

Independent Validation of Late-Stage Pressure Injury Surgical Treatment Algorithm Utilizing Ovine Forestomach Matrix: An Interim Analysis

¹Byron Holloway, DO, FACS; ²Abigail Chaffin, MD, FACS, CWSP, MAPWCA; ³John C. Lawlor, DPM; ⁴Michael T. Cormican, MD; ⁵Anthony N. Dardano, DO, FACS; ⁶Michael N. Desvigne, MD, FACS, CWS, FACCWS

¹Department of Surgery, AdventHealth West Florida, Tampa, Florida, USA; ²Division of Plastic Surgery, Tulane University, New Orleans, LA, USA; ³Associates in Medicine and Surgery, Fort Myers, FL, USA; ⁴Northeast Georgia Medical Center, Gainesville, GA, USA; ⁵Charles E. Schmidt College of Medicine, Florida Atlantic University, Boca Raton, Florida, USA; ⁶Department of Plastic Surgery, Abrazo Arrowhead Hospital, Glendale, AZ, USA;

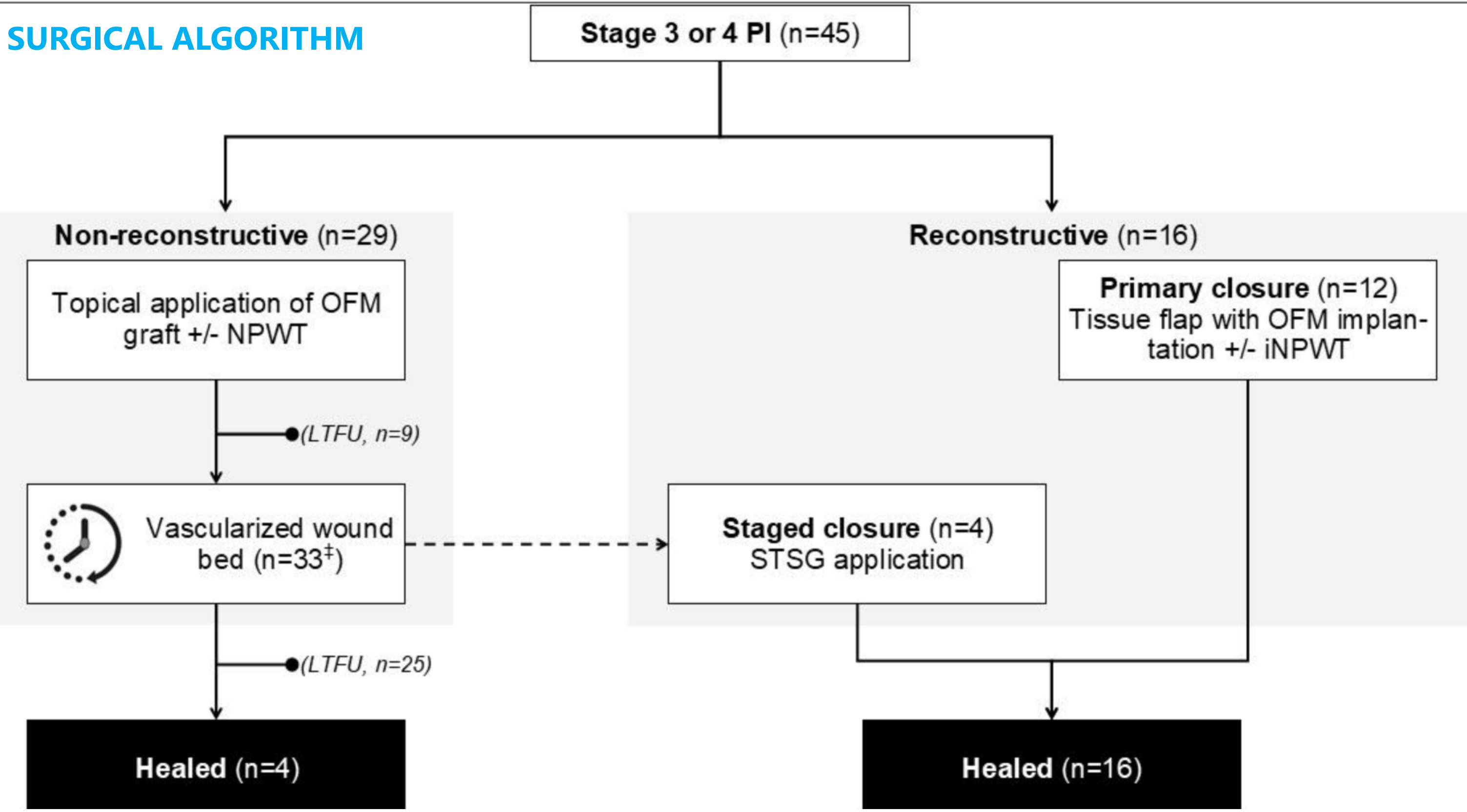
INTRODUCTION

The management of late-stage pressure injuries (PI) remains a substantial problem. 2016 Medicare data suggested an annual cost of \$22 billion and about 59% of these costs are disproportionately attributable to a small rate of Stages 3 and 4 full-thickness PI (1). Additionally, the average 6-month post operative healing rates for a stage IV PI is 31-34% and the post operative complication rate after flap reconstruction is reported to be 58.7% (2). Approaches to the surgical closure of late-stage PIs are varied and suffer from relatively high complication rates. As such, an algorithm for the reconstructive and non-reconstructive intervention for late-stage PIs was developed by an interdisciplinary panel and published to review the current state of the art and propose a treatment plan (3). This study evaluates the safety, efficacy, and reproducibility of this surgical algorithm utilizing a biologic graft as part of two distinct surgical pathways to optimize outcomes in these challenging defects.

