Medical Device Testing: Methods, Significance, and Clinical Applications

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GENERAL PURPOSE: To present a study conducting objective biomechanical testing of medical devices known to cause medical device-related pressure injuries (MDRPIs) in critically ill adults and comparing those results with clinical outcomes associated with each device.

TARGET AUDIENCE: This continuing education activity is intended for physicians, physician assistants, nurse practitioners, and nurses with an interest in skin and wound care.

LEARNING OBJECTIVES/OUTCOMES: After participating in this educational activity, the participant will:

1. Explain the results of the study of the relationships between objective biomechanical tests of medical devices and clinical outcomes that help inform clinicians using these devices.
2. Synthesize the background information that informed the study.

ABSTRACT

OBJECTIVE: To conduct bioengineering testing of devices that cause medical device-related pressure injuries (MDRPIs) in critically ill adults and compare testing results to the MDRPI clinical outcomes associated with each device.

METHODS: Following the identification of MDRPI from oxygen-delivery devices and nasogastric tubes in critically ill adults who were hospitalized between January 2016 and October 2022, the specific manufacturer and model number of the devices were identified. Twelve devices and two prophylactic dressings in original packaging were sent to a bioengineering laboratory for testing. Using an integrated experimental-computational approach, the compressive elastic moduli (E [MPa]) was measured for each device and prophylactic dressing and compared with the properties of normal adult skin. The authors hypothesized that devices with greater mechanical stiffness (ie, higher E [MPa]) would be associated with a greater number and severity of MDRPIs.

RESULTS: Researchers identified 68 patients with 88 MDRPIs. All PI stages except stage 4 were represented. Nasogastric tubes had the highest mechanical stiffness and were the most common MDRPI identified. In contrast, no soft nasal cannula MDRPIs were reported. Devices associated with the highest number of MDRPIs also had the highest E [MPa] values; researchers noted a moderate association between E [MPa] values and pressure injury severity. Prophylactic dressings had E [MPa] values within the range of normal adult skin.

CONCLUSION: The relative mechanical stiffness of a device is an important factor in MDRPI etiology. However, factors such as duration of device use, tightness when securing devices, correct fit, and heat and humidity under devices should be considered in predicting MDRPI severity.

KEYWORDS: bioengineering, critical care, mechanical stiffness, medical device-related pressure injury, nasogastric tube, pressure injury, prevention, Young modulus

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INTRODUCTION

Pressure injuries (PIs) have long been described as occurring secondary to prolonged or intense pressure/shear forces over bony prominences.[1] However, in 2008 the National Pressure Injury Advisory Panel recognized that PIs can also correspond to sites under medical devices.[2] Black and colleagues[3] first investigated characteristics of medical device-related pressure injuries (MDRPIs) in 2010, reporting that patients with a medical device were 2.5 times more likely to develop any PI. Perhaps more importantly, the investigators provided confirmation of the phenomenon of MDRPI, which accounted for 34.5% of all PIs in this seminal study.[3] The National Pressure Injury Advisory Panel now attributes PIs to prolonged and/or intense pressure/shear forces *usually* over a bony prominence or *related to a medical or other device*.[4] Updated PI definitions include medical and other devices as etiologies, adding a description for classifying MDRPIs on mucous membranes.[4] As opposed to PIs that occur with positioning over bony prominences, MDRPIs can occur over any soft tissue or mucosal membrane in contact with a device. In effect, the device is the source of pressure and shear forces, rather than the weight of the patient on the support surface.[5]

The pooled prevalence of MDRPI in critical care is 6.46% (95% CI, 1.97-13.11%).[6] However, lack of awareness of MDRPIs[7,8] and the inability to accurately report occurrences[9] may lead to underestimations of the frequency of these harmful and costly events. The National Database for Nursing Quality Indicators added MDRPIs as an *optional* metric in 2017.[10] Current ICD-10 definitions do not include medical devices as an etiology of PIs, many common sites for MDRPI are not listed as options when coding, and there is no ICD code for mucosal membrane PIs.[11] It should be noted that MDRPIs outside mucosal membrane should be staged using ICD staging codes, even if the injuries did not occur on a bony prominence. Therefore, studies using "big data" from discharge diagnoses may only include bony prominence PIs and cannot distinguish among patients with versus without device exposure (device in use). Thus, the impact to patients is likely vastly underestimated.

Medical devices are an essential component of many life-saving treatments in critical care. Despite the obvious benefits, medical devices can also cause harm to patients. Devices used on vulnerable areas of the face and neck are too often the cause of painful and disfiguring MDRPI. Critically ill adults, with an estimated 10 to 15 life-saving medical devices in use per patient,[12] are particularly vulnerable. Although any medical device can lead to MDRPI development, oxygen-delivery devices and nasogastric (NG) tubes are most frequently implicated in MDRPI occurrences.[6,13,14] Although the clinical problem has been defined in terms of devices leading to MDRPI occurrences, context is lacking because no objective measure of the mechanical properties of devices in use have been included in clinical studies. New advances in bioengineering may provide important clinical insights into the frequency of MDRPI occurrences with certain devices.

