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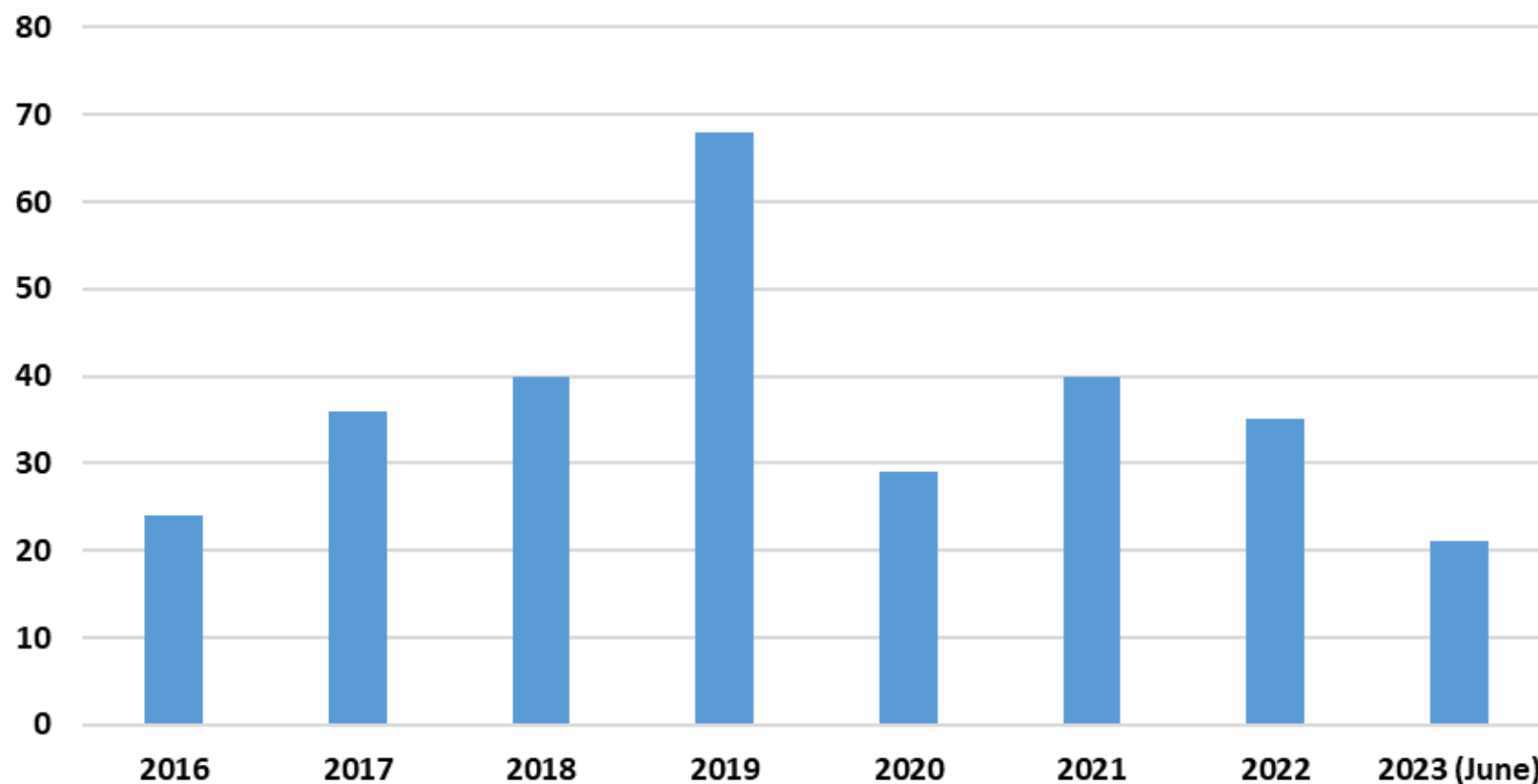
**OTAG 13/09/2023**  
**Clinical Governance Report**  
**2022/2023**

