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WATERJET ASSISTED CRANIOTOME FOR REDUCED DURAL TEARS

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BACKGROUND

A craniotomy is a procedure where a piece of the skull is removed in order to gain access to the brain. This is commonly done to remove brain tumors, treat epilepsy, and to treat traumatic brain injury. Currently, the craniotomy procedure involves drilling one or more burr holes and then using a craniotome to complete the cut. The craniotome consists of a rotating cutting tool and a dura guard, which is intended to prevent the cutting tool from touching the dura. However, even with the dura guard, dural tears occur in approximately 20-30% of craniotomy procedures [1], [2]. There are approximately 160,000 craniotomies performed per year in the United States [3]. Dural tears add time to the craniotomy procedure due to the increased difficulty in suturing the dura and the potential need to use synthetic dura material in order to reclose the dura. Also, if the dura tears while using the craniotome, the brain is no longer protected as the craniotomy is completed. There is a strong desire among neurosurgeons to have an improved tool for craniotomies that reduces the incidence of dural tears.

The proposed improvement to the craniotome is to use high pressure liquid, such as a sterile saline solution, to separate the dura from the cranium ahead of the craniotome in order to minimize the risk of the dura snagging on the dura guard (see Figure 1). In the literature, Tschan et al. have shown that high pressure water can be used to separate dura from skin after a decompressive craniotomy has been performed [4]. These previous results show that high pressure saline can be successfully used to separate dura from another surface without damaging the dura. In the proposed design, the high pressure waterjet will be incorporated into the dura guard design. The addition of a high pressure waterjet could be incorporated into an entirely new craniotome design or it could be designed as an attachment to an existing craniotome already on the market.

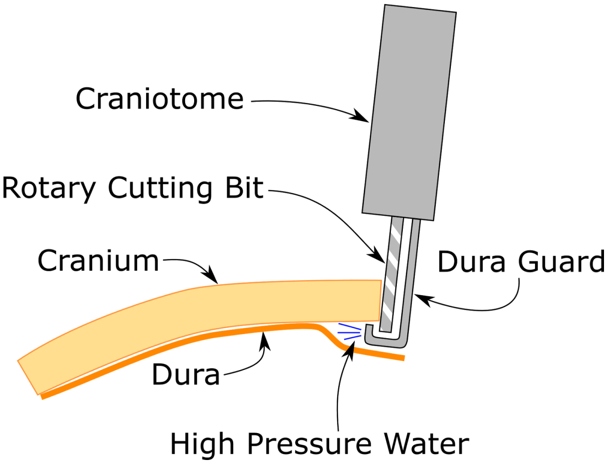

Figure 1. Proposed craniotome with high pressure waterjet.

High pressure saline is currently used by the Erbejet 2 waterjet dissector to cut and dissect soft tissues [5]. The Erbejet 2 is an FDA cleared device manufactured by Erbe USA, Inc. The FDA approved indications for use for this device include cutting and dissection in neurosurgical applications for both open and endoscopic surgery [6]. The proposed embodiment of the improved craniotome device described in this paper would use a high pressure pump similar to the one used by the Erbejet 2 device, which uses a disposable pump cartridge to maintain sterility.

Various features, such as the waterjet angle, suction, and nozzle shape, can be incorporated into this improved craniotome design. The angle of the waterjet on the dura guard can be set so that there is no possibility of the waterjet directly hitting brain tissue in the event that the dura tears. For example, the waterjet can be angled up towards the cranium. A suction feature can also be added to remove the fluid introduced by the waterjet. Additionally, the waterjet nozzle shape can be optimized for effectiveness. Potential nozzle shapes may result in a fan, circle, cone, or point shaped water stream.

METHODS

For the design of the craniotome waterjet, three subsystems had to be designed; the waterjet, the craniotome, and the synthetic cranium. These systems were designed to mimic the actual craniotomy procedure conditions and tools within a limited prototype budget.

The waterjet subsystem was designed to have a high pressure and low flow rate similar to the waterjet used in Tschan et al. To obtain the high pressures, a pressure washer capable of 11 MPa of pressure and 6 liters/min of flow was selected. A valve and two pressure gauges were added to the system to control flow and monitor pressure before and after the valve. A shunt flow path was added to handle the excess flow from the pressure washer pump. When the valve is opened, the craniotome waterjet receives a small flow rate at high pressure from the system. After the second pressure gauge, 3.2 mm flexible tubing is used to allow for mobility of the waterjet. The final tubing used is for the nozzle of the waterjet and has a 0.5 mm interior diameter. The pump and bypass flow configurations are shown in Figure 2.

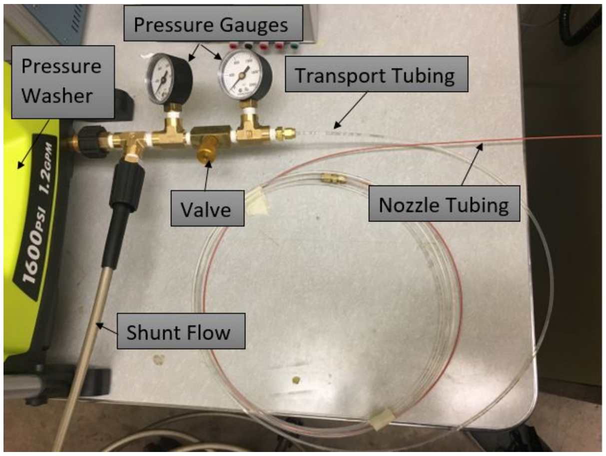

Figure 2. Waterjet Subsystem.

The next step was to develop the tool used to perform the craniotomy procedure. A Dremel 8220 rotary tool was selected since it has a similar size and operates at a similar speed compared to existing craniotome designs. The Dremel 8220 has an adjustable speed from 5,000 to 35,000 RPM. It can also accommodate a 3.2 mm bit. This bit size is very similar in size to the bits used for craniotomy procedures which range from 1.5 to 3.0 mm in diameter.

The Dremel tool was modified to incorporate an aluminum dura guard feature similar to existing craniotome designs. The custom dura guard was designed to fit over the attachment threads that are present on the end of the Dremel tool. The dura guard was designed to fit into a 16 mm burr hole, which is a common burr hole size used for craniotomy procedures. The nozzle from the waterjet is attached to the dura guard with an epoxy adhesive as shown in Figure 3. The nozzle has an angle of around 10 degrees upward to avoid directly spraying the brain with the pressurized water in the event of a dural tear.

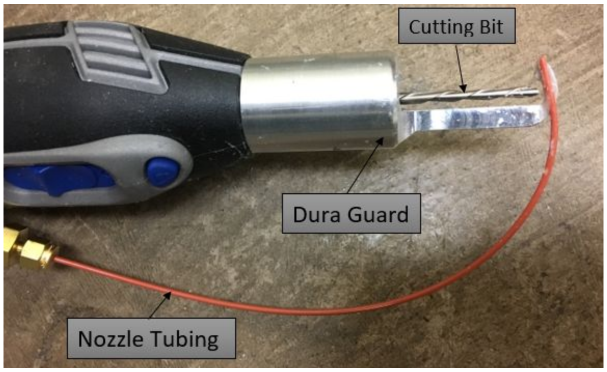

Figure 3. Dura guard and nozzle angle.

The synthetic cranium materials were selected to match the material properties and thicknesses of typical human cranium and dura. The cranium material was selected to be high-density polyethylene (HDPE). HDPE was chosen for its machinability properties [7]. A large square sheet of HDPE with a thickness of 6.4 mm was used to match typical cranium thickness. To replicate the Dura, a neoprene sheet of 0.8 mm thickness was used to match the typical thickness of human dura [8]. The neoprene was adhered to the HDPE with rubber cement to simulate the adhesion of the dura to the cranium.

Testing was performed using a pressure of 6.2 MPa and a flow rate of 350 ml/min through a 0.5 mm nozzle. The dremel was set to a speed of 25,000 RPM. Testing was performed starting on the edge of the synthetic model since the size of the current device does not allow it to fit within a bur hole due to the large bend radius of the nozzle tube. This issue will be addressed in future prototypes. Five test runs were performed, with each run alternating whether or not the waterjet was turned on.

RESULTS

Testing was recorded on video to evaluate the effectiveness of the waterjet to separate the dura from the cranium. The length of cut and the separation distance were recorded where the separation distance is how far the synthetic dura and cranium layers are separated in front of the cut. Figure 4 shows two test cuts of the synthetic cranium with (left) and without (right) the waterjet turned on.

Testing with the waterjet turned on in the left half of Figure 4 shows the craniotome smoothly making the cut and gliding over the dura. After separating the layers, the water flows backwards bringing chips from the cut with it. Testing without the waterjet in the right half of Figure 4 shows the dura binding on the dura guard and folding over. Figure 5 shows the results of two of the tests on the synthetic cranium viewed from the neoprene (dura) side of the synthetic cranium. The bottom half of Figure 5 shows the separation boundary where the neoprene (dura) has been separated from the HDPE (cranium).

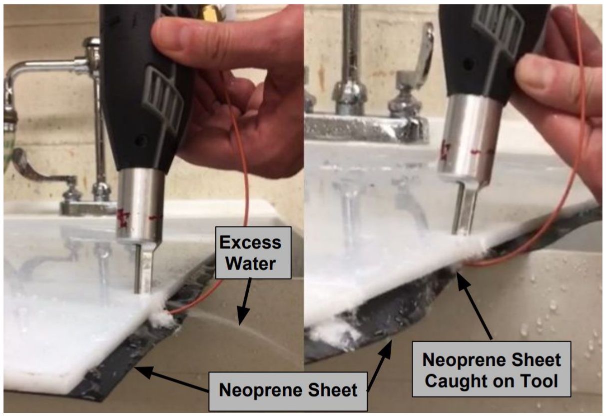

Figure 4. Test cut with (left) and without (right) the waterjet turned on.

