Performance of chronically implanted induction-powered oscillator epidural pressure transducers

H. Grady Rylander III, M.D., Jim L. Story, M.D., and H. Lyndon Taylor, Ph.D.

Bio-Medical Engineering Laboratory, The University of Texas at Austin, and Division of Neurosurgery, The University of Texas Health Science Center at San Antonio, Texas

Chronic measurements of epidural pressure made with an induction-powered oscillator transducer revealed several problems with the current design of the device. All transducers failed over a period of months due to the diffusion of extracellular fluid through epoxy seals, which resulted in corrosion of the electrical components. Significant fibrosis occurred around the circumference of the burr hole, which reduced the sensitivity of the transducers. Design modifications are suggested to circumvent these problems.

KEY WORDS • intracranial pressure • epidural transducer • transducer sensitivity • epidural pressure

Epidural pressure measurements can enhance the care of patients with acute and chronically elevated intracranial pressure (ICP). The ideal epidural pressure transducer has not been built, but improved transducer design has proven the feasibility of epidural pressure measurement. This report describes the performance of one type of epidural pressure transducer chronically implanted in four monkeys.

Materials and Methods

Four rhesus monkeys underwent implantation of induction-powered oscillator transducers (IPOT) in the epidural frontal area as described previously. Each transducer had a Teflon membrane over the foot of the bellows to isolate the metallic bellows transducing element from the epidural space. Epidural pressures were monitored daily, with the monkeys in both an upright and a supine position, during 1 year for two implants and during 5 months for two implants. After a period of 2 years, the monkeys were anesthetized and the transducers were removed. At the time of surgical removal, the compliance of the dura mater in a 1-sq cm area immediately under the transducer was measured using a Schiotz ophthalmic tonometer with a 7.5-gm weight, and this measurement was compared with the compliance at an unoperated site in the opposite frontal area. Rigid non-compliant structures yield a low scale reading because displacement of the plunger is limited, whereas compliant soft structures yield a high-scale reading because displacement of the plunger is great.

The monkeys were subsequently sacrificed, and the dura mater and cerebral cortex in the area adjacent to the transducer were examined microscopically to determine the extent of the foreign-body reaction and any toxicity from the transducer itself. The transducers were examined electrically, macroscopically, microscopically, and on x-ray film. Each transducer was disassembled to determine what damage had occurred from chronic implantation.

Results

The actual frequency measurements are presented in Fig. 1. Pressures can be calculated from the frequency measurement and the preoperative calibration function for each transducer. Each day the pressure varied when the monkey was in the upright and the supine position, but only the average pressure is shown in Fig. 1. Daily measurements were discontinued when the transducer readings were grossly unreasonable. Despite the large frequency drifts, all four transducers functioned electrically over the 5-month or 1-year test periods. All monkeys behaved normally throughout the test, and there were no infections.

Transducer removal was accomplished without difficulty. Each transducer was surrounded extracranially by a dense layer of fibrous tissue, which was
Chronically implanted pressure transducers

excised. The outer locknut of the transducer was loosened, and each transducer body was rotated 45° to align its inner feet with the four bone defects in the skull. Each transducer was then withdrawn without additional tissue excision. Hemostasis was maintained with bipolar cautery.

The dura mater around the circumference of each burr hole was densely fibrotic in each monkey. The dura immediately beneath the foot of each transducer was grossly normal in appearance, and compliance, measured with a Schiotz applination tonometer, gave a scale reading of 8 to 10 with the 7.5-gm weight. The compliance measured in an unoperated area of dura from the opposite frontal region for each monkey also gave a scale reading of 8 to 10 with a 7.5-gm weight. The Schiotz tonometer measured only the compliance in the central area of the dura mater immediately under the transducer.

A representative section of dura from immediately beneath the transducer is shown in Fig. 2. A chronic

Fig. 1. Daily measurements of transducer output frequency. The frequency measurements can be converted into predicted intracranial pressure using the preoperative transducer calibration functions provided in the insert.

Fig. 2. Photomicrograph of the dura showing marked fibrosis with foreign-body giant cells in the right of the photograph near the circumference of the burr hole, and minimal fibrosis on the left, toward the center of the burr hole. H & E, × 100.
granulomatous inflammatory reaction was present, with foreign-body giant cells and lymphocytes visible toward the circumference of the burr hole. The dura mater became histologically normal toward the center of the transducing area. Fibrosis of the dura mater was confined to the circumference of the burr hole. The cerebral cortex immediately under the transducer was histologically normal in all sections studied.

Each transducer functioned electrically immediately after removal, despite a dramatic change in the calibration function from that before implantation. The drop in the output frequency of all transducers produced a false-negative ICP. Recalibration of the transducers after removal indicated that all monkeys had epidural pressures of 5 to 20 cm H$_2$O when the transducers were removed.

Mechanical analysis showed that two transducers had defective epoxy cap seals and one transducer had a defective seal in the Teflon membrane over the foot of the bellows. The Teflon housing was macroscopically and microscopically unaltered by implantation. Each transducer exhibited macroscopic corrosion of the gold- and Paralene-coated nickel transducing bellows (Fig. 3). Microscopic examination of the bellows revealed pinholes through the full thickness. X-ray examination of the transducers showed a loss of density in the metallic convolutions of the bellows nearest the dura (Fig. 4). After disassembly, all metallic elements were found to be rusted, including the electronic housing and the electrical components. Electrical failure in three of the transducers occurred 3 years after implantation because of rusting of electrical components; rusting continued even after the transducers had been removed.

**Discussion**

This study revealed several deficiencies in the transducer design, but confirmed the feasibility of the chronic implantation of epidural pressure transducers. The dura remained compliant in the central transducing zone for as long as 2 years, and became fibrotic only at the circumference of the burr hole where a potential space was created by discontinuity in the plane of the foot of the bellows and the inner table of the skull. Histologically, no toxic effect was observed except for a generalized foreign-body reaction in the dura, which was most severe at the circumference of the transducer.

The Teflon transducer body was unaltered both macroscopically and microscopically by chronic implantation. Mechanical fixation of the transducer under the skull allowed rigid support throughout the implantation period and also permitted easy removal. Unacceptable transducer drift occurred in all transducers. The drift was unpredictable, but always in the direction of negative ICP or decreasing transducer frequency. For example, sensor No. 1 gave reasonable measurements of ICP for 9 months before drifting to negative ICP, whereas sensor No. 5 began to drift to negative ICP during the 1st week of implantation. An air leak in the bellows or loss of bellows elasticity...
Chronically implanted pressure transducers would have resulted in a falsely elevated ICP, not a falsely lowered pressure. Dural fibrosis would have changed the transducer sensitivity or would have falsely elevated the ICP measurement. Disassembly showed that tissue fluid had penetrated through the epoxy seals and caused extensive electrical damage resulting in the early frequency drift and the eventual electrical failure of the transducers. Corrosion of the transducing element also occurred, despite coating the bellows with gold and Paralene and isolating the bellows from the tissue with a Teflon membrane.

Conclusions

Chronic measurement of epidural ICP is feasible. Epidural pressure transducer design should incorporate these features:

1. The transducer should be of a low-displacement diaphragm type to accommodate for circumferential fibrosis.
2. The transducing diaphragm should be co-planar with the inner table of the skull to reduce the volume of the potential space between the dura and the skull which heals by fibrosis.
3. The transducing membrane should ideally be an inert elastic material like quartz. A metallic transducing element corrodes quickly, and a plastic transducing element creeps.
4. Teflon is an inert intracranial implant which does not deteriorate over a 2-year period in primates.
5. Epoxy seals are permeable to tissue fluid. Transducer drift and eventual transducer failure resulted from corrosion of the electrical components. The device must be hermetically sealed.

References


Manuscript received March 3, 1982.
Accepted in final form June 25, 1982.
This work was supported in part by the generous contributions of the Science Unlimited Research Foundation.

Address reprint requests to: Jim L. Story, M.D., Division of Neurosurgery, The University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Drive, San Antonio, Texas 78284.