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ABSTRACT

Recently, the use of electronic digital models has come into common use. GAC International Inc. is one company that has recently instituted a computer based electronic model program called Orthoplex. This company uses Cone Beam Computed Tomography (CBCT) scans of the original impression of a patient's dentition and converts this impression into an electronic representation viewable by the practitioner on a standard computer. The purpose of this study was to compare the accuracy and reliability of Orthoplex electronic models in relation to the current gold standard stone models. Candidates were selected from residents, patients, dental students, and staff of the University of Alabama at Birmingham Dental School. A total of 20 patients were included in the study after application of the inclusion and exclusion criteria. Polyvinyl siloxane impression material was used for the impressions of the maxillary and mandibular arches. Dental stone was used to pour up the initial diagnostic casts. The impressions were then sent to GAC International Inc. and converted to a digital model through the use of CBCT scan of the impression. The files were downloaded from the company website and accessed through the Orthoplex software. Measurements were made on the stone models and their digital counterparts in both the maxillary and mandibular arch. Six measurements were performed in each individual arch. Two sets of casts were chosen to be measured at three different time intervals to verify intraoperator error. Measurements were evaluated statistically using a least squares mean for analysis

of the intraoperator error and reported as the intraclass correlation coefficient (ICC) to verify reliability. The accuracy was verified with an analysis of variance reported at the 95% confidence level. There was a strong correlation for measurements with the ICC except for mesiodistal width of the left molar and the occlusogingival height of the right molar, which is based on the similarity between patients and not an accurate representation of the group differences. There was a statistical difference between the measurements at the 95% confidence level, but the clinical significance of these measurements is in question. Therefore, measurements made on electronic models are statistically different in relation to their accuracy, but the models are an effective way of storing and representing the actual dentition.

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INTRODUCTION

The profession of orthodontics has used diagnostic records and clinical examinations as part of the treatment planning process since the creation of the specialty itself. Diagnostic records are a valuable way to accumulate information about a patient's chief complaint and malocclusion in relation to the skeletal pattern and facial profile that the patient presents. It is also a method of documenting treatment starting conditions and supplementing the data gathered in the clinical examination. The information gathered from diagnostic records is only as accurate and reliable as the records themselves. Diagnostic records provide the practitioner with the information required to evaluate occlusal, skeletal, and soft tissue relationships after the clinical examination has been performed and the patient has left the office. The data gathered from these records is dependent on the quality and reliability of each individual section of the diagnostic exam.[1] In addition, diagnostic records are a safeguard to a practicing orthodontist against lawsuits pertaining to patient's treatment.

The standard of care for diagnostic records has been set forth by the American Association of Orthodontics. In 1988, the American Association of Orthodontists has recommended that the treatment planning process consist of eight different areas to gather and quantify information relating to a patients malocclusion. These are: patient and parent objectives; medical and dental history; clinical examination; full face and profile photographs; dental casts; intraoral photographs; lateral cephalograms; and complete intraoral and panoramic radiographs.[2,3]

Diagnostic records are used to gather information about a patient's soft tissue, skeletal, and dental structures in relation to three planes of space. The vertical, horizontal and sagittal planes of space must be evaluated by the orthodontist to gain an appreciation for the extent of the malocclusion and the skeletal classification of the jaws. The teeth and structures of the oral cavity, the occlusion, the facial and jaw proportions are all evaluated categorically in the diagnostic records.[1] Han[2], in a study relating treatment decisions to the orthodontic diagnostic records, indicated that 55% of orthodontic treatment plans derived from dental casts alone were unchanged regardless of other diagnostic records that were given to the practitioners for further consideration.

Dental casts have been used in orthodontic treatment planning for many years. There are two main types of dental replications that can be used for evaluation after the clinical assessment has been performed. The traditional "gold standard" has always been casts that were made out of dental stone. These stone models have stood the test of time and have been used universally for evaluation until recently. In the early 2000's electronic models were introduced and are commonly referred to as *electronic models*, *digital models* or *virtual models*. Regardless of what they are called, these images of models have given a digital alternative to practitioners to allow for a truly paperless system of recording and evaluating clinical data. Many companies have now converted traditional stone models into a three dimensional digital representation to be viewed on a computer screen and evaluated electronically. Advantages and disadvantages exist with both types, but the fact remains that the dental casts are required for proper diagnosis and treatment planning.

