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Comparing the accuracy of digital impressions with conventional impressions

Submission date
08/09/2015

Recruitment status
No longer recruiting

Registration date
29/09/2015

Overall study status
Completed

Last Edited
27/11/2015

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Taking impressions of teeth (dental impressions) are vital for all dental restoration surgeries. Traditionally, dentists take impressions by asking the patient to “bite down” on synthetic putty, so that a 3D mold of the teeth could be made. In recent years, the use of computerised systems has been used more and more in dentistry. Many dentists now use digital impression and scanning systems to take accurate impressions of the teeth, which are considered to be a faster and more accurate way of taking dental impressions. The aim of this study is to find out whether dental crowns (a tooth-shaped "cap" that is placed over a tooth) made using traditional impression methods (putty) or a digital impression system fit better in the patient.

Who can participate?
Healthy adults who are in need of one or two crowns on pre-molar teeth.

What does the study involve?
Two dental crowns are made for each tooth that requires a crown, one made from dental impressions taken traditionally (using putty) and one made using digital impression techniques. The fit of each crown is determined using a microscope. How well each of the crowns fit is then 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 crown 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?
Universidad Complutense de Madrid (Spain)

When is the study starting and how long is it expected to run for?
September 2010 to June 2012

Who is funding the study?
Straumann Implant system (Spain)

Who is the main contact?
Miss Cristina Zarauz

Contact information

Type(s)
Public

Contact name
Miss Cristina Zarauz

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
C.I.011/170

Study information

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

Study objectives
Null hypothesis: There is no difference in accuracy between the fit of the crowns fabricated with the digital impression and the conventional impression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité Ético de Investigaciones Clínicas CEIC (Ethical commette for clinical investigations, Spain), 02/03/2011, ref: E-09/377

Study design
Observational case crossover study

Primary study design
Observational

Secondary study design
Case crossover study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Accuracy of fit of crowns fabricated by 2 different impression systems, for healthy patients.

Interventions
Each tooth included in the study was the investigation unit (or specimen). Each tooth was prepared for crown, and 2 impressions were taken on each tooth (one digital & one conventional). 2 crowns were produced for each tooth, one with the conventional impression, and one with the digital impression.
These 2 crowns were tried on the prepared tooth, to replicate the misfit, and were left embedded in the replicated misfit, to be taken to process to the lab. Through embedding, this very thin layer of silicone (50 microns sometimes), is better stabilised. A third crown was produced by the conventional impression system (as it is still gold standard), to cement after we had done accuracy testing. Both impressions are commercially available and CE marketed and routinely employed as a standard of care. Added burden mounted to 5-10 minutes of extra chair time, as 2 impressions were taken, instead of one (impressions have no negative effect on the patient whatsoever), and later, at timepoint 2, it meant a total of 10 more minutes for the patient, as we did the accuracy testing before cementation of the final crown.

Intervention Type
Device

Primary outcome measure
Marginal misfit of zirconia-ceramic crowns measured in micrometers between 3 and 8 days after the replication of the fit.

Secondary outcome measures
Internal fit of zirconia-ceramic crowns measured in micrometers between 3 and 8 days after the replication of the fit.

Overall study start date
15/09/2010

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. In need of one or two (if located in contra-lateral quadrants and opposing arches) single crowns on pre-(molar) teeth
2. Subject tooth 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
26 crowns in the 21 patients.

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
27/01/2011

Date of final enrolment
20/03/2012

Locations

Countries of recruitment
Spain

Study participating centre
Universidad Complutense de Madrid
Plaza de Ramón y Cajal 3
Madrid
Spain
28040

Sponsor information

Organisation
Straumann Implant system

Sponsor details
Edificio Arroyo - A
Avda. de Bruselas, 38 - Planta 1
Alcobendas
Madrid
Spain
28108

Sponsor type
Industry

Website
http://www.straumann.es/

Funder(s)

Funder type
Industry

Funder Name
Straumann Implant System

Results and Publications

Publication and dissemination plan
The research is accepted for publication in the Journal for Clinical Oral Investigations.

Intention to publish date
30/09/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016		Yes	No