

Meta Analysis Dental Implants

Platform-switching implants and bone preservation: a systematic review and meta-analysis

J. F. Santiago Junior¹,
V. E. de Souza Batista², F. R. Verri²,
H. M. Honório³, C. C. de Mello²,
D. A. dF.Almeida², E. P. Pellizzer²

¹Department of Health Sciences, Sacred Heart University, Bauru, São Paulo, Brazil;

²Department of Dental Materials and Prosthodontics, Dental School of Araçatuba, UNESP – Universidade Estadual Paulista, Araçatuba, São Paulo, Brazil; ³Department of Scientific Methodology and Statistics, Bauru School of Dentistry, USP – University of São Paulo, São Paulo, Brazil

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Abstract. The aim of this study was to perform a systematic review and meta-analysis to evaluate the possible benefits of platform-switching (PSW) implants when compared to regular platform (RP) implants in the categories of bone preservation and longevity. This systematic review and meta-analysis was performed in accordance with the PRISMA statement, PICO question, and Jadad scale. The relative risk (RR) of failure and the mean difference for marginal bone loss were calculated considering a confidence interval (CI) of 95%. Heterogeneity and subgroup analyses were performed, and funnel plots drawn. Twenty-five studies (17 randomized controlled trials (RCTs) and eight prospective studies) involving 1098 patients and 2310 implants were analysed. The meta-analysis revealed a significant reduction in crestal bone loss for PSW implants compared with RP implants (-0.41 mm, 95% CI -0.52 to -0.29 , $P < 0.00001$). However, there was no statistically significant difference in implant failure (RR 1.10, 95% CI 0.6–2.02, $P = 0.75$). A reduction in bone loss with PSW implants was observed for the following subgroups: RCTs only, implants in the maxilla, and implants in the mandible. PSW implants presented lower bone resorption compared with RP implants. RCTs should be done to explain the possible biases.

Keywords: dental implants; alveolar bone loss; dental implant platform switching; meta-analysis; review.

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The introduction of larger-diameter implants during a period when compatible prosthetic components were not accessible allowed for standard prosthetic components (4.1 mm) to be used with large-diameter implants (5 mm and 6 mm). This concept became known as ‘platform switching’.¹ The first clinical case studies^{2–4} and retrospective studies^{1,5} on

platform switching indicated a lower rate of bone loss around these dental implants when compared with implants that received prosthetic abutments of the same diameter platform (Fig. 1).

Several theories have emerged to explain the lower bone loss with this platform-switching treatment modality.^{1,6–9} It has been suggested that positioning the

implant/abutment interface away from the bone crest allows the biological width to be determined horizontally, enabling the creation of an additional horizontal surface area for the attachment of soft tissue.⁷ The peri-implant microbiota is another relevant factor, since the design of these implants can increase the distance between the inflammatory cell infiltrate

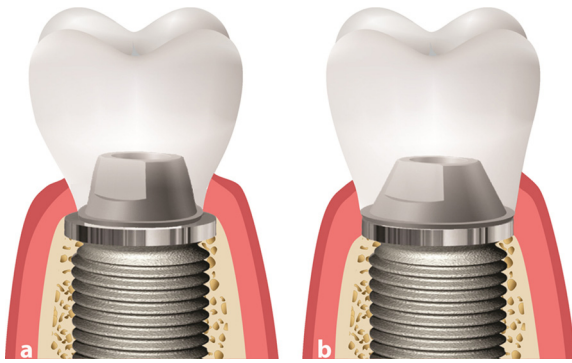


Fig. 1. Illustrative image of the platform-switching implant concept (A), showing a narrower prosthetic abutment and lower peri-implant bone loss when compared with the standard model of a regular platform implant (B).

and the bone crest, thereby minimizing the effects of inflammation on peri-implant marginal bone with platform-switching (PSW) implants.^{1,8} Finally, there is a biomechanical theory that relates the possibility of centralization stress on the long axis of these implants, thus reducing tension in the peri-implant cortical bone.^{6,9}

After the phenomenon of bone preservation was confirmed, clinical studies evaluating the platform-switching concept began to appear. However, several case reports presented a sample of 10 patients or fewer.^{3,4,10–13} Randomized controlled trials (RCTs) with the aim of comparing the effects of PSW implants and regular platform (RP) implants in patients have emerged in the last 5 years,^{14–27} allowing the preparation of literature reviews addressing the topic of bone preservation around these implants.^{28–32} However, there remains a need to clarify the effects of PSW implants in relation to marginal bone loss, as indicated by previous systematic reviews.^{7,33,34}

Recently, RCTs have been published addressing the issue of PSW implants,^{16–18,23–27} leading to the need for an updated analysis of published studies. Moreover, biomechanical studies have been published that may provide further insight into the proposed subject.^{9,35} Thus, the aim of this study was to conduct a systematic review and meta-analysis of the proposed topic. The null hypothesis was that PSW implants show a rate of bone remodelling similar to RP implants.

Materials and methods

This study was conducted in accordance with the criteria put forward in the PRISMA-2009 guidelines.³⁶ The PICO question was formulated. This study was

also performed with reference to other previous systematic reviews^{37,38} and meta-analyses.^{39,40}

Protocol and registration

This systematic review was registered in the PROSPERO database, an international prospective register of systematic reviews in health and social care (National Institute for Health Research, UK; pre-protocol CRD 42013005728).

Eligibility criteria

The studies selected for this analysis met the criteria established by the index PICO: (1) population: patients undergoing dental implant surgery; (2) intervention: patients receiving implants with a platform-switching geometry; (3) comparison: patients receiving implants with a regular abutment; (4) outcome: the main outcomes were the comparison of bone loss and implant survival rates (platform-switching and regular platform).

Inclusion criteria were the following: articles published in the English language; studies with at least 12 months of follow-up (clinical studies in humans); RCTs and prospective studies with at least five implants (titanium implants) placed in the control group (RP) and in the study group (PSW).

Sources of information

The MEDLINE/PubMed, Cochrane Central Register of Controlled Trials, and EMBASE databases were searched. These searches were conducted for articles published up until 1 July 2015. All studies identified by the inclusion criteria were analysed. Authors were contacted when necessary to obtain possible additional information.^{16,19,41–43}

Search

Key words available in medical subject headings (MeSH, PubMed) related to PSW implants and RP implants were selected. The Boolean search operators used were ‘Dental Implant Platform Switching’ and ‘Platform Switching, Dental Implant,’ and the key words were ‘dental implant–abutment design’ [MeSH Terms] OR (‘dental’ [All Fields] AND ‘implant–abutment’ [All Fields] AND ‘design’ [All Fields]) OR ‘dental implant–abutment design’ [All Fields] OR (‘dental’ [All Fields] AND ‘implant’ [All Fields] AND ‘platform’ [All Fields] AND ‘switching’ [All Fields]).

A manual search of journals published over the last 6 months was also done: *Clinical Implant Dentistry and Related Research*, *Clinical Oral Implant Research*, *Implant Dentistry*, *International Journal of Oral and Maxillofacial Surgery*, *Journal of Clinical Periodontology*, *Journal of Dental Research*, *Journal of Maxillofacial and Oral Surgery*, *Journal of Oral Implantology*, *Journal of Periodontology*, *Journal of Prosthetic Dentistry*, *Journal of Prosthodontics*, *Journal of Oral Rehabilitation*, *Oral Medicine*, *Oral Pathology*, *Oral Radiology*, and *Endodontics*, *Periodontology 2000*, *International Journal of Oral and Maxillofacial Implants*, and *International Journal of Periodontics and Restorative Dentistry*.

