Failure of a Heifetz aneurysm clip

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✓ A 16-year-old girl died from an acute subarachnoid hemorrhage following the fracture of a blade of a Heifetz aneurysm clip. The clip was manufactured from 17-7PH steel, which on metallurgical testing was found to be highly sensitive to intergranular corrosion. The fracture mechanism was stress corrosion, brought on by the combination of a stress load, an electrolytic environment, and a susceptible steel.

KEY WORDS • aneurysm clip • metallurgy • surgical instrumentation

The failure of clinically implanted surgical aneurysm clips due to stress corrosion cracking is a phenomenon that has recently become evident. All the reports to date describe the failure of only one brand of aneurysm clip, the Heifetz clip. In this paper, we report on the first known instance of a patient dying after an acute subarachnoid hemorrhage secondary to the fracture of a Heifetz aneurysm clip. We then discuss the metallurgical and mechanical phenomena that we believe led to the clip's failure.

Case Report

This 16-year-old female high-school student was first admitted to the neurosurgical service at Henry Mondor Hospital in December, 1975. She complained of severe generalized headaches associated with transient confusion that lasted for several hours. She had no other complaints, and her past history was unrevealing. The initial neurological examination was positive only for signs of meningeal irritation. Subsequent tests included a lumbar puncture that revealed bloody cerebrospinal fluid (CSF), and bilateral internal carotid and vertebral angiography that demonstrated an aneurysm at the bifurcation of the left internal carotid artery. Surgery was performed 4 days later, and the neck of the aneurysm was clipped with a Heifetz aneurysm clip.*

The postoperative period was uneventful. An angiogram taken 3 months later, in February, 1976, did not show the internal carotid artery aneurysm, and the operation was considered successful. The patient was discharged 3 days later after a completely normal neurological examination. She returned to school and was followed postoperatively with regular visits to the outpatient clinic.

On October 24, 1977, 22 months postoperatively, the patient suddenly became comatose. She had mydriasis of the left eye. A lumbar puncture demonstrated bloody cerebrospinal fluid, and an x-ray film of the skull showed that the aneurysm clip blade had fractured; the patient died before any further steps could be taken. The postmortem examination revealed massive bleeding from the aneurysm that had been surgically clipped. The fractured clip (Fig. 1), with one blade separated from the clip body, was found at the base of the aneurysm.

* Heifetz aneurysm clip, Catalog Number 659-105, manufactured by Edward Weck Co., P.O. Box 12600, Research Triangle, North Carolina.

FIG. 1. The fractured clip.
Metallurgical Studies

Methods

Surface Examination. The surfaces of the fractured clip were examined by scanning electron microscopy (SEM) and x-ray energy analysis.† The clip was studied in two conditions: first, in its state as removed, in which the surfaces of the metal were still partially covered with tissue and oxidation products; second, in the clean state after the clip had been immersed in Endox electrolytic cleaner to remove all the oxides and tissues residues without affecting the base metal. 19

Corrosion Susceptibility Tests. After the SEM examination and x-ray energy analysis were completed, the broken blade of the clip was subjected to a passivation-reactivation electrolytic test. 17 This test evaluates the relative susceptibility of the grain boundaries of the test material to electrolytic corrosion.

Chromium is the critical element that protects stainless steels from corrosion. Certain heat treatments that are used to strengthen the steel tend to precipitate chromium carbides in the grain boundaries (Fig. 2 left), a process which, in turn, depletes the adjacent regions of chromium (Fig. 2 right). As a result, the steel becomes “sensitized,” that is, it becomes sus-
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FIG. 4. Typical energy dispersive x-ray analysis of the oxide-covered areas of the clip as removed from the patient.

ceptible to electrolytic corrosion along the grain boundaries.

