EWMA Innovation Alliance

Bonvadis® :

The Active Healing Engine

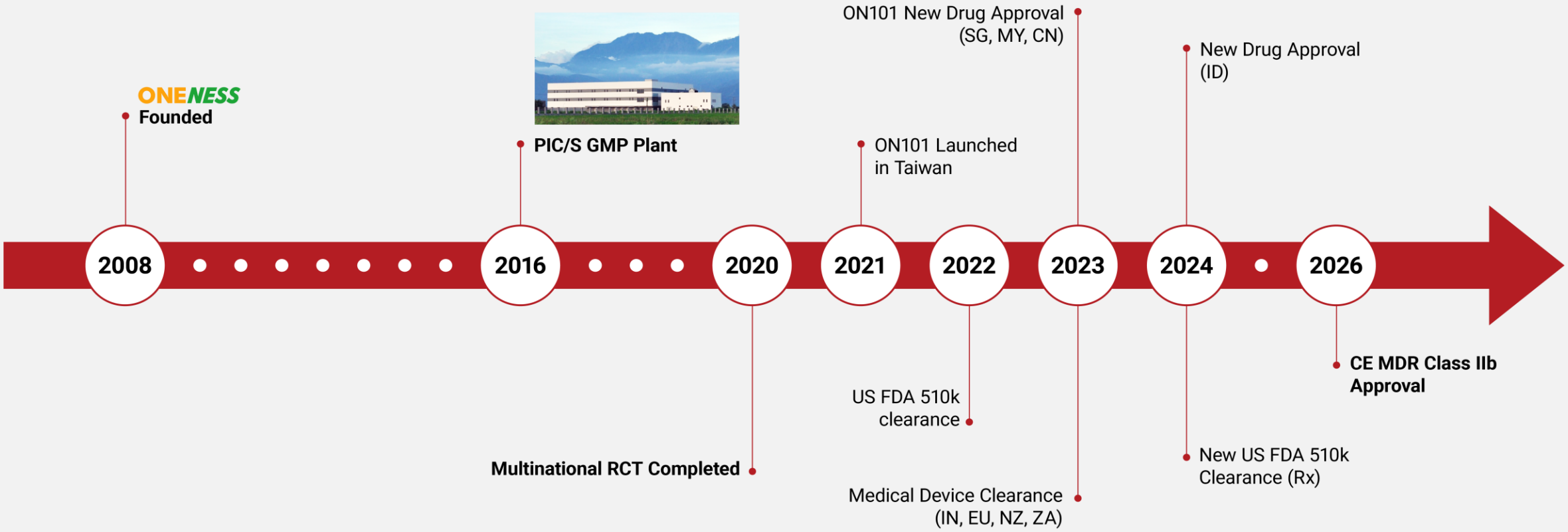
A Botanical Topical Cream Clinically Proven to Accelerate Chronic Wound Healing

(Research Code: ON101)



Moving Beyond Passive Protection in Chronic Wound Care

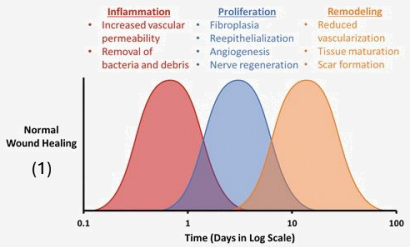
Company Roadmap



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Why Chronic Wound Fails to Heal: Macrophage Imbalance

Normal Wounds



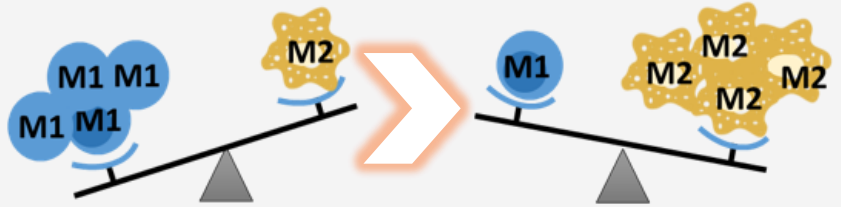
Hemostasis → Inflammation → Proliferation → Remodeling

Tissue damage phase

Tissue repair period

M2: anti-inflammatory

M1: pro-inflammatory



M1 Dominant

M2 Dominant

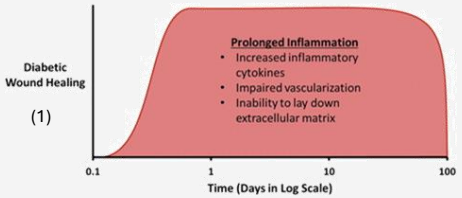
- ✓ Regulates VEGF to promote vascular proliferation
- ✓ Affect TGF-induced stem cells to promote fibroblast proliferation
- ✓ Granulation tissue growth

Chronic wounds

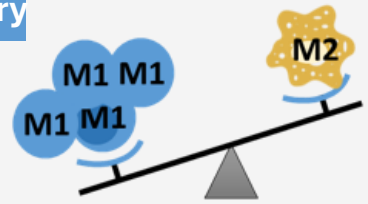
Hemostasis → Inflammation → ~~Proliferation~~ → Remodeling

Tissue damage phase

Tissue repair period



M1: pro-inflammatory



✓ Exclude invading pathogens

M1 Dominant

The "Inflammatory Arrest"

In chronic wounds, hyperglycemia and high MMP levels trap the wound in the **M1 phase**.

