THE ACCURACY OF INVISALIGN CLINCHECK PREDICTION COMPARED TO CLINICAL RESULTS

by

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DEDICATION

I would like to dedicate this thesis to my loving husband who uprooted his life to move with me from Texas to Ohio so that I could pursue my dream of becoming an Orthodontist. Thank you for your endless support and encouragement. I also want to dedicate this thesis to my parents for their unwavering support throughout my life. Thank you for instilling in me the values of hard work and perseverance and for always having the confidence in me.

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ABSTRACT

Objective: Our objective in this retrospective study was to examine how accurately the digital model prediction in ClinCheck® matches the final clinical digital model after completing a set of Invisalign® aligners.

Materials and Methods: The sample included 30 non-growing patients (60 arches) treated with Invisalign®. All subjects completed a full series of aligners and required a refinement series of aligners. Predicted models were obtained from the initial ClinCheck and the achieved models were obtained from the initial stage of the refinement ClinCheck. The two stereolithographic (STL) models were superimposed using Geomagic® Control X™ software via a best-fit algorithm. The three-dimensional differences were compared at four different tolerance levels of 0.25 mm, 0.5 mm, 0.75 mm, and 1.0 mm.

Results: The average amount of surface-surface overlap between the predicted and achieved models was 70.4% at 0.25 mm, 89.2% at 0.5 mm, 95.4% at 0.75 mm, and 97.6% at 1.0 mm.

Conclusion: At tolerance levels of 0.5 mm to 1.0 mm, the average percentage of surface-surface overlap for actual clinical models compared to predicted ClinCheck models is

greater than the expected 70%. However, at a tolerance of 0.25 mm, the predicted and actual models match at an average of 70%.

Keywords: aligners, superimposition, ClinCheck

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REVIEW OF THE LITERATURE

One of the major goals of fixed orthodontic appliances is to improve facial appearance, but, ironically, the traditional metal fixed appliances are not very esthetic. Manufacturers of orthodontic appliances have introduced different esthetic alternatives to the market including ceramic brackets, coated wires, and lingual brackets. One particular appliance that has gained popularity since its introduction to the orthodontic market in 1999 is Invisalign®. This system presents a set of clear aligners that progressively move the teeth with each aligner.

Although Align Technology Inc. is credited with introducing the clear appliance to the market, it was actually Kesling, in the 1940s, who pioneered the idea of using a clear aligner to straighten teeth in the final stages of orthodontic treatment.[1] Ponitz followed in the 1970s with the introduction of an 'Invisible Retainer'

building on Kesling's idea of moving teeth using a master study model to attain small tooth movements.[2,3]

Sheridan, popularized the use of Raintree Essix material to make clear aligners along with interproximal reduction (IPR) of enamel to align the teeth. However, Sheridan had to take a new impression at every visit and create a new setup as tooth movement progressed, which proved to be inefficient and time consuming.[3,4] In contrast, the Invisalign® system requires only a single impression and uses computer-aided design (CAD) and computer-aided manufacturing (CAM) to generate progressive tooth movement using a set of clear aligners. The technology of CAD/CAM enables the technicians to generate multiple tooth set-ups from that single impression.

Since the launch of Invisalign® in 1999, the appliance has undergone multiple alterations to improve its efficiency and ability to correct more complex malocclusions. The first generation of Invisalign® consisted of a series of progressive clear aligners with no auxiliaries or attachments and was intended for the correction of minor to moderate crowding and malrotations

of the teeth. The second generation of aligners added the use of basic attachments and incorporated intermaxillary elastics to enhance tooth movement.[3] In later generations, the Invisalign® appliance has evolved to feature advancements such as optimized attachments and power ridges. All these changes were aimed at improving the clear plastic aligner's ability to create predictable tooth movement. Another technological milestone for Align Technology occurred in 2011 when the company acquired the iTero® intraoral scanner, which allowed digital impressions to be sent in for the manufacturing of clear aligners in place of PVS impressions. In October 2012, Align Technology announced that beginning in January 21, 2013, all Invisalign® aligners would be manufactured using its new SmartTrack™ material.[5]

With the introduction of an efficient way of creating clear aligners for progressive tooth movement that did not require new impressions and new setups at each appointment, there were still many clinicians that questioned the performance of this new appliance. Could thermoformed plastic predictably move teeth and accomplish it as well as traditional braces? A number of

researchers set forth to answer these questions by using the American Board of Orthodontics (ABO) objective grading system (OGS) to assess the outcome of malocclusions treated with the Invisalign® system.

Djeu, et al. started the trend in 2005, using the ABO OGS to assess the outcomes of patients treated with Invisalign® and patients treated with traditional braces by the same ABO-certified orthodontist.[6] The retrospective cohort study measured the outcomes in each category of the OGS, which include: alignment, marginal ridges, buccolingual inclination, occlusal contacts, occlusal relations, overjet, interproximal contacts, and root angulations. The authors found that when comparing the mean overall OGS score from the Invisalign group to that of the braces group, the Invisalign group lost thirteen more points than the braces group. However, the two groups received similar scores for the categories of alignment, marginal ridge heights, interproximal contacts, and root angulations. The four OGS categories where the braces group scored significantly better than the Invisalign group were buccolingual inclination, occlusal contacts, occlusal relationships, and overjet.

One major limitation of this study was that the Invisalign group comprised the first forty-eight patients treated with Invisalign by the orthodontist. This factor could have affected the outcomes since the orthodontist had a much greater experience treating with traditional braces.[6]

In 2007, Kuncio, et al. used the ABO OGS to compare post-retention dental changes of Invisalign® and traditional fixed appliances.[7] This cohort study evaluated dental casts and panoramic radiographs from the time of appliance removal (T1) and at the time of post-retention, three years after appliance removal (T2). All subjects were instructed to wear a retainer full time for six months, and all subjects reported wearing their retainer for at least one year after appliance removal. This study found that there were no statistically significant differences between the OGS categories and the overall OGS scores for the Invisalign group and the Braces group at T1 or T2. In fact, the only statistically significant differences found between the two groups was that alignment got worse for the Invisalign group than the Braces group between T1 and T2.

Within each group, both groups showed statistically significant decreases in total alignment when OGS scores were compared between T1 and T2. Both groups showed statistically significant differences in mandibular anterior alignment, but only the Invisalign group showed a significant difference in maxillary anterior alignment. Even though the Invisalign group showed more deterioration in alignment between the appliance removal and post-retention, the mean alignment scores for the Invisalign group were better than those of the Braces group for both periods of observation, but the differences were not statistically significant. One limitation to this study was that retainer wear was self-reported by patients; there was no way of confirming that the patients actually wore their retainers for at least one year during the post-treatment period. Another limitation was the sample size in this study since each group had only eleven subjects. Lastly, as in the Djeu study, the Invisalign group consisted of patients who were among the first fifty patients treated with Invisalign in the orthodontist's practice. Therefore,

the results of this study must be considered with these limitations in mind.

Kassas, et al. looked at the treatment outcomes using the ABO grading system in 2013 at the University of Buffalo examining thirty-one cases out of 425 Invisalign® patients treated by an ABO-certified orthodontist.[8] All cases included in this study were classified as being of mild to moderate complexity which was defined as having a Discrepancy Index (DI) score of 10 to 20. The Discrepancy Index is the method that the ABO phase III clinical examination uses to objectively define the level of complexity of a case prior to treatment.[9,10] Unlike the two previously mentioned studies, this study did not compare the outcomes of the Invisalign® cases to cases treated with fixed appliances; Rather, this retrospective study employed the ABO OGS to score both the pre-treatment and post-treatment models for each case. With manual measurements completed on cast models using the ABO measuring gauge, the results of the study showed that there were statistically significant improvements in scores for the alignment category, buccolingual inclination category, and total OGS score after the

completion of treatment. The least amount of change was observed in the interproximal contact score. Negative changes in score were documented in the categories of occlusal relationship and occlusal contact, but these findings were not statistically significant. The finding of statistically significant improvement in buccolingual inclination with Invisalign® treatment differed from previous studies, which showed that root torque was difficult to control with clear aligners .[8] This study suggests the possibility that over time the Invisalign® appliance, as it has evolved, has improved its ability to control buccolingual inclination and/or clinicians have improved in their ability to treatment plan with the Invisalign® appliance.