Process of data collection

Study selection was organized independently by two calibrated examiners (J.F.S. and V.E.S.B.) and by a third reviewer (E.P.P.). Inter-examiner (kappa) tests were conducted to evaluate the selection of titles and abstracts, and complete reading with interpretation of the article, resulting in concordance test values of $\kappa = 0.88$, 1, 1 for MEDLINE/PubMed, $\kappa = 1$, 1, 1 for Cochrane Central Register of Controlled Trials, and $\kappa = 1$, 1, 1 for EMBASE. For the MEDLINE/PubMed database search, a meeting was required to reach consensus, in which all the discrepancies were discussed and resolved by the third reviewer (E.P.P.). All titles and abstracts evaluated as eligible were separated and analysed completely. A manual search of the journals was conducted by one reviewer (J.F.S.) and independently by another reviewer (V.E.S.B.), adding six articles to the original sample.^{19,27,41–44}

The selection of studies for the systematic review and meta-analysis is shown in detail in Fig. 2, as recommended in the literature.³⁶

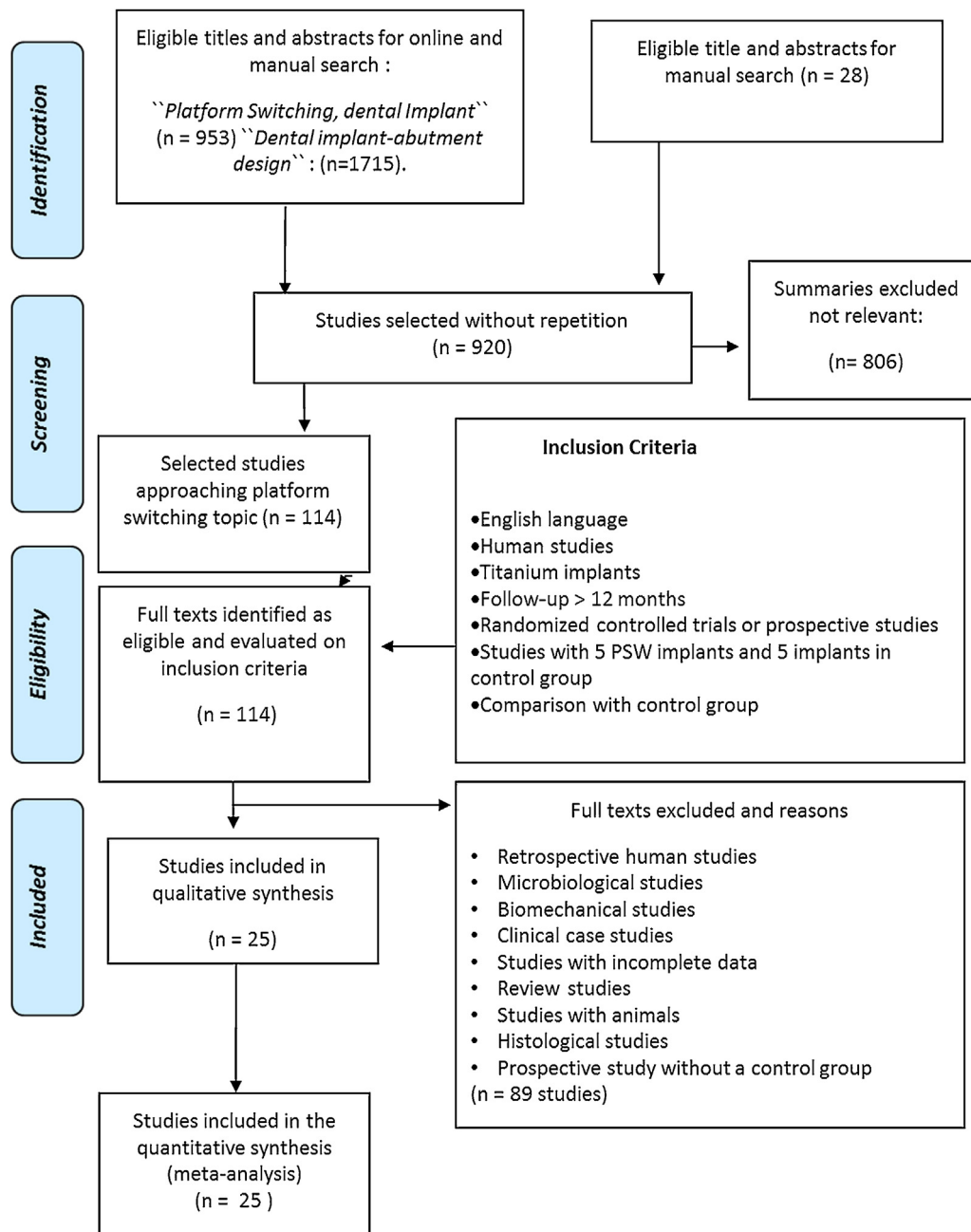


Fig. 2. Flow diagram of study selection for the systematic review.

Data items

The following data were extracted from each study: (1) author; (2) publication year; (3) number of patients; (4) number of implants and sites; (5) implant system; (6) length and diameter of implants; (7) timing of the installation of prostheses; (8) mismatching of the platform and implant; (9) bone remodelling rate for implants – platform switching and control group; (10) survival rate of implants for each situation analysed; (11) follow-up time after implant placement; and (12) study design analysed.

Quality analysis of the studies included in the systematic review

The quality of each study included in this review was assessed using the Jadad scale.⁴⁵ They were thus classified on a scale of 0–5, with a score above 3 indicating an appropriate study.

Summary measures

For the purpose of comparing the success rate of implants using the concept of platform switching with the regular platform (a dichotomous outcome), the risk ratio

(RR) with 95% confidence interval (CI) was used.^{33,46}

In order to analyse the rate of peri-implant bone loss (continuous outcome), the average bone loss for the RP implants and PSW implants was identified, and the overall standard deviation of each group was analysed. The weight contribution was also calculated in the analyses.

A *P*-value of <0.05 was considered to indicate statistical significance. The software program Review Manager was used for the meta-analysis, as well as to construct forest and funnel plots (RevMan version 5.3; The Nordic Cochrane Centre,

The Cochrane Collaboration, Copenhagen, Denmark, 2014).

Risk of bias in the studies

The fixed-effects model was used when there was no statistically significant difference, and the random-effects model was adopted when there was a statistically significant difference, i.e., a high level of heterogeneity between trials was considered significant for $P < 0.1$. Heterogeneity was assessed using the Q method (χ^2), and the value of I^2 was calculated. The statistical value of I^2 was used to analyse the variations in heterogeneity: I^2 above 75 (0–100) was found to indicate relevant heterogeneity.^{33,34} Funnel plots were used to assess heterogeneity.⁴⁷

Additional analyses

In order to analyse the sensitivity of the tests employed, a subgroup analysis was performed to identify any potential causes of heterogeneity.^{34,39,46} Specifically, the subgroups considered were (1) RCTs only, (2) installation in the maxilla, and (3) installation in the mandible. Furthermore, funnel plots (effect size vs. standard error) were used to evaluate bias, with asymmetry indicating a possible bias in the studies evaluated.^{33,34,46}

Results

The database search identified 1715 articles; Fig. 2 shows the article selection process. A total of 25 studies were eligible, reporting 1098 patients with 2310 implants placed. The average age of patients included in all of the studies, except for three clinical studies,^{13,43,48} was 50.73 years. The main results are summarized in Table 1.^{13–27,41–44,48–53}

Experimental design

Of the 25 studies selected, 17 were RCTs^{13,15–26,41,49–51} and eight were controlled prospective studies^{14,27,42–44,48,52,53}; these were published during the period 2007–2015. Three studies considered samples at two locations,^{17,21,49} 13 studies were conducted in only one centre,^{14–16,18,19,23,26,41–44,51,53} and five studies were multicentre^{22,24,25,27,50}; related data were unclear for four studies.^{13,20,48,52}

Patient selection

The studies analysed reported various inclusion criteria for patient selection.

Inclusion criteria encompassed healthy subjects, age >18 years,^{25,26,44} no medical contraindication,⁴⁹ non-smoking or smoking patients consuming ≤ 10 cigarettes per day^{25,26,43,49} or ≤ 20 cigarettes per day,⁵¹ a plaque and bleeding index $\leq 25\%$ and availability of longitudinal follow-up,⁴⁹ and a keratinized mucosa ≥ 4 mm and adequate thickness of soft tissue (medium/wide).^{15,25}

The exclusion criteria included sites of acute infection, history of bisphosphonate treatment, buccal gingival recession, periodontal disease in adjacent teeth,^{19,25,26,49} uncontrolled diabetes or pregnant/breast-feeding patients,^{21,23} sites of <7 mm in width, sites with buccolingual defects,²⁰ fenestrations or dehiscence, coagulation disorders, excessive consumption of alcohol or drugs and bruxism,^{14,24,25,44} osteoporosis, poor oral hygiene,⁴² temporomandibular disorders,¹⁷ previous irradiation at the implant site, psychological disorders, inability of the patient to provide informed consent,^{23,24,27,43,44,50} unrealistic expectations,⁵¹ implants installed with torque ≤ 35 N cm,^{24,26,41,44} American Society of Anesthesiologists (ASA) status $\geq III$,^{13,27} and patient was due to receive rehabilitation requiring a prosthesis with a cantilever.

