



Aroa Biosurgery (ARX) - Symphony Randomised Controlled Trial

... UNLOCKING REGENERATIVE HEALING FOR EVERYBODY

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Introduction



Substantial opportunity >\$US1B

**Significant market disruption.
Reimbursement reset to a flat fee.**

**Physicians now require proven products
at a reasonable price.**



CHIEF SCIENTIFIC OFFICER

Barnaby C. H. May, Ph.D.

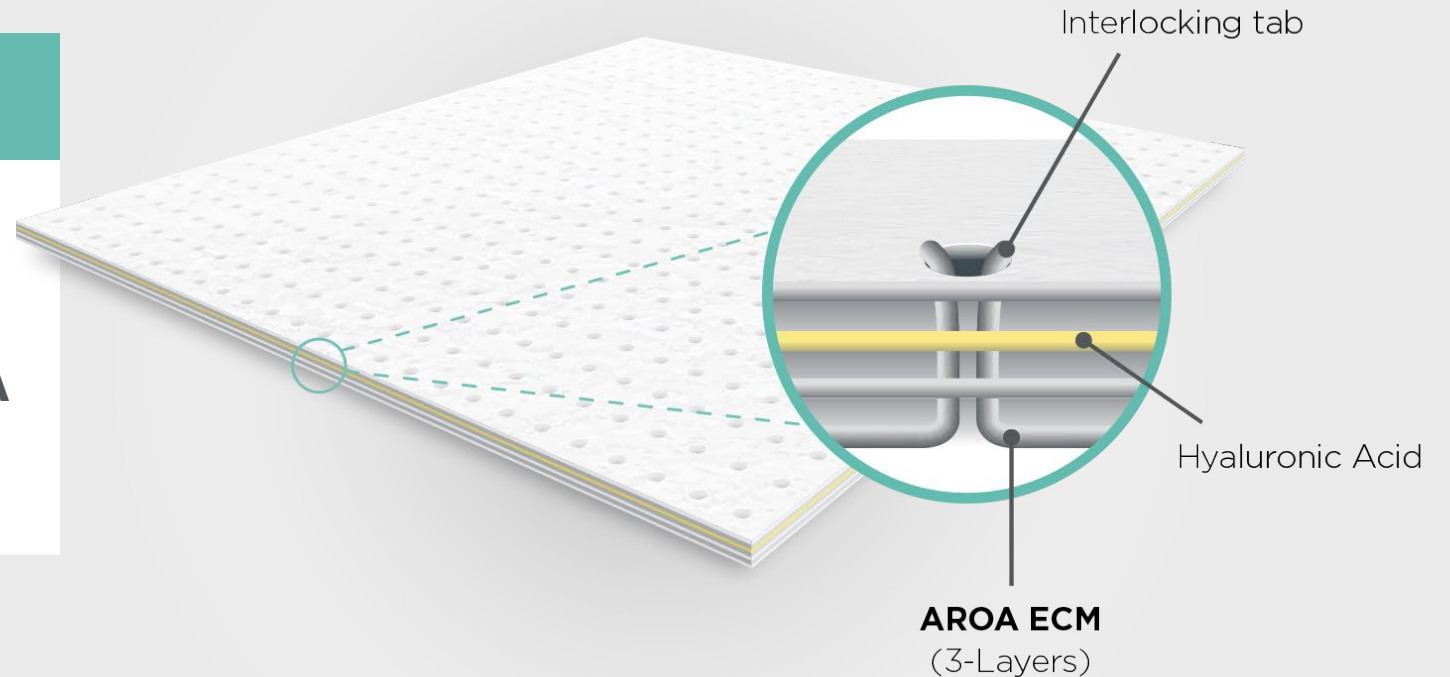
Symphony Proliferative Bioscaffold

For advanced wound closure



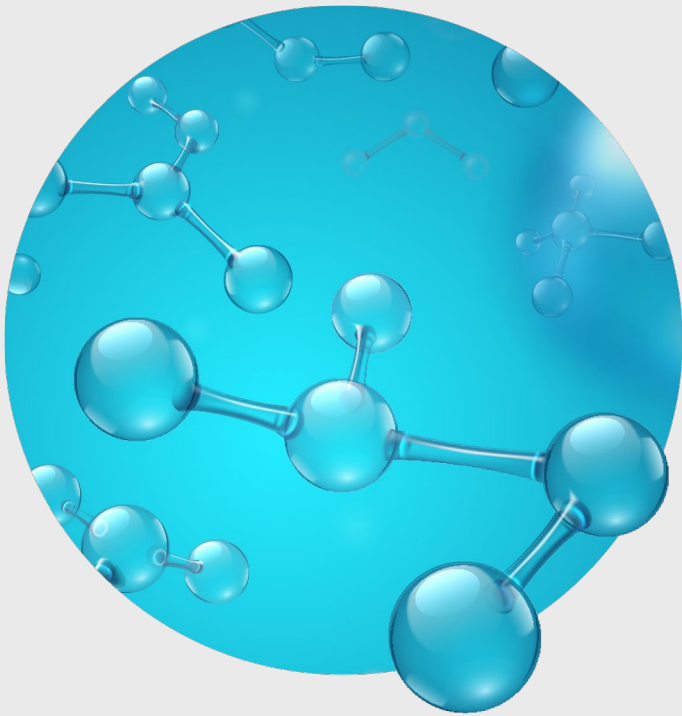
What is Symphony?

Symphony is an **advanced composite cellular and tissue product (CTP)**, comprising **layers of AROA ECM**, with a **layer of hyaluronic acid**



Symphony Proliferative Bioscaffold

Containing high molecular weight hyaluronic acid (HMWHA)



