LINEAR EVALUATION AND COMPARISON OF TRADITIONAL ORTHODONTIC
PLASTER MODELS VERSUS DIGITAL MODELS OBTAINED THROUGH
INTRAORAL SCANNING

by

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ABSTRACT

Introduction: The digital revolution has arrived and is propelling the field of orthodontics into a new age of continually evolving technology. Digital impression technology is now available to produce digital replications directly from a patient’s mouth through laser scanning. The purpose of this preliminary study of the Cadent iTero digital impression system was to determine how the accuracy and reliability of linear measurements made using digital models compare with measurements obtained from control and plaster models. Methods: Nine different polyurethane typodonts demonstrating common occlusal conditions were used as control models through which traditional plaster models and digital models were reproduced and compared. Twenty-four linear measurements were recorded for each typodont (1-9) and model type (control, digital, plaster). Measurements were repeated by the same operator at three separate time-points (intervals at least one week apart). Results: Mean linear measurements differed significantly by model type – p <0.0001. Tukey’s test demonstrated the mean value for digital models differed significantly from those of control and plaster models while means of control and plaster models were not significantly different. Measurements obtained from each model type were highly correlated and repeatable based on intraclass correlation evaluation (>0.99). Conclusions: Linear measurements obtained from digital models produced through the iTero digital impression system appear to be both accurate.
and reliable. Though statistically significant differences were demonstrated in this study, the magnitude of the differences was 0.06mm and is considered clinically insignificant by current orthodontic literature standards. The iTero digital impression system for creating digital models therefore appears to be an acceptable digital model development technique.
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INTRODUCTION

Background Introduction

Orthodontic stone models have traditionally been a crucial part of an orthodontist’s diagnostic armamentarium. Stone models are three-dimensional (3D) replicas of a patient’s dentition which provide measurements and facilitate analysis more easily and accurately than those obtained intraorally. Models are used for diagnostic evaluation, treatment planning, development of a problem list, fabrication of appliances or retainers, and as an overall record of treatment.\(^1,2\) Though models will undoubtedly continue to play a vital role in orthodontic treatment, the way in which we obtain them and the format in which we utilize them is rapidly changing.

Traditionally models have been produced using alginate (irreversible hydrocolloid) impressions poured up in a lab using orthodontic plaster (type II dental stone).\(^3\) This technique has many advantages as the materials are easy to work with, affordable, and provide adequate detail in the vast majority of cases.\(^4\) There are also disadvantages however as alginate is environmentally susceptible to change and must be handled appropriately and, in most cases, poured immediately.\(^5\) Orthodontic plaster also has inherent disadvantages relative to other stones (type III, IV, V) such as increased setting expansion and dimensional instability along with lower strength and resistance to abrasion and fracture.\(^6\)

There is no universal standard for acceptable error in orthodontics, therefore the amount of error deemed appropriate is based more on the purpose and final outcome for
which the impression or model is being used. For example, a model used for diagnostic purposes (evaluation of occlusal relationships: angle classification, crowding, overjet, overbite, etc.) that incorporates 3 percent expansion is not clinically significant as no appliances are fabricated and the expansion is relatively proportional. The occlusal relationship and overall malocclusion is unchanged and consequently the error incorporated has no effect on its diagnostic value. However, an Invisalign appliance seeking intimate adaptation and incorporating .25-0.5mm precision movements per aligner requires optimal accuracy for such precise movements. It is therefore most important to match the impression technique’s accuracy with the desired result’s accuracy requirements.

Technological advances of the 21st century are now providing innovative solutions to problems associated with traditional models as well as increasing accuracy and efficiency of standard procedures and practice management. Digital models are now capable of being produced through laser scanning of plaster casts, nondestructive scanning of plaster casts or impressions with computed tomography and intraoral laser scanning. These virtual casts facilitate simplified long-term storage and access while decreasing financial and logistical burdens associated with traditional plaster casts, as well as assisting communication between practitioners. In 2004, approximately 10 percent of all orthodontists in the United States and Canada were using digital models and popularity has been substantially increasing.

One of the most promising emerging technologies is cone-beam computed tomography (CBCT). CBCT scanning has the potential, in a single scan, to produce both the required radiographic data for diagnostic treatment planning as well as the digital
models.\textsuperscript{10,13} However, at this point the technology is not considered accurate enough to produce models to which appliances can be fabricated and is also an expensive commodity.\textsuperscript{11} CBCT also incorporates radiographic exposure which may not be desired or necessary for the purposes of obtaining diagnostic models.

Intraoral scanning appears to be the next step in the evolution of obtaining accurate digital models. Intraoral scanners eliminate the bulky traditional impression material by imaging the teeth with light technology produced and received by a wand positioned over the teeth. Full arch impressions can be obtained in as little as four to five minutes with pauses or breaks being taken whenever needed.\textsuperscript{14,15} This is especially an advantage in a patient with a severe gag reflex. Impression retakes and pouring time can also be eliminated as impressions can be evaluated in real time for corrections and modifications.\textsuperscript{14} These digital impressions may then be used for diagnostic purposes immediately or sent wirelessly to a laboratory for appliance fabrication.\textsuperscript{16}

Intraoral scanning potentially provides more accurate models through eliminating several error-associated steps such as the unpredictability of alginate’s environment stability as well as plaster models’ expansion characteristics.\textsuperscript{6,17,18,19} Digital intraoral scanning also has several other advantages over traditional techniques by reducing patient burden and discomfort, streamlining laboratory transfer and communication, eliminating messy impressions (set-up and clean-up) as well as model pouring, all of which reduce time and effort.\textsuperscript{3,9,12,20,21} This technology however is costly and has not been extensively studied for its precision and application in orthodontics. Though there have been several preliminary studies demonstrating accuracy in producing single-tooth restorations.
utilizing intraoral scanning technology, no studies have been performed on its ability to provide orthodontic models and their inherent accuracy and applications.\textsuperscript{16,22,23,24,25}

To summarize, models are an essential component for many orthodontic procedures and a predictable level of accuracy and precision must be ascertained of new methods to obtain models before they may be integrated into orthodontic practice. Understanding the accuracy and precision of models obtained through intraoral scanning is integral to knowing for what purposes these models can be utilized. It has yet to be determined whether models obtained through intraoral scanning can be used for orthodontic digital models to evaluate occlusal relationships alone, or whether they are accurate enough to produce precision appliance, retainers, etc. As new technology emerges, the accuracy must be measured back to the original standards. This study will begin answering the questions on accuracy of digital impressions by comparing linear measurements obtained through digital impressions versus those measurements obtained from the acrylic master models, as well as plaster models produced using a traditional method.

Conventional Impressions

\textit{History}

The earliest record of dental impressions dates back to the early 18\textsuperscript{th} century with Matthaus Purmann (1648-1711), a German surgeon who fabricated appliances through making sketches and wax models.\textsuperscript{26} The concept was continued with another German named Philipp Pfaff (1713-1766), dentist to Frederick the Great of Prussia, who was the first to describe a technique of taking actual impressions using wax softened in hot water.
and pouring them with Plaster of Paris to form a rigid cast.\textsuperscript{26} The concept of making dental impressions was continually refined and developed over the next century using various waxes, gutta percha and other thermoplastic materials.

