Flapless Implant Surgery Using an Image-Guided System. A 1- to 4-Year Retrospective Multicenter Comparative Clinical Study

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ABSTRACT

Purpose: The aim of this retrospective multicenter clinical study was to compare the survival rate of dental implants placed with two different surgical procedures: (1) a flapless surgical procedure using an image-guided system (IGS flapless protocol) and (2) the conventional technique (open flap without IGS) with a computed tomography scan.

Materials and Methods: Between 2001 and 2004, 552 implants were placed in 169 patients by six practitioners who used both protocols to restore completely and partially edentulous arches: 271 of them were placed with the IGS flapless protocol (test group) and 281 with the conventional procedure (control group). Each implant was categorized as "survival" or "failure" after 1 to 4 years of follow-up after prosthesis implantation. A preoperative classification was used to evaluate the anatomic features of each case. There was initially no possible comparison between these two groups because of the indication bias relative to the retrospective clinical study data characteristics. After a classic logistic regression analysis, propensity scores were used to reduce this bias: prognosis variables were included in a regression logistic model to define the probability for each implant to be treated with the IGS flapless protocol. Implants showing the same probability were categorized into three classes. The implants were then compared with each other within the same class.

Results: After the follow-up period, the cumulative survival rate was 98.57% in the control group and 96.30% in the test group. Whatever the statistical method used, no statistical differences between the two protocols were shown. Transmucosal implant placement showed a survival rate of 97%. Even though the initial conditions were less favorable, the survival rate in the test group was comparable with the standard protocol group.

Conclusion: Passing an implant through the gum does not interfere with osseointegration. The IGS flapless procedure makes it possible to use the flapless procedure, even though anatomic conditions were initially unfavorable.

KEY WORDS: computer-aided surgery, dental implant, flapless surgery, image-guided system, minimally invasive surgery, propensity scores, surgical flap

INTRODUCTION

Today surgery aims to exploit less invasive surgical procedures as much as is feasible. Patient and surgeon discomfort, time of surgery and hospitalization, esthetic damage, pain, and tissue trauma all need to be reduced. A number of authors have demonstrated that this should be possible.[1–3]

In oral implant placement, minimally invasive surgery often means a flapless procedure. Because it is a blind surgery, some authors limit the procedure to a bone crest at least 7 mm in width[1,2] in cases requiring a single-stage procedure[4–11] or in immediate implantation.[12]

To use the flapless procedure on a thinner crest, other teams have pioneered the use of the image-guided system (IGS), which objectives are twofold: defining an operative strategy that takes advantage of the localizing capabilities

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of imaging, and performing the previously defined operative procedure with a less invasive protocol using a suitable guidance system. The rationale of this approach is based on the precision of these systems.[13–22]

For dental implant placement, different approaches have been proposed to transfer the planned position to the surgical field,[23,24] such as navigating with an optical tracking system or a magnetic tracking system, using a template as a drill guide on the surgical field, fitted on soft tissue or on bone, or using a robot with a mechanical arm. Whatever technique is used, one hypothetical drawback of the flapless procedure is that it could interfere with osseointegration because of implant surface contamination and the deposition of epithelial and connective cells in the bone during surgical preparation. It has been demonstrated that, on a large crest, the success rate is comparable with the conventional procedure.[1,2]

The purpose of this retrospective multicenter comparative clinical study was to compare the survival rate of dental implants placed using an IGS based on a custom template associated with a flapless procedure with the conventional protocol. The preoperative anatomic conditions were also considered in this study.

MATERIALS AND METHODS

Methods

Between January 2001 and December 2004, every implant that was placed after computed tomography (CT) scan examination were considered in the study. Surgical placements were performed either with image-guided procedure (Easyguide™, Keystone-Dental, Inc., Burlington, MA, USA) or conventional procedure. Clinical considerations used to assign patients to one procedure or the other depend on the practitioner. All of the six practitioners involved in the study are members of the Department of Oral Surgery staff of the Hospices Civils de Lyon, France, and are considered as well trained for implant placement, are informed of the European Association for Osseointegration guideline for the use of CT images for implant dentistry,[25] and could treat the patients with both protocols.

Patients that needed preoperative bone graft, immediate loading, or immediate implantation after tooth extraction were excluded.