Why add a layer of hyaluronic acid (HA)?

- **HA** is a **naturally occurring component of tissue ECM** and plays an important role in **accelerating soft tissue repair**, including angiogenesis, cell proliferation and migration.¹
- **HA** has been shown to **reduce wound healing times**.²
- **HA** is extremely **hydrophilic** and can sequester ~1000 times its weight in water.³
- **Especially useful** where there is **risk of dehydration** of the device, or the underlying structures (bone and tendon).

Symphony Proliferative Bioscaffold

Addition of HMWHA increases keratinocyte migration



- Wound closure occurs via migration of keratinocytes

The addition of HMWHA to OFM increases keratinocyte migration*

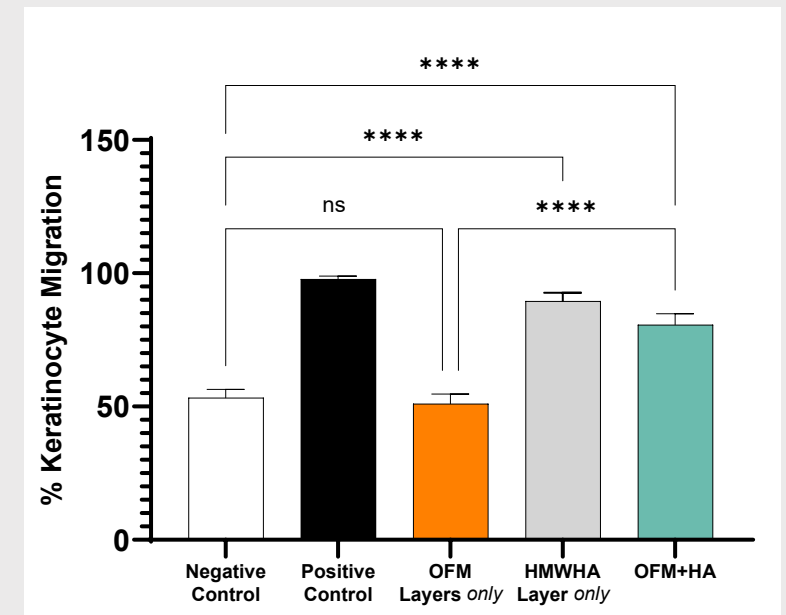
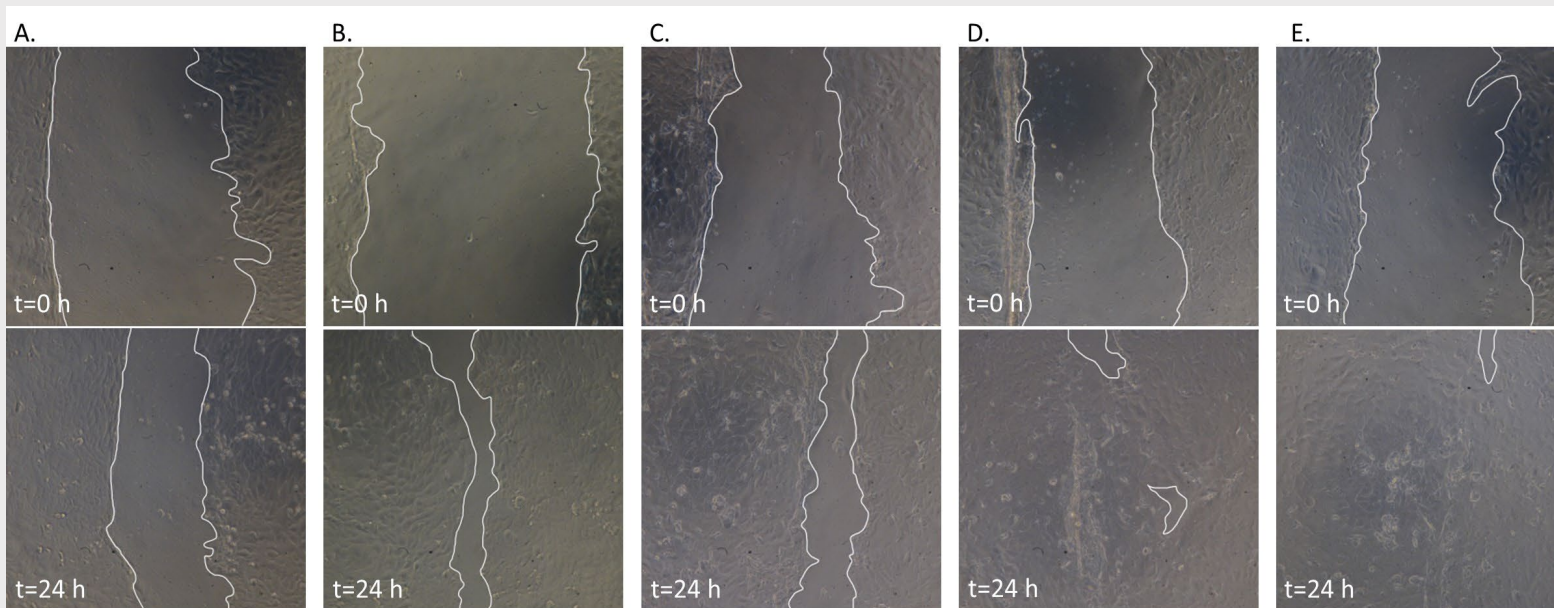


