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FINGER JOINT REPLACEMENT BY SILICONE RUBBER IMPLANTS AND THE CONCEPT OF IMPLANT FIXATION BY ENCAPSULATION

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Advances in surgical techniques during the past 10 years have significantly improved the possibility of restoring hand function in arthritic patients. In the hands of skilled surgeons, synovial resection, restoration of tendon balance, arthrodesis, and resection arthroplasty have been used with reasonable success (Bunnell, 1955; Clayton, 1962; Entin, 1964; Flatt, 1968; Riordan and Fowler, 1958; Laine, Sairanen, and Vainio, 1957; Lipscomb and Henderson, 1961; Swanson, 1961; Vaughan-Jackson, 1962). Attempts to replace joints with metal implants have met with mixed success and limited acceptance, for in most cases the bone has not tolerated the metal. Bone absorption and metal corrosion have negated many of the early good results obtained. However, the concept of prosthetic joint replacement is excellent, since the restoration of early joint motion with stability has obvious advantages over resection arthroplasty or joint fusion (Flatt, 1968).

6 per cent. of the general population suffer from rheumatoid or osteoarthritis and many have disabling hand problems. Also an increasingly large percentage of people in our industrial society suffer from traumatic disabilities of the small joints of the hand which would benefit from reconstruction.

The industrial development of medical-grade materials suitable for use in synthetic replacements has opened up new horizons in reconstructive surgery (Wesolowski, Martinez, and McMahon, 1966). The physician and biological engineer utilizing these advancements have improved the prognosis of what were once considered irretrievable physical disabilities.

Criteria for Joint Implant Replacement

Joint replacement problems revolve around the proper biomechanical design of the implant and the development of the ideal implant material. The criteria for ideal joint implant replacement are:

(1) To maintain joint space.
(2) To allow joint motion with stability.
(3) To be of simple and efficient design.
(4) To provide simple and durable fixation.
(5) To be resistant to stress and deterioration.
(6) To be biologically and mechanically acceptable to the host.
(7) To be easy to manufacture, sterilize, and use.
(8) To facilitate rehabilitation.

Joint resection arthroplasty works well in the hand if the joint space and alignment can be maintained. This frequently requires excessive postoperative fixation with pins and external support. The fixation, if overused, will compromise the expected range of useful motion, and in a considerable number of these cases the joints gradually stiffen and subluxate. Exceptional results do occur, however, and are related to the development of a supportive fibrous joint capsule, organized during the time when a guarded range of motion is allowed. In the finger, the proper amount of flexion-extension, limitation of lateral movement, and reduction of dorsopalmar subluxation is difficult to obtain but necessary for a good result. Therefore, one of the most important functions for a successful implant is to maintain proper joint alignment internally while allowing early motion as this new, functionally adapted, fibrous capsule matures. By continuing to support the important fibrous capsule and acting to keep the joint surfaces apart, the implant further serves its useful purpose early in the postoperative course.

Silicone Rubber Implants

The use of silicone rubber for implants replacing diseased and destroyed joints was suggested by our previous experience in developing an intramedullary-stemmed silicone rubber implant to cushion the end

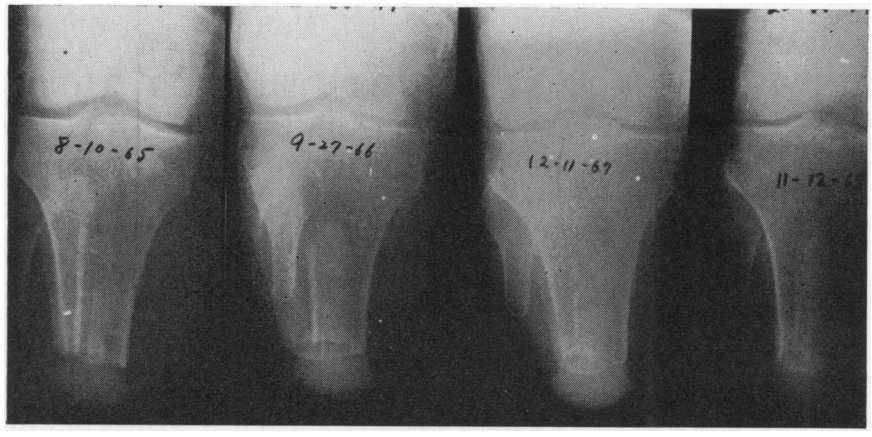

Fig. 36.—Silicone amputation implant in below-knee stump. Active patient uses end-bearing type prosthesis. Demonstrates soft tissue and bone tolerance to implant over a continuing period of activity.

of the long bone in lower extremity amputations (Fig. 36).

