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Nondestructive measurements of implant–bone interface shear modulus and effects of implant geometry in pull-out tests

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Push-out and pull-out tests are used for destructive evaluation of implant–bone interface strength. Because nondestructive mechanical tests would allow maintenance of an intact interface for subsequent morphological study, we developed such a test to determine the shear modulus of the interface by measuring the shear deformation of a thin layer adjacent to the implant. A polyurethane foam model was used to test the experimental setup on a group of nine cylindrical implants with three different lengths (15–48 mm) and three different diameters (5–9.7 mm). The shear modulus of the interface, as calculated from the pull-out test, was

validated against the shear modulus of the foam derived from tensile tests. The two values of shear modulus were well correlated ($R^2 = 0.8$, $p < 0.001$), thus encouraging further application of the setup for tests of implant–bone interface mechanics. In addition, we also examined the effects of implant length and diameter. The length of the implants had a significant influence on the interface shear modulus ($p < 0.05$), indicating that comparisons of this variable should only be made of implants with the same length. The length and diameter of the implants were not critical parameters for the ultimate fixation strength. © 1997 John Wiley & Sons, Inc.

INTRODUCTION

The mechanical competence of biological fixation of orthopedic implants is most often characterized by the strength of the implant–host interface. Usually, cylindrical plugs are tested after having been implanted *in vivo*. The strength of fixation is determined by dividing the maximum force measured in a push-out or pull-out test by the nominal surface area of the implant in contact with the host bone. Because these tests are destructive, the ability to examine the intact interface after the test is lost, although it is still possible to examine the implant itself or the host bed.

It would be helpful to have a nondestructive test to characterize the mechanical behavior of the interface so that mechanical and morphological assays of the intact interface could be performed in the same specimen. Obviously, the strength of fixation cannot be determined nondestructively, but it should be possible to determine the shear modulus of the interface zone. In addition, the modulus may prove to be more sugges-

tive about the type of tissues at the interface than the strength obtained from destructive tests. Measurement of elastic properties is much more difficult than measurement of the strength of fixation because the interface zone constitutes only a thin layer (usually less than 3 mm in most experiments).

It has been shown in push-out tests that certain test conditions, such as the modulus of the implant and the clearance of the hole in the supporting plate, can affect the calculated strength.¹ In pull-out tests, cylindrical implants varying from 5 to 9.7 mm in diameter and from 15 to 48 mm in length have been used by various laboratories.^{2–7} Because the stress distribution along the interface is usually not uniform, particularly for short implants, the actual strength values calculated from these tests may not be comparable.^{1,8} Similar limitations may apply to the interpretation of nondestructive interface modulus tests.

The purposes of the present study were to develop a nondestructive mechanical test of the implant–host bone interface shear modulus and to test the effects of varying diameter and length of the implants on the interface shear modulus and strength in trabecular bone.

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MATERIALS AND METHODS

A cylindrical steel implant with a diameter of 7 mm and a length of 48 mm was machined. Fine threads (#40, U.S. standard) were used as a surface finish. Polyurethane foam (RF-100, Daro Products, Butler, WI) was used to simulate the surrounding bone. Foam components underwent manual mixing for 1 min. Ten foam bone models with 7 × 48 mm implants were tested. Five of these foam bone models were made using the manufacturer's recommended ratio of 1.0 resin/0.9 isocyanate by weight. The other five models were formed using an altered mixing ratio of 1.0 resin/1.5 isocyanate. The increased fraction of isocyanate reportedly raises the modulus of the foam product.⁹ Implants were coaxially held inside a 35-mm diameter aluminum split mold (Fig. 1) while premixed foam was poured in the space between the implant and the mold. Coarse threads (#8, U.S. standard) had been machined on the inside of the mold to assure interdigitation between the mold and the foam model of the bone to assure a uniform stress transfer from the mold to the bone model. Models were left to harden for 24 h before the foam cylinder was retrieved from the mold. Excess foam extending beyond the distal portion of the implant was cut off. The model was refit into the mold (1, Fig. 2), which was then used as a holder for each model during the pull-out test. Tensile force (F , Fig. 2) was applied to the implant (2, Fig. 2) through a device consisting of an extended yoke (4, Fig. 2) surrounded by a 20-mm diameter sliding sleeve (5, Fig. 2), which was ground against the surface of the foam model (3, Fig. 2) surrounding the implant. An extensometer (6, Fig. 2) with a gauge length of 10 mm and range of ± 1 (model 2620-830, Instron) sensed longitudinal displacements between the yoke and the sleeve. Thus, in fact, the shear deformation in the thin

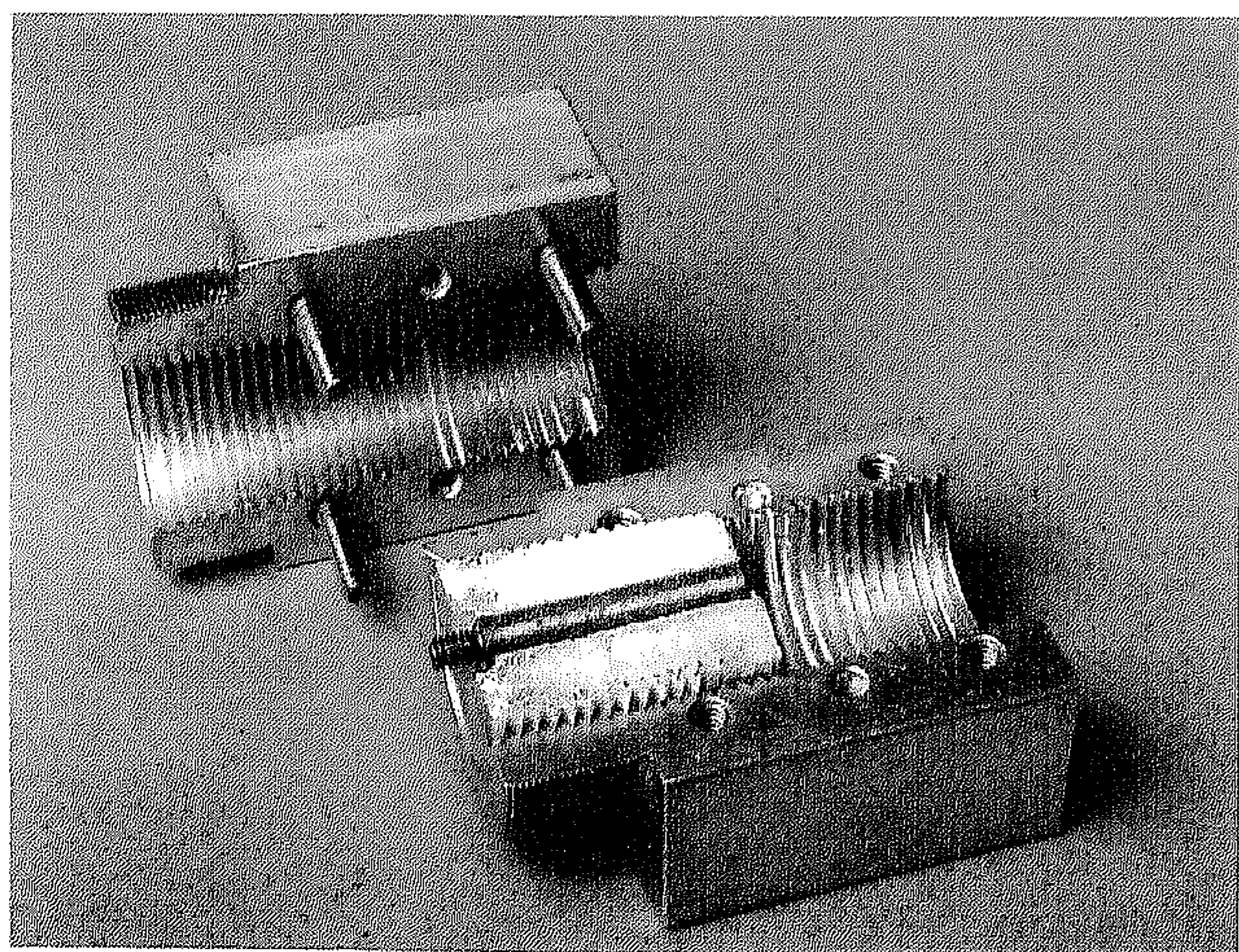


Figure 1. Split aluminum mold used to form foam models and to hold them during pull-out tests. Shown inside the mold are a foam model (sectioned longitudinally) with a cylindrical implant.

