Comparison of a Novel Deflective and Absorbent Neurosurgical Device to a Standard Neurosurgical Pattie: A Live Porcine Craniotomy Study

ABSTRACT

Objectives

A live porcine craniotomy study was performed to compare the behavior of ArmourSorb®, a novel patent pending deflective and absorbent surgical device (ASC; Salem, Massachusetts, USA), to the leading competitor's neurosurgical pattie when both are deliberately placed into contact with a high-speed rotating drill burr. A secondary objective was to compare the duration of moisture retention of ArmourSorb® with and without its protective layer to the leading competitor's pattie.

Methods

Lab observations were reviewed in 3 parts: gross observations by a Board Certified Neurosurgeon performing the study procedure, subgross analysis, and histologic analysis of underlying neural tissue. An additional analysis was performed as part of the overall evaluation of the new deflective device. Moisture retention between the ASC devices with and without the protective layer were compared.

Results

The ArmourSorb® surgical device achieved its primary design objective in preventing wrapping with the rotating burr and protected the underlying base material from shredding or fraying. All tested competitor patties perforated, wrapped, and shredded. Additionally, the inclusion of the protective layer allowed the ArmourSorb® devices to demonstrate a significantly longer mean duration of moisture retention compared to the leading competitor's pattie (66.1 minutes vs 34.8 minutes, respectively).

Conclusions

ArmourSorb® devices do not experience mechanical failure nor result in gross damage to underlying neural structures as was seen with the leading competitor's pattie when subjected to intentional interaction with a drill burr. Compared to the leading competitor's pattie, ArmourSorb® demonstrated remarkable mean duration of moisture retention that lasted up to nearly twice the duration of the leading competitor's pattie.

Surgical patties made of cotton, polyester, or rayon are commonly used to protect dura and other delicate structures during neurosurgical procedures. However, the unintentional contact of a rotating drill burr with the surgical pattie can occur when the surgeon is engaged in removing bone structure. If the drill burr makes contact with a standard neurosurgical pattie, the pattie can get caught, quickly perforate, wrap, spin, and eject debris back into the wound, contaminating the procedural field. This requires extensive cleanup inside and outside the wound to prevent gossypiboma of both large and small particulates.

These complications can pose significant challenges in the pattie accounting process, can increase the duration of the procedure, and can potentially impact procedural success especially if debris is retained.

To address these concerns, ArmourSorb® was designed and manufactured by American Surgical Company (ASC; Salem, Massachusetts, USA). ArmourSorb® is a novel, patent pending deflective and absorbent surgical device composed of an absorptive base material stitched to a protective surface layer to deflect surgical instruments, such as a rotating burr, and thereby protect vital neural or vascular structures while minimizing the device being wrapped or intertwined with surgical instrumentation. Its indication for use is to protect neural tissues from drying, abrasion, or contamination, and to absorb fluids.

A porcine craniotomy study was conducted to compare the new ArmourSorb® device with a standard neurosurgical pattie of a leading competitor. The results of this study were used to support an FDA 510(k) market clearance for the ASC device.

For inquiries regarding this study, samples, sales inquiries, or customer service, contact ASC at +1-800-343-0060 (*USA*) or +1-(781)-592-7200 (*International*), or email CustomerService@AmericanSurgical.com.

METHODS

Design

This study replicated the surgical applications that use high-speed drills near delicate structures in cranial procedures with an emphasis on a worst case scenario of drill approach in relative proximity to neural structures. A live porcine study model was undertaken to evaluate the protective and deflective capabilities of ASC's ArmourSorb® device compared to the leading competitor's pattie for cerebral protection during a craniotomy. The study protocol was reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) at Tufts University (Boston, Massachusetts, USA), where the test procedures were performed. Tissue samples were evaluated independently on both from the single live "worst case" porcine.

Procedures

A sedated and anesthetized animal was appropriately positioned. The specimen was positioned for a bilateral frontal/parietal approach by the surgeon with the goal of exposing the greatest amount of bilateral cerebrum. The incision was performed and the skin was separated from the skull by blunt dissection. The skin flap was secured to the frame by fish hooks and rubber bands. Periosteum was removed with a periosteal elevator.

