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BTLock Implants - the Evolution and Evaluation of a New Designed, Problem-Resolving Implant

SUMMARY

Objective: *The initial need for different implant systems to be developed in implant dentistry arose from the loose screw syndrome. The aim of this paper is to present a very new implant design with internal connection, named BTLock Implant, and also a 5-year clinical experience with BTLock implants. The objective of the study was to demonstrate the ability of the BTLock implant system to restore masticatory function in the partially edentulous patients over a 5-year period.*

Method and Materials: *BTLock implant is equipped with a very specific, new designed internal connection characterized with two 3-angled asymmetric designs with multi-leveled closure. When BTLock implant is cross-sectioned through the whole assembled implant, an asymmetric double-triangulated 3-leveled internal connection is visible. Optical micrograph of cross sectioned fixture and AutoCAD computer design show detailed complex 3-leveled internal connection. The BTLock system has an accurate and simple implant-level impression and a colour code indexing system, to facilitate abutment selection in the laboratory and outside of the clinical environment. Restorative components were customized with computerized AutoCAD graphic programme. The attention has been given to the implant-abutment connection. A national multi-centred clinical study was initiated at 4 selected private practices.*

Results: *The used design of BTLock implant system demonstrated high level of biomechanical stability. During 5-year period in the multi-centred study it was demonstrated that BTLock implants had an almost 98.2% success rate after the first year, 97.6% after the second year, 97.2% after the third, 96.8% after the fourth and 95.5% after the fifth year of post-restoration follow-up.*

Conclusion: *BTLock implant system with a new internal design between fixture and abutment can achieve a long-term biologic and mechanical stability when used to restore single missing teeth, over a long period of time.*

Key words: BTLock Implant, internal design

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Introduction

In recent years there has been a progressive increase in prosthetic implanting and the industrial marketing of implants. Numerous new implant designs and materials have become available over the last decade, each with special claims of superiority in restoring complicate cases[1]. Differences in existing clinical databases, study designs, and methods of determining failures/survivals are seldom standardized, which complicates comparison of clinical performance of these new designs[2]. Little information is available concerning the changes in stability of various designs and materials following clinical loading[3].

Despite the impressive clinical accomplishments with oral and maxillofacial implants, and the undisputed fact that implants have improved the lives of millions of patients, it is nevertheless disquieting that key information is still missing about fundamental principles underlying their design and clinical use. With some important exemptions, the design and use of oral and maxillofacial implants has often been driven by an aggressive, "copycat" marketing environment, rather than by basic advances in biomaterials, biomechanics, or bone biology.

A wide variety of implants now exist for use in many clinical indications, with over 50 companies listed by the US Food and Drug Administration (FDA) as being involved in the manufacture, marketing, and distribution of dental implants. While this situation is not necessarily a problem, in many instances new companies have entered the dental implant market by simply copying or making minor, incremental changes to the size, shapes, materials, and surfaces of competitors' products, while exaggerating the new products' effectiveness. In addition, busy clinicians, not always equipped to discern the difference between marketing hype and scientific advances, yet wanting to help their patients sooner rather than later, have often been too eager to use new implants in new clinical or basic science viewpoint[4].

For better or for worse, the current state of the oral implant field is such that a myriad of different types of implants are now being used in a very wide variety of clinical indications[5]. The initial need for different implant systems to be developed in implant dentistry arose from the loose screw syndrome with the original external hex design[6,7]. The loosening of small gold cylinder screws, as well as the larger titanium screws used to secure gold cylinders and machined abutments to the implants, was a constant problem when the restoration lacked a passive-fitting prosthetic framework. This lack of a passive fit would cause micro-vibrations, which would loosen the screws. These vibrations were the result of built-in stress from the forced fitted framework returning to its original dimension. Obviously, there were far fewer problems with screws loosening in a passive-fitting prosthetic framework. Little information is available concerning the screw-retained implant-abutment connections and particularities of its internal or external design.

