Review Article

Critical Appraisal Regarding the Publication "Implant Survival between Endo-Osseous Dental Implants in Immediate Loading, Delayed Loading, and Basal Immediate Loading Dental Implants: A 3-Year Follow-Up" as Published in Ann Maxillofac Surg 2017;7; 237-44, by the Authors R. Gharg (Corresponding Author), Neha Mishra, Mohan Alexander, Sunil K. Gupta

Stefan Ihde, Lukas Palka, Vivek Gaur, Antonina Ihde

Evidence and Research Department, International Implant Foundation, Munich, Germany

Abstract

This article analyses published prior article regarding the questions: is the study setup correct (true) and if comparable cases are evaluated for the compared methods. Futhermore the content, the pictures, the tables, the graphs and the pictures legends of the article and statistics are analysed for truth, relevance and applicability. We investigate furthermore if this article addresses all relevant questions regarding bias, the study groups, the evaluation of the outcomes and the evaluation of patient parameters such as burden of the treatment. As a result of the analysis, we state that the analysed article is misleading and it does not provide valuable information regarding decision making for other healthcare professionals in the dental implant field.

Keywords: Basal implants, comparison of methods, endo-osseous implants, immediate loading, implant loss, implant survival rate, implant therapy

Introduction

A critical appraisal (CA)[1] is a specific form of literature in medicine, which analyzes the existing literature regarding its validity under the aspects of study layout, methods, statistics, and results. This CA has been written and published because the article entitled "Implant Survival between Endo-osseous Dental Implants in Immediate Loading, Delayed Loading, and Basal Immediate Loading Dental Implants: A 3-year follow-up" does–in no aspect–meet the minimal demands for a scientific study nor a publication as presented below.

In the analyzed study, the authors compare "treatment outcomes" from conventional implant treatments (conventional 2-stage screw implants) with "basal implants (presumably BOI® and other screwable dental implants)," all implants were obtained from various manufacturers. Furthermore, the authors claim that they compare implant survival, but in fact, they do not compare any survival rates at all. It seems that they published the article before the 3-year period of "usage in function" for the 2-stage implants had even begun.

The corresponding author was asked three times in writing (E-mail) to explain various inconsistent aspects of this article (namely through E-mail as of January 03, 2018, January

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Address for correspondence: Prof. Stefan Ihde, Evidence and Research Department, International Implant Foundation, Leopoldstr. 116, DE-80802 Munich, Germany. E-mail: drsihde@gmail.com

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24, 2018, and February 04, 2018). He acknowledged the receipt of the questions drawn up by the International Implant Foundation two times, but he failed to give any answer, hence the decision to request the journal to publish this detailed CA.

Materials and Methods

In this section of the CA, we will first analyze the article regarding the following questions:

1. Is the study setup correct (true)? Are comparable cases used for both methods?
2. Are picture legends adequate for what is actually shown in the pictures? Do picture legends correspond to what is actually shown in the pictures?
3. Does the study represent random variation (chance) or is it biased?
4. Are valid statistics provided?
5. Do the clinical pictures and X-ray correspond with the written text?
6. Did the authors evaluate the results of the "control group" properly or at all?
7. Are all assessments properly drawn out of the clinical cases?
8. Is the denomination "comparative study" correct for this article, can this article be called a "study" at all?
9. Does the article provide valuable information regarding decision-making for other health-care professionals?

Analysis of the Citation (Results)

1. In the Materials and Methods section of the analyzed article, the authors mention that 34 endo-osseous and 18 basal implants were placed and the clinical outcomes were compared. The authors do not claim that the cases were treated consecutively, hence their study does not report on a cohort study, but it is simply a deliberately chosen assortment of cases. Neither randomization nor blinding is reported. Consequently, the study has to be rated as lower than the lowest level of evidence in scientific writing. This observation alone makes clear that this article does not meet the minimal requirements for being published in a reviewed journal. What is more important is, however, it directly leads to the conclusion that all "statistics" which were presented in this article (and displayed in Graphs 1-3 and Tables 1-7) are in fact irrelevant. Especially Tables 6 and 7 are misleading because there are no "study groups," as all cases have been specifically selected and grouped with an intention to prove things which are otherwise not provable. It seems that one of the four cases has even been switched from one arm of the "study" to the other one

