Research Proposal

Accuracy of intraorally scanned denture impressions compared to conventional border moulded impressions- an in vivo study.

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Introduction

The field of digital dentistry has seen significant breakthroughs and technological developments, making it one of the most up-to-date areas of practice for dental professionals. Extensive research is being conducted in the rapidly growing field of digital dentistry, with a particular focus on restorative dentistry. Digital scanning as part of the computer aided designed or computer aided manufacture (CAD/CAM) systems, has been introduced to dentistry in the middle of the 1980's. Intraoral scanning devices have gained wide usage in the treatment of single crowns, multiple fixed unit prosthesis, and more recently, in the field of implants and complete denture prosthetics (Gan et al., 2016).

The advent of intra oral scanners aimed to provide a smoother experience for the patient, and streamline the work flow by reducing the complications associated with using conventional tray-based impressions (Mörmann, 2006). Accordingly, dental practice has increasingly adopted digital technology, such as intraoral scanners (IOS), due to several advantages it offers over traditional impression techniques. These include reduced laboratory and chairside time and steps, as well as the ability to implement a fully digital manufacturing process (Zarone et al., 2020).

CAD/CAM technique has lately been used for the fabrication of complete dentures. Systematic review of in vitro studies by Wang et al. (2021) found that the accuracy of digital complete dentures is comparable to that of conventional complete dentures. Current research on digital dentures has shown that they require fewer clinical appointments and shortened time spent in the dental chair compared to conventional complete dentures. This can be particularly beneficial for edentulous geriatric patients who may find it difficult to spend extended hours on the dental chair. Furthermore, digital dentures may result in better patient satisfaction and clinical outcomes (Casucci et al., 2023). However, it is important to acknowledge the lack of adequate evidence addressing the efficacy of digital scanners for complete edentulous arches in a clinical setting.

Literature review

Digital vs conventional impressions

The selection of the technique and material used by clinicians to take an impression of the tissues that support the denture is crucial for ensuring proper fit and function. This includes achieving the correct extension and adaptation during both static and dynamic movements, which ultimately affects how well the denture stays in place. Incorporating IOS technology in removable prosthodontics has certain advantages and challenges. The direct intraoral scanning technique eliminates the need for physical impressions, thereby eliminating errors caused by distortion of elastomeric conventional impressions, inconsistencies in the water/powder ratio, and improper storage conditions of impressions or gypsum casts (Gan et al., 2016). However, many clinicians use conventional impression techniques for complete edentulous patients because the elastomeric material used in these techniques can record not only the edentulous arch but also the dynamic and static movements of mucosal soft tissues. These functional movements of the vestibular mucosa in relation to border molding and muscle activities, which are essential for shaping and extending the margins of the prosthesis, are difficult to capture with an IOS (Chebib et al., 2019, Casucci et al., 2023).

Furthermore, the incorporation of digital technology in clinical practice comes with additional constraints. For instance, there is a learning curve associated with acquiring the skills to effectively use this technology. Moreover, the acquisition of an IOS device can be costly. The superiority of digital impression over the conventional method is still a subject of controversy. Therefore, the conventional method remains the dominant technique in the field of removable prosthodontics (Casucci et al., 2023, Zarone et al., 2020). To favor one strategy over the other, it is necessary to have evidence-based research.

Accuracy of digital impressions

Accuracy consists of two main factors: precision and trueness ISO 5725-1 (2023). Given the extensive interest in digital workflow, the focus remains on the accuracy of new impression techniques in capturing the necessary data. Precision defines how near repetitive measurements are to each other whereas trueness defines how far-off the measurement diverges from the actual dimensions of the measured object (Ender and Mehl, 2013).

