stryker

SR PIP System
Proximal Interphalangeal Arthroplasty

Operative technique

SR PIP System
Proximal Interphalangeal Arthroplasty

Contents

This publication sets forth detailed recommended procedures for using Stryker devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to performing your first surgery.

All non-sterile devices must be cleaned and sterilized before use. Multicomponent instruments must be disassembled for cleaning. Please refer to the corresponding assembly / disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling (Instruments and Sizers V15106).

See package insert (Instructions for Use V15110) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

⚠ CAUTION

Unless otherwise specified, the Stryker GmbH nonactive devices have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the non-active implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Introduction

The prosthesis has two components, proximal and distal. There are five sizes that come with metal trial components and a full instrumentation set-up. The latter includes awls, rasps, sizers, inserters and extractors.

Proximal phalanx component (proximal component)

The proximal component is a metallic CoCr alloy with a symmetric shallow bicondylar anatomic configuration for the articular surface. The stock material behind the thin convex surface has been removed except for the stem attachment in order to preserve as much bony support for the device as possible.

The stem has been designed to fit the internal contours of the intramedullary cavity. This was done by reference to sagittal and coronal milled sections from fixed anatomic specimens. Sizes were based on anthropologic values.

Middle phalanx component (distal component)

The distal component is fabricated from ultra high molecular weight polyethylene (UHMWPE) and titanium. A metal backing is applied to the UHMWPE component. The articular surface is congruent with the surface of the proximal component. The integral stem has a cross-section compatible with the intramedullary cavity of the middle phalanx. This was done by reference to sagittal and coronal milled sections from fixed anatomic specimens. Sizes were based on anthropologic values.

Proximal interphalangeal joint replacement arthroplasty is designed to replace the articular surfaces of the head of the proximal phalanx and base of the middle phalanx in fingers.

Although lateral stability is a complex function of the chevron morphology of the joint condyles, the lateral bands of the extensor apparatus and other soft tissues, the primary constraint is largely dependent on the collateral ligaments. The prostheses are designed to minimize bone removal and thereby preserve, as much as possible, the ligamentous attachments.

Indications and contraindications

Indications

The SR PIP System is indicated for use in Arthroplasty of the PIP joint when either the:

- Patient is in need of a revision of failed PIP prosthesis(es); or
- Patient expects to place his / her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic arthritic PIP joint

Contraindications

- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis
- Skeletal Immaturity
- Infection

⚠ CAUTION

Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.

Humanitarian use device
The SR PIP System is authorized by Federal law for use in the arthroplasty of the PIP joint when either the:

- Patient is in need of a revision of a failed PIP Prosthesis(es) or
- Patient expects to place his / her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritic and post-traumatic arthritic PIP Joint

The effectiveness of this device for this use has not been demonstrated. Please see package insert for Adverse Effects and other essential product information.

Warnings

(See also the Patient Counseling Information in the instructions for use.)

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.
- Single use is defined as use of one implant or instrument on a single patient in a single surgical procedure.
- Reuse of instruments designated as single use has been associated with necrosis of bone leading to implant failure. It may also lead to sepsis and / or communication of potentially lethal viruses.
- Reuse of implants designated as single use has been associated with sepsis and / or communication of potentially lethal viruses.

Precautions

- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is quesitoned for any reason, the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting, or nicking the device.

Unless otherwise specified, the Stryker GmbH non-active devices have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the non-active implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Preoperative assessment & anatomy

X-Ray examination should include a carefully positioned PA of the hand as well as a true isolated lateral of the involved finger(s) (Fig. A & B). This allows a careful evaluation of the status of the joint. It is helpful to classify the degree of deformity of the joint in osteoarthritis and post traumatic arthritis as:

- 50% or < joint space narrowing
- >50% narrowing and erosions
- Bone stock loss, erosions and hypertrophic spurs
- The above plus subluxation, angulation and increased deformity

Particular attention should be paid to the dorsal rim, height of the base and status of the intramedullary cavity of the middle phalanx as alterations of these may determine the balance and stability of the joint.

It is also important to know the status of the soft tissues around the joint particularly in the latter condition. This should include adequacy of the skin and subcutaneous fat, the components of the extensor mechanism, the flexor tendons, palmar plate and collateral ligaments. Postoperative motion of the joint will be dependent on the gliding properties of these elements.

Final determination of prosthesis size will depend on the fit of the trial prostheses during surgery.

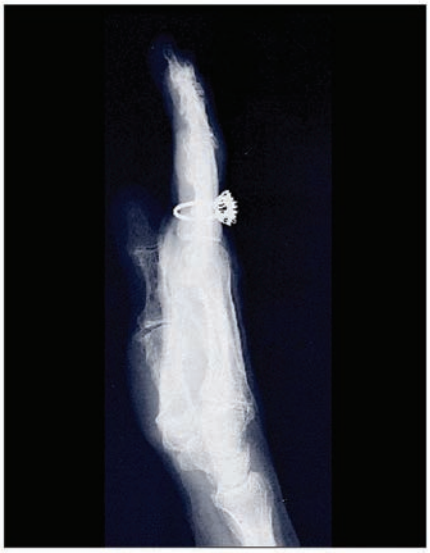

Fig. A

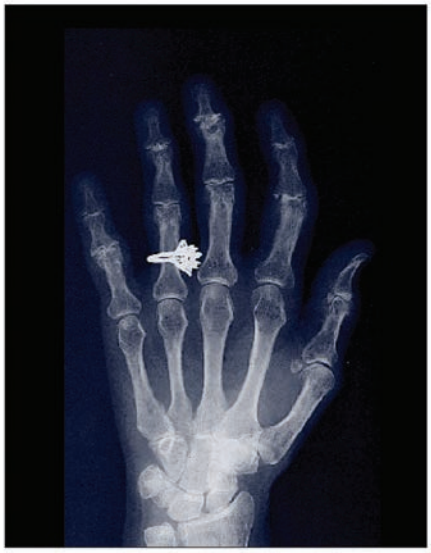

Fig. B

⚠ WARNING

If there is insufficient bone stock, inadequate intramedullary space, marked soft tissue compromise, chronic infection or similar problems, this arthroplasty may be contraindicated. If failure of the arthroplasty occurs, arthrodesis, fibrous arthroplasty or disarticulation may be necessary.