The level of device degradation/damage was measured by particulate matter evaluation in the surrounding surgical field and subjectively reviewed by visual examination. To prevent damage to the brain from a craniotomy foot plate or the rotating burr and reduce cranial bleeding, the outline of the craniotomy site was marked with a marking pen, then a high speed drill with a 6 mm ball type cutter was used to dissect along the line delineated by the marking pen. Each pass of the drill cut deeper into the cranium until the remaining bone was "tissue paper" thin. At this point the remaining bone was removed with a curette or periosteal elevator to remove the bone flap. The goal was to remove the bone flap and ensure the dura remained intact. At this point, the dura was resected with care to minimize bleeding and the cerebrum was exposed up to the cortical bone edge. Any intraoperative bleeding at this point was stopped.

The first pattie tested was the leading competitor's (size ½" x 1½") and followed by the new ArmourSorb® device (size ½" x 1½"). Patties were pre-moistened with sterile saline prior to placement as is standard in current clinical practice.

ArmourSorb® devices were tested on the left side of the cranial opening and the leading competitor's patties contralaterally. With the cerebrum exposed, the patties were placed between the cranium and the brain tissue. The nervous tissue was retracted between 3 mm and 5 mm by placing a malleable retractor over the device and applying minimal pressure.

The overlying boney structures were removed using a ball-type burr and a high-speed drill with a maximum speed of 80,000 rpm. The procedure began with the drill at a right angle to the cerebrum with the tip of the burr on the pattie or device. The rotating burr was engaged with one side of the burr touching cortical bone and one side of the burr slowly angled towards the pattie or device, eventually touching at a 90° angle. Since the burr's side is its most aggressive point, the side was allowed to come into contact with the pattie or device. The surgeon noted any displacement, fraying, or wrapping. The surgeon thinned the cortical bone for up to 30 seconds around the area of the pattie or device.

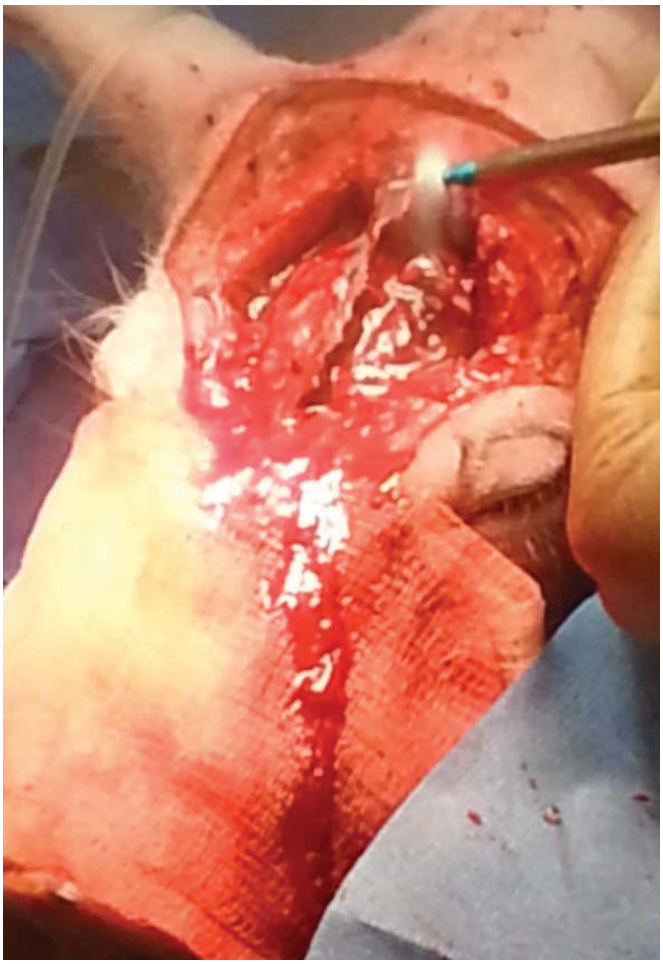
Per protocol, the live porcine case was euthanized immediately after the completion of all test procedures and produced 9 tissue samples for analysis. Submitted tissues were immersed and fixed in 10% neutral buffered formalin within 50 mL conical tissue culture tubes. Tissues were fixed for 3 days prior to subgross examination and submission for histologic processing. In addition to a review of the submitted tissues, the character of the fixative was evaluated for free hemoglobin (red tinge), red cells (gross thrombus), and grossly observable particulates (suspendable clear shards or threads).

