

# **Scan Time and Prosthetic Complications of Intraoral Scanning Versus Intraoral Photogrammetry for Full-Arch Titanium Framework with Zirconia Overlay Implant Screw-Retained Prostheses: A Randomized Clinical Trial**

Submitted for partial fulfillment of the **Ph D** requirements in Faculty of  
Dentistry  
Cairo University

By  
**Nour El Hoda Mahmoud Naguib El Tarabishi**



B.D.S. Cairo University (2017)

M.Sc. Cairo University (2023)

PROSR 6-2-1

**11-2-2025**

Supervisors' signature

1-   
2- 

Date

Head of department's signature



Protocol checklist				
Section and topic	Item no.	Checked item	Reported on page No.	Reviewer's check
<b><u>I. Administrative information</u></b>	1	Title	1	
	2	Protocol registration	1	
	3	Protocol version	1	
	4	Funding	1	
	5	Roles and responsibilities	1	
<b><u>II. Introduction</u></b>				
<b>A) Background and Rationale</b>	6 a	Research question	3	
		Statement of the problem	3	
		Rationale for carrying out the trial	3	
		Review of literature	3	
	6 b	Choice of comparators	4	
<b>B) Objectives</b>	7	Aim of the study	5	
		Hypothesis	5	
		Primary and secondary objectives	5	
<b>C) Trial design</b>	8	Trial design	5	
<b><u>III. Methods</u></b>				
<b>A) Participants, interventions &amp; outcomes</b>	9	Study setting	5	
	10	Eligibility criteria	6	
	11	Interventions	6	
	12	Outcomes	8	
	13	Participant timeline	9	
	14	Sample size	10	
	15	Recruitment	10	
<b>B) Assignment of interventions</b>	16	Allocation	10	
	16 a	Random sequence generation (Randomization)	10	
	16 b	Allocation concealment mechanism	10	
	16 c	Implementation	10	
	17	Blinding (masking)	10	
<b>C) Data collection, management, and analysis</b>	18	Data collection methods	10	
	19	Data management	11	
	20	Statistical methods	11	
<b>D) Monitoring</b>	21	Data monitoring	11	
	22	Harms	11	
	23	Auditing	11	
<b><u>IV. Ethics and dissemination</u></b>	24	Research ethics approval	12	
	25	Protocol amendments	12	

	26	Informed Consent	12	
	27	Confidentiality	12	
	28	Declaration of interests	12	
	29	Access to data	12	
	30	Ancillary and post-trial care	12	
	31	Dissemination policy	12	
<u>V. Appendices</u>	32	Informed consent materials	13	
	33	Biological specimens	14	
<u>VI. References</u>			15	
<u>Evidence based committee (Reviewers)</u>				
Name		Signature	Date	
1.	Amal Ali Swelem	Amal Swelem.		
2.				
<u>Research plan committee</u>				
Name		Signature	Date	
1.				
2.				

## **Administrative information:**

### **1. Title:**

Scan Time and Prosthetic Complications of Intraoral Scanning Versus Intraoral Photogrammetry for Full-Arch Titanium Framework with Zirconia Overlay Implant Screw-Retained Prostheses: A Randomized Clinical Trial

### **2. Protocol Registration:**

The study will be registered on **clinicaltrials.gov**.

### **3. Protocol version:**

This is the first version of the protocol. 11th February 2025 Protocol number: 1.

### **4. Funding:**

Self-funding.

### **5. Roles and responsibilities:**

#### **1. Prof. Amr Hosny Mostafa El Khadem (AK)**

- Professor of Prosthodontics, Faculty of Dentistry, Cairo University.
- Main supervisor. Responsible for randomization, data management, auditing, supervising clinical procedure, and final thesis revision.

#### **2. Dr. Nesma Mohamed Awaad (NA)**

- Assistant Professor of Prosthodontics, Faculty of Dentistry, Cairo University.
- Co-supervisor. Responsible for outcome assessment, data collection, providing technical expertise in clinical trial design, designing the splints and thesis revision.

#### **3. Nour El Hoda Mahmoud Naguib El Tarabishi (NT)**

- Researcher and principal investigator responsible for all the clinical and laboratory work.
- Writing the protocol and the final thesis.

#### **5.b Name and contact information for the trial sponsor**

Nour El Hoda Mahmoud Naguib El Tarabishi

- Email: [nourelhodaeltarabishi@dentistry.cu.edu.eg](mailto:nourelhodaeltarabishi@dentistry.cu.edu.eg)

#### **5.c Role of study sponsor and funders**

Department of Prosthodontics – Faculty of Dentistry – Cairo University is the sponsor of the trial. Without any influence on the study design or conduct, data collection, management, analysis or even data interpretation. The principle investigator will fund the implants and all the prosthodontics requirements of the research.

#### **5.d Role of the steering committee:**

##### **Role of the steering committee**

- Department of Prosthodontics, Faculty of Dentistry - Cairo University.

It is responsible for ensuring that the research idea follows the research plan of the department.

- Evidence-Based Committee, Faculty of Dentistry - Cairo University.

It is responsible for:

- PICO revision.
- Protocol revision.
- Revise the reported methodology.
- Medical biostatistics Unit (MBU)
- It is responsible for sample size calculation and reporting of statistical methods.
- The Ethical Committee, Faculty of Oral and Dental Medicine - Cairo University

It is responsible for:

- Ensuring that the trial does not violate privacy, ethical issues, or human rights.
- Supplying the main investigator with a template of informed consent.
- Approving the research, once it fulfils the required ethical criteria.
- Faculty and University Board

It approves the protocol once it is approved by the previously mentioned boards and committees.

## **II. Introduction:**

### **6. Background and rationale:**

#### **Statement of the problem:**

Full arch implant restorations are a vital treatment option to rehabilitate complete edentulism. Prosthetic complications in full-arch titanium frameworks with zirconium overlays are prevalent, often resulting in increased patient morbidity and higher clinical workload. Traditional impression techniques are time-consuming and pose accuracy challenges, potentially contributing to these issues (**Yuzbasioglu *et al.*, 2014; Bandiaky *et al.*, 2022**). There is a need to explore alternative methods that can provide comparable or superior outcomes with improved efficiency.

In this study intraoral scanning (IOS) and intraoral photogrammetry (IOP) will be compared. The comparison aims to evaluate if there is a difference in scanning time and prosthetic complication events between the two technologies regarding full-arch titanium framework with zirconium overlay.

#### **Rationale for conducting the research:**

IOS and IOP are emerging technologies in the field of prosthodontics that offer potential benefits over traditional impression techniques. These methods are becoming increasingly prominent due to their potential to enhance accuracy, reduce patient discomfort, and improve workflow efficiency (**Yuzbasioglu *et al.*, 2014; Bandiaky *et al.*, 2022**). The use of IOS and IOP for full-arch implant-supported prostheses, specifically with titanium frameworks and zirconium overlays, prompts examination of their impact on prosthetic outcomes such as scan times and complication rates.

Traditional impression techniques are time-consuming and pose accuracy challenges, potentially contributing to these issues (**Joda *et al.*, 2021**). Prosthetic complications in full-arch titanium frameworks with zirconium overlays are prevalent, often resulting in increased patient morbidity and higher clinical workload (**Gao *et al.*, 2024**). There is a need to explore alternative methods that can provide comparable or superior outcomes with improved efficiency (**Ma *et al.*, 2023**).

By comparing IOS and IOP, this research aims to determine whether these modern techniques can affect scan time and prosthetic complications. Such findings would be valuable for practitioners seeking to optimize clinical outcomes and streamline workflows, ultimately enhancing patient care and satisfaction.

#### **Review of literature:**

Intra-oral scanning (IOS) and intra-oral photogrammetry (IOP) have revolutionized the field of prosthodontics by offering a digital alternative to conventional impression-making techniques. These technologies provide numerous benefits, including enhanced accuracy, reduced patient discomfort, and streamlined workflows (**El Hussieny fayad *et al.*, 2024**). The clinical utility of IOS and IOP has been widely explored in various dental contexts, yet their specific impact on full-arch implant-supported prostheses requires further investigation.

Recent studies have compared the accuracy of IOS and IOP with conventional impression techniques. A study by Ma *et al.* (2021) demonstrated that for complete-arch implant rehabilitation, the IOP system showed the highest accuracy in terms of trueness and precision, followed by conventional techniques, and IOS providing the less accurate results (**Ma *et al.*, 2021**).

