DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 1998

Ms. Louise M. Focht
Avanta Orthopaedics, Inc.
9369-A Carroll Park Road
San Diego, California 92121

Re: H980002
Avanta Proximal Interphalangeal (PIP) Finger Prosthesis
Filed: July 17, 1998
Amended: July 27, August 11 and 20, and September 1, 8, 24 and 27, 1998

Dear Ms. Focht:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your humanitarian device exemption (HDE) application for the Avanta Proximal Interphalangeal (PIP) Finger Prosthesis. The Avanta PIP Finger Prosthesis is indicated for use in arthroplasty of the PIP joint when either the:

1. patient is in need of a revision of failed PIP prosthesis(es); or

2. 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.

CDRH is pleased to inform you that your HDE is approved subject to the enclosed "Conditions of Approval." You may begin commercial distribution of the device after you have submitted an amendment to this HDE with copies of the approved labeling in final printed form.

The sale, distribution, and use of this device are limited to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)) under the authority of section 515(d)(1)(B)(ii) of the act (21 U.S.C. 360e(d)(1)(B)(ii)). In addition, in order to ensure the safe use of the device, FDA has further restricted the device within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act (21 U.S.C. 352(q) and (r)).

FDA wishes to remind you that failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

CDRH will notify the public of its decision to approve your HDE by making available a summary of the safety and probable benefit of the device upon which the approval was based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/hdeinfo.html. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the HDE number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Any information to be submitted to FDA regarding this HDE should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above HDE number to facilitate processing:

Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Erin Keith at (301) 594-2036.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONDITIONS OF APPROVAL FOR AN HDE

I. APPROVED LABELING

As soon as possible and before commercial distribution of the device, the holder of an HDE should submit three copies of the approved labeling in final printed form as an amendment to the HDE. The supplement should be submitted to the Document Mail Center (HFZ-401), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

II. ADVERTISEMENTS

Advertisements and other descriptive printed materials issued by the HDE holder or private label distributor with respect to this device should not recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)) under the authority of section 515(d)(1)(B)(ii) of the act (21 U.S.C. 360e(d)(1)(B)(ii)), all advertisements and other descriptive printed material issued by the holder or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

III. HDE SUPPLEMENTS

Before making any change affecting the safety or probable benefit of the device, the HDE holder should submit a supplement for review and approval by FDA unless a "Special HDE Supplement" is permitted as described under 21 CFR 814.39(d)(2) or an alternate submission is permitted as described under 21 CFR 814.39(e). All HDE supplements or alternate submissions must comply with the applicable requirements under 21 CFR 814.39 of the Premarket Approval (PMA) regulation and under 21 CFR 814.108 of the Humanitarian Device Exemption regulation. The review timeframe for HDE supplements is 75 days except for those submitted under 21 CFR 814.39(e).

Since all situations which require an HDE supplement cannot be briefly summarized, please consult the HDE regulation for further guidance. The guidance provided below is only for several key instances. In general, an HDE supplement must be submitted:

1) When unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification; or

2) If the device is to be modified, and animal/laboratory or clinical testing is needed to determine if the modified device remains safe and continues to provide probable benefit.

HDE supplements submitted under 21 CFR 814.39(d)(2) "Special HDE Supplement - Changes Being Effected" are limited to the labeling, quality control, and manufacturing process changes as specified under this section of the regulation. This provision allows for the addition of, but

not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented upon acknowledgment by FDA that the submission is being processed as a "Special HDE Supplement - Changes Being Effected." Please note that this acknowledgment is in addition to that issued by the Document Mail Center for all HDE supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software, or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of an HDE supplement before implementation and include the use of a *30-day HDE supplement* or *periodic postapproval report*. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence to the HDE holder that the alternate submission is permitted for the change. Before this can occur, FDA and the HDE holder must agree upon any needed testing, the testing protocol, the test results, the reporting format, the information to be reported, and the alternate submission to be used.

Please note that unlike the PMA process, a supplement may not be submitted for a new indication for use for a humanitarian use device (HUD). An HDE holder seeking a new indication for use for an HUD approved under the provisions of Subpart H of 21 CFR 814, must obtain a new designation of HUD status for the new indication for use and submit an original HDE application in accordance with §814.104. The application for the new indication for use may incorporate by reference any information or data previously submitted to the agency.

IV. POSTAPPROVAL RECORD KEEPING REQUIREMENTS

An HDE holder is required to maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing institutional review boards (IRBs), as well as any other information requested by a reviewing IRB or FDA.

V. POSTAPPROVAL REPORTING REQUIREMENTS

Continued approval of the HDE is contingent upon the submission of postapproval reports required under 21 CFR 814.84 and 21 CFR 814.126.

A. ANNUAL REPORT

Annual reports should be submitted at intervals of 1 year from the date of approval of the original HDE. Reports for supplements approved under the original HDE should be included in the next and subsequent periodic reports for the original HDE unless otherwise specified in the approval order for the HDE supplement. Three copies identified as "Annual Report" and bearing the applicable HDE reference number are to be submitted to the HDE Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. Reports should indicate the beginning and ending date of the period covered by the report and include the following information required by 21 CFR 814.126(b)(1):

1. An update of the information required under §814.102(a) in a separately bound volume;

2. An update of the information required under §814.104(c)(2), (c)(3), and (c)(5);

3. The number of devices that have been shipped or sold and, if the number shipped or sold exceeds 4,000, an explanation and estimate of the number of devices used per patient. If a single device is used on multiple patients, an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate;

4. Information describing the applicant's clinical experience with the device. This shall include safety information that is known or reasonably should be known to the applicant, a summary of medical device reports made pursuant to 21 CFR 803, any data generated from postmarketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect the statement of contraindications, warnings, precautions, and adverse reactions in the device labeling; and

5. A summary of any changes made to the device in accordance with supplements submitted under §814.108 and any changes required to be reported to FDA under §814.39(b).

B. **ADVERSE REACTION AND DEVICE DEFECT REPORTING**

As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and probable benefit of the device, the holder shall submit three copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the Document Mail Center (HFZ-401), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. Such reports should be submitted within 10 days after the HDE holder receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

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(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved HDE that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the HDE holder's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the firm. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the holder shall be included in the "Annual Report" described under "Postapproval Reports" above unless otherwise specified in the conditions of approval for this HDE. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of occurrence for each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the HDE holder when determined by FDA to be necessary to provide continued reasonable assurance of the safety and probable benefit of the device for its intended use.

C. **REPORTING UNDER THE MEDICAL DEVICE REPORTING REGULATION**

The Medical Device Reporting regulation (MDR) (21 CFR 803) became effective on April 11, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices:

(1) may have caused or contributed to a death or serious injury; or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Events subject to reporting under the MDR regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements. FDA has determined, however, that such duplicative reporting is unnecessary. Therefore, whenever an event involving a device is subject to reporting under both the MDR regulation and the "Adverse Reaction and Device Defect Reporting" requirements, the report should be submitted in compliance with Part 803 and identified with the HDE reference number to Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, Maryland 20847-3002. For questions regarding the MDR regulation, please call (301) 594-2735.

Events included in periodic reports to the HDE that have also been reported under the MDR regulation must be so identified in the periodic report to the HDE to prevent duplicative entry into FDA information systems.

Copies of the MDR regulation and FDA publications, entitled "An Overview of the Medical

Device Reporting Regulation" and "Medical Device Reporting for Manufacturers," are available on the CDRH WWW Home Page (http://www.fda.gov/cdrh), through CDRH's Fact-on-Demand (FOD) at 800-899-0381 (FOD # 336, 1336, 509 and 987) or by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Lane
Rockville, Maryland 20850

SUMMARY OF SAFETY AND PROBABLE BENEFIT

I. General Information

Device Generic Name: Semi-Constrained Prosthesis, finger joint

Device Trade Name: Avanta Proximal Interphalangeal (PIP) Finger Prosthesis

Applicant's Name and Address: Avanta Orthopaedics, Inc.
9369-A Carroll Park Drive
San Diego, CA 92121

Humanitarian Device Exemption (HDE) Number: H980002

Date of Humanitarian Use Device Designation: December 22, 1997

Date of Panel Recommendation: The HDE was not taken to Panel. Refer to Section X of this document for the rationale used in determining that Panel review was unnecessary.

Date of Good Manufacturing Practices (GMP) Inspection: Inspections were performed in June 1997 and March 1998.

Date of Notice of Approval to the Applicant: SEP 28 1998

II. Indications for Use

The Avanta PIP Finger Prosthesis 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.

III. Device Description

The Avanta PIP Finger Prosthesis consists of a distal component which combines a titanium alloy stem with an ultra-high molecular weight polyethylene (UHMWPe) articulating surface, and a proximal component consisting of a cobalt-chromium-molybdenum articulating surface. The joint prosthesis is intended for use with or without bone cement. The device is semi-constrained because it limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has

no across-the-joint linkage. The two components of the implant articulate on their mating surfaces.

The proximal component is designed for implantation onto the distal end of the proximal phalanx. The distal component is designed for implantation into the proximal end of the middle phalanx. Both components are intended to articulate on each other allowing for 90 degrees of flexion/extension. The articular surfaces prevent dislocation of the joint through simulation of the natural joint implant articular surface. Both the proximal and distal components are designed to be used with or without cement.

The implant is available in five sizes. An alpha-numeric coding system is used to distinguish sizes. A full surgical instrument set with appropriately sized trials and broaches is available.

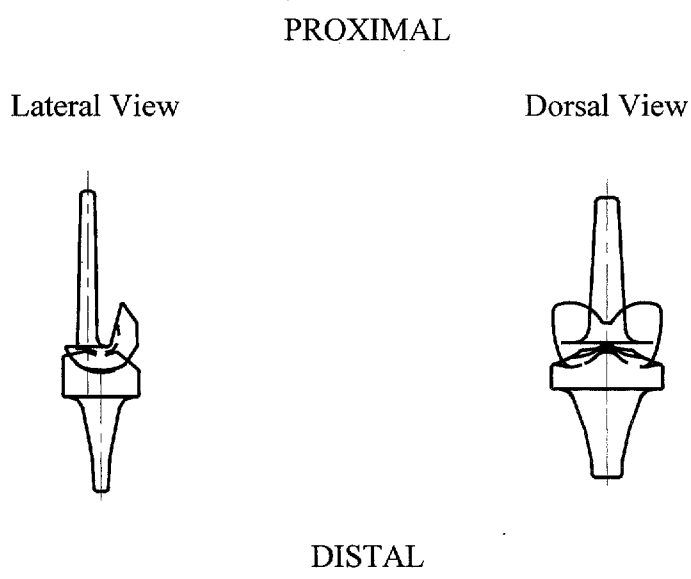

Figure 1. Proximal and distal components of the PIP joint implant in the extended position, lateral and dorsal view.

