Digital and Clinical Registration Methods in Assessing the Fit of Tooth-Supported Components in Selective Laser Melted Partial Denture Frameworks

by

Sarah Almoheeb Alabdullah

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submitted by Sarah Alabdullah in partial fulfillment of the requirements for

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in Craniofacial Science

Examining Committee:

Dr. Nesrine Mostafa, Assistant Professor, Department of Prosthodontics, UBC.
Supervisor

Dr. Chris Wyatt, Professor, Department of Prosthodontics, UBC.
Supervisory Committee Member

Dr. Alan Hannam, Professor, Department of Oral Health Sciences, UBC.
Supervisory Committee Member

Dr. Ya Shen, Associate Professor, Department of Endodontics, UBC.
Additional Examiner

Additional Supervisory Committee Members:

Dr. Anthony McCullagh, Clinical Associate Professor, Department of Prosthodontics, UBC
Supervisory Committee Member

Abstract

Objectives: Advances in three-dimensional (3D) printing technology have improved the fit of Partial Removable Dental Prostheses (PRDP) frameworks made by Selective Laser Melting (SLM). Conventionally, the gaps between master casts and these PRDPs have been evaluated using clinical replicas. More recently, digital evaluations have provided an alternative way to measure these gaps. The aim of this project was to assess the similarities and differences between digital and conventional methods used to evaluate the fit of SLM PRDP frameworks.

Methods: A printed resin master cast, representing a Kennedy class II mod 2 design with 5 pyramidal markers, was made from a dentiform model. 12 SLM Co-Cr PRDP frameworks were fabricated on this master cast by means of a digital design software. Gaps between the frameworks and the cast were assessed using the clinical replica method by inserting a silicone impression material prior to their seating, then measuring the silicon thickness at each marker with a caliper. Digital models of each framework and the master cast were scanned and registered with CloudCompare software also employed to measure 3D gaps at the 5 reference markers and 3 occlusal rests. The results were analyzed by one-way ANOVA and post-hoc Bonferroni tests.

Results: The mean gap between the frameworks and master cast for clinical registration was 13.96 ± 7 microns. The mean gap for digital registration was 70.76 ± 24 microns. Statistically significant differences among the pyramidal markers were found in both approaches. There were no statistically significant differences among the frameworks. In both cases gap measurements were well below a 300-micron limit considered clinically acceptable.

Conclusion: Both registration methods can help determine whether the fit of an SLM framework is clinically acceptable. Differences in the values they provide are most likely due to unique factors affecting both methods of measurement.

Lay Summary

Partial denture success and longevity relies on their metal framework superstructure fitting and precision that can either be assessed clinically or based on recently suggested digital method of assessment. With three-dimensional (3D) printing and milling; Computer Aided Designing and Computer Aided Manufacturing (CAD/CAM) improved the efficiency of partial denture fabrication. In this study, the fit of CAD/CAM 3D fabrication of partial denture framework was investigated in clinical and digital methods individually; it was concluded that both techniques are effective, and all framework samples showed clinically acceptable fit.

Preface

This research Project was done under the direct supervision of Dr. Nesrine Mostafa. The committee members included Dr. Christopher Wyatt, Dr. Alan Hannam, And Dr. Anthony McCullagh.

This in-vitro study involved a dentiform preparation, impression, and framework design that were done by the Author Dr. Sarah Alabdullah. Master Dental solutions Ltd. in Vancouver, Canada scanned and printed the master resin model. The scan of the model was surveyed and designed at A & P Dentallab in Victoria, Canada. The file was then sent to 3DRPD In Montreal, Canada, who fabricated all SLM frameworks. The samples were subsequently returned to A & P Dentallab for final adjustment, followed by digital scanning of the Frameworks at Integral Dental lab Vancouver, Canada. Digital registration protocol on CloudCompare was developed with the collaboration of the author Dr. Sarah Alabdullah and Dr. Alan Hannam. Dr. Alabdullah did all subsequent measurements, analysis, and data collection independently. And the statistical analysis was done by Dr. Jolanta Aleksejuniene.

This study did not require an approval from the UBC Research Ethics Board as it did not involve the use of any human subjects, animals or biohazardous materials.

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List of Symbols

%	Percentage
μm	Micron/Micrometer
x	Magnification
±	Plus or minus
&	And
#	Number
<	Less than
>	More than
γ	Gamma coefficient

List of Abbreviations

2D	Two Dimensional
3D	Three Dimensional
3DP	Three Dimensional Printing
Co-Cr	Cobalt Chromium
CAD/CAM	Computer Aided Design/Computer Aided Manufacturing
FDM	Fused Deposition Modeling
GPL	General Public license
ICP	Iterative Closest Point
ICC	Interclass Correlation
ISO	International Organization for Standardization
MC	Major Connector
Micro-CT	Micro Computed Tomography
Mm	Millimeter
PEEK	Polyether Ether Ketone
RP	Rapid Prototyping
PRDP	Partial Removable Dental Prosthesis
PVS	Polyvinyl Siloxane
RMS	Root Mean Square
SD	Standard deviation
STL	Standard Tessellation Language
SLA	Stereolithography
SLS	Selective Laser Sintering

SLM	Selective Laser Melting
SS	Stainless Steel

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Dedication

To my family for always having my back, especially my sisters Areej and Hanan, for continuously standing by my side, your words of encouragement have been my rock throughout life.

To my husband, who has shown me support, patience, and kindness during the toughest of circumstance even in my wildest ambition.

And finally, to my parents Thuraya Ossabi and Dr. Almoheeb Alabdullah, words can never describe how grateful I am to be your daughter. Your constant love, support, and prayers can get me through any endeavor.

Mom, thank you for teaching me kindness, humility, and generosity. And Dad, thank you for inspiring my confidence, independence, and hard work; I am the person I am today because of you.

To all, the hardest part was being away from you. Despite that, I hope I have fulfilled my promise of making you all proud.

Chapter 1: Introduction

1.1 PRDP Overview

Due to the increase in the aging population, the demand for dental treatment is increasing (1). Elderly patients with missing teeth might not be able to have implant-retained prothesis due to factors such as cost, health problems, or personal preference (2). Therefore, Partial Removable Dental Prosthesis (PRDP) are still a treatment of choice for many patients; with a current utilization of 13% (3) and a predicted future utilization of more than 20% (4). This increasing demand for PRDP and a scarcity of dental technicians to create these prostheses has opened the opportunity to develop digital technology and increase production efficiency. Such technology has recently become available by having chairside Computer Aided Design / Computer Aided Manufacturing (CAD/CAM) systems that are capable of providing dental restoration in less time, with reduced human errors and cross contamination (5).

The emergence of digital dentistry has offered precision and speed to the fabrication of dental prostheses. With fixed prosthesis showing adequate clinical accuracy, less chair side time, ease of fabrication, and reduced material cost as compared to conventional method of fabrication (6). Still, further research is needed to evaluate the viability of PRDP solutions created by these advances in digital technology.

1.2 PRDPs

Since the beginning of the 1900s, Partial Removable Dental Prostheses emerged as a prosthetic solution for partially edentulous patients. PRDP is defined as a prosthetic treatment option that

restores and replaces the missing oral structures to reproduce or preserve function, comfort, and esthetics using removable artificial components (7). They are commonly classified according to Kennedy's classification system based on the relation between the edentulous ridge and the remaining teeth (8). They can also be classified according to Bailyn's system that is founded on the type of support they attain; either tooth-supported, tissue-supported, or a combination of tooth and tissue-support (8). In tooth-supported or tooth and tissue-supported partial dentures, the abutment tooth structure provides vertical functional support via the rest seat component, while guide planes leaning on the abutment wall can also prevent dislodgment of the denture toward the edentulous ridge (7). The same abutment can additionally provide retention by means of direct retainers that are subdivided to retentive and reciprocal clasps depending on their position with the abutment's height of contour (9). On the other hand, tissue-supported components such as the denture base coverage and extension can provide support to the prosthesis by resting on primary bearing areas that can withstand the occlusal load during function (7). The precision in capturing and planning this componentry can be case and provider dependent, and it is detrimental to treatment longevity.

One of the commonly known factors that can affect treatment success in these prosthetic solutions is proper fit (10). With authors suggesting that one of the most common causes of partial denture wearer's dissatisfaction in conventional PRDPs is the poor fitting of the prosthesis (11); with a large number of PRDPs end up not being used due to their associated functional concerns (12). Therefore, it is up to the clinician to ensure that all components of the PRDP are adequate, and are assessed for overall fit, retention, stability, and support prior to prosthesis delivery in order to maintain periodontal and abutment tissue health (7).

1.2.1 PRDP Fabrication

From a clinical standpoint, PRDPs can be divided into two types depending on the duration of use: interim and definitive prostheses. Definitive prostheses typically involving metal casting, and interim prostheses are usually fabricated using acrylic resin base material.

Metal frameworks that are frequently made from cobalt chromium alloys, are used as a definitive prosthesis due to their durability, lightweight, cleanliness, and resistance to fracture; leading them to require more appointments, and thus imposing a higher cost of treatment (7). On the other hand, acrylic resin PRDPs are used mainly as an interim solution due to their reduced tooth support, longevity, and stability (7). Therefore, it is important to know the method of PRDP fabrication as it can influence the fit of these prosthetic solutions.

1.2.1.1 Conventional Fabrication of Metal Cast PRDPs

After diagnosis and treatment planning of a partially edentulous case for definitive prosthesis, preliminary impressions are taken to fabricate diagnostic models (13). Those models are used for abutment and undercut evaluation, design and framework options, and the fabrication of custom trays. Once abutment teeth are prepared, a final impression using the custom tray is taken (13). Followed by the master cast pouring and duplication to a refractory cast, that is used for final surveying, undercut block-out, wax pattern design, spruing, and investment to facilitate the burn-out or lost wax technique (14). Finally, the molten metal of choice is flowed under pressure into the investment mold and eventually resulting in a metal framework casting (14).

That framework is then finished and polished for intraoral try-in to confirm the framework fit prior to teeth set-up before the application of heat or cold cure acrylic for processing (7).

1.2.2 Errors in Conventional PRDP Casting

According to a three-part review of 243 potential errors possible in the fabrication of partial removable dental prosthesis, every step that was explained in the method of denture fabrication is vital; Diagnosis, treatment planning, mouth preparation, framework design, laboratory procedures, type of denture support, occlusion, and patient compliance all contribute to the success of the final prosthesis (15, 16).

Below, are examples of errors that can occur during the fabrication of a conventional metal alloy casting and their outcomes (15-17):

1. Improper guiding planes that can affect prosthesis stability.
2. Excessive depth of cast beading that can lead to tissue inflammation.
3. Incorrect block-out of undercuts that can modify the seating of the framework.
4. Inadequate relief areas that can lead to impingement of soft tissues.
5. Incorrect location of the wax sprue or size of the wax pattern that can cause internal deformation or porosity in the framework.

Some of these errors in conventional fabrication methods of PRDP could be minimized with CAD/CAM technology.

1.3 Digital Technology in Prosthodontics

Digital technology has grown significantly in the last decade (18). With CAD/CAM fabrication of dental prosthesis it can be divided into three elements: Data acquisition, data processing, and data manufacturing (19). And each one of those elements plays a part of what is frequently described in the literature as a digital workflow.

Data acquisition is when a physical object is captured and conveyed into a digital numerical file, that can be achieved using an intraoral or benchtop scan of the patient's dentition or replicated model respectively (19). Data processing and design is when those acquired digital files are being evaluated, manipulated, or visualized in a digital processing software (19). And manufacturing is when the prosthesis is constructed using different technologies including Rapid Prototyping (RP) that can be further defined into two categories: Subtractive manufacturing, and additive manufacturing (19-21).

1.3.1 Subtractive Manufacturing

It is the process of milling or cutting the desired material block using machine operated drills and saws, and although this method of fabrication can be highly accurate, limitations arise in material waste after milling (19). Which not only depicts economic and environmental drawbacks, but also imposes a difficulty in fine details production due to their dependency on the offered bur diameters (21).

1.3.2 Additive manufacturing

This is also known as “layered manufacturing” or in layman terms “3D printing” (20). It can formulate the desired prosthesis using the assembly of material products with reduced waste and finer details (19), which was the main shortcoming of subtractive manufacturing. And although some publications suggested that its precision is higher than subtractive manufacturing (22), further depth needs to be invested into possible differences related to the material involved, and its specific method of additive fabrication.