In keeping with the trend of using the ABO OGS as a criterion to compare Invisalign® treatment outcomes, Buschang, et al. used it to measure and compare the predicted ClinCheck model and actual posttreatment models.[11] ClinCheck is a software program created by Align Technology that shows the progression of expected tooth movement with each aligner from the initial impression to the final predicted position of the teeth

and occlusion. Krieger, et al. established a high concordance between initial casts and initial ClinCheck models, verifying that the model generated by ClinCheck was an accurate initial representation of the teeth.[12] Buschang, et al. set out to determine if the ClinCheck prediction of the final model accurately reflected the true final condition seen clinically, focusing specifically on the final occlusion produced by Invisalign® therapy. The study digitally measured the OGS scores for the ClinCheck model and the posttreatment model, which was created by scanning the final cast and converting that into an STL file. The authors found a statistically significant difference between the total OGS scores for the ClinCheck models and the posttreatment models, with the actual posttreatment models receiving more point deductions. The differences were also significant in the categories of alignment, marginal ridges, occlusal contacts, and occlusal relations, leading the authors to conclude that when using the OGS as a guideline, the ClinCheck models did not accurately predict the patient's immediate final occlusion. This study was completed on a small sample of twenty-seven

subjects treated consecutively, with no incorporated randomization. It remains questionable as to whether OGS scores can be used to adequately compare two models since the OGS was not designed for this but, rather, it was used as a tool to grade the outcome of a treatment to a specific standard.

Most recently, Li, et al. used the ABO model grading system to evaluate the effectiveness of Invisalign® in treating extraction cases.[13] This case-control study out of Hangzhou, China, compared the outcomes of Class I extraction cases between patients treated with Invisalign® only and patients treated with braces only. The pretreatment records were assessed using the DI, and the primary outcome was evaluated using the ABO OGS, which was used to score both pre- and post- treatment models. The study found that in both groups the mean scores for all OGS categories improved at the end of treatment and that statistically significant improvements in total OGS scores were observed. Interestingly, on average, the Invisalign group. required a longer treatment duration compared to the braces group This finding contrasts with previous studies which showed that

treatment time for Invisalign® is either shorter than or equal to the treatment time for braces; however, these studies involved non-extraction cases. [6,7,14] Li, et al. stated that they expected similar scores in the categories of alignment and interproximal contacts because previous studies had documented successful improvement in these areas.[6,15] On the other hand, the authors expressed that they did not expect comparable scores for marginal ridges and root angulation that they observed in this study. Therefore, according to this study, "Invisalign…can level arches as well as fixed appliances."[13] The authors attributed the good root control in the Invisalign extraction cases to proper attachment placement. Other studies have concluded that treatment with Invisalign® alone may not be able to satisfactorily correct occlusal relationships and overjet.[6,15,16] However, Li, et al. claimed that their results showed that Invisalign® might be able to correct anteroposterior discrepancies as well as braces. Three aspects of the Li study cause one to question this claim. First, all the subjects involved in this study had a Class I molar occlusion at the beginning of the study.

Second, elastics were used when necessary in both the Invisalign and braces groups, whereas in earlier studies no auxiliaries were employed. Third, earlier Invisalign studies tended to exclude extraction cases, so they did not have the extraction space to use to correct A-P discrepancies and/or excess overjet. Li, et al. concluded that the overall improvement in the OGS scores indicated that both the Invisalign appliances and braces were equally successful in treating class I adult extraction cases.[13] Although this was a well-designed randomized control trial, the study did have its limitations. Since Invisalign® is still considered a relatively new technique, the group of patients that were treated with Invisalign® was again among the treating orthodontist's first cases. In contrast, the orthodontist had many years of experience with fixed appliance.

Advances in technology and greater sophistication of CAD software allowed for improved measurement and manipulation of 3-dimensional digital models. These advancements facilitated the ability to evaluate tooth movement by superimposing digital models. Kravitz, et al. employed this superimposition technology to

investigate the predictability of Invisalign® treatment on the rotational movement of canines.[17] Specifically, the prospective clinical study out of the University of Illinois investigated the effect of attachments and interproximal reduction (IPR) on canines undergoing rotational movement with Invisalign. The sample included thirty-three maxillary and twenty mandibular canines from thirty-one patients treated with anterior Invisalign. The study looked at the efficacy of canine rotational movement with an attachment placed, interproximal reduction performed, or neither intervention. The study used ToothMeasure, Invisalign's proprietary measurement software, to superimpose virtual models of the ClinCheck predicted final tooth position and the actual posttreatment tooth positions. The ToothMeasure software allows an operator to reproducibly superimpose digital models on selected reference points with the superimpositions of the teeth accurate to within 0.2 mm and 1.0 degree.[18] According to an internal study, Align Technology claims that clinicians can expect 80% of the tooth movement shown on the ClinCheck.[4,19] The virtual models were superimposed using the posterior teeth as a

reference since only the anterior teeth were treated. The mean accuracy of canine derotations for all three treatment groups was 35.8% and there was no statistically significant difference in the accuracy of derotation of the canines between the groups. The authors concluded that vertical-ellipsoid attachments and interproximal reduction did not significantly improve the accuracy of canine rotation with the Invisalign system.[17] The data collection for this study was completed in December 2006, meaning that the treatment of these cases was completed before that date. The authors stated that all attachments were labially placed and centrally located.[17] Since the publication of this study, Invisalign attachments have changed, optimized attachments were introduced, and in 2013, the material used for Invisalign changed to SmartTrack™.[5] This study was limited by its small sample size and overcorrections were not accounted for, but the final predicted tooth position was used to compare to the achieved final tooth position. If overcorrection was included in the treatment plan, some of the teeth may have come closer to the desired position than was demonstrated from the measurements.

In a study published the following year by Kravitz, et al., the research group used digital superimposition again to investigate the efficacy of anterior Invisalign®.[15] This sample included thirty-seven patients treated with Anterior Invisalign® and assessed tooth movement of 401 anterior teeth. The prospective clinical study evaluated tooth movement by comparing the predicted movement projected by ClinCheck to the amount of tooth movement achieved after the completion of treatment with ToothMeasure used to superimpose the digital models. Polyvinyl siloxane (PVS) pre-treatment and post-treatment impressions were taken and sent to Align Technology and scanned by technicians to create digital pretreatment and posttreatment models. The authors specified that data collection was completed in 2006, which was prior to Align Technology acquiring and incorporating the iTero® (Align Technology, San Jose, Calif) intraoral scanner in 2011. The lead author superimposed the final stage digital model of the ClinCheck with the clinical posttreatment model using the untreated posterior teeth as reference points since they had remained stationary during treatment. The software

completed an efficacy analysis report after superimposition, which showed quantitative measurements for the predicted and achieved movements.[15] The authors explained that the method used to calculate the accuracy of predicted tooth movements was determined by: percentage of accuracy = 100% - [(|predicted-achieved|/ |predicted|) x 100%]. Specifically, this study investigated tooth movements involving labial expansion, lingual constriction, intrusion, extrusion, mesiodistal tip, labiolingual tip, and rotation. The authors found that in this sample, the mean accuracy of all tooth movements after Invisalign treatment was 41%. The most accurate tooth movement evaluated was lingual constriction of the mandibular canines which still only reached 59.3% of the predicted movement. The least accurate tooth movement, which has been supported by other studies,[20] was extrusion of the maxillary and mandibular central incisors, reaching only 18.3% and 24.5% of predicted movements, respectively. Additionally, the study found that the accuracy of derotation of canines was significantly lower than all other anterior teeth, and when the correction of maxillary canine

rotation exceeded 15 degrees, the accuracy of the movement was decreased. The authors listed five limitations in this study:

> (1) Posterior tooth movement was not evaluated because of the need to superimpose on stationary teeth. Thus patients were of mild difficulty, and few translational movements exceeded 2 mm. (2) Clinicians were instructed not to use auxiliaries…(3) Overcorrections were not accounted for. Many clinicians in the study requested overcorrection, but the final predicted tooth position was the measurement used. Therefore, even movements with low accuracy might have achieved their desired tooth position. (4) Tooth movement could have been influenced by the patient's age, periodontal support, root length, and bone density…(5) Patient satisfaction was not measured.[15]

In addition, since this study completed data collection in 2006, it did not take into account how advancements in the aligner material and changes in attachments may have improved the Invisalign system's ability to effect tooth movement. In other words, the findings from this study may be outdated and cannot be generalized and applied to efficacy of the current Invisalign appliance system.

The majority of the Invisalign efficacy studies investigated the movement of anterior teeth. [12,15,17,21] A dearth of knowledge about tooth movement in the posterior dentition existed. Simon, et al. recognized this void

and conducted a study that evaluated the efficacy of the clear aligners in tooth movements that required greater than 10 degrees of incisor torque, premolar derotation greater than 10 degrees, and molar distalization > 1.5 mm.[22] The models of thirty patients included in the study were evaluated retrospectively during 2011 and 2012 and were generated from alginate impressions taken prior to the beginning of treatment and immediately after finishing treatment. The casts were scanned using a laser scanner to create digital models. Simon used the Software Surface 10.0 (Imageware/Siemens PLM Software, Plano, Texas, USA) to superimpose the final phase of the ClinCheck digital model with the pre-treatment plaster cast digital model and to superimpose the final plaster cast digital model with the pre-treatment plaster cast digital model. As in Kravitz's study, untreated teeth were used to define the reference point for proper superimposition and the predicted final tooth positions and actual final tooth positions were superimposed with the pre-treatment tooth positions using a surface/surface matching algorithm.[22] Post-treatment translational and rotational tooth movements were measured in all three

planes of space by comparing them to the initial model. Simon, et al. determined the efficacy of the Invisalign treatment by calculating the difference between the parameters of the clinically achieved tooth movement and the expected amount of tooth movement predicted by ClinCheck.[22] The study found the overall efficacy for all the tooth movements evaluated to be 59.3% with the highest accuracy occurring with molar distalization and the lowest with premolar derotation. Distalization of maxillary molars achieved 87% accuracy. The accuracy of maxillary incisor torque was around 42%, and the accuracy of premolar derotation was around 40%. This article appears to be the only one to date that investigates the efficacy of Invisalign in carrying out predicted movements in posterior teeth. However, even though this study was published in 2014, it was completed before Align Technology incorporated SmartTrack™ material into all of its aligners. In fact, the authors wrote:

> "From the first quarter of 2013, a new aligner material called SmartTrack™ (LD30) was introduced to the orthodontic market by Align technology. To what extent the new aligner material influences the treatment efficacy needs to be investigated."[22]

Another limitation of this study was that it only investigated specific tooth movements that exceeded specific ranges, so it cannot be used to determine the efficacy of Invisalign® overall. Finally, the sample size in this study was small, and a larger sample size may have showed different results.

As mentioned earlier, one of the major advancements for Invisalign® was the acquisition of iTero® intraoral scanner by Align Technology in 2011.[23] Clinicians can now send intraoral scans directly to Invisalign® technicians, and the treatment plan is created directly from the scan. This cuts out the need to take a PVS impression, which is then sent to Align Technology and scanned by a technician to create a digital model. However, the addition of the iTero® scanner to the Invisalign® process is only beneficial if the scans are as accurate or better than those created from the PVS impressions. In 2013, Akyalcin, et al. carried out a study to determine the diagnostic accuracy of impression-free digital models.[24] They determined the accuracy of the iTero® intraoral scanner by scanning the maxillary and mandibular arches of sixty dry skulls and completing linear measurements in

all three dimensions of space as well as tooth-size arch-length analysis. Measurements were taken manually on the dry skulls with a caliper and digitally on the scanned arches using Studio Basic software (version 0.1; nettfabb, Lupburg, Germany). The study found near-perfect agreement between the manual measurements and those made on the iTero® models showing that models produced from iTero® scans are highly accurate.[24] Other studies have confirmed the validity and reproducibility of measurements made on digital stereolithographic models produced from intraoral scanners .[25-27]

There are a number of advantages to the use of the iTero® scanner for Invisalign® cases in place of traditional PVS impressions. Scans with iTero® avoid some of the negatives that come with PVS impressions such as impression instability and lacerated margins.[23] There is quality control built into the scanning software of the iTero® machine so that before the scan is sent to Align Technology, the clinician can see via color indicators areas that were missed in the scan. Although a PVS impression can be scanned visually for quality, there is not a second level of quality control showing the

clinician areas he or she did not capture in the impression. In fact, in a study that included 328 iTero® scans sent into Align Technology for the fabrication of Invisalign® aligners, less than 1% were rejected.[23] One could argue that aligners fabricated from an iTero® scan may fit better than those produced from a PVS impression, especially in a case involving severe crowding. When there is a large amount of crowding, it is difficult to produce a PVS impression that has smooth surfaces and no distortions, but an iTero® scanner can produce a near perfect replication of the teeth regardless of crowding.[23]

For years, orthodontists have employed photographs, cephalometric superimposition, and measurements on plaster casts to evaluate orthodontic posttreatment outcomes. However, with the introduction of digital models, such as those produced from intraoral scanners, one can evaluate outcomes by superimposing three-dimensional pretreatment and posttreatment models on each other to see changes that occurred due to orthodontic treatment. Changes in the dentition due to treatment can be measured by superimposing digital models produced at two different time points.[28,29] In order to establish

accurate superimposition of records taken at two time points, one must superimpose on an established stable structure.[28] The palatal rugae have been established as stable registration structures, but can only be applied to maxillary models and models that reproduce the palatal rugae.[30,31] One of the advantages of digital models over cast models is that it allows for the superimposition of models at two time points, permitting an assessment of the outcome of treatment. Additionally, digital models allow for the assessment of an achieved outcome with a planned setup, like that shown in ClinCheck. Grauer explained that spatial registration of the setup model on the final digital models is achieved by an iterative closest point (ICP) algorithm or 'best fit' of surfaces.[29] In order to assess differences between two digital models, a coordinate system must be defined. Both models must be registered on that coordinate system, and then the models can be superimposed so that differences between them can be evaluated. In order to superimpose two digital models, stable structures that did not change over time or treatment must be established and used as the registration areas. From their study where the

investigators assessed the reliability of registration of final digital models to digital models of initial setups, Grauer, et al. concluded that surface-to-surface registration of final orthodontic digital models to planned setup models is reproducible.[29] In addition, a study by Cha, et al. published in 2007 compared this surface-to-surface matching (best-fit method) to traditional superimposition of cephalometric radiographs in 30 extraction cases, and found that this method of 3D model superimposition was as reliable as traditional cephalometric superimposition for assessing orthodontic tooth movements.[32]

Many of the modern studies involving superimposition measurements of orthodontic digital models employ Geomagic™ software (Raindrop Geomagic, Inc, Morrisville, NC), formerly known as Rapidform™.[29,31,33,34] Geomagic™ is currently the best software available for performing accurate three dimensional superimpositions and measurements on digital STL models. Sousa, et al. used Geomagic™ software to perform measurements on 3D digital models and compared these with manual measurements performed directly on the dental casts with a digital

caliper.[34] The study found that there were no statistically significant differences between the manual and digital measurements, and concluded that the measurements completed on the digital models with Geomagic™ software were both accurate and reproducible.

