

## Fatigue Test Report, SMA3510MH

### I. Customer

#### 1. Client

Name : MEDIMECCA Co.,Ltd

President : Bo-Won Ahn

Address : 115, Gasndigital-2ro, Geumcheon-gu, Seoul, Korea(Daeryung Techno Twon  
3-cha 104, 109, 110, 448, Gasan-dong)

#### 2. Manufacturer

Name : MEDIMECCA Co.,Ltd

Address : 115, Gasndigital-2ro, Geumcheon-gu, Seoul, Korea(Daeryung Techno Twon  
3-cha 104, 109, 110, 448, Gasan-dong)

### II. File Information

Document Number : CDM-15-0032-05(E).hwp

Tester : Cheol-Hu Kim, Hye-Ju Jang

Period of Test : 2015-03-04 ~ 2015-06-24

Environment of Test : Temperature 24 °C, Relative Humidity 42 %

### III. Product Information

Item Name : implant, endosseous, superstructure, C20040.01, Class 2

Test Materials : implant, endosseous, superstructure

Product Name : ECTS420 including 1,880 models

Product Type	Model Number	Lot Number	Manufacture Date	Expiration Date
Abutment	SMA3510MH	MP1EFE80110009 ~ MP1EFE8011013 MP1EFE80110021~ MP1EFE8011027 MP1EFE80120001~ MP1EFE80120003	2015-02-12 2015-02-12 -	-
Fixture	ASFS3016MS	MF1EFE50010024,25 MF1EFE50010031~ MF1EFE50010043	2015.02.12	2020.02.11

Information of specimen

Type of fixture	Tapered	
Type of abutment	Two-piece Screw-retained	
Material of the tested parts	Abutment : n/s Fixture : n/s	
Casting material of the tested parts	-	
Coating or surface treatments	Abutment : n/s Fixture : n/s	
Diameter and length of the fixture	Max. diameter	D 3.2 mm
	Body diameter	D 2.9 mm
	Total length	L 15.5 mm
	Collar length	L -
Dimensions of the abutment(s) including the angle $\alpha$	Max. diameter	D 3.5 mm
	Total length	L 10.6 mm
	Length from connection part	-
Dimension of connect part	angle $\alpha$	

Information of testing geometry condition

The length of abutment after connection	8.0 mm
The length of fixture collar	-
The distance of the support level of the fixture from the nominal bone level	$(3.0 \pm 0.5)$ mm
The distance of loading centre from the support level of the fixture	11 mm Moment arm(y) : 5.5 mm
Assembly torque	30 N·cm
Schematic of test set-up for systems with pre-angled connecting parts	$30^\circ \pm 2^\circ$
Embedding medium and modulus of elasticity	Polyester resin, 7.0 GPa
Dimension of embedding medium holder	Top 16 mm Bottom 11 mm Height 20 mm
Materials and diameter of loading member	n/s, 6.0 mm
Design and manufacture of loading member	Designed and machined by client
Note.	-

Information of testing environment

Criteria of iteration without fracture	$5 \times 10^6$ cycles
Frequency(Hz)	14 Hz
Temperature and medium	$(20 \pm 5) ^\circ\text{C}$ , in air
Note.	—

**IV. Test Methods**

**1. Equipment**

- Torsion testing machine, Vortex-i, Mecmesin Co., U.K.
- Universal testing machine, Instron 3367, Instron Co., U.S.A.
- Fatigue testing machine, Instron 8841, Instron Co., U.S.A.
- Fatigue testing machine, Instron E3000, Instron Co., U.S.A.
- Digital caliper, CD-15CPX, Mitutoyo Co., Japan
- Polishing machine, FORCIPOL 1V, Netkon Instrument LTD., Turkey
- Image microscope system, SV-35, Sometech Inc., Korea

**2. Procedure**

**2-1. 30° Compressive Loads Test Method**

- 1) The number of specimens : 5 ea
- 2) Cross head speed : 1.0 mm/min
- 3) The 30° Compressive loads test was performed under compression mode in the universal testing machine until the specimen reached yield point and maximum load.

