

ConvaNiox™ provides a best-in-class, transformative solution for patients with diabetic foot ulcers.[1]

ConvaNiox is a two-part, multilayered, multimodal wound dressing that creates an optimised wound healing environment to increase the probability of healing of diabetic foot ulcers (DFUs) by combining an advanced dressing technology with an effective antimicrobial and antibiofilm agent, nitric oxide (NO).[2]

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The pathology of a DFU can be devastating

The global prevalence of diabetes increases each year. Diabetes is now considered by the World Health Organisation (WHO) as a global fast-growing pandemic.[3]

People with diabetes are especially prone to developing diabetic foot ulcers (DFU).[4]

Infection being the most common, severe, and costly complication, with high risk of morbidity and mortality due to lower limb amputation.[5]

In Australia, more than 4,400 diabetes-related amputations occur each year, the second highest rate in the developed world. Additionally, there are 10,000 hospital admissions annually for diabetes-related foot ulcers.[6]

Around 85% of diabetes-related amputations are considered preventable when wounds are detected early and managed appropriately, highlighting the need for earlier intervention, coordinated wound care and improved access to multidisciplinary support.[6]

It is estimated that diabetes-related foot disease management costs AUD $44,691 per patient per year.[7]

The the largest cost driver being hospital admissions, which accounts to 48% of total management costs.[7]

Nationally, the cost to the Australian healthcare system is estimated at AUD $3.08 billion in 2026, rising to AUD $3.81 billion by 2030.[7]

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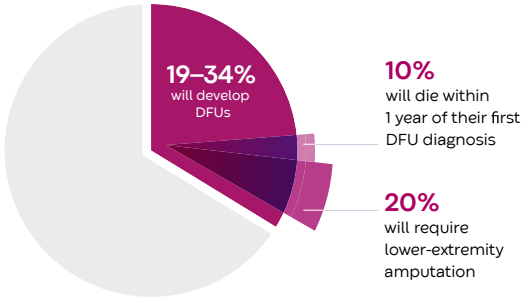
DFUs can have a significant impact on patients' lives, creating a disability burden, undermining independence, and taking a heavy emotional toll.[9]

Every 20 seconds a diabetic patient undergoes an amputation.[9]
A literature review reports that lower-limb amputation has a greater negative impact on the patient's quality of life than any other complication of diabetes.[3]

Roughly 40% of patients have a recurrence within 1 year after their ulcer healing.
Even after healing, the high rate of ulcer recurrence is a persistent challenge, requiring ongoing vigilance and care.[10]

Therefore, management strategies should focus on promoting rapid and complete wound closure, to minimise the risk of ulcer complications and restore patient's health-related quality of life to a 'pre-ulcer' status.[11,12]

537 million people worldwide have diabetes[8]



Adapted from McDermott K, et al. 2023.[8]

Learn more about DFUs

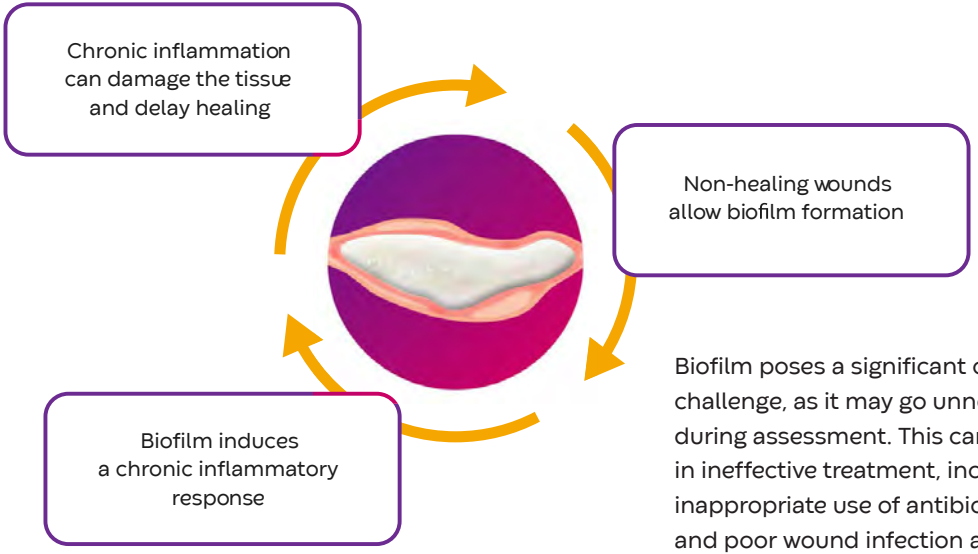


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Biofilm: The invisible barrier to healing

One of the main reasons why DFUs are so difficult to heal is due to the presence of biofilm, which promotes wound inflammation and can be tolerant to host defences and treatment options.This can lead to delayed healing and infection.[3]

