# Review

## The Effect of Flapless Surgery on Implant Survival and Marginal Bone Level: A Systematic Review and Meta-Analysis

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**Background:** The clinical outcomes of implants placed using the flapless approach have not yet been systematically investigated. Hence, the present systematic review and meta-analysis aims to study the effect of the flapless technique on implant survival rates (SRs) and marginal bone levels (MBLs) compared with the conventional flap approach.

**Methods:** An electronic search of five databases (from 1990 to March 2013), including PubMed, Ovid (MEDLINE), EMBASE, Web of Science, and Cochrane Central, and a hand search of peer-reviewed journals for relevant articles were performed. Human clinical trials with data on comparison of SR and changes in MBL between the flapless and conventional flap procedures, with at least five implants in each study group and a follow-up period of at least 6 months, were included.

**Results:** Twelve studies, including seven randomized controlled trials (RCTs), one cohort study, one pilot study, and three retrospective case-controlled trials (CCTs), were included. The SR of each study was recorded, weighted mean difference (WMD) and confidence interval (Cl) were calculated, and meta-analyses were performed for changes in MBL. The average SR is 97.0% (range, 90% to 100%) for the flapless procedure and 98.6% (range, 91.67% to 100%) for the flap procedure. Meta-analysis for the comparison of SR among selected studies presented a similar outcome (risk ratio = 0.99, 95% Cl = 0.97 to 1.01, P = 0.30) for both interventions. Mean differences of MBL were retrieved from five RCTs and two retrospective CCTs and subsequently pooled into meta-analyses; however, none of the comparisons showed statistical significance. For RCTs, the WMD was 0.07, with a 95% Cl of -0.05 to 0.20 (P = 0.26). For retrospective CCTs, the WMD was 0.23, with a 95% Cl of -0.58 to 1.05 (P = 0.58). For the combined analysis, the WMD was 0.03, with a 95% Cl of -0.11 to 0.18 (P = 0.67). The comparison of SR presented a low to moderate heterogeneity, but MBL presented a considerable heterogeneity among studies.

**Conclusion:** This systematic review revealed that the SRs and radiographic marginal bone loss of flapless intervention were comparable with the flap surgery approach. *J Periodontol 2014;85:e91-e103*.

### **KEY WORDS**

Dental implants; gingiva; gingival recession; meta-analysis; review; surgical flaps.

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he traditional approach to implant surgery involves flap reflection to access and visualize the underlying alveolar bone. Alternatively, the flapless approach can be used to simplify the procedure of implant placement in certain scenarios.<sup>1</sup> In this approach, the amount of remaining alveolar bone is often evaluated, and implant position is predetermined from three-dimensional radiography. Subsequently, the soft tissue in which the implant will be placed is removed using a soft-tissue punch or a scalpel without flap elevation. Sometimes, surgical guides are then used to guide and place the implant in the optimal position based on the presurgical planning. Sutures are generally not necessary. This approach is reported to significantly reduce the surgical time, lessen patient discomfort, and increase patient acceptance.<sup>2</sup>

The potential disadvantage to this technique is that it involves a masked approach in which certain surgical risks and complications may occur, including unrecognized bony dehiscence/fenestration and improper vertical implant position.<sup>3-5</sup> A clinical study<sup>3</sup> reported that the incidence of dehiscence/fenestration with the flapless approach is 4.73%. Therefore, adequate bone volume, a relatively flat alveolar crest, and a lack of severe ridge concavity are prerequisites for applying this technique. Additionally, a learning curve seems to exist with the flapless surgery. A higher implant failure rate was reported before the surgeon could adapt to this approach.<sup>3</sup>

Because of the fact that the flapless approach avoids elevation of mucoperiosteal flaps, the marginal bone level (MBL) might be maintained.<sup>1</sup> The periosteum and supraperiosteal plexus provide osteogenic potential and blood supply to the underlying alveolar bone. When the bone is denuded, the bone homeostasis shifts to a catabolic-dominant status, resulting in an increase in osteoclast activities and a net bone loss.<sup>6,7</sup> Several clinical studies<sup>8-11</sup> concluded that the flapless surgery is beneficial in preserving the marginal bone. The clinical significance of the reduced marginal bone loss is that the overlying soft tissues, including the papilla height, might also be maintained, which may enhance the esthetic outcome of the implant therapy.

Because the flapless procedure is technique sensitive, the implant survival rate (SR) might be negatively affected. Conversely, because of the fact that this approach is less invasive, the MBL might be preserved.<sup>12</sup> Previous systematic reviews<sup>4,13</sup> have provided descriptive analyses of the efficacy of the flapless surgery. This systematic review takes a further step to compare the SR and the amount of MBL of implants placed with the flapless approach and flap surgery by means of meta-analyses.

### **MATERIALS AND METHODS**

### Search Strategy

A search of five electronic databases, including PubMed, Ovid (MEDLINE), EMBASE, Web of Science, and Cochrane Central, for relevant studies published in the English language from January 1990 until March 2013 was performed. The search terms used, in which mh represented the MeSH terms and tiab represented title and/or abstract, included the following: ("dental implants"[mh] OR "dental implantation"[mh] OR (("implant"[tiab] OR "implants"[tiab]) AND (dental[tiab] OR oral[tiab] OR tooth [tiab]))) AND ("surgical flaps"[mh] OR "flap"[tiab] OR "flapless"[tiab] OR "flapped"[tiab]).

