

CANADIAN COUNCIL FOR  
DONATION AND TRANSPLANTATION



CONSEIL CANADIEN POUR  
LE DON ET LA TRANSPLANTATION

# **Human Tissue Importation Practices in Canada**

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**October 2006**

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**Prepared for the Canadian Council for Donation and Transplantation**

Deloitte Inc.

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## Executive Summary

Through previous work with the Canadian Institute for Health Information in 2003, the Canadian Council for Donation and Transplantation (CCDT) identified a supply-demand gap in Canada for certain types of human allograft tissues.

In January 2006, the CCDT chose to investigate and analyze current human tissue importation practices in Canada in order to gain a better understanding of the “unknown supply” required to meet tissue demand.

Specifically, the objectives of the project were:

- To quantify the volume and costs of imported musculoskeletal, cardiovascular and skin tissues from non-Canadian sources. This was to be accomplished through a demand and supply-side analysis (i.e., a representative survey of Canadian hospitals and foreign tissue distributors respectively). Products used by oral surgeons and dentists were excluded from this review as well as demineralized bone matrix.
- To document the names and the country of origin of major foreign providers that export tissues to Canada.
- To document the logistical, legal, regulatory and financial barriers and supports to importing tissues from outside Canada and to analyze the decision making process to importing tissue grafts from the surgeons’ and other primary decision makers’ perspective.

The following three surveys were prepared and sent to major Canadian hospitals as part of the demand-side analysis:

- Musculoskeletal tissue survey sent to 55 orthopaedic/neurosurgery centers
- Cardiovascular tissue survey sent to 20 cardiac surgery centers
- Skin tissue survey sent to 13 burn unit centers

In parallel, a supply-side analysis was also conducted consisting of 6 phone interviews with foreign-tissue suppliers (5 U.S.-based and 1 Quebec-based).

According to the data that was collected from Canadian hospitals, a total of 2,662 human allografts (imported and locally-sourced) were accounted for, of which 1,706 (~ 64%) were musculoskeletal grafts, 700 (~ 26%) were cardiovascular grafts and 256 (~10%) were skin grafts.

Total expenditures associated with these grafts were \$3.47 million of which \$1.36 million (~ 39%) were from musculoskeletal grafts, \$1.45 million (~ 42%) were from cardiovascular grafts and \$0.65 million (~19%) were from skin grafts. Table A summarizes the collected data from Canadian hospitals.

	Quantity of grafts			Total expenditures		
	Foreign suppliers	Canadian suppliers	Total Grafts	Foreign suppliers CAN\$	Canadian suppliers CAN\$	Total expenditures
<b>Musculoskeletal Grafts</b>						
Cancellous ground bone	234	370	604	\$178,753	\$200,283	\$379,036
Small structural grafts	131	134	265	\$170,722	\$78,498	\$249,220
Large Structural grafts	180	140	320	\$214,130	\$148,977	\$363,107
Tendons	35	172	207	\$47,721	\$110,268	\$157,989
Other soft tissues	113	197	310	\$91,485	\$122,789	\$214,274
<b>Sub-Total</b>	<b>693</b>	<b>1,013</b>	<b>1,706</b>	<b>\$702,812</b>	<b>\$660,815</b>	<b>\$1,363,627</b>
<b>Cardiovascular Grafts</b>						
<b>Sub-Total</b>	<b>395</b>	<b>305</b>	<b>700</b>	<b>\$389,223</b>	<b>\$1,062,255</b>	<b>\$1,451,478</b>
<b>Skin Grafts</b>						
<b>Sub-Total</b>	<b>20</b>	<b>236</b>	<b>256</b>	<b>\$108,900</b>	<b>\$545,636</b>	<b>\$654,536</b>
<b>TOTAL</b>	<b>1,108</b>	<b>1,554</b>	<b>2,662</b>	<b>\$1,200,935</b>	<b>\$2,268,706</b>	<b>\$3,469,641</b>

**Table A: Summary of survey results (graft quantity and costs incurred by type of supplier)**

The demand-side survey response rate, at 36%, was lower than anticipated. While this low response rate prevented the project team from extrapolating the above results in order to estimate the total quantities of tissues that are imported into Canada each year, the surveys did provide useful insights on:

- The type of tissues that tend to be more imported than others (e.g., 56% of large structural musculoskeletal grafts were imported vs. only 17 % of tendons - refer to table B - these results were consistent with our conversations with industry experts)
- The average cost differential between Canadian and U.S. tissue suppliers (e.g., tendons tended to be 2.13 times more expensive when imported from the U.S. - refer to table C). It is important to note that average costs and tissue suppliers listed are from survey responses and are not the result of a comprehensive review of all tissue banks.

	Quantity of grafts			Total expenditures		
	% from Foreign suppliers	% from Canadian suppliers	Total Grafts	% from Foreign suppliers	% from Canadian suppliers	Total expenditures
<b>Musculoskeletal Grafts</b>						
Cancellous ground bone	39%	61%	100%	47%	53%	100%
Small structural grafts	49%	51%	100%	69%	31%	100%
Large Structural grafts	56%	44%	100%	59%	41%	100%
Tendons	17%	83%	100%	30%	70%	100%
Other soft tissues	36%	64%	100%	43%	57%	100%
<b>Sub-Total</b>	<b>41%</b>	<b>59%</b>	<b>100%</b>	<b>52%</b>	<b>48%</b>	<b>100%</b>
<b>Cardiovascular Grafts</b>						
<b>Sub-Total</b>	<b>56%</b>	<b>44%</b>	<b>100%</b>	<b>27%</b>	<b>73%</b>	<b>100%</b>
<b>Skin Grafts</b>						
<b>Sub-Total</b>	<b>8%</b>	<b>92%</b>	<b>100%</b>	<b>17%</b>	<b>83%</b>	<b>100%</b>
<b>TOTAL</b>	<b>42%</b>	<b>58%</b>	<b>100%</b>	<b>35%</b>	<b>65%</b>	<b>100%</b>

**Table B: Summary of survey results (graft quantity and costs incurred by type of supplier)**

	Average price per graft		
	Foreign suppliers CAN\$	Canadian suppliers CAN\$	Price Premium Foreign/Canadian
<b>Musculoskeletal Grafts</b>			
Cancellous ground bone	\$764	\$541	1.41
Small structural grafts	\$1,303	\$586	2.22
Large Structural grafts	\$1,190	\$1,064	1.12
Tendons	\$1,363	\$641	2.13
Other soft tissues	\$810	\$623	1.30
<b>Cardiovascular Grafts (heart valves only)</b>	<b>\$5,821</b>	<b>\$4,054</b>	<b>1.44</b>
<b>Skin Grafts</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>

**Table C: Human tissue price differential – Foreign vs. Canadian suppliers (all prices in CAN\$)**

Furthermore, the surveys provided insight on the tissue purchase decision-making process in hospitals, perceived barriers to importing tissues in Canada, and the general level of tissue traceability from the hospital's perspective. The following is a brief summary of the insights gained:

- Half of all the respondents said that over the past 3 years, the cost differential between imported and Canadian-sourced tissue costs increased. Some attributed this cost increase to the lack of available Canadian tissue suppliers as well as to the additional costs incurred due to logistics and shipping.
- Almost half said that surgeons are the final decision makers when it comes to choosing a foreign tissue supplier.
- A third of the respondents said they have had to switch their Canadian-based human tissue supplier over the past 3 years (2003-05), almost double the amount that had to switch their

foreign tissue suppliers (17%). Reasons for supplier changes included inadequate post-transplant follow-up, shipping logistics and poor quality.

