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A Randomized Pilot Clinical and Microbiological Study Comparing Laser Microtextured Implants with and without Platform Switching

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Abstract: Minimising marginal bone loss around dental implants is of paramount importance. The success of methods such as platform switching (PS) and laser-micro-texturing (LM) are well documented. Whether or not a combination of these designs will further improve outcomes has not been studied previously. Hence, this prospective, randomized controlled single-centre pilot study compared the clinical and microbiological outcomes of implants with both PS and LM (test) to implants with only LM (control). A test and control implant were placed in thirteen patients totalling 26 implants. The primary investigated outcome was marginal bone level (MBL); secondary outcomes were peri-implant probing depths (PPD), bleeding on probing (BOP) and marginal tissue height (MTH). Additionally, the presence of five putative periodontal pathogens were assessed using real-time polymerized chain reaction. At 12 months the overall implant survival rate was 95.8%. MBL change was not found to be different between test and control at any time points, but a significant change was detected within the test implants at 6 months compared to baseline ($p = 0.006$). No differences were found in the secondary outcomes. Average PPD at 12 months was 2.68 ± 0.73 mm and 2.30 ± 0.46 mm and average change in MTH was 0.05 ± 0.72 mm and -0.24 ± 0.59 mm at tests and controls. No differences were reported in BOP frequency. Total periodontal pathogens count revealed no significant difference among control, test implants and adjacent tooth sites. Within the limitations of this study, it can be concluded that the addition of PS to LM implants does not significantly alter either short-term clinical outcomes or the vulnerability to pathogenic microflora colonization.

Keywords: bacteria; dental implants; laser-microtextured implant; marginal bone loss; microbiology; platform switching

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1. Introduction

Osseointegration has been defined as a direct and functional connection between bone and an artificial implant. Both macroscopic and microscopic characteristics of dental implants could influence the success of these procedures [1]. A fundamental goal of modern implant dentistry is to reduce the marginal bone remodelling after placement in order to maximise the predictability of treatment and to reduce the incidence of biological, mechanical and aesthetic complications. However, the cause of this initial bone remodelling is not fully understood; it has been hypothesized that multiple factors, such as the unique

anatomy of the peri-implant tissues [2], clinical decisions [3–6], operator experience [7] and implant designs [8,9] may influence the marginal tissue stability.

Among the implant design alterations aiming to reduce marginal remodelling are platform switching (PS) [10] and laser micro-texturing (LM) [11]. Both these technologies have shown promise in stabilisingperi-implant tissues. PS is a commonly used design to reduce marginal bone remodelling. It involves a "mis-match" of the abutment platform to the underlying implant restorative platform, where the abutment platform is reduced in circumference. This design is thought to reduce the crestal bone remodelling through a manipulation of the biological width or by moving the "micro-gap" at the implant abutment interface. The latter may reduce microbial irritation to the tissues. A recent systematic review did not find differences in marginal bone loss around PS and tissue level implants [12]. This hypothetical benefit was originally reported by Lazzara and Porter in 2006 [13] in a case series with a 13-year follow up. This technique has subsequently been adopted by many mainstream implant brands with varying interpretations regarding the magnitude of mismatch. This has also been followed by a plethora of clinical evidence for its utility [14–20]. Indeed, Canullo et al. [21] conducted a randomised controlled trial which involved 800 implants with varied degrees of platform mismatch. At 21 months, the control group with no platform mismatch was found to have an average of 1.49 mm crestal bone loss; the PS groups were found to have 0.99 mm, 0.82 mm and 0.56 mm of crestal bone loss depending on the degree of platform mismatch. This study concluded that the PS concept did maintain crestal bone levels and that this was also determined by the degree of PS. Furthermore, a systematic review by Chrcanovic et al. 2015 [22], including 28 studies, reported that with longer observation periods a greater difference between the PS and regular groups was noted. The authors also concluded that marginal bone loss was significantly lower at implants with PS than at implants with platform matching; this difference increased with the increasingfollow-up time and degree of mismatch between the implant platform and the abutment.

