



Summary of Stability Testing Performed by TRI® on the matrix® Implant System

Requirements

The requirements for the development of the **matrix**[®] abutment-free implant system was to achieve same or higher mechanical strength compared to conventional implant systems with either titanium or zirconium abutments.



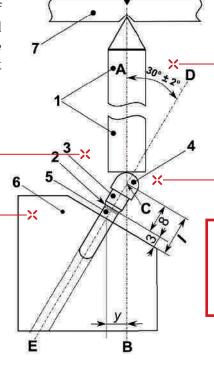
matrix[®] must be equivalent or stronger than conventional abutments.

Method

Mechanical performance testing of dental implants is strictly regulated and performed according to the standard ISO 14801:2016 under worst case conditions:

A bone-loss of 3mm is simulated to ensure worst-case loading conditions on the implant.

A patients lifetime must be simulated. This is ensured by running 5 million cycles @ 15 Hz for titanium and 2 million cycles @<= 2 Hz for zirconia.



A 30° angulation simulates worstcase loading conditions for single crowns in the molar area.

A long crown/test body must be used, creating a momentum arm of 5.5mm.

The test is passed if the specimen survives the simulated lifetime of the patient, i.e. 2 respective 5 MLN cycles.

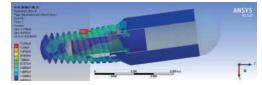
CONCLUSION

All tests prove that the **matrix**[®] implant line is on the same level or stronger than TRI[®] Classic Line with abutments. All tests were performed by independent and accredited labs according to ISO 14801:2016.



Overview of dynamic fatigue testing performed for matrix[®]:

- × Each test in table involves up to 15 implants, tested with millions of cycles each.
- X All worst case combinations between materials and indications tested.
- × Worst cases established by FEA calculations:



- × A tremendous amount dynamic and static testing has been performed.
- X Approximately 1 billion chewing cycles simulated.
- X All tests were performed according to ISO 14801:2016.

DYNAMIC 1	ESTS]		
Test ID	Implant	Abutment- Crown	Material	Screw
ID_1_BLM	BLM-37-11-P37	Abutment- Engaging	Ti	Scrw-2.25
ID_1_1_BLM	BLM-37-11-P37	Abutment- Engaging	Ti	Scrw-2.25
ID_1_2_TLM	BLM-37-11-P37	Crown	Ti	Scrw-2.25
ID_2_BLM	BLM-41-10-P37	Crown	Zr	Scrw-2.8
ID_2_1_BLM	BLM-37-11-P37	Crown	Zr	Scrw-2.8
ID_2_2_TLM	TLM-33-11-P37	Crown	Zr	Scrw-2.8
ID_2_3_BLM	BLM-37-11-P37	Crown	Zr	Scrw-2.8
ID_3_BLM	BLM-37-08-P37	Crown	Ti	Scrw-2.25
ID_3_1_BLM	BLM-37-11-P37	Crown	Ti	Scrw-2.25
ID_4_BLM	BLM-37-11-P37	Abutment- Non-Engaging	Ti	Scrw-2.25
ID_5_TLM	TLM-37-08-P37	Crown	Ti	Scrw-2.25
ID_6_TLM	TLM-41-11-P45	Crown	Zr	Scrw-2.8

STATIC TESTS

Test ID	Implant	Abutment- Crown	Material	Screw
ID_7_BLM	BLM-37-11-P37	Abutment- Engaging	Ti	Scrw-2.25
ID_8_TLM	TLM-41-11-P45	Crown	Zr	Scrw-2.8
ID_9_TLM	TLM-33-11-P37	Crown	Zr	Scrw-2.8
ID_10_BLM	BLM-37-11-P37	Crown	Zr	Scrw-2.8

Gallery

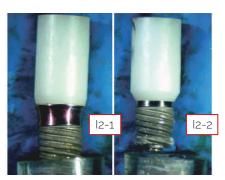


Sample I.D. BL-15 Max Load 463 N at 12.300 cycles

Fatigue Test Failure Mode -Implant crack below pot line & screw thread failure



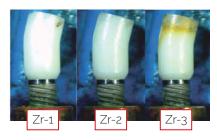
Fatigue Test Failure Mode - Implant crack below pot line



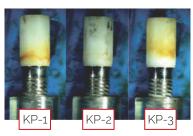
Post Fatigue - No failure at 2.000.000 cycles for sample I2-1, failure below pot line for sample I2-2 at 149.600 cycles

Failure modes in dynamic fatigue testing

These tests illustrate the mechanical stability of the matrix connection in an impressive way. The samples failed during the dynamic testing. The failure modes are related to the titanium that is equivalent to the classic implants lines including abutments. The **matrix**[®] interface were intact without damage after removal of the test body.



Post 2.000.000 Fatigue Cycles, No Failure



Post Fatigue Test -No Failure after 2.000.000 cycles

All worst case-combinations between materials and indications survived the 2 respectively 5 million cycles according to ISO 14801:2016. Implants, screws, test cylindres and the **matrix**[®] interfaces remained intact. These tests simulate a patient lifetime.