



Diagnostics in Wound Management

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Introduction to what we think is the future of diagnostics:

- Assessment in wound healing - a comprehensive type of monitoring
- We always look for clinical aspects, and then we move into co-morbidity, chronic diseases
- More and more, we are looking at biochemistry
- At the end, we always want to reach proper documentation with very high quality imaging in order to predict type of response

The purpose of diagnostics is to make an initial definition and diagnosis and to run clinical support, monitor for side effects, monitor for the effectiveness of treatment, predict outcomes and, if possible, a way of defining the type of reimbursement.

Wound diagnostics and assessment has to follow a step-by-step process, non-invasive for fragile patients, using reproducible and cost-effective methods.

We always start with clinical observation.

If there's not enough, we move to devices.

As dermatologists, we like to take tissue sampling and take ancillary tests.

Diagnostics:

We are lucky in dermatology, as we have plenty of devices.

These devices will become more and more available for regular diagnosis.

Indicator devices:

- Tissue sampling
- Biomarkers
- Immunocytochemistry



- Blood samples
 - Flowcytometry
 - Pathology

Already, diagnostics are available in kit form for MMPs to detect 2 different levels of prosthesis activity in venous leg ulcers and diabetic foot ulcers.

We think the future will have more and more biomedical sensors and have published a review paper on this, including current technology in this area of diagnostics.

I am happy to share the final interesting news about this project.

We were able to run our study from 2012-2016 under the supervision of the 7 Framework Program (Smart Wearable and Autonomous Negative Pressure Device for Wound Monitoring and Therapy). The acronym is SWAN-iCare.

€8,600,000 funded this project, completed last April.

Plenty of big labs in Europe were part of this, with a strong industry presence.

The University of Pisa took a big part.

It was able to develop a system focusing on 3 sensors:

- pH – inside the wound bed
 - Temperature
 - MMPs - optical fiber outside the wound bed
1. In-wound sensor devices were utilized.
 2. The negative pressure device did a good job, compared to the commercially available devices.
 3. The full device was found to be without patient discomfort through information gained from quality-of-life questionnaires.
 4. The patients wore the device for 1 week.



Study results:

Results are not publishable because we signed a confidentiality agreement with a journal. However, there was impact on the patients which will lead to faster wound healing which will lead to reduced morbidity and reduced amputation rates, and less hospitalization correlating with better mobility and improved quality of life.

Forecast – Impact on society and healthcare:

- Reduced healthcare costs
- Relatively less burden on the healthcare system thanks to remote monitoring
- Increased productivity (patient returns to work faster)
- Reduced daily nursing visits allowing for more new patients to be consulted and treated
- Impact on medical science: most effective wound care protocols available

Summary:

We continue to consult our patients in a clinical way.

We are moving more and more to tissue sampling.

The role of sensors in the cardiovascular area will increase, as they are the way to go for diagnostics, producing better prediction, better documentation, improved decision making and better patient outcomes.

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