- Two-thirds of respondents said that their tissue suppliers were AATB accredited, and just over half (55%) said that AATB accreditation was a requirement for them. On the other hand, 3 out of the 4 cardiovascular tissue survey respondents said that they did not know whether their tissue suppliers were accredited and that AATB accreditation was not a supplier selection criterion.
- Exporter 1 highlighted the financial advantage of dealing with allograft tissue buying groups for cost containment.
- A previous study<sup>1</sup> performed by Deloitte for the Quebec market outlined a total of 2,065 human musculoskeletal tissues (including imported, locally-sourced and internally sourced). The total number of grafts was distributed as such: 424 (~21%) were femoral heads, 606 (~29%) were cancellous ground bone, 258 (~12%) were structural grafts, 538 (~26%) were demineralized bone matrix, and 239 (~12%) were tendons. The total value of these grafts is estimated at \$1.92 million (excluding the value of tendons), of which \$1.59 million was sourced on external markets (i.e., not sourced internally).

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<sup>1</sup> Significant differences in both methodology and focus exist between both surveys. As such, any joint analysis of data or conclusions should be done with caution.

## Methodology

In order to document the tissue importation practices in Canada and to gain additional insight on the present import barriers faced by tissue suppliers, the project team pursued the following methodology:

1. **Conduct a demand side analysis:** Surveys were sent out to major Canadian hospital centers
2. **Conduct a supply side analysis:** Phone interviews were conducted with U.S. tissue suppliers

### Demand Side Analysis

The project team began by drafting a list of major Canadian hospitals that were likely to import human tissues (skin, cardiovascular and musculoskeletal tissues). Past reports prepared by the Canadian Institute for Health Information (CIHI), namely, the “*Supply of Human Allograft Tissue in Canada*” and the “*Demand of Human Allograft Tissue in Canada*” were reviewed and particular attention was paid to whom these surveys were sent to as well as their cited sources and references.

Three surveys (one for each human tissue category: skin, cardiovascular and musculoskeletal tissues) were prepared and sent to 88 major Canadian hospitals/health centers in all provinces except Newfoundland. The breakdown of the 88 surveys sent is as follows:

- Musculoskeletal tissue survey: sent to 55 orthopaedic/neurosurgery departments
- Cardiovascular tissue survey: sent to 20 cardiovascular surgery departments
- Skin tissue survey: sent to 13 burn unit centers

These surveys asked specific questions regarding the number of allograft tissues bought (and the corresponding dollar amount spent) for both U.S. and Canadian-sourced grafts. They did however exclude all issues and volumes relating to demineralized bone matrix (DBM).

### Survey response rate

As of July 7, 2006, 32 out of the 88 sent surveys were completed and returned, yielding an overall response rate of 36% (One province’s response rate was particularly low). This response rate is probably due to a number of factors such as the level of detail requested that required participants to research information to answer questions, the fact that information is rarely centralized with one individual in the hospital, the general high workload of the targeted departments, the difficulty to identify respondents within the hospital, and overall survey fatigue of respondents from being solicited by a number of actors.

While this low response rate prevented the Deloitte project team from getting a good estimate for the total quantities of tissues that are imported into Canada each year, the surveys did provide useful insight on a number of topics, including which tissues tend to be more imported than others (possibly due to unavailability), average cost differential between Canadian and U.S. tissue suppliers



and tissue purchase decision-making process in hospitals. Table D below summarizes the overall response rate by survey type:

	Surveys Sent	Surveys completed and returned	Response rate
Musculoskeletal tissue survey	55	23	42%
Cardiovascular tissue survey	20	5	25%
Skin tissue survey	13	4	31%
<b>Total</b>	<b>88</b>	<b>32</b>	<b>36%</b>

**Table D: Survey response rate by type of survey**

## Supply Side Analysis

### Methodology

Using proprietary databases as well as information gathered through interviews with industry experts, the project team drafted a list of for-profit and not-for-profit U.S. tissue suppliers and Canadian tissue distributors in order to schedule a phone interview.

### Results

A number of tissue suppliers were willing to be interviewed in order to share with us their statistics on Canadian tissue sales. Their comments on the general state of U.S.-Canadian human tissue shipments were quite insightful.

A number of tissue suppliers simply never returned repeated calls.

### General comments on the supply and demand side analyses

In an ideal setting, demand and supply statistics should match: imported tissue quantities reported by survey respondents (hospitals) would correspond (once a reasonable extrapolation methodology is used) to the quantities shipped by tissue suppliers (both foreign and Canadian distributors of U.S. tissue suppliers). However, given the low survey response rate, an accurate estimate of the total imported tissues in Canada proved difficult to tabulate: For instance, Exporter 1, said, during an interview, that they shipped a little less than 2% of their 350,000 grafts in 2005 to Canada (excludes demineralized bone grafts). This alone would yield up to 7,000 grafts shipped to Canada, while the combined 22 musculoskeletal survey respondents (major Canadian hospitals, albeit missing the majority of those in one province) yielded a total of only 693 imported musculoskeletal grafts.

## Survey Results

In order to gain insight on the human tissue importation practices in Canada, the following three surveys were prepared and sent to major Canadian hospitals:

- Musculoskeletal tissue survey sent to orthopaedic/neurosurgery centers
- Cardiovascular tissue survey sent to cardiac surgery centers
- Skin tissue survey sent to burn unit centers

These surveys asked respondents to **quantify** and **qualify** their tissue importation practices.

The results are presented in the following pages:

- **Section 1.0 and 2.0: Volume and costs of imported human tissues to Canada and Survey Results**

This section quantifies the number of tissues (excluding DBM) that were imported into Canada by the respondents. More specifically, it presents the answers to *Questions 1* and *2* that asked respondents to name their tissue suppliers, to quantify how many of each tissue type was purchased, and finally to specify the costs<sup>2</sup> associated with these purchases (for both Canadian and foreign-sourced tissues).

- **Section 3.0: Volume and costs of tissues used in Quebec**

This section outlines the results from a previous study conducted by Deloitte Inc. on the Quebec market in 2004. This study's goal was to accurately portray the volume and value of musculoskeletal grafts within the province of Quebec. As such, this section is meant only as additional information to the study at hand and should be interpreted on a stand alone basis.

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<sup>2</sup> Note: Unless otherwise specified, Canadian currency is used throughout this report.

## 1.0 Volume and costs of imported human tissues to Canada\*

\*Given the 36% survey response rate, the quantity and cost of the human tissues discussed in the next section represent only a portion of all imported allograft tissue in Canada. No data extrapolation was performed to estimate the total annual tissue quantities imported into Canada.

### 1.1 General findings

According to the data that was collected from all survey respondents, a total of 2,662 human allograft tissues (imported and locally-sourced) were accounted for, of which 1,706 (~ 64%) were musculoskeletal grafts, 700 (~ 26%) were cardiovascular grafts and 256 (~10%) were skin grafts (refer to figure 1).

Total expenditures associated with these grafts were \$3.47 million of which \$1.36 million (~ 39%) were from musculoskeletal grafts, \$1.45 million (~ 42%) were from cardiovascular grafts and \$0.65 million (~19%) were from skin grafts (refer to figure 2). Note that cardiovascular grafts accounted for only 26% of the total number of grafts but 43% of the expenditures. This is due to the fact that, on average, cardiovascular tissues cost more per graft than musculoskeletal and skin tissues, due to processing complexity and tissue matching requirements.

