MDT
Medical Device Testing Services

KAT Implants, LCC
MDT10074

KAT Implants LLC. KAT 3.0mm Implant and Angled Abutment 4.2 (20 degree angle) Fatigue Testing

Prepared by Medical Device Testing Services, Inc.

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TEST REPORT MDT10074

KAT Implants LLC. KAT 3.0mm Implant and Angled Abutment 4.2 (20 degree angle) Fatigue Testing

Device Manufacturer:
KAT Implants, LLC.
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Test Engineer: Calvin Chao
Report: MDT10074
Date: January 10, 2011

Purpose

The test was designed to determine the endurance of KAT 3.0mm Implant and Angled Abutment 4.2 (20 degree angle) per ISO 14801:2007(E) “Dentistry-Implants-Dynamics fatigue test for end-osseous dental implants”.

Scope

This bench top test was intended to provide the fatigue properties of the KAT 3.0mm Implant and Angled Abutment 4.2 (20 degree angle) when subjected to mechanical fatigue. The test was designed to find the 5 million cycle endurance limit of the device. Load was applied to a single implant and cyclically varied with pre-determined amplitude and the numbers of load cycles until failure occurrence was recorded. The implant was clamped to the test fixture with its longitudinal axis aligned to the loading direction at a 30º angle with the angle of the abutment pointing up at 20 degrees. The test was performed in ambient air at frequency of 3Hz to 10Hz for 5 million cycles or until failure occurred. An implant failure was defined as any material yielding, permanent deformation, loosening of the implant assembly or fracture of any component during or at the end of test. A number of specimens (at least 2) were tested at different values of the peak load to determine the fatigue properties. The test samples were selected from representative commercial products for testing.

Summary

The objective of this test was to determine the 5 million cycle endurance limit of KAT 3.0mm Implant and Angled Abutment 4.2 (20 degree angle). All test samples were selected from representative commercial products (KAT 3.0mm Implant and Angled Abutment 4.2 (20 degree angle)). The ‘test ready’ sample assemblies were prepared and provided by KAT Implants, LLC. Sample assemblies included KAT 3.0mm Implant and Angled Abutment 4.2 (20 degree angle). The test samples were provided mounted in Wood's metal. Wood’s metal has a Young's modulus of 9.7 GPa. A hemispherical loading member, the center of which lies on the central longitudinal axis of the free end of the connecting part and is l = 11,0 mm ± 0,5 mm from the support level of

the implant, measured on a line parallel to the central longitudinal axis of the implant body, was placed on each sample prior to testing.

The testing was conducted from Nov 30, 2010 through January 10, 2011 in the Medical Device Testing Services (MDT) lab on the SP-2800-001 tester.

One sample assembly was tested for static load. The sample assembly failed at a max static load of 1557 N (350 Lbs). Two sample assemblies were fatigue tested at 1100N (75% of max static load), two at 800N (55% of max static load), and one at 662N (45% of the max static load). Four (4) of these sample assemblies failed within 5 million cycles and one passed 5 million cycles at 800 N load. Three (3) sample assemblies were fatigue tested at a lower load 440 N (30% of max static load). Each of the three (3) sample assemblies maintained the structure integrity with no visible damage to the implant after the completion of 5 million cycles. Sample dimensions, loads and cycle counts can be found in tables 2a, 2b, and 2c.

KAT Implant System Dental Implants and Abutments are indicated for restoration of edentulous maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implants can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.

Ten mounted implant/abutment assemblies were provided by KAT Implants, LLC (manufacturer). Assemblies consisted of 3.0 x 14mm implants, Part Number 0013514 (Lot #A-1996) and Angled Abutment 4.2 20º Part Number 002201 (Lot #00097). Abutments were attached to the implants by means of a 3 degree locking taper connection. 25 Ncm of torque was applied by the manufacturer to the abutments to activate locking taper connection. Tested implants and abutments were machined from T6Al4V ELI alloy.

Samples were mounted in copper rings. Mounting material was Wood's metal with Young's modulus 9.7 GPa. Test was conducted to the ISO 14801: 2007 standard.