During the early 20\textsuperscript{th} century, many failed attempts were made at developing elastic impression materials until the early 1930s when hydrocolloid materials (agar and alginate) were developed.\textsuperscript{27} The difficult working properties of reversible hydrocolloid in combination with its scarcity in America during World War II, led to the chemical development of a native brown algae producing a dry alginate powder that, when mixed with water, formed an irreversible hydrocolloid alginate.\textsuperscript{26}

During the 1950s, many rubber-based products were developed as industrial sealants. It was from these rubber-based products developed for filling concrete gaps, that S.L. Pearson produced the first polysulfide rubber-based impression material in 1955.\textsuperscript{26} Though rubber-based impression materials had high tear strength, good flexibility, improved detail and a long working time, their unpleasant odor, poor dimensional stability and messy mixing left room for improvement.\textsuperscript{26,28,29}

Around the time of World War II, through non-dental related research seeking alternatives to natural rubber, elastomers were discovered. Elastomers are non-aqueous elastomeric impression materials with viscoelastic properties similar to rubber that are formed through cross-linking of long polymer chains.\textsuperscript{30} During the 1960s, polyethers were developed as the first elastomeric impression material specifically designed for dentistry, while condensation and addition-reaction silicones were developed during the 1970s.\textsuperscript{27} Developments since the 1970s have been primarily based around improvement of physical handling properties and biological interactions of the previously developed
materials. Improved properties, shortened setting times, increased shelf life, automated mixing techniques, and the introduction of hydrophilic addition reaction silicones have been some of the major developments since these materials’ first introduction.\textsuperscript{28,31,32}

\textit{Alginate Impressions}

Alginate (irreversible hydrocolloid) is currently the most widely used impression material in dentistry and orthodontics.\textsuperscript{3} Alginate impression material has several advantages for use in daily practice: it is affordable, hydrophilic (moisture/water compatible), has a high degree of surface detail, short setting time, adequate tear resistance and elastic recovery.\textsuperscript{28,33} It is easy to mix, generally palatable and, if handled correctly, has acceptable accuracy for orthodontic purposes. Alginate also has disadvantages; it is dependent on its environment and should be poured immediately as it undergoes imbibitions (absorbs water) and syneresis (releases water). This dimensional instability may be controlled through immediately pouring models after obtaining them. However, many offices use digital models or outsource appliances and retainers off site leading to shipping periods of two to seven days in various environmental conditions. Though for study models this may not be critical, it is often criticized when these impressions are used for fabrication of appliances or other orthodontic purposes requiring some precision due to the distortion that may have occurred during the delay in pouring.

For example, Coleman et al\textsuperscript{34} showed in a controlled laboratory study that models stored in a wet paper towel for up to one hour did not show significant distortion while those poured 24 hours after being taken showed significant distortion from the original. However, a study by Douglass et al\textsuperscript{35} on the clinical acceptability of orthodontic retainers
fabricated from stored alginate impressions found that there was no statistical difference in clinical acceptability of retainers fabricated off of appliances poured immediately, after 24 hours, or after 72 hours. Brugirard\textsuperscript{29} also challenged the idea of alginate distortion over time, finding that dimensional changes were between 0.06 and 0.13 percent for 12 and 24 hour storage when impressions were kept in a moist environment and the manufacturer’s directions were followed.

Bergman et al\textsuperscript{36} demonstrated that disinfection techniques may play a significant role in the accuracy of alginate impressions. Bergman demonstrated that large amounts of error in detail and accuracy occurred after an alginate impression is submerged for periods of time in disinfectant. However, when alginates were sprayed with the disinfectant solutions, all had acceptable dimensional stability (though some surface disinfectants can have a negative effect on surface detail and the manufacturer’s recommendations should be followed).\textsuperscript{37}

\textit{Polyvinyl Siloxane Impressions}

Though studies have found alginate to be both as accurate as and less accurate than polyvinyl siloxane (PVS) impression materials, there is no question whether PVS is more dimensionally stable than alginate.\textsuperscript{38} PVS is the second most common material used in dentistry and orthodontics today due to its high accuracy, elastic properties, mixing technique and dimensional stability.\textsuperscript{39} Many orthodontists choose PVS when fabricating appliances that require a high degree of accuracy as well as those incorporating a longer shipping and manufacturing process such as Invisalign aligners.
Modern-day PVS materials are modified and improved versions of the original condensation silicones with the difference being in the terminal group’s chemistry. The base and catalyst components of PVS are combined to produce an impression material with excellent detail reproduction, dimensional stability, superior tear strength and elasticity, neutral odor and taste and are dimensionally stable even up to one month.\textsuperscript{28,29,30,31,40}

According to the American Dental Association Specification No. 19, an elastomeric impression material has to be capable of reproducing details of 20 microns or less to be clinically acceptable.\textsuperscript{41} PVS materials are considered to reproduce the greatest detail of all impression materials and are frequently reported as the most ideal impression material because they exhibit a good balance of tear-strength, elastic recovery and permanent deformation while having superior dimensional stability.\textsuperscript{27,42,43} The permanent deformation in elastomeric impression materials is related to the degree of polymer cross-linking, while the tear strength is often more related to the degree of filler content and viscosity, such as light body (less viscous) versus heavy body (more viscous).\textsuperscript{44} PVS materials can absorb more than three times the energy up to the point of permanent deformation than other elastomers.\textsuperscript{45}

According to Mandikos,\textsuperscript{43} PVS materials show the smallest dimensional changes on setting of all elastomeric impression materials giving them superior dimensional stability. However, all rubber polymers (including elastomers) must contract slightly during polymerization as a result of cross-linking.\textsuperscript{46,47,48} Reductions in volume due to polymerization shrinkage have been reported to be 0.1 to 0.05 percent.\textsuperscript{43} In dentistry, this linear contraction corresponds well to the setting expansion of modern type III and type
IV stones, resulting in slightly larger replication of the preparation, providing some of the required space for luting agents.\textsuperscript{43,45,49}

Long-term dimensional stability of PVS has been reported extensively in the literature to be superior to all other impression materials.\textsuperscript{43} This acclaim is related to the impressions’ stability through changes of humidity, as well as the fact they do not undergo further chemical reactions or release byproducts. Many authors have shown PVS impressions have very little changes even up to four weeks with up to 0.025mm deformation occurring in that time period.\textsuperscript{40}

Traditionally the major disadvantage of PVS when compared with other rubber-based impression materials such as polyethers and polysulfides was its inherent hydrophobic properties. Though this tendency has not been entirely overcome, newly developed PVS impression materials have increased wettability and hydrophilic properties through adding polyether carbosilane surfactant.\textsuperscript{50} The new addition silicone impression materials with these hydrophilic modifications now have increased affinity for moist oral tissues (biocompatibility) as well as the liquid phase of gypsum providing more accurate casts with fewer surface bubbles.\textsuperscript{29,51,52}

Another disadvantage of additional silicone material is its inherent interaction with the sulfur contained in powdered latex gloves and rubber dams. The sulfur compounds inhibit the polymerization, and contact with gloves or hands not washed after using latex gloves should therefore be avoided. Baumann\textsuperscript{53} reported that concentrations as low as 0.005 percent can cause total inhibition of polymerization of PVS. Though not all latex products have inhibitory effects and interactions vary based on PVS
manufacturer and amounts of powder on gloves, it is necessary to avoid contact with all latex and use precautions such as vinyl gloves if contact is necessary.\textsuperscript{41,54,55}

Conventional impression techniques and materials are far from perfect. Impressions are challenging and their success or failure is multifactorial from both the dentist’s and the patient’s perspective. All types of impressions are restricted by patient behavior, tray selection, adhesive, viscosity/flow of material, working time, disinfection and, most of all, patient cooperation.\textsuperscript{56} Retaking impressions in a clinical setting is a large disruption to patient management and does not guarantee improved results. This often leads to a large percentage of impressions being sent to the laboratory that are deficient in some area.\textsuperscript{56} It has been reported that as many as 89 percent of impressions sent to a lab are inadequate or contain one or more observable errors.\textsuperscript{57} Therefore new methods of obtaining more accurate impressions at less of a cost both financially and physically are continually being developed and digital impression technology is the current avenue of exploration.

