

Long-term functional outcomes of primary cleft surgery

Submission date 30/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/03/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/05/2023	Condition category Surgery	<input type="checkbox"/> Individual participant data

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

ana.tache@uzbrussel.be

Contact information

Type(s)

Principal investigator

Contact name

Dr Ana Tache

Contact details

Laerbeeklaan 101

Brussels

Belgium

1090

+32 (0)494 17 73 25

ana.tache@uzbrussel.be

Additional identifiers

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 (O.G. 016), Reflectiegroep Biomedische Ethiek, Laerbeeklaan 101, 1090 Brussel, Belgium; +32 (0)2 477 55 84; commissie.ethiek@uzbrussel.be), ref: B.U.N. 143201836187

Study design

Retrospective cohort study

Primary study design

Observational

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

There were no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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

Brussels

Belgium

1090

Sponsor information

Organisation

Universitair Ziekenhuis Brussel

ROR

<https://ror.org/038f7y939>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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