Comparison of thermal spread with the use of an ultrasonic osteotomy device: Sonopet ultrasonic aspirator versus misonix bone scalpel in spinal surgery

ABSTRACT

Background: The development of high-speed rotating burrs has greatly advanced spinal surgery in recent years. However, they produce unwanted frictional heat and temperature elevation during the burring process. We compare the misonix bone scalpel (MBS) and the Sonopet ultrasonic aspirator to assess which would be the safer device in terms of the risk of thermal injury following laminectomy.

Methods: We describe an experimental nonrandomized study comparing two ultrasonic osteotomy devices. We use the device tip temperature and temperature of inner cortex of the lamina, following laminectomy, as the primary outcome. Our secondary outcome is to assess which device is associated with a lower risk of osteonecrosis and potential thermal injury to surrounding dura and nerves.

Results: The average device tip temperature for the Sonopet ultrasonic aspirator following the process of laminectomy was 36.8°C with a maximum temperature of 41.8°C. The average device tip temperature for the MBS following laminectomy was 48.6°C with a maximum temperature of 85.3°C.

Conclusion: Our results have demonstrated the safety of the Sonopet ultrasonic aspirator with the Nakagawa serrated knife with temperatures below the threshold for osteonecrosis and thermal neural injury. However, the MBS has shown to occasionally reach high temperatures above the threshold of potential thermal injury to surrounding nerves and dura for a very short period of time. We advise to withdraw and re-insert the ultrasonic tip repeatedly to re-establish adequate cooling and lubrication. Further studies should be carried out using cadaveric bone at body temperature to simulate more accurate results.

Keywords: Misonix bone scalpel, osteonecrosis, Sonopet ultrasonic aspirator, thermal injury

INTRODUCTION

The development of high-speed rotating burrs has greatly advanced spinal surgery in recent years. However, they have multiple limitations. They produce unwanted frictional heat and temperature elevation, during the burring process which has a detrimental effect on bone regenerating capacity and may lead to thermal necrosis of bone.[1] Even when using more recent diamond burrs, the proximity of rotating parts to structures such as nerves, vessels, and dura mater along with the associated heat damage to the surrounding tissues can limit their use or result in iatrogenic injury.[2] In fact, it has been shown, that nerve roots are at risk of damage from the heat generated by the burr on a high-speed drill penetrating bone.[3]

Due to the above challenges, there have been great advancements in the instrumentation used for osteotomies in spinal surgery. The use of ultrasonic vibration for the cutting of bone was developed several decades ago. Such devices originally developed for dentistry and first appeared in 1952 were they were quickly adapted, and their use

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developed. However, it was only the past few years that the tools and techniques have been adopted in the surgical field. Most recently, ultrasonic devices such as the Misonix Bonescalpel (MBS) and the Sonopet ultrasonic aspirator have risen in favor. Such devices have been developed to efficiently slice through bone while leaving elastic soft tissues largely unaffected during incidental contact.[6]

The incidence of complications in spinal surgery varies with reports suggesting anywhere between 10% and 38.6% of patients undergoing a surgical procedure will experience an adverse event.[2] Across the studies, the incidence of dural tears ranged from 1.6% to 9%.[2] Therefore, the development of these ultrasonic devices, which are designed for precise removal of rigid bone while remaining atraumatic to elastic soft tissues, are aimed at reducing the incidence of iatrogenic durotomy and neural injury.

METHODS

Aims and objectives
We compare the MBS, and the Sonopet ultrasonic Aspiration to assess which would be the safer device in terms of the temperature of the device tip and underlying bone reached following laminectomy. This will give us an indication as to which device is associated with a lower risk of osteonecrosis or thermal injury to surrounding structures such as dura and nerves.

Study setup
The Bone Simulating Samples used in the study were Synbone model LDPR1212. They were separated into individual vertebrae and placed aside for use in the experiments. Each vertebra was then set up in a tray with a central anchor to hold each vertebra in place. We used a k-type thermocouple device with a surface probe for temperature measurements.

Initial measurements included the baseline temperature of the device tip and the inner cortex of the lamina. To make these measurements, the surface probe of a type K thermocouple was placed over the device tip and the temperature recorded. This was referred to as the “baseline temperature of device tip.” After 5 min as the thermocouple returned to room temperature, the surface probe was placed at the inner cortex of the lamina, and the temperature obtained was recorded. This was referred to as the “Baseline temperature of inner cortex of lamina.” A unilateral laminectomy was performed by a senior consultant spinal surgeon.

Following laminectomy, before the point of tip penetration, the temperature of the inner cortex of the lamina was measured using the surface probe. We ensured that the surface probe was in direct contact with the inner surface of the lamina as opposed to the device tip in this setting. The laminectomy was repeated after another 5 min, and as the device tip penetrated the lamina, the temperature of the device tip post laminectomy was measured and recorded. In this setting, we ensured that the surface probe was in direct contact of the device tip as opposed to the bone surface. A total of 14 experiments were performed for each device. All were recorded and none were excluded.

The experiment was performed with the Sonopet ultrasonic aspirator using the Nakagawa serrated knife and then repeated for the MBS. The laminectomies were conducted by the same senior consultant spine surgeon, and the same type K thermocouple was used. All experiments were done in the same room at room temperature. All bone-simulating samples used for the experiment were of the same model manufactured of the same material, and all were stored at room temperature before use. Saline irrigation was used for both devices as it would normally be used in an actual theatre setting.

Statistical analysis
Statistical analysis was conducted using Minitab software version 17(Minitab inc, State College Pensylvania, USA). We began our analysis by assessing the change in temperature of the Sonopet ultrasonic aspirator device tip before and after laminectomy. The paired t-test was used to compare the mean temperatures of device tip before and after laminectomy with 95% confidence interval. The paired t-test was also used to assess the change in mean temperatures of the MBS device tip before and after laminectomy with 95% confidence intervals. Once these calculations were performed, the two sample t-test was used to compare the mean temperature rise for each device following laminectomy. We performed similar comparisons to the temperature of the inner cortex of the lamina using the MBS and Sonopet ultrasonic aspirator. During our analysis, we also compare the maximum temperatures reached by the device tip and the inner cortex of the lamina for each device.

RESULTS

We begin with presenting the results for the Sonopet ultrasonic aspirator mounted with the Nakagawa serrated knife. The average baseline temperature of the device tip for the Sonopet ultrasonic aspirator was 22.9°C. The average temperature of the device tip following laminectomy was 36.8°C. Therefore, the mean increase in temperature of the device tip following the process of laminectomy was 13.8°C. This was found to be statistically significant with a \( P < 0.05 \).
The average of temperature of the inner cortex of the lamina at baseline was 23.1°C. The average temperature of the inner cortex of the lamina following laminectomy was 31.0°C. Therefore, the mean increase in temperature of the inner cortex of the lamina following the process of laminectomy was 7.9°C. This was found to be statistically significant with a $P < 0.05$.

The maximum temperature of device tip for the Sonopet ultrasonic aspirator following laminectomy was 41.8. The maximum temperature reached of the inner cortex of the lamina following laminectomy was 39.7°C. These results are summarized in Figures 1 and 2.

The average size of the lamina used was 6.14 mm for the Sonopet ultrasonic aspirator.

**Misonix Bonescalpel**

The average baseline temperature of the device tip for the MBS was 23.3°C. The average temperature of the device tip following laminectomy was 48.6°C. Therefore, the mean increase in temperature of the device tip following the process of laminectomy was 25.3°C. This was found to be statistically significant with a $P < 0.05$.

The average of temperature of the inner cortex of the lamina at baseline was 23.6°C. The average temperature of the inner cortex of the lamina following laminectomy with the MBS was 35.0°C. Therefore, the mean increase in temperature of the inner cortex of the lamina following the process of laminectomy was 11.4°C. This was found to be statistically significant with a $P < 0.05$.

The maximum temperature of device tip reached following laminectomy was 85.3. The maximum temperature of the inner cortex of the lamina reached following laminectomy was 40.3°C. These results are summarized in Figures 3 and 4.

The average size of the lamina used for the MBS was minimally higher at 6.86 mm.

**DISCUSSION**

The MBS is an ultrasonic bone cutting device. It was first officially introduced by Misonix, USA, in 2012, after acquiring its full rights. Its assembly consists of an ultrasonic generator and an irrigation console that connects to a hand piece bearing a disposable cutting tip. The hand piece receives an electrical signal with the nominal frequency of 22.5khz from the ultrasonic console. The high accuracy of the MBS is a result of the back-and-forth micromotion (oscillation) of the Bone Scalpel's thin blade as opposed to the rotary macromotion of a drill's burr. The MBS has two attributes that provide greater safety. First, elimination of rotary motion avoids many of the risks associated with the drill, such as slipping off the cutting surface and entrapping important soft tissues. Second, The Bone Scalpel allows fine and precise bone cuts while repelling soft tissue, which minimizes the risk of dural injury.

In 2010, the Sonopet "Universal" hand piece was developed, which allows surgeons to use a single hand piece for both bone and soft tissue work simply by switching between various tips. The Sonopet ultrasonic aspirator is a versatile system for precise control of soft tissue while simultaneously allowing fine bone dissection in close proximity to delicate structures. The Sonopet ultrasonic aspirator, with its simplistic setup, delivers precise fragmentation, while allowing users to independently control power, suction, and irrigation with one hand piece. The Sonopet uses similar technology to achieve fine bone dissection by coupling torsional oscillation and longitudinal vibration.

![Figure 1: The Blue bar refers to the temperatures of Sonopet device tip taken before laminectomy. The Orange bar refers to the temperatures of the device tip following laminectomy. The X-axis refers to the experiment number](image1)

![Figure 2: The Blue bar refers to the temperature of the inner cortex of the lamina at baseline. The Orange bar refers to the temperature of the inner cortex of the lamina following laminectomy. The X-axis refers to the experiment number](image2)
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Osteonecrosis is a disorder precipitated by many conditions that result in situ bone death. The precise threshold for thermal osteonecrosis of human bone has been evaluated by multiple studies. Lundskog et al. used rabbit bone in 1972 and demonstrated the threshold for irreversible enzymatic disturbance to the cortical bone being 50°C when exposed for 30 s. In 1984 Berman et al. demonstrated that the cellular death caused by heat is immediately evident above 70°C. Other review articles report that if the temperature rises above 55° for a period longer than 30 s, serious damage will be done to bone.

Another risk that arises from the heat of friction generated between the rotating burr and bone is that of thermal damage to nerves. This particular risk has been evaluated by Hosono et al. Their study has shown that the temperature of the bone surface adjacent to the penetrating burr was often higher than 45°C and reached in excess of a 100°. In addition, they proposed that a C5 nerve root palsy can, therefore, occur due to thermal damage to the nerve root. In addition, Bull et al. further showed that 30% of patients who were exposed to hyperthermia at 41.8°C had symptoms of peripheral neuropathy within 24 h, which suggests susceptibility of peripheral nerves to heat.

Due to such concerning risks, Augustin et al. aimed to find an optimal condition where the increase in bone temperature and risk thermal injury during bone drilling would be minimal. With all combinations of parameters used, irrigation maintained the bone temperature below 47°C.

The above concerns of potential osteonecrosis and neural thermal injury have formed the basis of innovating safer modern instruments that reduce the risk of such complications during spinal surgery by incorporating methods of irrigation. The development of ultrasonic osteotomy devices such as the MBS and Sonopet ultrasonic aspirator has proven to be very successful.

