

A preliminary report from on physiological bone remodeling on KS versus TSIII implants for molar rehabilitations: a split-mouth, multicenter randomized controlled trial

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Abstract

Objective: To compare the clinical and radiographic outcomes of two implant systems with different implant–abutment connection designs—KS BA (4.0 mm diameter, 15° internal taper) and TS III BA (4.5 mm diameter, 11° internal connection)—used for molar rehabilitation. **Materials and Methods:** This multicenter, split-mouth, randomized controlled trial involved 42 patients, each receiving one KS and one TSIII implant. Inclusion criteria required healed posterior sites suitable for implants at least 8.5 mm long. Surgeries followed standardized protocols, and patients were rehabilitated with monolithic zirconia crowns bonded to titanium bases. Clinical follow-up was conducted at 6 months after prosthesis delivery. Primary outcomes were implant and prosthesis survival rates and any complications. Marginal bone levels (MBL) were measured radiographically at implant placement, prosthesis delivery, and 6-month follow-up. Patient satisfaction were also recorded. **Results:** A total of 87 implants (44 KS and 43 TSIII) were placed. At the time of analysis, 27 patients with 53 implants completed the 6-month follow-up. No implant or prosthesis failures and no complications were observed. At prosthesis delivery, mean MBL was 0.32 ± 0.27 mm for TSIII and 0.18 ± 0.32 mm for KS implants ($P = 0.029$). At 6 months, MBL increased to 0.34 ± 0.27 mm (TSIII) and 0.21 ± 0.32 mm (KS), with a statistically significant difference favoring the KS group ($P = 0.034$). All patients reported full satisfaction with functional and aesthetic outcomes. **Conclusion:** The KS implant system demonstrated significantly less marginal bone loss than the



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TSIII system, despite its narrower diameter. These preliminary findings support the clinical efficacy and mechanical reliability of the KS implant for molar restoration, suggesting it as a viable alternative in posterior sites, especially where bone volume is limited.

Keywords: dental implants; implant-abutment connection; KS implants; biological width; marginal bone levels; subcrestal position

Introduction

Dental implants are widely used to restore the function and aesthetics of missing teeth. While early success focused on osseointegration and survival, modern criteria now include minimally invasive surgery, natural aesthetics, stable occlusion, peri-implant health, patient satisfaction, and overall prosthetic success (1). The definition of “success” has shifted from purely clinical outcomes to a patient-centered model, where perceived function and aesthetics are key (2-7). Long-term result stability is now essential and is addressed through integrated treatment plans that place the patient at the center of care (3,8). Despite these advances, implant complications remain common. Mechanical issues (e.g., screw loosening, chipping, fractures) and biological problems (e.g., mucositis, peri-implantitis) can jeopardize implant survival and tissue health (4,9). A crucial element in preventing such complications is the stability of the implant–abutment connection, which serves as a key interface responsible for load transmission, mechanical integrity, and bacterial sealing. In this context, the TSIII implant, a bone-level implant with an SLA surface and 11° conical internal connection, was selected as the control due to its well-documented clinical reliability; a five-year prospective case series reported a mean marginal bone loss of 0.41 ± 0.30 mm, confirming its long-term stability (7). However, implant manufacturers have invested heavily in developing advanced connection systems that address these challenges effectively (10). Among recent innovations, the KS implant system (Osstem Implant, Seoul, South Korea) features an internal 15-degree tapered connection combined with a superhydrophilic, bioabsorbable apatite nano-coating (BA surface) applied over a clinically validated sand-blasted and acid-etched surface (SA surface). The BA coating is designed to gradually dissolve during the bone remodeling phase, progressively exposing the SA surface beneath and promoting the formation of dense, load-bearing lamellar bone. The innovative implant–abutment interface allows for greater angular compensation, improved prosthetic fit, and enhanced structural resistance to masticatory forces. According to manufacturer data and *in vitro* studies, (7) the KS system improves functional stress absorption and distribution, while the increased thickness of the coronal implant walls contributes to enhanced fracture resistance. These features make it particularly suitable for use in narrow alveolar ridges and clinical scenarios requiring narrow-diameter implants, expanding treatment possibilities for patients with limited bone availability. The modified

tapered connection ensures stable mechanical engagement through friction between conical surfaces, significantly reducing micromovements and bacterial microleakage—two critical factors in the prevention of marginal bone loss (7).