The following table summarizes the collected data from the surveys:

	Quantity of grafts			Total expenditures		
	Foreign suppliers	Canadian suppliers	Total Grafts	Foreign suppliers CAN\$	Canadian suppliers CAN\$	Total expenditures
<b>Musculoskeletal Grafts</b>						
Cancellous ground bone	234	370	604	\$178,753	\$200,283	\$379,036
Small structural grafts	131	134	265	\$170,722	\$78,498	\$249,220
Large Structural grafts	180	140	320	\$214,130	\$148,977	\$363,107
Tendons	35	172	207	\$47,721	\$110,268	\$157,989
Other soft tissues	113	197	310	\$91,485	\$122,789	\$214,274
<b>Sub-Total</b>	<b>693</b>	<b>1,013</b>	<b>1,706</b>	<b>\$702,812</b>	<b>\$660,815</b>	<b>\$1,363,627</b>
<b>Cardiovascular Grafts</b>						
<b>Sub-Total</b>	<b>395</b>	<b>305</b>	<b>700</b>	<b>\$389,223</b>	<b>\$1,062,255</b>	<b>\$1,451,478</b>
<b>Skin Grafts</b>						
<b>Sub-Total</b>	<b>20</b>	<b>236</b>	<b>256</b>	<b>\$108,900</b>	<b>\$545,636</b>	<b>\$654,536</b>
<b>TOTAL</b>	<b>1,108</b>	<b>1,554</b>	<b>2,662</b>	<b>\$1,200,935</b>	<b>\$2,268,706</b>	<b>\$3,469,641</b>

**Table 1A: Summary of survey results (graft quantity and costs incurred by type of supplier)**

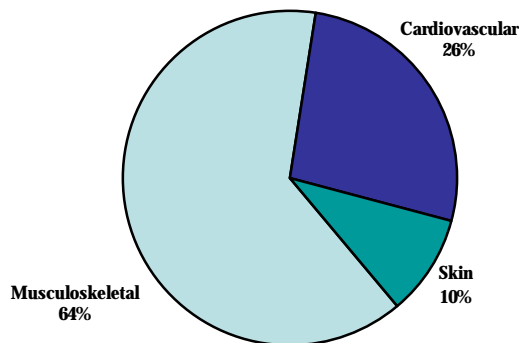


Fig. 1: Total volume of allografts, by type (Total = 2,662 grafts)

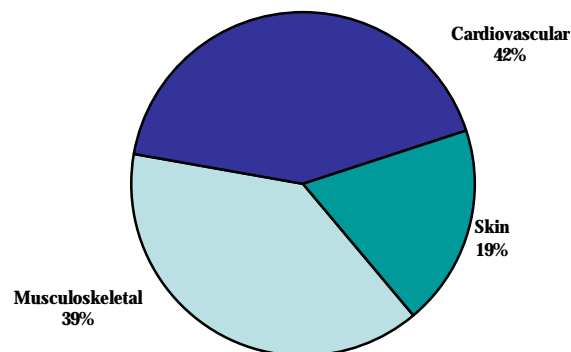


Fig. 2: Total expenditures on allografts, by type (Total = CAN\$3,47M)

Note that in CIHI's 2003 allograft tissue demand study, the total demand estimate for all grafts was between 21,643 and 41,020. The results from the 2006 survey (2,662 grafts) therefore represent at most 12% of the total demand accounted for in 2003.

## 1.2 Proportion of foreign vs. Canadian-sourced human tissues

The survey results were then used to calculate the proportion of imported human tissues from the U.S. vs. the total amount that are sourced from Canadian tissue suppliers. Table 2 below highlights the proportions for each tissue type.

	Quantity of grafts			Total expenditures		
	% from Foreign suppliers	% from Canadian suppliers	Total Grafts	% from Foreign suppliers	% from Canadian suppliers	Total expenditures
<b>Musculoskeletal Grafts</b>						
Cancellous ground bone	39%	61%	100%	47%	53%	100%
Small structural grafts	49%	51%	100%	69%	31%	100%
Large Structural grafts	56%	44%	100%	59%	41%	100%
Tendons	17%	83%	100%	30%	70%	100%
Other soft tissues	36%	64%	100%	43%	57%	100%
<b>Sub-Total</b>	<b>41%</b>	<b>59%</b>	<b>100%</b>	<b>52%</b>	<b>48%</b>	<b>100%</b>
<b>Cardiovascular Grafts</b>						
<b>Sub-Total</b>	<b>56%</b>	<b>44%</b>	<b>100%</b>	<b>27%</b>	<b>73%</b>	<b>100%</b>
<b>Skin Grafts</b>						
<b>Sub-Total</b>	<b>8%</b>	<b>92%</b>	<b>100%</b>	<b>17%</b>	<b>83%</b>	<b>100%</b>
<b>TOTAL</b>	<b>42%</b>	<b>58%</b>	<b>100%</b>	<b>35%</b>	<b>65%</b>	<b>100%</b>

Table 2: Summary of survey results (graft quantity and costs incurred by type of supplier)

Overall, 41% of musculoskeletal grafts were imported from the U.S. Within this category, small and large structural grafts as well as cancellous ground bone had the highest proportion of graft imports. On the other hand, only 17% of tendons and 36% of other soft tissues were imported. This is consistent with our interviews with industry experts and healthcare officials who confirmed that

tendons/soft tissue are often difficult to source from both U.S. and Canadian suppliers due to tissue scarcity.

Skin tissues were also seldom imported to Canada (only 8%) and this finding is again consistent with our conversations with burn unit personnel. According to them, locally-sourced fresh skin is readily available in Canada.

As for cardiovascular tissues, survey results showed that 56% of all tissues were imported. However, bovine grafts skewed these results as 100% of those are imported. When one considers only heart valves or pericardium, imports drop to 10% of total cardiovascular tissues, in line with our conversations with industry experts who said that cardiovascular tissues are among the most difficult human tissues to source from the U.S. (this will be discussed in more details in the cardiovascular tissue survey results section).

*\*\*Important note:*

*Given that a large number of small hospitals were not included in this survey, the above ratios need to be read within that context. An exhaustive survey asking all Canadian hospitals whether they buy or not imported tissues will likely yield different foreign expenditures/total expenditure ratios.*

### 1.3 U.S – Canadian human tissue price differential

Table 3 below summarizes the average price per graft for each tissue type, as reported by the survey respondents.

Across the board, one can conclude that U.S tissue prices are more expensive than Canadian-sourced tissues. The price differential was as low as +12% for large structural grafts and as high as 122% for small structural grafts. Heart valves cost on average 44% more when sourced from the U.S. No information was available for skin imports as practically no survey respondents reported purchasing skin tissues from U.S. suppliers. Again, it is important to mention that average prices are obtained from survey respondents and not an exhaustive review of tissue bank price lists.

	Average price per graft		
	Foreign suppliers CAN\$	Canadian suppliers CAN\$	Price Premium Foreign/Canadian
<b>Musculoskeletal Grafts</b>			
Cancellous ground bone	\$764	\$541	1.41
Small structural grafts	\$1,303	\$586	2.22
Large Structural grafts	\$1,190	\$1,064	1.12
Tendons	\$1,363	\$641	2.13
Other soft tissues	\$810	\$623	1.30
<b>Cardiovascular Grafts (heart valves only)</b>	\$5,821	\$4,054	1.44
<b>Skin Grafts</b>	n/a	n/a	n/a

**Table 3: Human tissue price differential – Foreign vs. Canadian suppliers (all prices in CAN\$)**

## 2.0 Survey results

### 2.1 Musculoskeletal tissues

Fifty-five (55) musculoskeletal (MSK) surveys were sent out to major orthopaedic and neurosurgery departments in Canada. Twenty-three (23) surveys were completed and returned, representing a response rate of 42% (note that at the time of writing this report, only two hospitals from one large province had sent back their survey).

