

Documenting the Evolution of Contemporary Eye Bank and Corneal Tissue Services in Australia

Heather M. Machin¹

ABSTRACT

This paper documents the continued evolution of Eye Banking in Australia and the role of Eye Banks in advancing corneal transplantation through corneal tissue provision. While outlining known historical dates and key contemporary practice demarcation points, this paper simultaneously identifies a paucity of historical documentation regarding the evolution of eye banking practice in Australia. This paper aims to document and preserve known historical and contemporary Australian Eye Banking practice for future generations; additionally, it hopes to encourage other nations, professional groups and service providers to document their own evolution and practice before it is lost to time.

Key Words: Australia, corneal tissue, eye banking, human biologicals, regulations.

Australian Eye Banks (AUEB) are the custodians of altruistic voluntarily donated human eye tissue. They recover, prepare and transfer donations, primarily to waiting Australian recipients who require sight preserving or restoring transplant surgery. Commencing services in Australia around 70 years ago, today AUEB are predominantly recognised for custodianship of corneal tissue (CT).

Very little has been documented about eye banking history in Australia, or the significant role AUEB have played in increasing access to corneal transplantation services across their nation. As such, there are only a handful of publicly available documents showcasing their evolutionary steps, and very few data sets dating back to the nation's first corneal transplant. As such, a majority of this paper will describe contemporary practice and present only known and available data. It simultaneously acknowledges key historical gaps within Australia's EB story. In presenting this paper, recognising Australia's historical deficits and documenting current practice, within the context of the broader eye care and human biological fields, it is hoped that some of Australia's EB practice will be preserved

for future generations. In turn, it will encourage others to chart their own evolution and practice before, like AUEB, historical facts and knowledge are lost to time.

Emergence of Australian Eye Banks

The first recorded corneal transplant occurred in Australia in 1941 in Brisbane!¹ The donor had died 12 hours prior. The whole eye was not enucleated. Only the cornea-scleral rim was removed. It was not placed in a transfer medium like it would be today. Instead, it was taken straight to a recipient awaiting a penetrating keratoplasty transplant.

Very little is known about the early days of EB practice in Australia. It has been suggested that the first informal AUEB opened, again in Brisbane, at the Mater Hospital in the late 1940s,² although the exact date is difficult to pin down. The period between the late 1940 and 1980s remains relatively unmapped and early AUEBs shared little resemblance to today's dedicated, organised providers. The service was ad-hoc, and often a *fridge in a room* was described as an eye bank. Service was dependant on the availability of unit registrars to locate and follow-up potential donors in public hospitals.³ While the world's first dedicated eye bank opened in New York in 1944,⁴ Australia did not catch-up with its international contemporaries until 1981 when the Flinders Medical Centre, Adelaide² opened Australia's first dedicated organised EB under the leadership of Dr. Doug Coster.

It was around that time that the Australian Federal Government introduced greater control and regulation of human biologicals, inclusive of eye tissue. This resulted in the AUEB and the corneal sector joining as one common voice² to provide a sector response to the regulatory changes. With the additional inclusion of New Zealand (NZ) (as Australian and New Zealand medical professional societies routinely collaborate), this group later evolved to become what we know today as the Australian and New Zealand Corneal Society (ANZCS). Dedicated contempo-

