

# Design, calibration and pre-clinical testing of an instrumented tibial tray

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## Abstract

An instrumented tibial tray was developed that enables the measurement of six load components in a total knee arthroplasty (TKA). The design is fully compatible with a commonly available knee arthroplasty product since it uses the original tibial insert and femoral component. Two plates with hollow stems made from titanium alloy are separated by a small gap. Six semiconductor strain gages are used for measuring the load-dependent deformation of the inner hollow stem. A 9-channel telemetry unit with a radio-frequency transmitter is encapsulated hermetically in the cavity of the prosthesis. The telemetry is powered inductively and strain gage signals are transmitted via a small antenna at the tip of the implant. The mean sampling rate is 125 Hz. The calibration of the prosthesis resulted in an accuracy better than 2% mean measuring error. Fatigue testing of the implant was performed up to 10 million loading cycles and showed no failure. The pending in vivo application will give further insight into the kinetics of TKA. The measured values will enhance the quality of future pre-clinical testing, numerical modeling in knee biomechanics and the patients' physiotherapy and rehabilitation. © 2007 Elsevier Ltd. All rights reserved.

*Keywords:* Knee joint; Total knee arthroplasty; Load; Measurement; Telemetry

## 1. Introduction

Knowledge of in vivo loads in total joint replacement (TJR) is required for a variety of reasons. Post-operative rehabilitation depends strongly on the physiotherapy. Partial loading for the first post-operative weeks is normally recommended after joint replacement surgery. However, the amount of true loading during patients' exercises remains speculative.

Pre-clinical testing of TJR components with materials testing systems and simulators needs information about the kinematics and kinetics to deliver realistic results. Numerical biomechanical modeling, such as finite element analyses (FEA) of bone remodeling, relies on kinetic input data. Predictions from these models can only be as accurate as the input variables.

Gait analysis and inverse dynamics are the most common methods for calculating joint forces during human movement. However, results show high variations

between different studies (Morrison, 1970; Seireg and Arvikar, 1975).

Data from instrumented hip prostheses and spinal fixators have been available for many years and give realistic information about the loading of these implants in vivo (Bergmann et al., 2001a; Rohlmann et al., 1994). These data support some of the theoretical analyses performed, but new and unexpected knowledge have also been obtained using these instrumented implants (Bergmann et al., 2004).

Efforts have also been undertaken to obtain in vivo measurements in the area of total knee arthroplasty (TKA). The first implantable device for TKA was an instrumented massive distal femoral replacement for patients suffering from cancer (Taylor and Walker, 2001). Strain gages were located approx. 20 cm proximal from the knee joint line. A mathematical approach was still necessary to get the loading data at the joint line level. Furthermore, excision of single muscles or changing muscle insertions altered the normal gait pattern in these patients.

An attempt to instrument a tibial baseplate was published by Kaufman et al. (1996). The design consisted of two baseplates separated by four posts, which enabled

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the measurement of the vertical force component only. The final version of this device was implanted in one patient (D’Lima et al., 2005).

A different approach for measuring all six load components in a TKA was presented by Singerman et al. (1999). However, only *in vitro* measurements were reported. Kirking et al. (2006) more recently showed a design for an instrumented tibial tray using the same design principle.

At this stage the knowledge of *in vivo* knee loading is still not sufficient to answer the named questions. As the number of total knee replacements is steadily increasing, the importance of this research will become even more relevant. The goal of this study therefore was to develop and test an instrumented tibial tray for *in vivo* applications measuring six load components using a primary TKR design. Testing includes the determination of the measuring accuracy after calibration and the fatigue resistance of the device.

## 2. Methods

### 2.1. Design

The instrumented tibial tray (Figs. 1 and 2) consists of two plates separated by a small gap. The hollow, concentric stems of both trays are electron beam welded distally. The proximal plate carries the snaplock mechanism for the tibial insert, whereas the distal plate is cemented onto the resected tibia. It is a cruciate substituting design, fully compatible with a proven TKA system (INNEX, Zimmer GmbH, Winterthur, Switzerland). Therefore standard ultracongruent tibial inserts, femoral components and instruments are used in combination with the instrumented baseplate.

