

CLINICAL STUDY OVERVIEW

Neobone[®] in Alveolar Ridge Preservation

Interim six-month results from a prospective observational study of a biphasic calcium phosphate bone substitute used for alveolar ridge preservation after tooth extraction in routine dental practice.

STUDY

Post-market prospective observational study
Study code: NeoDent01 · ClinicalTrials.gov
NCT07179497

SITE

Egas Moniz School of Health and Science
Caparica, Portugal

STATUS

Ongoing. Data from study initiation
through August 2026



01 • AT A GLANCE

Preserving the Alveolar Ridge After Extraction

Neobone® is a synthetic, resorbable bone substitute of hydroxyapatite and β -tricalcium phosphate, manufactured by Bioceramed. This ongoing study follows patients implanted with Neobone® granules for alveolar ridge preservation after tooth extraction, with planned follow-up to two years.

ENROLLED

31

Patients enrolled in the study from its initiation through August 2026, of a planned 66.

SIX MONTHS

6 of 10

Patients with available clinical data at the six-month follow-up showed radiographic bone regeneration. In all six, the regenerated bone was considered clinically viable for implant placement.

SAFETY

0 AEs or DDs

Adverse events (AEs) or device deficiencies (DDs) related to Neobone® at any visit to date.

Where Each Patient Is Today

Patients with data at each scheduled visit. Recruitment and follow-up are ongoing.



The 12 and 23-month visits have not yet been reached.

Interim results. All six-month follow-up results presented in this document are based on the first 10 patients who reached this visit. The study is ongoing and continues to recruit. Study limitations are set out on page 11.

02 · HOW TO READ THIS DOCUMENT

Four Questions, One Point of Context

An interim analysis can describe what happened to the treated sites and the patients who had them. This document is organised around four questions the data address, and the context needed to read them.

01	Did bone regenerate at six months? Radiographic regeneration was observed in 6 of 10 patients, and all six sites were considered viable for implant placement. The remaining four did not yet show sufficient radiographic evidence.	PAGE 7
02	Was ridge volume preserved? Volume was maintained, within 10% of baseline, in 5 of 10 patients. Mean individual reduction was 11.50%.	PAGE 8
03	What did early recovery look like? Pain and oral health-related quality of life (QoL) impact peaked in the first days after surgery and returned to baseline levels by Day 7. At six months, all 10 patients reported no pain and no impact on QoL.	PAGE 9
04	Were there safety concerns? No AEs or DDs were related to Neobone®. All AEs were mild, expected postoperative pain attributed to the surgical procedure.	PAGE 10

READING THE RESULTS IN CONTEXT

How do these results compare?

The study does not include a control group, so its results are read alongside the published literature. Systematic reviews report that alveolar ridge preservation with a bone graft reduces horizontal and vertical ridge shrinkage compared with spontaneous healing¹, while some dimensional change persists with every graft material evaluated². Outcomes also depend on socket anatomy and surgical technique.

03 • CONTEXT

Limiting the Loss, Not Preventing It

After a tooth is extracted, the alveolar ridge remodels and loses width and height. Alveolar ridge preservation places a graft in the fresh socket to limit that change and keep the site suitable for later treatment, including implant placement.

The aim is preservation, not augmentation. Published reviews describe ridge preservation with a graft as reducing post-extraction resorption compared with spontaneous healing, rather than eliminating it, with results that vary by graft material and by the anatomy of the socket^{1,2,4}.

This document summarises the interim results of a prospective post-market study of Neobone® in that indication, conducted at the Egas Moniz School of Health and Science in Portugal.

THE DEVICE

Neobone®

A synthetic, resorbable, implantable calcium phosphate ceramic bone substitute. Class III medical device.
Manufactured by Bioceramed in Portugal.

- 01 Biphasic composition of 75% hydroxyapatite and 25% β -TCP. The more soluble β -TCP phase supports progressive resorption.
- 02 Interconnected porosity designed to allow vascularisation of the implant.
- 03 Available as granules, blocks, cylinders and wedges. This study used GN420 granules.
- 04 Radiopaque and traceable on X-ray. Single use, gamma sterilised.

Intended Purpose

Neobone® is a single-use, gamma sterilised, implantable biodegradable medical device intended to be used in both adults and children in filling bony voids or gaps within the skeletal system that do not contribute to the structural stability of the bone, and in reconstructive dental and maxillofacial surgeries. These defects may arise from surgical procedures or result from osseous damage due to traumatic injury to the bone.

NON-NEGOTIABLE

Neobone® provides no mechanical or structural support. It must not be used where structural support is required, or at an implantation site that is unstable and not rigidly fixated. Refer to the Instructions for Use for full indications, contraindications, warnings, and precautions.

