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A comparison of different methods and materials to establish maximal intercuspal position

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A comparison of different methods and materials to establish maximal intercuspal position

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A Research Report submitted to the Department of Prosthodontics, School of Oral Health Science, Faculty of Health Sciences, University of the Witwatersrand, South Africa in partial fulfilment of the requirements for the Degree of MSc(Dent)

Supervisor: Prof CP Owen

Co-supervisors: Prof DG Howes

Prof JL Shackleton

Johannesburg, 2020.

DEDICATION

For my parents,

Hennie and Amór

And my dearest wife,

Rozanne.

DECLARATION

I, Herman Theo van den Bergh, declare that this research report is my own work. It has been submitted for the degree of Master of Science in Dentistry in the Faculty of Health Sciences at the University of the Witwatersrand, Parktown, Johannesburg, South Africa. It has not been submitted before for any other degree or examination at this or any other University.



……

This 9th day of November 2020

ABSTRACT

Purpose:

This was an *in-vivo* study to determine the most reliable method to record a patient's maximal intercuspal position by using two common methods with two popular registration materials.

Materials and Methods:

One set of full arch impressions of both jaws was done with vinyl polysiloxane impression material (Position Penta Quick, 3M ESPE, Germany) followed by four interocclusal registrations for each participant. One registration technique required more than one registration as the patient had to close through two different materials (Anutex Toughened modelling wax, Kemdent, UK and Jet Blue Bite, Coltene Whaledent, USA). In a second technique Jet Blue Bite (Coltene Whaledent, USA) was injected laterally/ buccally between the occluded tooth surfaces after mouth closure. Models were cast in type 4 stone under strict conditions and measurements done with a digital vernier calliper, accurate to 100 microns. Hand articulation of the casts were used as the control.

Results:

Statistical analysis showed significant discrepancies when the patient closed through both wax and PVS materials. No statistically significant differences to the control group were present when PVS was injected laterally after closure.

Conclusions:

Hand articulation proved to be the most accurate method to reproduce the maximal intercuspal position, in the fully dentate patient with horizontal and vertical occlusal stability. In all other clinical situations an appropriate combination of materials may be necessary, including the possibility of digital registrations.

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1. INTRODUCTION AND LITERATURE REVIEW

1.1. Introduction

General and specialised restorative dentistry is dependent to a great extent upon the patient's occlusion influencing the entire stomatognathic system and any changes made should be in complete harmony with the patient's existing biological occlusion (Wilson and Banerjee, 2004).

During the past century the study of occlusion has been diverse and continually evolving. Numerous concepts and theories have been proposed in the search for an "ideal occlusion" creating controversy between different schools of thought. This has created confusion in establishing treatment plans and rigid occlusal paradigms, especially for the treatment of those unfortunate individuals with orofacial pain (Türp et al, 2008).

Occlusal theories and treatment concepts have undergone a metamorphosis, from the earliest mathematical and geometric concepts, through the mechanical and morphological principles to a more holistic, physiologically based approach that aims to be less invasive and more patient centred.

1.2. Early occlusal concepts

1.2.1. 1800 - 1930

This was an era of occlusal theories that led to the development of multiple articulators, mainly for complete denture cases. Bilateral balanced occlusion in eccentric mandibular movements was the ideal (Becker and Kaiser, 1993).

Early occlusal concepts or theories, although well founded were criticised as being subordinate to the founder's personal beliefs and/or convictions, resulting in conclusions that were often found to be biased, rather than being based on sound scientific evidence. This line of critique is applicable to the theories proposed by researchers such as Bonwill and Spee (Türp et al, 2008).

1.2.2. The 1920s

During this time researchers started to focus their attention on the characteristics of the natural dentition as well as its reconstruction. Pankey and Mann devised a system to establish a bilateral balanced occlusal scheme in excursive mandibular movements (as advocated in the

preceding era that focused on complete dentures) by utilising the functionally generated path technique proposed by Meyer and combining it with Monson's spherical theory. When using this system, the posterior mandibular teeth were restored so that their buccal cusps conformed to the height determined by Monson's sphere. By using anterior guidance as a reference the posterior maxillary teeth received their occlusal form along the functionally generated path by means of the wax chew in registration as proposed by Meyer. The records were then placed on a vertical displacement articulator (Meyer, 1934 as cited by Becker and Kaiser, 1993; Meyer, 1959; Pankey and Mann, 1960).

1.2.3. Gnathology

Gnathology was first defined by Stellard in 1924: "The science that relates to the anatomy, histology, physiology, and pathology of the stomatognathic system and that includes treatment of this system on the basis of examination, diagnosis, and treatment planning" (Pokorny et al, 2008). In 1926 McCollum established the Gnathological society (McCollum and Stuart, 1955 as cited by Pokorny et al, 2008).

A major goal of Gnathology was to determine the rotational centres of the mandibular condyles (transverse horizontal axis), recording the border movements (by manipulated mandibular movements) of these centres and then reproducing these values on a three-dimensional fully adjustable articulator. This led to the development of the pantograph that recorded the three-dimensional movements of the condyles and fully adjustable articulators (or arcon articulators) such as the Stuart and Denar articulators, that could reproduce these border movements in the laboratory (Becker and Kaiser, 1993; Pokorny et al. 2008). A pantograph can be defined as "an instrument used to graphically record, in one or more planes, the paths of mandibular movement and to provide information for the programming of an articulator" (GPT-9, 2017).

1.2.4. Centric Relation and Interocclusal registrations

The concept of Centric Relation (CR) is central to Gnathology. Gnathologists manipulated the mandible to its most retruded border position and made lateral movements from this position, as the first official definition of CR in the inaugural edition of the Glossary of Prosthodontic Terms (GPT) in 1956 would prove with its definition of CR: "The most retruded relation of the mandible to the maxillae when the condyles are in the most posterior unstrained position in the glenoid fossae from which lateral movements can be made, at any

given degree of jaw separation" (GPT-1, 1956 as cited by Morgano et al, 2018; Pokorny et al, 2008). Gnathology saw CR as a three-dimensional concept or RUM- "the rearmost, uppermost and midmost position of the condyle in the glenoid fossa" (Pokorny et al, 2008).

CR has always been a controversial concept and the definition has been modified in most editions of the GPT, as the dental profession could not agree on a conclusive definition. This is due to the fact that CR is determined by the condylar position in the glenoid fossa, which is impossible to determine clinically. The controversy became all the more evident in the definition of CR in the GPT's 5th edition in 1987: "A maxillomandibular relationship in which the condyles articulate in the thinnest avascular portion of their respective disks with the complex in the anterior-superior position against the slopes of the articular eminences. This position is independent of tooth contact. This position is clinically discernable when the mandible is directed superiorly and anteriorly and restricted to a purely rotary movement about a transverse horizontal axis. This term is in transition to obsolescence" (GPT-5, 1987). At this stage the definition changed from a posterior position of the condyle in the glenoid fossa to an anterior position.

Seven definitions were given for CR in the 8th edition of the GPT and finally in the ninth edition the term became quite comprehensive by amalgamating multiple previous definitions (Morgano et al, 2018). The latest definition reads "a maxillomandibular relationship, independent of tooth contact, in which the condyles articulate in the anterior-superior position against the posterior slopes of the articular eminences; in this position the mandible is restricted to a purely rotary movement; from this unstrained, physiologic, maxillomandibular relationship, the patient can make vertical, lateral or protrusive movements; it is a clinically useful, repeatable reference position" (GPT-9, 2017).

