CHAPTER 39

BONE GRAFTS AND IMPLANTS IN SPINE SURGERY

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Recent advances in both fusion techniques and instrumentation have markedly facilitated the treatment of spinal disorders. Yet a significant number of patients exist who continue to have pseudarthroses. Despite the surgical advances the essentials of a successful spinal fusion still appear to be the effective application of sound bone grafting principles. These principles, along with the techniques, problems, and complications associated with bone grafting, are reviewed in this chapter.

The loss of bone in the spine often presents serious difficulties not seen in other areas. The most favorable replacement would still be a bone graft that fills the defect and becomes incorporated into the spine. However, the availability of appropriate bone to replace the loss is a significant problem. Alternatives to bone grafts, including a number of implants used to stabilize the spine, are also surveyed.

Bone grafts have often played the roles of scaffolds, bridges, spacers, fillers of defects, and replacements of bone lost. Immobilization of multiple motion segments is frequently necessary in the spine; great demands are made on bone grafts. In the lumbosacral spine, body weight and muscular forces impart loads equal to three or four times body weight. It is not surprising that the highest rate of bone graft failure is seen in the lumbosacral spine. Hence, the following is a discussion of technical problems, biomechanical and physiologic characteristics of bone grafts, and implants.

THE AUTOGRaFT

Autograft, or bone graft transplanted from one site to another in the same individual, is considered to be the most biologically suitable. Its advantages include:

1. Has superior osteogenic capacity
   a. Contributes cells capable of immediate bone formation
   b. Allows for bone induction by recipient bed where nonosseous
tissue is influenced to change its cellular function and become osteogenic.

2. Lack of histocompatibility differences or immunologic problems
3. Ease of incorporation
4. No disease transmission

The disadvantages include:
1. Additional incision or wider exposure, prolonged operative time, and increased blood loss
2. Increased postoperative morbidity
3. Sacrifice of normal structure and weakening of donor bone
4. Risks of significant complications
5. Limitations in size, shape, quantity, and quality

For optimal results harvest autogenous cancellous bone in the following manner.

1. In thin strips
   a. Not exceeding 5 mm in thickness
   b. To provide maximal exposure of superficial cells
   c. To allow rapid vascularization

2. Graft wrapped in a gauze soaked in patient’s blood
   a. To avoid exposure to high intensity lights
   b. Kept in temperature less than 42°C
   c. Not stored in saline or antibiotic solution
   d. Without the use of chemical sterilization

3. Transfer the graft to the recipient bed as soon as possible to
   a. Avoid exposure to air for more than 30 minutes
   b. Protect the viability of the surface cells

4. Place the graft
   a. In well-vascularized bone bed
   b. In well-decorticated bone surface (cancellous site is superior)
   c. With healthy soft tissue coverage
5. Minimize surgical trauma because, for example, high speed burring and inadequate irrigation retard healing

6. Position the cancellous surface
   a. On opposing cancellous surface
   b. On surrounding soft tissue with good blood supply
   c. So that total mass of graft is not too thick to prevent nutrient diffusion from recipient bed

7. Always avoid
   a. Dead space
   b. Hematoma
   c. Interposition of necrotic tissue

8. To minimize risk, be aware of
   a. Anatomy
   b. Potential complications

The iliac crest is the most versatile bone graft reserve. It is relatively subcutaneous and easy to harvest in prone, supine, lateral, or other positions. It is expendable, and it has a large reserve of cortical and cancellous bone. In addition, it allows carpentering of different shapes and sizes.

Anterior Iliac Crest Grafts

Anterior iliac crest bone grafts are used for anterior interbody fusion of the cervical, thoracic, or lumbosacral spine. The subcutaneous anterior superior iliac spine and iliac crest are easily palpable. The iliac tubercle is the widest portion where a large quantity of corticocancellous bone is found. (See Fig. 39-8.)

A skin incision is made parallel to or in line with the iliac crest. It is advantageous to center the incision over the iliac tubercle. The incision is carried down to the bone of the crest, and the muscles are elevated subperiosteally to expose the wing of the ilium.

The tensor fascia latae, gluteus medius, and gluteus minimus originate from the lateral aspect of the ilium. They are innervated by the superior gluteal nerve. The abdominal muscles are also attached to the iliac crest and are segmentally inner-
vated. The incision over the crest is therefore "internervous" and safe.

An appropriate osteotome or chisel may be used to outline a cortical window in the lateral iliac surface from which to procure the bone graft. Longitudinal parallel cuts may be made (Fig. 39-1). Strips of cancellous bone may be removed with a curved gauge. Care must be taken not to violate the inner table of the iliac wing where hernia is a significant potential complication.

Bone graft may be obtained from the inner table of the iliac wing. However, there are risks of peritoneal perforation and significant bleeding with formation of hematoma in the retroperitoneal space.

It is important not to carry the incision to or anterior to the anterior superior iliac spine. Injury to the lateral femoral cutaneous nerve or the inguinal ligament must be avoided. Detachment of the inguinal ligament may result in inguinal hernia. If bicortical bone is taken too close to the anterior superior iliac spine, fracture may occur. (See Fig. 39-6.) Avulsion of the anterior superior iliac spine may occur by the action of the attached muscles, such as the tensor fascia lata or sartorius.

Bone may be removed in the form of block, dowel, strips, and by way of cortical window or "trap door" (Figs. 39-1 to 39-4). The iliac crest contour can be preserved by removing the bone deep to the crest, or by temporarily detaching and repositioning it later (Fig. 39-5). The anterior superior iliac spine should be left intact to maintain normal appearance. The region of the iliac spine should not be weakened by removing bone adjacent to it. Fracture and displacement of the inguinal ligament may result (Fig. 39-6).

The wound should be closed properly. The muscles and fascia must be sutured to their original anatomic positions and the defects closed; an effective drain should be used.

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Fig. 39-1  Corticocancellous bone graft is obtained from lateral iliac surface using longitudinal parallel cuts with an osteotome or chisel.
Fig. 39-2  Horseshoe-shaped corticocancellous bone graft is obtained from iliac crest using osteotomes positioned parallel to each other.

Fig. 39-3  Dowel-cutting instrument is used to obtain iliac graft with two tooled cancellous surfaces and cortical faces on three sides for anterior spinal interbody fusion.

Fig. 39-4  Cortical "trap door" is used to gain access to iliac cancellous bone.
Temporary detachment of the iliac crest

The iliac contour is preserved intact

The defect is filled to avoid hernia (Bone cement may be used)

Fig. 39-5 Large iliac graft is obtained with preservation of the iliac contour.

Anterior superior iliac spine
Inguinal ligament

Fig. 39-6 Illustration of attachment of inguinal ligament to anterior superior iliac spine. Detachment of inguinal ligament may lead to inguinal hernia. Injury to lateral femoral cutaneous nerve should also be avoided.
Posterior Iliac Crest Grafts

The posterior iliac crest provides a large quantity of cortical cancellous bone graft. The posterior superior iliac crest is palpable under the skin dimple in the superior medial aspect of the gluteal region. The iliac crest curves cephalad and laterally from the posterior superior iliac spine.

An oblique, curved or vertical incision may be made over the posterior iliac crest or in line with it. The cluneal nerves cross the iliac crest 7 to 12 cm anterolateral to the posterior superior iliac spine (see discussion under Complications) and must be protected (see Fig. 39-13).

A midline spine incision may be extended distally and the posterior iliac crest approached laterally under the skin and subcutaneous fat. This avoids the use of a second skin incision.

The incision is carried down to the bone of the crest, and the muscles are elevated subperiosteally from the posterior lateral surface of the ilium. This approach does not denervate the muscles. The gluteus maximus, medius, and minimus originate from the lateral surface of the ilium. The superior gluteal nerve innervates the gluteus medius and minimus, and the inferior gluteal nerve innervates the gluteus maximus. The paraspinous musculature innervated segmentally originates from the iliac crest.

It is very important to remember the following rules.

1. Stay on bone and work subperiosteally.
2. Avoid the sciatic notch and protect the sciatic nerve.
3. Protect the superior gluteal vessels (see discussion under Complications) and protect the pelvic stability.
4. Avoid the sacroiliac joint.
5. Protect the posterior sacroiliac ligaments.

The removal of bone in the vicinity of the sciatic notch can weaken the thick bone that forms the notch. This can produce instability of the pelvis. It is important to stay cephalad to the sciatic notch and remove bone only from the false pelvis. For a landmark, an imaginary line dropped anteriorly from the posterior superior iliac spine with the patient in the prone position can be used as the caudal limit of bone removal (see Fig. 39-15, A and B). Care must be taken not to enter the sacroiliac joint, which may become a source of persistent pain and instability when injured.

A sharp surgical instrument (that is, an osteotome or tip of Taylor retractor) may injure the sciatic nerve deep to the sciatic notch. Laceration of the superior gluteal vessels is a significant danger in this region. The vessels leave the pelvis via the sciatic notch. A divided vessel can easily retract into the pelvis and presents a very alarming complication (see discussion under Complications) (see Fig. 39-14).

Nutrient vessels supplying the ilium found in the mid portion of the anterior gluteal line may present troublesome bleeding and should be controlled with Gelfoam, Surgicel, bone wax, or electrocoagulation.

A relatively painless bone graft donor site for lumbar spine fusion is possible by applying the following technique. A separate incision over the iliac crest is not made through the skin. The fascia through the wound of the lumbar surgery is grasped with Kochers clamps and pulled medially. The subcutaneous tissue is carefully elevated off the fascia laterally and caudally until the fascia immediately above the posterior iliac crest and posterior superior iliac spine is reached. A Taylor retractor is placed in the subcutaneous tissue lateral to the crest over the ilium posteriorly. The periosteum is not dissected from the ilium except from the superior-most crest. The fascia is incised over the crest, and an elevator is used to scrape the superior crest free of periost-
Fig. 39-7 A gouge is used to remove posterior "roof" of ilium and the cancellous bone between cortical layers.

Fig. 39-8 Cancellous bone is removed from iliac tubercle, anterior or posterior iliac spine region through small cortical opening.

tem to bare bone. Gouges are used to remove the "roof" of the ilium and the cancellous bone between the cortical layers, leaving the cortices intact laterally and medially with their soft tissue attachments (Fig. 39-7). This technique minimizes postoperative donor site pain and prevents uncomfortable scar tissue from forming over the ilium, as when the lateral cortices are removed.

When limited quantity of cancellous bone is required, the following methods may be advantageous:

Currettage allows harvest of cancellous graft with least morbidity through a small round cortical window using a sharp curette as shown in Fig. 39-8. Cancellous bone is most abundant in the posterior aspect of the iliac crest, followed by the iliac tubercle and anterior superior iliac spine areas.

A "trap door" cut in the anterior or posterior outer table of the ilium and hinged on muscles can be opened to allow access to cancellous bone. The trap door is closed at the end. Postoperative pain appears to be less with this technique. Cosmetic deformity is minimal (see Fig. 39-4).

Wolfe and Kawamoto\textsuperscript{185} reported a technique of obtaining full thickness bone graft from the anterior ilium. Incision is made through the iliac crest. The outer ridges of the iliac crest are split obliquely with the muscular and periosteal attachments remaining. All the iliac bone be-
I. Wolfe and Kawamoto's technique of obtaining full thickness bone graft from the anterior ilium. A sharp osteotome is used to make appropriate cuts shown above and in Fig. 39-10.

Fig. 39-9 Wolfe and Kawamoto's technique of obtaining full thickness bone graft from the anterior ilium. A sharp osteotome is used to make appropriate cuts shown above and in Fig. 39-10.

Fig. 39-10 The ridges of the iliac crest are split obliquely with the osteotome. The muscular and periosteal attachments should remain.

Fig. 39-11 A large full-thickness bone graft can be removed as shown, using Wolfe and Kawamoto's method.
neath this can then be removed. The edges of the crest may be reapproximated, thus minimizing cosmetic deformity, hernia, hematoma, and postoperative morbidity (Figs. 39-9 to 39-12).

COMPLICATIONS

Complications involving the iliac bone graft donor site are not uncommon. Although some of these complications may not be serious, they add to the patient’s discomfort and prolong the convalescence. The complications that are due to graft removal from the ilium include:

1. Major blood loss
2. Hematoma
3. Nerve injury (neuroma formation)
4. Severe pain (chronic pain)
5. Hernia
6. Cosmetic deformity
7. Fracture
8. Sacroiliac joint injury
9. Pelvic instability
10. Hip subluxation
11. Gait disturbance
12. Peritoneal injury
13. Ureteral injury
14. Heterotopic bone formation
15. Infection

Cockin reviewed 118 cases of iliac crest bone graft procedures and found major complications in 3.4% and minor complaints in 6%. There were two cases of meralgia paresthetica, one of hernia, and one of hip subluxation after extensive removal of the iliac crest. The minor complaints included wound pain, hypersensitivity, and buttock anesthesia.

Nerve Injuries

Possible nerve injuries include the following:

1. Lateral femoral cutaneous nerve
2. Iliohypogastric (lateral cutaneous branch) nerve
3. Superior cluneal nerve (cutaneous branches of dorsal rami L1, L2, L3)
4. Middle cluneal nerve (cutaneous branches of dorsal rami S1, S2, S3)
5. Sciatic nerve
6. Ilio-inguinal nerve
7. Femoral nerve
8. Superior gluteal nerve
9. Obturator nerve

Superior cluneal nerves are lateral branches of the posterior primary division of the upper three lumbar nerves that run posteriorly through the lumbosacral fascia at the lateral origin of sacrospinatus.
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Superior cluneal nerves
dorsal rami

Posterior superior iliac spine

Middle cluneal nerves
cutaneous branches
dorsal rami

Gluteus maximus

Iliohypogastric nerve
lateral cutaneous branch
Lateral cutaneous branch
of subcostal nerve (T12)

Fig. 39-13 Illustration of the nerves that may be injured during the procedure to remove bone graft from the iliac crest.

Vascular Injuries

Vascular injuries may include the superior gluteal artery (and vein), the deep circumflex iliac artery, the iliolumbar artery, and the fourth lumbar artery.

The superior gluteal artery is a branch of the internal iliac artery that curves around the rim of the sciatic notch as it leaves the pelvis. It may be injured when dissection is carried close to the sciatic notch. An osteotome or the sharp point of a Taylor retractor may enter the notch.
and pose similar danger to the artery. This complication can become alarming, since the divided vessel easily retracts into the pelvis (Fig. 39-14).

If the superior gluteal vessel is lacerated, it can be compressed locally and exposed for ligation or clipping. A finger may be used to apply direct pressure to the vessel against the bone. Kahn57 discussed the use of a Raney-modified Kerrison rongeur to remove the upper margin of the sciatic notch to expose the bleeding vessel. If the bleeding vessel is still not accessible, the patient may be positioned for a retroperitoneal or transperitoneal exposure of the vessel. Arterial occlusion by embolization or using a Fogerty catheter is another option.

Injury to the superior gluteal vessels can be prevented if the surgeon is well aware of the anatomy in this region. The bony origin of the gluteus maximus or the roughened area anterior to the posterior superior iliac spine is a good landmark and can be used as the caudal limit of bone removal (Fig. 39-15, A and B). An imaginary plumb line dropped from the posterior superior iliac spine with the patient in the prone position will pass through the bony rim of the sciatic notch. It is important to stay cephalad to this line.

Escalas and DeWald60 reported a case of combined traumatic superior gluteal arteriovenous fistula and ureteral injury complicating removal of bone graft from the posterior ilium. The tip of a Taylor retractor accidentally dislodged and penetrated into the sciatic notch to cause this unusual injury.

The deep circumflex iliac artery, the iliolumbar artery, or the fourth lumbar artery may cause troublesome bleeding when working on the inner table of the ilium. Occasionally, peritoneal perforation accompanies the arterial injury. The anatomic position of the arteries are illustrated in Figs. 39-16 and 39-17. It is very important to stay subperiosteally and carefully elevate the abdominal wall muscles off the crest and the iliacus muscles off the inner table of the ilium (Fig. 39-18).

A hernia through the iliac bone graft donor site may occur after the removal of full thickness bone from that site. It may appear as an iliac swelling, sometimes associated with pain or symptoms of bow-
Fig. 39-15 A, The bony origin of the gluteus maximus or the roughened area anterior to the posterior superior iliac crest is a good landmark and can be used as the caudal limit of bone removal. An imaginary plumb line dropped from the P.S.I.S. with the patient in the prone position will pass through the bony rim of the sciatic notch. The superior gluteal artery is adjacent to the bony rim. B, A large amount of bone graft can be removed safely if the surgeon stays cephalad to the P.S.I.S., the sciatic notch and the imaginary line joining them.

Fig. 39-16 Illustration of the anatomic positions of the arteries that may cause troublesome bleeding when working on the inner table of the ilium.
Fig. 39-17 The anatomic locations of the peritoneal wall and the vulnerable arteries are shown relative to the iliacus muscle and the inner wall of the ilium.

Fig. 39-18 It is very important to stay subperiosteally and carefully elevate the abdominal wall muscles off the crest and the iliacus muscle off the iliac wall before removing the bone from the inner table of the ilium.

Fig. 39-19 The large defect left in the iliac wall may be repaired and iliac contour restored using bone cement. Anchoring holes are made with a curette before the cement is applied.

Fig. 39-20 The iliac wing defect is filled with bone cement. Malleable blades are used to repair the iliac wall as shown.
el obstruction. Strangulated hernia and valvulae are very rare occurrences. Symptoms were reported to have occurred from 24 days to 15 years after the formation of the iliac defect.

Treatment requires the reduction of the hernia and repairing the defect by:

1. Using soft tissue advancement, imbrication, flaps, or fascial flaps
2. Using a prosthesis (tantalum or Marlex mesh)
3. Using methylmethacrylate cement to reconstruct the iliac wall (Figs. 39-19 to 39-21)
4. The Bosworth technique removing the remaining wings of the ilium on either side of the defect followed by layered soft tissue closure.

Pelvic Instability

Removal of a large quantity of bone graft from the posterior ilium may disrupt the mechanical keystone effect of the sacroiliac joint and the posterior sacroiliac ligament, causing instability. Lichtblau first reported such complications after a bone grafting procedure in which the posterior sacroiliac ligaments were postulated to be interrupted. The ensuing instability transferred the stress forces to the pelvic ring, causing fractures of the superior and inferior pubic rami. Coventry and Tapper reported six cases of pelvic instability following removal of bone graft from the ilium. The patients with such instability often developed symptoms indistinguishable from other spinal disorders. History of clicking or thudding, as well as pain in the thigh and gluteal region, is characteristic.

Sacroiliac stability is maintained by formation of the sacrum as a keystone with interlocking eminences and depressions, plus ligamentous support mostly in the posterior and superior aspect. Multiparous women with lax ligaments and anatomic variations in the sacroiliac joints are more prone to develop such pelvic instability. Radiologic examination of the entire pelvic ring is important. Changes in the sacroiliac joint, the pubic rami, and the symphysis pubis should be looked for.

The Tibia

The tibia provides strong full thickness cortical graft and is occasionally used in spine fusion. The subcutaneous anteromedial aspect of the tibia is a convenient donor site. The periosteum should be left intact and sutured over the defect. The condyles also supply cancellous bone. However, there are significant risks to the use of the tibia as a donor site. Biomechanically, it is changed from a closed section to an open one when bone graft is obtained from the tibia. It is markedly weakened and much less able to resist torsional and bending loads.

Frankel and Burststein discussed the effect of cortical graft removal from the tibia. They described the torque and angular deformation to failure of the tibia to be reduced to 30% of normal and...
energy absorption capacity to 10% of normal. Even when the corners of the cutout are rounded, open section overshadows any reduction in stress concentration gained.

Fatigue fractures are relatively high, and the tibia should be cast immobilized from 6 to 12 months after bone graft is obtained. Thus the disadvantages of autogenous tibial graft far outweigh the benefits.

The Fibula

Although the upper two thirds of the fibula may be removed as bone graft, the middle one third provides the best cylindrical cortical bone graft. The fibula graft is strongest in resisting compressive loading and can be depended on for longer periods of structural support in interbody fusion. For large defects in the vertebral bodies, fibula struts may be used to achieve stability. Because of the small amount of cancellous bone in the fibula, iliac cancellous graft should be supplemented to enhance osteogenesis.

Peroneal nerve injuries may occur when obtaining the graft from the proximal one third of the fibula. Valgus deformity of the ankle is a serious risk when the lower one third is violated. Significant donor site pain and compartment syndrome have also been reported.

Ribs have been used for thoracic spine fusion. However, their modest cortex and porous cancellous bone are rarely appropriate for lumbar spine fusion.

Free Vascularized Bone Grafts

Free vascularized bone grafts may be used to circumvent the disadvantage of large cortical grafts, most of which become necrotic. Recent progress in microsurgical techniques is making this possible. Continuing circulation and increased viability of the bone grafts facilitate the problem to that of fracture healing. Vascularized grafts are less dependent on the recipient bed for survival, and their use is advantageous in poorly vascularized bed after previous surgery, trauma, infection or irradiation. The fibula, rib, and anterior or posterior ilium may be used. However, their application is usually limited by the small size and need for time-consuming highly specialized microvascular techniques. In special circumstances the use of free vascularized bone graft may be advantageous in spine fusion.

Dupuis and coworkers used a free vascularized fibular graft in a case of progressive congenital kyphosis with success, following the work of O'Brien and Ostrup. In a similar situation, an avascular strut graft becomes weaker to the point of mechanical failure as it is replaced by creeping substitution, which may take two or more years to complete.

Muscle-pedicle bone grafting procedures were reported by Hartman and associates for failed lumbosacral spinal fusion. An iliac crest autograft with an intact quadratus lumborum muscle pedicle was used in this case.

ALLOGRAFTS

Allografts are the most frequently used alternatives to autografts in spine surgery. They are bones transplanted from one individual to another and are used to circumvent the problems encountered with autografts.

Allografts are readily available and come in a wide variety of shapes and sizes. They can provide immediate support and minimize the use of stabilization hardware or braces. Bone allografts can replace missing structures and become incorporated into the spine. They provide biologic scaffolding that is gradually replaced with the patient's own bone.

Major problems lead to decreased effectiveness of allografts. Immunologic rejection of implanted graft, delayed union, nonunion, and fracture of
the graft have not been uncommon. Incorporation of allografts by the host is slower. Vascular penetration is slower and less dense. There is less perivascular new bone formation when compared to autografts. Transmission of disease from allografts is also a serious concern.

The major weakness of the allograft is that it is dead and cannot contribute directly to osteogenesis, as do fresh autografts. Burwell found a way around this problem by combining the osteogenic potential of autogenous marrow with allografts. The use of autogenous marrow to provide superior osteogenic capability in allografts and xenografts, as well as autografts, is finding greater clinical application (see further discussion on xenograft and synthetic implants). The use of bank bone is very advantageous if storage problems, immunologic reactions, and infection could be eliminated.

The allograft must be aseptically obtained soon after death or properly sterilized and processed early to:
1. Minimize its antigenicity
2. Prevent degradation by proteolytic enzymes
3. Maintain the mechanical structure
4. Preserve the osteogenic induction property

**Freezing and Freeze-Drying**

Freezing and freeze-drying are the most widely used preservation methods that allow storage of bone in a biologically useful (but nonviable) state.*

Freezing of allografts is carried out as soon as possible after procurement. Currently, the length of safe storage for bone is not known. However, based on the knowledge of autolysis retardation by cold, lower temperatures are expected to extend the “shelf life” of allografts. At −15°C to −30°C, using a home type of mechanical freezer, long-term storage of bone is difficult. This form of freezing is not advisable because ice crystals grow rapidly in this temperature range and mechanically destroy the tissue viability. Freezing at −76°C is achieved in dry ice. At −60°C to −90°C using a laboratory type of mechanical deep freezer and at −150°C or colder using a refrigerator with cryogenic gases, more effective preservation of bone is possible. At temperature near −70°C, ice crystal formation is slower. Bones frozen to −70°C have been stored for several years and successfully applied clinically. Freezing in a cryoprotective agent such as glycerol at controlled cooling velocity may be a more effective option.

Freeze-drying is a process in which the bone is first frozen to −70°C and then sublimated in high vacuum. The bone is freeze-dried until the water content is reduced to 5% or less. The freeze-dried bone graft then can be shipped and stored conveniently at room temperature indefinitely in a vacuum container. Since freeze-dried bone is very brittle, it must be reconstituted by immersing in normal saline before use. The reconstitution time depends on the size and shape of the graft. Chips of bone may not require any rehydration, whereas large cortical bone may require up to 24 hours for reconstitution.

As for their clinical application in spinal fusion, Malinin and Brown reported the union rate of freeze-dried allografts under compression load (interbody or strut grafts) not to be delayed by low grade immunologic response. This is in contrast to a high incidence of resorption with cortical graft placed under tension posteriorly in the spine.

**Biomechanical Properties**

Biomechanical properties of bone grafts may be changed by the techniques used for preservation, although Sedlin’s study showed that freezing and thawing
do not significantly change the mechanical properties of bone.\textsuperscript{98}

Bright and Burstein,\textsuperscript{9} as well as Triantafyllou and coworkers,\textsuperscript{108} studied the biomechanical properties of freeze-dried and irradiated bones. Komender\textsuperscript{66} found that freezing to $-78^\circ$ C does not alter the mechanical properties of bone. Pelker and associates\textsuperscript{86} also concluded that freezing allograft bone to temperature as low as that of liquid nitrogen ($-196^\circ$ C) does not significantly alter the biomechanical properties. They showed that freeze-drying does diminish the torsional and bending strength but not the strength in compression. The data of Pelker and coworkers indicate that frozen bones are better suited than freeze-dried bones when they are subjected to torsional loads.\textsuperscript{85,86}

Both frozen and freeze-dried bones are acceptable when compressive forces are the primary concern. It must be remembered that the initial biomechanical properties of the bone graft will change with resorption, incorporation, and remodeling by the host. Surgical technique, internal fixation, and postoperative management must therefore be planned accordingly.

**Radiation, Heat, and Chemical Treatment of Allografts and Xenografts**

Although most of the aseptically procured cadaver bones do not require sterilization procedures, allografts or xenografts have been sterilized by physical means such as high energy radiation, and heat (boiling, autoclaving); and by chemicals such as merthiolate (Thimerosal), ethylene oxide, Propiolactone, or using antibiotic solutions. Some of these sterilization methods were used in the past and are discussed for historical interest only.

Radiation of at least 2 megarads is required to kill bacteria; 4 megarads inactivates some viruses.\textsuperscript{71} The same dose of radiation (2 to 4 megarads) needed for sterilization or to destroy antigens, also significantly impairs the inductive repair capacity of the bone graft.\textsuperscript{12,110,111} Increased solubility of collagen and glycosaminoglycan, destruction of bone matrix fibrillar network,\textsuperscript{12,18} and discoloration\textsuperscript{71} of irradiated bone have been reported. In cobalt-60 irradiated bone Ostrowski\textsuperscript{83} reported free radicals of unusual stability to be present, although their effect on the host tissue is unclear.\textsuperscript{71}

The effect of radiation on the biomechanical properties of bone is not well defined at this time. The effect seems to be minimal with low level radiation. Radiation doses exceeding 3 megarads are known to destroy bone matrix fibrillar network.\textsuperscript{12,18} There appears to be a significant drop of breaking strength of bone with more than 3 megarads. This effect is magnified when radiation is combined with freeze-drying. Komender noted 6 megarads of radiation reduced the strength in bending, compression, and torsion.\textsuperscript{66} Irradiation of freeze-dried bone with only 3 megarads markedly diminished the bending strength, but not the strength in compression or torsion.

Boiled bones have been used for graft material since the early part of this century.\textsuperscript{46} Although some good clinical results have been reported,\textsuperscript{46,124} boiled allografts and xenografts have generally produced undesirable consequences. Boiling destroys all inductive capacity.\textsuperscript{124} Heat may be intended to destroy transplantation antigen, but it only denatures the antigenic proteins into another unacceptable material.

Autoclaving of contaminated bone may be tempting to use in the operating room, but this produces haversian canal coagulation and denaturation of bone protein,\textsuperscript{12,71} which severely retard host incorporation.

Chemical processing of bone graft may
Present significant problems such as potential carcinogenesis and difficulty of penetration into bone. Propiolactone (1% solution) has been found to be more bacteriocidal than ethylene dioxide, which is more difficult to use. Propiolactone (1% solution) has been found to be more bacteriocidal than ethylene dioxide, which is more difficult to use.71

Merthiolate-treated grafts have in general produced poor results; 30% of the grafts failed in the study by Reynolds and coworkers.82 There appears to be three times as many failures as with autografts. Reduced callus formation and osteogenesis have been noted. When the graft fractured, there was minimal healing. When washed before use, no significant host sensitivity to Merthiolate was noted in Merthiolate-treated bone graft.71

Benzalkonium chloride completely destroys osteogenic inductive capacity of bone, according to Urist and associates.111 Antibiotic solutions do not penetrate completely into bone. Their germicidal effect in bone graft is variable. In general, antibiotics appear to inhibit the osteogenic inductive capacity of bone.83

**Bone Morphogenetic Protein**

Urist states that allograft bone must be removed from the donor within 4 to 8 hours after death or within the minimal biodegradable time.111 Radiation sterilization with more than two megarads, heating over 60°C, exposure to chemicals such as hydrogen peroxide, betapropiolactone, benzalkonium chloride, cryolysis, immediate freeze-drying, and prolonged storage at 0°C to 30°C must be avoided to preserve the inductive properties of the bone. Urist and coworkers have extensively studied osteogenic induction and discovered a bone morphogenetic protein (BMP) that is capable of inducing the differentiation of host periosteal mesenchymal cells into cartilage and bone.112 They have separated BMP from demineralized cortical bone and osteosarcomas of man and mouse. BMP is characterized as glycoprotein(s). Its clinical application now is being evaluated in the form of an injectable substance linked to different delivery systems.114

AAA bone is a chemosterilized, autodigested, antigen-extracted allograft developed and clinically tested by Urist and coworkers. It is an allogeneic bone of high osteogenic property and low immunogenicity prepared in five basic steps. Urist believes that BMP is also preserved by these measures.81,112,115

1. Lipids and cell membrane lipoproteins are extracted using chloroform-methanol.
2. Endogenous intra- and extracellular transplantation antigens are removed by neutral phosphate buffer autodigestion in the presence of sulfhydryl group enzyme inhibitors to preserve BMP.
3. Acid-soluble proteins are extracted and matrix demineralized by 0.6 N hydrochloric acid.
4. The bone is freeze-dried. Residual proteins including BMP are preserved.
5. The processed AAA bone is stored in sterile double plastic envelope and outer vacuum-sealed glass container.

Urist and Dawson113 reported 40 intertransverse process fusions in 36 cases of degenerative joint and disc disease including spinal stenosis and spondylolisthesis, as well as 4 cases of thoracolumbar fracture dislocation. A composite of AAA cortical bone strips and local autologous bone was used in all cases. There were over 80% excellent and good results with a nonunion rate of 12%.

**XENOGRAFTS**

Xenografts, or bones transplanted from other species, have been used in spine surgery.55,73 The application of ivory,54,69 animal horns,54 corals,52,53 and...
other exotic materials has been explored. Animal horns and ivory are very resistant to incorporation into the host bone.\(^{94}\) Fresh xenograft bones have been shown to be unacceptable. Invariably, they produce inflammation, fever, sequestration, resorption, or other manifestations of rejection.\(^{12}\) Fibrous envelopment occurs as a over a metal plate. Even when fusion takes place, sequestration of the xenograft is observed. Urist believes that xenografts should not be used in patients.\(^{111}\)

Bovine bones have been relatively popular because they incorporate and remodel with less difficulty.\(^ {94}\) Different types of preserved bovine bone have been tried since the nineteenth century.

1. Frozen calf bone
2. Freeze-dried calf bone (Boplan)\(^ {87}\) and
3. Decalcified ox bone\(^ {47}\) (as well as decalcified calf and sheep bone) evaluated experimentally and clinically, but found unsatisfactory

Deproteinized xenografts, including “os purim,” “anorganic bone,” “Oswestry bone,” and “Kiel bone,”\(^ {73,94-96}\) have also been tried.

“Kiel bone,” partly deproteinized bone from freshly killed calf, sterilized either by ethylene dioxide or by gamma radiation, has been commercially available. Experimental studies showed that it is very weakly antigenic and does not possess active bone-inducing capacity.\(^ {95}\) Since its introduction in 1957, Kiel bone has been used in almost every possible bone graft site, and varying success rates have been reported clinically.\(^ {55,73,94}\)

In spinal fusion, Jackson\(^ {56}\) noted that Kiel bone implant became surrounded by autogenous bone with time. For larger defects he recommended the use of autogenous and Kiel bone composite. Mc- Murray\(^ {78}\) presented clinical, radiologic, and histologic data on the fate of Kiel bone implants in four anterior spinal fusions that failed. Biopsies of the Kiel bone implants showed invasion by fibrous tissue. There was no ossification and no incorporation into the surrounding bone. Such deproteinized bone could be invaded by host new bone when placed in excellent vascular bed with potentially osteogenic cells. When impregnated with autogenous bone marrow cells, it may prove to be an excellent scaffolding with good bone conduction property.\(^ {94,95}\) Salama\(^ {94}\) and Salama and coworkers\(^ {36,96}\) reported good results using autogenous bone marrow-Kiel bone composite grafts in patients. The red marrow can be easily aspirated from the patient’s own iliac crest.

**SYNTHETIC IMPLANTS**

Synthetic implants can be prepared to fit any size or shape, but they have been traditionally considered to be subject to wear and not biologically incorporated into the host bone.\(^ {12}\) A number of implants fashioned from metals have been tried as replacement for bone in the spinal column (see, for example, Steffee’s titanium vertebral replacement: “Total Vertebral Body and Pedicle Replacement”\(^ {101,106}\)).

*Metal scaffolds* with the shape of bone being replaced may be covered by ground autologous bone grafts of small particle size. In animal experiments ingrowth of bone occurred over the total surface area of fiber metal implants and bone penetrated deep into the composite.\(^ {2}\)

*Titanium mesh implants* have been clinically applied by Leong,\(^ {62,64}\) and coworkers for anterior spinal fusion after discectomy in the lumbar spine. This porous implant allows ingrowth of bone and appears to obviate the use of bone graft. It acts as a spacer and can provide immediate stability, while allowing time for the slow ingrowth of bone and long-term stability.
Experimentally, porous titanium mesh blocks with a 50% void allow rapid ingrowth of bone in canine long bone. A 12-year follow-up was possible in two patients who are asymptomatic, and the implants have remained unchanged and undisplaced; 10 patients had more than 5-year follow-up. Of these, seven patients were asymptomatic, two had more than 70% symptomatic relief, and one retained a very stiff back. Radiologic analysis showed that disc height was maintained at 5 years with no movement between the adjacent vertebral bodies, often with bony overgrowth anterior to the implant.

**Nonmetallic Synthetic Implants**

There is a growing number of other synthetic implants being used as bone substitutes. According to Osborn and Nemcskey, the chemical nature of the implant determines the biodynamics and reaction of the recipient bed in the interaction with living bone. They considered the following materials:

1. Bone cement and stainless steel as biotolerant, resulting in distance osteogenesis with a fibrous layer separating the implant from bone
2. Alumina and carbon materials as bioinert, resulting in contact osteogenesis
3. Glass ceramic, calcium phosphate ceramics and hydroxyapatite ceramics as bioactive, resulting in bonding osteogenesis

Bioinert porous ceramics of alumina were noted by Beun and associates to be bound to bone by the ingrowth of bone 3 to 4 mm thick in regions exposed to compressive forces.

Thus far, evidence strongly suggests that porous calcium phosphate ceramics are the most biocompatible synthetic bone substitute with the ability to become chemically bonded by living bone and with a chemical composition devoid of toxicologic liabilities. They are shown to be superior to biodegradable polymers, such as polylactic acid and polyethylene acid, which have been considered as bone substitutes. The implants may be in dense form or porous. The minimum pore size for ingrowth of bone is shown to be 100 μm. Corals provide such porous structures.

Holmes and coworkers performed histologic and biomechanical studies in dogs using hydroxyapatite converted from sea coral calcite as bone substitute. The material was incorporated in bone and became almost as strong as the native bone. They also reported encouraging clinical application with fractures in 18 patients.

Another material, Replam Hydroxyapatite-Porites (RHAP), is a ceramic with three-dimensional interconnected porous material of calcium hydroxyapatite from the exoskeleton of porites (coral). It may be carved by the surgeon before implanting. RHAP was approved for evaluation in spinal fusion in several centers under Mooney and associates. (See Chapter 41.)

Bioactive and biodegradable porous ceramics of hydroxyapatite or tricalcium phosphate have been studied. Jarcho stated that they are usually well tolerated and become chemically bonded to bone by natural bone-cementing mechanisms.

Porous hydroxyapatite ceramics have been used in dog experiments for the spine and other skeletal defects. Porous ceramics and autologous marrow composites were studied by Nade and associates. Porous alumina, calcium aluminate, calcium hydroxyapatite, and tricalcium phosphate were placed with bone marrow into intermuscular sites. Bone was found to adhere to the ceramics and to penetrate the interior if the pore size were greater than 100 μm. The marrow cells were shown to play a significant part in new bone formation into the framework. Nade and coworkers believe that
the appropriate histocompatible biodegradable ceramic material would act as a scaffold by virtue of its porosity for retention of bone marrow cells, and provide mechanical strength, while bone ingrowth is progressing. This type of bone substitute would also allow a wide selection of sizes and shapes in sterile form.

Porous biodegradable ceramic and BMP composites were evaluated by Urist and coworkers,\textsuperscript{114} They reported that an aggregate of B-tricalcium phosphate and bone morphogenetic protein (TCP/BMP) induced the differentiation of cartilage in 8 days and in lamella bone in 21 days. The yield of new bone was more than 12 times greater from the TCP/BMP than from the BMP alone. It is possible that a porous ceramic acts as a slow-release delivery system to distribute BMP more favorably and to potentiate its activity.

Calcium phosphate-coated metallic implants showed superior bone-bonding characteristics according to Ducheyne and associates.\textsuperscript{39} Such implants may solve the problem of weak mechanical strength of ceramics, particularly the porous ones. Ceramic implants by themselves are probably unsuitable for restoration that would have to withstand significant impact, or torsional or bending stresses,\textsuperscript{56} as in the spinal column.

Calcium phosphate-containing bone cements are also being developed.\textsuperscript{55,73} Recently, calcium hydroxyapatite in powder form was used as an expander of a patient's own cancellous bone graft. It has been used in spine fusion, especially in children, when there is insufficient autologous bone graft available.\textsuperscript{68a}

**METHYLMETHACRYLATE CEMENT**

Knight\textsuperscript{59} was the first to report the use of acrylic cement to fix the cervical spines with chronic fracture dislocation, atlanto-axial subluxation, and cervical spondylisis. He also stabilized the lumbar spine using the cement in one patient with disc disease. Scoville and coworkers\textsuperscript{97} reported the use of acrylic plastic for vertebral replacement or fixation in metastatic tumor destruction of the spine.

In recent years the clinical use of methy1methacrylate cement for spine stabilization has become more popular. Harrington\textsuperscript{18} documented the use of methy1methacrylate for vertebral body replacement and anterior stabilization of the spine with metastatic tumor. His series included 14 patients treated by anterior decompression and stabilization using metal and the bone cement.

The strength of methy1methacrylate is about one half that of bone.\textsuperscript{122} Attempts have been made to strengthen the cement by adding fibers,\textsuperscript{74} but clinical data are still unavailable. After polymerization, methy1methacrylate becomes a rigid and brittle solid that can withstand significant compression. However, it fails under tension or shear forces. It is reasonable to use it in replacement of vertebral body where compression is the predominant force present. It is important to remember that when used alone the outer part of the cement mass is still subject to tension when bending and will fail with time in a clinical setting. The primary indication for application of methy1methacrylate in spinal stabilization is in patients with malignant disease and limited life expectancy.\textsuperscript{38,76} It should not be expected to provide long-term support of the spine.\textsuperscript{31}

In the spinal column, methy1methacrylate cement should be used with secure metal fixation such as the Dunn,\textsuperscript{22,33,41} Harrington, Luque, Steffee,\textsuperscript{103,105} or other instrumentation. It may be used as reinforcement for screws and hooks in cancellous bone. The cement does enhance fixation of implants by increasing the contact area, especially in osteoporotic bone.
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