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LOMA LINDA UNIVERSITY
School of Dentistry
in conjunction with the
Faculty of Graduate Studies

**Effect of Splinting Implant Scan Bodies Intraorally on The Trueness of Complete
Arch Digital Impressions: A Clinical Study**

by

Kawther Mahmoud Ali

A Thesis submitted in partial satisfaction of
the requirements for the degree
Master of Science in Prosthodontics

April 2022

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Each person whose signature appears below certifies that this thesis in his/her opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

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DEDICATION

This project is dedicated to my parents, my sisters, and my friends, who's constant support is the fuel to my achievements. My research committee faculty members Dr. Mathew Kattadiyil, Dr. Montry Suprono, and Dr. Antoanela Garbacea for their guidance and assistance throughout this project. In addition, Dr. Abdulaziz Alzaid, Dr. Roberto Savignano, and Dr. Jaime Lozada who were integral parts in making this research project possible.

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and helping me develop it. Dr. Roberto Savignano, for helping refine my methodology to the best possible and refining my geomagic and digital skills. For Dr. Lozada, for giving me the opportunity to conduct a part of my research project in the implant department. Also, Dr. Udochukwu Oyoyo for his statistical analysis and all his efforts. Thank you to every person who has made this project possible.

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ABBREVIATIONS

CAD-CAM	Computer-Aided Design & Computer-Aided Manufacturing
ISBs	Intraoral Scan Bodies
3D	3-Dimensional
IRB	Institutional Review Board
HIPAA	Health Insurance Portability and Accountability Act
PVS	Polyvinyl Siloxane
STL	Standard Tessellation Language
RS	Reference Scan
G1	Group 1
G2	Group 2
mm	Millimeter
LLU	Loma Linda University
LLUSD	Loma Linda University School of Dentistry

ABSTRACT OF THE THESIS

Effect of Splinting Implant Scan Bodies Intraorally on The Trueness of Complete Arch

Digital Impressions: A Clinical Study

by

Kawther Mahmoud Ali

Master of Science, Advanced Education Program in Prosthodontics
Loma Linda University, April 2022
Dr. Mathew Kattadiyil, Chairperson

Purpose: The purpose of this study was to investigate the effect of splinting scan bodies intraorally on the trueness and scan time of implant digital impressions of the edentulous arch.

Materials and Methods: Nineteen edentulous jaws undergoing fixed complete denture treatment with a minimum of 4 implants were selected for this study. Verified master casts of the patients' edentulous jaws were scanned with a desktop laboratory scanner and scan bodies to obtain a reference (control) scan for each patient. Intraoral scan bodies were hand tightened on all the implants in the edentulous arch and an intraoral scan was taken with an intraoral scanner for each jaw; these scans represented the first test group. The same scan bodies were splinted using floss and pattern resin and the edentulous arch was scanned again for all patients; these scans represented the second test group. The scan time for the first and second scan of each patient was recorded. To compare the trueness of the un-splinted scan to the splinted scan, the STL files of the two scans were superimposed to the control scan and positional and angular deviation were analyzed using Geomagic software. One sample T test was used to compare each group's distance and angular deviation to the control.

ANOVA test was conducted to examine the effect of the scan technique on trueness (distance deviation/angular deviation) and scan time ($\alpha=0.05$ for all tests).

Results: There was no statistically significant difference in 3-Dimensional global positional deviation ($p = .493$) or in the X ($p = .794$), Y ($p = .435$), and Z axes ($p = .871$) between the splinted and un-splinted scan groups. No statistically significant difference in angular deviation was found between the splinted and un-splinted experimental groups as well ($p = .250$). A statistically significant difference in mean scan time was found between group 1 (un-splinted) and 2 (splinted) ($p = .001$). The fastest scan time was found with the splinted group with an average of 2-minute faster scan time.

Conclusions: Splinting implant scan bodies intraorally does not affect the trueness of complete arch digital impressions but can reduce scan time.

CHAPTER ONE

INTRODUCTION AND REVIEW OF THE LITERATURE

It has been established that an implant supported prosthesis is a reliable and effective treatment option to replace missing teeth.¹ Making an accurate impression of the osseointegrated implant is an important step in the rehabilitation of patients with a well-fitting prosthesis.²⁻⁴ Inaccuracies with the impression can lead to both biological and mechanical complications as a result of misfit of the definitive prosthesis.^{5,6} The traditional approach to making an implant impression for the edentulous arch involves the use of impression copings that are connected to the implants and captured with elastomeric impression materials such as polyvinyl siloxane or polyether.⁷

With advancements in digital technology especially computer-aided design and computer-aided manufacturing (CAD-CAM) technology, it is now possible to use a digital workflow to obtain an implant impression.⁸ The digital workflow can be either direct or indirect.⁹⁻¹¹ The indirect digital workflow starts with making a conventional implant or abutment level impression that is poured with stone to create a master cast. The master cast is then scanned with a desktop optical scanner using laboratory scan bodies.^{12,13,14} With the direct workflow, intraoral scan bodies (ISBs) and an intraoral scanning device are used to make the direct digital impression of the arch. The intraoral scanner collects information using a light source and cameras to capture images which are then compiled and recorded as individual images or video and processed by the software into the scan that can be displayed on the computer screen.^{12,13,14} After the intraoral scan is captured, a digital implant analog is placed in a digital model in the

computer software with the chosen implant system and ISBs from the software library. Then, a CAD software is used for designing the restoration.^{12,13,14}

Most implant manufacturers and several dental companies and laboratories offer ISBs.¹⁵ Their designs differ according to material, shape, size, surface, connection, reusability, software, scanner compatibility, and cost.¹⁵ Any commercially available ISB consists of 3 parts: a scan region, a body, and a base. The scan region is usually the superior region with a flat side incorporated to help index the scan body and improve the surface recognition by the CAD software.¹⁵ The concept of scan bodies first started with a digitally scannable coded healing abutment that was introduced by Zimmer Biomet and their Encode system (Zimmer Biomet Dental, IN, USA).¹⁶ In 2008, Straumann Holding company launched the first scannable impression copings and named them “scan bodies”.¹⁷

While the overall quality of the digitized data depends primarily on the measuring system used, another important factor that can affect scan accuracy is the characteristics of the surface to be scanned.⁹ The quality of a digitized surface reconstruction and any subsequent measurements are generally accepted to be shape-dependent, whereas the type of material affects the number of points acquired.¹⁰⁻¹² Dull, smooth, and opaque surfaces are easier to scan than shiny, rough, or translucent ones, which can be especially challenging in the oral cavity, where saliva tends to create reflective surfaces and the hard and soft tissues have a variety of textures.¹³⁻¹⁴ The interplay between scanner technology and ISB design must also be considered when attempting to make an intraoral scan. Scanning technologies are proprietary and vary among manufacturers. Therefore, certain scanning systems may be better suited and more accurate when paired with a specific ISB

feature or design. It has been reported that the accuracy of scanning the three-dimensional position of dental implants with ISBs is between 14 and 21 micrometers.¹⁸ However, the accuracy of digital impressions with multiple ISBs can be affected by the distance between the ISBs, the depth of the implant, and the location within the scan and implant angulation.^{1,5,19,20}

