Report of a retrospective multi-center study of the early phase of implantological rehabilitations

# Performance of a novel implant design

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Numerous studies show an increased risk of complications or even loss of an implant in the early phase of implant rehabilitation. The purpose of this study was to evaluate the clinical performance of implants with a novel design (SICtapered, SIC invent AG).

## 1. Abstract

Materials and methods: In six private dental clinics 118 SICtapered Implants (SIC invent AG) were placed in 64 patients covering a variety of indications. They were retrospectively clinically assessed at six different stages, from implant placement to checkup after prosthetic restoration. For the very first cases treated within the scope of the present study, a follow-up period of up to 32 months has been reached. Thus, all cases include the early phase after implant placement. As a consequence, the results deliver scientific insight into the clinical reliability of the implants in exactly the period which is most critical in terms of osseointegration and marginal bone loss.

Results: Implants featuring the novel design outperform the early phase success rates reported in literature and reach a rate of 99 %. This result is confirmed by clinical as well as by radiological evidence. The radiological evaluation consistently shows a positive bone level stability. The bone resorption rates are substantially equivalent to the stage-related applicable criteria of Misch and Albrektsson which are internationally accepted.

Conclusion: Based on the results of the present study, this novel implant design exhibits positive effects which manifest themselves in both clinical and radiographic examinations and, in addition, in patients' satisfaction. The clinical performance in the early, critical phase shows a low degree of complications. The implant survival rate and the bone level stability meet high values which can be found in the referenced literature.

## 2. Introduction

Implantological treatment has been used for many years as a reliable method to compensate tooth loss and to help patients regain functional chewing comfort and a good quality of life. The long-term success rates published in the literature can be considered scientifically validated, but there remains a low risk of complications or even failure, which is very important for an individually affected patient. Consequently, the choice of treatment procedure and implant system should meet up-to-date standards in safety and predictability.

The largest clinical implant study in Europe by M. Krebs et al. 2013 [1], including more than 12,500 implants assessed, confirms good long-term success. Applying Kaplan-Meier statistics the cumulative survival rate (CSR) was 93.3 % after 204 months. The study proved a generally high implant survival rate. It also revealed and stated that a relatively high percentage of the failures occurred in the first year after implant placement and before prosthetic restoration.

These findings about implant loss in the early phase were affirmed by another large study by Knöfler et al. 2019 [2] including 10,165 implants. Most of the implant losses occurred during the healing period in the first months up to two years. The one-year survival rate of all implants was 97 %. Similarly, Lemmerman and Lemmerman stated that for 1003 implants, 75 percent of the implant losses occur in the early phase [3]. According to this knowledge from the literature, the first 1–2 years seem to be the most vulnerable time span in the life of an implant.

The aim of this study is therefore to analyze the clinical performance of the novel implant in this sensitive period of time and to come to a conclusion about the clinical reliability.

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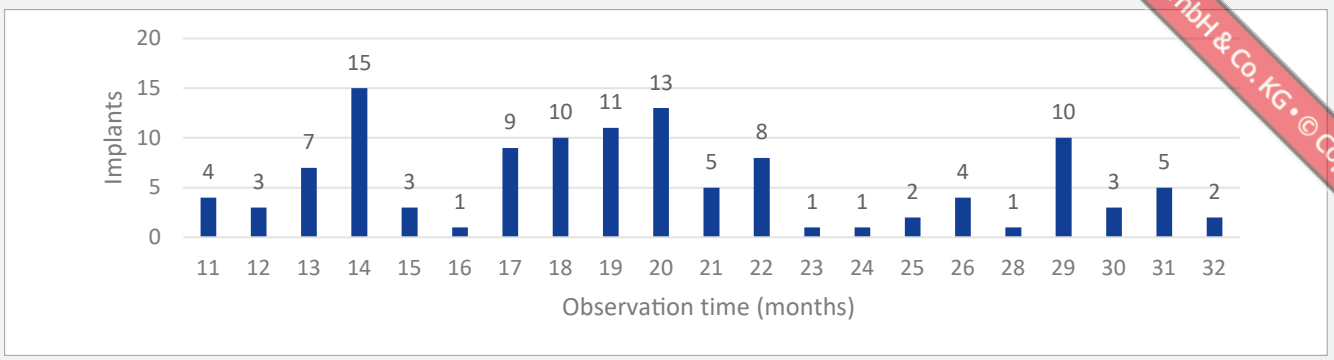



1 I Number of the implants being under observation (y-axis) for n months (x-axis)

The SICtapered Implants have been on the market since the 2nd quarter of 2018 and can therefore already have follow-up periods of up to 2 ½ years. During this period of time, the clinical behavior in the early phase (pre-prosthetic) and in many cases also in the subsequent prosthetic restoration phase can be reliably mapped. The cases will continue to be followed in the future so that the next part of the study will aim to deal with the long-term performance.

**3. Materials and methods**

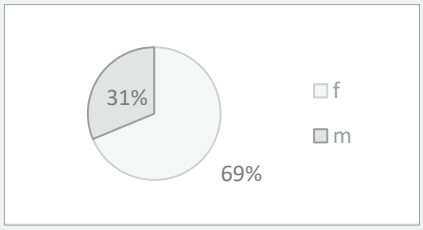
The clinical performance of the novel implants, a relatively new range of implants that came onto the market in 2018, is to be examined.

The study is designed as a retrospective observational study. The data was collected in 6 private dental clinics (see 7.) All practitioners have been practicing for years with a focus on implantology. One of the 6 dental clinics is an academic teaching practice of the University of Berne, Switzerland.

The patients received the implants in the time period between April 2018 and December 2019. Thus, the observation periods today range from 11 months to 32 months, with the average being 20 months, according to the following distribution (Fig. 1):

The practitioners made it possible to have a complete view of their treatment files and X-rays so that all of their SICtapered Implant cases since April 2018 have been recorded.

64 patients are included in this study: 20 male and 44 female patients (Fig. 2).




2 I Distribution of the patients referring to gender

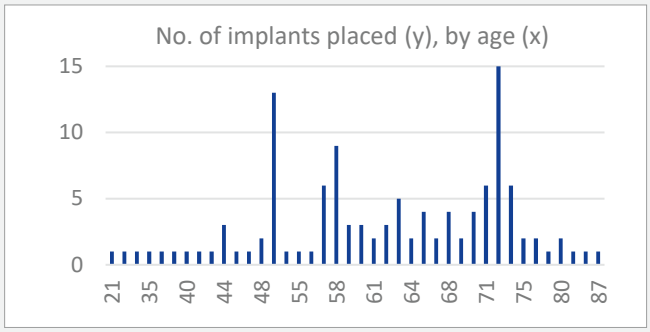
The age of the patients ranged from 21 years to 87 years. The average age was 60 years.