Ulrike Paulus, NHSBT/OTDT

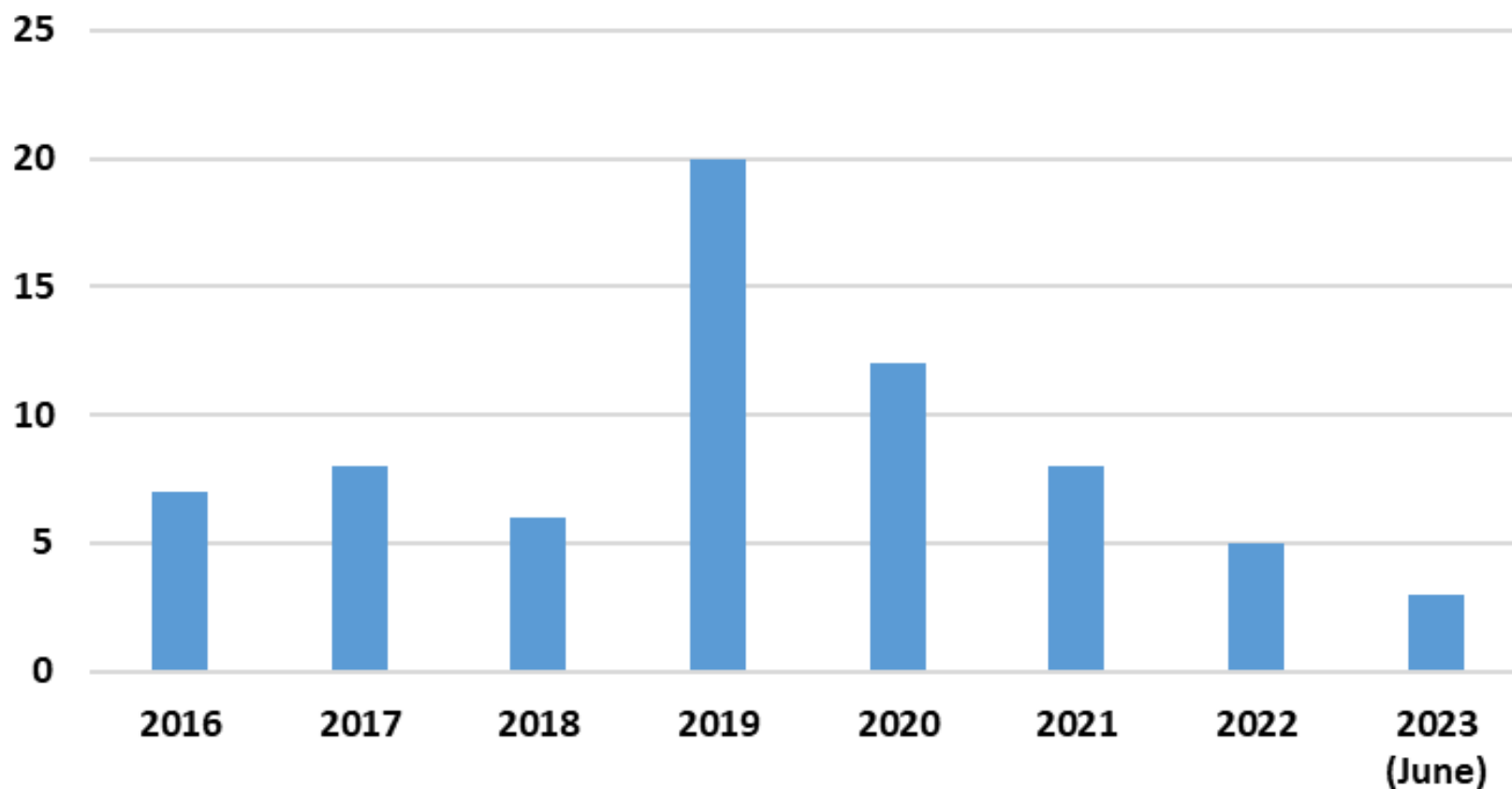
# Content

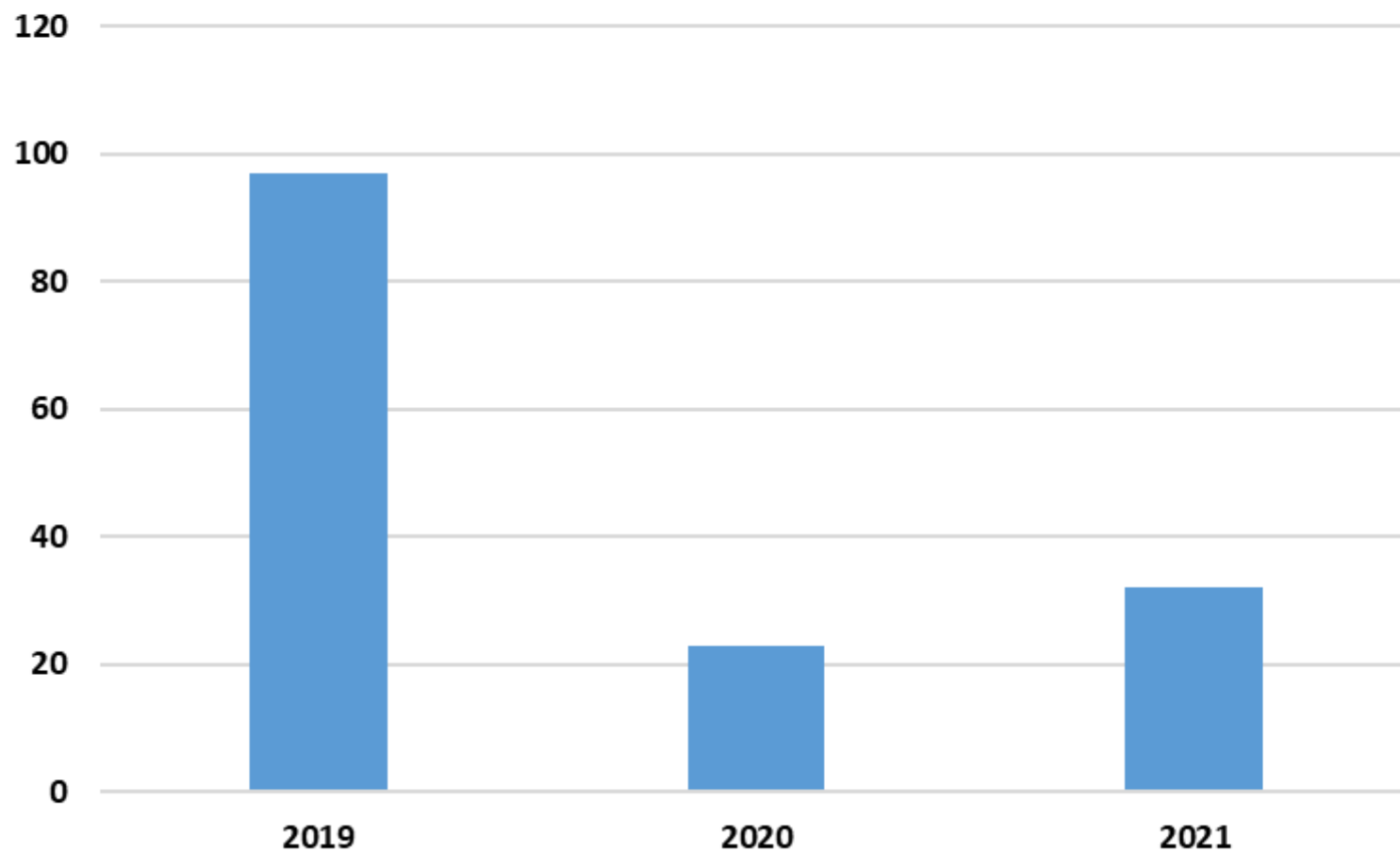
1. Overview – SAEARs, trends 2016 – 2023 (June)
2. Pre-cut service
3. General developments