All electronics and strain gages are housed in the cavity of the inner stem, which is closed by a lid that is also electron beam welded. A feedthrough from pacemakers (Biotronik, Germany) is laser welded into the lid. Two leads from the telemetry unit are soldered to pins passing the feedthrough. These pins are hermetically sealed to the titanium base material by means of a ceramic substrate and gold soldering. Six semiconductor strain gages (KSP 1-350-E4, Kyowa, Japan) are glued to

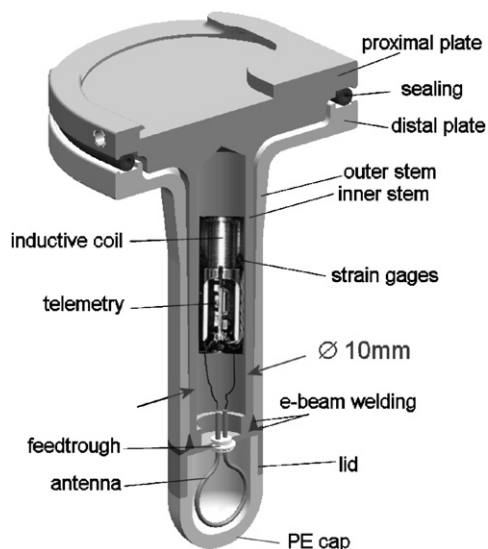


Fig. 1. Section through the instrumented tibial tray.

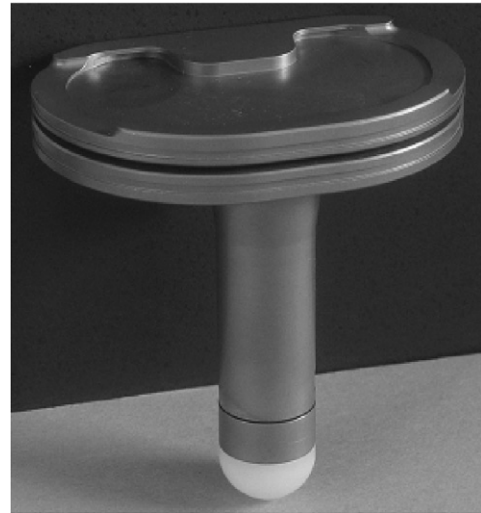


Fig. 2. Instrumented tibial tray. The proximal and distal plates are separated by a small gap; the UHMWPE cap is seen in white on the bottom of the implant.

the inner wall of the stem and measure the load-dependent strains. The strain gages are connected to a custom-made telemetry unit, which is powered remotely by an external coil. Strain gage signals are transmitted using an antenna made of niobium wire. An ultra-high molecular weight polyethylene (UHMWPE) or polyetheretherketone (PEEK) cap protects the antenna against mechanical damage.

A plastic sealing is incorporated along the circumference of the tray to avoid ingrowth of connective tissue. If ingrowth occurs the load will not pass exclusively through the stem, but also via the connective tissue. This may lead to an indefinitely high measuring error (Heinlein et al., 2006).

### 2.2. Electronics

A new generation of a custom-made telemetry transmitter (Graichen et al., *in press*) already used in hip, spine and shoulder implants was inserted into the cavity of the instrumented tibial tray. Power is supplied inductively at a low frequency of about 4kHz through the titanium implant to the coil inside the implant. Via an AC/DC converter the telemetry transmitter is supplied with the required power. The main part of the telemetry transmitter is the 9-channel telemetry chip, designed in 0.8  $\mu\text{m}$  BiCMOS technology. It has a current consumption of 1 mA for the required DC voltage between 4 and 6 V. The die area is  $2.0 \times 2.6 \text{ mm}^2$  and has 35 connection pads for wire bonding. It contains more than 7000 devices. The chip has a programming capability (Zener PROM) to optimize the function for strain gage applications.

Six input channels (1–6) serve for direct connections of semiconductor strain gages with nominal values of  $350 \Omega$ . Channel 7 is designed for a NTC sensor and used for chip temperature measurement. Channel 8 measures the DC voltage to control the inductive power supply and channel 9 is constant for synchronization at the receiver side. All input signals are multiplexed and pulse interval modulated (PIM). Variations of sensor resistances due to tolerances of the nominal values ( $\pm 10\%$ ) or initial strain after the application process are compensated by programming the Zener PROM.

