Science.
Applied to Life.™

Systagenix at a glance

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Global capabilities

Sales in nearly every geography

Sales & Marketing Operations in 69 geographies

Laboratory & Application Engineering in 50 geographies

Manufacturing & Converting in 35 geographies

Key
- Sales & Marketing
- Manufacturing & Converting
- Technical Capabilities

Systagenix S.A. at a glance

- Part of 3M Global
- 1 x manufacturing plant in Gauteng
- 3 x offices nationally
- 200 plus employees in four business units
- Healthcare, Consumer, Safety & Industrial and Transportation & Electronics B/U
- Systagenix – part of HCBG
- Manufacture and supply of multiple products and services to South African market (private and public), as well as SADC and Sub Sahara countries
- Top 50 most ethical companies around the globe
- BBBEE compliant

Delivering solutions across the care continuum in SA/SSA




- Leader in wound care and related products – rich history of innovation
- Delivering world class products to every corner of our country
- Supplying innovative and transformative medical devices to our entire population
- Believe that everyone should have access to healthcare, regardless of funding mechanism
- Health economics matters! As do clinical outcomes – cheaper not always better
- Giving caregivers the products they need
- Restore patients lives

The basis of our comments

Our comments are based, in part, on our experiences in the health sector, including in the Department of Transport (DoT) (RAF), Depart of Employment and Labor (DoEL) (Compensation Fund - COIDA), private and public sector, where we render our products and services as well.

Our comments are also based on experiences of our company, which operates in other countries where health insurance: national-, social health insurance or otherwise, exist.

The overarching principle on which healthcare should be provided, is evidence-based medicine, i.e. ensuring that all patients are entitled to appropriate care, based on research

- considering not only cost, but health outcomes

The NHI Bill, the Constitution and the benefits

The right of access to healthcare & social security and the limitation of rights (Constitution, sections 27 and 36)

The NHI Bill would have to, in its application, limit the rights of individuals

This would also be the case in its gradual implementation

The question therefore is, on what basis will the NHI Fund, through entities such as the Benefits Advisory Committee, the Benefits Pricing Committee and the Office of Health Products Procurement, make these decisions that would have to limit rights?

- No such principles to guide the limitation of rights are set out in the Bill, and specifically in relation to the supply of medical devices

Our proposal: include principles in the legislative criteria to be applied by NHI structures

The limitation of rights must be **evidence-based**, by the inclusion of evidence-based medicine as the criterion on which the BAC and OHPP, and in the end the NHI Fund, make their decisions on formularies and treatment guidelines

Not only cost ("the lowest possible price" - clause 11(2)(e)), but **health outcomes** must be considered

Create mechanisms whereby **deviations** (and not a rigid complementary formulary) is permissible, by healthcare professionals and entities to act in the best interest of patients, in particular with complex wounds, the inadequate treatment of which could lead to sepsis, loss of limbs, etc.

4 & 5. Funding the NHI; Role of medical schemes

As many other stakeholders, we remain concerned about the financial sustainability of the NHI

Very little is known as to how the NHI will be rolled out progressively, and if on a primary care basis, what that would mean for us, specifically in our business, for example:

- A patient who suffered a workplace accident?
- A diabetic foot patient, referred from a PHC Contracting Unit?
- Patients suffering from burns? Referral to tertiary institutions? Cost?

Medical schemes should not be limited to unknown “complementary cover”, as they alleviate pressure on the public sector and the NHIF in future

6. Procurement: value and outcomes

Evidence-based medicine and health outcomes

Apart from the absence of entrenching evidence-based medicine and health outcomes in products procurement, our concerns are with:

Clause 38(6): direct delivery (currently in the public sector we deliver to depots)

Clause 41(3)(b): all-inclusive fee to specialist and hospitals: will that include our products and if they are held accountable for outcomes?

Clauses 38(6), 34, 4(7)(c) and 8(2): Formularies appear to be strict, with no room to respond to health needs that may fall outside of such lists

Our proposal:

Formularies must be set on evidence-based medicine and-

- product lists (formularies) must flow from it and
- consider all patients – also those with wounds that are difficult to manage
- HTA will include all technology and inform clinical practice guidelines

The BAC, OHPP and NHIF must consult the bodies who are experts in wound care and which we list in our submission, when making decisions on wound care protocols, and the associated products

Provider payment mechanisms (not quite clear yet in the Bill), must ensure that providers are able to procurement to address their patient needs

7. Innovation

The NHI Bill is silent on how innovative medical devices will be adopted into the system.

