

Straumann® PURE Ceramic Implant System

A 100 % proof test ensures reliable implant strength

Ceramic implants provide a number of interesting benefits. Particularly, patient expectations for a metal-free alternative or an outstanding esthetic appearance can be fulfilled. However, the mechanical stability of ceramic implants has been questioned after mechanical failures of such implants have been documented in a few studies. Taking this issue into account, Straumann® has developed a ceramic implant with the aim to provide clinicians and patients with the peace of mind they deserve: the Straumann® PURE Ceramic Implant System, whose production process has been elevated to a new level of quality.

Before market launch, the Straumann® PURE Ceramic Implant System had to undergo rigorous mechanical tests (ISO 14 801¹ standard) in order to identify the ultimate fracture resistance and fatigue strength. According to the ISO norm 14 801, the implant-abutment system is fixed in a block with the coronal aspect of the system exposed in order to simulate a bone recession of 3 mm. A second block applies a cyclic load acting with a specific force (F) defined by the test requirements of the implant abutment system. The implant is positioned with an inclination of 30° towards the force axis with a distance of 11 mm to the embedded plane (Fig. 1). This strength test is crucial to determining the long term mechanical reliability of the completed implant treatment and restoration.

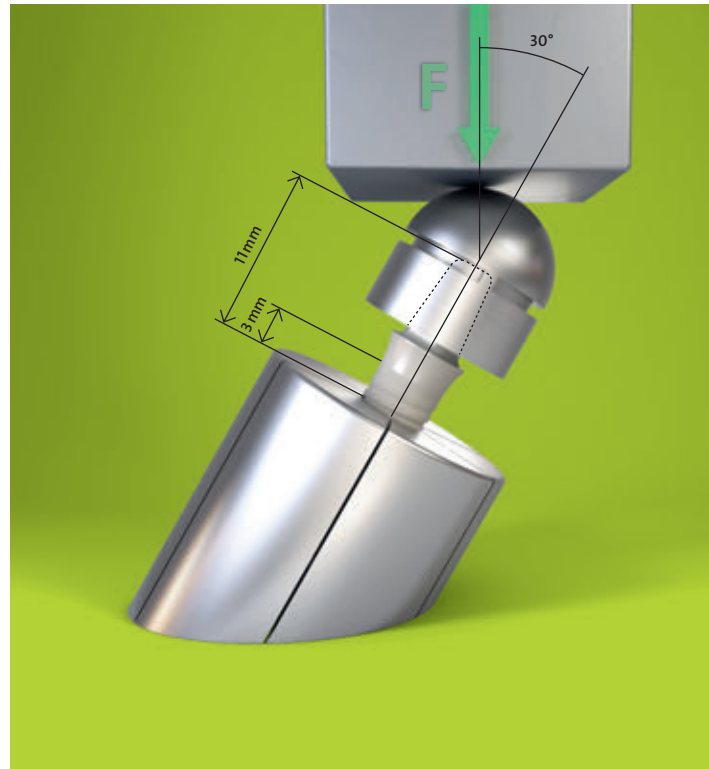


Fig. 1: Test setup according to ISO 14 801

THE STRAUMANN® PURE CERAMIC IMPLANT SYSTEM COMPARED TO THE STRAUMANN® STANDARD PLUS IMPLANT (TITANIUM)

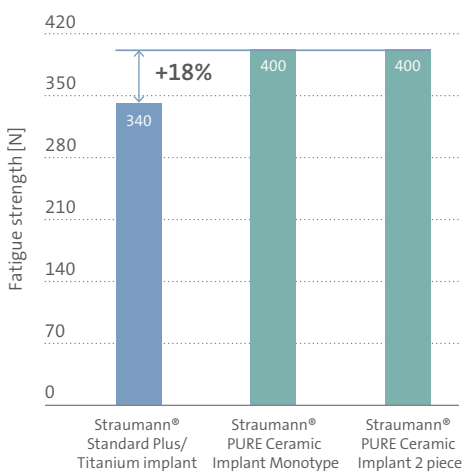


Fig. 2: Fatigue strength comparison of ceramic and titanium implants^{2,3}

The Straumann® PURE Ceramic Implant System was compared with Straumann® Standard Plus titanium implants, according to the same test setup described above. In materials science, fatigue is by definition the weakening of a material caused by repeatedly applied loads. Accordingly, this test simulates continuous chewing forces on the implant.