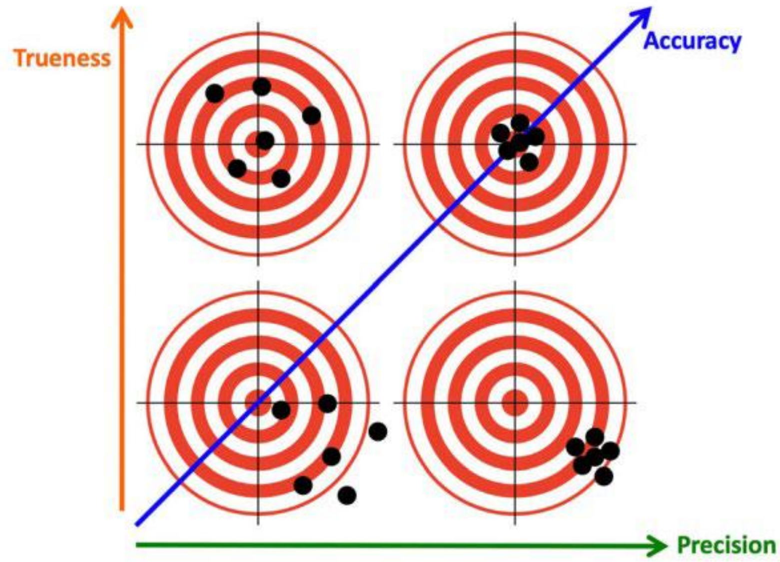

Figure 1. Illustration of the relationship between trueness, precision, and accuracy, as defined by International Standard Organization (ISO, 1994).

With the progress of intra oral scanning technology, the latest generation of scanners show enhanced precision and reduced scanning intervals. Over time, both software and hardware enhancements in scanners have also been worked on to help in securing the data. While the accuracy of an intra oral scanner is influenced by the quality of the scanned image, it also relies on the accuracy of superimposing the actual anatomical landmarks, which is dependent on algorithms in the scanner for image reconstruction (Srivastava et al., 2023).

In-vitro studies on accuracy of the digital impressions

In vitro studies have assessed the accuracy of digital impressions for dentated and partially dentated full arches in comparison to conventional impressions. These studies have shown various issues, such as the distortion of the digital scans and reduced accuracy, i.e. precision and trueness, when compared to conventional impressions (Ender and Mehl, 2013), (Malik et al., 2018). Likewise, Zarone et al. (2020), who examined and compared different intraoral scanning techniques on a model of completely edentulous maxilla, found that scanning complete edentulous arches presents challenges. This is because there are no visible landmarks in the larger scanning range of edentulous areas, which makes it difficult to accurately identify anatomical reference points.

Previous studies by Schimmel et al. (2021) examined how the operator's experience influences scan accuracy and time. Their results indicate that operators' experience observed shorter scanning times which can improve the accuracy of digital scans. However, they found that scans of the fully edentulous mandibular arch showed significantly better trueness when performed by inexperienced operators. Similarly, scans of the edentulous maxillary arch demonstrated significantly better precision from inexperienced operators. Nonetheless, these studies were conducted on edentulous arch models, which do not accurately replicate the actual intraoral conditions.

The technology utilized in scanners varies, resulting in possible differences in accuracy. In a study by Nulty (2021), the accuracy of nine IOSs and four lab scanners were compared. The result showed that all the scanners had a mean trueness of less than 60-micron deviation. This study indicated that the scanning of a completely edentulous arch is more difficult than scanning a dentate arch, and it suggests that the accuracy of these scanners in edentulous cases should be evaluated in future studies, given the rapid advancements in this a field of technology.

In-vivo studies on digital impressions

Current intraoral scanning devices have shortcomings with accurately scanning the soft tissue under selective pressure and capturing the movement of the soft tissues in denture-bearing areas. In a study conducted by Gan et al. (2016), the accuracy of intraoral digital impressions for whole upper jaws, including the full dentitions and palatal soft tissues, was compared. The study found that the flexible oral mucosa and smooth tooth surfaces, coated by saliva, can pose difficulties for clinicians when taking intraoral digital impression for removable partial dentures or complete dentures. Other limitations in terms of anatomical structure and accessibility in posterior areas make it challenging to use the IOSs effectively. Hence, these in-vivo studies reveal additional potential challenges encountered in comparison to the in-vitro experiments.