Table 4 below summarizes the overall findings for the 5 MSK tissue categories (cancellous ground bone, small structural grafts, large structural grafts, tendons and other soft tissues). A total of 1,706 musculoskeletal grafts were cited, representing a total expenditure of CAN\$1.36 million.

<b>Muskuloskeletal Grafts</b>					
Product		QTY		\$	
		Foreign	Canada	Foreign	Canada
Cancellous ground bone	Cancellous ground bone 10-30cc	123	219	\$ 67,223	\$ 101,535
	Cancellous ground bone 31-60cc	73	123	\$ 62,023	\$ 86,148
	Cancellous ground bone >60cc	21	0	\$ 22,766	\$ -
	Other cancellous ground bone	17	28	\$ 26,741	\$ 12,600
	<i>Category total</i>	<i>234</i>	<i>370</i>	<i>\$ 178,753</i>	<i>\$ 200,283</i>
Small structural grafts	Uni/bi-cortical dowels	3	0	\$ 4,981	\$ -
	Tri-cortical wedges/blocks	20	64	\$ 17,281	\$ 27,908
	Femoral or humeral rings/cross-sections	31	0	\$ 49,844	\$ -
	Fibula wedge	0	10	\$ -	\$ -
	Iliac crest	2	0	\$ 1,449	\$ -
	Wedge/strip	18	53	\$ 21,576	\$ 46,800
	Other bone dowels/wedges	57	7	\$ 75,591	\$ 3,790
	<i>Category total</i>	<i>131</i>	<i>134</i>	<i>\$ 170,722</i>	<i>\$ 78,498</i>
Large Structural Grafts	Fibula whole/segment	31	1	\$ 20,732	\$ 330
	Femoral whole/proximal/distal/shaft	8	34	\$ 31,130	\$ 37,707
	Femoral head	133	78	\$ 133,612	\$ 84,780
	Humerus whole/proximal/distal/shaft	2	0	\$ 4,810	\$ -
	Tibia whole/proximal/shaft	2	7	\$ 4,544	\$ 11,830
	Rib	2	0	\$ 837	\$ -
	Other	2	20	\$ 18,465	\$ 14,330
	<i>Category total</i>	<i>180</i>	<i>140</i>	<i>\$ 214,130</i>	<i>\$ 148,977</i>
Tendons	Achilles tendon (with/without bone strut)	13	24	\$ 17,258	\$ 26,738
	Anterior/posterior tibialis tendon	7	75	\$ 8,108	\$ 45,299
	Patella tendon with struts whole/half	2	22	\$ 7,018	\$ 11,264
	Other	13	51	\$ 15,337	\$ 26,968
	<i>Category total</i>	<i>35</i>	<i>172</i>	<i>\$ 47,721</i>	<i>\$ 110,268</i>
Other soft tissues	<i>Category total</i>	<i>113</i>	<i>197</i>	<i>\$ 91,485</i>	<i>\$ 122,789</i>
<b>Total</b>		<b>693</b>	<b>1013</b>	<b>\$ 702,812</b>	<b>\$ 660,815</b>

**Table 4: Survey results for musculoskeletal tissues (quantity and expenditures, by supplier type)**

### Breakdown of foreign-sourced MSK tissues:

Out of the 693 imported MSK grafts reported from survey respondents, the top 2 categories were cancellous ground bone (34%) and large structural grafts (26%). Tendons represented only 5% of all imported MSK tissues. (Refer to fig. 3 below). However, a representative from Exporter 1 estimated that 90% of all their shipments to Canada were cancellous ground bone and small structural grafts, 5% were large structural grafts and the remaining 5% were tendons and soft tissues.

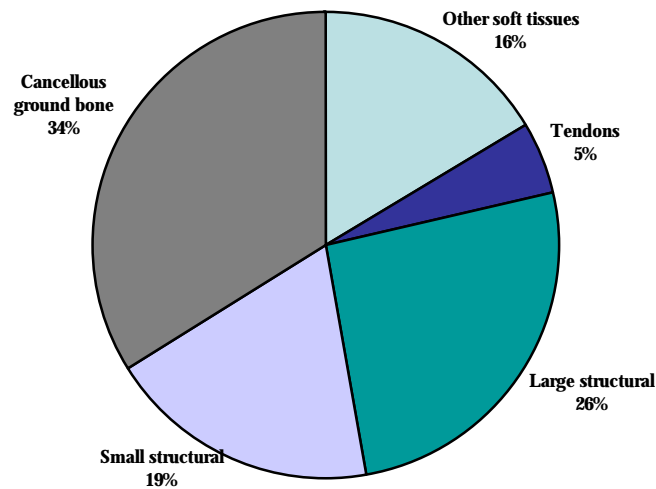


Fig.3: Breakdown of foreign-sourced MSK tissues, (Total =693 grafts)

### Breakdown of Canadian-sourced MSK tissues:

Respondents reported 1,013 Canadian-sourced MSK tissues, of which 37% were cancellous ground bone and 19% were other soft tissues (non-tendons). Tendons represented 17% of the tissues. (Refer to fig. 4 below).

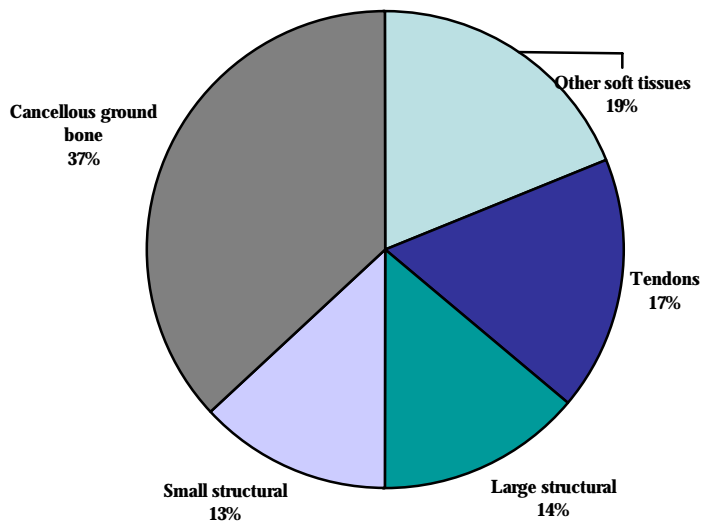


Fig. 4: Breakdown of Canadian-sourced MSK tissues, (Total =1,013 grafts)



### Proportion of foreign vs. Canadian-sourced musculoskeletal tissues

Overall, imported musculoskeletal tissues represented 41% of the total quantity purchased and 52% of total expenditures (refer to figures 5 and 6). Tendons and other soft tissues were the least imported categories: only 17% of tendons grafts (volume) and 36% of other soft tissues originated from foreign suppliers. This was consistent with our conversations with industry experts who stated that these tendons and soft tissues are difficult to source from foreign suppliers.

