INSTITUTE FOR PRESSURE INJURY PREVENTION

WCICT2017
20-21 June | Manchester, UK

Metrology Strategies for use as an Evidence Base in Device Evaluations

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This lecture is about the view of mechanical engineering on how we can use metrology to contribute to wound care and prevention of PIs related to medical devices. Once we have skin color change, it's already too late. How do we get the evidence we need for evidence-based prevention?

What is metrology?

There are different definitions in different fields. According to:

Dictionary of Physics: "The scientific study of measurement, especially the definition and standardization of the units of measurement used in science."

Dictionary of Chemical Engineering: "The study of weights and measures, and the units of measurement."

Bureau International des Poids et Mesures: "Metrology is the science of measurement, embracing both experimental and theoretical determinations at any level of uncertainty in any field of science and technology."

This last is my favorite - as it not only looks at theoretical, but also the practical.

As engineers, we measure lots of things on a daily basis to investigate failures and facilitate development.

Measures that relate to wounds:

- Length, area, volume of a wound
- Color changes
- Pressure
- Shear
- Friction
- Climate
- Elasticity
- Strength
- Force
- Time

As a mechanical engineer, we are always measuring parameters – now we're trying to bring that expertise to wound care.

Why do we need metrology?

1. To evaluate medical device performance. A bottle of shampoo can say "clinical skin care" or "it's good for the skin," just like many medical devices say "pressure release" or "pressure distribution," but we need to be able to REALLY know - exactly - what something can do. We need to be able to measure, document and prove.
2. Compare different products
3. Investigation for skin properties and the effect of aging/exposure/condition
4. Evaluation of changes... wound healing, infection

Metrology engineering fail example:

The Mars Climate Orbiter (1998) failed to convert imperial measurements to metric equivalents. This is a massive FAILURE in metrology. It flew too close to Mars and broke apart! If NASA would have had a better way to communicate, measure, and standardize, they could have saved $78 million.

Challenge: Uncertainty of measurements

We can measure things incorrectly, or with uncertainty. Even with the same mattress, same volunteer, same equipment – if the volunteer was in a slightly different posture when measuring, you get a different measurement: 30% difference in peak pressure! How many measurements do we need to take to have a robust method?

Same mattress cover, same shape of specimen, same tensile equipment. We measured in 3 different directions, and got different results each time! 75% difference in maximum stretch and 57% difference in maximum load!

That's why we need good methodology. For consistency.

Standardisation

- Robust measurement protocol – we need to be clear about our evaluation methods in our studies – they need to be able to be recreated with the same results. We must report any uncertainty.
- Controlled variables
- Use statistical experimental design methods
- Ensure traceability
- Report uncertainties
- Communicate methodologies

Case study: Static and dynamic mattress pressure mapping evaluation

- Compare 2 mattresses
- Pressure between volunteers and mattresses
- CONFORMat from Tekscan
- Anatomical locations including sacrum and heel
- Backrest elevation at 0, 30 and 45 degrees

Challenges:

We can't measure all anatomical positions and locations or posture – we had to ask the volunteers to stay in one posture consistently, which was hard. These were the challenges:

- Choice of the anatomical locations (can't measure every position)
- Posture of the volunteers (tricky: they're not trained to sleep with the same posture all the time)
- Duration of the measurement (different mattresses have different cycling time, so we had to ask the manufacturer what they recommended)
- Robust Measurement Methodology

- Settling time after switching on/ off air pump for dynamic mattress (it takes time for air go into the mattress)
- Location and orientation
- Standardisation of protocol
- Environmental control

How can Robust Results be Used for Evaluation and Progress?

If you have accurate and precise case study data and information plus skin properties, we can put it into a computational model and predict the influence of medical devices to skin and formation of PIs. Over 33% of PIs are as a result of medical devices.

We developed a computational model to evaluate medical devices for how likely they are to create PIs. The model simulates the deformation of skin and cutaneous blood vessels under mechanical loads. Ultimately, this means we don't have to trust manufacturers' claims that a device will not create PIs: we can model and predict it ourselves.

Further Development of Metrology

- Standardisation
  - Terminology
  - Measurement methods/ procedures
- Better Understanding
  - Effects of devices to skin and cutaneous blood vessels
  - Behaviours and characteristics of skin
- Application
  - Different measurement methods in the area of dermatology
  - Develop novel methods for skin measurement