Author Affiliations: ¹ Lions Eye Donation Service, University of Melbourne

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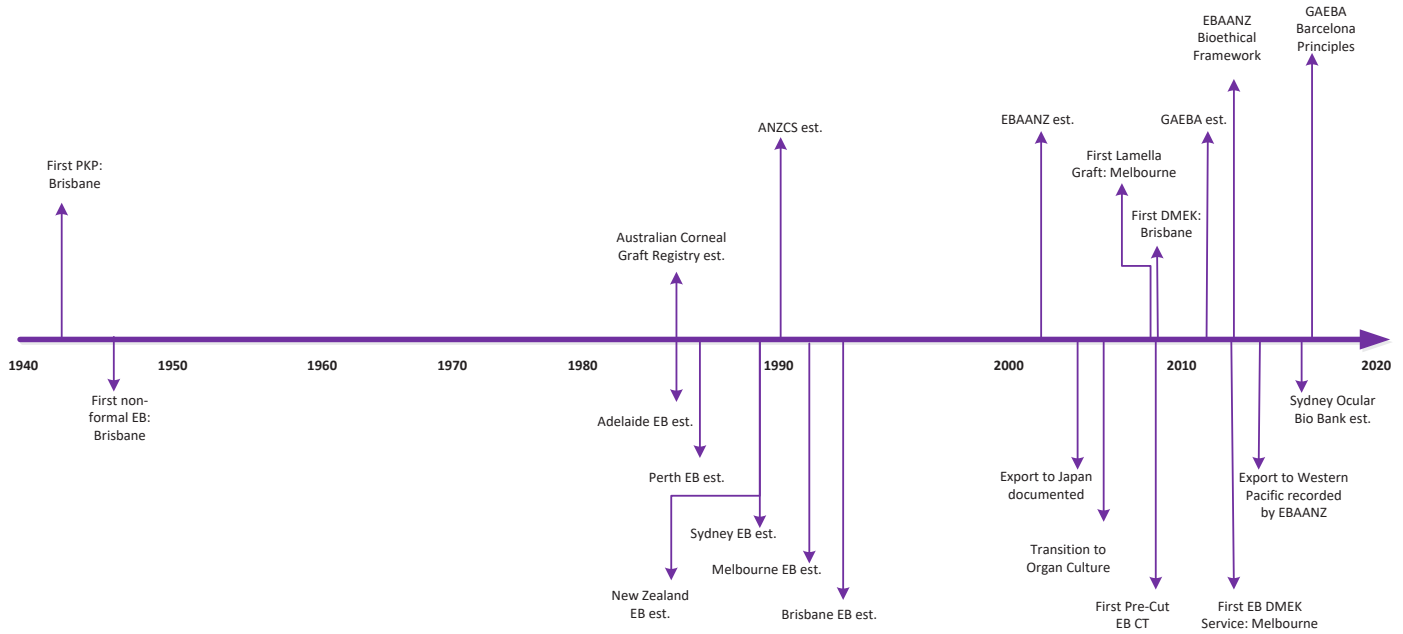


Figure 1: Timeline of Eye Bank Evolution in Australia (ANZCS: Australian and New Zealand Corneal Society; CT: Corneal Tissue; DMEK: Descemet’s Membrane Endothelial Keratoplasty; EB: Eye Bank; EBAANZ: Eye Bank Association of Australia and New Zealand; Est. Established; GAEBANZ: Global Alliance of Eye Bank Associations; PKP: Penetrating Keratoplasty)

rary AUEB were then established in Perth in 1986⁵, Sydney in 1989⁶, Melbourne in 1991,⁷ and Brisbane in 1992.⁸

CONTEMPORARY PRACTICE

Donor recovery

Operating within an opt-in donation system, the donation recovery model of AUEB differs from other countries. AUEB consent and recover tissue to match known surgical scheduled requests, rather than recovering all tissue and then searching for a recipient. The process is designed to ensure need is met without waste, however we note there are no formal definitions to describe *need*, how meeting need is determined or how this differs across the various jurisdictions. Generally, tissue is recovered from donors in major public hospitals or from the coronial office. Some AUEBs may also occasionally recover from nursing homes or funeral homes, if their state’s Tissue Act permits recovery in those locations.

Allocation

Through the Eye Bank Association of Australia and New Zealand (EBAANZ), a communitarian model of allocation is favoured. In their model, each AUEB recovers from their

jurisdiction and allocates in their jurisdiction. Jurisdictions without an AUEB (Tasmania, Northern Territory and the Australian Capital Territory) are co-managed by the local medical staff or Donatelif e retrieval teams (Donatelif e is the donation agency of the Australian Commonwealth Government’s Organ and Tissue Authority), and transferred to the closest AUEB. Similarly, those AUEBs allocate the next available tissue back into those jurisdictions when requests for tissue are made.

