Clinical and Radiographic Evaluation of OsseoSpeed EV Implants

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Purpose: To evaluate the survival rate (primary outcome) and the marginal bone loss (secondary outcome) of the OsseoSpeed EV Implants (Astra Tech Implant System, Dentsply Sirona Implants; hereinafter EV implants) used in a wide range of clinical scenarios and followed up to 8 years in a nonuniversity setting. ***Materials and Methods:*** All EV implants consecutively placed from 2013 to 2021 in a private dental clinic were included, and medical and radiologic records were retrospectively investigated. Independent reviewers collected 11 data types as potential influencing variables and measured the mesial and distal marginal bone levels to the nearest 0.5 mm on available radiographs, either panoramic or periapical. Tables of descriptive statistics were made at implant and patient levels. Univariate and multiple Cox regression models were adjusted for clustering effects and determined the hazard ratio (HR) and odds ratio (OR) for each independent variable collected. ***Results:*** The study sample consisted of 597 EV implants and 235 patients. During a mean follow-up of 42.1 ± 23 months (range: 10 to 94 months), 44 implants were lost (7.4%)—34 early (5.7%) and 10 late (1.7%)—in 38 patients (16.1%). The overall survival rate (SR) was 92.6% (CI: 90.5% to 94.7%), and the proportion of patients with all their implants surviving was 83.8% (CI: 79.1% to 88.5%). At the end of the study, the probability of survival of an implant that did not fail early was 98.2% (CI: 97.1% to 99.3%). Implant-level analysis identified two significant variables: implant diameter (HR 0.37, $P = .009$**) and immediate postextraction placement (HR 2.35, $P = .025$*). At the patient level, bruxism (OR = 3.29; $P = .009$**), history of periodontitis (OR = 2.18, $P = .030$*), and the number of implants placed (OR = 1.43; $P = .001$**) were found to be statistically significant. After removing dropouts and early failures from a sample of 528 implants, 412 (78%) had a marginal bone loss (MBL) ≤ 0 mm at the end of the observation time, and 106 surviving implants (22%) showed a mean MBL of 1.42 ± 1.08 mm (range: 0.25 to 6.75 mm). ***Conclusions:*** An overall medium-term SR of the EV implants was 92.6%. Four of five EV implants showed a mid-term MBL ≤ 0 mm, and 91.86% of implants completed the observation period with an MBL < 2 mm. Thus, the EV implant system was shown to be a valid alternative for routine use in a nonuniversity setting. Clinicians should remember that there is no 100% implant survival in everyday practice and that bruxism, periodontitis, narrow-diameter implants, and immediate placement are risk factors for a higher failure rate.
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Keywords: implant survival, implant failure, OsseoSpeed EV Implant, marginal bone loss, risk factors

Dental implant systems undergo rapid evolution, ultimately driven by their broad therapeutic indications. The effort of manufacturers to follow the demands of a growing market causes designs to change faster than clinical assessment, which means previous designs are still being evaluated in terms of medium- and long-term clinical results while new designs are being brought to market. However, clinicians need to understand the "real life" analysis of an implant's clinical performance before using it in their patients, with a recommended period of 10 to 15 years of follow-up.

OsseoSpeed EV Implants (Astra Tech Implant System, Dentsply Sirona) were the result of the continuous evolution of its predecessors, which already had extensive clinical documentation.[1,2] The EV implant is a threaded cylindrical implant with microthreads in the collar zone, a tapered apex with apical grooves, and a flat end. It has an internal conical abutment interface and a beveled margin, which leaves a small switching platform. Its moderately rough surface is manufactured by blasting and treating the surface with fluoride. These features are patented hallmarks of the Astra Tech Implant and are supported by clinical evidence.[3–7] The modifications for the EV implant consisted of increasing the wall thickness, resulting in greater robustness than its predecessor, the OsseoSpeed TX,[8] and configuring a single-position interface for custom abutments. Drilling protocols were also modified to achieve a stepwise undersize osteotomy adapted to the different bone densities to provide higher insertion torque values and optimize primary stability.[5]

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EV implants were first commercially available in January 2014. To date, the EV implant system was only documented in short-term clinical studies,[5] showing a high survival rate and stable bone levels at a 16-month mean follow-up. In a noninferiority trial, the EV was compared with its immediate preceding implant, the OsseoSpeed TX, and no significant differences were found in marginal bone loss at 12 months postloading.[9]

This retrospective study aims to evaluate the survival rate (SR) and the marginal bone loss (MBL) of the OsseoSpeed EV Implant system during a mean follow-up period of 42.1 ± 23 months used in a wide range of clinical scenarios in a nonuniversity setting.

MATERIALS AND METHODS

Study Design and Population

This observational study included all EV implants consecutively placed in the authors' private dental clinic from February 2013 to May 2021. No case of implant treatment was excluded from the study as long as the implants used were OsseoSpeed EV. Medical records and clinical and radiologic examinations performed at various follow-up intervals were retrospectively investigated.

The study followed the recommendations from the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. The Ethics Committee for Research with Medical Products of the Hospital General Universitario de Elche (Alicante, Spain) approved it with the registration code PI 51/2021.

The primary outcome was the proportion of failures to surviving implants, and the secondary outcome was the measured peri-implant MBL from the time of placement to the last available examination.

Definitions

An implant was considered a failure if it was mobile or exhibited clinical signs that led to implant removal. An implant was considered surviving if it was still in function at the last available follow-up. All implant losses were classified as failures regardless of cause and timing. Early failures were defined as those occurring during the healing period before the rehabilitation procedure, and late failures were defined as those occurring after the definitive prosthesis was placed.

Implants categorized as "unaccounted for" were from all patients who did not attend the review during the follow-up period. The most recent radiologic record date calculated the particular patient's follow-up time.

Patients with a history of periodontitis were categorized as those with at least four sites with clinical attachment loss ≥ 3 mm assessed by probing or those who had received periodontal therapy or dental extractions for periodontal reasons during the year before the placement of implants.

Indicators used to define parafunction included signs of teeth or restoration attrition with exposed dentin and facets, hypertrophic masticatory muscles, and the presence of fractured teeth or restorations.