Stone models were the initial and only three dimensional assessment tool used by orthodontists after the clinical exam was complete. Historically, dentists have been trying to capture exact replications of the teeth since the late 1600's. In 1684, a German surgeon made a reference to the use of beeswax to obtain dental impressions.[4] Although much has changed in the technology associated with the material used to fabricate an impression, the desire for accuracy of the impression material has remained constant. Gutta percha was used as an impression material in 1848, but it did not accurately replicate detail or maintain its dimensions long enough to be considered a viable option. Another option was Plaster of Paris, which was first used in dentistry as an impression material before it was used as a developing stone.[4] It was not ideally suited for taking impressions because of the brittleness of the material and the difficulty with removing an impression from the mouth once the material had set. The need for a material with ideal properties of strength and reliability was needed to be able to accurately replicate the natural dentition of a patient.

Irreversible hydrocolloid material, or alginate, was introduced to dentistry in 1943. At this time in history, alginate was seen in short supply due to the fact that Japan was the major producer of the main component, agar, which was obtained from seaweed. The United States was in the middle of World War II and, based on this fact, the U.S. was not able to procure the required amount to make the impression material to supply the demand.[4] Since then, alginate has been used in a wide variety of specialties and for practical purposes in general dentistry to replicate the teeth and tissues for further evaluation.

Polyvinyl siloxane (PVS) was invented and introduced in the 1970's as an alternative to alginates. With increased stability over alginate, PVS has become more popular in the specialty of prosthodontics than in orthodontics, despite the fact of the increased price. However, PVS has seen a resurgence in orthodontics with the emergence of digital models and computer generated treatment modalities requiring impressions fabricated from these elastomeric materials. Since the introduction of alginates and PVS, these materials have been used for the majority of impressions in orthodontics.

The most commonly used impression material for orthodontic models is the irreversible hydrocolloid impression material, or alginates. Alginate has been used since the early 1940's. It has been a mainstay of orthodontic practices because of the ease of use and the relatively low cost when compared with PVS. Alginate is not a dimensionally stable impression material, however. Alginate will begin to distort if not poured up in dental stone within ten minutes of being removed from the mouth.[5] This is irrelevant of the storage condition in relation to the water content of the surrounding environment, whether there is too much water or not enough. The movement of water out of the alginate is termed syneresis and the movement of water into the alginate is termed imbibition. As a result of these and other chemical reactions within the material, initial expansion and elastic deformation of the alginate occurs.[5] Alginate that is maintained in more humid conditions or at 100% relative humidity will still have a tendency to distort from the initial setting of the material.[6] Despite these shortcomings, alginates are still the predominant impression material for general use in most orthodontic practices and have provided the required accuracy demanded by the profession for decades.

Replication of a dentition is used as a means to evaluate oral structures with accuracy, but in a more conducive environment than the oral cavity. Nicholls is quoted as saying that dimensional stability is “the ability (of a material) to maintain accuracy over time”.[5, 6] If a material is truly dimensionally stable, this will allow more specific measurements to be taken and recorded.

PVS seems to be able to satisfy this demand for stability and allow for more precision when impressions are performed according to manufacturer’s instructions. PVS is being more widely used in dentistry because of the facts that they are extremely accurate according to the specifications required of elastomeric impression materials and they are odorless and virtually tasteless when compared with other impressions materials.[7,8] PVS, unlike alginate, comes in different viscosities according the needs of the practitioner who is using the material. Light, medium, and heavy body are the three available viscosities provided by most PVS manufacturers. Light body has a very low viscosity and heavy body has a high viscosity. All three consistencies will vary as to the amount of detail that they will be able to duplicate. In general, each of these PVS impression materials will need to replicate a line that is 0.020mm in width to be within standards of the international standard for dental elastomeric impression materials.[8] Light body is able to reproduce lines that is 1-2 micrometers wide.[9,10] The price of PVS impression materials is a major deterrent to its general use in orthodontics. PVS is ten times more expensive than alginate impression materials, and is warranted in limited applications is orthodontics.

PVS impression material has an increased dimensional stability when compared with irreversible hydrocolloid materials. The increased dimensional stability is mainly due to the type of reaction that occurs within the material. When the base and the catalyst are mixed prior to insertion in to the mouth, a polymerization reaction is started that will progress until the material has reached its final set. During this reaction, there is an inherent amount of shrinkage that occurs directly after removing the impression from the mouth. The amount of reduction can range from 0.1 to 0.05 percent.[11, 13,14] The shrinkage occurs within minutes and is usually complete by the time the impression is poured in dental stone.[10] The impression material is not dependent on storage conditions, such as humidity and temperature for its stability and relies on the initial reaction for its strength and accuracy. Therefore, it is more stable long term, and can be poured more than once with the same level of accuracy as the original.[9]

After an impression is taken with any impression material, it must be poured up in a dental stone to allow a positive reproduction of the negative impression of the teeth and tissues. The dental stone used in dentistry are products of gypsum. Gypsum products are a form of calcium sulfate hemihydrates ($Ca\ So_4 \cdot 1/2H_20$). The American Dental Association has classified these products into five types according to the ADA Specification #25.[12] Classifications of the products are as follows: Type I is impression plaster; Type II is model plaster; Type III is dental stone; Type IV is dental stone with high strength and low expansion, and Type V is dental stone with high strength, and high expansion. These different products have the same components, but all possess different physical properties making each suited for different purposes in dentistry.