Materials:

- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) distal component
- ASTM F75 cobalt chromium proximal component
- ASTM F136 titanium alloy Ti-6AL-4V

IV. Contraindications, Warnings and Precautions

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.

WARNINGS (See also the Patient Counseling Information Section)

- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.

PRECAUTIONS

- 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 questioned for any reason, the implant should not be used. Do not resterilize.
- 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.

PATIENT COUNSELING INFORMATION (See also Warnings)

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of total joint replacement components is difficult to estimate; it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.

V. Adverse Effects of the Device on Health

REPORTED ADVERSE EFFECTS

There has been some clinical experience with this device. In the US, 16 patients have been implanted with the device with a maximum length of follow-up of 6 months. In addition, eight patients in Sweden have been implanted with the device. In the US patients, the most commonly reported adverse events were post operative pain and flexor tenolysis. In the Swedish patients, two revision surgeries have been performed.

- see **Table 5: Complication for US Patients** in the Clinical Experience Section for reported adverse events associated with the device

POTENTIAL ADVERSE EFFECTS

General Surgery Related Risks
- bleeding
- infection
- loss of use of the hand
- permanent disability
- death

Joint Replacement Related Risks
- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue (e.g., numbness)
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- dislocation of the joint
- cement extrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint
- surgery may be started but a joint replacement cannot be done resulting in fusion of the joint

- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

VI. Alternative Practices and Procedures

Conservative early stage treatment includes joint injections, anti-inflammatory drug therapy (e.g., aspirin, NSAID) and avoidance of heavy stress through the joints (however regular, gentle, active exercises are needed to maintain joint range). Coban wrapping of the joints at night may also be used to help control swelling and subsequent morning stiffness. Occasionally, the wrapping may be combined with splinting.

Surgical intervention may restore some range of motion and is typically used when conservative measures no longer give relief. Surgical treatment may include fusion of the bones together, interposition arthroplasty with tendon or joint replacement surgery with a silicone spacer implant. Individuals who are very active and use their hands heavily may not be good candidates for silicone implants.

VII. Marketing History

Since 1996 to present, approximately 24 devices have been shipped to Sweden and 11 joints were implanted in Sweden. In the US, 18 prostheses have been implanted. The device has received the CE Mark for marketing in Europe.

The Avanta PIP Finger Prosthesis has not been withdrawn from the market for any reason related to safety or probable benefit of the device.

VIII. Summary of Studies

Both pre-clinical (biocompatibility and mechanical) and clinical testing were performed using the device.

A. Pre-clinical Testing

The device is constructed from materials commonly used in other total joint replacement devices. Therefore, extensive biocompatibility testing was not necessary to establish the safety of the materials used in the construction of this device. Table 1 contains a summary of the limited biocompatibility performed on the device.

Table 1. Biocompatibility testing performed.

Test Protocol	Components	Results
Minimal Essential Media (MEM) Elution	7	Pass
Limulus Amebocyte Lysate (LAL) Test	7	Pass
Bioburden Counts	6 (3 devices)	<1colony forming unit

Additional pre-clinical testing of the device design included fatigue testing, wear testing, finite element analysis (FEA) and cadaveric evaluations. The cadaveric evaluations were used to evaluate ease of implantation using the recommended surgical technique. The FEA testing provided was not validated. Therefore the FEA test results were not conclusive.

The results of the mechanical testing (fatigue and wear) indicate the device should have adequate mechanical properties for use in PIP arthroplasty when the patient is in need of a revision of failed PIP prosthesis(es); and the 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. Table 2 summarizes the mechanical test results.

Table 2. Mechanical testing.

Test Protocol	Samples	Results
Fatigue*	6 implants	No failures reported
Wear**	6 implants	Average wear rate $59mm^3/10^6$ cycles

* The fatigue testing was performed to 10,000,000 cycles in bovine serum with an off axis applied load of 45 lbs.

** The wear testing was performed in a modified hip simulator in bovine serum with an applied load of 45 lbs. Wear testing was performed out to 10,000,000 cycles.

B. Clinical Experience:

There has been some clinical experience with this device. In the US, 16 patients have been implanted with the device with a maximum length of follow-up of 6 months. In addition, eight patients in Sweden have been implanted with the device since September 1996.

A prospective randomized clinical study is being performed in the US, patients are randomized either into the experimental group which received the, Avanta PIP Finger Prosthesis or into the control, which received a silicone elastomer implant. Thirty-one patients have been randomized into the study to date. However only 18 of these patients

have had surgery performed to implant either the control device of the Avanta PIP Finger Prosthesis. Table 3 describes the patients randomized into the study, patients implanted with a device and the patient dropouts from the study. Thirteen of these patients have follow-up data which is summarized in Tables 4-6. Tables 4-6 describe the patient demographics, reported complications and length of follow-up for this clinical study to date. There are currently no articles published from this clinical study.

Table 3: US Patients

Patient Category	*Number of Patients*
Total Randomized into Study	31
Total Who Have Had Surgery	18
Total Still Enrolled But No Surgery*	10
Withdrew Prior to Surgery	3
Withdrew After Surgery (3 months post-op)	2
With Follow-Up Data**	13

* 10 Patients have not withdrawn from the study, but no surgery date has been scheduled. 9/10 of these patients are control patients.

** Data report forms have been returned on only 13 patients. Tables 4-6 describe the clinical results for these 13 patients.

Table 4: Demographics for 13 US Patients* with Follow-Up

Category	*Patients with Avanta PIP Implant*	*Patients with Silicone Implant*	*Total*
Male	6	1	7
Female	5	1	6
Mean Age**, SD	51.25±17.4 (n=8)	61 (n=1)	
Age Range (years)	24-71	61	
Osteo-arthritis	5	0	5
Post-traumatic arthritis	3	1	4
Rheumatoid Arthritis	2	1	3
Silicone Implant Revision	1	0	1

* Description of number of patients with more than one implant - There are 13 patients with 18 implants: one osteo-arthritic patient has 2 implants; one rheumatoid control patient has 3 implants; two post-traumatic patients have two implants.

** The sum of n≠13 because of the failure to record the age of the patient in 4 instances (3 Avanta PIP Finger Prosthesis and 1 silicone implant patients)

Table 5: Complications for 13 US Patients with Follow-Up

Complication	*Avanta PIP Patient(n=11)*	*Silicone Patient(n=2)*
pain (6 months post-op*)	4	0
edema	1	0
ulnar deviation	1	0
extensor lag	1	0
limited range of motion	1	0
cracked bone	1	0
snapping over dorsum with composite flexion	1	0
flexor tenolysis	3	0
subluxation	0	0
rotation	0	0
revision	0	0

* 5Avanta PIP patients experienced pain at 3 months post operative, and 9 Avanta PIP patients and 2 Silicone patients experienced pain 1-4 weeks postoperative.

Table 6: Number of US Patients(Implants) at Each Follow-Up Time Point*

Length of Follow-Up	*Avanta PIP Implant Patients (# implants)*	*Silicone Implant Patients (#implants)*
Post-op (1-4 weeks)	11 (14)	2 (4)
3 months	8 (9)	2 (4)
6 months	4 (5)	0
12 months	0	0
24 months	0	0
Post-op withdrawal	1 (1)	1 (3)

* The Avanta implant patient refused to return for continued therapy or follow-up visits. The control implant patient withdrew after the 3 months post-op visit. The reason for withdraw is not documented. The 3 month visit is the last visit for these patients.

A case series by Dr. Sollerman[1] reports on eight of his patients who have been implanted with a total of 11 Avanta PIP Finger Prostheses since September 1996. These patients have a mean age of 51 (31-66) years. The indications Dr. Sollerman reported for surgery were pain and stiffness due to post-traumatic arthrosis (4), rheumatoid arthritis (3), osteoarthritis (3) and Ehler-Danlos syndrome (1). Two revisions were performed, one due to extension lag caused by insufficient bone resection and one due to a rotational deformity. Dr. Sollerman has reported his early results show excellent pain relief and in most cases a functional range of motion, on average 48 (30-85) degrees with an extension lag of 11 (-10-25) degrees. The intrinsic stability of the device has been excellent in all cases in spite of severance of the collateral ligaments in seven joints. No signs of radiographic loosening have been observed in this unspecified short follow-up period.

1. Sollerman, C. Möller, K, **PIP Joint Arthroplasty with Noncemented Semiconstrained Implants**. Department of Hand Surgery, Sahlgrenska University Hospital, Göteborg, Sweden. 7th Congress of the International Federation of Societies for Surgery of the Hand. Vancouver, Canada May 24-28, 1998.

IX. Conclusions Drawn from Studies

The pre-clinical testing indicates the device design is adequate for its intended use. More specifically, the performance testing to assess mechanical properties demonstrates the fatigue and wear properties of the device are acceptable; the biocompatibility testing indicates the device is non cytotoxic, pyrogen free and can be sterilized; and the cadaveric testing shows the device can be implanted using the suggested surgical technique.

The limited clinical data available indicates no unexpected risk of illness or injury from use of the device compared to other surgical treatment options. Dr. Sollerman's postoperative range of motion and pain reduction results suggest a probable benefit to health from use of the device. The US patient group indicates a higher overall complication rate for the Avanta PIP Finger Prosthesis compared to the control group. However results currently available are insufficient to support any statistically valid conclusion.

The pre-clinical and clinical data suggest that the device will not expose patients to an unreasonable or significant risk of illness or injury, and that the probable benefit to health from use of the device outweighs the risk of injury or illness.

X. Panel Recommendation

This HDE was not taken to a meeting of the Orthopedics and Rehabilitation Devices Panel because other finger prostheses marketing applications have previously been reviewed by this panel. Therefore it was determined the Panel had already provided input into acceptable kinds of pre-clinical testing needed for a marketing application.

XI. CDRH Decision

CDRH determined that, based on the data submitted in the HDE, the Avanta Orthopaedics PIP joint implant will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risks of illness or injury, and issued an approval order on SEP 28 1998.

XII. Approval Specifications

Indications for Use: See section II above.

Hazards to Health from Use of the device: See Sections IV and V above.

XIII. Publications and Other Outside Information

1. Sollerman, C. Möller, K, **PIP Joint Arthroplasty with Noncemented Semiconstrained Implants**. Department of Hand Surgery, Sahlgrenska University Hospital, Göteborg, Sweden. 7th Congress of the International Federation of Societies for Surgery of the Hand. Vancouver, Canada May 24-28, 1998.

2. Beckenbaugh, R. D., Linscheid, R. L., **Arthroplasty, Operative Hand Surgery**, Churchill Livingstone, New York, Third Edition, Edited by David Green, 1993, pp143-187.

Product Insert:

HUMANITARIAN DEVICE. The Avanta PIP Finger Prosthesis is authorized by Federal law 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.

The effectiveness of this device for this use has not been demonstrated.

