

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/07/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/02/2021	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 partly 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
christopher.o'connor@ncl.ac.uk

Contact information

Type(s)
Public

Contact name
Mr Chris O'Connor

ORCID ID
<https://orcid.org/0000-0001-6809-2763>

Contact details
Newcastle School of Dental Sciences
Framlington Place
Newcastle Upon Tyne
United Kingdom
Ne2 4BW

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Newcastle Dental Hospital

Richardson Road

Newcastle upon Tyne

United Kingdom

Ne2 4AZ

Sponsor information

Organisation

Newcastle upon Tyne Hospitals Trust

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Industry

Funder Name

3M ESPE

Results and Publications

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