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An in-vivo method for biomechanical characterization of bone-anchored implants

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Abstract

Experimental equipment for in-vivo registrations of pull-out load vs displacement, applied torque vs angle of rotation, and lateral load vs lateral displacement has been developed. The set-up is designed for testing three implants inserted ina row and osseointegrated in, for instance, the proximal tibia of the beagle dog. The details of the set-up are described and considerations of the stress distributions are reported. © 1998 IPEM. Published by Elsevier Science Ltd

Keywords: Osseointegration; Biomechanics; Implant; Titanium; Fixation strength; Fixation stiffness

1. Introduction

Implants which are directly anchored to bone, without intervening fibrous tissue or bone cement, have been successfully used for anchorage of dental prostheses [1,2], for anchorage of epitheses and hearing aids [3], in hand surgery for anchorage of finger joint prostheses [4], and in orthopaedics for anchorage of amputation prostheses [5].

The biomechanical behaviour of the bone-implant interface in osseointegration has not been fully characterized. Accurate knowledge of the in-vivo boundary conditions might be helpful in finite element modelling and for developing optimal implant design. The strength of the interface in shear is a critical element.

The purpose of the present note is to describe the construction and operation of test equipment for evaluating the biomechanical properties of bone anchored (osseointegrated) implants in-vivo by torsion tests, pull-out tests and lateral loading tests.

2. Material and methods

The tests utilize three threaded commercially pure titanium implants (fixtures) with an outer diameter of 3.7 mm and with a square head on the central fixture and hexagonal head with internal threads on the side fixtures. The implants are installed in a straight line.

Special extensions (abutments) are mounted on the side fixtures and held fixed by the torsion test equipment [Fig. 1(a)]. After the torsion test, the special side abutments are disconnected and a pull-out test is performed on the distal fixture [Fig. 1(b)].

To perform lateral loading tests, a separate set of three fixtures is utilized. The middle fixture can be tested, applying a force perpendicular to the long axis of the bone [Fig. 1(c)], the proximal fixture can be subjected to lateral loading parallel to the long axis of the long bone [Fig. 1(d)].

2.1. Torsion test equipment

The torsion test set-up is schematically illustrated in Fig. 1(a). The equipment used to apply torque is shown in Fig. 2: a DC (direct current) motor (1) is connected via gears (2) to a gear train (3) (Muffet, type 2K, 3600:1, Mekanex, Solna, Sweden) with a ratio of 1–3600, i.e.