Moreover, the broader contact area between prosthetic components facilitates more effective load distribution, supporting long-term mechanical stability. The reduction in micromovements, coupled with enhanced mechanical stability, lowers the risk of crestal bone resorption and reduces the likelihood of screw loosening over time. The friction-fit mechanism also enhances prosthetic retention, making it a preferred solution in contemporary implantology (11).

Concurrently, there is increasing interest in minimally invasive implant surgery, which is appreciated by patients for reduced surgical trauma and postoperative discomfort, and by clinicians for simplified handling and procedural efficiency. In this context, the combination of narrow implants and modified Morse taper connections has demonstrated considerable promise, allowing implant placement in anatomically challenging areas while maintaining mechanical integrity and biological stability (12).

In light of recent clinical evidence and ongoing technological advancements in implant dentistry, it is essential to assess the performance of newly developed implant systems using rigorous scientific methodologies. Among the many factors influencing long-term implant success, the implant–abutment connection plays a central role in ensuring biomechanical stability, preservation of marginal bone, and maintenance of peri-implant tissue health (13).

The aim of this research is to compare, through a randomized study, the clinical and radiographic outcomes of two different implant systems (TSIII and KSIII) used in molar regions, both manufactured by the same company (Osstem Implant), but characterized by distinct implant–abutment connection designs and diameters. The null hypothesis (H_0) is that there are no significant differences between the two implant systems in terms of clinical and radiographic outcomes. The null hypothesis will be tested against the alternative hypothesis (H_1) that significant differences exist between the two systems. The present manuscript is reported according to the CONSORT guidelines.

Materials and methods

Study design

This study was designed as a multicenter, split-mouth, randomized controlled trial. Seven centers (5 private centers and 2 Universities) across Europe participated (Bulgaria, Hungary, Italy (3) Poland, Portugal), and each enrolled six patients who had lost at least two teeth in the molar regions of both maxilla or mandible, and required implant-supported prosthetic rehabilitation, totaling 42 patients. Each patient received both implant types (split-mouth design), resulting in 42 implants per group (test and control). Implants could be placed in adjacent sites. The research protocol has been approved at the coordinating center in Hungary (Health Science Council, The Scientific and Research Ethics

Commission (TUKEB) BM/1595-1/2025, Semmelweis University Faculty of Dentistry Department of Prosthodontics) and registered in [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT05843981). The study protocol was also approved to the other Academic center in Portugal (Faculty of Medicine – University of Coimbra). The study followed the principles of the 2013 Helsinki Declaration and Good Clinical Practice guidelines. All medical data were anonymized to protect patient identity. Written informed consent was obtained from all participants for data collection and treatment.

Inclusion criteria

- Partially edentulous patients in the molar area (maxilla and/or mandible) who require at least two implant-supported dental restorations.
- Subject over 18 years of age and able to sign an informed consent.
- The implant sites large enough to allow the placement of two implants of at least 4 mm (KS) or 4.5 (TS) mm in diameter and 8.5 mm in length.
- Smokers will be included and categorized into: 1) non smokers; 2) moderate smokers (smoking up to 10 cigarettes/day); 3) heavy smokers (smoking more than 11 cigarettes/day).
- In case of post-extractive sites, they must have been healing for at least 3 months before being treated in the study. Six months in case of previous augmentation procedures. Implants can be adjacent.

Exclusion criteria

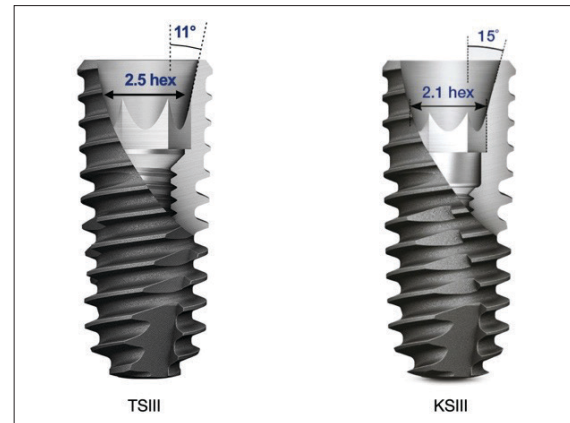
- General contraindications to implant surgery. (patients ASA III and IV).
- Patients irradiated in the head and neck area in the previous 5 years.
- Immunosuppressed or immunocompromised patients.
- Patients treated or under treatment with intravenous amino-bisphosphonates.
- Patients with untreated periodontitis.
- Patients with poor oral hygiene and motivation. (PI and/or BOP $\geq 25\%$).
- Previous guided bone reconstruction at the intended implant sites.
- Uncontrolled diabetes. (HbA1c $\geq 7\%$).
- Pregnancy or nursing.
- Substance abuser (alcohol and drugs).
- Psychiatric problems or unrealistic expectations.
- Lack of opposite occluding dentition in the area intended for implant placement.
- Patients with infection and or inflammation in the area intended for implant placement.
- Patients participating in other studies, if the present protocol cannot be properly adhered to.
- Patients referred only for implant placement and cannot be followed ant the treating centre.
- Patients unable to be followed for 5 years.

