Canadian Blood Services

TISSUE EXPERT COMMITTEE:

WHAT ROLE SHOULD SURGICAL BONE HAVE IN THE CANADIAN TISSUE SYSTEM?(DRAFT SOLUTION DESIGN PAPER)

1. Scope

This paper presents options available within the tissue system related to surgical bone banking. The central question is whether or not surgical bone banking should be a component of a coordinated national tissue system. Surgical bone, most commonly referring to femoral heads (FH), is a significant component of the tissue supply in Canada. Femoral heads are recovered from living donors as bi-product from total hip replacements and 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 OR prior to implantation. The report will evaluate the current role of surgical bone in the Canadian context and will assess the future state options for surgical bone banking activity by referencing international models.

2. Current State

Canada

In 2008, there were 15 Canadian tissue programs that were involved with surgical bone banking (excluding Quebec programs). Seven of these programs were considered "stand-alone" surgical bone banks that were not involved with recovering or processing tissue from deceased donors. Based on the responses from 14/15 programs, the total number of FHs recovered in 2008 was 1748, with the average number per bank at 125 (min. 4, max 458). Survey respondents indicated that 1271 FHs were released into usable inventory and 820 FHs were distributed from their programs to end-users in 2008[2]. In 2002, Canadian programs (excluding Quebec) released a total of 1,883 FHs into usable inventory[3], indicating a 33% decrease in surgical bone production had taken place by 2008.

The number of surgical bone programs within Canada has decreased significantly in the last number of 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 that are recovering and banking surgical bone in Ontario; eight programs have closed or halted their surgical bone banking activities. One other surgical bone banking program outside of Ontario has decided to stop their surgical bone banking activities due to the 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. This is certainly one factor in the closure of surgical bone banks in recent years.

---

[1] Kakaiyar. M. Regional programs for surgical bone banking, Clinical orthopaedics and related research, 1990, n°251, pp. 290-294

[2] National Survey for Supply of Allograft Tissue Preliminary Data Analysis – 2009.

[3] Canadian Council for Donation and Transplantation, Evaluation of Surgical Bone Banking and Utilization in Canada 2006

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

The roles and responsibilities for identification and referral of donors, obtaining consent and donor screening activities vary between programs. The majority of 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 varies between programs. In 2008, 5 of the 15 surgical bone programs were irradiating FH grafts. The decision to irradiate or not to irradiate FH grafts is often related to the historical practice of the program and the preference of their end-users.

United States

There are very few surgical bone banking programs in the United States[5] primarily due to the supply of deceased donor tissue in the United States. End-users have many options available to them; if a larger graft is 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.

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 5000 patients per annum. TS nursing staff train hospital based nursing staff, primarily in orthopaedic preoperative assessment clinics to offer femoral head (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 NBS TS documented quality procedures. TS staff arrange for the donation and bone samples for testing to be returned to one of the NHSBT tissue banks. The program does not undertake processing of surgically donated femoral heads; all FHs found suitable for clinical use are either issued as unprocessed fresh frozen donations, or they undergo gamma irradiation.[6]

3. Considerations

Safety Related:

- Bone from living donors may be considered safer when compared to bone from cadavers 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.[7] Note: Although this statement is 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 from the bone.

[5] Zou. S. et al. Probability of viremia with HBV, HCV, HIV, and HTLV among tissue donors in the United States N Engl J Med 2004; 351: 751

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

[7] Yates. P et. Al Processing of whole femoral head allografts: Validation methodology for the reliable removal of nucleated cells, lipid and soluble proteins using a multi-step washing procedure. Cell and Tissue Banking (2005) 6:277–285

However, 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. For post mortem donors, micro organisms of greater virulence that may have spread hematogenously from an endogenous source may be present. For living donors, it is unlikely that organisms of high virulence will contaminate the femoral head hematogenously, since prophylactic antibiotics are given routinely to all patients undergoing total hip replacement.[8] Note: If grafts are sterilized or irradiated there would be no differential in the risks of the using living donor grafts vs. deceased donor grafts.
- Most femoral heads are morselized and impacted and, in these procedures, the biological properties which determine graft incorporation are more important than the mechanical strength. It has been shown that a low dose of gamma irradiation does not affect the biological properties of a graft and this therefore seems a suitable method for decontamination [4, 9]

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 the alternative grafts that could be used. For example, if FHs are milled within the OR, an alternative product would be ground or chipped bone that 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.

4. 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 impacting efficiencies and safety. See examples, below. • There are costs associated with maintaining functioning tissue banks at all sites recovering surgical bone.

Examples of unstandardized processes:

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

[8] Vehmeyer. S. et al Bacterial contamination of femoral head allografts from living donors. Acta Orthopaedica 2002; 73 (2): 165–170

[9] Jinno et al. 2000

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

Option 2 – **Centralization and coordination of surgical bone banking.**

Have a standardized national program with trained staff at designated health care facilities with orthopaedic programs. Recovered tissue would be sent to centralized sites for storage and evaluation (e.g. NHSBT Tissue Service model).

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

Option 3 - Transition away from surgical bone banking.

Use femoral heads from cadaveric donors where whole femoral heads are required and provide preprocessed (ground/chipped) cancellous bone in procedures where femoral heads are morselized. e.g. US model.

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

Questions for Consideration:

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