BIOSYM

A Multicentre Randomised Feasibility Trial

Biological versus Synthetic Mesh in Implant-Based Breast Reconstruction

A Hamad · E Garreffa · K Grover · L Whisker · M Kaushik · F Tsang-Wright · J Beckhelling · A Goyal

Derby Clinical Trials Support Unit, University Hospitals of Derby and Burton NHS Foundation Trust

Do not use without authors' permission

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

Conflict of Interest Disclosure

- **Disclosures:** None.
- The authors declare no competing financial or non-financial interests related to this work.
- No external funding was received for this study.

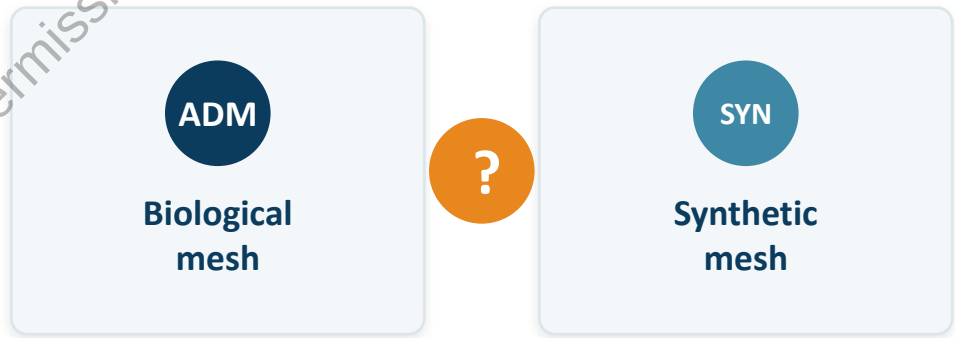
Do not use without authors' permission

BACKGROUND

Why We Need BIOSYM

- Biological (ADM) and synthetic mesh are both widely used in implant-based breast reconstruction (IBBR)
- Robust comparative evidence on safety, complications and patient-reported outcomes is limited
- Uncertainty for both patients and surgeons choosing between mesh types

Do not use without authors' permission



Which is safer? Which gives better patient-reported outcomes?

BIOSYM: the first UK-led feasibility RCT designed to test whether a definitive comparative trial is achievable

METHODS

Study Design

- Multicentre feasibility RCT across 5 UK breast units where service is run by Oncoplastic Breast Surgeons
- 1:1 randomisation to biological or synthetic mesh, stratified by site
- Randomisation was single-blinded
- Bilateral procedures received the same mesh in both breasts
- Outcomes assessed at baseline, 3 months and 6 months

