IMPLANT ARTHROPLASTY AT A CROSSROADS

John V. Vanore, DPM

For the past twenty years, implant arthroplasty of the first metatarsophalangeal joint (MPJ) has meant some form of silicone interpositional device. In the late 1960s and 1970s, surgeons quickly embraced these implants as a means to cure all pains in and around the first MPJ (Albin & Weil, Kalish & McGlamry, LaPorta).

For the most part, surgical reconstruction was simple, easy, and this lead to abuse. The abuse was that the technique of implant arthroplasty was indiscriminately applied to a broad patient population with too great a frequency and by today's standards, exceeding proper indications.

After longer periods of implantation, patients began to have biomechanical and host tissue reactions to the implants. Some surgeons abandoned the procedure and condemned the silicone implant itself as the problem. Once again we the surgeons are much to blame, yet it is much easier to place this responsibility elsewhere. Our discussion today will attempt to give proper perspective to silicone interpositional arthroplasty and explore considerations of alternative implant designs and materials.

What is the reality of silicone arthroplasty in the last decade of the twentieth century? In order to answer this question and determine where implant arthroplasty will be in the next decade, our past experiences will be examined, critical assessment will be made and predictions for future implants will be predicated upon present thought.

RATIONALE OF USAGE

Long-standing joint deformity and/or arthropathy of the first MPJ, specifically end-stage hallux valgus or degenerative arthrosis, usually requires some type of joint arthroplasty. These procedures are joint destructive in nature meaning that either one of both sides of the joint are sacrificed. This may involve resection arthroplasty with or without an implant or arthrodesis.

Our focus will be that of silicone implant arthroplasty. It is an adjunct to resection arthroplasty. Resection arthroplasty by itself usually is performed as a Keller type procedure with resection of the base of the proximal phalanx. These types of procedures are associated with instability of the great toe and or first metatarsal that contribute to a lack of toe purchase and lateral weight transfer. Swanson proposed implant arthroplasty to improve cosmesis, joint stability, and increase the likelihood of a reliable degree of joint motion. The interpositional implants were also expected to relieve symptoms of joint pain.

Silicone implantation, whether with hemi-implant or a double-stem device, is an interpositional arthroplasty. It is not a joint replacement procedure. Reference to the double-stem hinge as a total implant is inaccurate and confusing.

In the decade of the eighties, more papers on complications of implant arthroplasty have appeared than studies on its usage. Many of the problems related to implant arthroplasty have resulted from poor patient selection. Either the patient's functional demands were such that the durability of an implant procedure need be questioned or that biomechanical faults would likely ensue.

Implant arthroplasty as commonly performed today is not perfect, but it is a fairly reliable procedure particularly if the surgeon and patient have a clear understanding of the goals and objectives of the procedure.

HISTORY

Swanson (1952)
* Attempted 1st metatarsal head replacement with a non-cemented metal prosthesis; later-silicone metatarsal head.

Joplin (1960s)
* Formed seventy-nine surface replacement arthroplasties utilizing a non-cemented, short-stemmed Vitallium prosthesis in patients with hallux rigidus.
* Two varieties were implanted, either a phalangeal or a metatarsal prosthesis.

Seeburger (1960s)
* Intramedullary stem Vitallium metatarsal cap that was impacted.

Swanson (1968)
* Silicone Hemi Great Toe

Smith and Weil (1975)
* UHMW polyethylene phalangeal component and a stainless steel metatarsal component
* Intramedullary stems that were fixated with acrylic bone cement
* Procedure abandoned because of limited ROM and advent of Swanson silicone implants

Swanson (1977)
* Hinged silicone implant
* Double stem silicone implant modeled after a similar design utilized in the hand

Cutter (1978)
* Hinged barrel-stem silicone implant with dacron mesh

Weil (1978)
* Modified the Swanson Hemi Implant to Angled device to accommodate PASA

Mayo Clinic (1979)
* Two-component non-constrained total joint system manufactured by DePuy
* The metatarsal component was a small convex button with a short stem that was later lengthened to allow for better fixation.
* Problems occurred with loosening of the implant, modifications did not halt the problems and the joint system was never released for general usage.

LaPorta (1980)
* Sutter introduces hinged silicone rubber implant.
* Anatomical alignment of normal transverse & sagittal plane 1st MPJ alignments.

Lawrence (1980)
* Sutter introduces hinged silicone rubber implant.
* Attempted to reduce phalangeal base resection and improve hallucal purchase.

Swanson (1985)
* Titanium Hemi Great Toe

Kamphner (1985)
* Intermedics: two-component non-constrained joint replacement system of pyrolytic carbon.
* This biomaterial was proposed to solve the problems of wear and detritic phenomenon.
* This implant "squeaked" was never released for general use.

Koneig (1989)
* Total Joint System
* Originally a Dow Corning project later brought to market by Biomet.
* UHMW polyethylene phalangeal component
* Titanium metatarsal component, now Cobalt Chromium with plasma sprayed titanium coating for bio-integration.

Bio-Action (1991)
* Total Joint System
* Surface replacement arthroplasty of a cobalt chrome metatarsal component and UHMW polyethylene phalangeal base. Initial clinical studies pending.

BIOMATERIALS

Biomaterials utilized for joint implants have been chosen for their inertness and physical properties. Silicone rubber materials were selected for the inert and well-tolerated physiologic characteristics. The elastic moduli of metals are significantly greater than that of bone and were an initial choice for several investigators. Stainless steel has been used but possesses limited fatigue properties compared to materials such as titanium and cobalt chrome alloys. Cobalt chrome alloys are generally accepted to possess superior bearing characteristics to titanium although nitrogen bombardment of the surface has improved titanium's

surface properties. Titanium does possess an elastic modulus about half of cobalt chrome and has been cited for characteristics bio-integration.

How does the characteristics of a materials' elastic modulus influence its tolerance as a bearing surface for hemi arthroplasty? Silicone was chosen as a softer material; it was felt to be unlikely to cause adjacent surface damage. Titanium appears to be well-tolerated although problems may not be encountered until widespread clinical usage occurs and some years of follow-up. Currently, several materials are being considered for hemi-arthroplasty including metals and ceramics.

The double-stem hinged interpositional implant of silicone rubber is still the most widespread in acceptance and utilization. Dow Corning Wright, the manufacturer, recommends the concomitant use of titanium grommets as an interface between bone and the implant.

