

How successful and predictable are implants placed with flapless guided surgery in fully edentulous rehabilitations?

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A critical appraisal of a systematic review: V. Moraschini, G. Velloso, D. Luz, E. Porto Barboza: Implant survival rates, marginal bone level changes, and complications in full-mouth rehabilitation with flapless computer-guided surgery: a systematic review and meta-analysis. *International Journal of Oral and Maxillofacial Surgery* 2015; 44: 892–901

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Summary

Systematic review conclusion: The analysis of the studies included in this review revealed a high cumulative implant survival rate (97.2%) and a low marginal bone loss (1.45 mm) during 1–4 years of follow-up. However, associated surgical and prosthetic complications are often found, and there is a learning curve to achieve treatment success. Further longitudinal comparative studies should be conducted to improve this technique and its success rate.

Critical appraisal conclusion: Flapless guided implant surgery with immediate loading can be a successful and predictable treatment protocol for fully edentulous rehabilitations. Surgical and prosthetic complications can be expected depending on the amount of deviation created by inaccuracies or error occurring from 3D imaging to the transformation of data into a surgical guide, and improper positioning of surgical guides during surgery. Overall the evidence presented in this review is of a poor quality with descriptive statistics biased towards the Nobel BioGuide system and Nobel Biocare external hex implant. The evidence should be interpreted with caution when considering other systems, clinical effectiveness or cause-effect relationships (harmful effects).

Implications for clinical practice: Clinicians implementing this technology into their practice should follow the Adopt, Learn, Practice and Evolve (ALPE) paradigm to limit inaccuracies and increase successes. Acquire a CBCT scanner and master its diagnostic and treatment planning capabilities. Partner with a dental technician who has adopted and made the transition to digital workflow. Guided implant surgery is teamwork at its best. Follow the learning curve by starting with simple cases and develop basic surgical and prosthetic skills, then progressing to partially edentulous, and then fully edentulous cases. Select cases carefully, ensuring that there is adequate bone volume available. Appropriate selection of the type of prosthesis is fundamental in the beginning of the treatment planning. All aspects of the 3-D interactive treatment planning and guided surgery are based on basic surgical and prosthetic principles and practices.

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Clinical question

What are the implant survival rates, marginal peri-implant bone changes, and complications of guided surgery for the treatment of fully edentulous patients after a 1-year follow-up?

Review methodology

The methodology used in this systematic review was based on scientifically approved and accepted guidelines. A systematic search of the MEDLINE/PubMed and the Cochrane Central Register of Controlled Trials (CENTRAL) was conducted to retrieve studies that met predefined eligibility criteria, published up until July 2014. To be eligible for inclusion, studies had to meet the following criteria: (i) randomized clinical trials (RCTs), controlled clinical trials (CCTs), prospective and retrospective cohort studies, or case series (with >10 cases); (ii) published in English language; (iii) edentulous humans over 18 years of age (maxilla and/or mandible); (iv) a minimum follow-up of 1 year; and (v) at least 10 participants in each study sample. Studies where implants were installed in areas of bone regeneration, or included study participants with uncontrolled systemic diseases, untreated periodontal disease and using bisphosphonates were excluded. Two independent reviewers searched, screened, and selected studies according to the eligibility criteria for inclusion and data extraction. Differences between reviewers were resolved by discussion and consensus. Cohen's kappa statistic was used to measure the agreement of searches made by the two reviewers. The agreement measured between reviewers was almost perfect. The primary outcomes measured were survival rates, marginal bone changes, and implant complications. Quantitative analyses and subsequent meta-analysis were only possible for marginal bone level, as these were the only data that could be pooled. The pooled mean marginal bone loss with 95% confidence intervals (95% CI) was calculated using the random effect model. Statistical homogeneity was calculated using the Cochran Q-test combined with P-values and I² statistics. Data that could not be pooled, such as implant survival, accuracy, and complications, were analyzed using descriptive (qualitative) statistics.