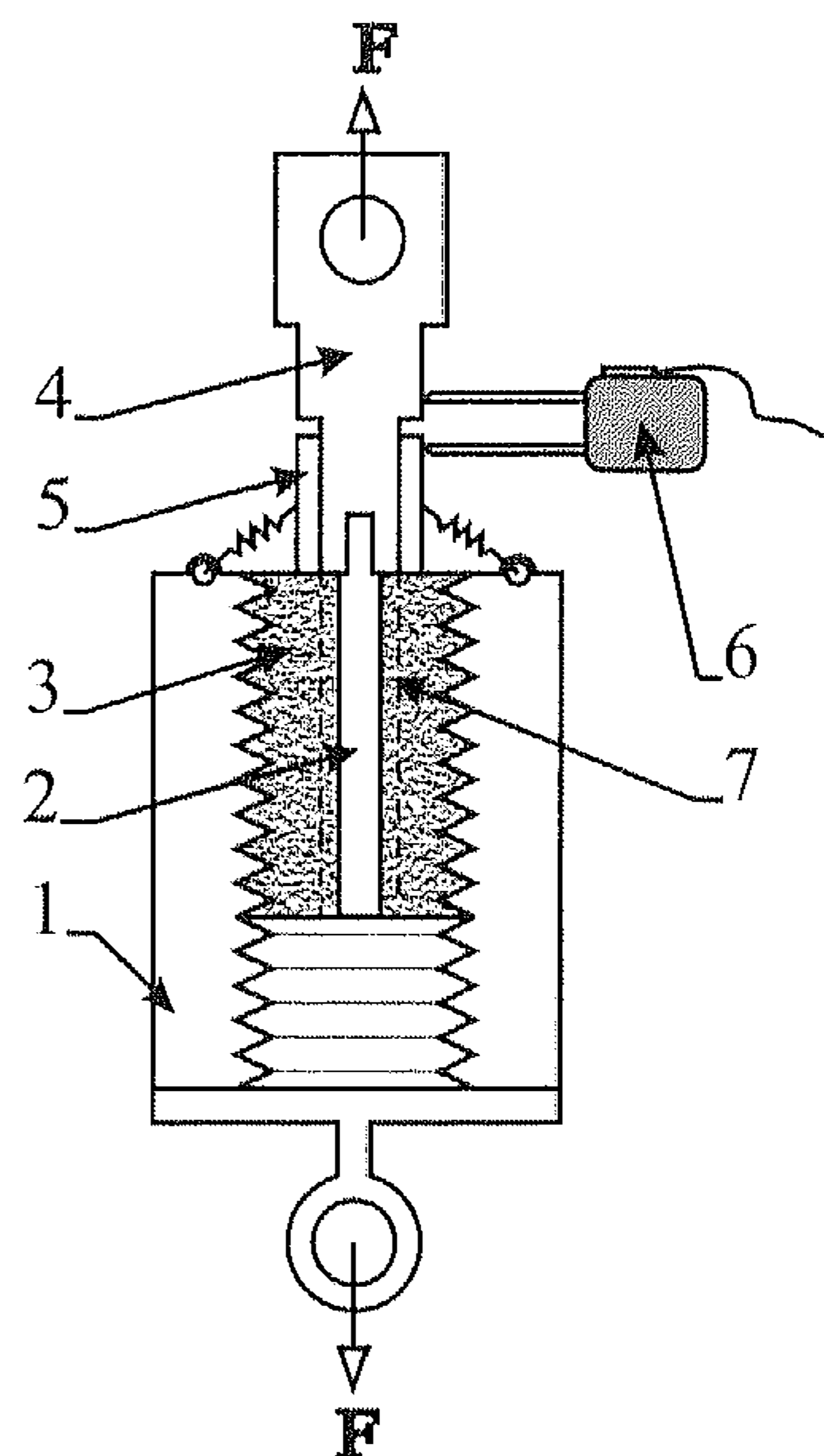


Figure 2. Experimental setup for a pull-out test (longitudinal cross section); 1, aluminum mold; 2, cylindrical implant; 3, foam model; 4, extended yoke; 5, sliding sleeve held against the foam surface by springs; 6, extensometer; 7, foam layer in which the interface shear modulus was measured; and F , tensile force applied to the setup.

foam layer (7, Fig. 2) adjacent to the implant was tested. Mechanical pull-out tests were performed on a servohydraulic materials testing machine (model 1321, Instron) at a loading speed of 0.25 mm/min. Load-displacement curves were recorded during each test. The initial linear portion of the curve was used to calculate the interface shear modulus. Because the measured displacement d can be expressed as

$$d = \int_{R_1}^{R_2} \gamma dr,$$

where γ is the deformation due to shear, R_1 is the radius of the implant, and R_2 is the radius of the sleeve. When the shear stress is expressed as the axial force over the area of the interface, the shear modulus of the interface, G_{if} , can be expressed as

$$G_{if} = F \frac{\ln R_2 - \ln R_1}{2\pi dL},$$

where F is the tensile force and L is the length of the implant.

Because the foam was the only material present at the implant-bone interface in our model (7, Fig. 2), we expected that the shear modulus of the interface foam layer would be the same as the shear modulus of the foam itself. Thus, for the purpose of validation, one specimen was prepared from each foam model tested to determine the tensile modulus. The tensile tests were performed on cylindrical specimens machined to ASTM standard E8 (gauge length of 25 mm and diameter of the waist portion of 6.25 mm) at 0.25 mm/min and calculations were based on the linear part of the load-deformation curve. The shear modulus of the