Scan time is a critical factor when considering the overall efficiency and patient experience in prosthodontic treatments. The study by Lawand *et al.* (2022) evaluated the effect of implant scan body modifications on the trueness and scan time of complete-arch intraoral scans (**Lawand *et al.*, 2024**). The results indicated that certain modifications could enhance scanning speed while maintaining accuracy. Eldabe and Botros (2025) also stressed

the importance of scan bodies in improving the ease and trueness of full-arch implant scans, which can potentially reduce scan times and related prosthetic complications (**Eldabe, Adel-Khattab and Botros, 2025**).

Prosthetic complications in full-arch implant-supported prostheses can arise from several factors, including the impression technique used. Research by Patel et al. (2023) highlights that while immediate placement and loading of implants yield successful outcomes, the associated prosthetic complications demand vigilant management across all treatment phases (**Patel et al., 2023**). Further, studies have suggested that the accuracy of impression techniques significantly impacts prosthetic fit, which in turn influences complication rates.

Framework materials play a pivotal role in the success of full-arch implant-supported prostheses. Delucchi et al. (2021) conducted a systematic review to analyze the clinical outcomes of different framework materials used in full-arch implant prostheses (**Delucchi et al., 2021**). The study found that materials like titanium and zirconia showed high cumulative survival rates and favorable outcomes, while highlighting the need for long-term studies to validate these findings (**Delucchi et al., 2021**).

The clinical performance of prostheses with titanium frameworks and zirconium overlays has been the subject of various studies. A study by Papaspyridakos et al. (2020) evaluated the complication rates and survival outcomes of full-arch implant-supported prosthesis (**Papaspyridakos et al., 2020**). The research indicated that while these prostheses offer promising results, they are not devoid of complications, necessitating continuous clinical evaluation and refinement of techniques.

This literature review underscores the need for comprehensive research on the impact of IOS and IOP on scan time and prosthetic complications in full-arch implant-supported prostheses. Understanding these aspects can lead to optimized treatment protocols, reduced patient morbidity, and enhanced clinical outcomes.

### **Explanation for choice of comparator**

The adoption of intraoral scanners (IOS) for full-arch implant-supported prosthesis rehabilitation has been validated through multiple recent studies, highlighting improvements in accuracy, efficiency, and patient comfort. Research indicates that full-arch digital impressions achieved through IOS may rival traditional methods, with various studies supporting the transition to fully digital workflows in implant dentistry.

Recent studies have demonstrated the validity of intraoral scanners (IOS) in capturing precise and accurate full-arch digital impressions. For instance, in a systematic review and meta-analysis by Floriani et al. (2023) nine studies were analyzed and the authors reported that IOS were more accurate in recording full arch implant supported prosthesis digital impressions compared to conventional physical impressions. The IOS presented 137.86  $\mu\text{m}$  compared to 182.51  $\mu\text{m}$  for conventional impressions (**Floriani et al., 2023**). The previously mentioned value is below the minimal acceptable clinical difference of 200  $\mu\text{m}$ . This validates IOS as a reliable tool for full-arch impressions, establishing it as a benchmark for comparison.

An invitro study compared the trueness and precision of PG, IOS, and conventional splinted open-tray impression technique. Each impression technique was performed 10 times on a master cast containing six implant abutment replicas. Standard tessellation language files (STL files) for all impression techniques were investigated after digitizing the master casts obtained from the conventional impression technique by a benchtop scanner. Results showed that accuracy of the PG system was highest followed by the conventional and IOS impression techniques (**Ma et al., 2021**). Evidently there is a need to investigate PG and IOS for scanning full -arch implant cases.

Sinada & Papaspyridakos (2021) emphasize the integral role of intraoral scanners in providing accurate full-arch digital impressions necessary for creating CAD/CAM verification jigs. Their findings suggest that while the accuracy of such impressions depends on advances in scanning technology, existing clinical evidence

indicates that IOS performance for full-arch impressions has improved significantly, making them comparable to conventional methods (**Sinada and Papaspyridakos, 2021**).

Furthermore, a study by Meneghetti et al. (2021) illustrated substantial advancements in techniques and workflows, integrating IOS with other technologies such as photogrammetry to improve outcomes for complete-arch restorations. This holistic approach to digital processes exemplifies the shift toward fewer clinical steps and enhanced patient experiences (**Meneghetti et al., 2021**). The common theme is an increasing consensus regarding the feasibility and accuracy of full-arch rehabilitation using intraoral scanners, despite occasional challenges noted in specific clinical scenarios.

