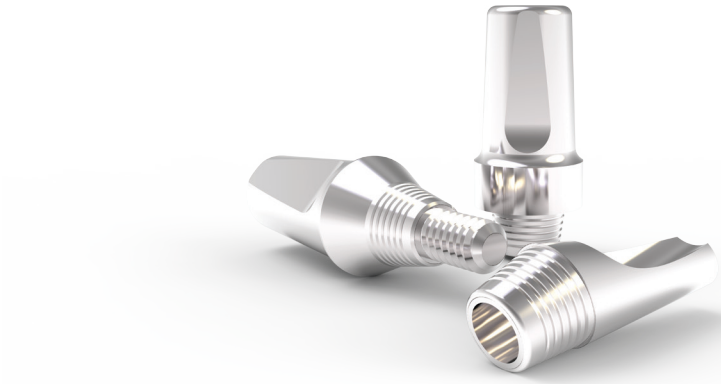
CE 1293 GMP ISO 13485

UFIT DENTAL IMPLANT



2011

Ufit® dental implant

Published Yonsei University Research

D. U. KIM (Changwon Mechanical Design Engineering)
H.J. KANG (Changwon Mechanical Design Engineering)
D.S. HONG (Changwon Mechatronics Engineering)
J.S. SHIM (Yonsei Unversity of Dentristry)
S.Y. LEE (T-Strong Inc.)

403, 433-8, Jangan-dong, Dongdeamun-gu, Seoul 130-100, Republic of Korea

The Ufit® Dental Implant History.

2001 JULY	***Established T.STRONG (Manufacturer)***
	Reported One year Clinical Experiments
2002 MAY	Registered Product Licensed by the Korea Food & Drug Administration (KFDA). Brand Name: UFIT
	Registered Product Licensed by the Busan Regional Korea Food & Drug Administration
2003 SEPT	Recognition of Materials & Components Enterprise by MCT (Materials & Components Technology)
	Certified ANSI/ISO/ASQ Q9001-2000. Certificate NO: 17162-QMS-2538
	Contracted for Dental Implant Technical in cooperation with KOREA INSTITUTE OF MACHINERY & MATERIALS (KIMM)
2003 OCT	Applied Patent Registration for Torque Wrench Driver Adapter
2004 FEB	Applied Patent Registration for Dental Locking Abutment
2004 FEB	***Established T.STRONG INC. (Corporation)***
2004 MARCH	Acquired Patent Registration for Torque Wrench Driver Adapter (Registration No. 0345598)
2004 MAY	Acquired Patent Registration for Dental Locking Abutment (Registration No. 0350606)
2004 AUG	Participated in Gyeong Nam Regional Specialized Industry and Technology Development
	(GYEONGNAM REGIONAL INNOVATION AGENCY, KOREA INSTITUTE OF SCIENCE AND TECHNOLGY EVALUATION AND PLANNING)
2004 SEPT	Contracted for Dental Implant Technology in cooperation with KOREA INSTITUTE OF MACHINERY AND MATERIAL (KIMM)
2004 OCT	Signed an Agreement for Technology Development for the Removal of 3D (Difficulty, Dirty, Danger)
	in Manufacturing (KOREA INSTITUTE OF INDUSTRIAL TECHNOLOGY)
	Success of TRANSPLANTATION test for External and Internal Type Dental Implant System (KOREA TESTING AND RESEARCH INSTITUTE)
2004 NOV	Designated as a CLEAN place of business (Ministry of Labor)
2004 DEC	Received a Commendation for Medical and Pharmaceutical Product superiority and Good Example Enterprise
2005 JUNE	Signed an Agreement for Technology Development (CHANGWON UNIVERSITY)
2005 OCT	Acquired Product License (Grade:4) from the KOREA FOOD AND DRUG ADMINISTRATION (KFDA)
2006 APR	Selected as Top Company with Best Technology Innovation in Business and Brand Sector by Sports Seoul (LIFE Section)
2007 SEPT	Acquired Certification from KOREA GOOD MANUFACTURING PRACTICE (KGMP) (Certificate No.: MGK-537)
2008 JAN	Sealing Abutment Development
2009 SEPT	Sealing Abutment Application
2010 FEB	***Applied Domestic Patent for Sealing Type Abutment***
2010 JUNE	Registered Product License of Sealing Type Abutment and Launching
2010 JUL	Registered Product License of Hybrid Surface Treatment of Laser Neck Implant
2010 AUG	***Established UFIT Implant Inc.***
2010 NOV	Renewal of KGMP Certificate (Certificate NO: KTR-AB-090778)
2011 FEB	***Applied PCT Patent for Sealing Type Abutment***
2011 JUL	***Received Certified ISO 130485 License, CE Product License (GT2 Fixture)***
	Established branches in Australia and The Philippines
2011 SEPT	***Received Domestic Patent for Sealing Type Abutment***

