SINGLE-PASS MICROKERATOME SYSTEM FOR EYE-BANK DSAEK TISSUE PREPARATION: IS STROMAL BED THICKNESS PREDICTABLE AND REPRODUCIBLE?

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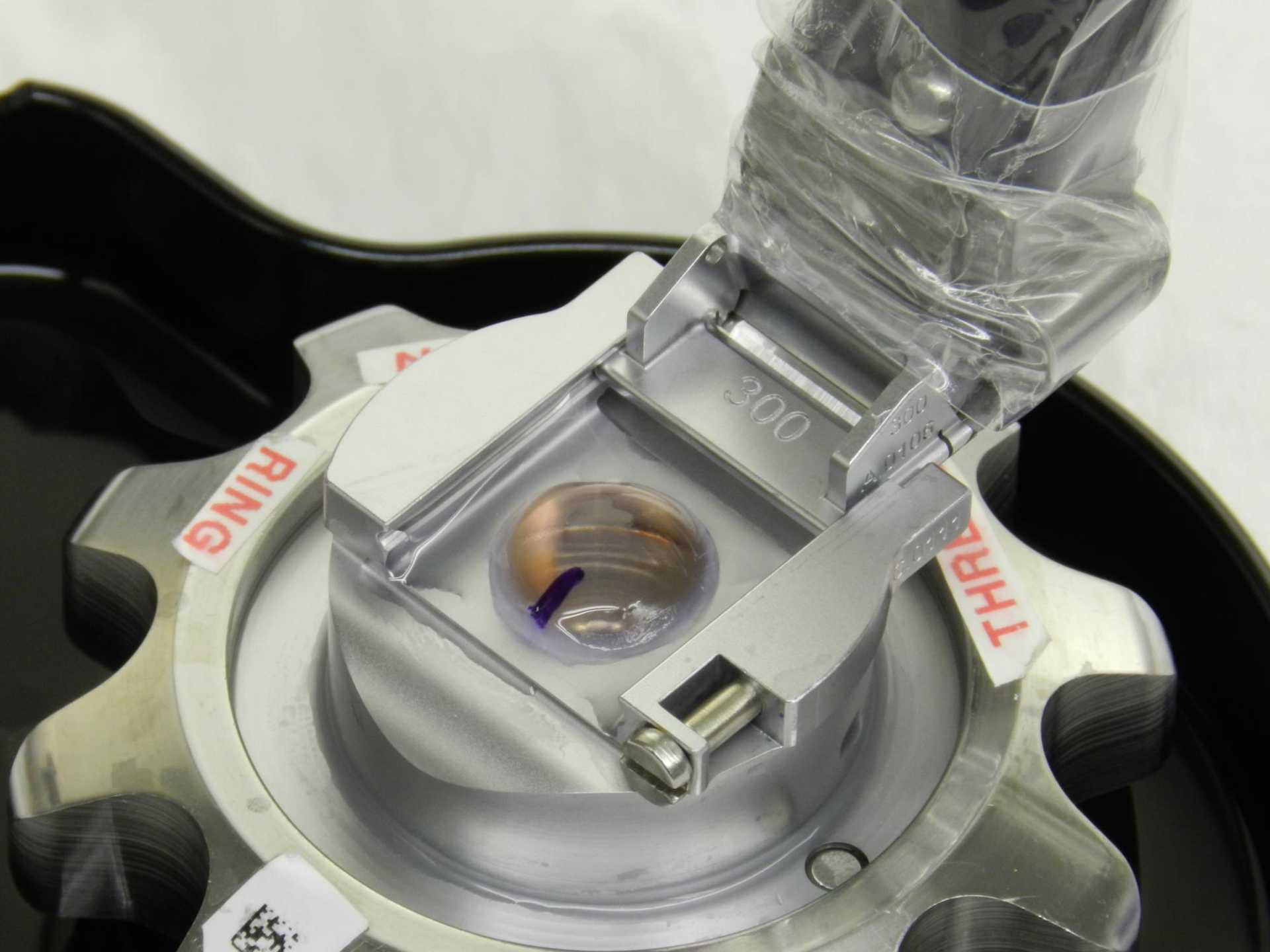
Sierra Donor Services
an extraordinary commitment to science, health and hope
A Division of DCI Donor Services

Financial disclosure

- No financial interest

Introduction

- 2006: eye banks began supplying DSAEK tissue
- Preparation increases OR efficiency and ensures tissue quality
- Sierra Donor Services uses Med-Logics (Med-Logics Inc, Athens, USA)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Introduction

- 2006: eye banks began supplying DSAEK tissue
- Preparation increases OR efficiency and ensures tissue quality
- Sierra Donor Services uses Med-Logics (Med-Logics Inc, Athens, USA)
- Most published data is with Moria (Moria International, Antony, France)

Purpose

- To evaluate the predictability and reproducibility of stromal bed thickness
- Using the ML7 Microkeratome Donor Cornea System manufactured by Med-logics, Inc (TX, USA)
- Single-pass donor DSAEK tissue preparation

The 3 questions:

1. Can this MK system cut tissue reliably?
2. Is this system safe in terms of tissue loss?
3. Is this system safe in terms of ECC?