Digital Impressions

\textit{History and Marketplace}

The concept of replacing conventional impressions with digital techniques has been around for a long time. Computer-aided design/computer-aided manufacture (CAD/CAM) technology has been used in some form industrially for half a century, but it wasn’t until the 1970s when Dr. Francois Duret envisioned its application in dentistry through his thesis entitled “Empreinte Optique” (optical impression).\textsuperscript{58} During the 1980s he developed the concept and obtained a patent for the first dental CAD/CAM device in
1984. During the same time period, a Swiss dentist, Dr. Werner Mormann, and an electrical engineer, Marco Brandestini, developed the concept for the first commercially viable CAD/CAM system introduced in 1987 by Sirona Dental Systems-CEREC (Chairside Economical Restoration of Esthetic Ceramics).\(^{58,59}\)

CEREC was developed off the principle of triangulation, using a light’s reflection off angled surfaces to acquire the tooth image.\(^{14}\) An opaque titanium dioxide powder coating is applied over the area to be scanned so that uniform light dispersion occurs, then margins of the preparation are virtually identified and the impression is complete.\(^{60}\) Chair-side restorations are milled out of pre-sintered blocks of ceramic material and delivered to the patient the same day, often with no waiting period or temporaries.\(^{61,62,63}\) Though the same day delivery is an advantage in convenience, disadvantages are also associated with this technique as restorations are milled from one block. The materials and preparations used for the restoration are limited in their type, shape, color, and properties.\(^{14}\) This can be a significant factor in obtaining esthetically pleasing anterior restorations that are customized to the patient’s dentition as well as fabricating of posterior bridges requiring a high degree of strength.

More recently, multiple companies and new technologies have emerged into the marketplace. CEREC currently has the market-share, but new technologies such as the Lava C.O.S. (Lava chairside oral scanner-3M Unitek), E4D (intraoral digitizer-D4D Technologies), and iTero (Cadent) are now available, and it has yet to be determined which company’s unique innovative software and scanning technique will distinguish itself as the future in digital impressions.\(^{14,64}\)
Intraoral scanning technology traditionally was based on CEREC’s triangulation technique. Triangulation uses a light source that illuminates an object while being positioned at an angle to the detector. However, triangulation of light has compromised accuracy when scanning two types of surfaces - curved surfaces where the angle of reflection may reduce the viewing area, and surfaces that don’t refract light similarly, such as natural teeth versus restorative materials.\textsuperscript{14,65} In an attempt to overcome the dissimilarity of different surfaces’ refractive characteristics, many systems require the use of a surface coating like titanium dioxide. This step however can be cumbersome and difficult to achieve consistency as the opaque coatings may be of different thicknesses, become contaminated with saliva, or may be disrupted by contact with the scanner. To overcome these issues of incorporated inaccuracies, both the iTero system and the Lava C.O.S. have developed modifications to the traditional triangulation technique of digital impressions.\textsuperscript{65}

The iTero system uses a laser scanning protocol known as “parallel confocal.” According to this principle of light, the scanner emits 100,000 beams of red light through a small pinhole and within one third of a second, the reflected light is converted into digital data.\textsuperscript{66} There is no need for a reflecting agent as the laser is able to reflect off all oral structures similarly and only the rays in focus will return through the filtering device.\textsuperscript{67} The iTero system additionally incorporates telecentricity (same field of view - non moving) which adds to its accuracy.\textsuperscript{65} A telecentric image does not incorporate compensations for magnification error necessary with triangulation technology that “hovers” over objects being imaged. This adds to its precision as well as ease of use and patient comfort.\textsuperscript{14,15,65}
The Lava C.O.S. captures images using “Active Wavefront Sampling” (AWS) which enables “3D Video in Motion” technology. While other digital impression scanners use warping of lasers and triangulation of light that require increased processing time and incorporate some level of distortion and correction, the Lava C.O.S. uses a real-time movie recording technique and image processing algorithms to obtain images. The Lava C.O.S. captures images the fastest of any scanner available due to its real-time image processing while adding to patient comfort. Imaging can start or stop at any point and any area within the mouth while capturing approximately twenty 3D data sets per second or close to 2400 data sets per arch (over 24 million data points).

There are currently no studies published related to the accuracy and application of digital impressions within orthodontic literature. The digital impression information available to date is associated with general dentistry: accuracy of crowns produced, time savings, production streamlining, etc. However, the results of these studies show many of the prospective advantages and disadvantages that potentially may be incurred in an orthodontic environment and are therefore important to evaluate.

**Advantages and Disadvantages**

Proponents of digital impressions suggest the technology offers significant advantages over traditional impressions in patient comfort, patient education, accuracy of mounting and bite registrations, stability and accuracy of dies, increased productivity, infection control, inventory, recordkeeping, crown remakes, and visualization of preparations. Potential disadvantages include cost, intraoral manipulation, and integration of technology into the office.
Digital impressions allow mounting and bite registrations to be verified immediately with optimal visualization on the monitor. This eliminates problems with patients not closing completely or posturing from maximal intercuspasion or moving from centric relation/occlusion.\textsuperscript{64} Many of the digital impression systems also have tools using the bite registration to evaluate tooth contacts, make arch or tooth measurements and review the preparations’ occlusal and proximal reductions, facilitating any adjustments that may need to be made before the final impression is submitted.\textsuperscript{64,65}

The digital impressions possess obvious advantages with infection control as clean up is often as simple as disposing of the removable cover on the wand. There is limited operatory setup, no extra step of boxing impressions or filling out a laboratory script after sterilization as everything can be done chair-side and wirelessly from the scanner.\textsuperscript{64,65} Digital impressions also eliminate the environmental factors such as heat, moisture, time and physical damage that influence stability and quality of traditional impressions.

Bulk of traditional impression material, tray size, as well as setting time of many materials can lead to discomfort and gagging within certain patients. Gagging is such a problem that there have been many articles devoted to the management of these patients and various techniques to be used in attempting to obtain accurate full arch impressions.\textsuperscript{68,69} There is an obvious advantage with intraoral scanning wands and devices for these individuals as they are less bulky, have less contact with the tongue or throat, and devices can be removed at patient’s request often without detriment to the scan in progress. Scans of specific areas can be completed in as little as 10 to 15 seconds or full arches within two to five minutes with minimal discomfort to the patient.\textsuperscript{14,64,65}
**Current Research**

There have been several entry level studies on the accuracy of intraoral data acquisition in comparison to conventional impressions within general dentistry. Luthardt et al\textsuperscript{25} evaluated conventional technique versus the Cerec 3D intraoral digitizing camera through an in-vitro study and found the accuracy of the digital version to be within 17 micron’s of the original model. Ender and Attin\textsuperscript{70} reported accuracy using Cerec 3D images of single tooth preparations to be within 19 microns while quadrant impressions had accuracy within 35 microns. However, a study by Kurbad\textsuperscript{60} demonstrated the titanium dioxide powdering required by Cerec may cause considerable error due to material buildup and therefore may affect final restoration adaptation.

The most notable clinical study to date on digital impressions was performed by Henkel\textsuperscript{16} in August 2007 and compared fixed prostheses generated from conventional versus those produced utilizing digital impressions. In this blind study, crowns produced using the iTero digital impression system were preferred over crowns generated using conventional impressions based on marginal fit, contacts, occlusion and time of adjustment in nearly 70 percent of the cases. Henkel found that the iTero crowns were judged as being more clinically acceptable than conventionally produced crowns (85 percent versus 74 percent respectively) and that there was a reduction in delivery time from 3.2 minutes with conventional to 2.4 minutes using the digital impressions. Through exit polling of patients and round-table discussions with the dentists and technicians participating in the study, Henkel reported, “Laboratory technicians saw an improvement in quality of crown preparations with digital impressions, patients found scanning more comfortable than conventional techniques, and dentists commented most on decreased
chair side time for adjustments at delivery.” Henkel hypothesized that the laboratory technicians’ evaluation of improved quality in this study was most likely attributed to the dentists’ increased ability to evaluate the impression using analytical software tools, as well as modify impressions with additional scans or preparations based on results of digital evaluation of the preparations.

