ISRCTN68311617 https://doi.org/10.1186/ISRCTN68311617

How braces can help make space for a dental implant to replace a missing tooth: a clinical study

Submission date
11/11/2025

Recruitment status
No longer recruiting

Registration date
12/11/2025

Overall study status
Completed

Last Edited
12/11/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looked at how braces (orthodontic treatment) can help people who are missing a single tooth by creating enough space in the mouth to place a dental implant. Sometimes, when a tooth has been missing for a while, the surrounding teeth shift and reduce the space needed for an implant. The aim of the study was to see how effective orthodontic treatment is in preparing this space so that a dental implant and crown can be placed successfully.

Who can participate?
The study included patients who were missing one tooth and had been referred to the orthodontic clinic because there wasn't enough space for a dental implant.

What does the study involve?
Participants were referred to the orthodontic clinic after an initial examination showed that the space for a dental implant was too small. They received orthodontic treatment (such as braces) to move the surrounding teeth and create enough room for the implant. The study followed their progress from the start of orthodontic treatment through to the end.

What are the possible benefits and risks of participating?
The main benefit of taking part was correcting the position of the teeth and creating enough space for a dental implant. This could improve both appearance and function. The risks were the same as those usually associated with orthodontic treatment, such as gum inflammation (gingivitis) and temporary tooth mobility.

Where is the study run from?
University of Medicine and Pharmacy of Craiova (Romania)

When is the study starting and how long is it expected to run for?
The study began in October 2022 and finished in November 2025.

Who is funding the study?
University of Medicine and Pharmacy of Craiova (Romania)

Who is the main contact?
Amelia Smaranda Rosianu, popescuameliasmaranda@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Miss Amelia Smaranda Rosianu

Contact details
Dr Victor Papillian street, No 8, E 11, First floor, Apartment 3
Craiova
Romania
200778
+40 753422359
amelia.popescu@umfcv.ro

Additional identifiers

Study information

Scientific Title
The role of orthodontic treatment in preparing the potential implant-prosthetic space for implant-supported single-tooth restorations. A prospective clinical study

Study objectives
The present study aimed to determine the effectiveness of orthodontic treatment in creating or opening the potential implant-prosthetic space necessary for implant-prosthetic restorations in single-tooth edentations, by comparing fixed orthodontic treatment with different types of brackets (metal, ceramic or sapphire) with that using Invisalign or Spark aligners.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/08/2023, University and Scientific Ethics and Deontology Committee (Petru Rares street, No 2, Craiova, 200349, Romania; +40 351443500; cosmin.cristea@umfcv.ro), ref: 156/30.08.2023

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Opening or creating the space for implants by orthodontic treatment in patients with single missing teeth.

Interventions
The prospective clinical study included patients with single missing tooth referred to the orthodontic clinic for the creation or opening of the space necessary for the insertion of an implant and subsequent prosthetic restoration with an implant-prosthetic restoration. They came from the oral rehabilitation clinic, where they presented themselves with the aim of placing an implant. Following the clinical examination, it was found that the potential implant-prosthetic space was diminished or closed, and as a result, the patients were referred to the orthodontist. The study followed the evolution of the patients from the moment of presentation to the orthodontist until the completion of orthodontic treatment, whether fixed or using aligners. Participants opted for fixed or mobile aligner devices taking into consideration the aesthetic aspect - those who preferred an aesthetic appliance opted for aligners. The financial aspect was also very important. Some patients preferred a fixed appliance because it was cheaper than the aligners, having the same efficiency.

A group received treatment with fixed metallic appliances because they had severe anterior crowding that could not be corrected with aligners device. The duration of the treatment is 2 - 2.5 years. Some needed miniscrews to debasculate the molars. Another group opted for saphire appliance, for aesthetic reasons. The efficiency was the same but it was more aesthetic and, as a consequence, more expensive. Finally, patients with mild dental abnormalities received treatment with aligners for 1 or 2 years, depending on the severity of the abnormality. Patient compliance was vital in these cases.

Intervention Type
Other

Primary outcome(s)
1. Occlusion angle class is measured using clinical examination at baseline
2. Position of the interincisive line relative to the mid-sagittal line is measured using clinical examination at baseline
3. Type of edentulism is measured using clinical examination at baseline
4. Location of edentulism is measured using clinical examination at baseline
5. Type of missing tooth is measured using clinical examination at baseline
6. Age of edentulism is measured using patient clinical records at baseline
7. Size of the edentulous space is measured using clinical examination at baseline
8. Type of orthodontic treatment is measured using patient clinical records at baseline
9. Duration of orthodontic treatment is measured using patient clinical records at the end of treatment
10. Size of the potential prosthetic space is measured using orthopantomograms (OPGs) and intraoral compass at baseline and during treatment
11. Change in size of the potential prosthetic space is measured using orthopantomograms (OPGs) and intraoral compass at baseline and during treatment

Key secondary outcome(s))

1. Types of movement of adjacent teeth measured using OPG-s and CBCT-s at the beginning of treatment
2. General associated diseases measured by general condition questionnaire at the beginning of treatment

Completion date
01/11/2025

Eligibility

Key inclusion criteria
1. Patients with single-tooth edentations, with the possibility of implant placement to replace the missing tooth
2. Patients with general conditions that do not contraindicate orthodontic treatment (ASA I or II)
3. Patients with stable occlusion
4. Patients who have accepted orthodontic treatment

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 years

Upper age limit
65 years

Sex
All

Total final enrolment
97

Key exclusion criteria
1. Patients with serious general conditions, ASA status grade above ASA II
2. Patients with extensive partial edentations, total edentations
3. Patients with unstable occlusion
4. Patients with skeletal anomalies requiring complex, orthognathic and orthopedic treatments

Date of first enrolment
01/10/2023

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
Romania

Study participating centre
Blutrot Medicine SRL
Gilort Street, No 9
Craiova
Romania
200778

Sponsor information

Organisation
University of Medicine and Pharmacy of Craiova

ROR
https://ror.org/031d5vw30

Funder(s)

Funder type
Not defined

Funder Name
Universitatea de Medicină şi Farmacie din Craiova

Alternative Name(s)
University of Medicine and Pharmacy Craiova, UMF, UMFCV, UMF Craiova

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Romania

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 publicly available repository.
Stored at the dental clinic Victory Dent in patient files. The data can be accessed on e-mail request (popescuandu@gmail.com).

IPD sharing plan summary

Available on request, Stored in publicly available repository