Prior to treatment, a clinical examination of the patient and a complete radiographic examination (panograms, parallel cone periapical films, and CT scan of proposed implant sites) were performed.

In the test group, a study of prosthesis was made on a diagnostic cast. After preliminary assessment, this prosthesis was duplicated in acrylic resin and then used as a scanning template. The prosthetic teeth were made with radiopaque resin so that it would be clearly visible on the CT scan.

In the control group, a CT scan without a radiographic template was performed.

Planning Procedure

Test Group. IGSs for oral implant placement consist of a software program for virtual implant placement and a suitable guidance system to carry out the previously defined operative strategy. In the EasyGuide protocol (Keystone-Dental Inc.), a template coupled with a drilling machine is used. Prior to surgery, the template is drilled according to the preoperative plan made with imaging software. To drill the template at the exact location, it is of primary importance to find a rigid mathematical transformation between the software program for virtual implant placement and the drilling machine. Therefore, a fiducial marker is fixed at the front of the previously fabricated scanning template for the scanning procedure so that it is outside the patient's mouth, in front of the maxilla of interest (Figure 1). Axial images are obtained from a fan-beam spiral CT scan. They are transferred to the EasyGuide planning software, which provides both reformatted anatomic planes passing by the planned implant axis, whatever its orientations, and three-dimensional (3-D) views: the axial cut and two reformatted views, perpendicular and tangential to the arch of the jaw. For each patient, the

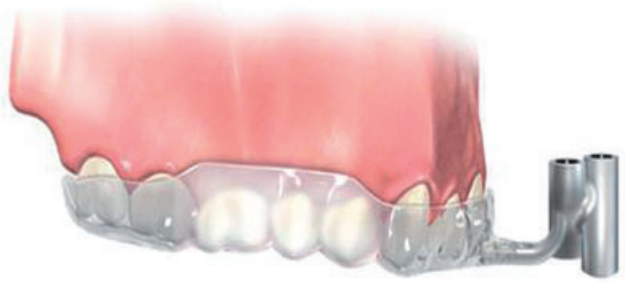

Figure 1 To drill the template at the planned location, an X-fiducial marker is fixed at the front of the previously fabricated scanning template so that it is outside the patient's mouth, in front of the maxilla of interest.

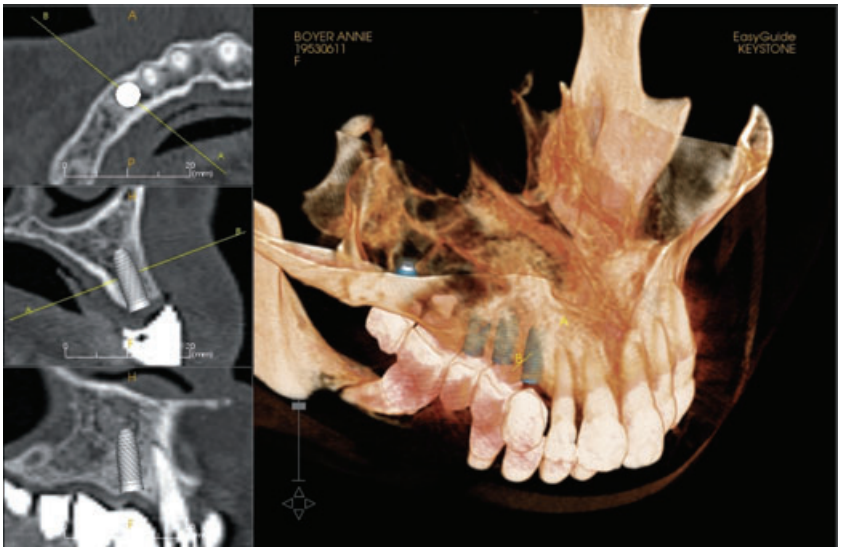

Figure 2 Implant positions are planned with the software according to the study prosthesis landmarks included on the scanning template and the available bone volume.

practitioner had to define the positions of the implants with the software according to the study prosthesis landmarks included on the scanning template and the available bone volume. The practitioner can interactively change the position of the planned implant on reformatted plane or on the 3-D view until the result is satisfactory. A simulation is carried out in real time both on the reformatted planes and on the 3-D view. Other reformatted planes are instantaneously recalculated so that cross-sectional views always go through the planned implant axis (Figure 2).

Control Group. In contrast, the control group undergoes the same CT, but patients have no surgical guide in place during the scanning or during the time of implant placement.

