



Canadian Blood Services
it's in you to give

***Donation and Transplantation
Canadian Eye and Tissue Bank Activity
Annual Report
January 1 to December 31, 2013***

A Report from the Canadian Eye and Tissue Data Committee

January 2016

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Executive Summary

Canadian Blood Services, on behalf of the Eye and Tissue Data Committee (ETDC), receives quarterly data submissions from all Canadian eye and tissue programs. Data definitions have been established and data training delivered to the Canadian eye and tissue community.

Canadian Blood Services maintains and collates data for review by the Eye and Tissue Data Committee. The purpose of this report is to provide information and insights into the Canadian supply of, and demand for, ocular and tissue allografts across Canada.

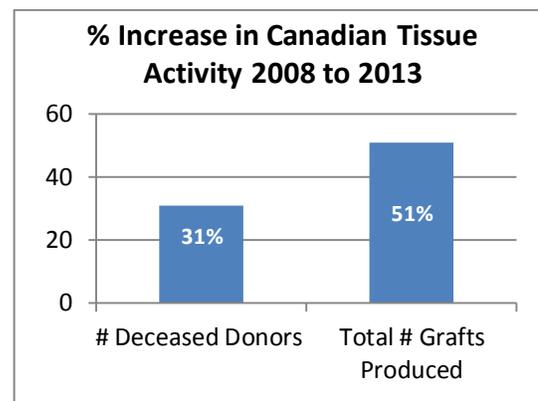
Prospective data collection was initiated in 2012. 2013 data was submitted from 18 eye and tissue banks (see Appendix B) representing a census of all Canadian eye and tissue banking activity. The only data set which is not a census of Canadian activity is approach and consent rate; analysis presented is based on the 11 programs which submitted this metric and provides visibility to the consent rate within those programs. Data on allografts imported by Canadian hospitals from the United States was not available.

In 2013 Canadian Eye and Tissue Banks received 41,595 referrals for potential tissue donors. In those approached 46% consented to tissue donation. Tissue was recovered from 4,383 deceased donors and 708 living donors. These donations resulted in the production of 17,464 grafts which were released for transplantation; 5,435 ocular (cornea and sclera) and 12,029 tissue (bone, skin, cardiac, surgical bone and amnion).

There has been an increase in tissue donation in Canada with a 31% increase in deceased tissue donation between 2008 and 2013. There has been a significant decrease in living tissue donation with a 60% (n=1,048) decrease in

surgical bone donation between 2008 and 2013. There has been a 51% (n=5,929) increase in the total tissue grafts processed and released for transplantation between 2008 and 2013.

There has been a 43% increase in the number of donors where ocular tissue was recovered (n=1,251) and a 47% increase in corneas produced and distributed by Canadian eye banks for transplantation (keratoplasty) between 2008 and 2013. There has been a small increase in the yield of cornea grafts (# corneas released for transplant per donor) increasing from 0.92 to 0.97 per donor between 2008 and 2013.



Data indicates that in 2013, 45% of all cornea transplants (keratoplasty) performed in Canada were endothelial keratoplasty; requiring post recovery processing of the cornea prior to transplant.

There has been a 37% increase in the number of donors where musculoskeletal, skin and or cardiac tissue was recovered. There has been a 78% increase in the number of bone, cardiac and or skin grafts produced from deceased donors between 2008 and 2013 (n=4,938). There has been a 29% increase in the yield of bone, cardiac and skin grafts per deceased donor between 2008 and 2013 from 11.3 to 14.6 grafts per deceased bone, cardiac and skin donor.

There has been no significant change in amnion donation and production between 2008 and 2013.

There has been amalgamation of services in four regions; two comprehensive banks incorporated eye banks under one administration and in two regions an eye bank and bone bank combined activities under one administration.

The initiation of prospective data collection provides all jurisdictions with insight into tissue donation activity as well as to the production and supply of ocular and tissue grafts. The prospective collection of data is a recent endeavour and programs are to be commended on their leadership and contributions.

This report provides valued information documenting significant changes in system

performance over the last five years and provides insight into the current tissue environment.

Moving forward, Canadian Blood Services will continue to work with the Eye and Tissue communities to advance and improve data collection and collation of performance data to support all programs and stakeholders in their valuable efforts to provide the donation and allograft services Canadians require.

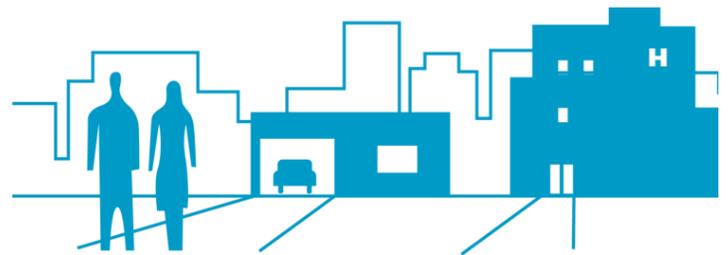


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Definitions

Amniotic Membrane: Amniotic membrane is the innermost layer of the placenta consisting of a thick basement membrane and an avascular stromal matrix. It is used as a graft and as a dressing to facilitate ocular surface reconstruction and to promote healing. Its' use in plastic surgery (burns, wound care), orthopedic, dental and general surgery is increasing.

Cancellous / Cortical Bone: There are two types of osseous tissue that form bones; cancellous "spongy" bone and cortical "compact" bone. Tissue banks mill/grind bone into cancellous cortical particles or powder which is used to pack bone voids in surgical repairs.

Chipped Bone: Is bone that has been processed into morsels which is used to pack bone voids in surgical repairs.

Consent Rate: Is the ratio of donors where consent for donation is obtained to the number of donor families approached for consent.

Deceased Donor: Refers to a donor where tissue is recovered following cardiac or neurological death.

Fresh Osteoarticular: Osteoarticular refers to a bone graft that contains a joint surface; such as a knee. Fresh refers to the fact that in order to preserve viability of joint tissue the graft is not frozen or cryopreserved. These grafts are refrigerated and usually transplanted within weeks of recovery.

Keratoplasty: Keratoplasty is a surgical procedure also known as corneal transplantation where the procedure is described as a replacement of abnormal host tissue with healthy corneal tissue from a donor. The replacement of the corneal tissue can either be partial or full depending on the severity of damage in the cornea.

Penetrating Keratoplasty: Corneal transplant with replacement of all layers of the cornea, but retaining the peripheral cornea.

Endothelial Keratoplasty (EK): Endothelial keratoplasty is a corneal transplant procedure where only a patient's compromised posterior layers of the cornea are removed and replaced by similar posterior corneal layers of a donor cornea. The advent of this procedure occurred in the early to mid-2000s after fifty years of performing penetrating keratoplasty in nearly all corneal transplant surgeries. EK has clearly established itself as the standard of care for patients with endothelial dysfunction. There are a number of types of EK procedures including DSAEK and DMEK

Descemet's Stripping (Automated) Endothelial Keratoplasty (DSAEK). The vast majority of EK today is DSAEK where the eye bank precuts the corneal tissue, or the surgeon precuts the corneal tissue in the operating room. The prepared (cut) graft is comprised of the donor tissue endothelium, Descemet's membrane and a thin, partial layer of the donor tissue's stroma.

Descemet's Membrane Endothelial Keratoplasty (DMEK): DMEK involves the transplantation of only the Descemet's membrane and endothelial layer of the cornea. DMEK has been described as a more

technically challenging surgical procedure than DSAEK but also has been reported to provide better, post-transplant patient visual acuity, lower rejection rates and faster visual recovery.

Deep Anterior Lamellar Keratoplasty (DALK or ALK): Is a partial thickness corneal transplant procedure used to treat disease or injury confined to anterior layers of the cornea: the epithelium, Bowman's layer and stroma. DALK is most often used to treat keratoconus and corneal scarring.

Living Donor: A donor where tissue is recovered from a live person; such as femoral heads which are recovered during total hip replacements or amnion which is recovered from the placenta in live births.

Ocular: Is a general term which refers to the tissues of the eye which include the cornea and the sclera.

Referral: A referral is when a death is referred to a donation organization or tissue bank for consideration or evaluation of donation potential. In some jurisdictions all deaths are referred and in others frontline health professionals may do a pre-screening and only refer deaths which have no obvious contraindications to donation.

Released to Inventory: Refers to grafts that has been evaluated, and deemed safe and suitable for transplantation, by a medical director, through the appropriate quality review and made available for transplantation. Prior to release grafts in the production process are considered quarantined.

Sclera: The sclera is the part of the eye commonly known as the "white". It forms the supporting wall of the eyeball, and is continuous with the clear cornea. Scleral grafts are widely used in ophthalmologic surgery.

Soft Tissue: A generic term for muscle, fat, fibrous tissue or other supporting tissue matrix. In tissue banking it often refers to fascia lata; the sheets of fibrous tissue enveloping, separating or binding together muscles and orders. Fascia lata is processed into grafts for use in surgical repairs.

Structural Bone Grafts: These are bone grafts that are intended to support weight. They are classified into large or small. Large grafts include femurs, fibulas and humerus. Small grafts include sized grafts such as cortical dowels, wedges and rings.

Surgical Bone: Femoral heads can be recovered from total hip replacements and evaluated for suitability to transplant. These femoral heads are referred to as surgical bone. Surgeons grind the femoral head in the operating room to produce cancellous powder or particles. With the advent of bank produced pre-packaged cancellous and the increasing regulatory requirements the demand for surgical bone has declined.

Tendon: Is a band of tough, inelastic fibrous tissue that connects a muscle with its boney attachment. Tendons commonly banked for use it sports medicine surgery include Achilles, Patellar and Tibialis.

Tissue: Tissue is a general term which refers to musculoskeletal (bone), cardiac and skin tissue (non-ocular tissues)

Yield: Yield refers to the number of grafts which are recovered and released (deemed suitable) for transplant per donor. Yield can be affected by contamination, recovery technique, processing technique and donor factors such as age and comorbid diseases.

1. Introduction

Canadian eye and tissue programs, in collaboration with Canadian Blood Services, support the reporting of system performance data to provide information and insights into the Canadian supply and the demand for ocular and tissue allografts across Canada. The Eye and Tissue Data Committee ETDC (see Appendix A) provides advice and guidance on definitions, collection and analysis of data related to eye and tissue banking activity in Canada. Canadian Blood Services receives quarterly data submissions and supports data management, analytics and reporting.

