

CLINICAL STUDY OVERVIEW

TriOSS[®] in Dental Bone Regeneration

Twelve-month results from a prospective, single-centre observational study of a synthetic β -TCP bone substitute in dental reconstructive surgery.

REGISTRATION

ClinicalTrials.gov NCT06813885

STATUS

Interim analysis, follow-up ongoing



01 • AT A GLANCE

One Year of Follow-Up. Consolidation Confirmed.

TriOSS® is a synthetic, resorbable beta-tricalcium phosphate bone substitute manufactured by Bioceramed. This study followed its use in routine dental reconstructive surgery, predominantly alveolar ridge preservation.

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Bone consolidation confirmed radiographically in every patient assessed at the 12-month visit.

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Adverse events reported at any assessment point across the first twelve months.

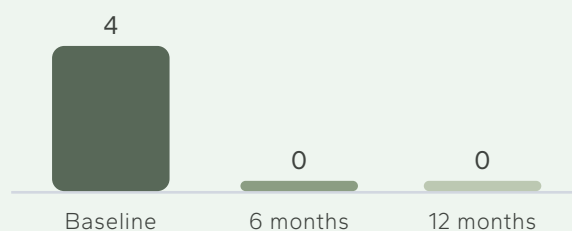
65/65

Of patients evaluated by radiograph at six months had regenerated bone assessed as suitable for implant placement.

Quality of Life

Oral health-related quality of life improved significantly across baseline, six months, and twelve months, and the improvement was sustained at one year.

Friedman test, $p < 0.001$ ($n = 45$)



Median OHIP-14 score. Lower is better.

Read this alongside the follow-up rates. Seventy-one of eighty patients completed the six-month visit (88.75%). Forty-six completed the twelve-month visit (57.50%). The full attrition picture and all study limitations are set out on page 9.

02 • CONTEXT

Why Real-World Data Matters

Bench data tells you what a material can do. Clinical follow-up tells you what it does in a working practice, in real patients, across the variability of everyday cases.

Under MDR 2017/745, post-market clinical follow-up is a regulatory requirement. For clinicians it answers something more immediate: what the graft site looks like six months from now, and what it looks like a year from now.

This document summarises the twelve-month interim results of a prospective, single-centre, single-arm observational study of TriOSS® in dental reconstructive surgery.

THE DEVICE

TriOSS®

A synthetic, resorbable, implantable calcium phosphate ceramic bone substitute composed of beta-tricalcium phosphate (β -TCP). Manufactured by Bioceramed in Portugal.

- 01 Chemical composition closely resembling the mineral phase of natural bone, which supports osseointegration.
- 02 Interconnected porosity that allows vascularisation of the implant.
- 03 Radiopaque, so the graft site remains traceable on standard radiographs. Single use, gamma sterilised.

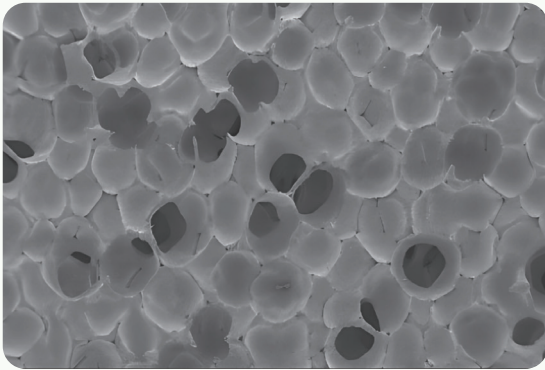
Intended Purpose

TriOSS® is a single-use, gamma-sterilised, implantable biodegradable medical device intended for use in both adults and children, for 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.

Important. TriOSS® does not provide mechanical stability and should not be used alone with the objective of stabilising any bone segment. Rigid fixation techniques may be required to ensure adequate stabilisation of the defect. Refer to the Instructions for Use for full indications, contraindications, warnings, and precautions.

Porosity at Two Scales

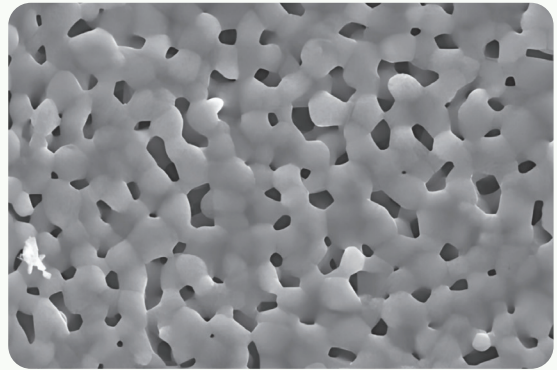
The structures composed of this calcium phosphate ceramic material are osseointegrated due to a chemical composition similar to the mineral phase of human bone, and due to the interconnected porosity that allows vascularisation of the implant.



