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A split-mouth comparative study up to 16 years of two screw-shaped titanium implant systems

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Abstract

Introduction: Many studies have dealt with the clinical outcome of oral implants, yet none applied a randomized split-mouth design for a long-term follow-up of similar implant systems.

Aim: To evaluate two oral implant systems with different surface characteristics in a randomized split-mouth design and to radiologically analyse peri-implant bone level and density over an up to 16-year period.

Materials and Methods: The study comprised clinical and radiographic records of 18 partially edentulous patients treated with both implant types randomly placed in either left or right jaw sides. Outcome was evaluated over time.

Results: Clinical and radiographic parameters showed no significant differences over time for both systems. Ten years after implant placement, a significantly increasing peri-implant bone density was noted, while Periotest values were found to be significantly decreasing. Fifteen years after implant loading, mean bone loss was 0.02 mm (range −1.15 to 1.51; SD 0.45) for Astra Tech® implants ($n = 24$) and 0.31 mm (range −0.98 to 2.31; SD 0.69) for Brånemark® implants ($n = 23$).

Conclusions: The study failed to demonstrate significant differences in the outcome of the peri-implant bone for two implant systems with different surface characteristics. The marginal bone level around oral implants changed <0.5 mm after 15 years of loading.

Key words: bone remodelling; implant systems; marginal bone level; osseointegration; split-mouth design

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From the early eighties, one has been able to replace routinely missing teeth by implant-borne restorations, which opened up a new treatment alternative in oral rehabilitation. The osseointegration technique, as first introduced by Brånemark et al. (1969), is nowadays a valid and frequently used treatment modality, accepted by the scientific community, for fully and partially edentulous patients. During the past two decades, a large number of longitudinal studies described this technique for prosthetic anchorage to the jaw bone. The long-term follow-up of implant therapy has shown encouraging results in many studies (Adell et al. 1990, Schmitt & Zarb 1990, Quirynen et al. 1991, Babbush & Shimura 1993, Buser et al. 1997, Heckmann et al. 2004, Rasmusson et al. 2005, Wennström et al. 2005). Nevertheless, implant failure can occur and may be related to a variety of reasons such as surface characteristics, poor bone quality, peri-implantitis, progressive bone loss, implant fracture and other local and systemic factors (Jaffin & Berman 1991, Røynesdal et al. 1998, Berglundh et al. 2002, Alsaadi et al. 2006, 2007, 2008a, b). It remains a matter of debate whether different implant surfaces and configurations, in particular, influence the success of implants.

Gotfredsen & Karlsson (2001) reported a 5-year prospective randomized, controlled multi-centre study, which included 50 partially edentulous patients with 52 fixed partial dental prostheses (FPDPs) placed on 133 Astra Tech® implants (turned *versus* TiOblast). From this study, the authors drew the conclusion that implants had a high survival rate and exhibited only

Conflict of interest and source of funding statement

The authors declare that they have no conflicts of interests.
While the initial 2-year follow-up study was supported (see van Steenberghe et al. 2000), there was no further financial support for this continued follow-up study until 16 years after implant placement.

small amounts of marginal bone loss. Further, no difference in treatment outcome could be found between the different surface textures. Wennström et al. (2004) came to the same conclusion from a study on restorations supported by either rough or turned implants in periodontitis-susceptible patients.

Schincaglia et al. (2007) reported a 12-month spilt-mouth study comparing turned and titanium dioxide (TiO_2)-coated surfaces immediately loaded with FPDPs in the posterior mandibles. The study demonstrated a success rate of 95%. No significant difference in terms of marginal bone level change between turned and TiO_2 implant surface was found. The authors concluded, however, that TiO_2-coated implants showed less change in the peri-implant bone level than turned ones, when placed at posterior sites.

Van de Velde et al. (2009) compared turned Brånemark® implants (Nobel Biocare, Gothenburg, Sweden) and surface-modified Astra Tech® implants with or without a micro-threaded neck (TiOblast®, Astra Tech, Mölndal, Sweden) that were placed in fully edentulous mandibles and immediately loaded. Implant design and surface did not seem to affect implant survival in the completely edentulous mandible. Yet, these factors seemed to influence bone remodelling during the first year of function, with significantly better results with surface-modified Astra-Tech® 1 year after implant placement.

Åstrand et al. (2004) and Renvert et al. (2008) compared the Astra-Tech TiOblast® implant (moderately rough surface, Astra Tech®) with the Brånemark Mark II® implant (turned surface, Brånemark® System, Nobel Biocare) for the treatment of 66 fully edentulous patients. The marginal bone level was determined radiographically immediately following implant installation, at abutment connection, at delivery of the prostheses and at 1-, 3-, 5- and 7-year follow-up examinations. The authors reported that the survival rate was high and that the mean marginal bone level change for the two types of implants was small and did not differ between systems.

