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Platform switching versus regular platform implants: 3-year post-loading results from a randomised controlled trial

Key words

ds *dental abutment, dental implants, implant–abutment interface, marginal bone loss, platform switching*

Purpose: To test the hypothesis that platform switching and regular platform implants would have different outcomes in single-tooth replacement against the alternative hypothesis of no difference. **Material and methods:** This study was designed as a randomised controlled split-mouth trial. Eighteen patients with bilaterally missing single premolars or molars to be restored with implant-supported single crowns, were consecutively enrolled. Implant sites were randomly assigned to be treated according to the platform switching concept (PS group), or with matching implant–abutment diameters (RP group). A total of 36 Nobel Replace Tapered Groovy implants were installed. All the implants were inserted in healed bone, with an insertion torque between 35 and 45 Ncm, according to a one-stage protocol. Both implant types were loaded with a screw-retained temporary crown 3 months after implant insertion. Definitive screw-retained single crowns were delivered 2 months later. Outcome measures were implant and prosthetic survival rates, biological and prosthetic complications, radiographic marginal bone level (MBL) changes, pocket probing depth (PPD) and bleed-ing on probing (BOP). Clinical data was collected at implant placement (baseline), and at 3, 9 and 36 months after loading.

Results: No patients dropped out and no implant failed. No prosthetic complications were recorded. One patient experienced mucosal inflammation with positive BOP (RP group) after 3 months, three patients had bilateral peri-implant mucosal inflammation with positive BOP at 6, 24 and 30 months after loading, respectively. There were no statistically significant differences between groups for complications (3/18 versus 4/18; P = 1.0; Odds Ratio = 1.333; 95% CI: 0.3467 to 5.1272). Nine months after loading, the mean MBL was 0.93 ± 0.26 mm in the RP group and 0.84 ± 0.23 mm in the PS group, with no statistically significant differences between groups (mean difference = 0.09 mm, 95% CI: -0.22 to 0.04, P = 0.18). Three years after loading, mean MBL was 1.09 ± 0.31 mm in the RP group and 1.06 ± 0.24 mm in the PS group, with no statistically significant differences between groups (mean difference = 0.02 mm, 95% CI: -0.06 to 0.10, P = 0.70). Marginal bone level changes between 3 years and baseline were 0.72 \pm 0.28 mm in the RP group and 0.71 \pm 0.27 mm in the PS group, with no statistically significant differences between the groups (mean difference = -0.00 mm, 95% CI: -0.07 to 0.07, P = 0.89). Mean PPD was 2.70 ± 0.52 mm in the RP group and 2.46 ± 0.69 mm in the PS group at 36 months after loading, with no statistically significant differences between the groups (mean difference = 0.23 mm, 95% CI: -0.05 to 0.35, P = 0.43). Mean BOP was 0.83 ± 0.96 mm in the RP group and 0.89 ± 0.99 mm in the PS group at 36 months after loading, with no statistically significant differences between the groups (mean difference = 0.07 mm, 95% Cl: -0.03 to 0.17, P = 0.77).



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Dr Silvio Mario Meloni University of Sassari Department of Surgical Microsurgical and Medical Sciences, Viale San Pietro 43/B 07100 Sassari, Italy. Email: melonisilviomario@ yahoo.it **Conclusions:** The clinical and radiographic outcomes of implants restored according to the platformswitching concept versus implants restored with the matching implant–abutment diameters are comparable, 3 years after loading.

Conflict of interest statement: This study was not supported by any company. All authors declare no conflict of interest.

Introduction

Several studies investigating matched abutment implants reported initial bone remodelling up to 2.0 mm during the first year of loading¹. Different factors seem to contribute to this physiological event such as implant neck design, implant connection and biological width establishment². Periimplant marginal bone loss could be a result of the establishment of a pathogenic microflora promoting the occurrence of mucosal inflammation and progressive bone resorption^{3,4}. In addition, biomechanical stress⁵, the position of the implant platform⁶ and a framework misfit⁷ could negatively affect the physiological bone remodelling that occurs after implant placement.