Introduction of new technologies constitutes an important facet of the health care service and delivery.

Innovative devices may provide:

- treatment for previously untreated conditions or improve devices where other devices have failed or where there were no further treatment options.
- reduced overall length of treatments, fewer admissions, reduced LoS, quicker recoveries, improved quality of life and overall productivity.
  - An example in AWD, healing time can be up to 40% quicker with innovative devices.

We support a mechanism for assessing and introduction of innovative technologies to ensure timeous access by patients and specialists in their fields.

This needs to be underpinned by health technology assessment (HTA)

9. HTA 57(3)(d) – under transitional arrangements

The Ministerial Advisory Committee on Health Technology Assessment for National Health Insurance, which must be established to advise the Minister on Health Technology Assessment, and which must serve as a precursor to the Health Technology Assessment agency that must regularly review the range of health interventions and technology by using the best available evidence on cost-effectiveness, allocative, productive and technical efficiency and Health Technology Assessment.

HTA Defined

Health Technology Assessment (HTA) WHO Definition:

Systematic evaluation of the properties and effects of a HT, addressing the direct and intended effects of this technology, as well as indirect and unintended consequences, aimed mainly at informing decision making regarding HT. HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods.

More recently the ISPOR Definition:

An evidence-based, multidisciplinary process intended to support healthcare decision making by assessing properties and effects of one or more new or existing health technologies in comparison with a current standard. Aiming at determining added value, HTA uses explicit analytical frameworks to determine the value of a health technology at different points in its lifecycle, based on research and the scientific method in a systematic, transparent, unbiased way. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

9. Health Technology Assessment (HTA)

HTA should not be used as a mechanism to restrict access, but to promote access to quality and cost-effective health care by our entire population

HTA includes economic evaluation, as one of the many assessment tools, but used with other equally important criteria to to inform decision making and is not used in isolation, as per the definition

We support the establishment of a HTA entity, as per the recommendations made through several initiatives addressing prioritization, management and allocation of health care resources.

Such a HTA entity should, based on international lessons learned and successful HTA implementation:

- Be independent, transparent and multidisciplinary
- Embrace new and innovative technologies providing a mechanism for rapid patient access
- Include mechanism for coverage with evidence development

HTA should not sit within the NHI

The NHI cannot be a producer and consumer of HTA recommendations.

Naturally influenced by the perspectives of the NHI

Fit for purpose

- Independent – avoids bias of the “owner”
- Dependant on life-cycle of the technology
- Avoid a one size fits all methodology ie inappropriate to use pharma assessment methods for non pharma ie devices
- Adaptable and pragmatic and consultative
- Guides clinical practice therefore must be frequently updated
- Balance national (burden of disease) and innovation (access to best care) priorities.

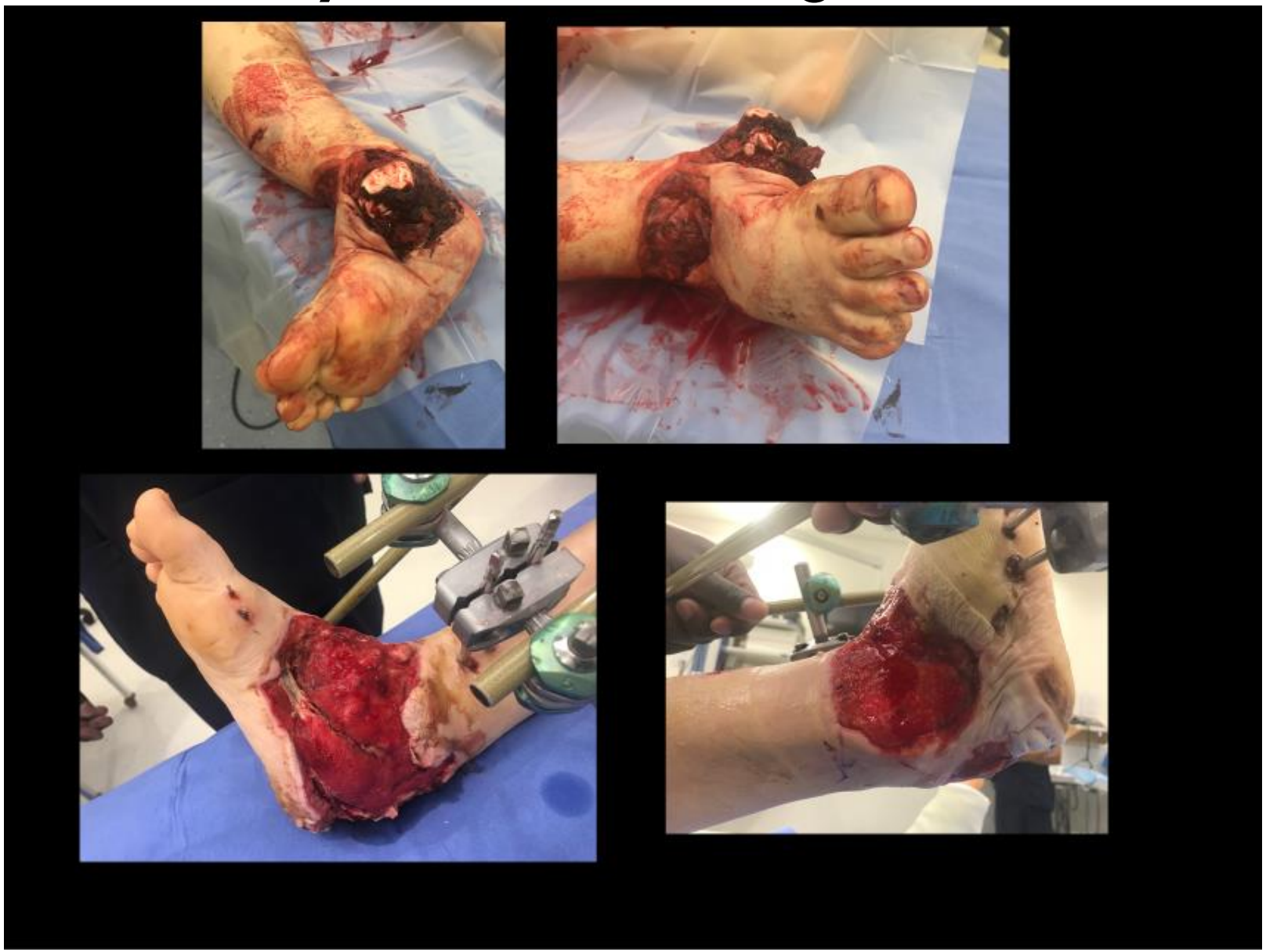
Evidence-based medicines & health outcomes in real life: All wound care are not the same…

3-part case series..

Warning… pictures that follow may be difficult to view for sensitive viewers

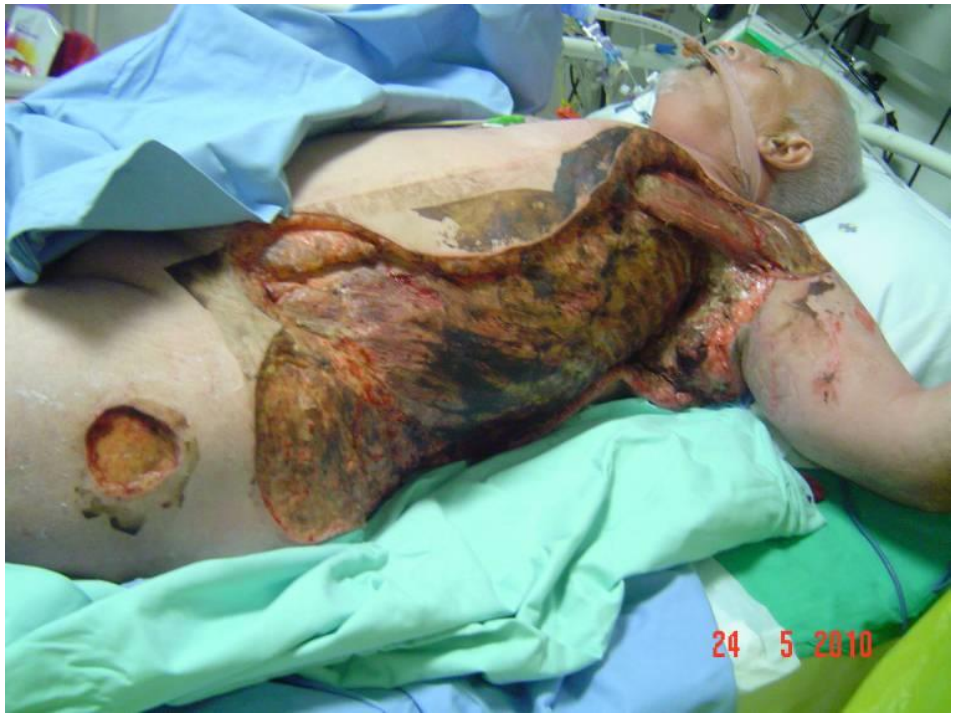
(patients have given consent to share pictures)

Case study 1 - Limb salvage



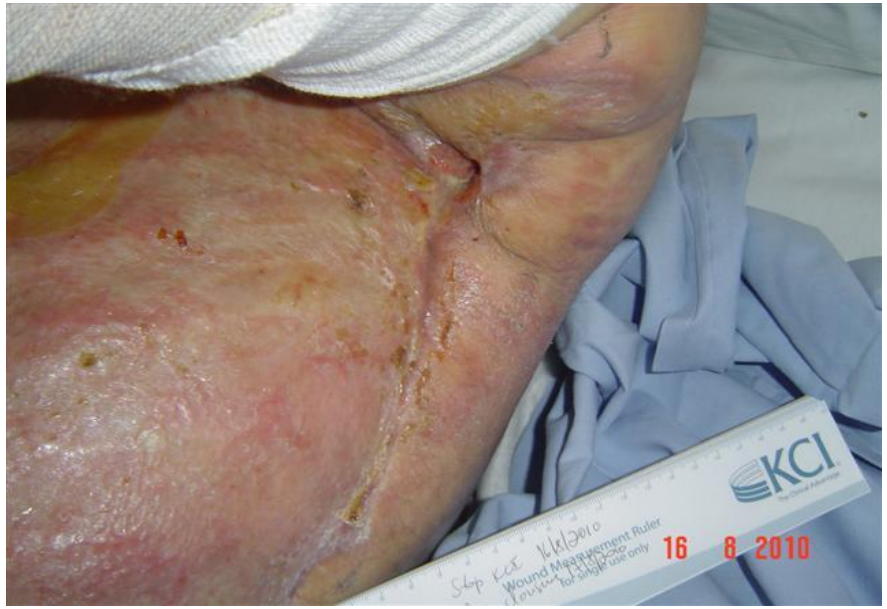
This child had a traumatic injury of the foot with limb threatening.
Vac Veraflo used as first line due to exposed bone and tendon and major tissue loss post surgical debridement. Grafted with dermal substitute and external fixation for stabilization.
Patient discharged with limb movement and rehabilitation. Limb saved after three weeks!

Case study 2 – N.F.

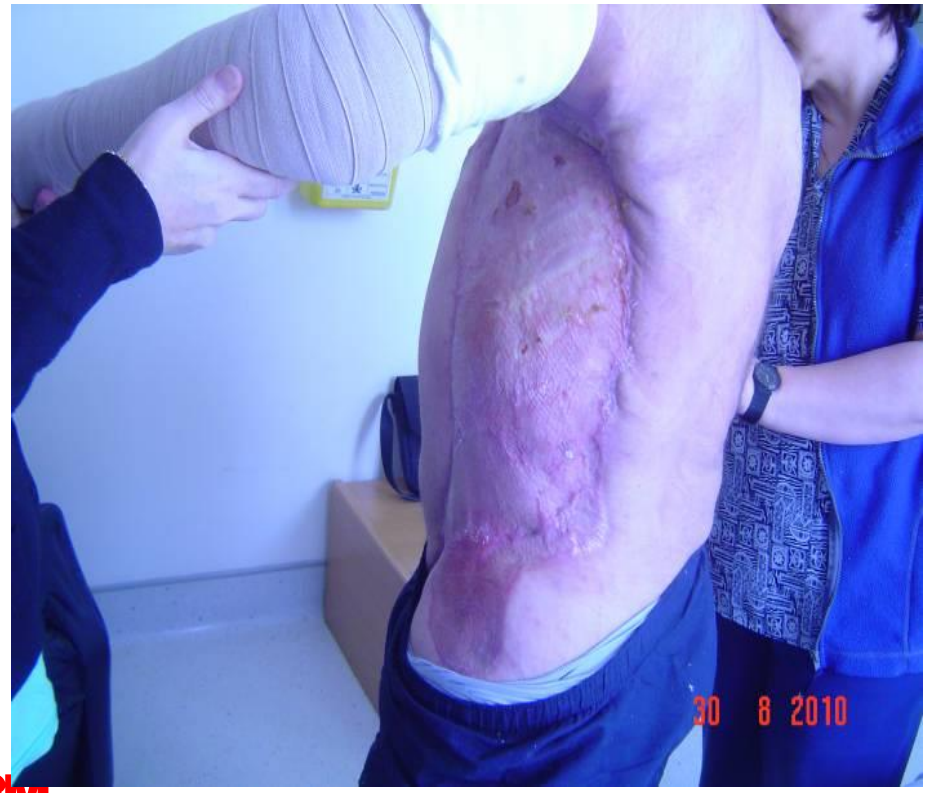


Necrotizing Fasciitis is also known as “flesh eating disease” is a rapid-acting, potentially deadly infection.

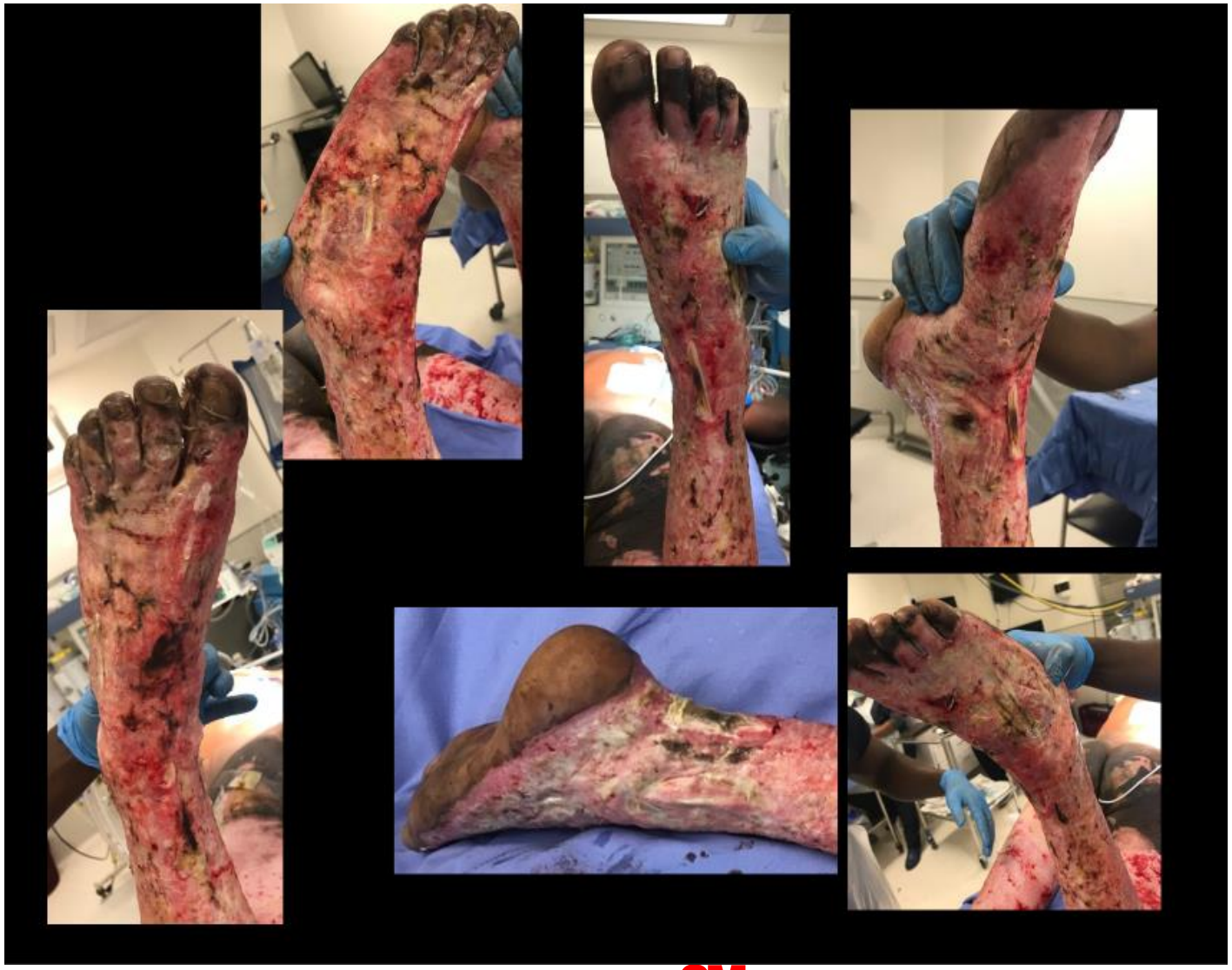
This condition is devastating in its ability to spread at a rapid rate. It can be caused by any type of injury that introduces micro-organisms into the subcutaneous tissue