Do not use without authors' permission



1 Screen & consent → 2 Randomise 1:1 → 3 Surgery → 4 3-month follow-up → 5 6-month follow-up

METHODS

Study Design

Sample: 60 patients planned, 65 randomized

Recruitment: Nov 2023 – Nov 2025

Sponsor / funder: UHDB NHS Foundation Trust

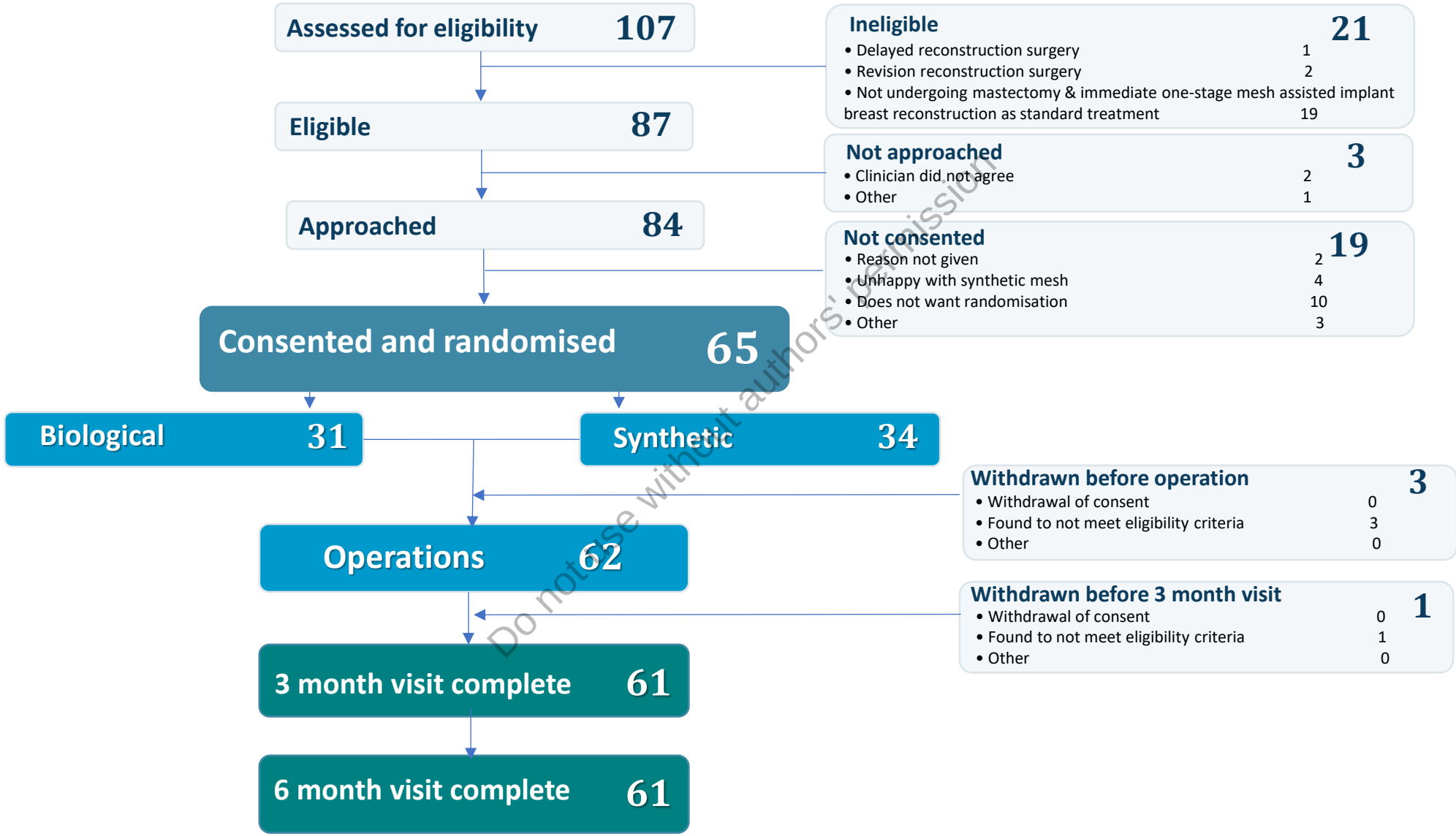
CI: Amit Goyal

Do not use without authors' permission

Outcomes collected

- **Primary:**
  - Clinician and patient acceptance
  - Recruitment rate
  - Mesh compliance
- **Secondary:**
  - Complications
  - BREAST-Q & EQ-5D-5L scores
  - Data completeness
  - Sample-size estimate

RECRUITMENT FLOW



Do not use without authors' permission

FEASIBILITY RESULTS

Primary Outcomes: All Criteria Met

✓ Clinician acceptance	*target > 50%*	**97%**
✓ Patient acceptance	*target > 20%*	**77%**
✓ Recruitment rate	*target > 30 / yr*	**32 / yr**
✓ Compliance with allocated mesh	*target > 80%*	**100%**

Do not use without authors' permission

→ ***A definitive multicentre RCT is feasible and acceptable to patients and clinicians***

FEASIBILITY RESULTS

Baseline Characteristics

Biological mesh (n = 29)

- Mean age: 51 years (95% CI 46–56)
- Median BMI: 27 (IQR 23–29)
- 83% White – British
- Mesh used: Braxon / Native (100%)

Synthetic mesh (n = 32)