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Ref. Advances in Wound Care Vol. 10, No. 9 DOI: https://doi.org/10.1089/wound.2020.1167

ONENESS

The Mechanism: Regulating the M1/M2 Switch

Rebalancing the immune response to restart the healing engine

M1 Macrophages
(inflammatory)



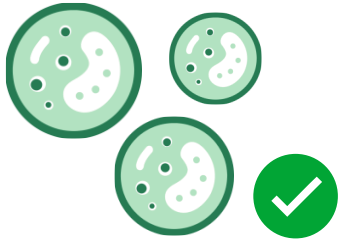
Inhibits Pro-inflammatory Cytokines
(IL-6, TNF-α, CXCL9/10)



Bonvadis® (ON101)

M1 to M2 Transition

M2a/c Macrophages
(Remodeling)



Promotes Healing Phenotypes
(Collagen Synthesis, Angiogenesis, CD206+, CD163+)

Via activating adipocyte progenitor cells (ADPCs)

*ON101 supports wound healing by creating a pro-healing microenvironment through a **dual-pathway macrophage switch**: it directly **suppresses existing M1 inflammation** while activating adipocyte progenitor cells (ADPCs) to secrete GCSF and CXCL3, which effectively drives the **phenotypic transition** of macrophages from a proinflammatory state toward a **pro-remodeling M2 state**.*

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Bonvadis®

Scientifically Proven Botanical Formulation

Composition: Extracts of Mexican Mint and Centella Asiatica extract.

Standards: Manufactured under US GMP standards with a standardized extraction process ensuring consistent potency.

Regulatory:
- FDA 510(k) Cleared (K251093)
- CE MDR Class IIb Approval



Mexican Mint

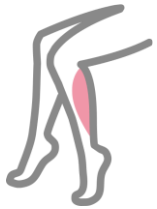


Centella Asiatica

Effective Across Multiple Wound Types



Diabetic Foot Ulcers (DFU)



Venous Leg Ulcers (VLU)



Pressure Ulcers



Post-surgical Wounds



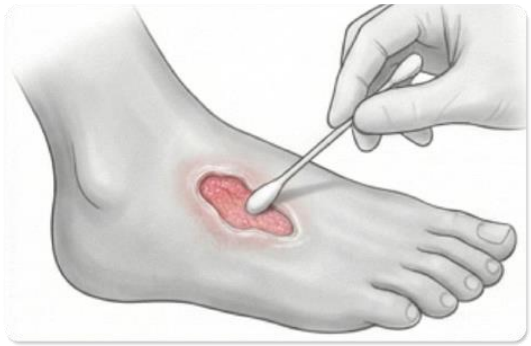
Burns
(1 st & Superficial 2nd Degree)

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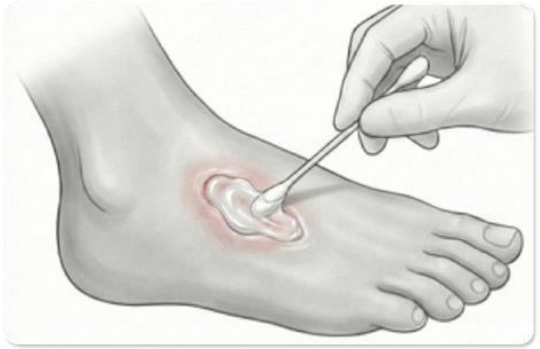
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Bonvadis®

Simple Application & High Safety Profile



(Apply after debridement)



(Squeeze onto wound bed)



(Use secondary dressing)

Safety

- No systemic absorption
- No contraindications with systemic diabetes treatments
- Suitable for long-term use

Specs

- Tube Size: 15g
- Storage: Room Temperature
- Shelf Life: Stable formulation



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ONENESS

The “Power Layer”: Seamless Clinical Integration

Integrating Macrophage Regulation without disrupting standard workflow

Systemic Antibiotics
(Infection Control)



NPWT
(Negative Pressure Wound Therapy)

