“Physiological” orbital implant

A. C. B. MOLTENI, J. H. J. VAN RENSBERG, B. VAN ROOYEN, AND E. ANCKER

From the Department of Ophthalmology, University of Stellenbosch, and Karl Bremer Hospital, South Africa

It is probably true to say that to-day most ophthalmologists insert an acrylic implant into the muscle cone after enucleation, to support and impart movement to an artificial eye. The requirements for successful implantation of an “Allen” or “Iowa” type acrylic implant are complete asepsis, anatomically correct placement within a reasonably intact muscle cone, and a reasonably thick layer of tissue burying the implant. Furthermore, an individually moulded prosthesis is usually needed to avoid late pressure necrosis of tissue over the implant (Reed, 1964). When these requirements are fulfilled, extrusion of implants is uncommon; but some implants are gradually displaced from the muscle cone or extruded at a steady, albeit slow, rate. This late extrusion is particularly likely to occur in chronic alcoholics or in patients who develop some debilitating disease.

Synthetic polyvinyl sponge has been used as an implant (Pearlman, 1953). This material becomes organized by host tissue and therefore does not migrate out of the muscle cone, but it is susceptible to infection at the time of insertion and the overlying tissues do sometimes break down. Should either of these accidents occur, it is usually impossible to eradicate sepsis in the presence of an indestructible porous foreign body and the implant must be removed.

This communication reports a trial of Kiel Bone as a buried orbital implant. Kiel Bone,* developed by Maatz (1964), is antigen-free cancellous calf bone and is ordinarily used for bone grafting in place of boiled cadaver or autogenous bone. The use of this material was prompted by the example of Guist’s carbonized cancellous bone spheres, which were mentioned by Spaeth (1941) as the best material for orbital implants; Spaeth’s list included drilled ivory spheres, decalcified bone, formalized cartilage, and gold Mule’s spheres as reasonably satisfactory, while strongly condemning implants of glass, fat, fascia lata, celluloid, sponge, peat moss, agar-agar, Vaseline, rubber, wire, silk, catgut, paraffin wax, and whole rabbit eyes.

The main disadvantage of Guist spheres was their fragile nature and liability to infection. Kiel Bone, however, is strong, is supplied sterile, and absorbs any of the currently available antibiotic solutions, after which it is easily cut with heavy scissors. It thus seemed probable that it could be used in relatively unfavourable cases and that once organized by host tissue it would form a robust and permanent implant. Unlike synthetic materials any contaminated or exposed portions could be broken down and removed by the host tissues.

Selection of cases

Kiel Bone implants were inserted into every case coming to enucleation with the exception of *grossly* septic cases and cases of advanced retinoblastoma. Of fifty patients, 38 were men and twelve were women. Their ages ranged from 2 to 78 years.

The indication for enucleation was recent trauma to the eye (24 cases), absolute glaucoma (12 cases), irritable phthisical eyes (12 cases), and retinoblastoma (2 cases).

Of the 24 cases of trauma, 21 were due to assault, and most of these patients had septic lacerations and fractures of the facial bones in addition to being in a poor state of general health as a result of chronic alcoholism.

Surgical technique

PREPARATION FOR OPERATION

Most patients were operated on as outpatients, either immediately or after a few days of local and systemic antibiotic therapy, together with parenteral vitamins B, C, and K where indicated.

ANAESTHESIA

General anaesthesia was used for children but most adults were operated on under neuralept analgesia (induced by Inapsin and Fentanyl intravenously) supplemented by a retrobulbar injection of 5 ml. 2 per cent. lignocaine.

PREPARATION OF BED FOR IMPLANT

After conjunctiva and Tenon's capsule were separated from the limbus, each rectus muscle was caught on a squint hook, and after a 3·0 silk stay suture had been sewn through the tendon, the muscle was detached from the globe. The optic nerve was crushed with a small artery forceps and cut. The eyeball prolapsed and its remaining attachments were divided. The four rectus muscles were pulled forwards and held by clipping the stay sutures to the drapes in order to display the depths of Tenon's space. Complete haemostasis was *deliberately not* obtained (Fig. 1).

FIG. 1 Socket prepared for insertion of implant. The rectus muscles are drawn forwards to facilitate the placing of the rough implant far back in Tenon's space

PREPARATION OF IMPLANT

A sterile cube of medium callus-promoting grade Kiel Bone was removed from its plastic envelope and immersed in a concentrated solution of Cephaloridine and Gentamycin as prepared for intramuscular injection. After wetting, the block was cut with heavy scissors to a hemisphere of the right size and grooves were scratched across the flat face to accommodate the rectus muscles (Fig. 2).

FIG. 2 *Implant cut to fit and grooved to accommodate rectus muscles*

PLACING OF IMPLANT

The shaped piece of Kiel Bone was placed well back in Tenons' space (flat face forward) and the tissues were pulled forwards around the implant to allow it to be buried without tension in the overlying tissues.

All four rectus muscles were manoeuvred into their corresponding grooves and united by a single buried suture of 4·0 silk after which the stay sutures were removed. Tenon's capsule was closed with a purse string suture of 3·0 silk, the socket plugged with Soframycin Tulle Gras, and the lids covered with a pad held in position by a crêpe bandage.

POSTOPERATIVE MANAGEMENT

Most patients were discharged from hospital a few hours after operation, when they received an intramuscular injection of long-acting penicillin, together with any vitamins deemed necessary.

Patients were given simple analgesics (aspirin compound or Paracetamol tablets) to take home and if infection was feared Tetracycline capsules (500 m.g. four times a day) were given for 5 days.

The plug was removed at the first follow-up visit after 3 to 5 days and the patients were given chloramphenicol ointment to insert. If patient co-operation was poor, local antibiotics were supplemented by long-acting penicillin given intramuscularly at weekly intervals until the sockets were soundly healed.

Artificial eyes were fitted and worn as soon as possible, generally from 4 to 6 weeks after enucleation.

Complications

EXPOSURE OF IMPLANT

Exposure occurred in six cases because of poor surgical technique, shattered orbital tissues, very poor general health, or radiotherapy.

H

In one case in which the patient had not come for follow-up the grossly infected implant was removed at another hospital. In the second case, which had received orbital radiotherapy, the tissues covering the implant broke down a year after insertion to reveal the central portion, which had not been organized by host tissue. The remaining four cases developed exposed areas of implant shortly after insertion. All five of these latter cases were treated by drilling away the exposed bone until it lay well below the surrounding tissues and brisk oozing of blood was encountered.

The resulting cavities all granulated and became epithelialized within 4 weeks.

POSSIBLE LOW-GRADE INFECTION

Four cases, two of which had received retrobulbar alcohol injections shortly before enucleation, showed prolonged oedema around the implants, with a serous discharge from the sockets. All resolved slowly but completely on treatment with tetracycline by mouth.

SOCKET GRANULOMAS

Pedunculated granulomas caused by infected exposed silk sutures developed in three cases and were cured by removing the offending suture and granuloma together using topical anaesthesia.

CONTRACTED SOCKETS

These developed in two cases; one followed radiotherapy and the other developed in a feeble-minded woman who resisted all efforts to teach her socket hygiene and refused to wear a prosthesis.

Results

Of fifty operations with 6 months to 2½ years' follow-up (average follow-up 11·2 months) 49 implants were satisfactorily incorporated into host tissue (in five cases after drilling away exposed portions) and one implant was removed.

The movements of these implants were full and free in 47 cases; the two cases in which movements were somewhat restricted followed radiation to the orbits for retinoblastoma. Standard reform type acrylic artificial eyes were fitted initially in all cases and gave very acceptable cosmetic results*.

Long-term behaviour

CLINICAL APPEARANCE

The host tissue response to implants was uniform—the initial oedema of tissues covering the implant gradually subsided, until by the eighth week a thick layer of non-inflamed connective tissue and conjunctiva remained. This layer very slowly became thinner until after approximately 1 year no further change occurred. The final state was one in which the overlying tissues closely followed the surface of the implant, being retracted into hollows and tightly stretched over protruding portions. In two cases single sharp spicules of Kiel Bone eroded through the conjunctiva 9 and 15 months, respectively, after insertion. Both patients were given chloramphenicol ointment to insert twice daily and continued wearing their prostheses. When seen again 2 weeks later the *spicules had disappeared* and the defects were healed (Fig. 3, opposite).

*Since this paper was submitted for publication, our series has risen to 105 cases with nine early exposures of the implant. Six of these implants were successfully retained while three had to be removed. So far (up to 3½ years) no late complications have been observed.

FIG. 3 *Socket after 2½ years, showing tissues closely applied to surface of implant*

RADIOLOGICAL APPEARANCE

Kiel Bone implanted into orbits showed up clearly on *x* ray and the first fifteen cases were *x*-rayed immediately after insertion and at 6-monthly intervals to assess whether any change in density was occurring. However, as no changes have been observed for up to 2½ years, subsequent patients were *x*-rayed once only to provide a baseline for future long-term studies (Fig. 4).

FIG. 4 *Radiological appearance of implant 2½ years after insertion*

HISTOLOGICAL APPEARANCE

Three specimens are available, two drill biopsies obtained 3 and 18 months respectively after insertion of the implants and an entire implant with surrounding tissues obtained at autopsy 7 months after insertion.

All three specimens showed a structure of amorphous basophilic Kiel Bone surrounded by fibrous tissue. This tissue, which showed numerous blood vessels and a moderate

infiltrate of chronic inflammatory cells after 3 months, had become relatively avascular and completely devoid of inflammatory cells by 18 months. There were no signs of decalcification or erosion of the actual Kiel Bone matrix in any of the specimens.

The *post mortem* specimen is of particular interest in that a portion of the implant was exposed and had been drilled away to allow conjunctiva to grow over the defect. The histological appearance of this area was similar to the adjacent unexposed portion, except that the layer of fibrous tissue between implant and epithelium was much thinner (Fig. 5).

FIG. 5 *Implant and surrounding tissue after 7 months. Photomicrograph. Haematoxylin and eosin. Arrow indicates area where exposed Kiel Bone had been drilled away to facilitate healing*

Discussion

Kiel Bone has fulfilled expectations and proved to be a very satisfactory implant material capable of being inserted into heavily traumatized and badly contaminated orbits where an acrylic or polyvinyl sponge implant would be contraindicated.

The Kiel Bone shares with polyvinyl sponge freedom from displacement out of the muscle cone; but in addition, when soaked in antibiotics, it can be inserted in the presence of overt (but not gross) sepsis.

The "self-sealing" behaviour of tissues after drilling away exposed portions is another great advantage. This behaviour, which was reported for Guist's bone spheres by Allen (1930) and McCoy (1932), is quite unlike that of exposed polyvinyl sponge or acrylic. We feel that it must be due to the fact that the Kiel Bone is attacked and removed by the body's defences where exposed and mildly infected, a process which is impossible with the synthetic plastics.

This behaviour, and the absence of late exposure, although all the patients continued to wear stock prostheses which made full contact only with the upper areas of the implant, suggests that late extrusion is highly unlikely.

The only question which remains is that of the ultimate fate of these implants; it is possible that, although not extruded, they may simply atrophy and shrink to nothing after 5 or 10 years. Indirect evidence on this question is available in that a Kiel Bone implant is essentially a mass of host scar tissue stiffened by a heavily calcified matrix and should therefore behave as an old calcified scar. Old scars of any sort frequently become calcified and this process may progress to heterotopic bone formation, both of which states tend to persist for life (Walter and Israel, 1965). These implants should thus last for very many years, if not for the patient's lifetime. For these reasons it is felt that Kiel Bone is a better

more versatile implant material than acrylic or polyvinyl sponge and that it ought to be used in preference to these materials.

Summary

- (1) The results of using antigen-free cancellous bone as an orbital implant in fifty cases of enucleation are reported.
- (2) The tissue response and the radiological and histological findings are described and discussed in relation to the long-term behaviour of these implants.

The authors would like to thank Dr. A. B. W. Ferreira for his help and encouragement, Prof. C. J. B. Muller for radiography of cases, Mr. J. Botha, principal technologist, for histological preparations, and Mr. L. Kopier of the Department of Medical Illustration for the photographs. We should also like to thank the Medical Superintendants of Karl Bremer Hospital for permission to publish these cases.

References

- ALLEN, T. D. (1930) *Amer. J. Ophthalm.*, **13**, 226
MAATZ, R. (1964) *Langenbecks Arch. klin. Chir.*, **308**, 1028
MCCOY, L. L. (1932) *Amer. J. Ophthalm.*, **15**, 960
PEARLMAN, M. D. (1958) *Ibid.*, **36**, 1756
REED, H. (1964) In "Modern Ophthalmology", ed. A. Sorsby, vol. 4, p. 934. Butterworths, London
SPAETH, E. B. (1941) "The Principles and Practice of Ophthalmic Surgery", 2nd ed., pp. 126-128. Lea and Febiger, Philadelphia
WALTER, J. B., and ISRAEL, M. S. (1965) "General Pathology", 2nd ed., p. 875. Churchill, London