Bone volume and bone quality were categorized according to the Lekholm and Zarb classification[10] and were assessed using CBCT images and the perceived resistance by the operator when drilling.

Clinical Procedure

Before surgery, patients received a complete clinical and radiographic examination and consultation to obtain informed consent regarding the planned treatment and expected prosthesis.

This study entailed a wide range of clinical procedures. Thus, different anesthetic techniques, including sedation, were used depending on the clinical situation. Likewise, antibiotic prescriptions and various bone augmentation procedures and biomaterials were applied depending on the case.

The osteotomy preparation and implant placement were performed according to the manufacturer's instructions. Manufacturer protocols were adapted to the surgical case's bone density and specificities. Prosthetic rehabilitation was performed by the authors working as a team and with identical protocols.

Both immediate loading protocols and delayed loading protocols (ie, a healing period of up to 6 months before loading) were included. Final restorations varied from fixed (single crowns or partial bridges) to removable (total or partial). Similarly, the abutments used varied according to the type of prosthesis placed. However, as the cohort's common characteristic, only the OsseoSpeed EV Implant system was used in all cases. Patients were followed up monthly for the first 3 months after prosthesis placement, and the maintenance protocol was scheduled every 6 months thereafter.

Data Collection

The data was obtained from the electronic medical record by reviewers independent of the researchers and explicitly trained. Statistical processing was also performed by a specialist who did not participate in the study. Dates of failures or last available examinations (for surviving implants) were noted.

Eleven data types were collected as potential influencers of implant survival and MBL. Therefore, the following data were included as study variables:

- The demographic data of the patient (age, sex, and surgery date)
- The presence of periodontitis or bruxism and the medical status (medical conditions included

diabetes, cardiovascular disease, osteoporosis, liver disease, and multiple sclerosis)
- The length and diameter of the placed implants in millimeters
- The insertion torque value (ITV) and implant stability quotient (ISQ) as obtained during and after implant placement
- The bone volume and density in the implant site
- The position of the tooth where the implant was inserted, according to the notation of the FDI (World Dental Federation)
- The timing of implantation after tooth extraction (immediate or not)
- Whether a bone augmentation procedure was used (yes or no)
- The timing of loading in months
- The type of abutment (Uni Abutment EV, Atlantis, Locator, or others)
- The type and extension of the prosthesis (single unit, partial, or complete arch; cement-retained, screw-retained, or removable).

Radiographic Examination

The bone level was measured in panoramic or periapical digital radiographs. To include bone remodeling from initial healing, a radiograph taken at implant placement was adopted as the baseline. Digital radiographs were exported to Sidexis software (Sirona Dental Systems), where an independent reviewer made linear measurements from the implant shoulder (the apical margin of the bevel) to the most coronal bone-to-implant contact at the mesial and distal. This measurement was adjusted according to implant length and pitch distance (Fig 1). To minimize projection distortions in the periapical radiographs, only those showing symmetric implant threads, demonstrating the perpendicularity of the beam, were taken into account (Fig 2). Magnification of panoramic radiography was corrected using the known implant length and the number of implant threads (Fig 3). Time from baseline and distances measured were recorded when a change in bone level was first observed and at the last available examination. An agreement on each unreadable radiograph was reached between the reviewer who was measuring and the two principal investigators. Unreadable records were counted as a percentage of total radiographs performed, and unmeasurable implants were classified along with dropouts.

Statistical Analysis

First, descriptive statistics using means and SD for quantitative variables and percentages for qualitative variables were applied to the primary and secondary outcomes—SR of implants and MBL, respectively—and the 11 independent variables recorded. Tables were made at the patient and implant levels, simple and combined with survival/failure and the presence or absence of MBL (yes/no). Likewise, life tables were made, and the Kaplan-Meier function was used to describe the cumulative SRs.

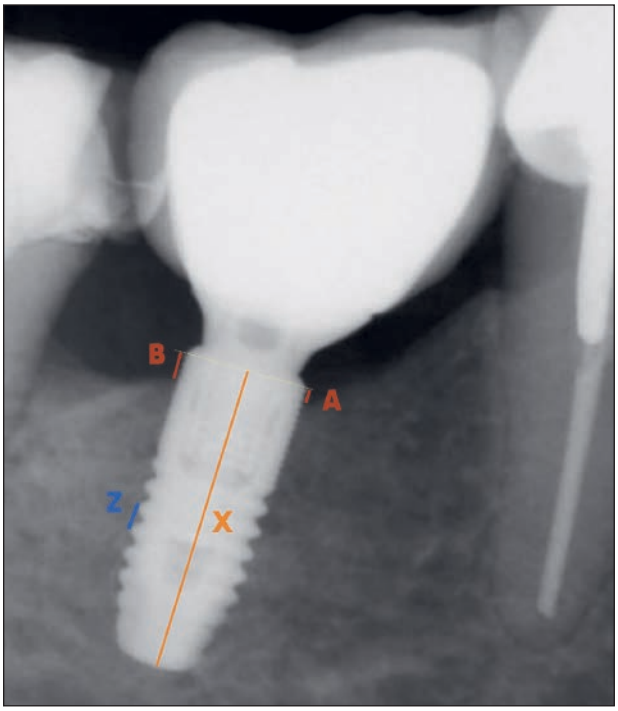


Fig 1 Using the available length of the implant (x = 9 mm) and the interthread distance (z = 0.66 mm), the bone levels A *(mesial)* and B *(distal)* can be reliably calculated with the help of software magnification.

To investigate the influence of the 11 independent variables on time to early and late implant failures, univariate Cox regression models, adjusted for clustering effects by using GEE (Generalized Estimating Equations), were run at the implant level. Logistic regression models were also conducted to analyze failure events at the patient level. Similar models were performed using GEE to analyze MBL presence at the implant level. The SR relationship was determined for each variable as a hazard ratio (HR) with a CI of 95% and odds ratio (OR), respectively. Factors found significant in univariate analysis were combined in multiple Cox and logistic models, considering a *P* value lower than .05 as significant.

