

Five-year Prospective Follow-up Report of the Astra Tech Standard Dental Implant in Clinical Treatment

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Between 1994 and 1999, 515 Astra standard implants were placed and documented prospectively in 107 patients. Of these implants, 364 were placed in original jawbone, 38 in areas augmented with local osteoplasty, and 113 in bone grafts from the iliac crest. The main indications for implantation were an atrophic edentulous alveolar crest (n = 361) and a shortened dental arch (n = 113). Single-tooth implants were excluded. In a special clinical examination, 56 patients with 258 implants were investigated. The average in situ time of the implants was 34.2 months. Failing osseointegration (n = 10), peri-implantitis (n = 10), and implant fracture (n = 1) in 15 patients resulted in the failure of 21 implants (4.1%). Three patients with 8 implants died from malignant tumor. Currently, 27 implants have been lost to follow-up, and 488 implants remain in situ (95.9%). Under analyses with different implant success criteria, the success rate decreased to 85%. Based on the results in this patient population, this implant was found to be a useful alternative to established implant systems for the indications analyzed. (INT J ORAL MAXILLOFAC IMPLANTS 2001;16:557-562)

Key words: dental implant, implant failure, marginal bone resorption, osseointegration, peri-implantitis

The number of new implant systems available is increasing as fast as the indications for dental implants. Often, these systems are clinically available before long-term observations of the established system have been published. Ekert and coworkers¹ showed good results for the Astra implant system in a 2-year follow-up study. After 5 years, the failure rate observed by Arvidson and associates² and Makkonen and colleagues³ was less

than 2% in 107 and 33 healthy, motivated, and mostly non-smoking patients, respectively. Clinical results for patients not selected according to health and oral hygiene were not available at that time. For this reason, the soft tissue situation, marginal bone loss, and implant failure were analyzed after 5 years of clinical experience using the Astra standard implant, an established ablative, surface-enlarged, self-tapping, cylindrical screw implant.

MATERIALS AND METHODS

Between September 1994 and August 1999, 515 standard implants (Astra Implant systems, Astra Tech, Mölndal, Sweden) were placed in 107 patients and documented prospectively. The most common implant lengths were 13 and 15 mm, with respective diameters of 3.5 and 4 mm (Table 1). Single-tooth implants were not used.

The implants were placed in the maxilla and mandible, in both the anterior (including the canine teeth) and molar regions (Fig 1). The main indication for implantation was an atrophic edentulous alveolar crest (70%). Patients with a shortened dental

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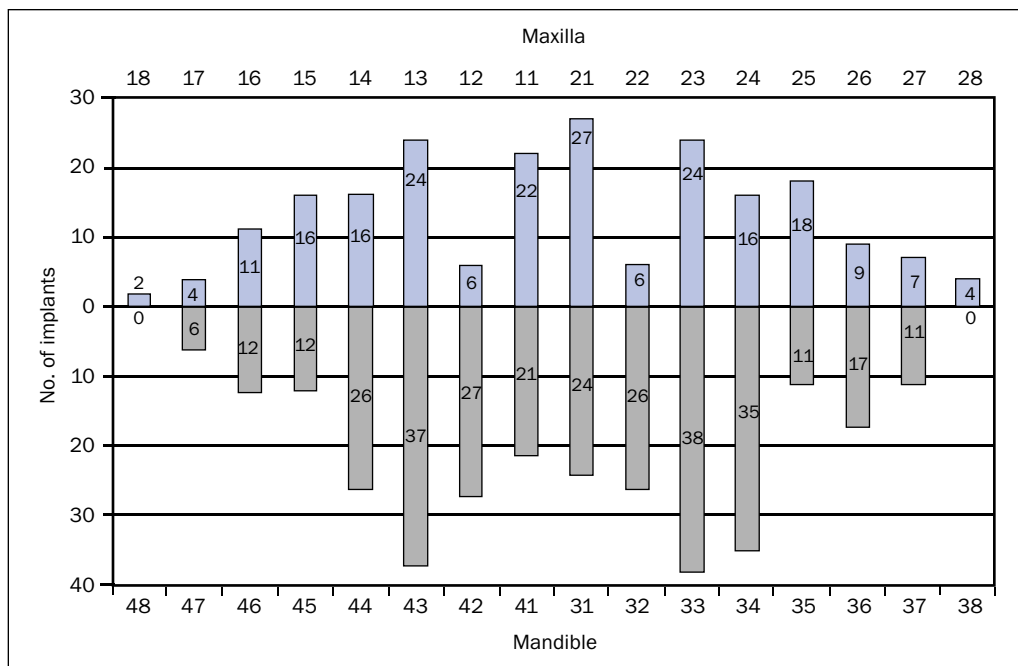
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Table 1 Distribution of Implant Lengths and Diameters (n = 515 in 107 patients)

