

An instrumented implant for *in vivo* measurement of contact forces and contact moments in the shoulder joint

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Abstract

To improve implant design, fixation and preclinical testing, implant manufacturers depend on realistic data of loads acting on the shoulder joint. Furthermore, these data can help to optimize physiotherapeutic treatment and to advise patients in their everyday living conditions. Calculated shoulder joint loads vary extremely among different authors [Anglin C, Wyss UP, Pichora DR. Glenohumeral contact forces. *Proc Inst Mech Eng [H]* 2000;214:637–44]. Additionally the moments acting in the joint caused by friction or incongruent articular surfaces, for example, are not implemented in most models.

An instrumented shoulder joint implant was developed to measure the contact forces and the contact moments acting in the glenohumeral joint. This article provides a detailed description of the implant, containing a nine-channel telemetry unit, six load sensors and an inductive power supply, all hermetically sealed inside the implant. The instrumented implant is based on a clinically proven BIOMET Biomodular shoulder replacement and was calibrated before implantation by using complex mathematical calculation routines in order to achieve an average measuring precision of approximately 2%.

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1. Introduction

The replacement of the humeral head subsequent to fractures, in cases of rheumatoid arthritis or arthrosis is a well-established surgical procedure, while the fixation of the glenoid component in the scapula has still been faced by unsolved problems [2]. Better knowledge of the loads acting in the glenohumeral joint is required to improve implant fixation and design, to help the patients not overload the endoprosthesis, and to influence physiotherapy of the shoulder joint in general. Furthermore, mechanical tests of new implants could be standardized when enough data are available to define average and maximum load profiles.

Data of the loads in the glenohumeral joint are calculated until now by simplified two or three-dimensional models [3,4] or measurements *ex vivo* [5,6]. Especially for complex movements, the results of these studies vary widely. This is caused mainly by simplifications of the complex structure of the joint with its high number of muscles and tendons involved, as well as by the co-acting joints of the shoulder girdle and any unknown muscle recruitment principles. These uncertainties are propagated if loads from calculated models are used as an input for finite element models [7].

If the contact forces in the joint can be measured with high accuracy, such data can be used as a ‘gold standard’ to validate the analytical models. Such validations were previously performed by Heller et al. [8] and Stansfield [9] for the lower extremities, using hip implant data from Bergmann [8,10].

Another important use of *in vivo* joint contact loads is the preclinical testing of new implants or fixation technologies with forces and moments of realistic values and directions.

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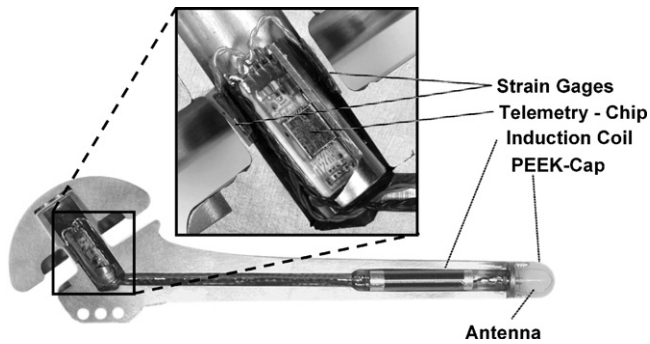


Fig. 1. Instrumented shoulder implant. Cross-section showing the internal induction coil, the antenna at the tip of the stem and the telemetry unit in the hollow neck.

The aim of this study is to describe the technical basis of an instrumented shoulder implant, developed to measure three force and three moment components which act on the humeral head.

2. Material and methods

2.1. Requirements for implant instrumentation

An instrumented, load-measuring implant must provide the following features:

- The safety of the patient must be guaranteed, requiring the same mechanical stability as a standard implant plus wireless power and data transmission.
- Required modification of the standard implant should not affect its function or the surgical procedure.
- The non-biocompatible electronics, consisting of load sensors, electronics and power supply, must be small enough to be placed inside the implant and must be hermetically sealed.
- All six load components, three forces and three moments, should be measured with good accuracy.
- The load sensors must be placed in an area of the implant where the complete load is transferred.
- The implant must be so stiff that its deformation under load does not influence the measured load components.

2.2. Implant design

To achieve these goals, the clinically proven Biomodular shoulder implant (Biomet Deutschland GmbH) was modified to house six strain gages, the nine-channel telemetry unit and an inductive power coil (Fig. 1). This implant was manufactured in one stem size and four head diameters from 44 to 52 mm.