Gypsum products used in dentistry have some degree of expansion before they reach their final set. Different manufacturers have attempted to apply modifications to their products to minimize this expansion, but have been unsuccessful in removing the expansion entirely. The expansion of the stone is due to growth and development of the crystalline hemihydrate lattice from the solution created when mixing it with water, and this development enlarges the gypsum crystals during setting.[13,14] The expansion that occurs has been estimated to offset the shrinkage that occurs in the PVS impression materials and can allow the positive reproduction of the teeth to be statistically accurate and may even be larger than the actual dentition.[6]

The term plaster models used in orthodontics is somewhat of a misnomer because it is actually a type III classification dental stone. The Type III stone most commonly used has an expansion rate of .09%, but other type III dental stones have expansion up to 0.14%, according to the manufacturer specifications.[15] The amount of reduction in the impression material is almost exactly the amount of the expansion of the stone and would, in effect, cancel the effect of either when comparing measurements to the original dentition. Stone casts are an integral part of orthodontic diagnosis and treatment planning and have been viewed as the gold standard for three dimensional verification of oral structures.

Electronic computer based models are gaining in popularity and acceptance in the orthodontic community. Digital conversion has seemed inevitable in every aspect of an orthodontic practice, and as the “technology age” becomes more of a necessity than a novelty, more and more practitioners are learning to use digital models as a means for assessing dental malocclusions.

There are advantages and disadvantages when using either digital or stone dental models as part of diagnostic records. Stone models are a mainstay with many orthodontic professionals and have distinct advantages when compared with digital images. Many practitioners like to have the "plaster in their hands" to be able to feel and evaluate the teeth in a true three dimensional likeness. Most orthodontists were educated this way and it is how they were trained to view occlusal discrepancies. Another advantage that stone offers is the cost of fabrication. Stone models are relatively inexpensive to make when compared with digital models. Most orthodontists do not view digital models as useful or necessary[16], and based on this, it is not likely that practitioners will change systems unless a distinct advantage is proposed.

The disadvantages with stone models relate to the physical nature of the model itself. Stone models are prone to breakage and damage. Stone is a brittle material and will fracture or chip when not handled correctly. There is also the disadvantage of storage of orthodontic models. Records need to be maintained for a specified number of years after treatment completion depending on legal requirements. The physical facilities required to store numerous records have been a dilemma that orthodontists have been dealing with for decades. Also, stone models do not allow for easy sharing of information and assessments with other professionals separated by distance. This can be cumbersome and inefficient when discussing multidisciplinary treatment plans with other participating professionals.

Many different studies and attempts have been made to convert these stone models to a more efficient and equally as effective form that can be easily manipulated and viewed by the common practitioner. The desire to have a completely digital record started long before any private companies came into the realm of proprietary digital model fabrication. Many different types of techniques have been used to try and convert models into a more manageable form.

Holography was one of the early techniques attempted to replicate the dental condition. Holography is a technique that utilizes scattered light from an object and records it on a specific material that will capture the information from the light. After the light scatter is recorded it is later reconstructed to appear exactly as the object did before it was converted to an image. This allows the observer to view the object on a two dimensional medium with the effect that it is a three dimensional object. Holography was first introduced in 1948 by a Hungarian physicist, Dennis Gabor, and it was claimed as a new type of microscopy.[17]

It was not until the introduction of lasers that advances came with the holographic technique. Leith and Upatnieks[18] used holography with laser beams to try to increase the accuracy with which the information was transferred to the recording material. Phillips[19] was responsible for increasing the definition and quality of the hologram through usage of a new technique within the photochemical process itself. Holography does allow direct measurements of three dimensional displacements and these measurements can be as small as a few micrometers.[20]

The main disadvantages of holography, according to Bell and Ayoub[21], relates to the increased cost of reproduction and the difficulty of producing the images. It requires a very specific camera to record the images in the holographic form. This technique also does not convert the object into a digital format that can be used on a computer or allow the image to be manipulated in any way, but must be viewed as a photograph on a two dimensional piece of paper. Holograms do allow a record to be more easily stored as a photograph would be stored in the patients permanent record, but will not be the method of choice to replace the stone model.

