Correlating biomechanical properties of medical devices with clinical outcomes in critically ill adults

Susan Solmos, PhD, RN, CWCN;[a,b] Amit Gefen, PhD;[c] Joyce Black PhD, RN, FAAN;[a] Aleksei Orlov, MSc;[c] Janet Cuddigan, PhD, RN, FAAN[a]

Affiliations: [a]University of Nebraska Medical Center College of Nursing; [b]University of Chicago Medical Center; [c]Tel Aviv University

Problem

- Medical device related pressure injuries (MDRPI) are a common adverse event[1,2]
- An urban academic medical center developed and implemented well-defined MDRPI prevention bundles in 2016 with periodic updates and frequent reinfusion of practice expectations
- Subjective assessment of new devices for MDRPI risk as member of MedSurg Value analysis Team
- Substantially reduced rates; however, 12 oxygen delivery devices, nasogastric tubes, or holders frequently implicated in occurrences

Goal

- Understand the relative differences among device composition and MDRPI risk
- Hypothesis: Devices with greater mechanical stiffness would be associated with a greater number and severity of MDRPI

Methods

- Comparative descriptive study exploring the relationship(s) between objective biomechanical tests of medical devices and clinical outcomes (MDRPI); IRB approved.
- Devices in original packaging were tested
- Using an integrated experimental-computational approach, the compressive elastic moduli (*E* [MPa]) was measured for each device and compared to the properties of normal skin.
- The elastic modulus 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.
- The elastic moduli of the selected devices were first measured using a modified ASTM D3574-11 test standard.
- These empirical measurements were compared to corresponding computational finite element simulations of the experiments to determine the mechanical properties via a 'reverse engineering' approach (Fig. 1). 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.

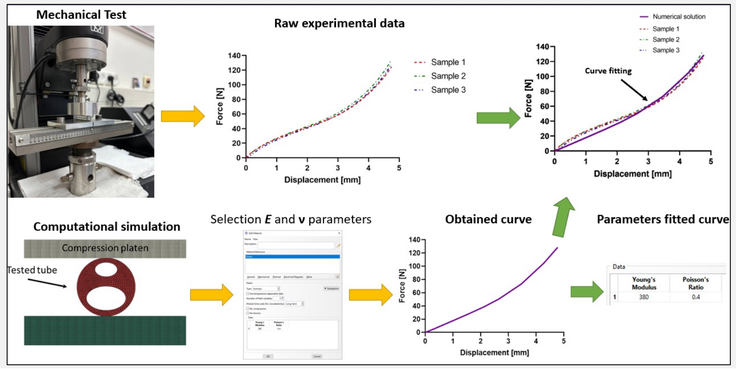


Fig. 1 Reverse engineering method

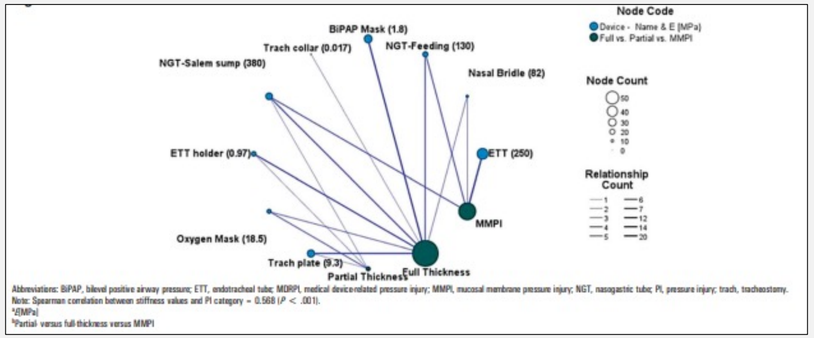
Results

Table 1. Characteristic 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.

Figure 2. Relationship between device stiffness and MDRPI category



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]MPa
[b]Partial versus full-thickness versus MMPI

Implications and Next Steps

- Relative mechanical stiffness of a device is an important factor in MDRPI etiology.
- Device selection incorporating the mechanical stiffness of devices can inform clinical practice.
- Modification of the material components of devices not compatible with the mechanical stiffness of the skin may ultimately reduce these harmful and potentially disfiguring occurrences.[4]
- Further exploration of patient and clinical use factors is underway in a larger case-control study involving this clinical cohort.

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