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DESIGN OF NEW ROOT-FORM ENDOSSEOUS DENTAL IMPLANT AND EVALUATION OF FATIGUE STRENGTH USING FINITE ELEMENT ANALYSIS

by

Hyung-Seop Han

A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Biomedical Engineering in the Graduate College of The University of Iowa

July 2009

Thesis supervisor: Professor Tae-Hong Lim



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CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's thesis of

Hyung-Seop Han

has been approved by the Examining Committee for the thesis requirement for the Master of Science degree in Biomedical Engineering at the July 2009 graduation.

Nicole M. Grosland

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CHAPTER I

INTRODUCTION

By late 1969, a pioneer named Branemark had published the first evidence of direct bone anchorage termed as osseointegration. He defined the term as a direct structural and functional connection between the living bone and the surface of a load carrying implant. He inserted submerged titanium implants with a machined surface in the jawbone of dogs. The result between the bone integration with the surface of the titanium implant gave great fixation strength [1]. This discovery led to the development of root-form endosseous dental implants. Furthermore, they have become the standard in dentistry in the last 20 years. According to the FDA, "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments," the root-form endosseous dental implant device refers to the fixture that is surgically implanted into the patient's bone. The root-form endosseous dental implant device is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore the patient's mastication function. At present, all of these root form implants are commonly perceived to be created equal in terms of their effectiveness for patient treatment.

The main problem with the current root-form endosseous dental implant design is long implantation process time to get to the usable condition. In fact, the clinical success rate is almost 100 % for 5 year follow up studies, but it takes literally months to



get these "new teeth" in. There is a new method called the "Immediate Loading procedure," which utilizes radiographic 3-dimensional CAT scans to make a totally accurate representation of the patients' jaw-that one may then construct a mechanical template of the jaw. This allows the dentist to place implants with extreme precision. However, this method has yet to prove its reliability since there are several reports of early failure due to minute errors in the implanting process.

Numerous dental implants are commercially available at present. However, there is no clear guideline providing best information about the critical parameters, such as endosseous root form, surface treatment, prosthetic attachment, placement technique or brand of implant, that result in any perceptible advantages to the patient in terms of the clinical result at the present time [2].

One approach to achieve faster loading by enhancing tissue responses at dental implant interfaces has been the introduction of ceramic- like calcium-phosphate (CP) containing materials as implant devices. One of the most important uses of CP materials has been the coating on metallic substrates; the most commonly used CP material type to coat metallic substrates is Hydroxyapatite (HA). HA is biocompatible and bioactive in the body. HA also displays an osteoconductivity; a property that encourages bone being formed to lie closely, or adhere, to a material's surface. This is especially useful for an implant where fast healing is required [3,4].

Favorable clinical results were reported for HA coated implants. They have a higher integration rate, promote faster bone attachment, and achieve direct bone bonding with higher interfacial attachment strength to bone when compared to uncoated metallic



implants [5]. HA dental implants are regarded as the benchmark of the dental implant surface treatment. Subsequently, there are currently various HA coated dental implants available in the market today.

However, HA coated dental implants have also been associated with clinical problems as well. One of the major concerns with plasma-sprayed coatings is the possible delamination of the coating from the surface of the titanium implant and the failure at the implant-coating interface despite the fact that the coating is well-attached to the bone tissue. The different layers of HA coating have been often reported to cause delamination and particle release under fatigue stress resulting in clinical failure of implants [6~9]. Coating delamination has been reported in dental situations where the efficacy of plasma-spraying is not optimal due to the size of the dental implants [10]. Loosening of the coating has also been reported, especially when the implants have been inserted into dense bone [11]. For all of the above reasons, the clinical use of plasma-sprayed HA-coated dental implants is limited.

Magnesium is a biocompatible lightweight metal. Magnesium has a very unique characteristic of dissolving readily in an aqueous solution that contains chloride ions [12]. It has been reported that magnesium forms a soluble and non-toxic oxide in body fluids that is harmlessly excreted with the urine [13]. Due to this unique characteristic, in the recent years, there has been significant increase in the research on magnesium and magnesium-based alloys into a development of new biodegradable orthopedic material [14]. As shown in Table 1, magnesium has a density of 1.738 g/cm³ at 20 °C, which is 35.6% lower than that of aluminum and 61.3% lighter than titanium [15]. The fracture



toughness of magnesium is greater than ceramic biomaterials, such as synthetic hydroxyapatite, while the elastic modulus and compressive yield strength of magnesium are closer to those of natural bone, compared to the case for other commonly used metallic implants [16].