In 2005 Christenson\(^57\) reported that 50 percent of conventional impressions do not show the entire preparation margin while surveys of laboratory technicians report that as high as 89 percent of impressions have incomplete registration of finish lines. Dentists using conventional impressions are often faced with the challenge of evaluating the cost and benefit of retaking an impression for minor imperfections with no guarantee of improved results and increased cost of materials and time. Intraoral impressions allow modification of scans to include any such areas without restarting the often seven minute and $25 procedure (not including dentist and staff-time).

The Lava C.O.S. was evaluated for its clinical performance by two blinded evaluators in a study by Syrek et al\(^76\) Using fit checker to evaluate marginal fit under a microscope, crowns produced using the Lava C.O.S. digital workflow were preferred 72 percent of the time due to improved mean marginal adaptation. Kugel et al\(^24\) also compared marginal accuracy and fit of Lava Zirconia copings using the Lava C.O.S., versus copings produced using PVS impressions and found both copings were equivalent, having no significant differences. Restorations in this blinded study were evaluated under magnification by visual inspection and tactile perception.

System repeatability is important to obtaining consistent and predictable results as scans taken at different time points should achieve similar results. In a study by
Balakrishnama,²² Lava C.O.S. showed a precision of between 6-11 microns on repeated scans over two weeks’ time and therefore a high reliability. Proponents of this technology believe the increased repeatability and accuracy of restorations are due to its unique “AWS” technology as well as control steps placed within the digital workflow and advanced stereolithography (SLA) technology used to fabricate restorations.

The physical accuracy of rapid prototyping systems such as stereolithography is a significant factor in regards to medico-legal concerns with using digital models. Many orthodontists resist digital impressions and models due to concern of litigation and liability incorporated with not being able to produce physical models. However, most companies providing digital impression technology are also able to produce physical model reproductions of these impressions using some type of rapid prototyping technology.

Many companies incorporating digital impression technology produce models for records or restorations through SLA. The dimensional accuracy of these models has been evaluated by a number of authors. Keating et al¹¹ compared measurements made on plaster casts versus a digital reproduction as well as its SLA fabricated model and found that while measurement differences made on plaster and digital model reproductions were not significant, the SLA model produced significant differences in measurements made in the Z-plane (inciso-gingival dimension). In another study evaluating actual bone skulls versus STL models produced from three-dimensional computed tomography (3D-CT), Barker et al²² found mean differences in measurements of 0.85mm. In similar studies, Kragskov et al³³ and Bill et al⁷⁴ found mean differences of -0.3 to 0.8mm between measurements made on 3D-CT images and SLA models.
Though there is no clear acceptance to what is a clinically or medico-legally an acceptable amount of error in cast reproductions, many authors who have studied these differences have suggested what they consider to be a clinically significant measurement difference. Hirogaki et al\textsuperscript{75} suggested orthodontic study models’ accuracy should be about 0.30mm while Schirmer and Wiltshire,\textsuperscript{76} suggest a measurement difference of less than 0.20mm was clinically acceptable. Bell et al\textsuperscript{77} regarded a mean difference of 0.27mm between archived study models and those measurements made by hand on plaster models was unlikely to have a significant clinical impact. Halazonetis\textsuperscript{78} reported an accuracy of 0.50mm was sufficient for laser scanning of the face and head but would be inadequate for producing study models.

Whether models are produced through SLA as in Lava C.O.S., milled from blocks of polyurethane material as with iTero Cadent, or virtually utilized through digital model software, models play an essential role in all facets of dentistry.

Orthodontic Models

Orthodontic models have played a crucial role in diagnosis, treatment planning, records, and appliance fabrication throughout the entire history of orthodontics. A three-dimensional representation (model) of the patient’s dentition allows more comprehensive evaluation through measurements and analysis as well as facilitates appliance fabrication.

In 1996, The American Association of Orthodontists (AAO) published a list of basic orthodontic records recommended to be obtained in their Clinical Practice Guidelines for Orthodontics and Dentofacial Orthopedics.\textsuperscript{79} According to the AAO, pretreatment and post-treatment records should include intraoral and/or panoramic
radiographs, cephalometric radiographs, dental models, intraoral and extraoral photos, as well as any additional indicated tests or procedures.\textsuperscript{3} Therefore study models of some form appear to be integral to an orthodontic treatment plan.

Up until the last decade when digital models became readily available, models have been fabricated using “plaster” type II dental stone. Although these physical models provide an unmatched physical representation of the dentition, they are not without disadvantages as storage, retrieval, diagnostic versatility and durability are all significant challenges.\textsuperscript{3}

In 1996 Cadent Inc. developed a scanning technique that created digital models specifically for orthodontics called OrthoCAD.\textsuperscript{12} Using conventional alginate impressions shipped by mail to the Cadent office in New Jersey, OrthoCAD produces digital models through laser scanning technology.\textsuperscript{12} Digital models are then transferred via the internet back to the orthodontist where they may easily be manipulated, evaluated, measured and stored for records purposes. However, both physical models and digital models have separate advantages and disadvantages. This leads to question whether digital models may eventually replace the “traditional plaster models” which have remained largely unchanged over the last 100 years. There are currently at least four companies offering digital model services with OrthoCad\textsuperscript{TM}-Cadent, emodels\textsuperscript{TM}-GeoDigm, 3M Unitek Lava\textsuperscript{TM}, and OrthoPlex\textsuperscript{TM} GAC being the largest companies involved. All of these companies use different proprietary techniques and methods of obtaining the models, and therefore it is difficult to say precisely how accurate digital models are in general. Both OrthoCad\textsuperscript{TM} and emodel\textsuperscript{TM} use laser scanning techniques to produce digital representations, while the more recent competitors in the market, 3M
Unitek Lava™ and OrthoPlex™, use direct impression computed tomography scanning. While most studies have been performed using OrthoCad and emodel software and their proprietary scanning techniques, newer computed tomography scanning technology shows potential to become the new standard, as it is not necessary to pour models, thus reducing error.

A preliminary study performed by Sung Kim and provided by 3M Unitek on their website compared digital models produced from plaster casts versus those produced using direct impression Computed Tomography (CT) scanning. In this study, they found models produced using CT direct scanning appeared to offer measurement accuracy advantages over those models involving a plaster pouring step. However, there is no study that compares models made from each of the proprietary techniques for their accuracy and precision, and therefore it is difficult to equate their accuracy advantages.

Though the AAO places an emphasis on models inclusion in standard orthodontic records, studies have produced results that question their necessity. Callahan et al performed a study that was designed to evaluate how information obtained from traditional plaster models contributed to diagnosis and treatment planning of orthodontic patients who were evaluated using digital photographs and radiographs alone. They found no clinically significant changes in treatment recommended by the orthodontists from their preliminary treatment plans based on digital photographs and radiographs alone versus final treatment plans made after model evaluation. The results of this study indicate that models may not be necessary for treatment planning of every orthodontic patient. However, Han et al demonstrated the value of study models for treatment planning when they compared treatment plans based on study models alone versus
treatment plans established based on photos and radiographs. Through this study they found little difference existed between treatment plans developed from study models alone versus those developed using all other records combined. This study therefore demonstrates their significance and versatility in developing an orthodontic treatment plan.