foam, G_{foam} , was calculated according to normal isotropic material conditions using data from the tensile test:

$$G_{\text{foam}} = \frac{E}{2(1 + \nu)}$$

where E is the axial modulus of the material and ν is Poisson's ratio.

Poisson's ratio of the foam was determined by compression loading of four cubic-shaped foam specimens with two separate extensometers for simultaneous measurements of the axial and transverse deformation. The average (\pm SD) Poisson's ratio of the foam was 0.36 ± 0.01 . A linear regression was performed to evaluate the relationship between the interface shear modulus (G_{if}) and the shear modulus (G_{foam}).

An additional eight cylindrical implants were machined to complete a set consisting of combinations of three different diameters (5, 7, and 9.7 mm) and three different lengths (15, 30, and 48 mm) for a total of nine implant sizes. Foam models with the standard ratio for components of $1.0 \times$ resin/ $0.9 \times$ isocyanate by weight were used. In addition to the test for the interface shear modulus as described above, specimens were tested to failure and the ultimate pull-out force was recorded. The ultimate shear stress σ_{ult} of the interface was calculated as

$$\sigma_{\text{ult}} = \frac{F_{\text{ult}}}{A}$$

where F_{ult} is the ultimate force and A is the nominal surface area of the implant.

Each implant size was tested in five replicates for a total of 45 foam bone models. Two-way analyses of variance (ANOVA) were used to test for the effects of the implant diameter and for the effect of implant length. Separate analyses were applied to interface shear modulus and to fixation strength. A significance level of 0.05 was used.