   The authors compare independent, randomly chosen cases and pretend that they represent two groups of cases. This violates all relevant principles of medical writing, statistics, and reporting
2. The second aspect that requires meticulous attention are single cases and pictures and picture legends. These cases are the core of the article, as all graphs, tables, and discussion are placed around it for support. All our assessments, which we lay out here, were based on the electronic version of the article, under various magnifications on the screen (using a MacBook Pro).

Case 1

Figure 1: The "preoperative orthopantomogram" presents a patient with profound periodontal involvement, deep pockets, and teeth with various lesions. In the main body of the article, the authors claim that this case was solved with delayed implant placement in the maxilla and the mandible. Any useful explanation to Figure 1 is missing, and we do not know why this Figure 1 or this case was chosen.

Figure 2: The "postoperative orthopantomogram" shows that eight 2-stage implants were placed in the maxilla and another eight 2-stage implants in the mandible. On this radiograph, we find two peri-apical lesions around 2-stage implants in the maxilla. Two implants in the upper jaw seem to be predominantly inside the maxillary sinus.

Figure 3 shows four different slides: the clinical situation during impression taking as well as three different clinical pictures of unacceptable quality, showing no relevant details at all. Hardly. any clinical information can be taken from such unprofessional pictures because minimal standards of dental intraoral photography were not met.

A radiological or clinical follow-up after 3 years (as promised in the title of the publication which claims that the "3-year outcome" is investigated) and reports on the outcome and implant survival of this case are missing completely. Table 2 (regarding Case 1) describes pain after the 3rd month; this event would require explanation in the article.

Case 2

Figure 4 shows the preoperative orthopantomograph of "Case 2."

Figure 5 shows the postoperative radiograph of "Case 2." The authors fail to explain why in the lower jaw, three teeth were left during treatment and why in the upper jaw one premolar was extracted while a single molar was left in. No information is given whether the teeth which remained have been included in the prosthetics or were left out or were extracted later.

Figure 6: Tooth 31 shows profound periodontal involvement, and the bone around the leftover three front teeth forms an unesthetic bone-supported eminence. Leaving tooth 31 in violated all known rules of dental implantology because this tooth has a very limited life expectation and the profound periodontal involvement imposes massive risks to the implant during the "healing" period. May be the authors have extracted those three teeth later on; we do not know this because there are neither pictures nor a description of the finished work.

As we neither see a panoramic overview of the finished case nor clinical pictures of this case after finishing (nor after 3 years),

we may assume that the outcome of this case did not meet esthetic standards.

Case 3

Figure 7 shows the preoperative orthopantomogram, displaying partly dentulous jaws and profound and active periodontal involvement in both jaws.

Figure 8: In the Materials and Methods section of the analyzed article, it has been mentioned that this case was solved with "four immediate implants" in the upper jaw and six immediate implants in the lower jaw. However, we observe five basal implants in the upper jaw and six basal/strategic implants in the lower jaw on the panoramic picture. The strategic position 13 (i.e., a location in the maxilla, where according to the rules of basal/strategic implantology must be placed in any case) was left out. It is unclear if this implant was lost or if the treatment provider failed to equip this position with another basal implant. We also observe that prosthetics show misfit on both distal implants in the range of about 4–7 mm (!), which raises the question, if one or both implants are connected to the prosthetic structure at all. Since also the strategic positions 17 and 27 are not equipped with basal implant (meaning distal support is completely missing), this case must be categorized as a severe case of maltreatment, done against the accepted rules of strategic implantology. It is amazing that the authors (who may or may not be the treatment providers) treated the case in such a way and/or failed to analyze the maltreatment in the article, nevertheless included the case in a "comparative study."

Case 4

Figure 10 shows the preoperative orthopantomogram, with the preplanning of two implants in the upper jaw and four implants in the lower jaw. From the picture, we can assume that this is not a traditional orthopantomogram, but a reconstruction made out of a computed tomography and that a digital planning for 2-stage implants was made.

