

AN EVALUATION OF STRENGTHS OF VARIOUS DENTAL IMPLANT SYSTEMS FROM STANDARDIZED FATIGUE TESTING

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OBJECTIVE

This study evaluates the fatigue strengths of implant systems of comparable size made from similar materials from various manufacturers (Nobel Biocare, Straumann and BIOMET 3i). The study specifically compares the endurance limits (highest fatigue loads the implant systems can withstand without failure) determined from testing of these implant systems using "worst-case scenario" with custom 30-degree angled abutments and following the guidelines for fatigue testing as specified in ISO 14801¹.

BACKGROUND

The definition of fatigue of metal is the changes in its properties when subjected to cyclic or repetitive loads². Metal fatigue results in premature failure or damage of a component or a system. On a microscopic level, it is a complicated metallurgical process which is difficult to accurately describe and model³. Fatigue is important to understand as metal can fail or fracture at a cyclic load value much lower than that under a single load application. It is highly beneficial to determine the durability of a dental implant and its components subjected to chewing forces and occlusal loads in application. The frequency and types of mechanical complications are expected to be different for each dental implant system. This is due to different manufacturing processes, structural designs and materials selection.

Regulatory bodies in many countries require data from cyclic fatigue testing of dental implants. A standardized implant fatigue testing protocol (ISO 14801) was developed by a panel of industry and academic experts for the Organization for International Standardization (ISO). The ISO recommendations were designed for single, endosteal, transmucosal dental implants tested under "worst case" applications. ISO does not specify acceptance criterion/criteria for the test results. Rather, it rests with the applicable regulatory bodies. The current study reports the results from testing three (3) different dental implant systems of comparative sizes and made from similar material using ISO protocol.

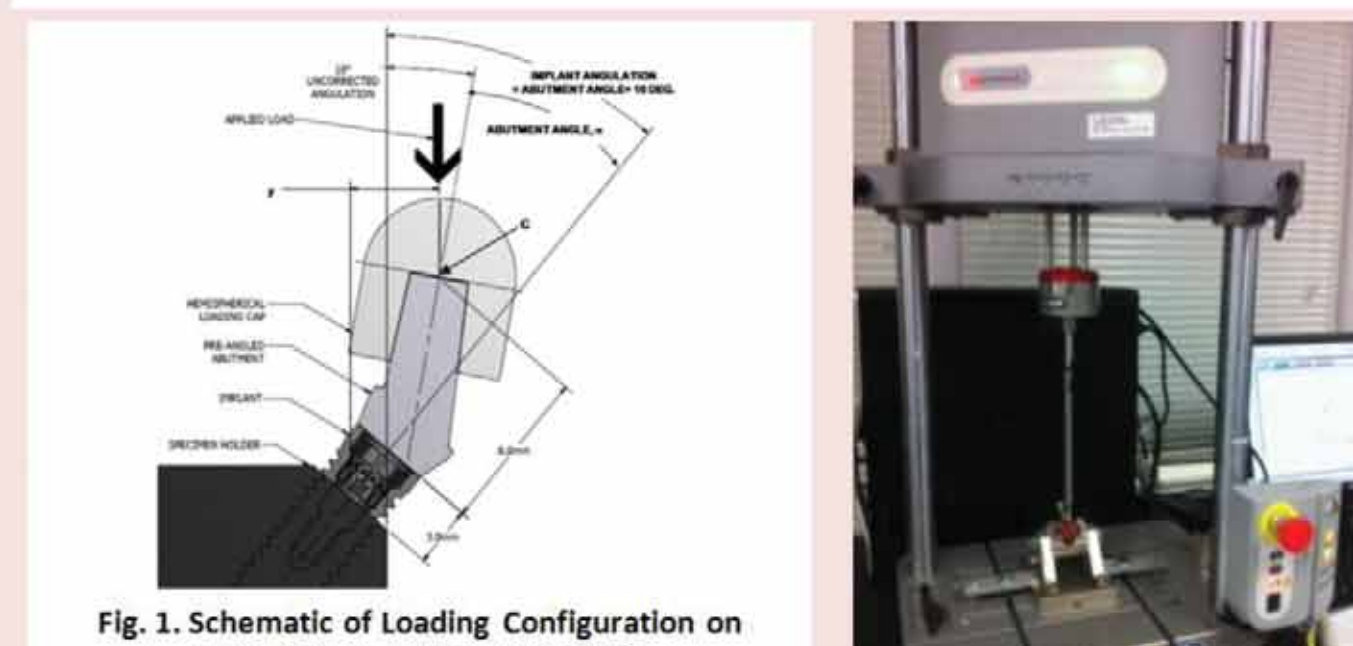
MATERIALS AND METHODS

Table 1 gives the detailed description of various components used for the implants systems testing in the study. Commercially available Replace implants (Nobel Biocare, 3.5mm D x 13.0mm L), Bone Level implants (Straumann, 3.3mm D x 13.0mm L), and Osseotite2 (BIOMET 3i, 3.25mm D x 13.0mm L), the closest possible comparative size implants, were procured and used for strength evaluation.