RESULTS

The shear modulus as estimated from the tensile test (G_{foam}) was well correlated with the experimental shear modulus of the interface based on the pull-out tests (G_{if}) with $R^2 = 0.80$ and $p < 0.001$. If we assume that a no-intercept regression model can be applied (Fig. 3), then the regression equation is

$$G_{\text{foam}} = 1.01G_{\text{if}}$$

The average (\pm SD) tensile modulus of the foam models were 103 ± 12 MPa (range 90–121 MPa) for the standard mixing ratio and 126 ± 20 MPa (range 109–160 MPa) for the altered mixing ratio.

The shear modulus of the interface, as calculated from the pull-out tests (G_{if}), was significantly affected by the length of the implant ($p < 0.05$) (Fig. 4). Neither the diameter nor the length of the implant had a sig-

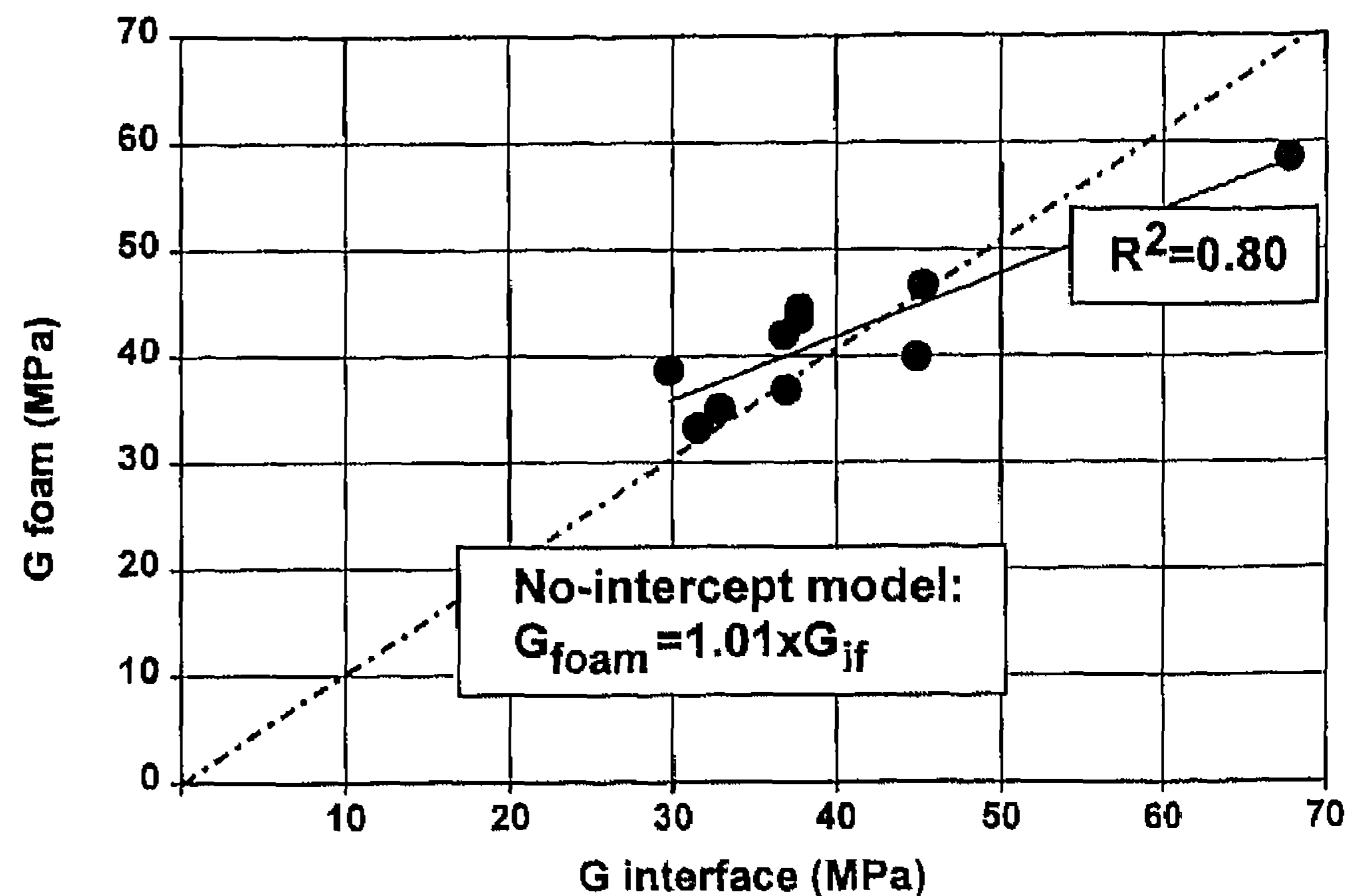


Figure 3. Regression analysis between the shear modulus of the foam (G_{foam}) and shear modulus of the interface (G_{if}). The solid line and R^2 value represents the regular linear regression. The dashed line and the regression equation represents a no-intercept model.

nificant influence on the ultimate shear stress of the interface (Fig. 5). All failures in the pull-out tests occurred in the foam immediately adjacent to the implant; the threads on the implants always had attached foam after the test.

DISCUSSION

The present study describes the development of a nondestructive test to measure the shear modulus of the interface zone of an implant placed in trabecular bone. We chose this site, rather than cortical bone, because most cementless joint replacement components are implanted in a trabecular bone bed. The elastic properties of the foam used in our study resemble those of human cancellous bone.⁹ In addition, the average diameter of bubbles in the foam (between 200 and 300 μm)⁹ was similar to trabecular separation of newly formed trabecular bone (between 300 and 400