The implant distribution related to the patients by age is as follows (Fig. 3 and 4):

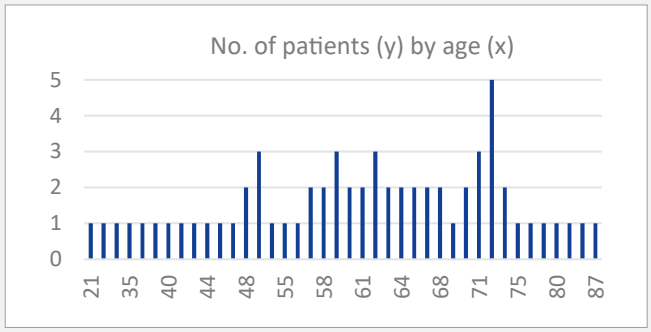
*Inclusion and exclusion criteria*

Patients of all ages and genders were treated. All implantological indications and prosthetic needs were accepted as well as all bone qualities ranging from D1 to D4, including cases, where bone augmentation measures were needed, ranging from marginal gap filling to huge bone block augmentation. All implant areas in upper and lower jaw were accepted (anterior, canine, premolar, molar region). Accordingly, no specific exclusion or inclusion criteria were applied but general contraindications (such as inappropriate medical/psychological/behavioral conditions) as well as local contraindications (such as, e.g., insufficient oral hygiene, oral tissue disorders, etc.) were considered according to good implantological practice [4] for treatment decision. Patients who met these contraindications were excluded from this study.

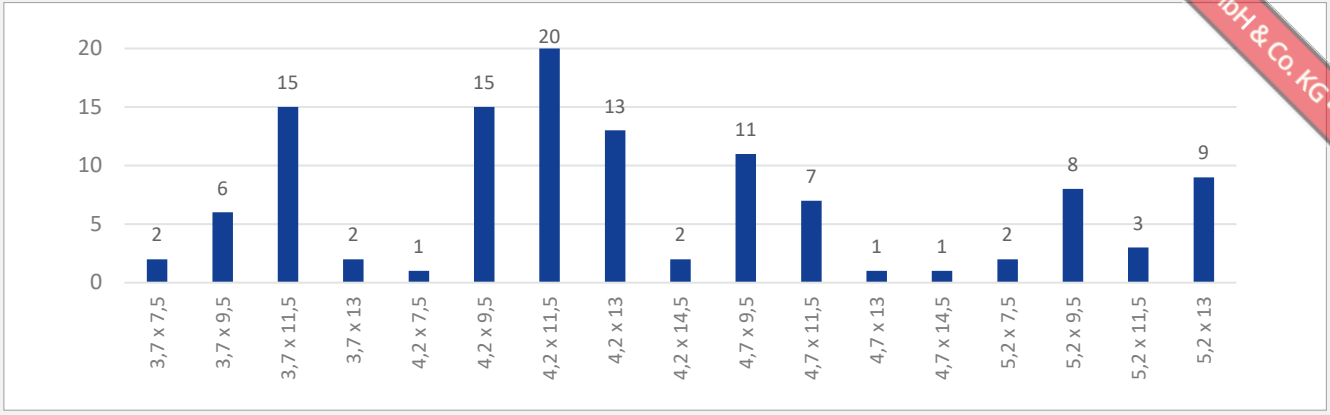
Consequently, three patients have been excluded from the cohort (of originally 67 patients) from the retrospective assessment because of strong individual reasons: One patient suffered from a long-lasting heavy attack of a diabetic disorder



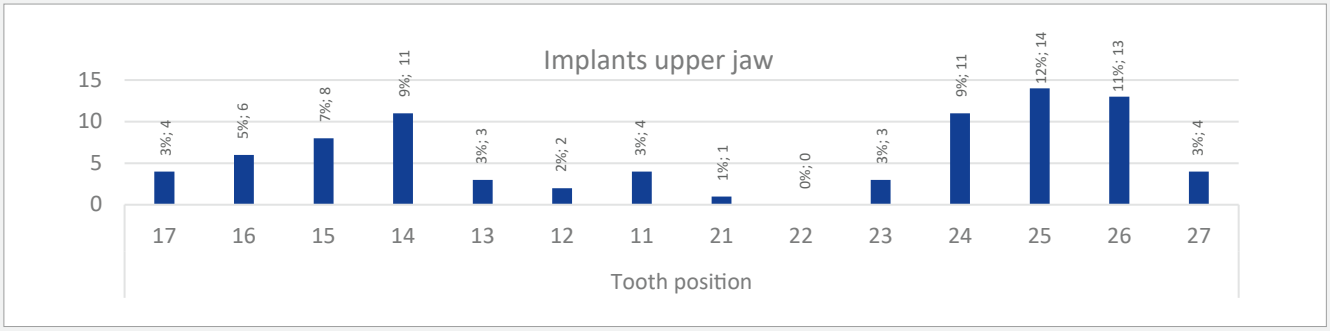

3 I Number of the implants placed referring to the age of the patients.



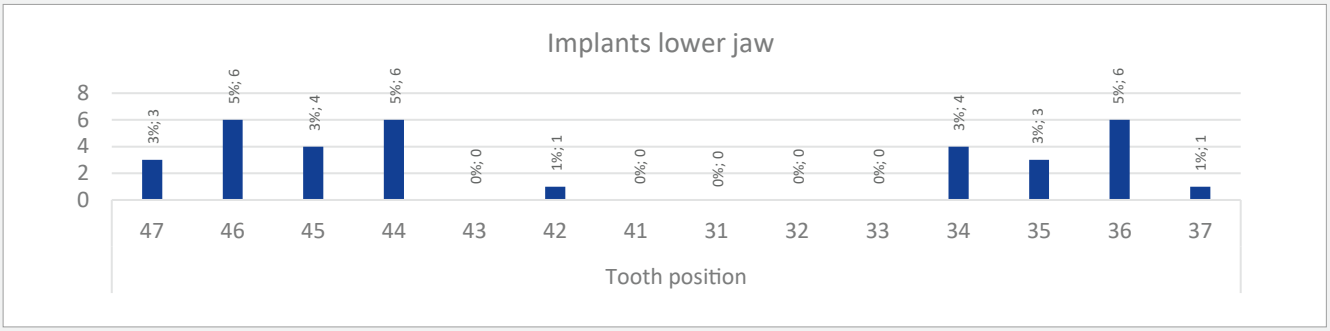

4 I Number of the patients referring to their age




5 I Number of implants placed (y-axis) having a combination of diameter/length as stated (x-axis)




6 I Distribution in percentage and number of the implants in the upper jaw referring to the area of placement




7 I Distribution in percentage and number of the implants in the upper jaw referring to the area of placement

that caused multiple wound healing disturbances, ending up with involvement of the oral cavity and limbs (toe amputation). One patient fell into an intolerable bad oral hygiene level and heavy smoking during healing phase. One patient failed to comply with using a splint to protect an implant just inserted but chewed on the gums in that area and chewed the implant into the sinus maxillaris. These events are, from a medical viewpoint, not related to the implant properties. Consequently, those patients have been excluded from the assessment in order to not distort the statistical results.