The preoperative planning was carried out directly on the CT scan images with implant template provided by the implant manufacturer. No software was used.

Surgical Procedures

For control group patients, the surgical procedure was conventional, with reflection of a soft tissue flap after a midcrestal incision. No surgical guide was used at the time of surgical placement.

In the test group, a flapless surgical procedure was used with the help of an image-guided template (EasyGuide).[20,26–27] Once the final positions of the implants are defined on the software, the scanning template is drilled in these exact positions by the drilling machine (Figure 3). After appropriate anesthesia is obtained, the drilled template is placed in the mouth in the same position as during the CT examination. For the completely edentulous patient, the template is secured to the underlying bone with two fixation screws in the facial plates to avoid inadvertent movement of the surgical guide during initial osteotomes.[28] Drill sleeves are inserted in the template holes. The first drill is passed through the sleeve, through the oral mucosa and the bone to make the pilot hole. Subsequent drills are made through the template and the oral mucosa or through the oral mucosa after the template has been removed. Three flapless techniques were considered: midcrestal

Figure 3 The drilled template according to planned positions.

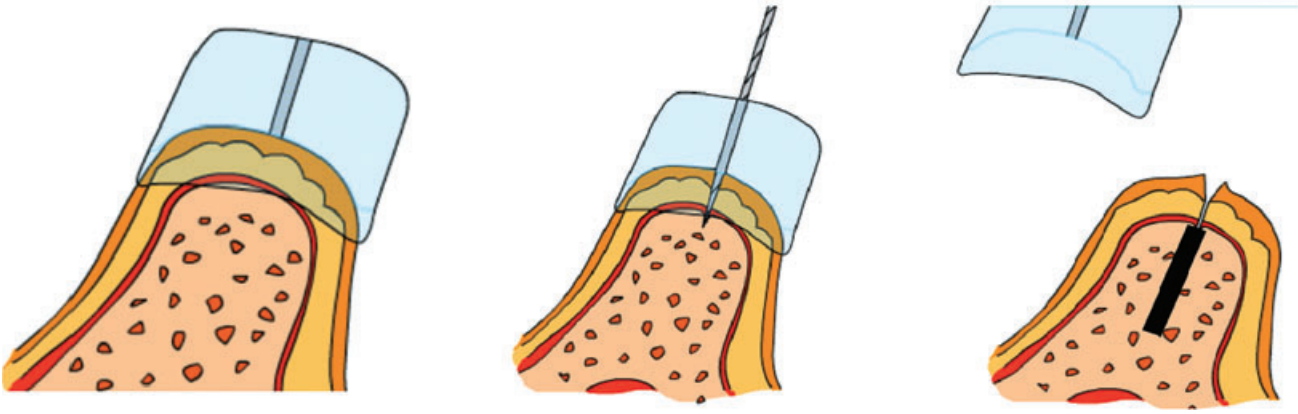

Figure 4 The first drill is passed through the template, through the oral mucosa and the bone to make the pilot hole. For subsequent drills, the template can be removed or maintained on the mucosa.

incision, circumferential incision, and no incision at all (Figures 4 and 5).

Data Records

During the 1- to 4-year follow-up period after implanting the prosthesis, patients were annually recalled to evaluate the survival rate of each implant. All patients attended all scheduled follow-up visits.

The success rate as defined by Albrektsson and colleagues (1986)[29] could not be quantified because the crestal bone loss around each implant was not assessed. Therefore, the implant survival rate was considered. An implant was qualified in the "survival" category when it presented no mobility, no pain, no mucosal inflammation, and no radiolucency around its surface.

To evaluate each case's parameters, an internal classification (Figure 6, A–C) based on the implant plan was elaborated. This classification was based on the bone width around the implant (evaluated on the preoperative CT scan, after the choice of implant length and width), which is recommended to be wider than 1 mm to permit a sufficient blood supply to the bone for osseointegration and for mechanical reasons.[30] The failure factor analysis was used for this classification:

Large was characterized by a greater than 1 mm width of bone surrounding the planned implant (Figure 6A).

Thin was characterized by a less than 1 mm width of bone around the planned implant. Apical part of the implant is not considered (Figure 6B).

Thin apical was characterized by a less than 1 mm width of bone in the apical part of the planned implant (Figure 6C).