The sensor values are fairly linearly transferred into time intervals from about  $300 \mu\text{s}$  ( $R = 300 \Omega$  or  $T = 46^\circ\text{C}$ ) to  $1600 \mu\text{s}$  ( $R = 400 \Omega$  or  $T = 20^\circ\text{C}$ ). Channel 9 has a time interval of  $150 \mu\text{s}$  and the pulse duration is  $10 \mu\text{s}$ . This results in a mean sampling rate of 125 Hz. The partly integrated radio-frequency oscillator is switched on only during the pulse, which results in a low power consumption of 5 mW. The transmitter frequency depends on the values of an external resonant circuit and is designed for the VHF band. Only a few additional passive components are

needed and connected to the integrated circuit on both sides of a thick-film hybrid circuit. The complete telemetry transmitter measures only  $6 \times 9.5$  mm.

All external components are built in a 19 in case (TELEPORT). The power oscillator is controlled by a microcontroller (ATmega8, AVR) to keep the induced voltage at a constant level. The frequency of the magnetic field is automatically tuned to the resonance frequency of the external power coil in series with a capacitor. An active antenna, placed close to the implant, receives the radio-frequency pulses. The receiver demodulates the signal and the microcontroller synchronizes the channels. Via an USB port all data are transferred to a personal computer for online display.

### 2.3. Calibration

The instrumented tibial tray can be mechanically regarded as a transmitter of six load components (three forces and three moments) from the femur to the tibia. The forces are the medio-lateral ( $F_{ML}$ ), antero-posterior ( $F_{AP}$ ) and axial compressive ( $F_{axial}$ ) forces, whereas the moments are the flexion–extension ( $M_{flex/ex}$ ), varus–valgus ( $M_{var/val}$ ) and internal–external ( $M_{int/ext}$ ) moment along the tibial axis, respectively. Therefore, a minimum of six strain gages is necessary and sufficient. The calibration is performed using the matrix method (Bergmann et al., 1993; Rohlmann et al., 1994). The load vector  $\underline{L}$  consists of the applied loads  $\underline{L} = (F_{ML}, F_{AP}, F_{axial}, M_{flex/ex}, M_{var/val}, M_{int/ext})$ . The six strain gage signals  $S_i$  are measured and the measuring matrix  $\underline{M}$  is computed according to  $\underline{L} = \underline{M} * \underline{S}$ . The matrix  $\underline{M}$  gives the relationship between the strain gage signals and the loads.

For calibration, a custom-made uniaxial materials testing system with a load cell (U2B, HBM, Germany) having an accuracy classification of 0.1% is used. The prosthesis is fixed in a clamping block and a calibration block is attached to the proximal plate to avoid damage to the prosthesis. Loads are applied at 21 points via stainless steel balls to avoid unknown shear forces (Fig. 3).

The example shown in Fig. 3 creates a load vector  $\underline{L}$  according to Eq. (1) with  $F$  being the externally applied force,  $l_{x,y,z}$  the corresponding

lever arms in the  $x$ -,  $y$ - and  $z$ -directions and  $\alpha$  the inclination of the clamping block, respectively. Due to the orientation of the prosthesis at this loading point the component  $F_{ML}$  is zero. The locations of the load application points are chosen in a way to cover the expected loading area in a TKA:

$$\underline{L} = \begin{pmatrix} 0 \\ F * \sin \alpha \\ -F * \cos \alpha \\ -F * (l_y * \cos \alpha - l_z * \sin \alpha) \\ -F * l_x * \cos \alpha \\ F * l_x * \sin \alpha \end{pmatrix}. \quad (1)$$

To accommodate changes in temperature and power level the implant is calibrated at three different temperatures ( $33 \pm 2^\circ\text{C}$ ) and three different power levels. During measurements the signals are then mathematically temperature and power compensated. The load is applied in 21 different locations on the calibration plate, resulting in 21 combinations of up to six load components for every temperature and power condition.

The signals of the prosthesis are collected using a custom-made receiver and are transferred via USB to a PC together with the signals from the load cell to allow for matrix calculation. After calibration, accuracy tests on various application points are performed to compare the applied and measured loads.

