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V. Leroy Leggitt

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ABSTRACT

NEW IN VIVO AND IN VITRO CALIBRATION TECHNIQUES FOR QUANTIFICATION OF LATERAL FORCE LEVELS THAT CAUSE IMPLANTS TO FAIL: A PROGRESS REPORT ON MONKEY RESEARCH

by

V. Leroy Leggitt

Two new techniques for quantification of forces generated by an expansion screw apparatus placed between pairs of cylindrical endosseous titanium implants are described, along with preliminary data gained from their use in *Macaca rhesus* monkeys. Strain gages were bonded to the expansion apparatus and were calibrated either directly by micro load cell, or indirectly by Instron Machine to reflect the applied force.

Immediate loads of up to 6 kilograms have been applied to the implants with no increase in mobility as verified by a Periotest device. No previous studies on the orthodontic uses of implants have evaluated *in vivo* forces of this magnitude in monkeys, used strain gages in quantification of applied loads, nor have they quantified mobility in terms of Periotest values.

The objective of this research is to define those load levels that cause these implants to fail.

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NEW IN VIVO AND IN VITRO TECHNIQUES FOR QUANTIFICATION OF LATERAL FORCE LEVELS THAT CAUSE IMPLANTS TO FAIL:

A PROGRESS REPORT ON MONKEY RESEARCH

by

XV. Leroy Leggitt

A Thesis in Partial Fulfillment of the Requirements for the Degree Master of Science in Orthodontics

June 1992

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

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Jim Harris provided initial technical consulting concerning the application of micro load cells and strain gages to this problem. Further review of the concept and significant contributions to apparatus design was by Garland Scott, Craig Andryko, Robert James, Subrata Saha, Joseph Caruso, Daniel Flores, and Silvio Emanuelli.

David Rynearson contributed the idea for the tantalium implants, and graciously supported us with his expertise in their use.

Assistance with the Instron machine calibration and use was by Paul Williams and Qiang Dai.

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INTRODUCTION

It is the objective of this ongoing research to document the lateral force levels that cause failure of hydroxyapatite coated titanium implants in monkeys. This paper introduces two new techniques for accurate measurement of forces applied to implants, and reports on preliminary data which show that these implants can withstand lateral forces on an order of magnitude greater than previously reported in the literature. A knowledge of these forces will enable the orthodontic clinician to use implants as anchorage within a biologically tolerated force range. This data will also be of primary interest to research implantologists who wrestle with questions concerning the cause of implant failure, and will be used to calibrate finite element analysis (FEA) models of implant behavior under load in the mandible. In this thesis, the orthodontic considerations will be evaluated.

Teeth necessary for anchorage are sometimes lost in patients needing orthodontic treatment. It has been proposed that osseointegrated implants may provide the missing anchorage and then be used as abutments for prosthetic reconstruction (Linder-Aronson and others, 1990).

Even in routine orthodontic treatment where teeth are not missing, the availability of anchorage (or lack of it) often determines the biomechanics employed by the orthodontist to achieve his treatment goals. Most anchorage used by orthodontists, pits more teeth against less teeth, one arch against the

1

other, or makes use of extraoral headgear type anchor points. If a practical means of gaining direct osseous loading (orthopedic anchorage) were developed, it could alter basic orthodontic biomechanics.

If implants can be shown through research to be useful in varied anchorage situations, not only would the biomechanical armamentarium of the orthodontist be expanded, but his reliance on traditional anchorage and patient cooperation would be reduced. An orthodontist who was unencumbered by cooperation and anchorage problems might be able to treat a much larger percentage of his patients without extracting teeth, without headgear, and without orthognathic surgery. Profile objectives might also be easier to achieve.

"Previous investigators have applied orthodontic forces to endosseous implants of various types. In the majority of these studies, forces were applied from implant to implant to test their stability under such loading (Smith 1979; Sherman 1978; Mendez and others, 1980; Roberts and others, 1984; Oliver and others, 1982, Gray and others, 1983; Turley and Roth, 1983). Other studies used an implant to facilitate the orthodontic movement of a tooth (Lubberts and Turley, 1982; Linder-Aronson and others, 1990), or the orthopedic movement of the maxilla (Turley and others, 1980; Smalley and others, 1988)." (Turley, 1988)

Of all the implant types previously studied, the endosseous titanium implants have provided the most encouraging results. Studies have shown excellent retention with titanium endosseous implants used for edentulous rehabilitation (Adell and others, 1981; Branemark and others, 1970). Their studies demonstrate that, under carefully controlled conditions, a rigid union of vital bone to the implant surface can be maintained indefinitely. This situation may be analogous to an ankylosed tooth that can function indefinitely without breaking its attachment to bone. Ankylosed teeth are not moved by even heavy orthodontic loading (Mitchell,1975), and have been used for palatal expansion in monkeys (Guyman and others, 1980). One difference between implants and ankylosed teeth, is that ankylosed teeth are vulnerable to resorption, whereas implants are not.

Mitchell's study (1975) showed that ankylosed teeth in a 37 year old man could not be moved by forces which ranged from 6 to 24 ounces, and Guyman (1980) showed that palatal expansion was achieved in rhesus monkeys by placing a "calibrated" 1-2 pound load on artificially ankylosed lateral incisors. The ankylosed lateral incisors did not move clinically or histologically. It is believed that osseointegrated titanium implants behave in a similar manner due to the lack of periodontal membrane.

Endosseous titanium implants have been subjected to lateral orthodontic forces in monkeys without failure (Linder-Aronson and others, 1990). In this study, elastic chain with a 60 gram force was used between a titanium implant and a natural tooth on one side of a monkey's mandible for eight weeks. It was found that the space between the implant and natural tooth decreased. As a control, the same force was applied on the other side of the mandible of the same monkey but this time between two implants. In this situation, no decrease in space between implants was observed over the same amount of time. In this experiment, the osseointegrated titanium implants did not move, nor did they appear histologically damaged by the lateral force of 60 grams. In this experiment, the implants were used successfully as orthodontic anchorage.

Roberts and others (1984), showed that a stainless steel spring stretched between osseointegrated titanium implants in rabbit femurs could withstand a 100 gram load for 4 to 8 weeks. The implant used by Roberts and others (1984), is remarkable, in that it was machined from commercial titanium and was of relatively small size (3.2 mm diameter, and 8 mm long).

Roberts and others (1989), used a somewhat different experimental protocol in dogs to place a 3 N (>300 gram) load between two titanium implants placed in intraoral locations. All their implants successfully resisted this 300 gram load for up to 13 weeks.

In 1988, Turley and others reported on orthodontic and orthopedic forces applied to titanium endosseous Implants. Orthodontic forces of 300 grams were produced between an implant and a natural tooth in dog mandibles. Orthopedic forces of 1000 grams were produced between implants in the zygoma and the maxilla of dogs. No failures were reported for up to a 32 week period.

Smalley and others (1988), achieved maxillary complex protraction in pigtail monkeys with precision springs applying an orthopedic force of 600 grams per side to titanium implants in the maxillary and zygomatic bones. No failure of the implants occurred during the tests. Other types of implants (other than endosseous titanium) have been evaluated when subjected to orthodontic or orthopedic force levels.

Pairs of Bioglass and Vitallium implants in rabbit femurs were loaded with forces of 60, 120, and 180 grams by Grey and others, (1983). These forces were generated by 0.022 by 0.008 mm stainless steel closed coil springs. The springs were previously calibrated by an Instron Material Testing Machine. After 28 days, no statistically significant amount of implant movement was detected and no implant failure was observed.

Vitreous carbon implants were studied by Sherman (1978), who found no implant failure due to loading the implants with a 175 gram force in dog mandibles.

None of the above studies (with the exception of Grey and others, 1983, who used an Instron machine to calibrate springs, and Turley and others, 1980, who calibrated springs with an Ohaus scale) have detailed methods of calibration of the force delivery system. Therefore the amount of force delivered is approximate and unclearly defined.

None of the above studies have attempted to define failure of the implant in ways other than gross clinical mobility. Clinical mobility is almost wholly subjective and a change in mobility from +1 to a +2 is usually due to drastic bone changes. In all fairness, histomorphometric analysis has been used by some of the above authors to judge the degree of osseointegration after loading for the experimental time period. Still their primary criteria for implant success is "firmness" and lack of "clinical mobility".

None of the above studies have documented the maximum force which may be applied to an osseointegrated implant without failure of the bone implant interface.

It is the express purpose of the present study to address these issues which have been lacking in previous research. To quantify force levels, we used Instron machine calibrated strain gages or micro load cell calibrated strain gages, and a Periotest device was used to electronically calculate mobility.

The Periotest device was introduced by Schulte and others (1983), and is used for objective discrimination of clinical mobility in natural teeth and implants. It consists of a microcomputer connected to a handpiece in which a rod held in low friction bearings is accelerated to impact with the implant. With impact, the implant is deflected and the rod braked. The microcomputer quantifies and displays a digital value which reflects this braking time. If the implant is mobile, the braking time will be longer and the corresponding digital Periotest value (PTV) will be greater than if the implant is rock solid.

Teerlink and others (1991), report on the use of the PTV's in the "clinical diagnosis of bone apposition toward implants". The PTV's of Branemark osseointegrated implants ranged between -4 and +2, with 87.5% of the measurements being less than zero.

According to the manufacturer, reproducability of PTV's is $+_1$ PTV for anterior teeth, and $+_2$ PTV's on posterior teeth. They compare a +10 PTV with Miller Scale +1 mobility values.

MATERIALS AND METHODS

Eight female *Macaca Rhesus* monkeys, two to three years in age, were selected as animal models. The animals were maintained in the animal care facility at Loma Linda University. In general, all teeth were extracted except for the permanent canines, and third molars (figure 1, B). This resulted in six edentulous areas into which implants were placed; maxillary right, maxillary left, maxillary anterior, mandibular right, mandibular left, and mandibular anterior. Anesthesia was accomplished by an intramuscular injection of ketamine (0.75 mg/kg body weight). Lidocaine 2% with 1/100,000 epinephrine was used for local anesthesia. Sterile technique involved draping the head and neck with sterile towels, and scrubbing the monkey's face and mouth with betadine.

Two months after the extractions were performed, one pair of Bio-vent 3.5 mm diameter hydroxyapatite coated plasma sprayed implants was placed into each edentulous area (figure 1, C). One implant of each pair was usually longer than the other, enabling us to predict that the short implant would fail first (if overloaded). Implant lengths were 13 mm, 10 mm, or 8 mm. The technique for implantation followed that recommended by Core-vent.

The implants were allowed to osseointegrate for one year before they were uncovered. At the uncovering surgery, covering bone was removed from the top of the implants, and a registration was made of the relative orientation of the implants by screwing titanium copings (Core-Vent TCT) into the implants and locking each pair of abutments together with cold cure acrylic (Trim). The

8



(A)

(B)



Figure 1. Schematic diagrams outlining major steps in the experimental procedure. (A) Shows the palate and dentition of a rhesus monkey (modified from Guyman et al. 1980); (B) illustrates the edentulous areas created by planned extractions; (C) shows the sites of implant placement in the edentulous areas; and (D) illustrates the placement of the experimental apparatus.

titanium copings were unscrewed (internal screws), and the abutments and plastic registration were removed as a unit. At the same surgical appointment, osseointegration was confirmed by Periotest readings. If the implants were mobile to percussion from the Periotest apparatus (>+10 PTV's), they were considered non-osseointegrated and were therefore not used in this study.

Implant analogs (Core-Vent IA3) were attached to the titanium copings and set in die stone. The resulting model (analogs in stone) exactly reproduced the geometry of the implants. This analog model was used to construct custom cast alloy abutments (figure 2). These custom cast abutments were waxed up with male hex type attachment to fit the female hex receptor of the implants. The use of the hex feature allowed us to minimize rotation around the center screw, thus maintaining an accurate geometry.

Several different configurations of the two abutments were used during the early phases of experimentation (figure 6), however, the standard configuration adopted for all monkeys except for the first monkey, was constructed as in figures 2-4 and described below.

The female threads of one side of a conventional 6 mm expansion screw from Rocky Mountain Orthodontics (#06591) were soldered to one of the custom cast abutments (abutment A, figure 2) in such a orientation that the expansion screw when turned would move exactly toward the long axis of the other abutment (abutment B, figure 2).

An oval ring made of .018" x .025" rectangular stainless steel wire was



Figure 2. Construction of abutment A and abutment B. Abutment A was constructed with female threads to accept the expansion screw. A strain gage was bonded to a 0.018"x0.025" stainless steel ring which was soldered to abutment B. The ring is shown in vertical orientation for illustrative clarity, but was actually oriented horizontal and parallel to the gingiva. A center screw held the abutments to the implants. A hex attachment (not shown) between the abutment and implant kept the abutment from rotating around the central screw.

constructed and soldered to abutment B in such an orientation that the flat plane of the ring was parallel to the gingiva (note that in figure 2, the ring is shown not parallel to the gingiva for clarity of illustration) and in line with the expansion screw, so that as the expansion screw was turned, it would contact the stainless steel ring in the same plane. A nonrigid connection was maintained between abutments so that the implants could respond independently to the applied force (figures 2 and 5). This geometry allowed a force to be placed between the two implant abutments by turning the screw (figure 5). This force passed through a line roughly perpendicular to, and directly through the long axis of the abutments. The stainless steel ring and the expansion screw were about 3 mm above the gingiva.

In order to measure the strain produced in the wire ring by the force of the expansion screw, a 1 mm long by 0.15 mm wide silicone semiconductor strain gage (Entran ESB-020-500) was bonded to the outside surface of the ring in a position that would not interfere with force application by the expansion screw. In this position, the length and resistance of the strain gage would increase as the force was applied by the expansion screw. The protocol for strain gage application was as follows and as illustrated in figures 3 to 5.

The ring-abutment-B apparatus was prepared for bonding of the strain gage by sandblasting the ring portion, and then degreasing thoroughly with Measurements Group Inc., CSM-1 degreaser (1-1-1 Trichloroethane). M-Prep Conditioner A (a water-based phosphoric acid surface cleaner) was applied to the



Strain gage application, M-Bond 610

M-Bond 610 covers the strain gage

Copper and gold leads twisted together and soldered

Wires twisted around the epoxy coatings

Devcon Super Epoxy stabalization

Devcon White Silicone Rubber sealent

Figure 3. Schematic diagrams of the strain gage bonding sequence.

bonding site and swabbed away with a single stroke of a cotton swab. M-Prep Neutralizer 5A (a water-based ammonia alkaline surface cleaner) was next applied and again was swabbed away with a single stroke of a cotton swab. The surface of the ring was now free of contaminants that might have interfered with the bonding of the strain gage to the stainless steel.

The epoxy resin used to bond the strain gage to the stainless steel was M-Bond 610, made by Measurements Group Inc., and recommended by Entran Devices Inc., (the maker of the strain gage) for use with this strain gage. A single layer of M-Bond 610 was applied to the prepared surface and placed in an oven and heated to 400° F for one hour. A second layer of M-Bond 610 was applied over the first and the strain gage applied directly into the wet epoxy. A jig to hold the abutment and strain gage gold leads in position was constructed from thermosetting modeling compound (Sculpey III, Polyform Products Co.). Oven heat was applied for the same temperature and time to cure this second coat of epoxy resin. Two additional overlay coats of M-Bond 610 were usually applied.

The thin gold leads of the strain gage were stabilized by application of a thin layer of Devcon Super Epoxy resin (1 min. set time). Two phono jack wires were prepared to be soldered to the gold leads by stripping both ends and on one end of the wire, clipping away all the copper strands except for one. This copper strand was similar in length and diameter to the gold lead of the strain gage. This end of the phono jack wire with one copper strand was glued to the bonding



Figure 4. Photograph of a stage in the bonding process. Note the sandblasted rectangular wire bent into a rough elipse and soldered to abutment B. The red and blue wires lead to the bridge and meter. The strain gage is embedded in the epoxy resin and the wire leads will be twisted together and soldered. The black foreground is the custom jig used to hold the apparatus during bonding.



both abutments. Hex attatchemnts to the implants kept the abutments from rotating when the expansion force was applied. The abutments are shown as circle A and circle B with center screws which tighten the abutments against the implants.

site adjacent to the strain gage with cyanoacrylate cement so that the copper lead and the gold lead were parallel and could be twisted together (figure 4). Thus, two altered phono jack wires were glued adjacent to the strain gage and each single copper strand was twisted with one of the gold leads from the strain gage. Rosin core electrical solder was applied at very low heat with a 15 watt soldering pencil. If the solder was applied too hot, the gold lead would disintegrate. The resistance of the strain gage was immediately checked with an ohmmeter to be sure the solder joints were excellent.

With electrical conductivity of the device confirmed, the soldered wires were twisted around the epoxyed assembly without touching each other and secured in place by a layer of Devcon Super Epoxy. This layer of super epoxy resin insulated the wires from each other, and from exposure to the external environment. Since epoxy resins are somewhat water soluble, Devcon White Silicone Rubber was applied over the complete bonding assembly and over the wires which exited from the bonding assembly. A watertight seal was prerequisite for long term performance in the oral environment.

The strain gage was connected to an external wheatstone bridge and the output from the bridge was measured in millivolts by a programmable MM45K-10/ST 4.5 digit transducer meter/power supply obtained from Entran Devices Inc. This meter is very sensitive with +/- 19,999 internal counts.

Each assembly thus constructed was found to have different strain output values for the same applied force (figure 8). This was due to several factors: the

strain gages were unmatched, the rings were of slightly different geometry, and the angulation of the implants was highly variable. Because of these differences in response rates, it was decided to calibrate each assembly individually.

In the first monkey direct intraoral calibration was accomplished by the use of a 5 mm diameter x 2 mm thick load cell (ELO-200-4) manufactured by Entran Devices Inc. This load cell was placed in series with the force, between the expansion screw on abutment A and the ring-strain gage assembly of abutment B (figure 5). As the expansion screw was turned, the force applied could be read simultaneously with the strain produced in the stainless steel ring. Several measurements were made to confirm the reproducability of the data (i.e. that the same strain was produced at the same force level). Then the load cell was removed from the system, and the expansion screw tightened against the ring/strain gage assembly until the same strain was reset. Once the calibrated strain was reset, it was logically assumed that the same force had been applied. At this point the expansion screw was locked in that position with cold cure acrylic or light cured composite. The acrylic or composite did not extend to lock the two abutments together, therefore they remained free to experience independent movement under load. The described apparatus was not in occlusal contact with opposing devices or dentition.

The expansion screw was not unlocked until the experiment was terminated. Only a single initial load was placed between each pair of implants. The thrust of this experiment was to determine the lateral force level that would cause osseointegrated implants to fail. Failure of the implants was defined as clinical mobility. To quantify mobility values, a Periotest device was used.

The Periotest device was developed by Siemens and German universities to measure support for the tooth provided by the periodontium. It has been applied by Teerlinck and others (1991) to the measurement of support for the implant provided by the bone tissue.

The Periotest device consists of a handpiece and processor unit. The handpiece contains a percussive rod tip which flies freely out of the head of the handpiece. When it contacts the implant, the rod decelerates rapidly, and when it reaches zero velocity, an electromagnet immediately causes the rod to recoil from the implant and back into the handpiece. The actual measurement is the amount of time the percussive rod is in contact with the implant. Each implant is percussed up to 16 times and the actual measurement is an average of the contact time over the 16 trials. The Periotest is able to measure subtle changes of implant resistance as small as 2-3% (Teerlinck and others, 1991).

In summary, a specific load was placed between two implants and the strain on one of the abutments recorded. The load cell was then removed, and the system reset to the same strain. Logically the reset strain was the result of an identical force. Thus the force applied was quantified and equal to the initial load cell output. The abutments were tested for mobility with the Periotest device immediately before load application and immediately after load application. These Periotest values were recorded as baseline indicators of osseointegration, and baseline indicators of mobility under load respectively. The abutments were periodically tested for degree of mobility with the Periotest device for periods of time of up to seven weeks.

In the first monkey (pilot study), four different methods of strain measurement were employed (figure 6). Alternate methods were instigated in response to specific problems which arose during force measurement.

When the strain gage was mounted directly on the expansion screw (figure 6, A), we found that the screw was so rigid that the range of strain output values was very narrow. It proved 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 (figure 6, B), the range of strain output dramatically increased, but it was noted that the rotation of the U-shaped loop was offcentered and produced oscillations in the load versus strain curves. In addition, it proved impossible to rotate the strain gage past the gingiva since the gage was located far from the center of rotation of the expansion screw, and gingival clearance was minimal even when the gage was bonded to the expansion screw directly.

To solve these problems, a .016x.016 stainless steel cut circle (figure 6, C) was soldered to the nonmovable abutment, and the strain gage bonded to this cut circle. This eliminated the problem of gingival clearance, but it was found that the cut circle of square wire was not rigid enough to resist lateral deflection during force application. As the force was applied, the cut circle asymmetrically



A) Strain gage mounted directly on the expansion screw

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

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



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

load cell expansion screw strain gage

Figure 6. The four different measurement devices used in the pilot animal.

bent and moved laterally toward the cut point. This always caused the load cell to be loaded with an off centered load, or to slip out of the assembly completely.

A complete circle of .016x.016 stainless steel wire soldered to the nonmovable abutment solved the above problems (figure 6, D). It gave a adequate range of strain output, equalized lateral deformation, and gave good gingival clearance.

With this assembly, we were able to apply more than 2.7 kg of force without increasing implant mobility in the pilot monkey (#8685). Since this was the load measuring limit of the load cell, another load cell had to be found with a greater load range. The consensus of the investigators was that an Instron machine should be used to calibrate each strain gage assembly extraorally. An Instron 1011 machine in the Biomaterials Lab at Loma Linda University was set up according to the diagram in Figure 7.

Uniaxial loading of the same type of strain gage assembly in the same direction as the expansion screw was accomplished by removing the expansion screw from an abutment A and sliding a plunger device through the screw hole until it touched the stainless steel ring of abutment B. The custom made plunger device was attached at the other end by a screw into the crosshead load cell of the Instron machine. The plunger was kept in this alignment (with the plunger replacing the expansion screw), and the crosshead lowered. When the plaster analog model settled into the jaws of a surveyor, the descent of the crosshead was terminated, and the surveyor tightened to maintain the alignment of the plunger



Figure 7. Instron 1011 materials testing machine and associated apparatus for extra-oral (in vitro) calibration of the strain gage assemblies used in monkey #9091 (the second monkey). Note the surveyor which was used to position the strain gage assemblies in the correct 3-dimensional location to receive the load. The compressive load was delivered by the plunger which was attached to the crosshead load cell of the Instron machine. The water bath kept the strain gages at simulated body temperature.

to the stainless steel ring. The surveyor base was locked in position with cold cure acrylic to prevent movement. A water bath was used to maintain a constant simulated body temperature of 37° C.

With the surveyor (and consequently the strain gage assembly) locked in position relative to the Instron machine, the crosshead was lowered at the rate of 1 mm per minute, to apply a load to the strain gage assembly. A two pen plotter was used to record the strain output of the wheatstone bridge simultaneously with the force applied by the Instron machine. Two curves were produced which showed how the load was related to the strain. Reproducible outputs of force and strain were observed so that an unknown *in vivo* force at a known *in vivo* strain could be calculated from the *in vitro* curves produced by the Instron apparatus. Each strain gage assembly produced repeatable relationships, even though strain peaks and slopes varied widely between assemblies (figure 8).

Most curves were calibrated at 37° C, 35° C, and 39° C. It was found that the strain curves at different temperatures had the same shape, but were shifted approximately 1.6 mv per 2°C. Strain curves moved toward increased resistance with increasing temperature (i.e. they shifted toward lower voltage output values).

In the second monkey, the temperature of the monkey was taken, a linear measurement was made by micrometer between abutment screws, and Periotest values recorded before force application. The expansion screw was tightened until the strain gage output equaled a target voltage corresponding to a target load. Then the expansion screw was locked in position with cold cure acrylic.



Figure 8. Simultaneous load and strain curves obtained during *in vitro* calibration of the strain gages used in monkey #9091. The strain curves are marked with a dot. In all tests, the load was 5 kg, and every strain gage assembly produced a differently shaped strain curve. Although different between assemblies, the same assembly consistently reproduced its characteristic curve over 3-5 trials. LL= lower left implant pair, etc.

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The monkey was allowed to come to temperature equilibrium and the strain voltage, temperature, linear distance between implants, and Periotest values recorded a second time.

Subsequent daily measurements included, temperature, strain, linear distance between abutments, and Periotest values.

The linear distance between abutments was important in application of our data to a finite element analysis model currently being developed by the Restorative Dentistry Department at Loma Linda University.

In the last monkey, we plan to inject tetracycline dyes at critical times to enable histologic analysis of the cellular processes occurring near the time of implant failure due to overwhelming lateral loads.

RESULTS

The pilot monkey (#8685) underwent full mouth extractions except for the canines and first premolars on September 25, 1990. Two months later, on November 27, 1990, five pairs of 3.5 mm diameter, hydroxyapatite coated plasma sprayed Bio-vent implants were placed.

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 with four pairs being of unequal length and the fifth pair (mandibular anterior) being of equal length.

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

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

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 registrations of implant position was done by endowel impression techniques in which a plastic post was placed into the implant 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. Five of these abutments were constructed, and it was found that none of them could be properly cemented in the correct orientation in the monkey's mouth. Some were cemented in incorrect orientations and the expansion screw turned to apply force to the second abutment of the pair, but the cemented post always broke loose due to offcenter loading and due to the short length of the cast post.

Attempts were made to solder the expansion screws to the stock titanium abutments supplied by Core-vent, but in our hands, it was impossible to solder to titanium. Core-vent recommended casting a low-temperature melting gold directly to the titanium abutments, but this also proved to be too difficult.

To solve these problems, the internal hex feature of the implants was used. Custom abutments were waxed up with a male hex feature which would slide directly into the female hex feature of the implant. This arrangement did not allow rotation and did not require cementation. But it did require 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

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experimental apparatus was as shown in figure 6-A, in which the strain gage was bonded directly to the side of the expansion screw. A 400 gram load was applied (as calibrated directly in the mouth by micro load cell) to the maxillary right pair of implants, and it was found that the mobility of the implants as tested by the Periotest apparatus did not change over the course of 12 days (Table 2 and figure 9). The posterior abutment experienced a sharp increase in PTV's on the fifth day after loading, but it was found that the screw holding the abutment in place was loose. The screw was tightened on the seventh day after loading, and the PTV's returned to initial values. The experiment was terminated after the appliance was damaged during testing.

Table 2. Periotest values (\overline{X} over 4 trials) obtained over 12 days. Initial load of 400 grams on the maxillary right implant pair in monkey #8685. Periotest values above 10 indicate a +1 clinical mobility. Top row numbers indicate days since load.

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







Another experiment with the same apparatus (figure 6, A) was started on August 15, 1991, at a load of 750 grams, in the upper left quadrant, and lasted for eight days (Table 3 and Figure 10) until the posterior abutment was unintentionally rotated. Over this period of time the implants were checked for mobility daily, and there was no clinically significant change in implant mobility.

Table 3. Periotest values (\overline{X} over 4 trials) obtained over 8 days. Initial load of 750 grams on the maxillary left implant pair of monkey #8685. Periotest values above 10 indicate a +1 clinical mobility. 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



These experiments taught us that a more sensitive 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 gram load. To improve sensitivity, 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



Figure 10. Periotest values (PTV's) obtained over 8 days in the maxillary left quadrant of monkey #8685 under a load of 750 grams. Calibration of the strain gage was by micro load cell (in vivo calibration). Note that the posterior implant was usually more mobile than the anterior implant. No PTV's greater than +10 occurred. PTV's above +10 indicate a clinically felt mobility, roughly equivalent to a Miller Scale value of +1. A= anterior implant; P= posterior implant.

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fixed cut circle apparatus as pictured in figure 6-C.

A load of 1,100 grams was placed on the maxillary right pair of implants on October 16, 1991. The fixed cut circle apparatus was used, and the experiment lasted 26 days with no increase in implant mobility (Table 4 and Figure 11).

Table 4. Periotest values (\overline{X} over 4 trials) obtained over 26 days. Initial load of 1,100 grams on the maxillary right implant pair in monkey #8685. Periotest values above 10 indicate a +1 clinical mobility. 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



The next attempts to use this fixed cut circle apparatus failed at higher load levels. An attempt to place this apparatus was made on November 12, 1991, in the mandibular right quadrant of the pilot animal. At 1,500 grams of load, 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. In this



Figure 11. Periotest values (PTV's) obtained over 26 days in the maxillary right quadrant of monkey #8685 under a load of 1,100 grams. Calibration of the strain gage was by micro load cell (in vivo calibration). Note that the posterior implant was always more mobile than the anterior implant. The anterior implant was 13 mm long, and the posterior implant was 8 mm long. PTV's above +10 indicate a clinically felt mobility, roughly equivalent to a Miller Scale value of +1. A= anterior implant; P= posterior implant.

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trial, 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 (D) of figure 6. On November 21, 1991, an elliptical 16² stainless steel fixed full circle apparatus at a 2,000 gram load, was placed in the mandibular right quadrant, but the trial was aborted due to damage of the strain gage during the calibration process.

Table 5. Periotest values (X over 4 trials) obtained over 48 days. Initial load of2,685 grams on the maxillary right implant pair in monkey #8685. Periotestvalues above 10 indicate a +1 clinical mobility. Top row numbers indicate dayssince load.

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



Successful use of the elliptical full circle appliance was first achieved in the Upper Right Quadrant where a load of 2,685 grams was applied on November 26, 1991. An increase in Periotest values occurred but the PTV's returned to normal



Figure 12. Periotest values (PTV's) obtained over 49 days in the maxillary right quadrant of monkey #8685 under a load of 2,685 grams. Calibration of the strain gage was by micro load cell (in vivo calibration). Note that the posterior implant was always more mobile than the anterior implant. The PTV peak on day 10 has not been explained, however, the PTV's were normal on day 49. PTV's above +10 indicate a clinically felt mobility, roughly equivalent to a Miller Scale value of +1. A= anterior implant; P= posterior implant.

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at the end of 48 days (Table 5 and figure 12).

On December 20, 1991, a force of 2850 grams 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. The same appliance design as in the preceding experiment was used (elliptical full circle of rectangular wire). The results were as in Table 6 and Figure 13.

Table 6. Periotest values (\overline{X} over 4 trials) obtained over 25 days. Initial load of 2,850 grams on the mandibular right implant pair in monkey #8685. Periotest values above 10 indicate a +1 clinical mobility. 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



Results of experiments on monkey #9091.

The second monkey (#9091) underwent full mouth extractions except for the canines and third molars on 9-28-90. Two months later, on 11-30-90, six pairs of 3.5 mm diameter, hydroxyapatite coated plasma sprayed Bio-vent implants were placed.

Three different lengths of implants were placed in the second monkey. Table 7 shows the location, position, and length of each implant. Of the six pairs



Figure 13. Periotest values (PTV's) obtained over 25 days in the mandibular right quadrant of monkey #8685 under a load of 2,850 grams. Calibration of the strain gage was by micro load cell (in vivo calibration). Note that the posterior implant was always more mobile than the anterior implant. PTV's above +10 indicate a clinically felt mobility, roughly equivalent to a Miller Scale value of +1. A= anterior implant; P= posterior implant.

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of implants placed, four pairs were of unequal length, and two pairs (maxillary and mandibular anterior) were of equal length.

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	Anterior	13 mm
Maxillary Right	Posterior	8 mm
Maxillary Anterior	Right	10 mm
Maxillary Anterior	Left	10 mm
Maxillary Left	Anterior	13 mm
Maxillary Left	Posterior	8 mm

Table 7. Implant locations, positions, and lengths for monkey #9091.

Three experiments were conducted on monkey #9091. In all cases, the strain gages were calibrated according to the in vitro technique in which an Instron machine was utilized (figures 5,7,8, and surrounding text). The strain gages were mounted on stainless steel "rings" as shown in figures 1-5, and figure 6-D. All measurements were repeated four times to ensure repeatability.

In the first experiment, a calibrated strain gage assembly was placed in the maxillary anterior edentulous area. During installation of the assembly, the

internal screw which tightens the abutment to the implant was stripped. Recovery of the stripped screw proved impossible. During recovery attempts, the implant was twisted out of the bone. This experimental site was abandoned due to physically induced implant loss.

In the second experiment, a 5 kilogram load was placed between implants in the maxillary left quadrant. The experiment was terminated on the second day because the stainless steel "ring" had slipped away from the expansion screw. This experiment is on hold until the geometry of the abutments can be improved, and the strain gage recalibrated.

In the third experiment, an Instron calibrated strain gage assembly was successfully used to apply a immediate load of 6,000 grams between the pair of implants in the lower right edentulous area. Before applying the load, the implants had slightly positive PTV's (Table 8 and figure 14), however once this load was applied, the PTV's dramatically became more negative as if the implants were now wedged tightly in bone tissue. The distance between the implants increased 1.5 mm upon loading, and then remained unchanged in that position for the duration of the experiment. No clinically significant increase in implant mobility was noted in the 26 days since load placement, that is, the PTV's did not exceed +10. There was an initial trend for the posterior implant to become more mobile with time for the first 7 days.

In this experiment, the posterior implant was consistently more mobile than the anterior implant even though the posterior implant was 3 mm longer.

Time	Anterior	Posterior	Distance
Preload PTV	+0.75	+3.5	0.3968"
Postload PTV	-6.25	-2.75	0.4564"
5 min.			
1 day	-6.00	-5.00	0.4661"
2 days	-5.75	-3.25	0.4630"
3 days	-4.25	-3.75	0.4596"
4 days	-5.25	-3.50	0.4581"
5 days	-5.00	-2.75	0.4611"
6 days	-5.00	-2.25	0.4629"
7 days	-6.00	-2.00	0.4610"
8 days	-4.75	-2.25	0.4606"
9 days	-5.00	-1.50	0.4604"
10 days	-4.75	-2.00	0.4623"
11 days	-5.50	-2.00	0.4616"
12 days	-4.25	-2.00	0.4606"
13 days	-5.00	-2.00	0.4615"
14 days	-5.50	-2.00	0.4606"
15 days	-5.50	-2.00	0.4608"
16 days	-6.00	-2.00	0.4595"
17 days	-5.00	-2.00	0.4601"
18 days	-6.00	-2.00	0.4614"
20 days	-4.75	-2.00	0.4606"
23 days	-5.00	-2.00	0.4646"
26 days	-4.50	-2.00	0.4606"

Table 8. Mandibular right implant pair PTV's; monkey #9091. 6,000 grams.



DISCUSSION

This pilot study has no statistical merit, it's merit lies in the novel and more accurate application of strain gage technology to the measurement of orthodontic and orthopedic loads placed on implants, and in the preliminary data which suggests that implants can withstand lateral forces several times greater than previously demonstrated. The objectives of the pilot experiments were simply to: 1) develop methods of force application, 2) develop methods of load measurement, and 3) determine load levels that would cause the implants to fail. All experimentation was done simply to probe the above questions. Statistical analysis of the data will have to await completion of the project.

Results achieved are quite encouraging in that heavy orthopedic forces greater than ever reported in the literature have been applied to these implants without a single failure. The general standard for implant failure in other studies has been clinical mobility, and rightly so, for when implants move, they lose their usefulness as root replacements, or as orthodontic anchorage.

In our study implant stability was judged by PTV's which are closely correlated with clinical mobility (Teerlink et al., 1991). 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 over time returned to a more solid reading. We considered implant failure to be a sudden increase in PTV's.

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Interpretation of the Test Data for Monkey #8685:

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) as 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. The significance of this mobility peak is unknown at this time and must await statistical analysis of a much larger sample. There are some things we do know about this mobility peak. First, we saw this peak disappear with time, and second, it occurred on an 8 mm implant which had been placed into a preparation which had perforated the right maxillary sinus. Because the mobility disappeared with time, our tentative conclusion is that the mobility was not a clinical problem. Further experimentation at similar load levels should shed light on this hypothesis.

In fact, our fifth test on monkey #8685 was done at force levels similar to those of the above test, and resulted in absolutely no change in implant mobility. In this case a 2,850 gram force was applied to the lower right quadrant, and the PTV's stayed depressed after implant loading. This pair of implants obviously could not have been placed into a perforated sinus. Another difference between the two experiments is that the posterior implant in this case was 10.5 mm long as compared with the 8 mm long implant in the preceding experiment. It appears that increased implant length, or lack of sinus perforation may have contributed to the greater stability of the lower right pair of implants.

The effect of the short 8mm implant placed into the perforated sinus was felt in all three experiments conducted in the upper right quadrant. In all three cases (400 g, 1100 g, and 2685 g), the posterior implant of the pair was consistently more mobile (by PTV standards) than was the anterior implant. In contrast, both implants placed into the lower right quadrant displayed PTV's similar to each other, with and without loading.

In this study single initial loads of 400, 750, 1100, 2685, and 2850 grams were applied by expansion screw to titanium implant pairs without a resultant increase in mobility. No previous study has documented implant success with a near 3 kg laterally applied load.

Interpretation of the Test Data for Monkey #9091:

Data collection on tests for monkey #9091 is continuing. In the lower right quadrant a 6 kilogram lateral load was placed. No increase in mobility has been observed in the 26 days since placement.

Upon loading, the mobility of the implants actually decreased immediately, along with a simultaneous increase in distance between the implant pair. These observations are consistent with the hypothesis that the implants were wedged into the bone tissue with such force as to lock them tighter in position.

This increased distance between the implants allows several alternate paradigms. It is possible that the mandibular bone underwent (1) bending under load, or (2) strong compressional deformation that allowed bodily movement of the implants. It is also possible that the custom cast abutments flexed under pressure. If indeed the metal flexed under load, it certainly did not undergo permanent deformation since permanent deformation did not occur during Instron calibration procedures in which the abutments were subjected to identical lateral forces.

Comparison of this Data with Previously Published Reports:

Although this pilot study has shown that osseointegrated implants can withstand lateral forces far in excess of loads previously reported by other authors, there are 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 reports 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 larger 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 likely true that implants do not move through the bone under load, but it is also likely true that bone under strain may bend or remodel in areas at or away from the implant interface. If bone bends progressively over time under load, an expansion screw force could be dissipated relatively quickly. This would make it difficult to compare our data with those obtained by authors who used springs or elastic chain.

The One Year Osseointegration Problem:

Some criticism of this research likely will focus on the one year lag time between implant placement and force application. Clearly this protocol is a much longer period of time than the four months usually allowed for osseointegration of implants in clinical situations. The critical argument will be that we allowed a longer period of time and that this increased time resulted in an greater degree of osseointegration, and consequently better results in the experiment than could be expected clinically.

There are two lines of evidence which seem to allow us to apply our data to clinical situations. First, the objective test of mobility by Periotest, is a direct measure of the degree of bone contact, therefore, a -2 PTV at 4 months should be equivalent in degree of osseointegration to a -2 PTV at 12 months (as long as implant lengths and locations were similar). Secondly, Gottlander and Albrektsson (1991) have shown that in rabbits, osseointegration does not increase in hydroxylapatite-coated implants in the interval between 6 weeks and 1 year.

From the above evidence, it seems clear that the one year lag time does not mean that these implants are more osseointegrated than they were at the normal 4 month uncovering time. It is likely that the degree of osseointegration remains constant after equilibrium is achieved with the surrounding bone tissue.

The Role of Overloading in Implant Failure:

There are two theories which are invoked to explain implant failure, they are, overloading and bacterial insult. If the 6 kg load does not cause implant mobility, the role of overloading as causal agent for failure will be diminished.

Monotonic Verses Cyclic Loading:

In analysis of these test results, it is important to distinguish between monotonic failure and "fatigue" failure caused by repetitive loading of the implants. In other studies (Rubin and Lanyon, 1984, and Lanyon et al, 1982) it has been shown 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 observed the effect of monotonic loading on the adaptive remodeling capabilities of the bone tissues (if any).

Suggested Further Study:

The immediate experiment is continuing and it is planned to use heavier forces until implant failure occurs. Because of the problem of increasing distance between the implants at 6 kilograms of lateral load, and because we would like to know if the bone is bending or if the bone is being compressed, tantalum implants will be used to mark bone tissue sites. Radiographs will be made before and after loading the implants. Comparison of the tantalum implant positions on preload radiographs with their positions on postload radiographs will help in the evaluation of this problem.

It is hoped that a future apparatus will withstand the intraoral environment for several days so that changes of strain over time can be observed. Preliminary data over 24 hours indicate that the load decreased by half in one experiment.

Further studies have already been launched from the platform of these data. Computer finite element analysis (FEA) models of the distribution of forces around osseointegrated implants in bone have been completed in the restorative dentistry department of LLUSD. These FEA models are highly theoretical and are based on mathematical equations which have not been demonstrated clinically. These FEA models cannot be useful until they can be calibrated by clinical data. Our method of load measurement lends itself well to providing the needed data on applied force and displacement under load.

In another study, the mandible of one of the monkeys will undergo a CAT scan and a computer tape made which will fully describe exact locations of the implants relative to cortical and medullary bone. This data will be merged with the FEA model, and with our data from load and displacement. It is hoped that such a flow of data from CAT scan to FEA (calibrated by the data from this study), might eventually be clinically useful in analysis of strains produced in the bone in the unique mandibles of individual patients.

Toward the end of this series of experiments, one of the monkeys will undergo bone labeling by tetracycline dyes followed by block section and preparation for histomorphomorphic analysis. It is hoped that such analysis will show whether remodeling has occurred in the bone under loads typical of this experiment. Furthermore, it would be nice to see the bone response to loads just lower than, equal to, and just greater than the critical force that causes implant failure.

Because this study has shown that these implants did not fail under several kilograms of force, it is tempting to think that it may be possible to reduce the size of the implant (length and diameter) and still be able to carry orthodontic forces (less than 500 grams) without failure. It may be possible to construct very small implants which could be placed in almost any location in the jaws to assist

in anchorage requirements. Further study might be directed toward evaluating lateral forces which cause smaller implants to fail. Smaller implants would probably be more useful to orthodontists in non-mutilated occlusions since an extraction site is not present to accept the standard sized implant.

CONCLUSIONS

Two new techniques have been developed to measure force levels applied to implants. First, a direct technique was developed in which strain gages were calibrated directly *in vivo* with the test apparatus (by micro load cell), and second, an indirect technique was developed in which an Instron machine was used to calibrate the strain gages *in vitro*.

We found that even a 6 kg lateral force did not cause failure of the implants. This suggests that orthodontists do not need limit their force range when using implants for anchorage.

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