

A Prospective Study of 400 Soft Tissue Reconstructions: Interim Analysis of the Ovine Forestomach Matrix MASTRR Registry

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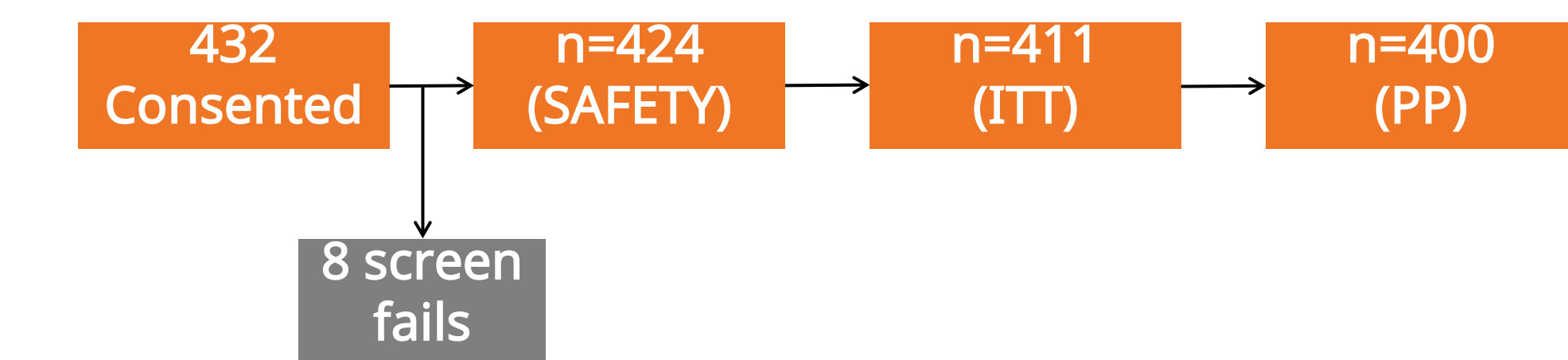
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INTRODUCTION

Clinical literature describing the inpatient use of bioscaffolds across surgical specialties most commonly relies on case series and retrospective analyses. Prospective registries are a valuable tool to capture long-term, real-world data and to monitor treatment outcomes in a patient population [1]. Here, we present the interim results of a large-scale, observational, multi-center, single-arm prospective registry investigating the safety and efficacy of ovine forestomach matrix (OFM) grafts across a wide range of surgical procedures and defect etiologies.

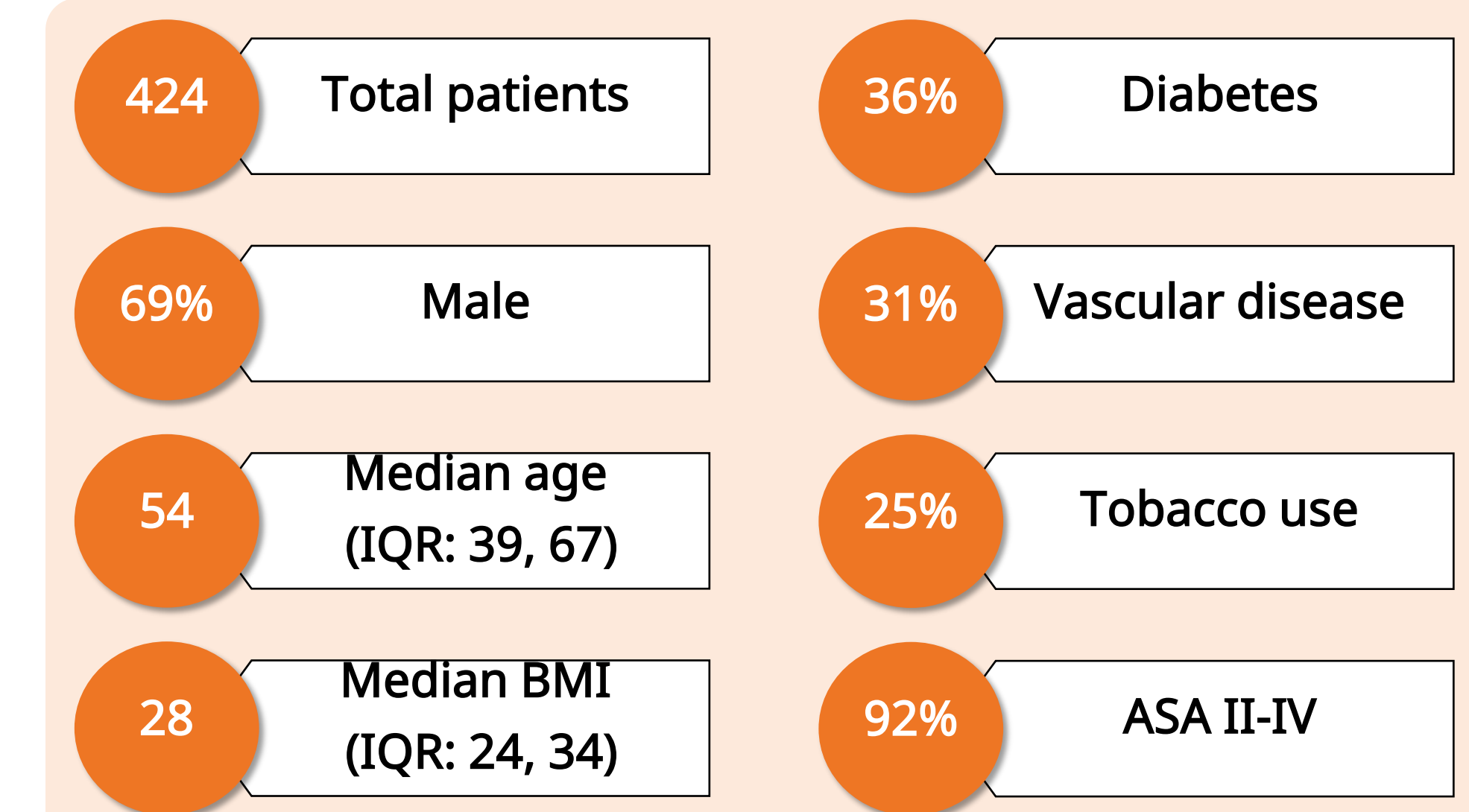
METHODS

This prospective observational study evaluated the safety and clinical outcomes of OFM grafts and/or particulate (Myriad Matrix™ and/or Morcells™, Aroa Biosurgery Limited, Auckland, New Zealand) in soft tissue reconstruction from a real-world registry study (NCT05243966). This interim analysis includes the first 432 patients enrolled across 10 US sites between May 2022 and June 2025. After receiving OFM as part of their reconstruction, patients were assessed for up to 18 months. The primary endpoint was the proportion of treatment emergent adverse events (AEs), per ISO14155. Time to tissue coverage, time to defect closure and product applications were quantified.

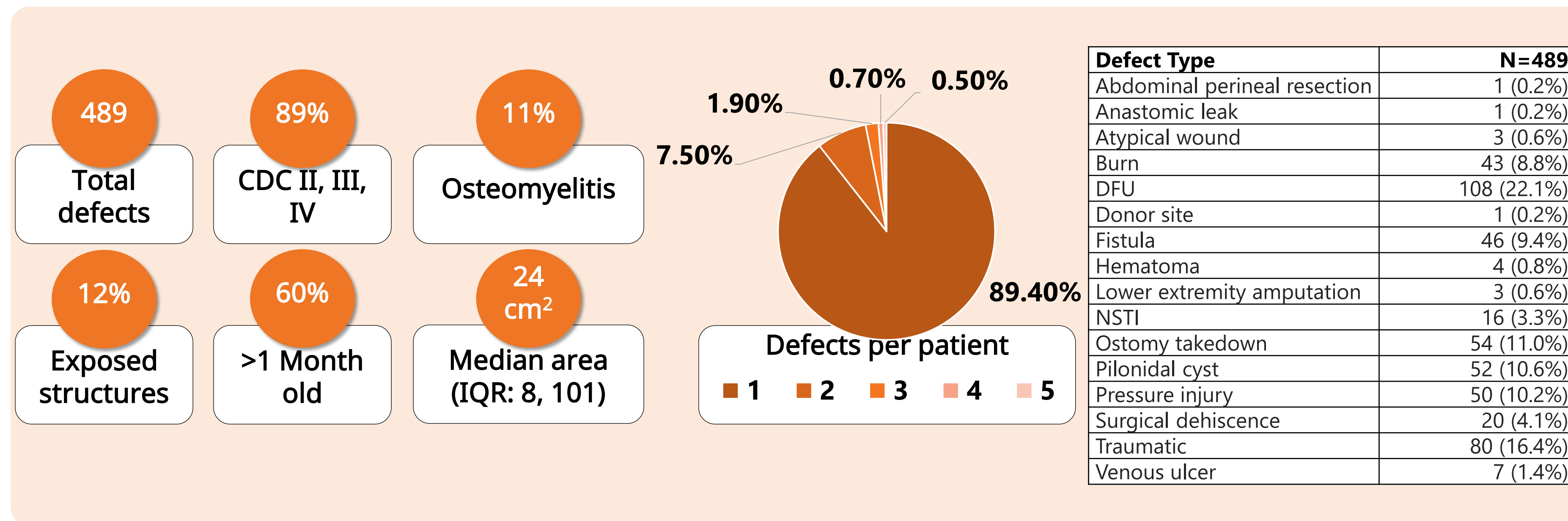


RESULTS (Safety Population)