Operative technique
Dorsal approach

Dorsal longitudinal incision

The procedure for a single finger may be performed with an axillary tourniquet under general anesthesia, Bier block, axillary block or metacarpal block and a finger tourniquet. Adequate precaution to avoid excessive tourniquet pressure is mandatory. Multiple fingers are best done under axillary block or general anesthesia.

The PIP joint may be approached from a dorsal, lateral or palmar aspect; but a dorsal longitudinal incision is preferred in most instances because of the improved exposure and ease of insertion of the prosthetic devices. The central slip may be incised centrally, dissected from the dorsal rim of the middle phalanx and each side reflected with its lateral band for the easiest exposure. However, repair of the central slip is less easily obtained due to the bony resection and fragility of the tendon.

Therefore the following technique is currently favored. A straight or curving incision is made over the dorsum of the PIP joint to expose the extensor apparatus (Fig. 1).

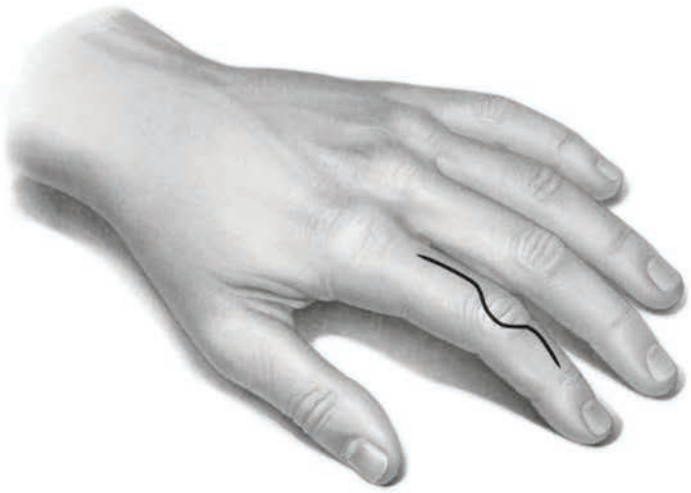

Fig. 1

Capsular exposure

The central slip is isolated proximal to the dorsal rim of the middle phalanx for one to two centimeters, cut transversely and then reflected distally. This allows exposure for resection of the articular surfaces of the head of the proximal phalanx and the base of the middle phalanx (Fig. 2).

An alternate incision is to reflect either side of the extensor apparatus through a mid-line splitting incision. This requires a repair of the central slip insertion during closure (see page 11).

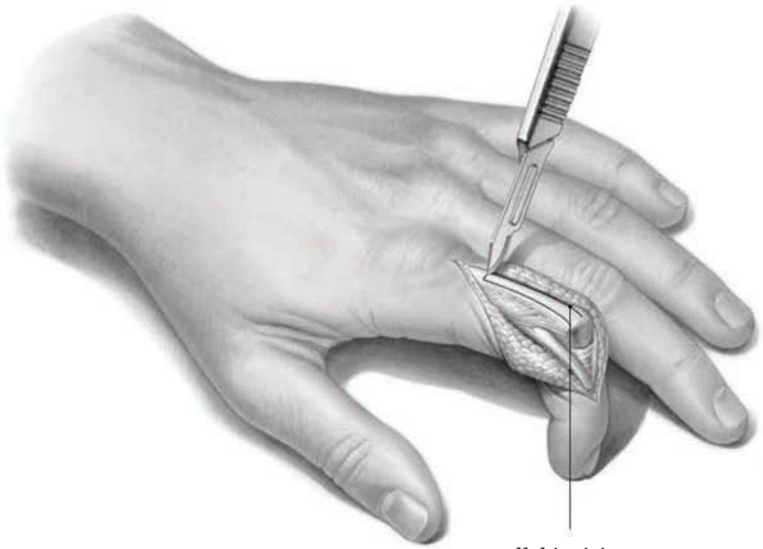

Fig. 2

Parallel incisions on either side of central slip

Operative technique
Dorsal approach

Exposing the joint

After exposure, the joint is partially flexed and the proximal attachments of the collateral ligaments are partially undercut with a #64 Beaver blade to better expose the articular surface of the head of the proximal phalanx (Fig. 3).

Proximal phalanx resection

A small powered saw is then used to remove the distal 2 to 3mm of the proximal phalanx.

The collateral ligaments are protected as much as possible (Fig. 4).

Volar and middle phalanx resection

The first cut is vertical removing the distal articular surface (Fig. 5). A second oblique cut is made to remove the volar protuberances of the articular condyles of the proximal phalanx. Third, with insertion of the central slip retracted distally, a thin slice of the articular surface of the base of the middle phalanx is then removed.