In all, 118 implants of all available dimensions (diameter x length) of the SICtapered Implant were placed according the following distribution (Fig. 5).

Implant selection and place of insertion (jaw, position) strictly followed medical indications (Figs. 6 and 7).

This results in following distribution by placement area (Table 1):

The implants were placed in all situations from extraction sockets to healed sites. In 82 (69 %) of the cases, bone augmentation measures were performed (Table 2).

The implant placement depths were chosen according to bone condition and restoration planning needs, following current implantological standards (Table 3 and Figs. 8 and 9).


8 and 9 I Different types of implant positioning relative to the alveolar crest

| | | | |
|---|---|---|---|
| **upper molar area** | 23 % | molar area* | 36 % |
| **lower molar area** | 14 % | | |
| **upper premolar area** | 37 % | premolar area* | 52 % |
| **lower premolar area** | 14 % | | |
| **upper anterior/canine area** | 11 % | anterior/canine area | 12 % |
| **lower anterior/canine area** | 1 % | | |

*When summing up upper area + lower area, certain deviations are due to rounding differences.

Table 1: Distribution in percentage of the implants inserted referring to the placement area.

| **augmentative measures performed before implant placement** | | | | | |
|---|---|---|---|---|---|
| sinus floor augmentation in Implant area | sinus floor augmentation adjacent to implant area | vertical/horizontal augmentation in implant area | vert./horiz. augmentation area adjacent to implant area | implant-bone gap filling | none |
| 29 (25 %) | 8 (7 %) | 26 (22 %) | 3 (3 %) | 16 (14 %) | 36 (31 %) |
| 82 (69 %) | | | | | |

Table 2: Number and percentage of the implants requiring augmentative measures

| **subcrestal** | **epicrestal** | **average epicrestal** | **supracrestal** |
|---|---|---|---|
| 16 | 19 | 64 | 19 |
| 14 % | 16 % | 54 % | 16 % |

Table 3: Number and percentage of the implants referring to the implant placement level

| **healing method applied to n (x %) implants (number of implants and percentage based on the total of all implants)** | | |
|---|---|---|
| closed | open, with gingiva shaper | open, with provisional crown |
| 92 (78 %) | 18 (15 %) | 8 (7 %) |

Table 4: Different post-implant-placement healing procedures

| **prosthetic restoration type** | | | | |
|---|---|---|---|---|
| single crown | crown (bridge) | bar (denture) | locator (denture) | none* |
| 43 | 57 | 6 | 8 | 4 |
| 36 % | 48 % | 5 % | 7 % | 3 % |

*'none' includes the implants which have not yet been prosthetically restored and the 1 implant loss

Table 5: Different types of prosthetic restoration

Samples of placement depths:
- supracrestal: implant shoulder above bone level
- epicrestal: implant shoulder on bone level
- avg. epicrestal: inclined situation with some parts of implant shoulder below, equal or above – but in avg. on bone level
- subcrestal: implant shoulder below bone margin

The bone cavity preparation and the placement of the implant were performed according to the manufacturer's instruction.

After implant placement, different healing procedures were applied (Table 4):
- closed healing (with a second surgery later on for implant uncovery, on average 23 weeks after placement)
- open healing with gingiva shaper
- open healing with provisional crown

All open healing cases were checked for adequate primary stability before the decision was made in favor of the open healing procedure. Primary stability was achieved in 100 % of the cases planned for open healing or direct provisional restoration.

After the healing period, the implants were prosthetically restored as shown below (Table 5).

## 4. Data assessment and consolidation

### 4.1. Data assessed and follow-up times

A total of 118 implants in 64 patients were assessed. The treatment data and the respective clinical findings were extracted from the patients' medical records. More than 250 X-ray images, which had been taken at different treatment stages, were also evaluated.

| | | | |
|---|---|---|---|
| $t_0$ | implant placement | | date of surgery |
| $t_1$ | post-surgical period | | avg. 9 days after surgery |
| $t_2$ | implant uncovering period | | avg. 23 weeks after implant placement |
| $t_3$ | prosthetic restoration period | impression/scan | avg. 28 weeks after implant placement |
| | | placement of restoration | avg. 30 weeks after implant placement |
| $t_4$ | follow-up check 1 | | avg. 37 weeks after implant placement |
| $t_5$ | follow-up check 2 → latest check | | avg. 70 weeks, → up to 135 weeks after i.p. |

Table 6: Time schedule for baseline and follow-up examinations

However, practitioners prefer different time intervals between implant placement and follow-up treatments/examinations. So the present study focuses on those data which were recorded in a substantially uniform way at the following points in time (Table 6).

The investigations at the points in time specified above covered the fields 'clinical status', 'radiological status' with their implantology-relevant subsections and 'patient satisfaction'.

### 4.2. Specifics and limitations

*General aspects of the data collection*

In Germany and Switzerland, patients' records are subject to the legal obligation to precisely document the course of treatment as well as all negative occurrences, such as complications, adverse effects, patient complaints etc. There is no obligation to document positive remarks, such as patient satisfaction etc. Nevertheless, many remarks of this kind are voluntarily entered into the records.

In accordance with this legal situation, the absence of negative entries for a documented treatment step was counted as 'no complications' but was not added to the explicitly positive entries.

It will be understood, that in a retrospective study we have to deal with heterogeneous data. The patient record entries from the six private dental clinics differ from each other in one way or another. Therefore, in particular the free-text statements of the practitioners in the patient records were assigned in a suitable manner to the corresponding categories of the international standards applied. These categories are listed below (Chapter 4.3).

*Specifics of implant figures in different observation periods*

Not all implants underwent every follow-up check, therefore the number of implants in some of the result tables differ from the number of total implants (118).

Depending on medical needs (e.g., the need to take an X-ray image), the time they are in place, the stage of prosthetic restoration etc., some records cannot be found in the implantologists' patient files. For example, an implant with open healing procedure and immediate restoration will not appear in the checkup phases from 'uncovering period' to 'prosthetic placement'. Furthermore, some patients underwent certain follow-up treatments such as the post-surgical check at their family dentist.

Especially some prosthetic-related treatment stages and respective follow-up checks have not been performed in the implantologists' practices for all implants, but some of them were prosthetically restored and intermittently checked in the referral dentists' practices. For this reason, the number of implants examined during the respective assessment stages may differ from the total number of 118 implants observed in this study.