Statistical power was estimated at 87.2%, for a relative risk of 3 and 95% CI, after correcting for intrasubject dependence, assuming a moderate correlation (ICC = 0.5).

RESULTS

The total study sample consisted of 597 EV implants placed in 235 patients, 87 male (224 implants) and

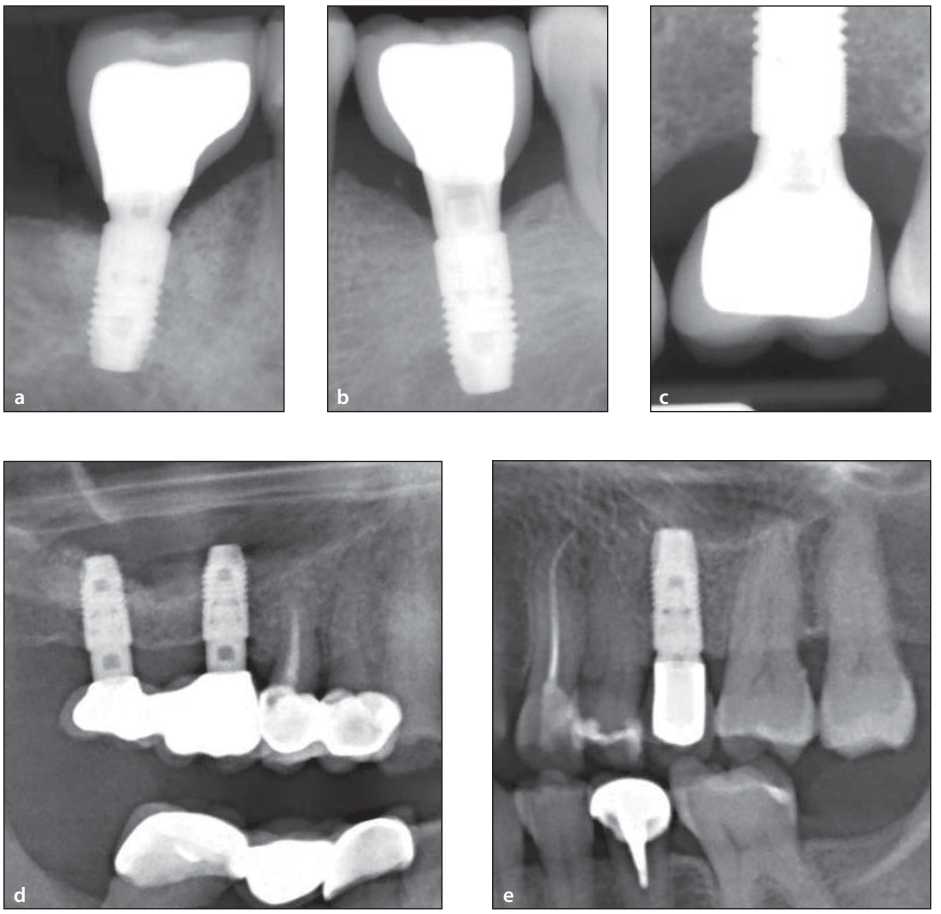


Fig 2 Examples of radiographs used to measure MBL in the study. *(a to c)* Periapical radiographs. *(d and e)* Enlarged areas of interest from panoramic radiographs.

148 female (373 implants), with a mean age of 59.2 years. Patients were treated in a private practice by one of two surgeons (E.C.L. or E.P.G.) and followed up for a mean period of 42.1 ± 23 months (range: 10 to 94 months).

During the observation period, 44 implants (7.4%) were lost—34 early (5.7%) and 10 late (1.7%)—in 38 patients (16.1%). Of the 563 implants that initially survived and received the prosthesis, 26 implants could not be followed up on because 11 patients did not attend the scheduled follow-up visits. In another nine cases, the radiographs were considered unreadable due to malposition in two panoramic radiographs of patients with neurologic diseases and seven periapical radiographs without perpendicularity or focused outside the region of interest, all of which were classified as dropouts (Fig 4).

Tables 1 and 2 show the results relating the variables recorded in the study with implant failure rates in percentages and with the *P* values obtained from simple logistic models. Table 1 includes the patient's profile, and Table 2 includes the implant's characteristics.

At the patient level, the proportion of patients whose implants all survived was 83.8% (95% CI: 79.1%–88.5%). Three factors influencing implant failure appeared to be statistically significant: bruxism (OR = 3.29; *P* = .009**), periodontitis (OR = 2.18, *P* = .030*), and the number of implants placed in a patient (OR = 1.43; *P* = .001**), as displayed in Tables 1, 3, and 4.

At the implant level, the overall SR was 92.6% (CI: 90.5% to 94.7%), and the proportion of patients with all their implants surviving was 83.8% (CI: 79.1% to 88.5%). The Kaplan-Meier cumulative survival curve is shown in Table 5 and Fig 5. Multivariate regression for total failures yielded two statistically significant variables: immediate implantation (HR 2.35, 1.11–4.96, *P* = .025*) and implant diameter (HR 0.37, 0.18–0.78, *P* = .009**) (Fig 6).

Of the total number of implants that failed, 34 did so early (5.7%) before prosthesis placement. Of these 34 early failures, premature loading was confirmed in 7 implants in four patients. In two patients, the prosthetic bases rested over implantation sites with visible decubitus around them. One patient declared pain after unintentionally chewing on the recently placed temporary fixed prosthesis, and another exhibited a lingual habit of pushing the healing caps. Both bruxism (HR 2.04, 1.01–4.13, *P* = .046*) and tooth position (HR in molars 0.35, 0.13–0.97, *P* = .045*) were significantly associated with the probability of early failure (Table 6).