Six semiconductor strain gages (350 Ω , type KSP 1-350-E4, Kyowa, Japan) are glued in the hollow neck of the implant. Three of them are arranged at 0° and three at 45° relative to the neck axis. The six force and moment components are calculated from the strain gage signals using the matrix

method [11]. The influence of changing body temperature on the strain gage values is compensated mathematically during calibration [12]. For this reason the temperature inside the implant is measured with an NTC (B57331-V2472, Epcos AG, Germany).

The inductive coil has a core made of Megaperm 40 L (Vakuumschmelze, Germany) to concentrate the magnetic field. It is located in the distal stem and supplied with energy during the measurements by an external coil, placed around the upper arm of the patient. The thin antenna wire at the lower end of the prosthesis is made of niobium and connected to the internal telemetry unit by a feedthrough which is also used in heart pacemakers and other instrumented implants [13]. The antenna itself is protected by a cap made of biocompatible polyetheretherketone.

2.3. Telemetry unit

The telemetry circuit is housed in a tube (8 mm diameter, 20 mm length) made of megaperm to shield it against the external magnetic field. The upper and lower ends of the implant are hermetically sealed to the outside by electronic beam welding.

The strain gages are connected to the thick-film hybrid circuit of the telemetry. Its ceramic substrate with dimensions of 9.5 mm \times 6 mm houses the telemetry chip itself, several capacitors and resistors and a NTC temperature sensor [14]. Additional to the strain gages, the telemetry is connected to the inner power coil and the antenna by 12 solder pads on the one side of the hybrid. The other side is used for programming the chip and adjusting the measuring ranges and zero points of the internal amplifiers. This side is cut off after programming.

The strain gage signals are transmitted approximately 150 times per second at a carrier frequency of 80 MHz by pulse interval modulation. Nine consecutive pulse intervals encode the resistance of the six strain gages, the implant temperature, the internal supply voltage and a synchronization signal. The power consumption is minimized to 5 mW to prevent any implant heating caused by a strong external magnetic field.

2.4. Calibration procedure

To achieve a good measuring accuracy the implant has to be calibrated under conditions similar to the situation *in vivo*. Therefore the implant is fixed by bone cement in a rigid calibration frame. Calibration of the implant is performed with a new method by applying combinations of forces and moments [15,16]. The calibration force acts at one of 21 steel balls on different positions of a metal block which is clamped tightly at the head of the implant (Fig. 2). This force increases and decreases from zero to a maximum within 30 s while 5000 strain gage readings are recorded. The applied external force results in a load vector \underline{L}_i which contains different combinations of moments and forces for each point ($i = 0-20$) depending on the lever arms and force orientations (Fig. 2).

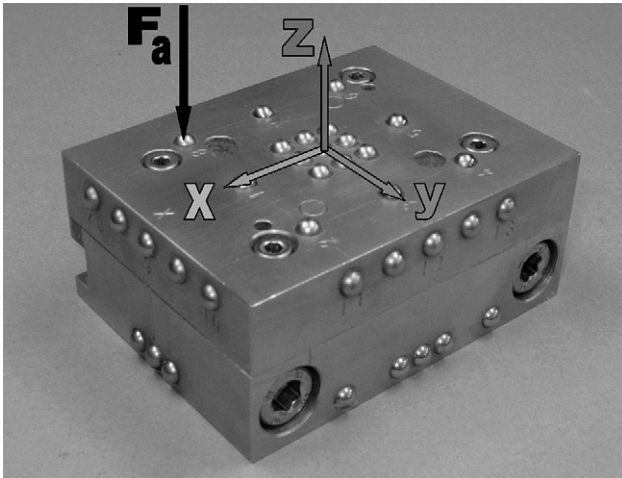


Fig. 2. Calibration block with various points of load application. Force F_a causes the force component $-F_z$ and the moment components $+M_y$ and $+M_x$ at the same time.

These data are used to set up the equation:

$$\underline{L}_i = \underline{D} * \underline{S}_i \Rightarrow \begin{array}{c|cccccc|c} F_{xi} & d_{11} & d_{12} & d_{13} & \cdot & \cdot & d_{16} & S_{1i} \\ F_{yi} & d_{21} & d_{22} & \cdot & \cdot & \cdot & \cdot & S_{2i} \\ F_{zi} & d_{31} & \cdot & \cdot & \cdot & \cdot & \cdot & S_{3i} \\ M_{xi} & d_{41} & \cdot & \cdot & \cdot & \cdot & \cdot & S_{4i} \\ M_{yi} & d_{51} & \cdot & \cdot & \cdot & \cdot & \cdot & S_{5i} \\ M_{zi} & d_{61} & \cdot & \cdot & \cdot & \cdot & d_{66} & S_{6i} \end{array}$$

with \underline{D} being the optimized 6×6 -measuring matrix, consisting of $d_{11} \dots d_{66}$ coefficients. With this matrix, the six load components in \underline{L} are calculated from the implant signals \underline{S} during the measurement. A detailed description of the calibration is described by Bergmann [12].