Manufacturers chose to test 3.0mm diameter implants with Angled abutment 4.2 20º because they represent the worst case scenario of the KAT Implant System (excluding the transitional 2.5mm implants which will not be indicated for use with the angled abutments). 3.0mm diameter implant is the smallest diameter implant in KAT System. Angled abutment 4.2 20º is the smallest diameter angled abutment in KAT System. Other Angled abutments of KAT Implants System (Angled abutment 4.6 20º and Angled abutment 5.4 20º) have the same degree angulation (20º), the same length (8.5mm) and have thicker walls.

Manufacturer specifies in the Instruction for Use that the implant shoulder (junction between machined and blasted surfaces) should be placed 1.0mm below the bone crest. Implant/abutment assemblies were mounted by manufacturer to simulate 3.0mm +/-.5mm bone loss around the implant. Implant shoulder location of all samples was 2.5mm – 3.0mm above the surface of the mounting media to simulate 3mm of bone loss.

Hemispherical loading element was provided by the manufacturer. It had 4mm diameter to fit over the Angled abutment and have sufficient thickness of the metal not to distort during the test; when

placed over the implant/abutment assembly the distance (L) between center of the hemispherical element and the mounting surface was 11mm +/-.5mm per 5.3.4 of the ISO 14801: 2007.

Equipment

1. MTS Tester (MDT SP2800-001)
2. WinTest® Controls and Software
    a. PCIM or PC 2543 controller card
    b. PCI control box
3. Computer, ≥ 400MHz CPU
4. Test sample assemblies, Quantity n=10
5. Test fixture: MDTS P/N 515489 rev. A
6. Thumb Screw: McMASTER-CARR P/N 1882A371
7. 10,000N (MDT ISN# 00255)
8. Caliper ISN (00026)

Procedures

The test followed test protocol and amendments agreed upon by MDT Services and KAT Implants. Medical Device Testing Services abides by our documented Quality Process for all testing services.

1. Assembly
    a. The equipment calibration schedules were verified to be up to date. Tester operation was verified by running the tester without samples. (Table 1)
    b. The test fixture MDTS P/N51549 was mounted on top of the load cell of tester MDT SP2800-001 and the thumb screw McMASTER-CARR P/N 1882A371 was screwed to the moving shaft. (Figure 1.)
    c. Test sample assembly was loaded into the test fixture P/N51549 and secured with two 6-32 set screws. (Figure 1.)
2. Static Test
    a. One sample was tested for max static failure load. The device was loaded with a pseudo-static load rate of 0.001 in/sec (0.025 mm/sec). Load and displacement data were collected during the entire duration of the test.
3. Fatigue Test
    a. Fatigue cyclic loading was implemented by cyclic indirect control with displacement feedback by WinTest controller.
    b. Each fatigue test was run at frequency at range 3Hz to 10Hz for max 5 million cycles or until failure occurred. Load under peak limits were activated in the Wintest controller to detect the number of cycles at which the failure occurred.
    c. Test loading occurred
    d. The total length of the specimen was measured and recorded before and after the test. If the specimen failed, the length was not measured.

KAT Implants LLC. Single Dental Implant Test - Equipment Calibration

No.	System	S/N or ID	Date Calibrated	Calibration Due Date
1	SP 2800 Lb Load Frame with WinTest Controller	SP-2800-001	11/15/2010	11/15/2011
3	Caliper	ISN 00026	03/24/2010	03/24/2011
4	10,000N Load Cell	ISN 00255	11/22/2010	11/22/2011

Table 1: Calibration schedule for the equipment used for KAT single dental implant test