Figure adapted from Smith MJ, et al. J Biomater Appl. 2022 Jan;36(6):996-1010.

***Preclinical evidence:** Smith MJ, et al. J Biomater Appl. 2022 Jan;36(6):996-1010



Armstrong et al | RCT

Study design in the context of coverage



Typical LCD / payer coverage criterion	How the Symphony RCT satisfies
Chronic DFU present $\geq$ 4 weeks despite conservative care	RCT enrolled ulcers present $\geq$ 4 weeks that had failed to respond to conservative management, following a standardized 2-week run-in of documented standard care
Wound classification within covered grades (Wagner 1–2)	RCT population was exclusively Wagner Grade 1 and Grade 2 DFUs — matching the grades commonly specified in coverage policy
Wound size within specified limits	Eligible ulcers measured 1–25 cm ² , consistent with typical covered size ranges
Non-infected wound	RCT required non-infected ulcers at enrollment
Adequate perfusion / vascular assessment	RCT required adequately perfused ulcers, assessed at screening
Standard of care applied (debridement, offloading)	Protocol mandated standardized wound bed preparation, weekly sharp debridement, and standardized offloading throughout
Evidence of effectiveness for the indication	Prospective, multicenter, blinded-adjudication RCT



SENIOR MEDICAL SCIENCE LIAISON

Brandon Bosque, DPM

A Composite Ovine Forestomach Matrix and Hyaluronic Acid CAMP for the Treatment of Full Thickness Wounds of the Foot in People With Diabetes: A Randomized Controlled Trial

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ABSTRACT

Diabetic foot ulcers (DFUs) are a devastating complication of diabetes that markedly affects quality of life and generates significant socioeconomic and healthcare burdens. When DFUs fail to respond to standard of care (SOC), advanced therapies including Cellular, Acellular and Matrix-like Products (CAMPs) are often employed. A novel composite CAMP comprising ovine forestomach matrix and high molecular weight hyaluronic acid, termed 'OFM-HA' has been developed for the treatment of chronic wounds and evaluated in a prospective multi-centre controlled trial. For this trial, 143 subjects were randomized to receive OFM-HA plus SOC or SOC alone for the treatment of chronic full thickness wounds of the foot in people with diabetes meeting prespecified eligibility criteria. The primary endpoint was the proportion of wounds healed by 12 weeks. Secondary endpoints included healing time, percentage area reduction, adverse events and changes in pain and quality of life. For the modified intent-to-treat population, 46% (31/68) of the OFM-HA plus SOC group healed by 12 weeks compared to 24% (17/72) in the SOC alone group ($p = 0.008$). Kaplan-Meier analysis favoured OFM-HA plus SOC over 12 weeks (log-rank $p = 0.023$). No unexpected safety-related occurrences were observed. OFM-HA plus SOC increased 12-week closure in this selected population. Interpretation is limited by post-randomization exclusions, differential withdrawal and an adjusted comparison close to the significance threshold ($p = 0.045$).