Stereophotogrammetry is another technique that has been used for electronic conversion of stone models. Pulfrich was the first scientist to invent a sterocomparator.[22] Initially, in dentistry, it was used to record the soft tissues of the face, but recent research has allowed for conversion of models to a digital format.[21] Photogrammetry itself is a technology utilizing the geometry of an object recorded from a photograph. A specific point on an object can be measured on the captured image and the distance between them can be calculated. Adding more cameras allows more complexity and more detail to be recorded. Stereophotogrammetry has two or more photographic images from different sites and at different angles recording the same point on an object. Through common mathematical calculations of triangulation, the exact position of the point can be recorded and detail of the image can be captured in a three dimensional computer based representation of this information.[21] Advancements in the field of computer graphics has made this, and many other types of electronic computer based analysis possible. Stereophotogrammetric techniques were utilized late in the 1980's for soft tissue analysis[23], and has now been evaluated for use in orthodontics to convert models to a digital format.[21]

Just as in the use of holography, the introduction of lasers to the realm of scanning objects increased the ability of researchers to capture minute detail and specific anatomy that was not possible before. The advent and use of computer aided design and computer aided manufacturing (CAD CAM) technology allowed the information captured through laser scanning to be converted to a digital format which in turn could be manipulated and viewed by practitioners.[24] There are two main scanning categories; contact scanning and noncontact scanning. Non-contact scanning is defined as the scanning process that never has the diode of the laser touch the surface of the object being scanned. It is the majority of the scanning that is used in the field of dentistry. This is true regardless of which discipline that is being referenced, and it was starting to become more commonplace in dentistry, especially in prosthodontics in the 1980's.[20]

Many different companies are incorporating digital models into the realm of products that they offer. Geodigm[25] and Orthocad[26] are the first and most commonly known companies that have offered electronic models. Each company utilizes different techniques for conversion of the impression sent from the practitioner's office to an electronic representation that can be viewed on a computer screen. Dental impressions are sent to the facilities where the actual scanning devices are located. Here the impression can either be made into a stone model for scanning or the impression itself can be scanned.

In the process of conversion used with a stone model, there are two different types of scanning that can occur. The first is the use of a noncontact laser to scan the surface and leave the model unharmed. This allows the model to be scanned in exact detail. The model can be scanned by a laser as described previously. Early lasers used point scanning which was very time consuming and not as detailed as later versions. Line laser scanning made it more expedient by recording many points at one time in a thin line that would systematically cover the entire surface of the model or object. Stripe laser scanning increased the number of points that were utilized and the information that was gathered by increasing the width of the laser line scan and thereby increased the data points that are gathered with a single pass reducing the number of passes that had to occur to record the entire surface of the object.[27] Only one object can be scanned at a time in most instances and it is a more time intensive process for a large number of impressions. It is also very difficult to include to scan an impression with this process because of undercuts that may be present in the impression itself.[28]

The second technique utilizing the stone model is a process that requires the sequential milling of the stone model at certain set increments and the scanning of the milled section with each pass. This is referred to as destructive scanning. It is very similar to how computed tomography captures scans of the body, but instead of scanning with slices of radiation, it actual mills the model to the designated thickness. The models is encased in a resin before it is milled to the desired thickness and scanned. Each scanned is combined with the others to create a three dimensional representation of the models. This is a more time intensive process per model and destroys the stone models in the conversion, but many models can be encased and milled at one time giving an increase in the efficiency of the conversion process.[28]

The second type of technique for conversion is the process of scanning the physical impression and not its positive reproduction of the stone model. The impression can be coated with a material that contains different metallic components that allows the laser to capture the data points in specific detail. A “direct line of sight” must be accomplished in order to account for any undercuts that may be present in the dentition. After the scan is complete, the information is processed the same way as the process that utilizes the stone models. An additional method of capturing the information for some more recent companies, such as GAC Inc. International[29], refers to the use of a Cone Beam Computed Tomography (CBCT) or Computed Tomography (CT) scanner that is normally utilized for industrial purposes, to capture the information necessary for digital conversion directly from the impression with no need of a prepared stone model. The ability to eliminate the production of a stone model reduces the inherent discrepancies between the impression and the model that is fabricated from it. This is a new technology and most of the studies that have been performed to verify the accuracy of these digital models were not constructed with the CBCT technology. Most of these were with the laser scanner. Many companies are currently converting to the CBCT due to the reduction in cost associated with production of a stone model.

