A COMPARISON OF THREE TYPES OF ORTHODONTIC STUDY MODELS

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KEYWORDS

Digital study models

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Printed study models

Intra-oral scanner

Three-dimensional (3D) printer

Accuracy

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Orthodontics

ABSTRACT

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Degree of Magister Scientiae in Orthodontic Research

Aim and objectives: The aim of this present study was to compare the accuracy of digital and printed study models with plaster study models, that are considered the gold standard.

The objectives were to compare the accuracy of measurements obtained from digital and printed study models with those of plaster study models, to establish which type of study model yielded the most accurate measurements in comparison to plaster study models and to identify possible disadvantages and errors that can be made using any of the three types of study models.

Methodology: A study sample of 50 patients attending a private orthodontic practice for orthodontic treatment participated in this present study. Patients' participation was voluntary and informed consent from all patients was obtained before participation commenced. In the case of minor patients, informed consent from a parent or legal guardian was obtained.

Dental impressions using alginate were taken from each patient and these were cast into plaster study models within 24 hours. Digital impressions using the TRIOS® intra-oral scanner by 3Shape were taken for the same patients and digital study models were generated using Ortho Analyzer™ software. These digital study model files were used to print study models using the Next Dent 5100 for Ceramill® 3D printer. The following measurements were taken from each arch of each study model: mesio-distal tooth width of permanent teeth 1-6, inter-molar width and inter-canine width. All plaster and printed study models were measured using an electronic digital calliper and the digital study models were measured using Ortho Analyzer™ software. The data were recorded using Microsoft Excel spreadsheets and statistically analysed by a statistician.

Results and discussion: Parametric techniques were used to analyse data. Descriptive analyses for all study models were conducted. Statistical analyses were done to determine any significant differences between the three types of study models. The *p* value was set at ≤0.05.

Only four of the 28 sets of observations were statistically and significantly different; with values of less than 0.05. These observations were mesio-distal widths of teeth 15 and 26, the inter-canine widths in the maxillary arches and the inter-molar widths for the maxillary arches. Pairwise comparisons were done to determine where the statistically significant differences existed. Out of the four sets of observations discussed above, the printed study models were statistically significantly different from their plaster counterparts, with the exception of the measurements taken for the mesio-distal width of tooth 15, where both digital and printed study model measurements differed significantly from the plaster study model observations. No other measurements from digital and printed study models were statistically different from those taken from plaster study models.

Inter-rater reliability was assessed to test the reliability and reproducibility of the results. Fifteen study models of each study model type were randomly selected, and these were measured by a second operator. The interclass correlation values of the plaster, digital and printed study models were 0.825, 0.861 and 0.880 respectively; and were clinically acceptable.

Conclusion: The researcher of this present study concluded that the measurements taken from digital and printed study models are as accurate as those taken from plaster study models and are therefore accurate enough to be used in a clinical environment.

May 2020

DECLARATION

I declare that *A Comparison of Three Types of Orthodontic Study Models* is my own work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

Amika Madhoo

5 May 2020

Signed: ……………………………………………

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KEY

The following key was used in data collection and recording:

MDW: mesio-distal width

ICW: inter-canine width

IMW: inter-molar width

MX: maxilla

MND: mandible

1/_1: plaster study models

2/_2: digital study models

3/_3: printed study models

Min: Minimum

Max: Maximum

CHAPTER 1

INTRODUCTION

An orthodontic diagnosis and treatment plan are formulated once a thorough assessment of the patient and the patient's presenting problems have been addressed (Bahreman, 2013:42). The patients' interviews are conducted to address their main complaints, to assess the medical and dental history and patients' physical growth patterns. The clinical examination consists of extra-oral and intra-oral examinations. Diagnostic tools that are vital to formulate a diagnosis include: a study model assessment, extra and intra-oral photographs, radiographs and cephalometric analysis (Bahreman, 2013:42).

A study model is an imperative part of orthodontic diagnosis and treatment planning (Bahreman, 2013:43). It is particularly important in the fields of prosthodontics and orthodontics (Polido, 2010:18). Study models are used to measure overjets and overbites, tooth size, arch lengths (Sjögren *et al*. 2010:482), Bolton analysis (Lemos *et al.* 2015:1) and can be used to predict the sizes of unerupted permanent teeth (Kumar *et al*. 2015: S465). Study models are also needed to evaluate arch form, symmetry and curves of Wilson and Spee (Correira *et al*. 2014:108). Space analysis, which is done using measurements obtained from study models, is used, in conjunction with other techniques, to determine whether extractions are required (Correira *et al*. 2014:108). The introduction of intra-oral scanners has presented practitioners with a more modern and user-friendly alternative to dental impressions (Polido, 2010:18). According to Reuschl *et al.* (2016:23), digital study models may replace the need for their plaster equivalents. The many advantages of digital study models eliminate the numerous problems that arise when using plaster study models (Fleming *et al*. 2011:2). Abizadeh *et al.* (2012:158) state that digital study models are appropriate for use in place of plaster study models, provided they are used in conjunction with other clinical findings.

Digital study models may also be used to print physical study models using a three-dimensional (3D) printer (Martin *et al*. 2015:143). The ability to print study models from digital impressions allows practitioners to make use of intra-oral scanners and still fabricate physical models without the conventional way of the use of impressions taking and plaster study models (Hazeveld *et al*. 2014:108).

The aim of this present study was to compare the accuracy of measurements taken from digital study models obtained from an intra-oral scanner, printed study models (from digital study model files by a 3D printer), with measurements taken from plaster study models; and to provide validation on the suitability of digital and printed study models to be used in a clinical setting.

CHAPTER 2

LITERATURE REVIEW

2.1. Intra-oral Scanners

The first computer aided design/computer aided manufacture (CAD/CAM) system developed specifically for dentistry was called CEREC, which stands for ceramic reconstruction, in 1979 (Kano *et al*. 2015:128). Sirona Dental Systems currently manufacture this technology and they introduced a chair side scanning device for dentistry (Martin *et al*. 2015:136). Cadent, a subsidiary of Align Technology that specialises in manufacturing orthodontic scanners, introduced dentistry to the concept of orthodontic scanning with their product called OrthoCAD™, where plaster study models or dental impressions were couriered to the OrthoCAD™ centre. These study models or dental impressions were scanned and converted to digital study models and made available to the practitioner (Kravitz *et al*. 2014:338). The availability of desktop scanners has enabled the creation of digital study models from scanning plaster study models or dental impressions (Martin *et al*. 2015:136); however, they are more likely to be used by large hospitals, clinics and dental laboratories (Martin *et al*. 2015:138). This method of obtaining digital study models is called the indirect method (Westerlund *et al*. 2015:509). In 2008, a system called iTero™, by Cadent, capable of intra-oral scanning was introduced (Kravitz *et al*. 2014:338). Intra-oral scanning is a direct method of obtaining digital study models by scanning patients' mouths using intra-oral scanners (Westerlund *et al*. 2015:509).

2.1.1. Applications of intra-oral scanning in orthodontics

It is necessary for practitioners to consider what system they will use, based on its applications (Martin *et al*. 2015:136). The ideal type of system would be one that produces digital study models of high accuracy and reproducibility, and allows digital study models to be analysed for measurements and occlusion and to be viewed in various planes (Wan Hassan *et al*. 2016:890). The system should also be cost effective and accessible (Wan Hassan *et al*. 2016:890-891).

Digital impressions are taken using intra-oral scanners and this method eliminates many of the disadvantages associated with conventional impression taking (Anh *et al*. 2016:4). These impressions are converted to digital study models (Anh *et al*. 2016:4) via the direct method (Westerlund *et al*. 2015:509). Intra-oral scanning technology enables practitioners to fabricate various orthodontic appliances, such as: clear aligners, custom made brackets, indirect bonding trays (Kravitz *et al*. 2014:337), palatal and lingual appliances and surgical stents used in orthognathic surgery (Martin *et al.* 2015:136). This technology is also useful in treatment planning (Martin *et al*. 2015:136) and simulating tooth movements (Kano *et al*. 2015:128).

2.1.2. The technology of intra-oral scanning

A digital intra-oral scanner is made up of three main parts: a wireless workstation, a handheld wand that has a built-in camera or sensor, and a computer monitor (Kravitz *et al*. 2014:338). Intra-oral scanners may be classified into two groups: video acquisition and still video acquisition methods (Park, 2016:354).

Numerous types of imaging technology can be used to capture an image, and the type used depends on the brand of the digital intra-oral scanner. Types of imaging technology include: accordion fringe interferometry, 3D in-motion video, triangulation, parallel confocal (Kravitz *et al*. 2014:339), active waveform sampling, optical coherent tomography, ultrasound (Ahmad and Al-Harbi, 2019:42-43), parallel confocal microscopy and Ultrafast Optical Sectioning (Martin *et al*. 2015:140). Each type of scanner differs in its resolution and this affects the quality of images produced (Park, 2016:357).

2.1.3. Advantages and disadvantages of intra-oral scanning

This type of technology poses benefits for both the practitioner and the patient. Intra-oral scanning eliminates the many disadvantages of conventional impression taking and plaster study models (Martin *et al*. 2015:137). The digital study model can be visualised three-dimensionally before scanning has been finalised (Lee and Gallucci, 2013:111). Re-scans can be done immediately if the image captured is unsatisfactory and can be undertaken without repeating the entire impression taking process (Lee and Gallucci, 2013:114). This method is suitable for patients with compromised teeth as a result of mobility or structure (Ahmad and Al-Harbi, 2019:31). Digital impressions can be sent immediately to a dental laboratory for processing and work completed by the laboratory can be sent back faster than if conventional practices were used (Wismeijer *et al*. 2014:1117). Digital impressions can be sent immediately to malpractice insurers for legal purposes (Kravitz *et al*. 2014:338). Laboratory transportation costs are eliminated (Martin *et al*. 2015:137). Digital study models can be stored electronically and retrieved easily (Anh *et al*. 2016:4). According to Kravitz *et al.* (2014:338), chair time and treatment time are both greatly reduced with the use of such technology, but this also depends on the practitioner (Martin *et al*. 2015:137). The workflow of a practice using digital intra-oral scanning can become more efficient as the practitioner and other staff members become more comfortable with the technology (Martin *et al*. 2015:137). Practitioners who use this type of technology in their practices can use it as a marketing tool (Westerlund *et al*. 2015:509).

Improved patient experiences at the dentist or orthodontist is an advantage of this technology, as conventional impression taking can be an unpleasant experience for many patients (Martin *et al*. 2015:137). Digital impressions are better tolerated by patients who have breathing difficulties and sensitive gag reflexes (Mangano *et al*. 2018:123). Patients can gain a better understanding of their treatment with an improved presentation of their diagnoses and treatment plans (Kravitz *et al*. 2014:338). Burzynski *et al.* (2018:540) reported that participants in their study felt that the digital technology was of importance. According to Wismeijer *et al.* (2014:1117), patients who had impressions taken for dental implants, preferred intra-oral scanning to conventional dental impressions. Burzynski *et al.* (2018:540) undertook a study, which compared patients' preferences between digital and conventional impression taking, and concluded that their participants preferred digital impression taking to the conventional method and that the method was well accepted.

According to Zhang *et al.* (2016:8), some challenges encountered using digital intra-oral scanners included scanning difficulties in the posterior mandibular molar area due to the movements of the tongue and the limited area the intra-oral scanner head can access. Patients with limited opening of the oral cavity, high amounts of saliva and movements of the tongue also contribute to scanning distortions and inaccurate images (Zhang *et al*. 2016:9). In terms of cost, the price of training, software updates and subscriptions can make the purchase of an intra-oral scanner very expensive (Ahmad and Al-Harbi, 2019:38). According to Ahmad and Al-Harbi (2019:38), the price of an intra-oral scanner can range from US$ 20 000-40 000, with an additional cost of approximately US$ 4 000 for annual fees.

When scanning the oral cavity, proper isolation needs to be implemented to ensure an accurate image is produced (Kravitz *et al*. 2014:341). Dry angles, cheek retractors, and saliva ejectors can be used to achieve this in conjunction with powder (Kravitz *et al*. 2014:341).

Some intra-oral scanners require the use of a powder made from titanium oxide or zirconium oxide, aluminium hydroxide and amorphous silica, which is sprayed onto the area of the oral cavity that needs to be scanned (Kravitz *et al*. 2014:340). The principle of using this opaque powder is to allow the light emitted from the scanner to disperse evenly and to improve the number of surface data points received by the scanner. This increases the accuracy of images produced (Kravitz *et al*. 2014:340) and the speed at which the scans are taken (Park, 2016:361). However, the application and removal of the powder can be uncomfortable for the patient, and furthermore, it can be harmful to the patient if not removed (Park, 2016:361). It can also affect the colour of the image (Ahmad and Al-Harbi, 2019:36).

Westerlund *et al.* (2015:509) conducted a study that compared the software of four different types of systems available on the market. These systems included: OrthoCAD™ by Cadent, Digimodel™ by OrthoProof™, Ortho Analyzer™ by 3Shape and O3DM by OrthoLab (Westerlund *et al*. 2015:511). These software systems are available for the analyses of digital study models obtained by the indirect method. After comparing these four systems, the researchers concluded that these software programs were not user-friendly and that practitioners would require training from experts or manufacturer representatives (Westerlund *et al*. 2015:516).

2.1.4. Types of intra-oral scanners

Various dental technology manufacturers have produced their own brand of intra-oral scanners with their unique form of scanning technology. Some of the intra-oral scanners available on the market include: Lythos ™ scanner by Ormco™, 3M™ True Definition by 3M ESPE, TRIOS® Scanner by 3Shape, iTero® by Align Technology Inc., IOS FastScan ™ by IOS Technologies Inc., Planmeca Planscan™ by E4D Technologies and CS 3500 Intra-oral scanner by Carestream Dental (Martin *et al.* 2015:140). As the TRIOS® Intra-oral scanner by 3Shape has been used by the researcher for this present study, this scanner will be discussed.

2.1.4.1. TRIOS® Intra-oral Scanner by 3Shape

This intra-oral scanner was introduced to the market in 2010 according to Martin *et al.* (2015:139). The technology it employs to capture surface data is called confocal scanning technology (Ahmad and Al-Harbi, 2019:42).