In conclusion, the recent literature consistently highlights the efficacy and evolving accuracy of intraoral scanners in full-arch implant-supported prosthesis rehabilitation. As digital technologies advance, it is expected that their integration into routine dental practice will enhance the precision of prosthetic reconstructions and streamline overall workflows in implant dentistry.

#### **Research question:**

What is the effect of intra-oral photogrammetry on scan time and prosthetic complications in patients receiving full-arch titanium framework with zirconium overlay implant screw-retained prostheses as compared to intra-oral scanning?

#### **7. Objectives:**

This study aims to evaluate the effect of intra-oral scanning and intra-oral photogrammetry on scan time and prosthetic complications in patients receiving full-arch titanium framework with zirconium overlay implant screw-retained prostheses.

#### **Hypothesis:**

The null hypothesis is that there is no difference between intra-oral scanning and intra-oral photogrammetry on scan time and prosthetic complications in patients receiving full-arch titanium framework with zirconium overlay implant screw-retained prostheses.

#### **Primary objective:**

P: Full-arch titanium framework with zirconia overlay screw-retained prosthesis.

I: Intra-oral Photogrammetry.

C: Intra-oral scanning.

O<sub>1</sub>: Scan time.

O<sub>2</sub>: Prosthetic complications.

#### **8. Trial design:**

Parallel group, two arm, and superiority trial with 1:1 allocation ratio.

### **III. Methods**

#### **A) Participants, interventions & outcomes**

#### **9. Study settings:**

Out clinic patients of department of prosthodontics – Cairo university



## **10. Eligibility criteria:**

### **Inclusion criteria:**

- Patients requiring maxillary and/or mandibular full arch screw-retained implant-supported prosthesis.
- Number of implants placed per arch ranging from 4-6 implants per arch.
- Completely edentulous patients with sufficient inter-arch space to receive fixed prosthesis (Crown height space 9-15 mm per arch).
- Adequate zone of keratinized mucosa (> 2mm width).
- Both genders.
- Acceptable oral hygiene.
- Cooperative patients.
- Controlled systemic diseases (Diabetes, hypertension).

### **Exclusion criteria:**

- Completely edentulous patients with insufficient inter-arch space to receive fixed prosthesis (Crown height space lesser than 9mm per arch).
- Completely edentulous patients with in-adequate zone of keratinized mucosa (< 2mm).
- Un cooperative patients.
- Poor oral hygiene.
- Uncontrolled systemic diseases (Diabetes, hypertension).

## **11. Interventions**

Completely edentulous patients that have received dental implants <sup>1</sup>and ready to start prosthetic steps of full arch screw retained prosthesis will be recruited and randomly divided into two groups.

### **IOS group (control group):**

IOS will be performed using commercially available IOS device. The scan data will be used to design and fabricate the full-arch screw-retained titanium framework with a zirconia overlay.

- Intra-oral scanner<sup>2</sup> will be used in the study to take a digital impression for the implants.
- 3D printed generic Scan bodies<sup>3</sup> with unified shape and length replacing the traditional transfer copings will be press fitted on the trans-mucosal abutments and pickup cylinders that are screwed on the implants to capture their position and intra-oral scanning will be done.
- With scan bodies in place, bite will be registered where, in case of completely edentulous upper and lower arches a 3D printed centric holding device <sup>4</sup>will be used to fix the vertical dimension at the desired height and the intra-oral scanner will capture the bite at this position, but in case of a completely edentulous arch opposed

---

<sup>1</sup> Bredent, made in Germany/ Dentis , made in Korea/ Root, made in Switzerland/ Jdental , made in Italy./ Dual , Made in Egypt

<sup>2</sup> Medit i700, made in South Korea

<sup>3</sup> Phrozen Shuffle xl 3D printer, and its own resin material, made in Taiwan

<sup>4</sup> Phrozen Shuffle xl 3D printer, and its own resin material, made in Taiwan

by dentulous arch , a green stick jig will be customized anteriorly to hold vertical dimension at the desired height and intra-oral scanner will be used to record the bite bilaterally.

