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REVIEW

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Narrative review regarding the applicability, accuracy, and clinical outcome of flapless implant surgery with or without computer guidance

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Abstract

Background: The advent of computer-guided surgery removed the need for complex surgical interventions such as extensive flap elevations, second stage implant exposure, and complications usually associated with conventional protocols.

Purpose: (a) Analyze available literature reporting on applicability, accuracy, clinical outcome of flapless surgery with or without computer guidance. (b) Evaluate quality of studies, in terms of scientific level of evidence and ethical committee approval.

Materials and methods: A PUBMED search was performed in July 2018. A first search was based on a general search string limited to "Dental Implants" and "flapless surgery." A second search focused on accuracy of computer-guided surgery using search string "Surgery, Computer-Assisted" or "guided surgery," and "Dental implants." The following inclusion criteria were applied: (a) studies in English; (b) human studies (excluding cadaver); (c) systematic reviews; (d) systematic reviews with meta-analysis. Reviews not mentioning accuracy were excluded in search 2.

Results: Nine reviews included in total. Implant survival ranged between 89% and 100%. Early surgical and prosthetic complications reported in 9.1% to 36.4% of reviewed papers. Tooth-supported guides show more accuracy than bone or mucosa-supported guides. Fully guided surgery yields higher accuracy, with lower values for horizontal coronal, horizontal apical and angular deviation (1.00, 1.23, and 3.13°mm, respectively) than those placed with half guided surgery (1.44, 1.91, and 4.30 mm, respectively). Thirty-four of 71 human studies included in nine reviews, mentioned ethical committee approval or compliance with Declaration of Helsinki.

Conclusions: Guided flapless surgery is comparable to free-hand surgery in terms of implant survival, marginal bone remodeling, and peri-implant variables. Clinicians advised to take care in all steps of the protocol, and include safety margins around virtually planned implants. Regarding compliance with research ethics, we should question whether scientific reports of clinical trials performed without an ethical umbrella are trustworthy. Compliance of ethics standards is imperative for submitted research papers.

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KEYWORDS

accuracy, complications, computer-assisted, dental implants, research ethics

1 | INTRODUCTION

Tooth loss is a burden for many patients as it affects both oral function and esthetics. The impact on patients' quality of life should not be underestimated, especially in fully edentulous patients.¹ It is well known that long-term denture-wearing is associated with increased discomfort due to on-going alveolar bone resorption. Dental implant supported reconstructions (bridges or overdentures) can overcome the drawbacks of the conventional denture. The use of dental implants for oral rehabilitation has become a highly predictable treatment for both partially and fully edentulous patients. According to the literature, good short and long-term results were reported for various treatment indications with implant survival ranging from 82% to 92%.²⁻⁵ Conventional implant placement protocols always involve a surgical intervention because they require a flap procedure whereby the mucoperiosteal flap is elevated to expose the bone. This increases the chance of postoperative complications such as bleeding, swelling, pain, and discomfort related to difficulties in wearing a removable prosthesis. Furthermore, flap elevation may result in soft tissue scarring and bone loss.⁶⁻⁸

2 | FLAPLESS IMPLANT SURGERY

Staffileno (1974) explained the rationale for minimal surgery⁹; a flapless approach avoids the elevation of a mucoperiosteal flap and keeps the periosteum in contact with the bone. Thereby, the supraperiosteal plexus remains intact, thus preserving its osteogenic potential and blood supply to the underlying bone. Bone denudation causes increased osteoclastic activity and leads to a net bone loss because the homeostasis shifts to a catabolic-dominant status. Clinical studies verify that marginal bone around dental implants is preserved when using flapless surgery.¹⁰⁻¹² Flapless surgery is reported as being less traumatic and time-consuming than the classical open flap approach, causing less postoperative swelling and pain, and consequently decreasing patient's discomfort.^{13,14}

3 | FREE-HAND FLAPLESS SURGERY

Several clinical trials, although often of a nonrandomized study design, evaluated the outcome of dental implants when using flapless surgery. In a long-term clinical study, single implants were installed in a one-stage flapless surgery without the use of computer-assisted guides.¹⁵ Equal clinical success was shown as those installed with conventional one-stage flap surgery. Overall, implant survival was 100% and stable bone conditions, indicative of a good long-term prognosis, were reported. The cases planned for a flapless approach had been strictly selected and an experienced clinician performed all procedures. Nevertheless, flapless

surgery in healed bone offers a good alternative to conventional surgery when carried out within the limitations of single-tooth restorations and with a delayed loading protocol. A disadvantage of flapless, free-hand surgery is that the true topography of the underlying available bone cannot be observed because the mucogingival tissues are not raised. This is important when only 2D radiographs are available (periapical or panoramic imaging), as visual inspection and clinical palpation may be insufficient to obtain the best presurgical planning in complex or compromised cases.¹⁶ It has been shown in a preclinical model study whereby specialists, dentists, and undergraduate students performed a flapless free-hand surgery on model, that there is a high risk of unwanted perforations, which can lead to esthetic problems or implant loss.¹⁷ Perforations often occurred due to mal-positioning of the drills.^{6,17}