Surgical and prosthetic procedure

In the test group, Osstem KS BA implants (4.0 mm diameter, 15° internal taper connection, Osstem Implant) were placed. In the control group, Osstem

TSIII BA implants (4.5 mm diameter, conventional 11° internal connection, Osstem Implant) were used (Figure 1). All patients underwent radiographic examination (periodical radiograph with paralleling technique) and professional oral hygiene treatment before surgery.

Figure 1. Comparison between TSIII and KSIII implants.



After enrollment, patients were instructed to rinse with 0.2% chlorhexidine mouthwash (Corsodyl, GlaxoSmithKline, Verona, Italy) for 1 minute, twice daily, starting 3 days before surgery and continuing for 1 week postoperatively. Prophylactic antibiotics included 2 g of amoxicillin–clavulanic acid or 600 mg clindamycin (for penicillin-allergic patients) 1 hour before surgery, followed by 1 g of amoxicillin (or 300 mg clindamycin) every 12 hours for 5 days.

All surgeries were performed under local anesthesia with articaine hydrochloride and adrenaline 1:100,000 (Orabloc, Pierrel, Milan, Italy). After crestal incision and full-thickness flap elevation, implant sites were prepared either freehand or with the aid of a surgical guide. Manufacturer's recommended protocols were followed (Osstem Implant). Bone quality was assessed subjectively. The first site was randomly assigned to receive either the KS (test) or TSIII (control) implants (Osstem Implant). Implants were placed at the crestal level or up to 2 mm subcrestally, based on anatomical conditions. Healing abutments were immediately connected if primary stability was ≥ 30 –35 Ncm. On the contrary, cover screw would be place and second stage surgery planned. Flaps were closed with Vicryl 4.0 (or equivalent). Baseline periapical radiographs were taken with paralleling technique, for each study implant to prevent the risk of systematic error in performing periapical radiographs. Two to three months post-placement, either digital or conventional impressions were taken. Within one month, monolithic zirconia crowns bonded to titanium links were delivered after testing implant stability. Occlusal contacts were adjusted for light contact with the opposing dentition. Clinical photographs and radiographs were taken. Oral hygiene instructions were reinforced. Patients were enrolled in a maintenance program with six-month intervals. At each visit, professional oral hygiene

sessions and clinical evaluations were performed, with particular attention to implant stability and occlusion. In addition, periapical radiographs were taken annually. According to the study protocol, patients were followed for research purposes for up to 5 years. Radiographs of both treatments are reported in figures

2-5. At each center, a single experienced clinician performed all surgical and prosthetic procedures, with optional assistance from a second clinician (e.g., a prosthodontist). All interventions and follow-ups were conducted at the respective sites using standardized materials and protocols to ensure consistency.

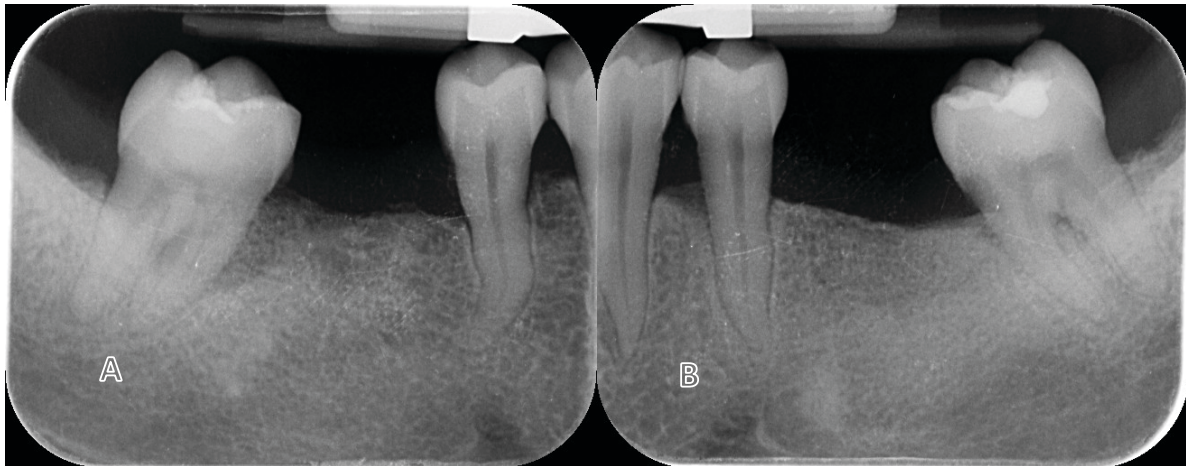


Figure 2. Initial scenario. Partially edentulous patients in the molar area, who require at two implant-supported restorations. A: KS site and B: TSIII site.



