



TOBB Ekonomi ve Teknoloji Üniversitesi

TOBB University of Economics and Technology

BIOMECHANICAL TEST REPORT

No. 12072012-42-01

Customer: Mode Medikal San. Ve Tic. Ltd.

Customer's Address: Abdi İpekçi Cad. Ak Makina İş Merkezi No:132 Bodrum
Kat B.Paşa İstanbul/TURKEY

Authorized Person: Oğuz AKYÜZ

Trade Mark: Mode Medikal

Subject: Torsion Test of Implant/Body Connecting Part Joints of
Endosseous Dental Implant Systems¹ – TS/ISO 13498

Product Name: Dental Implant

Date of Receipt: 06.07.2012

Material: Ti Grade 4

Lot Number: n.a.

Catalog Number: n.a.

Specimen Quantity: 5

Size: 10 (Ø4,1)

Test Number: 0607124201

Report Number: 12072012-42-01

Report Date: 12.07.2012

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Test Date	Principle Engineer	Head of Biomechanics Laboratory
12.07.2012	M.Fatih Örmeci 	Dr.Teyfik Demir

This test method is intended to provide a characterization of mechanical properties of tested specimens. It is not the intention of this specification to define levels of performance or case specific clinical performance of these devices, as insufficient knowledge to predict consequences of the use of any of these devices in individual patients for specific activities of daily living is available.

I. Torsion Test of Implant/Body Connecting Part Joints of Endosseous Dental Implant Systems – TS/ISO 13498

A. Test Method for Determining the Torsional Properties of Metallic Bone Screws

1. Purpose and Test Conditions:

This test method is used to measure the torsional yield strength, maximum torque, and breaking angle of the endosseous dental implants under standard conditions. The results obtained in this test method are not intended to predict the torque encountered while inserting or removing a endosseous dental implants in human or animal bone. This test method is intended only to measure the uniformity of the product tested or to compare the mechanical properties of different, yet similarly sized, products.

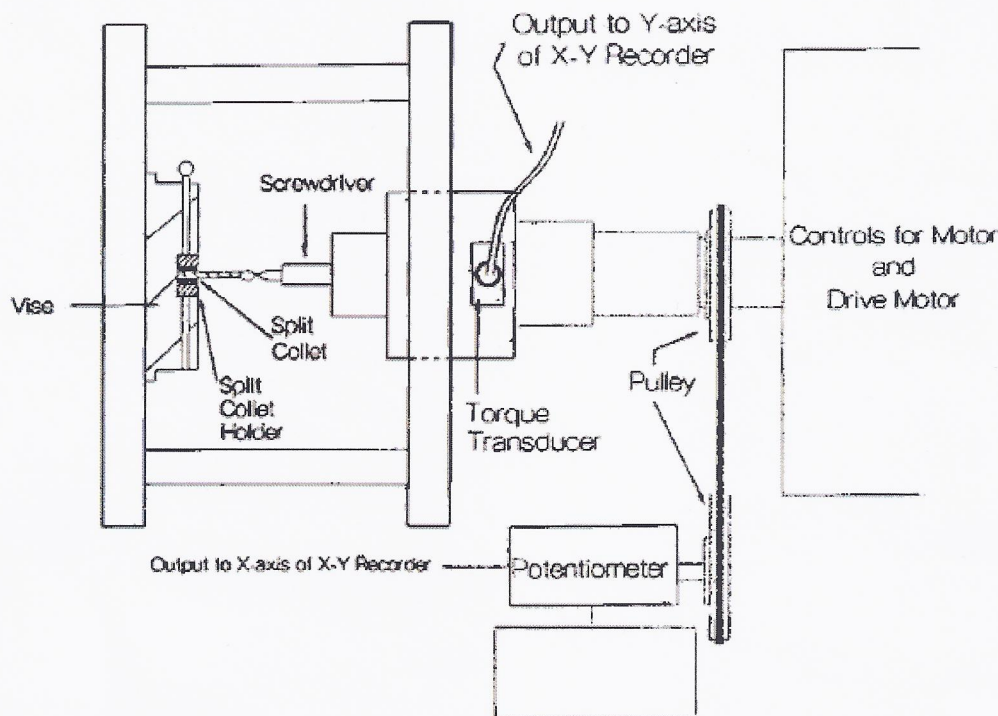



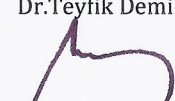
Figure A.1 Schematic View of Test Apparatus for Determining the Torsional Breaking Force and Breaking Angle².

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Table A.1 Specimen Identification and Test Conditions

Test Number	0607124201
Manufacturer	Mode Medikal San. Ve Tic. Ltd.
Product Name	Dental Implant
Material	Ti6Al4V
Lot Number	n.a.
Catalog Number	n.a.
Specimen Quantity	5
Size [mm]	10 (Ø4,1)
Surface Finish	Sandblasted
Standard Specification	HB-Cancellous Bone Screw
Grip Length Left [mm]	10
Grip Length Right [mm]	6
Offset Displacement [deg]	2
Rate of Loading [r/min]	2