Furthermore, there are 5 types of Additive manufacturing in the literature (20):

1) Stereolithography (SLA)
2) Three-dimensional printing (3DP)
3) Selective laser sintering (SLS)
4) Selective laser melting (SLM)
5) Fused deposition modeling (FDM) (20).

The description of each method is extensive, but to summarize these methods we can define them in a comparative manor as the following (20):

1) **Stereolithography** uses building platforms, which are added layer by layer through a liquid resin that is cured then bonded via ultraviolet laser.

2) **Inject based system** or 3D printing, uses a material powder and combines it with a liquid adhesive layer by layer that is bonded until the final object is formed.

3) **Selective laser sintering** is one of the methods used to fabricate metal frameworks. It uses a 3D model that is fused with the addition of material powder, that is then distributed layer by layer via laser technology compression.

4) **Selective laser melting** is also one of the methods in metal fabrication. It is a subcategory of SLS; it melts then fuses metal powders together in layers.

5) **Fused deposition modeling** uses a thermoplastic material injection with a controlled heat depositing in layers until the material solidifies.

1.4 Digital PRDPs

Apart from health care engineering, laser based manufacturing has been broadly used in commercial production such as automotive, aerospace, and aircraft that require complex metal geometry to be constructed at a high quality with a reasonable cost for mass operations (23). And although the technology was initially involved with prototype fabrication, it had quickly evolved into final product fabrication, which showed a fundamental advantage in the medical field for producing customized patient specific end-use products that require fine details. For example, digital fabrication in complete dentures can be done using both subtractive and additive pathways, showing acceptable accuracy when compared to the conventional methods of denture fabrication (24). On the other hand, definitive PRDPs require metal fabrication under subtractive methods can

be more complex due to their manufacturing challenges, processing errors, damage to machine drills while cutting metal frameworks, material waste, and high cost of equipment (25, 26). Nonetheless, the emergence of additive manufacturing in PRDP production has overcome some of these drawbacks by means of end-use components that are manufactured in a layer-by-layer manner through coalescing the metal powder, without the need for cutting tools. The technology also reduces material waste and potential drill damages associated with metal alloy fabrication (25).

Through the use of CAD/CAM technology, implant metal framework fabrication has also improved since using titanium metal that is milled under subtractive manufacturing which has displayed adequate precision when compared to titanium metal burn-out casting (27). However, Cobalt-Chromium (Co-Cr) frameworks for implant superstructures are often conventionally cast. Accordingly, when considering metal alloys for PRDP frameworks, there has been a previous recommendation on which alloys to consider; with authors suggesting that Co-Cr is a more suitable material of choice in definitive PRDP solutions than titanium solutions (28). And a few others even suggest avoiding the use of titanium in definitive prostheses due to their associated risk of hypersensitivity, in addition to reduced mechanical properties such as lower corrosion resistance and tissue biocompatibility (29, 30). This may explain why Cobalt-chromium is the main focus of recent improvements in digital methods of metal and framework fabrication using laser based additive manufacturing such as selective laser melting (SLM) or selective laser sintering (SLS) (19).

1.5 Mechanical Properties

According to the literature, the mechanical characteristics of SLS and SLM manufacturing of Co-Cr alloy showed superior properties when compared to conventionally cast Co-Cr (31, 32). Also agreeing is a recent study by Alageel et al that investigated two CAD/CAM metal framework manufacturing methods and compared it to conventional casting (32). The author investigated the material's internal components and grain size and concluded that frameworks produced by Rapid Prototyping had higher homogeneity leading to a higher fatigue resistance (32).

1.5.1 Accuracy

Authors that have investigated SLS suggested that it showed a higher accuracy and reproducibility when compared to conventionally cast PRDP frameworks (33). Other publications that assessed both laser sintering and laser melting methods in PRDPs, determined that digitally fabricated metal frameworks exhibited an accuracy that is eight times higher than the accuracy in conventionally cast frameworks (32).

1.5.2 Elastic modulus

In prosthodontics, an elastic modulus ratio is important for the maintenance of abutment teeth; the lower the elastic modulus of the alloy, the closer it gets to the elastic modulus of natural dentition causing less damage to the abutment involved in tooth-supported PRDPs. The literature demonstrates that selectively laser sintered alloys had a significantly lower elastic modulus than the conventional cast and selectively laser melted alloys (32).

1.5.3 Flexural bending, strength & toughness

The results from an investigation using a three-point bending test until failure showed that the bending yield of strength of laser sintered and laser melted alloys were significantly superior to cast alloys (32). Laser sintered alloys were also significantly higher in flexural strength and toughness when compared to cast and laser melted alloys. This is essential in PRDP frameworks since having a higher bending strength and toughness can reduce the risk of distortion failures (32).

1.5.4 Fatigue strength and resistance

By means of stress cycle testing after 6000 rotations simulating 5 years of clinical use, both selective laser sintering and laser melting showed a higher resistance to fatigue than conventionally cast alloys (32). Other recent papers that have compared fatigue strength in selective laser melting to cast cobalt-chromium PRDPs; concluded that SLM displayed a higher fatigue resistance (24, 34, 35). With one of the publications associating these improved mechanical properties to the refined microstructure related to their additive manufacturing method (35).

1.5.5 Micro-hardness & Porosities

Hardness and porosity can affect overall material use and longevity. Alageel et al used Vickers micro-hardness indenter and compared SLS, SLM, and cast frameworks to tooth enamel, the study showed that both SLS and SLM were significantly higher than conventionally cast alloys (32). Also, all metal frameworks were harder than tooth enamel, this fact needs to be kept in mind since

framework components can damage abutment teeth if clasp assembly and position were not planned properly (32).

Furthermore, when Porosities were evaluated using a mathematical formula that divides the material's weight by its volume, followed by an examination under Micro-CT; both laser sintered and laser melted alloys showed higher porosities than conventional casting, with laser sintering slightly higher than laser melted alloys (32). That has been explained in the literature to be due to poor hatch spacing; which can be controlled by optimizing the additive manufacturing parameters such as laser power, scanning speed, hatch spacing, and layer thickness (36, 37).

1.5.6 Biocompatibility & Corrosion

In a study evaluating alloy biocompatibility between selective laser sintered frameworks and conventionally cast frameworks, the results showed that both alloys were equivalent in host reaction response (32). Another report on selective laser melted alloy when compared to conventional, resulted in both of them being safe and biocompatible with human tissue causing no cytotoxicity (38). Also reported was a comparison of corrosive factors between rapid manufacturing and conventional casting of Co-Cr, authors noted that the rapid manufacturing alloy produced a safe value of corrosion resistance, and even performed better than conventionally cast alloys (39).

1.6 Methods of Assessing Fit in PRDP Frameworks

There is a remarkable shortage in PRDP literature, with many concepts that are based on inconclusive evidence or routine clinical practice (40). Overall, previous measures in assessing PRDP presented the importance of calculating the gap between the framework and its reference (26, 41). And after a full review on Medline, below is a summary of the three main methods of PRDP gap measurement and assessment:

- ***Visual inspection protocol***

The most qualitative technique of assessment in the clinical evaluation method. Typically, with the aid of a clinical explorer, clinicians and researchers may rely on their experience with a set criteria from the literature to assess the adaptation and fit of PRDPs (11). Most publications that relied on clinical assessment had calibrated investigators assessing intraorally, on the master cast, or both (11, 42-44). The main classical paper for clinical criteria was by Frank et al, where the authors established the following assessment protocol:

- All rests need to be well-seated.
- All rigid elements should touch the remaining teeth.
- The major connector should not impinge on the underlying soft tissue
- No visible relief space larger than 1 millimeter (mm) (11, 45).

- ***Clinical replica technique***

A measurable clinical method, where silicone registration material is applied between the tested framework and the cast or tissue surface (46-48). The replica could be sectioned or left on the

framework, then the material thickness is measured with an electronic caliper, digital camera, light digitizer, or stereomicroscope with different magnifications **(Table 2)** (46-48).

- ***Digital registration***

And finally, the most recent method is when the referencing model and metal framework are digitally scanned separately producing a Standard Tessellation Language (STL) file, followed by the evaluation of that STL file under a metrology software where both STL files are superimposed to color map the distanced gap between both objects (33, 45, 49).

1.6.1 Meshes and digital registration

Digital registration and simulation are familiar procedures in the scientific literature for measuring the deviational changes between two entities. However, it is a fairly recent technique to the dental field in which it calculates the gap between two scanned corresponding objects using STL files in order to assess the virtual alignment and fit in various prosthetic solutions (50).

And to begin a digital registration method, one must first start by scanning the physical object using a digital or industrial scanner into a 3-dimensional (3D) computer graphic representation file. Those files could be processed as point clouds; meaning a set of unorganized 3D points, or it could be converted from a point cloud into a polygon mesh; where each mesh is a collection of vertices and triangular faces that digitally expresses the virtual 3D shape of the scanned object (51, 52). In multidimensional object representation, a mesh can also provide the side information of the object, this helps in determining what is inside and outside of a given mesh by viewing their so

called normals, these normals are later represented as signed values when the distance measurements are computed between the objects (51).

Also important is the type of digital scanner used in data acquisition during digital registration; since the greater the scanner resolution and accuracy, the higher the 3D point count it obtained. This point count number will affect the distances between the mesh vertices, where smaller point counts mean sparcer vertices. Which will result in a mesh with a low density and a reduced representation of the scanned object leading to inaccuracies in the computed distances during digital registration (51). Making the method of data acquisition and output a key element in accurate object detailing and digital modeling (53).

Another factor that can affect registration is scanning outliers. When capturing an object's scanned data, a certain level of noise is retained, making the scanning software method in post processing of that noise a significant step to avoid miscalculating relevant information (54). Also, metrology software uses the nearest representative points in both parallel objects, and when registering that raw data if these cloud points are too far from their corresponding paired point due to a scanning error, the entire registration file will be affected (55). Thus, cropping clinically relevant components to reduce file size and focus their specific distance computation yields a more accurate registration method (54).

An additional aspect to consider, is that this software will generally analyze and compute digital data based on two methods; either cloud-to-cloud distances, or cloud-to-mesh distances. With cloud-to-cloud registration, the software assumes that both objects are of flat surfaces and will

measure the virtual points between them (51). However, in cloud-to-mesh registration the reference file is a flat surface in point clouds and only the compared file is converted into a 3D mesh, and so it will measure the distance from a point to a triangle vertex (51). That can be more suitable for geometrical shapes that have outer and inner surfaces such as the case in dental restorations. Therefore, a recommendation was made that the cloud-to-mesh approach would show less deviation and a more accurate distance measurement between files especially with 3-dimensional geometrical shapes (56).

When the calculated gap readings appear in signed values, studies have described it before as proximity and deviation of both files to each other, revealing tight areas of fit (45). However, software developers mention that signed values represent a directional reading; such as the direction of the compared file to its reference when superimposing both objects in the virtual field (51). This is important to be aware of since one statement indicates that the larger the numerical value the more distant the files are, while the other suggests observing the numerical value irrelative of the sign if the gap measurement is the outcome. And in order to overcome this issue, some metrology software allow you to compute the distances without a signed value analysis, or by using a mathematical formula to equalize the sign.

And finally, several studies stated that the “best fit algorithm” or “fine alignment” was used when digitally registering a mesh to a reference file (33, 45, 53). And although each software uses a different analysis method when attempting an overlap of corresponding files of non-similar objects, it is better to roughly approximate the files manually prior to final alignment in order to avoid an inverted or faulty registration process (56, 57).

1.6.2 Gap measurements from the literature

Historically, the most frequently used technique to assess the accuracy and fit of partial dentures in the literature is by evaluating the average gap between the prosthesis and the master model, which is usually done using a silicone impression material or replica technique with an electronic caliper (41). Recently, authors have suggested the reliability of the digital superimposition and registration technique that can preserve the sample and quantify the gap with a reduced marginal error (33). And with different componentry of PRDP, it is sensible to anticipate a variation in readings **(Table 1).** Stern et al detected that the average gap thickness between the occlusal rest and the rest seat was 69 to 387 Microns (μm) in conventional partial dentures (58). Another author Dunham et al in a clinical study reported a gap of 193 ± 203 μm for investment casting frameworks in conventional PRDPs, giving a range up to 828 μm to determine clinical acceptability (41).