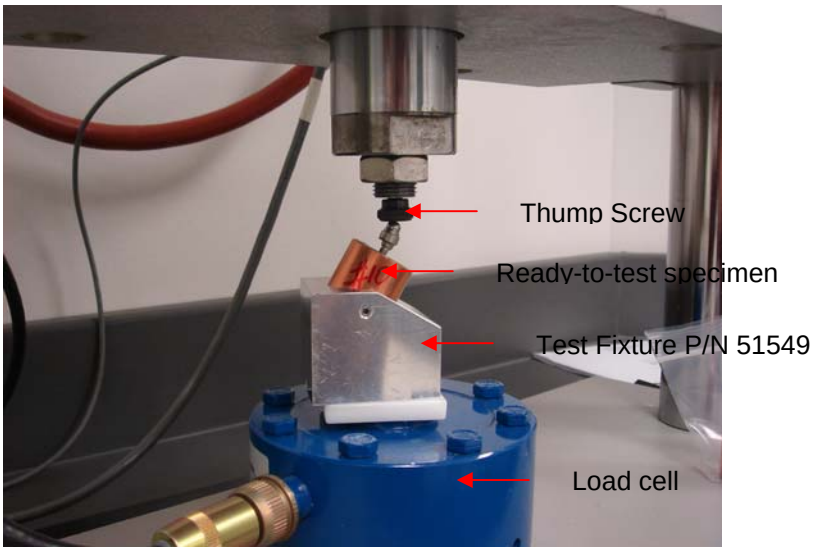

Figure 1: Test Fixture Setup of KAT single dental implant test

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Test Data

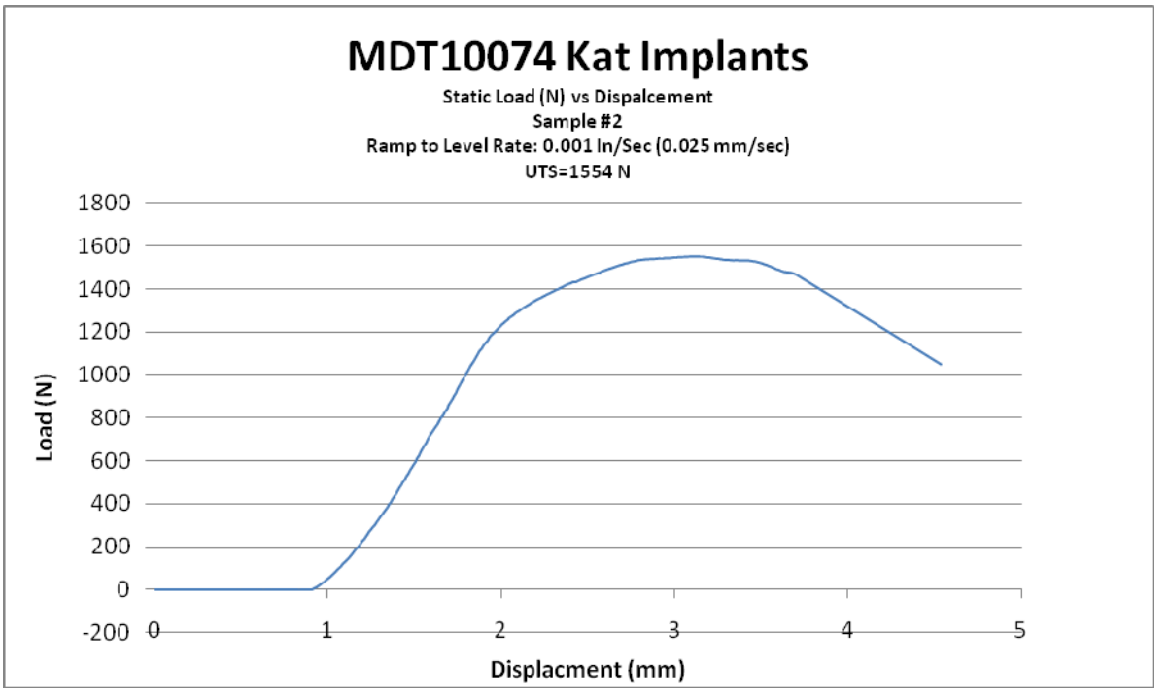

Figure 2: Static Load vs. Displacement specimen #2. Max static load 1554N.

Specimen ID	Figure Number	Cycles (count)	Load Peak (N)	% of max Static Load	Start Date	End Date	Testing Frequency (Hz)	Failure Mode
3		13927	1100	71%	11/23/2010	11/23/2010	3	Fractured
4		5298	1100	71%	11/23/2010	11/23/2010	3	Fractured
5	4	5000000	800	51%	11/23/2010	12/9/2010	3,6	Pass
6	5	2635787	800	51%	12/9/2010	12/15/2010	6	Fractured
7	6	2729738	660	42%	12/15/2010	12/20/2010	6,10	Fractured
8	7	5000000	440	28%	12/20/2010	12/28/2010	10	Pass
9	8	5000000	440	28%	12/28/2010	1/3/2010	10	Pass
10	9	5000000	440	28%	1/3/2010	1/10/2010	10	Pass

Table 2a: Summary of fatigue tests run until 5E6. Endurance level 425N.

