

Astra Tech Implant System®

Scientific Summary



Why we do what we do?

Our vision of a world where everyone eats, speaks and smiles with confidence permeates and inspires everything we do. We believe in an open-minded, passionate and genuine approach to the products and services we provide and in the way we do business.

—Because it matters.

Comprehensive solutions for all phases of implant dentistry



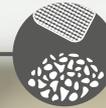
Professional and practice development

STEPPS™



Digital planning

Simplant®



Regenerative solutions

Symbios®



Implants

Ankylos®
Astra Tech
Implant System®
Xive®



Restorations

Atlantis®



Welcome

Are you looking for information about the outstanding results on maintained marginal bone levels and long-term clinical results when using Astra Tech Implant System? Or do you want to explore different solutions for implant placement in limited spaces and sloped ridges? You will find the answers here, and much more.

This Scientific Summary provides a synopsis of the published key research findings supporting the Astra Tech Implant System. Each summary is based on facts retrieved from the original research article.

The Scientific Summary focuses on the following topics:

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Summary by Dentsply Sirona Implants of facts retrieved from the original articles.

For a more comprehensive view of the documentation and research on our products, please refer to our Scientific Reviews. The Scientific Reviews are available for download at www.dentsplyimplants.com/science

To improve readability for our customers, Dentsply Sirona does not use ® or ™ in body copy. However, Dentsply Sirona Implants does not waive any right to the trademark and nothing herein shall be interpreted to the contrary.

A continuous evolution

Our groundbreaking innovations are the result of knowledge and understanding of the biological and clinical processes involved in dental implant therapy.

1985

Clinical use of the first generation of implants with Conical Seal Design and Connective Contour is initiated in a study at the Karolinska University Hospital in Stockholm, Sweden.

1989

The idea of blasting the implant surface with titanium dioxide particles to increase bone growth and osseointegration is presented and the TiOblast surface is born.

2007

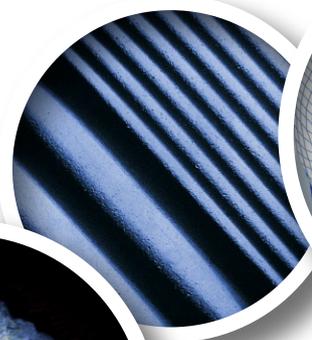
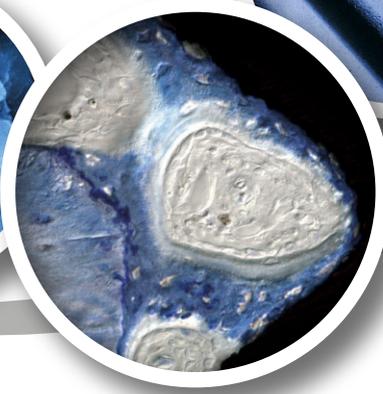
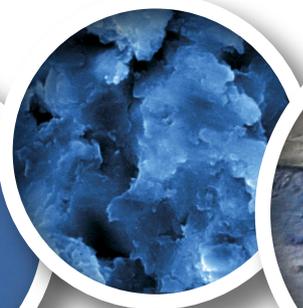
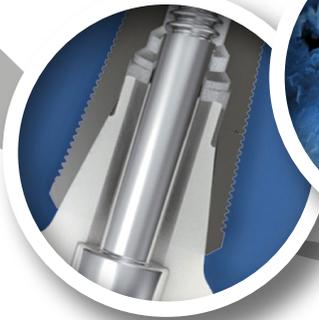
Atlantis patient-specific, CAD/CAM abutments introduced for the Astra Tech Implant System.

1990

The concept of a fluoride modified implant surface to help speed up the osseointegration process is conceived by a team at the University of Oslo, Norway. As a result, the first experimental pre-clinical studies on OsseoSpeed are initiated in 1993. In 2000, the first patient receives an OsseoSpeed implant at the University of Oslo. The first and only chemically modified implant surface - OsseoSpeed - is launched in 2004 at EAO in Paris.

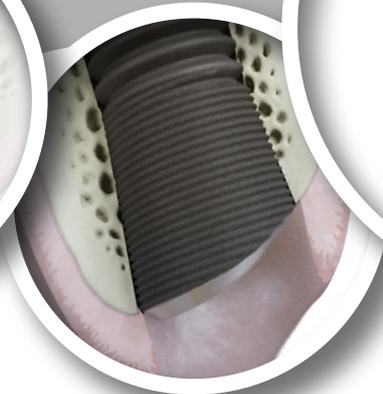
1991

The idea of minute threads on the implant neck to ensure positive biomechanical bone stimulation and maintained marginal bone level is born - MicroThread. After comparing 840 threads of different shapes and sizes, the optimal profile for positive stress distribution is identified.



2010

OsseoSpeed TX is launched. TX stands for tapered apex and it is introduced on the complete implant assortment.



2011

OsseoSpeed TX Profile, the unique, patented implant that is anatomically designed for sloped ridges, is introduced.

2014

Introduction of the Astra Tech Implant System EV. The design philosophy of the implant system is based on the natural dentition utilizing a site-specific, crown-down approach.

Featuring a unique interface* with one-position-only placement for Atlantis patient-specific, CAD/CAM abutments.

*Patent pending



Clinical documentation on Astra Tech Implant System®

The Astra Tech Implant System has four key features; the design of the implant-abutment connection, Conical Seal Design, the minute threads on the implant neck, MicroThread, the unique contour that is created when you connect the abutment to the implant, Connective Contour, and the OsseoSpeed surface.

The OsseoSpeed surface was launched in 2004 and is a follower and a further development of the moderately rough titanium surface, TiOblast, which has among the longest clinical prospective follow-up period reported in the dental implant literature.

The OsseoSpeed implant has been documented in several prospective clinical studies with a minimum of 1 year of follow-up. Results show that the implant can be safely used in a variety of indications in the maxilla and mandible, with a survival rate ranging from 94.5 to 100%. The same good results are reported for immediate loading protocols in the atrophic maxilla, in sinus lifted/grafted posterior sites and after immediate

installation in extraction sockets. Moreover, several studies have reported on good esthetics and high patient satisfaction.

Very small changes in Implant Stability Quotient values have been recorded for OsseoSpeed implants during the early healing, which is interpreted as a continuous gain in osseointegration and stability. Prospective clinical studies report on very small mean marginal bone level changes around OsseoSpeed implants after 1 year (range +0.06 - 0.54 mm), 2 years (range 0.11 - 0.6 mm), 3 years (range +1.6 - 0.88 mm) and 5 years (range 0.1 - 0.3 mm) in function. In fact, the majority of studies report a mean marginal bone loss of 0.3 mm or less after 1, 2, 3 and 5 years of function.

For a complete list of references supporting the Scientific Review "Clinical documentation on Astra Tech Implant System", please refer to www.dentsplyimplants.com/science

Astra Tech Implant System BioManagement Complex[®]

The unique combination of interdependent features of the Astra Tech Implant System BioManagement Complex ensures reliable, predictable and esthetic results both in the short and long term.



