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ACCURACY IN REPRODUCTION OF BOUNDED EDENTULOUS SADDLE AREAS USING DIFFERENT CAST FABRICATION METHODS: A COMPARISON.

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3365207

A Master's full thesis submitted in fulfilment of the requirements for the degree of Magister Scientiae in the Department of Restorative Dentistry, Faculty of Dentistry, University of the Western Cape.

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KEYWORDS

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3D printing

Gypsum casts

Edentulous saddles

Intraoral scanning

Restorative dentistry

Digital impressions

Digitized dentistry

Additive manufacturing

Dental models

ABBREVIATIONS

Abbreviation	**Meaning**
CAD/CAM	computer-aided design and computer-aided manufacturing
AM	additive manufacturing
RP	rapid prototyping
SM	subtractive manufacturing
DMLS	direct metal laser melting
SLM	selective laser melting
SLS	selective laser sintering
DLP	digital light processing
SLA	stereolithography
FFF	fused filament fabrication
STL	standard tessellation language
PLY	polygon
OBJ	object
RPD	removable partial denture
FPD	fixed partial denture
3D	three-dimensional
2D	two-dimensional
CrCo	chrome cobalt
mm	millimetres
ADA	American Dental Association
ICC	interclass correlation coefficient
ml	millilitres
g	grams
rpm	revolutions per minute
fig	figure
L	length
H	height
PIO	physical intra-oral
3DM	3D model
GM	gypsum model
IOS	intraoral scan
min	minimum
max	maximum
diff	difference
LoA	limits of agreement
No.	number

SYMBOLS

Symbol	**Meaning**
µm	micron/micrometre (1µm=0,001mm)
<	Less than
>	Greater than
≤	Less than or equal to
≥	Greater than or equal to

ABSTRACT

Accuracy in reproduction of bounded edentulous saddle areas using different cast fabrication methods: a comparison.

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Introduction.

A common patient-request when presenting to restorative clinicians is replacement of missing teeth either by means of a fixed partial denture (FPD) or a removable partial denture (RPD). For decades, dental casts have been fabricated via the conventional cast fabrication technique which presents with its own set of disadvantages. To address these disadvantages, digital cast fabrication has been presented as an alternative. This is done via intraoral scanning and subsequent three-dimensional (3D) printing of dental models. However, the stitching process in intraoral scanning can be inadequate for areas lacking adequate geometry, such as edentulous saddle areas. This study therefore evaluated whether digital methods can successfully replace or compare with the conventional cast fabrication method for partially edentulous jaws, in the construction of RPDs, by assessing the accuracy in reproduction of the edentulous saddle areas using both the conventional and digital methods of cast fabrication, in comparison to the in vivo presentation itself.

Aim.

To compare the accuracy of 3D printed dental models, digital models produced from direct intraoral scans and conventional stone models to the in vivo edentulous saddle area.

Methods and materials.

A cross-sectional study was carried out in a sample of 20 bounded edentulous saddle areas. For each sample: the physical intraoral length and height of the bounded edentulous saddle was measured using digital calibrated calipers in mm; an intraoral scan was taken, saved in standard tessellation language (STL) format and assessed as the digital cast; a 3D model was subsequently printed from the intraoral scan data; and an alginate impression was taken and a conventional cast was fabricated using Type 4 dental stone. The 3D printed models and conventional gypsum casts were digitized using an extraoral scanner and converted to STL files. Linear measurements of the length and height of each saddle were digitally made on the intraoral scan, digitized 3D printed and gypsum casts using third-party software and tabulated. In vivo measurements were used as the control, as researcher calibration, inter and

intra-rater reliability testing was conducted, using the intraclass correlation co-efficient (ICC).

Results.

In comparison to the physical intraoral measurements, the average accuracy for intraoral scanning/digital casts was 32.5±30µm, conventional gypsum casts were -48±20µm, and 3D printed models was 59.75±30µm ($p<.05$). The null hypothesis was rejected as the different cast fabrication methods did produce statistically significant results. However, all methods produced clinically acceptable results. All ICCs were >0.9 indicating excellent trueness and precision.

Conclusion.

All methods of cast fabrication used in this study produced clinically accurate results for restorative dental procedures and have proven to be accurate in reproducing the physical intraoral dimensions in bounded edentulous saddle areas up to 19.91mm in length and 8.29mm in height, within the limitations of this study. Despite displaying a level of contraction, digital casts obtained by means of intraoral scanning proved to be the most accurate, followed by the conventional gypsum casts which exhibited some expansion, and finally 3D printed models which displayed a high level of contraction. Further in vivo studies are required to determine whether the digital workflow can completely replace the conventional workflow which is the gold standard.

April 2022.

DECLARATION

I declare that ‘*Accuracy in reproduction of bounded edentulous saddle areas using different cast fabrication methods: a comparison’* is my own work. It has not been submitted for any degree or examination in any other university. All sources I have used or quoted have been indicated and acknowledged by complete references. All figures and tables are my own and all sources have been acknowledged in the text. I declare that no conflict of interest exists with the products, devices and instruments used in this study.

Full name: Ameera Yusuf Essa   Date: 11/04/2022

Signed:

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My parents, grandmother, siblings, family, and closest friends, who have always prayed for me, believed in me and shown up for me when it mattered most. Words can never express how much I love, appreciate and value you.

DEDICATION

This thesis is dedicated to my mummy. Love is in her heart, prayer in her hands, and paradise under her feet. When I think of my blessings, I thank the Almighty for you a million times over. You are the wind beneath my wings. I love you.

And to my grandfather, NanaPe, for all that you were and will always be to me. I love you eternally. Until we meet again…

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CHAPTER 1: INTRODUCTION

For centuries, dentistry has been evolving in a plethora of ways to improve patient care and gratification. One such way is via the introduction and incorporation of digital technology into general and specialized dental practice (Rekow, 2020; Dawood *et al.*, 2015). As a result of the new improvements and digital opportunities available, present-day dentistry is sometimes referred to as the “Golden Age of Dentistry”; and for good reason (Sravanthi *et al.*, 2020). From digital smile designs to computer-aided design (CAD) and computer-aided manufacturing (CAM) of restorations, digital dentistry is providing exciting opportunities for restorative clinicians (Fasbinder, 2010). The complete digital workflow has the potential to become a major game-changer for prosthodontics (Joda *et al.*, 2017).

Teeth and oral structures are required for the optimal human functioning of mastication, speech and aesthetics. Restorative dentistry is the branch of dental treatment which focuses on restoring teeth and oral structures to maintain and prolong their efficiency in conjunction with ensuring that the oral environment remains healthy. This includes ensuring correct and adequate occlusion, health of the teeth and supporting structures, together with aesthetic and functional rehabilitation when necessary (Walmsley *et al.*, 2007).

Lost tooth structure due to disease and replacement of missing teeth continues to be an integral part of everyday practice for many general dentists and restorative specialists (Sakaguchi *et al.*, 2019). One of the most common patient requests at initial visits to restorative clinicians is to address missing or lost teeth. This can be done either by means of a fixed partial denture (FPD) or a removable partial denture (RPD), each with different indications (Misch, 2015; Ehikhamenor *et al.*, 2010). Restorative options for partially edentulous patients are based on a variety of factors including patient preference, finances and aesthetic considerations. The Kennedy classification system to describe partial edentulousness, which is the most commonly used, has been employed in this research (Misch, 2015; Carr and Brown, 2011; Ehikhamenor *et al.*, 2010; Skinner, 1959). Patients presenting with Kennedy Class III or IV were invited to participate in this study.

Dental practitioners will agree that one of the most vital components for successful dental treatment planning and subsequent execution, is the dental cast/model, which is obtained by means of a dental impression (Sim *et al.*, 2019). Dental casts are used to aid in the fabrication and design of removable and fixed dental prostheses, by both dentists and dental technicians (Ehikhamenor *et al.*, 2010; Anusavice *et al.*, 2012). Much of the information acquired from an initial dental cast is used to accurately plan and execute treatment (Aragon *et al.*, 2016). Accurate and well-made dental impressions allow for the detailed recording of the teeth and soft tissues, the surrounding structures, arch form, occlusal planes and dental relationships (Brinker, 2018). This aids in providing the foundation for comfortable and lasting restorative outcomes (Brinker, 2018).

Traditionally, a dental cast is fabricated by obtaining a dental impression of the oral cavity by means of dental impression material in a stock tray or a custom tray. Depending on the type of treatment required and the extent thereof, different dental impression materials may be utilized. A gypsum stone cast is subsequently fabricated. This is referred to as the conventional dental workflow and has been used successfully for almost a century (Kerr *et al.*, 2019; Chochlidakis *et al.*, 2016).

The conventional dental impression procedure does, however, have certain shortcomings such as gagging, unpleasant taste, possible pain to the patient and occasionally prolonged setting times. This can negatively influence patient acceptance (Choi *et al.*, 2019). Furthermore, dimensional stability of both the impression material and gypsum stone, and the presence of excessive saliva and blood in the oral cavity, can have undesirable impacts on the outcomes of the subsequent models (Choi *et al.*, 2019).

Gypsum casts present their unique set of advantages and disadvantages with the main disadvantages being that of storage inconveniences, risk of damage or breakage, their heavy weight and difficulties in sharing their data with other professionals involved in the patient's care (Kasparova *et al.*, 2013). This necessitates the requirement for a reliable yet less tedious method of data collection, storage and transfer. Variations in dimensional stability of the gypsum and impression materials are also considered to be a disadvantage as it has the ability to negatively impact treatment outcomes by causing variable, unplanned issues such as ill-fitting prostheses and poor patient acceptance (Choi *et al.*, 2019).

In order to alleviate these drawbacks of traditional impression taking, digital impressions and intraoral scanning have been recommended as acceptable alternatives (Kang *et al.*, 2020; Ender *et al.*, 2019; Park and Shin, 2018). Time consuming steps in traditional impression taking such as tray selections, transportation to the dental laboratory for pouring and subsequent prostheses fabrication and polymerization of custom trays are eradicated with digital impressions (Choi *et al.*, 2019). Additionally, data can be permanently and securely stored on various software and web-based data storages. The data can also be transferred easily via digital platforms to various clinicians and technicians (Choi *et al.*, 2019; Park and Shin, 2018; Mangano *et al.*, 2017). This is especially effective in multi-disciplinary dental treatments (Kasparova *et al.,* 2013).

It is important to note that physical casts are still required for diagnostic evaluations, removable restorations and complex prosthodontic treatments. These include full mouth rehabilitations and appliance manufacturing (Choi *et al.*, 2019; Park and Shin, 2018; Brown *et al.*, 2018). For this, either a conventional gypsum cast or 3D printed cast is utilized (Choi *et al.*, 2019).

The advantages of digital models are numerous and include the following: no physical storage requirement, instant accessibility, ability to do digital diagnostic or treatment mock-ups, positive patient perceptions, ability to immediately send lab work to an outside laboratory, no risk of breakage, wear, degradation or loss, and an overall improved continuity of care (Kasparova *et al.*, 2013). However, digital models do come with some important disadvantages as well, namely: without a physical model, treatment planning for complex cases can be challenging and a physical model may still be required for appliance fabrication (Brown *et al.*, 2018; Fleming *et al.*, 2011). Furthermore, limitations in storing large amounts of data due to storage capacity constraints of hardware, data loss and unauthorized access to the patients' data are also disadvantages that may arise (Kasparova *et al.*, 2013). One of the drawbacks of a digital workflow is the high capital output required, however these costs may become insignificant if a well-constructed and efficient digital workflow is implemented (Imburgia *et al.*, 2017; Masri and Driscoll, 2015).

The collaboration between digital dentistry and restorative dentistry has yielded limitations. One of these is that in full arch scans, longer edentulous spans are not always accurately reproduced using intraoral scanners. The precision thereof is low (Braian and Wennerberg, 2019) and sometimes cannot be used as a replacement for conventional impressions and gypsum stone casts, which are currently regarded as the gold standard (Choi *et al.*, 2019; Reuschl *et al.*, 2016; Fleming *et al.*, 2011).

In vitro research is performed under ideal conditions in a laboratory. This allows a controlled, reproducible environment to be simulated at all times. In vivo research is conducted on human specimens, often in a clinical setting. This often gives rise to various additional factors that cannot necessarily be controlled as they would be under ideal conditions. In vivo dental research can be affected by many patient-specific factors such as presence of and amount of saliva in the oral cavity, amount of space in the oral cavity, and presence of plaque biofilm (Kokich, 2013). The available instruments for measuring data in vivo give rise to their own specific challenges and limitations as well (Fleming *et al.*, 2011). While in vitro and in vivo research are complementary, in vivo research can meritoriously show the overall possible effects and outcomes on human models and living objects.

Intraoral scanners rely on a built-in stitching process to accurately stitch multiple images together to form one continuous image. This, however, requires a suitable, complex object geometry whereas edentulous ridges have a very simple geometry, thus making it difficult to accurately stitch together the images (Schmidt *et al.*, 2020; Braian and Wennerberg 2019; Treesh *et al.*, 2018). There is a paucity of research available regarding the in vivo clinical applications of digital dentistry to edentulous saddle areas (Tasaka *et al.*, 2019). Most of the available studies regarding digital applications to edentulous saddle areas have been conducted in vitro only and further in vivo studies are required (Ender *et al.*, 2016).

This study therefore intended to evaluate whether digital methods can successfully replace or compare with the conventional impression-taking method for partially edentulous jaws, in the construction of RPDs, by assessing the accuracy in reproduction of the edentulous saddle areas using both the conventional and digital methods of cast fabrication, in comparison to the in vivo presentation itself. The null hypothesis was that there would be no significant difference between the accuracy of the casts produced by intraoral scanning, 3D printing, and conventional impressions, in comparison to the in vivo edentulous saddle area.

This thesis consists of eight chapters, followed by references and appendices. Chapter 2 consists of a review of the literature pertaining to various aspects of this thesis. Chapter 3 focuses on the aim and objectives of the study carried out. Chapter 4 outlines and describes the research methodology together with the participant selection criteria and sampling information. Chapter 5 sums up the results of the study and includes tables and graphs to depict the results. Chapter 6 consists of a discussion of the results obtained. Chapter 7 highlights the limitations of the study and recommendations for future studies based on the results obtained in this study. Chapter 8 summarizes the conclusions of the study and is followed by a list of references and addendums which provide further insight on specific aspects of the study.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

A recent systematic review observed that while dental impressions may be considered a trivial and relatively “normal” procedure in modern dentistry, dental prostheses are fabricated as part of routine dentistry (Aragon *et al*., 2016). In order to ensure meticulous prostheses fabrication, the dental impressions and subsequent working models require a high level of accuracy. Any successful restoration relies greatly on optimal marginal adaptation to the tooth structure and therefore requires a high-quality impression (Chiu *et al.*, 2020; Aslan and Ozkan, 2019). Poor accuracy of the dental impression leads to a poorly fitting prosthesis that in turn negatively impacts patient satisfaction (Chiu *et al.*, 2020; Kang *et al.*, 2020). This literature review will focus on digital and conventional impression methods and materials, edentulous saddles and their classification systems, and a review of the current literature comparing digital and conventional impressions and casts.

2.2 Digital impressions

The continuous development in dental processing ensures new opportunities in the various fields of dentistry in a completely virtual environment, without the traditional gypsum stone model (Rekow, 2020). This can be obtained using digital impressions and subsequent digital models. A digital dental impression is fabricated using intraoral scanning by means of an intraoral scanner. Digital impressions can be fabricated in two ways, namely, directly and indirectly (Winkler and Gkantidis, 2020). The direct impression technique consists of obtaining a digital scan of the oral cavity by means of an intraoral scanner, while the indirect method relies on the extraoral scanning of a cast fabricated from a conventional impression or scanning of the conventional impression itself (Claus *et al.*, 2018; Park and Shin, 2018; Lee *et al.*, 2015).

The dental models produced via the intraoral scanning method are referred to as digital models/casts. In order to fabricate a physical cast from the intraoral scan data, either a three-dimensional (3D) printing method or a milling method is used. While digital impressions boast many advantages, one of the undeniable drawbacks is that digital technology requires frequent updates and will always be transcended by even newer and smarter technology (Chochlidakis *et al.*, 2016). Many CAD/CAM operations make use of the indirect impression technique and therefore require high quality, accurate, non-distorted impressions and subsequent gypsum models of optimal accuracy in order to have a fair chance at producing clinically acceptable prostheses and restorations (Baig and Omar, 2021). Brown *et al*. (2018) has shown 0.20-

0.50mm to be the acceptable range for clinically accurate casts, whereas Ender *et al*. (2016) showed that deviations in excess of 0.10mm leads to inadequate fit of restorations.

2.2.1 Intraoral scanning

Intraoral scanning is carried out by means of an intraoral scanner. Intraoral scanners are devices that are utilized by trained individuals to obtain optical impressions of the oral cavity directly (Mangano *et al.*, 2017). Various scanning and imaging techniques are combined to ensure a superior user-experience when utilizing intraoral scanning technology. These include but are not limited to interferometry, active and passive stereovision and triangulation, optical coherence tomography, confocal microscopy, and phase shift principles (Logozzo *et al.*, 2014).

In order to obtain an intraoral scan, a light source, either a laser or structured light/fringe, is projected directly onto the object that requires scanning- in this instance, the dental arch. Implant scan bodies are available to accurately scan the dental arch for implant treatments (Mangano *et al.*, 2017).

The use of intraoral scanners by means of a structured light initiation system often requires powder-coating of the teeth and surfaces to be scanned, and can also sometimes cause a bulky, shadowed effect of scanned surfaces leading to distorted representation of structure, especially thinner objects such as the incisal edges of anterior teeth (Claus *et al.*, 2018). The powder-coating step can be uncomfortable for both patients and clinicians alike and therefore, the more recent intraoral scanning devices make use of confocal lasers as a light-source to decrease the hindrances associated with structured/fringe light sources (Claus *et al.*, 2018).

The TRIOS® 4 (3Shape, A/S) (Figure 1) intraoral scanner utilizes the confocal laser as its light-source, has a fast scan time and does not require powder-coating. The confocal light-source allows for a light oscillation to be produced by the illumination pattern created. An alternative focus plane of the illumination pattern is produced by the system with the focus plane position being variable, while allowing the spatial relation of the scanner to the object to remain fixed. A collection of thousands of 2-dimensional (2D) images are captured by the intraoral scanner and subsequently processed by the software to form a continuous pattern, referred to as a sub-scan, which is then converted to a 3D digital model of the teeth and gingiva (Logozzo *et al.*, 2014).

Figure 1: 3Shape TRIOS® 4 intraoral scanner.

3Shape TRIOS 4® — Advanced Digital Dental Scanner (3Shape, 2021).

Structured light-source scanners are widely used for extraoral or desktop scanning. For this process, imaging sensors capture the images of the dental and gingival structures which are then processed by the scanning software and subsequently, point clouds are generated. Triangulation of the point clouds is carried out by the same software in order to electronically generate a 3D framework/a surface model, which is the end result of the optical scanning stage and serves as the digital/virtual substitute of the conventional gypsum cast (Mangano *et al.*, 2017). When it comes to extraoral scanning, it is important to note that the triangulation procedure can give rise to distortions and discrepancies as well, if an adequate separating medium such as a powder coating is not utilized (Mangano *et al.*, 2017).

Figure 2: 3Shape D710 extraoral scanner.

3Shape D710 extraoral scanner (SculptCad, 2021).

The quality of an intraoral scan in vivo can be affected negatively by a variety of factors. These include scan pattern and technology, presence of blood, and saliva in the oral cavity. Dryness of the optical scanning field i.e. saliva contamination can impede the scanning process giving less accurate intraoral scan data, anatomy of the dental arch, occlusal plane slope. Other factors involved include the size of the oral cavity and tissue displacement, sulcular fluids, degree of mouth opening achievable, patient movements, anatomic features such as the lips, tongue and cheeks, and moisture from breathing (Winkler and Gkantidis, 2020; Chiu *et al.*, 2020; Latham *et al.*, 2020; Bosniac *et al.*, 2019; Kim *et al.*, 2018; Imburgia *et al.*, 2017). These are variables that can be completely ignored in vitro, yet could have undesirable effects in vivo, and as such need to be taken into consideration (Kim *et al.*, 2018; Imburgia *et al.*, 2017). Clinical difficulties also exist in accurately recording functional depths and the sulci areas with intraoral scanners (Rasaie *et al.*, 2021).

Intraoral scanning relies on different acquisition methods. In one of these methods, multiple images are gathered and stitched together to form a continuous image. For this to be done accurately and precisely, the image needs to be aligned. This alignment can only be achieved when an appropriate object geometry is present. Complex geometry is most often noted on the occlusal surfaces of molars and premolars due to the anatomy present and as such, these can be scanned accurately with ease. Edentulous spans are often translucent, constantly covered in saliva, and have a very simple geometry, and therefore cannot necessarily be aligned accurately, thus causing distorted depictions thereof when using some intraoral scanners due to the stitching process (Rasaie *et al.*, 2021; Schmidt *et al.*, 2020; Braian and Wennerberg 2019; Treesh *et al.*, 2018; Fang *et al.*, 2018). The alignment of intraoral scans in the edentulous maxillary and mandibular arches is still challenging (Rasaie *et al.*, 2021; Russo *et al.*, 2020). Another matter of interest raised in the literature is that the maxillary edentulous arch displays greater resiliency than the mandibular arch and could make intraoral scanning in the mandible less accurate than the maxilla (Hack *et al.*, 2020). However, further research is required to confirm this.

The accuracy of intraoral scanners, as defined by ISO 5725 (1994), relies on the sum of two main parameters, namely: trueness and precision. Trueness is the ability of the value of a test subject to correspond as closely as possible to the actual object being investigated and is most often referred to in terms of bias. Precision refers to the reproducibility and repeatability of the results when modifications to the test conditions are made (Mangano *et al.*, 2017; Imburgia *et al.*, 2017). An intraoral scanner should preferably have high trueness and high precision (Mutwalli *et al.*, 2018). If either of these variables is compromised, intraoral scanning would have negative impacts on a prosthodontic workflow (Mangano *et al.*, 2017). It is possible for intraoral scanners to have a high precision and low trueness or the other way around; however, this would be unsuitable for restorative and prosthodontic treatment as one of the main priorities in restorative treatment is reduction of the marginal gap (Mangano *et al.*, 2017). As such, particular care needs to be taken when using intraoral scanners in the prosthodontic workflow, to ensure that digital impressions and intraoral scans have an equal or higher accuracy than the conventional impression technique (Nedelcu *et al.*, 2018). An important aspect to note is the exact dimensions of the test subject need to be known, therefore trueness is difficult to measure in vivo. While measurements of small geometric shapes and objects are possible with extraoral scanners, these methods are not necessarily applicable intraorally and pose great difficulty, mainly due to dental geometry (Ender *et al.*, 2016).

Intraoral scan files can be saved in different file formats. One of the more widely used formats is the standard tessellation language (STL) format. STL files can basically be described as a collection of triangles, fused together to form a mesh of a 3D object (Figure 3). The 3D printers available today can print dental models from STL files with great ease and as with everything digital, advancements are constantly taking place and improvements being made. Intraoral scanners available on the market currently can also provide alternative file formats. These are the polygon (PLY) and object (OBJ) formats, which make use of a tessellation pattern with polygonal shaped facets and capture colour. The PLY and OBJ formats have excellent surface texture and allow for highly accurate, multi-coloured 3D models to be printed (Zhivago and Turkyilmaz, 2021; McCue, 2019). The TRIOS® 4 (3Shape, A/S) intraoral scanner is able to directly save files in the STL and PLY formats allowing for 3D printing and other functions to be performed without the need for additional applications to be used.

