Key Concepts for Effective Prevention and Technological Embodiments

Prof. Amit Gefen

In 2017, no field in medicine is based on visual assessments as much as wound care.

But that is going to change.

Technology is necessary for two objectives:

1. Prevention - nothing is more effective
2. Early detection - it is impossible to be fool proof in prevention

Focus on prevention:

- PIs comes in different shapes and forms – mild to very severe
- In the last 20 years, we have establishing that PIs do not progress in a linear way from mild skin irritation to devastating wound
- They MIGHT if it's a case of serious neglect, but normally they do not
- They develop through different pathways
- More serious cases typically develop from the INSIDE OUT
- That’s true for PIs and also for diabetic foot ulcers

The variety of patients is also substantial. There are elderly and youths. Common ground for each of these populations is impairment in MOTION or in SENSATION or both.

It could be someone losing consciousness, someone lying in the operating theater, anaesthetized.

A person does not have to be chronically impaired – just a certain period is enough –and they are exposed to this risk.

For many years, I’ve been pushing the gold standard – bioengineering research tools in the field of wound care to facilitate quantitative standard methods of evaluation to improve prevention and treatment.

Problem in the field:

- It's too heavily based on clinical trials.
- There are some fields (cancer research) where there are a lot of resources (like pharma companies) and they can fund randomized clinical trials in the billions over many years. They can make the investment and come up with new solutions. BUT the field of wound care isn't big enough or strong enough to rely on randomized clinical trials.
- If you look at our sponsors for this conference, none of them is the size of a big pharma company.
- More important than clinical trials in the wound care field is applied research based on everything that modern engineering and bioengineering can offer, like computer simulations.

Why computer simulations?

- Epidemiological studies and clinical trials do not normally reveal the details of injury cascades or mechanisms of action of interventions; they are limited to indicating risk factors or whether there is (statistically significant) efficacy or not.
- Modes of action of medical devices designed for prevention are, in particular, difficult to test in clinical settings, given that studies are costly and require large group follow-ups for long times.
- Computer simulations are complementary to clinical research in providing additional important insights regarding etiology, and in demonstrating mechanisms of action of potential interventions.

If a car company wanted to develop a new type of a car, it could design the car, crash it against the wall, improve it, crash it again, improve it, and end up, 10 years later, with a great car.

But instead of just crashing, they use computer simulations to ensure that they're not just burning money.

We should adapt the same concept and use computer modeling as a complimentary approach to clinical trials, much like they've been used in other fields of medicine (orthopedics and cardiovascular).

Before the FDA would approve an implant that needs to bear mechanical loads (stent, heart valve), it needs evidence that it has been tested in computer simulations that evaluated the different scenarios to make sure that the implant could withstand the forces that the body applies (joints, walls of the blood vessels, pressure blood flow is applying on the heart valve).

Test it in a huge variety of virtual scenarios on the computer, and you make sure your design can cope with whatever can happen in the body, including a fall, an episode of rise in the blood pressure.

Computer modeling has ENORMOUS potential to push wound treatment forward:

- We cannot just look at the skin and know everything.
- That's why we're developing sensors, an SEM scanner, and other technologies.
- The other way (complimentary, not alternative) is to simulate what's going on internally and you can do that patient-specific or population-specific for the purpose of research and product design development.

We know that cell death begins internally at sites of high distortion of soft tissues near bony prominences.

This allows you to build virtual environments with powerful computers that describe these interactions.

Control the exposure to that distortion.

You can control the frictional forces by minimizing the frictional coefficient, but you can also take other directions.

The computational approach must be coupled with experimental model systems

What we are actually seeing in the human body and how tissue responds to load, or with animal tissue, or the more sophisticated and more elegant tissue engineering

Also, to some extent, you can use cell cultures (although they cannot replicate the full complexity of living tissue).

What is the role of bioengineering in pressure injury prevention:

- The field of chronic wound care and wound prevention in particular rapidly closes the gaps with other fields of medicine (e.g. orthopedics, cardiovascular) in terms of employing state-of-the-art bioengineering approaches and methods for product design, selection and evaluation.
- Computer modeling facilitates formulation and testing of design concepts using standard, objective and quantitative measures, which consequently allows rationalized decision-making in either R&D or purchase decision processes.
- Multi-disciplinary teams integrating clinical and bioengineering expertise and close collaboration between academia and industry will continue to push the field forward, for the benefit of patients.

State in which cells are found when the body is weight-bearing:

Analogy to a torturing device – right now, the cells in your buttocks are experiencing tension and shear and the cytoskeleton is distorted, but you are protecting yourself, because you keep moving! Shifting!

But if your nervous system and your muscles can't respond, your cells break down

It takes less time than we used to think.

They can break down within minutes.

Practical conclusion: any device or piece of equipment (designed for prevention of PIs or equipment that can accidentally CAUSE a PI) should minimize deformation while interacting with the human body.

One of the most important things that I have done as President of NPUAP is to introduce the concept of a deep tissue injury (etiology chapter).

Practical issues and recommendations:

- A tissue tolerance curve describes the ability of a tissue to stay viable as it is subjected to deformation over a period of time.
- You can injure tissue immediately (if someone is hit hard with a hammer, an injury results in no time). That's what happens if loads are high enough.
- If the loads are very low, no injury will happen (I wear a watch 23 hours/day and I don't get a PI – why? Because the load is too low.)
- Surfaces can do 2 things: minimize friction or maximize contact area and provide envelopment and immersion.
- Goal is to push our patients as close as possible to the right part of the tolerance curve.

There is a tradeoff: if you envelope too much, you lose functionality.

If we design wheelchairs with too much envelopment, it would be too difficult to function.

Must minimize the exposure to tissue deformation internally.

Recent study:

What happens to skin tissue on the toilet?

- Shear distortion
- It's an offloading surface – offloads the center of the buttocks

* But gravity wants to pull you down
* The hole is too small

So, the body weight creates shear deformation which distorts internal tissues.

All of that on a very narrow surface that does not provide any redistribution of pressure (too narrow – too small of a contact area).

There IS, however, technology available from Molnlycke that conforms to the body and captures the contours of the body and minimizes internal tissue deformations by fitting the piece to the body of the individual (they do a headrest).

Prophylactic dressings do 2 things:

* Provide cushioning (immersion/envelopment locally, in a small region)
* Using a smart structure (layered) built like a sandwich of stiffer layers and softer layers, there is a structure that is designed to absorb shear

Computer modeling can determine, quantify, evaluate and improve the performance of the dressings.

Today's technology of running MRI sessions, importing 3-dimensional MRI data into powerful computers and analyzing this data 3-dimensionally, we can understand exactly how mechanical loads are being transferred

This helps us determine WHAT works and WHY it works – couple clinical trials with computer modeling work – that's the best way.