When comparing digital to conventional impressions, in vitro and clinical studies have shown that their accuracy is similar for single and short-span restorations.^{16,17,21-24} However, for long span or complete arch fixed prosthesis, the conventional impression technique has been reported to have higher accuracy.^{16,17,19,21-24,25} Gimenez et al (2015)²⁵ tested two intraoral scanners based on confocal microscopy and deemed that none of the scanners would be suitable for multiple-implant prosthesis; the deviation of the digital implant position from the actual implant positions ranged from 28 to 497 micrometers which exceeded the clinically acceptable levels. Also, according to Gimenez et al 2013, 2014, and 2015 for scanners with active wavefront sampling and parallel confocal technologies errors increased from first to last implant scanned in full arch edentulous implant digital impressions.^{25,26, 27} This was attributed to errors in stitching that accumulated as the scan path progressed from the first to last implant due to the absence of anatomic landmarks in fully edentulous arches.^{25,26,27} A systematic review by Alhlom et al²² (2018) reported that the range at which the trueness of digital impressions is less than the conventional impressions is 8 to 40 microns; that of precision is 7 to 50 microns. The study included in vitro studies conducted by Ender and Mehl 2011, 2013, 2015, and two in vivo studies conducted by Flugge et al 2013 and Ender et al 2015 that only looked

at precision not trueness.²² According to a systematic review by Zhang et al¹⁹ (2021) that included 29 in vitro studies and one in vivo study, the trueness of digital implant impressions ranged from .007 to .731 mm, and the precision ranged from .015 to .204 mm. Angular deviations were between .13 and 10.01 degrees.¹⁹ Difficulties in obtaining an accurate full arch digital impression stem from the absence or scarcity of quality reference points between the scan bodies. Images obtained from a scan with little reference points may not be stitched correctly.^{28, 29,30}

There are many advantages of digital impressions when compared to the conventional method.²² Some examples include reduced risk of distortion during the laboratory phases, improved patient comfort and acceptance, and improved efficiency.²² Splinting is one of the techniques introduced to conventional impression to increase its accuracy. It has been proposed that splinting may decrease micromovements of the impression copings due to pressure from the impression material while making and subsequent removal of the final impression.³¹⁻⁴⁶ The effect of splinting impression copings on the accuracy of implant casts has been studied but the results were inconclusive; some studies reported no difference in the accuracy between splinted and non-splinted impression techniques, while others advocated splinting for higher accuracy.

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In this study, a technique for splinting ISBs to increase the accuracy of full arch intraoral scanning, will be investigated. The mechanism hypothesized in this study on the effect of splinting is not like that proposed in conventional impressions. We suggest that splinting scan bodies intraorally may help create more reference points for the scanner to

identify and stitch images better. This may result in shorter scanning time and better localization of the 3-dimensional (3D) position of implants in the edentulous arch. Some techniques in the literature have been proposed to modify the surface topography of the edentulous arch to help increase scanning accuracy.^{47,48} Some in vitro and in vivo studies evaluated the effect of a printed scan body splinting device on the accuracy of full arch implant scans.^{49,50} However, to date, the authors are unaware of any published clinical study that has evaluated the effects of using this more convenient and traditional splinting technique for intraoral scanning of a completely edentulous arch.

Aim

This study aims to investigate the effect of splinting scan bodies intraorally on the trueness and scan time of implant digital impressions of the edentulous arch.

Null hypothesis: There will be no difference in the trueness and scan time of implant position in the complete arch intraoral scans with the splinted scan bodies as compared with un-splinted conventional scan.

CHAPTER TWO

MATERIALS AND METHODS

Approval from Loma Linda University Health Institutional Review Board was obtained on 4/20/21.

Subject Recruitment and Screening

Target study population was patients receiving dental treatment (fixed complete denture) in the Advanced Education Programs in prosthodontics and implant dentistry for maxillary or mandibular edentulous arches with 4-6 dental implants.

The inclusion criteria were as follows: patient must be at least 18 years old, able to sign consent for the study, in good general and oral health, and receiving treatment for 4-6 implant (implant or abutment level) fixed complete denture in at least one arch. The exclusion criteria were as follows: patients with failing or ailing implants according to Albrektsson (1986) criteria⁵¹, partially edentulous patients, and patients with systemic debilitating diseases, ataxia, trismus, neuromuscular disturbances, temporomandibular joint disorder, or limited mouth opening. For recruitment, patients who were planned for implant fixed complete denture in Loma Linda University School of Dentistry in periods from April to December 2021 were selected. IRB approved flyers were distributed to all patients with the inclusion criteria in the prosthodontics and implant departments to help in recruiting patients for the study. Patients who were interested were given the informed consent form to review and sign. The investigator (K.A.) answered all questions that the subjects had and signed the informed consent form. An oral hard and soft tissue

examination was performed by the investigator to enroll the patients in the study. A total of nineteen jaws were recruited in the study.

Informed Consent Process

All patients volunteered to sign an informed consent form that explains the study, procedures involved, duration, risks and benefits, as well as alternatives. Also, the procedure was explained verbally, and any questions were answered before starting the scanning process. All patients were mentally competent and had no mental illness or condition that would interfere with decision making and were fully capable of determining whether they want to participate or not. HIPAA (Health Insurance Portability and Accountability Act) compliance was followed as well. A copy of the informed consent form was given to the patient.

