To The Editor: You will certainly remember our conversation on the beginnings of neurosurgical journals. To substantiate my view on who had the first neurosurgical journal, I send you a copy of the first page of the first issue of the Zentralblatt für Neurochirurgie printed in Leipzig in 1936.

To substantiate my view on who had the first neurosurgical journal, I send you a copy of the first page of the first issue of the Zentralblatt für Neurochirurgie printed in Leipzig in 1936. As you can see, Harvey Cushing and Percival Bailey were among the coeditors. The Journal of Neurosurgery was first published in 1945. The editorial note of the first issue argued an American Journal of Neurosurgery had become necessary as the German Zentralblatt für Neurochirurgie by Dr. Tönnis was not available after 1939 because of the war. The Zentralblatt für Neurochirurgie, however, has continuously been published over the decades and is currently the official journal of the Deutsche Gesellschaft für Neurochirurgie.

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RESPONSE: I thank Professor Firsching for sending the masthead of Zentralblatt für Neurochirurgie and think our readers will enjoy seeing this and learning of its origin. (DOI: 10.3171/2008.11.00245)

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Metals in the central nervous system

To The Editor: In an issue of the Journal of Neurosurgery, Marotta et al. reported a successful eneurysmorrhaphy technique using endovascular stent delivery and stabilization of a cloth patch over the inlet to each of 8 experimental aneurysms in 5 laboratory pigs (Marotta TR, Gunnarsson T, et al: A novel endovascular clip system for the treatment of intracranial aneurysms: technology, concept, and initial experimental results. J Neurosurgery 108:1230–1240, June, 2008). These are elegant laboratory studies demonstrating a technique very likely to replace other endovascular enterprises for obliterating intracranial aneurysms. I want to support the endeavor by offering suggestions for the use of metals in and around the nervous system. The authors cut their mesh stent with a laser from a tube of 316 stainless steel. Stainless steel is the least satisfactory metal available for implantation, and it offers 2 sources of trouble in the present application. Grade 316 stainless steel is austenitic well over in the paramagnetic range, but cold working (distending and bending) and cutting can convert spots of its gamma iron back to alpha iron with its accompanying ferromagnetic behavior. Otological studies have shown that Grade 316L stainless steel (even more inert in body fluids and less likely to undergo iron conversion than 316) moves at 4.7 T, whereas a martensitic steel (frankly ferromagnetic) turned 90° and platinum did not move. Radiologists generally refuse to perform MR imaging studies in anyone harboring stainless steel because so much confusion has arisen as to which is ferromagnetic and which is not. No means are at hand to delineate one from the other once implanted. Fatal accidents have occurred. Because of this problem and because stainless steel offers no metallurgical advantage over other choices, it should never be implanted anywhere near or in the nervous system.

The other risk relates to corrosion in a body tissue environment. Stainless steel is in fact not stainless in all circumstances, and its resistance to corrosion is due to a continuous surface oxygen supply forming a protective coat of chromium oxide. Cutting, bending, drilling, twisting, tying, and other violence to the surface causes damage to the protective coating, and the metal rusts at these points. Also, wherever juxtaposed material interferes with oxygen supply, an oxygen deprivation anode develops and the metal rusts. Thus a piece of stainless steel submerged in sea water will remain shiny bright on bare surfaces, but it will rust under any area covered by an obstruction such
as a silicone washer or a barnacle. In the present application the polymer flap resting against the stent could create such anodes. Another source of corrosion is the placement of tantalum markers on the stainless steel mesh. The 2 metals are far enough apart in the Galvanic Series to provoke galvanic action. The markers in this instance should be of the same metal as the stent.2,3

Other available metals would be better and without the risks. For example, MP35N is nonferromagnetic, stronger than steel, and more corrosion resistant. It has served neurosurgery well for decades in aneurysm clips.1 Titanium weighs half as much as steel; it (and its alloys for medical applications) is strong and very corrosion resistant in body fluids. Tantalum is tough, malleable, and its affinity for oxygen protects it from electrolysis to the point of allowing it to behave as a noble metal when implanted. It has been used in neurosurgery for many decades for cranioplasty, to form malleable aneurysm clips at the operating table in the days before the era of spring clips,1 and it is the ideal material for wire sutures. Any one of these metals could be adapted to the construction of mesh stents. They are all adequately ductile.

