Normative reference:

PI-17 (certified procedure):
Implants for surgery - Partial and total knee joint prostheses -
Determination of contact conditions.

KNEE ENDOPROSTHESES

CONTACT PRESSURE

Beside the quality of the materials and surfaces used, the contact area between the femoral and tibial component plays an important role for the wear characteristic of knee endoprostheses.

A total contact area of 50-150 mm² can be assumed for most of the commonly used implant types. Assuming a yield stress of 20-25 MPa a transferable force of 1.00-3.75 kN can be calculated. Considering the in vivo loads of 2.25-4.0 kN even during normal walking the yield stress is locally exceeded. Different activities such as stair climbing produce even higher loads at mostly unfavourable flexion angles.

Beside the magnitude of the contact area, the distribution of the resulting compressive stresses has also a great influence on the expected wear. Additionally the mentioned mechanical parameters are variable regarding the flexion angle of the implant.

For the determination of the distribution pattern of compressive stresses pressure films can be used. Usually two pressure films are necessary: One film ('A-film') contains a red coloring agent which is enclosed in microscopic small plastic balls and released under defined pressure conditions. The second film ('C-film') develops and preserves the coloragent.

First the information about the stress magnitude is indicated by different color intensity. To convert the intensity into mechanical quantities a calibration is necessary. Due to a higher accuracy of meassurement, our lab performs a separate calibration immediately before the test: Different contact pressures (mostly n=10) are applied and analysed under defined loading conditions. The resulting calibration curve in general shows considerable deviations compared to informations provided by the producer.
Usually the implant is loaded under 0°, 60° and 90° flexion angle at load levels of 2.9, 3.3 and 3.6 kN. To take viscoelastic effects of the plastic material into account, the load is applied using a defined test speed and hold-time.

For the determination of the magnitude of the contact area and the distribution of the contact pressure two types of films with different response are used. Using the finer 'super low' film the real contact areas can be determined more accurately.

For the analysis and the representation of the results the generated impressions are scanned and converted into off-colors. Using a special software the different stress levels can be separated and the corresponding area is determined (see fig. 2). These informations are important especially for stresses above the yield stress of the material.

As a standard three flexion angles with the corresponding loads are tested. Due to plastic and viscoelastic effects, for every test new plastic components are required.

If desired the scaling of the stress is represented according a guideline of the customer.

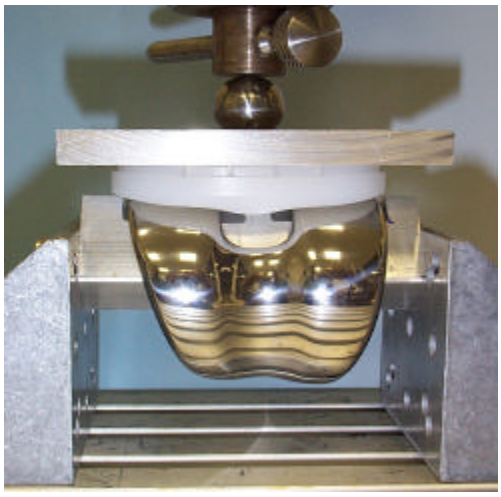

Fig. 1: Test setup for the determination of the contact pressure of a knee joint implant.

Fig. 2: Representaion of the contact area before the conversion into off-colors.

Data:

complexity:	medium
test medium:	air at room temperature
number of spec.:	1 per load case
cycles:	1-10
additional test procedures:	none

Literature:

Please contact Endolab GmbH

Links:

www.endolab.de
www.iso.ch