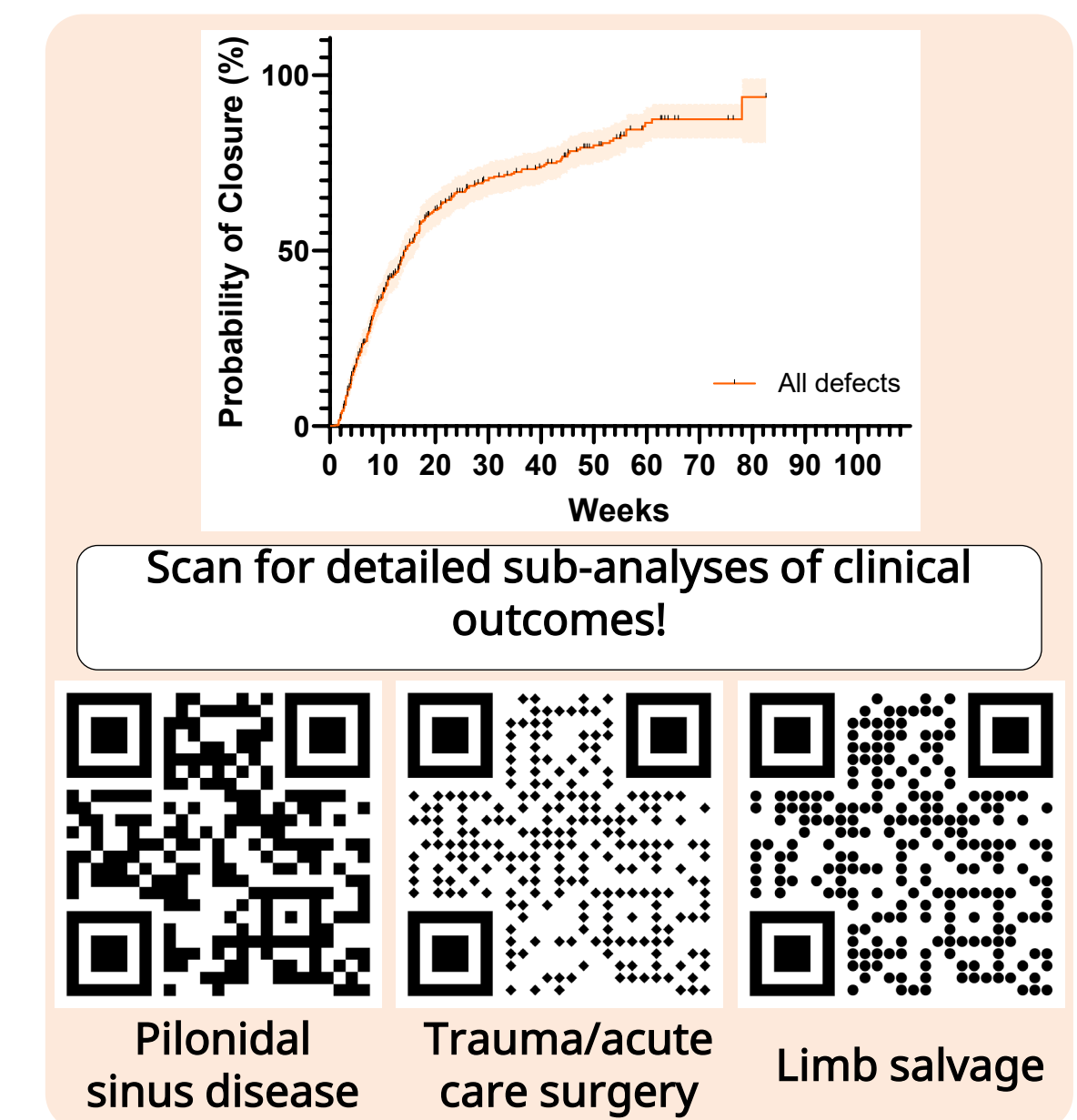
Patient characteristics



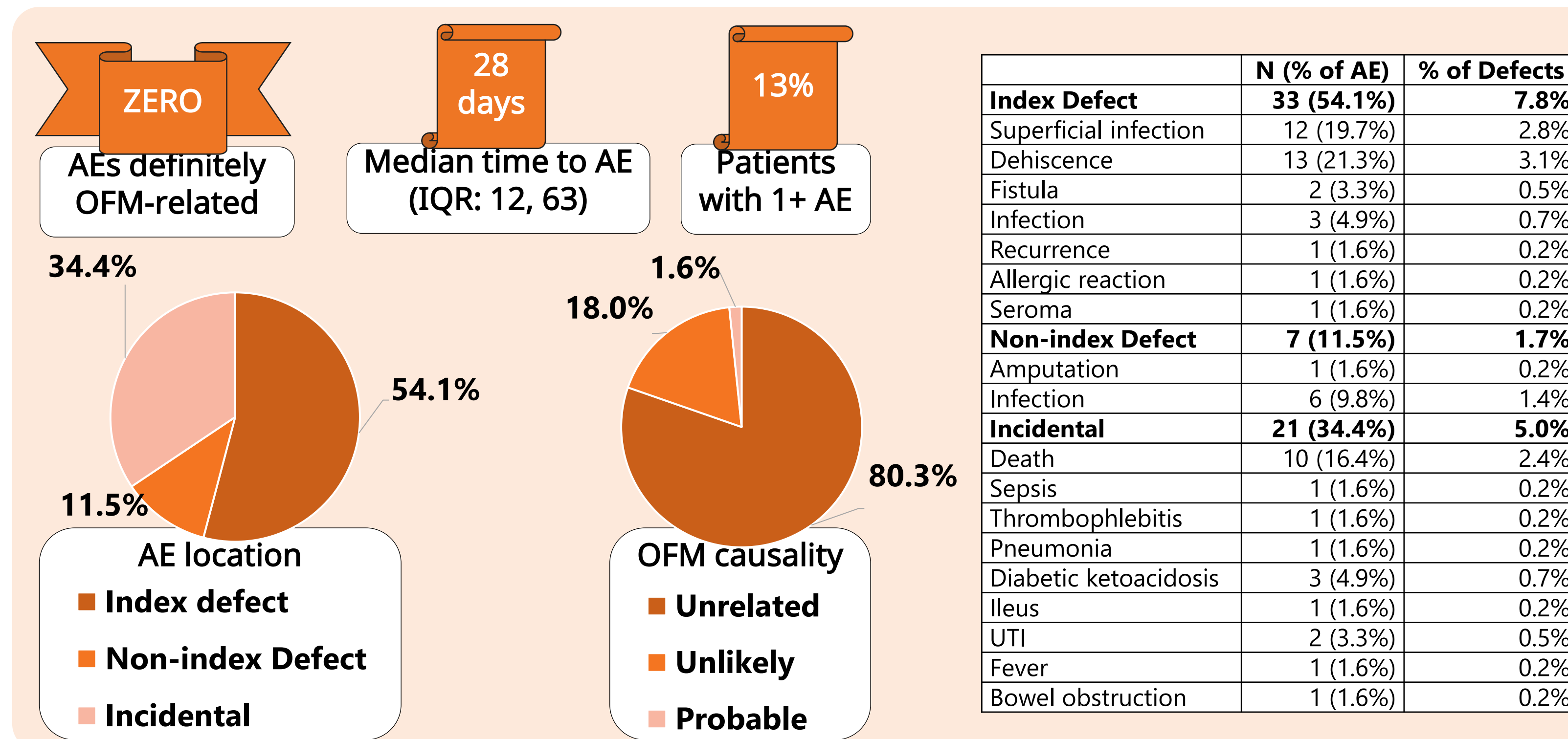
Wound characteristics



Healing outcomes (PP population)



Adverse events (AEs)



CONCLUSIONS

This dataset represents the interim findings of the largest ongoing prospective study on skin substitutes in soft tissue reconstruction. Despite the diverse and complicated patient population and defect etiologies, this study demonstrated that OFM can safely be used for various surgical applications. In fact, results indicate that OFM usage results in low adverse events that are generally not attributable to the device. Healing outcomes further show that in most cases, OFM requires only a single application, which likely contributes to effective granulation tissue coverage and definitive closure.

DISCLOSURES

TS, MB, CB, JC, MC, CD, PK, JL, PM, YN, AS, MV, and JW are consultants for Aroa Biosurgery Limited. BB, JS, AY, and BM are employees of Aroa Biosurgery Limited. Funding for this study was provided by Aroa Biosurgery Limited.

REFERENCES

[1] Posadas-Martinez et al. (2024) "The role of registries in improving health and bridging healthcare, research, education, innovation and development: a research department perspective" J Int Med Res.