MACROPORES

Space for Vascularisation

Interconnected macroporosity allows blood and cellular components to reach the interior of the graft. Scanning electron microscopy at 20× magnification. Scale bar 1000 µm.



MICROPORES

Surface for Exchange

Microporosity within the ceramic walls increases the available surface area. Scanning electron microscopy at 2000× magnification. Scale bar 10 µm.

TriOSS® absorbs local patient blood on implantation, including fibrin and angiogenic and osteogenic factors released by platelet degradation. It may alternatively be pre-impregnated with patient blood or autologous bone marrow to favour immediate absorption after placement.

Study Design

Design	Post-market, single-centre, single-arm, prospective observational study
Population	80 adult patients (>18 years) undergoing dental reconstructive surgery
Site	Egas Moniz School of Health and Science, Portugal
Principal investigator	Dr. João Botelho
Surgery period	March to April 2025
Device reference	TrG0215, irregular granules 1–2 mm
Follow-up schedule	Visit 1 (post-surgery) · Visit 2 (6 months) · Visit 3 (12 months) · Visit 4 (23 months, planned)
Primary endpoints	Bone consolidation on X-ray (Yes/No); adverse events and device deficiencies
Secondary endpoints	Technical success and clinician usability; patient quality of life (OHIP-14)
Ethics	ICH-GCP, ISO 14155, Declaration of Helsinki. Ethics Committee ID 1535/25



Patient Profile

Median age 47 years, range 19 to 82. Gender split 51.25% male, 48.75% female. Mean BMI 26.29 kg/m². Smokers represented 26.25% of the cohort.



Case Mix

Alveolar ridge preservation accounted for 95% of procedures (n=76). Post-extraction sockets were the predominant defect type (90%, n=72), concentrated in posterior regions. Median operative time 60 minutes.

Device placement was successful in all 80 patients, with no intra-operative complications related to the application of the device.

05 • RESULTS

Bone Regeneration at Six Months

Seventy-one of the 80 enrolled patients completed the six-month visit, a follow-up rate of **88.75%**.

RADIOGRAPHIC

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Patients assessed by radiograph. All showed continuous trabecular radiopacity without radiolucent defects or signs suggestive of impaired healing, findings consistent with graft integration and ongoing bone remodelling.

TELECONSULTATION

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Patients unable to attend in person, assessed by structured teleconsultation. No pain, swelling, or adverse events were reported, and remote evaluation indicated normal postoperative healing.

Counting both assessment routes, bone consolidation was confirmed in **71 of 71 patients** at the six-month visit.

SUITABILITY FOR IMPLANT PLACEMENT

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Classified as suitable (91.55%).

6

Inconclusive (8.45%), corresponding to patients without direct radiographic evaluation.

0

Classified as unsuitable because of inadequate bone regeneration.

Bone Regeneration at Twelve Months

Forty-six patients attended the twelve-month visit, a follow-up rate of 57.50%. All 46 underwent radiographic assessment.

Bone regeneration was confirmed in **every patient evaluated (46/46)**.

In the 45 patients assessed at both six and twelve months, the radiographic findings confirmed maintenance of the regenerative outcome over time. One further patient who had missed the six-month visit returned at twelve months, where successful bone regeneration was also radiographically confirmed.

Among the 26 patients who completed the six-month assessment but did not attend at twelve months, successful bone regeneration had already been documented at their last available study visit.

PATIENT FOLLOW UP

Enrolled	80
Visit 2 · 6 months	71 (88.75%)
Visit 3 · 12 months	46 (57.50%)
Visit 4 · 23 months	Planned

Loss to follow-up was mainly attributed to the inability to contact participants despite repeated attempts, orto personal and logistical constraints preventing attendance. All visits were conducted within the time windows specified in the clinical investigation plan.

Implant Outcome

One patient received a dental implant during the study. At the twelve-month assessment, the implant remained stable and functional, with no implant-related complications reported.

The decision not to proceed with implant placement in other patients was unrelated to bone regeneration outcome, reflecting anatomical factors, patient preference, or treatment planning.

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Implant survival at follow-up

06 • PATIENT-REPORTED OUTCOMES

Oral Health-Related Quality of Life

Quality of life was measured using the Oral Health Impact Profile-14 (OHIP-14), a validated 14-item instrument that assesses functional limitations, pain, psychological distress, and social disability.

ASSESSMENT	MEDIAN OHIP-14 (IQR)	CLASSIFICATION
Baseline · Visit 1	4 (13.00)	Low impact
6 months · Visit 2	0 (6.00)	Low impact
12 months · Visit 3	0 (0.00)	No impact

Statistical Analysis

Longitudinal analysis across the 45 patients with complete data at all three time points showed a statistically significant difference between baseline, six months, and twelve months.

