Canadian Blood Services
it's in you to give

Background Paper for the Tissue Expert Committee

What role should surgical bone play in the Canadian tissue donation and transplantation system?

Contents

Original version: January 2010
Reformatted: October 2011

1. Introduction

A. Background

Recognizing the need to improve the organ and tissue donation and transplantation (OTDT) system in Canada, the federal, provincial (except Quebec) and territorial governments in April 2008 asked Canadian Blood Services to take on new responsibilities related to OTDT. This included the development of a strategic plan for an integrated OTDT system, in collaboration with the OTDT community. As part of this work, three committees were formed – the Steering Committee, Organ Expert Committee and Tissue expert Committee – to help develop the recommendations through a formal, structured planning process.

This document is one of a series of background documents developed to help the committees in their discussions. These documents focused on the critical issues within the system, describing the current state and examining potential options and solutions. Conclusions from the committee discussions were consolidated and incorporated in the final recommendations of the final report. The full report, ***Call to Action: A strategic plan to improve organ and tissue donation and transplantation performance for Canadians***, can be found at organsandtissues.ca, along with the other background documents in this series.

Limitations of these documents:

- These documents were intended for an audience familiar with the subject matter and contain terms and acronyms that may not be in common usage outside the field.
- In some cases, original documents referenced draft materials which have now been finalized. In these cases, where possible, references have been updated. These situations are clearly marked.
- These documents provided an overview of the issue for further discussion by experts in the field of OTDT. The findings and evaluations contained in these documents are not comprehensive—they reflect what was considered to be most applicable to the issue at the time.
- Information in these documents presents knowledge available at the time of the OTDT committee meetings. These documents have been edited for consistency in style and format, but have not been updated to reflect new information or knowledge. References and web links also remain unchanged and may no longer be accurate or available.
- As these are background documents to the ***Call to Action*** report which is available in both English and French, they are available in English only. Requests for translation can be made to Canadian Blood Services using the contact information below.

Note: Production of this document has been made possible through a financial contribution from Health Canada. The views expressed herein do not necessarily represent the views of the federal, provincial or territorial governments.

For more information on these documents or the ***Call to Action*** report, please contact:

Canadian Blood Services
Organ and Tissues Donation and Transplantation
1800 Alta Vista Drive
Ottawa ON K1G 4J5

Phone: 613-739-2300
organsandtissues@blood.ca

2. Scope

What role should surgical bone play in the Canadian TDT system?

This paper presents options for including surgical bone banking as a component of a coordinated national TDT system in Canada. Surgical bone refers most commonly to femoral heads (FH), an important part of Canada's tissue supply. Recovered from living donors as a bi-product of total hip replacements, femoral heads (FHs) are used in surgeries such as hip and knee revision, spinal fusions and treatment of non-united fractures[1]. Grafts are generally milled or further shaped in the operating room (OR) prior to implantation. The paper evaluates the current role of surgical bone in the Canadian context and assesses future-state options for surgical-bone banking activity by referencing international models.

[1] Kakaiyar. M. (1990). Regional programs for surgical bone banking. *Clinical orthopaedics and related research*, 251: 290-294.

3. Current State

Canada

In 2008, there were 15 Canadian tissue programs (outside Quebec) involved with surgical bone banking. Seven of these programs were considered standalone surgical bone banks, and did not recover or process tissue from deceased donors. Based on responses from 14 of 15 programs, the total number of FHs recovered in 2008 was 1,748, with the average number per bank at 125 (minimum = 4; maximum = 458). In 2002, Canadian programs (excluding Quebec) released a total of 1,883 FHs into usable inventory.[2] Survey respondents indicated that, in 2008, 1,271 FHs were released into usable inventory and 820 FHs were distributed from their programs to end-users,[3] indicating a 33 per cent decrease in surgical bone production since 2002.

The number of surgical bone programs within Canada has also decreased in recent years. In 2006, a report on surgical bone banking in Canada identified 14 programs banking surgical bone within Ontario.[3] There are currently only six programs recovering and banking surgical bone in Ontario; eight have closed or halted surgical bone banking activities. One other surgical-bone banking program outside of Ontario has decided to stop its surgical bone banking activities due to increased operational costs for serological donor testing.[4] In-hospital surgical bone banks often find it difficult to maintain quality assurance systems with limited hospital resources—certainly one factor in some recent closures of these banks.

The roles and responsibilities for identification and referral of donors, obtaining consent and donor screening activities vary by program. Most programs do not perform any processing activities with surgical bone grafts (e.g., depletion of blood and marrow components). The practice of irradiating surgical bone grafts also varies by program. In 2008, five of the 15 surgical bone programs were irradiating FH grafts. The decision

[2] Canadian Council for Donation and Transplantation (2006). Evaluation of Surgical Bone Banking and Utilization in Canada.
[3] Canadian Blood Services (2009). Preliminary Data Analysis – National Survey for Supply of Allograft Tissue. Prepared for the CCDT

[4] Dermot, Kelly. (August 28, 2009). Personal communication.

to irradiate or not to irradiate these grafts is often related to past practice of a program and the preference of its end-users.