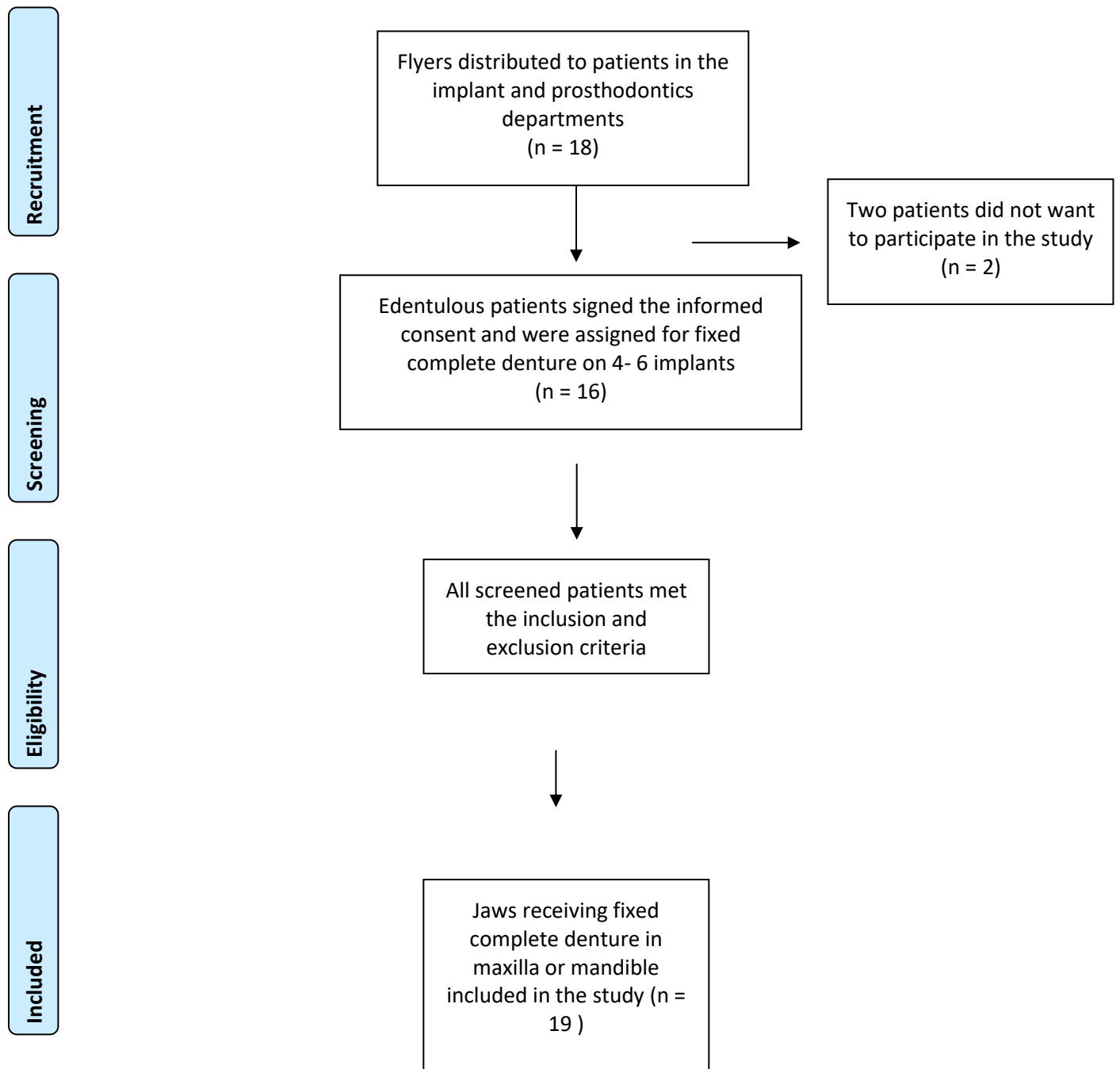


Figure 1. Showing a flow chart of the recruitment, screening, eligibility, and inclusion process

Master Cast Fabrication

As a part of patients' treatment process to fabricate a fixed complete denture, implant master casts were made following a conventional open tray splinted complete arch implant final impression using Polyvinyl Siloxane (PVS) impression material (Examix, GC America Inc, CA, USA). A standardized protocol was followed when making the full arch impression and master cast fabrication. The conventional impression procedure starts with screwing open tray impression copings depending on the patient's implant manufacturer and verifying the seating of the copings with periapical radiographs. Then, unwaxed dental floss (Vitis; Dentaaid, Barcelona, Spain) and pattern resin (GC Pattern Resin; GC America Inc, CA, USA) were used to splint the impression copings. An acrylic stock tray (Dentsply; DE, USA) received a thin layer of vinyl polysiloxane adhesive (3M Inc; MN, USA) that is air dried for 7 minutes per manufacturer instructions. An open-tray (direct) technique was used to make the final impression; windows were made in the custom tray to allow access to the impression posts. Then, heavy body PVS impression material was loaded in the tray. Light body PVS impression material was injected around the splinted impression copings. After 5 minutes of setting time, the impression posts were picked up with the impressions by unscrewing them through the access windows created in the prefabricated plastic tray. Implant replicas for Straumann and Nobel were screwed carefully into each impression post. The impression was then boxed, soft tissue replica (G-mask; Coltene Whaledent Inc, OH, USA) was placed around the impression copings prior to pouring to replicate the gingival profile and act as a substitute for gingiva on the tested cast. Then, the impression was poured with Type IV stone (Resin Rock, Whipmix Corp, KY, USA) (Figure 2). The

implant master casts were verified using temporary abutments with a custom jig fabricated using pattern resin material (GC Pattern Resin; GC America Inc, CA, USA). The custom jig was fabricated on the cast by first attaching temporary abutments based on each patient's implant manufacturer. Then, GC pattern resin was used to splint the abutments together. The splint was then sectioned, re-attached and removed after 18 minutes wait time. Then, intraorally, this jig was screwed on the patient's implant with one screw on one implant only. Visual and tactile inspection, alternate finger pressure test, one screw test, screw resistance test as well as periapical radiographs were used to verify if any misfit was noted between the verification jig and the implants.⁵² Verification of the cast was needed for the master cast to be part of this study. If misfit was noted, the final impression was repeated, then a new master cast was produced and verified with the same procedure mentioned above.



Figure 2. Showing a representative stone implant master cast of the mandibular arch of one patient with 4 implant replicas.

Scanning Technique

For all intraoral scanning procedures, one experienced operator (K.A.) performed the scanning procedure of all subjects.

a) Reference Scan (Control Group)

Based on each patient's existing implant manufacturer, proprietary intraoral scan bodies were used to scan the master casts using an ISO 12836 calibrated desktop scanner (3Shape D900L; 3Shape Inc, NJ, USA). The scanner's reported accuracy for implants was reported to be as close as 8 micrometers.⁵³ The ISBs were screwed into each implant replica in the master cast and then the cast was scanned using the desktop scanner to obtain

digitized model by reverse engineering of the cast surface. The digitized model was then saved as a standard tessellation language (STL) file to serve as the reference scan (RS) of the patient (Figure 3). This scan represents our control group.

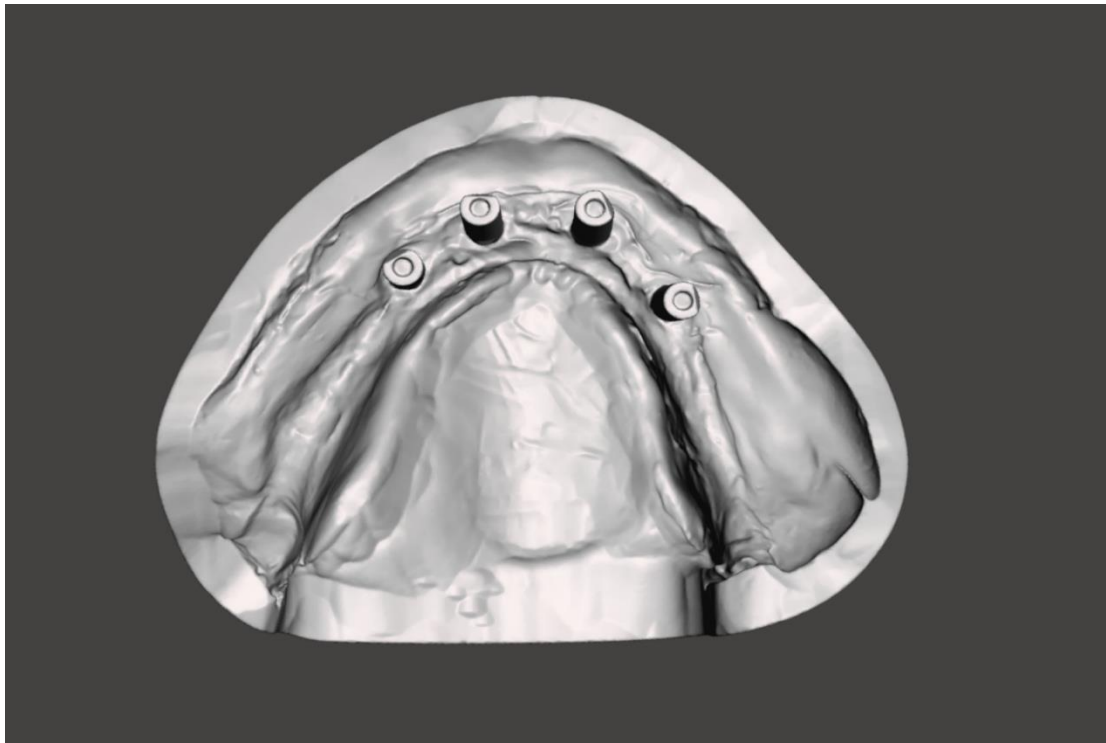


Figure 3. Showing a representative reference scan (control group) in STL format of the mandibular arch of one patient's master cast with 4 implant intraoral scan bodies.

b) Experimental Groups Scans

Group 1:

Intraorally, implant manufacturer proprietary intraoral scan bodies were screwed, and hand tightened in the patients existing implants. Visual and tactile inspection was used to verify seating. Intraoral scanner (3Shape Trios3; 3Shape Inc, NJ, USA; Food and drug registration ID 3015172511) was used to capture implant position. One investigator (K.A.)

that is experienced with intraoral scanning performed all intraoral scans for all patients. A standardized scan path was used according to the manufacturer's recommendation, which consists of scanning the occlusal surface, then the buccal surface, and then the palatal surface. All scans were timed from start to finish, and a scan is considered complete once the scan body surfaces are captured entirely and no major deficiencies (holes or artifacts) in the patient's edentulous ridge were present. This scan was saved as a STL file and represented the first test group of the patient in this study (G1). (Figure 4).