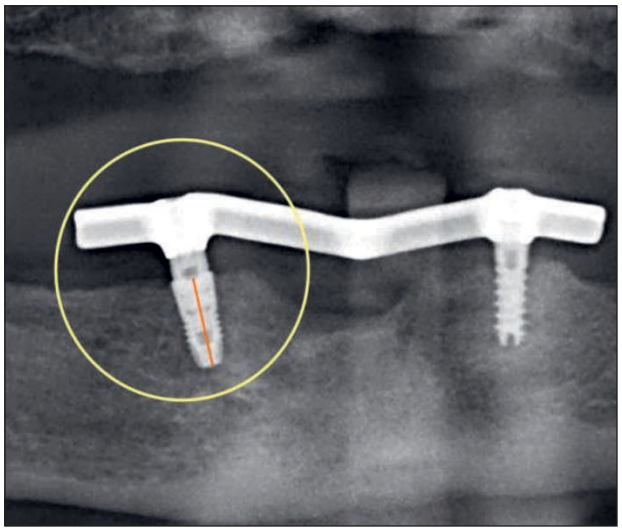


Fig 3 The rule of three allows for correction of the distortion of the panoramic radiograph.

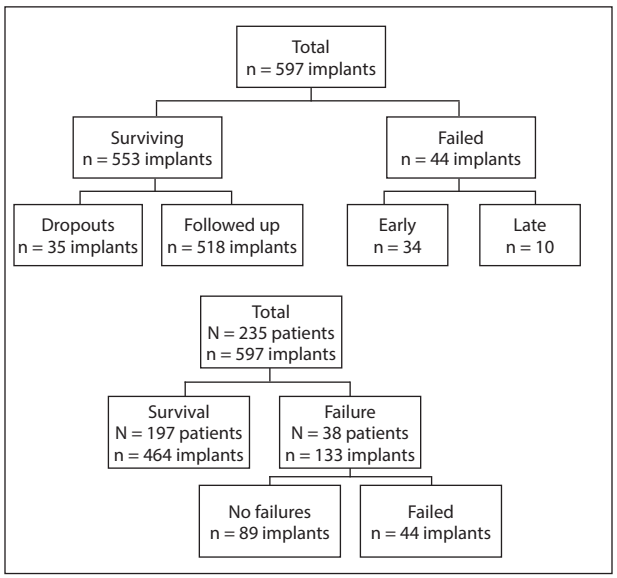


Fig 4 Flowchart of the study population. The upper chart describes the number of implants followed. The bottom chart describes the patients with either all implants surviving or some implant failure.

Another 10 implants failed late (1.7%), 8 of which had to be removed due to peri-implantitis and the other 2 due to implant fracture. All late losses had previously detected MBL. The probability of survival in the study of an implant that did not fail early was 98.2% (CI: 97.1% to 99.3%). Implants in the mandible were more likely to fail late. Both advanced age and implant length appeared to be significant protective factors for late failure (Table 7).

To analyze the MBL, early failures and dropouts were excluded, reducing the sample to 528 implants, of which 412 implants (78%) had an MBL ≤ 0 mm during the observation time and 106 surviving implants (22%, CI: 18.4% to 25.5%) showed an MBL ≥ 0.5 mm. The mean MBL for the 116 implants in which it was present (106 surviving implants and 10 late failures) was 1.42 ± 1.08 mm (range: 0.25 to 6.75 mm). The variables significantly associated with MBL were periodontitis (OR = 1.68; P = .062) and bone type C (OR = 2.03,

Table 1 Patient Profiles and Failure Rates

	Total	Failure rate	*P* value
No. of patients	N (%)	N (%)	
Smoking[§]			
No	158 (71.5)	22 (13.9)	
Yes	63 (28.5)	14 (22.2)	.726
Periodontal			
No	154 (65.5)	19 (12.3)	
Yes	81 (34.5)	19 (23.5)	.384
Bruxism			
No	209 (88.9)	29 (13.9)	
Yes	26 (11.1)	9 (34.6)	.009**
Diabetes			
No	217 (92.3)	34 (15.7)	
Yes	18 (7.7)	4 (22.2)	.961
Cardiovascular			
No	193 (82.1)	32 (16.6)	
Yes	42 (17.9)	6 (14.3)	.769
Osteoporosis			
No	216 (91.9)	36 (16.7)	
Yes	19 (8.1)	2 (10.5)	.490
Hepatic			
No	230 (97.9)	38 (16.5)	
Yes	5 (2.1)	0 (0.0)	–
Multiple sclerosis			
No	234 (99.6)	37 (15.8)	
Yes	1 (0.4)	1 (100)	–
Nephropathy			
No	234 (99.6)	38 (16.2)	
Yes	1 (0.4)	0 (0.0)	–
Stroke			
No	234 (99.6)	38 (16.2)	
Yes	1 (0.4)	0 (0.0)	–
Allergy to penicillin			
No	228 (97.0)	35 (15.4)	
Yes	7 (3.0)	3 (42.9)	–
Medical history			
No	88 (37.4)	10 (11.4)	
Yes	147 (62.6)	28 (19.0)	.629

P values were added from simple logistic models for the probability of failure: *P < .05; **P < .01; ***P < .001.
[§]Data are lacking for 14 patients.