Several clinical trials have shown that implants with platform switching had significantly less bone resorption compared with a traditional matching implant-abutment connection⁸⁻¹⁰. The concept of platform switching suggests an abutment or a suprastructure with a diameter at the implant-platform level that is smaller than the implant diameter. This configuration results in a circular horizontal step which enables a horizontal extension of the biological width. The rationale for platform switching is to locate the microgap of the implant-abutment connection which is away from the vertical bone-to-implant contact area. Compared with the conventional restorative procedure using an identical size implant and suprastructure diameter, platform switching is suggested to prevent or reduce crestal bone loss^{11,12}. Despite initial questionable evidence suggesting the platform switching concept has a positive effect on crestal bone stability¹¹⁻¹³, few studies reported similar outcomes compared to conventional procedures^{14,15}.

An interim 9-month post-loading report from this study showed that platform switching and

regular platform implants have similar clinical and radiographic outcomes in single-tooth replacements¹⁵. In the present study, we tested the hypothesis that platform switching implants (PS) and regular platform implants (RP) would have different outcomes in single-tooth replacement against the alternative hypothesis of no difference, 3 years after loading.

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This trial is reported according to the CON-SORT (Consolidated Standards of Reporting Trials) statement (http://www.consort-statement.org) for improving the quality of reporting of parallel-group randomised trials.

Materials and methods

Study design and patient selection

This study was designed as a randomised controlled split-mouth trial. The study was conducted in accordance with Helsinki Declaration guidelines between November 2011 and February 2013. Patients were recruited in three different centres. The study was explained thoroughly and all participants provided written informed consent prior to enrolment. Patients were treated by the same clinician (SM). Data were analysed at the Dentistry Unit of the University Hospital of Sassari, Italy. Patients were selected according to the following inclusion and exclusion criteria.

Inclusion criteria

- Age ≥ 18 years;
- Need for a single bilateral implant-supported crown in the posterior area;
- Stable interocclusal relationship;
- Residual bone height ≥10 mm;



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- Residual bone width ≥ 6 mm with at least 5 mm of keratinised gingiva crestally;
- Provided written informed consent.

Exclusion criteria

- General contraindications for implant surgery;
- Lack of occluding dentition in the area intended for implant placement;
- Periodontitis;
- Severe bruxism;
- Immunosuppression;
- Previous history of irradiation of the head and neck area;
- Uncontrolled diabetes;
- Heavy smoker (> 10 cigarettes/day);
- Probing pocket depth (PPD) > 4 mm and/or bleeding on probing (BOP) > 25%;
- Current or past treatment with bisphosphonates;
- Substance abuse;
- Psychiatric disorder;
- Inability to complete a 5-year post-loading follow-up;
- Lactation;
- Implant insertion torque less than 35 Ncm at implant placement.

Clinical procedures

All patients were evaluated clinically and their medical history was recorded. A preliminary screening, including the acquisition of intraoral and panoramic radiographs (Fig 1), was performed to evaluate the eligibility of potential patients. Patients who met the selection criteria received oral hygiene treatment and instructions. Afterwards all patients had a cone beam computed tomography (CBCT; Imaging Sciences International, Pennsylvania, USA) scan taken.

Amoxicillin and clavulanic acid (Augmentin, GlaxoSmithKline, Verona, Italy) 1 g was administered twice daily from 1 h before implant placement to 6 days post-surgery. Prior to implant placement, patients rinsed for 1 min with 0.2% chlorhexidine (Curasept, Curaden Healthcare, Saronno, Italy) mouthwash. Local anaesthesia was induced using articaine with adrenaline (1:100,000; Pierrel, Milan, Italy) immediately before surgery. A minimally invasive flap was designed with an intrasulcular and crestal incision, without releasing incisions. Drills were used to prepare the implant site according to bone density and the manufacturer instructions. Once the implant site was prepared to receive a 4.3 or 5.0 mm-diameter implant, the envelope containing a randomisation code to assign the PS and the RP implant site was opened by a blinded independent physician. Implants (Nobel Replace Tapered Groovy, Nobel Biocare, Goteborg, Sweden) with an anodised surface were placed with an insertion torque between > 35 and < 45 Ncm. One site received 8 or 10 mm-long Nobel Replace Platform Shift implants, a 4.3 mm body diameter with a 3.5 mm (Narrow Platform, fuchsia) implant-abutment interface or a 5.0 mm body diameter with a 4.3 mm (Regular Platform, yellow) implant-abutment interface. The contralateral site received identical implants (RP group) with matching implant-abutment diameters (4.3 mm, yellow or 5.0 mm, blue; Figs 2 and 3). Healing abutments were connected to



Fig 2 Regular platform (RP) and platform switching (PS) implants.