The marginal bone-level change that occurred for Astra TechTiOblast® implants with a moderately rough surface and for Brånemark Mark II® implants with a turned surface was also evaluated by van Steenberghe et al. (2000). The clinical trial included 18 partially edentulous patients who were treated with both implant systems in a split-mouth design. No significant difference between the two systems could be observed during the 2 years of observation, regarding probing pocket depth and change in the marginal bone level. The present study reports on the clinical and radiological status of peri-implant tissues up to 16 years after implant placement, of the same material as that reported by van Steenberghe et al. (2000).

Another feature that, besides marginal bone level, is considered to be important for long-term success is peri-implant jaw bone density. Attempts have been made to assess alveolar bone density. Digital subtraction radiography and computer-assisted densitometric image analysis have been established as sensitive techniques for the assessment of periodontal and peri-implant tissue changes (for review see Brägger 1994). In 1980, the concept of progressive loading arose based on empirical information supporting the idea that gradual loading or stimulation of bone tissue would allow bone to mature and to densify and to improve in quality (Misch 1999). Skalak (1983) and Roberts et al. (1987) reported that an increased density equates to greater strength and thus the ability to tolerate greater forces and permit successful implant-supported prosthetic treatment. Brägger et al. (1996) and Appleton et al. (2005) demonstrated an increase in bone density over the period of their 1- and 2-year follow-up studies on oral implants.

Within the present prospective study, the fate of the peri-implant hard and soft tissues of two comparable implant systems, but with a different surface topography, was compared using a randomized split-mouth design. The subgoals included an assessment of the surrogate parameters for implant outcome, namely clinical probing depths, peri-implant bone density and marginal bone level around osseointegrated oral titanium implants, and to track changes over time for both Astra TechTiOblast® and Brånemark Mark II® implants. Besides, an assessment of the prosthetic outcome was also included.

Material and Methods

Patients

The subject sample was recruited from the general Caucasian patient population consulting because of bilateral tooth loss related to periodontal breakdown in the posterior area (Kennedy Class 1), between November 1993 and December 1994 at the Department of Periodontology and the Department of Prosthetic Dentistry (University Hospitals, UZ KU Leuven, Leuven, Belgium) (van Steenberghe et al. 2000). A prospective split-mouth design was applied and implants were randomly placed in the left or the right side of upper or lower jaws. Potential patients were carefully screened according to a number of inclusion and exclusion criteria. In all subjects recruited, the periodontal status was treated and stabilized before implant placement. A further annual maintenance therapy allowed for a stable periodontal condition throughout the follow-up period. It consisted of at least one visit at the department with professional cleaning of the oral cavity and instructions for home care. If needed, the patients' dentist participated in maintaining a proper periodontal health.

A total of six males and 12 females were included, with a mean age (range) of 59.7 (44–75) and 50.6 years (32–63), respectively. In these 18 consecutive patients (19 jaws), a total of 95 implants (50 Astra Tech® and 45 Brånemark® System) were randomly distributed.

Ethical considerations

The study was performed in accordance with the principles of the Declaration of Helsinki and agreed by the ethical committee of the University Hospitals of KU Leuven. Patient consent was obtained after thorough information of the treatment was provided.

Implants

The Astra Tech® (A) (Astra Tech) implants were screw-shaped self-tapping TiO_2-blasted implants made of commercially pure titanium. The Brånemark® System implants (B) (Nobel Biocare) were screw-shaped self-tapping Mark II implants made of commercially pure titanium, with a turned surface.

Both companies provided their implants in sterile glass ampoules, the Astra Tech® implants in ultra-sterile water, the Brånemark® implants in vacuum. For the Brånemark® system, the following implant lengths were used: 10, 13, 15 and 18 mm. For Astra Tech®, the implant lengths were 8, 9, 11, 13, 15 and 19 mm. The A and B implants had a diameter of 4 and 3.75 mm, respectively (Table 1). The surgery was performed by an experienced periodontologist familiarized with both implant systems following the guidelines as defined by Brånemark et al. (1985). This means a two-stage procedure where abutments are placed 5 months after implant insertion. The prosthetic superstructures were all provided by one prosthodontist in training supervised by one staff member at the Department of Prosthetic Dentistry.

All FPDPs were ceramo-metal ones, with porcelain occlusal surfaces and all were screw-retained at abutment level. The set screw access holes were sealed with a composite. An equal contact between all teeth in maximal occlusion was aimed for. During excursions, canine as well as group guidance were allowed depending on the tooth positions in the arch. All tooth units in the FPDPs were cast as one unit. If passive fit was absent during framework try-in, the latter was sectioned, indexed and soldered again. Open embrasures for proximal cleaning by inter-dental brushes were considered as the standard hygienic design.