The aim of this paper is to present a new implant design, named BTLock Implant, and also to show clinical experiences. The new designed BTLock implant system with internal structure of *asymmetric double-triangulated 3-levelled internal connection* is a problem-solving new-designed implant created in order to achieve and improve primary stability of implant, screw tightening, anti-rotational stability, and anti-fluid and microbial penetration. Internal structure of mechanical constructions and comparison with known, very successful commercially available dental implants already present on the market, will be presented in details. 5-year post-restoration life table success rate will be presented. Further on, we shall discuss and analyze the importance of new designed improvements for: 1. primary stability of implants; 2. screw tightening; 3. the process of loosening and resistance to loosening; 4. anti-rotational stability; 5. anti-fluid and microbial penetration.

Material and Method

BTLock Implant design

A screw-type BTLock implant system, made of commercially pure titanium (Ti grade II), was designed with specific new type internal connection (Pat. Pend. PD2000C000757). In order to enhance aesthetic results, restorative components were customized with a computerized AutoCAD graphic program. Cross sections of the whole implant, fixture and the internal parts of implant structure were made, and light optical photomicrographs were taken (Fig. 1). The BTLock external, internal design and internal connection were compared with already known types of implants with internal (type A), external (type B) and conical (type C) connections. The attention has been given to the implant-abutment connection which, from biomechanical and clinical point of view, is a guaranty for high primary stability, double anti-rotational stability, good tightening and long survival time of implant.

Clinical study

A national multi-centred clinical study was initiated at 4 selected private practices. The objective of the study was to demonstrate the ability of the BTLock implant system to restore masticatory function in the partially edentulous patients over a 5-year period. Restorations in the maxillary and mandibular areas were chosen for prospective 5-year follow-up. From 1995 to 2002, 15.400 BTLock implants were implanted. 2911 implants inserted in various areas were controlled and analyzed in the prospective study. In order to obtain homogeneous data and to avoid divergent data due to different static and dynamic vectorial situations, only mandibular sites in partially edentulous areas, corresponding to teeth from first bicuspids to second molars, were included. The patients were divided into 2 groups according to the 2 different series of prosthetic implants used in the rehabilitation: the first group (1455 patients) was treated with titanium sand-blasted; the second group (1456 patients) received machined-acid-etched BTLock implants. The patients were between 25 and 65 years old at the time of implant placement. All the patients (927 males, 1984 females) referred for implant surgery were selected according to criteria described by De Bruyn et al[8], and all were treated by 4 different oral surgeons in 4 different private practices.

Implants were considered as successful when they were meeting with the success criteria proposed by the European Academy for Periodontology[9]. Criteria for exclusion from the study were: maxillary side, bruxism, Angle's Class II and III, abnormal chewing habits, poor oral hygiene, and inflammatory bone diseases. BTLock implants were inserted in an atraumatic 1-stage or 2-stage surgical procedures.

Results

General outcome

BTLock implants belong to a well-established and low risk approach of screw-type dental implant treatments (Fig. 1). The main components of the BTLock implant system are: complete line of threaded and cylindrical implants with all prosthetic and instrumentation components necessary for good restorative results in partially and totally edentulous patients (Fig. 2).