A 2018 digital analysis by Soltanzadeh et al divided PRDP gap readings into three categories; any reading from 0 – 50 μm was considered a tight fit, anything between 51 – 311 μm was an acceptable fit, and anything larger than 311 microns was theoretically not clinically acceptable (45) **(Table 2)**. And even though the authors noted that the conventional cast framework had a better fit than the selective laser melting method, they concluded that all sample comparisons between both techniques of fabrication were within the acceptable range (45). Yet, another study conducted by Forrester et al that compared three different types of additive manufacturing to conventionally cast frameworks, determined that SLM and resin 3D printing showed more accurate results than a fully conventional metal framework casting, with a recommendation to continue investigating these methods of fabrication to fully understand their capability (40) **(Table 3)**.

1.7 Rational

Overall, each technique of assessment exhibits advantages and disadvantages. With visual and clinical replica techniques although being relatively simple, it can occasionally result in qualitative data that is technique sensitive and subjective to the operator. Which explains the diverse ratio of gap measurements between studies **(Table 1)**. And while a laborious technique such as digital registration could be considered a quantitative approach, an argument could be made on whether that virtual registration is a correct representation of the clinical registration. leading to publications that compared this new technique of assessment to the replica technique in simple fixed prosthesis investigation (59, 60).

However, partial removable dental prosthesis involves broader guidelines in order to occupy tooth and tissue supported structures simultaneously, which can explain the absence of a similar comparison in removable prosthodontics. Thus, the rational for this study was to assess the applicability of digital registration in relation to conventional methods of clinical registration and observe their behavior and associated gap readings.

Table 1: Methods of assessment in conventional partial dentures

Author	Study type	Sample size	Design	Methods	Measuring device	Results & Gap measurement
Dunham et al 2006 (41)	In vivo	50 clasp assemblies	Not mentioned	Assessing accuracy of fit using 3 measurement point by PVS in clasps & rest seats	Stereomicroscope & electronic caliper in micrometers	Rest/seat 193-203 µm, tooth/tissue framework 136-160 µm & tooth/supported framework had 220-230 µm. 76% of the rests did not contact their designated surfaces
Anan et al 2015 (61)	In vitro	30 casts, 2 groups 15 each	Kennedy class III mod 1 mandibular	Compared fit of 2 different metal framework fabrication methods by measuring 3 points on each side between framework & alveolar ridge using a camera	Digital camera at 16.5 X graphics editing (Adobe). Total of 180 measurement in each framework in mm ruler	Gap measurement 159-153 µm, noted a smaller gap and better fit in in light cure modeling technique than conventional.
Diwan et al 1997 (62)	In vitro	42 frameworks	Kennedy class II mod 1. anterior palatal strap & modified palatal plate	Assessing accuracy of fit after 3 different storing durations. Measured 3-4 points using acrylic resin under metal Framework.	Using micrometer electronic caliber average of 4 readings	Gaps were ranging from 0.56-0.64 mm. Both design groups, exhibited deterioration in fit of major connectors with increased storage time gap discrepancies were larger towards the Middle of the palate.
Yung-tsung Hsu 2016 (43)	Case report	1 patient	Kennedy class II mandibular	A suggested technique to assess fit of framework intraorally and on the master cast using impression material	Visual inspection examine the thickness of the impression material at different locations; between the denture base and the tissue	Not applicable
Gowri et al 2009 (63)	In vitro	24 casts 12 test & 12 control	Kennedy class III mod 1 maxillary strap major connector	Assessed the effect of 4 anchorage holes in the cast on the fit of metal framework major connectors at 2 measurement points anteriorly (A) and posteriorly (P)	Profile projector x10 magnification	Better overall fit at anchorage test group. control group exhibited a greater gap discrepancy (0.44 ± 0.20 mm) than for the test group at point A (0.16 ± 0.10 mm). Larger gaps posteriorly at Point P for both specimens in the control group (0.65 ± 0.10 mm) than the test group (0.42 ± 0.24 mm)

Table 2: Methods of assessment in digitally fabricated partial dentures

Author	Study type	Sample size	Testing location	Design	Jaw	Investigation	Surveying	Technology	Device
Ye et al 2017 (48)	In vivo	15 (6 men & 9 women)	Framework	Kennedy class I, II, III, IV	Didn't specify	Visual inspection and replica technique	Digital design & survey	Selective laser melting	Camera & stereomicroscope
Gan et al 2018 (46)	In vivo	24 patients	Framework	N/A dentate, palatal plate MC	Maxilla	Visual inspection followed by replica	Digital design & survey	Poly-jet milling of clear resin	Stereomicroscope X30
Williams & Bibb 2006 (44)	In vivo	1 patient 2 casts	Framework	Kennedy class I	Mandible	Visual on the cast & patient	Digital design & survey	Selective laser melting	No device only clinical assessment
Lee et al 2017 (47)	In vivo	10 participants	Framework	Kennedy class I, II, III	Both	Replica technique	Digital design & survey	Rapid prototyping with resin	Stereomicroscope X130 & imaging program
Arnold et al 2018 (26)	In vitro	48 (4 groups, 12 in each)	Clasps	Kennedy class III mod. 1 palatal strap	Maxilla	Visual inspection	Digital design & survey	Wax inject, selective laser melting, wax milling, resin milling	Light microscopy X560
Soltanzadeh et al 2018 (45)	In vitro	40 samples (4 groups, 10 each)	Framework	Kennedy class III mod. 1	Maxilla	Digital comprehensive software	Conventional & digital design & survey	Rapid prototyping & casting,	Geomagic software 2014
Tregerman et al 2019 (42)	In vivo	27 samples (9 patients, 3 each)	Framework	Kennedy class I, II, III, & IV	Maxilla & Mandible	Visual inspection and survey	Conventional & digital design & survey	Conventional casting & selective laser melting	No device only clinical assessment
Chen et al 2019 (49)	In vitro	15 (5 groups, 3 in each)	Framework	Kennedy class I, II, III, & IV	Maxilla	Digital comprehensive software	Conventional & digital design & survey	Conventional casting & selective laser melting	Using PVS & Geomagic software 2012
Tasaka et al 2019 (33)	In vitro	2 frameworks	Framework	Kennedy class II mod. 1	Mandible	Digital comprehensive software	Digital design & survey	Conventional casting & selective laser sintering	GOM inspect software

Table 3: Gap measurements of digitally fabricated partial dentures

Author	Measurement location	Gap measurements & results	Level of evidence
Ye et al 2017 (48)	9 measurements of buccal, lingual and middle. An average of 3 points each	SLM frameworks showed a gap of 174 ± 117 µm Conventional frameworks showed a 108 ± 84 µm. gap differences were statistically significant	5
Gan et al 2018 (46)	9 landmarks, middle anterior & posterior. As well as the middle, left & right	Major connectors gaps were between 159.87- 577.99 µm in intra-oral category. And 120.83-536.17 µm in the extra-oral category.	5
Williams & Bibb 2006 (44)	Overall quality of fit based on clinical practice	Subjective evaluation of excellent fit intraorally SLM of SS suffered distortion of the clasps on the cast, no clinical try-in Excellent fitting of SLM of Co-Cr on the cast and patient	5
Lee et al 2017 (47)	Total of 348 in all framework components	Occlusal rests gaps 249.27 ±134.84 µm, clasps showed a gap of 162.33 ±131.2 µm, minor connector gaps 125.11 ±83.89 µm, major connector gaps 380.00 ±111.75 µm, and edentulous area gaps 328.30 ±264.73 µm	5
Arnold et al 2018 (26)	60 points measured from canine clasps (3 vertical & 3 horizontal). 50 points from molar clasps (2 vertical & 3 horizontal)	Conventional casting gaps 133 ±59 µm horizontally & 74 ±25 µm vertically Direct milling of PEEK gaps 43 ±23 µm horizontal & 38 ±21 µm vertically Direct resin Rapid Prototyping gaps 323 ±188 mm horizontal & 112 ±60 µm vertically Direct SLM gaps 365 ±205 µm horizontal & 363 ±133 mm vertically	5
Soltanzadeh et al 2018 (45)	8 locations per framework along rests, major connector, proximal plates, retentive and reciprocal arms	Conventional frameworks had better fit than digitally fabricated frameworks; however, both are clinically acceptable (50-311 µm) Tight fit (<50 µm gap) noted in rests and reciprocal arms in all groups Weakest fit was seen in the anterior portion of major connector in digitally fabricated frameworks	5
Tregerman et al 2019 (42)	Established a clinical criterion for acceptance of fit, corresponded intraoral evaluation with the master cast evaluation	The digital of framework method showed better fit than the analog method. However, the analog method showed better fit than the combination of digital-analog method of framework fabrication	5
Chen et al 2019 (49)	Assessed the soft tissue adaptation of PVS material measure every 0.5 mm of the major connector	Acceptable fit was noted in both methods, with an average gap of 0.15 to 0.33 mm for the SLM-printed frameworks and 0.15 to 0.28 mm for the cast frameworks. Maximum gaps were 0.29 to 0.73 mm for the SLM-printed frameworks and 0.32 to 0.63 mm for the cast frameworks	5
Tasaka et al 2019 (33)	Total of 22 measurement points were taken, to include all components of the frameworks	The distance range with the cast framework was 0.1850 ± 0.138 mm to 0.352 ± 0.143 mm. And for the SLS framework around 0.166 ± 0.009 to 0.123 ± 0.009 mm. The accuracy of fit depended on the component being examined. However, less discrepancy was found in the SLS framework, suggesting superior fabrication accuracy and reproducibility with SLS	5

1.8 Objectives

The aim of the project was to assess the similarities and differences between digital and clinical registration methods in evaluating the fit of partial denture metal frameworks.

1.8.1 Hypotheses

Null hypothesis:

There are similarities between digital and clinical registration methods in evaluating the fit of partial denture metal frameworks.

Alternative hypothesis:

There are differences between digital and clinical registration methods in evaluating the fit of partial denture metal frameworks.

1.9 Initial Trials

A few pilot experiments were initiated to evaluate the feasibility of different methodologies in assessing PRDP metal frameworks. Using a mandibular cast with teeth #34, 35, 37, 32, 31, 44, 45, and 46 removed and the associated cast partial removable dental prosthesis framework from the PRDP module at the University of British Columbia was used. The stone model was scanned using a 3-Shape benchtop scanner. A Dreve resin model was printed, and the framework was adjusted to fit the resin model. Thus, the pilot sample was fabricated.

1.9.1 Micro CT

The first attempt was made using a microcomputed tomography (micro-CT), as it is considered a non-destructive method that allows a three-dimensional evaluation of the sample (64). However, PRDP gap measurements between the framework and the model were not possible due to overall beam hardening when observing coronal cross sections (**Figure 1),** and scattered metal artifacts that overlapped the desired area of investigation (**Figure 2).**

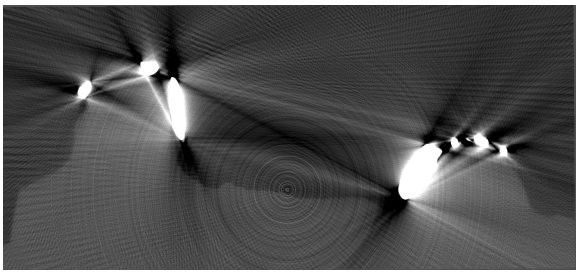

Figure 1: Micro CT image with beam hardening in a coronal cross section of the pilot sample.

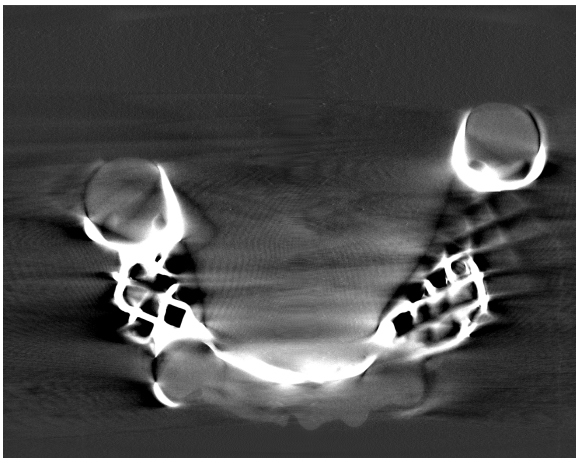

Figure 2: Micro CT image with metal artifacts in an transverse view of the pilot sample.

1.9.2 Triple scan

The second attempt was made based on a recently suggested technique labeled as triple scan by Holst et al; according to the author, the procedure relies on point cloud registration of two objects using 3 digital scans (50). Leading to a distance measurement that is reliable, accurate, and repeatable with a quantifiable method that can exhibit a factual 3-dimensional registration (50). The approach was initially modified to utilize the 3-Shape Anatomy Design software, which is a CAD/CAM solution that aids in visualization, design, and fabrication of dental restorative solutions.