OsseoSpeed[®] - more bone more rapidly

A chemically modified titanium surface with a unique nanoscale topography that stimulates early bone healing and speeds up the bone healing process.

MicroThread[®] - biomechanical bone stimulation

Minute threads on implant neck that offer optimal load distribution and stress values.

Conical Seal Design[™] - a strong and stable fit

A conical connection that seals off the interior of the implant from the surrounding tissue, minimizing micromovements and microleakage.

Connective Contour[™] - increased soft tissue contact zone and volume

The unique contour that is created when you connect the abutment to the implant.



Solutions for limited spaces and sloped ridges

The possibility of placing implants can sometimes be hampered due to anatomical limitations, e.g. the vertical bone height is reduced or the horizontal space is narrow. By using short or narrow implants, the need for bone augmentation and orthodontic treatment can be avoided. Moreover, the bone remodeling pattern after tooth extraction often leads to a sloped bone crest, and placement of regular implants might be unfavorable from a long-term, esthetical point of view. In this section, clinical results for the Astra Tech Implant System placed in limited spaces and sloped ridges are presented.

Summarized articles:

Implants of 6 mm vs. 11 mm lengths in the posterior maxilla and mandible: a 1-year multicenter randomized controlled trial	10
Clinical and radiographic evaluation of early loaded narrow-diameter implants: 3 years follow-up	11
Soft and hard tissue alterations around implants placed in an alveolar ridge with a sloped configuration	12
Randomized controlled multicentre study comparing short dental implants (6 mm) versus longer dental implants (11-15 mm) in combination with sinus floor elevation procedures. Part 1: Demographics and patient-reported outcomes at 1 year of loading	13

Implants of 6 mm vs. 11 mm lengths in the posterior maxilla and mandible: a 1-year multicenter randomized controlled trial

Authors: Gulje F, Abrahamsson I, Chen S, et al.

Published in: Clin Oral Implants Res 2013;24(12):1325-31.

Aim

It has been hypothesized that short implants poses as an alternative to augmentation procedures and longer implants in situations with limited bone height. The purpose of this randomized, controlled clinical investigation was to investigate and compare the clinical outcome of 6 mm versus 11 mm long implants placed in the posterior area.

Materials and Methods

In total, 95 patients were included in the study. To allow for randomized allocation of implant lengths, 6 mm or 11 mm, all patients needed to have a bone height sufficient to receive an 11 mm implant. All implants were OsseoSpeed implants, Ø4mm (Astra Tech Implant System, Dentsply Sirona Implants) and were placed using a 1-stage surgical technique. Loading took place within 48 days, restoring the implants with screw-retained 20° UniAbutments (Dentsply Sirona Implants) and a splinted fixed prosthesis. Follow-up visits were scheduled at time of loading, 1 month, 6 months and at 1 year. Plaque occurrence, probing depths, bleeding on probing, peri-implant bone changes, crown height as well as any adverse events were recorded during the study period.

Results

In total, 107 implants of 6 mm length were inserted in 49 patients, whereas 46 patients received 101 implants with a length of 11 mm. One year survival rates for 6 mm and 11 mm implants were 97% and 99% respectively. Mean marginal bone gain was recorded for both the 6 mm and the 11 mm group between time of loading and the 1 year follow-up, +0.06 mm and +0.02 mm respectively, Table 1. There was a significant

difference in crown height between the 2 groups, with an average of 11.0 mm for the 6 mm implants and 10.2 mm for the 11 mm implants.

There were no differences in bleeding on probing, probing depths, or presence of plaque between groups.

	Follow-up visit (months)		
	0 (loading)	6	12
Mean marginal bone levels (mm)			
6-mm implants	0.28	0.24	0.20
11-mm implants	0.46	0.45	0.41

Table 1. Recordings of mean marginal bone levels (mm) over time.

Adverse events were: 6 abutment screw loosening, 4 loosened healing caps, 2 fractured provisional prosthesis and 3 loosened definite fixed partial dentures.

Discussion and Conclusion

This 1 year prospective, randomized clinical study indicates that treatment with 6 mm long implants is as favorable as when treating patients with 11 mm long implants in the posterior region when there is a sufficient bone height. Whether short implants may be a predictable treatment option compared to bone augmentation and longer implants in areas with limited bone height remains to be investigated in future clinical trials.

Clinical and radiographic evaluation of early loaded narrow-diameter implants: 3 years follow-up

Authors: Maiorana C, King P, Quaes S, et al.

Published in: Clin Oral Implants Res 2015;26(1):77-82.

Aim

The aim of this prospective clinical study was to evaluate the clinical outcome of OsseoSpeed narrow (\varnothing 3 mm) implants placed in the upper lateral and lower incisal positions, when utilizing a one-stage surgical procedure applying an early loading protocol.

Material and Methods

This prospective, multicenter study allowed patients for inclusion if they were missing an upper lateral or lower incisor, provided the neighboring teeth were healthy and in occlusion.

OsseoSpeed TX 3.0S implants (Dentsply Sirona Implants) were placed according to a one-stage protocol. Following 6–10 weeks of healing, the healing abutments were changed to individually modified TiDesign abutments and metal-ceramic or all-ceramic single crowns were permanently cemented. Probing pocket depth (PPD), bleeding on probing (BoP), gingival zenith score (i.e. distance from mid incisal edge to buccal gingiva) as well as intra-oral radiographs were evaluated at time for implant placement, crown cementation, as well as after 6, 12 and 36 months of function.

Marginal bone level changes were analyzed by an independent radiologist, measuring mesial and distal distances from a reference point to the nearest bone crest in visual contact to the implant. An implant mean value was calculated.

Results

Sixty-nine patients received 1 or 2 narrow implants. In total, 97 implants with lengths between 11 and 15 mm were placed. Four implants were lost during the early healing phase, where the reason for failure was insufficient healing in three cases and infection in one case. No implant failures were reported after time of loading, giving a total implant survival rate of 95.5% and 100% survival rate from loading to 3 years.

The mean marginal bone level changed slightly from implant placement to loading by -0.34 mm. An average gain in marginal bone level was noted between loading and 12 months and was maintained at 3 years (Figure 1). The total mean marginal bone level change from implant placement to 3 years was -0.09 mm. However, when evaluating marginal bone level changes from time of loading to 3 years a significant ($p=0.0005$) gain of 0.33 mm bone was recorded.

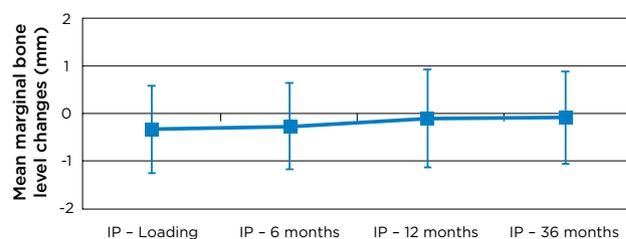


Figure 1. Marginal bone level changes from implant placement to the 3 year visit.