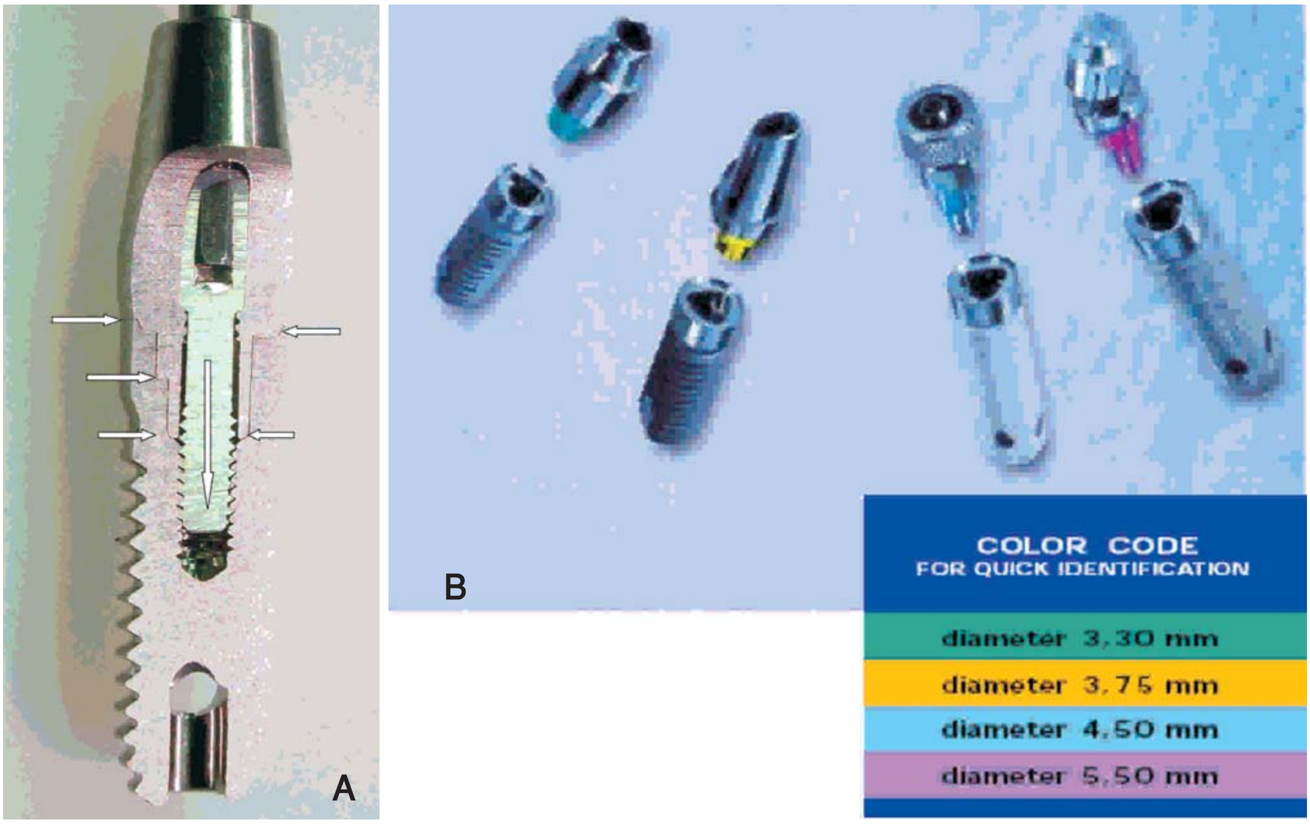

Figure 1. Final forms of BTLock implants.
A. *A cross-section trough the whole assembled implant (x50). An assimetric double-triangulated 3-levelled internal connection is visible with very good tightening match of fixture, pillar and abutment. Asymmetry of internal closure assures good fitting, good tightening, anti-rotational and anti-microbial penetration characteristics.* ***B.*** *The BTLock system provides both screw-retained and cement-retained restorative options. Restorative versatility and innovation is presented with few characteristic examples. BTLock implants are designed as treated or cylindrical fixtures with rough osteconductive and osteinductive surfaces such as: a) Machined; b) Titanium plasma sprayed (TPS); c) Hydroxyapatite (HA) coatings; d) Acid etched and sand-blasted coatings. Additionally, a colour code indexing, as very important practical parameter for implant manipulations, is available*