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Fig 3 Clinical view – platform switching and regular platform implants after installation.



Fig 4 Occlusal view of final prosthesis 3 years after loading.

implants at the time of surgery. Flaps were sutured with Vicryl 4.0 sutures (Vicryl, Ethicon Johnson and Johnson International, Sint-Stevens-Woluwe, Belgium).

A total of 80 mg of ketoprofen (Oki, Dompe, Milan, Italy) two or three times a day was prescribed for as long as required. Patients were instructed to rinse with 0.2% chlorhexidine (Curasept) for 2 weeks and to stay on a soft diet regimen for 10 days. Sutures were removed after 2 weeks. Three months after placement, implant stability was checked manually and silicone impressions were taken. Customised cast models were made. After 1 week, screw-retained temporary resin crowns were delivered on temporary titanium abutments. Six months after surgery, definitive metal or zirconia ceramic screw-retained crowns were delivered (Figs 4 to 6). Intraoral radiographs of the study implants were taken at implant placement (baseline), at implant loading (3 months later), 9 and 36 months after loading (Figs 7 and 8). Patients were then enrolled in an oral hygiene programme with recall appointments every 3 months for the first year and then twice per year.

The following outcome measures were recorded:

- Implant/crown failure;
- Complications;
- Marginal bone levels.

Implant/crown failure

Removal of implants were dictated by implant mobility, progressive marginal bone loss, infection or implant fracture. The stability of individual implants was measured by the prosthodontist (PM) at the time of temporary and definitive crown delivery (3 and 6 months after implant placement), by applying 35 Ncm of removal torque. One year after implant placement (9 months after loading), and 36 months after loading, implant stability was tested manually by the same prosthodontist (PM), with two dental mirror handles.

Complications

Prosthetic complications, such as fractures or chipping of the provisional or definitive ceramic crown, abutment mobility and biological complications, such as wound or implant infection, mucositis, abscesses or peri-implantitis were recorded.

Marginal bone levels

Peri-implant marginal bone levels (MBLs) were evaluated on intraoral digital radiographs taken with the parallel technique at the time of implant placement, and at 3, 9 and 36 months after loading. Radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. A radiologist, not previously involved in the study, evaluated

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Fig 5 Lateral view of final prosthesis of an RP implant 3 years after loading.



Fig 6 Lateral view of final prosthesis of an PS implant 3 years after loading.



Fig 7 Intraoral radiograph of an PS implant 36 months after implant placement.

all the radiographs. The distances from the mesial and distal interproximal bone to the horizontal interface between the implant and abutment (reference point) were measured with a software measurement tool (Digora for Windows 2.8, SOREDEX, Tuusula, Finland) that were calibrated for every single image against the space between the two threads, up to the nearest 0.1 mm. The mesial and distal measurements were recorded with reference to the implant axis and averaged between them.

Probing pocket depth (PPD) and bleeding on probing (BOP) were measured by a blinded operator with a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing, Illinois, USA) at 3, 9 and 36 months after loading. Three vestibular and three lingual values were collected for each implant.

Sample size and randomisation

Since this study was intended to be preliminary to a larger clinical trial, a priori sample size calculation was not performed. In each patient, the right or left molar or premolar were randomly allocated to receive



Fig 8 Intraoral radiograph of an RP implant 36 months after implant placement.

either PS or RP implants. The randomisation code was created by computer software (Excel, Microsoft, Washington, USA) by combining a sequence of randomised non-consecutive numbers matching the two different procedures (PS versus RP implants) with the right or left tooth, and it was assigned by an independent operator not otherwise involved in the trial. The numbers were placed in opaque envelopes. The left site was allocated as indicated in the envelope, while the contralateral site was treated during the same session, according to the other intervention. Data was collected in spreadsheets (Excel) by an independent physician at the Dentistry Unit, University of Sassari, Italy.