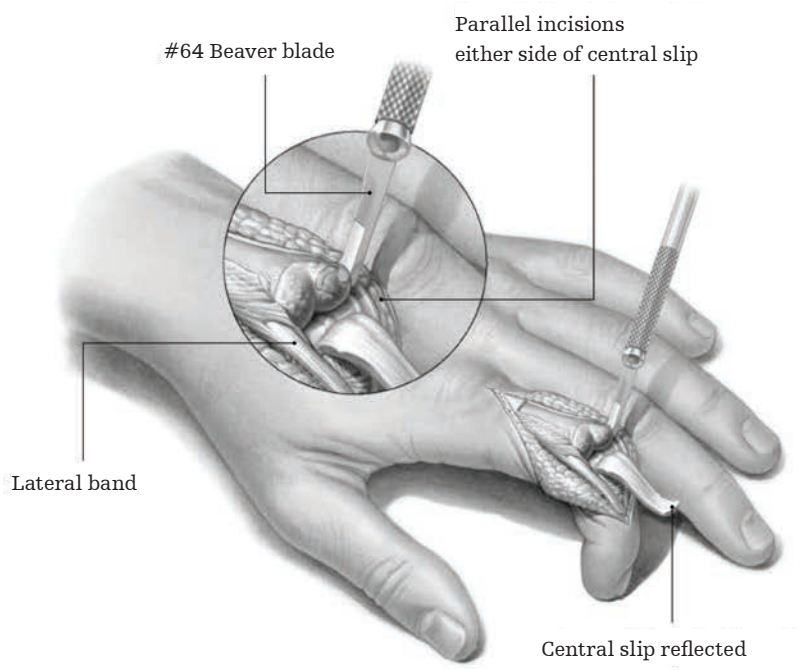

Fig. 3

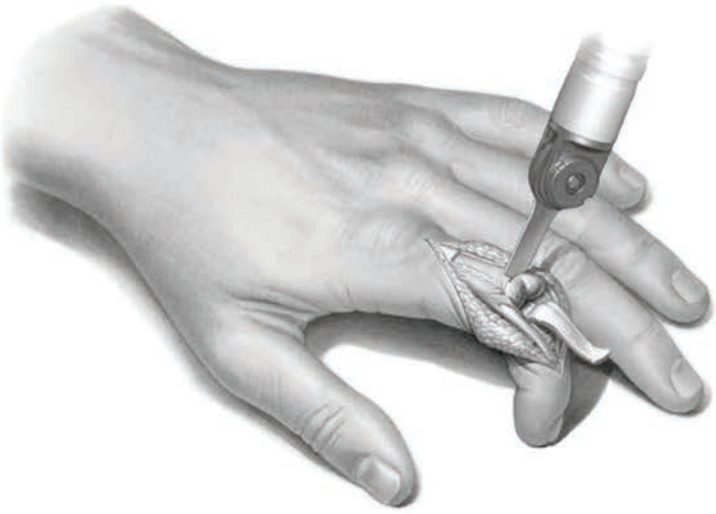

Fig. 4

Fig. 5

Operative technique
Dorsal approach

Proximal trial preparation

The intramedullary cavity is opened with a small awl (Fig. 6A).

A powered burr may be necessary to clear the entrance to the medullary cavity (Fig. 6B).

The hole is then enlarged with custom reamers to adjust the intramedullary contours for a proper fit of the trial component (Fig. 6C).

Fig. 6A

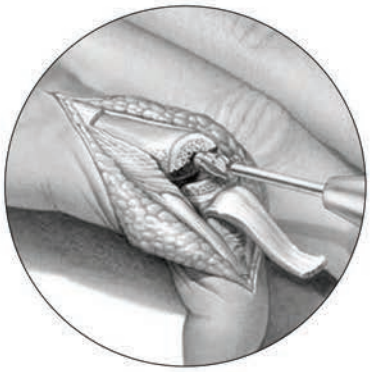

Fig. 6B

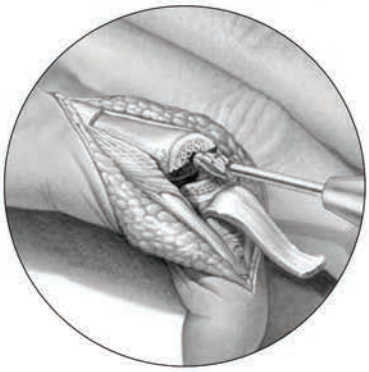

Fig. 6C

Proximal trial placement

A proximal trial prosthesis is introduced and reduced with the plastic impactor (Fig. 7). Secondary adjustments with the rasp and burr are often necessary to achieve a congruent alignment. Alignment and position are checked under the image intensifier.

An extractor may be used to remove both the proximal and distal trials. Extraction holes are on the lateral side of the trial.

Care should be taken not to apply excessive force or twisting of the trial which may cause the canal to widen thus minimizing the ability to obtain a press fit.

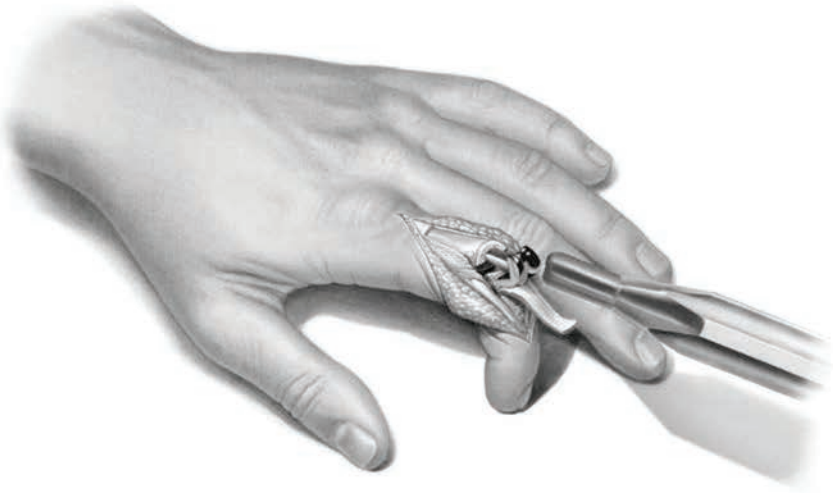

Fig. 7

Operative technique
Dorsal approach

Middle phalanx trial preparation

The intramedullary cavity of the middle phalanx is prepared in the same manner as that of the proximal phalanx.

The central slip may be retracted with a mosquito clamp or suture during the rasping (Fig. 8). The proximal trial component is removed to provide access for the rasp.

