Comparison of Fracture Behavior among Different One-Stage Implants under Cyclic Loading

Junghoon Yoo

D.D.S, Seoul National University, 2000

A Thesis

Submitted in Partial Fulfillment of The

Requirements for the Degree of

Master of Dental Science

at the

University of Connecticut

2010

APPROVAL PAGE

Master of Dental Science Thesis

Comparison of Fracture Behavior among Different One-Stage Implants under Cyclic Loading

Presented by

Junghoon Yoo, D.D.S.

Major Advisor: J. Robert Kelly

Associate Advisor: Douglas J. Adams

Associate Advisor: John R. Agar

University of Connecticut

2010

Acknowledgements

I would like to express my gratitude to all my advisory committee members. It could not be possible to finish my project without endless support from Dr. J.Robert Kelly. I also appreciate Dr. Douglas J. Adams his help on sample analysis, which provided me a lot of interesting information. And I cannot forget Dr. John R. Agar. He always believed me on what I had been doing. It was really fortunate to have him as my committee member and a program director.

I also thank all faculty members and co-residents in graduate prosthodontics program for supporting me throughout my residency. Without any one of them, I could not finish my three year training.

And I love my wife, Jongmin Oh. I will never forget her enormous support throughout my life. My lovely kids, Gayon, Jiho, and Chansuh, always make me smile. They replenished me every day. I appreciate my in-laws, Jack Oh and Kyunghee Park their dedication to support my family. My mother, Sooyeon Song, always encouraged, believed and supported me. I wish I could have my father, Seungjae Yoo today. He inspired me as a great dentist. And I also thank my brother, Sanghoon for his technical support on my thesis writing.

TABLE OF CONTENTS

Approval page ii

Acknowledgement iii

1. Background 1

Introduction 1

Fatigue fracture 3

Abutment and implant connection 4

One-stage implant system 5

Mechanical testing condidion-ISO14801 6

Previous in vitro test of the Stramumann implants 7

2. Objectives and hypotheses 8

3. Materials and Methods 10

Mechanical testing 11

Scanning electron microscopy(SEM) analysis 14

μComputed Tomography(CT) analysis and digital radiography 15

Statistic analysis 15

4. Results 16

Implant failure 16

Implant failure mode 17

Statistical analysis 20

Evaluation of the fracture surface –SEM analysis 23

μComputed Tomography(CT) analysis 34

5. Discussion 35

Survival of the samples 35

Failure mode of the implants and SEM analysis 36

6. Conclusions 42

7. Future work 43

8. Bibliography 44

Appendix 46

1. BACKGROUND

a. Introduction

Titanium was successfully introduced to dentistry as a tooth root substitute beginning in the early 1960's.[1] It is frequently used in aerospace and sport equipment primarily because of its high strength and corrosion resistance, which are also necessary characteristics for a dental implant material. Titanium derives its biocompatibility from formation of a passive oxide layer.[2] There are four ASTM grades of commercially pure (CP) titanium which are alpha phase in structure and titanium alloys which have a two phases of alpha and beta structure. Grade 4 CP titanium and Ti-6Al-4V are the forms most predominantly used in dental implants due to their comparable mechanical strengths. Ti-6Al-4V is the most widely used titanium alloy in dentistry.[3]

The concept of osseointegration was initially developed by Dr. Branemark and his colleagues in the early 1960's. [1] Initial work involved studying blood flow and wound healing in the bone marrow space with a "vital microscope" which was inserted in the rabbit fibula. The device consisted of a titanium chamber. After long-term study of bone marrow healing, the optical chamber could not be removed. Further research was performed to apply this strong bonding phenomenon for the support of dental prostheses, from complete dentures to single crowns. The clinical application in humans was successful.[3] Now, forty years after their research, many implant companies are making dental implants with different designs, surface textures, and connections. Success rates reported in the clinical literature are commonly over 90%.[4],[5],[6]

The early model of dental implants in the Branemark system utilized three screw connections including the fixture, abutment screw, and prosthesis screw.[1] The junction

between implant body and abutment was at the crest of bone where the stress from physiological function is concentrated.[7], [8] So this weak area was exposed to overloading from the transverse stress. Abutment screw loosening and fracture were reported, as a possible consequence of this design[9]. Goodacre et al.[9] reviewed implant complications and reported 1% implant fracture out of 12,157 implants, 2% of abutment screw fracture from 13,160 implants, and 4% of prosthetic screw fracture from 7094 impalnts. Eckert et al.[10] reviewed computer records in the Mayo Clinic and performed retrospective analysis of implant fractures with a total of 4,937 implants being selected. They reported 1.5% implant fracture in partially edentulous arches and 0.2% in edentulous arches. Jung et al.[11] recently reported on implant related complications in single crowns, with findings including 12.7% abutment loosening, 0.35% of screw or abutment fracture, and 0.14% of implant body fracture.

The Straumann implants were designed as a transmucosal hollow cylinder from the beginning. Until middle of 1980, this implant system was a one part system consisting of the endosseous portion and transmucosal connection part. Even though the design was changed to a two part implant, the connection between abutment and implant was designed to be over 2 to 3 mm above the crest of bone. Many considered the non-submerged design to be biomechanically advantageous compared to the bone level implant,[12] because the junction is away from the most stress concentrated area which is the crest of bone.[7] Levine et al. analyzed single tooth replacement with ITI implants and found 3 implant body fractures out of 157 samples. The fractured implants were hollow-screw or hollow-cylinder implants. No fracture was found in solid screw implants.[5], [6]

Occlusal overload is often cited as a significant risk factor for implant fracture. Balshi et al. reported 0.2% implant fractures from 4,045 implants during 5 years with all implant fractures were found in the patients who had parafunctional habits.[13] Fractured implants were mostly in the posterior region and exposed to bending overload conditions where there was a combination of cantilever load and bruxism or heavy occlusal forces.[14] Even though the excessive loading was considered to be the main etiology of implant fracture in most of the studies, there may be several other risk factors. Virdee and Bishop[15] suggested bending overload, manufacturing imperfections, restoration design, accuracy of fit of restoration, implant numbers, dimensions and positioning, marginal bone loss, occlusion and parafunctional habits, and chemical factors. These factors can be categorized into 1) loading condition 2) implant design 3) mechanical property of implant materials. The proper consideration of these factors in the treatment planning is critical to the longevity of the dental implant prosthesis.[14] Unfortunately, many of these factors are not clearly standardized. For example, without more engineering analysis we cannot even define what "overload" is, especially for any given patient.

b. Fatigue fracture

A fatigue fracture is the result of repetitive or cyclic loading at loads well below those that would cause failure during a single load application. Fatigue failure of a material can be analyzed on a microscopic level. Three steps of fatigue are identified in the microscope: initiation, propagation, catastrophic fracture. Surface scratches caused by handling or tooling the metal surface may create stress concentrators that become the first stage crack initiation site under cyclic loading. The second stage of fatigue fracture

involves stepwise crack growth, one step per load cycle, where fatigue striations (crack arrest marks) are created on the fracture surface. The last stage is the terminal propagation which happens very quickly, often resulting from monotonic ductile fracture.[16] In some of the studies of the implant fracture, the fracture surface was examined at the microscopic level. Morgan et al.[17] compared the fractured surfaces of clinically failed implants with those of experimentally fractured implants under different loading conditions. The surface of clinically fractured implants showed a fracture pattern of fatigue at the scanning electron microscopic level. The surface analysis examined by other studies showed similar results in which fatigue striation were found in the fractured surface in scanning microscopic images.[10], [18]

c. Abutment and implant connection

Biomechanical research on the connection between implant and abutment is limited. Balfour and O'Brien[19] evaluated three different connections (0.7 mm external hexagon, 0.6 mm internal octagon and 1.7 mm internal hexagon) under three different loading condition; torsional loading, combressive bending, and off-axis cyclic fatigue loading. They reported that the internal hexagon was found to provide more predictable results for single tooth replacement.

The connections of Branemark implants and Straumann implants were studied By Khraisat et al.[20] The Straumann implant was found significantly stronger than Branemark implant under 100 N cyclic load perpendicular to the implant axis. Perriard et al.[21] compared the Morse-taper design with synOcta design in the Straumann implant system. From the fatigue test and staircase analysis, no significant mechanical difference was detected between the two connection designs. Comparisons among seven different

implant systems was reported by Möllersten et al. [22] Two systems were external connection and five were internal. The joint depth was considered a contributing factor to determine the structural strength under static loading condition.

It is assumed that all implants manufacturers have performed backup research for the safeguard of consumers, both clinicians and patients. Some of the implant companies have been advertising the compatibility of their new implants to the "original" implants such as the Straumann design. However, there is little or no evidence from the peer-reviewed literature to support combining original implant components with these "clones." Even the results of simple comparisons between these implants are very limited, for example: differences in the screw and thread designs; differences in mechanical properties; differences in surface texture; and, differences in biologic activity.

d. One-stage implant system

The one-stage implant samples tested in this study are Straumann (Straumann, Basel, Switzerland), Stage-1(Lifecore Biomedical, Chaska, MN), One-stage implant (BlueSkyBio, LLC, Grayslake, IL) and Allfit SSO (Dr. Ihdedental Dental GmbH, Eching, Germany). The other three dental implant systems followed the original Straumann implant design especially in the connecting area. However, each system is different from each other to some extent. For example, Stage-1 implant from Lifecore still has a Morse-taper connection without positioning octagonal notches which are now a standard feature of the Straumann design. The connection of BlueSkyBio One-stage implant is claimed to be identical to the Straumann implant but the external thread is more coronally positioned. Moreover, this implant is made of Ti-6Al-4V alloy. Allfit SSO implant from Dr. Ihdedental is identical to the Straumann implant except the implant lengths which are

7, 9, 11, 13 and 15 mm. And the surface roughness is manufactured in different ways. Straumann implants have a sandblasted and etched surface. Resorbable blasting medium was used to Lifecore and BlueSkyBio implant systems.

e. Mechanical testing condition – ISO14801

Studies on mechanical comparison of different implants are not sufficient for both clinicians and researchers to judge the potential mechanical behavior of these various implants with nominally similar design. One helpful approach is to apply standardized the mechanical testing conditions to dental implants with certain designs. The first consensus guidance for fatigue testing of dental implants was ISO14801 in which the testing parameters for dynamic fatigue test for endosseous dental implants were defined. The general underlying principles of this testing protocol were 1) finished device testing, 2) multi-part endosseous dental implants testing, and 3) worst-case testing. The details of the testing conditions are defined in this document. The schematic testing model for no pre-angled connecting part was selected (ISO14801, 5.2.2, Figure 1).

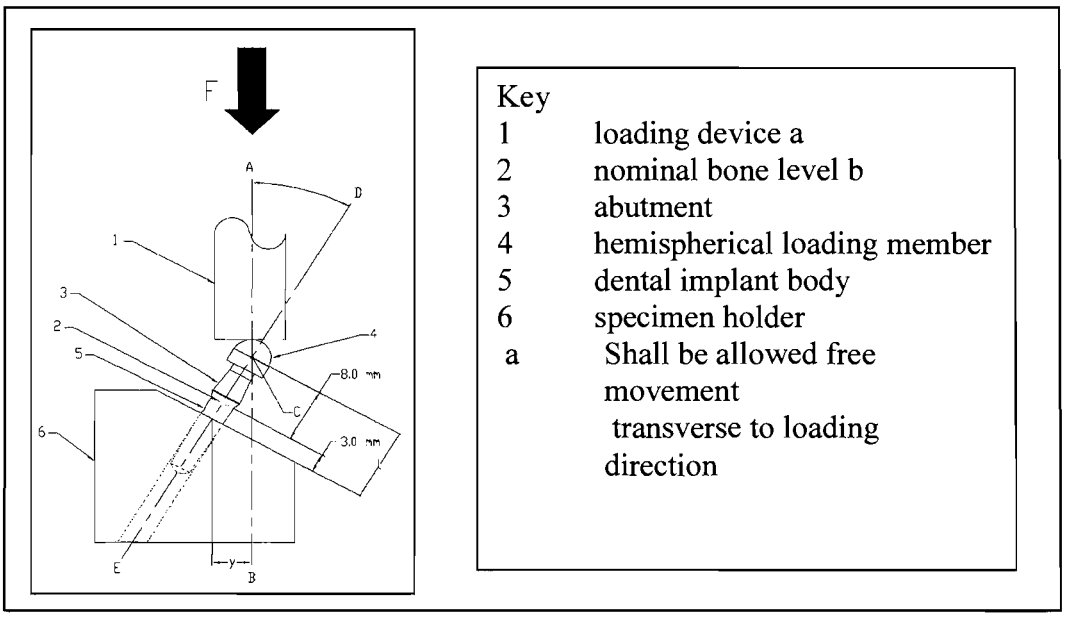

Figure 1: — Schematic of test set-up for systems with no pre-angled connecting parts

f. previous in vitro test of the Straumann implants

There are still a number of variables to control in mechanical testing of dental implants although ISO14801defined baseline conditions. Lee et al.[23] studied different variables in Straumann implant fatigue research. They investigated implant displacement/cycle under different loading frequency, 2 vs 30 Hz. Initial phase of failure, brittle fracture, was more frequently recorded in 2 Hz cycling rate. The dry/wet condition was also examined. The probability of fracture under wet condition (normal saline) was not significantly different from the dry condition (room air). Karl et al.[24] confirmed that fatigue failure was significantly higher in the low frequency (2 Hz versus 30 Hz) whereas the implant holding material (aluminium, acrylic, and fiber reinforced epoxy)and loading magnitude (420 N and 500 N) had a minor influence.

2. OBJECTIVES AND HYPOTHESES

a. Objectives

Dentists are often challenged to decide which implant system is appropriate in their patient care. There are hundreds of implant companies in the market and all claim that their systems meet the standard prerequisites for clinical use. However, many of these commercial dental implants often come out without sufficient experimental data for clinicians. One important benchmark evaluation of dental implants involves their mechanical behavior under cyclic loading.

This study will generate information about mechanical behavior of four different Straumann clones. The data coming from this project will be comparable with worldwide databases of implant fatigue behavior, since the experimental conditions will follow ISO 14801. Additionally, the data may be useful to other researchers comparing the fracture of laboratory and clinical specimens for the purpose of validating the fatigue protocol of ISO 14801. Previous study of fatigue testing performed by Barndt et al. (2008) and Lee et al. (2007) (UConn, MScD theses) reported failure load data for Straumann implants. Fatigue behavior of other Straumann clone implant systems which will be tested in this project can be compared to these previous results to provide a clinical perspective.

