

preHEAT

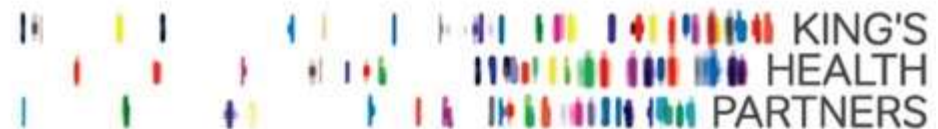
Local heat preconditioning and its effect on wound healing

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*National Institute for
Health Research*



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INTRODUCTION

- Skin sparing mastectomy - popular method of surgical treatment for cancer ¹
- Skin necrosis is a serious complication
 - Poor scarring
 - Longer hospital stay/more frequent dressings
 - Possibly need more operations

1. Omranipour *et al.* World J. Surg. Onc, 2008

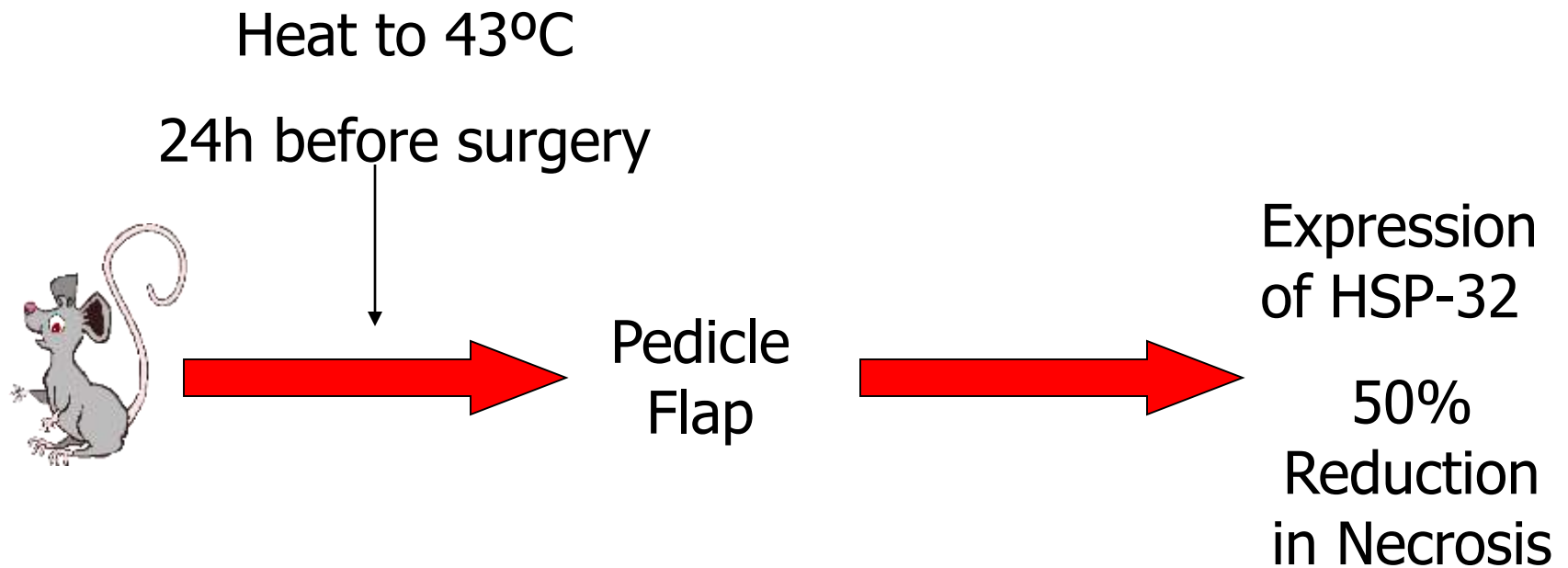
INTRODUCTION

- Patient factors associated with necrosis ⁴
 - BMI over 25
 - Breast tissue over 750g (C-Cup)
 - Sternal Nipple Distance over 25 cm



4. Davies *et al.* Breast, 2010

Background - Heat Shock Proteins (HSP's) & Supraphysiological stress ⁵



5. Harder *et al.* Ann. Surg, 2005

Background - HSP's & Supraphysiological stress

- Induction of HSP's
 - Prevents misfolding of DNA
 - Reduces cellular denaturation
 - Protects specific enzyme function
 - Promotes tissue vascularity

