ISRCTN12580798 https://doi.org/10.1186/ISRCTN12580798

A clinical study comparing a 3Dprinted method and traditional cutting zirconia for single dental restoration

Submission date 03/04/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 08/04/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/04/2026	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Traditional cutting zirconia (TCZ) for dental implant restoration is limited by high material waste, poor surface precision, and suboptimal periodontal compatibility, while digital colloidal deposition zirconia (DCDZ) – an additive manufacturing technology – has shown short-term advantages in esthetics and bonding strength, yet lacks 1-year follow-up data on periodontal health and gingival crevicular fluid (GCF) inflammatory factors. This study aims to fill this gap by comparing the long-term clinical performance of DCDZ and TCZ in single implant restoration.

Who can participate?
People aged 21-55 years in good general health requiring single-tooth dental implant restorations.

What does the study involve?
Screening and Grouping: Eligible participants will be randomly assigned by computer to one of two treatment groups.

Treatment: The observation group will receive crowns fabricated using DCDZ technology. The control group will receive crowns fabricated using TCZ technology. All participants will undergo standard tooth preparation, scanning, and bonding. The design, fabrication, and installation of the crowns will be performed by an experienced team of dentists.

Data Collection: Follow-up will be conducted at 6 months and 1 year after crown placement. Patients' teeth and gingiva will be examined, and plaque, gingival bleeding, and other health indicators will be assessed.

Small amounts of crevicular fluid (from the crevices between the gums and teeth) and plaque will be collected. These samples will be used to measure inflammatory marker levels and analyze the types of bacteria present.

At the one-year follow-up visit, a short satisfaction questionnaire will be completed, rating the patient's restoration in terms of aesthetics, comfort, and chewing function.

Participation Duration: The entire participation process includes the initial treatment and a one-year follow-up. Participation may be terminated early if serious complications related to the prosthesis occur or for medical reasons.

What are the possible benefits and risks of participating?
Possible Benefits:
This summary describes a research protocol. Therefore, the potential benefits and risks primarily relate to the dental treatment itself, as this is a clinical trial comparing two standard methods. The known effects for each type of restoration based on prior research are:
Possible benefits include restoring your missing tooth, improving your ability to chew comfortably and appearance, and contributing to scientific knowledge that helps improve treatments for future patients.

Known risks or side effects:
The restoration process involves routine dental procedures which may carry common risks such as temporary post-treatment sensitivity, minor gum inflammation, or the possibility of crown loosening or fracturing, which may require repair. The potential specific downsides of each material are not fully known; this study is designed to find that out.

Where is the study run from?
Department of Prosthodontics, Shaoxing Stomatological Hospital, China.

When is the study starting and how long is it expected to run for?
The planned start date for the study is December 2023, and patient recruitment is expected to continue until March 2025. The entire study, including the 1-year patient follow-up, is expected to run until sometime after March 2026.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Haibao Sun, sun_shaibao734bao@163.com

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Haibao Sun

Contact details
No. 399 Yan'an East Road, Yuecheng District
Shaoxing, Zhejiang
China
312000
+86 0575 88551175
sun_shaibao734bao@163.com

Additional identifiers

Funding Project No.
2023SKY091

Study information

Scientific Title
Comparative study of digital colloidal deposition and traditional cutting zirconia for single implant restoration

Study objectives
This study aimed to compare the efficacy of digital colloidal zirconia deposition (DCDZ) and conventionally cut zirconia (TCZ) in single-tooth dental implant restorations. Specifically, it evaluated the restorative effects of the two techniques, their impact on periodontal tissues (plaque index, gingival index, and gingival bleeding index), the detection rate of pathogens in subgingival plaque, the levels of inflammatory factors (TNF-α, IL-6, MMP-8) in gingival crevicular fluid, and patient satisfaction, with the goal of providing a reference for the selection of clinical dental restorative materials.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/12/2023, Shaoxing Stomatological Hospital (No. 399 Yan'an East Road, Yuecheng District, Shaoxing, Zhejiang, 312000, China; +86 0575 88551175; kqyybgs@126.com), ref: SL202302202

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied

Single molar implant restoration

Interventions
This was a prospective, randomized controlled trial. Eighty-four eligible patients were randomly assigned to two groups. The observation group (n=43) received digital colloidal zirconia (DCDZ) single crown restorations. The control group (n=41) received conventionally cut zirconia (TCZ) single crown restorations. Both groups underwent the same tooth preparation and bonding procedures. All clinical procedures were performed by the same team of senior dentists. The researchers responsible for follow-up assessments blinded the group assignments. Patients were followed up for one year, and various indicators were compared between the two groups.

Randomization methods used in the study were allocation randomization and blinding. The specific details are as follows:

Randomization Method:
The study implemented random grouping using a computer-generated random number table. The random sequence was generated via the "Random Number Generator" module in SPSS 27.0 software, with a set seed value of 20230101 to ensure reproducibility.

Procedure:
All eligible patients were sequentially numbered from 1 to 84 according to their first visit order. A researcher not involved in patient recruitment or treatment extracted the random number corresponding to each patient's number from the pre-generated table.
Patients with even random numbers were assigned to the observation group, while those with odd random numbers were assigned to the control group.

Concealment of Allocation (Sealed Envelope Method):
After determining the group assignment results, an independent statistician, who did not participate in the subsequent clinical procedures, placed the patient number and its corresponding group assignment into opaque, sequentially numbered, sealed envelopes.
When a patient completed the baseline assessment and was confirmed eligible for enrollment, the treating clinician opened the envelope corresponding to the patient's sequential number to reveal the group assignment. This process ensured that neither the clinicians nor the patients could predict or influence the grouping before enrollment, effectively avoiding selection bias.
In summary, the randomization process utilized computer software (SPSS) to generate the allocation sequence and employed sequentially numbered, opaque, sealed envelopes to implement allocation concealment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Digital colloidal deposition zirconia, traditional cutting zirconia

Primary outcome(s)
1. Restorative outcome measured using an assessment grading method (based on dimensions such as color matching, proximal contact, surface texture, integrity, and occlusion) at 12 months post-restoration

2. Periodontal health indicators measured using the Modified Plaque Index (mPLI), Gingival Index (GI), and Modified Sulcus Bleeding Index (mSBI) at 6 and 12 months post-restoration

Key secondary outcome(s))

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Aged 21-55 years
2. Systemic health: American Society of Anesthesiologists (ASA) physical status classification -
3. Oral and maxillofacial function: no masticatory dysfunction, occlusal stability
4. No parafunctional movements (night grinding, clenching teeth) confirmed by clinical examination and patient self-report
5. Normal cognitive function, able to complete 1-year follow-up
6. Regular dental arrangement, no severe crowding or spacing
7. Good oral hygiene: baseline modified plaque index (mPLI) ≤2, gingival index (GI) ≤1
8. Requiring single-tooth dental implant restorations

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
27 years

Upper age limit
41 years

Sex
All

Total final enrolment
84

Key exclusion criteria
1. Antibiotic use within 6 months before treatment
2. Destructive periodontitis (probing depth ≥6mm, attachment loss ≥3mm)
3. Salivary gland diseases affecting secretion
4. Poor compliance, inability to complete follow-up
5. Smoking ≥10 cigarettes/day
6. Systemic diseases (diabetes, autoimmune diseases) affecting wound healing

Date of first enrolment
12/12/2023

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Shaoxing Stomatological Hospital

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Haibao Sun, sun_shaibao734bao@163.com

IPD sharing plan summary
Available on request