The purpose of the present study is to compare the fracture of three one-stage implants, so called Straumann clone implants, with the original design Straumann dental implant under cyclic loading conditions.

b. Hypothesis

The following null hypotheses will be tested;

- There is no significant difference of failure outcome among four different one-stage implants from Straumann, Lifecore, BlueSkyBio, and Idhedental under cyclic loading.

- There is no significant difference in the failure mechanisms of those four implants.

3. MATERIALS AND METHODS

To simulate damage accumulation under masticatory conditions, cyclic loading is a more appropriate than static loading. It is known that damage accumulation can be very different under high numbers of low loads than under the application of one high load to failure. Fatigue fracture of the dental implants may occur after a certain number of repeated loads under specific condition. Occlusal contact is not the result of simple straight movement. Therefore, it is not simple to reproduce all clinical loading situations. To reduce the other variables, it is valuable to limit the mechanical test in a single tooth implant condition under repeated loading with standardized protocol.

ISO (International Organization for Standardization) 14801 specifies a method of mechanical testing of fatigue on the transmucosal type dental implant and its prefabricated components under worst case conditions. Three transmucosal type implants were tested under the protocol of ISO 14801: STAGE-1 (Lifecore Biomedical, Chaska, MN), One-stage implant(Blue Sky Bio, LLC, Grayslake, IL) and Allfit SSO(Dr. Ihde Dental GmbH, Eching, Germany).

Implant system	Product	Length (mm)	Implant Diameter (mm)	Platform diameter(mm)	Transmucsal part (mm)	Abutment height(mm)
LIFECORE	STAGE	12	4.1	4.8	1`.8	5.5
Blue Sky Bio	One	12	4.1	4.8	1.8	5.5
IHDE DENTAL	Allfit	13	4.1	4.8	1.8	5.5
straumann	Standar	12	4.1	4.8	1.8	5.5

Table 1: Implant and abutment selection specifications

Straumann 12 mm long, standard plus implant and 5.5 mm solid abutment was selected as a control. The same specification of implants and prosthetic parts from the clones were tested except the Allfit SSO (Dr. Ihde Dental GmbH, Eching, Germany)

implant because this system has 9, 11, 13, 15, and 17 mm lengths. The sample selection is shown in the Table 1.

a. Mechanical testing

The sample implants were embedded in an aluminum block (ASTM-B211; Small Parts Inc, Miami Lakes, FL, USA). Aluminum bases are tough enough to withstand testing conditions and aluminum falls within the elastic modulus range specified under ISO 14801. The specimen holder was sectioned into 15.9 mm thickness. A 12 mm deep channel was prepared in the center of the aluminum block with a 3.5 mm diameter twist drill in the engineering lathe. Tapping (4.1 mm diameter) was performed using corresponding tapping drills with hand wrench. The sample implants were placed in the aluminum block. The junction of smooth and rough implant surface was placed 3 mm above the embedding material surface, which represent "worst case" according to ISO 14801 (Figure 1).

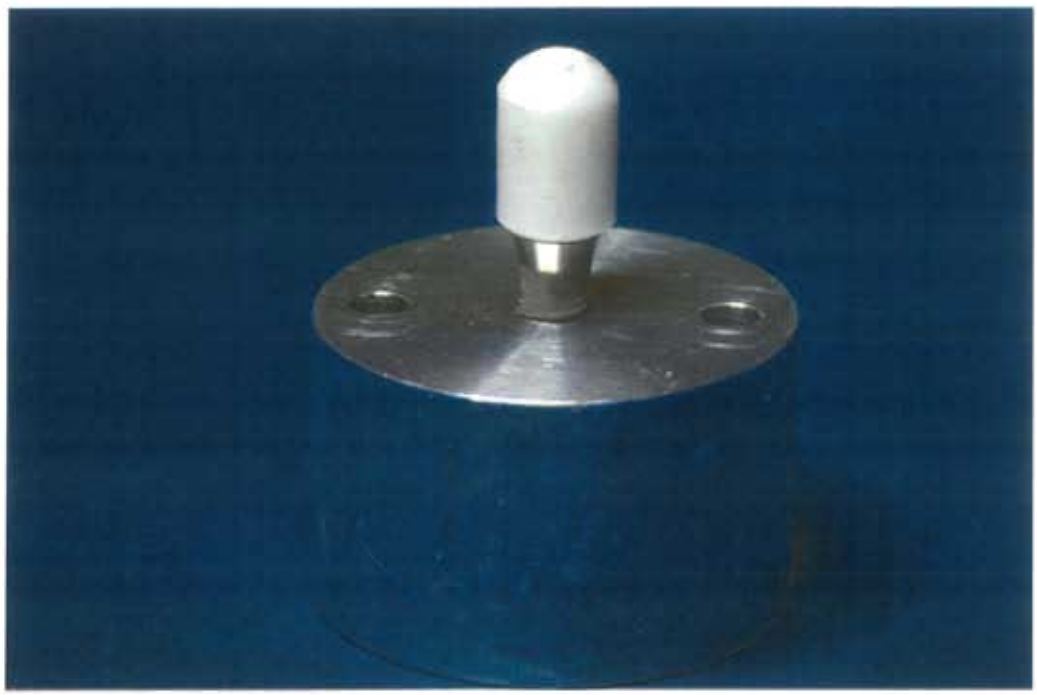

Figure 1. Embedded implant sample

Regular Neck 5.5 mm solid abutments (Straumann, Waldenburg, Switzerland) were torqued down in the embedded sample implants with 35 Ncm according to the manufacturer's manual. A zirconia test crown (Cercon, Dentsply Ceramco, Burlington, NJ) was delivered on the solid abutment without cement since the crown is under constant compressive load during cycling. The test crown was made in the previous study (Dr. Robert Kelly's biomechanical research group) with 8 mm distance between the implant platform and the center of the crown according to ISO14801 (Figure 1).

The embedded implant specimens were mounted at a 30° angle in the stainless steel specimen holding device which was designed to avoid the deformation from the experimental loading condition. The strength and the stability of this holding structure has been tested in a number of past experiments (Figure 2).

Figure 2. Mounted specimen according to ISO1480.

Components of the bearing race including the polyacetal ball bearings (low friction plastic, Delrin) and elastic bands holding the two bearing halves together were evaluated before each testing. These were replaced or refilled when any defect of the components was detected.

The cyclic loading was performed on the mounted specimens with the unilateral sinusoidal wave form. The magnitude of load was controlled between 20N and 500N using electroforce fatigue equipment (Bose-EnduraTEC ELF 3300, Eden Prairie, MN) and Win Test software (Bose Eden Prairie, Minnesota) (Figure 3).

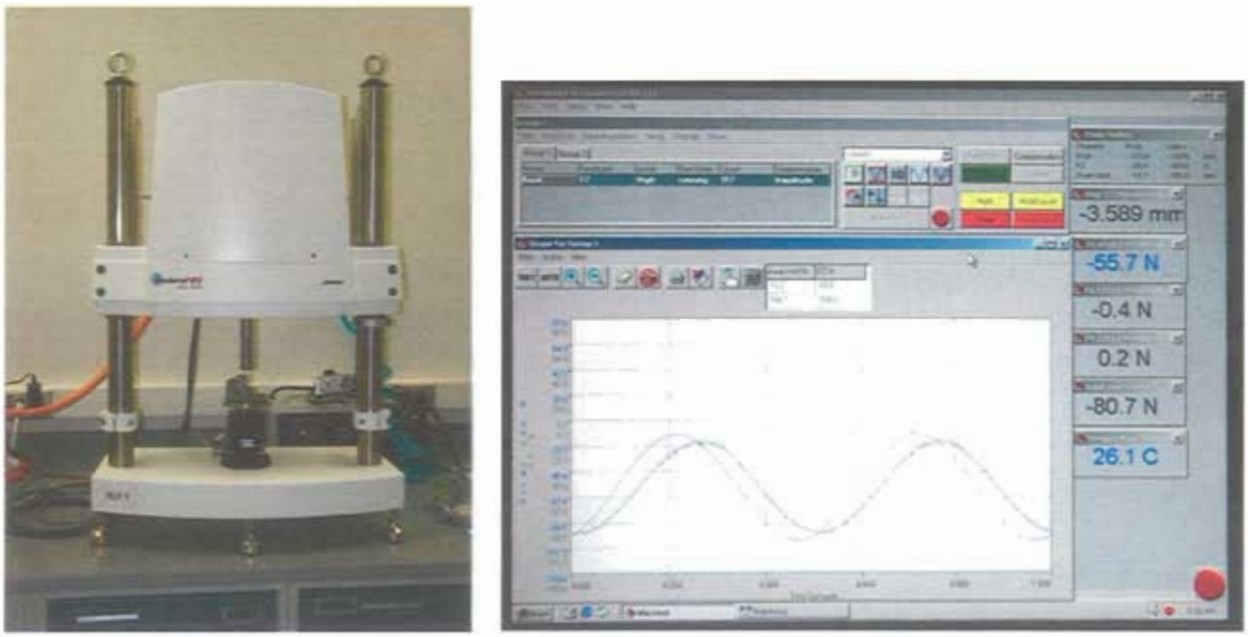

Figure 3. Endura TEC ELF3300 Mechanical testing unit and Win Test® software.

The maximum loading of 500N was chosen based on the previous experiments with the Straumnn implant. The frequency of load cycle was 2 Hz which was proven to be more fracture-inducible than 30 Hz in the previous study. The specimens were subjected to one million cyclic loadings under dry conditions. Fatigue machine was set to stop level at 0.5mm displacement from the initial condition. In the previous study, it

was found that 0.5 mm displacement routinely detected a well-developed crack within the implant. When a sample survived $1x10^6$ cycles it was considered to be a "runout". Abutment fracture alone was often only detected after the specimen survived after $1x10^6$ cycles. The abutment came out from the specimen without additional loading after the specimen was released from the loading cell.

b. Scanning electron microscopy analysis

Failed implants were carefully removed from aluminum base and shortened using a carborundum disc in order to mount at an appropriate level for the scanning electron microscope (SEM) machine. These specimens were cleaned in ultrasonic cleaner with lab dish soap (Contact 70, Decon Lab. Inc. King of Prussia, PA) and rinsed with water. Diluted acetone (1:3 in distilled water) solution was also used to clean the surface. Gold sputter-coating was performed to enhance SEM imaging.

The prepared specimens were evaluated with a tabletop SEM (TM-1000, Hitachi High-Technologies Europe GmbH, Krefeld, Germany)(Figure 4).

Figure 4. Tabletop Scanning electron microscope

The fracture origin was determined by tracing fatigue striations under high magnification (x1,000~x5,000). Initial brittle fracture was verified as a fracture origin. Three phases of fatigue failure were compared to the previous Straumann SEM images.

c. μComputed Tomography(CT) analysis and digital radiography

Digital dental radiographs (Schick CDR, Schick Technologies, Inc. Long Island City, NY) were taken to confirm the abutment fracture of incompletely separated samples.

One intact implant from each implant systems was carefully removed from the aluminum mount. Customized tube was fabricated to locate the sample implants in the μCT machine. Serial tomographic images were acquired in the implant longitudinal axis of the implants using μCT machine (μCT40,Scanco Medical AG, Bassersdorf, Switzerland). Cross-sectional images were analyzed to compare the design difference of each implant systems.

d. Statistical anaylsis

Fifteen samples for each implant design were tested under the loading condition described above. Cycles-to-failure were examined by statistical life testing analysis (Weibull++ and ALTA 7, ReliaSoft Corp., Tucson, AZ). A correlation between failure and three different clone implants was analyzed with Chi square analysis and logistic regression test.

4. RESULT

a. Implant failure

Two Lifecore implants, five BlueSkyBio implants and five Ihdedental implants failed within 1,000,000 cycles. Two additional abutment screw fractures were observed in BlueSkyBio implants and four Ihdedental implants had abutment screw fractures (Table 2).

Implant(failure)	Sample #	Lot #	Failure(cycles)	Failure mode
BlueSkyBio(7/15)	2	07-0088	277,380	I + A
	3	07-0088	1,000,000	A
	4	07-0088	93,258	I + A
	8	07-0088	527,758	I + A
	9	07-0088	676,815	I + A
	13	07-0088	1,000,000	A
	14	07-0088	68,748	I + A
Lifecore(2/15)	7	017664	321,132	I(bent)
	9	017664	32,436	I +A
Idhe(9/15)	2	169731107	345,522	I
	3	169731107	1,000,000	A
	4	169731107	1,000,000	A
	5	169731107	265,587	I
	6	169731107	1,000,000	A
	8	169731107	1,000,000	A
	9	169731107	9,412	I
	11	169731107	1,000,000	I (bent)
	15	169731107	86,724	I

I+A : implant and abutment fracture, I: Implant fracture only, A : Abutment fracture only

Table 2. Failure data of the specimen.

Chi square analyses of the failed samples including implant and/or abutment fracture are presented in Appendix 1. There is significant influence on the failure by the different implant systems (χ 2 = 37.962, df=3, $p < 0.001$). Different implants also significantly affect the mode of the fracture (χ 2 = 48.033, df=3, $p < 0.001$). Straumann

implant data were excluded in the second set of chi square analyses to evaluate the failure difference among other the implant systems. The results were also significant both in the failure outcome ($\chi^2 = 7.223$, df = 2, $p < 0.05$) but the fracture mode ($\chi^2 = 5.722$, df = 2, $p < 0.1$) among the BlueSkyBio, Lifecore, and Ihdedental implant system.

b. Implant failure mode

The data from the previous study (from Dr. Matthias Karl and Dr. Robert Kelly) showed that the entire sample of failed Straumann implants (n=44) had implant body fracture at the level of the base-implant junction. This failure mode was also seen in the Straumann clone implants in the present study along with two additional ones: 1) fracture only in the implant body which is corresponds to the original observations ofStraumann implants (figure5); 2) abutment fracture only (Figure 6); and, 3) abutment fracture combined with the body fracture(Figure 7). One of the Lifecore implants was fractured at the body thread in the same way as the Straumann implant failure. The other Lifecore implant had abutment and body fracture. Five BlueSkyBio implant had abutment and body fracture and two had only abutment fracture after 1,000,000 cycles. The fracture pattern of this implant was different from the Straumann implants. The fracture line was not on the base-implant junction. It was combination of horizontal and vertical fracture lines (Figure 8.). The horizontal fracture line lied in the smooth-rough surface junction. This finding was unique among the implant failure patterns. Ihdedental implants showed both body fracture only and abutment fracture only. The abutment fracture was found after 1,000,000 cycles.