Length (mm)	n	No. of 3.5-mm-diameter implants		No. of 4.0-mm-diameter implants	
		Female	Male	Female	Male
8	3	0	2	0	1
9	16	2	7	1	6
11	77	27	23	12	15
13	179	48	73	35	23
15	201	30	70	41	60
17	31	8	9	6	8
19	8	1	2	2	3
Totals	515	116	186	97	116
		302		213	

**Fig 1** Frequency and location of implants (n = 515 in 107 patients).

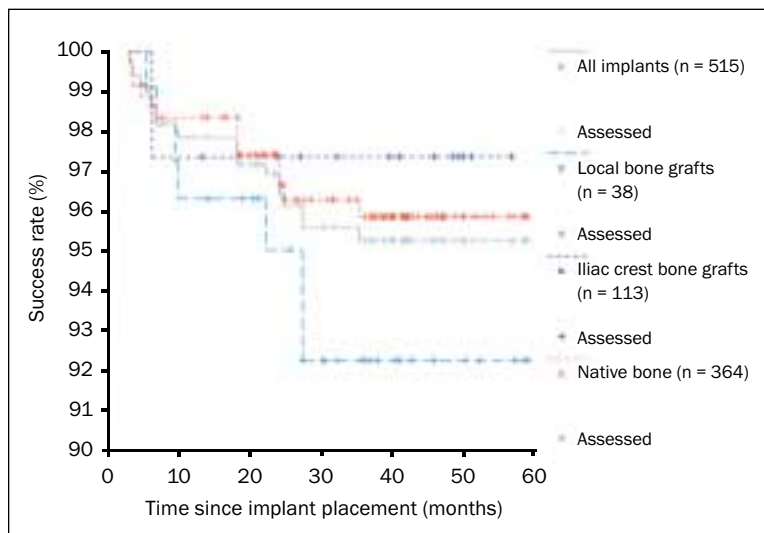
arch (eg, missing molars) (22%) or partial edentulism (8%) were also treated. Single-tooth replacements were excluded. Most implants (364) were placed in native bone, 113 were placed in iliac crest bone grafts, and 38 were placed in local bone grafts. Bone atrophy was the major reason for implantation.

In a special investigation that analyzed peri-implant hard and soft tissues from March to August 1999, 56 unselected patients (visited recall between March and August) with 258 implants were seen. The proportion of edentulous patients was 77.9%; 22.1% were partially edentulous, and 16.7% had a shortened dental arch. Consequently, most patients had a removable denture attached to a splinted gold bar.

In the investigated population, 16 patients with 79 implants in irradiated bone were included. Six patients had been irradiated before implant placement, and 10 patients received radiation treatment after implant placement.

The parameters observed were modified Plaque Index (PI)⁴; Sulcus Bleeding Index (SBI)⁵; extension of attached vestibular and lingual gingiva; peri-implant pocket depth (Plast-o-Probe styler, Dentsply, Ballaigues, Switzerland); sulcus fluid flow rate (SFFR) (Periotron 6000, Harco Electronics, Winnipeg, Canada); Periotest measurement (Periotest, Siemens AG, Bensheim, Germany); and Mobility Index (per the German Society of Periodontology).

Fig 2 Kaplan-Meier survival analysis of implants.



Actual bone loss was measured by a post-implantation orthopantomogram after comparison with a pre-operative radiographic examination (orthopantomogram, adjusted for magnification). All implanted patients were asked to answer a questionnaire (used routinely for recall investigation in the Clinic for Oral and Maxillofacial Surgery) to rate their personal impressions and condition, as well as implant success. Of a total of 107 mailed questionnaires (515 implants), 80 were returned and could be analyzed (385 implants, for a response rate of 74.8%).

