

## SPINAL IMPLANT

### MECHANICAL STRENGTH

The testing of spinal implants is up to now unsufficiently treated in standardized test procedures. Only one procedure for the determination of the mechanical properties of an internal fixateur is described (ASTM PS5-94). At the present standards comitees of DIN/EN, ISO and ASTM are working on drafts whose status is not yet official.

EndoLab GmbH classifies the testing of spinal implants as following:

- single components of modular implants
- connection elements of modular implants
- total assembly of modular implants
- arthrodesis implants

To test single components, in general mechanically simple material test procedures such as three-point bending of rods are used.

Connection elements of modular components are statically tested with regard to the achieved clamping strength (see fig.1). After a defined assembly of two components the axial peel strength or the torsional strength under a quasi-static load is determined.

In particular cases dynamic test procedures are performed to determine the clamping effects after dynamic loading or to examine the wear behavior of the clamping.

In general dynamic tests of totally assembled implants are performed under 'worst-case' loading conditions. Herein the bridging of a vertebra without any support is simulated (see fig.2). Two blocks made of UHMWPE serve as a vertebra replacement. Here the assembly of the fixation screws is important: The standardized method prescribes just a fixed constraint over the whole length. Clinical failure cases, however, show that the screw itself can be the weak point of the system. This can be avoided by a special shaping of the screw's borehole which reduces the support of the simulated vertebra clearly.

In general the dynamic load is applied with a frequency of 10 Hz up to 5 million cycles. Often the testing frequency is limited by the flexibility of the whole system and the power of the testing machine. The majority of the tests is performed in air at room temperature. According to the system a test in Ringer's solution can be indicated. Beside the pure axial compression test an additional torsional loading can be applied. As an increased test condition especially the quality of the connection elements is tested.

The testing of arthrodesis implants is performed analogous to the mentioned criteria. Two special adaptors made of polyacetal serve as an abutment. The shaping of these pieces is made according to the clinically planned preparation of the bone. EndoLab uses quasistatic and dynamic test procedures. Beside the pure axial loading condition torsion and/or bending are superposed. Due to a higher stiffness of the setup the test frequencies can usually be higher than for internal fixateurs.

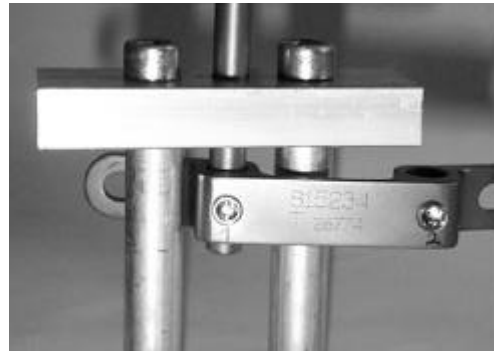


Fig.1: Determination of the clamping strength for a modular connection.



Fig.2: Test setup for the determination of the mechanical strength of an internal fixator.

#### Data:

complexity:	medium
test medium:	air at room temperature or Ringer's solution at 37°C
number of spec.:	5 static / 3 dynamic
cycles:	5 Mio.
additional evaluation:	SEM

#### Literature:

Please contact Endolab GmbH

#### Links:

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[www.spine.org](http://www.spine.org)  
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