There are three types of TRIOS® intra-oral scanners available for orthodontic treatment: the TRIOS® 3 Basic, TRIOS® 3 and TRIOS® 4 (www.3shape.com). The current generation of the TRIOS® intra-oral scanner is the TRIOS® 4. The scanner is equipped with heat-smart tips and 30% more battery life than its predecessors. This scanner differs from its predecessors as it utilises fluorescent technology that can also detect occlusal caries. Later this year, the company plans to launch a specific tip for the TRIOS® 4 scanner that can detect interproximal caries (www.3shape.com). The TROIS®3 was used in this present study and according to Ahmad and Al-Harbi (2019:42), it is fast, user-friendly and highly accurate. It uses a light emitting diode (LED) light source and is compatible with 3D printers and certain third-party milling companies (www.3shape.com). The software available with the scanner includes TRIOS® Smile Design and TRIOS® Treatment Simulator (www.3shape.com). Images can be scanned in black and white or colour; the black and white option being more affordable. The intra-oral scanner is available in a pen or handle grip and can be connected wirelessly (www.3shape.com). TRIOS® Move is a stand on wheels with an adjustable arm that incorporates an LCD screen that can swivel and has a USB port for the intra-oral scanner (www.3shape.com). According to Ahmad and Al-Harbi (2019:42), the intra-oral scanner scans at a rate of approximately 5 minutes per arch.

The unit is available as a mobile cart with an attached intra-oral scanner and a touchscreen (Martin *et al*. 2015:140). The TRIOS® Cart is also available as a battery operated unit, for the TRIOS 3® Basic and TRIOS® 3 intra-oral scanners (www.3shape.com). Another option for practitioners is the TRIOS® Pod, which can connect to a computer or laptop via a USB port (www.3shape.com) or to an iPad or a screen that is part of a dental chair (Martin *et al*. 2015:140). Scanning tips can be sterilised in an autoclave. (Martin *et al*. 2015:140). Apps such as Implant Studio, TRIOS® Design Studio and Splint Studio are available as additions for practitioners and an app, called the My3Shape app, exists for patients (www.3shape.com).

Ortho Analyzer™ software is used in conjunction with this intra-oral scanner. The size of the software is approximately 650 MB (Westerlund *et al*. 2015:514) and it can be used on a Microsoft Windows system (Westerlund *et al*. 2015:515). Using this software, practitioners can take linear measurements, conduct a space analysis and assess arch form, length and crowding (Martin *et al*. 2015:140). The software allows practitioners to incorporate cephalogram tracings, radiographs, digital photographs (www.3shape.com) and it can be combined with cone beam computed tomography (CBCT) images (Westerlund *et al*. 2015:515). Digital study models have a size of approximately 3 MB with this particular software (Westerlund *et al*. 2015:514). TRIOS® intra-oral scanners and software have also been approved to be used with a number of orthodontic appliance companies, such as: Orthocaps, ClearCorrect, Harmony, Insignia, Incognito, Suresmile, Invisalign and Suresmile Fusion (www.3shape.com). By using a cloud-sharing system, these orthodontic appliance suppliers can create appliances based on images taken using the TRIOS® intra-oral scanner. A software programme called 3Shape Communicate™ can be used to educate patients about their cases and liaise with dental laboratories. Practitioners or dental laboratories can print or mill certain appliances, such as indirect bonding, splints and metal bands (www.3shape.com).

Ortho Analyzer™ software can conduct the following analyses: Bolton analysis, arch length, overjet and overbite, tooth size and space analysis (Westerlund *et al*. 2015:512). The software allows the practitioner to compose a virtual set-up and articulate digital study models. Peer assessment review (PAR) index is not available with this software, but it is available with other brands such as Digimodel™ (Westerlund *et al*. 2015:515).

Burzynski *et al.* (2018:538) conducted a study comparing patients' experiences between impressions taken with the iTero and TRIOS® 3 Basic intra-oral scanners and conventional alginate impressions. Participants reported that the time taken to scan with the TRIOS® scanner was longer than when the iTero intra-oral scanner and conventional alginate impressions were used. Participants also felt their mouths were drier when TRIOS® intra-oral scanner was used (Burzynski *et al*. 2018:538). The authors attributed this perception due to the size of the head and wand of the iTero intra-oral scanner, which was smaller than the TRIOS® intra-oral scanner (Burzynski *et al*. 2018:539). The authors also conceded that since they had completed their study, a newer version of TRIOS® intra-oral scanner had been released, which made changes to its design to improve patient comfort (Burzynski *et al*. 2018:540).

Ortho Analyzer™ has been deemed suitable for use in a clinical environment (Czarnota *et al*. 2016:30). The software allows practitioners to analyse digital study models in a step by-step manner (Reuschl *et al*. 2016:23). Practitioners can manoeuvre the study models by tilting, zooming in and out and rotating (Reuschl *et al*. 2016:25). Czarnota *et al.* (2016:26) concluded that its results, when compared with those obtained from plaster study models, were reproducible. Saleh *et al.* (2015:305) also concluded that measurements from digital study models taken using Ortho Analyzer™ were acceptable from a clinical point of view, when compared with plaster study models.

2.1.5. Prevalence of Intra-oral Scanners

A study done by Park and Laslovich (2016:415) investigated the prevalence of the use of digital study models and other technologies available to orthodontists in the United States of America (USA). They found that 53% of responders, who made use of digital study models in their practices, used intra-oral scanners to obtain them (Park and Laslovich, 2016:418). iTero® by Align Technology was the most popular intra-oral scanner used by responders (Park and Laslovich, 2016:418). Responders cited its compatibility with the Invisalign® system as a reason for its popularity (Park and Laslovich, 2016:418). These researchers stated that the use of intra-oral scanners is becoming increasingly accepted amongst orthodontists (Park and Laslovich, 2016:418).

Figure 1: TROIS® 3 Intra-oral scanner by 3Shape

2.2. Digital Impressions

A dental impression is defined as an impression of the negative parts of the oral cavity, and this is used to make a cast of the oral hard and soft tissues (Hamalian *et al*. 2011:153). Materials such as alginate and polyvinyl siloxanes can be used to take a dental impression (Kravitz *et al*. 2014:338).

A digital impression is defined as a digital scan of the oral cavity using an intra-oral scanner (Martin *et al*. 2015:136). It is also defined as a non-contact impression (Ahmad and Al-Harbi, 2019:27). They are expected to replicate teeth and oral soft tissue accurately (Ahmad and Al-Harbi, 2019:29). Many types of intra-oral scanners are available on the market for practitioners (Martin *et al*. 2015:139). Intra-oral digital scanning benefits the fields of orthodontics (Ahmad and Al-Harbi, 2019:176). Surgical templates for implant-supported prostheses can be produced by using intra-oral scanners to scan dental arches (Ahmad and Al-Harbi, 2019:161). Intra-oral scanners can be used for aesthetic dentistry. Digital impressions for porcelain laminate crowns can be taken using intra-oral scanners (Ahmad and Al-Harbi, 2019:229).

2.2.1. Disadvantages of conventional impression taking

The process of impression taking is time-consuming as a tray must be selected and a material chosen and prepared (Polido, 2010:19).

The materials used to take conventional dental impressions have many disadvantages that can affect the quality of the study model produced (Martin *et al*. 2015:137). Impression materials, depending on their properties, are subject to shrinkage and mixing technique, and sensitive to temperature changes (Martin *et al*. 2015:137). Movement of the tray while the material is setting can affect the plaster study model produced (Polido, 2010:21). Bubbles and voids can appear in the material. The impression materials can also pull and tear (Kravitz *et al*. 2014:338). Insufficient adhesive application can cause the impression material to separate from the impression tray (Polido, 2010:21). Materials must also be disinfected before being sent to the dental laboratory for processing (Polido, 2010:19) and this can cause the set impression material to distort (Polido, 2010:21) Some patients may be allergic to certain ingredients found in impression materials (Martin *et al*. 2015:137).

Casting study models from conventional dental impressions is also time-consuming, as study models must be poured and articulated correctly (Polido, 2010:19). Plaster study models are also subject to incorrect trimming (Kravitz *et al*. 2014:338).

Impression taking is often an uncomfortable experience for most patients; especially those with a cleft lip or cleft palate and a sensitive gag reflex (Martin *et al*. 2015:137).

2.3. Study models

A study model is an essential part of orthodontic diagnosis and treatment planning (Bahreman, 2013:43). It has many uses including: space analysis, forming part of patients' treatment records, legal purposes, treatment progress (Kumar *et al*. 2015: S465), patient and parent education (Bahreman, 2013:54) and fellow peer demonstration and education (Kumar *et al*. 2015: S465).

2.3.1. Plaster study models

Plaster study models have been the 'gold standard' for study model analysis (Abizadeh *et al*. 2012:155). Measurements taken using a digital or analogue calliper have been considered reliable (Czarnota *et al*. 2016:23).

Plaster study models are considered an accurate representation of patients' occlusion and this claim is further validated by the well-fitting orthodontic appliances that have been formed using these study models (De Luca Canto *et al*. 2015:74). The advantages of plaster study models include its accuracy and reliability as the 'gold standard' of study models and they are easy and cheap to produce (Pachêco-Pereira *et al*. 2015:501). The method of conventional impression taking is generally well tolerated and accepted and therefore still favoured by many practitioners (Burzynski *et al*. 2018:534). The plaster study model can be handled in any plane, when measuring or assessing (Lemos *et al*. 2015:5). The process of taking a conventional dental impression is faster than a digital impression (Mangano *et al*. 2018:123).

Plaster study models have many limitations that digital models have overcome (Kumar *et al*. 2015: S465). Plaster study models are subject to breakage and damage (Czarnota *et al*. 2016:23). They can be misplaced (Abizadeh *et al*. 2012:158) and are also time-consuming to measure (Keating *et al*. 2008:191). For legal purposes, study models are required to be stored for a certain number of years and the storage of plaster study models is problematic due to their weight and size (Czarnota *et al*. 2016:23). Practitioners need to keep track of stock of materials required for conventional impressions (Burzynski *et al*. 2018:534).

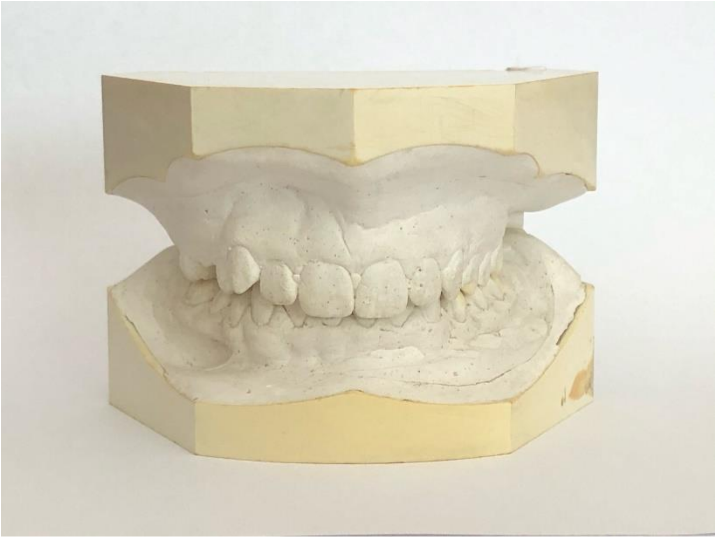


Figure 2: Frontal view of an orthodontic plaster study model

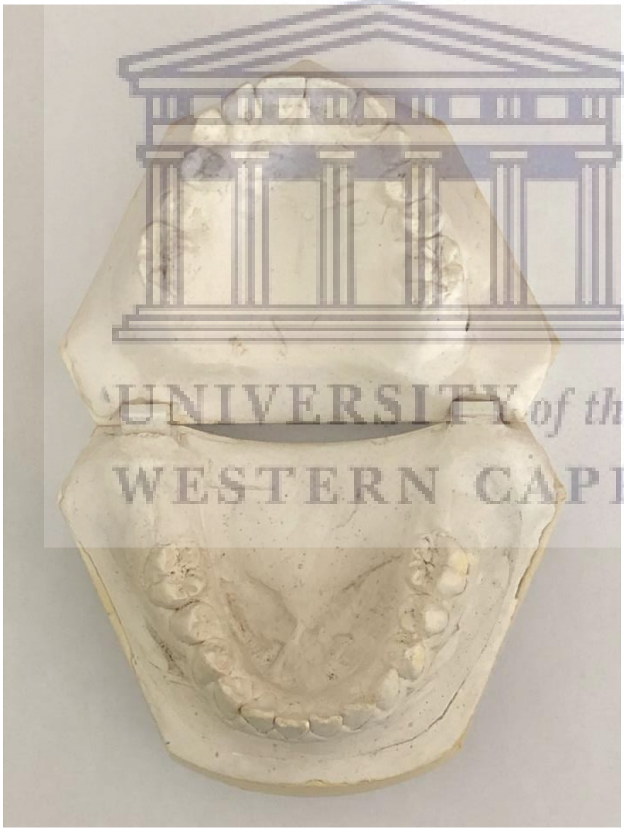


Figure 3: Arch view of an orthodontic plaster study model

2.3.2. Digital study models

Digital study models are also known as virtual models (Abizadeh *et al*. 2012:151). They were introduced to dentistry by Align Technology Incorporated in 1999. The programme that they produced was called OrthoCAD™, which scanned plaster study models to convert them to digital study models (Reuschl *et al*. 2016: 22). OrthoCAD™ used a 'destructive scanning' technique to generate a digital image of the plaster study model (Fleming *et al*. 2011:2). In 2001, GeoDigm Corporation produced a similar program, manufacturing 'emodels' that were made from scanning plaster study models with a non-destructive laser (Reuschl *et al*. 2016:22). Couriering plaster study models or impressions to these facilities was expensive so desktop scanners were introduced for dental practices and laboratories (Reuschl *et al*. 2016:22). A programme called Digimodel™ by OrthoProof™ could then generate a digital study model from a dental impression; a plaster study model was not needed with this particular programme (Fleming *et al*. 2011:2). CBCT is used in the Digimodel™ programme (Wan Hassan *et al*. 2016:886). As CBCT had become more commonplace in dental practices, sending impressions to dental laboratories became impractical (Jiang *et al*. 2016:130).

Digital study models are created by two methods, either a direct or indirect method (Czarnota *et al*. 2016:23). A direct method creates a digital study model after the patient's mouth is scanned using an intra-oral scanner (Czarnota *et al*. 2016:23). CBCT can also be used directly to obtain digital study models of patients' mouths but is unsuited to an orthodontic setting due to the amount of radiation of that patients would be exposed to during the course of their treatment (Kim and Lagravére, 2016:14); unless CBCT images are required for other reasons, such as planning implant placement or orthognathic surgery (Ahmad and Al-Harbi, 2019:62). The quality of images produced by CBCT is affected by orthodontic brackets, implants and other metal prostheses and restorations, and therefore it is not suitable for every orthodontic patient (Tarazona *et al*. 2013:5). An indirect method creates digital study models after conventional alginate impressions or plaster study models are scanned using a desktop scanner (Czarnota *et al*. 2016:23). According to Ahmad and Al-Harbi (2019:50), the sale of extra-oral scanners dominated the market, but this is changing in the favour of intra-oral scanners as the technology of intra-oral scanners has become more user-friendly and accurate.