6 years' experience in the development of proper implants for joint procedures, utilizing laboratory animals, laboratory fatigue testing of the materials, and clinical evaluation, has shown silicone rubber to have many of the requirement for the ideal implant material (Swanson, 1966).

Silicone rubber is a unique implant material which comes within the family of silicones (Braley, 1965; Roberts, 1967). The silicones are a combination of organic and inorganic materials. By utilizing a chain of silicone and oxygen atoms to which organic groups are attached, the chemist is able to blend the inertness of quartz with the ability of plastics to be fabricated. The silicone rubbers are heat-stable, do not appear to deteriorate with time, and have no adhesive characteristics. They possess good flexion characteristics and force-damping properties, but will tear easily if a laceration occurs in the surface. Correct design of the prosthesis can greatly improve the flexural durability of the silicone rubber implant. Machine testing has shown that a one-piece heat-vulcanized implant has much better wear advantages than a hand-carved or hand-moulded implant. The medical-grade silicones with which we are dealing do not produce tissue reaction when properly sterilized and should not be confused with industrial silicones that have additives which may be toxic.

The implants are made of a heat-vulcanized medical grade silicone elastomer stock (Dow Corning Co. "Silastic") (Fig. 37). They are formed in a mould at approximately 250° F. and under 325 lb. per sq. in. pressure. They are then cured for several hours at an elevated temperature in an air-circulated oven. The silicone elastomer stock from which the implants are manufactured is extremely important. The material of choice must provide adequate implant flexibility and have enough strength to maintain joint stability. Various silicone elastomer stocks were evaluated in the development of a joint replacement implant to determine the stock that would best satisfy the requirements of implant strength and flexibility.

Development of a flexible, heat-moulded joint replacement implant of silicone rubber for metacarpophalangeal arthroplasties in the rheumatoid arthritic hand has proceeded through many changes in design (Fig. 38). The intramedullary-stemmed one-piece design has satisfactorily fulfilled the specified requirements for joint replacement (Swanson, 1966). It provides a degree of stability, and, because of its intrinsic flexibility, can be used as a flexible hinge. It is as biologically inert as any material known and, being softer than bone, it is not so likely to stimulate absorption phenomenon as metal implants. 4 years of testing were involved in the development of this final design (Fig. 39). The present implants have been machine-tested for more

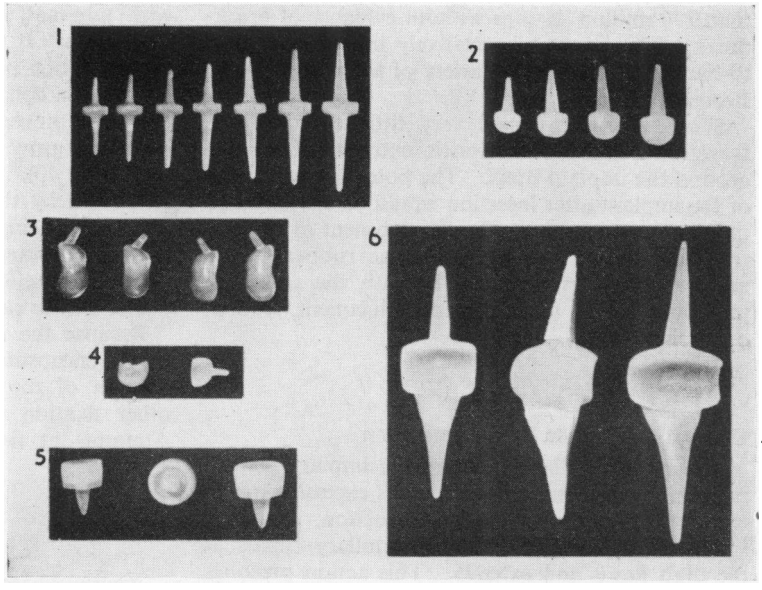

Fig. 37.—Silicone implants:
(1) finger joints,
(2) trapezium,
(3) carpal scaphoid,
(4) carpal lunate,
(5) radial head, (6) elbow.