PPD, BoP and gingival zenith score did not change significantly over the 36 months follow-up period. Pockets were on average 2.0 mm deep at permanent crown placement and 2.2 mm at the 3 year follow-up visit. Bleeding occurred at frequencies between 34% and 37% during the study. The gingival zenith score was 8.9 mm at baseline and 8.8 from at the 3-year follow-up visit.

Discussion and Conclusion

The 3-year clinical outcome shows that OsseoSpeed TX 3.0S is a safe and predictable treatment option where space is limited in the anterior region. Stable marginal bone levels from day of surgery were recorded around the implants as well as healthy soft tissues.

Soft and hard tissue alterations around implants placed in an alveolar ridge with a sloped configuration

Authors: Noelken R, Donati M, Fiorellini J, et al.

Published in: Clin Oral Implants Res 2014;25(1):3-9.

Aim

The purpose of this prospective, multicenter study was to evaluate the hard and soft tissue alterations around OsseoSpeed Profile implants when placed in healed sloped ridges.

Material and Methods

Sixty-five patients with a lingual-buccal bone height discrepancy of 2.0-5.0 mm and in need of a single tooth replacement received in total 65 OsseoSpeed Profile implants (Dentsply Sirona Implants).

A non-submerged protocol was used and all implants were inserted into healed sites (at least 3 months after extraction). The buccal rim of the implant was positioned in level with the buccal bone crest. Consequently, the lingual rim of the implant was situated below or at the lingual bone crest. Both conical cylindrical implants were placed, (4.5, 5.0 and 5.0S) with lengths between 9 to 15 mm and most implants were placed in the mandible (75%).



Clinical assessment of the buccal and lingual bone levels were conducted immediately after implant installation, before Healing Abutments (4.0/5.0) were connected, and then at a surgical re-entry 16 weeks after implant installation. The final single crown was cemented 21 weeks after implant placement. At that time point, probing pocket depth and clinical attachment levels were assessed and repeated at the 1-year follow-up.

Radiographic assessments of marginal bone levels were performed at implant placement (baseline), 16-week (re-entry), 21-week (crown placement) and at the 1-year follow-up.

Results

The mean lingual-buccal bone height discrepancy before implant placement was 2.74 mm (range 2-5 mm). The healing phase was uneventful for all patients and all but one patient attended the 1-year follow-up. At 16 weeks, the mean lingual bone reduction was 0.02 mm and the mean buccal bone reduction was 0.30 mm (clinical assessment). Mean interproximal bone level reductions were 0.38 mm and 0.54 mm at the 16 week and the 1-year follow-up, respectively (radiographic assessment) (Table 1).

Probing pocket depth is shown in Table 1. The mean clinical attachment level changed from -0.1 to 0.1 mm between 21-week and 1-year.

	16 weeks	21 weeks	1 year
Interproximal bone level reduction (mm)	0.38±0.82	0.69±0.91	0.54±1.29
Probing pocket depth (mm)	No data	2.2±0.8	2.5±0.7

Table 1. Hard and soft tissue data (mean values ± standard deviations). Bone level reductions are measured from baseline = implant placement.

Discussion and Conclusion

The authors conclude that healing around OsseoSpeed Profile implants resulted in only small hard and soft tissue alterations. Moreover, the discrepancy between the lingual and buccal bone levels were preserved.

Randomized controlled multicentre study comparing short dental implants (6 mm) versus longer dental implants (11-15 mm) in combination with sinus floor elevation procedures. Part 1: Demographics and patient-reported outcomes at 1 year of loading

Authors: Thoma DS, Haas R, Tutak M, et al.

Published in: J Clin Periodontol 2015;42(1):72-80.

Aim

The aim was to investigate whether 6 mm long OsseoSpeed implants may generate similar high survival rates as when placing longer implants in combination with sinus floor elevation procedures.

Material and Methods

Patients eligible for the study were partially edentulous in the posterior maxilla with a bone height between 5-7 mm. Following randomization the patients were assigned either to the non-grafted group receiving treatment with 6 mm long OsseoSpeed implants (Astra Tech Implant System, Dentsply Sirona Implants) or assigned to the grafted group where they were subjected to a sinus floor elevation procedure followed by simultaneous implant placement using 11-15 mm long OsseoSpeed implants. Particulated bovine bone combined with a resorbable membrane was used for the sinus lifts. Five months post implant insertion impressions were taken. Final prosthetic constructions, non-splinted single crowns, were delivered 6-7 months after implant insertion.

One year following prosthesis delivery, patients were recalled to register implant survival. In addition, an OHIP-49 questionnaire for patient-reported outcome measures were applied throughout the study period. Questions covered by the OHIP-49 questionnaire were: functional limitation, physical pain, physiological discomfort, physical disability, physiological disability, social disability and handicap. Cost for the surgical procedure for 1 single implant and time calculations were also made for the two treatment options.

Results

In total, 101 patients were included in the study. Fifty-one patients (70 implants) were allocated to the grafted group whereas 50 patients (67 implants) were assigned to the short implant group. At the 1 year follow up visit, all implants for the 97 attending

patients remained stable, rendering a survival rate of 100 %. The patient-reported outcome measures from the OHIP-49 questionnaire only revealed a statistically significant decrease for functional limitations and physical disability within the grafted group between time for patient screening and suture removal. The grafted group showed a higher number of short-term complications than the short implant group. Treatment time and costs are depicted in Figure 1. Surgery time spent per implant in the grafted group was significantly higher than for the short implant treatment group.

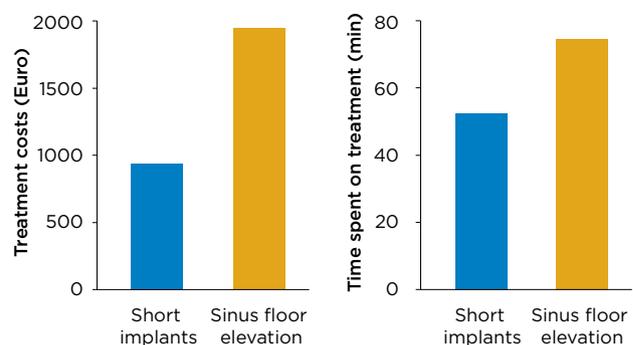


Figure 1. Treatment time and costs for the surgical procedure for 1 implant, calculated for short implant group versus sinus floor elevation group.

Discussion and Conclusion

From the results from this randomized controlled study it can be concluded that treating the atrophied posterior maxilla with either 6 mm long implants or longer implants in combination with sinus floor elevation are viable treatments, rendering high implant survival rates. Short implants may however be considered as the more favorable treatment option with less short-term patient morbidity, shorter treatment time as well as lower cost.



