



# Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws<sup>1</sup>

This standard is issued under the fixed designation F897; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This test method provides a screening test for determining the amount of metal loss from plates and screws used for osteosynthesis (internal fixation of broken bones) due to fretting corrosion in the contact area between the screw head and the plate hole countersink area. The implants are used in the form they would be used clinically. The machine described generates a relative motion between plates and screws which simulates one type of motion pattern that can occur when these devices are used clinically.

1.2 Since the environmental and stress conditions used in this test method may not be identical to those experienced by bone plates in the human body, this test method may produce fretting corrosion rates that are lower or higher than those experienced in practice. The recommended axial load of 400 N was selected as being in a range where the amount of fretting corrosion is not sensitive to small changes in axial load (**1**).<sup>2</sup> The combination of the recommended load and angular displacement are such that a measurable amount of fretting corrosion of surgical alloys occurs in a comparatively short period of time (7 to 14 days). (**Refs 1-3**)

1.3 The device is designed so as to facilitate sterilization of the test specimens and test chambers to permit testing with proteinaceous solutions that would become contaminated with microbial growth in nonsterile conditions.

1.4 The specimens used can be standard osteosynthesis implants or can be materials fabricated into the appropriate shapes.

1.5 This test method may be used for testing the fretting corrosion of metal plates and screws of similar or different alloy compositions, or it may be used for testing the fretting corrosion of metal-nonmetal combinations. This test method may also be used for wear or degradation studies of nonme-

tallic materials. This test method may be used as a screening test to rank the corrosivities of saline or proteinaceous solutions, or to rank metal-to-metal couples for resistance to fretting corrosion, or to study other material combinations.

1.6 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.7 *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety concerns associated with its use. It is the responsibility of whoever uses this standard to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

## 2. Referenced Documents

2.1 *ASTM Standards*:<sup>3</sup>

**D1886** Test Methods for Nickel in Water

**F86** Practice for Surface Preparation and Marking of Metallic Surgical Implants

**F382** Specification and Test Method for Metallic Bone Plates

**F543** Specification and Test Methods for Metallic Medical Bone Screws

**G1** Practice for Preparing, Cleaning, and Evaluating Corrosion Test Specimens

## 3. Summary of Test Method

3.1 A two-hole plate is attached to two plastic rods with bone screws, with flexible spacers between the plate and the rods, placed in a glass beaker, and the beaker sealed with a flexible rubber cover. This assembly is steam sterilized, and then a sterile solution is injected through the rubber cover into the beaker. This assembly is then mounted in the fretting apparatus which, when set in motion, produces a rocking motion and, therefore, a small cyclic displacement between the

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<sup>2</sup> The boldface numbers in parentheses refer to the list of references at the end of this standard.

<sup>3</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

mating surfaces of the plate and screws. The amount of fretting corrosion is determined at the end of the test by measurement of the weight loss of the plates and screws and by chemical analysis of the solutions.

**4. Significance and Use**

4.1 It is well known from examination of implants after use that plates and screws used for osteosynthesis are subjected to metal loss due to corrosion at the plate-screw interfaces. One of the mechanisms of this corrosive attack is fretting corrosion due to relative motion (micromotion) between the screw heads and plate-hole countersinks.

4.2 It is also known that release of corrosion products into the tissues surrounding an implant may have adverse effects on local tissue or have systemic effects. Thus, it is important to minimize the amount of tissue exposure to corrosion products.

4.3 Screws and plates are available in different configurations in accordance with Specifications F543 and F382. This test method may be used to evaluate the effects of different combinations of screw and plate designs. As new materials and device designs are developed for use in the treatment of fractured bones, it is important to determine the effects these developments have on the amount of metal loss due to fretting corrosion.

4.4 This test method provides a standardized screening test for ranking metal plates and screws in terms of resistance to fretting corrosion and for determining the influence of different solutions on fretting corrosion rates.

4.5 This test method may also be used to generate corrosion products either for chemical analysis of the products or for

testing for biological reactions to corrosion products using animal or cell culture methods.

4.6 It is well known that fretting corrosion rates depend on normal load or pressure, frequency, sliding amplitude, materials, surface treatments, and environmental factors. (4) Therefore, when determining the effect of changing one of these parameters (for example, material or environment), all others must be kept constant to facilitate interpretation of the results.

**5. Apparatus**

5.1 *Steam Autoclave*, capable of maintaining  $121 \pm 2^\circ\text{C}$  [ $250 \pm 4^\circ\text{F}$ ], and equipped with a thermometer, pressure gauge, vent cock, and a rack to hold the test assemblies above the water level.

