Shanghai Ninth Peoples Hospital affiliated to Shanghai Jiao Tong University School of Medicine
Clinical research protocol

project name:	Comparison of digital and traditional impressions in the absence of dental scanning
version number:	1.2
Version date:	14 September 2025
project leader:	Lai Hong-chang
Date of plan start and en	September 2025-December 2026

Researcher statement and program signature page

As the principal investigator of this research project, I will adhere to the Ethics Review Measures for Human Biomedical Research (Order No.11 [2016] of the National Health Commission), the Ethics Review Measures for Human Life Science and Medical Research (Guowei Jiaoke Fa [2023] No.4), and GCP ethical principles. The study will be conducted in accordance with the approved protocol by the ethics committee, ensuring scientific rigor while safeguarding participants health and rights.

Name: Lai Hongchang

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Date: __ 20250 320_____

Test plan · Catalog

一、scenario summary

project name	Comparison of digital and traditional impressions in the absence of dental scanning		
version number	1 .2	Version date	2 0250914
Applications and Participating units	Department of Oral Implantology, Ninth Peoples Hospital affiliated to Shanghai Jiao Tong University School of Medicine		
Nature of study	Randomized controlled	sample capacity	2 4
purpose of research	The passive positioning of restorations, complications within six months, and patient evaluation indexes were compared between traditional and digital molding methods for fixed restoration of whole arch implants.		
subject investigated	Patients with full arch implant fixation and restoration		
research technique	randomized controlled trial		
Inclusion criteria	Age 3 0-8 0 years old (including 3 0 and 8 0 years old), gender unlimited; patients have a segmental permanent fixed restoration of the whole arch on the maxilla or mandible; patients have completed bone union after implant surgery; patients voluntarily participate in the trial and sign an informed		
Exclusion criteria	The patient had severe pharyngeal reflex; the intermaxillary distance in the posterior tooth area was too small to install the molding column; the distance between the two implants was too small to install the molding column; the		

<table>
<tr><td colspan="2">Research progress plan</td><td colspan="5">202 5 July:
Complete ethical declaration and research registration;
From September 202 5 to March 202 6, the screening, enrollment, randomization and treatment of 2 4 qualified subjects were completed;
From March 202 6 to September 202 6 , a 6-month follow-up was completed for all subjects;
September 202 6-October 202 6:
(1) Complete the collation and analysis of all follow-up data;</td></tr>
<tr><td colspan="2">statistics
analytic procedure</td><td colspan="5">For continuous data with normal distribution, SAS 9.4 is used for statistical management and analysis. The ″mean ± standard deviation″ method is employed for descriptive statistics and parameter comparisons, with independent samples t-tests. When continuous data deviate from normal</td></tr>
<tr><td colspan="2">research findings
Form of publication</td><td colspan="5">The research results will be published in international professional journals</td></tr>
<tr><td colspan="2">Lead researcher</td><td>Lai Hong-</td><td>professional</td><td>professor</td><td>date of birth</td><td>1966.11.10</td></tr>
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Officers</td><td>surname and personal</td><td>date of birth</td><td>professional ranks and</td><td>have or not GCP</td><td colspan="2">Division of project work</td></tr>
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<tr><td>Fu Xiao-jiao</td><td>1 994.5</td><td>physician</td><td>have</td><td colspan="2">project implementation</td></tr>
<tr><td>CAI Zhengzhen</td><td>1 998.4</td><td>postgraduate</td><td>not have</td><td colspan="2">project implementation</td></tr>
<tr><td>Zhang Xiao</td><td>1 982.7.16</td><td>physician</td><td>have</td><td colspan="2">statistical analysis</td></tr>
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二、research background

Full-arch implant fixed restoration serves as an effective therapeutic approach for reconstructing both aesthetic and functional aspects of the maxillofacial system. The single-unit titanium bracket restorations require only 4-6 implants to complete, representing a common method for edentulous jaw implant fixation. The fabrication of such brackets

demands highly precise working models that can replace the need for intraoral implant position transfer, facilitating restorative design and processing. Traditional methods and digital techniques are employed to obtain working models for edentulous jaw implant restoration. Conventional approaches use window-type silicone rubber impressions to transfer implant positions before casting plaster models, while digital methods capture implant data through optical scanning and generate three-dimensional digital models. Currently, single-unit titanium bracket restorations are fabricated via digital design and machining. Consequently, traditional physical models must undergo comprehensive scanning before conversion into digital formats. Direct acquisition of implant positions through digital impressions simplifies errors in silicone impression preparation, plaster casting, and model house cleaning processes. The precision of digital impressions for edentulous jaw implants has been validated through laboratory studies and numerous clinical case reports. Our research team previously conducted systematic...Laboratory and clinical studies have compared the accuracy of traditional and digital archmolding techniques. Recently, a novel intraoral photogrammetric digital archmolding method has been applied for full-arch fixed prosthetic titanium bracket archmolding. While preliminary in vitro trials demonstrated comparable precision to external photogrammetry, further in vivo clinical trials are still required to evaluate its clinical efficacy. This study aims to investigate the archmolding accuracy of both digital and traditional methods in full-arch fixed prosthetic applications.