The authors have a clever and very promising concept, carefully evaluated preparatory to clinical adaptation and use. Perfected, this technique could significantly alter the treatment of acute intracranial bleeding. Would it not be the first available method for stopping hemorrhage in progress without risky disturbance of intracranial dynamics, or the risk of making bad matters worse through the artery? With the means at hand to stop escaping blood, every developing intracranial hemorrhage would then become the most urgent of therapeutic emergencies, the treatment effectively and reliably directed to stopping the current bleed, not primarily to preventing the next. Perhaps the authors already have in mind different metallurgy for the patients.

On the downside, under the alarming circumstances of having to remove this device, in the clinical setting, what are the choices? Or, suppose the guide wire or the balloon becomes entangled and resists safe extraction? As to terminology, such a promising new instrument seemingly would deserve a distinctive name of its own.

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References

Response: This letter is in response to Dr. McFadden’s inquiry. He posed several questions regarding the selection of stainless steel as a material for the endovascular clip system (eCLIPS).

First, we must correct an error in the article. The device is cut from 316L stainless steel and not 316 stainless steel as reported in the article in Materials and Methods on page 1231. We remain confident in the safety of this material selection, but we value Dr. McFadden’s comments and offer the following response to his specific concerns.

Grade 316L stainless steel is a material that is commonly used for endovascular implants and is considered industry standard. The appropriateness of this selection is backed by the many 316L stainless steel devices that are approved, marketed, and safely implanted in arteries and elsewhere in the body. The extent of testing and verification that these devices must undergo to achieve approvals can also provide confidence in their safety and the safety of the material. Examples of such products are the MULTI-LINK ULTRA stent (Abbott Vascular), Express Stent Systems (Boston Scientific), and the PALMAZ Balloon-Expandable Stents (Cordis Corp.).

Dr. McFadden commented that 316L stainless steel devices pose such a high risk of torque and displacement in MR environments that radiologists generally refuse to perform MR imaging studies in patients with these implants. The American Society for Testing and Materials International (ASTM) standards to which implantable endovascular devices must adhere have recently (and are currently) undergoing revision to help aid this situation (ASTM F2119-07, F2052-06, F2182-02a, F2213-06, and F2503-05). These standards now require all endovascular implants to state the specific MR conditions under which the device can be safely scanned, and also to state the expected outcomes under such conditions directly in the product’s literature.

Additionally, many endovascular devices are considered MR conditional (that is, safe under specific MR conditions) in fields of 1.5 and 3 T, but they are not tested and rated in fields as strong as the one mentioned in Dr. McFadden’s letter (4.7 T).

The corrosion properties of all implantable endovascular devices, including the eCLIPS, must be tested and reported according to an approved method (ASTM F2129). This includes (where applicable) pitting and crevice corrosion potential, and galvanic corrosion. During device manufacturing the eCLIPS device is fully passivated to inhibit corrosion.

The Tantalum markers on the eCLIPS device are fully encapsulated in the polymer material and therefore do not contact the 316L stainless steel device. This eliminates the potential for galvanic corrosion between these materials.

The polymer covering on the leaf completely encapsulates and is fully adherent to the stainless steel; thus, no electrolyte solution can stagnate between the metal and polymer to initiate crevice corrosion.

If there is a situation of inadvertent placement, the device can be snared and removed with risks similar to those of other undesirably placed neurovascular devices (such as coils and stents). To mitigate this, we are pursuing an eCLIPS device that can be positioned, checked,
and, if undesirably positioned, removed for repositioning prior to release.

With respect to proposing a distinctive name, we believe we have done so by using the term eCLIPS (endovascular clip systems). This uses the analogy of eclipse in the celestial sense. The intent of the device is to eclipse the opening of an aneurysm to affect flow, cause and retain the clot within the aneurysm, and then provide a scaffolding for permanent healing with new endothelium at the opening. Over time, the device would become integrated within the vessel and maintain a lumen for distal flow in addition to respecting perforating branch vessels near the aneurysm. The goal is to produce closure of the aneurysm like that of surgical clipping, but to do so from an endovascular approach rather than through a craniotomy.

We appreciate the time Dr. McFadden took to respond to the report and value his expert comments. We continue to develop the system and have incorporated modifications and improvements since the report was prepared. We hope that our response adequately addresses Dr. McFadden’s concerns. (DOI: 10.3171/2009.2.JNS08778)