

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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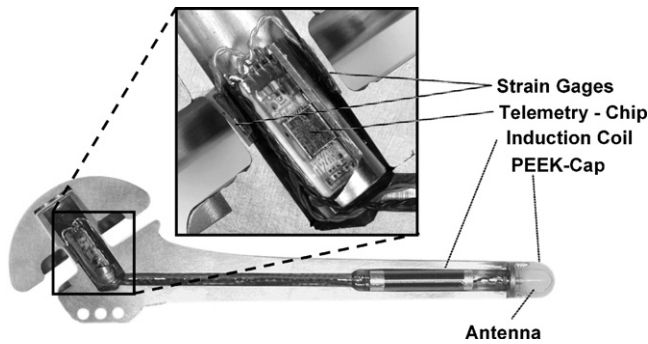


Fig. 1. Instrumented shoulder implant. Cross-section showing the internal induction coil, the antenna at the tip of the stem and the telemetry unit in the hollow neck.

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).

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