### 2.4. Pre-clinical testing

The instrumented tibial baseplate must fulfill the same safety criteria as a conventional product. For fatigue testing of metal tibial trays two standards exist: ISO 14879-1, and ASTM F1800-04. However, no loads are specified within these documents. There is only secondary literature available on this purpose, where unicondylar loads of 500 or 900 N are recommended for fatigue testing (Ahir et al., 1999; Yu et al., 2006). We consider these loads to be too low to evaluate the special design features of the instrumented tibial tray.

Fatigue testing therefore was performed (Fig. 4) according to the so-called “physiological tibia test” (Heinlein et al., 1999). For the support

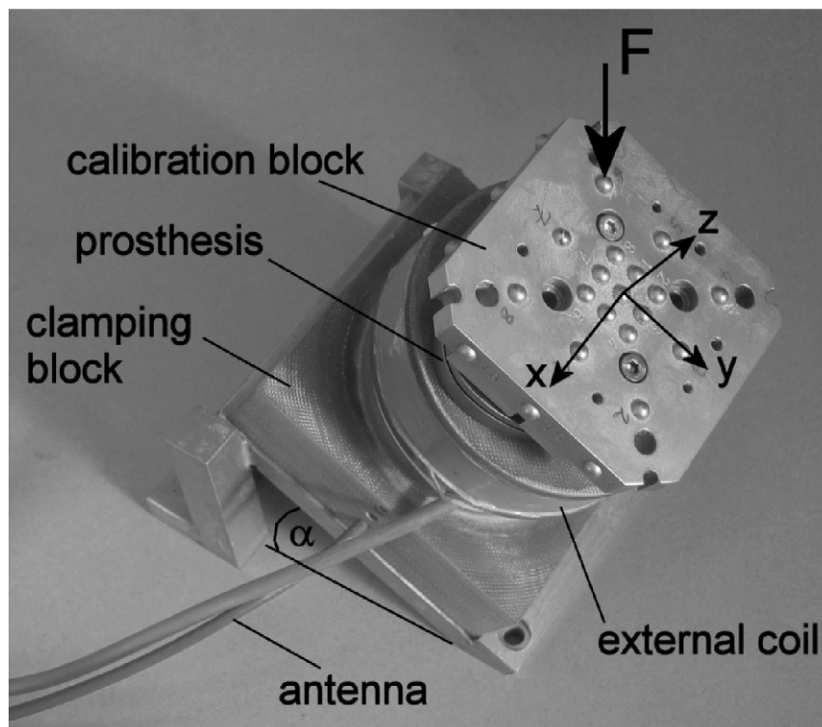


Fig. 3. Calibration setup. The prosthesis is fixed in a clamping block; the calibration block is attached to the proximal plate of the prosthesis and loaded at 21 points using a materials testing system. The load is applied via stainless steel balls to avoid shear forces.

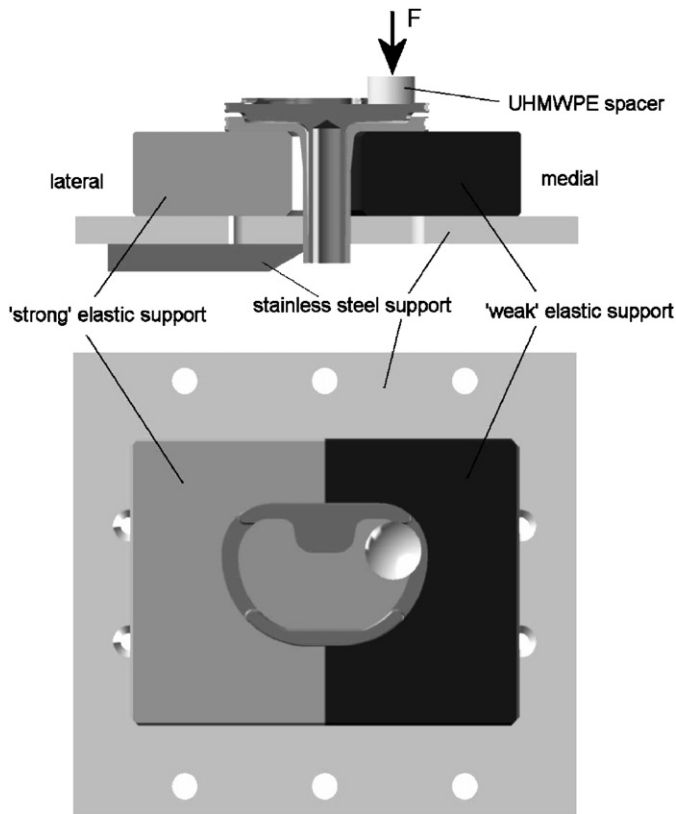


Fig. 4. “Physiological tibia test”: the medial side of the implant is supported by a weaker polyurethane block than the lateral side, to simulate a collapse of the bony structure medially; the stem is blocked in the lateral direction leading to additional stress in the radius between the stem and the inferior side of the distal plate.