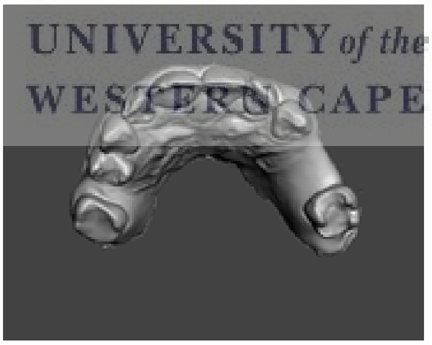


Figure 3: Digital image of a maxillary arch scan showing a bounded edentulous saddle in the second quadrant, in STL format.

2.2.2 3D printing

The introduction of 3D printing is changing the practice of dentistry (Sherman *et al.*, 2020). 3D printing is also known as additive manufacturing (AM) or rapid prototyping (RP). It is a process whereby material is added, layer by layer, to form a completed object by means of 3D digital data and a 3D printer. In a dental practice, this data is usually obtained by means of either an intraoral or extraoral scanner. When comparing additive and subtractive methods, AM has certain advantages over the subtractive manufacturing (SM) method. This includes decreased material wastage and improved object details in areas with more complex geometry (Zhao *et al.*, 2020; Revilla-Leon *et al.*, 2018; Alharbi *et al.*, 2017).

A review of the literature showed that the evaluation of accuracy of the 3D models produced by AM and SM for restorative dentistry have rarely been done, as these models are often used to study the accuracy in the field of dental orthodontics (Kim, 2018; Ender *et al.*, 2016). With regards to the field of prosthetic and restorative dentistry, such studies have been limited to single teeth or partial dental arches and often have limited methods of fabrication (Choi *et al.*, 2019; Bukhari *et al.*, 2018; Kim, 2018). It has been reported that the AM process has a greater accuracy than the subtractive method (Tancu *et al.*, 2019, Bae *et al.*, 2017). The thickness of the layers that are successively added in AM determines the surface finish and accuracy thereof, and thinner layers give rise to more accurate prints and a smoother surface finish (Brown *et al.*, 2018). The 3D model generation procedure itself can also give rise to a level of imprecision and inaccuracies with intraoral scanning (Winkler and Gkantidis, 2020), however, the newer models of 3D printers available today show great potential as an alternative to conventional gypsum models (Tancu *et al.*, 2019).

In prosthodontics, AM is used in a variety of applications, being used most often for RPDs and complete dentures, copings for fixed restorations and metal frameworks for dentures. Different methods of AM exist, and the most common methods employed are: direct deposition modelling/jetting, direct metal laser melting (DMLS), selective laser melting (SLM), selective laser sintering (SLS), digital light processing (DLP) and stereolithography (SLA) (Pereira *et al.*, 2020; Alharbi *et al.*, 2017). Of these, the photopolymerization methods- SLA and DLP, are the most widely used methods respectively in 3D printing for dental casts. (Zhao *et al.*, 2020; Kessler *et al.*, 2020). The P30 3D printer (Straumann® CARES) uses the DLP AM method (Figure 4). Fused filament fabrication (FFF) has also been identified as a 3D printing method with desirable properties such as cost-effectiveness and lack of restrictions on materials that can be used, however, its application to dentistry is limited, and it is most often used in fabrication of dental models and custom trays (Kessler *et al.*, 2020).

Figure 4: Straumann® P30+ 3D printer.

P30+ Semi-Automated 3D Printing for Dental Lab (Straumann® Group, 2021).

Some advantages, disadvantages, and applications of each method of AM are tabulated below (Table 1) (Zhao *et al.*, 2020; Kessler *et al.*, 2020; Alharbi *et al.*, 2017).

Table 1: Advantages, disadvantages, and applications of each method of AM.

Printing technique	Printing method	Advantages	Disadvantages	Applications
Direct deposition printing/jetting	Binder jetting	Lower cost Rapid production process	Rough surface finish Low mechanical strength	Dental models
	Material jetting	Lower cost Rapid production process Variety of material options	Layers may collapse during build process Rough surface finish Low mechanical strength	
	DLP jetting	Rapid production process Immediate solidification of each layer due to photopolymerization High surface quality	Post curing is required Only photopolymerized material can be used	Occlusal splints Resin mock-ups Dental models
Laser Sintering	DMLS SLM SLS	Possible to print object with 100% density	Thermal distortion Most expensive	Metal frameworks and copings Crowns and implants
Photopolymerization	DLP	Adequate build details Smooth surface finish Rapid production process Transparent objects are possible	Post curing is required Only photopolymerized material can be used	Dental models Surgical guides Temporary restorations Resin patterns Cast copings Gingival masks Dentures
	SLA	Good mechanical strength Smooth surface finish High dimensional accuracy Rapid production process Adequate build details	Only photopolymerized material can be used Post curing is required	
Material extrusion	FFF	Lowest cost Multicolour objects are possible	Rough surface finish Brittle materials	Custom trays, dental models

2.2.3 Milling

In contrast to 3D printing, milling, also known as “subtractive manufacturing” (SM), is a process whereby a material is cut by means of a cutting tool until the desired object form and geometry is obtained (Alharbi *et al.*, 2017). This type of material processing is utilized by CAD/CAM technologies since its introduction to the dental field in the 1980s and is currently dominating the digital dentistry field with respect to in-office prosthesis manufacture (Chiu *et al.*, 2020; Joda *et al.*, 2017; Van Noort, 2012). CAD/CAM technologies, by means of a milling unit (Figure 5), can be used to produce dental models and/or a variety of restorative solutions such as crowns, inlays, onlays and veneers, using various materials, without the need for physical casting (Joda *et al.*, 2017).

Figure 5: Ivoclar Digital PrograMill PM7 milling unit.

PrograMill PM7 (Ivoclar Digital, 2021).

SM can basically be described as starting out with a simple block of material, such as ceramic, which is then cut down with saws, blades and drills to achieve the required object with the desired geometrical characteristics (Kessler *et al.*, 2020; Bae *et al.*, 2017; Van Noort, 2012). The main disadvantage of this method is the amount of product that is wasted due to the cutting process. Often, more product is discarded than what is ultimately used for the end product, with literature showing that material loss can be up to 90% (Kessler *et al.*, 2020; Bae *et al.*, 2017). This makes SM less desirable as the cost increases with material wastage and the environmental burden thereof is also a concern (Bae *et al.*, 2017). Another limitation of the SM is that undercuts are not easily milled and could give rise to ill-fitting dental prostheses (Bae *et al.*, 2017). Undercuts are recessed areas of dental structures. This includes edentulous ridges, prostheses, teeth and restorations (Anusavice *et al*., 2012). However, digital workflows have benefitted greatly from SM technology, and the impacts thereof in dentistry are not to be negated (Joda *et al.*, 2017). CAD/CAM manufacturing allows for decreased laboratory workload and time, while producing adequately fitting, high strength prostheses (AlHelal *et al.*, 2017).

For actual physical casts, prosthodontic literature has reported RP/AM to be superior to SM in accuracy. Casts produced via RP/AM showed trueness in the region of 30-50µm (0.03-0.05mm) and precision within the range of 20-40µm (0.02-0.04mm) when compared to milled casts (Serag *et al.*, 2018). Gypsum blocks for SM casts have recently been introduced by manufacturers of dental materials, and claim to be able to produce more accurate casts due to the absence of elasticity (Choi *et al.*, 2019). Further studies regarding this and cost-effectiveness thereof are required.

CAD/CAM restorations are produced in a 3-part system. These are: scanning, design and manufacture (Sravanthi *et al.*, 2020). The scanning is carried out by means of an intraoral or extraoral scanner; the restoration is subsequently designed taking care to include necessary characteristics such as morphology, removal of undercuts and amount of space required for cement; and finally, a restoration is manufactured automatically and ready for placement in the oral cavity (Tzotzis *et al.*, 2020; Kirsch *et al.*, 2017). Different tools and instrument geometry, as seen in Figure 6, allow for different “cutting actions” to be performed and allows for the various anatomical features of restorations to be accurately designed and manufactured (Tzotzis *et al.*, 2020). The instrument geometry and milling strategy is machine-specific and can vary greatly (Bae *et al.*, 2017). Smaller diameter instruments and tools allow for deeper excavation to be carried out such as reproduction of cusps, fissures and deeper details; while larger diameter instruments can withstand a greater number of milling cycles (Bosch *et al.*, 2014).

Changing of instruments for detail incorporation is time consuming. Literature shows that 5-axial milling units are slower than 4-axial milling units (Bosch *et al.*, 2014). Interestingly, faster manufacturing of CAD/CAM restorations has shown to be less accurate and exhibits more marginal chipping of the produced restoration/s (Bosch *et al.*, 2014). There is ongoing research being carried out on milling software to enhance the functions and capabilities of milling units and instruments, particularly instrument geometry, to support engineering for CAD/CAM applications in dentistry (Tzotzis *et al.*, 2020).

Figure 6: Ivoclar PrograMill tools.

PrograMill tools (Ivoclar Digital, 2021).

2.3 Conventional impressions

A dental impression can be described as a negative replica of the contents of the dental arch (Sakaguchi *et al.*, 2019; Millstein, 1992). By means of various impression materials, based on the required application, the dental impression is obtained (Kerr *et al.*, 2019; Chochlidakis *et al.*, 2016). This impression is then poured using gypsum to fabricate a dental cast/gypsum cast (Sakaguchi *et al.*, 2019). The set gypsum cast is the positive replica of the dental arch and aims to accurately duplicate what is present in the oral cavity (Sakaguchi *et al.*, 2019; Millstein, 1992).

Impression taking can be considered an art, as the exact size of the teeth, relation and location relative to other structures in the oral cavity and available restorative space, must be accurately recorded for optimal prosthetic results (Terry *et al.*, 2006). Dental casts are utilized in the laboratory manufacturing of restorations and prostheses; and can also be used to identify, assess and address orthodontic malocclusions and occlusal discrepancies (Sakaguchi *et al.*, 2019). There are six major steps involved in the fabrication of a conventional gypsum cast. These are represented in Figure 7 below (Anusavice *et al.*, 2012).

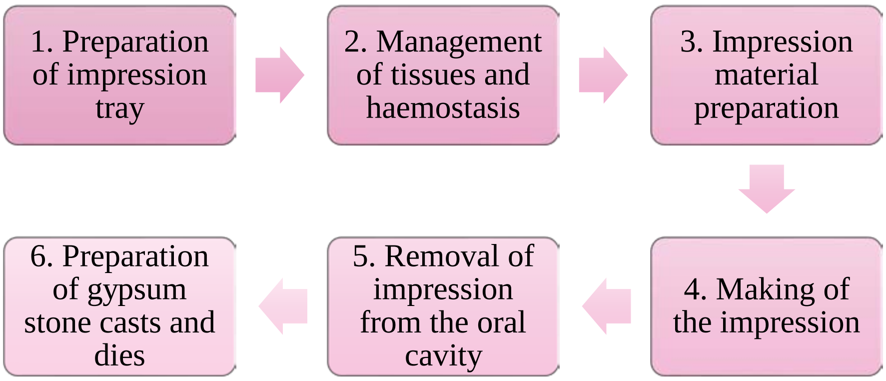


Figure 7: Steps involved in the fabrication of a conventional gypsum cast.

2.3.1 Classification of conventional dental impression materials

Impression materials are often classified based on their properties of elasticity once set (Wassell *et al.*, 2002). Elastic impressions are able to withstand forces which aim to dislodge them such as undercuts; while non-elastic impression materials will break or distort under heavy pressure and are unable to accurately record undercuts (Wassell *et al.*, 2002). The classification of impression materials is represented by the following diagram (Figure 8) and offers a brief timeline of when some were introduced into dental practice (Brinker, 2018; Terry *et al.*, 2006; Wassell *et al.*, 2002).

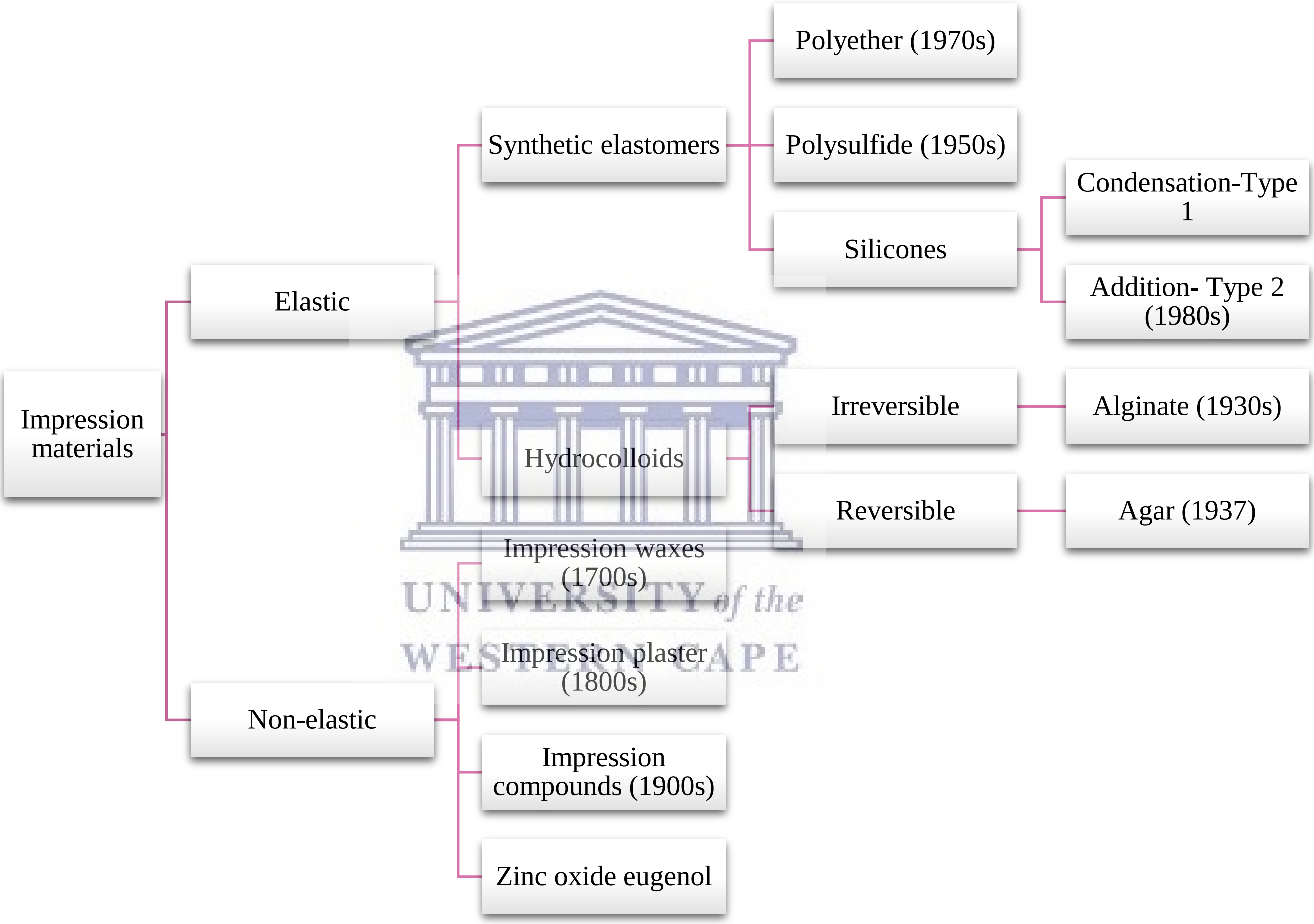


Figure 8: Classification of impression materials.

2.3.2 Properties of dental impression materials and possible drawbacks

The properties of the impression material must suit the application. Some of the main properties that must be considered are viscosity, tear strength and elastic recovery, hydrophilicity, dimensional stability and working and setting times (Brinker, 2018; Terry *et al.*, 2006). A summary of some of the properties of dental impression materials along with a brief description, relevance and drawbacks are presented in Table 2.

Viscosity can be described as the rate of flow of unset impression material (Terry *et al.*, 2006). It is also expressed as the rate of flow of the material, and is an important factor to consider as it directly affects the accuracy and detail that is captured by the impression (Sakaguchi *et al*., 2019; Brinker, 2018). This is determined by the amount of filler particles present in the material and can be classified in 4 ways namely: very high viscosity- an extremely thick material e.g. Putty; high viscosity- tray materials e.g. Alginates, medium viscosity and low viscosity- runny, flowable materials e.g. Wash material or syringe materials (Sakaguchi *et al*., 2019; Brinker, 2018). While materials with a lower viscosity provide more accurate finer details, these are often difficult to work with in the clinical setting and are the most prone to dimensional shrinkages (Terry *et al.*, 2006). The viscosity of the material aids in determining the suitability and application thereof in dental practice (Brinker, 2018).

Tear strength and elastic recovery refer to the way an impression material responds upon removal from the oral cavity and the ability of the impression to be stretched and then returned to its original shape, without tearing (Sakaguchi *et al*., 2019; Brinker, 2018; Terry *et al.*, 2006). Ideally, the elastic property of the material should allow the impression to stretch as it is removed and then return to its original shape and form without distortion (Brinker, 2018; Terry *et al.,* 2006). These properties can be negatively impacted by a variety of factors such as depth of the sulcus and naturally occurring undercuts (Brinker, 2018). If the material is distorted or torn upon removal from the oral cavity, the impression needs to be retaken and becomes more uncomfortable for the patient, and frustrating and costly for the clinician (Brinker, 2018). Materials that have the appropriate tear strength and elastic recovery are able to withstand multiple pours without much distortion, making these materials desirable in modern restorative dentistry (Sakaguchi *et al*., 2019; Terry *et al.*, 2006).

Hydrophilicity is the property which describes the affinity of a material to water (Brinker, 2018). Hydrophilic materials have a great affinity to moisture and are often desirable due to increased wettability which allows for more accurate impressions to be taken (Terry *et al.*, 2006). Conversely, hydrophobic materials have a weaker affinity to and often repel moisture, and therefore produce less accurate impressions as a result of the decreased wettability (Terry *et al.*, 2006). Hydro active materials are a combination of the hydrophobic and hydrophilic material properties and show greater accuracy in recording of surface details and a greater surface wettability (Brinker, 2018).

Dimensional stability is the property of the impression material that describes the ability of the completed impression to withstand temperature changes during transportation to the laboratory, as well as to remain unaltered for prolonged periods of time and be poured multiple times to allow the fabrication of multiple casts (Anusavice *et al*., 2012; Terry *et al.*, 2006). Some degree of distortion does occur upon removal of the impression from the oral cavity; however, the impression should rebound to its pre-removal dimensions (Anusavice *et al*., 2012). If the impression material changes dimensions, the need for a retake would be necessitated which is time-consuming and wasteful (Brinker, 2018; Terry *et al.*, 2006). Storage conditions and disinfection protocols can greatly affect the dimensional stability of impressions (Porrelli *et al*., 2021). Shrinkage can occur if water loss or evaporation occurs, this is referred to as syneresis. Conversely, imbibition, which is gaining of water, can cause swelling. Both shrinkage and swelling are unwanted distortions that ruin the impression rendering it unusable (Porrelli *et al*., 2021; Sakaguchi *et al*., 2019; Anusavice *et al*., 2012). As such, it is important that impressions are mixed and used following the manufacturer's guidelines, to ensure optimal results (Anusavice *et al*., 2012).

Working and setting times are critical aspects to consider as unset material can result in inadequate dental casts, giving rise to imperfect and inadequate restorations. The working time is the time it takes to mix an impression material and transfer it to the patient's mouth, or the time taken from the start of mixing to a point where the material can no longer be manipulated without introducing distortions and inaccuracies to the final set impression (Sakaguchi *et al*., 2019; Terry *et al.*, 2006). The setting time is the time taken for the impression material to set completely after placement into the patient's mouth, and be removed without breakage (Sakaguchi *et al*., 2019; Terry *et al.*, 2006). Very short working times are often undesirable for less-experienced clinicians as the material often sets rapidly, not allowing sufficient time for adequate placement of the tray into the mouth, thereby yielding inconsistent and poorer quality impressions. To increase working time, it is preferred to refrigerate impression materials prior to use or to use colder water in the case of alginates. Adjusting the water-powder ratio is not recommended to increase working time as that may negatively impact other properties of the material (Brinker, 2018; Terry *et al.*, 2006).

Temperature also affects working and setting times and materials should be prepared according to the manufacturer recommended guidelines (Sakaguchi *et al.*, 2019). Other factors such as cost effectiveness and taste also need to be considered but should not be the ultimate deciding factors in material selection (Sakaguchi *et al*., 2019).

Table 2: Summary of some properties of dental materials, descriptions, relevance and drawbacks.

Property	Description	Relevance	Drawback
Viscosity	The rate of flow of unset impression material	Directly affects the accuracy and detail that is captured by the impression	Lower viscosity materials provide more accurate finer details, but are often difficult to work with in the clinical setting and are the most prone to dimensional shrinkages
Tear strength and elastic recovery	The way an impression material responds upon removal from the oral cavity and the ability of the impression to be stretched and then returned to its original shape, without tearing.	Materials that have the appropriate tear strength and elastic recovery are able to withstand multiple pours without much distortion, making these materials desirable in modern restorative dentistry.	If the material is distorted or torn upon removal from the oral cavity, the impression needs to be retaken and is uncomfortable for the patient, and frustrating and costly for the clinician.
Hydrophilicity	The affinity of a material to water.	Hydrophilic materials have a great affinity to moisture allow for more accurate impressions to be taken.	Hydrophobic materials have a weaker affinity to and often repel moisture, and therefore produce less accurate impressions.
Dimensional stability	The ability of the completed impression to withstand temperature changes during transportation to the laboratory and to remain unaltered for prolonged periods of time and be poured multiple times to allow the fabrication of multiple casts.	Some degree of distortion does occur upon removal of the impression from the oral cavity; however, the impression should rebound to its pre-removal dimensions.	If the impression material changes dimensions, the need for a retake would be necessitated which is time-consuming and wasteful. Both shrinkage and swelling can occur, and are unwanted distortions that ruin the impression rendering it unusable.
Working and setting times	Working time is the time taken to mix an impression material and transfer it to the patient’s mouth. Setting time is the time taken for the impression material to set completely after placement into the patient’s mouth, and be removed without breakage.	Working and setting times are critical aspects to consider as unset material can result in inadequate dental casts, giving rise to imperfect and inadequate restorations.	Very short working times are often undesirable for less-experienced clinicians as the material often sets rapidly.