A hand search was also performed in dental and implant-related journals from January 2000 to February 2013, including *Journal of Periodontology*, Clinical Implant Dentistry and Related Research, International Journal of Oral & Maxillofacial Implants, Clinical Oral Implants Research, Implant Dentistry, International Journal of Oral & Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, Journal of Dental Research, Journal of Prosthetic Dentistry, International Journal of Prosthodontics, Journal of Oral Implantology, Journal of Clinical Periodontology, and International Journal of Periodontics & Restorative Dentistry. European Journal of Oral Implantology was searched from January 2008 to February 2013. Furthermore, a search in the references of included papers was conducted for publications that were not electronically identified. The search strategy was performed by one examiner (G-HL).

Studies were selected if they fulfilled the following inclusion criteria: human clinical trials including data on comparison of SR and changes of MBL between the flapless approach and conventional flap approach with a minimum of five implants in each technique and a follow-up period for at least 6 months after implant placement. Reviews and case reports were excluded, but the bibliographies of these studies were screened for potential articles to be included. Potential articles were examined in full text by two reviewers (G-HL and H-LC), and their eligibility for this review was confirmed after discussion. The level of agreement between the reviewers regarding study inclusion was calculated using  $\kappa$  statistics.

### Risk of Bias Assessment

The criteria used to assess the quality of the selected randomized controlled trials (RCTs) were modified from the randomized clinical trial checklist of the Cochrane Center<sup>14</sup> and the CONSORT (Consolidated Standards of Reporting Trials) statement,<sup>15</sup> which provided guidelines for the following parameters: 1) sequence generation; 2) allocation concealment

method; 3) masking of the examiner; 4) address of incomplete outcome data; and 5) free of selective outcome reporting. The degree of bias was categorized as low risk if all the criteria were met, moderate risk when only one criterion was missing, and high risk if two or more criteria were missing. Two reviewers (G-HL and H-LC) assessed all the included articles independently.

### Data Extraction

Data were extracted by two observers (G-HL and H-LC) independently from the papers that met the inclusion criteria. If any disagreement was found, an agreement was accomplished with a discussion. Demographic information was recorded for each study, including the following: 1) the study design; 2) sample size; 3) individual characters; 4) number of implants placed; 5) location of the implants; 6) surgical technique used; 7) loading protocols; and 8) follow-up period.

Additional variables, if there were any, recorded for each study were SR, changes of MBL and width of keratinized mucosa (KM), probing depth (PD), papillary index<sup>16</sup> (PPI), plaque index<sup>17</sup> (PI), modified plaque index<sup>18</sup> (mPI), and gingival index<sup>19</sup> (GI). If indicated, authors of the potentially qualified papers were contacted for more detailed data.

### Data Analyses

The primary outcome was SR, with MBL as the secondary outcome. The risk ratio of SR and the pooled weighted mean difference (WMD) of MBL were estimated using a computer program.<sup>†</sup> The contribution of each article was weighed. Random-effects metaanalyses of the selected studies were applied to avoid any bias being caused by methodologic differences between studies. Forest plots were produced to graphically represent the difference in outcomes of flapless and flap procedures for all included studies using implant as the analysis unit. A P value of 0.05 was used as the level of significance. Heterogeneity was assessed with  $\chi^2$  test and  $I^2$  test, which ranges from 0% to 100%, with lower values representing less heterogeneity. In addition, the funnel plot was used to assess the presence of the publication bias. Meta-regression was also performed to analyze the potential effect of confounding factors, including flapless techniques and loading protocols, on primary and secondary outcomes. The reporting of these metaanalyses adhered to the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analyses) statement.20

### RESULTS

The screening process is shown in supplementary Figure 1 in the online *Journal of Periodontology*. Electronic and hand searches yielded 1,262 articles, of which 40 articles were selected for full-text evaluation after screening their titles and abstracts. Twenty-eight articles<sup>2,3,5,8-11,21-41</sup> were further excluded; the reasons for exclusion are listed in Table 1. Twelve articles<sup>42-53</sup> are included in this systematic review. The main features and conclusions of the included studies are summarized in Table 2.

The  $\kappa$  value for inter-reviewer agreement for potentially relevant articles was 0.97 (titles and abstracts) and 0.90 (full-text articles), indicating an "almost perfect" agreement between the two reviewers according to the criteria of Landis and Koch.  $^{54}$ 

### Features of the Included Studies

Study design and patient features. Seven RCTs,  $^{42,44,48,49,51-53}$  one cohort study,  $^{45}$  one pilot study,  $^{43}$  and three retrospective case-controlled trials (CCTs) $^{46,47,50}$  were included. The age of the participants ranged from  $19^{45}$  to  $84^{47}$  years. In addition, average loading period varied among studies, with a mean follow-up period of 16.1 months, ranging from  $6^{44}$  to  $39^{50}$  months. Two included studies $^{43,44}$  placed implants immediately after tooth extraction; other studies placed implants in a healed ridge. Smokers were included in four studies;  $^{44,48-50}$  seven studies $^{42,43,45-47,51,53}$  did not report smoking status of patients.

