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Failure of Synthes Anterior Cervical Fixation Device by Fracture of Morscher Screws: A Biomechanical Study

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Summary: Anterior cervical fixation using the Synthes system has become increasingly popular. Two screw types for anchoring the plates include a "solid" titanium expansion screw and a plasma-sprayed fenestrated expansion screw that permits bony ingrowth. These screws were compared clinically and in the laboratory. In our first 20 cases using Synthes plates secured by Morscher fenestrated screws, 3 failures were observed, unilaterally in 1 patient and bilaterally in 2 others. In the unilateral screw failure, the contralateral screw was "solid" and did not fail. In the mechanical studies, screws were secured in the Synthes plate and embedded into methylmethacrylate and subjected to a sinusoidal bending moment to the midshaft of the screw. Load deflection data and cycles to failure were recorded. Fenestrated screws were found to demonstrate nearly twice as much deformation at failure and tolerated significantly fewer cycles to failure than did "solid" screws ($p < 0.05$). Because benefits of bony ingrowth into the screw are not well identified, the risks of fenestrated screw failure should preclude their routine use. **Key Words:** Anterior cervical fusion—Internal fixation—Anterior cervical plate—Biomechanics.

Anterior cervical plate fixation has become an increasingly popular technique to improve spinal stability after a variety of anterior decompressive surgical procedures for traumatic or degenerative instability (1,4). Systems presently available require either bicortical screw fixation to the cervical body without rigid fixation to the cervical plate, or unicortical vertebral body screw fixation with rigid fixation to the plate (2,7). The latter option, developed by Morscher with the screw design of Raveh, uses titanium hollow screws with plasma spray coating and fenestrations and a central locking screw (5,6). The fenestrations and plasma coating permit bony ingrowth and reduce screw backout, a complication recognized in other anterior cervical plating systems (2,3). The central locking screw expands the head of the outer screw into the plate to provide rigid attachment of the screw to the titanium cervical plate. This system in the United States has been distributed by Synthes Spine. In addition to the fenestrated screw, Synthes produces a "solid" screw that has no fenestrations, but has a hollow center to receive the locking set screw (Fig. 1).

In our initial experience with the implantation of

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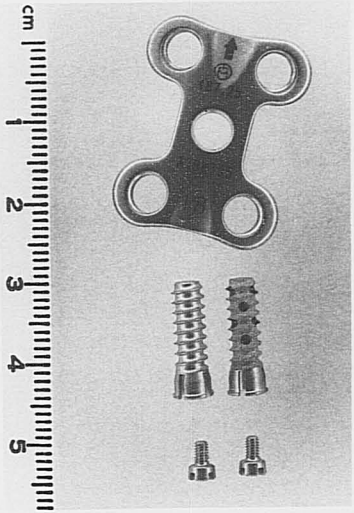

FIG. 1. Photograph of two types of Synthes bone screws, Synthes plate, and locking screws. Approximately 50% of screws used in the United States are hollow plasma-sprayed fenestrated type (right).

the Synthes anterior cervical plates in 20 patients, we experienced failure of the device by fracture of the fenestrated hollow screws in 3 patients. Failures were observed on radiographs obtained 3, 8, and 13 months postimplantation. All failures of fenestrated screws occurred through the first tier of holes closest to the plate. In two cases operative exploration revealed pseudoarthrosis although preoperative dynamic plain films did not demonstrate abnormal movement. The third case demonstrates minimal movement in dynamic cervical films consistent with failed union in an asymptomatic patient. No failures of the nonfenestrated Synthes screws were observed in the initial 20 cases or in 30 subsequent cases because the use of fenestrated screws was discontinued at our institution.

Studies of the mechanical integrity of the screws were not available from Synthes Spine. The screws were subjected to mechanical testing to study the relative weakness observed clinically of the fenestrated hollow titanium screw compared with the nonfenestrated screw.

CASE REPORTS

Case 1

A 32-year-old woman sustained a traumatic C4–C5 disc herniation with prominent radiculopathy including upper extremity pain and weakness. Diagnostic studies also revealed a kyphotic deformity with injured joint capsules and posterior ligaments. The patient underwent a C4–C5, C5–C6 discectomy, C5 partial osteotomy, iliac autograft, and Synthes plate fixation with plasma-sprayed fenestrated screws in C4 and C6. The patient experienced complete neurologic recovery. At 3 months, radiographs revealed fracture of both inferior screws and a persistent radiolucent line inferior to the bone graft suggestive of pseudoarthrosis (Fig. 2). Surgical exploration confirmed failed fusion. The plate was removed, the bone graft was revised, the patient was placed in an extended Philadelphia collar, and subsequently achieved satisfactory fusion.

Case 2

A 41-year-old patient with previous C5–C6 fusion and Caspar plate fixation presented with progressive myeloradiculopathy. Myelography and computed tomography demonstrated spinal cord impingement above and below the previous fusion. The patient underwent discectomy and ventral decompression at the C4–C5 and C6–C7 disc levels with Synthes plate fixation at each level using both fenestrated and solid screws. The patient initially experienced moderate pain relief and neurologic improvement but subsequently developed recurrent symptoms aggravated by neck flexion. Radiographs 8 months postoperatively revealed unilateral fracture of a fenestrated screw in the inferior position of the superior plate (Fig. 3). The contralateral screw was "solid" and did not fail. Surgical exploration revealed failure of fusion at the inferior portion of the iliac autograft at the C4–C5 level. The plate was removed, the graft was revised, and the patient was immobilized in a thermoplastic Minerva jacket. Symptoms have slowly improved, and solid fusion has occurred.

Case 3

The most recently identified case occurred in a 35-year-old woman with myelopathy/polyradiculopathy after a motor vehicle collision. Diagnostic studies re-

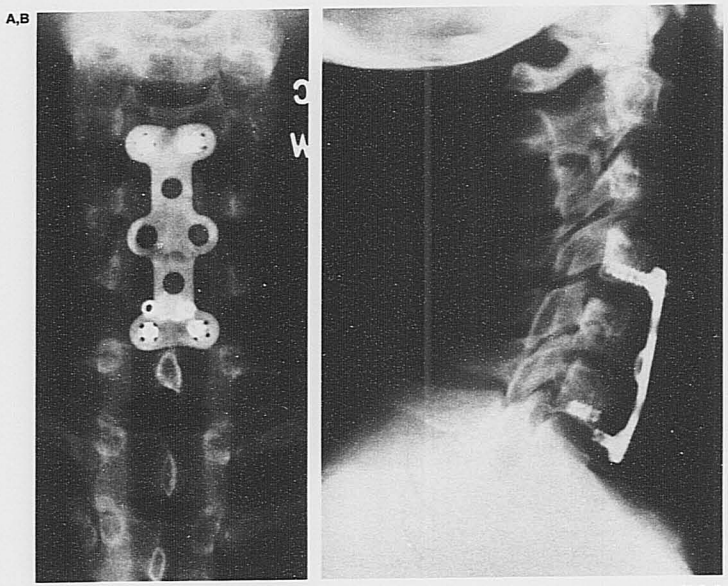

FIG. 2. A and B: Anteroposterior and lateral radiographs from case 1 demonstrate bilateral fracture of fenestrated inferior screws and line of pseudoarthrosis 3 months after surgery.

vealed multilevel spondylitic bars with ventral cord compression. The patient underwent three-level decompression, iliac autogeneic fusion, and anterior cervical plating from C4 to C7 with hollow fenestrated screws placed at these levels and into the bone graft. The patient experienced resolution of symptoms but was found to have a bilateral screw failure at the C7 level. Dynamic studies revealed slight motion indicative of failed union.

MATERIALS AND METHODS

The titanium plasma-sprayed hollow fenestrated screw is 14 mm long and 4 mm in diameter with four tiers of fenestrating holes ~1 mm in diameter (Fig. 1). Three holes in each tier occur in a single plane separated from the next tier by ~1 mm. Tiers of holes are rotated 60° out of phase with the adjacent tier. Threads are present on 11 mm of the screw's length and no holes occur in the top 3 mm of the threaded shaft. Approximately 12 mm of screw extend out of the plate when securely seated. The locking screw is 1.8 mm in diameter and 5 mm in length and when fully seated ends 1 mm from the first set of holes.

Biomechanical studies included both cyclic loads that may be anticipated in a clinical setting, and single-cycle uniaxial compressive loads to failure. For cyclic loading tests, the two types of titanium screws were secured with a locking screw into a Synthes plate and embedded 5 mm into polymethylmethacrylate (PMMA) (Fig. 4). This placed the PMMA midway between the second and third tiers of holes and ~4 mm from the end of the central locking screw. The other end of the plate was mounted to the piston of an electrohydraulic testing device (MTS, Minneapolis, MN, U.S.A.) to apply a sinusoidal bending moment to the midshaft of the screw (Fig. 5). The cyclic load applied was 200 N (45 lb) at one cycle per second. Fenestrated screws were subjected to 2,000 cycles each on four specimens, and "solid" screws were sub-

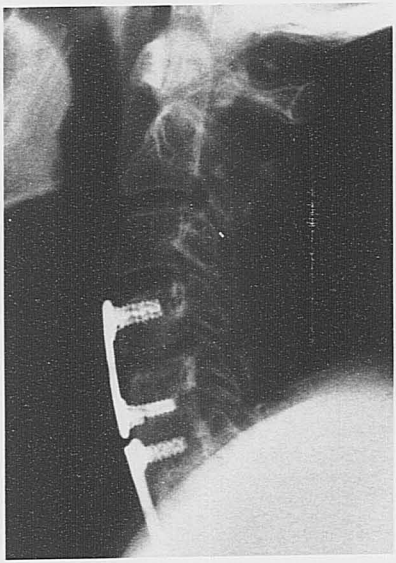

FIG. 3. Lateral radiograph from case 2 demonstrates unilateral fracture of fenestrated screw and nonfailure of contralateral solid screw. Evidence of nonunion is present at C4–C5 8 months after surgery.

jected to 10,000 cycles each on two specimens. Load and deformation data were recorded using a modular digital acquisition system (Kaye Instruments, Cambridge, MA, U.S.A.) capable of continuous signal sampling. The experiment was stopped if catastrophic failure of the screw occurred, and the number of cycles to failure was noted.

For single-cycle uniaxial compressive load to failure tests, a rate of deformation of 1 in/min was applied to the screws similarly mounted in metal while force and deformation were recorded for each screw type. Both load and deformation data were analyzed by standard paired *t*-test analysis.

RESULTS

In cyclic studies the plasma-sprayed fenestrated screws were found to demonstrate significantly greater deformation and much earlier fracture than the nonfenestrated screws did ($p < 0.05$) (Fig. 6). Mean cycles to failure for the fenestrated screws was 1,155 (SEM 127). Solid screws did not fail through 10,000 cycles, at which time testing was discontinued (Fig. 7). Hollow screw failures always occurred by fracture through the plane of fenestrations (Fig. 8).

Single-cycle uniaxial compressive load to failure tests of the solid screw occurred at 960 N compared with only 519 N for the fenestrated screw (Fig. 9).

DISCUSSION

Our clinical observations have suggested that the fenestrated screws are prone to failure. Biomechanical studies confirm and quantify this relative weakness and early failure. We speculate that the rigid screw plate interface becomes rigidly fixed to the vertebral body as bony ingrowth occurs into the fenestrated screw. If solid interbody fusion has not occurred by this time, the bending moment applied to the screw may exceed the material strength, resulting in screw failure. In our clinical cases of screw failure the fractured fragments grossly demonstrated good bony in-

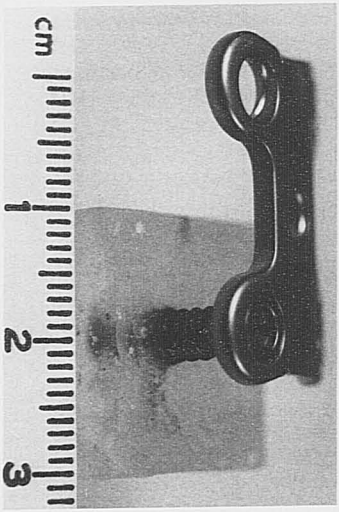

FIG. 4. Synthes screw embedded 5 mm in methylmethacrylate, creating bending moment at the midshaft of the screw.

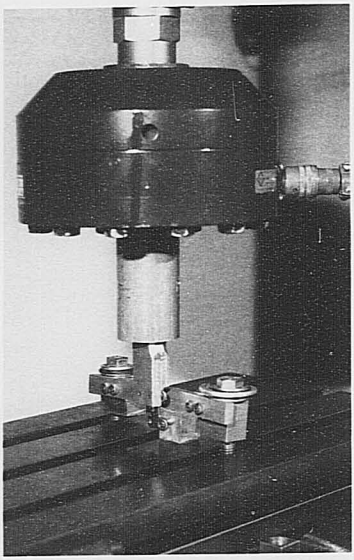

FIG. 5. Test apparatus shows Synthes screw mounted in methylmethacrylate block bolted to device frame and Synthes plate secured to MTS for cyclic testing.

growth such that the broken fragments could not be readily removed from within the vertebral body. Intact fenestrated screws also demonstrated good bony union with the body, but were readily removed with the standard screwdriver, yielding in a characteristic snap. The nonfenestrated screws are not only stronger, but do not acquire rigid fixation to the vertebral body by bony ingrowth. This may actually protect the screws from experiencing excessive bending moments by permitting some "toggle" at the screw/bone interface should fusion be delayed.

In all patients in the clinical series, rigid orthosis was used postoperatively for 10–16 weeks. For trauma cases with significant posterior instability, patients underwent simultaneous posterior stabilization and fusion. All grafts used both anteriorly and posteriorly were autologous iliac crest.

The incidence of failure of the fenestrated screws is not well established. These three cases of failure occurred in our first 20 cases and solid screws have been used exclusively in >30 cases since that time and no fractures have occurred. Suh et al. reported no cases of

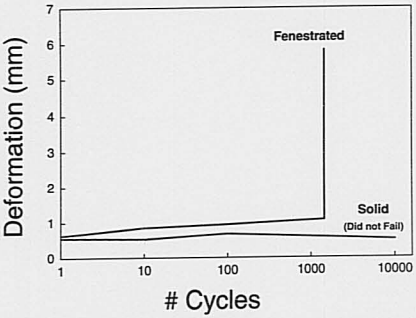

FIG. 6. Cyclic deformation curve shows increased motion of fenestrated screw and earlier failure.

screw failure in 13 cases (7). Several other series available in abstract form have reported fenestrated screw failures. At least 20 hollow fenestrated screw fractures have been reported in 8 series of 176 total plates used. This suggests a failure rate per device used of ~11%. Synthes Spine will not release the total number of fractured screws reported to them; however, they state that the ratio is <0.007% of all screws sold. It is un-

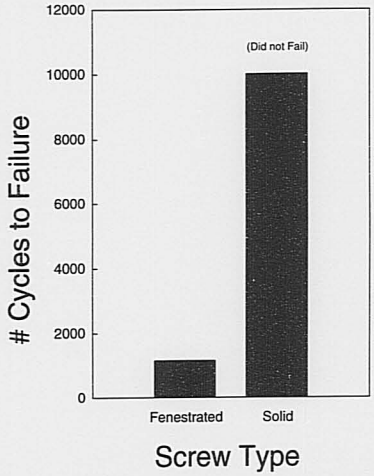

FIG. 7. Cyclic load with 200 N, no failure of solid screws by 10,000 cycles, and mean failure of fenestrated screws by 1,155 cycles (SEM 127).

clear how many of these patients required revision of instrumentation because of screw failure.

Design changes of the plasma-sprayed fenestrated screws such as reducing hole size or altering hole pattern to prevent them from occurring in a single plane should be investigated. However, because the benefits of bony ingrowth into the plasma-sprayed fenestrated screw are not yet well identified, one should avoid these screws altogether. No failures of "solid" (nonfenestrated) Synthes locking screws have been observed in our experience. Although definitive biomechanical studies and clinical evaluations comparing the effectiveness of the Synthes anterior locking plate with other anterior plating systems are not yet complete, the Synthes plate system with *nonfenestrated* locking screws appears to be an acceptable alternative to previous devices for anterior cervical fixation.

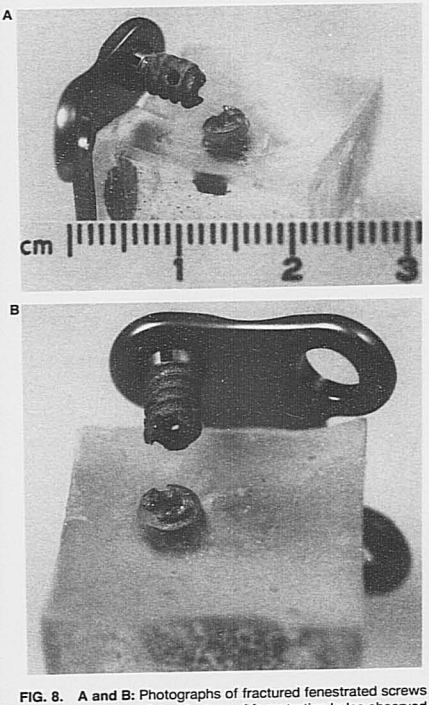

FIG. 8. A and B: Photographs of fractured fenestrated screws show typical failure through plane of fenestrating holes observed in both clinical and experimental failures.

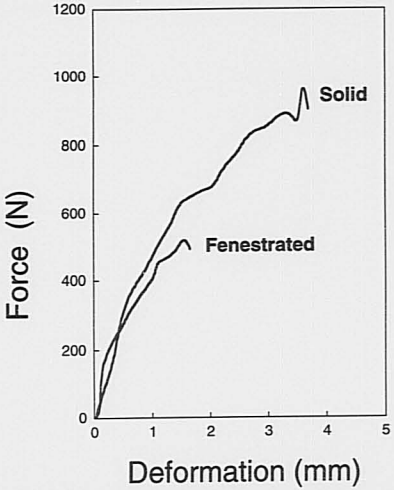

FIG. 9. Bending test force-deformation curve demonstrates increased deformation and earlier failure of fenestrated screw at 519 N compared with 960 N for the solid screw.

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