- The time taken to complete the scan will be recorded.
- The final prosthesis framework will be designed on the patient's scan using dental wings. The framework will be milled form titanium and then a zirconium overlay will be constructed.
- The final prosthesis will be delivered to the patient.
- Follow up of the patients will be done at 3 and 6 months to check if there are any prosthetic complications.

#### **IOP group (intervention group):**

IOP will be performed using a specialized photogrammetry system. The photogrammetry data will be used to design and fabricate the full-arch screw-retained titanium framework with a zirconia overlay.

- Intraoral photogrammetry<sup>5</sup> will be used in the study to take a digital impression for the implants.
- The scanner will be used to record the soft tissue anatomy and trans-mucosal abutments.
- 3D Scan bodies<sup>6</sup> will be fitted on the trans-mucosal abutments that are screwed on the implants to capture their position and scanning will be done.
- A scan of the soft tissue and scan bodies will finally be conducted.
- With scan bodies in place, bite will be registered where, in case of completely edentulous upper and lower arches a 3D printed centric holding device <sup>7</sup>will be used to fix the vertical dimension at the desired height and the intra-oral scanner will capture the bite at this position, but in case of a completely edentulous arch opposed by dentulous arch , a green stick jig will be customized anteriorly to hold vertical dimension at the desired height and intra-oral scanner will be used to record the bite bilaterally.
- The time taken to complete the scan will be recorded.
- The final prosthesis framework will be designed on the patient's scan using dental wings. The framework will be milled form titanium and then a zirconium overlay will be constructed.
- The final prosthesis will be delivered to the patient.
- Follow up of the patients will be done at 3 and 6 months to check if there are any prosthetic complications.

---

<sup>5</sup> 3D Shining

<sup>6</sup> 3D Shining Scan bodies

<sup>7</sup> Phrozen Shuffle xl 3D printer, and its own resin material, made in Taiwan

## 12. Outcomes:

Scan time will be recorded during the digital impression procedure, as the time taken to complete the digital impression. Prosthetic complications (e.g., screw loosening, framework fracture, zirconia chipping) will be recorded at 3 and 6-month follow-up period post-delivery and we will manage complications at the time of prosthetic complication occurrence.

Outcome	How to measure	When to measure	Rationale for choice of outcome	Unit of Measurement
Scan time	Time recorded by scanning software to complete the scanning process	At the visit of final impression and bite registration	To record the difference, if present, in time taken to complete the scan, for the sake of the patient and operator	Seconds
Prosthetic complications	Clinical examination	At 3, 6 months of delivery of final prosthesis	Clinical outcome that has a direct effect on restoration success	Number of events

### 13. Participant timeline

	STUDY PERIOD									
				Post-allocation						Close-out
TIMEPOINT	$-t_1$	$-t_1 + 1\text{week}$	0	$t_1$ start of clinical procedures	$t_1 + 1\text{ week}$	$t_1 + 2\text{ weeks}$	$t_1 + 3\text{ weeks}$	$t_1 + 4\text{ weeks}$	$t_3$ 3 months post prosthesis insertion	$T_x$ after 6 months from prosthesis insertion
ENROLMENT:										
Eligibility screen	✓									
Informed consent		✓								
Allocation			✓							
INTERVENTION:										
/IOS: full-arch screw-retained titanium framework with a zirconia overlay/										
Scanning the arch				✓						
Jaw relation/Bite registration				✓						
Designing and manufacturing						✓				
Titanium framework try-in							✓			
Final prosthesis delivery								✓		
CONTROL:										
/IOP: full-arch screw-retained titanium framework with a zirconia overlay/										
Scanning the arch				✓						
Jaw relation/Bite registration				✓						
Designing and manufacturing						✓				
Titanium framework try-in							✓			
Final prosthesis delivery								✓		
ASSESSMENTS:										
Scan time				✓						
Prosthetic complication									✓	✓

#### **14. Sample size:**

Scan time will be assessed as the 1<sup>st</sup> outcome, where Mean $\pm$  SD values will be used for this outcome. Entry 1 will be the (mean difference between 2 groups, mean and standard deviation of group 1, proportion 1 or estimated prevalence) = 8.59 $\pm$ 2.46, while entry 2 will be (standard deviation of control group, mean and standard deviation of group 2, proportion 2 or clinically important difference) = clinically important difference based on expert opinion=2. The used alpha level of significance will be 0.05 with an effect size used in calculation: 0.6366 and an 80% power of the study. The used statistical test will be Independent-t-test. Sample size calculation included 19 implants per group, total=38 implants with an increased number for anticipated missing data: 15% to compensate for drop outs, 25 implants per group, total of 50 implants.

