(Continued)

Most surgical instruments for laparotomy, laparoscopic, and Robotic surgery have variable weights. Hand held (22 gm.- 96 gm.) instruments are narrow and pointy. Retractors are heavier (150-200 gm.). All of them frequently encroach upon the face and commonly rest on it, unbeknownst to the surgeon or anesthesiologist.

Dropped and potential poking instruments around the unprotected face, even when covered with a drape, are obvious risks. Robotic cables, cameras, setup activity, articulating arms and instruments pose an even greater risk.

Numerous studies have looked at corneal abrasions, resulting in anesthesia protocols to prevent them. Their incidence is approximately 0.05-0.1% (5) In any cases there is not always an identifiable cause. Other than corneal abrasions, we have found no studies addressing mechanical trauma to the patient's face and eyes during supine surgery, in particular Robotic surgery.

In an unpublished database review of 1330 adverse operating room events over 4 years, we identified 12 face and eye injuries which did not result in permanent visual loss (0.9%). These events were independent of 20 anesthesia related eye, ET tube skin-tape, and tooth injuries.

This study shows that the high initial impact pressures of dropped objects have significant potential for mechanical injury to the unprotected face and eyes. In the absence of a protective protocol or device , as seen with this novel shield, the bare face and eyes could otherwise be injured.

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Patient Safety

Impact Studies of a Novel Patient Eye and Face Protective Shield.

savingeyes.com

Impact studies of a novel patient eye and face protective shield.

SAVINGEYES

A patient's face and eyes are at risk of injury under general anesthesia in the supine position. They are typically uncovered and without active protection during most surgery. This is particularly true for laparoscopic and Robotic surgery. Falling or dangling objects, IV lines, operating room staff hands, arms & elbows, Robotic arms, cables, surgical instruments, and fluids (prep solutions, irrigation, bodily fluids) are known hazards.

Figure 1

OSHA requires eye and face protection of operating room staff for prevention of injuries and infections (1). JCAHO offers no similar requirement for patients.

Prior studies measured the surface pressure of the face of volunteer subjects in a prone position while resting on a proprietary foam face cradle used for spinal surgery (2) (3). There are no studies which examine pressure or impact events in a supine position, the most common position for surgery.

We studied a novel single use face and eye protection shield constructed of PETG (Polyethylene terephthalate glycol), a molded thermoplastic polyester commonly used for medical devices and manufacturing. It is bonded to a polyurethane foam (memory foam) face cushion **(Fig. 1)** and secured in position with a latex free elastic strap.

Standardized weights of 50 gm, 100 gm. 200 gm, and 500 gm., each conforming to ANSI (American National Standards Institute) dimensions of diameter and taper, were dropped from a height of 60 cm through a guide tube onto the shield which was attached to a medical mannequin **(Fig. 2).**

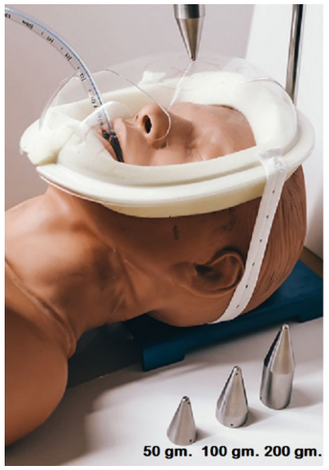

Figure 2

The Xsensor electronic sensor system was used to capture data at 2 locations: The mid-portion of the plastic shield and the interface of the foam to the face (4).

The system recorded multiple drops and the impact pressures (mm Hg.) of each weight, blunt end (25.4 sq mm.) and taper/ point end (3.1 sq mm,), as it contacted the shield **(Figure 3 data example).** The system also measured the resulting impact pressures between the foam pad on the forehead and the chin.

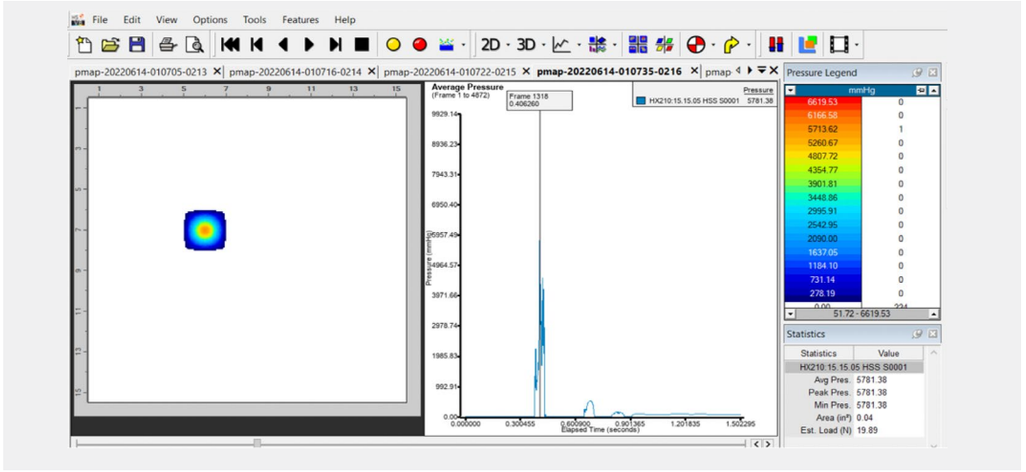

Figure 3- data sample.

200 mg weight, tip impact showing, left to right: a. area of impact, b. graph showing time and intensity of impact, and c. numerical display output of impact in mmHg and summary of pressures and area (sq in.).

Findings **(Table 1)** demonstrated high (red) impact pressures on the shield (348 mmHg. - 5410 mmHg). The variations were related to weight and area of impact, consistent with the physics of dropped objects: Height, weight (mass), area, time, acceleration, and gravity.

50g Blunt	Avg - mmHg	Peak - mmHg
Shield	348	612
Foam Forehead	83	108
Foam Chin	92	136
100g Blunt		
Shield	304	580
Foam Forehead	80	103
Foam Chin	109	158
200g Blunt		
Shield	484	1140
Foam Forehead	138	285
Foam Chin	101	141

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Table 1 **Red:** High impact (mmHg) with weight increase and orientation (blunt/point). **Green:** low impact scores show little or no change with weight increase and orientation (blunt/point).

The much lower (green) impact pressures on the face (76 mm. Hg to 138 mm Hg.) revealed only small variations, independent of weight. The final impacts were all similar This effect can largely be explained by the foam pad.

The foam acts like a shock absorber: It provides a deceleration distance due to its compressibility. It absorbs the impact and instantly disperses it over a larger area in contact with the face. This accounts for the lower and fairly constant values (green) of foam to face impact over the 50 gm – 500 gm range of dropped weights.

(continued on back)