Another ideal of gnathology was to have the Maximal Intercuspal Position coincide with CR and defined in GPT-5 as "the complete intercuspation of opposing teeth independent of condylar position" (GPT-9, 2017). This was also referred to as Centric Relation Occlusion (CRO) or Centric Occlusion (CO). The GPT's definition for CO also changed from the fifth edition when the definition of CR changed from a posterior to an anterior position. From the fifth edition the definition of CO has remained mostly the same, defined as "The occlusion of opposing teeth when the mandible is in centric relation. This may or may not coincide with

maximum intercuspation position" (GPT-5, 1987; GPT-9, 2017). The fifth edition stated that CO, as with CR, was a term in transition to obsolescence (GPT-5, 1987).

It is worthy to note that most of the research on CR was carried out by recording CR as a posterior-superior position, rather than anterior. Objective data regarding the reliability of recording the anterior-superior position is scarce, and this is a point of concern (Keshvad and Winstanley, 2000).

Methods of establishing the position of CR, recording it and transferring it to the articulator in the laboratory have changed over the years with many different techniques proposed. It started as direct interocclusal registrations in the nineteenth century, when the patient was usually instructed to close into a thermoplastic material, such as wax or compound, which was placed between the edentulous ridges creating a so called "squash bite" (Schloseer, 1941 as cited by Keshvad and Winstanley, 2000). Early use of interocclusal records included the use of wax by Christensen in 1905 and wax- and modelling compound by Brown, in 1954 (Christensen, 1905 as cited by Keshvad and Winstanley, 2000; Brown, 1954).

1.3. Literature review

To enable thorough planning of restorative work, the practitioner has to decide whether the patient's existing vertical dimension of occlusion (VDO) will be maintained or whether it needs to be adjusted. An adjustment of the VDO is usually indicated when reorganizing the dentate patient's existing intercuspal position (ICP) to a new position as well as when restoring the edentulous patient (Wilson and Banerjee, 2004).

In restoring the dentate and partially dentate patient using either fixed or removable prostheses, with the goal of treatment to maintain the existing VDO, then the patient's existing maximal intercuspal position (MIP) is the most appropriate occlusal reference to use. This position must, however, be easy to identify, it must be stable and comfortable at intercuspation and pathology must be absent. This is also referred to as a conformative approach (Wilson and Banerjee, 2004).

For the purpose of analysis, as well as fabricating prostheses, casts need to be mounted on adjustable articulators. These articulators can be programmed to simulate the patient's jaw movements in order to replicate the patient's border positions. If done accurately, this process

may enable the fabrication of prostheses that require minimal intra-oral adjustment (Warren and Capp, 1990; Freilich et al, 1992).

The process of transferring the intra-oral maxillo-mandibular relation to the laboratory must be meticulous to ensure that the mounted casts are an accurate representation of the inter-arch dental relationship. The adjustable articulator will be of no greater value than simpler versions if these processes are inaccurate (Schuyler, 1953; Schallhorn, 1957). This process can be done with or without an interocclusal record. The decision depends on the intra- oral condition of the patient.

To enable the laboratory to position the casts in an accurate and stable position resembling that of the patient, a tripod of vertical support, as well as horizontal stability between the casts are necessary for the articulation to be stable and reproducible (Freilich et al, 1992). This tripod should consist of a minimum of three widely spaced contacts between the opposing casts (Ziebert and Balthazar-Hart, 1984).

The tripodal stabilisation prevents wobbling or rocking of the casts when approximated and adequate horizontal stability will prevent rotation as well as translation of the casts in the horizontal plane. Good intercuspation usually results in good horizontal stability. Flattened or worn tooth surfaces may present with poor horizontal stability, as do those teeth prepared for prosthodontic restorations.

When the dentition consists of tripodal vertical stability as well as horizontal stability (which is usually the case when good intercuspation of a largely intact dentition is present) then an interocclusal record is unnecessary i.e. the casts may be articulated by hand, provided that full-arch impressions are made and the number of teeth being restored is kept to a minimum (Freilich et al, 1992; Krishna Prasad et al, 2012). An intervening occlusal registration material used in such cases may result in an increased VDO, which results in an erroneous recording of the ICP (Okeson, 1989). For the purpose of this study, the hand articulation method in maximum intercuspation will be referred to as the “best fit” record.

A dentition lacking poor vertical support or horizontal stability necessitates the fabrication of an interocclusal record (Freilich et al, 1992). Interocclusal records are used to relate the mandibular cast to the maxillary cast during articulation and can be defined as “a registration of the positional relationship of the opposing teeth or arches, a record of the positional

relationship of the teeth or jaws to each other" (GPT-9, 2017). Various authors have stated the importance of an accurate interocclusal record: "Any inaccuracy in the recording of centric maxillo-mandibular relation precludes accuracy in recording or transferring all eccentric positions" (Schuyler, 1953). "The interocclusal record used to relate the mandibular to the maxillary cast is the most important maxillo-mandibular relationship record in determining occlusal accuracy" (Warren and Capp, 1990).

Freilich et al, (1992) stated that errors in interocclusal registrations are to be expected, but that those errors can be minimised by proper execution of the appropriate type of record and stated: "In addition to saving chair time, reduced error in the interocclusal relationship of mounted casts decreases both the likelihood of making restorations without occlusal contact or the inadvertent perforation of an occlusal ceramic veneer where extensive intraoral adjustment is required".

The accuracy of interocclusal records is influenced by the properties of the interocclusal material, the recording technique, deviation of the mandibular position due to occlusal contacts, action of muscles of mastication and tissue changes within the temporomandibular joints (TMJ) (Vergos and Tripodakis, 2003). Techniques to cause relaxation of the masticatory muscles and by doing so "deprogramming" the movements of the mandible have been proposed. This concept is known as "myocentric occlusion" and has been investigated and harshly critiqued by investigators such as Remien and Ash, 1974; Kantor et al, 1973 and Strohaver, 1972. Remien and Ash stated that "Myomonitor centric is not reproducible because the reference point, rest position, varies on anterior-posterior head position, and its pulsed intercuspation position is anterior to centric relation and centric occlusion. Also, the axis of rotation is located anteriorly and inferiorly from the transverse horizontal (terminal hinge) axis. Clinically, it would appear to be difficult to integrate a verifiable and repeatable occlusal design (cusp-fossae, ridge and groove direction) with this concept". Both Strohaver and Kantor reported that the myomonitor technique recorded the mandible in a protrusive position. The efficacy of manipulating the action of the masticatory muscles and also the TMJ can thus be considered a questionable practice. To improve the accuracy of interocclusal records the clinician should rather focus on the type of material used in combination with the correct recording technique for the given clinical situation. These are factors within the clinician's control.

1.4. The properties/ requirements of an "ideal" interocclusal registration material

1. Initial resistance to closure must be as small as possible. Resistance to closure may cause deviation of the teeth before they occlude and thus cause the mandible to deviate from its natural position. Resistance may also cause mobile teeth to move.
2. The material must be dimensionally stable once polymerised.
3. After polymerisation the material must resist compression.
4. It must be easy to manipulate and easy to verify.
5. The incisal and occlusal tooth surfaces must be accurately recorded.
6. The material must be biocompatible (Mallone WFP and Koth DL, (1989) as cited by Michalakis et al, (2004)).

When indicated, interocclusal registrations are usually carried out by the direct interocclusal recording.

1.5. Direct check- bite interocclusal recordings

The direct "check- bite" is the oldest type of interocclusal record (Myers, 1982). Wieckiewics et al, (2016) considered the interocclusal record as the most common method of transferring jaw relation records from the patient to the articulator (Campos and Nathanson, 1999; Nagrath et al, (2014)). Vergos and Tripodakis, (2003) and Tripodakis et al, (1997) attributed the popularity of direct interocclusal records to the simplicity of the procedure. By using this method the patient closes into the recording material placed between the opposing occlusal surfaces.