Main results

Study characteristics

Thirteen prospective (10) and retrospective (3) case series observational studies published between 2005 and 2014 met the eligibility criteria. Considerable heterogeneity in the study populations, intervention, follow-up evaluation and

measurement of outcome was found between studies. The total study population consisted of 329 participants between the ages of 34 to 92 years. In total 2019 surface treated implants were placed in the maxilla or mandible. Most studies used external hex implants (11) whilst two studies used Morse-taper connection implants. The implants varied in length (7–18 mm) and diameter (3.3–5.0 mm).

Three virtual surgery systems were used in the studies namely, Nobel-Guide (Nobel Biocare AB, Sweden) (11 studies), Materialise (Materialise NV, Leuven, Belgium) (1 study), and Sinterstation HiQ (3D Systems, Rock Hill, SC, USA) (1 study) to fabricate 373 surgical guides. In all studies, intermediate abutments were used. Analysis of prosthetic procedures revealed that nine studies used an immediate prosthesis, whereas four studies used immediate loading provisional's. The definitive prostheses were manufactured 4–12 months after surgery.

The duration of follow-up ranged from 1 to 4 years, with a mean follow-up of 22.6 months. Patient follow-up included clinical examinations with visual inspection, probing, periapical radiographs (6 studies) panoramic radiographs (4 studies), CBCT scans (2 studies), analysis of primary and secondary implant stability using a torque meter (4 studies), resonance frequency (2 studies), and questionnaires about participant satisfaction (3 studies).

Implant and prosthetic survival rates

The mean cumulative implant survival rate at follow-up measured in all the studies was 97.2% (SD 3.49). Of the total implant losses (51); most (58.8%) were classified as delayed (4–24 months). The cumulative survival rate of the prosthesis ranged from 83.9% to 100%.

Complications

The pooled marginal bone loss was 1.45 mm (95% CI 1.02–1.89 mm), and heterogeneity was substantial (I² = 95%; P < 0.001). The studies that used more than five implants on each arch and those that used the All-on-Four concept, when analyzed separately, had pooled values of 1.47 mm (95% CI 1.16–1.79 mm) (I² = 97%; P < 0.001) and 1.43 mm (95% CI 0.68–2.18 mm) (I² = 97%; P < 0.001), respectively.

Of the 13 studies evaluated, only one did not report any complication. The most common surgical complications reported were: low primary stability (10 cases – 0.49%); surgical guide fracture (7 cases – 1.88%); surgical guide misfit (6 cases – 1.61%); Fenestration (4 cases – 0.20%); and one implant fracture.

Post-operative complications reported were: implant loss (51 implants – 2.53%); prolonged post-operative pain (13 individuals – 3.95%); mucositis (14 cases – 4.25%); marginal fistula/infection (7 cases); and peri-implantitis (5 cases – 0.25%)

Prosthetic complications reported in the studies were: prosthesis resin fracture (28 cases – 7.51%); Prosthesis resin element fracture (22 cases – 5.9%); extensive adjustment to occlusion (10 cases – 2.68%); Loose retaining screw (26 cases – 1.29%); misfit of the abutment – bridge (28 cases – 1.29%); and misfit of abutment to implant in 4 cases.

Conclusion

The analysis of the studies included in this review revealed a high cumulative implant survival rate (97.2%), and a low marginal bone loss (1.45 mm), during 1–4 years of follow-up. However, associated surgical and prosthetic complications are often found, and there is a learning curve to achieve treatment success. Further longitudinal comparative studies should be conducted to improve this technique and its success rate.

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Commentary

Background and importance

3-D imaging technology in combination with interactive treatment planning software has paved the way for virtual implant planning and guided implant placement. The main objectives of computer-guided dental implant placement and restoration is firstly to allow the precise planning of implant positions from computed tomography scans, and secondly to generate an accurate surgical guide that permits the surgeon to place implants precisely into planned positions allowing immediate prosthesis placement.¹

Implant dentistry is experiencing an increasing acceptance of 3-dimensional cone beam computer tomography (CBCT) scanners, primarily due to increasing availability, reduced radiation and lower costs. Through CBCT 3-D imaging data clinicians can now determine precise placement of implants in relation to bone anatomy dimensions and vital anatomical structures in the surgical site to be treated. The preoperatively virtually planned implant position can now be transferred into the patient's mouth by means of a surgical drill guide (static guide) fabricated in a dental laboratory stereo lithographically by computer-aided design (CAD)/computer-

aided manufacturing (CAM) technology or manually using mechanical positioning devices or drilling machines.