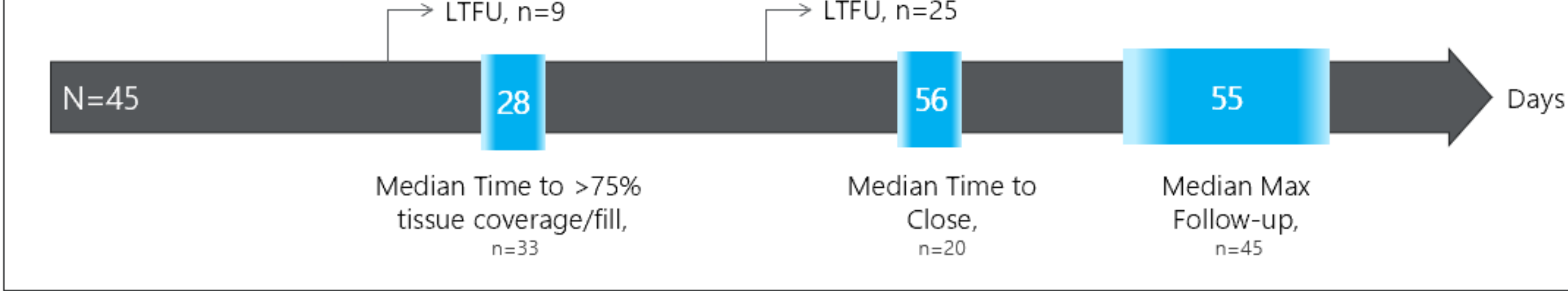
METHODS

This IRB-approved retrospective case series included n=45 Stage 4 PIs across 36 patients. Intervention proceeded according to the published surgical algorithm (reconstructive pathway and non-reconstructive pathway). In each case, a biologic graft comprising ovine forestomach matrix* (OFM) was included as part of the surgical intervention. Patients were followed and monitored for complications such as surgical wound dehiscence, hematoma, seroma, flap necrosis or infection.

SURGICAL ALGORITHM



RESULTS - OVERALL OUTCOMES



Median Product Applications, 1.0 [1.0, 1.0]

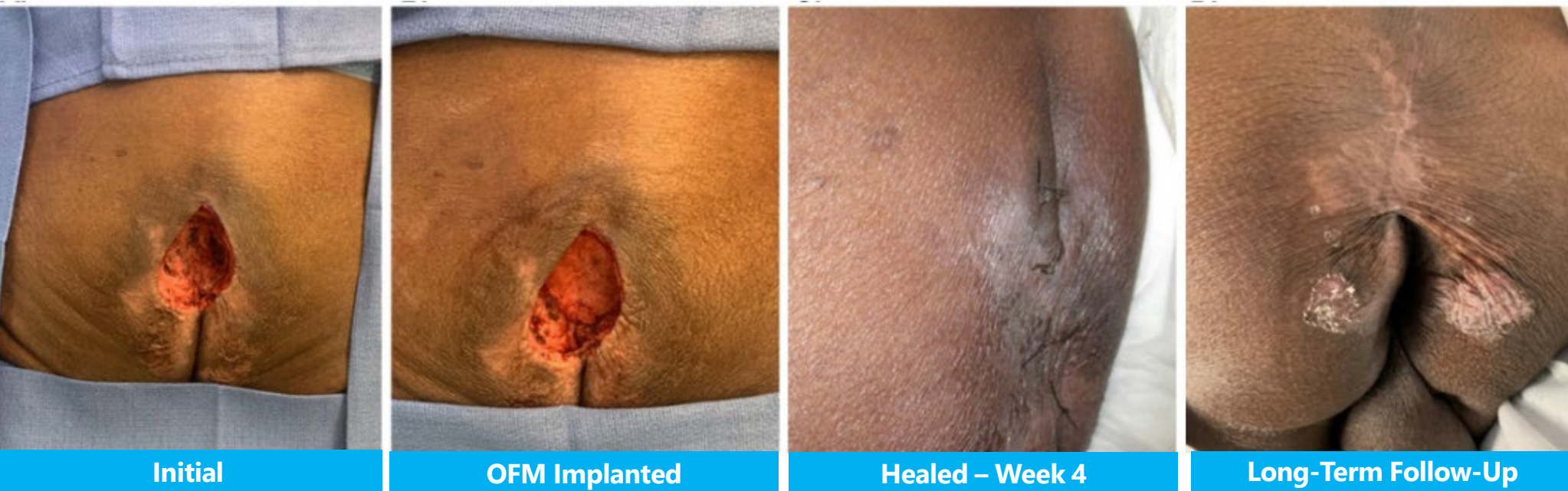
Complications: dehiscence (1, 2%); unrelated death (4, 9%)