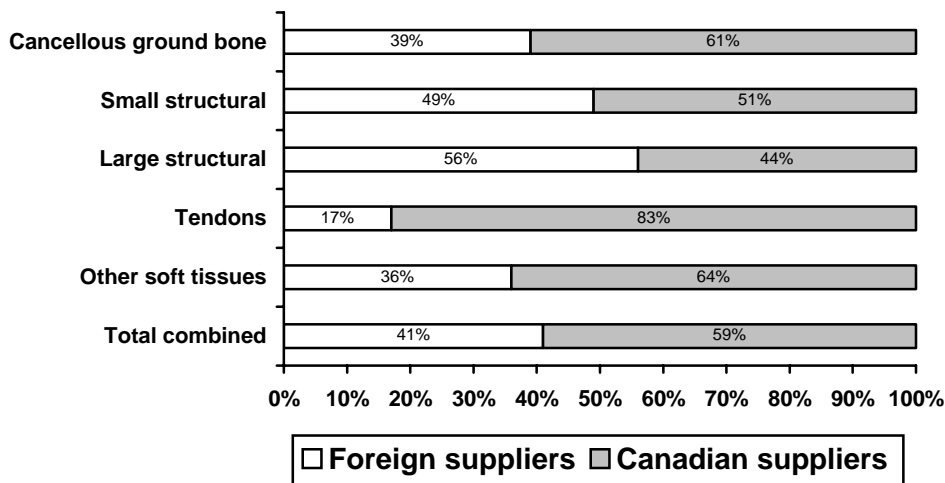


Fig. 5: Volume distribution of MSK tissues, by tissue and supplier type (Total = 1,706 grafts)

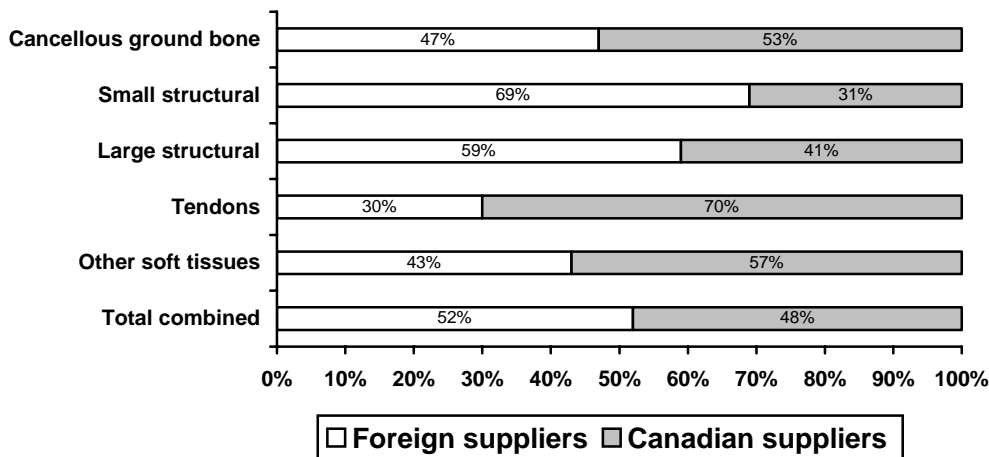


Fig. 6: Expenditure distribution of MSK tissues, by tissue and supplier type (Total = CAN\$1,363,627)

Table 5 below shows in greater detail the proportion of imported MSK tissues by sub-category.

<b>Muskuloskeletal Grafts</b>			
Product		Import as % of product quantity	Import as % of product value (\$)
Cancellous ground bone	Cancellous ground bone 10-30cc	36%	40%
	Cancellous ground bone 31-60cc	37%	42%
	Cancellous ground bone >60cc	100%	100%
	Other cancellous ground bone	38%	68%
	<i>Category total</i>	39%	47%
Small structural grafts	Uni/bi-cortical dowels	100%	100%
	Tri-cortical wedges/blocks	24%	38%
	Femoral or humeral rings/cross-sections	100%	100%
	Fibula wedge	0%	NA
	Iliac crest	100%	100%
	Wedge/strip	25%	32%
	Other bone dowels/wedges	89%	95%
	<i>Category total</i>	49%	69%
	Large Structural Grafts	Fibula whole/segment	97%
Femoral whole/proximal/distal/shaft		19%	45%
Femoral head		63%	61%
Humerus whole/proximal/distal/shaft		100%	100%
Tibia whole/proximal/shaft		22%	28%
Rib		100%	100%
Other		9%	56%
<i>Category total</i>		56%	59%
Tendons	Achilles tendon (with/without bone strut)	35%	39%
	Anterior/posterior tibialis tendon	9%	15%
	Patella tendon with struts whole/half	8%	38%
	Other	20%	36%
	<i>Category total</i>	17%	30%
Other soft tissues	<i>Category total</i>	36%	43%
<b>Total</b>		41%	52%

**Table 5: Proportion of musculoskeletal tissues that were imported (by quantity and expenditure)**

## U.S – Canadian musculoskeletal tissue pricing difference

Generally speaking, U.S. suppliers quoted higher prices than their Canadian counterparts: U.S./Canadian price ratios varied from as low as 0.92 to 12.89. Femoral heads were the only tissue type that seemed to be slightly more expensive in Canada (CAN\$1087 vs. CAN\$1005). All other human tissues were significantly more expensive from U.S. suppliers: 41% more for cancellous ground bone, 122% more for small structural grafts, 12% more for large structural grafts, 113% more for tendons and 30% more for other soft tissues.

Tissues like “patella tendons” were quoted at over CAN\$3,500 each from U.S. suppliers vs. only CAN\$512 from Canadian sources.

Table 6 below highlights the average prices paid for each MSK tissue type (in CAN \$).

<b>Muskuloskeletal Grafts</b>				
Product		Avg. Price		Price differential Foreign/Canada
		Foreign	Canada	
Cancellous ground bone	Cancellous ground bone 10-30cc	\$ 547	\$ 464	1.18
	Cancellous ground bone 31-60cc	\$ 850	\$ 700	1.21
	Cancellous ground bone >60cc	\$ 1,084	na	na
	Other cancellous ground bone	\$ 1,573	\$ 450	3.50
	<i>Category total</i>	\$ 764	\$ 541	1.41
Small structural grafts	Uni/bi-cortical dowels	\$ 1,660	na	na
	Tri-cortical wedges/blocks	\$ 864	\$ 436	1.98
	Femoral or humeral rings/cross-sections	\$ 1,608	na	na
	Fibula wedge	na	na	na
	Iliac crest	\$ 725	na	na
	Wedge/strip	\$ 1,199	\$ 883	1.36
	Other bone dowels/wedges	\$ 1,326	na	na
	<i>Category total</i>	\$ 1,303	\$ 586	2.22
	<i>Category total</i>	\$ 1,190	\$ 1,064	1.12
Large Structural Grafts	Fibula whole/segment	\$ 669	\$ 330	2.03
	Femoral whole/proximal/distal/shaft	\$ 3,891	\$ 1,109	3.51
	Femoral head	\$ 1,005	\$ 1,087	0.92
	Humerus whole/proximal/distal/shaft	\$ 2,405	na	na
	Tibia whole/proximal/shaft	\$ 2,272	\$ 1,690	1.34
	Rib	\$ 419	na	na
	Other	\$ 9,233	\$ 717	12.89
	<i>Category total</i>	\$ 1,190	\$ 1,064	1.12
Tendons	Achilles tendon (with/without bone strut)	\$ 1,328	\$ 1,114	1.19
	Anterior/posterior tibialis tendon	\$ 1,158	\$ 604	1.92
	Patella tendon with struts whole/half	\$ 3,509	\$ 512	6.85
	Other	\$ 1,180	\$ 529	2.23
	<i>Category total</i>	\$ 1,363	\$ 641	2.13
Other soft tissues	<i>Category total</i>	\$ 810	\$ 623	1.30
<b>Total</b>		\$ 1,014	\$ 652	1.55

**Table 6: Musculoskeletal tissue price differential – Foreign vs. Canadian suppliers (all prices in CAN\$)**

## Musculoskeletal tissues suppliers

A large number of both foreign and Canadian suppliers serve Canada's hospital centers (refer to table 7). The primary MSK tissue suppliers from the U.S. which accounted for a large portion all tissue imports are:

- Musculoskeletal Transplant Foundation (MTF)
- Regeneration Technologies Inc.: They distribute in Canada through Laswell Medical
- Community Tissue Services
- Tissue Net Inc.
- NorthWest Tissue Center, Allosource Inc., LifeNet Inc., U.S. Tissue and Cell Inc.

Cancellous ground bone		Small structural grafts	
Foreign Suppliers	Canadian suppliers	Foreign Suppliers	Canadian suppliers <sup>3</sup>
Regeneration Technologies	QE II Regional Tissue Bank	Musculoskeletal Transplant Foundation	Tissue Bank Manitoba
Community Tissue Service	CTC Edmonton	Regeneration Technologies	QE II Regional Tissue Bank
Musculoskeletal Transplant Foundation	Canmedica Corporation	Tissue Net	CTC Edmonton
Medtronic	Héma-Québec	Medtronic	Hema-Québec
North West Tissue Centre	Tissue Bank Manitoba	Community Tissue Service	
Tissue Net		North West Tissue Centre	
LifeNet			
U.S. Tissue & Cell			

Large structural grafts		Tendons		Other soft tissues	
Foreign Suppliers	Canadian suppliers	Foreign Suppliers	Canadian suppliers	Foreign Suppliers	Canadian suppliers
Musculoskeletal Transplant foundation	Mount Sinai Hospital	Musculoskeletal Transplant Foundation	Mount Sinai Hospital	Regeneration Technologies	Mentor
Regeneration Technologies	QE II Regional Tissue Bank	Regeneration Technologies	CTC Edmonton	Tissue Net	CTC Edmonton
Tissue Net	CTC Edmonton	Tissue Net	SK Transplant	Dura Patek	Anexxa Medical Technologies
Community Tissue Service	Tissue Bank Manitoba	North West Tissue Centre	QE II Regional Tissue Bank	Dura Gem	Minogue Medical
AlloSource	Hema-Québec	Blood & Tissue C. Central Texas			
American Red Cross	SK Transplant				
North West Tissue Centre					
U.S. Tissue & Cell					
Bone Bank Allografts					

**Table 7: Musculoskeletal tissue suppliers, as reported by survey respondents**

<sup>3</sup> A Canadian supplier does not necessarily indicate Canadian sourced tissue.

## 2.2 Cardiovascular tissues

Five (5) out of a total of 22 Canadian cardiovascular surgery units sent back a completed survey, representing a response rate of 23%.

Bovine cardiovascular tissues are included in this analysis as they represent a tissue type that is solely imported and represents a gap in the supply of allograft tissue.

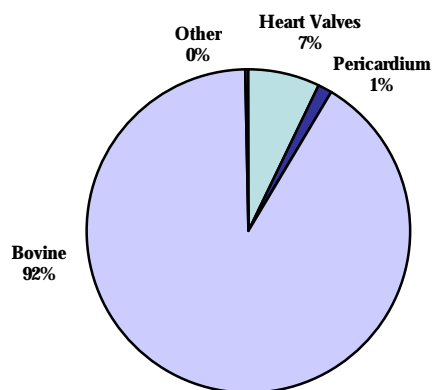
Survey results from the 5 respondents showed that in 2005, a total of 395 cardiovascular grafts were imported (total estimated value of \$389K) vs. 305 grafts that were Canadian sourced (total estimated value of \$1.06M) (refer to table 8).

Cardio				
Product	QTY		\$	
	Foreign	Canada	Foreign	Canada
Heart valves	29	248	\$ 168,795	\$ 1,005,400
Pericardium	5	47	\$ 2,723	\$ 21,855
Ascending/descending aorta	0	5	\$ -	\$ 15,000
Bovine	360	0	\$ 212,083	\$ -
Other	1	5	\$ 5,623	\$ 20,000
Total	395	305	\$ 389,223	\$ 1,062,255

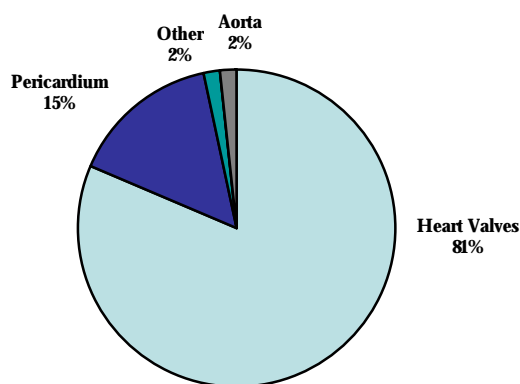
**Table 8: Survey results for cardiovascular tissues (quantity and expenditures, by supplier type)**

The distribution of cardiovascular tissues (in quantity) that were purchased also varied greatly depending on where they were sourced: Out of the 395 imported grafts, 92% were bovine tissues and only 7% were heart valves. This was in stark contrast with Canadian-sourced tissues, where 81% of reported grafts consisted of heart valves and 15% were Pericardium grafts (refer to figures 7 and 8).

Note that tissues included in the “other” category were specified as “saphenous vein” and “pulmonary allograft”.



**Fig 7: Breakdown of foreign-sourced cardio. tissues, (N=395)**



**Fig 8: Breakdown Canadian-sourced cardio. tissues, (N=305)**

### Proportion of foreign vs. Canadian-sourced cardiovascular tissues

Overall, 56% of all cardiovascular grafts (quantity) reported by the 5 respondents were imported from the U.S., representing 27% of total expenditures (refer to figures 9 and 10). Heart valves represented 10% of the total cardiovascular grafts purchased (or 14% of expenditures). Note that bovine grafts skewed the results as that they formed 92% of total imported grafts, and were 100% foreign sourced.

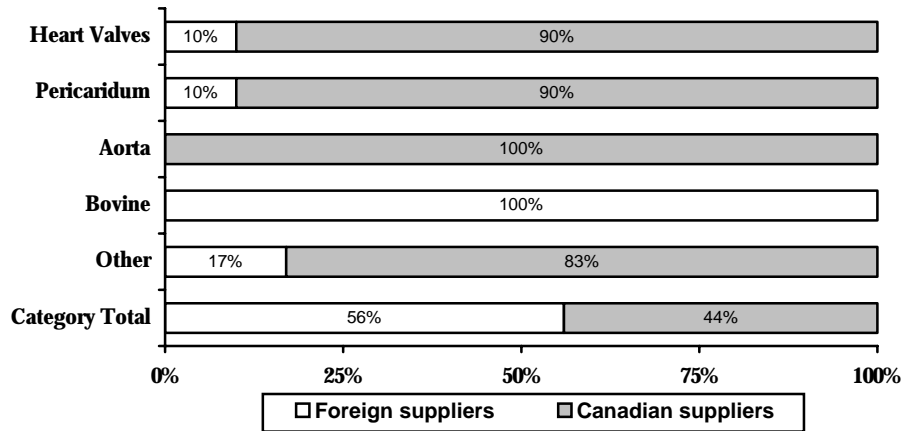


Fig. 9: Volume distribution of cardio tissues, by tissue and supplier type (Total = 700 grafts)