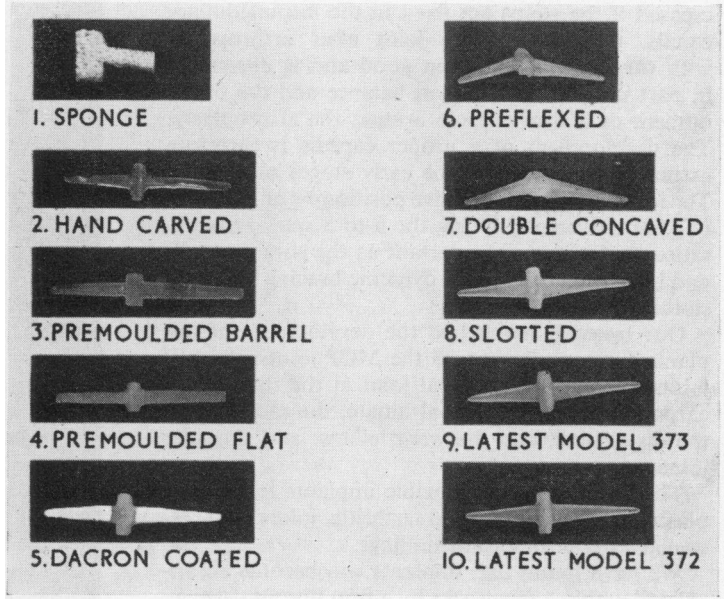

Fig. 38.—Design stage in development of finger joint implant. Heat-moulded one-piece implant of strong, flexible silicone rubber stock has proved successful.

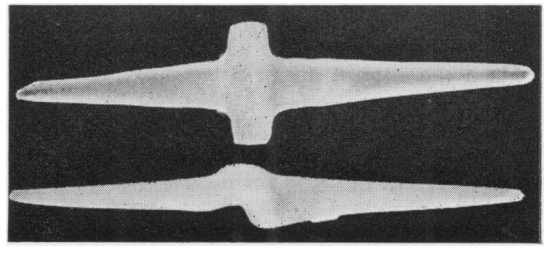

Fig. 39.—Intramedullary-stemmed finger joint implant of best test design.

than 130 million flexions without evidence of breakdown. The implant is relatively inexpensive, easy to handle, is made in a variety of sizes, and can be sterilized by autoclaving.

Silicone rubber causes very little reaction and therefore minimal fibroblastic activity takes place around the implant itself. The potential movement of the implant after insertion would be unrestrained unless protected during the development of the surrounding fibrous capsule. Silicone rubber should not be placed immediately beneath the skin but, preferably, under fat, a protective ligament, tendon, or fascia.

Concept of Fixation by Encapsulation

The intramedullary stems of the implant help to maintain alignment and prevent its excessive movement. The stems have a piston action, to a very small degree, within the intramedullary canals as the digit flexes and extends. This action prolongs the flex life of the implant, which is markedly decreased if the stems are fixed in the intramedullary canals. Stability of the joint after arthroplasty with this implant has been good and is dependent in part upon proper tendon balance and the development of a firm capsule around the arthroplasty. The development of a proper capsule is therefore extremely important in the early stages of healing. The immediate postoperative positioning and control of joint movement during the 6 to 8 week rehabilitation period are as important as the surgery itself, and these are achieved by dynamic bracing and physiotherapy.

Our research has led to the development of implants for replacement of the MCP joints, the PIP joints, the carpometacarpal joint at the thumb, the carpal scaphoid, the carpal lunate, the radial head, the distal ulna, and the wrist, elbow, and shoulder joints.

This 6-year study of flexible implants for arthroplasty, for destroyed and arthritic joints, has revealed several important findings.

We have found that implants will become encapsulated within a few weeks by a firm fibrous capsule. This is true of all implants, for the body always tends to wall off a foreign body. Such encapsulation can be used for the benefit of the patient. We have noted, that if the implant does not move for more than a 1-2 mm. distance, a firm fibrous soft tissue capsule will intimately surround the implant. At the joint level this takes on the character of a ligamentous structure. In the bone the fibrous capsule becomes closely surrounded by new bone formation, which further fixes the intramedullary stem of the implant, with minimal, hypertrophic bone reaction at the bone ends. If the intramedullary stem is not fixed by transfixion pins and if the implant is well seated so that the collar section of the implant at the cut bone end prevents unnecessary play of the implant, bone will grow right up to the implant in a short time (Fig. 40). Within 3 or 4 weeks the implant is well fixed by the surrounding tissues. Postoperative positioning and bracing therefore assume greater importance because of this capsule formation, and an effort has been made to aid this in our postoperative care.

Because the implant becomes so well stabilized by the encapsulation process, it is felt that no other fixation of the implant is required. In fact any other fixation of the implant is contraindicated. Attempts at fixing the implant, with cross pins,

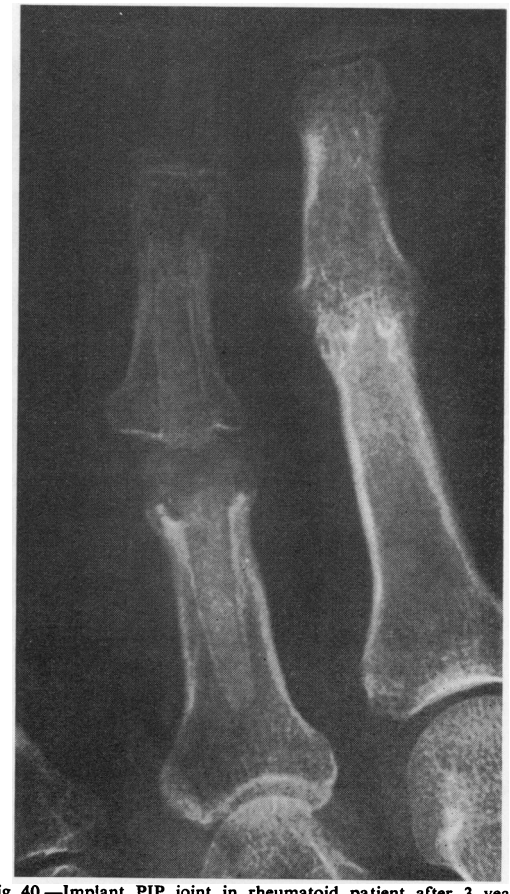

Fig. 40.—Implant PIP joint in rheumatoid patient after 3 years. Note bone production around intramedullary stems.

glueing, or with a Dacron cover on the intramedullary stems, has led to early breakage of the implant at the junction of the stem and central flexible portion. This has also occurred in the laboratory machine tests. It would appear that a slight amount of piston movement of 1 or 2 mm. actually improves the life of the implant. Forces which are developed around the implant on flexion and extension are not concentrated in one particular area and are spread over a broader section when a little movement is allowed to occur. Stability of the arthroplasty for both correction of ulnar drift and palmar subluxation have not been a problem in the many cases reviewed. As long as the postoperative positioning maintains the corrected position, there have been no significant recurrences of deformity. Rotation of the index finger which frequently occurs in the rheumatoid hand can also be prevented in the early postoperative phase by using a dynamic brace. It should be emphasized that other surgical procedures are as important in implant arthroplasties as in any arthroplasty.

Preparation of the Implant

Medical-grade silicone elastomers are extremely inert, but if contaminated by lint, fingerprints, and other foreign materials they can cause a foreign body reaction. It is therefore important that the implant be thoroughly cleaned before sterilization. The material is heat-resistant and can be autoclaved; but every effort should be made to eliminate the chances of contamination with other foreign bodies throughout the entire procedure. The implants should be handled with instruments rather than gloves. The following cleaning and sterilization procedure is recommended if the implants become contaminated or are not sterilized before packaging:

(1) Boil the implants with distilled water and a non-oily mild soap for 20 min.

(2) Rinse thoroughly in distilled water.

(3) Wrap in a lint-free cloth or place on a clean open tray and autoclave by one of the following methods:
   (*a*) high-speed instrument sterilizer—3 min. at 270° F.;
   (*b*) standard gravity sterilizer—30 min. at 250° F ;
   (*c*) pre-vacuum high-temperature sterilizer—normal cycle at 250° F.

Clinical Application

Arthroplasty in reconstructive surgery of the upper limb requires consideration of the following general indications for any implant arthroplasty;

(1) Good condition of the patient;
(2) Good neurovascular status;
(3) Adequate skin cover;
(4) Possibility of a functional muscle-tendon system;
(5) Availability of good postoperative therapy;
(6) A co-operative patient.

Metacarpophalangeal Joint

Indications for MCP joint implant arthroplasty have been:

(1) Fixed or stiff MCP joints;
(2) *x*-ray evidence of joint destruction or subluxation;
(3) Ulnar drift, not correctable by work on soft tissues alone;
(4) Contracted intrinsic and extrinsic musculature;
(5) Associated stiff interphalangeal joints.

SURGICAL PROCEDURE.—The technique described is for a typical rheumatoid hand (Fig. 41 *a* and *b*, overleaf).

A long transverse incision is made on the dorsum of the hand over the metacarpophalangeal joints. Dissection is carried down through the subcutaneous tissue to expose the hoods of the extensor tendons. Care should be taken not to injure the dorsal neurovascular structures, which can be easily retracted into the interdigital space during the procedure. The radial portion of the extensor hood is usually stretched out and the extensor tendons dislocated ulnarwards. Longitudinal incisions are made in the extensor hood parallel to the extensor tendons as far as possible and one-half the distance between the tendon and radial edge of the extensor hood (Fig. 42, overleaf).

The hood fibres are carefully dissected from the underlying synovium, and as much synovium as possible is removed. When joint destruction is enough to warrant a resection arthroplasty, the metacarpal head is removed at the neck with bone-cutting forceps (Fig. 43, overleaf).

No bony resection is performed from the proximal phalanx except for marginal osteophytes which might hinder the joint motion. Joint contractions should be completely released. The release of the volar plate is usually required for volar dislocation of the proximal phalanx.

The shortened ulnar intrinsic muscles are transected at the metacarpophalangeal level to correct or prevent ulnar deviation of the joints. The previously opened intramedullary canal of the metacarpal is reamed out with a curette or broach to facilitate insertion of the implant. In rare instances, the canal is too small to accept an implant of reasonable size and a pneumatic or other bone drill

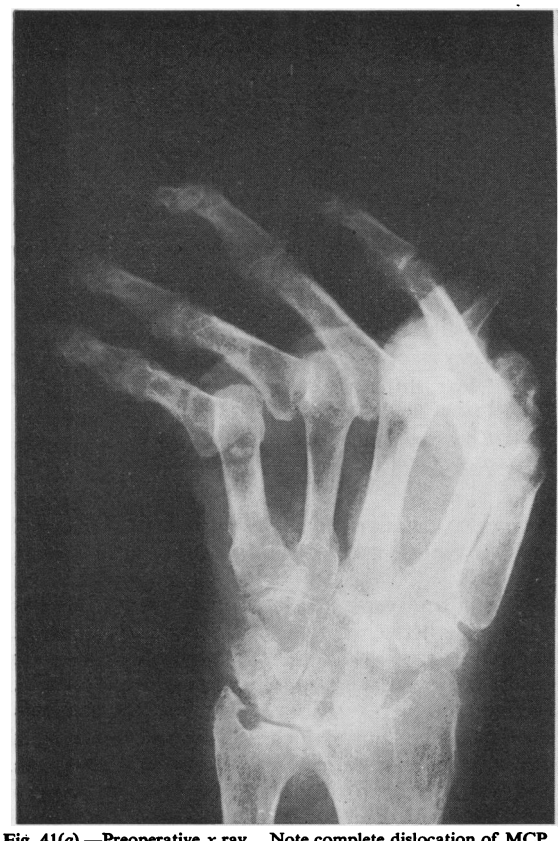

Fig. 41(*a*).—Preoperative *x* ray. Note complete dislocation of MCP joints.

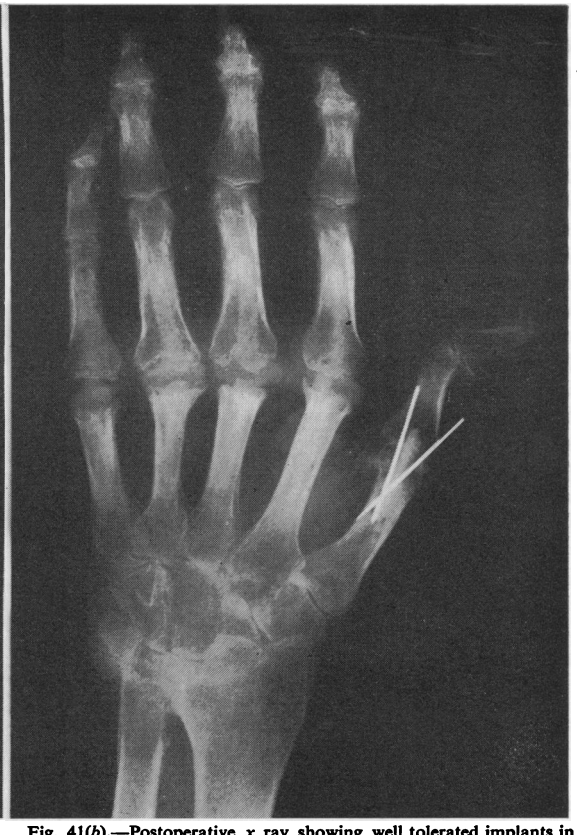

Fig. 41(*b*).—Postoperative *x* ray showing well tolerated implants in four MCP joints and fusion of thumb joint.

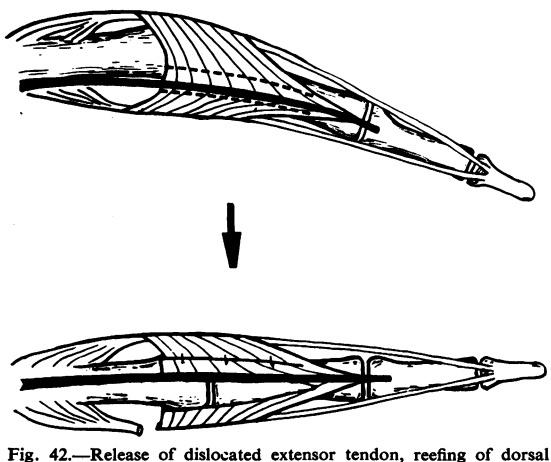

Fig. 42.—Release of dislocated extensor tendon, reefing of dorsal hood on radial side, incised ulnar intrinsics.

may then be used to enlarge it. A rectangular hole is made in the joint surface of the proximal phalanx with an osteotome or a knife and the intramedullary canal reamed in the same fashion as for the metacarpal. After making sure that the synovial tissue has been completely removed and the joints well reduced, the silicone finger joint implants are inserted. The following are important:

(1) Select the largest implant that the bones can accommodate;

(2) Rinse the implant thoroughly with saline solution before application;

(3) Handle the implant with a blunt instrument to avoid traumatizing the implant and contamination with other foreign bodies.

Reshaping of the implant should be avoided because any modification might create mechanical weakness, but shortening of the stem is permissible.

The proximal stem of the implant is first inserted into the metacarpal intramedullary canal and then the distal stem is flexed and guided into the proximal phalanx with the joint flexed and pulled distally (Fig. 44 *a* and *b*). The previously incised extensor

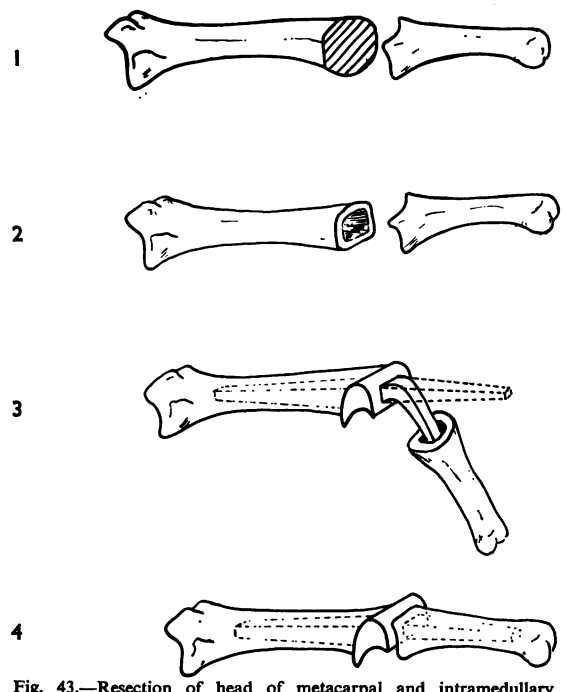

Fig. 43.—Resection of head of metacarpal and intramedullary insertion of stems of implant. The largest implant that can be well seated should be used.

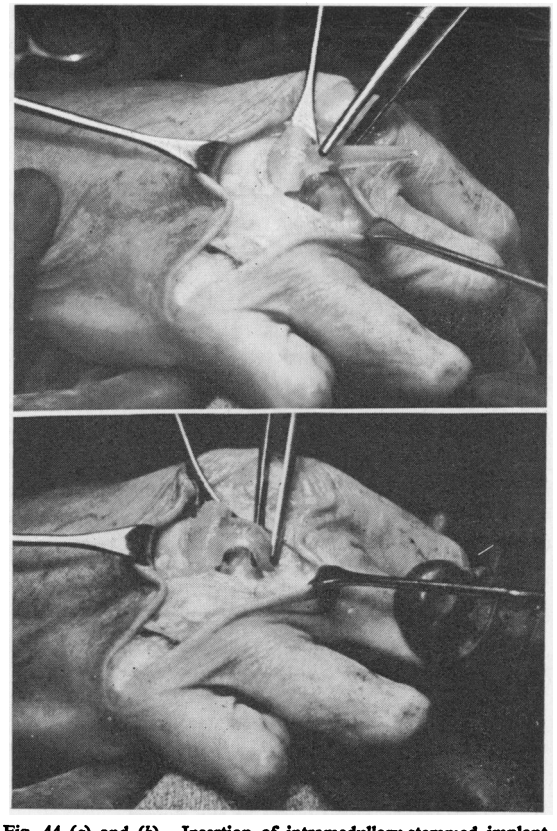

Fig. 44 (*a*) and (*b*).—Insertion of intramedullary-stemmed implant into MCP joint.

hood is sutured back in an overlapping fashion to relocate the extensor tendon slightly radially from the midline. The skin is closed and a small silicone rubber drain is left in place in the wound. A voluminous dressing is applied using fluffed out Dacron gauze, a conforming bandage, and an anterior plaster splint.