*Radiologic data*

The radiation protection ordinances in Germany and Switzerland allow patiens' exposure to X-rays only if this kind of diagnostics is following a diagnostic or treatment need and if no other comparably reliable method can be used. Therefore, in the present study not all practitioners took X-ray pictures at all stages of the treatment. (Example: In a case with irritation-free clinical appearance – such as, e.g., stable implant with low sulcus depth and no inflammation etc. – some practitioners consider an X-ray avoidable). For this reason, at some observation stages the number of radiologically assessed and clinically assessed implants may differ from each other.

The radiographs have all been assessed and cross-checked against the entries in the patient records.

Clinicians in their daily workflow don't assess radiologic data according to international classifications but according to the clinical relevance for the case. The huge variety of individual entries in the patient records have therefore been consolidated to the most relevant findings, i.e. whether and how much bone resorption is visible in the follow-up phases vs. status of implant placement, categorized in the practice-oriented grading as described in the following (Table 7).

### 4.3. Suitable international assessment criteria

In the literature, numerous different standards and criteria are used to assess the success of implants, but these are only comparable to a limited extent.

Exemplary internationally used standards according to R. Buch et al. 2003 [5] include the Albrektsson criteria (T. Albrektsson et al. 1986 [6]; T. Albrektsson & F. Isidor 1994 [7]); Jahn-d'Hoedt criteria; Buser criteria; NIH criteria; Naert criteria. In 2007, the ICOI Pisa Consensus Conference proposed the criteria according to Misch which have been in use since then (Misch et al. 2008) [8]; (M. Thöne-Mühling et al. 2011) [9].

For reasons of general dissemination and awareness, this study not only re-

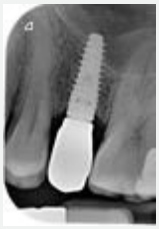
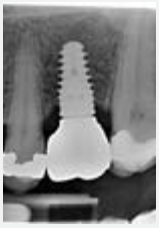
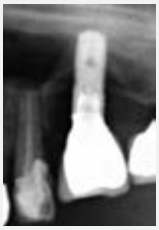
| practically-oriented classification | corresponds to findings | sample X-ray images |
|---|---|---|
| stable bone level vs. insertion | bone level at follow-up in average height the same as at implant placement stage (with a tolerance of +/- 0,5 mm due to different beam angles and/or different X-ray machines, e.g. OPT vs. IO) |  10 I bone level stable, unchanged (versus epicrestal insertion situation) |
| slight superficial bone resorption vs. insertion | bone level at follow-up in average ≤ 1.5 mm below status at implant placement (tolerances see above) |  11 I 0.7 mm recession at an 11.5 mm implant (vs. epicrestal insertion situation) |
| noticeable but not critical bone resorption vs. insertion | bone level at follow-up in average ≥ 1,5 and ≤ 3.5 mm below status at implant placement (tolerances ± 0.5 mm see above) |  12 I 1.6 mm recession mesial at a 9.5 mm implant (vs. epicrestal insertion situation) |
| critical bone resorption/failure/loss | worse than above, (≥ 4mm ) in worst case failure/loss |  13 I bone loss > 50 % of length (no suchlike picture available from this study, sample with other implant brand) |

Table 7: Bone resorption categorized in a practice-oriented grading

ports the practice-internal criteria noted by the participating clinics but also the international criteria of Albrektsson and Misch.

### 4.4. Albrektsson Criteria

The Albrektsson criteria [6, 7, 9] state:

1) After 5 years of loading, the implant survival rate should be at least 85 %, after 10 years at least 80 %.
2) The individually unblocked implant is clinically stable.
3) The radiograph shows no continuous peri-implant translucency.
4) The vertical bone loss should be less than 0.2 mm per year after the first year under load.
5) There are no permanent and/or irreversible symptoms such as pain, infection, neuropathy, paresthesia, or injury to the mandibular canal

and check for fulfillment/non-fulfillment.

### 4.5. Misch Criteria

The criteria according to Misch [8, 9] assess the success of the implant in 4 levels:

1) Success (optimum health)
   neither pain nor pressure-sensitivity under functional load, no mobility, < 2 mm radiographic bone loss since implantation, no exudation.
2) Satisfactory survival
   no pain under functional load, no mobility, 2–4 mm radiographic bone loss, no exudation.
3) Compromised survival
   Sensitivity to functional stress/load, no mobility, 4 mm radiographic bone loss, but less than ½ of the implant length, PD > 7 mm, possible exudation.
4) Failure
   Pain with functional load, mobility, radiological bone resorption, less than ½ of the implant length, exudation that cannot be treated, implant cannot be prosthetically treated (sleeper), implant no longer in situ.

### 4.6. Criteria application

The standards according to Misch and Albrektsson are internationally accepted and widely used for the assessment of implant success [5, 9]. However, they are designed in such a way that their criteria predominantly refer to implants which are already prosthetically restored.

| criterion and area / phase | $t_0$ | $t_1$ | $t_2$ | $t_3$ | $t_4$ | $t_5$ | remarks |
|---|---|---|---|---|---|---|---|
| 1 (clinical) | - | - | - | - | - | - | criterion is related to 5 years |
| 2 (clinical) | - | - | + | + | + | + | |
| 3 (radiological) | - | + | + | + | + | + | |
| 4 (radiological) | - | - | - | - | - | -,+ | $t_5$ depending on observation time |
| 5 (clinical) | - | + | + | + | + | + | |

Table 8: Elements of ALBREKTSSON Criteria (Chapter 4.4) applicable in respective phase

| criterion and area / phase | $t_0$ | $t_1$ | $t_2$ | $t_3$ | $t_4$ | $t_5$ | remarks |
|---|---|---|---|---|---|---|---|
| 1 (clinical/radiological) | - | +* | +* | + | + | + | * 'load' n.a. |
| 2 (clinical/radiological) | - | +* | +* | + | + | + | * 'functional load' n.a. |
| 3 (clinical/radiological) | - | +* | +* | + | + | + | * 'functional stress' n.a. |
| 4 (clinical/radiological) | - | +* | +* | + | + | + | * 'functional load' n.a. |

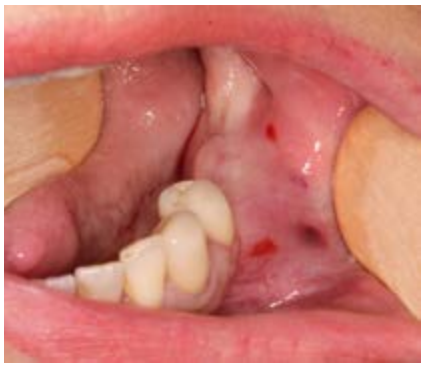
Table 9: Elements of MISCH Criteria (Chapter 4.5) applicable in respective phase

Since there are no general and comparable standards for evaluating the success of the implant in the 'intermediate steps' of an implant treatment, in the present study the standards outlined above were applied in a tailored way. In each follow-up examination exactly those subitems of each criteria were assessed which obviously made sense at the respective point of time (Tables 8 and 9).

