

Clinical Evaluation of Small-Diameter ITI Implants: A Prospective Study

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Purpose: Dental implants with a reduced diameter are designed for specific clinical situations, such as placement of implants where bone width is narrow or between adjacent teeth that have only a narrow space between them. They are particularly useful when replacing small teeth such as lateral maxillary and mandibular incisors. The aim of the present study was the clinical evaluation of 2-part ITI implants (full-body screws with a 3.3-mm diameter). **Materials and Methods:** One hundred forty-nine partially or completely edentulous patients received a total of 298 2-part ITI implants over a 10-year period. After a standard healing period (3 to 6 months), the implants were restored with fixed restorations such as single crowns or fixed partial or complete prostheses or overdentures. Complete prosthesis or overdenture in the edentulous jaw was the predominant type of restoration. All patients followed a strict maintenance program, with regular recalls at least once a year. The survival rate of the implants was analyzed, and prosthetic complications were assessed. **Results:** Three implants were lost during the healing phase on account of peri-implant infection. Two implant body fractures with an osseous length of 8 mm were observed (one after 2 years of observation, the other after 6 years). Four implants exhibited transient peri-implant inflammation that was treated successfully by interceptive therapy. The cumulative 5-year survival rate of the implants was 98.7% (96.6% after 6 years). Prosthetic complications were mostly limited to loose occlusal screws and sore spots caused by the denture base. **Discussion:** Within the limited observation period, failures of small-diameter implants were infrequent. Prosthetic complications were not dependent on the use of small-diameter implants. **Conclusion:** The use of 3.3-mm ITI implants appears to be predictable if clinical guidelines are followed and appropriate prosthetic restorations are provided. However, fatigue fracture may occur after a long period of function. *INT J ORAL MAXILLOFAC IMPLANTS* 2004;19:92–99

Key words: failures, small-diameter implants

The concept of osseointegration, ie, the direct anchorage of pure or alloyed titanium endosseous implants in the jawbone, was a breakthrough in oral rehabilitation. Experimental and clinical experience led to the establishment of clinical guidelines for the predictable achievement of

osseointegration. Current protocols include a low-trauma surgical procedure, primary stability of the implant in the congruent implant bed, and an unloaded healing phase.

For a time, submerging of the implant by means of a 2-stage procedure was thought to be a prerequisite.¹ However, experiments in which ITI implants (Straumann, Waldenburg, Switzerland) were intentionally not submerged yielded good, predictable results.² Various studies have demonstrated that successful osseointegration can be achieved in a 1-stage procedure.^{3–5} Comparative studies with submerged and nonsubmerged implants also have been published.^{6–8}

Small-diameter implants (diameter < 4 mm) have become commonly available with various implant systems (both submerged and nonsubmerged). These implants have increased and improved the treatment options for the clinical indications for which they were specifically designed: placing

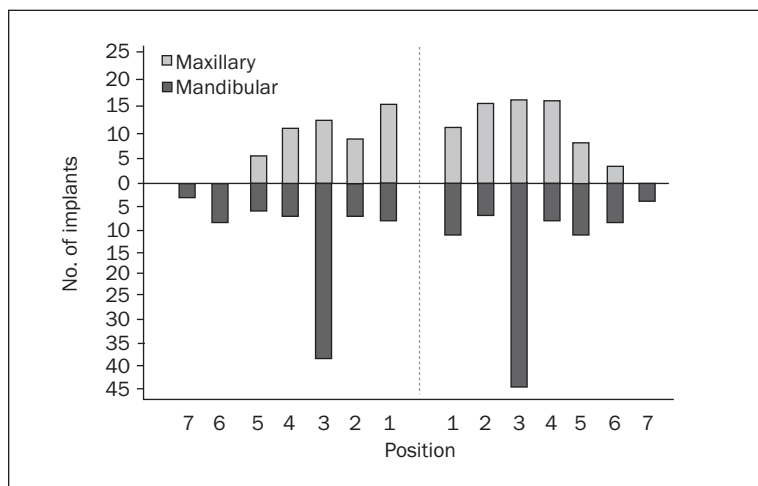
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Fig 1 Location of 3.3-mm ITI implants by approximate tooth position. 1 = central incisor; 2 = lateral incisor; 3 = canine; 4 = first premolar; 5 = second premolar; 6 = first molar; 7 = second molar.