Plaster Versus Digital Models

Traditional plaster models are the reliable gold standard and though their use is decreasing, they are still the most popular form of orthodontic models utilized. Plaster models have the advantage of being hand-articulated physical representations. Many practitioners do not like evaluating models in a digital format due to questions of accuracy in a litigious environment as well as general intimidation of computer skills. Plaster models lend themselves well to laboratory techniques in the office where they may arguably be evaluated and utilized more expeditiously, obtaining appliances or retainers quickly and with less overhead. Diagnostic set-ups and evaluations may be immediately performed on the physical version, and many orthodontists prefer supervising model fabrication, therefore increasing confidence in the accuracy of the models.

However the storage of plaster models causes significant hardship. The shortest time that plaster models used for records purposes should be kept, is based on the local statute of limitations period during which a malpractice lawsuit may be filed. This time ranges from five to 15 years by state and in an average practice seeing 300 new
patients a year, that means 6000 models over a 10-year span would have to be stored, requiring both significant time and space. \(^3\)

Digital models have many advantages over plaster models through their ease of accessibility, transfer and storage. \(^3,12\) They also provide a state-of-the-art educational tool for patients through their advanced 3D graphics. Digital model software can perform the same traditional measurements as those made on plaster models while also having the ability to be evaluated through transverse or vertical sectioning in any plane of space. \(^3,12\) Digital models also facilitate additional tools such as occlusogram views that identify contacts and show their relative positions and whether they may be heavy or light. \(^3,85\)

Digital models also allow sophisticated bracket positioning tools where virtual treatments with different plans (extraction versus non-extraction) can be performed and bracket positioning adjusted according to treatment goals and desires. \(^12\) The predictive nature of this tool optimizes treatment planning and time required to evaluate various set-ups which traditionally were done by setting each sectioned individual tooth in wax. Technology now allows custom appliances and wires to be fabricated through digital models, facilitating ideal bracket placement and custom indirect trays which in theory may reduce treatment times due to increased efficiency.

**Accuracy and Acceptance**

Many studies have been performed to evaluate the effect of transport time on the accuracy of digital models. This is due to the imbibition and syneresis that potentially causes distortion of the alginate material which is most commonly used for initial records in orthodontics. Dalstra and Melsen\(^{86}\) performed a study comparing the accuracy of
digital models produced from casts poured both immediately and following 3-5 days of mail transit time. This study demonstrated no statistical differences were found between the two sets of plaster casts and digital models. However, Alcan et al\textsuperscript{5} investigated plaster models poured immediately to those poured after one, two, three, and four days using three different alginate brands and found statistically significant differences between those poured immediately versus those poured in four days, as well as statistically significant differences between different alginate manufacturers. Both of the aforementioned studies showed statistical differences, however their opinion was that these differences were not clinically relevant when models were used for study model purposes.

Study models are often used to evaluate tooth-size and arch-length discrepancy using analyses based on measurements obtained from these models. These measurements and their accuracy, as well as repeatability, are therefore important to the overall usefulness of the study models for treatment planning purposes. The following studies evaluate and compare measurements and various analyses made on digital and plaster models.

Santoro et al\textsuperscript{7} compared measurements made on digital and plaster models to evaluate the reliability of the OrthoCad\textsuperscript{TM} system. Tooth size, overbite and overjet were evaluated on 76 randomly selected pretreatment patients. The results showed a statistically significant difference between the two groups for both tooth size and overbite. Though the magnitude of these differences ranged from 0.16mm to 0.49mm and was not considered to be clinically relevant, the digital measurements were consistently smaller than the manual measurements.
Zilberman et al\textsuperscript{8} evaluated the validity of tooth size and arch width measurements using conventional models versus OrthoCad\textsuperscript{TM} virtual models. Twenty setups using artificial teeth of known dimensions corresponding to different malocclusions were utilized in evaluating mesio-distal tooth dimension as well as inter-canine and inter-molar width. Results showed both methods were highly valid and reproducible for both tooth size and arch width. Though the differences were not found to be statistically or clinically significant, digital calipers’ measurements on plaster models showed the highest accuracy and reproducibility and were therefore recommended by Zilberman to be more suitable for scientific research.

Another important determination of whether digital models may be used as an alternative to conventional plaster models is whether measurements made at different time points as well as by different practitioners are repeatable. Quimby et al\textsuperscript{9} investigated this important point through evaluation of the accuracy (validity), reproducibility (reliability), efficacy, and effectiveness of measurements made on computer-based models. In this study, accuracy was evaluated by one examiner measuring 10 plaster and digital models made from a dentoform, twice. Reproducibility and efficacy was evaluated by two examiners measuring 50 plaster and digital models made from patients. Effectiveness was evaluated using 10 examiners measuring 10 plaster and digital models made from patients. Their conclusions were that measurements made from computer-based models appear to be generally as accurate and reliable as measurements made from plaster models, while efficacy and effectiveness in measuring digital models were similar to those of plaster models.
The Bolton tooth-size analysis is the most commonly used diagnostic tool in orthodontics for evaluating tooth size discrepancies.\textsuperscript{87} Sheridan\textsuperscript{87} reported that 91 percent of orthodontists polled only use a Bolton analysis when measuring tooth size. Achieving proper overbite and overjet in combination with a good functional occlusion requires that maxillary and mandibular teeth be proportional in size. In 1958, Bolton studied 55 patients with ideal occlusion and produced ratios for the mesiodistal sizes of maxillary and mandibular teeth. By defining both ratios for the sum of the anterior six teeth and the sum of 12 teeth (molar-molar), Bolton defined definite percentages for ratios of the mandibular to maxillary teeth: 77.2 percent anterior 6 and 91.3 percent molar to molar.\textsuperscript{88} Traditionally these measurements were obtained using vernier calipers or needlepoint dividers on plaster casts, and many studies have since been done to evaluate digital model software’s ability to reproduce Bolton analysis accurately and efficaciously.

Tomassetti et al\textsuperscript{89} compared three computerized Bolton analysis with the conventional cast method. No statistically significant error was found between the conventional methods and any of the computerized versions. The study demonstrated that computerized versions were not only accurate but also much faster to perform than the traditional method.

Mullen et al,\textsuperscript{21} in a similar study, evaluated accuracy and speed of space analysis using emodel digital models versus plaster models. Models from 30 patients were selected whereby measurements were obtained, molar to molar, on both plaster and digital models as well as the time it took to obtain them. Though they found a statistically significant difference in arch-length calculations and that the ball-bearing control placed within the cast was measured slightly greater on the emodel software, all measurements
were within 0.10-0.48mm, which is considered to be the range of operator error/reliability in calculations for plaster cast analysis, therefore deemed clinically insignificant. They also found that measurements were obtained significantly faster using emodel software than traditional cast measurement technique.

The American Board of Orthodontics (ABO) accepts pre-treatment digital models produced through OrthoCAD software for phase III ABO diplomate clinical examination. This further demonstrates the validity and accuracy of digital models used for both records and treatment planning. However, as a result of several studies evaluating the ABO objective criteria used in grading post-treatment clinical records, virtual models were not deemed an acceptable alternative to the traditional plaster models. Costalos et al \(^9_0\) evaluated the seven occlusal criteria used in the ABO’s object grading system – tooth alignment, vertical positioning of marginal ridges, bucco-lingual inclination of posterior teeth, occlusal relationship, occlusal contacts, overjet and interproximal contacts. While comparing measurements made on plaster casts using the ABO measuring ruler to those measurements taken on virtual models, they found means for alignment and bucco-lingual inclination were significantly different and therefore recommended not using digital models with the ABO objective grading of post-treatment models.