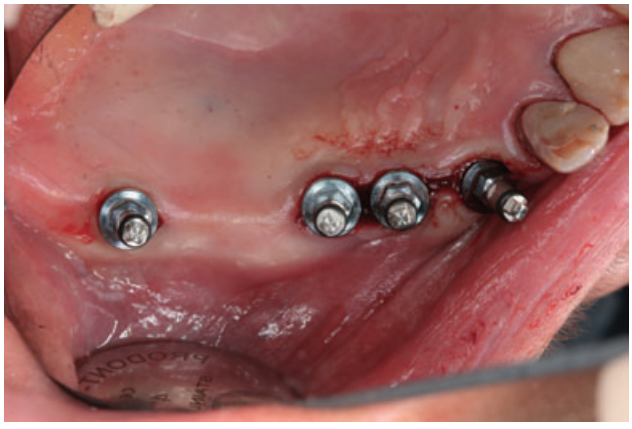

Figure 5 Transmucosal implant placements in the test group.

Statistical Methods

When clinical retrospective study is performed, the observational data recorded contain indication biases because double-blind principle and randomization cannot be used. Therefore, for the study, we have used propensity scores to reduce this bias in order to compare the clinical survival rate of flapless implant surgery associated with an IGS (flapless protocol) with the conventional open-flap surgical protocol without guidance system (conventional protocol).

Analysis of patient data is not possible in a retrospective study when the clinical indication for the procedure is not initially defined and is different for each practitioner. Therefore, only implant data were considered.

Test of the Group's Comparability. Each implant was statistically analyzed with the StatView® and Stata® 8.0 software (Stata Corporation, College Station, TX, USA).

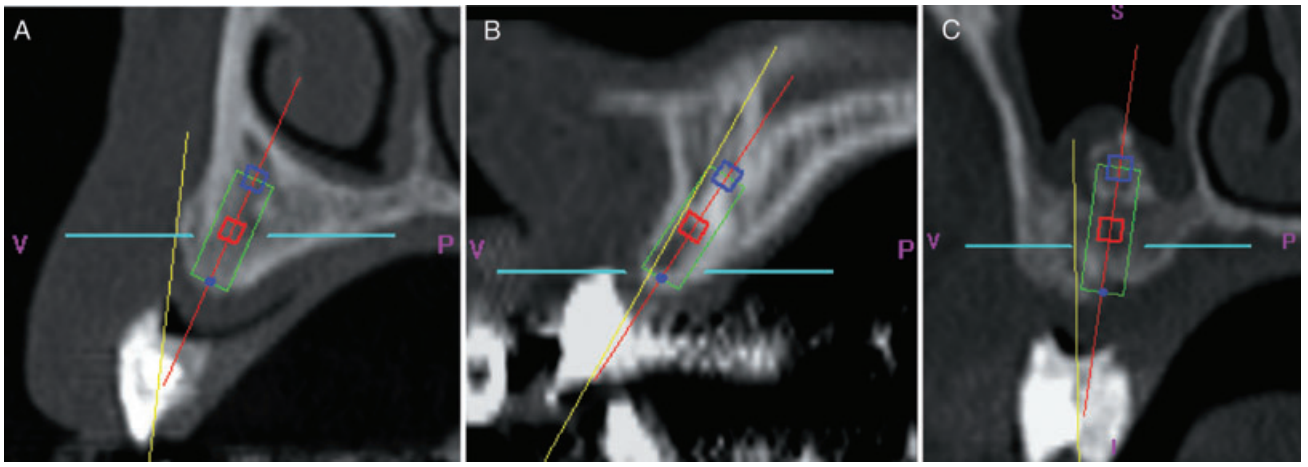

Figure 6 Three anatomic classes can be considered: (A) on the left, with more than 1 mm of bone everywhere around the implant; (B) in the middle, with less than 1 mm width of bone around the planned implant; the apical part of the implant is not considered; and (C) on the right, with less than 1 mm width of bone in the apical part of the planned implant.

The group's characteristics were compared. The mean comparisons were carried out using the Student's *t*-test, and the percentage comparisons using a chi-square test with a 5% first risk.

Failure Factor Identification. Failure factors were analyzed for all patients. The mean comparisons were carried out using a Student's *t*-test, and the percentage comparisons using a chi-square test with a 5% first risk.