**Installation site and restoration characteristics.** Of the selected studies, three studies<sup>43,48,53</sup> only included implants placed in maxillary arches, whereas another seven studies<sup>42,44-47,50,52</sup> had implants in both maxillary and mandibular arches. Patients in 11 studies<sup>43-53</sup> were reconstructed with fixed restorations, including single crown and partially or fully fixed bridge restorations. The other one study<sup>42</sup> included implants restored with fixed or implant-supported removable prostheses. In addition, all selected studies used implants with a rough body surface, and only one study<sup>53</sup> placed implants with a platform-switched abutment design.

**Flapless techniques.** Three different flapless procedures were introduced. Four studies<sup>42,46,51,53</sup> used a punch technique, six studies<sup>45,47-50,52</sup> introduced various drills to prepare the implant recipient sites, and two studies<sup>43,44</sup> placed implants in the extraction sockets (immediate implant placement).

**Loading protocols.** Of the selected studies, five studies<sup>43,45,48,49,51</sup> loaded the dental implants immediately after surgery, one study<sup>42</sup> used early loading protocol (at least 48 hours after implant placement but not later than 3 months afterward)<sup>55</sup> to restore the implants, another five studies<sup>44,47,50,52,53</sup> attached the prosthesis with a healing period of 3 to

<sup>†</sup> Review Manager (RevMan) v.5.0, The Nordic Cochrane Center, Copenhagen, Denmark.

### Table I.

### Summary of the Excluded Articles

Reason for Exclusion	References
No control group	Campelo and Camara $(2002)^3$ Rocci et al. $(2003)^8$ Covani et al. $(2004)^{22}$ Becker et al. $(2005)^9$ Van Steenberghe et al. $(2005)^{23}$ Oh et al. $(2006)^5$ Cannizzaro et al. $(2007)^{25}$ Malo et al. $(2007)^{26}$ Oh et al. $(2007)^{28}$ Rao and Benzi $(2007)^{10}$ Sanna et al. $(2007)^{10}$ Sanna et al. $(2007)^{11}$ Jeong et al. $(2011)^{36}$ Lee et al. $(2011)^{37}$ Tee $(2011)^{38}$ Pozzi et al. $(2012)^{40}$
No data for SR and marginal bone loss <6-month follow-up	Fortin et al. $(2006)^{24}$ Nickenig and Eitner $(2007)^{27}$ Cannizzaro et al. $(2008)^{30}$ Gabrić Pandurić et al. $(2008)^{31}$ Arisan et al. $(2010)^{2}$ Berdougo et al. $(2010)^{34}$ Lindeboom and van Wijk $(2010)^{35}$ Job et al. $(2008)^{33}$
<o-month td="" tollow-up<=""><td>Job et al. (2008) Al-Juboori et al. (2012)<sup>39</sup> Tsoukaki et al. (2013)<sup>41</sup></td></o-month>	Job et al. (2008) Al-Juboori et al. (2012) <sup>39</sup> Tsoukaki et al. (2013) <sup>41</sup>
Limited flap/mini-flap used as test group	Jeong et al. (2008) <sup>32</sup> Gomez-Roman (2001) <sup>21</sup>

6 months (conventional protocol), and the other one study<sup>46</sup> introduced all three loading protocols to restore the implants.

**Other features.** Three studies<sup>42,48,53</sup> introduced computed tomography (CT) to fabricate surgical templates and used CT-guided templates to assist implant placement. Another one study<sup>44</sup> included sites with a complete bone defect at the facial walls, and all patients underwent buccal bone augmentation before implant placement. Two studies<sup>44,51</sup> did adjustment for variables when performing statistical analysis.

### Risk of Bias Assessment

The results of risk of bias assessment for included RCTs are summarized in Table 3. Four studies<sup>48,49,51,53</sup> were considered to have a low risk of bias, and another two studies<sup>44,52</sup> were considered to have a moderate risk of bias; however, the other one study<sup>42</sup> was considered to have a high risk of bias. The results of funnel plot presented a symmetric distribution of included studies for MBL, indicating a potentially low risk of publication bias. However, the funnel plots should be interpreted with caution because of the mixture of various study designs as well as the limited number of studies included.

### Results of SR

Of the included studies, three studies<sup>50-52</sup> presented a 100% SR for both flap and flapless procedures; another one study<sup>53</sup> had one failed implant in each procedure and resulted in a 91.67% SR for each approach. The other studies<sup>42-49</sup> reported different implant SR for flap/flapless techniques. The average SR of the included studies is 97.0% (range, 90% to 100%) for flapless technique and 98.6% (range, 91.67% to 100%) for flap technique.

Meta-analysis for the comparison of SR among selected studies presented an overall risk ratio of 0.99 (95% confidence interval [CI] = 0.97 to 1.01), and no statistical significance (P = 0.30) was found (Fig. 1). For RCTs, the risk ratio of SR between implants placed with flapless and flap procedures was 0.99 (95% CI = 0.96 to 1.03, P = 0.76). For retrospective CCTs, the risk ratio of SR was 0.98 (95% CI = 0.94 to 1.02, P = 0.40). The comparisons presented a low (P value for  $\chi^2$  test = 0.99 and  $l^2$  test = 0%) to moderate (P value for  $\chi^2$  test = 0.19 and  $l^2$  test = 40%) heterogeneity among selected RCTs and retrospective CCTs, respectively. The combined effect for all subgroups also showed a low heterogeneity among studies (P value for  $\chi^2$  test = 0.94 and  $l^2$  test = 0%).