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Specimen number	L length of specimen pre-testing (mm) mean
1	11.41
2	11.15
3	11.37
4	11.45
5	11.50
6	11.04
7	11.01
8	11.56
9	11.50
10	11.32

Table 2b: Summary of L Length of specimen pre-testing.

Specimen ID	L length (mm)	Implant diameter (mm)	Load Peak (N)	Moment Arm calculated (mm)	Bending Moment (N.mm)
3	11.37	3.00	1100	2.00	2201.90
4	11.45	3.00	1100	2.02	2216.97
5	11.50	3.00	800	2.02	1619.20
6	11.04	3.00	800	1.95	1556.19
7	11.01	3.00	660	1.94	1280.46
8	11.56	3.00	440	2.03	895.08
9	11.50	3.00	440	2.02	890.56
10	11.32	3.00	440	1.99	876.99

Table 2c: Summary of Bending Moment

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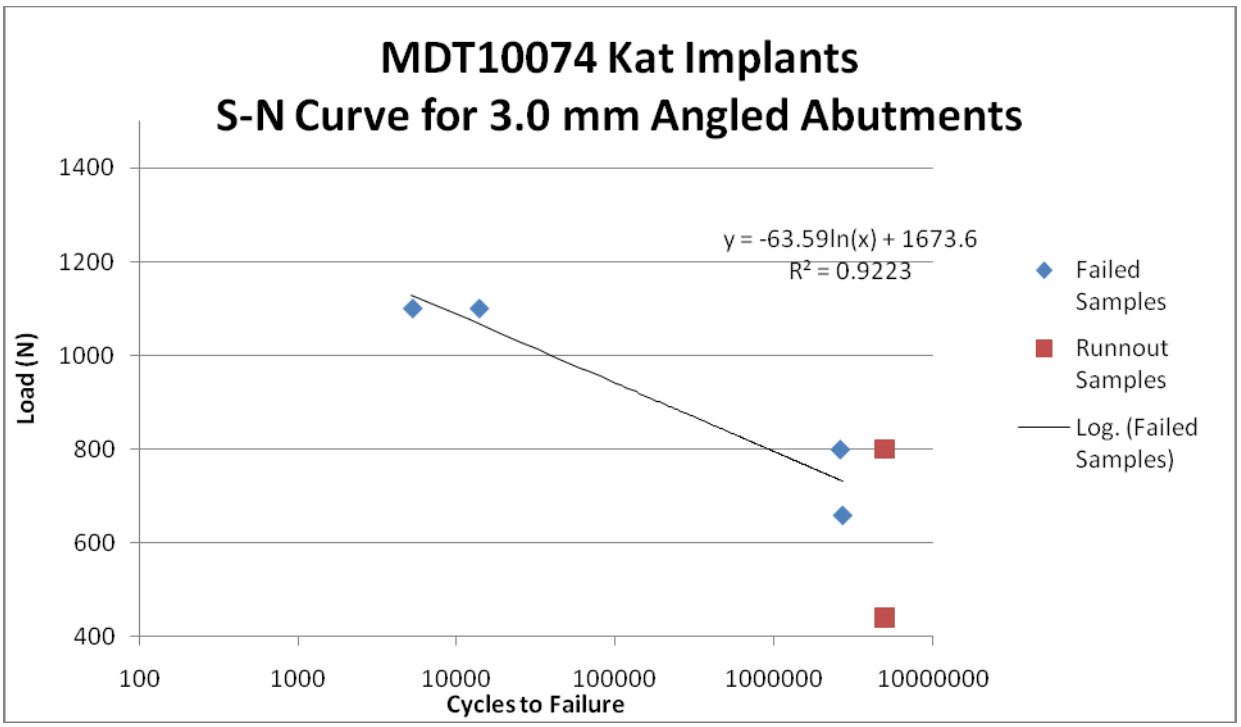

Figure 3: Load-Cycle Diagram for tests run until 5E6. Endurance level=440N equivalent to 862 N.mm bending moment.