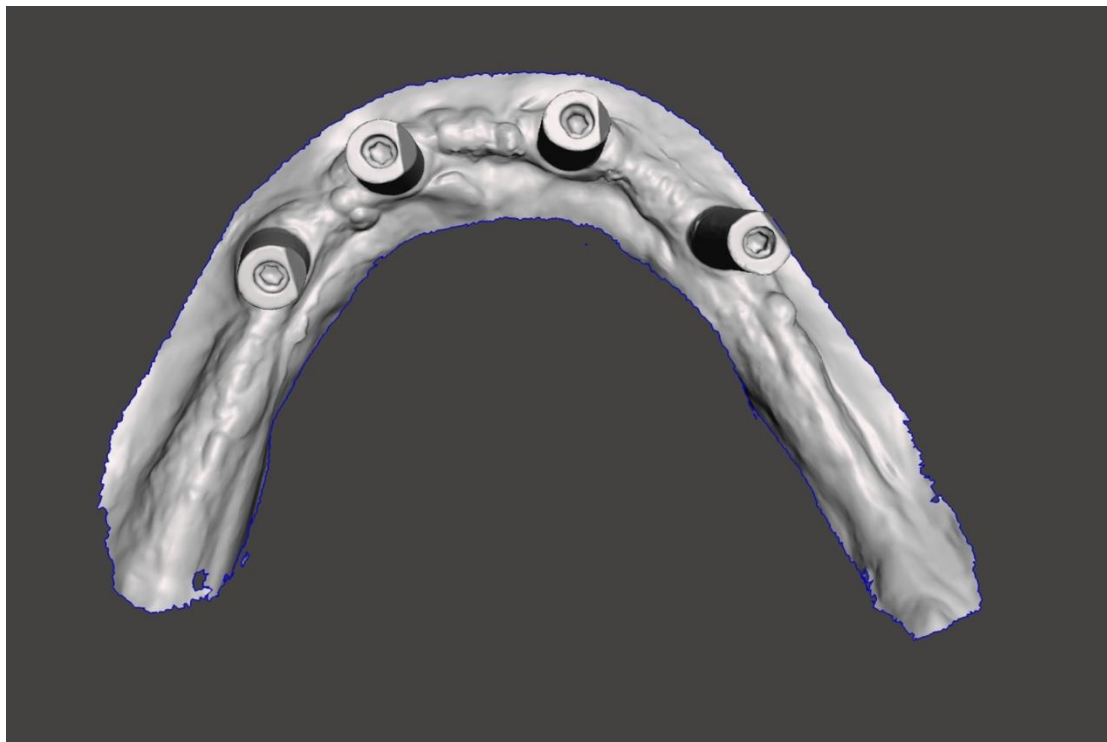


Figure 4. Showing a representative scan for the first test group (G1) of the mandibular arch of a patient with 4 implant intraoral scan bodies.

Group 2:

Following the completion of the first scan, all scan bodies were splinted using unwaxed dental floss and pattern resin material. After the material was set, the splint was sectioned and then re-attached intraorally. Then, notches were made on the splint to improve the scanning procedure. After that, a second intraoral scan was made with the splint in place in the same standardized manner described above for group 1. This scan was saved as a STL file and represented the second test group in this study (G2) (Figure 5).

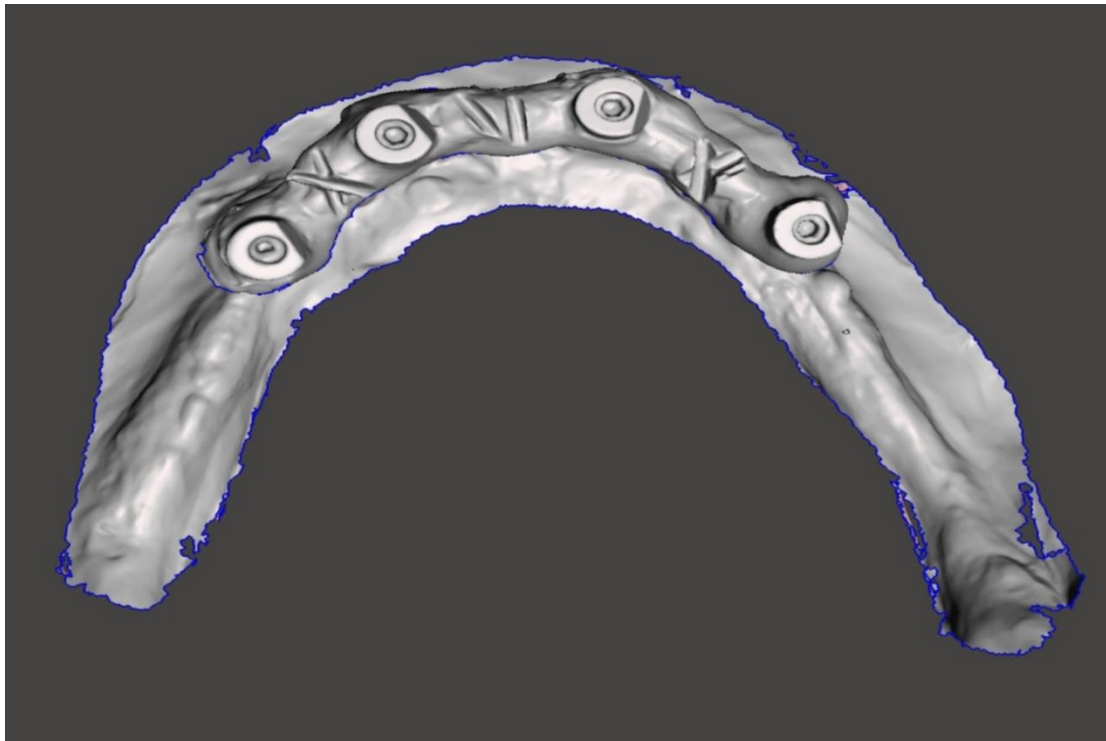


Figure 5. Showing a representative scan for the second test group (G2) of the mandibular arch of a patient with 4 splinted implant intraoral scan bodies.

Scan Body Information

CARES® (Straumann Inc; Switzerland) and Elos® (Nobel Inc; Sweden) were used for Straumann and Nobel implants respectively. Both scan bodies were made from polyether ether ketone PEEK material and were screwed into implants with a titanium screw. They both were cylindrical with an index; CARES® scan body was 9 millimeters in height and 5 millimeters in diameter while Elos® was 10 mm in height and 5 millimeters in diameter.