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ISO 13485


EVPU
CERTIFICATE
T.STRONG INC.
181-4, Uijeon-ri, Jinyeong-eup, Gimhae-si, Gyeongnam, Korea
Certification body of management systems hereby confirms that management system of above-mentioned organization has been assessed and certified as meeting requirements of
ISO 13485: 2003
for
Development, Production, Sales, R&D of Implant device

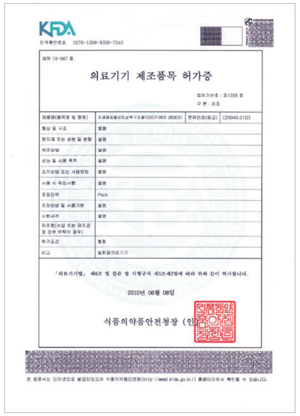
GMP Certificate


의료기기 제조 및 품질관리기준 적합인정서
(Certificate of GMP)
식품의약품안전청장
한국화학시험연구원장

CE Certificate


EVPU
NOTIFIED BODY No. 1293
EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM
No. 41069/101/1/2011/CE

Product License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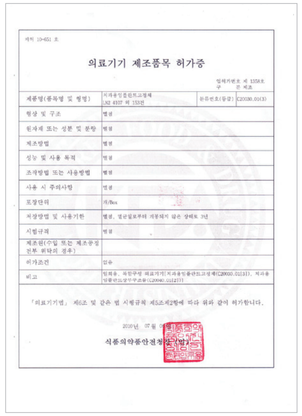
식품의약품안전청장

Product License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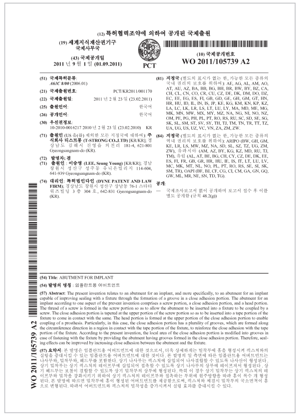
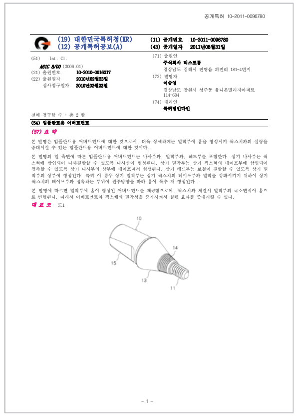
PCT


WO 2011/105739 A2

Domestic Patent


(19) 대한민국특허청(KR)
(12) 공개특허공보(A)

Patent Registration
for Torque Wrench Driver Adapter


실용신안등록증
위의 고안은 실용신안법에 의하여 실용신안등록 원부에 등록되었음을 증명합니다.
특 허 청

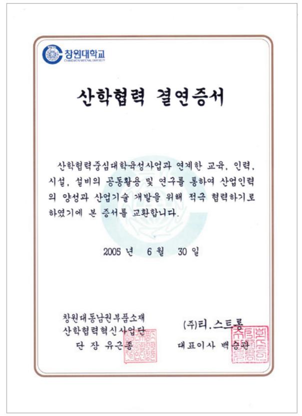
Patent Registration
for Dental Locking Abutment