Many studies have been performed attempting to make the true three dimensional stone models to a usable and accurate reproduction. These could be utilized by the professional with a reasonable amount of ease, and make storage easier whether utilizing a paper record or a digital one.

One of the earlier attempts was by Schirmer and Wiltshire[30] who attempted to utilize photocopies of stone models in a comparative study to evaluate the assessment and evaluation of space analysis manually and digitally. Photocopies were measured with a digitizer and the results were evaluated with computer software. These results were compared with manual measurements made by the same examiners who performed the digital measurements. They concluded that three dimensional images of casts cannot be accurately evaluated or reproduced when compared to the manual measurements of the stone models.

Kuroda and Motahashi [31, 32] developed a laser scanning system that was used to analyze dental casts to try and create a three dimensional computer graphic. They utilized a slit laser scanner with CCD cameras to record the data in 1996. Despite the fact that the process was fast and accurate, they found that they could not record samples beneath the overhangs in the dentition or soft tissue. The latter creates blind spots in the data and the resulting image that is being recorded. In 1999 they utilized two different slit laser scans from different axis' to eliminate the issue with the registration of data under overhangs in the natural dentition. They stated that " great efforts were made to minimize blind regions in the generation of a 3D computer graphic….the use of this system is feasible not only for treatment planning and diagnosis, but also for saving time and labor required to make the diagnostic cast". [32] They found their accuracy to be within .05mm from manual measurements to digital measurements, but the scanning process needed 40 minutes per arch to register all the data points necessary for an accurate computer graphic.

As the technology with which to record the data progressed, more commercial companies manufactured virtual models. In a correlating effect, the analysis of the accuracy of these reproductions increased. Tomassetti et al[33] evaluated the accuracy and the time needed to perform a Bolton tooth size analysis with 4 different methods. They utilized the traditional method with vernier calipers as the gold standard on 22 sets of models. They also utilized two software programs, Quickceph and Hamilton Arch Tooth System(HATS) software, to record the measurements digitally. They used one truly three dimensional computer based representation from OrthoCad (CADENT Inc.). They performed both an anterior Bolton ratio analysis and an overall Bolton ratio to see which of the methods was most accurate in its measurements and most efficient according to time spent performing the analysis. They concluded that "OrthoCad had less correlated results and the differences were of greater magnitude" [32] than the gold standard vernier calipers. They stated that 72.7% of the overall ratios and 81.8% of the anterior ratios were within 1.5 mm of each other, but stated that these were not clinically significant. They also stated that identifying proper landmarks was difficult with the OrthoCad system.

Garrino and Garrino[34] evaluated the digital and stone models of 40 patients utilizing the OrthoCad system. They identified landmarks on each cast and measured the casts two separate times with the OrthoCad software and with digital calipers at least two weeks apart. They compared the results of the two groups as well as the results to calculate inter and intraoperator error. Student t tests were performed to compare the means. They found that for both groups the digital casts had a reduced difference and were more accurate than the stone models. The increased precision was displayed with the value of the differences between the two consecutive measurements.[34]

In 2003, Santoro et al[35] compared Orthocad models with the stone models. They assessed 20 random patients with a full complement of teeth. The evaluation was carried out by two different examiners. The purpose was to compare the reliability of the Orthocad versus the stone models. They found a statistically significant difference between the two groups when comparing tooth size and overbite, with the digital study models being consistently smaller. With a range of 0.16mm to 0.49mm they concluded that these measurements were not clinically relevant. They did not find any difference between the two examiners and the two media when considering overjet.[35]

Studies concerning the validity of the measurements performed on the study models are of increasing frequency. Zilberman and colleagues[35] evaluated the validity of measurements made on 20 different models that were set up in varying malocclusions based on the positions of individual and fully adjustable teeth. Intercanine width, intermolar width, and mesiodistal tooth measurements were evaluated with vernier calipers with digital accuracy up to 0.01mm, and also on Orthocad software. They found that the measurements made directly on the cast with electronic calipers were more accurate and more easily duplicated. There were also less errors when comparing inter- and intraobserver measurements. Despite these findings, they stated that orthocad showed statistical correlation that was similar in comparison with the electronic calipers on stone models and concluded that "Orthocad accuracy is clinically acceptable".[35]