Surgical stage

Different medication protocols were recommended before the surgical stage. Oral hygiene was established before the procedure.^{21,23,26,49} Antibiotics and antiseptics were given 1 day before the procedure when surgery was proposed for immediate loading.⁴⁹ Furthermore, 1 g penicillin and clavulanic acid before surgery and every 12 h for 6 days,²¹ or 1 g amoxicillin/clavulanic acid 1 h before surgery and afterwards for 6 days (2 g/day),^{20,24,42,51} were proposed; another option was amoxicillin 1 g given 1 h before surgery and 1 g twice a day for 1 week after surgery.¹⁴ As well as these options, a single dose of 2 g of prophylactic antibiotic (amoxicillin/clavulanic acid or phenoxymethylpenicillin potassium) was recommended for use 1 h before surgery,^{22,26,41,43} and 1 g amoxicillin/clavulanic acid was recommended 6 h after surgery²² or 2 g/day of antibiotic (phenoxymethylpenicillin potassium) for 10 days.⁴³ Ibuprofen (600–800 mg) or ketoprofen (80 mg) was administered for pain control in some studies.^{16,24,26,41,44,51}

Regarding the distances between the implants and teeth, a minimum distance was observed between tooth and implant and between implant and implant of

2.5 mm,²⁰ or of 3 mm between implants and 1.5–2 mm between implant and tooth.^{15,23,25} Another option was to maintain a distance between tooth and implant of 1.5 mm and of 3 mm between implants.^{18,19,41}

A soft diet and gentle brushing were recommended for a period of time post-operative.^{20,26,44} Chlorhexidine mouth rinse 0.12%^{43,50} was often used for 1–3 weeks.^{14,15,20,43,44} In addition, the use of chlorhexidine was suggested at 0.2% for different periods.^{24,26,41,51}

In some studies, the surgical procedures of immediate extraction were conducted, maintaining the integrity of the lateral walls and avoiding fenestration or dehiscences.^{14,21,43,51} In two studies, all surgical procedures were performed by a single surgeon,^{19,42} and in one study, the surgical procedures were performed by any of 12 surgeons, each with more than 10 years of experience.²² One study used the procedure of maxillary sinus lifting when there was 4 mm of residual bone.²⁰

Bone quality was measured in some studies⁵⁴: this was of type I and II⁴²; II and III^{14,17,22}; I–IV^{43,50}; II, III, and IV¹⁹; and I, II, and III,⁵³ or dense (type I), normal (types II and III), and soft bone (type IV).²⁷

Number of patients, implants, follow-up, loading type, and location

In this meta-analysis, 1098 patients received 1177 PSW implants and 1104 RP implants (total 2266 implants, as duplicate implants were excluded¹⁶). The follow-up period ranged from 12 months^{15–19,24,25,41–44,48,50–52} to 60 months.⁵³ Furthermore, five studies considered the procedure of immediate loading,^{14,21,43,50,51} conducting the installation of the implants below the apex by 3 mm²¹ or 4 mm¹⁴, or at 2–3 mm subcrestally.⁴³ The initial torque was reported to be 32–45 N cm in one study,²¹ and ≥ 35 N cm in three studies.^{14,44,50} Moreover, in one study, when the distance between the implant and the buccal wall exceeded 1 mm, a mixture of bone matrix and blood was used,²¹ and in another clinical study, a mixture of autogenous bone and bovine matrix was used in all cases.⁵¹

Analysis of the implants

Some studies did not report the type of connection used.^{18–20,22,24,42,49,52} Nine studies used the internal connection^{13,15,21,23,25,27,43,44,48}, two used the external hexagon,^{16,53} and one used the Morse taper.¹⁷ Two systems of connections

Table 1. Features of the articles included in the review.

Studies	Authors						
	Canullo et al. ²⁰	Canullo et al. ²¹	Canullo et al. ⁴⁹	Cappiello et al. ⁴⁸	Crespi et al. ¹⁴	Dursun et al. ⁴²	
Study design	RCT	RCT	RCT	Prospective	Prospective	Prospective	
Patients (<i>n</i>)	31	22	9	45	45	19	
Age, years (mean)	52.1	50	59	NR	48.73	42.93	
Implants (<i>n</i>)	61 (G1, 17; G2, 13; G3, 14; CG, 17)	22 (G1, 11; CG, 11)	22 (G1, 6; G2, 5; G3, 6; CG, 5)	131 (G1, 75; CG, 56) ^b	64 (G1, 30; CG, 34)	32 (G1, 16; CG, 16)	
Implant location	Posterior maxilla	Maxilla	Posterior maxilla	NR	Maxilla and mandible	Maxilla and mandible	
Implant system ^a	Global	Global	Global	3i	Seven and Ankylos	PS system and SP system	
Connection	NR	Internal	NR	Internal	CG, EH; PSW, MT	NR	
Length (mm)	NR	NR	13	10, 11.5, 13	14	11	
Diameter (mm)	3.8, 4.3, 4.8, 5.5	5.5	3.8–5.5	4	3.8–5.5	CG, 3.75; PSW, 3.8	
Loading protocol (months)	Delayed	Immediate	Delayed	2	Immediate	Delayed	
Definitive rehabilitation (months)	3	2	2–3	12	6	3	
Implant–abutment diameter difference on each side (mm)	CG, 0; G1, 0.25; G2, 0.5; G3, 0.85	CG, 0; G1, 0.85	CG, 0; G1, 0.25; G2, 0.5; G3, 0.85	CG, 0; G1, 0.4	NC	G, 0.37	
Marginal bone level changes (mean (SD), mm)	G1, 0.99 (0.42) G2, 0.82 (0.36) G3, 0.56 (0.31) ^c CG, 1.49 (0.54)	G1, 0.3 (0.16) CG, 1.19 (0.35)	G1, 0.832 (0.3939) G2, 0.486 (0.2242) G3, 0.375 (0.1234) ^c CG, 1.358 (0.3939)	G1, 0.95 (0.32) CG, 1.67 (0.37) ^d	G1, 0.78 (0.45) CG, 0.73 (0.52)	G1, 0.84 (0.36) CG, 0.76 (0.41)	
Survival rate (%)	100	100	100	G1, 98.3; CG, 100 G1, 1	100	100	
Failures (<i>n</i>)	0	0	0	12	0	0	
Mean follow-up period (months)	33	25	36	12	24	12	
Jadad scale	4	5	4	1	2	1	
Studies	Authors						
	Enkling et al. ¹⁵	Fernández-Formoso et al. ¹⁷	Hurzeler et al. ⁵²	Kielbassa et al. ⁵⁰	Pieri et al. ⁵¹	Pozzi et al. ⁴¹	Prosper et al. ²²
Study design	RCT	RCT	Prospective	RCT	RCT	RCT	RCT
Patients (<i>n</i>)	25	51	15	177	38	34	60
Age, years (mean)	51	43.3	55.3	48.7	46.6	52.2	53.9
Implants (<i>n</i>)	50 (G1, 25; CG, 25)	114 (G1, 58; CG, 56)	22 (G1, 14; CG, 8)	325 (G1, 199; CG, 126)	40 (G1, 20; CG, 20)	88 (G1, 44; CG, 44)	360 (G1, 180; CG, 180)
Implant location	Posterior mandible	Maxilla and mandible	Maxilla and mandible	Maxilla and mandible	Posterior maxilla	Posterior mandible	Maxilla and mandible
Implant system ^a	SICace Invent	Straumann	3i	Nobel Biocare	Samo Smiler	Nobel Biocare	Bioactive
Connection	IH	MT	NC	IH, 117; EH, 82; CG, 126	G1, MT; CG, IH	G1, IH; CG, EH	NC
Length (mm)	9.5	CG, 8–12; PSW, 8–14	NC	10, 11.5, 13, 15, 16	NC	10–13	11, 13, 15
Diameter (mm)	4	3.3, 4.1, 4.8	5.0	3.5 or 4.3	NC	CG, 4.0; G1, 4.3	3.3, 3.8, 4.5
Loading protocol (months)	3	NC	NC	Immediate	Immediate	2	Delayed
Definitive rehabilitation (months)	12	NC	NC	12	4	4	3 (mandible); 6 (maxilla)
Implant–abutment diameter difference on each side (mm)	0.35	NC	0.45	NC	0.35	NC	0.25/0.35