Another method attempting to reduce crestal bone remodelling is the use of laser-microgrooves, otherwise known as laser micro-etching, LM, or by the commercial name "Laserlok" surfaced implants. This surface was developed to alter the way different cell lineages would respond to, and hence migrate across, the titanium surface. Human and animal histology has shown an alteration in the behaviour of cells to LM surfaces, possibly altering fundamental concepts such as collagen fibre orientation [23–26], with perpendicularly orientated collagen fibres as opposed to parallel [27]. Clinical evidence is mounting in favour of this technique reducing marginal bone loss in a similar manner to PS [28–33]. A systematic review, including 25 articles, was conducted to investigate clinical outcomes of implants with LM collars or LM abutments [34]. Only four of these studies were randomized controlled trials; half of the studies observed LM implants alone with no control group. Where there were control implants, these were most often machined collar implants. The implants were placed in different clinical conditions, with variable placement, timing and loading protocols, location, restoration and use of augmentation. The results consistently reported a relative reduction in peri-implant probing depths (PPD) and marginal bone levels (MBL) when using LM collars. However, those studies comparing LM collars to roughened collars of competing designs did not note differences [35,36]. Few studies reported on marginal soft tissues height (MTH) [37–39], but in three it was stated that LM reduced recession compared to machined collar controls [40–42]. The review [34] shows that LM implants consistently have clinically acceptable outcomes in both the short and medium term, and possibly a lower biological complication rate than machined collar implants. Whether there is any additional effect of LM when compared to roughened collars and competing macro-designs is not able to be determined from the current literature. Conversely, the propensity for these roughened collar or abutment surfaces to collect plaque is yet unanswered. As with PS, there is only a small amount of evidence to suggest that the marginal soft tissues are affected by these design alterations.

Whether or not a combination of these designs may be of further benefit is not reported in the literature. Hence, this study aimed to test the hypothesis that LM implants with PS (test) would result in reduced marginal tissue remodelling when compared to those without PS (control). MBL, MTH, PPD and bleeding on probing (BOP) were statistically compared between test and control implants. In addition, the abundance of perio-donto-pathogenic microbiota was compared among test, control and adjacent tooth to highlight possible differences in bacterial colonization.

2. Materials and Methods

2.1. Patients

The Human Research Ethics Committee of the Griffith University (Reference GU 2018/777) approved the protocol of the present study, which was registered with the Australia and New Zealand Clinical Trials registry on the 20 February 2019 (registration number is ACTRN12619000259145). All patients gave their informed consent to the treatments, which were performed in accordance with the Helsinki Declaration.

The study group included 13 partially edentulous patients, who required implants for the rehabilitation of two edentulous sites.

Patients were included in this study according to the following inclusion criteria:

- Requiring at least two implants which could be placed simultaneously;
- Non-grafted type IV bone [43] sufficient for placing an implant;
- Adequate band of keratinised tissues (at least 2 mm); if soft tissue grafting was required, a 2-month healing time was required before implant surgery;
- Opposing occlusion;
- Sufficient space for restoration (at least 7 mm of inter-arch space);
- Over 18 years of age;
- Availability for follow up appointments at 6 and 12 months after implant placement;

Exclusion criteria were:

- Untreated or poorly maintained periodontal disease and/or general dental care that had not been completed;
- Poor Oral Hygiene (Plaque index (PI) >20%);
- Para-functional habits (probable and above as defined by Lobbezoo et al. 2013 [44]);
- Current severe smoking habit (>10/day);
- Systemic illnesses which may compromise periodontal healing;
    - Uncontrolled diabetes
    - Radiation therapy
    - Bleeding disorders
- Regular prescription of medications which may alter outcomes;
    - Bone altering medications such as for osteoporosis
    - Blood thinning medications which will increase risk of bleeding
    - Chemotherapy medications
- Pregnancy;
- Consumption of illegal substances;
- Inability to give informed consent;

2.2. Implants and Componentry

Two titanium (Ti6Al4V) implants (7.5–18 mm × 3–5.8 mm) with the same internal hex-conical connection, tapered body and a self-tapping reverse buttress thread design were placed randomly: test–"Internal Tapered Plus", and control–"Internal Tapered" (Bio-Horizons, Birmingham, AL, USA). Both implants had LM collars, restorative platform sizes ranging from 3 mm to 5.7 mm, and the test implants also utilised a PS design. This was achieved via "stepping" down one restorative platform (e.g., the 4.6 mm body implant used a 3.5 mm platform rather than the standard 4.5 mm platform).

The healing abutments (Laser-Lok Healing Abutment, BioHorizons, Birmingham, AL, USA) presented a 1 mm LM band, situated on the apical aspect closest to the implant platform. These abutments are provided for corresponding platform widths, with narrow, regular and wide emergence options, and heights of 3 and 5 mm. The restorative abutments (Laser-Lok Titanium Base Abutment, BioHorizons, Birmingham, AL, USA) were manufactured from a titanium alloy (Ti-6Al-4V) and TiN coated, with a 1 mm wide LM zone at the collar and a minimal restorative height of 5 mm and designed to be placed with 30 Ncm of torque.