Different types of interocclusal registration materials and techniques may be used, depending on the purpose of the registration and the existing intra-oral condition, ranging from modelling wax, zinc-oxide eugenol paste, metallised wax, elastomers, polyether elastomers, compound, impression plaster or acrylic resins. Elastomers and polyether elastomers refer to conventional polyethers and addition silicones that have been modified by adding catalysts and plasticizers to enable its use as interocclusal registration materials. The ideal material should accurately capture the interocclusal relationship of the opposing arches, while maintaining dimensional stability according to Ghazal et al, (2008). Irrespective of the type of material and method used, the record should be dimensionally stable and give an accurate representation of the maxillomandibular position (Millstein et al, 1971; Strohaver, 1972; Millstein et al, 1973; Millstein and Clark, 1981; Myers, 1982; Lassila and McCabe, 1985;

Lassila, 1986; Warren and Capp, 1990; Freilich et al, 1992; Millstein and Hsu, 1994; Tripodakis et al, 1997; Vergos and Tripodakis, 2003; Michalakis et al, 2004; Ghazal et al, 2008).

Skurnik, (1969) described a procedure for registering accurate interocclusal records with wax. This technique required a good quality wax which was fairly hard but softened uniformly and remained soft throughout its working time. Although the author recognized a resistance to closure, he stated that such resistance was minimal and became negligible upon adequate softening of the wax. Ideally the wax record was stored on the opposing plaster cast (which must be accurate and free of imperfections) in a cool environment, but when transported to the laboratory it was advised to use a sealed polyethylene bag filled with water. Skurnik described wax as "probably the most maligned, yet most versatile recording material" and further stated that "unless they are properly handled, their value as recording agents may be completely invalidated" (Skurnik, 1969).

An interocclusal registration material may cause an obstruction to complete closure and result in a separation of the teeth according to Millstein and Hsu, (1994). Results of an *in-vitro* study by Millstein et al. in 1973 wherein two waxes of different hardness were compared, the following were proved:

- Complete closure through a wax rim was not possible when applying pressure similar to those clinically exerted by a patient, due to the resistance of the material.
- Regardless of the force applied during initial closure into the material, complete closure of the opposing models was never achieved.
- Resistance of closure is dependent on the toughness of the wax, closing pressure and the thickness of the wax rim (as a single or double thickness of wax may be used).
- Softer wax reduced the amount of resistance to closure
- Higher closing pressures reduced the effect of resistance to closure offered by the material.
- Subjecting a single and double thickness of wax to various closing pressures found that a single layer reduced the resistance to closure, but that the effect was more significant when using a tougher type of wax.
- The average heating temperature during the study was 126°F or 52°C.
- When reseating a model into a wax interocclusal record made at an earlier stage changes occurred in the vertical, rotational and translational dimensions, which were influenced by the seating pressure.

- The investigators were unable to reproduce the original wax recordings due to changes in the material.
- Different storage times were used, but results were inconsistent. It was concluded that no ideal storage time for wax records could be established.
- Investigators stated that the wax record is subject to various factors which cannot be consistently controlled, resulting in significant variations at the time of the record being made and thereafter. It was concluded that wax is unpredictable and unreliable, even with careful technique (Millstein et al, 1973).

An advantage to the increased resistance encountered when closing into wax is that it may be used to maintain a position in space, for example when a tooth apposes an edentulous gap. This is very important, as a tripod of vertical support has to be present when making a registration, requiring occlusal contacts. This may be difficult to achieve when using materials that are less resistant to closure than wax, such as elastomeric materials, in which case the recorded space will need to be established first. The latter material should result in a record that remains more accurate with less distortion (Millstein and Hsu, 1994; Ghazal et al, 2008).

In a study comparing five different interocclusal recording materials Lasilla, (1986) found that wax was a difficult material to use as it displayed a high resistance to closure even when heated close to its melting point. It did however stiffen rapidly upon cooling down. The author concluded that wax displayed considerable contraction upon cooling down, and due to a high coefficient of thermal expansion leading to dimensional instability, the material was deemed unreliable. It was advised to be used only in removable denture cases. Elastomers were also investigated in the same study and found to offer considerable resistance to closure after one minute from the start of mixing (the elastomer used was a silicone putty which is highly viscous). Volumetric change of the elastomeric material during record taking and the first 30 minutes thereafter was less than 0.5%. After 30 minutes this was found to be clinically insignificant, proving that the material had stable elastic properties. Elastomers should not be stored in water as moisture resulted in dimensional changes, but dry storage in a tightly sealed container maintained the dimensional stability for a long period of time. Millstein and Hsu, (1994) claimed that elastomers were accurate and also dimensionally stable once polymerized and that distortion was unlikely once the record was made. Disadvantages of elastomers included the need to predetermine the interocclusal recording space and a short working time (Lassila, 1986; Millstein and Hsu, 1994).

Vergos and Tripodakis, (2003) confirmed that vertical discrepancies were produced when patients closed into the jaw transfer record. Transferral of these records to the casts resulted in even larger discrepancies, proving the importance of an accurate fit of the interocclusal record on the study or working casts. PVS and polyether produced less vertical errors than did wax, but the difference was considered insignificant (Vergos and Tripodakis, 2003). Accurate repositioning of the casts may be a challenge, as the material used to register the record may not reproduce the occlusal morphology accurately enough. Tripodakis et al. proved in 1997 that simple removal and repositioning or transferring of an interocclusal record influences the vertical relationship of the two members of a model apparatus of the casts respectively (Tripodakis et al, 1997).

In a study comparing Polyether, PVS, wax and zinc oxide-eugenol interocclusal materials Michalakis et al, (2004a) found that wax records presented with considerable linear changes and were not suited for interocclusal registrations.

Ghazal et al, (2008) showed that vertical discrepancies existed when casts were articulated with interocclusal registrations present. Polyether and vinyl polysiloxane caused smaller discrepancies than did aluminium and hydrocarbon wax. The discrepancies caused by vinyl polysiloxane and polyether materials were considered to be statistically insignificant. The elastomeric materials also showed better dimensional stability and increased resistance to deformation when compared to waxes. Waxes produced more resistance to closure. Vertical discrepancies in all of the materials investigated increased with storage thereof. Ghazal et al, (2017) in a study on condylar displacements caused by interocclusal records, proved that vinyl polysiloxane and polyether records resulted in statistically significantly lower displacement of *in-vitro* simulated condyles on an adjustable articulator, when compared to aluminium- and hydrocarbon wax compounds. It was further stated that elastomers were easily manipulated, offered very low resistance to closure, produced precise detail in tooth structure and were easy to trim once polymerized. The authors were of the opinion that elastomers are the most commonly used interocclusal recording material, although clinicians still frequently use wax as well (Ghazal et al, 2008; Ghazal et al, 2017).

Michalakis et al, (2004) studied the viscosity, working and setting times of elastomeric interocclusal registration materials to evaluate their resistance to closure as a property of its consistency. The authors found that PVS had a reduced flow characteristic when compared to polyether as well as zinc oxide- eugenol, but it was easier to use and displayed a faster working time, which is

favourable when recording a jaw relationship. In a second study by Michalakis et al, (2004a) the PVS material presented with fewer linear discrepancies when compared to wax and zinc oxide-eugenol. PVS did however display a weight change when exposed to moisture after polymerization which necessitates dry storage conditions. Michalakis et al, (2004b) conducted a third study and proved that PVS had a greater resistance to compression than did wax and zinc oxide- eugenol.