To ensure statistical independence, statistical calculation of only the worst implant in each patient (greatest probing depth) was analyzed in relation to data from the individual questionnaires. *P* values $\leq .05$ were regarded as statistically significant.

For determination of the influence of different parameters, uni- and multivariate linear regression analyses were executed. Many clinical parameters were not normally distributed (SBI, PI, Periotest, etc). Therefore, the Spearman correlation coefficient was used for the analysis of clinical parameters. Kaplan-Meier survival function was used for description of survival rates.

RESULTS

There was a 2% primary loss of implants (10 implants in 10 patients). Another 10 implants were lost as a result of peri-implantitis; 3 of these were in irradiated arches (of 79 implants in irradiated arches; 76 implants are still in situ, with a mean survival time of 3.1 years). One was lost as a result of horizontal implant fracture. The cumulative failure

rate was 4.1% (21 lost implants in 15 patients). During the observation period, 3 patients (with 8 implants) died. As of August 1999, 488 implants remained in situ. Five patients with 27 implants had been lost to follow-up. The average observation time of implants was 2.8 years (34 months), with a maximum of 4.8 years (59 months). The Kaplan-Meier survival analysis is shown in Fig 2.

For 27 patients, recall was not possible during the recall period included in this study. Three of these patients (8 implants) died. Nineteen patients (95 implants) had participated in the routine recall and were not interested in a second investigation. Five patients with 27 implants were lost to follow-up. Therefore, a total of 56 patients (258 implants) specified above could be examined, which represents the total population for which calculations were made.

The observed results in 56 patients with 258 implants were as follows. Clinical evaluation of oral hygiene using SBI and PI showed sufficient hygiene (grade 0 or I) in 81% of sites (Fig 3). There was a roughly equal incidence of grades II and III PI, while grade III SBI was found in only a few sites. Attached gingiva with a height greater than 1 mm was seen buccally in 67% of implants and lingually in 80% of implants. The peri-implant pocket depth measured lingually and buccally was less than 4 mm in 81% of sites (Fig 4). The SFFR ($n = 127$) was increased in 21% of implants. In the Periotest measurement, 98% of implants had physiologic values, and the value was increased (> 9) in 4 implants. The manually and visually rated Mobility Index was usually zero, but grade I instability was seen in 3 patients. The mean marginal bone loss for all investigated implants was 1.5 mm

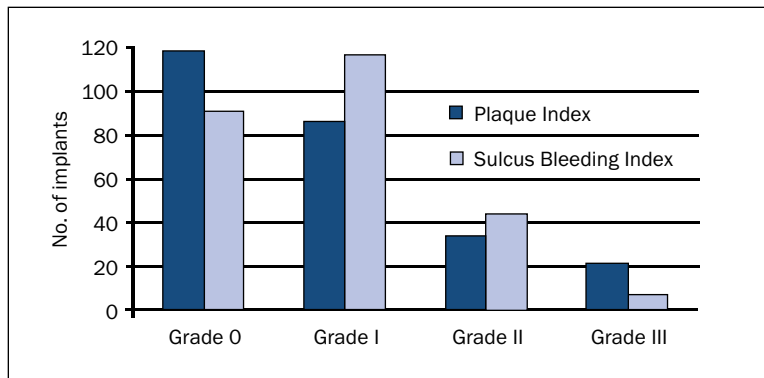


Fig 3 Distribution of Plaque Index and Sulcus Bleeding Index scores (n = 258 in 56 patients).

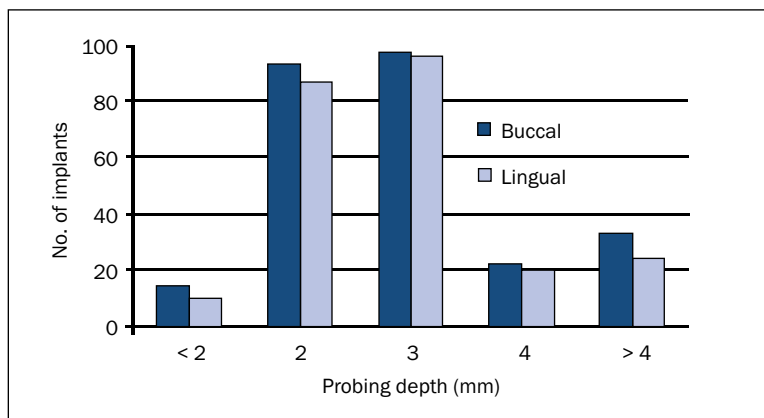


Fig 4 Distribution of probing depths (n = 258 in 56 patients).