Reliability of measurements is an important aspect of data gathered by an orthodontist during an examination. Quimby et al[37] evaluated the accuracy and the reliability of the electronic models. They had 50 casts from random patients evaluated and measured by 2 examiners and compared the data between the two. They also had 10 random patients' casts measured and compared by 10 examiners to verify the reliability of the electronic software. They concluded that with a correlation that was greater than .90, there is a high degree of reliability between stone models with electronic calipers and a completely digital evaluation system, such as the Orthocad system, in their study. They also found that significant differences existed between all ten examiners, and each examiner differed significantly between stone and digital models. Nonetheless, they concluded that they were able to demonstrate the accuracy and reliability of electronic model software with this study.[37]

It is appropriate to discuss the relevance of significance when relating to the reproduction of models. Statistical significance is beyond reproach, but there comes a discussion on the idea of clinical significance. Many authors have been quoted with their different ideas on clinical significance. Schirmer and Wiltshire[30] stated that any measurement less than 0.20 mm is clinically acceptable, and Hirogaki[38] stated that the required level of accuracy should be at 0.30mm, but Santoro[35] stated that anything less than 0.49 is not clinically significant. But the question must be asked that if we are trying to go to a digital age, shouldn't the technology be as accurate as what we can accomplish manually? Some CT scanners in industrial use are recording accuracy to the level of microns, why should we accept anything less for our evaluation of the natural dentition?

The purpose of the current study is to verify the accuracy and reliability of the digital models and software (Orthoplex) developed and designed by GAC Inc, International, corp. This company utilizes the Cone Beam Computed Tomography (CBCT) scanner and this technology is relatively new in the history of digital models. Laser scanners have been verified as reliable, but the accuracy of the CBCT in the orthodontic and dental literature has, up to the present time, not been validated.

MATERIALS AND METHODS

The study sample was obtained from the patients, staff, residents, and dental students at the University of Alabama at Birmingham School of Dentistry Postgraduate Orthodontic Clinic. IRB approval was given through the University of Alabama at Birmingham Internal Review Board. Participants were required to have a full complement of teeth from second molar to second molar in the maxillary and mandibular arches. Patients were also required to be healthy with no significant medical history. The dentition needed to have normal morphology with no significant wear or restorations present that would prevent accurate landmark identification. Twenty random participants were selected who met the criteria and each were consecutively assigned a number 1-20 for identification purposes. Informed consent was reviewed with each participant and signed.

Appropriate maxillary and mandibular impression trays (COE Disposable Spacer Trays, GC America Inc., Alsip, IL) were selected for each patient. Tray adhesive (TruTack Tray Adhesive, Ortho Technology, Tampa, FL) was used on each tray. Impressions were taken with polyvinyl siloxane (PVS) impression material (Super hydrophilic impression material monophase fast setting, First Quarter, San Ramon, CA) on each patient for the maxillary and mandibular arch. Each impression was poured up into vacuum mixed dental stone (Microstone, Whip Mix, Louisville, KY) and the stone models were removed and marked for identification. The PVS impressions were sent to GAC International, Inc. for scanning (Industrial Micro CT Prexion, Inc, Manteo, CA) and conversion to a digital model image. The software used for evaluation fo the digital models was Orthoplex (version 2.14) software from GAC International Inc. The electronic models were downloaded from the GAC website to the Orthoplex software on a personal laptop computer (Latitude D820, Dell).

Measurements were made on maxillary and mandibular arches on the stone models and on the digital models. The manual measurements made on the stone models were performed with digital calipers (CEN-Tech 6 inch digital calipers, 47257-OVGA) that had the capability of recording measurements to the nearest 0.01mm. The Orthoplex digital software was utilized to perform the measurements on the digital models and also was capable of recording to the nearest 0.01mm. The three planes of space were incorporated in the assignment of the measurements to accomplish a three dimensional evaluation. These measurements consisted of 6 different site evaluations; mesiolingual cusp tip to mesiolingual cusp tip of second molars (ML 7-7), cusp tip to cusp tip of canines (3-3), mesiodistal width of the left central incisor (MD L1), mesiodistal width of the left first molar (MD L6), occlusogingival height of the right canine(OG R3), and the occlusogingival height of the right first molar (OGR6). These six measurements were made at 3 different time intervals on the first 2 patients initially to determine the amount of intraoperator error present in the stone models and the digital models independently. These measurements were performed on each type of model for the 20 patients. The measurements were made with digital calipers (china, harbor freight tools) on the stone models, and the orthoplex software on the digital models. Both types were measured to the nearest .01mm.

Statistical Analysis

Measurements for the sample comparing the reliability of the operator to perform the same measurements at different time points were analyzed using the method of least squares with the standard error of the mean. The reliability was reported as the intra-class correlation. An analysis of variance was performed to compare the accuracy of the measurements when comparing the stone models to the digital representation at a 95% confidence level with the resulting mean difference between the two different model types.