**2-2. Fatigue Test Method**

- 1) Normative reference : ISO 14801:2007(E)
- 2) The number of specimens : 3 ea at each of at least four loads.
- 3) Load waveform : Sine
- 4) Control mode : Load control
- 5) The fatigue testing was carried out with a unidirectional load, and the load was varied sinusoidally between a nominal peak value and 10 % of this value.
- 6) The appropriate starting load was 80 % of the maximum load measured in 30° compressive load test.
- 7) The subsequent tests were repeated at lower loads to search final fatigue limit.
- 8) If the specimen was withstood the criteria cycles of iteration without fracture ( $5 \times 10^6$  cycles) at any load, that load was recorded as the fatigue limit.

**V. Test Results**

Results	Fatigue limit	Fatigue limit : 250 N (There were no crack, breakage, deformation and loosening of screw when tested in accordance with testing method.)
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VI. Attachments

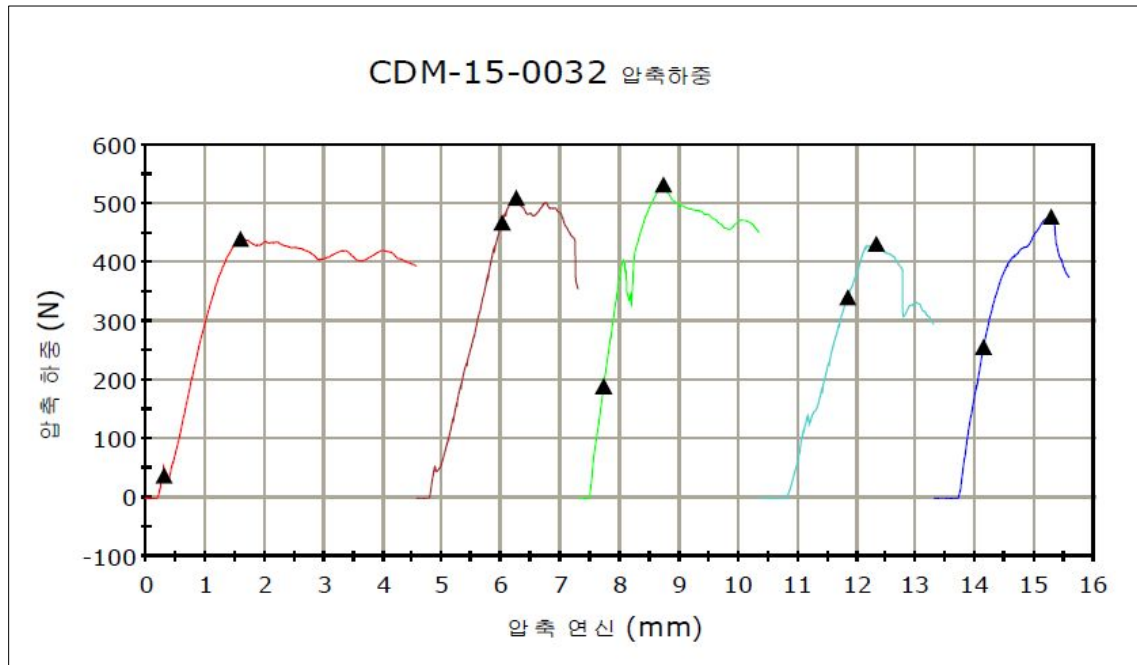
1. 30° Compressive Loads Test Results

1-1. 30° Compressive Loads Test Result Summary

1. Test Result					
1.1. Results	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
1.2. Max load(N)	440.37	509.85	531.84	431.64	477.79
1.3. Mean	478.298 N (SD: 43.238 N, CV: 9.04 %)				
2. Conclusion					
2.1. 30° Compressive Loads	478 N				

1-2. Load-Distance Graph

Experimental code : CDM-15-0032  
 Date : 2015-03-09  
 Mode : Compression  
 Cross head speed : 1.0 mm/min



Y axis : Compressive loads(N), X axis : Deformation (mm)