4 | GUIDED FLAPLESS SURGERY

Mal-positioning of the drills, when using free-handed flapless surgery, may be overcome with the use of guided surgery based on computed 3D tomography scan analysis. These techniques have been introduced in the late 1990's and more and more clinical studies are being published.¹⁸ Commonly, two types of guided implant surgery protocols are described in the literature; static and dynamic. The former refers to the use of a static surgical template, which reproduces the virtually planned implant position directly from computerized tomographic data to a surgical guide. Intraoperative modification of the implant position is not possible.¹⁸⁻²⁰ With the static systems, the planned implant location is usually transferred to the surgical template by a specially designed drilling machine.²¹ Another system, called the stereolithographic method, uses specifically designed software to virtually plan and design the surgical stent, which is fabricated using polymerization of ultraviolet-sensitive liguid resin.²² The second type of guided surgery, the dynamic approach, has the key difference of allowing intraoperative changes of the implant position during surgery.^{19,20}

A variety of 3D diagnostic techniques are available for this purpose; computed tomography (CT), cone beam computed tomography (CBCT) or magnetic resonance imaging (MRI). Data relating to bone volume, bone quality or anatomical restrictions can be processed and evaluated in virtual implant simulation software. This information allows a preoperative view of anatomical structures within the jawbone and is related to the scanning template as well as the future restoration. Virtual implant positioning can be planned according to restorative goals and anatomic limitations, ultimately leading to the manufacture of a guiding template that can be used during surgery. This method of implant placement allows drilling through sleeves that mimic the virtual planning.²³ D'haese et al²⁴ published a detailed paper explaining planning and implementation for guided implant placement.

5 | ACCURACY

Accuracy evaluation for 3D guided surgery can be performed by comparing preoperative virtual planning with the postoperative location of the implants in the jaw bone. This is performed by matching virtual planning with the actual position as visible on the 3D images using specific software.¹⁵ Verhamme et al (2015)²⁵ introduced the implant position orthogonal projection (IPOP) method to evaluate accuracy of guided surgery. First, a perpendicular plane and tangent plane to the dental curve were created, corresponding with the bucco-lingual plane and mesio-distal plane, respectively. Then, the planned and actual implants were (orthogonally) projected on the bucco-lingual plane and mesio-distal plane (Figure 1). The tip and shoulder point deviations inside the bucco-lingual and mesio-distal plane were calculated by an orthogonal projection of the postoperative implants on the planned implants within these planes. In addition the angular and depth deviations were also calculated.²⁶

6 | AIM

The aim of this review was primarily to analyze the available literature reporting on the applicability, accuracy and clinical outcome of flapless surgery with or without computer guidance, and secondarily, to scrutinize the quality of these reviews, in terms of the scientific level of evidence as well as ethical committee approval.

7 | MATERIALS AND METHODS

7.1 | Focus question

In human patients receiving implant treatment, does guided surgery, compared with flapless free-hand surgery, give better clinical outcome with respect to implant survival rates, marginal peri-implant bone changes and complications?

7.2 | Search strategy

A PubMed search was performed on July 1, 2018. A first search was based on a general search string limited to ("dental implants"[mesh]) and "flapless surgery" and called search 1 (Figure 2).

A second search, search 2, focused on accuracy of computerguided surgery and was carried out using the search string ("surgery, computer-assisted"[mesh] OR "guided surgery" and "dental implants"[mesh] (Figure 3).







FIGURE 2 Search process and generated outcome of search 1 focusing on the general aspects



7.3 Selection criteria

Studies with the highest level of scientific evidence, that is, systematic reviews preferably with meta-analysis, were sought. The following inclusion criteria were applied: (a) studies in the English language; (b) studies in humans: (c) systematic reviews: (d) systematic reviews with meta-analysis.

Animal studies, cadaver studies, any studies that were not a review and reports of techniques were excluded.

The inclusion criteria were the same for search 2 as for search 1. The exclusion criteria were also similar, however, any studies not mentioning accuracy were also excluded.

7.4 Screening process

Two independent reviewers (E. N. N. and J. D.) performed a PubMed search according to the guidelines outlined in the research strategy and screened the resulting studies by analyzing titles and abstracts first. In the second phase of the study, the complete texts were selected for careful reading and analysis according to eligibility (inclusion and exclusion) criteria for future data extraction. Differences between reviewers were resolved by discussion and consensus.