		1		
Properties	Natural bone	Magnesium	Ti alloy	Synthetic
				hydroxyapatite
Density (g/cm ³)	1.8-2.1	1.74-2.0	4.4-4.5	3.1
Elastic modulus (GPa)	3-20	41-45	110-117	73-117
Compressive yield Strength (MPa)	130-180	65-100	758-1117	600
Fracture toughness (MPam ^{1/2})	3-6	15-40	55-115	0.7

Table 1. Summary of Material Properties

Source: M.P. Staiger et al. Magnesium and its alloys as orthopedic biomaterials: A review. Biomaterials 27 (2006) 1728-1734

However, the fast corrosion of pure magnesium in the physiologic environment with pH level (7.4-7.6) and high chloride concentration prevents the orthopedic use of an implant made of pure magnesium alone [16]. Orthopedic implants must be able to retain their mechanical integrity while the tissues heal. This means that biodegradable implants are required to possess sufficient strength to prevent sudden catastrophic/premature failure while they are allowed to dissolve [14].

The long-term goal of this study is to develop new dental implants that can induce better and faster osteointegration induced by Mg-Ca alloy coating on the bone screw portion. The purposes of this preliminary study were to develop a prototype and to



investigate the effect of the Mg-Ca alloy coating and its degradation on the fatigue strength of the newly developed implant through finite element simulations and fatigue tests.



CHAPTER II

LITERATURE REVIEW

Dental implants are believed to date back to Egyptian times when seashells were trimmed and shaped before being hammered into the jaw to replace missing teeth. Slots were made into the bone and the shells were wedged in to potentially fuse with the bone due to their calcium carbonate content [17]. In Europe, the earliest reference to an implant in modern literature appeared in a French work published in 1809. This literature shows that dentists were experimenting with implants made out of lead and extracted teeth of human and animal [18-19]. As the 20th century started, dentists continued to search for materials and designs that would survive for more than a brief period after implantation. The first major breakthrough came in 1941 when a Swedish doctor, named Gustav Dahl, placed a metal structure below the periosteum; vertical extensions protruded through the gingival [20]. This breakthrough led to the development of the technique for placing subperiosteal implants in the United States by two dentists, Aaron Gershkoff and Norman Goldberg, from Providence, R.I. As shown below in Figure 1, subperiosteal implants consist of a metal framework that attaches on top of the jawbone but underneath the gum tissue.





Source: Thomas D et al. Dental Implants: Are They for Me. University of Connecticut Health Center.

Another breakthrough came with the work of Leonard I. Linkow of New York, who in 1964 introduced a blade implant shown in Figure 2 that eventually became the most widely used implant design in the 1970s. The name of the implant derived from their blade-like portion which is the part that gets embedded into the bone. Blade implants are not used frequently in present time due to their weak tolerance to stress and strain. However, they do find an application in areas where the residual bone ridge of the jaw is too thin to place root form implants [21].





Figure 2. Endosseous Implants

Source: Thomas D et al. Dental Implants: Are They for Me. University of Connecticut Health Center.

The true birth of modern dental implant came in the late 1950s by a Swedish biologist and physician named Per-Ingvar Brånemark. He was studying bone healing response and regeneration in order to observe the functioning of bone marrow in vivo. He adapted an experimental chamber that had been used in England for insertion into rabbit ears. However, he was unable to obtain tantalum which was the material used in the original experiment. As a substitute material, he used titanium to make a chamber that could be inserted into rabbit legs. After a series of investigations, he found the titanium chamber could not be removed from the rabbit bone [18-19]. Brånemark reportedly was not struck by the significance of this turn of events until sometime after 1960 when he accepted a professorship in the Department of Anatomy at Gothenburg University. In



Gothenburg University, Brånemark and his team investigated the workings and structure of human blood cells under a number of conditions using an adaptation of the titanium chamber placed in the upper arms of human volunteers. This experiment provided a great deal of information about the nature of blood. In addition, it showed the researchers that the titanium appeared uniquely compatible with the human soft tissue and skin, provoking no adverse immunological reactions. It is at this point that Brånemark began to contemplate using titanium for medical applications [1, 19].

In the years that followed, Brånemark and his team designed titanium screws and inserted them into the jaws of beagle dogs to study the conditions needed to achieve a solid bond between the bone and the metal. They studied the biomolecular processes that occur when titanium is placed in living tissue. As this understanding advanced, Brånemark believed it was necessary to coin a new term to refer to the in-growth of the bone into the threads and crevices of titanium. He finally settled upon "osseointegration," derived from the Latin words os (bone) and integro (to renew) [1, 19]. Similar to many of the great inventions out there today, this serendipity discovery ultimately led to the development of endosseous root form implants which are the most common type of implants in use today.