Table 1 (Continued)

Studies	Authors						
	Enkling et al. ¹⁵	Fernández-Formoso et al. ¹⁷	Hurzeler et al. ⁵²	Kielbassa et al. ⁵⁰	Pieri et al. ⁵¹	Pozzi et al. ⁴¹	Prosper et al. ²²
Marginal bone level changes (mean (SD), mm)	G1, 0.53 (0.35) CG, 0.58 (0.55)	G1, 0.68 (0.88) CG, 2.23 (0.22)	G1, 0.22 (0.53) CG, 2.02 (0.49)	IH, 0.95 (1.37) EH, 0.64 (0.97) CG, 0.63 (1.18)	CG, 0.51 (0.24) G1, 0.2 (0.17)	CG, 1.15 (0.34) G1, 0.68 (0.34)	CG, 0.193 (0.474) G1, 0.055 (0.234)
Survival rate (%)	100	100	100	IH, 96.6; EH, 96.3; CG, 97.6	CG, 100; G1, 94.7	100	CG, 96.7; G1, 100
Failures (n)	0	0	0	10 (IH, 4; EH, 3; CG, 3)	1	0	6
Mean follow-up period (months)	12	12	12	12	12	12	24
Jadad scale	3	3	1	3	3	2	3
Studies	Authors						
	Telleman et al. ¹⁹	Telleman et al. ¹⁸	Trammell et al. ¹³	Vandeweghe and De Bruyn ¹⁶	Vigolo and Givani ⁵³		
Study design	RCT	RCT	RCT	RCT	Prospective		
Patients (n)	17	78	10	15	144		
Age, years (mean)	53.7	49.8	NC	57	37		
Implants (n)	62 (G1, 31; CG, 31)	113 (G1, 55; CG, 58)	25 (G1, 13; CG, 12)	15 (G1,15; CG, 15) ^e	182 (G1, 97; CG, 85)		
Implant location	Maxilla and mandible	Maxilla and mandible	Mandible	Maxilla and mandible (posterior)	Maxilla and mandible (posterior)		
Implant system ^a	3i	3i	3i	Southern Implants	3i		
Connection	NC	NC	IH	EH	EH		
Length (mm)	8.5	8.5	8.5, 10, 11.5, 13	7	NR		
Diameter (mm)	4.1 or 5.0	4.1 or 5.0	4, 5, or 6	7	5		
Loading protocol (months)	Delayed	Delayed	Delayed	Delayed	Delayed		
Definitive rehabilitation (months)	3	3	6	6	4		
Implant–abutment diameter difference on each side (mm)	0.35 or 0.4	0.35 or 0.4	0.45	1	0.5		
Marginal bone level changes (mean (SD), mm)	G1, 0.53 (0.54) CG, 0.85 (0.65)	G1, 0.51 (0.51) CG, 0.73 (0.48)	G1, 0.99 (0.53) CG, 1.19 (0.58)	G1, 0.66 (0.47) ^e CG, 0.94 (0.42)	G1, 0.6 (0.2) CG, 1.1 (0.3)		
Survival rate (%)	93.6	CG, 93.1; CG, 94.5	100	100	100		
Failures (n)	4 (G1, 2; CG, 2)	CG, 4; G1, 3	0	0	0		
Mean follow-up period (months)	12	12	24	12	60		
Jadad scale	3	1	2	2	1		
Studies	Authors						
	Enkling et al. ²³	Del Fabbro et al. ²⁷	Glibert et al. ⁴³	Meloni et al. ²⁴	Pozzi et al. ²⁶	Wang et al. ⁴⁴	Guerra et al. ²⁵
Study design	RCT	Prospective	Prospective	RCT	RCT	Prospective	RCT
Patients (n)	25	51	48	18	34	19	68
Age, years (mean)	51	55.4	>18	48	52.2	55.4	52.84
Implants (n)	50 (G1, 25; CG, 25)	117 (G1, 55; CG, 62)	115 (G1, 45; CG, 70)	36 (G1, 18; CG, 18)	88 (G1, 44; CG, 44)	30 (G1, 15; CG, 15)	146 (G1, 74; CG, 72)
Implant location	Posterior mandible	Maxilla and mandible	Maxilla and mandible	NR	Posterior mandible	Maxilla and mandible	Posterior mandible
Implant system ^a	SICace Invent	Dental Tech	3i	Nobel Biocare	Nobel Biocare	Superline	Camlog
Connection	IH	IH	IH	NR	G1, IH; CG, EH	IH	IH
Length (mm)	9.5	8–16	8.5–15	8 or 10	8.5–13	8–12	9–13
Diameter (mm)	4.0	3.75 and 4.75	4.0 and 5.0	4.3 and 5.0	3.9 and 4.1	4.5	3.8, 4.3, 5.0

Table 1 (Continued)

Studies	Authors						
	Enkling et al. ²³	Del Fabbro et al. ²⁷	Glibert et al. ⁴³	Meloni et al. ²⁴	Pozzi et al. ²⁶	Wang et al. ⁴⁴	Guerra et al. ²⁵
Loading protocol (months)	Delayed	2/4–6	Immediate non-occlusal/delayed	Delayed	Delayed	Delayed	Delayed
Definitive rehabilitation (months)	4	2/4–6	3	6	4	3	2–3
Implant–abutment diameter difference on each side (mm)	0.35	0.5, 0.75, 1.25	0.45	0.35	0.2	0.6	0.3, 0.35
Marginal bone level changes (mean (SD), mm)	G1, 0.69 (0.43) CG, 0.74 (0.57)	G1, 0.33 (0.19) CG, 0.48 (0.26)	G1, 0.63 (0.18) CG, 1.02 (0.14)	G1, 0.84 (0.23) CG, 0.93 (0.26)	G1, 0.83 (0.27) CG, 1.29 (0.42)	G1, 0.04 (0.08) CG, 0.19 (0.16)	G1, 0.40 (0.46) CG, 0.69 (0.68)
Survival rate (%)	100%	G1, 90.3%; CG, 96.5%	100%	100%	100%	100	G1, 97.3%; CG, 100%
Failures (n)	0	G1, 5; C, 2	0	0	0	0	G1, 2
Mean follow-up period (months)	36	36	12	12	36	12	12
Jadad scale	3	3	2	5	3	3	3

CG, control group; EH, external hexagon; G, different groups (1, 2, 3); IH, internal hexagon; MT, Morse taper; NC, not clear; NR, not reported; PSW, platform-switching; RCT, randomized controlled trial; SD, standard deviation.

^a Global: Global, Sweden-Martina, Padua, Italy; 3i: 3i Implant Innovations, Palm Beach Gardens, FL, USA; Seven: Seven Sweden-Martina, Padua, Italy; Ankylos: Dentsply Friadent, Mannheim, Germany; PS system: Revois, Curasan AG, Frankfurt, Germany; SP system: tapered Screw vent, Zimmer Dental, Carlsbad, CA, USA; SICace Invent: SICace, SIC Invent, Basel, Switzerland; Straumann: Straumann, Basel, Switzerland; Nobel Biocare: Nobel Biocare, Gothenburg, Sweden; Samo Smiler Implants: BioSpark, Burlington, MA, USA; Bioactive: Bioactive Covering SLA, Winsix, London, UK; Southern Implants: Max Implants – Southern Implants, Irene, South Africa. Dental Tech: Dental Tech Srl, Misinto, Milan, Italy. Superline: Superline, Dentium USA, Cypress, CA, USA; Camlog: Camlog Biotechnologies AG, Basel, Switzerland.

^b This study considered the placement of 56 control implants and 75 test implants (PSW); however 73 PSW concept implants (1 failed implant) and 55 control implants were included in the follow-up (Cappiello et al.⁴⁸).

^c This PSW group was considered for the meta-analysis (Canullo et al.²⁰ and Canullo et al.⁴⁹).

^d The data shown by authors for bone loss were related to 73 PSW implants and 55 control group implants (Cappiello et al.⁴⁸).