When the MCP joint of the thumb is involved, fusion of the joint is recommended, provided the carpometacarpal joint is adequate, because the MCP joint requires good lateral stability in a power pinch. When indicated, other operative procedures are added to the MCP joint arthroplasty. These include repair of tendons, correction of PIP joint deformities, synovectomy of the wrist joint with resection of the distal end of the ulna and Lister's tubercle, and radial head resection. The surgical time is also used to operate on other affected joints by another team or to inject joints with hydrocortisone and "Thio-tepa".

Thirty patients (52 hands), 4 male and 26 female, all suffering from severe rheumatoid arthritis, have had MCP joint implant arthroplasties in the past 4 years, with 196 implants inserted. Three patients required re-operation for fracture of prototype implants. All of the patients have subsequently had greatly improved functional and cosmetic appearance, with apparently good acceptance of the implant by the host tissues. The results impress us as far superior to our previous experience with other techniques of joint arthroplasty in the rheumatoid patient.

Proximal Interphalangeal Joint

Indications for PIP joint implant arthroplasty have been:

(1) The desire or need for mobility;
(2) The possibility of adequate tendon balance;
(3) An inadequate MCP joint.

Twelve patients, seven male and five female, have had PIP arthroplasties using 24 silicone rubber intramedullary-stemmed implants. Eight were for rheumatoid arthritis and four for trauma. If a

good extensor tendon mechanism was present, or was provided at operation, good functional results were usual with up to 75 per cent. of normal motion, good stability, and good acceptance of the implant by the host tissue.

PROCEDURE.—A lateral incision on the ulnar side or an S-curved incision over the dorsum is made and the extensor apparatus and joint are exposed. Every effort should be made to keep the extensor mechanism intact, especially the central slip (Tubiana and Valentin, 1964). If necessary, the extensor mechanism must be reconstructed. Whenever possible, the collateral ligaments, especially the radial one, are preserved. Bone resection and insertion of the implant are performed in the same fashion as for the metacarpophalangeal joints. Size 1, 2, and 3 implants are usually used for the joint. A brace is worn postoperatively to allow motion of the joint only in the flexion-extension plane.

Carpometacarpal Joint of the Thumb

Indications for trapezium implant arthroplasty are:

(1) Pain and/or internal derangement;
(2) Arthritic changes on *x* ray;
(3) Resistance to conservative measures;
(4) Inadequate distal joints of the thumb.

Eight patients have had resection of the trapezium and replacement with an intramedullary-stemmed, mushroom-shaped implant. The intramedullary stem is introduced into the shaft of the first metacarpal with the rounded head extending into the space previously occupied by the trapezium. Eight patients with disabling rheumatoid or osteoarthritic carpometacarpal joints of the thumb have had excellent functional results with essentially normal motion, good strength, and no apparent untoward reaction within the two years of follow-up.

PROCEDURE.—Either a radial or palmar approach is used. The access to the joint is easy, but care should be taken not to injure branches of the radial artery or nerve and to preserve as much of the joint capsule as possible. The trapezium is excised either *en bloc* or piecemeal and the trapezium implant is inserted with its stem inserted into the first metacarpal. The incised capsule should be sutured back tightly to prevent displacement of the implant. A short arm cast holding the thumb in palmar abduction is worn for 4 to 6 weeks postoperatively.

Carpal Scaphoid

Indications for carpal scaphoid implant arthroplasty are:

(1) Disabling pain and/or decreased function;
(2) Localized osteoarthritic changes;
(3) Non-union with a small proximal fragment;
(4) Aseptic necrosis;
(5) Resistance to conservative measures.

Implants of appropriate sizes have been designed for carpal scaphoid replacement. Patients have undergone surgery with satisfactory results, although it is too early for a final evaluation.

Implants of appropriate sizes have also been designed for the carpal lunate. Indications for this procedure are essentially the same as for carpal scaphoid implant arthroplasty.