Surgical Protocol Comparison. After a classical logistic regression (LR) analysis, the propensity scores were used to reduce bias: prognosis variables were included in a regression logistic model to define the probability that each implant would be treated with the IGS flapless protocol. Implants showing the same probability were grouped into three classes. The implants were then compared with each other within the same class.

RESULTS

The groups were not comparable because of the way patients were allocated to interventions and because the precise details of the interventions intended for each group were not defined prior to the study. Therefore, to reduce that bias and reliably compare the survival rate of the two groups, propensity scores were used[31–35] in an attempt to reconstruct, after the fact, a situation similar to random assignment, albeit only with respect to observed prognostic variables. This has advantages when the outcome is rare, the treatment is common, and there are many prognosis variables, as is the case in implant treatment.

The population included 169 consecutive partially or completely edentulous patients (111 females [65.7%] and 58 males [34.3%] ranging in age from 20 to 84 years [mean, 53.1 years ± 14.5 years]) were treated with the placement of 552 dental implants in the maxilla ($n = 317$ [57.4%]) or the mandible ($n = 235$ [42.6%]).

One hundred thirty-eight (81.6%) patients presented no systemic disease; 22 (13%) were smokers; 11 (6.5%) presented a cardiac disorder, controlled diabetes, high blood pressure, a high cholesterol level, or heart murmur; and 4 (2.4%) presented a psychological or neurological problem (nervous breakdown, Parkinson's disease, epilepsy, or anorexia).

One hundred implants were placed in completely edentulous patients, 206 in Kennedy class III or IV (156 plural and 49 unitary) and 247 in class I or II.

In the maxilla, 102 implants were placed in the anterior area and 215 in the posterior area. In the mandible, 29 were placed in the anterior area and 206 in the posterior area.

Implant Width and Length

One hundred nineteen (21.6%) were thin implants (≤3.5 mm), 409 (74.1%) were standard diameter (between 3.5 and 4.5 mm), and 24 implants were wide implants (≥4.5 mm). Ninety-nine implants were short implants (<10 mm), 373 were standard implants (between 10 and 14 mm), and 80 were long implants (≥15 mm).

The test group comprised 271 patients who were treated with the flapless procedure combined with the

CAD Implant® system (Keystone Dental, Inc.). The control group was made up of 281 patients who were treated with the conventional (open-flap) procedure that did not use an IGS.

The IGS flapless group was 7 years younger than the conventional group (mean age, 50.4 years ± 13.8 vs 56.9 ± 14.3; $p = .0028$).

No statistical differences were noted for sex ratio, tobacco smokers, state of health, and period.

Statistical Differences Between Each Group

- *Practitioners* ($p < .0001$): Some practitioners used the IGS flapless protocol almost systematically after CT examination (97%), whereas others used it rarely (13.7% and 9.8%).
- *Tooth replaced* ($p = .0248$): More maxillary teeth ($p = 0.0048$), in particular molars and central incisors, were found in the IGS flapless group, although more mandibular teeth were found in the conventional group.
- *Implant length and diameter* ($p < .0001$): In the conventional group, more short implants (<10 mm) and long implants (≥15 mm) were placed, whereas in the IGS group more thin- and wide implants were placed.
- *Implant's planning classification*: ($p = .06$): More *large* class implants were found in the conventional group (62.6%) than in the IGS flapless group (52.8%) (Tables 1 and 2).

Also, it appears that the IGS flapless group was characterized by more unfavorable predictive factors than the conventional group.

Survival Rate

Fourteen implants were lost during the follow-up period. Four with the conventional procedure and 10 with the IGS procedure. The cumulative survival rate is respectively 98.57% and 96.30%. Whatever the statistical method used, no significant are demonstrated:

- Use of an LR model: The simplest LR model, which includes only the "IGS-flapless" and "failure" factors, shows a nonsignificant 2.65 odds ratio ($p = .1$). When failure factors are included in the LR model, the calculated 2.98 odds ratio is not significant ($p = .09$) too. The LR model quality is not very good because all "failures" are classed like "success" and the area under the ROC curve is only 61%.

TABLE 1 Distribution of Implant Class in the Conventional and the IGS Flapless Group

Class	Conventional	IGS Flapless	Total
Thin apical	45	52	97
Thin	60	76	136
Large	176	143	319
Total	281	271	552

IGS = image-guided system.