Figure 3. Implant placement. A: KS site and B: TSIII site.

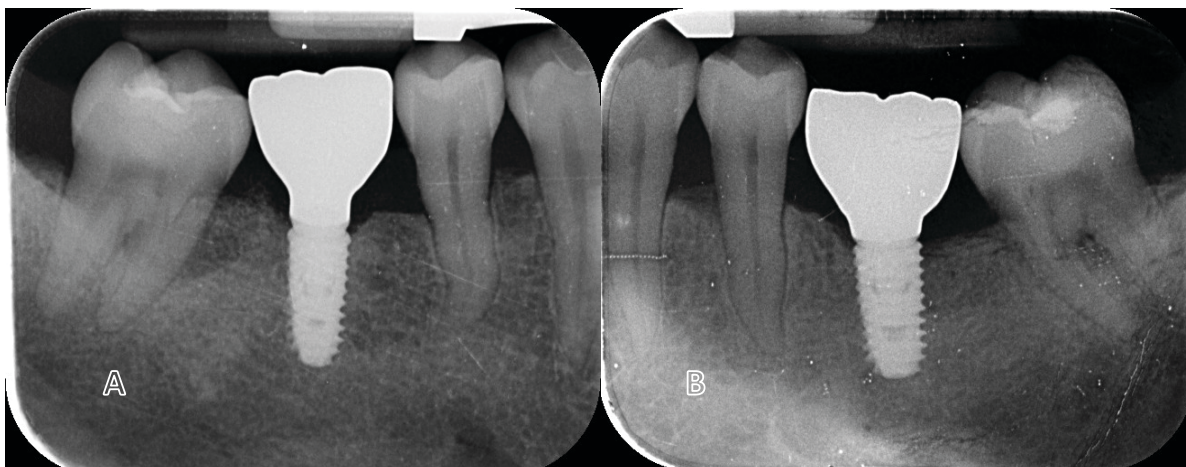


Figure 4. Definitive, screw-retained, restorations. A: KS site and B: TSIII site.

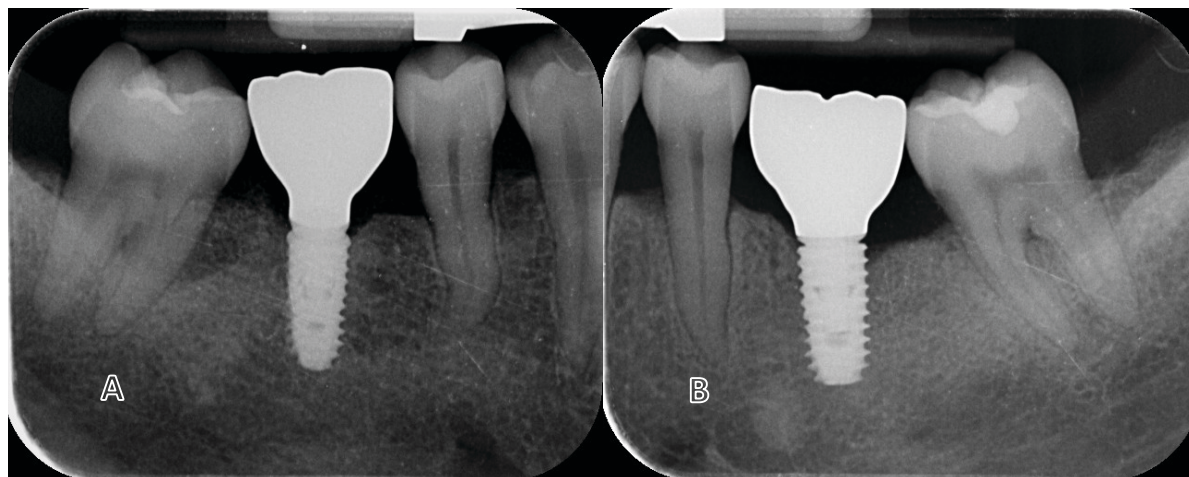


Figure 5. Six-month follow-up. A: KS site and B: TSIII site.