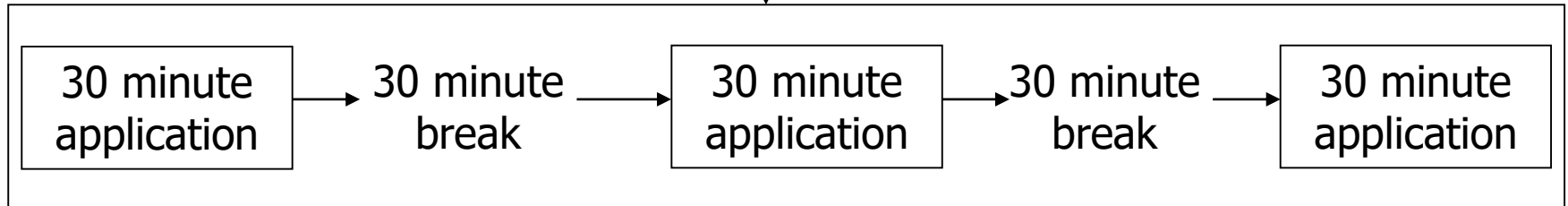


5. Harder *et al.* Ann. Surg, 2005

PATIENTS & METHODS

24 hours prior to surgery at Home

Hot water heated to 43° C and poured
into hot water bottle

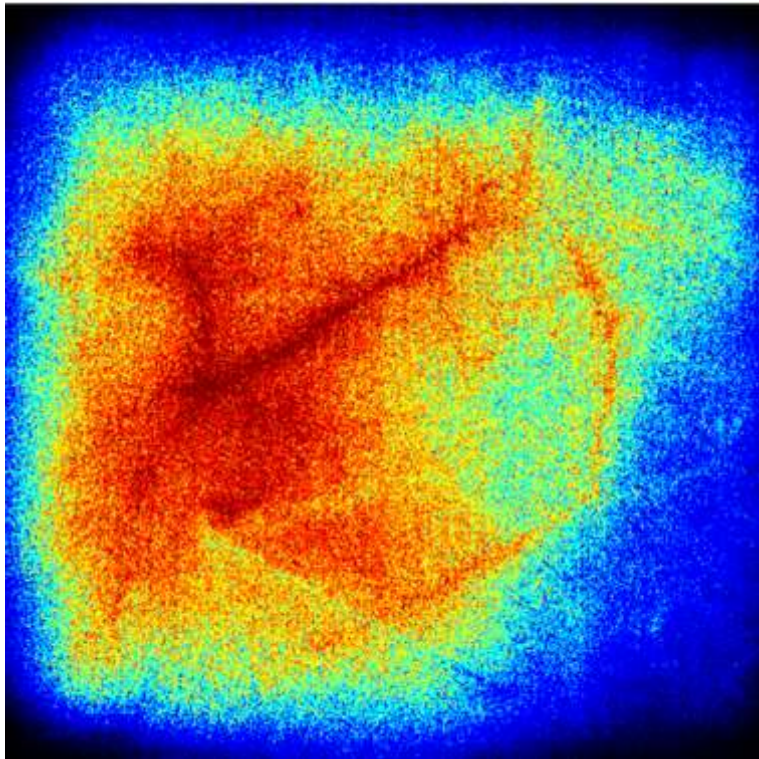


LDI Imaging

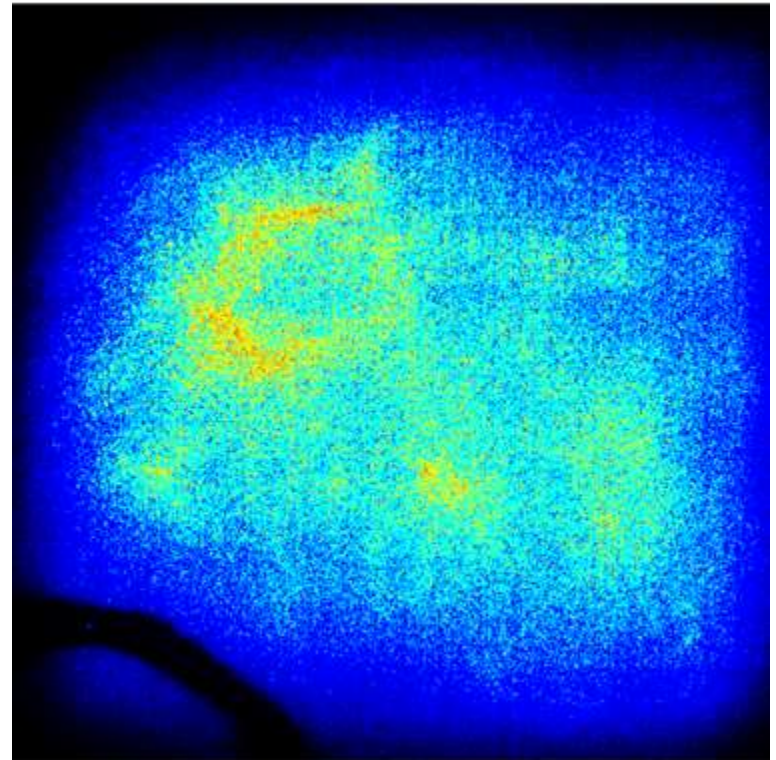


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LDI Imaging – Pre-Op 24 hours post heat preconditioning