Figure 11 shows a "postoperative orthopantomogram" with eight 2-stage implants placed in the upper jaw and 8 basal/strategic implants in the lower jaw. The rotated tooth 34 had not been removed which is considered a wrong treatment plan in strategic implantology because rotated teeth deviate from the path of the osteons and jaws, such obstacles are considered to be "nonstandard," leading to higher risk for complications. The screwable basal implant in area 32 seems not to be connected to the bridge at all and the crown is about 6 mm too short, although we can see that the dental technician has created a crown in this location. Severe misfit of prosthesis in the lower jaw is again significant for this case, and we wonder how the prosthetic treatment provider has managed to keep the bridge (i.e., plane of bite) within the required parallelism to the plane of Camper. The base plates of both distal and lateral basal implants are inserted too high (too crestal, in the alveolar bone) in the mandible, i.e., above the "white line." Such base plates have to be placed (as already the name of the technology "basal implantology" indicates) in the basal part of the jaw bone. Due to this misplacement, the prognosis of those implants and the case as a whole is doubtful. The case should be considered for a number of reasons (maltreatment). The slight distal inclination of the screwable basal implants 42 and 43 contradicts the clear rules (methods) of strategic implantology. All anterior basal implants are chosen quite short, i.e., they do not utilize the available vertical bone adequately. Neither explanation nor mentioning for all these obvious mistakes of the surgeon is given in the text.

Figure 12 shows three different clinical views of the upper jaw without prosthetic treatment and the lower jaw with a circular metal-to-ceramic bridge.

While we find eight implants on the postoperative panoramic picture [Figure 11], Figure 12 seems to reveal that only five implants were included in the prosthetic part of the treatment. We have to assume that at least three implants were lost, which resembles a survival rate of only 62.5% compared to 100% (presumably) in the lower jaw, where basal implants had been installed in an immediate load protocol. On our request, the authors have failed to address this point in the correspondence which had taken place prior to the preparation of this CA. They also refused to submit 3-year postoperative clinical pictures or radiographs for our evaluation.

While the treatment plan for Case 4 obviously included the placement of 2-stage implant in the distal lower jaw, this was not done. We have to assume that the treatment provider failed with this plan due to a lack of bone, and he/she then moved the patient to the other (opposite) arm of the study. Hence, the cases for both groups were not chosen randomly: the lower jaw of Case 3 was probably untreatable with the 2-stage system. Probably, augmentation was not approved by the patient or seemed not feasible. Hence, this case switched study groups after 2-stage implants were not feasible. This must be considered to be a severe violation of recognized principles of clinical medical research. Such an event is not rare as we will explain in the discussion later on; it does not allow however to include such cases into comparative studies.

We would like to mention at this point that the "intent-to-treat" principle means the following in our practical work in implant dentistry:

- All patients who are willing to undergo treatment (i.e., who request treatment in a clinic which is involved in a study) must be included into a study or our personal statistics, even if they later refuse treatment (e.g., because they refuse bone augmentation, or if treatment costs are too high, or if they cannot afford being without teeth during the "healing time")
- All patients in whom a treatment attempt was made must be included in the study (in the correct group)
- If preimplant surgery fails (e.g., sinus lift), all implants which were planned for placement in the augmented field but were never placed due to the failure of the augmentation must be counted as failed (although they were never placed)

- Even cases where all implants are successful but were placed so unfavorably, that regular mastication on fixed or removable chewing surfaces from 6 to 6 in both jaws could not be placed (as it presumably happened in Case 2, lower jaw), must be considered to have a doubtful, reduced outcome. Outcomes and the pretreatment situation must be rated regarding esthetics, implant survival, and patient comfort and satisfaction.

It seems that this important principle was violated throughout the "study."

In general, we have to state that postprosthetic radiographs are missing for all 2-stage cases, not one single case done with 2-stage implants has been observed in the period of 3 years (as stated in the headline of the publication). Hence, the title is misleading and does not correspond to the clinical or radiographical case follow-up.