#### **15. Recruitment:**

Recruitment will be done by NT Patients will be selected from the outpatient clinic of Prosthodontics Department – Cairo University. The department patient's database will be reviewed and possible candidates for the trial will be called. All patients satisfying eligibility criteria will be consecutively included in the study (consecutive sampling).

#### **B) Assignment of interventions**

##### **16. Allocation:**

###### **16a. Randomization:**

Block randomization using computer-generated random block sizes will be carried out by AK only.

###### **16b. Allocation concealment mechanism:**

The participants will be allocated into the two studied groups by computerized sequence generation using (Excel for Windows; Microsoft Corp).

###### **16c. Implementation**

AK is the person who will generate the allocation sequence and who is responsible for ensuring proper randomization and allocation concealment. He is involved in neither the scanning procedure and prosthetic complication recording nor the data collection.

#### **17. Masking/blinding:**

The patients and operator not blinded to treatments. The statistician and outcome assessor (NA) will be blinded to the treatments.

#### **C) Data collection, management, and analysis:**

##### **18. Data collection methods**

###### **18. A. Plans for assessment and collection of outcomes:**

The collected data will include participants age, gender, previous medical and dental history, type of arch, number of implants per arch and outcomes data. NT will be responsible for data collection. The collected data whether personal or numerical will be stored on excel sheets as an electronic copy and printed hardcopy sheets. The outcome data regarding scan time and prosthetic complication will be recorded at the final impression stage and the planned follow up visits respectively. Numerical data will be presented as mean and standard deviation, all data will be reported at a 95% confidence interval and alpha level of significance of 0.05%

**18. B Plans to promote participant retention and complete follow-up:**

- Telephone numbers and address of all subjects in the study will be recorded as a part of the signed consent.
- All subjects will receive a phone call at the time of the pre-determined follow up dates.
- Paying transportation fees.

**19. Data management:**

All paper sheets that are concerned with person or outcome data will be stored in a locked cabinet and in the computer at the Department of Prosthodontics. The excel sheets of the patient's data will be stored in the computer of the Department of Prosthodontics - Faculty of Dentistry. They will be password-protected. Password will be known to the principal investigator and supervisors only to prevent unauthorized access to data and double data entry.

**20. Statistical methods:**

Data will be analyzed using appropriate statistical software. Continuous variables will be compared using independent t-test or Mann-Whitney U tests. Categorical variables will be compared using chi-squared or Fisher's exact tests. A  $p$  value  $< 0.05$  will be considered statistically significant.

**D) Data monitoring:****21. Monitoring**

AK will monitor the data. He will have access to the data and will report any harmful effects of the treatment and hence give guidance about modifying or discontinuing the trial.

Stopping Guidelines:

The following guidelines will be followed for excluding the patient from the trial:

- The study will be discontinued if more than 40% of the participants suffered implant failure.
- Failure of the participant to comply with trial requirements.

**22. Harms**

No harms are expected and any adverse actions will be reported and treated.

Criteria for discontinuing

- Any relevant deterioration in the health of the participant possibly affecting participation in the trial.

**23. Audit**

Auditing of the study will be done by the data monitoring principle (AK), who has the right to modify or discontinue the trial.

#### **IV. Ethics and dissemination**

##### **24. Research ethics approval**

Research ethics approval: This protocol will be reviewed, approved and agreed upon by the Ethics Committee [Research Ethics Committee Cairo University Faculty of Dentistry] and an approval number will be provided to the trial protocol.

##### **25. Protocol amendments**

Any modifications to the title, research question, interventions or methods of analysis in the protocol will be reported and agreed upon by the Prosthodontics Department, evidence-based committee and data monitoring principle.

##### **26. Informed consent**

The trial will be explained to the participants by the principal investigator. The researcher will discuss the interventions and possible harms with participants and obtain written consent (in Arabic) from the patients willing to participate in the trial. An appendix of the consent form is attached to the protocol.