Clinical assessments

After implant placement, annual recalls were organized for periodontal maintenance and full prosthetic check-up. The following periodontal parameters were recorded:

- The sulcus bleeding index (Mühlemann & Son 1971) at buccal, lingual, mesial and distal sites.
- The presence of plaque (yes/no) scored by running a periodontal probe parallel to the abutment surfaces at the same sites.
- The probing pocket depth at the same sites.
- The Periotest values (PTV) (Siemens AG, Bensheim, Germany) were recorded at 1 and 10 years after implant installation. During follow-up, all periodontal parameters were measured by one and the same periodontologist (R.J.). Besides, the yearly prosthetic evaluation included a check of occlusion and articulation. Small occlusal grinding was adjusted if necessary. Furthermore, other complications were also noticed, such as small porcelain chipping that could be polished, retightening or replacement of one or more set screws, composite renewal of the set screw access holes, etc. In addition, stability of the FPDPs was clinically checked by a senior staff member of the Department of Prosthetic Dentistry by tearing the FPDP between thumb and index finger, while pressing to perceive movement. Finally, the outcome of the FPDPs was recorded. A prosthesis was considered a failure, if for any reason renewal was necessary (e.g. due to implant loss, fracture of the FPDP need for full porcelain reveneering).

Radiographic examinations

Conventional intra-oral radiographs were taken using the paralleling technique, with position holders and a long-cone radiographic unit (Gendex GX-1000®, General Electrics, Fairfield, CT, USA) for the first 10 years of follow-up. All conventional radiographs were digitized with a transparency scanner (Snapscan 1236®, AGFA, Mortsel, Belgium) at 800 dpi, as such that these could be used for marginal bone level and density measurements. Then, digital intra-oral radiographs were made following the paralleling technique using the Digora® photostimulable phosphor plates and the MinRay® intra-oral radiographic system (Soredex, Tuusula, Finland). The radiographic examination was repeated annually to assess changes of the marginal bone level.

Analysis of the change in the marginal bone level

The mesial and distal marginal bone-level change over time was assessed by comparing intra-oral radiographs taken at FPDP installation and those up to 15 years later. Marginal bone level was assessed at both the mesial and distal surface of each implant. In first, the reference level that started from the abutment connection point of the assessed implant was indicated (Fig. 1). Then, the bone level was measured from the reference level to the first bone-to-implant contact level using Adobe® Photoshop software (Adobe System Incorporated, San Jose, CA, USA). The measurements were initially made in pixel format. Linear measurements (mm) could be performed after calibration of the images according to the respective implant lengths (Fig. 2). Bone-level measures were also performed at the distal aspect of the neighbouring tooth, if visualized on the same radiograph.

Analysis of the changes in bone density

Radiological bone density was evaluated at both mesial and distal sides of the implants by measuring the

Table 1. Implant length of Astra Tech® (A) and Brånemark® (B) implants

Implant length (mm)	A (∅ 4 mm) (*n*)			B (∅ 3.75 mm) (*n*)		
	beginning of the study	11 years after implant placement	16 years after implant placement	beginning of the study	11 years after implant placement	16 years after implant placement
7				1	1	1
8	10	6	6			
9	8	4	4			
10				17	10	11
11	10	6	5			
13	8	4	2	15	9	7
15	12	7	5	10	4	2
18				2	2	2
19	2	2	2			
Total number of implants	50	29	24	45	28	23

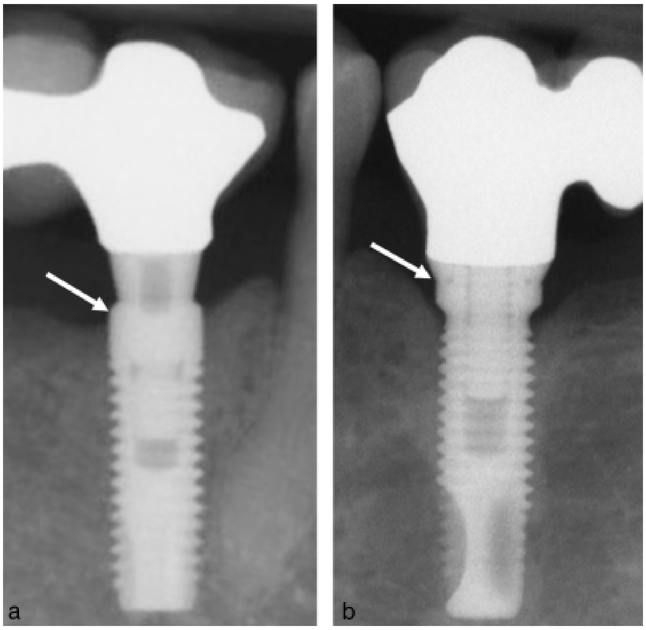

Fig. 1. The abutment connection point (arrow) was used as the reference point for marginal bone level measurement for both Astra Tech® (A) and Brånemark® implants (B).

