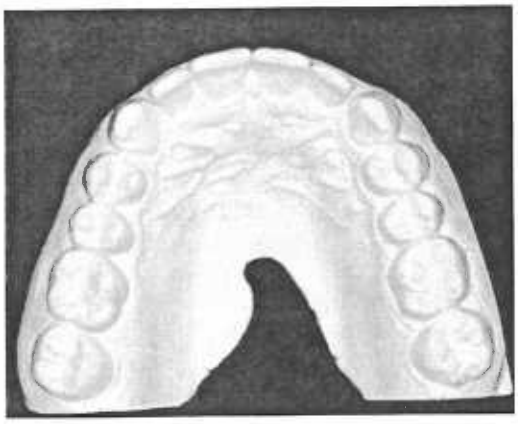
Pre-treatment

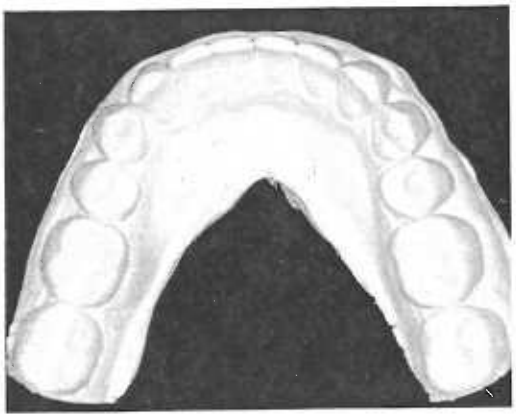
CASE 1- 3Y- ABO post-treatment score= 23











Post-treatment

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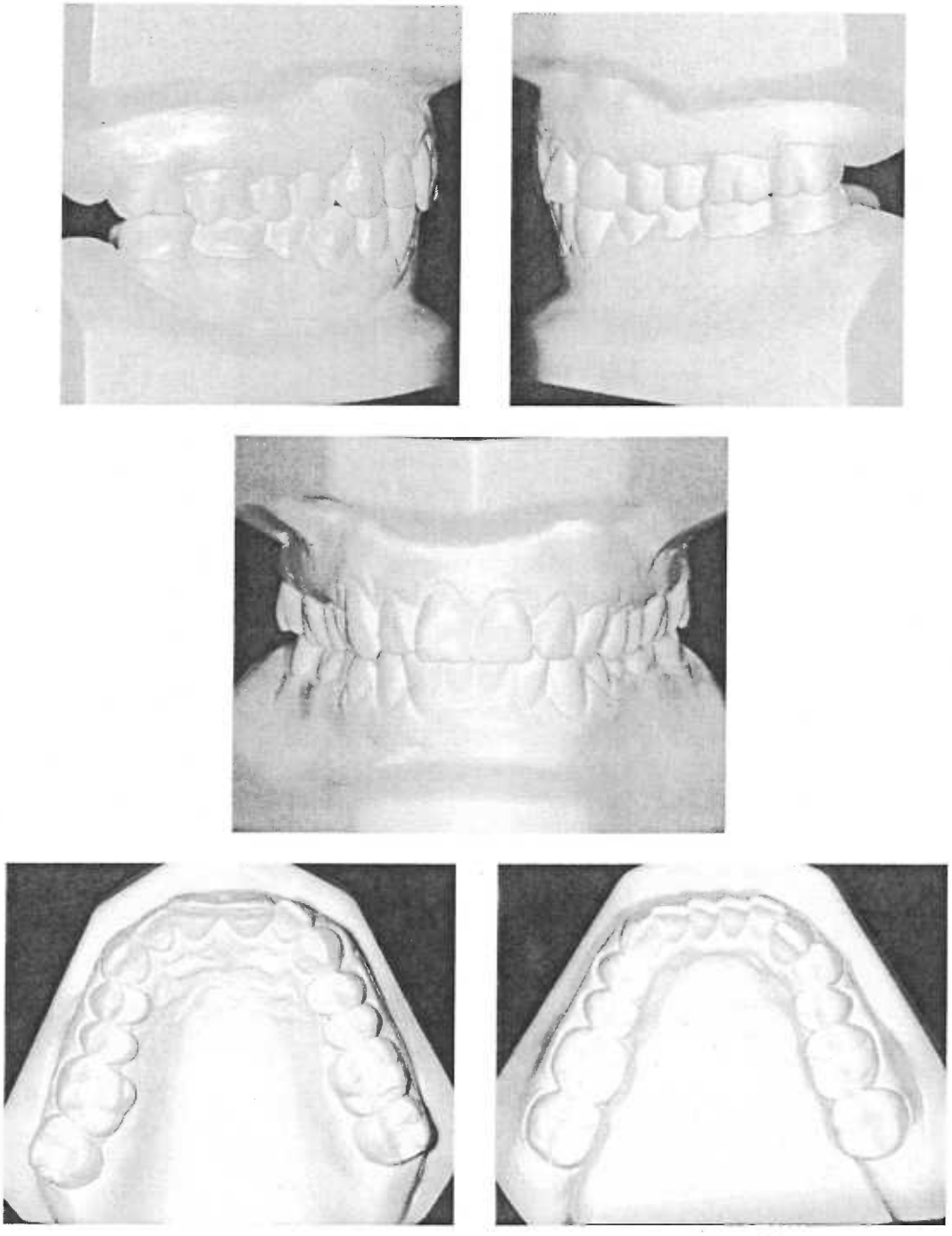