Scan Time

The scan time for each test group (G1, G2) for each patient recorded automatically in the intraoral scanner software was documented in an excel data collection sheet. Scanning time was defined as the time needed to complete intraoral implant full arch digital impression with no major deficiencies (holes or artifacts) in the patient's edentulous ridge or scan bodies present.

Evaluation of the Trueness of Scanning Technique

Trueness is defined as the amount of average distance and average angular deviation between the corresponding scan bodies in the test scan and the reference scan.

a) Positional Deviation

Test scan 1 and test scan 2 were superimposed over the RS of the same patient using the best-fit algorithm of a professional engineering software program (Geomagic Inc, NC, USA). A coordinate system was created and used throughout the entire inspection to measure the 3D distance deviation of the scan bodies. For the positional deviations, a cross section was created from a flat plane dissecting each scan body, and the center point is located and compared with the corresponding point on the RS, giving positional changes

in the X, Y, and Z directions. The scan bodies used for each measurement were labeled 1 through 4...etc, and the same labels were used for every inspection. The distance deviation is calculated by entering the raw data into the distance formula to generate the 3D distance deviation for each scan body and then averaged among the total scan bodies on the model.

b) Angular Deviation

To determine the angular deviation, cylinders were fitted to each scan body by using the same computer software program, and a central axis is generated for each. The nominal axis from the RS is considered to be at an angle of zero, and the resultant 3D angle between the RS and test scans is recorded and then averaged to generate the angular deviation among the total scan bodies in the patient's scan.

Note that the scans superimpositions and measurements for positional and angular deviation were repeated three times to ensure validity.

Statistical Analysis

The selected effect size was 40 microns for positional deviation, 0.25 degrees for angular deviation, and 1 minute for scan time. The selected standard deviation was 5 microns for positional deviation, 0.5 degrees for angular deviation, and 30 seconds for scan time; these numbers were based on the findings of a previous in vitro study by Mizumoto et al (2019)⁵⁴. Based on the previously mentioned effect size and standard deviation, as well as alpha of 0.05, and 80% power, a total sample size of 19 per group was calculated using G*Power 3.1. Descriptive statistics of the mean and standard deviation of the positional deviation (represented in millimeters), angular deviation (represented in degrees), and scan time (represented in minutes) were calculated. ANOVA test was conducted to examine the effect of the scan technique on trueness (distance deviation/angular

deviation) and scan time. The scan time for each group was recorded and compared between the two groups using ANOVA test and analysis of the number of implants and arch effect was accounted for. One sample T test was used to compare the difference between the control (reference scan) with each group individually in terms of positional and angular deviation. Shapiro Wilk test was used to test normality. Statistical analysis was completed using Jamovi⁵⁵ and R Core⁵⁶ software with alpha of 0.05.

The dependent variables evaluated were total angular deviation, 3D global positional deviation, X deviation, Y deviation, and Z deviation. The independent variables evaluated were group1 (conventional un-splinted scanning technique) vs group2 (splinted scanning technique), maxilla vs mandible, and implant manufacturer: Straumann vs Nobel.

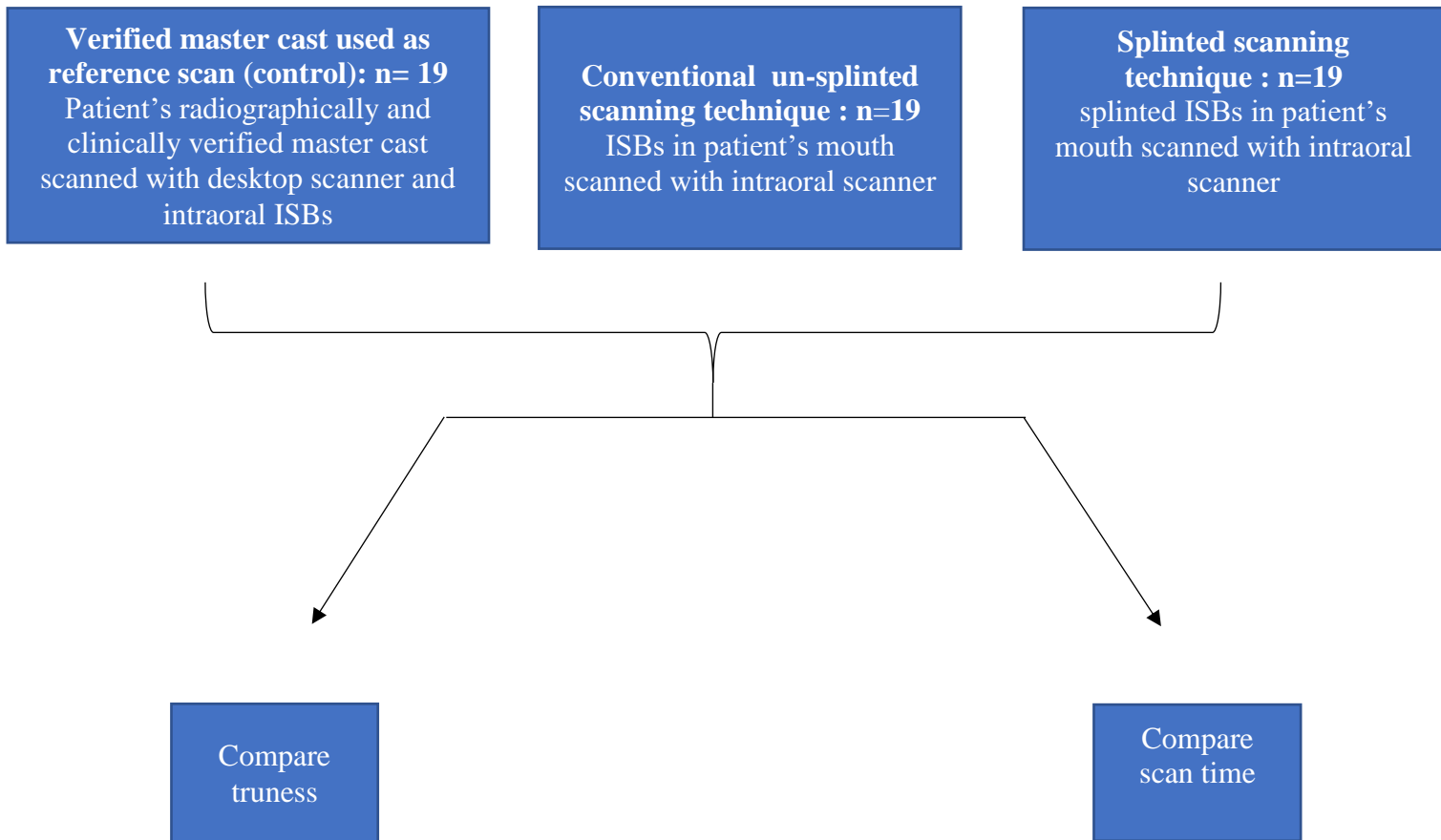


Figure 5. Schematic diagram of study material and methods.