The Unites States

There are few surgical-bone banking programs in the United States,[5] primarily because there is a reasonable supply of deceased donor tissue in the United States. End-users have many options; for example, in the case of a larger graft required for surgery, whole femoral heads from deceased donors can be ordered, and pre-packaged ground or chipped cancellous bone grafts are readily available for filling bone cavities.

[5] Zou. S. et al. (2004). Probability of viremia with HBV, HCV, HIV, and HTLV among tissue donors in the United States. *New England Journal of Medicine*,351: 751.

The United Kingdom

The NHSBT Tissue Service (TS) in the UK has a large living donor program. The living bone donor program operates in collaboration with 91 orthopaedic departments across the country and recovers FHs from over 5,000 patients per annum. TS nursing staff train hospital-based nursing staff—primarily in orthopaedic preoperative assessment clinics—to suggest FH donation to suitable patients undergoing total hip replacement surgery. Hospital nursing staff are trained to undertake initial donor selection and seek consent to donation, using TS procedures. TS staff train hospital theatre staff to collect the donated FH according to NHSBT TS documented quality procedures and arrange for the donated bone to be returned to one of the NHSBT tissue banks. The program does not undertake processing of surgically donated FHs; rather, all FHs found suitable for clinical use are either issued as unprocessed fresh frozen donations, or undergo gamma irradiation.[6]

[6] Pink. F, et al. (2006). Donor exclusion in the National Blood Service Tissue Services living bone donor programme. *Cell and Tissue Banking*, 7:11–21.

4. Considerations

Safety related:

- Bone from living donors may be considered safer than cadaveric bone due to the opportunity to obtain reliable medical history directly from the donor rather than from relatives who may be unaware of certain medical or life-style risk activity. Note: Although mentioned in the literature, no specific data was obtained to support this assertion.
- Unprocessed bone can transmit blood borne pathogens, but the risk of transmission can be significantly reduced by removing blood and marrow. Historically, orthopaedic surgeons have expressed a preference for unprocessed bone due to its better handling characteristics.[4]
- There may be a reduced risk of bacterial contamination of grafts from surgical bone donors when compared to post-mortem

donors. Micro-organisms of greater virulence, and that may have spread hematogenously from an endogenous source, may be present in post-mortem donors. Organisms of high virulence are unlikely to contaminate the living-donor FH hematogenously, since prophylactic antibiotics are given routinely to all patients undergoing total hip replacement. Note: If grafts are sterilized or irradiated there is no difference in risk between using living donor or deceased donor grafts.

- Most FHs are morselized and impacted. In these procedures, the biological properties that determine graft incorporation are more important than the mechanical strength. It has been shown that a low dose of gamma irradiation seems a suitable method for decontamination, as it does not affect the biological properties of a graft.[4,7]

[7] Jinno et al. (2000).

General:

- Although recovery costs are minimized by the use of tissue that would otherwise be discarded from a surgical procedure, a thorough cost-benefit analysis is required. The total costs of the surgical-bone banking process should be evaluated against the benefits of obtaining approximately 50 g of tissue from each living donor.
- A more comprehensive understanding of the exact uses of FH grafts within Canada would assist in understanding alternative grafts that could be used. For example, if FHs are milled within the OR, an alternative product would be ground or chipped bone, which is currently available pre-processed. If FHs are shaped within the OR, FHs from cadaveric donors could be used, if available.
- An understanding of the uses of FH grafts may also provide insight on the most appropriate processing or sterilization steps for FHs.

5. Options

Option 1 — Status quo

Keep existing surgical bone programs and processes in their current state.

Strengths	Weaknesses
• Infrastructure and processes exist to supply needs of regional end-users.	• Unstandardized donor screening, recovery and testing processes affect efficiencies and safety (see examples below). • There are costs associated with maintaining functioning tissue banks at all sites that recovering surgical bone.

Examples of unstandardized processes:

- In some programs, only a cursory donor screening occurs prior to FH recovery and banking, resulting in high number of subsequently rejected FHs.

- Some programs routinely irradiate FHs while others do not irradiate FHs at all.
- Programs have varied practices for bacterial contamination testing of the FHs

Option 2 — Centralization and coordination of surgical bone banking

A standardized national program with trained staff at designated healthcare facilities with orthopaedic programs. In an approach similar to that in the NHSBT Tissue Service model, recovered tissue would be sent to centralized sites for storage and evaluation.

Strengths	Weaknesses
• A standardized donor screening, recovery and testing program could be implemented and monitored. • The program could be expanded to realize donor potential at other orthopaedic centres that do not recover FHs.	• There would be significant implementation costs to establish a coordinated system (e.g., development and validation of standard processes, establishment of an audit program). • Additional shipping costs to transfer surgical bone to a centralized or regional centre, and for distribution of grafts to end-users.

Option 3 — Transition away from surgical bone banking

When whole femoral heads are required, use FHs from cadaveric donors; when femoral heads are morselized, provide pre-processed (ground or chipped) cancellous bone, as in the US model.

Strengths	Weaknesses
• Use of pre-processed allograft bone reduces the processing steps within the OR at the time of implantation.	• Lost opportunity to obtain bone grafts that are readily available.

Questions for consideration:

- Is there a need for surgical bone programs to continue, or are alternative products available?
- If surgical bone programs do continue, are they within the scope of a future national system?