of the tibial tray, two polyurethane blocks with different stiffnesses are used to simulate the medial tilting of the tibial tray as has been reported in TKR patients (Moreland, 1988). Additionally, the stem of the implant is fixed in the lateral direction, to simulate cortical contact. In this condition a worst-case scenario is created, which stresses both the proximal plate medially as well as the distal plate in the radius between the stem and the inferior side. Testing is performed on a servo-hydraulic machine, running at a frequency of 6 Hz over 10 million cycles with a sinusoidal load of  $\Delta F = 4000$  N ( $F_{\min} = 444$  N,  $F_{\max} = 4444$  N,  $R = 0.1$ ), applied solely on the medial side. The test arrangement is embedded in Ringer’s solution at 37 °C to simulate the physiological environment. To find out at which load value the proximal and distal plates come into contact, the force–displacement curves of the load applicator are analyzed (Fig. 5). A clear rise in the slope of this curve is expected, as the stiffness of the tested implant changes dramatically if the gap closes.

### 3. Results

#### 3.1. Design

An instrumented tibial tray was developed (Fig. 1) that is only slightly changed compared to the original clinically used model. The metal tray thickness is increased by 5 mm, which is compensated for by using thin tibial inserts in surgical cases where normally thick tibial inserts would be necessary. The design is intended for the use of an

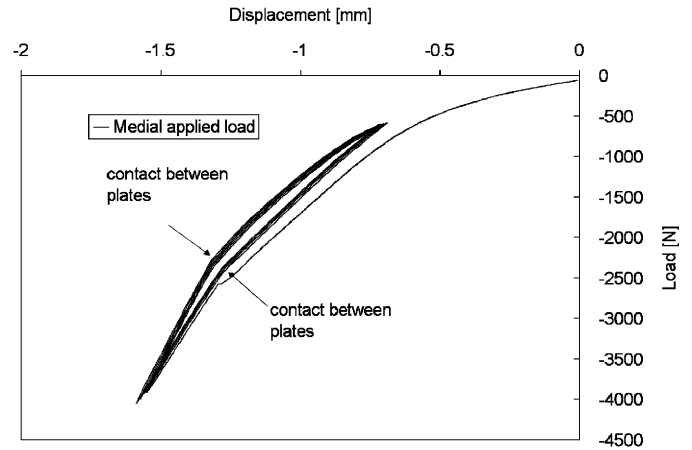


Fig. 5. Load–displacement curve from fatigue testing; the arrows indicate the point of contact between the proximal and distal plate.

ultracongruent insert, where the posterior cruciate ligament is resected, which is a routine procedure. The antero-posterior and medio-lateral widths of the implant are 74 and 50 mm, respectively, corresponding to a mid-size tibial tray.

#### 3.2. Calibration

The instrumented tibial baseplate has a mean measurement error below 2% full-scale output. The individual values for each load component can be seen in Table 1. The applied loads are 750, 650 and 2000 N for the forces and 14, 13 and 8 Nm for the moments, respectively. The comparison between the applied and measured loads for one sample load case is illustrated in Fig. 6. The vertical load from the materials testing system is applied to the prosthesis, which is oriented inclined relative to the load applicator. This results in the simultaneous application of five out of six possible load components, namely  $F_{AP}$ ,  $F_{axial}$ ,  $M_{flex/ex}$ ,  $M_{var/val}$  and  $M_{int/ext}$ . The coefficient of correlation is better than 99.6% for all applied load components.

#### 3.3. Pre-clinical testing

The first prototype of an instrumented tibial baseplate failed during fatigue testing due to a fracture of the distal plate. Therefore, the geometry was changed leading to a higher nominal resistance, which was calculated by means of FEA.