Pre-treatment

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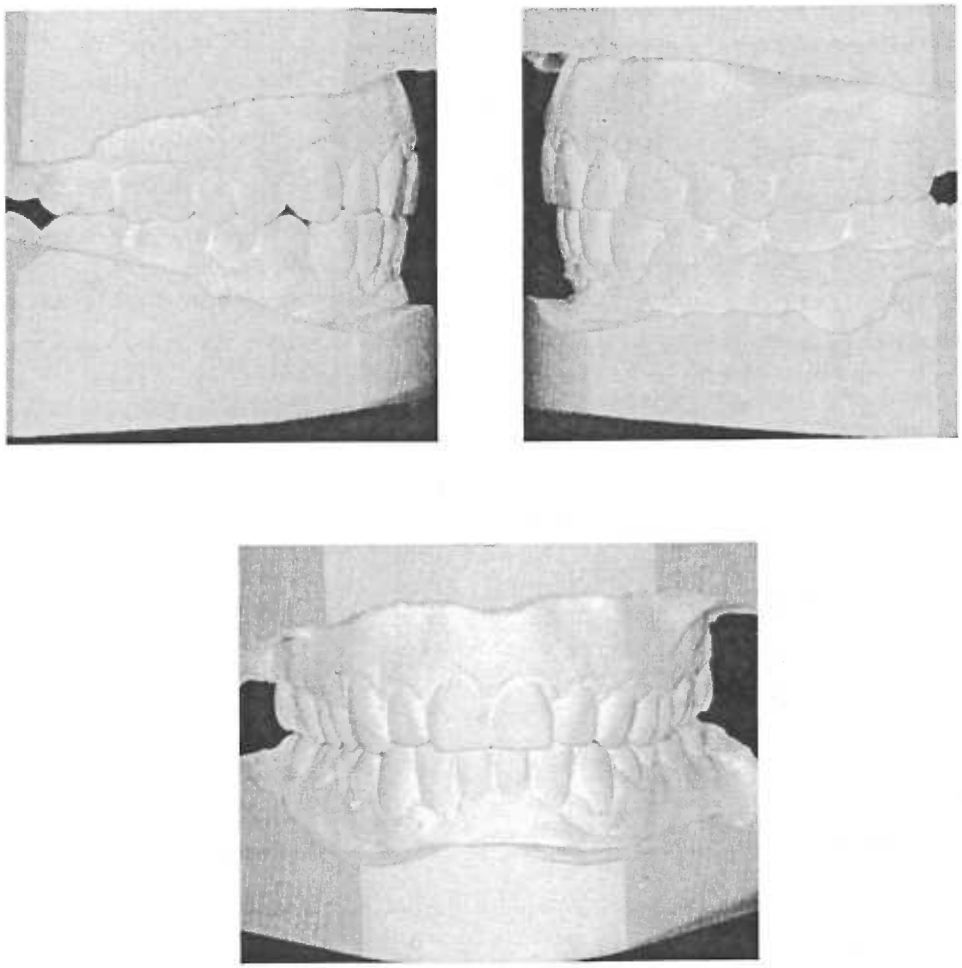
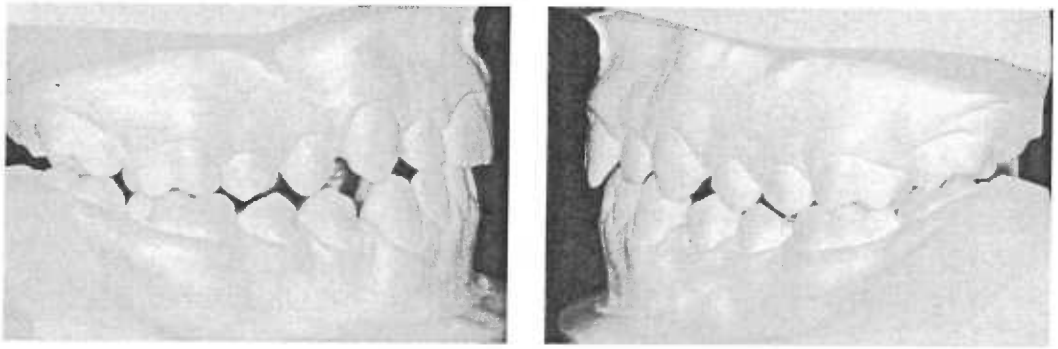
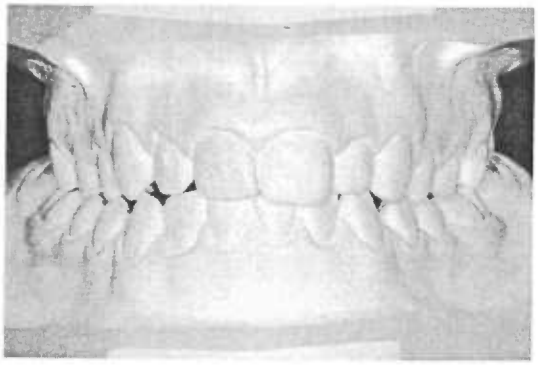
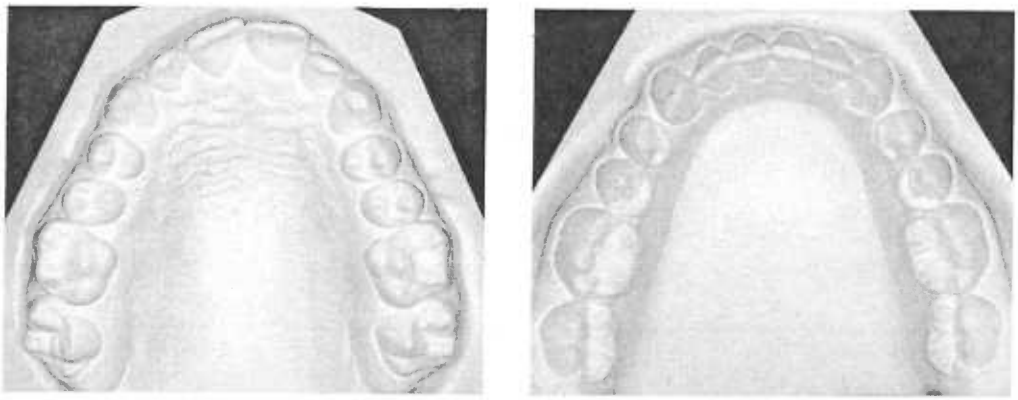


