We have designed, built and tested a novel device for placing intradural neurmodulator implants directly on the pial surface of the spinal cord. This applier tool is designed for ergonomic handling of delicate electro-mechanical devices such as the Iowa-Patch™ spinal cord stimulator implant, which is aimed at overcoming certain shortcomings in the performance of standard epidural stimulator devices. The applier is approximately 14 cm long, 6 mm in diameter, made of stainless steel components, and has simple and reliable mechanisms for the attachment and release of the implant from it. We describe the design of the device, details of its construction, and its performance during in vivo testing of somatosensory evoked potentials in an ovine model of intradural spinal cord stimulation.

Keywords: Spinal cord, Neuromodulation, Tissue surrogates, Pial surface, Intradural devices

Introduction and background

Our laboratories are developing a novel method of neuromodulation for the treatment of intractable pain which involves placing a miniaturized, wireless intradural implant on the pial surface of the spinal cord [1]. By putting the electrodes of this stimulator implant in direct physical contact with the target tissues, the current density distributions can be optimized within the internal fibre pathways while minimizing the shunting effect of the cerebrospinal fluid, which poses a significant performance limitation on standard existing epidural stimulators because of its high conductivity relative to that of the spinal cord itself [2]. An artist’s depiction of what the device, referred to as the Iowa-Patch™ or I-Patch, would look like when situated on the spinal cord is shown in Figure 1a and a photo of an early (wired) prototype is shown in Figure 1b. As suggested there, the array of electrodes will be on the underside of the central oval portion of the device, and the soft flexible arms would secure it to the outer surface of the spinal cord over an arc of approximately 240° of contact. In an alternative configuration, the I-Patch would rest only on the upper surface of the spinal cord with the arms secured to the denticulate ligaments instead of around the body of the spinal cord itself. In either case, a microfabricated antenna and circuit on board the device enable wireless coupling to a separate epidural controller unit that transmits a frequency-modulated signal for subsequent decoding and distribution of pulses to the selected electrodes during stimulation cycles.

Several important issues associated with the mechanics of the I-Patch must be understood before a device suitable for use in pilot studies in patients can be made available. These include the thickness and compliance of the substrate, the shape and circumferential stiffness of the attachment arms, and the creep and relaxation characteristics over time of the structural material. To aid in the evaluation of these questions, we have synthesized a silicone surrogate that mimics the anatomical and biomechanical characteristics [3], as well as the pulsatile nature [4], of actual human spinal cord and we use it as an exact-scale, robust, in vitro model for testing purposes.

An additional mechanical issue of particular significance is the means and method of actually placing the I-Patch onto the spinal cord during the implantation procedure. To address it, we have designed, built and tested an applier tool that is able to accomplish this delicate task with minimal risk to any of the neural tissues within the spinal canal. In what follows, we present the design principles and the details of construction of this applier device, and describe its performance when used during in vivo ovine trials wherein a wired version of the I-Patch device was safely and efficaciously installed on the exposed spinal cord of the adult sheep models. We then discuss the potential applicability of the device for implantation of the I-Patch in patients, and close with recommendations for future work.
Materials and method of use

Functional requirements
The applier tool must be able to hold the cm-scale I-Patch such that the arms are open and it is ready to be positioned on the surface of the spinal cord. It must be easy to manoeuvre within the space created by the access laminectomy and durotomy, and it must allow for the release of the I-Patch onto the surface of the spinal cord without mechanical disturbance of or inadvertent contact with the surrounding nerve rootlets or other anatomical structures and tissues. The applier tool should also be of small profile so as not to block the neurosurgeon’s view, be of simple construction to maximize reliability and ease of sterilization, and be ergonomic in feel to the neurosurgeon doing the procedure.