2.3.2.1 Alginate as an impression material for removable prosthodontics

Alginate is classified as an irreversible hydrocolloid impression material (Porrelli *et al.*, 2021; Borges de Olival *et al.*, 2018; Anusavice *et al*., 2012; Rubel, 2007). A “sol” resembles a solution but consists of a colloid of solid particles in a continuous liquid medium (Sakaguchi *et al.*, 2019). When a suitable reactor is added, sols can be transformed into a “jelly-like” or gel consistency. The liquid state of this reaction most often consists of water or another liquid, giving rise to the term “hydrocolloid” (Sakaguchi *et al*., 2019; Lemon *et al.*, 2003). Alginate, an elastic, insoluble gel, is produced as a result of a chemical reaction between alginic acid- a marine plant derivative and calcium sulphate. Initially, when the alginate material is mixed with water, a sol is formed. The ensuing chemical reaction creates the set final impression in a gel-form. The alginate impression compound powder consists of: sodium phosphate, soluble alginate, and calcium sulphate dehydrate. The calcium sulphate functions as the “reactor” with the alginic acid as the “reagent”. Sodium phosphate acts as the retarder and controls the setting time. Insoluble calcium phosphate is formed via the addition of water to the alginate compound, as the phosphate ions from the sodium phosphate react with the calcium ions from the calcium sulphate. Insoluble calcium alginate gel is formed, after the depletion of the available phosphate ions, when soluble alginate reacts with calcium ions. This gel is insoluble in water and is the final set impression (Sakaguchi *et al*., 2019; Anusavice *et al*., 2012; Rubel, 2007; Lemon *et al*., 2003).

Irreversible hydrocolloids are among the most acceptable impression materials in dentistry (Borges de Olival *et al.*, 2018; Lemon *et al.*, 2003), mainly due to the easy handling properties combined with good detail reproducibility, acceptable taste, patient comfort and cost effectiveness (Porrelli *et al.*, 2021). Alginate is often referred to as an elastic impression material, which allows for its use in a variety of restorative procedures (Sakaguchi *et al*., 2019). However, a more accurate description would be that alginate is a visco-elastic material, as it exhibits both elastic sol and viscous liquid properties, which explains the rubber-like texture of the set material. It is hydrophilic allowing for good wettability of the oral structures and subsequent clear reproduction of the oral structures (Sakaguchi *et al*., 2019; Rubel, 2007).

One of the drawbacks of alginate is the low dimensional stability as distortions can occur (Rubel, 2007). Shrinkage and contraction of the impression can occur in the event of syneresis and swelling can occur if imbibition ensues (Porrelli *et al.*, 2021). Thus, it is imperative that alginate impressions be poured immediately or at least within 30 minutes of the impression being acquired (Porrelli *et al.*, 2021; Sakaguchi *et al.*, 2019). Additionally, a study by Taylor *et al.* (2002), showed that Blueprint® alginate exhibits superior surface reproduction following a “dip” in sodium hypochlorite for disinfection, and thus indicated that Blueprint® does not absorb disinfectant as readily as some other brands of alginate.

The American Dental Association (ADA) specifies that dimensional changes of elastomeric impression materials should not exceed 0.05% (Pal *et al.*, 2014). Alginate in metal stock trays has proven to be a clinically acceptable impression protocol in the construction of removable prostheses in restorative dentistry (Baig and Omar, 2021); and is still widely used in practice. One study has shown adequate fit of RPDs fabricated by means of an alginate impression, when poured within 30 minutes of the impression being taken (Baig and Omar, 2021). The same study showed no discernible variations between chrome cobalt (CrCo) RPD frameworks fabricated by means of addition silicone impressions and those produced by alginate impressions (Baig and Omar, 2021). This implies that there is currently no published data that definitively proves the superiority of addition silicones over alginate as the impression material of choice in RPD treatment, or vice versa.

2.3.3 Criteria for ideal dental impressions

A crucial step in any successful restorative treatment and outcome is an accurately made dental impression (Chiu *et al.*, 2020; Aslan and Ozkan, 2019; Terry *et al.*, 2006). The ultimate criteria do differ greatly between practitioners; however, the basics are a combination of: tray selection, appropriate material selection, adequate volume of impression material, accurate timing, sufficient haemostasis, tissue management, and moisture control (Terry *et al.*, 2006). An interesting observation according to the literature, is that the usage of the latest materials is not necessarily the driving force for restorative clinical success, but rather the impression technique implemented by the clinician (Terry *et al.*, 2006).

The characteristics of an ideal dental impression are represented in Figure 9 (Swelem and Abdelnabi, 2016; Terry *et al.*, 2006).

Appripriate thickness of material in order to withstand tearing and distortion when removed from the oral cavity.

Impression borders are of proper thickness, well-extended, rounded and smooth, devoid of pressure areas, bubbles, voids, tears and drags.

A homogenous consistency of material without any air bubbles.

The loaded tray is centralized upon insertion with adequate bonding between the tray, adhesive and impression material.

Accurate fine detail replication which is free from debris, saliva and blood.

Impression still firmly adhering to impression tray, completely set upon removal from the oral cavity and distortion free.

Figure 9: Characteristics of an ideal dental impression.

2.3.4 Gypsum products used in conventional dental cast fabrication and factors to consider

Gypsum products have served the dental profession for many years and their applications in dentistry have been documented widely (Sakaguchi *et al.*, 2019). A gypsum product is composed essentially of calcium sulphate hemihydrate ($CaSo4.2H2O$) with necessary fillers and modifiers such as colourants and flavourings (Hamdy *et al.*, 2020; ANSI/ADA, 1985). A vast majority of gypsum products are obtained from natural gypsum rock (Sakaguchi *et al.*, 2019). Gypsum products are typically classified as one of 5 types (ISO 6873) as represented in Table 3 below (Hamdy *et al.*, 2020; Sakaguchi *et al.*, 2019; ANSI/ADA, 1985). Each type of gypsum for dental applications has the same chemical composition with variances in the particle shapes and sizes, based on the production technique (Hamdy *et al.*, 2020; Sakaguchi *et al.*, 2019). The chemical reaction with water of all types of gypsum is the same; however, the differences are the physical properties they exhibit (Sakaguchi *et al.*, 2019).

Table 3: Classification and applications of dental gypsum.

Type	Classification	Properties/uses
1	Dental plaster and impression plaster	Mounting of dental casts, Impression material
2	Dental plaster	Dental models
3	Dental stone	Dental models
4	Dental stone and improved stone	High strength and low expansion, Dental models
5	Dental stone	High strength and high expansion, Die fabrication.

While gypsum is not directly used as a dental restorative material, it is commonly used in dental cast fabrication for both clinical and laboratory procedures, due to its lower cost, suitability for use with elastomeric impression materials and ease of use (Heshmati *et al.*, 2002; Millstein, 1992). According to Millstein (1992), dental impressions are often studied to determine their accuracy, however the casting of such impressions is rarely studied. Even with the great amount of literature available today, literature on the exact effects of inadequate pouring and casting of dental models is still lacking. For restorative and prosthodontic procedures, dimensional stability and accuracy are properties of particular importance in dental cast fabrication (Heshmati *et al.*, 2002). The different types of gypsum have different applications, and for restorative and prosthodontic procedures, gypsum types 4 and 5 are most often used (Sakaguchi *et al.*, 2019; Heshmati *et al.*, 2002).

The success of a gypsum product in its application in prosthodontic procedures depends greatly on it meeting certain specifications (Duke *et al.*, 2000). In theory, calcium sulphate hemihydrate should exhibit volumetric contraction upon setting based on its chemical composition (Sakaguchi *et al.*, 2019). However, one of the drawbacks of gypsum as shown in the literature, is that gypsum products tend to expand upon setting (Sakaguchi *et al.*, 2019; Millstein, 1992). Naturally, this would give rise to some level of distortion in the set dental cast (Millstein, 1992). As such, this property must always be considered in the dental cast fabrication procedure for restorative dentistry. For an accurately fitting dental prosthesis to be produced, minimal setting expansion is required (Hamdy *et al.*, 2020; Kenyon *et al.*, 2005). The expansion is believed to be as a result of out-thrusting of individual crystals formed by the out-of-solution precipitation of dihydrate calcium sulphate, which is a by-product of the gypsum setting reaction. This results in an increased external mass (Millstein, 1992). The role of setting expansion, as determined by the manufacturer, is quoted to the clinician, and is not to be negated (Sakaguchi *et al.*, 2019; Millstein, 1992). The application of gypsum products in a clinical environment differs greatly and sometimes greater setting expansion is preferred e.g. in the case of full coverage occlusal splint fabrication, whereas a gypsum product with the lowest setting expansion would be preferred in the case of partial denture fabrication. The ADA Specification No. 25 specifies that gypsum products for dental use should not exceed 0.1% (ANSI/ADA, 1987). According to the ADA specifications, all linear measurements of final expansion should be made at least 2 hours after mixing (Heshmati *et al.*, 2002).

Fine detail reproduction and dimensional accuracy are of great importance for true anatomical structure replication (Pal *et al.*, 2014). Several dental applications require an increased wettability of solids by means of liquids with reduced surface tensions to ensure adequate flow of gypsum over the impression to allow fine detail replication (Sakaguchi *et al*., 2019). The inclination of a liquid to spread over the surface of a solid is referred to as the "wetting power" of the liquid. Hydrophobic impression materials do not always receive adequate wetting from gypsum and often require a wetting agent (Sakaguchi *et al*., 2019).

The use of alginate as an impression material requires certain steps to be carried out prior to the casting of the dental model (Sakaguchi *et al*., 2019). This includes rinsing of the impression surface to remove any exudate caused by syneresis (Anusavice *et al*., 2012). Exudate will retard the setting time of the gypsum (Sakaguchi *et al*., 2019; Anusavice *et al*., 2012; Carr and Brown, 2011). The calcium sulphate dihydrate in dental gypsum is somewhat soluble while the alginate gel contains water. As such, the prolonged contact of the set gypsum cast and alginate impressions is not recommended as the surface detail can be easily damaged and the surface quality would be significantly decreased (Sakaguchi *et al*., 2019). This would render the cast inadequate for restorative purposes. While gypsum products have their drawbacks, the have served the profession effectively for decades (Sakaguchi *et al*., 2019).

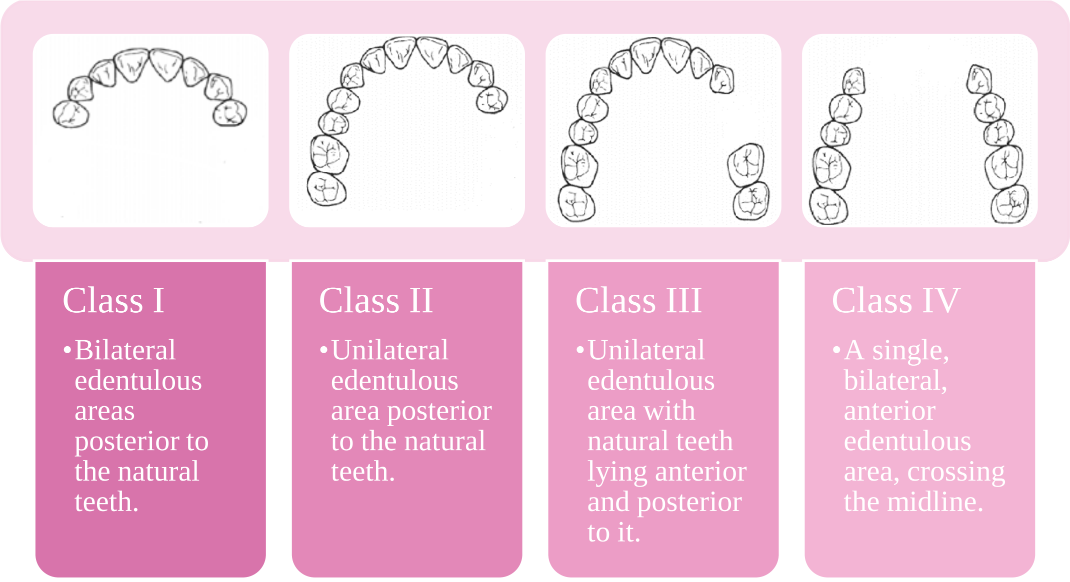
2.4 Edentulous saddles

Edentulous saddles are often referred to when describing areas where a tooth or teeth would usually be present (Ehikhamenor *et al.*, 2010). Partial edentulism is the term used to describe arches with edentulous spaces present. While the term is not literally correct, and there is great debate among clinicians about whether it should be used to describe an arch with missing teeth, it is still used routinely in clinical practice and in the literature (Polychronakis *et al.*, 2013).

The causes of tooth-loss are numerous and include orthodontic treatment, caries, periodontal disease, tooth impactions, trauma, as well as cystic and neoplastic lesions (Ehikhamenor *et al.*, 2010). Despite the fact that there has been a great decline in the prevalence of tooth-loss over the past several years, there is a notable distribution in the pattern of tooth-loss, leading to a vast variation in the combination of teeth missing in partially edentulous patients (Carr and Brown, 2011). The literature shows maxillary tooth-loss to occur more frequently, with the mandibular canines and incisors often being the last remaining teeth present in the oral cavity (Polychronakis *et al.*, 2013; Carr and Brown, 2011; Ehikhamenor *et al.*, 2010; Jiménez-Castellanos *et al.*, 2005). Posterior tooth-loss has also been shown to occur more often than anterior tooth-loss (Polychronakis *et al.*, 2013; Ehikhamenor *et al.*, 2010).

2.4.1 Classification of edentulous saddles

The need exists to have a universal classification system for partial edentulism to support effective communication between the clinician and the dental technician, especially to aid in determining the appropriate major connectors to be used in RPDs (Polychronakis *et al.*, 2013; There have been several proposed classification systems for partial edentulism, and many are currently in use. Naturally, this has given rise to great confusion amongst clinicians in deciding which classification system to adopt (Carr and Brown, 2011). The most commonly used classifications in the literature are those initially proposed by Kennedy, Skinner and Applegate (Carr and Brown, 2011). The Kennedy classification is the most widely used and accepted system due to its simplicity, and is depicted in Figure 10 below (Polychronakis *et al.*, 2013; Carr and Brown, 2011; Pun *et al.*, 2011; Ehikhamenor *et al.*, 2010; McGarry *et al.*, 2002; Skinner, 1959).



Class I

- Bilateral edentulous areas posterior to the natural teeth.

Class II

- Unilateral edentulous area posterior to the natural teeth.

Class III

- Unilateral edentulous area with natural teeth lying anterior and posterior to it.

Class IV

- A single, bilateral, anterior edentulous area, crossing the midline.

Figure 10: Kennedy classification of partial edentulism.

A combination of the Kennedy classification and Applegate's modifications, which describes modifications as edentulous areas presenting in addition to any of those represented in the Kennedy classification, is often noted as the universally accepted description (Carr and Brown, 2011). For example, Kennedy Class III modification 2 would be referring to a unilateral edentulous area with teeth presenting anterior and posterior to it, with 2 additional edentulous saddle areas (Figure 11).

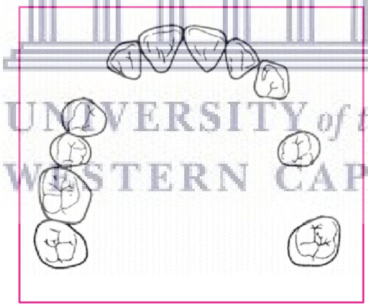


Figure 11: Pictorial representation of Kennedy Class III Modification 2.

The literature is inconsistent when it comes to determining which Kennedy classification is most prevalent in patients seeking prosthodontic treatment; with some studies showing the Kennedy Class I to be the most common (Gad *et al.*, 2020; Polychronakis *et al.*, 2013; Pun *et al.*, 2011), and others showing the Kennedy Class III to present more frequently (Ehikhamenor *et al.*, 2010; Al-Dwairi, 2006).

2.5 Review of the available literature on digital versus conventional impression methods

Digital applications in restorative dentistry regarding accuracy and reliability are being researched widely. The available literature is most commonly divided into 3 main groups. These are: evaluation of the impression i.e., the intraoral scan, accuracy of the physical or virtual working cast, and the fit of the restorations obtained from the digital workflow (Serag *et al.*, 2018). This section explores the literature regarding the accuracy of physical and virtual casts and is summarized in Table 4.

The literature is divided when it comes to determining the accuracy and superiority of conventional gypsum models compared to 3D printed models and intraoral scanning. An in vitro study by Choi *et al.* (2019) measured the accuracy of models produced via the conventional impression technique, intraoral scanning and subsequent 3D printing using the SLA and DLP methods and milling of study models from a novel gypsum block. The reference model consisted of a maxillary dental arch with tooth preparations for an inlay, a single crown, and a three-unit fixed dental prosthesis (FDP). Choi *et al.* (2019) concluded that conventional gypsum stone models displayed a greater degree of accuracy for full arch impressions than 3D printed and digitally milled models.

Intraoral scanning has shown to be more accurate and precise than extraoral scanning and conventional impression methods in single tooth and fixed prosthetics, up to a maximum of 10 units, without any extended edentulous spans (Tancu *et al.*, 2019; Nedelcu *et al.*, 2018). A study by Tancu *et al.* (2019) used digital calipers to measure specified distances on conventional gypsum models, gypsum models from indirect digital impressions, and 3D printed models obtained from direct intraoral scanning. The study consisted of 3 participants. The results of their in vivo study showed intraoral scanning to be comparable to gypsum models. The 3D models displayed slight inaccuracies; however, these were still clinically acceptable and comparable to conventional methods (Tancu *et al.*, 2019).

According to Serag *et al.* (2018), digital workflows produce casts which contain slight dimensional inaccuracies; however, these can ultimately be equivalent to gypsum casts obtained from traditional impressions as the inaccuracies are not statistically significant. The results of their study indicated a mean accuracy of 44±33µm for casts fabricated from conventional polyvinyl siloxane (PVS) impressions and 44±20µm for digital casts using an intraoral scanner (Serag *et al.*, 2018).

Ahlholm *et al.* (2018) found that 3D printed models and intraoral scanning are acceptable alternatives to conventional impressions in certain instances such as single crowns and short-span fixed prostheses. With regards to full arch impressions, the conventional impression technique has shown better accuracy than intraoral scanning and 3D printing (Alholm *et al.*, 2018).

Kuhr *et al.* (2016) suggests that the accuracy of digital impressions in extended spans and full arches has not been widely studied due to the lack of a suitable method of measuring. High precision optical scanners cannot be used to measure the jaws of a human due to inaccessibility, and as such, this poses a great deal of difficulty in obtaining an accurate and reliable reference data set. The study aimed to determine a new method for obtaining a reference data set using metal spheres placed on the occlusal surfaces of teeth. The study included 50 participants. The results of their in vivo study show that for full arch impressions, the digital workflow is less accurate than the conventional impression technique, with conventional impression accuracy being 15±4µm (0.015±0.004mm) and intraoral scanning accuracy using the TRIOS® Care (3Shape, A/S) intraoral scanner being 23±9 µm (0.023±0.009mm) (Kuhr *et al.*, 2016).

An in vivo study by Schmidt *et al.* (2020) followed the same outline as Kuhr *et al.* (2016) by using markers on specified teeth and measuring pre-determined distances. Schmidt *et al.* (2020) found that the TRIOS® 4 Pod wireless and the Primescan intraoral scanners showed the least deviation for short spans, up to one quadrant, with the Primescan yielding the lowest deviation (mean (trueness) ± standard deviation (precision)) for digital impressions (33.8 ± 31.5µm= 0.0338 ± 0.0315mm), followed by TRIOS® 4 Pod (65.2 ± 52.9µm= 0.0652 ± 0.0529mm). These are the latest scanners available on the market, with the most recent software updates and that could potentially explain why they show the greatest accuracy. However, for long spans, the conventional impression method proved more accurate (Schmidt *et al.*, 2020). One limitation noted for their study was the extremely small sample size of 5 patients only and the need for further studies with larger sample sizes was deemed necessary (Schmidt *et al.*, 2020).

A systematic review by Fleming *et al.* (2011) concluded that evidence for recommendation of digital models as an alternative to conventional gypsum models is of inconsistent quality and further studies are required**.** The authors also raised the concern that much of the error noted in accuracy studies could be a result of point identification, rather than a direct attribution to the measuring device or software (Fleming *et al.*, 2011). As such, the advancements in digital technologies may provide better point identification and more consistent results (Fleming *et al.*, 2011).

A point of interest raised in the literature is that digital scanning of the anterior region showed greater accuracy than the posterior region with both intraoral and laboratory scanners (Kang *et al.*, 2020). An in vitro study by Treesh *et al.* (2018) correlated that local errors and deviations in excess of 100µm (0.1mm) were noticed in the posterior scanned segments.

In 2019, Bohner *et al.* conducted a systematic review assessing accuracy of digital scanning in facial, intraoral and skeletal tissues. The intraoral scan data displayed a great degree of variation with trueness being between 17µm and 378µm, and precision between 55µm and 116µm for dentate and partially edentulous full arch scans. Intraoral scanning was considered accurate enough for clinical applications in dentate and partially edentulous arches (Bohner *et al.*, 2019).

Brown *et al.* (2018) conducted a study assessing the accuracy of 3D printed dental models, via the polyjet and DLP techniques, for its use in orthodontics. The study used the gypsum cast measured with digital calipers calibrated to 0.01mm as the gold standard, and concluded that 3D printed models could serve as acceptable replacements for conventional gypsum models in orthodontics (Brown *et al.*, 2018). The range for clinical accuracy has been determined to be from 0.2mm to 0.5mm. The DLP 3D printed models showed a mean difference of 0.29mm compared to the conventional gypsum cast, and were therefore concluded to be clinically accurate (Brown *et al.*, 2018).

An in vivo study by Hayama *et al.* (2018) to establish whether a larger scanner head affected the intraoral scan generated, found conventional impressions to be far superior to digital methods in both trueness and precision in Kennedy Class I and III situations when a larger scanner head is used. When using a smaller scanner head, greater deviations in accuracy occur. The results of the study concluded that intraoral scanners are limited in their application to extended edentulous spans and full arches (Hayama *et al.*, 2018).

A systematic review by Rasaie *et al.* (2021) on the accuracy of intraoral scanners in recording of denture-bearing areas showed intraoral scanners to be comparable to the conventional impression technique in recording bony oral structures covered with attached mucosa i.e., the hard palate and residual ridges, and partially edentulous arches (Rasaie *et al.*, 2021).

While the digital impression technique does have a steep learning curve, especially in areas with movable tissues i.e., hamular notches and retromolar pads, a study by Tregerman *et al.* (2019) to evaluate the fit of RPD frameworks in Kennedy Class I, II and III cases using different techniques found a completely digital workflow ($p<.001$) to be superior to the conventional workflow ($p<.001$) in partially edentulous jaws. The study comprised of 3 different denture bases being constructed for each of the 9 participants using 3 different cast fabrication techniques- a conventional cast with a hand-made denture base, scanned conventional cast whereby a 3D printed base was fabricated and an intraoral scan with subsequent 3D printed denture base. A combined conventional-digital technique ($p=.008$) proved to be inferior to both the complete digital and complete conventional workflows (Tregerman *et al*., 2019).

An in vitro study by Muallah *et al.* (2017) to determine the accuracy of full arch scans using intraoral and extraoral scanners made use of a 3D printed cast as the reference model. Their study was conducted to determine the accuracy of full arch scans in application to day-to-day orthodontics. A gypsum model was fabricated by means of a polyvinyl siloxane impression of the master model and poured using Type 3 gypsum. The gypsum model was scanned using an extraoral scanner. Specified areas were pre-determined and cylinders were placed on the master and gypsum models, and linear measurements of these were made using digital software. The conclusions of the study were that shorter distances displayed better trueness and precision than longer spans, but overall intraoral scanning and extraoral scanning both proved to be comparable to conventional gypsum techniques, and can be recommended for use in orthodontics (Muallah *et al*., 2017).