2.3. Surgical Procedure

Full implant planning procedures were conducted prior to implant placement and trial inclusion. Presurgical evaluation encompassed photographs, full mouth impressions, and clinical measurements relevant to restorative space and gingival tissues. Diagnostic wax-ups were then produced by private dental laboratory (Apex Dental Gold Coast Dental Laboratory, Queensland, Australia), which were referenced against the CBCT to confirm prosthetically driven implant placement. A surgical guide (pilot-guide) was then prepared for implant surgery. All patients underwent the same surgical protocol, and in each patient the two implants were placed in an alternating sequence determined by computer randomization. The operator was blind to whether the implant was test or control until both osteotomies were completed. The implants were placed by Senior Residents in the Specialist Program in Periodontics and Oral Implantology under the supervision of Clinical Senior Staff (AQ and AS), whilst data collection was conducted by a single researcher (JC), with the exception of baseline radiographs which were collected by the surgical operators.

Local anesthesia was achieved via an infiltration of Lidocaine 2% 1:80,000 (Novocol Pharmaceutical of Canada, Cambridge, ON, Canada). A mid-crestal full thickness flap was raised with maximum effort to preserve the keratinized tissue on both the buccal and lingual aspects while exposing the osteotomy sites. The sites were prepared according to the manufacture's indications, aiming for single-stage non-submerged healing. At least one of each implant (test and control) was placed in each patient. Implants were placed with the mesial and distal platform flush with the crest. Relevant LM healing abutments were placed to finger tightness for anticipated emergence profile and gingival height. After placement of the implants the flaps were closed using 5.0 or 6.0 monofilament sutures, which were left in place for 14 days. Patients were instructed to be on a liquid-soft diet for 3 days, then gradually returning to a normal diet. Analgesics (ibuprofen, 600 mg) immediately post-surgery, then every 8 h for 2–3 days were prescribed. Paracetamol with or without the addition of codeine was used for break through pain if required. Patients used antiseptic mouthwash (Chlorhexidine 0.2%) post-surgery until suture removal.

2.4. Prosthetic Procedure

At 10–12 weeks, the successful integration of the implants was confirmed via a periapical radiograph taken utilising a Rinn Holder and the long-cone paralleling technique at 70 kW/7.5 mA, a percussion test, and via removal and replacement of the healing abutment to finger tightness [45]. The implants were then referred to the restorative dentists for fabrication of the crown. Screw retained crowns were constructed on Ti-base abutments of either porcelain-fused-metal or monolithic-zirconia according to the restorative dentists' preferences. During these procedures the abutments were stored in saline solution [32]. A stent to allow consistent soft tissue readings was created in 3Shape (1.3.4.7, 3Shape A/S, Denmark) prior to crown insertion using STL files, or a from a scan of the final crown (3Shape E3 lab scanner, 3Shape A/S, Copenhagen, Denmark). This was then 3D-printed (Dental SG resin with a Form2, Formlabs, MA, USA) prior to crown insertion.

2.5. Radiographic Measurements

Baseline radiographs were taken at implant placement; Rinn holders were utilised with a long cone paralleling technique [46]. Subsequent radiographs were taken at the

integration check, at restoration placement, and at the 12-month follow-up. Radiographs were then analysed using ImageJ (National Institutes of Health, MD, USA). Full sized ".tiff" files were exported from the image capture software. Guidance marks were then drawn to indicate the implant shoulder and centre of the implant body. The first bone to implant contact was measured from the shoulder and recorded for both the mesial and distal aspect of the implant. The radiographic length was measured from the centre of the platform to the implant apex. Using Excel v16 (Microsoft, WA, USA), the actual implant length was used to calculate the radiographic distortion. The mean of these two measurements was also derived (Figure 1).

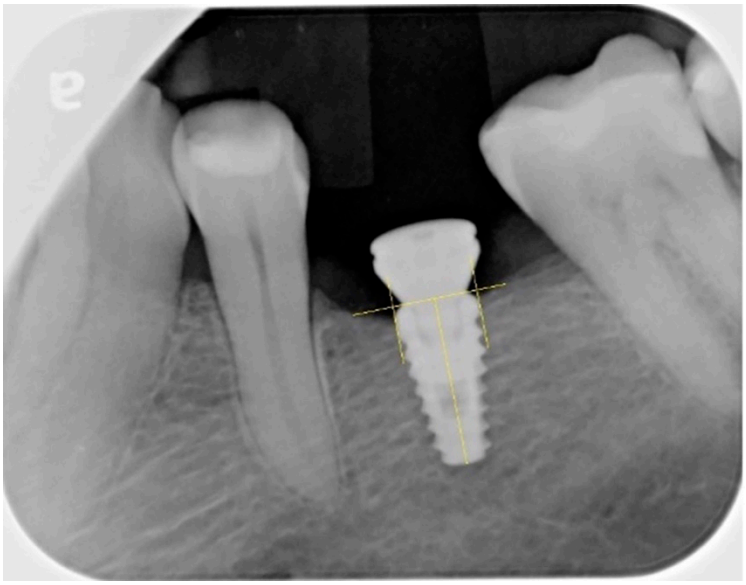

Figure 1. Radiographic image showing the procedure for marginal bone level (MBL) measurement.