In the tables below showing the results of the follow-up examinations the categories are consistently tagged with the extension '(app.c.)' for 'applied criteria', e.g. 'Albrektsson (app.c.)' or 'Misch (app.c.)'.

## 5. Exemplary presentation of the clinical approach

In order to briefly illustrate the clinical approach, a typical treatment is shown as performed in the context of the present study.



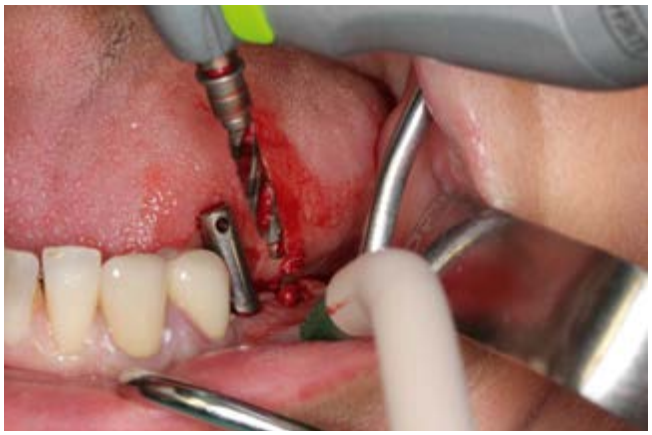
14 I Pre-operative view

The patient had lost two teeth (35 + 36) and, as a result, was in need of two implants (Fig. 14). In addition, two crowns (33 + 34) had to be replaced. The treatment comprised inserting two implants (SIC tapered, SIC Invent, Basel; Figs. 15 to 18), temporary restoration (Figs. 19 and 20), and final restoration with two tooth-borne and two implant-borne crowns (Figs. 21 to 25).

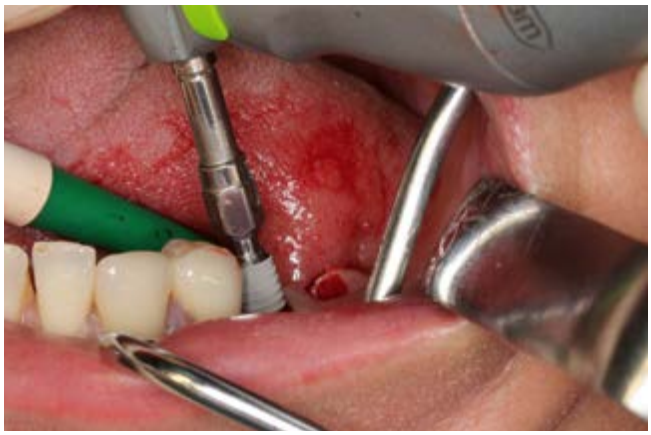
## 6. Results

In the following, the assessment results on clinical performance, radiological performance and patient satisfaction are described and statistically evaluated.

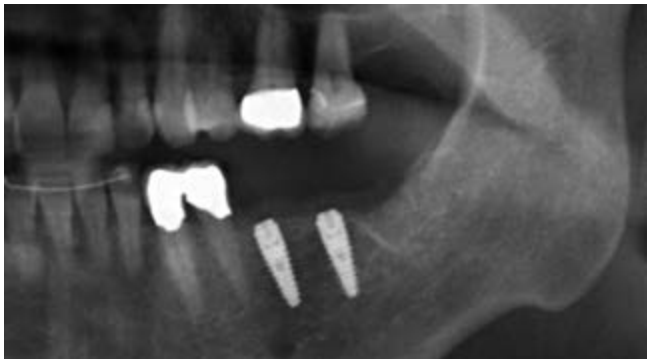
The statistics are kept on an implant basis. Calculating on a patient basis would be imprecise, as some patients have multiple implants with different findings.



15 I Passage of the drill at implant site of 36

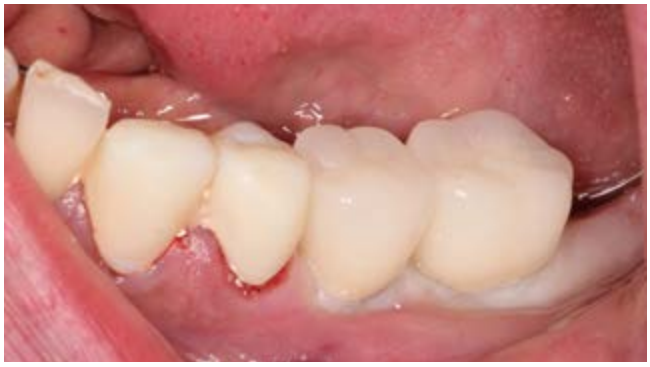


16 I Insertion of the implant at implant site of 35

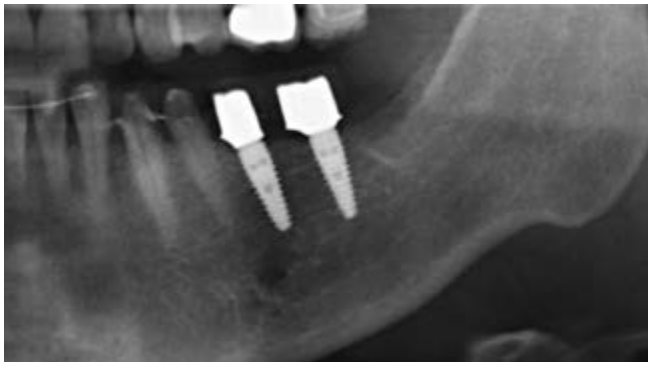


17 I Post-OP X-ray control

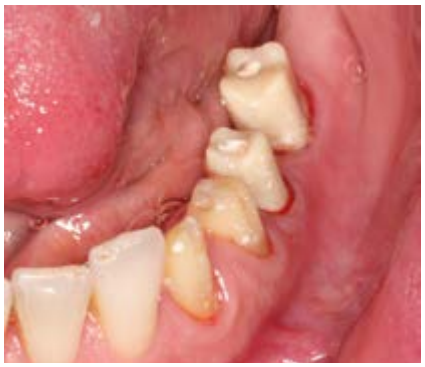
18 I Reapproach, individualized (PMMA) abutments for soft tissue management

