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

Submission date
11/12/2017

Recruitment status
No longer recruiting

Registration date
27/02/2018

Overall study status
Completed

Last Edited
14/01/2022

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Additional identifiers

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Medical condition: ASA -score ≥ 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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes