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Long-term functional outcomes of primary cleft surgery

Submission date	Recruitment status	[_] Prospectively registered
30/03/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/03/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/05/2023	Surgery	

Plain English summary of protocol

Background and study aims
Reconstruction of the alveolar process (the thick ridge of bone that contains the tooth sockets) and its adjacent platform is the final step in surgery for patients with a cleft palate. The aim of this study is to assess the success rate of autogenous mid-secondary alveolar bone grafting.

Who can participate?
Patients with a cleft palate operated on at Universitair Ziekenhuis Brussel between 1991 and 2020

What does the study involve?
Patients' charts are analysed to assess the success of the bone grafting.

What are the possible benefits and risks of participating?
No risks are expected. Based on the results the researchers can assess and improve treatment if needed.

Where is the study run from?
Universitair Ziekenhuis Brussel (Belgium)

When is the study starting and how long is it expected to run for?
May 2018 to December 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Ana Tache
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Contact information

Type(s)

Principal Investigator

Contact name
Dr Ana Tache

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Success rate of mid-secondary alveolar cleft reconstruction using anterior iliac bone grafts: a retrospective study

Acronym
LTFOPCS

Study objectives
The aim of this study is to assess the success rate of autogenous mid-secondary alveolar bone grafting following a standardized protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/05/2018, Institutional Research Ethics Board of Vrije Universiteit Brussel (Commissie Medische Ethiek (0.G. 016), Reflectiegroep Biomedische Ethiek, Laarbeeklaan 101, 1090 Brussel, Belgium; +32 (0)2 477 55 84; commisie.ethiek@uzbrussel.be), ref: B.U.N. 143201836187

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Veau III and Veau IV cleft palate

Interventions
Alveolar repair through iliac bone graft took place as warranted at 8-11 years of age to accommodate canine eruption and development, along with premaxillary repositioning osteotomy of bilateral complete clefts. In some cases, early bone grafting was performed prior to the eruption of cleft-side lateral incisors. Presurgical orthodontics (fixed or removable Hyrax or Haas expander) served to expand and align the maxillary arch in advance of these grafts.

As of 2012, a collagen biomatrix (TissuDura; Baxter AG, Vienna, Austria) was applied at times (not routinely) below the repaired nasal layer (Vicryl 5-0; Ethicon, Somerville, NJ, USA) and stabilized by adding fibrin sealant (Tisseel; Baxter). Bone marrow was aspirated from the iliac crest using a 50-mm Jamshidi needle (Handlex; Medax, Poggio Rusco, Italy). Cancellous bone was harvested through a medially based trap-door technique from the anterior iliac crest (Video) with the use of Champy 8 mm and 5 mm Bone Biopsy Instruments (KLS Martin Group, Tuttlingen, Germany). The harvested bone was particulated using a bone mill and mixed with bone marrow aspirate; afterwards, was syringe-condensed into the alveolar cleft and manually molded. After suturing of oral mucosa (Vicryl 4/0), fibrin sealant was employed to affix the mucoperiosteal flaps onto the transplanted bone. A nasal packing with an inner airway tube (Ivalon; First Aid Bandage Company, New London, CT, USA) was inserted and remained in place until hospital discharge (average, 2 days). At the donor site, a continuous anesthetic elastomeric pump (Baxter International Inc, Deerfield, IL, USA) was placed. Patients were discharged wearing the pump as a pouch, which was removed 3 days postoperatively (on average).

Intervention Type
Procedure/Surgery

Primary outcome measure
Success rate of autogenous mid-secondary alveolar bone grafting assessed using patient charts from between 1990 and 2020. Criteria for success were: long-term preservation of alveolar bone stock, ability of spontaneous or orthodontic-guided eruption and periodontal health of permanent lateral incisors and canine teeth, absence of exposed root structures for teeth adjacent to clefts, absence of fistula and successful placement of osseointegrated implants as

warranted. Failure of alveolar bone grafts was indicated by radiographically demonstrable total or near-total graft loss requiring reintervention.

Secondary outcome measures
There were no secondary outcome measures

Overall study start date
02/05/2018

Completion date
31/12/2020

Eligibility

Key inclusion criteria
All cleft patients receiving secondary alveolar bone grafts between 1991 and 2020 were reviewed

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
124

Total final enrolment
124

Key exclusion criteria
1. Lost to follow-up
2. Incomplete files

Date of first enrolment
01/01/1991

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Belgium

Study participating centre
Universitair Ziekenhuis Brussel
Laerbeeklaan 101, 1090
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Sponsor information

Organisation
Universitair Ziekenhuis Brussel

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Sponsor type
Hospital/treatment centre

Website
http://www.uzbrussel.be/u/view/en/17362-Home.html

ROR
https://ror.org/038f7y939

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
30/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from Ana Tache (ana.tache@uzbrussel.be). Anonymized radiological imaging and the extraction data table will be available upon request. Access to the charts is forbidden due to privacy law in Belgium. Consent of patients was obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2022	22/05/2023	Yes	No