In a recent systematic review conducted by Casucci et al. (2023), the accuracy, time required, and satisfaction of patients were assessed for digital impressions compared to conventional impressions taken for removable prostheses on edentulous arches. The review included six clinical in vivo studies focusing on accuracy, specifically trueness, while precision was not addressed. The review concluded that there is limited scientific evidence available on the use of IOS for edentulous arches, particularly in terms of scanning time and patient satisfaction. Although, the study determined that digital scanning seems to be a predictable method for capturing impression of the attached mucosa in edentulous patients, the studies consistently found discrepancies in the peripheral areas, especially the soft palate and the vestibule, emphasizing the need for further research investigating the abilities of IOSs in edentulous arches and their suitability for removable prostheses. In addition, scanning fully edentulous arches may be further complicated due to the presence of mobile tissues and saliva. On the other hand, a systematic review that examined clinical studies comparing the accuracy of digital impressions to conventional impressions in fixed prosthodontics, found that conventional impressions are more accurate than digital impressions in clinical situations (Giachetti et al., 2020).

Alternative contemporary systematic review examining the accuracy of IOSs for recording completely edentulous arches, included eight in vivo studies, six of which coincided with the previous review, while two were modern found that IOSs provide clinically acceptable digital scans. However, the message remains identical, improvements are still needed to aid in capturing movable mucosa. In cases with unfavorable ridge anatomy or when denture retention is considered necessary through compressing the tissue, digital intraoral scanning is not advised. Also, it is recommended that when scanning the vestibule, capturing the entire surface area in one scan is suggested to avoid faults. While IOSs can be used in the fabrication of complete denture prosthetics for edentulous arches, careful case selection is still crucial (Srivastava et al., 2023).

Effect of scan length and strategy

The inside of the oral cavity is a small, confined space, which makes it difficult to fully capture the entire space just with a few pictures. To acquire a 3D image of the surface inside the oral cavity, the scanner takes multiple small "point cloud" shots during the scanning process. Furthermore, it combines all those smaller point clouds into one big 3D point cloud. Finally, it connects all the points in that cloud to create a smooth, triangulated 3D surface model (Waldecker et al., 2024).

Recent study reported by Waldecker et al. (2024) found that missing upper teeth led to greater measurement errors in the 3D scans and longer scanning paths resulted in linearly increasing distance deviations. Angular and tooth axis deviations did not increase linearly with longer scans. Accuracy of complete-arch intraoral scans based on confocal microscopy versus optical triangulation a comparative in vitro study by Moritz Waldecker (2021) found that scanning accuracy is reduced as the scan-path length is expanded by comparing short and long distances. Recent in-vitro study by Zarone et al. (2020) compared the accuracy of three different scanning strategies using a single intraoral scanner, TRIOS 3 (3Shape), on two edentulous maxillary reference typodonts - one with defined palatal rugae and one without. The outcomes showed that scans performed on the typodont with less distinct anatomical landmarks had better accuracy than those made on the typodont with more defined landmarks. On the smooth typodont, there was no difference between the three scanning techniques. However, on the wrinkled typodont, the buccal-palatal scanning technique was more accurate than the palatal-buccal approach, while the S-shaped technique showed no significant difference. The study concluded that the scanning strategy had a major impact on the accuracy of scans for the completely edentulous maxilla. Limitations of this in-vitro study include the lack of clinically relevant factors such as oral temperature, humidity, soft tissue characteristics, and intraoral anatomy. Contrary to the previous report, Kim et al. (2017) studied the effect of an artificial landmark on a long edentulous space on the accuracy of intraoral digital impressions an in vitro report and concluded that the utilization of an alumina mock landmark enhanced the trueness and precision.

Deviation measurement

Recent study by Al Hamad and Al-Kaff (2023) found that certain areas of both the upper and lower arches showed positive deviations, with a color range of 1.4 to 1.8 mm mainly located in the buccal dynamic regions. In the static areas, a mixed outline observed some regions with positive deviations, while others had negative deviations. The range for both types of deviations in these static areas was 0.2 to 0.4 mm.