8 RESULTS

Search 1 focused only on papers regarding flapless implant surgeries in clinical trials and yielded in total 85 papers, of which 73 were

FIGURE 3 Search process and generated outcome of search 2 focusing on accuracy

human studies. These included six reviews but one only included immediate implant placement and restoration²⁷ and another was irrelevant to the topic.²⁸ The four reviews²⁹⁻³² included in this study are summarized in Table 1.

Voulgarakis and coworkers (2014)²⁹ selected 23 articles from a total of 225 initially retrieved articles. The papers evaluated the outcome of three treatment protocols; free-handed surgery, guided surgery with and without 3D computer guided navigation (the former is also called stereolithographic surgery). The included studies had a prospective or retrospective design but randomized control trials were not available. Furthermore, a variety of outcomes were reported, using various implant systems and different observation periods. Because of the heterogeneity of the reported data it was not possible to perform a meta-analysis. The same was true for the systematic review carried out by Vohra et al (2015),³² where they compared the crestal bone loss around implants placed in healed sites using flapped and flapless surgical techniques, based on 10 clinical studies.

Lin et al (2014)³⁰ focused on the clinical results of flapless surgery and performed a meta-analysis on implant survival and peri-implant bone loss based on 12 studies, including seven RCT's. Moraschini et al (2015)³¹ reported on survival, marginal bone level changes and complications with guided surgery based on a meta-analysis including 13 studies.

In the two previously mentioned meta-analyses, an average implant survival of 97.2% to 98.6% was described. One systematic review³² did not report on the implant survival, only on crestal bone loss. The survival, as published in the three remaining reviews, ranged between 89% and 100%. One should bear in mind that the follow-up

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 TABLE 1
 Overview of the selected papers, reporting implant outcome variables, complications, and scientific level of evidence as described

Author	Design	Protocol	Number of studies included	Number of implants analyzed	Mean CSR (%) ± SD (%)	Range CSR (%)	Follow-up in months Mean [Range]	Mean marginal bone level changes (mm) (SD) [range]	Mean prosthetic survival (%)	Scientific level of evidence
Moraschini et al 2015	SR + M-A	GS	13	2019	97 +/- 3,49	89,2-100	22,6 [12-48]	1,45 (NR) [0.83-1.9]	83.9-100	1
Voulgarakis et al 2014	SR	Overall F-FL G-FL	23 4 17	NR	NR NR NR	89-100 98,3-100 89-100	NR [12-120] NR [12-48] NR [12-60]	NR (NR) [NR] NR (NR) [0.09-1.40] NR (NR), [0.55-2.6]	NR	1
Lin et al 2014	SR + M-A	Overall FL CS	12	NR	NR 97,0 98,6	NR 90-100 91,2-100	16.1 [6-39]	0.03 -0.11-0.18	NR	1
Vohra et al 2015	SR	Overall CS and F-FL	10 10	576	NR	NR	NR [2.5-48]	NR (NR) [1.35-1.9]	NR	1

Abbreviations: CS, conventional surgery; CSR, cumulative survival rate; F-FL, freehanded flapless; FL, flapless; G-FL, guided flapless; GS, guided surgery; M-A, meta-analysis; NR, not reported; SR, systematic review.

time was rather short; this ranged from 3 to 48. Based on all the included systematic reviews, summarizing 45 clinical trials in total, it can be concluded that free-hand surgery is comparable to guided flapless surgery in terms of implant survival, marginal bone remodeling and peri-implant variables. All of the authors do, however, send a message to warn clinicians when using this technique because safety margins need to be taken into account.

Implant treatment outcome, however, should not only depend on implant survival or bone level stability over time. In the light of evaluating cost-effectiveness, biological and technical complications, as well as the cost-benefit, should be taken into account. Table 2 summarizes the two systematic reviews reporting on postoperative complications, surgical complications, and prosthetic complications.

Search 2 focused on the accuracy of flapless guided surgery and yielded 340 articles of which 13 were reviews of studies performed in humans. In total 5 of 13 papers were rejected because, they were merely describing technicality or practical use without mentioning any well-defined 3D accuracy outcomes.³³⁻³⁷ One paper only summarized expert opinions under the form of a consensus report,³⁸ and was therefore also excluded. Another paper²⁹ did not pertain to qualitative accuracy assessment and was also excluded. The review by Vercruysse et al (2008)³⁹ is a narrative and descriptive (historical) review on the available techniques. Although a number of papers were useful in the context of accuracy, only 13 of 63 mentioned papers reported (incomplete) data on 3D accuracy.

The final papers considered relevant were Schneider et al (2009),²³ Tahmaseb et al (2014),²⁰ Moraschini et al (2015),³¹ Raico Gallardo et al (2017),⁴⁰ Bover-Ramos et al (2018),⁴¹ and D'haese et al (2012).⁴² The latter was additionally selected after reading other papers.