Right Heated Breast

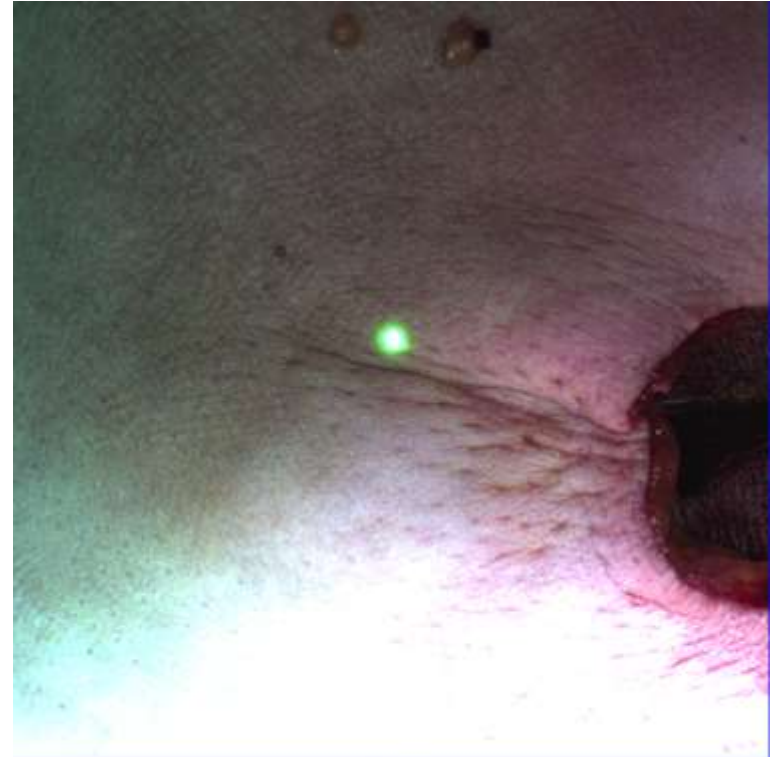


Left Control Breast

LDI Imaging – Post Mastectomy Intraoperative images

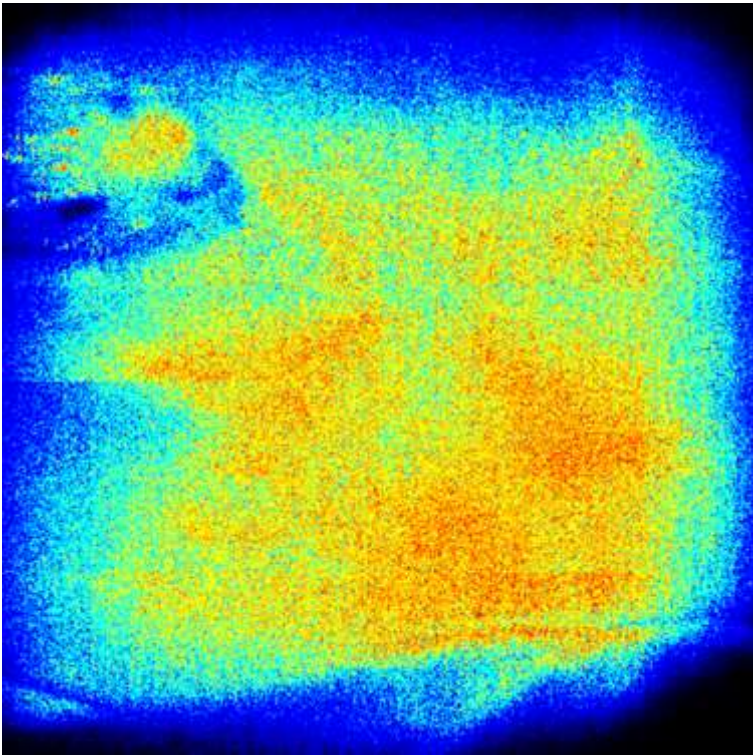


Right Heated Breast

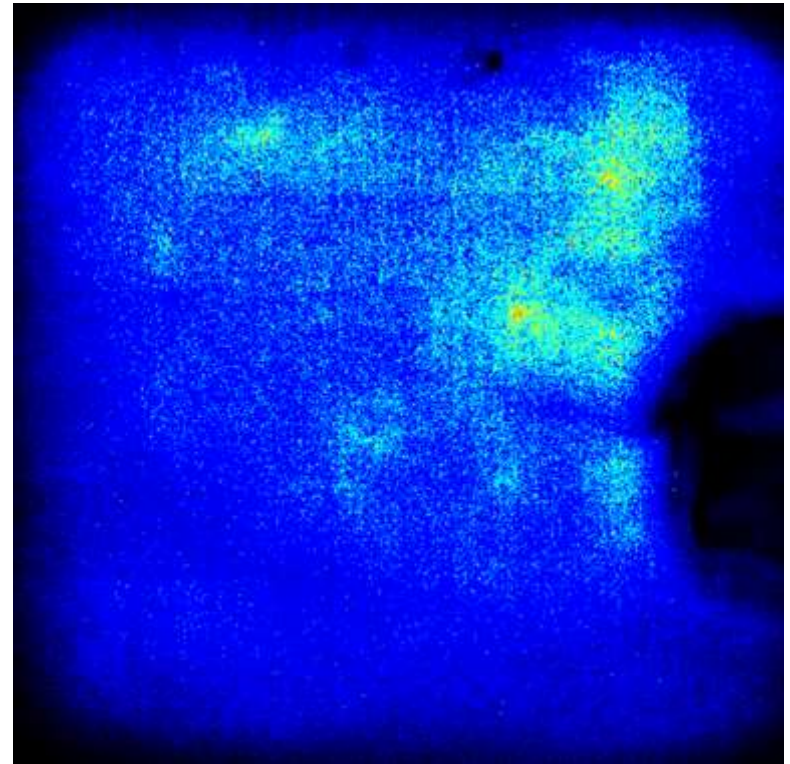


Left Control Breast