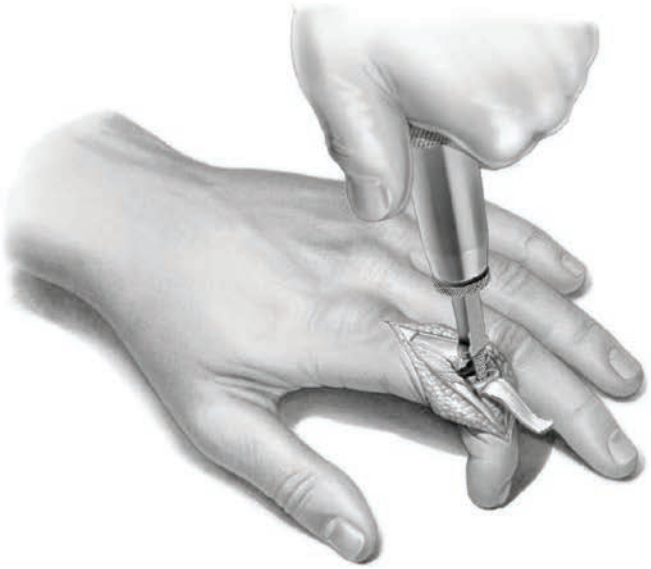

Fig. 8

Middle phalanx trial placement

The distal trial prosthesis is then inserted and reduced with the plastic impactor. The proximal trial prosthesis is then reinserted and a trial reduction of the joint made. Revision may be necessary until the base of the articular component fits flush against the cortical rim of the middle phalangeal base (Fig. 9).

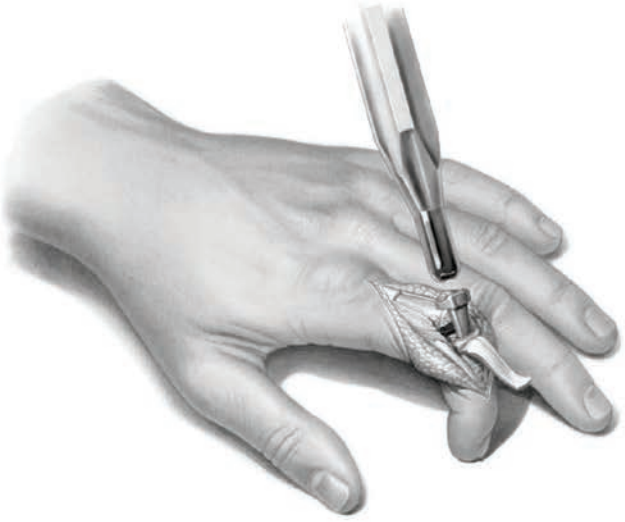

Fig. 9

Trial reduction

With both trial prosthetic components inserted, the finger should flex passively with ease but have minimal lateral play or laxity with distraction. The flexion should allow the finger tip to approximate its usual contact area on the thenar surface of the palm. The finger should extend fully with proximal tension applied to the central slip. Position and alignment are again checked under the image intensifier (Fig. 10).

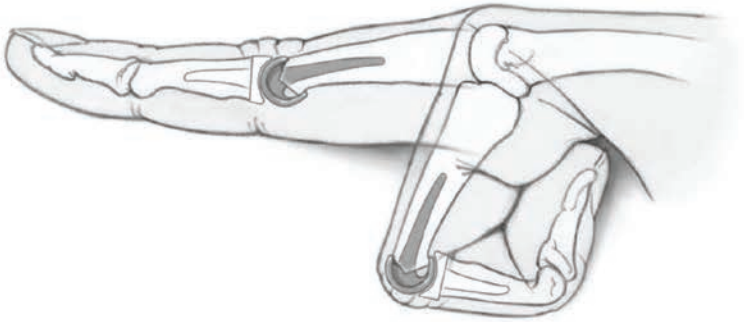

Fig. 10

Operative technique
Dorsal approach

Trial removal and implant preparation

The extractor is used to remove the trial prosthetic components during the adjustment stages (Fig. 11A).

The bony canals are irrigated first with cooled saline and then a prophylactic 0.5% neomycin solution. The intramedullary cavities are then vacuum dried by inserting a small tipped suction cannula. Polymethyl Methacrylate (PMMA) cement is then injected through a shortened #14 Intracath into the medullary cavities using a small syringe (Fig. 11B). The implants are seated and their positions checked with image intensification. The finger is again cooled with saline irrigation during curing of the cement. The tourniquet may be released when the cement begins to set.

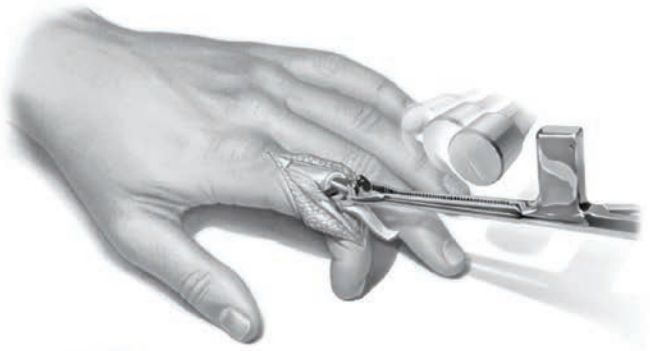

Fig. 11A

Fig. 11B

Closure

After the cement is set, the extensor apparatus is repaired. The extensor apparatus is fragile in this area and should not be strangled or torn with excessive suture material. The length of the reflected central slip should be adjusted to balance the PIP and DIP joint angles.

A row of 4.0 or 5.0 nonabsorbable sutures is applied narrowly to the adjacent portion of the extensor apparatus on either side so as not to adversely affect mobility of the lateral bands. Repair of the extensor with multiple fine sutures allows commencement of earlier joint motion with less risk of extensor lag developing (Fig. 12A). The skin is closed with nonabsorbable sutures (Fig. 12B) and a splint reinforced dressing is applied with the finger extended.

