Post-surgical pathologies associated with intradural electrical stimulation in the central nervous system: design implications for a new clinical device

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Introduction

The Human Spinal Cord Modulation System (HSCMS) utilizes a new version of the HSCMS that is designed to enable more precise activation of targeted pathways within the spinal cord. This method, termed the subdural HSCMS, offers a number of distinct advantages: the placement of the stimulating electrode array was originally subdural but eventually, due to certain post-surgical complications, it became exclusively epidural. We are developing a method of spinal cord stimulation that is designed to precisely activate targeted pathways within the spinal cord. This method, termed the subdural HSCMS, offers a number of distinct advantages: the placement of the stimulating electrode array is subdural.

Results

Figure 1. The electrode-bearing surface of an early prototype version of the HSCMS. The device is shown in place on an exposed section of ovine spinal cord during an acute in vivo trial. This particular device is made of a nearly transparent thin film of silicone, had nine electrodes arranged in a 3 x 3 array, and was held in place by clips attached to dural flaps.

Animal Studies: Acute Pathologies Chronic Pathologies

Surgically-induced

Mechanically-induced

Electrically-induced

Human Patients: Acute Pathologies Chronic Pathologies

Surgically-induced

Mechanically-induced

Electrically-induced

Table 2. Summary of the acute and chronic pathologies of surgically placed intradural spinal cord stimulators in human patients.

Normal

Seroma

CCompression

D Infection

E Hematoma

Figure 3. Summary of the types of neurological complications reported during the early clinical use (ca. 1970) of intradural spinal cord stimulators in patients.

Conclusions

Many of the histological changes observed develop in reaction to placement of a mechanical implant on the surface, or within the substance of the brain or spinal cord, and are not associated with adverse clinical consequences.

Similar histological changes also occur following implantation of other, non-stimulating devices into brain or spinal cord (e.g., silicone catheters for CSF diversion or the convection-enhanced delivery of agents).

The results of these studies provide consistent evidence of the safety of electrical stimulation below well described tissue injury thresholds.

References


REFERENCES

Table 1. Summary of the acute and chronic pathologies of surgically placed intradural spinal cord stimulators in various animal models.

Summary of the acute and chronic pathologies of surgically placed intradural spinal cord and/or brain electrical stimulators in various animal models. This information was obtained using an extensive literature search specifically targeting animal modeling of SCS.

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