Skin Grafts /Substitutes

Oxygen & Compression Therapy

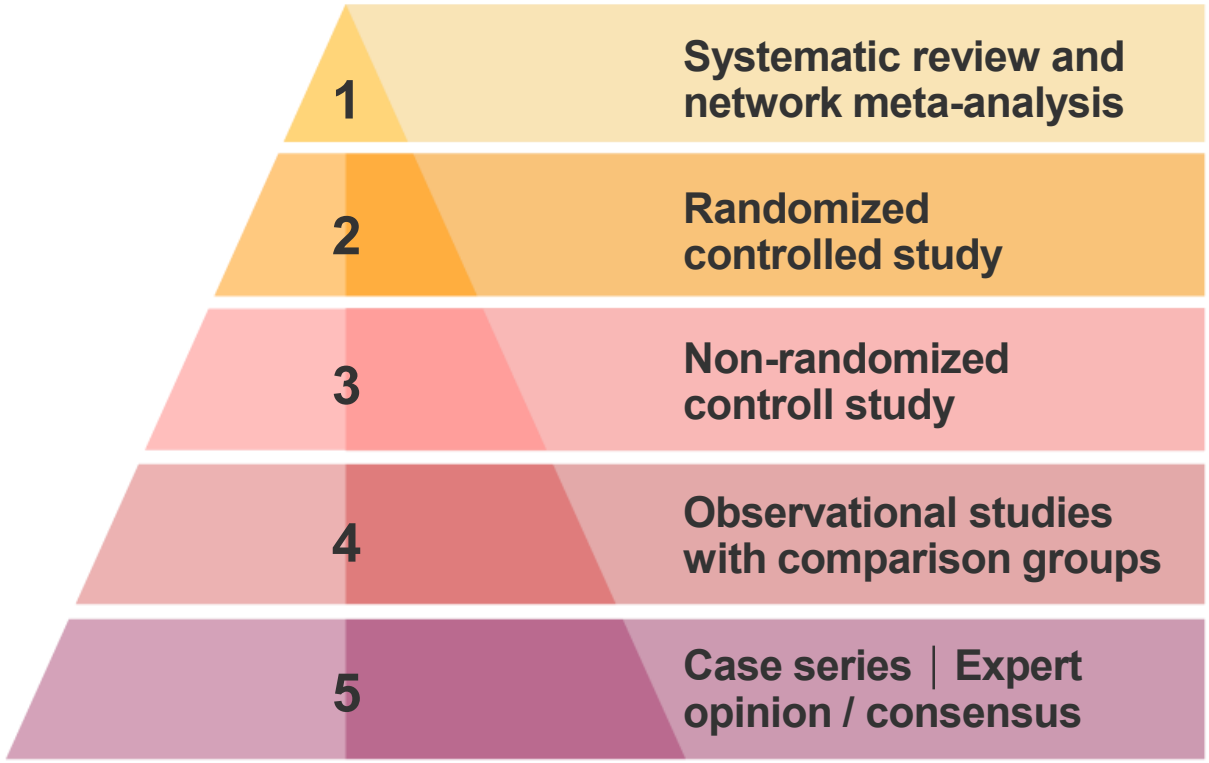
Bonvadis® fits into and optimized the existing ecosystem of advanced wound care.

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Bonvadis®

Validated by The Scientific Community

Globally Validated by Science, RCT and RWE



Manuscript under preparation

JAMA Network Open | Advances in Wound Care | Hindawi

2 ongoing

Aesthetic Surgery Journal | IWJ | JWC

Mayo Clinic Proceedings | IWJ

中华内分泌代谢杂志 | Acta Cardiologica Sinica | current issues in molecular biology | JWC | Gavin Publishers

Case Reports in Clinical Medicine | 中華民國糖尿病學會

"Clinically proven to accelerate healing across all wounds, even hard-to-heal wounds."

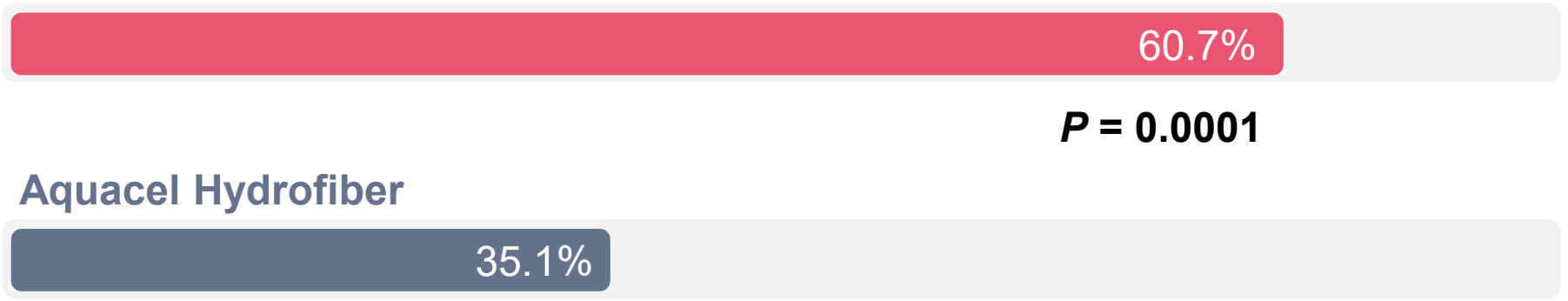
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Multinational RCT: Superior Healing vs. Standard of Care

JAMA Network Open. 2021

Complete Healing Rate (16 Weeks)



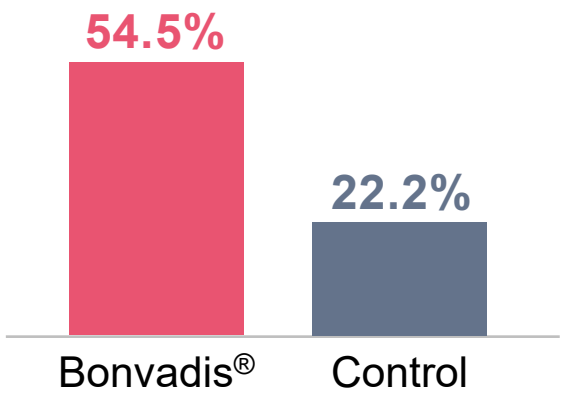
- Multi-center, Randomized Controlled Trial (N=236). Head-to-head comparison.
- Bonvadis® demonstrated a ~25% higher probability of complete closure.

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Overcoming "Hard-to-Heal" Barriers

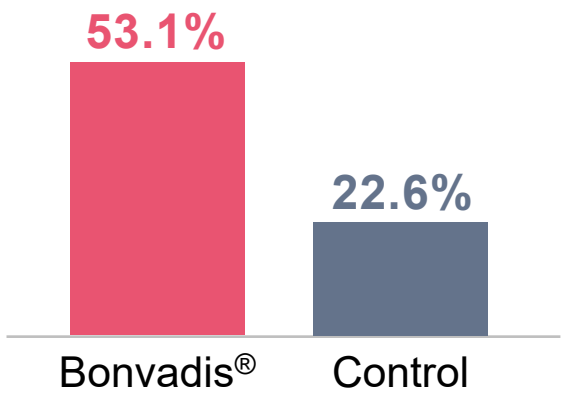
Proven Efficacy in High-Risk & Difficult Cohorts

Ulcers > 5 cm^2



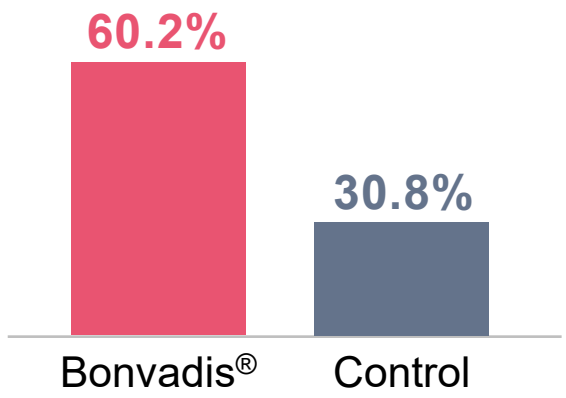
($P < 0.0056$)

Duration ≧ 6 Months



($P < 0.0272$)

Wagner Grade 2



($P < 0.0001$)

The tougher the wound, the wider the performance gap against standard of care.

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Real-World Evidences (n=178)

Study Enrollment

Wagner Grade 2,3,4

down-grading

DFU patients undergoing hospitalized SOC with adjuvant therapies ：

- Vascular reconstruction including PTA and bypass
- Infection control
- Pressure relief
- Surgical debridement
- Hospitalization
- Dermal regeneration template (DRT)
- NPWT
- Skin graft or flap surgery
- Silver foam dressing
- Minor amputation

Wagner Grade 1 (n=4)

Wagner Grade 2 (n=60)

Wagner Grade 3 (n=16)

ON101
Monotherapy
(N=80)

Wagner Grade 1 (n=6)

Wagner Grade 2 (n=71)

Wagner Grade 3 (n=21)

Current Best Care

- **Dermal regeneration template (DRT)**
- **NPWT**
- **Skin graft or flap surgery**
- **Silver foam dressing** (N=98)

Primary outcome:

Ulcer Healing
W1 in 1 month
W2 in 4 months
W3 in 4 months

Secondary outcomes
Amputation after healing

Exploratory outcomes
Consumption and benefit of ON101



Mayo Clinic Proceedings 2025

ONENESS

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Baseline Characteristics

Characteristic	ON101 (n=80)	Standard Care (n=98)
Age, years (mean±SD)	62.5 ± 15.1	68.7 ± 13.2
Dialysis patients	16 (20.0%)	28 (28.6%)
Wagner Grade 1	4 (5.0%)	6 (6.1%)
Wagner Grade 2	60 (75.0%)	71 (72.4%)
Wagner Grade 3	16 (20.0%)	21 (21.4%)
Mean Ulcer size at index, cm^2	5.6	4.5
HbA1c ≥75 mmol/mol	19 (23.8%)	24 (24.5%)
IDSA 1	18(22.5%)	72 (73.5%)
IDSA 2	54 (67.5%)	24 (24.5%)
IDSA 3	8 (10%)	2 (2%)