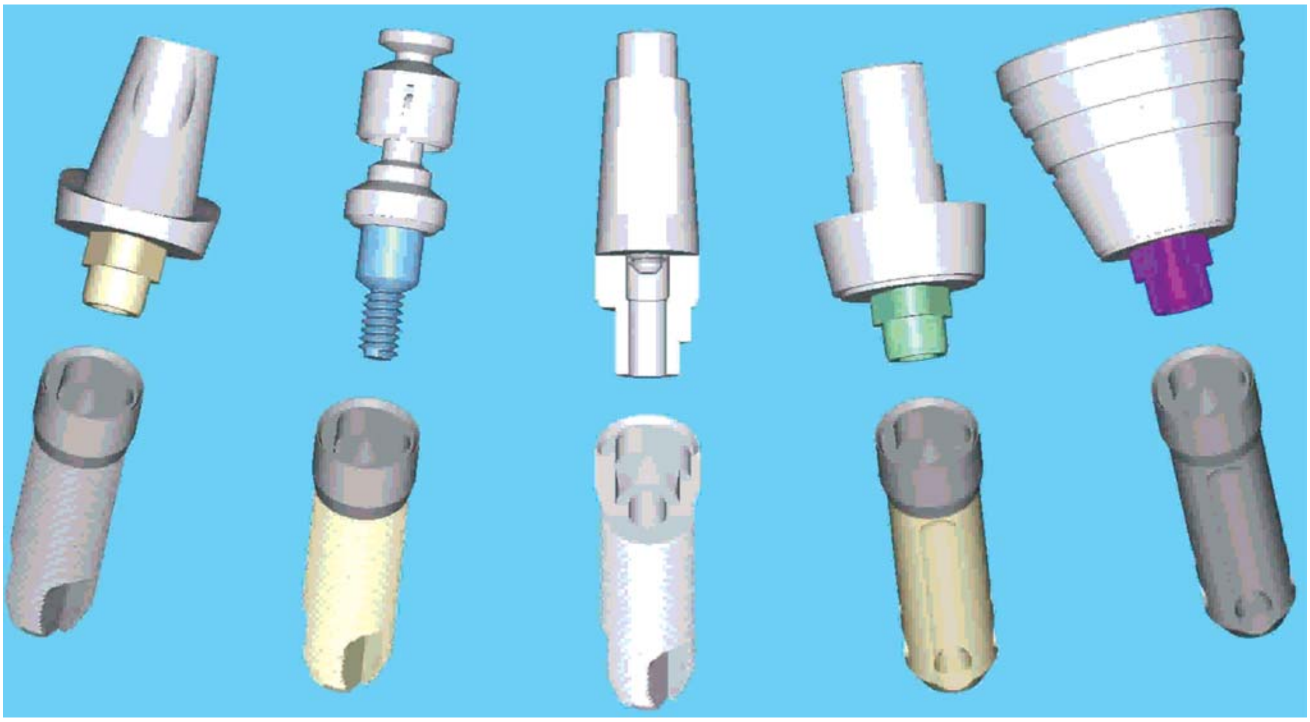

Figure 2. Prosthetic solutions of BTLock implant system: Restorative versatility and innovation is presented with few characteristic examples (AutoCAD design). All these peaces contribute to the high level of success and to the excellent aesthetic results