Another research by Masri et al. (2020) evaluating the adaptation of CDs fabricated using IOS technique and conventional technique results showed no significant deviations:

- Overall surface: 0.502 ± 0.035 mm
- Posterior palatal seal: 0.447 ± 0.089 mm
- Anterior border seal: 0.659 ± 0.099 mm
- Ridge crest: 0.579 ± 0.092 mm

- Palatal area: 0.357 ± 0.089 mm

The palatal area appears to be the region with the least deviation, while the highest incidence of discrepancy was found to be in the anterior border seal.

3 Shape Trios scanner

3Shape is a conspicuous dental scanning company that was founded in 2000 by Tais Clausen and Nikolaj Deichmann. Their dental scanners are widely used in dental practices. The way the 3Shape scanners work explained by Singer (2024) is by shining a light onto the object being scanned, like the dentition with soft tissues. The light bounces off the object and gets redirected back to a sensor in the scanner. This allows the scanner to capture a sharp, detailed image of the scanned surface. Using these individual images, the scanner software then builds a 3D digital model of the scanned area. The 3Shape Trios intraoral scanner can capture around 2,500 of these images per second. From every 100 or so of these individual images, the scanner software creates a "sub-scan" - which is broadly a 3D point cloud representation that includes color information of what the scanner is capturing. These point clouds are organized into triangles.

Aims and Objectives

Aim 1:

To compare the trueness of digital impression captured using an intra oral scanner, in a completely edentulous arch, in comparison to a conventional impression obtained from the same patient.

Null hypothesis 1: There are no statistically significant differences in trueness between the digital and conventional impression techniques for complete edentulous arch.

Aim 2:

To compare the precision of the 3 digital impressions for complete edentulous arches obtained from the same patient.

Null hypothesis 2: The digital impressions of a complete edentulous arch would not be different when the digital impression is repeated multiple times.

Null hypothesis 3: The precision of the digital impressions is not different in the maxillary and mandibular arch.

Research question

Is the accuracy of IOSs similar to conventional border moulded impressions in a completely edentulous arch (maxillary or mandibular)?

Research methodology

This study proposal will be submitted for Institutional Review Board (IRB) approval it will be conducted in agreement with the Declaration of Helsinki of ethical human research practice. Prior to participation, each subject will sign an informed consent.

Each subject provided will sign informed consent prior to participation. All personal information collected will be anonymous and securely protected with a study code number. There will be no data which could personally identify participants of the research study. Any future published work will also be unidentified and will not include any personal information regarding the individuals participating in this study.

Research design

- A non-randomized clinical trial, in which participants will be recruited and digital and conventional impressions will be obtained for them at the same time by the same operator.

Patient Sample

The determination of the sample size needed will be based on previously reported study the trueness of intraoral scanning of edentulous arches: A comparative clinical study by (Al Hamad and Al-Kaff, 2023) given RMS (root mean square) means 0.21 and 1.51 and SD 0.03 and 0.28 respectively for static and dynamic maxillary.

The sample size calculation formula is expressed as N=2 $\frac{(Z_{\alpha/2}+Z_{\beta})^2}{(ES)^2}$ where N represents the sample size per group. In this case, the standard normal value $Z\alpha/2$ is 1.96 for a significance level α of 0.05, and $Z\beta$ is 0.84 for a desired power of 80%. The effect size ES is 0.82, and the square of the effect size is 0.7. By replacing these values into the formula, we can calculate the sample size for different scenarios. Based on the calculations, a total of 10 participants will be recruited, and the control and test impression techniques will be conducted and compared for each patient.

$$N=2\,\frac{(Z_{\alpha/2}+Z_{\beta})^2}{(ES)^2}$$

N = sample size per group

$Z_{\alpha/2}$ = standard normal value Z-value for a significance α = 0.05 which is 1.96

Z_{β} = standard normal Z-value for the power of 80%, which is 0.84

ES = 0.82 (effect size)

$$(ES)^2 = 0.7$$

Patient selection

A total of 10 participants, attending Dubai Dental Hospital in collaboration with Mohammed Bin Rashid University MBRU, requiring complete denture prothesis treatment or follow up on previous prosthesis will be included in the study following the inclusion criteria. In addition, any participant who has recently been edentulous (at least 6 weeks) will be involved after attaining their approval. Patients speaking Arabic and or English languages will be recruited in the study, and prior to any procedure, comprehensive verbal explanations will be provided to them. Dentate patients and those un-willing to participate and presenting with gag reflux will be excluded from the study.