### Results of the Meta-Analyses for MBL

Three studies<sup>44,51,53</sup> did not publish the standard deviation of mean difference for MBL, and one study<sup>50</sup> used radiographs taken an average of 3.1 months after implant insertion as baseline measurements instead of radiographs taken at implant placement. Of these studies, data of one study<sup>53</sup> could be retrieved from the authors. In addition, one study<sup>52</sup> published data with three interrupted follow-up periods, and the data of 6-month follow-up were selected for investigation. To avoid the bias from combining different designed studies,<sup>14</sup> meta-analysis with the same study design was performed as a subgroup (Fig. 2).

The statistical results from each of the selected studies were converted into effect sizes and combined in the meta-analysis. None of the comparisons for MBL showed statistical significance when examining pooled results of RCTs and retrospective CCTs. For RCTs, five articles<sup>42,48,49,52,53</sup> were included. The WMD was 0.07 mm, with a 95% CI = -0.05 to 0.20 mm (P = 0.26). For retrospective CCTs, two articles were included.<sup>46,47</sup> The WMD was 0.23 mm, with a 95% CI = -0.58 to 1.05 mm (P = 0.58). For combined analysis, the WMD was 0.03 mm, with a 95%

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# Features of the Included Articles

	Main Conclusions	Implants placed using flapless technique with CT-guided surgical stents could be possible and yield a high success rate.	A high I-year SR was achieved for IIP with the flapless technique in the maxilla.	IIP with and without flap elevation could be successfully used even in the presence of bone defects. Less predictable bone augmentation in the flapless technique was noted.	The flapless technique might be a predictable procedure. However, it yielded higher bone resorption than the flap approach.
Outcomes (T / C)	MBL (mm)	-0.5 (0.3) / -0.6 (0.3); P = 0.38	-0.74 (1.34) / -1.02 (1.60); ?	-0.05 (?) / -0.05 (?); P >0.05	-2.0 (1.4) / -1.4 (0.8); ?
Outco	SR (%)	/ 001 97.8	96.6 / 97.9	/ 06 / 001	/ 696 / 601
	Restoration Types	O/d/S	S/P	Ś	S/P
	CT-Guided Restoration Template Types	Xe Xe	°Z	°Z	°Z
	Loading Protocols	Early max: 3 months; mand: 2 months	Immediate	Conventional	Immediate
Implants/Prostheses	Flapless Technique	Punch	≙	≙	Drill preparation
	Location	I 6 max ant I8 max post; 8 mand ant; I7 mand post	47 max ant 29 max post	8 max ant; 5 max post; 1 mand ant; 6 mand post	21 max ant 30 max post; 1 mand ant; 20 mand post
	Follow-Up Period (months)	σ	2	Ś	12
		45	47	0_	64
	No. of T	<del>7</del>	29	<u>°</u>	32
	Smokers No. No. Included of T of C	~	~	Ker	~
Participants	Age (years) and Sex	46 (9); 7 females, 5 males	?; 25 females, 8 males	30 to <i>67</i> ; 12 females, 8 males	I 9 to 79, 22 females, I 9 males
	Ę	12	ŝ	50	4
	Design	RCT	Pilot	RCT	Cohort 41
	Authors (year)	Ozan et al. (2007) <sup>42</sup>	Villa and Rangert (2007) <sup>43</sup>	Covani et al. (2008) <sup>44</sup>	Maló and Nobre (2008) <sup>45</sup>

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	Main Conclusions	For implants placed with the flapless technique, the failure rate was significantly higher, and marginal bone resorption was slightly lower.	Flapless surgery could benefit from a less straining procedure without affecting the high success rate of dental implant surgery.	Implants could successfully integrate in the posterior maxilla using a flapless approach with immediate loading.	There were no statistically significant differences for prosthetic and implant failures, complications, and MBL between procedures.
Outcomes (T / C)	MBL (mm)	-2.1 (1.4) / F -2.8 (1.5); ?	-0.36 (0.81) / 1 -0.22 (0.56); ?	-1 (0.58) / 1 -0.77 (0.39); P >0.05	-0.24 (0.29) / -0.33 (0.50); P >0.05
Outco	SR (%)	92.1 / 100	98.3 / 98.5	97.3 /	97.4 / 97.0
	estoration Types	S/P	S/P	۹	S
	CT-Guided Restoration Template Types	Ž	Ŝ	Kes	Ž
	Loading Protocols	Immediate/ early: 95; conventional: 22	Conventional	Immediate	Immediate
Implants/Prostheses	Flapless Technique	Punch	Drill preparation	Drill preparation	Drill preparation
	Location	45 max; 72 mand	49 max ant; 87 max post; 4 mand ant; 77 mand post	All max post	~
	Follow-Up Period (months)	10.2	24	<u>∞</u>	12
		4	203	34 24	67
	No. of T	76	174 203	36	76
	Smokers No. No. Included of T of C	~	~	Kes Kes	Yes
Participants	Age (years) and Sex	Average of 50; 23 females, 20 males	23 to 84; 125 females, 93 males	39 to 75; 9 females, 4 males	22 to 65; 20 females, 20 males
	⊆	43	218	<u>~</u>	04
	Design	CCT, retro	CCT, retro	RCT	RCT
	Authors (year)	Sennerby et al. (2008) <sup>46</sup>	Rousseau (2010) <sup>47</sup>	Van de Velde et al. (2010) <sup>48</sup>	Cannizzaro et al. (2011) <sup>49</sup>