Polyether elastomers as an interocclusal registration material display superior flow characteristics and thus a smaller resistance to closure when compared to PVS. The accuracy and dimensional stability is also better than that of PVS, but it consists of disadvantages that negate its use as an interocclusal registration material. These include a very long setting time and accuracy that exceeds that of the plaster casts. This implies that the material may interfere with reseating of the casts upon mounting it for articulation in the laboratory. A significant disadvantage is the price, which is higher than the other materials used (Michalakis et al, 2004b; Krishna Prasad et al, 2012).

Michalakis et al, (2004a) reported that zinc oxide- eugenol has to be used with a carrier and that it takes a long time to set. This material also presented with more linear changes than the elastomers and was deemed not ideal for interocclusal registrations. Fattore et al, (1984) found zinc oxide-eugenol to be reliable, but that it tend to stick to teeth, dehydrates and cracks, compromising parts of the record. This material was unable to be used for articulation more than once.

Hoods-Moonsammy et al (2014) reported that elastomers, specifically polyvinyl siloxane (PVS) monophase and polyether elastomers produce accurate and reliable impressions, but that distortion is inevitable in all materials investigated. Furthermore, the study showed that distortion is cumulative in each step of the process, which is of great concern as this particular study was done *in-vitro* under strictly controlled circumstances. In a clinical setting the cumulative effect of distortion would be even greater.

2. AIMS AND OBJECTIVES

2.1. Aim

The aim of this study was to compare the accuracy of two commonly used interocclusal registration materials, using two techniques for direct interocclusal maxillo-mandibular registrations typically used in private practice, and to compare these with hand-articulation.

2.2. Objectives

1. To devise a consistent and reliable method of measuring the relationship between articulated maxillary and mandibular casts
2. To compare two methods for registering the maxillo-mandibular jaw relation, using two commonly used interocclusal registration materials, namely base-plate wax and polyvinyl siloxane
3. To compare these methods and materials to hand articulation

2.3. Null hypothesis

The null hypothesis was that there would be no statistically significant difference in the materials or the techniques.

3. METHODS AND MATERIALS

3.1. Study participants

Twenty volunteer BDS students at the University of the Witwatersrand, School of Oral Health Sciences, were used as study participants. A convenience sampling method was used whereby first- and second year students were approached as the researcher and students could easily meet at the University's premises. Students were given a brief overview of the study and those interested were given participant information sheets and consent forms to become acquainted with the study (Appendix 1).

Ethical approval was granted by the Human Research Ethics Committee (medical) of the University of the Witwatersrand, Johannesburg (Number M181103, Appendix 2). Permission to carry out the study at the hospital was approved from the Wits Dental Hospital Research Risks Committee. Participation was on a voluntary, signed consent basis, and participants' casts were numbered so that their participation was entirely anonymous. There were no financial implications for any of the participants.

A single visit was arranged for each individual in the study, and the researcher was the only clinician to conduct the procedures on each participant. At the visit a medical and dental history was taken and a limited oral examination performed to ensure that the participant met the inclusion criteria.

The inclusion criteria for each participant were:

1. Age >18yrs
2. Restoration free with continuous dentate arches to at least the second molars.
3. Stable interocclusal scheme with no malocclusion.

Exclusion criteria:

1. Any history of orthognathic surgery, facial trauma or facial surgery.
2. Presence and/or history of TMJ disorders.

3.2. Methods and Materials

3.2.1. Methods

During the visit for each participant the operator took one full-arch impression of both the maxillary and mandibular arches using standard metal box trays. The impression material used was Position Penta Quick Vinyl Polysiloxane (3M ESPE, Germany) using a Pentamix™ automatic mixing machine (3M ESPE, Germany). This material is a polyvinyl siloxane (PVS) monophase that was shown by Hoods-Moonsammy et al, (2014) to produce accurate and reliable impressions.

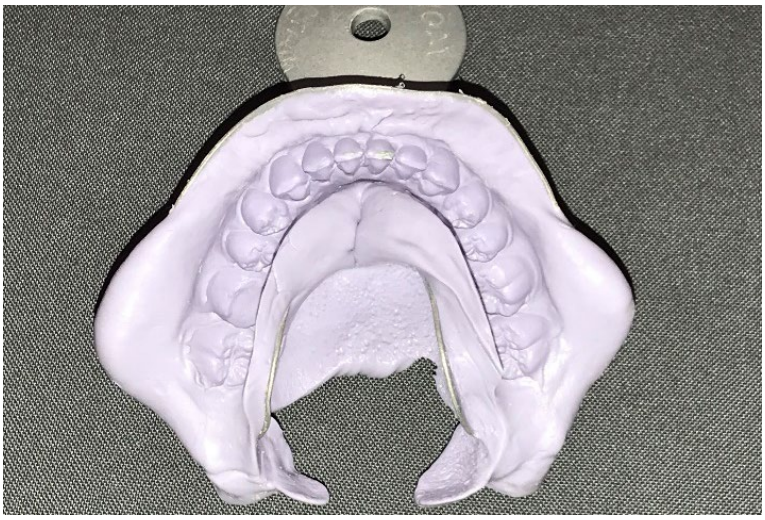

Figure 3.1 Example of full arch impression

The impressions were followed by four interocclusal registrations (Fig. 3.2). These interocclusal registrations were carried out in random order to eliminate the effect of variation in biting pressure and/or fatigue of the participant over the course of the appointment.



Figure 3.2 A full set of interocclusal registrations. Top and bottom left represents Wax 1 and Wax 2; Top right registration represents PVS1 (M1); Bottom right represents PVS2 (M2)

The interocclusal registration materials used were:

1. Baseplate modelling wax (Anutex Toughened modelling wax, (ISO type 1 soft classification) (Kemdent, UK) as this correlates with the softer wax used in the study by Millstein et al, (1973) offering lower resistance to closure
2. Addition-cured polyvinyl siloxane material (PVS): Jet Blue Bite Registration material (Coltene Whaledent, USA) in the form of cartridges with static mixing tips, inserted into a mixing gun. This material is readily available in South Africa and marketed as having a 30 second working time and 40 second intra-oral setting time.

The interocclusal registration methods used were as follows:

1. Wax registrations were made in accordance with the method prescribed by Skurnik (1969). A double sheet of wax was softened and then moulded to the shape of the patient's occlusal table. The wax rim was uniformly heated in a thermal bath at 52°C, as described by Millstein et al, (1973). The patient was instructed to close gently into their habitual occlusal position with all their teeth together. The wax was then cooled down with cold water, both in the mouth and after being removed. Three interocclusal registrations of this type were made, two with wax ("method one") and one with Jet Blue

Bite ("method one"). The wax records were repeated twice, as the patient's biting force was anticipated to change during repetitive function, yielding different results. The chronological order in which the wax and PVS records were made was changed with each patient (Skurnik, 1969; Millstein et al, 1973).

2. "Method two" was a closed interocclusal registration using Jet Blue Bite registration material. This unpublished technique (the author was unable to find any publication documenting this technique) is demonstrated on commercial literature websites. The PVS material was injected laterally/buccally between the occluded tooth surfaces after the patient has been instructed to close gently into their habitual occlusal position with all their teeth together. One of these records was made for each patient.

All materials used were from the same batches for each material and used according to each manufacturer's instructions. Interocclusal records were stored in cool temperatures (below 23°C), wax records in sealed polyethylene bags with water and silicone materials in dry, tightly sealed containers (Skurnik, 1969; Lassila, 1986; Wieckiewicz et al, 2016).

Impressions were cast in in model formers with a uniform base thickness of at least 5mm using type 4 stone mixed under vacuum.

3.2.2. Measurements

Measurements of the models were made by the same operator (the researcher) over three different occasions under the same conditions adhering to the same guidelines and procedures. Cast models were not mounted on an articulator, to prevent the introduction of possible mounting errors but instead were hand articulated / positioned in the "best fit" position for the control measurement and positioned by hand with intervening interocclusal records for those test measurements. All measurements were carried out using a digital Vernier calliper accurate to 100μm (Fig. 3.3).