LDI Imaging – Post Mastectomy Intraoperative images

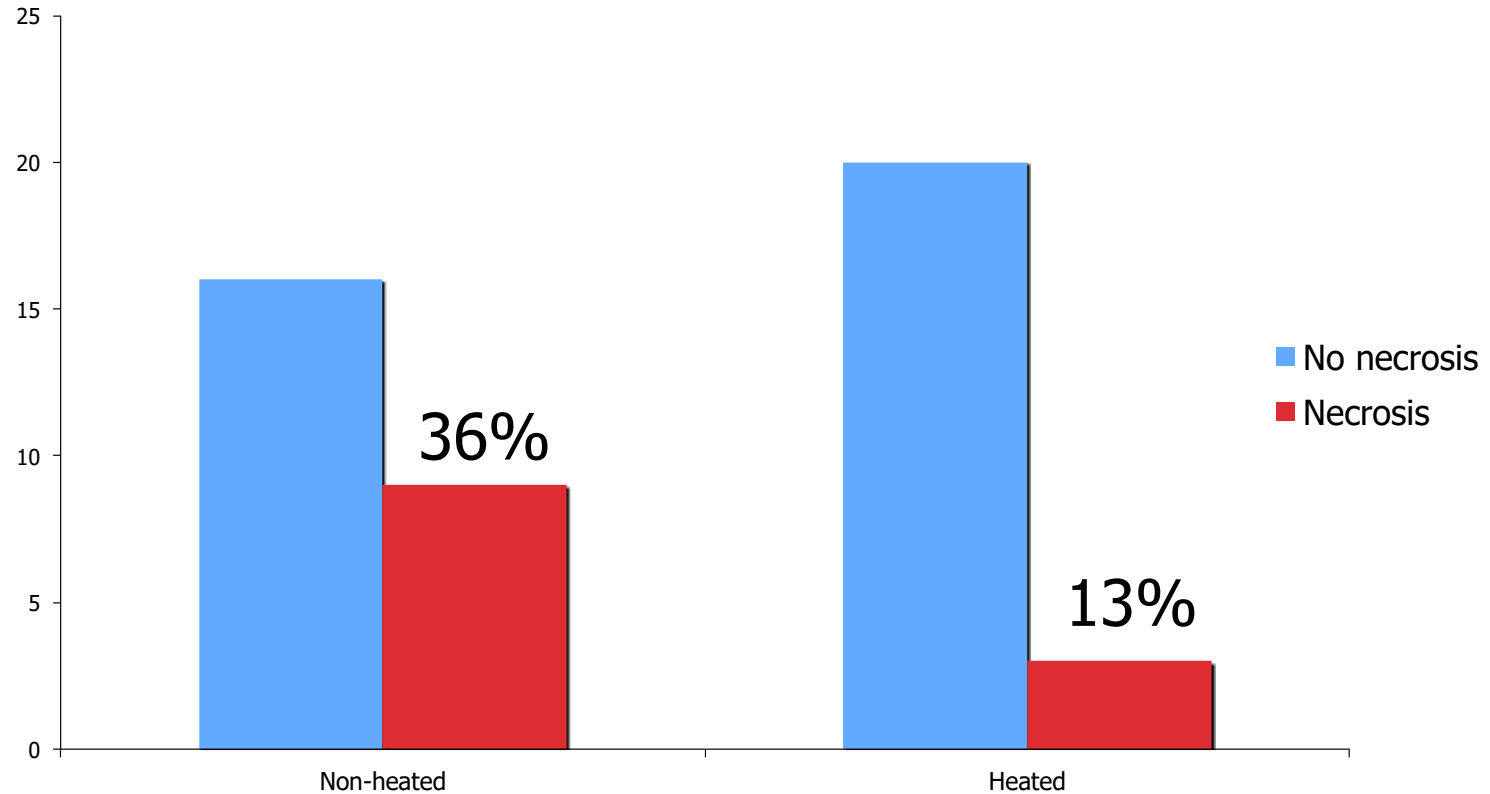


Right Heated Breast



Left Control Breast

RESULTS – skin flap necrosis



Issues

- Low quality data
- Non-randomised
- No standardisation on skin necrosis measurement
- Difficult to change practice

