STABILITY EVOLUTION OF ALFA GATE BIOACTIVE COATING® IMPLANTS DURING HEALING PERIOD

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Summary

Commercial oral implantology grew during the 1980s. Osseointegration was being used to permanently affix bridges and individual teeth into patients' mouths. The implants proved to be successful in over 90% of the cases. The modern dental implant had arrived!

Over the next two decades, technology has only continued to improve the process. For instance, slight modifications to the titanium proved to increase healing time. As time goes by and as the practice of dentistry advances, patients will continue to see dental implants becoming quicker, easier, and less painful.

Key words: dental implant, implant stability quotient (ISQ) ,implant surface modification, osseointegration, Alfa Gate dental implants.

Introduction:

Placement of dental implants in edentulous people is an efficacious method for the replacement of missing teeth [13]. According to the literature, more than 1300 types of dental implants are available, in different materials, shapes, sizes, lengths and with different surface characteristics or coatings [6]. The success rate for osseointegration of dental implants has been shown to be very high for many different designs and brands of implants [23, 11,18]. Primary stability, which is one of the most important criteria of implant integration and success rate, depends on especially of the geometry of the implants (length, diameter, shape, and thread) besides the surgical technique, volume, and mechanical quality of local bone [42,21]. 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 [37]. It is proportioned with implant success rate, depends of bone remodelling induced by a mechanical stress situation during the initial phase of bone healing and surface modification of the implants [12]. According to current literature, there are discussions concerning ability of implants to withstand early or immediate loading in order to reduce waiting time for the patient. In addition to mentioned parameters of the primary and secondary stability, the implant surface osteologic characteristics are factors which affect the implant bone response and quality of the bone implant interface [4,29]. Surface treatment helps to enhance secondary stability after insertion by promoting osseointegration [25,12,16].Various methods have been developed and tested in order to coat metal implants, e.g. plasma-spraying, sputter-deposition, sol–gel coating, electrophoretic deposition or biomimetic precipitation [29,2]. Recently a new surface implant system with a completely resorbable, fixed adhesive calcium-phosphate (CaP) coating (Bioactive®) is available (figure 1). It is a 5 grade titanium alloy with microstructure, internal hexagon, spiral, conical, self drilling, self tapping, double thread system, with deep and especially sharp threads decreasing towards the implant shoulder, enabling implant self-retention. Bioactive® coating is a newly developed electrochemical process for implant coating in an aqueous solution containing calcium and phosphate ions. According to the manufacture dates the calcium phosphate coating properties are: large active surface with high capillarity effect on blood; stimulation of the body's own osteosynthesis; substitution of Bioactive® coating by young bone directly on the implant surface within 6 – 10 weeks postoperative; low coating thickness of 20-30 µm.

Therefore, the aim of the present study was to investigate the early outcome of a recently developed dental implant with CaP coating (Alfa Gate, Israel) in 6 weeks of usage in mandibular clinical situations.

Purpose and tasks

1- To investigate the early outcome of a dental implant with bioactive Calcium-phosphate (CaP) coating in the first 6 week of usage in mandibular clinical situations, for determination if it is possible early prosthetic loading.

1- Methodical elaboration for measurements of implant stability dynamics.

1- Determination of critical time in implant dynamics.

Different times for loading dental implants

Primary implant stability and lack of micromovements are considered to be two of the main factors necessary for achieving predictable high success of osseointegrated oral implants (Albrektsson 1981). A successful osseointegrated oral implant is anchored directly to bone, however, in the presence of movement a soft tissue interface may encapsulate the implant (Brunski 1979) causing its failure. To minimize the risk of soft tissue encapsulation, it has been recommended to keep the implants load-free during the healing period (3 to 4 months in mandibles and 6 to 8 months in upper jaws) (Branemark 1977).

In general, during the healing period removable prostheses are used, however many patients find these temporary prostheses rather uncomfortable and it would therefore be beneficial if the healing period could be shortened without jeopardizing implant success. In 1990 the first longitudinal clinical trial was published suggesting that implants could be loaded immediately or early in the mandibles of selected patients (Schnitman 1990). Nowadays immediate and early loaded implants are commonly used particularly in mandibles of good bone quality (Branemark 1999). Some authors also advocate that the use of some specific implant surface preparation is able to reduce the healing time (Roccuzzo 2001).

2.5 Bioactive Calcium phosphate coating and S.L.A surface vitro comparison

Alfa Gate "BioActive calcium phosphate (Cap) coated dental implants were tested at the Bruce Rappaport Faculty of Medicine at the Technion-Israel Institute of Technology to determine whether the TCP coating could induce Increased affinity, attachment and growth of bone forming cells (osteoprogenitors).

