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Diagnosis of implant stability and its impact on implant survival: a prospective case series study

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Abstract

Objectives: To assess the predictability of implant stability assessment either clinically or by resonance frequency analysis (RFA).

Material and methods: This prospective case series study evaluated 4114 consecutive SLA Straumann® implants in two private clinics. Primary stability was classified in four categories, depending on the degree of implant rotation when tightening the healing cap: A (no rotation at all), B (light rotation with a feeling of resistance), C (rotation without resistance) and D (rotation and lateral oscillation). In one clinic ($n = 542$ implants), RFA method was also used the day of the surgery (Osstell 1) and at restoration placement (Osstell 2). Survival rates were stratified according to the clinical classification categories using life table analysis. The association between Osstell 1 and 2 and the clinical classification was tested with ANOVA.

Results: 3899 implants were classified as stable (A) and 213 as unstable (B–D). Their survival rates were 99.1% and 97.2%, respectively. The unstable implants were further classified in B (158), C (51) and D (4), with survivals of 98.1%, 94.1% and 100%, respectively, being these differences statistically significant ($P < 0.009$). Using Osstell®, implants were stratified in two groups according to a predefined threshold of implant stability quotient (≥ 60). At the Osstell 1 measurement there was no significant association between primary stability and implant survival ($P < 0.753$). In Osstell 2, however, the association was significant ($P < 0.001$).

Conclusions: Only secondary stability RFA values were able to significantly predict implant outcomes, but not primary stability values. There was a good correlation between RFA and the proposed clinical classification of primary stability.

Oral implants have demonstrated a high predictability supporting fixed prosthetic rehabilitations provided certain conditions are met during their surgical installation and healing, leading to osseointegration. When the implant is stable in the bony bed during placement and during healing, new bone will predictably fill the bone-to-implant interface and most of the implant surface will become in direct contact with living bone (Ivanoff et al. 1996; Lioubavina-Hack et al. 2006). The attainment of this biological process, therefore, depends both on the primary implant stability at surgical insertion and in the lack of micro-movements during the healing period (Friberg et al. 1999a, 1999b; Ivanoff et al. 1996; Lioubavina-Hack et al. 2006). In the original clinical implant protocols, osseointegration was achieved by long initial healing periods (3–6 months) in which implants remained unloaded to assure an undisturbed bone apposition onto the implant surface (Albrektsson et al. 1981).

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The development of new implant surfaces and improved surgical approaches has, however, changed this paradigm, both improving the primary stability at implant insertion and by promoting of early osseointegration. This has enabled a marked reduction of this initial unloaded healing period, even to a point of immediate/early loading, provided implants demonstrate a high primary stability (Esposito et al. 2009). Primary stability at implant installation is achieved by the physical congruence between the surgically created bone bed and the implant, which is dependent from the macroscopic implant design, the surgical technique and the bone density (Glauser et al. 2004; O'Sullivan et al. 2004; Akkocaoglu et al. 2005; Sennerby & Meredith 2008). During the osseointegration healing period, bone gradually forms inside the implant threads and thus, the secondary stability is attained by an incremental degree of bone-to-implant contact. Different experimental studies have documented these healing events during this critical period and have shown that the process of new bone formation onto the implant surface is coupled with bone remodelling at the bone bed (Berglundh et al. 2003). This is translated clinically in a critical period during which, the primary stability decreases, while the secondary stability is getting established. During this transition, the risk of micro-movements and the potential for impairment of the osseointegration is enhanced (Oates et al. 2007). In order to avoid these risks, it would be desirable to have precise diagnostic tools to determine the minimum implant stability that would enable functional loading without jeopardizing implant outcome.

Several studies have tested different diagnostic methods aimed to assess implant stability. These methods range from those strictly based on clinical criteria, such as the clinical perception of implant resistance to rotation or the cutting resistance of the implant during its insertion (Orenstein et al. 1998; Friberg et al. 1999a, 1999b; Bischof et al. 2004), to those that utilize more objective and quantifiable criteria, although are invasive in nature, such as reverse torque measurements or histomorphometry, and therefore, can only be used in animal experiments. Two non-invasive diagnostic methods have been developed and tested to provide an objective, although indirect evaluation of implant stability and osseointegration, the Periotest® and the resonance frequency analysis (RFA) (Schulte & Lukas 1993; Meredith et al. 1996; Meredith et al. 1997; Isidor 1998). The RFA is a bending test of the implant–bone interface, where a transducer applies an extremely small bending force that is transmitted as a lateral force to the implant and then its displacement is measured. This system mimics the clinical loading condition of an implant, albeit of a much reduced magnitude. The first RFA device clinically available (Osstell®) consisted on a battery-driven frequency response analyzer and a transducer that was pre-calibrated for the different implant systems. The transducer was screwed to an implant fixture or abutment and elicited a quantitative outcome, *the implant stability quotient* (ISQ) ranging from 1 (lowest stability) to 100 (highest stability). The most recent RFA device is wireless, where a metal rod (peg) is connected to the implant by means of a screw (Osstell® Mentor) and it is excited by the magnetic pulses elicited from a handheld computer. This diagnostic device has been extensively used in experimental and clinical research for the last 10 years and has demonstrated a good correlation between the obtained ISQ values and the degree of stiffness between the implant and the bone (Meredith 1998; Becker et al. 2005; Zix et al. 2005; Kessler-Liechti et al. 2008; Sennerby & Meredith 2008; Zix et al. 2008). In fact, studies that have monitored ISQ values during implant healing have demonstrated a good correlation between clinical stability assessed by ISQ values and the biological events leading to osseointegration (De Smet et al. 2005; Huwiler et al. 2007). Similarly, implants demonstrating a failure in the osseointegration have shown low ISQ values or a shift towards low values (da Cunha et al. 2004; Glauser et al. 2004). In spite of these results, however, there is still a lack of precise information on the correlation between ISQ values and the short- and long-term implant outcomes, mostly with regards to implants with low primary stability. Moreover, it is still unclear how RFA values relate with the clinical perception of implant stability. The objective of this clinical investigation is therefore, to assess the predictability of implant stability assessment either clinically or by RFA in predicting the outcomes of implant therapy. As a secondary objective, this study aims to correlate ISQ values with the operator's clinical perception of implant resistance to rotation.

Material and methods

A total of 1680 patients were included in this prospective case series. These patients belonged to two private clinics, where 4114 SLA® (Straumann AG, Waldenburg, CH, Switzerland) implants were placed consecutively during 42 months (February 2004–September 2007). These implants served as abutments of different prosthetic rehabilitations, including single unit crowns, fixed partial bridges and full rehabilitations, both fixed and removable. These implants once loaded, were followed during varying periods, ranging from 6 months to 3 years.

All implants were placed by the same two surgeons (D.R. & L.A.) in their respective clinics. Before the start of the study, both clinicians agreed and were calibrated on the use of a classification system based on the clinical primary stability assessed by the perception of implant resistance to rotation when tightening the healing cap.

This classification (clinical perception to rotation) includes the following categories:

A. the implant does not rotate at all;
B. there is a light rotation with a feeling of resistance;
C. the implant rotates without resistance;
D. there is both rotation and lateral oscillation of the implant.

In one of the clinical centres (Centre 2), implant stability was also measured with RFA using the Osstell Mentor® device (Osstell AB, Gothenburg, Sweden). Two measurements were obtained, one after the implant was inserted (Osstell 1) and the other once the healing period was completed before the placement of the prosthetic restoration (Osstell 2) (mean: 2.8 months; range: 2–4 months). These RFA measurements were repeated at least twice with two different transducers, until obtaining ISQ values with a variation within ± 2. In case of discrepancy the mean ISQ value was used for the analysis. The transducer was screwed manually and the measurement device was directed perpendicularly. RFA analysis was carried out in 542 consecutive implants.

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Table 1. **Distribution of stable and non-stable implants, CPR classification and rates of succcess and failure of implants according to clinical stability (A) and non-stability(B–D)**

Centre	Patients	Implants	Stable A	Non-stable B–D	CPR class				% success		% failures		
					A	B	C	D	A	B–D	A	B–D	Significance
1	1482	3572	3399	171	3399	132	38	1	3365 (99.0%)	166 (97%)	34 (1%)	5 (2.9%)	
2	198	542	500	42	500	26	13	3	497 (99.4%)	41 (97.6%)	3 (0.6%)	1 (2.4%)	
Total	1680	4114	3899	213	3899	158	51	4	3862 (99.1%)	207 (97.2%)	37 (0.9%)	6 (2.8%)	$P<0.009$

χ^2-test demonstrated statistically significant differences.

Table 2. **Life table analysis for the stable (type A) and non-stable (types B + C + D) implants**

Interval starting time	Implants entering this interval	Implants exposed to risk	Implants withdrawn during this interval	Implant failures (terminal events)	Probability of failure (%)	Probability of surviving (%)	Cumulative probability of surviving (%)
Life table stability type A							
0	3899	3899	0	34	0.87	99.13	99.12
3 months	3862	3862	0	3	0.08	99.92	99.05
1 year	3859	3859	0	0	0	100	99.05
3 years	3859	3859	0	0	0	100	99.05
Life table stability types B + C + D							
0	213	213	0	6	2.82	97.18	97.14
3 months	203	203	0	0	0	100	97.14
1 year	203	203	0	0	0	100	97.14
3 years	203	203	0	0	0	100	97.14

Table 3. **Survival and 3-year follow-up of stable (type A) and non-stable (types B–D) implants according to the CPR classification**

CPR	Implants	Failures	Before load	After load	1 year	2 years	3 years
A	3899	37 (99.1%)	31 + 3*	3	3	0	0
B	158	3 (98.1%)	3	0	0	0	0
C	51	3 (94.1%)	3	0	0	0	0
D	4	0 (100%)	0	0	0	0	0
Total	4114	43 (98.9%)	40	3	3	0	0

*Three implants failed after immediate loading (these implants were included in the 'before loading' group).

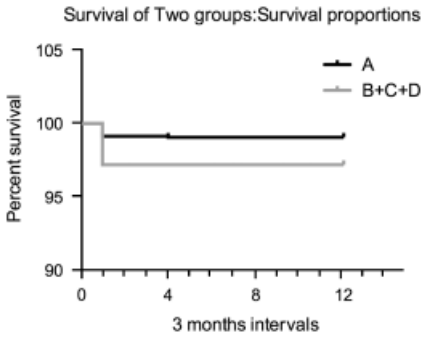

Fig. 1. Survival curve for stable implants (type A) and non-stable implants (types B+C+D)

In both centres, an implant was considered as a failure in presence of an infection not amenable for therapy and in presence of implant mobility when screwing the abutment at 35 N.

Data analysis

A life table analysis was constructed to assess implant survival in both centres. Survival rates were stratified according to the categories from the clinical classification used and the possible association between implant outcome and these categories was evaluated by the χ^2-test.

A threshold value of ISQ = 60 was used to stratify implants by stability (stable/non-stable), in both Osstell 1 and 2 measurements. These values were correlated with implant outcome and this relationship was assessed with the χ^2-tests and Fisher exact test.

To study the possible association between the primary stability assessed with RFA in Osstell 1 and the categories from the clinical classification, the mean ISQ values in Osstell 1 and in each of the four clinical categories were tested with the ANOVA test with the Bonferroni *post hoc* test.

Results

A total of 4114 implants were placed consecutively in 1690 patients in two clinical centres, centre 1 (3572 implants) and centre 2 (542 implants). Once the implants were definitively restored, they were followed for a period ranging between 6 months and 42 months. The distribution of the implants in the two centres is presented in Table 1. From all implants placed, 3899 (95%) were diagnosed as fully stable (category A) and 213 (5%) as unstable (categories B–D pulled together). From all implants classified as A, 37 failed, resulting in a cumulative survival rate of 99.1%. In the unstable group, six implants failed, resulting in a 97.2% survival rate. The ability of the clinical perception to rotation to predict implant failure is shown in Table 1. There was a statistically significant association between the unstable group and implant failure ($P<0.009$). The life table analysis of the implants according to the clinical categories is presented in Tables 2 and 3. Fig. 1 depicts the Mantel–Hantzel survival curve demonstrating that all implants except three failed before placing the restoration and all failed within the first year of function.

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Table 4. **Predictive value for failing implants in Osstell 1 and 2 using a threshold of ISQ = 60**

	Number of implants	Success	Failures	*P*-value (Fisher)
Osstell 1				
>60	505 (93.2%)	501 (99.2%)	4 (1.6%)	*P*=0.753
<60	37 (6.8%)	37 (100%)	0 (0%)	
Total	542 (100%)	538 (99.3%)	4 (0.7%)	
Osstell 2				
>60	521 (96.1%)	521 (100%)	0 (0%)	*P*<0.001
<60	21 (3.9%)	17 (80.9%)	4 (19.1%)	
Total	542 (100%)	538 (99.3%)	4 (0.7%)	

ISQ, implant stability quotient.

Table 5. **Relationship between Osstell 1 and 2 values with the primary stability assessed clinically and characterized as stable (A) and non-stable (B–D)**

	CPR	*N*	Mean (ISQ)	SD	*P*-value
Osstell 1	A	500	73.96	6.28	*P*<0.001
	B–D	42	63.31	10.03	
Osstell 2	A	500	76.74	6.99	
	B–D	42	72.24	7.93	

ISQ, implant stability quotient.

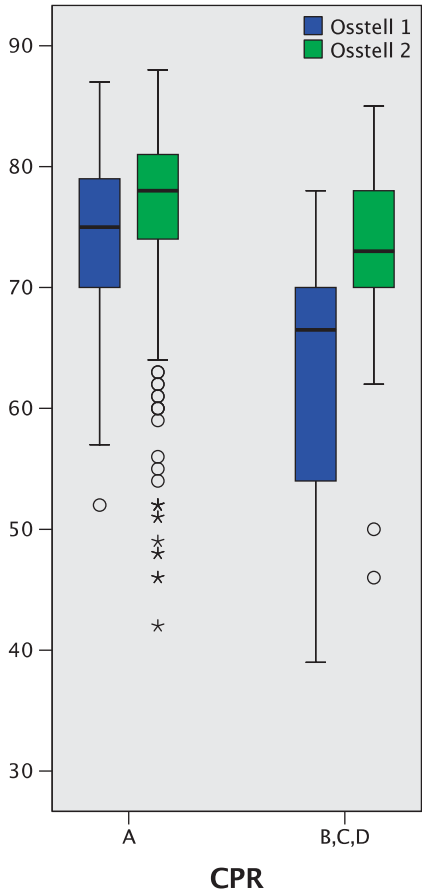

Fig. 2. Relationship between Osstell 1/Osstell 2 and stable/non stable implants. **Student t test $P \leq 0.001$, °paired student t test $P \leq 0.001$.

In centre 2 ($n = 542$), the ability of the RFA Osstell 1 and 2 measurements to predict implant failure using the threshold value of ISQ = 60 was tested. The results are presented in Table 4. RFA Osstell 1 failed to significantly predict implant failure ($P < 0.753$). However, Osstell 2 RFA demonstrated a statistically significant correlation ($P < 0.001$), In fact, there were no implants with ISQ > 60 at Osstell 2 that failed. However, from the 21 implants demonstrating ISQ values ≤ 60, four failed representing a 19% failure rate.

When the implants were aggregated as stable (A) and unstable (B–D) its association with the ISQ values was statistically significant for both Osstell 1 and 2 measurements Table 5 and Fig 2. Table 6 and Fig. 3 shows the RFA results at Osstell 1 and 2 distributed according the clinical categories. There was also a statistically significant association between the different clinical categories and their corresponding RFA values at Osstell 1 ($P < 0.001$) and 2 ($P < 0.001$).

Discussion

In this prospective case series study with more than 1500 patients and 4000 implants, we have evaluated the diagnostic validity of primary implant stability to predict implant outcomes. This primary stability was tested with two methods, the surgeon's clinical perception and by the Osstell Mentor®. With the first method, implants with primary stability (category A) demonstrated a significantly higher survival (99.1%) than implants belonging to the other three categories aggregated (97.2%). Although in both groups the survival rates were high, the failure rate increased according to the degree of lesser resistance to implant rotation (category B, 98.1% vs. category C, 94.1%). These results are in agreement with Orenstein et al. (1998), that followed 2641 implants, reporting that the survival rate in implants without primary stability (93.8%) was also significantly lower than the survival in primary stable implants (97.5%). These results are also in agreement with other clinical studies that have correlated implant stability and implant survival (Friberg et al. 1991; Orenstein et al. 1998; Sjostrom et al. 2005) and probably reflect the importance of an undisturbed healing in order to achieve adequate osseointegration, as it has been emphasized by different investigations (Pilliar et al. 1986; Aspenberg et al. 1992; Szmukler-Moncler et al. 1998; Lioubavina-Hack et al. 2006). In fact, Lioubavina-Hack et al. (2006) demonstrated experimentally the adverse effect of lack of primary stability on osseointegration. Furthermore, Ivanoff et al. (1996) verified histologically in rabbits that different ranges of primary stability influenced significantly the osseointegration process.

In spite of this demonstrated negative impact between lack of primary stability and implant survival, it is, however, remarkable the high implant survival rate (97.2%), achieved in these *unstable implants*, which is comparable with the results reported in other studies evaluating primary stable implants (Buser et al. 1997; Jemt et al. 2003; Fugazzotto et al. 2004; Fugazzotto 2008) and higher than in other studies evaluating unstable implants (Friberg et al. 1991; Orenstein et al. 1998; Balshi et al. 2007). The reason for this positive outcome probably lies on the implant surface used, as suggested from the results of the study by Orenstein et al. (1998) that demonstrated a higher success rate in mobile implants coated with hydroxylapatite (100%) than in implants without this coating (81.5%). Also Balshi et al. (2007) attained higher implant survival rates in unstable implants with a rough surface when compared with implants with a turned surface (91.7% vs. 70%). In this clinical study we have used implants with a moderately rough surface

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Table 6. **ANOVA test to assess differences between Osstell 1 and 2 values in each of the four categories of the CRP classification**

	Number of implants	Mean (ISQ)	95% CI Lower	95% CI Upper	*P*-value (ANOVA)
Osstell 1					
A	500	73.96	73.41	74.52	$P<0$
B	26	67.65	64.59	70.72	
C	13	58.31	52.65	63.97	
D	3	47.33	34.83	59.84	
Total	542	73.14	72.53	73.75	
Osstell 2					
A	500	76.74	76.12	77.35	$P<0.001$
B	26	71.35	67.73	74.96	
C	13	73.62	69.74	77.49	
D	3	74	65.39	82.61	
Total	542	76.39	75.78	76.99	

ISQ, implant stability quotient.

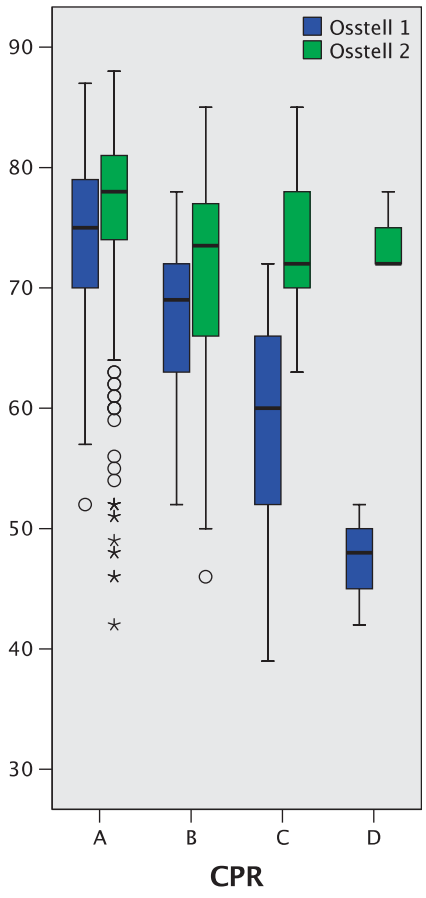

Fig. 3. Comparison between Osstell 1 and 2 for each of the CPR classification categories.

(Straumann SLA®). Implants with this micro-surface topography have shown excellent results in both experimental and clinical studies (Buser et al. 1991; Sammons et al. 2005) and their biological and clinical behaviour has shown to be superior, when tested against other implants with different micro-surface roughness (Buser et al. 1991; Wong et al. 1995; Li et al. 2002; Sammons et al. 2005). It is noteworthy that all implants with implant stability category D characterized by rotation and lateral mobility achieved osseointegration and long-term stability. This fact has also been reported by other authors, provided these implants are left submerged and unloaded during healing (Aouate 2004; Balshi et al. 2007)

As a non-invasive method to quantify the primary and secondary stability we used the evaluation of the RFA by the Osstell Mentor®. At implant placement (Osstell 1) this measurement was unable to predict implant outcome. In fact, there was not a single implant with Osstell 1 ISQ ≤ 60 that failed. These results are in agreement with studies evidencing the inability of RFA values to predict implant failure (Huwiler et al. 2007), while on the contrary, other studies have demonstrated a significant association between lack of primary stability measured by RFA and implant failure (Sjostrom et al. 2005). These discrepancies may be due in part to the many possible confounding factors that influence the outcome of unstable implants during healing (bone quality, loading during healing, type of implant surface, etc.). In contrast, the evaluation of RFA values to assess implant secondary stability (Osstell 2) demonstrated a statistically significant correlation with implant outcome. In fact, no implant with ISQ ≥ 60 failed, while 19% of implants (4/21) with ISQ ≤ 60 failed. These differences probably reflect differences in the degree of osseointegration attained, with a lower bone-to-implant contact in those implants with lower ISQ values, thus being more susceptible to excessive functional loading (Rasmusson et al. 2001). Different authors have attempted to establish thresholds for primary (Nedir et al. 2004; Ottoni et al. 2005; Huwiler et al. 2007) and secondary stability (Nedir et al. 2004) capable to predict higher risks for implant failure. In primary stability, although some authors have proposed ISQ thresholds from 49 (Nedir et al. 2004) to 60 (Liddelow & Henry 2007; Schincaglia et al. 2007; Stephan et al. 2007) the results are heterogeneous and mostly derived from studies evaluating immediate functional loading protocols (Liddelow & Henry 2007; Schincaglia et al. 2007; Stephan et al. 2007). In secondary stability assessment, the results obtained in this study are in agreement with Nedir et al. (2004) that reported a security threshold of 47 ISQs for recommending the screwing of a prosthetic abutment at 35 N. These results were obtained with the prior Osstell® device, which is reported to measure approximately 10 ISQ units lower than the current Osstell Mentor® device (Valderrama et al. 2007).

When assessing whether different degrees of primary stability according to the clinical classification would correlate with ISQ values measured with Osstell, both stable (A) and unstable implants (B– D) achieved higher ISQ values in Osstell 2, what demonstrates a higher bone–implant rigidity throughout the healing period, irrespective form the degree of primary stability (Bischof et al. 2004; Nedir et al. 2004; Huwiler et al. 2007; Strnad et al. 2008) corroborates the rapid osseointegration demonstrated by the SLA implant surface (Roccuzzo et al. 2001; Cochran et al. 2002). The unstable implants, however, did not reach the same ISQ values in Osstell 2 when compared with the stable implants. This may be explained because we used the same standard protocol with fixed healing periods without functional loading of 2–4 months, and this time was probably not long enough to complete osseointegration. The correlation between the obtained ISQ scores in Osstell 2 after the healing period (secondary stability) and the degree of osseointegration is still in debate (Meredith et al. 1997; Akca et al. 2006; Aparicio et al. 2006; Ito et al. 2008; Sennerby & Meredith 2008) with some authors advocating that what the ISQ

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values really represent is not the real bone-to-implant contact, but the stiffness of the bone-to-implant complex (Bischof et al. 2004; Turkyilmaz et al. 2009). In fact, it seems that only the most coronal third of the implant is what determines the degree of rigidity measured by RFA (Nkenke et al. 2003; Gedrange et al. 2005; Miyamoto et al. 2005). Irrespective of its significance at microscopic level, this investigation in agreement to other clinical studies (Friberg et al. 1999a, 1999b; Glauser et al. 2004; Nedir et al. 2004; Vanden Bogaerde et al. 2005) have shown the clinical relevance of using RFA, mainly in the assessment of secondary stability.

In summary, this study has shown that the attainment of primary implant stability is not a prerequisite for osseointegration and long-term implant survival. The clinical classification used based on the clinician perception (CRP classification) demonstrated diagnostic validity to predict implant survival. The Osstell Mentor® failed to predict the implant outcome when used at implant installation (primary stability), but however, when used after the healing period (secondary stability), significantly predicted implant failures.

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