Using a 3-Shape intraoral scanner, both cameo and intaglio surfaces of the framework were captured producing a Standard Tessellation Language (STL) file. Followed by a benchtop scan of the model resulting in an additional STL file and inserting both files into the designing software. Continued with a 3rd scan that was acquired by aligning both scans manually using 3 selected points as references to simulate a bite scan arrangement; where the software proceeds by evaluating

all three scans resulting in a cross-sectional numerical data that was calculated based on the final alignment in order to measure the gap between the framework and the model. However, although the technique showed simplicity that included readily available equipment, a noticeable limitation of this method is that it can only generate a 2-dimensional (2D) evaluation of the required gap measurement. Making it difficult to differentiate between buccolingual dimensions and mainly viewing anteroposterior gap distances between the framework and the referencing model (**Figure 3)**.

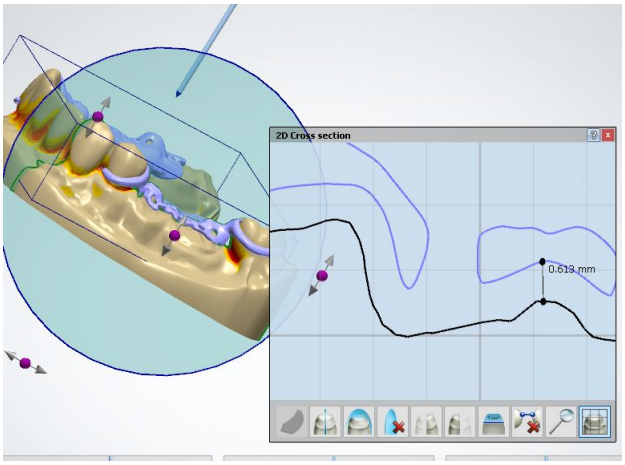

Figure 3: 3-Shape designing software alignment, note the 2D cross sectional gap measurement between the framework and the model.

Afterwards, it was agreed that a 3-dimensional sample evaluation would be a superior assessment method of PRDPs following a similar approach that has been used with dental prosthesis assessment (45, 50).

To attempt this analysis, digital scanners and metrology software were required. Therefore, a 3-Shape scanner and CloudCompare (CloudCompare, version 2.10, GPL) were used, which is a point cloud and mesh processing software that is able to align two STL files to evaluate the distance between them. However, due to the complexity of a PRDP design the initial trials resulted in the collision of both files causing them to overlap. Which was speculated to be caused by several points attempting to align the meshes leading to negative values, making it difficult to assess the gap between the framework and the model (**Figure 4).**

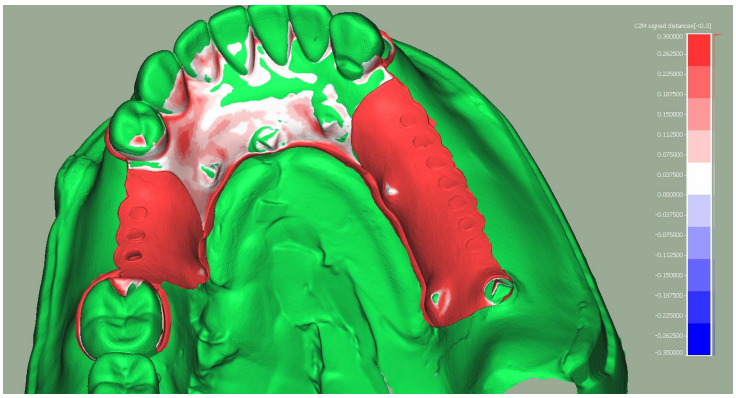

Figure 4: CloudCompare pilot alignment, note the anterior framework and reference point collision with the model.

To overcome that issue, several tactics were tried in order to understand that phenomena that eventually resolved by segmenting the paired reference points before the attempted alignment method. That was done using Meshmixer (Meshmixer, Autodesk, Inc); a 3-dimensional prototype with a high-resolution designing tool for meshes and prototype evaluation. This final alignment approach of using designated refence points on the framework to their counterparts on the model prior to the full framework resulted in an improved overall STL file alignment, leading to the method that was used for this experiment.

Chapter 2: Materials and Methods

2.1 Sample Size

Based on previous studies (49, 63), and the pilot study data and initial trials; a sample size calculation was done that resulted in a required 10 samples in order to detect a significant mean difference of 50 μm between the groups, with a standard deviation of 20 μm. Therefore, the power analysis was set with γ at 0.05 to allow for 80% power. Leading to a total sample size of 12 selective laser melting frameworks that were included as test subjects in this project.

2.1.1 Denture design

A partially edentulous mandibular dentiform (Kilgore international, INC) was used with missing teeth #36, 35, 32, 44, 45, 46, and 47. And based on the partially edentulous status, the Dentiform was classified as Kennedy class II modification 1. On the dentiform, abutment tooth #37 was prepared with a mesial occlusal rest seat, a mesial guiding plane, for a circumferential Aker clasp engaging the distal undercut. And abutment tooth #34 was prepared with a distal occlusal rest seat, a distal guiding plane, for an Aker clasp engaging the mesial undercut. And finally tooth #43 with a cingulum rest seat on the lingual surface, a distal guiding plane, for an Aker clasp engaging the mesial undercut. The framework design was developed to simulate restoring the missing teeth using a lingual plate major connector, a mesh framework in the edentulous areas of #36, 35, 32, 44, 45, 46, and #47 with a tissue stop that was added to the posterior free end saddle on the mandibular right edentulous area. Finally, nail heads were added to simulate future missing tooth replacement in sites #36, 35, 31, and 44 **(Figure 6)**.

2.2 Impressions & Master Cast

A primary alginate impression was taken using a stock tray (CEO spacer trays, GC America Inc, USA) and poured into type 3 ISO stone by Whip Mix (Whip Mix corporation, Louisville, USA) according to the manufacturer's instructions. The stone model excess was trimmed, and a line was drawn all around the borders of the diagnostic model to mark a line 2 mm shorter than the oral vestibule, highlighting the extensions of the custom tray. Then, using a flame torch to soften pink baseplate wax (COLTENE Group, Switzerland), one layer was added to cover all tissue support surfaces, and two layers were applied to cover all abutments and remaining teeth on the diagnostic model. Followed by mixing and adapting Ivolen; a self-curing tray material (SR Ivolen, Ivoclar Vivadent, ON, Canada) to the previously marked line. After self-curing for 35 minutes, the custom tray was removed from the diagnostic model, where adjustments were made using a straight handpiece and an acrylic bur to smoothen the peripheries of the custom tray, and the wax spacer was afterwards removed from the tray in preparation for the final impression (7).

A thin coat of lubricant (COE-Soft, GC America Inc) was applied on the dentiform all around the soft tissue area; to simulate oral moisture conditions and avoid impression distortion during removal, and an adhesive brush was used to apply a uniform coat of tray adhesive (3M ESPE VPS, Germany) on the intaglio surface of the custom tray. Leaving the tray to dry for 15 minutes based on the manufacturer's instructions.

Using a dispensing gun, a light-body silicone impression material (Aquasil Ultra+, DENTSPLY Sirona, NC, USA) a type of an addition reaction silicone was extruded to confirm even material flow prior to tray application. Then a syringe mixing tip was added to the dispensing gun, and the

impression material was dispensed on rest seat preparations, guiding planes of abutment teeth #37, 34, 43, and all major connector supporting areas. Meanwhile, and with a similar bleeding and dispensing method, a mixing tip was added to a medium-body silicone impression material cartridge (Aquasil Ultra+, DENTSPLY Sirona, NC, USA) the impression material was loaded on the intaglio surface of the custom tray, and the tray was vertically seated on the dentiform. The Impression tray was removed after 9 minutes to ensure proper material setting at room temperature, and the final impression was checked for voids, tears, distortion, separation from the tray, full anatomy replication, and rest seat recording.

Afterwards, a type 4 stone (Silky-Rock, Whip Mix corporation, Louisville, USA) was mixed using a vacuum mixer (VPM2, Whip Mix corporation, Louisville, USA), and poured over a stone vibrator (Whip Mix corporation, Louisville, USA). Once the stone was set, the tray was carefully separated from the cast using a lab knife, and the stone model was evaluated to ensure the absence of defects, bubbles, or fractured teeth. The stone cast excess was trimmed to have an 11 mm base height, a 3 mm surrounding land area, and tooth #31 was removed using a straight handpiece with a round and another round-taper acrylic burs (Laboratory burs, Peter Brasseler LLC, USA).

Using the same straight handpiece and burs, six mm vertical depth holes were drilled on to the model in 5 different locations, mesial to tooth #37, Distal to tooth #34, at the #31 area, distal to #43, and at the distal tissue stop location in the mandibular right side in area #47 (Figure **4**). Carving wax (Instep scanning wax, Whip mix corporation, USA) was heated and applied using an electric wax knife (Waxlectric II, Renfert, Germany) to insert the pyramid shaped scanbodies

(Omnicam L grey, DENTSPLY Sirona, NC, USA) to be utilized as reference markers for standardized digital integration.

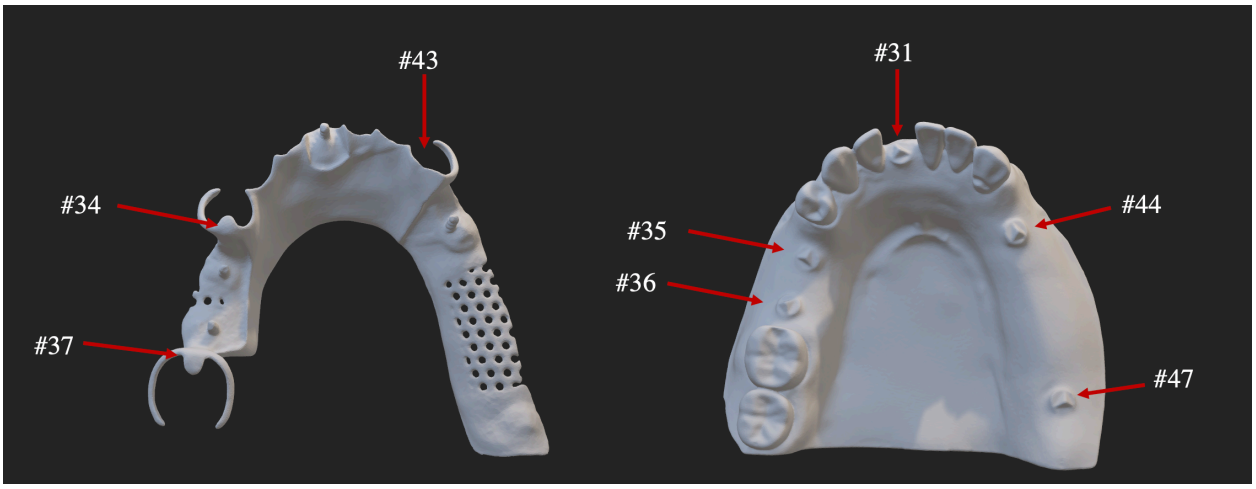

Figure 4: Framework and master model with red arrows indicating the location and labeling of landmark areas: Rest areas #37, 34, 43 and markers #36, 35, 31, 44, 47.

2.2.1 Digital scanning and designing

The stone cast was scanned with calibrated benchtop Sirona scanner (inEos X5, DENTSPLY Sirona, NC, USA) which generated a Standard Tessellation Language (STL) file, that was used to print out a master resin cast (Ortho model resin OD01, Shining 3D, China) using a 3D printing device (AccuFab-D1, Shining 3D, China).

Using the Argen Digital software (Dental system, 3shape, Denmark) and the master cast STL file, the PRDP framework was virtually surveyed and designed on the cast. A block out was done to undercuts that are 0.8 mm in depth or larger, and a mesh design was added to edentulous areas with a resin gap of 0.6 mm **(**Figure **5)**. The major connector was drawn on the lingual of mandibular anterior teeth in a scalloped design below the contact points, extending 2 mm above the floor of

the mouth, and a 2 mm relief around the gingival tissue areas (Figure **5)**. All pyramidal reference marker points were covered with the plated framework design, for a tight fit. Rests, clasp assemblies, major, and minor connectors were added to partial denture design. And a supporting bar strut was added in a cross-arch direction posteriorly, in order to reduce warping of the metal during framework fabrication.