CHAPTER THREE

RESULTS

The total number of patients recruited in this study was 18. Two patients dropped out from the study because they refused to sign the informed consent. The attrition rate was 10%. No adverse events occurred while conducting this study. Shapiro wilk test was used for normality and the results were statistically significant ($p = <.001$). Levene's test was used to test the homogeneity of variances and was statistically significant ($p = .003$). The raw data for distance deviation, angular deviation, and scan time for all patients are shown in Figures 7-8. All patients' variables are presented in Table 1. The results of one sample T test are shown in Table 2. The results of the ANOVA test are shown in Table 3.

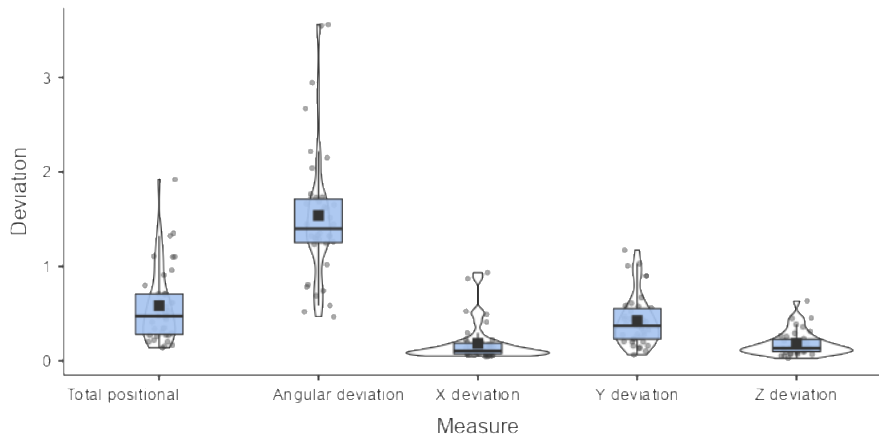


Figure 7. showing all patients' deviations in both groups from the control (3D global positional deviation in millimeter, angular deviation in degrees, and linear deviations in X, Y, Z axes respectively in millimeters).

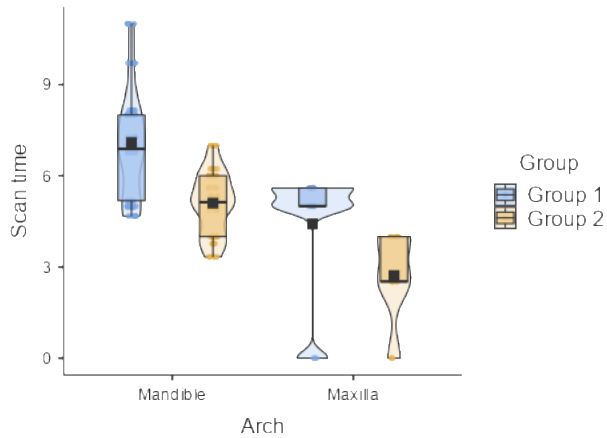


Figure 8. showing all patients’ scan time in minutes plotted against arch type (Maxilla Vs Mandible). Group 1 in blue indicates un-splinted conventional scan. Group 2 in yellow indicates splinted scan

Table 1. Shows sample numbers according to variables (number of implants, arch, implant manufacturer, scan level)

Variables								
Number of samples	Arch		No. of Implants		Implant Manufacturer		Scan level	
	Maxilla	Mandible	4	>4	Straumann	Nobel	Abutment	Implant
	4	15	7	12	13	6	18	1

Table 2.

One sample T test results comparing positional and angular deviation between conventional impression and digital impressions (both splinted and un-splinted groups)

Property	df	Mean Difference	p
Group 1 positional deviation	18	.62	< .001
Group 2 positional deviation	18	.55	< .001
Group 1 x deviation	18	0.197	< .001
Group 2 x deviation	18	0.173	< .001
Group 1 y deviation	18	0.441	< .001
Group 2 y deviation	18	0.412	< .001
Group 1 z deviation	18	0.179	< .001
Group 2 y deviation	18	0.191	< .001
Group 1 angular deviation	18	1.53	< .001
Group 2 angular deviation	18	1.55	< .001

df= degrees of freedom

p= p value

Mean difference denotes the difference in value in comparison to the control group

Table 3.

ANOVA test results comparing positional and angular deviations between conventional un-splinted and splinted groups

Property	Type III Sum of Squares	df	Mean Square	F-ratio	p
3D global positional deviation	.087	1	.087	.481	.493
x- deviation	.003	1	.003	.069	.794
y- deviation	.049	1	.049	.624	.435
Z- deviation	.000	1	.000	.027	.871

Angular deviation	.010	1	.010	.026	.874
--------------------------	------	---	------	------	------

df= degrees of freedom

***p*= *p* value**

According to one sample T test, there was a statistically significant difference in positional (3D global, x, y, and z axes) and angular deviation between the conventional impression and the un-splinted digital impression for each jaw ($p < 0.001$). The mean deviation of the un-splinted digital impression in comparison to the control conventional group was .62 millimeters for positional deviation, and 1.53 degrees for angular deviations. There was also a statistically significant difference in positional (3D global, x, y, and z axes) and angular deviation between the conventional impression and the splinted digital impression for each patient ($p < 0.001$). The mean deviation of the splinted digital impression in comparison to the control conventional group was .55 millimeters for positional deviation, and 1.55 degrees for angular deviations. The average 3D global positional deviation for all intraoral scans from the reference scan ranged from 0.137 to 1.9 mm with a mean of 0.58 mm. The average angular deviation for all intraoral scans ranged from 0.5 degrees to 3.5 degrees with a mean of 1.5 degrees. Comparing the y, z, and x axes: the y deviation was the highest (mean of 0.4) in comparison to x and z deviation (mean of 0.185)

The 3D global positional deviation difference between the two groups ranged from .007 to .7 mm. However, ANOVA test revealed that there was no statistically significant difference in 3D global positional deviation ($p = .493$) and in the x ($p = .794$), y ($p = .435$), and z axes ($p = .871$) between the splinted and un-splinted groups. When the variables (number of implants, arch, implant manufacturer) were evaluated, no

statistically significant difference in three-dimensional global deviation was found ($p=.863, .774, .917$) respectively. The results of the ANOVA test of the variable effects on 3D global positional deviations are shown in Table 4.

Table 4.
ANOVA test results comparing 3D global positional deviation with different variable (number of implants in arch, arch type, implant manufacturer)

Angular deviation	Type III Sum of Squares	df	Mean Square	F-ratio	<i>p</i>
No. of Implants in the arch	.005	1	.005	.030	.863
Maxilla Vs Mandible	.015	1	.015	.084	.774
Straumann Vs Nobel	.002	1	.002	.011	.917

df= degrees of freedom
***p*= *p* value**

Angular deviation differences between the two groups ranged from (.8 - .04 degrees). However, no statistically significant differences in angular deviation were found between the two groups ($p = .874$). The arch, and implant manufacturer did not influence angular deviation; however, the number of implants. In the arch affected angular deviation for both groups. A statistically significant relationship was found between the number of implants and the angular deviation ($p = .001$). No statistically significant differences were found for the following dependent variables (arch type, implant manufacturer) ($p = .437, .719$) respectively. The results of the ANOVA test of the variable effects on angular deviations are shown in Table 5.