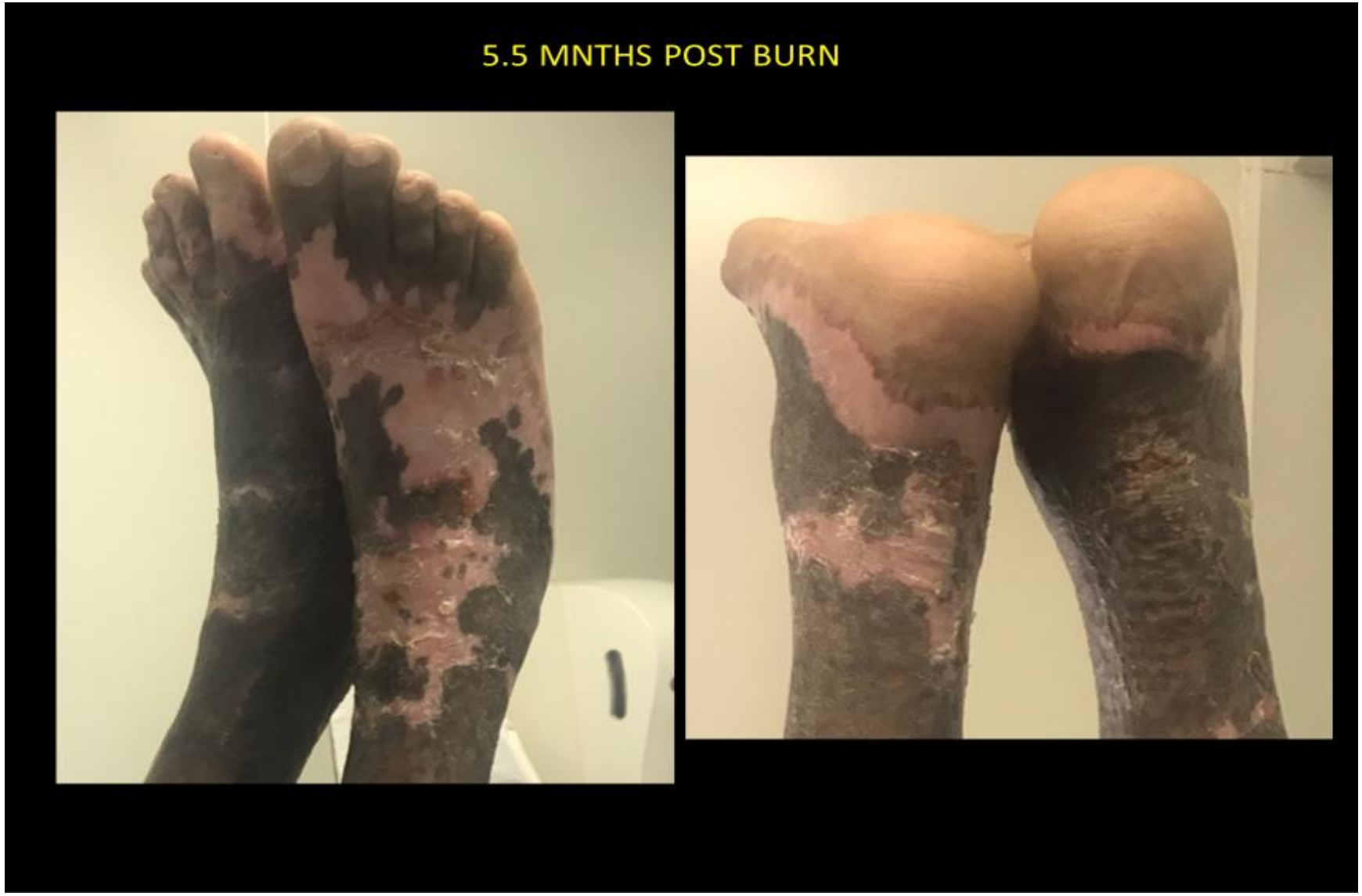
Patient was fully healed and discharged after only 11 weeks



Case 3: Full thickness burn-VAC Veraflo as first line therapy followed by grafting and Core NPWT



Case 3 – End-result



Conclusion:

In all three cases presented, the use of a new technology (VAC Veraflo), supported by Evidence Based Medicine and clinical outcomes, improving citizens lives, and in severe cases, preserved limbs and even life itself.

“What seems expensive now, will be cheaper in the long run”