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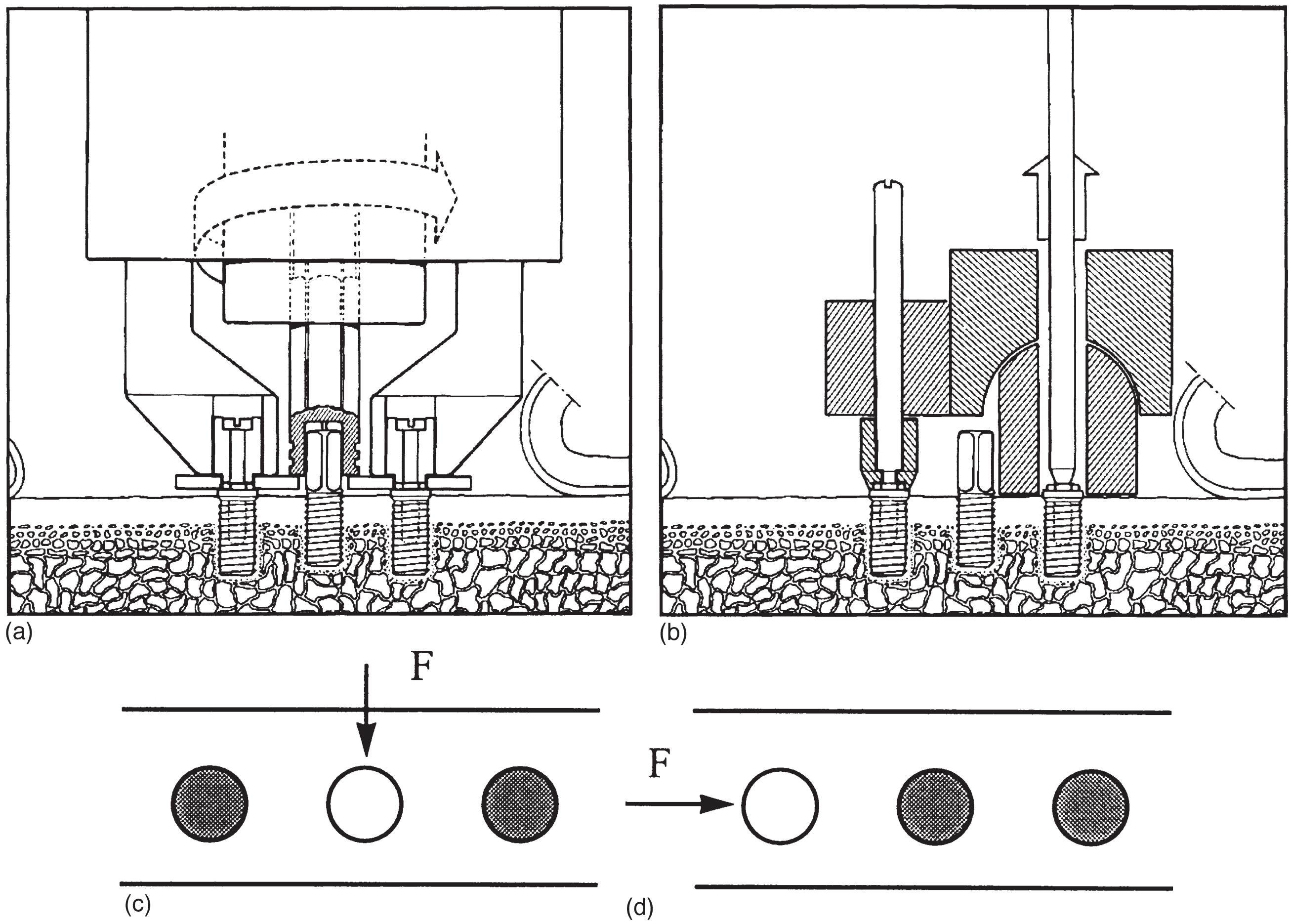

Fig. 1. (a–d) Arrangements of three fixtures and auxiliary apparatus for torsion, pull-out, and lateral loading tests. The side fixture to the left is the proximal and the side fixture to the right is the distal fixture. (a) Torsion test set-up. The side fixtures are fixed to the torque test jig and the central fixture is tested in torsion. (b) The pull-out test set-up (cross-section). The distal fixture is tested in tension by the rod with the arrow. The bone surrounding the fixture being tested is restrained by the spherical cap. The proximal side fixture is immobilized by a clamp. (c) Schematic diagram of lateral load test with force F applied transversely to the central fixture. The side fixtures (shaded) are held fixed by a heavy jig. (d) Schematic diagram of lateral load test with force F applied parallel to the long axis of the bone. The shaded fixtures are held fixed relative to the test machine bed.

one turn of the motor unit produces 0.1° of rotation of the final axis of the gear train. The gear unit is connected to a torque sensor (4). By glueing two double strain gauges (Type N22-FA-5-120-11 SHOWA Measuring Instruments Co. Ltd, Tokyo, Japan) to the circular ring segment of the sensing element at 45° relative to the long axis, an electrical signal was derived corresponding to the applied torque. The strain gauges were incorporated into a Wheatstone bridge whose output was fed into a precision amplifier (Type 9823, DMS-Spiese-und-Verstärkerbaustein, Burster Präzisionsmesstechnik, Gernsback, Germany). The torque sensing element was calibrated to an accuracy of ± 2% of the reading down to 0.01 Nm. The angular displacement of the torque sensing element was registered with a Rotary Variable Differential Transformer (RVDT30A, Schaevitz Engineering, Pennsauken, New Jersey, USA). The RVDT (5) was connected to the deformation element via gears (Fig. 2). The maximum error was calibrated to the below ± 0.1°. The angular rotational speed was 2°/min during the torsion tests. The signals from the strain gauges and the RVDT were transformed on line by an analogue to digital converter (Lab Master, Dennis Bergström Trading AB, Stockholm, Sweden) and fed to a recording computer (PC AT-2, IBM, Boca Raton, Florida, USA).