Background

Medical device-related PIs are localized damage of the soft tissue or mucous membranes compressed under a medical device.[4] Many medical devices are composed of stiff and rigid materials to avoid device collapse or occlusion during treatment. Devices with greater stiffness, those that are poorly fitted, or those strapped on too tightly will lead to greater compression of soft tissues.[15-17] The resulting pressure and/or shear force compresses vulnerable tissues under the device, causing deformation-induced cellular damage.[16-19] This cellular damage secondary to deformation can occur within minutes and in turn triggers an inflammatory response. Inflammatory response-related tissue damage, ischemic damage, and reperfusion injury may be concurrent or overlap depending on patient comorbidities, such as impaired perfusion and oxygenation.[16-19] Additional patient risk factors relate to the condition of the soft tissues and mucous membranes, including a lack of conditioning and an altered microclimate. The application of a device against the skin alters the skin microclimate, and is exacerbated by the added humidification common with some devices (eg, bilevel positive airway pressure [biPAP]).[15-17,20]

Understanding the risk associated with medical devices is a key component of MDRPI prevention guidance.[15-17] Current guidance for MDRPI prevention includes routine skin assessment, rotating or repositioning devices periodically, use of prophylactic dressings beneath devices, and selecting devices with lower risk of MDRPI development.[15,17] Guidance for selecting devices that are less likely to result in MDRPI occurrence suggests considering device design, composition, contact area, and size selection.[15,17] However, no standards exist for objective measurement of MDRPI risk based on device characteristics. Understanding unique risk factors inherent to device design or composition is essential to inform interventions to prevent these common, painful, and disfiguring occurrences.

Therefore, the objectives of this study were to (1) conduct bioengineering testing of medical devices known to cause MDRPIs in critically ill patients hospitalized in a large academic medical center and (2) compare testing results to the MDRPI clinical outcomes associated with each device.

METHODS

Study Design

This study was designed as a comparative descriptive study exploring the relationship(s) between objective biomechanical tests of medical devices and clinical outcomes. The study

design and methods were approved by the Institutional Review Boards at the University of Chicago Medical Center and University of Nebraska Medical Center. A waiver of consent was approved for this retrospective study. De-identified medical records were stored in an Excel file (Microsoft) on a secure Box server.

Clinical setting. The clinical study setting is the University of Chicago Medical Center, a Magnet-designated academic medical center with 811 adult and pediatric licensed beds and level 1 trauma services in Chicago, Illinois. There are currently 104 licensed adult critical care beds encompassing the intensive care specialties of cardiothoracic surgery/cardiovascular, medical, surgical/trauma, neurologic, and burn. The study site has a well-developed and documented protocol for MDRPI prevention that provides a consistent context for examination of MDRPI.

Bioengineering lab. The author Amit Gefen has a significant history of performing state-of-the-art experimental (test bench) and computer modeling and simulation studies of medical devices and consumables. In the context of the current work, this laboratory contains material testing machines with various load cells and jigs for mechanical testing of biomedical materials as well as computational facilities for high-performance bioengineering computation, including dedicated workstations with installed specialized software for modeling and simulation.

Participants and Materials

Participants in clinical database. Researchers used MDRPI occurrences from the quality improvement (QI) database to identify critically ill adults with MDRPI secondary to oxygen-delivery devices and NG tubes from January 1, 2016 through October 13, 2022. Any devices used on limbs or other anatomic locations were excluded. Following guidance from the National Database for Nursing Quality Indicators,[21] during the COVID-19 pandemic not all patients with COVID-19 were included in monthly QI surveys. Specifically, no QI surveys were conducted in April 2020 or January 2022, coinciding with COVID-19 surges. In May 2020, patients in isolation were excluded from the QI survey.

Participant inclusion criteria were: (1) adult patients aged 18 years or older; (2) use of one or more oxygen-delivery devices (eg, endotracheal tube or tracheostomy for mechanical ventilation, biPAP, continuous positive airway pressure, high-flow oxygen, nasal cannula, face mask) or NG tube in use during hospitalization; (3) length of stay of 24 hours or greater; (4) present for one or more QI surveys while hospitalized in intensive care; and (5) development of one or more hospital-acquired MDRPIs secondary to oxygen-delivery devices or NG tubes independently verified and staged by two or more certified wound care nurses. This process to verify the etiology of identified lesions has been described in prior PI studies on critically ill adults conducted at the organization.[22,23]

PI prevention program and QI surveys. The organization has a formal PI prevention program in place that incorporates current guidelines and is routinely updated as new evidence is published. Monthly QI surveys (point prevalence studies) inform continuous QI efforts and are conducted with detailed data collection corresponding to (1) bony prominence and stage; (2) medical device type, locations(s), and stage; and (3) other common skin injuries, locations(s), and degree of tissue damage. At least one skin care team RN (champion) is selected on every unit to conduct the QI surveys and serve as a unit resource. Bony prominence-related PI, MDRPI, and other skin injuries of interest are independently assessed by at least two certified wound care nurses to determine etiology and stage (if applicable). The QI survey results, rounding observations, and skin care team RN observations inform continuous quality improvement efforts such as the MDRPI prevention guidelines (see Table 1).