Anatomical Background

Humans are provided with two sets of teeth, which make their appearance at different periods of life. Those of the first set appear in childhood are called the



deciduous teeth. The deciduous teeth are twenty in number: four incisors, two canines, and four molars, in each jaw. Those of the second set are named permanent. The permanent teeth are thirty-two in number as shown in Figure 3 below: four incisors, two canines, four premolars, and six molars, in each jaw [22].



Figure 3. Permanent Teeth

Source: Henry Gray. Anatomy of the Human Body. 1918.

Human teeth, like most teeth of vertebrates, are composed of a hard thin working surface called enamel that overlies the bulk of the tooth composed of a softer more pliant material called dentin. As shown in Figure 4 below, each tooth consists of three major



portions: the crown, projecting above the gum; the root, imbedded in the alveolus; and the neck, the constricted portion between the crown and root [22].

Enamel is the hard, shiny, white outer surface of the tooth. Tooth enamel is the hardest substance in the human body. Pulp is located at center of the tooth and contains blood vessels and nerves. It nourishes the dentin which is the hard but porous tissue located under both the enamel and cementum. The dentine forms the principal mass of a tooth.

Cementum is a layer of tough, yellowish, bone-like tissue that covers the root of a tooth which helps to hold the tooth in the socket. A root is the anchor of a tooth that extends into the jawbone. The number of roots range from one to three and they are surrounded by the soft tissue called gingiva (gum). Cementums are embedded with fibers called the peridontal membrane. The periodontal membrane is a strong, fleshy tissue between the tooth and tooth socket that holds the tooth in place. It also acts as a shock absorber when different set of loads are applied on the tooth.





Figure 4. Tooth Anatomy

Source: American Dental Association. Tooth Anatomy. 2008.



Biomechanical Design of Dental Implants

It is quintessential to understand the fundamentals and the components of the implant before introducing any new design, modifications, to the clinically proven Branemark dental implant (95% success for implants in the mandible and 85~90% for the maxilla after 5 years) [2, 23]. The following reviews of the literatures were done to understand the biomechanical theories behind the implant and to offer a justification for the new design.

Implant diameter is the dimension measured from the peak of the widest thread to the same point on the opposite side of the implant [24]. It is considered to be more important than the implant length in the distribution of loads to the surrounding bone. At least 3.25 mm in diameter is required to ensure adequate implant strength and most implants are approximately 4 mm in diameter [24]. From a biomechanical standpoint, the use of wider implants allows an engagement of a maximal amount of bone, and a theoretically improved distribution of stress in the surrounding bone [25]. It has been confirmed that more bone contact area provides increased initial stability and resistance to stresses [26]. The increase in diameter will result in a higher percentage of bone contact by increasing the surface area of the implant. Previous research, done by Misch CE et al, shows that increasing the diameter in a 3 mm implant by 1 mm increases the surface area by 35% over the same length in overall surface [27]. Another research, done by Mahon JM et al, shows that increasing the diameter of an implant results in a decrease in the abutment strain for a given load [28]. This means that an implant can obtain



improved implant strength and resistance to fracture by appropriately increasing the diameter of implants [29]. Implant diameters up to 7 mm are available but they are not so widely used since sufficient bone width is uncommonly encountered.



Figure 5. Diameter of Implant

Implant length is the dimension from the platform to the apex of implant. Most common lengths are between 8 and 13mm which correspond quite closely to normal root length. It has been an axiom in the implant dentistry that longer implants guarantee better success rates even though there is no proven linear relationship between implant length and success rate of the implant [24]. The use of short implants has not been recommended because it is believed that occlusal forces must be dissipated over a large implant surface area to prevent excessive stresses at the interface [30]. Over the years, commercially available 7mm implants (usually the shortest on a company's lineup) reported higher failure rates compare to 8.5mm, 10mm and 11.5mm implants [2]. The



relationship between initial mobility and implant length has not been established. Several mechanical analyses have supported the view that increasing the implant length may only increase success rate to a certain extent [31].



Figure 6. Length of Implant

There are basically four types of prosthetic attachment: the external hex, internal hex, internal taper (morse taper), and spline. An ideal prosthetic attachment is one that will allow complete security in the union and the ability to replace components in exactly the same orientation at any time. It should also allow for a variety of prosthetic components and have a means of providing for alignment correction in cases of malplacement [32].