### All reports of adverse events and reactions 2016 - 2023 (June)



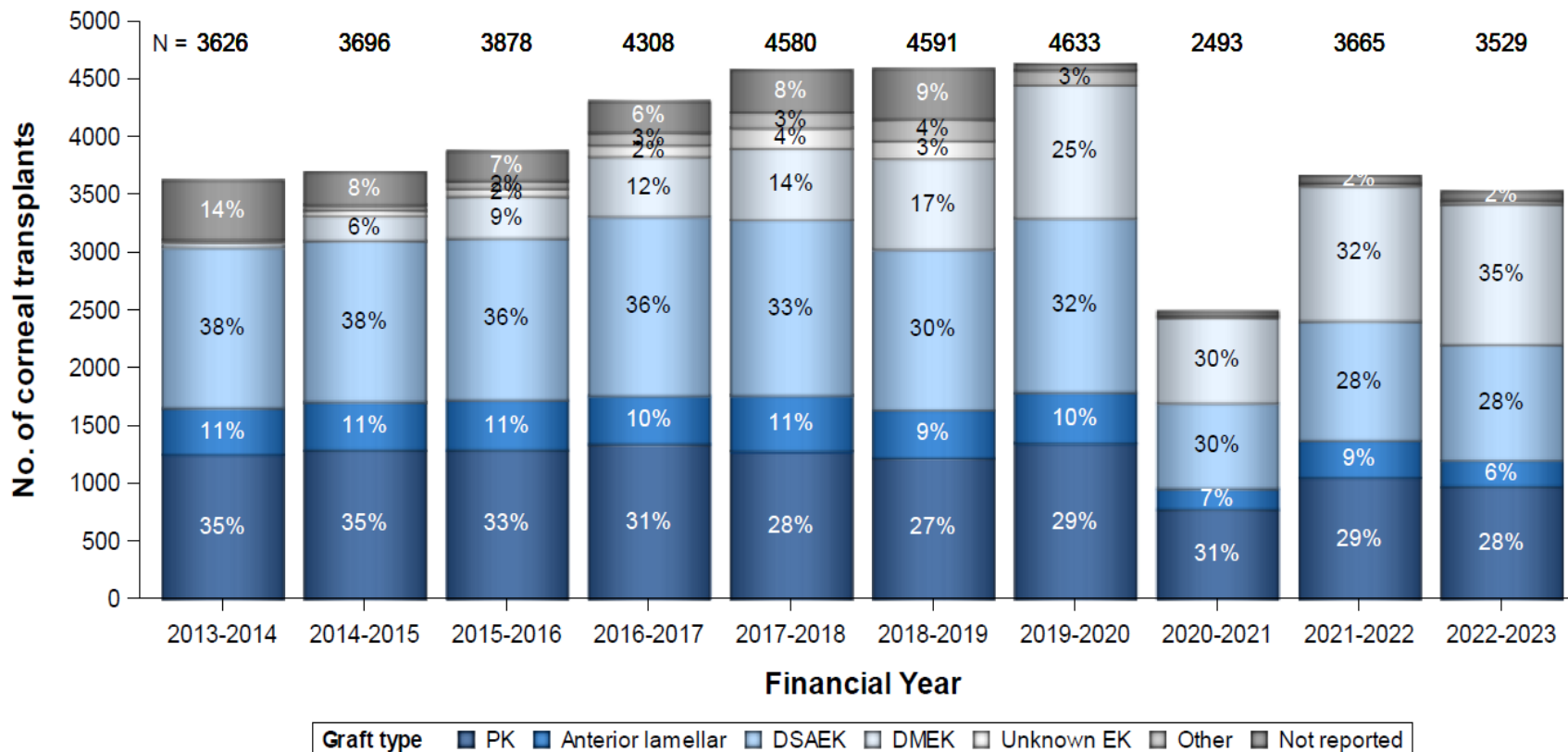
### Graft failure trends 2016 - 2023 (June)



**PGF reported to registry**

# Update : DMEK and donor DM *Blood and Transplant*

Figure 10.3 Number of corneal transplants in the UK by graft type, 1 April 2013 - 31 March 2023



Between April 2013 to March 2019, unknown EK grafts have been imputed such that historic grafts and grafts by surgeons that have never reported a DMEK transplant are assumed to be DSAEK transplants

Taken from Cornea Activity report, 2023: <https://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/>

# 2022 - June 2023: DMEK grafts, SAEARs and donor DM

<b>All grafts</b>	<b>5000+ (estimate)</b>
<b>DMEK grafts</b>	<b>1500+ (estimate)</b>
<b>All SAEARs</b>	<b>56</b>
<b>DMEK related SAEARs</b>	<b>28/56</b>
<b>DMEK preparation problems</b>	<b>16/28</b>
<b>Donor DM identified</b>	<b>7/16</b>

# NHSBT service for pre-cut tissue for DS(A)EK

- July 2019: Transfer of pre-cutting service from Manchester to Filton eye bank
- Since then two suspensions of service, followed by process modifications:
  - - routine post-cut pachymetry
  - - **routine OCT imaging of pre-cut grafts**
- **audit** of initial 30 grafts (1 week, 1 month, 3 months), commenced Dec 2022, completed spring/summer 2023