Surgeons in Australia obtain tissue by placing their request with their local AUEB. That AUEB is responsible for recovering locally or arranging tissue from another Australian jurisdiction, to assist local shortfalls. Most jurisdictions participate in a two-way tissue sharing system. The tissue sharing system is designed to retain the relationship between the surgeon and the EB and ensure tissue need is examined at the local level first. Occasionally, individual AUEB do allocate directly to a surgeon, however this is reserved for specific instances such as provision of a particular cut-type over an agreed duration, and is conducted in consultation with the local EB. The communitarian method also ensures a cooperative relationship is in place, and it removes competition for tissue placement, resource waste, and the development of a marketplace.

A majority of corneal transplant surgery takes place in public eye-only urban hospitals, general metropolitan hospitals and standalone Ambulatory Surgery Centres. They are predominantly private facilities. This reflects the distribution of ophthalmologists in Australia within urban centres, and the nature of the Australian health system which encourages individuals of a certain financial status to participate in the private health insurance scheme. Additionally, most corneal transplant surgery in Australia is provided as a day-surgery procedure.

Post-operatively, Australian surgeons and AUEB have voluntarily participated in the world's longest longitudinal co-operative analysis of corneal transplant outcomes, known as the *Australian Corneal Graft Registry* (ACGR). In operation since 1985, the ACGR, housed at Flinders Medical Centre Adelaide, collates information, volunteered by surgeons, on some 33,000 transplants since inception. The registry quantify outcomes via descriptive, univariate and multivariate sectorial analysis of the donor, AUEB, recipient, surgeon, graft type and the operative procedure.⁹ This remains the most comprehensive record of corneal transplant numbers in Australia. Of note, transplant (and donor) numbers prior to the commencement of the ACGR were not collated by any governing agency or health department. Data capturing has improved somewhat in recent times, particularly over the past 5-7 years, with both the EBAANZ and the Australia and New Zealand Eye and Tissue Donation Agency¹⁰ (who receive data from EBAANZ and individual AUEB) continually increasing their data collection sets.

While Australian recipients may be required to fund some aspects of their hospital stay and the procedure (depending on their level of public or private health cover), they do not pay for the provision of the CT, which is funded by the government's Medicare system or the recipient's private health insurance company, who reimburse the AUEB directly. CT costs are determined by the individual AUEB. They are based on a cost-recovery price structure. They outline their prices, publicly, on the Australian Prosthesis Register.¹¹

Technology and Innovation

Preservation: Over the years, the AUEBs have ensured that donation and corneal services remain on par with other high-resource industrialised nations. AUEBs supported the introduction of hypothermic cold preservation storage medium. Today, Adelaide and Brisbane continue to use hypothermic storage as their primary preservation medium. In the early part of the 21st century, AUEBs started to explore normothermic organ culture medium, and by 2005

this became, and remains, the dominant preservation medium for Melbourne, Perth and Sydney.

Database and tracking: AUEBs are amongst the first EB group (and the first of any tissue-type in Australia) to commence implementation of a nationwide Electric Donor Record (EDR) system. This system provides tracking standardisation across the country, and network interaction with the EDR primary partner - the National Organ Donation Agency. The EDR Eye Module, developed and based on the iTransplant software system, originally devised for USA EB's, *went live* in Australia in 2018, with each AUEB responsible for the implementation. To date, Adelaide and Perth have completed the implementation phase. Preparation for the Australian module required significant alterations from the original USA module, in order to reflect the diverse practices (e.g. different preservation methods) of the AUEB, and the government's requirement for future integration with their broader national organ and tissue tracking system. In this process, Australia also commenced a nationwide implementation of the international tracking and surveillance nomenclature system ISBT128, a system developed during the Persian Gulf War to solve blood labelling issues.¹² Such tracking systems allow for full traceability and recognised labelling.¹² This is especially important when tissue can be transferred across local and national borders, when knowledge of the full life cycle is required.

Surgical techniques

While Penetrating Keratoplasty (PKP) and lamella grafting was widely debated during the 18th to early 20th century,¹³ PKP reigned supreme for decades,¹⁴ and continues to be favoured within lower resource locations,¹⁵ as a treatment choice for corneal opacification¹⁶. In recent times however, lamella grafting has experienced a global renaissance, as the treatment option for specific diseased layers of the cornea.¹⁶

The lamella grafting technique, *Descemet's Scraping Automated Endothelial Keratoplasty* (DSAEK), was first performed in Melbourne, by Australian surgeon Dr. Rasik B Vajpayee, at the Royal Victorian Eye and Ear Hospital in the 2008,¹⁷ but the technique required careful tissue preparation at the operating table by the surgeon. To combat the time required to cut the tissue, and to improve services, Melbourne moved towards a pre-cut tissue service, providing Australia's first pre-cut tissue to a Vajpayee patient in 2009. Perth were next to follow.

In the late 2000s, *Descemet's Membrane Endothelial Keratoplasty* (DMEK) started to gather global interest, and Brisbane's Dr. Andrew Apel becoming the first Austra-

lian surgeon to perform the procedure. The Melbourne EB followed by adding additional pre-cut DMEK services in 2014.¹⁸ AUEBs that provide pre-cut services also offer pre-cut training to their local surgeons, and today all but one AUEB provides a pre-cut DSAEK service.

Institutional arrangements and EBAANZ

Despite the establishment of the ANZCS in the 1990s, it was not until 2003 that EBAANZ formed,¹⁹ under the leadership of Drs. Grant Snibson and founding Chairperson Doug Coster.²⁰ EBAANZ and ANZCS continued to remain as partners, ensuring an open feedback loop between the AUEB and surgeon. Established to support the ANZ EB in the delivery of their services, through representation, cooperation and education,²¹ EBAANZ membership is per the EB. All five AUEB and the Auckland EB at the Department of Ophthalmology, University of Auckland, New Zealand, are founding and remaining members.

Today, EBAANZ is recognised within the national and global sector. It is a founding partner of the Global Alliance of Eye Bank Associations (GAEBA), established in 2014,²² and is actively engaged by Donatelife, and their Medical Standards are also recognised by their regulator, the Therapeutic Goods Administration (TGA). Within the eye care sector, EBAANZ partners with groups such as the Royal Australian and New Zealand College of Ophthalmologists and the Australian Ophthalmic Nurses Association National Council's state-based independent partners, on a variety of projects relating to eye tissue. For example, in 2016, EBAANZ were the first eye bank association to work with stakeholders to develop a resource for operating theatre facilities, on safe care and handling of tissue (the *National Guidelines: A Resource for Australian Hospitals, Operating Theatres and day surgery staff regarding the care and handling of human tissue for ocular transplantation*.²³)

Inspired by its interaction with the GAEBA, and influenced by the World Health Organization's human cell, tissue and organ transplant recommendations, EBAANZ became the first EB association to establish a regional *Bioethical Framework for Policy and Procedure* in 2015.²⁴ This was followed in 2018 by the global equivalent, *The Barcelona Principles: An agreement on the use of human donated tissue for ocular transplantation, research, and future technologies*,²⁵ for which EBAANZ played a leading development role.

Organisation Models

Despite governing attempts in the late-2000 to amalgamate all tissue types into one multi-bank within each state,²⁶ AUEB have remained predominantly stand-alone facilities,

with their facilities predominantly staffed by post-graduate level medical-science and nursing professionals. They remain affiliated with benevolent organisations, such as Lions Clubs, and hospital and/or university ophthalmology departments. Sydney (New South Wales), and Brisbane (Queensland) are the only State Health Department managed AUEB. They are both multi-tissue banks.

Due to the transition towards bio-therapeutics and greater requests for research tissue, all AUEBs provide consented research tissue to human ethics approved research projects. While all AUEBs provide some form of bio banking service, it was not until 2017,^{6, 27} in Sydney, that Australia formed the country's first formal biobank, *The Australian Ocular Biobank*, under the leadership of Dr. Gerard Sutton and Jane Treggion, in collaboration with the Sydney University Save Sight Institute, and under the governance of the New South Wales Organ and Tissue Donation Service²⁷.

All AUEBs, and all but one Australian tissue bank, are not-for-profit organisations. They do not split their recovery, processing and allocation services or transfer altruistic donations from their (or their affiliates) not-for-profit (NFP) recovery arm into a for-profit (FP) shareholder incentivised arm. While such models do not occur in the AUEB sector, they are familiar with such models as similar versions operate within the Australian musculoskeletal tissue sector.²⁸ To date, AUEBs have remained critical of such a split or FP model, and have been active participants in their national governance, and the global conversation, regarding the retention of NFP bioethical norms and standards within the sector. AUEB have, at this stage, sought to retain their communitarian approach, whereby tissue is treated and retained as a public resource for the shared benefit of all within a NFP supply-line.

Governance and Regulations

Each state and territory has in place their own Tissue Act. This provides the parameters of donation and use within that jurisdiction. The Acts, limited in their scope, only deal with consent and removal of tissue.²⁹ While there is no uniformed approach across the Australian human biologicals sector,²⁶ biologicals such as CT are mostly governed by a health or medical-science department within the Australian Government, and regulated by the TGA. All biologicals are managed and licensed by the TGA in accordance with the *Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products* (cGMP).³⁰ The code provides guidance on the collection, processing, testing, storage, release for supply, and quality management within Australia. While complying with the code, each biological

requires different regulatory treatment and oversight.

The TGA maintains a range of biological framework — *Australian Regulatory Guidelines for Biologicals*³¹ that provide information to the manufacturer, sponsor (those who process and manage the biological, such as an EB), healthcare professional and the public, on the legal arrangements in Australia. The biological framework uses a four-stage categorisation system that approves or does not approve the inclusion of a biological (that are otherwise exempt, approved or authorised) and their restrictions. CT is categorised as a Stage 3 biological. Biologicals are then registered on the *Australian Register of Therapeutic Goods* (ARTG), prior to use in Australia or internationally. Imports must also be listed on the ARTG and may only enter the country if demonstrated that domestic supply cannot meet domestic need. A permit, under a strict special access scheme, is then granted to allow the import, for instance, if emergency CT from New Zealand is required.

Guidelines and Frameworks

As mentioned previously, EBAANZ developed their bioethical framework in 2015. EBAANZ then participated in the development of a global framework, *The Barcelona Principles*, alongside other countries and numerous sector stakeholders. Both frameworks adhere to the *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*, 2010. AUEB also adhere to the *National Health and Medical Research Council* guidelines, titled: *Ethics and the exchange and commercialisation of products derived from human tissue – background and issues*³² to guide practice, however these guidelines are currently under review, and the sector eagerly await the release of the next edition.

Governing recommendations

Australia has had several key sectorial reviews of the human tissue sector. Notably, 2008 when the *Council of Australian Governments* agreed to implement a world's best practice approach to organ and tissue donation and transplantation. This led to the development of *The Organ and Tissue Authority* in 2009²⁶ with the gift relationship as the central underlying ethical principle. More recently, Price Waterhouse Cooper (PWC) were commissioned by the Government to complete a sectorial analysis of the Australian Eye and Tissue Sector²⁸ Their report reviewed the demand, supply and use of eye, bone, and skin and heart valve services across the country, comparing service models, professionalism and outcomes. The report was significantly critical of the general tissue sector, offering caution in terms of importation, the for-profitization and

the bundling of tissues as one sector without recognition of the unique management, use, waitlists and needs of the individual tissue type. While recommending some national oversight, PWC outlined the need for some specific tissues to be overhauled. Within the report, CT fared well, being the only tissue type identified to be entering a potential surplus-to-surgical-need phase, however we note that the definition regarding meeting need and surplus-to-need, was not clearly described. The report also outlined that while some national oversight is necessary, AUEB should retain their national communitarian approach, and their feedback loop with the surgeons. In addition, the report also proposed any surplus CT currently not recovered could be recovered and exported. To date, there has been no formal analysis of Australia's exportation potential or other domestic surplus use options (e.g. retention for research, training or future therapies) or how such service would be provided and funded.