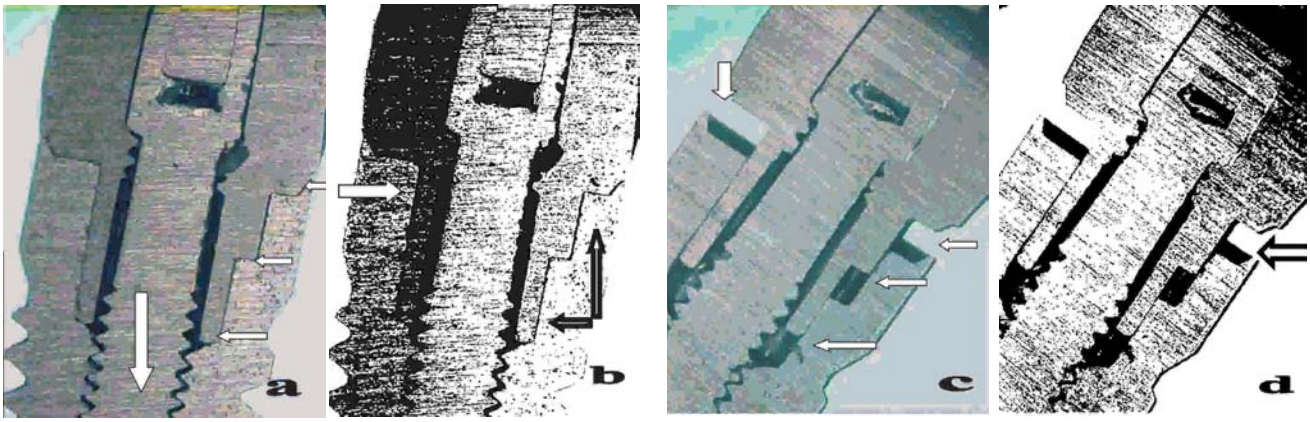

Figure 3. BTLock implant system - Asymmetric design with multi-levelled closure. Arrows show cross-sectioned asymmetric double-triangulated 3-levelled internal connection. BTLock design ensures a tight relationship between the abutment and the fixture, providing stability and strength of the implant. This design prevents micro-leakage and micro-mobility, thus maintaining tissue health

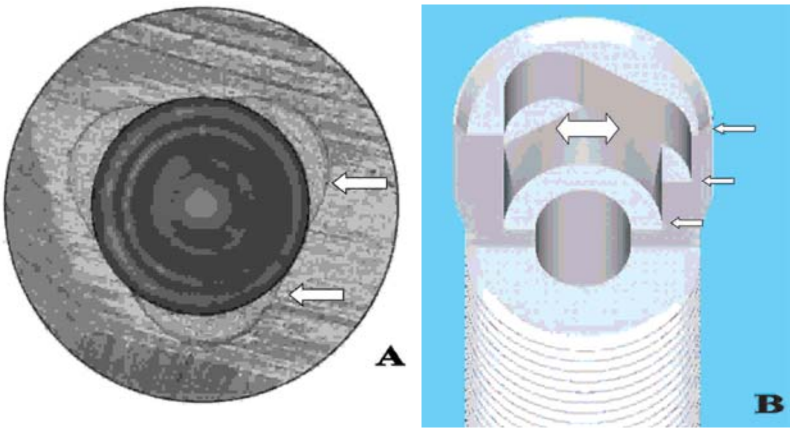

Figure 4. Optical micrographs (x50) of BTLock implant as transversal cross-section (A) and autoCAD design (B). Asymmetric double-triangulated 3-levelled internal connection as a guaranty of high stability between fixture, pillar and abutment and anti-rotational stability is visible