Braian and Wennerberg conducted an in vitro study in 2019 to determine the trueness and precision of 5 intraoral scanners in edentulous and partially dentate mandibular arches. The models were prepared with cylinders being added at pre-determined locations to aid in linear measurements, following the same pattern of investigation as Muallah *et al.* (2017). Their results show that in shorter spans, i.e., the inter-cylindrical measurements, the trueness was ≤50µm for dentate scans and precision ≤35µm. Completely edentulous scans show trueness ≤94µm and precision of ≤97µm. This infers that in shorter spans, dentate scans had almost 3 times greater precision than completely edentulous scans. The conclusion of the study was that intraoral scanning is accurate in shorter spans ranging from 16-22mm; however, in complete arch scans the precision in edentulous arches is extremely low. This was attributed to the stitching process being unable to accurately stitch the edentulous areas due to little surface detail and geometry in those areas (Braian and Wennerberg, 2019).

A study by Fang *et al.* (2018) on recommending a digital intraoral scanning technique for edentulous jaws, reported the lack of available literature and technique recommendations for such scans. They also attributed the stitching process and lack of suitable geometry in edentulous areas as a cause for decreased accuracy in scanning of those areas. To overcome this, they used a resin marker on the palate of a completely edentulous maxilla and deleted the resin marker using a software program. While the accuracy of intraoral scanners has been evaluated by numerous studies in vitro; the consensus was that more clinical research and studies are required to determine whether the accuracy of digital scans is clinically acceptable for edentulous jaws (Fang *et al.*, 2018).

In 2019, an in vitro study by Sim *et al.* to compare the accuracy of conventional and digital casts for fabrication of fixed prostheses found gypsum models to exhibit expansion, while contraction was observed in intraoral scans and 3D printed models. The outcomes of the study showed intraoral scanning to be similar to the conventional impression technique. The results of this study indicate trueness and precision to be 28.49±.74 µm and 22.79±5.76 µm respectively for conventional gypsum models, 28.09±2.11 µm (trueness) 34.07±5.83 µm (precision) for intraoral scanning, and 55.16±2.70 µm (trueness) and 54.93±8.44 µm (precision) for 3D printed models. While the differences were not extreme, another conclusion drawn from this study was that 3D printed models cannot completely replace conventional gypsum models and further enhancements to the digital workflow need to be made. This was attributed to contraction of the 3D printed models as a result of the 3D printing process (Sim *et al.*, 2019). Additionally, as an in vitro study, patient-specific factors such as blood, saliva, muscle action and limited mouth-opening were not considered and further studies in vivo are required (Sim *et al.*, 2019).

AlRumaih (2021) conducted a literature review of 33 papers to assess the applications of intraoral scanning in removable prosthodontics. The author concluded that while intraoral scanning seems to be a viable option for removable prosthodontics, due to reduction in chair-time and lab costs, further clinical studies assessing the accuracy thereof are required before completely replacing the conventional impression technique (AlRumaih, 2021).

A study by Soto-Alvarez *et al.* (2020) measured bucco-lingual and mesiodistal measurements of teeth to determine the reliability, reproducibility and validity of the measurements obtained from intraoral scans, for forensic purposes. Digital calipers calibrated to 0.01mm were used for the analogue measurements and were regarded as the control, due to their proven accuracy and reliability (Soto-Alvarez *et al.*, 2020; Viciano *et al.*, 2013). The interclass correlation coefficients (ICC) were excellent (ICC>0.9) for the intraoral scan measurements and the digital calipers, and both were regarded as being clinically acceptable. A similar study by Rajshekar *et al*. (2017) correlated that measurements made on conventional dental study casts were similar to those on digital models. The measured ICCs were excellent (ICC>0.9), and both methods can be regarded to be clinically acceptable.

Saleh *et al.* (2015) conducted a study to determine whether digital measurements from intraoral scans can adequately replace the measurements made on conventional gypsum study models. The study compared plaster, digital, printed, and resin models of different types of malocclusion. The mean differences between all the types of models assessed was 0.10 to 0.19mm. The conclusion of the study was that using digital calipers for measurements of dental structures is reliable and reproducible, and the reproducibility of digital models compared with plaster models was excellent (Saleh *et al.*, 2015).

Research is ongoing and the possibilities of digital applications in restorative dentistry and prosthodontics are endless, especially with the continuous software upgrades and product enhancements constantly being introduced to the market. By improving the patient experience, more patients will be encouraged to take care of their oral health, and subsequently their overall systemic health (Chen *et al.*, 2020).

Table 4: Summary of available literature comparing conventional and digital cast accuracy.

Author, Year	Method of study	What did they measure	Outcome
Choi *et al*., 2019	In vitro study	The accuracy of models produced via the conventional impression technique, intraoral scanning and subsequent 3D printing using the SLA and DLP methods, and milling of study models from a novel gypsum block.	Conventional gypsum stone models displayed a greater degree of accuracy for full arch impressions than 3D printed and digitally milled models.
Tancu *et al*., 2019	In vivo study	Used digital calipers to measure specified distances on conventional gypsum models, gypsum models from indirect digital impressions, and 3D printed models obtained from direct intraoral scanning (3 participants).	Intraoral scanning was found to be comparable to gypsum models. The 3D models displayed slight inaccuracies; however, these were still clinically acceptable and comparable to conventional methods.
Serag *et al*., 2018	In vitro study	Compared the accuracy of dies fabricated by PVS impressions and the different intraoral scanners.	Conventional gypsum models fabricated from PVS impressions showed a slightly higher accuracy than digital casts
Ahlholm *et al*., 2018	Systematic review	The accuracy of conventional versus digital impression techniques (19 articles were reviewed).	3D printed models and intraoral scanning are acceptable alternatives to conventional impressions in single crowns and short-span fixed prostheses. Conventional impression technique showed better accuracy than intraoral scanning and 3D printing in full arches.
Kuhr *et al*., 2016	In vivo study	Aimed to determine a new method for obtaining a reference data set using metal spheres placed on the occlusal surfaces of teeth (50 participants).	For full arch impressions, the digital workflow is less accurate than the conventional impression technique.
Schmidt *et al*., 2020	In vivo study	Used markers on specified teeth and measured pre-determined distances.	TRIOS® 4 Pod wireless and the Primescan intraoral scanners showed the least deviation for short spans, up to one quadrant.
Fleming *et al*., 2011	Systematic review	Evaluated whether the use of digital methods for various orthodontic measurements is valid and reliable (17 articles were analysed).	Evidence for recommendation of digital models as an alternative to conventional gypsum models is of inconsistent quality and further studies are required. Also raised the concern that much of the error noted in accuracy studies could be a result of point identification, rather than a direct attribution to the measuring device or software.

Bohner *et al.*, 2019	Systematic review	Assessed accuracy of digital scanning in facial, intraoral and skeletal tissues.	Intraoral scanning in dentate and partially edentulous arches was considered accurate enough for clinical applications.
Brown *et al.*, 2018	In vivo	Accuracy of 3D printed dental models, via the polyjet and DLP techniques, for its use in orthodontics. The study used the gypsum cast measured with digital calipers calibrated to 0.01mm as the gold standard.	3D printed models could serve as acceptable replacements for conventional gypsum models in orthodontics.
Hayama *et al.*, 2018	In vivo study	Whether a larger scanner head affected the intraoral scan generated.	conventional impressions were found to be far superior to digital methods in both trueness and precision in Kennedy Class I and III situations when a larger scanner head is used. When using a smaller scanner head, greater deviations in accuracy occur.
Rasaie *et al.*, 2021	Systematic review	Accuracy of intraoral scanners in recording of denture-bearing areas.	Intraoral scanners are comparable to the conventional impression technique in recording bony oral structures covered with attached mucosa i.e., the hard palate and residual ridges, and partially edentulous arches.
Tregerman *et al.*, 2019	In vivo study	3 different denture bases were constructed for each of the 9 participants using 3 different cast fabrication techniques- a conventional cast with a hand-made denture base, scanned conventional cast whereby a 3D printed base was fabricated and an intraoral scan with subsequent 3D printed denture base	Completely digital workflow (p<.001) was superior to the conventional workflow (p<.001) in partially edentulous jaws. A combined conventional-digital technique (p=.008) proved to be inferior to both the complete digital and complete conventional workflows.
Muallah *et al.*, 2017	In vitro study	Accuracy of full arch scans using intraoral and extraoral scanners made use of a 3D printed cast as the reference model.	Conclusions of the study were that shorter distances displayed better trueness and precision than longer spans, but overall intraoral scanning and extraoral scanning both proved to be comparable to conventional gypsum techniques, and can be recommended for use in orthodontics
Braian and Wennerberg, 2019	In vitro study	Trueness and precision of 5 intraoral scanners in edentulous and partially dentate mandibular arches. The models were prepared with cylinders being added at pre-determined locations to aid in linear measurements, following the same pattern of investigation as Muallah *et al.* (2017).	In shorter spans, dentate scans had almost 3 times greater precision than completely edentulous scans and intraoral scanning is accurate in shorter spans ranging from 16-22mm.

Sim *et al*., 2019	In vitro study	Compared the accuracy of conventional and digital casts for fabrication of fixed prostheses	Intraoral scanning is comparable to gypsum casts, 3D printed models cannot completely replace conventional gypsum models and further enhancements to the digital workflow need to be made. This was attributed to contraction of the 3D printed models as a result of the 3D printing process.
AlRumaih, 2021	Literature review	Applications of intraoral scanning in removable prosthodontics (33 papers were analysed).	While intraoral scanning seems to be a viable option for removable prosthodontics, further clinical studies assessing the accuracy thereof are required before completely replacing the conventional impression technique
Soto-Alvarez *et al*., 2020	In vitro/in vivo study	Measured bucco-lingual and mesiodistal measurements of teeth to determine the reliability, reproducibility and validity of the measurements obtained from intraoral scans, for forensic purposes.	The interclass correlation coefficients (ICC) were excellent (ICC>0.9) for the intraoral scan measurements and the digital calipers, and both were regarded as being clinically acceptable.
Rajshekar *et al*., 2017	In vitro study	Measurements of arch widths and tooth crowns on 80 sets of dental casts were made to determine the reliability of intraoral scan measurements on human dental casts.	Measurements made on conventional dental study casts were similar to those on digital models. The measured ICCs were excellent (ICC>0.9), and both methods are clinically acceptable.
Saleh *et al*., 2015	In vitro study	Determined whether digital measurements from intraoral scans can adequately replace the measurements made on conventional gypsum study models.	Using digital calipers for measurements of dental structures is reliable and reproducible, and the reproducibility of digital models compared with plaster models was excellent

2.6 Rationale for study

As is evident from the literature, the conventional impression technique brings about many variables and concerns. It is clear that further clinical studies regarding the accuracy of intraoral scanning in edentulous areas are required. To the knowledge of the researcher, no current studies have investigated the accuracy of representation of bounded edentulous saddle areas specifically (Kennedy Classes III and IV) via intraoral scanning, subsequent 3D printed models, and conventional impressions with subsequent gypsum models; in comparison to the in vivo edentulous saddle area. This study intended to bridge that gap. The following chapter outlines the aim, objectives and null hypothesis of the study.

CHAPTER 3: AIM AND OBJECTIVES OF STUDY

3.1 Aim

To compare the accuracy of 3D printed dental models, digital models produced from direct intraoral scans and conventional stone models to the in vivo edentulous saddle area.

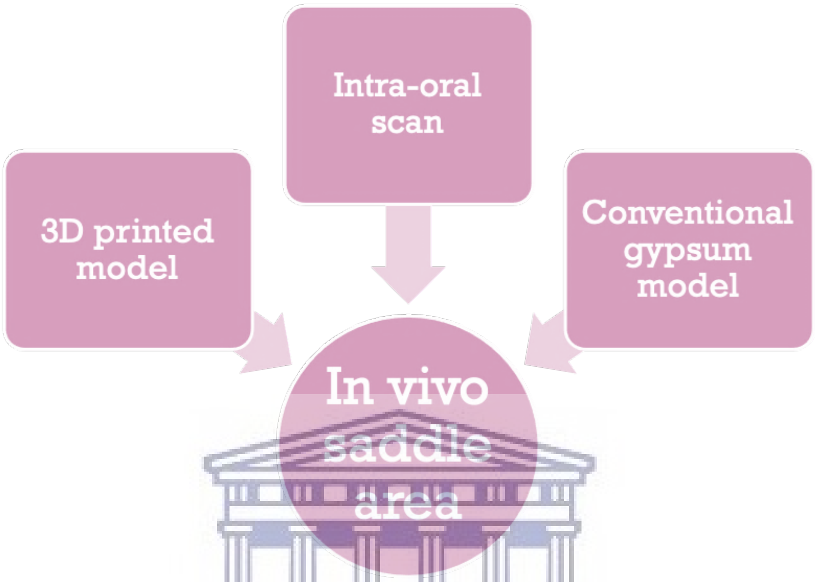


Figure 12: Diagrammatic representation of aim.

3.2 Objectives

1. To measure the length of the edentulous saddle span in the dental arch, the corresponding 3D printed model, intraoral scan and conventional gypsum stone model.
2. To measure the height of the edentulous span in each method of acquisition.
3. To determine the maximum edentulous span length (in millimeters) that can be accurately represented by intraoral scanning, conventional gypsum casts and 3D printed models.

3.3 Null hypothesis

The null hypothesis was that there would be no significant difference between the accuracy of the casts produced by intraoral scanning, 3D printing, and conventional impressions, in comparison to the in vivo edentulous saddle area.

The following chapter explores the research methods and materials employed for this study.

CHAPTER 4: METHODS AND MATERIALS

4.1 Introduction

With the aim, objectives and null hypothesis having been discussed in the previous chapter, this chapter describes the research design, research instruments and methodology employed in this study, together with the data and statistical analysis information, and ethical considerations.

4.2 Study design

Cross-sectional study.

4.3 Study participants and site

Patients presenting for prosthodontic treatment at a private dental practice, Matrix Dental Specialists in Cape Town, South Africa.

4.4 Inclusion and exclusion criteria

4.4.1 Inclusion criteria

1. Patients with bounded edentulous saddles (Kennedy Class III or IV) seeking prosthodontic treatment.
2. Only permanent teeth present in the mouth.
3. Good quality impressions, intraoral scans, gypsum casts and 3D printed models.

4.4.2 Exclusion criteria

1. Patients with severely tipped/tilted teeth on any side of the edentulous saddle as parallel tooth surfaces were required for the accurate and reproducible positioning of the digital callipers (Larson *et al.*, 2002). There is a paucity of literature available to aid in determining the severity of tipped teeth and no classification of tipped teeth exists as yet. As such, determination of degree of tipping was done at the researcher's discretion for this study.

4.5 Sample size and sampling strategy

4.5.1 Sample size

The sample size estimation was discussed with a statistician. Based on a similar study by Kim (2018), with a pooled standard deviation of 11.67, the estimated sample size was 10 per group. With 4 groups (physical intraoral, 3D printed models, conventional gypsum models, intraoral scans), a total of 40 models was required= 10 participants (4 models per participant). For this study, 20 participants were identified and included to improve the power of the study.

4.5.2 Sampling strategy

A convenience sampling strategy was used for this study. While convenience sampling is a non-probability strategy, it is widely used in clinical research (Elfil and Negida, 2017). For this study, the convenience sampling strategy was used on the basis of patient accessibility (Elfil and Negida, 2017). Due to the study being conducted at a specific site, Matrix Dental Specialists, only patients presenting to this facility fitting the inclusion and exclusion criteria were invited to participate. Patients fitting the criteria were identified at the point of screening and were invited to participate in the research. Patients were later informed of the date on which the researcher would see them. Regarding patients with more than one edentulous saddle in the same arch i.e., Kennedy Classification with modifications: each edentulous saddle area was treated as a separate sample. Different quadrants with bounded edentulous saddles in the same patient were regarded as different samples.

4.6 Methodology

The methodology for this study was adapted from studies by Schmidt *et al*. (2020), Brown *et al*. (2018), Sim *et al*. (2019), Kim (2018) and Muallah *et al*. (2017).

Researcher calibration and inter-rater reliability.

Researcher calibration was carried out using 10 bounded edentulous saddles from patients who fitted the inclusion and exclusion criteria but did not form part of the final study sample. The length and height of the edentulous saddle in vivo, on the intraoral scan, gypsum model and 3D printed model, was measured for each patient by the main researcher (AE) and supervisor/experienced examiner (WF) independently. The data was compared, analysed and discussed until calibration and consensus occurred. In the case of a large discrepancy, a third-party, the co-supervisor (SM) was consulted.

The main researcher (AE) measured the length and height of the edentulous saddle area intraorally using mathematical dividers (Figure 13a) for each saddle. This measurement was transferred extra-orally (Figure 13b) and measured using digital vernier callipers (Blue-Point®, MCAL6A), calibrated to two decimal points (Figure 13c). These measurements were conducted digitally for the 3D printed model, gypsum cast, and intraoral scan. The same measurements were repeated by the supervisor (WF). All measurements were tabulated in a Microsoft Excel spreadsheet (See Appendix V), and an intraclass correlation coefficient (ICC) calculation was carried out (See Table 5).

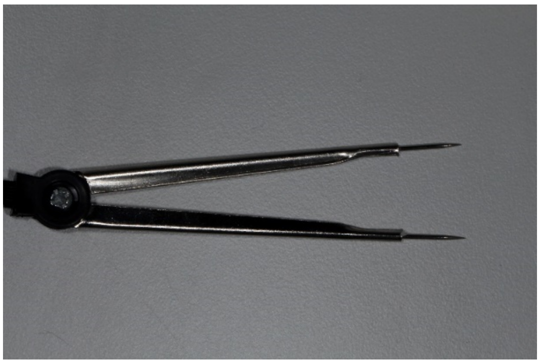


Figure 13a: Mathematical dividers.

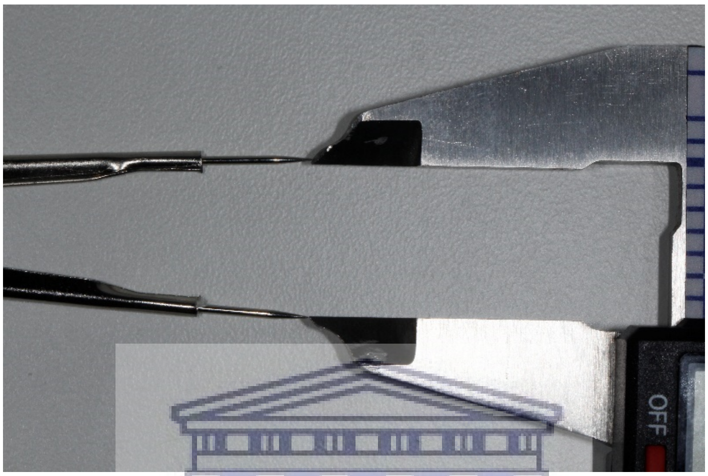


Figure 13b: Extraoral transfer of intraoral measurements using Blue-Point®, MCAL6A digital vernier calipers calibrated to two decimal points (mm).

Figure 13c: Blue-Point®, MCAL6A digital vernier calipers calibrated to two decimal points (mm).

Physical measurement of the edentulous saddle intraorally.

Each patient (n=20) was seated in the dental chair and the location of the saddle (FDI System) was recorded. The length of the edentulous saddle was measured intraorally using mathematical dividers. The measurement was then transferred extraorally and measured in millimetres, using digital calibrated vernier callipers (Blue-Point®, MCAL6A) calibrated to two decimal points (0.01mm), from the distal aspect of the tooth on the mesial side of the saddle to the mesial aspect of the tooth on the distal side of the saddle (Figure 14a). The height of the saddle was measured in the same way, using mathematical dividers and then in millimetres, using Blue-Point®, MCAL6A digital vernier callipers calibrated to two decimal points, at the midpoint of a line extending from cusp tip to cusp tip of the teeth on each side of the saddle to the first soft tissue contact point covering the ridge (Figure 14b). The measurements were tabulated in a Microsoft Excel spreadsheet (See Table 6).

Figure 14a: Physical intraoral measurement of length with mathematical dividers, which was transferred extraorally and measured using Blue-Point®, MCAL6A digital vernier calipers calibrated to two decimal points.

Figure 14b: Physical intraoral measurement of height with mathematical dividers, which was transferred extraorally and measured using Blue-Point®, MCAL6A digital vernier calipers calibrated to two decimal points.

Intraoral scan acquisition.

The same patient's cheeks were retracted with cheek retractors or a dental mirror to assist the researcher in accessing the oral cavity and to aid with moisture control. The dental arch with the edentulous saddle/s present, i.e. the maxilla or mandible, was then scanned using the TRIOS® 4 (3Shape, A/S) intraoral scanner following the manufacturer's instructions of switching the device on and subsequent scanning (Software version 1.7.19.1). The selected arch was scanned according to the recommended guidelines and scan strategy (Figure 15). The scan strategy for both arches consisted of three swipes. For the lower arch: occlusal, lingual, buccal; and occlusal, buccal, palatal for the upper arch. The scan was subsequently evaluated on the monitor. Areas of insufficient detail and clarity were rescanned until a correct, completed scan was obtained. The intraoral scan obtained was then directly converted to a standard tessellation language (STL) file within the software and the scanner was switched off and disinfected for use with the next patient.

Figure 15: Intraoral scan of maxilla using TRIOS® 4 (3Shape, A/S).

Fabrication of gypsum model.

A conventional impression of the same arch was taken with an irreversible hydrocolloid impression material (Blueprint® Alginate, Dentsply® Sirona), in a stock-tray sprayed with adhesive (Fix®, Dentsply®). Alginate has a working time of 1,25- 4,5 minutes and a setting time of 1,5-5 minutes. The material was mixed according to the manufacturer's recommended water to powder ratio which is 2x 25ml scoops (included in bag) of powder mixed with 34ml of water with a temperature of approximately 23 degrees Celsius (Dentsply, 2021). The impression was taken in a temperature-controlled environment not exceeding 25 degrees Celsius. The impression was rinsed in cold water to remove any blood or saliva, and was subsequently disinfected, and poured immediately or within 30 minutes. To ensure excellent quality impressions, the impressions were evaluated by the researcher, a prosthodontist and the dental technician, prior to casting. If the impression could not be poured within 30 minutes, it was wrapped loosely in a moist paper towel and stored in a plastic bag to prevent moisture-loss. If the impression was stored, it was rinsed prior to pouring to prevent exudate caused by syneresis. The gypsum cast (Figure 16) was fabricated using Interrock New® (Interdent®, Slovenia) Type 4 dental stone (colour: ivory), due to its high strength and low expansion properties, following the manufacturer's guideline which is 20ml water to 100g of powder (Interdent, 2017), mixed in a vacuum- Twister Venturi® (Renfert®) for 60 seconds at 400rpm, and was allowed to set for 30-45 minutes before removal from the impression body (Sakaguchi *et al.*, 2019).