Outcome Measures

Primary outcome measures were:

- **Incidence of implant failure**: reasons for implant failure are implant mobility and/or any infection dictating implant removal, and/or implant fracture and/or any other mechanical complication rendering the implant unusable. To evaluate implant failure, the stability of each individual implant were measured by the local blinded outcome assessors manually tightening the screws with a torque of 30 Ncm at abutment connection at initial loading. At 6-month, 1,3 and 5 years after loading, individual implants were manually tested for stability by rocking the crown with the handles of two dental instruments.
- **Incidence of prosthesis failure**: a prosthesis was considered as failed whether it will not be possible to place the prosthesis because of implant failure or a prosthesis that has to be remade for any reason.
- **Number and type of complications (incidence of complications)** were recorded and reported per study group. Technical (fracture of the framework and/or the veneering material, screw loosening, etc.) and/or biologic (pain, swelling, suppuration, peri-implantitis, etc.) complication were considered.
- Secondary outcome measures are:
- **Rate (expressed in mm) of peri-implant marginal bone level (MBL) changes** were assessed on periapical radiographs took with the paralleling technique at implant placement, at initial loading, 6-month, 1,3 and 5 years after loading. In case of an unreadable radiograph, the radiograph has to be made again. Ideally digital radiographs should be taken, otherwise radiographs on conventional films will be scanned into TIFF format with a 600 dpi resolution, and stored in a personal computer. Peri-implant marginal bone levels were measured using the Scion Image (Scion Corporation, Frederick, MD, USA) software. The software was calibrated for every single image using the known distance of the first two consecutive threads. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm. Reference points for the linear measurements were:

the coronal margin of the implant collar and the most coronal point of bone-to-implant contact. Bone levels were measured at both mesial and distal sides and averaged. Bone levels were averaged at implant level and finally at group level.

- **Patient satisfaction**. At 6-month, 1,3 and 5 years after loading, the independent outcome assessor at each centre will ask to the patient the following questions (separately for each implant):
 - 1) Are you satisfied with the function of your implant-supported prostheses? Possible answers: yes absolutely, yes partly, not sure, not really, absolutely not.
 - 2) Are you satisfied with the aesthetic outcome of your implant-supported prostheses? Possible answers: yes absolutely, yes partly, not sure, not really, absolutely not.
 - 3) Would you undergo the same therapy again? Possible answers: "yes" or "no".

Outcome assessors evaluated all the outcomes in each center.

Sample size

Sample size was determined based on the primary outcome variable—implant failure rate—using a one-sample asymptotic z-test for a single proportion. The statistical assumptions included a null hypothesis probability of 0.5 and an alternative probability of 0.7, with a two-sided alpha level set at 0.05 and statistical power at 85%. Accounting for an anticipated dropout rate of 25%, the minimum number of implants required was calculated to be 71. To strengthen the robustness of the analysis, a total of 84 implants were planned. The study involved seven centers, each responsible for enrolling six patients who required at least two implants in the posterior region, resulting in a final cohort of 42 patients (84 implants in total), evenly distributed between the two study arms (42 KS implants and 42 TSIII implants).

Randomization and sequence generation

The Randomization was performed using computer-generated random numbers (random.org) and was centralized. Sequentially sealed, opaque envelopes

containing the allocation sequence were prepared and provided by the study advisor (MT). Allocation concealment was ensured by having the surgeon open the sealed envelope only after implant sites preparation, immediately prior to implant placement. Due to the different implant-abutment connections, operator blinding was not feasible, nor was blinding of the centralized radiographic evaluator. However, patients, outcome assessors, and statistical analysts were blinded to the type of implant used. An independent examiner at each center was responsible for performing all clinical measurements, which were subsequently submitted to a centralized outcome assessor for comprehensive evaluation.

Statistical analysis

All data analysis were carried out according to a pre-established analysis plan by a biostatistician with expertise in dentistry blinded to group allocation. Differences in the proportion of dichotomous outcomes (e.g. prosthesis and implant failures, complications) were compared between the groups using a chi-square test. Mean differences between groups for continuous outcomes (e.g. peri-implant marginal bone level changes) were compared using an independent sample t-test for pairwise comparisons. Comparisons between each time points and the baseline measurements were made by paired t-tests, to detect any changes in marginal peri-implant bone levels for each study group. All statistical comparisons were conducted at the 0.05 level of significance.