The formation of digital study models depends on the technology used for each brand of intra-oral or desktop scanner and its associated software. CAD/CAM technology made it possible for the dental arch to be scanned three-dimensionally. It was first used for dental restorations, but its applications into other fields of dentistry have since grown (Martin *et al*. 2015:136). CAD/CAM technology can scan plaster study models to convert them to digital study models, or it is available as a computer software programme that can manipulate digital study models (Kumar *et al*. 2015: S467). Laser scanning or technology that combines stereophotogrammetry creates digital study models (Abizadeh *et al*. 2012:151). Digital study models are created and stored as Standard Tessellation Language (STL) open format files (Martin *et al*. 2015:138) or other flexible open file formats, such as PLY and OBJ files (Martin *et al.* 2015:139). Standard Tessellation Language is one of the few terms that can be used for the acronym STL (Ahmad and Al-Harbi, 2019:6). The original acronym stood for STeroLithography; it is a 3D file format that is used by CAD software (Ahmad and Al-Harbi, 2019:7). The STL file is in black and white but can be converted into a variety of colours depending on its application, by CAD software (Ahmad and Al-Harbi, 2019:7).

Digital study models have numerous advantages. Digital files do not require the physical storage space needed by plaster study models (Fleming *et al*. 2011:2); they are stored electronically (Veenema *et al*. 2009:281). Digital study models can be subjected to an objective grading system (De Luca Canto *et al*. 2015:66), such as the American Board of Orthodontics scoring (ABO) or PAR (Fleming *et al*.2011:2). The digital files can be sent worldwide instantly for laboratory work, consultation, referral or educational purposes (Reuschl *et al.* 2016:22), eliminating the need for transport (Wan Hassan *et al*. 2016:886). They are not subject to physical damage or loss as plaster study models are (Veenema *et al*. 2009:281). Retrieval of digital study models is easier than having to physically find plaster study models in a storage space (Fleming *et al*. 2011:2). Digital files are easier to file and organise (Abizadeh *et al*. 2012:185). They can be electronically stored with patients' records (Asquith and McIntyre, 2012:531). Computer software that is available with intra-oral and desktop scanners can analyse and manipulate digital study models (Shahid *et al*. 2016:176). This software allows practitioners to design dental prostheses and orthodontic appliances (Dowling *et al*. 2013:1272). Virtual set-ups can also be created with this software (De Luca Canto *et al*. 2015:66). The software can measure study models for practitioners, which makes study model analyses less time-consuming (Correira *et al*. 2014:112). Laboratory fees are reduced with such technology (Pachêco-Pereira *et al*. 2015:501). For those practitioners who favour running a paperless practice, digital study models provide an alternative to plaster study models (Zilberman *et al*. 2003:301). Using digital technology in dentistry may appeal to some patients, as it is a more modern approach to dentistry (Zilberman *et al*. 2003:302).

One of the most significant disadvantages of digital study models is the fact that practitioners cannot physically hold, view or feel the study model (Asquith and McIntyre, 2012:531). Digital study models are 3D objects that are viewed two-dimensionally, which requires some adjustment from practitioners who are used to analysing and holding 3D plaster or printed study models (Abizadeh *et al*. 2012:158). The accuracy of measurements can be affected by difficulty in distinguishing landmarks on the digital study models (Sjögren *et al*. 2010:483). Abizadeh *et al.* (2012:158), stated that inaccuracies in mesio-distal tooth width measurements could be due to difficulty in finding the widest portion of the crown. Digital study models cannot be articulated in relation to the tempero-mandibular joint (Lemos *et al*. 2014:2). Practitioners will need to orientate themselves and practise locating certain planes and landmarks on digital study models. Analysis of crossbites has been especially problematic (Abizadeh *et al*. 2012:158). Storing digital study models requires maintenance, as digital files need to be backed up regularly and files must be password protected to ensure patients' records are kept confidential (Abizadeh *et al*. 2012:158). The size of electronic storage space needs to be considered as the computer software that generates and analyses digital study models requires space. The size of digital study models can range from less than 1 megabyte to 25 megabytes. The number of arches and resolution of the image affects the size of the file (Martin *et al*. 2015:137). Data loss is also a risk that must be considered (Correira *et al*. 2014:111). Technical support for the computer software that receives the scanned data and converts it to digital study models is required (Lemos *et al*. 2014:2). Plaster study models that are sent to dental laboratories for conversion to digital study models can be damaged or lost (Jiang *et al*. 2016:134). The indirect method of obtaining digital study models can be time-consuming (Kim and Lagravére, 2016:18); and this method means that practitioners are dependent on a company or dental laboratories for their study models (Correira *et al*. 2014:111). Digital study models acquired by indirect means are only as accurate as the conventional impressions or plaster study models that were scanned (Ahmad and Al-Harbi, 2019: 51). The equipment and software are very expensive (Correira *et al*. 2014:111).

The use of digital study models in orthodontic practices is increasing and becoming widespread due to their convenience (Kim and Lagravére, 2016:14). According to Hazeveld *et al.* (2014:108), the use of digital study models has been well received by orthodontists. Some practitioners deem that they can replace the use of plaster study models (Dalstra and

Melsen, 2009:40). Others think that while the measurements obtained from digital study models are acceptable for use in a clinical setting, (Hazeveld *et al*. 2014:109), it has not become commonplace to work without plaster study models (Hazeveld *et al*. 2014:108). Kim and Lagravére (2016:18), conclude that digital study models have certain limitations that need to be taken into account. Hazeveld *et al.* (2014:108) state digital study models may supplement traditional plaster study models. Pachêco-Pereira *et al.* (2015:506) based their research on that digital study models may only be used accurately in the treatment planning of patients with a Class II malocclusion. Saleh *et al.* (2015:304) found the accuracy of measurements between plaster and digital study models similar and concluded that digital study models are accurate enough to replace the need for plaster study models (Saleh *et al*. 2015:305-306). Kumar *et al.* (2015: S468) compared the accuracy of linear measurements and anterior Bolton's ratio of digital study models created by CBCT and CAD/CAM with plaster study models and concluded that digital study models can replace plaster study models. Correira *et al.* (2014:108), compared space analyses taken manually using an electronic digital calliper on plaster study models with digital study models, obtained by scanning the same plaster study models (Correira *et al*. 2014: 109). A brass wire was also used for measuring. The digital study models were analysed using software available with the desktop scanner (Correira *et al*. 2014:109). The researchers concluded that the results of the space analyses did not differ, with the exception of measurements taken using the digital calliper, but these differences were deemed not statistically significant (Correira *et al*. 2014:104). All other dental records, such as patient information, photographs, radiographs have become digitised (Pachêco-Pereira *et al*. 2015:506); study models have also now followed the trend. Patients' records can now become fully electronic with the use of digital study models (Joffe, 2004:344).

Czarnota *et al.* (2016:27) states that the American Board of Orthodontics objective grading system considers deviations of <0.5 mm in anterior-posterior, vertical and transverse planes inconsequential in a clinical environment. Wan Hassan *et al.* (2016: 887) used a mark of 0.5 mm as the clinically acceptable range for differences in measurements found in their study which compared measurements between plaster and digital study models. Saleh *et al.* (2015:304) found an increase of 0.1 mm in measurements taken from digital study models but these differences were deemed clinically insignificant in comparison with its plaster counterparts. In their study, a range of 0.1-0.18 mm between measurements of the same points on the software was found but they concluded that these differences were within a clinically acceptable range (Saleh *et al*. 205:305).

Prevalence of the use of digital study models has become increasingly popular in Asia, Western Europe, USA and Australasia according to Martin *et al.* (2015:136). Park and Laslovich (2016:415) conducted a survey to investigate the use of digital technology used by orthodontists in the USA. The survey was sent to members of the American Association of Orthodontists (AAO) and although their response rate was low, they reported that 46% of responders who worked in the private sector made use of digital study models (Park and Laslovich, 2016:416). Of those using digital study models, 53% used intra-oral scanners to obtain them (Park and Laslovich, 2016:418). These researchers also stated that 34% of practitioners who still used plaster study models in their practices, plan to switch to using digital study models (Park and Laslovich, 2016:418).

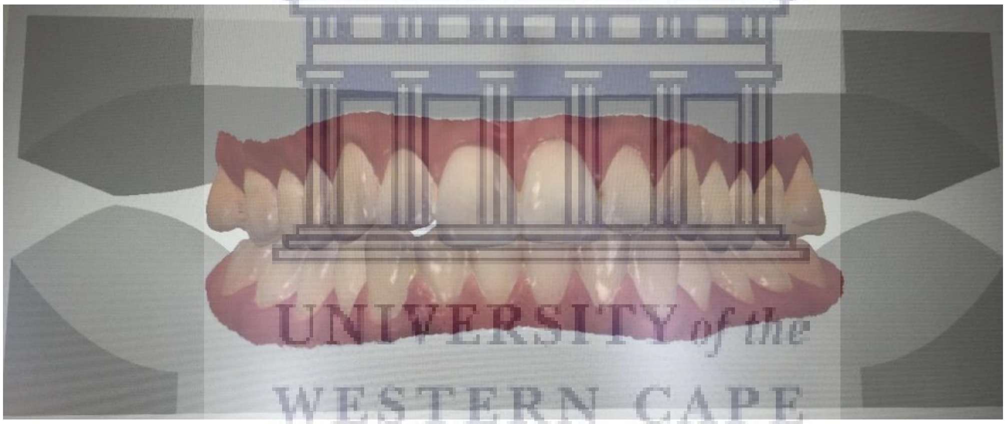


Figure 4: Frontal view of a digital study model

Figure 5: Arch view of a digital study model

2.3.3. Three-dimensionally (3D) printed study models

Digital study models are the blueprints for printing 3D study models using a 3D printer (Dawood *et al*. 2015:524). 3D printed objects can be manufactured in two ways: an additive method or a subtractive method (Reuschl *et al*. 2016:23). The additive method refers to objects that are created by adding one layer at a time until the entire object is built (Dawood *et al*. 2015:521), while the subtractive method creates an object by cutting it out of a solid piece of material (Torabi *et al*. 2015:2). The additive method of 3D printing is also known as rapid prototyping (Dawood *et al*. 2015:521). Study models are produced using the additive method of 3D printing (Hazeveld *et al*. 2014:108-109). The subtractive method is used in restorative dentistry (Torabi *et al*. 2015:2).

Digital study models are the digital files from which study models are printed (Hazeveld *et al*. 2014:108). The digital study model is created by CAD software and translated to an STL file. This file is processed by slicing the model (Lee *et al*. 2015: 219) and the model is built in incremental layers, followed by post curing (Hazeveld *et al*. 2014:109).

A variety of 3D printers are available on the market. Their different technologies make each type of printer suited for different aspects of dentistry (Lee *et al*. 2015:217).

Stereolithography apparatus (SLA) 3D printers use photopolymers to build 3D objects (Dawood *et al*. 2015:252). Saleh *et al.* (2015:302) conducted a study, comparing the accuracy of linear measurements taken from plaster, digital, acrylic and study models printed by a 3D printer from files of digital study models. The type of 3D printer used was an SLA printer, Object Eden250™, manufactured in Massachusetts, USA (Saleh *et al*. 2015:302). The researchers of this study concluded that the study models printed using this printer were highly reproducible (Saleh *et al*. 2015: 306). Keating *et al.* (2008:193) conducted a study, where one of their objectives was to assess the accuracy of 3D printed models printed from digital study models. The printer used in this study was also an SLA printer, a SLA250/40, manufactured by 3D Systems Incorporated in California, USA (Keating *et al*. 2008:194). The material used was an epoxy-based resin and the layers used to build the study models were a thickness of 0.15 mm (Keating *et al*. 2008:194). Plaster, digital and printed study models were measured and compared (Keating *et al*. 2008:194). Measurements taken from the *z*-planes of the plaster and printed study models were significantly different; the measurements taken from the printed study models were smaller than those from the plaster and digital study models (Keating *et al*. 2008:194). The 3D printed study models shrunk after printing, causing the differences in accuracy (Keating *et al*. 2008:198). The researchers of that study concluded that more accurate 3D printer technology is required for more accurate results (Keating *et al*. 2008:200). However, more recent research shows that printed study models can be used as an alternative to plaster study models, as 3D printers that are available on the current market produce study models that are clinically acceptable (Ahmad and Al-Harbi, 2019:139).

Hazeveld *et al.* (2014:109) compared the reproducibility and accuracy of study models printed by three different types of 3D printers to plaster study models. The 3D printers used in this study were: powder binder, jetted photopolymer and digital light processing printers (Hazeveld *et al*. 2014:109). These printers fall into the categories of binder jetting, material jetting and vat polymerisation 3D printers respectively (Ahmad and Al-Harbi, 2019:10-11). The mean differences in measurements taken between plaster study models and models created from jetted photopolymer and digital light processing (DLP) printers were lower than those measurements taken from study models printed from the powder binder printer (Hazeveld *et al*. 2014:112).

According to Lee *et al.* (2015:218), fused deposition modelling (FDM) and PolyJet™ printers are the most advanced 3D printing technologies available on the market. The researchers of that study compared these two technologies by comparing extracted molar teeth to replicas printed by FDM and PolyJet™ printers (Lee *et al*. 205:218-219). The replica teeth printed by the PolyJet™ printer showed a higher accuracy than those printed from the FDM printer (Lee *et al*. 2015:223). The study concluded that while differences were noted, they were not clinically significant (Lee *et al*. 2015:224).

Advantages of 3D printed study models include the fact that the study model is a physical one (Hazeveld *et al*. 2014:108), and this option caters to practitioners who want to physically hold and manipulate a study model (Dalstra and Melsen, 2009:36). Physical study models are also needed to construct orthodontic appliances (Hazeveld *et al*. 2014:108). The use of such technology can be time-saving (Torabi *et al*. 2015:6). Should a physical representation of a patient's dentition be required for legal reasons from a practitioner who makes use of a digital study model system, a 3D printer can provide a replica (Keating *et al*. 2009:191).

The type of 3D printer technology affects the accuracy of study models produced (Lee *et al*. 2015:223). A significant disadvantage of printed study models is that materials shrink during the building process, or study models shrink after the post curing process (Hazeveld *et al*. 2014:112). This shrinkage affects measurements on the *z*-plane, which results in inaccurate measurements of clinical crown heights (Hazeveld *et al*. 2014:112). Hazeveld *et al.* (2014:111) also reported that identifying landmarks on printed study models was problematic, as the materials used were rough in texture and dark in colour. These difficulties can lead to errors in linear measurements (Hazeveld *et al.* 2014:112). However, material jetting printers can be used with a variety of materials that are diverse in properties. Materials are available in several colours and multicolour materials can be used to print a single object (Ahmad and Al-Harbi, 2019:16). Transparent materials are also available (Ahmad and Al-Harbi, 2019:16). Keating *et al.* (2008:198) also reported that the researchers of their study claimed difficulty in measuring printed study models, as the translucency of the clear epoxy-based resin made it challenging to identify certain landmarks. The lack of detail in cervical margins of teeth in study models was also problematic (Keating *et al*. 2008:198). 3D printing technology is also very expensive and not many practitioners can afford this type of equipment (Nayar *et al*. 2015: S217). Another disadvantage is the complexity of the technology and equipment that will require expert help (Torabi *et al*. 2015:6).