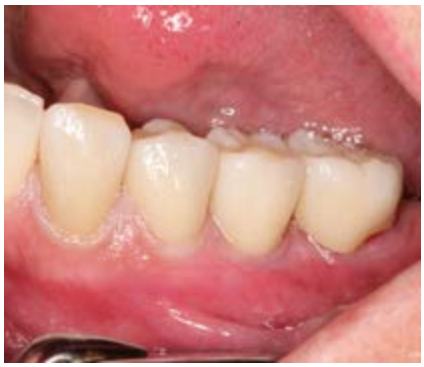


19 I Adhesively luted provisional crowns (33, 34, 35, 36)

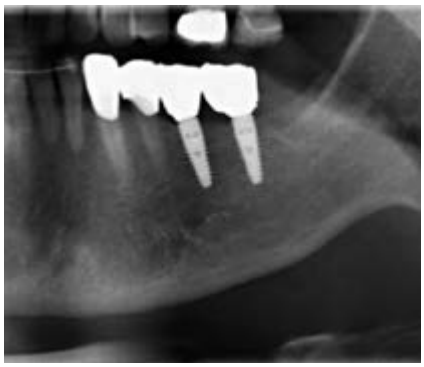


20 I X-ray control after placement of the long-term provisional crowns (35 weeks after implant placement, $t_3$)

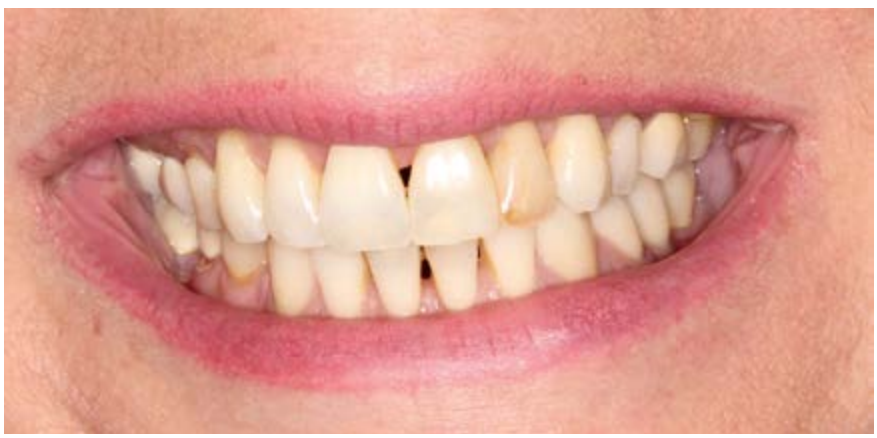




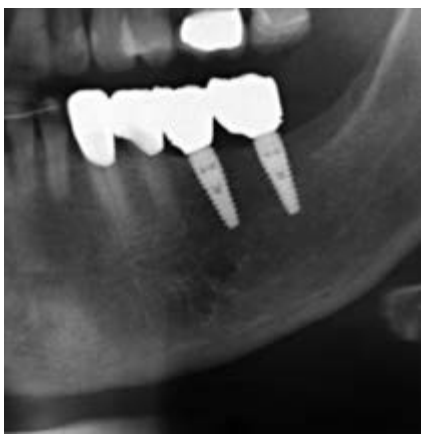
21 and 22 I Placement of the four crowns, two of them tooth-borne (33 + 34) and two implant-borne (35 + 36)



23 I X-ray control after placement of the final ceramic restorations (prosthetic check 1, 57 weeks after implant placement, $t_4$)



24 I Final result: the clinical outcome after prosthetic restoration and maturation of the tissue



25 I Final X-ray control (prosthetic check 2, 135 weeks after implant placement, $t_5$)

For reasons of clarity, the following tables only show the implants applicable to the respective observation phase. For more detailed information such as patient numbers or implants that cannot be evaluated for a phase, please refer to the links at the end of the article.

## 6.1. Follow-up examinations at specific points during the observation period

*6.1.1. $t_0$ – Implant placement surgery*
All implant placements could be performed according to the planning and following the manufacturer's treatment protocol.

Although 69 % (82 impl.) of the 118 implant placements were performed in conjunction with bone augmentation procedures, no complications or adverse effects were reported in any case.

No patient mentioned dissatisfaction at this stage.

Wound management could be realized as planned in all cases, according to the closed or open healing procedure.

*6.1.2. $t_1$ – Post-surgical check*
The post-surgical check was done on average 9 days after implant placement. All implants were in place and free of problems. No complications or adverse effects were reported.

98 % of the implants showed no irritations or complications at the post-operative follow-up visit; only 2 % showed temporary minor post-operative irritations, such as superficial inflammation, slight swelling or discomfort which were stage-appropriate to the extent of the surgery (Table 10). Patient satisfaction was high, no dissatisfaction was expressed (Table 11).

*6.1.3. $t_2$ – Implant uncovering phase*
The implants which underwent closed healing procedure were uncovered on

**$t_1$**

| post-surgical period $t_1$ average time after implant insertion: 9 days | | | | |
|---|---|---|---|---|
| **clinical assessment $t_1$** | **clinical findings from practice records** | | | |
| implants assessed at that stage | positive remarks about situation | no pathological findings noted | temporary minor irritations | persistent irritation/ inflammation or failure |
| 108 | 88 | 18 | 2 | 0 |
| 100 % | 81 % | 17 % | 2 % | 0 % |

| clinical criteria acc. Misch (app.c.) | | | | clinical criteria acc. Albrektsson (app.c.) | |
|---|---|---|---|---|---|
| 1: 'success (optimum health)' | 2: 'satisfactory survival' | 3: 'compromised survival' | 4: 'failure' | Albrektsson criteria fulfilled | Albrektsson criteria failed |
| 108 | 0 | 0 | 0 | 108 | 0 |
| 100 % | 0 % | 0 % | 0 % | 100 % | 0 % |

Table 10 I Clinical results of follow-up examination, on avg. 9 days after implant insertion

| patient satisfaction $t_1$ | satisfaction-related entries from practice records | | | |
|---|---|---|---|---|
| implants recorded acc. this parameter at that stage | patient proactively expresses satisfaction | no criticism noted | patient asks for improvement | patient unsatisfied |
| 108 | 40 | 68 | 0 | 0 |
| 100% | 37% | 63% | 0% | 0% |

Table 11 I Patient-satisfaction-related entries from practice records, on avg. 9 days after implant insertion

**$t_2$**

| uncovering period $t_2$ average time after implant insertion: 23 weeks | | | | |
|---|---|---|---|---|
| **clinical assessment $t_2$** | **clinical findings from practice records** | | | |
| implants clinically assessed | positive remarks about situation | no pathological findings noted | temporary minor irritations | persistent irritation/ inflammation or failure |
| 88 | 21 | 65 | 1 | 1 |
| 100 % | 24 % | 74 % | 1 % | 1 % |

| clinical criteria acc. Misch (app.c.) | | | | clinical criteria acc. Albrektsson (app.c.) | |
|---|---|---|---|---|---|
| 1: 'success (optimum health)' | 2: 'satisfactory survival' | 3: 'compromised survival' | 4: 'failure' | Albrektsson criteria fulfilled | Albrektsson criteria failed |
| 87 | 0 | 0 | 1 | 87 | 1 |
| 99 % | 0 % | 0 % | 1 % | 99 % | 1 % |

Table 12 I Clinical results of follow-up, on avg. 23 weeks after implant insertion

average 23 weeks after implant placement (Table 12). All implants were in place, but one had to be explanted due to missing osseointegration at that stage. All other implants were stable, well osseointegrated and free of problems.