Table 5.
ANOVA test results comparing angular deviations with different variable (number of implants in arch, arch type, implant manufacturer)

Angular deviation	Type III Sum of Squares	df	Mean Square	F-ratio	<i>p</i>
No. of Implants in the arch	6.134	1	6.134	15.983	<.001
Maxilla Vs Mandible	.238	1	.238	.621	.437
Straumann Vs Nobel	.050	1	.050	.131	.719

df= degrees of freedom
***p*= *p* value**

In terms of scan time, the time taken to scan an edentulous arch ranged from 3 to 8 minutes. A statistically significant difference in scan time was found between the two groups (splinted and un-splinted group) ($p = .001$). Conventional un-splinted scanning techniques took a longer time in comparison to the splinted technique. The splinted group showed an average of 2-minute faster scan time compared to the un-splinted group. Moreover, the maxillary arch scan was consistently faster than the mandibular arch with a statistically significant difference of ($p = .001$). The maxillary arch had an average of 2-minute faster scan time. Figure 9 depicts the relationship between scan time and arch.

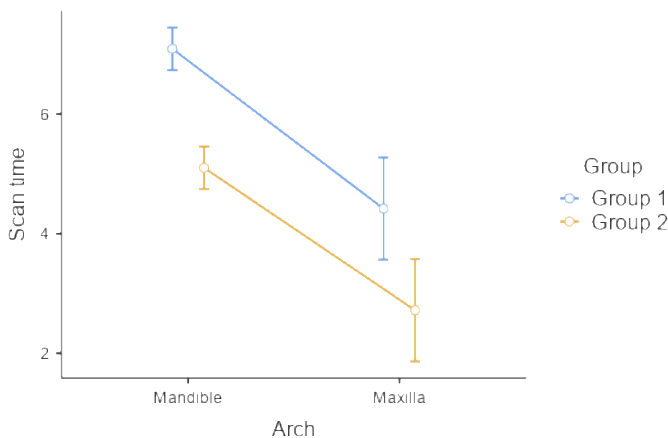


Figure 9. depicts the relationship between scan time in minutes and arch (maxilla vs mandible) in both groups. Group 1 in blue represents the conventional un-splinted scan. Group 2 in orange represents the splinted scan.

CHAPTER FOUR

DISCUSSION

This study analyzed the trueness and scan time of edentulous full arch intraoral scans taken with an intraoral scanner and scan bodies conventionally and compared it with a new technique that involves splinting intraoral scan bodies. The null hypothesis was rejected as there was a statistically significant difference in the scan time of complete arch digital implant impression between splinted and un-splinted groups; however, the trueness of complete arch digital implant impressions showed no statistical difference between splinted and un-splinted groups.

According to the results of this study, the conventional impressions were more accurate than the full arch digital impressions with or without the splint and the results were statistically significant. This is consistent with another study by Alikhasi et al⁵⁷ (2018) compared the accuracy of conventional and digital impressions of the completely edentulous maxilla with four implants using TRIOS intraoral scanner; the linear and angular deviations reported in the previous study ranged from .188 to .162 mm and .585 to 0.364 mm, respectively; the previous numbers fall within the lower range of deviations found in our study. Also, one clinical study by Chochlidakis et al⁵⁸ (2020) had a similar design to our study and they investigated digital vs conventional impressions on 16 edentulous maxillae with 4, 5, and 6 implants; they found that the 3D deviations between virtual casts from intraoral full-arch digital scans and digitized final stone casts generated from conventional implant impressions was .162 +/- .077 mm. The deviations found in the previous study also fell in the lower range of numbers resulting from our

study. They also concluded that the deviations were clinically acceptable. However, they used root mean square measurements as opposed to the method used in our study and they only included maxillary arches; they also only scanned the maxillary arches when fiducial markers were present in the palate which might have affected the scanning process, superimposition in Geomagic software, and the resulting deviation values. In addition, a recent retrospective study by Pappasyridakos⁵⁹ et al (2022) investigated 36 edentulous jaws maxillary and mandibular and compared intraoral scans of the patients with extraoral scans of their verified master casts for complete fixed implant supported prosthesis. They concluded that the 3D implant deviation differences between the full-arch digital and conventional impressions lie within the clinically acceptable threshold. The cumulative 3D deviations between virtual casts from intraoral full-arch digital scans and digitized stone casts generated from conventional implant impressions were found to be $.088 \pm .024$ mm which was lower than the values that we found in our study.

When analyzing systematic reviews on the topic, the results of two systematic reviews by Alhlom et al²² (2018) and Zhang et al¹⁹ (2021) concluded similar findings to our study; they concluded that full-arch digital implant impressions taken using intraoral scanners are not sufficiently accurate for clinical application and that accuracy varies greatly with inter-implant distance, scan body type, intraoral scanner type, and operator experience. However, one systematic review by Pappasyridakos et al⁶⁰ (2020) that was based on 5 in vitro studies had opposing results; they reported that the mean 3D implant deviation between conventional and digital impressions was $.0082$ mm and the digital impressions had nominally less deviation, but it was not clinically significant ($p = .72$);⁶⁰ Of the 5 studies that were included in the systematic review, 2 studies used True

Definition (3M ESPE, St Paul, MN) scanner to compare accuracy and three used Trios (3Shape, Copenhagen, Denmark). The result was favoring digital scan when True Definition (3M ESPE, St Paul, MN) was used and the difference was .074 mm, while it slightly favored conventional impression when Trios (3Shape, Copenhagen, Denmark) was used, and the difference was .017 mm; this may be more consistent with the findings from our study. However, both results were not statistically significant ($p = .31$ and $p = .13$, respectively).

The mean positional deviation of the digital impression in comparison to the control conventional group in our study was .62 millimeters and .55 millimeters for unsplinted and splinted groups respectively. The mean of positional deviation in both groups resulting from the study was above 150 microns which is considered the acceptable clinical cut off value for misfit;⁶¹ this means that digital impressions may not produce acceptable fitting prostheses. However, the results should be interpreted with caution because we did not evaluate the fit and accuracy of the final prosthesis. Converting the intraoral scan to a fabricated prosthesis/framework requires steps that include the fabrication of a digital cast with implant analogs, digital design of a framework, and final milling or printing of the prosthesis. This may lead to compounded errors and may compromise the fit of the final prosthesis. It should be noted that a recent randomized control trial by Capparre et al⁶² (2019) investigated the difference in accuracy of digital versus conventional impressions for screw retained fixed full arch maxillary prosthesis;⁶² the study concluded that the fit of the fixed prosthesis fabricated through the digital approach resulted in acceptable accuracy and marginal fit. However, the study included extraoral scanning of a provisional implant supported prosthesis as part of the

workflow and this may confound the results obtained. In addition, the article only included maxillary prostheses; the maxillary palate may provide more fixed reference markers in comparison to the mandible. More research is needed to prove that a prosthesis fabricated solely through a full arch edentulous scan for the maxillary and mandibular arches is acceptable in accuracy and predictable.