Implant Design

Joint implants have generally been designed in close resemblance of the osseous structure or structures that it was meant to replace. An important consideration is that the implant also allow for a similar direction and range of motion. Hemi-arthroplasties are often the initial choice in attempting to keep the procedure as simple as possible. Interpositional devices have been devised to allow motion between diseased joint segments. As the metatarsal head is generally the most diseased segment; this was the initial attempt of replacement with joint arthroplasty. Swanson, Seeberger and Joplin have all attempted metallic metatarsal heads and failure ensued. Certainly reasonable success has been noted with silicone and now metallic hemi-phalangeal implants. As the metatarsal head is often severely degenerated, materials that withstand such articulation are being investigated.

Several hinged devices have been marketed and each are a variation of Swanson's original concept of a flexible non-cemented material with medullary stems. The central hinge allows for motion within a single plane, the sagittal plane, for flexion and extension of the great toe. Devices have been fabricated that take into account the normal degree of abduction or extension of the hallux compared to its metatarsal.

Total joint systems attempting to replace both sides of the first MPJ have yielded little success. Koenig recently has revitalized hopes that a total joint system may yet be possible. Actually, the initial success of Swanson's interpositional devices lead to the abandonment of the Weil and Smith system.

Host Reaction/Biocompatibility

Ideally biocompatibility requires the implant to be: (a) chemically inert or free from biodegradation; (b) capable of withstanding the stresses imposed on it; (c) durable or possess an integrity of structure without modification of its physical properties because of the biological environment; (d) nonirritating, eliciting only a benign, local tissue response particularly in regard to the absence of local or systemic toxicity, including allergy or hypersensitivity, carcinogenicity, and pyrogenicity.

During the late 1970s and early 1980s, implantation was being performed for broader indications and in younger individuals. Problems were encountered in cases of fracture or fragmentation of the implant. The silicone debris may incite an inflammatory response or even granulomatous reaction of the periarticular soft tissues and even bone. Silicone debris has also been found in proximal lymph nodes and is believed to spread by non-contiguous routes through the lymphatic system.

A significant number of these cases of implant fracture and inflammatory reactions could be traced to inappropriate use or patient selection. The host response to the joint implant is paramount and may determine the ultimate success or failure of a particular implant. Host response encompasses not only the biological reaction with regard to compatibility but also the physical interaction of the implant or implants on a mechanical basis. These biological and physical relationships should be nondetrimental to both the host and the implant for the remaining lifetime of the patient.

INDICATIONS

Appropriateness of utilization is of paramount importance when considering implant arthroplasty in any surgical candidate. There is no denial that complications have occurred with the various silicone implant procedures but we have also

learned a great deal along the way. Possibly surgeons and subsequently their patients had unrealistic goals and expectations of the surgical procedure. Most importantly, the indications of usage were too broad without consideration of the functional limitations.

Indications have become more limited in an effort to improve results and minimize failures. Implant arthroplasty yields a good frequency of success in cases of first MPJ reconstruction due to arthrosis.

Implant arthroplasty is an effective adjunct to resection arthroplasty but does not replace primary joint reconstruction. Joint preservation procedures are always more desirable particularly in the younger patient. Implant arthroplasty does not duplicate a normal joint but usually produces a satisfactory functional alternative.

The expectations of implant arthroplasty are:

1. A pain-free functional joint
2. A relative maintenance of toe purchase and proprioception
3. Adequate active and passive metatarsophalangeal joint motion
4. Rectus alignment of the hallux with reduction of the deformity

The appropriate performance of adjunctive procedures is essential to the success of implant arthroplasty. Implant arthroplasty cannot be relied upon to reduce elevated intermetatarsal angles. In the presence of significant metatarsus primus elevatus, a first MPJ implant will not be successful.

Certainly the great majority of patients undergoing implant arthroplasty are selected because of secondary degenerative arthritis. This may be secondary to an orthopedic deformity such as hallux valgus, hallux varus, and metatarsus primus elevatus or trauma as with intra-articular fracture or previous surgery. With appropriate utilization, a high percentage of good results can be expected with a rather small revision rate.

Indications for implant arthroplasty of the first MPJ can be approached both from the standpoint of symptomatology and clinical pathology. The presenting symptoms should indicate abnormalities of joint dynamics and joint structure. These may include joint crepitus, joint pain, and limitation of motion. Deformity is often present, and secondary degenerative arthrosis is a consequence of long-standing deformity.

During the 1980s, an increasing number of implants became available for clinical usage. Interpositional implants began as spacers for the resected portion of base as in a Keller procedure. Later, due to the large number of implants utilized for hallux valgus, the angulated hemi was introduced. The standard great toe implant was indicated for a rectus foot while the angled implant was recommended for an abducted great toe. Not long thereafter, the double stem interpositional implants were introduced with various types of central hinges to allow movement between the metatarsal and its phalanx.

The 1980s witnessed an explosion in the use of silicone implants. A philosophy pervaded the podiatric profession that the hemi-implant was a more conservative procedure and that it should be utilized in cases of lesser degrees of arthrosis. Thereafter, the use of silicone implants was dealt a serious blow with the myriad of reports of complications, in particular the phenomenon of detritic synovitis.

Observations Regarding First MPJ Implant Arthroplasty

From a biomechanical and functional perspective, hemi arthroplasty may be superior to a double-stem implant. Hemi silicone arthroplasty is a pathologic procedure. Implant arthropathy has been described and attributed to the use of hemi silicone implants. Implant arthroplasty regardless of the device utilized is a joint destructive procedure. It is not reasonable to debate that hemi implantation is a more conservative procedure or less destructive than use of a double-stem implant. Implant arthroplasty should be restricted to definite indications. Broad and inappropriate usage is probably the primary reason for the negative perception of silicone implants. In some parts of the country, silicone implants were abandoned. The rationale for such is obscure. Surgeons need to assess the reasons for failure as well as success. With proper patient selection and good surgical techniques, silicone implant arthroplasty is a viable clinical option.

Clinical thought, however, has been that the hemi implant procedure is a more conservative procedure and may be more appropriate in cases of lesser degrees of joint arthrosis. It is the author's preference to avoid implant arthroplasty

altogether in cases of lesser degrees of arthrosis. The use of implant arthroplasty should be reserved for cases that are not salvageable by techniques of primary joint reconstruction.

Joint preservation alternatives should be considered in cases of lesser degrees of arthrosis, particularly in younger and more active individuals. These alternatives include:

(a) Cheilectomy
(b) Osteotomy to correct biomechanical causes of arthrosis e.g. metatarsus primus elevatus
(c) Osteotomy for joint decompression/relaxation
(d) Subchondral abrasion of articular defects

In cases of profound arthrosis of the first MPJ, a double-stem implant in recommended, e.g., stage IV hallux rigidus. It is now well recognized that the use of hemi implant in the face of degenerative, irregular joint surfaces will probably lead to abrasion or wear of the articulating silicone implant and the potential for soft tissue and/or bony pathology.

Joint destructive alternatives to implant arthroplasty include: Resection Arthroplasty; First Metatarsophalangeal Joint Arthrodesis; Total Joint Replacement

End Stage Hallux Valgus With Arthrosis and an Elevated Intermetatarsal Angle.

Long-standing hallux valgus is often associated not only with adaptive changes at the first MPJ but also with degenerative changes as a result of a poorly functioning, noncongruous articulation. The first intermetatarsal angle may or may not be elevated. As a general rule, an intermetatarsal angle greater than 16 degrees to 19 degrees often requires basal abductory osteotomy.

A problem arises when a surgeon expects the double stem implant to provide correction of the deformity, i.e., hallux abductus and metatarsus primus varus. Surgical soft tissue releases and reconstruction as well as bone resection is paramount to the degree of correction that is obtainable. A surgeon that relies upon the implant only often observes recurrent deformity.

Senile Hallux Valgus

The elderly patient with hallux valgus, a flexible intermetatarsal angle and an apropulsive gait is an excellent candidate for reconstruction with double-stem hinged arthroplasty. Without osteotomy, an implant arthroplasty may correct mild to severe degrees of hallux valgus with a minimum of disability to the patient.

In this particular case, the author proposes that a lesser degree of arthrosis is most often the situation but that the age of the patient, greater than sixty-five years old, or the quality of the patient's bone, would not generally be appropriate for reconstruction by osteotomy. These are often the patients who because of their age and medical status benefit the most from implant arthroplasty. Prolonged convalescence and immobilization is avoided and disability is minimal. Rehabilitation with immediate ambulation is typical allowing the patient independent daily living.

The geriatric patient makes minimal functional demands of the reconstruction usually presenting with an apropulsive gait, long-standing deformities and often concomitant arthrosis. Cosmetic results as well as reduction of deformity are often dramatic while rehabilitation and disability are minimal.

With implant or resection arthroplasty, preoperative criteria including the degree of hallux abductus, lateral adaptation of the first metatarsal head, intermetatarsal angle, and limitation of joint motion are all less of a consideration.

Postoperative care usually involves three to four weeks in a wooden surgical shoe followed by immediate return to a laced gym shoe or oxford. The authors do recommend caution in the patient with severe hallux valgus and a high intermetatarsal angle. Returning these patients to regular shoes and an absence of splinting prior to one month postoperatively may jeopardize maintenance of correction. A certain period of splinting or immobilization of the arthroplasty in the corrected position allows for reparative fibrosis to aid stability.

Hallux Valgus

Cases of long-standing hallux varus that were not recognized early, were ignored, or were simply long in development with subsequent arthrosis may be very difficult to correct and may occur in a younger more active patient population. Joint relaxation is paramount in the treatment of hallux varus and in long-standing cases, bony adapta-

tion and degenerative changes complicate the surgical correction. The implant does possess transverse plane stability, but cannot be relied upon to provide stability to the reconstruction.

Implant arthroplasty is not without complications and in the younger patient, this must be considered. Implant procedures are joint destructive and significantly affect the biomechanical function of the foot, for example, lateral weight transfer with resultant metatarsalgia. Arthrodesis of the first MPJ although usually avoided may be the more appropriate for the patient in the second or third decade. This may be a much more satisfying or permanent solution.

Rheumatoid Foot

Pan metatarsal head resections or modifications of the Hoffman-Clayton type procedures have been performed with success in the rheumatoid foot with hallux valgus and lesser metatarsophalangeal luxations. With the advent of silicone implants, the Hoffman-Clayton procedures were first combined with the Keller and hemi-implant. Many of these procedures failed because of the length discrepancy created between the unaltered first metatarsal and the significantly shortened lesser metatarsals. The hallux was inherently unstable and lateral dislocation was common.

Today, modified Hoffman-Clayton procedures are performed with resection of the distal portion of the first metatarsal and utilization of a double-stem hinged implant. This gives a good deal of stability to the hallux and yields an excellent cosmetic result.

In a patient with reasonable good bone stock, first MPJ arthrodesis is a good alternative and may be combined with pan-metatarsal head resections. Yu has suggested that this may be a preferred method of forefoot arthroplasty.

SURGICAL TECHNIQUE

The following description is a recommendation for Swanson double-stem implant arthroplasty with titanium grommets. (Fig. 1) Other double-stem silicone implants are available but not with the grommets. These are clearly important adjuncts to the longevity and success of the procedure. Some comments are made regarding hemi-silicone implants although their use can no longer be recommended. Variants in technique for the insertion of a hemi-implant will be noted as implants are under development and use of materials such as titanium and ceramics.

Approach

A medial or dorsomedial incision is used. The length of the incision may vary depending on the need for basal osteotomy but its usual length is approximately 7 cm. Transverse superficial venous tributaries are usually ligated and are small in the distal portion of the incision.

Capsulotomy

The initial incision through the skin and subcutaneous tissue should be extended down through the superficial fascia exposing the metatarsophalangeal joint and its associated extensor hood complex. As in most hallux valgus surgery, anatomic dissection of the skin and subcutaneous tissues from the medial joint capsule is recommended if capsular correction is part of the repair. In cases of a rectus toe as in hallux rigidus, only limited underscoring of the medial skin and subcutaneous tissues is necessary.

A linear or lenticular capsular approach between the tendons of extensor hallicus longus and extensor hallucis capsularis has proven ade-

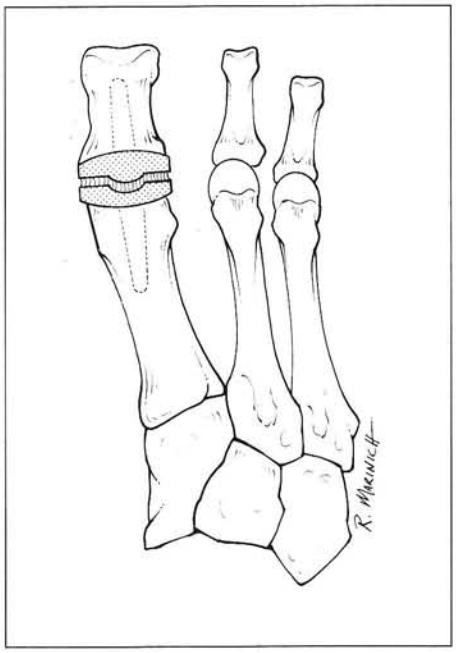

Fig. 1. Implant insertion

quate. Alternate capsulotomies include the inverted L which is usually extended as a T for exposure of the proximal phalanx. The capsular incision begins proximally at the margin of the skin incision but distally the deep incision is carried onto the proximal phalanx only as needed for resection of the base of the proximal phalanx. Subperiosteal dissection combined with medullary reaming may threaten the phalangeal vascular integrity.

Articular exposure begins with subperiosteal dissection dorsally on the first metatarsal and proximal phalanx. Often it is easiest to follow the path of least resistance. This means if the joint capsule is more easily dissected laterally from the phalangeal base, then the capsular dissection should begin there. The medial and lateral metatarsophalangeal joint collateral and sesamoidal ligaments are released.

Meticulous subperiosteal dissection on the dorsal, medial, and lateral portions of the proximal phalanx will maintain the musculotendinous units as functional as possible. Dissection of the plantar attachments is accomplished following the osteotomy for base resection.

Bone Resection

Removal of the base of the proximal phalanx usually accomplishes relaxation of the first MPJ, although in cases of long-standing hallux valgus a lateral release and fibular sesamoidectomy may also be necessary. Recurrent valgus deformity in patients with high IM angles, additional bone resection from the metatarsal has proven helpful in reducing or maintaining reduction of the IM angle.

Initial bone resection should begin at the phalanx. Approximately one-third of the proximal phalanx is resected through an osteotomy perpendicular to desired final long axis of the hallux. This must include as assessment of the degree of interphalangeus present. Visual inspection of the hallux in neutral position as well as in some degree of flexion at the interphalangeal joint is helpful. The osteotomy usually parallels the eponychial nail fold.

The phalangeal osteotomy should just penetrate the plantar cortex. From this point, careful dissection of the soft tissues from the bone will help maintain integrity of the plantar capsule and the aponeurotic insertions of the tendons. Actually, after removal of the base, there should be no violation of the plantar tissues, i.e., the long flexor should not be exposed.

The degree of degenerative osteophytosis and size of the medial eminence will help determine the need for peripheral metatarsal head resection. This becomes extremely important in cases of double-stem hinge arthroplasty in osteopenic bone. The first metatarsal head cortical margins should be maintained so as to give the greatest amount of support to the metaphyseal trabecular. Even though the silicone implant is soft, implant loading may disrupt the bony architecture and fracture through the bone.

Although, the medullary canal may be reamed directly through the articular surface, it is recommended that the articular surface be resected to provide close apposition of the hinge portion of the implant.

With the use of Sutter implants, flat surfaces opposing the hinge portion of the implant are encouraged because of its design. This is a very important consideration with the use of the Lawrence implant wherein the correct placement of the implant is dependent on proper angular bony resection of both the first metatarsal and proximal phalanx. A template is available.

Of course, if a hemi implant is being utilized, then no resection of the first metatarsal is performed. To give additional stability to the joint reconstruction, the integrity of the lateral capsule should be maintained.

The articular surface of the first metatarsal should be resected closer to a perpendicular to the ground rather than a perpendicular to the long axis or declination of the first metatarsal. This aids in placement of the implant high in the metatarsal and will maintain the plantar condyles for their articulation with the sesamoids. This will allow for distal excursion of the sesamoids on the metatarsal head with dorsal extension of the joint.

The objective is to maintain stability of the first metatarsal, the hallux, and the weight-bearing potential of the medial column. In an attempt to avoid lateral metatarsalgia associated with inadequate first metatarsal stability, bony resection of the first metatarsal is kept to a minimum. A surgical dilemma arises though. Minimizing bone resection is felt to limit the biomechanical faults of the procedure yet inadequate bone

resection is probably the single greatest cause of postoperative malalignment.

The exception to minimizing first metatarsal head resection in the double-stemmed implant arthroplasty is with forefoot arthroplasty, e.g., Hoffman-Clayton type operation. Forefoot reconstruction of the rheumatoid foot involves total head resection of the lateral metatarsals achieving a somewhat normalized bony parabola. As a result, some degree of resection of the first metatarsal is also necessary; this usually involves at least one half of the first metatarsal head. This bone resection is also helpful in reducing both large degrees of hallux abductus and metatarsus primus varus.

Canal Preparation

The medullary canals in both the first metatarsal and proximal phalanx are drilled in a tapered fashion. The canals should reflect a negative mold of the implant stem. Implant sizers are utilized to determine the extent of canal preparation necessary.

The location of the implant stems within the medullary canals is important. Both within the phalanx and metatarsal, the canals should be placed as dorsal as possible so as to avoid bony abutment with dorsiflexion. The canal within the metatarsal should also be skewed laterally to avoid overhang or prominence of the hinge medially.

Most often a small side cutting or football burr, for example the 4.0-mm oval side curring burr, is utilized to begin the intramedullary canals. Following the initial drill hole, the canal is best enlarged to the desired size through the use of intramedullary rasps. If using the Dow Corning Wright silicone implants, a complete set of rasps for both the proximal and distal stems in each progressive size are available. The shape of the canal is begun with the smallest rasp and then progressively a larger one is utilized until the desired size is obtained. Alternatively, a rasp on the reciprocating saw may be used. Intermittently, the size of the canal is assessed with the use of the implant sizers.

As described earlier, titanium grommets are available for the Swanson double-stem implants. These are recommended as only beneficial consequence can be anticipated. Each size implant has a corresponding pair of grommets which are press-fit into the medullary canals of the metatarsal and proximal phalanx. It is not usually necessary to enlarge the medullary canals for fit of the grommet. In most patients with hallux valgus undergoing implant arthroplasty, the bone density is soft to normal, therefore, the grommet can easily be press-fit with finger pressure. In cases of hallux rigidus and degenerative joint disease, the bone is dense and sclerotic. In these cases, it is necessary to round the margins of the medullary canals similar to the contour of the grommet.

Dow Corning Wright is developing separate instrumentation for the insertion of the grommets. These include a rasp for contouring the mouth of the medullary canal and an inserter. The inserter or seater improves the surgeon's ability to press fit the grommet. In dense bone, it may be used as a tamp and tapped with a mallet.

Implant Insertion

Once the canals are prepared to their exact size, copious irrigation is performed to remove all bone debris that in itself may cause an inflammatory response. The correct size implant is requested and usually placed in saline or antibiotic solution.

The only permissible tampering with the implant is shortening of the stem. With the regular stem implants it is common to remove 2- to 3-mm of the distal stem. This is usually performed with the implant held wit blunt instruments on a wet metallic surface and the implant cut with a new scalpel. Any other remodeling of the implant must be avoided in that early failure of the implant may be precipitated by a stress riser. Today, shortening is no longer necessary since the introduction of the short stem implants by Dow Corning.

The implant is then brought to the operative field in a cup of antibiotic solution and placed directly into the wound. The medullary stem of the first metatarsal is inserted first. Plantarflexion of the hallux then allows insertion of the distal stem into the proximal phalanx. Insertion of the implant should be performed without the implant touching the skin.

It must be remembered that flexible implant arthroplasty is an adjunct to resection arthroplasty. This type of interpositional arthroplasty is

dependent on adequate bone resection and soft tissue release to alleviate the preoperative deformity. Considerations with regard to the intermetatarsal angle must also be addressed.

Capsular Repair

Capsular closure is performed with the surgeon's preference of absorbable materials. The author's choice is 2-0 or 3-0 Dexon or Vicryl and the medial margin of the extensor hood is also incorporated into the capsular closure. This accomplishes a very important function of medializing or maintaining the vector of pull of the tendon of extensor hallucis longus. Bow-stringing of this tendon laterally may destroy the stability of the joint reconstruction yielding transverse and frontal plane deformities postoperatively.

In cases of significant hallux abductus, additional medial capsular repair is recommended. This may include intra-osseous suture of the medial collateral ligament to the phalanx and the medial sesamoidal ligament and the proximal extent of the collateral ligament to the medical epicondylar region of the metatarsal head. Alternatively, a capsuloplasty may also be accomplished to give additional transverse plane stability. This involves modification of the original linear or lenticular capsulotomy just prior to insertion of the implant usually with the implant sizer in place. A vertical incision is made in the distal extent of the medial capsule. A transverse capsulotomy is then performed just above the tibial sesamoid extending proximally at least to the metatarsal neck. This capsular flap may then be advanced anteriorly or distally. Suture is first performed dorsally from distal to proximal and then the plantar portion repaired.

LaPorta has also recommended suture of the intersesamoidal ligament to the long flexor to help stabilize the hallux and prevent posterior displacement of the sesamoids (G.A. LaPorta, unpublished observations). Kalish and McGlamry in 1974 recommended reattachment of the intrinsic musculature with suture through drill holes in the proximal phalanx. At present, tethering the long and short flexors is recommended.

Closure

Subcutaneous and skin closure is left to the surgeon's preference. Drains are usually not necessary and a small amount of corticosteroid, usually dexamethasone phosphate, infiltrated peri-articularly will diminish postoperative edema and pain.

A fluff compression dressing is utilized postoperatively splinting the toe in a rectus position and maintaining it in a somewhat plantarflexed position to aid in postoperative toe purchase.

Ambulation is allowed immediately postoperatively with a surgical shoe. In cases of isolated first metatarsophalangeal flexible implant arthroplasty, ambulation in a flexible-soled shoe may sometimes be begun as early as three weeks postoperatively without any other form of toe splinting. This actually helps to increase range of motion and minimize edema. Severe and long-standing preoperative deformities should be splinted in a rectus position for a somewhat longer length of time. Moderation in activity is emphasized early on and the patient is followed with serial postoperative visits and radiographic examinations.

RADIOLOGY

Surgical intervention for orthopedic pathology is often predicated on radiographic findings. In the assessment of a surgical procedure, postoperative radiographic studies offer vital information. Besides obtaining preoperative films, radiographic examination is performed immediately postoperatively, at six weeks, three months, six months, one year, and at yearly intervals postoperatively whenever possible.

The immediate postoperative examination is important because it allows initial assessment of surgical technique, such as bone resection, reaming of the medullary canal, seating of the implant, joint alignment, and overall correction of the preoperative deformity.

Joint alignment must be assessed postoperatively. Besides recognizing if the stem or stems are well seated, the joint alignment in the frontal, transverse and sagittal planes is evaluated regardless of the type or specific implant utilized.

If malalignment of the implant or joint segments are noted initially, surgical judgement or technique is probably to blame. Malalignment or joint instability does not improve but certainly may worsen. Consideration of pathological loading or stressing of the implant must be acknowledged. Eccentric loading may result in deforma-

tion, fatigue fracture, and microfragmentation, and the bony and soft tissue pathology associated with it.

Between three and six months postoperatively, radiographic examination is helpful in demonstrating hallucal purchase and sagittal plane position of the first metatarsal on the weight-bearing lateral projections. It is also the author's routine to take pirouette lateral projections to objectively evaluate first MPJ extension and first metatarsal position.

Serial radiographs will reveal soft tissue and in particular bony pathology. For example, the radiographs from three months to one year postoperatively show a gradual development of ectopic bone. New bone formation at either side of the resected bone surfaces is common. Excessive bony proliferation is associated clinically with limitation of motion. Ectopic bone is noted as early as three months postoperatively and is well formed by nine to twelve months. The author's experience has shown little further proliferation beyond one year postoperatively.

Postoperatively, between six and twelve months, the radiograph will show a peripheral sclerosis surrounding the perimeter of the stems within the medullary canals. This is a consistent finding and is believed to be physiological versus pathological.

Serial radiographs beyond one year are also helpful in evaluating implant failure caused by deformation and fatigue fracture because this is rare before this time. The soft tissue profile may reflect synovitis, capsular hypertrophy, and granuloma formation. These are also not common before one year postoperatively and should not be confused with postsurgical edema.

Bony pathology in the early postoperative stage may include osteomyelitis, or resorption adjacent to the medullary stems as in fibrous hyperplasia. This may be associated with pathological fracture as also occurs in aseptic necrosis. The latter are difficult to appreciate without serial examinations or late stage findings. Proliferation of a fibrous tissue interface is seen to some degree in all cases.

Bone cysts associated with hemi-implants are first noted by six months postoperatively and grow to maturity by three years postoperatively. These have for the most part remained asymptomatic and are rarely associated with pathological fracture or limitation of motion. Usually along the margins of the stems within the medullary canal a sclerosis develops along the perimeter as previously described.

Again, because of the general lack of documented long term postoperative findings and results of implant arthroplasty, continued observation of the patient is recommended particularly in the form of radiographic examinations. In addition, postoperative findings must be interpreted in light of the preoperative state of the musculoskeletal tissues.

COMPLICATIONS

In 1982, Vanore, O'Keefe and Pikscher formulated a classification of the complications of first metatarsophalangeal implant arthroplasty. The classification particularly addressed the problems noted with patients who had undergone hemi arthroplasty. Since that time, the surgical practice of implant arthroplasty has predominantly involved the use of the double-stem designs. Some modifications have thus been made but the complications have remained grouped into five main categories: implant failure, postoperative joint alignment abnormalities, various abnormalities of the bone and soft tissue and biomechanical failure of the joint.

Biomaterial Failure

Intrinsic failure refers to problems encountered when in vivo physiologic or pathologic forces exceed the limits intended for normal use of the implant. The physical properties of the device is defined both by the material as well as its structural configuration.

Deformation may occur in situations where loading forces exceed the elastic limit of the material or from repetitive cyclic loading adversely affecting the physical properties of the material. Deformation is identified as observable plastic changes in the topography of the implant.

Extrinsic failure is the result of tampering with the implant, or artificially creating defects within its structure thus influencing the physical properties of the device.

The physical properties of the implant material should ideally be similar to the tissues they are asked to replace. Most metals possess elastic

moduli of much greater magnitude than cartilage or bone. This is associated with deformation of the articular surface and bone absorption in cases of hemi implantation. Bone absorption or loosening of the implant has also been a problem in total joint systems of stainless steel and high density polymers.

Deformation occurs along the collar and articulating surface of the hemi implant. Factors responsible include eccentric placement of the implant on the metatarsal and irregularities of the metatarsal head; either may localize the applied loads.

Fracture with abnormal loading, long term plastic deformations develop and usually precede fatigue fractures. Repetitive loading may also weaken the material or introduce a flaw into the substance of the implant. This may then go on to complete fracture of the implant into two or more pieces.

Microfragmentation involves the production of wear debris from the joint interface, medullary shearing, or corrosion and breakdown of a particular material.

Alignment Abnormalities

Alignment abnormalities are usually the result of errors in surgical judgement or technique. They also make up the majority of cases of revision surgery.

Transverse plane instability gives rise to medial or lateral deviation of the hallux following hemi-implant arthroplasty and is well recognized. The double-stem implant is a fully constrained device but is no substitute for adequate joint reconstruction. The implant may impart some transverse plane stability but should not be relied upon for such. Plastic set deformation can also be observed in double stem devices.

Transverse plane stability of the double-stemmed prosthesis is dependent on its correct alignment (geometrical reaming of the medullary canal) in the frontal plane and avoidance of axial rotation.

Sagittal plane instability may be seen as dorsal or plantar subluxations of the first MPJ. Hallux extensus or dorsal subluxation is more frequently encountered and may occur with either the double-stem or hemi design.

Axial rotation of the hallux is often associated with severe hallux valgus deformity of the first toe and metatarsophalangeal joint. Axial rotation of the hallux will often occur if the intermetatarsal angle has not been addressed.

Adjacent Bone Abnormalities

Aseptic or ischemic necrosis of bone was first reported by Arenson and Weil involving the proximal phalanx. Etiology of this abnormality is believed to be secondary concomitant subperiosteal dissection and reaming of the medullary canal. This most common radiographic abnormality involves the disintegration of the proximal phalanx and its subsequent remodeling. It is our contention that the radiographic abnormality or so-called "engulfment" of the implant results from osseous collapse of the surrounding bone. As repair occurs, the radiographic appearance may be one of complete osseous encapsulation of the implant.

Ectopic bone or bony proliferation at the margins of the resected bone is a very common finding and probably occurs to some extent in every case. This and periarticular fibrosis are probably responsible for limitation of joint motion.

Bone detritus or the presence of particulate foreign material in bone has been noted, particularly with polymers. It has been implicated as causative of chronic inflammatory reactions or an osteitis within the substance of the bone itself.

Bone cysts have been noted with some degree of frequency after hemi silicone arthroplasty. These appear as radiolucencies in the subchondral cancellous bone that progress to definitive osteolytic cavitation within the first metatarsal head. These bone cysts are usually asymptomatic although occasionally pathologic fracture through the articular surface and subchondral bone may occur.

Bony erosion or destruction has also been seen both within the medullary canals of the proximal phalanx and first metatarsal secondary to fibrous replacement. A benign, although at some times quite invasive, fibrous hyperplasia has been noted. This has yielded pathologic fractures as well as ballooning and a soap bubble appearance to the remaining bone. Fibrous hyperplasia has been implicated as a cause of chronic pain in the early postoperative period, i.e., within 6 to 12 months.

Erosions have also been noted at the level of the articular surface with hemi interpositional arthroplasties of the silicone moiety. The articulation of a hemi arthroplasty is one of hyaline cartilage with a foreign surface. Under these circumstances, it is not illogical to expect that the hyaline cartilage that remains would undergo degeneration and sequential pathologic changes. Tracking or erosion of the articular surface by the implant has been demonstrated. Joint disorganization has been noted and the authors feel that this may be the result of disruption of normal joint dynamics in it nutritive role for the articular surface, i.e., "stress-dependent metabolic homeostasis". Cartilage breakdown may thus be a consequence of hemi interpositional arthroplasty. Cartilage breakdown and degenerative changes are believed to be more common with a metallic interpositional device.

Soft Tissue Abnormalities

Pathologic host response in the soft tissue has also occurred with the various implant arthroplasties. The most common of these is reactions to particulate silicone. These can occur in the form of reactive detritic synovitis, foreign body reaction with granuloma formation, and a reactive fibrous hyperplasia. Silicone prostheses when implanted within the body, whether in bone or soft tissue, are followed by encapsulation. Silicone in large pieces usually becomes encapsulated and does not elicit much in the way of inflammatory response by the body.

Microfragmentation of silicone implants has already been identified and may lead to both soft tissue and/or bony pathology. Often little tissue reaction is noted. Problems are encountered in situations where large amounts of debris are produced, e.g., a hemi implant articulating with a degenerated metatarsal head. Large amounts of debris are also associated with implant fractures. In either situation, detritic synovitis or other tissue reaction to the foreign body may occur.

Usually within the implant arthroplasty there is a hypertrophy of the joint capsule due to fibrous hyperplasia, although it is not considered a pathologic event. Occasionally, a significant foreign body reaction and/or soft tissue granuloma may form either intra or extra capsular secondary to particulate debris.

Inflammatory reactions in patients with implant arthroplasty has been noted, although etiologically it could not be contributed to a reaction to silicone. Certainly, infections may originate inflammatory reactions. Postoperative wound infections seen shortly postoperatively have responded to appropriate treatment without the need for removal of the implant. Deep infections usually require removal of the implant to allow drainage of the wound and to avoid chronic osteomyelitis.

Biomechanical Joint Failure

Several biomechanical problems associated with implant arthroplasty or joint replacement procedures have been identified. Some are inherent to the procedure while others may be traced to technical error.

Surgical judgements and indications of usage are a consideration. The surgeon must recognize that implant arthroplasty is a joint destructive procedure. In the younger and more active patient, the surgeon should utilize alternatives to implant arthroplasty whenever possible. Implant arthroplasty improves cosmesis and function of the foot compared to resection arthroplasty, however, even in the best of surgical results, normal biomechanics cannot be attained. There is a disruption of the intrinsic muscle stability of the great toe and dynamic toe purchase. Along with this, the first metatarsal stability is diminished as well as its reciprocal motion between the first metatarsal and the phalanx. Functional elevation of the first metatarsal and resultant lesser metatarsalgia is not uncommon. These are all considered biomechanical inadequacies associated with almost any implant arthroplasty and certainly there are techniques may minimize these problems. Alternative procedures need to be examined for appropriateness to the patient and his functional requirements, e.g., the assembly line worker may require the durability afforded by arthrodesis.

RESULTS

Initial reports showed improved clinical results from the rehabilitative and cosmetic viewpoint although these were based on short-term follow-up. 1974, Albin and Weil reported virtually no

complications in over 1000 cases of hemi implant arthroplasty although the average patient follow-up was only 12.5 months. Their conclusions were based on clinical examination of 50 feet and radiographic examination of 100 feet.

1974, Kalish and McGlamry reported good results in 243 cases of the Swanson hemi-implant utilized for hallux valgus and hallux rigidus. Their conclusions were based on short term observations and they admitted that long term follow-up was necessary to determine the true efficacy of the procedure.

LaPorta et al. 1976, another short term study, they reported significant postoperative improvement in over 90% of the procedures. They major problems encountered were alignment abnormalities which were related to technique. They concluded that the addition of a hemi-implant predictably improves the functional and cosmetic results of the Keller arthroplasty. The vast majority of the procedures were performed for hallux valgus presumably with secondary arthrosis.

Swanson's own reports of his use of the hemi-implant reveal a longer follow-up than the previous studies with the majority of the procedures being performed for rheumatoid arthritis. He also identified several complications not previously reported, for example; nonspecific inflammatory reactions, implant damage, avascular necrosis of the first metatarsal head, and heterotopic bone although the with a very small incidence. Interestingly, Swanson found a few cases of cystic erosion of the first metatarsal head but contributed it to pre-existing pathology, rheumatoid arthritis. Our own findings reveal the greatest incidence of first metatarsal head cysts in patients with degenerative arthritis and good bone stock.

Cracchiolo and Swanson reviewed their combined cases predominantly for rheumatoid arthritis, 133 of the 159 procedures. Two cases of deep sepsis occurred, although pain was completely relieved or diminished in all cases. Interestingly, Swanson's patients show twice the mean degree of dorsiflexion and greater reduction of deformity that those of the senior author. Certainly this illustrates the learning curve and need for attention to the nuances of implant surgery.

One of the most legitimate retrospective studies was conducted by Weil et al. in 1984. They reported on 484 implant procedures in 311 patients with an average follow-up of 3.1 years. Only 18 of the 484 procedures required revision; 3 due to implant failure, 6 infection, and 9 due to persistent pain. This study is of note in that the patient population is older and that each patient presented with joint pain. They reported 70% good to excellent results in 484 patients with an average age of 61 years.

These results compared to Kampner's 12 year experience with the Cutter and Sutter barrel stem designs. 103 implants were placed in 71 patients with a follow-up of 7.4 years, minimum 12 months. He separated cosmesis from pain relief with 70% good to excellent results regarding cosmesis and 80% regarding relief of pain. He did experience 10 fractured implants but these all occurred in implants with the external polyester jacket. After 1978, the Cutter implant was modified with elimination of the jacket, and improvement in the hinge and silicone rubber material.

Over the past 10 years, Vanore, O'Keefe & Pikscher have performed over 1000 implant procedures with approximately 20% implanted with grommets. Our revision rate is less than 2%, and, although the incidence of ectopic bone, malalignment and limited motion are not uncommon, these usually do not require revisionary procedure.

Patient selection is paramount to a successful outcome; alternative procedures should be employed for younger patients and in those with limited arthrosis. This is actually the rationally for abandonment of the hemi implant. Although, it is a more functional device, it should not be utilized in cases of a degenerated or abrasive metatarsal head. In cases of lesser degrees of arthrosis, nondestructive joint reconstruction is clearly the better choice.

Antibiosis and Prophylaxis

Initially, the major fear with regard to postoperative complication was of wound infection. In no report involving any significant number of cases have postoperative wound infections occurred with any frequency. In the series of reports previously mentioned involving over 2000 implant arthroplasties, there is a startling absence of postoperative wound infections.

Even to this date, implant arthroplasty has not shown any increased frequency of infections compared to other surgical procedures of the first

MPJ regardless of antibiotic usage. The 1987 Kern Hospital study revealed an infection rate of 0.38% in 265 cases of isolated implant arthroplasty over a five year period. During this time, prophylactic antibiotics were only administered to 17 patients of the total 265. The rationale was that since the infection rate was so low, only those patients with multiple risk factors received peri-operative antibiosis. The use of a silicone implant alone was considered insufficient.

A deep wound infection is a catastrophic even for an implant arthroplasty. This is probably the major indication for antibiotic prophylaxis. Deep wound infection usually requires removal of the implant and failure of the procedure. Also, the medicolegal implications of elective surgery suggest that all joint implant surgery be covered with peri-operative antibiosis.

It is our general practice to administer prophylactic antibiotics peri-operatively. Our usual preference is cefazolin due to its well documented tissue and bone levels following intravenous administration. One dose 30 minutes preoperatively is probably all that is necessary, although a second dose postoperatively may also be judicious.

The use of wound lavage with dilute antibiotic solution is often used although its efficacy is not well documented. Intraoperative lavage with a good volume of almost any physiologic solution and atraumatic surgical technique are the primary deterrents to potential bacterial colonization.

TOTAL JOINT REPLACEMENT

Total joint systems have been designed as two-component semi-constrained or nonconstrained articulations for the first metatarsophalangeal joint. The former allows for only sagittal plane motion whereas the latter allows motion in more than one plane. Materials used for opposing articular surfaces are chosen for their low coefficient of friction and their minimum wear characteristics. The accepted standard is a cobalt chromium alloy with ultra high molecular weight polyethylene.

With the success of total hip replacements, surgeons keep hoping for an analogous first metatarsophalangeal joint device. One day it may come. Some very prominent surgeons, Johnson and Weil and Smith have designed, placed in clinical trials and then abandoned their implants. The combination of stainless steel with ultra high molecular weight polyethylene has been utilized by Richards and DePuy. These implants were dissimilar in design and yet neither met with the clinical success to warrant general release.

The Intermedics concept was to offer an implant system with a metatarsal and a phalangeal component that could be utilized individually as a hemi arthroplasty or together as a total joint system. This implant also never went beyond usage of the developing surgeon. Some wear products were also noted as black debris although associated with minimal tissue reaction.

A similar attempt was made by Zeichner using component silastic implants; the convex condular implant for the metatarsal and the hemi great toe in the phalanx. Good results were reported in 20 patients, all with a rectus foot type, in this attempt at joint replacement with component devices retaining the patients joint axis. A range of motion exceeding 40 degrees was reported although there was a limited discussion of results nor did a follow-up report appear.

The concept of a total joint system was again revived by Koenig, who modeled after a total joint replacement system for the knee. This involved a two component articulating device with the metatarsal component made of titanium and the phalangeal one of UHMW polyethylene. He reported good initial success although the device was abandoned by the initial manufacturer due to economic infeasibility of manufacturing the metatarsal component of cobalt chromium is usually the material of choice for a bearing total joint system. Theoretically, polyethylene does not wear as well with titanium as with cobalt chromium. As a result, Biomet, now produces this device with a metatarsal component with the surface hardened through bombardment of the titanium articulating surface with ionized nitrogen. As UHMW polyethylene has also been shown to be subject to cold flow, the phalangeal component is available with a titanium backing to reduce the possibility of deformation.

Problems with earlier metal components for the metatarsal involved bone resorption and loosening of the stem due to imposed stresses. The plantar ledge of this design was devised not for weightbearing but for translation of loading forces from the stem and unto the greater portion of the metatarsal.

The Biomet Total Toe System is available for general use although the initial clinical trials were somewhat limited. Koenig did report a mean range of motion of 50 degrees in 18 procedures at 18 months postoperative. He recommends the implant for a wide range of deformities with arthrosis but admits that good alignment and seating of the components is best accomplished in patients with hallux rigidus. (Personal Communication: Richard Koenig, 1990).

The design characteristics of joint replacement systems have varied. The Mayo Clinic design as well as the pyrolitic implant were not much more than convex metatarsal and concave phalangeal buttons. Actually, this has also been attempted using Dow Corning Wright silicone hemi great toe and condylar implants. The Richards implant possessed a dorsal flange in an attempt to allow dorsiflexion of the phalanx on the metatarsal head while the Biomet Total Toe possesses a limited dorsal extension and a longer plantar flange.

CONCLUSIONS

In the past, silicone implant arthroplasty had been viewed more as a joint replacement procedure rather than a augmentation to resection arthroplasty. Much of the literature dealing with silicone arthroplasty and double-stem silicone implants, in particular, had been titled as "joint replacement or a total joint." Possibly the surgeons and subsequently their patients had unrealistic goals and expectations of the surgical procedure. Most importantly, the indications of usage were too broad without consideration of the functional limitations.

Indications have become more limited in an effort to improve results and minimize failures. Implant arthroplasty yields a good frequency of success in cases of first metatarsophalangeal joint reconstruction due to arthrosis. The deformity of hallux valgus, the degenerative conditions of hallux rigidus, and the arthritides, best described by rheumatoid arthritis, are among the most legitimate indications.

Implant arthroplasty is an effective adjunct to resection arthroplasty but does not replace primary joint reconstruction. Joint preservation procedures are always more desirable particularly in the younger patient. Implant arthroplasty does not duplicate a normal joint but usually produces a satisfactory functional alternative.

With appropriate utilization, a high percentage of good results can be expected with a rather small revision rate. Implant arthroplasty is a useful technique of joint reconstruction regardless of the cause of the arthrosis. Implant arthroplasty has proven to be a rewarding procedure for both patient and surgeon. It is a valuable part of the foot surgeon's armamentarium that should not be carelessly applied.

Whenever the joint is reconstructible by osteotomy and/or arthroplasty, the authors recommend alternatives to implant arthroplasty, particularly in the younger patient. Initial reports may have mislead surgeons into believing that implantation regardless of deformity would secure a pain-free postoperative state. In the late 1970s, the lead to over-utilization in cases where the joint should not have been sacrificed. Today, surgeons are aware of the potential for various complications and how to avoid such. Implant arthroplasty revision rates appear comparable to that of other first MPJ procedures.

Advances such as the titanium grommets may increase the life span of the implant arthroplasty and help limit complications. Continued improvements in surgical techniques and development of specialized instrumentation for insertion allow more predictable results among various surgeons.