Transnational allocation

Through EBAANZ, AUEB engage in a trans-Tasman agreement with the Auckland-based NZ EB³³ In this cooperative, if either nation is unable to provide for a recipient, they contact the cooperative members, who then transfer the CT to the requesting EB. The receiving EB then dispatches the tissue to the surgeon. This method reduces confusion and the need for surgeons to contact or work with multiple CT providers. This also ensures tissue movement between Australia and New Zealand is tracked and recorded, and wait lists are monitored. Additionally, it ensures that cross-border sharing does not undermine local services or support the creation of a tissue marketplace. The trans-Tasman arrangement is also based on a cost-recovery model. Through examining the EBAANZ data over the past 5 years, Australia indicated that they transferred 94 CT to NZ between 2014-2018 (Table 1). While Australia, during the same period, did not import from NZ, their trans-Tasman sharing arrangement remains in place. This supports Australia, should they need to request emergency CT from NZ³⁴.

Historical affiliation between Australian surgeons and their peers in lower-resource locations has resulted in AUEB providing some humanitarian CT to the Western Pacific Region, primarily being Myanmar and New Caledonia, as identified during the EBAANZ 2014-2018 recording period. One publication in 2004 also indicated that Australia exported to Japan, however the degree of engagement, and terms of the arrangement are unclear.³⁵ In the instance of humanitarian provision, AUEB and/or their philanthropic partners (e.g. the organisations managing the development

Table 1: Donor and corneal tissue recovery and allocation rates within Australia, including transnational allocation through a formal arrangement with New Zealand (a Trans-Tasman Agreement) and ad-hoc. humanitarian purposes outside of Australian and New Zealand (ANZ) Region. (EBAANZ internal data recording from 2014 – 2018).

	2014	2015	2016	2017	2018	Total
Donors	1,139	1,415	1,272	1,361	1,387	6,574
Corneal Transplants	1,894	2,124	2,074	2,155	2,231	10,478
Exported CT to NZ	7	2	6	37	42	94
Imported CT from NZ	0	0	0	0	0	0
Exported CT outside of ANZ	22	0	15	17	9	63

program) have predominantly covered the costs for such efforts. EBAANZ commenced collection of their non-ANZ allocation data in 2014. Their data indicates that 63 CT have been exported for humanitarian use during that 5 year-period.³⁴ Exportation engagement, at this stage, remains ad-hoc.

While CT has been exported from Australia, AUEBs are not routine exporters. This is primarily due to the AUEB model of recovering CT to meet scheduled booked surgeries only. This means that AUEBs do not have quantities of recovered CT readily available to export. AUEBs could recover more tissue and formally participate in transnational activity, as a response to the global need, but to do so, they would need to evaluate their own capacity to provide internationally, while ensuring domestic services are not disadvantaged. Their review would also require examination of the Australian public’s willingness to routinely export, and additional revision of the donation education and consent process, as exportation is not a routine component of the donation conversation in Australia.

CONCLUSION

AUEBs have played a significant role in the advancement and accessibility of corneal transplant services in Australia, especially since 1980 (Diagram 1). Unfortunately, very little has been recorded, and several key historical facts remain unknown (e.g. there is no database going back to 1941 outlining the total donor or recipient numbers in Australia). In providing this overview, it is hoped that some aspects of historical and current practice can be preserved for future generations. In turn, it is hoped that the paucity of historical details will encourage other nations, professional groups and sectors to follow suit by capturing their own evolutionary steps and historical milestones before they too are lost to time.

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