Minimising the risk for pressure ulcers in the operating room using a specialised low-profile alternating pressure overlay

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Among the many different care settings associated with an increased pressure ulcer (PU) risk, the operating room (OR) is being recognised as a particularly dangerous environment, with at least 1 in 10 patients developing intraoperative PUs. The "cause and effect" of the OR on PU development is a barrier, as PUs are often blamed on the postoperative settings and care practice, which shifts the focus away from the OR setting itself. Nevertheless, the specific rigid constraints that apply in the OR and which are unique to this environment, namely, the inability to reposition patients during the surgical period and the need to have them on a 'stable' support surface that implies use of relatively stiff padding materials, lead to body exposure to extreme conditions of sustained tissue deformations. Accordingly, the risk of PUs, which are triggered and driven by these sustained tissue deformation exposures, is especially high on the operating table (OT). The basic OT design has changed very little over at least a century and OT pads, in particular, did not evolve despite the well-known risk for intraoperative PUs. A new alternating pressure overlay system, designed for OR use, offers a robust solution for the above problems and makes substantial technological progress in a field where contemporary medical technology is generally poor. The relevant laboratory work and clinical research that were reported recently in this regard are reviewed here from a bioengineering perspective, to highlight the importance of such a novel technology in PU prevention among surgical patients under the unique restrictions that apply in the OR setting.

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Pressure ulcers (PUs), which are caused primarily by exposure of soft tissues to sustained distortions and deformations (Gefen, 2019; Gefen et al, 2019), are associated with significant suffering and healthcare costs which are expected to grow as the population ages and chronic diseases spread. If a PU is hospital-acquired, it may further involve expensive litigation, and can also contribute to a rise in the institutional and staff liability insurance premia, and in addition, can negatively impact the hospital quality measures. Among the different care settings that are associated with an increased PU risk, the operating room (OR) is widely being recognised as a particularly dangerous environment (Ellsworth and Iverson, 2006; Fawcett, 2011). Surgical patients are, by definition, at a high risk for developing PUs due to the lack of sensation and their immobility during the course of surgery, as well as through much of the recovery phase (Wicker and Nightingale, 2010; Alderden et al, 2011; Kimsey, 2019). A PU observed within 3 days after surgery should be considered an intraoperatively-acquired injury (Karadag and Gümüskaya, 2006; Aronovitch, 2007; Primiano et al, 2011; Fawcett et al, 2014; Kimsey, 2019). The overall incidence rates of these intraoperatively-acquired PUs vary substantially, but there is no doubt that these rates are persistently high. The average prevalence

of PUs for surgeries that are longer than 2–3 hours, e.g. some hysterectomies, most of the cardiac and spinal operations, and many of the neurological procedures is at least 9% (Hayes et al, 2015; Engels et al, 2016; Chen et al, 2019). The PU incidence rate increases with the time on the operating table (OT), being 9% for 4–5 hour procedures, 10% for 5–7 hour surgeries and over 13% for operations that are longer than 7 hours (Scott et al, 2001; Price et al, 2005). In other words, at least 1 of 10 surgical patients develops an intraoperative PU if their procedure lasts more than 2 hours.

Schoonhoven and colleagues (2002) further found that with every additional 30 minutes following a 4-hour operative time, the PU risk increases by 33%. For cardiovascular and orthopaedic surgeries the prevalence appears to be much greater, up to 36–38% of the patients (Pokorny et al, 2003; Galivanche et al, 2019) i.e. more than 1 in 3 patients, likely because these are typically longer procedures, particularly coronary bypasses and spinal fusions. Overall, the above reported variation in prevalence rates reflects marked differences in biomechanical tissue conditions at the various surgical positions. Other contributing factors to the variability in reported prevalence of intraoperative PUs are the variety in OT mattress or pad types and if applicable, use of positioning and securement devices (Katzengold and Gefen, 2019), implementation of preventative protocols (including use of prophylactic dressings in the OR; Yoshimura et al, 2020) and clearly, the variable conditions, ages and health status among the surgical patient population. Importantly, from a practical clinical perspective it should be considered that a 2-hour surgery can imply 6 or more hours of immobility for the patient, when also considering the preparation and recovery times.

In addition, postoperative pain, separate from the surgical site pain has been documented in the literature (Powers et al, 2002) and may indicate a deep tissue injury (DTI) which resolved, and did not develop into a clinically visible PU.

The OR setting, including the use of anaesthetic agents, introduce specific, unique and influential risk factors that are added to the common risk factors for PUs. In particular, surgical positioning may apply unusual and elevated localised tissue deformations and stress concentrations, however, repositioning during surgery is unfeasible, and so, these localised tissue distortions and stresses are being sustained continuously for hours. For example, the park-bench position, which is often being used in brain surgeries where access to the posterior fossa is required, has been identified as involving a relatively high PU risk (11%), especially if the surgery lasts for more than 6 hours (Yoshimura et al, 2015; 2016).

In addition, the blood loss associated with surgery that results in lower arterial pressures, combined with the lower body temperature, which causes vasoconstriction (anesthesia affects the autonomic thermoregulatory response) reduce the soft tissue perfusion levels, especially at the highly distorted and deformed tissue sites. This, in turn, increases the susceptibility to ischaemic tissue damage that results from these sustained tissue deformation exposures (Gefen et al, 2019).

Use of catecholaminergic vasopressors (e.g. norepinephrine, epinephrine or dopamine) to manage the intraoperative hypotension may further cause vasoconstriction in small blood vessels and, thereby, promote ischemia-reperfusion damage or reduce the microvascular perfusion even more, due to contraction of the larger vessels (Aronovitch, 2007; Fife and Gkotsoulias, 2019). The reduced tissue perfusion synergistically contributes to lowering the body temperature, especially in soft tissues at the peripheries, such as the heels, as circulation is driving the heat convection in tissues (De Backer and Foulon, 2019). A drop of 1.8°C in the core body temperature which is common during surgery or post-op recovery (Yoshimura et al, 2015; Engels et al, 2016; Zeevi et al, 2018) increases the PU risk by ~20% (Fred et al, 2012). When data in the Fred et al (2012) work was analysed for the effect of gender, it indicated that PU risks of men are more affected by core body temperature drops (perhaps due to the more lean body mass and higher metabolic rates of males), i.e. a male intraoperative PU risk would rise by 25.5% for a drop of 1.8°C in their core body temperature.

During surgeries that last 2–4 hours, the body temperature characteristically drops to between 34.5°C–36°C, however, after 3–4 hours of surgery, the core temperature of the body plateaus at approximately 34.5°C, which is 2.5°C below the normative (basal) core temperature level (Bindu et al, 2017). Furthermore, between 30% and 40% of all surgical patients remain hypothermic on admission to the post-anesthesia ICU (Bush et al, 1995), so at least part of their post-op recovery period should be considered as exposing these patients to hypothermia-related high PU risk as well. The aforementioned data, therefore, indicate that for the longer procedures, which

last more than 3–4 hours, the overall PU risk rises by ~28%, or by ~35% for just the men, due to the core body temperature drop *per se*, which is consistent with the Schoonhoven et al (2002) study findings. Indeed, cases of administration of norepinephrine or vasopressin, where the mean arterial pressure dropped below 60 mmHg or after a cardiac arrest, correlated with a statistically significantly greater likelihood of post-surgical PU diagnosis (Cox, 2013; Cox and Roche, 2015).

That said, it should be noted that vasopressors are often being used for saving lives and sometimes, as a last resort, e.g. in brain trauma patients (Hylands et al, 2017). Hence, taking the aforementioned PU risk may be an informed-decision, but nevertheless, better PU preventative technologies which are specific to the OR can mitigate this high risk.

Another pivotal factor to consider in the context of PU prevention in the OR is the surgical position. For example, some common surgical positions, e.g. the Trendelenburg or Reverse Trendelenburg positions involve substantial tilting of the OT (Schonauer et al, 2004; Servant et al, 2009; Wicker, 2015; Van Wicklin et al, 2018), which considerably increases the static frictional forces and the respective tissue distortions in shear, due to the 'patient migration' phenomenon (Lustig et al, 2020). The resultant high PU risk due to static frictional forces increases even further if the surgical patient is overweight or obese (Yoshimura et al, 2020), but may also rise for patients who have an abnormally low bodyweight, or who are atrophied or bony (Sopher and Gefen, 2010; Karg et al, 2019).

Moreover, surgical procedures also involve use of various equipment for life-support (e.g. for ventilation and intravenous tubing), as well as for surgical access (e.g. retractors) that altogether induces additional localised forces on the surface of the body, in excess of the bodyweight forces that would have applied at a non-surgical hospital environment. Furthermore, such intense tissue exposures to sustained mechanical loading cannot be detached from the pre-operative history, for example, admission through the emergency department or any interventional procedures prior to the operation (e.g. cardiac catheterisation, interventional radiology or endoscopy which did not succeed and required immediate surgery).

Accordingly, in some cases, a PU may begin to form pre-operatively and then exacerbates rapidly in the OR, as the patient is completely motionless and insensate. Regardless of whether the injury initiated pre-operatively and progressed in the OR, or has formed and developed during the course of surgery, it is recognised that many of the intraoperative PUs are deep tissue injuries (DTIs) that present themselves on the skin, i.e. in visual skin assessments, only postoperatively (Grap et al, 2019).

The unique design requirements from a good support surface for intraoperative use

It is obviously unfeasible to influence the duration of a surgery (or the post-op recovery time), or to reposition a patient during their operation. Accordingly, prevention should be aimed primarily at decreasing the effects of the bodyweight forces (in the form of both pressure and shear) on locally distorting skin and underlying soft tissues throughout the operation. Lowering the exposures of tissues to sustained, localised deformations and stresses can be achieved, effectively, by increasing the immersion and envelopment of the body into the support surface placed on the OT, as well as by providing relief periods that substitute (a non-surgical) repositioning.

The OT is the primary equipment used for positioning patients, and accordingly, the support surface placed on the OT is the key determinant of the levels of soft tissue deformations and stresses which define the causative intraoperative PU risk factor (Gefen et al, 2019; Gefen, 2019).

The most common OR support surface types are non-powered pads (i.e. thin mattresses) or overlays which are made of foams, viscoelastic polymers, gels or a combination of these materials (de Oliveira et al, 2017). The standard, basic OT pad is a low-profile (thin) foam or polymer gel mattress which constitutes a relatively hard surface.

Specifically, the most common support surfaces are made of 2-inch elastic foam covered with black, conductive, laminated vinyl fabric, which are designed for good stability — a basic surgical requirement (Scott, 2015; 2016). Such a thin pad must be made of a relatively stiff foam material to prevent bottoming-out (the thinner the support surface, the greater is its tendency to bottoming-out), which implies that bodyweight forces have to be distributed over substantially smaller contact areas, resulting in greater interface pressures and shear (Rogan, 2007). In fact, the stiffness properties of existing OT pads may be up to 10-times (~30 kPa) the stiffness values of non-

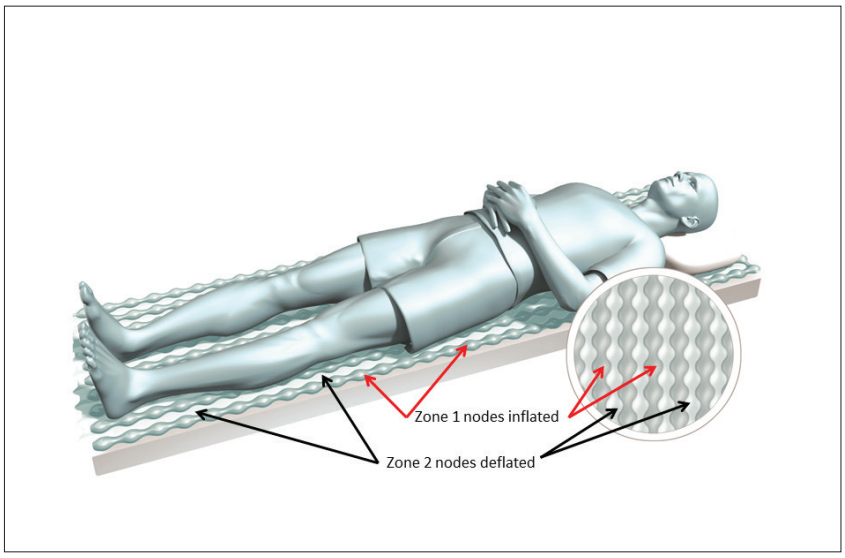

Figure 1. The new surgical support surface technology reviewed here, which employs a low-profile alternating pressure (AP) overlay. This AP-overlay achieves alternating support and relief using independent rows of nodules (marked as zones 1 and 2 on the image). These alternating rows of nodules inflate and deflate cyclically at preprogrammed intervals: The nodules which are inflated at a given time support the body whereas the deflated nodules result in pressure relief.