Material and Methods

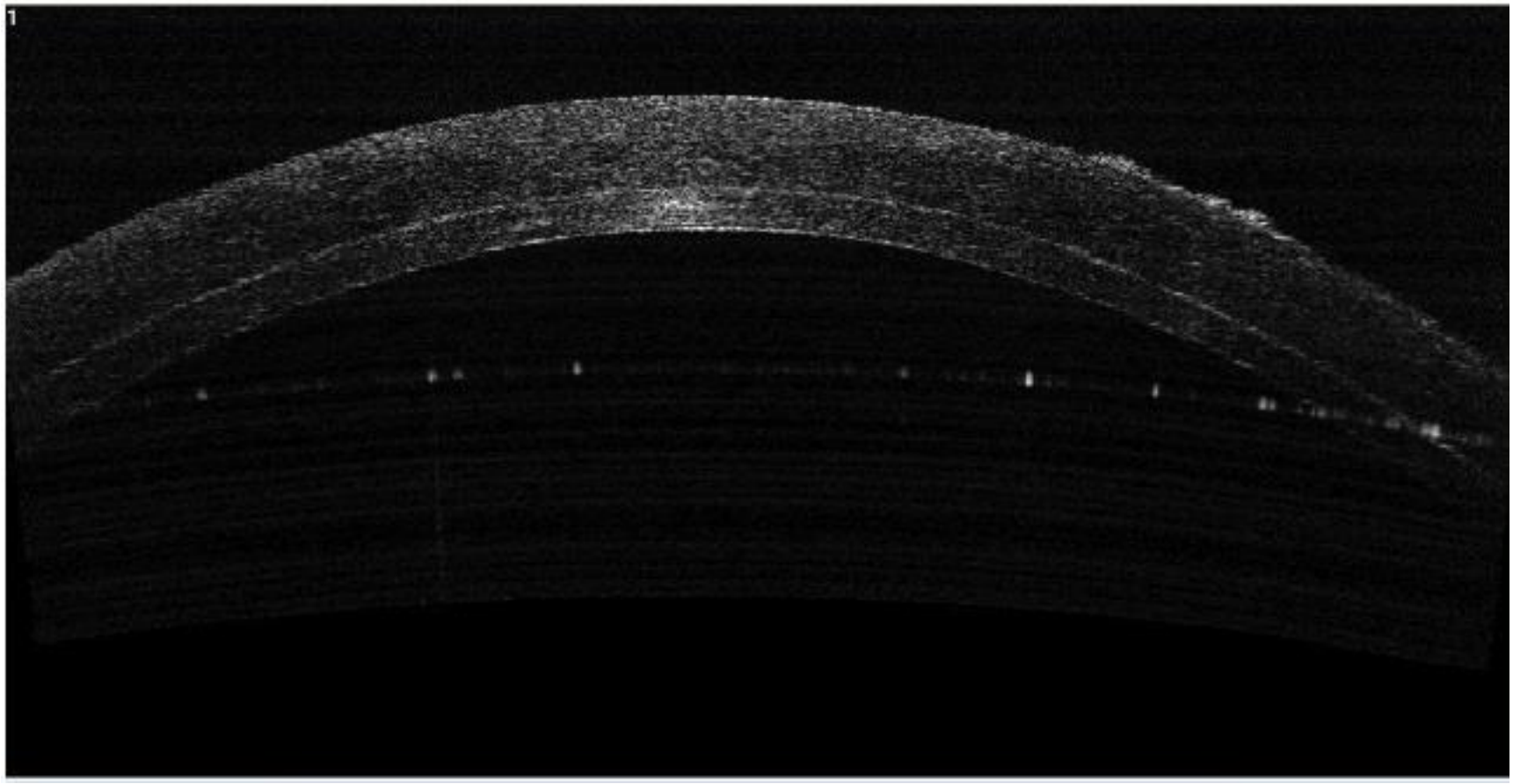
- Retrospective chart review
- 256 consecutive corneal tissue preparations
- June 2013 to August 2014
- Sierra Donor Services

Surgeon thickness preference

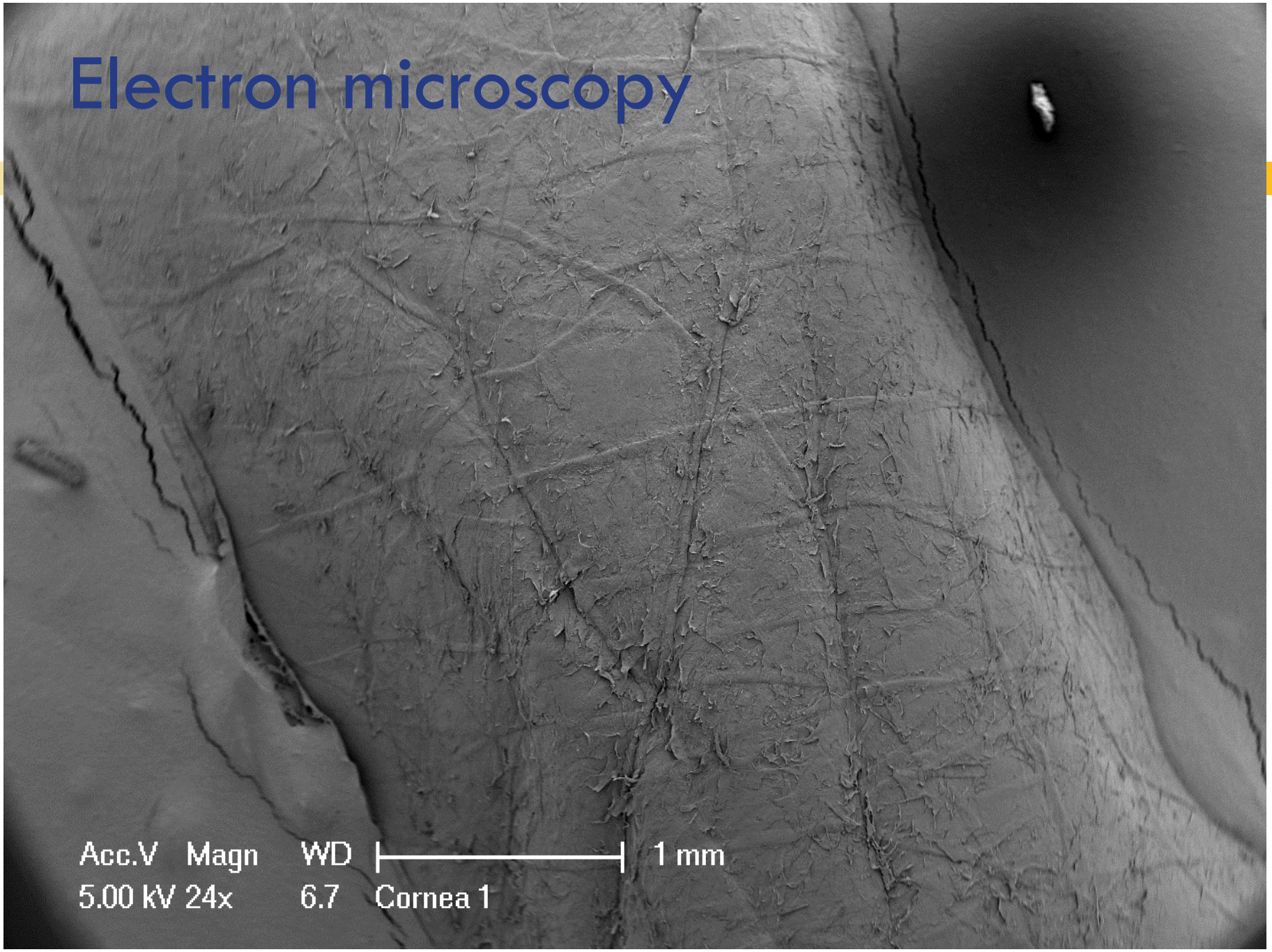
<91µm	•Group A
90-120µm	•Group B
120-160µm	•Group C