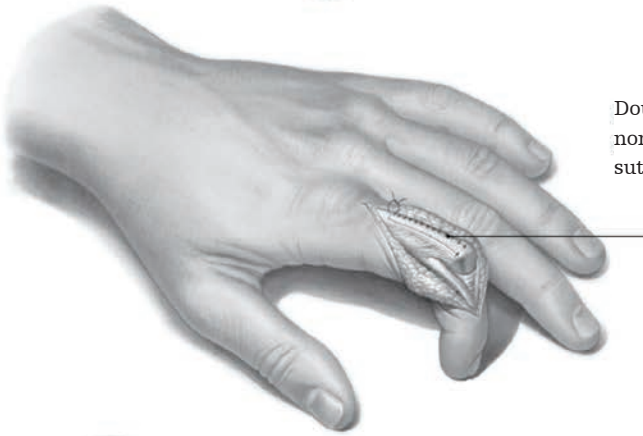

Fig. 12A

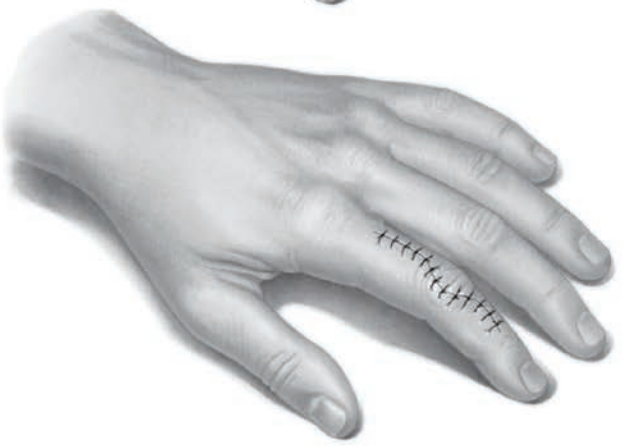

Fig. 12B

Operative technique
Dorsal approach

Alternate closure

Two drill holes are made at the dorsal cortex of the base of the middle phalanx. A 3.0 or 4.0 nonabsorbable suture is passed through the drill holes prior to cementing the distal component (Fig. 13A).

The finger is then extended and the suture is passed through the thickened aspect of the central slip (Fig. 13B). With full extension, the suture is tied with minimal tension.

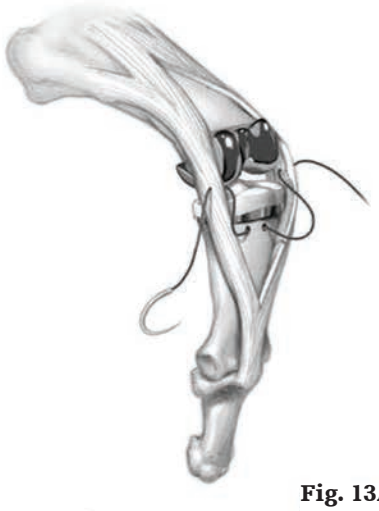

Fig. 13A

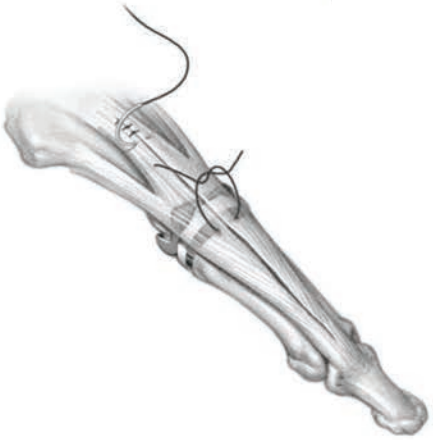

Fig. 13B

Post-operative care: Dorsal approach

Post-operatively the PIP joint is held in neutral extension for one to seven days depending on the immediate status of the soft tissues. The DIP joint may be flexed independently as soon as the patient is capable. This allows excursion of the lateral bands to help prevent adhesions. If the integrity of the extensor reconstruction was well done, early motion of the PIP joint may help lessen extensor adhesions and gain joint excursion. If the finger is swollen, elastic wraps to reduce edema during rest periods may be helpful. Exercises and splinting are best started under supervision of a hand physiatrist or therapist.

Exercises of the DIP joint may begin immediately if the PIP joint is suitably constrained. PIP exercises may be begun gradually at two to seven days. A dynamic splint is often helpful in the early phases of rehabilitation (Fig. 14). This may prevent hyperextension at the PIP joint with a static extension block, but provide an elastic sling to help return the finger to neutral after the joint has been flexed. The dynamic splint may be discontinued when extension is assured, but a nocturnal and rest static splint for protection should be used for several weeks.

Exercise periods of 5-10 minutes 5-6 times per day may be gradually increased as tolerated. Return of the joint to neutral after each flex is encouraged. If an extension lag increases, static splinting back into extension for an additional 2-4 weeks may allow the central slip mechanism to recover its function. Passive motion is seldom indicated and is to be discouraged until 6 weeks postoperatively. Ideally a range of 0° to 90° is sought however, if a stable pain free 60° arc of motion is obtained, the result is considered good.