The passivation-reactivation test procedure is straightforward. The test sample is immersed in a normal saline solution and connected to the positive end (anode) of a variable power supply. The current is monitored as the voltage is increased. In the passivation step, an increasingly greater positive voltage is established, and the current produces a pattern (Fig. 3A) typical of a build-up of an oxide protective layer. Then, in the reactivation step, the voltage is reduced and reversed (Fig. 3B). In a fully passivated sample, practically no change in current takes place as the voltage becomes increasingly negative. In a sensitized sample, however, the reversed voltage will be followed by a sharp rise in the current, which indicates localized metal dissolution (corrosion). Metals with a high rise in current during the reactivation step are thus more susceptible to corrosion and its sequelae.

Results

SEM and X-Ray Energy Dispersive Spectrography. Low magnification SEM examination of the fractured surface of the clip as removed revealed both oxides and tissue residues. When the components of these residues were analyzed with x-ray energy dispersive spectrography (EDS), we found unusually large amounts of phosphorus, an element not normally seen in EDS analysis of uncorroded samples of 17-7PH steel (Fig. 4).

After the surface oxides and tissue residues were removed with Endox, a few more details could be observed. At high magnifications, we saw many deep cracks traversing the surface with numerous secondary cracks following the grain boundaries (Fig. 5). These are all characteristic of an intergranular mode of fracture. We also saw evidence of abraded and scraped metal which, upon EDS analysis, was also found to be 17-7PH steel. We concluded from the cracking pattern and the fibrosis found over certain cracked regions that a major crack had opened in the surface sometime before the final fracture, and that the two separated surfaces had rubbed against one another.

Passivation-Reactivation Tests. The Heifetz clip, passivated Type 304 stainless steel, and sensitized
Type 304 stainless steel were all tested. In all three, the voltage was increased to 200 mV at the rate of 100 mV/min, with the current density following a typical smooth curve. As the voltage was decreased and then reversed at the same rate, the current density for the desensitized 304 steel followed a smooth curve that practically retraced the up-curve. With the sensitized 304 steel, there was a sudden jump in the current density that indicated a dissolution reaction at the grain boundaries. In the case of the broken clip blade (17-7PH steel), there was a very sharp increase in the current density that indicated a susceptibility to corrosive attack even greater than the sensitized 304 stainless steel (Fig. 6).

The SEM's in Fig. 7 demonstrate the material's response to the passivation-reactivation tests. In the polished condition before the test, all three samples had a featureless surface (Fig. 7A). After the test, the passivated 304 surface remained unchanged (Fig. 7B). This particular stainless steel is very resistant to intergranular corrosive attack. The sensitized 304 steel showed some deep etching at the grain boundaries which is consistent with focal dissolution (Fig. 7C). The effect of the passivation-reactivation test on the 17-7PH steel was quite marked. The original smoothly polished surface was marred by very deep etching and a severe disintegration of the surface grain structure (Fig. 7D). These tests demonstrate that, compared to passivated Type 304 stainless steel, the 17-7PH steel used in the Heifetz clips is highly susceptible to intergranular corrosive attack.

![Fig. 6. The passivation-reactivation test. The clip (17-7PH) is compared to desensitized and sensitized 304 stainless steel.](image-url)
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Fig. 7. Scanning electron micrographs of test metal surfaces before and after the passivation-reactivation tests of Fig. 6. × 800. A: Typical featureless appearance of all three materials, which have been polished before the test. B: Surface of desensitized 304 steel after the test (Curve 1, Fig. 6). C: Partial grain boundary etching in sensitized 304 steel after test (Curve 2, Fig. 6). D: Severe intergranular etching in 17-7PH steel (Heifetz clip) after the test (Curve 3, Fig. 6).

Fig. 8. Diagram showing factors that accelerate the rate of stress corrosion cracking.
Another possibility has been described by Kossowsky, et al., in which a bimetal zone was created by the mechanical abrasion between the clip and its applicer and the subsequent transfer of metal from one surface to another. Laing has described a curious problem that involves the local microenvironment of an implant. After surgery, hematomas may collect, and even quite small ones are important if they touch the implants. If soft tissue and bone were devitalized, differences in oxygen content would occur as the pH of the wound dropped to as low as 4 with CO₂ accumulation.