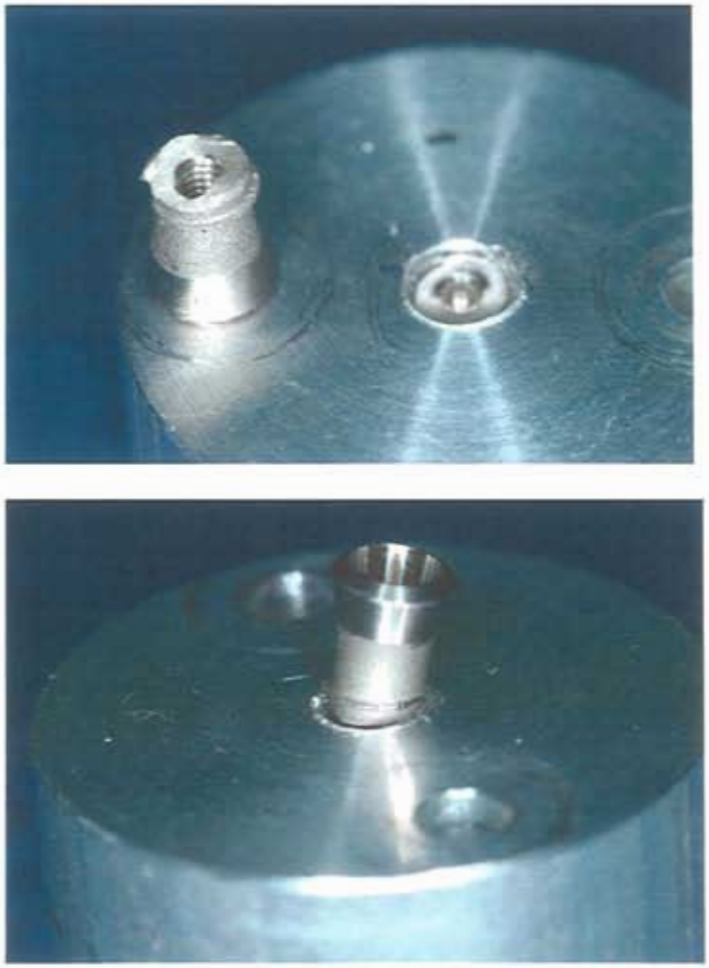

Figure 5. Implant body fracture (Top; Ihdedental #15, Bottom; Lifecore #7).

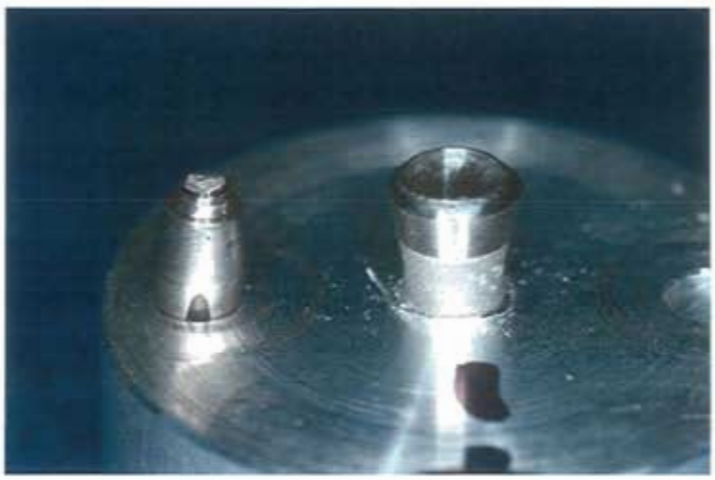

Figure 6. Abutment fracture (Ihdedental #3).

Figure 7. Implant and abutment failure(BlueSkyBio #3,4,8,9).

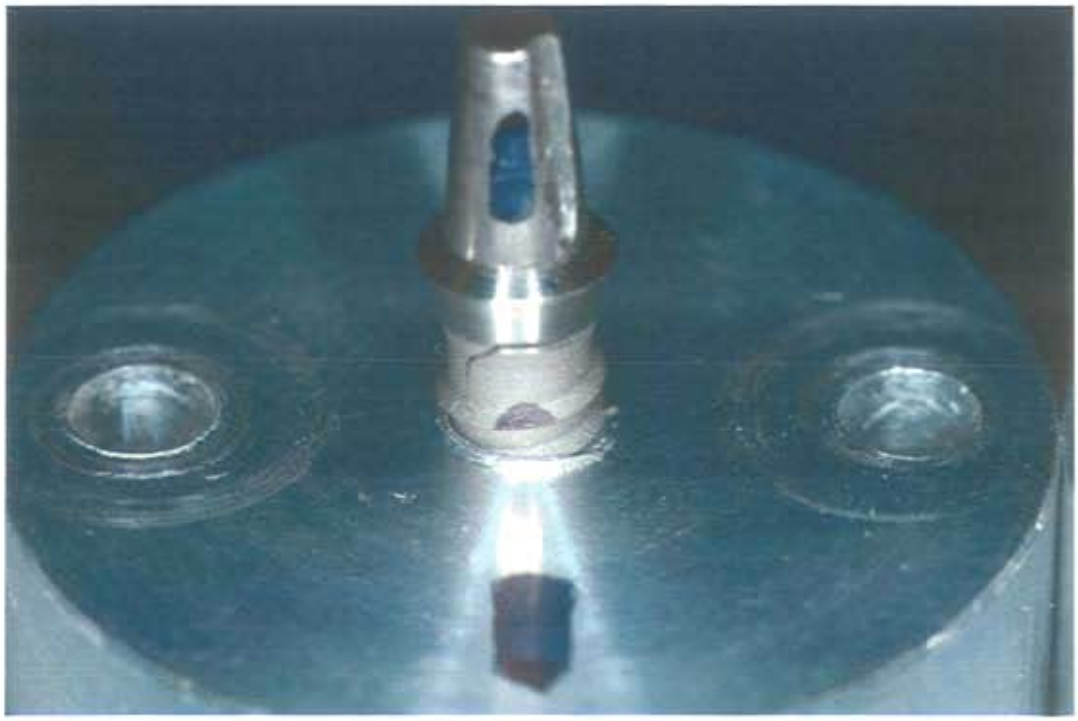

Figure 8. Implant and abutment failure (BlueSkyBio #4).

c. Statistical analysis

Weibull++ unreliability plots showed that failure for all tested implants (Lifecore, BlueSkyBio, and Ihdedental) fit a common failure distribution that was statistically different from that for Straumann implants (Figure 9). The results indicated that the original Straumann implant had more failures than its clones under these conditions and was more likely to fail at less than 10^6 cycles.

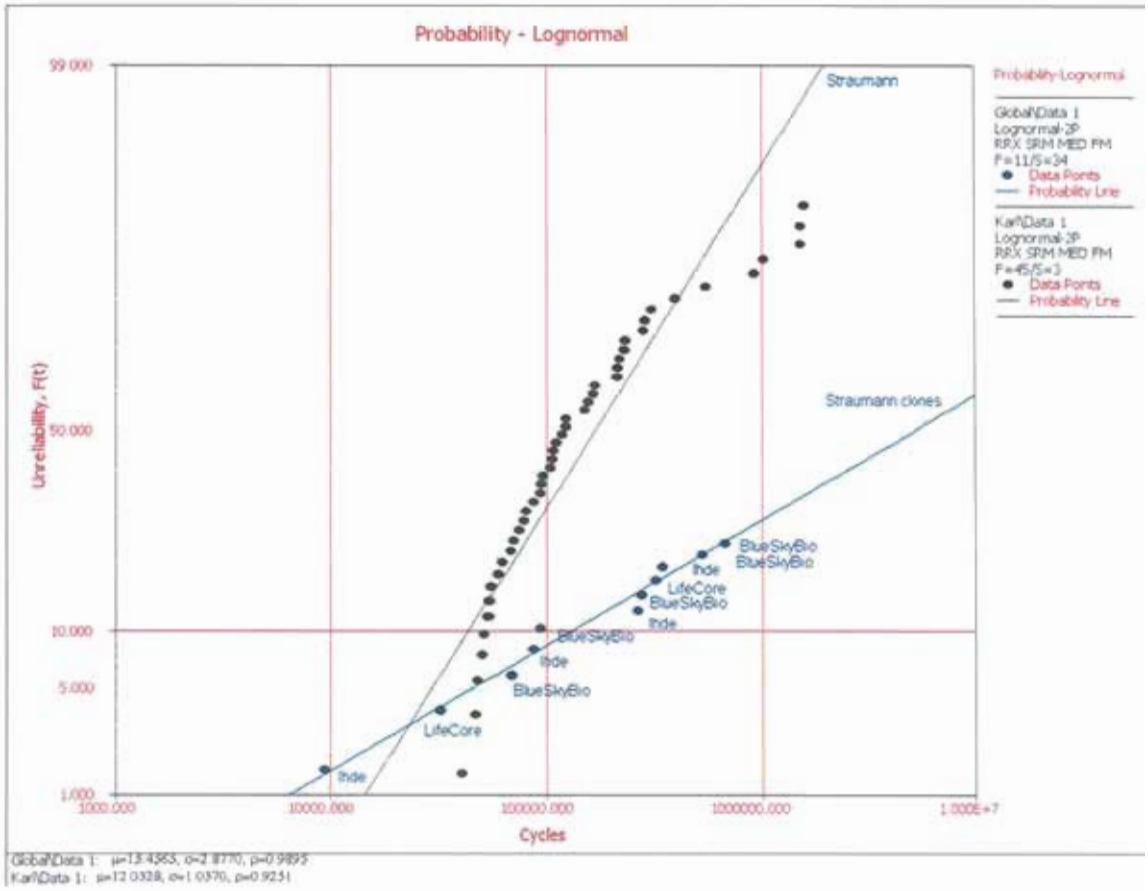

Figure 9. Lognormal unreliability plot (Straumann vs Straumann clones)

The failure mode was labeled in the same plots. Abutment and/or implant fracture modes was spread evenly on the probability curve. The failure mode was not correlated to the loading cycles (Figure 10). Also the "hidden" abutment screw fractures could not

be included in the Weibull++ analysis because it was impossible to determine the exact cycle number of abutment failure.

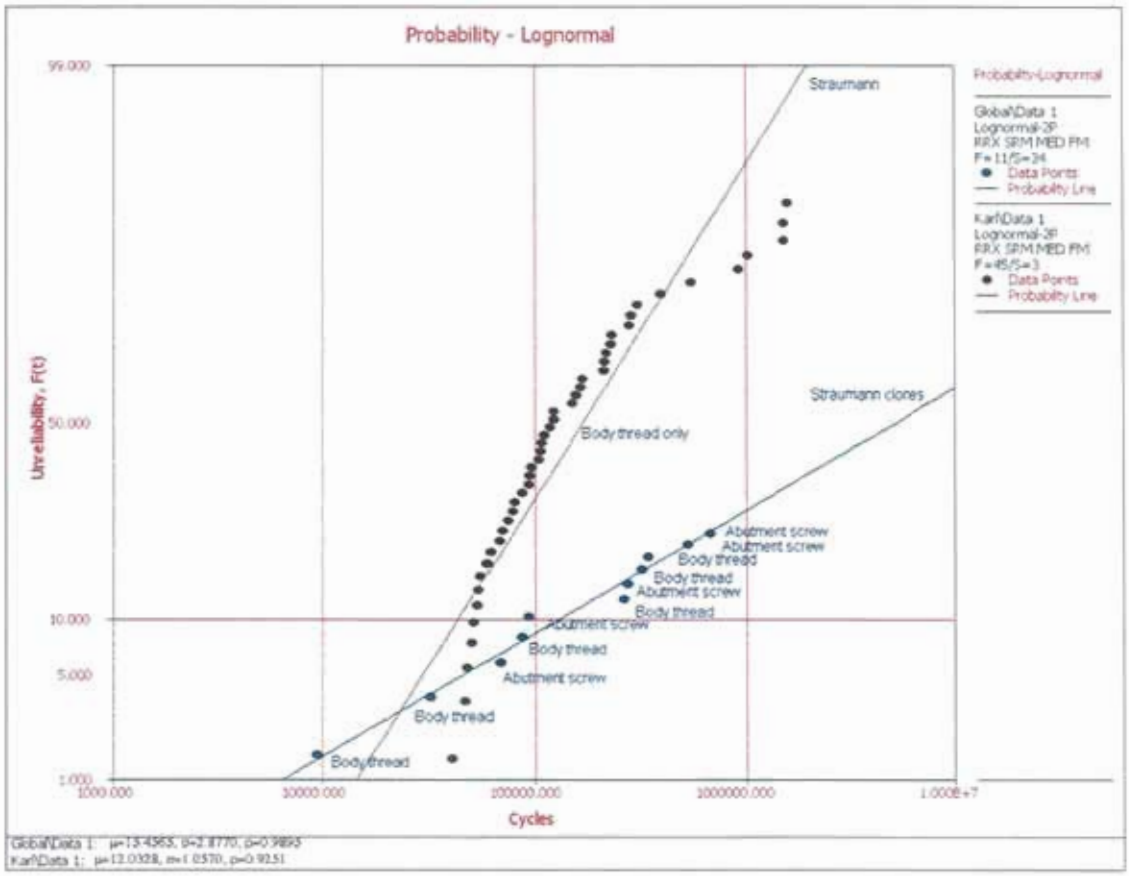

Figure 10. Lognormal unreliability plots (failure mode).

Figure 11 shows the survival expectancy of Straumann implant clones. The loading cycle was extended. According to this analysis, Straumann implants had less survival cycles (1 million vs 1 billion).

In the logistic regression, the Lifecore implant was set as a reference. Table 3 demonstrated failure probability of the other implants compared to Lifecore implants. The remaining three implants- Straumann, BlueSkyBio and Ihdedental had significantly higher failure probability than Lifecore.