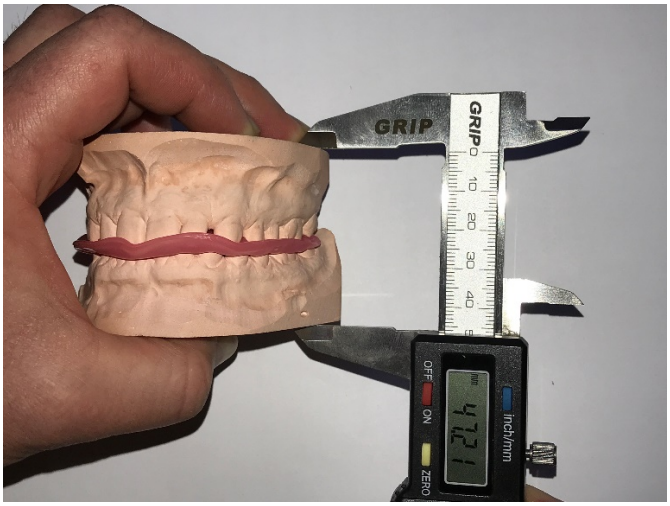

Figure 3.3 Measurements being made with a digital Vernier calliper

Each patient's upper and lower models were marked with four consistent points (marked 1 to 4) on the anterior, posterior, and sides of the models corresponding to the midline position anteriorly and posteriorly, and that of the first molar on either side: each point was measured five times by the operator in a randomised sequence. This resulted in five measurements (5 determinations of a single observation) for each of the four experimental conditions per method-material combination, from which the average value (mean) was used as the final measurement. Each patient's model therefore had 4 average values per method-material combination, one for each measurement position. This process was repeated on three separate occasions.

For the hand articulated measurements when no interocclusal registration material was present, the casts were held in three positions (Fig. 3.4):

- HA1 (M): at the centre or middle of the cast base: this will be the control for all other measurements;
- HA2 (L): left of centre when facing the cast from an anterior direction;
- HA3 (R): right of centre when facing the cast from an anterior direction.

The aim of using these three handheld positions was to determine if any inaccuracies result from rocking or tilting of the casts due to irregular finger pressure (without an interocclusal record present to stabilise the casts).

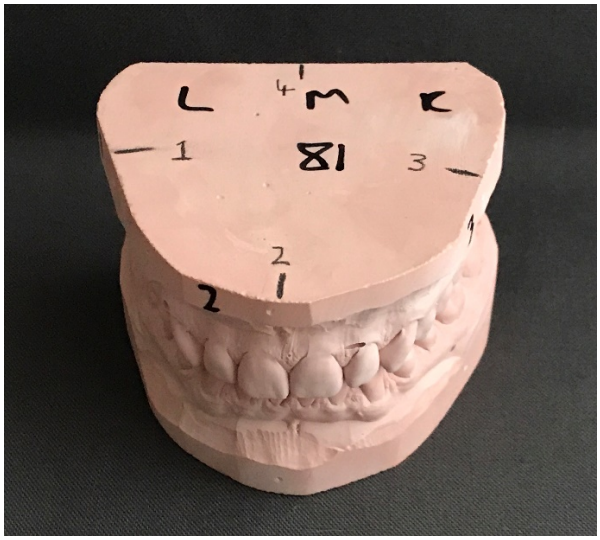

Figure 3.4 Four measurement points marked for measurement. Also note the handheld positions for middle (centre), Left of centre and Right of centre

The four material-method combinations were labelled as follows:

- PVS1 (M1): PVS material, method one (Fig. 3.5).
- PVS2 (M2): PVS material, method two (Fig. 3.6).
- Wax1: Wax registration material, method one.
- Wax2: Wax registration material, method two (Fig. 3.7).



Figure 3.5 PVS material recording of full arch using method one

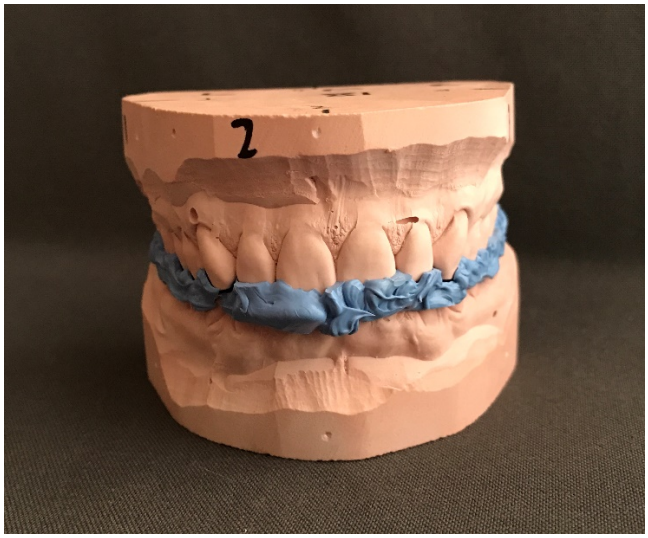

Figure 3.6 PVS material using method two



Figure 3.7 Wax registrations, used for Wax1 and Wax2

Method HA1 (M) was the control, so in all the other measurements the control values were subtracted to become the outcome value used for analysis. HA1 (M) was used as the control as all of the participants had an intact occlusion with vertical and horizontal stability in maximum intercuspal position, as per the inclusion criteria. In this scenario hand articulation of the casts is the most accurate form of articulation as confirmed by Freilich et al, (1992) and Prasad et al, (2012).

3.3. Data analysis

3.3.1. Sample size

A pilot study was carried out to estimate the expected effect size and differences if any between methods. The researcher had one set of full arch maxillary and mandibular impressions, as well as three interocclusal registrations made on himself by a clinician colleague. The interocclusal records included one wax and two polyvinyl siloxane records made according to the methods described below. The measurements made from the different materials and techniques were compared and found to differ significantly. This resulted in merit for the speculation that there were differences between the materials and techniques and that further testing was justified, using the same method.

Based on information from this small pilot study, the between-material effect size, f, was estimated as 0.32. For the determination of such an effect size in a repeated-measures model with 80% power at the 5% significance level, a minimum sample size of 16 patients was required. Sample size calculations were carried out in G*Power (Faul et al, 2007).

3.3.2. Statistical analysis

The outcome value across the three measurement occasions was analysed to determine the intra-rater reliability between each pair of measurement occasions and if possible, to select a single occasion for further analysis. The intra-rater reliability was assessed using the Intraclass Correlation Coefficient (ICC).

Descriptive analysis was carried out on the selected outcome, categorised by material, position and material-position combination. A repeated measures regression analysis was used with outcome as the dependent variable; material, position, and their interaction as fixed effects; and patient as a repeated measures effect. Hence Outcome = k0 + k1(material) + k2(position) + k3(material x position interaction), where k0…k3 are regression coefficients to be estimated.

Data analysis was carried out using SAS version 9.4 for Windows. The 5% significance level was used.

4. RESULTS

4.1. Participants in the study

There were 20 participants who volunteered to take part in the study. From these only 17 met the inclusion criteria. Records for each of the 17 eligible patients consisted of an upper and lower stone cast model and four interocclusal registrations to produce seven material-method combinations per patient that could be measured.

4.2. Intra-rater assessment

The Intraclass Correlation Coefficients are shown in table 4.1.

Table 4.1 ICC values as per occasion

OCCASION	ICC
First vs second	0.88
First vs third	0.81
Second vs third	0.84

The intra-rater reliabilities for all pairs of occasions were high so the measurements were reproducible and it was decided to use the measurements from the first occasion for further analysis.