To assess intra-examiner reliability, radiographs for six implants which were not included in the study were analysed according to the above radiographic analysis protocols 1-week apart. The measurements were compared using the Pearson's correlation coefficient (r) (Prism 8, GraphPad Software, CA, USA). A reliable repeatability frequency (r: 0.9759) was obtained. All measurements were performed three times, and the average value was used.

2.6. Clinical Measurements

Baseline MTH, measured as the distance between the base of the stent reference notch to the first contact of the probe with the gingival margin at six sites, was recorded shortly after the placement of the crown, and one week after the restoration placement for PPD to allow for abutment-sulcus healing [47]. PPD was recorded at six sites per implant and sites presenting BOP were recorded in a dichotomous fashion [48]. A PCP UNC-15 probe (Hu-Friedy, IL, USA) was used for all recordings. These recordings were repeated at the 12-month review appointment. Five patients, each showing two teeth (single and multirooted) with PPD >4 mm on at least one aspect of each tooth were used to calibrate the investigator. Calibration was considered satisfactory when the two measurements were similar to the millimeter at >90% level.

2.7. Microbiologic Analysis

The microbiologic analysis was performed by means of a real-time polymerized chain reaction (RT-PCR) technique using Carpegen% Perio Diagnostics Test (Carpegen, Münster, Germany) according to the instructions of the manufacturer. Six months after the surgical placement of the dental implants, subgingival samples were collected with paper points of the peri-implant sulcus and adjacent tooth sulcus. The sampling area was isolated with

cotton gauzes, and accurate suction was performed, as well as supragingival scaling with Teflon or plastic curettes for implant maintenance. Paper points were inserted in four different sites for each implant included in the study (buccal, mesiobuccal, distobuccal, and lingual). The paper points were removed after 20 s with careful attention not to touch the oral mucosa and coronal surfaces. The points were then dropped in plastic sterile falcon tubes. An adjacent tooth was also evaluated for microbiologic analysis. The RT-PCR analysis was consequently assessed to test the quantitative and qualitative presence of the following periodontal and peri-implant pathogens using species-specific probes: *Aggregatibacter actinomycetemcomitans* (AA), *Porphyromonas gingivalis* (PG), *Prevotella intermedia* (PI), *Fusobacterium Nucleautum* ssp. (FN), *Treponema denticola* (TD), and *Tannerella forsythensis* (TF). Results were expressed in Genome Equivalents (Geq)/mL $\times 10^3$.

2.8. Statistical Analysis

Study power was calculated assuming MBL as the primary outcome. A previous paper [49] was used to assume standard deviation of 0.17 mm and a clinical relevance of 0.5 mm. Assuming a within participant correlation of 0.2, it was calculated that twenty participants each with two implants would be required to have 80% power with a 0.05 alpha to detect a 0.15 mm or greater difference. Data were analyzed using SPSS software, version 13.0 (SPSS, Chicago, IL, USA). The statistician was blind to test and control implants.

Mean values and standard deviations (mean $\pm$ SD) were calculated for each demographic and clinical variable. Normality of clinical data was assessed by Shapiro-Wilk test. Then, repeated-measures analysis of variance (ANOVA) was performed to compare clinical outcomes of test and control implants at baseline, 6-month and 12-month follow-ups. Multivariate ANOVAs were performed on microbiological outcomes among test, control and adjacent tooth. A p value < 0.05 was considered statistically significant.

3. Results

From February 2019 to December 2019, 119 patients expressed interest in the study (Figure 2); after a phone consultation 32 patients appeared eligible for the study and were invited to undergo a chairside consultation.

Out of 32 patients, 18 matched the inclusion and exclusion criteria, and were included in the trial. Five of these 18 patients were indefinitely delayed due to personal circumstances. Between March 2019 and October 2019, 13 pairs of implants were placed in 13 patients successfully (mean age: 61 years; range: 29 to 91; five males and eight females, non-smokers) (Table 1).