Results

Post-cut Anterior Segment OCT



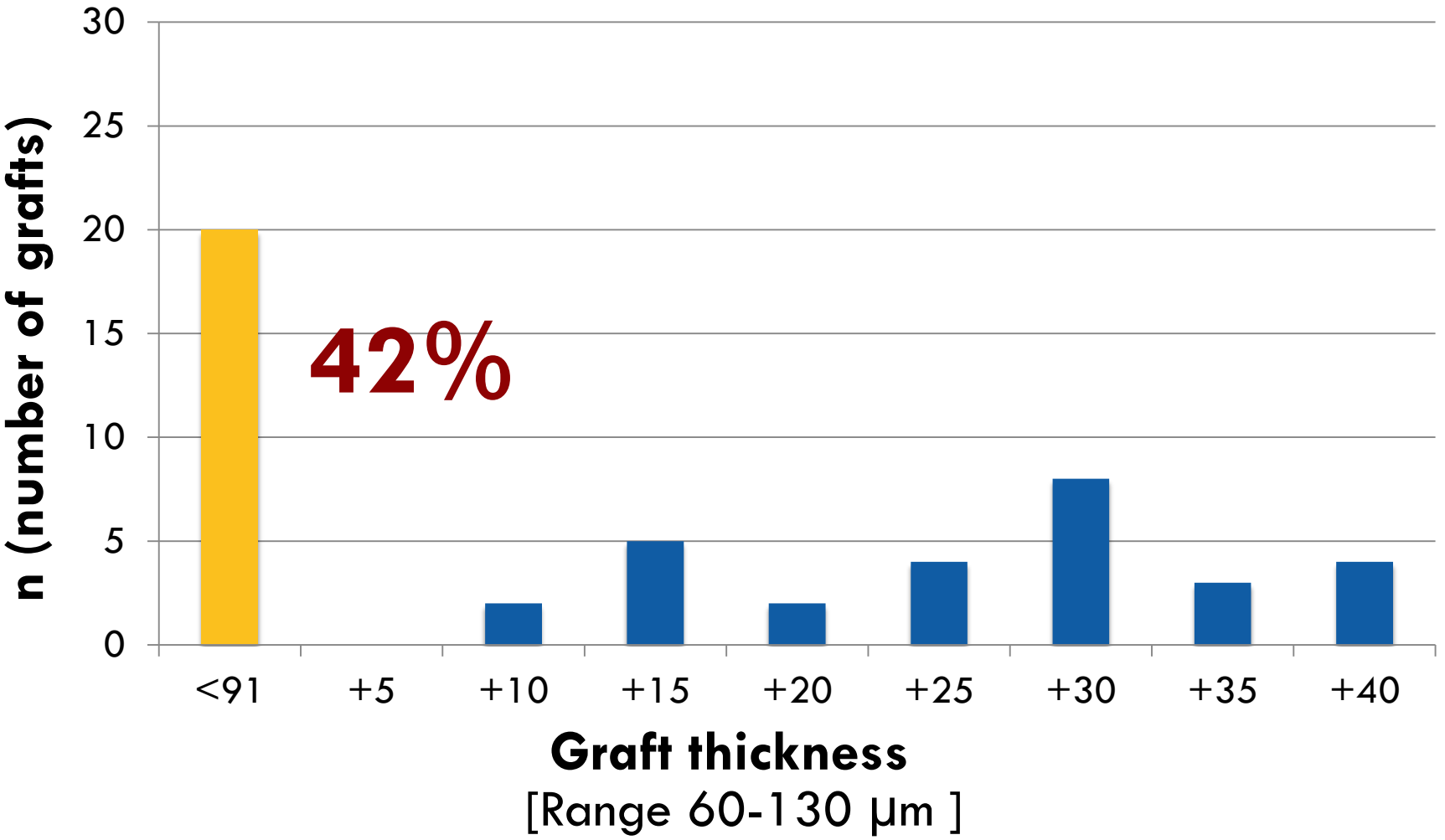
Electron microscopy



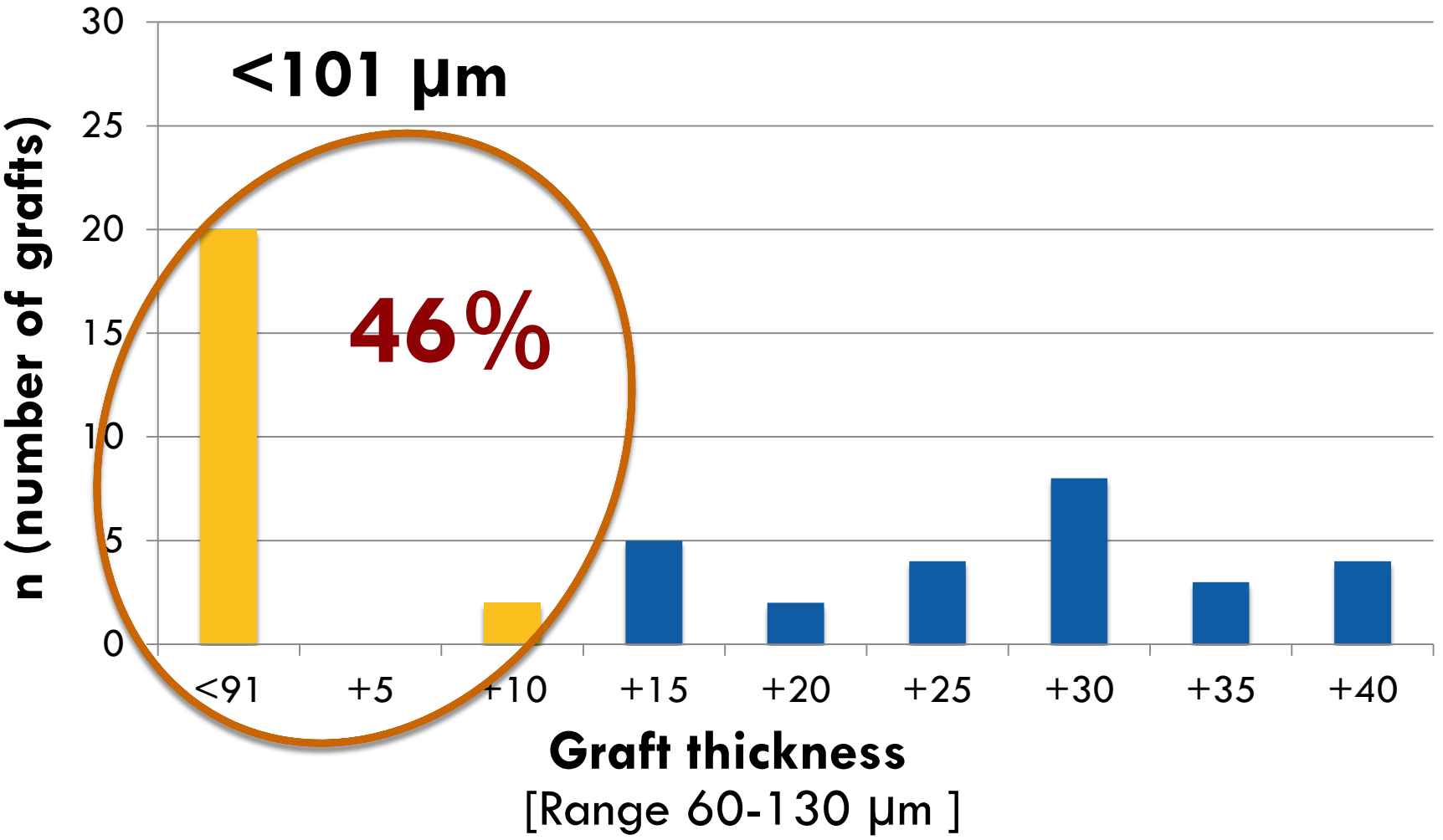
Graft thickness

Average thickness	Total (A+B+C) n = 249	A (<91) n = 48	B (90-120) n = 152	C (120-160) n = 49