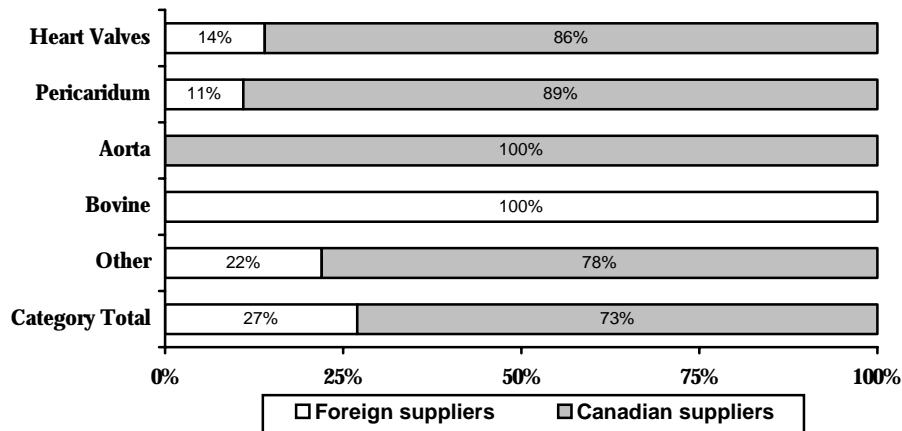


Fig. 10: Expenditure distribution of cardio tissues, by tissue and supplier type (Total = CAN\$1,451,478)

## U.S – Canadian cardiovascular tissue pricing difference

Just like with the majority of musculoskeletal tissue prices, cardiovascular tissue prices from U.S. suppliers were more expensive across the board: Pericardium grafts cost CAN\$545 from U.S. suppliers vs. CAN\$465 from Canadian sources, a 17% differential. Heart valves were 44% more expensive when purchased from U.S. suppliers (CAN\$5,821 vs. CAN\$4,054). Nevertheless, respondents said that availability, not pricing, was their most critical purchasing decision criterion.

Table 9 below highlights the average prices paid for each cardiovascular tissue type in 2005

Cardiovascular tissue category	Avg. Price (CAN\$)		Price Premium Foreign / Canadian
	Foreign	Canada	
Heart valves	\$ 5,821	\$ 4,054	1.44
Pericardium	\$ 545	\$ 465	1.17
Ascending/descending aorta	na	\$ 3,000	na
Bovine	\$ 589	na	na
Other	\$ 5,623	\$ 4,000	1.41

**Table 9: Cardiovascular tissue price differential – Foreign vs. Canadian suppliers (all prices in CAN\$)**

## Cardiovascular tissue suppliers

The following is a list of all the foreign and Canadian cardiovascular tissue suppliers as reported by survey respondents:

Heart valves		Pericardium	
Foreign Suppliers	Canadian suppliers	Foreign Suppliers	Canadian suppliers
Edwards Lifesciences	CTC-Edmonton	na	Anexxa Medical technologies
Medtronic	QE II Regional Tissue Bank		Minogue Medical
Cryolife	HSC Toronto	Ascending / descending aorta	
American Red Cross		Foreign Suppliers	Canadian suppliers
North West Tissue Centre		na	CTC-Edmonton
Medtronic of Canada			Hema-Québec
St-Judes Medical			
Bovine		Others	
Foreign Suppliers	Canadian suppliers	Foreign Suppliers	Canadian suppliers
Vascuguard	Minogue Medical	American Red Cross	Force 3 Medical
Synovis Surgical Innovation		Cryolife	
Medtronic			

**Table 10: Cardiovascular tissue suppliers, as reported by survey respondents**

### 2.3 Skin tissues

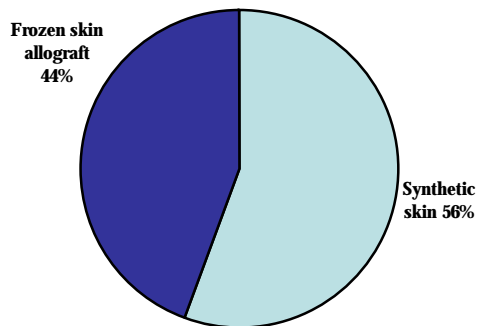
A total of 13 Canadian burn unit centers were contacted and 4 replied for a response rate of 31%. Unfortunately, the completed surveys omitted much needed information to allow for an accurate representation of the total quantity and the cost differential of tissues purchased. Therefore the results in the following tables and figures, particularly the ratios, are to be read with caution.

Table 11 below summarized the survey findings.

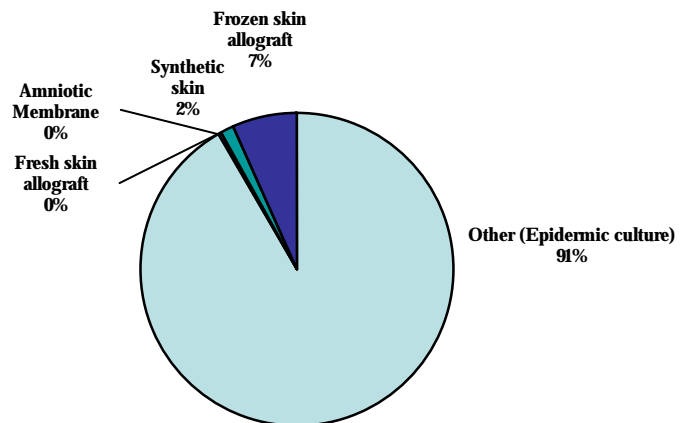
Skin Grafts					
Product	QTY			\$	
	Foreign		Canada	Foreign	Canada
Frozen skin allograft	na		230	\$ 48,400	\$ 36,110
Fresh skin allograft	na		na	\$ -	\$ -
Synthetic skin	na		5	\$ 60,500	\$ 8,379
Amniotic Membrane	na		1	\$ -	\$ 1,148
Other (Epidermic culture)	20		na	\$ -	\$ 500,000
Total	20		236	\$ 108,900	\$ 545,636

**Table 11: Survey results for skin tissues (quantity and expenditures, by supplier type)**

Total reported expenditures totalled CAN\$108,900 from U.S. suppliers and CAN\$545,636 from Canadian suppliers. Imported skin tissue expenditures were comprised of the following: 56% synthetic vs. 44% frozen skin (note that 20 units of “porcine xenografts” were also cited under “Other” but no dollar amount was specified). Canadian-sourced skin grafts had a \$500,000 “epidermic culture” category which represented 91% of all skin purchases from within Canada. (Refer to figures 11 and 12 for the breakdown of tissue expenditures by supplier type).



**Fig. 11: Breakdown of foreign-sourced skin tissue expenditure**



**Fig.12: Breakdown of Canadian-sourced skin tissue expenditure**



### Proportion of foreign vs. Canadian-sourced skin tissues

According to the survey results from the 4 respondents, 57% of frozen skin and 88% of synthetic skin expenditures were foreign-sourced (refer to figure 13).

While a number of burn unit center representatives stated that they seldom ever buy skin tissues from U.S. suppliers, one burn unit center did have a cost concern with respect to buying a new tissue-engineered skin from a U.S. supplier.