The calibration is done at three different temperatures and three power supply levels in order to compensate mathematically the varying body temperature and the changing supply voltage caused by slight relative motions between the external coil on the arm of the patient and the internal coil in the implant.

2.5. Coordinate system

From CT data, the implant position relative to the humerus is obtained. Force and moment components are measured in the implant-based coordinate system used during calibration (Fig. 3). They are then transformed to a humerus-based coordinate system [17] for evaluation of the data.

2.6. Implant safety tests and sterilization

To ensure the safety of patients with this permanent implant, both analytical and mechanical strength tests were performed. For a fatigue test, the implant was cemented without support of the upper 45 mm of the shaft and cyclically loaded five million times perpendicular to the shaft with a

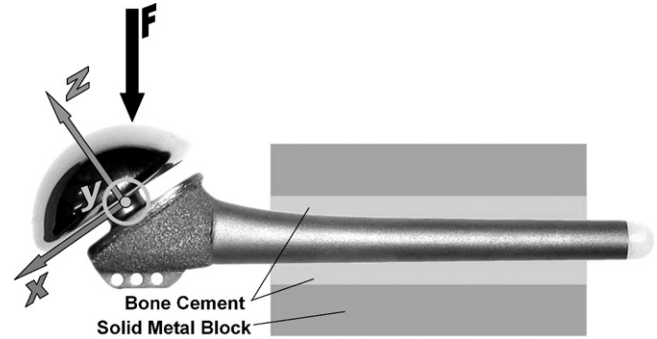


Fig. 3. Implant coordinate system with the Z-axis in implant neck orientation, the Y-axis points out of the plane. The force F of 1500 N represents the maximum load during fatigue testing.

maximum force of 1500 N at a frequency of 3.4 Hz (Fig. 3). This represents an extremely strong bending moment and an assumed total proximal bone resorption.

The quality of every weld used to seal the electronics is tested by analyzing micrograph sections of test samples welded in one production cycle with the implants. Additionally a leakage test in water under vacuum is performed.

Gas sterilization of the implant is conducted by an approved external company, specialized in ethylene oxide sterilization.

2.7. Surgical procedure

The instrumented prosthesis is implanted using a standard surgical deltoid-pectoral approach with bone cement. After resection of the humeral head, the humerus is reamed to the stem size of the implant plus 1 mm for the cement mantle.

Prior to the final fixation, a test-implant is inserted to evaluate the best fitting head size. No glenoid component is used. Special focus is laid on the cleaning of the area around the implant neck to make sure that no bone cement remains between the stem and head. A cement bridge in this area might transfer some part of the loads and thus lead to unpredictable errors in measurement.

2.8. External measurement equipment

To receive and convert the signals of the implant, a power generator, RF Receiver and a control unit are integrated in a 19" case (Fig. 4). The control unit is microprocessor-based (Atmel, AVR ATmega 8, San Jose, CA, USA). It regulates the strength of the external magnetic field, based on the transmitted signal of the internal supply voltage, synchronizes the signals and suppresses potential signal errors. A notebook with customized measurement software and a software oscilloscope allow for control of the implant signals.

Video images of the patient's activities, spoken comments and transmitted load data are stored synchronously on a

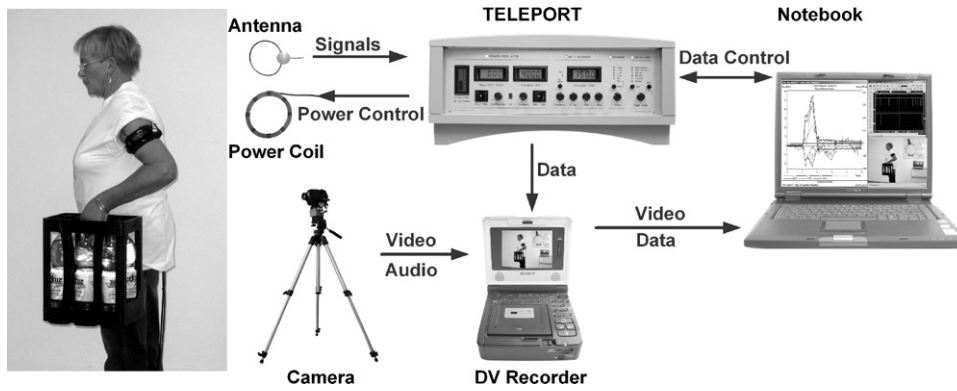


Fig. 4. Measurement setup. Implant signal receiving and supply power control with the external measurement device (Teleport). Data and video are stored together on digital video tape. Laptop for data control and real time load display.