##### **27. Confidentiality**

All study-related information will be stored securely. All participants' information will be stored in locked file cabinets in areas with limited access. Photos, reports, personal and administrative data forms will be identified by an ID number to maintain participant confidentiality. Records that contain names or other personal identifiers will be stored separately from study records and will be identified by a code number as well. Local databases will be secured with password-protected access system.

##### **28. Declaration of interest**

No conflict of interest is to be declared.

##### **29. Access to data**

Patients' data whether personal or outcome data are only accessed by the secretary of the Department and the data monitoring committee member (AK). This is important to prevent accidental data loss, double data entry and keep patients' confidentiality.

##### **30. Post-trial care**

All patients will complete their treatment by the same operator at the outpatient clinic of the Department of Prosthodontics. The participants will be followed up by AK, NA and NT even after the trial ends to treat patient's complaints and prevent any possible complications.

##### **31. Dissemination policy**

Trial results will be available in the database department and a copy of the thesis will be available at the department library and at the official site of the Egyptian Universities Libraries Consortium. Final report of the trial will be also published in an international journal.

## **V. Appendices**

### **32. Informed consent**

#### **Informed Consent of Volunteers**

Title of the Research (in Arabic): Scan Time and Complications of Prosthodontics Using Intraoral Scan vs. Intraoral Photogrammetry for Implant-Firmed Complete Dentures with Full Titanium Frame and Zirconia Cap: A Randomized Clinical Trial

Objective of the Research:

This study aimed to compare, if any, the difference in scan time and complications of prosthodontics using intraoral scan versus intraoral photogrammetry for implant-firmed complete dentures with full titanium frame and zirconia cap.

Introduction to the procedure and its details (work plan): - A digital imaging scan of the patient's mouth will be performed. - The jaw will be scanned using intraoral scanning and intraoral imaging, and the scan time will be recorded. - The final prosthesis will be delivered. - Finally, the patient will be followed up with pre-scheduled appointments. - Direct benefit to the volunteer:

-Obtaining a stable prosthesis on high-quality implants. - Scientific and general benefit of the research: - Determining the scan time and complications of prosthetics using intraoral scanning versus intraoral imaging for complete implant-supported dentures made of a full titanium frame with a zirconia cap. - Side effects, risk levels, and how to manage them: - Gum inflammation or ulceration resulting from failure to follow denture cleaning instructions. This will be addressed by emphasizing adherence to denture cleaning

Patient's full understanding of the research steps: Reading [ ] Oral explanation [ ] Other [ ]

- I have carefully read and understood the purpose and nature of this research study, and I understand what is necessary to carry out these procedures.

- The investigating physician has informed me of the possible treatment alternatives to this research.

- The investigating physician has informed me of all the potential risks of this research and how to manage them.

- I consent to the imaging, recording, and all types of radiological examinations that must be performed in this study, provided that my identity is not disclosed.

- I have provided an accurate report of my medical history. I have informed the doctor of all unusual health reactions or allergies to medications, foods, insect bites, anesthetics, dust, or any other substances, as well as any abnormal bleeding or other relevant health conditions.

I declare that I am not participating in any other research from the beginning to the end of this study and that I will inform the investigating physician if I participate in any other research during this period.



I undertake to return any medical equipment used in the research upon its discontinuation or completion.

After reviewing the available research information, the volunteer or their designated representative is free to choose whether or not to participate. If they agree, they should complete the required information. The volunteer has the right to withdraw from the research without giving reasons, provided that the researcher has the right to retrieve any medical equipment or instruments used for the research that are in the volunteer's possession (as designated by the researcher).

The physician in charge of the research pledges to maintain the confidentiality of the volunteer's information, specifying the methods used to ensure confidentiality, such as replacing names with code numbers or blurring facial features in photographs, if possible (etc.).

The volunteer has the right to keep a photocopy of the informed consent form for the research they volunteered for.

Volunteer's Name: Date of Birth:  
National ID Number (if applicable)  
Parent or Guardian's Name (if applicable): National ID Number:  
Address: Phone Number:

Date:

Researcher's Signature: Date:

Research Supervisor's Signature (in the case of theses): Date:

Data to be completed by the committee

This research has been approved by the committee under  
number

--	--	--	--

### 33. Biological specimens

Not available.