CAUTION

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

DESCRIPTION

The Proximal-Interphalangeal Finger Prosthesis consists of an ultra-high molecular weight polyethylene (UHMWPe) component with a titanium alloy stem which may be cemented to the shaft of the prepared middle phalanx, and a cobalt chromium stem component which is inserted into the prepared proximal phalanx. The cobalt chromium surface articulates with the UHMWPe component to form a semi-constrained prosthetic replacement for the proximal interphalangeal joint. The implant is available in five sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation.

Materials:

- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) distal component
- ASTM F75 cobalt chromium proximal component
- ASTM F136 titanium alloy Ti-6AL-4V

INDICATIONS

The Avanta PIP Finger Prosthesis 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.

WARNINGS (See also the Patient Counseling Information Section)

- 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.

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 questioned 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.

ADVERSE EVENTS

REPORTED ADVERSE EVENTS

There has been some clinical experience with this device. In the US, 16 patients have been implanted with the device with a maximum length of follow-up of 6 months. In

addition, eight patients in Sweden have been implanted with the device. In the US patients, the most commonly reported adverse events were post operative pain and flexor tenolysis. In the Swedish patients, two revision surgeries have been performed.

- For more details see **Table 5: Complication for US Patients** in the Clinical Experience Section for reported adverse events associated with the device

POTENTIAL ADVERSE EFFECTS

General Surgery Related Risks

- bleeding
- infection
- loss of use of the hand
- permanent disability
- death

Joint Replacement Related Risks

- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue (e.g., numbness)
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- dislocation of the joint
- cement extrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint
- surgery may be started but a joint replacement cannot be done resulting in fusion of the joint
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(;) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

CLINICAL EXPERIENCE

There has been some clinical experience with this device. In the US, 16 patients have been implanted with the device with a maximum length of follow-up of 6 months. In addition, eight patients in Sweden have been implanted with the device since September 1996.

A prospective randomized clinical study being performed in the US, patients are randomized either into the experimental group which received the, Avanta PIP Finger Prosthesis or into the control, which received a silicone elastomer implant. Thirty-one patients have been randomized into the study to date. However only 18 of these patients have had surgery performed to implant either the control device or the Avanta PIP Finger Prosthesis. Table 3 describes the patients randomized into the study, patients implanted with a device and the patient dropouts from the study. Thirteen of these patients have follow-up data, which is summarized in Tables 4-6. Tables 4-6 describe the patient demographics, reported complications and length of follow-up for this clinical study to date. There are currently no articles published from this clinical study.

Table 3: US Patients

Patient Category	*Number of Patients*
Total Randomized into Study	31
Total Who Have Had Surgery	18
Total Still Enrolled But No Surgery*	10
Withdrew Prior to Surgery	3
Withdrew After Surgery (3 months post-op)	2
With follow-up Data**	13

* 10 Patients have not withdrawn from the study, but no surgery date has been scheduled, 9/10 of these patients are control patients.
** Data report forms have been returned on only 13 patients. Tables 4-6 describe the clinical results for these 13 patients.

Table 4: Demographics for 13 US Patients with Follow-up

Category	*Patients with Avanta PIP Implant*	*Patients with Silicone Implant*	*Total*
Male	6	1	7
Female	5	1	6
Mean Age**, SD	51.25*17.4 (n=8)	61 (n=1)	
Age Range (years)	24-71	61	
Osteo-arthritis	5	0	5
Post-traumatic arthritis	3	1	4
Rheumatoid Arthritis	2	1	3
Silicone Implant Revision	1	0	1

*Description of number of patients with more than one implant. There are 13 patients with 18 implants: one osteo-arthritic patient has 2 implants; one rheumatoid control patient has 3 implants; two post-traumatic patients have two implants.

**The sum of n not equal to 13 because of the failure to record the age of the patient in 4 instances (3 Avanta PIP Finger Joint and 1 silicone implant patients)

Table 5: Complications for US Patients

Complication	*Avanta PIP Patient(n=11)*	*Silicone Patient(n=2)*
pain (6 months post-op*)	4	0
Edema	1	0
ulnar deviation	1	0
extensor lag	1	0
limited range of motion	1	0
cracked bone	1	0
snapping over dorsum with composite flexion	1	0
flexor tenolysis	3	0
subluxation	0	0
rotation	0	0
revision	0	0

* 5Avanta PIP patients experienced pain at 3 months post operative, and 9 Avanta PIP patients and 2 Silicone patients experienced pain 1-4 weeks postoperative.

Table 6: Number of US Patients (Implants) at Each follow-up Time Point*

Length of follow-up	*Avanta PIP Implant Patients (# implants)*	*Silicone Implant Patients (# implants)*
Post-op (1-4 weeks)	11 (14)	2 (4)
3 months	8 (9)	2 (4)
6 months	4 (5)	0
12 months	0	0
24 months	0	0
Post-op withdrawal	1(1)	1 (3)

* The Avanta implant patient refused to return for continued therapy or follow-up visits. The control implant patient withdrew after the 3 months post-op visit. The reason for withdraw is not documented. The 3 month visit is the last visit for these patients.

A case series by Dr. Sollerman[1] reports on eight of his patients who have been implanted with a total of 11 Avanta PIP Finger Protheses since September 1996. These patients have a mean age of 51 (31-66) years. The indications Dr. Sollerman reported for surgery were pain and stiffness due to post-traumatic arthrosis (4), rheumatoid arthritis (3), osteoarthritis (3) and Ehler-Danlos syndrome (1). Two revisions were performed, one due to extension lag caused by insufficient bone resection and one due to a rotational deformity. Dr. Sollerman has reported his early results show excellent pain relief and in most cases a functional range of motion, on average 48 (30-85) degrees with an extension lag of 11 (-10-25) degrees. The intrinsic stability of the device has been excellent in all cases in spite of severance of the collateral ligaments in seven joints. No signs of radiographic loosening have been observed in this unspecified short follow-up period.

1. Sollerman, C. Möller, K. PIP Joint Arthroplasty with Noncemented Semiconstrained Implants. Department of Hand Surgery, Sahlgrenska University Hospital, Göteborg, Sweden. 7th Congress of the International Federation of Societies for Surgery of the Hand. Vancouver, Canada May 24-28, 1998.

SURGICAL PROCEDURES

A manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedures before use.

PATIENT COUNSELING INFORMATION (See also Warnings)

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

While the expected life of total joint replacement components is difficult to estimate it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION

- This component has been sterilized by ethylene oxide or gamma radiation.
- **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 questioned for any reason, the implant should not be used.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY

Avanta Orthopaedics Inc., warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

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AVANTA PIP FINGER PROSTHESIS
SURGICAL TECHNIQUE

The proximal interphalangeal joint (PIP) is subject to disability secondary to traumatic arthrosis (TA) and osteo arthrosis. Symptoms include pain, weakness, limited range of motion and deformity. Disability in one finger frequently affects the adjacent fingers particularly on the ulnar side of the hand. Here the common profundal muscle belly to the third, fourth and fifth fingers may limit motion to all if one is impaired (quadriga effect).

Surgical treatment alternatives for severe proximal interphalangeal joint deformity include arthrodesis, arthroplasty and amputation. Preservation of motion favors arthroplasty when feasible. Arthroplastic techniques include fibrous interposition[1], palmar plate advancement [2,3]; metallic or metalloplastic hinges[4,5,6]; or one piece polymeric plastic hinge devices. Insertion of such prostheses often requires resection of the joint beyond the attachments of the collateral ligaments due to the length of the articular components). [7,8,9,10,11,12]

The present prosthetic design for the Avanta PIP Finger Prosthesis was based on the premises that:

1) A semi-constrained finger prosthesis may give a more physiologic articulation than a constrained prosthesis.
2) A properly centered anatomical configuration may more reliably restore tendon moments to the joint.
3) Minimal bony excision and preservation of the collateral ligaments may provide a more stable joint particularly to imposed lateral forces. [10,13,14,15,16]
4) Preservation of the capsule may allow diversion of some of the transverse forces and axial torques from the prosthesis endosteal interface to the lateral cortices through the collateral ligaments.
5) A more physiologic force distribution may diminish the mechanical contribution to osteolysis and subsidence at the bone prosthesis interface.

In the USA the Avanta PIP Finger Prosthesis is a Humanitarian Use device 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.

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.

(Figures and size charts)

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.

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.

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 section compatible with the intramedullary cavity of the middle phalanx.

(Figure III)

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

1. 50% or < joint space narrowing;
2. >50% narrowing and erosions;
3. Bone stock loss, erosions and hypertropic spurs;
4. 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.

The size of the prosthesis to be used may be determined by overlaying the PIP sizing template, which has a 3% parallax enlargement, over the X-ray. Final determination of prosthetic size will depend on the fit of the trial prostheses during surgery.

Caution: If there is insufficient bone stock, inadequate intramedullar 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.

DORSAL APPROACH AND INCISION

1

FIGURE 1

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 (FIGURE 1).