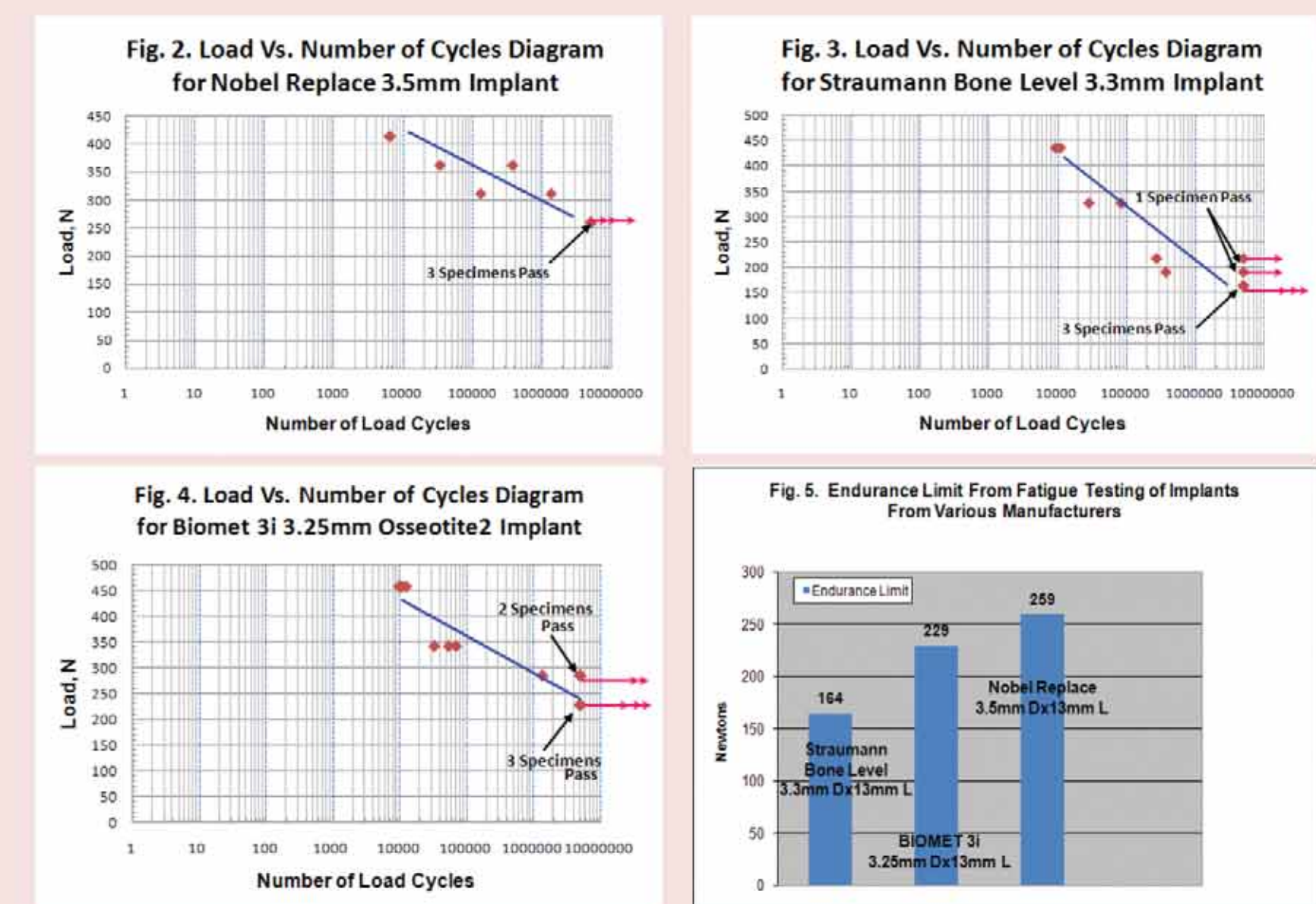
- Custom 30° angled abutments and matching screws, both made from Ti alloy, were used on Nobel Replace and Straumann Bone Level implants whereas standard Gold-Tite screws were used on Biomet 3i implants.
- All implants were mounted in phenolic resin (with elastic modulus of 17 GPa to simulate 3mm bone resorption and corresponding abutments were mounted with abutment screws torqued to recommended torque levels (35 N-Cm for both Straumann and Nobel Biocare groups and 20 N-Cm for Biomet 3i group).
- Fatigue testing was conducted to evaluate the endurance limits of the 3 implant systems per ISO 14801 methodology with loading being done at 40° to the implant axis (10° under-corrected) and at 15 Hz. Static testing was initially done to determine the starting point for fatigue testing for each group of implants.
- Instron ElectroPuls materials testing system, model E1000, calibrated to factory standards was used. The schematic of loading configuration used in testing is shown in Fig. 1 along with an image of Instron E1000 system.