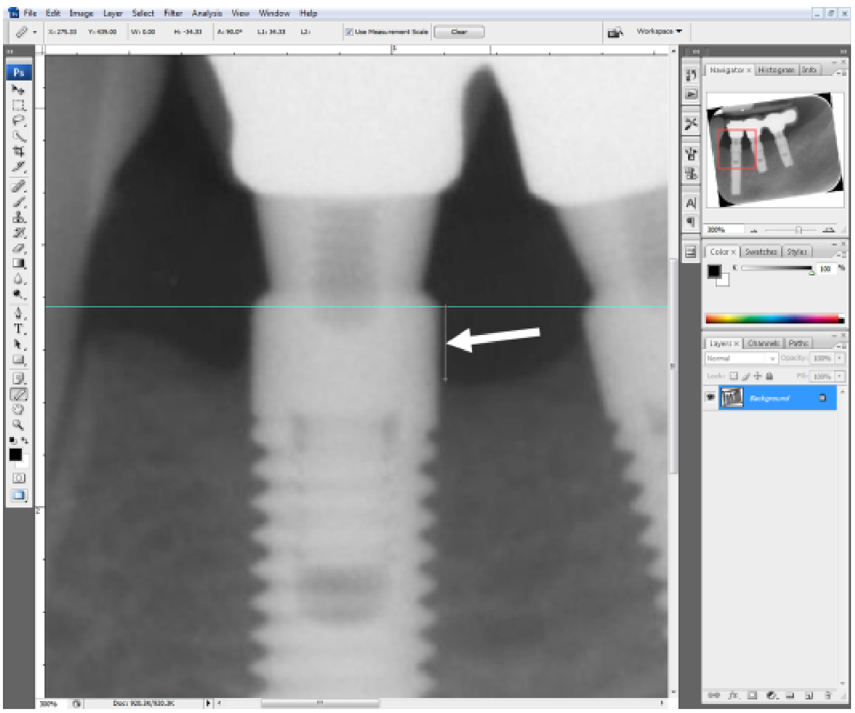

Fig. 2. The measurement of the marginal bone level was carried out using the Adobe® Photoshop software. The white arrow is pointing at the ruler tool measuring the distance from the reference level to the first bone-to-implant contact.

grey values using dedicated software (Densito®). Densito® is a densitometric software program, which is developed for radiological grey-level analysis of oral radiographs (Nackaerts et al. 2007). It uses the background of the radiograph as a reference, on the basis of which the mean bone density can be determined (Fig. 3).

Statistical analysis

All data were gathered and statistically analysed by means of Statistica® for Windows software version 5.1 (Statsoft, Tulsa, OK, USA) with the *p*-level set at 0.01. Descriptive statistics were performed by determining mean values, standard deviations (SD) and cumulative frequencies. Intra- and inter-individual variations were based on repeated measures of two independent observers and calculated by means of the coefficient of variation (CV%), which should be lower than 4% for good agreement. Clinical and radiographic parameters were subjected to analyses on patient level as well as implant level. Linear regression analyses were used to establish the changes in marginal bone level and pocket probing depth over time. Subsequently, Wilcoxon matched pairs test were carried out to establish differences between both implant systems on both patient and implant level.

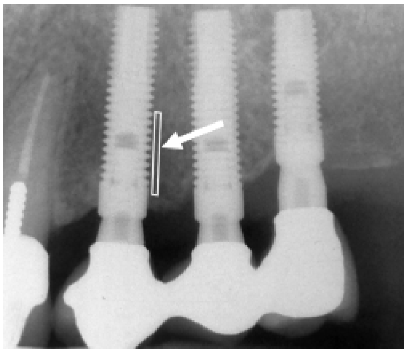

Fig. 3. The bone density measurement was performed on the Densito® software. The white arrow shows a small area adjacent to the implant selected for grey value evaluation.

Results

During the follow-up period, 6/18 patients dropped out. The reasons were one patient deceased, three patients moved and could not be traced any longer, while two stopped coming for the recall visits, because of limited mobility by increasing age. Furthermore, for a certain number of patients, radiographs were taken with some 2- to 5-year time intervals, yet they still came on recall visits for periodontal and prosthetic set-up. This may explain some variability in the figures in Tables 2 and 3.