Precut cornea in µm	514±71 (364-648)	515±59 (418-628)	514±80 (364-648)	518±43 (424-612)
Postcut graft in µm	114±30 (60-183)	97±23 (60-128)	113±21 (77-179)	134±43 (89-183)

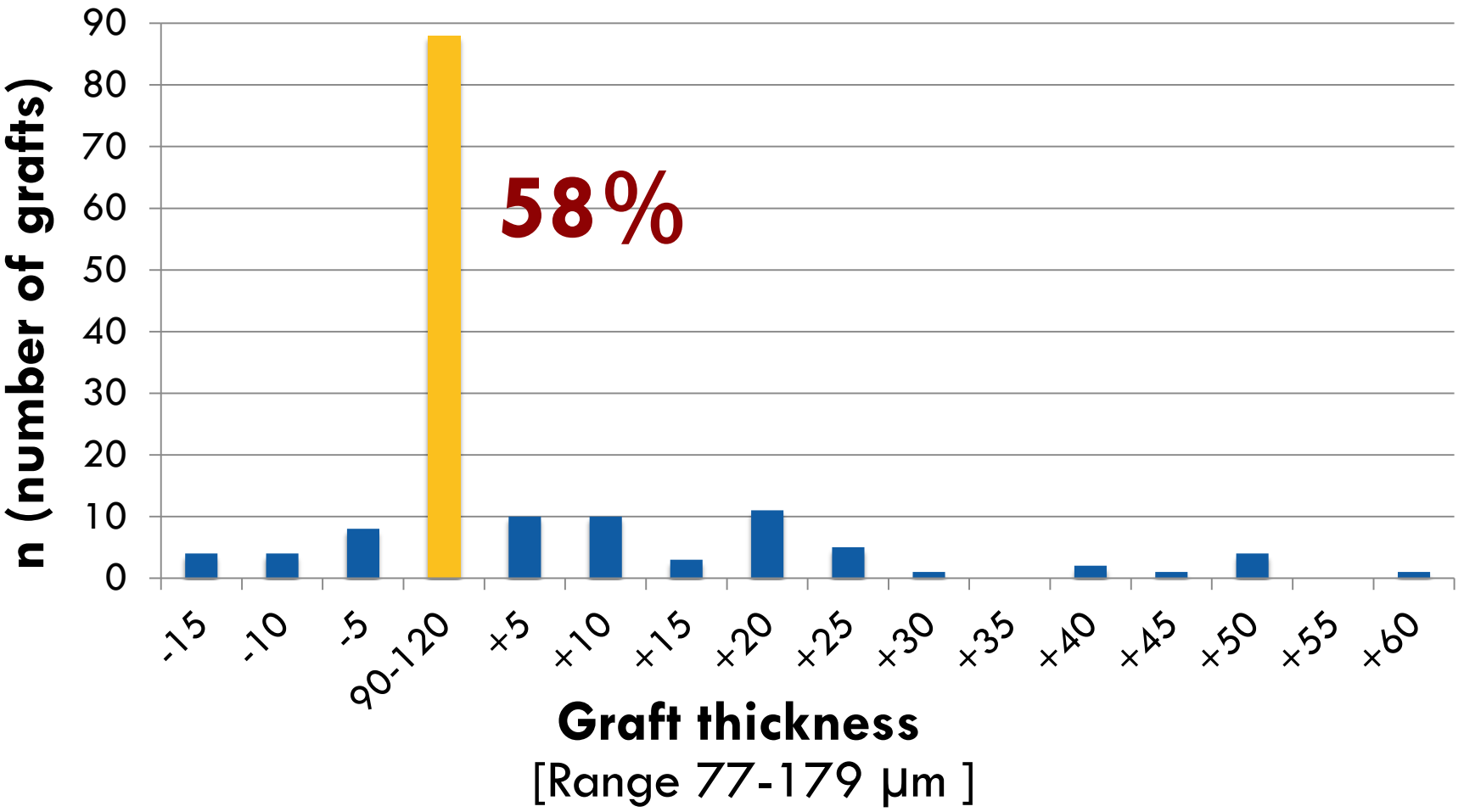
Group A – Number of grafts in target range (<91 microns)