Another problem we have noted previously with a fractured Heifetz clip is the inordinate amount of phosphorus seen on the fractured surface. In the electrolytically active environment, the phosphorus may accentuate the galvanic conditions and slowly etch away at the grain boundaries. Indeed, our own data and the data in the literature indicate that 17-7PH semi-austenitic, precipitation-hardened stainless steel, in various conditions of heat treatment and strength, is prone to stress corrosion and intergranular failure in mild acidic aqueous solutions.

With our present report, a total of 12 known cases of Heifetz clip failures now exist in the literature (Table 1). Dujovny, et al., were the first to analyze the cause of failure and to report the details. Subsequent communications with Hayakawa (personal communication, 1980) provided us with data that suggested a similar failure mechanism in the Heifetz clip that he extracted. The clip also failed, in our report, and once again the mechanism was stress...

**TABLE 1**

*Reported cases of Heifetz clip failure*

<table>
<thead>
<tr>
<th>Authors &amp; Year</th>
<th>Year of Surgery</th>
<th>Time to Fracture</th>
<th>Method of Discovery</th>
<th>Evolution</th>
</tr>
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<tbody>
<tr>
<td>Hayakawa, et al., 1976</td>
<td>1974</td>
<td>7 mos</td>
<td>x-ray film of skull</td>
<td>reoperation &amp; clipping of aneurysm data not released</td>
</tr>
<tr>
<td>Heifetz &amp; Week (quoted by Quest &amp; Countee, 1977)</td>
<td>1975 five cases before 1977</td>
<td>10 mos</td>
<td>x-ray film of skull angiography</td>
<td>aneurysm neck obliterated reoperating &amp; clipping of aneurysm; clip not recovered</td>
</tr>
<tr>
<td>Quest &amp; Countee, 1977</td>
<td>1975</td>
<td>11 mos</td>
<td>x-ray film of skull</td>
<td>no filling of aneurysm</td>
</tr>
<tr>
<td>Servo &amp; Puranen, 1977</td>
<td>1974</td>
<td>18 mos</td>
<td>x-ray film of skull</td>
<td>no filling of aneurysm</td>
</tr>
<tr>
<td>Edner, et al., 1978</td>
<td>1974</td>
<td>18 mos</td>
<td>x-ray film of skull</td>
<td>no filling of aneurysm</td>
</tr>
<tr>
<td></td>
<td>1974</td>
<td>24 mos</td>
<td>x-ray film of skull, angiography</td>
<td>patient died; aneurysm thrombosed</td>
</tr>
<tr>
<td>Edner, et al., 1978</td>
<td>1977</td>
<td>6 mos</td>
<td>autopsy</td>
<td>patient died due to fatal hemorrhage</td>
</tr>
<tr>
<td>Dujovny, et al., 1979</td>
<td>1975</td>
<td>22 mos</td>
<td>autopsy</td>
<td></td>
</tr>
<tr>
<td>Kossowsky, et al., 1982</td>
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corrosion cracking. This case is particularly notable in that it is the first in which a death occurred directly as the result of a clip's failure.

We are currently unable to estimate the number of Heifetz clips used annually in this country, although anecdotally it is said to be one of the most widely used clips in the United States. We thus recognize that the reported incidence of failure due to fracture is very low. However, all reports of failure involve Heifetz clips, and our study has demonstrated that this clip is very susceptible to stress corrosion fracture. Because this is a newly recognized phenomenon, its true prevalence is difficult to evaluate. Therefore, we recommend the following steps be taken: 1) each clip should be individually identified and marked, the identification number of the clip should be entered in the patient's chart, and the manufacturer should provide the physician with all data pertinent to that particular clip; and 2) all excised clips should be rigorously examined metallurgically, and any abnormal conditions noted and immediately reported to the manufacturer, the Food and Drug Administration, and the American Society for Testing and Materials.

No material has been produced to date that satisfies all of the requirements for implants. In this report, for example, we have presented data that suggests that there are intrinsic problems with 17-7PH stainless steel in terms of its viability as an implant. Improvements are constantly being studied and sought. As time passes, new materials coupled with a clearer understanding of body stresses and the body environment will result in superior appliances and their superior performance.

Acknowledgments

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References


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