ISRCTN11587056 https://doi.org/10.1186/ISRCTN11587056

Clear aligners versus fixed orthodontic appliances in surgery first orthognathic surgery

Submission date	Recruitment status	[_] Prospectively registered
28/05/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/06/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/07/2023	Oral Health	

Plain English summary of protocol

Background and study aims
Dentofacial deformities are caused by discrepancies in the shape and size of the jaws, leading to dental malocclusions (misalignment) and facial disharmony. This condition is traditionally addressed with a combined orthodontic and surgical treatment, consisting of a previous phase of orthodontics with fixed brackets to align teeth, orthognathic surgery to put the upper and lower jaw in their ideal position, and a final phase of orthodontics to make the final adjustments. In the last few decades, clear removable aligners such as Invisalign have become very popular due to their convenience, ease of use and aesthetics. However, clear aligners have been little used in the orthognathic surgery field. The aim of this study is to compare the advantages of clear aligners with traditional fixed brackets, in terms of oral health and patients' satisfaction, when used in orthognathic surgery.

Who can participate?
Patients with dentofacial deformities who seek an ortho-surgical correction of their problem

What does the study involve?
Participants undergo a complete orthodontic and surgical study to see if they are eligible for this type of surgery, undergo 3D planning and virtual surgery to decide the dental movements and the movements of the jaws, and are randomly allocated to one of the two groups of the study (brackets and Invisalign). They are treated with bonding of brackets in the first group, and dental scanning for the manufacture of the clear aligners in the second group, and undergo orthognatic surgery under general anaesthetic, recovery from surgery, periodontal measurements, and quality of life questionnaires. Participants attend the usual appointments with the orthodontist and the surgeon during the healing process and the brackets are removed when treatment is completed. All these steps are the usual daily practice, only periodontal measurements and answering the questionnaires are specific to this study.

What are the possible benefits and risks of participating?
The benefits of this study are those derived from the orthodontic and surgical correction of a dental deformity: correct alignment of teeth, improved occlusion (the contact between teeth),

and a balanced and aesthetic facial profile. The risks are, likewise, derived from the treatment: facial swelling, oral sores, lip or cheek numbness, usually temporary. There is no specific risk derived from the study intervention itself (periodontal and quality of life assessment).

Where is the study run from?
Ramon y Cajal University Hospital and the orthodontic clinic, Madrid (Spain)

When is the study starting and how long is it expected to run for?
March 2016 to February 2019

Who is funding the study?
Align Research Award Program International

Who is the main contact?
Patricia de Leyva
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
095/17

Study information

Scientific Title
Surgery first and Invisalign. A comparative assessment of periodontal health and quality of life in postsurgical orthodontic treatment with Invisalign or traditional fixed appliances: a randomized controlled trial

Acronym
SFINVIS

Study objectives
Patients with dentofacial deformities undergoing Surgery-First orthognathic surgery and postsurgical orthodontics with clear aligners have a better quality of life and better periodontal health than those treated with Surgery-First orthognathic surgery and postsurgical orthodontics with traditional fixed appliances (brackets).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/05/2017, Ethics Committee of Clinical Research of Hospital Universitario Ramón y Cajal (Instituto Ramón y Cajal de Investigación Sanitaria, Ctra. de Colmenar Viejo, Km. 9,100 Planta – 2 derecha (28034), Madrid, Spain; +34 (0)91 336 81 47; irycis@irycis.org), ref: 095/17

Primary study design
Interventional

Study design
Single-center two-arm parallel randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dentofacial deformity

Interventions
Baseline characteristics including periodontal status and quality of life are recorded. All patients in the study receive professional oral hygiene treatment by an experienced dental hygienist. They are also instructed on the same standardized oral hygiene protocol before and during orthodontic treatment. This includes the proper use of toothbrush and interdental brushes three times daily. Baseline data recording and hygiene treatment take place before random allocation.

Allocation concealment is achieved with sequentially numbered, opaque, sealed envelopes, containing the treatment allocation cards. Envelopes are prepared before commencement of the trial, and they are kept locked and safe. Randomization and its implementation are performed by two different investigators. Blinding of patient, surgeon and orthodontist is not possible. However, outcome assessment is blind since data is coded for each patient. Besides, all periodontal measurements are performed by an independent technician, who remains unaware of the objectives of the study.