Statistical analysis

Statistical analyses were conducted using QI Macros SPC software (version 2010, KnowWare International, Connecticut, USA) for Microsoft Office Excel. All values were presented as mean, mean difference, standard deviation and 95% confidence intervals. Differences in the proportion of patients with prosthesis failures, implant failures and complications (dichotomous outcomes) were compared between PS and RP implants using the McNemar test. The difference of means of marginal bone levels and periodontal parameters (PPD and BOP) between groups were compared at insertion, at 6 and 12 months after implant placement, and at 3 years after loading, by using a matched paired t-test conducted at the 5% level of significance.

Results

Twenty-five patients were screened between May and October 2011, but seven patients did not meet the selection criteria for the following reasons: three refused to adhere to a strict clinical and radiological follow-up, three had insufficient bone height and one had insufficient bone width. Eighteen patients (8 males and 10 females), with a mean age of 48 (range: 28 to 70 years) were considered eligible and treated. In total, 36 implants were placed in sites healed for at least 2 months with an insertion torque between 35 and 45 Ncm. No patient dropped out of the study within 3 years after loading. No deviation from the original protocol occurred. Data were collected at baseline, and at 3, 9, and 36 months after implant loading.

Implant survival

No implant mobility, infection or implant fracture occurred. All implants were stable at the end of the study.

Prosthetic and biological complications

No prosthetic complications were observed. No major biological complications were recorded in either group. One patient experienced mucosal inflammation with a positive BOP (RP group) after 3 months. One patient had bilateral peri-implant mucosal inflammation with a positive BOP after 6 months. Improved oral hygiene reduced the peri-implant inflammation. After oral hygiene instructions were given, the inflammation resolved. Two patients experienced bilateral mucosal inflammation 24 and 30 months after loading, with a positive BOP, which

resolved after oral hygiene instructions were given. There were no statistically significant differences between groups (3/18 versus 4/18; P = 1.0; Odds Ratio = 1.333; 95% CI: 0.3467 to 5.1272).

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Peri-implant marginal bone levels (Tables 1a to 1b)

The average change in interproximal MBL was analysed for each implant. Mean MBL 3 months after loading was 0.63 ± 0.17 (95% CI: 0.55 to 0.71) for RP implants and 0.58 ± 0.17 (95% CI: 0.50 to 0.64) for PS implants. No statistically significant difference was observed between the groups (P = 0.14). Nine months after loading the mean MBL was 0.93 ± 0.26 (95% CI: 0.81 to 1.05) for RP implants and 0.84 ± 0.23 (95% CI: 0.73 to 0.95) for PS implants. No statistically significant difference was observed between the groups (P = 0.18). Thirty-six months after loading, mean MBL was 1.09 ± 0.31 mm (95% CI: 0.85 to 1.13) in the RP group and 1.06 ± 0.24 mm (95% CI: 0.93 to 1.15) in the PS group, with no statistically significant differences between groups (P = 0.70).

Three months after loading, a difference in MBL changes between the two groups was 0.26 ± 0.15 (95% CI: 0.19 to 0.33) for RP implants and 0.23 ± 0.13 (95% CI: 0.17 to 0.30) for PS implants. No statistically significant difference was observed between the groups (P = 0.57). Nine months after loading, a difference in MBL changes between the two groups was 0.56 ± 0.22 (95% CI: 0.46 to 0.66) for RP implants and 0.50 ± 0.27 (95% CI: 0.37 to 0.62) for PS implants. No statistically significant difference was observed between the groups (P = 0.38). Marginal bone level changes between 36 months after loading and baseline were 0.72 ± 0.28 mm (95% CI: 0.56 to 0.81) in the RP group and 0.71 \pm 0.27 mm (95% CI: 0.57 to 0.82) in the PS group, with no statistically significant differences between groups (P = 0.89).