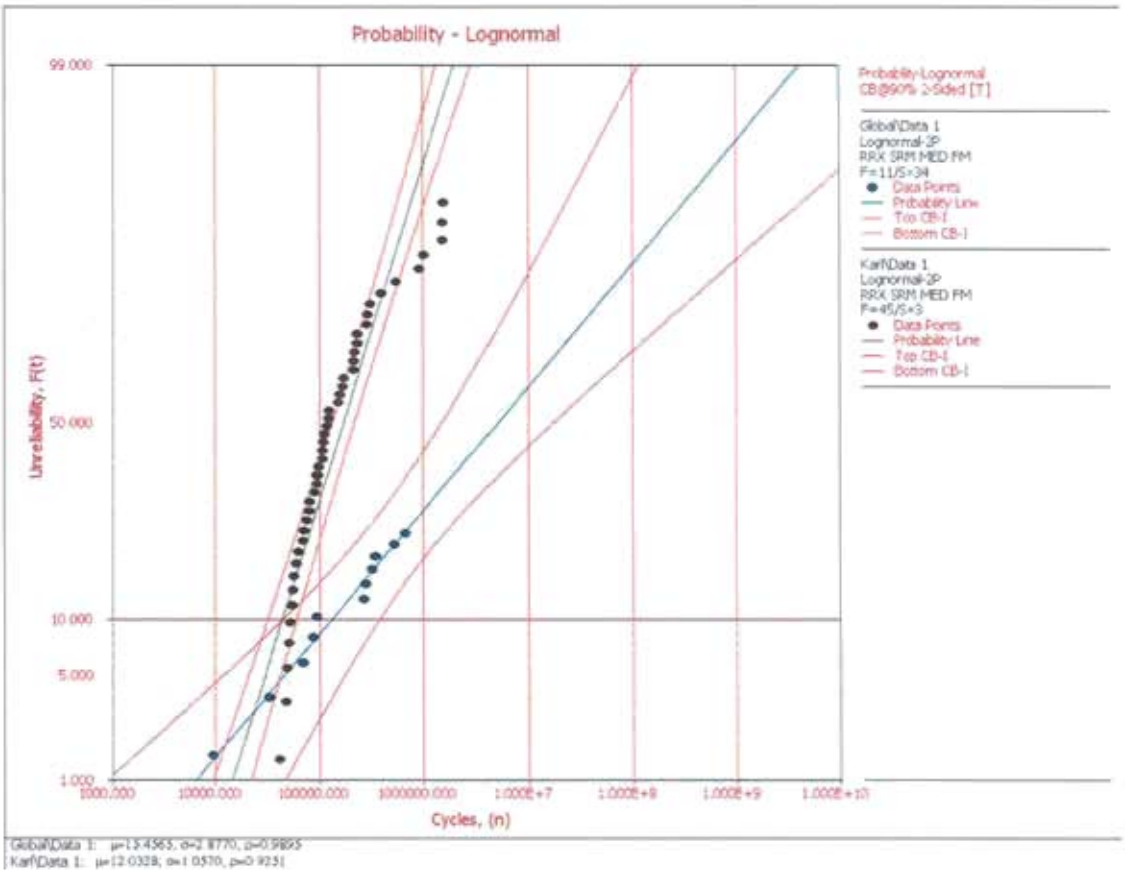

Figure 11. Lognormal unreliability plots (extended cycles).

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1	Lifecore			24.658	3	.000	
	Straumann	4.557	.966	22.262	1	.000	95.333
	BlueSkyBio	1.738	.919	3.577	1	.059	5.687
	Ihdedental	2.277	.925	6.068	1	.014	9.750
	Constant	-1.872	.760	6.073	1	.014	.154

Table3. Logistic regression test.

d. Evaluation of the fracture surface- SEM analysis

The SEM images (Figure 12) show various stages of crack propagation, including brittle fracture, fatigue striations and final ductile failure. In Straumann implants, the origin of fracture was easily determined.

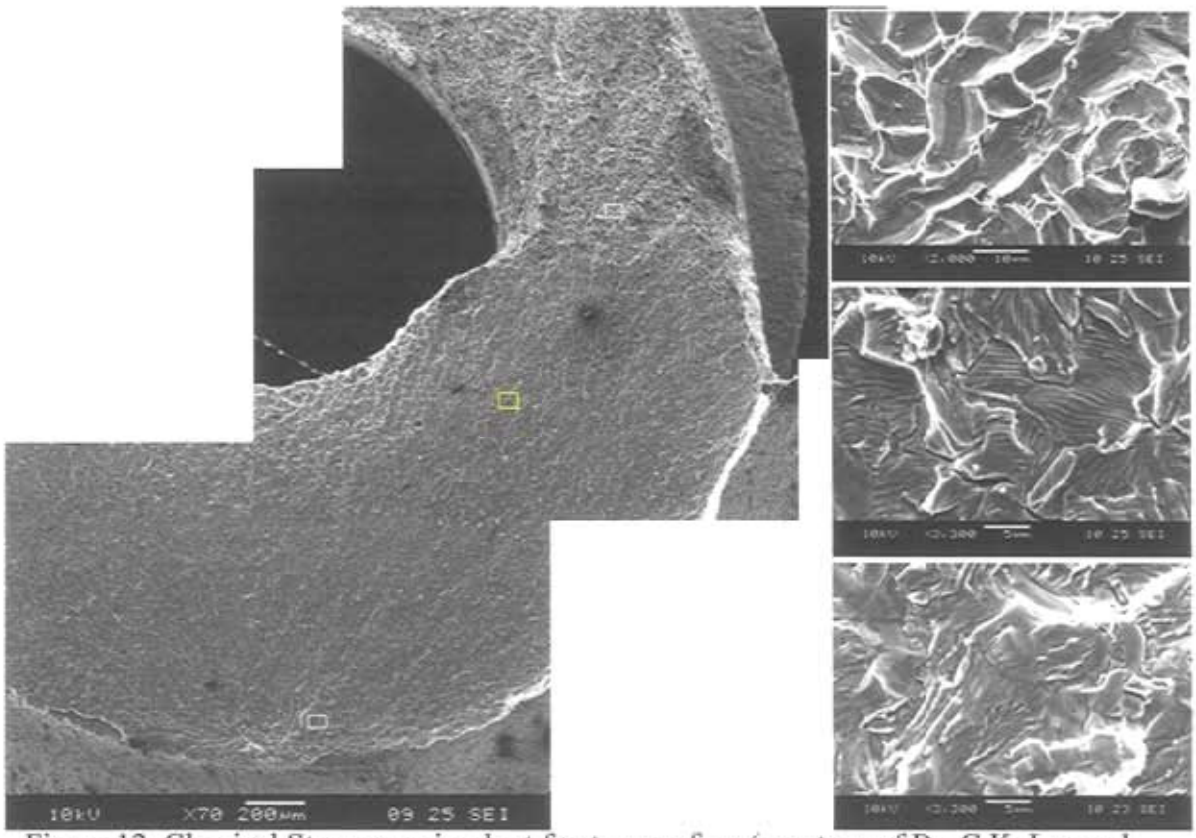

Figure 12. Classical Straumann implant fracture surface (courtesy of Dr. C.K. Lee and Dr. J.R. Kelly). The boxed areas in the low magnification image(left) are shown at higher magnification at the right

1) Lifecore implant

Lifecore implants had two different fracture modes. The Lifecore #7 implant was not fractured completely and a SEM image could not be obtained. Lifecore #9 implant had a combined fracture at the higher level from the base. The SEM of this sample revealed both implant and abutment fracture pattern (Figure 13). The failure origin in the

implant body was not as obvious as the Straumann implant but it was observed in the abutment fracture surface (Figure 14, 17). Fatigue striation and ductile fracture patterns were found both in implant and abutment fracture surfaces (Figure 15, 16, 18, 19).

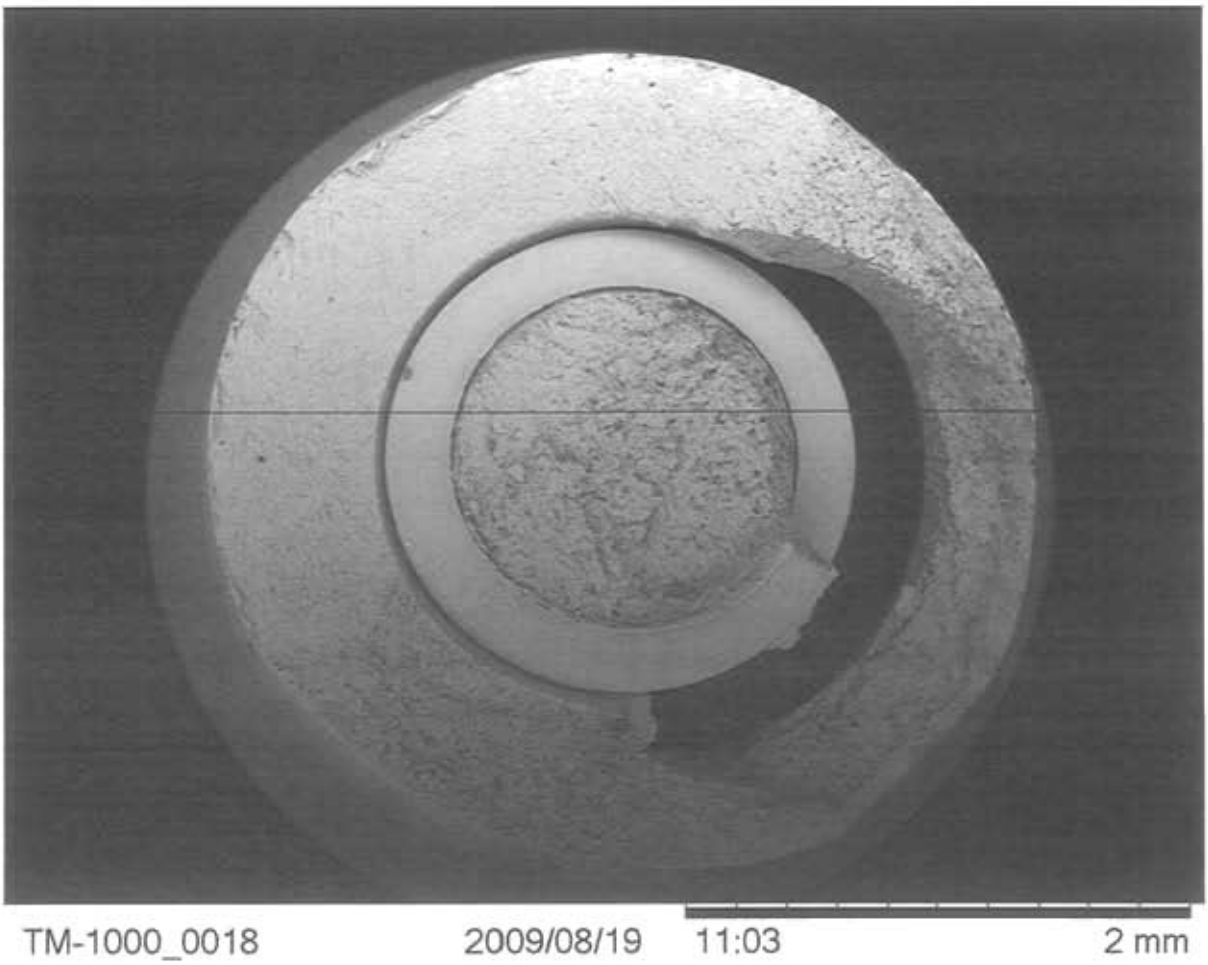

Figure 13. Fracture surface of abutment and implant (Lifecore #9).

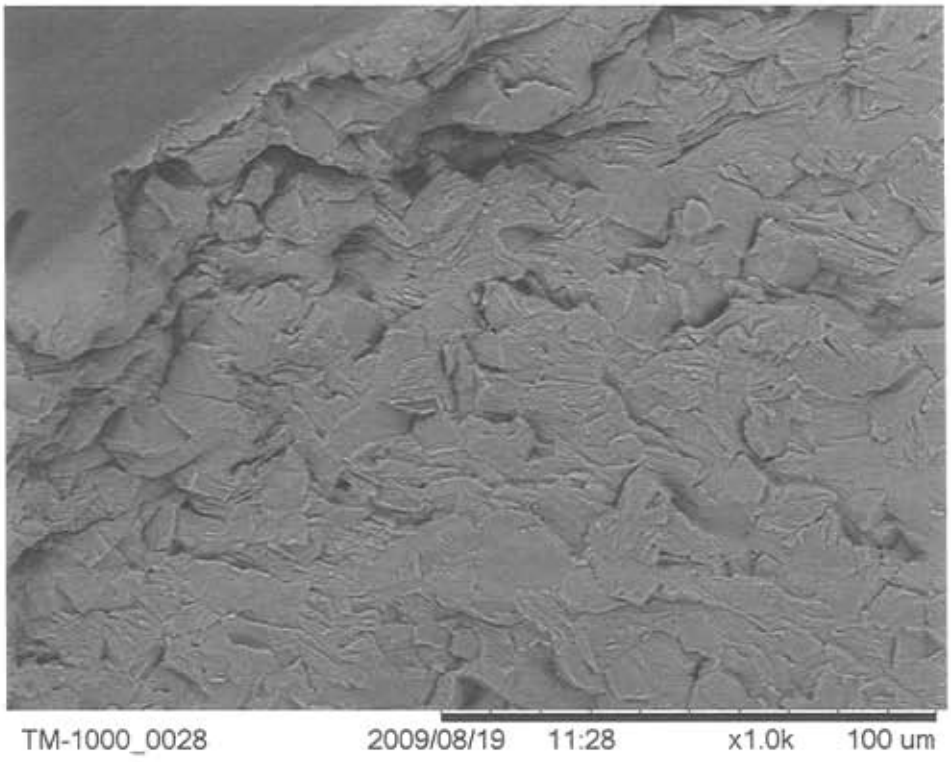

Figure 14. Suspected fracture origin on the implant (Lifecore #9 implant).