Figure 7. Types of Prosthetic Attachment

The external hex type is the original prosthetic connection for the dental implants designed by Dr. Brånemark. It is the most common type of prosthetic attachment and has proven to be a stable prosthetic attachment for all kinds of restorations [33-34]. An internal hex type is a fairly common attachment with a greater stability due to its longer hex. One major disadvantage is a possible fracture of the thin fixture head. It is also more expensive compared to the external hex and patent rights are constantly being argued in the market. Internal tapered attachments allow for an abutment to be friction seated into the head of the implant fixture. It is simpler to use because there are no screws involved but there is no way to accurately re-seat an abutment. Similar to the internal hex type, there is a possibility of a fixture head fracture. The spline has proven to be more stable



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than other types with respect to anti-rotation. Its main problem is the weak resistance to lateral force [33-34]. Theoretically, an external hex type would be more prone to loosening since the abutment screw must withstand the load. Compared to an internal type, loads are distributed to the surface of the fixture to result in less loosening. However, screw loosening rate is not any higher for external hex type in reported clinical in vivo studies [24, 32].

It is a widely accepted fact that the thread geometry has a significant effect on implant biomechanics. Most implants in the market today have a serrated thread to enhance initial stability and increase surface contact area [35, 36]. Another important factor in an implant thread is a pitch which stands for the number of thread per unit length. Improvement in contact area between bone and implant were shown by increasing pitch and depth between individual threads [5]. A previously performed study by the National Center For High-Performance Computing (NCFHC) shows that the sliding distance between the implant and the bone is generally higher in the region of the upper thread and the end thread of fixture as shown in Figure 8a. The sliding distance measures the movement of implant under loading where the bone to implant interface is not fixed but placed next to each other with a set of friction coefficients. This study also shows that the maximum sliding distance is larger in the step thread implant than in the uniform thread implant. It is possible to improve the implant initial stability and long-term survival by reducing implant to bone sliding distance. The Von Mises stress around bone is also larger in the step thread model than in the uniform thread model. This implies that the step thread implant is more likely to become loose after being implanted [37].





Figure 8. Result Of Finite Element Analysisa) 3D models used in studyb) Result of finite element analysis study

Source: National Center for High-Performance Computing. "Two Fixture Designs of Immediately Loaded Dental Implants." (2002)



Materials of Dental Implants

The range of metals used for dental implants has become limited to cobaltchromium(Co-Cr) alloy, commercially pure titanium, and a titanium alloy (Ti6Al4V) as these provide a good corrosion resistance and reasonable fatigue life. However, osseointegration is a property particularly unique to titanium [38]. Osseointegration requires a bio-inert material and osteophilic surface. There are three distinct phases in the process of osseointegration. The first phase is a direct bone healing where the preexisting bone matrix is exposed to the body's extracellular fluid enabling growth factors and proteins to trigger and activate bone repair. The second phase occurs upon the repair of bone where the first bone that is formed is a woven bone. This is formed within the first 4-6 weeks post-surgery. In the third phase, 4-6 weeks post-surgery, the bone structure changes and adapts to the applied load. The structure of the bone becomes a lamellar (or parallel fiber) bone. Osseointegration provides great implant stability in the body and cellular attachment with the implant.

The successful applications of magnesium-based alloys as degradable orthopedic implants are mainly inhibited due to their high degradation rates in physiological conditions [39]. The Mg-Ca alloys are mainly composed of two phases: $\alpha(Mg)$ and Mg2Ca. The mechanical properties and biocorrosion behaviors of these phases can be adjusted by controlling the Ca content and the processing treatment. Biocompatibility tests of Mg-Ca alloy done by Zijian Li et al. also demonstrated its qualification as orthopedic biodegradable materials.



Thickness of the coating affects resorption and the mechanical properties of the implant. Thickness of the HA coating for dental implants can be up to 20 micrometers [16]. The Mg-Ca Alloy will dissolve too fast to display any real benefit if it is coated thin. It will also result in poor mechanical properties of the coating. Therefore, a new shape of titanium base was proposed to overcome this problem. The proposed titanium base will be dipped into an aqueous solution of Mg-Ca alloy and then threaded after it solidifies to achieve the similar shape profile as the Branemark implant. The idea is that the Mg-Ca alloy will degrade overtime leaving space to be replaced by formations of bone material. The proposed titanium base shape will increase the contact surface area which will provide more stability compared to the original Branemark implant. In addition, the proposed design will be easier to take out, compared to the traditional shape, due to its helical shape.