## 2. Fatigue Test Results

### 2-1. Fatigue Test Result Summary

<b>80 % (382 N) Test Results</b>			
Results	Specimen 1	Specimen 2	Specimen 3
Max. load(N)	382	382	382
Min. load(N)	38.2	38.2	38.2
The moment arm(y)	5.5	5.5	5.5
Bending moment(N·mm)	2103	2103	2103
Angle of axis( °)	30	30	30
Loading frequency(Hz)	14	14	14
Number of cycle(Cycle)	36212	2	945
Fracture	Fixture	Fixture, Screw	-
Crack	-	-	-
Deformation	Screw	-	Fixture ,Screw
Loosening of screw	-	-	-
The distance of loading centre from failure point	11.6 mm	12.9 mm	10.4 mm
Conclusion	Fail	Fail	Fail
Note	-	-	-

<b>64 % (306 N) Test Results</b>			
Results	Specimen 1	Specimen 2	Specimen 3
Max. load(N)	306	306	306
Min. load(N)	30.6	30.6	30.6
The moment arm(y)	5.5	5.5	5.5
Bending moment(N·mm)	1683	1683	1683
Angle of axis( °)	30	30	30
Loading frequency(Hz)	14	14	14
Number of cycle(Cycle)	58199	8341	15355
Fracture	Screw	-	Fixture, Screw
Crack	Fixture	-	-
Deformation	-	Fixture, Screw	-
Loosening of screw	-	-	-
The distance of loading centre from failure point	11.5 mm	10.4 mm	11.0 mm
Conclusion	Fail	Fail	Fail
Note	-	-	-

58 % (275 N) Test Results			
Results	Specimen 1	Specimen 2	Specimen 3
Max. load(N)	275	275	275
Min. load(N)	27.5	27.5	27.5
The moment arm(y)	5.5	5.5	5.5
Bending moment(N·mm)	1513	1513	1513
Angle of axis( °)	30	30	30
Loading frequency(Hz)	14	14	14
Number of cycle(Cycle)	5065383 over	845502	230926
Fracture	–	Fixture, Screw	Fixture, Screw
Crack	–	–	–
Deformation	–	–	–
Loosening of screw	–	–	–
The distance of loading centre from failure point	–	12.6 mm	12.9 mm
Conclusion	Pass	Fail	Fail
Note	–	–	–

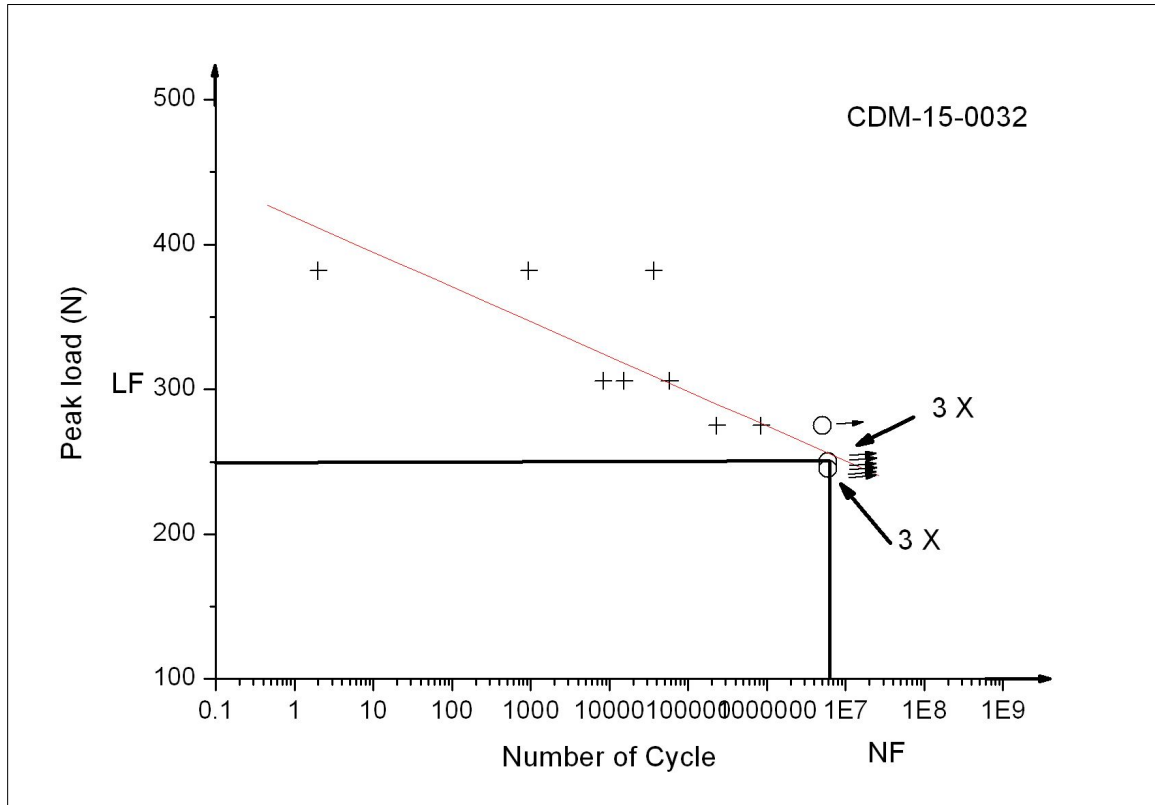
52 % (250 N) Test Results			
Results	Specimen 1	Specimen 2	Specimen 3
Max. load(N)	250	250	250
Min. load(N)	25	25	25
The moment arm(y)	5.5	5.5	5.5
Bending moment(N·mm)	1375	1375	1375
Angle of axis( °)	30	30	30
Loading frequency(Hz)	14	14	14
Number of cycle(Cycle)	6000000 over	6000000 over	6000000 over
Fracture	No	No	No
Crack	No	No	No
Deformation	No	No	No
Loosening of screw	No	No	No
Conclusion	Pass	Pass	Pass
Note	–	–	–
Requirement	The fatigue limit shall be more than 250 N. There shall be no crack, breakage, deformation and loosening of screw when tested in accordance with testing method.		
<b>Conclusion</b>			
Fatigue limit	<b>Fatigue limit : 250 N</b> (There were no crack, breakage, deformation and loosening of screw when tested in accordance with testing method.)		