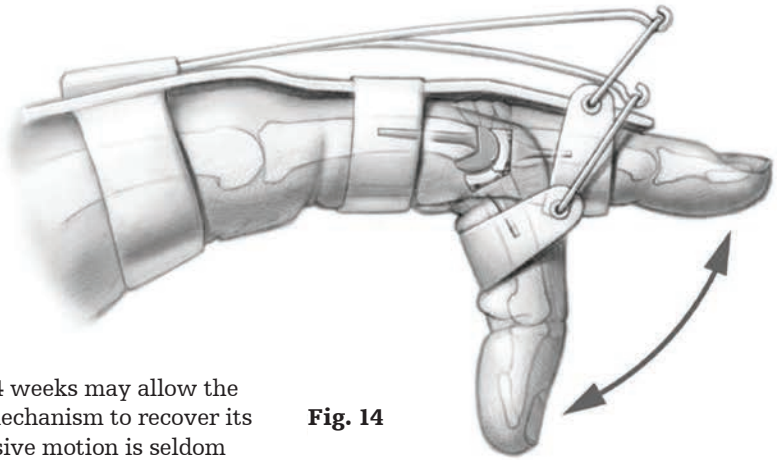

Fig. 14

Operative technique
Palmar approach

Palmar approach and incision

On some occasions such as a hyperextension posture of the finger (swan neck deformity) a palmar approach may be elected. The skin is incised in a zig-zag fashion (Brunner incision) (Fig. 1).

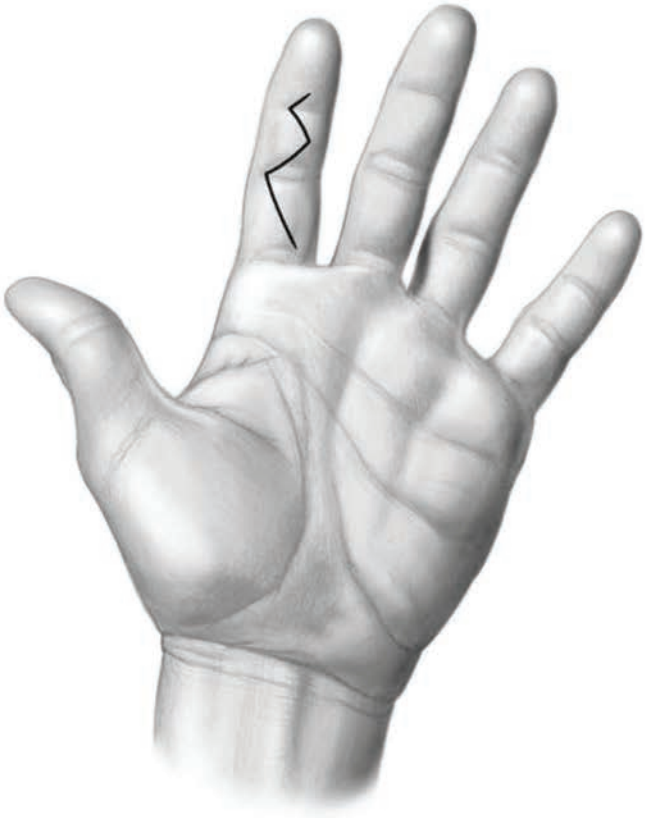

Fig. 1

Capsular exposure

The flexor tendon sheath is first exposed (Fig. 2A).The flexor tendon, together with the palmar plate, may be released from the distal aspect of the proximal phalanx, the accessory and proper collateral ligaments and the base of the middle phalanx on one side; so that it may be reflected laterally (Fig. 2B). Alternately, a partial release of the flexor tendon sheath containing the C1, A3 and C2 pulleys at the PIP level is performed to allow lateral retraction of the flexor tendons. Then the palmar plate is released from the volar rim of the middle phalanx and retracted.

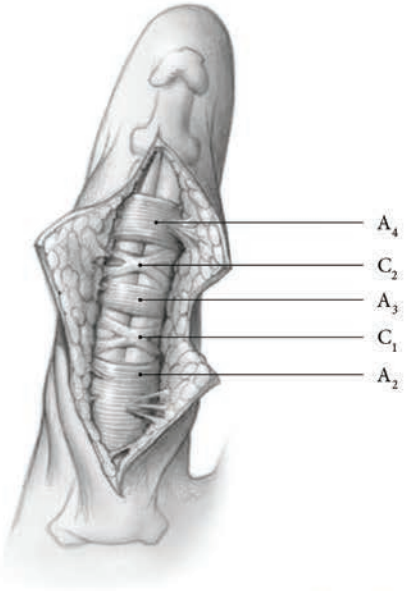

Fig. 2A

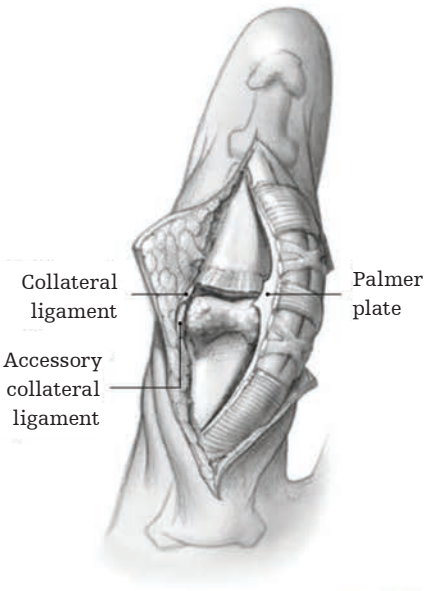

Fig. 2B

Operative technique
Palmar approach

Surface resections

The articular surfaces are removed in reverse order from the dorsal approach. The proximal phalangeal condyles are removed with a 45° angled cut, and the remaining dorsal aspect of the articular surface with a vertical cut.

The base of the middle phalanx is also removed with a vertical cut. This is done carefully so as to preserve the insertion of the central slip which lies dorsally (Fig. 3A and 3B).

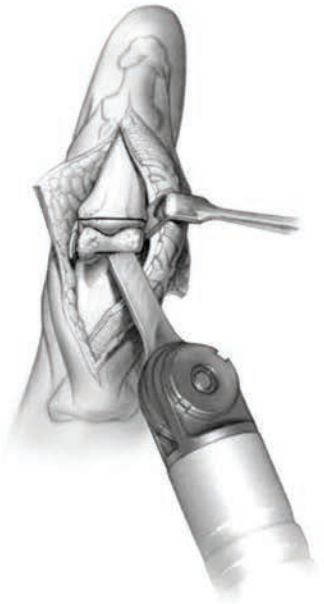

Fig. 3A

Trial placement

Preparation of the intramedullary cavities is performed similar to the dorsal technique (Fig. 4A). Hyperextension of the middle phalanx aids introduction of the broaches. The trial components are inserted and motion checked in a fashion as described in the previous section on the dorsal approach.

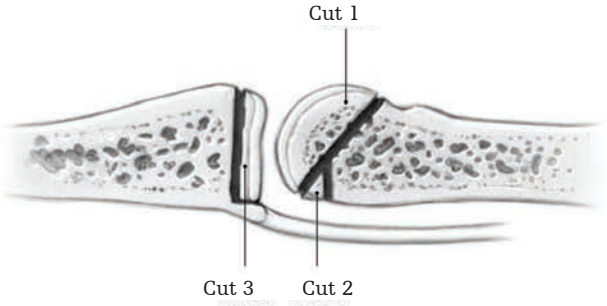

Fig. 3B

Trial removal and implant preparation

After the trial reduction is complete, small drill holes are made at the base of the middle phalanx and distal aspect of the proximal phalanx to facilitate repair of the palmar plate and tendon sheath complex (Fig. 4B).

The implant(s are seated in a similar fashion as described in the previous section in dorsal approach, Fig. 11A-11C regarding cementing technique and final implant

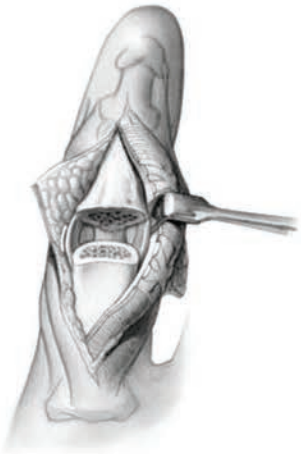

Fig. 4A

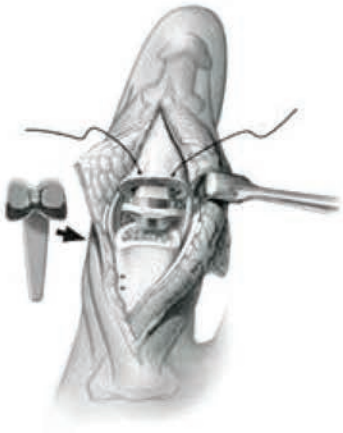

Fig. 4B

Operative technique
Palmar approach

Closure

The palmar plate should be reattached with 3.0 nonabsorbable sutures through small drill holes in the palmar rim of the base of the middle phalanx at the time of closure to prevent the development of a hyperextension deformity. Additional sutures to reapproximate the lateral aspect of the annular pulleys to the accessory collateral ligament and bone will help prevent bowstringing of the tendons (Fig. 5A). Final X-Ray confirmation of alignment and position is obtained (Fig. 5B and 5C). The skin is closed in a conventional manner, and the finger splinted in slight flexion. Multiple fingers may be done at the same procedure with consideration for time constraints of the tourniquet.

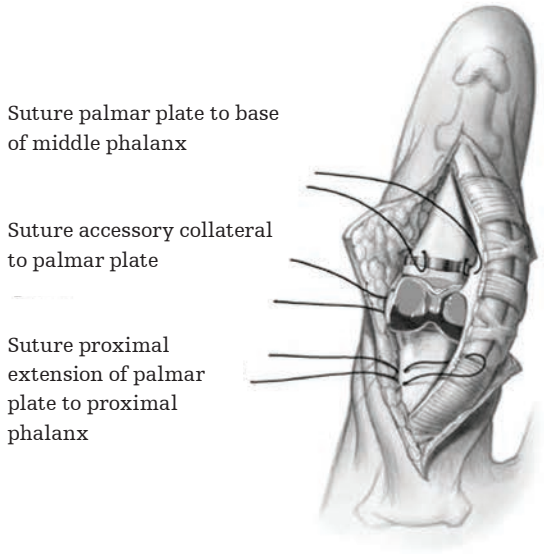

Fig. 5A

Post-operative care: Palmar approach

If the dorsal extensor insertion integrity is satisfactory, the finger may be held in 15º-20º flexion for the first two to three days. Motion exercises may begin gingerly with isolated flexion of the DIP joint on the first postoperative day. PIP flexion may begin slowly but with a return to full extension during each cycle.

If extension cannot be obtained after each flexion, a dynamic extension exercise splint may be applied during exercise periods. A static extension splint for rest periods and night time may be utilized for a sufficient period to obtain persistent satisfactory extension.

The supervision of a hand physiatrist or hand therapist is recommended to provide guidance and encouragement. Elevation during both daytime and at night is important to control swelling and avoid post-operative stiffness. Elastic wrapping for edema control especially for nocturnal wear may also be helpful. Buddy taping of the involved finger to an adjacent finger may also be beneficial. The finger may be somewhat swollen for a number of weeks post-operatively and may remain somewhat enlarged at the joint level for several months.