Fourteen implants were placed in mandibular molar sites, four in maxillary molar sites, five in mandibular premolars sites and three in maxillary premolar sites. Patient #13, who had a history of treated localised stage III grade B periodontal disease, was excluded despite successful osseointegration as he was unable to complete the implant restorative process due to a combination of personal circumstance and COVID-19 disruptions. Patient #12 was excluded from the final analysis as a mechanical failure was detected at the 12-month review (4.6 $\times$ 7.5 mm control implant with a >1 crown to implant ratio, located in the upper left first molar site). Hence, 11 pairs of implants were included in the final analysis.

Implants were restored with screw retained single crowns, manufactured from monolithic zirconia with the exception of patient #2 who received two porcelain-fused metal crowns.

As these numbers fell short of the requirement for statistical power as calculated, this study is treated as a "pilot study".

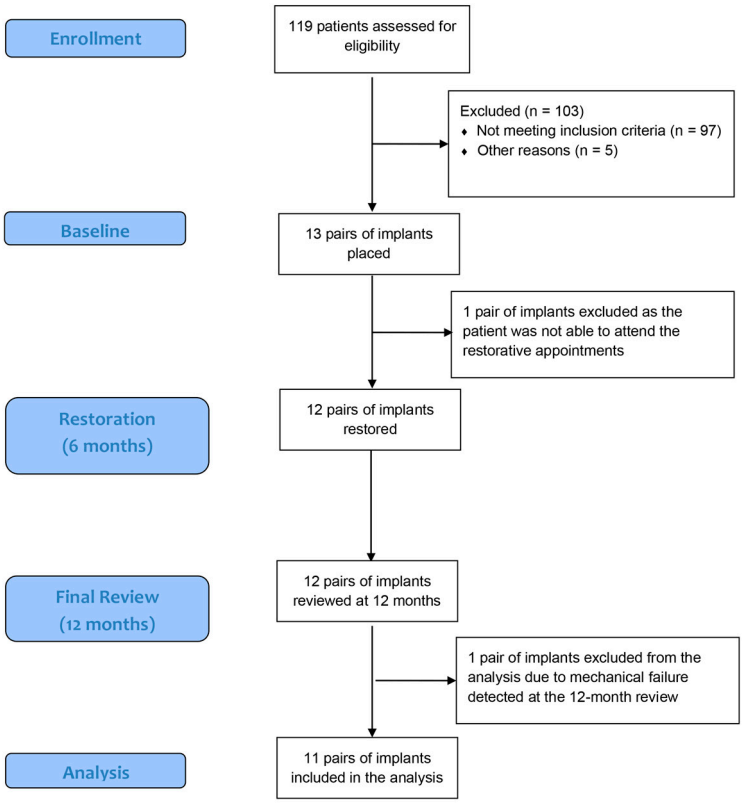

Figure 2. Consort Flow Diagram.

Table 1. Patient demographics, site and size of the implants.

Patient	Age	Sex	Control Implant (Location; Size-mm)	Test Implant (Location; Size-mm)
Patient 1	91	M	46; 4.6 × 9	36; 4.6 × 9
Patient 2	63	F	14; 3.8 × 12	47; 4.6 × 7.5
Patient 3	45	F	15; 3.8 × 10.5	46; 4.6 × 9
Patient 4	45	F	35; 3.8 × 9	36; 4.6 × 9
Patient 5	77	F	36; 3.8 × 9	35; 3.8 × 10.5
Patient 6	58	F	45; 3.8 × 9	46; 4.6 × 9
Patient 7	74	M	26; 4.6 × 9	16; 4.6 × 7.5
Patient 8	57	F	46; 4.6 × 9	36; 4.6 × 9
Patient 9	70	M	35; 4.6 × 7.5	36; 4.6 × 7.5
Patient 10	29	M	46; 4.6 × 10.5	36; 4.6 × 9
Patient 11	61	F	27; 3.8 × 9	36; 4.6 × 9
Patient 12	54	M	26; 4.6 × 7.5	25; 3.8 × 9
Patient 13	56	F	36; 4.6 × 9	35; 3.8 × 9

3.1. Clinical Outcomes

Marginal Bone Level MBL measurements were conducted on radiographs taken at baseline, 6 and 12-month follow-ups (Table 2). Due to possible differences in MBL values at baseline between test and control implants, a statistical comparison between test and control implants was performed on the difference between MBL values at 6-month or 12-month follow-ups and MBL value at baseline (i.e., $\Delta MBL_{6\text{-month}} = MBL_{6\text{-month}} - MBL_{baseline}$; $\Delta MBL_{12\text{-month}} = MBL_{12month} - MBL_{baseline}$).

Table 2. Mean ± sd and median for the temporal evolution of all clinical outcomes.

