

Regenerating lost jaw bone using patient specific 3D-printed re-sorbable polycaprolactone mesh versus a titanium mesh

ACTRN12626000156381

Status	RECRUITING
Sponsor	University of Queensland
Enrollment	60 participants

Plain Language Summary

This study is looking at a new way to rebuild jaw bone that has been lost — for example, after a tooth extraction or due to gum disease — so that dental implants can be placed. Researchers are comparing two types of custom-made, 3D-printed mesh devices: one made from a biodegradable plastic called polycaprolactone (PCL) that dissolves in the body over time, and one made from titanium, which is a metal that stays in the body permanently. Both meshes are shaped specifically for each patient's anatomy.

The PCL mesh is already approved in Australia for other uses (like sutures and fillers), but using it to regrow jaw bone is experimental. The hope is that the dissolving mesh will guide new bone to grow, reduce surgery time, and lead to better recovery compared to the metal mesh. After the bone has grown, dental implants can be placed.

You may be eligible if you are aged 18–65, are generally healthy, need dental implants to replace up to 6 teeth, and have a jaw bone defect that prevents implant placement. You must also not smoke heavily, not be pregnant, and not have conditions that interfere with bone healing.

Key Eligibility Criteria

Inclusion (7)

- Individuals aged between 18 and 65 years, medically healthy or with mild controlled systemic disease, able to undergo oral surgical procedures under local or general anaesthesia (ASA I and II; American Society of Anesthesiologists, Schaumburg, Illinois, USA).
 - Adequate plaque control (FM plaque and BOP scores less than or equal to 25%) at study baseline
 - Dental implant placement replacing up to 6 teeth in a partially dentate patient
 - Vertical alveolar ridge defect (with or without a horizontal component) of ≥ 2 mm or combined buccal and palatal/lingual horizontal defects in the region of interest preventing dental implant placement in a prosthetically driven position or with an unstable defect morphology necessitating staged bone augmentation.
 - Teeth at the surgical site which require removal are extracted a minimum of 12 weeks prior to ridge augmentation
- ... and 2 more (see full listing online)

Exclusion (9)

- Pregnancy at the time of recruitment
 - Alcoholism or chronic drug abuse
 - Patients who smoke more than 10 cigarettes per day
 - Medications or pathology which interferes with bone formation
 - History of local radiation therapy
- ... and 4 more (see full listing online)

Locations (1 total)

QLD, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12626000156381>

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