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Comparing the fit of ceramic inlays made from silicone and digital impressions of the mouth

Submission date
17/05/2021

Recruitment status
No longer recruiting

Registration date
07/06/2021

Overall study status
Completed

Last Edited
08/08/2024

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Inlays are a type of tooth restoration used to treat cavities in the teeth. Inlays are fitted into the grooves of the tooth and the shape of the hole/cavity. Computer-aided design/computer-aided manufacturing (CAD-CAM) can be used to produce inlays with a better fit, which is crucial to avoid bacterial leakage and clinical complications. Using a traditional impression technique (using a silicone putty to create a mould of the tooth) may assure a precise reproduction with a close fit. The aim of this study is to compare inlays made based on digital impressions using CAD /CAM techniques or traditional silicone impression techniques.

Who can participate?
Healthy adults who are in need of one or two inlays on molar teeth

What does the study involve?
An inlay will be made for each tooth that requires an inlay from dental impressions taken traditionally (using putty) or made using digital impression techniques. The fit of each crown is determined using a microscope. How well each of the crowns fit will then be compared.

What are the possible benefits and risks of participating?
A benefit of taking part in the study is that participants are able to receive their dental inlays at a discounted price. The risks of participating are minor and include the general risks associated with dental surgery.

Where is the study run from?
University of Granada (Spain)

When is the study starting and how long is it expected to run for?
September 2019 to January 2021

Who is funding the study?
Instituto Odontologico Integral Avanzado (IOIA) (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPP-R-001

Study information

Scientific Title
Clinical evaluation comparing the fit of ceramic inlays obtained from silicone and digital intraoral impressions

Study objectives
There is no difference in accuracy between the fit of the inlays fabricated with the digital impression and the conventional impression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/05/2020, comite etico de la universidad de Granada (Ethical committee of Granada University, Vicerrectorado De Investigacion Y Transferencia, University of Granada, 48 Gran via De Colon, Granada, 18071, Spain; +34 (0)958243008; investigacion@ugr.es), ref: #1456/CEIH /2020

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Dental cavities

Interventions
Each tooth included in the study is the investigation unit (or specimen). Each tooth is prepared for inlay, and two impressions are taken on each tooth (one digital and one conventional). One inlay is produced for each tooth with a conventional impression or digital impression. Randomization is conducted using a mobile application. After fitting the definitive restoration to the clinical preparation, with no occlusal checkup, it is placed in the oral cavity and an impression is taken of the occlusal and non-occlusal interfaces using polyvinyl siloxane addition silicone. Samples are stored in transparent, hermetic bags that are coded to ensure their analysis in a blinded fashion. The same restoration used for the measurements is then cemented in the dental preparation for which it was prepared.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Inlays made using CAD/CAM techniques, inlays made using silicone impression techniques

Primary outcome measure

Marginal gap of ceramic inlays measured using white light confocal microscopy between 3 and 8 days after the replication of the fit

Secondary outcome measures
Overextension of ceramic inalys measured using white light confocal microscopy between 3 and 8 days after the replication of the fit

Overall study start date
01/09/2019

Completion date
01/01/2021

Eligibility

Key inclusion criteria
1. In need of 1-2 (if located in contra-lateral quadrants and opposing arches) inlays on molar teeth
2. Subject tooth/teeth are free of clinical symptoms
3. No requirement for additional endodontic treatment expressed by the presence of a periapical radiolucency around an endodontically treated tooth or a root canal filling <3 months
4. Adequate level of oral hygiene expressed by the absence of signs of periodontal inflammation, bleeding on probing, and periodontal pocket depth <4 mm

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
31 inlays in 31 patients

Total final enrolment
31

Key exclusion criteria
1. Advanced periodontitis affecting the mobility of the teeth (mobility degree 2 or higher)
2. Clinical history of bruxism
3. Pregnant or lactating females
4. Marginal preparation situated deeper than 1 mm subgingival

Date of first enrolment
18/05/2020

Date of final enrolment

01/09/2020

Locations

Countries of recruitment
Spain

Study participating centre
University of Granada
School of Dentistry
Prosthodontic Section
Campus de Cartuja S/N
Granada
Spain
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Sponsor information

Organisation
Instituto Odontologico Integral Avanzado, SL

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Instituto Odontologico Integral Avanzado, SL

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/02/2024	08/08/2024	Yes	No