		Baseline		6-Month Follow Up		12-Month Follow Up	
		Control	**Test**	**Control**	**Test**	**Control**	**Test**
MBL	(mean ± sd)	0.30 ± 0.34	0.23 ± 0.24	0.63 ± 0.41	0.51 ± 0.48	0.52 ± 0.43	0.48 ± 0.56
MBL	median	0.17	0.16	0.62	0.32	0.41	0.23
ΔMBL	(mean ± sd)	//	//	0.33 ± 0.43	0.28 ± 0.35	0.23 ± 0.39	0.25 ± 0.38
MTH	(mean ± sd)	7.53 ± 1.67	7.79 ± 1.40	//	//	7.29 ± 1.62	7.83 ± 1.02
MTH	median	7.00	7.33	//	//	7.17	7.83
ΔMTH	(mean ± sd)	//	//	//	//	−0.24 ± 0.59	0.05 ± 0.72
PPD	(mean ± sd)	2.05 ± 0.41	2.21 ± 0.31	//	//	2.30 ± 0.46	2.68 ± 0.73
PPD	median	2.10	2.25	//	//	2.30	2.50
BOP	(mean ± sd)	//	//	//	//	1.18 ± 1.25	1.00 ± 1.00
BOP	median	//	//	//	//	1.00	1.00

MBL: marginal bone level (mm); ΔMBL: difference between MBL value at 6-month or 12-month and MBL value at baseline (mm); MTH: marginal tissue height from stent base (mm); ΔMTH: difference between MTH value at 12-month and MTH value at baseline (mm); PPD: peri-implant probing depths (mm); BOP: bleeding on probing.

Mann-Whitney non-parametric tests comparing the ΔMBL accounting for the two independent factors (test and control implants) showed no significant differences at 6-month ($p = 0.30$) and 12-month follow-ups ($p = 0.85$).

As second level analyses, the temporal evolution of MBL values for test and control implants was statistically evaluated separately. The Friedman nonparametric statistic for correlated samples showed significant differences in MBL values for baseline, 6-month and 12-month follow-ups in test implants ($p = 0.004$) (Figure 3). Post-hoc analysis showed a significant difference between MBL values at baseline and at 6-month follow-up ($p = 0.006$). The same trend was found in the control implants, but the difference was not considered statistically significant ($p = 0.067$).

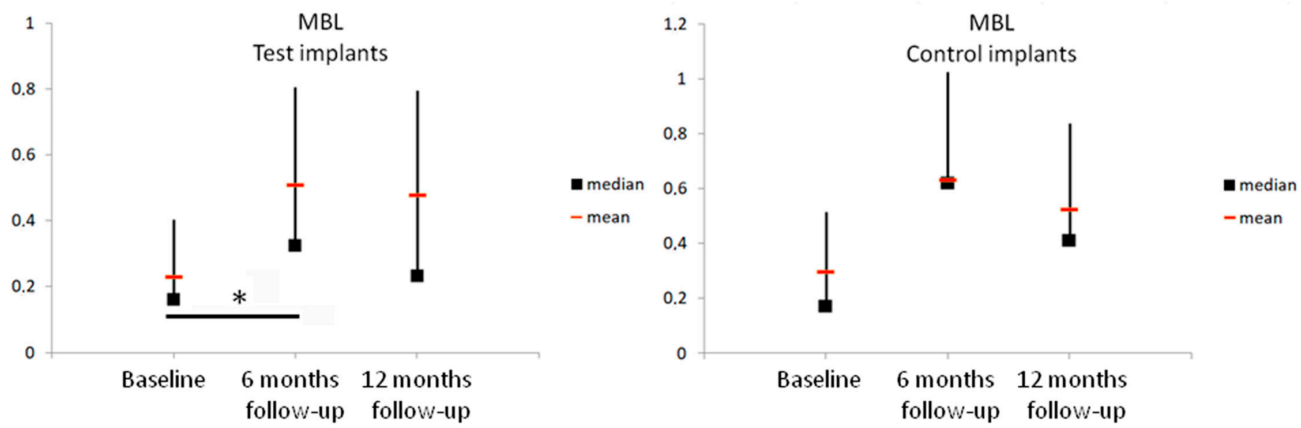

Figure 3. Marginal bone level (MBL) results for test and control implants.

Marginal Tissue Height. As for MTB measurements, a first statistical comparison was performed between test and control implants on the difference of MTH values at 12-month follow-ups and baseline (i.e., $\Delta MTB_{12\text{-month}} = MTB_{12month} - MTB_{baseline}$). Mann-Whitney tests showed no difference on ΔMTH values at 12-month follow-ups between test and control implants ($p = 0.40$). In addition, MTH values were not significantly different at baseline and at 12-month follow-up in test ($p = 0.95$) and in control ($p = 0.20$) implants when test and control implants were analysed separately.