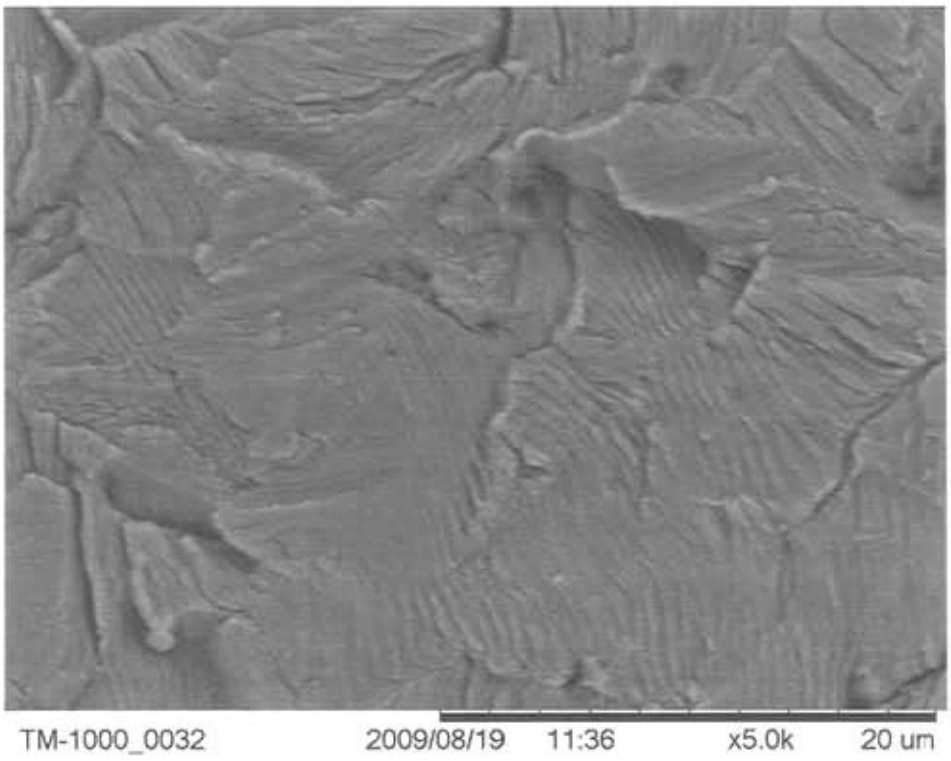

Figure 15. Fatigue striation on the implant (Lifecore #9 implant).

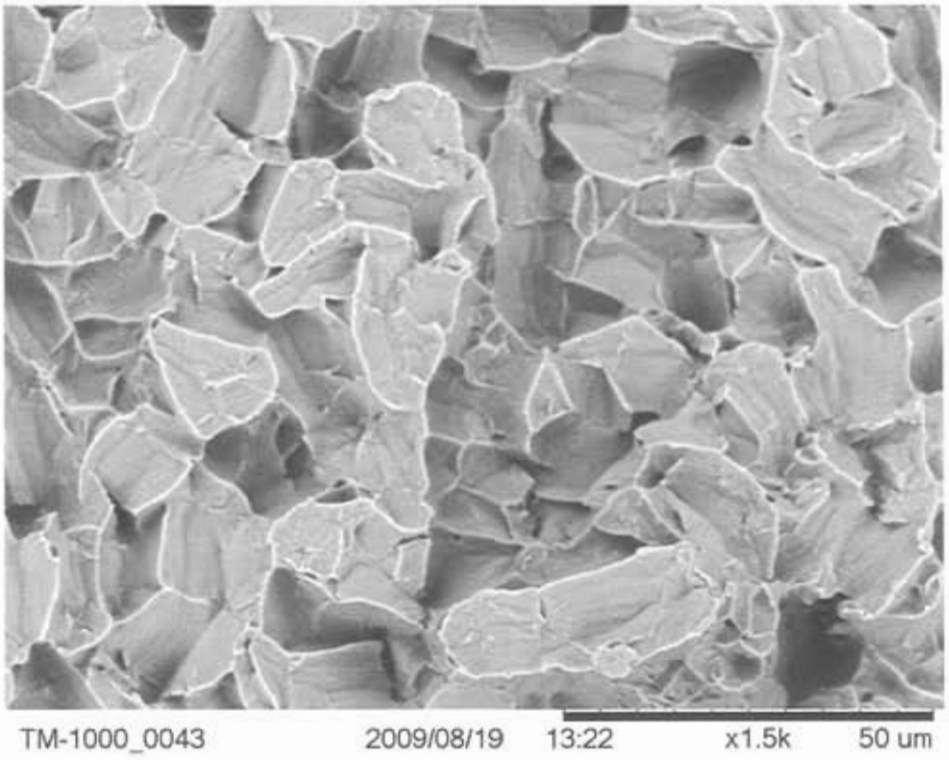

Figure 16. Ductile fracture on the implant (Lifecore #9 implant).

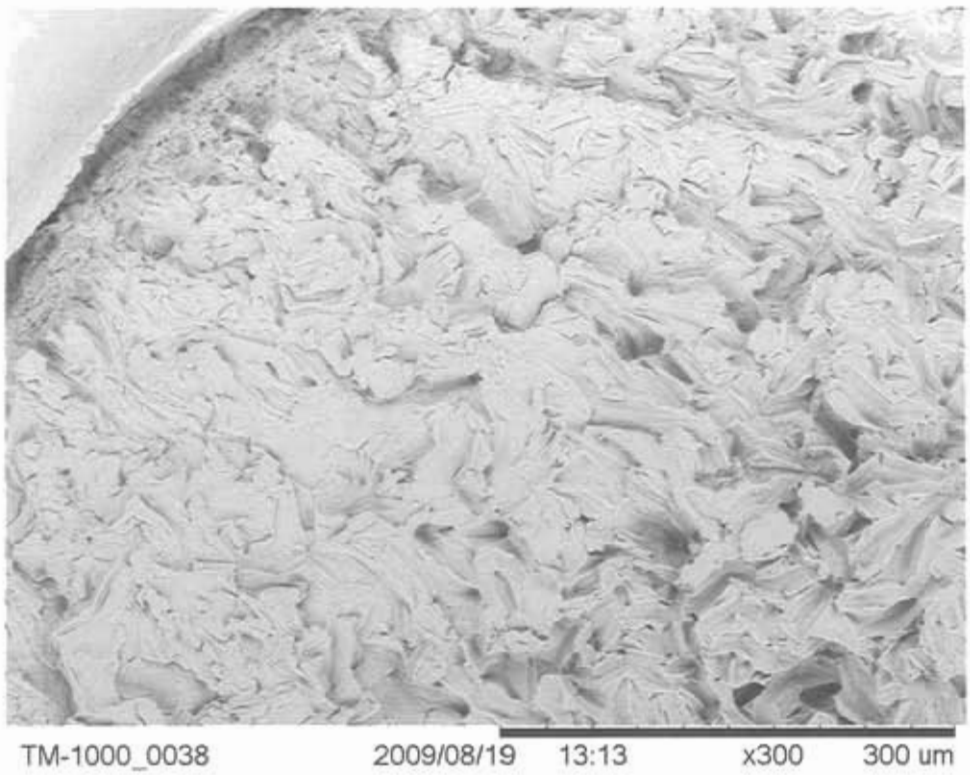

Figure 17. Fracture origin of the abutment fracture (Lifecore #9 implant).

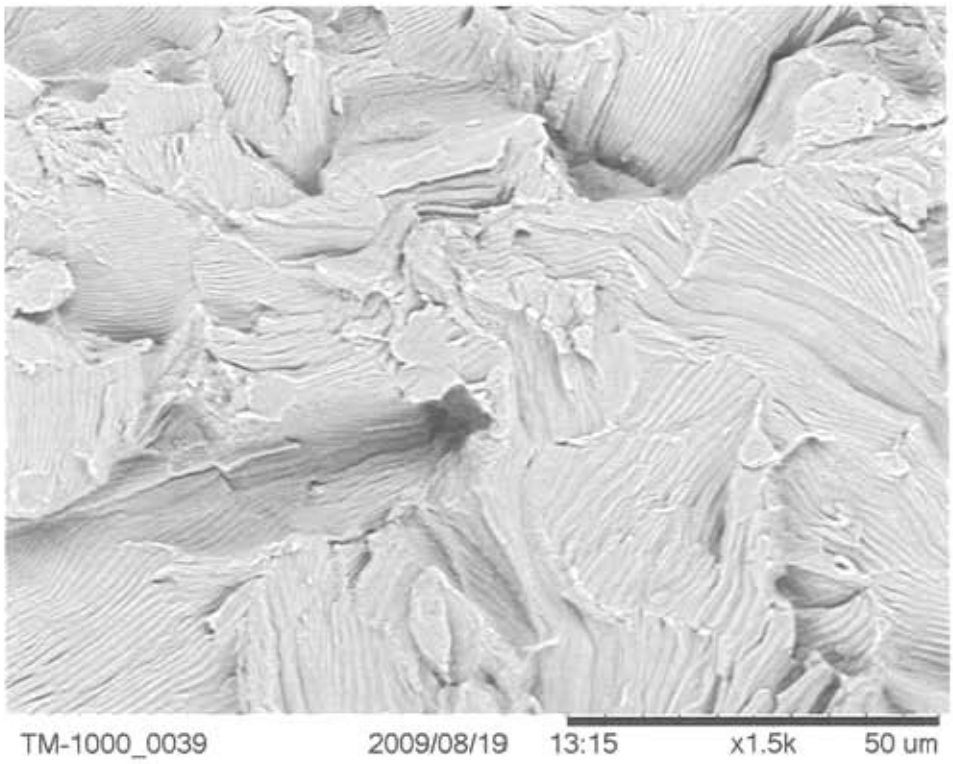

Figure 18. Fatigue striation on the abutment (Lifecore #9 implant).

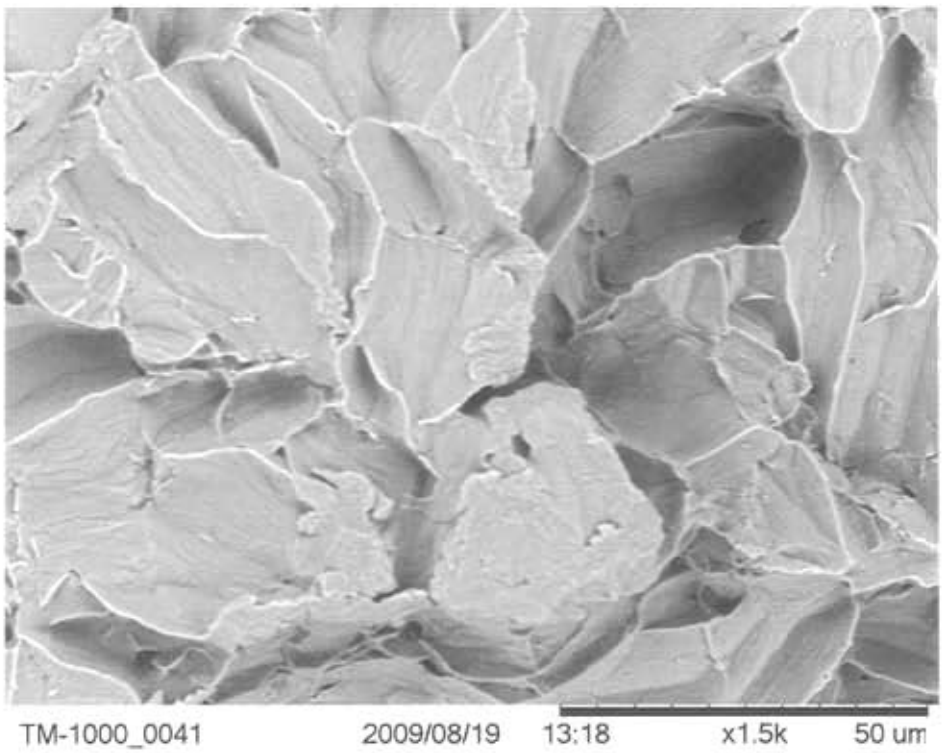

Figure 19. Ductile fracture on the abutment (Lifecore #9 implant).

2) Ihdedental implant

Fracture surfaces of Ihdedental implants were virtually identical to the Straumann implant (Figure 20) . The origin of fracture was identified without difficulty and higher magnification showed brittle fracture at the fracture origin (Figure 21). Fatigue striation also presented at the higher magnification (Figure 22). Abutment failed samples also showed fatigue striation in the broken surface but the origin was not as clear as in the SEM of Straumann implant surfaces (Figure 23).

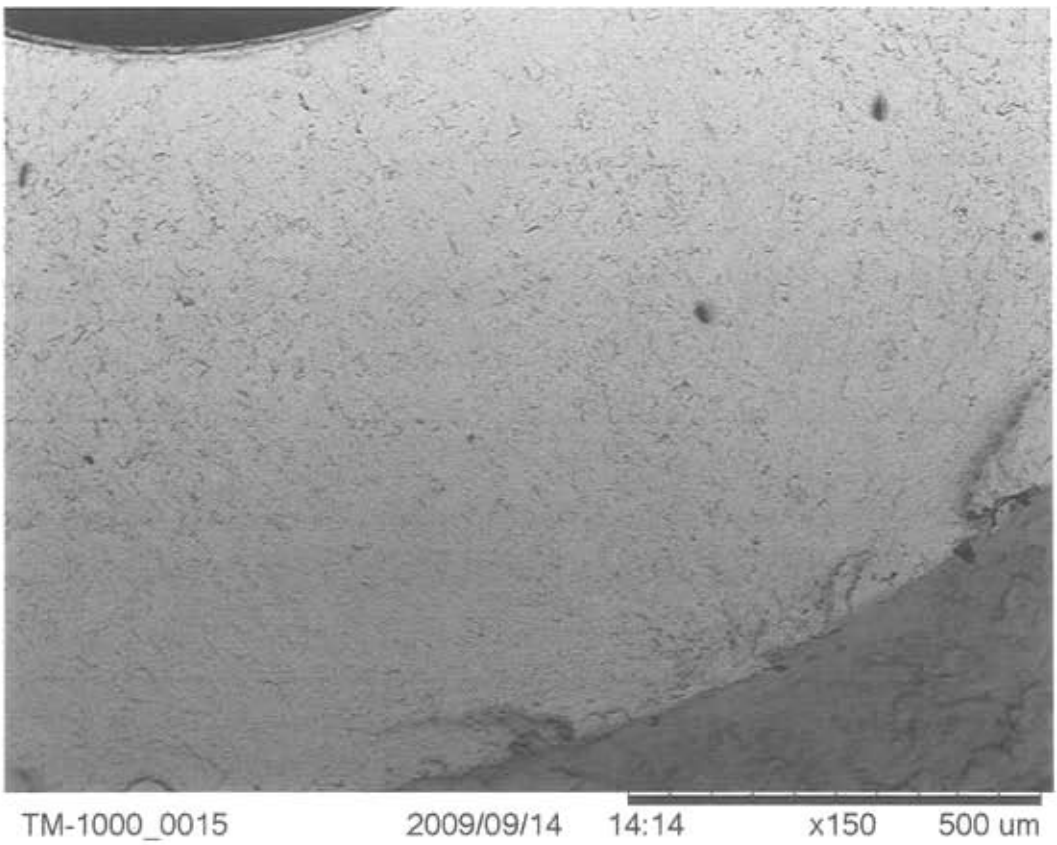

Figure 20. Fracture surface (Ihdedental #15 implant).