5.2 *Microbalance*, with a 0.01-mg scale.

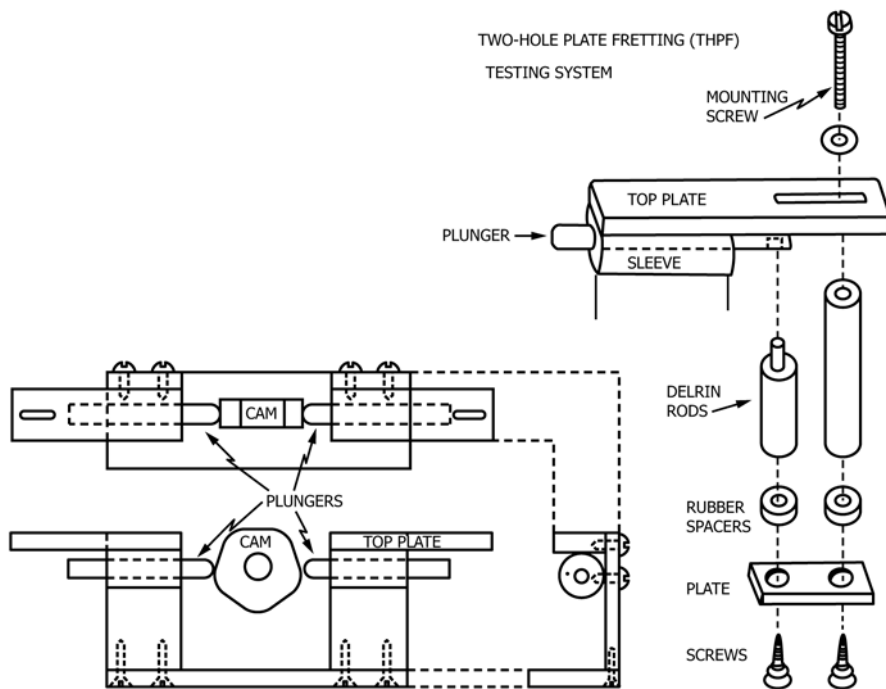
5.3 *Fretting Apparatus*, as described in 5.3.1 – 5.3.4 and illustrated in Fig. 1 and Fig. 2.

5.3.1 The fretting apparatus is driven by a slow speed gear motor connected to a horizontal rotating shaft. Round disks with machined flats (cams) are mounted on the shaft as shown in Fig. 1. For multiple specimen testing, there may be more than one cam on the drive shaft.

5.3.2 The flats on the cams are machined so as to produce  $2^\circ$  of relative motion between the posts of the test assemblies.

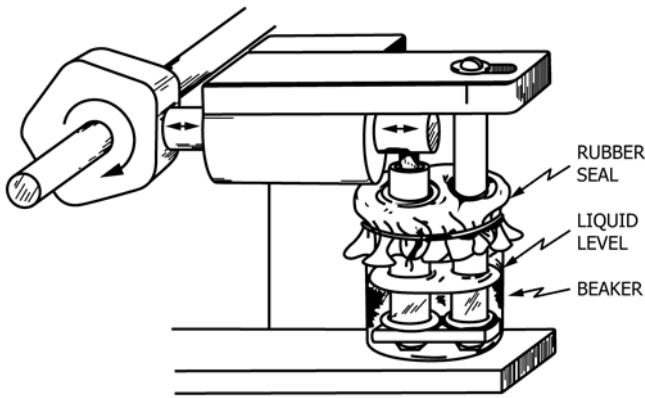
NOTE 1—A suggested combination of short post length and plunger displacement is a 5-cm post with a 1.9-mm displacement.

5.3.3 The shaft rotation rate and the number of machined flats shall be such that the flats produce one oscillation of the plunger per second.



NOTE 1—Figure shows assembly drawings of one pair of test positions on each side of a cam, and of the relationships between the screws, plate, spacers, and polyacetal rods.

**FIG. 1 Two-Hole Plate Fretting (THPF) Testing System**



**FIG. 2 Assembled Test Chamber with Rubber Seal**

5.3.4 Test assembly holding and driving frames are mounted symmetrically on each side of the rotating cams. The oscillating plunger is springloaded and held in the guide sleeve. The hole in the top plate is slotted to permit adjustment of the position of the test assemblies.

5.4 *Test Assemblies*, consisting of two plastic rods, and two flexible spacers, the two-hole plate, two bone screws, one beaker, and the rubber cover.

5.4.1 The longer rod is threaded at one end to mate with a mounting screw, while the other end is threaded to mate with the bone screw.

5.4.2 The shorter rod has a reduced diameter at one end to mate with the oscillating horizontal plunger, while the other end is threaded to mate with a bone screw.

5.4.3 The flexible spacers made of, for example, polydimethylsiloxane or buna-n, are used to maintain axial loads on the screws and to permit the necessary axial displacements associated with the rocking motion of the screws, while at the same time preventing fatigue failure of the screws. The screws are tightened such that there is a  $400 \pm 50$  N load on the screws; a different load may be used, but in such cases the load must be reported (see 10.1). In actual operation, it may be easier to measure the screw torque rather than the axial load; a method for determining the relationships between torque and load is given in Appendix X2.

5.4.4 *Test Specimen Plates and Screws*, as described in Section 7.

5.4.5 *Beakers*, autoclavable borosilicate glass.

5.4.6 *Rubber Cover*, made from a thin piece of flexible rubber with two holes punched out to make a tight fit around the plastic rods. Heavy gauge (0.3 mm thick) latex dental dam has been used effectively for this purpose. The cover is secured to the beaker with wire, rubber bands, or by some other appropriate device.

## 6. Reagents and Materials

6.1 The basic test solution shall be 0.9 % NaCl in distilled water. Measure the pH of the solutions before conducting the test. If necessary, buffer them to ensure they are in the range of 6.5 to 7.5.

6.2 Other solutions may include other “physiologic” saline and electrolyte solutions for injection (USP) or saline and

protein solutions. If proteins are used, the solutions shall be sterile in accordance with 8.1.5. Protein solutions may either be purchased sterile, or sterilized by filtration. These shall be reported in accordance with 10.1.

## 7. Test Specimens

### 7.1 Plates:

7.1.1 The plates used for these tests may be cut from commercially available plates for osteosynthesis.

7.1.2 Plates may be fabricated from 3.5-mm or thicker metal sheet or strip. Holes may be prepared in accordance with Specification F382. Holes may be round, or slotted, or “self-compressing” type.

### 7.2 Screws:

7.2.1 Screws used for this test may be commercially available bone screws. Heads should be spherical, although other shapes may be used.

7.2.2 Screws may be fabricated from rod stock in accordance with Specification F543.

7.3 Test specimens may be used in the condition as received from the implant manufacturer; custom fabricated specimens should be prepared in accordance with Practice F86.

## 8. Procedure

### 8.1 Test Assembly Preparation (see Fig. 1):

8.1.1 Clean the plates and screws ultrasonically with detergent or other degreasing agent to ensure that they are free from grease and dirt. Rinse them with distilled water, and immediately dry them in warm air.

8.1.2 Weigh the plate and each screw separately. Then weigh the three together on a microbalance to an accuracy of 0.01 mg.

8.1.3 Attach the plates to the posts with the rubber spacers and bone screws. Tighten the screws so as to create a  $400 \pm 50$  N axial load on the screws. After a correlation has been developed for relating torque and axial load for the particular metal(s), screw head, and plate hole configuration used, determine the load indirectly by measurement of the screw torque.

8.1.4 Place the assembled test specimens in a borosilicate beaker, add the test solution, and seal the top with the rubber cover with the tops of the posts projecting through the gasket.

8.1.5 If the test solution contains proteins that might support microbial growth, then the test assembly and solution must be sterile. Steam sterilize the test assembly for 20 min at 121°C prior to adding the liquid. Inject the sterile test liquid into the beaker using a sterile syringe and needle by carefully opening a small space between the post and the gasket.

### 8.2 Test Assembly Mounting:

8.2.1 Mate the short plastic rod to the horizontal plunger, and attach the longer rod to the top plate of the assembly holder with the mounting screw.

8.2.2 Start the motor and check that there is full motion of the horizontal plunger. It may be found that the elastic recoil of the elastomeric spacers is such that the plunger springs do not maintain plunger-cam contact during the complete oscillation cycle. Adjust the position of the mounting screw to ensure that

contact is maintained. Run the test continuously for one million cycles. If the test is not run continuously, report details of all interruptions.

### 8.3 Test Completion:

8.3.1 At the completion of the designated number of days of fretting corrosion, stop the motor and remove the test assembly.

8.3.2 Remove the gasket seal, and remove the screws and plates from the spacers and plastic rods.

8.3.3 Ultrasonically clean the test specimens in their test liquids to remove all excess corrosion products.

8.3.4 Pour the test liquid and residue into a screw cap container, measure the pH of the solution, and store the liquid for chemical analysis. If the solutions contain organic materials, the container should be sterile. Determine the concentration of the appropriate metals by atomic absorption spectrophotometry. The concentration of nickel may be determined in accordance with Test Methods **D1886**.

8.3.5 Ultrasonically clean the plates and screws in detergent and rinse with distilled water. Dry with warm air prior to reweighing. Additional cleaning with a stronger solution may be necessary, for example, with 10 % oxalic acid or other solutions in accordance with Practice **G1**.

8.3.6 Weigh the plates and screws separately. Then weigh them together on a microbalance to an accuracy of 0.01 mg.

## 9. Calculation or Interpretation of Results

9.1 Calculate the change in weight of the plate and each screw separately, and as a total weight loss when the three are weighed together.

## 10. Report

10.1 The report shall contain a detailed description of the materials used for manufacture of the plate and screws, for example, chemical composition, grain size, hardness, and inclusion content, the design and dimensions of the plate and screws, the surface condition of the metal(s), the axial load on the screws if other than  $400 \pm 50$  N, the pH before and after the test and the composition of the test solution, and the details of the fretting cycle and type of cleaning solution used.

10.2 Report the amount of fretting corrosion as follows:

10.2.1 the weight loss of the individual components,

10.2.2 the total weight loss, and

10.2.3 the amount of corrosion products in the solution.

10.3 Describe the appearance and damage associated with the region that underwent fretting corrosion.

## 11. Precision and Bias

11.1 The precision and bias of this test method have not been determined.

## 12. Keywords

12.1 corrosion-surgical implants; cracking-stress-corrosion; loading tests-surgical materials/applications; orthopaedic medical devices-bone plates; orthopaedic medical devices-bone screws; osteosynthesis; seals; stress-metallic materials; testing methods-surgical implants

## APPENDIXES

### (Nonmandatory Information)

#### X1. STATEMENT OF RATIONALE FOR TEST METHOD F897

X1.1 This test method was developed as an ASTM standard based on the published results of Brown and Merritt (**1-3**). They have shown that this type of device can be used to generate a measurable amount of weight loss and metal release due to fretting corrosion in a comparatively short time of 7 to 14 days. The results were sufficiently reproducible to permit comparison between metals or test solutions with comparatively small sample groups. Their results also have demonstrated that the method can be used to generate sufficient amounts of corrosion products for studies of the biological effects of corrosion products. The device presented is an example of how to get the relative motion pattern desired; other drive mechanisms may be employed.

X1.2 The load of 400 N was not selected to simulate load that would be incurred *in vivo*, but rather to permit the system to function with small return springs. It has also been reported (**1**) that the amount of fretting corrosion is not sensitive to

small load variation in this range. The cycle rate was selected to simulate an *in vivo* condition, and to minimize effects due to heating and fluid agitation. The rubber gasket seals are used to minimize fluid concentration changes due to evaporation, as well as to permit the use of proteinaceous solutions with minimal risk of microbial contamination. Sterilization of the components and solutions is necessary when proteinaceous solutions are used, but is not necessary for electrolytes without proteins. Operation of the test at room temperature, rather than 37°C body temperature was selected to minimize the problems of evaporation, equipment breakdown, and microbial growth associated with the higher temperature.

X1.3 This test method may be used to compare the fretting corrosion rates of different metals and the effects of different solutions. It is not intended to be a quality control type of test, nor a required test for new material development.

## X2. METHOD TO DETERMINE THE RELATIONSHIPS BETWEEN SCREW TORQUE AND AXIAL LOAD

X2.1 This test method uses an electromechanical load cell from a testing machine that is capable of measuring tensile loads.

X2.2 Attach a polyacetal rod to the load measuring end of the load cell. Mate one end of the rod to the cell, and thread the other end of the rod to match the thread of the screws used in the fretting corrosion test.

X2.3 Construct a metal platform perpendicular to the load measuring axis. Support the platform with metal rods attached to the mounting frame of the load cell. The support rods should

be long enough to leave 3 mm clearance between the platform and the end of the polyacetal rod. Drill a hole in the platform to permit insertion of the test screw through the platform and into the polyacetal rod.

X2.4 Insert the test screw through a test plate hole, through the elastomeric spacer, through the hole in the platform and into the threaded polyacetal rod. Tighten the screw with a torque measuring instrument capable of reading torque to  $\pm 0.1$  Nm. Record the torque required to produce axial loads of 300, 350, 400, 450, and 500 N.

## REFERENCES

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- (4) Sherwin, M. P., Taylor, D. E., and Waterhouse, R. B. "An Electrochemical Investigation of Fretting Corrosion of Stainless Steel," *Corrosion Science*, Vol 11 ( 1971), pp. 419–429.

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