



Clinical and  
Laboratory  
Performance of

**BONE  
PLATES**

Harvey/Games, editors



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# **Clinical and Laboratory Performance of Bone Plates**

*J. Paul Harvey, Jr. and Robert F. Games, editors*

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# Foreword

This publication, *Clinical and Laboratory Performance of Bone Plates*, contains papers presented at the symposium of the same name, held in Atlanta, GA on 5 May 1993. The symposium was sponsored by ASTM Committee F-4 on Surgical Materials and Devices. J. Paul Harvey, Jr. of Pasadena, CA and Robert F. Games of Smith & Nephew Richards, Inc. in Memphis, TN presided as symposium chairmen and are editors of the resulting publication.

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# Overview

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This manual is the result of a symposium on clinical and laboratory performance of bone plates, organized by Committee F-4 of ASTM, in an effort to stimulate the production of new standards for the clinical performance of bone plates. The standards for design of bone plates and standards for laboratory testing of bone plates are in existence, but neither type of standard takes into account clinical performance, which is the *raison d'être* of these plates.

One major difficulty in writing performance standards is that when we clinicians are asked what stress and strain occurs in anatomical bones and what strength and stiffness should manufacturers provide in apparatus used to maintain fixation of fractures in these bones, we have no specific answers. When a fracture occurs, we ordinarily try to reduce the fracture and maintain a reduction by immobilizing the bone by some device such as plaster of Paris cast, external fixation device, plates attached to the bones by screws, or an intramedullary rod, or perhaps other means. We then immobilize the area by a plaster of Paris cast or a splint of some type to prevent motion of the bones involved, which means immobilizing the joints above (proximal) and below (distal) to the fracture. Most function of the bone is prevented by these measures, but not all. Some motion beyond the area fixed will cause muscle activity acting on the immobilized area. Fractured bones in the lower extremity are usually prevented from weight-bearing by the use of crutches, wheelchair, or bed rest for varying periods of time. If the clinician thinks that the fixation device is strong enough and there is preferably total contact of the bone fragments, one may not immobilize the area at all, particularly in the upper extremities, and may allow early weight-bearing in the lower extremities. Therefore, it becomes apparent that the clinician will be helped by understanding the meaning and significance of the numbers provided by bioengineers and manufacturers in relationships to the tests done on the devices, particularly plates, provided by manufacturers and engineers. Conversely, it is important that engineers and manufacturers should understand the problems facing the clinician and the amount of his knowledge, or lack of knowledge, about the factors affecting these problems in a clinical setting.

Obviously, if the clinician knew the exact forces and their directions when applied to bones as function occurs, engineers and manufacturers could simply provide a device whose strength, easily determined by tests, would be sufficient to counteract the forces applied. In the instance of plates, fixation to the bone has not been considered, but screws are commonly used to hold the plate in place. The plate must be of such a design as to fit or be bent to fit the anatomy for bone involved, and be of such a size as to fit easily within the elastic soft tissue envelope covering the bone in question. Plates as well as screws used to fix fractures in bones in the hand and finger are obviously different in size in all dimensions from the plate used to fix fractures of the femur. The plates may also be attached to intramedullary devices at one end, such as an intramedullary nail (for the femoral neck) or an intramedullary blade for fixation, particularly but not only of the ends of the femur.

Many other factors enter into the performance of bone plates. A common factor is biocompatibility, but we will leave the studies and standards for pure materials or composite materials to the groups interested in materials. Design of plates has a major effect on performance. We have learned through clinical experience that plate application directly into the bone with loss of periosteum, either by stripping the periosteum or direct compression in the area of the undersurface of the plate, will cause loss of blood supply in the bone immediately under the plate and result in some bone necrosis immediately under the plate. This finding has, of course,

caused a change in the design of plates, providing limited contact between the bone and the plate. Another factor entering into the picture is the stiffness of the plate. All bones to maintain strength and mineral content must be stressed continuously. Just simple immobilization in a splint will cause osteoporosis and weakening in a whole bone or bones not being used. Similarly, if we apply a stiff plate to bone, we will find that the bone is not stressed in the area of the plate, and osteopenia will occur. There is weakness of this area of bone compared to the area of bone exposed to ordinary stress from activity. Therefore, materials of various stiffness are being considered for use in bone plates.

The materials used for plates usually are nonabsorbable within the body. This means that after healing occurs, particularly with plates made of materials whose modulus of elasticity is more rigid than bone, the plate provides a stress riser at either end, and this creates the risk of fracture when sudden severe force is accidentally applied. Therefore, most plates, particularly in younger patients, are removed, thus necessitating a second operation with the risk of increased weakness at the site of empty screw holes for a period of time. Thus the possibility of bioresorbable plates has occurred. Factors to be considered in this instance are the initial strength of the bioresorbable plate and the rapidity of change in the strength of the plate as resorption takes place along with expected healing of the bone.

Hopefully the combination of weakening plate and strengthening bone will be maintained at or above normal strength through the healing period. We realize these are a few of the performance standards of concern. There are probably many more that we do not recognize as yet, but will become apparent as we follow our patients in the future.

This technical manual begins with Section I, entitled Screws, containing paper one, "The History and Development of Orthopedic Screws," by T. Sehlinger and D. Seligson. Although screw function in bone is a separate topic with separate standards, no discussion of plate performance can be done without recognition of the screw being part of the construct. We immediately realize that the screw design and its torque have an effect on a plate being held in place as discussed in paper two, "Effects of Design and Screw Torque on Stresses in Spinal and Fracture Plates: A Photoelastic Study," by A. Heiner and S. Brown.

Section II on Materials and Design deals with some of the basic portions of this subject. Paper three, by F. Baumgart and S. Perren entitled, "Rationale for the Design and Use of Pure Titanium for Internal Fixation Plates" and paper four by J. Disegi and D. Cesarone entitled "Metallurgical Properties of Unalloyed Titanium Limited Contact Dynamic Compression Plates," emphasize the difference in the modulus of elasticity between titanium and stainless steel (at present the most frequently used material to make plates). The less stiffness of the plate, the more opportunity for stress to pass through the bone while the plate is fixed to the bone. The concern about avascular necrosis under the plate is the reason for presenting paper five in this section, "The Concept of Biological Internal Fixation Using Limited Contact Plates," by F. Baumgart and S. Perren.

Section III, Testing Methods, contains those papers discussing testing methods. The first paper could be considered in Section II, since it discusses a new material for making plates poly(lactic acid). However, since the paper (number six), "Theoretical Strength Comparison of Bioresorbable (PLLA) Plates and Conventional Stainless Steel and Titanium Plates Used in Internal Fracture Fixation," by A. Nazre and S. Lin uses testing methods to compare the two plates, we have arbitrarily placed it in this section. This paper studied one of the bioresorbable plates now available, although it does not study change in strength as resorption occurs. It at least gives us a starting point and does discuss the first concern; does the plate have the strength to hold the bone in good position when first applied? The next paper (number seven), "Techniques in the Application of ISO 9585 Test Methods for the Determination of Bone

Plate Bending Properties,” by D. Cesarone and J. Disegi compares the properties of stainless steel and titanium. It also discusses the limitations in performing the tests and the care needed to properly understand the values obtained. Paper eight, entitled “Cyclic Cantilever Fatigue Testing of Compression Hip Screw Plates,” by R. Peterson, G. Lynch, and T. Brasher uses a simple mechanical bending test to make a comparison of the fatigue strength of the same area in different products.

Section IV, Clinical Application, has as a first paper (number nine), entitled “The Weakest Link in Bone-Plate-Fracture System; Changes with Time,” by S. Kato, L. Latta, and T. Malinin presents an overview of our clinical problem in the application to maintain reduction of fractures and the weak sites occurring after the plate is removed. The second paper (number ten) in this section, entitled “Mechanical Evaluation of Internal and External Fixation for Metacarpal Fractures,” by A. Ouellette, S. Kato, K. Nakamura, L. Latta, and W. Burkhalter compares the relative strength of types of fixation devices in a small bone, both freestanding and as contained in its normal anatomical setting. Another paper (number eleven), entitled “Biomechanics of Ulnar Osteotomies and Plate Fixation,” by J. Rayhack, S. Glasser, E. Milne, and L. Latta compares the maintenance of reduction of an osteotomy site, which has been osteotomized (transected) in two different fashions. The last paper, number twelve in this publication, is a purely clinical paper demonstrating the end result of low contact dynamic compression plates in human beings. It is entitled “The 3.5 Millimeter Limited Contact Dynamic Compression Plate: A Preliminary Report of Technical Advantages,” by J. Seiler, III, J. Jupiter, M. Miller, M. Albert, and M. Doxey.

This volume is not a definitive study, but rather provides us with a series of examples of our present status concerning the use of plates for the maintenance of reduction of fractures and factors pertaining to these plates. Using these studies and others in the literature, and more importantly, others to be conceived and performed, we hope to be able to better understand the clinical performance of bone plates and be able to write performance standards for this function.

To quote Dr. Ian Clark, a good friend and a long-time laborer on Committee F-4, “The two criteria of ‘strength’ and ‘stiffness’ will become increasingly important now that there are many advocates of titanium, plastic and composite plates, nails, and other fracture fixation systems. It is important that: (a) appropriate test methods be set up and (b) surgeons, manufacturers, and academic personnel have the same level of communication.”

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