^e The implants (total of 15 implants PSW/non-switched) were considered PSW concept on one side and control group on the other side, therefore mean bone loss was analysed for both the switched and non-switched side (Vandeweghe and De Bruyn¹⁶).

were used in some studies: external hexagon in the control group and Morse taper in the PSW group¹⁴; internal hexagon and external hexagon in the PSW group⁵⁰; Morse taper in the PSW group and internal hexagon implants in the control group⁵¹; and internal hexagon implants in the PSW group compared with external hexagon implants in the control group.^{26,41}

Regarding surface treatments, the following types of implant were installed: surface treatment with micro-roughness,⁴⁹ sandblasting and etching,^{15,21,22,49} 0.3-mm machined neck,²¹ machined neck^{22,25} and micro-threads in the coronal portion,^{21,49,51} machined neck (0.8 mm) and surface titanium plasma spray,¹⁴ medium-rough surface,^{14,23} TiUnite (Nobel Biocare, Gothenburg, Sweden) surface,^{26,41,50} dual acid-etched surface,⁴³ titanium oxide enriched with calcium and phosphorus,⁵¹ SLA surface,⁴⁴ and NanoTite (3i Implant Innovations, Palm Beach Gardens, FL, USA).¹⁹

Timing of loading and final prosthesis

The definitive loading time was at least 2 months^{21,49} and a maximum of 12

months.^{15,25,48,50} Fixed prostheses,^{16,18–20,27,43,49,50,52} singles,^{15–17,19,21,26,27,41,43,50,53} and full-arch prostheses^{27,50} were used. The occlusal materials employed included ceramic fused to metal crowns in the permanent rehabilitation,^{14,41,42,48,51} full ceramic crowns cemented in a titanium or zirconium abutment,⁵¹ and acrylic resin crowns in temporary rehabilitations.¹⁴

A few complications were reported, such as loosening of the screw of a temporary abutment¹⁴ and prosthetic screw loosening mainly occurring in the molar area.⁴⁴ Kielbassa et al.⁵⁰ reported complications in implant-supported prostheses: loosening or loss of cementation of cemented crowns, or screw loosening (provisional). Furthermore, Pieri et al.⁵¹ reported two complications in the control group (RP): screw loosening and a fractured prosthesis, as it was reported that the provisional prosthesis loosened and had to be re-cemented. Furthermore, a titanium abutment was replaced with a zirconium abutment for aesthetic reasons.⁴³ Other studies with follow-up of 1–5 years did not indicate any type of prosthetic complication.^{24,53}

The authors recommended follow-up visits once every 6 months,^{21,49} or at different times: 1, 3, 6, or 12 months.⁴² Vigolo and Givani⁵³ suggested visits every 3 months during the first year and once every 6 months in subsequent years.

Methodological quality and risk analysis of studies

In an analysis of the quality of all studies included in this systematic review, the Jadad score ranged from 1 to 5. Seventeen RCTs and eight prospective studies were evaluated. The final scores are shown in Table 1; the full form of analysis is described in Appendix A.

There are some important concerns. Different models of randomization were employed for blinding of the patients (single-blind study). Authors used predefined tables, a randomization list,^{17,20,21,25,49,50} or software that generated a list of numbers.^{15,18,22–24,26,27,41,51} Furthermore, randomization in one study was done by letter method.¹³ The method of randomization was not reported in some of the RCTs,^{14,52} or there was a randomization of the position of the implants^{19,25–27}; other

prospective studies did not report a randomization system.^{42-44,48,53}

The pre-defined table or block-randomization list for randomization was used efficiently by several studies.^{17,20,21,25,49,50} In addition, some studies used software^{15,18,26,41,51} and some used envelopes.^{16,20-22,26,41,49,50} The system of tables and software allowed for the distribution of patients in the two study groups (PSW and control) according to the variables sex, age, gingival biotype, and tooth position²¹; localization²⁰; age, sex, and bone type¹⁷; sex, age, and smoking habit⁵¹; placement area and bone quality²²; and sex, age, location of the implant (maxilla or mandible), and number of implants.¹⁸ On the issue of randomization, Kielbassa et al.⁵⁰ found that randomization, although adequate, was unable to cover all of the possible interferences, such as the position of the implant.

With regard to blinding, two double-blind studies were included,^{21,43} there were 12 single-blind studies,^{14,15,17,20,22,24,26,27,41,49,51,53} and 11 studies did not present the data or presented unclear information.^{13,16,18,19,23,25,42,44,48,50,52} A power calculation to determine the appropriate sample size was performed in only eight studies^{15,18,22,26,27,41,50,51}; other studies included groups/subgroups of small samples of implants (≤ 15)^{13,20,21,49,52} or patients (≤ 15).^{16,49,52}

Some relevant information was missing, such as the connection type selected^{18-20,22,24,42,49,52}, the length of implants used,^{20,21,51-53} the diameter of the implants employed,⁵¹ the mean age of the patients analysed,^{13,43,48} the implant localization,^{24,48} the time of final rehabilitation,^{17,52} measures of the implant/abutment relationship,^{14,17,41,50} and the abutment diameter used.^{14,42}

Meta-analysis

Primary outcome

The primary outcome was the average bone loss (in millimetres) around the implants. All 25 studies (prospective studies and RCTs) were included in the final sample.^{13-27,41-44,48-53} In this sample, two studies included subgroups of PSW with various differences between the implant and abutment diameters (Canullo et al.²⁰: group 1, 0.25 mm; group 2, 0.5 mm; group 3, 0.85 mm; Canullo et al.⁴⁹: group 1, 0.25 mm; group 2, 0.50 mm; group 3, 0.85 mm). In both cases, group 3 of the PSW sample was selected for comparison with the control group (Table 1). Vandeweghe and De Bruyn¹⁶ showed a total of 15 implants in their clinical study, and the mean overall bone loss was calculated from both the switched and controlled sides. For inclusion, studies had to have a minimum follow-up of 12 months. The follow-up in the studies included in this review ranged from 12 months^{15-19,24,25,41-44,48,50-52} to 5 years,⁵³ with a mean longitudinal follow-up of 19.8 months.

In this context, 18 studies showed a statistically significant difference in favour of the use of PSW implants for bone preservation.^{13,16-22,25-27,41,43,48,49,51-53} However, seven studies did not show a significant difference when comparing the control group and PSW group.^{14,15,23,24,42,44,50}

The meta-analysis conducted with 17 studies, considering only RCTs, revealed significant bone loss in the control group compared with the PSW group, with a mean difference (MD) of -0.41 mm (95% CI -0.58 to -0.24 , $P < 0.00001$; Fig. 3). The χ^2 of heterogeneity was 218.51 ($P < 0.00001$, $I^2 = 93\%$).

In the next phase, when evaluating all the studies together, both prospective studies and RCTs (25 studies), it was observed that 1177 PSW implants and 1104 RP implants were installed; however, Vandeweghe and De Bruyn¹⁶ considered implants as having a PSW side and a control side. The average bone loss around the PSW implants was less than 0.57 mm (range 0.04–0.99 mm). This average was lower than that of the control group: 0.98 mm (range 0.19–2.23 mm). The meta-analysis conducted on the 25 groups (RCTs and prospective studies) revealed significant bone loss in the control group compared with the PSW group, with MD -0.41 mm (95% CI -0.52 to -0.29 , $P < 0.00001$; Fig. 4). The χ^2 of heterogeneity was 375.57 ($P < 0.00001$, $I^2 = 94\%$).

Secondary outcome

In a specific analysis of the number of implants lost during follow-up, studies showed no statistically significant difference when comparing the control group and PSW group.^{13-27,41-44,48-53} Of the total implants, 21 PSW implants and 17 RP implants failed.

In an analysis based on fixed effects, there was no statistically significant difference in the failure of implants (RR 1.10, 95% CI 0.6–2.02, $P = 0.75$; Fig. 5). No heterogeneity was observed intra-study ($\chi^2 = 6.5$, $P = 0.48$) or inter-study ($I^2 = 0$).

Analysis of subgroups

Several subgroups of variables were analysed in order to identify possible heterogeneity in the primary outcome.