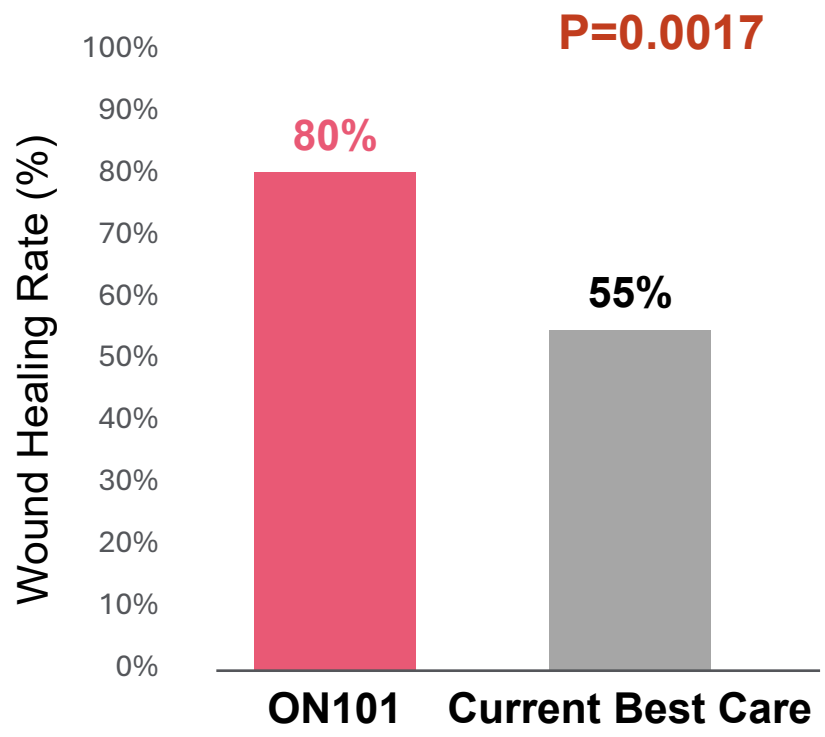
Mayo Clinic Proceedings 2025

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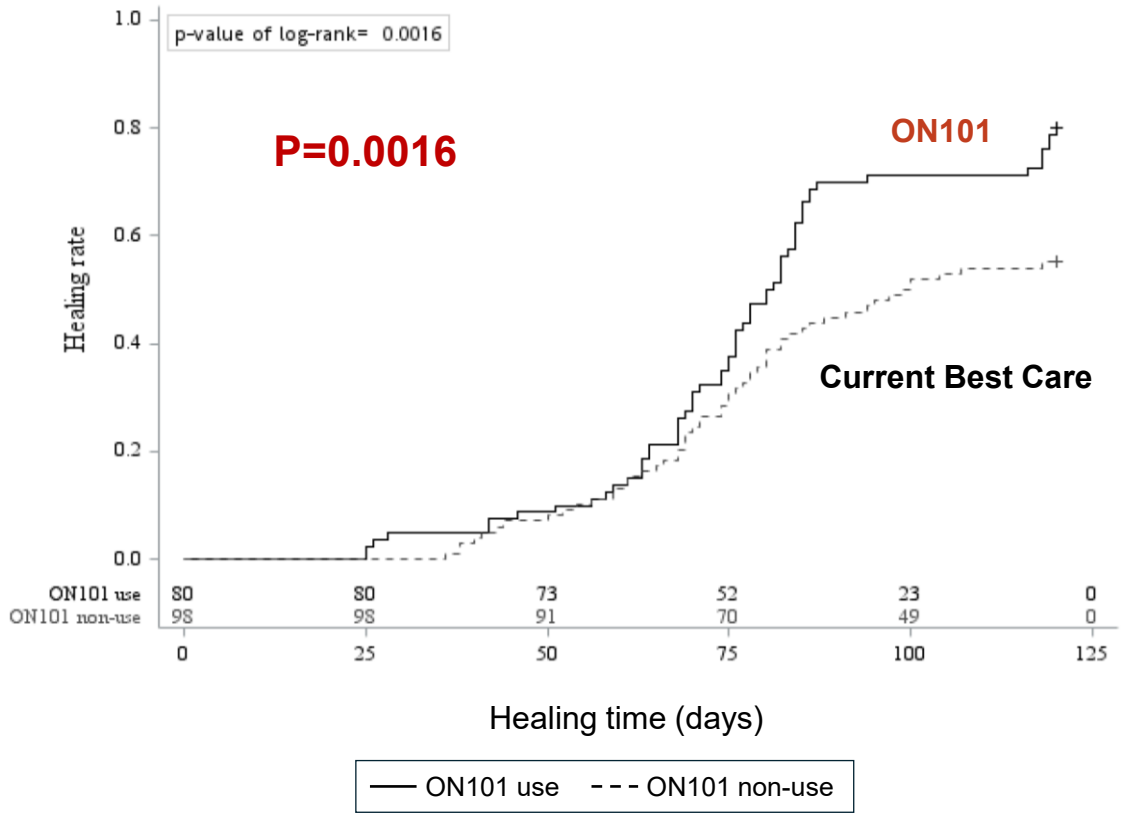
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Primary Endpoint : Incidence of Wound Closure

Ulcer healing rate and healing time within 120 days



Current Best Care: Dermal regeneration template (DRT), NPWT, Skin graft or flap surgery, silver foam dressing



Mayo Clinic Proceedings 2025

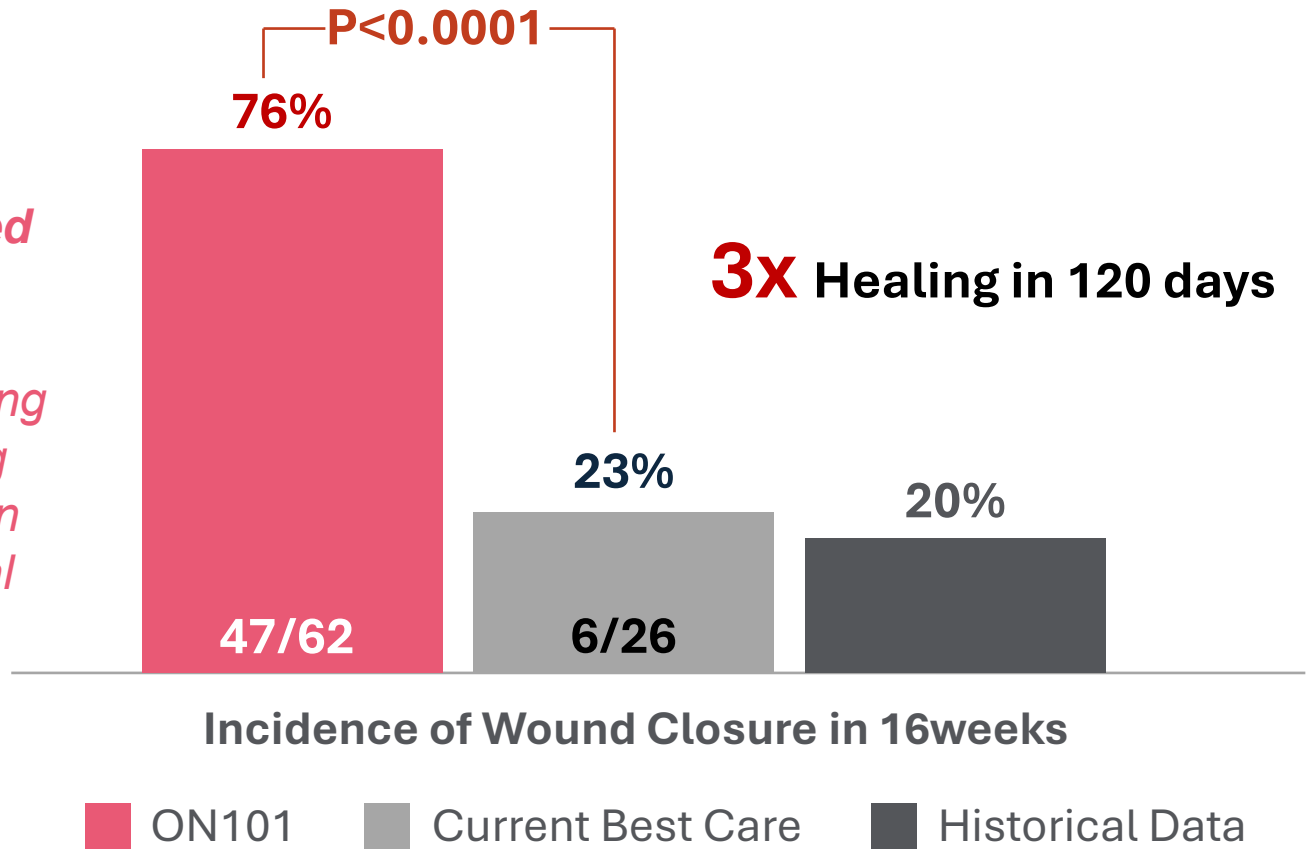
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ONENESS

Early Intervention in Infected DFUs

Infected DFU (IDSA 2/3)

*Allows **early wound bed optimization and supports antibiotic stewardship** by activating local immunity, moving beyond sole reliance on antibiotics/antimicrobial treatments*



[1] Mayo Clinic Proceedings 2025
[2] Best care include the use of dressing (with or without silver) + negative pressure wound therapy, skin substitute or surgical intervention
[3] Diabet Med. 2018 Jan; 35(1): 78–88. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5765512/

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ONENESS

Consistent Efficacy Across Disadvantaged Subgroups



Bonvadis delivers reliable results even in clinically disadvantaged patients with large, long-duration, or infected ulcers.

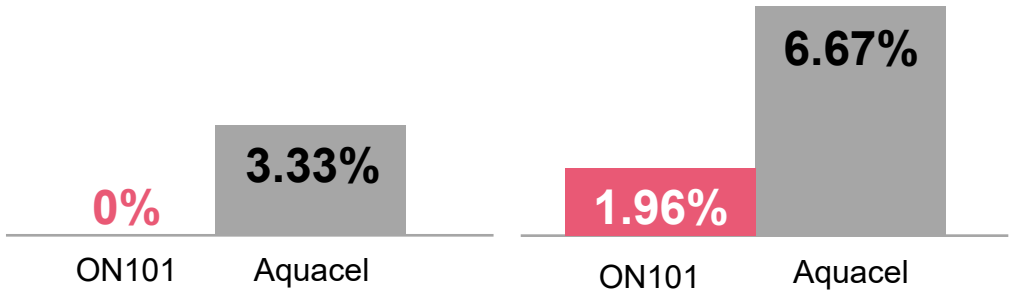
Mayo Clinic Proceedings 2025

Reduced Amputation Incidence

MRCT study[1]