Hazeveld *et al.* (2014:112) concluded that the differences in accuracy between printed study models and plaster study models were clinically insignificant. Lee *et al.* (2015:224) concluded that while differences from measurements taken from the extracted and replica teeth were noted, they were not clinically significant, and therefore, the FDM and PolyJet™ printers are considered accurate enough to be used for orthodontic purposes. The mean deviation was statistically insignificant, at 0.047 mm for the FDM replica teeth and 0.038 mm for the PolyJet™ teeth, but these differences are not significant in a clinical setting (Lee *et al*. 2015:223). Saleh *et al.* (2015:301) compared the accuracy of acrylic, digital, plaster and models printed by a 3D printer and concluded that measurements taken from the printed study models were as accurate as the other types of study models. Torabi *et al.* (2015:6) also concluded that the accuracy of study models produced by 3D printing is high.

In a study researched by Keating *et al.* (2008:197), the authors tried to determine a range of measurement that would be considered statistically significant between different types of study models. They reported studies that varied in their opinions, with measurements ranging from 0.20 mm to 0.50 mm (Keating *et al*. 2008:197). Their own study concluded that the mean differences between plaster and digital study models on all planes (*x, y* and *z*) were statistically insignificant at a measurement of 0.14 mm (Keating *et al*. 2008:194). The measurements made on the *x* and *y* planes between plaster and printed study models were also statistically insignificant, but on the *z* planes the measurements differed due to thickness of the layers of the printed models (Keating *et al*. 2008:198).

Ahmad and Al-Harbi (2019:138) have concluded after consulting numerous studies that although the difference between measurements taken from plaster and printed models is statistically significant, the results are acceptable within in a clinical environment. A mean difference of 0.1 mm between natural and cast teeth has been deemed acceptable; however, a difference of up to 0.4 mm has also been accepted among practitioners (Ahmad and Al-Harbi, 2019:138). The difference of 0.25 mm between plaster and printed study models has been acknowledged as clinically acceptable (Ahmad and Al-Harbi, 2019:139).

Figure 6: Frontal view of a printed study model

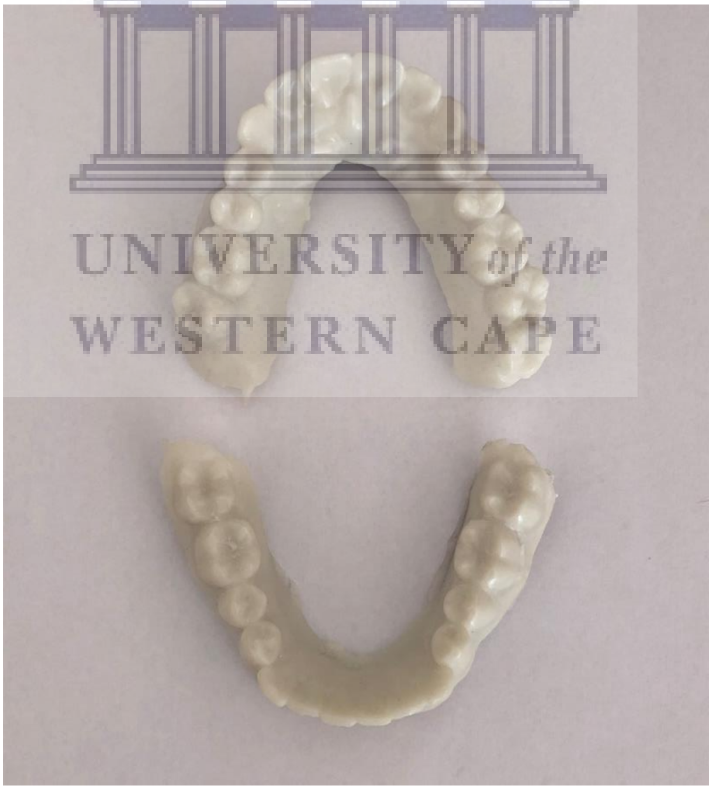


Figure 7: Arch view of printed study model

2.4. <u>Three-dimensional printing in dentistry</u>

3D printing is defined as a process in which an object is manufactured by adding layer upon layer of the desired material until a physical object is formed (Dawood *et al*. 2015:521). It is also known as rapid prototyping and more descriptively as additive manufacturing (Dawood *et al*. 2015: 521). Additive manufacturing is used to print study models (Ahmad and Al-Harbi, 2019:139). 3D printing, aided by CAD/CAM technology, is widely used in dentistry (Dawood *et al*. 215:522). Subtractive manufacturing is a process by which an object is formed by a solid mass of material (Srinivas *et al*. 2019:125). The importance of 3D printing is orthodontics is increasing, as it can be used to print study models (Lee *et al.* 2015:218).

The technology of 3D printing can be described in five basic stages. The first step is obtaining an image of the physical object that requires printing. CAD technology is then used to design the object. The CAD file is then converted to an STL file format which is sent to the 3D printer software. The software converts the STL file to G-code. the language that the 3D printer uses when it slices the image required for printing. After the object has been printed, it undergoes a post-processing stage before it can be utilised (Ahmad and Al-Harbi, 2019:6).

2.4.1. <u>Applications of three-dimensional printing in orthodontics</u>

Digital study models used in orthodontics are stored as digital files, reducing the need for storage space, and can be easily retrieved when required (Saleh *et al*. 2015:303). A disadvantage of digital study models is that practitioners will not be able to physically 'handle' a digital study model (Joffe, 2004:346). Study models can be printed with a 3D printer, using the digital study model as a blueprint (Dawood *et al*. 2015:524). Practitioners may print study models in their practice, should they decide to invest in a 3D printer, or digital files can be sent to a dental laboratory that can print the models for them (Mahamood *et al*. 2016:268).

Various types of 3D printers are available on the market and each type uses different forms of technologies to produce 3D objects (Lee *et al*. 2015:218). Objet30 Orthodesk ® by Stratasys ™ is a type of PolyJet™ 3D printer designed specifically for orthodontics. According to Lee *et al.* (2015:218), two types of 3D printers are the most efficient on the market: the PolyJet™ printers and solid-based fused deposition modelling printer, also known as an FDM 3D printer. This printer is the most frequently used printer, but PolyJet™ printers are liquid-based and produce objects of better quality (Lee *et al*. 2015:218).

The Invisalign® system utilises CAD/CAM technology and digital study model software to realign teeth (Malik *et al*. 2012:203). The digital study models are printed using a 3D printer (Dawood *et al*. 2015:524) and a series of clear aligners are created for the patient to wear during the course of treatment (Malik *et al*. 2012:203).
Other uses in orthodontics include the creation of appliances and orthodontic wires that can bend using robotic technology based on intra-oral scanning and CBCT (Dawood *et al*. 2015:524).

2.4.2. Applications of three-dimensional printing in other fields of dentistry

3D printing can be utilised in oral and maxillofacial surgery to print anatomical models of the skull, jaws or other facial structures, and can be used by surgeons to plan and practise their surgeries (Nayar *et al*. 2015: S218). These medical models have led to the creation of new surgical procedures (Dawood *et al*. 2015:522). Using medical models to plan surgeries shortens surgical time and, therefore, reduces patients' surgical risks (Torabi *et al*. 2015:3).

In dental implant surgery, drill or cutting guides can be printed using 3D printing technology (Dawood *et al*. 2015:523). CAD/CAM technology allows practitioners to plan implant procedures and create drill guides using 3D imaging and computer software (Nayar *et al*. 2015: S218). It is important to use 3D printers that are highly accurate and materials that can be sterilised, and according to Dawood *et al*. (2015:523) some of the best materials that are used to print drilling guides cannot be sterilised.

In prosthetic dentistry, implant abutments, bridge structures and crown and bridge copings can be manufactured by 3D printing technology, with the aid of CAD/CAM technology (Dawood *et al*. 2015:523). A 3D printer can manufacture a dental prosthesis in wax and the manufactured wax prosthesis can be cast in metal by a dental technologist (Torabi *et al*. 2015:5). This is an indirect method of creating metal prosthetic structures (Dawood *et al*. 2015:523). A direct method would entail a 3D printer printing prosthetic structures from metal using selective laser sintering or selective laser metal technology (Torabi *et al*. 2015:5). Digital study models fabricated for restorative dentistry may be printed using 3D printing technology. These models can be used to display restorations (Dawood *et al*. 2015: 524).

3D printers can also utilise data from computed tomography (CT) images and magnetic resonance imaging (MRI) (Srinivas *et al.* 2019:126).

2.4.3. Materials used in three-dimensional printing technology in dentistry

The types of materials used to print 3D objects depend on the type of 3D printer used (Ahmad and Al-Harbi, 2019:129). Resins, plaster of Paris (Dawood *et al*. 2015:526), waxes (Torabi *et al*. 2015:5), metal and metal alloys (Dawood *et al*. 2015:523), nylons, elastomers (Dawood *et al*. 2015:526), paper (Ahmad and Al-Harbi, 2019:129), ceramics and thermoplastic composites may all be used (Torabi *et al*. 2015:4). The types of metals and metal alloys that can be used for 3D printing include stainless steel, cobalt alloys, titanium and its alloys (Dawood *et al*. 2015:527). The chemistry of most materials produced by manufacturers is not known for proprietary reasons (Ahmad and Al-Harbi, 2019:129).

2.4.4. Types of three-dimensional printers in dentistry

Five categories of 3D printers can be used in dentistry; namely: vat polymerisation, powder bed fusion, material jetting, binder jetting and material extrusion (Ahmad and Al-Harbi, 2019:10-11). Each printer is suitable for specific fields of dentistry and uses specific types of materials based on its technology (Dawood *et al*. 2015: 525). Many factors must be taken into consideration when choosing a 3D printer; namely: type of material used, cost, accuracy and speed of final product and process, as well as design restrictions (Ahmad and Al-Harbi, 2019:9).

2.4.4.1. Vat polymerisation printers

Three types of 3D printers utilise light-curing technology to form 3D objects. These types of printers include: stereolithography (SLA/STL), digital light processing (DLP) and continuous digital light processing (CDLP/CLIP) printers (Ahmad and Al-Harbi, 2019:10). SLA and DLP are the two main printers in this category that are used in dentistry (Ahmad and Al-Harbi, 2019: 118)

a. *Stereolithography printers*

In 1984, Charles Hull developed the first 3D printer known as a stereolithography apparatus (SLA). An SLA printer consists of three main components: an ultra-violet (UV) laser, a model building platform and a vat that contains the photosensitive liquid resin (Torabi *et al*. 2015:3). A physical object is formed by liquid resin and is cured by a scanning laser to form layers (Dawood *et al*. 2015:526). The layers are chemically bonded to one another (Ahmad and Al-Harbi, 2019:10). After the printed object is removed from its supporting structures, it is rinsed with a solvent and cured again with a UV light (Ahmad and Al-Harbi, 2019:12). Micro-stereolithography is a more current version of the above process. The technology employs a higher resolution and the resulting thickness of the layers that can be formed is less than 10 µm (Srinivas *et al*. 2019:126). These printers have a high resolution and are very accurate, and as a result, are considered the gold standard of 3D printers. They are used to print orthodontic aligners and study models (Ahmad and Al-Harbi, 2019:120) and surgical drill guides (Torabi *et al*. 2015:3). Multiple material stereolithography uses a variety of materials to print a single object (Srinivas *et al.* 2019:127). The technology has some disadvantages. Complex objects can be formed at a rapid rate using this type of printer, but only light-curable liquid resin or polymers can be used, and these materials can irritate the skin and nasal mucosa on inhalation. A support structure is formed with the object and must be removed. The printer is expensive and has a limited shelf-life (Dawood *et al*. 2015:526). Desktop versions of these printers cost between US$2 000 and 15 000, making them one of the more expensive types of printers on the current market (Ahmad and Al-Harbi, 2019:129). When an object is being printed from a variety of materials and a new material is required for a specific part of the object, the existing material must be drained out before the new material can be added, making the process laborious and time-consuming (Srinivas *et al*. 2019:126). Overhanging parts can result from over curing or difficulty in controlling the layer thickness of highly viscous resin (Srinivas *et al*. 2019:126). Examples of brands of SLA printers available are Zenith, 3D Systems and Formlabs (Ahmad and Al-Harbi, 2019:12).

b. Digital Light-Processing printers

This printer was created by Larry Hornbeck in 1987 (Ahmad and Al-Harbi, 2019:12). It uses liquid polymers and wax-like materials to form physical objects that are built upside down on a platform with a supporting structure (Dawood *et al*. 2015:525). These printers can print using transparent materials (Ahmad and Al-Harbi, 2019:121). A projector light source cures each layer of material which is used to build up the object needed (Dawood *et al*. 2015:525). These printers are faster than SLA printers (Hazeveld *et al*. 2014:110) and the technology is on the lower end of the cost scale as less material is required (Ahmad and Al-Harbi, 2019:12), but the materials required are expensive (Dawood *et al*. 2015:525). The variety of materials that can be used by these printers is limited (Hazeveld *et al*. 2014:110). Objects produced are of good quality (Dawood *et al*. 2015:525). These printers have many applications in dentistry and are capable of printing study models, customised impression trays and surgical drill guides (Ahmad and Al-Harbi, 2019:121). Examples of manufacturers that produce these types of printers are Rapidshape and EnvisionTEC (Ahmad and Al-Harbi, 2019:12). They cost approximately between US$2 000 and 5 000 (Ahmad and Al-Harbi, 2019:129).