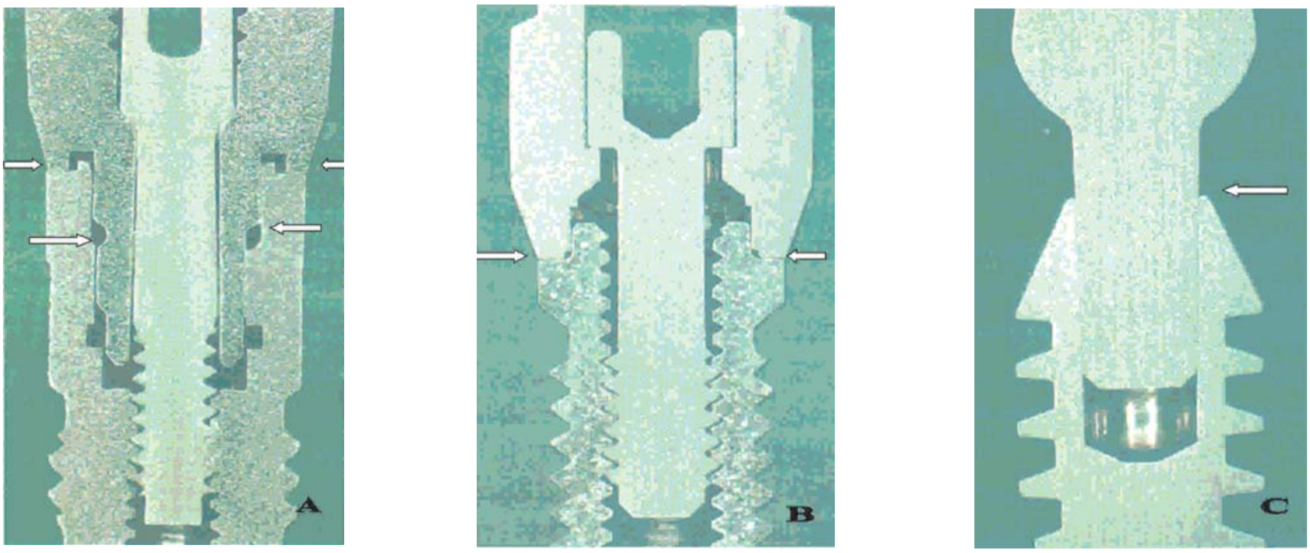

Figure 5. Optical micrographs (x50) of 3 representative classes of commercially available implants: A) with internal connection (arrows show symmetric 1-level closure); B) with external hex connection (arrows show symmetric 1- level closure); C) conical seal connection

External design

Surface of BTLock implants was treated mechanically and chemically to get particular topographic surface conditions (Fig. 1 B and Fig. 2). Applied physical and chemical changes on implant resulted in rough microcrystalline surface clearly showing turning marks with some small pits. Such topography and roughness could improve its biocompatibility, osseointegration and durability, which are required[4,10-12] for long-term osseointegration in the living body. Different surface treatments to get *rough surface* present an increase in surface area over the smooth surface, and thus also more retention in the bone[13,14]. In that way both physical and chemical conditions conducive for osteogenic progenitor osteoblasts were created, necessary for an interfacial guided osteogenesis at the implant surface. BTLock implant's surface was treated in following ways: a) as standard machine cut; b) acid-etched; c) combination of acid-etched chemical and mechanical sand blasted; d) plasma spray treatment (TPS); and e) hydroxyapatite (HA) micro-particles spraying. These chemical and mechanical surface manipulations had 2 key results in common: changes on the TiO_2 (titanium oxide) layer reactivity, and changes in surface fine topography, which altogether gain much better BTLock implant osseointegration.

The BTLock system provides both screw-retained and cement-retained restorative options. BTLock implant system offers restorative versatility and aesthetic innovations (Fig. 2) to satisfy every need. A few characteristic examples of BTLock implant system are presented in figure 2. All these peaces contribute to the high level of biomechanical stability and to the excellent aesthetic results. The BTLock system has an accurate and simple implant-level impression and *colour code indexing system* to facilitate abutment selection in the laboratory and outside of the clinical environment. These implants can be placed wherever a tooth or several teeth are missing, when enough bone is available to accommodate them. However, even if the bone volume is not sufficient to place implant, bone grafting procedures within reasonable limits should be initiated in order to benefit from these implants. BTLock implant can be directly loaded, even in the posterior bone of the mandible. The increased primary stability of this implant system avoids localized overloading reactions in the bone and contributes to the successful osseointegration of the implants.

Internal design - Implant-abutment connection

BTLock implant is equipped with a very specific, new designed internal connection (Fig. 3), characterized with two 3-angled asymmetric designs with multi-levelled closure (Pat. Pend. PD 2000C000757, Italy). When BTLock implant is cross-sectioned, an *asymmetric double-triangulated 3-levelled internal connection* is visible (Figs. 1, 3, and 4). Optical micrograph of the cross sectioned fixture in details is presented in figure 4. Auto CAD computer design shows even more complex 3-levelled internal connection (Fig. 4B). This design of the BTLock implant system with *asymmetric double-triangulated 3-levelled internal connection* between fixture and abutment demonstrates a double level of anti-rotation, and high level of biomechanical stability. Internal connection of BTLock implant allows for simple self-guiding seating of the abutment without the need for an intraoral radiograph to check that it is correctly seated. Therefore, BTLock design ensures a tight relationship between the abutment and the fixture, providing stability and strength of the implant. This design prevents micro-leakage and micro-mobility, thus maintaining tissue health. Optical micrographs of the cross-sectioned BTLock's implant abutment (Fig. 3), when compared with similarly prepared 3 representative classes of well known implants present on the market (Fig. 5 A-C), show a visible internal structure with characteristics of strong friction fit and anti-rotation design. A 3-levelled closure inside the BTLock implant prevents any fluid or bacteria penetration.