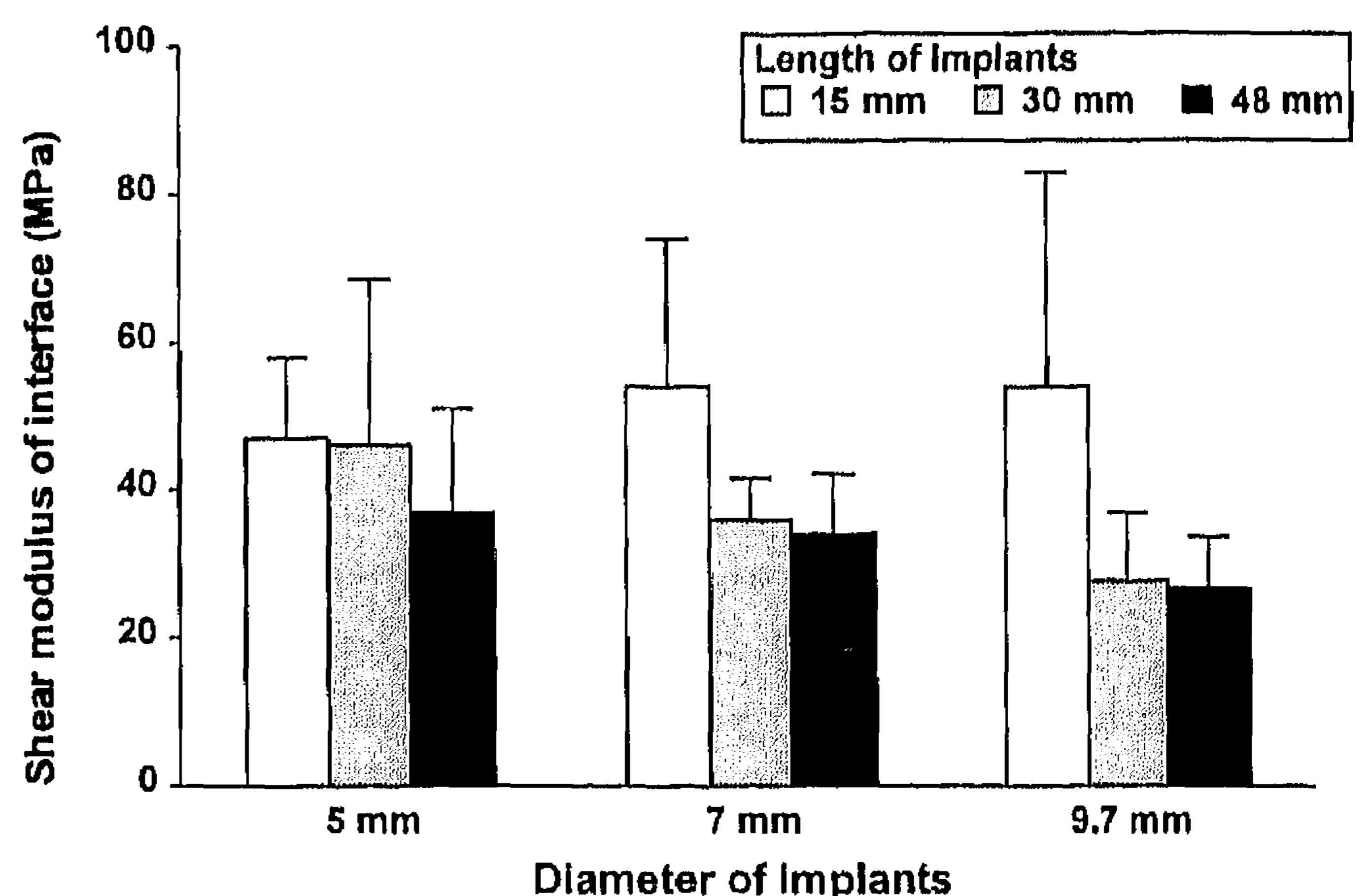


Figure 4. Interface shear modulus as a function of implant geometry.