Post-treatment

CASE 3- 4K- ABO pre-treatment score= 84

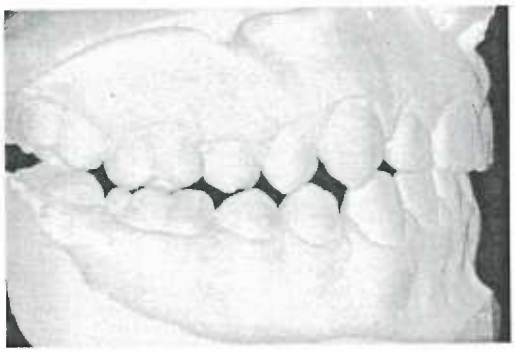
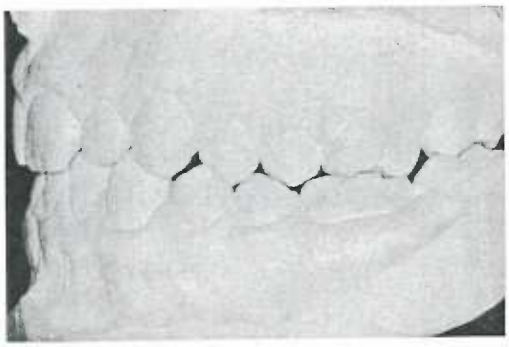
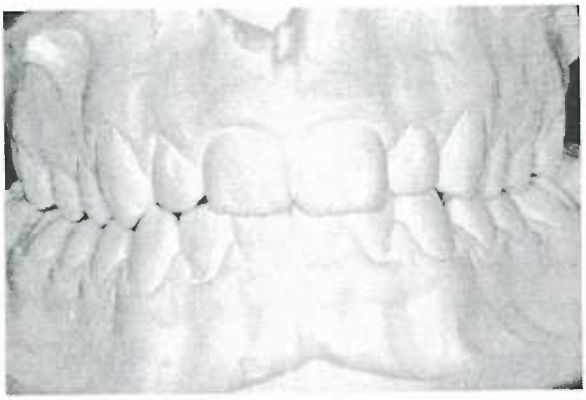
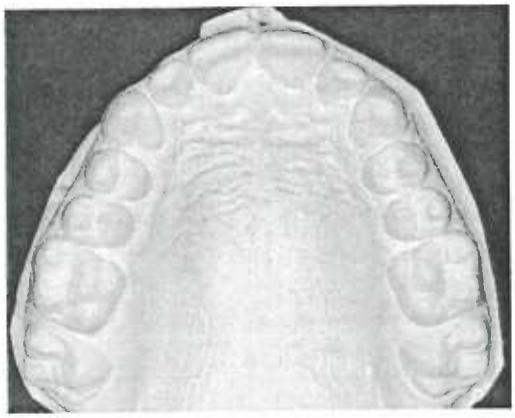






Pre-treatment

CASE 3- 4K- ABO post-treatment score= 69


Post-treatment