digital video recorder [14]. During the measurement, the patient wears the external power coil and a small loop antenna with an integrated amplifier around the upper arm close to the tip of the implant stem.

Both the implant loads and patient’s video are displayed by custom-made software and exported into screen videos (Fig. 5). These screen videos and the raw data are stored in

the database Orthoload which will be accessible via internet (www.orthoload.com).

2.9. Approvals

Implantation in up to 10 patients was approved by the Ethics Committee of the Charité and by the state health

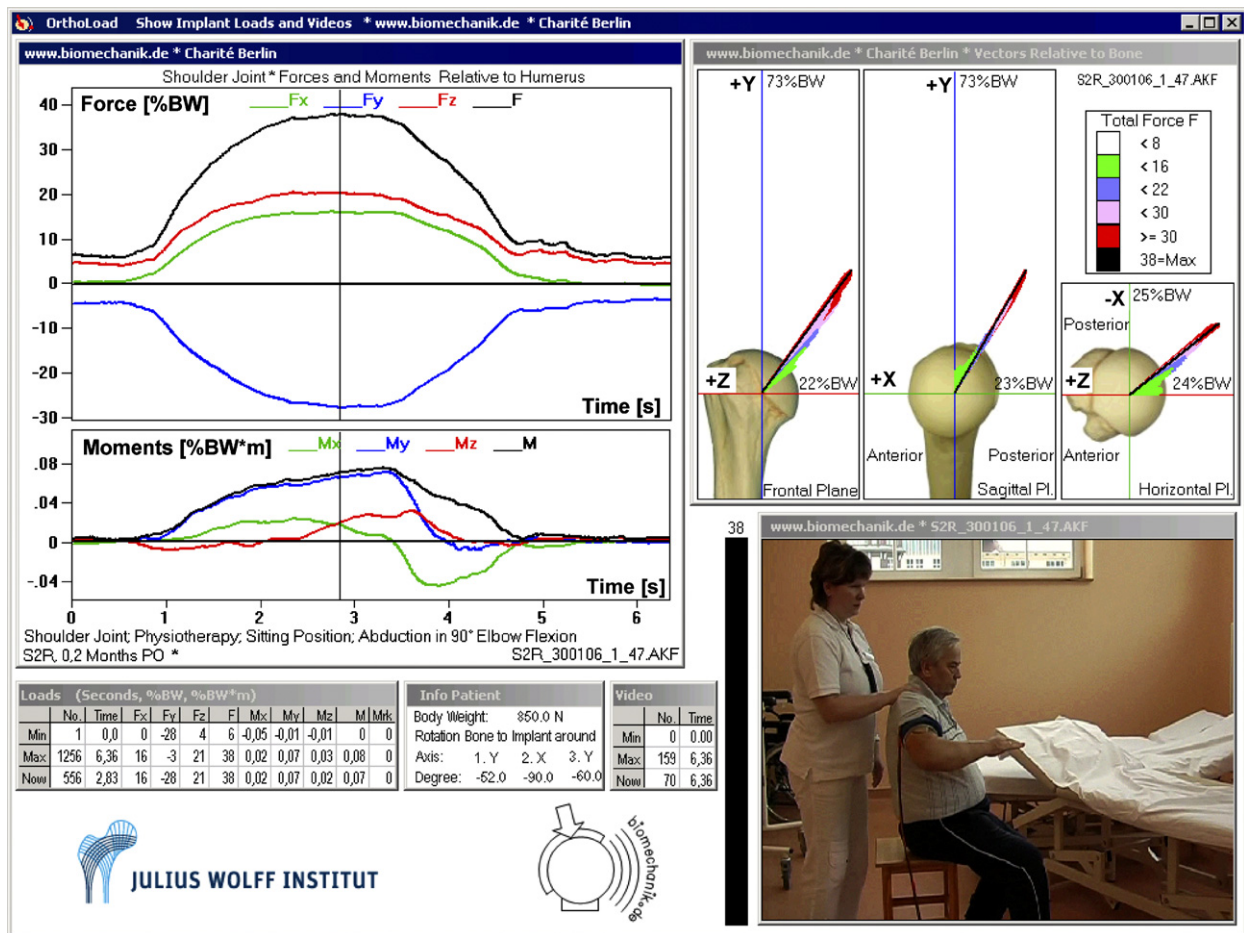


Fig. 5. Screen video as accessible via internet. Implant measurements and patient activity two weeks postoperative. Top left: diagram of force and moment vs. time; top right: force vector plots in three body planes; bottom left: data table and video control button; bottom right: patient video.

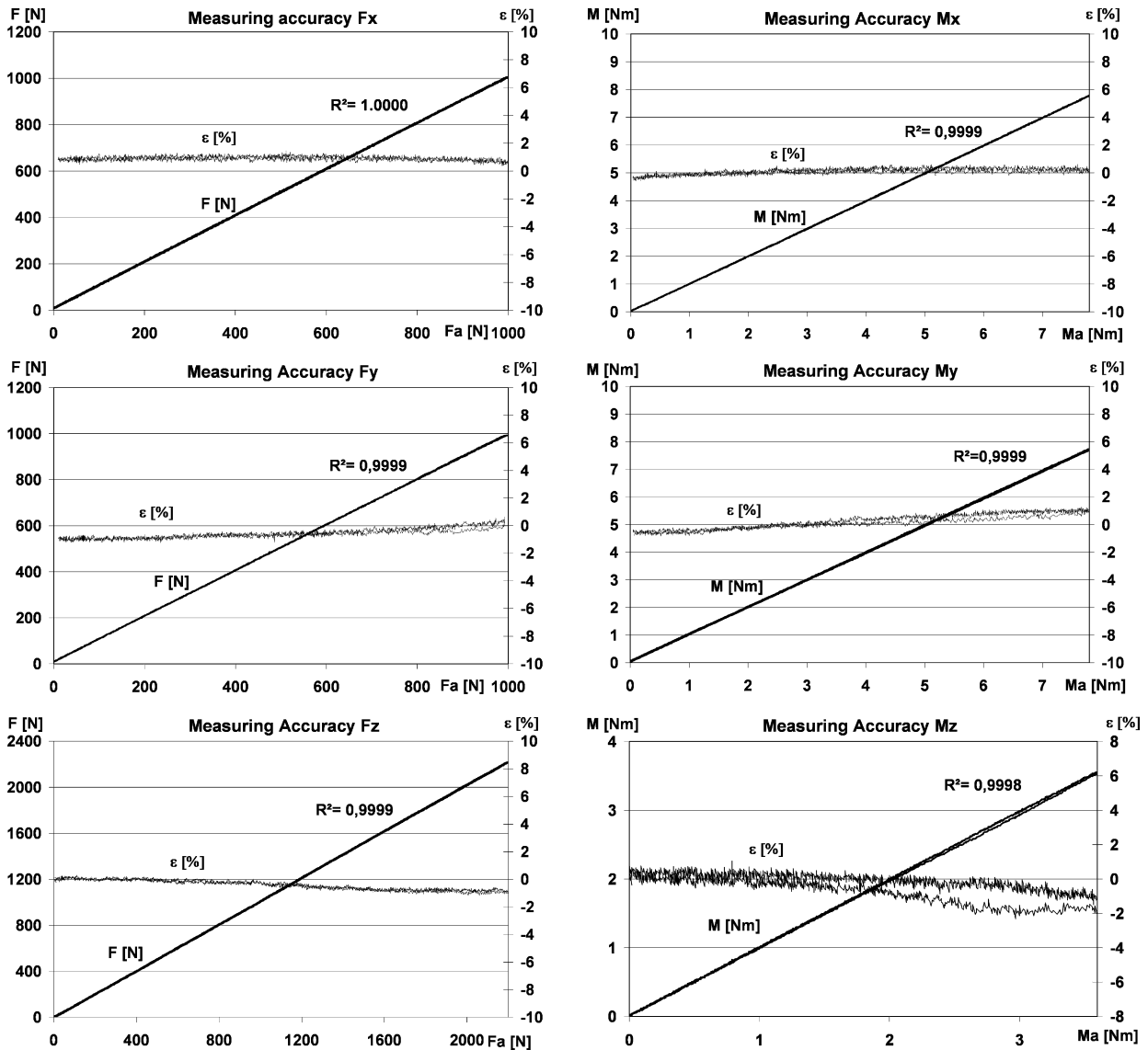


Fig. 6. Measured load components vs. applied components. Left scales: absolute values. Right scales: relative error in percent; left diagrams: forces F_X , F_Y , F_Z ; right diagrams: moments M_X M_Y M_Z .