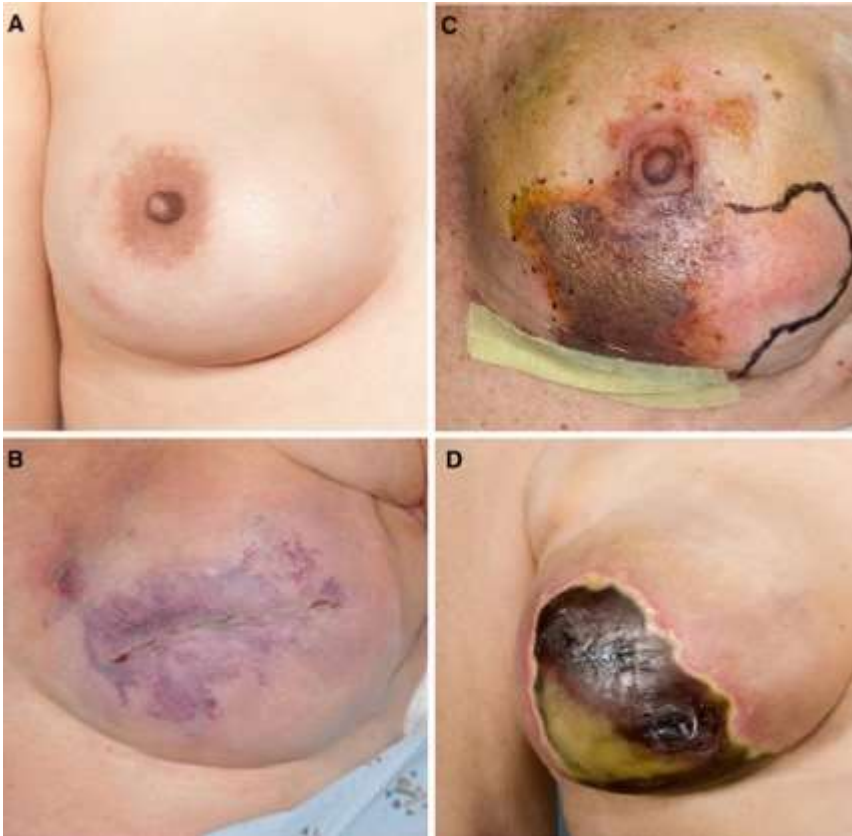
preHEAT

- NIHR RfPB funding £216,533
- Randomised-control prospective study using hot water bottles
- Feasibility trial
- 180 patients
- 3-years
- Inclusion – all patients undergoing immediate breast reconstruction
- Develop robust protocol for definitive multicentre trial