Graph 1

In this graph, the authors list up the time which is necessary for the operations.

- Case 1: Fifteen 2-stage implants in fully healed bone (presumably flapless) were placed in 1.5 h (average time for placement: 6 min per implant)
- Case 2: Ten 2-stage implants were placed without any extraction following an open flap procedure in about 2.2 h (average time for placement: 14 min per implant)
- Case 3: Four molars and 14 single-rooted teeth were extracted and 11 basal implants were placed within 4 h. The authors fail to distinguish between the time necessary for extractions and the time necessary for implant placement and impression taking, hence the time period of 4 h cannot be compared to anything else
- Case 4: If we compare the preoperative radiograph [Figure 10] and the postoperative radiograph [Figure 11], then it becomes clear that the upper jaw was treated with 2-stage implants long after the extraction, while we may assume that the lower jaw was treated in an immediate protocol at the same time when the teeth were extracted in the lower jaw. The authors fail to clarify to which procedure the "operative time, hours, and left violet vertical bar" refer to.

In a serious comparison, the total chair time for all procedures should be counted together: extractions, surgical after care, impression taken for intermediate dentures, implant placement, secondary surgery (uncovery operation), and time for impression taking should be compared to the one-step procedure.

It seems that treatment times were not counted together although between extraction and implant placement–at least in the upper jaw–many months must have passed.

Table 5 does not help in the clarification because no explanation of the reason for the pain is given in months 1 and 3.

Graph 2

This graph lists up "pain" as measured by Visual Analog Scale; however, the authors fail to explain if the pain was felt around the basal implant of the crestal implants in those cases where both types were used. Pain in week 1 indicated that this is postoperative pain, while pain during weeks 2 and 12 must stem from other reasons. The authors do not identify pain and they seemingly leave a patient in pain without treatment.

Graph 3

This graph shows that in Case 3 (both jaws treated with basal implants), the postoperative patient satisfaction is logically reached faster than that in 2-stage protocols and that after 12 months all patients are satisfied. As both jaws were treated with surgery at different time periods (the lower jaw was done immediately post-extraction, while the upper jaw was done after the bone had healed and extraction sockets were not present any more), we may assume that the low satisfaction of these patients at the time points 1st and 2nd weeks and 3 months is due to missing or removable prosthetics in the upper jaw (which is due to the inability to provide immediate loading with the help of the chosen 2-stage implant system).

Tables 1-7

Due to the fact that data in all tables are inconsistent (see point 1 of the results section of this article), further analyzing in detail is not done here.

We furthermore analyze the written statements given in page 243 regarding the cases and considering the content and truth.

Advantages of Basal Implants

- Claim 1: Regarding achievable stability: The comment on achievable stability of the implant is not backed by any hard data, no Periotest® or test with Ostell® device is backing that claim. A differentiation between lateral basal implant and screwable basal implant is missing
- Claim 2: There is no evidence that basal implant placement is less technique sensitive. Differentiation between lateral basal implant and screwable basal implant is also missing for this claim. If the authors should mean by this, that the strategic implants work even if the prosthetic treatment has failed/is faulty [as shown in Figures 3 and 4], they might be correct however
- Claim 3: The statement that there are no minimal requirements for lateral and screwable basal implant placement regarding the necessary amount of bone is dangerously misleading. Strategic implants are placed in a way that cortical bone is utilized, especially bone which is not in the position of the latter (or previous) tooth.

Drawbacks of Basal Implants

- Claim 1: The authors claim that basal implant is a "single-unit prosthesis" which is not true. An implant is an implant, it is never a prosthesis. It is furthermore not true that basal implants can be replaced much easier than crestal implants because such replacement can be done even if large amounts of bone are missing (i.e., due to peri-implantitis). In fact, main indications of basal implants include replacements after crestal implant (and bone) loss and reconstruction after severe bone loss due to peri-implantitis[2]
- Claim 2: This claim does not seem to be justified. Looking at the fact that many of the basal implants were not placed in the correct (strategic) position and considering that prosthetics show severe misfit, we may draw conclusions that the treatment provider was not acquainted with basal implants while he/she worked with these designs (or he/she was a beginner) and hence it took a long time for the treatment provider. On an average, the placement of screwable basal implant takes between 15 and 25 min per jaw (with ten implants placed), if all teeth are preextracted and the wounds are healed. This time period is comparable to Case 1, Graph 1.