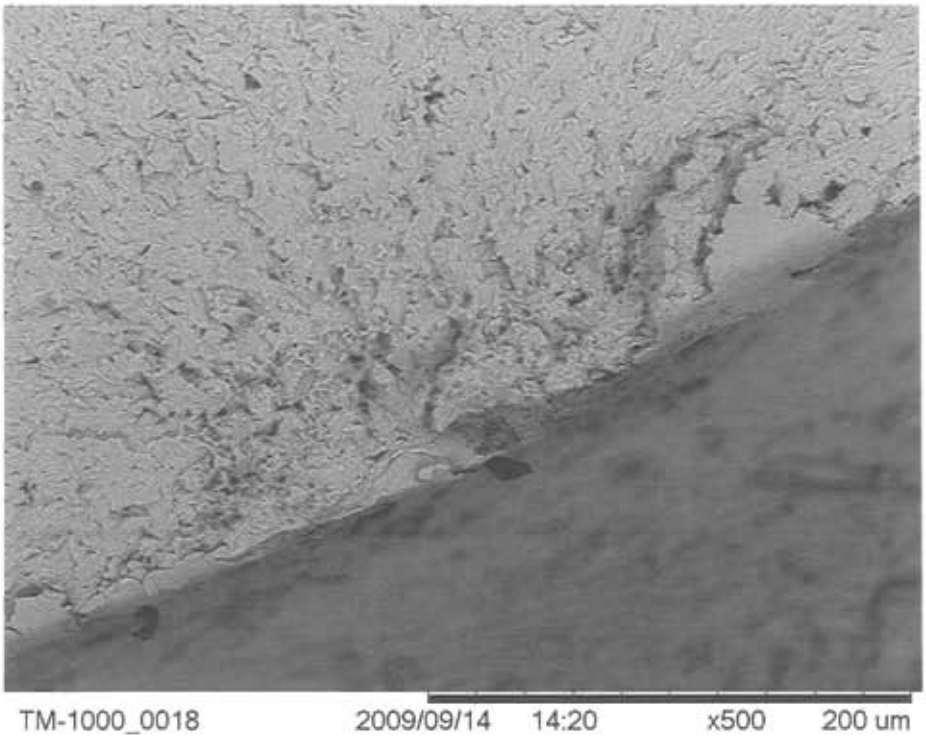

Figure 21. Higher magnification of fracture origin (Ihdedental #15 implant).

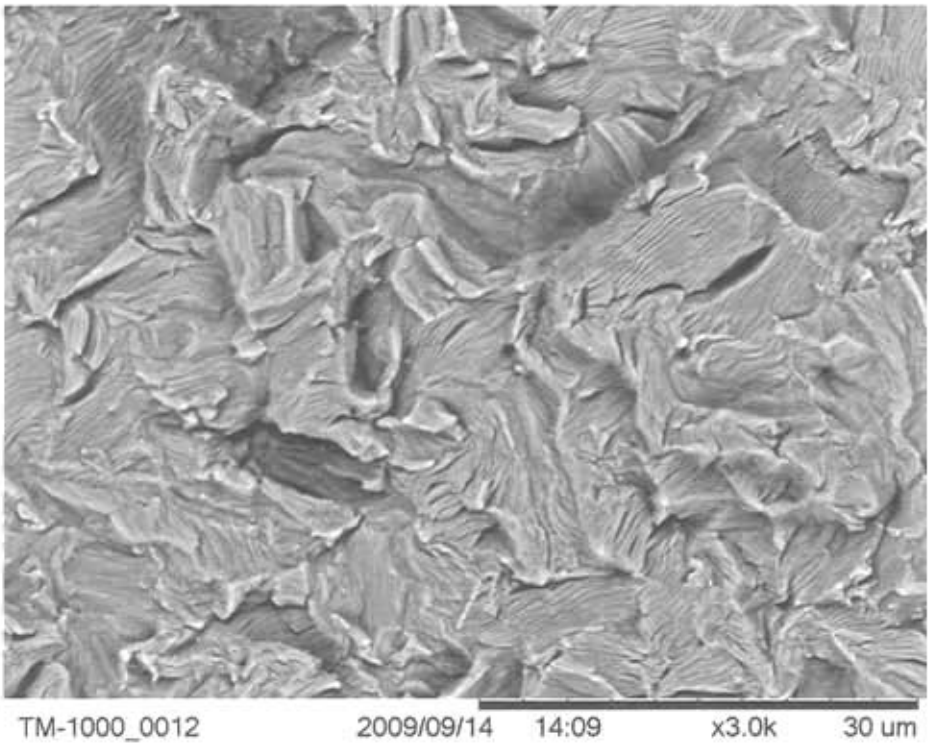

Figure 22. Fatigue striation of implant fracture (Ihdedental #15).

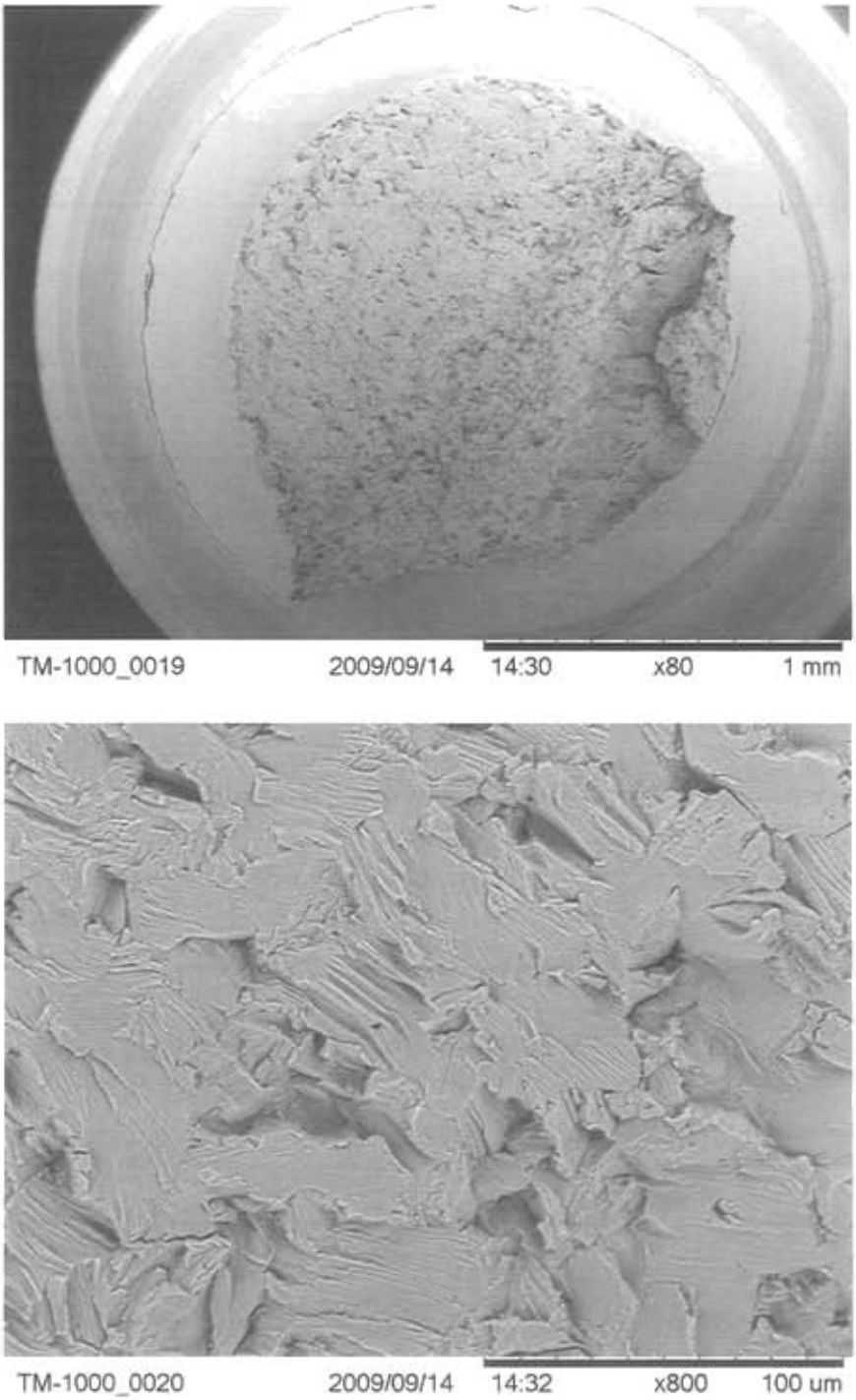

Figure 23. Abutment fracture surface (Ihdedental #4 implant).

3) BlueSkyBio implant

Fracture behavior of the BlueSkyBio implants was entirely different. The failure origin was difficult to identify. At low magnification, fractured surface did not exist in one plane. There was sharp a projection on side. Y shape line was detected the abutment fractured side (Figure 24). There were several suspected origins on the implant side (Figure 25 boxes). Fatigue striation and ductile fracture were also found on the fracture surface.

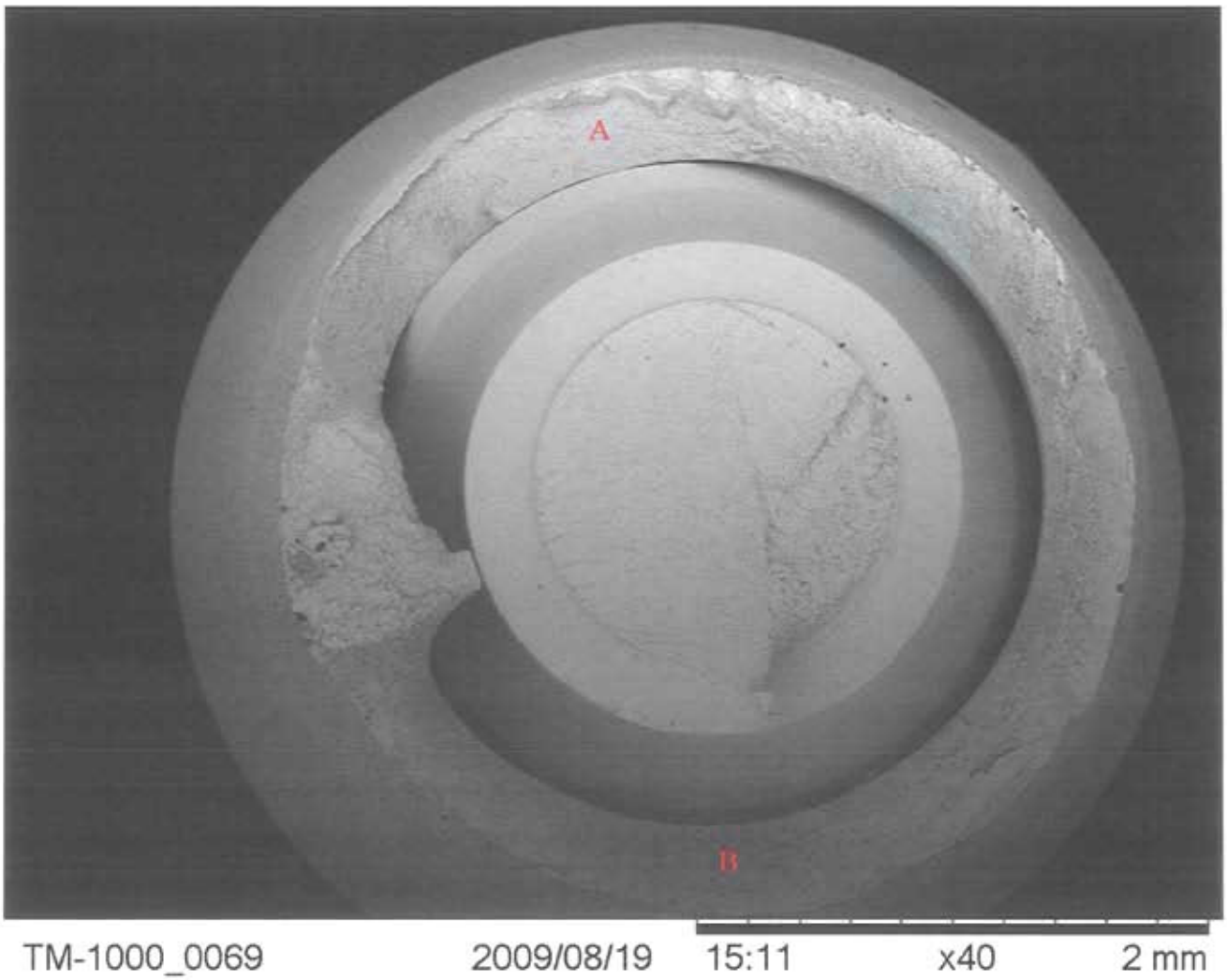

Figure 24. Fracture surface of implant (BlueSkyBio implant#2),

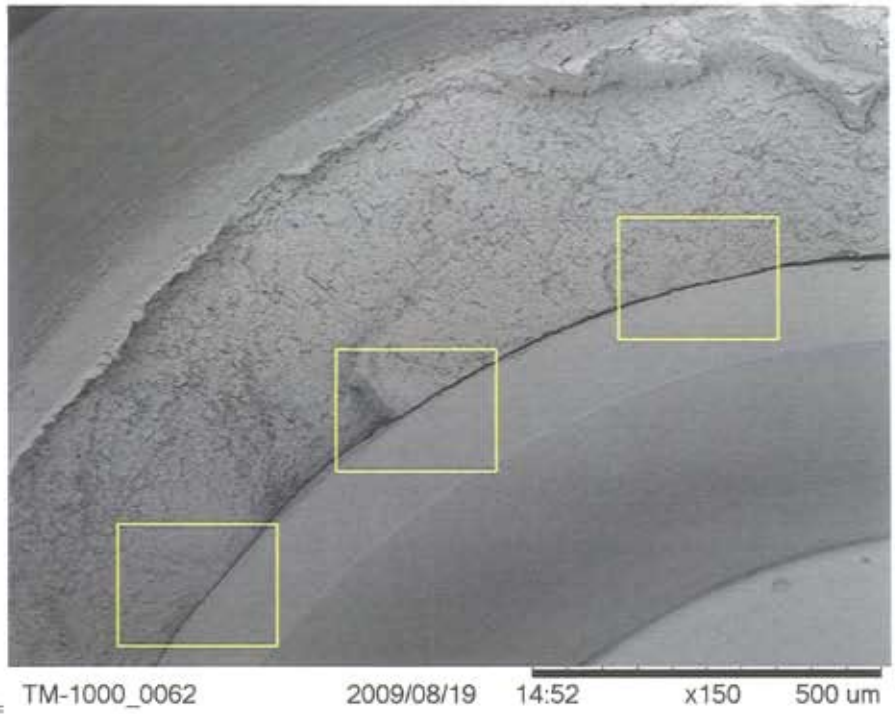

Figure25. Suspected fracture origin of implant (BlueSkyBio #2 implant).