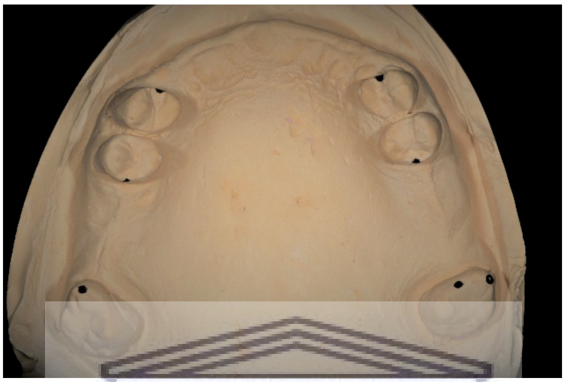


Figure 16: A set conventional gypsum cast poured using ivory Interrock New® (Interdent®) Type 4 dental stone.

3D printing of dental model.

A 3D model (Figure 17) was printed from the intraoral scan data. The STL file was shaped and prepared for printing using the Dental Wings DWOS 2021 Cares Visual Model builder (Software version: 15.0.20.36682). The 3D model was printed using the Straumann® Cares P30 3D printer and Straumann® P Pro Cast resin (Grey) (Straumann®, Institut Straumann, Basel, Switzerland), using an additive manufacturing technique with standard build layers of 50µm. The printing software used was Autodesk® Netfabb® 2022 and model parameters were set as: base hollowed, 2.5mm offset, horse-shoe shape.

Figure 17: A 3D printed model, printed from intraoral scan data using grey Straumann® P Pro cast resin.

Digitization of gypsum and 3D casts.

The gypsum casts were then scanned using the 3Shape D710 extraoral scanner (Firmware version: 5.04.03) and converted to STL files. The 3D printed models were also scanned using the same scanner, and converted to STL files (Kim, 2018).

Measuring and analysing differences by means of an inspection software.

Linear measurements of the length (Figure 18a) and height (Figure 18b) of the saddle on the intraoral scan, digitized 3D printed and gypsum casts were automatically made using Autodesk® Meshmixer© (Software version: 3:5.474) and tabulated (See Table 6). The in vivo measurements were used as the control, as researcher calibration, inter and intra-rater reliability testing was conducted.

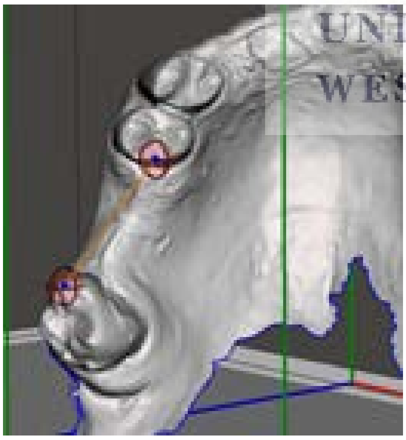


Figure 18a: Depiction of length measurement using Autodesk® Meshmixer© software.

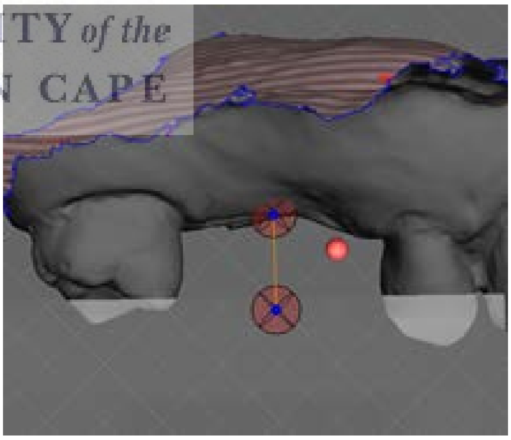


Figure 18b: Depiction of height measurement using Autodesk® Meshmixer© software.

Intra -rater reliability testing.

To assess intra-rater reliability, the same measurements (lengths and heights of the saddle in vivo, on the 3D printed model, gypsum model and intraoral scan) were repeated by the main researcher (AE) on 50% of the study sample (every second patient), after a two-week interval. The measurements were tabulated in a Microsoft Excel spreadsheet (See Appendix VI), and the ICC calculation was subsequently carried out (See Table 12).

Calibration of intraoral scanner.

Regular calibration of the intraoral scanner is required for reproducible readings to be obtained. This differs between different scanners and should be carried out as per manufacturer's guidelines. The TRIOS® 4 (3Shape, A/S) requires calibration after 20 scans. This is carried out by placing the scan tip on the scanner and using the 'Calibration' function under 'TRIOS' on the 'Settings' page. The intraoral scanner was calibrated after 20 uses, according to manufacturer guidelines (3Shape, 2021).

4.7 Data and statistical analysis

Microsoft Excel was used for data cleaning, editing, sorting, and coding. Each Microsoft Excel file/spreadsheet was then imported into StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC. All continuous data were analysed using means (to assess trueness) and standard deviations (SD) (to assess precision). Intra class correlation (ICC) coefficients were used to determine the accuracy of the different modalities to the gold standard (physical intraoral measurements). ICC was also used for the calibration, inter and intra-rater reliability. ICC is a statistical method of measuring uniformity between pairs of test subjects or larger samples by calculating mean squares (Koo and Li, 2016; McGraw and Wong, 1996). Mean squares refer to estimates of population variance among a specified data-set (Koo and Li, 2016). ICC also measures the agreement and degree of correlation between measurements (Koo and Li, 2016). Accuracy was further tested using the Bland-Altman plot by assessing agreement between the data-sets (Koo and Li, 2016). Bland-Altman plots are widely used graphical representations of agreements between methods and raters in quantitative studies (Gerke, 2020; Kalra, 2017). For the Bland-Altman plots, often, a pair of observations is made on the same subject using different methods (Gerke, 2020). The means and differences are then calculated and presented using a scatter plot (Gerke, 2020). All statistical tests were analysed using StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC. Boxplots were used to demonstrate the median and interquartile range of continuous data. All tests were deemed statistically significant at $p < 0.05$.

4.8 Ethical considerations

Ethics approval (BM20/9/6) was sought from UWC Biomedical Research Ethics Committee (BM-REC) (See Appendix I). Permission was obtained from the private practice, Matrix Dental Specialists (See Appendix II-III). Patient anonymity was maintained at all times. Each patient was assigned a numerical identifier (a-j for calibration sample and 1-20 for the study sample). The information is known by the main researcher (AE) only and electronic data is stored on a password safe computer. The electronic data (STL files of the scans and data collection sheets) and physical models will be stored for a duration of 5 years by the main researcher (AE). Informed consent was sought from the patient, who was requested to sign a consent form and had been informed that participation in the study is completely voluntary (See Appendix IV). Patients were informed of the benefits, risks, how to address complaints, and the maintenance of confidentiality associated with participation in the study. Patients were also informed of their right to refuse and/or withdraw from the study at any point and that their decision would not negatively influence their treatment at the facility. No additional costs were incurred by the patient.

4.9 Conflict of interest

The author declares that no conflict of interest exists with this research, nor any financial interest in the products used for this study at the time of publication (See Appendix VII). This study was done purely for research purposes, and to contribute to the available literature regarding in vivo digital applications in restorative dentistry and removable prosthodontics.

CHAPTER 5: RESULTS

5.1. Introduction

The research methods and materials were explored in the preceding chapter. This chapter provides a description of the results of the study.

The final sample size for this study was 20 bounded edentulous saddles. 8 measurements were made on each edentulous saddle- the length (L) and height (H) measurements of the edentulous saddle areas for the physical intraoral (PIO), 3D printed model (3DM), conventional gypsum model (GM), and intraoral scan (IOS); and a total of 160 measurements were analysed. Anterior saddles comprised 40% of the final sample (n=8) while posterior saddles comprised the remainder (Table 6).

5.2. Researcher calibration/ inter-rater reliability results

Two raters, AE and WF, observed and recorded the length and height measurements of the edentulous saddle areas for the physical intraoral, 3D printed model, conventional gypsum model, and intraoral scan, for 10 bounded edentulous saddles that did not form part of the study (n=10). This was tabulated on a Microsoft Excel spreadsheet (See Appendix V). This served as the inter-rater reliability measurement. The ICC was calculated and tabulated (Table 5). A two-way mixed effects model was used with 2 raters and absolute agreement.

Table 5: Researcher calibration and inter-rater reliability ICC.

Tested Variable	ICC (Average)	95% CI
PIO L	0.9999952	0.9999807 to 0.9999988
3DM L	0.9999948	0.999979 to 0.9999987
GM L	0.9999948	0.9999797 to 0.9999987
IOS L	0.9999929	0.9999731 to 0.9999982
PIO H	0.999991	0.9999658 to 0.9999977
3DM H	0.9999594	0.9998459 to 0.9999898
GM H	0.9999769	0.9998928 to 0.9999944
IOS H	0.9999785	0.9999179 to 0.9999946

The ICC for each variable and the 95% confidence interval (CI) for each was greater than 0.90 indicating excellent inter-rater reliability (Koo and Li, 2016).

5.3. Final data results

The raw data was captured in a Microsoft Excel spreadsheet (Table 6). The length and height measurements of the edentulous saddle areas for the physical intraoral, 3D printed model, conventional gypsum model, and intraoral scan, for each of the 20 samples (n=20) were recorded. Means, standard deviation (SD) and mean differences were calculated.

Table 6: Final data collection recordings in mm (n=20).

	Saddle location	Anterior/ Posterior	PIO L	3DM L	GM L	IOS L	PIO H	3DM H	GM H	IOS H
1	15	Posterior	5.54	5.51	5.64	5.52	7.05	7.02	7.09	7.04
2	24,25	Posterior	13.29	13.23	13.39	13.24	7.64	7.57	7.68	7.61
3	16,17	Posterior	17.24	17.16	17.27	17.18	7.89	7.82	7.91	7.83
4	23-24	Anterior	13.56	13.49	13.59	13.53	8.29	8.21	8.32	8.25
5	15,16	Posterior	15.29	15.23	15.32	15.25	7.69	7.62	7.73	7.64
6	11,12	Anterior	19.91	19.88	19.96	19.9	8.05	7.99	8.08	8.02
7	24,25	Posterior	12.7	12.58	12.78	12.63	4.79	4.7	4.84	4.73
8	26,27	Posterior	17.52	17.46	17.56	17.47	5.84	5.79	5.87	5.82
9	12	Anterior	7.76	7.73	7.79	7.75	6.43	6.41	6.5	6.43
10	25-27	Posterior	17.89	17.79	17.95	17.81	5.88	5.76	5.92	5.82
11	23	Anterior	7.37	7.34	7.41	7.37	4.39	4.36	4.46	4.38
12	24-26	Posterior	19.43	19.34	19.47	19.36	4.25	4.17	4.29	4.2
13	25	Posterior	8.85	8.79	8.91	8.86	4.46	4.43	4.48	4.45
14	46	Posterior	11.04	10.96	11.07	10.99	5.78	5.75	5.88	5.79
15	41-42	Anterior	11.34	11.31	11.38	11.34	6.65	6.62	6.68	6.63
16	25-26	Posterior	14.62	14.54	14.66	14.57	7.44	7.34	7.5	7.36
17	35-37	Posterior	19.53	19.44	19.56	19.47	6.22	6.13	6.28	6.15
18	33	Anterior	7.43	7.41	7.46	7.42	8.03	7.98	8.09	8
19	32-31	Anterior	11.65	11.63	11.7	11.65	6.18	6.15	6.22	6.18
20	13-14	Anterior	11.06	11.01	11.11	11.05	6.92	6.85	7.01	6.9

The physical intraoral measurements were used as the control.

Anterior edentulous saddle recordings: Longest (L) =19.91mm and shortest (L)=7.37mm. Largest height (H)=8.29mm and smallest height (H)=4.39mm (PIO measurements- Table 6).

Posterior edentulous saddles recordings: Longest (L)=19.53mm and shortest (L)=5.54mm. Largest height (H)=7.89mm and smallest height (H)=4.25mm (PIO measurements- Table 6).

5.3.1. Mean and standard deviation (SD) results for each variable.

The longest overall edentulous saddle length recorded was 19.91mm and the shortest was 5.54mm. The largest overall height recorded was 8.29mm and the smallest was 4.25mm, as represented in Table 7 and Figure 19.

Table 7: Mean measurements of each variable in mm (n=20).

Variable	n	Mean (trueness) ± SD (precision)	Min	Max
PIO L	20	13.151 ± 4.46	5.54	19.91
3DM L	20	13.092 ± 4.44	5.51	19.88
GM L	20	13.199 ± 4.45	5.64	19.96
IOS L	20	13.118 ± 4.44	5.52	19.90
PIO H	20	6.4935 ± 1.299	4.25	8.29
3DM H	20	6.4335 ± 1.296	4.17	8.21
GM H	20	6.5415 ± 1.297	4.29	8.32
IOS H	20	6.4615 ± 1.295	4.20	8.25

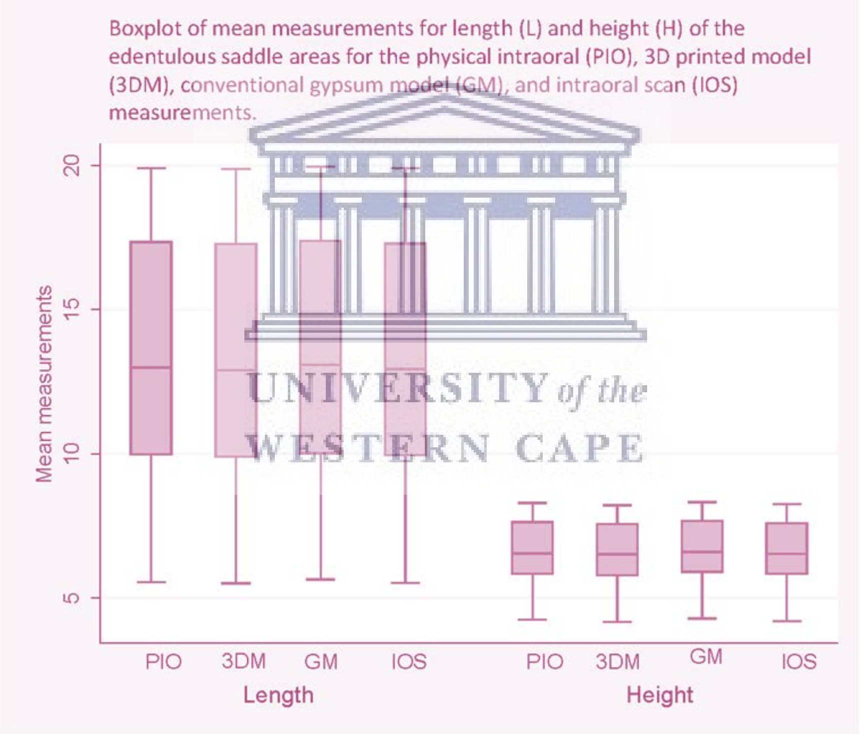


Figure 19: Boxplot of mean measurements for length (L) and height (H) of the edentulous saddle areas for the physical intraoral (PIO), 3D printed model (3DM), conventional gypsum model (GM), and intraoral scan (IOS) measurements.

Figure 19 shows the means, upper and lower quartiles, as well the maximum and minimum lengths and heights noted for each variable. The results were evenly distributed amongst all variables.

5.3.2. Mean differences and standard deviation (SD) results for each variable to assess trueness and precision.

Table 8 and Figure 20 illustrate the agreement between the mean differences of each variable tested namely: the length and height measurements of the edentulous saddle areas for the physical intraoral, 3D printed model, conventional gypsum model, and intraoral scan. The physical intraoral measurement for length and height for each variable was used as the control.

Table 8: Mean differences and SD of PIO and other variables for L and H, in mm (n=20).

Variable	n	Mean (trueness) ± SD (precision)	Min diff	Max diff
diff_PIO-3DM L	20	0.0595 ± 0.03	.02	.12
diff_PIO-GM L	20	-0.048 ± 0.02	-.1	-.03
diff_PIO-IOS L	20	0.033 ± 0.03	-.01	.08
diff_PIO-3DM H	20	0.06 ± 0.03	.02	.12
diff_PIO-GM H	20	-0.048 ± 0.02	-.1	-.02
diff_PIO-IOS H	20	0.032 ± 0.03	-.01	.08

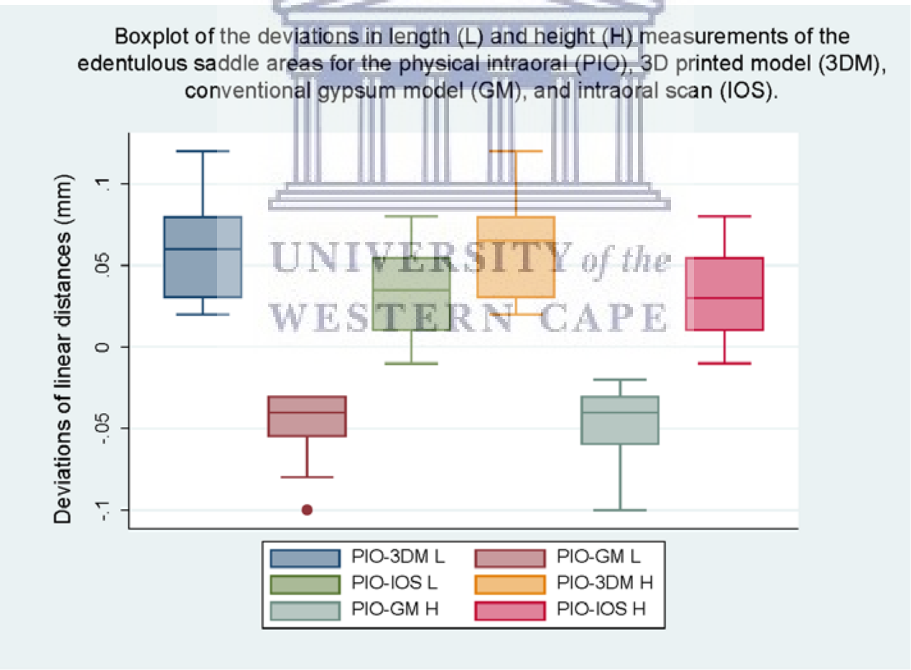


Figure 20: Boxplot of the deviations in length (L) and height (H) measurements of the edentulous saddle areas for the physical intraoral (PIO), 3D printed model (3DM), conventional gypsum model (GM), and (IOS).

Figure 20 shows the mean differences, upper and lower quartiles, as well the maximum and minimum deviations in lengths and heights noted for each variable.

The largest deviation noted was -0.1mm (PIO-GML and PIO-GM H). PIO-IOS displayed the greatest agreement for length (PIO-IOS L: 0.033±0.03) and height (PIO-IOS H: 0.032±0.03) measurements, while PIO-3DM displayed the least agreement (PIO-3DM L: 0.0595±0.03 and PIO-3DM H: 0.06±0.03).

5.3.3. Bland-Altman plots.

Bland-Altman plots were used to further test accuracy by evaluating the agreements for the differences in length and height measurements of the edentulous saddle areas for the physical intraoral, 3D printed models, conventional gypsum models, and intraoral scans, as represented in Table 9. The Bland-Altman plots for each refer below (Figures 21 to 26).

Table 9: Summary of results of Bland-Altman plots for length (L) and height (H) measurements of the edentulous saddle areas.

Variable	Mean difference (mm)	95% CI (mm)	Limits of agreement (LoA)
PIO-3DM L (Fig. 21)	0.0595	0.046 to 0.073	0.0013 to 0.1177
PIO-GM L (Fig. 22)	-0.048	-0.058 to -0.038	-0.0923 to -0.0037
PIO-IOS L (Fig. 23)	0.033	0.020 to 0.046	-0.0232 to 0.0892
PIO-3DM H (Fig. 24)	0.06	0.047 to 0.073	0.0031 to 0.1169
PIO-GM H (Fig. 25)	-0.048	0.058 to -0.038	-0.0918 to -0.0042
PIO-IOS H (Fig. 26)	0.032	0.021 to 0.043	-0.0193 to 0.0833

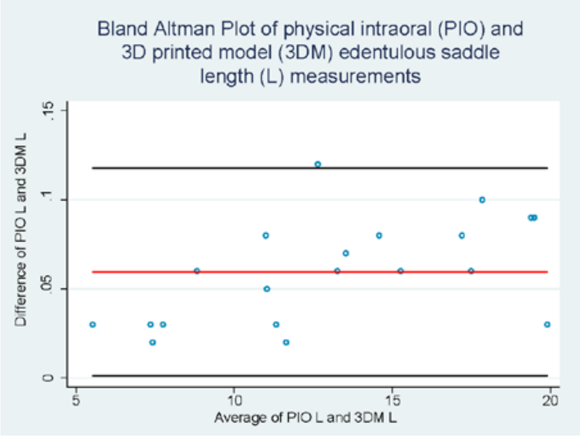


Figure 21: Bland Altman Plot of PIO-3DM L

Bland Altman Plot of Physical intraoral and

3D printed model length measurements.

- mean of difference is 0.0595
- SD of difference is 0.02911
- lower limit of difference is 0.0013
- higher limit of difference is 0.1177
- LoA: 0.0013 to 0.1177
- Mean difference: 0.0595 (95%CI: 0.046 to 0.073)

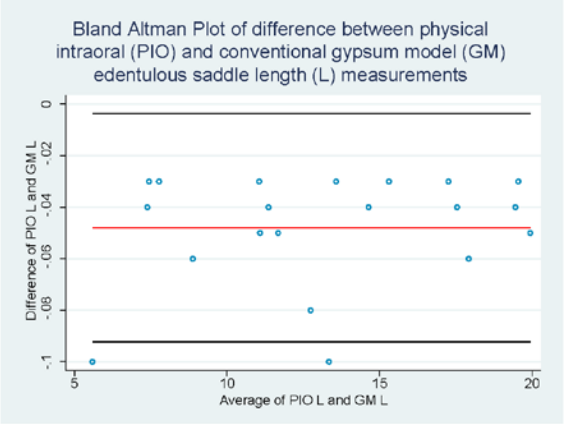


Figure 22: Bland Altman Plot of PIO-GM L

Bland Altman Plot of Physical intraoral and conventional gypsum model length measurements.

- mean of difference is -0.048
- SD of difference is 0.02215
- lower limit of difference is -0.0923
- higher limit of difference is -0.0037
- LoA: -0.0923 to -0.0037
- Mean difference: -0.048 (95%CI: -0.058 to -0.038)

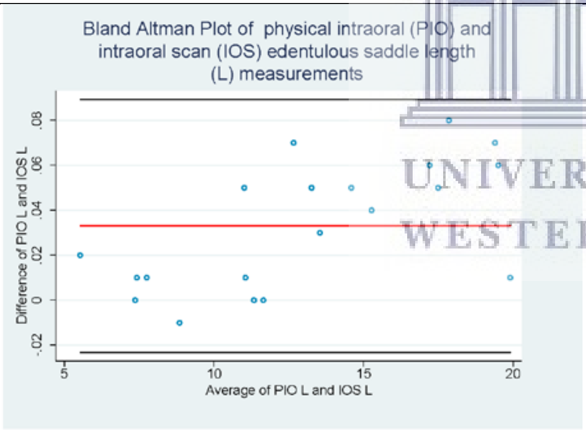


Figure 23: Bland Altman Plot of PIO-IOS L

Bland Altman Plot of Physical intraoral and intraoral scan length measurements.