Device design and components
A schematic diagram of the device we designed to meet these requirements is shown in Figure 2a. The central feature of it is a slender tube with a small mounting block affixed to the
The tip of the mounting block is machined with a radius that accommodates the curved structure of the I-Patch, which, in turn, is an approximate match to that of the dorsal arc of the spinal cord itself. (Ko et al. [5] provide average values of the spinal cord diameter as a function of position along its length.) A segment of slightly larger tubing is slid over the main tube and acts as a translation stage relative to it. Lengths of 3-0 suture are attached to the arms of the I-Patch, passed through guidance grooves on the lateral sides of the mounting block, and then affixed to small wire clamps at the proximal end of the suture-holder block that is secured to the proximal end of the translation-stage tube. A lead screw inside the main tube is terminated at the proximal end by a knurled nut and locknut, and at its distal end by a travelling nut with a pin inserted into one of its lateral faces. The pin extends through a slot milled out of the main tube. Thus, when the nut assembly at the top of the tube and, hence, the lead screw is turned, the travelling nut and pin assembly moves axially along the length of the slot. A tensioning spring works against the proximal side of the travelling nut and an inner lip on the proximal end of the main tube, in order to insure that the axial position of the nut/pin assembly can only be changed by rotation of the lead screw and won’t otherwise slide within the main tube. The distal end of the translation-stage tube is affixed to the pin on the travelling nut. Hence, when the lead screw is turned, the translation-stage assembly moves axially relative to the main tube. In this way, the suture strings fixed to the I-Patch arms at one end and to the suture-holder block on the other, can be drawn back to open the arms of the I-Patch for placement on the spinal cord, and then gently closed around it by reducing the tension via distally directed movement of the translation stage. The sutures can then be snipped and removed, leaving the I-Patch safely in place at its target location.

An auxiliary device was also designed and manufactured in order to facilitate the coupling of the I-Patch onto the applier tool prior to use, and the full system (auxiliary device and applier) is shown in Figure 2b. A support rod mounted in a stable platform has a c-clamp at its upper end into which the applier tool can be slid and which then holds it vertically in place. A perpendicularly oriented rider is positioned at the lower end of the support rod and it serves as the base onto which the I-Patch is placed in preparation for attachment of it to the applier tool. The rider has parallel grooves milled into its face to accommodate the arms of the I-Patch. The assembly consisting of the support rod, platform, upper c-clamp and rider is referred to as the fixation device.

For attachment, the applier tool is lowered down within the c-clamp until the curved distal end of its mounting block rests on the upper surface of the I-Patch (which is on the rider). The clamp is then carefully snugged to keep the applier tool in place, and the sutures are attached to the I-Patch arms and to the wire clamps on the top of the suture-block holder on the translation-stage tube. The position adjustment nut is then rotated to apply tension to the suture strings by movement of the translation stage, thus opening the arms of the I-Patch while keeping it securely in place against the underside of the mounting block. The c-clamp is then opened and the applier tool now loaded with the I-Patch can now be removed from the fixation device, and it is ready for use in the surgical procedure.

**Details of construction**

The overall length of the applier tube is 14.5 cm. The main tube is of 6 gauge stainless steel (5.1 mm in outer diameter). The mounting block at the distal end is of stainless steel, approximately 12 mm long, 8 mm thick, and 8 mm wide. It has a centre hole bored partially into its depth to accommodate the insertion of the main tube, which is then fixed in place by set screws. The distal end of the mounting block is milled down to a width of 5 mm, and the radius of curvature of its distal surface matches that of the fixation device’s rider (7.5 mm). Rotation of the 4-40 lead screw inside the main tube provides for approximately 6 mm of travel for the translation stage, which corresponds to the axial length of the slot milled into the outer tube. The translation stage tube is of 3 gauge stainless steel (6.3 mm in outer diameter), and the suture-holder block which is affixed to it is of stainless steel, approximately 8 mm long, 13 mm wide and 8 mm thick, with a clearance centre hole bored through it to allow for travel over the main tube. It is secured to the proximal end of the translation stage tube with set screws, and it has two stiff stainless steel wires (0.6 mm in diameter) mounted one each on opposite sides of the holder block, which serve to clamp the suture strings in place against the block and thus maintain them under tension during adjustment of the translation stage position. A pair of parallel grooves milled into the front face of the suture-holder block are available as guide ways for the suture strings, to help insure proper placement of them under the steel wire clamps. The base plate of the fixation device is of aluminium, 7.5 × 7.5 × 2.5 cm in its dimensions. The support rod is of stainless steel 13 cm long and 9 mm in diameter. The c-clamp used to position the applier tool within the fixation device is of stainless steel, 1.8 cm × 1.8 cm × 4.4 cm, with a channel approximately 6.5 mm wide and 12 mm deep milled into it for placement of the applier tool. A knurled set screw is used to hold the applier in place within this channel. The rider positioned at the bottom of the support rod is 15 mm in diameter and 4 cm long, with an off-axis clearance hole that allows it to be slipped onto the support rod in a direction perpendicular to the support rod axis, and a set screw recessed axially into the rear face of the rider to secure it to the support rod. The front end of the rider is milled 1 cm deep on either side of its axis, to a width of 5 mm in the upper half and a width of 9 mm in the lower half, for the purpose of accommodating the I-Patch arms during the mounting process as described above.

**Clinical testing**

**Protocol for in vivo study**

The applier tool was tested during the course of an institutionally approved, acute in vivo study of somatosensory evoked potentials (SSEP) obtained via spinal cord stimulation with a wired I-Patch device placed directly on the spinal cord of two adult male sheep (40 kg) under deep anaesthesia. The early-stage prototype I-Patch used in these experiments was of polyetheretherketone (PEEK). It is shown in Figure 1b.
top-side down against a scale, with the arms pointing upward and the electrodes positioned along its centre-line. Prior to implantation of the I-Patch, a craniotomy was performed and a standard high density recording-grid array was placed subdurally on the brain as done in patients [6], and the ability to obtain SSEP responses was confirmed via electrical stimulation of the contralateral tibial nerve. At that point, multi-level thoracic laminectomy and durotomy was performed, the I-Patch was placed on the spinal cord using the applier tool as described below, the spinal cord was then stimulated, and the SSEP were obtained from the recording grid on the surface of the brain. After the procedure, the animal was euthanized and cordotomy was performed to obtain a spinal cord tissue segment that included the region where the I-Patch had been placed, for subsequent histological analysis.

**Functional performance**

As the first step towards preparing the I-Patch for implantation via the applier tool, it was placed on the milled end of the rider of the fixation device and loops of suture string were fitted one each into slots that had been cut into the end of each arm. Then, the applier tool was inserted into and lowered within the fixture device until its mounting block rested on top of the I-Patch, and the c-clamp’s set screw was tightened to hold it in place. The free ends of the loops of suture strings from the I-Patch arms were then brought up to the suture-holder block on the translation stage and secured in place there by the steel wire clamps, thus completing attachment of the I-Patch to the applier as shown in Figure 3a. Now, by rotation of the lead screw, the translation stage could be moved upward over the surface of the main tube, thus applying tension to the distal ends of the arms of the I-Patch and causing them to open, as shown in Figure 3b. Given the pitch of the 4-40 lead screw used in this version of the apparatus (1.6 threads per mm), the ends of the roughly 5 mm long arms of the I-Patch would each spread laterally away from the central axis of the applier at a rate of ≈0.7 mm per turn, thus providing a very fine degree of control over the opening and closing of the arms. At that point, the I-Patch was ready for placement on the spinal cord. As seen in Figure 4a, the I-Patch could then be carefully positioned precisely where needed on the surface of the spinal cord, the dura from which had been retracted to create the zone of insertion. The translation stage was then moved forward via rotation of the lead screw, thus lowering and closing the arms of the I-Patch around the spinal cord, and the suture strings were then snipped. This released the I-Patch from the applier which was then withdrawn from the surgical field. As per Figure 4b, the end result was that the I-Patch had been safely positioned on the spinal cord and the stimulation experiments could begin.

**Discussion and conclusions**

**Results of use**

The applier tool performed as designed and made it possible to place a subdural implant such as the I-Patch on the surface of the spinal cord with safety and ease. It took only about one minute to place the I-Patch on the spinal cord, snip the suture strings to release the arms, and then withdraw the applier tool. The design is robust and simple in nature, employing only a small number of moving parts. It can be held in the hand like a pen during use, and the fine thread of the lead screw allows for very precise adjustment of the opening arc of the I-Patch arms, thus allowing the neurosurgeon to situate the I-Patch on the spinal cord with minimum risk of insult to the pial
might incorporate a small battery powered dc motor into the proximal end of the device, with a momentary button switch perhaps located on the suture-holder block. The arrangement would likely be similar in form and function to that used by Howard et al. [10] to determine the insertion forces needed to safely advance surgical probes into temporal lobe tissues. Such an improvement would eliminate the need for two-handed operation during adjustment of the position of the translation stage, thus constituting a useful advance in the ergonomic design of the device.

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Declaration of interest: Authors Howard, Utz and Gillies may receive patent royalties from any commercial licensing of the Iowa-Patch™ intellectual properties that might be negotiated receive patent royalties from any commercial licensing of the Iowa-Patch™ intellectual properties that might be negotiated

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