A low number of studies considered the installation of implants in the maxilla

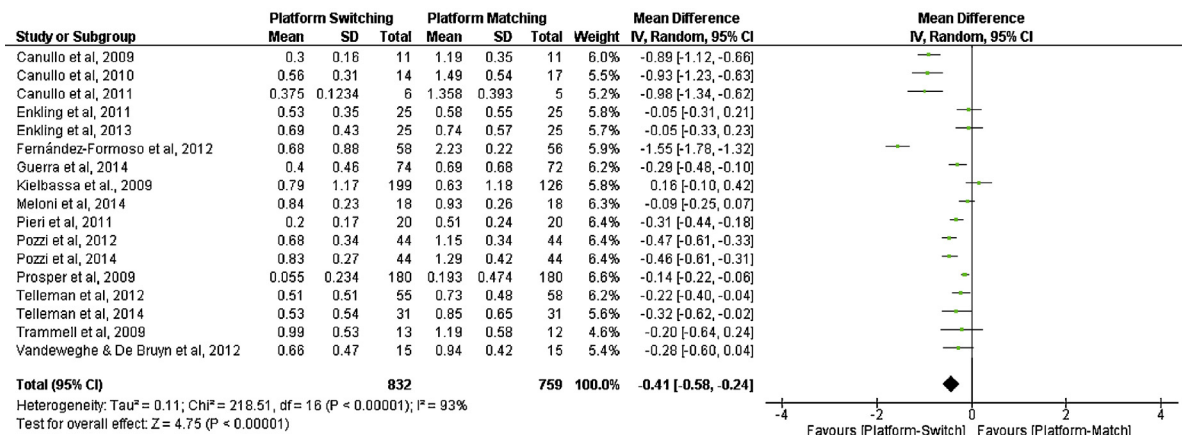


Fig. 3. Comparison of peri-implant bone loss between platform-switching implants and matching platform implants: randomized controlled trials (SD, standard deviation; IV, inverse variance; CI, confidence interval; df, degrees of freedom.).

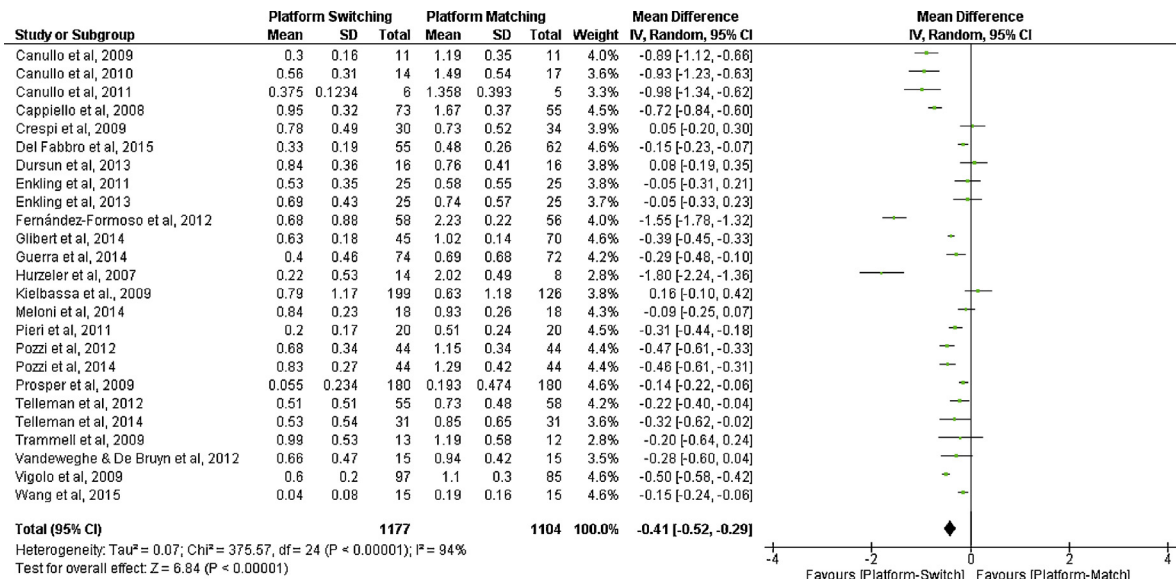


Fig. 4. Comparison of peri-implant bone loss between platform-switching implants and matching platform implants: randomized controlled trials and prospective studies (SD, standard deviation; IV, inverse variance; CI, confidence interval; df, degrees of freedom).

only; this sample showed a greater preservation of bone tissue for PSW implants when compared to RP implants (MD -0.76, 95% CI -1.16 to -0.37, P = 0.0001; Fig. 6A). Similarly, there was greater preservation of bone tissue in PSW implants installed in the mandible (MD -0.29, 95% CI -0.44 to -0.13, P = 0.0002; Fig. 6B).

Risk of bias in studies

The heterogeneity of the studies was considered low ($\chi^2 = 6.54, P = 0.48, I^2 = 0\%$)

in the category of failed implants, so the fixed-effects model was used. In contrast, the heterogeneity observed in studies of the primary outcome (marginal bone loss) and other subgroups was relevant ($\chi^2 = 375.57, P < 0.00001, I^2 = 94\%$), therefore the random-effects model was used.

The funnel plot showed clear asymmetry in relation to the mean differences of the studies analysed for marginal bone loss (Fig. 7A); however, symmetry of the funnel plot was demonstrated for the implant failure analysis (Fig. 7B). The possible

bias in these analyses is related to the small sample size found in some studies.

Discussion

The benefits of PSW implants shown in the past decade regarding the preservation of bone^{1,3,4} have been discussed extensively in the literature.^{18,19,41,42} In the last 8 years (2007–2015) there has been considerable interest in developing prospective trials and/or RCTs, which has provided a sample of relevant studies (2266 implants) for systematic review

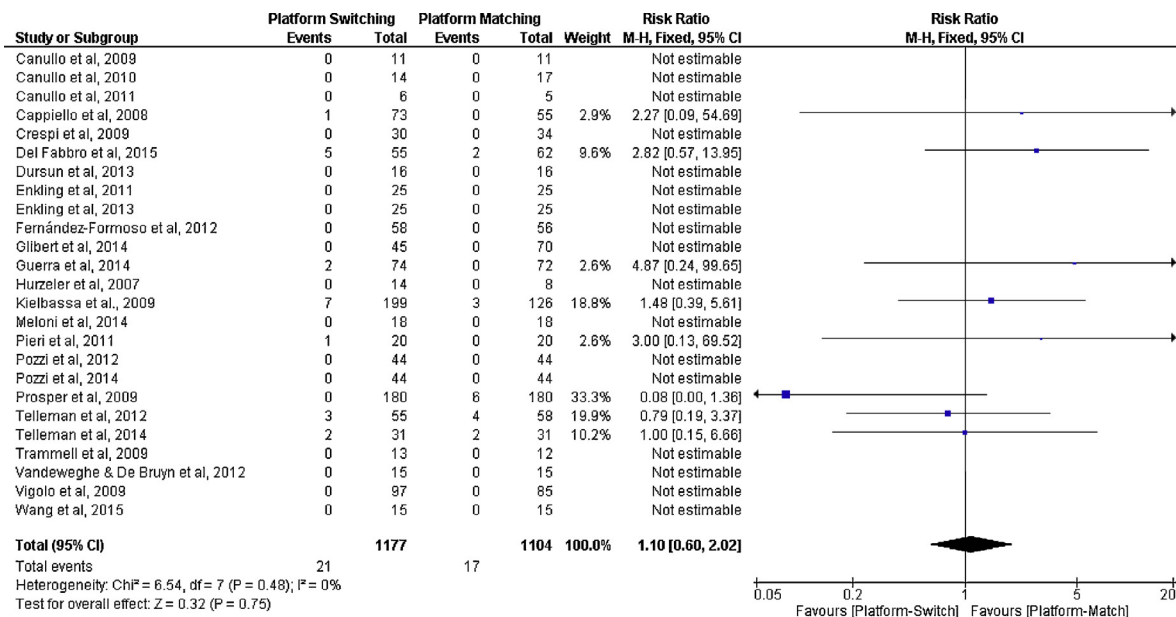


Fig. 5. Comparison of implant failure between platform-switching implants and matching platform implants. (M-H, Mantel-Haenszel; CI, confidence interval; df, degrees of freedom).