Biofilm and chronic inflammation[4,13]



Biofilm poses a significant clinical challenge, as it may go unnoticed during assessment. This can result in ineffective treatment, including inappropriate use of antibiotics, and poor wound infection and healing outcomes.[14-16]

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The presence of biofilm is known to delay wound healing[17] and it can be difficult to eradicate.[18]

Treatment options for hard-to-heal wounds that are likely compromised by biofilm include antimicrobial dressings and, if infection is diagnosed, systemic antibiotics.[19]

However, chronic wound biofilms often responds poorly to antibiotic regimens, rendering their extensive use ineffective and even indiscriminate, given the risk of emergence of antibiotic-resistant strains.[20]

The increased tolerance of biofilm microorganisms to conventional antimicrobial agents compared with their planktonic counterparts poses a significant clinical problem.

Bacterial biofilms are reported to be up to 10,000 times more resistant to antibiotics than free planktonic bacteria, leading to chronic infections even after antibiotic treatment.[21] Given the increasing prevalence of antibiotic-resistant bacteria, treatment with systemic antibiotics is less effective today, highlighting the need for antimicrobial, antibiofilm agents that do not foster resistance.[3,21,22]

Learn more about Bio film

ProNOx1 Randomised Controlled Trial[1]

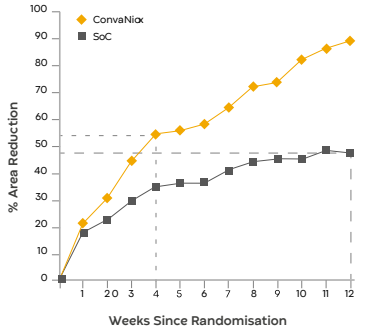
The ProNOx1 study was a multicentre, prospective, observer-blinded, parallel-group, randomised controlled trial that assessed the safety and efficacy of ConvaNiox compared to standard of care (SoC) dressings, when used in diabetic foot ulcers (DFUs), including infected DFUs.

Key findings

The ProNOx1 study has shown that ConvaNiox significantly improved median wound area reduction, and significantly increased the number of wounds healed, compared to SoC, at 12 weeks.

3x faster DFU area reduction

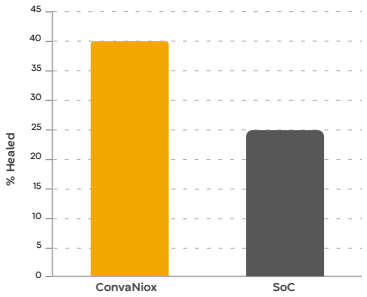
Wound area reduction over 12 weeks



ConvaNiox resulted in significantly greater median percentage area reduction of DFUs at 12 weeks compared to SoC, both in the intention to treat (ITT) and per protocol (PP) analysis with the PAR at week 4 for ConvaNiox arm being equivalent to PAR at week 12 in SoC arm (ITT, PP)
ITT: 88.6% vs 46.9% (p=0.016) illustrated above
PP: 98.5% vs 52.1% (p=0.012)

60% more DFUs healed

Percentage of ulcers healed at 12 weeks



ConvaNiox resulted in significantly more completely healed DFUs at week 12 compared to SoC, both in the intention to treat (ITT) and per protocol (PP) analysis.
ITT: 40% vs 25% (p=0.049) illustrated above
PP: 49% vs 30% (p=0.040)

Adapted from Edmonds ME, et al. 2018.[1]
ConvaNiox referred to as EDX110 in ProNOx1 study.

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ProNOx1 Randomised Controlled Trial [1]

Other results

- ConvaNiox resulted in significantly greater median percentage area reduction of DFUs of ≤6 months' duration at 12 weeks (97%) compared to SoC (55%) (p=0.040) (ITT)
- ConvaNiox resulted in significantly greater median percentage area reduction of DFUs of ≥1 cm^2 in area at 12 weeks (82%) compared to SoC (29%) (p=0.007) (ITT)
- The treatment of DFUs with ConvaNiox was well tolerated
- There were no significant differences in the total Severe Adverse Events (SAEs) recorded between the two groups. However, there were fewer occurrences of SAEs related or possibly related to the ulcer in the ConvaNiox group compared with the SoC group (p=0.049)

ProNOx1 study



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ConvaNiox dressing

ConvaNiox is a two-part, multilayered, multimodal wound dressing.[2]

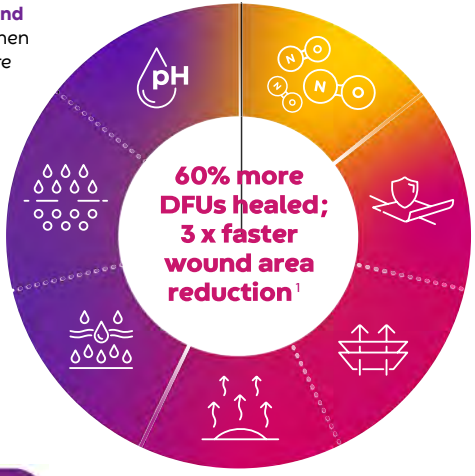
The combined effects of each feature of the ConvaNiox dressing composition addresses multiple fundamental challenges of hard-to-heal wounds:[2]

Optimised wound healing environment to increase the probability of healing of diabetic foot ulcers[2]

Creates and maintains a moist wound environment, donating moisture (when required), regulating wound moisture balance to support autolytic debridement.