三、test objective

3.1 Main purpose

When a segmental titanium bracket is fixed and restored for the whole arch, the passive positioning of the restoration is compared with that of traditional and digital impressions

3.2 Secondary purposes

When a segmental titanium bracket is used for fixed restoration of the whole dental arch, the patient evaluation index and the doctor evaluation index are compared with those of traditional impression and digital impression restoration within half a year

四、experimental method

4.1 Overall design of the test

Randomized, single-blind, single-center, parallel-controlled, non-inferiority trial

4.2 Sample size

The pre-test results showed that the clinical score of the control group was 4.22±0.63 The clinical score of the experimental group was 4.0 ± 0.71. A one-sided test was set with a significance level α 0.0 5 and a power (检验效能) of 80%. The threshold Δwas calculated based on a 1-point difference in clinical scores. Using PASS software, the minimum sample size per group was determined to be at least 1 1 cases. Considering a 10% dropout rate, the final sample size for each group was set at 1 2 cases, totaling 24 cases.

4.3 Random (according to the actual design of the study)

Through simple randomization, a randomized number table is generated. The SAS program will be stored in the randomization process records to ensure reproducibility of the random number coding. After qualified participant screening, researchers assign random numbers. They then sequentially open envelopes by drawing numbers, meticulously recording the openers identity and time. Participants are subsequently allocated to two groups based on these randomized results.

4.4 Control and blind method (selected according to the actual design of the study)

4.4.1 Control selection

Traditional die removal

4.4.2 Blind implementation

This trial blinded the physicians who evaluated the effectiveness of the study and the patients who participated in the clinical trial. The physicians who evaluated the clinical effectiveness did not know the random grouping and followed the routine procedure to evaluate the effectiveness of the restoration after placement

4.5 Interview time point (selected according to the actual design of the study)

1 .Take model patients and doctors evaluation

Passive placement evaluation of stents

2 .Dentin in restoration T 0

3 .Denture restoration 3 months T 1

4 . Denture restoration 6 months T 2

五、Selection, withdrawal and management of subjects

5.1 Diagnostic criteria

The patient had no natural teeth in the arch and was implanted with a prosthesis to carry out fixed restoration of the whole arch.

5 .2. Inclusion criteria

Age 30-80 years old (including 30 and 80 years old), gender unlimited;

The patients maxillary or mandibular teeth are planned to be fixed with permanent restoration by full arch implantation;

The patient was implanted with an implant to complete the bone union;

The patient voluntarily participated in the trial and signed the informed consent form

5 .3. Exclusion criteria

The patient had severe pharyngeal reflex;
The intermaxillary distance of the patients rear tooth area is small and the mold column cannot be installed;
The distance between the two implants is too small to install the take-off column;
The patient has temporomandibular joint disease, unable to open the mouth for a long time to cooperate with the mold taking operation;
Other patients who were determined by the investigator to be unsuitable for inclusion.

5.4 Elimination and exit criteria

5.4.1 Cull criteria

Those who have been selected into this trial and belong to one of the following conditions shall be excluded.

（ 1） Violation of important entry criteria;

（ 2） Poor compliance;

（ 3） No observations were made after randomization.

5.4.2 Exit criteria

Subject withdrawal refers to the case in which a selected subject is determined by the investigator to withdraw from the trial when it is not appropriate for the subject to continue the trial.

（1） In the event of aggravation or deterioration of the condition during the trial, emergency measures must be taken;

（2） In the trial, the subject developed certain comorbidities, complications or specific physiological changes that make it unsuitable to continue the trial;

5.4.3 Data processing for withdrawn subjects

Regardless of the reason, complete clinical data should be retained for participants who withdraw from the trial. All withdrawn subjects must complete both the trial conclusion form and the case withdrawal reasons section in the Case Report Form. The withdrawal reasons generally fall into six categories: adverse events (including drug-related reactions and allergic responses), treatment failure (deterioration of condition or complications), protocol violations (poor adherence), loss to follow-up (voluntary withdrawal), sponsor discontinuation, or other valid reasons.