Houle, et al. used Geomagic™ Qualify in a study that investigated the predictability of transverse changes with the Invisalign® system by comparing the ClinCheck changes in each arch with the actual clinical changes in the transverse dimension in each arch.[19] All pre- and posttreatment models were produced by an iTero scanner, and the digital arch width measurements were completed on the ClinCheck and the iTero digital models using Geomagic™ Qualify software. The study found that the mean accuracy of predicted expansion of the maxilla with Invisalign was 72.8% and the mandible was 87.7%. The investigators concluded that expansion with Invisalign becomes less accurate as movement moves more posteriorly and that expansion with Invisalign involves more tipping than bodily movement. They came to this second conclusion because they found more accurate expansion at the cusp tips than at the gingival margins, thereby

suggesting to plan for overcorrection when expanding with Invisalign. This study did not include patients treated with the SmartTrack™ material.

It is clear that the Invisalign appliance has evolved since its introduction with the first generation of aligners merely relying on the aligner alone to achieve tooth movement.[3] Since those initial aligners, the system has advanced incorporating attachments and later optimized attachments and power ridges to better create desired tooth movement. Align technology incorporated the iTero scanner to make the process of fabricating aligners more efficient and more accurate. Since the Invisalign system has not been on the market as long as many of the fixed appliances, there are fewer studies available on the efficacy of this system. In a systematic review looking at the efficacy of clear aligners, Rossini, et al. concluded the studies published to date in this area were lacking in quality due to various methodological insufficiencies preventing any evidence-based conclusions.[20] Furthermore, as the Invisalign appliance changes, new studies are necessary

to investigate whether or not the alterations make the appliance more efficacious and predictable.

The purpose of the following study is to investigate how accurately the final ClinCheck model predicts the final position of all teeth in the arches after the completion of a full set of Invisalign aligners made with SmartTrack™ material and generated from an iTero scan. Unlike some of the earlier studies, all the cases included in this study were treated by an orthodontist experienced in Invisalign. In fact, the orthodontist is a Top 1% Invisalign provider, meaning he is among the most experienced clinicians in orthodontic treatment with Invisalign. The final ClinCheck is a very important tool in case acceptance by the clinician and by the patient. If there are areas in which the ClinCheck inaccurately projects tooth movement, the clinician cannot rely completely on this prediction when submitting a case to Invisalign. However, if the clinician is aware of the movements or areas where the ClinCheck predictions are more accurate and those that are less precise, he or she can alter the treatment plan to include overcorrection,

mid-course correction, or final refinements to ensure the best final outcome.

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STATEMENT OF THESIS

The objective of this retrospective study was to examine how accurately the digital model prediction in ClinCheck matches the final clinical digital model after completing a set of Invisalign® aligners. All cases were treated by a top Invisalign® provider using SmartTrack™ material. Predicted STL models and actual final clinical STL models were superimposed and the three-dimensional differences between the teeth in the entire arch were compared.

Null Hypothesis: The average tooth positions of the digital model produced by intraoral scan at the end of Invisalign® treatment using SmartTrack™ material is greater than or equal to 70% of the final predicted tooth positions of the digital model produced by ClinCheck®.

Alternative Hypothesis: The average tooth positions of the digital model produced by intraoral scan at the end of Invisalign® treatment using SmartTrack™ material is

less than 70% of the final predicted tooth position of the digital model produced by ClinCheck®.

The Accuracy of Invisalign ClinCheck Prediction Compared to Clinical Results

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ABSTRACT

Introduction: Our objective in this retrospective study was to examine how accurately the digital model prediction in ClinCheck® matches the final clinical digital model after completing a set of Invisalign® aligners. **Methods:** The sample included 30 non-growing patients (60 arches) treated with Invisalign®. All subjects completed a full series of aligners and required a refinement series of aligners. Predicted models were obtained from the initial ClinCheck and the achieved models were obtained from the initial stage of the refinement ClinCheck. The two stereolithographic (STL) models were superimposed using Geomagic® Control X™ software via a best-fit algorithm. The three-dimensional differences were compared at four different tolerance levels of 0.25 mm, 0.5 mm, 0.75 mm, and 1.0 mm. **Results:** The average amount of surface-surface overlap between the predicted and achieved models was 70.4% at 0.25 mm, 89.2% at 0.5 mm, 95.4% at 0.75 mm, and 97.6% at 1.0 mm. **Conclusion:** At tolerance levels of 0.5 mm to 1.0 mm, the average percentage of surface-surface overlap for actual clinical models compared to predicted ClinCheck models is greater than the expected 70%. However, at a tolerance of 0.25 mm, the predicted and actual models match at an average of 70%. The clinician should plan for overcorrections and one to two refinement scans from the initiation of treatment with clear aligners in order to achieve optimal clinical results.

Keywords: aligners, superimposition, ClinCheck

INTRODUCTION

Invisalign® (Align Technology, Santa Clara, CA, USA) was introduced to the orthodontic marketplace in 1999 by Align Technology, Inc. as an esthetic alternative to traditional braces. Since its launch, the Invisalign® appliance has undergone numerous changes to increase its effectiveness in addressing more complex malocclusions.[1] With each new generation of aligners, Invisalign® has introduced innovations such as attachments, optimized attachments, and power ridges.

Two major advancements intended to increase the precision of the clear aligners were the acquisition and incorporation of the iTero® intraoral scanner and the introduction of SmartTrack™ material. The iTero® intraoral scanner was acquired by Align Technology in 2011, and the digital models produced by this intraoral scanner have been shown to produce reproducible near-perfect measurements as compared to manual measurements and are able to reproduce detailed anatomy better than traditional PVS impressions.[2–6] Invisalign® changed material to SmartTrack™ material for all aligners manufactured after January 21, 2013. According to the company, this proprietary material is a physical advancement that allows for the delivery of a more constant force and better conformation to the shape of the teeth and attachments permitting more predictable tooth movement.[7] What sets SmartTrack™ apart from the standard aligner material is that it applies less force upon initial insertion and maintains a constant force over the wear

period. The previous material delivered a greater force upon initial insertion creating more discomfort during the first day of wear, and then the force quickly deteriorated. In addition, the SmartTrack™ material has higher elasticity so that the aligner can stretch around the attachments and contours of the teeth and then return more closely to its original conformation. This higher elasticity allows for better tracking than with the previous material.[7]

A number of studies have investigated the effectiveness of the Invisalign® appliance by using the ABO grading system or the PAR index to determine how well the clear aligners performed.[8–12] Other studies measured the efficacy of clear aligners by comparing the clinical results to cases treated in fixed appliances.[9–11,13]

Kravitz, et al.[14,15] employed superimposition to evaluate the efficacy of tooth movement with Invisalign® aligners. These studies only evaluated the tooth movement in the anterior region and were performed prior to the incorporation of the iTero® intraoral scanner and the introduction of SmartTrack™ material. These studies concluded that in the mean accuracy of predicted anterior tooth movement with Invisalign treatment was 41%, with the most accurate tooth movement achieving only 59.3%.[15]

The purpose of this retrospective study is to evaluate how accurately ClinCheck predicts the clinically achieved tooth positions for the entire arch treated with the modern Invisalign® appliance. In other words, this study

looks at how closely the digital model produced as the final stage of the ClinCheck matches the digital model generated from an iTero scan taken after completion of the final stage of aligners. In addition, this study investigates the correlation between accuracy of the ClinCheck prediction to the number of aligners. What sets this study apart from previous clear aligner studies is that the sample was collected from a private practice setting where the orthodontist is a top-tier Invisalign® provider, the entire sample was generated from intraoral scans as opposed to PVS impressions, and the subjects were all treated with aligners made of SmartTrack™ material.