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2. Test Results

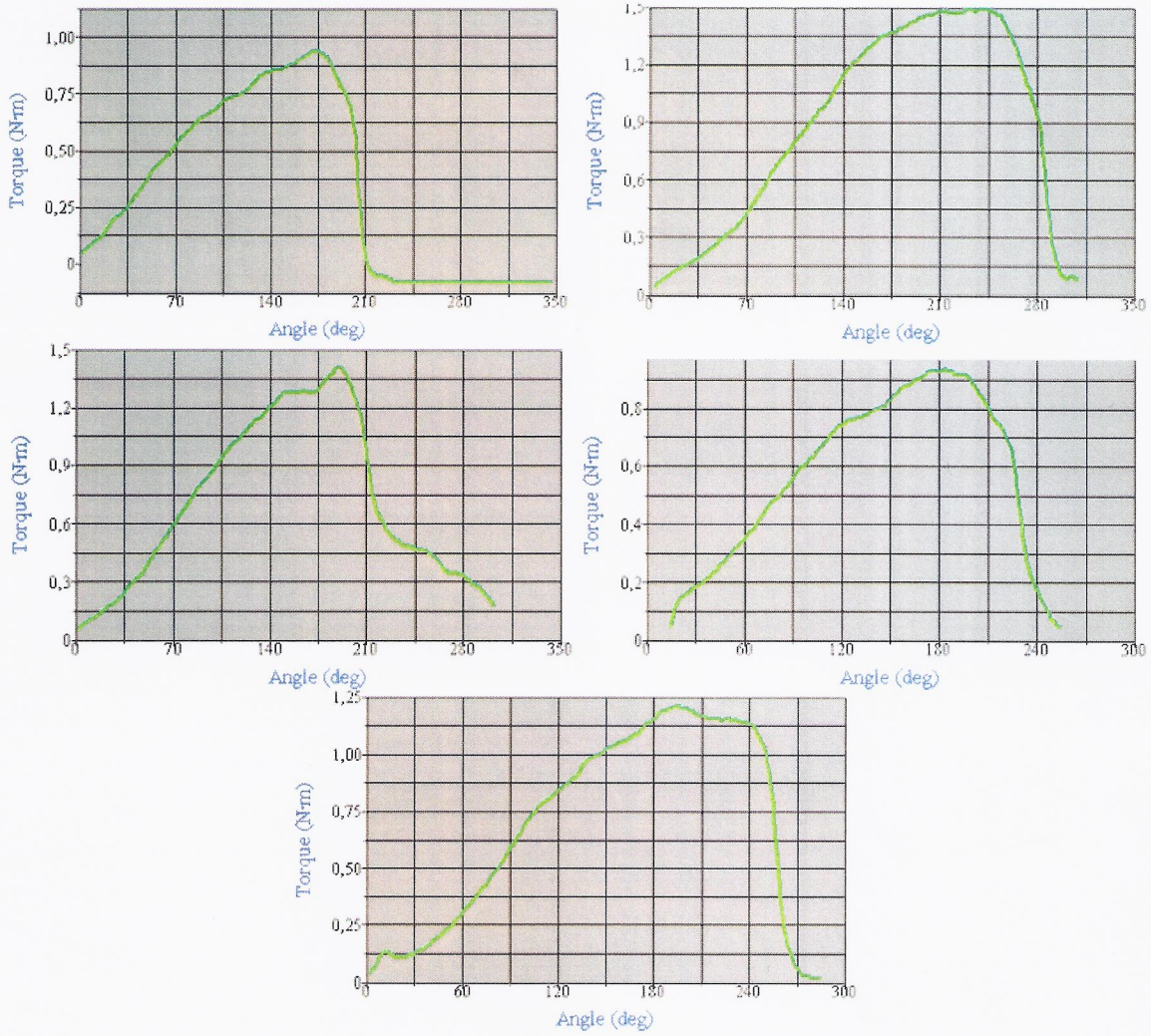


Figure A.2 Torque vs. Degree Plots

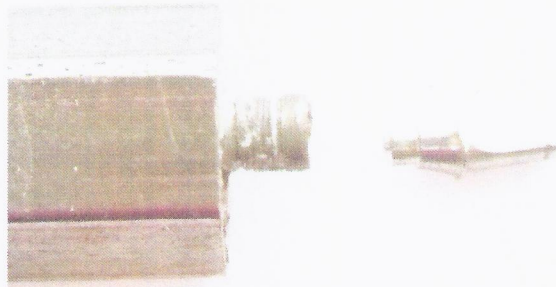



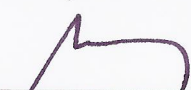
Figure A.3 Specimen tested herein (no: 1.3).

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Table A.2 Results of Torsional Properties of Tested Specimens

Sample	Torsional Yield Strength [N*m]	Yield Displacement [mm]	Torsional Stiffness [N*mm/deg]	Maximum Torque [N*m]	Breaking Angle [deg]	Fracture Location	Test Machine Serial Number
1.1	0,64	88	7,27	0,94	169	Connecting Bolt	55MT2J8467
1.2	1,37	171	8,01	1,49	228	Connecting Bolt	55MT2J8467
1.3	1,28	156	8,21	1,41	187	Connecting Bolt	55MT2J8467
1.4	0,76	126	6,03	0,94	182	Connecting Bolt	55MT2J8467
1.5	0,81	117	6,92	1,21	242	Connecting Bolt	55MT2J8467
Mean	0,972	131,6	7,29	1,198	201,6	-	-
S.D	0,330	32,76	0,877	0,257	31,58	-	-

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Conclusion

- Mean torsional peak torque was 1198 N*mm of tested specimens.
- Torsional stiffness was 7.29N*mm/deg of tested specimens.



References

- [1] TS/ISO 13498
- [2] ASTM F 543-07^{€1} – Fig.A1.1

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