Probing pocket depths

Nine months after loading (1 year after implant placement) the mean PPD values were 2.74 ± 0.49 mm (95% CI: 2.51 to 2.97) for RP implants and 2.70 ± 0.38 mm (95% CI: 2.53 to



	Regular (RP)		Switch (PS)		P value	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
Baseline	0.37 ± 0.18	0.29 – 0.45	0.35 ± 0.18	0.27 – 0.43	0.55	0.02 ± 0.16	-0.10 – 0.05
3 months	0.63 ± 0.17	0.55 – 0.71	0.58 ± 0.17	0.50 – 0.64	0.14	0.05 ± 0.14	-0.12 – 0.01
9 months	0.93 ± 0.26	0.81 – 1.05	0.84 ± 0.23	0.73 – 0.95	0.18	0.09 ± 0.27	-0.22 – 0.04
36 months	1.09 ± 0.31	0.85 – 1.13	1.06 ± 0.24	0.93 – 1.15	0.70	0.02 ± 0.24	-0.06 – 0.10

 Table 1a
 Mean marginal bone levels after loading (mm).

*Values represent mean \pm SD (patients n = 18).

No significant differences among groups (P > 0.05).

 Table 1b
 Difference in marginal bone level changes between the two groups (mm).

	Regular (RP)		Switch (PS)		P value	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
3 months	0.26 ± 0.15	0.19 – 0.33	0.23 ± 0.13	0.17 – 0.30	0.57	-0.03 ± 0.22	-0.13 – 0.07
6 months	0.56 ± 0.22	0.46 – 0.66	0.50 ± 0.27	0.37 – 0.62	0.38	-0.07 ± 0.31	-0.21 – 0.08
36 months	0.72 ± 0.28	0.56 – 0.81	0.71 ± 0.27	0.57 – 0.82	0.89	-0.00 ± 0.16	-0.07 – 0.07

*Values represent mean \pm SD (patients n = 18).

No significant differences among groups (P > 0.05).

 Table 2a
 Mean PPD values (mm).

	Regular (RP)		Switch (PS)		P value	Mean difference	
	Mean ± SD	95% Cl	Mean ± SD	95% CI		Mean ± SD	95% CI
3 months	2.67 ± 0.62	2.38 – 2.95	2.76 ± 0.55	2.51 – 3.01	0.64	0.10 ± 0.90	-0.32 – 0.51
9 months	2.74 ± 0.49	2.51 – 2.97	2.70 ± 0.38	2.53 – 2.88	0.77	0.00 ± 0.66	-0.30 – 0.30
36 months	2.70 ± 0.52	2.43 – 2.91	2.46 ± 0.69	2.18 – 2.82	0.43	0.23 ± 0.18	-0.05 – 0.35

* Values represent mean \pm SD (patients n = 18).

No significant differences among groups (P > 0.05).

Table 2b Changes in PPD values (mm).

	Regular (RP)		Switch (PS)		P value	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
Between 3 and 36 months	0.04 ± 0.22	-0.06 – 0.10	-0.28 ± 0.41	-0.08 – 0.40	0.10	-0.23 ± 0.31	-0.48 – 0.08

*Values represent mean \pm SD (patients n = 18).

No significant differences among groups (P > 0.05).

2.88) for PS implants, with no statistically significant difference between them (P = 0.77). Thirtysix months after loading, mean PPD values were 2.70 ± 0.52 mm (95% CI: 2.43 to 2.91) for the RP group and 2.46 ± 0.69 mm (95% CI: 2.18 to 2.82) for the PS group, respectively, with no statistical difference between the groups (P = 0.43). During the 3-year follow-up examination, changes in PPD values were 0.04 ± 0.22 mm (95% CI: -0.06 to 0.10) in the RP group and -0.28 ± 0.41 mm (95% CI: -0.08 to 0.40) in the PS group (P = 0.10). All data are summarised in Tables 2a and 2b.

Bleeding on probing

The mean BOP values measured 9 months after implant loading were 1.28 ± 0.75 (95% CI: 0.93 to 1.63) for RP implants and 1.39 ± 0.78 (95% CI: 1.03 to 1.75) for PS implants, with no statistically significant difference between the groups (P = 0.16).