51 % (245 N) Test Results			
Results	Specimen 1	Specimen 2	Specimen 3
Max. load(N)	245	245	245
Min. load(N)	24.5	24.5	24.5
The moment arm(y)	5.5	5.5	5.5
Bending moment(N·mm)	1348	1348	1348
Angle of axis( °)	30	30	30
Loading frequency(Hz)	14	14	14
Number of cycle(Cycle)	6000000 over	6000000 over	6000000 over
Fracture	–	–	–
Crack	–	–	–
Deformation	–	–	–
Loosening of screw	–	–	–
The distance of loading centre from failure point	–	–	–
Conclusion	Pass	Pass	Pass
Note	–	–	–

2-2. Test set-up



2-3. Load-Cycle diagram



+ Fractured Specimens  
 O Surviving Specimens

2-4. Photographs of specimens 6 cuts



Specimen before test



80 % (382 N) specimen after test





640 % (306 N) specimen after test



58 % (275 N) specimen after test



52 % (250 N) specimen after test

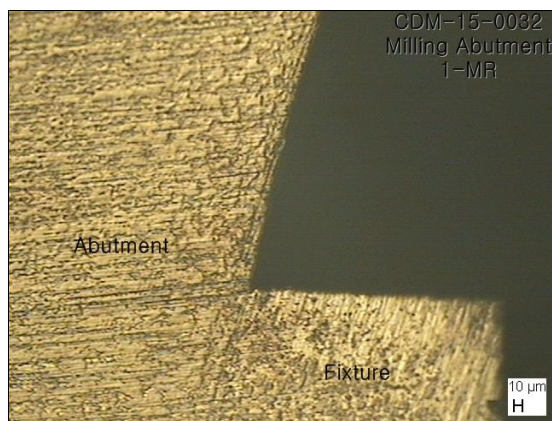
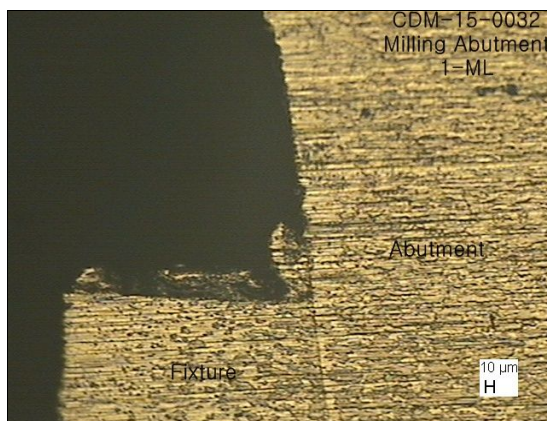