28

CENTRAL SLIP REFLECTION AND CAPSULAR EXPOSURE

2

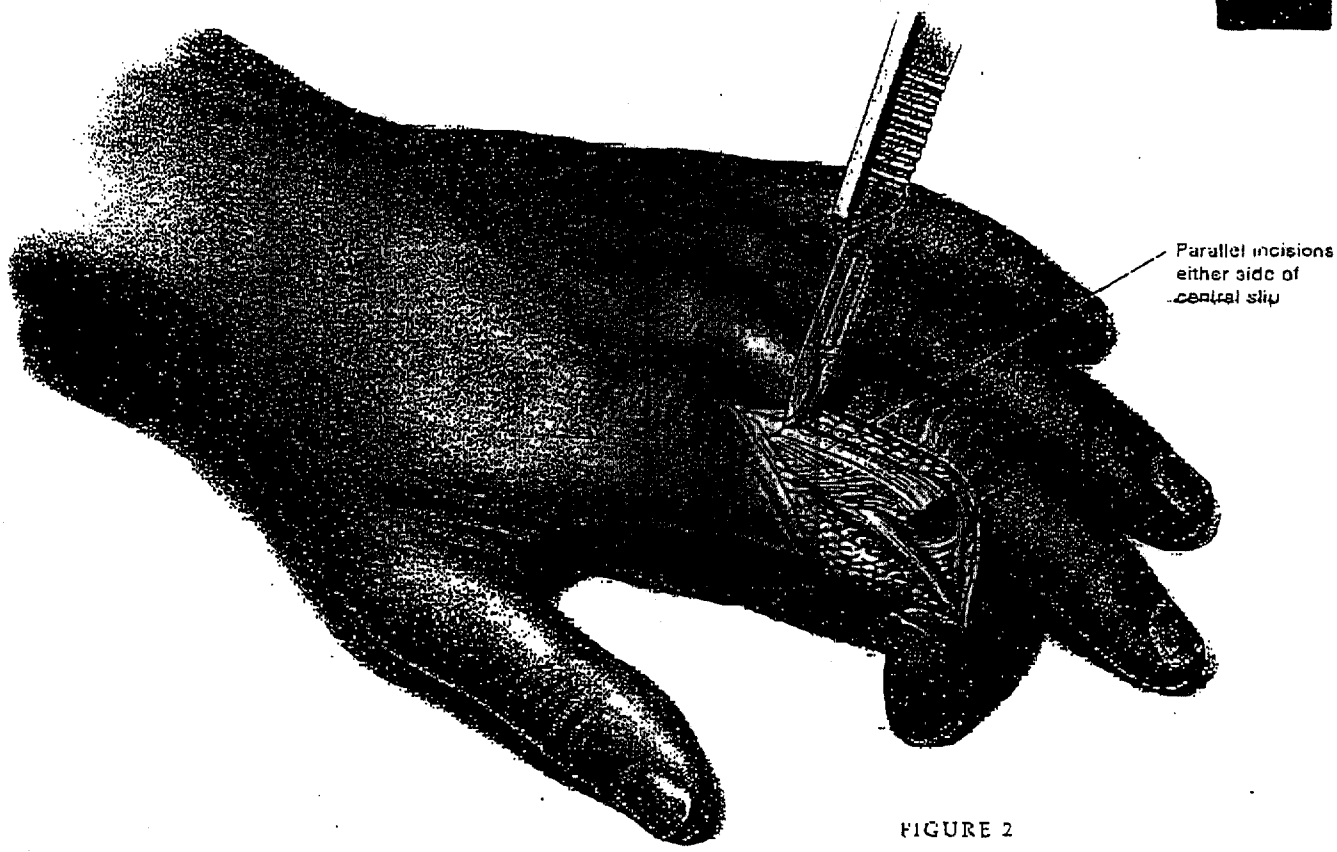

FIGURE 2

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 (FIGURE 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 P. 16).

28

EXPOSING THE JOINT

3

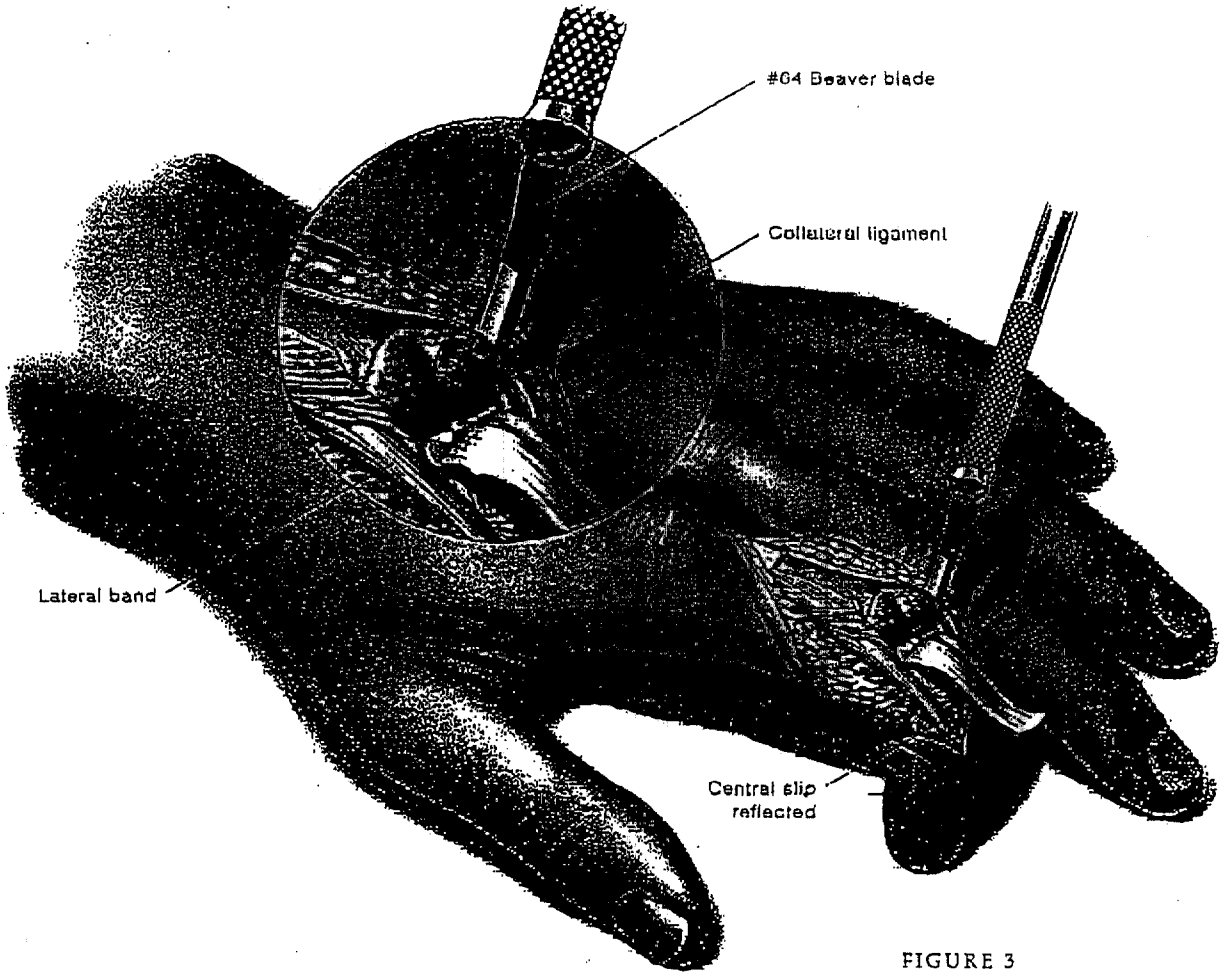

FIGURE 3

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 (FIGURE 3).

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PROXIMAL PHALANX RESECTION

4

FIGURE 4

A small powered saw (such as MicroAire®) is then used to remove the distal 2 to 3mm of the proximal phalanx. The collateral ligaments are protected as much as possible (FIGURE 4).

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VOLAR AND MIDDLE PHALANX RESECTION

5

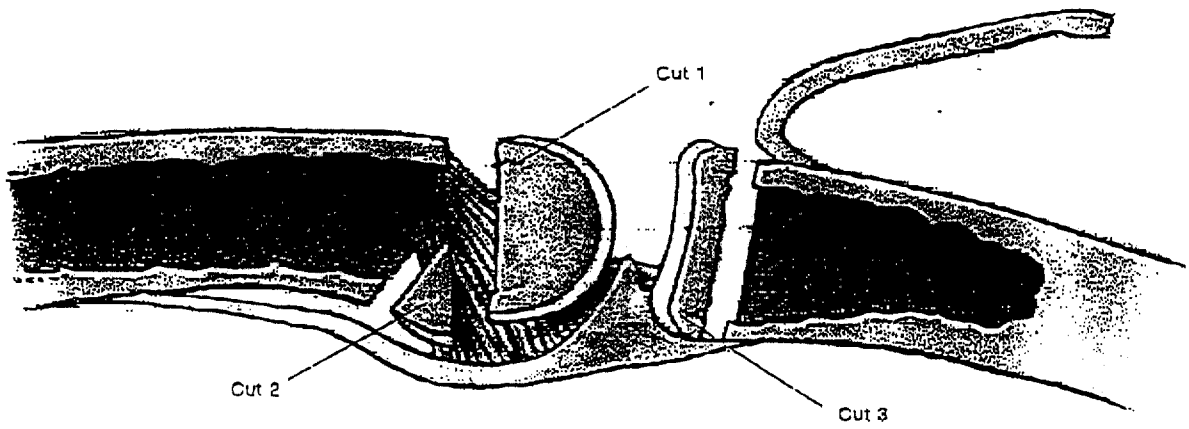

FIGURE 5

The first cut is vertical removing the distal articular surface (FIGURE 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.

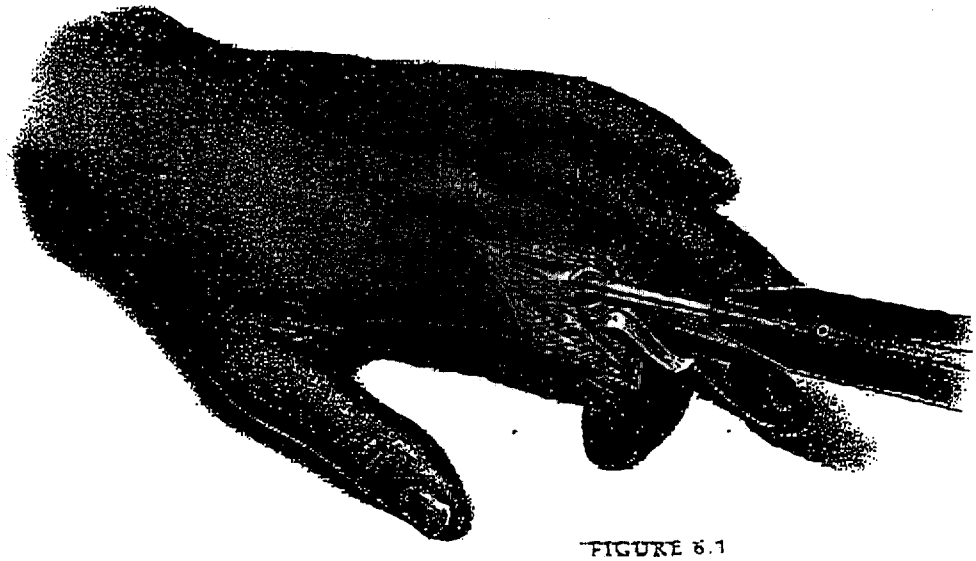

FIGURE 6.1

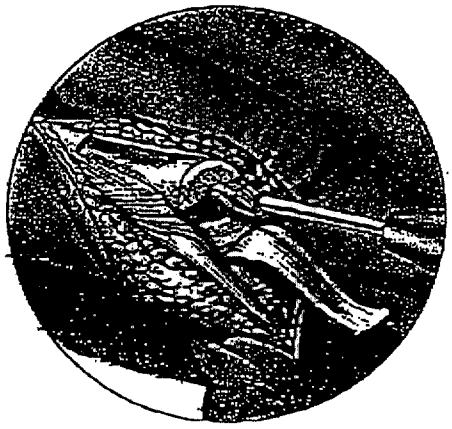

FIGURE 6.2

FIGURE 6.3

The intramedullary cavity is opened with a small awl (FIGURE 6.1). A powered burr may be necessary to clear the entrance to the medullary cavity (FIGURE 6.2). The hole is then enlarged with custom reamers to adjust the intramedullary contours for a proper fit of the trial component (FIGURE 6.3).

