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Laboratory Study

Safety and efficacy of a novel ultrasonic osteotome device in an ovine model ☆

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ABSTRACT

The use of ultrasonic technology for bone removal offers the potential advantages over the use of traditional hand instruments or cutting burrs of more precise bone resection and reduced soft-tissue injury. While the use of modified ultrasonic aspirators has been described for bone removal in spinal surgery, none of these instruments has been systematically examined to evaluate safety and efficacy. Thus, we compared laminectomies using traditional instruments, and traditional instruments with an ultrasonic osteotome, in an ovine model. We used a combination of clinical examination, intra-operative and post-operative neuromonitoring and histological analysis to evaluate safety. The secondary endpoint of efficiency was assessed by examining operative times. No significant difference was found between groups in neurophysiology or the Tarlov clinical rating scale. Histology revealed inflammatory or reparative changes in 6/8 experimental animals and 2/4 control animals with a single section in an experimental animal revealing focal nerve root disruption and mild axonal loss. A single durotomy was noted in both the control and experimental groups. Operative time for the experimental group was significantly shorter than the operative time for the control group.

1. Introduction

Bone removal, through laminectomy and laminotomy, is essential to spinal surgery. Traditionally, laminar bone removal has been performed with hand instruments such as Kerrison punches and Leksell rongeurs. The development of the high-speed pneumatic drill with rotating burrs facilitated the removal of bone and exposure of the neural elements in the spine. All surgical tools carry the risk of durotomy from incorporation of dura into the device, abrasion of the dura from the rotating tip, and neural injury from compression and avulsion.

Ultrasonic devices work by creating highly localized tissue disruption through the generation of vibratory forces. Examples of these devices in spinal surgery include ultrasonic aspirators and dissectors for removal of tumors, bone, and intermediate-density tissues. Some of the earlier efforts for ultrasonic bone removal met with limited success due to insufficient performance, poor ergonomics, difficulty of use and set-up, and associated complications during clinical use.

Recently, adaptations of this technology have allowed for bone dissection along a narrow cutting blade that vibrates longitudinally at high frequency and with small stroke. The described ultrasonic osteotome allows for the creation of narrow cuts with reduced bone debris. By combining a narrow blade with a self-irrigating system this device provides lubrication and cooling into the cutting cavity and limits the potential for both mechanical and thermal injury. Soft tissue has higher elastic properties than osseous structures and can withstand higher amounts of impact energy. Theoretically, this creates an extremely well-controlled environment for bone removal while reducing the risk of injury to the dura and neural elements.

An ovine model was utilized to evaluate the safety and efficiency of laminar bone dissection using an ultrasonic osteotome compared to the traditional methods of the high-speed pneumatic drill and the Kerrison punch. Our primary endpoint was to evaluate the device for safety using a combination of histology, neurophysiology, and clinical grading scales. Secondary endpoints included surgical efficiency and ease of use.

2. Materials and methods

2.1. Ultrasonic osteotome device

The ultrasonic osteotome system (Misonix BoneScalpel, Misonix, Farmingdale, NY, USA) is a bone-cutting device, which uses

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linear, ultrasonic action instead of rotary, powered motion to remove bone. The unit consists of a tabletop generator, irrigation pump, hand piece and an assortment of tips from 10 mm to 20 mm in cutting length and 0.5 mm to 1.0 mm in thickness (Fig. 1). This device operates at 22.5 kHz frequency and uses a blunt ultrasonic blade that is continuously irrigated through the tip, allowing the surgeon to create straight or smoothly curved cuts in any bony plane. The device has integrated irrigation through the tip to reduce the potential for local thermal necrosis. Tissue response to the ultrasonic blade differs according to tissue elasticity and length of exposure.

2.2. Operative procedures

Twelve sheep were selected, individually housed and treated according to standard laboratory practices. Eight surgeries were performed using the ultrasonic osteotome device and four procedures were performed as a control using traditional means. All operations were performed by the senior author (WCW). The sheep were placed under general anesthesia using acepromazine–ketamine and maintained with isoflurane following intubation. No nitrous oxide or pharmacological paralytic were given at any time during the surgical phase of the procedure. For post-operative somatosensory evoked potential (SEP) studies, animals were sedated with ketamine but were not intubated

Each animal was placed prone and a midline incision was made, centered about the L5 spinous process. Dissection was carried out through the subcutaneous tissue and the dorsal muscle attachments were dissected from the spinous processes, laminae and facet joints at L3–L5. A complete *en bloc* laminectomy with preservation of the facet joints of L3 to L5 was performed in the experimental group with the ultrasonic osteotome being used to dissect the lamina, and the Kerrisson punches and Leksell rongeurs to remove the ligamentous attachments. In the control group, a high-speed drill with a 3-mm bit (MidasRex, Medtronic, Minneapolis, MN, USA) was used together with Kerrisson punches and Leksell rongeurs. The dura and nerves were inspected for injuries. Dural repairs were performed when necessary. The operative time was measured from the beginning of the laminectomy until the L3–L5 lamina was removed, exposing the dura and the epidural space.

Fig. 1. Photograph showing the Misonix generator and handpiece with attached tip.

2.3. Neurophysiological monitoring

Baseline SEP were obtained prior to surgical intervention, after induction of general anesthesia, and 48 days to 64 days after surgery using identical stimulation and recording parameters with the animal under sedation. Bilateral thoracic and pelvic limb stimulation was performed independently for the generation of SEP recordings. Baseline and post-operative thresholds, amplitudes, and latencies were compared.

The dorsal branch of the ulnar nerve was stimulated on the lateral aspect of the forelimb while the tibial nerve was stimulated on the lateral aspect of the hind-limb using subdermal needle electrode pairs. Averages were computed for 128 trials.

A greater than 50% reduction in primary somatosensory cortical amplitude, or in the cervically recorded response, or a prolongation of response latency (>10%) not related to changes in anesthesia, were viewed as being significant. These criteria have been previously validated and agreed upon in the literature as being of optimal sensitivity and specificity for detecting iatrogenic injury in the spinal cord.

Bilateral forelimb and hind-limb electromyographic (EMG) recordings were made from appropriate thoracic and pelvic muscle groups bilaterally in all animals, and any spontaneous EMG activity during the surgical period was noted. EMG activity was collected in a "free running" mode and was not averaged. Spontaneous EMG activity was collected throughout the duration of the surgical procedure and any spontaneous EMG activity during the immediate post-operative recovery was noted. Lack of any detectable EMG activity was considered in each instance to be baseline. All occurrences of spontaneous EMG activity, regardless of frequency or duration, were recorded and documented.

2.4. Functional and histological analysis

Weekly clinical neurological and behavioral evaluations examined gait, reflex reaction, bowel and bladder function and pain response beginning 1 week following surgery. The rear extremity Tarlov scale was utilized for neurologic assessment.[1] Following sacrifice, tissue sections were stained with hematoxylin and eosin and glial fibrillary acidic protein (GFAP) and neurofilament immunostains. The integrity of the dura, nerve roots, and bone was assessed in both groups.

2.5. Statistical analysis

The data for laminar bone removal times were analyzed using non-parametric statistical analysis because of the relatively small sample size (Mann–Whitney *U*-test). Differences were considered statistically significant at $p < 0.01$. The data for neurophysiological monitoring are reported as means ± standard deviation and were analyzed using non-parametric statistics (Mann–Whitney *U*-test).