Implant outcome

Similar bone quantities and bone qualities were found for both implant systems. When implant lengths are considered (Table 1), it can be con-

Table 2. The mean marginal bone loss of Astra Tech® (A) and Brånemark® (B) implants and the number of implants, which were measured in both systems

Year after implant placement	A in mm (SD, range)	A (n)	B in mm (SD, range)	B (n)
6	0.02 (0.32, −0.97* to 1.43)	50	−0.05 (0.34, −1.07 to 0.88)	45
9	0.13 (0.70, −0.72 to 2.74)	37	0.00 (0.37, −1.07 to 0.83)	34
11	0.16 (0.60, −0.86 to 2.46)	29	0.01 (0.40, −1.07 to 0.72)	28
12	0.27 (0.84, −0.71 to 4.34)†	21	0.05 (0.45, −1.07 to 0.93)	20
13	0.19 (0.73, −0.75 to 4.27)†	29	0.05 (0.46, −1.07 to 1.01)	27
14	0.29 (0.86, −0.56 to 4.86)†	29	0.05 (0.44, −1.07 to 0.99)	27
15	0.50 (1.23, −0.57 to 4.88)†	11	0.32 (0.42, −0.31 to 0.97)	9
16	0.02 (0.45, −1.15 to 1.51)	24	0.31 (0.69, −0.98 to 2.31)	23

*Negative values (−) mean that the bone level on the measured year was situated more coronally compared with baseline.
†The increase in maximal bone loss 12–15 years after implant placement could be explained by the peri-implant bone level changes in one patient only. This patient could not yet be recalled for the 16-year follow-up, explaining the discrepancy in bone loss range between 15 and 16 years after placement of A implants.

Table 3. The proportion of loss of Astra Tech® (A) and Brånemark® (B) implants with marginal bone loss ⩾0.50 mm during 16 years of follow-up

Year after implant placement*	Patients (n)	A (n)	A with marginal bone loss ⩾0.50 mm (n)	Proportion of A with marginal bone loss ⩾0.50 mm	B (n)	B with marginal bone loss ⩾0.50 mm (n)	Proportion of B with marginal bone loss ⩾0.50 mm
6	18	50	6	3/25	45	3	1/15
9	14	37	10	10/37	34	4	2/17
11	12	29	7	7/29	28	4	1/7
12	8	21	5	5/21	20	5	1/4
13	11	29	5	5/29	27	8	8/27
14	11	29	10	10/29	27	7	7/27
15	4*	11	4	4/11	9	6	2/3
16	9*	24	5	5/24	23	9	9/23

*On these recall visits, intra-oral radiographs could not be taken in all patients.

cluded that especially in the Astra® (A) group, many short implants were used (eight of 9 mm, 10 of 8 mm). Of the 45 B implants placed, one was lost during the initial healing period (before abutment installation) as a consequence of non-osseointegration, while none of the A implants were lost throughout the observation period. Forty-four implants of the B group were included. A cumulative success rate of 97.7% for Brånemark® and 100% for Astra Tech® implants after 16 years was found. With regard to prosthetic complications of the FPDP under investigation, the following could be noted. None of these failed during the 16-year follow-up study. Complications such as refilling of the set screw access holes were most frequently recorded (half of the cases). At the yearly recall, the prosthesis stability was manually checked. In 8% of the cases, some doubt arose about set screws loosening, the latter were retightened. Porcelain chipping that could be polished occurred in very few cases only (3%).

Clinical findings

Up till 15 years after loading the implants, no further loss of implants occurred. During the entire time frame, three patients lost five teeth, because of furcation problems and subterminal periodontal breakdown ($n = 3$) or restored tooth fracture ($n = 2$). The number of remaining teeth in the same jaw ranged from three to 12, with on average six in the upper jaw and eight in the lower jaw.

Initial probing depths were not significantly different for both implant systems (mean 2.6 mm, SD 0.5 for A, mean 2.5 mm, SD 0.4 for B). Fairly stable and non-significantly different probing depths were noted over time for both implants systems, on subject as well as implant level (simple regression analysis, $p > 0.1$). Subsequently, Wilcoxon matched pairs test could not detect any differences between both implant systems ($p > 0.5$). Changes in periodontal probing depths in the same jaw were also not significant (simple regression analysis, $p > 0.1$). Overall, pocket probing depths were <4 mm around implants and adjacent teeth. Pockets of 4 mm or more were noted on <15% of all measured sites around teeth and implants. Also, bleeding on probing occurred in less than a fifth of all measures. Furthermore, most patients maintained a good oral hygiene during the entire follow-up period.

The mean PTV of all implants significantly decreased on average from (−2.65) at year 1 to (−4.25) 10 years after implants installation (Fig. 4).

Radiographic findings

The present study shows no significant differences in bone loss till 16 years after implant installation both within and between the two implant systems.

