

# Feasibility study of the uLab treatment planning software

<b>Submission date</b> 13/06/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/02/2020	<b>Condition category</b> 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

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 usual 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

**ORCID ID**  
<https://orcid.org/0000-0003-1900-4098>

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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).

**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

### Healthy volunteers allowed

No

### Age group

All

### Sex

All

### 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.

## Funder(s)

Funder type  
Industry

Funder Name  
uLab Systems Inc.

## Results and Publications

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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes