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Ability of Cylindrical Root Form Implants to Withstand Controlled Lateral Forces

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ABSTRACT

ABILITY OF CYLINDRICAL ROOT FORM IMPLANTS TO WITHSTAND CONTROLLED LATERAL FORCES

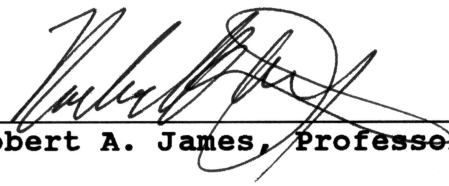
By

Silvio Emanuelli

The ability of root form implants to withstand lateral forces has been investigated in animal model. Two new techniques for quantification of forces generated by a loading device have been developed and tested. The strain gages bonded to the loading device were calibrated either intraorally by a micro load cell, or in laboratory by Instrom Machine.

Preliminary results indicate that laterally applied continuous forces up to 6,000 grams do not elicit failure of root form implants.

Each person whose signature appears below certifies that this thesis in their opinions is adequate, in scope and quality, as a thesis for the degree Master of Science.



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ABILITY OF CYLINDRICAL ROOT FORM IMPLANTS TO WITHSTAND CONTROLLED LATERAL FORCES

by

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A Thesis in Partial Fulfillment
of the Requirements for the Degree Master of
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INTRODUCTION

Research is needed for advancement in the understanding of implant failure and the possible clinical application of implants as orthodontic anchorage.

The literature suggests that overloading plays an important role in implant failure. Skalak (1) stated that "any force applied to the implant is transmitted to the bone without changes of magnitude or duration. Consequently the bone may be overstressed or fractured if sudden large impact forces are applied to the fixtures". He also stated that "although extensive data are not available on the failure loads of osseointegrated implants, the clinical experience indicates that the failure loads are well above the usual bite forces".

Lindquist (2), analyzing his results in a population of 46 patients treated with fixed tissue integrated prosthesis during an observation period of 3 to 6 years, concluded that "oral hygiene was found to be the most important factor associated with marginal bone loss. According to the analysis functional and loading factors were also of importance. Parafunctional activity, such as bruxism, both reported as tooth clenching and recording of occlusal wear on the prosthesis, led to increased bone loss.

The correlation between the length of the cantilever extensions and bite force on one side, and some bone loss values on the other side also indicated possible influences of overloading".

Hoshaw (3) conducted test to determine the effect of loading on root form implants placed in one cortex of whole fresh frozen dog tibiae. Branemark implants 7 mm long were axially and cyclically loaded at the rate of 50 N/sec. Failure was not observed for a 200 N load up to 3000 cycles. At 400, 600, 650, 700, and 800 N the cycles to elicit failure were 6356, 564, 7, 4, and 1 respectively. Brunsky (4) reported on interfacial shear strength, failure load of different implant material and configuration by push out single cycle overloading.

Macrointerlock implant samples macroporous coated, or with large threads or grooves cut into the surface, without "bioactive" coatings yielded a shear strength range from about 5 to 30 MPa that corresponds to failure forces of about 622 to 1532 N (5, 6, 7, 8, 9, 10). For macrointerlock systems with "bioactive" calcium phosphate coatings, data from the transcortical dog femur model show 32 week strengths of from 10.53 +/- 3.29 MPa to 12.12 +/- 2.43 MPa for uncoated versus HA-coated titanium implants. These values correspond to forces of 595-685 N (11).

For a microinterlock system without "bioactive" coatings the range of interfacial shear strength is about 1-4 MPa, corresponding to forces of from 68 to 230 N (12). HA coated microinterlock systems yield values of 6.07 +/- 1.29 MPa for shear strength versus values of 1.21 +/- 0.77 MPa for uncoated specimens. These stresses correspond to failure forces of about 68 N for titanium uncoated implants versus 343 N for HA-coated Ti-6Al-4V. The site of failure for HA coated samples was at the interface of the HA to the substrate metal (13).

Limitations of these experiments are due to the animal experimental models in which implants were tested in purely cortical bone, and the application of the forces by single cycle overload in a push out mode. These studies could actually overestimate the failure forces for implants in human bone of a mixed cortico-cancellous nature (4). The determination of the ability of root form implants to withstand lateral forces is important because there has been a considerable increase in demand for orthodontic correction of malocclusion in adults.

Orthodontists are being called upon to align teeth prior to prosthetic restoration in mutilated dentitions where lack of anchorage is a limiting factor.

Anchorage control is a major concern in the design of the orthodontic appliance. Extraoral anchorage, although stable, depends on patient cooperation. Intraorally derived anchorage does not require extensive cooperation and is generally more acceptable to the adult patient. In recent years there has been a notable interest in the use of implants as anchorage for both prosthetic and orthodontic appliances.

In 1945 Gainsforth and Higley (14) made a futal attempt to gain orthopedic anchorage by placing metallic screws and wires in the mandibles of dogs. Linkow (15, 16, 17), in 1970, published several reports of clinical studies utilizing implants as anchorage to move teeth. In the first use of endosseous implants for anchorage, they were subject to failure when placed under heavy laterally directed forces (18, 19, 20, 21). However, another study conducted by Gray and Steen (22) tested Bioglass-coated and uncoated Vitallium implants under lateral loads of 60-180 grams for a period of 28 days without failure.

An osseointegrated implant has been regarded as being similar to an ankylosed tooth, which is thought to function indefinitely without loss of its attachment to bone (23, 24, 25). Ankylosed teeth are not moved by heavy orthodontic loads (orthopedic force) and have been used as stable abutments for palatal expansion in monkeys (26).

This implies that "osseointegrated" implants should provide the same anchorage as an ankylosed tooth.

Roberts (27) placed pairs of multipart titanium implant systems, under 100 grams of lateral force, in long bones of rabbits for a period of 4-8 weeks. Only one of the 20 implants failed to remain rigid. Smalley (28) tested extraoral titanium implants as anchorage for orthopedic protraction of the maxillofacial complex in monkeys. He loaded the implants with lateral forces of 600 grams for a period of 8-12 weeks without any failures.

Few attempts have been made to study the effect of orthopedic lateral forces on "osseointegrated" titanium implants placed intraorally (29, 30, 31). Also, no attempt has been made to determine the amount of orthodontic force that can be placed on the implant without causing failure of the bone implant interface. To test the ability of implants to withstand forces Roberts (27) used springs placed between implants in long bones. Springs allow you to determine the exerted force level. Weaknessess of this loading device are the decay of force levels and the inability to monitor the level of force overtime. Servohydraulic test systems, used by Hoshaw, cannot be used readily intraorally.

The ability of the dental implant and its supporting tissues to withstand force depends on the nature of the applied force, the biomechanical characteristic of the implant, the bone response to mechanical stimulation, and the nature of the bone implant interface (32).

Force

The human natural dentition is capable of exerting a great deal of force. Their axial components are in the range of 200 to 2440 N and the lateral components are about 30 N (32). For dentures that are supported by dental implants vertical closure forces of from 42 to 412 N have been measured (33). Orthodontic and orthopedic forces are in the range of from 25 to 500 gr (34).

Implant's mechanical characteristics

The mechanical characteristics of an implant are dependent on the composition of the implant itself as well as the design. Intrinsic properties which include the elastic moduli, yield point, ultimate tensile strength, compressive strength, fatigue strength and hardness pertain to the material. Structural mechanical properties depend on

the intrinsic material properties and on the geometrical shape of the device. Dental implants are usually metallic devices made of titanium, titanium alloy, or cobalt crome alloys and may be treated on the surface with coating or other treatment. The design features of dental implants varies greatly (32).

Bone response to mechanical stimulation

The mechanical properties of bone have been extensively investigated. Bone is a complex anisotropic nonhomogeneous material with time-dependent viscoelastic properties (35, 36). Bone macromodeling controls the architecture of growing bone and is controlled itself in part by dynamic strains caused by the mechanical loads applied to bone (37, 38, 39). Wolff proposed in the 1890s that mechanical usage could evoke changes in the internal architecture of the bones (38). Two generally accepted and abundantly supported (39) assumptions about the mechanical determinants of bone architecture are: Under some circumstances the mechanical load on a bone can cause it to modify its architecture (40). The architectural change induced by a loading alteration usually improves the ability of the bone to carry the new loads (41, 42).

In 1963 and 1964, Epker and Frost (39, 41, 42) proposed general principles or laws to predict specific structural changes caused by specific changes in usage (43, 44, 45). They postulated that, for the bone modeling system, dynamic strains and/or strain rates equal to or greater than some minimum effective strain will initiate adaptive bone macromodeling, while lesser strain does not. The minimum effective strain for bone modeling represents a range of strain and/or strain rates below which strains do not appear to produce any modeling, above which they often do, and between which they do so with increasing regularity.

In vivo strain studies (46, 47, 48) suggest the range of the lower magnitude limit may be approximately 1000 microstrain (0.001 units) of tension or compression strain, and its upper limit 2000-2500 microstrain.

Studies which have included the femur and the tibia have been conducted in an effort to determine ultimate ability of both bovine and human bone tissue to withstand stress and strain (49). The values for the ultimate stress of human bone are: 133 MPa in tension, 193 MPa in compression, 51 MPa in tension applied in a plane perpendicular to the long axis, 133 MPa in compression applied in a plane perpendicular to the long axis, and 68 MPa in shear. The maximum stress that a bone can resist is strain-rate dependent (35).

Nature of the implant bone interface

The Branemark group in earlier studies (23, 24, 25, 50) claimed that, under carefully controlled conditions, a rigid union of vital bone to the titanium implant can be maintained indefinitely. In the absence of any pathology, continuous remodelling of the bone supporting the implant apparently maintains the rigid bone/implant interface in the presence of functional loading forces associated with mastication (22). Albrektsson (50) studied the attachment of bone to titanium specimens with TEM and SEM analyse. He stated that in an osseointegrated fixture "bone was not separated from the titanium surface by any fibrous tissue membrane. Collagen bundles were seen at the distance of 1 to 3 microns from the interface. Collagen filaments were observed closer to the interface, but always separated from the titanium surface by a proteoglycan layer of a minimal thickness of 200 A. This proteoglycan layer was partly calcified, and calcified tissue was observed in direct continuity with the implant surface at the resolution level of the equipment used, i.e., 30 to 50 A. Bone cells, and processes from them, were likewise separated from the titanium surface by a proteoglycan layer of a few hundred angstroms in thickness."

In a study by Sennerby (51), a method involving electrochemical dissolution of the bulk metal was used in order to study the intact interface zone between calcified bone and titanium implants with transmission electron microscopy (TEM). In this study of "in ground sections (about 10 microns thick) implant threads in the cortical bone were filled with mineralized bone after 12 months. In these sections the bone appeared to be in direct contact with the implant surface without any intervening connected tissue and
were thus, according to conventional criteria, 'osseointegrated'. However, when the same sections and the surface of the tissue implant bloc, were examined through a scanning electron microscope with a back scattered electron detector (BS-SEM), a narrow zone 2-10 microns wide, always separated the implant from mineralized tissue. The absence of this zone in the relatively thick ground sections is an artefact caused by overprojection of the dense metal and bone. Observation with TEM confirmed the presence of an interface zone which did not contain hydroxyapatite. The arrangement of the collagen and the absence of fibroblasts shows that this tissue is not connective tissue but rather decalcified bone tissue." A report by the same author in the same year concluded that the interface zone previously

In 1992, while reporting on the removal torque for screw-shaped pure titanium implants inserted in rabbit tibia and the femoral part of the knee joint, Sennerby found that the rupture occurred between the implant surface and the calcified bone (53).

Chemical bonding has been demonstrated at the ultrastructural electron microscopic level between the dense hydroxylapatite and bone (54,55). Long term maintenance of the rigid osseous fixation involves continuous remodeling of the interface and supporting bone (56).

The purpose of this study is to explore the efficacy of implants as orthodontic anchorage and to determine the critical lateral force overload (physiologic limit) for the monkey animal model. A loading device with the following characteristics was designed, fabricated, and tested: 1) capable of exerting lateral forces between coupled root form implants; 2) retrievable from the implants, yet providing solid connection with the implant body; 3) capable of exerting a given yet verifiable force overtime; 4) tolerable for the animals; 5) and incapable of deteriorating in an oral environment.

By conducting a pilot study the range of the amount of applied lateral forces required for implant failure was determined. This study attempts to answer these questions:

1. Is there a predictable periimplant clinical behavior for different forces applied, and how much force can be placed on an implant without causing failure?

2. Is the stability of an implant dependent upon specific intraoral location?

This study reports on preliminary observations of the animals and covers the design, construction, and application of the loading device.

MATERIALS AND METHODS

In this animal study paired root form implants were placed in edentulous sites created in the oral cavity of macaca rhesus. After the bone healed the implants were connected to a loading device capable of applying a given amount of force. The change in implant mobility and deflection measured between two fixed reference points was evaluated overtime. Pilot studies were performed in order to develop and test the loading device and to gather preliminary data on two of the animals.

Animals

The chosen animal model consisted of eight macaca rhesus monkeys. They were between 2 and 3 years old and weighted approximately 10-15 kg. The animals were housed in individual cages. Ventilation, temperature and humidity were controlled to provide an optimal environmental condition for the monkeys (60).

Diet

Water was always available, and sufficient food was provided to meet their nutritional requirements.

General surgical management

Before the surgical procedures each animal was anesthetized by an intramuscular injection of Ketamine (5 mg/Kg body weight). The technique for implantation followed the protocol recommended by the manufacturer and a modified draping was used for sterile purposes. After the face and the mouth were appropriately scrubbed with Betadine two sterile operating room towels (approximately 30 inches in length, with two sterile small caliber towel clips) were used for draping the head and neck (61).

The surgical protocol for the placement of the implants involved:

- Local anesthesia (lidocaine 2%, epinephrine 1:100,000)
- Incision (Bard-Parker #15)
- Elevation of the full thickness flap
- Preparation of the osseotomies as prescribed by the manufacturer (62)
- Placement of the implants
- Repositioning of the flaps and suturing

Each pair of implants was uncovered by following this surgical protocol:

- Local anesthesia
- Incision (Bard-Parker #15)
- Elevation of the full thickness flap
- Location of the implants
- Placement of screwable abutment posts
- Repositioning of the flaps and suturing

Implants

The implants used were Bio Vent, 3.5 mm D HA coated and plasma sprayed, purchased from the Core-Vent Corporation (57, 58, 59, 62). Implant lengths of 8, 10.5, and 13 mm were used to form couples with one long and one short implant.

Loading device

The loading device had an expansion screw that exerted force on a wire to produce force between the implants. Fig.1 The wire and the expansion screw are able to exert force on the implants through the posts that are secured to the implants with fixation screws. This device consists of two parts called male and female. Each part connects with the implant via an interlocking hex mechanism and a fixation screw. The housing of the expansion screw is soldered to the male part and the wire that transfers the load from the expansion screw is soldered to the female part. A strain gage (63) is glued to the wire and two wires extend from it. Both parts are custom waxed on a cast duplicating the intraoral location of the implants to insure optimum interimplant distance. Accurate quantification of the force applied was accomplished with the use of strain gauges glued

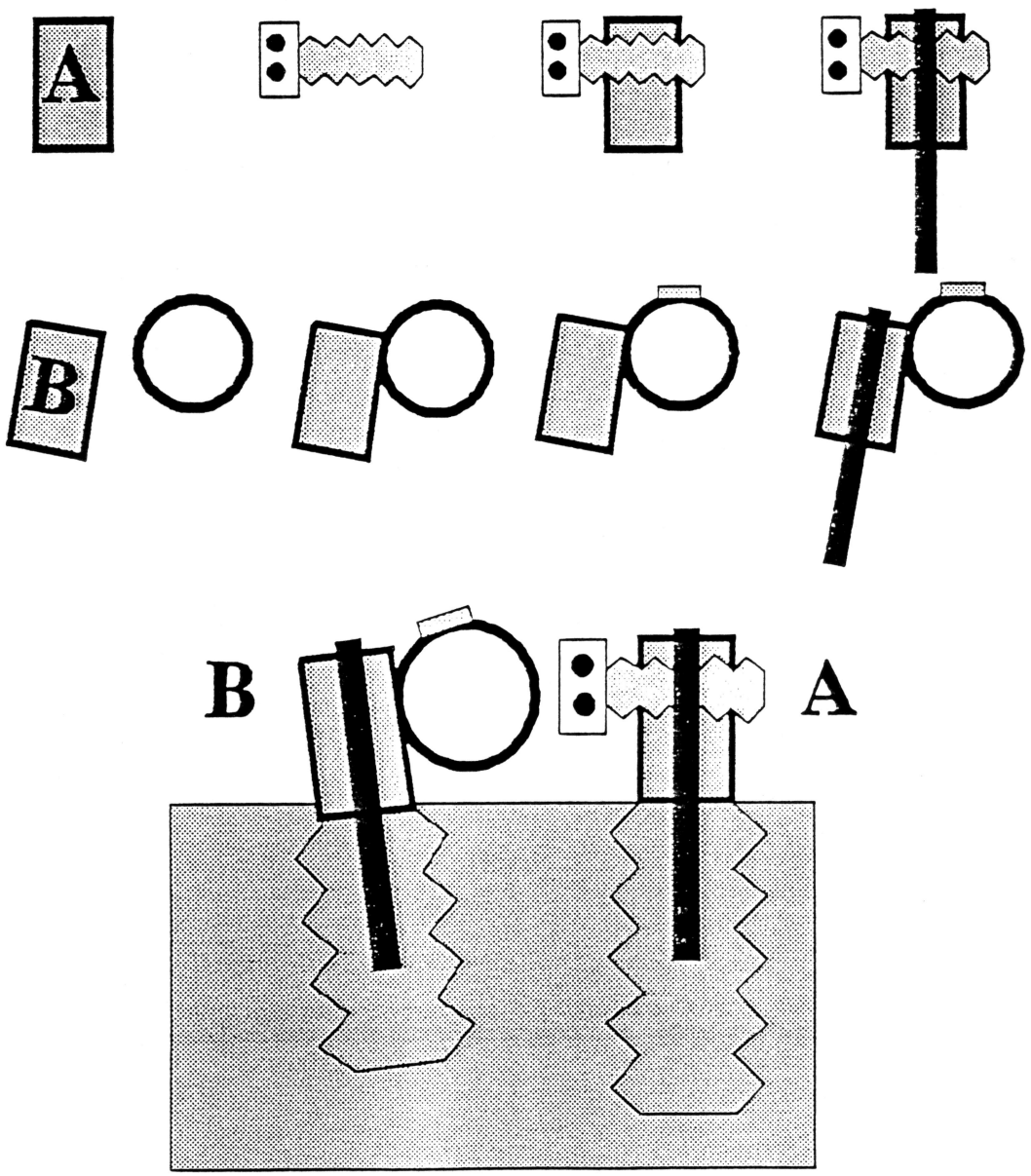


Figure 1. Construction of loading device. The male part (A) is constructed so that the housing will accept the expansion screw. A strain gage is bonded to a 0.018" X 0.025" stainless steel wire soldered to the female part (B). The ring is shown vertically for clarity but is actually horizontal.

directly to the metallic wire onto which the expansion screw is acting. Fig.2 These strain gages were connected to a digital output device so that the amount of strain applied could be recorded. Strain gages by Entran (EBS-020-120) are 1 mm long by 0.15 mm wide and were epoxied (Micro Measurements M-Bond 610) to a flattened area of the wire. An Entran MM45 series-low cost 4 1/2 digit transducer meter/power supply was used to quantify the output of the strain gage.

In the first monkey (pilot study) four different methods of strain measurement were employed. Fig.3 It was necessary to use alternate methods in response to specific problems which occured when measuring. When the strain gage was mounted directly on the expansion screw we found that the screw was so rigid, and the range of strain output was so small, that it was difficult to distinguish load levels adequately.

When the strain gage was mounted on the bend of a 0.028" round stainless steel U-shaped loop, the range of strain output increased, but the rotation of the U-shaped loop was off center and produced oscillations in the load versus strain curves. In addition, it was impossible to rotate the strain gage past the gingiva because the gage was located too far from the center of rotation for the expansion screw; and gingival clearance was minimal even when the gage was bonded to the expansion screw directly.

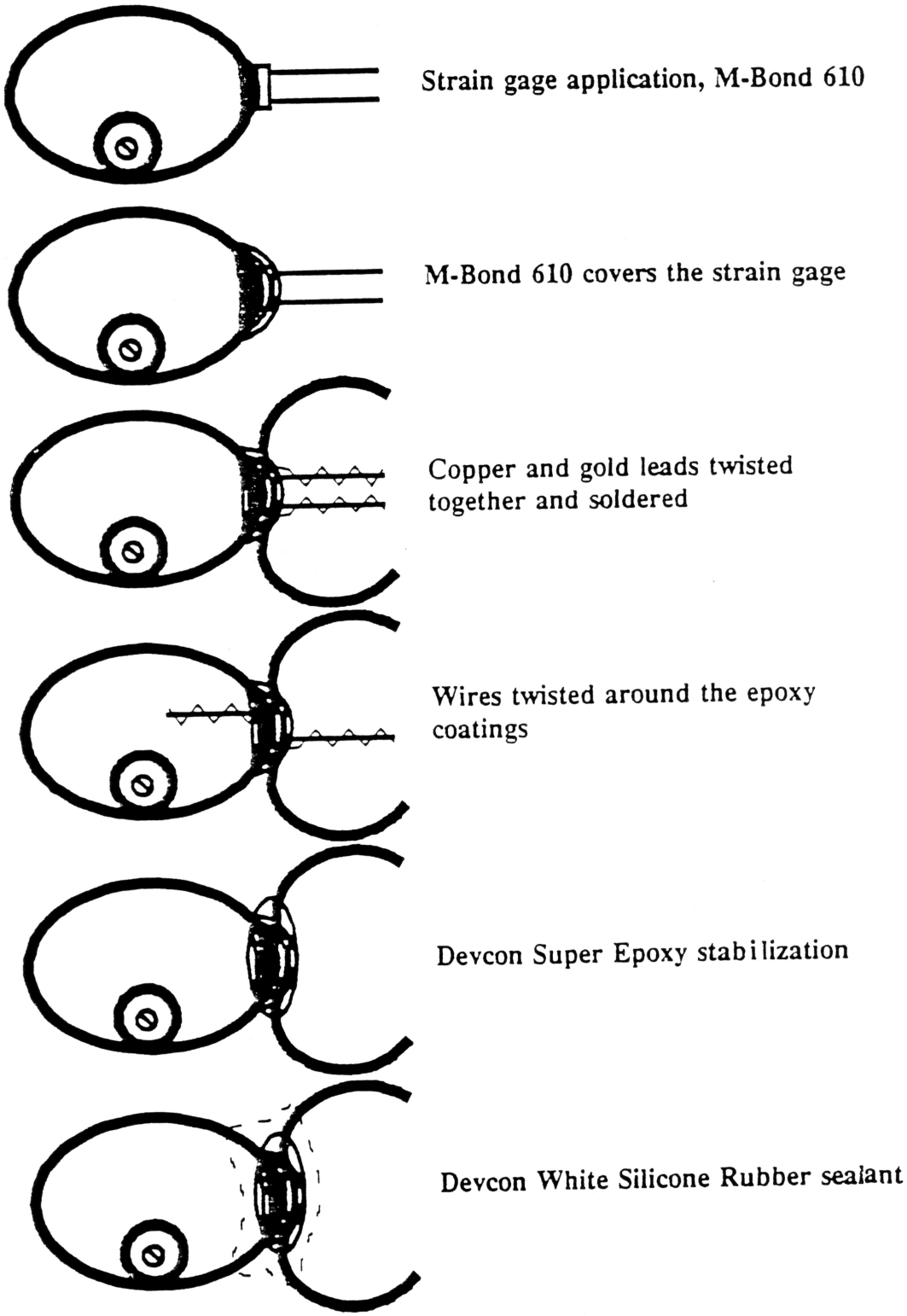
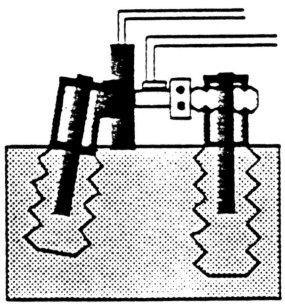
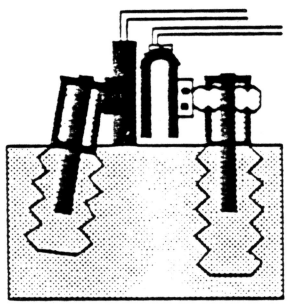


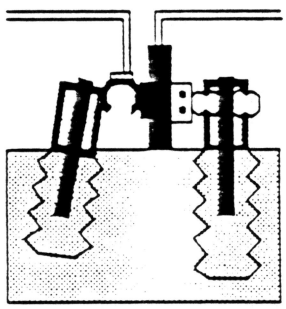
Figure 2. Schematic diagrams of the strain gage bonding sequence.



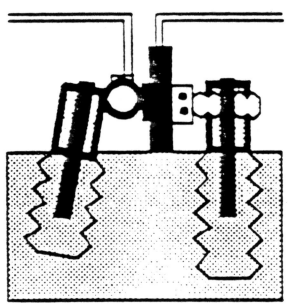
Strain gage mounted directly on the expansion screw



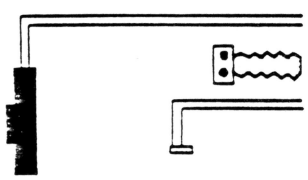
Strain gage mounted on the bend of a U-shaped wire which was in turn soldered to the expansion screw



Strain gage mounted to a fixed cut circle of rectangular stainless steel wire



Strain gage mounted to a fixed circle of rectangular stainless steel wire



load cell
expansion screw
strain gage

Figure 3. Four different loading devices used in the pilot animals.

Next a 0.016" by 0.016" stainless steel cut circle was soldered to the non-movable abutment, and the strain gage bonded to this cut circle. This eliminated the problem of gingival clearance, but the wire was not rigid enough to resist lateral deflection during force application. The cut circle was, in fact, bending and moving laterally causing the load cell to be loaded with an off centered load or to slip out of the assembly completely. A complete circle of 0.016" by 0.016" stainless steel wire soldered to the non-movable abutment solved the above problems. This provided an adequate range of strain output, equalized lateral deformation, and gave good gingival clearance.

Calibration of the strain gages was determined intraorally by load cells used in conjuction with the force applied (Entran ELO-200 Series low profile load cell, 5mm wide by 2mm thick), or extraorally by bench calibration with an Instron mechanical testing machine. Fig.4 Intraoral calibration was adequate to measure more than 2.7 Kg of force. Since this was the measuring limit of the load cell, each strain gage assembly was calibrated extraorally when higher force levels were employed. Extraoral calibration requires a carefully controlled environment in the laboratory setting. The objective of the extraoral calibration was to mimic as accurately as possible the experimental conditions and to create reproducible data helpful in the experimental procedures. Fig.5

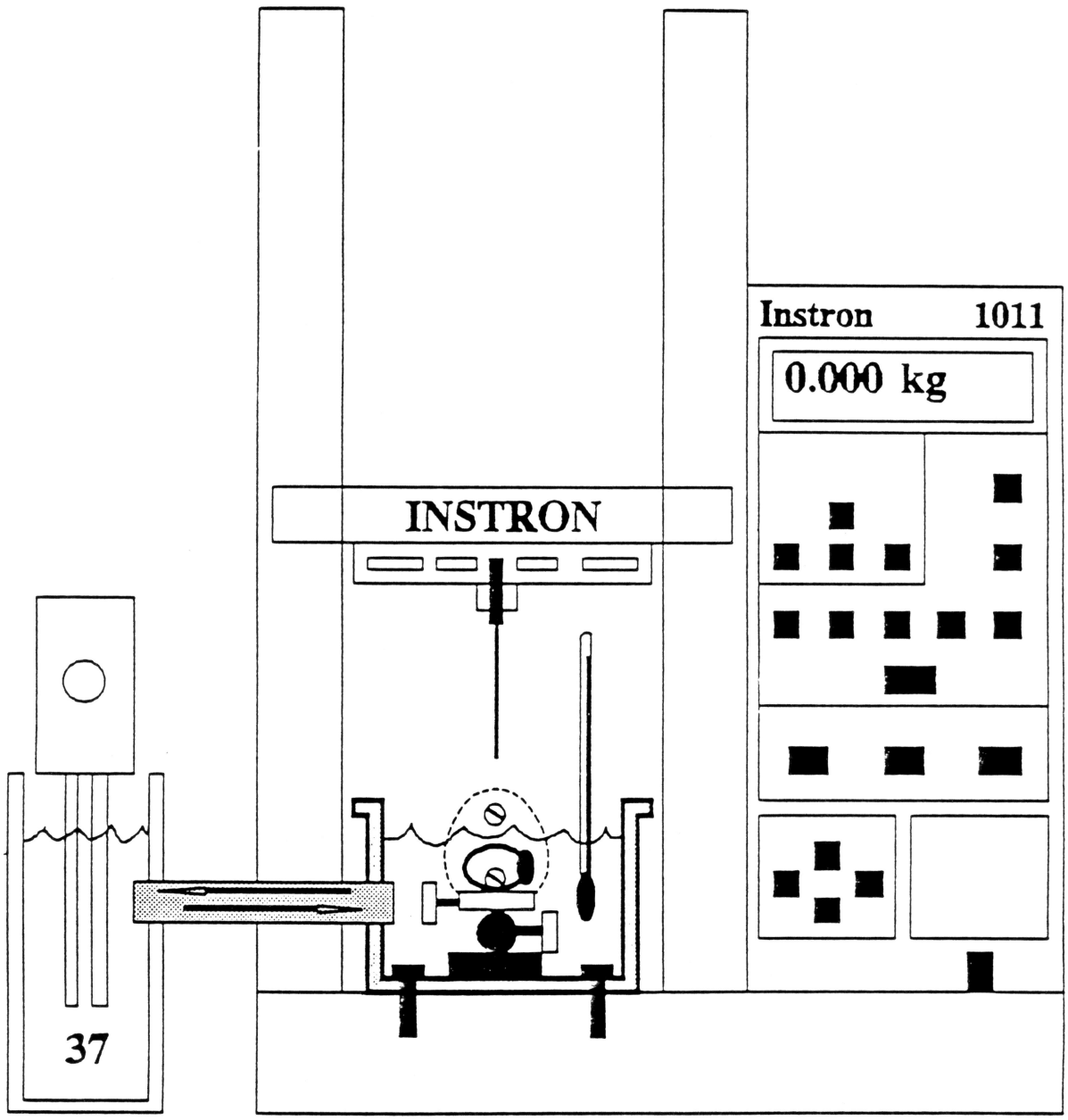


Figure 4.Instron 1011 machine and associated apparatus for extraoral calibration of the strain gages used with the second animal.

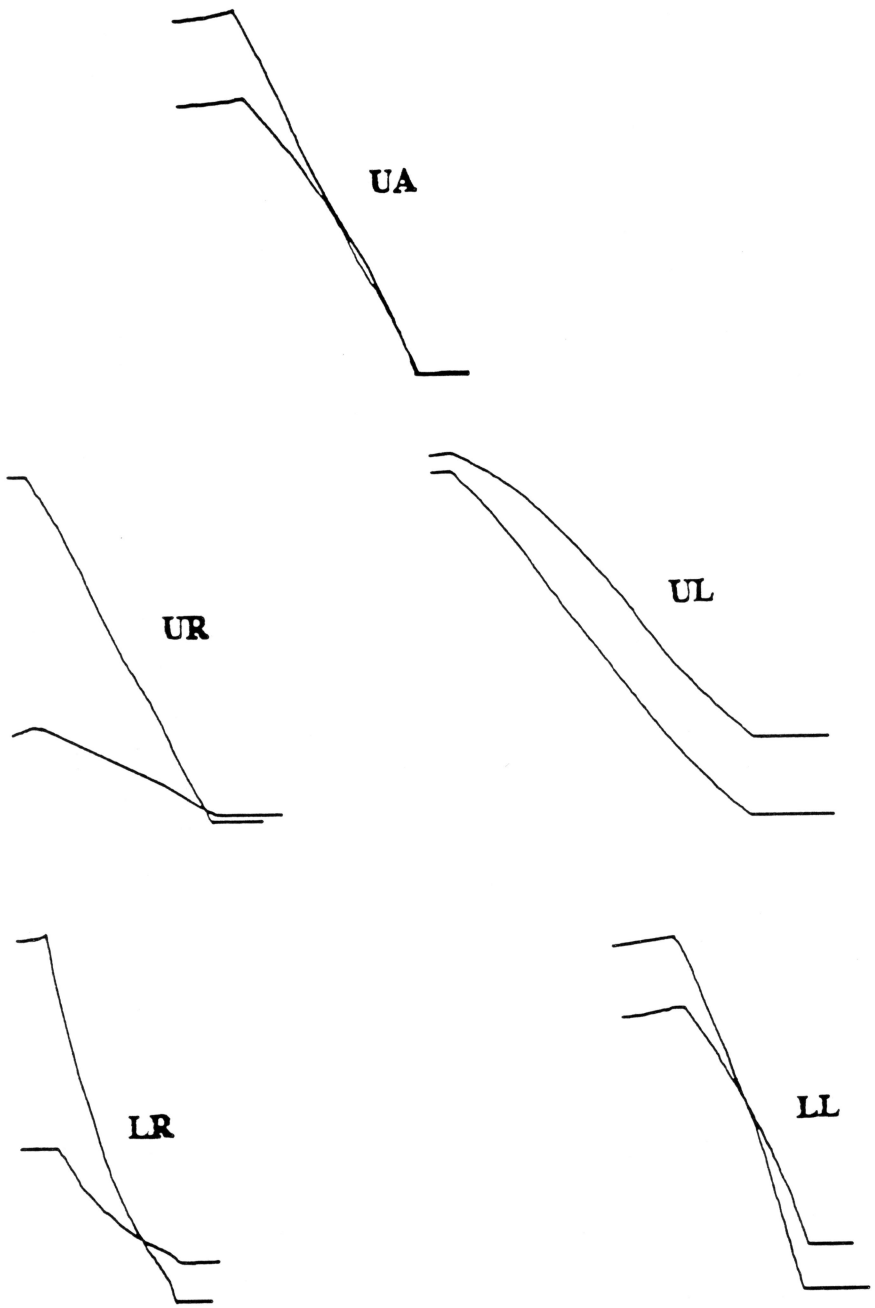


Figure 5. Load versus strain curves obtained from in vitro testing of the strain gage assemblies used in the second monkey. The same assembly consistently reproduces its characteristic curve.

Since strain gage output varies with changes in temperature and with the position and direction of the application of force, the experiment included a temperature control device in the form of a water bath. Force on the wire, in the same direction and position as the expansion screw, was applied with the use of a metal plunger. In order to calibrate the loading device a bench calibration protocol was established. An Instron machine (Instron Universal Testing Instrument- Model 1011) was used for the application of the loads. A low capacity load cell (50 Kg.) was mounted on the Instron machine. The inferior jig, which consisted of a cast obtained from the transfer impression of the position of the implants, made it possible to stabilize the female part of the loading device. The cast was then placed in a stone base that was held by the inferior part of a survejor. The inferior base of the surveyor had an universal ball attachment that allowed for fine adjustments of its position, and could be glued to the metal plate fixed to the Instron machine with acrylic resin. The metal mounting plate was fixed to the Instron machine with two screws and held the water basin in place. This plate and the basin were treated with silicone in order to stop any water leakage. A circulating system driven by an electric pump, an accurately positioned tubing system, and a thermometer helped to maintain a constant water temperature

in the basin. The male part of the loading device was supported by a metal plunger the same diameter as that of the expansion screw head. It was then screwed directly to the load cell on the mobile part of the Instron machine. The superior jig, screwed into the receptor of the Instron machine, ended with a small point and was positioned so that the force was directed on the flat part of the wire on the female post of the loading device. Fig.4 An example of the data showing the relationship between the applied load and the recorded strain of the metallic wire is shown in Fig.5

Measuring device

The measurements of the given forces were obtained from an amplifier that indicated the strain (63) in millivolts and the force measured by the load cell in grams. Details can be found in the description of the loading device.

For the assessment of the mobility of the implant a Periotest device was used (64, 65, 66). Periotest was developed by Siemens after 10 years of research and measures the support provided by the periodontal ligaments for the teeth or by the bone for implants. Since it was impossibe to measure tooth deflection by means of a fast method suitable for routine dental use, and it was absolutely necessary to have a fixed reference system, a system was developed by which the actual measurement is the amount of

time that a percussive rod is in contact with the tooth or implant. Changes in the periodontal structure affect the periodontal damping characteristics as well as the mobility.

The Periotest device consists of a handpiece and processing unit. The handpiece contains a percussive rod tip which flies freely out of the head of the handpiece. When the rod tip makes contact with the implant, the rod decelerates rapidly. Upon reaching zero velocity, an electromagnet immediately causes the rod to recoil from the implant and re-enter the handpiece. The rod taps on the abutment/tooth 16 times in 4 seconds. The sensor measures the amount of time the rod is in actual contact with the surface. The 16 measurements are registered in milliseconds. The microprocessor converts these millisecond measurements into Periotest values (PTV's) which range from -08 to +50. Currently Periotest seems to be the most reliable and objective means of assessing implant stability (66).

For the measurements of deflection, a micrometer was used to measure the distance between two fixed reference marks on the abutments. The mean of four measurements was used in our measuring procedures both for PTV's and movement.

Experimental procedures

The pilot monkey (#8685) underwent full mouth extractions, except for the canines and the first premolars, on September 25, 1990. Two months later, on November 27, 1990, five pairs of hydroxyapatite coated plasma sprayed Bio-vent implants were inserted.

Three different lengths of implants were placed in the pilot animal. Table 1 shows the location, position, and length of each implant. Five pairs of implants were placed, four pair were unequal in length and the fifth pair (mandibular anterior) was equal in length.

Table 1. Implant locations, positions, and length for monkey #8685.

Location	Position	Length
Mandibular Right	Posterior	10.5 mm
Mandibular Right	Anterior	13 mm
Mandibular Anterior	Right	10.5 mm
Mandibular Anterior	Left	10.5 mm
Mandibular Left	Anterior	10.5 mm
Mandibular Left	Posterior	13 mm
Maxillary Right	Anterior	13 mm
Maxillary Right	Posterior	8 mm (perforation)
Maxillary Left	Anterior	13 mm
Maxillary Left	Posterior	8 mm

Initial experiments involved the design of abutments that could be used to hold an expansion screw strain gage assembly in place so that the implants could be loaded with lateral forces. Early registration of the implants positions was done by endowel impression techniques. A plastic post was inserted into the implants and a polysulfide impression was taken of the endowels and seating surface of the implants. In the lab, a cast post type of abutment was constructed to which female threads of an expansion screw were soldered. After constructing five of these abutments it was determined that not all of them could be properly cemented in the correct orientation in the monkey's mouth. Some were cemented in the correct orientation in the monkey's mouth and some were cemented in incorrect orientations. The expansion screw was used to apply force to the second abutment of the pair. However, the cemented post always broke loose, just to the short length of the cast post, due to off-center loading.

Attempts were made to solder the expansion screws to the stock titanium abutments supplied by Core-Vent, but we were unable to do so. Core-Vent recommended casting gold, which has a low melting point, directly to the titanium abutments; however this also proved to be too difficult to accomplish.

To solve these problems, the internal hex feature of the implants was used. Custom abutments were waxed with a male hex feature which would slide directly into the female hex feature of the implant. This arrangement did not allow for rotation and did not require cementing; however, it did require an accurate registration technique.

The first of many experiments in the pilot animal began on August 11, 1991, nine and one half months after placement of the implants. The experimental apparatus is shown in the first diagram in Fig. 3 in which the strain gage was bonded directly to the side of the expansion screw. When a 400 gram load (calibrated in the mouth using a micro load cell) was applied to the maxillary right pair of implants, it was found that the mobility of the implants as tested by the Periotest apparatus did not change over a period of 12 days (Table 3 and Fig. 6). When the posterior abutment experienced a sharp increase in PTVs on the fifth day after loading, it was found that the screw holding the abutment in place was loose. After the screw was tightened on the seventh day after loading, the PTVs returned to their initial values. The experiment was terminated because the appliance was damaged during testing. We found that the epoxy resin had softened and could be easily removed from the expansion screw. We decided that the resin needed waterproof protection.

Another experiment with the same apparatus (first diagram Fig. 3) was started on August 15, 1991 at a load of 750 grams which lasted eight days (Table 4 and Fig. 7), at which time the posterior abutment was unintentionally rotated. During this period of time the implants were checked daily for mobility. There was no clinically significant change in implant mobility. This 750 gram load was applied to the maxillary left pair of implants.

These experiments taught us that a more sensitive measuring apparatus was necessary. In setting the above loads a change of 1 mv output from the strain gage resulted in a difference of approximately 500 grams. A series of bench tests were performed to evaluate the sensitivity of different types of apparatus. From the results of these tests, we decided to try a fixed cut circle apparatus as pictured in the third diagram in Fig. 3.

A load of 1,100 grams was placed on the maxillary right pair of implants on October 16, 1991. During the 26 days of the experiment the fixed cut circle was used with no increase in implant mobility (Table 5 and Fig. 8). Further attempts to use this fixed cut circle apparatus failed at higher load levels. An attempt to place this apparatus in the mandibular right quadrant of the pilot animal was made on November 12, 1991. When the load reached 1,500 grams the solder joint broke and the experiment was terminated.

On the same day, a similar cut circle apparatus was placed in the maxillary right quadrant. During this test, the ring always slipped, and off-center flexure occurred at loads above 1,500 grams. This experiment was terminated because of the off-center loading at higher load levels. To avoid off-center loading it was necessary to abandon the cut circle apparatus and adopt the fixed full circle design shown in the fourth diagram of Fig. 3. On November 21, 1991, an elliptical 16.2" stainless steel fixed quadrant was put into place. This test was aborted due to damage to the strain gage during the calibration process.

Successful use of the elliptical full circle appliance was first achieved on November 26, 1991 when a load of 2700 grams was applied to the upper right quadrant. An increase in PVT's occurred but returned to normal within a 48 day time period.

On December 20, 1991, a force of 2,850 gr. was applied to the mandibular right pair of implants in the pilot monkey. Twenty five days later on January 14, 1992, there was no change in implant mobility. This time the elliptical full circle rectangular wire was used.

The second monkey (#9091) received full mouth extractions exept for canines and third molars on September 28, 1990. Two months later, on September 30, six pairs of implants were placed as described in Table 2.

The loading device was calibrated and tested to exert 6,000 grams and was placed on the right mandibular implants on April 5 1992. The initial, postload, and subsequent strain values were recorded. Failure of the strain recording apparatus occourred during the second day post load. The PTV's and displacement measurements were recorded daily.

Table 2. Implant locations and length for monkey #9091

Location	Position	Length
Mandibular Right	Posterior	13 mm
Mandibular Right	Anterior	10 mm
Mandibular Anterior	Right	10 mm
Mandibular Anterior	Left	10 mm
Mandibular Left	Anterior	13 mm
Mandibular Left	Posterior	10 mm
Maxillary Right	Posterior	8 mm
Maxillary Right	Anterior	10 mm
Maxillary Anterior	Right	10 mm
Maxillary Anterior	Left	10 mm
Maxillary Left	Anterior	10 mm
Maxillary Left	Posterior	8 mm

RESULTS

The PTV's of the implants tested in the first monkey #8685 are shown for the initial load of 400 gr. in Table 3 and Fig. 6; for the initial load of 750 gr. in Table 4 and Fig. 7; for the initial load of 1,100 gr. in Table 5 and Fig. 8; for the initial load of 2,685 gr. in Table 6 and Fig. 9; for the initial load of 2,850 gr. in Table 7 and Fig. 10.

The PTV's and displacement values of the device tested in the second monkey at force values of 6,000 gr. are shown in Fig. 11.

Table 3. Periotest values obtained over 12 days. Initial load of 400 grams on the maxillary right implant pair in monkey # 8685. Top row numbers indicate days since load. Note that the posterior implant was always more mobile than the anterior. The PTV peak on days 6-7 can be explained by the posterior fixation screw becoming loose.

UR	Pre	Post	1	2	3	4	5	6	7	8	9	10	11	12
Ant.	0.0	-0.8	0.5	0	-.3	0	0.3	-.3	0.5	0	0.5	0	0	0
Post.	5	5	5	5	5	5.8	15	16	16	5	4.8	3.5	5	4.8

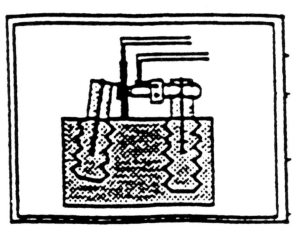


Table 4. Periotest values obtained over 8 days. Initial load of 750 grams on the maxillary left implant pair in monkey # 8685. Top row numbers indicate days since load.

UL	Pre	Post	1	2	3	4	5	6	7	8
Ant.	0.3	1.0	1.25	1.75	2.75	2.0	-0.25	2.75	2.75	3
Post	7	3.75	3.5	3.0	2.25	2.5	5.25	5.25	4.25	4.25

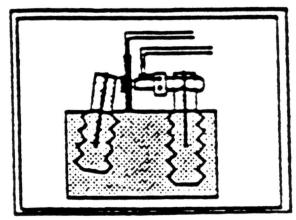


Table 5. Periotest values obtained over 26 days. Initial load of 1,100 grams on the maxillary right implant pair in monkey # 8685. Top row numbers indicate days since load.

UR	Preload	Postload	1	12	13	26
Ant.	3	-0.5	-0.5	2	0	2.75
Post.	6.25	2.75	2.75	5.5	7.5	5.25

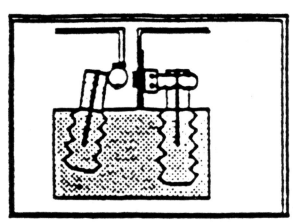


Table 6. Periotest values obtained over 48 days. Initial load of 2,685 grams on the maxillary right implant pair in monkey # 8685. Top row numbers indicate days since load. The peak of PVT on day 10 is unexplained, however, after 49 days the PVT had returned to normal values.

UR	Preload	Postload	7	10	49
Anterior	+3.00	+1.00	+0.50	+4.75	+0.25
Posterior	+2.50	+6.25	+7.25	+11.75	+5.5

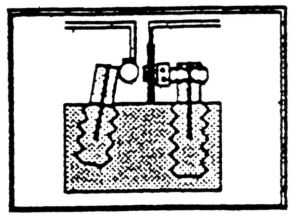
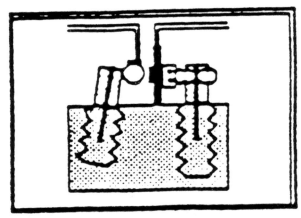


Table 7. Periotest values obtained over 25 days. Initial load of 2,850 grams on the mandibular right implant pair in monkey # 8685. Top row numbers indicate days since load.

LR	Preload	Postload	25
Anterior	+2.00	0.00	-0.25
Posterior	+3.25	+1.75	+2.00



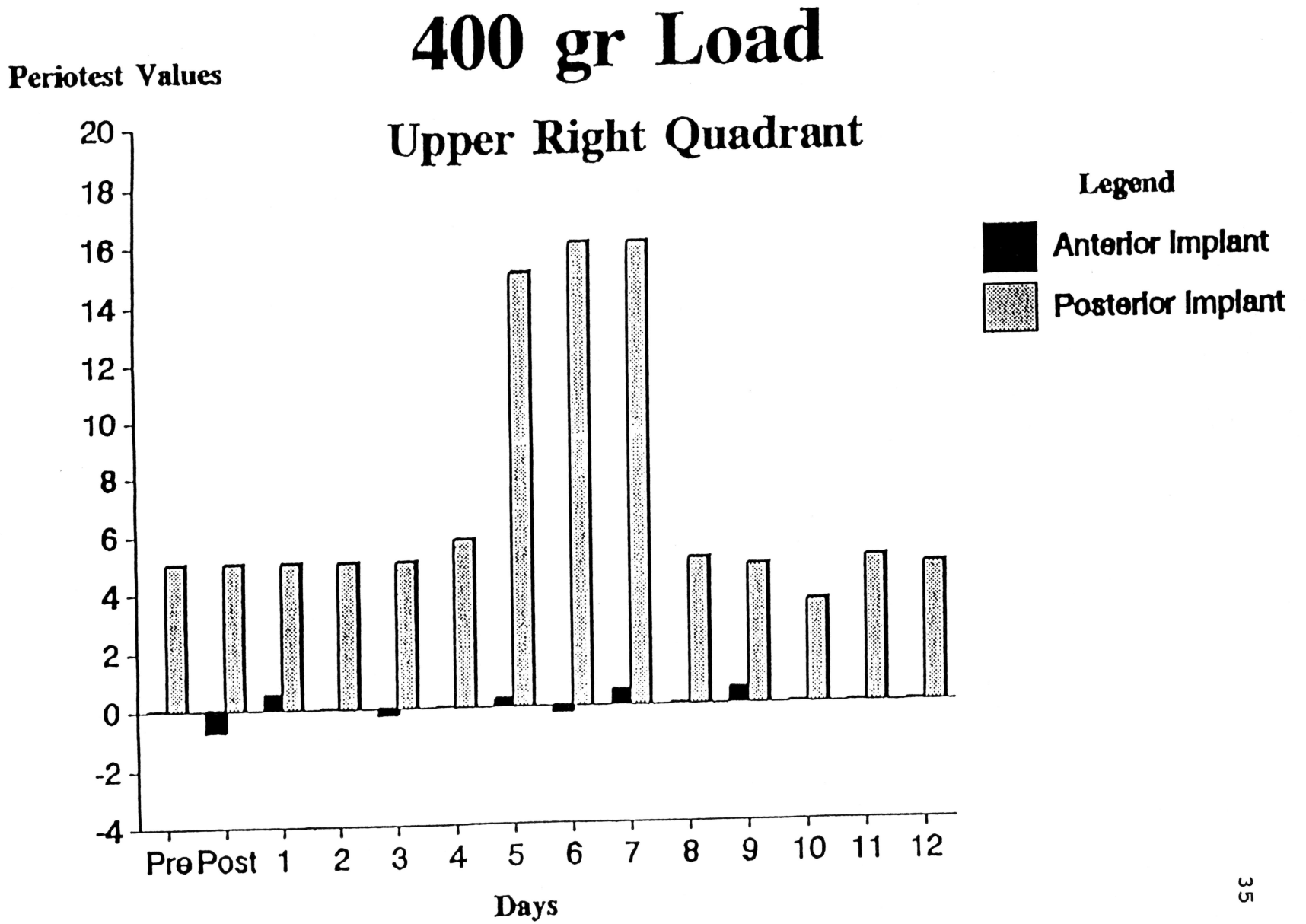

400 gr Load
Upper Right Quadrant
Periotest Values
20
18
16
14
12
10
8
6
4
2
0
-2
-4
Pre
Post
1
2
3
4
5
6
7
8
9
10
11
12
Days
Legend
Anterior Implant
Posterior Implant

Figure 6

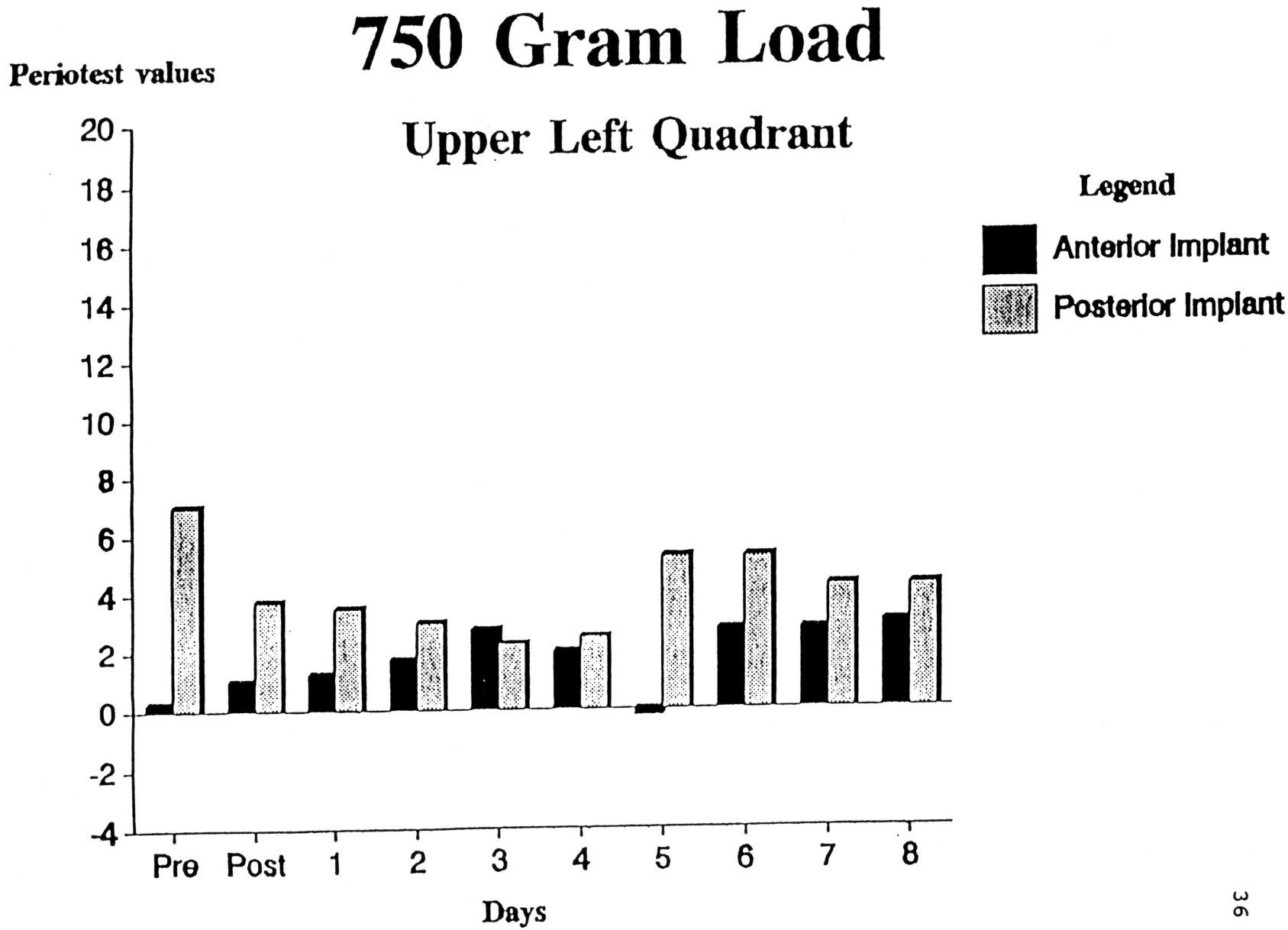

750 Gram Load
Upper Left Quadrant
Periotest values
20
18
16
14
12
10
8
6
4
2
0
-2
-4
Pre
Post
1
2
3
4
5
6
7
8
Days
Legend
Anterior Implant
Posterior Implant

Figure 7

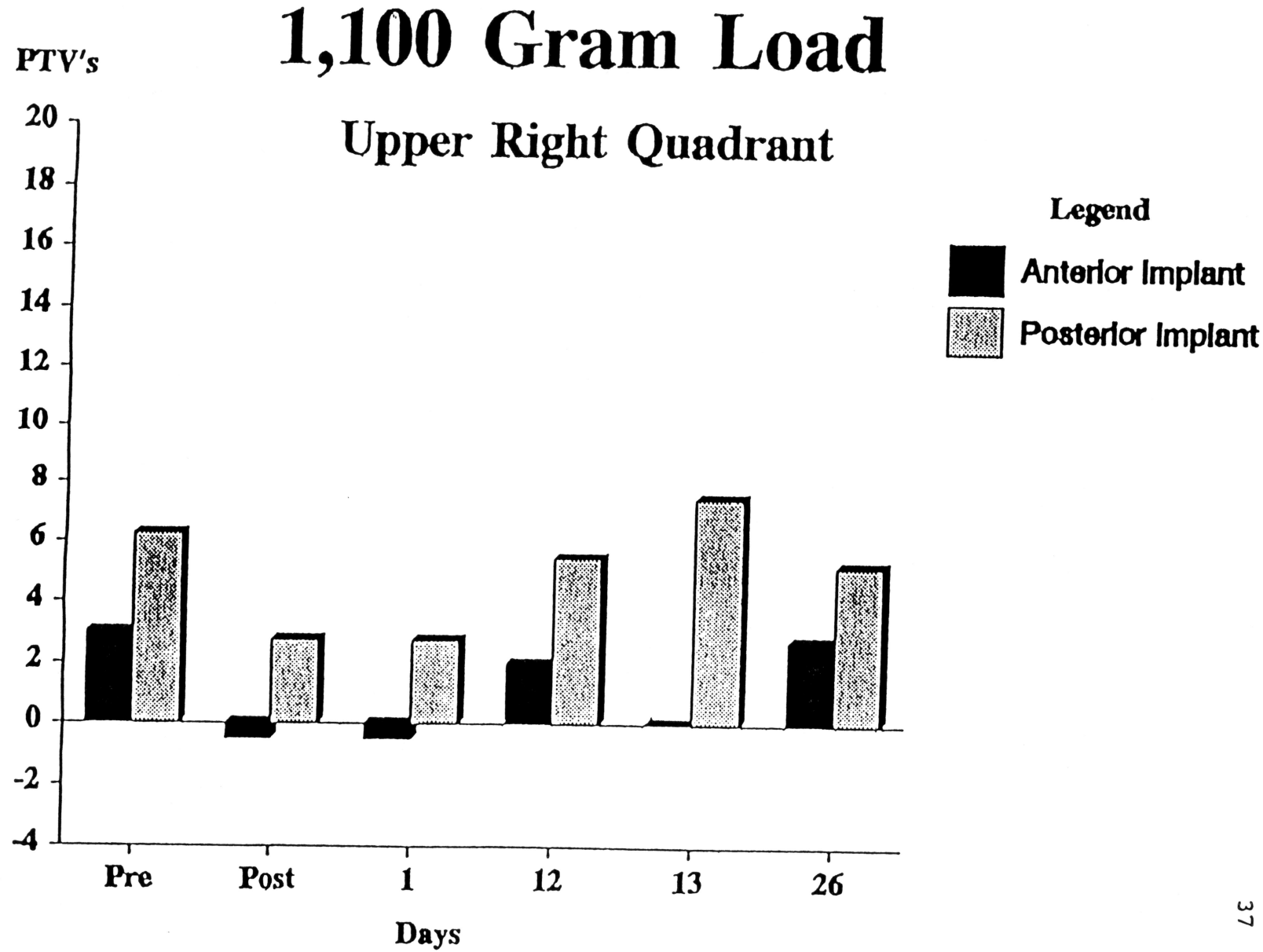

1,100 Gram Load
Upper Right Quadrant
PTV's
20
18
16
14
12
10
8
6
4
2
0
-2
-4
Pre
Post
1
12
13
26
Days
Legend
Anterior Implant
Posterior Implant