Table 2 Implant Characteristics and Failure Rates

	Total	Failure rate	*P* value
No. of implants†	n = 597	44 (7.4)	
Length			.699
6 mm	70 (11.7)	5 (7.1)	
8 mm	79 (13.2)	3 (3.8)	
9 mm	119 (19.9)	8 (6.7)	
11 mm	213 (35.7)	21 (9.9)	
12 mm	2 (0.3)	0 (0.0)	
13 mm	98 (16.4)	5 (5.1)	
15 mm	16 (2.7)	2 (12.5)	
Diameter			.030*
3.0 mm	54 (9.0)	6 (11.1)	
3.6 mm	261 (43.7)	24 (9.2)	
4.2 mm	230 (38.5)	12 (5.2)	
4.8 mm	52 (8.7)	2 (3.8)	
ITV	n = 489		.075
	19.2 ± 11.4 (17.0)		
ISQ	n = 145		.533
	68.5 ± 13.2 (71.0)		
Bone volume	n = 590		.428
A	169 (28.3)	17 (10.1)	
B	290 (48.6)	17 (5.9)	
C	128 (21.4)	10 (7.8)	
D	3 (0.5)	0 (0.0)	
Bone density	n = 590		< .001*** ?
D1	24 (4.0)	2 (8.3)	
D2	237 (39.7)	20 (8.4)	
D3	296 (49.6)	22 (7.4)	
D4	33 (5.5)	0 (0.0)	
Arch			.078
Maxilla	326 (54.6)	19 (5.8)	
Mandible	271 (45.4)	25 (9.2)	
Position			.416
Anterior	110 (18.5)	12 (10.9)	
Premolar	179 (30.0)	15 (8.4)	
Molar	308 (51.6)	17 (5.5)	
Immediate placement			.024*
No	420 (70.4)	23 (5.5)	
Yes	177 (29.6)	21 (11.9)	
Bone augmentation			.676
No	315 (52.8)	21 (6.7)	
Yes	282 (47.2)	23 (8.2)	.961
Healing time (months)	n = 563		.281
	5.9 ± 3.6 (5.0)		
Abutment type			< .001*** ?
Stock for screw-retained	350 (62.2)	3 (0.9)	
Custom CAD/CAM	175 (31.1)	7 (4.0)	
Locator	12 (2.1)	0 (0.0)	
Other	26 (4.6)	0 (0.0)	
Prosthesis type			< .001*** ?
Single-unit	164 (20.1)	7 (4.3)	
Partial fixed	232 (41.2)	2 (0.9)	
Full arch fixed	122 (21.7)	0 (0.0)	
Partial removable	27 (4.8)	1 (0.8)	
Complete removable	18 (3.2)	0 (0.0)	
Retention			< .001*** ?
Screw-retained	499 (88.6)	10 (2.0)	
Cement-retained	24 (4.3)	0 (0.0)	
Frictional	40 (7.1)	0 (0.0)	

†N: number of implants (%) or mean ± SD (median).
P values are from simple logistic models for the probability of failure:
*$P < .05$; **$P < .01$; ***$P < .001$. ?: noncomparable groups.

P = .034*). In addition, when the postplacement ISQ ≥ 69.2, no subsequent MBL was detected. Early MBL detection, either before or after placement of the prosthesis, was a predictor of late failure (*P* < .001***), as the models showed that a higher MBL implied shorter survival times (HR = 2.48, *P* = .002**)—that is, each additional 1 mm of MBL multiplied the HR of failure by 2.5. Figures 7 and 8 show the evolution of MBL over time from placement of the prosthesis and from the first detection of bone loss, respectively.

DISCUSSION

Regarding the study's primary outcome, the percentage of missing data (35 implants, 5.8%, assessed as unaccounted for) can be considered acceptable for a reliable estimate in the study population. Although the study sample had no exclusions, the dropout rate

Table 3 Probability of Failure According to Patient Profile (Simple Binary Logistic Regression Model)

	OR	95% CI	*P*-value
Sex			
Male	1		
Female	0.78	0.38–1.57	.775
Age	1.00	0.98–1.03	.833
Smoker			
No	1		
Yes	1.77	0.84–3.72	.135
Medical history			
No	1		
Yes	1.84	0.84–3.99	.125
Bruxism			
No	1		
Yes	3.29	1.34–8.07	.009**
Osteoporosis			
No	1		
Yes	0.59	0.13–2.66	.490
Cardiovascular			
No	1		
Yes	0.87	0.34–2.23	.769
Periodontitis			
No	1		
Yes	2.18	1.08–4.40	.030*
Diabetes			
No	1		
Yes	1.54	0.48–4.95	.471
No. of implants placed	1.43	1.15–1.78	.001**

*$P < .05$; **$P < .01$; ***$P < .001$.

Table 4 Probability of Failure According to Patient Profile (Multiple Logistic Regression Model)

	OR	95% CI	*P*-value
Bruxism			
No	1		
Yes	3.44	1.35–8.78	.010*
Periodontitis			
No	1		
Yes	1.92	0.92–4.01	.084
No. of implants placed	1.40	1.11–1.75	.004**

*$P < .05$; **$P < .01$; ***$P < .001$.

Table 5 Life Table

Time	Survival	Standard error
3 months	0.953	0.009
6 months	0.946	0.009
1 year	0.944	0.009
1.5 years	0.942	0.010
2 years	0.942	0.010
2.5 years	0.936	0.010
3 years	0.934	0.011
3.5 years	0.934	0.011
4 years	0.926	0.012
4.5 years	0.916	0.014
5 years	0.916	0.014
5.5 years	0.916	0.014
6 years	0.905	0.017
6.5 years	0.884	0.027
7 years	0.842	0.049

*$P < .05$; **$P < .01$; ***$P < .001$.

is about half the usual statistical estimates. During a mean observation period of 42.1 months (range: 10 to 94 months), the study showed an overall SR of 92.6% (CI: 90.5% to 94.7%). This figure aligns with other similar long-term studies with different implant brands, some from an academic setting and some from diverse private practices.[1,11–16]

To be considered successes, the surviving implants must be evaluated according to some success criteria. However, these criteria are still debated and remain an open question.[17–20] Besides MBL, the current approach considers multiple parameters related to the implant, the peri-implant soft tissue, the prosthesis, and patient satisfaction.[18] Nevertheless, the standardization of success criteria is still missing.[21] In addition, some of these parameters were not homogeneously recorded in the present retrospective study. For this reason, the SR was selected, and the life table was not classified according to success criteria, except for MBL.

Early Failure

Early failures represented 78% of all registered failures (5.7% of the total sample) and occurred in the first 3 months after surgery due to lack of osseointegration. This observation is consistent with most clinical studies on implant survival, where early failure is more common than late failure. In a cohort of 9,080 implants, early failures were found to be 83.48% of the total failures.[22] Five-year retrospective studies yielded early failure rates of 5.79%,[23] 5.74%,[24] and 6.68%, respectively.[25] One study