PROXIMAL TRIAL PLACEMENT

7

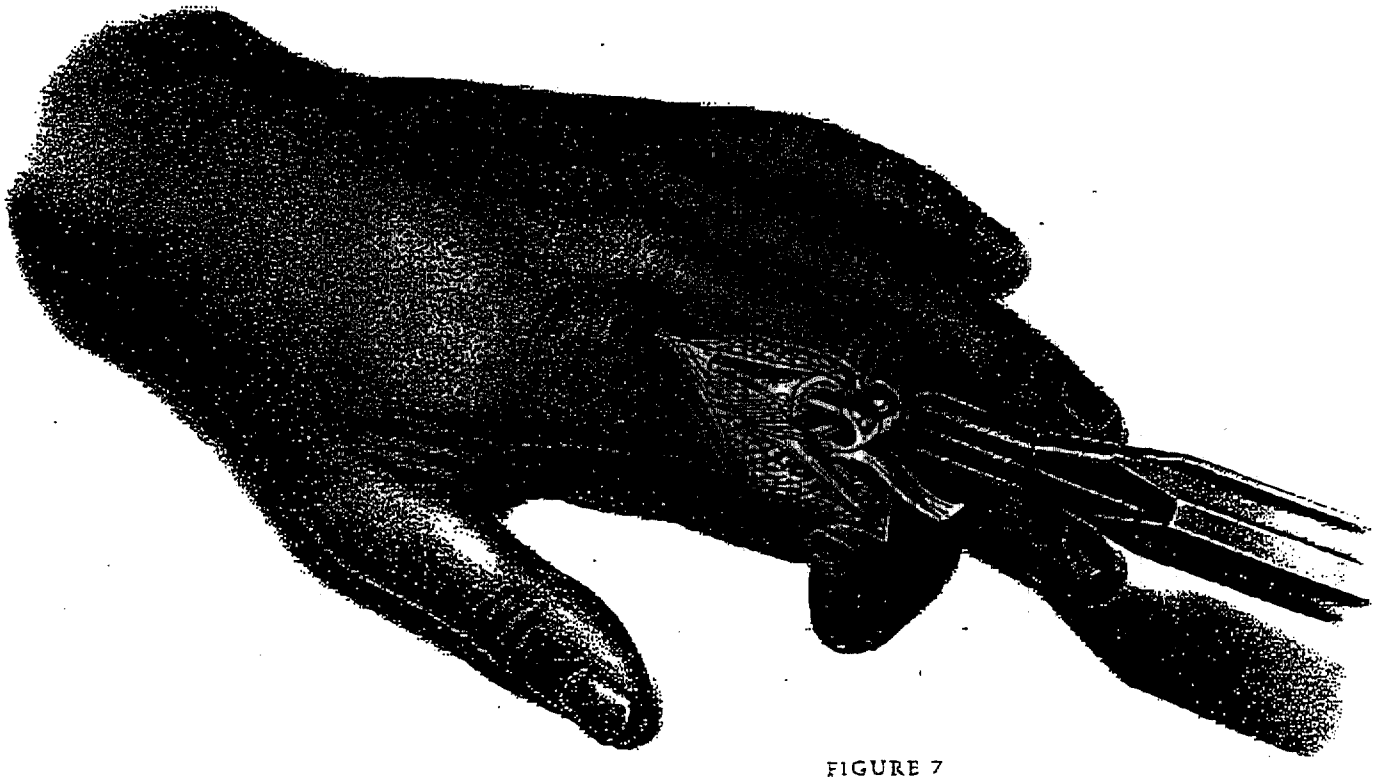

FIGURE 7

Proximal trial prosthesis is introduced and reduced with the plastic impactor (FIGURE 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.

MIDDLE PHALANX TRIAL PREPARATION

8

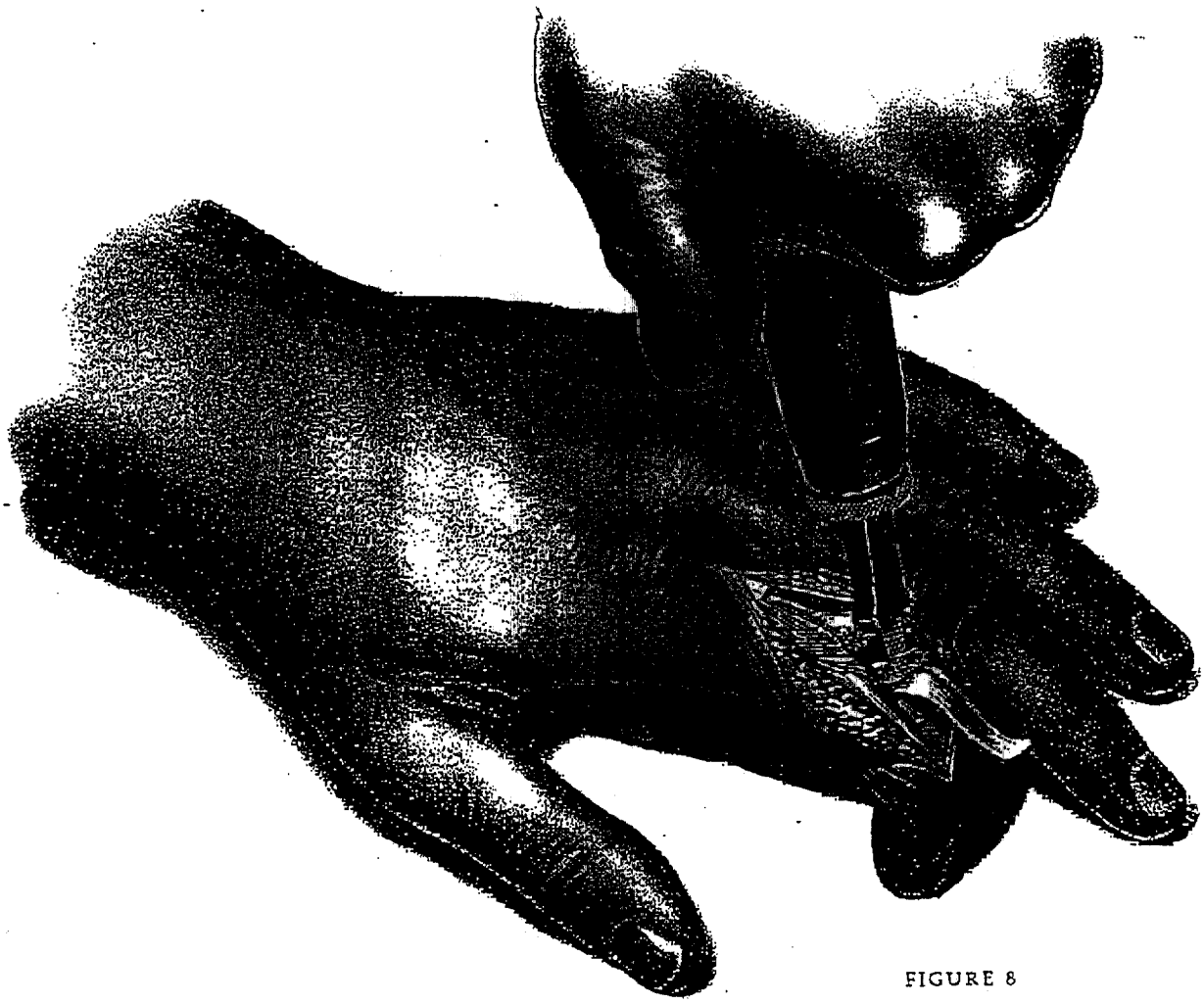

FIGURE 8

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 (FIGURE 8). The proximal trial component is removed to provide access for the rasp.

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MIDDLE PHALANX TRIAL PLACEMENT

9

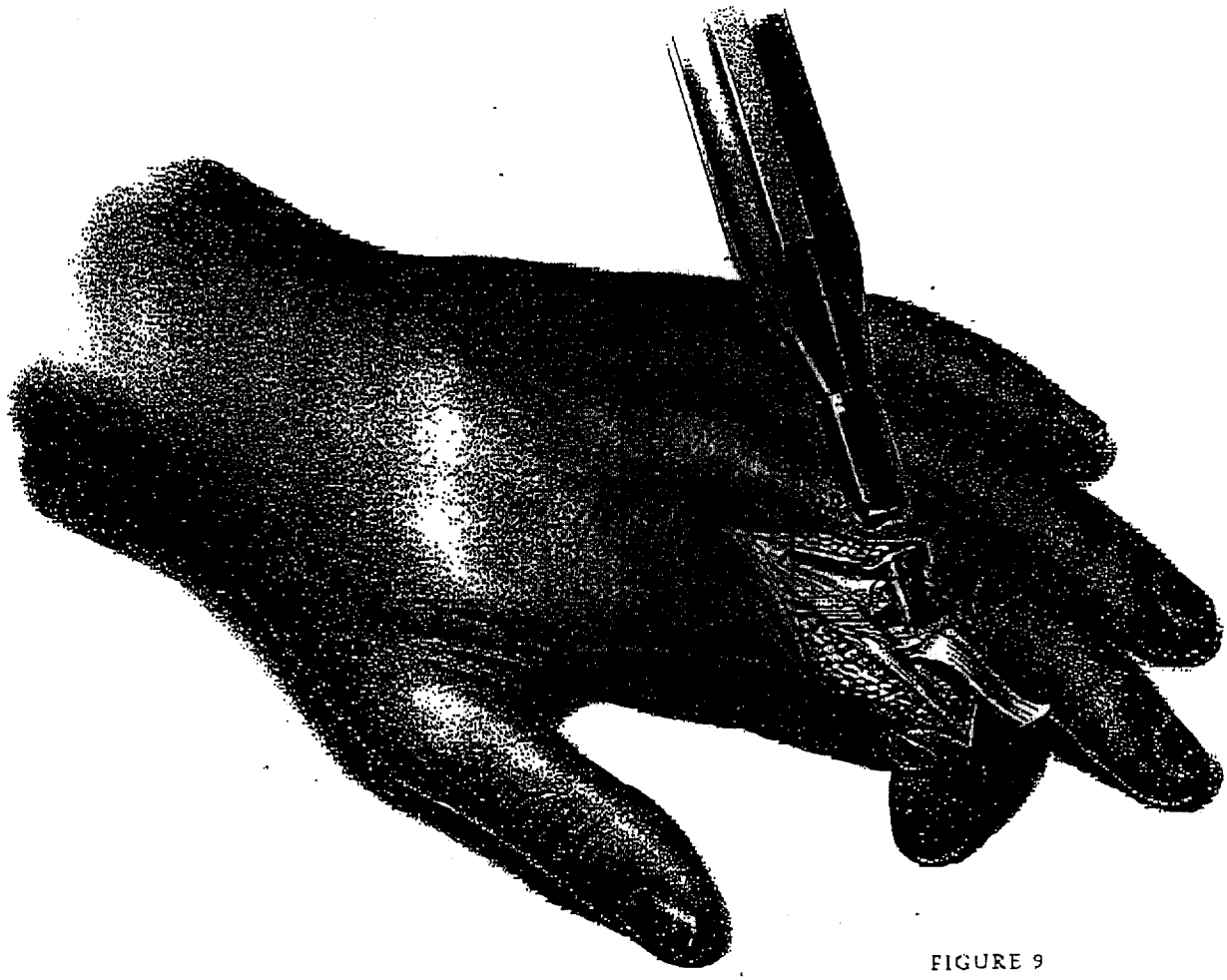

FIGURE 9

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 (FIGURE 9).