The use of CBCT to plan the placement of implants and the use of surgical guides, aided by specific software, has ruled out the necessity for using a flap. It has been hypothesized that flapless surgery would potentially result in reduced surgery time, less postoperative complications and reduced patient discomfort.^{2, 3} Guided implant surgery has also given new impetus to prosthetic driven implant dentistry by optimizing the mutual interaction between the surgical and prosthetic teams. When the planned prosthesis is incorporated into these computed tomography images, the planning can take into account both the jawbone anatomy and the biomechanics of the planned superstructure. Precise preoperative planning with interactive software and CAD/CAM has now also made possible the production of a prosthesis and immediate loading in a relatively predictive manner, thereby reducing the treatment time and increasing patient comfort.¹ Few studies have evaluated the survival and success of prostheses placed using computer-guided techniques.

Are the results valid?

This review presents with various limitations that may introduce bias and therefore potentially affect the quality and the validity of the evidence.

The studies included in this review were descriptive case series studies and therefore generally regarded as a low level of evidence. The weakness of case series studies is that they are generally very susceptible to bias because they lack comparative or control groups.⁴ Many variables may have changed during the treatment period. It is also impossible to determine whether the observed outcome would likely have occurred in the absence of exposure. Overall the studies were biased towards the NobelGuide guided surgery system and Nobel Biocare implants.

Not all participants within and across studies had the same exposure and the same risk of outcome. For instance six studies did not report whether smokers were included. This variable is fundamental in the analysis of marginal bone changes and implant survival data because it is known to increase risk of implant complications and failures. Jaw type, number of implants and implant size and opposing dentition also varied between studies.

The circumstances and methods for measuring outcome were also not similar between studies. Different methods were used for measuring outcome and no study reported the standardization methods used for the radiographs. Because of the heterogeneity in study designs included in the

systematic review comparison of different static computer-assisted implant systems used in the included studies was impossible.

The study design, inconsistency and imprecision in the research methodology, potentially increases the risk of bias resulting in poor quality of evidence. Although the descriptive statistics reported in this review have some prognostic and descriptive value, the findings from this review should be interpreted with caution with regards to cause-effect relationships.

What were the key findings?

The key findings were a high cumulative survival rate (97,2%; SD 3.49), and a low marginal bone loss (1.45 mm; SD 0.38) with flapless guided surgery and immediate loaded prosthesis for an edentulous rehabilitation over 1-4 years follow-up. Implant failures (51 implants), followed by prosthesis fracture (28 cases) were the most commonly reported complications. Most implant failures occurred at 4-24 months and were associated with low primary stability, parafunctional habits or patients not following instructions in the first months after immediate prosthetic loading.

The estimate of marginal bone levels was characterized by wide confidence intervals between studies. This can be contributed to the fact that studies generally had small sample sizes and lacking power. Overall the descriptive statistics is biased towards the Nobel Bio guide system and Nobel Biocare external hex implant. The results of the meta-analysis and the descriptive statistics has limited prognostic value and limited clinical significance due the lack of a control group for comparative analysis.

How are the results of this review applicable in clinical practice?

Continued expansion and adoption of this technology into clinical practice is a reality.

Technology requirements

A basic requirement for flapless computer-guided implant placement is a CBCT scanner. These are very costly, however invaluable to the clinician in any sphere of dentistry. There are many treatment planning software programs and providers of surgical guides, with some closed systems associated with particular implant systems, whereas others are open platforms for use with all dental implants. Each computer-assisted guiding systems has its variations, advantages and disadvantages that the clinician has to learn and master. Clinicians have to consider the compatibility of

the implant system they are using and the virtual software system platforms they want or could use.