Results

A total of 42 patients with 87 implants (44 KS BA [test group] and 43 TS III BA [control group]) were followed and data analyzed. CONSORT flow diagram is reported in Figure 6.

The mean age at the time of implant placement was 50 ± 12.1 years old. Twenty-seven patients were male and 15 female. Nine patient were moderate smokers. No drop-outs were recorded, however, at the time this manuscript has been written, only 27 patients with 53 implants (27 KS BA [test group] and 26 TS III BA [control group]) completed the six month (after prosthesis delivery) follow-up. Several deviation from the original protocols were recorded and showed in the table 1.

No drop-outs were recorded. Overall, there were no failures of implants or prostheses, and no complications were encountered. Marginal bone levels (MBL) were evaluated at implant placement, crowns delivery and six month later. At implant placement, the mean MBL was 0.03 ± 0.09 mm in the TS group and 0.04 ± 0.13 mm in the KS group. At prosthesis delivery (3 months later), mean MBL was 0.32 ± 0.27 mm in the TS group and 0.18 ± 0.32 mm in the KS group. The marginal bone loss between baseline and prosthesis delivery was 0.26 ± 0.24 mm in the TS group and 0.16 ± 0.30 mm in the KS group. The difference between groups was statistically significant with lower value for KS group (0.10 ± 0.23 mm; $P=0.029$). At the 6-month follow-up (9 months after implant placement), the mean MBL was 0.34 ± 0.27 mm in the TS group and 0.21 ± 0.32 mm in

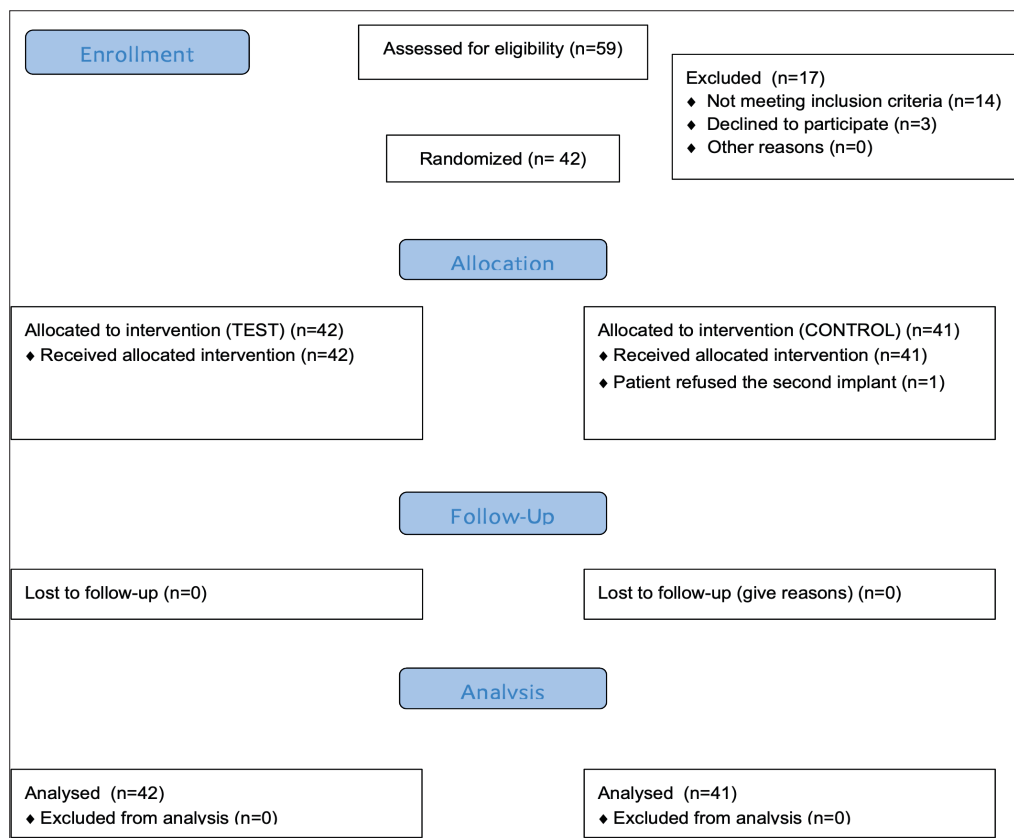


Figure 6. CONSORT flow diagram.

Table 1. Deviation from the original protocols within centers.

