Alveolar ridge preservation with a xenograft (Bio-Oss® Collagen) and a collagen matrix (Mucograft® Seal) or a free connective tissue graft versus spontaneous healing:*A 5-year follow up

Published: 06-11-2023
Last updated: 08-04-2024

The aim of this study is to evaluate esthetic and clinical outcomes and patient satisfaction following single-tooth replacement in the anterior maxilla in patients treated with a xenograft and a collagen matrix or a free connective tissue graft...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON53947

Source
ToetsingOnline

Brief title
Mucograft Follow-up

Condition

- Bone and joint therapeutic procedures

Synonym
bone defect, extraction site

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dental implant, ridge preservation

Outcome measures

Primary outcome

Comparison of the level of the buccal marginal gingiva (midfacial mucosa level)

between ARP versus spontaneous healing

Secondary outcome

Peri-implant esthetic score (PES) and white esthetic score (WES),

complications, implant survival; and success, Plaque Index, Modified bleeding

index, Gingival Index, Probing Depth, PROMs, bone and soft tissue volumetric

dimensional changes.

Study description

Background summary

Early implant placement with alveolar ridge preservation (ARP) using either a collagen matrix or a palatal graft rendered similar esthetic, clinical and PROMs to early implant placement without ARP, up to 1 year after functional loading.

Study objective

The aim of this study is to evaluate esthetic and clinical outcomes and patient satisfaction following single-tooth replacement in the anterior maxilla in patients treated with a xenograft and a collagen matrix or a free connective tissue graft versus spontaneous healing 5 years after loading

Study design

prospective observational study with 5-year follow-up

Study burden and risks

The measurements performed in this research are analyses of the peri-implant soft tissue and radiological analyses. Participation in this research is not dangerous and the patients are not at risk. The radiographs and cone beam CT (CBCT) scans are taken, whether or not the patient is participating in this research. In case of pregnancy the the radiographic analysis is postponed till after pregnancy. In case the patient wants to withdraw from this research this does not have any consequence

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients were included in a prospective randomized clinical trial comparing alveolar ridge preservation with a xenograft and a collagen matrix or a free connective tissue graft versus spontaneous healing (MEC-2015-016;NL49965.078.14).

Exclusion criteria

Patients treated with radiotherapy during follow-up in the head-and-neck region or current chemotherapy; disability (mental and/or physical) to maintain basic oral hygiene procedures.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2023
Enrollment:	75
Type:	Anticipated

Medical products/devices used

Generic name:	Mucograft Seal and Bio-Oss Collagen
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-11-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05663385
CCMO	NL82943.078.23