The uncovering procedure caused temporary minor inflammatory irritation in only one case but even in this case it did not result in any complications.

Only the patient who lost an implant expressed dissatisfaction. In no other case any criticism has been noted.

*6.1.4. $t_3$ – Prosthetic restoration phase*

The prosthetic restoration phase started on average at 28 weeks after implant placement with the impression taking or optical scan and ended approximately 30 weeks after implant placement with the placement of the superstructure (crowns, bridges, dentures with bars or locators).

The assessment results in detail from this stage are as follows (Table 13-15):

*6.1.5. $t_4$ – Prosthetic follow-up 1 check*

The prosthetic follow-up check 1 took place on average at 37 weeks after insertion. It covered the performance of implants and of those prosthetic restorations, which had already been placed, according to the detailed criteria, see table below (Table 16):

*6.1.6. $t_5$ – Follow-up 2 check*

The last follow-up period started with the final check that took place on average 70 weeks after implant placement but was extended to mid-December 2020, the date when this report was finalized (Table 18a-b and 19).

**t3**

| prosthetic placement period $t_3$ average time after implant insertion: 28 – 30 weeks | | | | | |
|---|---|---|---|---|---|
| **radiological assessment $t_3$** | **radiological findings from practice records** | | | | |
| implants radiologically assessed | stable bone level vs. insertion | slight super-ficial bone resorption vs. insertion | noticeable but not critical bone resorp-tion vs. insertion | critical bone resorption/ failure/loss | |
| 79 | 67 | 11 | 1* | 0 | |
| 100 % | 85 % | 14 % | 1 % | 0 % | |
| **radiological criteria acc. Misch (app.c.)** | | | | **radiological criteria acc. Albrektsson (app.c.)** | |
| 1: 'success (opti-mum health)' | 2: 'satisfactory survival' | 3: 'compromised survival' | 4: 'failure' | Albrektsson criteria fulfilled | Albrektsson criteria failed |
| 78 | 1* (3mm) | 0 | 0 | 79 | 0 |
| 99 % | 1 % | 0 % | 0 % | 100 % | 0 % |

Table 13 I Radiological results of follow-up, on avg. 28-30 weeks after implant insertion

* same implant

| **clinical assessment $t_3$** | **clinical findings from practice records** | | | |
|---|---|---|---|---|
| implants clinically assessed | positive remarks about situation | no pathological findings noted | temporary minor irritations | persistent irritation/ inflammation or failure |
| 106 | 22 | 84 | 0 | 0 |
| 100 % | 21 % | 79 % | 0 % | 0 % |

| **clinical criteria acc. Misch (app.c.)** | | | | **clinical criteria acc. Albrektsson (app.c.)** | |
|---|---|---|---|---|---|
| 1: 'success (opti-mum health)' | 2: 'satisfactory survival' | 3: 'compromised survival' | 4: 'failure' | Albrektsson criteria fulfilled | Albrektsson criteria failed |
| 106 | 1 | 0 | 0 | 106 | 0 |
| 99 % | 1 % | 0 % | 0 % | 100 % | 0 % |

Table 14: Clinical results, on avg. 28-30 weeks after implant insertion

| **patient satisfaction $t_3$** | **satisfaction-related entries frompractice records** | | | |
|---|---|---|---|---|
| implants recorded | patient proactively expresses satisfaction | no criticism noted | patient asks for improvement | patient dissatisfied |
| 106 | 31 | 75 | 0 | 0 |
| 100 % | 29 % | 71 % | 0 % | 0 % |

Table 15: Patient-satisfaction-related entries from practice records, on avg. 28-30 weeks after implant insertion

## t4

| prosthetic follow-up 1 $t_4$ average time after implant insertion: 37 weeks | | | | | |
|---|---|---|---|---|---|
| **radiological assessment $t_4$** | | **radiological findings from practice records** | | | |
| implants radiological assessed | | stable bone level vs. insertion | slight super-ficial bone resorption vs. insertion | noticeable but not critical bone resorp-tion vs. insertion | critical bone resorption/ failure/loss |
| 28 | | 26 | 1 | 1 (see t3) | 0 |
| 100 % | | 92 % | 4 % | 4 % | 0 % |
| **radiological criteria acc. Misch (app.c.)** | | | | **radiological criteria acc. Albrektsson (app.c.)** | |
| 1: 'success (opti-mum health)' | 2: 'satisfactory survival' | 3: 'compromised survival' | 4: 'failure' | Albrektsson criteria fulfilled | Albrektsson criteria failed |
| 27 | 1 (see $t_3$) | 0 | 0 | 28 | 0 |
| 96 % | 4 % | 0 % | 0 % | 100 % | 0 % |
| **clinical assessment $t_4$** | | **clinical findings from practice records** | | | |
| implants clinically assessed | | positive notes about situation | no pathological fin-dings noted | short term minor discomfort | persistent irritation/ inflammation or failure |
| 90 | | 25 | 64 | 1 | 0 |
| 100 % | | 28 % | 71 % | 1 % | 0 % |
| **clinical criteria acc. Misch (app.c.)** | | | | **clinical criteria acc. Albrektsson (app.c.)** | |
| 1: 'success (opti-mum health)' | 2: 'satisfactory survival' | 3: 'compromised survival' | 4: 'failure' | Albrektsson criteria fulfilled | Albrektsson criteria failed |
| 89 | 1 | 0 | 0 | 90 | 0 |
| 99 % | 1 % | 0 % | 0 % | 100 % | 0 % |

Table 16: Radiological and clinical results, on avg. 37 weeks after implant insertion

| **patient satisfaction $t_4$** | **satisfaction-related entries frompractice records** | | | |
|---|---|---|---|---|
| implants recorded acc. this parameter at that stage | patient proactively expresses satisfaction | no criticism noted | patient asks for improvement | patient dissatisfied |
| 90 | 18 | 71 | 1 | 0 |
| 100 % | 20 % | 79 % | 1 % | 0 % |

Table 17: Patient-satisfaction-related entries from practice records, on avg. 37 weeks after implant insertion

