5-YEAR PROSPECTIVE CLINICAL STUDY OF EARLY LOADED BIONIQ IMPLANTS WITH BIOACTIVE ALKALI-ETCHED SURFACE. RESULTS AFTER 1-YEAR OF FOLLOW-UP

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Abstract

The goal of the study is to assess the short- and long-term success rate of endosseous bioactive implants in partially edentulous patients treated with two-stage implant placement of early loaded BioniQ implants (LASAK Ltd.).
The report evaluates, clinically and radiographically, the success rate of BioniQ implants, the stability and behavior of hard and soft tissues surrounding the implants in the course of the healing period and the one-year loading period.
A total of 97 implants were consecutively placed in native bone in 43 edentulous and partially edentulous patients. After 1 year in function, all implants and restorations were stable and healthy. The cumulative implant success rate, based on life table analysis, was 100 % after 1 year of loading. The mean change in marginal bone level (ΔMBLp), after 1 year of loading, was 0.28 mm (SD 0.46) from the time of implant placement and 0.09 mm (SD 0.35) from prosthesis placement. A loss of bone tissue higher than 1 mm after one year in function has been shown in 2.2 % of implants from the placement of prosthetic restoration and 7.5 % from the implant placement. The BioniQ system showed a mean marginal bone loss over 1 year well below what was hitherto accepted as a success.
The results, within the range of the one-year observation period of the implants in function, demonstrate the high success rate of BioniQ implants, the high stability of peri-implant hard and soft tissues and the implant reliability and predictability when early loaded.

Introduction

In the last twenty years, the use of titanium endosteal implants has become the standard of clinical practice in the rehabilitation of edentulous or partially edentulous patients. This significant progress in dental implantology is based on the concept of osseointegration, first described by Brånemark (1969–1977). Osseointegration has become the basis of modern dental implantology (1, 2).
The Brånemark surgical protocol dominated dental implantology for more than two decades. The protocol delivered good long-term results in implantations. However, the patients had to comply with strict protocol requirements, especially during the 3- and 6-month healing period of the non-loaded implants. By the end of 1990s, the protocol began to lose its exclusive position and, furthermore, the attitude that the machined/turned surface of the intraosseous part of the implant is optimal, was mostly abandoned (3).
Already in the 1980s and 1990s, multiple studies evaluating the alternative surfaces of titanium implants, especially rough surfaces (4, 5, 6, 7) and bioactive surfaces (8, 9), were initiated. Such alternatives would facilitate better contact of the bone and the implant surface and, thus, enable shortening the healing period prior to loading.

First, the bioactive surfaces were prepared by coating the titanium substrate with bioactive ceramic materials, most often hydroxyapatite (10). Numerous experimental and clinical studies (11, 12) confirmed the ability of titanium implants with plasma-sprayed hydroxyapatite to accelerate osseointegration during the healing period. However, the problematic long-term stability of the hydroxyapatite coating in the biological environment (13) limited its wider clinical application.

Bioactivation of the titanium surface using, a chemical-treatment method instead of coating, eliminated the limitations of the bioactive coated titanium surfaces (14). This novel surface-modifying technology is based on chemical bioactivation of the titanium, resulting in a 3D, macro-, micro- and nanostructured hydrophilic titanium surface exhibiting bioactive properties, known as the BIO-surface (15, 16).
The advantages of the BIO-surface were demonstrated in a histometric study in an animal model (17), as well as on the basis of in vitro tests. In these tests, the cell behavior on the BIO-surface was observed and compared to polished, sand-blasted and acid-etched surfaces (18).
The success rate of the dental implants with the bioactive surface (IMPLADENT – BIO-surface; LASAK Ltd.) was documented in clinical trials employing the shortened treatment protocols of early (19, 20) and immediate loading (21, 22). Recently, the BIO-surface was used in combination with a novel design of the endosteal BioniQ dental implant with a conical implant-abutment connection.
The aim of the proposed study is to clinically and radiologically evaluate the success rate of the BioniQ implant, and the stability and behavior of peri-implant hard and soft tissues during the healing period and after one year of the implant in function.
Measurement of peri-implant bone loss/gain over time is considered to be a sensitive tool for the clinical assessment of the success rate of the implant (23). Therefore, together with the implant success criteria, the changes in marginal bone levels at individual time intervals of the treatment were considered as the primary endpoints in the clinical evaluation of the tested implants.
Hypothesis: Bone resorption of the early-loaded BioniQ implants will correspond to the implant success criterion of maximum mean bone loss of 1.0 mm (ΔMBLp) within the first year in function and maximum mean bone loss of 0.2 mm per year in the 5-year follow-up.

Materials and methods

Patient selection

Eligible patients receiving the implant treatment at the "Dental clinic, Radhošťská 4, Prague 3, Czech Republic", who met the selection criteria, were included in the prospective study.
Patient inclusion criteria for the study: Male and female patients 18+ years old, sufficient alveolar bone volume, alveolus without significant horizontal and/or vertical bone defects without the need for an augmentation procedure, implantation into the healed alveolar site 5–6 months following the extraction (3–4 months for single-rooted teeth), bone density D1, D2, D3 or D4 (according to the Lekholm-Zarb classification modified by Misch) (14) and a non-infected alveolar site. The treated patients had to have received full information about the treatment, and the advantages and disadvantages of the chosen procedure. The patients confirmed their agreement with their participation in the study by signed informed consent. The study was conducted in accordance with ethical principles and the Helsinki Declaration (1975, 2000).
Patient exclusion criteria for the study: Patients were excluded from the study due to general health contraindications for oral surgery, age lower than 18 years and smoking (more than 10 cigarettes per day).

Characteristics of the tested implants

Self-tapping screw-type BioniQ implants of cylindrical shape (Straight S3.5 BIO; S4.0 BIO; S5.0 BIO implants) and conical shape (Tapered T4.0 BIO; T5.0 BIO implants) with diameters of 3.5, 4.0 and 5.0 mm and lengths of 8, 10, 12, 14 and 16 mm were used in the study. The surface of the intraosseous part of the implant (fixture) was bioactive, hydrophilic BIO-surface and the connective tissue contact surface was modified BIO-surface. The abutment-fixture interface was a conical connection.

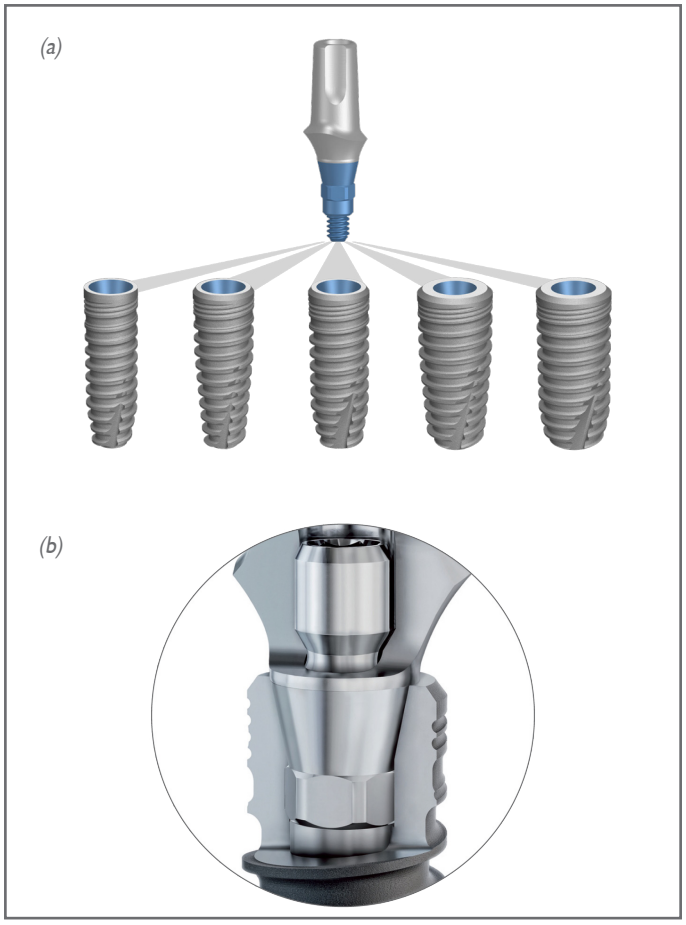


Fig. 1: (a) Cylindrical S3.5, S4.0, S5.0 and conical T4.0, T5.0 BioniQ implants with a single prosthetic platform; (b) the Q-Lock connection of the abutment and the intraosseous part of the implant (fixture) ensures a tight seal, adjustability, toughness and prosthetic flexibility.

Implant stability – Resonance Frequency Analysis

The stability of the implants was assessed using an Osstell ISQ device (Osstell AB, Sweden). The contactless measurement was based on RFA (Resonance Frequency Analysis). The ISQ (Implant Stability Quotient) was determined using two measurements perpendicular and parallel to the axis of the alveoli.

Marginal Bone Level measurement

The MBL (Marginal Bone Level) was determined from radiographs perpendicular to the central axis of the implant on the both sides of the implant (mesial MBLm and distal MBLd), in relation to the Reference Level (RL) of the implant shoulder (Fig. 2). The final value MBLp was determined as an average of the mesial MBLm and distal MBLd values. The length of the implant was used as a gauge.

The change in the marginal bone over time ΔMBLm, ΔMBLd, ΔMBLp was determined as the difference in the values measured at the individual time intervals in relation to the baseline at the time of implantation (implant placement MBL IM) or to the baseline at the time of placement of the dental prosthesis MBL (DP).

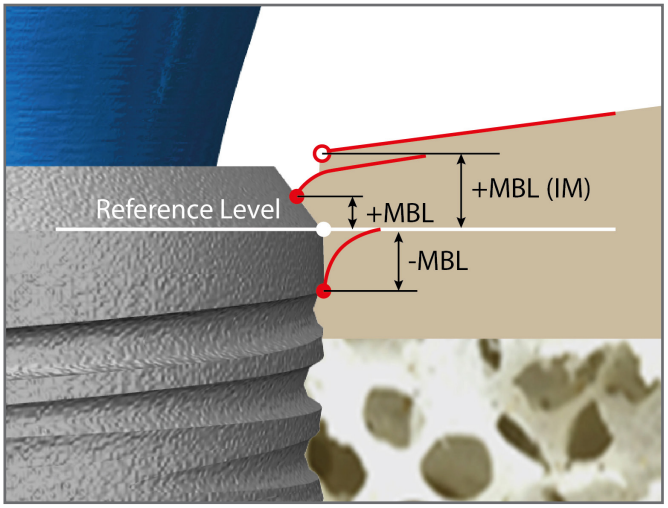


Fig. 2: Illustrative scheme of the measurement of the Marginal Bone Level (MBL), determined by the distance of the most apically/cervically located point of contact of the marginal bone and the implant (red dots) from the Reference Level (RL) given by the collar of the implant (white dot, line). If the Reference Level of the implant (white dot) is below the Marginal Bone Level (red dot), the MBL value is marked as positive (+MBL), otherwise it is marked negative (-MBL). The value of the Marginal Bone Level measured immediately after the implantation MBL (IM) corresponds to the position (submersion) of the implant in the alveolar bone just after insertion.

Facial Gingiva Level Measurement

Facial Gingiva Level (fGL), mesial Papilla Level (mPL) and distal Papilla Level (dPL) were measured in relation to the reference level of the incisal edge tangential to the apex. The measurements were performed at the time of placement of the dental prosthesis fGL (DP), dPL (DP), mPL (DP), after 3 months, 6 months and 1 year in function. The changes of Gingiva and Papilla Levels over time ΔfGL, ΔmPL and ΔdPL were determined according to the differences in levels measured at time intervals, related to the level at the time of placement of the dental prosthesis.

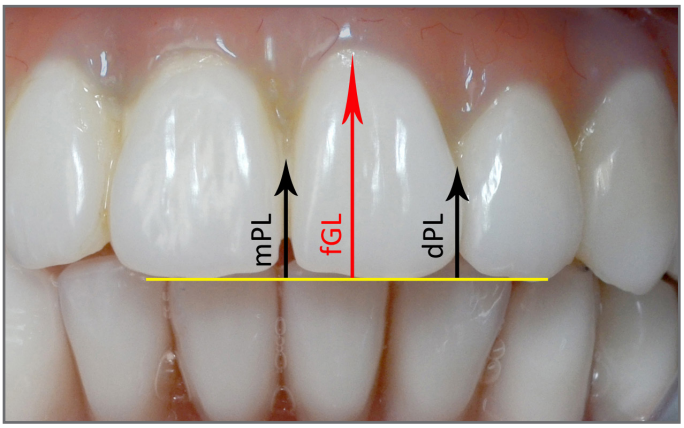


Fig. 3: Illustrative scheme of determination of the facial Gingiva Level (fGL) and mesial (mPL) and distal (DPL) Papilla Level.

Modified Plaque Index (mPI)

The plaque was assessed clinically at the mesial, distal, buccal and lingual surface as the average of four measurements. Score on a scale of 0–3: 0 – no plaque; 1 – scarce plaque deposits, removable by a probe; 2 – moderate plaque deposits, visible by eye; 3 – extensive plaque deposits.

Modified Sulcus Bleeding Index (mSBI)

The sulcus bleeding was assessed clinically using a probe at the mesial, distal, buccal and lingual surface as the average of four measurements. Score on a scale of 0–3: 0 – no bleeding on probing; 1 – isolated drop of blood; 2 – bleeding on the sulcus margin; 3 – profuse bleeding.

Surgical protocol

The dental implant placement was performed in a two-stage surgery with a shortened healing period – early loading (25). The patient was asked to rinse with a 0.12% chlorhexidine solution for two minutes immediately before the surgery. The implantation was performed under local anesthesia. Mucoperiosteal flaps were raised and the alveolar ridge equalization was performed, using a rotary drill, only to the necessary extent. Following equalization the implants were placed using the non-submerged protocol crestally (MBLp = 0.3 mm), supracrestally (MBLp < 0.3 mm), or the submerged protocol subcrestally (MBLp > 0.3 mm) (Fig. 4). The implants were placed subcrestally especially when reduced risk of soft tissue traumatization during the osseointegration was required, in thin gingival biotypes and in the esthetic area.

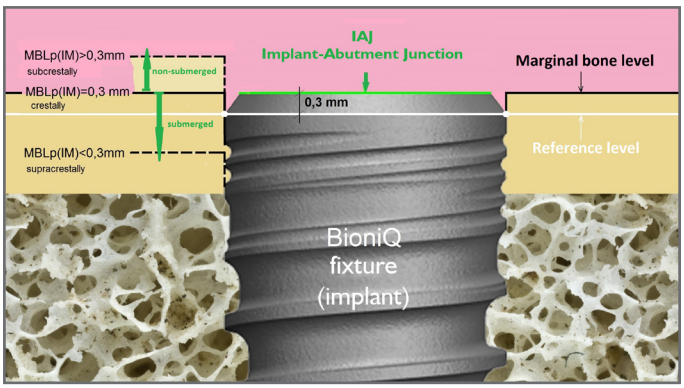


Fig. 4: Illustrative scheme of the non-submerged insertion of the BioniQ implant, i.e. the IAJ (Implant-Abutment Junction) is leveled with or over the Marginal Bone Level (MBLp ≤ 0.3 mm), and submerged insertion, i.e. the IAJ is below the Marginal Bone Level (MBLp > 0.3 mm). The reference level, given by the collar of the implant (white dot, white line), is, in the BioniQ implants, always at a 0.3 mm distance from the IAJ.

The fixtures were covered with soft tissue during the healing period. The healing period lasted longer than 48 hours and less than 3 months (25) in both the upper and lower jaw, with a mean healing period of 2.6 months for all the embedded implants (n = 97). After the healing period, the second stage of the implantation (2SI) was initiated. The cover screw was removed and replaced by a gingiva former. Two to four weeks later, when the mucosal peri-implant canal was formed, the gingiva former was replaced by an appropriate abutment, using a fixing screw and tightened using torque moment of 25 Ncm. Chlorhexidine gel was applied to the screw thread prior to use. Immediately after the implantation (IM) and after the healing period of the second stage of the implantation (2SI), intraoral X-rays were performed and the stability of the implant was measured using RFA.

Prosthesis protocol

To achieve a good quality and stable implant collar closure, the prosthetic phase of the implant was initiated roughly three weeks after the second-stage surgery. In the single-tooth implants, the crown was positioned 0.5–1.0 mm below the free gingival margin and cemented. Two or more implants were mostly treated with screw-retained or cemented restorations (mostly milled) with passive fit and free articulation. Edentulous jaws were treated by insertion of two implants in the lower jaw in the cuspid region with the condition that, in the opposite jaw, there was a removeable denture. The LOCATOR overdenture attachment system was used where the retentive inserts were installed on chair. The the individual prosthesis types, used in the current study, and the numbers of the inserted implants are shown in Table 1.

Evaluation of the success rate of the implant

The evaluation of the success rate of the implants was performed throughout the treatment at given time intervals at the second stage of the implantation (2SI), at the placement of the dental prosthesis (DP), after three (DP3m) and six (DP6m) months and after one year (DP1y) in function (after the placement of the restoration).

For the evaluation of a successful implant, the modified Albrektsson's criteria after Buser were used (26): (1) The implant is immobile when tested clinically, (2) there is no evidence of peri-implant radiolucency, (3) there is no chronic discomfort (pain, dysesthesia-sensory processing disorder, foreign body sensation, foetor ex ore), (4) there are no recurrent peri-implant infections. An implant is failed when it is removed or explanted for any reason. An implant was marked as surviving when it remained in the jaw as a load-bearing dental implant, but did not meet all the success criteria.

Statistics

Descriptive statistics were used to evaluate the acquired data. The data are presented as mean values plus standard deviation, in box plots and tables. Since not all the data had a normal distribution (Kolmogorov-Smirnov test), the median, maxima, minima and quantiles were included in the descriptive statistics together with the mean values and standard deviation. Some of the patients received multiple implants. Therefore, the influence of parameters on marginal bone change throughout the treatment was considered in a linear mixed effect model. The patient was the random effect (independent variable). Life table analysis was used to determine the interval and cumulative success rate of the implants. The statistical analysis was performed using Statistica 12 software. A value of p less than 0.05 was considered to be statistically significant.

Results

From June 18, 2014 to March 3, 2015, a total number of 44 patients, with an average age of 57.6 years (18–75 years), were treated with 97 implants, out of which 39 were implanted in the upper jaw and 58 in the lower jaw.

All the placed implants healed successfully and all the patients attended the follow-ups at 3, 6 and 12 months after the implantation (Fig. 5 and Fig. 6).

The planned follow-up for one patient (one implant) after six months, and for three patients (six implants) after 12 months, after the placement of the restoration will take place after the data collection for this study is finished. After one year in function, all the implants and restorations were evaluated as successful, stable and functional and no implant was marked as failed according to the defined criteria. The success rate of the implants was 100 % after 1 year in function (Table 2).

	Number of restorations (Number of implants)							
Restoration type	Single crown	Connected crowns	Linear bridge (3 units)	Multiple bridge	RFDM	Bars	LOCATOR attach.	Total number
Upper jaw	11 (11)	3 (6)	2 (4)	3 (8)	1 (6)	1 (4)	-	21 (39)
Lower jaw	12 (12)	4 (8)	7 (14)	1 (1)	4 (21)	-	1 (2)	29 (58)
Total number	23 (23)	7 (14)	9 (18)	4 (9)	5 (27)	1 (4)	1 (2)	50 (97)

Table 1: Individual prosthesis types used and the number of the inserted implants

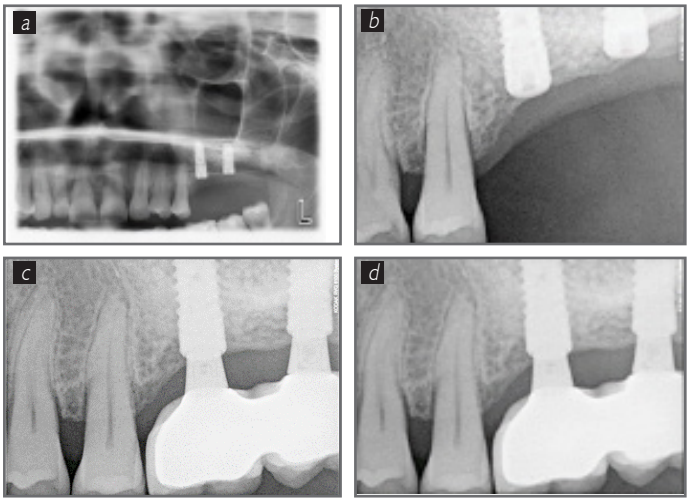


Fig. 5: Radiographs of (a) two implants inserted (IM) in the upper jaw (position 26, 27); (b) after the healing period, at the second stage of implantation (2SI); (c) 6 months after the placement of the final restoration (DP6m); (d) 1 year after placement of the final restoration (DP1y).

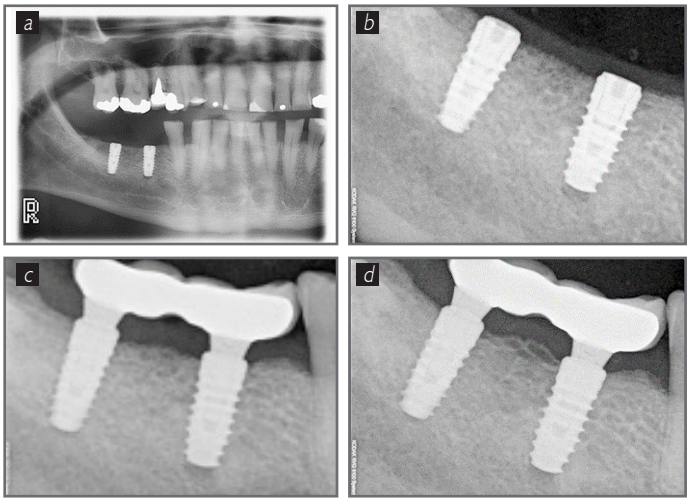


Fig. 6: Radiographs of (a) two implants inserted (IM) in the lower jaw (position 46, 47); (b) after the healing period, at the second stage of implantation (2SI); (c) 6 months after the placement of the final restoration (DP6m); (d) 1 year after placement of the final restoration (DP1y).

Time interval	Number of implants in the interval	Number of failed implants in the interval according to the criteria	Number of implants in the interval with missing data*	Number of assessed implants in the interval	Interval success rate %	Cumulative success rate %
IM – DP	97	0	0	97	100	100
DP – DP3m	97	0	0	97	100	100
DP – DP6m	97	0	1	96	100	100
DP – DP1y	96	0	6	90	100	100
DP – DP2y	90	0	76	14	-	-

*Implants in patients, whose follow-up was scheduled after the data collection in the study ended.

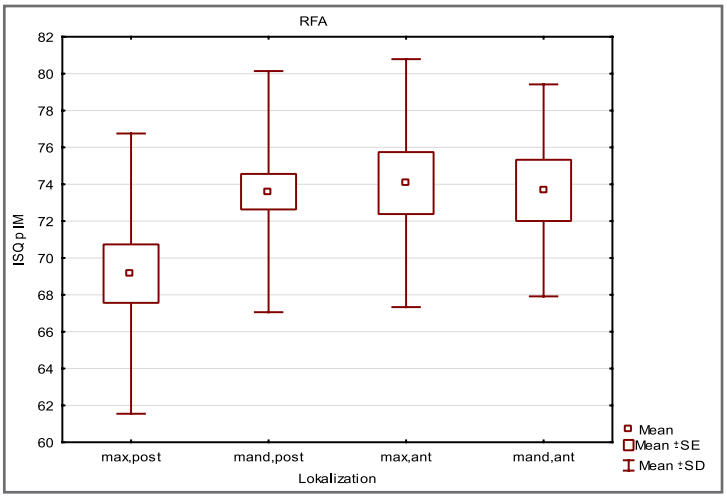
Table 2: The life table analysis

Primary stability and osseointegration of the implants

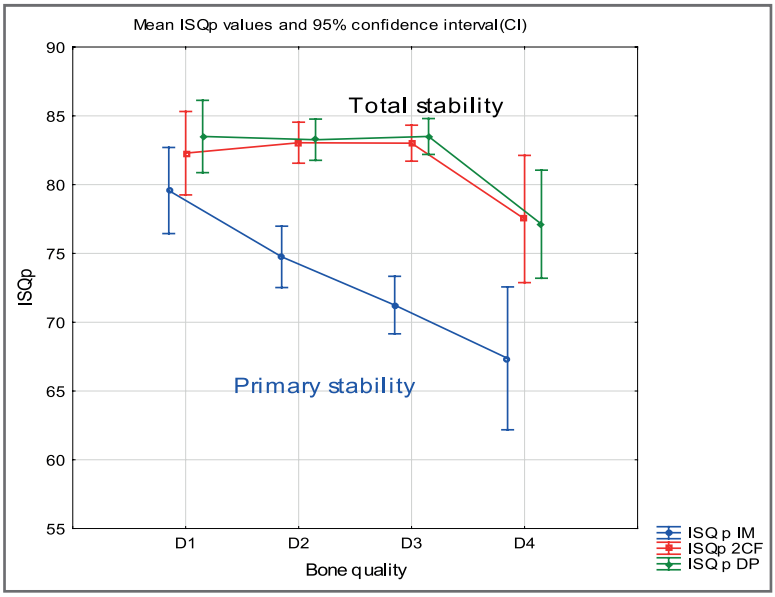
The mean value of primary stability ISQp (IM) of all the implants was 72.6 (SD = 6.9; n = 97). The primary implant stability in the lower jaw 73.6 (SD = 6.3; n = 58) was higher than in the upper jaw 71.2 (SD = 7.6; n = 39). However, the difference was not statistically significant (p = 0.088).

The lowest primary stability was found in the posterior area of the upper jaw (maxilla:posterior), ISQp (IM = 69.2 ±7.6). Higher primary stability was found in the anterior area of the upper and lower jaw (max:ant, mand:ant, mand:post). However, the difference was not statistically significant (p = 0.051) (Graph 1).

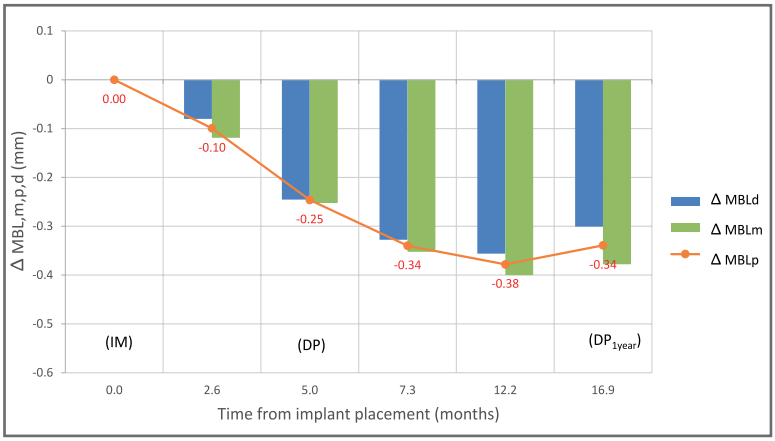
The primary stability was distinctly influenced by the bone density of the alveolar socket. With decreasing bone quality D1 > D2 > D3 > D4, the decrease in primary implant stability was statistically significant (p = 0.00066) (Graph 2). The results demonstrate the osseointegration potential of the BIO-surface and its tolerance of the unfavorable conditions of osseointegration, such as lower primary stability or lower quality of the alveolar socket. The same level of osseointegration was obtained in the shortened healing period in early-loaded BioniQ implants, regardless of the initial primary stability or alveolar socket bone density. The difference in total stability (Graph 2) of the osseointegrated implants inserted in bone with varying bone density D1, D2, D3 was not statistically significant at the second stage of the implantation (2SI) as well as at the placement of the dental prosthesis (DP) (p = 0.870 for (2SI), p = 0.642 for (DP)).



Graph 1: The mean primary stability ISQp (IM) of the BioniQ implants according to the implant localization.



Graph 2: The primary ISQp (IM) and the overall stability ISQp (2SI); ISQp (DP) of the BioniQ implants in relation to the alveolar socket bone density.



Graph 3: Mean change in the Marginal Bone Level ΔMBLp at the control time intervals in relation to the baseline at the time of implantation, mesial ΔMBLm and distal ΔMBLd. (IM) – implantation (implant placement); (DP) – placement of the dental prosthesis; (DP1y) – one year after placement of the dental prosthesis.

Marginal bone stability

Table 3 shows the statistically evaluated values of Marginal Bone Level MBLp as the average of mesial and distal values in relation to the level at the collar of the implant (Fig. 2), measured during the follow-up immediately after implantation (IM), at the second stage of implantation (2SI), at the placement of the dental prosthesis (DP) and after 3, 6, 12 and 24 months (DP3m, DP6m, Dp1y, DP2y) of the implant in function.

Change in Marginal Bone Level in relation to the baseline at the time of implant placement (IM)

The mean change in Marginal Bone Level between the implantation and the second stage ΔMBLp (2SI – IM), the placement of the dental prosthesis ΔMBLp (DP – IM) and after 3, 6 and 12 months ΔMBLp (DP3m – IM), ΔMBLp (DP6m – IM), ΔMBLp (DP1y – IM) in function are shown in Table 4. The mesial and distal values of the change in marginal bone in relation to the baseline immediately after the implantation are shown in Graph 3.

The main bone loss was discovered in the period between implantation and the placement of the dental prosthesis ΔMBL (DP – IM) = -0.246 mm (SD = 0.42). The bone loss was several times higher in comparison to the bone loss in the period between the placement of the dental prosthesis and the measurement after the first year in function ΔMBL (DP1y – DP) = -0.090 mm (SD = 0.36).

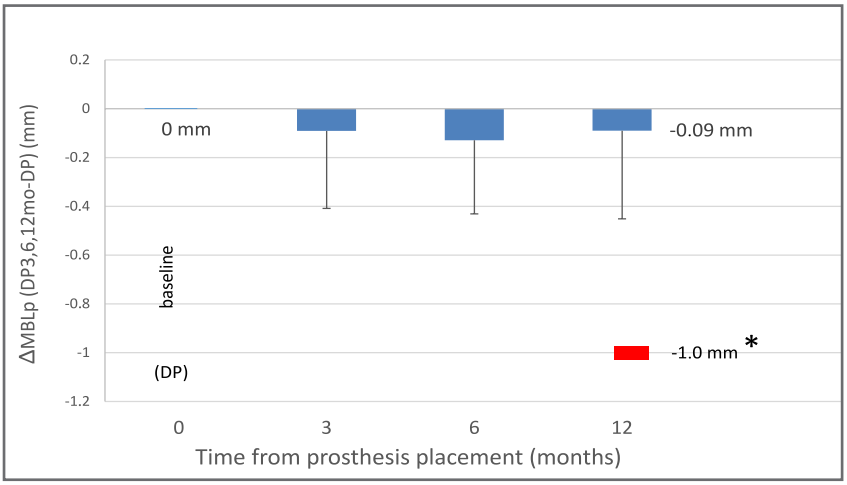
The post-hoc analysis showed statistically significant bone loss between the implantation (IM) and the placement of the dental prosthesis (DP) (p = 0.0005). However, the additional bone loss occurring between the placement of the dental prosthesis (DP) and first year in function (DP1y) was not statistically significant (p = 0.155).

Phase of the follow-up measurement	Mean Marginal Bone Level MBLp (mm)							
	N of valid measurements	Average	Median	Minimum	Maximum	Lower quartile	Upper quartile	St. deviation
IM	97	0.308	0.00	-0.250	2.000	0.000	0.500	0.439
2SI	97	0.216	0.00	-0.500	1.500	0.000	0.500	0.390
DP	97	0.077	0.00	-1.000	1.250	-0.050	0.000	0.411
DP3m	97	-0.023	0.00	-2.000	1.250	-0.100	0.000	0.496
DP6m	96	-0.066	0.00	-1.500	1.250	-0.250	0.000	0.508
DP1y	90	-0.018	0.00	-1.500	1.250	-0.250	0.250	0.520
DP2y	14	0.089	0.00	-1.000	1.250	0.000	0.000	0.551

Table 3: The mean Marginal Bone Level at individual follow-up time intervals

Intervals between the follow-up measurements	Mean change in Marginal Bone Level ΔMBLp (mm) during the individual phases after the implantation		
	N of valid measurements	Average	St. dev.
(2SI – IM)	90	-0.099	0.289
(DP – IM)	90	-0.246	0.423
(DP3m – IM)	90	-0.340	0.520
(DP6m – IM)	90	-0.378	0.586
(DP1y – IM)	90	-0.339	0.566

Table 4: The mean change in Marginal Bone Level ΔMBLp (mm) at time intervals after the implantation

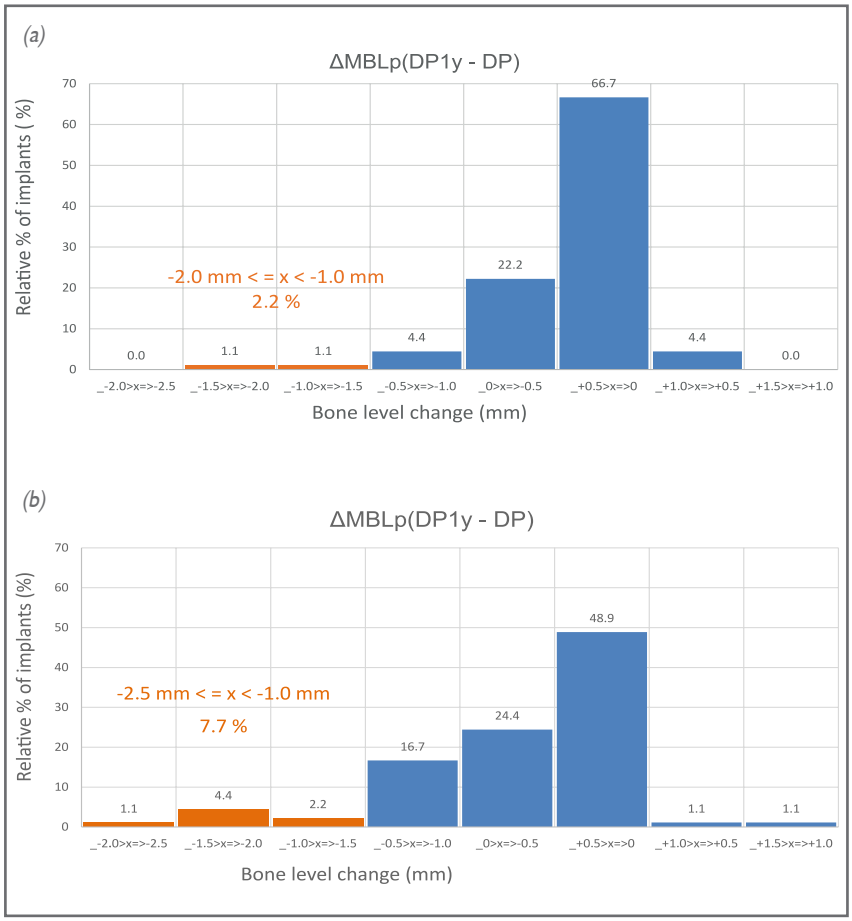


Graph 4: Mean changes in the Marginal Bone Level of the loaded implants after 3, 6 and 12 months from the placement of the dental prosthesis. Red mark represents the generally accepted standard peri-implant bone loss (23).

Change in Marginal Bone Level of the implant in function

Statistical evaluation of the acquired data of change in Marginal Bone Level after 3, 6 and 12 months from prosthesis placement is shown in Table 5. The changes in Marginal Bone Level after 3, 6 and 12 months in function -0.09 mm (SD = 0.32), -0.13 mm (SD = 0.30) and -0.09 mm (SD = 0.36) show the overall stability of the marginal bone during the first year in function and the differences are not statistically significant (p = 0.155).

The absolute value of the mean peri-implant bone loss during the first year in function after the placement of the dental prosthesis ΔMBLp (DP1y – DP) is minimal 0.09 mm (SD = 0.36) and is far below the generally accepted bone loss of 1.0 mm (p < 0.05) and even below half of its value of 0.5 mm (p < 0.05) (Graph 4). These results indicate, that we have enough evidence to reject the null hypothesis and accept the claim.



Graph 5: The relative distribution of the implants (n = 90), expressed as a percentage, according to the category of change in the Marginal Bone Level one year after in function (a) from the placement of the dental prosthesis, (b) from implantation.

However, the significance of the mean values of Marginal Bone Level and their change is limited, since the implants with bone loss are compensated by the implants exhibiting bone gain. Therefore, the analysis of the numbers of implants in the individual marginal bone loss category was conducted in the study (Graph 5). Such an analysis provides a more detailed picture of the bone remodeling. Bone loss higher than 1.0 mm after one year in function was seen in 2.2 % of the implants (2 implants) after the placement of the dental prosthesis and in 7.8 % of the implants (7 implants) after the implantation. Zero or positive change (gain) in Marginal Bone Level was seen overall in 72.2 % (66.7 % + 4.4 %) of the implants after one year in function after prosthesis placement and in 51.1 % (48.9 % + 1.1 % +1.1 %) of the implants after implant placement (Graph 5).

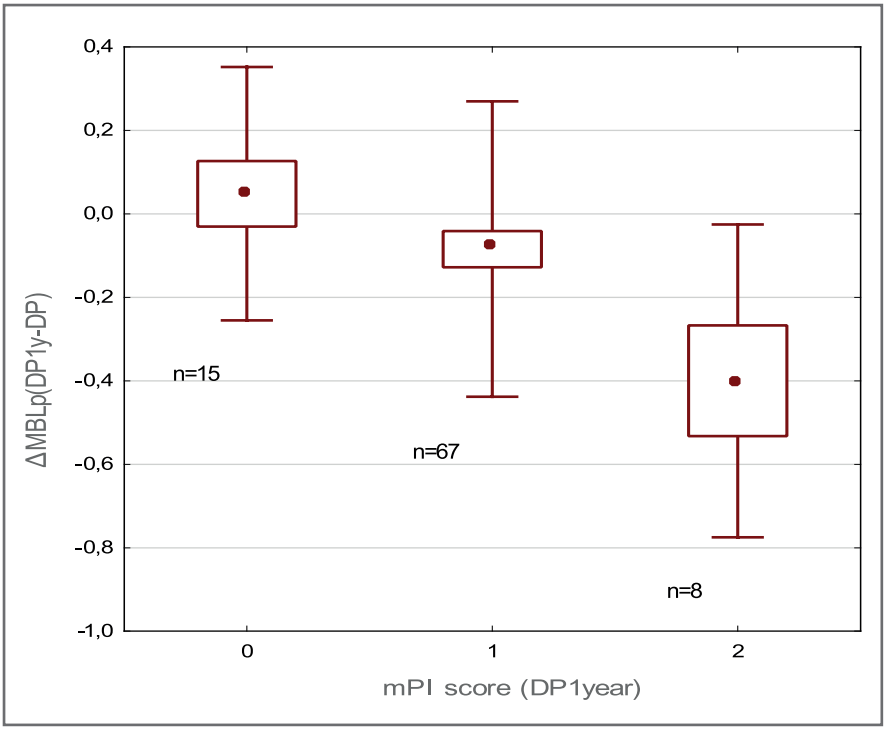
Dental hygiene and the extent of gingivitis was evaluated using the modified Plaque Index mPI and modified Sulcus Bleeding index mSBI. Outcomes throughout the treatment are shown in Table 6. The results show a decrease in the plaque presence and bleeding during the first year of the implant in function. Furthermore, it was demonstrated that the implants with a lower mPI score showed a significantly lower resorption of the alveolar bone after the first year in function (p = 0.00044) (Graph 6). However, the influence of the mSBI score, in regard to the alveolar bone resorption, was not proven to be statistically significant (p = 0.43506).

Intervals between the follow-up measurements	Mean change in Marginal Bone Level ΔMBLp (mm) 3, 6 and 12 months after the dental prosthesis placement		
	N of valid measurements	Average	St. deviation
(DP3m – DP)	90	-0.091	0.317
(DP6m – DP)	90	-0.129	0.302
(DP1y – DP)	90	-0.090	0.361

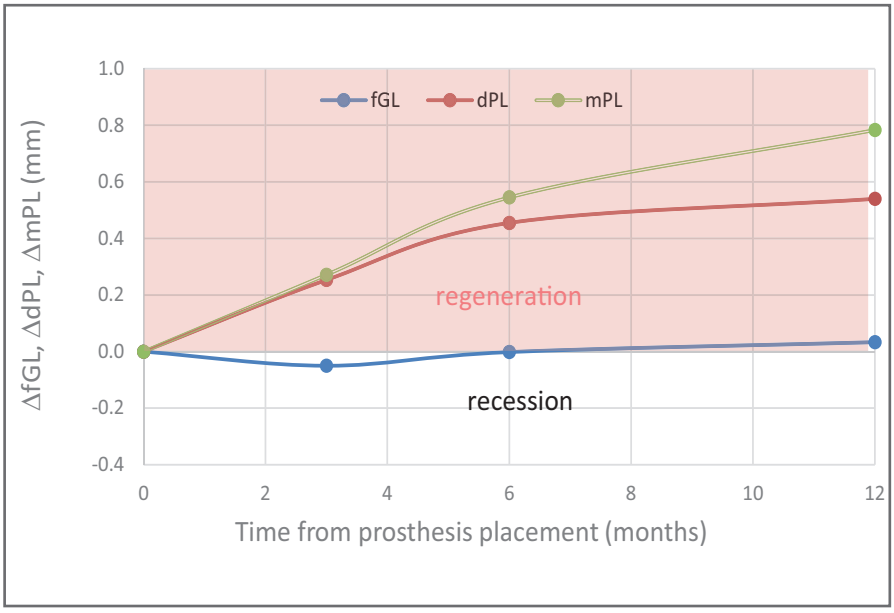
Table 5: The mean change in Marginal Bone Level ΔMBLp (mm) after 3, 6 and 12 months in function

Phase of follow-up measurement	Frequency according to the Plaque Index mPI score, (n)			
	Score 0	Score -1	Score -2	Score -3
DP3m	11	61	18	-
DP1y	15	67	8	-
Phase of follow-up measurement	Frequency according to the Sulcus Bleeding index mSBI score, (n)			
(Score)	Score 0	Score -1	Score -2	Score -3
DP3m	54	23	3	-
DP1y	72	17	1	-

Table 6: The frequency of plaque and bleeding occurrence in the total number of implants (n = 90), according to the Plaque Index mPI score and Sulcus Bleeding mSBI score, after 3 months (DP3m) and 1 year (DP1y) after the placement of the dental prosthesis.



Graph 6: The effect of the mPI score on the mean change in Marginal Bone Level after one year of implantation ΔMBLp (DP1y – IM).



Graph 7: Mean changes in facial Gingiva Level ΔfGL and mesial ΔmPL and distal ΔdPL Papilla Levels after 3, 6 and 12 months after the placement of the dental prosthesis (n = 30).

Stability of the facial Gingiva Level and mesial and distal Papilla Levels

The acquired data of the level of facial gingiva margin and the mesial and distal papilla levels in relation to the reference level 3, 6 and 12 months (DP3m, DP6m, DP1y) after the dental prosthesis was placed for all the implants with single and connected crowns (n = 30) were statistically evaluated. The mean changes in the facial gingiva level and distal papilla levels after 3, 6 and 12 months (DP – DP3m, DP6m and DP1y) after the placement of the dental prosthesis for single and connected crowns are shown in Graph 7.

The results indicate spontaneous regeneration (growth) of the papillae during the follow-up period of one year after the crown placement (mesial p = 0.0413; distal p = 0.160). Partial recession (decrease) in facial gingiva was observed during the first 3 months. Afterwards, between month 6 and 12, stabilization was observed. However, the differences are not statistically significant (p = 0.797).

Discussion

The results presented in the clinical study after 1 year of the implants in function demonstrate the high success rate of the BioniQ implants and the high stability of the peri-implant hard and soft tissues.

The mean change in the Marginal Bone Level (ΔMBLp) during the first year of the implants in function is low -0.09 ±0.36 mm and the value is close to approximately one-third (27 %) of the overall change in the Marginal Bone Level after implantation -0.34 ±0.57 mm. Therefore, the main bone loss occurs prior to implant loading in the period between implantation and the placement of the dental prosthesis 0.246 ±0.42 mm.

The results are in accordance with the best documented implant systems, such as the results of a multicenter study by Hammerle (17) and colleagues (18) of Straumann Bone Level SLActive implants, with marginal bone loss after one year in function of 0.17 ±0.64 mm after the placement of the dental prosthesis and 0.47 ±0.65 mm after implantation. The loss of alveolar bone during the first year of the implants in function represents approximately one-third (36 %) of the overall bone loss after implantation.

Gottfredsen (19) reported mean marginal peri-implant bone loss of Astra Tech AB, Astra Tech ST,

early-loaded implants after first year in function of 0.21 ±0.49 mm after the placement of the dental prosthesis and 0.63 ±0.62 mm after implantation. The study also showed a minor alveolar bone loss during the first year of the implants in function, representing one-third (33.3 %) of the overall bone loss after implantation.
The mean changes in Marginal Bone Level ΔMBLp represent the extent of peri-implant bone resorption in the given period independent of the chosen Reference Level (RL) of the implants. Therefore, these values are used for evaluating the success rate of the implants and for the mutual evaluation of the stability of the marginal bone in different implant systems.
On the contrary, the mean Marginal Bone Level MBLp indicates the distance of the nearest apical/cervical point of contact of the marginal bone and the implant from the Reference Level (RL). The chosen RL differs across the individual studies according to the implant design or the procedure, and, thus, limits mutual comparison.

Nevertheless, in this study, the statistically evaluated Marginal Bone Level after first year of the implant in function MBLp (DP1y) = -0.02 ±0.52 mm (Table 3), represents the stabilized peri-implant bone 0.32 mm apically from the IAJ, which is a reference level frequently mentioned in the literature.

Conclusion

1) The results of the study indicate the high success rate of the BioniQ implant and its distinctive stability in hard and soft tissues after the first year in function.

2) The mean change in the Marginal Bone Level (ΔMBLp) after the first year in function of the early-loaded implants was -0.09 ±0.36mm after the placement of the prosthesis and -0.34 ±0.57 mm after implantation. Bone loss higher than 1 mm after one year in function was shown in 2.2 % of the implants after placement of the dental prosthesis and in 7.8 % of the implants after implantation.
3) Alveolar bone loss after the first year in function after the placement of the dental prosthesis was significantly lower in comparison to the generally accepted standard for successful implants.
4) The results demonstrate that the BioniQ implant with the bioactive BIO-surface is reliable and predictable in the procedure with a shortened healing time for the early-loaded implants.

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