2.4.4.2. Powder bed fusion printers

The types of printers in this category include multi-jet fusion (MJF), selective laser sintering (SLS), selective laser melting (SLM/DMLS) and electron beam melting (EBM) (Ahmad and Al-Harbi, 2019:10). The printers that have dental applications in this category are SLS and SLM printers (Ahmad and Al-Harbi, 2019:118).

a. *Selective laser sintering printers (SLS)*

These printers can be used to print objects using polymers or metal and metal alloys (Srinivas *et al*. 2019:127). Nylon and thermoplastic composites, ceramics and investing casting wax can also be used (Torabi *et al*. 2015:4). The printer has a building platform that descends as the object is built, layer by layer. A scanning laser melts the material, which is available as a fine powder, and each layer is formed in this manner (Torabi *et al*. 2015:4). The polymers used in this printer are used to print study models, anatomical models and surgical drill guides (Dawood *et al*. 2015:526). The printer also uses metal and metal alloys to print prosthetic frameworks for implants and partial dentures (Dawood *et al*. 2015:527). These types of printers can utilise a vast range of materials and unused powder can be reused (Srinivas *et al*. 2019:126). Accuracy is dependent on the particle size of the materials utilised by the printer (Srinivas *et al*. 2019:127). Although it produces objects of high accuracy, the equipment requires plenty of floor space, so it would only be practical to use in a dental laboratory. The machinery is difficult to maintain. It produces nanoparticle and metal powders that are hazardous to inhale and poses a safety risk (Dawood *et al*. 2015:527). An inert gas chamber must be used so that a consistent temperature is maintained and oxidation does not occur (Srinivas *et al*. 2018:127-128). Its current price for a desktop version is approximately US$5 000.

b. Selective laser melting and direct metal laser sintering printers (SLM and DMLS)

SLM and DMLS printers are used to manufacture implant abutments, chrome-cobalt removable partial denture frameworks, copings for crowns and metal study models (Ahmad and Al-Harbi, 2019:122). These printers can produce objects that are highly detailed (Ahmad and Al-Harbi, 2019:15). Metals used by SLM printers include aluminium and titanium and DMLS printers use stainless-steel, nickel and chrome-cobalt (Ahmad and Al-Harbi, 2019:14). SLM/DMLS printers are suitable for use in industry (Ahmad and Al-Harbi, 2019:15).

2.4.4.3. Material jetting printers

There are three types of material jetting printers available; namely: material jetting (MJ), nano-particle jetting (NPJ) and drop on demand (DOD) (Ahmad and Al-Harbi, 2019:11). Only MJ printers will be discussed as it is the main printer in this category that has dental applications.

a. *Material jetting printers (MJ)*

MJ printers work in a similar manner to inkjet printers (Lee *et al*. 2015:219). These printers are used to print study models, and anatomical models (Dawood *et al*. 2015:526). PolyJet™ printers are an example of such a printer (Lee *et al*. 2015:219). A physical object is formed by fine layers that are created by liquid photopolymers sprayed onto a build-up tray and cured with a UV light (Hazeveld *et al*. 2014:110). A support structure is also printed (Dawood *et al*. 2015:527). Although Dawood *et al.* (2015:527) find the presence of the support structure a disadvantage because it is difficult to remove, Lee *et al.* (2015:220) state that in a PolyJet™ printer, a support structure is created only when complex structures are printed and it is made from a gel-like material that can be easily removed. The objects printed from a PolyJet™ printer do not require post curing and can be used immediately (Lee *et al*. 2015:220).

Other materials, such as waxes and resins can also be used in this type of printer and it may have multiple printer heads. This gives the printer the ability to print with different materials simultaneously, and materials can be mixed to enhance properties of certain materials (Dawood *et al*. 2015:526). The materials used for these printers are expensive and cannot be sterilised using heat (Dawood *et al*. 2015:525). They are, however, available in various colours (Ahmad and Al-Harbi, 2019:16). The properties of materials used by these printers are inferior to those materials used in SLA printers (Hazeveld *et al*. 2014:110). These printers print objects of high quality and resolution (Dawood *et al*. 2015:525), but according to Hazeveld *et al.* (2014:110), the detail of objects produced is not as intricate as that produced by SLA printers. Ahmad and Al-Harbi (2019:123) state that objects produced are of inadequate accuracy. The MJ printer is only available for industrial purposes at a cost of US$85 000 (Ahmad and Al-Harbi, 2019:129).

2.4.4.4. Binder jetting printers

These printers are also known as an ink-based or 3DP printers (Torabi *et al*. 2015:3). This technology process has been licensed by the Massachusetts Institute of Technology (MIT) (Srinivas *et al*. 2019:128). These printers eject a layer of fine powder onto a tray and a liquid dispensed from an inkjet type printer head is dispensed onto the powder layer in droplets (Torabi *et al*. 2015:4). Once the layer is complete, another layer of powder is dispensed, thus the object is formed by a layering technique (Torabi *et al*. 2015:4). A pigmented liquid is used and consists mostly of plaster of Paris (Dawood *et al*. 2015:526). These printers are user-friendly (Hazeveld *et al*. 2014:110) Objects can be printed in colour. The end product is fragile even though it is coated with an epoxy resin or cyanoacrylate after printing to increase its surface hardness. This type of printer can be used to print study and anatomical models (Dawood *et al*. 2015:526). Its use in surgery is limited as the materials cannot be sterilised (Dawood *et al*. 2015:526). Only a few types of materials can be used (Hazeveld *et al*. 2014:110). Although the materials and equipment are cheaper than other 3D printers (Hazeveld *et al*. 2014:110), the models produced are not accurate enough for use in prosthodontics (Dawood *et al*. 2015:525-526). Printers used for dental purposes use dental ceramic powders to make all-ceramic restorations (Ahmad and Al-Harbi, 2019:123).

2.4.4.5. Material extrusion printers

a. *Fused deposition modelling printers (FDM)*

These types of printers were one of the first 3D printing technologies produced and are available for home use (Dawood *et al*. 2015:527). This printer consists of a nozzle that heats and deposits material onto a building platform, building the object layer by layer, from the bottom up (Lee *et al*. 2015:219). Each layer usually has a thickness of 0.25 mm (Srinivas *et al.* 2019:128). The nozzle moves in both vertical and horizontal directions and dispenses material for the object and supporting structure (Lee *et al*. 2015:219). Material for the supporting structure may be the same used to print the object or of a different water-soluble material (Dawood *et al*. 2015:527). The supporting structure can be trimmed and rinsed off with a detergent (Ahmad and Al-Harbi, 2019:128). Only thermoplastic material may be used with this printer and it has a limited capacity to print intricate biological objects (Dawood *et al*. 2015:525). Examples of materials that can be used are acrylonitrile butadiene and polycarbonate (Srinivas *et al*. 2019:128). These printers are cheaper to use as material and equipment are more readily available than those for other types of printers (Srinivas *et al*. 2019:128). A desktop version is available from between US$100- and 2 000 (Ahmad and Al-Harbi, 2019:129). This type of technology does not use resin or chemical curing, so no over-curing and overhangs occur (Srinivas *et al*. 2019:128). The printing process is very slow and larger objects can take a few days to finish (Srinivas *et al*. 2019:128). The technology produces objects of lower resolution than other types of printers, so a process is needed to ensure the objects have a smooth finish (Srinivas *et al*. 2019:128).

2.4.5. Advantages and disadvantages of three-dimensional printing technology

According to Dawood *et al.* (2015:528), dentists and dental laboratories are largely familiar with digital dentistry and increasingly making use of 3D printing technology. While this may be true for Britain and other developed countries, the scope of this type of practice in South Africa remains to be seen. The data files that are used to print 3D objects are STL files and these files can be shared via the internet (Srinivas *et al.* 2019:132). Sharing and learning certain surgical procedures can be done, as the files allow printing of an exact replica of instrumentation, stents or models (Srinivas *et al*. 2019:132). It is convenient to have an in-house 3D printer, as a restoration or appliance can be delivered to patients on the same day (Ahmad and Al-Harbi, 2019:177). Additive manufacturing eliminates many of the time-consuming finishing processes that laboratory-made restorations, appliances and study models require (Ahmad and Al-Harbi, 2019:116).

3D printing technology in dentistry has become very diverse and is of particular value in the fields of prosthodontics and orthodontics (Torabi *et al*. 2015:6). According to Ahmad and Al-Harbi (2019:138) the field of orthodontics has benefitted the most from 3D printing. In prosthodontics, the numerous types of printers and materials available means that a variety of prosthetic dental components can be manufactured digitally (Torabi *et al*. 2015:6). Prosthetic facial and dental components and implants are becoming cheaper to manufacture via 3D printing due to competition between manufacturing companies (Srinivas *et al*. 2019:131). When 3D printing is the manufacturing process for certain components, the use of other resources that would be required for traditional manufacturing process decreases (Srinivas *et al*. 2019:131). The process is faster than traditional milling, with 3D printed objects being completed in hours (Srinivas *et al*. 2019:132). 3D printers are reportedly easy to use, being similar to inkjet or laser printers (Ahmad and Al-Harbi, 2019:126).

Customised medical and dental products such as surgical instrumentation and implants can be produced by 3D printing (Srinivas *et al*. 2019:131). This can lead to improved success of surgeries and shorter duration of patient recovery time (Srinivas *et al*. 2019:131). According to Srinivas *et al.* (2019:132), materials are becoming cheaper due to the variety available.

More research needs to be done before concluding that 3D printing is considered as good as or better than current practices (Dawood *et al*. 2015:529). Although some types of printers and materials are cheaper than others, this technology is still very expensive (Dawood *et al*. 2015:525); however, according to Srinivas *et al.* (2019:131), companies are lowering the cost of small production runs due to competition. The price varies according to the type of printer and whether a desktop or industrial unit is required (Ahmad and Al-Harbi, 2019:128). The cheapest desktop printer is a desktop FDM printer; currently priced at US$100 and the most expensive is an SLA printer that can cost up to US$15 000 (Ahmad and Al-Harbi, 2019:129). Objects printed by the majority of 3D printers require post-processing and depending on the type of printer and material used, the process can become complex and time-consuming (Ahmad and Al-Harbi, 2019:128). Products produced by binder jet, stereolithography and SLS printers take over a day to post-process (Ahmad and Al-Harbi, 2019:128). Standardisation in the 3D printer industry is not enforced (Ahmad and Al-Harbi, 2019:9). Study models that are printed with coloured materials and have a rough surface are problematic to measure because identifying landmarks is challenging (Hazeveld *et al*. 2014:111). Some printers, such as EBM and SLS printers, produce dust that is harmful to inhale, so guidelines need to be created to guarantee the safety of those who use such equipment (Dawood *et al*. 2015:525). Different brands of printers are not compatible with each other (Ahmad and Al-Harbi, 2019:9).

Figure 8: Next Dent 5100 for Ceramill® 3D printer (DLP printer)

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

3.1. Aim and Objectives

The aim of this present study was to compare the accuracy of measurements taken from digital study models obtained from an intra-oral scanner, and printed study models, printed from digital study model files by a 3D printer, and with measurements taken from plaster study models.

The objectives were:

- To compare the accuracy of measurements obtained from digital and printed study models with those taken from plaster study models.
- To establish which type of study model yielded the most accurate measurements in comparison to plaster study models.
- To identify possible disadvantages and errors that can be made using any of the three types of study models.

3.2. Research Hypothesis

The aim of this present study was to compare the accuracy of measurements taken from plaster study models with those from digital and printed study models obtained from an intra-oral scanner.

The null hypothesis stated that no significant differences in the accuracy of measurements will be found between the three different types of study models.

The research question was:

Are the measurements taken from digital and printed models as accurate as those taken from plaster study models?

3.3. <u>Delimitation of Study Area</u>

The following criteria were used when selecting patients:

- Patients with permanent teeth, 1-6, in each arch.
- No orthodontic appliance present.
- Only patients that required impressions and study models for their treatment records were asked to participate.
- No mixed dentition.

3.4. <u>Study design and sample description</u>

The design of this present study was a comparative descriptive study. The study population consisted of 50 patients attending a private orthodontic practice for orthodontic treatment. The study population was a heterogeneous group consisting of 37 female patients and 13 male patients. Participating patients were between the ages of 9- and 58 years.

Only patients who required impressions and study models as part of their orthodontic diagnoses and treatment planning were included in this present study.

Inclusion criteria:

- Impressions were only taken from patients who required it as part of their treatment.
- Patients who had permanent teeth 1- 6 were used as the mesio-distal widths of these teeth needed to be measured and compared.

Exclusion criteria:

- Patients who did not require impressions or study models.
- Patients who had missing permanent canines and first permanent molars.
- Patients with mixed dentition.
- Patients with fixed orthodontic appliances.

The participating of 9 years of age had no primary teeth present in her mouth so she was included this present study. This patient also had her permanent canines and first permanent molars as required for this present study.

3.5. Mesio-distal tooth Width Measurement

The mesio-distal tooth widths of each permanent tooth, 1-6, per quadrant was taken by measuring the widest portion of the tooth from the mesial contact point of the tooth to the distal contact point of the tooth (Khan *et al*. 2011:82).

Numerous studies have shown that measurements obtained from digital study models are acceptable to use in a clinical setting (Hazeveld *et al*. 2014:109). The software that is part of the TRIOS® 3Shape intra-oral scanner, Ortho Analyzer™, can measure tooth sizes and arch length and conduct a space analysis (Westerlund *et al*. 2015:512).

An electronic digital calliper was used to measure the plaster and printed study models. For plaster and printed study models, measurements taken using either an analogue or electronic digital calliper are considered reliable (Czarnota *et al*. 2016:23).

The mesio-distal tooth widths of permanent teeth 1-6 of each arch for all study models were measured. Ortho Analyzer™ software was used by the researcher of this present study to measure the mesio-distal tooth widths of all required teeth on the digital study models and measurements were given in millimetres.

An electronic digital calliper was used to measure the mesio-distal tooth widths of permanent teeth, 1-6, for the plaster and printed study models. These measurements were given in millimetres.

All measurements were recorded on data spreadsheets designed using Microsoft Excel (Appendix A) and statistically analysed by a statistician.

3.6. Inter-canine Width Measurement

The inter-canine width of each arch is the distance between permanent canines in an arch. It is measured from the cusp tip of the right canine to the cusp tip of the left canine in each arch in the occlusal plane (Abizadeh *et al*. 2012:153). This method was used to measure the inter-canine widths for all plaster, digital and printed study models.

Ortho Analyzer™ software was used by the researcher of this present study to measure the inter-canine widths for all digital study models. An electronic digital calliper was used to measure the inter-canine widths for all plaster and printed study models. The calliper was placed on the cusp tip of one canine to the cusp tip of the opposing canine in the same arch. The measurements were given in millimetres.

All measurements were recorded on data sheets designed as Microsoft Excel spreadsheets (Appendix A) and statistically analysed by a statistician.

3.7. Inter-molar Width Measurement

The inter-molar width of each arch is the distance measured between the first permanent molars in an arch. It was measured for all plaster, digital and printed study models from the mesio-buccal cusp of the right first permanent molar to the mesio-buccal cusp of the left first permanent molar in each arch (Abizadeh *et al*. 2012:153).

Ortho Analyzer™ software was used by the researcher of this present study to measure the inter-molar widths for all digital study models. All measurements were given in millimetres. An electronic digital calliper was used to measure the inter-molar widths for all plaster and printed study models. The measurements were given in millimetres.

All measurements were recorded on data sheets designed as Microsoft Excel spreadsheets (Appendix A) and statistically analysed.