authorities. A certified institution tested mechanical stability of the modified implant, biocompatibility of the components in contact with human tissues, and the external telemetry device including the external power coil. Before implantation, the patients are informed in detail about the surgical procedure, the instrumented implant and the cooperation required from them during the measurements. They give their written consent to implantation, measurements and publication of their images. An additional special insurance is provided as well.

2.10. Patients and measurements

The instrumented prosthesis was implanted in 6 patients so far, all suffering from osteoarthritis of the shoulder. Implantations in up to 10 patients together are planned.

3. Results

3.1. Measuring error

The measuring errors of multi-component load transducers can be specified in different ways. A high coefficient of determination (R^2) between measured and applied components [18] does not necessarily indicate a good measuring accuracy, because occasional measurements with high errors can diminish R^2 only slightly. Furthermore a constant error (Fig. 6, top left) or an error which decreases or increases with the load (Fig. 6, bottom left) would not effect R^2 at all. Relative errors of a certain force component can be defined relative to the maximum of the same component during one calibration cycle (I), its maximum during the whole calibration (II) or the resultant of all three component maxima during the

whole calibration (III). We chose method (II) for determining the errors and include cross-talk in the given values.

Due to the very short neck of the instrumented shoulder implant, the point of load application is very close to the position of the strain gages where the deformations are measured. Local deformations of the head, dependent on the load distribution between head and glenoid, can therefore lead to different strain gage readings for the same load. This effect is one of the basic problems of instrumented implants [19].

Nevertheless the maximum peak error remained around 1% for all force and moment components, except the torsional moment M_Z (Fig. 6), for which relative maximum peak error was approximately 2%. The values of R^2 between measured and applied load components were always above 0.9998. These values include the cross-talk between all six components (cross-talk values are not shown in Fig. 6).

Filtering of the signals is possible due to the high transmission rate of about 150 Hz and can be utilized to reduce the characteristic high frequency peak errors [19].

3.2. Telemetry

The telemetry transmission rate of 150 Hz makes this shoulder implant well-suited to measure even fast movements or short force impacts acting on the shoulder joint. The low power consumption and the temperature sensor which is included offer furthermore the possibility of observing temperature changes during continuous activities.

3.3. First measurements

The first measurements show low loads during the first postoperative time, which rapidly increase with proceeding rehabilitation. The loads during physiotherapy are low compared to some activities of daily living [20], Fig. 5 shows an abduction motion of 45 deg with a resultant force of approximately 40% BW one week postoperatively. This is similar to previous mathematical studies [4,21]. The force direction is remarkably constant during the whole motion cycle of abduction. The magnitude of the loads is expected to be strongly dependent on the muscular situation and therefore on the functional results of the patients.

4. Discussion

This study has shown that measurement of the contact loads acting in the shoulder joint with an instrumented shoulder prosthesis is possible. The high measurement frequency, the low power consumption and the included temperature control allow even measurements of long-lasting and demanding activities.

The accuracy achieved is close to that of industrial force transducers although the short neck of the shoulder implant is unfavourable because local deformations at the locations of load application at the head may influence the strain gage

readings. Many of the measuring errors (Fig. 6) are caused by high frequency noise of the transmitted signals. This noise is a result of interference between the frequencies of data transmission and power supply (4 kHz). Most of these high frequency errors can be filtered out mathematically. The relative errors of the torsional moment M_Z (Fig. 6; bottom right) are due to the difficulty in applying a high torsional moment at the smooth head of the implant during calibration. For the same reason, high torsional moments are not expected to be present *in vivo*. However, the absolute values for M_Z are comparable to those of the other components.

The implant presented here will lead to new findings regarding the function of shoulder implants and the treatment of patients with shoulder problems. However, intensive effort necessary to achieve a good measuring accuracy, as well as the time and high costs of measurements and evaluations will, in our opinion, rule out the routine use of such implants in the future.

Conflict of interest

The authors declare that neither the authors nor members of their families have a current financial arrangement or affiliation with the commercial companies whose products may be mentioned in this manuscript

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.medengphy.2008.07.011](https://doi.org/10.1016/j.medengphy.2008.07.011).

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