실용신안등록증
위의 고안은 실용신안법에 의하여 실용신안등록 원부에 등록되었음을 증명합니다.
특 허 청

CLEAN place of business
(Ministry of Labor)


CLEAN 사업장 인정서
사업장명 : (주)티스트롱
대 표 자 : 백 승 관
소 재 지 : 경남 김해시 진영읍 의전리 181-4
귀 사업장을 안전하고 쾌적한 「CLEAN 사업장」으로 인정합니다.
2004년 12월 30일
노 동 부 장
한국산업안전공단 이사장

Agreement for Technology Development
(Changwon University)


창원대학교
산학협력 결연증서
산학협력중심대학육성사업과 연계한 교육, 인력, 시설, 설비의 공동활용 및 연구를 통하여 산업인력의 양성과 산업기술 개발을 위해 적극 협력하기로 하였기에 본 증서를 교환합니다.
2005 년 6 월 30 일
(주)티.스트롱
대표이사 백승관

DEVELOPMENT OF A NEW SEALING ABUTMENT FOR IMPROVING THE CONTACT STATE BETWEEN THE ABUTMENT AND FIXTURE

D. U. KIM,[1] H.J. KANG,[1] D.S. HONG,[2] J.S. SHIM,[3] S.Y. LEE[4]

1) Changwon Mechanical Design Engineering
2) Changwon Mechatronics Engineering
3) Yonsei Unversity of Dentristry
4) T-Strong Inc.

RESEARCH OBJECTIVE :

After the concept of body and noble metal osseointegration had been reported, many researches, experiments and clinical applications had passed, scientific verifications were made and the effectiveness of reliable implants was proven. But the size and shape of screw, screw joining force and the chewing force is still being researched. The present research is to address the loosening problem in the conventional abutments by proposing to make a sealing abutment with a different shape in which its usefulness is verified by the Finite Element Analysis.

RESEARCH MATERIALS AND METHOD :

Analysis is done by using the Fatigue Experimental Method ISO 14801 Application for Conventional Dental Implant System. Here the Finite Element Analysis on the contact state where the stress is put between the abutment and the fixture is considered, 3D Modeling using ANSYS Workbench is done, and separate case analysis is done on the Sealing abutment and the Conventional abutment.

RESULT :

1. Separate case analysis is done on the Sealing and conventional abutment
2. In the case of the conventional abutment, there is less contact in the fixture. Here gaps can be seen in the abutment and the fixture.
3. In the case of the Sealing abutment, few gaps occurred in the fixture section. This means that contact capacity in the abutment and fixture is excellent.
4. In the case of the sealing abutment, when 774.98MPa of pressure and 880MPa of material tensile strength is allowed in the contact part, form separation occurring in the elastic region can be seen.

CONCLUSION :

The ideal basis of the conclusion is that as gaps frequently appear on the fixture portion when conventional abutment is used, the sealing abutment idea is proposed and the analysis performed has verified the result. Therefore in this research, the proposed sealing abutment's new concept of having the high contact capacity as the pressure in the cylindrical surface is uniformly distributed, a very effective sealing effect can be seen.

Main Words: Sealing abutment, Implant, Finite Element Analysis, Sealing, Surface Contact

INTRODUCTION

After the concept of body and noble metal osseointegration had been reported, many researches, experiments, and clinical applications had passed, scientific verifications were made and the effectiveness of reliable implants was proven. Therefore, the role of implants as teeth replacement and researches on its biofunctionalilty are actively progressing.