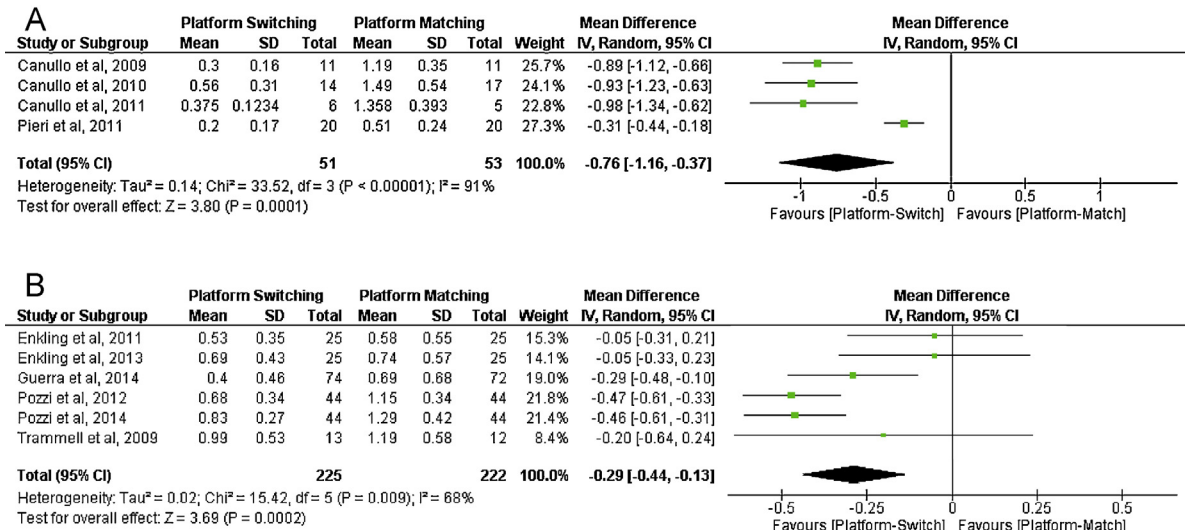


Fig. 6. Comparison of peri-implant bone loss for implants installed in the maxilla (A), and for implants installed in the mandible (B), between platform-switching implants and matching platform implants (SD, standard deviation; IV, inverse variance; CI, confidence interval; df, degrees of freedom.).

(platform switching). In the studies included in this review, there was a positive tendency towards randomization of the patients, and some studies were of the multicentre type,^{21,22,49,50} allowing the methodologies to be reproduced across different centres.^{22,24,25,27,50}

Careful patient selection was conducted in the studies included in this review.^{13–27,41–44,48–53} There was an attempt to exclude patients with systemic disorders (diabetes, osteoporosis, radiation exposure, bisphosphonate use, and coagulation disorders) and an infectious process at

peri-implant sites, as well as those with harmful habits (cigarette smoking, drug use, poor oral hygiene). In a study by Romanos and Nentwig, the effect of immediate loading implant use (PSW type) in non-smokers and smokers (more than 1 packet/day for at least 10 years) was analysed, with no significant differences found in success rates, inflammation, or bone loss.⁵⁵ Thus, the benefits of bone preservation with PSW implants should be analysed in other groups of patients, such as those with bruxism and those who smoke, and also in patients with other systemic conditions.

With regard to the medication protocol used, diverse protocols were adopted, including antibiotic prophylaxis in the period before surgery,²¹ use after surgery for a minimum of 1 week,^{14,20,42,43,51} or a single dose.^{22,41} In a recent systematic review and meta-analysis, Ata-Ali and Ata-Ali⁵⁶ indicated that the use of systemic antibiotics does not exercise a preventive effect against infection postoperatively and that RCTs on a large scale must be prepared before recommendations can be made regarding the best antibiotic, timing of administration, and dose employed.

The main finding of this study was that the level of bone loss with PSW implants was significantly lower than that found with the use of RP implants (P < 0.00001); therefore, the null hypothesis proposed initially was rejected. These results were analysed for different subgroups, such as implants placed in the maxillary region or in the mandible region, and these factors did not influence

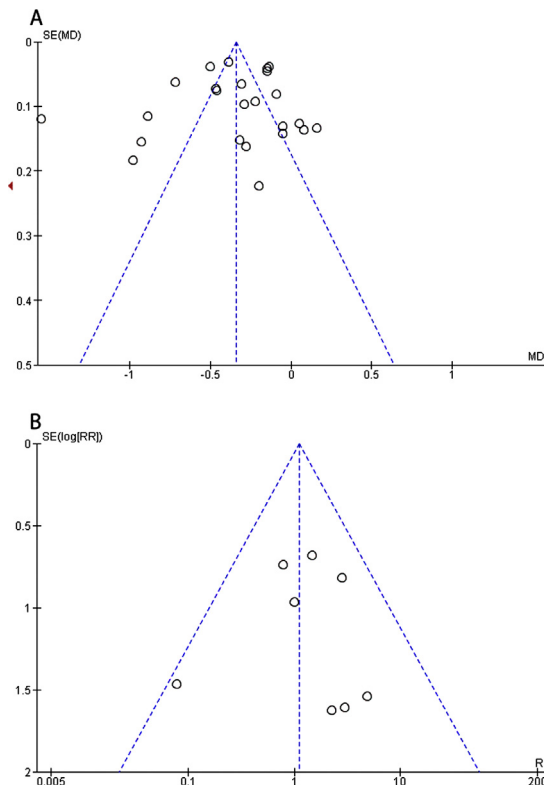


Fig. 7. Funnel plots for the assessment of publication bias: outcomes ‘peri-implant bone loss’ (A), and ‘failed implants’ (B).

the primary results. These data corroborate those of meta-analyses performed previously.^{33,34} PSW implants can increase the distance of inflammatory cells (micro-gap) from the bone margin,¹⁴ thereby maintaining bone tissue.^{20,48} Moreover, the possibility of optimization of a biological space horizontally, the improved load distribution on bone tissue,²⁰ and the absence of micro-motion⁴² may result in the protection of peri-implant soft tissue and bone.

The studies analysed in this meta-analysis considered mainly the posterior maxilla and mandible, and only one study found a higher failure rate in the posterior maxilla region.¹⁹ An important shortcoming of the studies is that PSW implants were rarely evaluated aesthetically.⁴²

The different surgical techniques used respected a minimum distance between implant and tooth and between implant and implant.^{15,18–20,41} Two studies showed that there was higher bone preservation when the PSW implant concept was used in the installation of an implant adjacent to an implant; however, no significant differences were observed in the condition of a single implant.^{18,19} Furthermore, some authors showed the advantage with regard to bone preservation of implants placed within a region with a favourable gingival biotype, presenting the best soft tissue condition and lowest bone loss for PSW implants,^{16,18} as well as demonstrating lower crestal bone loss for implants placed in regions where there is greater availability of bone.⁴³ This demonstrates the need for studies assessing other gingival biotypes.

Only a few studies installed implants in bone of different qualities^{14,17,19,22,27,42,43,50,53}; regrettably most studies did not provide an accurate description of the type of bone analysed. One study reported that the installation of the implant and healing abutment in single-stage surgery gave similar results in the preservation of bone in the PSW implants and the control group.⁴²

Another relevant factor was the level of bone at which the implants were installed; Telleman et al.¹⁸ emphasized the installation of PSW implants at the bone level, as did other authors.^{20,52} Cochran et al.⁵⁷ showed that PSW implants installed under the cortical bone showed more significant resorption when compared with implants placed at the bone level; however, further studies are required to evaluate these conditions.