Results

Fatigue tests were run at four levels of load peak. Three sample assemblies survived at 440N load peak for 5 million cycles. The testing indicates that the endurance level of the dental implant product is at least 440N (equivalent to 887.54 N.mm bending moment).

Revision	Description of revision	Date

Medical Device Testing Services (MDT) tests are conducted in accordance with *A2LA ISO/IEC 17025:2005*. In compliance with this standard, MDT test reports include complete and accurate documentation of the test protocol and results. Information including the specific test conditions, statements of compliance or non-compliance with test protocol, statements of the estimated measurement uncertainty, and opinions or interpretations may be provided. Any test method deviations, additions or exclusions are documented and reviewed with the customer prior to beginning the test. Results only relate to the items tested, opinions and interpretations will be clearly marked as such in the test report. Additional information required by customer specific, or customer group specific, methods will also be noted.

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Appendix

Plots of peak load vs. cycle for all samples.

1100N (71% of max Static Load) Peak Load Tests:

Load peak and valley data was not taken for specimen #3 and #4

800N (51% of max Static Load) Load Peak Tests:

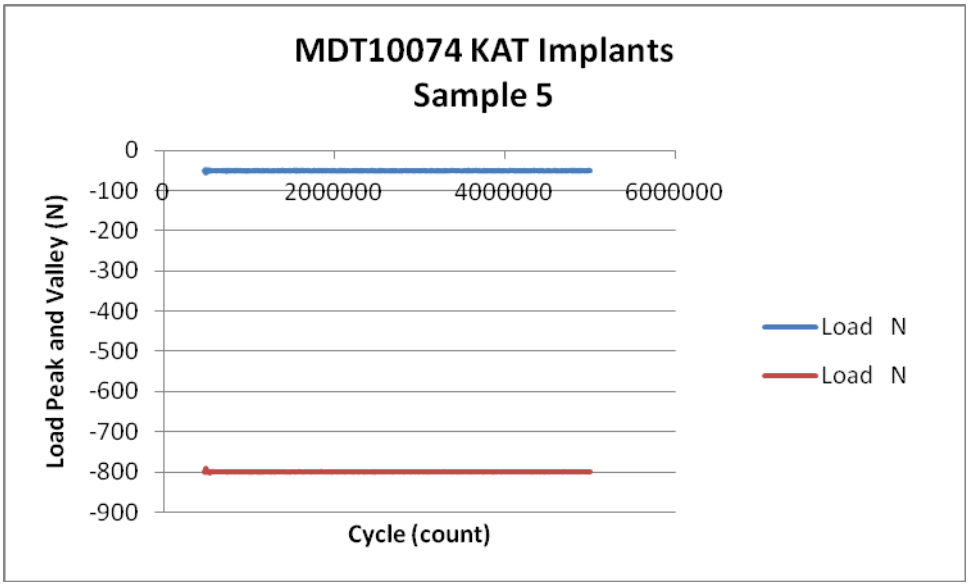

Figure 4: Load Peak and Valley vs. Cycle of specimen #5

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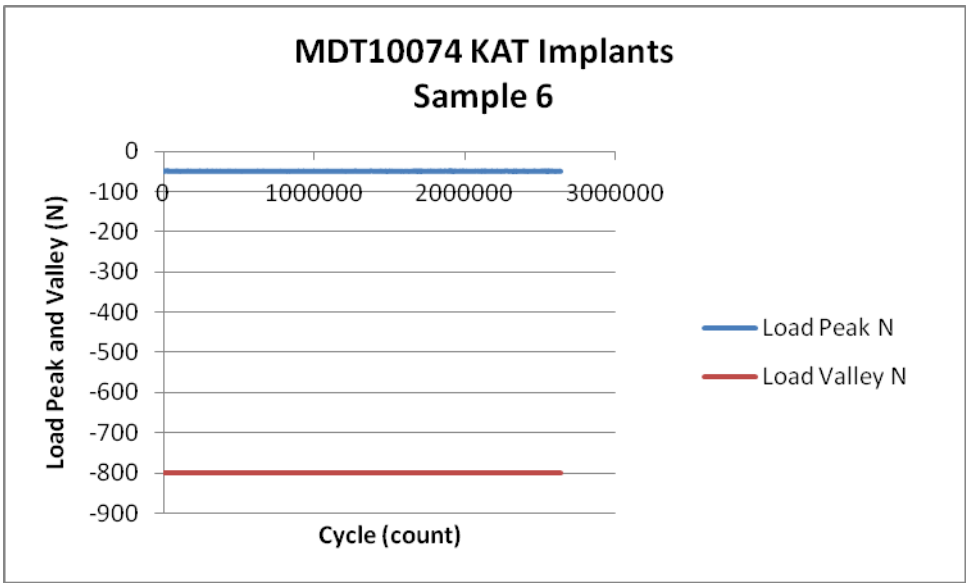