The study involved the culture of human osteoprogenitors on S.L.A surfaced and CaP coated Alfa Gate dental implants. Cell growth and metabolic activity were Followed in culture (10 Days) and the implants were examined by Scanning Electron Microscopy (SEM) to determine the presence of and adaptation of bone-forming cells on the TCP coated and standard implants, to test the stability of CaP coating

Bioactive CaP-coated implants demonstrated hydrophilic properties and human bone-forming cells attached readily to the surface interface while very few cells adhered to the S.L.A. surface.

Subsequent incubation on the implants, replication rates of osteoprogenitor cells was 600% greater on the CaP coated implant than on the S.L.A. surfaced implant.

SEM analysis revealed that bone-forming cells adhered to the entire surface area of the Bioactive implants. The cells demonstrated well formed projections and tissue-like monolayers.

Materials and Methods

Study of the 6 weeks function of 16 oral implants in 6 patients, in the mandibular clinical situations we have evaluated the clinical and para clinical parameters to predict implant outcomes and dynamic evolution .We initiated a short-term prospective study on Bioactive Alfa Gate implants. The following para clinical analyses were determined to access the necessary dates for success and survive rate of implants: The implant primary and changed stability of 6 weeks stability (the resonance frequency analysis (Osstells Mentor® (RFA) Osstell AB, Gothenburg, Sweden) which was done weekly and the result was registered to make the statistical comparison.

3.1 Inclusion criteria

The inclusion criteria were: patients eligible for enrolment were of either sex, older than 18 years of age who had received at least one Alfa Gate Bioactive implant (Alfa Gate, Israel) in the time period between January 2010 and February 2010; patient's agreement to a 6 weeks follow-up period; fixed prosthetic rehabilitation. Exclusion criteria were: prosthetic treatment with removable prosthesis on implants, acute and chronic sinus infections, maxillary cysts, tumors, root tips, physical and psychiatric severe consideration that will affect the implant procedure or history of chemotherapy and radiotherapy of the maxillofacial and cervical areas and severe smoking. There were, however, no restrictions on bone quality and quantity or addition bone grafting and regeneration procedures intended for implant placement. No other inclusion or exclusion criteria were applied.

3.2 Surgical Procedures

All surgeries were performed under local anaesthesia with 3 patient with open flap (fig. 3.1) and 3 with flapless (fig 3.2) access to the bone. Osteotomy preparations of neo alveolas were performed with low speed high-torque drill units using intense irrigation with a cold saline solution. During each site preparation of the neo alveolas for the implants, the bone quality II to III was recorded. All implants were placed manually and final torque was measured with a manual torque control wrench (fig 3.3) with result of 35-45 Ncm. And each implant was covered with healing abutment (fig 3.4) for easy access For the quantitative evaluation of implant stability, RFA was recorded with the Osstell Mentor device. Orthopantomographic X-ray images were used for calculation of radiological bone loss and the respective success criterion.

3.3 Measurement procedure.

Measurement procedure is done weekly with exact interval of 7 days, during this procedure the healing cap will be removed and

The smartpeg(fig 3.5) will be installed on the implant, Osstell will be used to measure the RFA from the transducer (fig 3.6).

After the result collection the smartpeg will be removed and a syringe with levomecol (fig 3.7) will be injected to the implant orifice, and the healing abutment will be installed again.

3.4 Statistics

For the statistical evaluation, implant-related data were calculated.

For statistical calculation, Fisher's exact test was used. A difference was considered to be significant when the p value was <0.05. The Kaplan-Meier survival function was used for the description of survival rates.

Aprtioiation of reverce torque force for removing healing cap with out affecting implant stability

The aims of our proposed research are: determination the forces that is needed to insert the healing cap and the material that will act as enhancer for re-