Measuring necrosis

- “Yes/No” binary assessment of necrosis
 - Superficial/Partial/Full-thickness
- SKIN Score
- Area of necrosis using transparent grid

SKIN Score



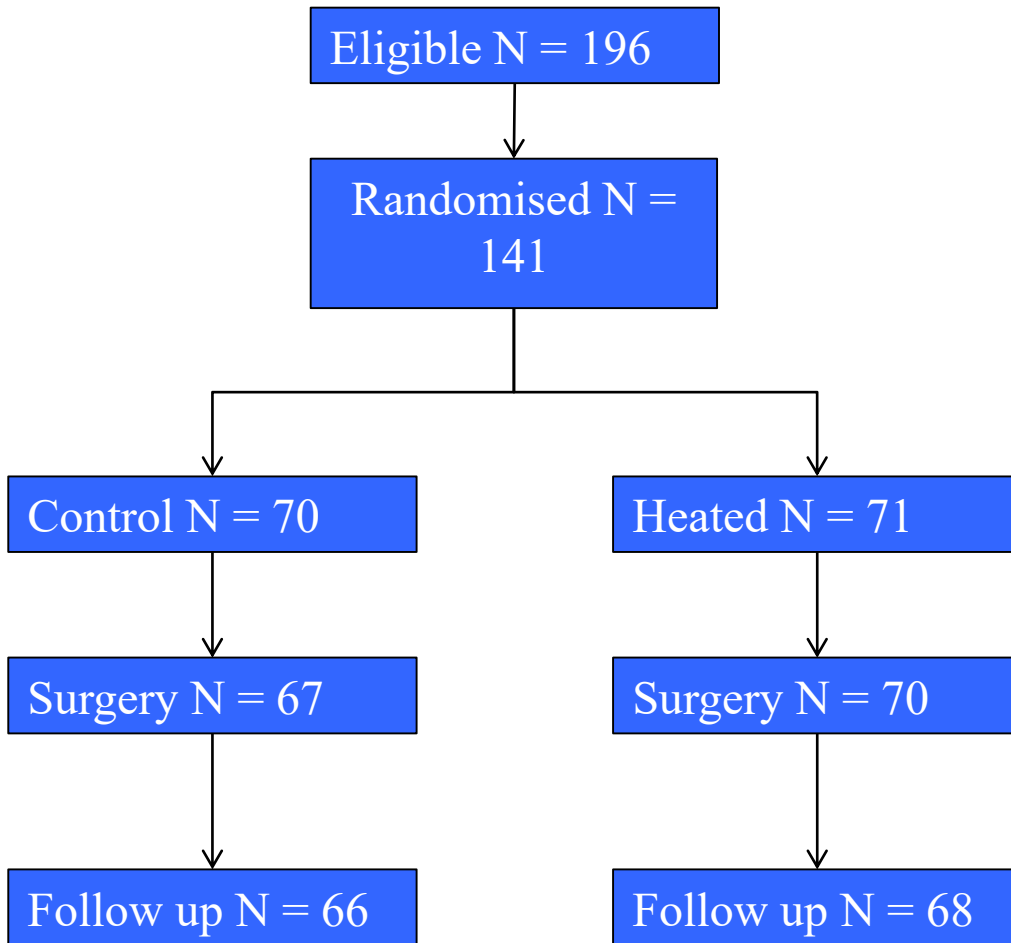
- Developed at Mayo Clinic
- Correlates with reoperations
- Reproducible
- Combined with area