Study Design

Design	Post-market, single-centre, single-arm, prospective observational study
Population	Adult patients (> 18 years) undergoing reconstructive dental surgery with Neobone®. In this analysis, all for alveolar ridge preservation after tooth extraction
Site	Egas Moniz School of Health and Science, Caparica, Portugal
Principal investigator	Dr. João Botelho
Planned sample	66 patients
Timepoints	Visit 1 (Baseline) · Visit 2 (Immediately after surgery) · Visit 3 (Day 7) · Visit 4 (6 months) · Visit 5 (12 months) · Visit 6 (23 months)
Primary endpoints	Bone regeneration at 6 months by CBCT, with clinical viability for implant placement. AEs and DDs at every visit
Secondary endpoints	Technical success and surgeon satisfaction · Oral health-related QoL (OHIP-14) · Radiographic bone density (HU) · Pain (VAS 0–10) · Bone volume change from baseline
Key exclusions	Active or chronic infection, metabolic disorders, severe degenerative disease, sites allowing graft migration, conditions requiring structural support, unstable non-fixed sites, sensitivity to the implant material
Registration	ClinicalTrials.gov NCT07179497
Ethics	Approved by the Ethics Committee of Egas Moniz School of Health and Science. Conducted in accordance with ISO 14155, ICH-GCP and the Declaration of Helsinki. Written informed consent from all patients

Volume Maintenance Threshold

A reduction of 10% or less from baseline volume was classified as maintenance. The threshold is broadly consistent with the magnitude-of-effect framework of Canullo et al., in which effects within the 0–10% range were considered clinically irrelevant¹.

Data Quality

Pseudonymised data captured in REDCap. A structured monitoring plan in line with ICH-GCP covers consent, eligibility, source data, and AE and DD reporting.

05 · COHORT

Who Was Treated, and How

Thirty-one patients were enrolled from the study's initiation through August 2026, all for alveolar ridge preservation at a tooth extraction site. No patient withdrew.

Patient Profile

Baseline, 31 patients.

GENDER

Male  18 · 58.06%

Female  13 · 41.94%

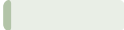
SMOKING HABITS

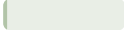
Smokers  4 · 12.90%

Non-smokers  27 · 87.10%

MEDICAL HISTORY

Hypertension  7 · 22.58%

Osteoporosis  2 · 6.45%

Diabetes  1 · 3.23%

CONCOMITANT MEDICATION

Yes  4 · 12.90%

Mean age 51.90 ± 18.90 years, range 20 to 86.
Mean BMI 26.40 ± 4.64 kg/m². No patient had osteopenia or prior cancer treatment.

The Procedure

Surgical records, 31 patients.

Device Neobone® GN420 granules, all cases

Quantity 1 unit in 30 patients · 0.5 unit in 1

Defect volume, median (IQR) 139 (149) mm³

Defect volume, range 22.95 – 601 mm³

Operative time, median (IQR) 30 (15) min

Operative time, range 10 – 240 min

Correct use and placement 31 of 31

Postoperative CBCT 31 of 31

Barrier membrane added 19 of 31 · 61.29%

06 • QUESTION ONE

Did Bone Regenerate at Six Months?

At the six-month follow-up, the 10 patients who had reached this visit underwent CBCT assessment to evaluate radiographic evidence of bone regeneration and the suitability of the site for implant placement.

RADIOGRAPHIC BONE REGENERATION

6 of 10

Patients with available clinical data at six months.



● Bone regeneration observed, viable for implant

○ Not yet sufficient radiographic evidence of bone regeneration

Every site that showed bone regeneration was considered clinically viable for implant placement. The remaining four sites were not considered suitable for implant placement at this visit.

RADIOGRAPHIC BONE DENSITY

1117_{HU}

Median at six months, IQR 240, in the 10 sites assessed. Values ranged from 340 to 1409 HU, and varied across sites.

IMPLANT PLACED BY SIX MONTHS

1 of 10 patients

Implant timing followed routine clinical decisions. Implant outcomes are scheduled from the 12-month visit.

The Four Sites Without Sufficient Bone Regeneration Evidence

In these patients the graft material remained more clearly distinguishable from the surrounding native bone, or appeared partially encapsulated. Published evidence shows that bone formation and maturation continue through the six-month healing period³, and the relatively high hydroxyapatite content of Neobone® is associated with slower material resorption. These findings may therefore reflect the ongoing evolution of the grafted sites. The 12-month follow-up is planned to further assess bone maturation and consolidation in these four cases.

07 · QUESTION TWO

Was Ridge Volume Preserved?

Bone volume at the treated site was measured on CBCT at baseline and at six months in the same 10 patients.

BASELINE

1612 mm³

Mean ± 581. Range 842 to 2489 mm³.

