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Feasibility study of the uLab treatment planning software

Submission date	Recruitment status	[X] Prospectively registered
13/06/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/06/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/02/2020	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Traditional orthodontic treatment planning practice has remained substantially unchanged for the past 20 years. Ulab Systems Inc. (“Ulab”) has developed a new digital treatment planning software that is significantly faster than the conventional treatment planning software on the market.
The purpose of this study is to gather data regarding the fit of the dental appliance(s) fabricated from the treatment plan generated from Ulab Systems, Inc. for treating crowding and spacing malocclusions (or imperfect positioning of teeth) in approximately 500 patients within the age range of 7-80. The study is evaluating the Ulab Systems, Inc. software and not the actual appliances that participants will be wearing. Only standard laboratory practices and approved materials will be used to create your appliances.

Who can participate?
Patients between 7 and 80 years old, with mild to moderate spacing or crowding of their teeth.

What does the study involve?
Gathering data about the fit of dental appliances created from images of a patients teeth using treatment planning software from uLab Systems, Inc. This data will be gathered during ususal treatment sessions.

What are the possible benefits and risks of participating?
The study may or may not help patients, however it may help patients in the future. There is no anticipation of any problems and the only discomfort would be minor tooth soreness that is normal during tooth movement.

Where is the study run from?
The study will be run by selected investigators at their local dental practices.

When is the study starting and how long is it expected to run for?
August 2019 to August 2021

Who is funding the study?
uLab Systems Inc., CA, USA

Who is the main contact?
Mr Scott Rehage

Contact information

Type(s)
Public

Contact name
Mr Scott Rehage

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ULAB102

Study information

Scientific Title
Evaluation of appliance fit and treatment outcome with use of the uLab system

Study objectives
It is expected that the appliances fabricated from the Ulab software will fit much better than conventional clear orthodontic appliances, mainly because Ulab is the only system that retains the actual digital gingival information. In turn, it is expected that appliances made from the digital data will fit the dentition of the patient much better.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/06/2019, Veritas IRB (8555 Transcanada Hwy, Suite 201, Montreal, QC H4S 1Z6, Canada; +1.866.384.4221; infoirb@veritasirb.com), ref: 16358-14:02:2

Study design
Non randomised interventional

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Orthodontics - treating crowding and spacing malocclusions

Interventions
Throughout the study successive dental appliances will be provided to gradually reposition patients teeth and the fit of the devices will be assessed by the investigator. Each office visit will take approximately one hour. This study will last as long as it takes to straighten patients teeth, approximately 6 months to 1 year or longer, and will include visits to the study doctor’s office approximately every 4 to 8 weeks. Dental appliance(s) fabricated from the STL file generated from the Ulab treatment planning software

The Ulab software will use a computer as a tool to assist in programming a series of sequential tooth movements to ensure appropriate, consistent forces on the patient’s teeth per investigators desired prescription. The investigator will program a treatment plan using the Ulab software, and determine how many steps will be required to achieve the desired treatment outcome. Once the treatment plan is programmed by the investigator, they can fabricate the appliances in their own office or via a third party orthodontic laboratory, using the standard dental laboratory practices and approved materials used by the dental industry.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure

Percentage of dental appliance with acceptable fit (pass/fail), measured during patient consultations (approx. every 6 months).

Secondary outcome measures
1. Oral hygiene based on gender and age (poor/fair/good), measured during patient consultations (approx. every 6 months).
2. Patient compliance (poor/fair/good), measured during patient consultations (approx. every 6 months).

Overall study start date
01/06/2019

Completion date
01/06/2021

Eligibility

Key inclusion criteria
1. Between 7 and 80 years of age
2. Fully erupted 7 to 7 upper and lower
3. Permanent dentition
4. Class I Mild to moderate spacing case (1-6 mm)
5. Class I Mild to moderate crowding cases (1-6 mm)

Participant type(s)
All

Age group
All

Sex
Both

Target number of participants
500

Key exclusion criteria
1. The legally authorized representative/ guardian is unable or unwilling to consent.
2. Patients with periodontal disease that would preclude orthodontic treatment.
3. Extraction other than a single lower incisor
4. Cases requiring autorotation of the mandible for vertical/A-P correction
5. Severe deep bites to be opened to ideal
6. Cases with erupting permanent teeth or mixed dentition
7. Pre-orthognathic surgery cases
8. Short clinical crowns
9. Up righting of severely tipped teeth (tipped greater than 45 degrees)
10. A-P corrections greater than 2mm
11. Cases with multiple missing teeth
12. Untreated periodontal disease
13. Existing decay/poor restorations

14. Resolution of moderate-severe CR-CO discrepancy
15. Severe open bites to be closed to ideal
16. Significant TMJ symptoms/pathology
17. Unidirectional movement of an entire dental arch
18. Closure of posterior open bite
19. Correction of impacted dentition/forced eruption

Date of first enrolment
01/07/2019

Date of final enrolment
01/07/2020

Locations

Countries of recruitment
Canada

Study participating centre
Dr. Paul Pocock - Smiles by Pocock
224 West Esplanade
Suite 600
North Vancouver
Canada
BC V7M 1A4

Study participating centre
Dr. Joseph Stanley - All Smiles Orthodontics
560 Main St
#35Place
Saint John
Canada
E2K 1J5

Study participating centre
Dionne Orthodontics
12329 Tecumseh Rd
Tecumseh, Ontario
Canada
N8N1M5

Study participating centre

Family Braces North Clinic - Dr. Fouad Ebrahim
Beacon Hill Shopping Center
11820 Sarcee Trail NW
Calgary
Canada
T3R 0A1

Sponsor information

Organisation
uLab Systems Inc.

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
uLab Systems Inc.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/08/2022

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date