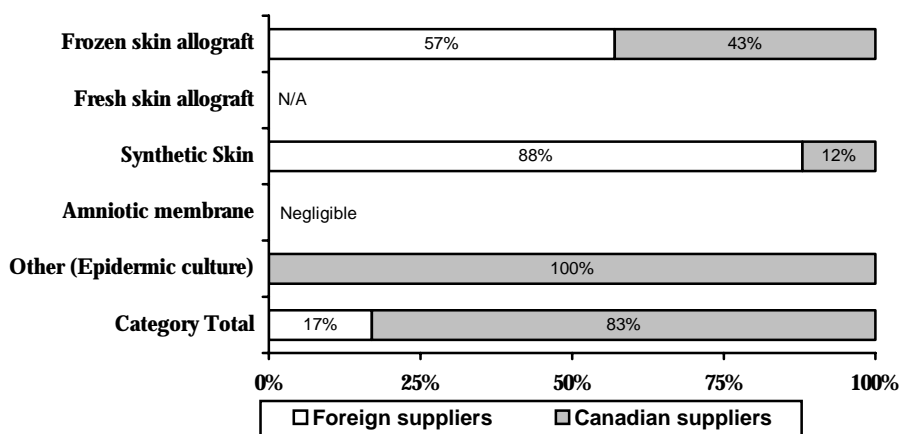


Fig. 13: Imported skin graft expenditures as a percentage of total expenditures

### Skin tissue suppliers

The following is a breakdown for the cited skin graft suppliers by skin category (table 12): One burn-unit respondent said that they processed all their fresh skin demand internally. They also mentioned that they recently decided to buy from a closer supplier due to transportation related issues.

Frozen Skin Allograft		Fresh Skin Allograft		Synthetic Skin	
Foreign Suppliers	Canadian suppliers	Foreign Suppliers	Canadian suppliers	Foreign Suppliers	Canadian suppliers
na	QE II Regional Tissue Bank	na	Quebec Transplant	Integra	Canada Microsurgical
	CTC Edmonton			Johnson & Johnson	
Amniotic Membrane		Other			
Foreign Suppliers	Canadian suppliers	Foreign Suppliers	Canadian suppliers		
na	Labtician Ophthalmics	EZ Derm	Laboratoire Loex		
		Brennen Medical			

Table 12: Skin tissue suppliers, as reported by survey respondents

### **3.0 Volume and market for musculoskeletal tissues in Quebec**

#### **3.1 Quebec study context & methodology**

##### **Context**

In the fall of 2004, Deloitte assisted Héma-Québec in defining and understanding the business environment surrounding musculoskeletal graft in Quebec. Specifically, the main objective of the study was to determine the actual market size for musculoskeletal graft in Quebec and to understand the sourcing methods used by Quebec hospitals.

##### **Methodology**

The Deloitte project team drafted, in collaboration with Héma-Québec, a survey to identify key areas of interest and identify volumes used by hospitals in Quebec. In this case, the categories of musculoskeletal tissues used were different than those specified in the CCDT survey, and were as follows:

- Femoral heads,
  - Cancellous ground bone,
  - Structural grafts (includes both small and large structural grafts), and
  - Demineralized bone matrix (DBM).
- Tendons were also included but did not yield clear volumes due to the high level of autograft in tendon related surgery.

In Quebec, 56 of the 119 hospitals have orthopedic departments, in which the 255 orthopedists currently work. To obtain a better response rate, the complete survey was sent to all 255 orthopedists and also to the head nurse in charge of orthopedics at all 56 hospitals.

This survey asked specific questions regarding the number of allograft tissues used in orthopedics (thus including internally sourced tissues), the related suppliers which hospitals used in the case of externally sourced tissues. The surveys also asked respondents to discuss a number of issues related to their internal and external tissue sourcing practices, their product and service preferences as well as the level of use of autograft, allograft and synthetic tissues in different types of surgery.

##### **Survey response rate**

In the course of this study, out of the 56 hospital surveys sent out, 48 provided completed responses. These 48 hospitals employed 93% of Quebec's 255 orthopedists, and included all major users of musculoskeletal grafts in the province. Furthermore, 41 of the 255 orthopedists also provided responses, thus providing a possibility to cross validate responses from select hospitals.

### 3.2 General findings from Quebec Study

According to the data that was collected from all survey respondents, a total of 2,065 human musculoskeletal tissues (including imported, locally-sourced and internally sourced) were accounted for. The total number of grafts was distributed as such: 424 (~21%) were femoral heads, 606 (~29%) were cancellous ground bone, 258 (~12%) were structural grafts, 538 (~26%) were demineralized bone matrix, and 239 (~12%) were tendons<sup>4</sup>.

The total value of these grafts is estimated at 1.92 million dollars<sup>5</sup> (excluding the value of tendons), of which 1.59 million was sourced from external markets (i.e. not sourced internally). The proportion of all grafts (excluding tendons) sourced on the marketplace would represent ~81% of the total volume of grafts or ~83% of the market value. The rest of the market being served through internal bone banks at a few hospitals.

The following table summarizes the collected data from the survey

	Quantity of grafts			Market size		
	External Volume	Internal Volume	Total Grafts	External Market Value CAN\$	Internal Market Value CAN\$	Total Market Value CAN\$
Femoral heads	287	137	424	\$341,320	\$162,929	\$504,249
Cancellous ground bone	436	170	606	\$239,241	\$93,283	\$332,524
Structural grafts	222	36	258	\$484,419	\$78,554	\$562,973
Demineralized bone matrix	538	-	538	\$522,984	\$0	\$522,984
<b>Sub-Total</b>	<b>1 483</b>	<b>343</b>	<b>1,826</b>	<b>\$1,587,964</b>	<b>\$334,766</b>	<b>\$1,922,730</b>
Tendons	N/A	N/A	239	N/A	N/A	N/A
<b>TOTAL</b>	<b>1 483</b>	<b>343</b>	<b>2,065</b>	<b>\$1,587,964</b>	<b>\$334,766</b>	<b>\$1,922,730</b>

**Table 3.1: Market volumes and size for Quebec market**

<sup>4</sup> Note that tendon volumes were not directly included in the original study as a large part were deemed to come from autograft interventions. The identified volume is based upon the proportion of knee reconstructions declared to have been done using allograft tissues by the respondents, and should be interpreted with caution.

<sup>5</sup> Note that the value derived for the total market is based upon an average unit price for each category and not on actual purchase amounts supplied by respondents, and that given the uncertainty of volumes relating to tendons these were not included. The average unit price was calculated using the average price of Héma-Québec, the Halifax QEII tissue bank and the American Red-Cross. For structural grafts the average price of a distal femur with condyle was used to extrapolate the total value of the segment.

### 3.3 Main suppliers to the Quebec market

While the original survey did not include specific questions relating to Canadian or foreign suppliers of tissues, certain suppliers were identified as being more prominent within the province of Quebec. As outlined in the following table a few suppliers have exclusive relationships with specific hospitals in Quebec.

Main suppliers	Location	# of hospitals served in Quebec	Number of hospitals using exclusively the supplier
Rubinoff Bone and Tissue Bank Mount Sinai Hospital	Toronto, Ontario	9	4
Regional Tissue Bank QEII Health Sciences	Halifax, Nova Scotia	5	2
Musculoskeletal Transplant Foundation (MTF)	Edison, New Jersey	16	2
Northwest Tissue Center	Seattle, Washington	2	None
Regeneration technologies (RTI)	Alachua, Florida	2	None
Héma-Québec (tissus)	Quebec, Quebec	14	4

**Table 3.2: Main suppliers to Quebec hospitals**

## **Conclusion**

While the low survey response rate prevented extrapolation of results to estimate the total quantities of tissues that are imported into Canada each year, the surveys did provide useful insights on the types of tissues that are imported and their relative proportion of the total allograft volume, as well as cost differentials. The average prices quoted should not be taken to be absolutes as tissue bank price lists were not reviewed during the survey process.

These findings provide a starting point for commencing a targeted review of sources of tissue grafts in Canada.