

THE EFFECTS OF RIGIDITY OF INTERNAL FIXATION PLATES ON LONG BONE REMODELING

A Biomechanical and Quantitative Histological Study

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The effect of rigidity of internal fixation plates on long bone remodeling was studied using two types of plates with considerable differences in stiffness. The plated bones were subjected to bioengineering, quantitative histological, and cortical thickness studies after 9 and 12 months. The biomechanical results, together with the quantitative histological measurements of the macroscopic architecture, showed that tissue characteristics of the plated bones were similar. However, because of the larger cortical area, the less rigidly plated femora can sustain significantly higher loads and energy before failure. Cortical thickness measurements also showed that rigid plate immobilization results in thinning of the cortex of the underlying bone. The experimental results suggest that cortical bone remodels according to functional stress demands, and the osteoporosis secondary to rigid plate protection is consequent to thinning of its cortex.

Key words: internal fixation plates; stiffness; osteoporosis; cortical thinning; biomechanical properties; quantitative histology

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This investigation is a continuation of our study to determine whether the osteopenia caused by protection from stress in plated bones can be reduced by the use of less rigid fixation devices (Woo et al. 1976, Akeson et al. 1975). A less rigid fixation plate requires the plated bone to carry more of its normal

physiological stress, and thus induces remodeling to stronger bone following Wolff's law (Cochran 1969, Perren et al. 1969, Hutzschenreuter et al. 1969, Chamay & Tschantz 1972). The benefits of this type of fixation are that a shorter period of external protection should be required to reach acceptable bone strength for unprotected activity once the plate is surgically removed. It remains to be shown whether comparable union rates can be achieved with plates of reduced stiffness.

Previous experiments by this labora-

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tory utilized two internal fixation plates with significant differences in bending and axial stiffness for fixation of mid-shaft osteotomies of the canine radius. Clinical and biomechanical evaluations of the healed bones at 4 months post-operatively showed the rate of healing and the strength characteristics to be similar (Woo et al. 1974). Quantitative histological evaluation of these bones revealed lower cortical porosity and more new bone formation in the less rigid plated side (Akeson et al. 1975). The investigation presents a second experimental model using the intact canine femur to study the effect of rigidity of fixation plates on long-term bone remodeling.

MATERIALS AND METHODS

The materials selected for this study were graphite fiber methacrylate resin composite (GFMM) and conventional vitallium. The difference in moduli of elasticity for GFMM ($1-4 \times 10^5$ kg/cm²) and vitallium (26×10^5 kg/cm²) is approximately an order of magnitude (Woo et al. 1974). Hence, a GFMM plate of similar geometrical design as a vitallium plate would have a bending and axial stiffness one-tenth that of the vitallium plate. The plates used were of identical dimensions and configurations. They were 9 cm long and had six screw holes. Both plates had identical sized screw holes and countersinks. The location of screw holes was also the same (Figure 1).

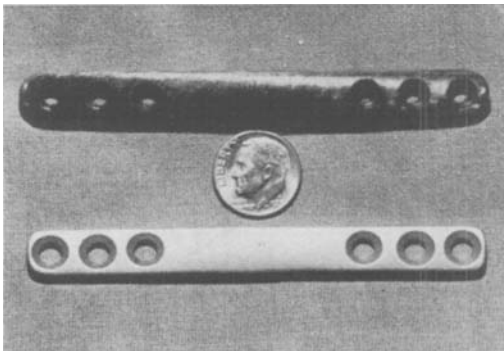


Figure 1. Photograph of the GFMM and Vitallium plates used for the canine femora.

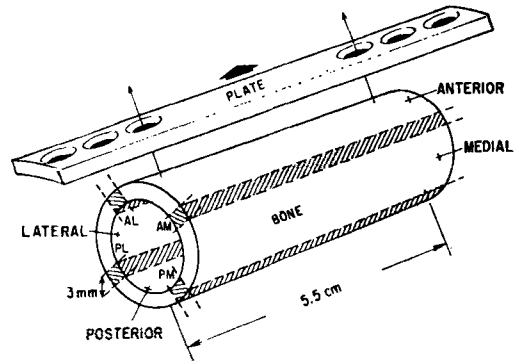


Figure 2. A schematic diagram showing the system of identification used for the eight segments subdivided from the mid-diaphysis of the canine femur. Note that the plate was applied on the anterior (A) surface of the bone.

Animal studies

Six adult mongrel dogs with an average weight of approximately 20 kg were used as experimental animals. After confirming skeletal maturity by x-ray, the right and left femora of each animal were plated on the anterior surface with a vitallium and a GFMM plate, respectively. A skin incision centered over the lateral thigh was used to expose the femur. The periosteum was then stripped from the bone anteriorly and the plate was positioned on the shaft. Screw holes were drilled using a centering drill guide and the holes were tapped. Three screws were used at each end to fasten the plate onto the bone. The wound was then irrigated with sterile saline and closed routinely. The animal was redraped and the contralateral femur was plated in an identical procedure.

Three of the animals were maintained for 9 months, and three were maintained for 12 months post surgery. The animals remained in individual cages for 4 weeks and were then sent to an animal farm where they were allowed freedom to exercise. Routine x-rays were made at monthly intervals. Starting 16 weeks prior to sacrifice the animals were given 750 mg daily of oxytetracycline (Terramycin) for 8 weeks and dimethylchlortetracycline (Declomycin) 450 mg daily for the remaining 8 weeks for quantitative histological studies.

Specimen preparation and bioengineering tests

The animals were sacrificed with Euthanasia and the femora were harvested. The mid-diaphysis of the femoral specimen was cut to obtain four longitudinal test strips, 3.0 mm wide and 5.5 cm long. The four strips were labeled

AL, AM, PM, and PL, representing anterior lateral, anterior medial, posterior medial, and posterior lateral segments, respectively (Figure 2). These bone specimens were submerged in a 37° C saline filled tank and subjected to 4-point bending test to failure. The bioengineering test procedure was described in detail in a previous publication (Woo et al. 1976). Bioengineering tests were not done on the remaining four larger segments, i.e. anterior, medial, posterior and lateral segments (shown in Figure 2), because of the irregular curved geometry. These larger segments, together with the four smaller (3.0 mm wide strips) segments were analyzed by quantitative histological procedures, however. Eight pairs of normal canine femora were also cut and subjected to 4-point bending tests under identical testing conditions. The results of the normal canine femora were compared with the experimental femora.

Quantitative histological methods

The eight segments of each femur were aligned in a parallel sequence, fixed in absolute alcohol, infiltrated with methacrylate monomer under vacuum, embedded in a mold, and cured under UV light. When the plastic was sufficiently hardened, the block was trimmed, and 120 μ sections were cut serially using a milling bone saw equipped with a diamond-edged, 12½ cm diameter saw blade. The width of the saw blade was 500 μ . Very slow cutting speeds and continuous water cooling were used to minimize fragmentation. The serial sections were ground down to approximately 70 μ thick using wet and dry sandpaper with absolute alcohol as a lubricant. Finally the sections were polished by hand to 50 μ thick with ground glass plates. After washing with several changes of alcohol, sections were cleaned in xylene and mounted conventionally.

Each of the sections was scanned by a rectangular grid eye piece at 80 \times magnification as described by Harris & Weinberg (1972). This is a random point count technique which permits quantitative scanning of the entire cortical area by moving the grid over the section in a checker board manner. Categories of bone counted included unlabeled cortical bone, tetracycline labeled cortical bone, and porosity.

Cortical thicknesses of all eight segments of the femur were also measured optically using a graduated magnifying glass (7 \times) accurate to 0.1 mm. The thickness of each segment was measured at three places, i.e. at the midpoint, and at both ends. All measurements were made by two independent observers and the mean values were calculated.

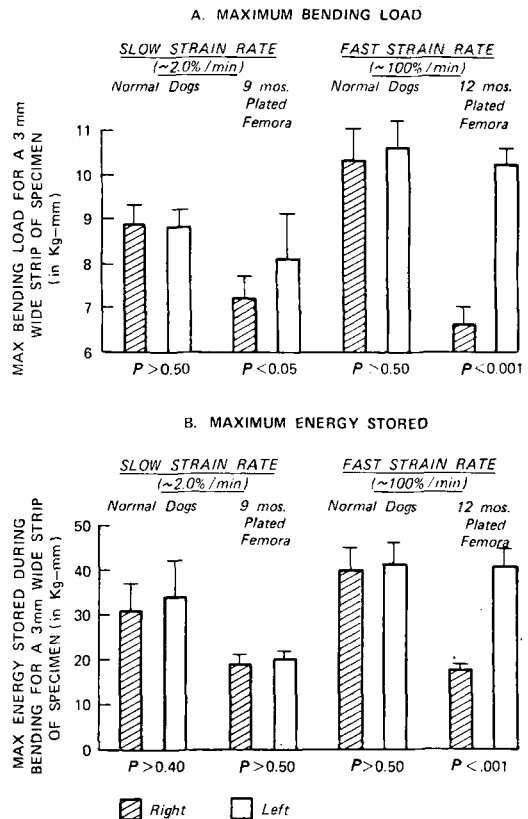


Figure 3. Histograms showing the differences in maximum bending load and maximum energy stored in the Vitallium (right) and GFMM (left) plated femora. Since there were no significant left and right differences in the normal femora, the significant differences in the experimental femora are concluded as results of plate fixation. P values given underneath the bars are for differences between right and left sides.

RESULTS

The GFMM plated femora were not remarkably different in gross appearance from the vitallium plated femora. A few carbon particles were evident in adjacent tissues near the screw hole sites where the screw hole tap had abraded the plate during surgery on the GFMM side. The overlying capsule appeared inert, with no evidence of accumulation of serous exudate. The histological appearance of the membrane was essentially as previously reported for a short-term study of

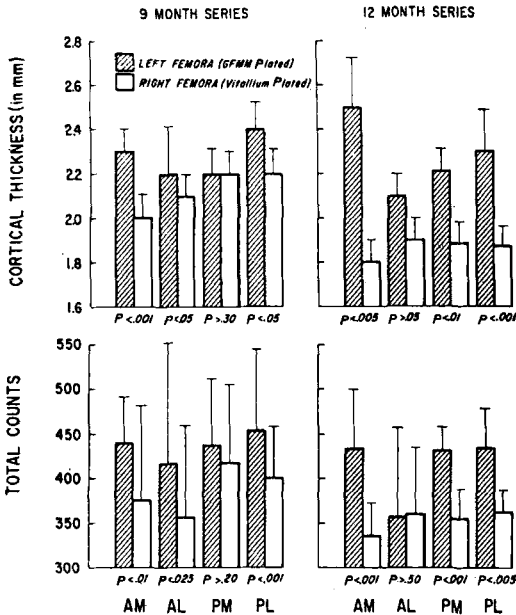


Figure 4. This histogram shows cortical thickness and total counts (cortical area) of 3 mm wide bone strips from homotypic segments of the plated left and right femoral diaphyses. Note that only those segments where the cortical areas are different also showed simultaneous differences in cortical thickness.

fracture healing using GFMM plates (Akeson et al. 1975).

The bioengineering data and methods of computation were presented in detail in an earlier communication (Woo et al. 1976). The test results of the mechanical properties (bone as a material) of the AL, AM, PM, and PL segments of the femora showed no significant difference in the ultimate bending strength (σ_t) and the flexural modulus of elasticity (E) between the less rigid, GFMM plated femora and the more rigid, vitallium plated femora. Also, σ_t and E for the anterior (AM and AL) segments were similar to those of posterior (PM and PL) segments for both the GFMM and vitallium plated femora. In addition, essentially no significant difference in σ_t or E existed between the plated femora or the normal femora.

Measurements of the structural properties of the femur (bone as an organ), i.e. maximum bending load and maximum energy stored, showed a significant advantage of the GFMM plated over the vitallium plated femora. The GFMM plated femora sustained a larger maximum load and absorbed more energy before failure than the vitallium plated femora. As the duration of plating increased from 9 to 12 months, the structural differences became more marked (Figure 3). The difference in maximum bending load increased from 12.5 per cent to 55 per cent and the difference in maximum energy absorbed increased from no significant difference at 9 months to more than a factor of two at 12 months.

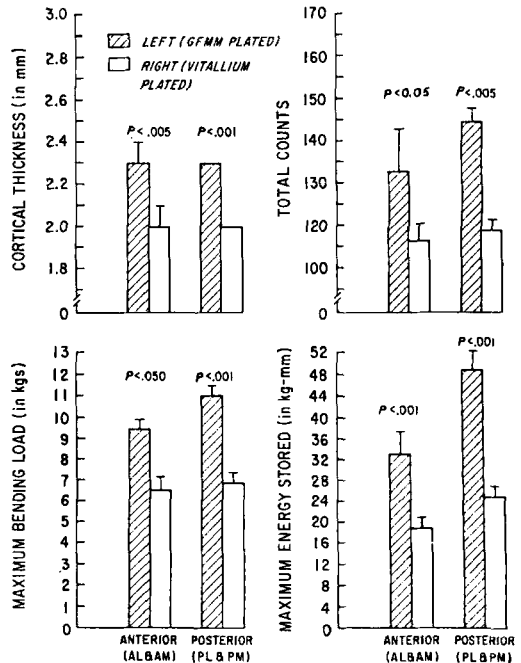


Figure 5. A comparison of anterior (AL & AM) and posterior (PL & PM) segments of 12 month plated femoral diaphyses. Consistent statistical differences were found in cortical thickness, quantitative histological data, and bioengineering test results between left (GFMM plated) and right (Vitallium plated) specimens.

Table 1. A comparison of cortical thickness and total counts of segments of bone from the left and right femoral diaphysis. Note that consistent statistical differences were obtained for the corresponding thickness and total count data.

	A		AM		M		PM		P		PL		L		R		AL	
	L*	R*	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
9 month series																		
Cortical thickness (in mm)																		
Mean	2.2	1.9	2.3	2.0	2.4	2.0	2.2	2.2	2.1	2.2	2.4	2.2	2.4	2.0	2.2	2.1	2.2	2.1
Std. Err.	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.1	0.2	0.1
t-test	P < .001		P < .001		P < .005						P < .050		P < .005		P < .050		P < .050	
Total counts																		
Mean	400	192	154	125	332	221	145	138	246	268	152	134	278	232	153	121	153	121
Std. Err.	39	36	6	21	17	19	13	16	44	24	18	11	29	39	33	17	33	17
t-test	P < .001		P < .001		P < .001						P < .025		P < .025		P < .050		P < .050	
12 month series																		
Cortical thickness (in mm)																		
Mean	2.1	1.7	2.5	1.8	2.2	1.7	2.2	1.9	2.3	1.8	2.3	1.9	2.0	1.8	2.1	1.9	2.1	1.9
Std. Err.	0.1	0.1	0.2	0.1	0.1	0.1	0	0.1	0.1	0	0	0	0.1	0.1	0.1	0.1	0.1	0.1
t-test	P < .001		P < .005		P < .001		P < .010		P < .010		P < .001		P < .010		P < .010		P < .010	
Total counts																		
Mean	259	230	144	112	294	230	144	119	232	185	145	120	237	204	119	120	119	120
Std. Err.	9	25	13	7	29	54	5	6	17	22	9	4	17	13	19	15	19	15
t-test	P < .005		P < .001		P < .005		P < .001		P < .001		P < .001		P < .001		P < .001		P < .001	

* L = Left femur (GFMM plated).
 • R = Right femur (Vitalium plated).

Table 2. A comparison of the thickness of posterior and anterior cortices of GFMM and Vitalium plated femora. This comparison shows that the thickness of the posterior cortex of the vitalium plated femur was significantly greater than that of the anterior cortex, i.e., osteoporosis occurred beneath the plate. No such difference in cortical thickness was observed for the GFMM plated femur.

	AL,A,AM	PM,P,PL
1) 9 month series		
a) Left (GFMM plated)	2.3±0.3	2.3±0.4 (<i>P</i> > 0.50)
b) Right (VIT plated)	2.0±0.4	2.3±0.2 (<i>P</i> < .005)
2) 12 month series		
a) Left (GFMM plated)	2.2±0.4	2.3±0.2 (<i>P</i> > 0.50)
b) Right (VIT plated)	1.7±0.3	1.9±0.1 (<i>P</i> < 0.05)

Cortical thickness results

The cortical thickness of the corresponding left and right segments (homotypic areas) were compared. The cortical thickness of the GFMM plated femora was consistently greater than the vitalium plated femora (Figure 4 and Table 1). The thickness data from PM, P, and PL segments were pooled and termed the posterior side and compared statistically with the pooled AM, A, and AL segments termed the anterior side. For the vitalium plated femur, the posterior cortical thickness was significantly greater than the anterior side for both the 9 and 12 month series (*P* < 0.005 and *P* < 0.05, respectively), whereas on the GFMM side there was no anterior-posterior cortical thickness difference for either series (Table 2).

Quantitative histological results

Random grid area counting was performed on seven serial cross-sectional slides obtained from the midshaft of each femoral diaphysis. The detailed data are presented in Table 3. There was no

significant left and right difference in percentage of unlabeled bone, labeled bone or porosity for either the 9 or 12 month series with the exception of PM and PL in the 12 month series, which showed significant porosity differences. Unlabeled bone ranged from 78 to 97 per cent of the cortical area; whereas the tetracycline labeled bone and porosity each ranged from a minimum of 1 per cent to a maximum of 11 per cent of the cortical area. A comparison of any one segment of bone with the remaining seven segments in the same femur also showed no consistent difference in percentage of unlabeled bone, labeled bone, or porosity.

However, a comparison of the total counts of the segments from the homotypic left and right femora revealed a significantly larger number of counts on the GFMM side in most of the segments (Table 1). In addition, only those segments where the total counts were significantly different also showed significant difference in cortical thickness (Figure 4). These results confirmed the validity of the statistical counting method used because the total counts should be proportional to the area of bone. That is, since the width of all the segments was 3 mm (AM, PM, PL, and AL segments were cut to this width), the cortical thickness should directly correspond to the total counts as the results have demonstrated.

DISCUSSION

Two plates with considerable differences in bending stiffness were applied on the anterior surface of opposite canine femoral diaphyses for 9 and 12 months duration to study the effect on long bone remodeling. The bioengineering evaluation of the femoral specimens showed no significant difference in mechanical properties as represented by the maximum bending strength (σ_t) and the elas-

Table 3. Quantitative histological data from the homotypic segments of bone from the left and right femoral diaphysis. The difference between left and right homotypic segments was compared statistically using Student's t-test on all categories of quantitative histological studies. Significant differences are indicated by appropriate P values. All data are presented in percentage of total cortical bone area.

	A		AM		M		PM		P		PL		L		AL	
	L*	R*	L	R	L	R	L	R	L	R	L	R	L	R	L	R
<i>9 month series</i>																
Unlabeled bone																
Mean	77.8	84.9	81.9	85.1	88.1	93.0	91.7	93.9	87.2	92.2	87.5	93.0	84.8	93.8	84.4	88.8
Std. Err.	8.0	3.3	5.1	5.5	4.8	2.3	3.3	1.8	4.8	1.3	3.9	1.5	5.1	1.8	7.1	4.6
Labeled bone																
Mean	9.6	7.7	9.9	5.3	6.3	3.7	5.2	2.2	8.0	4.4	9.2	2.7	10.5	3.0	8.7	3.7
Std. Err.	3.3	2.6	3.6	2.3	3.8	1.9	2.8	0.8	4.3	0.9	3.5	0.6	4.9	0.8	4.5	1.8
Porosity																
Mean	10.8	5.3	5.1	1.4	2.8	2.5	1.7	1.5	2.0	1.4	2.1	1.6	2.7	1.6	5.2	1.2
Std. Err.	5.8	3.4	2.3	0.5	1.5	1.8	0.9	0.8	1.0	0.6	1.0	0.5	1.8	1.3	2.9	0.6
<i>12 month series</i>																
Unlabeled bone																
Mean	88.0	94.7	85.0	94.4	92.6	96.3	90.0	96.8	89.0	94.0	86.7	95.1	89.6	93.5	90.4	92.6
Std. Err.	5.1	2.2	5.0	1.4	2.7	0.6	2.8	0.9	5.3	1.8	4.3	1.5	4.3	2.3	2.8	5.2
Labeled bone																
Mean	5.7	2.2	8.4	2.9	2.6	1.3	6.9	1.0	5.3	3.0	6.8	2.3	6.4	2.9	6.4	5.2
Std. Err.	3.1	1.7	2.8	0.9	1.2	0.8	2.3	0.5	2.5	1.3	3.9	1.2	2.6	1.6	2.1	4.8
Porosity																
Mean	4.0	1.2	5.3	0.8	1.8	0.5	3.1	0.3	2.8	1.8	4.6	1.1	3.3	1.7	1.7	1.0
Std. Err.	2.1	0.6	2.1	0.6	1.3	0.3	1.1	0.2	1.7	1.2	1.8	0.9	1.7	1.2	0.8	0.9
							$P < 0.05$									$P < 0.05$