Each specimen was removed from the conical tube and placed on a white surface for visual examination. Examinations were conducted using an Olympus SZX-12 Stereomicroscope on which was mounted a Diagnostic Insight SPOT camera driven by SPOT 4.5 software. Digital photomicrograph bitmap (bmp) image files were stored to the hard disk of a microcomputer. The specimens were cut in cross-section perpendicular to a surface marked by the presence of attached hemorrhage or overlying meningeal structures. Both halves of the tissue were placed in cross-section within standard microtomy cassettes and submitted for routine paraffin embedment and preparation of glass histologic slides. Tissues were paraffin embedded and 4 to 5 micron thick sections were mounted on glass slides stained with hematoxylin and eosin stain (H&E) and then cover-slipped.

Each section was reviewed using an Olympus BX-61 compound microscope equipped with a Diagnostic Insight 4 megapixel camera driven by SPOT 4.5 software. Section review was accomplished at a range of magnifications ranging from low power scanning (1.25x objective) to high dry magnifications (40x objective) with observations noted to the case record. Photomicrographs were utilized to document observations. Macrophotographs were taken at 1.25x magnification to document the appearance of the tissues, and photomicrographs at higher magnifications were taken to document specific observations.

The matching of plane and polarized photomicrographs was performed in some instances to document the refractile appearance of specific features. This was accomplished by first taking the plane photomicrograph and then sliding in a polarized lens between the objective and the vision plane without moving the slide and then taking a second photomicrograph. The camera software automatically adjusted the exposure intervals to compensate for the substantial loss of lighting intensity associated with cross-polarization. There were no other manipulations of the photomicrographs beyond adjustments to image size.

Figure 1. Wrapping of the leading competitor's pattie.



RESULTS

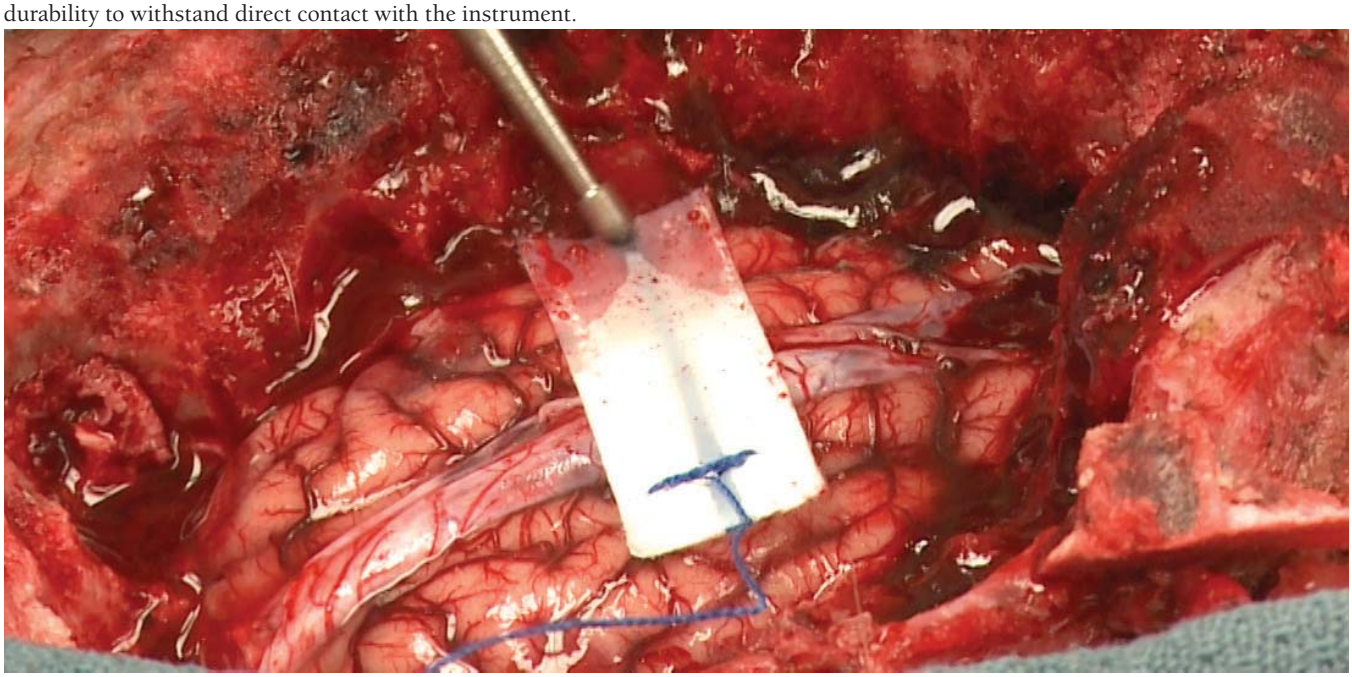
Gross Observations

The investigator neurosurgeon reported gross observations (**Table 1** below). The deflective device clearly demonstrated its ability to prevent wrapping and protect underlying neural structures. The study was originally designed to evaluate 10 patties of the leading competitor, but required amendment after the drill overheated from the iatrogenic wrapping of the competitor's devices. **Figure 1** above shows a photograph captured at the moment one of the leading competitor patties became wrapped in the drill burr, spinning and ejecting fluid and debris.

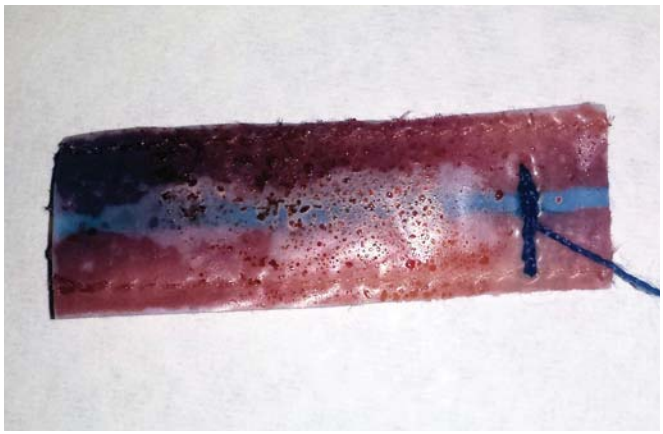
Table 1. Gross observations of the investigator neurosurgeon.

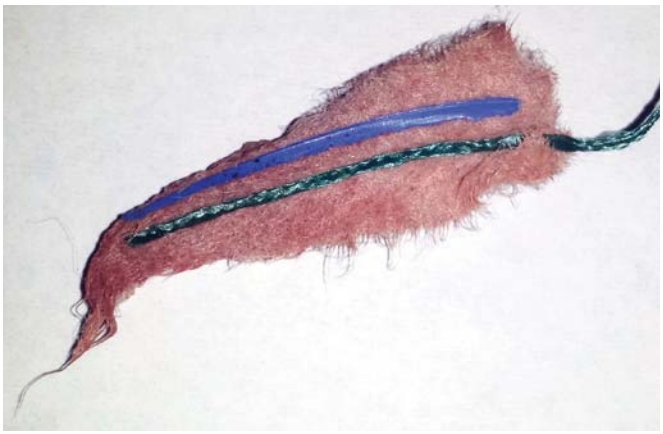
Pattie Type	Pattie Number	Perforation	Wrapping/ Displacement	Gross Pathology
ArmourSorb®	1	No	No	No trauma
ArmourSorb®	2	No	No	No trauma
ArmourSorb®	3	No	No	No trauma
ArmourSorb®	4	No	No	No trauma
ArmourSorb®	5	No	No	No trauma
ArmourSorb®	6	No	No	No trauma
ArmourSorb®	7	No	No	No trauma
ArmourSorb®	8	No	No	No trauma
ArmourSorb®	9	No	No	No trauma
ArmourSorb®	10	No	No	No trauma
Leading Competitor	1	Yes	Yes	Contusion
Leading Competitor	2	Yes	Yes	Contusion
Leading Competitor	3	Yes	Yes	No trauma

Figure 2. A high-speed rotating drill burr comes into contact with ArmourSorb® (below), which demonstrates deflective resistence and durability to withstand direct contact with the instrument.



Figures 3 and 4. Post-procedure photographs of ArmourSorb® (bottom left) and the leading competitor pattie (bottom right). All competitor patties were destroyed in similar fashion.