Inclusion criteria

- Patients attending DDH for complete dental prosthesis.
- Fully edentulous patients
- All alveolar ridge classifications of Cawood and Howell 1988 (Cawood and Howell, 1988)
- Above 18 years old
- Arabic and English-speaking patients
- Good physical health (ASA class 1 or 2)
- Willing to provide informed consent.

Exclusion criteria

- Dentate patients
- Implant attachment supported complete denture.
- Patients un-willing to participate (non-consented patients)
- Patients with severe gag reflex
- Patient mentally unstable, drug users or alcoholics

Primary outcome

- Compare accuracy of digital scanning by assessment of trueness through measuring the differences between the conventional impression technique (control) & IOS impression technique (test) of both static and dynamic tissues.
- Assessing the precision by measuring the differences between more than one superimposed STL file.

Secondary outcomes

- Differences in terms of trueness and precision of both maxillary and mandibular arches.

- Difference in terms of trueness and precision of scanned attached and mobile areas.

Data acquisition

All impressions will be acquired by a single operator (AA) who has experience in the use of intraoral scanners in regular clinical practice and adequately trained to conduct conventional and digital impressions, thereby ensuring good intra-investigator reproducibility (Kappa). Digital impressions will be the initial step in the impression-taking process, followed by conventional impression to standardize the sequence for all participants. Subsequent to relevant training, the same investigator will perform each phase of data generation.

Digital impressions

Edentulous maxillary and mandibular arches will be scanned using IOS TRIOS 5 (3Shape, Copenhagen, Denmark), running on software Unite version 24.1, following the guidelines of Prof. Dr. Lo Russo edentulous scanning strategy (Lo Rosso) the manufacturer's instructions of the same scanner.

The scanning strategy will be done within four stages. Scan sequence for the maxillary edentulous arch: 1) the scanning process will initiate from the tuberosity of one side and continue along the center of the residual ridge towards the tuberosity of the opposite side. 2) coming back to the midline to complete the scan of the palate with smooth zig zag movements. 3) scanning the buccal aspect of the ridge towards the midline of the incisive foramen of one side. 4) scanning the buccal aspect of the ridge towards the midline of the incisive foramen of the opposing side of the ridge. The third and fourth stage scanning process, the tip of the intra oral scanner device should be slightly rotated facing the vestibular slope of the ridge. (Figure 2).

Scan sequence for the mandibular edentulous arch: 1) the scan will begin from one side of the retromolar pad area lingually with the scanner slightly tipped, across the ridge towards the midline. 2) scanning process will begin from the midline of the ridge buccally continuing to the retromolar pad area of the same side. 3) the scan will restart from the midline of the opposite side towards the retromolar area lingually, and the fourth stage will be continued buccally. (Figure 2).