Center 1	Patient 1 at center 1, the implant in position 1 (TSIII implant) was inserted with an insertion torque of 20 instead of 35. Healing abutment was placed and the implant integrated safely.
Center 5	Patient 3 at the center 5 refused the second implant (TSIII implant) for panic attach after the first implant was placed.
Center 6	Patients 1,2,3,5, and 6 were not correctly randomized. They receive only one implant type (no split-mouth design).
Center 6	Patient 4 at center 6, the implant in position 2 (KS implant) was inserted with an insertion torque of 25 instead of 35. Healing abutment was placed and the implant integrated safely.
Center 7	Patients 1,2,3,4 and 6 all the implants were inserted with an insertion torque ranging between 25 and 30. Healing abutment was placed and the implant integrated safely.

the KS group. The difference from baseline (implant placement) was 0.29 ± 0.25 mm in the TS group and 0.19 ± 0.30 mm in the KS group. The difference between groups was statistically significant with lower value for KS group (0.09 ± 0.24 $P=0.034$). All the data are reported in table 2.

TS = Test Group, KS = Control Group, MBL = Marginal Bone Level.

Patient satisfaction was assessed at the 6-month follow-up through a structured questionnaire. All 27 patients who completed the follow-up responded positively to all three questions. Specifically, 100% of patients reported being fully satisfied with the functional outcome and aesthetic result. All except one indicated they would undergo the same therapy again (96.3%). No patient expressed uncertainty, dissatisfaction, or regret regarding the treatment received.

Discussion

This multicenter RCT compared clinical and radiographic outcomes of two Osstem implant systems—KS (4.0 mm, 15° internal taper, single platform) and TSIII (4.5 mm, 11° internal connection, dual platform)—for molar replacement in the maxilla and mandible. The primary aim of this study was to assess the clinical performance and complication rates when using a narrower 4.0 mm implant for molar rehabilitation. The null hypothesis was partially rejected. No statistically significant differences were found when comparing

primary outcomes (implant and prosthesis survival rates and complications) and patients' satisfaction. The secondary aim was to assess whether the novel tapered connection of the KS implant would lead to reduced marginal bone loss (MBL) compared to the TSIII implant. In this contest, the null hypothesis—asserting no significant differences between the two systems regarding marginal bone levels—was rejected. A statistically significant difference in marginal bone loss was observed at the time of prosthetic delivery ($P = 0.029$), with the KS group demonstrating superior bone preservation. This trend toward greater bone stability in the KS group was maintained at the 6-month follow-up and reached statistical significance ($P = 0.034$), suggesting consistent clinical benefits.

It is important to clarify that the KS implant should not be considered an evolution of the TS system, but rather a distinct design with specific mechanical and clinical advantages. One of the most clinically relevant findings of this study is the favorable performance of the 4.0 mm KS implant in posterior regions—an anatomical context where traditional protocols often recommend a minimum implant diameter of 4.5 mm. These results support the safe and effective use of narrower-diameter implants in molar areas, aligning with evidence from high-strength titanium-zirconium alloy implants, which have also demonstrated success in similar posterior applications (14,15).

Another key advantage of the KS system is its unified

Table 2. Marginal Bone Level (MBL) results.

Time Point	TS Group (mean $\pm$ SD)	KS Group (mean $\pm$ SD)	Between-Group Difference (mean $\pm$ SD)	P-value
Implant Placement (Baseline MBL)	0.03 ± 0.09 mm	0.04 ± 0.13 mm	—	—
Prosthesis Delivery (3 months)	0.32 ± 0.27 mm	0.18 ± 0.32 mm	—	—
MBL Change from Baseline to 3 Months	0.26 ± 0.24 mm	0.16 ± 0.30 mm	0.10 ± 0.23 mm	0.029
6-Month Follow-Up (9 months total)	0.34 ± 0.27 mm	0.21 ± 0.32 mm	—	—
MBL Change from Baseline to 9 Months	0.29 ± 0.25 mm	0.19 ± 0.30 mm	0.09 ± 0.24 mm	0.034

prosthetic platform, which eliminates the distinction between mini and regular platforms. This feature simplifies the clinical workflow, particularly in multi-unit or full-arch rehabilitations, by streamlining prosthetic component selection and reducing the likelihood of technical errors. The platform uniformity also facilitates prosthetic planning and inventory management.