All nursing staff receive education regarding PI prevention (including MDRPI protocols) upon hire and a minimum of annually thereafter. Frequent reinfusion of protocols with 5-minute rounding in-services occurs, including reinfusion of the MDRPI preventive mnemonic and prevention of high-risk devices. These MDRPI protocols and mnemonic are available on the intranet for each device paired with an image of the MDRPI. The hospital-acquired PI prevention program lead (first author) is also a standing member of the value analysis team. For new products, there is a subjective assessment for risk of MDRPI as compared with current devices in use (stiffness, flexibility). Formal pilot studies are conducted (by S. Solmos) to track MDRPI outcomes prior to potential conversion of devices to inform QI efforts and ensure optimal patient outcomes. Collaboration with supply chain personnel and other key clinical partners is essential.

Site-specific clinical guidelines for overall MDRPI prevention as well as targeted interventions for these specific devices were implemented in January 2016 and updated periodically to incorporate new evidence (see Table 1.) Essentially, the MDRPIs represented in the clinical database (Excel file, secure server) occurred despite current evidence-based protocols and strategies for MDRPI prevention.

Materials for biomechanical testing. Oxygen-delivery devices, NG tubes, and preventive dressings were identified by the manufacturer and sizes most commonly used during the specified timeframe. Samples of 12 devices and two dressings were sent to an internationally known bioengineering testing laboratory with extensive experience in testing medical devices.

Procedure

Using an integrated experimental-computational approach, the authors compared the stiffness (ie, the elastic moduli) of the tested skin-contacting devices. The elastic modulus

Table 1. MDRPI MNEMONIC AND PREVENTIVE INTERVENTIONS IN PLACE FOR HIGH-RISK DEVICES

M: Medical Device Type	D: Document Skin Assessment (Under Device)	R: Rotate/Reposition/Resize	P: Protect/Prevent	I: Identify Additional Factors; Educate Patient/Family
NG tube	Assess internal and external nare every 6 h (after flushing).	Retape daily, reposition in center of nare. Consider securing to gown to prevent movement.	Use skin prep under tape/bandage; assess potential to discontinue NG tube. Consider bridle.	Facial edema or tubes that cannot be repositioned increase risk of MARSI
ET tube	Assess every 2 h: lip, tongue, and oral mucosa. Assess twice per shift: ears, cheeks, and back of neck. Time assessment with turning/repositioning.	Reposition slightly (width of ET tube) every 2 h and during oral care: start at right, rotate to left, restart at right. Ensure ventilator arm is in correct position, replace tube holder every 7 d and PRN.	Oral care every 4 h and moisturizer to lips/mucosa. If proned, use fluidized positioner to offload cheeks and ear.	Facial or lip edema, lesions/sores in mouth/lips. Replace tube holder if facial or lip edema is present. Poor perfusion and multi-organ failure may increase risk.
BiPAP	Assess areas at risk (including beneath protective dressings) twice every shift during skin assessment and oral care, including bridge of nose, nasolabial folds, chin, and beneath straps.	Secure straps with the least amount of tension needed to obtain adequate seal. Reposition every shift and as needed to ensure correct placement. RT to resize if needed.	Apply foam dressings (1 x 2 in) to bridge of nose and nasolabial folds or use elastomer gel product	Facial edema, moisture, no teeth, no gag reflex. RT to resize if facial edema is present.
Trach plate	Assess areas at risk (including beneath dressing) under trach plate twice every shift with trach care.	Secure straps with finger width space between collar and skin; adjust if edema present.	Suture removal in 7 d. If no sutures, use split foam dressing under trach plate and change as needed to minimize moisture. Apply bordered foam dressing under trach plate if erythema noted. If copious secretions, apply clear film barrier (avoid stoma).	Head and neck edema, copious secretions. Prior radiation may increase risk.
Oxygen mask	Assess areas at risk (including beneath protective dressings) twice every shift during skin assessment and oral care, including bridge of nose, nasolabial folds, chin, and beneath straps.	Secure straps with the least amount of tension needed to obtain adequate seal. Reposition every shift and as needed to ensure correct placement.	Apply foam dressings (1 x 2 in) to behind ears, bridge of nose, and nasolabial folds	Facial edema, moisture
Nasal cannula	Assess areas at risk twice every shift during skin assessment and oral care, including cheeks, columella (between nostrils), behind ears, and neck.	Secure with least amount of tension needed to keep in place. Reposition every shift and as needed to ensure correct placement. If admitted with nasal cannula, replace with soft version.	Use soft nasal cannula. Apply foam dressings (1 x 2 in) behind ears and to cheeks if needed.	Facial edema

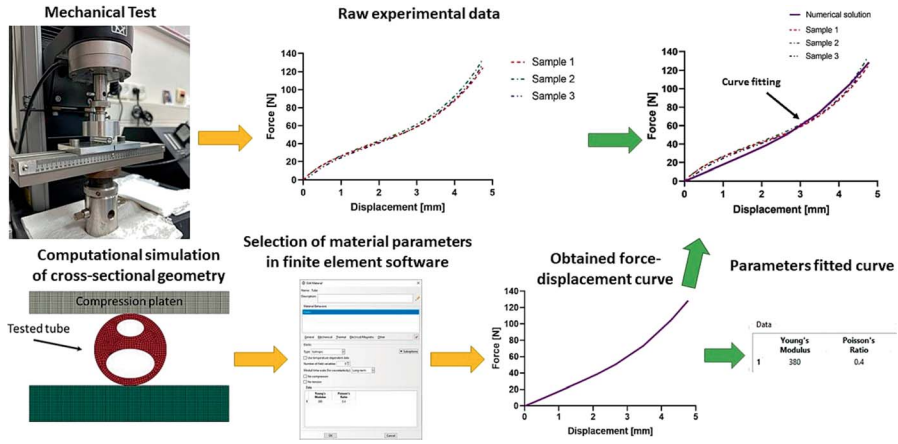
Abbreviations: BiPAP, bilevel positive airway pressure; ET, endotracheal; MARSI, medical adhesive-related injury; MDRPI, medical device-related pressure injury; NG, nasogastric; PRN, as needed; RT, respiratory therapy; trach, tracheostomy.
MDRPI mnemonic and interventions © Solmos. Adapted with permission.

quantifies the resistance of the tested material to non-permanent, or elastic, deformation and is calculated as the ratio of the applied mechanical stress over the resulting extent of material strain. They further compared the elastic moduli of the selected devices and materials with the corresponding properties of native skin. The elastic moduli of the selected devices were first measured using a modified ASTM D3574-11 test standard (Figure 1). These empirical measurements were then compared to corresponding computational finite element simulations of the experiments to determine the mechanical properties via a 'reverse engineering' approach. The authors extracted the elastic moduli of the skin-contacting material components by matching the empirical and numerical force-displacement curves per each tested medical device and extracting the elastic modulus associated with the best fit according to the minimum root mean square of differences (see Figures 1 and 2).

RESULTS

The authors identified 68 patients with 88 MDRPI secondary to oxygen-delivery devices, tube holders/stabilizers, or NG tubes. Six of the 68 patients had MDRPI occurrences due to two devices. See Figures 3 and 4 for the distribution

Figure 1. REVERSE ENGINEERING METHOD FOR CALCULATING THE STIFFNESS OF TESTED MEDICAL DEVICES



of MDRPIs by device and by stage. Medical device-related PIs occurred most frequently with NG tube and endotracheal (ET) tube use, accounting for 47% of all MDRPIs in the clinical database. These devices also had the highest elastic modulus (stiffness) values.

The characteristics of ICU-acquired MDRPIs (device types implicated and stage) are described in relation to the elastic modulus values for each device (Table 2). The unit of analysis is the MDRPI rather than the individual patient. The elastic moduli of the two tested dressing types were within the 10 to 100 kPa range, which falls within the range of stiffnesses of adult skin. The other devices excluding tube holder (TH) #2 and TH #4 were all varying distances outside of this range (Figure 5).

When MDRPI were reclassified for severity as partial thickness (ie, stage 1 and stage 2) or full thickness (ie, stage 3, stage 4, unstageable, or deep tissue pressure injury [DTPI]) or mucosal membrane pressure injury (MMPI), this reclassified scale had a moderate correlation (Spearman correlation = .568, $P < .001$) with the device stiffness (E [MPa]) of the device causing each MDRPI. Partial-thickness injuries accounted for 7.8% of all MDRPIs, full-thickness for 55.7%, and MMPI for 36.4%. Figure 6 provides a relationship map depicting each of these associations. Whereas full-thickness and MMPI MDRPI occurred with devices with the highest elastic moduli (ie, ET and NG tubes), devices with much lower stiffness (ie, tracheostomy plates) contributed to 15% of all full-thickness MDRPI identified.

DISCUSSION

This study provides new clinical and bioengineering insights regarding MDRPI development. The authors examined the compressive stiffness properties of NG tubes, oxygen-delivery devices, and holders implicated in MDRPI development during ICU admissions from January 2016 through October 2022 at an urban academic medical center. Device-specific preventive protocols were implemented in January 2016 and have been updated routinely to include new evidence. Despite focused QI efforts, MDRPI occurrences are common with these devices. Oxygen-delivery devices accounted for 62% of MDRPIs identified. Holders or ties for these oxygen-delivery devices were attributed to an additional 10% of MDRPIs. These findings are similar to reports that the head and

Figure 2. EXAMPLES OF COMPUTATIONAL FINITE ELEMENT SIMULATIONS

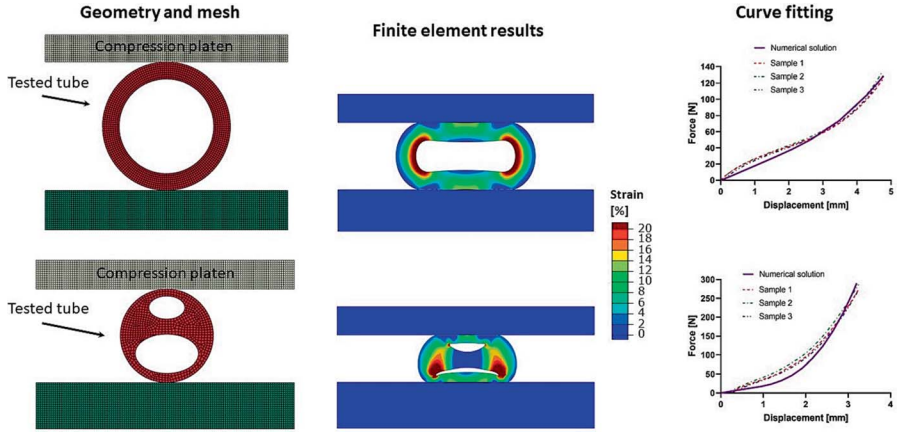


Table 2. CHARACTERISTICS OF ICU-ACQUIRED MDRPI

Device Type	Device Stiffness, *E* [MPa]	Total MDRPI, n (%)	Stage 1, n	Stage 2, n	Stage 3, n	Stage 4, n	Unstageable, n	DTPI, n	MMPI, n
NGTss	380.0000	12 (14)	1	0	0	0	4	2	5
ETT	250.0000	20 (23)	0	0	0	0	0	0	20
NGTft	130.0000	9 (10)	0	0	0	0	2	2	5
Nasal bridle	82.0000	4 (5)	0	0	0	0	1	1	2
Oxygen mask	18.5000	7 (8)	0	4	0	0	2	1	0
Trach plate	9.34000	13 (15)	0	1	5	0	7	0	0
BiPAP mask	1.8000	14 (16)	0	0	1	0	1	12	0
ETT holder	0.9700	8 (9)	0	1	2	0	1	4	0
Trach collar	0.0167	1 (1)	0	0	1	0	0	0	0
Total, n (%)		88 (100)	1 (1)	6 (6.8)	9 (10.2)	0 (0)	18 (20.5)	22 (25)	32 (36.4)

Abbreviations: BiPAP, bilevel positive airway pressure; DTPI, deep tissue pressure injury; ETT, endotracheal tube; MDRPI, medical device-related pressure injury; MMPI, mucosal membrane pressure injury; NGTft, nasogastric tube feeding tube; NGTss, nasogastric tube Salem sump; trach, tracheostomy.
Note: Reports on 68 patients with 88 total MDRPIs. No MDRPI reported for nasal cannula (E = 30 MPa), gel prophylactic dressing (E = 0.026 MPa), or foam prophylactic dressing (E = 0.035 MPa). Dressings tested alone, not as a prophylactic dressing in combination with a device.

neck are the most common anatomic locations for MDRPI,[24] with oxygen-delivery devices being most frequently implicated.[14,24] The present findings suggest that understanding the unique properties of medical devices, particularly their mechanical stiffness in comparison to adult skin, is an essential element of preventing MDRPI.

Oxygen-Delivery Devices

The acuity level in the ICU typically warrants noninvasive or invasive mechanical ventilation with infrequent nasal cannula use. Patients in the ICU who receive invasive mechanical ventilation require an ET tube or tracheostomy. The need to avoid inadvertent occlusion (eg, biting on tube), the propensity to overtighten to ensure securement and avoid accidental dislodgement, and application to sites without prior conditioning are potential explanations for the high rates of MDRPI occurrence with these devices.[15-17]

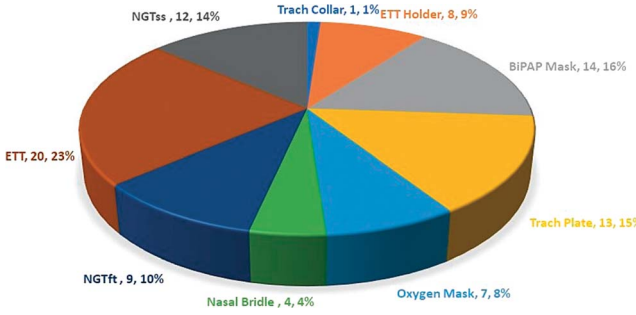
The present findings indicate that the mechanical stiffness of ET tubes warrants further research as a risk factor for MDRPI development. A certain degree of stiffness is important to prevent collapse or occlusion of the tube; however, the optimal balance between the stiffness required to maintain tube patency and avoid tissue injury has not been established. When compared with the elastic modulus of adult skin, ET tubes were among the stiffest of the devices tested. The resulting pressure and tissue deformation, which are exacerbated if the ventilator arm is improperly positioned, are additional factors to consider for future research.

Although the stiffness of tracheal tube plates is relatively low (E = 9.3 MPa), these devices accounted for 15% of all MDRPI in this sample (n = 13); all but one were full-thickness injuries. The practice of suturing plates in place for the first 7 days coupled with a confined moist space, overtightening of tracheostomy ties, and ventilator arm positioning undoubtedly affect MDRPI development. With newly created tracheostomies that have plates sutured in place, the ability to clean beneath the plate and options to further offload with preventive dressings are limited.

Current guidance for MDRPI risk by device type includes bioengineering insights related to device stiffness and overall contact area relative to the expected tolerance for pressure and resulting tissue deformation.[17] Device with greater degrees of stiffness will likely increase the risk of MDRPI development, with lesser duration of pressure causing greater tissue deformation and leading to MDRPI development. Subjective assessment of the stiffness of medical devices is used at the study site to inform device selection and potential product conversions with pilots of devices when feasible. Although this is a useful guide, understanding objective stiffness values specific to common devices in use will further inform device selection. Subjectively, the current tracheostomy plate in use is less

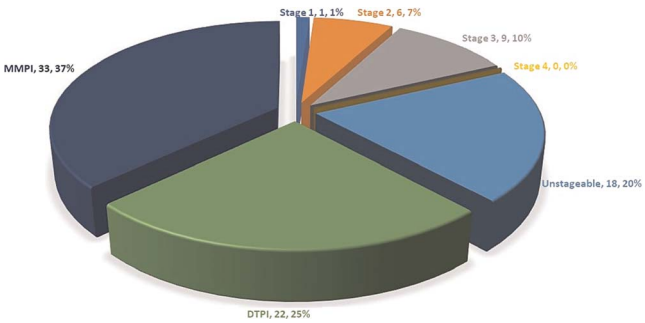
Figure 3. MDRPI BY DEVICE TYPE

No MDRPIs were reported for nasal cannula or prophylactic dressings.



Abbreviations: BiPAP, bilevel positive airway pressure; ETT, endotracheal tube; MDRPI, medical device-related pressure injury; NGTft, nasogastric tube feeding tube; NGTss, nasogastric tube Salem sump; trach, tracheostomy.

Figure 4. MDRPI BY STAGE



Abbreviations: DTPI, deep-tissue pressure injury; MDRPI, medical device-related pressure injury; MMPI, mucosal membrane pressure injury.

stiff/more flexible than the prior device used for the majority of the study period. In fact, the mechanical stiffness of the prior device, when measured objectively in the laboratory setting, is almost twice as stiff as the current device (9.3 MPa vs 5.4 MPa). Objective measurements are needed to fully inform device selection. These results underscore the need for standardized testing of medical devices to inform device selection, preventive interventions, and ultimately, a redesign of devices that lead to harm.[9,15-17]

Noninvasive ventilation devices in use included biPAP and nonrebreather masks. Collectively, these devices accounted for 24% of all MDRPIs identified. Prior insights from bioengineering studies have informed preventive interventions at the study site, including not overtightening straps, checking for proper fit/size, and using prophylactic dressings beneath devices.[25-27] These devices are applied to sites with little subcutaneous tissue (eg, nasal bridge), often with no prior loading/conditioning, and can cause an altered microclimate from humidification. Although the mechanical stiffness of biPAP masks have been the subject of prior bioengineering studies, the present results demonstrate that the nonrebreather mask in use is substantially stiffer than the biPAP mask.

Preventive interventions used beneath these devices include the use of foam dressings.[25,26] Providers selected preventive products based on available evidence; the ability to routinely (at least every shift) assess beneath preventive dressings; and efforts to improve clinical outcomes related to dressing use, including avoidance of medical-adhesive-related skin injury. Accordingly, hydrocolloids are not used for prevention efforts at the study site. Three bordered flexible foam dressings with a silicone adhesive are applied to the bridge of the nose and nasolabial folds for prevention of MDRPI. Alternatively, an elastomer gel product that covers the same contact areas may be used. In both instances, the intervention avoids adding additional steps such as making a pattern and cutting a larger dressing to fit. This may increase the adoption/use of the dressings in the busy ICU setting. Notably, the elastic modulus/mechanical stiffness of both dressings used in the ICUs tested within the range of adult skin, demonstrating compatibility with skin stiffness. Other dressings might meet these qualifications as well;[27] however, only devices/dressings used at the clinical study site were tested. Future research should include product design/materials and the use/efficacy of these alternative dressings in reducing pressure and tissue deformation in the clinical setting. The combined stiffness of the prophylactic dressing and the device in contact with the skin should be considered.

Although nasal cannulas are commonly attributed to MDRPI occurrences,[24,28] no nasal-cannula-related MDRPI were identified in the present study. One plausible explanation for this finding is the conversion by this hospital to soft nasal cannulas in early 2016 with no subsequent MDRPI identified, similar to findings from Duerst and colleagues.[29]

NG Tubes

Nasogastric-tube-related MDRPIs were commonly identified at the study site; this finding is in contrast to prior reports in which MDRPIs secondary to ET tubes and tracheostomy plates occurred more frequently than NG-tube-related MDRPI.[24] Because NG tubes cannot be rotated from one naris to the other and instead are positioned in the center of the naris (a relatively small opening), there is limited opportunity to offload all tissues in contact with the tube. Two types and sizes of NG tubes are commonly in use in the study setting: an 18fr NG sump tube and a 10fr NG feeding tube. One possible explanation for the number of NG-tube-related MDRPIs may involve the diameter of the tube. Although the contact area is small[17] in comparison with larger devices, the contact area in

Figure 5. MAPPING THE STIFFNESS PROPERTIES OF PROPHYLACTIC DRESSINGS AND SKIN-CONTACTING MATERIALS IN MEDICAL DEVICES WITH RESPECT TO THE STIFFNESS OF ADULT SKIN

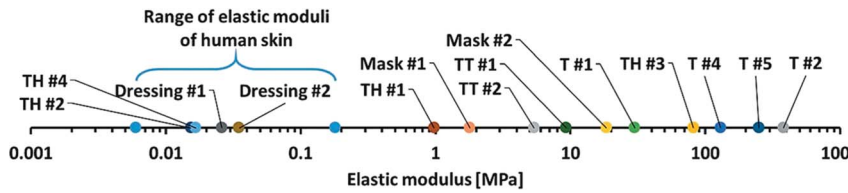
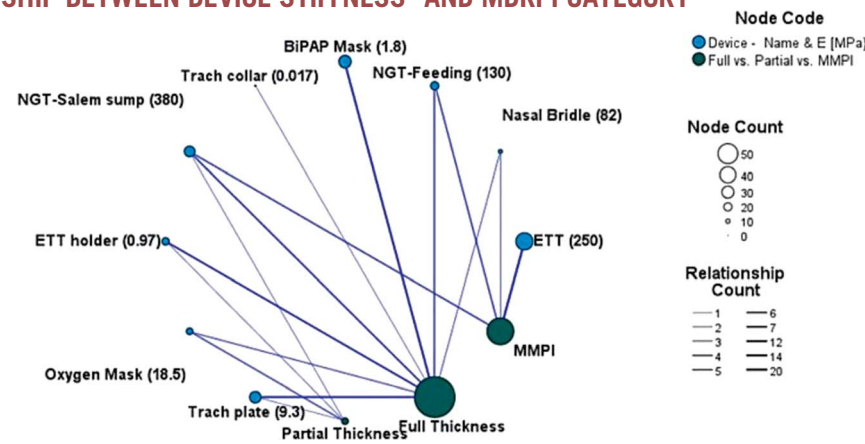


Figure 6. RELATIONSHIP BETWEEN DEVICE STIFFNESS[a] AND MDRPI CATEGORY[b]



Abbreviations: BiPAP, bilevel positive airway pressure; ETT, endotracheal tube; MDRPI, medical device-related pressure injury; MMPI, mucosal membrane pressure injury; NGT, nasogastric tube; PI, pressure injury; trach, tracheostomy.
Note: Spearman correlation between stiffness values and PI category = 0.568 ($P < .001$).
[a]*E*[MPa]
[b]Partial- versus full-thickness versus MMPI

proportion to the application site is an essential consideration for relative risk of MDRPI. The diameter of the NG sump tube is 78% larger than the NG feeding tube (5.94 mm vs 3.33 mm, respectively), making contact with sensitive mucous membranes likely. These tissues are unlikely to be conditioned to the loading.[15-17] The 10fr NG tube, which is used for feeding, was the third-stiffest device among those tested. The 18fr NG sump tube was the stiffest of all the devices measured and also the most commonly used NG tube in the ICU because of the need for suction or decompression. The large diameter of the tube in comparison to the naris size coupled with the mechanical stiffness warrants further investigation. The use of the smallest size feasible to meet medical needs is a clinical implication that should be considered in light of these findings to reduce MDRPI occurrences.[15-17] Manufacturers of these devices should re-examine the design, material properties, and intended use to determine if a redesign can reduce MDRPI development while still meeting the intended usage.[9,15-17]

Tube Holders or Stabilizers

Devices are often secured in place with commercial devices, which are also implicated in MDRPI occurrences. Tube holders or stabilizers were attributed to 15% of MDRPIs including the ET tube holder, nasal bridle, and tracheostomy collars/ties. The majority of MDRPIs were related to the ET tube holder in use. These MDRPI occurred beneath the upper lip stabilizer and under the skin barrier pads applied to the cheeks. The mechanical stiffness of the skin barrier pads with plastic support is substantially higher than that of the upper lip stabilizer. One potential explanation for the occurrence of MDRPI with the ET tube holder is its use with proning. Although providers proned patients with acute respiratory distress syndrome throughout the study period, a greater number of patients required proning during the COVID-19 pandemic. Application of the device to a patient who later develops marked facial edema may contribute to increased tube tension, tissue shear, and deformation, all in an area that is difficult to assess because prone positioning is maintained for long periods of time.

Limitations

The results of the present study reflect the objective measurements of devices on the hospital formulary with typical sizes used. Findings may not be generalizable to other manufacturers' devices because of the proprietary nature of device design and composition. Patients with COVID-19 are underrepresented in the sample. Patient and clinical use characteristics (eg, patient physiologic status and duration of device use) would provide greater insights into the unique risk factors for MDRPI development.