implants in single-tooth gaps with limited interdental space, and particularly for the replacement of incisors. They have also been used where the width of the partially or completely edentulous ridge is limited. It seems that the guidelines developed for surgical placement and prosthetic restoration of standard-sized implants have been applied to small-diameter implants. Only a few published studies have focused exclusively on the use of small-diameter implants.⁹⁻¹¹ Although positive treatment outcomes have been reported, long-term results and multicenter studies have not been obtained to confirm their predictable use.¹² Multicenter studies of ITI implants have included only implants with a standard diameter of 4.1 mm.^{13,14}

A reduced diameter means a reduction in the contact surface between the implant and the bone, and one might ask whether osseointegration is sufficient to withstand loading forces. Decreasing the diameter also means increasing the risk of implant fracture due to reduced mechanical stability and increasing the risk of overload. At a consensus conference, it was suggested that 3.3-mm implants be used with caution.¹⁵ It was further suggested that clinicians avoid using them for placement of single crowns in zones of heavy load and that they be splinted, preferably with standard-size implants.¹⁵ In cases where bone width is narrow, local bone augmentation to enable the use of standard-size implants is an option. Techniques for local bone augmentation have been described, and their successful application has been documented.¹⁶ However, augmentation techniques increase the treatment time and costs and are invasive.

The aim of the present study was the clinical evaluation of 3.3-mm ITI implants that had been consecutively placed over a 10-year interval.

MATERIALS AND METHODS

All patients included in the present study had been consecutively recruited and treated at the Department of Prosthodontics (surgery and prosthesis fabrication). All patients signed an informed consent. The implant surgery was done by 2 surgically trained prosthodontists; the prostheses were fabricated in the course of the advanced specialty training program. A group of 3 dental hygienists was responsible for organization of the recall program and regular maintenance. Over a time period of 10 years, 154 patients, 50 men (32%) and 104 women (68%), consecutively received a total of 298 2-part ITI implants with a reduced diameter of 3.3 mm. Various types of prostheses were fabricated, some of which were supported exclusively by reduced-diameter implants and some of which were supported by a combination of reduced-diameter implants and standard-diameter implants (ie, 4.1 mm diameter). The total number of prostheses was 177; some patients received more than 1 prosthesis. The age of the patients ranged from 19 to 87 years, with a median of 62 years. All small-diameter implants were solid-screw type implants with an intraosseous length of 8, 10, or 12 mm. One hundred twenty-seven implants (43%) were placed in the maxilla and 171 (57%) in the mandible. Small-diameter implants were used for the following clinical indications: narrow buccolingual width of the maxillary or mandibular ridge in completely and partially edentulous patients and small single-tooth gaps in the mandible and maxilla. Implants with an intraosseous length of 10 mm were used most frequently ($n = 126$; 42%), followed by 12-mm-long implants ($n = 112$; 38%) and 8-mm-long implants ($n = 60$; 20%). Fig 1 shows the distribution and number of implants related to the position in the maxilla and mandible. Fig 2 gives an overview of the length of implants related to position in the jaw.

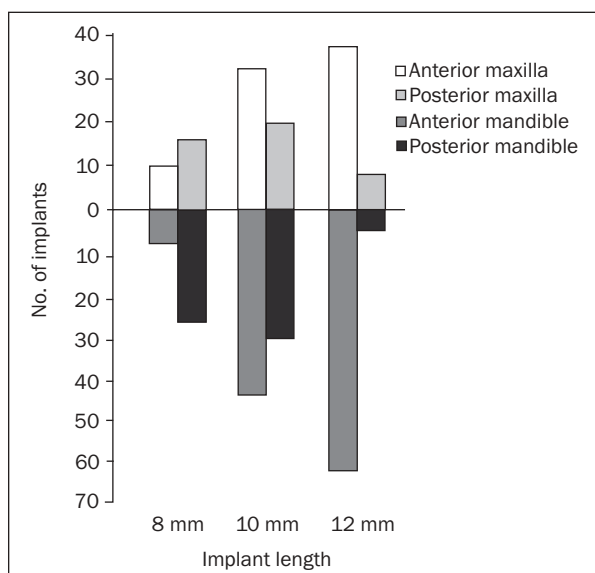


Fig 2 Location of 3.3-mm ITI implants, classified according to length (8, 10, or 12 mm).