Two-year follow-up

80% reduction in amputation rates



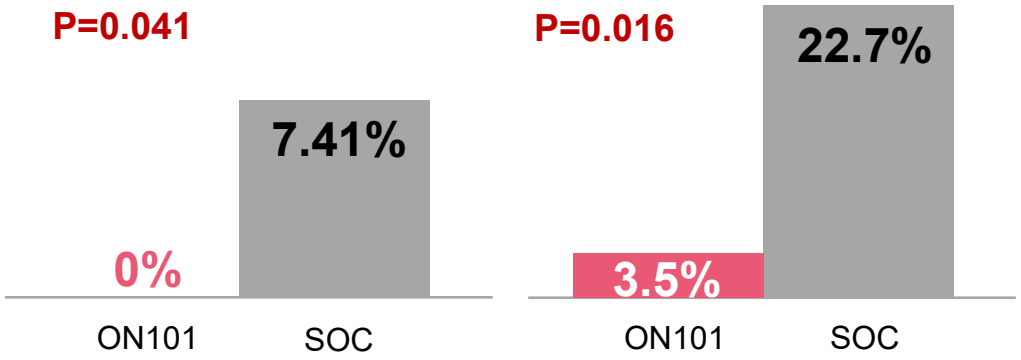
After healing, the major amputation rate was followed for two years

After healing, the minor amputation rate was followed for two years

Real-world Study[2]

One-year follow-up

85% reduction in amputation rates



After healing, the amputation rate was followed up for one year

Patients with high-risk DFU amputation were followed (ischemic infection population) one-year amputation rate

[1] Retrospective data collection from MRCT
[2] Mayo Clinic Proceedings 2025

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EGYPT REAL-WORLD STUDY (n=23) E-Poster: EN1355

Powerful Adjunct to NPWT

- **100% wound closure (vs. 5.6% SOC+NPWT) by 16 weeks**
- **Early wound bed optimization leading 4.5 times shorter mean healing time than SOC+NPWT**
- **Significantly reduced NPWT duration by 50%**



Prof. Mohamded Sharkawy

MD

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ACCELERATED HEALING AND IMPROVED PATIENT OUTCOMES WITH ON101 TOPICAL CREAM AS AN ADJUNCT TO NPWT IN DIABETIC FOOT ULCERS: REAL-WORLD STUDY

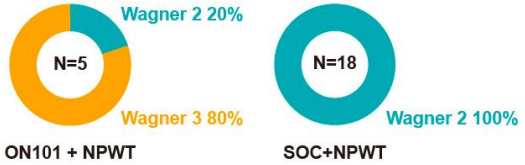
Yi-Wei Liao[1], Mohamed Sharkawy[2]
[1]Oneness Biotech Co., Ltd., Taipei, Taiwan R.O.C, [2]Vascular Surgery Department, Cairo University Hospital, Cairo, Egypt

Aim

Diabetic foot ulcers (DFUs) often require negative pressure wound therapy (NPWT) to reduce wound size and prepare the wound bed for closure or grafting, yet many ulcers fail to achieve timely closure. This study evaluated whether combining ON101 topical cream with NPWT improves healing outcomes compared with standard of care (SOC) plus NPWT.

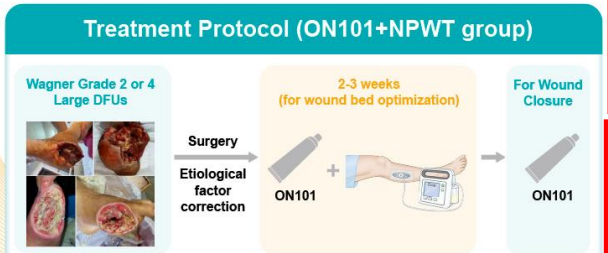
Method

- **Study & Design:** Retrospective, observational study
- **Sample Size:** Total 23 patients with IDSA Grade 2 infected DFUs
- **Wagner grade:**



- **Ulcer size (Mean):** 60±49.4 cm² (ON101+NPWT) vs. 22.2±20.6 cm² (SOC+NPWT)
- **Clinical Outcomes:**
  - Healing rate
  - Time to closure
  - NPWT duration
  - Amputation rate
  - Rehospitalization rate
  - Mortality.