Implications for Practice and Future Research

Studying the root causes of MDRPIs and effective means to mitigate their risk will lead to improved quality of life for patients and considerable cost savings, which can otherwise be invested in further treatment of the primary morbidity. Developing relevant bioengineering methods is essential to ultimately create laboratory standards to test the safety of medical devices that come in contact with the surface of the body.

This research contributes to the evolving knowledge of unique factors implicated in MDRPI etiology, which is complex and multifaceted. Conceptually, MDRPI development can be attributed to three factors: (1) patient factors such as tissue tolerance, edema development, and contact surface contours; (2) device factors, such as design and materials used; and (3) clinical use factors,

such as proper device size, fit, securement, and rotation; prophylactic dressings; and routine skin assessments (see Figure 7 for greater detail). The present study findings demonstrate that devices with low stiffness (relative to other devices) can lead to MDRPI occurrences. This underscores the need to consider not just device factors but also patient and clinical use factors. For example, a device with low stiffness can cause an MDRPI if the hours of device requirement are high and/or the device is not rotated. Clinical use factors and patient factors may be modifiable and can help reduce the patient's risk of MDRPI occurrence.

Although some device factors may not be modifiable, opportunities exist for further collaboration between device manufacturers, bioengineers, and clinicians. The development of objective methods to determine the associated risk of MDRPI by device characteristics (design, materials, intended function) to inform purchasing decisions, formularies, and the risk/benefit of particular devices is a necessary next step. Testing standards for medical devices are necessary to inform device selection and prevention efforts. An integrated approach to device selection that incorporates bioengineering testing, including the mechanical stiffness of devices, will inform clinical practice.[9,17] Modification of the inherent risk associated with the material components of these devices that are not compatible with the mechanical stiffness of skin may ultimately reduce MDRPI occurrences.

In this study, the authors examined device factors from bioengineering testing of device stiffness in association with clinical outcomes. Further exploration of patient and clinical use factors is underway in a larger case-control study involving this clinical cohort.

CONCLUSIONS

The relative mechanical stiffness of a device is an important device-related factor in the etiology of MDRPI. However, other factors such as duration of device use, tightness when securing the device, correct fit, and heat and humidity under the device should be considered in predicting MDRPI severity. Much like bony prominence PIs,[18,19] a complex interplay of factors likely contributes to the development of MDRPI. Patient factors such as perfusion and oxygenation, edema, and skin condition are likely to impact the risk of MDRPI development. Clinical use factors include required duration of tube use, correct selection and placement of devices, and MDRPI preventive measures.

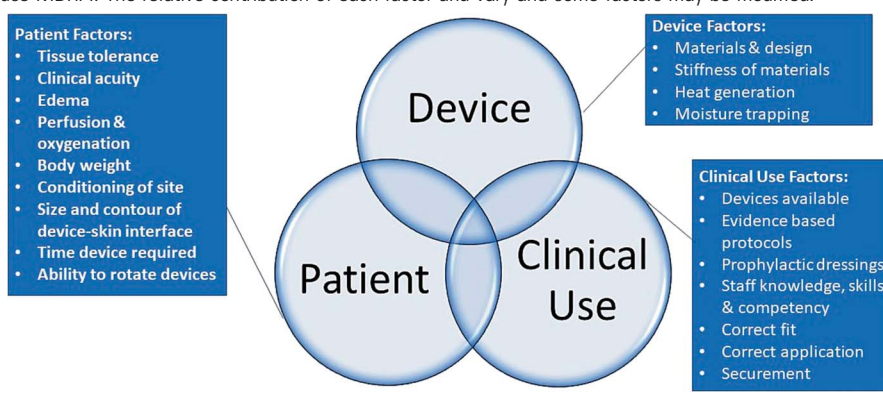
Clinicians may be unable to detect early tissue injury because of challenges in fully assessing the skin under a medical device, either due to securement (eg, sutured tracheostomy plate) or required patient positioning (eg, prone). The amount of melanin in the patient's skin may also obscure early signs of injury. Research is needed to examine the device-associated risk in the clinical setting in association with patient factors and clinical use factors, particularly in critically ill adults where device use is necessary to treat critical illness. ●

PRACTICE PEARLS

- MDRPI preventive interventions should address (1) patient factors, (2) device factors, and (3) clinical use factors.
- A multidisciplinary approach to MDRPI prevention is needed, including supply chain, respiratory therapy, and other clinical experts.
- Implementing device-specific preventive interventions for high-risk devices with frequent reinforcement/practice prompts can reduce harmful MDRPI occurrences.
- Objective measurement of the mechanical stiffness of medical devices is needed to fully inform device selection, preventive interventions, and ultimately a redesign of devices that lead to harm.

Figure 7. FACTORS INTERACTING TO CAUSE MDRPI

All factors interact to cause MDRPI. The relative contribution of each factor and vary and some factors may be modified.



Abbreviation: MDRPI, medica device-related pressure injury.

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