Marginal bone maintenance

Many years of research and documentation have revealed that the marginal bone level around the Astra Tech Implant System is well maintained. In this section we present the outstanding results and small variations in bone resorption pattern from various study reports. As a consequence of the well-preserved marginal bone, excellent esthetics is achieved.

Maintenance of the marginal bone around the Astra Tech Implant System EV is also presented in this section.

Summarized articles:

Marginal bone preservation in single-tooth replacement: a 5-year prospective clinical multicenter study	16
Effect of microthread on the maintenance of marginal bone level: a 3-year prospective study	17
Multicenter RCT comparing two related implant systems	18
A multifactorial analysis to identify predictors of implant failure and peri-implant bone loss	19

Marginal bone preservation in single-tooth replacement: a 5-year prospective clinical multicenter study

Authors: Donati M, La Scala V, Di Raimondo R, et al.

Published in: Clin Implant Dent Relat Res 2013;E-pub July 25, doi:10.1111/cid.12117.

Aim

To date, there are not many long-term clinical studies focusing on the comparison of conventional versus immediate loading of single tooth implants. The aim with this 5-year prospective study was to radiologically and clinically investigate the outcome for single-tooth implant rehabilitation in the esthetic area when applying either a conventional or immediate functional loading protocol.

Material and Methods

In total, 151 patients in need of single tooth replacement in the area premolar to premolar in the mandible or maxilla were included. Patients were randomly allocated to 1 out of 3 treatment groups; Group 1: conventional load with submerged healing for 3 months, Group 2: Immediate functional load and Group 3: Immediate functional load in combination with an osteotome technique. All 161 placed implants were OsseoSpeed implants (Astra Tech Implant System, Dentsply Sirona Implants) with diameter 4.0 or 4.5 mm and lengths between 8-13 mm.

During the study period the following clinical parameters were recorded; plaque, bleeding on probing, probing pocket depths, and width of keratinized mucosa and papilla height, all registered at the 3, 12 and 60 months follow-up visits. At these follow-ups standardized intraoral radiographs were taken to enable analysis of marginal bone level changes.

Results

Of the 151 patients included in the study, 133 (140 implants) attended the 5 year follow-up, presenting an overall survival rate of 95.6%.

The increase of plaque and bleeding on probing from 1 to 5 years were similar for implants subjected to immediate or conventional load. At 5 years lingual/palatal sites had a pocket probing depth of ≤ 3 mm in around 90% of the sites, whereas the corresponding values for the proximal sites were 70%, with no difference between different loading protocols.

The papilla height increased for all groups between loading and 5 years. The opposite was found in width of keratinized mucosa which decreased between 0.1 to 0.3 mm. Again, no differences between groups were found.

The mean marginal bone changes during the study period are shown in Table 1. No statistical difference with respect to either bone levels or bone level changes could be detected between the groups.

Mean marginal bone remodeling (mm)			
	Conventional load	Immediate load	Immediate load with osteotome
Mean	-0.26	-0.30	-0.29
SD	1.22	0.91	1.31

Table 1. Mean marginal bone remodeling following 5 years in function.

Discussion and Conclusion

This prospective, randomized, controlled study could show that single-tooth rehabilitation with OsseoSpeed implants in the esthetic area is a predictable treatment in a long-term perspective, irrespective of loading protocol applied.

Effect of microthread on the maintenance of marginal bone level: a 3-year prospective study

Author: Lee DW, Choi YS, Park KH, et al.

Published in: Clin Oral Implants Res 2007;18(4):465-70.

Aim

This 3-year prospective study aimed to compare two rough microtextured surfaced (RMS) implants, one with and one without the MicroThread (MT) feature, to determine the impact of MT on the long-term marginal bone levels.

Materials and Methods

Seventeen patients requiring implant therapy for replacement of at least two adjacent teeth were enrolled in the study. Implants (Astra Tech Implant System, Dentsply Sirona Implants) were either RMS (4.0 mm Ø, TiOblast) or RMS/MT (4.5 mm Ø, ST). Within the same edentulous area of each patient both implant types were installed in a randomized order. A two-stage surgical protocol was utilized and prostheses were delivered 3 weeks after implant exposure.

At time for prosthetic delivery (baseline) and annual follow-ups, recordings of pain, implant stability, gingival inflammation and superstructure complications were measured along with evaluation of periimplant bone levels from intra-oral radiographs.

Results

A total of 34 implants were inserted, of which 22 were in the maxilla and 12 were in the mandible. All implants osseointegrated and all prostheses were successfully delivered without complications or symptoms up to the 3-year recall visit. The mean marginal bone level changes measured for both groups are depicted in Table 1.

Mean marginal bone reduction (mm)		
Time	RMS - MicroThread	RMS - only
1 year	0.14	0.28
2 years	0.21	0.48
3 years	0.24	0.51

Table 1. Mean marginal bone level reduction over time.

The values for the RMS/ MT implants were consistently significantly lower than for RMS-only implants ($P = 0.001 - 0.002$). In addition there was a notable trend indicating that the rate of bone reduction was lower for those implants which had a MicroThread, particularly from baseline to the end of the first year, ($P = 0.002$). The amount of bone reduction was significantly higher for both implants when comparing the first year to those subsequent.

Discussion and Conclusion

In the current study both implant types had an identical RMS to the top of the implant and both utilized an internal 11° conical interface which should in theory dictate identical biologic width requirements. In addition the use of healing abutments and a two-stage approach was identical for both implant types ruling out these factors as confounding variables when measuring bone level changes. While it is recognized that the implants varied in diameter by some 0.5 mm, this has been shown in a previous study not to have influenced bone reduction. As such it is believed that this study allowed a true interpretation of the influence of the MicroThread on the bone, although it is accepted that patients will have had different periodontal susceptibilities.

This study clearly showed that implants that benefited from MicroThread demonstrated a significantly lower marginal bone reduction over a 3-year period compared to implants without MicroThread.

Multicenter RCT comparing two related implant systems

Authors: Stanford C, Barwacz C, Raes S, et al.

Published in: Academy of Osseointegration congress 2015; poster #38.

Aim

A new version of the Astra Tech Implant System has recently been introduced, Astra Tech Implant System EV. The aim of this randomized, controlled, prospective, multicenter study was to evaluate and compare the marginal bone level changes for OsseoSpeed EV and OsseoSpeed TX implants. Secondary, the aim was to assess the surgeons' perception of primary implant stability for both implant types.

Material and Methods

Five clinics participated in the study, and 120 partially edentulous patients were randomized with either test (OsseoSpeed EV, Dentsply Sirona Implants) or control implants (OsseoSpeed TX, Dentsply Sirona Implants). Fifty-nine patients received 79 test implants and 61 patients received 87 control implants. All implants were placed in healed sites. For implant installation the insertion torque curve and peak insertion torque value (ITV) were recorded using a calibrated surgical hand-piece linked to a computer. Moreover, the surgeon's perception of primary implant stability was recorded using a questionnaire. Six to 8 weeks after implant placement the final prosthetic restorations (single crowns or fixed partial bridges) were cemented onto the final abutments (TiDesign TX or TiDesign EV, Dentsply Sirona Implants). Marginal bone levels were evaluated from radiographs taken at implant installation, prosthetic restoration, and at 6, 12 and 24 months post loading.