4.3. Descriptive analysis

The descriptive data for the study are shown in Tables 4.2 and 4.3.

Table 4.2 Difference measurements (mm) between material-method combinations and control

Material-Method	Measurement Location	N	Mean Values	Standard Deviation	Median	Interquartile range	
HA2 (L)	1	17	-0,048	0,125	-0,010	-0,112	0,038
	2	17	0,006	0,177	0,082	-0,152	0,124
	3	17	-0,008	0,215	0,000	-0,122	0,066
	4	17	-0,031	0,202	-0,026	-0,104	0,118
		Mean	-0,020	0,180	0,011	-0,123	0,087
HA3 (R)	1	17	0,012	0,106	0,040	-0,058	0,086
	2	17	0,029	0,198	0,102	-0,074	0,164
	3	17	0,022	0,169	0,016	-0,046	0,134
	4	17	-0,057	0,196	-0,032	-0,100	0,096
		Mean	0,001	0,167	0,032	-0,070	0,120
PVS1 (M1)	1	17	0,657	0,349	0,592	0,450	0,762
	2	17	0,420	0,366	0,426	0,112	0,766
	3	17	0,817	0,487	0,790	0,630	1,158
	4	17	0,933	0,361	0,898	0,716	1,130
		Mean	0,707	0,391	0,677	0,477	0,954
PVS2 (M2)	1	17	0,177	0,228	0,132	0,054	0,388
	2	17	0,171	0,278	0,180	0,036	0,290
	3	17	0,190	0,402	0,132	0,052	0,232
	4	17	0,031	0,213	0,044	-0,066	0,226
		Mean	0,142	0,280	0,122	0,019	0,284
WAX1	1	17	0,786	0,705	0,530	0,300	1,436
	2	17	0,723	0,784	0,470	0,346	1,272
	3	17	0,866	0,780	0,828	0,276	1,312
	4	17	0,930	0,809	0,932	0,224	1,370
		Mean	0,826	0,769	0,690	0,287	1,348
WAX2	1	17	0,537	0,406	0,406	0,336	0,762
	2	17	0,598	0,495	0,492	0,332	0,836
	3	17	0,771	0,620	0,672	0,332	1,192
	4	17	0,651	0,522	0,488	0,294	0,970
		Mean	0,639	0,511	0,515	0,324	0,940

Table 4.3 Difference measurements (mm) with the four locations combined for each of the material-method combinations

Material	Measurement Location	N	Mean	Std Dev	Median	Interquartile range	
HA2 (L)	Four measurement locations combined	68	-0,020	0,180	-0,008	-0,118	0,089
HA3 (R)		68	0,001	0,171	0,020	-0,083	0,117
PVS1 (M1)		68	0,707	0,431	0,720	0,445	0,942
PVS2 (M2)		68	0,142	0,291	0,128	0,029	0,240
WAX1		68	0,826	0,757	0,521	0,280	1,386
WAX2		68	0,639	0,512	0,486	0,330	0,937

Figure 4.1 shows the box-and-whisker plots for the outcome. It appears that there are differences between the material-method combinations, with some displaying a higher spread of data than others.

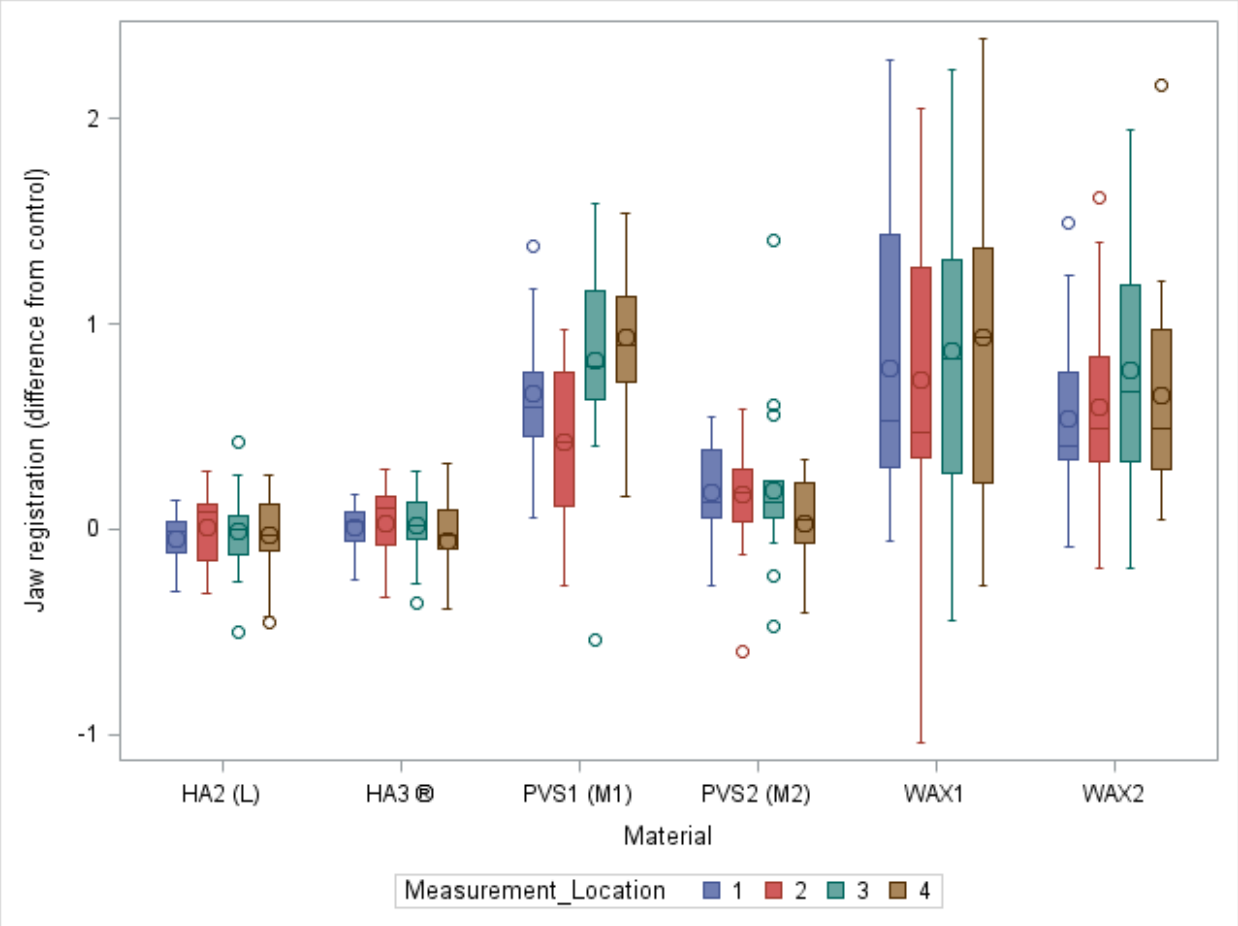

Figure 4.1 Box-and-whisker plots illustrating outcome values

PVS1 (M1), Wax1 and Wax2 are closely related in terms of median and mean values. Their interquartile ranges are closely associated, but it is noticeable that the spread of interquartile- and full range of measurements for Wax1 and Wax2 are larger, especially Wax1. These

factors indicate outcome values that may differ considerably from the control group. The measurement locations lie close to each other in all of the groups, which might imply less influence on the outcome than the different material-method combinations.

4.4. Regression Model

Table 4.4 shows the source data for the full model.

Table 4.4 Source table for the full regression model

Effect	Num DF	DF	F	p
Material-method	5	368	64.75	<.0001
Measurement Location	3	368	1.9	0.13
Material-method*Location	15	368	1.28	0.21

Only the effect of material-method was significant. The material-method / location interaction was removed from the model, but measurement location was retained as the measurement location was integral to the study, giving the final model in Table 4.5.