(range, 0.5 to 8.0 mm) after an average of 34.2 months in situ. In 244 implants (95%), the marginal vertical bone loss was equal to 4 mm, while it exceeded 4 mm in 14 implants. The average horizontal bone resorption was 0.9 mm (range, 0.5 to 4 mm) (Fig 5). The implants with increased peri-implant bone loss (n = 14) included all implants with a Mobility Index greater than 0 (n = 3) or a Periotest measurement greater than 9 (n = 4).

Of the questionnaires returned, 47 of 80 patients (59%) participated in regular follow-up after implantation. If indicated, 71 patients (89%) would agree to undergo implant placement again; 80% (64 patients) reported no disability as a result of implant placement. The personal rate of satisfaction after implant-prosthetic treatment, rated on a scale of 1 to 6 (with 1 being the highest rating and 6 being the lowest), was excellent or very good (levels 1 and 2) in 80% of the population. Only 5% of the patients had an unsatisfactory implant outcome (level 6) (Fig 6). The operation was considered very comfortable by 77% of treated patients, in contrast to 7%, who were dissatis-

fied. Evaluation of the prosthetic treatment revealed 50 satisfied patients (62%) versus 6% dissatisfied patients. If necessary, 88% of patients who underwent the procedure would do so again, and 95% would recommend the procedure to someone else.

The Spearman correlation analysis showed no significant correlations between the clinical parameters and subjective criteria, such as attached gingiva, probing depth (buccal and lingual), and bone loss (according to orthopantomograms).

DISCUSSION

At the end of the study period, the in situ survival rate was 95.9%. These results are similar to the findings of Ekert and coworkers.¹ However, only 77% of investigated implants remaining in situ could be considered truly successful when the strict criteria of Albrektsson and colleagues were applied.^{6,7} According to Albrektsson and colleagues,⁷ no signs of peri-implant infection should exist. The authors considered a probing depth

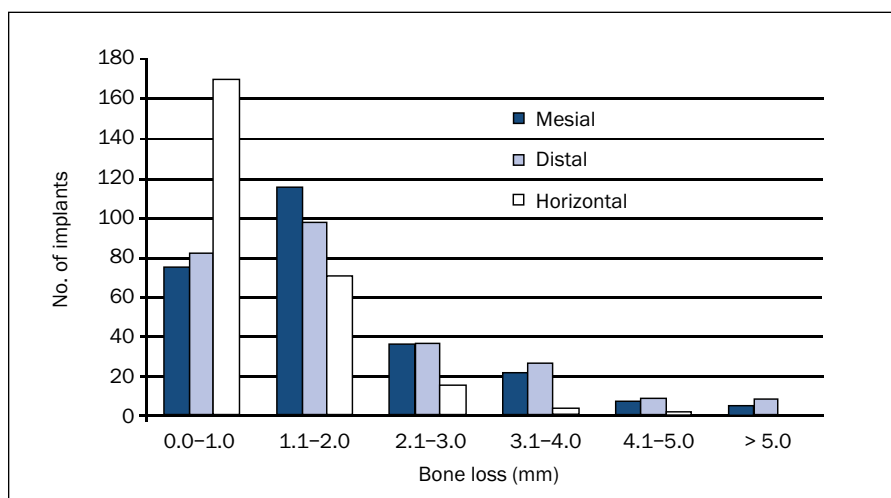


Fig 5 Peri-implant marginal bone loss (n = 256 in 56 patients).

