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THE JOURNAL OF BONE & JOINT SURGERY (BRITISH)

Supply and demand of bone allograft for revision hip surgery in Scotland

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The Scottish National Blood Transfusion Service is the main provider of bone for grafting in Scotland. Bone is procured only from live donors, following very strict selection criteria, and we have investigated whether the amount being collected was adequate.

Our current harvest of approximately 1700 femoral heads per year is shown not to be enough to meet the future demand for revision surgery of the hip. Many more of these operations are being undertaken, and impaction grafting is being used increasingly.

We have calculated the predicted rates of collection and usage for the next four to five years so that we can expand our service in a controlled fashion.

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Small bone allografts are collected, tested, 'fresh frozen' and distributed by the five regional transfusion centres of the Scottish National Blood Transfusion Service (SNBTS) based in Glasgow, Edinburgh, Dundee, Aberdeen and Inverness.

All these regions collect femoral head allografts from patients undergoing elective primary total hip replacement (THR), most with a diagnosis of osteoarthritis (OA). Some regions also collect tibial plateaux, but these are a small proportion of the total. Bone is not collected from patients with fractured neck of the femur or rheumatoid arthritis, or from cadavers or multi-organ donors.

Collected bone is tested for mandatory viral markers and bacteriological infection. If these tests are negative it is frozen and quarantined for six months. The donor is then retested for the viral markers and, if these tests are clear, the bone is released for use. When a bacteriological infection is found, bone does not have to be discarded but can be processed further. This occurs in 10% to 15% of all available bone.

Small bone allografts are used in a number of orthopaedic operations such as spinal fusion and in trauma, but particularly in revision of THR. We investigated the available supply of fresh-frozen bone allografts from live donors in Scotland, and attempted to predict the total demand for their use in revision THRs.

Materials and Methods

Supply of fresh-frozen bone allografts. The overall availability of such allografts from live donors can be calculated by estimating the rates of primary elective THR for OA. The annual Standard Morbidity Records (SMR 1), as coded by the Office of Population Censuses and Surveys (OPCS), for primary THR in Scottish hospitals from 1989 to 1994, were studied[1] and the number of primary elective replacements calculated as described by Williams et al.[2,3] This was compared with the SNBTS[4] information on the number of potential bone donors in order to check the accuracy of coding in each hospital and to indicate whether the SNBTS was collecting bone from all available patients.

Although the numbers are relatively small they were considered to be adequate to provide relatively crude predicted rates. Once we had shown that the SMR 1 figures were relatively accurate, estimates of the number of operations expected for the period 1996 to 2001 were made, using varied assumptions concerning the factors which influence the demand for hip surgery, including the incidence of disease, the impact of population changes and resource constraints.

An upper range of predicted rates of surgery for 1996 to 2001 was derived by taking the average proportional rate of change in the rates and numbers of elective primary THR for OA from 1989 to 1995, using the formula:

$$q_n = (1+r)\, q_{n-1}$$

where n is the year, q is the quantity and r is the proportional rate of change. This gives an indication of the current trend

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Table I. SMR 1 records were used to determine the total number of THRs for OA and the SNBTS records (where available) were used to determine the total number of potential femoral head donors. The source of the SMR 1 records was the Information and Statistics Division of the CSA, Edinburgh. The SMR 1 data relate to calendar years and the SNBTS data to fiscal years

	1989		1990		1991		1992		1993		1994	
Region	SMR 1	SNBTS	SMR 1	SNBTS	SMR 1	SNBTS	SMR 1	SNBTS	SMR 1	SNBTS	SMR 1	SNBTS
S.E.	655		673		698		700		739	724	765	759
West*	1035		1047		1067		1140		1138		1188	
North†	197		223		262		242		234	141	225	211
N.E.	194		196	163	300	275	323	369	405	456	438	551
East‡	468		396		323		266	140	238	238	272	278

* data are captured differently and cannot be used for this analysis
† North total for 1993 is for seven months
‡ East total for 1992 is for five months

Table II. Rates per 100 000 population for primary elective THR with the diagnosis of OA between 1989 and 1995 as well as upper and lower predicted rates up to 2001

	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
Rates	48.78	48.15	50.52	51.1	53.1	55.65	57.15						
Upper predicted								58.68	60.26	61.88	63.54	65.25	67
Lower predicted								55.28	55.4	55.6	55.8	56.1	56.3

and assumes that the rate of growth recorded from 1989 to 1994 will be maintained during the next five years.

A lower range of estimates for primary THR is based on the assumption that the number of primary THRs for OA is reaching a plateau and that the demand for operation is being met. Using the General Registrars Office data on population predictions for 1995 to 2001,[5,6] lower estimates were calculated based on the age- and sex-specific rates of THR in 1995 using the formula:

$$q_n = q_{1995}/p_n$$

where n is the year, q is the quantity and p is the projected population for that year.

To estimate the available supply of bone we subtracted from these totals the number of potential donors who will be deferred for medical reasons, those who will probably not consent and those who will require an autologous graft at operation, from our projected number of THRs. We assumed that the criteria for operation, and the rates of medical deferral, consent and autologous use would remain constant.

Estimates of the supply from live donors depend on the ability of the SNBTS to collect the bone, and on the loss due to positive testing for virological and/or bacteriological markers. Bone which tests positive for viral infection is discarded, but that showing bacteriological contamination can be processed further and used clinically. We assumed these factors to be constant, and also assumed that there was minimal wastage of bone.

The demand for bone. The future demand for bone was assessed from the predicted rates of operations in which allograft is currently used, or may be used. The key operation is revision of a THR, and we used the same assumptions to estimate the number of such operations during 1995 to 2001. We applied linear regression to monthly data from 1984 to 1995 to check the accuracy of our predicted rates for revision of THR calculated using the proportional rate of change based on the annual figures from 1989 to 1995. The total demand for bone was then derived from the average number of femoral heads used in each procedure. Allowance was made for the effect of possible changes in technique which could affect the amount of allograft needed.

Results

Comparison of the numbers of potential donors. The total number of primary THRs carried out in NHS hospitals in Scotland from 1989 to 1994 for OA is shown in Table I, which also shows the number of potential donors notified to the SNBTS Bone Banks. The number of discharges recorded on SMR 1 corresponded well to the potential donors identified by the bone banks, showing that most of the available femoral heads were collected.

Predicted rates of collection. The number of THRs carried out for OA increased throughout all age groups between 1989 and 1995. Using these figures the maximal and minimal predicted rates for elective THR for OA per 100 000 population until 2001 are shown in Table II (Fig. 1).

Unsuitable donors. We try to obtain femoral heads from all appropriate donors, but rigorous medical screening rules out 48%. The use of autologous bone in primary THR will decrease the amount available for allogeneic transplant, although the amount so lost is now small. Bone is rarely discarded because of a positive mandatory marker. The number of femoral heads collected by the SNBTS is shown in Table III with the number issued to Scottish hospitals. The number of bones issued has increased significantly and is now approaching the limits of supply.

Predicted demand. The number of revision THRs increased in all age groups between 1984 and 1995. On these figures, using the methods previously described, the upper and lower predicted rates per 100 000 population to 2001 are shown in Table IV (Fig. 2). The difference in the predicted rates for revision THR is wide, depending on the

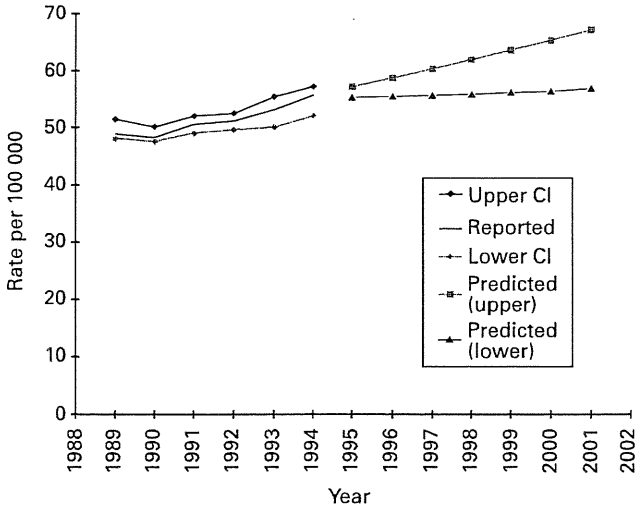

Fig. 1

Primary THR where the patients were admitted with the principal diagnosis of OA. The rates of elective THR are reported for 1989 to 1994 and predicted for 1995 to 2001.

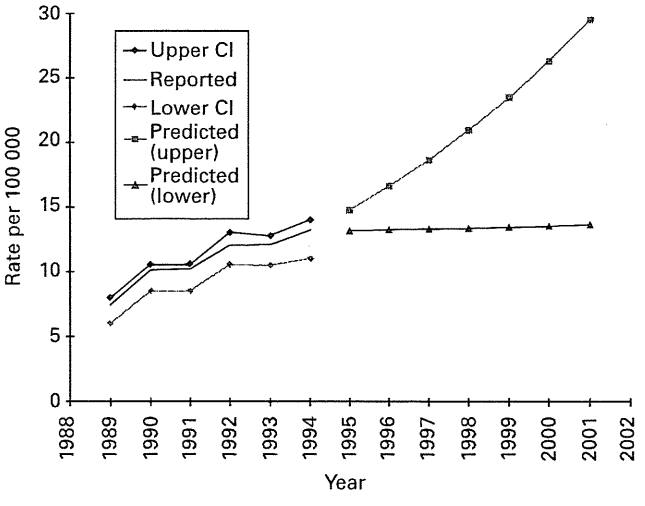

Fig. 2

Revision of, or conversion to, prosthetic replacement of the hip. The rates of demand are reported for 1989 to 1994 and predicted for 1995 to 2001.

Table III. The annual number of femoral heads collected by the SNBTS and the number (where available) issued to Scottish hospitals between 1990 and 1995. It is not possible to break down the number of bones issued by operation, although most are for revision of THR. A six-month quarantine period is an essential requirement and therefore bone collected in one year may be issued the following year

Bone	1990	1991	1992	1993	1994	1995
Collections	163	275	509	1559	1641	1778
Issues			438	1061	1329	1567

Table IV. Rates per 100 000 population for revision THR between 1989 and 1995 as well as upper and lower predicted rates to 2001

	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
	7.43	10.1	10.2	12.03	12.1	13.2	14.75						
Upper predicted								16.6	18.61	20.88	23.42	26.26	29.46
Lower predicted								13.19	13.14	13.28	13.34	13.42	13.49

model used, and therefore a different statistical approach was used. Figure 3 shows the monthly discharges after revision THR reported on the SMR 1 between 1984 and 1994. This suggests that some grouping of the data may be appropriate, but linear regression provides an acceptable estimate of the equation for the line (Fig. 4), and analysis suggests that the model is acceptable (t value highly significant at $p < 0.01$). Estimates of revision THR up to 2001, based on this latter model, are shown in Table V. These results, if included in Figure 2, lie below the predicted upper rates for available bone and well above the lower estimates. This suggests that the model for establishing the ranges of prediction is valid and it was therefore used.

Ratios of revision THR to total THR. The Health Care Evaluation Unit of the University of Bristol estimates that the rate of revision, which was 11% of the total number of THRs carried out in Scotland in 1994, could rise to as much as 40%.[2,3] The projections in Table V show that the rate will have increased to 15% by 1998 and to 20% in 2001.

Quantity of bone per revision. Not all THRs require bone grafting, but the amount of bone required for revision surgery has increased significantly in recent years because of the introduction of impaction grafting. The demand for bone is influenced by both the increase in the rate of revision and the quantity of bone required for each procedure. Table VI shows our projections for the numbers of revision procedures and the bone requirements, expressed in femoral head equivalents. Figure 5 shows an estimate of potential requirements, assuming that 1.5 femoral heads are required for each revision. These estimates may be low since the amount of bone required at each operation is rising. The demand may well exceed the supply in 1997 to 1998.

Discussion

The Scottish Blood Transfusion service has served as a prototype for other tissue banks within the UK. The similar requirements for storage and testing of blood and

Fig. 3

Histogram of monthly discharges after revision THR between 1984 and 1994.

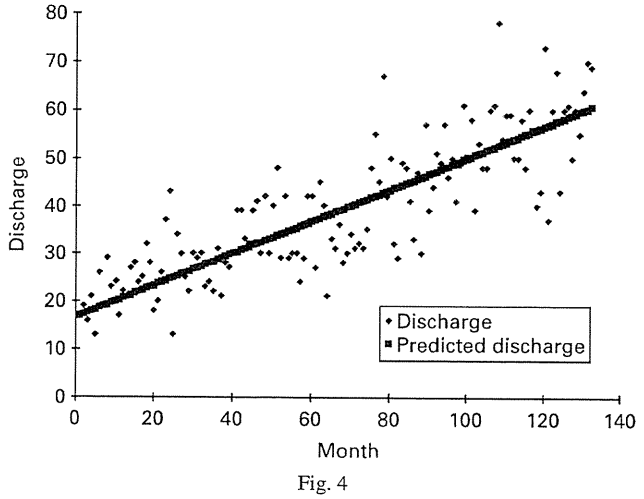

Fig. 4

Month line fit plot of the number of discharges after revision THR between 1984 and 1994.

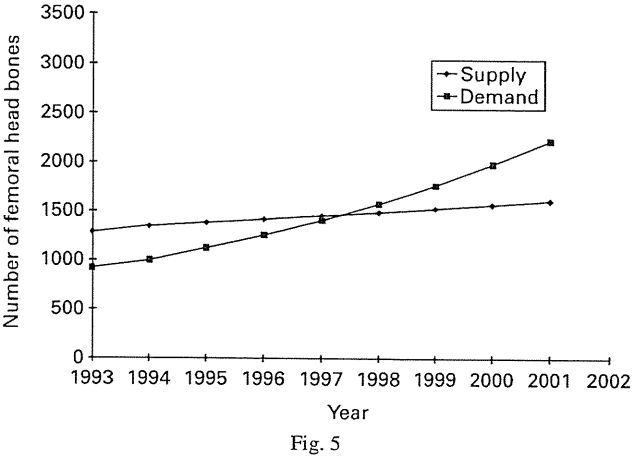

Fig. 5

Supply of bone *v* demand for bone. Central predictions for the supply of femoral head bones and central predictions for demand from revision THR and revision TKR (1.5 bones per revision).

Table V. Annual ratios of projected (central) revision THR to total THR for 1993 to 2001 (primary THR includes all diagnoses). The source of the SMR 1 records was the Information and Statistics Division of the CSA, Edinburgh

	1993	1994	1995	1996	1997	1998	1999	2000	2001
Recorded/projected primary THR	5377	5592	5725	5860	5999	6141	6287	6436	6588
Recorded/projected revision THR	612	667	747	837	938	1051	1177	1319	1477
Ratio of revision to total hip surgery	0.10	0.11	0.12	0.12	0.14	0.15	0.16	0.17	0.20

Table VI. Recorded and projected demand for bone from revision or a primary prosthetic replacement of the hip

	1993	1994	1995	1996	1997	1998	1999	2000	2001
Recorded/projected revision THR	612	667	747	837	938	1051	1177	1319	1477
Demand at 1 head/revision	612	667	747	837	938	1051	1177	1319	1477
Demand at 1.5 heads/revision	918	1000	1120	1255	1407	1576	1765	1978	2215
Demand at 2 heads/revision	1224	1334	1494	1674	1876	2102	2354	2638	2954

bone, and the experience of the SNBTS has resulted in the development of bone banking along similar lines to blood procurement. We obtained bone only from live donors who were in-patients for primary THR, and currently this provides about 1700 femoral heads each year.

Our study has shown that the SNBTS is being notified of most of the potential donors. This shows an efficient use of available resources, but also indicates that there is little

potential for increasing the supply of bone from these sources, unless there is an increase in the number of primary hip replacements.

This source cannot meet the demand for revision surgery of the hip or for other operations because of the increase in the number of revisions and the use of techniques which require more bone, such as impaction grafting which may use up to five femoral heads. Other studies have reached similar conclusions.[7-9]

The demand for allograft cannot be met from current sources. There is a significant loss of potential donors because of rigorous selection and screening, which is unavoidable since safety is paramount. The use of bone from other live donors has been considered, such as those having surgery for fracture of the neck of the femur, but logistic difficulties and concern about bone quality have prevailed.

To maintain self-sufficiency we need to consider using cadaver donors, but there are many problems in relation to this, which need further consideration. Our study has reviewed the supply and demand of bone only for revision surgery of the hip, but more will be needed for other operative techniques. This emphasises the need for further appraisal of potential sources.

Data for this study were supplied by the Information and Statistics Division of the Common Services Agency of the National Health Service in Scotland. Assistance has been received from Professor W. J. Gillespie (Department of Orthopaedic Surgery, University of Edinburgh).

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同種骨移植のための Bone Bank Network

名古屋大学整形外科

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【はじめに】

人工股関節再置換術の方法として同種骨を使用したimpaction bone graftingの優れた成績がGieやSlooffらにより報告されている[1,2]．現在，著者らの施設でも人工股関節再置換術にimpaction bone graftingを取り入れ，短期ではあるが良好な成績をおさめている[3,4]．このようにimpaction bone graftingを行う症例，施設の増加に伴い，同種骨移植材料としての大腿骨頭の需要が増加してきている．このため，大腿骨頭を不要とする病院から，必要とする病院への供給システムが必要となってきている．著者らは，大腿骨頭供給システムとしてBone Bank Networkを設立し，その整備に取り組んでいる．

Bone Bank Networkとは図1に示すごとく，基幹病院を中心として各病院と連係をとり，摘出された大腿骨頭を収集，保存，供給するシステムである．

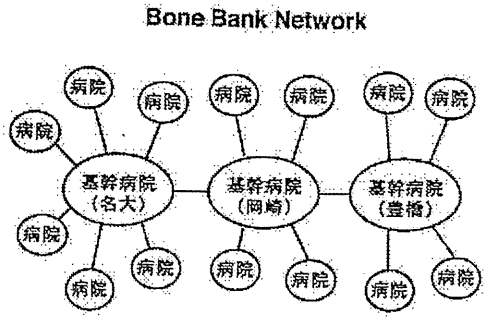

図1

今回，Bone Bank Networkの整備に先立ち，Bone Bank Networkとして供給可能な大腿骨頭数を割り出すこと，Bone Bank Networkを稼動するにあたって問題点を明らかにすることを目的に，名古屋大学整形外科関連病院における同種骨移植状況，大腿骨頭摘出数，術前感染症検査状況を調査検討したので報告する．

【対象および方法】

名古屋大学整形外科の関連68病院に，平成12年4月17日アンケートを郵送し回答を得た．

【結果】

回答病院数56，有効回答率82%であった．回答のあった56病院での大腿骨頸部内側骨折と変股症による年間大腿骨頭摘出総数は1348個であった．同種骨移植を実施している病院は21病院37.5%であり，年間134件の同種骨移植が行われていた（図2）．この21病院中，同種骨を移植前に加温処理していたのは7病院であった．残る14病院の内，放射線照射をしていた1病院を除いた13病院ではまったく処理を行っていなかった．

倫理委員会の有無に関しては有り46%，無し54%と約半数の病院が倫理委員会を設置していた（図3）．摘出した大腿骨頭を保存している病院は22病院，42%あった

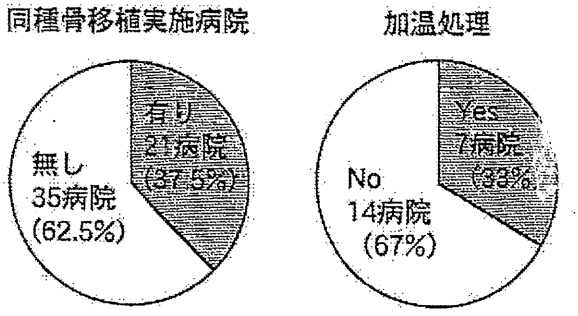

図2

（図4）．このうち32%の病院では倫理委員会の許可を得ていたが，68%では許可を得ていなかった．骨頭を摘出保存している病院で，骨頭提供同意書を使用しているのは32%のみであった（図5）．反対に同種骨移植を行う場合の同種骨移植実施同意書は48%約半数の病院で使用していた．摘出した骨頭の保存温度は95%の病院で-70℃以下で，-70℃以上は1病院だけであった（図6）．骨頭専用の冷凍庫を所有しているのは55%で，残りの45%は検体用の冷凍庫などとの供用であった．

感染症検査に関してはB型肝炎，C型肝炎は100%，梅毒は1病院を除いた全病院で検査していた．しかし，HIVは28病院（55%）の病院でしか検査していなかった．HTLV-1に関してはわずか8病院（16%）で検査しているのみであった（図7）．

Bone Bank Networkへ骨頭提供可能であるかという設問には，25病院（45%）が可能，8病院（14%）が不可能，23病院（41%）が未定であった（図8）．反対にBone Bank Networkからの骨頭を使用可能かという設問に対しては，23病院（41%）が可能，5病院（9%）が不可能，28病院（50%）が未定であった．

以上の結果より，年間大腿骨頭摘出総数からBone Bank Networkに骨頭提供不可能な病院とすでに同種骨移植で骨頭を使用している病院での摘出骨頭数を除くと549個になった．すなわち，この数が計算上ではBone Bank Networkに提供可能だが廃棄されている大腿骨頭数であることがわかった．

【考察】

今回の調査で，名古屋大学整形外科関連病院における同種骨移植状況は，骨頭保存から同種骨移植までquality control, informed consentを含めて各病院様々な方法で行っていることがわかった．このためBone Bank Networkを潤滑に行っていくには日整会ガイドライン[5,6]に乗っ取ったプロトコールの統一が必要であると思われた．このため我々は，Bone Bank Network事務局を設置しBone Bank Networkからプロトコールの提供，保存用バッグの提供，保存バッグ用シールの提供を行うこととした．

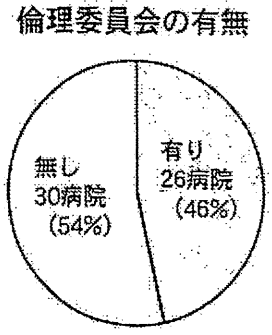

図3

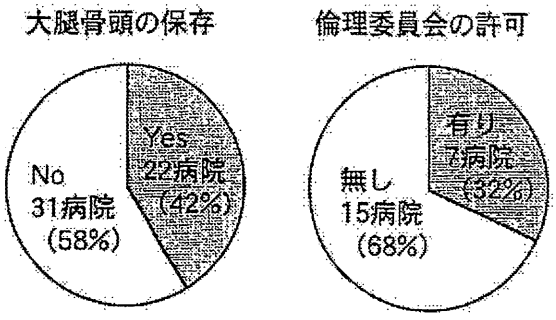

図4

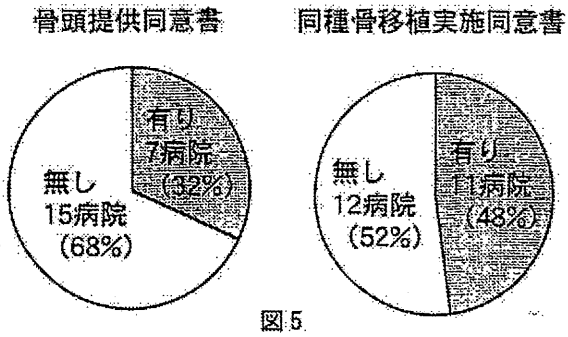

図5

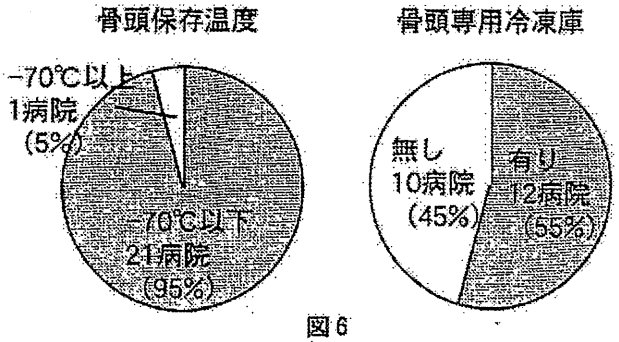

図6

術前あるいは骨頭提供者の感染症検査に関しは，HIV と HTLV-1 は保険点数が認められていないため実施していない病院が多いことがわかった．これに対し，日整会ガイドラインでは同種骨採取にあたり HIV と HTLV-1 検査は必須であるとなっている．同種骨移植を行う場合，disease transmission 防止の観点よりドナーの梅毒，B 型肝炎，C 型肝炎，HIV，HTLV-1 検査は必ず行うべきである．日整会ガイドラインの矛盾を解消するためには，保険行政の改善が必要であると思われた．

現在，利用可能だが廃棄されている大腿骨頭が愛知県内関連病院で年間549個もあることがわかった．今後増加し

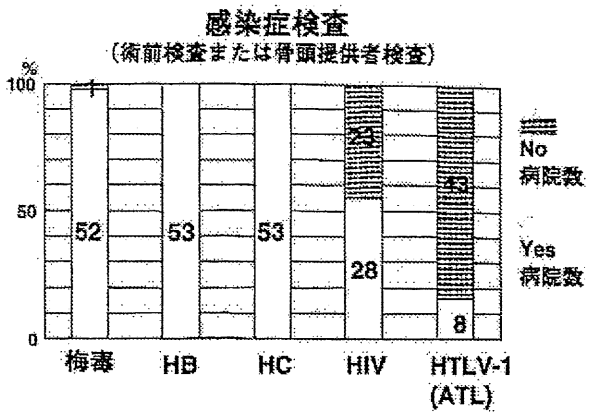

図7

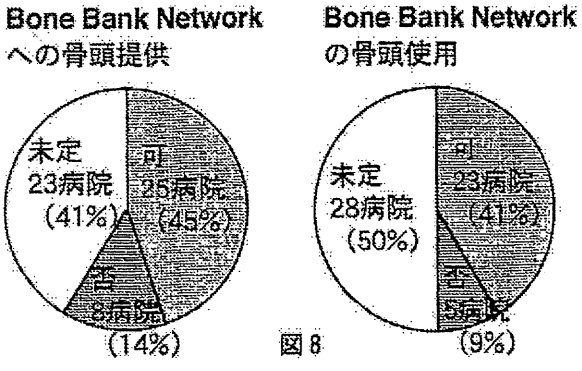

図8

ていくと思われる骨欠損を伴った人工関節再置換術に対応するために，これらの摘出骨頭を quality control のもと有効的に収集，保存，供給するシステムづくりが重要である．

【謝辞】

今回のアンケートならびに Bone Bank Network に協力して下さっている名古屋大学整形外科関連病院と先生方に深謝いたします．

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