5-year post-restoration life table success rate

During a 5-year period, in the multi-centred study, it was demonstrated that BTLock implants had an almost 98.2% success rate after the first year, 97.6% after the second year, 97.2% after the third, 96.8% after the fourth, and 95.5% after the fifth year of post-restoration follow-up (Tab. 1). Standardized radiographs demonstrated high level of marginal bone gain (Fig. 6) and excellent osseointegration after 2 years period (Fig. 6A and 6B). There were few adverse events, with only 1 case of peri-implantitis. No case of abutment loosening was detected in a 5-year period.

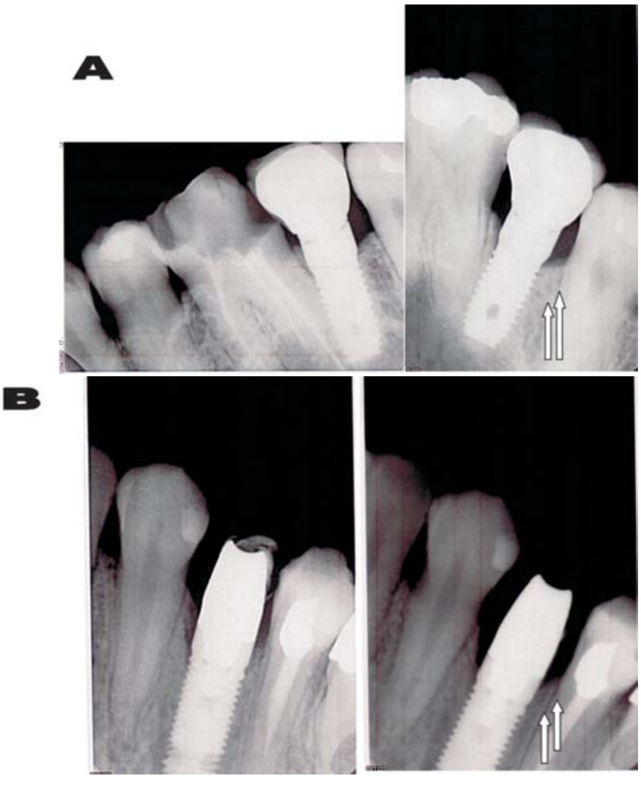

Figure 6. BTLock implant in clinical practice. Radiographs of BTLock implants in area 37 (A) and 44 (B) at the day of insertion (left), and 2 years after loading (right). The implants are clinically healthy and it is possible to observe a very good osseointegration of implants without any bone loss during the time (arrows)

Table 1. A 5-year post-restoration success rate with BTLock implant restorations

No. Implants/ No. Patients	Time period (months)	Success Rate Life Table
2911 / 1152	0-12 months	98,2%
2911 / 1152	13-24 months	97,6%
2911 / 1152	25-36 months	97,2%
2911 / 1152	37-48 months	96,8%
2911 / 1152	49-60 months	95,5%

Discussion

There is no question that the clinical success of an implant depends heavily on treatment planning, implant placement, design and fabrication of the final prosthesis, and the patient's personal hygiene[7]. It is imperative that the implant system selected has well-documented, long-term clinical data, so that we can confidently assure the patient of the predictable results. In keeping with the aforementioned parameters, there are many choices of dental implant systems: straight-walled or tapered; threaded or cylindrical; machined, coated, or enhanced titanium or titanium alloy; and external or internal connection. There are abundant clinical researches demonstrating that surface coatings and surface enhancements improve the biologic effect in poor-quality bone[13,14]. Additional issues to consider when selecting an implant system include the location of the implant, aesthetic requirements, quality/quantity of bone and soft tissue, and the planned surgical protocol (immediate placement, 1-stage surgery, 2-stage surgery, or immediate loading)[15].

Numerous new implant designs and materials have become available over the last decade, each with special claims of superiority in restoring complicate cases[16]. It has recently been observed that in implants with screw-retained abutments, in *in vitro* as well as *in vivo* conditions, bacteria can penetrate inside the internal cavity of the implant as a consequence of leakage at the implant-abutment interface[17]. An alternative to screw-retained abutments is represented by implants that can receive cemented abutments. In this case, the abutment goes through a trans-mucosal friction implant extension (collar), and is cemented inside the internal portion of the implant. Apart of that, the mechanical strength and anti-rotational stability of the abutment play a decisive role for the immediate function of implants.