* L = Left femur (GFMM plated).
 * R = Right femur (Vitallium plated).

tic flexural modulus of bone (E) between the vitallium (rigid) plated and GFMM (less rigid) plated femora. The mechanical properties of the plated femora were also similar to the normal canine femora. The quantitative histological evaluation of the same segments of the bone were consistent with the biomechanical data. No significant difference in percentage of unlabeled old bone, tetracycline labeled new bone, or cortical porosity existed between the femora immobilized by these different plates. The values for cortical porosity obtained in the plated bone were in the range of those of the normal canine long bones reported by Harris & Weinberg (1972), and Enneking et al. (1972). The above observations suggest that the macroscopic architecture of bone, and hence its resulting mechanical properties, remained unchanged in spite of plate immobilization.

Gross architectural differences, however, were seen. Thinning of the cortical wall due to medullary canal enlargement was noted. This occurred to a greater degree on the rigid plated side. The 4-point bending test results showed that the GFMM plated femora have superior structural properties to the vitallium plated femora. Since the mechanical properties of the bones are the same, the greater structural strength in the GFMM plated side should be a result of increase in bone mass. Again, this biomechanical observation was corroborated by the histological measurements (total counts) and by the cortical thickness measurements, where consistent results were found (Figure 5).

The logical conclusion of this investigation based on the quantitative histological and biomechanical measurements would be that rigid plate immobilization of long bone results in osteopenia because of reduction in normal bone stress. However, such stress protection does not seem to alter the substance of bone; yet the net amount of cortical bone

is significantly reduced, probably as a result of increased resorption on the endosteal surface.

The present quantitative histological results are not to be confused with the osteotomized or experimental fractured model that was presented earlier (Akeson et al. 1975). In the earlier model the cortical porosity values were significantly higher (7 per cent for GFMM plated radius, and 14 per cent for stainless steel plated radius). With an identical tetracycline labeling period (16 weeks) the present models have only 1 to 11 per cent of new bone formation as represented by the tetracycline labeled bone. These values were much lower than the labeled bone area of stainless steel plated (23 to 28 per cent) and GFMM plated (35 to 49 per cent) osteotomy sites of the radial diaphyses. In the osteotomized model, of course, accelerated bone formation and resorption were seen as a result of repair. However, potential advantages of a less rigid internal fixation plate for long-term skeletal fracture fixation were suggested in the experiment just concluded. Long-term studies of fracture healing which give information on effects of plates of varying bending stiffness on the remodeling phase of fracture repair will be required to be certain that this observation is valid.

The present study also opens the possibility of using other potential surgical materials as less rigid internal fixation plates. In addition to the GFMM material, we are investigating a plate made of titanium alloy (Ti-6Al-4V) (Bardos 1974), designed to have a bending stiffness ten times less than a conventional stainless steel plate. These plates are being used in an osteotomized canine femur model, and studies up to 18 months are in progress. A considerable amount of work remains to be done to evaluate the implications of material properties and design of implants on bone histology and architecture. An

opportunity will exist to achieve optimization of design and material selection for skeletal implants once the response of bone to implants of varying stiffness is understood in detail. Only then can the trade-offs between the need for rigid fixation in early repair and less rigid fixation for later remodeling be understood and the lessons applied effectively.

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