51 % (245 N) specimen after test

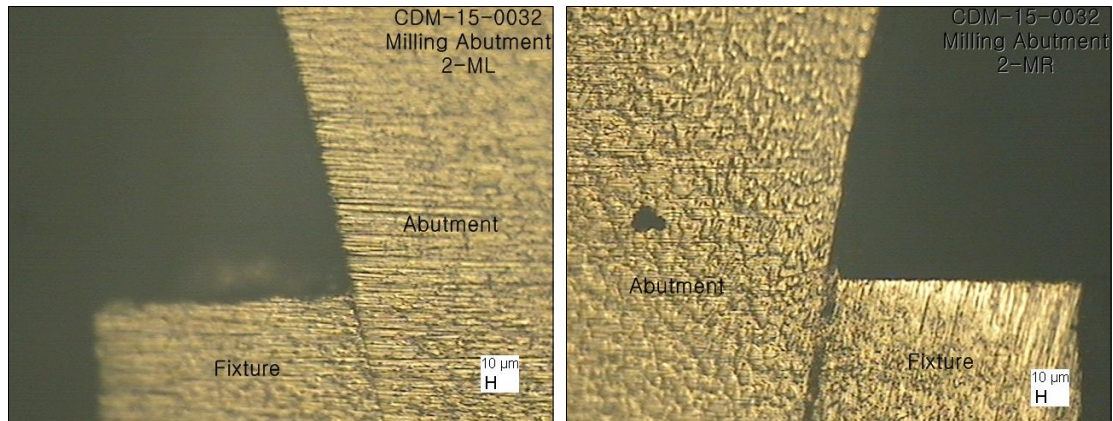
\* All 15 specimens were capped with machined metal cap and tested.

2-5. Photographs of adaptation accuracy 6 cuts

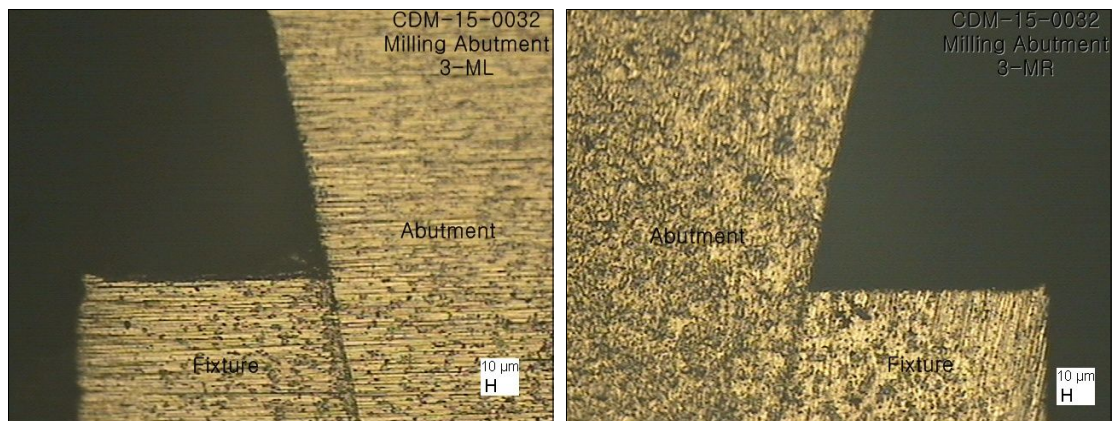
250 N Specimen 1





250 N Specimen 2



250 N Specimen 3



Affirmation	Tests performed by Name : Cheol-Hu, Kim 	Approved by Title : Technical Manager Name : Ja-Yong, Shin 
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2015-06-24

Testing & Development Center for Dental Materials  
Kyung Hee University

End.

Translated at 2015-07-29 by Yun-Kyong Hong 