This document reports on Canadian eye and tissue donation, production and distribution data for January 1 to December 31, 2013. Data was submitted from all 18 eye and tissue banks (see Appendix B) and represents a census of Canadian recovery, production and distribution activity. This report also compares 2013 activity levels to data from 2008. The 2008 data from all provinces except Quebec was sourced from two surveys published in 2010 by Canadian Blood Services: “Supply of Human Allograft Tissue in Canada” and “Demand for Ocular Tissue in Canada”.^{1,2} Quebec data for 2008 was obtained from a 2008/2009 Hemi-Québec annual report detailing system performance activity.³

Data elements for 2008 and 2013 were available and comparable for the majority of data sets. For 2 data elements, *number of multi-tissue donors* and *number of corneas transplanted* (Quebec); data was extrapolated from 2008 data points to provide the best estimates possible.

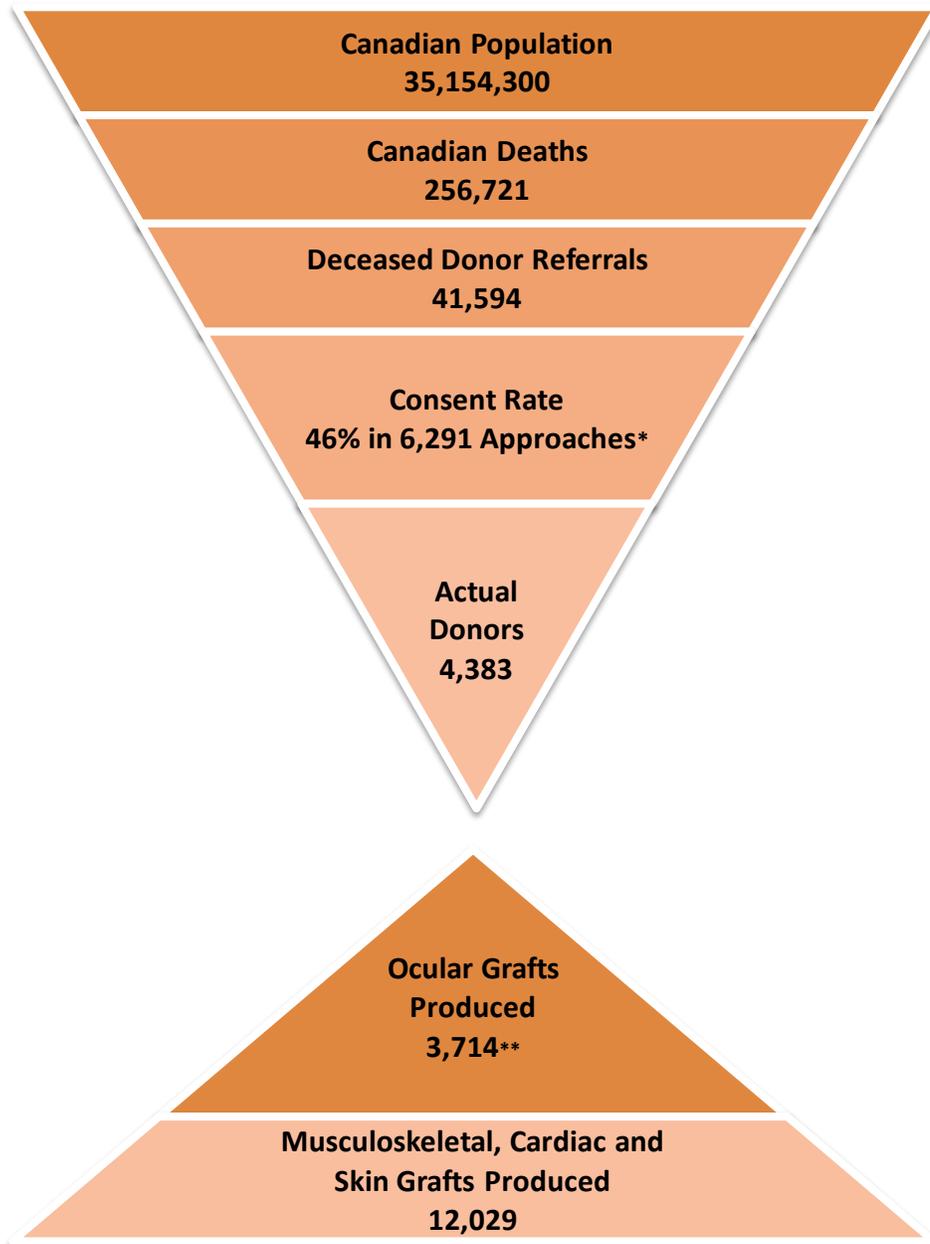
Canadian Blood Services and the Eye and Tissue Data Committee would like to express their sincere appreciation to the members of the Canadian eye and tissue community who participated in this data collection and who continue to support the collection and collation of national activity data. Moving forward, Canadian Blood Services will continue to work with the eye and tissue communities to advance and improve data collection and analysis to support all programs and stakeholders in their valuable efforts to provide the donation and allograft services Canadians deserve.

¹ Canadian Blood Services (2010). Supply of Human Allograft Tissue in Canada - Final Report 2010, www.organsandtissues.ca

² Canadian Blood Services (2010). Demand for Ocular Tissue in Canada - Final Report January 2010 www.organsandtissues.ca

³ Héma-Québec (2009). 2008-2009 Annual Report – March 2009 www.hema-quebec.ca

2. Canadian Eye and Tissue 2013 Overview



Population and death data sourced from Statistics Canada.

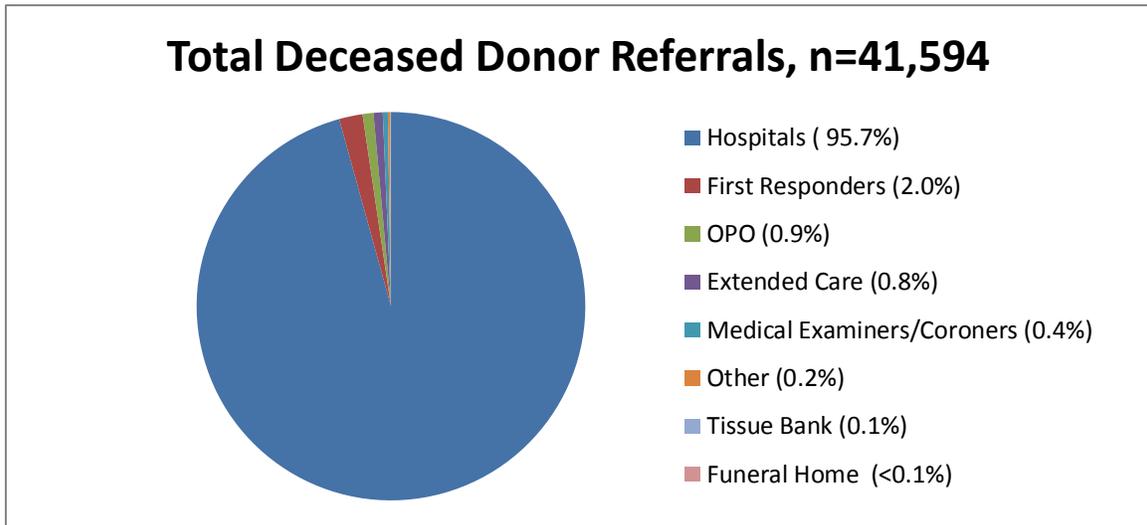
* Data from 11 programs that collect data on the number of approaches and consent rate

** Includes cornea and sclera production

3. Deceased Donation

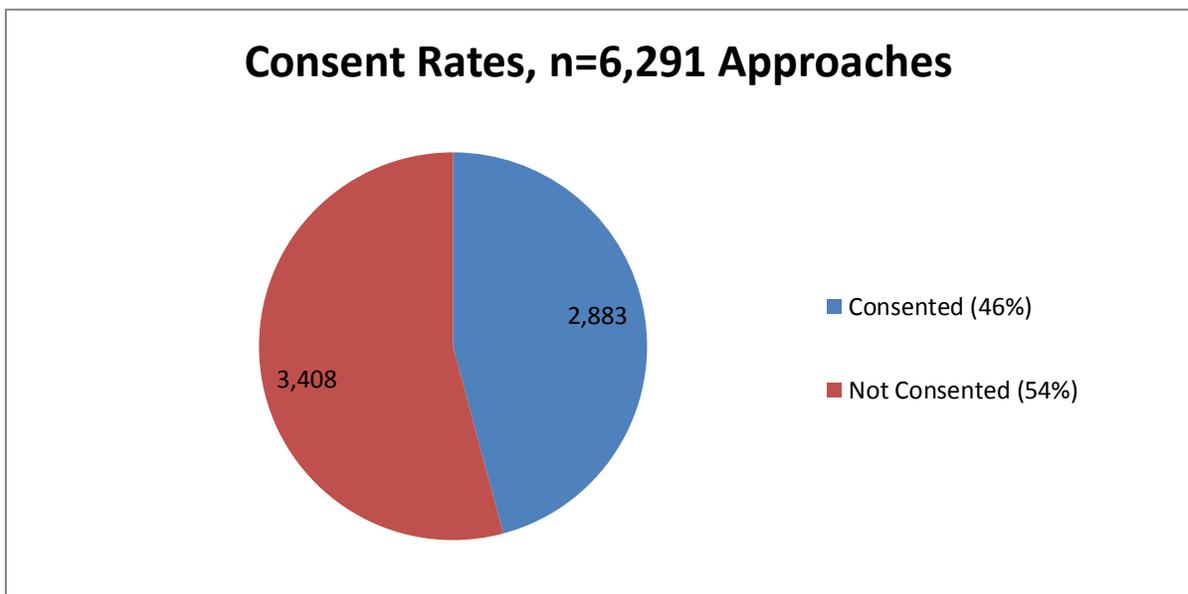
Total Deceased Donor Referrals

In 2013, 41,594 deaths were identified and referred for initial screening/consideration of tissue donation potential. Hospitals were by far (95.7%) the largest source of referrals.



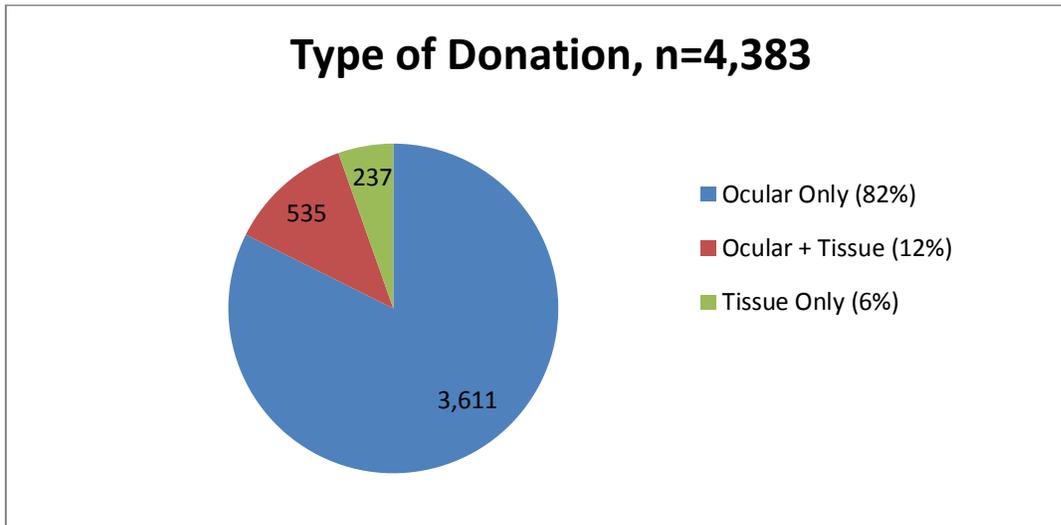
Consent Rate

In 2013, 11 programs provided data on 6,291 approaches for deceased tissue donation. A consent rate of 46% was identified.



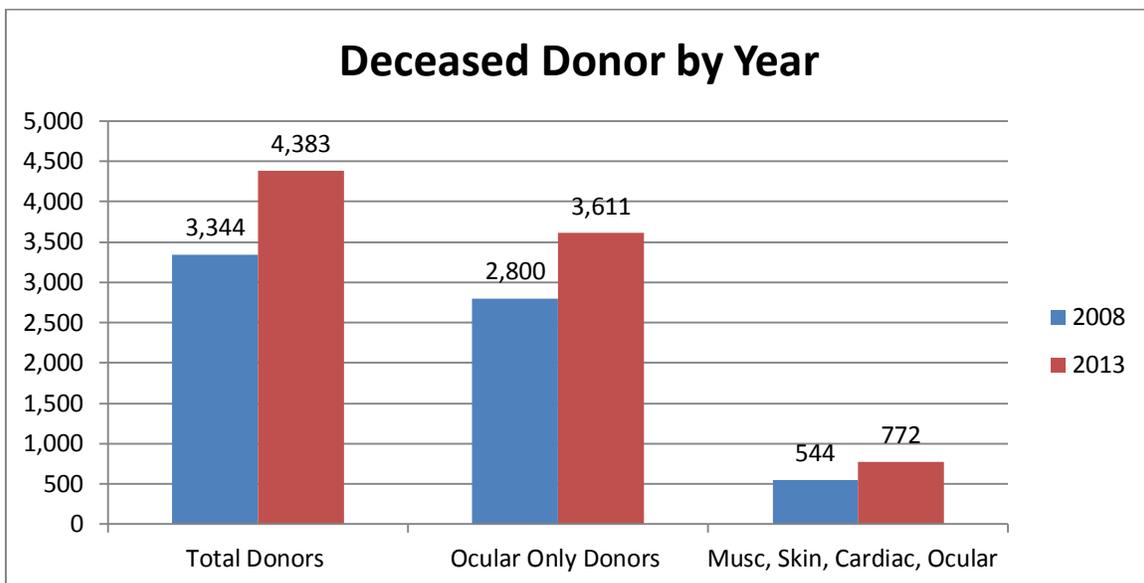
Deceased Donation

In 2013, there were 4,383 deceased ocular and tissue donors in Canada. The vast majority of these donors (82%) were ocular only donors.



Deceased Donor 2008 vs. 2013

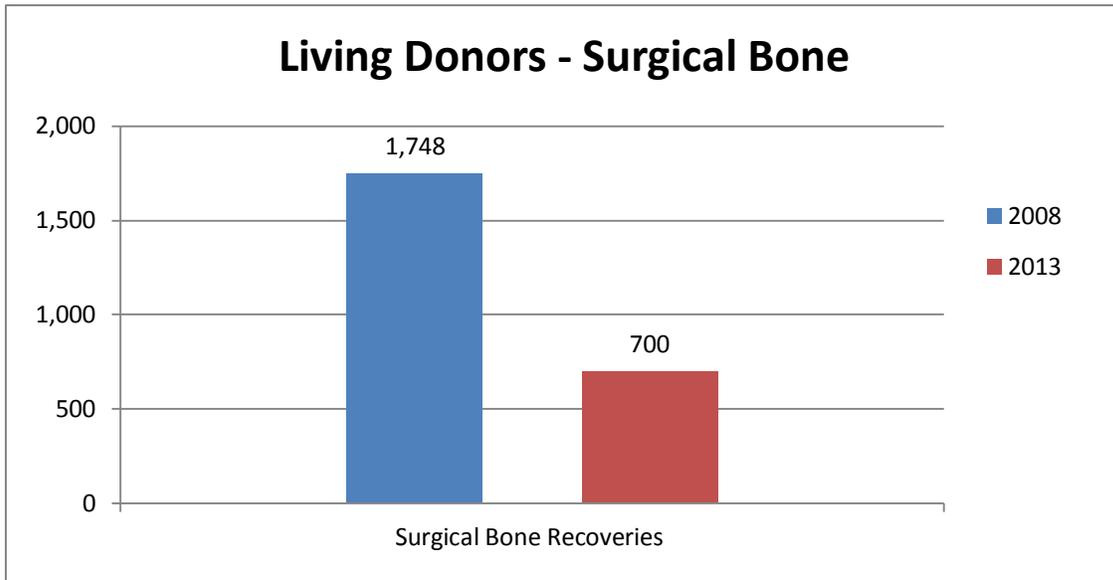
In 2008 musculoskeletal, skin or cardiac tissue was recovered in 16% of deceased tissue donors as compared to 18% of deceased donors in 2013. In 2008 ocular tissue was the only tissue recovered in 84% of deceased donors. In 2013 ocular tissue was the only tissue recovered in 82% of deceased donors.



4. Living Donation

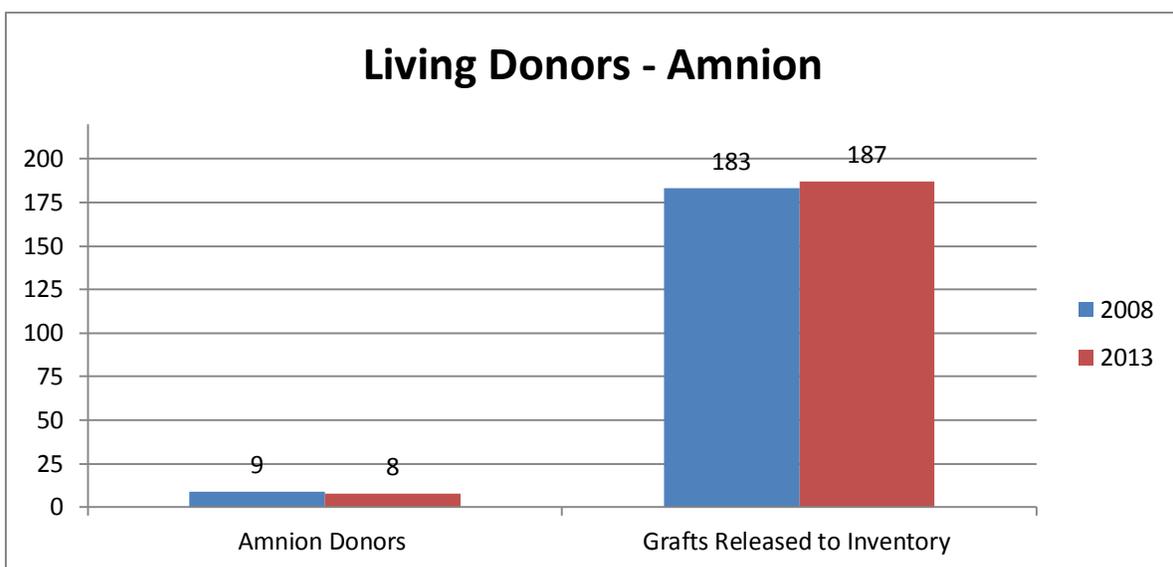
Living Donors – Surgical Bone

In 2013, five programs reported recovering femoral heads during total hip replacement surgery. There has been a 60% decrease in surgical bone donation since 2008.



Living Donors – Amnion

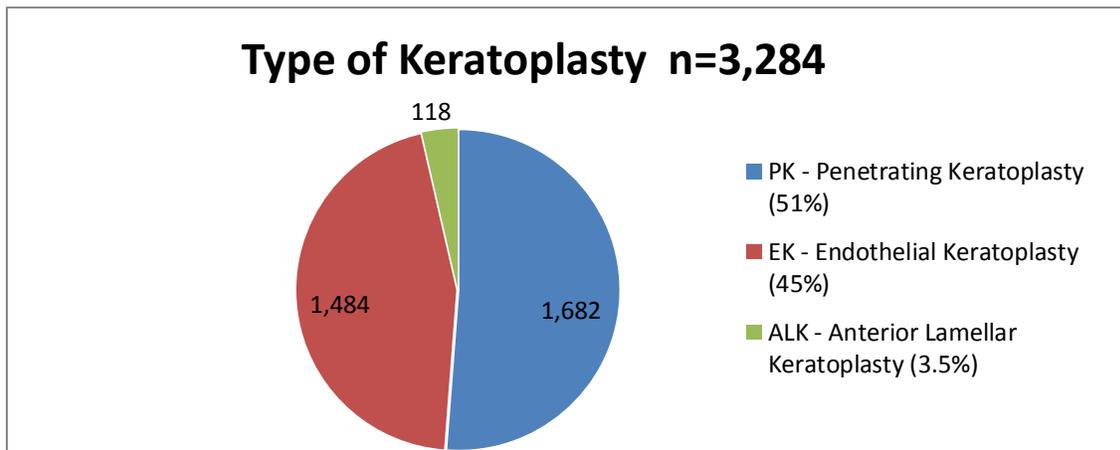
In 2013, two programs reported recovering amnion from living donors and produced 187 grafts. There has been no change in amnion donation between 2008 and 2013.



5. Production and Distribution

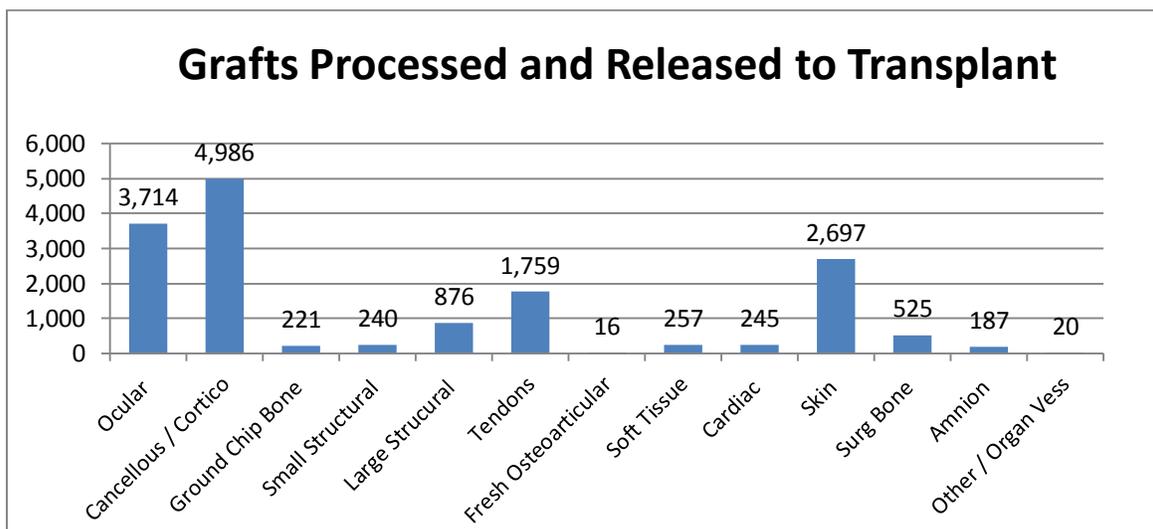
Corneas Distributed for Transplant (Canadian Produced)

In 2013, Canadian eye banks produced and distributed 3,284 corneas for Keratoplasty (cornea transplant). This does not include grafts which were imported from outside of Canada for transplant. Forty-five percent of all cornea transplants performed in Canada were endothelial keratoplasty, requiring post recovery processing of the corneal tissue. In 2013, three Canadian eye banks provided this processing service. In regions where an eye bank does not provide this service the processing is completed by the surgeon in the operating room.



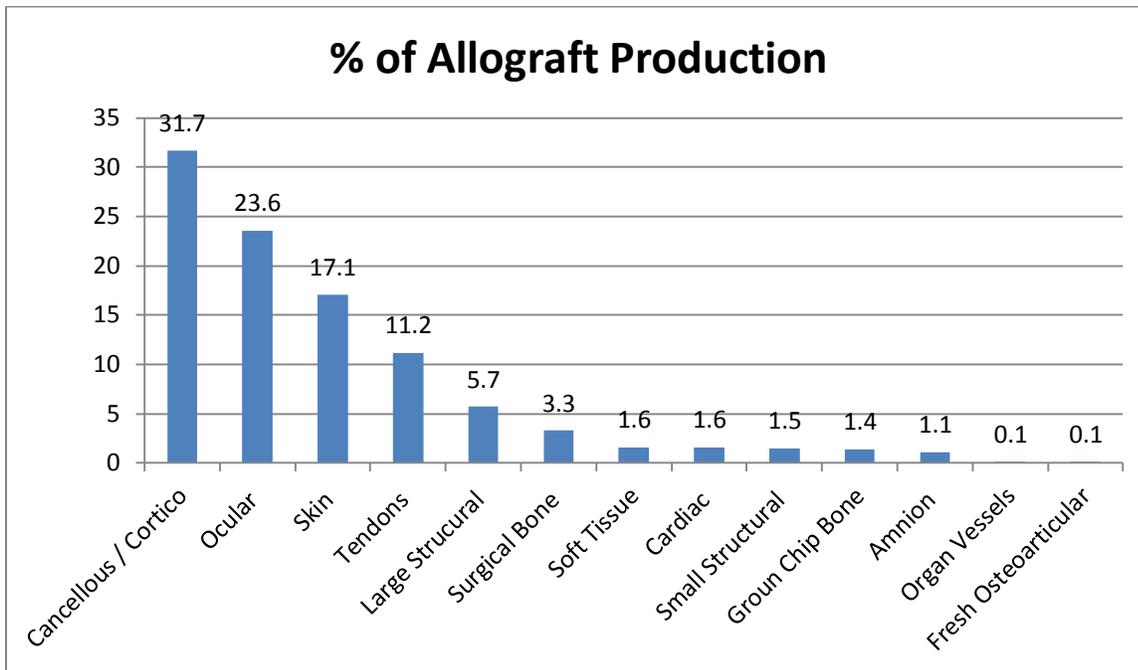
Tissue Grafts Processed and Released to Transplant: Type of Graft

In 2013, 15,743 ocular, musculoskeletal, cardiac, skin, surgical bone and amnion grafts were produced by Canadian banks and released for transplant. This does not include grafts which were imported from outside of Canada.