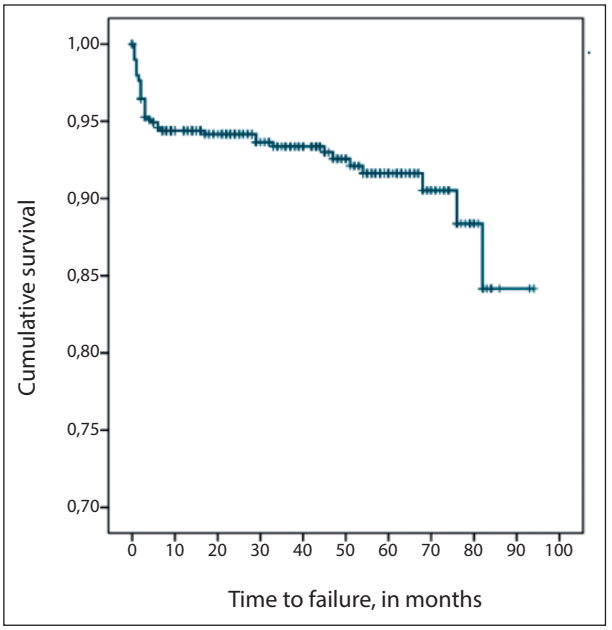
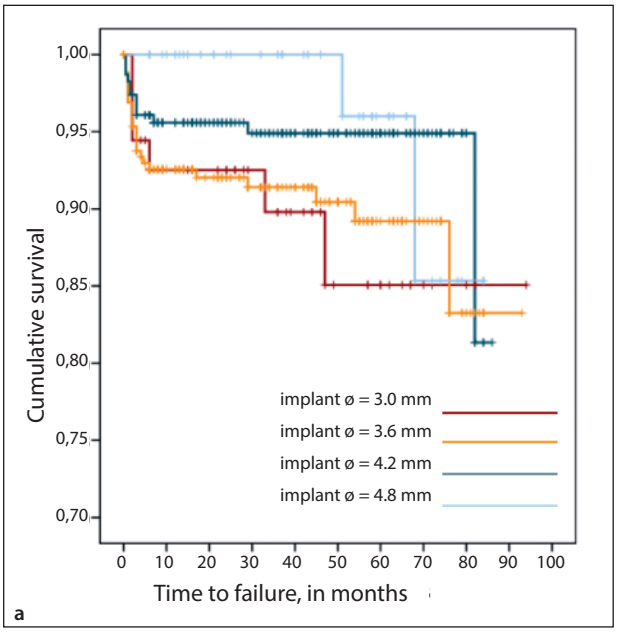


Fig 5 Kaplan-Meier diagram.



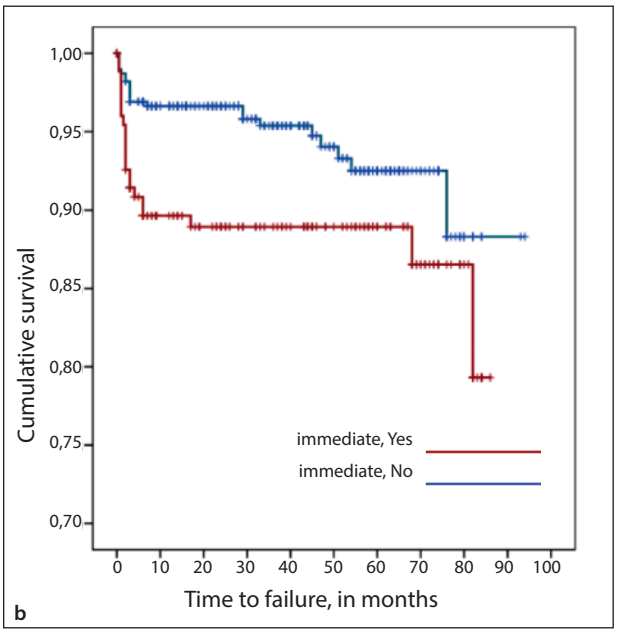


Fig 6 Cumulative SR for implant diameters *(a)* and immediate implant placement *(b)*.

with 30,959 implants reported an early failure rate of 1.3%,[26] while another with 11,311 implants reported an early failure rate of 1.4%,[27] and a recent retrospective study on 6,113 implants reported an early failure rate of 1.6%.[28] It can be speculated that more balanced early failure rates were obtained in those extensive population studies. At the same time, the setting can always influence a smaller analysis, the patients included, and the operators' personal interpretation of the clinical indications.

Late Failure

Late failures were 22% of all failures (10 implants, 1.7% of the total sample) and always were preceded by progressive MBL. Eight of these late failures (80%) were associated with peri-implantitis, ultimately leading to implant removal. This finding is consistent with a 10-year longitudinal retrospective study reporting 79.3% of implant failures associated with earlier diagnosis of inflammation or peri-implantitis.[29] Other cohort studies concluded that early MBL was a predictor of peri-implantitis,[2,19] consistent with the present study's significant result of early MBL detection as a predictor of late implant failure.

The two implant fractures reported in the present series (0.33% of the total) deserve special mention. Both were found in parafunctional patients, one at the implant body and the other at the neck level. The former was preceded by an MBL reaching half of the length, thus increasing the lever arm. The latter had a position slightly deviated mesially but did not show previous signs, although some mechanical instability may have preceded this type of fracture. The incidence of this severe complication remained at the level of previous reports.[30,31] Although a small number precludes drawing meaningful conclusions, the EV system seems more robust than its predecessors.[8]

Periodontal Involvement

Regarding risk factors for implant failure or bone loss, a history of periodontal disease doubled the risk of failure at the patient level compared to periodontal health. It was also a predictor of MBL, raising the risk by 68%. Both findings are consistent with some meta-analysis

Table 6 Early Failure According to the Variables Found Relevant in the Univariate Analysis

	HR	95% CI	*P* value
Bruxism			
No	1		
Yes	2.04	1.01–4.13	.046*
Diameter			
	0.67	0.33–1.38	.278
Tooth position			
Incisors	1		
Canines	0.91	0.22–3.68	.892
Premolars	0.66	0.29–1.54	.339
Molars	0.35	0.13–0.97	.045*

*$P < .05$; **$P < .01$; ***$P < .001$.