- mean of difference is 0.033
- SD of difference 0.0281
- lower limit of difference is -0.0232
- higher limit of difference is 0.0892
- LoA: -0.0232 to 0.0892
- Mean difference: 0.033 (95%CI: 0.020 to 0.046)

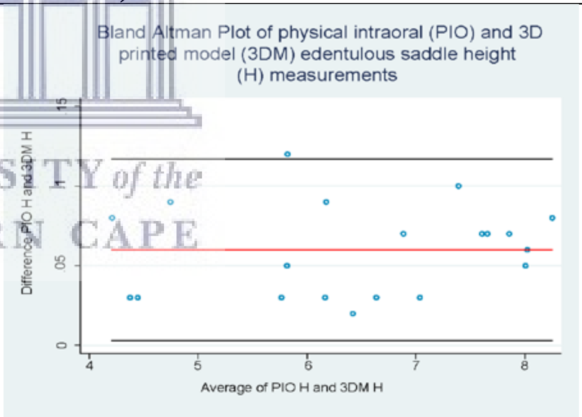


Figure 24: Bland Altman Plot of PIO-3DM H

Bland Altman Plot of Physical intraoral and 3D printed model height measurements.

- mean of difference is 0.06
- SD of difference is 0.0285
- lower limit of difference is 0.0031
- higher limit of difference is 0.1169
- LoA: 0.0031 to 0.1169
- Mean difference:0.06 (95%CI: 0.047 to 0.073)

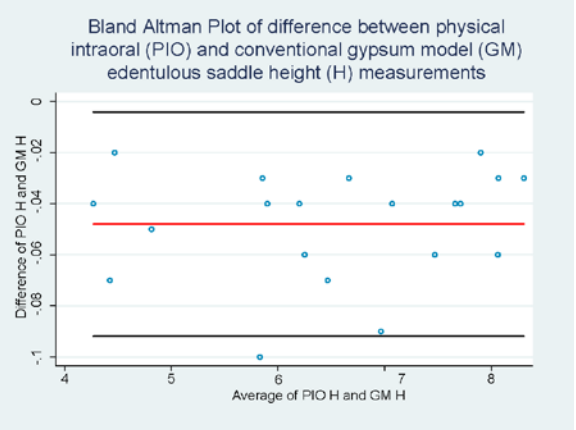


Figure 25: Bland Altman Plot of PIO-GM H.

Bland Altman Plot of Physical intraoral and conventional gypsum model length measurements.
- mean of difference is -0.048
- SD of difference is 0.0219
- lower limit of difference is -0.0918
- higher limit of difference is -0.0042
- LoA: -0.0918 to -0.0042
- Mean difference: -0.048 (95%CI: 0.058 to -0.038)

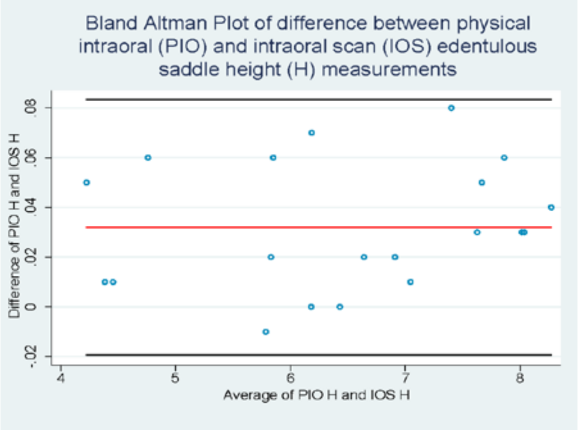


Figure 26: Bland Altman Plot of PIO-IOS H.

Bland Altman Plot of Physical intraoral and intraoral scan length measurements.

- mean of difference is 0.032
- SD of difference is 0.0257
- lower limit of difference is -0.0193
- higher limit of difference 0.0833
- LoA: -0.0193 to 0.0833
- Mean difference: 0.032 (95%CI: 0.021 to 0.043)

5.3.4. ICC-intra class correlation coefficient for each variable to assess trueness.

ICC was calculated to further aid in assessing the trueness for each variable compared to the control which was the physical intraoral (PIO) measurements (Tables 10 and 11). This was carried out for the length and height measurements.

Table 10: ICC for Length in different dimensions (trueness).

	Physical intraoral
3D printed model	0.99989 (95%CI: 0.9878 to 0.999)
Conventional gypsum model	0.99993 (95%CI: 0.9907 to 0.9999)
Intraoral scan	0.99995 (95%CI: 0.99923 to 0.9999)

Table 11: ICC for Height in different dimensions (trueness).

	Physical intraoral
3D printed model	0.9987 (95%CI: 0.8606 to 0.9997)
Conventional gypsum model	0.99918 (95%CI: 0.94599 to 0.9999)
Intraoral scan	0.99951 (95%CI: 0.99091 to 0.99988)

The ICC for all recorded measurements were greater than 0.90 indicating an excellent level of trueness for each method of cast fabrication (Koo and Li, 2016). The intraoral scan showed the highest level of trueness in both length (0.99995; 95% CI: 0.99923 to 0.9999) and height (0.99951; 95% CI: 0.99091 to 0.99988).

5.4. ICC for intra-rater reliability assessment and precision confirmation.

After a two-week interval, the main researcher (AE) recorded the length and height measurements of the edentulous saddle areas for the physical intraoral, 3D printed model, conventional gypsum model, and intraoral scan, for 50% of the samples (n=10) (See Appendix VI), and the ICC was calculated (Table 12). This served as the intra-rater reliability assessment as well as the repeatability measurement to confirm the precision. A single-rater, two-way mixed effects model was used, with absolute agreement. The ICC for each variable and the 95% confidence interval for each was greater than 0.90 indicating excellent inter-rater reliability and precision (Koo and Li, 2016).

Table 12: ICC for intra-rater reliability and reproducibility.

Tested Variable	ICC (Individual)	95% CI
PIO L	0.9999952	0.9999801 to 0.9999988
3DM L	0.9999934	0.9999744 to 0.9999983
GM L	0.9999979	0.9999921 to 0.9999995
IOS L	0.9999925	0.9999716 to 0.9999981
PIO H	0.9999714	0.9998344 to 0.9999934
3DM H	0.9999857	0.9999439 to 0.9999964
GM H	0.9999742	0.9998975 to 0.9999936
IOS H	0.9999457	0.9997935 to 0.9999863

5.5 Combined average of means and SD of each variable

Table 13: Combined average of means and standard deviation (SD) of variables in mm.

Variable	**n**	**Average of mean (trueness) ±SD (precision)**
PIO-IOS	20	0.0325±0.03
PIO-GM	20	-0.048±0.02
PIO-3DM	20	0.05975±0.03

The combined averages for each variable were as follows:
PIO- IOS L and PIO-IOS H was 0.0325±0.03mm (32.5±30µm), PIO-GM L and PIO-GM H was -0.048±0.02mm (-48±20µm), and PIO-3DM L and PIO-3DM H was 0.05975±0.03mm (59.75±30µm) and $p < .05$.

The results of the study have been described in this chapter. The subsequent chapter provides a detailed discussion on the findings of these results.

CHAPTER 6: DISCUSSION

This chapter provides an in depth discussion of the results described in the previous chapter. The vast majority of contemporary literature comparing digital and conventional cast fabrication has been conducted in vitro. This does not accurately represent the in vivo milieu; therefore, it has been recommended that more in vivo studies be carried out (Tasaka *et al*., 2019, Sim *et al*., 2019; Ender *et al*., 2016). This study aimed to add to the available literature pool by comparing casts fabricated via digital and conventional methods in vivo.

The intraoral scans (IOS) are regarded as digital casts and the 3D printed models (3DM) are a result of the intraoral scans, rendering them a part of the digital workflow. The TRIOS® 4 (3Shape, A/S) intraoral scanner (Figure 3), which was used for this study, is one of the latest intraoral scanners on the market. Literature has shown this scanner to deliver the some of the most precise scans (Schmidt *et al*., 2020). The Straumann® Cares P30 3D printer (Straumann®, Institut Straumann, Basel, Switzerland) (Figure 4) was used for this study and the 3D printed models (3DM) were printed using the DLP method of AM, in build layers of 50µm as recommended in a study by Choi *et al.* (2019). This is one of the most widely used and acceptable methods of 3D printing (Kessler *et al*., 2020; Choi *et al*., 2019). In a study by Brown *et al*. (2018), models printed using the DLP method showed a mean difference of 0.29mm and are regarded as clinically acceptable. Milling/SM was not used for cast fabrication in this study due to the high costs and environmental burden associated with SM of dental casts (Kessler *et al*., 2020; Bae *et al*., 2017)

The conventional method of cast fabrication has many factors to consider. Stringent impression taking and material handling was adhered to for this study. The characteristics of an ideal impression (Figure 9) as recommended by Swelem and Abdelnabi (2016) and Terry *et al.* (2006), were strictly monitored for this study. Each alginate impression was examined and assessed by the main researcher (AE), supervisor (WF) and dental technician prior to casting. Impression materials and gypsum each bring about their own concerns. While alginate is often criticised for its low dimensional stability (Rubel, 2007), it still exhibits excellent handling characteristics and is widely used (Baig and Omar, 2021). For this study, Blueprint® alginate (Dentsply® Sirona) was used in metal stock trays, following manufacturer's guidelines, and has been shown in the literature to be the most stable alginate impression material with a dimensional change of only 0.001±0.006mm (Porrelli *et al.*, 2021). Alginate impressions need to be rinsed prior to pouring due to the compounding effect of syneresis causing expansion of set gypsum casts (Sakaguchi *et al.*, 2019; Anusavice *et al.*, 2012). All impressions taken for this study were rinsed and disinfected immediately. These were then wrapped in moist tissue paper and transported to the laboratory for casting within 30 minutes of the impression being taken, as recommended by Porrelli *et al.* (2021) and Sakaguchi *et al*. (2019), to ensure all correct protocols were followed in order to introduce as few inaccuracies as possible.

The conventional gypsum models for this study were casted using Type 4 dental stone, as Types 4 and 5 gypsum are most commonly used for restorative procedures (Sakaguchi *et al*., 2019; Heshmati *et al.*, 2002). According to ADA Specification No. 25, gypsum products for dental use should not exceed 0.1% (ANSI/ADA, 1987). The gypsum used for this study was Interrock New® (Interdent®) Type 4 dental stone which has a setting expansion of 0.07% after 2 hours (Interdent, 2017). The gypsum was mixed and each model was casted according to manufacturer guidelines by the same dental technician, overseen by the main researcher (AE), to ensure standardisation. The measurements were made at least 2 hours after separation of the impression from the cast as recommended by Heshmati *et al*. (2002), to prevent exudate caused by syneresis (Sakaguchi *et al*., 2019).

For the current study, the Kennedy classification system was used due to this being one of the most commonly used and accepted classifications of partial edentulism (Polychronakis *et al.*, 2013; Carr and Brown, 2011; Pun *et al.*, 2011; Ehikhamenor *et al.*, 2010; McGarry *et al.*, 2002; Skinner, 1959). Bounded edentulous saddles were chosen in order to have consistent landmarks to aid in measurements of the lengths and heights of the saddles as parallel tooth surfaces were required for the accurate and reproducible positioning of the digital callipers (Larson *et al.*, 2002). While human error is always a concern, having constant identification points aimed to decrease the range of error (Fleming *et al.*, 2011). Digital calipers calibrated to 0.01mm were used to measure the physical intraoral bounded edentulous saddle lengths and heights (PIO L and PIO H) which were used as the control measurements due to their widespread use, accuracy and reliability as shown in the literature (Soto-Alvarez *et al*., 2020; Tancu *et al*., 2019; Braian and Wennerberg, 2019; Brown *et al*., 2018; Muallah *et al*., 2017; Rajshekar *et al*., 2017; Saleh *et al*., 2015).

The results of the study were calculated as described in the statistical analysis portion of the methodology. Accuracy is a combination of trueness and precision (ISO 5725, 1994). Means, mean differences and standard deviation (SD) calculations were carried out where the mean differences indicated trueness and the SDs indicated precision (Schmidt *et al*., 2020). ICC was used to aid in assessing inter-rater reliability/calibration and intra-rater reliability; as well as to further confirm trueness. To further confirm precision as a repeatability measurement, the intra-rater reliability ICC was used. Bland-Altman plots were used to further confirm accuracy. While the methodology for this study was adapted from previous studies in the field of digital dentistry (Schmidt *et al*., 2020; Sim *et al*., 2019; Brown *et al*., 2018; Kim, 2018; Muallah *et al*., 2017); there is currently no published in vivo study that assesses the reproduction of bounded edentulous saddles using different cast fabrication techniques. Thus, it is difficult to compare the results of this study with previous studies.

The researcher calibration/inter-rater reliability (Table 5) for this study (ICC >0.90) showed excellent agreement between both observers (AE and WF) (Koo and Li, 2016).

Table 8 and Figure 20 illustrate the accuracy (mean [trueness]±SD[precision]) between the mean differences of each variable tested namely: the length (L) and height (H) measurements of the edentulous saddle areas for the physical intraoral (PIO), 3D printed model (3DM), conventional gypsum model (GM), and intraoral scan (IOS). The physical intraoral measurement for length and height for each variable was used as the control. The mean differences were used to determine trueness and the SDs determined precision (Schmidt *et al*., 2020). The mean differences were calculated using the control (PIO) minus the variable (3DM, GM or IOS). Thus, a negative value represented on average that the variable was over-estimated compared to the control; and a positive value represented on average that the variable was under-estimated compared to the control. This implies that a negative value indicated expansion while a positive value indicated contraction. It is evident that the intraoral scan had the greatest agreement with the physical intraoral measurements among the tested variables, followed by conventional gypsum model which showed a degree of expansion, and finally 3D printed model which had the lowest agreement and demonstrated contraction of the models. The intraoral scan measurements also demonstrated a degree of contraction; however, this was to a lesser degree than that of the 3D printed models. The findings of conventional gypsum models displaying properties of expansion while intraoral scans and 3D printed models displayed a level of contraction can be correlated with a study by Sim *et al.* (2019) who reported the same findings. One possible explanation for 3D models displaying greater levels of contraction is that the contraction exhibited by intraoral scanning was incorporated into the subsequent 3D printed models.

The accuracy of the intraoral scans was 0.033±0.03mm (33±30µm) for the length and 0.032±0.03mm (32±30µm) for the height measurements, -0.048±0.02mm (-48±20µm) for the length and height measurements for the conventional gypsum casts, and 0.0595±0.03mm (59.5±30µm) for the length and 0.06±0.03mm (60±30µm) for the height measurements for the 3D printed models (Table 8 and Figure 20). The results of the intraoral scan accuracy are similar to those presented by Braian and Wennerberg (2019) who found the accuracy of intraoral scans to be 50±35µm. The accuracy for the TRIOS® 4 (3Shape, A/S) intraoral scanner as determined by Schmidt *et al*. (2020) was 65.2 ± 52.9µm and differed slightly to those found by the researchers for the current study. This can possibly be attributed to improved software of the TRIOS 4 (3Shape, A/S) scanner, as there are constant upgrades being made to intraoral scanning software (Schmidt *et al*., 2020). The current study results for intraoral scanning accuracy more closely resembled the results found for the Primescan (Dentsply® Sirona) which was 33.8 ± 31.5µm (Schmidt *et al*., 2020). The results for the current study for the conventional gypsum models and intraoral scans are comparable to those found by Sim *et al*. (2019) who determined trueness and precision of intraoral scans to be 28.49±1.74µm and 22.79±5.76µm respectively for conventional gypsum models, 28.09±2.11µm (trueness) 34.07±5.83µm (precision) for intraoral scanning. The results presented by Sim *et al*. (2019) of 55.16±2.70µm (trueness) and 54.93±8.44µm (precision) for 3D printed models differed from those found in the current study in terms of precision. This can be attributed to a variety of factors including but not limited to Sim *et al*. (2019) using a different 3D printer and different resin to the current study, and the printing and post-cure times. The results for the conventional gypsum models and intraoral scan accuracy also closely resembled those found by Serag *et al*. (2018) of 44±33µm for conventional gypsum models and 44±20µm for intraoral scanning, as well as 3D printed models whose trueness has been recorded to be 30-50µm and precision of 20-40µm (Serag *et al*., 2018).

The Bland-Altman plots (Table 9 and Figures 21-26) were used to further test the accuracy. For each method of cast fabrication compared to the control (PIO), the majority of the recordings fell within the Bland-Alman limits of agreements (LoA) and the agreement was very high. However, the differences between physical intraoral and 3D printed model measurements for length (Figure 21- PIO-3DM L), and physical intraoral and conventional gypsum model height measurement differences (Figure 25- PIO-GM H) showed one (n=1) outlier each, and the difference between physical intraoral and conventional gypsum model length (Figure 22- PIO-GM L) had 2 (n=2) outliers indicating that these datasets did show some level of disagreement. The abnormally distributed data (outliers) were all related to the posterior bounded saddles, and it is possible that the posterior saddles were reproduced with less accuracy than the anterior bounded edentulous saddles. However, all results were still regarded as clinically acceptable due to the differences all being less than 0.1mm (Ender *et al.*, 2016). It is also important to note that due to a convenience sample being used for this study, anterior bounded edentulous saddles were slightly under-represented (40% of final study sample) and similar outliers could possibly be prevalent for anterior saddles in a larger study sample. The majority (60%) of the final study sample for the current study comprised posterior saddles (Table 6). This correlates with studies by Ehikhamenor *et al.* (2010) and Al-Dwairi (2006), who found the Kennedy class III to present most frequently.

For the length measurements (Table 9), the smallest difference was noted between physical intraoral and intraoral scan measurements (Figure 23- PIO-IOS L), followed by the difference between physical intraoral and conventional gypsum model (Figure 22- PIO-GM L). The largest difference in length was noted between physical intraoral and 3D printed model measurements (Figure 21- PIO-3DM L). Similarly, for the height measurements, the smallest difference was noted between physical intraoral and intraoral scan measurements (Figure 26- PIO-IOS H), followed by the difference between physical intraoral and conventional gypsum model (Figure 25- PIO-GM H). The largest difference in height was noted between physical intraoral and 3D printed model measurements (Figure 24- PIO-3DM H). This shows that intraoral scan measurements had the highest agreement with physical intraoral measurements in both length and height. This correlates with a study by Tancu *et al.* (2019) who found intraoral scanning to be the most accurate and comparable to gypsum models, with 3D printed models showing the least accuracy while still being clinically acceptable. The shrinkage of 3D printed casts can be attributed to a variety of factors including type of resin used, post-cure time, size of build layers and the type of RP used; however, the effects have not been noted to be significant enough to render the cast “clinically unacceptable”. Serag *et al.* (2018) also found the accuracy of digital casts (intraoral scans) to be comparable with conventional gypsum casts.

To verify the trueness of each method of cast fabrication compared to the control (PIO), ICC calculations were carried out for the lengths and heights for each method (Tables 10 and 11). Intraoral scans showed the best trueness for length measurements, followed by conventional gypsum models and finally 3D printed models (Table 10). For the height measurements, the intraoral scans displayed the best trueness as well, followed by conventional gypsum models and 3D printed models (Table 11). Overall, intraoral scans displayed the best trueness and 3D printed models displayed the least. The height measurements in all methods displayed slightly lower trueness values than length measurements. However, all ICCs were >0.9, thus implying that excellent trueness was exhibited by all methods of cast fabrication (Koo and Li, 2016).

The intra-rater reliability (Table 12) for this study (ICC >0.90) showed excellent agreement upon repeated measurements of 50% of the study sample by the main researcher (AE), and also tested the precision (repeatability) of the results (Table 12). All ICCs were >0.9 indicating an excellent repeatability, and consequently precision, of all variables in the study (Koo and Li, 2016).

The longest recorded physical intraoral saddle for this study (PIO L) was 19.91mm (Tables 6 and 7). According to Braian and Wennerberg (2019), intraoral scanning is accurate in lengths of 16-22mm. Although a convenience sample was used, all lengths of the bounded edentulous saddles in the current study fell within this range.

The largest difference among the variables presented for the physical intraoral length and height- conventional gypsum model length (PIO-GM L and PIO-GM H), and was calculated to be 0.1mm for each (Table 8). According to Ender *et al*. (2016), deviations in excess of 0.1mm produce ill-fitting prostheses, however, the limits for clinical accuracy of casts according to the literature lie within the range of 0.2-0.5mm (Brown *et al*., 2018). All differences measured among the variables for this study were equal to or less than 0.1mm and all casts fabricated in this study (intraoral scans, conventional gypsum models and 3D printed models) can thus be regarded as clinically accurate and acceptable for restorative procedures.

The average accuracy for PIO-IOS was 32.5±30µm, PIO-GM was -48±20µm, and PIO-3DM was 59.75±30µm and $p<.05$ (Table 13). Based on the results of this study, the null hypothesis must be rejected as the different cast fabrication methods did produce statistically significant results. However, despite displaying statistically significant differences, all methods (conventional workflow as well as intraoral scanning and subsequent 3D model printing) produced clinically acceptable results of dimensional differences less than 0.1mm (Ender *et al*., 2016).

CHAPTER 7: LIMITATIONS AND RECOMMENDATIONS FOR FUTURE STUDIES

As with any research, the author recognizes that limitations exist. These can be found below together with possible recommendations for future studies.

Measurement of the physical intraoral bounded edentulous saddle areas was carried out using mathematical dividers and transferred extra-orally as the digital calipers were too large to be placed in the oral cavity without discomfort. This could possibly have given rise to minor discrepancies. A need exists for a different method or device to measure physical intraoral structures for further in vivo studies to be carried out.

Severely tipped teeth were part of the exclusion criteria for this study and was based on clinician discretion due to the lack of a suitable classification system. A classification system to determine severity of tipped teeth should be formulated.

Only one 3D printer, printing method and resin was used. A comparison of different resins, 3D printers and methods can be assessed in further studies to determine which would produce the most accurate models.

Only one brand and type of gypsum was used. Future studies can assess different brands and types of gypsum to ascertain which produces the best casts.

Alginate was used as the impression material for this study. Future studies could be carried out using different materials such as Polyvinyl siloxane to assess if different outcomes are obtained.

Only one intraoral scanner was used. Future in vivo studies could be carried out using the same methodology to determine if other intraoral scanners produce the same outcomes.

Due to a convenience sample being used for this study, both maxilla and mandible were tested. Future studies can assess either only the maxilla or the mandible to verify the results found in this study, as the literature suggests that maxilla is more resilient than the mandible (Hack *et al*., 2020).

This study assessed 20 samples only. Future studies should include a larger sample size to verify if the results obtained from this study are reliable and repeatable, especially in longer edentulous saddle areas.

CHAPTER 8: CONCLUSION

Based on the results of this study, it can be concluded that all methods of cast fabrication used in this study produced clinically accurate results for restorative dental procedures. Despite displaying a level of contraction, digital casts obtained by means of intraoral scanning produced the most accurate reproduction of length and height in bounded edentulous saddle areas, followed by the conventional gypsum casts which exhibited some expansion. The 3D printed models derived from intraoral scans displayed the least accuracy of the tested methods and displayed a high level of contraction.

The trueness for all methods of cast fabrication was very high (ICC>0.9). All measurements were also highly repeatable and reproducible (ICC>0.9) indicating excellent precision. Digital and conventional cast fabrication methods were therefore proven to be accurate in reproducing the physical intraoral dimensions in bounded edentulous saddle areas up to 19.91mm in length and 8.29mm in height, within the limitations of this study.