SIX MONTHS

1451 mm³

Mean ± 598. Range 568 to 2395 mm³.

MEAN REDUCTION

11.50 %

Individual change ranged from -0.16% to -32.50%.

Volume Classification at Six Months

Maintenance defined as a reduction of 10% or less from baseline. 10 patients.

Maintained (≤ 10% reduction)



5 of 10

Reduction greater than 10%



5 of 10

The reduction from baseline to six months was statistically significant (paired t-test, $t(9) = 3.95$, $p = 0.003$).

Reading the Volume Result

In alveolar ridge preservation, the clinical goal is to limit post-extraction resorption and preserve the volume and dimensions of the ridge. Systematic reviews and clinical trials report that ridge preservation with a graft reduces shrinkage compared with spontaneous healing¹, that no graft material fully prevents dimensional loss after extraction^{2,5,6}, and that results depend on the material and on socket anatomy, including the integrity of the buccal wall⁴. One patient in the reduction group had a fracture of the buccal plate during extraction, with a 22% volume reduction. With 10 patients, these results are preliminary.

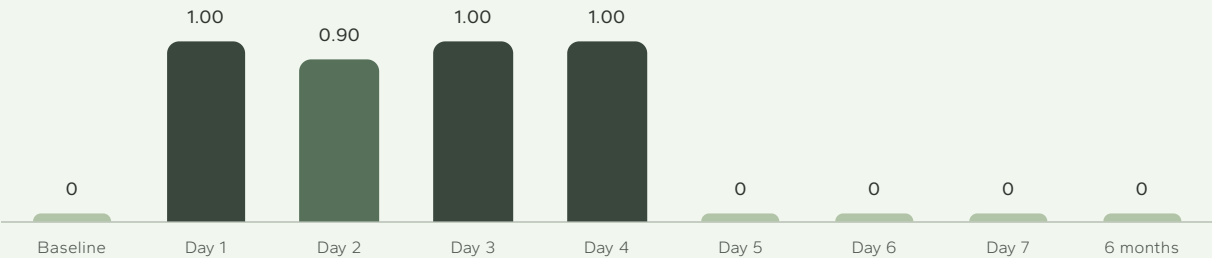
08 · QUESTION THREE

Pain and Quality of Life After Surgery

Patients recorded pain (VAS, 0 to 10) and oral health-related QoL (OHIP-14, 0 to 56, higher scores mean greater impact) before surgery and daily for the first postoperative week. Daily data were available for 29 patients.

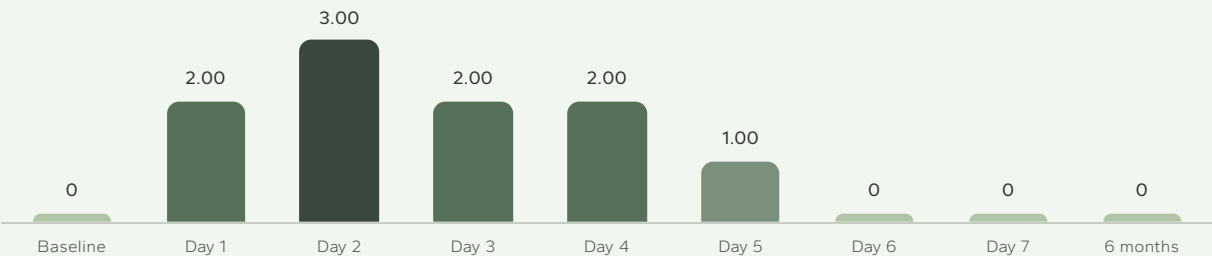
Pain · Median VAS Score

Baseline n = 31 · Days 1 to 7 n = 29 · Six months n = 10



Oral Health-Related QoL · Median OHIP-14 Score

Baseline n = 31 · Days 1 to 7 n = 29 · Six months n = 10



Back to baseline by Day 7. Both scores changed significantly across the first week (Friedman, $p < 0.001$). Day 7 did not differ from baseline for pain ($p = 0.109$) or QoL ($p = 0.529$). One patient needed additional analgesia at Day 7.

At six months. All 10 patients with available data reported a VAS score of 0 and an OHIP-14 score of 0, indicating absence of reported pain and of oral health impact on QoL at this timepoint. The observed reduction in postoperative pain is consistent with the expected clinical use of the device.

Safety Profile

AEs and DDs were recorded at every visit and assessed for their relationship to Neobone®, to other devices, and to the surgical procedure.

ADVERSE EVENTS

29 AEs

Reported in total. None was related to Neobone®.

SERIOUS ADVERSE EVENTS

0 SAEs

No event needed medical or surgical therapy.