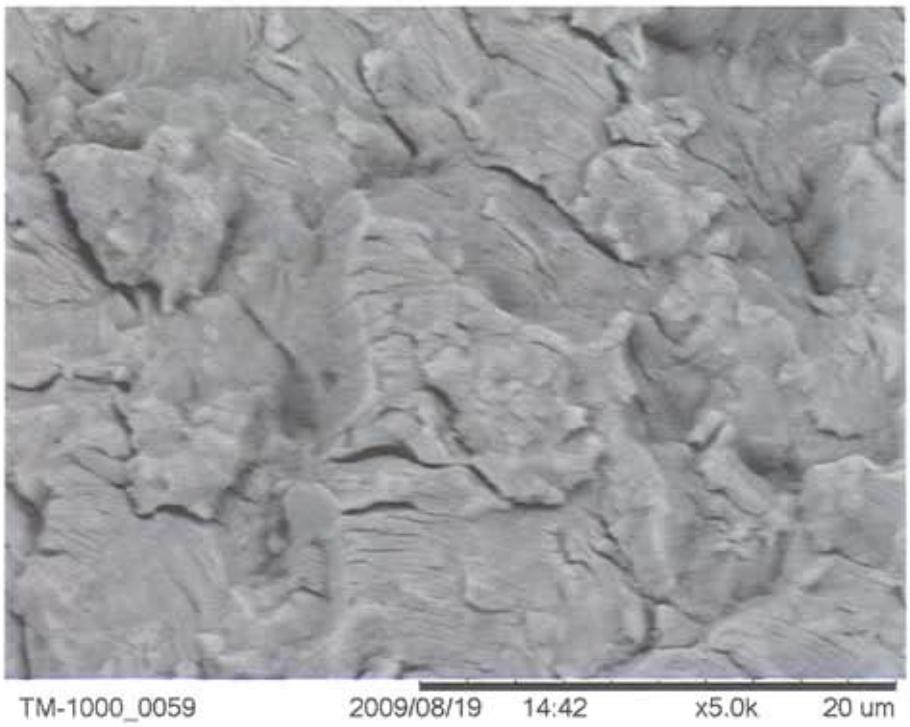

Figure 26. Fatigue striation of fractured surface (A area of Figure 24,.BlueSkyBio #2 implant).

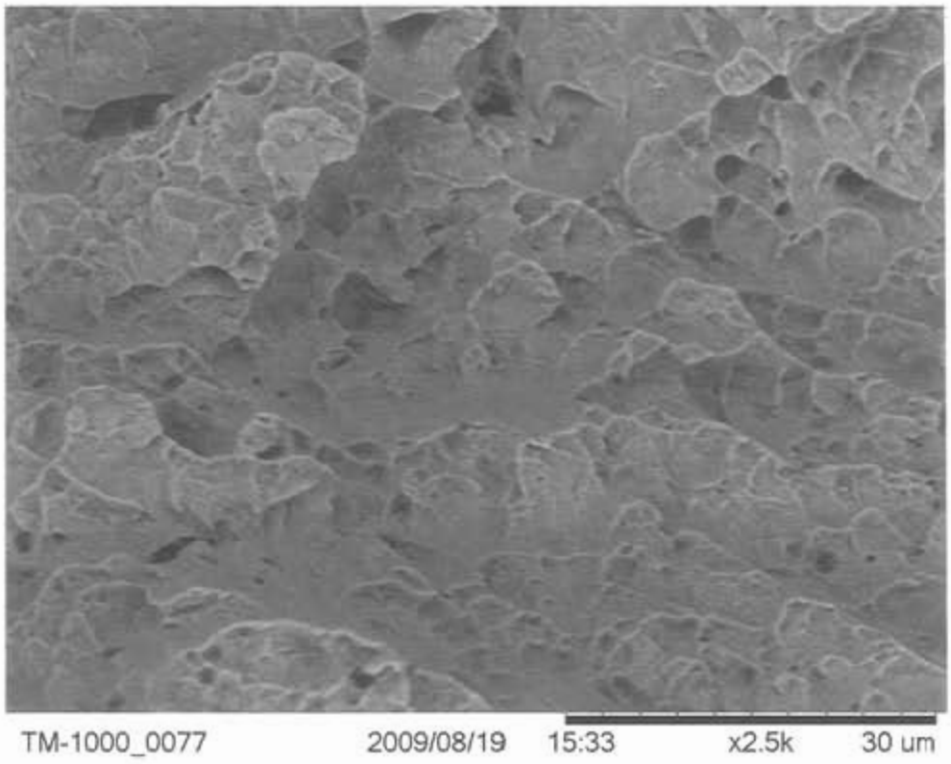

Figure 27. Ductile fracture on the implant (B area of Figure 24. BlueSkyBio#2 implant).

e. μComputed Tomography(CT) analysis

Cross-sections of each implants were obtained and compared. The depth of channel for the abutment screw was different. Compared to the Straumann implant the clone implants had deeper channel into the implant body. BlueSkyBio implant had the deepest channel. As expected, Lifecore implants had no space for synOcat connection between abutment and implant but the other implants showed it. BlueSkyBio implant had different coronal taper from the Straumann implant and the implant thread height was located more coronally as the company advertised. In the Ihdedental implant, the internal thread height was observed at the more coronal location compared to the other implants. (Figure 28.)

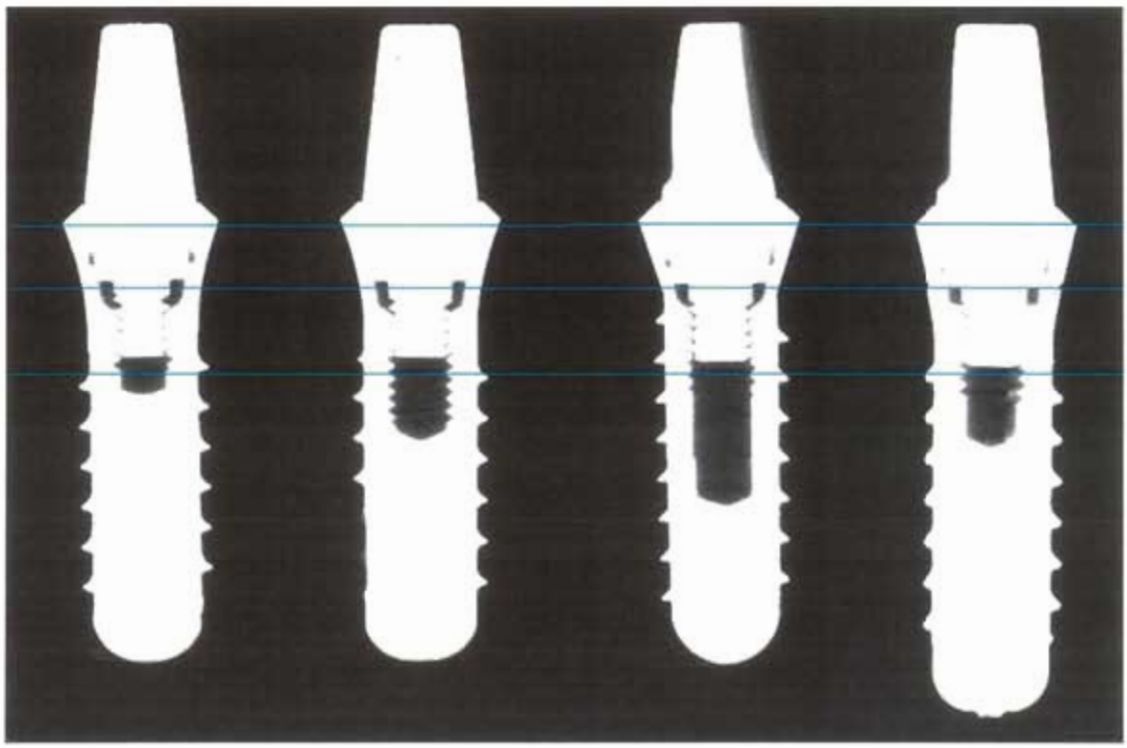

Figure 28. Cross-section of the sample implants (From left: Straumann, Lifecore, BlueSkyBio, and Ihdedental implants). The first line indicates platform of the implants. The second line is the level of the junction between smooth and rough surface, and the third one is simulated bone level.

5. Discussion

a. Survival of the samples

In the present study, two of the Lifecore implants, five of the BlueSkyBio implants and five of the Ihdedental implants failed after fewer than 1,000,000 cycles. This number increased after inclusion of the abutment fractures occurring within 1,000,000 cycles but not detected until the loading was completed. The result of Chi square analyses indicated a significant difference in failure and failure mode among the different implants ($p < 0.001$, Appendix 1). The difference in failure and its mode still remained after the original Straumann implant was excluded ($p<0.05$, $p<0.1$, Appendix 1). Logistic regression demonstrated the significantly higher failure of Straumann, BlueSkyBio, and Ihdedental implants compared to Lifecore implants (Table 3). All of these observation and statistical results indicated that the Straumann implant is more prone to fracture by cyclic loading than clone implants.

However, to date there have been no clinical reports of fractures in standard diameter Straumann one-stage solid-screw implant. This indicates that the clone implants may work biomechanically in the same way as the original Straumann implant in clinical situations. Therefore, differences (likelihood and mode) may only signal that clinical differences may or may not appear at lifetimes much greater than experienced for the Straumann implant currently.

One weakness of the present study is sample size of failed implants. Loading conditions were chosen that were expected to cause most if not all implants to fail, based on previous experience with the Straumann implants However, the total number of failed clone implants was only 18 out of 45 implants. A similar number (30 or more) of failure

in clone implants, at least in Lifecore and Idhe, was expected prior to the experiment because those implants were made of same grade cp titanium whereas Ti-6Al-4V alloy was used for BlueSkyBio implant. Moreover, in case of pure abutment fracture, the cycle of fracture was not able to be recorded because the implant and abutment was still connected at the end of the loading cycles. As a result, these failed abutment specimens could not be interpreted in the failure analysis. The survival behavior would be demonstrated better if there were more failed samples for each group. In that case, the failure probability distributions of each implant system could be analyzed.

It is not clear why the reliability is different, because there are many variables affecting on the implant fracture such as the titanium material itself, machining conditions, surface manufacturing (to roughen the implant), thread design/position, implant wall thickness, etc.. It is beyond the scope of this study to explain the reason for different failure rates among the four implants. To figure out the reason, the specimens should be tested in a more extensive test and likely under more severe condition.

b. Failure mode of the implants and SEM analysis

It is interesting that there were three different failure modes. Of course, every single failure had its own characteristics but three categories used in this study could cover all of the fracture patterns in the failed specimens. The classical type of fracture occurred at the root of the thread in the area of the junction between implant and base because this is the area where the morphological irregularity exists and where the loading force is concentrated according to previous finite element analysis (FEA) (Figure 29). All of the failed Straumann implants, one of the Lifecore implants, four of the Ihdedental

implants and none of the BlueSkyBio implants were in this category. The fractured site of this category was found at the root of the thread near the base. The fractured surface of these implants observed in the SEM was identical to the original Straumann fracture. It was a classical fatigue fracture: brittle fracture (crack pop-in), fatigue striation, and catastrophic ductile fracture.

Two samples each from Lifecore and Ihdedental implants were not completely fractured but bent in the opposite direction to loading. These samples might be fractured

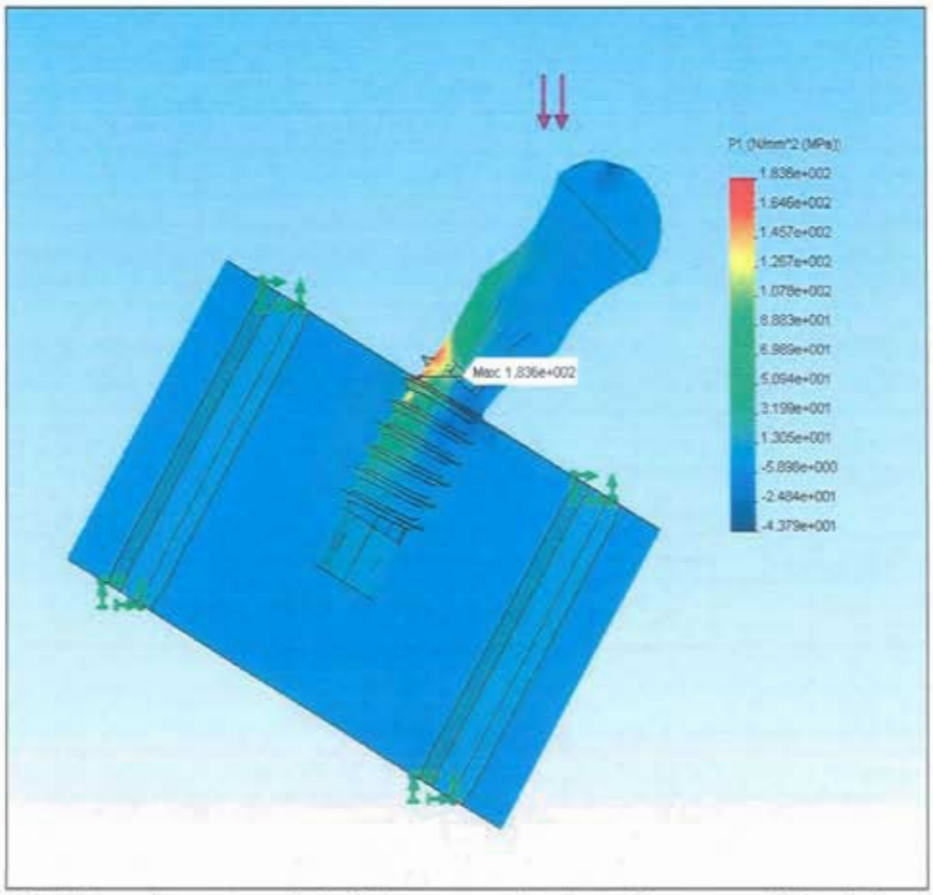

Figure 29. Finite element model of Straumann implant (Courtesy of Dr. Robert Kelly).

out if the definition of displacement limit had been set higher than current setting (>0.5mm). Some of the clinical findings of peri-implant bone loss might accelerate this

type of implant fracture. The implant body fracture may follow (1) bone loss exposing threads (stress concentrating features) and (2) an increased lever arm due to the bone loss. Peri-implant bone resorption may involve the micromovement of the implant along with induced soft tissue ingrowth [18].