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			Participants					<u>_</u>	Implants/Prostheses				Outco	Outcomes (T / C)	
Authors (year)	Design	c	Age (years) and Sex	Smokers Included	No. of T	No. of C	Follow-Up Period (months)	Location	Flapless Technique	Loading Protocols	CT-Guided Restoration Template Types	Restoration Types	SR (%)	MBL (mm)	Main Conclusions
De Bruyn et al. (2011) <sup>50</sup>	CCT, retro	64	20 to 79; 27 females, 22 males	, Kes	28	25	ŝ	26 max ant; 16 max post; 2 mand ant; 9 mand post	Drill preparation	Conventional	Ž	ы	/ 001	-1.40 (0.8) / -1.27 (1.1); P >0.05*	Single implants installed with flapless surgery showed equal clinical success as those installed with conventional flap surgery
Froum et al. (2011) <sup>5</sup> 1	RCT	60	?; 35 females, 25 males	~	27	25	12	~.	Punch	Immediate	°Z	Ś	/ 001	-0.60 (1) / -0.78 (1); P >0.05	High SRs and stable MBL and PDs were achieved regardless of whether a flapless or flap protocol was used.
Sunitha and Sapthagiri (2013) <sup>52</sup>	RCT	04	25 to 62; 15 females, 25 males	Ž	20	20	24	18 max ant; 10 max post; 4 mand ant; 8 mand post	Drill preparation	Conventional	° Z	Ś	001	0 to 6 months: -0.03 (0.05) / -0.20 (0.06); 6 months to 1 year: -0.07 (0.01) / -0.35 (0.25); 1 to 2 years: -0.09 (0.02) / -0.47 (0.40); P <0.05	Flapless implant surgery resulted in lesser loss of interproximal bone and also resulted in better papillary fill when compared with the flap technique.
Bashutski et al. (2013) <sup>53</sup>	RCT	24	?: 14 females, 10 males	~	2	2	5	5 max ant; 19 max post	Punch	Conventional	Xes	S	91.67 / 91.67	P > 0.05 (?) / -0.6(?) P > 0.05	A flapless protocol might provide a better short- term esthetic result, although there appeared to be no long-term advantage.
? = unclear/n placement; S Standard devi * Baseline wa	ot report = single ations ar	ed; T = implant e show aph tak	P = unclear/not reported; T = implants placed with flapless technique placement; S = single implants; P = fixed implant-supported partial de plandard deviations are shown in parentheses; P values with statistica * Baseline was radiograph taken a mean of 3.1 months after implant	ed with fla plant-supp ss; <i>P</i> value 3.1 month	pless pried s with s after	technic partial statist r impla	que; C = imp l dentures or tically signifi int insertion.	2 = unclear/not reported; T = implants placed with flapless technique; C = implants placed with flap technique; max = maxilla; mand = mandible; ant = anterior; post = posterior; IIP = immediate implant placement; S = single implants; P = fixed implant-supported partial dentures or full dentures; O = implant-supported overdentures CCT = case-controlled trial; retro = retrospective. Standard deviations are shown in parentheses; P values with statistically significant differences are marked in bold. * Baseline was radiograph taken a mean of 3.1 months after implant insertion.	lap technique; n implant-support	nax = maxilla; mi ed overdentures ( I.	and = mandib CCT = case-c	le; ant = an <sup>i</sup> ontrolled tria	terior; pos Il; retro =	st = posterior; IIF retrospective.	č = immediate impla

Effect	of	Flapless	Surgery	on	Implant	Outcomes

Yes		Yes Yes		Yes Yes	Yes Yes
? Yes No No	Yes Yes	Yes Yes	Yes	Yes	Yes
~ No V	Yes	Yes			
No No			Yes	2	Yes
	No	No	Yes	Yes	٥Z
Incomplete outcome data adequately addressed Yes Yes Yes	Yes	Yes	NA	NA	Yes
Free of suggestion of selective outcome reporting Yes Yes Yes	Yes	Yes	Yes	Yes	Yes
Estimated potential risk of bias High Moderate Low	Low	Low	Low	Moderate	Low

CI = -0.11 to 0.18 mm (P = 0.67). However, all comparisons presented a considerable heterogeneity among studies. For RCTs, the P value for  $\chi^2$  test was 0.01 and  $\hat{P}$  test was 68%; for retrospective CCTs, the P value for  $\chi^2$  test was 0.005 and  $\hat{P}$  test was 87%; for combined analyses, the P value for  $\chi^2$  test was <0.001 and  $\hat{P}$  test was 79%. To investigate potential publication bias, the funnel plots of meta-analyses for comparisons of SR and MBL were demonstrated in supplementary Figures 2 (SR) and 3 (MBL) in the online *Journal of Periodontology*.

