Fluid Immersion Simulation (FIS) for Perioperative Pressure Ulcer Prevention

White Paper

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a) In general

The incidence of perioperative pressure ulcers (PPUs) over the past 5 years has NOT decreased but increased. According to a 2014 publication from the National Pressure Ulcer Advisory Panel the incident rate for pressure ulcers attributed to the operating room range from 5% to 53.4% with a mean of 15% based on results from multiple studies. The most prevalent surgery types include: Cardiac 29.5%; Orthopedic 20%-55%; General/Thoracic 13%-29.3%; Urology 14.4%-17%; and Vascular 9.8%-16%. In addition to these significant risk has been reported in trauma surgery, the bariatric population, and in reoperations. As a result, substantial patient harm has been reported leading to complications, disfigurement, disability, and death. Despite published guidelines specific to the operating room (OR) significant gaps in knowledge, practice, and research exist. In 1988 Gendron stated “Surgery is one of the few times when a normally healthy individual may be placed at risk for PU development.”

Several risk factors have been linked to pressure ulcer development in surgical patients. The Scott Triggers® is a concurrent trigger system that provides real-time identification of an at-risk surgery patient. The tool assesses four factors:

1. Age >62 years;
2. Albumin level <3.5 g/dL or BMI <19 or >40;
3. ASA scores of 3 or greater;
4. Time on the table >180 minutes.

Two or more yes answers help to identify risk thus indicating the need for a prevention protocol. The triggers are based on research conducted at the VA Medical Center in Memphis, TN. The Munro scale is a risk assessment scale for the operating room and is currently undergoing validation studies and implementation testing. This risk assessment scale was funded by Cardinal Health and AORN foundation.

I have observed that PPU's occur as a result of contributing factors can be divided into three distinct periods of operative care including pre-operative, intraoperative and postoperative care.

1. Preoperative: Once the decision is made to have surgery the preoperative period begins. We assess the patient’s unique intrinsic factors that are often out of our control such as (age, comorbidities, diagnosis, nutritional and health status).

2. Intraoperative: Factors occurring during surgery such as: time on the table, hypothermia, blood loss, hypotension, anesthesia type, draping, device use, pooled fluids, and surgical position may impact risk. Intraoperative factors that can be controlled by the OR staff include the type of support surface used and positioning devices. Support surfaces must be able to provide stability of the body and articulation to meet the needs of various surgical positions while supporting the weight of the individual to prevent bottoming out. Ideally the device would allow for immersion of the body into the surface in order to adequately maintain capillary flow to the tissues to prevent ischemia and subsequent cell death. The device must meet the standards for fire codes, be radiolucent, and have the ability to withstand multiple cleaning with harsh solutions for disinfection.

Other factors to consider include surgical position, positioning devices, and other devices used in patient care, assessment and monitoring. Shear and friction can contribute to PU development and can

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be caused from lateral transfers and various surgical positions. Lateral transfer devices that are used in safe patient handling are considered best practice but if left underneath the patient can contribute to negativity. Negativity occurs when there are layers of materials placed between the patient and the support surface. Lateral transfer devices left underneath the patient as well as drapes, warming, or cooling devices, may negate the ability of the support surface to provide immersion of an individual to redistribute pressure points.

3. **Postoperative:** Includes how well we recover the patient relative to mobilization, nutrition, respiratory, skin status, pain control, pressure redistribution, and hemodynamic status.

b) **Current methods of prevention**

Numerous studies suggest that the “conventional/standard” OR table pad (2 inches/5.08 cm thick, elastic foam covered with black conductive laminate vinyl fabric) may be a potential hazard for high-risk patients. Nevertheless, there is insufficient evidence to conclude which surface is most effective for prevention. It is not currently known what type of table pads are currently being utilized the thousands of OR suites nationwide in the US. Based on my personal experience within the Veteran’s Health Administration (VHA) as program manager for 10 VA hospitals in 8 states and as co-chair of the VHA National Skin Integrity Committee and my contacts within AORN the conventional/standard 2 inch pad is considered to be standard practice either alone or in combination with various overlays and positioning devices to include gel, foam, or static air. Additionally, a protective foam dressing may be applied to protect the skin. There are various viscoelastic multi-foam and gel combinations on the market. Standardization of care is a barrier to consistent practice.

The NPUAP International Guidelines recommend the use of a High-Specification reactive or alternating pressure support surface on the operating table for all individuals identified as being at risk of pressure ulcer development. Strength of Evidence = B.

- **High Specification “Non-powered” mattress:**
  - Foam alternative such as viscoelastic polymer foam
  - Density (35 kg/m³/2.18 PCF)
  - Hardness (ability to carry weight)
  - Indentation force deflection (IFD) 35-130 (density hardness minimum grade)
  - Support factor IFD: 1.75 to 2.4
  - Depth (3.5 in or higher for OR)
  - Mattress cover (MVTR).

- **High Specification “Powered” mattress:**
  - Limited research on powered devices in the OR
  - Alternating air studies were conducted in 1999, but were inconclusive as to whether the reduction in pressure ulcers was related to the multi-segmented AP air mattress or the postoperative pressure redistribution or to a combination of both. Currently the NPUAP does NOT recommend small cell alternating air mattresses or overlays (<10 cm) for pressure ulcer prevention.
c) Future trends

I have over 24 years’ experience developing PUP programs for the operating room. My opinion is that the fluid immersion simulation (FIS) pad is a superior technology to any I have seen on the market to date. It has been used successfully for prevention of pressure ulcers in high-risk patients in all clinical and outpatient settings. There has been little movement from industry to improve upon the products that are currently available. Ideally high specification support surfaces such as FIS would be integrated into all procedural tables in the operating room, cardiac catheterization labs, and hybrid ORs. High specification technology needs to be incorporated into all surgical positions and case types particularly the supine and prone position and in cardiac and orthopedic cases which have inherent risks. Devices should be ergonomic to provide appropriate positioning while offloading pressures and distributing pressure as needed. The devices would be reusable, easy to clean, and integrating common practices into the OR “PICK” lists and case cart systems for all high-risk individuals. Standardizing care will help a high reliability operating room environment to promote patient safety.

Consumers drive the market but the barrier is the awareness and lack of knowledge of the key stakeholders, primarily the surgeons and anesthesiologists. In contrast both the Association of Peri-Operative Nurses (AORN) and the Wound Ostomy Continence Nurse Society (WOCN) recognizes that a pressure ulcer in the surgical patient population is a growing patient safety issue. Most OR staff do not have the expertise in pressure management and are not aware of differences in support surfaces and the need to “offload” and redistribute pressure. A joint effort is needed to improve practice in all surgical settings.

In 2015 AORN chartered a task force including AORN subject matter expert members and representation from WOCN to develop a Perioperative Pressure Ulcer Prevention online toolkit for both association and society members. The toolkit will be introduced at the 2016 Expo in Anaheim, California. The purpose is to provide current evidence-based tools, references, and education materials in an effort to raise awareness of the risk and promote zero harm from perioperative pressure ulcers. The toolkit will be presented to the membership on Sunday April 3, 2016 and will describe the toolkit components, and illustrate a strategic plan to raise awareness, improve communication, and competency around a vision of eliminating patient harm from pressure ulcers in the high-risk surgical population. The toolkit is meant to strengthen perioperative pressure ulcer prevention efforts, supplementing or adding to an institution-wide comprehensive pressure ulcer prevention program.

Additionally, the NPUAP Research Committee “S31” is in the process of developing standardizing support surface testing and reporting system. The goal of this group is to (1) establish standardized terminology for describing and discussing support surfaces, (2) establish standardized tests to accurately report characteristics common to support surfaces that are believed to be related to the extrinsic factors associated with skin breakdown (3) identify and standardize methods to evaluate the effective life of a support surface.

Other devices that are new to the operating room include the ability to measure and display real-time tissue interface pressure mapping for the OR staff. The XSENSOR X3 PX100 pressure mapping system was used in a recent comparison study of OR table surfaces.
Highlighting any US-specific issues e.g. reimbursement

a) Cost of treatment
Health Care costs are increasing yearly and are estimated to be between $44,000 and $12,000 per pressure ulcer with a total US cost of 11 billion dollars a year. Hospital Acquired Pressure Ulcers (HAPU) have been described as a pandemic as the current estimates do not identify the true scope of the problem. It is estimated that 15% of acute care patients have pressure ulcers and that incidence has increased by as much as 63% in recent years.

b) Litigation for pressure ulcers in the US
There are more than 17,000 pressure ulcer related lawsuits filed annually in the US, this is second only to wrongful death lawsuits. The average awards are around $250,000, with the highest being 312 million dollars. As a legal consultant who deals with pressure ulcer litigation I have noticed an increased trend in cases related to the operating room and the cardiac catheterization suite. I recently consulted with a hospital where a surgical patient was awarded $883,000 due to development of an operating room acquired pressure ulcer.

c) Penalties/Reimbursement/Performance measures
The U.S. Centers for Medicare and Medicaid Services views a pressure ulcer as a “never event” and therefore the development of a pressure ulcer can lead to significant monetary penalties. Furthermore, in an era of value-based reimbursement, hospital performance scores are increasingly tied to reimbursement rates. In October 2014, as mandated in the Affordable Care Act, the quartile of hospitals with the highest HAPU rates will be penalized a 1% pay reduction for all Medicare patients.