Table 7 Analysis of the Time until Late Failure According to Patient Profile and Implant Characteristics

	HR	95% CI	*P* value
Age			
	0.93	0.87–0.99	.034*
Length			
	0.77	0.59–1.01	.056
Arch			
Maxilla	1		
Mandible	8.33	1.61–43.1	.011*

*$P < .05$; **$P < .01$; ***$P < .001$.

concluding that periodontitis is a risk factor for implant loss, peri-implantitis, and higher implant-bone loss.[32–35] One study found no association between an initial diagnosis of periodontitis and implant failure.[36] It could be presumed and confirmed by the authors of this retrospective study that the strict treatment followed in their periodontal clinic could partly explain their results. An epidemiologic study calculated an OR of 3.3 for early failure in periodontal patients but without association with late failure.[27] However, the study focused on implant losses and not on peri-implantitis, which is an indicator of late failure according to the aforementioned meta-analysis.

Bruxism

As outlined in the Materials and Methods section, the variable "bruxism" was defined in the study by three clinical signs, without pretending to delimit a scientific definition of parafunctional pathology. A strong association of bruxism with total and early failures was found (see Tables 1 and 2). Bruxers showed more than three times the risk of implant failure compared to nonbruxers, at both the implant and patient levels. Bruxism was related to technical and not biologic complications in the literature.[37,38] Although not significant, 23.2% of bruxers had MBL, and half of these had previous mechanical complications. A 5-year study showed a 73.5% SR in bruxers,[39] similar to the present study's 65.4% medium-term SR obtained for bruxers.

Number of Implants

The analysis found that a greater number of implants placed implied a significantly higher risk of losing some. This is in agreement with other authors who have also reported the number of implants placed as a predictor of late failures.[19,40] However, the significance of this parameter could be related to the fact that these patients have lost many teeth due to periodontitis, lifestyle, medical conditions, or any other crucial reason. Therefore, these patients may be considered more likely to lose implants.

Immediate Placement

In concordance with previous reports, immediate implantation of fresh extraction sockets was confirmed to be a risk factor.[13,25,41] The study detected an HR for failure more than double that of delayed implant placement. This circumstance may have biased the SR toward a lower figure because 177 implants (29.6% of the sample) were immediately placed, and another 14 (2.3%) were immediate replacements after previous implant failures, thus implying higher risks. Only 22 out of 177 immediate implants were immediately loaded, most splinted in multiple-unit prostheses. However, the higher failure detected in immediate implantation cannot be attributed to loading.

Implant Geometries

In the present study, implant length tended to be a protective factor for late failure but without statistical significance to early failure. Two meta-analyses reported no difference in failure rates between short (≤ 8 mm or < 10 mm) and long (≥ 10 mm) implants[42] and between extra-short (≤ 6 mm) and longer (≥ 10 mm) implants.[43] However, another extensive meta-analysis including 353 publications with more than 185,000 implants showed a 2.5-times higher long-term risk of failure for implants < 10 mm than for implants > 10 mm.[44] Despite

the controversial literature, a possible explanation for the finding of the present study is that the longer the implant, the more resistance to mechanical overloading and the longer resistance to MBL before failure. In addition, shorter implants used to be placed in posterior areas, where bone height is limited. On the other hand, most factors leading to early failure can be related to a lack of initial osseointegration, which often occurs regardless of the length of the implant. Still, the multivariate analysis associated implant diameter with failure because the risk of implant loss would be halved for each additional 1 mm in diameter increase (–51%). Interestingly, the association was only found with early and not with late failure. It can be thought that the diameter reduction up to 3 mm in the EV implant does not entail a severe biomechanical risk leading to late loss. However, a higher risk could have been assumed by using narrow implants in sites with reduced bone volume, which could have induced this association between smaller diameter and early failure. Previous systematic reviews also found more implant failures with narrow diameters,[45,46] but others did not.[47] The reason for these different results remains unclear. Many confounding factors may influence failure rates related to implant geometries, so it is not easy to draw precise conclusions. More well-controlled studies are needed to clarify this point.

Marginal Bone Loss

Regarding MBL, the secondary outcome, 78% of the implants did not have any MBL at the end of the observational period. For the 22% of implants with some bone loss, the mean MBL after averaging mesial and distal was 1.6 mm (range: 0.5 to 7.5 mm). Leaving aside the multiple factors that can lead to MBL,[48,49] there is no figure for the amount of bone loss that can be assumed to be acceptable and maintainable in the long term. A bone loss of 1.5 mm in the first year after loading is generally accepted, followed by 0.2 mm annually.[50] However, it must be taken into account that in this report, the reference radiograph was taken on the day of implant placement to include the bone remodeling of the healing period before prosthetic loading. Indeed, the generally stipulated approach of using the reference radiograph on the day of prosthesis placement is no longer valid for the increasingly used early or immediate loading protocols.[51] If the baseline radiograph had been obtained some weeks after surgery, the initial bone remodeling to establish the biologic width would have been ruled out, and thus the MBL would have been lower. In the Pisa Consensus, 2 mm of bone loss at 1 year postsurgery was categorized as a success (Implant Quality Scale Group I).[17] Therefore, 2 mm would be the cut-off point between normal and pathologic bone loss.[19] The proportion of implants in the study reaching the threshold of ≥ 2 mm MBL in mesial or distal at the end of the follow-up period was 8.14% (43 implants). Accordingly, the SR compatible with a successful MBL (≤ 2 mm) would have been 91.86%.

In addition to the previously discussed periodontitis, the analysis found a significant association of MBL with bone type C. Low bone volume has been associated with implant failure[52] but rarely with MBL. This relation might be due to the reduced thickness of the bone surrounding the neck of the implant. Because there is no periodontal vascular network, the crestal bone becomes unstable below a "critical thickness," and resorption is the biologic response[53,54]; in addition, a thinner crest would support heavier stress and strains, thus risking overloading.

Limitations

Unfortunately, due to the heterogeneous clinical interventions of the study, various parameters could not be validly analyzed, especially those related to prosthetics. Indeed, the removable, cement-retained, and friction-retained prostheses, with their corresponding abutment and retention types, were represented in a small proportion and did not present any failures. With a total number of 10 losses, it is usual to have levels of a factor with 0 failures, and therefore its HR would be 0 ($P < .001$), rendering invalid any statistical comparison between the different categories.