TABLE 2 Frequency of Implant Class in Conventional and IGS Flapless Group

Class	Conventional	IGS Flapless	Total
Thin apical	16	19.2	17.6
Thin	21.4	28	24.6
Large	62.6	52.8	57.8
Total	100	100	100

IGS = image-guided system.

Propensity Scores Used

The implants are then compared with each other within the same class with a new logistic regression model. The 0.46 (0.05–3.9) odds ratio obtained after bias selection reduction shows that the IGS flapless protocol did not decrease the implant survival rate level in comparison with conventional protocol ($p = .48$).

The distribution of lost implants in each group for each year of implantation is shown in Tables 3 and 4.

The total of patients does not equal 169 because of cases treated with both protocols or in two phases of treatment in different years.

These results are associated with the learning curve and patient selection. As patient selection and technique improved, the failure rate decreased, although the number of implants placed increased (Figure 7 and Table 5).

Failure Factor Determination

The failure factors show no influence from age, sex, year of implantation, type of protocol (conventional or IGS flapless), practitioner, length or diameter of implant, edentulousness, and type of incision (punch, crestal incision, or transmucosal placement) Table 6.

No statistical differences ($p = .14$) were apparent between the use of transmucosal implant placement and the other procedures (Table 7).

TABLE 3 Cumulative Survival Rate for Implants Placed with the Conventional Protocol

Year of Implantation	Patients	Implants	Lost	Survival Rate (%)	Cumulative Survival Rate (%)
2001	15	50	2	96	96
2002	11	43	0	100	97.84
2003	18	73	0	100	98.79
2004	32	115	2	98.26	98.57
Total	76	281	4		98.57

TABLE 4 Cumulative Survival Rate for Implants Placed with the IGS Flapless Protocol

Year of Implantation	Patients	Implants	Lost	Survival Rate (%)	Cumulative Survival Rate (%)
2001	5	9	0	100	100
2002	18	58	4	93.10	94
2003	23	67	3	95.52	94.77
2004	53	137	3	97.81	96.30
Total	99	271	10		96.30

IGS = image-guided system.

The failure factors showed by this analysis were tobacco (6.5% of failure vs 1.7%; $p = .0177$), jaw (4.1% of failure in the maxillary vs 0.4% in the mandible; $p = .0055$), tooth replaced (9.4% of failure for the maxillary central incisors and 9.7% for the maxillary molars; $p = .0021$), and implant planning classification (6.2% of failure for the *thin apical* class, 1.5% for the *thin* class, and 1.9% for the *large* class; $p = .04$) (Table 7).

DISCUSSION

The statistical method used in this study may seem unusual. Prospective randomized trials are indeed the gold standard to obtain reliable clinical results. But, in surgery and in medicine in general, clinical studies of new technologies are subjected to the pressure of being assessed on a maximum number of patients in a minimum amount of time. Therefore, numerous clinical studies are retrospective studies and consider only one group. To compare two groups, statistical analysis of retrospective clinical data poses a certain number of problems. Various factors introduce biases: no definition of how participants were allocated to interventions, interventions intended for each group are not precisely detailed, and no control on the quality of the data collected. The combination of these factors means that the two groups cannot be compared. The use of propensity

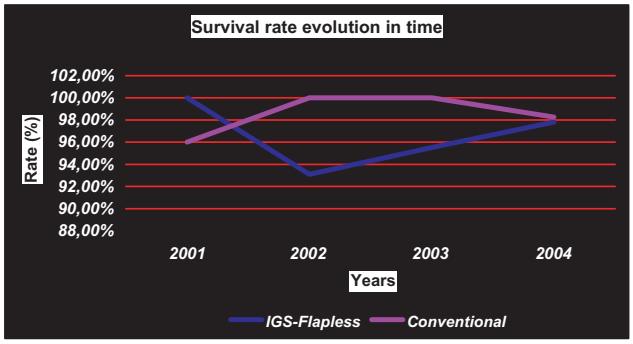

Figure 7 Survival rate evolution over time.