CHAPTER III MATERIALS AND METHODS

The design was finalized with all the specifications chosen from the extensive literature reviews follow the market standard. New implant will consist of proposed new helical coating, 4 mm in diameter, 10 mm in length, external hex prosthetic type, uniform thread profile with standard pitch size of 0.6 mm, and clinically proven serrated self tapping threads to obtain initial stability and increase contact surface. Finalized 3D model shown in Figure 9 below was constructed using ProEngineer software.



Figure 9. Finalized BAM Implant Design Magnesium Alloy Part (Left) and Titanium base part (Right)



Computer simulations have become a useful part of mathematical modeling of many natural systems in physics (computational physics), chemistry, biology, human systems in economics, psychology, social science, and in the process of engineering new technology to gain insight into the operation of those systems or to observe their behavior. The main advantage of computer simulations is that it is safe, efficient and cheap. A computer simulation technique called the finite element analysis (FEA) is used in engineering analysis. It uses a numerical technique called the finite element method (FEM) which calculates an approximated solution of partial differential equations and integral equations. A common use of the FEA is to determine the stresses and displacements in mechanical objects and systems. It is used for new product designs, and in existing product refinement. A common FEA program called ANSYS can be used in order to predict the effectiveness of the new design before it is tested in vivo. ANSYS Workbench 11.0 was used to carry out two different finite element analyses.

Static Loading Experiments

The first simulation setup followed a published research by Bozkaya et al at Northeastern University in Boston [40]. The implant fixture is placed inside a bone block to simulate full osseointegration and the load is applied on the abutment. The bone block is modeled as a cylinder with a 20 mm diameter and 22 mm height around the implant. The cortical bone is modeled at the top and bottom of the cylinder as 2 and 3 mm thick layers, respectively, with an elastic modulus of 13.7 GPa. The trabecular bone is modeled as a 17 mm thick layer between two cortical layers, with an elastic modulus of 1 GPa.



The material properties of the implant were based on the certificate of conformity and the literature [41]. The mechanical properties of the titanium alloys used are shown in Table 2. The structures in the models are all assumed to be homogeneous, isotropic and linearly elastic. Both Branemark and the proposed implant were modeled in 3D using ProEngineer software.

Elastic Modulus Ultimate Strength Poisson's Ratio Yield Strength 1.16 E11 Pa 0.34 2.2 E8 Pa Abutment 1.4 E8 Pa Abutment Screw 1.16 E11 Pa 0.34 1.4 E8 Pa 2.2 E8 Pa 1.16 E11 Pa Fixture 0.34 1.4 E8 Pa 2.2 E8 Pa Magnesium Alloy 4.5 E10 Pa 0.35 1.96 E8 Pa

Table 2. Material Properties in Finite Element Analysis

Source: Wang K et al. The use of titanium for medical applications in the USA, Materials Science and Engineering, A213 (1996) 134-137.

The maximum biting forces of molar and incisor were determined from current literature. The biting forces were measured with the biting fork placed between the first molars and between the incisors. In the males, the maximal bite force measured in the molar region was 39 kg (382 N) and 18 kg (176 N) in the incisor region. Corresponding values for the females were 22 kg (216 N) and 11kg (108 N) [42, 43]. Most dental implants with 10 mm length are used in incisor region and therefore 180 N was used in the simulation as a maximum biting force. Both BAM and branemark implant models' stress values were calculated using von Mises stress and compared with each other. As



the worst case scenario, BAM implants without the magnesium part to simulate full biodegradation and osseointegration after implantation were also modeled.

Branemark Design	Number of nodes	Number of element
Cortical bone	3,681	1,029
Fixture	9,214	4,419
Magnesium part	3,305	1,402
Trabecular bone	14,318	9,053
Total	30,518	15,903

Table 3. Finite Element Model for BAM Implant

Table 4. Finite Element Model for Branemark Implant

BAM Design	Number of nodes	Number of element
Cortical bone	3,432	913
Fixture	6,391	2,981
Trabecular bone	18,831	11,973
Total	28,654	15,867

Table 5. Finite Element Model for BAM Implant without Magnesium Alloy part

BAM Design	Number of nodes	Number of element
Cortical bone	3,960	1,174
Fixture	9,214	4,419
Trabecular bone	20,151	12,822
Total	33,325	18,415



24





c) Implant inside bone block



Fatigue Experiments

Another simulation was performed to the study fatigue life of the new implant design. This simulation's purpose is to verify that the titanium part of the proposed design is strong enough to achieve the fatigue life (5 x 10^6 Cycle) suggested by the International Organization for Standardization (ISO). ISO provides more specific specifications and constraints in ISO 14801 — Fatigue test for endosseous dental implants. These specifications and constraints shown in Figure 11 were strictly followed for both simulation and testing. The endosseous dental implant is clamped at a distance $3.0 \text{ mm} \pm 0.1 \text{ mm}$ apically from the nominal bone level and such that it makes a $30^\circ \pm 1^\circ$ angle with the loading direction of the testing machine. Simulation is carried out with a unidirectional load with a frequency less than 15 Hz. This load varies sinusoidally between the nominal peak value and 10 % of the peak's value [44].