Splinting

Postoperative splinting of the MCP joint implant must provide for alternating flexion-extension movement and maintenance of a full range of joint motion (Fig. 45 *a* and *b*). It is important to develop a tight capsule on the radial side to prevent any further tendency toward ulnar deviation, as well as to give stability in pinch adaptations. A simple adjustable brace (The Pope Brace Foundation, Kankakee, Illinois) can be fitted on the patient as soon as the postoperative swelling and discomfort have decreased, usually in 3 to 5 days. The extension portion of the brace is worn night and day for 3 weeks. In the following 3 weeks, the extension portion is alternated with the flexion portion during the day, and the extension portion is worn at night. Then, depending upon joint flexibility and maintenance of position, the brace is discarded or worn only occasionally to maintain the position of the fingers.

Bracing of the PIP joint must also provide alternating movement in the flexion-extension arc without allowing lateral movement. A simple, inexpensive brace that the patient understands must be provided to hold the finger both in extension and in increasing degrees of flexion. The use of this bracing has been found to be simple and acceptable to patients in our practice. It should be emphasized that the postoperative care of these patients must be maintained by the surgeon concerned and not delegated to another.

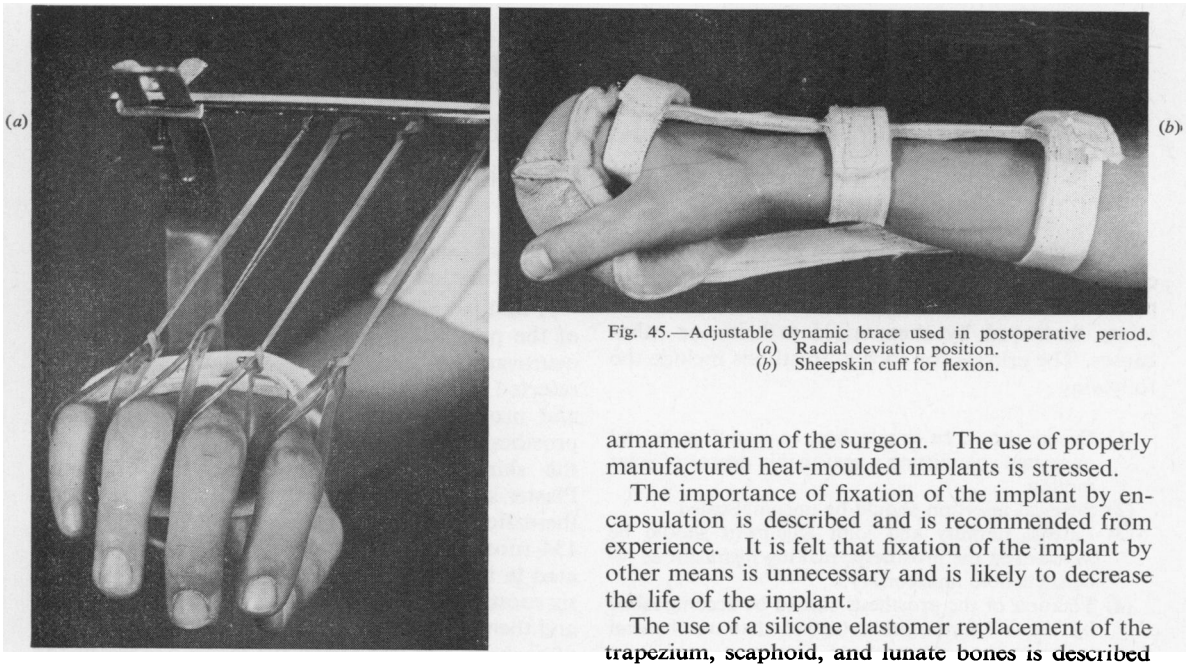

Fig. 45.—Adjustable dynamic brace used in postoperative period.
(*a*) Radial deviation position.
(*b*) Sheepskin cuff for flexion.

armamentarium of the surgeon. The use of properly manufactured heat-moulded implants is stressed.

The importance of fixation of the implant by encapsulation is described and is recommended from experience. It is felt that fixation of the implant by other means is unnecessary and is likely to decrease the life of the implant.

The use of a silicone elastomer replacement of the trapezium, scaphoid, and lunate bones is described and recommended for patients who are suffering from painful arthritis of these joints.

These implants are undergoing clinical trial in 150 hand surgical clinics around the world. Their final place in reconstructive surgery will have to await a later comprehensive statistical evaluation.

Summary

The development and use of Silastic silicone elastomer for flexible intramedullary-stemmed implants for arthritis or destroyed MCP or PIP joints can be recommended as an excellent addition to the