1 | Introduction

Diabetic foot ulcers (DFUs) are a devastating complication of diabetes that markedly affects quality of life and generates significant socioeconomic and healthcare burdens throughout the world. Globally, 18.6 million people are affected by a

DFU each year, translating to an estimated \$USD2.5 trillion in international burden by 2030 [1, 2]. Approximately 34% of people with diabetes develop a DFU during their lifetime [3]. DFUs are notoriously difficult to treat due to neuropathy, poor vascular perfusion, impaired fibroblast and keratinocyte function, disrupted moisture balance, chronic inflammation

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A Composite Ovine Forestomach Matrix and Hyaluronic Acid CAMP for the Treatment of Wagner Grade 1 and 2 Diabetic Foot Ulcers: A Randomized Controlled Trial

David G. Armstrong, Dennis P. Orgill, Robert D. Galiano, John C. Lantis, Alexander M. Reyzelman, Robert J. Snyder, Adam L. Isaac, Marissa J. Carter, Charles M. Zelen



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Study snapshot



Design

Prospective,
multicenter,
parallel-group
**Randomized
Controlled Trial**

Population

Adults with chronic
**Wagner Grade 1
and 2 DFUs**

Control

**Standard of care
(SOC) alone**

Intervention

Symphony + SOC
(OFM-HA + SOC)