Regarding implant design, Wang et al.⁴⁴ indicated that similar values of marginal bone level change to PSW and RP

implants may occur with the use of conical internal connections, which allow a greater biological seal. Indeed, it has been reported that different implant designs (body, connection, and collar), as well as the diameter of the implant, may influence the peri-implant bone loss results.²³

Long implants were predominantly used,^{13,20–22,41,48–50} as there was a tendency to use large-diameter implants. This may be an important explanation for the lower rates of bone loss with PSW implants.^{23,24} Biomechanical studies using photoelastic analysis and three-dimensional finite element analysis have shown a better distribution of stresses for wide-diameter implants.^{9,35} The literature indicates that the use of a wide implant with a narrow abutment introduces a new biological space, allowing the adaptation of horizontal peri-implant tissues, which may contribute to better bone preservation.⁴¹ Other studies have indicated that an increase in diameter is biomechanically adequate.^{20,21,49}

It has been suggested that the longest distance of bone crest for the abutment could be favoured by an increase in diameter of the implant.^{33,34} In this regard, the use of large-diameter implants may be a bias in the analysis. Enkling et al.¹⁵ indicated no advantages of using platform switching for implants with a regular diameter; however, they stated that the positive results described in the literature may have been observed because of the larger diameter implants used.^{13,14,20,22,48,52}

The use of large-diameter implants may explain the low level of complications for implant-supported prostheses in the studies included in this review.^{14,50,51} In fact, the use of wide-diameter implants can help reduce the stresses in implant-supported prostheses.^{35,58} This occurs because there is a greater area for stress distribution. The data showed reduced rates of complications for the prosthesis. On the other hand, a biomechanical study has shown a greater overload of abutments and screw prostheses for regular (4-mm) diameter implants.⁶

Studies included in the present review showed that the implants used had high primary stability in bone tissue.^{14,21,50} Some studies considered the use of micro-threads,^{21,24,26,49,51} which may have increased the initial stability of the bone interface.²¹ The studies assessed different body geometries and implant threads.^{14,15,19,21,22,41,49,50} This may be a limitation and bias of the present review. Furthermore, some authors considered different connections for the PSW implant group.^{14,26,41,50,51}

One criterion that should be considered is the type of connection used in implants. There is little information with high scientific evidence on the effect of implant connections in bone remodeling.⁴¹ The use of connections that can reduce lateral forces and minimize screw loosening is important in the posterior region of the maxilla or mandible.⁵⁹ In this context, internal connections can decrease the micro-motion, reduce tensions, and prevent bacterial contamination.⁴¹ This study indicated the advantage of the use of implants with different connections associated with the PSW concept; however, some studies did not report the type of connection used (Table 1). It is important to highlight that the Morse taper connection was the most effective in terms of bone preservation.^{14,17,51}

Biologically, the positive effect of Morse taper connections can be related to the small micro-gap, which is considered to be lower than 1 μm .⁵¹ This type of implant may allow an adequate biological seal, preventing the spread of bacteria. Furthermore, a recent biomechanical study has shown that the use of this geometry of implant acts more favourably on the distribution of stress in the peri-implant region.⁵⁹

One important criterion evaluated in surgeries involving immediate extraction and immediate loading was the maintenance of the integrity of the lateral walls of bone tissue.²¹ In this context, Crespi et al.¹⁴ stated that the minimal difference in bone loss between PSW implants and control implants may have been due to the conditions of minimally invasive surgeries. This was also discussed by Pieri et al.,⁵¹ who indicated that the maintenance of the architecture of the surgical alveolus could explain the positive bone preservation outcomes.

Another important factor is that some studies assessed the implants at 1 year of follow-up.^{15–19,24,25,41–44,48,50–52} However, it is reported that there is a greater change in biological tissue during the first 4 months because of healing abutment surgery, impressions, and the constant modification of peri-implant soft tissue.^{15,20} On this topic, Pozzi et al.⁴¹ found a significant difference in bone loss in the initial 4 months, and the greatest change in bone tissue occurred during surgical placement of the abutment.

The concept of a randomized trial was used for most studies,^{13,15–26,41,49–51} but the method was not well outlined in some prospective studies.^{14,42,48,52} One of the significant limitations observed was that peri-implant bone loss measurements

were taken for only the mesial and distal regions of the implants – the buccal and lingual aspects were not assessed.²⁰ An important factor that must be considered in the next trial is related to sample size; some studies raised concerns regarding this factor,^{42,50} suggesting the necessity of studies with larger numbers of patients and multicentre studies.

In the assessment of the quality of the studies included and possible publication bias with the Jadad criteria, an appropriate level (≥ 3) was not observed for all clinical studies evaluated (Table 1). Heterogeneity between studies was assessed using subgroup analyses to identify factors that could have affected the outcome.^{33,34} However, the benefit of the PSW implant concept was determined in all analyses. Studies also showed limitations

including, for example, allocation concealment, as reported previously by Annibaldi et al.³³

This systematic review included studies published more recently.^{16–19,23–27,41–44} The use of PSW implants could be recommended in areas of limited bone height.⁴⁸ Increasing the distance from the bone crest to the abutment improved bone preservation, as also found in previous studies.¹⁹ Adequate hygiene control and regular patient visits should be encouraged. Finally, further RCTs with sample sizes sufficient for statistical calculation should be performed in the near future.

In conclusion, platform-switching implants showed greater relevant bone preservation when compared to regular platform implants. Platform-switching implants showed a failure rate similar to

that of regular platform implants. RCTs with long follow-up periods should be performed.

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Competing interests

None declared.

Ethical approval

Not required.

Patient consent

Not required.

Appendix A. Quality assessment of studies

Jadad Quality Scale Questions	Authors Scale/year	Canullo 2011	Canullo 2009	Canullo 2010	Cappiello 2008	Crespi 2009	Dursum 2013	Enkling 2011	Fernández 2012	Hürzeler 2007
Was the study described as randomized?	(0 or +1)	1	1	1	0	1	0	1	1	1
The method of randomization was described in the paper, and that method was appropriate.	(0 or +1)	1	1	1	0	0	0	1	1	0
Was the study described as double-blind?	(0 or +1)	1	1	0	0	0	0	0	0	0
The method of blinding was described, and it was appropriate?	(0 or +1)	0	1	1	0	0	0	0	0	0
The method of randomization was described, but was inappropriate	(0 or -1)	0	0	0	0	0	0	0	0	0
The method of blinding was described, but was inappropriate	(0 or -1)	0	0	0	0	0	0	0	0	0
Was there a description of withdrawals and dropouts?	(0 or +1)	1	1	1	1	1	1	1	1	0
Total		4	5	4	1	2	1	3	3	1
Jadad Quality Scale Questions	Authors Scale/year	Kielbassa 2009	Pieri 2011	Pozzi 2012	Prosper 2009	Telleman 2012a	Telleman 2012b	Tramell 2009	Vandeweghe 2012	Vigolo 2009
Was the study described as randomized?	(0 or +1)	1	1	1	1	1	1	1	1	0
The method of randomization was described in the paper, and that method was appropriate.	(0 or +1)	1	1	1	1	1	1	1	0	0
Was the study described as double-blind?	(0 or +1)	0	0	0	0	0	0	0	0	0
The method of blinding was described, and it was appropriate?	(0 or +1)	0	0	0	0	0	0	0	0	0
The method of randomization was described, but was inappropriate	(0 or -1)	0	0	0	0	0	0	0	0	0
The method of blinding was described, but was inappropriate	(0 or -1)	0	0	0	0	0	0	0	0	0
Was there a description of withdrawals and dropouts?	(0 or +1)	1	1	1	1	1	0	0	1	1
Total		3	3	3	3	3	2	2	2	1
Jadad Quality Scale Questions	Authors Scale/year	Enkling 2013	Del Fabbro 2014	Glibert 2014	Meloni 2014	Pozzi 2014	Wang 2013	Guerra 2014		
Was the study described as randomized?	(0 or +1)	1	1	0	1	1	1	1		
The method of randomization was described in the paper, and that method was appropriate.	(0 or +1)	1	1	0	1	1	1	1		

(Continued)

Questions	Jadad Quality Scale	Authors Scale/year	Enkling 2013	Del Fabbro 2014	Glibert 2014	Meloni 2014	Pozzi 2014	Wang 2013	Guerra 2014
Was the study described as double-blind?		(0 or +1)	0	0	1	1	0	0	0
The method of blinding was described, and it was appropriate?		(0 or +1)	0	0	1	1	0	0	0
The method of randomization was described, but was inappropriate		(0 or -1)	0	0	0	0	0	0	0
The method of blinding was described, but was inappropriate		(0 or -1)	0	0	0	0	0	0	0
Was there a description of withdrawals and dropouts?		(0 or +1)	1	1	0	1	1	1	1
Total			3	3	2	5	3	3	3

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Address:

Joel Ferreira Santiago Junior
 Department of Health Sciences
 Sacred Heart University
 USC
 10-50 Irmã Armanda
 Bauru
 São Paulo 17011-160
 Brazil
 Tel.: +55 14 2107 7112
 E-mail: jf.santiagojunior@gmail.com