Conditions for discontinuation of the trial at 5.5

（ 1） Trial termination refers to the complete suspension of a clinical trial before its completion as planned.

（ 2） If serious safety problems occur in the test, it should be stopped in time;

（ 3） In the experiment, it is found that there are major mistakes in the formulation of the test plan or major deviations in the implementation, which makes it difficult to evaluate the drug effect;

（ 4） Other circumstances requiring suspension.

5.6 Subject management

5.6.1 Subjects recruitment methods

This study will screen subjects from a continuous patient population at the Department of Oral Implantology, Ninth Peoples Hospital affiliated with Shanghai Jiao Tong University School of Medicine. One researcher will provide information about the study to potentially eligible patients and solicit informed consent from interested subjects

5.6.2 Informed consent process

Prior to initiating any study procedures, participants must personally sign the latest approved version of the informed consent form with a date. Researchers will provide written consent documents to patients and conduct verbal explanations. After confirming eligibility criteria, participants will be enrolled in the study and sign the informed consent form, after which all research-related procedures and operations may proceed.

Researchers must provide participants with comprehensive information about the study, including: the exact nature of the research; the study protocols impacts and limitations; known side effects and risks associated with participation. Participants are explicitly informed that they may withdraw from the study at any time for any reason, without being

required to provide reasons for withdrawal. Their right to participate in medical treatment and the quality of care will not be compromised as a result.

六、Test process (selected according to the actual design of the study)

6.1 Introduction of test equipment

Endoscopic photogrammetry: it is a new type of equipment which uses the principle of photogrammetry and digitizes the endoscopic scan to obtain the three-dimensional position of implants. It has the characteristics of high precision and high efficiency in vitro research.

6.2 Instrumental methods

Intraoral photogrammetry: The shining Elite intraoral scanner was used. Before use, ensure that the calibration is within the date. First, scan the gums, then perform intraoral photogrammetry, and then merge the data of both.

6 .3 treatment courses and visit points

(1) Sign the informed consent form;

(2) Imaging examination of bone union of implant, percussion and stability examination;

(3) Examination of the patients mouth opening and space for posterior tooth restoration, pharyngeal reflex test using intraoral scanner, and taking photos to record the condition of the mouth;

(4) Preparation of traditional silicone rubber windowed clasp mold and digital scanning mold, patient evaluation and doctor evaluation;

(5) According to the random grouping situation, a one-piece titanium bracket restorations were made according to the corresponding impression data;

(6) Try on a segmental titanium stent in the mouth, and conduct clinical scoring of stent insertion and X-ray examination;

(7) After proper trial wearing of the bracket, complete the subsequent processing of the restoration. After the completion of wearing the restoration, the secondary screw is re-applied to 1 5 N.cm。

(8) 3 months reexamination, X-ray examination, open the screw hole to check whether the secondary abutment screws of the fixed restoration are loose, and reforce the secondary screws to 1 5 N. cm。

(9) In June, the X-ray was examined, and the screw hole was opened to check whether the secondary abutment screws of the fixed restoration were loose. The secondary screws were re-applied to 1 5 N.cm。

VII. EVALUATION INDICATORS

7.1 Baseline indicators

Demographic data: name, sex, age, etc.;

Physical examination: mouth opening, pharyngeal reflex, temporomandibular joint;

General clinical data: number of implants, width of keratinized mucosa around implants.

7.2. Effectiveness evaluation

7.2.1 Main evaluation index Passive Inlay Score (FVP-R) for a segmental titanium abutment of a restoration.

- Alternating finger pressure method to check whether the stent is loosened (0,1)
- Double side single screw test direct vision combined with probing for gaps (0,1)
- All screws were visually combined with probing to see if there was a gap (0,1)
- Screw resistance experiment whether the screw is smooth (0,1)
- Whether there is a gap in the X-ray line (0,1).

7.2.2 Secondary evaluation indicators

Patient evaluation index and doctor evaluation index during sampling

1、Patient evaluation index

Comfort score, tension score, pain score, nausea score

Doctor evaluation index

Scoring the ease of installation of scanning/transfer rods during the mold removal process, scoring the fluency of the mold removal process (fluency of individual tray

positioning/scanning), scoring the impact of patient response on the doctors operation (pharyngeal reflex/open mouth), and scoring the doctors tension.