Endpoints

**Proportion of
patients healed
after 12-weeks**

Time to heal, PAR,
AEs, QoL

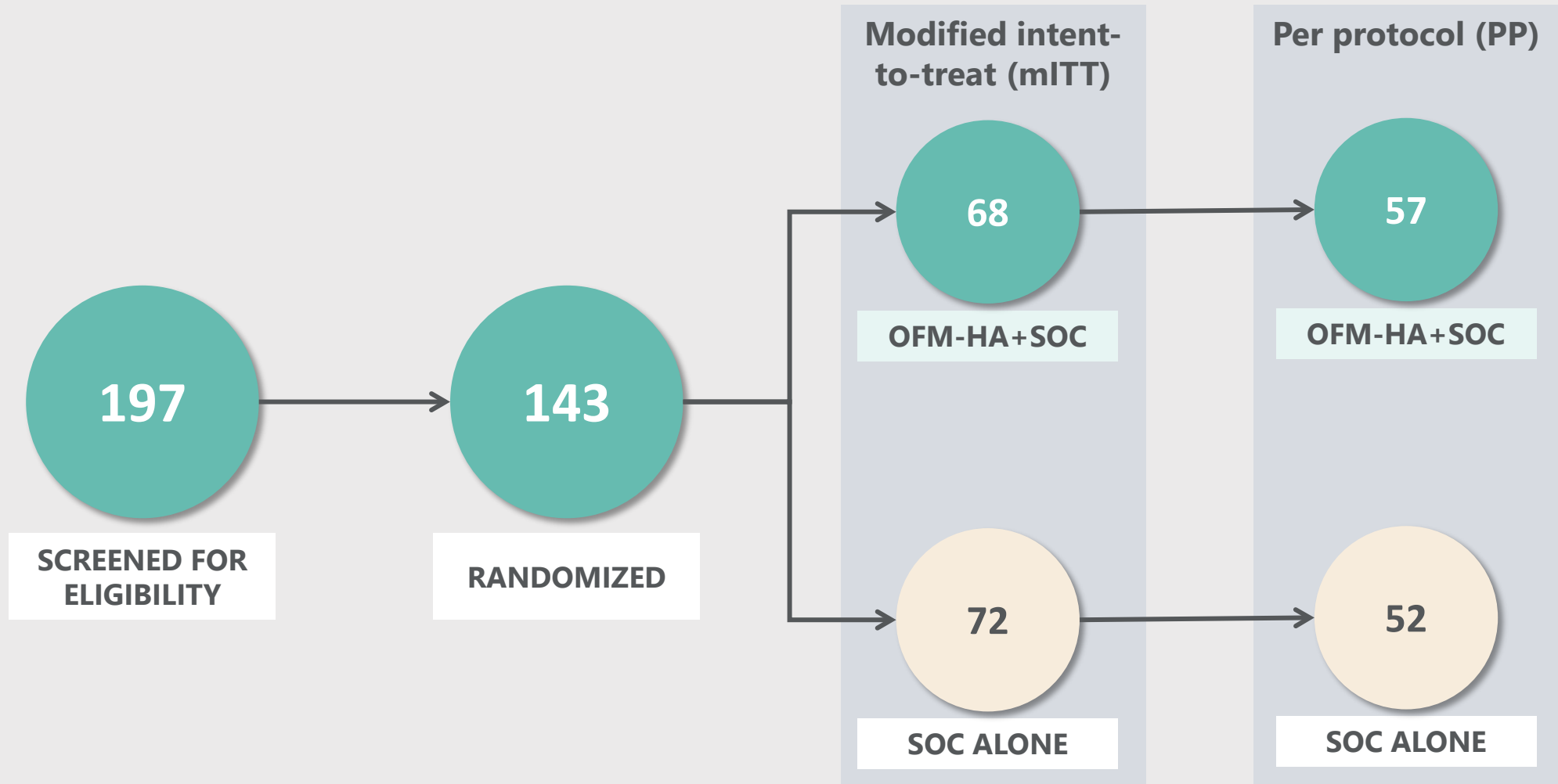
Armstrong et al | RCT

Study protocol



Armstrong et al | RCT

Enrollment and populations



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Subject-related variables

Variable	OFM-HA + SOC	SOC	p
Age (years)(SD)	59.5 (9.87)	61.0 (10.25)	0.40
BMI (SD)	29.9 (6.04)	31.0 (7.21)	0.49
Diabetes duration (years)(SD)	18.4 (10.45)	15.2 (10.21)	0.048
Prior DFU count (SD)	2.6 (3.22)	3.1 (2.98)	0.19
Concurrent DFUs at screening	10 (15)	10 (14)	1.0
History of DFU recurrence (%)	35 (52)	50 (69)	0.038
Major amputation (%)	5 (7)	3 (4)	0.49
Minor amputations:			
0 (%)	40 (59)	33 (46)	0.078
1 (%)	17 (25)	17 (24)	
2 (%)	6 (9)	14 (19)	
≥3 (%)	5 (7)	8 (11)	
Creatinine (mg/dL) (SD)	1.2 (0.43)	1.2 (0.42)	0.77
HbA1c			
At randomization (SD)	8.4 (1.76)	7.5 (1.57)	0.004
At EOS (SD)	7.7 (1.71)	7.3 (2.07)	0.033
Mean blood sugar (mg/dL)(all visits) (SD)	193 (80.01)	188 (70.64)	0.96

mITT population shown

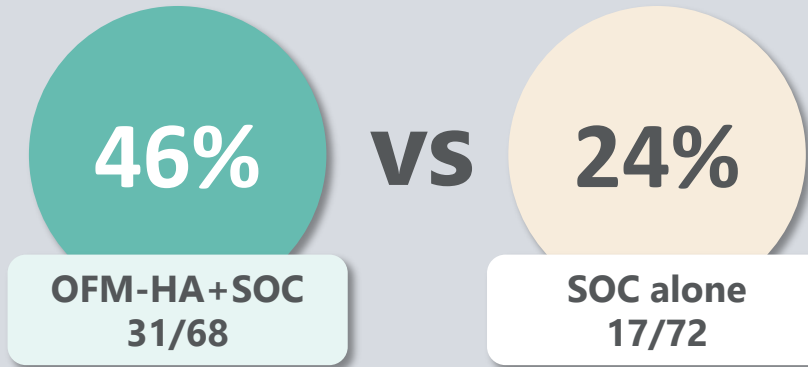
Variable	OFM-HA plus SOC	SOC	P
Wound area (cm ²)(SD)	3.0 (3.41)	4.2 (4.53)	0.078
Wound age (weeks)(SD)	17.7 (11.32)	17.6 (12.61)	0.66
Plantar (%)	48 (71)	47 (65)	0.59
Medial (%)	41 (60)	40 (56)	0.47
Forefoot (%)	36 (53)	32 (45)	0.53
Depth (mm)(SD)	2.4 (5.46)	1.9 (2.19)	0.96
Wagner Grade 1(%)	37 (54)	42 (58)	0.73
Wagner Grade 2(%)	31 (46)	30 (42)	
Offloaded(%)	68 (100)	67 (93)	0.059
Offloading, mean of visits (%) (SD)	88.8 (8.36)	87.6 (9.80)	0.63
Number of debridements (SD)	10.0 (4.19)	9.8 (3.68)	0.38