The retrospective data upon which this study was conducted did not include organized soft tissue reporting. This limitation prevents a complete description of implant statuses. Indeed, some surviving implants could be at risk with signs of inflammation, although most may have already been recorded as surviving implants with MBL. For this reason, the authors believe that the study captures the overall clinical picture despite this weakness.

Retrospective clinical observation carries an inherent risk of bias, which can reduce the validity of the results. Indeed in the current study, data were recorded without previously defined study protocols, and evaluation was made a posteriori with the possible missing detection of minor complications. Despite this limitation, bias could have been minimized because the study population was made of consecutive treatments with EV implants, and patient selection had no exclusions. Still, on the other hand, the lack of exclusion criteria makes it difficult to have the numerous confounding factors adequately controlled.

In addition, the private environment could have often made it difficult to strictly adhere to the requirements of a study. However, this setting makes it possible to be considered representative of the actual use of an implant system in routine clinical practice. Indeed, evidence-based treatments and controls are difficult

to fulfill in the private clinical setting,[36] a circumstance that is hardly captured in academic research.[35] Therefore, compared to studies in the university setting, the external validity of this type of study could be assessed as relevant for the effectiveness of the treatment in daily practice.

The different timing in follow-up radiographs is another limitation because it leaves the description of the clinical outcome incomplete. This heterogeneous evaluation made it impracticable to closely relate the bone levels measured with the clinical evolution of the implants. Historical data yielded differences in the timing of radiographs. Therefore, some patients may have been monitored more frequently than others. As this limitation was known, statistics were calculated after stratifying the follow-up radiographs over time intervals, thus minimizing this potential disparity and tracing the evolution of MBL over time. Aside from some outliers in the scatterplots, there was a marked overall trend toward stable peri-implant bone levels in Fig 7, with the center line relatively horizontal over time. The dots strongly deviating from the central tendency would correspond to the so-called "loser type" of implants.[19] Figure 8 shows a steeper center line pointing to the progression of MBL from the first detection to the final radiograph.

Radiographic measurement of peri-implant bone levels shows an intrinsic imprecision below the threshold of 1 mm,[17,55] as evidenced by the intra- and inter-examiner differences often found[56] and the systematic overestimation compared with surgical measurement.[57] In the present study, it was decided to set the bone loss detection threshold at 0.5 mm, since applying a resolution of tenths of a millimeter to the radiographic estimation of the bone level can be considered a mathematical precision not reproducible in actual practice.[17] The utilization of panoramic radiography in nearly 70% of the MBL measurements could be a weakness because periapical radiographs have been considered the best way to assess MBL.[47,58] However, panoramic radiography was performed using a reproducible, standardized parallel technique. Some authors found it reliable[19] and without significant differences with periapical radiographs when measuring bone levels.[51,59,60]

Despite these limitations, this retrospective study based on medical records allows valid conclusions about its objectives: first, the failure rate and SR, and second, the presence and amount of radiographic MBL of the EV implant system in routine use in a private practice setting. Accordingly, the possible influence of multiple factors on early and late failure rates was also statistically analyzed.

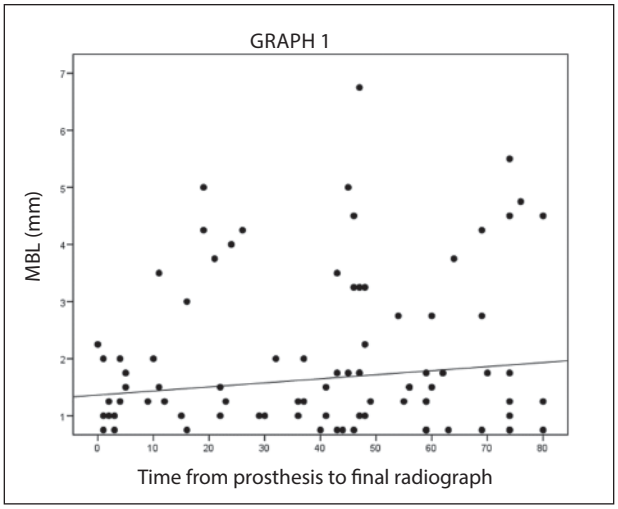


Fig 7 Progression of MBL from the time the prosthesis was fitted to the last available radiographic control.

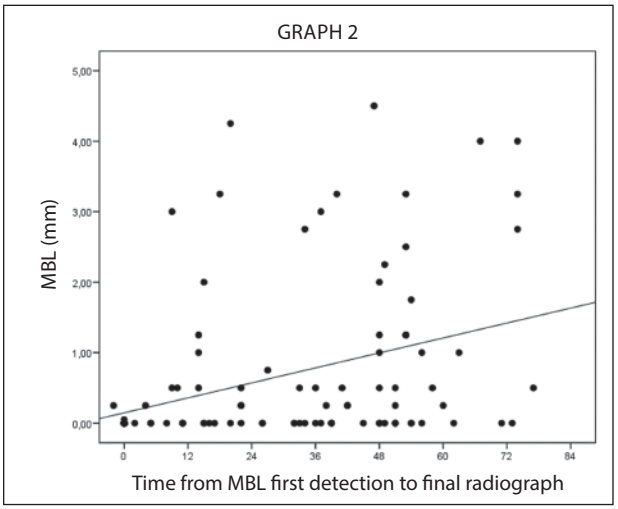


Fig 8 Progression of MBL from first detection of bone loss to the last available radiographic control.

CONCLUSIONS

The SR of the OsseoSpeed EV Implants after 1- to 8-year follow-up was 92.6%, a rate considered acceptable considering that there was no selection of patients in the sample studied. At the end of the observation period, four EV implants out of five had a midterm MBL ≤ 0 mm, and 91.88% of all implants had an MBL below the 2 mm threshold. Therefore, it can be concluded that the EV implant system can be considered a valid alternative for routine use in a nonuniversity setting.

It can also be concluded that bruxism, history of periodontitis, implant diameter, and immediate postextraction placement affect implant survival. The other potential risk factors for implant failure that were checked were not found to be statistically significant. Clinicians should remember that implant survival never

reaches 100% in actual practice and that bruxism, periodontitis, narrow-diameter implants, and immediate placement were risk factors for a higher failure rate.

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