Spinal canal surrogate for testing intradural implants

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We have designed, built and tested an anthropomorphic-scale surrogate spinal canal, for use in preliminary evaluations of the performance characteristics of a novel intradural spinal cord stimulator. The surrogate employs a silicone mock spinal cord with semi-major and semi-minor diameters of 10 and 6 mm, respectively, commensurate with those of actual thoracic-level spinal cord. The axial restoring force provided by the 300 µm thick silicone denticulate ligament constructs on the mock cord is ~ 0.32 N mm⁻¹ over a 1.5 mm range of displacement, which is within a factor of 2 of that measured by others in human cadaver specimens. Examples of testing protocols of prototype intradural stimulators that employ this device are discussed.

Keywords: Spinal cord, spinal canal, spinal cord stimulator, neuromodulation, intradural implants

1. Introduction and background

We are developing a novel intradural method of spinal cord stimulation for the treatment of chronic pain. The method calls for the electrode-bearing implant to be placed directly on the pial surface of the spinal cord [1] in order to avoid the effects of electrical current shunting by the cerebrospinal fluid (CSF) and optimize the selective modulation of the targeted dorsal column fibres. In this approach, the patient will undergo laminectomy and durotomy, and the implant will be placed on the pial surface of the dorsal spinal cord. The dura will then be surgically re-approximated, incorporating the exit site of the implant leads into the closure. The leads will in turn be connected to a pulse generator positioned under the patient’s skin. The method and device design features that safely secure the implant onto the spinal cord are critical elements of the procedure. The position of the spinal cord within the dura-lined spinal canal changes as the patient bends, twists or otherwise changes position or posture [2,3]. The fixation portion of the device must allow the implant to maintain its position on the mobile cord without exerting forces that will tether or mechanically injure the cord or damage the delicate electrical leads spanning the space between the cord and dura.

To facilitate investigation of fixation techniques, we have preliminarily employed both in vitro [4,5] and in vivo [6,7] models of intradural implantation of our device, which is referred to in the literature as the Iowa Patch™ or I-Patch spinal cord stimulator. Our purpose here is to describe an improved version of our previous in vitro models, the design of which has been informed by the results from our in vivo studies.

2. Methods and results

In its present design configuration, the I-Patch consists of a 130 µm thick strip of very soft and flexible silicone, ~6 × 12 mm in width and length, with up to 12 platinum electrodes (0.7 mm diameter) installed on the underside, which makes contact with the spinal cord. Each electrode has a lead made of 43 µm diameter 35N LT® nanograin damage resistant (NDR®) wire with 25 µm thick tetrafluoroethylene/ethylene copolymer (ETFE) insulation. The leads extend from the electrodes as a bundle and pass through a dural cuff that serves as a seal against CSF leaks. The I-Patch assembly and leads are held in position within the spinal canal by a thin subdural scaffold made of polyetheretherketone (PEEK), which prevents the dura from collapsing onto the pial surface, while allowing the implant to move with the spinal cord without frictional contact or binding with the scaffold. A schematic illustration of this experimental arrangement is shown in Figure 1a and a photograph of an early engineering-grade prototype device is shown in Figure 1b. The I-Patch is subject to a number of complex mechanical and fluid mechanical interactions with the spinal cord, dura and CSF, and the spinal canal surrogate described below enables investigation of them and the possibility of test to failure (TTF) of the key components of the device.

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The central feature of this surrogate is the mock spinal cord [4], which is constructed of silicone that has been moulded to an oval cross-sectional shape that simulates the mid-thoracic semi-major and semi-minor adult cord diameters of ~10 and 6 mm, respectively [8]. Indentation testing by durometer was used to confirm that the elastic modulus of the mock cord (0.41–0.44 MPa) was similar to that of fresh human cadaver samples as determined by others via low-strain-rate stress relaxation measurements [9]. In the present version, the mock cord was modified to include thin wings of silicone of 10 mm wide by ~0.3 mm thick that extend bilaterally from the semi-major diameter, along its full length (6 cm). These wings can be trimmed to simulate the structure of the denticulate ligaments [10], which suspend the spinal cord within the thecal sack. A photograph of the mock spinal cord with the electrode-bearing silicone strip draped across it is shown in Figure 2.

The structure of the surrogate spinal canal test rig is shown in Figure 3a. To insure mechanical stability, the entire assembly is milled from a solid block of clear Plexiglas™. The spinal canal chamber is of anthropomorphic dimensions, ~ 18 mm wide and deep, with a working length equivalent to three vertebral segments. As seen in Figure 3a, the bilateral wings on the mock spinal cord have been trimmed to roughly approximate the anatomical shape of the denticulate ligaments, with the tips clamped between opposing stainless steel rails to simulate the actual meningeal attachment on the inner lining of the dura. (This arrangement is obviously more reminiscent of a spinal fusion configuration than it is of neighbouring compliantly coupled vertebrae, but, as described below, it serves as a useful test bed for evaluations of I-Patch components.). An o-ring groove surrounds the spinal canal chamber and a Plexiglas™ lid can be secured to the top to form a seal to contain saline solution or water to simulate the CSF. Figure 3b shows an end-on view of this arrangement, incorporating a further refinement: a length of polyvinylchloride (PVC) tubing has been split in half axially, with the two halves used to sandwich the mock spinal cord to simulate the dura. While this tubing is thicker and stiffer than the actual dura, its main attribute is visual transparency, which permits one to monitor the structures inside.

In addition to biological fidelity in relation to certain anatomical aspects of the spinal canal surrogate, there are also specific dynamical properties of it designed to at least partially replicate the in vivo situation. For instance, it is known...
[10] that the avulsion force needed to detach the denticulate ligament from its attachment point (i.e. the yield strength of the tissue) is from 0.8–1.0 N. Likewise, the force needed to pull the surrogate’s denticulate ligaments from their fixture points can be varied over that range by simply adjusting the tensioning screws in the stainless steel clamps (see Figure 3a). Of greater interest are the mock spinal cord’s suspension characteristics relative to the need to simulate the actual cord’s axial, lateral and transverse movements within the dura, as mentioned above. In that regard, the soft coupling provided by the 300 µm thick silicone denticulate ligaments allows the mock spinal cord to mimic, either statically or cyclically, any of the cord motions produced by changes in posture or movement of the patient. For example, with its denticulate ligaments fixed in place, one of our mock spinal cords of the type shown in Figure 3a was subjected to axial loading using a force gauge mounted on a translation stage. The (flat) distal end of the plunger of the gauge (Extech Instruments FG-5000, Nashua, New Hampshire, USA, 10 mN resolution) was abutted face-to-face against the (flat) terminus of the cord, and force-vs-distance measurements were then recorded as the translation stage was advanced. Over a 1.5 mm range of travel, a linear fit ($R^2 = 0.99$) to the resulting data revealed that the model had an axial stiffness of ~0.32 N mm$^{-1}$. This compares favourably with the measurements made by Reid [11] of the force required to displace the spinal cord within normal-posture cadavers, the mean value of which, over three spinal canal specimens, was found to be 0.23 N mm$^{-1}$ over a range of 3 mm.

3. Discussion and conclusions

The outcome of this effort has been a test bed that provides a useful means for evaluating a number of different design and performance characteristics of intradural implants. An example is shown in Figure 4, which is a photograph of an early, non-clinical prototype of our intradural stimulator device under evaluation within the surrogate spinal canal. The electrode-bearing element is in place on the mock spinal cord, which can be displaced axially as needed to examine, for example, under what conditions the implant separates from the mock cord surface, if the scaffolding twists underneath the dura, etc., all as a function of the mock cord’s motion. By evaluating such effects in this simple but robust in vitro model, a number of such issues can now be addressed prior to the need for expensive in vivo trials.

In fact, the surrogate spinal cord and the I-Patch prototype shown in Figure 4 have recently been used to take the first measurements of the vertical component of force applied by the I-Patch onto the surface of the surrogate cord as the device is lowered into place on it. The force measurements were made with a precision load-cell sensor having a resolution of 10 µN. These data have given us the quantitative first insights into the actual mechanical performance of the silicone loop in the device and are informing our final design of it, in particular the need for very soft compliance within the loop as the device settles onto the cord’s surface. The results from this effort will also serve as validation data for a finite element model of the I-Patch implantation process.

One additional refinement that has been introduced recently is the ability to replicate the very small, heartbeat-driven ‘breathing mode’ pulsations of the spinal cord [12], which are ~100 µm in amplitude. This is done by embedding an angioplasty balloon axially within the silicone parenchyma of the mock spinal cord at moulding. After it is cured and ready for use, one can then cyclically inflate it pneumatically [5] to replicate the small-amplitude pulsations. Additional improvements will eventually allow for simulation of the cranio-caudal pulsations observed by Mikulis et al. [13] which were found to be on the order of 0.4–0.5 mm, and for circulation of mock CSF in imitation of the slow, steady flow of actual CSF over the spinal cord surface. Other future work might include the incorporation of silicone strands that replicate the presence of the nerve roots and more precise trimming of the dural-side lengths of the denticulate ligaments, as in both cases this will help to improve the anatomical fidelity of the model, especially in terms of restrictions on spinal cord motions.

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Declaration of interest: Howard and Gillies may receive patent royalties from any commercial licensing of the Iowa-Patch™ intellectual properties that might be negotiated by their respective institutions.

References