Researches on Implants are about the size and the shape of thread, the size and shape of the abutment, the screw joining torque and the chewing force. Of them, the effect of chewing force on bone loss, sinking and loosening conditions has been reported. In the case of conventional abutment loosening occurs. The perfect contact of wide surface to surface is thought possible but in reality is impossible. The teeth characteristics and repetitious chewing force shown in Fig. 1, the surface contact deformation causes gap in the fixture. When a gap or loosening occurs, adhesion of bacterial material to the teeth causes teeth sinking and fracture in the fixture, the patient has to go to the hospital again because the gap has to be tightened and have the inconvenience of having another fixture treatment. Various researches are being done to reduce the gaps and improve the existing implants.

The various components of the manufacturing phase are as follows; the manufacturing precision by the time of implant making, the precision of the machine itself, the manufacturing process according to used tool and wear, the temperature change according to time, the vibrational effect of machine and tool, and the error in linear Interpolation Algorithm which decreases the manufacturing precision when two axis move simultaneously.

The method for solving problems like this is to increase the grinding process; the precision quality is increased by one stage so the cost of production increases. The grinding process presents a difficulty in the normal process for the fixture which has a very small inside diameter of not more than 3.5mm. To complement this research, factors were searched for methods of improvement, implant placement and the effect of implant manufacturing to show the important role of abutment features and design concept.

In this research the concept of the abutment design is to have a new design that considers the proposal of a sealing abutment and the contact state between fixtures in which the effectiveness of the present product is verified by the Finite Element Analysis.

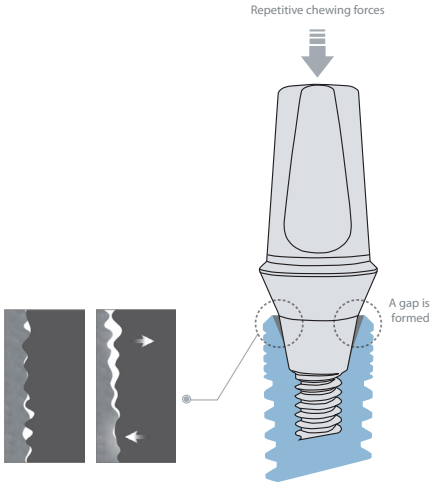


Fig. 1
External force in the conventional abutment creates gaps

Research Subject and Method

1. Sealing Abutment Proposal

When coupling Fixture and Abutment, surface contact on the Tape is needed for the inner surface of the fixture and the outer surface of the abutment. Also the perfect contact surface of the fixture and abutment in the tape surface processed by Lathe Machining is impossible in reality.
Theoretically, the loosening mechanism known in fixtures and abutments that happens at local contact is unpredictable due to local plastic deformation which forms the gap in that part. The constant chewing pressure on the gap eventually causes the loosening of the screw. Fig. 1 shows the current state occurring in the gap in the external surface of the conventional abutment. Food debris gets in between the minute gaps which cause the loosening of the screw, sinking and fracture in the fixture occurs.
This research is to address the problem of fixture and abutment surface contact with the development of an abutment that has a new feature. Or, by making grooves in the Taper circumference of the abutment that acts as chewing force in the teeth, the chewing pressure on the contact surface is concentrated. Such relatively flat elastic deformation occurs on the circular surface of abutment with coherent pressure. When chewing force is applied on the contact surface, the contact is more adhesive and a more effective sealing effect is formed with the elastic deformation of the surface to surface contact
Such sealing effect is often used in industrial and real life. The elastic rubber of the tire thread in the tore structure concentrates the force in the concave space when force is subjected to the ground and the surface contact area. A wider surface in the piston ring or the sole of the shoes when used uniformly distributes the contact force overall making it more effective.
When such original principal application in the abutment is applied, the distribution of force in the protruded circumference of the abutment prevents the screw from loosening and the abutment from swaying. Fig. 2 shows such developed concept of the sealing abutment.