Of the six systematic reviews, five included a meta-analysis, These are summarized in Table 3. They can be considered as the highest scientific evidence available at this time, as described by the Oxford Centre for Evidence-Based Medicine (2011).⁴³ The Oxford Centre for Evidence-Based Medicine (2011)⁴³ adjusted the scientific levels of evidence in order to facilitate using the system, and ranked the scientific levels of evidence in the following descending order; (a) systematic reviews of randomized control trials, individual randomized controlled trials with narrow confidence level, all randomized controlled trials, (b) systematic reviews of cohort studies, individual cohort study or low quality randomized controlled trials, (c) individual case control studies, (d) case series, and finally, (e) expert opinions without critical appraisal.

Schneider et al (2009)²³ evaluated the postoperative position of the implants (or deviations) and compared them with the virtually planned position. The authors reported higher deviations when the stereolithographic surgery was followed by immediate chair-side provisionalisation with a previously prepared fixed bridge. Additionally, late prosthetic complications were found in 12% of the patients. Based on their data they performed a meta-analysis revealing that the mean horizontal deviations are 1.1 to 1.6 mm but with higher maximal deviations. The larger deviations in particular may cause nerve disturbances, damage to anatomical structures such as sinuses and nose, and later lead to prosthetic complications.

In a review performed by Tahmaseb et al (2014),²⁰ as part of the 2013 ITI consensus conference, 14 survival and 24 accuracy studies were included. The clinical survival rate was reported as 97.3% based on 1941 implants. However, in 36.4% of the treated cases, intraoperative or prosthetic complications were also reported. Those included template fractures during surgery, intraoperative changes to the treatment plan because of limited implant stability, need for unplanned bone grafting, prosthetic screw loosening, misfit, and prosthesis fractures. Based on the meta-analysis the authors concluded, there is no evidence yet suggesting that computer-assisted surgery is superior to conventional surgery in terms of safety, outcome, morbidity, or efficiency.

Moraschini et al (2015)³¹ carried out a systematic review of 13 clinical studies, and found a survival rate of 97.2% of 2019

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by the Oxford Centre for Evidence-Based Medicine (2011)

TABLE 2 Overview of the review papers reporting on complications encountered during surgery and postoperatively

Author	Design	Protocol	Number of studies reporting on complications/ total number of studies included	Complications mentioned by the authors Postop Intraoperative events Postoperative events prosth		Postoperative prosthetic
Moraschini et al 2015	SR + M-A	GS	12/13	(Number of Occurrences in total) Low implant stability (10) Fracture of guide (7) Misfit of the guide (6) Implant fenestration (4)	(% of all implants included in the study) Implant failure (3%) Infections (8%) Low primary stability (10%) Persistent pain (2%) Peri-implantitis (14%)	(% of all implants included in the study) Fracture of resin (13%) Loosening of component (7%) Extensive occlusal adjustments (3%) Misfits (9%)
Voulgarakis et al 2014	SR	Overall F-FL G-FL	17/23	Complications reported in 9/23 studies; Fracture of guide (6-10%) Fenestrations (3%) Bone dehiscences (2%)	Reported in 12/23 studies: Pain (5/12) Implant mobility (7/12) Absence of keratinized mucosa (7/12) Peri-implantitis(7/12)	Reported in 14/23 studies: Fracture of the guide in (8/14) Adjustments due to misfit in (8/14) Loosening of components in (6/14)

Abbreviations: CS, conventional surgery; F-FL, freehanded flapless; FL, flapless; G-FL, guided flapless; GS, guided surgery; M-A, meta-analysis; NR, not reported; SR, systematic review.

implants, as well as low marginal bone loss (1.45 mm) for the guided surgery technique during a 1 to 4 year follow-up period. The associated complications included implant loss (2.53%), provisional and definitive prosthesis fracture, surgical guide fracture, low primary stability or even implant fenestration. It was concluded that there is certainly a learning curve involved with guided surgery in order to achieve treatment success.

Raico Gallardo et al (2017)⁴⁰ included four studies, which had analyzed accuracy, to carry out the meta-analysis. The studies were divided into three groups comparing the following type of guides; mucosa-supported vs bone-supported guides, mucosa-supported vs tooth-supported guides, and finally tooth-supported vs bonesupported guides. Results are shown in Table 3. Interestingly, mucosasupported and tooth supported guides did statistically significantly better than the bone-supported guides, with higher comparative accuracy for coronal, apical and angular deviations. However, no statistical difference was found between the mucosa-supported and toothsupported guides.