The optimized prosthesis successfully passed the fatigue testing over 10 million cycles with a maximum load of 4444 N without any adverse effects. The load–displacement curve shows that the two plates come into contact between 2300 and 2400 N (Fig. 5) if a unicondylar load is applied. Up to this value the whole load is borne by the stem and the welding.

Table 1  
Error values in (% full scale output) and applied loads for the instrumented tibial tray

	$F_{ML}$	$F_{AP}$	$F_{axial}$	$M_{flex/ex}$	$M_{var/val}$	$M_{int/ext}$
Mean (%)	1.7	1.1	1.5	1.0	0.6	1.2
Max (%)	4.4	2.8	3.1	2.4	1.1	3.4
Applied loads (N, N m)	750	650	2000	13.7	12.6	7.7

The mean error is below 2%.

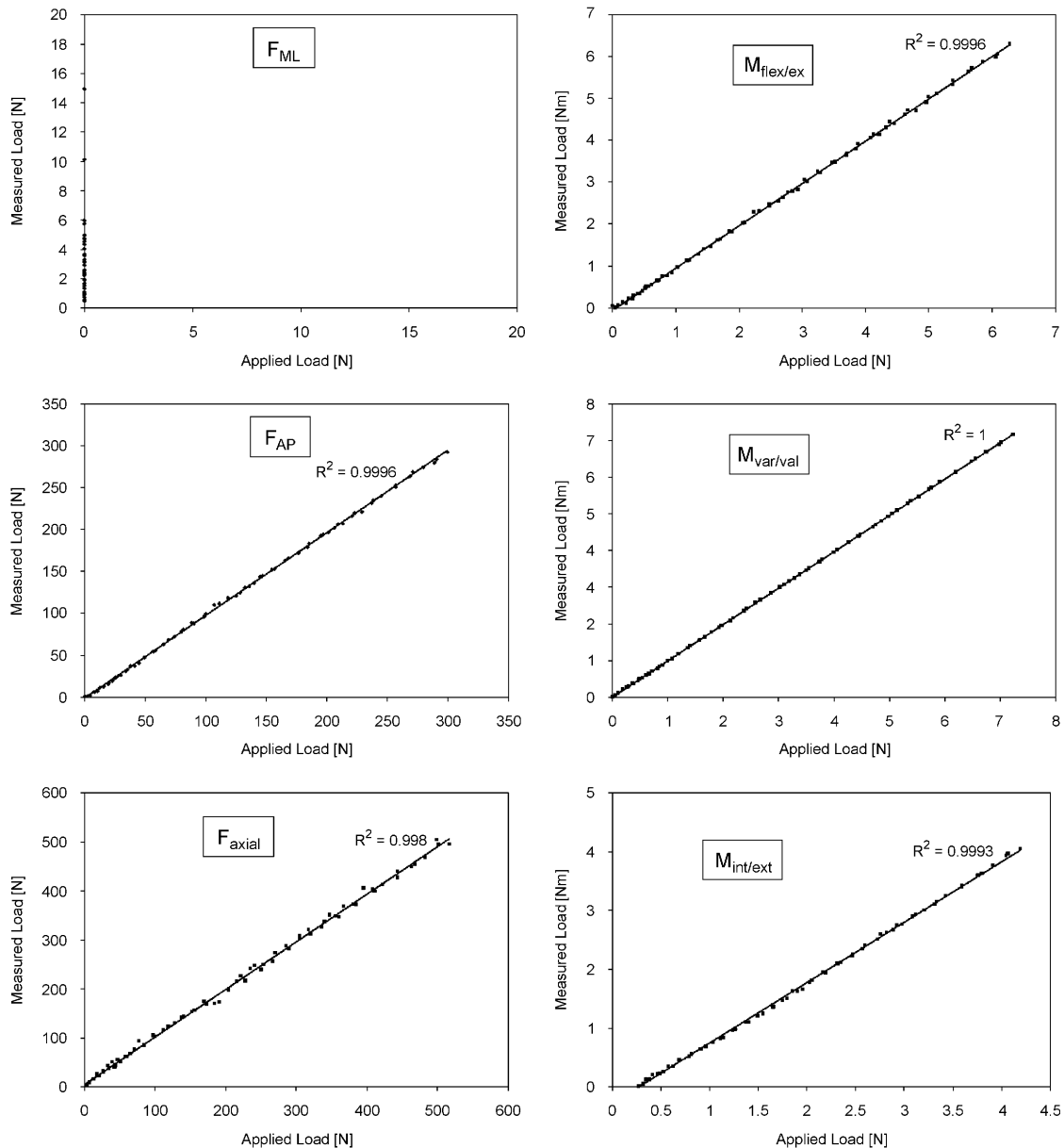


Fig. 6. Sample comparison between applied and measured loads during multiaxial loading. In this configuration five out of six possible loading components were acting simultaneously. The medio-lateral shear force  $F_{ML}$  was not acting.

If contact occurs, the load is transmitted through the distal plate and the stem is protected from overloading. Testing according to ISO and ASTM protocols with a load of 900 N as recommended is not appropriate for this special design, as it does not close the gap.

#### 4. Discussion

The design of this instrumented prosthesis is capable of measuring axial compressive forces in the range of approx. 3 times body weight during unicondylar loading. Clinically this is the case during condylar lift-off (Dennis et al., 2001).

If the medio-lateral compressive force distribution is more symmetrical and the resultant force more central, the measuring range is approx. 2 times higher. Both the medio-lateral and antero-posterior shear forces can be up to approx. 1 times body weight. At higher loads the two plates come into contact and the loads bypass the stem. This is a safety mechanism, as the dimensions of a typical TKA do not allow unlimited deformation of the stem. Higher values, if necessary, could be measured by changing the stem length and diameter. However, in vivo measurements of knee joint forces are scarcely available and the certainty of the chosen measurement range will remain unclear until the first in vivo measurements are performed. Furthermore, there will be large intraindividual variations between patients, e.g. the patient weight and activity level.