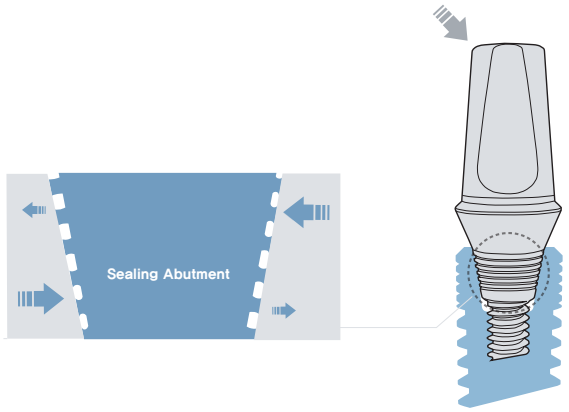


Fig. 2
Grooves in the sealing abutment

2. Finite Element Analysis on the Sealing Abutment

2.1 Analysis Constraints

In this research, analysis is done by using the Fatigue Experimental Method ISO 14801 Application for Conventional Dental Implant System. Force is applied on the upper portion of the abutment with an inclined force of 30. Table 1 shows the mechanical properties of the abutment and fixture.
In reality, fractures appear between the abutment and the fixture. Modeling is done on the contact state portion between the fixture and abutment with focus on the portion of the contact state except that this portion is simplified in modeling.

	Abutment	Fixture
Density	$4430 kg/mm^3$	
Poissons Ration	0.342	
Tensile Strength,Yield	790MPa	
Tensile Strength, Ultimate	860MPa	
Compressive Yield Strength	860MPa	

Table. 1
Mechanical Property of Ti-6A1-4V

2.2 Analysis Result

Separate analysis is done on two cases of conventional and sealing abutment. The bar is the same as the modeling in Fig. 3 and the slip on the mutual contact between the abutment and the fixture is shown.
In fig. 4 the boundary conditions are the same, the external fixture is in fixed support and the symmetry modeling is given symmetry conditions. In Fig. 5 a pretension load of 177.4N is applied to the space between the abutment and the fixture same as in the screw's initial pressure. In reality, this is applicable to 0.35Nm of the screw joining torque. Meanwhile a 250N external chewing force is applied to the upper part of the abutment in a 30 slope, and the contact state of the abutment and the fixture has a 0.2 friction coefficient.

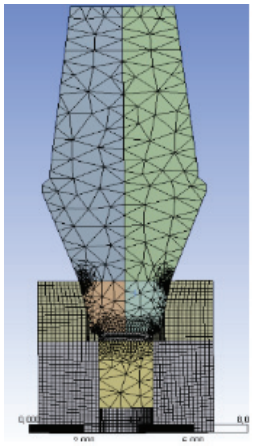


Fig. 3
Modeling of the abutment and fixture

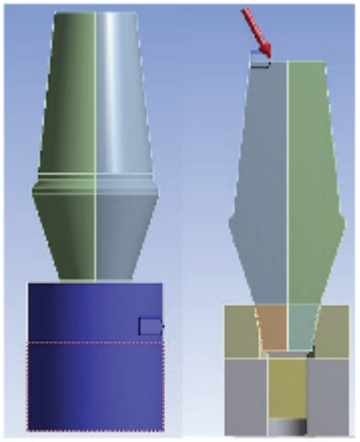


Fig. 4
Boundary Conditions

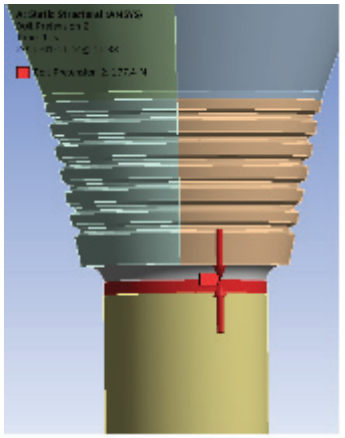


Fig. 5
Preloaded Joining Force

3. Analysis Result

Analysis on two separate cases as screw joining force and 30 slope force is considered. Case 1 is the analyzed condition of the abutment without grooves as in the case of the conventional abutment and case 2 is abutment with grooves as in the case of the sealing abutment. Figure 6 and Table 2 shows the analysis result.
In Fig 6(a) upper right and lower left portion result shows blue color which means there is no contact in the fixture. That is, in between the Abutment and the fixture, gap can be seen. Whereas in Fig 6(b) the gap can only be seen on the top right of the projected sedentary part of the sealing abutment and in other parts the force is relatively distributed. This means that the gap almost does not occur overall. In the above symmetry modeling drawing, considering the opposite situation, it is known that gaps occur more in conventional abutment than in sealing abutment.