3.8. Data Collection

Patients' participation was voluntary and informed consent from all participating patients was obtained before participation commenced. In the case of minor patients, informed consent from a parent or legal guardian was obtained (Appendix B). Fifty patients participated in this present study. A conventional impression using Kromogel® Advance alginate was taken for all patients and plaster study models were cast from these impressions. The plaster for the study models were mixed by hand and were all cast by the same operator. Digital impressions of patients' mouths were taken using the TRIOS® 3 Shape intra-oral scanner and its software generated the digital study models. The researcher of the present study took all impressions to ensure standardisation. The scanning process was done according to a specific scanning technique to ensure that each scan was taken in the same manner. The Next Dent 5100 for Ceramill® 3D printer, a DLP 3D printer, printed study models from the digital study model files and the same measurements that were taken from the plaster and digital study models were taken from the printed study models. Measurements from the digital and printed study models were compared for accuracy against the plaster study models as plaster study models are considered the gold standard for study model analysis (Abizadeh *et al*. 2012:155). The same printer was used to print all study models. The researcher of the present study measured the plaster and printed models with the same electronic digital calliper to ensure standardisation, and the data were statistically analysed by a statistician.

The mesio-distal tooth width for each tooth on the plaster and printed study models were measured as follows: one tip of the digital calliper was positioned on the mesial contact point of the tooth and the other tip was positioned on the distal contact point at the widest portion of the tooth, and the distance between these two points was measured in millimetres as given on the screen of the digital calliper. The inter-canine widths were measured on the plaster and printed study models as follows: one tip of the digital calliper was placed on the cusp tip of the right permanent canine and the other tip was positioned on the cusp tip of the left permanent canine tooth in the corresponding upper and lower arches and the distance between the two points was measured in millimetres as given on the screen of the digital calliper. The inter-molar widths of plaster and printed study models were measured as follows: one tip of the digital calliper was placed on the mesio-buccal cusp of the right first permanent molar and the other tip was positioned on the mesio-buccal cusp of the left first permanent molar in the corresponding upper and lower arches. The distance between the two points was recorded in millimetres as given on the screen of the digital calliper. An orthodontic felt tip marker was used to mark all points of reference on all plaster and printed study models. OrthoAnalyzer™ was used to measure all digital study models. The mesio-distal tooth widths for each tooth in the digital study models were measured as follows: a full-arch view was used, and the cursor of the computer mouse was placed on the mesial contact point at the widest portion of the tooth and the cursor was then dragged to the distal contact point. The points were shown as blue dots and a blue line connected the two dots. The software displayed the measurement in millimetres. The inter-canine widths for each arch of the digital study models were measured by the researcher placing the cursor on the cusp tip of the right permanent canine and subsequently dragged to the cusp tip of the left permanent canine. Two blue dots represented the two points on the cusp tips and a blue line connected the dots. The software displayed the measurement in millimetres above the line. The inter-molar width of each arch of the digital study models were measured by the researcher placing the cursor on the mesio-buccal cusp of the right first permanent molar and subsequently dragged to the mesio-buccal cusp tip of the left first permanent molar. Two blue dots represented the two points on the cusp tips and a blue line connected the dots. The software displayed the measurement in millimetres above the line.

One of the supervisors of this present study, a private orthodontist, assisted the researcher with calibration of the electronic digital calliper to ensure that all plaster and printed study models were measured in the same manner. The supervisor also demonstrated to the researcher how to measure digital study models using OrthoAnalyzer™ to ensure that all digital study models were measured the same manner. Each study model was numbered for reference and confidentiality purposes and all data were recorded on Microsoft Excel spreadsheets.

3.9. Generalisability

The results of the present study apply to general dentists, orthodontists and other dental specialists who need to take impressions and require study models for diagnoses and treatment planning of their patients. The results can only apply to those who make use of intra-oral scanners, digital impressions, 3D printers and printed models, or those who are considering acquiring such equipment and using such techniques in their practices. This present study could apply to dental schools who are educating their students at undergraduate and postgraduate levels to use such techniques and practices.

3.10. Validity

All conventional dental impressions were taken using Kromogel® Advance Alginate by Wright Health Group Ltd. and these were cast into plaster study models. The Kromogel® Advance alginate was mixed according to the manufacturer’s instructions using an automatic alginate mixer called Hurrimix™ Alginate Mixer. The plaster study models were cast by the same operator with the same type and brand of dental stone and mixed according to the manufacturer’s instructions to ensure standardisation. The plaster was mixed mechanically. To ensure standardisation and consistency, measurements were taken a standardised drying time of 24 hours was established between the casting and setting of the plaster study models and measuring them. It has been shown in a study by Kati *et al.* (2017) that study models that are air dried for 24 hours at 22ºC or in a microwave oven at low power (400 Watts) for 5 minutes can be used for manipulation.

Plaster and printed study models: The same electronic digital calliper was used to measure all plaster and printed study models. A calibration structure was established with the aid of one of the supervisors of the present study, a private orthodontist, to ensure that all study models were measured in the same manner. The method of measuring the variables that were compared for accuracy in this present study is the method of choice when measuring study models for orthodontic treatment planning purposes. Printed study models can be measured using an analogue or electronic digital calliper and either method is considered reliable (Czarnota *et al.* 2016:23).

Digital study models: Numerous studies have shown that measurements obtained from digital study models are acceptable for use in a clinical setting (Abizadeh *et al.* 2012:158, Hazeveld *et al*. 2014:109, Saleh *et al*. 2015:305-306, Wan Hassan *et al*. 2016:895). Ortho Analyzer™ was used to obtain measurements from the digital study models required for the present study. These measurements were considered valid as it was the same computer software programme that was used to measure the variables required.

The methods by which measurements from all three types of study models were obtained are considered valid as these methods are routinely used by practitioners.

An acceptable range for differences between measurements obtained from the three different types of study models was established at 0.5 mm. Czarnota *et al.* (2016:27) state that the American Board of Orthodontics objective grading system considers deviations of ≤0.5 mm in anterior-posterior, vertical and transverse planes inconsequential in a clinical environment. Wan Hassan *et al.* (2016: 887) used a mark of 0.5 mm as the clinically acceptable range for differences in measurements found in their study.

3.11. **Inter-rater Reliability of Data**

To address the issue of the reproducibility and reliability of measurements, an inter-rater reliability technique was utilised. A total of 15 plaster, 15 digital and 15 printed study models were randomly selected and a second operator (KJ), measured the study models. The same electronic digital calliper that was used by the researcher of this present study, was used by the second operator to measure the plaster and printed study models. Ortho Analyzer™ was used by the second operator to measure the digital study models. This method of reliability is imperative to validate the aim of this present study as research done by Reuschl *et al.* (2016:24), found that mandibular inter-molar widths were found to be larger when measured by one of their operators, although the difference was not statistically significant (Reuschl *et al*. 2016:24). The measurements were then analysed by a statistician.

3.12. Data Analysis

Mesio-distal tooth widths of permanent teeth 1-6, inter-canine widths and inter-molar widths for each arch of each study model were measured and captured on Microsoft Excel spreadsheets. Demographic information of the patients, such as age and gender, were also captured.

All data were checked by a statistician and supervisors of this present study.

3.13. Statistical Methods

The data collected by the researcher of this present study were analysed by a statistician.

Parametric techniques were employed to compare the accuracy of measurements taken from the plaster, digital and printed study models.

3.14. Logistics

The patients who participated in this present study were attending the private orthodontic practice of one of the supervisors of this present study, an orthodontist, for treatment and that required impressions and study models. The data required for this present study was taken from their records following the informed consent and permission of participating patients. Plaster study models were cast from conventional impressions taken using alginate. The digital impressions were taken with an intra-oral scanner and computer software generated digital study models from the digital impressions. A 3D printer printed study models from the same digital impressions. The treatment of patients was carried out by the private orthodontic specialist.

3.15. Time Frame

The time frame for this present study was 12-20 months.

3.16. Ethical Considerations

Research should only take place with the voluntary consent of all participants (Moodley and Naidoo, 2010:98) and be done considering the ethical principles established in the Declaration of Helsinki, drafted in 1964 (Moodley and Naidoo, 2010:101).

Ethical approval was requested and granted from the University of the Western Cape Senate Biomedical Research Ethics Committee (Appendix C). Participation for this present study was voluntary and only patients who required impressions and study models as part of their treatment record were considered. Participants were informed that participation was anonymous, voluntary and that they were at liberty to withdraw their participation from the study at any time without any penalty or impact on their treatment. Participants were assured of privacy and confidentiality. An informed consent form and information sheet with a detailed explanation of the intention of the study and how the findings were used was provided, and in the case of minor patients, with the permission of their parents or legal guardians. An example of the information sheets and informed consent forms can be found as Appendix B.

3.17. Ethical Statement

This study did not involve treating any patients who chose to participate in this present study. Any treatment required was done subsequently by the private orthodontist. Only patients who required dental impressions and study models as part of their treatment were asked to participate, and informed consent was obtained before their dental impressions and study models were used for this present study. The patients who participated were not identifiable from their records as all study models were numbered for reference and patient confidentiality purposes. No personal information, other than age and gender, was used included in this present study.

3.18. <u>Materials and Equipment</u>

The following materials, equipment and instrumentation were used in this present study:

- Alginate
  Irreversible hydrocolloid impression material was used to take impressions for plaster study models. Kromogel® Advance Alginate by Wright Health Group Ltd. was used and mixed according to the manufacturer's instructions. All impressions were disinfected after they were taken.
- Hurrimix™ Alginate Mixer
  An automatic alginate mixer used to mix alginate for all dental impressions.
- Impression trays
  Plastic or metal stock trays were used to carry impression material.
- Dental stone
  Dental stone was used to cast the plaster study models.
- Intra-oral scanner
  The 3Shape TRIOS® 3 intra-oral scanner was used to take digital impressions of patients that participated in the present study. The technology that this scanner utilised is called Ultrafast Optical Sectioning. Ortho Analyzer™ is the software that is available with the TRIOS® intra-oral scanner. This software processed the digital impressions and created digital study models from data received from the scanner. Digital study models were stored as STL files (Martin *et al*. 2015:139-140).

- 3D printer
  The 3D printer that was utilised was the Next Dent 5100 for Ceramill® printer manufactured by 3D Systems. It has a 1920x1080 pixel resolution and each layer that is printed has a thickness of 30-100 µm. The material was mixed on a LC-3D mixer before it was used. Each study model took approximately 30-35 minutes to print with a supporting structure. After the study models were printed, the supporting structures were removed, and the study models were rinsed with an alcohol solvent. The study models were then cured for 10 minutes in the LC-3D Print Box that uses a UV light to cure the study models. The study models were then ready to be used (www.amanngirbach.com).

- Electronic digital calliper
  An electronic digital calliper was used to measure the plaster and printed study models.
- Orthodontic felt tip marker
  This marker was used to mark reference points on the plaster and printed study models when measuring.

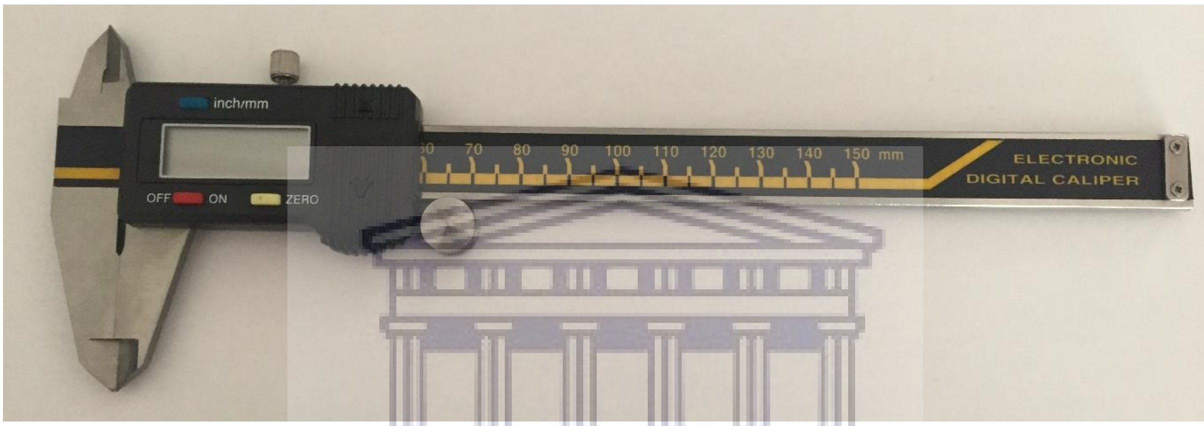


Figure 9: Electronic digital calliper

3.19. <u>Disclosure</u>

The researcher and supervisors of this present study have no financial interests in the companies whose equipment and materials are included in this research.

CHAPTER 4

RESULTS

The study population consisted of 50 participating patients; 37 were female and 13 were male patients. Participating patients were between the ages of 9- and 58 years. One patient was under the age of 10 years, 38 patients were between 10- and 20 years, 6 patients were between 20- and 30 years, 2 patients were 30- and 40, 2 patients were between 40- and 50 years and 1 patient was over 50 years.

Each participating patient had three sets of study models, totalling 150 study models used in this present study. A total of 28 observations for each study model was measured. These observations were taken once by the researcher and once by a second operator. The measurements for each study model included: mesio-distal widths of permanent teeth 1-6, per quadrant, per arch and the inter-canine and inter-molar widths in each arch.

The data were submitted to a statistician for statistical analyses to determine whether any significant differences between measurements taken from all three types of study models existed.

Descriptive analyses for each type of study model were taken, including the mean measurement for each observation, as well as standard deviation. The minimum(min) value represents the smallest measurement in millimetres recorded from one of the study models and the maximum(max) value is the largest measurement in millimetres recorded from one of the study models respectively. If the minimum is 0, it means that the tooth number in question was missing. The results are tabulated in Table 1.

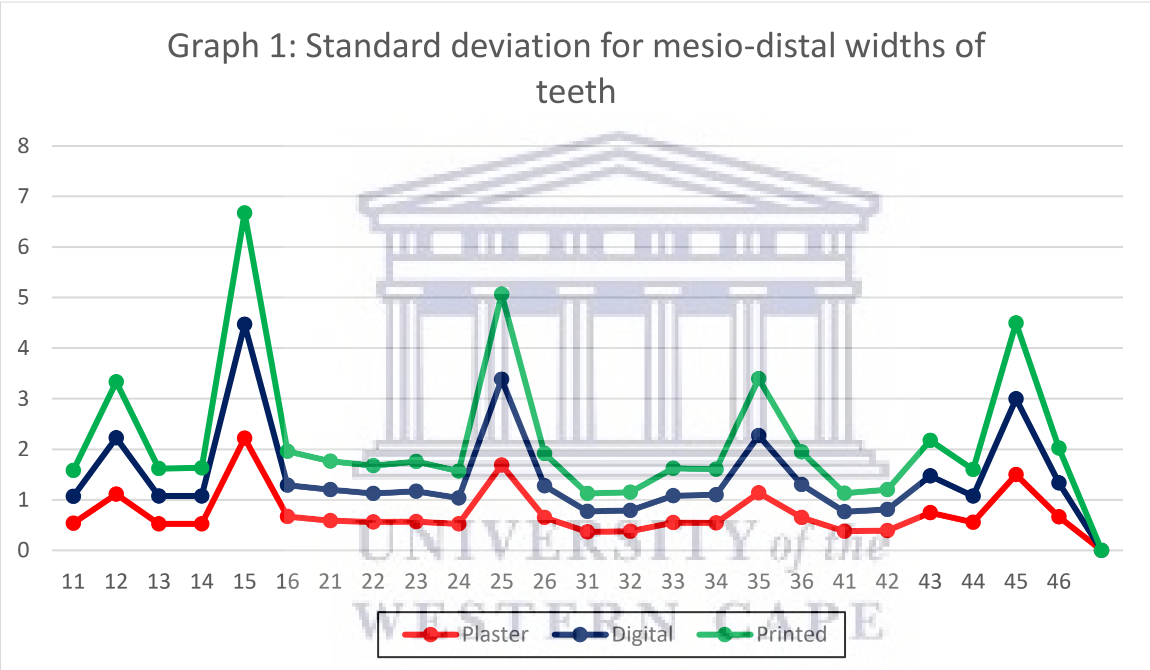
Table 1: Descriptive analyses for plaster, digital and printed study models.