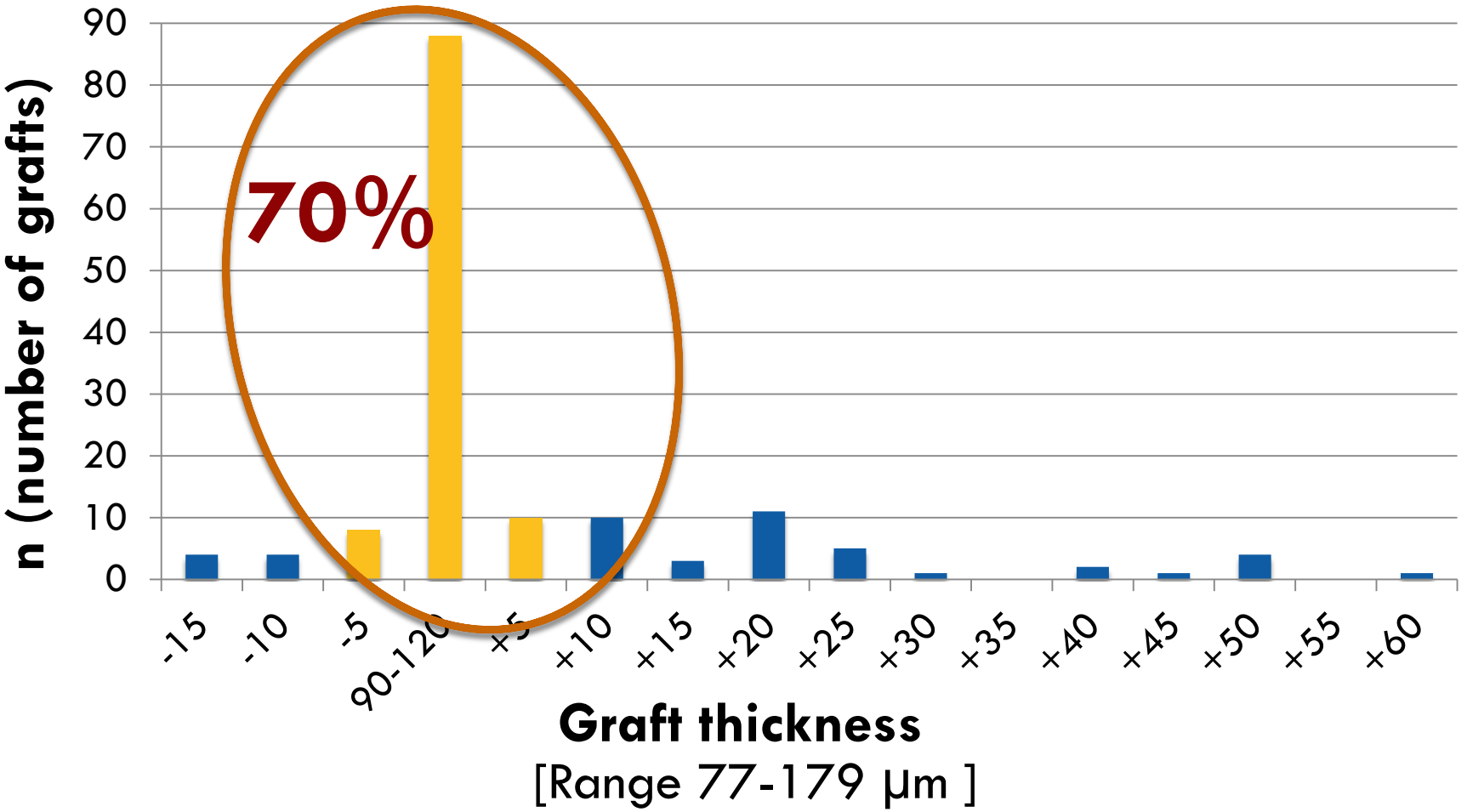
Group A – Number of grafts in target range (<91 microns)



Group B – Number of grafts in target range (90-120 microns)



Group B – Number of grafts in target range (90-120 microns)