MATERIALS AND METHODS

The Case Western Reserve University (CWRU) Institutional Review Board (IRB) approved this study (IRB-2016-1673). Data was collected retrospectively from the Invisalign website records of patients treated in the private practice of J.W. All records were from ClinChecks generated after February 28, 2013 and prior to October 7, 2016. An assumption was made that the achieved clinical models would have 70% surface-surface overlap agreement with the predicted models. This assumption was based on the findings of previous aligner studies as well as the claim by Align Technology

that the Invisalign® appliance is able to clinically achieve 80% of tooth movement predicted by the ClinCheck and on previous Invisalign® studies.[16,17] The sample comprised of 60 arches from 30 adult patients (7 men, 23 women) with an average age of 37 years and 1 month (range: 19y 0m to 63y 4m). The number of aligners worn to treat these cases ranged from 12 aligners to 55 aligners. All patients included in the study received Invisalign treatment at the private practice of J.W., a top 1% Invisalign provider and Invisalign faculty at CWRU. Aligners were changed every two weeks, as was the treatment protocol at that point in time.

The inclusion criteria were defined as: (1) non-growing patients treated exclusively with the Invisalign® system; (2) patients that required a refinement after completing a full series of Invisalign® treatment; (3) Invisalign prescriptions for both the initial and refinement stages of treatment were generated from an iTero scan; (4) patients who had both arches treated with Invisalign; and (5) patients who began Invisalign® treatment after February 2013 and completed treatment and the refinement scan before October 2016.

The exclusion criteria were defined as: (1) patients who required a mid-course refinement; (2) patients who did not complete the full set of Invisalign aligners; (3) patients with attachments still in place at the time of the refinement scan; (4) patients who underwent restorations between the initial series of aligners and the refinement series of aligners; (5) patients that

underwent extraction for the purpose of orthodontic treatment; and (6) patients with craniofacial anomalies.

From the treating orthodontist's Invisalign doctor site account, 113 subjects were identified as meeting the inclusion. From this group, 30 subjects were randomly selected using a random number generator. Digital models were exported from the Invisalign doctor site as stereolithography (STL) files. The final predicted model and the initial refinement model were exported for each arch. The initial refinement model represented the actual clinically achieved movement of the teeth after the completion of the initial series of aligners.

The predicted and achieved models were imported into MeshLab (open-source, version 1.3.3; http://www.meshlab.net). The program was used to digitally remove the artificial gingiva from the STL models (**Figure 1**). The new models with only the teeth present were saved as STL files and imported into Geomagic® Control X™ software (3D Systems, Morrisville, NC, USA) for superimposition. The final predicted model and the achieved model for each arch were superimposed using the software's best-fit algorithm (**Figure 2)**. The three-dimensional differences between the surface overlap of the two models were compared at four different tolerances of 0.25 mm, 0.5 mm, 0.75 mm, and 1.0 mm (**Figure 3** & **Figure 4**). One examiner performed all superimpositions and measurements (A.W.B.).

Statistical Analysis

Statistical analysis was performed with SPSS version 17.0 for Windows (Statistical Package for the Social Sciences, SPSS 17.0, Inc., Chicago, IL, USA). Descriptive statistics were used to evaluate the data for each tolerance setting (**Table I**). Descriptive statistics were also evaluated for the three-dimensional distances between the predicted and actual models (**Table II**). A one-sample t-test was performed to compare the means for each tolerance setting to the hypothesized mean of 70% agreement between the predicted and actual models (**Table III**). After a two-week interval, 10 arches were randomly selected and measurements were repeated to determine intrarater reliability. In addition, a Pearson correlation analysis was performed in order to determine if there is a correlation between the number of aligners and percent in tolerance for each tolerance setting (**Table IV**).

RESULTS

Of the total number of patients that initiated Invisalign® treatment between February 2013 and October 2016, 173 patients fit the initial inclusion criteria. From that group, a number were discarded because they had worn 1 to 3 overcorrection aligners. The final sample of 30 patients that had both

arches treated was randomly selected from the remaining 113 cases. This sample consisted of 23 females and 7 males with an average age of 37 years and 1 month (range: 19y 0m to 63y 4m).

Descriptive statistics are shown in Table I for each tolerance level setting and Table II shows descriptive statistics for the three-dimensional differences in mm between the superimposed predicted and actual models. For the entire sample, the mean distance between the superimposed models was .29 mm ± .20 mm. At the lowest tolerance setting of 0.25 mm, the average percent in tolerance was 70.4% ± 20.4% (median = 71.56%). A 70.4% surface overlap correlation was observed between the predicted models and the actual clinical models at a tolerance level of 0.25 mm. At a tolerance setting of 0.5 mm, the mean surface overlap between the two models was 89.2% ± 12.0% (median = 92.3%). For the tolerance setting of 0.75 mm the mean surface overlap was 95.4% ± 7.6% (median = 99.0%). Finally, at the highest tolerance setting, the average surface overlap between the models was 97.6% ± 5.0% (median = 99.99%). For all the tolerance levels except for the 0.25 mm setting, the mean surface-surface overlap between the achieved and predicted models was greater than the assumed 70%.

The average number of aligners for this sample was 25.3 aligners with a range from 12 to 55 aligners. The Pearson correlation test showed that

there was a statistically significant correlation (p=0.01) between the number of aligners used and the percent surface-surface overlap for each tolerance setting. The correlation was negative, meaning that as the number of aligners increases, the amount of surface overlap decreases.

The Cronbach Intraclass correlation was 1.000 (95% confidence interval) for the measurements that were retested, meaning that there was 100% agreement between the initial measurements and the retested measurements. Since the measurements are run by a computer algorithm, this agreement would be expected.

DISCUSSION

Orthodontic treatment with clear aligners has increased in popularity over the past decade. A rising number of patients come into orthodontic offices specifically requesting treatment with clear aligners. The expertise of the orthodontist is of utmost importance in setting up the treatment plan for each case treated with the Invisalign® appliance. In order to visualize an Invisalign® treatment plan, the orthodontist must rely on the digital rendering presented in ClinCheck® Pro. The tooth movements that the orthodontist witnesses in the ClinCheck software influences whether he or she hits submit to manufacture aligners or decides to make further changes in the treatment plan. In addition, the ClinCheck software is a tool used to explain the

treatment plan to the patient. The predicted outcome projected by the ClinCheck shows the patient and the orthodontist what they can expect the teeth to look like at the end of treatment with a set of aligners. Therefore, it is important to know, from a clinical standpoint, how much the orthodontist can rely on that ClinCheck to get the expected outcome.

It is difficult to compare the results in this study to previous superimposition studies that evaluated clinical results compared to predicted results of Invisalign® treatment because previous studies looked at specific movements of specific teeth. These studies were also completed prior to the introduction of SmartTrack material and did not employ the iTero scanner. Kravitz, et al.[15] examined specific movements of anterior teeth. These movements were either linear or rotational movements. The mean accuracy of all tooth movements measured in that study was 41% with the most accurate movement being lingual constriction of the mandibular canines at 59.3%. In our study, at the lowest tolerance setting, the average agreement between predicted and achieved surface overlap for the models was 70.4% suggesting that the improvements in the modern Invisalign® appliance have permitted better predictability of the results.