DEVICE DEFICIENCIES

0 DDs

No DD involving Neobone® was reported.

AEs and DDs by Visit

VISIT	PATIENTS ASSESSED	PATIENTS WITH ≥ 1 AE	NEOBONE® DDS
Visit 2 · Immediately after surgery	31	0 · 0.00%	0
Visit 3 · Day 7	29	20 · 68.97%	0
Visit 4 · 6 months	10	0 · 0.00%	0

AEs Reported at Visit 3 (Day 7)

Every AE reported was postoperative pain. All were Grade 1 (mild), non-serious and expected, attributed to the surgical procedure and not to Neobone® or any other device. All resolved without treatment or consequences. No new or unexpected risks were identified.

Reading the Interim Data

The study is ongoing. These are the points to consider when interpreting the data available to date.

01 Limited Six-Month Data

Although 31 patients contributed to baseline and immediate postoperative assessments and 29 to early postoperative assessments, data from 10 patients were available at the six-month follow-up. This restricts the interpretation of the longer-term endpoints, particularly bone volume changes and radiographic bone regeneration. The six-month results should be considered preliminary until additional patients and longer-term data become available.

02 No Comparator Group

The study does not include a control group, which limits direct comparison with alternative treatments or spontaneous healing. Pain and QoL outcomes allow comparisons within each patient between baseline and follow-up, and the results are read alongside the published literature.

03 Anatomical and Surgical Variability

Socket morphology, pre-existing bone defects, bone wall integrity, extraction site and tooth position, as well as surgical technique, wound closure, use of an adjunctive barrier membrane and postoperative management, may influence dimensional changes independently of the graft material^{2,4}. Volumetric classification should be read together with the clinical and radiographic findings.

04 Ongoing Follow-Up

Recruitment continues towards 66 patients, and the 12 and 23-month visits, including implant placement and implant clinical success, are still to come. As more patients are enrolled and longer-term data become available, the study will provide further evidence on bone regeneration, volume preservation and safety.

05 Routine-Practice Scheduling

Nine Day 7 visits fell outside the protocol window of 7 ± 1 days, reflecting routine clinical scheduling. All planned data were collected.

What Six Months Show So Far

In 31 patients treated for alveolar ridge preservation in routine practice, Neobone® was placed as intended in every case. Early postoperative symptoms returned to baseline levels within seven days, and no device-related safety concerns were identified. At six months, 6 of the first 10 sites assessed showed sufficient radiographic evidence of bone regeneration and were considered suitable for implant placement.

Placed as Intended

Correct use and placement confirmed in 31 of 31 procedures. Median operative time 30 minutes (IQR 15).

Recovery Within a Week

Median pain and oral health-related QoL impact returned to baseline levels by Day 7. At six months, both measures were zero for all assessed patients.

No Device-Related Events

All AEs were mild, expected procedural pain. No DDs involving Neobone®.

As a synthetic bone substitute, Neobone® avoids the donor-site morbidity associated with autologous grafting. It fills the socket and supports the healing site. It does not provide structural support. The 12-month analysis will add more patients, implant outcomes, and the evolution of the sites still maturing at six months.



FULL REPORT AVAILABLE ON REQUEST

Request the Full Clinical Investigation Report

This overview summarises the NeoDent01 interim Clinical Investigation Report. To consult the full report, including all tables, statistical analyses and references, or to discuss Neobone® in your clinical setting, contact our team.

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SOURCE

Clinical Investigation Report, NeoDent01, version 02, September 2026. Interim analysis, data from study initiation through August 2026. Author: Mariana Afonso. Reviewer: Alice Ferreira.

Study title: Evaluation of the safety and performance of the Neobone®: a prospective observational study in dental area.

Principal investigator: Dr. João Botelho. Sub-investigators: Dr. Angel Lobito, Dr. João Gaspar, Dr. Leonel Lima.

Clinical site: Egas Moniz School of Health and Science, Caparica, Portugal.

Registration: ClinicalTrials.gov NCT07179497

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NOTE ON DENOMINATORS

Thirty-one patients were enrolled and assessed at baseline and immediately after surgery. Twenty-nine contributed Day 7 data. Ten had reached the six-month visit at the time of analysis. Six-month regeneration, volume, density, pain and QoL figures are calculated from those 10. Percentages are calculated from the number of patients assessed at each visit, and the denominator is shown in each case.

SELECTED REFERENCES

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Neobone® is a Class III medical device manufactured by Bioceramed. **This document is intended for healthcare professionals and distribution partners. It is not intended for patients and does not replace the Instructions for Use.** Always read the Instructions for Use before use. Neobone® provides no mechanical or structural support. Data presented are interim results from an ongoing, single-arm, post-market observational study and are subject to the considerations set out on page 11. Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user is established.