mITT population shown

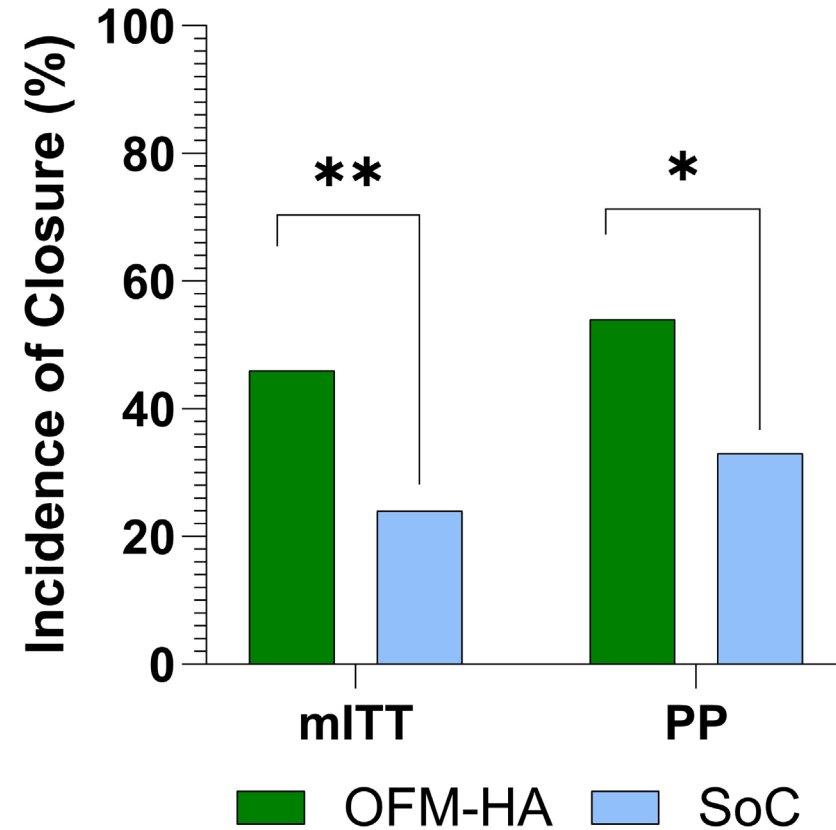
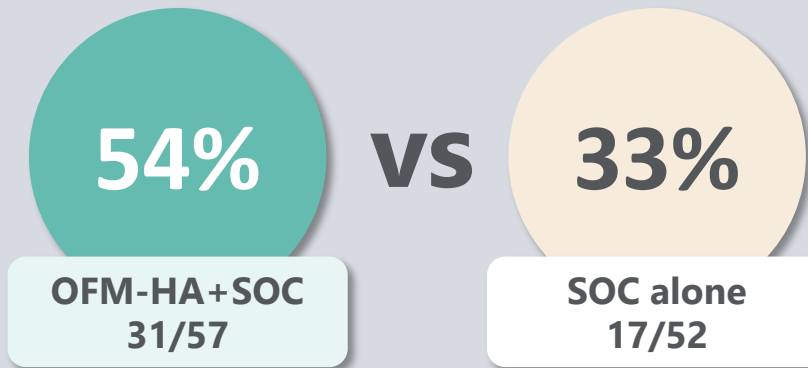
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Primary endpoint: Incidence of closure at 12-weeks