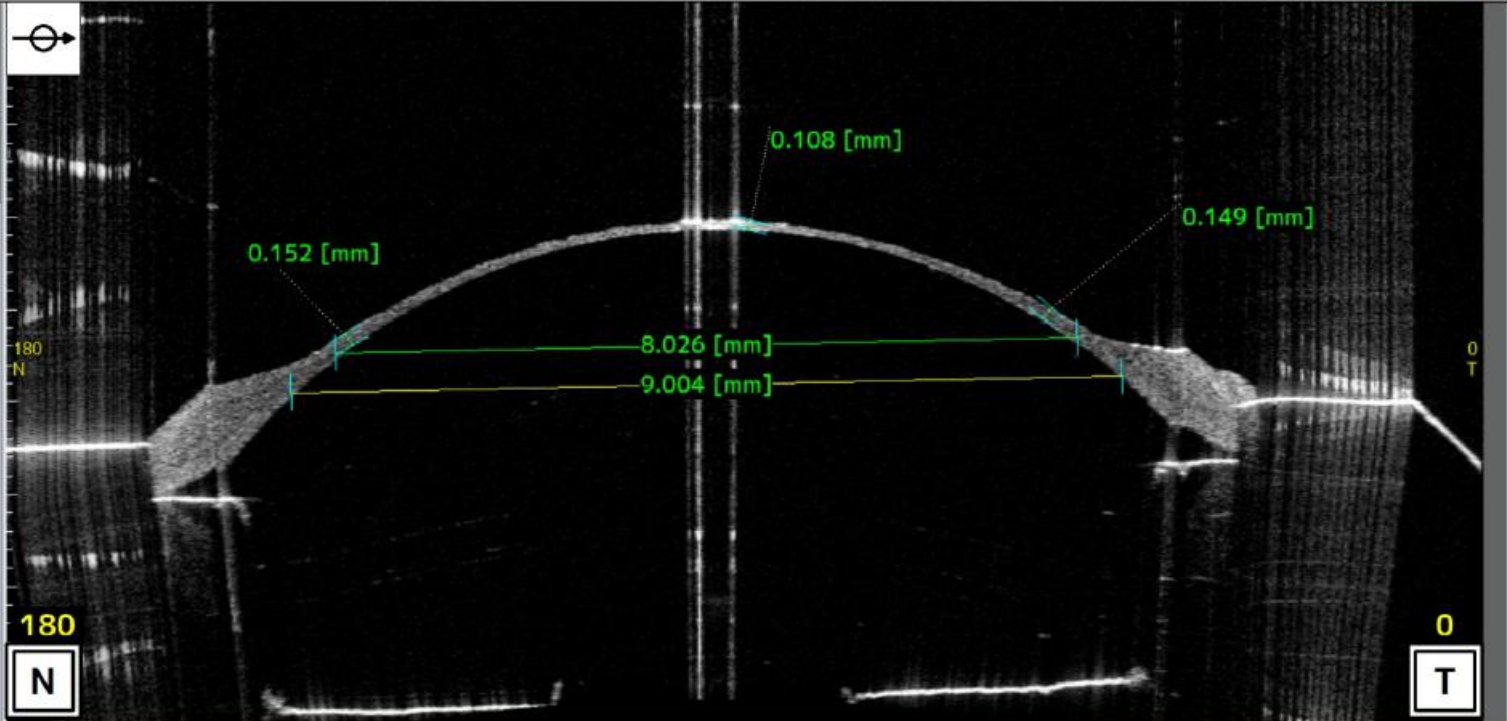
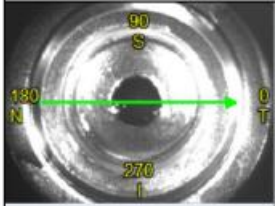
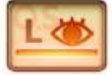
# 2D Analysis

ID: g170023307034f right

Name:

Exam Date: 13/Aug./2023 12:04:13

Comment:



- SS-Left
- AR-Left
- SS-Right
- AR-Right
- Lens-F



180° (Nasal)	500um	750um
AOD [mm]	---	---
ARA [mm <sup>2</sup> ]	---	---
TISA [mm <sup>2</sup> ]	---	---
TIA [°]	---	---

180° - 0°	
CCT [um]	---
ACD[Endo.][mm]	---
LV [mm]	---
LT [mm]	---
ACW [mm]	---

0° (Temporal)	500um	750um
AOD [mm]	---	---
ARA [mm <sup>2</sup> ]	---	---
TISA [mm <sup>2</sup> ]	---	---
TIA [°]	---	---

# Pre-cut tissue for DS(A)EK


- Communication with users and other eye banks on best practice, and matters of consensus:
- Advice on trephination in theatre & information on marking of tissue – presented at previous OTAG meetings
- Further updates to Information sheet
- Advice to all surgeons to report SAEARs - reminder letter
- Discussion around how to communicate & agree minor deviations from release specification
- Long-term FU of outcomes through transplant registry

# General notes & developments

- Importance of SAEAR reports! – reminder letter
- Further updates to the SAEAR form in progress
- Need to communicate that all issued grafts are specific to the request – swapping grafts in hospital for different types of transplant may lead to a graft being unsuitable
- Cornea grafts do not automatically fulfill donor eligibility criteria for use of the scleral rim or consent for R & D - if need additional information, contact the eye bank
- Overlap: SAEARs – unused tissue
- Introduction of Chlorhexidine rinse in both NHSBT eye banks

## B Braun Medical: product recall

- Saline contaminated with traces of Midazolam
- One affected batch: used in the eye bank in Liverpool, grafts issued end of 2021/beginning 2022 (x200 cornea grafts plus some sclera)
- Possible risk of allergic reaction
- Clinical risk now likely minimal but please make contact if concerned and report SAEARs as required
- Formal communication to follow

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Many thanks to Arthur Childs,  
QA Filton, for invaluable help with qpulse