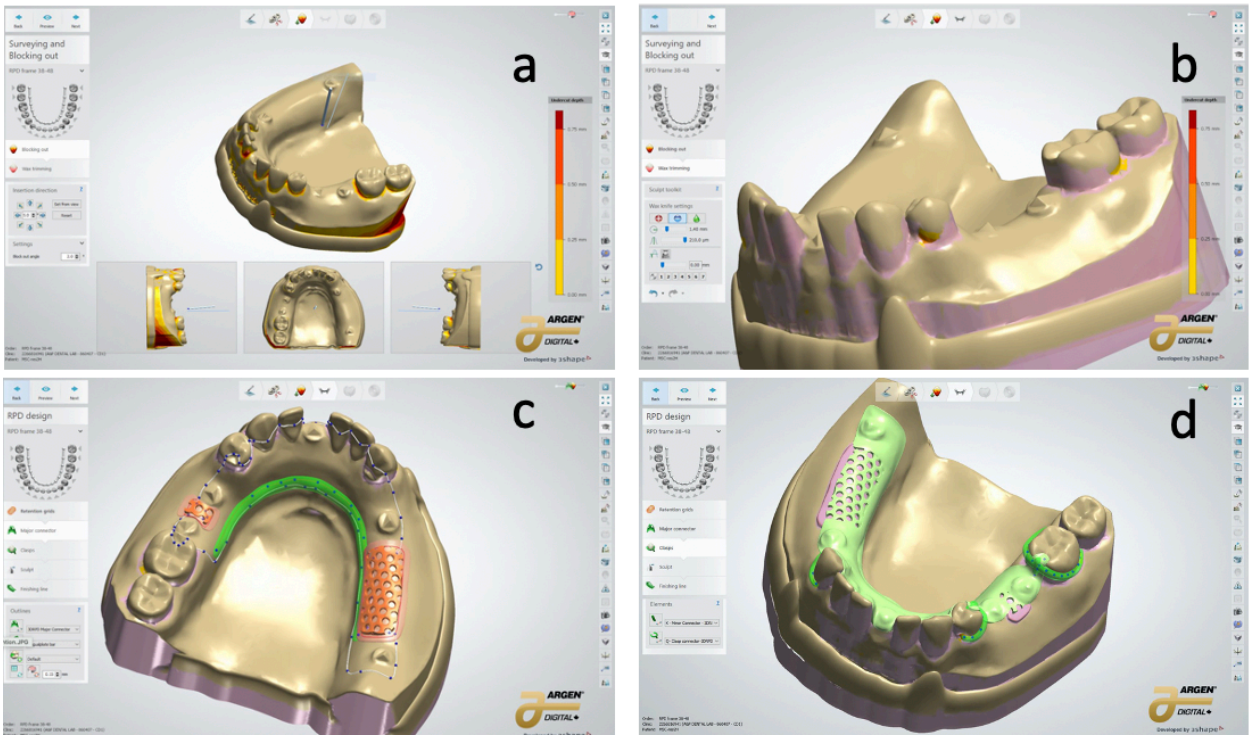

Figure 5: Master cast surveying and designing on Aregn digital software by 3shape (a) Red and yellow colors display the undercut detection (b) undercut block-out, note the pink simulation of wax coverage, (c) mesh design in edentulous areas followed by major connector dimensional markings, (d) final Kennedy class II mod 2 framework design.

2.2.2 Framework fabrication and digitization

The framework design STL file was sent to 3DRPD (3DRPD, Montreal, Canada) to fabricate a total sample of 12 PRDP frameworks, using Cobalt chrome martial in a selective laser melting manufacturing technique **(**Figure **6)**. After fabrication, the supporting structures from the frameworks were removed and all 12 frameworks were adjusted to fit the master resin cast, followed by sandblasting the intaglio surface to facilitate future scanning and digital fit assessment (**Figure 7**). The samples were scanned with a calibrated benchtop scanner (E4, 3-Shape, Denmark) to generate STL files for digital assessment of the printed frameworks, which included scanning the master model and the intaglio surface of each framework.

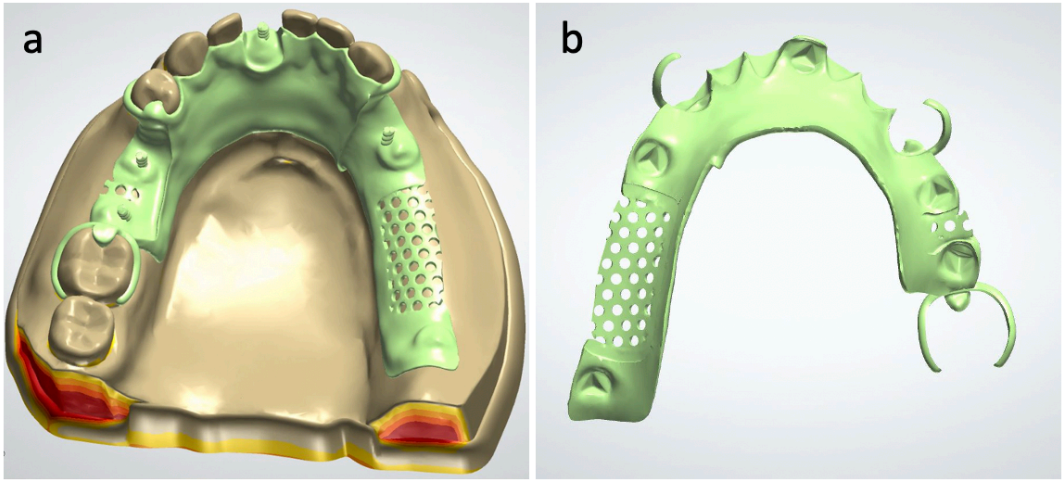

Figure 6: (a) Final PRDP framework design; cameo surface view, (b) designed framework; Intaglio surface view. Note the 5 pyramidal reference markers.

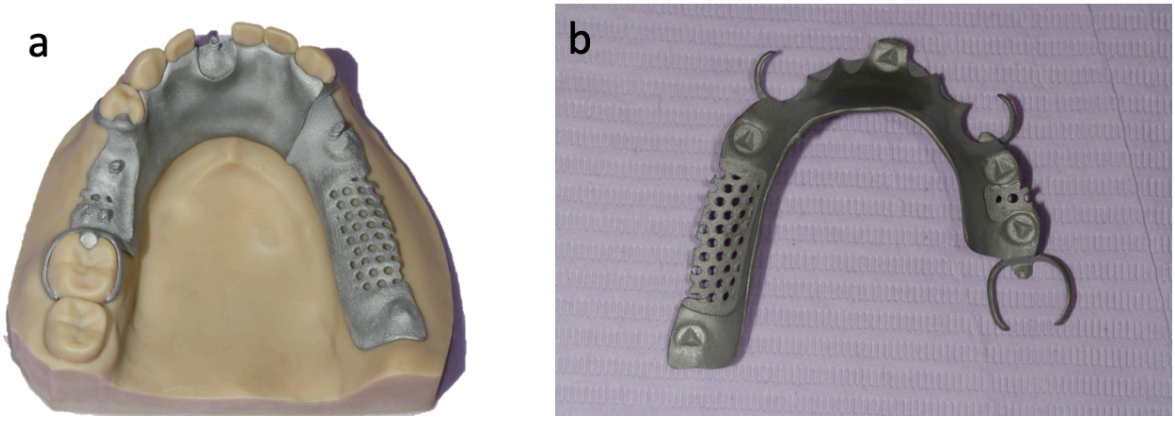

Figure 7: (a) SLM framework seated on resin printed master model after adjustment, (b) intaglio surface view of an SLM framework sample.

2.3 Digital Registration and Analysis

Using a 3D point cloud and mesh handling software (CloudCompare, 2.10 for mac, GPL), the master resin cast STL file was imported creating a point cloud mesh. Firstly, the base of the model was cut off, then the mesh was labeled and subdivided to increase the file density that would help with fine registration later on. Each framework mesh was also imported separately into CloudCompare, labeled, then subdivided in a standardized manner **(Figure 8)**.

Using a 3D modeling software (Meshmixer, Version 11.5, Autodesk, Inc) the subdivided master model mesh was imported and segmented using the "select" tool for the following 8 locations; abutment teeth #37, 34, 43 and marker reference points on areas #36, 35, 31, 44, and 47 and the segmented master resin mesh file was saved in an STL format for future alignment. Each subdivided framework was also imported into Meshmixer and manually oriented to the master model segment to approximate both files, and subsequently saved to that orientation **(Figure 9)**. The frameworks were segmented afterwards to the same designated 8 locations with their model

counter parts including the occlusal rests on #37, 34, 43, and markers #36, 35, 31, 44, 47 from the intaglio surface only, thus excluding the cameo surface and any other part of the framework **(Figure 9).**

All framework files were saved in STL format and labeled from 1-12 as markers and rests. In CloudCompare, the master model segmented file was imported with each framework one at a time, where both STL files had computed normals for improved visualization of each mesh **(**Figure **10)**. This was followed by a rough alignment using the 5 model pyramidal marker tips as reference points, to their paired counterpart on the framework intaglio surface of each marker (**Error! Reference source not found.**). Both files were then finely registered using all point clouds of the segmented framework to the referenced model **(**Error! Reference source not found.**)**. After fine registration, the distance map between them was calculated for each individual segmented pair of markers together or rest and rest seat, in order to evaluate the Gaussian distribution for normality and the Root Mean Square (RMS) of distance measurement in millimeter units that were converted later on to microns for each framework **(Figure 12 - Figure 13)**.

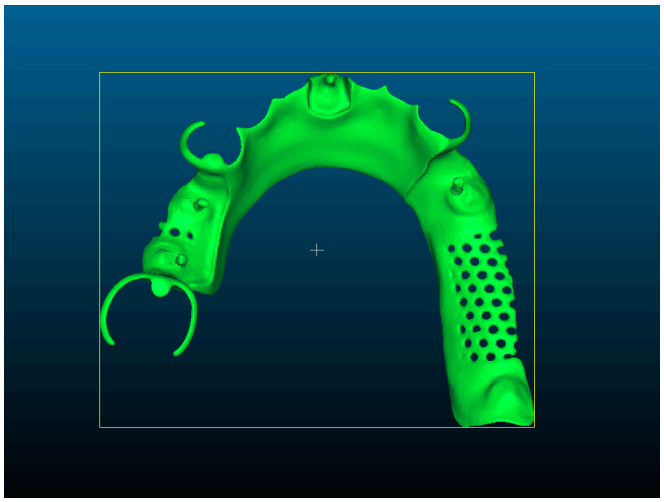

Figure 8: Imported framework STL file into CloudCompare.