Draws wound exudate and its components into the dressing by **creating a high osmotic gradient** which stimulates fluid flow into the dressing.

Neutralises the alkaline pH of chronic wound exudate within the dressing, lowering pH to a more acidic level which is **inhibitory towards microorganisms and favourable to healing.**



Antimicrobial and antibiofilm protection[2]

Generates **nitric oxide**, an effective antimicrobial and antibiofilm agent, exerting a combination of actions within the dressing to **provide antimicrobial protection, and disrupt, kill and prevent biofilm formation,** including antibiotic-resistant and single species biofilms, polymicrobial biofilms, and fungal biofilms.

Enhanced dressing capability[2]

The absorbent protective layer provides an **effective barrier to external bacterial** penetration.

Continually **absorbs and retains wound fluid**, then evaporates excess moisture due to its high moisture vapour transmission rate.

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Nitric oxide's unique properties have led to innovative applications for wound treatment,[1,21] and since exogenous NO is an effective antimicrobial and antibiofilm agent with low resistance risk,[21,23] it holds promise in improving wound care and patient outcomes.

Antimicrobial action

Nitric oxide's antimicrobial action stems from its ability to freely penetrate microbial cells, breaking down components of cell walls and membranes, and destroying multiple intracellular targets such as DNA, and enzymes involved in DNA, replication and metabolism.[23,24]



Learn more about nitric oxide

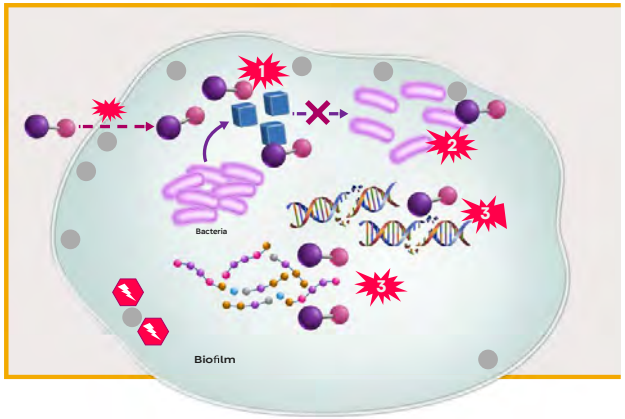
1. NO increases the permeability of microbial cells
As a small, lipophilic molecule, NO freely penetrates inside bacteria, inactivating both external and internal cell wall and membrane proteins with a dose-dependent breakdown of the lipid bilayer, leading to degradation and increased permeability of microbial cells.[25-29]

2. NO inhibits replication
As NO moves into the microbial cell, it can also destroy microbial DNA and inhibit its replication, leading to microbial cell dysfunction and death.[26,30,31]

3. NO disrupts vital microbial processes
NO also disrupts metabolic and respiratory processes by inactivating iron-sulphur clusters, which are essential enzyme co-factors for gene expression, metabolism, and cell respiration.[32-34]

Antibiofilm activity

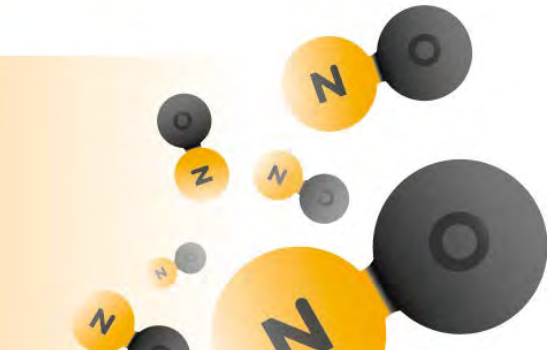
NO's antibiofilm action comes from its ability to expose bacteria and inhibit the biofilm's mechanisms of defence and tolerance.[26,35]



1. Biofilm matrix breakdown
NO breaks down the protective extracellular polymeric substances that form the biofilm structure, allowing further penetration of NO, other antimicrobials, and host defences to reach the microorganisms within.[36-39]

2. Bacterial dispersal
Even at low doses, below bactericidal concentration, NO signals the bacteria to disperse, exposing them.[26]

3. Impaired bacterial communication
NO impairs bacterial communication, reducing both biofilm formation and bacterial virulence to reduce infection risk, while making the biofilm more susceptible to antimicrobials.[39-41]



Have a Question?

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