3

10

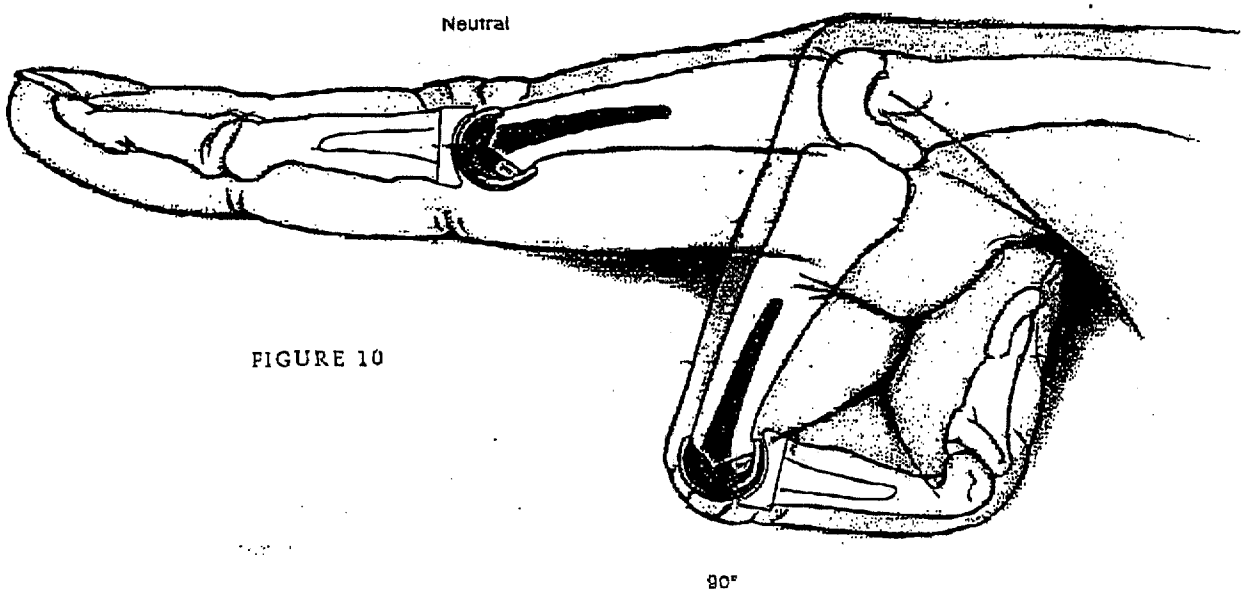

FIGURE 10

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 (FIGURE 10).

2A

TRIAL REMOVAL AND IMPLANT PREPARATION

11

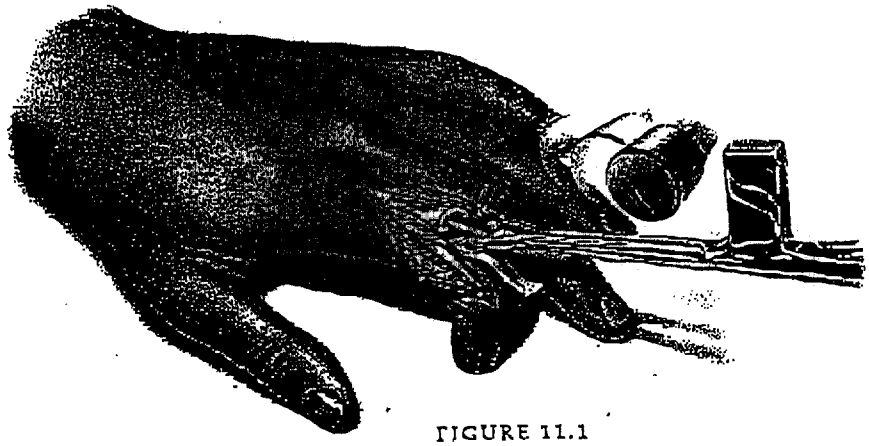

FIGURE 11.1

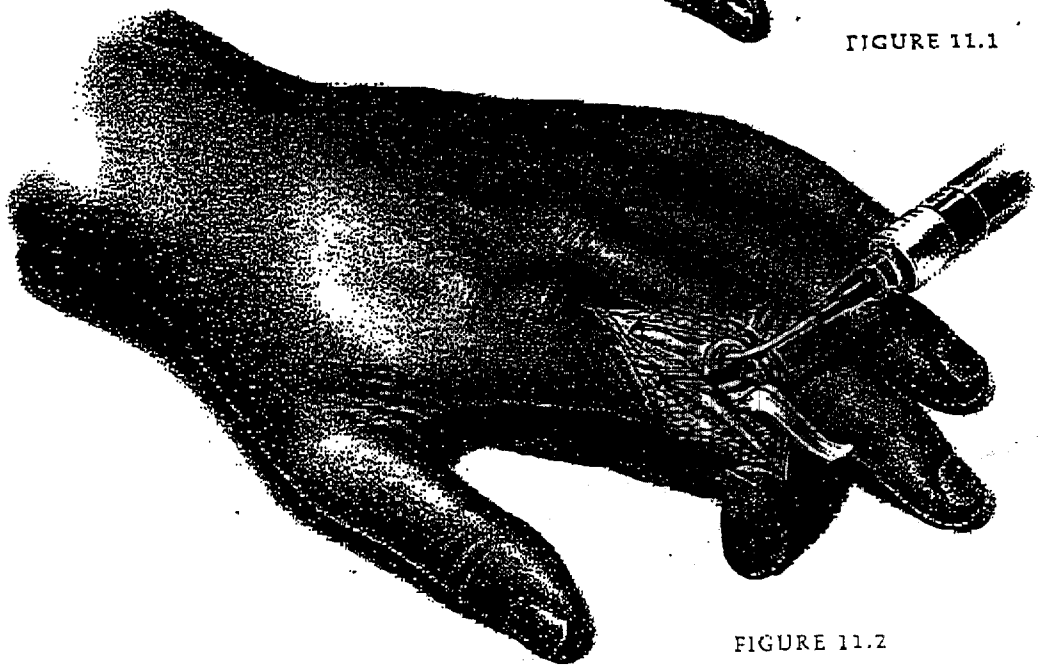

FIGURE 11.2

The extractor is used to remove the trial prosthetic components during the adjustment stages (FIGURE 11.1).

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 canula. Polymethyl methacrylate (PMMA) cement is then injected through a shortened #14 Intracath™ into the medullary cavities using a small syringe (FIGURE 11.2). The components 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.

12

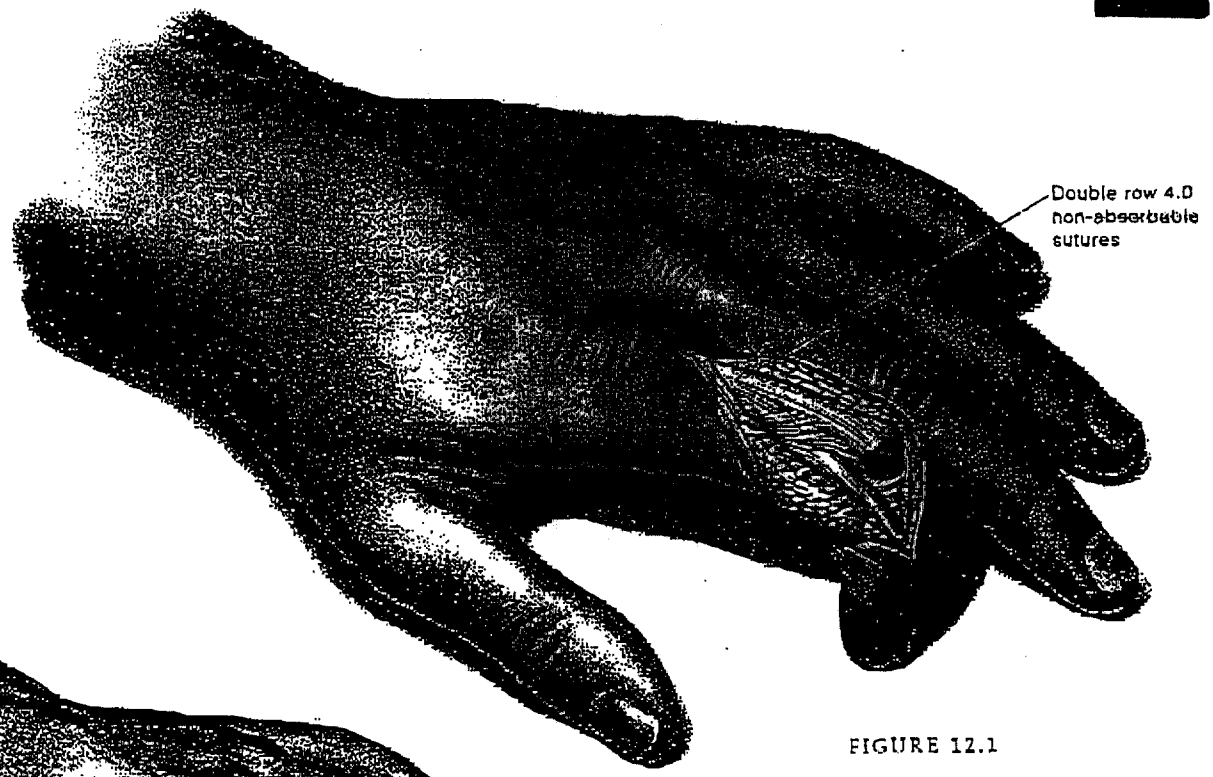

FIGURE 12.1

FIGURE 12.2

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 (FIGURE 12.1).

The skin is closed with nonabsorbable sutures (FIGURE 12.2) and a splint reinforced dressing is applied with the finger extended.

39

ALTERNATIVE CLOSURE FOR A DORSAL TENDON SPLITTING INCISION

13

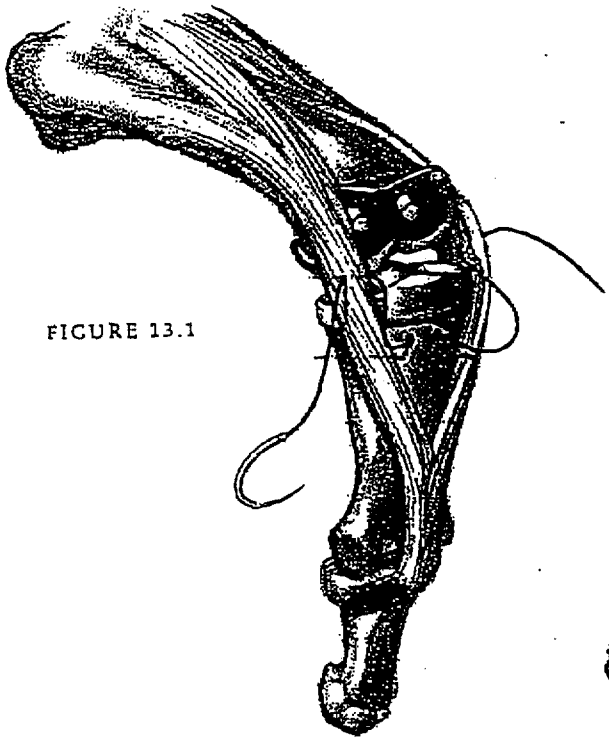

FIGURE 13.1

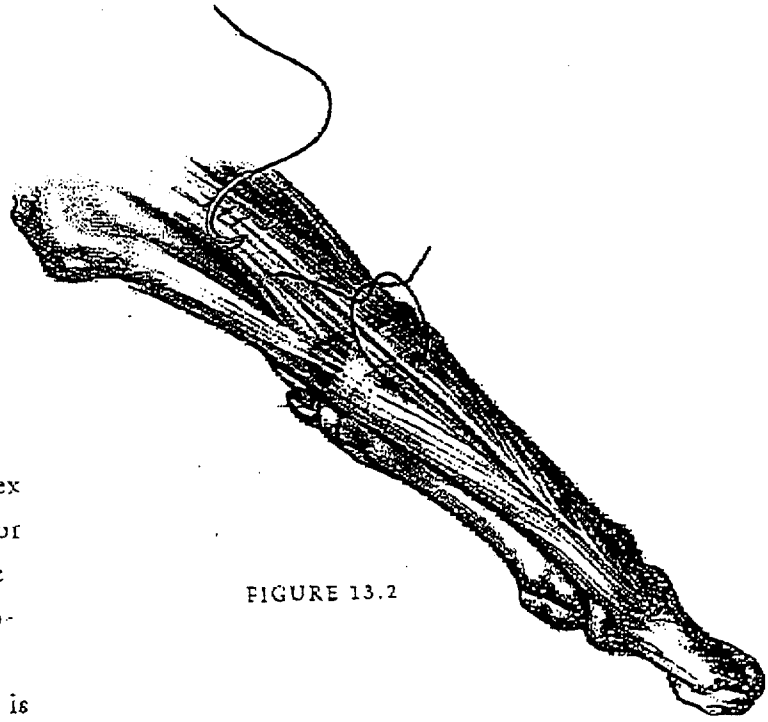

FIGURE 13.2

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 (FIGURE 13.1).

The finger is then extended and the suture is passed through the thickened aspect of the central slip (FIGURE 13.2).

With full extension, the suture is tied with minimal tension.

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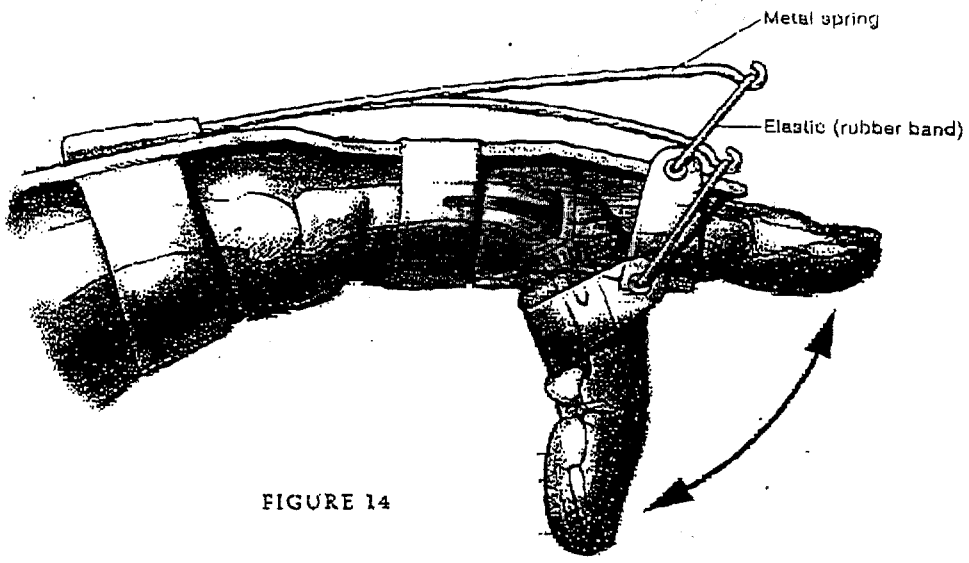

FIGURE 14

Postoperatively 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 will 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 are begun gradually at two to seven days. A dynamic splint is often helpful in the early phases of rehabilitation (FIGURE 14). This should 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 are 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 but if a stable pain free 60° arc of motion is obtained, the result is considered good.

40

PALMAR APPROACH AND INCISION

P1

FIGURE P1

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) (FIGURE P1).

42

P2

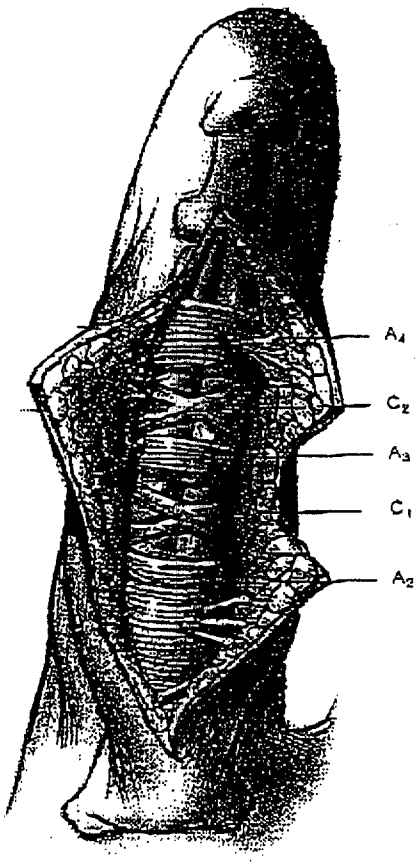

FIGURE P2.1

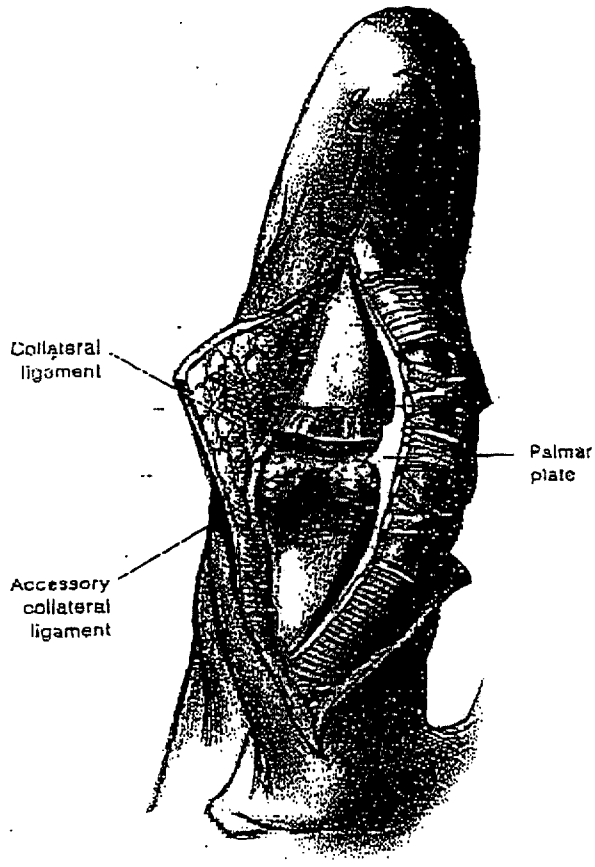

FIGURE P2.2

The flexor tendon sheath is first exposed (FIGURE P2.1). 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 (FIGURE P2.2).

Alternately, a partial release of the flexor tendon sheath containing the C_1, A_3 and C_2 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.

12

SURFACE RESECTIONS

P3

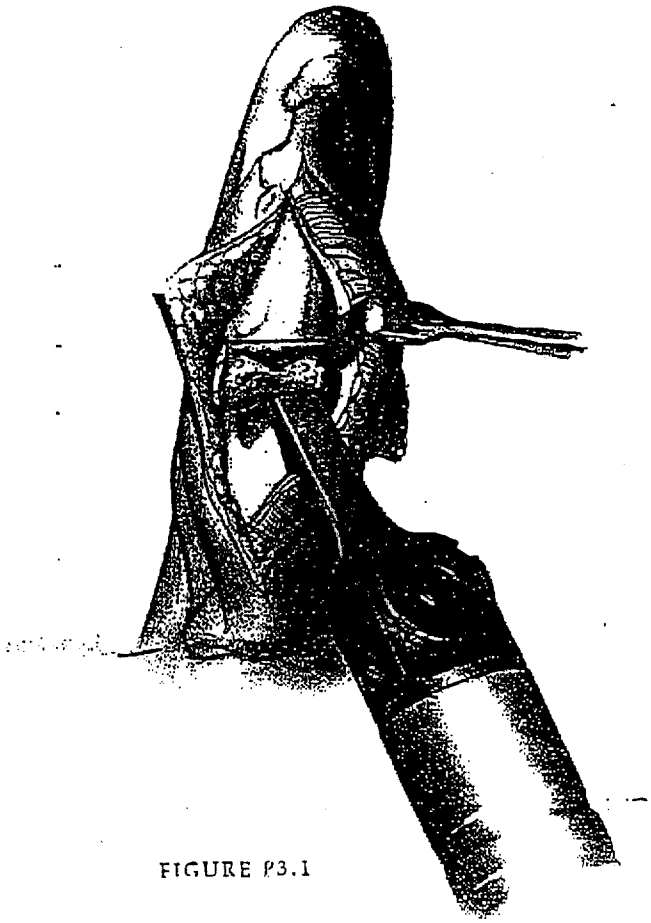

FIGURE P3.1

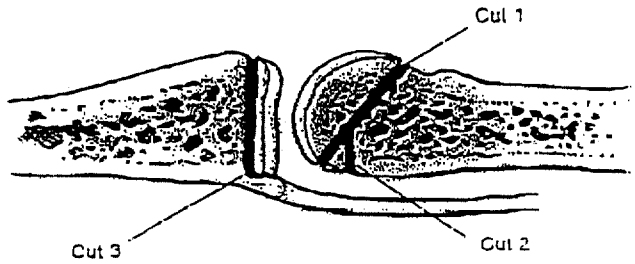

FIGURE P3.2

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 (FIGURES P3.1 AND P3.2).

P4

FIGURE P4.1

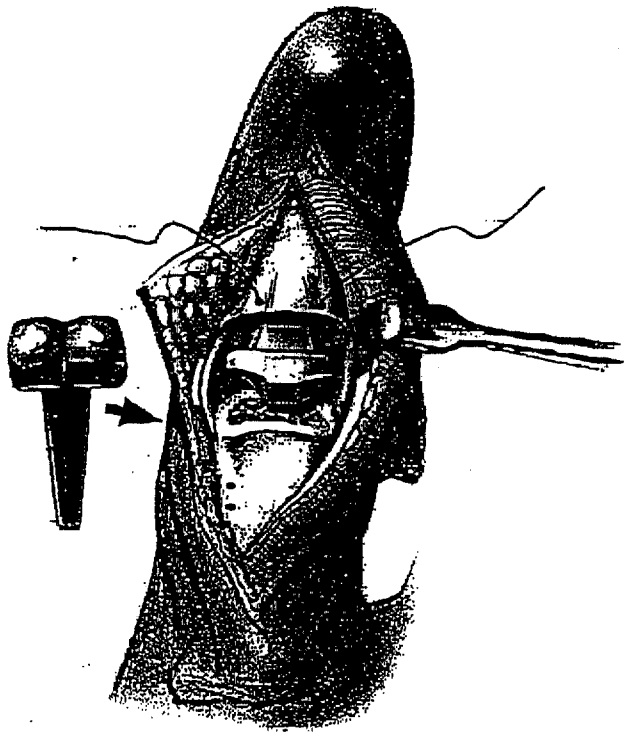

FIGURE P4.2

Preparation of the intramedullary cavities is performed similar to the dorsal technique (FIGURE P4.1). 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. 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 (FIGURE P4.2).

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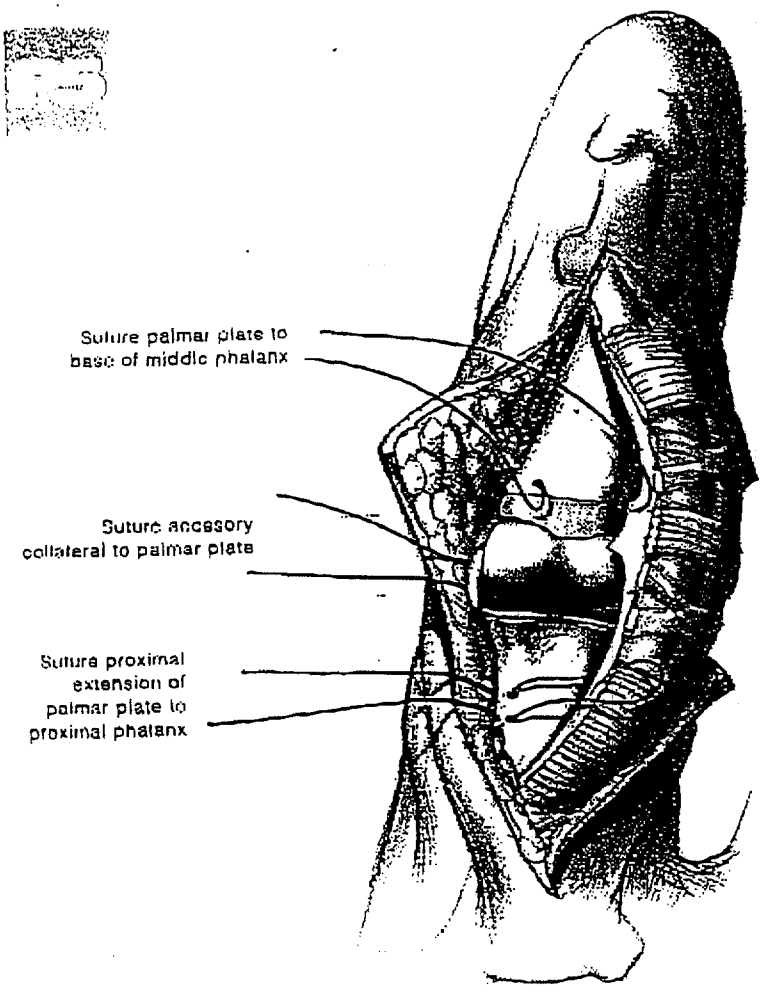
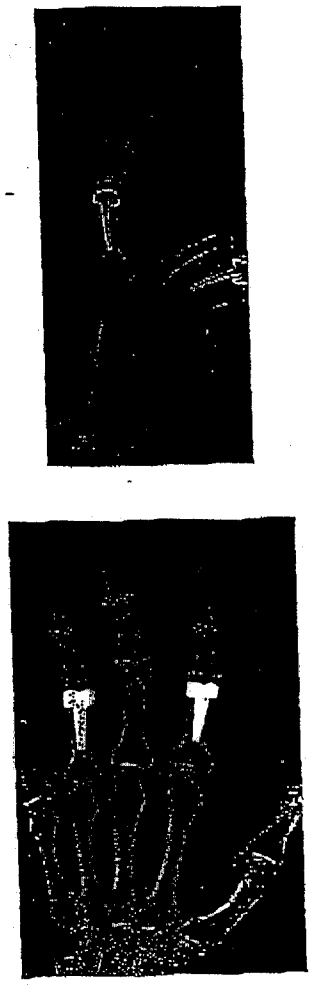


FIGURE P5.1



FIGURES P5.2 & P5.3

he 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 (FIGURE P5.1).

Final X-ray confirmation of alignment and position is obtained (FIGURES P5.2 & P5.3). 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.

POSTOPERATIVE CARE FOR THE PALMAR APPROACH

IV

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

If extension cannot be obtained after each flexion, a dynamic extension exercise splint is applied during exercise periods. A static extension splint for rest periods and night time is 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 postoperative stiffness. Elastic wrapping for edema control especially for nocturnal wear is also helpful. Buddy taping of the involved finger to an adjacent finger may also be beneficial. The finger will be somewhat swollen for a number of weeks postoperatively and may remain somewhat enlarged at the joint level for several months.

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

V FOLLOW-UP

Follow up exams should 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 follow-up intervals. Alignment of the finger(s), intramedullary alignment of the prostheses, cement mantle adequacy, evidence of loosening or subsidence should 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 silastic arthroplasty or by disarticulation.

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DEVICE TESTING

A mechanical test program of the devices was begun in May of 1996. This consists of two parts; a fatigue test and a wear test using a protocol similar to that used earlier on the MCP Components. The details of this protocol are available. Stability testing in a cadaveric model is reported in: Uchiyama et al. Kinematics of the Proximal Interphalangeal Joint of the Finger After Surface Replacement. Submitted to journal of Hand Surgery, Cooney WP, Beckenbaugh RD, Linscheid RL.

IntracathTM is a trademark of Becton Dickinson.

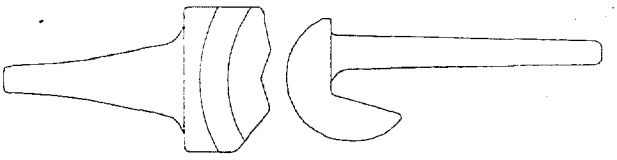
MicroAire® is a registered trademark of MicroAire® Surgical Instruments.

Avanta PIP Finger Prosthesis is available in the USA as Humanitarian Use Devices 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.

SP



Photograph or drawing of the implant

HUMANITARIAN DEVICE. The Avanta Proximal Interphalangeal (PIP) Finger Prosthesis is authorized by Federal law for use in arthroplasty (surgery) 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.

The effectiveness of this device for this use has not been demonstrated.

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.

INTRODUCTION:

Avanta Orthopaedics has developed an implant for the Proximal Interphalangeal (PIP) finger joint. The PIP joint is the joint which is the second one from the end of your finger. This implant is available for sale in the United States as a humanitarian use device. A humanitarian use device is one, which is used for conditions or diseases which typically affect fewer than 4000 people in the United States per year, and when there is no comparable device marketed to treat/diagnose those conditions or diseases. Your physician has determined that you may benefit from implantation of this finger joint implant. **You should be aware that the effectiveness of this device for this use has not been demonstrated.**

DESCRIPTION OF SURGICAL PROCEDURE:

This surgery involves the use of a finger joint replacement device for treatment of patients with certain kinds of arthritis (osteo-arthritis or post traumatic arthritis) and who expect to place their hands in heavy loading situations, or patients needing revision of a failed implant placed in the PIP joint.

A joint replacement surgery is an operation where the arthritic joint is removed and a metal and plastic joint is inserted to replace the natural joint. The surgery is expected to last about 2 hours. The procedure is done in the operating room and requires general anesthesia or an axillary block. (General anesthesia effects the entire body and is accompanied by a loss of consciousness. An axillary block results in anesthesia of the hand and forearm only. A tourniquet is applied to the arm to prevent bleeding during the surgery.)

In joint replacement surgery, your hand is opened at the finger joint, and the bones are trimmed. The metal and plastic joint replacement parts are fixed to the bones using bone cement or used in a cementless application. Antibiotics are usually given during and after the operation to prevent infection, as is normal in these cases, with current surgical treatment. After the operation, your hand will be in a bandage. This will be removed two to five days following the operation. You may need to wear a splint for up to 3 weeks. When the bandage or splint is removed, you will start physical therapy.

FORESEEABLE RISKS:

General Surgery Related Risks

- bleeding
- infection
- loss of use of the hand
- permanent disability
- death

Joint Replacement Related Risks

- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue (e.g., numbness)
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- dislocation of the joint
- cement protrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint

- surgery may be started but a joint replacement cannot be done resulting in fusion of the joint
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

POTENTIAL BENEFITS:

- improved range of motion
- relief of pain
- improved grip and pinch strength.

ALTERNATIVES:

You should thoroughly discuss the options for treating your finger joint with your doctor before selecting surgery as an alternative. Arthritis of the Proximal Interphalangeal Joint can be treated non surgically or with surgery. The non surgical options include the use of splints, joint injections and medications (including the use of aspirin type drugs).

Current surgical treatments include fusion of the bones together, surgery on the joint with tendon or joint replacement with silicone implants. Fusion has the benefit of relieving pain, and restoring pinch strength, however it has the limitation of no motion in that joint. Fusion may be a preferable treatment of the index finger when compared to silicone implants when good pinch strength is needed. It is possible that a fusion procedure may need to be revised due to undesirable motion between the two bones.

Joint replacement, with silicone implants has been available for a number of years and has the advantages of relieving pain and allowing motion at the joint. Some of the risks of silicone implants include the possibility for breakage, deformation, and side to side instability. If you are very active and use your hands heavily, you may not be good candidates for silicone implants.

You should be aware, all implants will wear over time with use. Therefore some degree of wear particle formation is inevitable with all implants including those made of silicone. The patient's biological response to these particles is variable. There are also reports in the medical literature suggesting a possible link between silicone implants and immunological abnormalities and autoimmune rheumatic disorders.

SB

WARNINGS:

- It is unlikely that your finger joint will be restored to the condition it was before your injury, arthritis or previous surgery. You should discuss your expectations of having surgery with your doctor before having surgery, as this procedure may not meet your expectations.

- You should be 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.

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