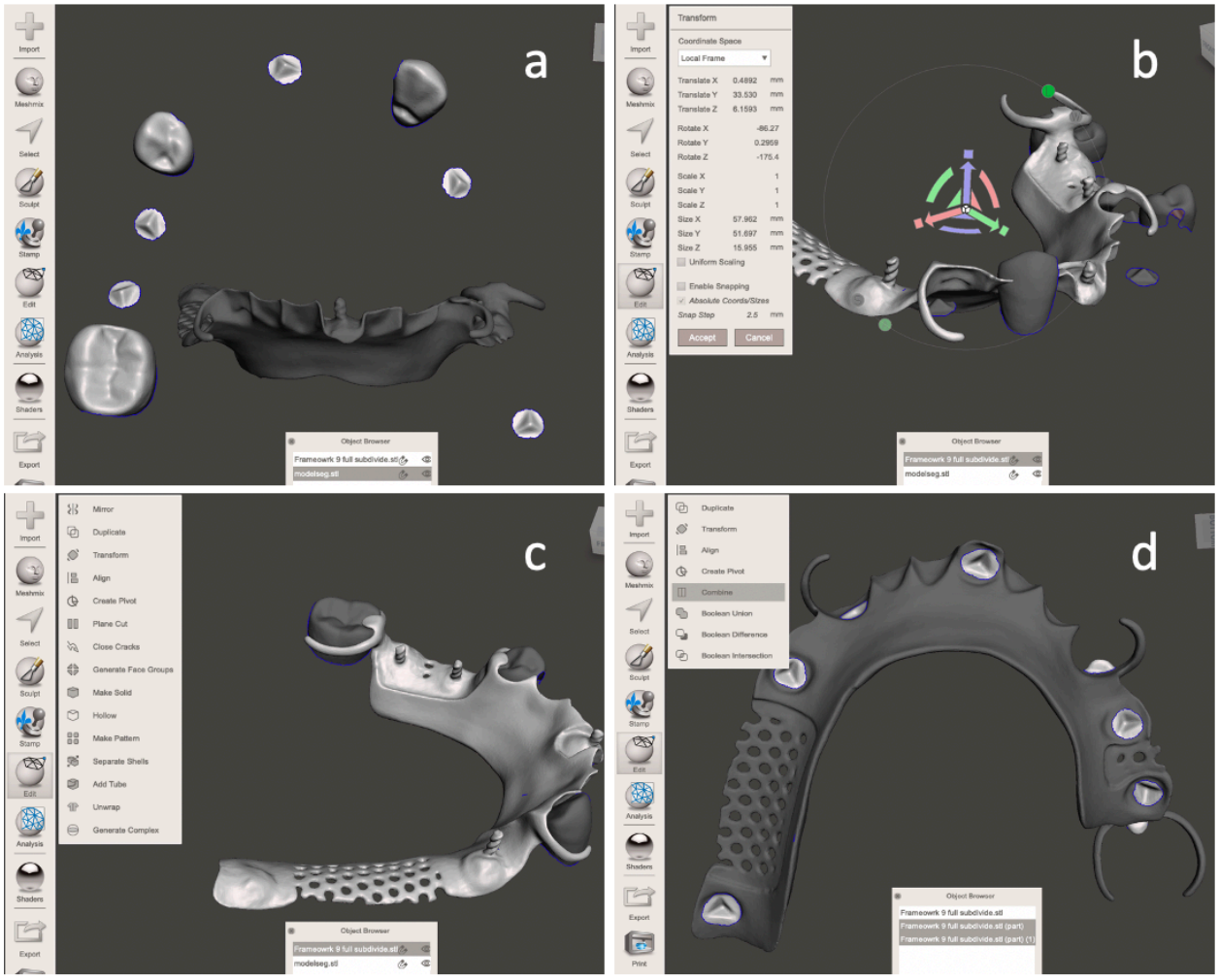

Figure 9: (a) Segmented master model and framework mesh imported in to MeshMixer, (b) Orientation of the framework to the master model for approximated manual alignment, (c) Manually aligned master model and framework, (d) Framework segmentation of markers and rests.

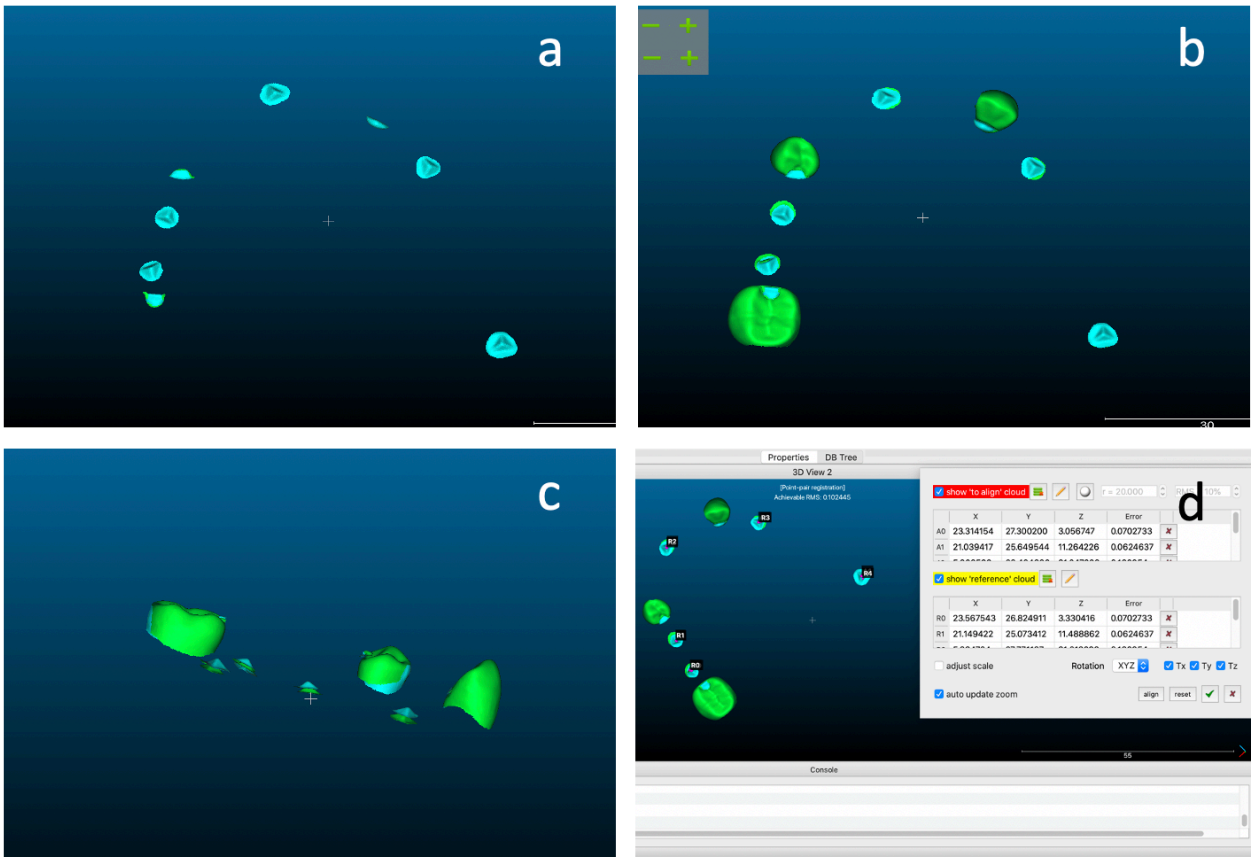

Figure 10: (a) Occlusal view of the segmented framework only on CloudCompare (b) occlusal view of the segmented master model and framework after approximation on Meshmixer (c) Lateral view of approximated segments (d) Rough alignment on CloudCompare using the paired designated points on the marker tips between the master model and the framework.

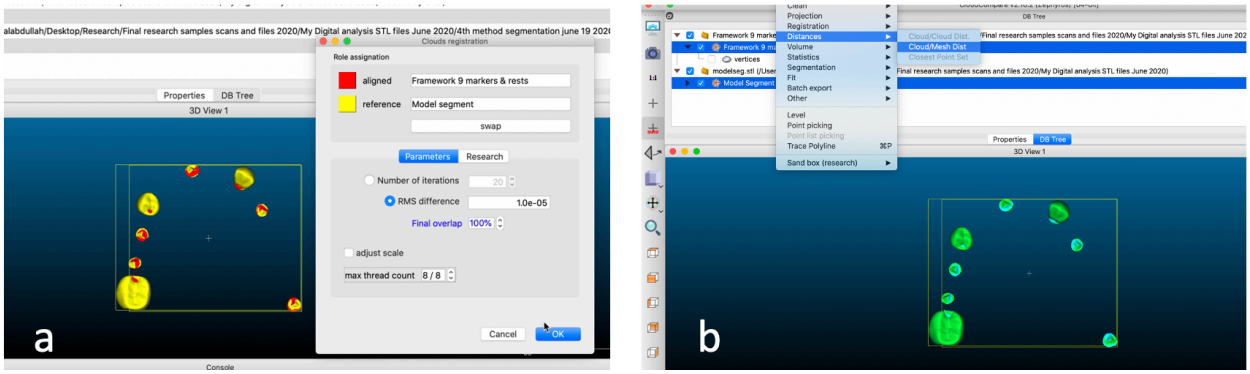

Figure 11: Fine alignment on CloudCompare; not the model was used as a reference in the registration, (b) Distance measurement selection after fine registration of model and framework.

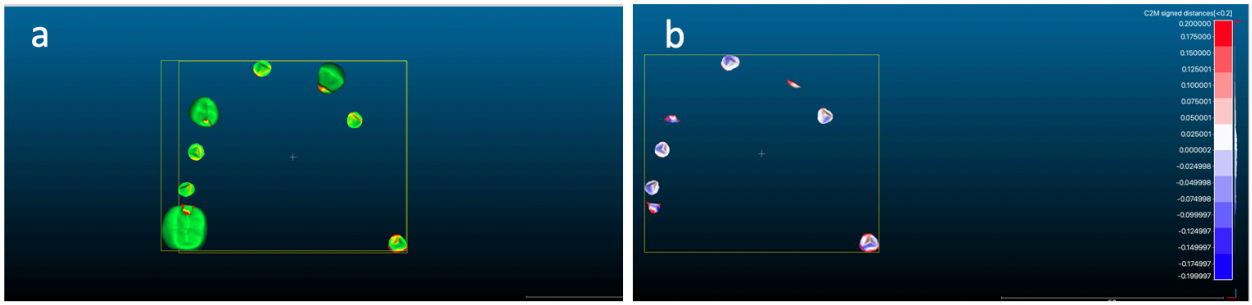

Figure 12: (a) Digitally registered master model and framework on CloudCompare (b) a distance color map of a digitally registered framework markers and rests, note color coded map on the right.

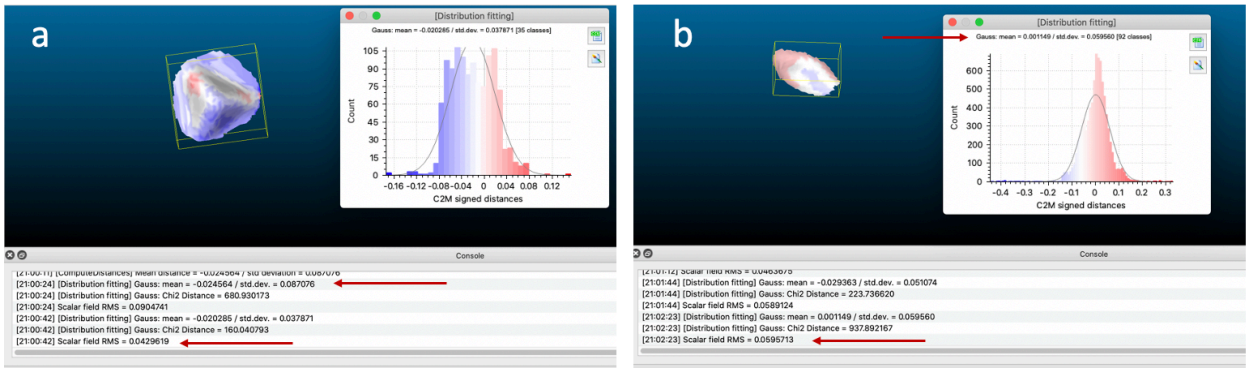

Figure 13: (a) Framework 4 Gaussian distribution histogram of a digitally registered marker #44, (b) cingulum rest #43 on CloudCompare. With both files showing the color-coded map, RMS value (mm), mean (mm), and standard deviation as pointed by the red arrows.

2.4 Clinical Registration and Analysis

Prior to clinical registration, all of the 12 frameworks were initially tried on the master resin model to ensure full seating and stability. Each framework was then removed and a light-body silicone impression material (Aquasil Ultra+, DENTSPLY Sirona, NC, USA) was applied on the intaglio surface on all 5 pyramidal reference markers. The framework was inserted on the master model and a finger pressure was applied on the major connector, occlusal rest, and edentulous areas for 4 minutes until setting. After careful removal of the framework from the model, the Polyvinyl Siloxane (PVS) replicas were inspected for tears, distortion, or damage **(**Figure **14)**. The replica thickness was then measured using an electronic caliper (Digital brake Rotor Gauge micrometer, Anytime Inc., CA, USA) at the center, mesial, distal and lingual locations on the pyramidal markers. Yielding 4 readings for each marker, and 20 readings for each framework.

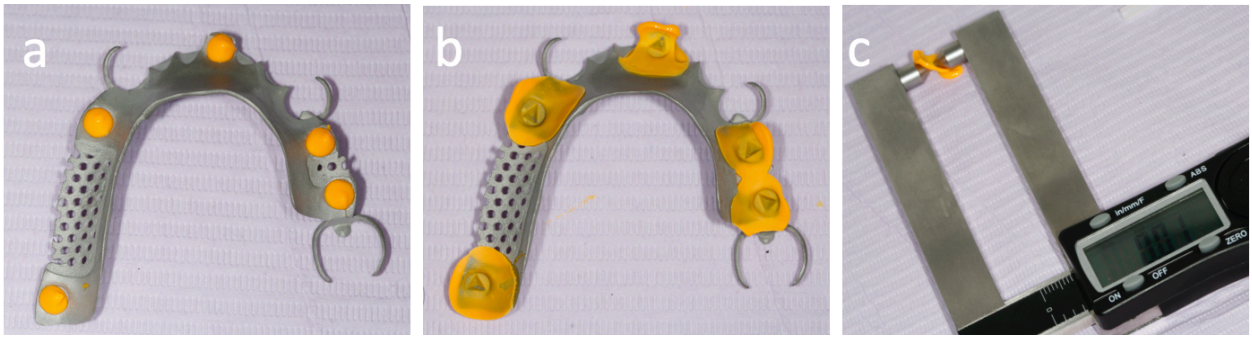

Figure 14: (a) Light body PVS applied on the framework marker area (b) Framework with PVS replica after setting and separation from the master model (c) an electronic caliper measuring the thickness of a PVS replica for clinical registration.