Treatment Protocol

The following exclusion criteria were applied:

- Heavy smoking, ie, > 15 cigarettes a day
- Unsatisfactory oral hygiene
- Severe systemic disease that would not allow a short surgical intervention
- Drug abuse
- Psychologic disorders
- Irradiated bone
- Bone grafts or local guided bone augmentation before implant placement

A standard low-trauma surgical procedure¹⁷ was used, followed by a healing phase of 3 months in the mandible and 4 to 6 months in the maxilla, depending on the bone structure as assessed during the surgical procedure. Since the ITI implant system involves a 1-stage surgical procedure, patients had to comply with a meticulous oral hygiene program during the healing phase. The patients had provisional prostheses adapted that were not directly connected to the implants. After the healing phase, the successfully integrated implants were restored with a definitive prosthesis. These restorations included single crowns and fixed partial and complete prostheses and overdentures. A complete prosthesis or overdenture in the edentulous jaw was the predominant type of restoration, since the study population included a large number (> 50%) of edentulous patients. Many of these patients had been edentulous for a long time and exhibited narrow, atrophic ridges. Placement of small-diameter implants was indicated to avoid the additional surgical procedures that would have

been required for bone augmentation. All prosthetic restorations and bars were screw retained and mounted to an octa-abutment. Only 5 implant-supported fixed partial prostheses were cemented, again using the octa-abutment in combination with an individually cast suprastructure.

Maintenance and Follow-up

When the new prostheses were completed and placed, peri-implant parameters were recorded and radiographs taken. All patients were instructed to follow a strict maintenance program, with annual recall visits according to a standard protocol. Some temporary dropouts were registered for annual intervals, but only 1 patient was permanently withdrawn from the study. Thus, all but 1 patient were still available for a clinical examination in the context of this study. During recall examinations, the patients' hygiene was checked, bleeding on probing was assessed, and probing depths that exceeded 4 mm were registered. Further, technical complications related to the prostheses and implant components were evaluated, and necessary maintenance service was provided. Annual radiographs were not taken, since most patients would not consent. Thus, calculation of mean annual crestal bone loss was not possible.

Clinical Examination and Data Collection

At the annual examination, each implant was classified according to the following clinical criteria¹³:

- Successful osseointegration, ie, absence of peri-implant infection, mobility, or complaints of pain
- Recurrent peri-implant infection with subsequent successful treatment
- Implant failure related to untreatable infection
- Implant failure related to mobility
- Implant failure caused by fracture

Prosthetic maintenance was classified as follows^{18,19}:

- Complications with implant components and anchorage structure, eg, loosening or fracture of abutment, tightening and/or replacement of occlusal screws, broken bars, or loose, lost, or broken bar retainers
- Repairs of fractured prostheses, porcelain veneers, or overdenture teeth
- Redesign of prostheses (required for various reasons)
- Adjustments (eg, relining of denture base, occlusal adjustment) for various reasons (eg, sore spots, hyperplasia underneath denture)

All registered data were processed using the computer program Excel (Microsoft, Redmond, WA).

Table 1 Prostheses with 3.3-mm Implants

Type of prosthesis	No. of prostheses	No. of 3.3-mm implants loaded	Total no. of implants related to prostheses*
Overdenture			
Maxillary	46	97	204 (107)
Mandibular	74	131	152 (21)
Fixed complete			
Maxillary	2	3	14 (11)
Mandibular	3	9	14 (5)
Fixed partial (implant-supported)			
Maxillary	12	12	27 (15)
Mandibular	15	18	41 (23)
Fixed partial (implant- and tooth-supported)			
Maxillary	3	3	4 (1)
Mandibular	5	5	7 (2)
Single crowns			
Maxillary	12	12	12
Mandibular	5	5	5
Total	177	295	480 (185)

*Parentheses indicate no. of implants with standard diameter.

Statistical Analysis

Descriptive statistics were used for patient demographics, distribution of implants, and prosthetic complications. A life table analysis was calculated for implant survival.²⁰ The term *survival* was applied, since annual radiographs were not available. However, at the clinical examinations performed in 2001 and 2002 in the context of this study, most implants would have been considered successful according to most of the criteria proposed by Buser and colleagues,¹³ except for the lack of radiographic bone loss measurements.

