Allograft bone transplantation: a Sheffield experience

M T Khan FRCS
Specialist Registrar in Orthopaedics

I Stockley MD FRCS
Consultant Orthopaedic Surgeon

Northern General Hospital, Sheffield

Key words: Allograft bone; Experience

There has been an increase in demand for allograft bone in recent years. This type of bone provides an excellent material to fill in bony defects, but could be associated with an incidence of infection.

Any newly established tissue bank has to meet the very stringent criteria to process and store bone and maintain a donor and recipient database to avoid transmission of infection.

The Sheffield Tissue Bank has been functioning since 1989 and until 1993 has provided bone allografts to 220 patients; these have been used mainly to reconstruct defects at revision hip and knee arthroplasty and for scoliosis surgery.

There have been no cases of disease transmission and the rate of infection has been reduced by strict screening protocols.

This paper outlines our experience, problems and success with human bone banking.

Methods and material

Bone retrieval

Bone recovery may be performed either in a sterile operating theatre or in a non-sterile, but clean environment. Tissue retrieval must be performed in a professional and dignified manner reflecting respect for the donor.

Reconstruction materials must allow for natural positioning of the limb.

The process of allograft bone retrieval has been well described by Tomford et al. (18). We base our retrieval procedures on the guidelines described by the American Association of Tissue Banks 1987.

Live donors

After initial screening, all patients undergoing primary total hip replacement are considered for femoral head donation. The patients are counselled by an admission sister for serological testing.

The advent of more sensitive and diverse laboratory assays enables more thorough objective screening of donors. All patients consenting for bone donation are tested for HIV at the time of donation and after 90 days, hepatitis B, hepatitis C, VDRL, and treponema pallidum antibodies.

The femoral heads donated at the time of primary hip arthroplasty are then kept in quarantine for 6 months before repeat serology testing.

Cadaveric donors (multiorgan donors)

Specific written consent is obtained by informed consent from the legal next of kin before bone is harvested. Donors are screened by obtaining a full medical and social
history and then, only if this is complete, serology tests are undertaken.

Contamination of large allografts at retrieval is a significant problem. All bone allografts are secondarily sterilised with gamma radiation after processing to try to overcome this.

**Fresh osteochondral allografts**

The transplantation of living articular cartilage for the reconstruction of articular defects, requires a different approach. The standard screening procedures are undertaken as described previously.

The joint, usually the knee, is removed under sterile conditions en bloc without breaching the joint capsule. It is then stored in sterile Hartman's solution containing an appropriate antibiotic, eg cefuroxime and transported on wet ice. Transplantation is performed within 12-24 h of the donor's death.

**Bone processing**

Processing involves removing any attached soft tissue, cutting down the size of large specimens and milling the bone into bone chips. The final product is triple packed and labelled with a unique identification number. There is no pooling of bone or cross-contamination between the donors.

All the allograft bone is stored in temperature regulated and alarmed refrigerators at −70°C.

All but fresh osteochondral grafts are secondarily sterilised with a certified minimum dosage of 25 kGy of gamma radiation from a cobalt source. Transportation for irradiation or to the prospective recipient is carried out in dry ice. The unused grafts are therefore accepted back into the bone bank if not thawed out.

Five basic bone products are thus produced:

1. Intact femoral heads.
2. Morcellised bone in 50 g packets.
3. Cortical struts of 15-25 cm length.
4. Bulk allografts (eg hemipelvis, proximal femur, distal femur, proximal tibia).
5. Patellar and Achilles tendons.

**Documentation**

A unique number is allocated to each donor. This number is marked on all the bone products derived from that donor and is matched against returning information from each recipient. This system allows for easy tracing of bone transplants from any donor; however, it is dependent upon the return of the 'implantation information report'.

**Data collection**

Our database of donors and bone products have provided data concerning the source, amount and type of the bone processed. These data also include the serological and microbiological results and certified minimum/maximum doses of irradiation received by each packet.

Audit of the results of bone allograft transplantation is dependent upon return of the 'implantation information report' by the orthopaedic surgeon.

**Results**

**Bone donation and processing**

In all, 374 femoral heads have been donated by patients undergoing primary hip replacement, of these, 73 (19.5%) had to be discarded because a second HIV test was not undertaken.

Positive initial bacterial cultures were found in 8 (2.1%), faulty packaging in three and one donor had serological evidence of hepatitis C infection. These specimens had to be discarded. Since 1991, every live male donor has been double tested for HIV antibodies. There have been no positive results to date. Females over the age of 70 years only require a single HIV test. The femoral heads are provided as whole femoral heads or morcellised into bone chips.

There were 55 cadaveric donors and three of these also donated fresh osteochondral grafts. This bone was processed into the following end products:

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morcellised bone (50 g packs)</td>
<td>80</td>
</tr>
<tr>
<td>Strut grafts</td>
<td>45</td>
</tr>
<tr>
<td>Bulk grafts</td>
<td>15</td>
</tr>
<tr>
<td>Osteochondral grafts</td>
<td>03</td>
</tr>
</tbody>
</table>

**Bone implantation**

Most of the recipients were males (123) compared with 97 females. The age range varied from 17 to 85 years.

Of all the culture specimens taken at the time of bone donation and implantation, only six were found to be positive at the time of donation, while four were found to be positive at the time of use. One donor was found to be hepatitis C positive.

The organisms identified are listed in Table I. Implantation information forms were not returned in 37 (17%) cases.

From a retrospective review of 220 available case notes (340 units of bone), nine patients who had undergone revision arthroplasty developed signs of infection postoperatively. Of these, one went on to develop deep infection and the others settled with antibiotic treatment. The patient who developed a deep infection was an 86 year-old-male patient third time revision hip surgery with impaction bone grafting. He developed a deep infection and needed débridement. No further surgery was offered because of the general poor health of the patient.

The infective organism was *Staphylococcus epidermidus* and allograft specimens did not grow any organisms.
Table I. Reported infection of allograft bone 1989–1993

<table>
<thead>
<tr>
<th>Type of allograft</th>
<th>Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detected at use</td>
<td></td>
</tr>
<tr>
<td>HTB/93/0210*</td>
<td>Propionobacter</td>
</tr>
<tr>
<td>HTB/93/0124</td>
<td>Coag. neg. Staph. aureus</td>
</tr>
<tr>
<td>HTB/93/0617 + 0619</td>
<td>Aerobic micrococci</td>
</tr>
<tr>
<td>Femoral head</td>
<td>Coag. neg. Staph. aureus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Detected at donation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral head</td>
</tr>
<tr>
<td>Elbow graft*</td>
</tr>
<tr>
<td>HTB/93/0230</td>
</tr>
<tr>
<td>Femoral head</td>
</tr>
<tr>
<td>Femoral head</td>
</tr>
<tr>
<td>Femoral head</td>
</tr>
</tbody>
</table>

* Bulk allograft

Discussion

The demand for allograft bone shows a relentless increase. The demographic data (Fig. 1) for the recipients reflects a wide range of indications. The majority of recipients (85%) required allograft bone for revision hip and knee surgery. Spinal fusion and scoliosis surgery accounted for 15%.

Contamination and infection

A wound infection is diagnosed if there is erythema, discharge and positive culture swab. Deep sepsis is confirmed if aspiration reveals organisms.

The infection rate of 4.09% in this series compares with 3.6% reported by Pellicci et al. (17) and 5.5% by Callaghan et al. (3) for other large series of revision arthroplasties where allograft bone was not consistently used.

This audit of our tissue bank reveals results that match the high standards reported by others (1,4,6,7,10–12,17). The level of detected contamination of bone at implantation was 5.4% which compares with previous reports by Kavanagh et al. (14) (8.8%) and Tomford et al. (18) (6.9%). This is better than the 11% reported by Ivory and Thomas (10).

Most authors agree that some type of secondary sterilisation (1,2,5–7,10–12,15,17) is required to avoid unacceptable rates of contamination. Gamma irradiation is efficient but does have a deleterious effect on bone strength (8,9). The effect of radiation on osteoinduction is not known.

No significant complication which could be attributed solely to irradiation of bone was noticed in this series.

Of the femoral heads, 17% had to be discarded because of non-availability of the second blood test, incomplete consent forms or incomplete donor details. This can be improved and we are trying to address to this problem.

The storage of bone at –70°C, allows storage for up to 5 years; we tend not to have any excess, instead we are always struggling to meet the demand.

When judging the effect of allograft bone implantation, each procedure must be considered in context.

For adolescents undergoing scoliosis surgery, the major benefit is in avoiding the donor site morbidity associated with harvesting of autograft bone.

Of the 35 patients in this series who underwent spinal surgery, there were no reported infections and only one pseudarthrosis.

Revision arthroplasty surgery has increased dramatically over the years. Wear particles combined with loosening are intimately related to progressive lysis of bone. This may result in massive bone loss such that conventional methods of reconstruction prove inadequate. Allograft bone implantation allows for the reconstruction of these severely destroyed joints, where the alternative may be a Girdlestone’s pseudarthrosis with its associated instability and shortening.

Conclusions

The success of a tissue bank depends on the enthusiasm of the personnel involved; in identification of donors,
screening and packaging of grafts, and record keeping. It also demands full co-operation of the surgeons using the processed tissue. The running of the bank also needs medical supervision for exclusion of inappropriate donors and secretarial support for record keeping. In addition, a surgical team is required for the retrieval of large cadaver grafts.

We recommend:
1 Whenever a new bone bank is set up, its performance should be carefully audited at regular intervals to check the quality of tissue provided.
2 The prospective collection of donor and recipient data is essential.
3 Secondary sterilisation of allograft bone can reduce the contamination rate.
4 Wastage of the allograft tissue should be avoided by careful donor selection and meticulous processing techniques.

References

Received 3 November 1997