REPLACEMENT OF THE LUMBAR VERTEBRAE OF SHEEP
WITH CERAMIC PROSTHESSES

TAKAO YAMAMURO, JITSUHIKO SHIKATA, HIDEO OKUMURA, TOSHIKAKITSUGI,
YOSHIKAKAKUTANI, TOORUMATSUI, TADASHIKOKUBO

From the Faculty of Medicine, Kyoto University

We prepared a prosthesis for the replacement of the lumbar vertebrae of sheep, using apatite- and wollastonite-containing glass-ceramic. The material is stronger than human cortical bone and has the special feature of chemical bonding to bone. Ten sheep underwent replacement of L3 and L4 vertebrae, without bone grafting. The animals were killed at intervals from three months to 27 months after operation, and the interface between the prosthesis and bone was examined radiologically, histologically and crystallographically. Bone bonding with the prosthesis had occurred in half the implants. It took at least one year for bonding to be complete, but an apatite layer on the surface of the prosthesis was observed as early as three months after the operation, suggesting the possibility of much earlier bone bonding if more rigid fixation of the prosthesis had been provided.

In cases of primary or metastatic tumours of the vertebral body, burst fractures, or abnormal ossification of spinal ligaments with subsequent paralysis, it is sometimes necessary to perform total or subtotal resection of two or more vertebrae. Such large bone defects are difficult to fill using only autologous bone. If substitution is required only for a short time, alumina ceramic or metal prostheses can be used in combination with bone cement. However, in time there is a risk of displacement of such prostheses due to loosening.

We made a prosthesis for the replacement of the lumbar vertebrae of sheep, using apatite- and wollastonite-containing glass-ceramic (called A-W·GC hereafter) which was stronger than human cortical bone and was capable of bonding chemically with adjacent living bone. The results of its use are reported here.

Table I. Chemical composition of A-W glass-ceramic

<table>
<thead>
<tr>
<th>Weight (per cent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MgO</td>
</tr>
<tr>
<td>CaO</td>
</tr>
<tr>
<td>SiO2</td>
</tr>
<tr>
<td>P2O5</td>
</tr>
<tr>
<td>CaF2</td>
</tr>
</tbody>
</table>

Table II. Mechanical properties of A-W glass-ceramic

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bending strength</td>
<td>200 to 220 MPa</td>
</tr>
<tr>
<td>Compressive strength</td>
<td>1000 MPa</td>
</tr>
<tr>
<td>Elastic modulus</td>
<td>120 GPa</td>
</tr>
<tr>
<td>Vickers hardness</td>
<td>680 MPa</td>
</tr>
<tr>
<td>Density</td>
<td>3.08 × 10³ kg/m³</td>
</tr>
<tr>
<td>Fracture toughness</td>
<td>2.0 MPa/m²/²</td>
</tr>
</tbody>
</table>

THE PROSTHESIS

A-W·GC was developed in 1982 at Kyoto University. It is a hybrid material consisting of three phases of apatite, wollastonite and glass with the composition shown in Table I (Kokubo et al 1982, 1986). Its compressive strength, bending strength and elastic modulus are higher than those of human cortical bone (Table II). In fatigue...
and ageing tests, virtually no deterioration occurred over very long periods (Kitsugi et al 1986, 1987; Kokubo et al 1987).

The results of biocompatibility tests using cultured cells (Kotoura and Yamamuro 1987) and observations of tissue reactions in vivo have indicated excellent biocompatibility (Nakamura et al 1985). When an A-W·GC block was implanted into the tibia of a rabbit (Nakamura et al 1985), or fixed on the surface of the cortex of a rabbit tibia (Yoshii et al 1988), in both cases it became firmly bonded with bone by eight weeks. Nakamura et al (1985) reported that the strength of its bonding was so great that the bone was frequently broken by the detaching test.

Using A-W·GC with these characteristics, we prepared columns 10 mm and 12 mm in diameter and 15 mm and 30 mm in length, respectively.

**EXPERIMENTAL ANIMALS AND SURGICAL TECHNIQUE**

We used 10 castrated male sheep, three to five years old and weighing from 40 to 60 kg at the time of operation. Under general anaesthesia, with halothane by intratracheal intubation, the animals were operated on in the lateral position. A longitudinal skin incision was made over the left posterolateral lumbar region and the left side of the lumbar spine was approached retroperitoneally by exposing the transverse processes of the third and fourth lumbar vertebrae and resecting them. The intervertebral disc between L3 and L4 was removed with about half the vertebral bodies above and below. The bone defect thus produced was then filled with a vertebral prosthesis.

In the first two cases the bone defect was small and a vertebral prosthesis 15 mm in length was used without any fixation. In the other eight cases, bone defects 30 mm long were produced and vertebral prostheses of that length were inserted. In these cases the prosthesis was securely fixed, with Zielke's instrumentation in seven cases and with bone cement in one case (Table III, Figs 1 and 2).

The animals were immobilised for two days postoperatively with a specially made body brace to protect against violent movements after wakening from general anaesthesia.

**OBSERVATIONS**

One animal died due to anaesthesia complications shortly after the operation. The other nine animals were killed at various times from three months to 27 months postoperatively. Each organ was examined macroscopically and the lumbar spine was radiographed. After removing the Zielke’s instrumentation (or the bone cement), the upper and lower lumbar vertebrae, with the prosthesis between, were fixed in 10% phosphate-buffered formalin for 90 days, dehydrated in a 70%, 80%, 90% and 100% graded series of ethanol over a seven-day period and then embedded in polyester resin. Sections, 2 mm thick, were made using a cutting machine designed for hard tissue and equipped with a 200 µm thick diamond tip (Exakt BS-3000, Exakt Co, West Germany). Some specimens, after surface grinding, were gold coated, at a thickness of about 200Å with Multi Coater (VX-10A, Eiko Engineering Co, Tokyo), and the interface between the prosthesis and the bone was examined for silicon, calcium, phosphorus and magnesium content using a scanning electron microscope (SEM, Hitachi X-650, Tokyo) and an energy dispersive X-ray microanalyzer (EPMA, Horiba EMAX-2200, Kyoto). A segment includ-
At the time of death, the hearts, lungs, livers and kidneys all appeared normal.

In the two cases in which 15 mm prostheses were implanted (killed at 24 months and 27 months respectively) bone bonding was observed radiologically between L3 and L4 vertebrae and no radiolucent zone was seen in the areas surrounding the prostheses (Fig. 3). The prostheses were bonded directly to the trabeculae of the cancellous bone and even at sites in which trabeculae were lacking, we observed irregularly shaped new bone, about 12 μm in thickness, covering the prosthetic surfaces (Figs 4 and 5).

In seven of the eight cases which received a 30 mm implant, some displacement of the prosthesis had occurred despite fixation with Zielke’s instrumentation or bone cement (see Fig. 6). However, there was no case of dislocation of the prosthesis. When the interfaces between the prosthesis and the vertebrae were examined by radiography and CMR, direct bonding to both vertebrae was observed in four cases, bonding only to the L3 vertebra in one case, and there was no bonding at all in four cases (see Table III and Fig. 7). The morphological findings at the sites of bonding were like those shown in Figures 4 and 5.

SEM-EPMA and XDF analyses of the interfaces whether bonded or not, always showed a Ca·P-rich layer, 60 to 75 μm thick, on the surface of the prosthesis. This layer was confirmed to be apatite by crystallographic analysis (see Figs 8 and 9).

DISCUSSION

Autografts, allografts, xenografts and synthesised materials have all been used to fill large bone defects in the vertebrae, but there are problems involved with each material. With autologous bone, the donor site is the problem when the bone defect is large. Allografts suffer from decreasing mechanical strength during the process of their absorption and replacement, and may collapse causing subsequent paralysis. Moreover, the use of allografts is still illegal in certain countries, including Japan. Xenografts continue to be antigenic even after chemical treatment. If bone is sintered at high temperatures its antigenicity disappears and it becomes like synthesised hydroxyapatite, but its mechanical strength is inadequate for use as a vertebral prosthesis (Ueno et al 1985).

Synthetic materials have been tried for many years, and several studies on the use of polymethylmethacrylate (PMMA) have been reported (Scoville et al 1967; Cross, White and White 1971; Dunn 1977; Harrington 1981; Siegal, Tiqva and Siegal 1985; McAfee et al 1986). However, PMMA cannot endure long-term use as a vertebral prosthesis because its mechanical strength is insufficient and it is not fully biocompatible as compared to titanium alloy or the bioceramics. Ono et al 1972 and Ono and Tada 1975 prepared a metal prosthesis to...
replace a vertebral body and fixed it in place with bone cement. Such a prosthesis certainly provides sufficient mechanical strength, but loosening at the cement/bone interface may occur in the long-term. An alumina ceramic prosthesis, similar in design to the metallic implant, has recently been used extensively in clinical practice (Fuji et al 1981; Taguchi et al 1981; Tsuji, Tatezaki and Itoh 1981), but, as cement is required for its fixation to bone, it may prove unsuitable for long-term use for the reasons as mentioned above. Presently, the use of such prostheses is restricted to the short-term replacement for malignant metastases in the vertebrae.

However, in our experiments, in which implantation periods ranged from three months to 27 months, bonding between the prosthesis and bone was seen in only half the cases and then it took about a year to become complete. Nevertheless, the surfaces of unbounded prostheses were all covered by an apatite layer about 60 μm thick. This layer was slightly thinner than that seen in the bonded zones but crystallographically they

More recently, Waisbrod (1988) used prostheses made from cancellous metal with a pore size of 800 to 1500 μm, in the treatment of metastatic tumours of the vertebrae. New bone grows into the pores and fixes the prosthesis. However, the area of metal surface exposed to the body fluids is large and elution of metal ions may create a problem in the long-term.

A-W·GC is a bioactive ceramic significantly stronger than synthesised dense hydroxyapatite or human cortical bone. Its mechanical properties, shown in Table II, are considered to be adequate for use as a vertebral prosthesis in man. From the experiments on rabbit tibiae, the bonding strength of A-W·GC with bone, eight weeks after implantation, was shown to be equivalent to that of dense hydroxyapatite 25 weeks after implantation (Nakamura et al 1985; Kitsugi et al 1987). Moreover, the bonding strength of A-W·GC with bone after 25 weeks of implantation was so great that the bone frequently broke, before the material could be detached. The material was therefore considered suitable for a vertebral prosthesis both on mechanical and on biological grounds.
were identical. These facts suggest that failure of bonding may be due to a failure of fixation rather than to any defect of the prosthetic surface. The animals sometimes moved violently on wakening from general anaesthesia and they were difficult to control even with body braces. The methods of internal fixation which we used may have failed to prevent movement at the bone/implant interface.

This explanation gains some support from our limited experience with A-W-GC implants in man (Yamamuro et al. 1984) in which we have observed early and complete bonding in cases where good fixation was achieved.

Although none of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article, benefits have been or will be received but are directed solely to a research fund, foundation, educational institution, or other non-profit institution with which one or more of the authors is associated.

REFERENCES