According to the results obtained, it can also be concluded that intraoral scanning/digital casts are a suitable alternative and can replace conventional gypsum casts for partially edentulous arches; however, further research is required to determine whether 3D printed casts can entirely replace conventional gypsum casts which are seen as the gold standard.

The results of this study are consistent with the literature; however, further in vivo studies are required to determine whether the digital workflow can completely replace the conventional workflow that has been used for decades.

CHAPTER 9: REFERENCES

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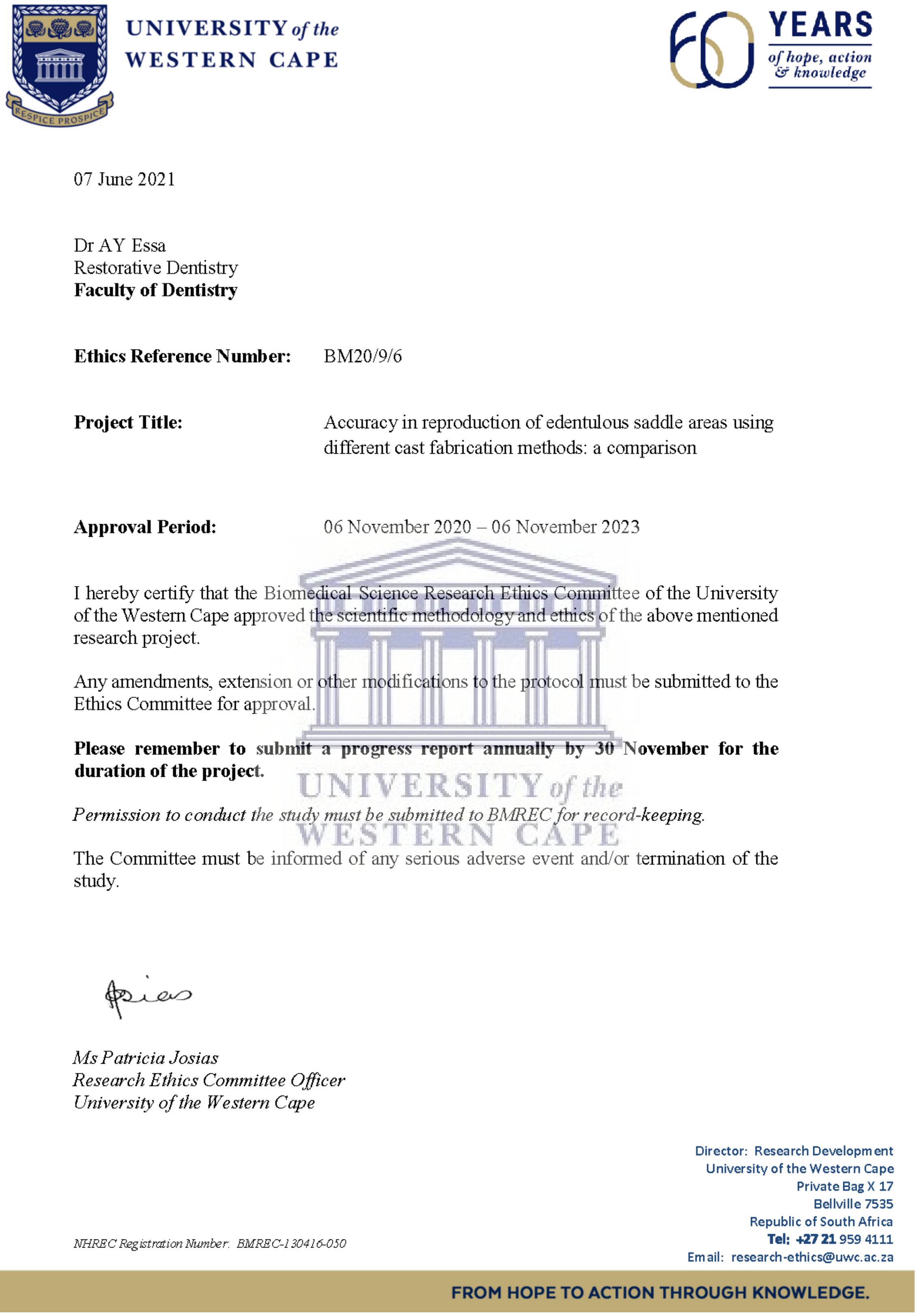
CHAPTER 10: APPENDICES

Appendix I- Ethics clearance.



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& knowledge

07 June 2021

Dr AY Essa
Restorative Dentistry
Faculty of Dentistry

Ethics Reference Number: BM20/9/6

Project Title: Accuracy in reproduction of edentulous saddle areas using different cast fabrication methods: a comparison

Approval Period: 06 November 2020 – 06 November 2023

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 annually by 30 November for the duration of the project.

Permission to conduct the study must be submitted to BMREC for record-keeping.

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

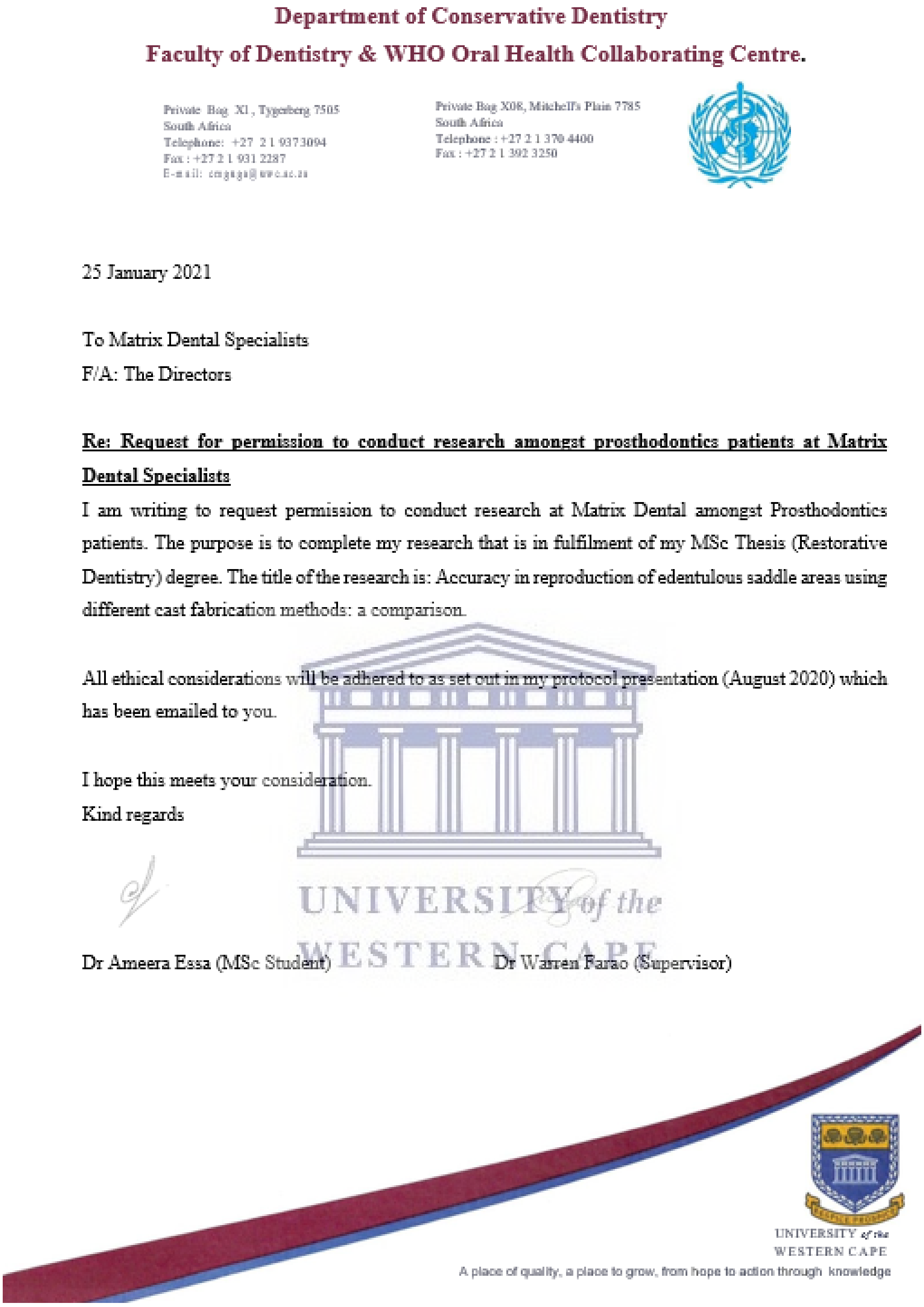
Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

NHREC Registration Number: BMREC-130416-050

Director: Research Development
University of the Western Cape
Private Bag X 17
Bellville 7535
Republic of South Africa
Tel: +27 21 959 4111
Email: research-ethics@uwc.ac.za

FROM HOPE TO ACTION THROUGH KNOWLEDGE.

Appendix II- Letter of request to private practice (Matrix Dental Specialists) to conduct research amongst patients presenting for prosthodontic treatment.



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E-mail: cmgaga@uwc.ac.za

Private Bag X08, Mitchell's Plain 7785
South Africa
Telephone : +27 2 1 370 4400
Fax : +27 2 1 392 3250

25 January 2021

To Matrix Dental Specialists
F/A: The Directors

Re: Request for permission to conduct research amongst prosthodontics patients at Matrix Dental Specialists

I am writing to request permission to conduct research at Matrix Dental amongst Prosthodontics patients. The purpose is to complete my research that is in fulfilment of my MSc Thesis (Restorative Dentistry) degree. The title of the research is: Accuracy in reproduction of edentulous saddle areas using different cast fabrication methods: a comparison.

All ethical considerations will be adhered to as set out in my protocol presentation (August 2020) which has been emailed to you.

I hope this meets your consideration.
Kind regards

Dr Ameera Essa (MSc Student) Dr Warren Farao (Supervisor)

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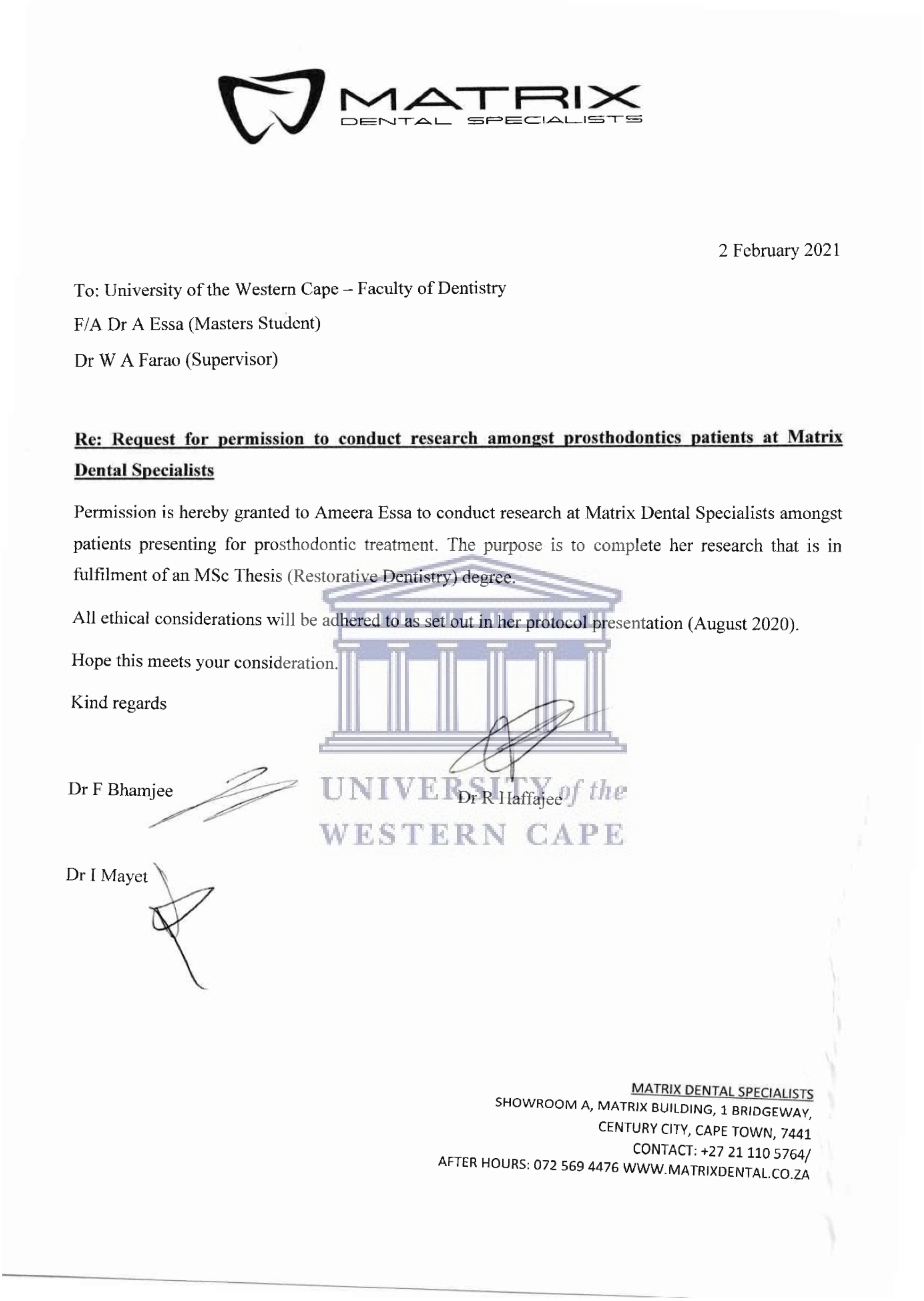
Appendix III- Permission letter from Matrix Dental Specialists (Private practice) to carry out research at their facility.



MATRIX
DENTAL SPECIALISTS

2 February 2021

To: University of the Western Cape – Faculty of Dentistry
F/A Dr A Essa (Masters Student)
Dr W A Farao (Supervisor)

Re: Request for permission to conduct research amongst prosthodontics patients at Matrix Dental Specialists

Permission is hereby granted to Ameera Essa to conduct research at Matrix Dental Specialists amongst patients presenting for prosthodontic treatment. The purpose is to complete her research that is in fulfilment of an MSc Thesis (Restorative Dentistry) degree.

All ethical considerations will be adhered to as set out in her protocol presentation (August 2020).

Hope this meets your consideration.

Kind regards

Dr F Bhamjee

Dr R Haffajee

Dr I Mayet

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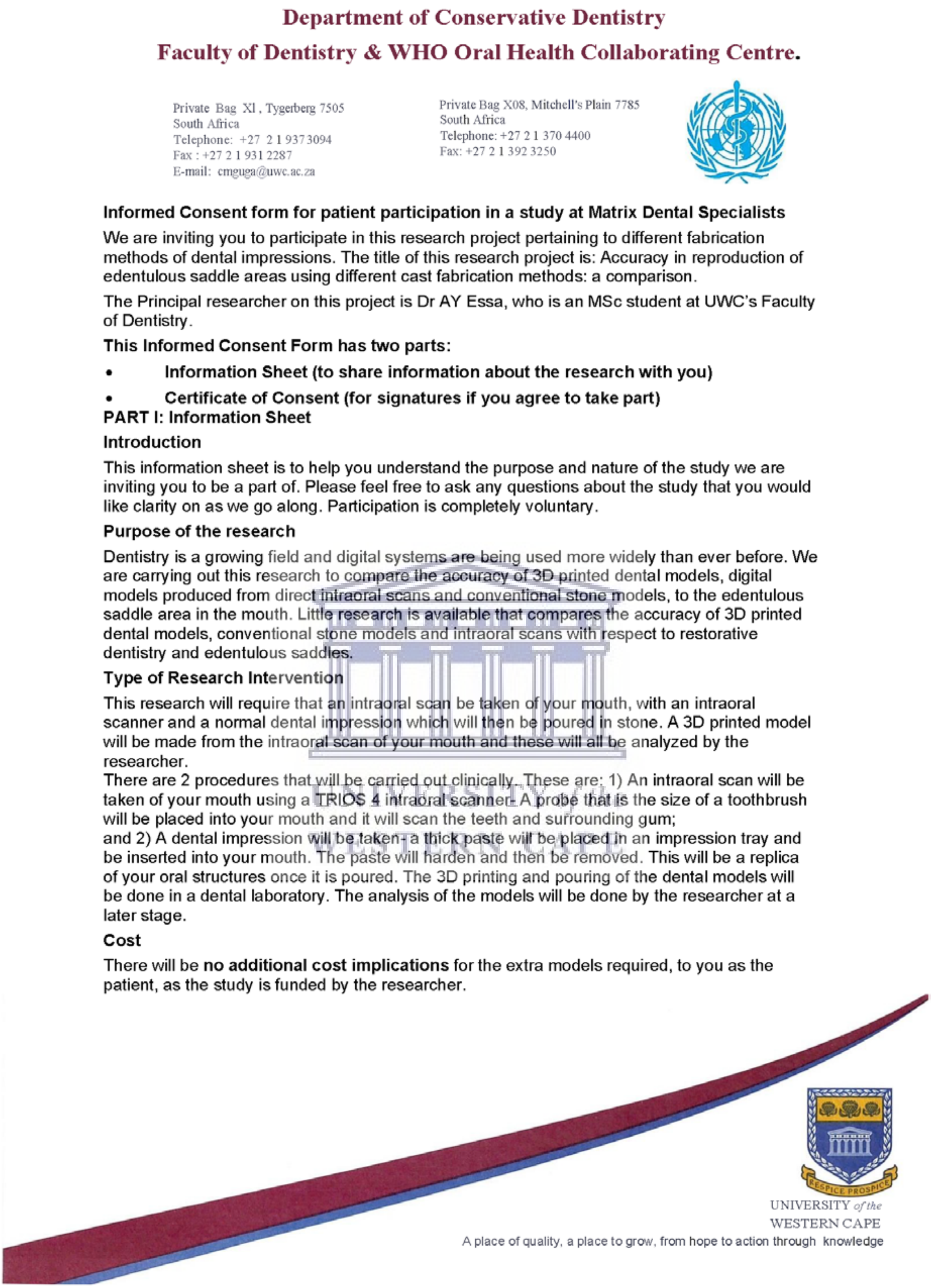
Appendix IV- Consent form for participants.



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Fax: +27 2 1 392 3250

Informed Consent form for patient participation in a study at Matrix Dental Specialists

We are inviting you to participate in this research project pertaining to different fabrication methods of dental impressions. The title of this research project is: Accuracy in reproduction of edentulous saddle areas using different cast fabrication methods: a comparison.

The Principal researcher on this project is Dr AY Essa, who is an MSc student at UWC's Faculty of Dentistry.

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

PART I: Information Sheet

Introduction

This information sheet is to help you understand the purpose and nature of the study we are inviting you to be a part of. Please feel free to ask any questions about the study that you would like clarity on as we go along. Participation is completely voluntary.

Purpose of the research

Dentistry is a growing field and digital systems are being used more widely than ever before. We are carrying out this research to compare the accuracy of 3D printed dental models, digital models produced from direct intraoral scans and conventional stone models, to the edentulous saddle area in the mouth. Little research is available that compares the accuracy of 3D printed dental models, conventional stone models and intraoral scans with respect to restorative dentistry and edentulous saddles.

Type of Research Intervention

This research will require that an intraoral scan be taken of your mouth, with an intraoral scanner and a normal dental impression which will then be poured in stone. A 3D printed model will be made from the intraoral scan of your mouth and these will all be analyzed by the researcher.

There are 2 procedures that will be carried out clinically. These are: 1) An intraoral scan will be taken of your mouth using a TRIOS 4 intraoral scanner- A probe that is the size of a toothbrush will be placed into your mouth and it will scan the teeth and surrounding gum;
and 2) A dental impression will be taken- a thick paste will be placed in an impression tray and be inserted into your mouth. The paste will harden and then be removed. This will be a replica of your oral structures once it is poured. The 3D printing and pouring of the dental models will be done in a dental laboratory. The analysis of the models will be done by the researcher at a later stage.

Cost

There will be **no additional cost implications** for the extra models required, to you as the patient, as the study is funded by the researcher.

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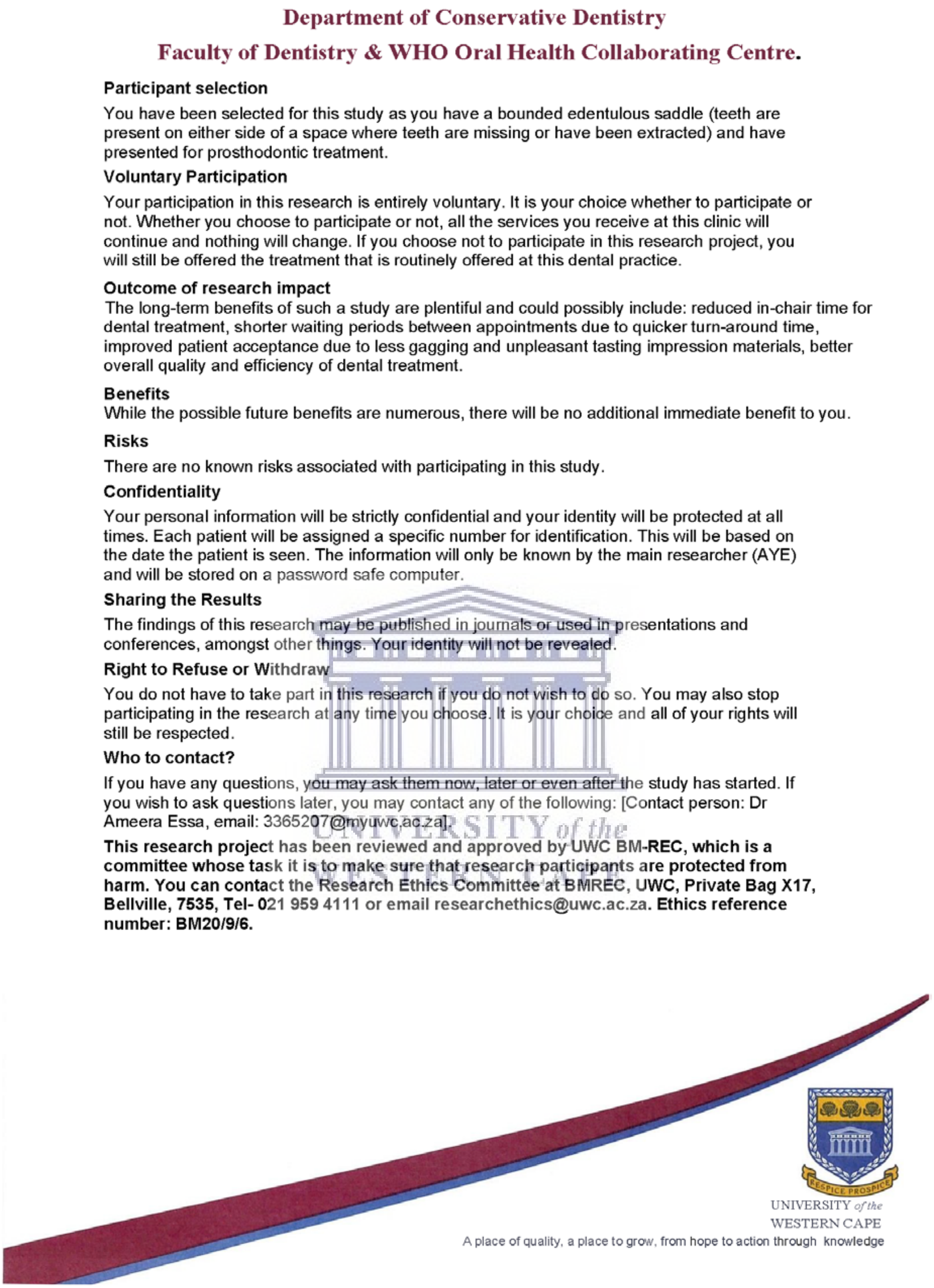

Department of Conservative Dentistry

Faculty of Dentistry & WHO Oral Health Collaborating Centre.