2.2. Pull-out test set-up

For pull-out tests, a hemisphere (with a hole of diameter 6.0 mm, for the loading rod) was used to support the surrounding bone during the test. This allows for the axis of the fixture not being precisely perpendicular to the bone surface. This hemisphere fitted into a specially designed rigid jig which was anchored to the bed of the testing machine. The overall deformation of the jig was less than 0.1 mm for an applied load of 2.0 kN. A rod was mounted onto the distal fixture for testing and connected to the movable head of the test machine. A simi-

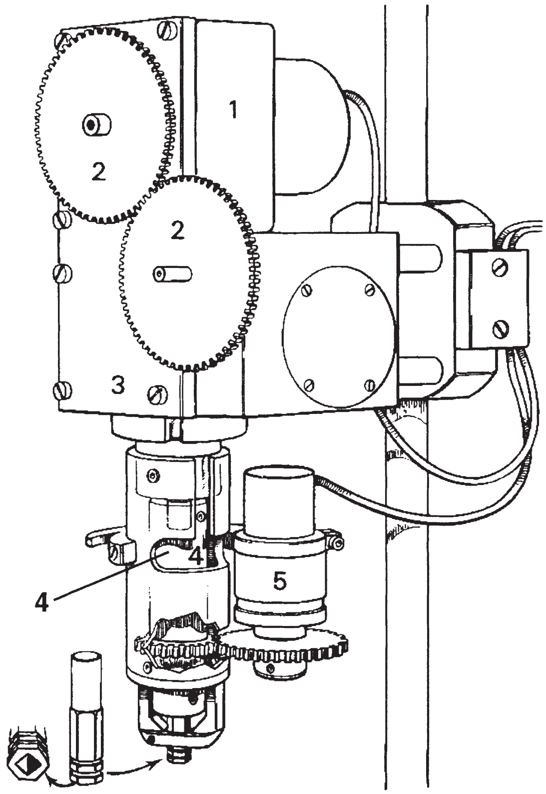

Fig. 2. The motor (1), gear (2), gear train (3) and sensing elements (4,5) used to apply and measure torque and angular displacements.

lar rod was placed in the proximal side fixture serving as a guide for alignment [Fig. 1(b)].

2.3. The lateral load test set-up

Lateral load tests were performed on sets of fixtures in which all three fixtures were identical to the side fixtures described above. For lateral transverse loading, the central fixture was loaded, while the side fixtures are held fixed relative to the test bed [Fig. 1(c)]. For lateral axial loading, the proximal fixture is loaded and the other two fixtures were held fixed [Fig. 1(d)]. The load was applied 5 mm above the upper end of the threads.

For the pull-out tests and the lateral load tests a universal testing machine (Instron Model 4202, Instron Corporation, USA) was used to apply loads. The resolution in load is ± 1% of the reading down to 1/50 of the load cell capacity. The accuracy of position measurements (axially) is ± 0.1 mm. A software package (LABPAC, Dennis Bergström Trading AB, Stockholm, Sweden) handled the communication with the computer via an IEEE-488 interface to digitize and record the data.

3. Discussion

Previous investigations of the torsional capacity of implants have measured ultimate removal torque [6]. The present test equipment allows for loading and unloading as well as registration of deformation hence the biomechanics of the interface can be more thoroughly explored in this regard. The torsion test is assumed to primarily be probing the interface mechanics, because the fixture will transfer stresses to the bone through the interface region and it is weaker than the intact bone.

In contrast to the torsion tests, the results of pull-out tests are assumed to be dependent more on the properties of the bone surrounding the implant and less on the properties of the interface. It is assumed that the implants are not damaged in these tests and that they will move essentially as rigid bodies while deforming the surrounding bone, because the modulus of elasticity of titanium is an order of magnitude greater than that of bone; 110 GPa [7] and 18 GPa [8], respectively. The threads constitute an efficient load transfer mechanism, from the fixture out to the surrounding bone with or without shear stresses being generated in the interface region.

It would be desirable to be able to translate measured loads directly to stress–strain data for the varying test geometries and amount and distribution of the bone present. This will require detailed computation of stress distributions on the one hand and equally detailed histologic information on the density and distribution of the bone surrounding the fixtures in each case on the other. Neither of these analyses has been carried out as yet.