Figure 11. Test Specifications and Constraintsa) Schematic diagram of experimental system from ISO 14801b) 3D Model of the schematic diagram used in fatigue simulation



Sines method was used for the fatigue life calculation. This method reduces multiaxial stress into an equivalent uniaxial stress. While ANSYS Workbench uses it along with S-N curve to estimate the fatigue life. It can be represented by the equation 1 below.

$$\sqrt{(\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_3 - \sigma_1)^2} + m(\sigma_{m1} + \sigma_{m2} + \sigma_{m3}) = \sqrt{2}S_{Nf}$$
(1)

Where m is the coefficient of mean stress influence and S_{Nf} is the uniaxial, fully reversed fatigue strength that is expected to give the same fatigue life on uniaxial smooth specimens as the multiaxial stress state. $\sigma_1, \sigma_2, \sigma_3$ are alternating components of the stresses and $\sigma_{m1}, \sigma_{m2}, \sigma_{m3}$ are the mean components of the stresses calculated using equation 2 [45].

$$\boldsymbol{\sigma}_{\mathrm{mi}} = \frac{1}{2} \left(\boldsymbol{\sigma}_{\mathrm{imax}} - \boldsymbol{\sigma}_{\mathrm{imin}} \right) \tag{2}$$

S-N curve, also known as a Wöhler curve is a graph of the magnitude of a cyclical stress (S) against the logarithmic scale of cycles to failure (N). Fatigue material model of titanium alloy (Ti-6Al-4V), shown in Figure 12, is used for this simulation. Sines method can be used to calculate the estimation of fatigue life.





Figure 12. S-N Curve of Titanium Alloy (Ti-6Al-4V)

Source: Jung-Hun Son et al., 2006, Fatigue Life Estimation of Implant Using a Finite Element Method., J Korean Acad Prosthodont.

To validate the simulation and verify the fatigue life of the new design, ninety prototypes shown in Figure 13 were built and fatigue tests were conducted in exactly same setting as the computer simulation using 810 Material Test System (MTS 810). The MTS 810 system shown in Figure 14 is completely integrated testing packages to let one easily obtain information about the mechanical properties of any materials or components.





Figure 13. BAM Implant



Figure 14. 810 Material Test System



Jig shown in Figure 15 was manufactured to clamp the prototypes according to the ISO 14801.



Figure 15. Jig for the Fatigue Test



CHAPTER IV

RESULTS

Static Loading Experiment Results

Maximum Von Mises stresses occurred at the fixture, cortical bone and trabecular bone for BAM implant are shown below in Table 6. The BAM implant without the magnesium alloy part to assume full biodegradation after implantation and Branemark implant are also presented in Table 6.

	Equivalent (Von Mises) stress in MPa				
	BAM Implant	BAM Implant BAM implant without Branemark Implant			
		Magnesium alloy part			
Fixture	73.5	73.6	66.3		
Magnesium Part	21.9				
Cortical Bone	11.1	12.3	11.3		
Trabecular Bone	7.90	7.34	7.38		

Table 6. Maximum Von Mises stresses (MPa)

Results show that BAM implant would perform in a reasonable manner well under the ultimate strength of both cortical (170 MPa) and trabecular bone (less than 10 MPa depending on the porosity) [46]. Figures 16-19 shows the stress distribution in graphics.





Figure 16. Finite Element Analysis Result of Fixtures in Pa

BAM Implant (Left), BAM Implant without Magnesium Alloy (center) and Branemark Implant (Right)



Figure 17. Finite Element Analysis Result of Magnesium Part in Pa



Figure 18. Finite Element Analysis Result of Cortical Bone in Pa BAM Implant (Left), BAM Implant without Magnesium Alloy (center) and Branemark Implant (Right)





Figure 19. Finite Element Analysis Result of Trabecular Bone in Pa. BAM Implant (Left), BAM Implant without Magnesium Alloy (center) and Branemark Implant (Right)

Fatigue Experiment Results

Fatigue life simulations were carried out until they reached the fatigue limit (5 x 10^{6} Cycle) or until they showed signs of deformation with unidirectional load of 150 N, 300 N, 400 N, and 500 N. BAM implant without magnesium part was used to assume complete biodegradation and osseointegration. Table 7 shows fatigue simulation conditions and results for the BAM implant.