surgical medical mattresses (~3 kPa), which can be manufactured with a much thicker profile (Haex, 2004; Katzengold and Gefen, 2019). This imposes greater tissue deformations on the OT pad compared to those that form when the same individual lies on a thicker and softer foam mattress, e.g. on an intensive care unit (ICU) bed (Oliveira et al, 2018). Additional reduction of the body-support contact area may originate from the use of added linen, from heating pads and warming devices that are placed under the patient to reduce the risk of intraoperative hypothermia, or from suboptimal (stiff) dressings applied for prophylaxis (Levy et al, 2017; Schwartz et al, 2018). Use of multiple layers of linen or warming devices on standard OT pads further compromises the (already limited) immersion and envelopment capacity of these surgical pads, which further increases the risk of PU development (Scott et al, 2001; Feuchtinger et al, 2006; Aronovitch, 2007; Williamson et al, 2013).

It is evident that the engineering design constraints for OR support surfaces are much stricter than those for medical support surfaces which are intended for ICU or general ward use: The specific OR necessities contradict the basic biomechanical requirements for tissue protection from PUs, particularly with regards to the low-tech, non-powered OT foam/gel pads. First, OT pads and overlays (each and when applied together) need to be thin and low-profile relative to the conditions that apply for non-OR beds (e.g. ICU beds). The thinner profile is required in the OR to minimise the risk of falls from the OT (Toussaint et al, 2013), and also, to form a stable surface for the surgical team to be able to work without wobbling the patient when operating. Precision surgeries, particularly neurological, cardiovascular or tumor removal procedures require high stability of the patient body, which is typically achieved on a thin surgical support surface.

However, thin support surfaces cannot provide considerable immersion and envelopment of the patient body. Moreover, there is an interplay between thickness and stiffness of the support surface, namely, a thinner support surface must be made of stiffer (foam, gel) materials to prevent bottoming-out. Given that repositioning is not feasible for preventing PUs in the OR, and since conventional immersion and envelopment design strategies do not fit the OR setting for the above reasons, alternative means of tissue protection are much needed in the OR, to augment the limited protection capacity of the existing low-tech surgical support surfaces.

Biomechanical benefits of a low-profile alternating pressure surgical overlay

To address the problems reviewed above, namely, the lack of a feasible repositioning option and the firm requirement for stability and steadiness of the operated patient, a new surgical support surface technology, employing a low-profile alternating pressure (AP) overlay (Dabir Surfaces Inc, Chicago, IL, USA), has been recently introduced *[Figure 1]* (Joseph et al, 2019; Karg et al, 2019).

The AP feature, which has been reported to contribute to PU prevention in non-surgical settings (Vanderwee et al, 2005; Sauvage et al, 2017; Meaume and Marty, 2018; Shi et al, 2018), provides pressure redistribution via loading/unloading cycles. The aforementioned specific AP surgical overlay is thin and has been designed to be placed over a standard foam/gel OT pad. Once placed on the OT pad, the AP-overlay facilitates the delivery of cyclic micro-motion repositioning, to compensate for the no-repositioning and low immersion and envelopment offered by the bare OT pad. The height of this overlay is less than 25 mm at full inflation (and less when deflated), with rows of 650 interconnected semi-spherical nodules (each having a base diameter of 25 mm). These nodules are arranged in two zones that alternately inflate. Hence, the nodules that are inflated at a certain moment in time support the

body, whereas the deflated nodules provides temporary pressure relief. The inflation/deflation of the offset rows of nodules is computer-controlled and adjustable; the manufacturer recommends a 10-minute cycle speed (i.e. 5 minutes of alternating inflation of each of the two zones). This generates gentle body micro-motions that are substantially slower than any manual repositioning regimes applied for PU prevention in non-OR settings.

Moreover, the quasi-static movements of the body that are caused by these slow inflation-deflation cycles do not interfere with any of the surgical procedures, including the most sensitive ones. That is, a patient placed on the aforementioned AP-overlay is perceived by surgeons to be fully stable in the course of the surgical manipulations, even during precision neurosurgical procedures as demonstrated by questionnaires to neurosurgery OR teams (Joseph et al, 2019).

Importantly, as evident from pressure mapping data (Karg et al, 2019), the above AP-overlay provides periodic offloading of the sacral area which is the most susceptible region for intraoperative PUs in supine surgical patients (Grap et al, 2019). Periodic relief of sacral tissues cannot be achieved by other clinically feasible means, such as using positioners or prophylactic dressings. This low-profile AP technology, which does not compromise on patient stability during surgery is, therefore, a unique solution for the OR.