Post-hoc pairwise comparisons showed significant differences between every pair of time points.

Friedman test: $\chi^2(2) = 38.2, p < 0.001$
Baseline to 6 months: $p = 0.001$
Baseline to 12 months: $p < 0.001$
6 to 12 months: $p < 0.001$

What the Scores Show

At the twelve-month visit, all participants recorded the lowest possible OHIP-14 score, indicating a complete absence of self-reported oral health-related quality of life impairment one year after surgery.

At baseline, the domains most frequently affected were those related to pain and discomfort during meals. Psychological and social domains were the least affected throughout.

Interpretation. These outcomes are associated with the surgical treatment as a whole. The study has no comparator group, so the improvement cannot be attributed to the bone substitute in isolation.

Safety Profile

ASSESSMENT	ADVERSE EVENTS	DEVICE DEFICIENCIES
Visit 1 · post-surgery	None (0/80)	None
Visit 2 · 6 months	None (0/71)	11 (15.49%)
Visit 3 · 12 months	None (0/46)	None

No Adverse Events

No adverse events were recorded at any point across the first twelve months of follow-up. No infections, allergic reactions, persistent inflammation, wound dehiscence, or graft rejection were reported.

Device Deficiencies

Eleven device deficiencies (DD) were documented at six months, all classified as granule loss and all categorised as performance-related. They were detected during the early wound-healing phase and were consistent with superficial particle displacement rather than biological intolerance or device malfunction.

No action was required, no harm occurred to any participant or other individual, and no patient discontinued use of the device or withdrew from the study.

08 • PRACTICAL CONSIDERATIONS

Granule Size and Site Anatomy

TriOSS® is available in a range of granule sizes. In anatomically confined sites such as narrow or shallow extraction sockets, larger granules may be more difficult to place, compact, and retain. Smaller granule references may offer advantages in these clinical scenarios.

The study used a single reference throughout (TrG0215, 1–2 mm irregular granules), so this observation derives from clinical feedback rather than from a comparison between references. The final choice of granule size rests with the clinician, based on the specific clinical situation.



FROM THE INSTRUCTIONS FOR USE

Fill the defect progressively, using gentle compaction to achieve stable filling without excessive pressure. Avoid excessive compaction or overfilling. Ensure a hermetic, tension-free soft tissue closure so that the graft stays contained and migration is prevented.

09 • LIMITATIONS

Where This Evidence Ends

Presented in full, because evidence is only useful when its boundaries are visible.

01 Interim Analysis

The study is ongoing. Visit 4 is scheduled at 23 months and will address the durability of the regenerative effect and long-term safety.

02 Follow-Up Attrition

The twelve-month follow-up rate was 57.50% (46 of 80 enrolled patients). Reasons were mainly the inability to contact participants despite repeated attempts, or personal and logistical constraints.

03 No Comparator Group

The absence of a control arm limits the ability to contextualise the results against autologous bone or alternative graft materials.

04 Imaging Method

Radiographic assessment was based on conventional periapical radiographs and clinical evaluation. Volumetric measures such as CBCT-derived bone gain or radiographic bone density were not part of this protocol.

05 Single Centre, Single Reference, Dental Only

All procedures were performed at one site using one TriOSS® reference, in dental reconstructive surgery. The results do not extend to orthopaedic applications.

10 • IN PRACTICE

What Twelve Months of Follow-Up Show

Across twelve months of follow-up, TriOSS® supported consistent bone consolidation, maintained a favourable safety profile, and was associated with sustained improvement in patient-reported oral health.



The Outcome Held

The regenerative result documented at six months was maintained at twelve months in every patient reassessed.



Ready for Rehabilitation

Bone formed was assessed as suitable for implant placement in every case evaluated by radiograph.



No Adverse Events

Across the full observation period, no adverse events were recorded at any assessment point.

As a synthetic β -TCP, TriOSS® also avoids the donor-site morbidity associated with autologous grafting and is radiopaque, so the graft site remains traceable on standard radiographs.

CONTINUE THE CONVERSATION

Request the Full Data Set

The complete clinical investigation report is available on request. Our clinical and technical teams can support case planning, reference selection, and product training.

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SOURCE

Clinical Investigation Report TriOSSD01, version 02, 31 July 2026.

Author: Mariana Marques Afonso. Reviewer: Alice Ferreira.

Study title: Evaluation of the safety and performance of the TriOSS®. A prospective observational study in Dental area.

Registration: ClinicalTrials.gov NCT06813885

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TriOSS® is a Class III medical device. 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. Data presented are interim results from an ongoing prospective observational study and are subject to change as further follow-up data become available. 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.