### Results of Meta-Regression

Two confounding factors, flapless techniques and loading protocol, were analyzed using metaregression analysis. For SR, the two confounding factors did not significantly influence the outcome in any subgroup or combined analysis. For MBL, loading protocol was not considered as a confounding factor because no significant correlation was detected. However, flapless technique with immediate implant placement showed a significant correlation when compared with punch/drilling techniques. Thus, the combined analysis of MBL should be interpreted with caution. If the only pilot study<sup>43</sup> using immediate implant placement as a flapless technique was eliminated from the meta-analysis, the WMD of MBL for combined analysis was 0.02 mm, with a 95% CI = -0.13 to 0.17 mm (P = 0.77).

# Results for Other Recorded Peri-Implant Variables

Other peri-implant variables, including the changes of KM width, PPI, PD, PI, mPI, and GI, were recorded (Table 4). Two RCTs<sup>48,53</sup> compared the difference of KM width between the flap and flapless techniques, and one study<sup>53</sup> showed significant reduction of KM width for the flapless procedure. For PPI, two RCTs<sup>52,53</sup> studied the effect of flap elevation on papillary fill, and one study<sup>52</sup> showed significant benefit for flapless procedure. Meta-analysis showed that there is no significant difference between flap and flapless procedures (WMD was 0.51, with a 95% CI = -0.20 to 1.23, P = 0.16; see supplementary Fig. 4 in the online *Journal of Periodontology*). PD,<sup>51</sup> PI,<sup>53</sup> mPI,<sup>45</sup> and GI<sup>53</sup> were evaluated in some studies and did not present any statistical significance.

### DISCUSSION

In the current review, dental implants placed with flapless and flap techniques reached high SR, 97.0% (ranged from 90% to 100%) and 98.6% (ranged from 91.67% to 100%), respectively, with a mean follow-up period of 16.1 months. The meta-analysis concluded that the SR between the two interventions is not statistically significantly different (risk ratio = 0.99 with 95% CI = 0.97 to 1.01). This is in agreement

Table 3.

**Risk Assessment of Publication Bias for the Included RCTs** 

	Flaple		Flapp			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	IV. Random, 95% CI	IV. Random, 95% CI
1 RCTs							
Bashutski et al. 2013 <sup>53</sup>	11	12	11	12	0.6%	1.00 [0.79, 1.27]	
Sunitha and Sapthagiri 2013 <sup>5</sup>	2 20	20	20	20	3.7%	1.00 [0.91, 1.10]	
Cannizzaro et al. 201149	74	76	64	66	10.3%	1.00 [0.95, 1.06]	Ť
Froum et al. 2011 <sup>51</sup>	27	27	25	25	6.1%	1.00 [0.93, 1.08]	
Van de Velde et al. 2010 <sup>48</sup>	35	36	34	34	5.5%	0.97 [0.90, 1.05]	
Covani et al. 2008 <sup>44</sup>	9	10	10	10	0.5%	0.90 [0.69, 1.18]	
Ozan et al. 2007 <sup>42</sup>	14	14	44	45	2.8%	1.00 [0.90, 1.11]	
Subtotal (95% CI)		195		212	29.3%	0.99 [0.96, 1.03]	<b>T</b>
Total events	190		208				
Heterogeneity: Tau <sup>2</sup> = 0.00; C	chi <sup>2</sup> = 0.9	3, <i>df</i> =	6 (P = 0.9)	9); /² =	0%		
Test for overall effect: Z = 0.3	1 (P = 0.	76)					
2 CCTs							
De Bruyn et al. 201150	28	28	25	25	6.3%	1.00 [0.93, 1.07]	±
Rousseau 201047	171	174	200	203	48.8%	1.00 [0.97, 1.02]	
Sennerby et al.200846	70	76	41	41	5.7%	0.93 [0.86, 1.00]	
Subtotal (95% CI)		278		269	60.8%	0.98 [0.94, 1.02]	•
Total events	269		266				
Heterogeneity: Tau <sup>2</sup> = 0.00; C	chi <sup>2</sup> = 3.3	4, df = :	2 (P = 0.1	9); /2 =	40%		
Test for overall effect: Z = 0.8	4 (P = 0.	40)					
3 Pilot							
Villa and Rangert 2007 43	28	29	46	47	5.0%	0.99 [0.91, 1.07]	+
Subtotal (95% CI)		29		47	5.0%	0.99 [0.91, 1.07]	•
Total events	28		46				
Heterogeneity: Not applicable							
Test for overall effect: Z = 0.3		74)					
4 Cohort							
Maló and Nobre 200845	31	32	40	40	4.9%	0.97 [0.89, 1.05]	-+
Subtotal (95% CI)		32		40	4.9%	0.97 [0.89, 1.05]	
Total events	31		40				
Heterogeneity: Not applicable							
Test for overall effect: Z = 0.8		41)					
Total (95% CI)		534		568	100.0%	0.99 [0.97, 1.01]	•
Total events	518		560				
Heterogeneity: Tau <sup>2</sup> = 0.00; C	chi <sup>2</sup> = 4.7			.94); /²	= 0%		I         I         I           0.5         0.7         1         1.5
Test for overall effect: Z = 1.0							