Simon, et al.[18] used superimposition to evaluate the amount of incisor torque, premolar derotation, and molar distalization achieved with Invisalign® aligners. They found that the overall efficacy for all tooth movements was

59.3%. Although our study did not break down specific tooth movements, the overall accuracy at the lowest tolerance setting is higher than this previous study, which was completed prior to the introduction of SmartTrack™ and used laser scanned cast models rather than iTero® intraoral scans.

A more recent study by Houle, et al.[17] investigated the predictability of transverse changes with the Invisalign® system by comparing the changes in the transverse dimension in each arch projected by ClinCheck with changes achieved clinically. Like the current study, this study employed models produced from an iTero® intraoral scanner. They found the mean accuracy of predicted expansion of the maxilla with Invisalign® was 72.8% and of the mandible was 87.7%. This study only investigated one aspect of tooth movement, but the results more closely resemble the findings in our study.

The results of our study suggest that better results were achieved with better technology and more clinical experience with Invisalign® aligners. This advanced technology includes iTero® intraoral scans as opposed to PVS impressions and SmartTrack™ material as opposed to conventional aligner material.

There are a number of limitations associated with this study. All patients included in the study required a refinement scan for an additional set of aligners, indicating that either the patient was not satisfied with the end result of the first set of aligners or the treating orthodontist specifically

planned for a second set of aligners from the initiation of treatment. In other words, based on the clinician's vast amount of experience, he planned that the initial set of aligners would only get the patient part of the way to the ultimate treatment goal. Another limitation was the use of the best-fit algorithm to superimpose the predicted and actual models. The reason this method was used was that it did not place any restrictions on tooth movement and allowed for comparison of tooth movements achieved in the complete arch. Studies have shown that surface-to-surface registration of final orthodontic digital models to a planned set-up is reproducible.[19,20] In addition, a study by Cha, et al. showed that this surface-to-surface matching best-fit superimposition method is as reliable for assessing orthodontic tooth movement as traditional cephalometric superimposition.[21]

One must understand that 70.4% accuracy or 89.2% accuracy does not necessarily mean 70.4% or 89.2% clinical efficacy. In other words, the ClinCheck is approved based on the mechanics that the clinician plans to optimize the final outcome for the case. For example, in a fixed appliance case, the clinician who places a reverse curve arch wire does not desire for the arch form to resemble that curve at the end of the case; rather, he or she uses that reverse curve arch wire to achieve the desired mechanics to level that arch. In the same manner, overcorrections are planned into a ClinCheck for a case so that the desired results are achieved. These overcorrections

could not be taken into account for this study design. Therefore, the results achieved with Invisalign® may have been closer to the clinical goals than the ClinCheck goals.

The results of this study show that in order to improve the outcomes of treatment with clear aligners, the clinician needs to take advantage of the intraoral scanning technology available. The orthodontist should plan for overcorrections and refinement scans as part of the initial treatment plan in order to get achieve optimal results. The need for a refinement scan should not be viewed as failure of the aligner system, but rather as the equivalent of the finishing and detailing stage done in fixed appliances.

Since clear aligner therapy is a newer form of orthodontic treatment compared to fixed appliances, continued studies are needed to make conclusions about what an orthodontist can expect in terms of clinical outcomes. Early studies that looked at outcomes with Invisalign® evaluated cases that were the orthodontists' first set of patients to treat with the appliance. [8–11] This study, on the other hand, had a sample from a very experienced Invisalign® orthodontist. It would be helpful to look at how the clinical outcomes compare to the predicted outcomes among orthodontists with varying amounts of experience with clear aligner treatment. A future study could also look at how accurately the occlusion predicted by the ClinCheck is reproduced clinically by using a similar superimposition process

as used in this study. This study looked at the arches individually, and looking at arches treated together could add valuable information to the knowledge base about treatment with progressive clear aligners.

CONCLUSION

At tolerance levels of 0.5 mm to 1.0 mm, the average percentage of surface-surface overlap for actual clinical models compared to predicted ClinCheck models is greater than the expected 70%. However, at a tolerance of 0.25 mm, the predicted and actual models match at an average of 70%. In addition, there is a negative correlation between the number of aligners and the amount of predicted tooth movement achieved.

At the lowest tolerance level, the Invisalign ClinCheck was 70.4% accurate after the completion of one series of aligners, but since overcorrections were not taken into account, it is likely that the treatment was greater than 70% clinically effective. With improvements in technology and operator skill level, Invisalign can be both a highly effective and predictable treatment. In order to maximize the efficacy of the clear aligner system, the treating orthodontist should plan one or two refinements from the initiation of treatment just as one would plan a finishing and detailing stage with fixed appliances.

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Table I. Descriptive statistics for sample of 60 arches treated with Invisalign®.

	0.25 mm % in tolerance	0.5 mm % in tolerance	0.75 mm % in tolerance	1.0 mm % in tolerance
Mean	70.431580	89.219545	95.391583	97.598932
Median	71.564200	92.338600	99.019350	99.985600
Variance	417.340	143.958	58.401	25.218
Std. Deviation	20.4289111	11.9982607	7.6420848	5.0217284
Minimum	26.9002	50.113	67.5795	78.8140
Maximum	100.0000	100.0000	100.0000	100.0000
Range	73.0998	49.8887	32.4205	21.1860

Table II. Descriptive statistics for 3-D distances between predicted and actual models for sample of 60 arches treated with Invisalign®.

	3-D Comparative distance (in mm)
Mean	.293363
Median	.273200
Variance	.042
Std. Deviation	.2042709
Minimum	.0000
Maximum	.9118
Range	.9118

Table III. One Sample t-test for each tolerance setting.

				95% Confidence Interval of the Difference	
	t	df	Mean Difference	Lower	Upper
0.25 mm% in tolerance	.164	59	.4315800	-4.845767	5.708927
0.5 mm % in tolerance	12.408	59	19.2195450	16.120066	22.319024
0.75 mm % in tolerance	25.737	59	25.3915833	23.417423	27.365743
1.0 mm % in tolerance	42.571	59	27.5989317	26.301682	28.896182

*α = .05
**critical t value for 59 df = 1.6711

Table IV. Pearson Correlation test to determine correlation between number of aligners and percent in tolerance for each setting.

		# Aligners
0.25 mm % in tolerance	Pearson Correlation	-.656**
	Sig. (2-tailed)	.000
	N	60
0.5 mm % in tolerance	Pearson Correlation	-.652**
	Sig. (2-tailed)	.000
	N	60
0.75 mm % in tolerance	Pearson Correlation	-.589**
	Sig. (2-tailed)	.000
	N	60
1.0 mm % in tolerance	Pearson Correlation	-.527**
	Sig. (2-tailed)	.000
	N	60

**Correlation is significant at the 0.01 level.

Figure 1: Removal of artificial gingiva from STL models using MeshLab.