The authors furthermore failed to mention that the time for extracting all teeth shown in Figure 1 has to be also considered. Since lateral basal implants are placed always in an open flap procedure, the surgery takes naturally long time, but it does not require prior bone augmentation. If we were to compare cases which are done with (separate) augmentation or bone block to cases without augmentation utilizing lateral basal implants, it becomes clear that the basal procedure is not only fast, but also less invasive and less demanding for the patient. The authors failed to compare cases which are easily comparable.

It is unrealistic and misleading to compare cases like Case 1, where all teeth were extracted in a separate procedure (with the time not measured), where healing time took place, during which the patient was presumably treated with removable dentures (in civilized countries, this would be done), not measuring the time necessary for extraction, postextraction aftercare, intermediate prosthetic step before the final reconstruction (like dentures), to Case 3 where all these were done in one single procedure (presumably including the cleaning of the bone after extractions, suturing of multiple sites, impression taking, and provisional prostheses). Likewise, also the costs for these intermediate treatment steps should have been considered.

Limitations of the study

The obvious limitations of the analyzed study are as follows:

- Cases are chosen specifically to prove something (which may lead to the conclusion that the study is biased)
- Both the treatment provider and the persons doing the assessment were not blinded
- We assume that the treatment provider who has placed the basal/strategic implants had no valid authorization (of the implant manufacturer) for this system and he/she was not under adequate supervision
- Patients did not enter "their arm" of the study randomly (as at least the treatment plan and the result of Case 3 show), any randomization is missing
- In the group of 2-stage implants, the bridges are not always supported by implants [see Figure 5, there must be a massive cantilever in the left distal mandible], hence we may assume that this patient did not receive adequate prosthetic treatment. This patient did not receive teeth from the 1st molar of one side to the 1st molar of the other side. We have to assume that this patient (although equipped and treated with implants) was left partly as an oral cripple, without enough teeth for normal bilateral and equal mastication
- The treatment providers may be "the same" for both arms of the study; however, the following must be taken into consideration:
  - Long operation time in the basal implant "group" and
  - Prosthetics which do not meet esthetic standards
  - Choice of inadequate implant positions for the basal/strategic implants
  - Missing but definitely necessary extraction of impacted tooth in Case 4
  - Failure to equip the strategic positions in all cases treated with basal implants
  - Severe underequipment of the upper jaw in Cases 3 and 4 with basal implants
  - Unnecessary trans-sinusal implant placement in Case 3, Figure 9 (with so much good bone being visible distally to the implant).

Indicate without doubt that the treatment provider working with basal implants was novice and more lucky than anybody else regarding the (very high) treatment success.

In case of failure, his/her license as a treatment provider should be under consideration by the relevant authorities.

Furthermore, we want to point out that from the patients' point of view also, "healing time" is "treatment time;" it is the period during which the patient is under treatment. The treatment time starts at the moment when the first cut for an augmentation is made or the teeth are extracted, until the last final crown is cemented or screwed onto the healed implants. In the analyzed study, the treatment time for 2-stage implants is presumably many months or more than a year, while the treatment time for basal/strategic implants is typically 3 days.

If a treatment provider considers a 4-h intervention too long and too burdensome for the patient, he/she may include an anesthesiologist into the treatment with a little bit of propofol and Dormicum, for which the patient will neither notice nor remember those hours at all. It is however by no means possible to shorten the time necessary for such a 2-stage implant treatment. Patients have to suffer through those months without any chance for relief.

Comments on the Discussion

Although the main part of the article, the "study" has to be considered to be meaningless and wrong; it makes sense to pay attention to a few details which the authors discuss:

"The other two important factors might be the amount of trauma patient can bear (more in BOI®), number of visits and implantologists' preference and satisfaction."