Results

The majority of patients received 1 implant placed in the premolar or molar area (95% of sites), where 53% of the implants were placed in the maxilla. Mean ITV was 30±13 Ncm and 22±9 Ncm for OsseoSpeed EV

and OsseoSpeed TX, respectively. In line with these results, the surgeons also reported a perception of higher primary implant stability for the OsseoSpeed EV implants as compared to OsseoSpeed TX implants. To date, 105 patients completed their 2-year follow-up visit. Mean marginal bone level changes measured from implant installation to the 2-year follow-up were minimal for both groups, with no significant difference between the two groups (Table 1). In total, 6 implants were lost (5 test, 1 control) from implant placement.

	OsseoSpeed EV	OsseoSpeed TX
N	67	67
Mean	-0.06	-0.06
SD	0.58	0.93

Table 1. Mean marginal bone level changes (mm) between implant installation and 2 year.

Discussion and Conclusion

This prospective, randomized, controlled, multicenter study revealed the same good clinical outcome for both OsseoSpeed EV implants and OsseoSpeed TX implants. Marginal bone level changes were small and did not differ between the groups. However, an enhanced perception of implant stability was shown for OsseoSpeed EV implants as compared with OsseoSpeed TX implants.

A multifactorial analysis to identify predictors of implant failure and peri-implant bone loss

Authors: Vervaeke S, Collaert B, Cosyn J. et al.

Published in: Clin Implant Dent Relat Res 2015;17 Suppl 1:e 298-307.

Aim

The purpose of this retrospective cohort study was to identify risk factors for implant failure and bone loss using a statistical multivariate analysis.

Material and Methods

Patients referred to and treated at the Department of Periodontology & Oral Implantology School of Dental Medicine, Gent University, Belgium, between November 2004 and December 2007 were reviewed for possible inclusion. The only inclusion criterion was having had the implant(s) for more than 2 years. No exclusion criterion was applied. Patients' files were scrutinized by an external investigator. An external reviewer analyzed the radiographs at implant placement (baseline) and at the annual recall visits.

Several variables (predictors) were extracted from the patients' records and a Cox proportional hazard regression analysis was performed for impact evaluation of implant survival and the Mann-Whitney U-test was used for the impact on bone levels. Multivariate analysis consisted of the linear mixed-effect model.

Results

In total, 376 patients with 1,320 OsseoSpeed implants (Dentsply Sirona Implants) were followed on average for 32 months (24–65 months). Cumulative implant survival rate was 98.4%. A mean bone reduction of 0.36 mm (SD 0.68) from day of implant surgery to, in mean, 32 months of follow-up was found (1,288 readable radiographs). Multivariate analysis showed that only smoking habit and recall status (compliance with recall visits) were associated with implant survival. Furthermore, smoking habits and type of treated jaw were associated with bone loss.

Discussion and Conclusion

The multivariate analysis showed that implant related factors did not affect the clinical outcome, while smoking and willingness to attend recall visits were identified as risk factors for implant loss. Predictors for bone loss were being a smoker and treatment in the maxilla. It was speculated that having experienced an implant failure made the patient more willing to attend follow-up visits.

Treatment protocol n=number of implants	Survival %	Bone reduction mm
Immediate loading, n=649	99.5	-0.33
Delayed loading, n=460	96.1	-0.33
2-stage surgery, n=211	100.0	-0.51

Multivariate analysis of treatment protocol did not show any relationship on survival ($p=0.497$) or bone-loss ($p=0.346$).

Smoking habits n=number of implants	Survival %	Bone reduction mm
Smokers, n= 1017	96.9	-0.57
Non-smokers, n= 290	98.8	-0.30

Multivariate analysis of smoking habit showed that smoking habit had an effect on both implant survival ($p=0.001$) and bone loss ($p < 0.001$).

Jaw of treatment n=number of implants	Survival %	Bone reduction mm
Maxilla, n=757	99.3	-0.42
Mandible, n=563	97.2	-0.28

Multivariate analysis of type of treated jaw showed only impact on bone loss ($p < 0.001$).

Implant design n=number of implants	Survival %	Bone reduction mm
Cylindrical, n=866	98.2	-0.36
Conical, n=454	98.9	-0.36

Multivariate analysis of implant design did not show any impact on implant survival ($p=0.633$) or bone loss ($p=0.263$).

Prosthetics n=number of implants	Survival %	Bone reduction mm
Fixed full bridge, n=689	99.7	-0.38
Fixed partial, n=419	97.4	-0.36
Overdenture, n=50	100.0	-0.21
Single tooth, n=165	95.2	-0.32

Multivariate analysis of prosthetic solution did not show any impact on implant survival ($p=0.233$) or on bone loss ($p=0.388$).



Long-term clinical results

The long-term clinical documentation (i.e. ≥ 5 years) is one of the most important tools when showing evidence that the Astra Tech Implant System is efficient, reliable and safe. The clinical success is due to three reasons: the biomechanical and clinical principles of the Astra Tech Implant System BioManagement Complex, the excellent work of the dental professionals, and the continuous oral care by the patients. In this section, long-term clinical results up to 16 years are presented.

Summarized articles:

Immediate provisionalization of dental implants placed in healed alveolar ridges and extraction sockets: a 5-year prospective evaluation	22
A 10-year prospective study of single tooth implants placed in the anterior maxilla	23
A split-mouth comparative study up to 16 years of two screw-shaped titanium implant systems	24
Early and immediate loading of titanium implants with fluoride-modified surfaces: results of 5-year prospective study	25
Early loading of surface modified implants in the posterior mandible - 5 year results of an open prospective non-controlled study	26
Effect of surface topography of screw-shaped titanium implants in humans on clinical and radiographic parameters: a 12-year prospective study	27

Immediate provisionalization of dental implants placed in healed alveolar ridges and extraction sockets: a 5-year prospective evaluation

Authors: Cooper LF, Reside GJ, Raes F, et al.

Published in: Int J Oral Maxillofac Implants 2014;29(3):709-17.

Aim

This prospective multicentre study aimed to evaluate long-term clinical results of OsseoSpeed implants when placed in either healed sites or in extraction sockets in the anterior maxilla and immediately provisionalized.

Material and Methods

Patients in need of single implant treatment in the anterior area were assigned either to the healed site group or the fresh extraction socket group depending on their clinical condition. All patients received OsseoSpeed implants (Dentsply Sirona Implants) that were immediately provisionalized. Following 8 weeks of healing the provisional crown was removed, impression made and 3 to 4 weeks later the patients received the permanent ceramic crown.

