

Ease of use of digital impression systems for dentists of different ages

Submission date 11/12/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/01/2022	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Intraoral digital impression (IDI) is a new procedure introduced to dental practice to assure more comfort to the patient and improve quality and the time usage of dentists. Being new, IDI needs practice to become easier for dentists. The aim of this study is to compare the facility of learning and quality of impressions done by different practitioners of different age categories using IDI.

Who can participate?

Healthy volunteers aged 22 and over

What does the study involve?

Dentists of three age categories are recruited: category A are dentists aged over 40 with no previous experience in the use of IDI, category B are pre-graduate dental students aged under 25 with no previous experience in the use of IDI, and category C are practitioners experienced with IDI. Patients are assigned to the different groups of dentists. Each patient has conventional impressions using trays and silicone material, and models of their teeth are poured in plaster. Three randomly chosen groups start with the 3Shape system and the other three with the LAVA system (same procedure for the two systems). On the first day, the dentists have an introduction session to IDI systems, 15 minutes training on a plastic model, and create a digital impression of the patients (time and quality of the IDI are recorded). On day 2 and day 3 the dentists do 60 minutes of training on each other, rotating each 20 minutes, so each dentist can do 20 minutes practice, 20 minutes assisting, and 20 minutes as a patient. On day 4 the dentists create another digital impression of the patients (time and impression quality are recorded). By the end, the groups switch systems and the same steps are repeated so that each group has used both systems.

What are the possible benefits and risks of participating?

There are no risks of any kind for the patients participating in this study.

Where is the study run from?

1. Geneva School of Dentistry (Switzerland)
2. University Complutense Madrid (Spain)

When is the study starting and how long is it expected to run for?
December 2017 to March 2018

Who is funding the study?
University of Geneva (Switzerland)

Who is the main contact?
Prof. Irena Sailer

Contact information

Type(s)
Scientific

Contact name
Prof Irena Sailer

Contact details
Division de Prothèse Fixe et Biomateriaux
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.0 (Date 11/10/2017)

Study information

Scientific Title
Ease of use and adaptability of clinicians of different generations to different intraoral digital impression systems

Study objectives
1. No differences will be found between groups with respect to times spend completing the intraoral digital impressions
2. No differences will be found between groups with respect to quality of the digital models

Ethics approval required

Old ethics approval format

Ethics approval(s)

Comité d'éthique du canton Geneve (ethics committee of Geneva canton) - approval pending

Study design

Observational study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Intraoral digital impression - dentistry

Interventions

The study is held in 2 centers (Geneva school of dentistry and University Complutense Madrid). In each center, 6 dentists of 3 age categories will be recruited:

Category A: dentists aged > 40 years with no previous experience in the use of Intraoral Digital Impression Systems

Category B: pre-graduate dental students, aged < 25 years, with no previous experience in the use of Intraoral Digital Impression Systems

Category C: control practitioners experienced with IDI systems

6 groups will be formed of 3 dentists: 1 of each category, and 1 patient will be assigned to each group. The recruitment of the 6 patients per center will be done prior to the attribution, patients are healthy adults with good oral hygiene and oral stability. Each patient will have conventional impressions using trays and silicone material, and models of his teeth will be poured in plaster to be the control models.

Once formed, 3 randomly chosen groups will start with 3Shape system and the other 3 with the LAVA system (same procedure for the 2 systems), and by the end , groups will switch systems so that each group would have used both systems.

On the first day, groups will have an introduction session to IDI systems, 15 min training on a plastic model, and baseline digital impression on patients (time and quality of Basleine IDI are recorded)

Day 2 and day 3: 60 minutes of training on each other, rotating each 20 min, so each dentist can do 20 min practice, 20 min assisting, and 20 min as a patient

Day 4: Test digital impression on patients (time and impression quality recorded)

By the end, groups will switch systems so that each group would have used both systems and same steps are repeated. Impression times recorded will be analysed by computer. Using Geomagic X software, the quality of the IDI impressions will also be compared to the initial plaster models.

Intervention Type

Behavioural

Primary outcome measure

Time needed to complete an intraoral digital impression, measured in minutes and seconds using a stopwatch, for the first impression (baseline impression) and the final impression done after two training sessions

Secondary outcome measures

Quality of the digital impressions compared to the initial plaster models, measured quantitatively by calculating using Geomagic X software:

1. Percentage of completeness of region of interest of digital model
2. Cumulative noise and errors of region of interest of digital model

Overall study start date

01/12/2017

Completion date

30/03/2018

Eligibility

Key inclusion criteria

1. ≥ 22 years of age
2. Capable of providing written informed consent
3. Obtained informed consent from the patient
4. Intra-oral health
5. Patients with adequate oral hygiene Plaque Index $< 20\%$, BoP $< 20\%$
6. Occlusal stability (fully dentate or partially edentulous: no more than 1 tooth missing per quadrant)

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

6 patients per center (12 patients in total)

Key exclusion criteria

1. Medical condition: ASA -score \geq III
2. History of radiotherapy in the head and neck region
3. History of bisphosphonate medication
4. Women of childbearing potential with a positive urine pregnancy test
5. Patients unwilling or incapable of understanding and signing the informed consent
6. Dental disease: active caries or periodontal inflammation

Date of first enrolment

01/12/2017

Date of final enrolment

01/02/2018

Locations

Countries of recruitment

Spain

Switzerland

Study participating centre

Clinique Universitaire de Médecine Dentaire

Faculté de Médecine Section de médecine dentaire

Rue Michel-Servet 1

Geneva

Switzerland

1211

Study participating centre

University Complutense Madrid

Spain

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Sponsor information

Organisation

University of Geneva

Sponsor details

Division of fixed prosthodontics and biomaterials
Faculté de Médecine
Section de médecine dentaire
Rue Barthélemy-Menn 19
Geneva
Switzerland
1211

Sponsor type

University/education

Website

<https://www.unige.ch/medecine/dentaire/fr/organ/de/divi/>

ROR

<https://ror.org/01m1pv723>

Funder(s)

Funder type

University/education

Funder Name

Université de Genève

Alternative Name(s)

University of Geneva, UNIGE

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Switzerland

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

01/04/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2021	14/01/2022	Yes	No