ISRCTN91819122 https://doi.org/10.1186/ISRCTN91819122

Implant bed preparation with Er:YAG laser for dental implants

Submission date	Recruitment status	[_] Prospectively registered
20/05/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/05/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/05/2026	Oral Health	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Study information

Scientific Title
The effect of Er:YAG laser biomodification of the implant site surface on osseointegration: a randomized controlled clinical study

Study objectives
To compare outcomes between closed (two-stage) and open implantation protocols using sequential RFA measurements in a randomized cohort of 90 patients, while ensuring groups are comparable in demographic characteristics and bone quality according to the Misch classification.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/10/2023, Scientific Ethics Committee at the Medical University of Plovdiv (Vasil Aprilav 15 A, Plovdiv, 4000, Bulgaria; +359 882 513 739; kne@mu-plovdiv.bg), ref: 6

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Basic science, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Dental implant site preparation, Er:YAG laser use

Interventions
Implants and Operating Setup
Conical osseointegrable implants from the Alpha-Bio NeO system (Alpha-Bio Tec, Petach Tikva, Israel) and the BTK BT Konic system (Biotec Implants, Vicenza, Italy) were used. Implants of 8, 10, and 11.5 mm length and 3.2, 3.75, 4.0, and 4.2 mm diameter were selected. To enhance comparability, implants with parameters known to produce relatively low primary stability were used. All trepanations were performed with a Bien-Air Chiropro motor (Bien-Air Dental SA, Berne, Switzerland) and a reduction implant handpiece with continuous external irrigation with sterile 0.9% NaCl. Local infiltration anaesthesia was achieved with 4% articaine + adrenaline (1: 100 000 or 1:200 000).

Case Group: Rotary Osteotomy + Er:YAG Laser Biomodification
After intra- and extraoral disinfection, a horizontal incision was made along the alveolar ridge, slightly to the lingual side, with two relaxing incisions where indicated. A vestibular mucoperiosteal flap was elevated using an implantology raspator.Standard osteotomy was performed with the surgical kit of the corresponding system. The final drill diameter was 0.1–1.2 mm smaller than the implant diameter. The sequence consisted of marking the implant position with a round bur, (pilot drilling to the planned length and depth-gauge verification, progressive widening with calibrated drills at 600–800 rpm, and shaping of the cortical entry with the corresponding profile drill.

The bone surface was then biomodified with an Er:YAG laser (LiteTouch, Light Instruments Ltd., Yokneam, Israel; λ = 2940 nm). For the bone biomodification step, the program Granulation Tissue Ablation Non-contact was used. The tip emits energy at 90° to its longitudinal axis over a 180° sector; therefore, treatment was performed in two opposing quadrants (vestibular and oral) for approximately 2–3 minutes per quadrant, starting from the depth of the cavity and moving towards the entrance with light rotational movements. The same parameters were used in every patient of the case group throughout both Subtask 1 and Subtask 2.

The implant was inserted manually with a carrier and finally torqued to 40 N·cm with a torque wrench. A SmartPeg was screwed onto the implant and primary stability was measured. After the measurement, a cover screw was placed, and the flap was repositioned without tension and sutured with interrupted 4/0 and 5/0 atraumatic sutures.
Control Group: Conventional Rotary Osteotomy Alone
In the control group, the surgical sequence was identical to that of the case group up to the completion of the rotary osteotomy.

Crucially however, the bone surface of the prepared cavity was not subjected to any additional biomodification: the Er:YAG laser step was omitted. After completion of the rotary osteotomy, the implant was placed and torqued to 40 N·cm using the same protocol, and the SmartPeg was attached for primary stability measurement. Asepsis, anaesthesia, flap design, suturing, antibiotic prophylaxis, postoperative instructions, and timing of suture removal were identical to those of the case group, so that the only systematic difference between the two arms was the

addition of Er:YAG biomodification in the cases.
Subtask 2: Open (Single-Stage) Protocol

In Subtask 2 (15 cases + 15 controls), implants were placed using an open protocol that allowed repeated, non-invasive RFA measurements during early healing. Instead of a full mucoperiosteal flap, a mucosal cap of the implant diameter was excised, or a small incision along the alveolar ridge was made. In the case group, the soft-tissue cap was removed using the Er:YAG laser in a soft-tissue cutting program (settings: 200 mJ, 35 Hz, water spray level 5–6, contact mode, crystal tip 0.4 × 17 mm). In the control group, the cap was excised with a scalpel or a tissue punch. After exposure, periosteum and soft tissue were removed from the bone, and the operative sequence then matched that of Subtask 1 within the corresponding randomized arm – i.e. either rotary + Er:YAG (cases) or rotary alone (controls). After primary stability measurement, the implant was covered by an appropriately sized gingival former, allowing repeated RFA measurements at days 10, 20, and 30, and at month 3 without re-opening the surgical field.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Primary: ISQ mesiodistal (MD) time-by-group interaction; Secondary: ISQ vertical orientation (VO); proportion of implants with ISQ ≥ 70, measured using Resonance Frequency Analysis (RFA) at implant placement for primary stability for Subtask 1 (closed protocol), at 3 months (after implant re-exposure) for secondary stability; at placement for primary stability for Subtask 2 (open protocol); with additional measurements at days 10, 20, and 30, and secondary stability measured at 3 months

Key secondary outcome(s)

Completion date
20/11/2025

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Good general health; no severe systemic conditions
3. Previously extracted mandibular premolar(s) or molar(s) (≥ 6 months prior)
4. Sufficient bone volume (premolar area); implant diameter ≤ 4.2 mm, length ≤ 11.5 mm; no augmentation required
5. D2 or D3 bone density (Misch classification) on CBCT
6. Written informed consent provided

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
21 Years

Upper age limit
77 Years

Sex
All

Total final enrolment
90

Key exclusion criteria
1. Insufficient bone volume or density
2. Active malignancy
3. Osteoporosis or previous radiotherapy to the jaws
4. Bisphosphonate, immunosuppressive, anticoagulant, or antiplatelet therapy
5. Titanium hypersensitivity; pregnancy
6. Active inflammatory disease of the oral cavity; mental illness; heavy smoking; significant family burden of implant failure

Date of first enrolment
09/10/2023

Date of final enrolment
20/11/2025

Locations

Countries of recruitment
Bulgaria

Sponsor information

Organisation
Medical University Plovdiv

ROR
https://ror.org/02kzxd152

Funder(s)

Funder type

Funder Name
Medical University Plovdiv

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available