## VI. References

- Bandiaky, O. N. *et al.* (2022) 'Comparative assessment of complete-coverage, fixed tooth-supported prostheses fabricated from digital scans or conventional impressions: A systematic review and meta-analysis', *Journal of Prosthetic Dentistry*, 127(1), pp. 71–79. doi: 10.1016/j.prosdent.2020.09.017.
- Delucchi, F. *et al.* (2021) 'Framework materials for full-arch implant-supported rehabilitations: A systematic review of clinical studies', *Materials*, 14(12), pp. 1–18. doi: 10.3390/ma14123251.
- Eldabe, A. K., Adel-Khattab, D. and Botros, K. H. (2025) 'Trueness of tooth modified scan bodies as a novel technique for edentulous full arch implant supported dental prosthesis: an in vivo prospective comparative study', *BMC Oral Health*, 25(1). doi: 10.1186/s12903-024-05172-y.
- Floriani, F. *et al.* (2023) 'Linear Accuracy of Intraoral Scanners for Full-Arch Impressions of Implant-Supported Prostheses: A Systematic Review and Meta-Analysis', *European Journal of Dentistry*, 17(4), pp. 964–973. doi: 10.1055/s-0042-1758798.
- Gao, Y. *et al.* (2024) 'Knowledge structure and research hotspots on digital scanning for implant-supported complete-arch prosthesis: A bibliometric analysis', *Heliyon*, 10(17). doi: 10.1016/j.heliyon.2024.e36782.
- El Hussieny fayad, noha, Abofadle, A. and Bahig, D. essam (2024) 'Accuracy of different digital data acquisition work flows for full arch maxillary implant prostheses (an invitro study)', *Egyptian Dental Journal*, 70(1), pp. 461–471. doi: 10.21608/edj.2023.245517.2763.
- Joda, T. *et al.* (2021) 'Time-efficiency and cost-analysis comparing three digital workflows for treatment with monolithic zirconia implant fixed dental prostheses: A double-blinded RCT', *Journal of Dentistry*, 113(July). doi: 10.1016/j.jdent.2021.103779.
- Lawand, G. *et al.* (2024) 'Effect of implant scan body geometric modifications on the trueness and scanning time of complete arch intraoral implant digital scans: An in vitro study', *The Journal of Prosthetic Dentistry*, 131(6), pp. 1189–1197. doi: 10.1016/j.prosdent.2022.06.004.
- Ma, B. *et al.* (2021) 'Accuracy of photogrammetry, intraoral scanning, and conventional impression techniques for complete-arch implant rehabilitation: an in vitro comparative study', *BMC Oral Health*, 21(1). doi: 10.1186/s12903-021-02005-0.
- Ma, J. *et al.* (2023) 'Accuracy of digital implant impressions obtained using intraoral scanners: a systematic review and meta-analysis of in vivo studies', *International Journal of Implant Dentistry*, 9(1). doi: 10.1186/s40729-023-00517-8.
- Meneghetti, P. *et al.* (2021) 'A fully digital approach for implant fixed complete dentures: A case report', *Journal of Esthetic and Restorative Dentistry*, 33(8), pp. 1070–1076. doi: 10.1111/jerd.12798.
- Papaspyridakos, P. *et al.* (2020) 'Technical Complications and Prosthesis Survival Rates with Implant-Supported Fixed Complete Dental Prostheses: A Retrospective Study with 1- to 12-Year Follow-Up', *Journal of Prosthodontics*, 29(1), pp. 3–11. doi: 10.1111/jopr.13119.
- Patel, R. *et al.* (2023) 'Differences in Dental Implant Survival between Immediate vs. Delayed Placement: A Systematic Review and Meta-Analysis', *Dentistry Journal*, 11(9), pp. 1–16. doi: 10.3390/dj11090218.

Sinada, N. and Papaspyridakos, P. (2021) 'Digitally Designed and Milled Verification Jigs Generated from Photogrammetry Data Acquisition: A Clinical Report', *Journal of Prosthodontics*, 30(8), pp. 651–655. doi: 10.1111/jopr.13409.

Yuzbasioglu, E. *et al.* (2014) 'Comparison of digital and conventional impression techniques: Evaluation of patients' perception, treatment comfort, effectiveness and clinical outcomes', *BMC Oral Health*, 14(1). doi: 10.1186/1472-6831-14-10.