2、time

Time to wear a tooth

Time to adjust jaw

3、function evaluation

1、Mouthstick test

2、Voice Evaluation V AS

3、Smile aesthetics evaluation V AS

4、Stability of repair (yes/no)

3. Complications (dental baseline, 3 months and 6 months):

BIOLOGICAL COMPLICATIONS: 1. Imaging: MBL

2. Probing: BOP, PD, PL, MH

3. Soft tissue cracking, soft tissue hyperplasia and hypertrophy, bridge soft tissue inflammation

4. Peri-implant disease

Mechanical complications: 1. Screw fracture, screw loosening

2. The sealing material falls off

3. Broken repair materials, etc

4. Satisfaction evaluation

Patient satisfaction questionnaire (when wearing teeth)

OHIP-14 questionnaire (3 and 6 months)

7.3 Safety evaluation

adverse event

(1) Definitions

Complication rate (at each visit): the segmental titanium stent was not in place, or the stent and screw were broken.

(2) Recording of adverse events

During the trial, the adverse event record form should be filled in truthfully, recording the occurrence time, severity, duration, effective measures taken and outcome of the adverse event.

VIII. Data quality assurance

8.1 Quality control and assurance

All participants in the study will receive standardized training on the steps of the study, including questionnaires, blood sample collection and storage, preoperative examinations and treatments, and implementation of interventions.

8.2 Data management

The primary data will be stored and retrieved from Shanghai Ninth Peoples Hospital. After analyzing data retrieved from the main databases, participants will be identified through specific participant numbers and/or codes in supplementary databases. CRF forms will be in written format, with identifiers removed and identification codes assigned. These codes will be securely stored separately from the data. Names and any other identifying details will not be included in electronic files of supplementary research data. All documents will be securely stored and accessible only to authorized personnel. Researchers will archive original files, informed consent forms, and patient questionnaires for each participant. Additionally, researchers will maintain a list of enrolled participants to facilitate matching with Case Report Forms (CRFs), clinical records, X-ray films, intraoral scanning images, and clinical specimens.

IX. STATISTICAL ANALYSIS

9.1 Analyzing the data set

ITT set (intended treatment analysis set), PP set (analysis set in accordance with the protocol)

9.2 Statistical methods

Statistical analysis was performed using SAS9.4 software. All statistical tests in this study employed one-sided methods, with P values below 0.05 considered statistically significant. Data were described using "mean ± standard deviation" and compared through parametric tests, specifically the independent samples t-test. For non-normal distribution of continuous data, median-based analyses were conducted alongside non-parametric methods, with the WILCOXON rank sum test employed for comparisons.

X. Ethical requirements and informed consent

10.1 Ethics Committee review

This protocol, written informed consent documents, and materials directly related to participants must be submitted to the ethics committee. The study may only commence after obtaining written approval from the ethics committee. Investigators are required to submit annual reports to the ethics committee at least once per year (if applicable). When suspending or concluding a study, investigators must notify the ethics committee in writing. All changes made during the study (such as revisions to the protocol and/or informed consent documents) must be promptly reported to the ethics committee and shall not be implemented without prior approval, except for modifications aimed at eliminating clear and direct risks to participants. In such cases, the ethics committee will be notified immediately.

10.2 Informed consent

Researchers must provide subjects or their legal representatives with an easily understandable and ethics committee-approved informed consent form, allowing sufficient time for them to review the study details. Participants may not be enrolled until they have signed the written consent. Throughout the study period, all updated versions of the informed consent form and related documentation will be provided to participants. The consent form shall be retained as a critical clinical trial record for future reference.

XI. Insurance (based on risk selection studies)

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XII. REFERENCES

1. Maló P, de Araújo Nobre M, Lopes A, Ferro A, Gravito I. All-on-4® Treatment Concept for the Rehabilitation of the Completely Edentulous Mandible: A 7-Year Clinical and 5-Year Radiographic Retrospective Case Series with Risk Assessment for Implant Failure and Marginal Bone Level. Clin Implant Dent Relat Res. 2015;17 Suppl2:e531-41.

2. Tang Y, Yu H, Wang J, Qiu L. Implant Survival and Complication Prevalence in Complete-Arch Implant-Supported Fixed Dental Prostheses: A Retrospective Study with a Mean Follow-up of 5 Years. Int J Oral Maxillofac Implants.2023;38:84-93.

3. Di Fiore A, Meneghello R, Graiff L, Savio G, Vigolo P, Monaco C et al. Full arch digital scanning systems performances for implant-supported fixed dental prostheses: a comparative study of 8 intraoral scanners. J Prosthodont Res. 2019;63:396-403.