The second category of failure mode is abutment thread fracture. Two of the BlueSkyBio implants and four of the Ihdedental implants were classified as pure abutment fracture. All of the abutment screw fractures were detected after 1,000,000 cycles of loading. The Morse taper feature and the internal connection between abutment and implant may explain this phenomenon. The connection is not only by the screw but also by the Morse taper surface, which maintained the integrity of two parts even though one of the holding mechanisms (screw) was destroyed. The specimen could survive by the close friction fit of the tapered feature.

The location of the broken abutment was at the level of the base-implant junction where the stress was concentrated. This is very interesting because it is indicated that the abutment screw still had been under loading stress even though the Morse taper connection was working between the two different parts. Or the precision of machining the connection may also be suspected as a factor in over-stressing the abutment screw.

The third failure mode is combined implant and abutment fracture in Lifecore and BlueSkyBio implants. These specimens were unique because they had many different features from the classical Straumann implant failure. First, the location of the cracking is above the junction between implant and base. In case of the BlueSkyBio implants, a series of samples shows different stages of failure (Figure 7). The abutment fracture was also found in the sample of initial cracking phase (Figure 30).

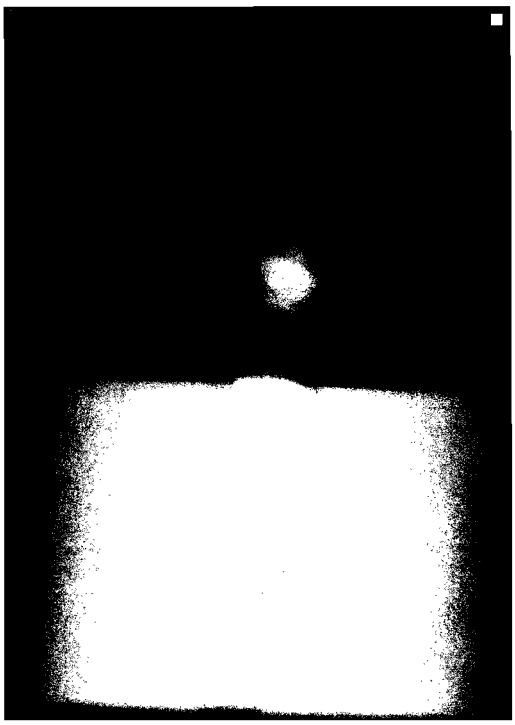

Figure30. Abutment fracture was observed on the radiograph (BlueSkyBio #9).

In the SEM image, the brittle fracture initiated from the inside where the abutment contacted the implant. These findings indicate that the abutment fracture occurred first and the entire load was transferred to the inside of the implant until it broke. This is a totally different fracture mechanism from the original Straumann implant.

Compared to the BlueSkyBio implant, the Lifecore implant has a simpler fracture plane. This phenomenon can be explained by the difference of two implant connections. Lifecore stage-1 implant still maintains the original Morse taper design through the entire connection (Figure 31). Meanwhile, the BlueSkyBio implant claims a synOcta compatible connection design (Figure 32). Originally, Straumann changed the Morse taper into the synOcta connection to give more room to the prosthetic option simply by making internal octagonal slot in the internal Morse taper surface of the implant. This modification made the implant wall thinner than the original design. The difference of

thickness in this area might result in the different failure morphology in the third type of failure (combined fracture) between Lifecore and BlueSkyBio implants in the present study.

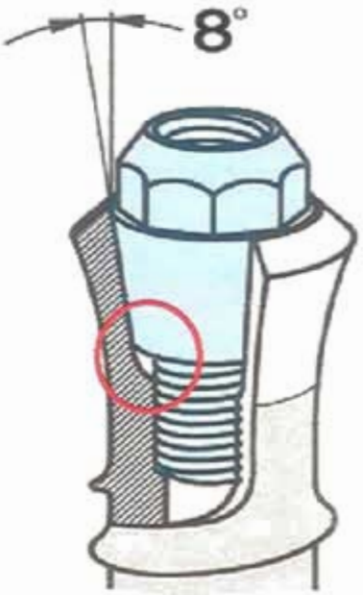

Figure 31. Morse taper

Figure 32. SynOcta design

The initial crack of the implant in the Lifecore #9 specimen started at the root of the abutment screw where there is small space (red circle in Figure 31). The BlueSkyBio implant started to break at the level of the synOcta indicating slot. In either case, the abutment screw fracture preceded the catastrophic fracture.

The cross-sectional view of micro CT images showed designing difference among the implants. The depth of the abutment screw channel was not same. BlueSkyBio implants had deepest channel.The other clone implants had deeper channel than Straumann. The overall outline forms of each implant system were not identical. Thread shape and the level of the thread were different. Moreover, degree of taper at the 1st thread area was different especially in BlueSkyBio implants. Notch was found around the

junction between smooth and rough surface of the Ihdedental implant. The exact dimension and its effect on the fracture behavior are beyond the present study. Whole set of designing information may be investigated in finite element analysis, which will provide information about the designing effect on fracture behavior of different implant systems.

6. Conclusion

Within the limit of the present study, the following conclusions can be made:

- Four one-stage implants exhibited different failure probabilities as well as different failure modes when tested under 2 Hz of cyclic load (20~500 N).
- Straumann clone implants followed a common probability of failure curve which differed from the Straumann implant under predetermined testing condition.
- Three different failure mechanisms were recognized; 1) implant body fracture, 2) pure abutment thread fracture, and 3) combined fracture of implant and abutment. Some clone implants demonstrated identical body failure to Straumann implant. Clone implants, however, demonstrated abutment fracture with or without implant body fracture, which suggests important design differences in the clone implants.
- Fracture surfaces evaluated under scanning electron microscope illustrated typical fatigue fracture. Three stages of fatigue fracture were observed: 1) brittle fracture (origin of fracture), 2) crack propagation, and 3) catastrophic ductile fracture.

7. Future work

Baseline in vitro failure data of various one-stage implants was obtained in this study. A Larger sample size would provide more detailed survival curves of individual clone implants. Those results will provide the basic mechanical information to manufacture standard implants.

The loading condition in this test was determined to destroy the samples in vitro. However, it was unknown how much load was clinically relevant. It would be helpful to define a clinically adequate loading condition to predict the behavior of the dental implants. Also, in this study, the test was performed on a single implant restoration under the condition of 3 mm bone loss. It would be meaningful to study failure under various conditions such as restoration on the several implants, cantilever prosthesis, excessive crown-implant ratio etc.

Abutment fracture is clinically more prevalent than implant body fracture although implant fracture is more disastrous. Abutments with different designs and materials may demonstrate different failure modes. Moreover, the bone level implant recently became a standard implant in the esthetic region. The zirconia abutment is becoming more popular to achieve proper esthetic outcome. The anterior area of the maxillary arch is the area where the supporting bone is prone to resorption and where the occlusal force is delivered in an off-axis angle to the implant. And the connection between implant and abutment is supposed to be located at the stress concentrating area, the alveolar crest. The testing conditions which simulate this anterior esthetic implants, for example, a zirconia abutment on the different bone level implant would give basic information to the clinicians.

8. Bibliography

1. Branemark, P.-I., *The Osseointegration and its experimental background. . .* J prosthet Dent., 1983. Sep. **50**(3): p. 400-410.
2. O'Brien, W.J., *Dental Materials and Their Selection*, in *Chapter 23. Implant and bone augmentation* Quintessence books.
3. Donachie, M.J., *Titanium: A Technical Guide.* 2000, ASM International, .
4. Lazarra, e.a., *Retrospective multicentre analysis of 3i endosseous dental implants placed over a five-year period.* ClinOralImplRes, 1996. 7: p. 73-83.
5. Levine, R.A., et al., *Multicenter retrospective analysis of the ITI implant system used for single-tooth replacements: results of loading for 2 or more years.* Int J Oral Maxillofac Implants, 1999. **14**(4): p. 516-20.
6. Brocard, D., et al., *A multicenter report on 1,022 consecutively placed ITI implants: a 7-year longitudinal study.* Int J Oral Maxillofac Implants, 2000. **15**(5): p. 691-700.
7. L. Borchers, P.R., *Three-dimensional Stress Distribution Around a Dental Implant at Different Stages of Interface Development* J Dent Res 1983. **62**(2): p. 155-159.
8. Clelland, N.L., Ismail, Y.H., Zaki, H.S., Pipko, *Three-dimensional finite element stress analysis in and around the Screw-Vent implant.* International journal of oral & maxillofacial implants, 1991 **6**(4): p. 391-398 44.
9. Goodacre, C.J.,Bernal G, *Clinical complications with implants and implant prostheses.* J Prosthet Dent, 2003. **90(2)** p. 121-32.
10. Eckert, S.E., et al., *Analysis of incidence and associated factors with fractured implants: a retrospective study.* Int J Oral Maxillofac Implants, 2000. **15**(5): p. 662-7.
11. Jung R.E, P., B.E., Glauser, R., Zembic, A., Zwahlen, M., Lang, N.P. , *A systematic review of the 5-year survival and complication rates of implant-supported single crowns.* Clin. Oral Impl. Res., 2008. **19**: p. 119-130.
12. Scacchi, M., *The development of the ITI A DENTAL IMPLANT SYSTEM Part 1: A review of the literature.* Clin Oral Impl Res, 2000. **11**(suppl): p. 8-21.
13. Balshi, T.J., *An analysis and management of fractured implants: a clinical report.* Int J Oral Maxillofac Implants, 1996. **11**(5): p. 660-6.
14. Rangert, B., Krogh, P.H., Langer, B., Van Roekel, N., *Bending overload and implant fracture: a retrospective clinical analysis.* International journal of oral & maxillofacial implants 1995. **10**(3): p. 326-334.
15. P. Virdee, K.B., *A review of the aetiology and management of fractured dental implants and a case report.* British Dental Journal, 2007. **203**: p. 461-466.
16. ASMHandbookCommittee, *ASM Handbook Vol. 12 Fractography.* Vol. 12. 1987: ASM International.
17. Morgan, M.J., D.F. James, and R.M. Pilliar, *Fractures of the fixture component of an osseointegrated implant.* Int J Oral Maxillofac Implants, 1993. **8**(4): p. 409-14.
18. Piattelli, A., et al., *Light and scanning electron microscopic report of four fractured implants.* Int J Oral Maxillofac Implants, 1998. **13**(4): p. 561-4.
19. Balfour, A. and G.R. O'Brien, *Comparative study of antirotational single tooth abutments.* J Prosthet Dent, 1995. **73**(1): p. 36-43.

20. Khraisat, A., et al., *Fatigue resistance of two implant/abutment joint designs.* J Prosthet Dent, 2002. **88**(6): p. 604-10.
21. Perriard, J., et al., *Fatigue resistance of ITI implant-abutment connectors -- a comparison of the standard cone with a novel internally keyed design.* Clin Oral Implants Res, 2002. **13**(5): p. 542-9.
22. Mollersten, L., P. Lockowandt, and L.A. Linden, *Comparison of strength and failure mode of seven implant systems: an in vitro test.* J Prosthet Dent, 1997. **78**(6): p. 582-91.
23. Lee, C.K., Karl, M., Kelly, J.R. *Evaluation of test protocol variables for dental fatigue research* Dent Mat, 2009(25):p.1419-25
24. Karl, M., Kelly, J.R. *Influence of loading frequency on implant failure under cyclic fatigue conditions Dent Mat*, 2009(25):p.1426-32

Appendix

1. Chi Square tables for failure/survival

Implant	Failed (1*)	Survivor (0*)	Total
Straumann (1)*	44	3	47
BlueSky Bio (2)	7	8	15
Lifecore (4)	2	13	15
Dr. Idhe (3)	9	6	15
Total	62	30	92

* indicated code for SPSS data

Category	O	E	O-E	$(O-E)^2$	$(O-E)^2/E$
1	44	31.674	12.326	151.932	4.797
2	3	15.326	-12.326	151.932	9.913
3	7	10.109	-3.109	9.664	0.956
4	8	4.891	3.109	9.664	1.976
5	2	10.109	-8.109	65.751	6.504
6	13	4.891	8.109	65.751	13.443
7	9	10.109	-1.109	1.229	0.122
8	6	4.891	1.109	1.23	0.251
	92				37.962

$\chi^2 = 37.962$, df = 3, $p < 0.001$

2. Chi Square tables for failure origin

Implant	Body thread (0*)	Abutment screw (1*)	Total
Straumann	44	0	44
BlueSky Bio	0	7	7
Lifecore	2	0	2
Dr. Idhe	4	5	9
Total	50	12	62

* indicated code for SPSS data

Category	O	E	O-E	$(O-E)^2$	$(O-E)^2/E$
1	44	35.484	8.516	72.524	2.044
2	0	8.516	- 8.516	72.525	8.516
3	0	5.645	- 5.645	31.868	5.646
4	7	1.355	5.645	31.868	23.519
5	1	1.613	-0.613	0.376	0.376
6	1	0.387	0.613	0.376	0.376
7	4	7.258	-3.258	10.615	1.463
8	5	1.742	3.258	10.615	6.093
	62				48.033

$\chi^2 = 48.033$, df = 3, $p < 0.001$

3. Chi Square tables for failure/survival

Implant	Failed	Survivor	Total
BlueSky Bio	7	8	15
Lifecore	2	13	15
Dr. Idhe	9	6	15
Total	18	27	45

Category	O	E	O-E	$(O-E)^2$	$(O-E)^2/E$
1	7	6	1	1	0.167
2	8	9	-1	1	0.111
3	2	6	-4	16	2.667
4	13	9	4	16	1.778
5	9	6	3	9	1.5
6	6	9	-3	9	1
	45				7.223

$X^2 = 7.223$, df = 2, $p < 0.05$

4. Chi Square tables for failure origin

Implant	Body thread	Abutment screw	Total
BlueSky Bio	0	7	7
Lifecore	2	0	2
Dr. Idhe	4	5	9
Total	6	12	18

Category	O	E	O-E	$(O-E)^2$	$(O-E)^2/E$
1	0	2.333	-2.333	5.444	2.333
2	7	4.667	2.333	5.444	1.167
3	2	0.667	0.333	0.111	0.111
4	0	1.333	-0.333	0.111	0.111
5	4	3	1	1	0.333
6	5	6	-1	1	1.667
	18				5,722

$X^2 = 5.722$, df = 2, $p < 0.1$