Peri-implant Probing Depths. PPD values where not found to be significantly different between test and control implants at baseline ($p = 0.47$) and at 12-month follow-up ($p = 0.25$). In addition, PPD values were not significantly different at baseline and at

12-month follow-up in test (p = 0.12) and in control implants (p = 0.35) when test and control implants were analysed separately.

Bleeding on Probing. At 12-month follow-up no significant difference was found between test and control implants (p = 0.81).

It is worth nothing that only two implants in a single patient had "visible" inflammation and "line or droplet" BOP, which is not reflected in the dichotomous recordings of BOP. This was diagnosed as peri-implant mucositis according to the newest classifications [50]. On further investigation this was diagnosed as caused by "incorrect flossing technique" and it was resolved in themonths following oral hygiene technique instructions and revision.

Failures. All implants were placed with no detectable surgical complications. After transmucosal healing, all 13 pairs of implants were successfully integrated. One patient dropped out before restoration. Through the study only one failure was noted. This was a "late failure" [51] detected at the 12-month review. Hence, the overall implant survival rate was 95.8%. The failed implant was a 4.6 × 7.5 mm control implant placed in a maxillary molar site, with a >1 crown to implant ratio in a male patient. The implant experienced 1.5 mm of marginal bone loss from placement to integration; however, no further bone loss or obvious radiopacity was noted at the 12-month follow up. PPD was found to be less than 5 mm circumferentially on the failed implant with no "abnormal" BOP, recession or visible inflammation. The failure was only detected when mobility was noted via tapping the implant. The patient retrospectively reported mild discomfort on biting in the region a few months prior to the failure being detected. The cause of failure was diagnosed as a "mechanical overload". The implant was removed uneventfully. The patient subsequently exited from the study and the implant was later replaced after adequate healing time was allowed.

3.2. Microbiologic Outcomes

RT-PCR showed the presence of FN, TD and TF in 75%, 100% and 92% of patients, respectively. AA was absent in all patients, PG was present in only one patient (8%) and PI was detected in 58% of patients, thus these bacteria were not included in the subsequent statistical analyses due to their low incidence value in the analysed samples. Kruskal-Wallis nonparametric statistics showed no differences between test, control and adjacent tooth in the abundance of FN (p = 0.67), TD (p = 0.62) and TF (p = 0.72) when analysed separately. The sum of all these bacteria were also not significantly different among test, control and adjacent tooth (p = 0.83).

The presence of these bacteria (FN, TD and TF) was similar for the implants and for the tooth adjacent to the implants (Table 3). The only significant difference was in the test implants where the percentage of patients showing the presence of TD was higher than the presence of FN ($\chi 2$ = 6.8, p = 0.01).

Table 3. Subgingival microbiota from RT-PCR along test, control implants, and adjacent teeth.

	FN			**TD**			**TF**		
	Test	**Control**	**Tooth**	**Test**	**Control**	**Tooth**	**Test**	**Control**	**Tooth**
abundance (mean ± sd)	6.1 ± 13.9	76.1 ± 256.3	1.3 ± 1.7	77.2 ± 265.4	10.5 ± 34.5	2.5 ± 7.7	9.4 ± 26.3	8.9 ± 24.6	1.8 ± 5.4
abundance (median)	0	390	470	250	249	249	249	249	249
presence (% of patients)	42	58	67	92	92	75	75	67	67

Abundance is expresses as (Geq)/mL × 10^3. **FN:** *Fusobacterium nucleatum*; **TD:** *Treponema denticola*; **TF:** *Tannerella forsythensis*.

These results evidenced that the implants did not show a different abundance of bacteria compared to the tooth and that the test and the control implants had no difference in bacterial colonization.

4. Discussion

As dental implants continue to enter the "main-stream" of dentistry, demand for predictable dental implant therapy continues to grow. To what extent implant design modifications such as PS and LM can tweak and perfect an already predicable, albeit imperfect, treatment modality is still an unanswered question. Both LM collars and PS collar designs have shown promise in clinical application. However, to the authors' best knowledge, no study has been conducted to test whether the addition of PS to LM collar implants and abutments will show additional benefit over and above LM collar implants and abutments alone.