On average, 16 years after implant placement, the mean marginal bone loss for the A system was 0.02 mm (range −1.15 to 1.51; SD 0.45), while for the B system it was 0.31 mm (range −0.98 to 2.31; SD 0.69) (Tables 2 and 3 and Figs 5–7). Marginal bone level changes were not significantly different over time for both implant systems (simple regression analysis, $p > 0.1$). Further analysis using Wilcoxon matched pairs test revealed no significant differences between both implant systems ($p > 0.5$). For the distal site of the adjacent tooth, the registered marginal bone loss during the follow-up period was on average 0.5 mm (SD 0.7; range 0–2.5 mm). This was also a remarkably low number considering the average age at final recall and the length of the follow-up period. Results were confirmed on a

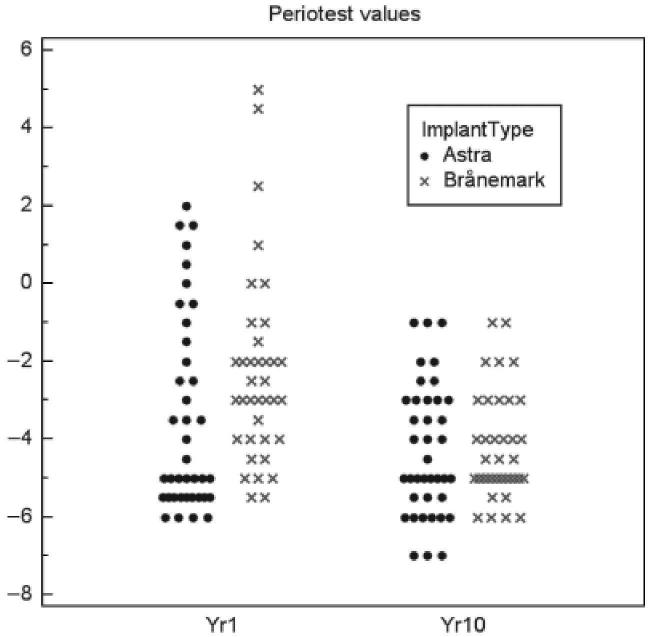

Fig. 4. Mean Periotest value (PTV) significantly decreasing from 1 to 10 years after implant installation. The mean PTV of Astra® at year 1 is −3.2 and at year 10 is −4.3. For Brånemark®, the mean PTV at year 1 is −2.1 and −4.2 at year 10.

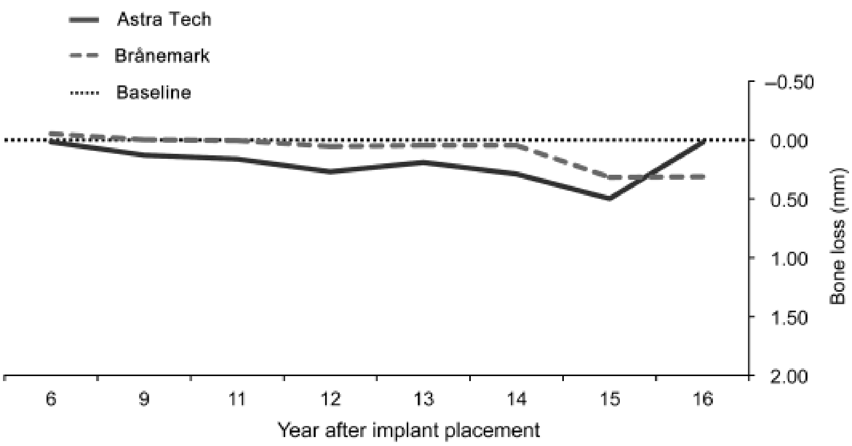

Fig. 5. The average bone level change from baseline around Astra Tech® and Brånemark® implants up till 16 years after implant placement. There is no significant difference in marginal bone loss between the two systems and the marginal bone loss remained below 0.5 mm.

patient level, as no significant bone loss in time could be reported (simple regression analysis, $p > 0.05$), with a mean marginal bone loss 15 years after loading of 0.03 mm (range −0.46 to +0.43; SD 0.27) for the jaw site with A system implants *versus* 0.02 mm (range −0.42 to +0.40; SD 0.26) for the jaw site with B system implants. This difference was not significant (Wilcoxon matched pairs test, $p > 0.5$).

With regard to the bone density measurements, both systems showed a significant increase 10 years after implant placement. The mean bone density had increased 8.2% for (A) and 7.7% for (B) (Table 4).

Inter- and intra-observer variabilities of the measurements of bone loss and mean bone density were expressed with the coefficient of variation (CV%), which was below 4% for all measurements, indicating good intra- and inter-observer agreement (Table 5).