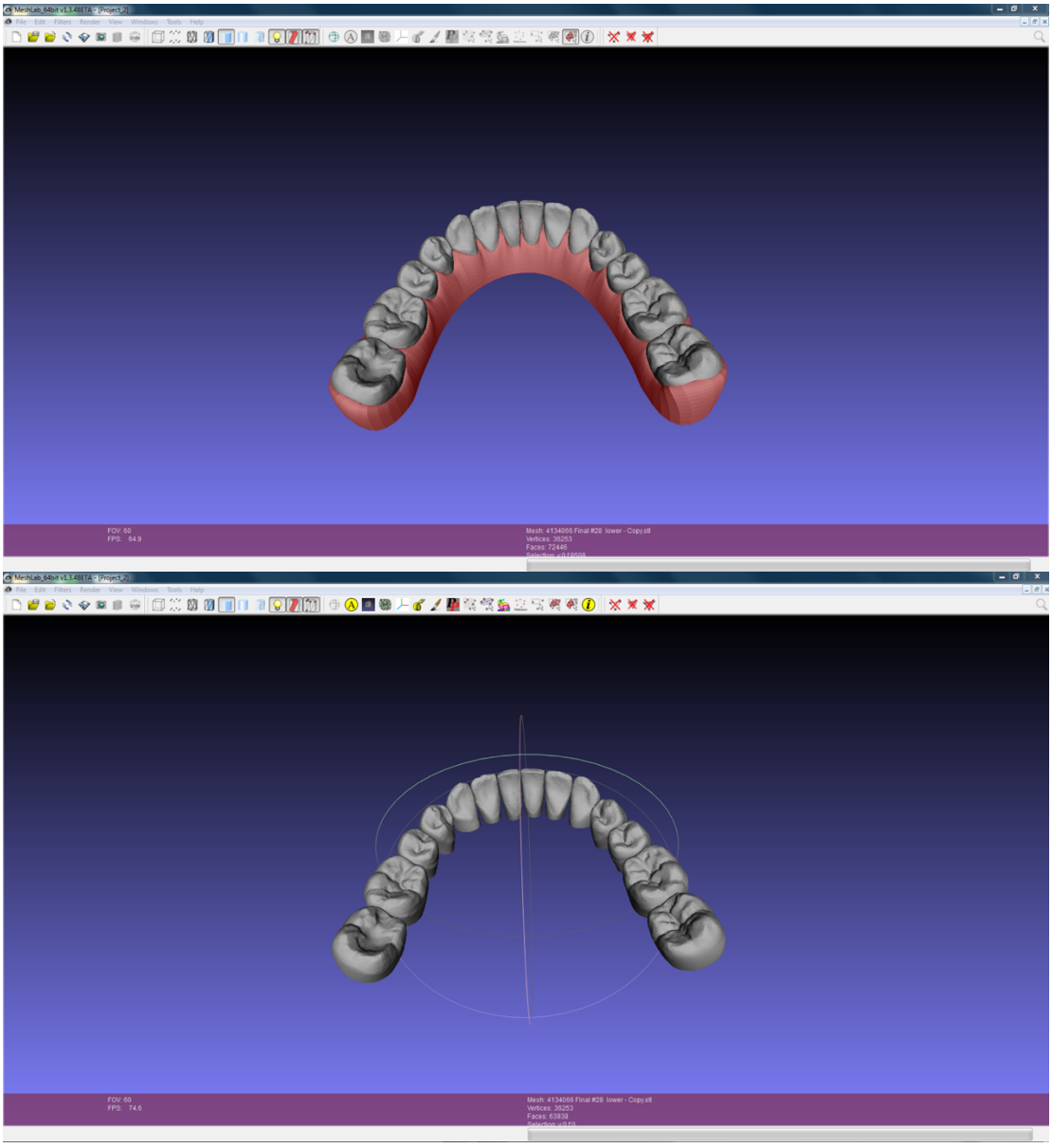


Figure 2: Example of best fit superimposition between predicted model (blue) and actual model (green).

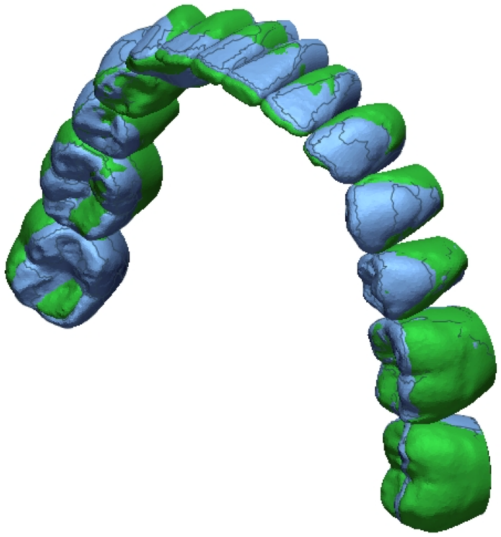
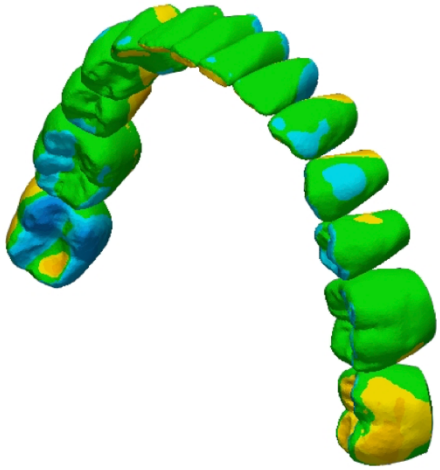
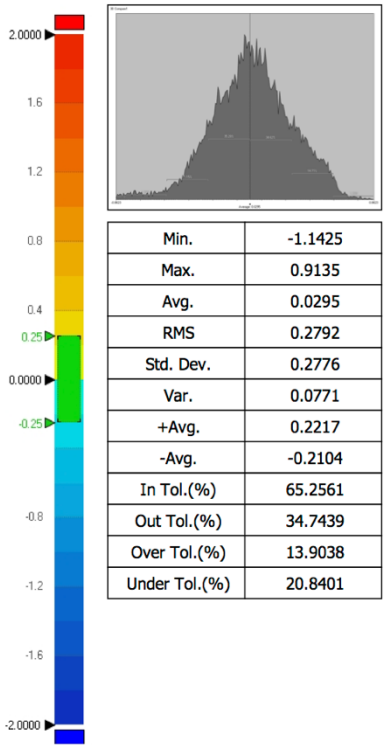


Figure 3: Example of report generated for 3D comparison between predicted and actual models at tolerance setting of 0.25 mm.

3D Compare1



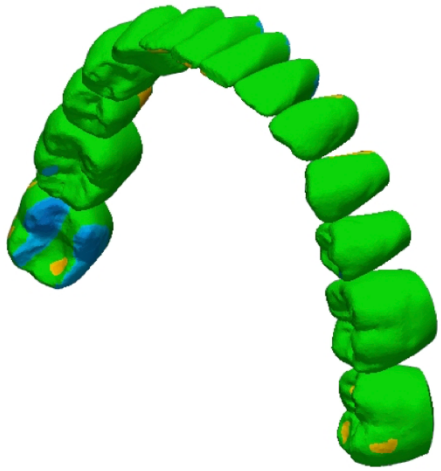


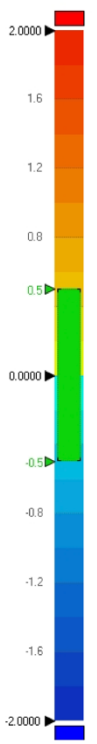
Min.	-1.1425
Max.	0.9135
Avg.	0.0295
RMS	0.2792
Std. Dev.	0.2776
Var.	0.0771
+Avg.	0.2217
-Avg.	-0.2104
In Tol.(%)	65.2561
Out Tol.(%)	34.7439
Over Tol.(%)	13.9038
Under Tol.(%)	20.8401

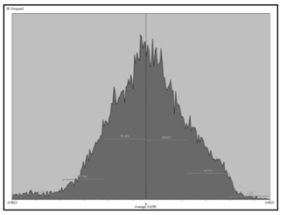
Product Name	4134066	Department	ortho	Date	May 24, 2017
Part Name	lower	Inspector	alw135	Unit	mm

Figure 4: Example of report generated for 3D comparison between predicted and actual models at tolerance setting of 0.5mm.