The mean angular deviation of the digital impression in comparison to the control conventional group was 1.53 and 1.55 degrees for un-splinted and splinted groups. In this study, the resulting angular deviation reached about 3.5 degrees in some samples (mean was 1.54 degrees); this may result in inaccurately fitting prosthesis since the clinically acceptable level of angular deviation was 0.4 degrees according to Andriessen.²⁸

The positional and angular deviations reported in this study fall within the trueness ranges reported in the literature; for example, Zhang reported that the positional deviation of digital implant impressions ranged from .0076 to .732 mm, and angular deviations were between 0.13 and 10.01 degrees.¹⁹ The mean positional (.5 mm) and angular deviations (1.54 degrees) of digital impressions obtained in this study fall within that range. However, the higher level of 3D global deviations obtained in this study is much higher than what was reported in the literature; this may be because in our study, the plane level at which those measurements were made were at the most superior plane of the scan body. Obtaining the measurements closer to the base of the scan body (closer to the Implant platform) may give smaller deviation values and may be more clinically relevant. For example, for our study, the mean positional deviation at the base of the scan body will be .52 for un-splinted group and .46 for the splinted group which is 60 to 90

microns less deviation than if obtained at the top of the scan body. That is why a study on the prosthetic level may be most clinically relevant than in vitro and in vivo studies that investigate the digital impressions alone. Moreover, previous studies might have used different intraoral scanners, different reference scanners to digitize the master cast, different reverse engineering analysis programs that use different algorithms and different deviation measurement methods or superimposition techniques than ours. Also, in our study, different variables existed which explained the wide range of results: different implant manufacturers, arch type, scan level, and and implant numbers and angulations might have affected the wide range of deviations found. Also, most of the values reported in the literature came from in vitro studies which might explain why the deviations in the literature were lower since casts don't have saliva or movable tissues that may affect the accuracy. It should be noted that the interquartile range matched the studies in the literature if we do not include the maximum values.

Splinting theoretically can increase the fiduciary points for the scanner and decrease inaccuracies. However, the findings in this study showed that with the additional fiduciary markers introduced by the GC pattern resin, the positional and angular deviation (trueness) of 3D implant position in the edentulous arch was similar between splinted and un-splinted groups. This is consistent with a previous in vitro study by Garbacea et al⁵⁰ (2022), in which a printed scan body splinting device did not increase the accuracy of full arch implant scans.⁵⁰ On the contrary, Mizumoto et al⁵⁴ (2019) showed that introducing extra reference points in the form of glass beads or pressure indicating paste in an edentulous implant model may decrease inaccuracies.⁵⁴ Itturrate et al⁴⁹ (2019) also concluded that a

printed splinting device can help improve the accuracy of full arch digital impressions; they evaluated the trueness and precision of invitro edentulous scans with and without an auxiliary geometric design and they found that the AGD improved the trueness by 10-60 mm and the precision by 7-20 mm.⁴⁹ They concluded that the device helped resolve the lack of anatomic landmarks in edentulous patients as well as allow a more fluent scanning process. Moreover, in an in vitro study on a partially edentulous cast, Kim et al⁴⁷ (2016) evaluated the accuracy of intraoral scanners of a long edentulous space with and without artificial alumina land marker; they concluded that the use of an alumina artificial landmark in an edentulous space improved the trueness and precision of the intraoral scanners tested. However, when analyzing the differences in trueness and precision of the reported outcomes with and without land markers the artificial landmarks improved the trueness by about 10 micrometers) and precision by (30 micrometers) which may not be clinically significant).⁴⁷ Pozzi et al (2022)⁶³ conducted an invitro study in which he compared full arch implant impressions of edentulous arches with and without an easily assembled printed splint (printed modular chain); he concluded that angular and linear discrepancies were markedly reduced with a splint.⁶³ Retana et al⁶⁴ (2020) also conducted an in vitro study analyzing the effect of splinting scan bodies on the trueness of digital impressions; He concluded that splinting the scan bodies can improve the trueness of digital complete arch implant scans due to the improvement in morphological landmarks for the stitching process regardless of the type of the IOS or the inter-implant distance.⁶³ In vitro studies, however, do not account for the effect of saliva, the movable tissue, and tongue muscles that may affect intraoral scanning.

In this study, the number of implants in the arch affected the angular deviation for both groups. A statistically significant relationship was found between the number of implants and the angular deviation ($P = .001$). The angular deviation values in this study were higher if the number of implants were less (4 only). These findings may be consistent with other studies in the literature in which the number of implants and inter implant distance affected the accuracy of intraoral scans.^{15, 19, 22} Beuer et al¹⁴ (2008) conducted a clinical study which found that jaw traversing distances of more than 40 mm led to more scanning errors. Also, in an in vitro study by Flugge et al⁶⁵ (2016), it was found that the precision of intraoral scanners decreased with an increasing distance between the scan bodies. Retana et al⁶⁴ (2022) found that increasing the inter-implant distance decreased the trueness values of complete arch digital implant impression regardless of splint use. This can be explained by the fact that more implants mean more fixed reference points and that leads to better stitching of the images by the intraoral scanner software. This was also explained by Van der Meer et al⁶⁶ (2022) who stated that with the increase in length of the arch and distance, angular errors might increase in IOSs because of accumulating errors.⁶⁶

For scan time, splinting significantly reduced scan time in this study and it can be explained in that a fixed device like a splint leads to more fixed reference markers that are easier to scan in comparison to movable soft tissue. The splint position was also closer to the scan body index in comparison to the soft tissue and hence, may be more easily detectable. This is like a previous study by Mizumoto et al⁵⁴ (2020) in which adding additional reference markers to edentulous implant casts scanned with scan bodies also shortened scanning time.⁵⁴ It should be noted that finding a method of splinting that

is faster than GC pattern resin may be beneficial since the time taken for the fabrication of the splint may take up to 20 minutes. This is because scan time ranged from 3 to 8 minutes and splinting decreased the scan time by an average of 2 minutes. Therefore, having a an easily assembled printed splint (printed modular chain) like what was done in the study by Pozzi et al (2022)⁶² will help with providing a splint that can be assembled to any arch form in seconds and thus would affectively shorten scan time. The maxilla was also significantly faster to scan than the mandible regardless of the splint. This may mean that the palate can aid in quick detection and stitching by the intraoral scanner software; this is consistent with an in vitro study by Mizumoto et al⁶⁷ (2019) who evaluated the effect of stitching or unstitching the palate and the scan body position on the accuracy (trueness and precision) of intraoral digital implant scans of a completely edentulous maxilla with four implants; they reported that the mean angular deviation in stitched technique 0.4 degrees and in unstitched technique as 0.5 degrees. The maxilla differs from the mandible in surface topography, surface area, amount of movable tissue, absence of the tongue or movement during mandibular movement.⁶⁸ The absence of topographical advantages like rugae in the mandible adds challenge when scanning as well as mandibular deformation when opening. ⁶⁸ However, one study by patzelt and others revealed contradictory results; in their study the greatest deviations were found in the maxillary jaws.⁶⁹

This study has some limitations that needs to be addressed. Some alignment errors might have been introduced from Geomagic alignment software. However, repeating each superimposition, alignment, and measurements three times helped ensure the validity of the results in this study. Also, Geomagic software has been reported to be

acceptable according to O'Toole et. Al⁷⁰ (2020); the authors concluded that when appropriate analysis was used, the system was able to quantify the degree of change and can be recommended depending on the accuracy needed to diagnose a condition.⁷⁰

Clinical relevance of the findings will have to be further explored through prosthesis level studies with even larger sample size. This is because conclusions of most studies about digital impressions are based on scan results and have a lot of heterogeneity since the scan bodies used were from different materials, height, and measured at different distances from the implant platform. Also, most studies in the literature were in vitro studies with different study designs and evaluation methodologies, such as the IOS and scan body selected, operator experience, scanning strategy and modification techniques used, and the implant connection, depth, angulation and inter-implant distance in the study models and different program algorithm correction.

CHAPTER FIVE

CONCLUSIONS

Within the limitation of the present study, splinting scan bodies intraorally does not affect the trueness of full arch edentulous implant digital impressions. However, scan time of complete arch digital implant impression is faster when splinting between scan bodies.

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