Figure 5: Load Peak and Valley vs. Cycle of specimen #6

660N (42% of max Static Load) Load Peak Tests:

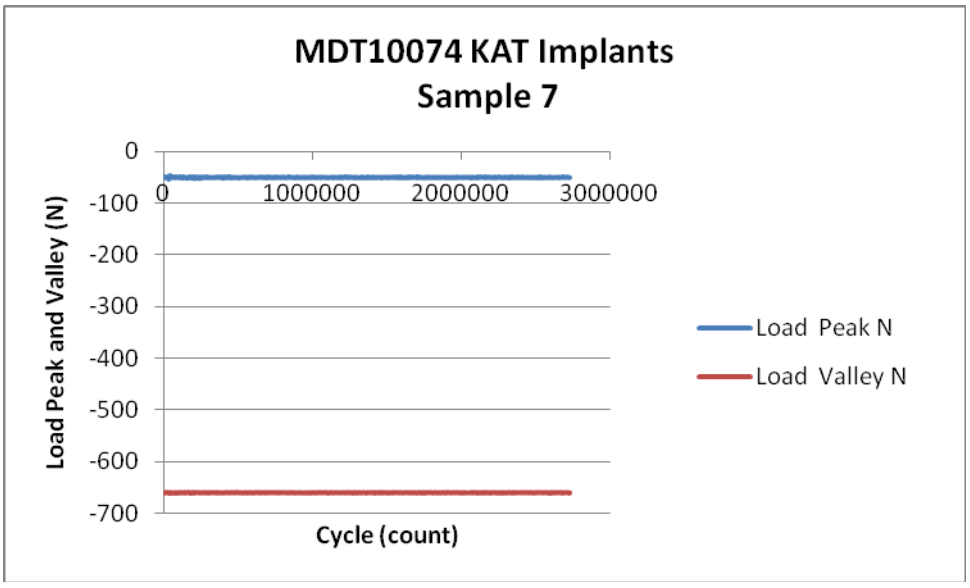

Figure 6: Load Peak and Valley vs. Cycle of specimen #7

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440N (28% of max Static Load) Load Peak Tests:

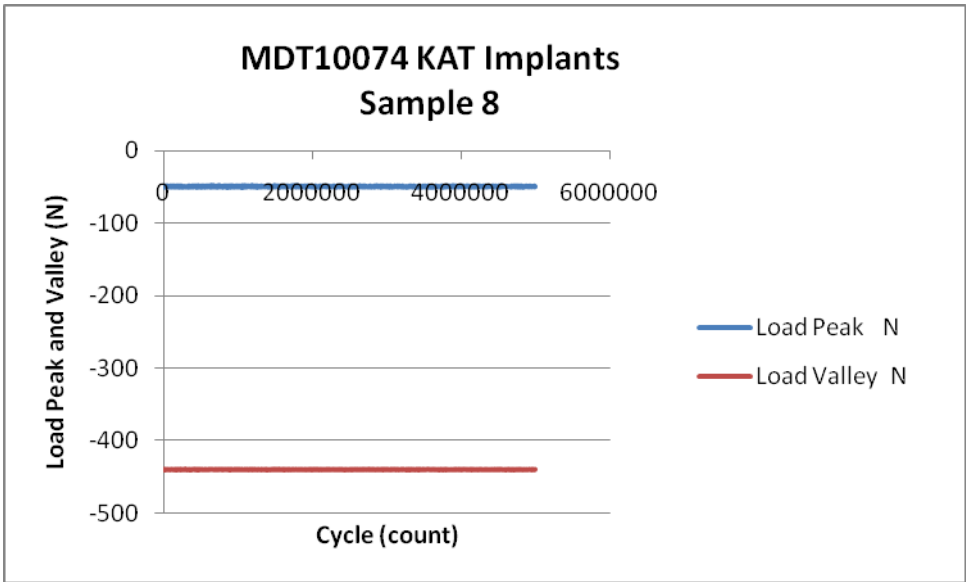

Figure 7: Load Peak and Valley vs. Cycle of specimen #8

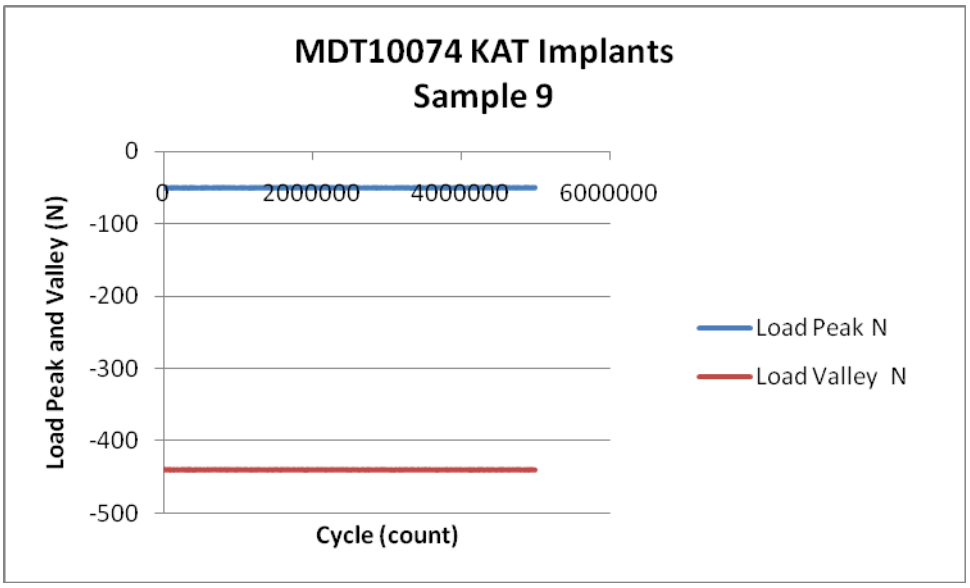

Figure 8: Load Peak and Valley vs. Cycle of specimen #9

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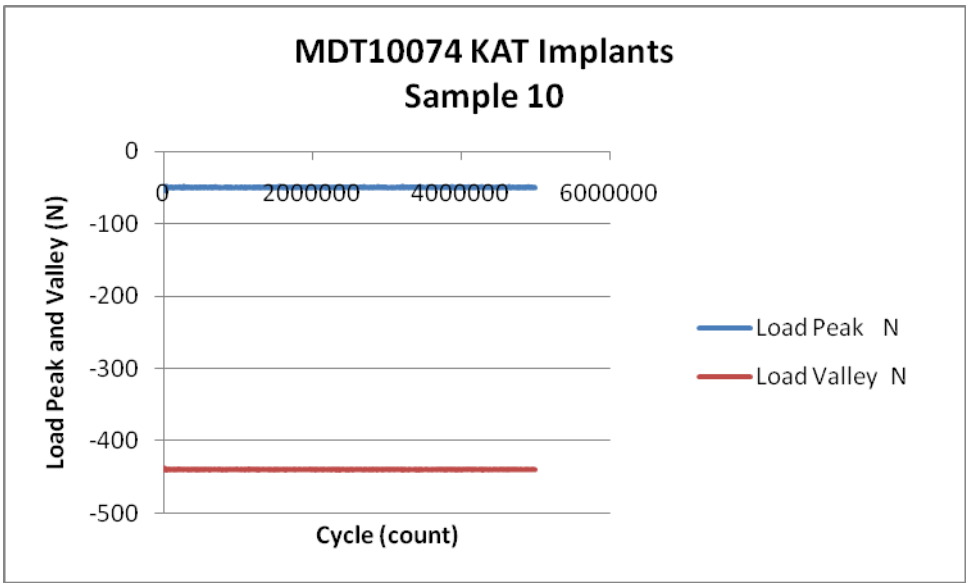

Figure 9: Load Peak and Valley vs. Cycle of specimen #10

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