Table 4.5 Final regression model

Effect	Num DF	DF	F	p
Material-method	5	383	64.05	<.0001
Measurement Location	3	383	1.88	0.13

Only the effect of the material-method was significant, therefore this was investigated further by means of *post-hoc* tests. The estimated least-squares (LS) mean outcome is shown in Fig. 4.2 for each material-method combination.

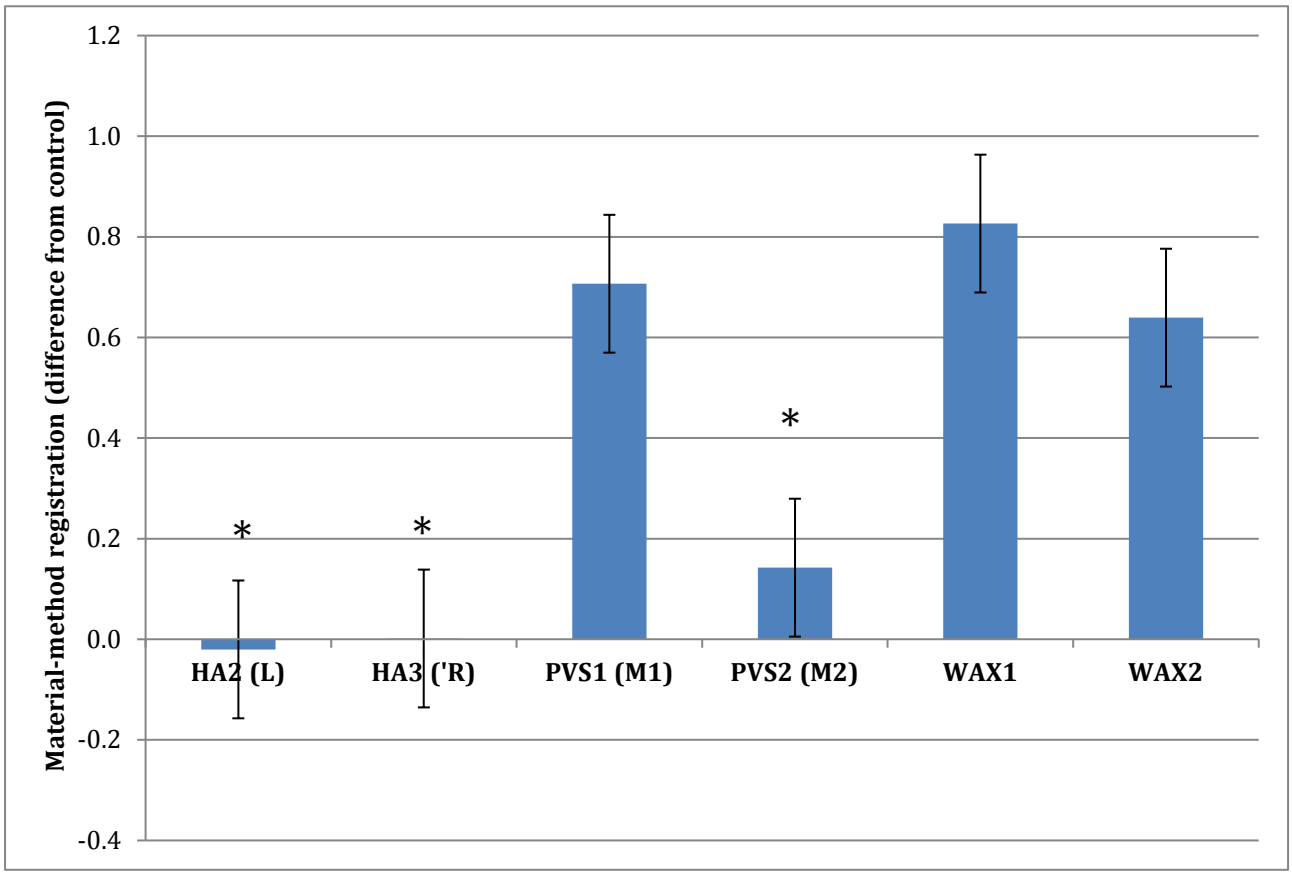

Figure 4.2 Estimated Least Squares mean outcome for each material-method combination. Error bars indicate the 95% confidence interval for the mean. * indicates significant differences ($p < 0.0001$) from the other methods

The estimated LS-mean was significantly lower for HA2 (L), HA3 (R) and PVS2 compared with PVS1, WAX1 and WAX2 (all $p < 0.0001$). The 95% confidence intervals for HA2 (L) and HA3 (R) included zero, so it is reasonable to conclude that they were not significantly different from the control group.

5. DISCUSSION

5.1. Hand articulation method

It was decided not to articulate the casts on a conventional articulator, but rather to articulate by hand to eliminate possible errors in the articulating process (Schuyler, 1953; Schallhorn, 1957). All participants in the study had a full complement of teeth up to the second molars, with no malocclusion and a stable, reproducible maximal intercuspal position (MIP). This was especially important as the casts of a dentition with vertical and horizontal stability in MIP can be accurately articulated by hand, without an intervening interocclusal material present, according to Freilich et al, (1992). As hand articulation eliminates the need for an interocclusal record it provided an accurate control.

The process of measuring different areas on a cast when articulating it by hand involves rotating the casts while applying inward finger pressure on the casts (toward the occlusal surface) consistently to the centre portion of the base of the cast. This method (referred to as HA1 (M)) was used as the control value. To determine whether holding the casts off-centre would generate inaccuracies, two sets of measurements were made where the finger pressure was applied to the left and right of centre of the casts. The results showed that these measurements were not significantly different from the control method. The mean differences were 20 and 1 μm for the left and right pressure measurements respectively, with maximum recorded differences being 424 and 316 μm respectively: these would not be clinically significant. Therefore different finger pressures did not influence the measurement outcome and hand articulation when possible, is indeed accurate.

5.2. Wax interocclusal registration method

Guidelines to achieving accurate wax records as set out by Skurnik (1969) and Millstein et al, (1973) were used as a basis for the patients to close into their habitual occlusal position.

There have been reported differences in the recommended wax to be used for jaw registration (Skurnik 1969; Millstein at al 1973). This study used a soft baseplate modelling wax that is known to be in general use. However, the results showed that even when adequately softened and consistently heated in a uniform manner in a standardised procedure, significant discrepancies were observed when compared with the control measurements. The mean differences were 826 and 639 μm for the first and second methods respectively, with

maximum recorded differences of 2.4 and 2.2mm respectively. These would produce clinically significant errors.

These results are consistent with the findings by Lasilla, (1986) who concluded that considerable dimensional instability was present when using wax records, and with Michalakis et al, (2004a) who concluded that even though the wax they used was metallised, it was inaccurate and unsuitable for interocclusal registration purposes.

5.3. Vinyl Polysiloxane, method one

This method required PVS registration material be squeezed onto the occlusal surfaces of the lower teeth in a replicate manner to the placement of wax onto those teeth. The patients were then asked to close in the same manner as with the wax, into their habitual occlusal position.

The difference of the measurements was significantly different to the control, with a mean of 707 μm, and a maximum of 1.6mm, which would render this clinically unacceptable.

5.4. Vinyl Polysiloxane, method two

To utilise this technique the patient was instructed to close into their habitual occlusal position as beforehand, and to keep closed as the PVS material was squeezed onto the buccal aspect of the closed teeth engaging the occlusal line where the maxillary and mandibular teeth intercuspate.