Composition of Canadian Allograft Production

In 2013 cancellous/corticocancellous bone accounted for 31.7% of all grafts produced and released in Canada, ocular grafts accounted for 23.6% of all grafts produced and released and skin accounted for 17.1% of all grafts produced and released for transplant.



6. Comparative Summary: 2008 and 2013

Canadian Eye and Tissue Banking Activity 5 Year Comparison

Activity	2008	2013	% Change
Deceased donors	3,344	4,383	+31%
Living donors	<u>1,757</u>	<u>708</u>	<u>-60%</u>
Total donors	5,101	5,091	+0%
Deceased donor referrals	18,421	41,594	+126%
Ocular only donors	2,800	3,611	+29%
Ocular and tissue donors	228	535	+135%
Tissue only donors	<u>316</u>	<u>237</u>	<u>-25%</u>
Total deceased donors	3,344	4,383	+31%
Surgical bone donors	1,748	700	- 60%
Amnion donors	<u>9</u>	<u>8</u>	<u>-11%</u>
Total living donors	1,757	708	-60%
Corneas processed and released for transplant	2,239	3,284	+47%
Ocular donors	<u>2,895</u>	<u>4,146</u>	<u>+43%</u>
Cornea yield (Canadian donors only) per donor	.08	0.8	0%
Total bone, skin and cardiac grafts processed and released for transplant	6,359	11,297	+78%
Deceased donors	<u>544</u>	<u>772</u>	<u>+37%</u>
Tissue yield (non-ocular) per donor	11.7	14.6	+25%

Canadian Eye and Tissue Bank Services

Since 2008, there has been an amalgamation of services in four regions; two comprehensive banks incorporated eye banks under one administration and in two regions an eye bank and bone bank combined activities under one administration.

Type of Bank	2008	2013
Comprehensive Tissue Banks*	5	6
Eye Banks	7	4
Musculoskeletal Banks	4	3
Skin Banks	1	1
Cardiac Banks	1	1
Surgical Bone Banks	7	2
Total	25	17

*Comprehensive is defined as recovering and/or processing more than one tissue type. A surgical bone bank is defined as a bank which recovers only surgical bone. Some musculoskeletal and comprehensive banks recover surgical bone.

Conclusion

The prospective collection and collation of national eye and tissue bank activity represents a milestone for the Canadian tissue community. Data provides insight into the Canadian supply and demand and as data accumulate more sophisticated trend analysis will help inform donation and production targets and strategies to better align supply with demand.

Appendix A: Eye and Tissue Data Committee Membership

Member	Title	Program
Brenda Weiss (Chair)	Patient Care Manager Ophthalmology Clinic, Misericordia Eye Bank	Misericordia Health Centre, Winnipeg, MB
Mike Bentley	Manager, Transplant Services	Comprehensive Tissue Centre, Edmonton, AB
Mary Gatién	Director NB Organ Donor Program, Director NB Eye and Tissue Bank	New Brunswick Eye and Tissue Bank, Saint John and Moncton, NB
Hugo Fournier	Directeur de l'exploitation des Tissus Humains	Héma-Québec, Québec City, QC
Ronn Ginther	Coordinator	Saskatchewan Transplant Program, Saskatoon, SK
Alison Halliday	Senior Technologist	Ontario Professional Firefighters' Skin Bank, Toronto, ON
Christine Humphreys	Provincial Resource Centre Manager – Tissue	Trillium Gift of Life Network, Toronto, ON
Cynthia Johnston	Quality Leader	Regional Tissue Bank, Halifax, NS
Mijani Ridic	Unit Manager, Lions Eye Bank	Southern Alberta Organ and Tissue Program, Calgary, AB
Gary Rockl	Senior Tissue Specialist	Southern Alberta Tissue Program Calgary, AB
Linda Sharpen	Manager	Eye Bank of Canada (Ontario Division), Toronto, ON
Chris Snow	Director	Tissue Bank Manitoba, Winnipeg, MB
Balram Sukhu	Manager	Mount Sinai Allograft Technologies, Toronto, ON
Ivan Yan	Head Technologist	Eye Bank of British Columbia, Vancouver, BC

Appendix B: List of Contributing Programs

British Columbia

- Eye Bank of British Columbia, Vancouver
- Island Health Bone Bank, Victoria

Alberta

- Southern Alberta Tissue Program, Calgary
- Lions Eye Bank of Calgary, Calgary
- Comprehensive Tissue Centre, Edmonton

Saskatchewan

- Saskatchewan Transplant Program, Saskatoon

Manitoba

- Tissue Bank Manitoba, Winnipeg
- Misericordia Eye Bank, Winnipeg

Ontario

Trillium Gift of Life Network manages the collation and submission of data from Ontario eye and tissue banks including:

- Eye Bank of Canada (Ontario Division), Toronto, Ontario
- The Hospital for Sick Children Tissue Laboratory, Toronto, Ontario
- Ontario Professional Fire Fighters Skin Bank, Toronto, Ontario
- Mount Sinai Allograft Technologies, Toronto, Ontario
- Lake Superior Centre for Regenerative Medicine, Thunder Bay, Ontario

- St. Michael's Hospital Surgical Bone Bank (ceased recovery March 2013).

Quebec

- Héma-Québec, Saint Laurent

New Brunswick

- New Brunswick Eye and Tissue Bank, St. John and Moncton

Nova Scotia

- Regional Tissue Bank, Halifax