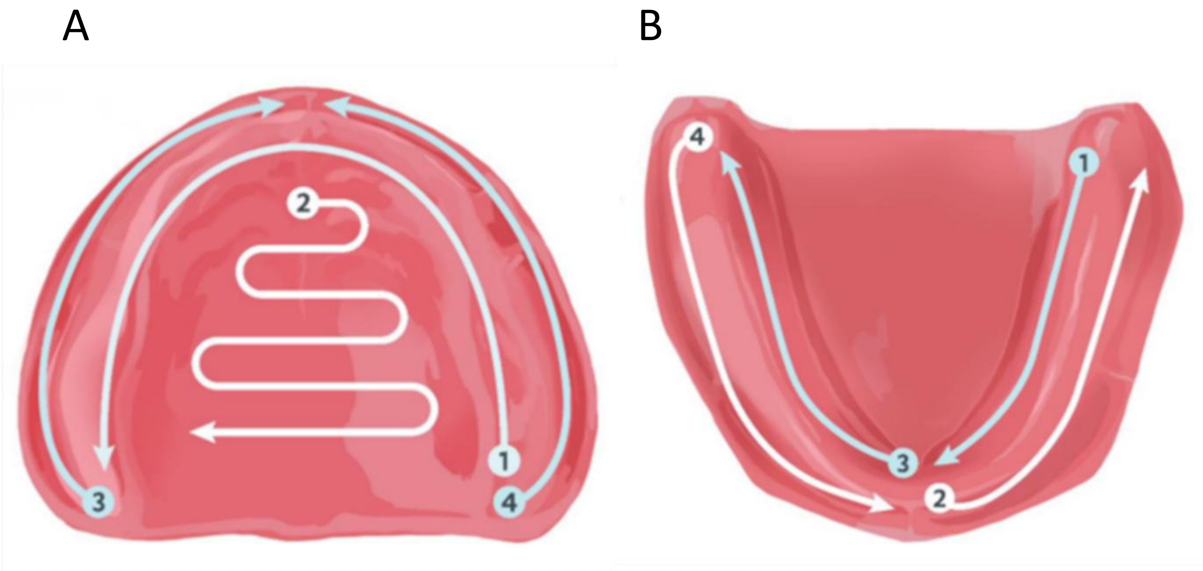

Figure 2. Representation of the scan strategy: A. Maxilla, B. Mandible. Source: Russo 2020, Edentulous Scan Strategy available from: https://www.3shape.com/-/media/files/news-pdf/prof-dr-lo-russo-edentulous-scan-startegy-jan2020.pdfv=8de884d2-7c39-45b7-ae68-35d43e3c4e29.

The intraoral scan will be performed 3 times by the principal investigator to assess the precision. All scans for the same arch will be taken on the same day.

Conventional impressions

During the first visit a preliminary alginate impression (Palgat Plus Quick, 3M ESPE, Milan, Italy) of the edentulous arch using a stainless-steel tray (ASA Dental, Milan, Italy) will be acquired to create a study model. Afterwards, on the study model, an outline of the working area on the model will be drawn to fabricate custom trays specially customized for the patients' edentate arch, by using the product (Photo-tray, Dental Farm Dental Equipment, Italy), which is a light-hardening material made from light-curing resin indicated for custom tray impressions. Following the manufacturer's instructions, polymerization of the custom tray in an ultra-violet light curing unit (Eclipse Junior, Dentsply, Germany) will take about 20 minutes in daylight. Light curing unit will be used to cure the top of the tray on the model, and the curing time will take up to 3-5 minutes, subsequently the inside of the tray without the model will be cured within 3-5 minutes. Final impression will be recorded conventionally using the custom-made photo-tray (Photo-tray, Dental Farm Dental Equipment, Italy), and thermoplastic impression compound ''green stick'' for border molding (Kerr, Kerr Corporation, California, USA) including a high-accuracy impression material. Specifically, the polyvinylsiloxane medium body monophase (Hydrorise Monophase; Zhermack, Badia Polesine Rovigo, Italy), which will be used as the "gold standard" reference for the impression. Afterwards the impression model will be scanned using the laboratory scanner (Ceramill map400, AMANNGIRRBACH, Pforzheim, Germany). The scanning images taken from the impression model will be superimposed on the initial intra oral scan taken from the edentulous arch by using (Geomagic Control X, Artec 3D System, Morrisville, USA), the trueness will then be measured. As trueness protocol requires superimposing the dental models obtained from the same subject with different impression methods (conventional impression) and measuring how close their readings are to one another. High precision and high trueness will result in high accuracy and will be determined by (Geomagic Control X 2022, Artec 3D System, Morrisville, USA) following the measurements on the markers.

Superimposition Software

Geomagic Control X 2022, Artec 3D System, Morrisville, USA. Offers a comprehensive collection of metrology tools for dimensional inspection, surface analysis, and automated inspection. This includes capabilities such as best-fit alignment, color mapping, and programmed reporting. The software is designed with an innate sensitive interface and simplified workflow to make quality measurement processes efficient and user-friendly.