3D Compare2







Min.	-1.1425
Max.	0.9135
Avg.	0.0295
RMS	0.2792
Std. Dev.	0.2776
Var.	0.0771
+Avg.	0.2217
-Avg.	-0.2104
In Tol.(%)	92.6368
Out Tol.(%)	7.3632
Over Tol.(%)	3.2376
Under Tol.(%)	4.1256

Product Name	4134066	Department	ortho	Date	May 24, 2017
Part Name	lower	Inspector	alw135	Unit	mm

APPENDIX 1

IRB approval



NOTICE OF EXEMPTION #4

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

CWRU IRB Protocol Number:	**IRB-2016-1673**
Protocol Title:	***"Accuracy of Clinical Results of Invisalign System Compared to the ClinCheck Prediction"***
Responsible Investigator (RI):	**Juan Martin Palomo**
Co-Investigator (CI):	**Allison Becker**
RI Department:	**Case Western Reserve University IBC and SBER IRB - DEN - Orthodontics**
Exemption Date:	**10/07/2016**

This protocol is exempt under the #4 category because this involves *EXISTING RETROSPECTIVE DE-IDENTIFIED* data. Prospective data is NOT included in this exemption. If you intend to collect prospective data for this study, then this study might not be eligible for an exemption and you must contact the Institutional Review Board (IRB) office as soon as possible.

De-identified pre-existing data collected **after 10/07/2016** are NOT covered by this exemption.

The CWRU IRB has deemed the above protocol EXEMPT under 45 Code of Federal Regulations (CFR) part 46.101(b)(4). The IRB will not conduct subsequent reviews of this protocol.

PLEASE NOTE THAT THIS ONLY APPLIES TO EXISTING DATA.

IF YOU WISH TO CHANGE THIS EXEMPTED PROTOCOL IN ANY WAY, YOU MUST SUBMIT AN ADDENDUM REQUEST AND WAIT FOR IRB APPROVAL PRIOR TO IMPLEMENTING ANY PROTOCOL CHANGE.

Any changes to the protocol that put it under the purview of the CWRU IRB would require a formal application to, and approval of, the CWRU IRB prior to implementation of the change. Contact the CWRU IRB office for further assistance.

APPENDIX 2

RAW KEY

Arch	Arch treated
U	Maxillary arch
L	Mandibular Arch
Age	Age in years
Aligners	Number of aligners worn in treatment
RMS	Root mean squares showing average positive distance between predicted and achieved models (in mm)
0.25 mm	0.25 mm tolerance setting
0.50 mm	0.50 mm tolerance setting
0.75 mm	0.75 mm tolerance setting
1.0 mm	1.0 mm tolerance setting

APPENDIX 3

RAW DATA

				3D Compare	0.25 mm	0.50 mm	0.75 mm	1.0 mm
Arch	Pt	Age	Aligners	RMS	In Tol.(%)	In Tol.(%)	In Tol.(%)	In Tol.(%)
L	2869440	32	45	0.6105	55.9903	76.7617	86.2964	90.5832
U	2869440	32	45	0.5174	50.9896	77.1064	86.9747	92.403
L	2985659	59	45	0.7315	46.581	71.876	81.9829	87.3354
U	2985659	59	45	0.3828	49.5604	80.1657	94.5527	99.2026
L	2993894	29	17	0.3495	48.1139	83.2328	98.77	100
U	2993894	29	17	0.3634	66.0181	87.0834	93.1894	96.9901
L	3013794	32	24	0.2084	80.5874	96.8873	99.6731	100
U	3013794	32	24	0.1943	82.4688	98.0659	99.882	100
L	3344123	47	41	0.9118	32.9739	56.211	70.1502	78.814
U	3344123	47	41	0.716	40.6652	63.2498	76.4247	84.8895
L	3438498	55	13	0.1965	82.634	97.8072	99.7937	100
U	3438498	55	13	0.3189	53.9972	87.4618	99.5177	99.9857
L	3443072	57	20	0.2671	74.1639	92.0404	98.1099	99.7278
U	3443072	57	20	0.3126	58.5877	89.6167	97.9679	99.5842
L	3592504	39	33	0.304	64.3928	90.9785	97.5725	99.2307
U	3592504	39	33	0.6996	40.7496	66.6616	80.431	86.7678
L	3609590	54	22	0.2138	77.8588	97.427	99.8977	100
U	3609590	54	22	0.3192	57.9627	88.5286	97.7411	99.677
L	3701906	35	28	0.4359	72.9863	84.6096	89.2128	93.5195
U	3701906	35	28	0.3727	51.5349	83.2263	94.7791	98.7547
L	3727777	24	29	0.3069	58.0523	89.0743	99.171	99.9004
U	3727777	24	29	0.3386	52.5833	85.2371	98.2996	99.9855
L	3727976	38	35	0.2251	77.0095	96.1668	99.4549	100
U	3727976	38	35	0.4661	42.2381	72.2597	88.055	96.4656
L	3877079	28	40	0.3522	58.041	86.3754	95.1496	98.3456

U	3877079	28	40	0.7795	26.9002	50.1113	67.5795	79.3072
L	3893497	34	24	0.2239	80.3297	96.2403	99.0022	99.6168
U	3893497	34	24	0.1368	92.7932	99.1792	100	100
L	3907297	26	18	0.3871	59.4869	86.9356	93.4929	96.2774
U	3907297	26	18	0.3182	70.1421	89.4761	95.6338	98.241
L	3918380	21	22	0	100	100	100	100
U	3918380	21	22	0	100	100	100	100
L	3931760	38	19	0.0062	100	100	100	100
U	3931760	38	19	0.0003	100	100	100	100
L	4058517	31	12	0.177	86.5291	98.8339	99.8658	100
U	4058517	31	12	0.1386	92.8488	99.3145	100	100
L	4119128	30	12	0.1523	89.1049	99.5498	100	100
U	4119128	30	12	0.1782	88.3152	97.9575	100	100
L	4134066	28	28	0.2792	65.2561	92.6368	98.5884	99.8535
U	4134066	28	28	0.3418	60.478	87.7578	96.4368	98.3169
L	4144968	43	16	0.293	60.7627	90.7205	99.0365	99.9911
U	4144968	43	16	0.1774	85.5205	98.4035	99.9979	100
L	4144980	63	18	0.2672	66.5563	94.021	99.4811	99.9523
U	4144980	63	18	0.2307	80.2993	94.6398	98.7851	100
L	4149116	37	22	0.171	85.573	99.815	100	100
U	4149116	37	22	0.3605	56.1148	84.8582	94.7966	98.6813
L	4231425	38	21	0.2087	79.7031	97.2074	99.8135	100
U	4231425	38	21	0.1811	84.513	99.3988	100	100
L	4231477	19	13	0.0028	100	100	100	100
U	4231477	19	13	0.0065	100	100	100	100
L	4266703	29	13	0.0061	100	100	100	100
U	4266703	29	13	0.0014	100	100	100	100
L	4328514	47	55	0.2928	61.6766	90.9288	98.7596	99.8754
U	4328514	47	55	0.4132	43.0481	78.8609	92.8997	98.3178
L	4332016	41	13	0.1616	88.0345	99.6691	100	100

U	4332016	41	13	0.1775	91.209	96.6952	99.2428	100
L	4361680	33	28	0.177	88.6554	97.0015	100	100
U	4361680	33	28	0.178	87.0023	98.7859	99.6505	100
L	4119158	49	32	0.4609	40.1372	71.0683	88.9434	97.422
U	4119158	49	32	0.6005	38.1641	64.995	78.4393	87.9209