Discussion

The present study is a split-mouth study evaluating two implant systems (Astra® and Brånemark®) up to 16 years after implant placement, the continuation of a previous 2-year follow-up study, carried out by the same research group (van Steenberghe et al. 2000). In that report, there was neither significant difference in the clinical findings nor in the change of marginal bone level after 1 and 2 years between both implant systems. This could be confirmed by the present follow-up study, up to 16 years after implant placement. The influence of factors such as implant length, abutment length, jaw of treatment and type of prosthetic material on peri-implant bone loss is well known (Jemt & Lekholm 1993, Røynesdal et al. 1998). However, in this randomized controlled split-mouth design, such factors might have been washed out when comparing both systems. When focusing on the radiologic differences, no significant changes were found between both systems. Yet, it should be said that after 16 years of implant placement, the bone level from the reference for the Astra Tech® system [mean (SD) = 0.40 (0.59) mm] was located on average 1.39 mm more coronally than for the Brånemark® system [(mean (SD) = 1.79 (1.06) mm]. This can be explained by differences in implant design. In a recent study, Van de Velde et al. (2009) found significant differences in bone loss between both implant systems during the first remodelling year; yet, the present study did not reveal such differences during later years.

Because of the initial loss of one of the implants in the Brånemark® group, the present study showed a small difference in cumulative success rate between both systems, yet without any statistical significance. Although both implants are made of commercially pure titanium, are screw-shaped and installed in a two-stage procedure, their surface characteristics are different. According to the EAO Consensus statement (Wennerberg & Albrektsson 2009), the surface of the Astra® implants is moderately roughened by TiO_2 blasting, reaching S_a values of approximately 1.2 μm, while the surface of Brånemark® system

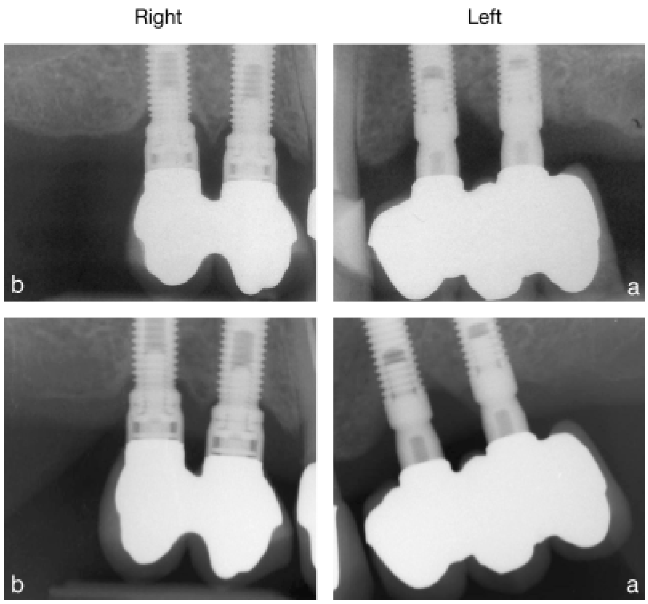

Fig. 6. Radiographs of implant systems (A) and (B) of the same patient at baseline (upper row) and after 15 years of implant placement (lower row).

Fig. 7. Clinical photographs from the same patient after 15 years of implant placement.

Table 4. The average bone density change compared with baseline (%) around Astra Tech® (A) and Brånemark® (B) implant systems before and 10 years after implant placement

Year after implant placement	A (%)	B (%)
1	1.5	1.1
2	3.6	2.7
3	5.4	3.2
4	7.2	4.3
5	8.9	5.3
6	11.1	6.4
7	12.5	7.5
8	13.0	8.5
9	10.3	9.6

Table 5. Inter- and intra-observer variabilities of the measurements of marginal bone loss and bone mean bone density expressed with the coefficient of variation (CV%)

	Bone loss	Bone density
Intra	1.07	1.06
Inter	1.21	1.14

implants is classified as minimally rough, having horizontal grooves due to the turning procedure, with S_a values of approximately 0.7 μm.

In other long-term studies on oral implants, only 6% losses for 7 mm Brånemark® implants were reported in a prospective multi-centre study with 5 years of observation (Lekholm et al. 1994). In a long-term evaluation of non-submerged ITI® implants, Buser et al. (1997) reported that 12-mm-long implants demonstrated slightly better results than 8 mm implants, although the observed differences were not statistically significant. A 5-year follow-up study of Astra Tech® implants reported a marginal bone loss of 0.26 mm (SD 0.53) (Arvidson et al. 1998). A 10-year clinical and radiographical study reported by Heckmann et al. (2004) showed good long-term bone height results. The authors explained this by the fact that all implants were placed in the inter-foraminal area where bone quality is favourable and these implants were placed somewhat deeper than recommended in the original protocol. Another 10-year follow-up study of TiOblast® implant (Astra Tech) by Rasmusson et al. (2005) reported a cumulative survival rate of 96.9%. The mean marginal bone loss was reported at 0.15 mm/year. In the 5-year single-tooth implant restorations study using Astra Tech® self-tapping implants by Wennström et al. (2005), the mean total bone level change over the 5-year interval was −0.14 mm (SD 1.04) on subject level and −0.11 mm (SD 1.00) on the implant level. The frequency of implants with a 5-year bone loss of ⩾1 mm was 13%. Approximately 50% of the implants showed no bone loss.

