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DEMAND FOR HUMAN ALLOGRAFT
TISSUE IN CANADA: INTEGRATING DENTAL
INDUSTRY DEMAND
FINAL REPORT SEPTEMBER 2003

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**Demand for Human Allograft Tissue
in Canada:
Integrating Dental Industry Demand**

**Final Report
September 2003**

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Executive Summary

In November 2002, the Canadian Council for Donation and Transplantation engaged the Canadian Institute for Health Information (CIHI) to conduct the CCDT Project 4.1—Supply and Demand for Human Tissue in Canada. This project is the first phase of a multi-phase, multi-year process to make recommendations for a Tissue Banking and Transplantation model of services for Canada. This model would address tissue donation, processing, distribution, access, quality, informatics, safety and governance.

The CCDT Project 4.1 is considered a foundation phase to document the “lay of the land” with regard to Canadian tissue banking and related activities, as they exist today. These initiatives will position the CCDT Tissue Committee to identify areas of focus for future initiatives deemed necessary to gather the additional data and information required to recommend an appropriate Canadian model.

In May 2003, a document was completed which represented the CCDT Project 4.1 deliverable of *Demand for Human Allograft Tissue in Canada—Final Report*. This Demand study focused on a range of key users of allograft tissue in Canada (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn unit/plastic surgeons), their product preferences, and predicted use of tissue in the future.

Results of an earlier Environmental Scan and subsequent Key Informant Interviews provided evidence that another key User Group of allograft tissue is the Canadian Dental Industry, namely periodontists and oral and maxillofacial surgeons. A separate project component was initiated to focus on the Dental Industry. This report presents the results specific to the demand of the Canadian Dental Industry, and in combination with the results from the previous study *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*.

For the purposes of this study the Dental Industry User Groups have been defined as all practicing periodontists in Canada (239) and all practising oral and maxillofacial surgeons in Canada (355). This is per the current mailing lists of the Canadian Academy of Periodontology (CAP) and the Canadian Association Oral and Maxillofacial Surgeons (CAOMS).

Demand surveys were mailed to all members of both dental User Groups. The overall combined Dental Industry response rate (including periodontists and oral and maxillofacial surgeons) was 16.8%, varying from a high of 21.2% in the West to 13.3% in the Atlantic region. The response rate for the periodontist survey was 26.3%, varying from a high of 29.5% in the West to 24.7% in the Central region. The response rate for the oral and maxillofacial surgeon survey was 10.4%, varying from a high of 12.8% in the West to 6.9% in the Atlantic region.

Dental specialists use a wide range of grafting products, often in combination. These include: autogeneous tissue, allograft, xenograft and synthetic products. Extrapolating survey respondent demand across 3 ranges results in the following totals of current annual demand for allograft tissue by the Canadian Dental Industry:

- €# Low range—44,974 grafts
- €# Medium range—66,340 grafts
- €# High range—88,034 grafts

In each range the periodontist User Group accounts for over 90% of overall demand by the Dental Industry.

Predicted increases in allograft tissue use by the Dental Industry over the next 1-2 years range from a low of 0% for structural grafts and soft tissue to a high of 10.2% for mineralized freeze-dried bone products. When predicted increases in allograft tissue use over the next 1-2 year period are applied to the extrapolated respondent demand, predicted annual usage of allograft tissue by the Canadian Dental Industry is as follows:

- €# Low range—48,625
- €# Medium range—71,710
- €# High range—95,151

The majority of Dental Industry users indicated that they obtain their allograft tissue products from American Tissue Banks (80% for periodontists and 77% for oral and maxillofacial surgeons). In addition, users stated that they access tissue from the U.S. as demineralized (DMB) bone products and many of the highly specialized products that they use are not available through Canadian Tissue Banks.

Comments on the Dental Demand surveys pointed strongly to the lack of information that dental specialists have regarding Canadian Tissue Bank services and the safety of the products they produce. When considering the factors relating to decisions to purchase outside of Canada, safety appears to be the most important (for over 50% of respondents).

The Dental Demand study has provided important information about user preferences for the characteristics of a preferred supplier of allograft tissue. The highest rated preferences (96% and 82%) were for accredited and Canadian Tissue Banks. The majority of respondents indicated that the features of provider screening for quality standards and a model for recipient tracking and adverse outcome monitoring were preferable. Sixty (60) percent of respondents indicated that they agreed or strongly agreed that they preferred a not-for-profit tissue bank. Interestingly, similar results were reported with respect to whether Tissue Banks should generate profits.

A segment of the study focused on the trends and technologies that could increase or decrease the use of allograft tissue in the future. Highlights of the responses include the following:

- ⌘ The aging population, increased interest in maintaining oral health and increased interest in cosmetic procedures were cited as factors that will increase the demand for allograft tissue.
- ⌘ The possibility of disease transmission, improved intra-oral autograft techniques and the emergence of alternative products were cited as trends that could result in decreased demand for allograft tissue.
- ⌘ Survey respondents indicated trends toward increasing numbers of many procedures that require the use of grafting products.

The study identified the commercial products that dental specialists frequently purchase for use in their practice. A listing of these commercial products and their sources is provided in Appendix B of this document. In addition to these commercial products, survey respondents listed a number of generic products that they use. These include:

- ⌘ Demineralized freeze dried bone (cortical powder, putty, porous)
- ⌘ Mineralized freeze dried bone allograft powder
- ⌘ Freeze dried cortical bone
- ⌘ Platelet derived growth factor (PDGF), platelet rich plasma (PRP)
- ⌘ Biocoral
- ⌘ Collagen membranes, neuro-substances
- ⌘ Enamel matrix proteins/derivatives
- ⌘ Hydroxyapatite

The Supply and Demand studies have provided a number of opportunities to gain an in-depth understanding of the range of procedures for which human allograft tissue is used by dental specialists, the details of which are documented in this report. In addition, Key Informant Interviews provided invaluable information also detailed within this document.

With the completion of this report, results from previous project phases can now be considered in context with the Dental Industry results. The annual Current Demand for the Canadian Dental Industry (periodontists and oral and maxillofacial surgeons) can now be compared to that of the non-dental User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn unit/plastic surgeons), as reported in the *Demand for Human Allograft Tissue in Canada, Final Report – May 2003*:

User Group	Range of Annual Current Demand (grafts per year)
Dental Industry	
⌘ Periodontists	41,505–82,663
⌘ Oral and Maxillofacial Surgeons	3,469–5,371
Non-Dental User Groups	34,442–62,098
All User Groups	79,416–150,132

Data gathered in relation to the predicted increase in use of allograft tissue over the next 1–2 year period for the Canadian Dental Industry (periodontists and oral and maxillofacial surgeons) can now be compared to that of the non-dental User Groups as reported in the *Demand for Human Allograft Tissue in Canada, Final Report—May 2003*:

User Group	Range of Predicted Demand (grafts per year)
Dental Industry	48,625 to 95,151
Non-Dental User Groups	42,589 to 77,210
All User Groups	91,214 to 172,361

The results of this study have highlighted a number of differences within the industry when comparing the 2 dental User Groups.

Based on survey data, demand for tissue by periodontists significantly outweighs that of oral and maxillofacial surgeons by more than 15:1. This discrepancy raised concern that there may be underreporting by the oral and maxillofacial surgeons. The project team used 2 methods to analyze survey data and validate the lower numbers:

- ≠ Estimated range of demand using extrapolated survey results—3,469 to 5,371
- ≠ Estimated range of demand using extrapolated survey procedure counts—4,680 to 7,248

These results indicate that survey data was internally consistent; however, when analyzing levels of activity by oral and maxillofacial surgeons within the hospital setting using a national database (Hospital Morbidity Database), average annual procedures for 1998–2000 were in excess of 14,000 procedures. If it is assumed that at least one graft is used for the majority of these procedures, and that there are additional procedures completed by these surgeons outside the hospital setting, actual numbers could potentially be higher. It should be noted that it is very likely that a percentage of these 14,000 + procedures did not include the use of allograft tissue. Nevertheless, the reader should be aware that the Demand survey results may be somewhat understated for the oral and maxillofacial surgeon User Group.

Comparing features of practice for periodontists and oral and maxillofacial surgeons may also explain some of the differences in demand. Periodontal practice focuses on “building up” structures and “filling in” spaces. It is conceivable that 100% of periodontists use some form of grafting material in all procedures. Within the specialty of oral and maxillofacial surgery there are a percentage of surgeons who likely never use grafting material, such as those surgeons who do extractions solely.

Periodontists primarily work in the community in their own practice or with others. These clinicians require very good tracking mechanisms for procedures, purchases of material and other critical information as payment sources such as third party payers require it. Oral and maxillofacial surgeons working in a hospital setting may be much further removed from the data that is tracked for their procedures and the related costs of material.

The type of tissue used by these User Groups also differs. Periodontists have a significant demand for demineralized and mineralized freeze dried bone which is likely exclusively ordered from the U.S. Oral and maxillofacial surgeons access cancellous bone, small and large structural bone (e.g. hemi-mandibles), some of which are available from Canadian Tissue Banks.

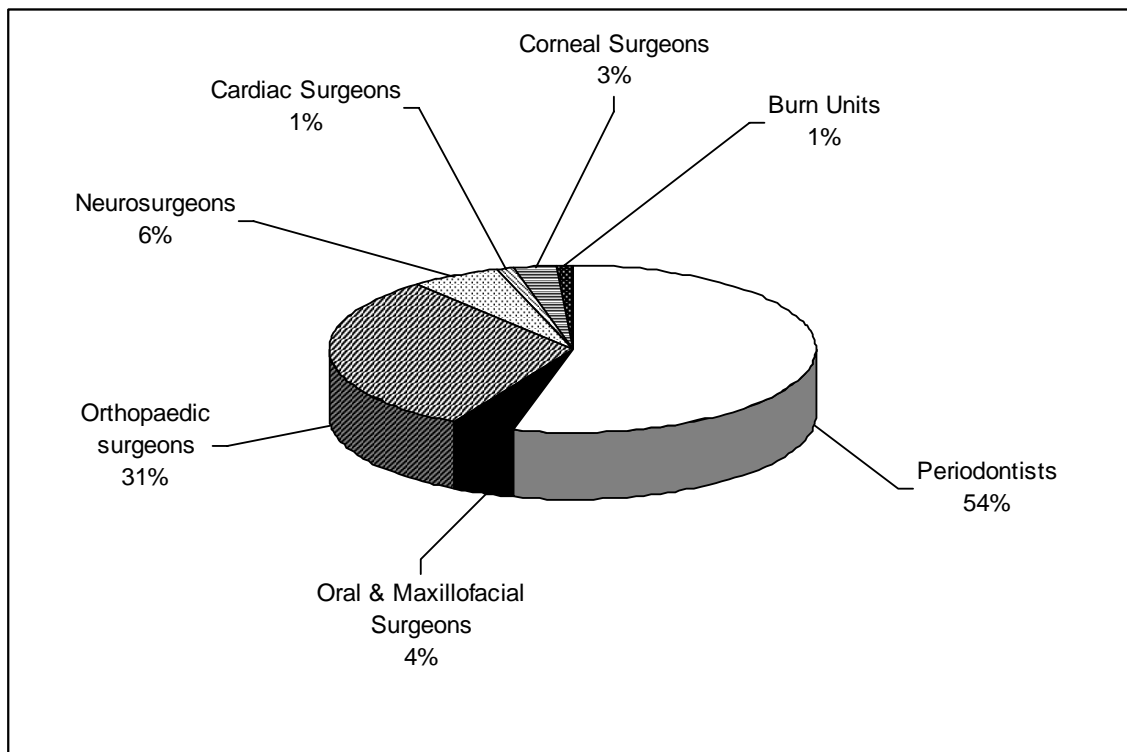
When comparing the proportion of tissue types used by these 2 groups there appear to be differences and similarities:

- ≠ Over 80% of all tissues used by both groups are in the demineralized and/or mineralized freeze dried bone categories;
- ≠ Periodontists demand for soft tissue accounts for 7% of their total; for oral and maxillofacial surgeons this is 5%;
- ≠ Periodontists demand for skin accounts for 12% of their total; for oral and maxillofacial surgeons this is 8%; and,
- ≠ Use of mineralized freeze dried bone makes up 33% of all tissues used by periodontists.

It is particularly interesting and notable to consider the extrapolated demand for periodontists as compared to other User Groups. Using the middle range for extrapolated demand, the following table compares the relative contribution of the various Users Groups to total current demand for allograft tissue (medium range):

User Group	Extrapolated Demand—Medium Range	
	Number of Grafts	% of Total
Periodontists	61,912	54%
Oral and Maxillofacial Surgeons	4,428	4%
Orthopaedic surgeons	35,666	31%
Neurosurgeons	6,856	6%
Cardiac Surgeons	1,089	1%
Corneal Surgeons	3,391	3%
Burn Units	1,614	1%
Total	114,956	100%

The following figure further illustrates the results presented in the previous table:



At the medium range periodontists ($n = 179$) use almost double the number of grafts as compared to orthopaedic surgeons ($n = 770$). If Canada's tissue banking services are to meet the needs of all User Groups in the future, demand by the Dental Industry, and in particular of periodontists, should be a key consideration.

Demand surveys for the Dental Industry and for the non-dental User Groups included a number of sections that were consistent across all User Groups. These included sources and access to tissue, use of alternatives, characteristics affecting selection of supplier, user preferences and current trends. The project team compared the general results in these topic areas and this analysis is included in the summary section of this document.

The CCDT studies on Supply and Demand have permitted estimations of shortfalls (or surpluses in some cases for certain tissue types) of allograft tissue across Canada and regionally. With the addition of the Dental Industry data a more complete picture of these estimations can be made.

The *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*, detailed a current shortfall/surplus across the 3 ranges for the non-dental User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn unit/plastic surgeons) as follows:

- €# Low range—annual shortfall of 23,713 tissues or 69% of total extrapolated demand
- €# Medium range—annual shortfall of 37,887 tissues or 78% of total extrapolated demand
- €# High range—annual shortfall of 51,369 tissues or 83% of total extrapolated demand

With the addition of demand from the Dental Industry User Groups (periodontists, oral and maxillofacial surgeons), the shortfall/surplus across the 3 ranges rises as follows:

- €# Low range—annual shortfall of 68,687 tissues or 86% of total extrapolated demand
- €# Medium range—annual shortfall of 104,227 tissues or 91% of total extrapolated demand
- €# High range—annual shortfall of 139,403 tissues or 93% of total extrapolated demand

As reported in the *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*, the extrapolated demand adjusted for the predicted shortfall/surplus (incorporating the survey respondents predicted increase in tissue use over the next 1-2 year period) for the non-dental User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn unit/plastic surgeons) is as follows:

- €# Low range—annual shortfall of 31,860 tissues or 75% of total predicted demand
- €# Medium range—annual shortfall of 49,706 tissues or 82% of total predicted demand
- €# High range—annual shortfall of 66,481 tissues or 86% of total predicted demand

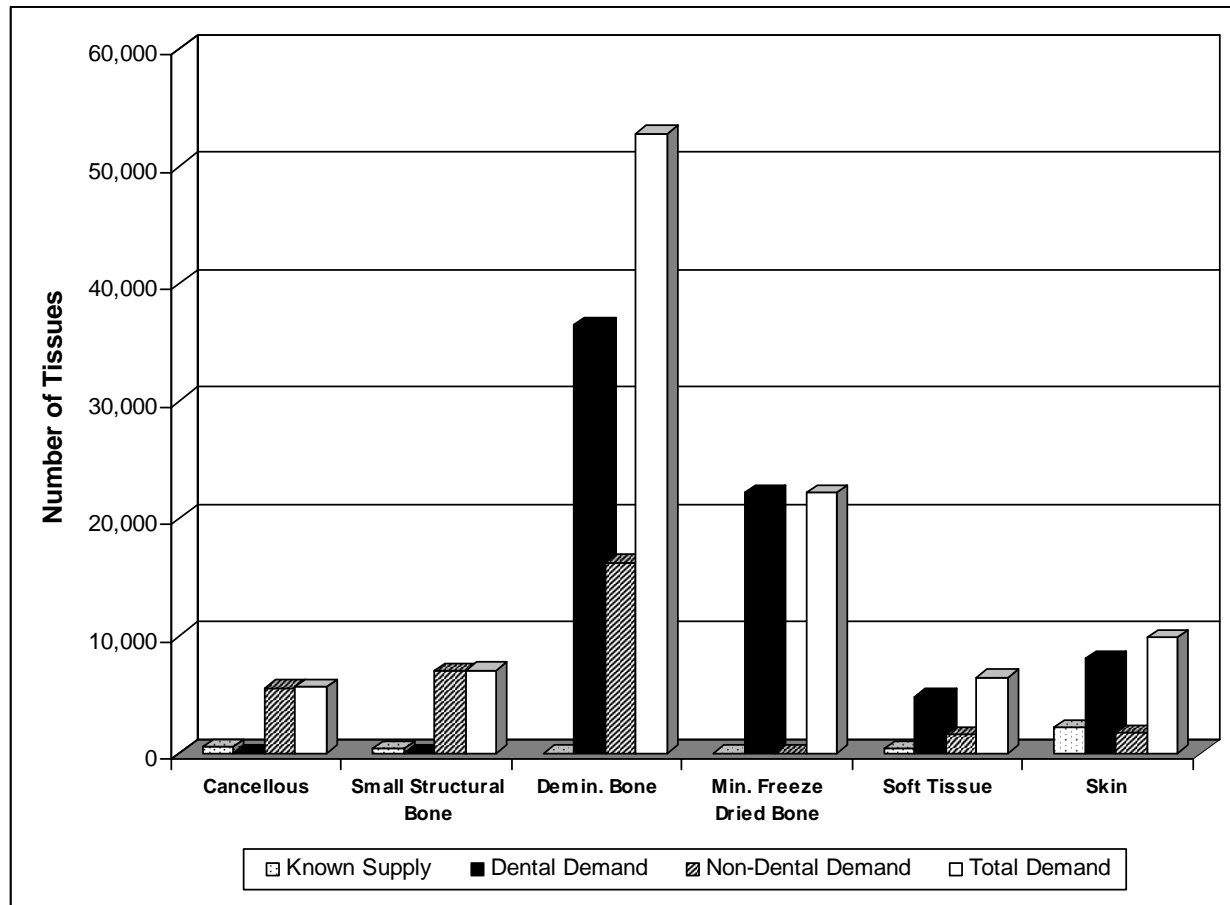
With the addition of demand from the Dental Industry User Groups (periodontists, oral and maxillofacial surgeons), the predicted shortfall/surplus across the 3 ranges rises as follows:

- €# Low range—annual shortfall of 80,485 tissues or 88% of total predicted demand
- €# Medium range—annual shortfall of 121,416 tissues or 92% of total predicted demand
- €# High range—annual shortfall of 161,632 tissues or 94% of total predicted demand

The following graph contrasts demand at the medium range by Total Demand, and Demand for dental and non-dental groups versus Known Supply of allograft tissue in Canada for the tissue types utilized by the Dental Industry.

This snapshot of Known Supply and Demand for allograft tissue in Canada highlights the fact that tissue products utilized most by the Dental Industry (demineralized bone and mineralized freeze dried bone) are not currently supplied by Canadian Tissue Banks. In addition, it reveals significant shortfalls for other tissue types as compared to total demand (dental and non-dental).

Known Supply vs. Dental, Non-Dental, and Total Demand by Relevant Tissue Type at Medium Range



In summary, the completion of this final component of the CCDT Project 4.1 to study Supply and Demand for Human Allograft Tissue in Canada has permitted a comprehensive study of the demand by key User Groups and comparisons with Known Supply.

The Dental Industry contribution to overall Demand is significant and there are unique features such as the type of tissue used, the sources for these products and the methods used to obtain it. In particular, there is a major reliance of the dental User Groups on accessing tissue commercially from the U.S., either directly or through distributors.

The major portion of products they use (demineralized bone and mineralized freeze dried bone) are not produced in any form in Canada. In addition, in contrast to the non-dental User Groups which primarily function in hospital/acute-care settings, the Dental Industry has a large component of specialists working in the community in private practice settings.

The study results have also verified that the Dental Industry and non-dental User Groups share similar views on characteristics influencing selection of supplier, and preferences for characteristics for tissue banks. The most striking differences between the 2 groups are the source of tissue, (primarily the U.S.) and the types of tissue products utilized. The majority of the products utilized by the Dental Industry are highly specialized, commercialized and involve more complex manufacturing processes than the tissues currently produced by Canadian Tissue Banks.

Another common thread in both Demand studies is the general lack of knowledge of User Groups regarding Canadian tissue banking services, how to access tissue, safety and accreditation standards and how the current system is working.

Several factors identified in the *Demand for Human Allograft Tissue in Canada, Final Report May 2003* that influence or constrain the level of Current Demand for allograft tissue in Canada are relevant to the Dental Industry:

- ⚡ Healthcare resource constraints for OR time and limited budgets for purchasing products (particularly for hospital-based oral and maxillofacial surgeons);
- ⚡ Use of alternative products (autografts, xenografts, synthetic) and combination products either due to limited access/resources or concerns regarding safety;
- ⚡ Historical user preferences;
- ⚡ Research and development focussed on biologics, tissue engineering and other emerging technologies; and
- ⚡ Lack of information/knowledge regarding the risks and efficacy of using allograft tissue, existing standards and services relevant to tissue banking in Canada.

The development of a Canadian Tissue Banking Model which will address the needs of all users, including the Dental Industry, must take into account the unique features of this industry and the tissues required. The results of this study *Demand for Human Allograft Tissue in Canada: Integrating Dental Industry Demand*, reinforce the recommendations made in the May 2003 report, outlining the key requirements for a Canadian Tissue Banking Model:

- ⚡ Public and clinical education regarding the safety, sources and efficacy of allograft tissue;
- ⚡ Adequate government funding to monitor, evaluate and implement equitable services across Canada, and in particular to provide the needed infrastructure, expertise and resources for provision of large volumes of tissue that is currently not produced in Canada;
- ⚡ Ongoing research and development focused on emerging technologies and evaluation; and
- ⚡ Comprehensive data tracking mechanisms and outcomes reporting that are consistent across hospital based and community based settings.

Background

In November 2002, the Canadian Council for Donation and Transplantation engaged the Canadian Institute for Health Information (CIHI) to conduct the CCDT Project 4.1—Supply and Demand for Human Tissue in Canada. This project is the first phase of a multi-phase, multi-year process to make recommendations for a Tissue Banking and Transplantation model of services for Canada. This model would address tissue donation, processing, distribution, access, quality, informatics, safety and governance.

The CCDT Project 4.1 is considered a foundation phase to document the “lay of the land” with regard to Canadian tissue banking and related activities, as they exist today. These initiatives will position the CCDT Tissue Committee to identify areas of focus for future initiatives deemed necessary to gather the additional data and information required to recommend an appropriate Canadian model.

This foundation phase, Supply and Demand for Human Tissue in Canada comprises four major components:

- ≠ Environmental Scan (December 2002);
- ≠ Supply of Human Allograft Tissue in Canada (April 2003);
- ≠ Demand for Human Allograft Tissue in Canada (May 2003); and
- ≠ Demand for Human Allograft Tissue in Canada: Integrating Dental Industry Demand (September 2003)

The Environmental Scan was a critical step in preparing for the core project activities of studying Supply and Demand for Human Tissue in Canada. The findings of this scan were used to develop the data collection instruments for both Supply and Demand studies. Key Informant Interviews were conducted for all components of the project and played a major role in the development of data collection instruments and in identifying survey respondent groups.

The Supply component of the project (*Supply of Human Allograft Tissue in Canada—Final Report, April 2003*) focused on existing services and Tissue Banks in Canada known to recover, process and distribute allograft tissue to users.

The Demand component of the project (*Demand for Human Allograft Tissue in Canada—Final Report, May 2003*) focused on the range of key users of allograft tissue in Canada (surgical specialists excluding the Dental Industry), their product preferences and predicted use of tissue in the future.

Results of the Environmental Scan and Key Informant Interviews provided evidence that another key User Group of allograft tissue is the Dental Industry, namely periodontists and oral and maxillofacial surgeons. A separate project component focused on the Dental Industry including national surveys, data analysis and reporting. This report presents the results specific to the demand of the Canadian Dental Industry and in combination with the results presented in *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*.

Introduction and Purpose

The Dental Industry Demand study focuses on key users of allograft tissue in Canada (periodontists and oral and maxillofacial surgeons), their product preferences, and predicted use of tissue in the future. This report provides the methods, results, and findings as they relate to the study of *Demand for Human Allograft Tissue in Canada: Integrating Dental Industry Demand*.

The purpose of this study is:

- €# To estimate Current Demand for human allograft tissue (cancellous, demineralized and mineralized bone, structural bone, skin, soft tissue) in Canada by the Dental Industry;
- €# To predict demand for allograft tissue in Canada by the Dental Industry;
- €# To investigate common dental procedures using allograft tissue, factors affecting Dental Industry demand; and,
- €# To evaluate demand by the Canadian Dental Industry in relation to non-dental demand and Known Supply.

In addition, this study combines Demand by the Dental Industry with the summary results reported for other key User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn units/plastic surgeons) in the report, *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*.

The findings of the Environmental Scan and interviews with key informants pointed to 3 methods for studying Demand. These included:

1. Structured interviews with key/high volume users of allograft tissue from the Dental Industry.
2. Demand Surveys for select User Groups and Tissue Types: structured survey instruments for 2 specialties: periodontists and oral and maxillofacial surgeons.
3. Methods for estimating demand of allograft tissue in Canada using existing databases and survey results.

The purpose of this report is to provide the results of these methods, and to provide observations based on these results and comparative analysis for Supply and Demand for human allograft tissue in Canada.

Dental Industry Demand Surveys

Overview of Methodology

The CCDT had requested that the project team investigate the feasibility of studying the allograft tissue uses and needs of the Canadian Dental Industry. The first phase of this study, the *Environmental Scan, December 31st, 2002* (pg. 29-30) included a web-based review of common products used by the Dental Industry. In subsequent phases of this project, the team conducted Key Informant Interviews that included meetings with representatives from the periodontal and oral and maxillofacial surgical groups. These meetings revealed that the Dental Industry is a significant consumer of various forms of human allograft tissue and that there is potential for this use to increase in the future.

The project team recommended a number of strategies to collect data in relation to the demand for human allograft tissue by the Dental Industry. The primary strategy was the use of structured surveys for targeted User Groups of allograft tissue. High volume Dental Industry User Groups were identified as follows:

- Periodontists; and
- Oral and maxillofacial surgeons.

The survey design and content was developed to include consistency across User Groups while at the same time building in unique and customized content where appropriate. The surveys were reviewed by representatives of the 2 dental User Groups prior to finalization. In general, all surveys included questions addressing:

- Estimated use of allograft tissue over a weekly, monthly or yearly period;
- Predicted increase or decrease in demand for tissue in the future;
- Sources and access to allograft tissue;
- Characteristics affecting selection of tissue supplier; and
- Trends and emerging technologies affecting demand.

The surveys included questions asking for common types of dental procedures that require allograft tissue. Surveys were also customized based on information gleaned from interviews and recommendations of key informants. Copies of the 2 surveys are included in Appendix A.

For both Dental Industry User Groups the “universe of specialists” was surveyed. The sources of the survey samples were as follows:

1. Periodontists—current mailing list of the Canadian Academy of Periodontology (CAP).
2. Oral and maxillofacial surgeons—Current mailing list of the Canadian Association of Oral and Maxillofacial Surgeons (CAOMS) for both members and non-members.

Two cover letters accompanied each survey. The first letter was a joint CIHI/CCDT letter that provided background information and general instructions. The purpose of the second letter was to provide support and endorsement of the project on behalf of the national

organizations representing the User Groups. In the case of the periodontist survey the letter was from the President of the CAP. For oral and maxillofacial surgeons the letter was from a key user of allograft tissue and a well known member of this professional group. The survey frames for these 2 User Groups are outlined in more detail as follows:

1. National Survey for Demand of Allograft Tissue Products by Periodontists. The survey was mailed to 240 periodontists (see Table 1 below for details).

Table 1. Survey Frame: Periodontists

Province/ Territory	Total Mailer (N)	Total Mailer Distribution (%)
N.L.	1	0.4%
P.E.I.	-	-
N.S.	11	4.6%
N.B.	4	1.7%
Que.	37	15.4%
Ont.	109	45.4%
Man.	11	4.6%
Sask.	6	2.5%
Alta.	22	9.2%
B.C.	39	16.2%
Total	240	100.0%

2. National Survey for Demand of Allograft Tissue Products by Oral and Maxillofacial Surgeons. The survey was mailed to 355 oral and maxillofacial surgeons (see Table 2 below for details).

Table 2. Survey Frame: Oral and Maxillofacial Surgeons

Province/ Territory	Total Mailer (N)	Total Mailer Distribution (%)
N.L.	3	0.8%
P.E.I.	2	0.6%
N.S.	20	5.6%
N.B.	4	1.1%
Que.	82	23.1%
Ont.	166	46.8%
Man.	17	4.8%
Sask.	6	1.7%
Alta.	21	5.9%
B.C.	34	9.6%
Total	355	100.0%

Assumptions

The analysis presented in this report is based on the following assumptions:

- ⚡ Health conditions do not vary dramatically across the country;
- ⚡ Clinical practice within a specialty does not vary dramatically across the country; and
- ⚡ Within the various User Groups, data provided by survey respondents will be reasonably representative of the User Group as a whole.

Limitations

There are several limitations associated with the analysis presented in this report as follows:

- ⚡ Project stakeholders and key users pilot tested the surveys prior to finalization. Enhancements were made to the final design and content of each survey; however, all respondents may not have interpreted each question consistently.
- ⚡ In some cases survey respondents did not complete some questions/sections.
- ⚡ Many of the questions asked the users to provide data regarding allograft usage or an **estimate** of usage.
- ⚡ Readers of this report are cautioned that the projections for Canadian demand of allograft tissues contained within this report may be influenced by respondent bias. Respondents may be biased toward frequent users of allograft products and non-respondents may be biased toward those who are less frequent users of allograft tissue. The projections have been calculated across several ranges in an attempt to offset the impact of this potential bias.
- ⚡ The analysis, extrapolation, and estimation methods provided in this report incorporate the use of existing national databases that may be subject to some inaccuracies.
- ⚡ In some cases the analysis, extrapolation and estimation methods rely on historical data.
- ⚡ If response rates for the 2 User Groups are compared, the periodontists rate of 26.3% is significantly higher than that of the oral and maxillofacial surgeons (10.4%). The lower response rate of oral and maxillofacial surgeons could be a limitation in the interpretation of the data specific to oral and maxillofacial surgeons.

Response Rates

1. National Survey for Demand of Allograft Tissue Products by Periodontists.

Overall, the response rate was 26.3%, varying from a high of 29.5% in the West to 24.7% in the Central region.

Survey response rate was calculated by deleting the surveys where:

≠ The respondent indicated the survey was not applicable to his/her practice (n = 1); one respondent indicated that he had retired).

≠ The survey was not returned by July 18, 2003.

The details of the response rate are provided below in Table 3:

Table 3. Response Rate: Periodontist Survey

Region	Total Mailer (N)	Survey Returned (N)	Response Rate (%)
Atlantic	16	4	25.0%
Central	146	36	24.7%
West	78	23	29.5%
Total	240	63	26.3%

2. National Survey for Demand of Allograft Tissue Products by Oral and Maxillofacial Surgeons.

Overall, the response rate was 10.4%, varying from a high of 12.8% in the West to 6.9% in the Atlantic region.

Survey response rate was calculated by deleting the surveys where the survey was not returned by August 21, 2003.

The details of the response rate are provided below in Table 4.

Table 4. Response Rate: Oral and Maxillofacial Survey

Region	Total Mailer (N)	Survey Returned (N)	Response Rate (%)
Atlantic	29	2	6.9%
Central	248	25	10.1%
West	78	10	12.8%
Total	355	37	10.4%

3. Combined Response

The overall combined Dental Industry response rate (including both periodontists and oral and maxillofacial surgeons) rate was 16.8%, varying from a high of 21.2% in the West to 13.3% in the Atlantic region.

The details of the combined response rate are provided below in Table 5.

Table 5. Response Rate: Combined Periodontist and Oral and Maxillofacial Surveys

Region	Total Mailer (N)	Survey Returned (N)	Response Rate (%)
Atlantic	45	6	13.3%
Central	394	61	15.5%
West	156	33	21.2%
Total	595	100	16.8%

Results: Survey Respondent Demand

The survey respondents were requested to provide a variety of statistics in relation to their current and predicted use of allograft tissue. The results are presented in the sections that follow.

Results by Tissue Type and User Group

The sections below provide an overview of demand based on data reported in the Demand Surveys. The information has been organized by tissue type and user group and reflects data as reported by respondents. The data reflected in this section **has not been extrapolated**.

Allograft Bone Tissue

Table 6. Demand for Bone Products—As per Survey Responses

Users	Pre-packaged Cancellous (50cs's) Per Year	Packages of Demineralized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products	Structural Bone Grafts per Year
Periodontists (n = 63)		10,477	7,097	
Oral and Maxillofacial Surgeons (n = 37)	10	561		7
Total	10	11,038	7,097	7

Allograft Skin and Soft Tissue

Table 7. Demand for Allograft Skin Products and Soft Tissue—As per Survey Responses

Users	Skin Products (e.g. Alloderm) per Year	Soft Tissue (e.g. fascia lata) per Year
Periodontists (n = 63)	2,586	1,630
Oral and Maxillofacial Surgeons (n = 37)	50	30
Total	2,636	1,660

Synthetic Bone Substitutes and Xenograft Bone Products

Respondents were questioned about their use of synthetic bone substitutes and xenograft grafting products as during Key Informant interviews, users indicated these products are sometimes used as substitutes for human allograft tissue (mainly due to budgetary constraints). Should a Canadian Tissue Banking model result in the increased availability of cost-effective human allograft products, the usage of synthetic and xenograft grafting products may be reduced as a proportion of this demand could shift to human allograft tissue products.

Table 8. Synthetic and Xenograft Products—As per Survey Responses

Users	Synthetic and Xenograft Bone Products per Year
Periodontists (n = 63)	17,168
Oral and Maxillofacial Surgeons (n = 37)	946
Total	18,114

Extrapolation of Demand Survey Results

Introduction

To adjust for the fact that the survey response was less than 100% of surveys mailed, the results of the survey were extrapolated to provide estimates of what the results might have reflected if a greater proportion of users had responded. In all cases it was assumed that data provided by those who responded to the surveys would be representative of the User Group.

User Groups

For the purpose of this project the User Group is considered to be the number of users in a particular specialty who are most likely to be users of human allograft tissue in Canada.

The Dental User Groups have been defined as follows:

- ≠ Periodontists: This survey was forwarded to a list of 240 believed to represent all practicing periodontists in Canada. One survey was eliminated due to a retirement, leaving the User Group in Canada defined as 239 periodontists.
- ≠ Oral and Maxillofacial Surgeons: This survey was forwarded to a list of 355 believed to represent all practicing oral and maxillofacial surgeons in Canada.

The table below provides a summary of the number of users in each User Group. These numbers will be used as a basis for extrapolation of survey data and predicted demand.

Table 9. Summary of Dental User Group Numbers for Extrapolation Purposes

User Group	Number Used for Extrapolation Purposes
Periodontists	239
Oral and Maxillofacial Surgeons	355

Methodology for Extrapolation

Key Informant Interviews, and information gathered during the Environmental Scan Phase of the project, suggested that procedures/budgets, user preferences, access to allograft tissue (or perceived access), concerns about safety/liability etc. influence allograft usage. As a result, where other options exist, certain users may not be as likely to use allograft tissue as others. To allow for these variations the survey data has been extrapolated across a series of ranges. This will provide a picture of what demand might look like at various levels of usage.

The methods of extrapolation across the various User Groups are described below:

4# Periodontists (n = 239)

Periodontists have a variety of options available to them for many of the procedures they perform. These include synthetic and xenographic bone substitutes as well as autografts. Interviews indicated that usage within this group might vary significantly due to preferences and types of procedures performed. As a result, the data received from the periodontist group has been extrapolated across 3 ranges as follows:

4# assuming a 50% User Group response rate (n = 120)

4# assuming a 75% User Group response rate (n = 179)

4# assuming a 100% User Group response rate (n = 239)

4# Oral and Maxillofacial Surgeons (n = 355)

Oral and maxillofacial surgeons also have a variety of options available to them for many of the procedures they perform. These include synthetic and xenographic bone substitutes as well as autografts. Key Informant Interviews suggested that usage could vary somewhat due to types of procedures performed, access to tissue, and preferences. In addition, a number of these users (estimated to be 15%) specialize in extractions only and as a result do not use grafting material. Taking these factors into consideration, the data received from the oral and maxillofacial surgeon User Group has been extrapolated across 3 ranges as follows:

4# assuming a 55% User Group response rate (n = 195)

4# assuming a 70% User Group response rate (n = 249)

4# assuming a 85% User Group response rate (n = 302)

Extrapolation by Tissue Type and User Group

The following table presents allograft tissue demand data extrapolated for the periodontist and oral and maxillofacial surgeon User Groups

Table 10. Dental Demand for Allograft Tissues—Survey Responses Extrapolated

User Group	Pre-packaged Cancellous (50cs's) per Year	Packages of Demineralized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Structural Bone Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
Periodontist User Group—Extrapolation Across Ranges						
Periodontists—50% extrapolation (n = 120)		19,956	13,518		4,926	3,105
Periodontists—75% extrapolation (n = 179)		29,768	20,165		7,348	4,631
Periodontists—100% extrapolation (n = 239)		39,746	26,924		9,810	6,183
Oral and Maxillofacial Surgeon User Group—Extrapolation Across Ranges						
Oral and Maxillofacial Surgeons—55% (n = 195)	53	2957		37	264	158
Oral and Maxillofacial Surgeons—70% (n = 249)	67	3775		47	337	202
Oral and Maxillofacial Surgeons—85% (n = 302)	82	4579		57	408	245

Extrapolated Demand by Province

The tables provided in this section provide an overview of the extrapolated demand organized by province.

Methodology for Extrapolation by Province

The following table outlines the percentage allocation of the User Groups by province. Information sources used to determine these calculations are listed below.

Table 11. Ratios Used for Extrapolation of Demand by Province

Province	Periodontists % Allocation by Province ^a	Oral and Maxillofacial Surgeons % Allocation by Province ^b
N.L.	0.4	0.9
P.E.I.	0.0	0.6
N.S.	4.6	5.6
N.B.	1.7	1.1
Que.	15.5	23.1
Ont.	45.6	46.7
Man.	4.6	4.8
Sask.	2.5	1.7
Alta.	9.2	5.9
B.C.	15.9	9.6
Total	100.0	100.0

Source for Allocation:

^a 2003 Mailing list—Canadian Academy of Periodontology (adjusted for 1 recently retired periodontist)

^b 2003 Mailing list—Canadian Association of Oral and Maxillofacial Surgeons

Extrapolated Demand for Tissue by Province and User Group

Table 12 presents the extrapolated demand for allograft tissue at 3 different ranges for periodontists—50%, 75% and 100%.

Table 12. Extrapolated Demand for Allograft Tissue by Province for Periodontists

	Packages of Deminerlized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
Periodontists at 50% Extrapolation Rate (n = 120)				
N.L.	84	57	21	13
P.E.I.	0	0	0	0
N.S.	918	622	227	143
N.B.	334	226	82	52
Que.	3,089	2,093	763	481
Ont.	9,101	6,165	2,246	1,416
Man.	919	622	227	143
Sask.	501	340	124	78
Alta.	1,837	1,244	453	286
B.C.	3,173	2,149	783	493
Total at 50%	19,956	13,518	4,926	3,105
	Packages of Deminerlized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
Periodontists at 75% Extrapolation Rate (n = 179)				
N.L.	125	84	31	19
P.E.I.	0	0	0	0
N.S.	1,370	928	338	213
N.B.	498	338	123	78
Que.	4,609	3,122	1,138	717
Ont.	13,576	9,197	3,351	2,112
Man.	1,370	928	338	213
Sask.	747	506	185	116
Alta.	2,740	1,856	676	426
B.C.	4,733	3,206	1,168	737
Total at 75%	29,768	20,165	7,348	4,631

Table 12. Extrapolated Demand for Allograft Tissues by Province for Periodontists (cont'd)

	Packages of Deminerlized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
Periodontists at 100% Extrapolation Rate (n = 239)				
N.L.	166	113	41	26
P.E.I.	0	0	0	0
N.S.	1,829	1,239	451	285
N.B.	665	451	164	103
Que.	6,153	4,168	1,519	957
Ont.	18,127	12,279	4,474	2,820
Man.	1,829	1,239	452	285
Sask.	998	676	246	155
Alta.	3,659	2,478	903	569
B.C.	6,320	4,281	1,560	983
Total at 100%	39,746	26,924	9,810	6,183

Table 13 presents the extrapolated demand for allograft tissue at 3 different ranges for oral and maxillofacial surgeons—55%, 70% and 85%.

Table 13. Extrapolated Demand for Allograft Tissue by Province for Oral and Maxillofacial Surgeons

	Pre-packaged Cancellous (50cs's) per Year	Packages of Deminerlized Bone Products per Year	Structural Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
Oral and Maxillofacial Surgeons 55% Extrapolation Rate (n = 195)					
N.L.	1	25	0	2	1
P.E.I.	0	17	0	2	1
N.S.	3	166	2	15	9
N.B.	1	33	0	3	2
Que.	12	683	9	61	37
Ont.	25	1,383	17	123	74
Man.	2	142	2	13	7
Sask.	1	50	1	4	3
Alta.	3	175	2	16	9
B.C.	5	283	4	25	15
Total at 55%	53	2,957	37	264	158
	Pre-packaged Cancellous (50cs's) per Year	Packages of Deminerlized Bone Products per Year	Structural Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
Oral and Maxillofacial Surgeons 70% Extrapolation Rate (n = 249)					
N.L.	1	32	0	3	2
P.E.I.	0	21	0	2	1
N.S.	4	213	3	19	11
N.B.	1	42	1	4	2
Que.	16	872	11	78	47
Ont.	31	1,765	22	157	95
Man.	3	181	2	16	10
Sask.	1	64	1	6	3
Alta.	4	223	3	20	12
B.C.	6	362	4	32	19
Total at 70%	67	3,775	47	337	202

Table 13. Extrapolated Demand for Allograft Tissue by Province for Oral and Maxillofacial Surgeons (cont'd)

	Pre-packaged Cancellous (50cs's) per Year	Packages of Deminerlized Bone Products per Year	Structural Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
Oral and Maxillofacial Surgeons 85% Extrapolation Rate (n = 302)					
N.L.	1	39	1	3	2
P.E.I.	0	26	0	2	1
N.S.	5	258	3	23	14
N.B.	1	52	1	5	3
Que.	19	1,058	13	94	57
Ont.	38	2,141	27	191	115
Man.	4	219	3	20	12
Sask.	1	77	1	7	4
Alta.	5	271	3	24	14
B.C.	8	438	5	39	23
Total at 85%	82	4,579	57	408	245

Summary of Extrapolated Data

This section provides a summary of the extrapolated data across 3 ranges:

€# Low Range:

4# Periodontists extrapolated to 50% of User Group

4# Oral and maxillofacial surgeons extrapolated to 55% of User Group

€# Medium Range:

4# Periodontists extrapolated to 75% of User Group

4# Oral and maxillofacial surgeons extrapolated to 70% of User Group

€# High Range:

4# Periodontists extrapolated to 100% of User Group

4# Oral and maxillofacial surgeons extrapolated 85% of User Group

The following Tables 14 to 17 summarize the extrapolated data across the ranges and by province within each range.

Table 14. Summary of Extrapolated Data Across Ranges by User Group

Users	Pre-packaged Cancellous (50cs's) per Year	Packages of Demineralized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Structural Bone Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year	Total per Year
Low Range							
Periodontists—50% of User Group		19,956	13,518		4,926	3,105	41,505
Oral and Maxillofacial Surgeons—55% of User Group	53	2,957		37	264	158	3,469
Total Extrapolated Demand—Low Range	53	22,913	13,518	37	5,190	3,263	44,974
Medium Range							
Periodontists—75% of User Group		29,768	20,165		7,348	4,631	61,912
Oral and Maxillofacial Surgeons—70 % of User Group	67	3,775		47	337	202	4,428
Total Extrapolated Demand—Medium Range	67	33,543	20,165	47	7,685	4,833	66,340
High Range							
Periodontists—100% of User Group		39,746	26,924		9,810	6,183	82,663
Oral and Maxillofacial Surgeons—85% of User Group	82	4,579		57	408	245	5,371
Total Extrapolated Demand—High Range	82	44,325	26,924	57	10,218	6,428	88,034

Table 15. Summary of Extrapolated Data by Province (for both User Groups)—Low Range

Province	Pre-packaged Cancellous (50cs's) per Year	Packages of Demineralized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Structural Bone Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
N.L.	1	109	57	0	23	14
P.E.I.	0	17	0	0	2	1
N.S.	3	1,084	622	2	242	152
N.B.	1	367	226	0	85	54
Que.	12	3,772	2,093	9	824	518
Ont.	25	10,484	6,165	17	2,369	1,490
Man.	2	1,061	622	2	240	150
Sask.	1	551	340	1	128	81
Alta.	3	2,012	1,244	2	469	295
B.C.	5	3,456	2,149	4	808	508
Total	53	22,913	13,518	37	5,190	3,263

Table 16. Summary of Extrapolated Data by Province (for both User Groups)—Medium Range

Province	Pre-packaged Cancellous (50cs's) per Year	Packages of Demineralized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Structural Bone Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
N.L.	1	157	84	0	34	21
P.E.I.	0	21	0	0	2	1
N.S.	4	1,583	928	3	357	224
N.B.	1	540	338	1	127	80
Que.	16	5,481	3,122	11	1,216	764
Ont.	31	15,341	9,197	22	3,508	2,207
Man.	3	1,551	928	2	354	223
Sask.	1	811	506	1	191	119
Alta.	4	2,963	1,856	3	696	438
B.C.	6	5,095	3,206	4	1,200	756
Total	67	33,543	20,165	47	7,685	4,833

Table 17. Summary of Extrapolated Data by Province (for both User Groups)—High Range

Province	Pre-packaged Cancellous (50cs's) per Year	Packages of Demineralized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Structural Bone Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
N.L.	1	205	113	1	44	28
P.E.I.	0	26	0	0	2	1
N.S.	5	2,087	1,239	3	474	299
N.B.	1	717	451	1	169	106
Que.	19	7,211	4,168	13	1,613	1,014
Ont.	38	20,268	12,279	27	4,665	2,935
Man.	4	2,048	1,239	3	472	297
Sask.	1	1,075	676	1	253	159
Alta.	5	3,930	2,478	3	927	583
B.C.	8	6,758	4,281	5	1,599	1,006
Total	82	44,325	26,924	57	10,218	6,428

Extrapolated Data Specific to Oral and Maxillofacial Procedures

In a section of their survey, the oral and maxillofacial surgeon User Group was asked to estimate, in relation to 4 common procedures where tissue is likely utilized, the number of procedures that they performed per year and the type of grafting material used. The 4 procedures were as follows:

- ⌘ Replacement for bone lost (post trauma, cancer surgery)
- ⌘ Gingioplasty
- ⌘ Partial ostectomy of facial bone, except mandible
- ⌘ Reconstruction of mandible with associated resection

The most common types of tissue used for these procedures were demineralized bone and bovine/synthetic products.

The following table summarizes the average number of procedures extrapolated across the 3 ranges:

Table 18. Average Number of Procedures (Oral and Maxillofacial) Extrapolated Across 3 Ranges

	Average Number Procedures per Surgeon	Low (195 surgeons)	Medium (249 surgeons)	High (302 surgeons)
Replacement for bone lost	15	2,925	3,735	4,530
Gingioplasty	5	975	1,245	1,510
Partial ostectomy of facial bone	2	390	498	604
Reconstruction of mandible	2	390	498	604
Total		4,680	5,976	7,248

Predicted Demand

Survey respondents were asked if they believed that their use of allograft tissue would increase, decrease or stay the same over the next 1 to 2 years, and by what percentage.

Table 19. Periodontists—Predicted Increase in Demand

Tissue	N	Number Reporting Increase	Number Reporting Decrease	Number Reporting No Change	Average Percentage Increase
Demineralized Bone Products	55	22	5	28	8.4%
Mineralized Freeze-Dried Bone Products	50	19	2	29	10.2%
Allograft Skin Products	51	15	3	33	4.9%
Allograft Fascia	40	3	0	37	0%*

* Although 3 respondents reported an increase in the use of allograft fascia, none provided an estimate of the percentage increase.

Table 20. Oral and Maxillofacial Surgeons—Predicted Increase in Demand

Tissue	N	Number Reporting Increase	Number Reporting Decrease	Number Reporting No Change	Average Percentage Increase
Pre-Packaged Cancellous Bone	32	8	3	21	3.4%
Demineralized Bone Products	34	12	3	19	11.2%
Structural Bone	28	0	1	27	0%*
Allograft Soft Tissue (e.g. fascia)	30	2	0	28	0%**
Allograft Skin Products	27	5	0	22	8.5%

* Although 1 respondent reported a decrease in the use of structural bone, this response was considered to be an outlier resulting in an overall predicted increase of 0%.

** Although 2 respondents reported an increase in the use of allograft fascia, none provided an estimate of the percentage increase.

The following table summarizes the average increase in the use of allograft tissue predicted by the various respondent User Groups over the next 1–2 year period.

Table 21. Summary—Predicted Percentage Increase in Use of Allograft Tissue (next 1–2 years)

	Pre-packaged Cancellous (50cs's) per Year	Packages of Demineralized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Structural Bone Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
Periodontists	n/a	8.4%	10.2%	n/a	4.9%	0%
Oral and Maxillofacial Surgeons	3.4%	11.2%	n/a	0%	8.5%	0%

The table on the following page provides a summary of the extrapolated demand adjusted for predicted increases in use of allograft tissue over the next 1–2 year period.

Table 22. Summary of Extrapolated Demand Adjusted for Predicted Increase per Year in Use of Allograft Tissue

Extrapolated Demand Ranges	Pre-packaged Cancellous (50cs's) per Year	Packages of Demineralized Bone Products per Year	Packages of Mineralized Freeze Dried Bone Products per Year	Structural Bone Grafts per Year	Skin Products per Year	Soft Tissue (e.g. fascia lata) per Year
Low Range	53	22,913	13,518	37	5,190	3,263
Predicted Increase 1–2 year (%) ^a	3.4%	8.4% (P) 11.2% (O)	10.2%	0%	4.9% (P) 8.5% (O)	0%
Predicted 1–2 year Increase	2	1,676 (P) 331 (O)	1,379	0	241 (P) 22 (O)	0
Total Predicted Demand—Low Range	55	24,920	14,897	37	5,453	3,263
Medium Range	67	33,543	20,165	47	7,685	4,833
Predicted Increase 1–2 year (%)	3.4%	8.4% (P) 11.2% (O)	10.2%	0%	4.9% (P) 8.5% (O)	0%
Predicted 1–2 year Increase	2	2,501 (P) 422 (O)	2,057	0	360 (P) 28 (O)	0
Total Predicted Demand—Medium Range	69	36,466	22,222	47	8,073	4,833
High Range	82	44,325	26,924	57	10,218	6,428
Predicted Increase 1–2 year (%)	3.4%	8.4% (P) 11.2% (O)	10.2%	0%	4.9% (P) 8.5% (O)	0%
Predicted 1–2 year Increase	3	3,339 (P) 513 (O)	2,746	0	481 (P) 35 (O)	0
Total Predicted Demand—High Range	85	48,177	29,670	57	10,734	6,428

Note:

^a Percentage predicted increase followed by (P) refers to the periodontist respondent group, (O) refers to the oral and maxillofacial surgeon respondent group.

Sources and Access to Allograft Tissue

Survey respondents were asked about the sources of their allograft tissue. Their responses are outlined in the table below:

Table 23. Source of Allograft Tissue by User Group

	Periodontists	% Periodontists	Oral and Maxillofacial Surgeons	% Oral and Maxillofacial Surgeons
Number of Responses 100% Canadian TB	3	6%	1	4%
Number of Responses 100% American TB	40	80%	20	77%
Number of Responses 100% "Other"	2	4%	0	0%
Number of Responses 100% "Unknown"	1	2%	2	8%
Number of Responses Consisting of a Variety of Sources	4	8%	3	11%
Total Number of Responses	50	100%	26	100%

The respondents were asked about the percentage of procedures they currently perform where their preference would be to use an allograft tissue, but where an alternative is utilized because allograft tissue is not readily available. Their responses are outlined in the table below:

Table 24. Percentage of Procedures Using Alternatives When Allograft Tissue Preferred

User Group	Number of Responses for User Group	Average Percentage Procedures an Alternative is Used
Periodontists	46	19.9%
Oral and Maxillofacial Surgeons	20	23.8%

Respondents who purchase allograft from sources other than Canadian Tissue Banks were asked to rank specific factors (1 representing most important and 4 representing least important) in terms of relevance to their decision to purchase outside of Canada. The factors were as follows:

- ☒ Not available in Canada;
- ☒ Speed and consistency of service;
- ☒ Price; and,
- ☒ Safety.

The responses across both dental User Groups are illustrated in the following table and figure:

Table 25. Number of Responses Re: Factors for Purchases Outside of Canada

	Not Available in Canada	Speed and Consistency of Service	Price	Safety
Least important	20	11	19	4
Less important	6	19	22	7
More important	13	16	13	12
Most important	15	8	0	31
Total	54	54	54	54

Note: As this question required respondents to rank factors on a scale of 1-4, all incomplete answers were excluded from the results presented above.

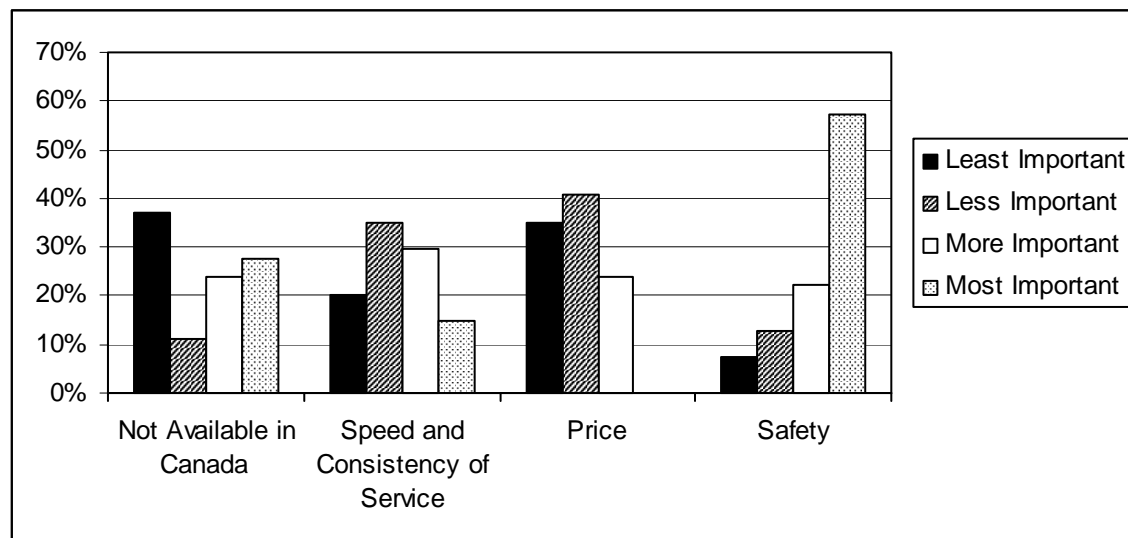


Figure 1. Percentage of Responses Re: Factors Relevant to Purchases Outside of Canada

Comments from Survey Respondents: Access, Safety and Outcomes

Survey respondents provided some insight on their views regarding access to human allograft tissue and the reasons why they do or do not elect to use this type of tissue. In general, periodontists and oral and maxillofacial surgeons state that they access tissue from the U.S. as demineralized and specialized bone products are not available in Canada. Oral and maxillofacial surgeons tend to access a wider range of products, including structural bone such as hemi-mandibles. Although small and large structural bone is available in Canada, hemi-mandibles are not available (even in larger comprehensive Canadian Tissue Banks), and are difficult to source in the U.S.

Comments on surveys also highlighted the lack of information dental specialists have regarding Canadian Tissue Bank services and the safety of the products they produce. Another theme in the survey comments focused on the understanding and belief of many surgeons that alternative products (autogenous, xenograft and synthetic) have better outcomes for patients. In particular, many oral and maxillofacial surgeons stated a preference for the use of autogenous bone.

The following list of quotes will provide the reader with some examples of the comments from periodontists and oral and maxillofacial surgeons as they relate to access, safety and outcomes:

Access

- €# American suppliers offered us their products and services years ago;
- €# Not aware of Canadian Tissue Banks, need for marketing;
- €# Where are the Canadian Tissue Banks?
- €# Only aware of American Tissue Banks and their certification status: also most courses or lectures refer to U.S. banks;
- €# Cost;
- €# There are great concerns over how tissues are obtained. I would use artificial (lab) materials, if the results were the same, but they are not. I have always preferred preparation techniques before looking at any graft materials as I believe we set-up a systemic response towards future grafts and transplants;
- €# I was a regular user of DMB prior to the difficulty of getting the material from the American Tissue Bank. I switched to Xenograft (Bio Oss). However, if a Canadian Tissue Bank was available, I would like to have the ability to access DMB more readily;
- €# Previous supplies of bone allograft from the U.S. can no longer be shipped to Canada. Only Canadian supplier that I am aware of is GenSci;
- €# I would welcome a Canadian Tissue Bank as long as the product provided had equal or better quality than the existing products I use today. The price needs to be competitive. The product needs to be safe, readily available and easy to use. I am indifferent with regards to using non-profit or for profit.

Safety

- ⚡ I use mostly the patients' bone for safety, success and cost;
- ⚡ Patients are uncomfortable with someone else's tissue;
- ⚡ Patient preference—some want only autogenous bone;
- ⚡ Public is too distrustful;
- ⚡ There is still risk of disease transmission;
- ⚡ Patient acceptance;
- ⚡ For safety reasons, mostly use autogenous grafting with barrier membrane and platelet rich plasma (PRP);
- ⚡ Allograft bone—issues re: disease transmission, even if only a potential;
- ⚡ In most of the reconstructive, pre-prosthetic procedures that I have performed I have used split thickness skin grafts harvested from the patient (autogenous);
- ⚡ Patients prefer not to use allograft;
- ⚡ Always prefer person's own bone if available. Only when not available use of allografts becomes necessary;
- ⚡ Patient declines allograft based on ethics of using human products;
- ⚡ It is much easier to "sell" the idea of bovine bone products to patients compared to human—especially with the stigma of U.S. human bone source. Tragedies of the 80's have not been forgotten;
- ⚡ The proven safety of the allograft products will be very important from the patient's point of view;
- ⚡ Do not use any material for grafting other than autogenous bone. New variant CJD a concern (Prions) via dura mater graft (bovine). Can HIV or Hep C be transmitted through allograft?
- ⚡ Most patients prefer synthetic grafting materials for grafting purposes to minimize their perceived risks of disease transfer from donors.

Outcomes

- ⚡ There are no good double blind long-term i.e. 3 to 5 years research on any guided tissue regeneration techniques that show it is better than the control;
- ⚡ Autogenous bone is best;
- ⚡ I suspect allografts will be the ideal choice for grafting when BMPs are readily available and stable;
- ⚡ I believe this will increase dramatically over the next many years. The use of them has improved results significantly;
- ⚡ This topic is very important as well as research on BMPs, platelet rich plasma (PRP) and growth factors;

- ⊘ Periodontal disease is not a life threatening problem. I find it incredible that periodontists are willing to risk disease transmission for surgical treatments that have limited additional positive outcomes to surgical techniques that have no risk of transmission;
- ⊘ I feel preferred choice for grafting is autogenous bone;
- ⊘ It is debatable if allograft is preferred choice. I use autogenous bone only, for superior results to allograft;
- ⊘ Excellent success with autografts;
- ⊘ Results much better with bovine products.

Products Commonly Used by the Dental Industry

Respondents were asked to identify the commercial products they commonly purchase for use in their practice. The results by product name are provided in the table below:

Table 26. Commercial Products Commonly Used by the Dental Industry

Product Name	Number of Responses (Oral and Maxillofacial Surgeons)	Number of Responses (Periodontists)
Dynagraft	20	24
Grafton DBM	3	17
AlloGro	0	2
AlloMatrix	3	0
Regenafil	0	0
Regenaform	0	0
Alloderm	5	23
Bioglass, Perioglass	5	9
Bio-Oss	22	46
Biogran	7	15
Other Products Listed in Surveys:		
⊘ Emdogain		
⊘ Osteograft		
⊘ BioGide		
⊘ Pep-Gen		
⊘ Ossix		

A listing of some of these commercial products and their sources is provided in Appendix B. In addition to these commercial products, survey respondents listed a number of generic products that they use. These include:

- ⊘ Demineralized freeze dried bone (cortical powder, putty, porous);
- ⊘ Mineralized freeze dried bone allograft powder;
- ⊘ Freeze dried cortical bone;
- ⊘ Platelet derived growth factor (PDGF), platelet rich plasma (PRP);
- ⊘ Biocoral;
- ⊘ Collagen membranes, neuro-substances;
- ⊘ Enamel matrix proteins/derivatives; and,
- ⊘ Hydroxyapatite.

A useful summary of periodontal regeneration techniques and products used is presented in the table below:

Table 27. Periodontal Regeneration Techniques and Products

For Periodontal Defects— Bone Substitutes	For Periodontal Defects— Biologic Modifiers	For Ridge Augmentation— Bone Substitutes
Regenafil (RTI), Grafton gel	Emdogain (enamel matrix derivative)	DFDBA, FDBA (bone allografts)
Bio-Oss, Osteograft-N (bovine bone skeleton)	Pep-Gen (cell binding peptide)	Regenaform, Regenafil, Grafton Putty, Flex
Perioglass, Biogran (synthetic mineral sources)	PDGF (Platelet derived growth factor)	Bio-Oss Cortical Block

Bone Substitutes, David B. Rosen, DMD 1999, www.periodont.com/bone_substitutes.htm

Annual Expenditures for Graft Products

The respondents were asked to estimate their total annual expenditures in relation to human allograft, xenograft and synthetic bone substitute products. The following table provides specific input from the 2 User Groups:

Table 28. Annual Expenditures for Graft Products

	Average Annual Expenditure	Reported Range
Periodontists n = 45	\$6,487	\$200–\$45,000
Oral and Maxillofacial Surgeons n = 19	\$3,695	\$500–\$20,000

Informed Consent for Use of Products

Respondents were also asked if they required their patients to sign an informed consent for any of the products they used. Results show that one third of periodontists responding required informed consent and one half of oral and maxillofacial surgeons required informed consent.

Table 29. Informed Consent for use of Products

	% Indicating Yes	% Indicating No
Periodontists n = 58	34%	66%
Oral and Maxillofacial Surgeons n = 29	50%	50%

Characteristics Affecting Selection of Supplier

Respondents were asked to rate (1 through 7) how strongly factors relating to quality and service would impact their selection of a supplier for allograft tissues. A rating of **1** indicated the factor was not important while a rating of **7** indicated that the factor was very important in terms of selection of a supplier. The factors that were rated appear in the table below:

Table 30. Quality and Service Factors Influencing Selection

Quality Factors
Graft Characteristics (Ease of application, meets technical expectation)
Quality Assurance Program (Tissue Bank has accreditation status or demonstrated quality programs)
Demonstrated Safety Record (Tissue Bank has a record of taking action to minimize the risk of disease transmission)
Service Factors
Speed of service delivery (Tissue is distributed/received within acceptable timelines)
Consistency of service (Service is provided dependably and reliably each time)
Availability of tissue (Sufficient tissue is always available to meet needs)
Price (Price is lower than competitors)

Table 31. Numbers of Responses (for both User Groups) Re: Characteristics Influencing Selection of Supplier

Rating	Graft Characteristics	QA	Safety	Speed	Consistency	Availability	Price
1	1	3	3	1	1	2	4
2	1	0	0	0	0	0	3
3	2	0	0	4	2	1	6
4	4	2	2	17	10	5	17
5	5	2	2	22	18	11	24
6	24	3	4	24	30	38	14
7	50	78	77	19	27	31	21
Total	87	88	88	87	88	88	89

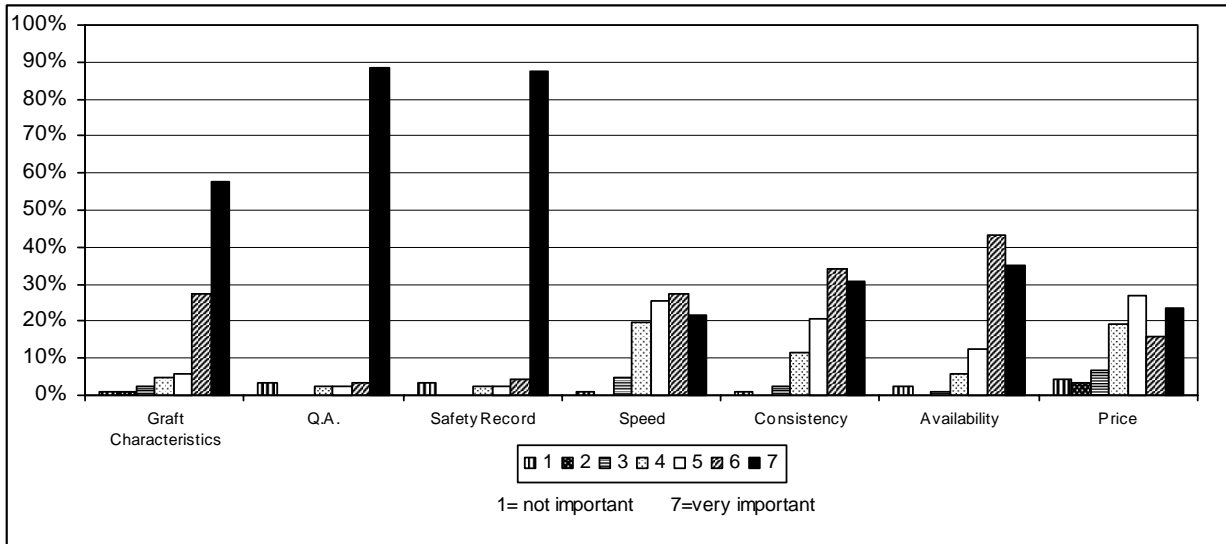


Figure 2. Percentage of Responses Re: Characteristics Influencing Selection of Supplier

Respondents were asked to indicate their degree of agreement/disagreement with a series of six statements related to the characteristics of preferred Tissue Banks.

1. Given a choice between a profit and a not-for-profit Tissue Bank with comparable quality products, I would give preference to the not-for-profit Tissue Bank (n = 96).

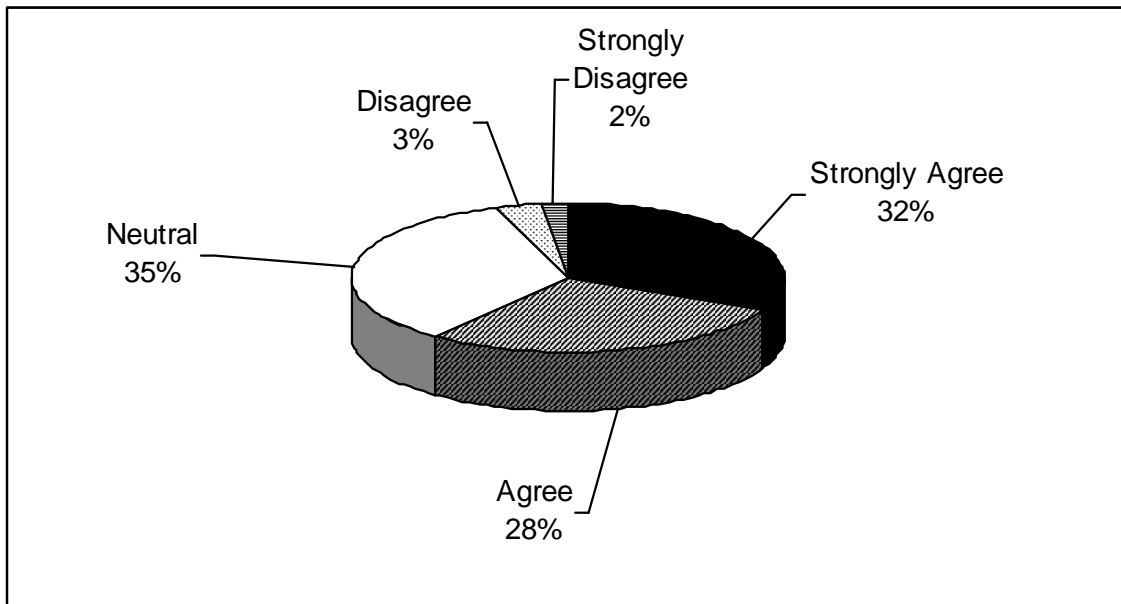


Figure 3. Preference for Not-for-profit Tissue Bank

- Given a choice between a Canadian and an American tissue bank with comparable quality products I would give preference to the Canadian tissue bank (n = 97).

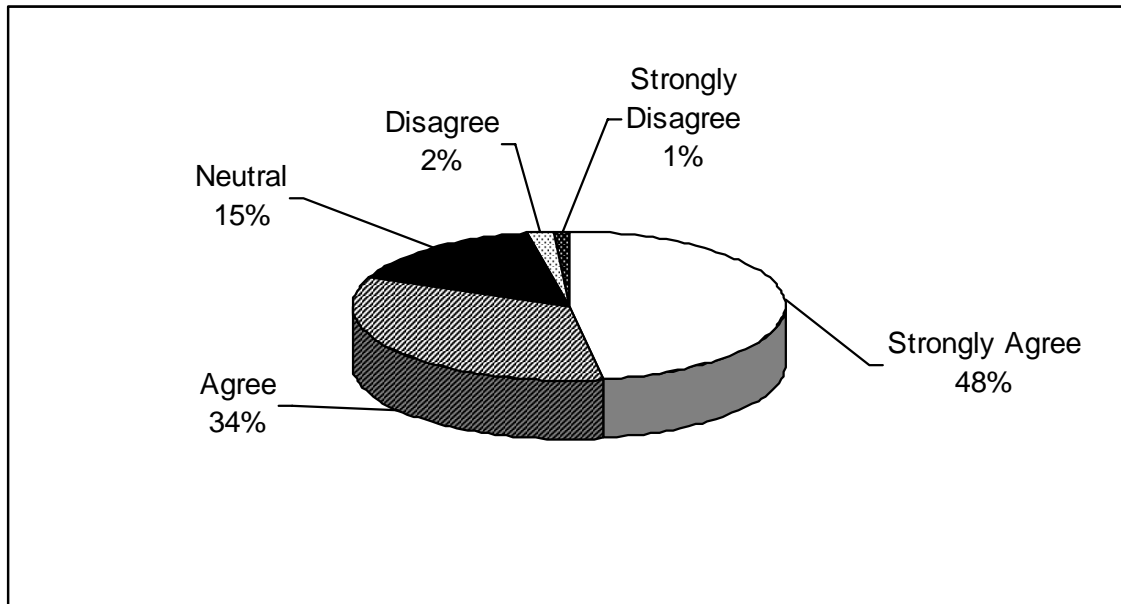


Figure 4. Preference for a Canadian Tissue Bank

- Given a choice between an accredited and non-accredited bank with comparable quality products I would give preference to the accredited tissue bank (n = 97).

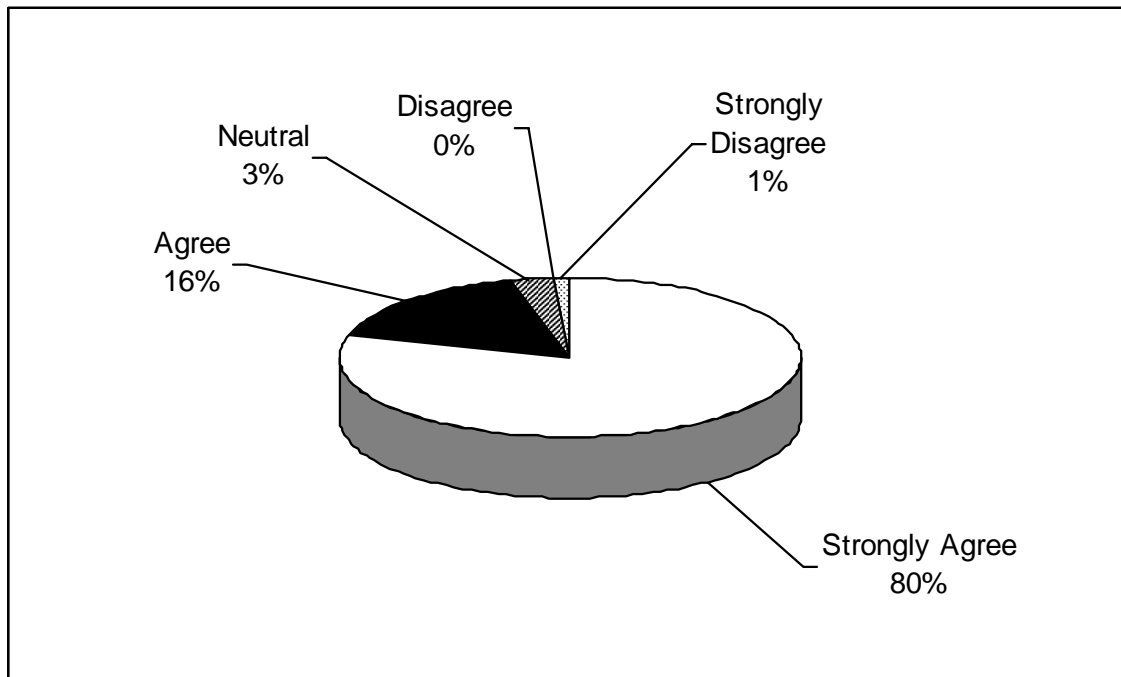


Figure 5. Preference for Accredited Tissue Bank

4. I would utilize a fee for service model which screens providers of allograft tissue to ensure they meet established quality standards (n = 92).

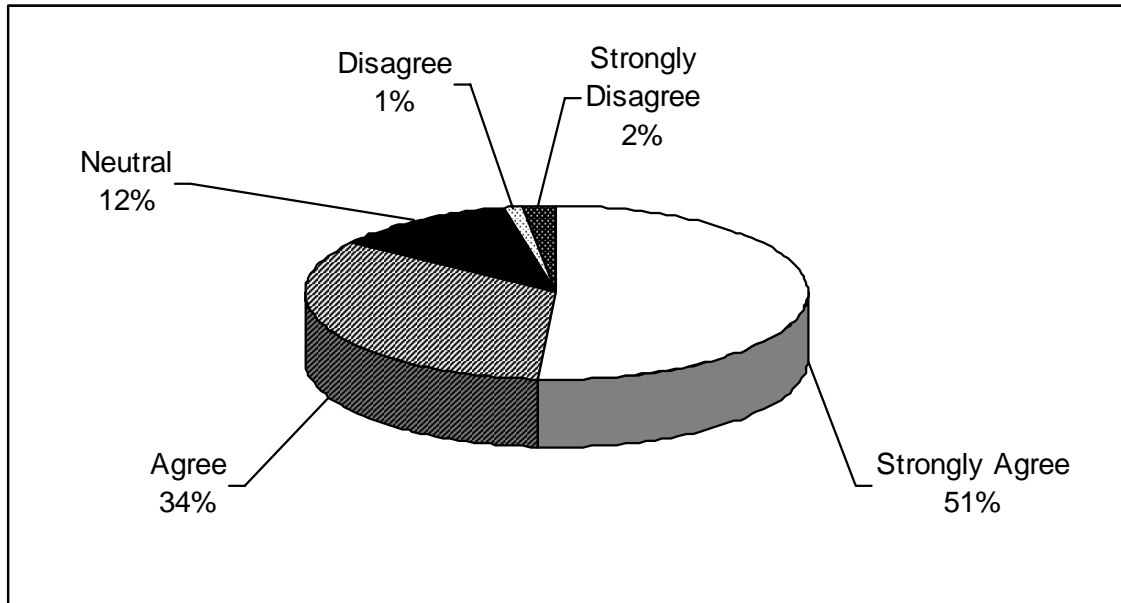


Figure 6. Fee for Service—Screening for Quality Standards

5. I would utilize a fee for service model which provides support in recipient tracking and adverse outcome monitoring (n = 93).

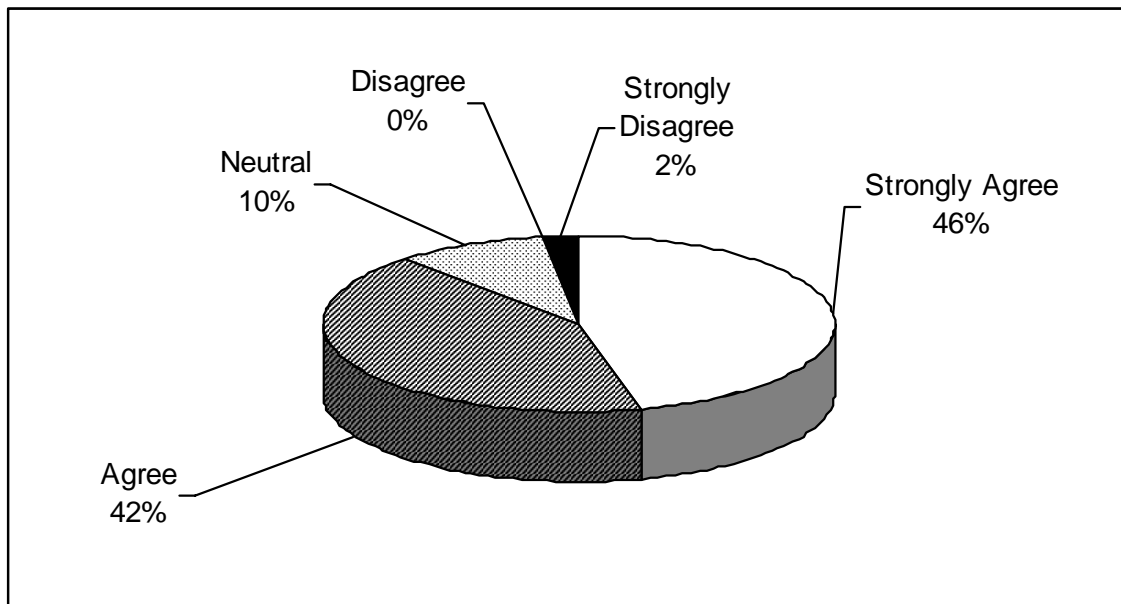


Figure 7. Fee for Service—Tracking and Adverse Outcome Monitoring

6. Tissue banks should be able to generate profits on products they produce from donated tissue (n = 94).

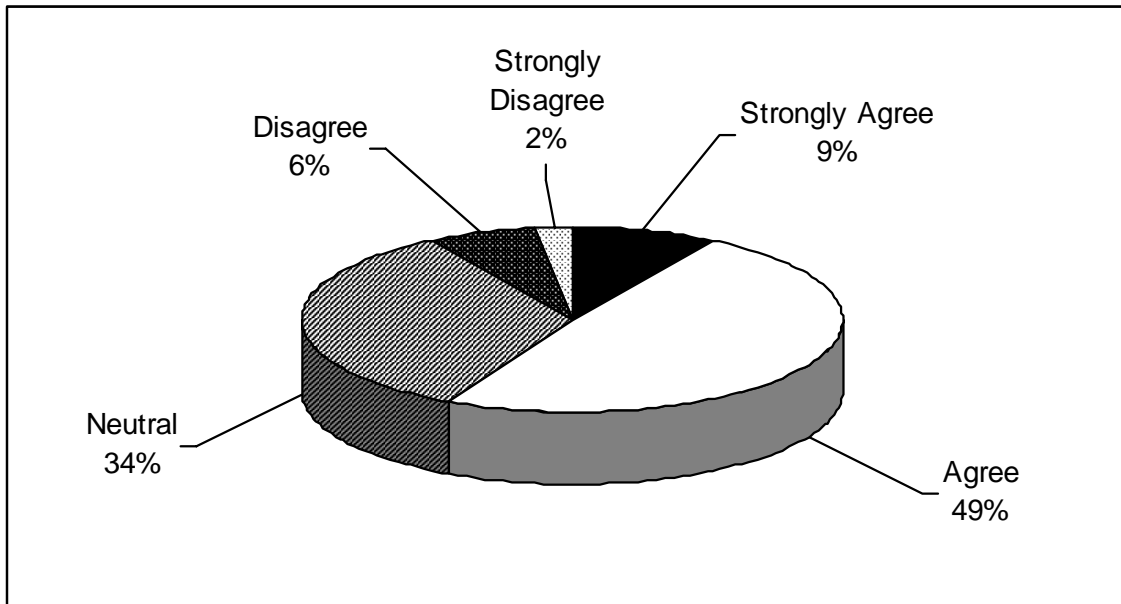


Figure 8. Tissue Banks Should Generate Profits?

The following table highlights the trends in responses to the previous 6 questions by grouping the “strongly agree” and “agree” and grouping “strongly disagree” and “disagree”.

Table 32. Summary of User Preferences Re: Characteristics of Tissue Banks

	% Strongly Agree or Agree	% Neutral	% Strongly Disagree or Disagree
Preference for not-for-profit TB	60%	35%	5%
Preference for Canadian vs. U.S. TB	82%	15%	3%
Preference for Accredited TB	96%	3%	1%
Fee for service model with screening providers for quality standards	85%	12%	3%
Fee for service model for recipient tracking/ monitoring outcomes	88%	10%	2%
TB generates profits	58%	34%	8%

Trends and Emerging Technologies Affecting Use of Allograft Tissue

All Dental Demand survey respondents were asked to identify trends and technologies that would impact their use of allograft tissue. The following summary provides the information documented on the surveys.

Table 33. Trends and Technologies Affecting Change in Use of Allograft Tissue

Trend – Increased Use of Tissue	Trend – Decreased Use of Tissue
<ul style="list-style-type: none"> ⊘ Better results. ⊘ Tissue culturing which involves the use of BMP. ⊘ Use of BMP for onlay grafting, sinus lifts, bony augmentation around implants, reconstructive work. ⊘ All grafting applications in periodontics and implant dentistry. ⊘ Maintaining oral health and function results in more implant dentistry. ⊘ The aging population. ⊘ Maintenance of dentition. ⊘ Regeneration vs. reconstruction philosophy. ⊘ Increased identification of disease states. ⊘ Increased interest in maintaining health. ⊘ More predictable bone grafting techniques are allowing for increased implant placement. ⊘ Increased use of Alloderm and Emdogain. ⊘ The incorporation of growth factors which might increase reliability. ⊘ More of the population is requiring treatment. ⊘ Soft tissue grafts for cosmetic/esthetic reasons. ⊘ More predictable non-autogenous bone augmentation. ⊘ Increased periodontal osseous defects. ⊘ Acceptance of bone concentration techniques with dental extraction/increase demand for implant work. ⊘ Use of PRP (platelet rich plasma) and other bone inducing agents for alveolar ridge augmentation. 	<ul style="list-style-type: none"> ⊘ Improved intra-oral autograft techniques, platelet rich plasma (PRP). ⊘ Possibility of disease transmission. ⊘ Emerging alternative products. ⊘ Use of Emdogain for ridge splitting techniques. ⊘ For periodontal defects use of combination techniques will result in less use of bone grafts. ⊘ Use of barrier membranes. ⊘ Bioengineering e.g. enamel matrix protein, BMP. ⊘ Growth factors, protein, hormone modulators and synthetic bone matrices will decrease the demand for human allografts. ⊘ More sophisticated instruments and procedures that render autogenous graft harvesting easier. ⊘ Use of synthetic products e.g. BioGlass.

Trend – Increased Use of Tissue	Trend – Decreased Use of Tissue
<p>Increasing numbers of the following procedures:</p> <ul style="list-style-type: none"> skin grafting ridge augmentation implants sinus elevation grafting for esthetics gingival grafting bone regeneration (soft) bone grafts to maintain teeth socket preservation prior to implant placement guided tissue regeneration, including bone generation extractions large area connective tissue grafting onlay socket fill augmentation around implants 	

Dental Industry Surveys—Key Observations

Response Rate

- ⌘ The overall combined Dental Industry response rate (including periodontists and oral and maxillofacial surgeons) was 16.8%, varying from a high of 21.2% in the West to 13.3% in the Atlantic region.
- ⌘ The response rate for the periodontist survey was 26.3% varying from a high of 29.5% in the West to 24.7% in the Central region.
- ⌘ The response rate for the oral and maxillofacial surgeon survey was 10.4% varying from a high of 12.8% in the West to 6.9% in the Atlantic region.
- ⌘ The periodontists response rate of 26.3% is significantly higher than that of the oral and maxillofacial surgeons at 10.4%.
- ⌘ In general, the periodontist User Group provided more detail on the surveys and returned more surveys in which all questions were completed.

Respondent Demand and Common Uses of Allograft Tissue

- ⌘ Respondents use a variety of tissues including pre-packaged cancellous ground bone, demineralized bone, mineralized freeze-dried bone, structural grafts, soft tissue and skin.
- ⌘ The tissue and bone grafting products used in the greatest volume by Dental Industry users include demineralized bone, mineralized freeze-dried bone, and synthetic and xenograft bone products.
- ⌘ Of the commercial products reported by these User Groups, “BioOss”, a bovine product was reported most frequently by both periodontists and oral and maxillofacial surgeons.
- ⌘ Respondents were questioned about their use of synthetic bone substitutes and xenograft bone products as interviews had indicated that these products are often used as substitutes for human allograft (mainly due to budgetary constraints). A more accessible and affordable source of allograft tissue products could result in a shift in demand away from synthetic and xenograft based products.

Extrapolated Respondent Demand

- ⌘ The Dental Industry User Groups were defined as all practicing periodontists in Canada (239) and all practising oral and maxillofacial surgeons in Canada (355). This is per the current mailing lists of the Canadian Academy of Periodontology (CAP) and the Canadian Association Oral and Maxillofacial Surgeons (CAOMS).
- ⌘ Extrapolating respondent demand across 3 ranges results in the following totals of annual demand for allograft tissue:
 - Low range—44,974 grafts
 - Medium range—66,340 grafts
 - High range—88,034 grafts
- ⌘ In each range the periodontist User Group accounts for over 90% of overall demand for the Dental Industry.

€# To verify the significant difference in usage by periodontists and oral and maxillofacial surgeons the project team used 2 methods to estimate demand from survey data. The estimated ranges of demand using both methods was consistent:

Estimated range of demand using extrapolated survey results—3,469 to 5,371

Estimated range of demand using extrapolated survey procedure counts—4,680 to 7,248 (see page 31)

€# The extrapolated demand highlights the provinces that would potentially have the highest demand for tissue, namely Ontario, Quebec, British Columbia and Alberta (in this order).

Predicted Demand

€# Predicted increases in allograft tissue use by the Dental Industry over the next 1-2 years range from a low of 0% for structural grafts and soft tissue to a high of 10.2% for mineralized freeze-dried bone products. The second highest predicted increase was for skin (~7%).

€# When predicted increases in allograft tissue use over the next 1-2 year period are applied to the extrapolated respondent demand, predicated annual usage of allograft tissue increases as follows:

Low range—48,625

Medium range—71,710

High range—95,151

Access and Sources for Allograft Tissue

€# The majority of Dental Industry users indicated that they obtain their allograft tissue products from American Tissue Banks (80% for periodontists and 77% for oral and maxillofacial surgeons).

€# The percentage of procedures which are currently performed where an alternative to allograft tissue is used due to lack of access was reported at 19.9% and 23.8%, for periodontists and oral and maxillofacial surgeons respectively.

€# Periodontists and oral and maxillofacial surgeons stated that they access tissue from the U.S. as demineralized and specialized bone products are not available in Canada.

€# Oral and maxillofacial surgeons access a wider range of products including structural grafts such as hemi-mandibles (not available from Canadian Tissue Banks and difficult to source in the U.S.).

€# Comments on the surveys pointed strongly to the lack of information that dental specialists have regarding Canadian Tissue Bank services and the safety of the products they produce.

€# Respondents provided the names of commercial products commonly used. The Dental Industry uses a wide range of grafting products, often in combination. These include: autogenous tissue, allograft, xenograft and synthetic products.

€# Comments on the surveys confirm information gathered via the Environmental Scan and Key Informant Interviews which suggested that there are varying opinions or “schools of thought” among dental specialists as to which products or combination of products result in superior outcomes for patients.

- €# Oral and maxillofacial surgeons in particular, express a preference for autogenous bone and a belief that outcomes are superior for patients as compared to allograft tissue.
- €# Considering the factors relating to decisions to purchase outside of Canada, safety appeared to be most important (for over 50% of respondents).

User Preferences for Characteristics of Tissue Banks

- €# The highest rated preferences (96% and 82%) were for accredited and Canadian Tissue banks.
- €# The majority of respondents indicated that the features of provider screening for quality standards and a model for recipient tracking and adverse outcome monitoring were preferable.
- €# Sixty (60) percent of respondents indicated that they agreed or strongly agreed that they preferred a not-for-profit Tissue Bank. Interestingly, a similar response was received in relation to whether Tissue Banks should generate profits.

Trends and Technologies Affecting Demand

- €# The aging population, increased interest in maintaining oral health and increased interest in cosmetic procedures were cited as factors that will affect demand for allograft tissue.
- €# The possibility of disease transmission, improved intra-oral autograft techniques and the emergence of alternative products were cited as trends that could result in decreased demand for allograft tissue.
- €# Survey respondents indicated trends toward increasing numbers of many procedures that require the use of grafting products.

Other Observations

- €# Reported average annual expenditures for grafting products were more than double for periodontists as compared to oral and maxillofacial surgeons. The maximum annual expenditure for periodontists was \$45,000 and \$20,000 for oral and maxillofacial surgeons.
- €# Informed consent—50% of oral and maxillofacial surgeons reported that informed consent was obtained for use of grafting products while 34% of periodontists reported obtaining informed consent.

Common Uses of Allograft Tissue in Dental Procedures

In the process of executing the Supply and Demand studies, there have been a number of opportunities to gain an in-depth understanding of the range of procedures for which human allograft tissue is used within the Dental Industry.

Data on specific uses of tissue have been identified in the *Environmental Scan*, the literature review and collected from Key Informants Interviews with representatives from the Dental Industry. In addition, comments from survey respondents regarding current trends/procedures complimented the listing. The following table presents a listing of common dental procedures reported by periodontists and oral and maxillofacial surgeons.

Table 34. Dental Procedures Requiring Allograft Tissue

Common Procedures
<ul style="list-style-type: none"> ## Replacement for bone lost (e.g. post trauma, post cancer surgery) ## Gingioplasty, gingival grafts—full and muco-gingival grafts ## Alveoloplasty ## Partial ostectomy of facial bone, except mandible ## Reconstruction of mandible with associated resection ## Extraction socket preservation ## Connective and soft tissue grafting ## Osseous defects for periodontal ## Sinus lift ## Onlay grafts ## Grafting associated with dental implants ## Ridge augmentation, alveolar ridge augmentation, vertical augmentation
<ul style="list-style-type: none"> ## Survey respondents indicated trends for increasing numbers of the following procedures: <ul style="list-style-type: none"> skin grafting ridge augmentation implants sinus elevation alveolar and sinus reconstruction grafting for esthetics gingival grafting bone regeneration (soft) bone grafts to maintain teeth socket preservation prior to implant placement guided tissue regeneration, including bone generation extractions large area connective tissue grafting onlay grafting socket fill augmentation around implants

Key Informant Interviews

Methodology

In the initial planning phases of the CCDT 4.1 project on Supply and Demand of Human Allograft Tissue in Canada, Key Informant Interviews were identified as an important method. The strategy for planning interviews was based on the major components of the CCDT 4.1 project. The interviews were planned in 2 steps:

1. Targeted interviews for the purpose of collecting background information that would contribute to the Environmental Scan, to inform the development of the Supply Survey and to collect initial information on demand issues.
2. Targeted interviews for the Demand studies, with key users of allograft tissue in Canada, in particular those using bone, soft tissue, cardiovascular, ocular and skin.

Step 1 Interviews (Environmental Scan and Supply)

Through the initial planning phases and discussions with CCDT and CIHI representatives, a number of key individuals were identified as critical resources to the CCDT 4.1 project on Supply and Demand of Human Tissue in Canada.

Although the primary purpose of these interviews was to contribute to background information for tissue banking in Canada, valuable information on the topic of Supply was also collected. Results of these interviews as they apply to Supply are reported on in the *Supply of Human Allograft Tissue in Canada—Final Report April 2003*.

Step 2 Interviews (Demand)

These interviews were planned with a focus on the key users of human allograft tissue in Canada, including, but not limited to surgeons in a variety of specialties, including representatives from the Dental Industry. The criteria for planning these interviews included:

- ≠ Representatives of surgical specialties that commonly use allograft tissue;
- ≠ Users of tissue types included in project scope (bone and tendons, soft tissue, cardiovascular tissue, ocular tissue, skin);
- ≠ Range of users from different types of facility (community based, large teaching hospitals, centres of excellence); and
- ≠ Individuals who are leaders in their field with provincial and/or national perspectives on the issues affecting supply and demand of human allograft tissue.

Limitations

In many cases, information obtained through Key Informant Interviews with users and tissue-banking representatives reflected their personal preferences, opinions, observations and/or local processes and practices. The information provided by key informants has not been endorsed, nor does it necessarily represent the opinion of any health care organization, professional association or surgical specialty.

Highlights of Key Informant Interviews: Dental Industry

Input received from interviews has contributed to the wide range of results presented in this report. In many cases, the information provided during interviews supported and complimented the data submitted by survey respondents.

In all instances, interviews with key users of allograft tissue were conducted to meet common objectives regardless of the tissue type, as follows:

- ≠ To identify the common procedures for which specialists/surgeons use allograft tissue;
- ≠ To identify factors affecting demand for allograft tissue, including barriers to use, emerging trends and technologies impacting demand;
- ≠ To obtain opinions on the predicted increase or decrease in demand for tissue in the future; and where appropriate; and,
- ≠ To obtain advice on the content of draft Demand surveys and recommended contacts.

Emerging trends and common uses of allograft tissue documented during interviews are detailed in 2 sections of this report—*Trends and Emerging Technologies Affecting Use of Allograft Tissue* and *Common Uses of Allograft Tissue in Dental Procedures*. These sections also include procedures and trends reported by survey respondents.

Highlights of the interviews with representatives from the Dental Industry, organized by theme appear below:

General

- ≠ The use of bone products in oral surgery and periodontal procedures is very common and increasing. It results in improved outcomes for patients and can result in decreased length of stay in inpatient facilities.
- ≠ New combination products using DMB are becoming more popular, for example, the combination of synthetic material and DMB.
- ≠ One of the issues that has been noted concerning DMB products is that there is no standardization in terms of the amount of BMP (bone morphogenic protein) they contain.
- ≠ Although synthetic and xenograft alternatives are often used, there is anecdotal evidence that patients do not do as well and that they seem to experience more pain than they do when human allograft based products are utilized.
- ≠ Canadian specialists have contributed to the body of knowledge and science related to the use and effectiveness of BMP and DMB products. The research and development expertise within Canada could be leveraged to support a Canadian model of tissue services in the future.
- ≠ Safety is an important concern for users.

Barriers/Access to Allograft Tissue

- €# Access to Canadian allograft tissue is an issue for the Dental Industry as they are frequent users of DMB and other specialized products and these are not available in Canada.
- €# The decision to use human allograft versus a synthetic or xenograft alternative is often influenced by cost as synthetic and xenograft products are considerably cheaper.
- €# One user (oral surgeon) commented his use would increase by 300% if there was a safe and reasonably priced source of allograft tissue in Canada. He indicated that he would use allograft tissue everyday.
- €# Users practicing in hospital settings often encounter administrative budgetary constraints that significantly restrict their tissue use.
- €# Many in the dental community would prefer not to purchase from U.S. based companies and their suppliers. Use of multiple “middlemen” results in pricing that incorporates several layers of profit. A safe, reliable and reasonably priced source of Canadian tissue would be attractive.
- €# Package sizes of commercially available products tend to be too large and result in significant waste.

Uses and Trends

- €# The use of grafting products by periodontists is increasing due mainly to the following:
 - Dental implants are more popular;
 - Generalists (dentists) have been educated by the periodontal community in terms of best practices and are referring patients more frequently;
 - The aging population experiences an increasing rate of break-down of teeth that had originally been preserved by root canals;
 - Bone is being replaced earlier in the cycle of periodontal disease; and,
 - Implants are very successful, at a rate of approximately 96% of the time.
- €# The uses for allograft skin may decrease over time with increased use of alternatives such as synthetic and bovine collagen products.
- €# Periodontists will often achieve bone growth through using a combination of the patients’ own platelets (platelet rich plasma or PRP) and a product such as Bio-Oss. These procedures are commonly carried out in the periodontists’ offices.
- €# A proportion of oral and maxillofacial surgeons (~ 15%) likely do not use any type of grafting material as they specialize in extractions.

Estimation of Dental Industry Demand Using Existing Databases

Purpose

A limited number of oral and maxillofacial surgeons (37) were able to complete surveys for this project. In an effort to provide additional evidence for the number of procedures performed that could involve the use of some form of grafting material, a national database was used to produce counts of procedures.

Methodology

The project team used the Hospital Morbidity Database (HMDB), a hospital separation database managed by CIHI. A listing of commonly performed procedures was developed and confirmed with an oral and maxillofacial surgeon working in a hospital setting. CCP procedure codes (Canadian Classification of Procedures) for the year 2000 were counted.

Results

The following table provides data from the HMDB for 3 years (1998–2000) by procedure:

Table 35. Oral and Maxillofacial Procedure Counts for Year 2000 (HMDB)

Procedure Description	CCP Count for Year		
	1998	1999	2000
Rhinoplasty with bone or cartilage graft	298	212	213
Other rhinoplasty or septoplasty (includes repair of septal perforation)	5,682	4,674	4,041
Repair and plastic operation of nasal sinus	231	185	183
Gingioplasty by graft (bone) (soft tissue)	80	70	59
Alveoloplasty (includes That with graft or implant)	455	432	415
Other repair of mouth (includes That with mucosa or skin graft)	300	233	222
Other plastic repair of palate (with graft)	1,134	1,047	1,176
Open reduction of facial fractures (includes codes 88.11-88.19)	4,117	4,111	4,061
Partial ostectomy of facial bone, except mandible (includes bone graft)	214	193	177
Total mandibulectomy with reconstruction	40	39	38
Temporomandibular arthroplasty	426	388	322
Augmentation genioplasty (includes bone graft)	944	1,012	1,010
Reconstruction of mandible with associated resection (includes bone graft)	508	438	441
Reconstruction of other facial bone with associated resection (includes bone graft)	328	334	292
Total resection of facial bone except mandible with associated reconstruction	18	23	22
Bone graft to facial bone (autogenous/bone bank/ heterogenous graft)	1,232	1,227	1,127
Full thickness skin graft to lip and external mouth	22	35	17
Other free skin graft to lip and external mouth	120	111	113
Total	16,149	14,764	13,929

Key Observations

- €# Based on the number of procedures (13,929) it could be assumed that at least one graft (i.e. a package of demineralized bone or bovine/synthetic bone substitute or autogenous graft) would be required for these procedures.
- €# In comparison to these numbers, the extrapolated survey data for oral and maxillofacial surgeons resulted in a range of demand from 3,469 to 5,371 allograft tissues.
- €# Additional survey data used to estimate demand specific to oral and maxillofacial surgeons produced a range of demand from 4,680 to 7,248 (see page 31).
- €# The average number of annual procedures from 1998–2000 based on HMDB is 14,947.
- €# Considering that it is likely that a percentage of these procedures did not include the use of allograft tissue, the demand for allograft tissue by oral and maxillofacial surgeons compared across the 3 methods seems fairly consistent; however, given that the HMDB reflects only procedures conducted in hospitals, while the Demand survey addressed oral and maxillofacial surgeons regardless of their location of practice, it may be that the survey results are somewhat understated for this User Group.

Limitations

- €# The Hospital Morbidity Database (HMDB) is hospital based. Only procedures conducted in hospitals are included. Those procedures done by periodontists or oral and maxillofacial surgeons in private dental practices are not reported.
- €# Analysis of HMDB data was limited to a 3 year period (1998–2000).
- €# Grafting materials used in these procedures may include tissue types other than allograft, i.e. autogenic, synthetic, xenographic.
- €# Hospitals reporting data included those specializing in paediatrics, where practice patterns and use of allograft tissue may differ from adults.
- €# Procedures included in this analysis are primarily conducted by oral and maxillofacial surgeons but may also be conducted by other surgical specialities.

Demand Versus Known Supply

This section provides a comparison of the extrapolated demand for Dental Industry User Groups and other User Groups versus the Known Supply (defined as the supply of allograft tissue being produced by known Canadian Tissue Banks) as detailed in the *Supply of Human Allograft Tissue in Canada—Final Report, April 2003*.

As reported in the *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*, the current shortfall/surplus across the 3 ranges for the non-dental User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn unit/plastic surgeons) is as follows:

- €# Low range—annual shortfall of 23,713 tissues or 69% of total extrapolated demand
- €# Medium range—annual shortfall of 37,887 tissues or 78% of total extrapolated demand
- €# High range—annual shortfall of 51,369 tissues or 83% of total extrapolated demand

With the addition of demand from the Dental Industry User Groups (periodontists, oral and maxillofacial surgeons), the current shortfall/surplus across the 3 ranges rises as follows:

- €# Low range—annual shortfall of 68,687 tissues or 86% of total extrapolated demand
- €# Medium range—annual shortfall of 104,227 tissues or 91% of total extrapolated demand
- €# High range—annual shortfall of 139,403 tissues or 93% of total extrapolated demand

For the purpose of this report, and to permit comparisons to results as presented in the *Demand for Human Allograft Tissue in Canada—Final Report, May 2003* report, the structural grafts reported by the Dental Industry have been grouped under “Small Structural Grafts”. With the exception of hemi-mandibles, the structural grafts demanded by these users are considered “small” in size.

The following figure contrasts Demand at the medium range by Total Demand, and Demand for dental and non-dental groups versus Known Supply of allograft tissue in Canada for the tissue types utilized by the Dental Industry.

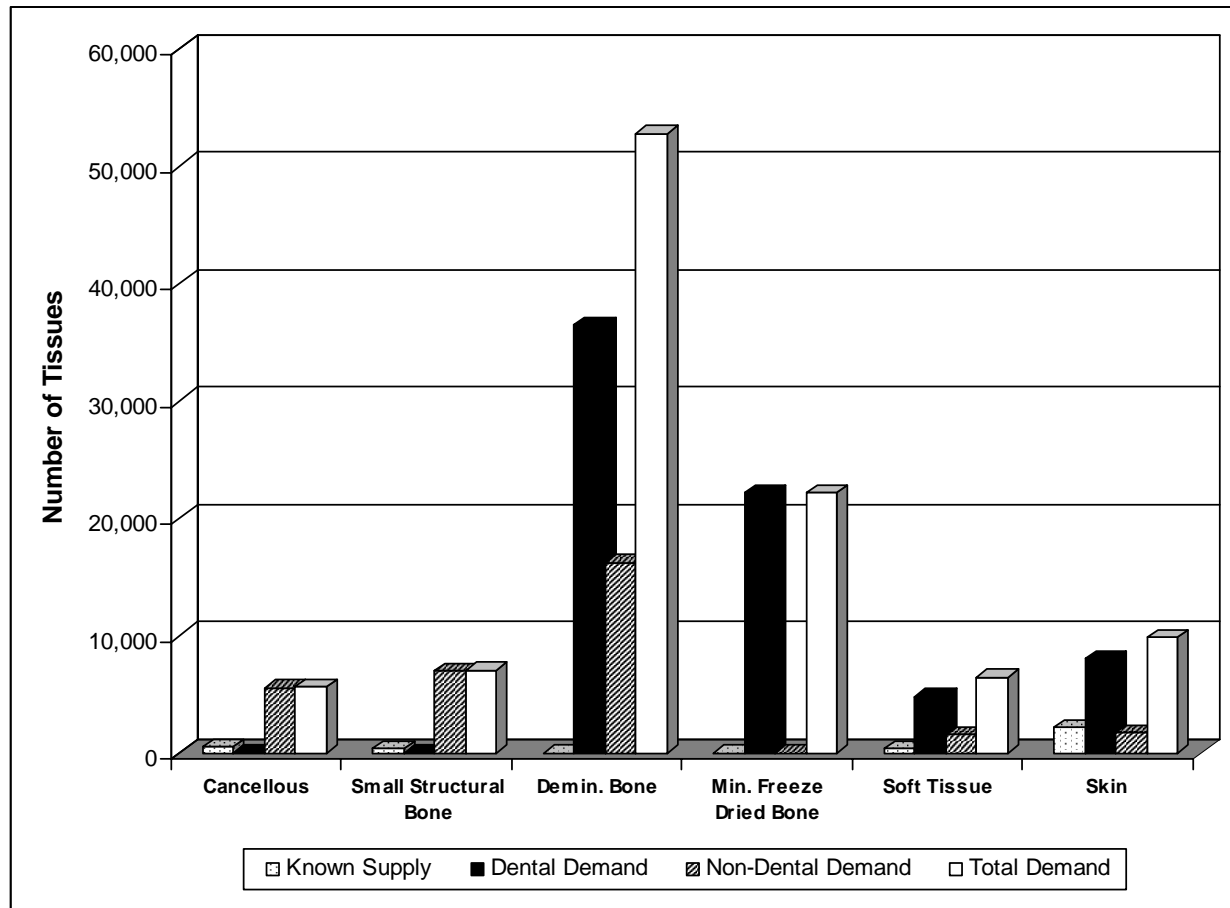


Figure 9. Known Supply vs. Dental, Non-Dental, and Total Demand by Relevant Tissue Type at Medium Range

Table 36. Summary of Extrapolated Demand Versus Known Supply Across Ranges for All Tissue Types

Users	Surgical/ Cancel. Bone per Year	Cancel. Bone (50cc packages)	Small Structural Grafts per Year	Large Structural Grafts per Year	Demin. Bone (packages) per Year	Mineral. Freeze-Dried Bone (packages) per Year	Tendons per Year	Soft Tissues per Year	Cardio. Tissues per Year	Skin Grafts/ Products per Year	Ocular Tissues per Year	Total per Year
Total Extrapolated Demand—Non Dental User Groups Low Range	7,720	3,002	3,724	3,319	8,652		1,128	803	1,089	1,614	3,391	34,442
Total Extrapolated Demand—DENTAL USER GROUPS Low Range		53	37		22,913	13,518		3,263		5,190		44,974
Total Known Supply	1,503	541	423	1,534	0		466	416	249	2,210	3,387	10,729
Predicted (Shortfall)/Surplus Low Range	(6,217)	(2,514)	(3,338)	(1,785)	(31,565)	(13,518)	(662)	(3,650)	(840)	(4,594)	(4)	(68,687)
Total Extrapolated Demand—Non Dental User Groups Medium Range	11,581	4,503	5,586	4,979	12,978		1,691	1,204	1,089	1,614	3,391	48,616
Total Extrapolated Demand—DENTAL USER GROUPS Medium Range		67	47		33,543	20,165		4,833		7,685		66,340
Total Known Supply	1,503	541	423	1,534	0		466	416	249	2,210	3,387	10,729
Predicted (Shortfall)/Surplus Medium Range	(10,078)	(4,029)	(5,210)	(3,445)	(46,521)	(20,165)	(1,225)	(5,621)	(840)	(7,089)	(4)	(104,227)
Total Extrapolated Demand—Non Dental User Groups High Range	15,441	5,626	6,598	6,639	16,648		2,255	1,204	1,643	1,614	4,430	62,098
Total Extrapolated Demand—DENTAL USER GROUPS High Range		82	57		44,325	26,924		6,428		10,218		88,034
Total Known Supply	1,503	541	423	1,534	0		466	416	249	2,210	3,387	10,729
Predicted (Shortfall)/Surplus High Range	(13,938)	(5,167)	(6,232)	(5,105)	(60,973)	(26,924)	(1,789)	(7,216)	(1,394)	(9,622)	(1,043)	(139,403)

The following 3 tables contrast the Known Supply of Canadian allograft tissue, as determined by the Supply study, with the extrapolated demand across the 3 ranges by region. The predicted annual shortfall/surplus is also highlighted by tissue product and region (Atlantic, Central and West)* and includes both dental and non-dental User Groups.

Table 37. Known Supply Versus Extrapolated Demand—Low Range

Tissue Product	Atlantic				Central				West			
	Known Supply	Extrap. Demand—Low Range Non-Dental	Extrap. Demand—Low Range Dental	Predicted Annual (Shortfall) Surplus	Known Supply	Extrap. Demand—Low Range Non-Dental	Extrap. Demand—Low Range Dental	Predicted Annual (Shortfall) Surplus	Known Supply	Extrap. Demand—Low Range Non-Dental	Extrap. Demand—Low Range Dental	Predicted Annual (Shortfall) Surplus
Cancellous/Surgical Bone	145	576	0	(431)	859	5,089	0	(4,230)	499	2,055	0	(1,556)
Cancellous Ground Bone	467	208	5	254		1,953	37	(1,990)	74	841	11	(778)
Small Structural Grafts	256	242	2	12	96	2,398	26	(2,328)	71	1,084	9	(1,022)
Large Structural Grafts	215	248	0	(33)	924	2,187	0	(1,263)	395	884	0	(489)
Demin. Bone Products	0	619	1,577	(2,196)	0	5,656	14,256	(19,912)	0	2,377	7,080	(9,457)
Mineralized Freeze-Dried Bone	0	0	905	(905)	0	0	8,258	(8,258)	0	0	4,355	(4,355)
Tendons	78	84	0	(6)	71	744	0	(673)	317	300	0	17
Soft Tissues	179	43	221	(85)	74	503	2,008	(2,437)	163	257	1,034	(1,128)
Cardio. Tissues	35	76	0	(41)	152	686	0	(534)	62	327	0	(265)
Skin Grafts/Products	1,050	202	352	496	21	705	3,193	(3,877)	1,139	707	1,645	(1,213)
Ocular Tissues	281	281	0	0	1,691	2,166	0	(475)	1,415	944	0	471
Total	2,706	2,579	3,062	(2,935)	3,888	22,087	27,778	(45,977)	4,135	9,776	14,134	(19,775)

* Regions are defined as: Atlantic—provinces east of Quebec; Central—Quebec and Ontario; West—provinces west of Ontario

Table 38. Known Supply Versus Extrapolated Demand—Medium Range

Tissue Product	Atlantic				Central				West			
	Known Supply	Extrap. Demand—Med. Range Non-Dental	Extrap. Demand—Med. Range Dental	Predicted Annual (Shortfall) Surplus	Known Supply	Extrap. Demand—Med. Range Non-Dental	Extrap. Demand—Med. Range Dental	Predicted Annual (Shortfall) Surplus	Known Supply	Extrap. Demand—Med. Range Non-Dental	Extrap. Demand—Med. Range Dental	Predicted Annual (Shortfall) Surplus
Cancellous/Surgical Bone	145	862	0	(717)	859	7,636	0	(6,777)	499	3,083	0	(2,584)
Cancellous Ground Bone	467	313	6	148	0	2,929	47	(2,976)	74	1,261	14	(1,201)
Small Structural Grafts	256	363	4	(111)	96	3,596	33	(3,533)	71	1,627	10	(1,566)
Large Structural Grafts	215	370	0	(155)	924	3,284	0	(2,360)	395	1,325	0	(930)
Demin. Bone Products	0	926	2,301	(3,227)	0	8,489	20,822	(29,311)	0	3,563	10,420	(13,983)
Mineralized Freeze-Dried Bone	0	0	1,350	(1,350)	0	0	12,319	(12,319)	0	0	6,496	(6,496)
Tendons	78	126	0	(48)	71	1,115	0	(1,044)	317	450	0	(133)
Soft Tissues	179	65	326	(212)	74	752	2,971	(3,649)	163	387	1,536	(1,760)
Cardio. Tissues	35	76	0	(41)	152	687	0	(535)	62	326	0	(264)
Skin Grafts/Products	1,050	202	520	328	21	705	4,724	(5,408)	1,139	707	2,441	(2,009)
Ocular Tissues	281	281	0	0	1,691	2,166	0	(475)	1,415	944	0	471
Total	2,706	3,584	4,507	(5,385)	3,888	31,359	40,916	(68,387)	4,135	13,673	20,917	(30,455)

* Regions are defined as: Atlantic—provinces east of Quebec; Central—Quebec and Ontario; West—provinces west of Ontario

Table 39. Known Supply Versus Extrapolated Demand—High Range

Tissue Product	Atlantic				Central				West			
	Known Supply	Extrap. Demand—High Range Non-Dental	Extrap. Demand—High Range Dental	Predicted Annual (Shortfall) Surplus	Known Supply	Extrap. Demand—High Range Non-Dental	Extrap. Demand—High Range Dental	Predicted Annual (Shortfall) Surplus	Known Supply	Extrap. Demand—High Range Non-Dental	Extrap. Demand—High Range Dental	Predicted Annual (Shortfall) Surplus
Cancellous/Surgical Bone	145	1,150	0	(1,005)	859	10,180	0	(9,321)	499	4,111	0	(3,612)
Cancellous Ground Bone	467	396	7	64	0	3,670	57	(3,727)	74	1,560	18	(1,504)
Small Structural Grafts	256	440	5	(189)	96	4,262	40	(4,206)	71	1,896	12	(1,837)
Large Structural Grafts	215	494	0	(279)	924	4,377	0	(3,453)	395	1,768	0	(1,373)
Demin. Bone Products	0	1,199	3,035	(4,234)	0	10,909	27,479	(38,388)	0	4,540	13,811	(18,351)
Mineralized Freeze-Dried Bone	0	0	1,803	(1,803)	0	0	16,447	(16,447)	0	0	8,674	(8,674)
Tendons	78	168	0	(90)	71	1,486	0	(1,415)	317	601	0	(284)
Soft Tissues	179	65	434	(320)	74	752	3,949	(4,627)	163	387	2,045	(2,269)
Cardio. Tissues	35	114	0	(79)	152	1,037	0	(885)	62	492	0	(430)
Skin Grafts/Products	1,050	202	689	159	21	705	6,278	(6,962)	1,139	707	3,251	(2,819)
Ocular Tissues	281	366	0	(85)	1,691	2,828	0	(1,137)	1,415	1,236	0	179
Total	2,706	4,594	5,973	(7,861)	3,888	40,206	54,250	(90,568)	4,135	17,298	27,811	(40,974)

* Regions are defined as: Atlantic—provinces east of Quebec; Central—Quebec and Ontario; West—provinces west of Ontario

The next table provides a comparison of the extrapolated predicted demand (extrapolated demand adjusted for predicted increases in use of allograft tissue over the next 1–2 year period) for Dental Industry User Groups and other User Groups versus the Known Supply of Canadian tissue.

As reported in the *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*, the predicted shortfall/surplus across the 3 ranges for the non-dental User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn unit/plastic surgeons) is as follows:

- €# Low range—annual shortfall of 31,860 tissues or 75% of total predicted demand
- €# Medium range—annual shortfall of 49,706 tissues or 82% of total predicted demand
- €# High range—annual shortfall of 66,481 tissues or 86% of total predicted demand

With the addition of demand from the Dental Industry User Groups (periodontists, oral and maxillofacial surgeons), the predicted shortfall/surplus across the 3 ranges rises as follows:

- €# Low range—annual shortfall of 80,485 tissues or 88% of total predicted demand
- €# Medium range—annual shortfall of 121,416 tissues or 92% of total predicted demand
- €# High range—annual shortfall of 161,632 tissues or 94% of total predicted demand

Table 40. Summary of Extrapolated Predicted Demand Versus Known Supply Across Ranges

Extrapolated Predicted Demand Ranges	Surg. Bone	Cancellous (50 cc packages)	Small Structural Bone	Large Structural Bone	Dem. Bone (packages)	Mineral. Freeze-Dried Bone (packages)	Ten-dons	Soft Tissue	Cardio-vascular	Skin Products	Ocular	Total per Year
Total Predicted Demand—Non Dental User Groups Low Range	9,727	3,715	4,692	4,182	10,862	0	1,421	1,092	1,122	1,775	4,001	42,589
Total Predicted Demand—DENTAL USER GROUPS Low Range	0	55	37	0	24,920	14,897	0	3,263	0	5,453	0	48,625
Total Known Supply	1,503	541	423	1,534	0	0	466	416	249	2,210	3,387	10,729
Predicted (Shortfall)/Surplus—Low Range	(8,224)	(3,229)	(4,306)	(2,648)	(35,782)	14,897	(955)	(3,939)	(873)	(5,018)	(614)	(80,485)
Total Predicted Demand—Non Dental User Groups Medium Range	14,592	5,572	7,038	6,274	16,293	0	2,131	1,637	1,122	1,775	4,001	60,435
Total Predicted Demand—DENTAL USER GROUPS Medium Range	0	69	47	0	36,466	22,222	0	4,833	0	8,073	0	71,710
Total Known Supply	1,503	541	423	1,534	0	0	466	416	249	2,210	3,387	10,729
Predicted (Shortfall)/Surplus—Medium Range	(13,089)	(5,100)	(6,662)	(4,740)	(52,759)	(22,222)	(1,665)	(6,054)	(873)	(7,638)	(614)	(121,416)
Total Predicted Demand—Non Dental User Groups High Range	19,456	6,987	8,313	8,365	20,917	0	2,841	1,637	1,692	1,775	5,227	77,210
Total Predicted Demand—DENTAL USER GROUPS High Range	0	85	57	0	48,177	29,670	0	6,428	0	10,734	0	95,151
Total Known Supply	1,503	541	423	1,534	0	0	466	416	249	2,210	3,387	10,729
Predicted (Shortfall)/Surplus—High Range	(17,953)	(6,531)	(7,947)	(6,831)	(69,094)	(29,670)	(2,375)	(7,649)	(1,443)	(10,299)	(1,840)	(161,632)

Summary

This report, *Demand for Human Allograft Tissue in Canada: Integrating Dental Industry Demand*, completes the final phase of the CCDT Project 4.1 to study Supply and Demand of Allograft Tissue in Canada. Results of other phases, *Supply of Human Allograft Tissue in Canada* and *Demand for Human Allograft Tissue in Canada* can now be considered in the context of the Dental Industry results.

The Dental Industry study has provided estimates of the Current Demand for human allograft tissue in Canada as reflected through survey results sent to 2 primary User Groups—periodontists and oral and maxillofacial surgeons. When extrapolated across the “universe” of these User Groups, using estimation methods across three ranges, the estimated Current Demand for allograft tissue in the Canadian Dental Industry ranges from a low of 44,974 grafts per year to a high of 88,034 grafts per year.

The annual Current Demand for the Canadian Dental Industry (periodontists and oral and maxillofacial surgeons) can now be compared to that of the non-dental User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn unit/plastic surgeons), as reported in the *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*:

Table 41. Annual Current Demand for Dental Industry and Non-Dental User Groups

User Group	Range of Annual Current Demand (grafts per year)
Dental Industry	
Periodontists	41,505–82,663
Oral and Maxillofacial Surgeons	3,469–5,371
Non-Dental User Groups	34,442–62,098
All User Groups	79,416–150,132

A summary of the annual Current Demand (across the 3 estimation ranges) by user group and tissue type is presented in the following table:

Table 42. Summary of Annual Current Demand by Dental Industry and Non-Dental User Groups and Tissue Type

Tissue Product	Range of Demand for Periodontists	Range of Demand for Oral and Maxillofacial Surgeons	Range of Demand for Orthopaedic Surgeons	Range of Demand for Neurosurgeons	Range of Demand for Cardiac Surgeons	Range of Demand for Burn Units	Range of Demand for Corneal Surgeons
Surgical/ Cancel. Bone			7,720–15,441				
Cancel. Bone—50cc packages		53–82	2,246–4,493	756–1,133			
Small Struc. Grafts		37–57	2,024–4,048	1,700–2,550			
Large Struc. Grafts			3,319–6,639				
Demineralized. Bone Products	19,956–39,746	2,957–4,579	7,339–14,679	1,313–1,969			
Mineralized freeze dried bone	13,518–26,924						
Tendons			1,128–2,255				
Soft Tissues	3,105–6,183	158–245		803–1,204			
Cardio. Tissues					1,089–1,643		
Skin Grafts	4,926–9,810	264–408				1,614	
Ocular Tissues							3,391–4,430
Total	41,505–82,663	3,469–5,371	23,776–47,555	4,572–6,856	1,089–1,643	1,614	3,391–4,430

Data gathered in relation to the predicted increase in use of allograft tissue over the next 1–2 year period for the Canadian Dental Industry (periodontists and oral and maxillofacial surgeons) can now be compared to that of the non-dental User Groups as reported in the *Demand for Human Allograft Tissue in Canada, Final Report—May 2003*:

Table 43. Predicted Demand for Dental Industry and Non-Dental User Groups

User Group	Range of Predicted Demand (grafts per year)
Dental Industry	48,625 to 95,151
Non-Dental User Groups	42,589 to 77,210
All User Groups	91,214 to 172,361

The remainder of the Summary section provides the reader with some discussion on key considerations identified by the project team, as well as a synthesis of the Dental Industry Study results with other components of the CCDT Project 4.1 addressing Supply and Demand. These topics include:

- ##Comparing Demand: Periodontists and Oral and Maxillofacial Surgeons
- ##Comparing Demand: Dental Industry and Non-Dental User Groups
- ##Comparing Other Survey Results: Dental Industry and Non-Dental User Groups
- ##Demand and Known Supply: Impact of Dental Industry on Estimated Shortfall of Tissue

Comparing Demand: Periodontists and Oral and Maxillofacial Surgeons

The results of the Dental Industry study have highlighted a number of differences within the industry when comparing the 2 User Groups. The following points are of note:

1. Based on survey data, demand for tissue by periodontists significantly outweighs that of oral and maxillofacial surgeons by more than 15:1. This discrepancy raised concern that there may be under-reporting by the oral and maxillofacial surgeons. The project team used 2 methods to analyze survey data and validate the lower numbers:
 - ## Estimated range of demand using extrapolated survey results—3,469 to 5,371
 - ## Estimated range of demand using extrapolated survey procedure counts—4,680 to 7,248

These results indicate that survey data was internally consistent. However, in investigating levels of activity by oral and maxillofacial surgeons within the hospital setting using a national database (Hospital Morbidity Database), average annual procedures for 1998–2000 were in excess of 14,000 procedures. If it is assumed that at least one graft is used for the majority of these procedures, and that there are additional procedures completed by these surgeons outside the hospital setting, actual numbers could potentially be higher. It should be noted that it is very likely that a percentage of these 14,000+ procedures did not include the use of allograft tissue. Nevertheless, the reader should be aware that the Demand survey results may be somewhat understated for the oral and maxillofacial surgeon User Group.

2. Comparing features of practice for periodontists and oral and maxillofacial surgeons may also explain some of the differences in Demand. Periodontal practice focuses on “building up” structures and “filling in” spaces. It is conceivable that 100% of periodontists use some form of grafting material in all procedures. Within the specialty of oral and maxillofacial surgery there are likely a percentage of surgeons who never use grafting material, such as those surgeons who do extractions solely. Periodontists primarily work in the community in their own practice or with others. These clinicians require very good tracking mechanisms for procedures, purchases of material and other critical information as payment sources such as third party payers require it. Oral and maxillofacial surgeons working in a hospital setting may be much further removed from any data that is tracked for their procedures and the related costs of material.
3. The type of tissue used by these User Groups also differs. Periodontists have a significant demand for demineralized and mineralized freeze dried bone which is likely exclusively ordered from the U.S. Oral and maxillofacial surgeons access cancellous bone, small and large structural bone (e.g. hemi-mandibles), some of which is available from Canadian Tissue Banks.

When comparing the proportion of tissue types used by these 2 groups there appear to be differences and similarities:

- €# Over 80% of all tissues used by both groups are in the demineralized and/or mineralized freeze dried bone categories;
- €# Periodontists demand for soft tissue accounts for 7% of their total; for oral and maxillofacial surgeons this is 5%;
- €# Periodontists demand for skin accounts for 12% of their total; for oral and maxillofacial surgeons this is 8%; and,
- €# Use of mineralized freeze dried bone makes up 33% of all tissues used by periodontists.

Comparing Demand: Dental Industry and Non-Dental User Groups

It is particularly interesting and notable to consider the extrapolated demand for periodontists as compared to other User Groups. Using the middle range for extrapolated demand, the following table compares the relative contribution of the various Users Groups to total Current Demand for allograft tissue:

Table 44. Summary of Annual Allograft Tissue Demand (Medium Range) by User Group

User Group	Extrapolated Demand—Medium Range	
	Number of grafts	% of Total
Periodontists	61,912	54%
Oral and Maxillofacial Surgeons	4,428	4%
Orthopaedic surgeons	35,666	31%
Neurosurgeons	6,856	6%
Cardiac Surgeons	1,089	1%
Corneal Surgeons	3,391	3%
Burn Units	1,614	1%
Total	114,956	100%

The following figure further illustrates the results presented in the table above:

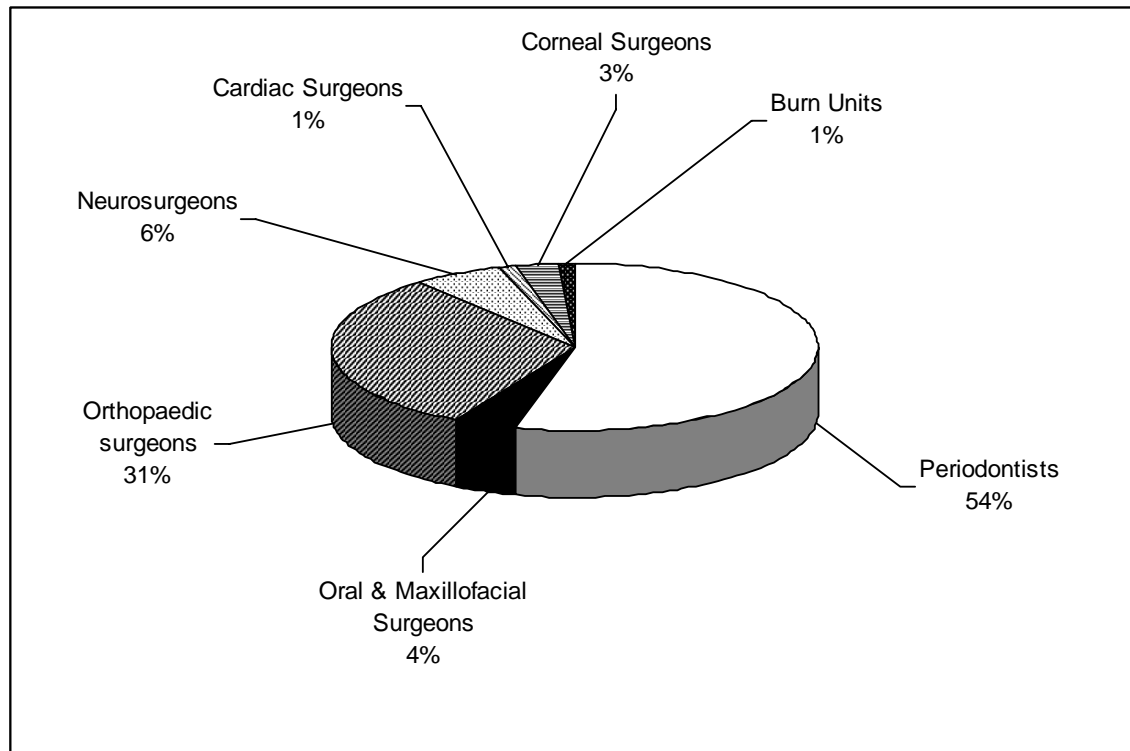


Figure 10. Summary of Annual Allograft Tissue Demand (Medium Range) by User Group

When extrapolating data at the medium range, periodontists (n = 179) use almost double the number of grafts as compared to orthopaedic surgeons (n = 770). If Canada’s tissue banking services are to meet the needs of all User Groups in the future, demand of the Dental Industry, and in particular of periodontists, should be a key consideration.

Comparing Other Survey Results: Dental Industry and Non-Dental User Groups

Demand surveys for the Dental Industry and for the non-dental User Groups included a number of qualitative sections that were consistent across all User Groups. These included sources and access to tissue, use of alternatives, characteristics affecting selection of supplier, user preferences and current trends. The project team compared the general results in these topic areas and included them in the table below:

Table 45. Comparing Qualitative Survey Data for Dental Industry and Non-Dental User Groups

Dental Industry (Periodontists, Oral and Maxillofacial Surgeons)	Non-Dental User Groups (Orthopaedic Surgeons, Neurosurgeons, Cardiac Surgeons, Corneal Transplant Surgeons, Burn Unit/Plastic Surgeons)
Sources and Access	
<p>## The majority of Dental Industry users indicated that they obtain their allograft tissue products from American Tissue Banks (80% for periodontists and 77% for oral and maxillofacial surgeons).</p> <p>## Important reasons for purchasing outside of Canada were: "safety" (80%) "not available in Canada" (52%).</p>	<p>## The non-dental User Groups reported on average that they access tissue from American Tissue Banks 17% of the time.</p> <p>## Important reasons for purchasing outside of Canada were: "not available in Canada" (71%) "speed and consistency of service" (69%).</p>
Use of Alternatives	
<p>## The percentage of procedures which are currently performed where an alternative to allograft tissue is used due to lack of access was reported at 19.9% and 23.8%, for periodontists and oral and maxillofacial surgeons respectively.</p>	<p>## This percentage is comparable to that reported by the orthopaedic surgeon User Group (19%).</p>

Table 45. Comparing Qualitative Survey Data for Dental Industry and Non-Dental User Groups (cont'd)

Dental Industry (Periodontists, Oral and Maxillofacial Surgeons)	Non-Dental User Groups (Orthopaedic Surgeons, Neurosurgeons, Cardiac Surgeons, Corneal Transplant Surgeons, Burn Unit/Plastic Surgeons)
Characteristics Affecting Selection of Supplier	
<p>∅# The most important characteristics were:</p> <p>“quality assurance” (90%) “safety record” (88%) “graft characteristics” (58%)</p>	<p>∅# The same three characteristics were the most important:</p> <p>“safety record” (69%) “quality assurance” (68%) “graft characteristics” (38%)</p>
User Preferences for Tissue Banks	
<p>∅# Agreement on preferred characteristics of Tissue Banks were highest for:</p> <p>“preference for accredited TB” (96%) “preference for Canadian vs U.S. TB” (82%) “fee for service model, monitoring outcomes” (88%)</p>	<p>∅# Similar results for preferred characteristics of Tissue Banks:</p> <p>“preference for accredited TB” (98%) “preference for Canadian vs U.S. TB” (94%) “fee for service model, monitoring outcomes” (79%)</p>
Current Trends	
<p>There were a number of similar themes for both groups vis a vis trends and technologies affecting demand:</p> <p>∅# an aging population.</p> <p>∅# increasing numbers of restorative, reconstructive and tissue replacement procedures.</p> <p>∅# some emerging evidence for improved outcomes with use of allograft tissue.</p> <p>∅# ongoing debates regarding the efficacy of allograft versus autograft or other substitutes.</p> <p>∅# autograft is often a “fallback” strategy due to lack of availability and/or concern over disease transmission with allograft.</p> <p>∅# significant developments in the area of biologics and tissue engineering.</p> <p>∅# use of bone morphogenic protein.</p> <p>∅# use of demineralized bone products and combination products (xenographic, synthetic, platelet rich plasma).</p>	
Other	
<p>Other common themes emerging from the study of both Dental and other User Groups:</p> <p>∅# lack of information and knowledge regarding the Canadian Tissue Bank services.</p> <p>∅# concerns regarding the safety of using allograft tissue.</p> <p>∅# concerns regarding patients’ acceptance of use of human tissue.</p>	

Demand and Known Supply: Impact of Dental Industry on Estimated Shortfall of Tissue

The CCDT studies on Supply and Demand have permitted estimations of shortfalls (or surpluses in some cases for certain tissue types) of allograft tissue across Canada and regionally. With the addition of the Dental Industry data, a more complete picture of these estimations can be made.

The *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*, detailed a current shortfall/surplus across the 3 ranges for the non-dental User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn unit/plastic surgeons) as follows:

- €# Low range—annual shortfall of 23,713 tissues or 69% of total extrapolated demand
- €# Medium range—annual shortfall of 37,887 tissues or 78% of total extrapolated demand
- €# High range—annual shortfall of 51,369 tissues or 83% of total extrapolated demand

With the addition of demand from the Dental Industry User Groups (periodontists, oral and maxillofacial surgeons), the shortfall/surplus across the 3 ranges rises as follows:

- €# Low range—annual shortfall of 68,687 tissues or 86% of total extrapolated demand
- €# Medium range—annual shortfall of 104,227 tissues or 91% of total extrapolated demand
- €# High range—annual shortfall of 139,403 tissues or 93% of total extrapolated demand

As reported in the *Demand for Human Allograft Tissue in Canada—Final Report, May 2003*, the extrapolated demand adjusted for the predicted shortfall/surplus (incorporating the survey respondents' predicted increase in tissue use over the next 1-2 year period) for the non-dental User Groups (orthopaedic surgeons, neurosurgeons, cardiac surgeons, corneal transplant surgeons, burn unit/plastic surgeons) is as follows:

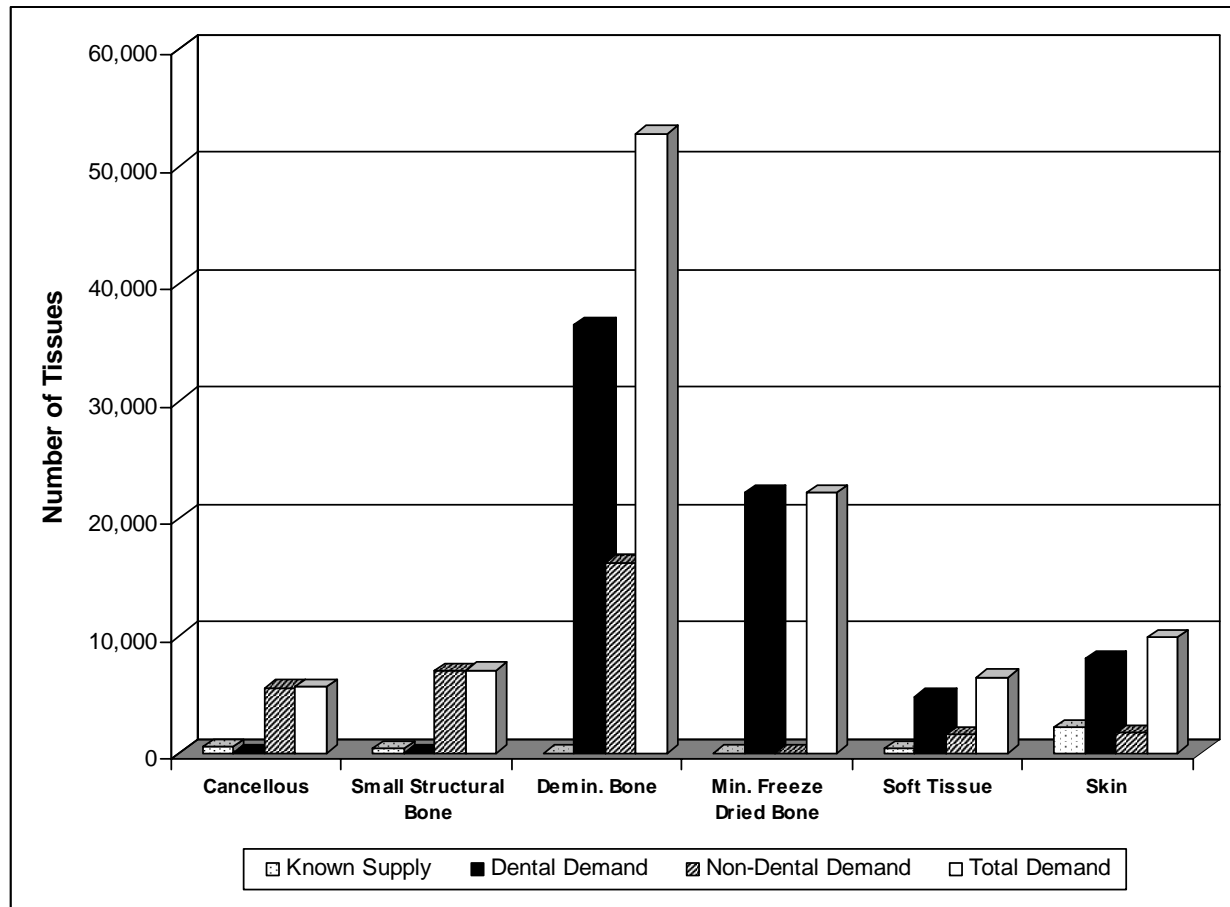
- €# Low range—annual shortfall of 31,860 tissues or 75% of total predicted demand
- €# Medium range—annual shortfall of 49,706 tissues or 82% of total predicted demand
- €# High range—annual shortfall of 66,481 tissues or 86% of total predicted demand

With the addition of demand from the Dental Industry User Groups (periodontists, oral and maxillofacial surgeons), the predicted shortfall/surplus across the 3 ranges rises as follows:

- €# Low range—annual shortfall of 80,485 tissues or 88% of total predicted demand
- €# Medium range—annual shortfall of 121,416 tissues or 92% of total predicted demand
- €# High range—annual shortfall of 161,632 tissues or 94% of total predicted demand

The following graph contrasts Demand at the medium range by Total Demand, and Demand for dental and non-dental groups versus Known Supply of allograft tissue in Canada for the tissue types utilized by the Dental Industry.

Known Supply vs. Dental, Non-Dental, and Total Demand by Relevant Tissue Type at Medium Range



This snapshot of Known Supply and Demand for allograft tissue in Canada highlights the fact that tissue products utilized most by the Dental Industry (demineralized bone and mineralized freeze dried bone) are not currently supplied by Canadian Tissue Banks. In addition, it reveals significant shortfalls for other tissue types as compared to Total Demand (dental and non-dental).

With the significant number of grafts estimated for periodontists and oral and maxillofacial surgeons added to the estimations for other User Groups across Canadian regions, the following table provides a comparison by region (Atlantic, Central and West):

Table 46: Summary of Known Supply, Demand and Shortfalls by Region for All User Groups

	<i>Atlantic</i>				<i>Central</i>				<i>West</i>			
	Known Supply	Extrap. Demand—Non-Dental	Extrap. Demand—Dental	Predicted Annual (Shortfall) Surplus	Known Supply	Extrap. Demand—Non-Dental	Extrap. Demand—Dental	Predicted Annual (Shortfall) Surplus	Known Supply	Extrap. Demand—Non-Dental	Extrap. Demand—Dental	Predicted Annual (Shortfall) Surplus
Low range	2,706	2,579	3,062	(2,935)	3,888	22,087	27,778	(45,977)	4,135	9,776	14,134	(19,775)
Medium range	2,706	3,584	4,507	(5,385)	3,888	31,359	40,916	(68,387)	4,135	13,673	20,917	(30,455)
High range	2,706	4,594	5,973	(7,861)	3,888	40,206	54,250	(90,568)	4,135	17,298	27,811	(40,974)

* Regions are defined as: Atlantic—provinces east of Quebec; Central—Quebec and Ontario; West—provinces west of Ontario

This permits comparison of the relative shortfall by region as compared to total demand (high range):

- Atlantic: shortfall of 7,861 is 74% of total demand for this region;
- Central: shortfall of 90,568 is 96% of total demand for this region;
- West: shortfall of 40,974 is 91% of total demand for this region.

This points to the Atlantic region as having the lowest shortfall relative to demand (although it is still 74% of total), as compared to the other 2 regions. This is consistent with results from the other studies showing that the Atlantic region is reasonably well served for its tissue needs, with the exception of products for the Dental Industry and other User Groups requiring demineralized and mineralized freeze dried bone products. In addition, it highlights the fact that for Atlantic and Central regions, the addition of Dental Industry demand almost doubles total demand for these regions. This trend is less marked in the Western region.

In summary, the completion of this final component of the CCDT Project 4.1 to study Supply and Demand for Human Allograft Tissue in Canada has permitted a comprehensive study of the Demand by key User Groups and comparisons with Known Supply.

The Dental Industry contribution to overall Demand is significant and there are unique features such as the type of tissue used, the sources for these products and the methods used to obtain it. In particular, there is a major reliance of the Dental User Groups on accessing tissue commercially from the U.S., either directly or through distributors. The major portion of products they use (demineralized bone and mineralized freeze dried bone) are not produced in any form in Canada. In addition, in contrast to the non-dental User Groups which primarily function in hospital/acute-care settings, the Dental Industry has a large component working in the community in private practice settings.

The study results have also verified that the Dental Industry and non-dental User Groups share similar views on characteristics influencing selection of supplier, and preferences for characteristics for tissue banks. The most striking differences between the 2 groups are the source of tissue, (primarily the U.S.) and the types of tissue products utilized. The majority of the products utilized by the Dental Industry are highly specialized, commercialized and involve more complex manufacturing processes than the tissues currently produced by Canadian Tissue Banks.

Another common thread in both Demand studies is the general lack of knowledge of User Groups regarding Canadian tissue banking services, how to access tissue, safety and accreditation standards and how the current system is working.

Several factors identified in the *Demand for Human Allograft Tissue in Canada—Final Report, May 2003* that influence or constrain the level of Current Demand for allograft tissue in Canada are relevant to the Dental Industry:

- ⌘ Healthcare resource constraints for OR time and limited budgets for purchasing products (particularly for hospital-based oral and maxillofacial surgeons);
- ⌘ Use of alternative products (autografts, xenografts, synthetic) and combination products either due to limited access/resources or concerns regarding safety;
- ⌘ Historical user preferences;
- ⌘ Research and development focused on biologics, tissue engineering and other emerging technologies; and
- ⌘ Lack of information/knowledge regarding the risks and efficacy of using allograft tissue, existing standards and services relevant to tissue banking in Canada.

The development of a Canadian Tissue Banking Model which will address the needs of all users, including the Dental Industry, must take into account the unique features of this industry and the tissues required. The results of this study *Demand for Human Allograft Tissue in Canada: Integrating Dental Industry Demand* reinforce the recommendations made in the May 2003 report, outlining the key requirements for a Canadian Tissue Banking Model:

- €# Public and clinical education regarding the safety, sources and efficacy of allograft tissue;
- €# Adequate government funding to monitor, evaluate and implement equitable services across Canada, and in particular to provide the needed infrastructure, expertise and resources for provision of large volumes of tissue that is currently not produced in Canada;
- €# Ongoing research and development focused on emerging technologies and evaluation; and
- €# Comprehensive data tracking mechanisms and outcomes reporting that are consistent across hospital based and community based settings.

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Appendix A

Dental Industry Demand Surveys

SECTION # 1 UTILIZATION OF ALLOGRAFT TISSUE FOR ORAL & MAXILLO-FACIAL SURGERY

In order to estimate the demand for human allograft products in Canada, please provide your average allograft utilization per YEAR when completing questions 1 - 6.

- | | # |
|---|---------------------|
| 1. What is your estimated use (per YEAR) of <u>pre-packaged cancellous</u> allografts?
(please write # of packages by package size - package size being #of cc's per pkg.) | _____ of _____ cc's |
| 2. What is your estimated use (per YEAR) of <u>demineralized bone products</u>
(please write number of packages). | _____ of _____ cc's |
| 3. What is your estimated use (per YEAR) of <u>structural</u> bone allografts such as mandibles, bone dowels, wedges or rings per month? (please write number) | _____ |
| 4. What is your estimated use (per YEAR) of <u>soft tissue</u> (i.e. fascia lata, tendons)?
(please write number) | _____ |
| 5. What is your estimated use (per YEAR) of allograft <u>skin</u> (i.e. # grafts)? (please write number). | _____ |
| 6. What is your estimated use (per YEAR) of <u>bovine</u> &/or <u>synthetic</u> bone products (eg. BioOss)? (please write number of packages). | _____ |

7. For the following common Oral & Maxillo-facial procedures, please indicate the average number of procedures you would perform in a typical year. Assuming no barriers of cost and availability of allograft tissue, please indicate the % of these procedures that would involve the use of allograft tissue (i.e. bone, soft tissue, skin).

Procedure	# of Procedures per Year	Type(s) of Allograft Tissue Used in Procedure (please check all that apply)	% of Procedures Requiring Allograft Tissue
a. Replacement for bone lost, eg. Post trauma, post cancer surgery		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata / tendons <input type="checkbox"/> Skin <input type="checkbox"/> Bovine / synthetic <input type="checkbox"/>	
b. Gingioplasty		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata / tendons <input type="checkbox"/> Skin <input type="checkbox"/> Bovine / synthetic <input type="checkbox"/>	

National Survey for Demand of Allograft Tissue Products by Oral & Maxillo-facial Surgeons –June 2003

Procedure	# of Procedures per Year	Type(s) of Allograft Tissue Used in Procedure (please check all that apply)	% of Procedures Requiring Allograft Tissue
d. Partial ostectomy of facial bone, except mandible		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata / tendons <input type="checkbox"/> Skin <input type="checkbox"/> Bovine / synthetic <input type="checkbox"/>	
e. Reconstruction of mandible with associated resection		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata / tendons <input type="checkbox"/> Skin <input type="checkbox"/> Bovine / synthetic <input type="checkbox"/>	
f. Other (please specify):		Cancellous bone <input type="checkbox"/> Demineralised bone <input type="checkbox"/> Structural bone grafts <input type="checkbox"/> Fascia lata / tendons <input type="checkbox"/> Skin <input type="checkbox"/> Bovine / synthetic <input type="checkbox"/>	

8. Please fill out the table below indicating whether you believe you will experience an increase, decrease or no change in use of each type of **allograft** tissue over the coming 1-2 years. If you indicate an increase or decrease please estimate by what %.

<u>Tissue Type</u>	<u>Increase/Decrease (Please check)</u>	<u>% Change</u>
Pre-packaged Cancellous Allograft	Increase <input type="checkbox"/> Decrease <input type="checkbox"/> No Change <input type="checkbox"/>	
Demineralized Bone Products	Increase <input type="checkbox"/> Decrease <input type="checkbox"/> No Change <input type="checkbox"/>	
Structural Bone Allograft (i.e. mandibles, bone dowels, wedges or rings)	Increase <input type="checkbox"/> Decrease <input type="checkbox"/> No Change <input type="checkbox"/>	
Soft Tissue Allograft (i.e. fascia lata, tendons)	Increase <input type="checkbox"/> Decrease <input type="checkbox"/> No Change <input type="checkbox"/>	
Allograft Skin	Increase <input type="checkbox"/> Decrease <input type="checkbox"/> No Change <input type="checkbox"/>	

National Survey for Demand of Allograft Tissue Products by Oral & Maxillo-facial Surgeons –June 2003

%

14. Of all the procedures you do where your preference would be to use human allograft tissue, for what % must you use an alternative (autograft, xenograft, mechanical device, synthetic device) because allograft tissue is not readily available?
15. In your opinion, what are the **main reasons** why you don't use allografts when they are the **preferred choice** for a surgical procedure? Please write in reasons.

Both Canadian and American tissue banks provide allograft tissue to Canadian surgeons. Questions 16 - 22 ask you to indicate how strongly each characteristic would influence your selection of a supplier / source for these allograft products.

Reason	Not Important	⇔	Very Important				
Quality							
	Please circle number for rating:						
16. Graft Characteristics (ease of application, meets technical expectation)	1	2	3	4	5	6	7
17. Quality Assurance Program (Tissue Bank /supplier has accreditation status or demonstrated quality programs)	1	2	3	4	5	6	7
18. Demonstrated Safety Record (Tissue Bank / supplier has a record of taking action to minimize the risk of disease transmission)	1	2	3	4	5	6	7
Service							
	Please circle number for rating:						
19. Speed of service delivery (tissue is distributed/received within acceptable timelines)	1	2	3	4	5	6	7
20. Consistency of service (service is provided dependably & reliably each time)	1	2	3	4	5	6	7
21. Availability of tissue (sufficient tissue is always available to meet needs)	1	2	3	4	5	6	7
22. Price (price is lower than competitors)	1	2	3	4	5	6	7

National Survey for Demand of Allograft Tissue Products by Oral & Maxillo-facial Surgeons – June 2003

Questions 23 to 28 consist of statements in relation to the selection of allograft tissue sources. Please indicate whether you agree or disagree with these statements.

Please circle one selection for each question:

23. Given a choice between a profit and a not-for-profit Tissue Bank / supplier with comparable quality products, I would give preference to the not-for-profit Tissue Bank / supplier.
Strongly Disagree Disagree Neutral Agree Strongly Agree
24. Given a choice between a Canadian and an American Tissue Bank / supplier with comparable quality products I would give preference to the Canadian Tissue Bank / supplier.
Strongly Disagree Disagree Neutral Agree Strongly Agree
25. Given a choice between an accredited and non-accredited bank / supplier with comparable quality products I would give preference to the accredited Tissue Bank / supplier.
Strongly Disagree Disagree Neutral Agree Strongly Agree
26. I would utilize a fee for service model which screens providers of allograft tissue to ensure they meet established quality standards.
Strongly Disagree Disagree Neutral Agree Strongly Agree
27. I would utilize a fee for service model which provides support in recipient tracking and adverse outcome monitoring.
Strongly Disagree Disagree Neutral Agree Strongly Agree
28. Tissue banks / suppliers should be able to generate profits on products they produce from donated tissue.
Strongly Disagree Disagree Neutral Agree Strongly Agree

SECTION # 4 TRENDS & EMERGING TECHNOLOGIES

29. Are there trends or emerging technologies, which, when available will increase or decrease your demand for allograft tissue? Please name the trend / technology and note applicable procedures / application below:

Increase/Decrease Demand	Trend / Emerging Technology	Procedure / Application
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		

National Survey for Demand of Allograft Tissue Products by Oral & Maxillo-facial Surgeons –June 2003

30. Other comments on the future of allograft tissue use in oral & maxillo-facial surgery:

**THANK YOU FOR YOUR TIME AND EFFORT TO COMPLETE THIS SURVEY!
PLEASE FAX TO CIHI, ATTENTION KIM BADOVINAC at (416) 481-2950 BY FRIDAY JULY 4th,
2003**

FOR FURTHER INFORMATION CONTACT:

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National Survey for Demand of Human Allograft Tissue Products by Periodontists - May 2003

SECTION # 1 – UTILIZATION OF ALLOGRAFT TISSUE PRODUCTS

Estimated use of human allograft and/or substitutes:

1. In the table below **estimate the number of procedures you perform on a WEEKLY basis** and check off the types of products that you currently utilize for these procedures.

Periodontal Procedure	Estimated # procedures per <u>WEEK</u>	De-Mineralized Bone Products (e.g. DynaGraft)	Mineralized Freeze Dried Bone Allograft	Synthetic Bone (e.g. Biogran)	Xenograft Bone (e.g. Bio-Oss)	Human Allograft Skin (e.g Alloderm)	Human Fascia Allograft
Extraction Socket Preservation		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Osseous Defects for Periodontal		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sinus Lift		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Procedures (specify):		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. In the table below estimate the **number of procedures you perform on a MONTHLY basis** and check off the types of products that you currently utilize for these procedures.

Periodontal Procedure	Estimated # procedures per <u>MONTH</u>	DeMineralized Bone Products (e.g. DynaGraft)	Mineralized Freeze Dried Bone Allograft	Synthetic Bone (e.g. Biogran)	Xenograft Bone (e.g. Bio-Oss)	Human Allograft Skin (e.g Alloderm)	Human Fascia Allograft
Grafting Associated with Dental Implants		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ridge Augmentation		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Procedures (specify):		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

National Survey for Demand of Human Allograft Tissue Products by Periodontists - May 2003

3. Please fill out the table below indicating whether you believe you will experience an increase, decrease or no change in use of each type of **allograft** tissue over the coming 1-2 years. If you indicate an increase or decrease please estimate by what %.

<u>Tissue Type</u>	<u>Increase/Decrease</u> <u>(Please check)</u>	<u>% Change</u>
Demineralized Bone Products (e.g. DynaGraft)	Increase <input type="checkbox"/> Decrease <input type="checkbox"/> No Change <input type="checkbox"/>	
Mineralized Freeze-Dried Bone Allograft Products	Increase <input type="checkbox"/> Decrease <input type="checkbox"/> No Change <input type="checkbox"/>	
Allograft Skin (e.g. Alloderm)	Increase <input type="checkbox"/> Decrease <input type="checkbox"/> No Change <input type="checkbox"/>	
Allograft Fascia	Increase <input type="checkbox"/> Decrease <input type="checkbox"/> No Change <input type="checkbox"/>	

4. What percentage of your **allograft** tissue products are currently provided by a: (please write %)

- Canadian Tissue Bank _____
 - American Tissue Bank / Company OR Commercial Distributor _____
 - Other (specify) _____
 - Unknown _____
- 100%**

5. Of all the procedures you do where your preference would be to use human allograft products, for what % must you use an alternative (autograft, xenograft, mechanical device, synthetic device) because allograft tissue is not readily available?

6. If you obtain human allograft products (including bone matrix or powder – demineralized or other) from sources other than Canadian Tissue Banks, please rank the following factors in terms of their **relevance to your decision to purchase outside of Canada / or from U.S. companies via a distributor.**

(please write #1 for most important and # 4 for least important)

- Not available in Canada _____
- Speed and consistency of service _____
- Price _____
- Safety _____

Other Comments re decision to purchase from other than Canadian Tissue Banks:

National Survey for Demand of Human Allograft Tissue Products by Periodontists - May 2003

7. Please check off the products you commonly purchase for use in your practice:

- | | | | |
|-------------|--------------------------|----------|--------------------------|
| Dynagraft | <input type="checkbox"/> | Alloderm | <input type="checkbox"/> |
| Grafton DBM | <input type="checkbox"/> | Bioglass | <input type="checkbox"/> |
| AlloGro | <input type="checkbox"/> | BioOss | <input type="checkbox"/> |
| AlloMatrix | <input type="checkbox"/> | Biogran | <input type="checkbox"/> |
| Regenafil | <input type="checkbox"/> | | |
| Regenaform | <input type="checkbox"/> | | |

Others: (Please Specify)

_____	<input type="checkbox"/>	_____	<input type="checkbox"/>
_____	<input type="checkbox"/>	_____	<input type="checkbox"/>

8. If possible, please provide an estimate of your total annual expenditures in relation to the purchase of human allograft, xenograft and synthetic bone substitute products. \$.00 Per year

9. Do you require your patients to sign an informed consent for any of the products you use? **Yes**
(please check) **No**

If Yes, for which products:

SECTION # 2 CHARACTERISTICS AFFECTING YOUR SELECTION OF SUPPLIER

Questions 10 - 16 ask you to indicate how strongly each characteristic would influence your selection of a supplier / source for these allograft products.

	Reason	Not Important	⇒	Very Important
--	--------	---------------	---	----------------

Quality

Please circle number for rating:

- | | | | | | | | |
|---|---|---|---|---|---|---|---|
| 10. Graft Characteristics
(ease of application, meets technical expectation) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 11. Quality Assurance Program
(Tissue Bank/supplier has accreditation status or demonstrated quality programs) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 12. Demonstrated Safety Record
(Tissue Bank/supplier has a record of taking action to minimize the risk of disease transmission) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Service

Please circle number for rating:

- | | | | | | | | |
|---|---|---|---|---|---|---|---|
| 13. Speed of service delivery
(tissue is distributed/received within acceptable timelines) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 14. Consistency of service
(service is provided dependably & reliably each time) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 15. Availability of tissue
(sufficient tissue is always available to meet needs) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 16. Price
(price is lower than competitors) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

National Survey for Demand of Human Allograft Tissue Products by Periodontists - May 2003

Questions 17 to 22 consist of statements in relation to the selection of allograft tissue sources. Please indicate whether you agree or disagree with these statements.

Please circle one selection for each question:

17. Given a choice between a profit and a not-for-profit Tissue Bank/supplier with comparable quality products, I would give preference to the not-for-profit Tissue Bank/supplier.
Strongly Disagree Disagree Neutral Agree Strongly Agree
18. Given a choice between a Canadian and an American Tissue Bank/supplier with comparable quality products I would give preference to the Canadian Tissue Bank/supplier.
Strongly Disagree Disagree Neutral Agree Strongly Agree
19. Given a choice between an accredited and non-accredited bank with comparable quality products I would give preference to the accredited Tissue Bank/supplier.
Strongly Disagree Disagree Neutral Agree Strongly Agree
20. I would utilize a fee for service model which screens providers of allograft tissue to ensure they meet established quality standards.
Strongly Disagree Disagree Neutral Agree Strongly Agree
21. I would utilize a fee for service model which provides support in recipient tracking and adverse outcome monitoring.
Strongly Disagree Disagree Neutral Agree Strongly Agree
22. Tissue Banks/suppliers should be able to generate profits on products they produce from donated tissue.
Strongly Disagree Disagree Neutral Agree Strongly Agree

SECTION # 3 TRENDS & EMERGING TECHNOLOGIES

23. Are there trends (e.g. aging population, disease states) or emerging technologies (e.g. new procedures, new products), which, when available will increase or decrease your demand for human bone and soft tissue allografts? Please name the trend / technology and note applicable procedures / application below:

Increase/Decrease Demand	Trend / Emerging Technology	Procedure / Application
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		
Increase <input type="checkbox"/> Decrease <input type="checkbox"/>		

24. Other comments on the future of allograft tissue use in periodontology:

**THANK YOU FOR YOUR TIME AND EFFORT TO COMPLETE THIS SURVEY!
PLEASE FAX TO CIHI, ATTENTION KIM BADOVINAC at (416) 481-2950 BY FRIDAY JUNE 20TH,
2003**

FOR FURTHER INFORMATION CONTACT:

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Appendix B

Grafting Products Used by Dental Industry

Tissue Type	Product	Company	Web Site
Human allograft – Demineralized bone	Grafton® Demineralized Bone Matrix (DBM) Other products: <ul style="list-style-type: none"> ⌘ Grafton® Demineralized Bone Matrix (DBM) Gel ⌘ Grafton® DBM Flex ⌘ Grafton® DBM Putty ⌘ Grafton® DBM Crunch ⌘ Grafton® DBM Matrix PLF ⌘ Grafton® DBM Matrix Plugs 	Osteotech, Inc. 51 James Way, Eatontown, NJ, 07724	www.osteotech.com
Human allograft – Demineralized bone	DynaGraft Other products: <ul style="list-style-type: none"> ⌘ DynaCan® ⌘ OrthoBlast™ 	GenSci Regeneration Sciences Head Office: 1235 Bay St. Suite 1000, Toronto, ON, M5R 3K4	www.gensciinc.com
Human allograft – Demineralized bone	AlloGro®	AlloSource	www.allosource.org
Human allograft – Demineralized bone	ALLOMATRIX® CUSTOM Bone Graft Putty ALLOMATRIX® Injectable Putty IGNITE™ ICS Injectable Cellular Scaffold	Wright Medical Technology, Inc. 5677 Airline Rd., Arlington, TN, 38002	www.wmt.com
Human allograft	AlloDerm®	LifeCell Corporation One Millennium Way Branchburg, New Jersey 08876-3876 Telephone: 1-908-947-1100 e-mail: CorporateCommunications@lifecell.com	http://www.biohorizons.com/alloderm.htm http://www.alloderm.com/ordering/products/dental.cfm

Tissue Type	Product	Company	Web Site
Synthetic bone substitutes	Bioglass Perioglas® Biogran® Methylmethacrylate (HTR)		www.3i-online.com www.perioglas.com
Collagen membranes	BioGide® Ossix™	Osteohealth Co., Shirley, NY Colbar RandD Ltd	www.colbar.com
Xenograft (bone substitutes)	Bio-Oss® (bovine) Osteograf-N® (bovine) Biocoral® (calcium carbonate from real coral)	Osteohealth Co., Shirley, NY	www.ceramed.com www.biocoral.com
Biologic modifiers	<ul style="list-style-type: none"> ⌘ Emdogain®Gel (an enamel matrix derivative, protein-rich gel extracted from pig tooth buds) ⌘ Pep-Gen™ (cell binding peptide) ⌘ PDGF (platelet derived growth factor) 	Biora, Inc. 415 North LaSalle Street, Suite 615 Chicago, Illinois 60610 U.S.A. Toll Free: (888) 246-7287 Tel: + 1 312 832 1414 Fax: + 1 312 832 1429	www.biora.com

Description of Grafting Products Used by Dental Industry

Additional details and descriptions for a number of products that appear to have increasing use in the Dental Industry are included below:

Alloderm

Alloderm is real human dermal tissue that is decellularized to remove the risk of rejection or inflammation. It is then freeze-dried through a patented process that maintains the crucial elements of the tissue structure (collagen, elastin, and proteoglycans) and packaged with a shelf life up to 2 years. AlloDerm is available in various sizes to increase keratinized gingiva, for soft tissue flap extensions over bone grafts, and for recession defects.

BioActive Glasses

The bioactive glasses are particulate materials, slowly resorb and when mixed with fluids in a periodontal defect, form an adherent surface layer of silicon, calcium, fluoride and sodium which binds the graft to bone. They obliterate defects well, are not inductive of bone formation, but conduct mineralization by promoting absorption and concentration of proteins used by osteoblasts to form the extracellular matrix of bone.

Collagen Membranes

Ossix is produced by Colbar RandD Ltd, an Israeli-based company which has a technology that offers a more durable scaffold for tissue engineering. The technology allows for the first time the precise programming of the collagen matrix that is used in tissue repair. The three year old company has a dental product for tooth implantation on the market in the US and a second product for correcting contour deficiencies in clinical trials in Europe.

Biologic Modifiers

EmdogainGel is a resorbable, implantable material, which consists of hydrophobic enamel matrix proteins premixed with the vehicle solution, Propylene Glycol Alginate. It is intended as an adjunct to periodontal surgery for topical application onto exposed root surfaces. After a single gel application, EmdogainGel leaves only a resorbable protein matrix on the root surface.

EmdogainGel is a product, which, in a biological way, recreates the tooth attachment lost due to periodontitis. The main ingredient in Emdogain is amelogenin. This protein has an important function in the creation of teeth and their support, but is produced only during the time that our teeth are developed.

Pep-Gen is a synthetic amino acid sequence identical to that found in the non-allogenic portion of the collagen molecule. The material is combined with an anorganic microporous bovine bone. The portion of collagen protein incorporated in the graft is thought to be responsible for binding fibroblasts and osteoblasts in the material matrix.

The most recent biologic modifier is platelet derived growth factor (PDGF). Since this material is derived from the patient's own platelet rich plasma it is not a commercial preparation. Marx et al have described this process. One hundred and fifty milliliters of

whole blood is drawn into a citrated container. The platelet rich plasma is separated using a platelet separator, like a centrifuge, and it is added to autogenous or allogenic bovine bone. After placement of the graft material-enriched PDGF, a coat of PRP plasma is placed over the graft area and the flaps closed.

Platelet rich plasma is high in concentration of three growth factors: PDGF (platelet derived growth factor), TGF-B (transforming growth factor beta) and IGF (insulin-like growth factor). The spin down process of platelets increases the concentration by 300%.

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