Participants are randomly assigned with an allocation ratio of 1:1 to postsurgical orthodontic treatment with either clear aligners (Invisalign group) or fixed appliances (brackets group). All patients are eligible for a surgery-first OS approach. The Invisalign system is used in all clear aligner cases. All surgical procedures are performed by the same surgical team, led by the senior surgeon. All patients are treated by an Invisalign certified orthodontist with experience in OS. All patients sign an informed consent document. The initial diagnostic workup, preoperative

planning, orthodontic preparation and surgical execution proceed according to the standardized protocol for SF orthognathic procedures. The diagnostic work-up includes a routine clinical assessment by the multidisciplinary orthodontic and surgical team. Dental casts and intraoral scanning, X-rays, cone-beam computed tomography (CBCT) and facial photographs are obtained. Likewise, CAD/CAM splints are fabricated following the 3D virtual orthodontic setup and virtual surgical simulation. Patients allocated to the brackets group also undergo a preoperative orthodontic appointment 1 week prior to surgery for brackets bonding. Patients in the Invisalign group undergoing non-segmented maxillary surgery also have an orthodontic appointment 1 week before surgery for intraoral scanning in order to fabricate the aligners.

The patients are operated upon under general anesthesia. Single jaw or bimaxillary surgery is performed, depending on the individualized treatment plan. For patients in the Invisalign group, four to eight transmucosal 2.0 mm screws are placed before incision. If the maxilla needs segmentation, eight screws are placed; in one-piece maxillas, four screws are used. Surgery proceeded according to the standard protocol, being the same for both groups. The duration of surgery is recorded.

All patients have the first appointment with the orthodontist 1 week after surgery. The brackets group begin orthodontic treatment following that appointment, within the first 10 days after surgery. Patients in the Invisalign group and with segmented maxillary surgery are scanned within the first or second week, depending on the swelling, and started using the aligners as soon as they are delivered, in the third week after surgery. Patients in the Invisalign group with non-segmented maxillary surgery begin to use the first aligner within the first 10 days after surgery. The finishing criteria are the same for each group. They were established following standard practice, in accordance with the American Board of Orthodontics Objective Grading System.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Measured immediately before surgery, 1 month after surgery and at the end of study:
1. Plaque index assessed by visual inspection of the plaque accumulation and recorded according to the modified index of Loe (0-3)
2. Quality of life measured using Orthognathic Quality of Life Questionnaire (OQLQ-22)

Key secondary outcome(s)
Measured immediately before surgery, 1 month after surgery and at the end of study:
1. Probing depth (PD) and bleeding on probing (BP) assessed by periodontal probing on the gingival pocket and recorded in milimetres (PD) and as absent or present (BP)
2. Quality of life assessed using the short version of the Oral Health Impact Profile (OHIP-14)

Completion date
02/02/2019

Eligibility

Key inclusion criteria
1. Skeletal malocclusion requiring combined surgical and orthodontic treatment without extractions
2. Informed consent for this novel protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
28

Key exclusion criteria
1. Temporomandibular joint disorders or severe symptoms
2. Uncontrolled periodontal disease
3. Severe crowding requiring extractions
4. Class II division 2 malocclusion with overbite or severely altered curves of Spee
5. Severe asymmetry

Date of first enrolment
01/05/2016

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario Ramón y Cajal
Ctra de Colmenar km 9100
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Sponsor information

Organisation
Instituto Ramón y Cajal de Investigación Sanitaria

ROR
https://ror.org/03fftr154

Funder(s)

Funder type
Industry

Funder Name
Align Research Award Program International

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. These datasets could be shared upon request to the principal investigator of the study Patricia de Leyva (patricia.leyva@salud.madrid.org). The database was generated in a private Excel file and was only shared with the statistician, no other clinicians and no patients had access to this information; only coded data were stored (no personal identifiers or names) and all patients gave informed consent to participate in the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2023	19/07/2023	Yes	No
Abstract results		01/05/2019	04/03/2022	No	No