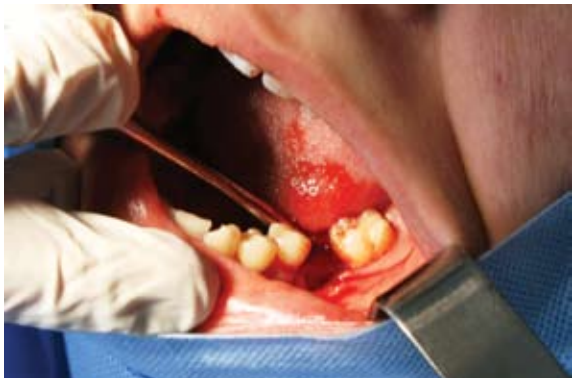

Fig.3.1. open flap

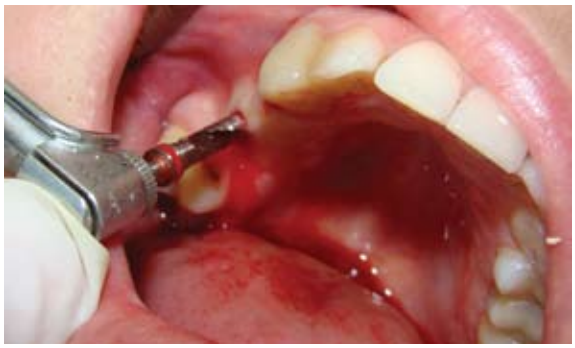

Fig.3.2. flapless

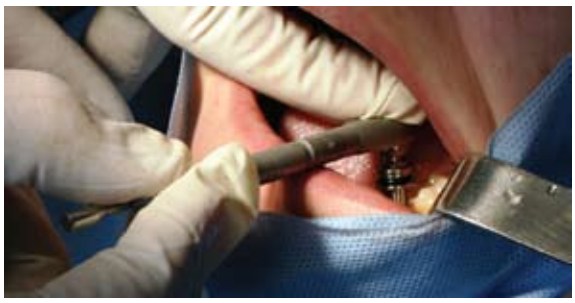

Fig.3.3. torque wrench

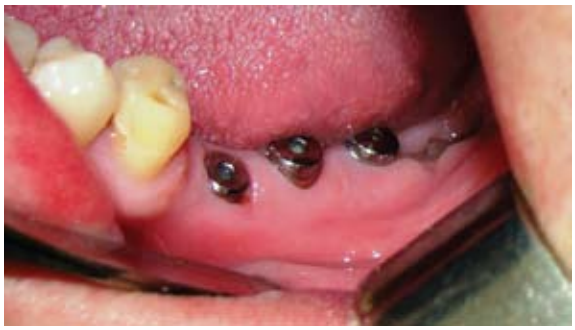

Fig.3.4. Healing abutment

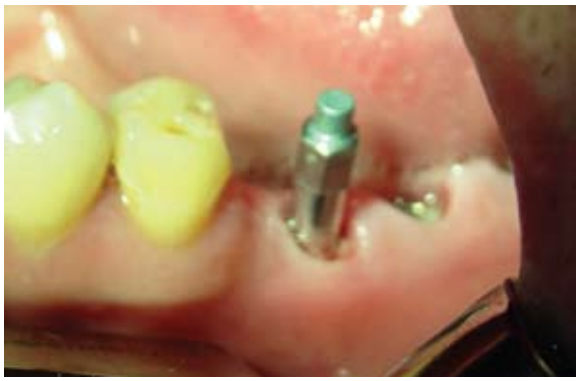

Fig.3.5. Smartpeg installed in the implant

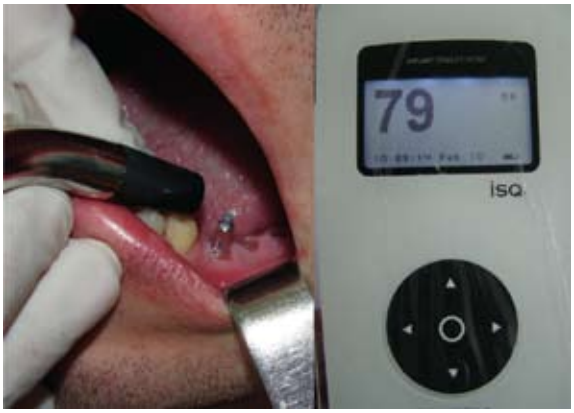

Fig. 3.6. Osstell measurement

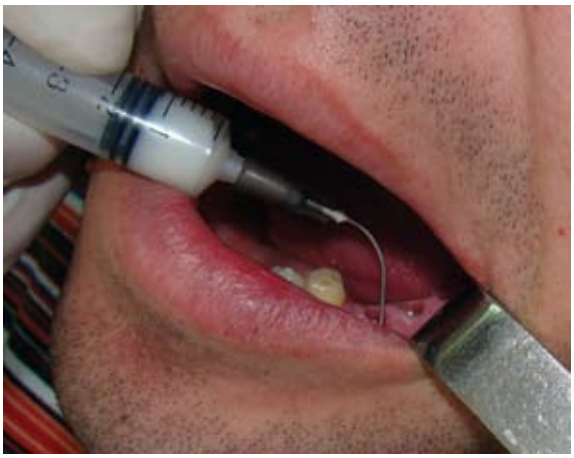

Fig. 3.7. levomecol injection

moving the healing cap with out any resistance torque or difficulties.