Some approximate average stress behaviour may be defined by simplified analyses. This is most obvious for the torsion test. Assuming that sliding occurs at the interface, an average shear stress can be accurately computed for the screw as a whole. But to be a useful criterion, it must be taken into account that only a certain percentage of the fixture area has a close apposition to bone. By the use of histomorphometric data an estimate of the interfacial shear strength in torsion, τ_t, can be calculated as:

$$\tau_t = \frac{M/r}{A_T(\%bc)} \tag{1}$$

where M = applied torque, r = mean thread radius, A_T = total fixture surface area, $\%bc$ = percentage of interface area A_T in direct contact with bone.

For the pull-out tests, any approximate theory will probably be less realistic than the simple shear stress computation in torsion [9,10].

For the pull-out test, an average shear stress can be readily computed for a cylinder with a diameter equal to the outer diameter of the threads and a length equal to an effective length of the part of the fixture integrated in the bone. The effective length is calculated as the bone thickness multiplied by the relative amount of bone present in the area surrounding the threads. The shear stress in pull-out, τ_p, can then be estimated as:

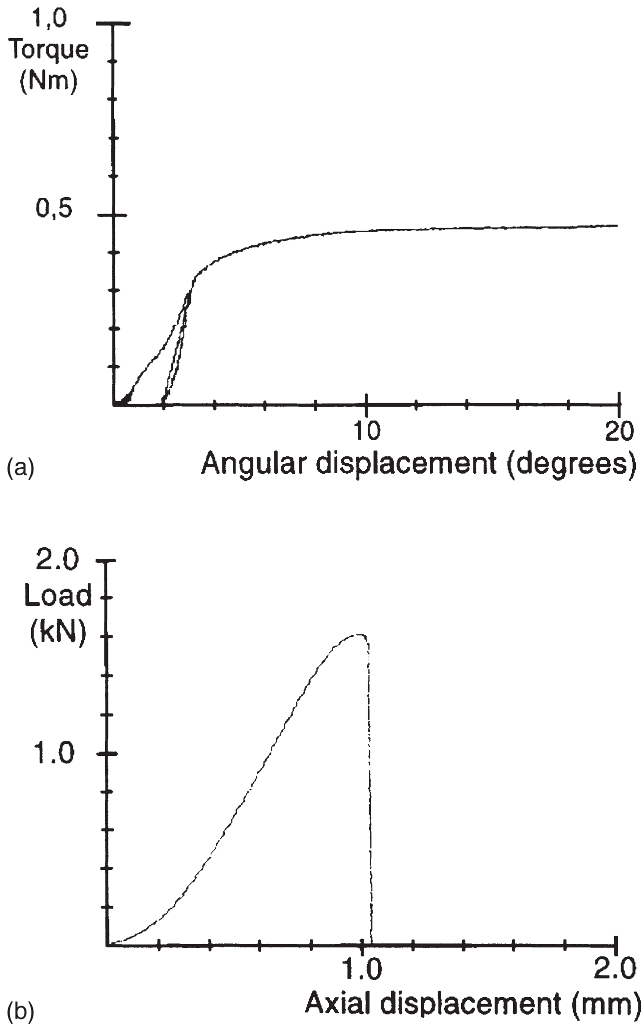

Fig. 3. (a–b) Sample test results obtained with the equipment described herein applied to living (anaesthetized) beagle dogs. (a) Sample torsion test result. Unloading an reloading was done after about 3° of rotation with a remaining irrecoverable angular deformation of about 2°. (b) Sample pull-out test result.

$$\tau_p = \frac{F}{2\pi r_o h(\%ba)} \qquad (2)$$

where F = pull out load, r_o = outer fixture radius, h = bone thickness and $\%ba$ = fraction of cross-sectional area occupied by bone. The results of pull-out tests are regarded primarily as a measure of the surrounding bone quality under the prevailing testing conditions.

The lateral load test is the most difficult to interpret in regard to calculating stresses. Probably a finite element analysis would be helpful for this interpretation. However, any such computations would have to take into account that there will be some deformation of the bone between the fixture being loaded and the remaining fixtures which are held rigidly fixed with respect to the test machine bed. Thus, 3D analyses including the entire bone around all three fixtures would be necessary.

Two samples of raw test data (taken on anaesthetized beagle dogs) are shown in Fig. 3(a,b). The torsion test [Fig. 3(a)] shows some irrecoverable deformation even after very small angular displacements. The pull-out test [Fig. 3(b)] shows a larger elastic region. More extensive experimental results will be reported in a subsequent paper [11].

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