In the present study, analysis of the results of the changes in peri-implant bone density did not reveal any statistically significant differences between two implant systems. However, an increasing trend in bone density was observed for both implant systems. This observation is in accordance with results of previous studies showing an increased density at the peri-implant junction of screw-type implants (Brägger et al. 1996, Barone et al. 2003, Appleton et al. 2005). The increased peri-implant bone density change could be attributed to positive loading aspects (Roberts 1988). All bone density measurements were performed on the scanned conventional radiographs from 1 to 10 years after implant placement. After this period, radiographs were digitally acquired using a phosphor plate system. As a result, the follow-up radiographs were taken in digital format, which explains why the bone density measurements were stopped as the results would be no longer reliable for further comparisons. Initially, PTV values could only be measured after implant placement and 10 years later. Indeed, annual removal of the FPDPs is not advisable for such PTV registration. Apart from a significant increase in implant PTV, peri-implant bone density was also found to be significantly increasing. Both factors have been related previously (Tricio et al. 1995).

Apart from the radiographic parameters, clinical parameters were also measured and reported to remain stable during the follow-up period. From previous studies, there seems to be no significant effect of implant type and surface roughness on the peri-implant microflora (Renvert et al. 2008). Furthermore, for well-maintained implants, microbiota seem to resemble those associated with healthy dental conditions (Quirynen & Listgarten 1990).

These statements are in agreement with the present findings, in which hardly any changes in periodontal and peri-implant pocket probing depths were noted over the follow-up period. Few patients only suffered bad oral hygiene and as a consequence some deepened pockets around teeth and implants. It should be stated that considering the age of the patient sample at implant placement and the length of the follow-up period, it is not surprising that some patients suffered from less refined handedness over the years with, as a consequence, deterioration of the oral hygiene and deepened pocket probing depths. Yet, the overall group showed a remarkable stability in clinical as well as radiographical periodontal and peri-implant measures, corresponding to the literature on a longitudinal comparison of Astra and Brånemark implants (van Steenberghe et al. 2000, Renvert et al. 2008, Eliasson et al. 2009, Laurell & Lundgren 2009, Van de Velde et al. 2009). Except during the first year of remodelling (Van de Velde et al. 2009), no clinical significant differences could be found between both implant systems, up till 15 years after implant loading.

Contrary to the rather disappointing prosthetic outcome (61%) reported in a systematic review (Pjetursson et al. 2007), the prosthesis stability of the present ones remained excellent up to 15 years after loading. This might be due to the yearly recall program in which small corrections could be anticipated such as, e.g. screw loosening, and points to the importance of regularly recall to lower mechanical problems in implant-supported restorations.

The result of the present randomized controlled follow-up study demonstrated that marginal bone loss during the first year of function, as well as annually thereafter, was small and did not significantly vary between both implant types. This observation is in agreement with previous findings, including the use of Astra Tech® and Brånemark® implants (Gotfredsen et al. 1992, van Steenberghe et al. 2000, Åstrand et al. 2004, Wennström et al. 2004, Schincaglia et al. 2007). The bone density at the implant–bone interface was similar for both implant types and improved in the years following implant placement. Larger study samples are needed to verify the small differences between treatment concepts.

Conclusions

The present randomized split-mouth study demonstrated that there are no statistically significant changes in clinical pocket probing depth or radiographic marginal bone level around osseointegrated oral implants over time. The mean radiographic bone loss after the first year was small and was <0.5 mm for both implant systems up to 15 years after prosthetic loading. Surface characteristics of the two implant systems did not significantly alter the outcome of the peri-implant bone. The long-term data obtained through this study add evidence to the choice of treatment for the posterior edentulous jaw by means of implant-supported prostheses.

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Clinical Relevance

Scientific rationale for the study: Previous studies have compared bone loss around different implant systems in shorter follow-up periods. The present study is a randomized split-mouth study over a follow-up period up to 16 years.

Principal findings: Overall radiological observations demonstrated that the vast majority of osseointegrated implants showed <0.5 mm marginal bone loss up to 15 years after loading. This study did not reveal significant differences in marginal bone loss around two implants with different surface characteristics.

Practical implications: The long-term data obtained through this randomized split-mouth prospective study support the reliability of posterior edentulous jaw rehabilitation by means of implant-supported prostheses.