RESULTS

Failures and Biologic Complications with Implants

Of 298 implants, 3 had to be removed during the healing phase. Of the 295 loaded implants, 228 (77%) were used in combination with mandibular and maxillary overdentures, 12 (4%) with fixed complete prostheses in edentulous jaws, 30 (10%) with implant-supported partial prostheses, and 8 (3%) with implant/tooth-supported fixed partial prostheses. Seventeen implants (6%) replaced a single missing tooth. Table 1 gives an overview of the use of 3.3-mm-diameter implants in combination with standard-size (4.1-mm-diameter) implants for support of various prostheses. Fifty-six of the 185 standard-size implants were located in the mandible (23 posterior, 33 intraforaminal) and 129 in the maxilla

(65 posterior, 64 anterior). All but 4 fixed partial and complete prostheses and overdentures were supported by a combination of small-diameter and standard-size implants (100% of maxillary implants). However, 53 of 74 mandibular overdentures were supported exclusively by small-diameter implants.

Table 2 shows the implant failures and biologic complications. The 3 implants that failed during the healing phase were all in a single patient, who exhibited an untreatable peri-implant infection. After removal of the implants, this patient underwent local bone augmentation. Four implants of a standard diameter (4.1 mm) were subsequently placed. Two late failures occurred in 2 patients after an observation period of less than 2 years in one case and more than 6 years in the other (Figs 3a and 3b). In the latter case, an implant replacing a single premolar exhibited a fracture at the level of the crestal bone. The implant body itself, which was 8 mm long, showed all signs of stable osseointegration. In the former case, the implant was located at the site of a maxillary canine supporting a short-span fixed partial denture in conjunction with a standard-size, 10-mm-long implant. The fracture occurred in the same way, at the crestal bone level. In 4 patients, interceptive therapy became necessary because of recurrent peri-implant inflammation with suppuration and slightly increased probing depth. For 2 of these implants, professional cleaning was prescribed, followed by a phase of administering chlorhexidine rinse. For 1 implant, Periochips (Karr Dental, Horgen, Switzerland) were applied repeatedly, and 1

Table 2 Complications and Failures of Implants

Patient/sex	Position of implant (s)	Type of failure or complication	Implant length (mm)	Type of restoration	Time in situ (mo)
Female	Mandibular right canine	Infection*	12	Overdenture planned	Healing period
	Mandibular left central incisor		12		
	Mandibular left canine		12		
Female	Maxillary left first premolar	Fracture*	8	Single crown	79
Male	Maxillary right canine	Fracture*	10	Fixed partial prosthesis	33
Male	Mandibular left central incisor	Infection [†]	10	Mandibular overdenture	81
Female	Mandibular right canine	Infection [†]	12	Mandibular overdenture	63
Male	Maxillary right lateral incisor	Infection [†]	10	Maxillary overdenture	61
Female	Mandibular right canine	Infection [†]	12	Mandibular overdenture	7

*Implants removed.

[†]Temporary infection, interceptive supportive therapy provided; implants maintained.



Fig 3a Radiograph of single 3.3-mm implant (length 8 mm) replacing a right maxillary premolar.

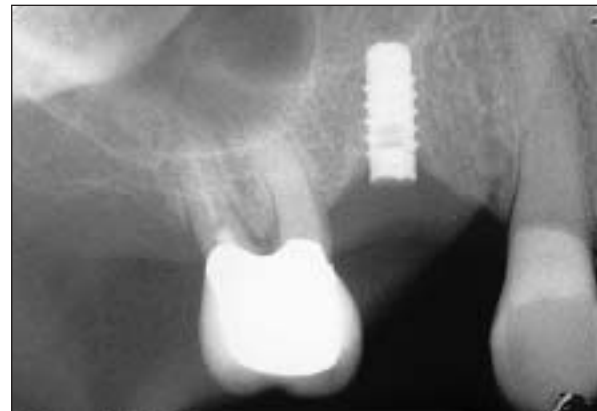


Fig 3b Same case as shown in Fig 3a. The radiograph shows the fracture of the implant at the crestal bone level after an observation time of > 5 y.

implant was treated using guided tissue regeneration (GTR) with a resorbable membrane (Geistlich, Entlebuch, Switzerland). GTR resulted in a reduction of the probing depth but also in a small persisting recession on the buccal aspect of the implant, leaving some threads visible. The threads were smoothed by polishing the implant surface, and the implant has been maintained without further complications. Altogether, 143 patients remained free of any complications or failures of implants.

Table 3 shows the life table analysis of 298 placed implants with the cumulative survival rates (CSRs). The 5-year CSR was 98.7%. One late implant failure occurred after a 6-year observation period; thus, the CSR after 6 years was 96.6%.