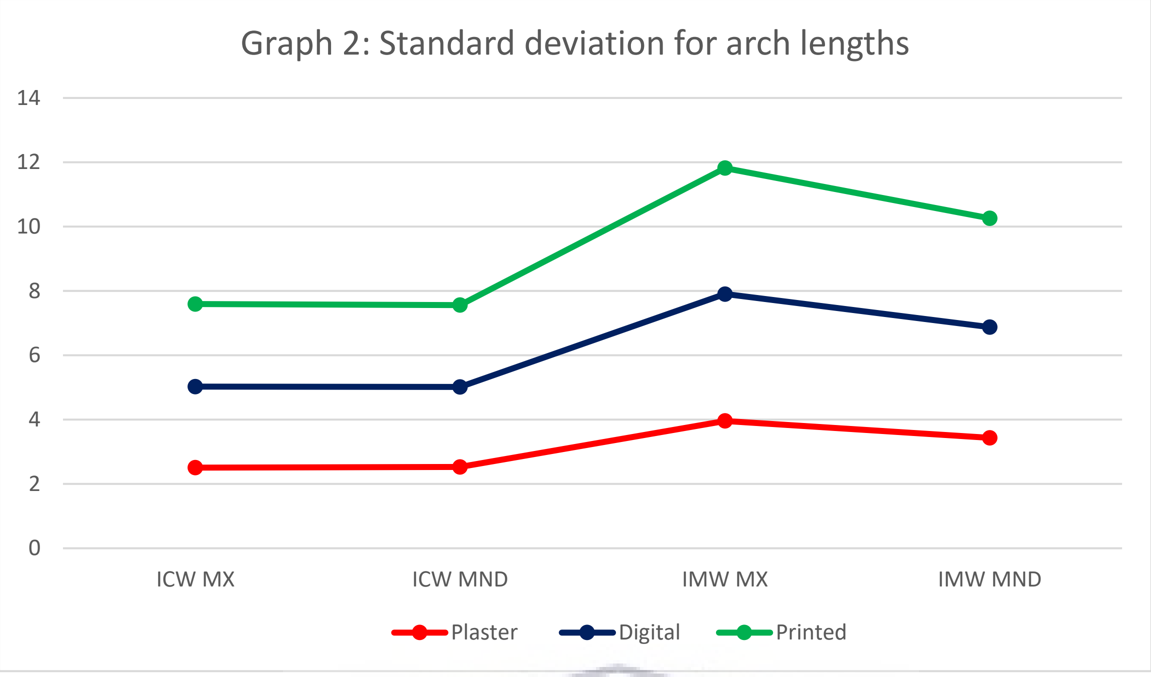
	Min	Max	Mean	Std deviation		Min	Max	Mean	Std deviation
Tooth 11					Tooth 21				
Plaster	8,04	10,3	8,8432	0,53635	Plaster	7,91	10,6	8,796	0,58888
Digital	8,06	10,36	8,8284	0,53236	Digital	7,79	10,65	8,7828	0,6106
Printed	8,11	10,2	8,823	0,51241	Printed	7,88	10,4	8,8222	0,56025
Tooth 12					Tooth 22				
Plaster	0	8,04	6,6858	1,11203	Plaster	5,31	7,92	6,8458	0,56001
Digital	0	7,92	6,667	1,1102	Digital	5,36	8,04	6,8676	0,56639

Printed	0	7,94	6,72	1,1078	Printed	5,55	7,93	6,8374	0,54643
Tooth 13					Tooth 23				
Plaster	5,36	8,72	7,7526	0,52373	Plaster	5,04	8,41	7,646	0,56753
Digital	5,58	8,61	7,7708	0,55042	Digital	5,1	8,55	7,6368	0,60316
Printed	5,31	8,52	7,7322	0,54314	Printed	5	8,56	7,6108	0,58542
Tooth 14					Tooth 24				
Plaster	5,8	8,41	7,1802	0,52058	Plaster	6,2	8,36	7,2156	0,52455
Digital	5,76	8,59	7,2028	0,55259	Digital	6,11	8,34	7,2066	0,50777
Printed	5,93	8,31	7,1574	0,55738	Printed	6,31	8,31	7,1944	0,53207
Tooth 15					Tooth 25				
Plaster	0	7,55	5,8126	2,21832	Plaster	0	7,64	6,3154	1,68402
Digital	0	7,65	5,876	2,24907	Digital	0	7,81	6,3456	1,69978
Printed	0	7,51	5,7626	2,20355	Printed	0	7,67	6,2986	1,6795
Tooth 16					Tooth 26				
Plaster	8,46	11,57	10,1778	0,66645	Plaster	9,04	11,94	10,2006	0,64745
Digital	8,57	11,58	10,2014	0,62009	Digital	9,04	11,69	10,241	0,63078
Printed	8,31	11,57	10,1466	0,67484	Printed	9,07	11,56	10,1208	0,63905
Tooth 41					Tooth 31				
Plaster	4,58	6,2	5,3034	0,37656	Plaster	4,72	6,17	5,3852	0,36212
Digital	4,32	6,17	5,2514	0,38446	Digital	4,5	6,37	5,3534	0,40656
Printed	4,67	6,24	5,2814	0,36626	Printed	4,67	6,11	5,3942	0,35292
Tooth 42					Tooth 32				
Plaster	5,05	6,7	5,9074	0,39044	Plaster	5,17	6,72	5,9706	0,3801
Digital	5,21	7	5,9536	0,41611	Digital	5,17	6,9	6,0064	0,41034
Printed	5,13	6,85	5,9372	0,39626	Printed	5,21	6,73	5,9938	0,36033
Tooth 43					Tooth 33				
Plaster	2,6	7,89	6,808	0,74369	Plaster	6,02	8,53	6,8962	0,551
Digital	3	8,08	6,8108	0,72847	Digital	5,81	8,5	6,8954	0,52706
Printed	2,99	7,97	6,8518	0,69999	Printed	6,1	8,55	6,9286	0,54456
Tooth 44					Tooth 34				
Plaster	6,15	8,45	7,2288	0,55231	Plaster	6,33	8,51	7,2666	0,53929
Digital	6,26	8,43	7,2194	0,51959	Digital	6,29	8,47	7,2584	0,56019
Printed	6,21	8,47	7,2276	0,52867	Printed	6,45	8,64	7,2736	0,5069
Tooth 45					Tooth 35				
Plaster	0	8,06	6,8462	1,49907	Plaster	0	8,23	7,0352	1,13748
Digital	0	8,24	6,884	1,49471	Digital	0	8,35	7,0478	1,13174
Printed	0	8,33	6,8244	1,50101	Printed	0	8,13	6,9954	1,12612
Tooth 46					Tooth 36				
Plaster	9,15	12,26	10,9822	0,6646	Plaster	9,69	12,46	10,9948	0,65145
Digital	9,19	12,4	10,9818	0,67049	Digital	9,89	12,5	10,9974	0,65073
Printed	9,28	12,31	10,982	0,68685	Printed	9,7	12,58	10,9998	0,64605
ICW MX					ICW MND				
Plaster	30,89	42,52	34,6868	2,50635	Plaster	21,63	30,95	26,7506	2,52553
Digital	30,94	42,49	34,6948	2,52393	Digital	21,62	31,1	26,7198	2,49033

Printed	31,46	42,56	34,8476	2,5597	Printed	21,29	31,13	26,784	2,54398
IMW MX					IMW MND				
Plaster	30,11	56,98	51,111	3,95632	Plaster	39,49	59,11	45,443	3,43002
Digital	30,23	56,96	51,1484	3,94939	Digital	39,4	59,33	45,4092	3,4493
Printed	30,35	56,88	51,222	3,91223	Printed	39,38	58,95	45,4178	3,3776

Graph 1 illustrates the standard deviation for mesio-distal widths of teeth in the three models and Graph 2 the standard deviation for arch lengths.





4.1. Tests Within-Subjects Effects

Tests of within-subjects effects evaluation was done to determine whether any significant differences in measurements taken from all three models exist. The significant value for sphericity assumed is set at p=0.05. If the significant value found between all three measurements for each type of model is $p \leq 0.05$, a statistically significant difference between the measurements exists. According to the data analyses, only four sets of measurements were found to be statistically significantly different in each type of model; namely mesio-distal widths of teeth 15 and 26 that had significant values of 0.001 and 0.000 respectively, the inter-canine widths in the maxillary arches that had a significant value of 0.001 and the inter-molar widths for the maxillary arches that had a significant value of 0.025. The significant values of all other observations are tabulated below in Table 2 and the values that are statistically significant as discussed are highlighted.

Table 2: Significant values of sphericity assumed for tests of within-subjects effects

Measurement	Significant value
11	0.733
12	0.138

13	0.402
14	0.325
15	0.001
16	0.120
21	0.235
22	0.531
23	0.350
24	0.730
25	0.219
26	0.000
31	0.368
32	0.261
33	0.291
34	0.861
35	0.117
36	0.984
41	0.152
42	0.363
43	0.161
44	0.915
45	0.164
46	1.000
ICW MX	0.001
ICW MND	0.477
IMW MX	0.025
IMW MND	0.594

4.2. Pairwise comparisons

The significant values of sphericity assumed of the tests within-subjects effects were $p \leq 0.05$ for 4 sets of measurements: the mesio-distal widths of teeth 15 and 26, the inter-canine widths in the maxillary arches and the inter-molar distances in the maxillary arches. These values indicate that statistically significant differences between these measurements taken from the three types of study models exist. In this instance, pairwise comparisons must be taken into account to determine where the significant differences exist. This test directly compares the study models against each other. In the case of the mesio-distal widths of tooth 15, both digital and printed study model measurements are statistically significantly different from the plaster study model measurement with significant values of 0.033 and 0.033, respectively. In the case of the mesio-distal width of tooth 26, the printed study model measurement is statistically significantly different from the plaster study model measurement with a significant value of 0.011. The digital study model significant value was 0.064, which makes it not statistically different from the plaster study model measurements. The significant value for the inter-canine widths in the maxillary arches taken from printed study models was 0.002, making it statistically significantly different from the plaster study model measurements. The digital study model significant value was 0.781, making it not statistically significantly different from the plaster study model measurements for inter-canine widths in the maxillary arches. The significant values for the inter-molar widths of both digital and printed study models were 0.126 and 0.016 respectively, making the measurements from the printed study models statistically significantly different from the plaster study model measurements. Out of the four sets of observations discussed above, it must be noted that the printed study models were the models that were statistically significantly different from their plaster counterparts, with the exception of the measurements taken for the mesio-distal width of tooth 15, where both digital and printed study model measurements differed significantly from the plaster study model observations.

The significant values for the pairwise comparison tests are tabulated below in Table 3 with the discussed values highlighted.

Table 3: Pairwise comparisons

Plaster model measurement	Digital model significant value	Printed model significant value
11	0.504	0.425
12	0.399	0.230
13	0.393	0.479
14	0.338	0.455
15	0.033	0.033
16	0.270	0.212
21	0.574	0.148
22	0.339	0.720
23	0.669	0.109
24	0.663	0.382
25	0.149	0.542

26	0.064	0.011
31	0.169	0.757
32	0.067	0.275
33	0.971	0.183
34	0.701	0.795
35	0.566	0.110
36	0.899	0.844
41	0.014	0.396
42	0.176	0.217
43	0.909	0.068
44	0.686	0.954
45	0.117	0.489
46	0.986	0.994
ICW MX	0.781	0.002
ICW MND	0.476	0.546
IMW MX	0.126	0.016
IMW MND	0.126	0.488

4.3. Inter-rater Reliability

Fifteen study models of each study model type were randomly selected, and these were measured by a second operator (KJ). The same electronic digital calliper that was used by the researcher was used by the second operator to measure the plaster and printed study models. Ortho Analyzer™ was used to measure the digital study models. Comparing the results of the second operator with those of the researcher is necessary to establish the reliability and reproducibility of these results obtained from the study models.

An interclass correlation technique is used to measure inter-rater reliability of quantitative data. The total measurements of each model were analysed for inter-rater reliability. The intraclass correlation values of the study models are tabulated in Table 4 below.

Table 4: Inter-rater reliability of study models

Study model	Interclass correlation value
Plaster	0.825
Digital	0.861
Printed	0.880

Based on the 95% confidence interval of the interclass correlation estimate, these values fall within the 'good' category of reliability. Results between the values of 0.75- and 0.9 are classified as having a 'good' reliability. Those that are greater than 0.9 are classified as being of excellent reliability.

CHAPTER 5

DISCUSSION

Plaster study models have been well established as the 'gold standard' of study models (De Luca Canto *et al*. 2015: 66, Abizadeh *et al*. 2012:155, Reuschl *et al*. 2016: 22, Pachêco-Pereira *et al*. 2015:501, Wan Hassan *et al*. 2016:887, Fleming *et al*. 2011:2). Furthermore, measuring study models using electronic digital callipers has also been considered the most validated method of measuring study models (Czarnota *et al*, 2016:23. Fleming *et al*, 2011: 13, Zilberman *et al*. 2003:304, Wan Hassan *et al*. 2016:886, Reuschl *et al*. 2016:22, Abizadeh *et al*. 2012:155, De Luca Canto *et al*. 2015:66). However, there are many disadvantages associated with plaster study models and conventional impression taking. The rise of digital technology and 3D printing in dentistry has given dental practitioners alternative techniques to fabricate study models using the conventional method of utilising alginate dental impressions and orthodontic or dental stone (Jiang *et al*.2016:130). Plaster study models require storage and are susceptible to loss and physical damage (Wan Hassan *et al*. 2015:301). The use of digital study models eliminates these disadvantages and numerous studies have shown that they are a reliable and clinically acceptable alternative to their plaster counterparts (Abizadeh *et al*. 2012:152, Saleh *et al*. 2015:306, Wan Hassan *et al*. 2016:895, Fleming *et al*. 2011:14, Czarnota *et al*. 2016:30). A major disadvantage is that a digital study model is not a physical object and cannot be physically manipulated or held (Asquith and McIntyre, 2012:531). Printing study models using 3D printers allows practitioners to obtain a physical representation of digital study models. Several studies have concluded that although the difference between measurements taken from plaster and printed models is statistically significant, the results are acceptable within a clinical environment (Ahmad and Al-Harbi, 2019:138, Hazeveld *et al*.2014:114, Saleh *et al*. 2015:306).