The primary outcome evaluated in the present study was the comparison between test and control implants on the difference in MBL values at 6 months and 12 months follow-ups compared to baseline (ΔMBL values in Table 2). No significant differences between test and control implants were found in the temporal variation of MBL values. MBL changes obtained in the present study are smaller than those found via meta-analysis for both LM collar implants: 0.72 mm (95% CI: 0.59 to 0.85 mm) [11] and PS implants, 0.49 mm (95% CI: 0.38 to 0.60 mm) [16]. However, it should be stressed that the present study is shorter in duration than many studies included in the meta-analysis and further bone remodelling may occur over time. The marginal bone loss in both groups is well within the success criteria proposed by Albrektsson: less than 1.5 mm bone loss after the first year in function, and less than 0.2 mm per year [52]. According to the newest classifications of peri-implant health and disease, there is no maximum value of early marginal bone remodelling after placement of an implant; however, all implants were well below the 3-mm threshold to diagnose peri-implantitis without a previous radiograph as proposed by the newest classifications [50]. The average MBL change from baseline, 6-month and 12-month follow-ups in test implants was found to be statistically significant, although there was no statistically significant change noted from 6-month to 12-month. Hence, in the present investigation the bulk of the bone remodelling appeared to have occurred in the first 6 months after placement. No clinically statistically significant bone remodelling was detected in the months following restoration. This is in agreement with a study by Herman et al. where marginal bone remodelling was detectable radiographically as early as one month after placement of transmucosal implants in a dog model [53] and it is also corroborated by a study by Vandenweghe et al. [54] where the vast majority of bone remodelling was seen to occur in the first 6 months of placement in immediately loaded implants.

From baseline to final review, there was a slight gain in MTH (0.5%) in test implants, but this increase was not significant. MTH variation in soft tissues was not found to be different between test and control implants. Such little soft tissue remodelling could be considered "successful" given the apparent tissue stability. These changescompare favourably to the soft tissue changes reported around LM collar implants which range from 0.16 ± 0.3 mm to 1.08 ± 0.4 mm [40,41].

PPD values did not change significantly over time in control and test implants. In addition, PPD values were not different between test and control implants at baseline and at final review. Although there is no PPD strictly defining disease [50], the most recent classification indicates that, without previous records, a PPD equal or greater than 6 mm with BOP and signs of inflammation can be considered as peri-implantitis [50]. Furthermore, deep PPD is associated with a higher chance of BOP [55] which in turn is predictive of progressive bone loss [56]. Hence, test and control implants appeared to have clinically acceptable readings at both time points, and no signs of "disease associated" pocket depths were recorded.

Regarding the BOP, no difference was found in the recordings between tests and controls at the 12-month follow-up. Of the six sites probed, the average number of BOP positive sites per implant was 1.18 ± 1.25 and 1.00 ± 1.00 for control and test implants, respectively. At the final review, no BOP was recorded in 9 out of 22 implants and 3 out of 10 patients. Literature suggests that 19%–65% of implants have peri-implant mucositis [57].

In the present study 59% of the implants tested positive for BOP; however, these data should not lead to an incorrect diagnosis of peri-implant mucositis. Indeed, the recent classification requires a line or droplet of BOP rather than simply a drop for peri-implant mucositis diagnosis [58]. In the present study, only one implant (4.5%) was diagnosed with peri-implant mucositis due to "line and droplet" BOP production along with visible inflammation, which was resolved after oral hygiene revision. This percentage compares favourably to the data reported in a recent study where 19.5% of LM implants were diagnosed as having peri-implant mucositis [59], although that study was 5 years in duration and hence to draw conclusions from this comparison would be inappropriate.

Finally, the microbiologic differences between LM implants with PS (test) and without PS were compared.

5. Conclusions

To the authors' best knowledge, this is the first randomized, although pilot, study aimed at evaluating the microbiologic differences between these two types of implant characterized by an identical body design and surface, but a different platform width. No statistical differences were found in the abundance of periodontal pathogens between test, controls and adjacent teeth. These results indicate that LM surface does not appear to promote a "pathogenic" plaque accumulation when compared to the surface of natural teeth. This might be due to this kind of microgeometry which claims to alter soft tissue responses to dental implants, establishing a predetermined site for connective tissue attachment and a subsequent "seal" [23,24,28,29]. These data also show that the presence of PS does not further alter bacterial colonization. Important limitations of the present study are the small sample size and the short follow-up period. Accordingly, final confirmation of findings needs further studies with longer periods of observation with an increased number of implants.

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Abbreviations

LM	laser micro-texturing
PS	platform switched
MBL	marginal bone level
PPD	peri-implant probing depth
BOP	bleeding on probing
MTH	marginal tissue height; Δ-change in
FN	*Fusobacterium Nucleautum* ssp.
TD	*Treponema denticola*
TF	*Tannerella forsythensis*
AA	*Aggregatibacter actinomycetemcomitans*
PG	*Porphyromonas gingivalis*

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