Periapical radiographs were taken at day of surgery (baseline), at permanent crown placement, after 6 months, and at 1, 2, 3, 4 and 5 years after implant placement to record changes in the peri-implant hard tissues. Other clinical parameters registered at these follow-ups were papilla height, mucosal zenith score, occurrence of plaque and bleeding on probing.

Results

In total 113 patients received 113 OsseoSpeed implants, 55 patients in the immediate implant group and 58 patients in the healed sites group. Four implant failures occurred during the first year, 3 of which were placed in extraction sockets and 1 placed in a healed site, and 15 patients were lost to follow up. At 5 years, 45 and 49 implants in respective group were evaluated.

Following 5 years in function the overall implant survival rate was 96.5%, with no statistically significant difference between implants placed in extraction sockets or in healed sites. From implant placement to the 5-year follow-up the marginal bone was well maintained where almost all implants placed in extraction sockets revealed bone gain, and 59% of the implants placed in healed ridges showed gain or no marginal bone change (Figure 1). Implants placed in extraction sockets showed an average bone gain of 2.06 mm (SD±2.38) whereas implants placed in healed ridges measured an average bone gain of 0.10 mm (SD±1.28).

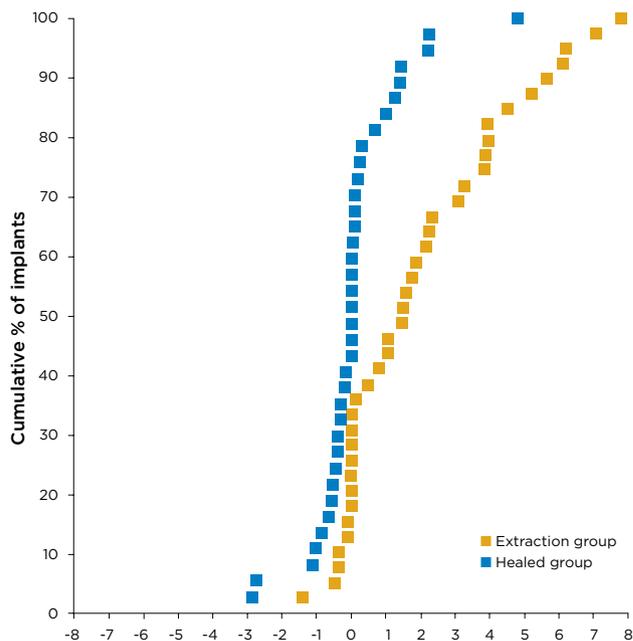


Figure 1. Cumulative marginal bone level changes from implant placement to the 5-year follow-up.

All patients showed good soft tissue health confirmed by low frequencies of both bleeding on probing and plaque occurrence. From the time of definite crown placement to the 5-year follow-up, the papilla height increased over time and did not differ between the groups. The mucosal zenith scores showed stable levels and were similar for both treatment groups.

Discussion and Conclusion

During this 5-year study there was no significant difference in marginal bone levels between implants placed in fresh extraction sockets or in healed ridges. The peri-implant tissues were healthy and stable around immediately loaded OsseoSpeed implants throughout the whole study period.

A 10-year prospective study of single tooth implants placed in the anterior maxilla

Author: Gotfredsen K.

Published in: Clin Implant Dent Relat Res 2009;14(1):80-7.

Aim

The aim of this study was to present 10-year data from a cohort of single-tooth implant replacements placed in both an early and delayed manner and report on both biological and mechanical outcome.

Material and Methods

Twenty healthy patients, required replacement of a single missing tooth in the anterior segment were included. Patients were assigned either to the group for early placement or delayed placement. Implants (Astra Tech Implant System implants, Ø 4.5 mm, Dentsply Sirona Implants) were placed with the bevel leveled with the lingual crest. Submerged healing was allowed for 6 months. Early placed implants were restored using prefabricated abutments while those in the delayed placement group received preable abutments. All implants were restored with cemented metal-ceramic crowns.

Clinical and radiographic assessments were made within 2 weeks of crown cementation (baseline) and annually thereafter. Examinations included an assessment of implant/crown immobility, pain sensation, plaque scores, bleeding on probing and recording of any biological or technical complications. Patients were asked to score the esthetics and function of the crown at the 3- and 10-year visit on a 10 cm VAS scale where 0 = dissatisfied and 10 = very satisfied.

Results

While some patients were absent from the occasional annual review all patients were seen across the study. One patient missed the final review, but was available for a telephone interview. Thus it was possible to confirm a 100% survival rate for implants and a 90% survival rate for crowns. With regard to complications, one patient had mucositis at the 10-year review, two crowns required re-cementation, three crowns fractured and two abutment screws-loosening occurred. Patient VAS scale results are depicted in Figure 1.

At the 10-year follow-up the mean marginal bone reduction measured 0.64 mm for early placed implants and 0.86 mm for implants with delayed placement. There was no significant difference over time or between the groups for any of the clinical or radiographic parameters assessed.

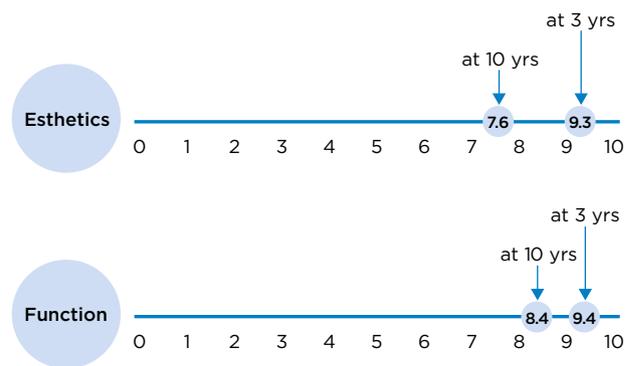


Figure 1. VAS scale results from 3 and 10 year follow-ups with respect to esthetics and function.

Discussion and Conclusion

Results of the current study corroborate the findings of previous systematic reviews with respect to both implant and crown survival. The maintenance of marginal bone in the current study was superior to that anticipated by established criteria, while technical complications with the crown appeared more consistent with previous studies. However the use of the more robust preable abutment appeared to resolve the problems of decementation and abutment screw loosening. It can be concluded that the Astra Tech Implant System implant is well suited for single-tooth replacement and that patient scores for function and esthetics, although reducing over time, remained high even after 10 years.

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

Authors: Jacobs R, Pittayapat P, van Steenberghe D, et al.

Published in: J Clin Periodontol 2010;37(12):119-1127.

Aim

The aim of this randomized split-mouth design study was to compare long-term outcome with respect to bone levels changes for 2 different implant systems having either a machined or a rough implant surface.

Material and Methods

Eighteen patients, all with bilateral posterior edentulism were included in the study.