## t5

| follow-up $t_5$ average time after implant insertion: 70 weeks | | | | | |
|---|---|---|---|---|---|
| **radiological assessment $t_5$** | | **radiological findings from practice records** | | | |
| implants radiologically assessed at this stage | | stable bone level vs. insertion | slight super-ficial bone resorption vs. insertion | noticeable but not critical bone resorp-tion vs. insertion | critical bone resorption/ failure/loss |
| 21 | | 17 | 4 | 0* | 0 |
| 100 % | | 81 % | 19 % | 0 % | 0 % |
| **radiological criteria acc. Misch (app.c.)** | | | | **radiological criteria acc. Albrektsson (app.c.)** | |
| 1: 'success (opti-mum health)' | 2: 'satisfactory survival' | 3: 'compromised survival' | 4: 'failure' | Albrektsson criteria fulfilled | Albrektsson criteria failed |
| 21 | 0* | 0 | 0 | 21 | 0 |
| 100 % | 0 % | 0 % | 0 % | 100 % | 0 % |

*the 1 implant mentioned in t3 and t4 has timewise not yet reached this (t5) observation period

Table 18a: Radiological results, on avg. 70 weeks after implant insertion

$t_5$

| clinical assessment $t_5$ | clinical findings from practice records | | | |
|---|---|---|---|---|
| implants clinically assessed | positive remarks about situation | no pathological findings noted | temporary minor irritations | persistent irritation/ inflammation or failure |
| 46 | 9 | 37 | 0 | 0 |
| 100 % | 20 % | 80 % | 0 % | 0 % |

| clinical criteria acc. Misch (app.c.) | | | | clinical criteria acc. Albrektsson (app.c.) | |
|---|---|---|---|---|---|
| 1: 'success (optimum health)' | 2: 'satisfactory survival' | 3: 'compromised survival' | 4: 'failure' | Albrektsson criteria fulfilled | Albrektsson criteria failed |
| 46 | 0* | 0 | 0 | 46 | 0 |
| 100 % | 0 % | 0 % | 0 % | 100 % | 0 % |

Table 18b: Clinical results, on avg. 70 weeks after implant insertion

*see remark under previous table

| patient satisfaction $t_5$ | satisfaction-related entries frompractice records | | | |
|---|---|---|---|---|
| implants recorded acc. this parameter at that stage | patient proactively expresses satisfaction | no criticism noted | patient asks for improvement | patient dissatisfied |
| 46 | 5 | 41 | 0 | 0 |
| 100 % | 11 % | 89 % | 0 % | 0 % |

Table 19: Patient-satisfaction-related entries from practice records, on avg. 70 weeks after implant insertion

### 6.2. Entire observation period

At the end of this study, not all study implants had reached the same age (see section 3) and correspondingly not all reached the same follow-up stage. For an overall evaluation of all implants at the end of this study (Dec. 2020), the records of the latest available follow-up were assessed to obtain a final status information for each implant. The table below shows the consolidated results of the performance of the implants examined over the study period according to the respective latest follow-up and most recent records in the patients' files (Table 20).

**clinical and radiological**

**clinical appearance and functionality according to latest practice records**

| implants assessed | implants in place and functional, without constraints | implants in place and functional, with minor tissue recession | implant failure/loss |
|---|---|---|---|
| 118 | 115 | 2* | 1 |
| 100% | 97% | 2% | 1% |

**overall evaluation and classification (merged clinical and radiological) according to applicable criteria of Misch**

| implants classified | classifiable | | | | not classifiable** |
|---|---|---|---|---|---|
| | 1: 'success (optimum health)' | 2: 'satisfactoy survival' | 3: 'compromised survival' | 4: 'failure' | |
| 97 | 94 | 2* | 0 | 1 | 21 |
| 100% | 97 % | 2% | 0% | 1% | |

*1 implant is the same case as in the detailed tables above (stable since t3 ) + 1 implant with moderate bone recession (2.5 mm) detected only after t5 in the most recent X-ray, therefore doesn't appear in the previous tables

**overall evaluation and classification (merged clinical and radiological) according to applicable criteria of Albkretsson**

| implants classified | classifiable | | not classifiable** |
|---|---|---|---|
| | fulfillment of criteria | no fulfillment of criteria | |
| 97 | 96 | 1 | 21 |
| 100% | 99% | !% | |

**implants which have not reached both, clinical and radiological follow-up in at least t3 stage or higher cannot be assessed for combined overall classification. (see links at the end of the article)

Table 20: Overall radiological and clinical results at the end of the study

In the overall assessment, not all 118 implants could be clearly assigned to the applicable Misch or Albrektsson criteria over the entire observation period due to the absence of sufficient X-ray images at the respective follow-up periods (see link at the end of this article).

Nevertheless, all implants – except for a single case of an early implant loss – are still in place and clinically performing (Tables 21 and 22).

### 6.3. Conclusion

Compared to the results known from literature and the findings of the studies listed in section 2, the survival rate of the novel implant design in the early phase (99 %) surpasses the rate described (97 % after one year) in the most actual large study by Knöfler et al. [2].

The radiological evaluation consistently shows a positive bone level stability with bone resorption rates that are substantially equivalent to the stage-related applicable criteria of Misch [8] and Albrektsson [6, 7] which are internationally accepted [5, 9, 10].

This novel implant design exhibits positive results in the clinical, radiographic, and patient satisfaction areas based on the study results.

The clinical performance examined in the early critical phase seems to have a low degree of complications in accordance with the referenced literature.

For reasons of clarity, the tables in section 5.1 and 5.2 only show the implants applicable to the respective observation phase. For more detailed information, such as the numbers of implants or patients [I and (P)] that cannot be evaluated for a phase, please scan the QR-Code below:

Also, you can find a list of individuals and participating clinics to whom I would like to express my gratitude by scanning the QR-Code below:

The references are available at www.teamwork-media.de/literatur

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| | acc. prosthetic-related entries from practice records | | | | | |
|---|---|---|---|---|---|---|
| **prosthetic restoration** | implants recorded acc. this parameter at that stage | prosthetic restoration in place and fully functional | prosthetic restoration in place with minor constraints (e.g. sharp edges, occlusion corrections, denture pressure points, etc.) | prosthetic restoration in Place, but with possible risk | Failure of prosthetic restoration and/or implant Loss | prosthetic restoration not (yet) provided |
| | 118 | 111 | 2 | 1* | 1 | 3 |
| | 100% | 94% | 2% | 1% | 1% | 2% |

*this is the single implant listed in t3 and t4 under 'satisfactory survival' with the bone recession of 3 mm

Table 21: Overall prosthetic results referring to practice records

| | satisfaction-related entries from practice records | | | | |
|---|---|---|---|---|---|
| **patient satisfaction** | implants recorded acc. this parameter at that stage | patient ‚proactively' expresses satisfaction | no criticism noted | pat. asks for improvement (due to minor discomfort) | patient dissatisfied (heavy discomfort or failure) |
| | 118 | 24 | 90 | 3 | 1 |
| | 100% | 20% | 76% | 3% | 1% |

Table 22: Summary of patient-satisfaction-related entries from practice records