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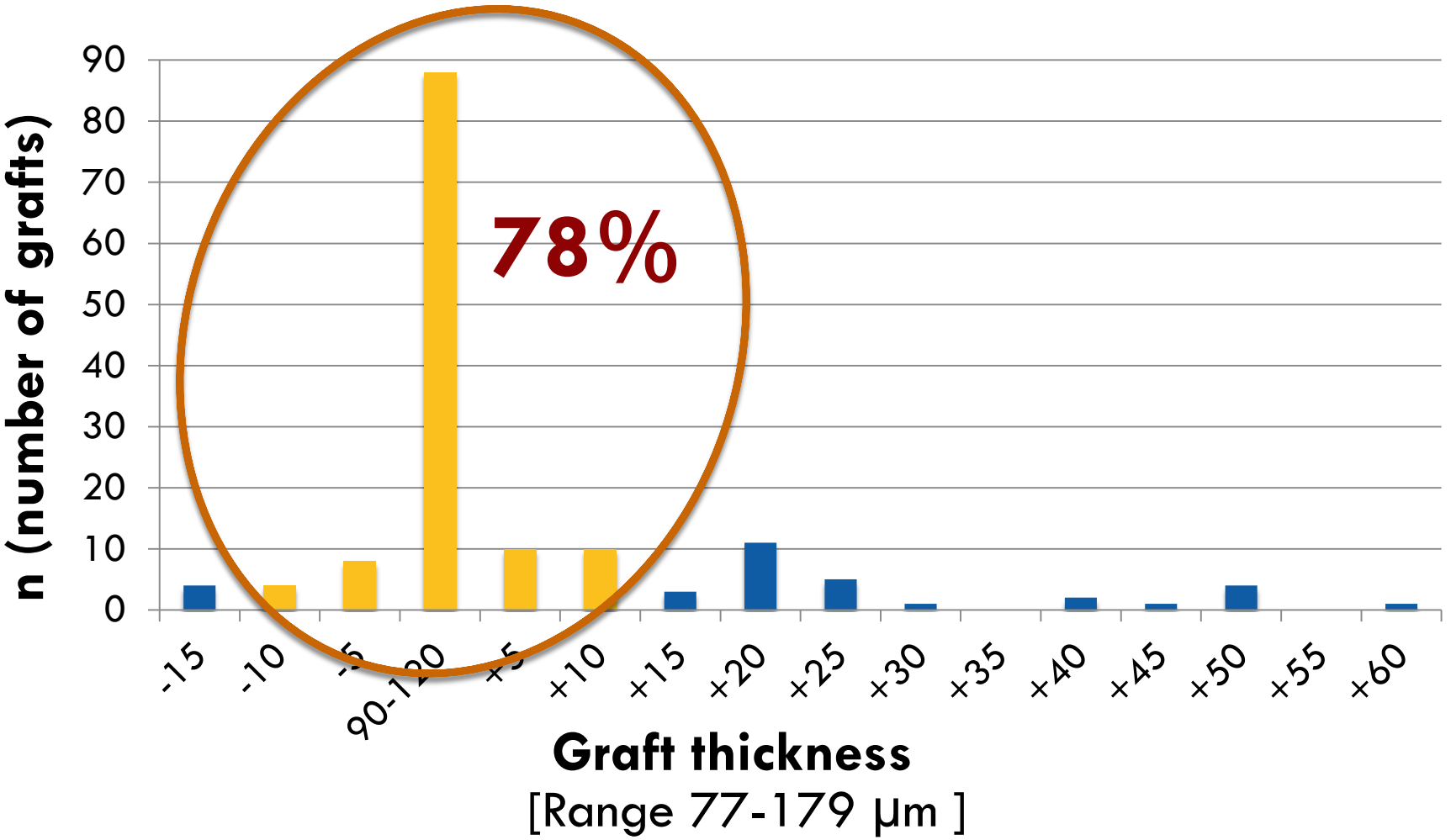
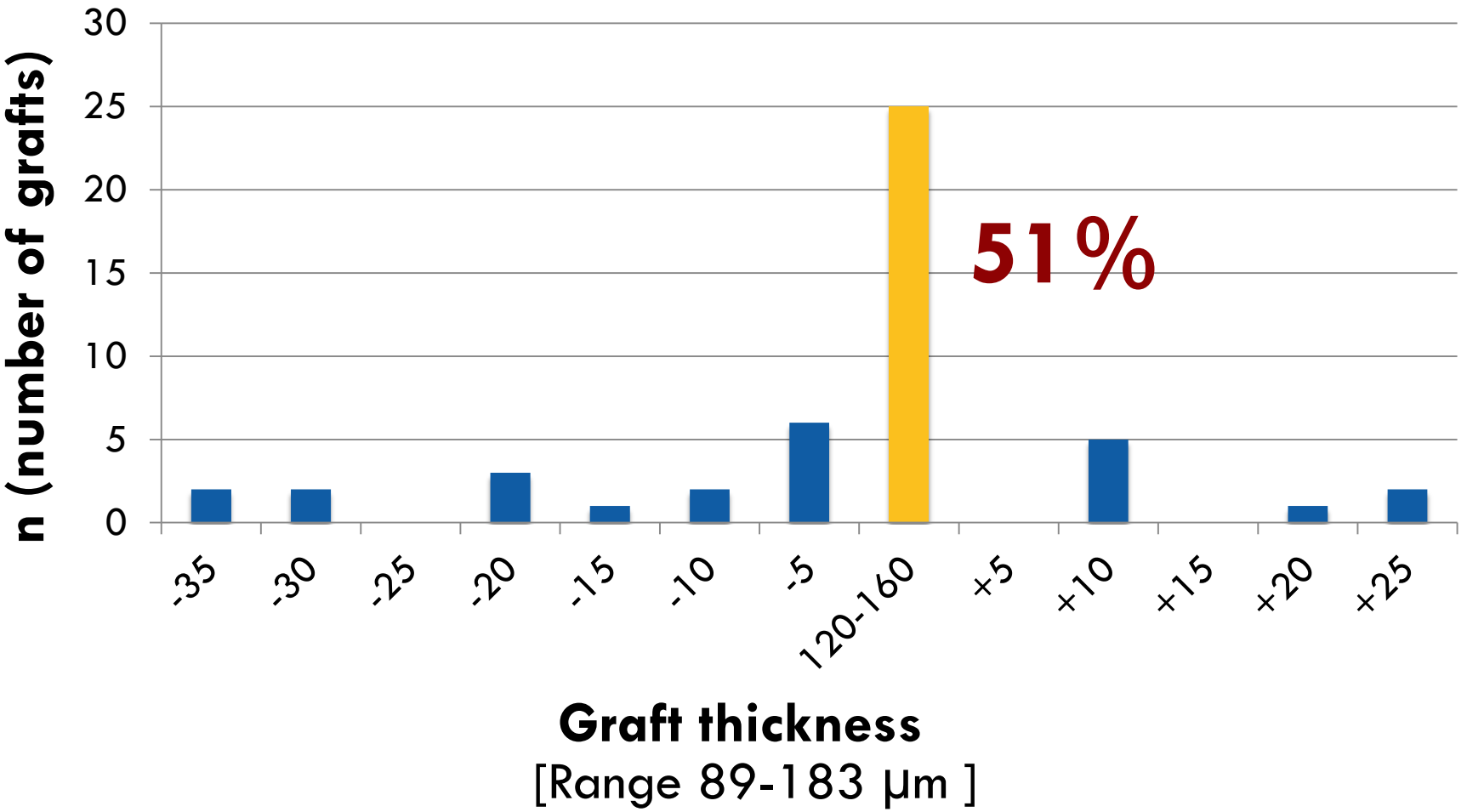