BTLock implant is the new designed system of *asymmetric double-triangulated 3-levelled internal connection.* BTLock implant system is a problem-solving new design, created in order to achieve and improve primary stability of implant, screw tightening, anti-rotational stability and anti-fluid and microbial penetration. It was important to provide a synchronized geometry of BTLock implant, both on the male and female parts of implant fixture. Conceptually, by manufacturing the male anti-rotational asymmetric double-triangulated long pillar with a self locking taper, and seating it into the mating female, also double-triangulated cup (Fig. 4B) with frictional resistance, the intimate locking connection eliminates the effect of occlusal vibration. The longer pillar-fixture connection of BTLock implant also distributes forces deeper within the implant, shielding the retention screw from excessive loading (Fig. 1A and Fig 3A). Lateral forces could be transmitted directly to the walls of the implant and the implant-abutment mating bevels, providing greater resistance to interface opening than with a butt-joint connection.

Rotational freedom (misfit) for BTLock implant with minimal finger pressure tightening was 0 degree when fully tightened to 30 Ncm (data not presented). The light microscopy cross-sections of BTLock system document an intimate internal contact and interference fit that result in abutment rotational stability, which is very important for optimal occlusion and forces distribution[18,19]. Binon[20] and Luterbacher et al[21] demonstrated that many systems suffered inaccuracies, both in the diameter of the implant resulting in unevenness, gaps and recesses on the abutment interface, and in the abutment itself. The number one restorative problem with retrievable systems is loose screws[2,20]. The recent focus on rotational misfit has resulted in reassessment of the machining tolerance of external hexagonal and their abutment counterparts[20]. Several manufacturers have reduced the rotational misfit between coupling hexagons to less than 4 degree in an effort to reduce screw joint failure[22]. Another design concept is an internal hexagonal recess within the implant body and a tapered hexagonal extension on the abutment. Close inspection of literature did not give sufficient data to compare with our results. No similar internal connection design is present on the market. Comparing with other types of internal connections presented in figure 5, completely different symmetric one-levelled closures, non comparable with BTLock *asymmetric double-triangulated 3-levelled internal connection*, could be observed.

The BTLock implant has a long pillar entering into fixture, much longer than in similar implant systems (Fig. 1A). This is another advantage for biomechanical stability and optimized masticatory forces distribution.

This prospective study evaluated the safety and efficacy of the BTLock implant restorations in premolar-molar mandibular areas during the 5-year follow-up. We got good treatment results because of the very strict selection criteria to reduce risk, and because we used the BTLock implant system that is proven in practice. This type of design offers a closed and tight relationship between a fixture imparting superior bending strength and elasticity, which exceeds those of other implants having a flat-to-flat interface (Fig. 5).

Conclusions

Results of the current study provided evidence that, under the condition of this initial investigation, BTLock root-form implant system has following advantages:

1. The *asymmetric double-triangulated 3-levelled internal connection* of the BTLock implants is a basis of the increased primary biomechanical stability of implant;
2. Besides an optimized distribution of forces at the implant-abutment interface, the mechanical strength and anti-rotational stability of the abutment have decisive role for the immediate function and longevity of BTLock implants;
3. The BTLock system has an accurate and simple implant-level impression and colour code indexing system to facilitate abutment selection in the laboratory and outside of the clinical environment;
4. Strong consideration should be given to the gingival level closure, which assures good fitting, good tightening and therefore anti-fluid and anti-microbial penetration;
5. Documented long-term clinical survival rates are the evidence of excellent clinical performances of this new BTLock design;
6. Scientific innovation and further research will be our next goal. We live in a very new society, where patient demands and expectations are high. To satisfy our patients, we need ongoing research and development of innovative products. We have to be ready, able, and willing to accept these changes and, further, to be able to incorporate them easily into our practice.

It can be concluded that the BTLock implant can achieve long-term biologic and mechanical stability when used to restore single missing teeth, over a long-term period.

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