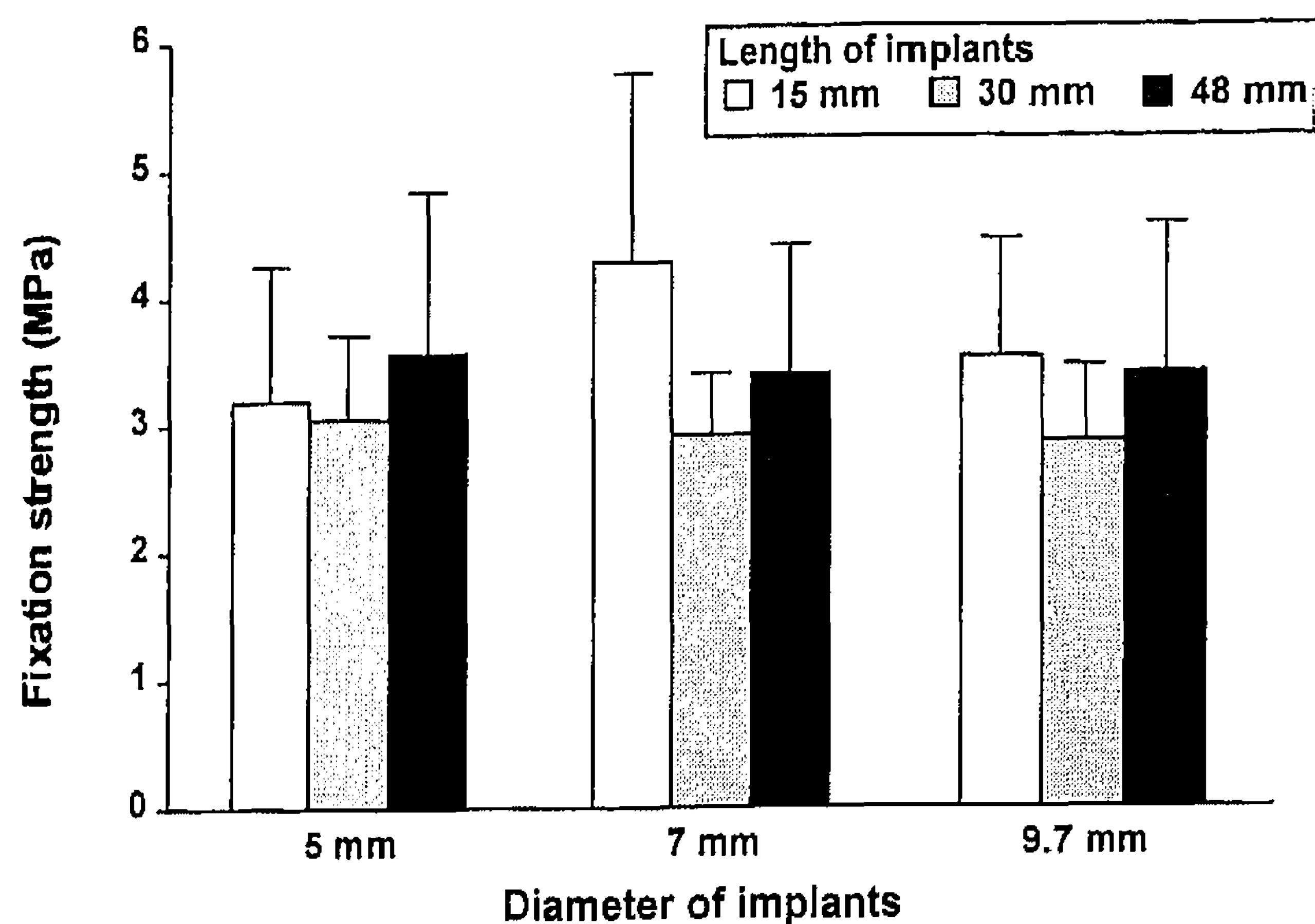


Figure 5. Fixation strength as a function of implant geometry.

μm) in a canine model.⁷ The site of failure during the destructive portion of the tests (immediately adjacent to the implant) was similar to that reported for pull-out tests from a bone bed. The fixation strength in the present study was comparable to the strength of biological fixation of similar cylindrical implants. Thus, the present model is a good simulation of the biomechanical environment encountered during pull-out tests from trabecular bone.

The shear modulus values obtained from the interface and values calculated from the tensile tests of foam specimens were well correlated, thus encouraging further application of the setup for tests of implant-bone interface mechanics. Based on the results of the linear regression, one could extrapolate the results to bone tissue with an elastic modulus beyond the range tested in this study (from 90 to 160 MPa).

It has been reported from theoretical models^{1,8,10} that interface stress around cylindrical implants is not just a function of load and interface area, but depends on the specific geometry (length and diameter). The local effects at the ends of the implant substantially affect the stress distribution, and a uniform distribution can only be expected along the middle portion of the implant. However, experimental data from push-out and pull-out tests are often processed as if there were a uniform stress distribution along the whole length of the implant. If short cylinders are used, stress distribution effects at the ends may overlap, thus eliminating the middle portion, where the uniform interface stress calculations would have been applicable.

The length of the implants had a significant influence on the interface shear modulus, indicating that comparisons should only be made of implants with the same length. The length and diameter of the implants were not critical parameters for the ultimate fixation strength. Thus, similar to results reported for push-out tests,⁸ one can compare strength values from pull-out tests of implants of different dimensions if the

implants are in the range of lengths and diameters tested in the present study.

The shear modulus of the interface zone is essentially uncharacterized. This information would be of particular use as input into finite element models where the nature of the connection between the implant and host can now only be roughly approximated. It can be argued that the shear modulus may be more indicative of the tissue type at the interface than the strength of fixation because dense fibrous tissue can give a fixation strength at times approaching that given by bone ingrowth.⁴

This work was supported by NIH Grant RO1AR42862.

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Received October 5, 1995

Accepted March 8, 1996