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A two year clinical follow up of the single visit crown, comparing two different placement techniques

Submission date
18/07/2016

Recruitment status
No longer recruiting

Registration date
22/07/2016

Overall study status
Completed

Last Edited
01/02/2021

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A crown restoration is a type of dental treatment which completely caps or encircles a tooth or dental implant. The adult dental health survey in 2009 suggested that 37% of adults who still had teeth in England Wales and Northern Ireland had at least one crown restoration. There is an estimated 47.6 million crowns across England, Wales and Northern Ireland. The single visit crown is a new technique which can be made and fitted in a single visit to the dentist. They promise to offer a long-lasting restoration that looks good and costs less than a traditional crown (for which impressions need to be taken and a temporary solution used until the crowns are ready). The aim of this study is to assess how easy the crowns are to make and how well the crowns perform over a short period.

Who can participate?
Adults who need to have at least one crown.

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups receive the same single visit crown (SVC) but have it fitted using different techniques. For all participants, the treatment sessions involve a single operator preparing and fitting the crown. The operator finds out which group the patient has been allocated to only when the tooth has been prepared and is ready to receive the crown. The crown is then manufactured and tested for its fit. The crown isn't cemented in place unless both patient and operator are entirely satisfied with it. The operator records how well the crown fits before it is cemented in place and a series of photographs are taken. For participants in the first group, the single visit crown will be shaped entirely on the prepared tooth in the patients mouth (this is called the direct method). For participants in the second group, the crown is shaped party in the mouth but also in part on a replica model of the tooth made by the dentist (this is called the indirect technique). The subject will then return to the clinic for regular checks on the crown: at baseline (after 7-28 days), 6 months, 1 year and 2 years. They also complete satisfaction questionnaires about the crowns on each review and have a series of photographs taken of their mouths and replica models of the crowns taken.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Newcastle Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2015 to August 2019

Who is funding the study?
3M ESPE (UK)

Who is the main contact?
Mr Chris O'Connor
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Contact information

Type(s)
Public

Contact name
Mr Chris O'Connor

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NU-SVC2

Study information

Scientific Title
A two year post market clinical follow up of a composite single visit crown, comparing a novel indirect workflow to an established direct workflow: A pilot study

Study objectives
SVC-IN crowns will not perform differently to the SVC-D crowns over the course of the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 2 Research Ethics Committee, 18/11/2016, ref: 16/NE/0318

Study design
Single-blind single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Dental caries/occlusal trauma

Interventions
26 study numbers will be randomly allocated to the two study arms using software from the website www.sealedenvelope.com. The study numbers will be randomly allocated into random blocks of 4 or 2. The additional 6 numbers are randomised to allow up to 3 repeats from each arm of the study should a crown be withdrawn from the study because of workflow failure (either operator or patient are not happy with final crown). The randomised list is blanked by a member of staff not involved in the trial and stored in the research facility. When the subject is enrolled to the trial neither patient nor operator will know the allocated arm of the study. This is revealed to the operator by a research nurse who reveals the allocation and tells the operator. The second blinded evaluator will not have the randomisation revealed through the duration of the trial.

Each arm of the study will receive the same single visit crown (SVC).

Arm one: Participants will receive the crown via a direct technique. In this technique the crown is fabricated and relined directly on the crown preparation using flowable composite using the existing IFU of the single visit crown which was released commercially in Japan in 2013.

Arm two: Participants will receive a SVC using a new indirect workflow. This time the crown is initially shaped in the mouth but is relined on a trimmed silicone chairside die which is made from a small sectional impression of the prep.

The treatment will take one appointment for both arms of the study. Both arms of the study will have four review appointments over two years: one at baseline (7-28 days), 6 months, 1 year and 2 years.

Intervention Type
Device

Primary outcome measure
Crown adaption is measured through a composite score of marginal adaption, marginal contour, approximal contact point, approximal contour, occlusal contact and aesthetic anatomical form, as determined baseline (7-28 days), at 6 months, 1 year and 2 years.

Secondary outcome measures
1. Crown performance is determined according to criteria from the world dental federation at baseline, 6 months, 1 and 2 years
2. Patient satisfaction at baseline, 6 months, 1 and 2 years
3. Time required fabricating the SVC
4. Reviewing study design

Overall study start date
01/09/2015

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Have read, understood and signed an informed consent form
2. Aged 18 years and over
3. Willing to comply with the study procedures
4. In need of at least one full-coverage posterior crown restoration

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. Lack of capacity to be able to consent to the research project and/or inability to follow study instructions
2. Known allergies or idiosyncratic responses to any product used during the study
3. A complicating medical condition (e.g. infectious disease, blood coagulation disorder, risk of endocarditis, general weakened immunity, oral pathology, chronic diseases, requiring use of antibiotic before treatment)
4. Participation in another dental research study within the last month
5. Requiring extensive treatment prior to the provision of the fixed restoration
6. Active primary disease; caries or symptoms of pulpal or apical pathology to the remaining teeth
irreversibly compromised structural integrity of the dentition that cannot be restored as part of the provision of treatment
7. A history of advanced periodontal disease with teeth of grade two or three mobile

Date of first enrolment
01/09/2016

Date of final enrolment
30/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Dental Hospital
Richardson Road
Newcastle upon Tyne
United Kingdom
Ne2 4AZ

Sponsor information

Organisation
Newcastle upon Tyne Hospitals Trust

Sponsor details
Level 1 Regent Point
Newcastle Upon Tyne
England

United Kingdom
NE3 3HD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
3M ESPE

Results and Publications

Publication and dissemination plan
The findings of this research will be disseminated locally (at departmental meetings), and nationally and internationally via presentations at research conferences. The results of the research will be written up for submission for publication in peer reviewed national and international journals. It is likely that the findings of this research will be of interest to the general public, and Newcastle University has an established press office for communicating findings of research to the press in an appropriate format. At all times, plans to disseminate the findings of the research will be based on agreement between the researcher and the academic supervisors.

Intention to publish date
31/08/2020

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?
HRA research summary			28/06/2023	No	No