RESULTS

The sample characteristics of the measurements for the digital and the stone models when comparing intraoperator error at separate time points is illustrated in Table 1. The least squares mean was calculated with a standard error of measurement to allow for a proper comparison within the class of measurements. The intraclass correlation was given for each measurement in the digital and the stone model to compare the reliability of the examiner within the two different media. There was a strong correlation reported for each of the measurements with the exception of the mesiodistal width of the left molar and the occlusogingival height of the right molar. All other measurements showed a strong correlation resulting in a confidence within the operator to perform the measurements reliably from one type to another.

TABLE 1. Method of Least Squares (Standard Error of the Mean) analysis with the intra-class correlation coefficient to evaluate reliability (* not correlated).

Measurements	**Digital**	**ICC**	**Stone**	**ICC**
ML 7-7	44.24 (2.42)	0.9949	44.80 (2.42)	0.9980
3-3	31.41 (3.29)	0.9980	31.47 (3.29)	0.9990
MD L1	7.13 (1.20)	0.9905	7.34 (1.20)	0.9990
MD L6	11.15 (0.15)	0.0000*	11.47 (0.15)	0.9441
OG R3	8.98 (0.37)	0.9077	9.79 (0.37)	0.9077
OG R6	5.70 (0.14)	0.3141*	6.08 (0.14)	0.7750

The p values for analysis of variance of the measurements comparing the accuracy between the stone and digital models as well as the mean difference are shown in Table 2. Four out of the twelve measurements were statistically significant. The maxillary cusp tip from canine to canine, mesiodistal width of the maxillary left central incisor, occlusogingival height of the maxillary right canine, and the occlusogingival height of the mandibular right canine all showed a p value less than 0.05%. The difference between stone and digital models for all measurements was less than 0.5mm.

TABLE 2. Analysis of Variance to account for accuracy between the stone and digital models. (* statistically significant at $p<0.05$)

Measurements	p-value	Mean Diff
Maxilla		
ML 7-7	0.4965	0.21
3-3	0.0429*	0.50
MD L1	0.0361*	0.17
MD L6	0.2849	0.13
OG R3	0.0183*	0.41
OG R6	0.2763	0.12
Mandible		
ML 7-7	0.4359	-0.24
3-3	0.2101	-0.31
MD L1	0.3743	0.07
MD L6	0.8506	-0.02
OG R3	0.0324*	0.37
OG R6	0.1431	0.17

DISCUSSION

The purpose of this study was to verify the accuracy and reliability of the electronic model representation from a CBCT scan of an impression to reproduce the actual dentition and compare it to a physical stone model of the same dentition. The measurements were made on stone casts that were poured from a PVS impression. These stone models served as the "gold standard" for the current study. Measurements were taken from the electronic representation and compared to the measurements taken from the stone models, with each medium. The initial intra-operator error was determined to be reliable based on the fact that the initial measurements had been taken at three different time points. This was in an attempt to test for any intraoperator error that may have been present from the "gold standard" stone model to the digital model. The measurements taken at three different intervals on the digital models, for the most part, had as strong a correlation as the measurements taken on the stone models. The results showed that each measurement on the specific medium within itself had a strong correlation between the separate time points (ICC>0.90) except for two measurements that showed a low correlation. There was a weak correlation when comparing the MDL6 and the OGR6 measurements. Upon review of the data sets, the intra-class correlation coefficient (ICC) showed very low reliability for these two measurement sets. This was due to the fact that the patient measurements were very similar to each other, even though they were from different patients. The ICC is a ratio and is dependent on variability between measurements. Because the measurements were almost identical between the patients analyzed, it showed a low correlation, but was not a true representation of the reliability displayed between the groups. The limitation lies within the variability between the units,[39] and therefore the measurements within the operator are not deemed to be uncorrelated.