In a study conducted by Waters et al, they found that the new CMS rules for non-payment of hospital acquired condition did not affect improvement in the rate of HAPU. This indicates that our current practice is not effective despite pressure for non-payment from the government. The HAC’s Initiative was associated with improvements in CLABSI and CAUTI trends, conditions for which there is strong evidence that better hospital processes yield better outcomes. However, the HAC’s Initiative was not associated with improvements in HAPU or injurious fall trends, conditions for which there is less evidence that changing hospital processes leads to significantly better outcomes.

d) Growth of surgery in the US
According to a 2010 report from National Center for Health Statistics (NCHS) 51.4 million surgical procedures were performed in the US and of those 19.2 million are age 65 and older. The average overall incident rates for surgically acquired pressure ulcers is 15%, this means a potential 7 million individuals could be at risk for this complication. In a study presented at a meeting of the American Association of Orthopedic Surgeon (AAOS) the number of hip replacements is expected to increase by 174% over the next 20 years. This is an increase from 332,000 to 909,680 procedures. The current range for incidence of pressure ulcers in the orthopedic surgery population is 20-55%. If we do nothing to improve the current state, the numbers of new pressure ulcers could reach 200,000 ulcers in the hip replacement population alone.
Clinical comparison of the pad vs. other products or practices

There is limited research on powered high specification OR table surfaces. Kirkland-Walsh et al. conducted an IRB approved study comparing four different OR surfaces to identify the most effective pressure redistribution surface for prolonged OR procedures.\textsuperscript{12} Methodology included using healthy individuals and pressure mapping measuring the lowest average interface pressure, lowest peak interface pressure and the highest skin contact area. A power analysis was conducted to determine sample size at 90\% level. The devices tested were:

1. Standard three-layer viscoelastic memory foam surgical table surface “Standard Surface”;
2. Air-inflated static seat cushion that was used under the sacral area and placed over a standard surgical table surface;
3. A two-layer OR surface consisting of a top layer of non-powered self-contouring copolymer gel and a bottom layer of high density foam “Self-contouring gel/foam”;
4. Fluid immersion simulation surgical surface “Dolphin pad\textsuperscript{8}”.

The fluid immersion simulation surgical surface was the only powered device and outperformed all tested surfaces in providing the lowest average interface pressure and peak pressures in the sacral area.\textsuperscript{12} The air-inflated static seat cushion provided the best distribution according to the surface contact area however the accuracy of testing a seat cushion only versus a full table pad is questioned. Additionally, the air-inflated cushion is NOT radiolucent and therefore has limitations in the operative setting. In addition, the method used in the study was interface pressure measurement. This is a 2 dimensional measurement of a 3 dimensional body. This tool is helpful in recognizing high-pressure areas consistent with pressure points but does not tell you if the device is improving capillary flow.

In contrast a study was conducted with the Division of Plastic Surgery at University of California San Diego at the VA La Jolla Medical Center on healthy subjects utilizing laser Doppler flowmetry to assess vascular occlusion on various operating room table pads. The 10 subjects were placed on four surfaces, a standard foam pad, an engineered viscoelastic foam product, a fluid gel device (no longer manufactured), and the fluid immersion simulation (FIS) surface (Dolphin). The lowest average percent occlusion was recorded on the FIS surface at 12.20\%, followed by the fluid gel at 78\% the standard foam at 97.59\% and the engineered foam at 98.29\% vascular occlusion. The FIS surface was the only powered surface but demonstrated a striking difference in occlusion of vasculatures in this very small study.\textsuperscript{20}

At the Massachusetts General Hospital, Boston, MA an inter-professional team implemented a Quality Improvement (QI) intervention in high-risk cardiac surgery patients N=398. Previously the team identified numerous pressure ulcers including deep tissue injuries in this surgical population. The intervention included placing the FIS table pad in all cardiac surgery suites and monitoring the skin integrity both pre-operatively and post-operatively. The outcome of the study demonstrated a 0\% incidence rate for HAPUs.\textsuperscript{21}

A case study was published comparing the FIS full mattress technology to Air Fluidized therapy in the treatment of post-operative myocutaneous flap surgery patients.\textsuperscript{22}
Limitation(s) of the pad and situation(s) where it is not effective

The limitations of the device are few. I am aware of limitations in orthopedic surgery where a pegboard is utilized or in certain surgical spine procedures when the Jackson table or the Wilson frame are utilized. It is best utilized in supine position and chair positions but can be used in most surgical positions due to the ability to articulate the pad. There are no limitations for weight limits as the FIS device can be utilized in patients up to 1000 lbs., and there is a pediatric and neonatal feature that allows for the device to be used in this population. As with all patients there should be special care in Trendelenburg position to avoid patient sliding. The device is powered and would require training of the perioperative staff in appropriate setting and use as well as biomedical engineering for maintenance issues.

My personal experience

In 2005 we performed a small clinical evaluation of the FIS pad in the operating room at the Memphis VA Medical Center in Memphis TN. The pad was in trial for about one week on several high-risk cases. The skin integrity was assessed both pre- and postoperatively for two days. There were no pressure injuries noted in this high-risk population. The surgical team did not report any adverse issues with the use of the device. The results were not formally documented.

Due to my personal experience and success with the product I was comfortable recommending the device to other OR and wound nurses in the VHA healthcare system and my professional organizations as part of a comprehensive OR skin bundle. At that time, we did not procure the FIS for the operating room however we did purchase 90 units for our spinal cord injury inpatient unit. We had a reduction of HAPU in our SCI population and eventually reduced the time and cost associated with rental of air fluidized therapy beds.

Over the years I have received numerous anecdotal reports of efficacy of the product in high-risk populations. These include pediatrics, spinal cord injury, bariatric, cardiac and others. The VAMC Medical Center in La Jolla, California implemented the FIS OR table pads for their spinal cord injury center and reported ZERO HAPU in their surgical population for over 5 years. The Veteran Integrated Service Network (VISN) 23 in a head to head evaluation of multiple OR surfaces selected the FIS pad which was standardized in every hospital in their network. The VAMC in Los Angeles, California recently procured the OR table pads as part of their comprehensive HAPU prevention program.

Several hospitals in the Boston area have integrated the FIS therapy into their operating rooms. This includes Massachusetts General Hospital, Boston Children’s Hospital, Boston Women’s Hospital and Tufts. Massachusetts General Hospital performed a QI study of 398 high-risk cardiac surgery patients the incidence of pressure ulcers was 0%.

Most of my hands-on experiences in the operating room has been with non-powered devices. I conducted a study comparing the efficacy of the Alto™ table surface from Allen Medical Systems with the standard pad with clinical significance. Additionally, I have used the Tempur-Pedic® pad (3 ½ in only) from Mizuho OSI®. However, I have noted limitation with both these devices primarily in the heel and sacral areas. These devices must be used in conjunction with other offloading devices as part of a comprehensive program or you may continue to have positioning injuries.
White Paper – Perioperative Pressure Ulcer Prevention. Fluid Immersion Simulation (FIS) Efficacy

In 2009 I became the program manager for the operating room and skin integrity programs for VISN 16, which encompassed 10 Veteran Hospitals in 8 states in the US with more than 445,000 veterans seeking care annually. As part of the strategic plan we replaced all of the OR table pads with a static device primarily the Tempur-Pedic® pad (3 ½ in only) from Mizuho OSI®. This was a total cost of $80,000 US. We demonstrated a reduction in HAPU in surgical patients across the network but particularly at the Houston VAMC. This resulted in a cost avoidance of 2.4 million dollars’ in prevention of pressure ulcers over a 2-year period.

The Baylor College of Medicine conducted a study of 21,377 surgical patients at the Michael E. DeBakey VA Medical Center in Houston Texas by utilizing the Scott Triggers® to identify high-risk surgical patients. 7,000 high-risk surgical patients (≥2 triggers) were assessed for pressure ulcers after implementing a HAPU bundle. The incidence rate of HAPUs dropped from 3.37% to 0.89% (p=0.004) and was sustained over a 14-month period. Although this particular study did not utilize the FIS pads it demonstrates the need to provide an inter-professional approach utilizing a tool to identify at risk individuals and implementation of an “OR Skin Bundle” for successful outcomes.

OR table surfaces are only one piece of a comprehensive program for prevention. In the Perioperative Pressure Ulcer Prevention Program (PPUPP) I outline a 10-step process to develop a strategic plan to improved patient outcomes. Included in this strategy is the concept of “Universal Pressure Precautions” which includes upgrading all functional OR suites to a high specification OR table pad. This is the cornerstone for success.

Kindest Regards

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White Paper – Perioperative Pressure Ulcer Prevention. Fluid Immersion Simulation (FIS) Efficacy

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