Laboratory and clinical evidence of efficacy

The published work of Karg and co-authors (2019) is a comprehensive bioengineering evaluation of the above-described AP-overlay, *in vivo*. They focused on the risk of ischemic and ischemia-reperfusion damage, which, as discussed above, is especially high in the OR, given the combined effects of surgical blood loss, vasopressors and hypothermia. Hence, the influence of the AP feature of the aforementioned powered overlay on sacral tissue perfusion and oxygenation quality was investigated.

This study tested sacral skin blood flow in a loading scenario similar to that observed in OR clinical settings: Lying supine on an OR pad for an extended period of time (60 minutes). The subject group (n=19) had wide ranges of age (46.9 ± 21.2 years) and body mass index (26.1 ± 5.4 kg/m^2). Their sacral skin blood flow was monitored using a 2-mm thick, low-profile laser Doppler optic probe. The mean sacral skin blood flow on the OR pad with the AP-overlay was 40% greater than for the OR pad alone during the full loading session (one full inflation and deflation) and 76% greater during deflation at the sacrum. This could be explained by the statistically significantly (39%, P<0.001) lower measured sacral interface pressures during the deflation cycle of the AP-overlay, with respect to the corresponding interface pressure data for the OT pad alone. Accordingly, the Karg et al (2019) study suggests that the cyclic reductions in localised interface pressures facilitated by the AP-overlay improved sacral tissue perfusion on the OT.

A large cohort clinical study conducted in American ORs (n=100 patients) by Joseph and colleagues (2019) confirmed the clinical benefits of the above bioengineering laboratory findings. Participants in the Joseph et al (2019) trial were neurosurgical patients who underwent supine surgery for 2 hours or longer, while positioned on the above-described AP-overlay. The PU incidence data of this cohort were compared with historical controls (n=292 patients) who were operated at the same facility. The historical data were extracted from electronic health records completed within the 2 years prior to the trial period. The group who were positioned on the AP-overlay received the same standard-of-care for PU prevention that is usually provided by the facility, and which was also given to the historical controls. Hence, application of the AP-overlay intraoperatively was the only experimental factor distinguishing the study group from the historical controls.

Accordingly, the primary outcome measure was the perioperative incidence rate of PUs (up to 5 days post-op) in the cohort where the AP-overlay has been used, versus the corresponding incidence rate in the historical controls who received the standard preventative care of the facility and were also operated on a standard OT pad. In addition, the researchers used questionnaires to collect information regarding the level of acceptance of the AP-overlay by the surgeons, the OR teams and the post-op (ICU) care staff. The results of the Joseph et al (2019) work demonstrated that none of the patients who received the AP-overlay developed perioperative PUs, as opposed to an incidence rate of 6% in the historical controls (i.e. 18 PUs for the 292 patients). The responses to the questionnaires further indicated that the AP-overlay technology was well-accepted by all the care provides who were involved.

Summary and conclusions

Intraoperatively-acquired PUs are devastating,

costly and very common, affecting between 1 of 10 and 1 of 3 of the cumulative surgical patient population. Often, the 'cause and effect' of the OR on PU development is a barrier, as the injury is blamed on the post-operative settings and care practice, which shifts the focus away from the OR setting itself (Scott, 2015). The specific rigid restrictions that apply in the OR, and which are unique to this clinical environment, namely, the inability to reposition patients during the surgical period and the need to have them on 'stable' support surfaces, which in fact translates to relatively stiff support surfaces, lead to patient body exposure to extreme sustained tissue deformation conditions.

Accordingly, the risk of PUs, which are triggered and driven by sustained soft tissue deformations, is especially high on the OT. The OT evolved very little for at least a century (Petty, 1996; Peters et al, 2013) and, likewise, OT pads are a good example of a stagnated medical technology, despite the known risk for intraoperative PUs. The AP-overlay system discussed here is a robust solution for the above problems, and a substantial technological progress as evident from both bioengineering laboratory work (Karg et al, 2019) and clinical research (Joseph et al, 2019).

Future improvements may include embedded sensor technology that would further allow for patient-specific, real-time adjustments of the AP feature, depending on the body characteristics, type and length of the surgery and the body system responses to the surgical procedure, to fit this emerging technology into the personalised-medicine framework. Finally, additional studies with larger sample sizes, multiple surgical specialties and clinical settings will help better understand the effectiveness of this AP overlay in preventing PUs across the continuum of care. WINT

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