CONCLUSION

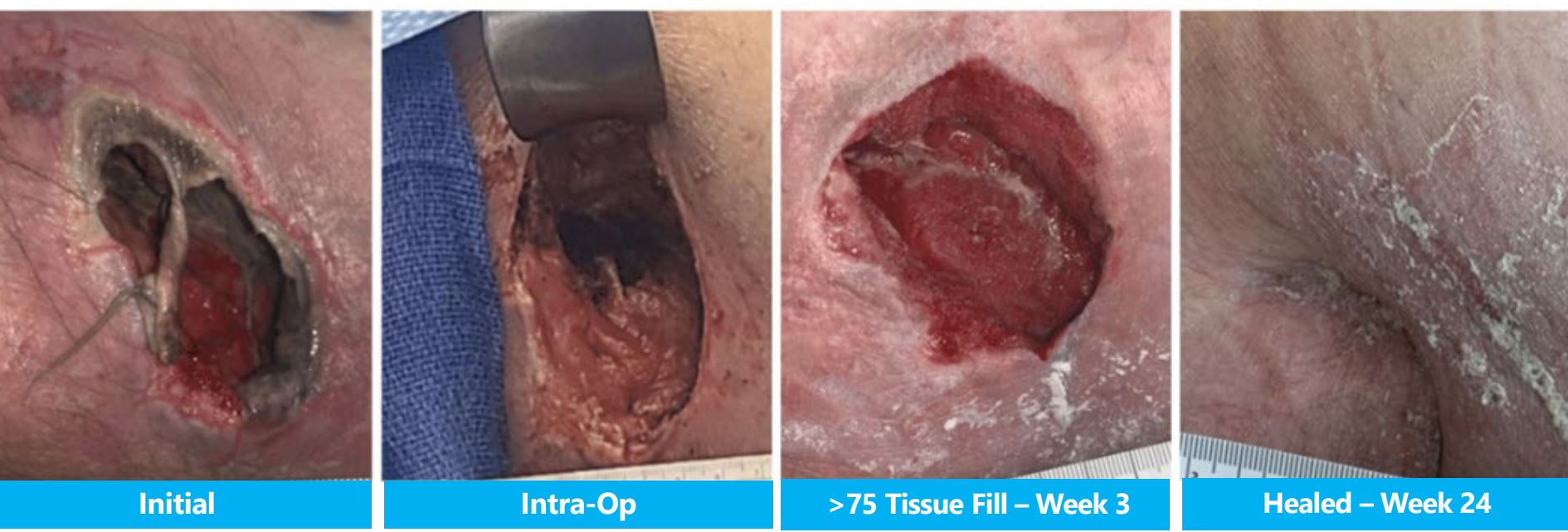
Findings suggest two-arm PI surgical algorithm utilizing advanced biologic technology, such as OFM provides

- Reproducible, safe, and clinically effective treatment option for late-stage PI
- Favorable outcomes and low post-operative complications
- Non-reconstructive approach for community hospitals with limited access to advanced plastic surgery

RECONSTRUCTIVE PATHWAY– MYOCUTANEOUS FLAP



NON-RECONSTRUCTIVE PATHWAY – SECONDARY INTENT



NON-RECONSTRUCTIVE -TO- RECONSTRUCTIVE CROSS-OVER PATHWAY – SPLIT-THICKNESS SKIN GRAFT



RESULTS - RECONSTRUCTIVE

Reconstructive	16 (36%)
Time to close, ±SE, days	32±5
Maximum Follow-up, median [IQR], days (n)	127 [61, 152] (16)

RESULTS – NON-RECONSTRUCTIVE

Non-Reconstructive	29 (64%)
Time to >50% tissue fill/coverage, median [IQR], days (n)	13 [8, 25] (24)
Time to >75% tissue fill/coverage, median±SE, days	28±5
Time to close, median±SE, days	172±46
Maximum Follow-up, median [IQR], days (n)	32 [15, 74] (29)

REFERENCES: [1]Padula WV, Delarmente BA. The national cost of hospital-acquired pressure injuries in the United States. Int Wound J. 2019;16(3):634-40. [2]Bamba R, Madden JJ, Hoffman AN, Kim JS, Thayer WP, Nanney LB, Spear ME. Flap Reconstruction for Pressure Ulcers: An Outcomes Analysis. Plast Reconstr Surg Glob Open. 2017;5(1):e1187.[3] Awad SS, Stern JD, Milne CT, Dowling SG, Sotomayor R, Ayello EA, et al. Surgical Reconstruction of Stage 3 and 4 Pressure Injuries: A Literature Review and Proposed Algorithm from an Interprofessional Working Group. Advances in Skin & Wound Care. 2023;36(5):249-58.