Subgross and Histologic Observations

Gross and subgross review of the tissues suggested a greater amount of hemorrhage was attached to the tissue obtained from the leading competitor's pattie material than the ASC device material.

Histologic observations compared the cerebral tissue following craniotomy. The study compared the tissues underlying 2 craniotomy sites as protected by the ArmourSorb® device and the leading competitor's pattie. There were 9 specimens from this case available for review, which included 5 specimens from the ASC site and 4 specimens from the leading competitor's site.

Almost all observations were common to both surgical sites. The following observations were noted:

1. Hemorrhage applied to the surface of the white matter. The depth of the hemorrhage varied from thin to quite thick. While there were differences between specimens in terms of attached hemorrhage, differences between the 2 different protection sites were difficult to demonstrate.
2. The hemorrhage frequently included bone fragments that ranged from small to modest. The observed bone fragments varied from single, modestly sized fragments to groups of smaller fragments.
3. The meningeal tissue (pia and arachnoid) was usually avulsed from the cerebral surface and was frequently located within the hemorrhage.
4. Injuries to the white matter were occasionally observed and were noted as either areas of surface discontinuity or intra-cerebral hemorrhage.

MOISTURE RETENTION SUBSTUDY

An important characteristic of a neurosurgical pattie is its ability to retain liquid. Pre-moistened patties aid in tissue moisture retention, protect tissue, and protect neural vascular structures while reducing tissue adherence. Additionally, heat generated from the microscope and the drying effect of the ambient operating room environment tends to pull moisture from the patties, reducing their ability to keep tissue moist and increasing the possibility of tissue adherence. A change to pattie materials may impact moisture retention. Drying times were measured with a Loss on Drying (LOD) moisture analyzer.

SUBSTUDY METHODS

The drying times of a ½" x 1½" ArmourSorb® protective layer device with an ASC Ray-Cot® rayon substrate (part number 89-08, lot 2011/11 BF) was compared to a ½" x 1½" ASC Ray-Cot® rayon pattie without a protective layer (part number 60-08, lot 2012/02 DL) as well as the leading competitor's pattie using an A&D MX-50 moisture analyzer. The MX-50 analyzer was set to automatic analysis mode at static 50°C conditions with an endpoint change of ≤.02% weight per minute.

For analysis, 2 runs for all 3 devices were conducted (2 ArmourSorb®, 2 Ray-Cot®, and 2 patties of the leading competitor). All were immersed in distilled water for 10 seconds, removed, and allowed to drip for 30 seconds. They were then placed in the analyzer with the radiopaque marker side (top) facing up. The second patties for each respective device were tested similarly.

SUBSTUDY RESULTS

Mean drying times of the tested patties or devices are reported in **Table 2** below. The samples containing the protective layer exhibited significantly longer drying times than the leading competitor device at up to nearly twice the duration.

Table 2. Mean drying times of ArmourSorb®, Ray-Cot®, and the Leading Competitor.

	Mean Drying Time
ArmourSorb® (89-08; Ray-Cot® with protective layer)	66.1 minutes
Ray-Cot® (60-08; without protective layer)	38.4 minutes
Leading Competitor	34.8 minutes

CONCLUSIONS

At the end of the device interrogation, no ArmourSorb® devices displayed perforation (**Figure 3**) whereas all samples of the leading competitor's patties perforated (**Table 1** and **Figure 4**). Of the 10 ASC device investigations, no displacement or wrapping was seen. All 3 of the leading competitor's patties experienced wrapping/displacement.

Particulate tests showed all the particles were greater than 100 µm and ranged up to 4000 µm. Observations at both sites were similar and typical of craniotomy procedures. Therefore, the subgross and histologic evaluations suggest that these 2 materials are not significantly different in terms of particulate debris and cerebral hemorrhage.

The initial bench and animal study results suggest that the subject ArmourSorb® device does not experience mechanical failure nor result in gross damage to underlying neural structures as can be seen with the leading pattie when subjected to intentional interaction with a drill burr. A protective layer covering an absorptive base layer allows ArmourSorb® to retain moisture for much longer periods of time. ASC received FDA 510(k) clearance for ArmourSorb® on June 20th, 2013.