TiOblast implants (Astra Tech Implant System, Dentsply Sirona Implants) were placed in one side and Brånemark System implants with machined surface were placed in the other side. Following 5 months of submerged healing final delivery of screw-retained fixed partial metal-ceramic dentures took place.

Following prosthetic delivery, i.e. baseline, clinical and radiological assessments took place at annual recalls. Sulcus bleeding index, presence of plaque, probing pocket depth and bone densities were recorded as well as marginal bone levels. The bone levels were measured from the reference level to the first bone-to-implant contact. Periotest values were recorded at the 1 and 10-year follow ups. Recording of biological complications, porcelain chipping re-tightening of abutment or bridge screws etc. was also performed.

Results

No differences between the implant systems with regards to any parameter evaluated at any time point were detected. The implant survival rate at 16 years was 97.7% for the Brånemark System and 100% for the Astra Tech Implant System. Porcelain chipping and screw retightening occurred at 3% and 8%,

respectively, with a 100% bridge survival noted for both systems. Between year one and 10 the Periotest value decreased whereas radiographic bone density increased. The mean marginal bone level changes are displayed in Table 1. The bone level around Astra Tech Implant System was located closer to the implant abutment junction, at a distance of 0.4 ± 0.59 mm, while the corresponding figure was 1.79 ± 1.06 mm for the Brånemark implants. When measuring the bone loss at neighboring teeth it was found that on average 0.5 ± 0.7 mm bone was lost during the 16 year period.

Mean marginal bone level changes (mm±SD) (prosthetic delivery – 16 years follow-up)		
	Astra Tech Implant System (rough surface)	Brånemark System (machined surface)
Implant level	-0.02±0.45 n=24	-0.31±0.69 n=23

Table 1. Marginal bone level change from baseline to 16-years follow-up. No significant difference in bone loss between the systems was noted during the observational period.

Discussion and Conclusion

Clinical and radiographic parameters remained stable during the entire 16 year follow-up period and were not different between the systems. Surface topography had thus no effect on hard and soft tissue variables in this randomized split-mouth clinical trial. These results are similar to what has been reported previously in other long-term clinical studies on Astra Tech Implant System.

Early and immediate loading of titanium implants with fluoride-modified surfaces: results of 5-year prospective study

Authors: Mertens C. and Steveling HG.

Published in: Clin Oral Implants Res 2011;22(12):1354-60.

Aim

The aim was to prospectively evaluate whether a fluoride modified implant surface has a positive clinical effect over a 5-year period.

Material and Methods

Seventeen patients all eligible for rehabilitation with 2-5 implants were treated with in total 49 OsseoSpeed implants (Dentsply Sirona Implants). Thirty-three implants were placed in the maxilla and 16 in the mandible using a one-stage surgical protocol with flap elevation. In total, 14 implants were immediately loaded with Direct Abutments (Dentsply Sirona Implants) and provisional crowns, while 35 implants were early loaded using healing abutments. Impression was carried out at 6 weeks, and the final restoration was delivered at 8 weeks in most situations. Prosthetic restoration consisted primarily of single crowns (31), but also fixed partial (4) and a fixed full bridge (1). Implant survival, complications, oral health parameters, Jemt's papilla index and radiological bone level were assessed during the study. Radiographic success was evaluated according to Albrektsson's criteria (1986). The mesial and distal first visible bone-to-implant contact was recorded on radiographs calibrated for distortion, by an independent radiologist. At the 5-year follow-up, patients also filled in a questionnaire about their subjective response to the implant-supported rehabilitation.

Results

Fifteen patients with 42 implants were able to attend the 5-year follow-up. One patient died and one patient was lost to follow-up. Mean marginal bone reduction after 5 years of loading, irrespectively of loading protocol, was 0.1 mm (SD 0.4). Immediately loaded implants, as well as early loaded implants both showed good long-term bone preservation, 0.18 mm and 0.00 mm respectively, p 0.265.

Implant survival rate was 97% (1 implant failed before loading). However, radiographic success was 100%, according to Albrektsson et al., 1986. Clinical complications were restricted to 1 implant which showed signs of peri-implantitis. Papillae were present (score 2 or 3) in situations with neighboring teeth. No technical complications were recorded during the study period. All patients were "very satisfied" with regards to their prosthesis at the 5-year visit.

OsseoSpeed	Final prosthetic connection	5 year follow-up
Mean marginal bone remodeling from loading	-	-0.1 mm
Implant survival	97%	97%
Plaque Index	26%	6.1%
Signs of inflammation	16%	4.2%
Papilla score 0 or 1	31%	25%
Papilla score 2 or 3	69%	75%

Table 1. Mean marginal bone remodeling, implant survival, plaque index, signs of inflammation and papilla score evaluated per implant site at time for final prosthetic delivery and at the 5-year follow-up.

Discussion and Conclusion

This study was undertaken to evaluate the clinical effect of a fluoride-modified implant surface over a long-time follow-up. Patients with varying indications, periodontal status and bone quality was included. It was concluded that fluoride-modified implants, as studied here, show high survival and high success rate over a 5-year follow-up period.

Early loading of surface modified implants in the posterior mandible – 5 year results of an open prospective non-controlled study

Authors: Schliephake H, Rodiger M, Phillips K, et al.

Published in: J Clin Periodontol 2012;39 (2):188-95.

Aim

The main objective with this trial was to evaluate the long-term clinical and radiographic outcome when applying an early loading protocol using OsseoSpeed implants placed in the posterior mandible.

Material and Methods

General criteria for implant treatment and specific conditions such as no need for grafting, no immediate placement in extraction sockets, being a non-smoker, the need of at least 2 implants (in molar position and splinted) and an initial stability enough to be early loaded, had to be fulfilled for patient inclusion. OsseoSpeed implants (Astra Tech Implant System, Dentsply Sirona Implants) of varying lengths and dimensions were placed and UniAbutments (Dentsply Sirona Implants) were connected in a 1-stage surgical approach. Sutures were removed after 2 weeks and impression was taken 6 weeks after surgery. Screw-retained metal ceramic bridges were delivered within 7 weeks of implant placement. Clinical variables evaluated consisted of bleeding on probing, plaque index and the recording of technical and biological complications. Radiographic measurement of the marginal bone level was performed at implant placement, at time of loading, 3 and 6 months post loading and at yearly visits. Implant stability by means of resonance frequency analysis (ISQ values) was performed regularly during the first year.

Results

At time of loading the patient group consisted of 44 patients with 50 restorations supported by 123 OsseoSpeed implants. Two patients diseased and 1 patient was lost to follow-up during the 5 year follow-up period. At the final visit a 100% bridge survival and 100% implant survival were reported.

Three patients were diagnosed with peri-implantitis, 1 patient experienced numbness in the lip and 1 patient developed a postoperative infection, all which could be resolved. Four abutments loosening, 5 bridge screw loosening/fractures and 9 ceramic chippings occurred.