When measuring the fatigue strength, a fixed force is acting repeatedly on the implant-abutment system. For this specific test, two Tissue Level implants with an endosteal diameter of \varnothing 4.1 mm were selected.

The Straumann® PURE Ceramic Implant System shows a higher fatigue strength compared to a titanium implant with titanium abutment (Fig. 2).

THE STRAUMANN® PURE CERAMIC IMPLANT MONOTYPE COMPARED TO A COMPETITOR PRODUCT

Additionally, the mechanical performance of the Straumann® Pure Ceramic Implant Monotype was tested in comparison with another commercially available ceramic implant (Z-Look Evo Rapide Implant from Z-Systems), in conformity to ISO 14801¹. Beyond fatigue strength the ultimate fracture resistance was evaluated, by applying a static force on the implant which was constantly increased until a part of the system failed. While both systems show similar fatigue resistance and

hence are equally good to resist the normal mastication forces, the Straumann® PURE Ceramic Implant Monotype (Ø3.3 mm and Ø4.1 mm) significantly outperformed Z-Systems implants (Ø3.6 mm and Ø4.0 mm) in the most critical property for ceramic implants which is the resistance against forced rupture (Fig. 3). The test results show, that the reduced-diameter (Ø3.3 mm) PURE Ceramic Implant Monotype withstands higher static strength compared to the wider Z-look3 Ø3.6 mm implant, even though it has a smaller diameter.

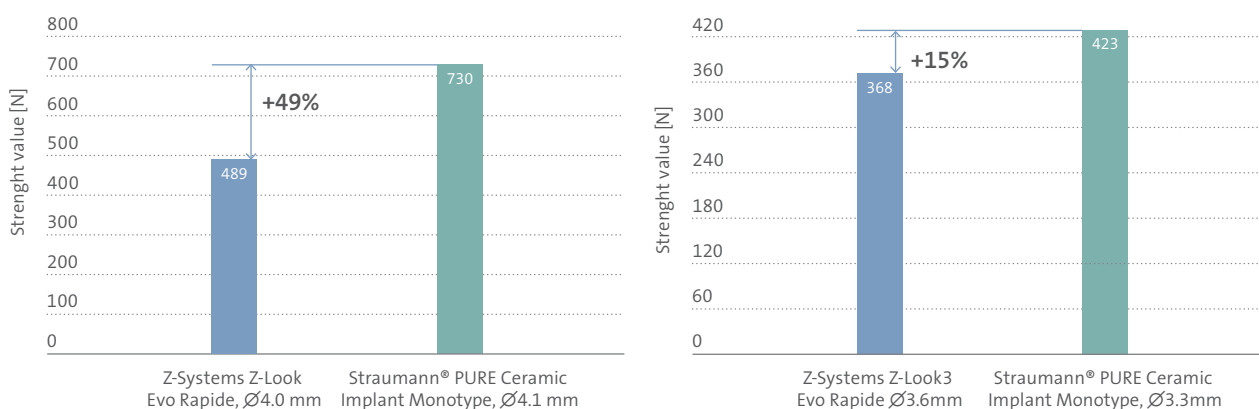


Fig. 3: Ultimate fracture resistance

STRAUMANN® PURE CERAMIC IMPLANT SYSTEM 100% PROOF TESTED

Every single Straumann® PURE Ceramic implant has to undergo a proof test before it leaves the Straumann® production facility. During this mechanical quality test procedure according to ISO 14801 setup, the implant is additionally rotated at least once 360° around its axis to test the implant in all directions. During this rotation a load is applied that assures that surviving implants are qualified for delivery to the customer.

Ceramic implants from Straumann® are designed to support loads above what is expected in actual use, demonstrating safety and exceptional design integrity. The Straumann® PURE Ceramic implant System 100% proof test is a unique process in the history of dental implant production and ensures an unprecedented level of quality assurance and ultimate safety.



References

- 1 ISO Standard 14 801:2007 2 Data on file (internal data) 3 Data on file (comparison test)

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