2.5 Statistical Analysis

For all statistical analyses, the SPSS software version 27 (SPSS, Chicago, ILL, USA) was employed. The gap widths between each of the 12 frameworks and the master model were analyzed separately for each registration technique using descriptive statistics and one-way ANOVA with post hoc Bonferroni adjustment tests. The intra-rater reliability of clinical registration gap measurements was assessed with an Intraclass Correlation Coefficient (ICC). The duplicate recordings of 30 randomly selected cases were done by a calibrated examiner. The ICC = 0.88 indicates acceptable level of intra-rater reliability (65).

Chapter 3: Results

3.1.1 Digital Registration

Overall, the mean gap measurement of RMS readings across the frameworks in the digital registration method was 70.76 ± 24 microns for all samples, with a median of 40 – 90 microns as visualized by the boxplot representation **(Figure 15) (Table 4**).

When viewing the RMS readings across different landmarks, the mean for all 5 markers was 65.27 ± 23 microns, and for the 3 rests was at 81.63 ± 22 microns **(Figure 16).**

The mean comparison with one-way ANOVA and post hoc with Bonferroni test revealed that there were no statistically significant differences between the frameworks when measured using the digital assessment method **(Table 4)**.

However, there were statistically significant differences among the 8 landmarks in digital registration between marker #47 and #36, 35, and 44 **(Table 5 - Table 6)**.

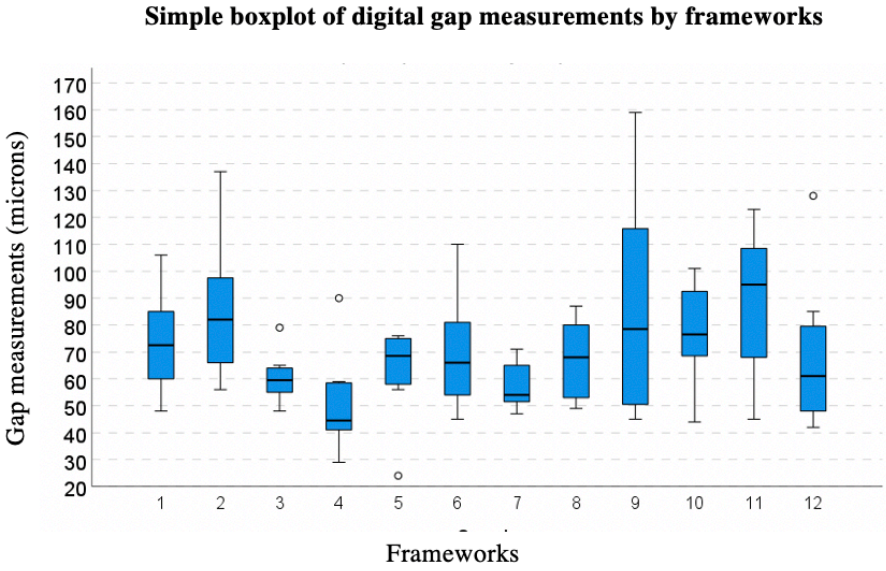

Figure 15: Boxplot representation of digital registration gap readings across the frameworks.

Table 4: Comparison of digital registration measurements across frameworks.

Digital registration measurement in micron units		
Framework	**Mean ± SD**	**Significant Differences**
1	73.6 ± 18.7	P > 0.05
2	85.5 ± 25.9	
3	60.5 ± 9.2	
4	50.8 ± 18.5	
5	62.8 ± 17.3	
6	69.6 ± 21.4	
7	57.3 ± 8.6	
8	67.2 ± 14.8	
9	86.7 ± 42.3	
10	77.5 ± 18.4	
11	88.8 ± 26.5	
12	68.3 ± 28.1	

One-way Anova with post hoc Bonferroni adjustment

No statistically significant differences were noted across the frameworks (P > 0.05)

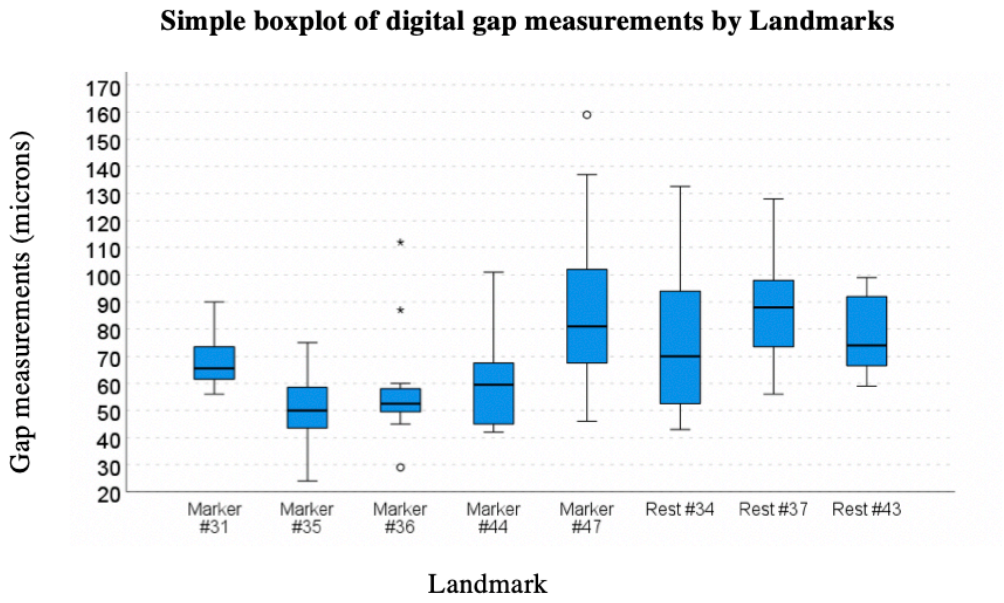

Figure 16: Boxplot representation of digital registration gap readings across the landmarks.

Table 5: Comparison of digital registration measurements across marker landmarks.

Digital Registration Measurement of Markers in Microns		
Landmark	**Mean ± SD**	**Significance Differences**
Marker #36	58.1 ± 21.4	Marker #36 vs #47 ($P < 0.05$)
Marker #35	50.6 ± 13.2	Marker #35 vs #47 ($P < 0.05$)
Marker #31	68.2 ± 10.1	-
Marker #44	60.1 ± 16.8	Marker #44 vs #47 ($P < 0.05$)
Marker #47	89.0 ± 33.1	Marker #47 vs #36, 35, 44 ($P < 0.05$)
One-way Anova with post hoc Bonferroni adjustment		

Table 6: Comparison of digital registration measurements across rest landmarks

Digital Registration Measurement of Rests in Microns		
Landmark	**Mean ± SD**	**Significant Differences**
Rest #37	86.2 ± 20.2	P > 0.05
Rest #34	76.0 ± 30.2	
Rest #43	77.4 ± 13.7	

One-way Anova with post hoc Bonferroni adjustment

There were no statistically significant differences between the rests (P > 0.05)

3.1.2 Clinical Registration

When visualizing the boxplot for clinical registration across the frameworks, it was noted that most of the clinical registration patterns were relatively similar; with a mean gap reading of 13.96 ± 7 microns **(Figure 17)**. As for the gap readings across the five landmarks, marker #47 displayed a higher variation than the other landmarks **(Figure 18)**. Finally, when comparing the gap based on the reading location, no substantial differences were observed across the readings **(Figure 19)**.

The mean comparison with one-way ANOVA and post hoc with Bonferroni revealed that there were no statistically significant differences between the frameworks in clinical registration **(Table 7)**. However, there were statistically significant differences between the landmarks with marker #36 and #44, 47 and also within the reading locations between the mesial and lingual sites **(Table 8 - Table 9).**

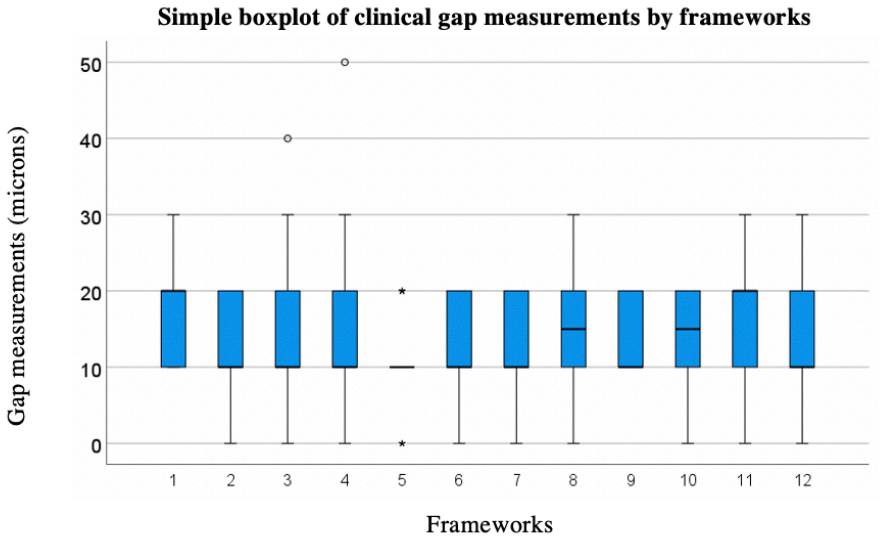

Figure 17: Boxplot representation of clinical registration gap readings across the frameworks.

Table 7: Comparison of clinical registration measurements across frameworks.

Clinical registration measurement in micron units		
Framework	**Mean ± SD**	**Significant Differences**
1	17.5 ± 5.5	P > 0.05
2	11.0 ± 7.1	
3	15.0 ± 9.4	
4	16.0 ± 10.4	
5	11.0 ± 5.5	
6	12.0 ± 6.1	
7	12.0 ± 6.9	
8	14.0 ± 8.2	
9	14.0 ± 5.0	
10	14.0 ± 6.8	
11	17.0 ± 8.0	
12	14.0 ± 8.8	
One-way Anova with post hoc Bonferroni adjustment		
No statistically significant differences were noted between the frameworks (P > 0.05)		

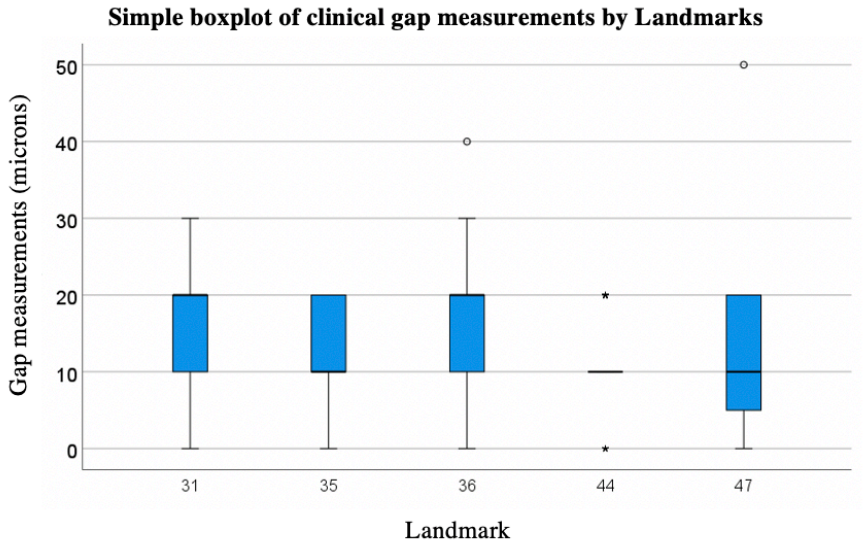

Figure 18: Boxplot representation of clinical registration gap readings across the landmarks.

Table 8: Comparison of clinical registration measurements across marker landmarks.