This present study differed from previous studies as it used intra-oral scanners to create digital study models which were subsequently measured for comparison against plaster and printed study models. Abizadeh *et al* (2012:152) used an extra-oral scanner, R250 Scanner by 3Shape® to scan plaster study models that were then digitised to create digital study models. These were compared to plaster study models. Jiang *et al* (2016:131) used CBCT to scan dental impressions that were subsequently converted to digital study models. Reuschl *et al* (2016:23) used the D800 extra-oral scanner by 3Shape® to scan plaster study models to create digital study models. Czarnota *et al* (2016:2016) used the D700 extra-oral scanner by 3Shape® to digitise their plaster study models.

The manner in which study models are routinely measured impacts the resultant measurements. An electronic digital calliper was used to manually measure plaster and printed study models. The operator measuring the study models is required to position the tips of the calliper on very specific landmarks to render a result; and the result is displayed on the screen of the electronic digital calliper and recorded (Bell *et al*. 2003:222). When computer software is used to measure digital study models, the practitioner must click on specific landmarks and the software calculates the resultant measurement (Bell *et al*. 2003:222). Intra- or inter-operator reliability needs to be accounted for in both methods of measuring as a certain degree of variability will occur (Bell *et al*. 2003:222). Intra- or inter-operator reliability is essential to determining how reproducible the resultant measurements from digital and printed study models are. In this present study, the study models' interclass correlation values based on a 95% confidence index were classified as 'good' reliability, as the values fall between the range of 0.75- and 0.9. Although these results do not reflect an 'excellent' reliability, these results could be due to difficulties in identifying certain landmarks and inexperience of the researcher in using Ortho Analyzer™.

This present study had three objectives; the first being to compare the accuracy of measurements taken from digital and printed study models compared with those taken from plaster study models, as already mentioned considered the gold standard of study models in dentistry (Wan Hassan *et al*. 2016:887). Only 4 of 28 sets of observations taken from digital and printed study models proved to be statistically significantly different from those taken from their plaster equivalents; therefore, it can be established that the measurements taken from digital and printed study models are not significantly different, from a statistical point of view, to measurements taken from plaster study models.

The second objective was to establish which type of study model was the most accurate in comparison to plaster study models. Since the results from the digital and printed study models proved to have been statistically on par with the results from plaster study models, it can be established that measurements taken from digital and printed study models are both equally as accurate as those taken from plaster study models.

The last objective was to identify any disadvantages and errors that can be made with any of the three types of study models. The disadvantages of each study model have been discussed in the literature review. The disadvantages associated with plaster study models include the laborious and time-consuming processes of pouring and finishing of plaster study models. The disadvantages encountered by the researcher included the time taken to become accustomed to measuring digital study models with Ortho Analyzer™ software. Practitioners must practise measuring study models with this programme to become familiar with orientating the study models and identifying landmarks. Abizadeh *et al.* (2012:158) stated that practitioners do require a period of adjustment to learn how to view a 3D object two dimensionally. It is also time-consuming in the beginning. The disadvantages encountered by the researcher regarding printed study models included the time-consuming process of printing each study model. Each study model took approximately 30-35 minutes to print. Extra time for removing supporting structures, brushing study models with solvent, post processing curing, and finishing must also be considered. The supporting structures are made with the same material as the study models, so wastage of materials does occur. Practitioners need to familiarise themselves with the printer software in order to design supporting structures that do not allow for unnecessary wastage of material. The storage of plaster and printed study models was problematic. However, these disadvantages are minimal in comparison to the disadvantages associated with the use of plaster study models; therefore, printed and digital study models are easier to use for clinical purposes.

The results of this present study are similar to previous studies that researched the accuracy of digital and printed study models for orthodontic practice. Hazeveld *et al.* (2014:109) compared plaster study models and three types of study models printed by three different rapid prototyping techniques, namely: 3D printing, jetted photopolymer and DLP. They measured the clinical crown heights and mesio-distal widths of teeth of all permanent teeth, 1-6, in each arch and found a statistically significant difference in one measurement only, the clinical crown heights of the teeth from the 3D printed models (Hazeveld *et al*. 2014:111).

This present study could have been improved by including measurements in the *z*-plane for comparison, e.g., overjet, overbite and clinical crown heights, as Hazeveld *et al*. (2014:112) concluded that post-curing shrinkage of printed study models affected measurements in the z-plane as well as clinical crown heights. Intra-operator reliability tests could have also improved the results of this present study and further validated the accuracy of digital and printed study models in comparison to plaster study models.

Abizadeh *et al.* (2012:158) compared measurements from plaster and digital study models and found that significant differences between the two types of study models existed but these differences were clinically irrelevant. They also found the repeatability of digital study models when compared with their plaster equivalents to be acceptable for use in a clinical environment (Abizadeh *et al*. 2012:158). Saleh *et al.* (2015:305) also concluded that the reproducibility of digital and printed study models was favourable in comparison with plaster study models. The reliability of the study models in this present study was found to be ‘good’ and but not ‘excellent’. While this is relevant statistically, clinically it is acceptable. Czarnota *et al.* (2016:30) found that the distances on digital study models were often smaller than those taken from plaster study models and as a result, many of their results showed significant differences but these were deemed irrelevant clinically. They therefore concluded that digital study models are accurate enough for clinical use.

Reuschl *et al.* (2016:26) concluded that although landmark identification will differ between practitioners, the differences are not clinically relevant and that measuring digital models using computer software is accurate enough to be used instead of measuring plaster study models with callipers.

CHAPTER 6

CONCLUSION

Study models form a vital part of orthodontic treatment planning, their use in space analysis being very important (Bahreman, 2013:43). The 'gold standard' of study models, plaster study models (Wan Hassan *et al*. 2016:887) have many disadvantages, including their storage for legal purposes, and this has brought about alternative methods (Abizadeh *et al*. 2012:151). Advances in digital technology in dentistry have given practitioners other types of study models to use.

The advantages of digital study models are numerous. No storage, impression materials or transport are required (Ahmad and Al-Harbi, 2019:31). Digital impressions are more comfortable for the patient, the gag reflex decreases and patients find it easier to breathe during the process (Anh *et al*. 2016:4). Ahmad and Al-Harbi (2019:31) predict that digital impressions will become the new standard of impression taking in a few years. Digital study models, with the use of CAD technology, allow for 3D printing of study models when needed (Ahmad and Al-Harbi, 2019:31).

According to Ahmad and Al-Harbi (2019:138) the field of orthodontics has benefitted the most from 3D printing. Although digital study models are more popular, the need for a physical study model still exists for appliance construction and for those practitioners who want a tangible study model (Hazeveld *et al*. 2014:145). 3D printers available for orthodontic use are capable of printing study models that are accurate enough to be used in the place of plaster study models (Ahmad and Al-Harbi, 2019:139).

This present study aimed at providing validation that digital and study models printed by a 3D printer are accurate enough to be used in a clinical environment. The results of this present study reflect that these two types of study models are as accurate as their plaster equivalents, but their limitations must be considered.

The limitations of this present study include that patients with mixed dentition were not included; mostly adolescents and adult patients participated. Ahmad and Al-Harbi (2019:140) state that most studies concerning digital dentistry and 3D printing do not include children and more studies including this group of patients are required as the majority of patients that seek orthodontic treatment are children. Only one brand of intra-oral scanner and 3D printer was used in this present study; more studies using other manufacturers and types of intra-oral scanners and 3D printers are needed to investigate whether they are also accurate enough to use in a clinical setting.

The researcher of this present study has concluded that the measurements taken from digital and printed study models are as accurate as those taken from plaster study models and are therefore accurate enough to be used in a clinical environment.

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APPENDICES

APPENDIX A: Example of data sheet

	MDW 11_1	MDW 11_2	MDW 11_3	ICW 1	ICW_ 2	ICW_ 3	IMW _1	IMW _2	IMW _3	M/F	AGE
P 1											
P 2											
P 3											
P 4											
P 5											
P 6											
P 7											
P 8											
P 9											
P 10											

Please note: This table represents the Microsoft Excel spreadsheet used to capture all data. The spreadsheet, due to the number of teeth measured, is too vast in size to display the entire document. Only one tooth number (11) is represented on this table but the Microsoft Excel spreadsheet included all permanent 1-6, for each arch for 50 patients.

Key:

P: Patient

MDW: Mesio-distal tooth width

11: tooth number 11 (first permanent incisor in first quadrant)

1: Plaster study model

2: Digital study model

3: Printed study model

ICW: Inter-canine width

IMW: Inter-molar width

MX: Maxilla

MND: Mandible

APPENDIX B: Informed consent and information sheet

Faculty of Dentistry: Department of Orthodontics and Paediatric Dentistry

Private Bag X1, Tygerberg 7505, Tel: 021 937 3106 Fax: 021 931 2287

Dear Patient

Dr A Madhoo is a postgraduate student at the Faculty of Dentistry, University of the Western Cape. An impression of your mouth taken using a material and scanner as part of your orthodontic examination will be used by her as part of a research project. Your impressions will be converted to plaster and digital models of your mouth and the digital model will be used to print a plastic model of your mouth using a 3D printer. She will be comparing the accuracy of measurements taken from the plaster and digital models with that taken from the printed model. Taking impressions of patients' mouths and analysing models are part of routine orthodontic treatment. There is no additional cost for participating in the research project; other than the cost of treatment set out to you by Dr Keith Johannes.

Your participation is completely voluntary. Should you choose not to participate in this research project, it will not affect any treatment you receive. Should you wish to withdraw your participation from this research project, you may do so at any time. It will not affect any treatment you receive subsequently. The information that we take from your impressions and models is strictly confidential. Your records will be numbered so that you will not be identifiable by your records. No information taken from your dental and medical records will be used in this research project and will be kept confidential.

Should you have any queries or need more information regarding this research project or your participation, please contact Dr Amika Madhoo on her contact number: 076 379 6761 or via email: amika.madhoo@gmail.com.

Thank you for your understanding and participation.

This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.

Biomedical Research Ethics Committee, Department of Research Development

Tel: 021 959 2948/49/88 or 021 959 2709

UNIVERSITY *of the* WESTERN CAPE

Faculty of Dentistry: Department of Orthodontics and Paediatric Dentistry

Private Bag X1, Tygerberg 7505

Tel: 021 937 3106 Fax: 021 931 2287

Consent form

I,____understand the information that has given to me regarding my participation in this research and I hereby give my consent for my impressions and study models to be used for Dr A Madhoo's research project.

I understand that:

1. My impressions and study models are going to be used for a research study.
2. My impressions and study models will be numbered to assure anonymity and all my information and records will be treated with strict confidentiality.
3. My participation in this study comes at no extra cost to my treatment, other than that set out by Dr K.C Johannes.
4. My participation is voluntary and I may withdraw participation at any time, should I feel the need to do so, and that my decision will not affect any treatment I receive subsequently.

Patient's full name and signature:

Witness's name and signature:

Date:

Information sheet and Informed consent for minor patients

UNIVERSITY *of the* WESTERN CAPE

Faculty of Dentistry: Department of Orthodontics and Paediatric Dentistry

Private Bag X1, Tygerberg 7505, Tel: 021 937 3106 Fax: 021 931 2287

Dear Parent/legal guardian of patient

Dr A Madhoo is a postgraduate student at the Faculty of Dentistry, University of the Western Cape. An impression of your child's mouth taken using a material and scanner as part of your orthodontic examination will be used by her as part of a research project. Your child's impressions will be converted to plaster and digital models of your child's mouth, and this digital model will be used to print a plastic model of your child's mouth using a 3D printer. She will be comparing the accuracy of measurements taken from the plaster and digital models with that taken from the printed model. Taking impressions of patients' mouths and analysing models are part of routine orthodontic treatment. There is no extra cost for participating in the research project; other than the cost of treatment set out to you by Dr Keith Johannes.

Your child's participation is completely voluntary. Should you choose for your child not to participate in this research project, it will not affect any treatment your child shall receive. Should you wish to withdraw your child's participation from this research project, you may do so at any time. It will not affect any treatment your child will receive subsequently. The information that we take from your child's impressions and models is strictly confidential. Your child's impressions and study models will be numbered so that your child will not be identifiable by his/her records. No information taken from your child's medical and dental records will be used in this research project and will be kept confidential.

Should you have any queries or need more information regarding this research project or your child's participation, please contact Dr Amika Madhoo on her contact number: 076 379 6761 or via email: amika.madhoo@gmail.com.

Thank you for your understanding and participation.

This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.

Biomedical Research Ethics Committee, Department of Research Development

Tel: 021 959 2948/49/88 or 021 959 2709

UNIVERSITY of the
WESTERN CAPE

Faculty of Dentistry: Department of Orthodontics and Paediatric Dentistry

Private Bag X1, Tygerberg 7505

Tel: 021 937 3106 Fax: 021 931 2287

Consent form

I,______________________________parent/legal guardian of
understand the information that has given to me regarding my child/ward's participation in this research and I hereby give my consent for my child/ward's impressions and study models to be used for Dr A Madhoo's research project.

I understand that:

1. My child/ward's impressions and study models are going to be used for a research study.
2. My child/ward's impressions and study models will be numbered to assure anonymity and all my child/ward's information and records will be treated with strict confidentiality.
3. My child/ward's participation in this study comes at no extra cost to my child/ward's treatment, other than that set out by Dr K.C Johannes.
4. My child/ward's participation is voluntary, and I may withdraw my child/ward's participation at any time, should I feel the need to do so, and that my decision will not affect any treatment my child/ward receives subsequently.

Parent/legal guardian's full name and signature:

Witness's name and signature:

Date:

APPENDIX C: Ethical clearance from Biomedical Science Research Ethics Committee of the University of the Western Cape

UNIVERSITY of the WESTERN CAPE

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08 June 2018

Dr A Madhoo
Faculty of Dentistry

Ethics Reference Number: BM18/3/20

Project Title: A comparison of three types of orthodontic study models.

Approval Period: 06 June 2018 – 06 June 2019

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

PROVISIONAL REC NUMBER -130416-050

FROM HOPE TO ACTION THROUGH KNOWLEDGE.