### Figure 1.

Meta-analysis for the comparison of SR among selected studies. For RCTs, the risk ratio of SR between implants placed with flapless and flap procedures was 0.99 (95% CI = 0.96 to 1.03). For retrospective CCTs, the risk ratio of SR was 0.98 (95% CI = 0.94 to 1.02). For all selected studies, the overall risk ratio of SR was 0.99 (95% CI = 0.97 to 1.01). A lack of statistical significance was shown in all comparisons (for RCTs, P = 0.76; for retrospective CCTs, P = 0.40; for combined analysis, P = 0.30). IV: inverse-variance analysis.

with previous studies<sup>1,13,30,34</sup> and indicates that implant placement without raising a flap is as predictable as the conventional flap approach. Nevertheless, in the included studies, the selection criteria for the flapless approach were strict, and the surgeons who performed the procedures are experienced. These factors have to be considered when interpreting the results.

According to the results of the meta-analyses, the MBL did not show a significant difference between flap and flapless procedures, no matter what types of studies were analyzed. This revealed that the flapless procedure may not influence bone remodeling, examined at the macroscopic scale. On the contrary, two clinical trials<sup>33,41</sup> with short-term follow-up (3-and 4-month follow-up, respectively) reported a significant reduction of marginal bone resorption with the flapless approach. It is possible that the flapless procedure might have a beneficial effect on maintaining bone level at the early stage of healing. As the healing proceeds, the bone reparative mechanism

catches up in the flap procedure; eventually, no difference in marginal bone height can be observed. In addition, other studies<sup>3,45</sup> argued that flapless surgery did not allow direct visualization of the alveolar ridge and therefore the implant could not be positioned as well as in the flap approach, which resulted in more bone loss. Besides, to remove adequate bone for placement of the healing abutment, a countersinking procedure might be overdone in the flapless surgery, which could lead to more marginal bone loss.<sup>50</sup> It is prudent to say that there is not enough evidence that the flapless procedure can preserve marginal bone; therefore, this technique may have no long-term esthetic benefit and should not be highly recommended for cases aimed to achieve esthetic outcomes.

Several peri-implant parameters, including PD, Gl, Pl, and mPl, are evaluated in the current review to investigate the effect of the flapless procedure on the peri-implant tissue health. Most studies did not show statistically significant differences in the above examined param-

eters. In one included study<sup>53</sup> that showed significantly higher Pl and Gl in the flapless procedure at short term (3 to 9 months), these differences were no longer statistically significant at 15 months. Therefore, the results demonstrated that the flapless procedure could achieve long-term peri-implant soft tissue health, which is similar to the traditional flap approach. However, there is a lack of soft tissue data in relation to flapless surgery; therefore, it is suggested that future research should focus on this aspect of treatment outcome when comparing flap with flapless approaches.

Although there is a tendency of greater PPI in the flapless technique, indicating that more papillary fill might happen after the flapless procedure, the metaanalysis did not present a statistical significance. The finding might be attributed to comparable interproximal bone loss as the flap technique or inadequate sample sizes included in the analysis (n = 2). However, the sacrifice of KM width was documented as one of the major drawbacks for the flapless approach.<sup>1,48,53</sup> This could lead to an unsatisfactory

	FI	apless		FI	apped			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV. Random, 95% CI	IV. Random. 95% Cl
RCTs									
Ozan et al. 2007 <sup>42</sup>	-0.5	0.3	14	-0.6	0.3	44	15.2%	0.10 [-0.08, 0.28]	<b>*</b> -
Van de Velde et al. 201048	-1	0.58	35	-0.77	0.39	34	13.2%	-0.23 [-0.46, 0.00]	
Cannizzaro et al. 201149	-0.24	0.29	74	-0.33	0.5	65	16.8%	0.09 [-0.05, 0.23]	t-
Sunitha and Sapthagiri 201352	-0.03	0.05	20	-0.2	0.06	20	19.7%	0.17 [0.14, 0.20]	1.1
Bashutski et al. 201353	-0.45	0.42	11	-0.6	0.89	11	4.7%	0.15 [-0.43, 0.73]	
Subtotal (95% CI)			154			174	69.6%	0.07 [-0.05, 0.20]	•
Heterogeneity: Tau <sup>2</sup> = 0.01; C	chi² = 12	2.47, di	f = 4 (P)	= 0.01)	; /2 = 6	8%			
Test for overall effect: Z = 1.1	2 (P = 0	0.26)							
CCTs									
Sennerby et al.2008 46	-2.1	1.4	70	-2.8	1.5	41	5.0%	0.70 [0.14, 1.26]	
Rousseau 201047	-0.36	0.81	171	-0.22	0.56	200	16.6%	-0.14 [-0.28, 0.00]	
Subtotal (95% CI)			241			241	21.6%	0.23 [-0.58, 1.05]	
Heterogeneity: Tau <sup>2</sup> = 0.31; C	hi² = 7.	99, df	= 1 (P =	= 0.005)	; /2 = 8	37%			
Test for overall effect: Z = 0.5	6 ( <i>P</i> = 0	).58)							
Pilot									
Villa and Rangert 200743	-0.74	1.34	28	-1.02	1.6	46	3.7%	0.28 [-0.40, 0.96]	
Subtotal (95% CI)			28			46	3.7%	0.28 [-0.40, 0.96]	
Heterogeneity: Not applicable	J								
Test for overall effect: Z = 0.8	1 ( <i>P</i> = 0	).42)							
Cohort									
Maló and Nobre 2008 45	-2	1.4	31	-1.4	0.8	40	5.1%	-0.60 [-1.15, -0.05]	
Subtotal (95% CI)			31			40	5.1%	-0.60 [-1.15, -0.05]	
Heterogeneity: Not applicable	j.								
Test for overall effect: Z = 2.1	3 (P = 0	0.03)							
Total (95% CI)			454			501	100.0%	0.03 [-0.11, 0.18]	+
Heterogeneity: Tau <sup>2</sup> = 0.03; C	;hi² = 38	3.72, di	f = 8 (P	< 0.000	001); /*	<sup>2</sup> = 79%			
Test for overall effect: Z = 0.4									-2 -1 0 1 2
		/							Favors flapped Favors flapless