The measurements to test the accuracy between stone and digital models had p values that were not statistically significant for the null hypothesis at a 95% confidence level for eight out of the twelve measurements. The four that were statistically significant were the 3-3, MDL1, OGR3 for the maxillary arch and the OGR3 for the mandibular arch. It is the examiner's opinion that out of the measurements taken, the MDL1 and the OGR3 were the most difficult to measure on a consistent basis from stone models to computer representations of the models. The exact contact point when comparing the mesiodistal dimension of the central incisor in the maxillary arch was more difficult to assess in three planes of space when utilizing the Orthoplex proprietary software for the electronic models. Nominal skipping in numbers in the software when attempting to register data points was observed. This increased the difficulty when trying to record the measurements to the nearest 0.01mm. When comparing the digital models to the stone models, stone models seemed to be much easier to get a determinate point at which to make an accurate measurement. The gingival margin on the canines also was difficult to assess with accuracy when comparing measurements that were recorded to the second decimal point. The distinction of the most gingival portion of the clinical crown and the zenith of where the gingival margin ended was more indistinct on the canines when compared to the molars in the software. This may be due to the inexperience of the examiner, or the early version of the software that has since had many updates allowing for more contrast and detail in the representations. The analysis of variance reports the differences as statistically significant, which is in agreement with previous reports.[32, 34, 36]

In comparison of the recorded measurements on the two different media, there was inconsistency as to which one showed larger measurements then the other. This was in contrast to the study by Quimby et al[37] who showed that the larger measurements occurred on the digital system except for overbite and overjet. Santoro[35] reported that the digital system measurements were consistently smaller than the same measurements on stone model and these also did not quite correlate with the present study. This current study used PVS impressions rather than irreversible hydrocolloid material used in other studies and would seem to be more dimensionally stable allowing for the variability to be the result of examiner fallibility and/or the proprietary software.

The statistical significance of the p values has been described, but the question remains as to the clinical significance. When comparing the mean difference of all the measurements that were assessed as statistically significant, the difference was never greater than 0.5 mm with the range being from 0.37 mm to 0.5 mm for the measurements described as clinically significant. It is the view of the author that the differences present between the measurements seem to be small enough that treatment plans or modes of treatment would not be altered based on these differences in assessment between the two systems, but some authors propose that any difference greater than 0.3mm is deemed clinically significant.[21, 30, 38] Nonetheless, when describing technology that seems to be progressing to the level of accuracy of microns, 0.5mm can be of clinical importance for study models and evaluation. It has been argued that this is of little consequence in view of the overall goal of the electronic models to allow for a more complete and truly electronic record, easier storage for practitioners, and easier communication between professionals as well as between the clinician and the patient, but with advances in treatment and technology it could be deemed clinically significant.

The strength and reliability of the study could be improved by increasing the number of timepoints for each measurement for each medium. Performing these measurements for both the intraoperator error and the accuracy and reliability studies would have offered a distinct increase in the quality and power of the current study. Also when evaluating the accuracy of the models, specific physical reference points could be incorporated into the models to allow for a replicated measurement and distinct points for evaluation. Doing this on the two different types of models would allow for verification of the accuracy of the system and not the accuracy of the examiner to replicate points on a natural dentition.

CONCLUSIONS

The results of the present study illustrate the accuracy and reliability of measurements when comparing the stone models with the electronic models. Electronic records have been a desire in orthodontics for many years. The last step for an electronic record has been the conversion of the dental model, the only true three dimensional object in the orthodontic record. Breakage of the model, lack of storage space, and ease of transport and communication have been a drawback of dental models since there use in the specialty. Many concepts and ideas have been researched and tried to replicate dental models for use in an electronic record, but it has not been until recently that there has been a truly accurate way to fabricate and convert dental models to an electronic format. The present results show that the CBCT scan of the dental impression and conversion of the scan into an electronic representation of the models has proved to be an effective way to evaluate a patient's malocclusion in the diagnostic stages, even thought the results showed statistical significance in the null hypothesis. Clinical significance has been shown to be in question due to the fact that many authors state that the level of significance required to achieve clinical relativity differs from study to study.

The present study compared measurements made from stone models and digital models. The evaluation of intraoperator error showed that an inexperienced operator can effectively and reliably make accurate measurements at different points in time. It also showed that despite the statistical significance, that the accuracy of the models is within clinical significance to prove useful to the healthcare provider. With the increase in technology and the demands of the profession, the accuracy will need to be increased to satisfy the clinical requirements for the general use in day to day practice. This study supports the use of digital models as an accurate replacement of the stone models that have been used in orthodontics for decades.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD FOR HUMAN USE APPROVAL FORM

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on October 26, 2010. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56 and ICH GCP Guidelines.

Principal Investigator: BERCHTOLD, THOMAS E

Co-Investigator(s):

Protocol Number: **X080128004**

Protocol Title: *Accuracy and Reliability of Plaster Models vs Electronic Models*

The IRB reviewed and approved the above named project on 12-2-09. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 12-2-09

Date IRB Approval Issued: 12-2-09

Marilyn Doss

Marilyn Doss, M.A.
Vice Chair of the Institutional Review
Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

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