

Alpha-Bio Ltd.

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1 PURPOSE

The aim of this document is to establish the procedure for fatigue testing.

2 BACKGROUND

The mechanical properties of Alpha-Bio's raw material for implants are well known and describes in ASTM F 136. In order to make sure that our manufacturing processes do not increase the risk of mechanical failure, we execute this protocol for Fatigue testing.

3 EQUIPMENT AND MATERIALS

1. Hydraulic Instron 8800R-type machine with a load cell of 1kN capacity.
2. Aluminum block slanted 10° relative to vertical for the **SPI** implant.
3. Aluminum block slanted 35° relative to vertical for the **ITO** implant.
4. SPI type implant and 25° angled abutment.
5. ITO type implant and non-angled abutment.

4 APPLICABLE DOCUMENTS

1. Guidance provided by FDA: "Class II Special Control Guidance Document: Root form Endosseous Implants and Abutments".

5 PROCEDURE

The fatigue test comprise from two separate parts; static loading and dynamic loading.

The test is performed under room condition (20°C) and for the dynamic part the conditions are 3÷15 Hz loading frequency of the Instron machine for up to 5×10^6 loading cycles (R=0.1 cycle ratio => Maximum cycle load versus Number of cycles).

The test was performed using a hydraulic Instron 8800R-type machine with a load cell of 1kN capacity. As specified in the Guidance the load will be applied to the abutment at the angle of 35° . This will ensure that the implant/abutment system is subjected to joint compressive and lateral (shear) loads of the most extreme ratio characteristic of intraoral use.

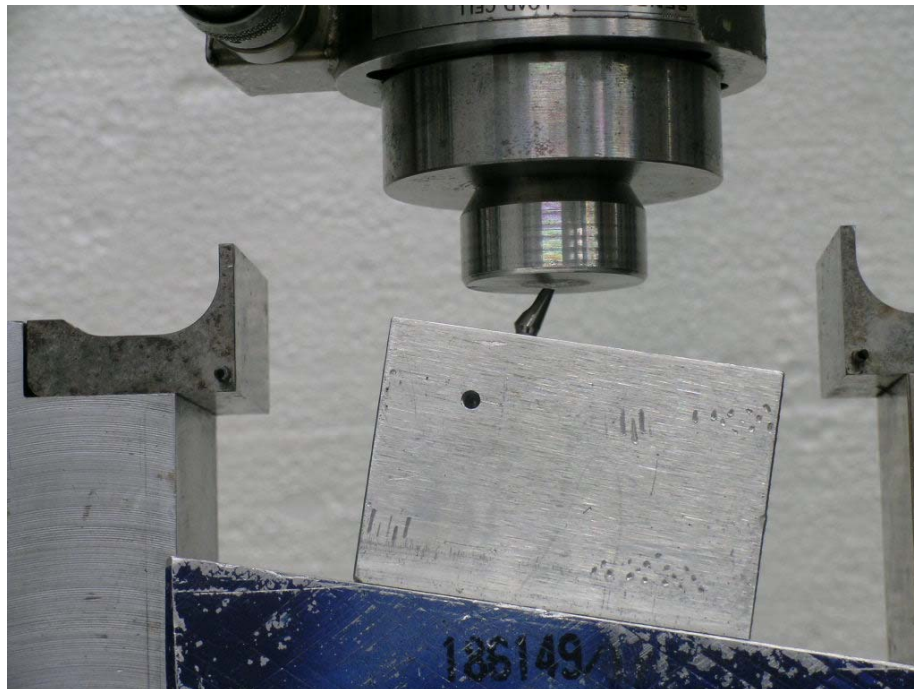
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5.1 Procedure steps

1. For the SPI implant, screw the implant into an aluminum block slanted 10° relative to vertical. The top of the implant is about 4 mm above the block surface.
2. For the ITO implant, screw the implant into an aluminum block slanted 35° relative to vertical. The top of the implant is about 4 mm above the block surface.
3. Affix the abutment to the implant by a screw (SPI) or directly with its threaded end (ITO).
4. Apply the static load to the end of the abutment vertically, so that the angle between the load direction and the abutment axis is 35° .
5. For the dynamic loading, repeat steps 1, 2 and 3.
6. Apply the fatigue loading, in room temperature conditions with the frequency of 15 Hz, on the tested sample.

5.2 Examples of properly attached tested samples



View of the SPI type implant assembly loaded at the end of the abutment.

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View of the ITO type implant assembly loaded at the end of the abutment.

6 REPORT OF RESULTS

For each implant specimen, a separate report is required.

For each original report, two signed documents (by the person who execute the procedure and by his/her supervisor) are required.

The format for the report will be as follows:

1. Cover page (date, name of the test, client name, subject of work, time of execution, signatures and titles)
2. Introduction.
3. Test procedure.
4. Test results (presented in a template and a graph: Maximum load (N) versus Number of cycles).
5. Summary and conclusions (attach relevant pictures).