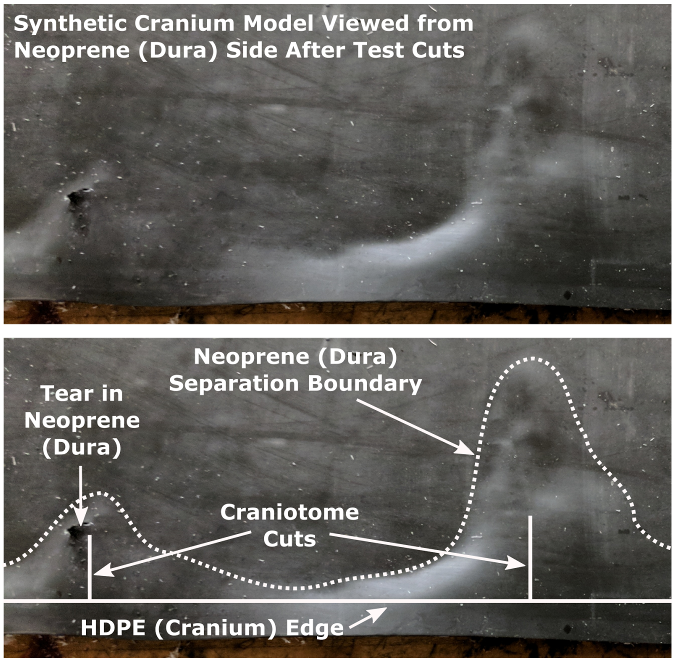

Figure 5. The top figure shows the neoprene side of the synthetic cranium model after test cuts were performed without (left) and with (right) the waterjet turned on. The bottom figure is the same figure with the cut locations and the separation boundary highlighted.

The test performed without the waterjet turned on shows little separation of the layers in front of the cut. A puncture of the neoprene layer can be seen at the end of the cut forcing the test to stop (see the left half of Figure 5). This was caused by the dura guard pushing the neoprene layer and eventually folding it over into the cutting bit.

The test performed with the waterjet turned on shows separation of the layers further in front of and around the cut. The waterjet pushes the neoprene away from the HDPE leaving a clear path for the cutting tool. The dura does not get caught in or get punctured in any of the tests performed with the waterjet turned on. Table 1 compares the dura-cranium separation distance ahead of the cut for each of the tests.

Table 1. Separation distance results.

Test Type	**Dura-Cranium Separation Distance Ahead of Cut (mm)**
Water	44.5
Water	28.7
Water	47.8
No Water	6.4
No Water	3.3

Table 1 quantifies the impact that using the waterjet has on the separation distance ahead of the cut. The cases without the waterjet turned on have an average separation distance of 4.9 mm. This is approximately the distance from the cutting bit to the front of the dura guard. In contrast, the cases with the waterjet turned on have an average separation distance of 40.2 mm. Enabling the waterjet results in an order of magnitude increase in the distance that the dura and the cranium are separated ahead of the cut.

INTERPRETATION

The results obtained from this experiment show that the utilization of a waterjet for the craniotomy procedure can be very beneficial. The separation distance in front of the cut prevents the dura from catching on the dura guard and from being damaged by the cutting bit. Using a waterjet attachment on a craniotome has the potential of improving the outcomes of craniotomy procedures by reducing complications caused by dural tears.

The next steps for this project are to bring the waterjet craniotome design closer to the point of commercialization. The waterjet dura guard attachment can be improved. As seen in Figure 3, the large bend radius of the nozzle tubing prevents the cutting tool from easily fitting in a burr hole for testing. A new model was developed that incorporates a flow path for the water within the dura guard eliminating the need for the bulky external nozzle tubing. It was 3D printed with the stereolithography process using the Somos WaterShed XC material. This material was chosen because of its water resistance and durability. The 3D printed dura guard is shown below in Figure 6.

This dura guard will be attached to the current system and more testing will be conducted. To more closely mimic the actual craniotomy procedure, this dura guard will be tested by starting the cut in a predrilled burr hole rather than starting the cut on the edge of the synthetic cranium model.

Once these proposed changes to the prototype have been tested with the synthetic cranium model, the prototype will be tested with a cadaver model. The tool will be tested using a simulated craniotomy procedure where burr holes drilled in the cranium will be connected using the prototype craniotome. This planned cadaver testing will verify the performance of the waterjet assisted craniotome design in conditions very close to the actual surgical conditions where it is intended to be used.

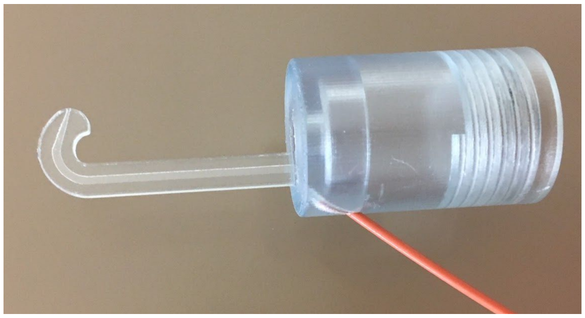

Figure 6. Dura guard with internal flow path.

ACKNOWLEDGMENTS

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