In a recent meta-analysis carried out by Bover-Ramos and coworkers (2018),⁴¹ deviations between planned and clinical positions of the implants were found in all 34 articles included in the study (3033 implants analyzed in total). Accuracy analysis was carried out for all of the articles, including fully and partially guided protocols; however, only 22 of these were clinical studies (the remaining being cadaver or in vitro studies). Therefore, for the purpose of this study, only the clinical studies were mentioned when referring to accuracy measurements. The findings are summarized in Table 3. When comparing the two guided protocols, it was observed that implants placed

with fully guided surgery reached lower values for horizontal coronal, horizontal apical, and angular deviation (1.00, 1.23, and 3.13 mm, respectively) than those placed with partially guided surgery (1.44, 1.91, and 4.30 mm, respectively). Partially guided surgery denotes when the osteotomies are drilled used a drill guide, but final implant placement is carried out without a guide. It was concluded that fully guided surgery yields higher accuracy as compared with partially guided surgery. It was advised to leave a distance as a safety margin in order to avoid damage to crucial anatomical structures; 1.3 mm in relation horizontal coronal deviation, 1.7 mm for the horizontal apical deviation and at least 4.7° in relation to the angular deviation.

D'haese and coworkers (2012)⁴² reviewed 31 clinical studies in total, whereby 10 reported on accuracy. They did not perform a metaanalysis but concluded that guided surgery yields a more accurate placement than free-hand implant placement. Nevertheless, both from cadaver and clinical studies, it was obvious that guided surgery is far from accurate. Deviations at the shoulder of the implant hamper the accurate fit from the prosthetic reconstruction and it seems that chair-side modifications are always necessary to adapt the occlusion and articulation. They suggested that at least a 2 mm apical safety margin from the planned position is required to avoid any critical ana-tomical structures.

One must bear in mind that when stereolithographic surgery is combined with immediate loading using provisionalisation, it can influence the survival and success due to initial remodeling. This is due to the fact that the "baseline" is at the time of implant installation, as opposed to "baseline" for the conventional implant protocol which is at the moment of implant loading as the osseointegration process

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	Scientific Level of Evidence	1	L	E.
	Complications	Early surgical: 9.1% on patient level 2.5% on implant level On <i>prosthetic level</i> : 18.8% of the patients had prosthetic complications 7.3% of patients had misfit between abutment and prosthesis Late prosthetic complications: 12% of patients	Overall number of complications (patient level): 125 patients of 434 patients treated (36.4%), Type of complications: Surgical template fractures: 3.5% Treatment plan changes: 2% Implant loss by absence of primary stability: 10.2% prosthesis fractures: 2.9% Misfit of the prostheses: 18% need for extensive occlusal adjustments: 4,6%	Intraoperative events (total number of occurrences): Low implant stability (10) Fracture of guide (7) Misfit of the guide (6) Implant fenestration (4) Postoperative (% all implants included in the study): Implant failure (3%) Infections (8%) Infections (8%) Low primary stability (10%) Persistent pain (2%) Persistent pain (2%) Peri-implantitis (14%) Peri-implantitis (14%) Peri-implantitis (14%) Postoperative Prosthetic (reported in 14/23 studies): Fracture of the prosthesis in (8/14) Loosening of components in (6/1\$)
	Mean angular deviation (°); [95% Cl]; (n sites)	5.26 mm [3.94-6.58] (321)	3.89 mm; [0-21.16] (1854)	4.57 mm; [NR]; (NR)
0	Mean apical deviation (mm); [95% Cl]; (n sites)	1.63 mm; [1.26-2.0] (281)	1.39 mm; [0.3-7.1] (1465)	1.46 mm; [NR]; (NR)
	Mean coronal deviation (mm); [95% Cl]; (n sites)	1.07 mm; [0.76-1.22] (321)	1.12 mm; [0.0-4.5]; (1530)	1.13 mm; [NR]; (NR)
-	Number of studies	8 accuracy studies + 10 clinical studies	24 accuracy studies/14 clinical studies	2 accuracy studies of 13 clinical studies in total
	Design	SR + M-A	SR + M-A	SR + M-A
	Author	Schneider et al (2009)	Tahmaseb et al (2014)	Moraschini et al (2015)

TABLE 3 Overview of the review papers reporting on accuracy and complications with guided 3D-surgery