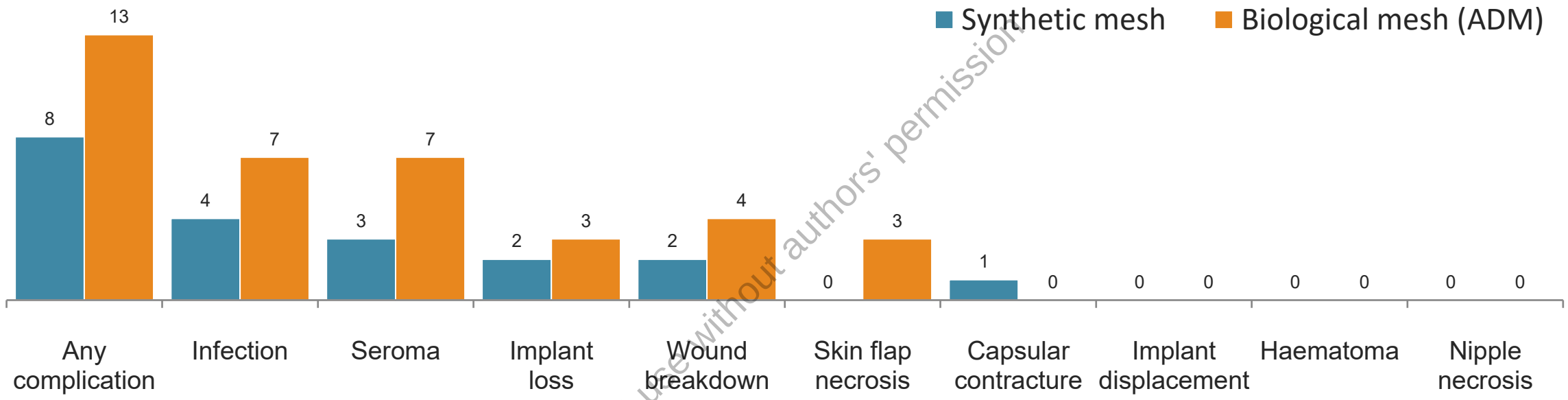
- Mean age: 50 years (95% CI 45–55)
- Median BMI: 24 (IQR 22–28)
- 94% White – British
- Mesh used: TiLOOP pocket/bra (87.5%), TIGR (12.5%)