Group C – Number of grafts in target range (120-160 microns)



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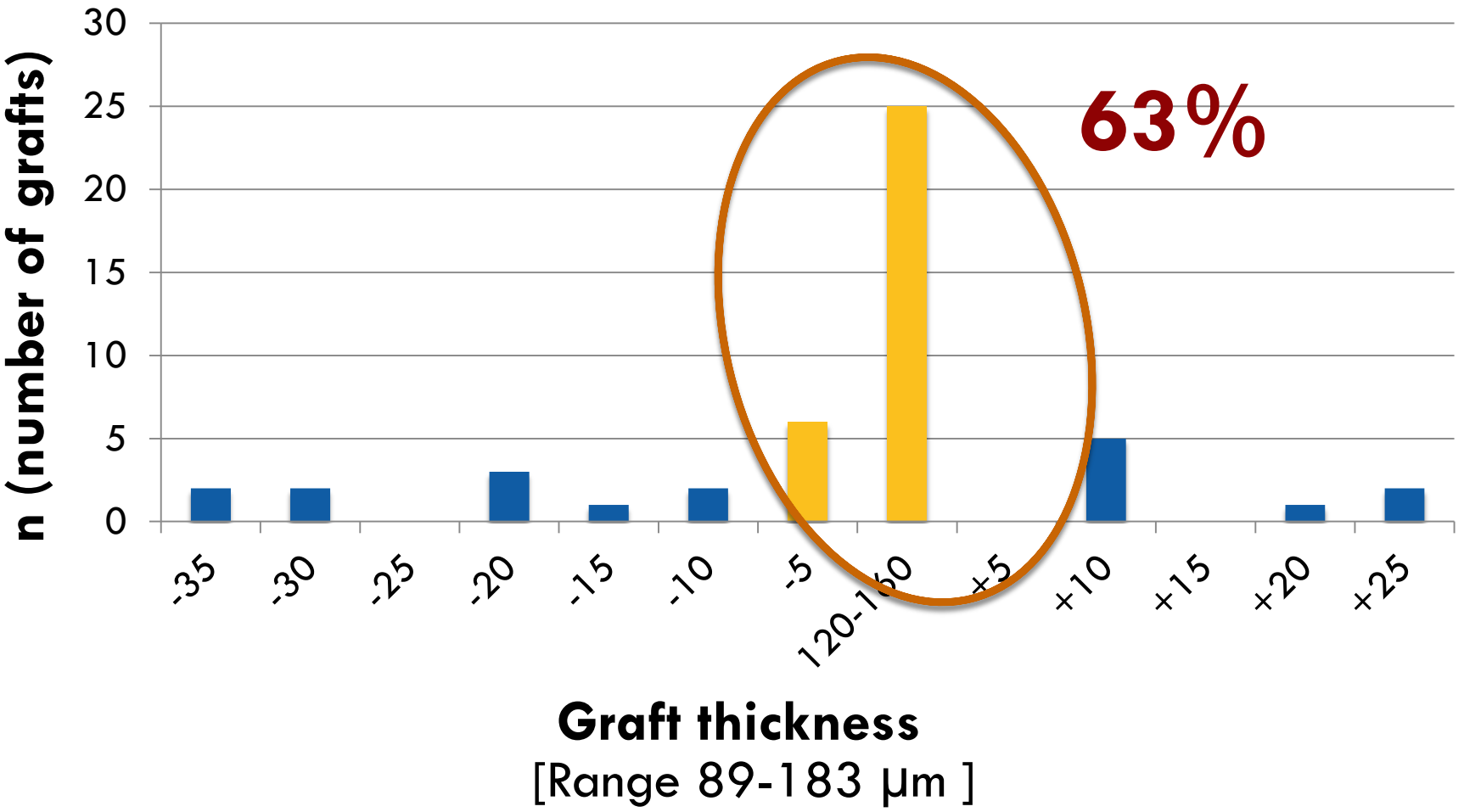