And to determine if the factor of time has any relation with healing cap implant resistance.

Our aims of the present study are: (1) Determination of the forces and material that needed to insert the healing cap (Alfa Gate, Israel) on the bioactive implant (Alfa Gate, Israel), without increasing resistance when removing the healing cap part, without affecting implant stability.

And to determine if the factor of time has any relation with increasing the healing cap implant connection resistance

We intend to perform a para-clinical research study to solve aims of our work.

By the results that we had measured during our test , not surprisingly the vasilin had the main lubrication effect during the reveres torque measurements.

But also we saw that the levomecol had a similar effect with a very minor differences, but on the other hand the levomecol have another antibacterial and anti-inflamatory effect, because it is Combined preparation containing chloramphenicol and Methyluracilum. So after this results of the test we recommend to use levomecol as lubrication material for the healing cap during the 6 weeks implants follow-up with Osstell and Alfa Gate implants.

Documentation of implant stability dynamics during the 6 weeks.

4.2.1 Stabilty coefcient after insertion

Table 4.2.1.1 Weekly data collection for the subjected implants.

Implant # / Week	0	1	2	3	4	5	6
1	59	80	73	71	70	70	70
2	66	52	68	75	73	70	70
3	62	62	53	62	68	69	70
4	62	55	59	62	64	64	65
5	76	70	75	89	81	82	83
6	69	66	68	73	75	74	74
7	67	60	66	70	71	71	71
8	61	65	66	67	68	69	69
9	76	64	68	68	68	68	68
10	78	78	80	74	73	73	73
11	82	76	78	74	72	72	72
12	73	72	70	65	67	67	68
13	58	51	59	64	68	72	72
14	65	62	63	66	67	67	68
15	64	60	61	65	68	70	70
16	64	61	63	67	67	69	69
MEAN	67.625	64.625	66.875	69.5	70	70.438	70.75

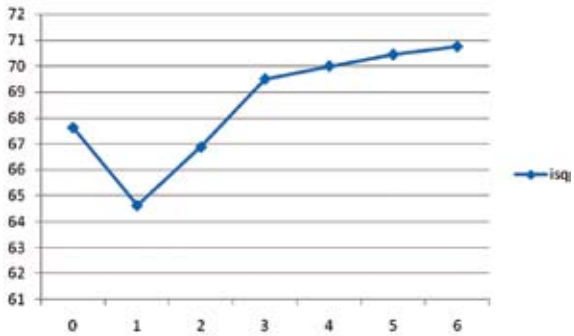

Fig 4.2.1.8 Dynamic evolution of the measured implant during the 6 weeks, from week 0 which is at surgery time, we can notice the sharp reduction of Implant stability after one week from surgery with ISQ mean of 64.63, which is the loosing of mechanical stability , and till the week 4 it is critical time for implant osseointegration, and in week 6 all implants has ISQ more than 65 which is the stability required for implant prosthetic

Table 4.2.1.9 Measurement deviation

	N	Minimum	Maximum	Mean	Std. Deviation
V18	7	64.63	70.750	68.23	2.29
Valid N (listwise)	7				

Measurement deviation of ISQ value during the 6 weeks research, the Standard deviation of 2.29 and the mean was 68.23 ,the maximum ISQ value was recorded was 70.75 ISQ at week six and the minimum ISQ value that was recorded is 64.63 ISQ at week 1 after surgery, as we notice after one wek implant loss the mechanical stability and at week 6 implant have a high biological stability, wich is recommended for implant loading.

In the data that was collected, we can notice that during the first and the second week the mean stability was reduced and from the third week started to

have increase in the mean stability coefficient., tell the week 6 we had a mean of 70.75 ISQ and the minimal was 65 ISQ, which by the recommendation of Other studies, for loading. This phenomena very noticeable in (figure 4.2.15), and in this specific week all the studied implant had an ISQ MORE THAN 65.

5. Conclusions:

1. The stability dynamics of Alfa Gate Bioactive implant showed, that during the first till fourth week it has the minimum implant stability with critical time in implant bone integration.
2. During the sixth week after implantation the stability coefficient for all implants was more than 65 ISQ, which was possible for implant loading.
3. The elaboration method in vivo that was used during this research is inoffensive and may be used in other studies.

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