Participant selection

You have been selected for this study as you have a bounded edentulous saddle (teeth are present on either side of a space where teeth are missing or have been extracted) and have presented for prosthodontic treatment.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will still be offered the treatment that is routinely offered at this dental practice.

Outcome of research impact

The long-term benefits of such a study are plentiful and could possibly include: reduced in-chair time for dental treatment, shorter waiting periods between appointments due to quicker turn-around time, improved patient acceptance due to less gagging and unpleasant tasting impression materials, better overall quality and efficiency of dental treatment.

Benefits

While the possible future benefits are numerous, there will be no additional immediate benefit to you.

Risks

There are no known risks associated with participating in this study.

Confidentiality

Your personal information will be strictly confidential and your identity will be protected at all times. Each patient will be assigned a specific number for identification. This will be based on the date the patient is seen. The information will only be known by the main researcher (AYE) and will be stored on a password safe computer.

Sharing the Results

The findings of this research may be published in journals or used in presentations and conferences, amongst other things. Your identity will not be revealed.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Who to contact?

If you have any questions, you may ask them now, later or even after the study has started. If you wish to ask questions later, you may contact any of the following: [Contact person: Dr Ameera Essa, email: 3365207@myuwc.ac.za].

This research project has been reviewed and approved by UWC BM-REC, which is a committee whose task it is to make sure that research participants are protected from harm. You can contact the Research Ethics Committee at BMREC, UWC, Private Bag X17, Bellville, 7535, Tel- 021 959 4111 or email researchethics@uwc.ac.za. Ethics reference number: BM20/9/6.

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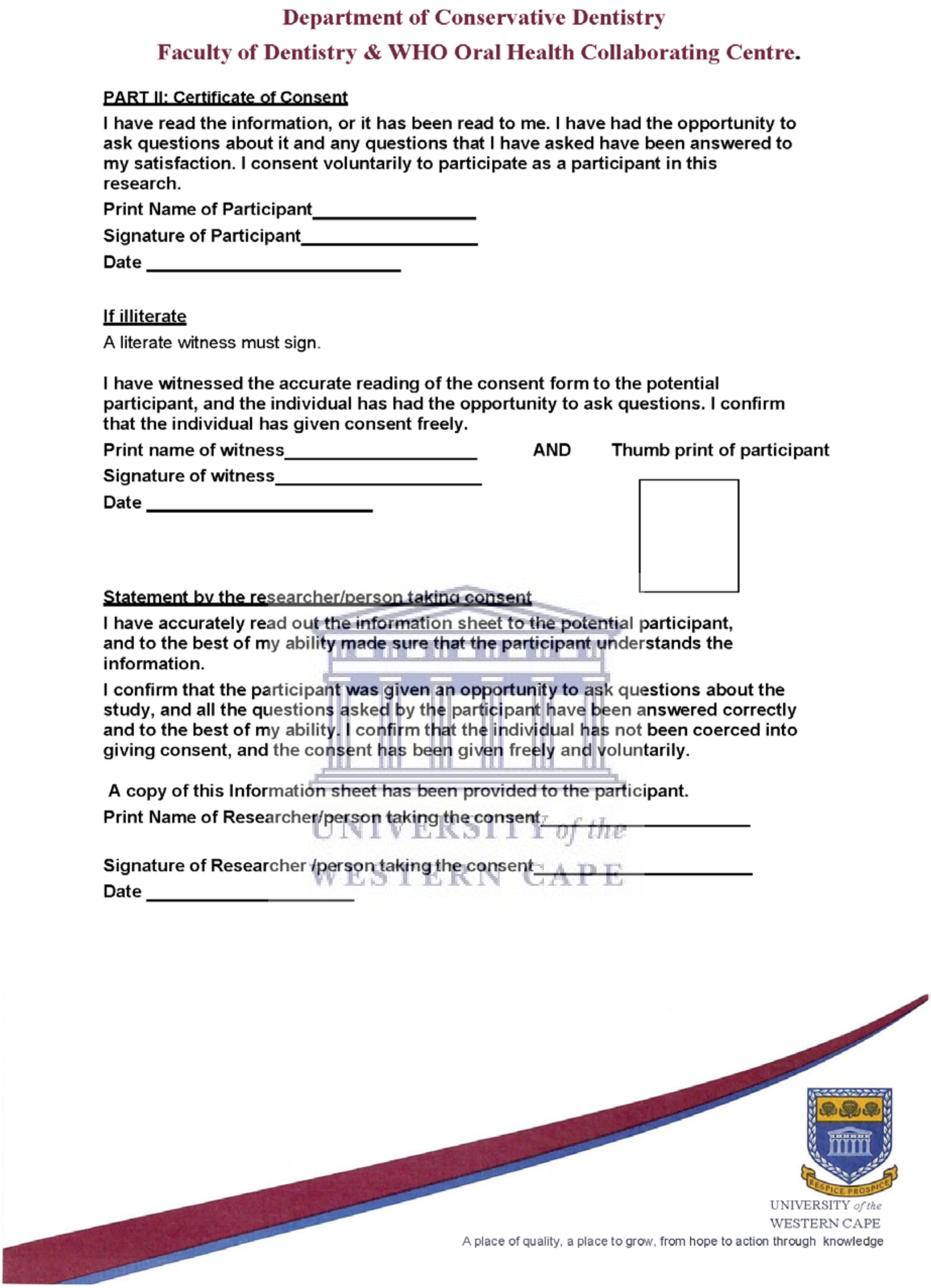

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PART II: Certificate of Consent

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant________________

Signature of Participant_________________

Date _________________________

If illiterate

A literate witness must sign.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness___________________ AND Thumb print of participant

Signature of witness_____________________

Date ______________________

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the information.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Information sheet has been provided to the participant.

Print Name of Researcher/person taking the consent_____________________

Signature of Researcher /person taking the consent_____________________

Date ____________________

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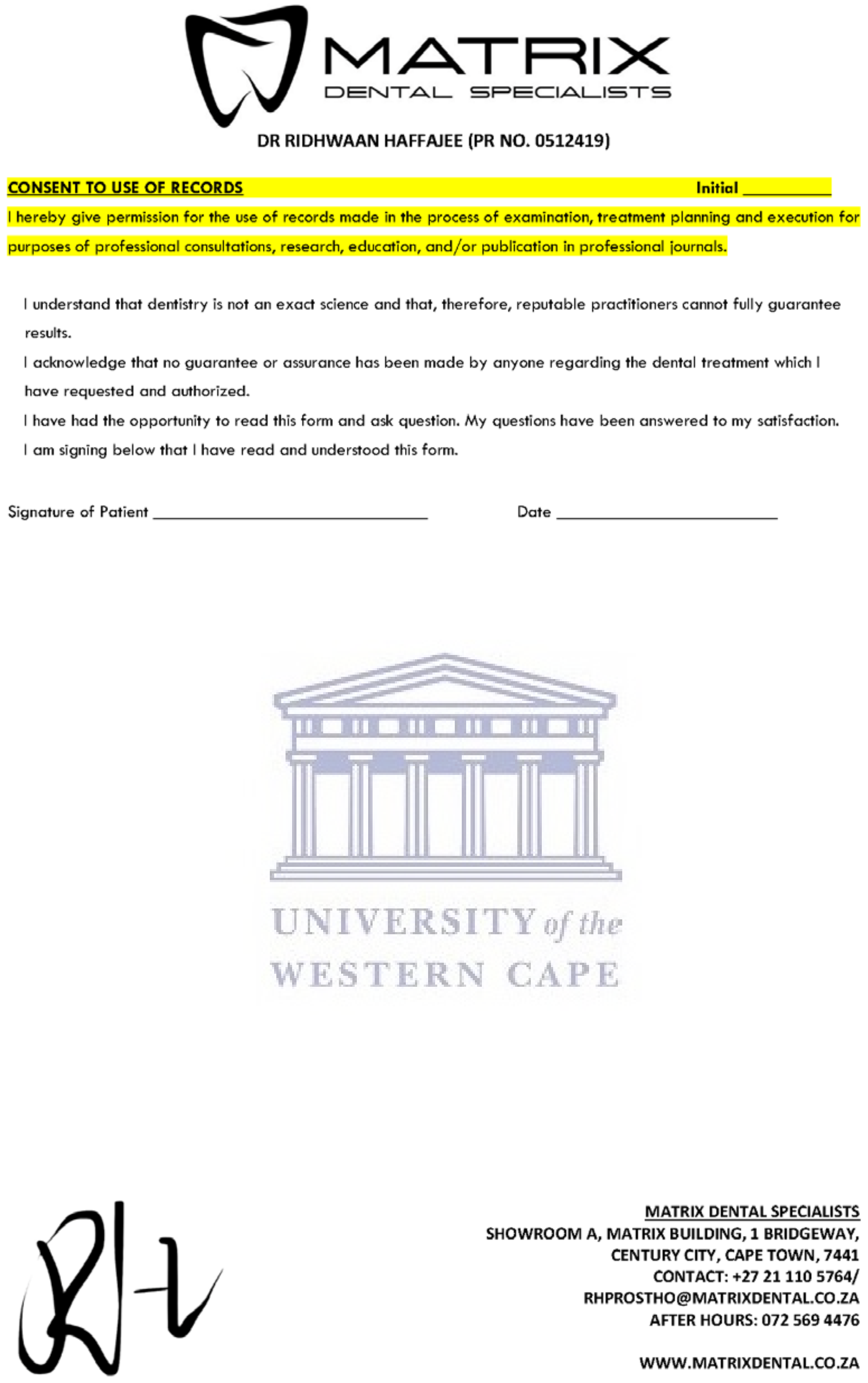

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DENTAL SPECIALISTS

DR RIDHWAAN HAFFAJEE (PR NO. 0512419)

CONSENT TO USE OF RECORDS **Initial** __________

I hereby give permission for the use of records made in the process of examination, treatment planning and execution for purposes of professional consultations, research, education, and/or publication in professional journals.

I understand that dentistry is not an exact science and that, therefore, reputable practitioners cannot fully guarantee results.

I acknowledge that no guarantee or assurance has been made by anyone regarding the dental treatment which I have requested and authorized.

I have had the opportunity to read this form and ask question. My questions have been answered to my satisfaction.

I am signing below that I have read and understood this form.

Signature of Patient ______________________________ Date ________________________

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Appendix V- Researcher calibration/ Inter-rater reliability data collection sheet.

AE	Saddle location	PIO L	3DM L	GM L	IOS L	PIO H	3DM H	GM H	IOS H
a	21	8.21	8.16	8.24	8.2	4.15	4.1	4.21	4.12
b	14-15	10.55	10.51	10.63	10.53	5.01	5	5.08	5.03
c	23-25	6.07	6.0	6.11	6.03	9.55	9.37	9.47	9.52
d	21	8.42	8.41	8.47	8.42	4.84	4.87	4.92	4.82
e	16	9.65	9.63	9.77	9.67	4.96	4.91	4.98	4.92
f	21-22	14.73	14.72	14.79	14.73	4.02	3.98	4.12	4.04
g	26	10.02	9.98	10.05	9.99	7.86	7.82	7.95	7.85
h	14	7.32	7.26	7.44	7.3	4.70	4.5	4.09	4.75
i	22	6.82	6.79	6.89	6.8	5.62	5.56	5.26	5.59
j	24-25	11.81	11.70	11.87	11.72	5.68	5.73	5.64	5.7

WF	Saddle location	PIO L	3DM L	GM L	IOS L	PIO H	3DM H	GM H	IOS H
a	21	8.21	8.18	8.24	8.2	4.15	4.11	4.21	4.13
b	14-15	10.57	10.52	10.65	10.55	5.01	4.99	5.08	5.03
c	23-25	6.06	6.01	6.09	6.05	9.54	9.39	9.48	9.53
d	21	8.43	8.41	8.47	8.42	4.84	4.89	4.91	4.83
e	16	9.67	9.63	9.78	9.66	4.97	4.91	4.99	4.93
f	21-22	14.73	14.72	14.79	14.73	4.02	4	4.11	4.03
g	26	10.01	9.96	10.04	9.98	7.86	7.81	7.94	7.83
h	14	7.31	7.26	7.44	7.3	4.70	4.51	4.07	4.73
i	22	6.82	6.79	6.89	6.8	5.62	5.6	5.24	5.61
j	24-25	11.80	11.68	11.89	11.75	5.71	5.69	5.60	5.73

Appendix VI- Intra-rater data collection sheet.

Reading 1	**Location of saddle**	**Anterior/ Posterior**	**PIO L**	**3DM L**	**GM L**	**IOS L**	**PIO H**	**3DM H**	**GM H**	**IOS H**
2	24,25	Posterior	13.29	13.23	13.39	13.24	7.64	7.57	7.68	7.61
4	23-24	Anterior	13.56	13.49	13.59	13.53	8.29	8.21	8.32	8.25
6	11,12	Anterior	19.91	19.88	19.96	19.9	8.05	7.99	8.08	8.02
8	26,27	Posterior	17.52	17.46	17.56	17.47	5.84	5.79	5.87	5.82
10	25-27	Posterior	17.89	17.79	17.95	17.81	5.88	5.76	5.92	5.82
12	24-26	Posterior	19.43	19.34	19.47	19.36	4.25	4.17	4.29	4.2
14	46	Posterior	11.04	10.96	11.07	10.99	5.78	5.75	5.88	5.79
16	25-26	Posterior	14.62	14.54	14.66	14.57	7.44	7.34	7.5	7.36
18	33	Anterior	7.43	7.41	7.46	7.42	8.03	7.98	8.09	8
20	13-14	Anterior	11.06	11.01	11.11	11.05	6.92	6.85	7.01	6.9

Reading 2	**Location of saddle**	**Anterior/ Posterior**	**PIO L**	**3DM L**	**GM L**	**IOS L**	**PIO H**	**3DM H**	**GM H**	**IOS H**
2	24.25	Posterior	13.27	13.21	13.37	13.26	7.64	7.57	7.68	7.62
4	23-24	Anterior	13.56	13.49	13.59	13.53	8.29	8.21	8.32	8.25
6	11,12	Anterior	19.92	19.88	19.95	19.9	8.07	7.99	8.1	8.03
8	26,27	Posterior	17.52	17.46	17.56	17.47	5.84	5.79	5.87	5.82
10	25-27	Posterior	17.88	17.8	17.96	17.81	5.88	5.76	5.93	5.83
12	24-26	Posterior	19.43	19.34	19.47	19.36	4.26	4.17	4.29	4.21
14	46	Posterior	11.04	10.96	11.07	10.97	5.78	5.75	5.86	5.76
16	25-26	Posterior	14.62	14.54	14.66	14.57	7.46	7.36	7.5	7.38
18	33	Anterior	7.4	7.37	7.46	7.38	8.03	7.98	8.09	8.01
20	13-14	Anterior	11.05	11	11.1	11.04	6.93	6.86	7.01	6.91

Appendix VII- Letter from Straumann® Group South Africa.

straumanngroup

27 September 2021

University of the Western Cape

Tygerberg Oral Health Centre

Department of Restorative Dentistry

Att: Dr W Farao

Dear Dr Farao

I, Angelique Geel (Digital/Ortho Specialist Straumann Group South Africa), hereby acknowledge that the 3Shape Trios 4 intraoral scanner was loaned to Dr Ameera Essa and resins for 3D printing were given to her for her Masters research entitled: 'Accuracy in reproduction of edentulous saddle areas using different cast fabrication methods: a comparison.'

The intraoral scanner was loaned and the resins were provided at no cost to Dr Essa as a gesture of goodwill, and we do not have any expectations or demands with regards to the findings on her research.

Please do not hesitate to contact our offices for any further queries with regards to the above.

My contact email angelique.geel@straumann.com

Kind regards

Angelique

AGeel.

Appendix VIII- Data management plan.

University of the Western Cape

Data Management Plan

Faculty- Dentistry

Department- Restorative dentistry

Administrative Data

Project title- Accuracy in reproduction of edentulous saddle areas using different cast fabrication methods: a comparison

Registration details (registration number)- BM20/9/6

Funder- self-funded

Grant number- N/A

Abstract - project description (include the research questions)- Attached

Principle Investigator (PI)- Ameera Yusuf Essa

ORCID (PI)- 0000-0001-5445-9042

Contact details of the PI- ameeraessa@gmail.com/ 3365207@myuwc.ac.za

The timeframe of the research project- November 2020-April 2022

Date the DMP was created / submitted- April 2021

Data

What will be collected? Describe the data and formats (raw and refined/cleaned data).
Intraoral scans and physical models (conventional and 3D printed), as well as measurements in the physical intraoral area.

When describing formats, please identify storage requirements by (expected file sizes and quantities).
STL files, Data recording in Microsoft Excel spreadsheets. Approximately 2GB of storage space will be required.

Is your data original or will you reuse existing data (or a combination)?
Original data.

How will the data be collected? (e.g. interview; questionnaire; observation)
Physical measurements using digital calipers, intraoral scans using an intraoral scanner, and conventional impressions.

Which software and version will be used?
Microsoft Office ProPlus 2021

Which operating system is used at the time of collecting the data?
Microsoft Windows 11 x64

Documentation (legislation, policies and guidelines)

Applicable legislation for legal compliance (e.g. Protection of Personal Information Act - POPIA)- POPIA

Institutional and funder policies- N/A

Metadata schema and version used (e.g. Dublin Core)- N/A

Desciptive document (How the data was analysed and how it is used. Upload this document with the data onto the repository).
Attached.

Applicable Memorandum of Understanding (MOU) that defines roles and responsibilities for data collection, administration and sharing.- Consent form attached.

Ethical compliance and approval

Have you received ethical approval (attached letter)- Yes. BM20/9/6.

How will you obtain consent?- Consent form. Attached for perusal

How will you handle intellectual property issues?- N/A

How will you manage copyright concerns? N/A

How will you manage confidentiality concerns? No foreseeable confidentiality concerns as all ethical guidelines were adhered to.

Secure Storage and Backup

How will the primary (raw) data be securely stored?- Password controlled file on a password controlled laptop as well as backup to an external potrable hard drive (WD Elements- 1TB).

Where will the refined data be stored?- Same as primary

How will you share public data?- All data is anonymous

How will you address security and backup?- No foreseeable security issues as all access is password controlled.

Data Sharing

Are the any funder or institutional restrictions on sharing the data?- N/A

How will the data be shared?- Microsoft Excel data collection sheets will be stored on UWC Thesis repository and can be requested via email to the main researcher

How will data be securely shared?- Email or direct transfer of Microsoft Excel data collection sheets only. No other identifying information will be shared.

Data Selection, Preservation (Archiving) and Retention

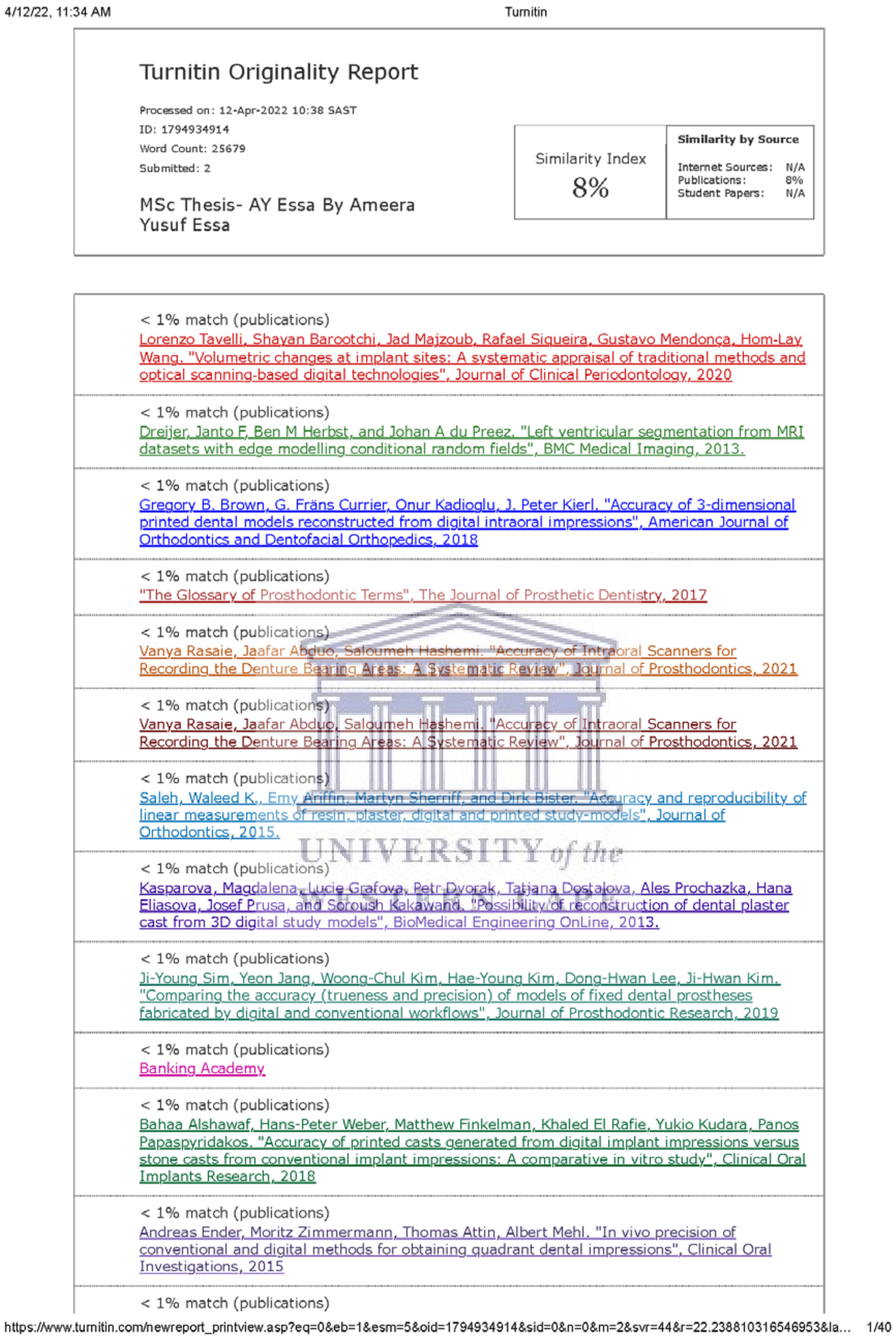
Which data will be shared?- Raw digital data collection sheets only will be shared. No patient names or identifiers will be shared.

What is the long term storage plan?- Physical models will be kept in an access controlled locked cupboard in for a maximum of 2 years. Digital data will be stored for a maximum of 5 years on the laptop and external hard drive as described.

How long is the data expected to be stored?- Physical models will be kept for a maximum of 2 years. Digital data will be stored for a maximum of 5 years.

E
N
D

Appendix IX- Turnitin report.



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