From a prosthetic standpoint, the 15-degree internal taper connection of the KS implant provides enhanced angular compensation, improving prosthetic fit in cases involving non-parallel implant placement—often a challenge in complex anatomical scenarios. Compared to standard 11-degree connections, the increased taper angle may allow for better management of divergent implant axes. Nevertheless, as with most internal connection systems, it is advisable to either place the definitive abutment at the time of surgery or use abutment converters to optimize the mechanical seal and minimize soft tissue disruption during subsequent prosthetic phases. Despite its wider taper angle, the KS connection exhibits mechanical behavior similar to that of a Morse taper connection, due to its high-precision friction fit and enhanced mechanical stability. This interface may support subcrestal placement of up to 3 mm in specific clinical scenarios. Recent biomechanical studies have highlighted the importance of implant macrogeometry in promoting mechanical engagement and biological integration. In particular, tri-oval implant designs have demonstrated superior stability in bone surrogate models and finite element analyses, showing improved stress distribution, primary stability, and preservation of peri-implant bone under load compared to traditional round designs (16-18). While the KS system does not share the same tri-oval macrodesign, its internal friction-fit and tapered connection appear to produce comparable clinical advantages in terms of marginal bone preservation and implant stability, particularly in narrow diameter applications.

In the present study, the KS implant's reduced physiological marginal bone remodeling during biological width formation implies a potential for deeper placement, which could further enhance soft tissue support. Although the differences are statistically significant at both crown delivery and the 6-month follow-up, the overall results may be considered clinically negligible. However, the observed reduction of approximately 40% could be a critical factor in maintaining physiological bone remodeling as close to zero as possible. This may potentially lead to a reduction in biological and technical complications over long-term follow-up (19).

While current manufacturer guidelines recommend crestal-level or 1–2 mm subcrestal positioning, future studies may explore the biological behavior and clinical benefits of placing KS implants at depths of 2–3 mm, similar to other high-stability platforms. Such an approach could further improve soft tissue integration and long-term aesthetics, especially in patients with thin biotypes or compromised gingival architecture (20-23). Preliminary findings from this study also suggest that the KS system may be particularly advantageous in challenging clinical scenarios—such as in patients with limited bone volume or in posterior maxillary and

mandibular regions—where the ability to use a reduced-diameter implant with high mechanical resistance can minimize or even eliminate the need for bone grafting procedures. The observed equivalence in clinical performance between the 4.0 mm KS and 4.5 mm TSIII implants in load-bearing posterior sites further supports the feasibility of this approach.

The main limitation of this study are some deviation from the original protocol. Patients 1, 2, 3, 5, and 6 at Center #6 did not follow the intended split-mouth randomization. These cases were retained to avoid additional bias related to center-specific experience with one implant system. Re-randomization was also avoided to minimize delays and increased costs. Similar pragmatic approaches have been documented in multicenter clinical trials to maintain feasibility without compromising overall study integrity (24).

Other limitations include the relatively short follow-up period (6 to 9 months post-placement) and the modest sample size. While adequate for preliminary comparisons, these constraints prevent definitive conclusions about long-term success and biological stability. Future follow-ups involving larger cohorts and extended observation periods (3 to 5 years) will be critical for confirming these early findings. In addition, split-mouth design has the distinct advantage of removing a lot of inter-subject variability from the estimated treatment effect. Methods of statistical analyses for split-mouth design have been well developed. However, little work is available on sample size consideration at the design phase of a split-mouth trial (25, 26).

This results of the present study must to be interpreted as preliminary report. The minimal marginal bone remodeling observed in this preliminary report supports the potential for further investigations into the subcrestal placement of KS implants. Nonetheless, further randomized controlled trials are required to validate these findings.

Conclusions

Within the limitations of this study, the reduced-diameter KS implant demonstrated significantly lower marginal bone loss compared to the TSIII implant, with no complications observed in either group. These results suggest superior peri-implant tissue stability with the KS system in molar sites. Long-term, large-scale clinical trials are warranted to validate these findings and further elucidate the clinical benefits of the KS implant design.

Funding

Osstem Implant donated the materials used for the research; however, the company never interfered with the evaluation of the research, data collection and writing of the manuscript.

Institutional Review Board Statement

All data were evaluated at the Department of Medicine, Surgery, and Pharmacy, University of Sassari, Italy. The research protocol has been approved (approval

code: XXX) and registered in ClinicalTrials.gov (NCT05843981). The study followed the principles of the 2013 Helsinki Declaration and Good Clinical Practice guidelines. All medical data were anonymized to protect patient identity. Written informed consent was obtained from all participants for data collection and treatment. Each center obtained approval from the local ethics committee, where required.

Informed Consent Statement

Written informed consent was obtained from all participants for data collection and treatment.

Conflicts of Interest

Most of the authors are key opinion leader for the company (Osstem Implant). However, all the authors declare no conflict of interest in this research.

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