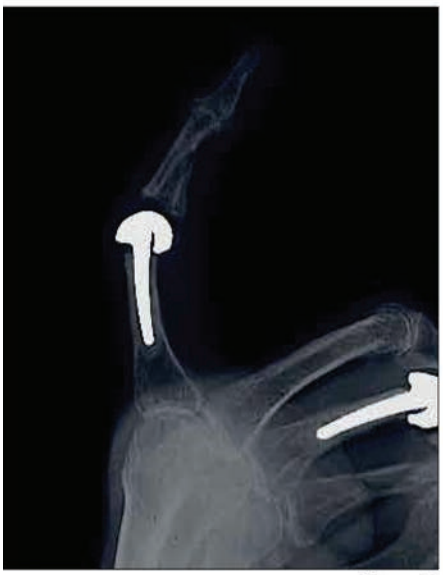

Fig. 5B

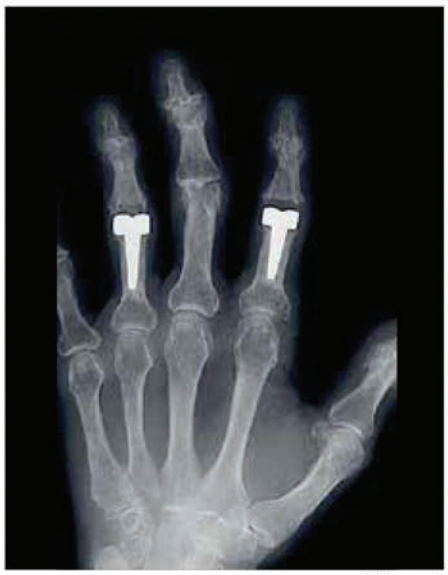

Fig. 5C

Skin sutures are removed when healing is completed, usually between 12 to 18 days.

Operative technique
Follow up

Exams

Follow up exams may include range of motion, grip strength, pinch strength, alignment and subjective response. X-Ray examination to ascertain joint congruity and alignment are taken during the alignment of the prostheses, cement mantle adequacy, evidence of loosening or subsidence may be recorded.

Complications

Complications may include wound breakdown from excessive swelling or infection, subluxation or dislocation may be the result of misalignment of the components, insufficient bony stock, soft tissue deficits or inadvertent trauma in the postoperative period. Patients with a significant boutonniere or swan neck deformity are more likely to have this recur unless adequate soft tissue repairs have been undertaken. Component loosening, polyethylene fracture or cold flow deformity are possible though unlikely. Some loss of motion may occur with subsidence or heterotopic bone formation over time.

Salvage

In the event of collateral ligament or central slip failure, a secondary reconstructive procedure may be necessary. A failed arthroplasty may be treated by arthrodesis, fibrous or silicone arthroplasty or by disarticulation.

Clinical publications

1. Carroll RE, Taber TH. Digital Arthroplasty of the Proximal Interphalangeal Joint. Journal of Bone and Joint Surgery [AM], 36: 912-920, 1954.
2. Ostgaard SE, Weilby A. Resection Arthroplasty of the Proximal Interphalangeal Joint. Journal of Hand Surgery [BR], 18: 613-615, 1993.
3. Eaton RG, Malerich MM. Volar Plate Arthroplasty of the Proximal Interphalangeal Joint: A Review of Ten Year's Experience. Journal of Hand Surgery [AM], 5: 260-268, 1980.
4. Brannon EW, Klein G. Experiences with a Finger-Joint Prosthesis. Journal of Bone and Joint Surgery [AM], 41: 87-102, 1959.
5. Flatt AE. Restoration of Rheumatoid Finger-Joint Function: Interim Report on Trial of Prosthetic Replacement. Journal of Bone and Joint Surgery [AM], 43: 753-774, 1961.
6. Condamine JL, Benoit JY, Comtet JJ, Aubriot JH. Proposed Digital Arthroplasty Critical Study of the Preliminary Results. Ann Chir Main, 7: 282-297, 1988.
7. Sibly TF, Unsworth A. Fixation of a Surface Replacement Endoprosthesis of the Metacarpophalangeal Joint. Proc Inst Mech Eng, 205: 227-232, 1991.
8. Flatt AE, Ellison MR. Restoration of Rheumatoid Finger-Joint Function: A Follow-Up Note After Fourteen Years of Experience With a Metallic-Hinge Prosthesis. Journal of Bone and Joint Surgery [AM], 54: 1317-1322, 1972.
9. Beevers DJ, Seedham BB. Metacarpophalangeal Joint Prosthesis: A Review of Past and Current Designs. Proc Inst Mech Eng, 207: 194-206, 1993.
10. Linscheid RL, Dobyns JH. Total Joint Arthroplasty. The Hand Mayo Clinic Proc, 54: 516-526, 1979.
11. Beckenbaugh RD. New Concepts in Arthroplasty of the Hand and Wrist. Arch Surgery, 112: 1094-1098, 1977.
12. Steffee AD, Beckenbaugh RD, Linscheid RL, Dobyns JH. The Development, Technique and Early Clinical Results of Total Joint Replacement for the Metacarpophalangeal Joint of the Fingers. Orthopedics, 4: 175-180, 1981.
13. Chao Ey, Opgrande JD, Axmear FE. Three-Dimensional Force Analysis of Finger Joints in Selected Isometric Hand Functions. Journal Biomech, 9: 387-396, 1976.
14. An KN, Chao EY, Linscheid RL, Cooney WP III. Functional Forces in Normal and Abnormal Fingers. Orthop Trans, 2: 168-170, 1978.
15. Tamai K, Ryu J, An KN, Linsheid RL, Cooney WP III, Chao EY. Three-Dimensional Geometric Analysis of the Metacarpophalangeal Joint. Journal of Hand Surgery [AM], 13: 521-529, 1988.
16. Linscheid RL, Chao EY. Biomechanical Assessment of Finger Function in Prosthetic Joint Design. Orthop Clin North America, 4: 317-320, 1973.
17. Linscheid RL, Murray PM, Vidal MA, Beckenbaugh RD, Development of a Surface Replacement For Proximal Interphalangeal Joints.The Journal of Hand Surgery [AM], vol 22A, No 2: 286-298, March 1997.

Trauma & Extremities

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Manufacturer:

Stryker GmbH
Bohnackerweg 1
2545 Selzach
Switzerland

stryker.com

Content ID: SRPIP-ST-1, Rev 3 01-2021