Scientific Level of Evidence	£						(Continues)
tions							
Complica	(NR)						
Mean angular deviation (°); [95% CI]; (n sites)	Mucosa-supported guides vs bone-supported guides Greater reduction in the angle deviation in mucosa-supported guides (P = .02)	1.08 mm; [0.18-1.99] (NR)	Tooth-supported guides vs bone-supported guides Deviation was statistically lower when tooth-supported (P < .001)	1.41 mm; [1.82 to -0.99] (NR)	Mucosa-supported guides vs tooth-supported guides no significant difference	0.42 mm; [1.30-0.45] (NR)	
Mean apical deviation (mm); [95% Cl]; (n sites)	Mucosa-supported guides vs bone-supported guides higher accuracy for mucosa-supported (P = .04)	0.48 mm; [0.03-0.93] (NR)		Tooth-supported guides vs bone-supported	guides Higher accuracy for the tooth-supported guides (P = .001)	–0.50 mm; [–0.80 to –0.20] (NR) Mucosa-supported guides vs	tootn-supported guides
Mean coronal deviation (mm); [95% Cl]; (n sites)	Mucosa-supported guides vs bone-supported guides higher accuracy for the mucosa-supported (P = .002)	0.48 mm; [0.17-0.78] (NR)	The second s	roour-supported guides vs bone-supported guides Tooth-supported guides statistically higher	accuracy (P = .01) -0.37 mm; [-0.66 to -0.09] (NR)	Mucosa-supported guides vs tooth-supported guides no significant difference 0.09 mm; [-0.10 to 0.29]	
Number of studies	4 accuracy studies used in the Meta-Analysis, divided into groups comparing mucos-supported vs tooth-supported guides						
Design	SR + M-A						
Author	Raico Gallardo et al (2016)						

TABLE 3 (Continued)

TABLE 3 (Continued)

Scientific Level of Evidence		1	-
Complications		(NR)	 5/31 studies reported the following surgical and technical complications (0/4 accuracy studies reported on complications); Intraoperative events Low implant stability Fracture of guide Misfit of the guide Postoperative Peri-implant pathology Peri-implant pathology Postoperative prosthetic Occlusal material fracture of the prostoperative of the prostoperative fracture of the prostoperative of the prostoperative prosthetic Peri-implant pathology Postoperative prosthetic Occlusal material fracture of the prostoperative of the prosthesis Loosening of retaining screws Slight discrepancies between the abutments and implants Midline deviation of prosthetic Fractures of the complete acrylic
Mean angular deviation (°); [95% Cl]; (n sites)		3.98 mm; [3.31-6.62]; (NR)	3.54 mm; [NR]; (NR)
Mean apical deviation (mm); [95% Cl]; (n sites)	no significant difference 0.01 mm; [-0.33 to 0.35] (NR)	1.40 mm; [1.16-1.64]; (NR)	1.64 mm; [NR]; (NR)
Mean coronal deviation (mm); [95% Cl]; (n sites)		1.10 mm; [0.91-1.28]; (NR)	1.04 mm; [NR]; (NR)
Number of studies		34 accuracy studies 22/34 in vivo studies	31 studies 4/31 in vivo studies reporting on accuracy
Design		SR + M-A	ĸ
Author		Bover-Ramos et al (2018)	(2012) (2012)

Abbreviations: CS, conventional surgery; F-FL, freehanded flapless; FL, flapless; GS, guided surgery; LR, Literature Review; M-A, meta-analysis; NR, not reported;R, review; S, systematic review.

TABLE 4 Evaluation of formal ethical approval in all studies included in the following 9 reviews; (1) Schneider et al 2009, (2) Lin et al 2014, (3) Moraschini et al 2015, (4) Voulgarakis et al 2014, (5) Tahmaseb et al 2014, (6) Vohra et al 2015, (7) Raico Gallardo et al 2016, (8) Bover-Ramos et al 2018, (9) D'haese et al 2012

Reference	Cited in review paper	Type of study	Ethical committee approval
Van de Velde et al 2010	2, 6	RCT	EC-A
Tsoukaki M et al 2013	6	RCT	EC-A
Bashutski et al 2013	2, 6	RCT	EC-A
Vercruyssen et al 2014	8	RCT	EC-A
Arisan et al 2010	5, 7, 8	PCCT	EC-A
Di Giacomo et al 2005	1, 8, 9	PCS	EC-A
Van Steenberghe et al 2005	1	PCS	EC-A
Ersoy et al 2008	5	PCS	EC-A
Johansson et al 2009	3	PCS	EC-A
Ozan et al 2009	1, 7, 8, 9	PCS	EC-A
Van Assche et al 2010	8	PCS	EC-A
Ozan et al 2011	5	PCS	EC-A
Vasak et al 2011	8	PCS	EC-A
Platzer et al 2011	5	PCS	EC-A
Arisan et al 2012	5	PCS	EC-A
Pettersson et al 2012	5, 8	PCS	EC-A
D'haese et al 2012	8	PCS	EC-A
Katsoulis J et al 2012	6	PCS	EC-A
D'haese et al 2012	3	PCS	EC-A
Di Giacomo et al 2012	3, 8	PCS	EC-A
Vasak et al 2012	4	PCS	EC-A
Landazurri et al 2013	3	PCS	EC-A
Arisan et al 2013	8	PCS	EC-A
Browaeys et al 2014	3	PCS	EC-A
Verhamme et al 2014	8	PCS	EC-A
Van de Wiele et al 2014	8	PCS	EC-A
De Bruyn et al 2011	2, 6	RCCT	EC-A
Cassetta et al 2012a	8	RCCT	EC-A
Ersoy et al 2008a	7	RCS	EC-A
Ersoy et al 2008b	8	RCS	EC-A
Komiyama et al 2008	1	RCS	EC-A
Komiyama et al 2012	3	RCS	EC-A
Cassetta et al 2012b	7	RCS	EC-A
Cassetta et al 2012b	8	RCS	EC-A
Ozan et al 2007	2	RCT	EC-NA
Covani et al 2008	2	RCT	EC-NA
Froum SJ et al 2011	6	RCT	EC-NA
Cannizzaro et al 2011	2	RCT	EC-NA
Froum et al 2011	2	RCT	EC-NA
Al-Juboori MJ et al 2012	6	RCT	EC-NA
Sunitha and Sapthagiri 2013	2, 6	RCT	EC-NA
Chen et al 2010	8	PCCT	EC-NA
Beretta et al 2014	8	PCCT	EC-NA
Fortin et al 2004	1	PCS	EC-NA
Wittwer el al. 2007	4	PCS	EC-NA