Table 2 shows that the joining force in Case 2 is twice as high as in Case 1. In this case joining force of the sealing abutment is relatively higher than that of the conventional abutment which means more effective sealing effect.
Whereas, Table 2 shows the max. stress in case 1 and case 2 which has a little difference. Considering the tensile strength of 880 mpa in two cases, the change in elastic range that occurs can be seen.
At least in the shown result, the circumferential distribution and the joining force of the sealing abutment is higher than that of a conventional abutment which means that the sealing effect is much effective.

Fig. 6 Analysis Result

	Max Stress	*Contact Pressure*	*Max Deformation*
Case 1	374.9 MPa	362.16 MPa	2.14×10^{-2} mm
Case 2	334.6MPa	774.98 MPa	2.07×10^{-3} mm

Table. 2
Result of the FEA

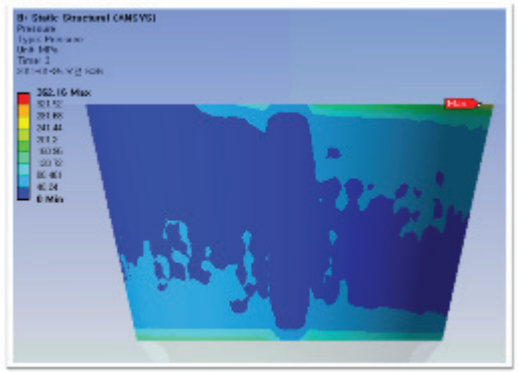


Fig. 6
(a) Conventional Abutment

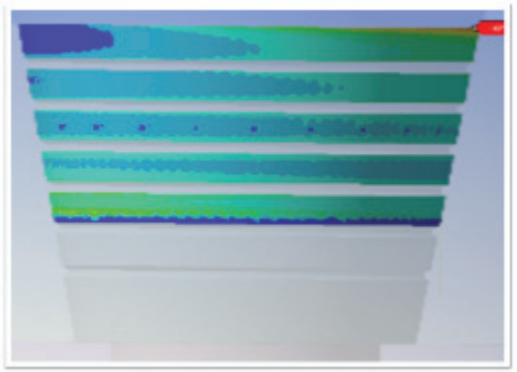


Fig. 6
(b) Sealing Abutment

CONCLUSION

The present research is the idea of reducing the gap that occurs in conventional abutment that appears between the abutment and the fixture, and proposes the abutment that has grooves that forms the sealing abutment. Finite element analysis in consideration of the pretension and surface contact is performed and verified.
Analysis on conventional abutment is also performed and the result is compared. In comparison of the sealing abutment and the conventional abutment, it showed that the joining force of the sealing abutment is higher, gaps in between the fixture and the abutment relatively does not occur and the elastic range of the abutment has also been seen. Therefore this research proposes the concept that the circumferential force distribution and the joining force of the sealing abutment is much higher than the conventional abutment thus having a much greater sealing.

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A revolution in dental implant system.

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UFIT Ufit Implant INC.

TEL. +82 2-2217-0028
FAX +82 2-2217-0008

HeadOffice
403, 433-8, Jangan-dong, Dongdeamun-gu,
Seoul 130-100, Republic of Korea

General Manager
Kim Choung Lim

TEL. +82-2-2217-0028
MOB. +82-10-2617-0342
E-mail. chounglim.kim@ufitimplant.com

Assistant Manager
Amy Lee

TEL. +82-70-7720-3471
MOB. +82-10-6777-7606
E-mail. amy.lee@ufitimplant.com