Table 1. Description of the Various Components Used

Test Component	Type	Catalog No.	Lot No.	Diameter (D, mm)	Length (L, mm)	Height (H, mm)	Platform (P, mm)	Angle (Degree)	Material Used	Manufacturer
Implant	Osseotite 2	XIFNT3215	893237	3.25	13	NA	NA	NA	C.P Titanium	Biomet 3i
Abutment	Angled	30° P SP	1011548P	3.4	8	2	3.8	30	Ti-6Al-4V-ELI	Biomet 3i
Screw	NA	HUNING	861632	NA	NA	NA	NA	NA	Ti6AL4V-GOLD	Biomet 3i
Test Cap	NA	mini	P-412	NA	NA	NA	NA	NA	Ti-6Al-4V-ELI	Biomet 3i
Implant	Bone Level	31-2112	14513	3.3	12	NA	NA	NA	C.P Titanium	Straumann
Abutment	30°L/DAC SBL	EDA	1024017V	3.3	8	NA	NA	30	Ti-6Al-4V-ELI	Biomet 3i
Screw	NA	SCR SBL-1-G	75054	NA	NA	NA	NA	NA	Ti-6Al-4V-ELI	Biomet 3i
Test Cap	NA	NA	P-412	NA	NA	NA	NA	NA	Ti-6Al-4V-ELI	Biomet 3i
Implant	Replace	32213	42200, 41796, 38121, 38522	3.5	13	NA	NA	NA	C.P Titanium	Nobel Biocare
Abutment	30°L/DAC	EDA	1042601V	3.5	8	NA	NA	30	Ti-6Al-4V-ELI	Biomet 3i
Screw	LOAC	SCR NB 51	C-12215	NA	NA	NA	NA	NA	Ti-6Al-4V-ELI	Biomet 3i
Test Cap	PSP Mini	NA	NA	NA	NA	NA	NA	NA	Ti-6Al-4V-ELI	Biomet 3i



RESULTS AND DISCUSSION



Figures 2, 3 and 4 show the Load vs. Number of Cycles graphs for Nobel Replace, Straumann Bone Level, and BIOMET 3i Osseotite2 implant systems. The endurance limit is defined as the highest load that an implant system can withstand without failure (with 3 successive test specimens passing at that load) for 5 x 10⁶ cycles. For the 3 implant systems i.e. Nobel Replace, Straumann Bone Level, and BIOMET 3i Osseotite2, the endurance limits from testing were determined to be 259N, 164N, and 229N, respectively. Figure 5 shows the graphical representation of the test results.

It can be seen that the larger diameter (3.5mm) Nobel Replace implant system showed highest endurance limit among the 3 implant systems. For almost the same size implants (3.25mm vs. 3.3mm diameter), the Biomet 3i Osseotite2 implant system exhibited higher endurance fatigue strength compared to Straumann Bone Level implants system.

The literature search revealed that the 3.3mm diameter Straumann Bone Level implant system exhibited ~185N endurance limit in ISO 14801 testing⁴. Similarly, for the 3.5mm diameter Nobel Replace implant system, the published endurance limit is 197N⁵. The test data provided by these sources appears to be obtained for systems comprising straight abutment

with testing done at 30° loading angle. The present study, as explained elsewhere, has been done on systems with 30°-angled abutment and with 40° loading angle, strictly adhering to the ISO 14801 protocol. This is a potential reason for the variation in the results between the published data and the current study.

CONCLUSIONS

Fatigue testing per ISO14801 protocol on 3 different implant systems of comparable size from various manufacturers with custom 30° angled abutments and matching screws revealed the following:

- Slightly larger size Nobel Replace implant exhibited the highest endurance limit of 259N.
- BIOMET 3i Osseotite2 implant showed higher endurance limit than the comparable size Straumann Bone Level implant (229N vs. 164N).

REFERENCES

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4. Bone Level Implant Scientific Review (USLIT 302 12/09)– Straumann, 2009.
5. Nobel Replace Tapered Brochure (23119A GB0910) – Nobel Biocare, 2009.

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