Bleeding on probing varied between 7.9% and 13.0% throughout the study period. Plaque accumulation was 28.6% at time for loading and had decreased to 17.4% at the 5 year follow-up. The ISQ values decreased significantly from 73.3 at implant placement to 71.9 at 2 weeks. They were, however, 73.2 at 6 weeks and continued to increase during the first year of function, to 77.7 at the 1-year follow-up. Mean marginal bone level change from implant placement to loading was -0.21 mm. From loading and onwards some gain occurred resulting in a total change from implant placement to 5 years of -0.08 mm. Sixty-one implants (49.6%) showed no change in bone levels during the observational period. Yearly bone levels are shown in Table 1.

	Time from loading (years)					
	0	1	2	3	4	5
Mean marginal bone level (mm)	0.80	0.59	0.64	0.51	0.68	0.67

Table 1. Mean marginal bone levels over time.

Discussion and Conclusion

This study shows that the OsseoSpeed implant is a safe and predictable implant when treating posterior edentulism and applying an early loading protocol. Soft tissue health and marginal bone can be preserved at a constant level throughout 5 years of function.

Effect of surface topography of screw-shaped titanium implants in humans on clinical and radiographic parameters: a 12-year prospective study

Authors: Vroom MG, Sipos P, de Lange GL, et al.

Published in: Clin Oral Implants Res 2009;20(11):1231-1239.

Aim

This prospective, randomized, double blind study aimed to compare the marginal bone response and peri-implant soft tissue status around moderately rough and machined implants with identical geometry.

Material and Methods

Twenty edentulous patients all received 4 implants (Astra Tech Implant System, Dentsply Sirona Implants); 2 with TiOblast surface and 2 with machined surface. Thus, the patient acted as its own control. Following randomization, the implants were placed in the anterior mandible. Implants were submerged for 4 months before definitively restored with a bar and an overdenture construction.

Clinical and radiographic follow-up occurred at loading (baseline), 6-months, annually for 5 years and with a final follow-up after 12 years. Clinical parameters included plaque index, presence or absence of calculus, bleeding on probing, pocket depth, and an estimation of the location of the gingival margin.

Intra-oral radiographs were taken using a standardized technique. Images were digitalized and the distance from the implant/abutment junction to the most coronal bone-to-implant contact was recorded.

Results

Two machined implants failed to osseointegrate, but were replaced and the new implants were included in the follow-up analysis. All implants remained in function at the 12-year visit. Seven patients were lost to follow-up. Most of the clinical parameters remained stable from baseline to the 12-year visit (Table 1). Little or no signs of calculus were observed. Marginal bone levels were well maintained during the study period (Table 2). Surface type did not seem to influence the clinical or radiographical parameters. There were no significant differences between surface type at any time frame or across the entire study period.

	Loading		12-years	
	Machined	TiOblast	Machined	TiOblast
Plaque Index (%)	19	19	39	34
Bleeding Index (%)	20	25	33	41
Location gingival margin* (mm)	2.10	2.00	1.71	1.63
Pocket depth (mm)	2.35	2.25	2.53	2.69

Table 1. Mean values of the clinical parameters at baseline and at 12 years

*The distance from fixed reference point i.e. the implant shoulder to the peri-implant mucosa margin.

	1-year		2-year	
	Machined	TiOblast	Machined	TiOblast
MBLC (mm)	-0.02	-0.20	+0.01	+0.01

Table 2. Mean marginal bone level change (MBLC) from baseline to 1 respectively 12 years.

Discussion and Conclusion

Surface topography had no effect on hard and soft peri-implant tissues in this randomized clinical trial on edentulous patients. Hence, there is no evidence for the moderately rough TiOblast surface being more susceptible to peri-implant infections than a machined implant surface. The result corroborates with other long-term studies reporting healthy soft tissue and well preserved marginal bone around moderately rough TiOblast implants^{1,2}.

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Checklist for critical reading of clinical documentation and scientific articles

Reading scientific articles and clinical documentation is essentially about being able to judge how reliable the results are and what they mean for you in your clinical work. In order for a scientific article to be deemed credible, certain data must be present. Here is a list of important and necessary information to look for:

- Purpose of the study**
Why was the study performed? The purpose should be compared with the conclusion.
- Type of study**
Is it a prospective or retrospective study? Generally, prospective studies are better, since the criteria are set before the patients are treated.
- Number of clinics involved**
How many clinics are involved? More than one clinic should be involved in the study, in order to judge the possibility of repeated results.
- Number of patients**
How many patients are included in the study?
- Inclusion and exclusion criteria**
What are the criteria for a patient to be included in or excluded from the study?
- Number of implants for upper and lower jaws respectively**
The number of implants should always be listed separately for upper and lower jaws, including failure statistics, as the treatment prognosis is different in each jaw. An additional advantage is if you can see the difference between anterior and posterior treatment.
- Follow-up**
How many implants have been followed for how long? When did the follow-up start; at installation or at loading?
- Indications**
Which indications are covered in the study; single, partial or full bridge? If it is a full bridge, is it fixed prosthesis or overdenture?
- Loading**
When were the implants loaded (immediate, early or conventional loading)?
- Implants lost**
A study should include both the number of implants and number of patients not accounted for during the entire follow-up period. It should also include the reasons for drop-outs.
- Success criteria**
What is a successful result according to the authors? It is important that the success criteria are clearly described.
- Other important parameters**
How were the results verified? Was x-ray used when determining bone levels? How were bone levels measured? Was the bridge removed to control implant stability?
- Statistical analysis of success and failure rates**
A study should include statistical facts and figures to reveal how many implants were actually followed up and for how long. It should also include a "worst-case" analysis, meaning a calculated failure rate assuming that all drop-outs were lost implants.
- Complications**
If there are complications or drop-outs, they should be clearly described.
- Conclusion**
The conclusion should be compared with the purpose of the study. Was it fulfilled? What does the study actually tell you? How does the result affect your daily clinical work?

About Dentsply Sirona Implants

Dentsply Sirona Implants offers comprehensive solutions for all phases of implant therapy, including Ankylos®, Astra Tech Implant System® and Xive® implant lines, digital technologies, such as Atlantis® patient-specific solutions and Simplant® guided surgery, Symbios® regenerative solutions, and professional and business development programs, such as STEPPS™. Dentsply Sirona Implants creates value for dental professionals and allows for predictable and lasting implant treatment outcomes, resulting in enhanced quality of life for patients.

About Dentsply Sirona

Dentsply Sirona is the world's largest manufacturer of professional dental products and technologies, with a 130-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets a comprehensive solutions offering including dental and oral health products as well as other consumable medical devices under a strong portfolio of world class brands. As The Dental Solutions Company™, Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. Dentsply Sirona's global headquarters is located in York, Pennsylvania, and the international headquarters is based in Salzburg, Austria. The company's shares are listed in the United States on NASDAQ under the symbol XRAY.

Visit www.dentsplysirona.com for more information about Dentsply Sirona and its products.