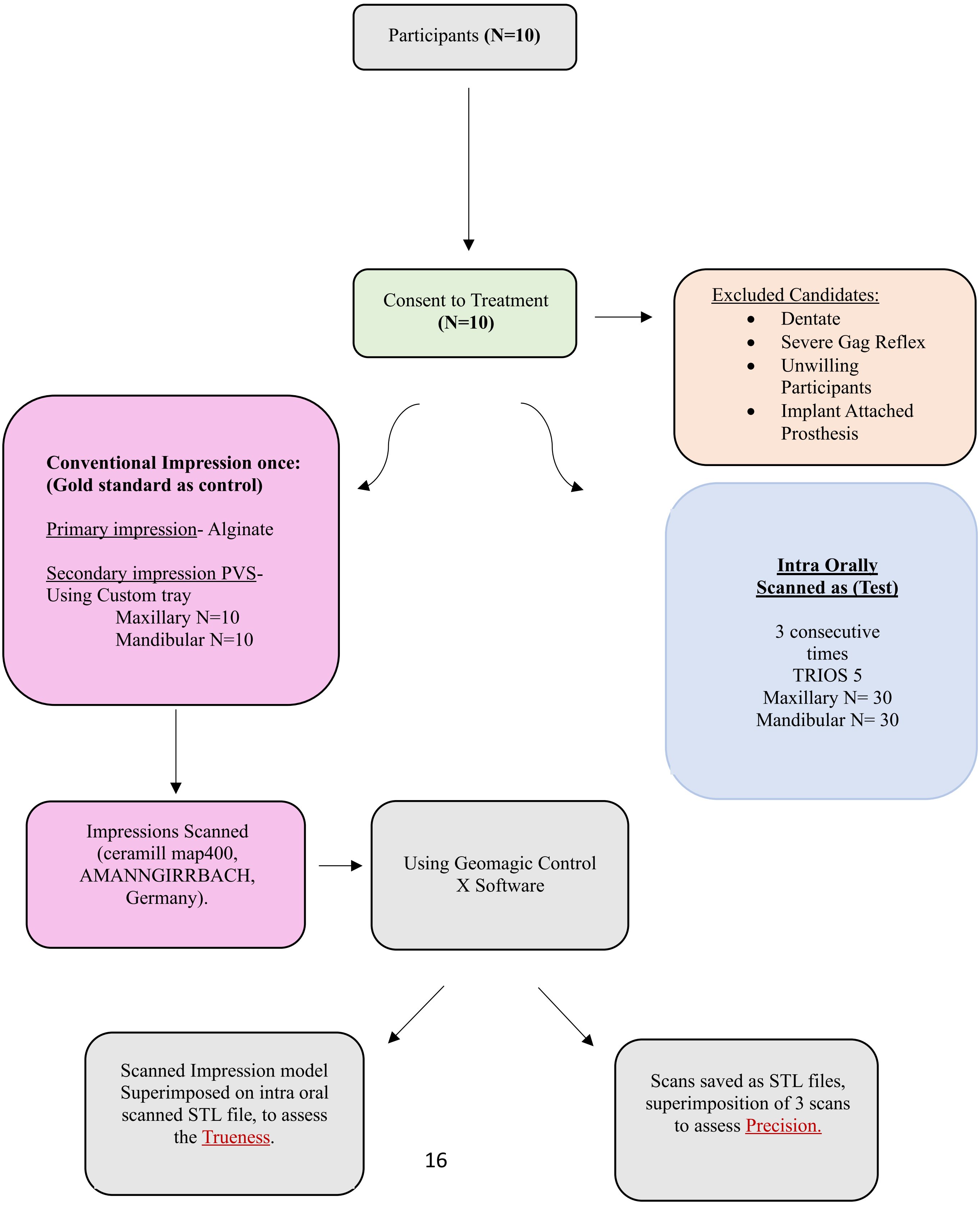

Figure 3. Experimental Design: Flowchart illustrating the experimental design with IOS, and conventional impressions used. Accuracy evaluation by comparison to reference conventional impression and precision evaluation by cross-comparison.