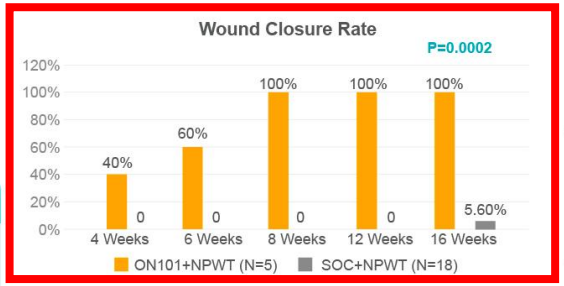
Treatment Protocol (ON101+NPWT group)

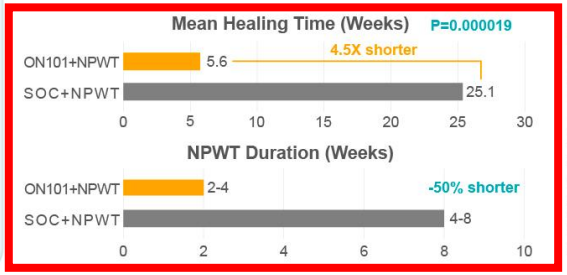


1. **Apply ON101 to the ulcers and leave it for 5 mins.**
2. NPWT dressing is then put on to the ulcer and start suction.
3. NPWT dressing is changed every 2-3 days (without changing the can).
4. ON101 is reapplied during the dressing change.

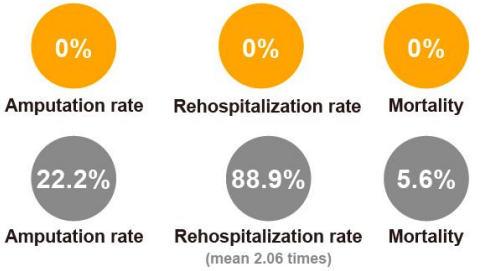


Results / Discussion:





1-Year Follow-Up



Conclusion:

In DFU patients receiving NPWT, adding ON101 enhances granulation and epithelialization, supporting faster healing, shorter treatment duration, and lower risks of amputation and morbidity. As an adjunct to NPWT, ON101 may streamline wound recovery, lessen healthcare burden, and improve patient quality of life, highlighting its clinical and economic values in advanced wound care.

BREMEN, GERMANY 6 - 8 MAY 2026 EWMA 2026 DE WU DEUTSCHER WundD·A·CH

EU Validation: Italian DFU Patients in Private Practice

AMEXIPIED 2025

Bonvadis®

Clinical Experience with Bonvadis® Cream in the Management of Diabetic Foot Ulcers

Ceconexpo, Morelia, Michoacán



Dr. Giacomo Clerici

Diabetic Foot Surgeon
Gruppo OspedalieroLeonardo GOL
PoliclinicoAbano Terme (Padua)
Policlinico di Sassari
COQ Centro Ortopedico di Quadrante (Omegna VCO)
Member of the Board of the IADFS

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Real-world Evidence using Bonvadis® in DFU - Methods

- Prospective, single arm observational study (single DF Center);
- **20 patients** enrolled between Apr to Sep , 2025; follow up to 20th Sep
  - HbA1c 7.9 ± 1.0%.
  - TcPO 47 ± 8 mmHg (35–60).
- All patients received Bonvadis® ***(every other day, 3 times per week) plus standard care .***
- Primary endpoint: 4 week ulcer area reduction;
- Secondary: complete healing and time to healing.
- Statistical Analysis: SPSS (IBM)

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Real-world Evidence using Bonvadis® in DFU - Characteristics

Table 1. Demographic and clinical characteristics.

Variable	Value
Age, mean ± SD (years)	68 ± 9
Male sex, n (%)	14 (70%)
Smokers, n (%)	8 (40%)
Dialysis, n (%)	3 (15%)
HbA1c %, mean ± SD	7.9 ± 1.0
TcPO■ mmHg, mean ± SD	47 ± 8 (35–60)

Table 2. Outcomes.

Variable	Value
Ulcer area baseline, mean ± SD (cm^2)	8.2 ± 2.5
Ulcer area 4w, mean ± SD (cm^2)	4.6 ± 1.4
Reduction at 4w, mean ± SD (%)	41.8 ± 12.5
Healed by Sept 20, n (%)	11 (55%)
Median time to heal, days (range)	42 (21–84)

- Baseline ulcer area 8.2 ± 2.5 cm^2 > 4.6 ± 1.4 cm^2 at 4 weeks ***(-41.8 ± 12.5%)***.
- By Sep 20, 11/20 (55%) healed; ***median time to healing 42 days***.
- The treatment was well-tolerated
- No adverse events were observed

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Real-world Evidence using Bonvadis® in DFU – Case 1





T 0





T 30 days
(Sept 19) still ongoing

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Bonvadis®

Heal Faster, Heal Better

The Bonvadis® Value Proposition



Biological Optimization

- Modulates the micro-environment (M1→ M2) to promote active tissue healing and break the inflammatory roadblock.
- Simple topical use to advance standard care.



Clinical Advancement

- Higher complete closure rates and shortened time-to-heal.
- Early wound bed optimization and supports antibiotic stewardship.
- Avoid escalation to surgical interventions.



Economic Efficiency

- Shortened episode of care for hard and chronic cases. Reduced hospital dependance and lower amputation risks, saving thousands for medical system and patient quality life.

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Bonvadis®



Where Healing Begins,
Hope Moves Forward

Accelerating the transition from Inflammation all the way to Remodeling.

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Research Code: ON101 ONENESS