Okunami et al \(^9_1\) also deemed digital models insufficiently accurate for measuring buccolingual inclination, though found no significant differences in measurements for alignment, marginal ridges, overjet, and interproximal contacts. Hildebrand et al \(^9_2\) also compared plaster versus digital grading using the ABO objective grading system and found scores from digital models exceeded the scores from plaster models by an average of nine points. Differences were found to be statistically significant within scores made
for alignment, occlusal contact and overjet. Digital models have therefore demonstrated acceptability by the ABO for some clinical uses such as initial records, while deemed not acceptable for other purposes such as final ABO graded models.

With new technology in digital models and digital impressions being developed at a rapid pace, care must be taken to compare new techniques back to the gold standard of plaster models. Through measurements made on conventionally developed plaster models and digital models produced through Cadent iTero’s digital impression technology, the purpose of this preliminary study of the Cadent iTero digital impression system was to determine how the accuracy and reliability of linear measurements made using digital models compare with measurements obtained from control and plaster models.
SPECIFIC AIMS OF STUDY

1. Determine the accuracy of linear measurements made on digital casts produced using the iTero digital impression system, relative to control and plaster models.
2. Determine the reliability and repeatability of measurements obtained from each model type (control, digital, plaster).
3. Determine whether the iTero Digital Impression System is an acceptable means of producing digital orthodontic models.
MATERIALS AND METHODS

Master models

In this study, nine different urethane typodonts from Allesee Orthodontic Appliances (AOA-Sybron Dental Specialties Inc. Sturtevant, WI.) were used to evaluate the accuracy of linear measurements made on plaster models and those made on digital models obtained from a digital impression (intra-oral scan), relative to the master (urethane) models. The “Ortho Series Models” (set of nine common occlusal representations) consists of: five class 1 typodonts (4 of 10 arches with crowding), three class 2 typodonts (4 of 6 arches with crowding) and one class 3 typodont (1 of 2 arches with crowding). All typodonts included 28 permanent teeth; second molar to second molar on both upper and lower models.

To obtain repeatable points of reference for individual teeth on all three models, artificial landmarks centered over the contacts of adjacent teeth were placed on the master (urethane) models from the distal of the first molar on the right side, to the distal of the first molar left side, on both upper and lower casts. Preparations were designed to facilitate access of a digital caliper to both mesial and distal defined points on each tooth from a perpendicular position, relative to the preparations. Preparations for all posterior teeth were placed on the occlusal surfaces therefore measurements were all obtained from the occlusal (Figure 1). Anterior tooth preparation locations were individualized based on the presence of anterior crowding; models without crowding had preparations placed over contact points from the lingual, while models with crowding where teeth were displaced
facially had preparations placed from the facial, thereby allowing perpendicular access. Though the actual tooth size was reduced due to inter-proximal preparations, the study was designed to enable consistent points of reference so that individual linear measurements could be compared as precisely as possible between each model type.

The inter-proximal preparations were performed using a #6 round bur (Brassler-H1-31-018, 6 fluted carbide) with a high-speed hand piece and prepared to the depth of the bur (approximately 2mm), in the same plane as desired perpendicular measurement. An Endo-Z bur (Dentsply International- E015224000000), long tapered with a non-cutting tip, was then used to remove any lipping or undercuts left within the preparation. Undercuts were removed to prevent undermined plaster that would potentially be degraded during repeated measurements as well as to prevent tearing of impression material due to undercut preparations. The landmarks size was not standardized as it was not important to the study, the preparations were made only to define repeatable mesio-distal limits for measurements of the individual teeth.

Measurements were performed three times for each model and type (master, plaster, and digital) at three separate time intervals at least one week apart thereby facilitating intra-operator error evaluation. Twenty-four tooth measurements were recorded by a single evaluator per typodont (9 typodonts ).
Figure 1. Digital caliper measurement of AOA “Ortho Series” model.

Conventional Impression Technique

Materials

Table 1. Materials for conventional impressions and dental stone models.

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>LOT #</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquasil Ultra XLV (Cartridge)</td>
<td>Dentsply Caulk</td>
<td>090903</td>
<td>2012-09</td>
</tr>
<tr>
<td>Aquasil Ultra Heavy (Cartridge)</td>
<td>Dentsply Caulk</td>
<td>090609</td>
<td>2012-06</td>
</tr>
<tr>
<td>3M ESPE VPS Tray Adhesive</td>
<td>3M ESPE</td>
<td>334002</td>
<td>2012-01</td>
</tr>
<tr>
<td>COE Disposable Perforated Spacer Tray – 22D</td>
<td>GC America</td>
<td>250071</td>
<td></td>
</tr>
<tr>
<td>Model Stone (White)</td>
<td>Whip Mix</td>
<td>082050908</td>
<td></td>
</tr>
</tbody>
</table>
Method

Dual-phase, one-step impression technique. Prior to the application of tray adhesive (3M ESPE VPS), the COE impression tray was tried on the dentoform for proper fit and extension (Figure 2). A thin layer of tray adhesive was brushed onto the COE disposable spacer tray (size 22D) surfaces that would be covered with impression material. The adhesive was allowed to dry for 10 minutes.

Figure 2. COE disposable perforated impression tray and 3M ESPE VPS tray adhesive.

Aquasil Ultra XLV (type 3: light-body consistency, Classification ISO 4823) and Aquasil Ultra Heavy (Type 2: medium-bodied consistency, Classification ISO 4823) cartridges were used with hand-powered Heraeus Kulzer Dispensing Guns (Model #DS 50, Heraeus Kulzer D-41538 Dormagen SW). A small amount of base and catalyst was dispensed prior to placing mixing tips on both cartridges while initial mix from mixing tip was also discarded to ensure mixing ratio of 1:1. An intraoral tip was added to the mixing tip on the Aquasil Ultra XLV gun in order to insert impression material within
preparation areas (Figure 3). The Aquasil Ultra XLV was applied within tooth preparations inter-proximally as well as over adjacent surfaces, dispensing continuously from first molar to first molar on master model. The complete arch COE disposable impression tray with adhesive was then loaded with impression material and seated over model with light finger pressure to stabilize the tray.

A single operator completed all impression procedures with vinyl gloves worn throughout procedure. Mixing for both impression materials was completed in one minute for each impression. The impression was allowed to polymerize at 20 degrees Celsius and humidity of 27%. Impressions were removed from model after six minutes.

Figure 3. Aquasil Ultra XLV (cartridge), Aquasil Ultra Heavy (cartridge).

*Pouring PVS Impression With Orthodontic Stone*

Impressions were stored at ambient room temperature for 48 hours. Red rope wax and boxing waxes were placed surrounding impression using sticky wax to fix wax to impression material. Impressions were poured using distilled water (20 degrees Celsius) accurately measured in a measuring cylinder with Type III orthodontic stone (Whip Mix

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Corporation, Louisville, US) accurately measured on a digital scale, in a ratio of 28ml water to 100 grams of stone. Water and stone were hand mixed for 10 seconds in a wet vacuum bowl (Whip Mix Corporation, Model #6500, Louisville, US) and then vacuum mixed for another 30 seconds under 26 psi in a Whip Mix Combination unit. The stone was poured into models on a vibrator at room temperature of 20 degrees Celsius and 30% humidity.

The models were separated from impressions 24 hours after being poured to allow maximal stone setting prior to removal thereby reducing chance of cast fractures. Casts were inspected for bubbles and other visible defects in the area of preparation (Figure 4). Three casts with incomplete registrations of inter-proximal preparations were discarded and impressions were repeated using the previously described method. Casts were then stored at ambient room temperature until measurements were obtained.