Data Collection

Each conventional impression will be scanned once, and three scans will be conducted on each arch. Each scan data will be converted to standard tessellation language (STL) file format for the purpose of standardization and subsequent digital processing. Each scan will be imported individually into a 3D design and analysis software program (Geomagic Control X 2022, Geomagic, Morrisville, USA).

Trueness and Precision Analysis through Deviation Measurement

Each scan will be divided into dynamic and static regions. The dynamic region will include the mobile tissues at the periphery, which serve as the functional border of complete dentures. The static region will involve around 2 mm short of the depth of the sulcus, and 2 mm short of posterior palatal seal area.

The areas with maximum deviation will be compared in the following regions:

Dynamic areas:

1- Labial sulcus

2- Buccal sulcus (right and left)

3- Lingual sulcus in the mandible (right and left)

4- Post palatal seal area

5- Hamular notch area

Static areas:

1- Palatal rugae

2- Buccal slopes of the alveolar ridge (right and left)

3- Palatal slopes of the alveolar ridge in the maxilla (right and left)

4- Lingual slopes of the alveolar ridge in the mandible (right and left)

5- Anterior alveolar ridge crest

6- Posterior alveolar ridge crest (right and left)

The scan STL files of conventional and digital impressions will be aligned using Geomagic software's Initial and Best-Fit Alignment functions. The software's Best Fit Alignment feature applies an Iterative Closest Point algorithm (ICP) to align the test file to the reference file.

Accuracy in terms of precision requires the superimposition of multiple scans from the same arch. The precision will be evaluated by quantifying the deviation observed after aligning two STL datasets of the same arch. The analysis will involve conducting two-way pairwise comparisons between scan 1, 2, and 3 of the same arch. Each comparison will be done twice, first with scan 1 as the reference and again with scan 2 as the reference. The mean of deviation measures will be determined by calculating the average of the discrepancies.

To evaluate accuracy in terms of trueness, it is necessary to compare different impression methods and assess the agreement between the mean of multiple test results and the reference value. Therefore, the IOS scans and the physical impression scans will be compared by overlying the scan images. The scan of conventional impression will serve as the reference file. The root mean square (RMS) will be calculated as the square root of the average of both positive and negative values, according to the formula:

$$RMS = \sqrt{\frac{\sum_{i=1}^{n} (X1, i - X2)^2}{\sqrt{n}}}$$

n= total number of measuring points,

X1,i= the measuring point of the reference data,

*X*2,I= the measuring point of the IOSs.

The trueness analysis will be presented through the color-difference map and the numerical values of minimum, maximum, average variation, and RMS. The three-dimensional analysis will be finalized by comparing the scans within the defined tolerance range of -100 μm to +100 μm as minimum and maximum values. Then, the deviation measure for the dynamic, static, and the overall areas will be recorded, and the color differences will be displayed and analyzed.

Statistical Analysis

The data will be entered into the computer using IBM-SPSS for Windows version 29.0 (SPSS Inc., Chicago, IL). Continuous variables will be described by using measures of central tendency and measures of dispersion. The Shapiro-Wilk will be used to test the normality of the trueness and precision measurements. Independent paired t-test will be used to compare measurements between conventional and intraoral scan, if the measurements are normally distributed otherwise Wilcoxon will be used as non-parametric test to administrate these comparisons. A P-value of less than 0.05 will be considered significant in all statistical analyses.

Significance of this Research Study:

As society undergoes continuous evolution and life expectancy increases, there is a growing demand for innovative and high-quality dental treatment and care. Individuals seek not only effective dental solutions but also comfortable, effective, and positive experiences. Technology plays a pivotal role in our daily lives, and as clinicians, we recognize the importance of continuing education to provide the community with the best possible dental care. The purpose of this research study is to explore the advantages and limitations of technological intraoral devices. By comparing them to the established gold standard process, we aim to gather valuable information that will develop our understanding and knowledge. This will enable us to better serve the public by providing them with the most valuable and effective dental care possible. The significance of this study lies in its potential to contribute to the advancement of dental practices and improve the overall patient experience, aligning with the evolving needs and expectations of the community.

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