MR-based measurement of spinal cord motion during flexion of the spine: implications for intradural spinal cord stimulator systems

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Abstract
This study develops a means of delivering electrical stimuli directly to the pial surface of the spinal cord for treatment of intractable pain. This intradural implant must remain in direct contact with the cord as it moves within the spinal canal. Therefore, magnetic resonance imaging was used to measure the movement of the spinal cord between neutral and flexed-back positions in a series of volunteers (n = 16). Following flexion of the back, the mean change in the pedicle-to-spinal cord dorsal root entry zone distance at the T10-11 level was (8.5 ± 6.0) mm, i.e. a 71% variation in the range of rostral-caudal movement of the spinal cord across all patients. There will be a large spectrum of spinal cord strains associated with this observed range of rostral-caudal motions, thus calling for suitable axial compliance within the electrode bearing portion of the intradural implant.

1. Introduction and background
A limiting factor in the efficacy of epidural spinal cord stimulation for the treatment of intractable pain is the inability of the standard devices to selectively modulate the targeted neural fibres without inadvertent stimulation of neighbouring non-targeted structures, e.g. the dorsal nerve rootlets. This is a consequence of the shunting effects of the relatively high conductivity CSF located between the epidural electrodes and the spinal cord surface, migration of the leads following implantation, the formation of epidural scar tissue and several other such problems. The result is limited therapeutic efficacy in up to half of all patients having a standard epidural stimulator [1]. The Human Spinal Cord Modulation System (HSCMS) is being developed to improve this situation. It is an intradural device [2] placed via durotomy directly onto the pial surface of the spinal cord, thus avoiding the electrical shunting effects of the CSF and lead migration issues and enabling more focused delivery of the stimulus currents into the targeted regions [3].

The design features of the wired version of the implanted component of this device are shown in Figure 1. The electrode bearing surface at the bottom of the device makes contact with the dorsal surface of the spinal cord. It consists of a thin membrane (0.6 mm thick) of silicone into which are embedded six stimulating electrodes. The individual leads from the electrodes are configured in loops which join to form a single lead cable that exits the spinal canal. This cable is held in a stable position relative to the spinal canal by a titanium strap (termed the Oya Strap) that is secured to the lateral margins of the boney spinal canal. The dura is closed underneath the Oya Strap, forming a water-tight seal that prevents CSF leak. The restoring forces in the compressed lead loops inside the subdural space create a gentle pressure on the electrode membrane [4] (<15 mm Hg, which is within the range of normal intrathecal pressures) to keep it in contact with the spinal cord as it moves within the spinal canal. It is important that this membrane remains stably in place and does not lift off the surface during rostral-caudal displacement of the cord or slide laterally from its midline position, the latter to prevent potentially harmful contact with the dorsal root entry zones (DREZ).

Therefore, the lead loops of the device must be designed such that they accommodate all of the relative motion between the implant on the spinal cord surface and the lead exit point which is at a fixed position at the dural exit site under the Oya strap. Moreover, the membrane must conform to the shape of the dorsal surface of the spinal cord in order for the electrodes to make uniform direct contact with the pial surface. This means that the radius of curvature of the membrane must closely approximate that of the oval-shaped spinal cord. It should also subtend as large an angle as possible of the dorsal arc, while leaving a small buffer zone on either side that separates the lateral edges of the membrane from the dorsal rootlets. These requirements call for knowledge of (1) the spinal cord’s thoracic morphology and (2) its axial motion within the spinal canal as a function of spinal flexion.
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across a large number \((n = 50)\) of patients [5]. The present

study addresses the second point through implementation of

an experimental protocol aimed at measuring the flexion-

driven rostral-caudal movement of the spinal cord.

2. Materials and methods

2.1. Patient position within the magnet

In order to allow for spinal flexion during imaging, a 1.5 T

Magnetom Espree (Siemens, Erlangen, Germany) magnet was

utilized to take advantage of its larger bore size, which was

designed to accommodate bariatric patients. Informed consent

was obtained from a total of 16 healthy volunteers ranging in

age from 23–58. Each volunteer was first imaged in a supine

neutral position and then imaged in a maximal attainable flexed

position. To obtain the maximal flexion of the spine, patients

were given three basic positioning instructions. The first was to

rotate their hips/pelvis backwards towards the gantry as far as

possible to remove the lumbar lordosis and straighten the

lumbar spine. The second was to curl their upper back, neck and

head forward so that their shoulders were as close to their knees

as possible. The third instruction was then to tuck their chin

down as close to their chest as possible. While attaining this

flexed position in the bore, a variety of foam wedges and

pillows were utilized for added support so that the patient could

remain as still as possible during image acquisition. Maximal

flexion was limited by volunteer flexibility in 14 of the patients.

In only two patients was flexion limited by MR bore size. Not

surprisingly, these were also the two tallest patients with

heights of 2.03 and 1.98 m (6’8” and 6’6”).

2.2. Imaging protocol

Each volunteer had a vitamin E capsule taped to their midline

lower thoracic spine for help in level localization. A sagittal

HASTE sequence was performed initially as a localizer both for

vertebral level counting and identification of a more focal field

of view centred over the region of lowest thoracic spinal nerves

and the conus medullaris. In order to acquire anatomic images

with enough resolution to accurately measure intervals

between spinal nerve dorsal root entry zones, a CISS sequence

was selected for its high spatial resolution. Although this is a

highly T2-weighted sequence, acquisition time still required

2 min 5 s. This length of time initially caused too much motion
degradation during flexed imaging to make accurate measure-

ments. The use of the pillows and foam wedges provided just

enough support for volunteers to remain still and in a state of

quiet respiration for the required 2 min duration. This

minimized breathing-related artifacts which, like the residual

motions induced by the cardiac cycle, otherwise limit the

imaging resolution that can be obtained. Hence, the measure-

ments we have are technically an average during quiet

respiration. All neutral and flexed sequences were obtained

utilizing \(TR = 4.35\) ms, \(TE = 2.18\) ms, slice thickness = 0.8 mm, matrix size = 192 × 192, one acquisition per

average, 192 phase encoding steps, field of view = 200 mm and

a 70° flip angle.

2.3. Measurement algorithm

Imaging was obtained in the coronal plane. Three-dimen-
sional multiplanar reconstruction software was utilized on a

Carestream PACS station to aid in measurement. The T10 and

T11 nerve roots were identified. A cranial caudal measure-

ment was made in a plane parallel to the spinal canal between

the DREZ of T10 and T11. (The exact position of the entry

zones was confirmed by assessing sequential axial images to

develop the full cranial aspect of the nerve originating from

the spinal cord.) As shown in Figure 2, the difference between

this measurement on the neutral and flexed images is a

measure of spinal cord contraction/expansion along the

rostral-caudal axis. Next, a cranial caudal measurement was

made from the DREZ of the T10 nerve root along the same

plane as the prior measurement, to the level of a plane

orthogonal to the spinal canal at the level of the inferior T10

pedicles. The latter were selected as a reference point of the

bony canal inside of which the spinal cord moves. The

difference between these measurements represents cord

movement within the bony canal. An example of a coronal

image on which the relevant anatomical features are identified

is shown in Figure 3.

Lastly, a cranial caudal measurement of the change in

conus tip position was made. In order to accurately accom-

plish this, the position of the conus tip was first identified on

the neutral images with reference to a landmark within the

bony spinal canal at the same cranial-caudal level. This

landmark was then identified on flexed imaging and a cranial

caudal measurement was made from that level to the level of

the new conus position. This measurement also represents

movement of the spinal cord within the canal.

3. Results

The spinal cord should move rostrally during flexion and

should lie in its most caudal location when the patient is in the

neutral position. The measured change in the pedicle-to-spinal

cord DREZ distance across all patients between the neutral

and flexion positions ranged from 1.9–18.0 mm, with a mean

and standard deviation of 8.5 ± 6.0 mm. The inter-DREZ

distance across all patients between the neutral and flexion

positions ranged from −2.0–6.7 mm, with a mean and
The mean and standard deviation for the rostral-caudal conus movement was found to be 6.4 ± 4.1 mm within an overall range of 1.1–11.4 mm. The fractional variations in these findings (standard deviation/mean) are very large, 71%, 74% and 64%, respectively. This reflects the wide variability in the capacity of individual subjects to maximally flex the spine, as well as possible inter-subject variability in spinal cord mechanical characteristics.

4. Discussion

Several previous studies have reported both gross anatomical and image-based measurements of spinal cord motions and related mechanical parameters, some of which are relevant to the HSCMS design issues discussed above. For instance, Figley and Stroman [6] found that the amplitude of the cardiac-driven pulsation of the anterior-posterior (A/P) component of bulk cord movement in 10 immobile patients was 0.60 ± 0.34 mm in the cervical and upper thoracic region. However, as found in their subsequent study on eight immobile patients [7], this value was <0.10 mm in the lower thoracic region (T4/T5 and below), with excursions of the same size along the left/right axis, thus setting the lower limits on the size of bulk cord motions in those directions. Much larger changes (millimetre-scale) in the A/P position of the spinal cord relative to the dura were found in patients who purposely changed posture or carried out flexion/extension manoeuvres during imaging [8,9]. See also the reviews of Harrison et al. [10] and Cox [11]. Furthermore, it has long been known that flexion and extension of the spine produces centimetre-scale axial stretching motions of the spinal cord and dura along the rostral-caudal (R/C) direction relative to the other structures forming the spinal canal [12]. However, that work was carried out on fixed-tissue samples from cadavers and there are no reported equivalent series of in vivo measurements that use a similar protocol. While all of these studies have provided very useful background information, an effort focusing specifically on determination of the axial component of spinal cord motion within the region targeted for HSCMS implantation was needed to complete the picture.

Moreover, from a biophysical perspective, the findings presented here can also be used to yield the ratio of the spinal cord’s mean stretch-to-mean axial movement over a full flexion cycle: 3.5 mm/8.5 mm ≈ 40%. That is, on average across all patients, it required 1 mm of net axial displacement of the cord to stretch it ∼0.4 mm in length. However, as discussed above, there were large variations between patients and this makes it difficult to draw generalized conclusions about the mechanics of the spinal cord in relation to certain aspects of its interaction with the HSCMS. For instance, estimates of the net strain within its parenchyma will depend strongly on the assumptions made regarding how the spinal cord’s stretch is distributed over its length, as that will be governed at least in part by the anisotropies in its structure in a given patient. In the worst case, for some patients, high levels of parenchymal strain could mean that the HSCMS electrodes might slide across the spinal cord’s surface unless the membrane is compliant enough to accommodate this component of the cord’s axial motion. On the other hand, in those cases where the stretching component is more localized within a given region of the typically 45 cm long cord, the strain would likely be smaller, foreseeably 1% or less, thus resulting in little relative motion between the HSCMS electrodes and the spinal cord. A large animal (ovine)
in vivo trial is now underway to investigate chronic interactions between the HSCMS and the spinal cord surface and histologic examination of explanted samples for evidence of tissue damage will be carried out. (The preliminary data from an earlier acute (non-survival) ovine in vivo study [3] showed no evidence of tissue disruption.)

Lastly, from a HSCMS design perspective, it is now clear that the lead loops of the devices implanted in some patients must be sufficiently large to permit a total rostral-caudal range of motion of up to ~2 cm for the cord/membrane relative to the Oya Strap fixation point, i.e. 1 cm rostral and 1 cm caudal from the neutral position. HSCMS prototypes with loop area 160 mm², when placed on a custom-designed silicone surrogate spinal cord arrangement [13,14] can accommodate axial movement of the surrogate cord over most of that range of displacements without lift-off of the membrane at either the rostral or caudal extremes of displacement. Careful bench top studies now underway will evaluate prototype devices with both larger and smaller loop areas and membrane lengths, to test for potential lift-off or other movement of the HSCMS as a function of spinal cord displacement and rotation. However, beyond these biomechanical design considerations, the natural scar formation processes will also play a role in stabilizing the position of the electrode-bearing membrane on the surface of the spinal cord. A separate series of in vivo studies, now also underway, are investigating that point. Lastly, other future studies will include extending the number and age range of volunteers in the imaging protocol discussed above, to broaden the scope of our findings.

5. Conclusions
MR-based measurements of the rostral-caudal motions of the spinal cord during flexion of the spine were made in a series of 16 volunteers. The results indicated that there were large variations, ≈ 70%, in the magnitude of that motion from person to person, with implications for the design of the intradural components of the HSCMS. In particular, there will be a spectrum of spinal cord strains associated with flexion-driven motion of the cord. Having suitable axial compliance within the electrode bearing portion of the HSCMS will reduce the risk of potential irritation of the pial surface by the HSMCS in those patients where the intraparenchymal strains are large enough to induce some sliding motion of the electrodes. In patients with small levels of strain, there would be little relative motion between cord and HSCMS, meaning that there would be small risk of any skidding of the electrodes on the pial surface. Also, the net axial travel of the spinal cord relative to the Oya Strap fixation device of the HSCMS is within the range that can be accommodated without lift-off of the electrode bearing portion of the HSCMS for some of the devices that were preliminarily tested. More definitive and systematic evaluations are underway.

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The first two authors have made equal contributions to this work and are therefore designated as co-first authors. We thank Hiroyuki Oya, MD, Hiroto Kawasaki, MD, W. R. Smoker, MD, and H. Chen for several useful discussions and technical assistance. We also thank R. Shurig and colleagues of Evergreen Medical Technologies LLC for skillful fabrication of the prototype HSCMS devices and for the illustration used in Figure 1. AMS subject classification: 92C10; 92C.

Declaration of interest
Authors Viljoen, Dalm, Reddy, Gillies and Howard may receive patent royalties from any commercial licensing of the HSCMS intellectual properties that might be negotiated by their respective institutions.

References