Do not use without authors permission

Groups were broadly well matched for age, comorbidity and cancer indication

SAFETY

Complications: 0–3 Months



Do not use without authors' permission

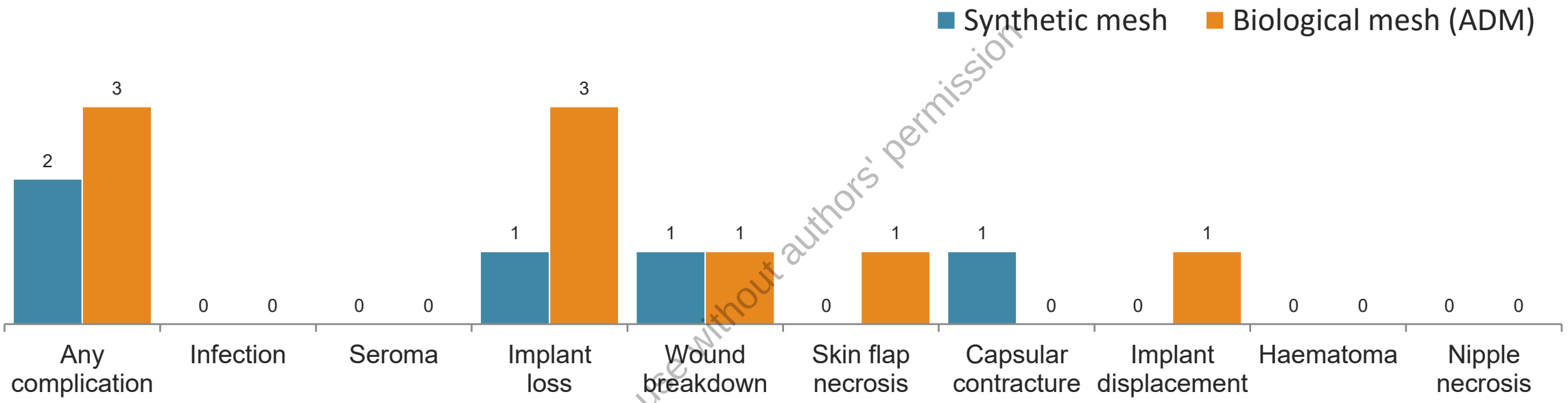
≥ 1 complication by 3 months

25% synthetic vs **45%** biological

Infection and seroma were the most common early complications, more frequent with biological mesh

SAFETY

Complications: 3–6 Months



Do not use without authors' permission

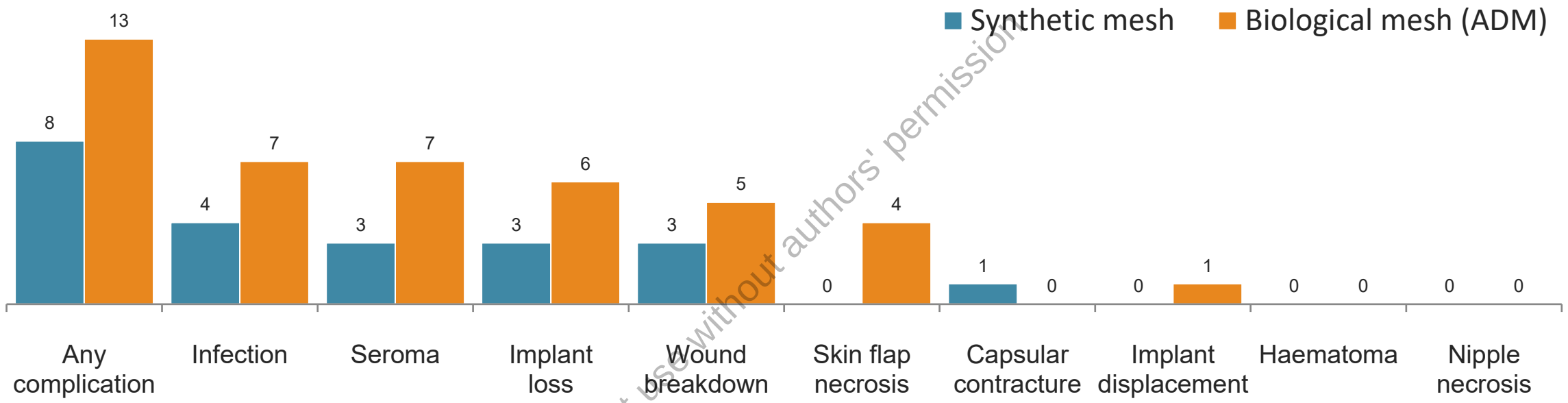
New complications, 3–6 months

2 synthetic vs **3** biological patients

Far fewer new events than in the first 3 months — mostly implant loss and wound breakdown, often continuing from earlier problems