TABLE 4 (Continued)

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Reference	Cited in review paper	Type of study	Ethical committee approval
Malo et al 2007	3	PCS	EC-NA
Rao and Benzi 2007	4	PCS	EC-NA
Malo et al 2008	2, 6	PCS	EC-NA
Job et al 2008	6	PCS	EC-NA
Gillot et al 2010	3	PCS	EC-NA
Nikzad and Azari 2010	4	PCS	EC-NA
Behneke et al 2012	5, 8	PCS	EC-NA
Marra et al 2013	3	PCS	EC-NA
Berdougo et al 2010	4	RCCT	EC-NA
Rousseau 2010	2	RCCT	EC-NA
Campelo and Camara 2002	4	RCS	EC-NA
Fortin et al 2003	1	RCS	EC-NA
Vrielinck et al 2003	1	RCS	EC-NA
Nickenig and Eitner 2007	1	RCS	EC-NA
Sanna et al 2007	1	RCS	EC-NA
Sennerby et al 2008	2	RCS	EC-NA
Yong and Moy 2008	1	RCS	EC-NA
Valente et al 2009	8, 9	RCS	EC-NA
Puig 2010	3	RCS	EC-NA
Nickenig et al 2010	5, 8	RCS	EC-NA
Meloni et al 2010	3	RCS	EC-NA
Rousseau 2010	4	RCS	EC-NA
Jeong et al 2011	4	RCS	EC-NA
Cassetta et al 2013a	5, 8	RCS	EC-NA
Cassetta et al 2013b	8	RCS	EC-NA
Mischkowski et al 2006	1	-	-

Abbreviations: EC-A, ethical approval available; EC-NA, ethical approval not available; PCCT, prospective case control trial; PCS, prospective case series; RCCT, retrospective case control trial; RCS, retrospective case series; RCT, randomized clinical trial.

is nearly completed, roughly 3 months after implant placement. In addition, manipulation of the installed implants during immediate provisionalization could cause additional deviations, especially in osteoporotic patients or in areas with limited bone density.

It is striking that, despite the largely spread use of the guided surgical approach, so many complications and inaccuracies are encountered. Based on the fact that these surgical/prosthetic techniques are widely promoted, one could expect that proper clinical research would be performed prior to commercialization on the implant market. As a clinician, one expects that scientific scrutiny be implemented in order to be sure that the quality of the treatment and safety of the patient is guaranteed.

Although it was not the scope of this paper to scrutinize in detail the original papers reported in the literature, a closer look was taken at the quality, in particular the research ethics, of the studies mentioned in the nine systematic reviews; (1) Schneider et al (2009),²³ (2) Lin et al (2014),³⁰ (3) Moraschini et al (2015),³¹ (4) Voulgarakis et al (2014),²⁹ (5) Tahmaseb et al (2014),²⁰ (6) Vohra et al (2015),³² (7) Raico Gallardo et al (2017),⁴⁰ (8) Bover-Ramos et al (2018),⁴¹ (9) D'haese et al (2012).⁴² An overview is presented in Table 4.

A total of 173 studies were discussed between the nine reviews. Seventy-five of these are cadaver or model based (in vitro) studies. For these, approval from an ethical committee was not required and these studies were not included in the results of implant outcomes or accuracy analyses. Eight studies were not clinically relevant and did not report on accuracy or implant outcomes. One paper was not available for full text reading.⁴⁴ This leaves 90 available human studies, 18 of which are duplicates, that is, mentioned in more than one review paper, rendering a total of 71 individual, relevant, human studies.

From the 18 articles included in the review by Schneider et al (2009),²³ 8 were excluded because they were not clinical studies. Of the remaining 10 clinical studies, only 4 of the 10 had ethical committee approval and 6 did not mention ethical committee approval or comply with the Declaration of Helsinki. In total seven articles were cadaver or model studies⁴⁴⁻⁴⁹ and the paper of Mischkowski et al (2006)⁴⁴ was not available for reading.