Skills requirements

This procedure is technique sensitive and has a learning curve that must be mastered. The clinician requires education and special skills in impression techniques, taking and interpreting CBCT images and then communicating images into the digital workflow system for further processing. The clinician also requires enhanced skills in securing the surgical guide in the correct position and using the correct sequence of surgical drills. Implants placed with flapless guided surgery basically means working blind in the 3D implant positioning environment, therefore this technique is especially indicated in those cases with good bone volume. When there is limited bone volume even a .5mm misplacement of the guide or deviation of drill bits toward the buccal can mean the difference between success and failure. A fundamental consideration for every clinician therefore is to choose the right cases (i.e. adequate bone volume) suited for guided surgery. Increasing accuracy is of critical importance. Deviations may reflect the sum of all errors or inaccuracies occurring from 3D imaging to the transformation of data into a surgical guide, to the improper positioning of the latter during surgery. Possible sources of deviation and error (inaccuracies) include: patient movement during the scanning process; incorrect positioning of the scan prosthesis; acquisition of patient anatomic data and building of the model for the production of the stereo lithographic guide; malpositioning and stabilization of the surgical template; incorrect angulation of the drill within the guide guide.⁵ All these factors have to be taken into consideration by the clinicians to develop a skill-set that will increase successes and reduce failures and complications. Basic conventional implant surgery skills are an essential requirement before embarking on guided surgery. In fact clinicians should be differentiating between localized areas of rehabilitation such as a posterior sextant, anterior sextant or even a single tooth before progressing to full cross-arch surgery. Each one has different parameters and skill set requirements.

Cost

Full mouth rehabilitations with flapless guided implant surgery are expensive for the patient and time consuming for clinician. However, this technology although costly will save the patient a significant reduction in treatment time and morbidity due to the number of surgical procedures.

Risks and benefits

With flapless guided surgery there is an increased risk of overheating and dose of radiation. Other disadvantages are there is less feel regarding assessing the bone quality, also, no grafting or ridge splitting is possible with this technique. Finally, it requires much more time from the clinician to plan, prepare and perform the surgery. Furthermore, if an implant is lost a new CBCT and surgical stent may be required which could further increase radiation, treatment time and cost. Overall, benefits to the patients exceed the risks. When placing multiple implants, the time saving is there however the real benefit is the accuracy of placement. The patient should generally have less discomfort and no or minimal swelling.

Dental laboratory technician

There is one other catalyst that is important for the continued expansion and adoption of the digital workflow technology namely, the dental laboratory technician, is an integral part of the implant team and should be entirely fluent in the use of virtual CAD/CAM design software, and have invested in the necessary equipment to provide these services as the technology continues to evolve.

Clinical resolution

Cone beam computed tomography, computer-guided software systems, and surgical guide fabrication technologies are providing clinicians with advanced diagnostic tools enabling enhanced implant planning, surgical intervention capabilities, and links to the CAD/CAM process that will continue to evolve over the next decade.

This case series review assessed survival rates and complications of flapless guided implant surgery of fully edentulous rehabilitations over a period of time.

The authors concluded that guided flapless surgery with prosthodontically driven implant placement in fully edentulous rehabilitation cases can be successful (97,2% cumulative survival rate) and predictable (low marginal bone loss -1.45 mm). However, minor surgical and prosthetic complications can be expected after 1-4 years.

Guided-surgery applications are dependent on careful diagnosis using the advanced tools that 3-D CBCT imaging offers in combination with advanced interactive treatment planning software. It has numerous advantages for the patient and those clinicians that are prepared to invest time in the learning curve. Despite the advantages of 3D guided procedures, 3D deviations are expected at the time of implant placement potentially resulting in surgical or prosthetic complications.

This review does not assess or compare different systems; flapless (mucosal supported guides) with non-flapless (bone-supported guides); guided versus freehand implant placement. It also does not provide any information on accuracy of the system or cost and time effectiveness. These issues can only be done by comparative analytic studies.

Disclosure and disclaimer

Dr Johan Hartshorne is trained in clinical epidemiology, biostatistics, research methodology and critical appraisal of research evidence. This critical appraisal is not intended to, and do not, express, imply or summarize standards of care, but rather provide a concise reference point for dentists to aid in understanding and applying research evidence from referenced early view or pre-published articles in top ranking scientific publications and to facilitate clinically sound decisions as guided by their clinical judgement and by patient needs.

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