SAFETY

Complications: Full Study Summary



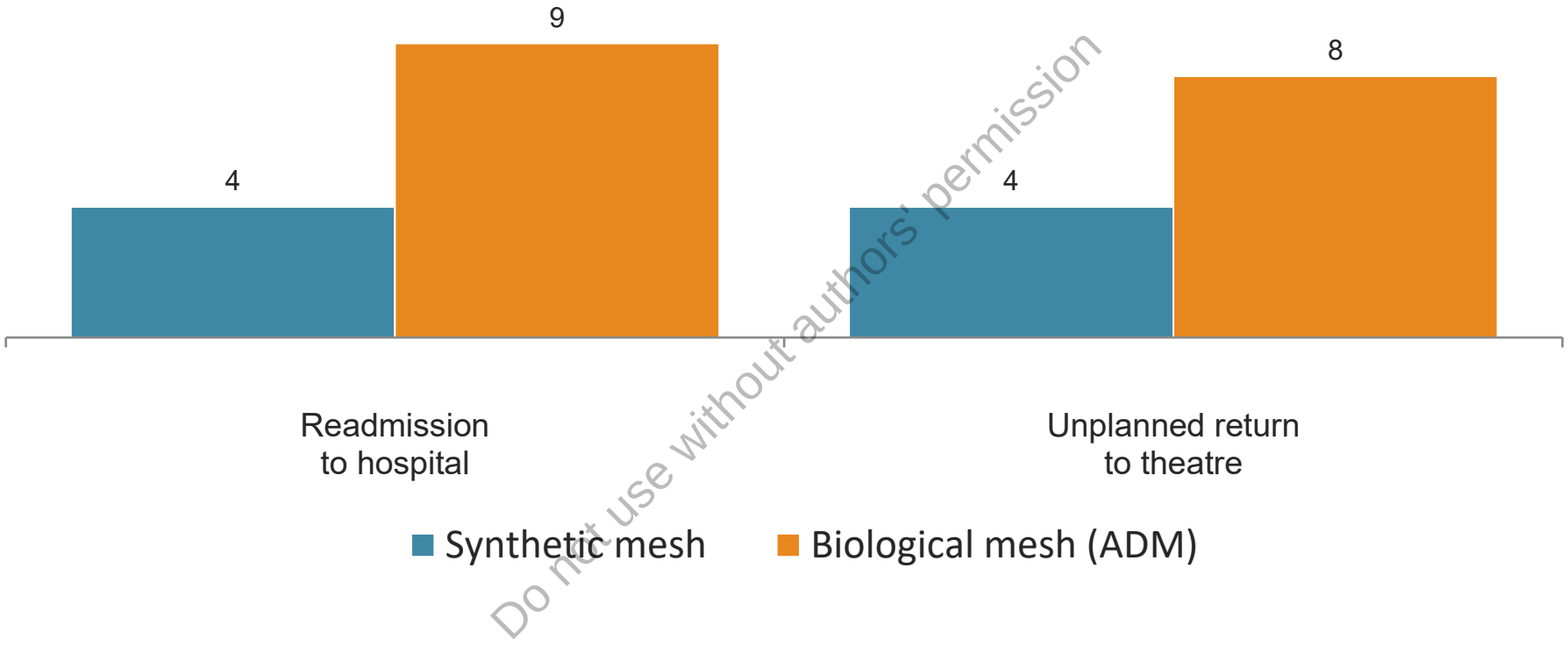
Do not use without authors' permission

8 patients had 2 complications each
(2 synthetic, 6 biological)

No serious adverse events
1 non-serious AE (red breast syndrome, biological mesh)