At this point, we have to state that the authors lack even minimal understanding on the nature of strategic/basal implantology. Strategic implants are today the preferred devices in dental implantology in many countries due to the following:

- They help to avoid bone augmentation
- They utilize resorption of stable basal cortical bone in its original place, as it was recommended by P-I Branemark throughout his life
- They allow immediate loading in many cases, which is the patient's preferred protocol of treatment (the treatment provider's preferences are not important in the first place).

Operative trauma, pain, and swelling after placement of lateral basal implants (e.g., BOI® and Diskimplants) are definitely larger compared to screwable basal implants; however, trauma, pain, and swelling are much lower (for both types) if compared to an alternative treatment protocol which includes bone augmentation. Bone augmentations are typically done with an open flap procedure. The authors fail to differentiate between the different types of basal/strategic implants throughout the whole article and they fail to reveal that treatment plans which include bone augmentation (sinus lift, nose lift, external augmentations, etc.). They also fail to include that bone augmentation carries risks by itself and that the necessity of bone augmentation reduces the amount of potentially treatable patients because, for example, smokers and patients with various diseases will hardly ever find a treatment provider who is willing to make this treatment step. Even if all patients in the "study" have really been healthy, middle-aged nonsmokers, this point should be discussed in detail if both methods (2-stage implantology and strategic implantology) are compared seriously.

In our view, it is not possible to compare cases if the same treatment provider treats with both methods in one study and especially in one single center. One reason being that patient assignment to one of the groups can never be randomized because the difficult cases showing atrophy will typically be relocated to the basal group or they will not get treatment at all. Case 3 is such an example. It has to be furthermore considered that if both arms of the study are to be done in the same center, patients are required to give their informed consent about 2-stage treatment, for example, including bone augmentation and which patient would agree to this invasive and long-lasting treatment if the treatment provider will offer strategic implant treatment as an alternative on the spot?

The correct methodological and statistical approach would be to request controlled data from specialized centers for each technology and to compare them.

However, even if such a study would be set up, the center offering the 2-stage treatment would have to register all cases with strong and very strong atrophy as failure (with all nonplaced implants which would be included in a typical treatment plan counted as failed although they were never placed) because the "intent-to-treat" principle demands this.

This rigid statistical approach may sound strange in our profession, but please consider the following example: a patient fractures his arm, it is a complicated, open fracture, and in hospital, they refuse to treat this patient because he "does not have enough bone" or his/her case is "too complicated." Such comparable undertreatment is done regularly in conventional dental implantology and around the world, while in centers applying the technology of strategic implantology, hardly ever a patient has to be sent away for these reasons. In other words: while in 2-stage implantology, the "Intent-to-Treat Principle" is constantly severely violated, even the worst cases of pronounced atrophy can be treated with high chances for success in strategic implantology.[3]

The term "patient selection" which is frequently used in 2-stage implantology describes nothing else but a planned violation of the "Intent to Treat" principle.

Conclusion

Considering the results of this analysis, all questions raised in the Materials and Methods section of this publication must be answered with a straight "No." Hence, on the scale of ethical and professional acceptability, this article and the clinical work of the authors receive only red marks.

We want to point out that (other than in the title of the article) implant survival rate was not reported at all in the group of the 2-stage implants, whereas in the group of the basal/strategic implants, we assume that it was 100%. We have to assume, however, that at least in Case 1 and Case 2, several 2-stage implants have failed. We can determine this without seeing postprosthetical radiographs.

Scale of ethical and professional acceptability of the analyzed article: Ann Maxillofac Surg 2017;7; 237-44, by R. Gharg (Corresponding author), Neha Mishra, Mohan Alexander, Sunil K. Gupta): minus 9.

Their article should be fully removed by the journal from online publishing or a reference and link to this critical appraisal

should be made. The authors should remove their article from their CV or include reference to the CA.

In our opinion, the particular article has never undergone a qualified review prior to publishing.

The authors furthermore failed to answer the request of the International Implant Foundation, they totally refused to clarify the situation. Hence, the publication of this CA became necessary.

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Conflicts of interest

There are no conflicts of interest.

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