Taylor and Walker (2001) reported compressive forces up to 2.5 times body weight and AP shear forces of 0.5 times body weight in a massive distal femoral replacement. D'Lima et al. (2005) reported up to 3 times body weight compressive forces during level walking using an instrumented tibial tray. This is in good agreement with the results from Morrison (1970), who calculated 2.7 times body weight during gait analysis. However, there are also reports that show much higher force values, e.g. Seireg and Arvikar (1975) found 6.7 times body weight for compressive forces and 2.5 times body weight for shear forces. Better knowledge of especially the shear forces acting in the knee joint may increase the possibilities of developing new and innovative TKR designs.

Numerous analytical models of TKR are available predicting kinematics, kinetics, UHMWPE wear and many more parameters. Validation of such models is strongly dependent on in vivo measurements. Since the introduction of video fluoroscopy, aspects of kinematic behavior of TKR in vivo are widely known now (Banks and Hodge, 2004; Dennis et al., 2003). However, kinetic data has yet to be obtained to the same degree. The results from D'Lima et al. (2005) and Taylor and Walker (2001) give a first estimate of expected loading in TKR to some degree, but have to be enhanced using different types of prosthesis and more patients.

Besides the load measurements the presented design of an instrumented tibial baseplate is also capable of measuring the temperature inside the prosthesis. The effect of different activities such as walking and cycling on the temperature in TJR was investigated using instrumented hip implants (Bergmann et al., 2001b). It was found that the peak temperature rose to about 43 °C after 1 h of walking.

Pritchett (2006) used temperature sensors placed percutaneously in volunteers undergoing TKR. He found an increase in temperature of up to 9 °C, a result confirming the observations in the hip prostheses. Also interesting in this study is the finding that the baseline temperature before activities in healthy knees was only 31 °C and in TKR between 32 and 35 °C, respectively. Normally, simulator studies (Walker et al., 2000) and materials testing

especially on UHMWPE are conducted at 37 °C (Kurtz et al., 2002; Ries and Pruitt, 2005). According to Ries and Pruitt (2005), the Young's modulus decreases from 833 MPa at 20 °C to 648 MPa at 37 °C. Lower temperatures would result in an increase in the Young's modulus and therefore a decrease in strains in the UHMWPE components, which would be favorable.

It will be interesting to see if the in vivo application of our prosthesis confirms the previously found results. Cadaver tests already show a trouble-free handling of the prosthesis and smooth data transmission under realistic conditions.

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