SAFETY

Unplanned Readmissions and Return to Theatre

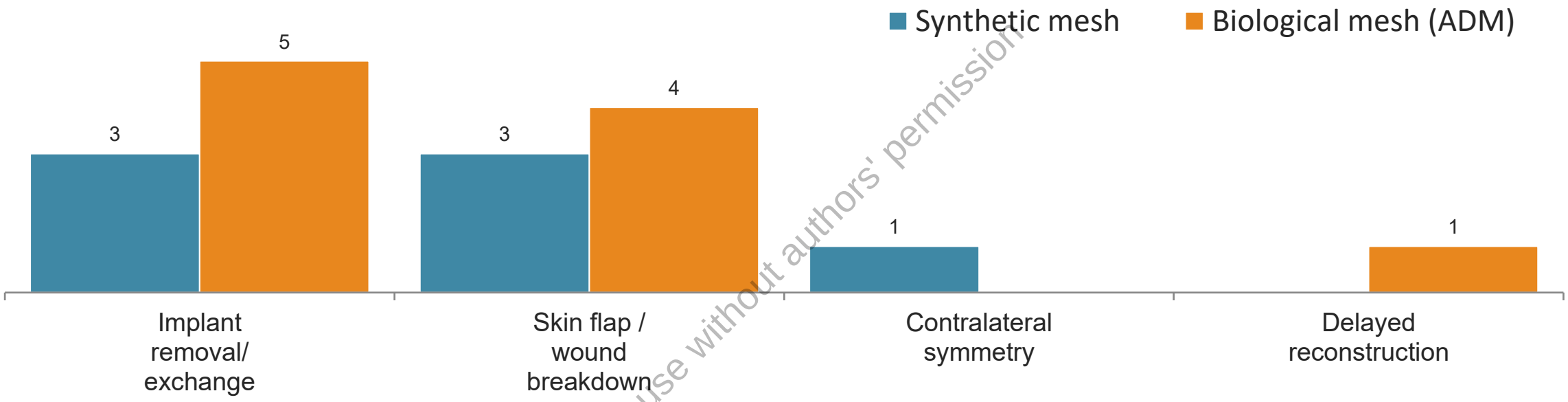


Do not use without authors' permission

Readmission and return to theatre were both more frequent with biological mesh

SAFETY

Reasons for Further Surgery



Do not use without authors' permission

Implant removal/exchange and wound-related surgery were the leading reasons for returning to theatre in both groups

Most patient wouldn't have had symmetrisation surgery (or lipofilling) 6 months post-op, but may require it later down the line

SECONDARY OUTCOMES

Patient-Reported Outcomes

Breast Q

Satisfied with implant
Wrinkling seen/felt, 6 months

50% biological **82%** synthetic

Satisfaction with breasts scale

- Two week window-restricted analysis: biological group appears to improve (+3.5) vs synthetic (–2.6) at 6 months
- Sensitivity analysis (all responders, any timing): difference disappears (–0.3 vs +0.4)

Do not use without authors' permission

- Only 4 patients had submuscular implants – all had synthetic meshes, which may have favoured synthetic meshes in terms of satisfaction with wrinkling
- Biological-mesh patients were less likely to complete the “satisfaction with breasts” and “sexual wellbeing” scales, especially at 6 months
- EQ-5D-5L showed little sensitivity to change in either group — should we still use in the definitive trial?

CONCLUSIONS

What We Learned

Feasibility demonstrated

- All 4 progression criteria met
- Recruitment target achieved — a UK first for this field
- 100% compliance with allocated mesh
- 91% overall PROM/complications data completeness

Refine before the definitive trial

- Reassure patients that clinicians don’t see individual PROM answers
- Drop EQ-5D-5L — limited sensitivity in this population
- Review the ±14-day PROM assessment window
- Revisit sample-size assumptions for “satisfaction with breasts”

Do not use without authors permission

REFERENCES

Outcome Measures & Methodology

1. Pusic AL, Klassen AF, Scott AM, Klok JA, Cordeiro PG, Cano SJ. Development of a new patient-reported outcome measure for breast surgery: the BREAST-Q. Plast Reconstr Surg. 2009;124(2):345–353.
2. Voineskos SH, Klassen AF, Cano SJ, Pusic AL, Gibbons CJ. Giving meaning to differences in BREAST-Q scores: minimal important difference for breast reconstruction patients. Plast Reconstr Surg. 2020;145(1):11e–20e.
3. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727–1736.
4. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Ann Intern Med. 2010;152(11):726–732.

Trial Documentation

5. BIOSYM Feasibility RCT. ClinicalTrials.gov identifier: NCT05449691.
6. BIOSYM Final Statistical Analysis Report, V5 (19 August 2026). Derby Clinical Trials Support Unit, University Hospitals of Derby and Burton NHS Foundation Trust.
7. IRAS project ID: 315581.

Do not use without authors' permission

Thank You

Questions & Discussion

Acknowledgments:

- Derby Clinical Trials Support Unit
- Participating patients and PPI contributors
- The five recruiting UK breast units
- University Hospitals of Derby and Burton NHS Foundation Trust (sponsor & funder)

BIOSYM · ClinicalTrials.gov NCT05449691 · IRAS 315581

Do not use without authors' permission

OPEN to international sites!
Please contact: amit.goyal@nhs.net