Figure 4- Plaster casts image.
Digital Impression Technique

Method

Digital impressions were obtained using the iTero (Cadent, Inc. Carlstadt, NJ, US) impression machine. Full arch scans of the master models were taken per manufacturer recommendations. Three scans of each tooth were taken: buccal, occlusal, and lingual views. Voice prompts and visual images on the computer screen guided the operator through a series of successive scans of the model and bite registration (Figure 5).

After completion of one arch, scan was reviewed as a 3D model to confirm that teeth and preparations were imaged successfully and any additional scans needed due to incomplete registration were then obtained before the model was sent to Cadent laboratory via the internet.
Digital data sent to Cadent laboratories was evaluated by Cadent laboratory technicians and any scanning artifacts were removed according to standard protocol. Ortho Series Models were mailed to Cadent for verification of results as well as any additional scanning deemed necessary for production of final digital models. Digital models were returned via email as Three Dimension Markup Language (3DM) files to be measured and evaluated using Cadent OrthoCad (Cadent, Inc. Carlstadt, NJ, US) proprietary 3D model analysis software (Figure 6).

**Manual Measurement Technique**

A hand held digital caliper (CEN-TECH 6-inch digital caliper, 47257-OVGA), was used to manually measure both the master models and plaster models. This caliper had a measurement resolution of 0.01mm and was accurate to ±0.02 mm in the 0-100mm range.
All models were measured under magnification with a headlamp as accessory light. Inter-proximal preparations as described previously were used to define points of measurement for each tooth. Using the cavosurface line angle of the preparations as a mesio-distal limit, the smallest mesio-distal dimension for each tooth (24 per typodont) was recorded by placing the tip of the digital calipers at the most occlusal portion (cavosurface line-angle) of the preparation adjacent to each tooth (Figure 7).

**Figure 7. Manual measurement technique.**

Digital Measurement Technique

Indirect measurements were recorded for all teeth using Cadent OrthoCad 3D digital model software (Version 3.0) with accuracy of 0.1mm. Using the Orthocad software tooth measurement tools, each tooth’s points of measurement (cavosurface line-angles, mesio-distally located) were oriented in X/Y/Z planes (Figure 8) according to the long-axis of the crown and the locations of interproximal preparations (Figure 9). The same reference points of measurement were used for digital measurements as those
utilized in manual measurements. The ability to individualize X/Y/Z planes in the OrthoCad software allowed measurements to be obtained in similar planes of space as those utilized during manual measurements (ie. posterior measurements were obtained using points as close as possible to those obtained using the digital caliper oriented perpendicularly to the occlusal plane).

Figure 8. Plane orientation utilized in location of cavosurface line-angle.

Figure 9. Plane orientation with long axis of crown.
**Statistical Methods**

Mixed-model ANOVA was used to evaluate differences in mean measurements by model type, controlling for differences among teeth and accounting for multiple measurements on each experimental unit.

Tukey’s test was used in conjunction with ANOVA to evaluate how the means of each model type compared to each other through a pair-wise analysis.

Mixed-model analysis of variance (ANOVA) was used to estimate intraclass correlation (ICC) as a measure of reliability for replicate measurements made on the same tooth. Variability due to differences in means among typodonts was removed from the residual variance by including a term representing typodont as a fixed effect in the model. Separate estimates of ICC were calculated for measurements made on Control, Plaster, and Digital models.

Power to detect a difference in means among the 3 groups was approximated based on paired t-tests, after removing variability due to differences in means among typodont’s. A Bonferroni-type adjustment was used to account for three pair-wise comparisons among the groups. Alpha was set at 0.0167 for each comparison, and two-sided testing was used.

The largest observed standard deviation of pair-wise differences was 0.12mm, and power calculations were based on this value. The study sample size of 216 observations per group provides 80% power to detect a difference of 0.027mm between group means. This sample size provides > 99% power to detect a difference of 0.06mm, the conventional “medium effect size”, equal to one-half of the standard deviation.
RESULTS

Mean measurements differed significantly by model type (control, digital, plaster) - p <0.0001, but not by typodont (Table 2). Tukey’s test demonstrated the mean value for digital models differed significantly from those of control and plaster models, while means of the control and plaster models were not significantly different (Table 3).

The intraclass correlation coefficient (ICC) for digital models was the least correlated when evaluating both ICC and individual measurements obtained from the data. However, the measurements ICC values were above 0.99 for all three systems of evaluation, demonstrating a high reliability for replicate measurements made on the same tooth using each model type (Table 4).

Table 2. Mean measurements by typodont and model.

<table>
<thead>
<tr>
<th>Effect</th>
<th>Num DF</th>
<th>Den DF</th>
<th>F Value</th>
<th>Pr &gt; F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typodont (1 through 9)</td>
<td>8</td>
<td>202</td>
<td>1.26</td>
<td>0.2656</td>
</tr>
<tr>
<td>Model (control, digital, plaster)</td>
<td>2</td>
<td>430</td>
<td>53.71</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Table 3. Tukey’s test of mean measurements of control, plaster and digital.

<table>
<thead>
<tr>
<th>Effect</th>
<th>model</th>
<th>_model</th>
<th>Estimate</th>
<th>Standard Error</th>
<th>Pr &gt;</th>
<th>Adjustment</th>
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<tr>
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<td>Control</td>
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<td>-0.06475</td>
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<td>&lt;.0001</td>
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<tr>
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Table 4. ICC values obtained through mixed-model ANOVA analysis.

<table>
<thead>
<tr>
<th>ICC Value</th>
<th>Control</th>
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<tr>
<td>ICC Value</td>
<td>0.9972</td>
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DISCUSSION

The goal of this preliminary study of the Cadent iTero digital impression system was to evaluate how linear measurements made using digital models obtained through the iTero scanner, differed from the control and traditional plaster model measurements for both accuracy and reliability. Intraoral digital impression technology is rapidly developing with multiple full-arch scanners now available, such as CEREC® AC, E4D Dentist™, iTero™, and Lava™ Chairside Oral Scanner. Though several preliminary studies have been published reporting accuracy of single tooth impressions/restorations of between 17-19 microns and quadrant impression accuracy to be within 35 microns, no studies have reported on the accuracy of linear measurements as used with orthodontic analysis obtained through digital impressions. As new digital impression technology is developed, it is essential to evaluate its accuracy and reliability relative to well established methods such as traditional impressions and plaster models.

Results of the study demonstrate excellent accuracy for linear measurements of both plaster and digital models when compared to the control group measurements. Mean differences found in this study were 0.06 mm for digital and plaster models (Table 5). The results compare favorably with those obtained by Keating et al11 (mean difference of 0.14 mm for linear measurements on digital and plaster models) where digital models were captured using a highly accurate well established laser scanning device (Minolta VIVID900), which maps a triangulate 3D mesh model through integrated computer
software. When results are contrasted with the current most popular method of orthodontic cast digitization (OrthoCad proprietary technique) as evaluated by Liefert et al, Quimby et al, and Santoro et al, results appear to demonstrate increased accuracy whereby the differences between plaster and digital casts mean measurements were found to be between 0.15-0.66 mm.

Table 5. Evaluation of mean measurements for all three model types.

| Effect | model | Estimate | Standard Error | DF | t Value | Pr > |t| |
|--------|-------|----------|----------------|----|---------|-------|---|
| model  | Control | 5.8052   | 0.1029         | 203| 56.43   | <.0001|
| model  | Digital | 5.8699   | 0.1029         | 203| 57.06   | <.0001|
| model  | Plaster | 5.8054   | 0.1029         | 203| 56.43   | <.0001|

OrthoCad’s traditional method of digitization as evaluated by the aforementioned authors is very different from the method evaluated in this study. Traditionally, alginate impressions are obtained of the patients dentition and shipped to OrthoCad’s processing facility in New Jersey. Plaster models are then poured at the facility and encased in a contrasting urethane resin which is sliced and scanned incrementally through a computer manipulated system using a destructive scanning technique (accurate to approximately 50 microns). The traditional OrthoCad scanning method is therefore limited by the accuracy of the impressions that are received, which may incorporate poor registration of teeth and significant distortion due to variable environmental conditions. In a study evaluating the relationship between digital model accuracy and time-dependant deformation of alginate impressions, Alcan et al demonstrated significant deformation of alginate impressions occurred after just one day, with >1mm deformation after four days often occurring. Digital impression systems consequently have a clear advantage over
traditional digitization techniques, as impression registration is immediately available for review and environmental influences are eliminated.