Maximum Load (N)	Minimum Load (N)	Frequency (Hz)	Fatigue Life
500	50	14	0 Cycle
400	40	14	5,460 Cycle
300	30	14	344,000 Cycle
150	15	14	5 x 10 ⁶ Cycle

Table 7. Fatigue simulation conditions and results for the BAM Implant



Simulations were conducted in 300 N, 400 N and 500 N as well, to compare and validate the simulation results with experiment results. Figures 20-23 shows the fatigue analysis results in graphics using unit of cycle.



Figure 20. Fatigue Life Result for the BAM Implant with Maximum Load of 150 N Abutment (Left), Fixture (center) and Abutment Screw (Right)



Figure 21. Fatigue Life Result for the BAM Implant with Maximum Load of 300 N Abutment (Left), Fixture (center) and Abutment Screw (Right)





Figure 22. Fatigue Life Result for the BAM Implant with Maximum Load of 400 N Abutment (Left), Fixture (center) and Abutment Screw (Right)



Figure 23. Fatigue Life Result for the BAM Implant with Maximum Load of 500 N Abutment (Left), Fixture (center) and Abutment Screw (Right)

Table 8 shows fatigue simulation conditions and result for Branemark implant.



Maximum Load (N)	Minimum Load (N)	Frequency (Hz)	Fatigue Life
500	50	14	5,781 Cycle
400	40	14	64,797 Cycle
300	30	14	$5 \ge 10^6$ Cycle
150	15	14	5 x 10 ⁶ Cycle

Table 8. Fatigue simulation conditions and results for the Branemark Implant

Simulations were conducted in 400 N and 500 N as well to compare and validate the simulation result with experiment result. Figure 24-27 shows the fatigue analysis results in graphics.



Figure 24. Fatigue Life Result for the Branemark Implant with Maximum Load of 150 N Abutment (Left), Fixture (center) and Abutment Screw (Right)





Figure 25. Fatigue Life Result for the Branemark Implant with Maximum Load of 300 N Abutment (Left), Fixture (center) and Abutment Screw (Right)



Figure 26. Fatigue Life Result for the Branemark Implant with Maximum Load of 400 N Abutment (Left), Fixture (center) and Abutment Screw (Right)



Figure 27. Fatigue Life Result for the Branemark Implant with Maximum Load of 500 N Abutment (Left), Fixture (center) and Abutment Screw (Right)



Following the computer simulations, actual prototypes were built with the same design specifications and tested using MTS 810. Table 9 shows fatigue test conditions and results for the BAM implant.

Maximum Load (N)	Minimum Load (N)	Frequency (Hz)	Fatigue Life
700	70	14	3,600 Cycle
			3,600 Cycle
500	50	14	
300	30	14	173,612 Cycle
			208,081 Cycle
250	25	14	360,000 Cycle
150	15	14	5 x 10 ⁶ Cycle
			5 x 10 ⁶ Cycle

Table 9. Fatigue test conditions and results for the BAM Implant

Figure 28 and 29 shows the fractured dental implants from the fatigue test.





Figure 28. Fractured Implant from Fatigue Test with Maximum Load of 700 N Failed at 3,600 Cycle (Left) and Failed at 3,600 Cycle (Right)



Figure 29. Fractured Implant from Fatigue Test with Maximum Load of 300 N Failed at 173,612 Cycle (Left) and Failed at 208,081 Cycle (Right)



CHAPTER V

DISCUSSION

There are many factors to consider in order to achieve success in the development of new dental implant. Minor changes in shape, length, diameter, and material used in implant can heavily influence the success rates [26]. The understanding of how these factors affect the implant design allows the engineers to more accurately predict the potential outcome of new dental implant design. The main advantages of proposed BAM implant design are rapid osseointegration due to biodegradation of magnesium alloy and reduction in abutment stresses and strain due to increased bone to implant contact surface area. Initial stability of implant is achieved by utilizing the shape of the clinically proven Branemark dental implant.