Prosthetic Complications

Prosthetic problems were recorded, and maintenance service was provided regularly. Table 4 gives an overview of prosthetic problems. Eighty-four patients (56.8%) never exhibited any prosthetic complications. Some patients experienced the same problem several times. Most prosthetic problems were easily resolved. One small porcelain fracture

was repaired, since the fixed partial prosthesis was screw retained and could be removed. Redesign of 2 overdentures became necessary for esthetic reasons. More service was provided in the first years after delivery of the definitive prostheses.

DISCUSSION

The present study reports on results and use of small-diameter ITI implants. Based on the CSRs, the study results could be considered favorable. Although 3 implants were lost during the healing phase, indicating a failure rate of 1%, it cannot be concluded that osseointegration of ITI implants with a reduced diameter is impaired. Multicenter reports^{13,14} have exhibited an early failure rate of about 0.5%, which appears to be very low compared with what is commonly reported in the literature. In the present study, the 3 implants that failed during the healing phase were placed intraforaminally in a single patient in a delayed immediate surgical procedure (4 weeks after tooth extraction). The failure appears to have resulted from problems with bone resorption, remodeling, or

Table 3 Life Table Analysis of 298 Implants

Interval (y)	No. of implants at start of interval	Dropouts during interval	Implants at risk	Failures during interval	Survival rate within period (%)	Cumulative survival rate (%)
0*	298	0	298	3	99.0	99.0
0-1	295	3	292	0	100.0	99.0
1-2	271	9	262	1	99.6	98.7
2-3	200	12	188	0	99.6	98.7
3-4	148	10 [†]	138	0	100.0	98.7
4-5	122	9	113	0	100.0	98.7
5-6	91	6	85	0	100.0	98.7
> 6	56	4	52	1	98.1	96.6

*Healing period.

[†]One patient with 2 implants dropped out permanently.**Table 4 Overview of Prosthetic Problems**

Category	Year							Total
	1	2	3	4	5	6	≥ 7	
Anchorage								
Loosening abutment	0	1	1	0	1	0	0	3
Fracture abutment	0	0	0	0	0	0	0	0
Tightening occlusal screws	7	7	3	1	6	1	0	25
Tightening bar retainer	6	1	2	1	1	3	1	15
Broken, loose, or lost retainer	3	2	2	1	0	0	0	8
Broken bar (extension)	4	1	0	0	1	0	0	6
Repairs								
Fractured denture base	0	1	0	0	0	0	0	1
Fractured fixed prosthesis	0	0	0	0	0	0	0	0
Fractured denture teeth	0	1	0	0	0	0	1	2
Fractured porcelain veneer	0	0	0	0	1	0	0	1
Redesign*								
Denture	0	0	0	0	0	1	1	2
Fixed prosthesis	0	0	0	0	0	0	0	0
Adjustments								
Sore spots	19	3	3	1	0	0	1	27
Relining denture	4	4	1	0	0	1	0	10
Occlusal adjustment	8	1	2	0	1	0	0	12
Hyperplasia	0	1	0	0	0	0	0	1

*One overdenture was changed to a new prosthesis.

a chronic infectious process which were not well controlled. Thus, the etiology of these failures was infection, not biomechanical problems.

An experimental study, however, showed that removal torque was increased with wider implants.²¹ Another study compared pull-out resistance of small-diameter (3.25 mm) and large-diameter (4.25 mm) implants and also evaluated the relationship between bone density and the mechanical stability of the implants.²² Large-diameter implants showed a higher pull-out force than small-diameter implants; however, the difference was not statistically significant.

There was a significant positive correlation between pull-out resistance and bone density for both implant types. In another study, which compared standard- and narrow-diameter Brånemark System implants placed in the anterior maxilla, 2

early failures were believed to be caused by loose bone structure rather than by the implant diameter.²³ In a retrospective analysis of 468 solid-screw ITI implants under long-term observation, 16% were small-diameter implants.²⁴ Since only a small number of implants were lost, no conclusion could be drawn regarding diameter. A prospective study dealing with fixed prostheses in the edentulous mandible and Astra Tech implants also reported on the use of small-diameter (3.5 mm) implants.²⁵ The success rate was high, but the authors did not specify the results related to the diameter of the implant. In the present study population, the 298 small-diameter implants constituted more than 60% of the implants the patients received. Of the 180 standard-diameter implants, 1 had to be removed due to an untreatable infection.