Closed envelope system

- Good adherence – both staff and patients
- Simple
- Cost effective
- Reliable



RESULTS



Recruitment rate
72%

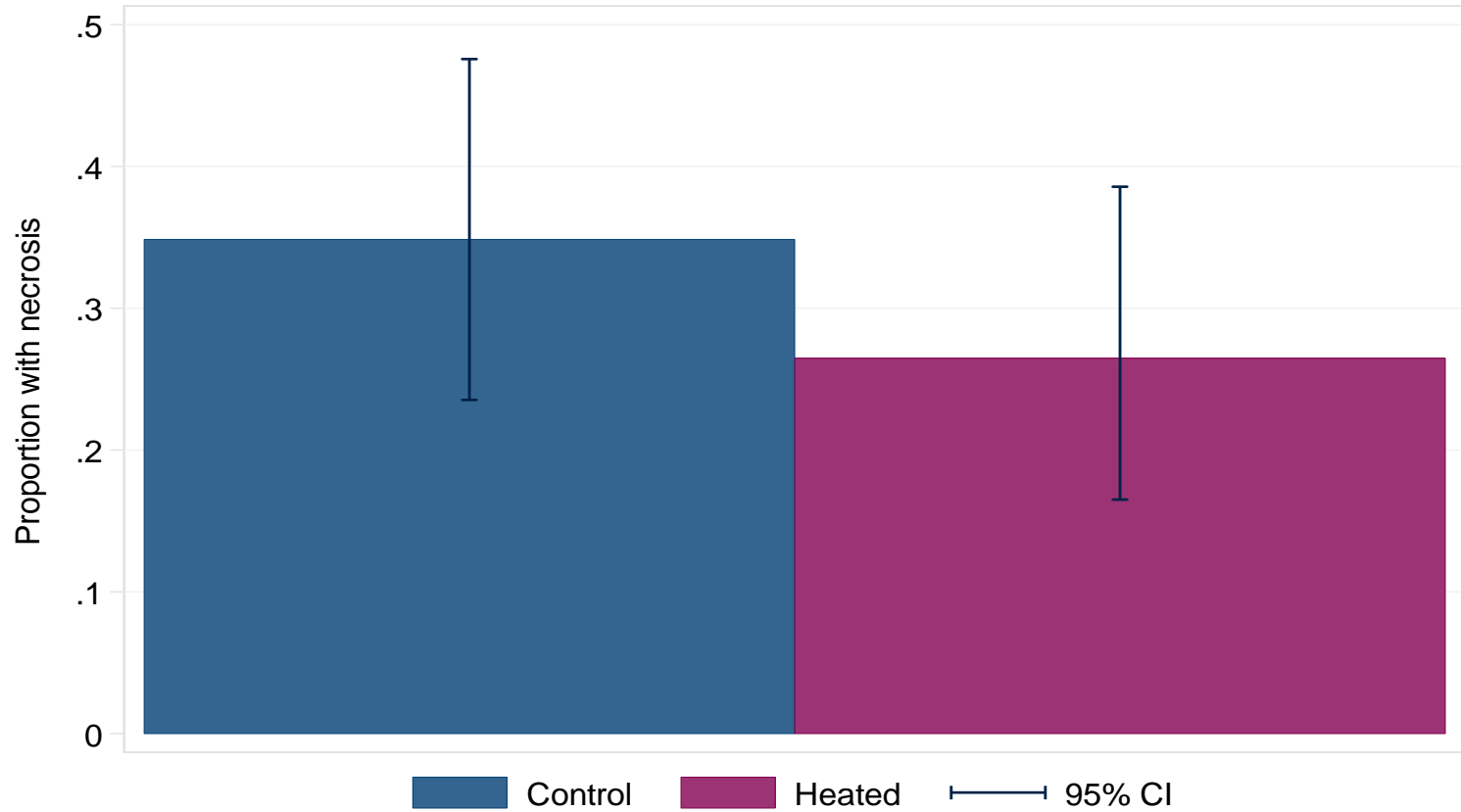
Adherence rate
76%

Follow up rate
98%

RESULTS

Criteria	Yes/No	SKIN Score	Wound Area
Kappa stat	0.84	0.79	0.57
Sample size for multicentre RCT	1096	1556	2866

RESULTS



Challenges

- Data collection
 - Doctors!!
- Human resource
 - Portfolio trial
 - CRN support?

Conclusions

- Feasible & safe trial
- Yes/No assessment of necrosis primary outcome
 - Secondary outcome – need for surgery
- Blinding closed envelope system works
- Keep things simple
- Move forward with HTA NIHR grant application