Table 3a Mean BOP values.



* Values represent mean \pm SD (patients n = 18).

No significant differences among groups (P > 0.05).

Table 3b Changes in BOP values 3 years after loading.

	Regular (RP)		Switch (PS)		P value	Mean difference	
	Mean ± SD	95% CI	Mean ± SD	95% CI		Mean ± SD	95% CI
Between 3 and 36 months	-0.49 ± 0.66	-0.69 – -0.31	-0.61 ± 0.78	-0.73 – -0.47	0.70	-0.11 ± 0.68	-0.24 - 0.04

*Values represent mean \pm SD (patients n = 18). No significant differences among groups (P > 0.05).

Thirty-six months after loading, mean BOP values were 0.83 ± 0.96 mm (95% CI: 0.54 to 1.46) in the RP group and 0.89 ± 0.99 mm (95% CI: 0.55 to 1.45) in the PS group, with no statistical difference between them (*P* = 0.77). During the 3-year follow-up examination, changes in BOP values were -0.49 ± 0.66 mm (95% CI: -0.69 to -0.31) in the RP group and -0.61 ± 0.78 mm (95% CI: -0.73 to -0.47) in the PS group (*P* = 0.70). All data are summarised in Tables 3a and 3b.

Discussion

The purpose of this study was to compare clinical and radiographic outcomes of PS and RP implants. The hypothesis that PS and RP implants would show different outcomes in single-tooth replacement was rejected in favour of the null hypothesis of no difference. Overall the 36-month post-loading results confirm the preliminary 9-month post-loading report¹⁵, demonstrating that implants restored according to PS showed similar outcomes to implants with matching implant–abutment diameters (RP).

The main limitation of this study was a lack of allocation concealment. The envelope containing the randomisation code was opened before implant installation, while it should have been opened at healing abutment connection. However, this study was designed as a split-mouth randomised controlled trial, avoiding possible influencing factors such as the patient biotype, bone density and/or lifestyle. Other limitations are that a priori sample size calculation was not performed, thus a small sample size might have hidden some differences between the groups.

Marginal bone loss around different types of implants occurs mostly during the first year of function and it seems to occur regardless of any efforts made to prevent it^{16,17}. Peri-implant bone resorption seems to be mediated by the inflammatory response, but this topic is still controversial¹⁸. Hence, up to now, there is a lack of scientific evidence explaining the mechanisms concerning MBL around implants overall and the different types of connections and neck configurations. Recently, Esposito et al in a 5-year post-loading randomised clinical trial comparing implants with an internal connection and which were platform switched against implants with external connections and which were not platform switched, did not find any statistically significant differences between the two different connections and neck design types¹⁹. According to Bateli et al²⁰, in order to preserve marginal bone around dental implants a multifactorial approach is required.

Results from clinical studies and a systematic review reports that the bone resorption around implants can be reduced by moving the implant–abutment junction away from the bone crest^{17,21-24}. Atieh et al, in a systematic review, concluded that platform-switched implants presented lower bone resorption compared with regular platform implants, and that the degree of marginal bone resorption is inversely correlated to the implant-abutment mismatch²². Several recent systematic reviews showed less enthusiastic results, suggesting cautious interpretation of these results, due to the heterogeneity of the included studies^{25,26}. Accordingly, the results from the present randomised controlled trial confirmed that implants with platform switching do not preserve crestal bone more effectively in comparison with implants with a traditional implant-abutment connection. Furthermore, most comparative studies tested wide-diameter implants versus regular-diameter implants, both restored with the same abutment^{11,27}. In this scenario, the implantabutment mismatching was obtained by increasing the platform of the implant, maintaining the same dimension of the abutment. On the contrary, in the present research, implants with identical diameters were used in a split-mouth design. As assumed in the first preliminary report¹⁵, the same implants inserted in the same patients could have similar outcomes. However, no major evidence can be obtained due to several limitations of the study; hence, the effect of the platform-switching concept remains controversial.

Conclusions

PS and RP implants seem to have similar clinical outcomes in bilateral single tooth replacements, even after 3 years after final loading. The results of our study should be confirmed by further randomised clinical trials with a larger sample size.

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