Importantly, the MBS manual describes the importance of irrigation with use during bone osteotomy. They document that the device tip and irrigation temperatures may exceed the tissue necrosis point if insufficient irrigation flows or if the tip is not removed relative to tissue; therefore, a continuous, lateral sweeping motion is recommended to minimize contact duration with the ultrasonic tip and minimize heat buildup. The Sonopet follows a similar technology where saline flows coaxially around the tip to suspend fragmented tissue and cool the tip.

Our results have clearly demonstrated the increase in temperature of the device tip and inner cortex of lamina that occurs post laminectomy. We now discuss the potential risk of osteonecrosis and thermal injury to surrounding nerves when both devices are used.

When performing a laminectomy with the Sonopet ultrasonic aspirator, the temperature of the inner cortex of the lamina varied between a minimum of 29.3 and a maximum temperature of 33.7°C, following the procedure. As mentioned earlier, the majority of the literature described a threshold temperature above 50° for signs of osteonecrosis to become apparent. Therefore, the risk of osteonecrosis, when the Sonopet ultrasonic aspirator is used with a Nakagawa serrated knife, is low. When taking the tip device into consideration, the temperatures for the Sonopet ultrasonic aspirator varied from a minimum temperature of 33.4 to a maximum temperature of 39.7°C post laminectomy. The majority of the literature describes temperatures of 45°C before nerve thermal injury. As a result, the risk of thermal injury to surrounding nerves is also low.

We next analyze the results of the MBS. When used for laminectomy, the temperatures of the inner cortex of the lamina ranged from a minimum of 32.8–40.3 with an average
of 34.9°C. When compared to the literature this is safely below the threshold of 50°C. Therefore, the MBS along with the Sonopet ultrasonic aspirator would have a low risk of osteonecrosis when used for laminectomy.

However, when the temperature of the MBS device tip was measured following laminectomy, the temperature range varied from a minimum of 36.7°C–85°C with an average temperature of 48.6°C. This is clearly a wide range of temperatures, but one thing was noticed with the use of the MBS. Following laminectomy, the temperature of the tip device did reach high temperatures like that of 85°C, but within less than a second, the temperature significantly drops with continued irrigation. This explains the reason why the temperatures recorded for the tip of the MBS post laminectomy were not all as high as 85°C. As demonstrated by Berman et al., cellular death caused by heat is immediately evident above 70°C. Therefore, there is a potential risk of thermal injury to nerves when the MBS was used for laminectomy. It is also essential to note that there was a small difference in the average sizes of the lamin samples used for each device. This is a small difference, and natural variability normally exists between human lamina in spinal surgery. However, the difference can slightly interfere with results of direct comparison between the two devices.

It is important to acknowledge that the samples used for this study were made of low-density polyurethane foam. Although this is meant to resemble human cancellous bone, they are not identical. Human bone has more water content than low-density polyurethane foam; hence, results of this study should be interpreted with caution. To the best of our knowledge, there have not been any studies that directly compare the heat produced with bone osteotomy devices when used against polyurethane and human bone, which limits the external validity of the study. Further studies should be carried out using cadaveric bone at body temperature to simulate more accurate results.

CONCLUSION

Our results have demonstrated the safety of the Sonopet ultrasonic aspirator with the Nakagawa serrated knife. The average and maximum temperatures of the device tip and inner cortex of the lamina reached post laminectomy were well below the threshold for osteonecrosis or that of thermal injury to surrounding nerves. However, the MBS has shown to reach occasional high temperatures above the threshold of potential thermal injury to surrounding nerves and dura; therefore, a continuous, lateral sweeping motion should be strictly followed as recommended when in use. In addition, we advise to withdraw and re-insert the ultrasonic tip repeatedly to re-establish adequate cooling and lubrication. Further studies should be carried out using cadaveric bone at body temperature to simulate more accurate results.

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Conflicts of interest

There are no conflicts of interest.

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