Figure 8

2,685 Gram Load

Upper Right Quadrant

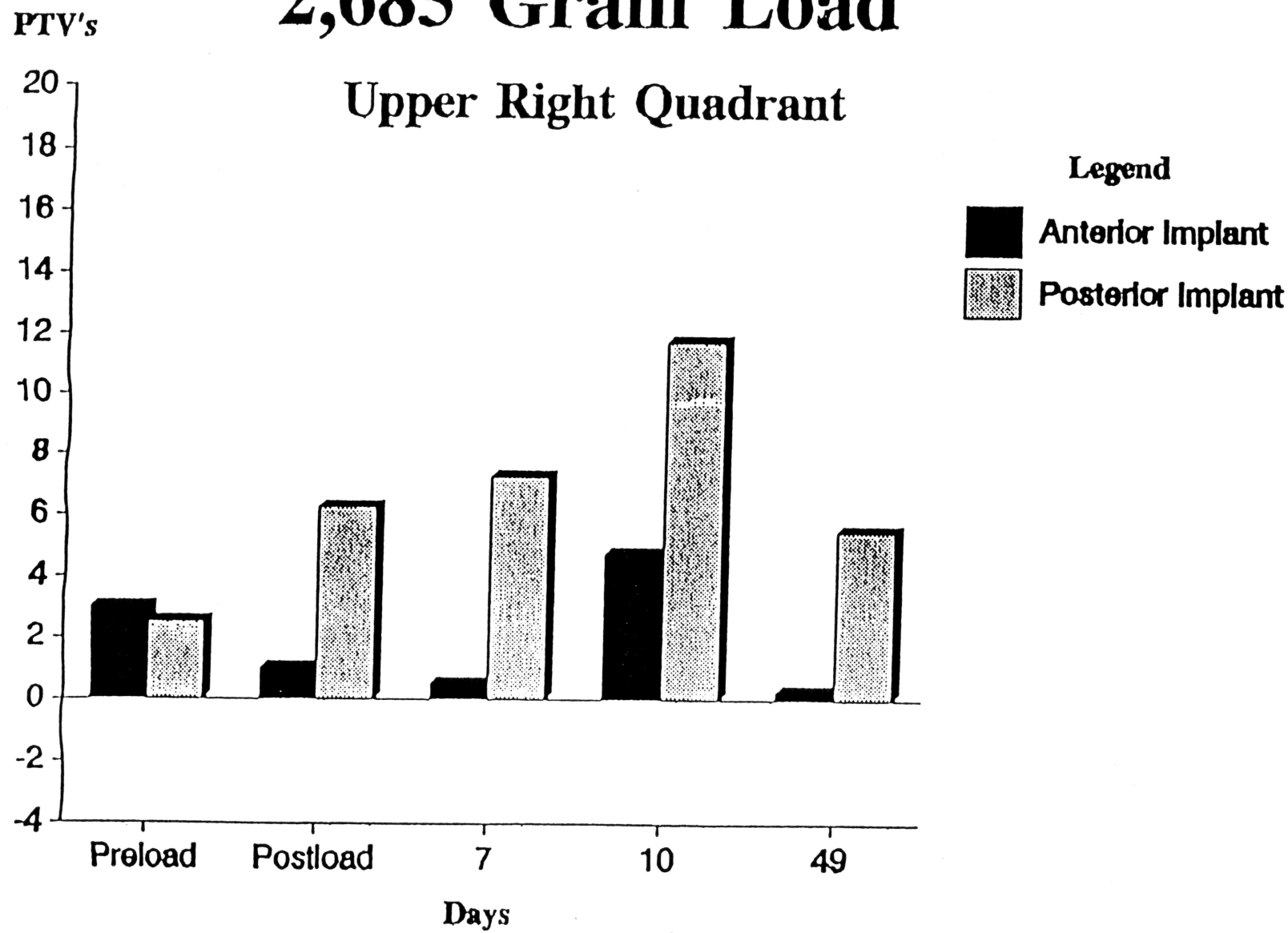


Figure 9

2,850 Gram Load

Lower Right Quadrant

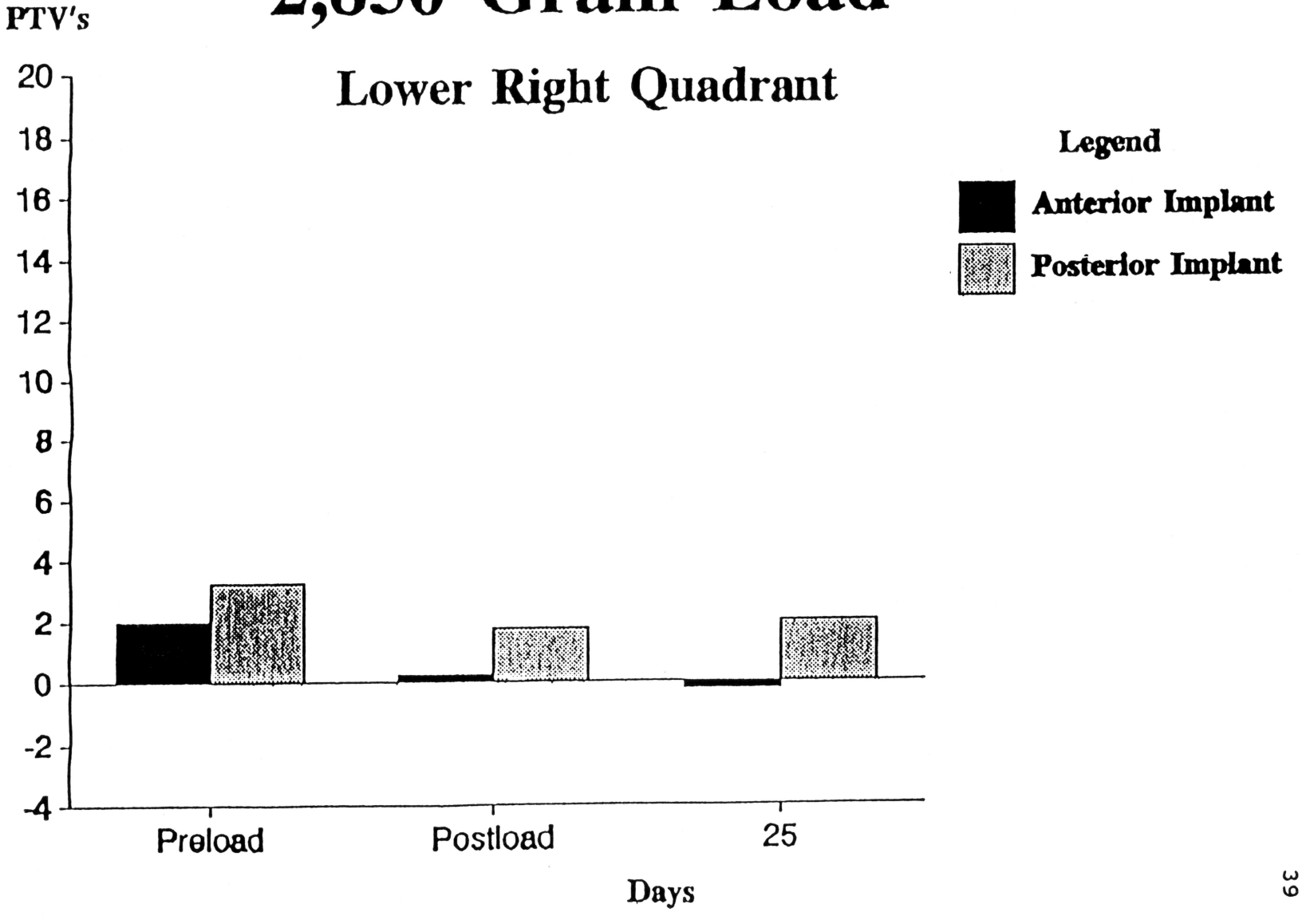


Figure 10

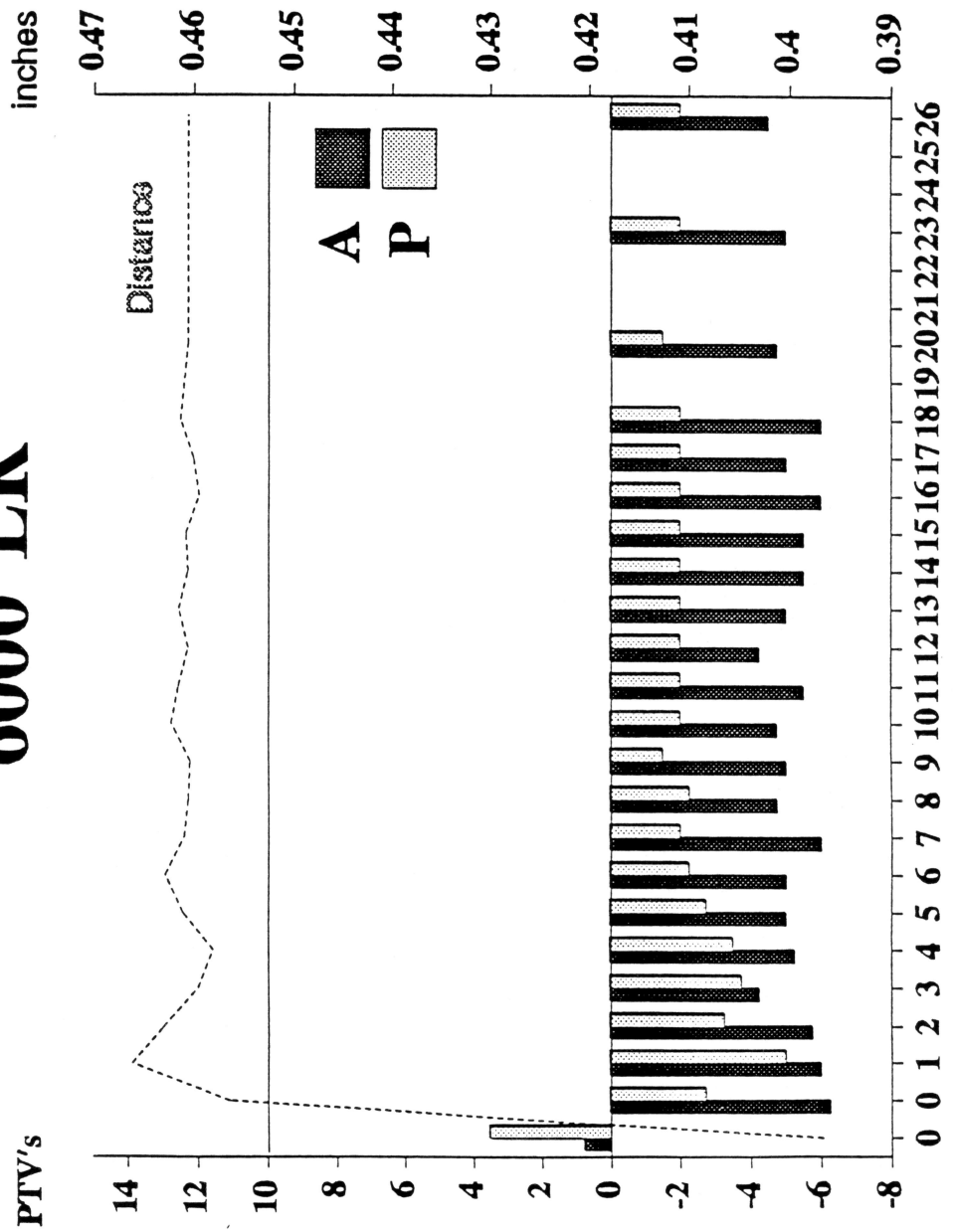

6000 LR
PTV's
inches
Distance
A
P
Days
14
12
10
8
6
4
2
0
-2
-4
-6
-8
0.47
0.46
0.45
0.44
0.43
0.42
0.41
0.4
0.39
0 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26

Figure 11

DISCUSSION

In this pilot study strain gage technology has been applied to the measurement of orthodontic and orthopedic loads placed on implants. Methods for force applications and measurements were developed and preliminary observations on load levels that would cause implant failures were reported. Preliminary data suggests that implants can withstand lateral forces several times greater than previously demonstrated.

The general standard for implant failure in other studies has been clinical mobility. In our study implant stability was judged by PTV's which are closely correlated with clinical mobility (64). Our data rarely exceeded +10 PTV's (+1 clinical mobility), and when it did, there was either a mechanical problem with the apparatus, or the PTV's in time returned to a more solid reading.

In our test at 400 grams on the upper right quadrant of monkey #8685, on the fifth day the PTV's of the posterior implant sharply rose to levels which might have been interpreted as implant failure (+16 PTV). It was found on further examination, that the screw which held the abutment to the implant had loosened, and when the screw was

retightened, the PTV's returned to the exact levels (+5 PTV's) that had been experienced in the first phase of the experiment. This indicates that no change in mobility occurred due to force application.

The second instance of PTV's exceeding +10 occurred in the test at 2,685 grams on the upper right quadrant in monkey #8685. In this experiment, the posterior implant experienced a +11.75 PTV on day 10, however, after 49 days the PTV's returned to normal values. The significance of this mobility remains questionable.

Although this pilot study has shown that osseointegrated implants can withstand lateral forces far in excess of loads previously reported by other authors, there were some differences between our force delivery system (expansion screw) and the force delivery system used by most other studies. These differences may confound comparison attempts.

All previous studies used a spring or elastic chain to apply the force between implants or between an implant and a natural tooth. These force delivery mechanisms produce continuous orthodontic force over time. This force is not dramatically reduced by minor movement of the tooth or implant. In our study we wanted to apply forces greater than those that could be produced by a spring or elastic chain, so an expansion screw was used to apply the force. Since implants behave as ankylosed teeth without a

periodontal membrane, we assumed that the implants would not move through the bone, therefore, once a load was applied it would remain constant.

Such an assumption may or may not be valid. It is more than likely true that implants do not move through the bone under load, but it is also probably true that bone under strain may bend or remodel in the area of or away from the implant interface. If bone bends progressively over time under load, expansion screw force could be dissipated relatively quickly. This would make it difficult to compare our data with that obtained by authors who used springs or elastic chain.

In analysis of these test results, it is important to distinguish between monotonic failure and "fatigue" failure caused by repetitive loading of the implants. It has been shown (35, 36, 37, 45) that multiple loading, cyclic loading, or progressive loading causes adaptive remodeling of the skeletal tissues. It may not be as clear that monotonic loading can also ameliorate remodeling of bone tissue. Our studies involve strong monotonic loading only. It will be interesting to observe the effect of monotonic loading on the adaptive remodeling capabilities of the bone tissues (if any). If a 6 kg load does not cause implant mobility, the role of overloading as a causal agent for implant failure could be diminished.

Technical problems in the design, construction, and application of the loading device made it impossible to follow the original plan for which the healing time (for implant placement and loading) would have been 6 months. This could have influenced the characteristics of the implant bone interface, thereby effecting our findings.

However, Gottlander's (67) report on HA-coated implants inserted in rabbit tibiae showed that with histomorphometric analysis there was a direct bone to implant contact percentage of 65.1% +/- 11.6% after six weeks. This percentage did not vary in the specimens examined that yielded 59.5% +/- 12.2% up to one year after they healed. This could indicate that the delay in loading did not effect our results.

CONCLUSION

Two new techniques have been developed to measure force levels applied to implants. We found that even a 6 kg lateral force did not cause failure of the implants. This suggests that overload may play a more limited role in implant failure than was believed before; and that orthodontists do not need to limit their force range when using implants for anchorage. Further investigations are needed, and are currently being performed, to determinate the critical force value able to elicit failure of root form implants.

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