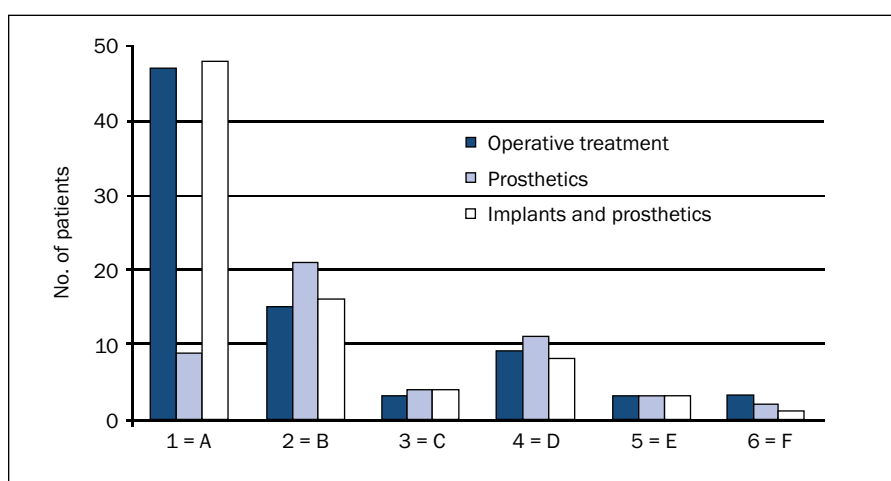


Fig 6 Evaluation of patient satisfaction with operative treatment, prosthetic treatment, and overall implant treatment (1 = highest rating to 6 = lowest rating) (n = 80 patients).

of 4 mm or more a sign of peri-implant infection and assessed such implants as partially successful. With the implant success criteria of Jahn and d'Hoedt,⁸ the rate of complete success reached 71%. The poor results using the success criteria of Jahn and d'Hoedt⁸ resulted from the inclusion of subjective evaluations from the patients (a score of 3 or better). Since there was no correlation between the clinical situation and patients' subjective opinions ($P = .67$ to $P = .91$ for operative treatment, implants, and prosthetics), the success rate using the criteria of Jahn and d'Hoedt has to be considered carefully. Success criteria were also defined by the 1979 Harvard/National Institutes of Health Conference⁹ and Buser and associates.¹⁰ Under these criteria, the success rates were 84.1% and 85.7%, respectively (Table 2).

It should be noted that only 4 (n = 5 implants) of the 15 patients with implant losses were examined in the special examination of 56 patients, so the complication rate may have been higher in the total (non-selected) group of implant patients. Since there was a minimal number of irradiated patients (n = 16), a statistically significant conclusion does not seem possible.

CONCLUSIONS

The 95.9% survival rate of implants in this study population appears to be comparable with the results of other studies.^{1,11} Under established implant success criteria, the rate of success decreases to at least

Table 2 Success Criteria for Dental Implants

Study	Implant	Mobility Index	Radiographs	Bone loss	Infection/Inflammation	Other
Schnitman and Shulman (NIH) (1980) ⁹	In situ	0-1	Peri-implant radiographic translucency is graded but not included in definition of success	Vertical bone loss is less than 1/3 of vertical implant length	Gingivitis can be treated successfully No signs of inflammation	No lesion of nerve, teeth, maxillary sinus, or bottom of nasal cavity
Albrektsson et al (1986) ⁶	In situ	0	No peri-implant radiographic translucency	Vertical bone loss is less than 0.2 mm/year after the first year post-implantation	No signs of inflammation <i>Authors' comment:</i> Probing depth over 4 mm was considered comparable to infection	No lesion of nerve
Buser et al (1990) ¹⁰	In situ	0-1	No permanent peri-implant radiographic translucency		No sign of peri-implant infection with putrid secretion	Absence of persistent pain, dysesthesia, and/or foreign-body feeling
Jahn and d'Hoedt (1992) ⁸	In situ	0-1	The peri-implant gap in radiograph must be smaller than 0.5 mm on all sides	The angular bone defect (mean of mesial and distal radiographic measurements) has to be less than 30% of endosseous part of implant	Probing depth must be less than 4 mm in 2 sequential recalls	Personally rated satisfaction must be 3 or better (on scale of 1 to 6, with 1 as highest score)

85.7%. Based on the results of this limited investigation, the Astra implant system may be considered a useful alternative to existing implant systems and may be recommended for standard indications: partially edentulous patients, a shortened dental arch, or an edentulous alveolar crest with or without bone grafting.

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