### Figure 2.

Meta-analysis for the comparison of MBL among selected studies. For RCTs, the WMD in MBL between implants placed with flapless and flap procedures was 0.06 (95% CI = -0.07 to 0.20). For retrospective CCTs, the WMD in MBL was 0.23 (95% CI = -0.58 to 1.05). For combined analysis, the WMD was 0.03 (95% CI = -0.13 to 0.18). A lack of statistical significance was shown in all comparisons (for RCTs, P = 0.34; for retrospective CCTs, P = 0.58; for combined analysis, P = 0.74).

esthetic outcome as well as poor peri-implant soft tissue health.<sup>53,56,57</sup> Therefore, adequate KM should be present for performing a flapless surgery.

In the present review, studies using immediate implant placement and immediate loading protocols are included. Metaregression was subsequently performed to avoid any bias from these potential confounding factors. Although for MBL, flapless technique with immediate implant placement showed a significant correlation when compared with punch/drilling techniques, this difference also might be from the various study designs.43 Currently, whether the use of flapless techniques in combination with immediate implant/restoration protocols is beneficial or futile to achieve esthetic outcomes showed conflicting results.<sup>58,59</sup> Therefore.

### Table 4.

### **Results of Peri-implant Variables Among Included Studies**

References	Design		No. of C	KM Width (mm)	PD (mm)	PPI	PI	mPl
Maló and Nobre (2008) <sup>45</sup>	Cohort	32	40					1.35(0.8) / 1.05 (0.9);
Van de Velde et al. (2010) <sup>48</sup>	RCT	36	34	Baseline: 2.94 (1.63) / 3.85 (0.9); 18 months: 3.14 (1.89) / 4.08 (1.54);				P >0.05
Froum et al. (2011) <sup>51</sup>	RCT	27	25	P >0.05	2.20 (0.75) / 2.26 (0.84);			
Sunitha and Sapthagiri (2013) <sup>52</sup>	RCT	20	20		P >0.05	2.80 (0.02) / 1.95 (0.40);		
Bashutski et al. (2013) <sup>53</sup>	RCT	12	12	-0.27 (?) / -0.69 (?); <b>P</b> < <b>0.05</b>		<b>P &lt;0.05</b> 2.64 (0.54) / 2.52 (0.52); <i>P &gt;</i> 0.05	. ,	

? = unclear/not reported; T = implants placed with flapless technique; C = implants placed with flap technique.

All results of variables are reported as T / C. The standard deviations are shown in parentheses. P values with statistical significant differences are marked in bold.

the decision on the flap design might be determined by patient comfort, the need for access and ridge augmentation, and experience level of the surgeon. $^{60}$ 

The theory that smoking is a risk factor for increasing dental implant failure has been well established.<sup>29,61-63</sup> The evidence showed that smokers have higher risk of implant failure, peri-implantitis, and loss of MBL than non-smokers.<sup>29,61</sup> Sanna et al.<sup>29</sup> reported an SR of 98.9% for non-smokers and 81.2% for smokers when performing flapless implant placement, which was statistically significant. Furthermore, the average marginal bone resorption was 2.6 and 1.2 mm in the smokers and non-smokers, respectively. Therefore, smoking should be considered a risk factor for the flapless approach. However, in the current review, none of the included studies analyzed the effect of smoking on primary and secondary outcomes; thus, additional studies are encouraged to investigate the effect of smoking on implant SR as well as MBL when introducing the flapless technique.

Several limitations of the current review are presented. First, the number of the included papers is low (n = 12). Second, there are various degrees of heterogeneity and publication bias. Heterogeneity is related to the presence of confounding factors within and among the selected studies, for example, study designs, follow-up periods, loading protocols, implants placed immediately after tooth extraction or in a healed ridge, and smoking habits of participants. Only two included studies<sup>44,51</sup> adjusted for the related confounding factors. Third, MBL was assessed by means of series radiographs in all selected studies. However, the changes of buccal bone level might not be accurately measured because of the limitation of radiographs as well as flapless study design. Fourth, the current review only includes studies written in English, and there was only one author performing a literature search, which could introduce a publication bias. Fifth, the patient-based outcome measures and surgical risk/complications are not analyzed in the current review; these interesting topics are of clinical importance and worthy of additional investigation.

### CONCLUSION

This systematic review reveals that the SR and radiographic marginal bone loss of flapless intervention were comparable with the flap surgery approach.

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