TABLE 5 Protocol Distribution Over Time

Year of Distribution	IGS Flapless		Conventional		Total
2001	10	16.7%	50	83.3%	60
2002	57	57%	43	43%	100
2003	67	47.9%	73	52.1%	140
2004	137	54.4%	115	45.6%	252
	271		281		552

IGS = image-guided system.

scores can reduce these biases and provide reliable conclusions that can be further discussed.[31–34]

The disadvantage of the flapless procedure, with or without IGS, can be that the implant surface might be contaminated or that epithelial or connective cells from oral mucosa are deposited in the hole in the bone, which can interfere with osseointegration. This study demonstrates no survival rate difference between the flapless and the open-flap protocols (respectively 96.3% and 98.57%). There were 10 failures with the IGS group and 4 with the conventional group. The vast majority of failures occurred on two patients for the flapless group. Furthermore, given the small number of failures overall (10 and 4 to 271 to 281 implants, respectively), statistical analysis does not show any difference between the two groups. This confirms previous clinical studies[1,2] and a histological study.[36]

TABLE 6 Transmucosal Placement Failures

	Survived	Failed	Survival Rate (%)
Transmucosal placement	97	3	97
Other protocols	441	11	97.5
Total	538	14	

TABLE 7 Failure Factors

Factors	Significance	*p*
Age	NS	.7
Sex	NS	.27
Tobacco smoker	S	.0177
Implantation year	NS	.7
Protocol (IGS flapless or conventional)	NS	.1
Practitioner	NS	.45
Implant length	NS	.93
Implant diameter	NS	.87
Jaw	S	.0055
Position	S	.06
Planning classification	S	.04

IGS = image-guided system; NS = not significant; S = significant.

In this study, several planning classes were created based on anatomic conditions related to the implant choice and treatment planning, including the surgeon's choices for implant position and angle, length and diameter, and the type of surgery (with or without osteotomes).

As flapless implant placement is a blind technique, Campelo and Camara[1] suggest a minimum of 7 mm of bone width and substantial training to use the appropriate technique. This study demonstrates that the IGS technique can be used to place an implant on a thin crest, even when the planning stage has shown that there is less than a 1 mm width of bone around the implant. In fact, 47.2% of the implants placed with IGS in this study (28% in *thin* class and 19.2% in *thin apical* class) had a high survival rate, respectively 1.5% and 6.2% of failures. It also demonstrates that there are more failures when there is less than 1 mm of bone in the apical part of the planned implant because of a buccal concavity or an intrusion of the implant on the sinus.

In the IGS flapless group, more *thin* and *thin apical* classes were found. This is probably because surgeons prefer using the guided system when anatomic conditions are not optimal (less than 1 mm surrounding the implant) to treat atrophic bone. This corresponds to the maxillary molar area, where the sinus volume limits the bone height, and the esthetic zones.

The flapless technique maintains periosteal attachment and blood supply to the bone. Flapless surgery does not modify the gingival shape following approximation of the surgical wound; should increase the

success of immediately loaded implants by maintaining the blood supply; reinforces the periosteum, thus acting as a support for the labial plate as it expands when an osteotome pushed into the osteotomy site is used; and significantly reduces treatment time related to reflection and closure of the tissue flap.[37–40] Furthermore, with the flapless procedure, patients experience less pain and for a shorter period of time.[3]

Thus, in our opinion, the need for an IGS should be discussed with regard to how we wish surgery to evolve; imprecision toward precision, complex toward simple surgery, and stress toward relative patient and surgeon comfort, all points to flapless surgery. It should provide reproducibility by providing the surgeon with reliable preoperative information and very precise drilling guidance during the surgical phase. This has a significant impact on systematizing treatment success when considering the protection of vital structures, esthetics, and biomechanics by eliminating possible manual placement errors and by matching the planned position to prosthetic requirements.

Although the application of the IGS in the medical field is gaining ground because this field of activity requires a high level of precision and safety, many questions remain regarding cost and irradiation. The drawback of the IGS for oral implant placement lies in the use of the CT scan as the radiological modality providing the necessary 3-D information. Nevertheless, CT requirements are described for several clinical situations.[19,40] Furthermore, the number of implant placements by a variety of practitioners of different levels of experience is increasing. Thus, the IGS may be of greater importance to some clinicians than to others in obtaining a high success rate. We can also presume that the recent and future development of IGS applications, both for surgical and prosthetic protocols, will justify the use of CT examination even when CT requirements are not already described. Higher doses and higher costs, which are the main drawbacks of CT scans when compared to conventional tomography, can be significantly reduced by using the cone-beam CT scan technique.[41,42]

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