Clinical Registration Measurement of Markers in Microns		
Landmark	**Mean ± SD**	**Significant Differences**
Marker #36	17.7 ± 8.5	Marker #36 vs #44, 47 ($P < 0.05$)
Marker #35	13.7 ± 5.6	-
Marker #31	15.2 ± 6.8	-
Marker #44	11.67 ± 5.1	Marker #44 vs #36 ($P < 0.05$)
Marker #47	11.46 ± 9.4	Marker #47 vs #36 ($P < 0.05$)
One-way Anova with post hoc Bonferroni adjustment		

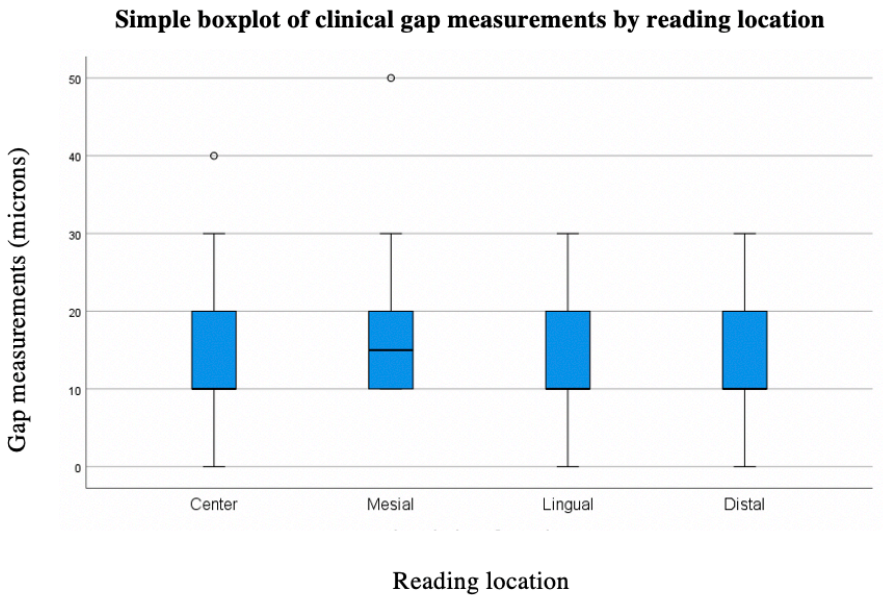

Figure 19: Boxplot representation of clinical registration gap readings across reading locations.

Table 9: Comparison of clinical registration measurements across reading locations

Clinical Registration Measurement of Reading Location in Microns		
Location	**Mean ± SD**	**Significant Differences**
Center	15.0 ± 6.7	-
Mesial	16.1 ± 7.6	Mesial vs lingual ($P < 0.05$)
Lingual	12.0 ± 7.7	Lingual vs mesial ($P < 0.05$)
Distal	12.6 ± 7.7	-

One-way Anova with post hoc Bonferroni adjustment

3.2 Discussion

Historically, the most frequently used technique to assess the accuracy and fit of partial dentures in the literature is by evaluating the average gap between the prosthesis and the master model, which is usually done using a silicone impression material or replica technique with an electronic caliper (41). Recently, authors have suggested the reliability of the digital superimposition and registration technique that can preserve the sample and quantify the gap with a reduced marginal error (33), leading to publications that compared this new technique of assessment to the replica technique in simple fixed prosthesis investigation (59, 60). However, partial removable dental prosthesis involves broader guidelines in order to occupy tooth and tissue supported structures simultaneously, which can explain the absence of a similar comparison in removable prosthodontics. Thus, the objective of this study was to assess the similarities and differences between digital and clinical registration methods in evaluating mandibular selective laser melted partial denture metal frameworks.

A few studies have tested digital registration for the analysis of PRDP (33, 45, 49). However, this is the first study to evaluate both digital registration and clinical assessment using the replica technique. This study also utilized a more complex PRDP design (Kennedy Class II mod 2) which was not investigated before and provided a detailed protocol for the digital assessment method.

In this project, each registration method was statistically analyzed independently due to the differences in each measurement techniques; with digital registration computing hundreds of points to calculate the distances and deviation in a virtual field using a Root Mean Square RMS

formula, and the clinical registration involving four preselected reading locations with an electronic caliper device operated in a physical field by an investigator. The study outcome revealed that the framework comparison had no statistical significance between the samples in both clinical and digital registration, therefore the first null hypothesis could not be rejected. And although landmarks showed differences between the groups, all gap measurement values for all the samples in both clinical and digital registration were within clinically acceptable limits (45). As for the overall trends in findings, each method of registration differed in mean values and variability across the groups. Nonetheless, both methods were still within clinically acceptable values with no substantial numerical differences in outcome findings.

Generally, when considering the accuracy in PRDP, a variation in the literature is observed with regards to clinical relevance and acceptability of gap measurements, which can remarkably range between 50 microns up to 800 microns (26, 41, 45, 47). That discrepancy could be due to several factors such as framework design, measuring device, fabrication technique, or the type of components under examination. Arguably, some authors indicated that gaps to a certain limit in removable prosthesis can be within tissue tolerance and eventually alleviated by soft tissue remodeling (49). Unfortunately, that is not the same for tooth engaging components, and as a result they require a closer and more accurate fit. Our study involved occlusal rests and landmarks that were designed to have a tight fit representing tooth-supported components with a Kennedy Class II modification 2 design, resulting in a mean of 13.96 microns in clinical registration and 70.76 microns in digital registration. And when comparing our results to previous investigations that have utilized the replica technique of clinical registration, our study showed a mean occlusal rest gap of 81.63 microns, and those studies concluded that an occlusal rest gap that is less than 380

microns is clinically acceptable (41, 47, 58). Other publications that have used a digital approach of gap measurement and registration, have concluded that an overall framework gap of less than 311 microns, and a 50 to 80 microns gap for tooth engaging components is considered clinically acceptable, which is also in agreement with our results that showed a digital registration mean of 65.27 microns across all markers (45, 49).

All framework samples were uniformly adjusted by an experienced lab technician in order to mimic a realistic case delivery step as recommended by Soltanzadeh et al for future approaches prior to assessing fit (45). This could indicate a future advantage of digital registration that could be implanted at the laboratory level by assessing prostheses fit to a master cast or preparation die in order to plan the necessary adjustments or in some cases a remake prior to its delivery to the dentist, saving a lot of time and potentially chair-time cost.

Currently, and depending on the software being used, digital registration indicates a steep learning curve and cost; thereby focusing implementation at research and academic facilities such as Geomagic (Geomagic Control, 3D systems, USA) and GOM (GOM inspection, ZEISS group, Germany). In this study, a free and open-source software (CloudCompare, 2.10 for mac, GPL) was used in order to facilitate a broader application for day-to-day clinical and laboratory use. It is important to know which metrology program is involved since one of the factors affecting digital registration is how the operating software manipulates STL file superimposition and how both files are aligned; with a recent publication that compared the CloudCompare and GOM software concluded that CloudCompare exhibited a better alignment result than GOM (56).

As for the specific processes that the program can employ, a simple method is what is called the Match Bounding-Box Centers that can transform one file as a reference and the other file to the center of that reference file all while keeping both file bounded within a simulated box (51). Another method is Iterative Closest Point (ICP) which as the name dictates, selects the nearest point of each cloud or mesh file and calculates the distances between them (66). The ICP method in CloudCompare has been utilized in this project as it displays better alignment results when compared to other methods of registration (56, 66).

The authors speculate whether the values in the digital registration should be thought of as an approximation of acceptability as opposed to a precise number, since the objects can rotate in different axes that may not be possible in the physical dimension. For example, two digital files may have areas of alignment that can overlap and others that are distant, giving them signed values that demonstrate their direction in the virtual field rather than the measured gap between them (67). Therefore, the selected outcome measurement algorithm for digital registration in this study was the RMS readings, as it calculates the square root of the mean values in squared distances between both registered files, taking into account the mean and the standard error incorporated in the final gap registration after averaging the signed values (56, 67, 68).

Another feature that digital registration can provide is whether the gap measurements are normally distributed among the registered files **(Figure 13)**. Along with the RMS values, mean, and standard deviation, CloudCompare can also demonstrates a Gaussian Distribution histogram that can be a simple indication if the registration is flawed or if there is an issue with the mesh file itself that is commonly caused by the perceived noise from low density resolution files (51).

The use of referencing landmarks has been reported in the literature to aid in the standardization of the digital registration process (45, 69, 70). These landmarks, especially when made from scannable material, may improve the data acquisition factors in edentulous areas that are usually more difficult to scan. This, in turn, causes a positive effect on the digital method of registration and analysis which may not be a feasible approach in a clinical setting.

Clinical registration with silicone material is currently one of the common methods in prosthesis fit assessment intraorally. Although the process is simple and economical, limitations may occur when acquiring the gap in close fitting areas such as tooth engaging components. This may lead to locking of the prosthesis intraorally or even tearing of the replicated silicone material, making the gap thickness calculation unattainable. The same silicone applied incorrectly may also affect the full seating of the prosthesis or cause pressure distortion in the underlying soft tissue. Therefore, a recommendation was made to use a low viscosity silicone material in attempting this method of registration (43, 46).

When measuring the thickness of the silicone replica, care must be taken on exerting pressure during electronic caliper thickness calculations that might stimulate the elasticity of the material leading to reduced gap readings. Another limitation in clinical registration that needs to be recognized is the accuracy threshold in electronic calipers. For example, if the threshold was 0.01 mm then any reading below that threshold would be rounded down to 0.00. Nonetheless, both limitations and the differences they cause in the recorded gap readings are usually minimal and possibly inconsequential.

In this study, the total number of readings collected was 240 for clinical registration, and around 96 for digital registration. However, within the 96 in digital registration, the software will calculate hundreds of points prior to giving a final reading for each individual area of assessment. That difference in numerical representation of the landmarks is another reason why both methods were statistically analyzed individually.

Presently, each technique for prosthesis assessment carries a certain level of accumulated error. Digital registration is affected by the digital scanner accuracy, STL file resolution and density, and metrology software superimposition technique. On the other hand, while clinical registration is reputed as a simple technique, it can incorporate a fair level of subjectivity and human error. In this study, when observing the results of each method, clinically acceptable gaps and differences were noted leading to the assumption that both techniques have produced practical results. And the differences in the values they provide are most likely due to unique factors affecting both methods of measurement.

Several publications compared rapid prototyping methods of fabrication to conventional casting of PRDP framework, with a few suggesting a better fit in the RP method (33, 42) and others suggesting a superior fit in conventional casting (45, 49). However, all publications concluded that both conventional and RP methods produced clinically acceptable gap measurements (33, 42, 45, 49). This study agrees with preceding publication assumptions that rapid prototyping of metal frameworks tested under two different assessment methods produced clinically acceptable results.

3.3 Strengths and Limitations

A few studies have tested digital registration for the analysis of PRDP (33, 45, 49). However, this is the first study to evaluate digital registration protocols with a classical approach and clinical assessment. And with most previous publications investigating Kennedy class III designs, another advantage is the use of a Kennedy Class II mod 2; that is usually more challenging to investigate and thus can be a good contribution for future studies.

Digital registration can be laborious in nature, and typically under proprietary software applications with a limited description in dental field papers. This publication involved a step-by-step protocol using an open-sourced software to offer an alternative for the general public to utilize digital registration in a clinical or day-to-day setting.

A limitation in this study is the small sample size, and although a sample size calculation was done after the pilot studies; a higher sample size could improve the power analysis and reduce the marginal error in the resulting outcome. Another limitation is the fact that it is an in vitro study, with a static master cast that does not fully mimic a dynamically challenging clinical scenario.

Chapter 4: Conclusion

This study involved two methods of assessment in a SLM partial removable dental prosthesis framework that included digital and clinical registration. Based on the outcomes of this investigation the null hypothesis could not be rejected and suggested the following conclusion:

- There were no statistically significant differences among the frameworks in both digital and clinical registration.
- There were statistically significant differences among the landmarks in both digital and clinical registration, but these differences were not clinically relevant.
- All resulting gap measurements in clinical and digital registration methods were within clinically acceptable levels.
- SLM frameworks that were investigated under digital and clinical methods of registration showed clinically acceptable gap outcomes.

4.1 Clinical Relevance

With the evolving digital technologies and innovative prosthesis fabrication methods, digital registration has the potential to be a reliable, nondestructive, and 3-dimensional prostheses assessment and communication tool. Moreover, SLM methods of PRDP framework fabrication showed clinically acceptable gap readings.

4.2 Future Direction

This study presented an in vitro examination of two different prosthesis assessment tools, that could direct future research to relate both techniques under clinical investigation. Furthermore, future clinical reports that will measure the fit and accuracy potential of rapid prototyping PRDPs in a clinical setting under different Kennedy designs, manufacturing facilities, or even lab technicians would expand referencing data in the field and thus decreases the shortage in the literature.

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