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TABLE 5Overview of the total number of clinical studies,
corresponding ethical committee approval, and scientific level
of evidence as described by the Oxford Centre for Evidence-Based
Medicine (2011)

Study design	Number of studies with ethical committee approval	Number of studies with no mention of ethical committee approval	Level of evidence
RCT	4	7	2
PCCT	1	2	3
PCS	21	11	4
RCCT	2	2	3
RCS	6	15	4
Total number	34	37	71

Abbreviations: EC-A, ethical approval available; EC-NA, ethical approval not available; PCCT, prospective case control trial; PCS, prospective case series; RCCT, retrospective case control trial; RCS, retrospective case series; RCT, randomized clinical trial.

From the studies included in the review by Lin et al (2014),³⁰ 11 were applicable due to being clinical studies. Of these 11, only 3 had approval, 8 did not mention any ethical committee approval or compliance with the declaration of Helsinki.

From the studies included in the review by Moraschini et al (2015),³¹ 11 studies were applicable due to being clinical studies, and from these only 6 had ethical approval.

Only 1 of the 8 studies had ethical committee approval from the studies included in the review by Voulgarakis et al (2014).²⁹ In the review by Tahmaseb et al (2014),²⁰ a total of 6 of 10 articles received ethical committee approval and 1 was not applicable as it was a cadaver study.⁵⁰ The review carried out by Vohra et al (2015)³² included 5 studies with ethical committee approval of the total of 10.

All 4 of the articles used in the meta-analysis carried out by Raico Gallardo et al (2017)⁴⁰ had ethical committee approval.

Bover-Ramos et al (2018)⁴¹ included 34 studies in total, 4 of which were cadaver studies and 8 "in vitro." This left 22 remaining clinical studies, of which 14 received ethical committee approval, and 8 studies that did not mention any ethical committee approval or compliance with the Declaration of Helsinki.

From the 31 studies included in the review by D'haese et al (2012),⁴² 3 were applicable due to being clinical studies "in vivo." Two of these three had approval.

The results are summarized in Table 5 and give insight into the availability of ethical committee, or any other clinical board, approval as well as the scientific level of evidence of the original studies, based on the 2011 Oxford Centre for Evidence-Based Medicine.⁴³ The original studies were consulted to collect this information.

It is striking that merely 34 of the 71 human studies mentioned in the nine review papers had any mention of ethical committee approval or of complying with the Declaration of Helsinki.

One can argue that ethical committee approval was only enforced since 2014, and some of the articles included were published prior to that date. However, the Declaration of Helsinki, which is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association independent of ethical committee approval, has been in effect since 1964. The Declaration is an important document in the history of research ethics as it is the first significant effort of the medical community to regulate research itself, and forms the basis of most subsequent documents.

Regarding the quality of the studies used in the systematic reviews, from 71 studies evaluating the flapless surgical protocol, 52 are case series. This means that these studies described the outcome of a flapless approach without including any control group. Only 11 of 71 studies are randomized control trials, which offer the highest level of evidence, with only 4 of these mentioning ethical committee approval. There are also 4 retrospective case control trials and 3 prospective case control trials which could be considered of reasonable quality for a study, however, once again, less than half of these mention ethical committee approval.

It is interesting that the authors of one of the meta-analyses reviewed in this study⁴⁰ also evaluated the quality of the studies included. It was found that none of the studies reported sample size, not all studies described calibration of the surgeons or assessors, and only two studies mentioned the management of potential confounders. The majority of the studies included were of medium-level methodological quality according to Raico Gallardo et al (2017).⁴⁰

9 | CONCLUSION

In conclusion, despite the obligation to submit clinical studies for independent evaluation by an ethical committee in order to protect patients, it seems that this was not the case in the majority of the retrieved papers. The so-called the highest scientific evidence from the systematic review papers should be questioned because of the poor number (less than 25%) of high quality papers, and their inconsistent methodological quality. One can question whether the patients have been given a safe treatment option when being part of the performed treatment or whether we can completely trust the scientific reports of clinical trials that are performed without an "ethical umbrella."

It can be deduced that guided flapless surgery is comparable to freehanded surgery in terms of implant survival, marginal bone remodeling and peri-implant variables. With regards to guided flapless surgery, the results from the studies strongly suggest that there is an association between guide support, the protocol used and clinical accuracy of computer-guided surgery, wherein tooth-supported guides show more accuracy than bone or mucosa-supported guides, and fully guided surgery yields higher accuracy compared to partially guided surgery.

The technique is still very sensitive to cumulative errors, therefore clinicians are advised to take great care in all steps of the guidedsurgery protocol, and in particular, to include safety margins around the virtually planned implants.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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