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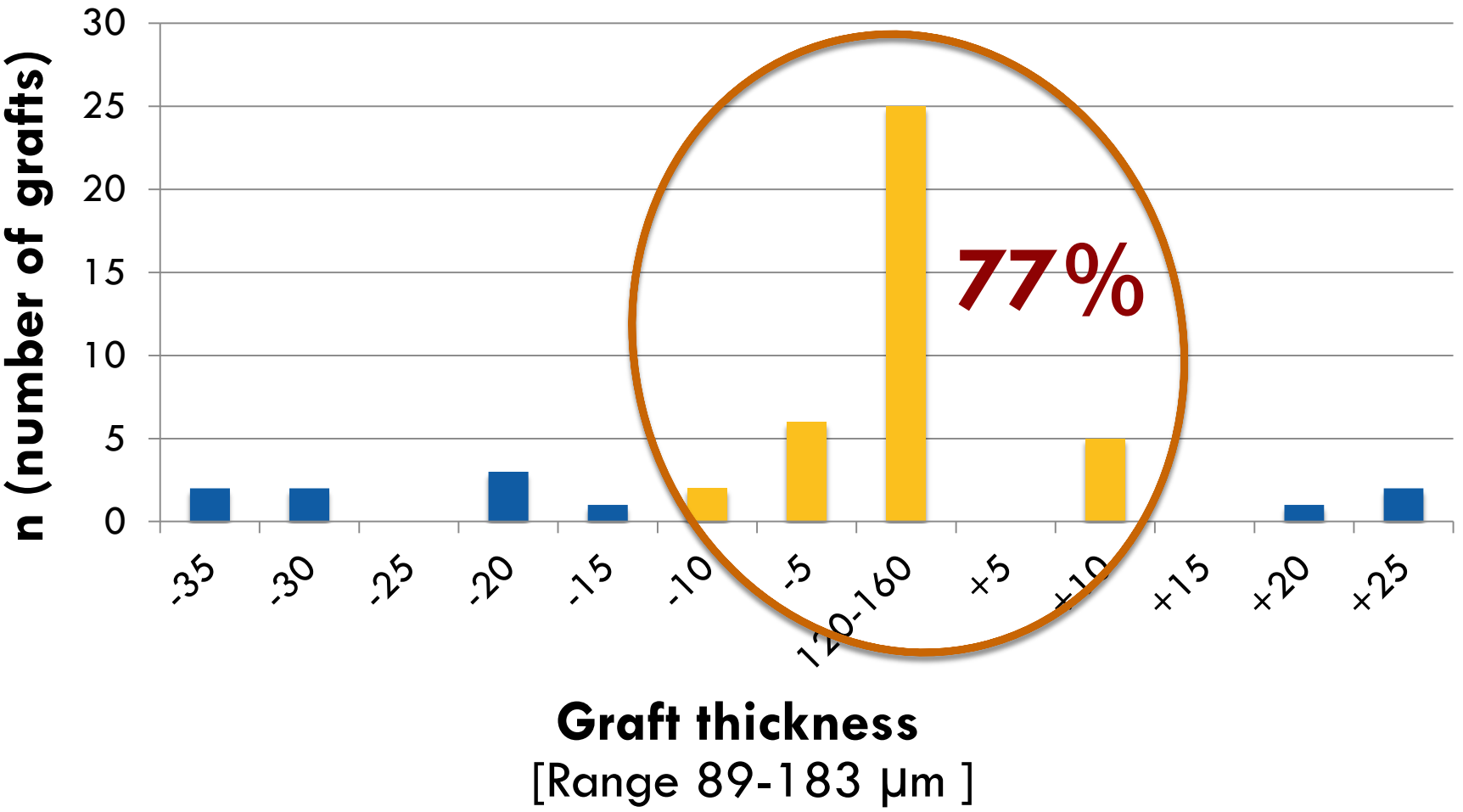


Tissue loss and disqualification

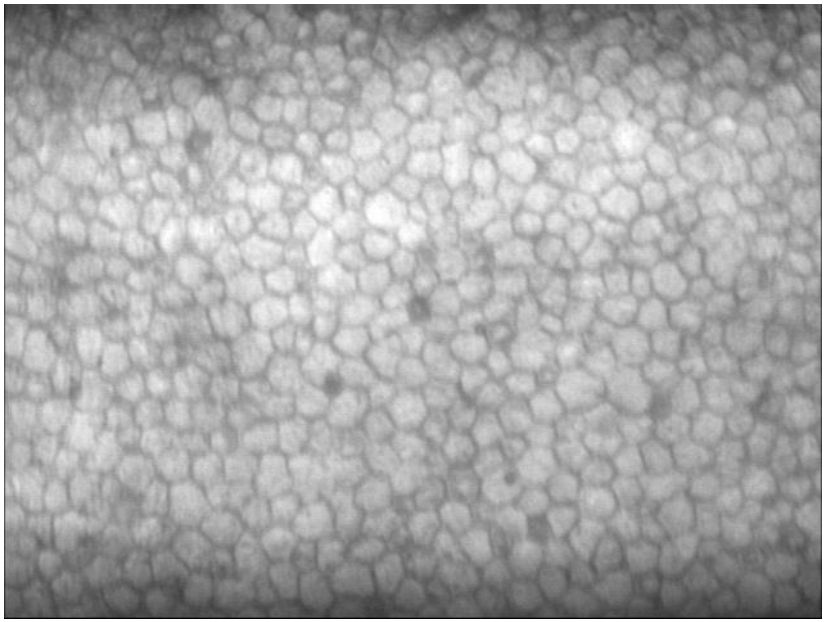
Tissue loss and disqualification

A	3	2 in first 11 cuts
B	4	2 in first 42 cuts
C	0	0

Tissue disqualification

- Total of 7 failed procedures
  - 2,7% of all attempts
- Of which: 4 in first 53 attempted procedures
- After learning curve adjustment:
  - 1,5% in the last 200 attempts

Endothelial cell count



Endothelial cell count

Average ECC	Total (A+B+C) n = 249	A (<91) n = 48	B (91-120) n = 152	C (121-160) n = 49
Precut ECC	2955±224 (2786-3484)	2945±190 (2825-3413)	2962±241 (2273-3484)	2938±199 (2632-3401)
Postcut ECC	3013±250 (2252-4053)	3028±262 (2667-4063)	3014±256 (2252-3778)	2981±207 (2646-3460)

Discussion

Question 1:

Can this system cut

donor tissue reliably?

Cutting reliability

- Average cut 114±30µm
  - Most studies: average varies 145µm and 199µm[1,2,3,4,5,6,7]
  - UT-DSAEK specific studies:
    - Busin M, et al. (2013)[8]:
      - 100% <151µm
      - 95,6% <131µm
      - 78,3% <101µm

      Discarded tissue rate = 2,1%
    - Woodward MA, et al. (2014)[9]:
      - 65% <101µm

      Perforation tissue rate = 23-29%

Question 2:
Is this system safe
in terms of
Tissue disqualification?

Tissue disqualification

- Overall discarded tissue rate = 2,7%
- Last 200 procedures = 1,5%

  - Kanavi MR, et al. (2014)[10]: 2,6%
  - Kelliher C, et al. (2009)[2]: 1,5% (5%→0,5%)
  - Chen ES, et al. (2008)[11]: 2,5%

Question 3:
Is this system safe in terms of **Endothelial Cell Count?**

Endothelial cell count

- Average post-cut ECC = 3013 ± 250 cell/mm^2
  - 66%: higher ECC after cutting process
  - Kelliher C, et al. (2009)[2]: 66,8% increase in post-cut ECC
    - ? Bias before or after cutting
      - Descemet folds
      - Sampling error

Conclusion

Conclusion

- The ML7 Microkeratome Donor Cornea System manufactured by Med-logics, Inc (TX, USA) allows for single-pass donor DSAEK tissue preparation
  - Comparable to other MK systems

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Questions?