mITT: $p=0.008$



PP: $p=0.033$

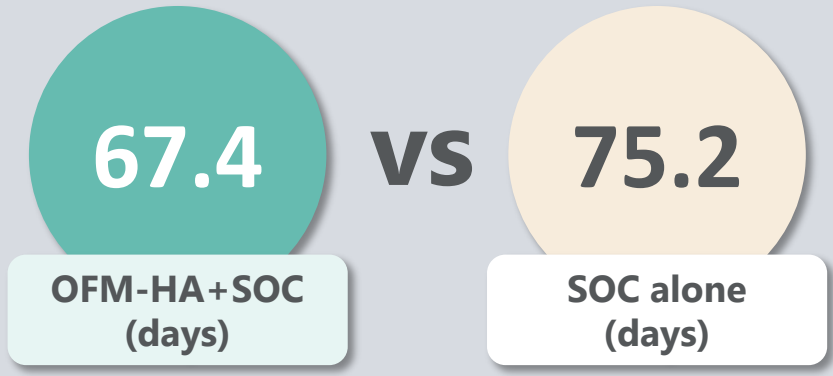


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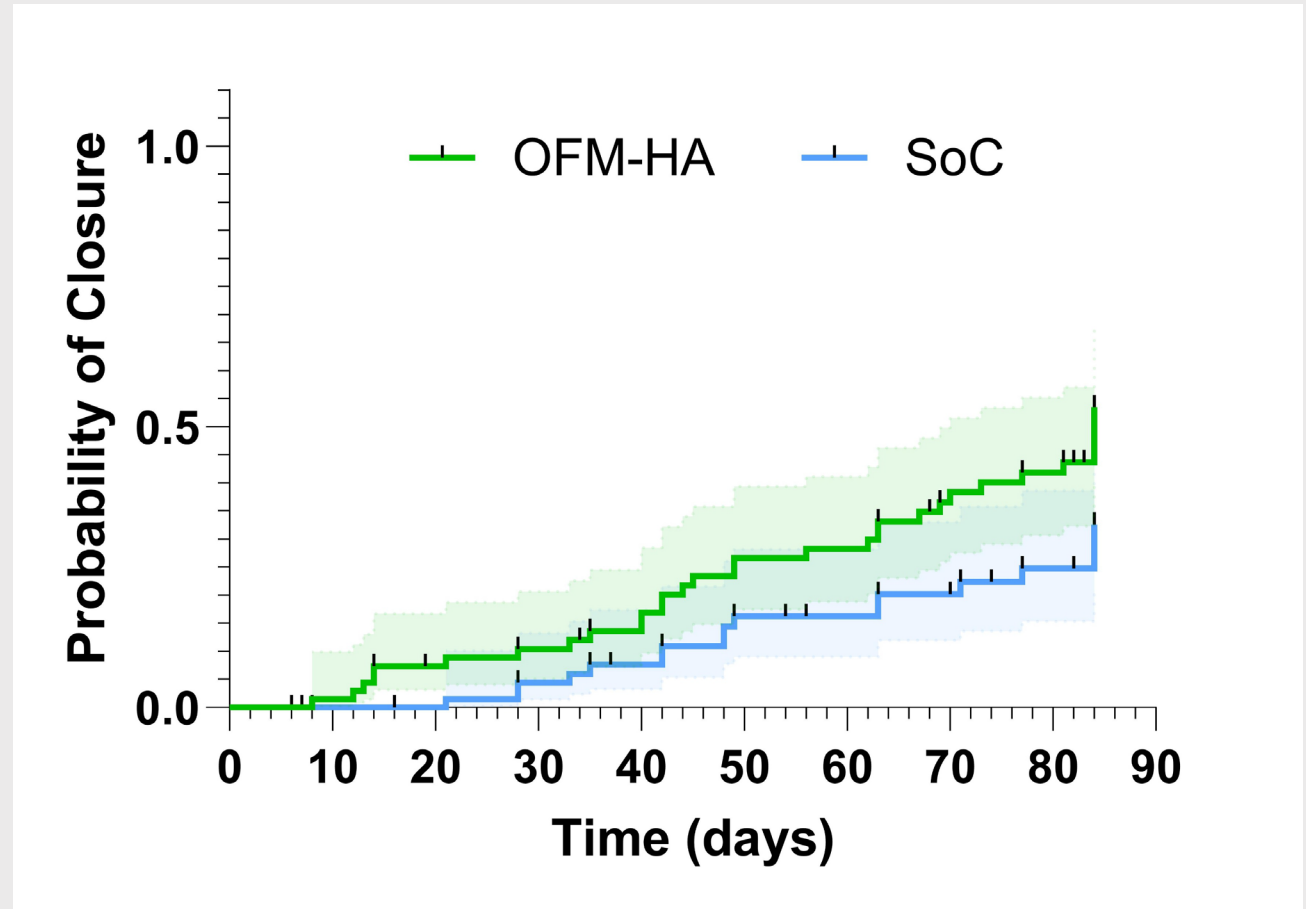
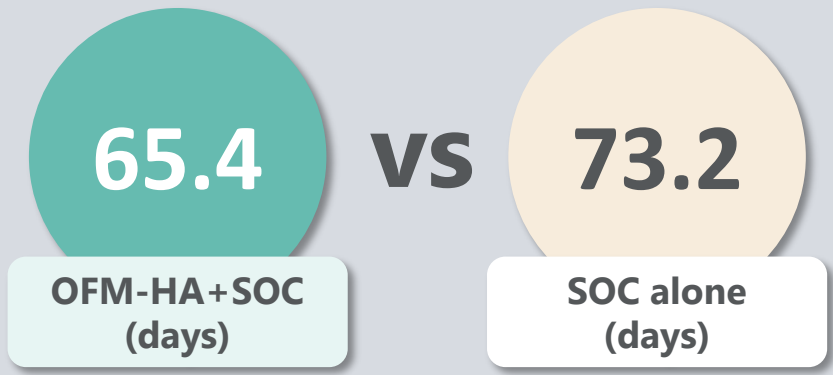
Secondary endpoint: Time to closure