Many studies have evaluated the accuracy of digital models developed through laser technology. Mean differences between digital and control models in these studies have been found to be between 0.00-0.70 mm. The challenge in comparing results found in this study directly with those of other studies is in the variety of laser technology, analyses, and measurement protocols therein utilized by the various authors.

In this study, the mean tooth size using the digital evaluation was found to be larger relative to the control and plaster model measurements (Table 5). Though the difference was minimal, linear measurement data obtained from digital intraoral impressions has not been reported on previously in the literature, and this would be a notable observation if a pattern were to be established in future studies. Previous studies evaluating digital data have often found decreased linear measurements on digital models relative to control models. This pattern has been demonstrated through both traditional methods of orthodontic cast digitization as used by OrthoCad, and on newer of methods of digital model acquisition such as through cone-beam computed tomography (CBCT) scans.

Mullen et al compared arch length evaluations of plaster and digital models and found maxillary and mandibular arch length measurements to be approximately 1.5 mm smaller when measured using digital models. They attributed the difference to difficulty in finding the greatest mesio-distal width of the teeth with digital software. Santoro et al compared measurements made on digital and plaster models and found all recorded digital measurements were smaller than manual measurements, ranging from 0.16 mm to
0.49 mm. They suggested differences are most likely attributed to alginate shrinkage during transportation, but could be related to intrinsic differences in measurement techniques (digital versus manual) and digital software familiarity and experience. Schirmer and Wiltshire\textsuperscript{76} also found digital cast measurements to be smaller than manual measurements. They hypothesized the difference was related to difficulty of measuring a 3D model in two dimensions. Utilizing an entirely different method of digital model acquisition than the aforementioned studies, Baumgaertel et al\textsuperscript{95} and Lascala et al\textsuperscript{96} evaluated CBCT digital models whereby measurements obtained tended to underestimate measurements taken directly from the physical models. Both studies found measurements to be proportionally smaller and therefore suggested differences to be caused by a systematic error in the CBCT measurement method.

A Tukey’s test utilizing simultaneous pair-wise comparisons was utilized for further evaluation of the sample means. Though similar to a t-test, Tukey’s test corrects for the increased likelihood of type 1 error occurring during multiple comparisons and identifies where differences between two means are greater than the standard error would be expected to allow. Results for this study indicated that digital measurements differed significantly from both control and plaster measurements ($p < 0.0001$), while plaster model and typodont (control) measurements had no significant differences (Table 3). The results thereby imply that plaster models are more accurate for duplicating linear measurements made on control models than digital models and may therefore still be considered the “gold-standard.”

In lieu of statistically significant differences frequently found between plaster and digital casts as demonstrated in this study, authors in similar studies report findings as
clinically insignificant (Table 6). Schirmer and Wiltshire suggest measurement differences of less than 0.20 mm as clinically acceptable, while Hirogaki et al. proposed orthodontic study models’ accuracy should be within 0.30 mm. Bell et al. regarded a mean difference of 0.27 mm as clinically insignificant, while Halazonetis suggested a 0.50 mm difference was acceptable for 3D laser surface scanning of the face but insufficient for orthodontic cast purposes.

Table 6. Studies reporting statistical significance as clinically insignificant.

<table>
<thead>
<tr>
<th>Author</th>
<th>Orthodontic Evaluation</th>
<th>Statistically Significant</th>
<th>Clinically Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Santoro et al. (2003)</td>
<td>Tooth-size, overbite, overjet</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Zilberman et al. (2003)</td>
<td>Tooth-size, Arch-Width (linear)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Stevens et al. (2006)</td>
<td>Bolton analysis, PAR index</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Mullen et al. (2007)</td>
<td>Arch length, Bolton</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

The topic of clinical significance and relevance, however, should be reevaluated as new technology surrounding computer-assisted orthodontic treatment is developed. The future of orthodontics surrounds customized brackets, personalized arch-wires, rapid prototyping of trays for indirect bonding, and computer-assisted treatment planning. The engineering accuracy and technology surrounding each of the aforementioned technologies has surpassed the clinical abilities of orthodontic practitioners where 0.2-0.5 mm error is considered clinically insignificant. The challenge now pertains towards developing data-collection methods such as digital impressions and clinical techniques such as indirect bonding that incorporate engineering technology and modern capabilities. As long as biology is an orthodontic limitation and
gene therapy is still in the distant future, it is the integration and development of digital technology that will facilitate decreased treatment time and improved results.

The reliability of models produced through the Cadent iTero digital impression system in this study was demonstrated through both the small difference in mean measurements between digital and control models as well as the intra-class correlation results for repeated digital measurements. Intra-class correlation coefficient (ICC) values were estimated using measurements obtained from the same models at different time-points (at least one week apart) and were highly correlated >0.95. The high ICC values demonstrate both the operator and the technique were highly correlated and reliable in obtaining repeatable measurements. However, though all ICC values showed good correlation, the digital ICC value was less than the control and plaster values (Table 4). The reduced correlation may infer that increased variability of measurements may have occurred in digital models relative to plaster or physical models.

Results of this study may not be reproducible clinically as several factors may have influenced the accuracy obtained. 1) Points of measurement on each tooth were clearly defined by preparations placed on control typodonts. Preparations to aid in repeatability of comparative model assessment are not possible to reproduce in a clinical setting. However, as previous studies have reported challenges associated with accurately relating digital and plaster model measurements, preparations were key to study design. The goal of this study was to evaluate the digital scanner’s ability to reproduce 3D models accurately and reliably, not to test the direct clinical application or ability to define repeatable points using manual and digital measurement techniques. 2) Time was not a factor in obtaining measurements. Care was taken to obtain as accurate
measurements as possible through magnification and careful evaluation on both digital and physical models. 3) In order to prevent incorporation of error due to operator inexperience, control typodonts were submitted to Cadent iTero laboratory technicians for additional scans if deemed necessary.

Future studies surrounding this technology should incorporate analysis using x, y, and z coordinates in order to verify that digital impressions are true duplicates in three dimensions. Linear measurements were a limitation of this study as they do not confirm that points of measurements were from the same 3D coordinate on each of the models - only the length of the measurement is confirmed. However, the linear nature of this study demonstrated validity of digital model measurements obtained through digital impressions using the iTero digital intraoral impression system, as measurements from digital intraoral impressions were very similar to those obtained from the control and plaster model groups. Measurements from the digital group were also highly correlated at separate time-points showing repeatability of digital software. Digital models obtained through the iTero impression system therefore appear to be both accurate and reliable for traditional orthodontic analysis and records purposes.
CONCLUSIONS

1. Linear measurements obtained from digital impressions produced by the Cadent iTero digital impression system were very accurate (0.06mm mean difference).

2. Repeat measurements using digital impressions were very reliable.

3. When contrasted with accuracy accepted for current orthodontic model digitization methods, digital models produced using the iTero digital impression system were more accurate than traditional methods of digitization and are therefore suitable for current orthodontic records and analysis purposes.

4. Plaster models showed better correlation to control models than digital models produced using the iTero digital impression system.
REFERENCES


