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

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Problem

- Medical device related pressure injuries (MDRPI) are a common adverse event.
- An urban academic medical center developed and implemented well-defined MDRPI prevention bundles in 2016 with periodic updates and frequent reinforcement 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.

Results

- Comparative tests 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.

Figure 2. Relationship between device stiffness and MDRPI category

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.
- Further exploration of patient and clinical use factors is underway in a larger case-control study involving this clinical cohort.

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