mITT: $p=0.023$



PP: $p=0.041$



Shown Kaplan Meir survival curve for mITT population

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Secondary endpoint: Adverse events

OFM-HA+SOC (mITT)

50%

AE RATE

13%

INDEX ULCER
INFECTIONS

1

OSTEO/
GANGRERE

1

MINOR
AMPUTATION

SOC alone (mITT)

51%

AE RATE

17%

INDEX ULCER
INFECTIONS

7

OSTEO/
GANGRERE

3

MINOR
AMPUTATION

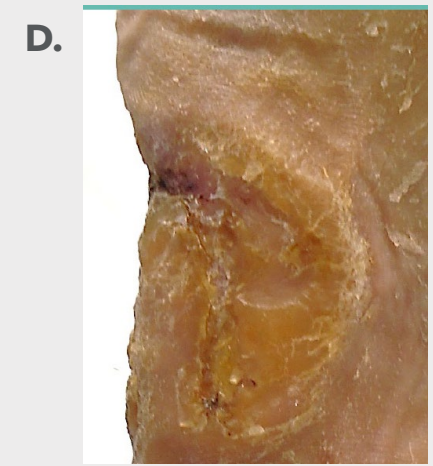
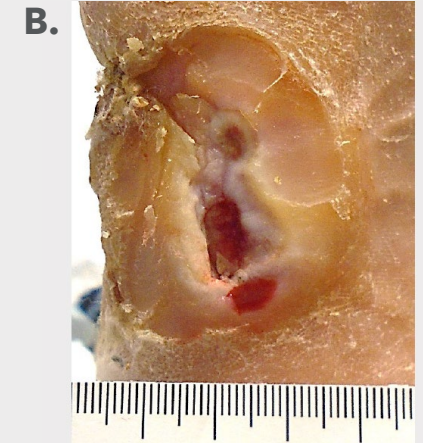
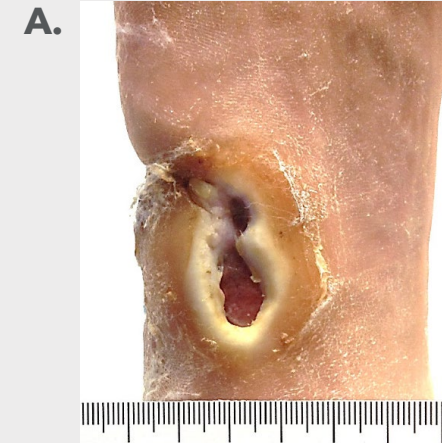
**Next slide contains wound
imagery**

Case Example: Right Plantar Midfoot DFU

58-Year-old, male - Wagner 2 DFU Right Plantar Foot

- **A.** Day 0: 2.6 x 1.2 x 0.1 cm
- **B.** Week 1, 84% area reduction
- **C.** Week 3, 90% area reduction
- **D.** Week 4, 100% epithelialized

No complications nor recurrences, healing confirmed at visit 2 weeks



Armstrong et al | RCT

Summary

- OFM-HA+SOC was effective in **a mixed Wagner 1 and 2 population**
- Significantly **increased incidence of wound closure** – 57% more DFUs closed with OFM-HA+SOC vs SOC alone
- Significantly **reduced mean time to wound closure** – closure reduced by 7.8 days (mean)
- No unexpected device related adverse events
- **Lower incidences of infection** in DFU treated with OFM-HA+SOC – scope for future studies or analysis



FOUNDER AND CHIEF EXECUTIVE OFFICER

Brian Ward, BVSc MBA

What this means

Confidence

from RCT study design,
CRO & authors

Demonstrates efficacy

which is important
for adoption

Audit Defensibility

product choice is clinical
and not financial

Supports Payor Coverage

CMS/MACs & private
payors

Supports Value Analysis Committee Processes

enabling hospital adoption

Unlocks Sales



ARO A BIOSURGERY

Questions & Answers



Thank you for attending



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