Bone augmentation procedures are often used to enlarge the local bone site to enable the placement of standard-size implants.^{16,26,27} Bone grafts harvested from the chin or retromolar area require invasive, complex surgical techniques, and the additional risks must be considered.^{28,29} In the present study, approximately 40% of small-diameter implants were placed in the intraforaminal area for overdenture support in elderly patients. Elderly patients are not considered ideal candidates for local bone augmentation, which is an invasive treatment. This more conservative approach obviates the need for invasive treatment. In a recent systematic review of biological and technical failures, implant fractures were mentioned in at least 80% of the selected papers, but the incidence of this type of failure was low (less than 1%) and not dependent on the implant system used.³⁰

It is unlikely that peri-implantitis would occur more often with small-diameter implants. In an ITI multicenter study,¹³ the failure of 23 loaded implants (about 1%) was ascribed to peri-implant infection. In the present study, there were 4 loaded implants (1.4%) with manifestations of peri-implantitis that could be treated successfully and maintained. There were 2 late failures in the present study, both fractures of the implant, one after an observation period of less than 2 years and the other after an observation period of more than 6 years. Retrospectively, one of these failures was not surprising, since an 8-mm-long implant replaced a well-sized premolar with a large occlusal platform. The ratio of crown size to implant length was also unfavorable. Thus, normal loading forces may have been overload, and the weakest link of the system was the implant. The second implant fractured in a patient who was diagnosed with bruxism. In addition to the broken implant, which, in conjunction with a standard-size implant, supported a fixed partial prosthesis in the maxilla, the patient also exhibited a fracture of a natural tooth (a maxillary incisor, endodontically treated) that was not connected to the prosthesis. Although it is more common in the maxilla than in the mandible for loose bone structure to lead to implant failure, in the present cases the weakest link was the implant and not the implant-bone interface in the maxilla. A recent study on implants of various diameters suggested that biomechanical aspects of the bone-implant interface may have a greater impact on stability of the implants than the diameter itself.³¹

A review study came to the conclusion that technical and biomechanical problems were more frequently a reason for implant failure than peri-implant infections.^{32,33} Osseointegrated implants lack a periodontal membrane; they lack an adaptive mechanism to help them cope with loading forces and overload.

Therefore, it was suggested that mechanical complications and fractures may be encountered more frequently with implants than with natural teeth.³⁴

Prosthetic complications could be an indication of misfit and undue loading, which also might result in fractures of the implants or complications with implant components. Therefore prosthetic results also were reported in the present study. The majority of prosthetic restorations were maxillary and mandibular overdentures in combination with a rigid U-shaped bar. These overdentures were supported either exclusively by small-diameter implants or by a combination of small-diameter implants and standard-diameter implants, the latter being less numerous. From the results of the present study it can be concluded that small-diameter ITI implants are adequate for overdenture support, particularly with a connecting bar. Serious prosthetic problems were not frequent, but with removable prostheses, typical maintenance service such as tightening of bar screws, tightening or changing of bar retainers, or treatment for sore spots was needed regularly.^{19,35} With overdentures there are more components and therefore more elements subject to technical problems compared to fixed prostheses. The lowest rate of prosthetic problems was observed with single crowns. Our results for single crowns with screw retention are equivalent to those in a recently published study.¹⁸ It is commonly seen that more service is necessary in the first years after delivery of the final prostheses, and this was also confirmed by the present findings. Altogether, the prosthetic problems appeared to be independent from the use of small-diameter implants. However, considering the single implant fracture, the suggestion that only small incisors be replaced by 3.3-mm ITI implants supporting single crowns should be followed. In the anterior zone, loading forces are reduced. Bending moments and lateral guidance can be controlled by adhering to the occlusal scheme of the natural teeth.

CONCLUSIONS

- The survival rate of small-diameter ITI implants seems to be comparable to that of standard-diameter ITI implants.
- The use of small-diameter implants can be recommended for various indications to avoid expensive and time-consuming local bone augmentation procedures.
- In particular, mandibular overdentures can be successfully supported by two 3.3-mm-diameter implants and appeared to be a predictable treatment modality in this patient population.

- It must to be taken into account that fatigue fracture is a type of late failure that may appear after a long period of function. Guidelines provided by the manufacturer for the use of small-diameter implants should be followed.

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