Result from the static loading analysis can be used to validate proposed simulation method and to explain crestal bone loss and early implant failure at the implant-bone interface after applying excess loading. In clinical situations, cortical bone will bear more load than trabecular bone since the cortical bone is stronger and more resistant to deformation compared to trabecular bone [47,48]. Figures 16-19 clearly shows that the simulation predicted higher concentration of stress in cortical bone region compared to trabecular bone region. Result also shows that the high concentration of stress occurs primarily where bone is in contact with the implant. Previous study done by Holmes et al also found that when all factors are equal, greater overall stress occurs in the



smaller area of bone in contact with the implant body [49]. It is evident that applying an excess amount of loading will cause higher concentration of stress in contact region and ultimately lead to bone loss and implant loosening.

Result from the fatigue analysis shows that the proposed design can be used as a permanent root-form endosseous dental implant solution. The Branemark implant fatigue life simulation result shows that Branemark implant would achieve fatigue limit of 5 x 10^6 cycle suggested by the ISO at 150 N and 300 N. This is a reasonable estimation since the Branemark implants display 95% success rate after 5 years and 90% after 10 years [23]. As shown in Figure 30, the results obtained in simulation of Branemark implant type comply with existing literature. The calculated fatigue simulation data is in accordance with the findings of Jung-Hun Son et al [50].



Source: Jung-Hun Son et al. "Fatigue Life Estimation of Implant Using a Finite Element Method". J Korean Acad Prosthodont. 2006 Aug;44(4):414-420.



Both simulation and experimental result proved that the BAM implant would achieve a fatigue limit of 5×10^6 cycle suggested by the ISO at 150 N. Considering the maximum voluntary bite force of human incisor is about 150 N, this suggests that the BAM implant can be used as a permanent root-form endosseous dental implant solution. The result of the FEA computation depends on many individual factors, including material properties, boundary conditions, interface definition, and also on the overall approach to the model [51]. There are several assumptions and simplifications made in the simulation process to optimize the calculation speed. It is apparent that the simulation does not provide an exact solution. However, as shown in Figure 31, the computer calculated simulation data can provide a close approximation of experimental fatigue behavior, validating the accuracy of proposed fatigue life estimation method.



Figure 31. Comparison of Calculated Fatigue Life Simulation Data and Experimental Data



The location of the fatigue failure in the implant system was estimated with a high accuracy in the simulation. As shown in Figure 32, the computer simulation data showed high concentration of stress in the possible region of fatigue fracture. This prediction was also validated with the experimental result displaying similar fatigue fracture location.



Figure 32. Fracture Location after Fatigue Test

In near future, miniature pigs will be used in the animal testing to verify the benefits of proposed design. Miniature pigs were chosen as a test subject since the size of their jawbone is as thick as a human's jawbone. These pigs are used frequently in dental surgery since the tooth structure of the miniature pig closely resembles that of human more than any other species as shown in Figure 33 and 34 [52].





Figure 33. Mandible of Miniature Pig



(I2/C1/P2/M3) [Human]



(I3/C1/P4/M3) [Micro-pig®]

Figure 34. Comparison of Tooth Structure

Thirty two prototypes and thirty two regular Branemark implants (control) will be manufactured. Each miniature pigs will have four prototypes and four controls on its premolar and molar as shown in Figure 35.





Figure 35. Extraction of Premolar and Molar Region a) Before the extraction of premolar and molar region b) After the extraction of premolar and molar region

Two miniature pigs will be sacrificed in two weeks interval. Histological and histomorphometric evaluation of the implants will be performed to monitor the bone growth; while the pull out test will be performed to monitor the fixation strength. Tests' duration will be a total of 8 weeks. If the BAM implant demonstrates fast and reliable bone growth to promote early osseointegration during this period, the test will advance to be conducted on human patients.



CHAPTER VI

CONCLUSION

One of the vital factors in the dental implant design process is to investigate the fatigue behaviors. In this study, a three-dimensional finite element analysis model was constructed to investigate the fatigue behaviors of new dental implant design and fatigue test was done in order to prove the reliability of proposed design. There could be limitations of the study due to the assumptions made on the properties of the materials in the finite element models and due to the simplification of the interface between implant and holding jig device. Nevertheless, It was shown that computational modeling and 3D simulation using finite element analysis enabled the realistic prediction of dental implant fatigue behavior.

The main advantage of performed computer simulations is that it is fast, efficient and cheap. A comparison of the calculated fatigue life with experimental fatigue life data displayed the accuracy and reliability of the computer simulation method. The proposed method for estimating fatigue behavior can be applied to other dental implant designs to improve the implant and the implant designing process. New implants can be designed and justified in computer simulation using finite element analysis before they are produced to save time and money.



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