The results showed that that the measurements for this group were not significantly different from the control. The mean value was 142 μm; however, although the interquartile range was small, (0.029 to 0.240), the maximum recorded difference was 1.4 mm, which may indicate that this method is technique sensitive, perhaps as a result of the instruction to the patient to keep in a closed position without movement.

Ghazal et al, (2017) reported that PVS offers low resistance to closure, and found that the vertical discrepancies recorded were not statistically significant. However, in the present study, the method of closure into the material (method one) was found to be statistically significantly different. Therefore the second method would appear to be more accurate,

although the range of differences may produce an inaccuracy which might be clinically significant.

5.5. Limitations

The following aspects may limit the findings of the current study:

- Only two among multiple available types of interocclusal registration materials were used, but this was specifically done as these two materials are commonly used in private practice among general dentists and a study encompassing a wider range of materials was impractical for the scope of this project.
- Only the vertical discrepancies were measured and not the horizontal discrepancies, as that would have resulted in a study with a scope larger than currently possible.
- Resistance to compression of the materials was not tested, as this was also beyond the scope of this study.

6. CONCLUSION AND RECOMMENDATIONS

Modelling wax is relatively inexpensive and easy to manipulate, which might explain the reason for its continued popularity. However, the results of this study are in agreement with the findings of Millstein et al, (1973) that, in a fully dentate situation, wax is unpredictable and unreliable, even when a standardised technique is used. Its use should perhaps be restricted to those clinical situations where there is little alternative, such as when teeth appose an edentulous gap or in the fully edentulous patient, but then as a base for the use of a more appropriate inter-occlusal registration material.

The use of PVS in a similar manner to that of wax, was also found to be unsuitable. Its use to record the tooth positions when the patient has closed into an intercuspal position was more accurate, but appears to be technique sensitive, as some measurements would have clinically significant implications.

When a stable intercuspal position is present exhibiting a tripod of vertical support and horizontal stability, then the results of this study would indicate that hand articulation of the casts would be the most accurate form of locating them in preparation for mounting on an articulator.

It is recommended that in all other clinical situations, such as in partially edentulous arches or in worn dentitions, further studies be carried out to determine the most consistent and accurate method of jaw registration, using an appropriate combination of materials. In addition, the use, or adjunct use of intra-oral scanners would provide further evidence of the most appropriate methods and materials.

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APPENDICES

APPENDIX 1 Participant information sheets and consent forms

Participant Information Leaflet

STUDY TITLE: A comparison of different methods and materials to establish maximal intercuspal position.

INVESTIGATOR: Dr Herman van den Bergh
Tel: 082 493 3061
Email: 2016045@student.wits.ac.za
INSTITUTION: School of Oral Health Science, Faculty of Health Sciences, University of the Witwatersrand

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S): Daytime Tel : 031 242 6189 After hours: 082 595 6101

To the Participant: *This consent form describes the study, and requests you to participate. If you have any queries, please contact the Investigator.*

Introduction

Good Day my name is Herman van den Bergh

I am a postgraduate student studying towards a master's degree (MScDent) at the University of the Witwatersrand, I would like to invite you to consider participating in a research study. Your participation in this study is entirely voluntary and refusal to participate will involve no penalty or loss of benefits to which you may otherwise be entitled.

This information leaflet is to help you to decide if you would like to participate. You should fully understand what is involved before you agree to take part in this study. If you have any questions, please do not hesitate to ask me. You should not agree to take part unless you are satisfied about all the procedures involved. If you decide to take part in this study, please complete and sign the informed consent form.

Purpose of the study

The aim of this study is to compare the accuracy of two commonly used interocclusal (bite) registration materials (namely baseplate/ pink wax and an elastomeric material (Polyvinyl Siloxane), using two techniques for direct interocclusal maxillo-mandibular registrations typically used in private practice, and to compare these with hand-articulation.

Length of the study and number of participants

We will be asking Oral Health Sciences students from first to final year to participate, on a purely voluntary basis, and need a minimum of 16 participants. Should you wish to participate I would need one short session with you of 30 minutes to do a brief examination of your mouth. This will include a few short questions regarding your medical and dental

history. This ensures that you do not have known allergies to the materials used and information regarding work that was done in your mouth and whether you have had braces in the past. If the study's inclusion criteria are met, I will take two impressions of your mouth, one of the lower- and one of the upper teeth. Thereafter I will take your bite in 4 different ways. This simply involves closing into a soft material (either wax or elastomeric material) until it sets. After this is done I will use those impressions and bites to do some measurements in the laboratory to analyse and compare. These data will be used without disclosing your personal information in any way, as the models will be coded separately and randomly.

Your rights as a participant in this study

Your participation in this study is entirely voluntary and you can decline to participate at any time, without stating any reason. There are no foreseeable risks to the procedure. Standard diagnostic procedures will be performed, no work will be done on your teeth.

Financial arrangements

There are no financial implications for you and no compensation will be paid. The results of the study will be published to the benefits of students and the dental practitioner.

Ethical approval

This study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (the version most recently amended at the General Assembly of World Medical Association in October 2013) , which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.

Confidentiality

All information obtained during the course of this study, including personal data and research data will be kept strictly confidential.

Data that may be reported in scientific journals will not include any information that identifies any of the participants in this study.

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) CONTACT DETAILS:
Chairperson: Dr. Clement Penny
Email: Clement.Penny@wits.ac.za
Tel: 011 717 2301
Administrators - Ms Zanele Ndlovu/ Mr Rhulani Mkansi/ Mr Lebo Moeng Tel 011 717 2700/2656/1234/1252
Email: HREC-Medical.ResearchOffice@wits.ac.za
STUDY TITLE: A comparison of different methods and materials to establish maximal intercuspal position.

INVESTIGATOR: Dr Herman van den Bergh

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) CONTACT DETAILS:

Chairperson: Clement.Penny@wits.ac.za
Tel: 011 717 2301
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Email: HREC-Medical.ResearchOffice@wits.ac.za

INSTITUTION: School of Oral Health Science, Faculty of Health Sciences, University of the Witwatersrand

Informed Consent

By signing this document,

- I hereby confirm that I have been informed about the nature, conduct, benefits and risks of this study
- I have received, read and understood the above written information (Participant Information Leaflet) regarding this study.
- I am aware that the results of the study, including any personal details will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by Dr van den Bergh.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

Participant

Printed Name: …… Signature ……

Date and time……

Study Doctor

I, Dr Herman van den Bergh, herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Signature …… Date and time ……

APPENDIX 2 Ethical Clearance

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research & Post Graduate Affairs)

TO: Dr HT van den Bergh
School of Oral Health Sciences
Department of Oral Rehabilitation
Medical School
University

E-mail: 2016045@students.wits.ac.za

CC: Supervisor: Professor DG Howes <Dale.Howes@wits.ac.za>
and <HREC-Medical.ResearchOffice@wits.ac.za>

FROM: Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 08/02/2019

REF: *R14/49*

PROTOCOL NO: **M181103** *(This is your ethics application study reference number. Please quote this reference number in all correspondence relating to this study)*

PROJECT TITLE: *A comparison of different methods and materials to establish maximal intercuspal position*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to the Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr HT van den Bergh

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M181103

NAME: (Principal Investigator)	Dr HT van den Bergh
DEPARTMENT:	School of Oral Health Sciences Department of Oral Rehabilitation Medical School University
PROJECT TITLE:	A comparison of different methods and materials to establish maximal intercuspal position
DATE CONSIDERED:	30/11/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professor DG Howes
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	08/02/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date of the meeting when the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore reports and re-certification will be due early in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

13-02-2019
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 3 TurnItIn Report

Filters used:

Exclude Quotes

Exclude Bibliography

Exclude sources of less than 2%.

Report:

