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Pyrocarbon Finger Joint Implant

An Evidence-Based Analysis

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Table of Contents

Background

Clinical Need

Patients suffering from finger joint pain or dysfunction due to arthritis and traumatic injury may require arthroplasty and joint replacement. This intervention is indicated for the finger joints when medical management has failed to relieve the pain or when the digit deformity is interfering with hand function and activities of daily living (ADL). Surgical procedures can greatly improve function and relieve pain, allowing patients to maintain independence and improve their quality of life.

For patients with metacarpophalangeal (MCP) deformities, surgical options include synovectomy, intrinsic release/transfer, extensor tendon relocation, arthrodesis, and implant arthroplasty. Relatively few surgical options exist for the painful arthritic interphalangeal (PIP) joints. Currently, patients with arthritis of the PIP joints have 2 surgical options—arthrodesis or implant arthroplasty. (1) Arthrodesis provides excellent pain relief and stability. However, it sacrifices finger function in exchange for these benefits.

The goals of implant arthroplasty of the finger joints are pain relief, correction of deformity, and improvement in the function and appearance of the hand. Many prosthetic implants have been designed for the replacement of MCP and PIP joints. The most popular finger implant is the Swanson prosthesis, a single piece of silicone that acts as a flexible space. (2) Several silicone finger joint prostheses designs have tried to improve upon the Swanson prosthesis. (2)

The shortcomings of the silicone implants are implant fracture, bone reaction adjacent to the implant, implant dislocation, and silicone synovitis. As in other joints, anatomically and biomechanically sound restoration of the MCP and PIP joints with compatible materials is a realistic expectation. The longevity of the implant is also important especially for younger patients.

Several important points regarding the design of optimal finger implants for proper digital function have been defined. (3) The ideal finger implant would have the following characteristics: It would

- Provide adequate stability and a functional range of motion (ROM)
- Have mechanical advantages and evenly distributes stress across the joint
- Be easily implantable
- Have biocompatibility and low-wear characteristics

Pyrolytic-based materials have proved to be strong, durable, and chemically non-reactive in the body. (4) It has been proposed (3) that an anatomically shaped prosthesis should have a virtual, rather than a fixed, axis at its instant centre of rotation, which allows a combination of motions and that a larger contact area could distribute peak loads better.

Diseases and Conditions

The etiologies of the articular destructions of the finger joints include rheumatoid arthritis (RA), osteoarthritis (OA), trauma, and systemic lupus erythematosus (SLE).

Rheumatoid arthritis

RA is an inflammatory condition and a destructive disease. The exact cause is unknown, but it is believed to be caused by an autoimmune response. The joints most commonly affected by RA are the

wrist, MPC, PIP, joints of the thumb, and the small joints of the feet. In RA, the synovial membrane that protects and lubricates joints becomes inflamed. As a result of synovitis, the supporting structure of the MCP joints fails. This results in ulnar deviation of the fingers, subluxation, and the development of fixed flexion deformities. Swan neck deviation of the fingers may occur. Muscles and tendons on one side of the joint may overpower those on the other side, pulling the bones out of alignment. (See Appendix 2.)

The arthritic PIP joint demonstrates fusiform joint swelling. With progression of the condition, marginal osteophytes (Bouchard nodes) become evident with progressive lateral deviation of the digits.

Management of patients with this disease relies on understanding of the effects of pain, stiffness, instability of the joint, deformity, and their effect on daily living.

Osteoarthritis

OA results from wear and tear on the joints. It involves the destruction of cartilage that protects bones. The result is loss of shock absorption and damage to the ends of the bones.

Post-traumatic arthritis

Trauma, such as injury to the ligaments, muscles, tendons around a joint, or bone fracture can lead to inflammation and pain, making the joint susceptible to further damage. This can eventually lead to joint destruction and OA. The PIP joints are subject to disability secondary to traumatic arthritis. Disability in one finger frequently affects the adjacent fingers.

Systemic lupus erythematosus

SLE is a multisystem disease of unknown cause in which tissues and cells are damaged by autoantibodies and immune complexes. Ninety percent of the cases occur in women of childbearing age, suggesting hormonal abnormality as a risk factor. The disease involves the joints, most frequently the MCP and PIP joints of the hands, wrists, and knees. About 10% of the patients develop swan-neck deformities of the fingers and ulnar drift at the MCP joints.

Incidence and Prevalence of Arthritis

Rheumatoid Arthritis

The population-based disease registry of Rochester, Minnesota (5) showed that the average annual age-adjusted incidence rate for RA in the American population was 21.6 per 100,000 for males and 48 per 100,000 for females. The incidence rate increased with age in both sexes, with a female to male ratio of 2.3 to 1. Data from the same registry showed a decline in the incidence rate of RA in women between 1964 and 1974. The authors suggested that this decline could be related to the increased use of oral contraceptives during the same time period.

The prevalence of RA was fairly constant in North American whites, approaching 1%. Two Aboriginal nations had prevalence rates 3 to 7 times higher than that in whites. It has been suggested that environmental factors are associated with this disease. The prevalence of definite RA increases with age in both sexes and approaches 2% in males and 5% in females over age 55.

Osteoarthritis

OA is considered to be the most common joint disease among the white population. (6) The prevalence of OA in hands and feet has been reported to be as low as 4% at ages 18 to 24 and as high as 85% at ages 75 to 79, with an overall prevalence rate of 37%. (Cited in 6) Moderate and severe cases are rare in individuals under age 45, but are almost twice as prevalent in females than in males. (6) Alaskan Inuit had the lowest rate of OA (21.9% for males and 23.6% for females) and Blackfeet Indians had the highest prevalence rate (61% for males and 74% for females). The prevalence rate of OA in North America is shown in Table 1.

Table 1:Prevalence Rate of Osteoarthritis in North America*

Age group (years)	Males (%)	Females (%)
18–24	-	-
18–79	37.4	37.3
65+	78.0	87.0

*From Neuberger, 1984 (6)

Systemic lupus erythematosus

The prevalence of SLE in the United States varies from 15 to 50 per 100,000 population. It is more common in blacks than in whites. Hispanic and Asian populations are also susceptible.

Types of Joints

There are 4 types of joints in the body:

- Fixed joints: These joints, such as skull bones, absorb shock, but cannot move.
- Hinge joints: These joints, such as knee joints, allow movement in 2 directions only.
- Pivot joints: These joints, such as elbows, allow for rotating movements.
- Ball-and-socket joints: These joints, such as hips or fingers, allow the most movement because the joint consists of the rounded end of one bone fitting into the hollow part of another bone, making swinging and rotating movements possible.

Range of Motion

The MCP joints are the key joints for finger function. These joints allow extension–flexion, adduction–abduction, and some rotation. The PIP joints are hinged joints, with a functional stability throughout an arc of flexion and extension. Under normal conditions, the MCP joint attains approximately 15° hyperextension and 90° flexion for a total of 105°. The PIP joint normally has a 115° ROM.

The 2 important functions of the hand for ADL are to pinch, as in holding a pencil, and to grip, as in holding a cup. Patients with arthritis often have difficulty doing these functions.

Range of Motion Required for Activities of Daily Living

There are 3 types of motion: normal motion, which is the active ROM, functional motion, which is that arc of motion needed to accomplish a designated task, and total arc of motion, which is the sum of the individual joint positions for a given finger. Functional ROM for ADL has been measured in normal hands. A functional arc of motion between 33° and 73° (mean, 61°) for MCP joints and between 36° and 86° (mean 60°) for PIP joints is considered to be necessary for most ADL (7). Full active and functional ROM of the finger joints for 11 ADL are shown in Appendix 3.

The Technology

Pyrocarbon Material

Pyrocarbon, a form of pyrolytic carbon, is a strong, ceramic-like material. Pyrolytic carbon was originally developed in the late 1960s for permanent nuclear waste enclosures. Because the material was found to be strong, durable, and resistant to wear, it became the standard in the manufacture of heart valves. Pyrocarbon has now proved to have an excellent track record for durability and biocompatibility.

Pyrocarbon Prostheses

The implants are made of a 0.42 mm thick pyrolytic carbon coating over an appropriately shaped graphite substrate. The devices consist of a ball and socket articulation with anatomically shaped stems to be inserted intramedullary without bone cement. A small amount of tungsten has been added to the graphite substrate so that prostheses components can be clearly visible on radiographs.

Currently Ascension MCP and Ascension PIP are the only pyrocarbon finger joint implants available in Canada (Appendix 4). The manufacturer of the Ascension MCP and Ascension PIP is Ascension Orthopedics Inc., which develops and manufactures pyrocarbon implants for replacement of the small joints of the hand, upper extremity, foot, and radial head.

The Ascension MCP is a 2-piece prosthesis for the total replacement of the MCP joints. The prosthesis is a semiconstrained, uncemented device. The proximal component replaces the metacarpal head and the distal component resurfaces the articular surface of the phalange. Intramedullary stems stabilize both components.

The Ascension PIP was developed to replace the PIP joints. The prosthesis is a 2-piece, bicondylar, semiconstrained, uncemented total joint. Each component has an articulating surface, a subarticular collar, and an intramedullary stem. This bicondylar articulation allows joint flexion–extension motion while restricting adduction–abduction motion. An anatomically shaped stem is designed to fill the medullary canal and promote component fixation.

Regulatory Status

The Ascension MCP was the first total finger joint implant of its kind to receive United States Food and Drug Administration (USFDA) pre-market approval. Ascension MCP received CE Mark *(Conformité Européenne)* approval in December 1999 and was introduced in Europe in January 2000. The technology received USFDA pre-market approval in November 2001 and became available in the United States in January 2002.

Ascension PIP, the second pyrocarbon finger joint implant developed by Ascension Orthopedics Inc., received USFDA approval under Humanitarian Device Exemption[1] (HDE) to market the product as a Humanitarian Use Device (HUD) in March 2002 (Appendix 6).

Ascension MCP and PIP are the only pyrocarbon finger implants that are available in Canada. Health Canada has issued medical device licences for the Ascension MCP and Ascension PIP.

Ascension MPC	Licence # 23846, Class III device
Ascension PIP	Licence # 32081, Class III device

Alternative Technologies

The most commonly used artificial finger joint implant is the Swanson implant, a single piece of silicone elastomer that functions as a flexible spacer. The 2 stems slide freely within the medullary canals of the finger bones. The prosthesis is now manufactured from a silicone material called Flexspan.

Various nonsilicone implants have been designed: the constrained or fixed hinge, semiconstrained, minimal-constrained, and surface replacement designs. These newly designed implants include the Saffar, the Digitale, the Wecko fingergrundgelenk prosthese, the Digitos, the DJO3A, the Mathys, and the Avanta SR. These designs, described below, are either recently available or under investigation.

1. The Saffar MCP and PIP (DIMSO S. A., Mermande, France) are non-cemented semiconstrained titanium polyethylene prostheses.

2. The Digitale MCP prosthesis (Procerati, Paris, France) is a titanium-coated, anatomically contoured stainless steel sleeves for bony fixation.

3. The Wecko fingergrundgelenk prosthese (Implant Service, Hamburg, Germany) is an assembled constrained hinge with stems that slide into bone apposition sleeves.

4. The Digitos, (OSTEO A.G., Selzach, Switzerland) is a new implant, a cemented modular constrained hinged-type prosthesis. This device was designed for unstable joints with impaired collateral ligaments.

5. The DJOA3 implant (Landos, Chaumont, France) designed by Condamine for MCP and PIP joints uses elastic fixation of ellipsis-shaped polyethylene stems wedged into the intramedullary canals. The stainless steel surface of the metacarpal proximal component is spherical and the articular surface of the proximal phalangeal component is cylindrical.

6. The Mathys (Mathys Ltd, Bettlach, Switzerland) MCP and PIP prostheses is made of polyacetyl resin proximal components and polyester distal components, which snap-lock together with a twisting manoeuvre.

7. The SR MCP and SR PIP finger joint implants made by Avanta Orthopedics are 2-piece semi-constrained finger prostheses. The distal component is made of an ultrahigh molecular weight polyethylene (UHMWPe) articulating surface and stem, and the proximal component consists of a cobalt-chromium-molybdenum articulating surface.

Avanta Orthopaedics has received an HDE from the USFDA to market SR MCP and SR PIP finger joint implants as an HUD in March 2002. Health Canada has issued licences to SR MCP and SR PIP implants.

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[1]These implants are not available or licensed in Canada

Literature Review On Effectiveness

Objectives

1) To identify the subset of patients who might benefit from the pyrocarbon finger joint implants
2) To compare the effectiveness and safety of the pyrocarbon finger joint implants with that of the most commonly used implants for MCP and PIP joint arthroplasty

Methods

To review the published literature on pyrocarbon finger joint implants, a search of MEDLINE and EMBASE from January 1**,** 1996 to January week 1, 2004 was undertaken.

Results of the Literature Search

The search yielded 6 citations that mentioned pyrocarbon finger joint implants. One of the 6 articles was in English (8), 1 was in French, (9) and 4 were in German (10–12). The English- language article contained useful clinical data for pyrocarbon MCP joint implant. Non-English articles were translated and reviewed. The French article studied a hinge-type implant made of pyrocarbon. The German articles described only the technology and did not contain clinical data. In addition, the results of 2 studies (13;14) published as abstracts, were included in the assessment.

A study (15) that published long-term follow-up results of silicone finger joint implants was used for comparison purposes. A recently published literature review (16) of silicone MCP implants was identified and reviewed for further information.

Level of Evidence

The level of evidence was assigned according to the scale based on the hierarchy by Goodman (1985). (See Table 2.) An additional designation "g" was added for preliminary reports of studies that have been presented to international scientific meetings.

Table 2: Quality of Evidence: Pyrocarbon Finger Joint Implant

Type of Study (Design)	Level of Evidence	Number of Eligible Studies Analysed
Large RCT*, systematic reviews of RCTs	1	
Large RCT unpublished, but reported to an international scientific meeting	1(g)†	
Small RCT	2	
Small RCT unpublished, but reported to an international scientific meeting	2(g)	
Nonrandomized trial with contemporaneous controls	3 a	
Nonrandomized trial with historical controls	3 b	
Nonrandomized controlled trial unpublished, but reported to an international scientific meeting	3 g	
Surveillance (database or register)	4 a	
Case series, multi-site	4 b	1 on MCP joints
Case series, single-site	4 c	
Case series unpublished but presented to an international scientific meeting	4(g)	2 On PIP joints
TOTAL		**3**

*RCT refers to randomized controlled trial; † refers to "grey literature."

Results of the Literature Review

A. Pyrocarbon MCP Joint Implants

Mayo Clinic Study

Cook et al. (8) studied 53 patients: 44 who had RA, 3 who had OA, 5 who had post-traumatic arthritis, and 1 who had SLE. Forty-four patients were female and 9 were male. The average age at the time of operation was 58 years (range, 21–85).

From December 1979 to February 1987, 151 pyrocarbon MCP implants were inserted. Fifty-four index fingers, 43 long fingers, 28 ring fingers, and 26 small fingers were treated with the pyrocarbon implant. Fifty-one patients were right-hand dominant and 101 implants were placed in dominant hands.

Twenty patients (51 functioning implants) died after the implant had been *in situ* for an average of 7.2 years. Three patients (11 implants) were lost to long-term follow-up. Although no patient was excluded from the study, the long-term follow-up data with an average of 11.7 years (10.1 to 16 years) was available for only 26 patients (71 implants). Nineteen of the 26 patients (62 implants) had RA, 4 (4 implants) had post-traumatic arthritis, 2 (4 implants) had OA, and 1 (1 implant) had SLE. A complete set of preoperative, postoperative, and follow-up radiographs was available for 53 of 71 implants.

The mean arc of motion significantly increased by 13° between the preoperative and long-term follow-up measurements ($p=.01$). The arc of motion of the long finger increased 19°; the ring finger, 16°; the index finger, 10°; and the small finger, 11°. The increase in ROM was associated with a significant improvement in the extension of the long finger ($p=.003$), ring finger ($p=.03$), small finger ($p=.02$), and all fingers combined ($p<.001$). An overall increase of 16° in extension of MCP joints was observed. Active flexion did not change significantly between the preoperative and long-term follow-up measurements. The average ROM of the MCP joint of each finger and all fingers combined is shown in Table 3.

Table 3: Average Range of Motion of MCP Joint of Each Finger and All Fingers Combined

	Range of motion in degrees* (mean ± SD)				
	Index finger (n=20)	**Long finger (n=16)**	**Ring finger (n=13)**	**Small finger (n=14)**	**All fingers (n=71)**
Preoperative					
Extension deficit	-33±20	-44±20	-44±26	-47±37	-40±25
Active flexion	72±16	78±15	85±14	87±17	79±17
Arc of motion	39±22	33±19	41±23	42±30	39±23
Early postoperative					
Extension deficit	-24±17	-21±14	-24±9	-17±16	22±16
Active flexion	66±17	67±12	66±22	61±27	65±19
Arc of motion	43±18	46±14	42±22	44±20	43±18
Long-term follow-up					
Extension deficit	-27±22	-25±20	-22±18	-21±20	-24±20
Active flexion	75±22	77±13	78±17	73±35	76±22
Arc of motion	49±25	52±23	57±27	53±27	52±25

Ref (8)

*A neutral position of the MCP joint was recorded as 0 degrees; hyperextension and flexion were recorded as positive values; extension deficits were recorded as negative values.

Pyrocarbon joint arthroplasty appeared to provide a more functional arc of motion with the digital joints in a less flexed position. Although a 13° improvement in the arc of motion may not be clinically significant, it should be taken into consideration that further deforming forces due to rheumatoid progress continues and acts adversely. Figure 1 shows the average joint motion before arthroplasty and at the final follow-up.

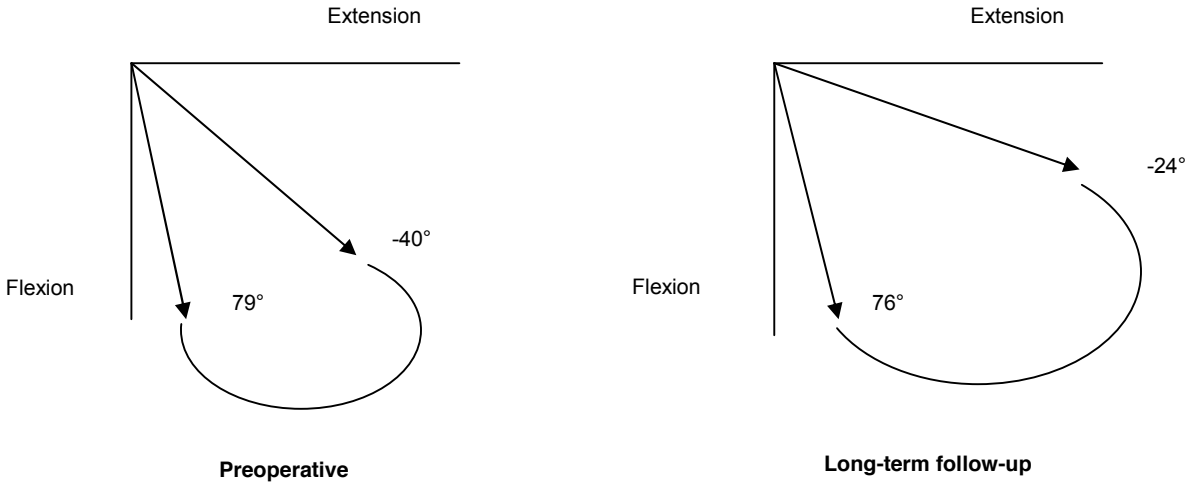

Figure 1: Average Joint Motion Before and After Pyrocarbon Arthroplasty

At the time of long-term follow-up, ulnar deviation averaged 19°, which was equivalent to the preoperative values (mean deviation of 20°). The pyrocarbon implant appeared to have halted the progression of ulnar deviation.

Eighteen (12%) of the 151 implants in 11 patients were revised. The reasons for revision were mostly subluxation, dislocation, or soft tissue imbalance. In 1 case, the reason for revision was a fracture due to heavy lifting that occurred 9 years postoperatively. Fourteen were replaced with a silicone-elastomer or another type of implant. The 4 remaining implants were removed due to loosening and a pyrocarbon implant was inserted with the addition of bone cement, bone graft, or both.

There were no clinically observed instances of synovitis. None of the revised implants had any visible wear or deformity of the surfaces of the stems. Tissues from 10 hands with revision were submitted for pathological evaluation. There were 4 instances of chronic inflammation and 3 instances of proliferative synovitis. No evidence of intracellular particles or particulate synovitis was found.

Radiolucency was observed in 12 implants. Six of the 12 implants were in 1 patient who had RA. None of these patients had clinical signs of loosening of the implant. Sixteen of the 53 implants that were evaluated radiographically showed evidence of severe subsidence at the time of long-term follow-up.

The 18 revised implants, the 11 implants that were lost to follow-up, and the 7 implants that were dislocated at the time of long-term follow-up were categorized as failures. There was a mean annual failure rate of 2.1% ± 3.2% (range, 0–9.4%). The 5-, 10-, and 16-year implant survival rates were as follows:

5 years	82.3% (95% confidence interval 74.6–88.2)
10 years	81.4% (95% confidence interval 73.0–87.8)
16 years	70.3%

The 16-year implant survival rate for women was notably lower than that for men (69% versus 82%). The diagnosis of RA was also associated with a lower 16-year implant survival rate (68% versus 84% for other diagnoses).

Figure 2 illustrates survival curve for the pyrocarbon MCP joint implants.

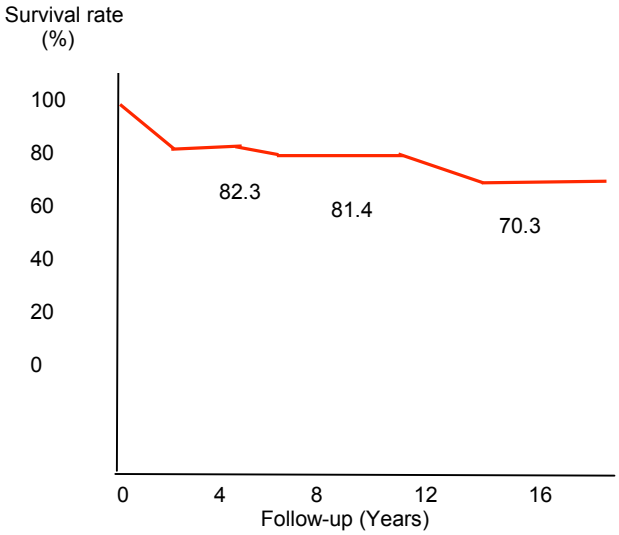

Figure 2: Survival Rate for the Pyrocarbon MCP Joint Implants

Subgroup Analysis

The retrospective case series by Cook et al. (8) formed the basis for USFDA Summary of Safety and Effectiveness Data (SSED) for the device and its PreMarket Approval. In USFDA data, patients were stratified and evaluated based on 2 baseline medical conditions: 1) OA/post-traumatic arthritis, and 2) RA/SLE.

In the USFDA SSED, 53 patients (147 implants) with a mean follow-up of 8.5 years (range, 1.7 to 17.2 years) were considered for evaluation. Separate success and failure criteria were defined for the OA/trauma and RA/SLE patient groups. Each implant was determined to have an outcome of excellent, good, unsatisfactory, or indeterminate. Implants with an excellent or good outcome were considered a success, and implants with an unsatisfactory outcome were considered a failure. Patients lacking information were considered indeterminate.

The 1 to 5 year and the long-term effectiveness analysis for RA/SLE cohort are shown in Table 4.

Table 4: RA/SLE Pyrocarbon MCP Joint Implant 1 to 5 Year and Long-Term Effectiveness Results

	Implants (N=138)	
	1–5 years No. (%)	Long-term No. (%)
Success	82 (59) (46 excellent, 36 good)	51 (37) (30 excellent, 21 good)
Failure	37 (27)	73 (53)
Indeterminate	19 (14)	14 (10)

For the OA/trauma group, effectiveness criteria were defined for a greater than 2-year treatment outcome analysis. Two years was set as a minimum amount of time that the surgical improvement must be maintained to be deemed successful. The results are shown in Table 5.

Table 5: OA/Trauma Pyrocarbon MCP Joint Implant Effectiveness Results

	Implant (N=9) No. (%)
Success	7 (78) (6 excellent, 1 good)
Failure	1 (11)
Indeterminate	1 (11)

The 6 implants that had an excellent outcome had their last evaluation ranging from 3.5 to 16 years. The implant with a good outcome had a last evaluation at 17 years, and the implant with indeterminate outcome had a 0.5-year evaluation demonstrating good improvement. Of the 6 implants with excellent results, all but 1 demonstrated an increase in ROM. All implants demonstrated no joint pain at final evaluation except for the unsatisfactory implant that had pain secondary to loosening that occurred 1.1 years after implantation.

European Publications on Pyrocarbon MCP Joint Implant

Three German citations (10–12) discussed pyrocarbon MCP joint implants. These articles did not contain clinical data, but discussed the issues of finger joint arthroplasty and pyrocarbon implants. Rehart et al. (10) indicated that pyrocarbon MCP joint implants provide a ROM between 30° and 40° depending on the joint that has been replaced.

Beckenbaugh et al. (11) discussed the ideal indications for the device. The authors indicated that the stability of the implant within the bone is time-dependent and is achieved through appositional bone

fixation. The authors stated that the ideal indication for pyrocarbon joint arthroplasty is for primary or post-traumatic arthrosis of the joints and that caution must be taken in using pyrocarbon implants for people with RA because of they tend to have tender marrow/medulla and the thin cortical bones. The authors also stated that, for pronounced finger deformities, silicone finger implants might be preferable because not enough stability could be achieved with the pyrocarbon finger joint implant. A complete MCP joint luxation with proximal migration has been considered as a contraindication for pyrocarbon joint arthroplasty.

Semlitsch and Willert (12) discussed the application of bone cement in arthroplasty of upper and lower extremities. The authors have argued that with a cementless implantation, one cannot always attain a long-lasting positioning of the prosthetic parts, and that, with the silastic implantation, this will never be attained.

B. Pyrocarbon PIP Joint Implants

The results of 2 studies on pyrocarbon PIP joint implants were published as abstracts (9;10). In addition, a French study on PIP joint implant was translated and reviewed for additional information. (9)

First study on pyrocarbon PIP joint implant

Eleven patients who had hand injuries with considerable functional loss and pain were referred to 1 of 2 tertiary care centres (Wrightington Hospital [United Kingdom] and CUF Hospital [Portugal]). (13) Ten were males and 1 was female. The age of the patients was between 33 and 62 years. The mean time between injury and surgery was 24.6 months. The mean arc of motion was 2° preoperatively, but improved to 62° by 18 months postoperatively. Two of the 11 patients needed revision surgery due to distal implant malposition resulting from altered anatomy. All 11 patients were pain-free at the end of an 18-month review.

Second Study on Pyrocarbon PIP Joint Implant

The outcomes of pyrocarbon PIP joint arthroplasty with 45 implants in 32 patients (11 post-traumatic arthritis, 11 OA, 10 RA) were reviewed. (14) Preoperatively, pain was a significant factor, as well as deformity, joint instability, and decreased ROM. Six to 12-month follow-up results showed reduced pain, improved ROM, and stability of the joint. Five patients required additional procedures including reduction of subluxation, flexor tenolysis, excision of nodule, and volar plate tightening.

French Study on Pyrocarbon PIP Joint implant

Moutet et al. (9) studied a different type of pyrocarbon joint implant: a hinge-type implant made of pyrocarbon. The authors described an original digital articular implant made of titanium and pyrocarbon. The digital articular implant is made of 2 connectors alloyed with the titanium TA6V ELI (Extra Low Interstitial). The authors indicated that it is the pyrolytic carbon coating that makes this implant original. The use of titanium is for the rigidity and solidity of the medullary stems. The implant is made of a 0.5 mm thick pyrolytic carbon coating over a graphite substrate allowing high resistance to wear and minimal abrasion of contact surfaces. Ten implants has been tested in laboratory under over 60 million continuous cycles of direct flexion–extension, and no rupture of the hinge has been observed.

This study included 13 patients (10 men and 3 women), mean age of 44.5 years (range, 23–69 years). Fifteen arthroplasties were performed on 13 PIP and 2 MCP joints. Two patients had simultaneous double implants on PIP joints. Most of the patients had post-traumatic arthritis (10 patients), 4 patients had OA, and 1 patient had RA. Arthroplasty was performed 1 to 10 years after the causal event. The average follow-up was 20 months, with a minimum of 1 year and a maximum of 4 years.

The implants were put in place with the use of cement, which was introduced by syringe into the diaphyseal mountings previously prepared. The average ROM was 13.75° preoperatively and increased to 47°. Table 6 shows the improvement in the arc of motion following arthroplasty.

Table 6: Average ROM in Degrees for Pyrocarbon Finger Joint Implants

	Preoperative Mean degrees	Postoperative Mean degrees
Extension deficit	-5.00	-22.50
Flexion	18.75	69.00
Arc of motion	13.75	47.00

Preoperatively, 10 of the 13 PIP joints were continuously painful or painful at the least movement. The 2 MCP and the 3 PIP joints were painful upon movement only. Postoperatively, 11 of the 13 PIP joints were pain-free. Mild pain remained in 2 PIP joints and the 2 MCP joints at the end of active flexion against resistance.

Grip strength improved by 56% and pinch strength improved by 49%. The joints were stable and no abnormal lateral movement was observed. The x-rays did not show any indication of osteolysis. One patient who had a fracture due to a bad fall had to be treated by looping a steel wire. However, the functional results were poor and the patient requested the amputation of this unusable finger.

Four Generations of Finger Implants

Since the 1950s, over 30 different designs of finger joint implants have been proposed. These devices are categorized into 4 generations. The first generation refers to the metallic hinge designs. (17) These were followed in the 1960s by the development of the second generation of single-piece silicone implants with the concept of using a flexible hinge as a joint spacer. The Swanson implant, the original silicone implant, was an articulated constrained device designed by Swanson in 1972 for arthritic finger joints. (18) However, Swanson never suggested that this implant should be regarded as a replacement prosthetic joint; rather, it should be considered simply as a flexible space maker.

Over the last 30 years, more articulated, constrained silicone implants (hinged) based on the Swanson concept were developed. The first Swanson prostheses were manufactured from conventional Silicon elastomer (CSE) or "372," and later designs were developed from high performance (HP) elastomer. (16) The rate of fracture has been found to be less with new HP Silastic than with original CSE material. (16) However, MCP joint arthroplasty remained a challenge since strong forces applied by the functioning tendons and ligaments during flexion–extension movements caused subluxation and fracture of the implants. Fracture tends to occur at the junction of the distal stem and hinge of the prosthesis. (16) The third generation of the finger implants applied a new concept: a 2-piece design for finger prosthesis. (19) The fourth generation of the finger implants, a non-constrained ball and socket design, was developed in 1970s with pyrocarbon materials.

Finger joints implants have been designed primarily for the MCP joint. The PIP joint is a less common site of arthroplasty than the MCP joint, and the distal interphalangeal (DIP) joint is generally fused rather than replaced. The MCP joint allows flexion–extension, adduction–abduction, and some rotation. The local soft tissue structures make an important contribution to the joint function and stability.

With the silicone implants, the inherent flexibility of the material allows some adduction–abduction as well as flexion–extension movements. Silicone implants depend on an encapsulation process for long-term joint stability. After surgery, the prosthesis becomes fixed by the formation of a fibrous capsule, and scar tissues support the implant. It has been shown that the integrity of a silicone implant becomes less important following encapsulation. Implant fracture does not confer loss of function once the encapsulation process around the prosthesis has occurred. (15;16)

Choice of Implant Material

Silicone implant arthroplasty of the MCP joint for patients with RA is a greater surgical challenge than for those with OA and traumatic arthritis. In RA, the outcome of arthroplasty depends on the extent of soft tissue damage, whereas in OA and traumatic arthritis, the surrounding soft tissues tend to be in better condition, allowing a better opportunity for restoration of function. In addition, the progression of RA may continue after surgery.

In RA, the severity of disease strongly influences the biomechanics of the finger joints. The grip and pinch strength are diminished by RA, so the associated joint force is diminished. Across the spectrum of severity of RA, the grip strength changes by a factor of 4. (20) The maximum grip strength has been shown to be 238 N^2 for normal individuals, 102 N for OA patients and from 19 to 87 N in patients with RA, depending on the severity of the disease. (20)

In severe RA, when the adjacent ligaments and soft tissue are badly damaged, silicone MCP joint arthroplasty is a final salvage procedure with the surgical goals of correcting deformities, improving appearance, and providing pain relief. For these patients, it is less likely that forces generated by the pinch and grip will lead to fracture of the prostheses. However, the inflammation associated with RA can lead to stretching of the tendons and ligaments resulting in loss of balance, subluxation of the joint, and reduction in ROM. For these patients, the satisfactory short-term outcomes of MCP joint arthroplasty with silicone implants are not maintained over time. (15) Implant fracture is common and bone reaction adjacent to the implant results in bone shortening. Since these patients do not have sufficient musculotendinous support for hand functions, they are not good candidates for pyrocarbon finger joint implants for restoration of finger function.

Pyrocarbon implants, however, can be considered for patients with mild RA in whom soft tissues such as the capsule and collateral ligaments, which are the primary movers of the MCP joint, are better preserved. For these patients, silicone MCP joint arthroplasty is not appropriate, and successful outcomes cannot be expected because ligaments and capsules are still strong enough for movements and may result in fracture or dislocation of the prostheses.

[2] Newton

Failure Analysis of Silicone Implants

The benefits of Swanson and other silicone prostheses are alleviation of pain, improved appearance, and a more functional arc of motion. Joyce and Unsworth (16) reviewed the literature and performed a failure analysis of the Swanson finger prosthesis for the MCP joint. They reported a fracture rate of up to 85% after 5 years. However, in their review, 2 studies reported 0% fracture rate. A number of factors were indicated that might explain such a large difference. These factors include how fracture was defined, different properties of a variety of silicone materials used, length of follow-up, and patient characteristics including variation in the severity of disease.

Joyce et al. (16) reported that the fracture rates were lower in studies that did not use routine follow-up x-rays for all patients. When x-rays were used for all patients, fracture rates as high as 26%, 10.4%, and 9.3% were reported. In addition, the prosthetic material was found to influence the fracture rate. Joyce et al. (16) reported the fracture rates of 14% and 15% for CSE prostheses compared with 8% and 9% for HP prostheses. In their review, one further factor influencing the fracture rate was the duration of follow-up.

Studies of retrieved silicone prostheses show that fracture is more likely to take place at the junction of the distal stem and the hinge. (16) (See Appendix 5.) Swanson and Sutter prostheses appear to share the same fracture mode, and this similarity may say much about the nature of loading in MCP joints affected by RA where subluxing forces often dominate. (2) Fractures of silicone MCP joint implants may not affect the revision rate because the function of the MCP joint is not usually impaired.

The prosthesis failure with silicone implants is thought to be caused by a number of factors:

1. Silicone materials are at risk of damage from the adjacent bone and can be easily damaged either during insertion or after surgery. Fracture of the prosthesis can be initiated by small cuts produced by the sharp spurs from the bones. The subluxing forces in rheumatoid hands cause the cortical bone of the proximal phalanx to impinge on the distal stem of the prosthesis. Once a small abrasion has been produced, fatigue failure rapidly follows at the junction of the distal stem and the hinge of the prosthesis. This theory was proposed by Joyce et al. (16) and agrees with the clinical findings for Swanson and Sutter MCP joint implants.

To protect the prosthesis from cuts and abrasions by the bone, circumferential titanium grommets were introduced in 1987 to reduce the incidence of fractures. Swanson et al. (21) reported that fracture rates with grommets were 0.7% compared with 13% without grommets. The authors noted that bony spicules occurred less frequently in the group with grommets (23%) than in the group without grommets (68%). The authors also commented that most of the non-fractured prostheses (without grommets) had cuts and abrasions, implying that fracture would have eventually occurred.

2. The second factor for failure could be that the prosthesis flexes not only at the hinge, but also at the stems. (2) The retrieved Swanson prostheses photographed by Weightman et al. (22) show distortion of the stems. The prosthesis appeared to have been deformed into an arc from its initial straight aspect. (22)

3. Destructive bone changes (osteolysis) may occur following implantation of a silicone prosthesis in the MCP joint. Cortical erosions and erosion of the MCP and proximal phalanx bone ends have been reported by many authors. (16) Some authors have suggested that such changes in the bone are likely to be due to the Swanson prosthesis being free to glide in the medullary canals (piston phenomenon), (23) whereas others have argued that the destructive changes are due to silicone synovitis. (24;25)

4. The response of the host tissues to the implant is a serious long-term problem with silicone implants. Silicone particles and microparticles, caused by wear debris, are a hazard with all silicone implants.

Silicone particles as small as less than 1 μm in size from fingers, wrist, and elbow joints were found (26) with x-ray spectroscopy. Silicone synovitis is a foreign body reaction to particulate materials and can cause severe damage to adjacent bones and joints. (27) It typically presents more than 2 years after arthroplasty and is characterized by the recurrence of pain, stiffness, and swelling of the joint after initial relief of symptoms following arthroplasty. (24) The silicone microparticles are generated by cyclic physiologic bearing, shear, and compression forces. (24) Peimer et al. (25) have argued that a reaction due to synovitis can be strong enough to lead to fracture. The destructive synovitis can be arrested by synovectomy, implant removal, and curettage of the lytic lesions in bones. (24, 27) Functional salvage requires arthrodesis or conversion arthroplasty. Patients with silicone implants need to be followed indefinitely.

5. The severity and progression of the underlying disease appear to influence clinical results. Some authors noted that failure of the prosthesis was related to the involvement of other joints of the upper extremity and to the condition of the wrist joint.

6. The activity level of the patient is an important consideration in selection of the implant for arthroplasty. Younger patients who are active and strong, trauma patients with good tendons and soft tissues, and patients with OA may have relatively high grip and pinch strength compared with older patients or patients with severe RA. Therefore, the risk of implant fracture with silicone implants is much higher among these patients. It has been shown that for younger patients, the number of fractures increases over time. (16)

Studies on Silicone Implants

Review Article on Silicone Finger Joint Implants

Joyce and Unsworth (16) summarized the results of the studies on silicone MCP joint implants since 1990 (Table 7).

Table 7: Summary of Clinical Results of Studies on Silicone MCP Joint Implants Since 1990*

Study	Mean follow-up (years)	Patients (n)	Implants (n)	ROM (degrees)	Fracture rate (%)	Material (If specified)
Maurer et al. 1990	8.9	105	446	48	15.0 8.0	CSE† HP‡
Kirschenbaum et al. 1993	8.5	27	144	43 active	10.0	HP
Wilson et al. 1993	9.6	77	375	29 active	3.2	
Olsen et al. 1994	7.0	16	60	30 active	22.0	HP
Gelman et al. 1997	8.0	264	901	Pre 40 Post 50	14.0 9.0	CSE HP
Ilansraj et al. 1997	5.2	71	348	Pre 38 Post 27	3.4	HP
Schmidt et al. 1997	3.5 4.3 10.1	- - -	57 with grommets 91 102	Unchanged	0 17.0 27.0	With grommets
Swanson et al. 1997	5.8	38	139 with grommets 31	Unchanged	0.7 13.0	With grommets (HP) HP

*Adapted from Joyce and Unsworth 2002 (16)

†CSE refers to silicone elastomer; ‡HP refers to high performance

Results of a Long-Term Follow-Up Study on Silicone Joint Implants

More recently, Goldfarb et al. (15) published the results of long-term follow-up of 208 MCP arthroplasties with silicone joint implants. The authors provided follow-up information on 36 patients who were followed for a mean of 14 years. The results show that 130 (63%) implants were broken, and 45 (22%) were severely deformed at the time of follow-up. Only 33 (16%) of the 208 implants were intact. The patients expressed satisfaction with the function of only 38% of the hands, and only 27% of the hands were pain-free at the time of final follow-up. The authors concluded that the outcome after silicone MCP joint arthroplasty in patients with RA could not be maintained over time. However, compared with the preoperative values, the extension deficit at the time of final follow-up was decreased, MCP joint flexion was decreased in all fingers ($p<.001$), and the total arc of motion in the long and ring fingers increased significantly ($p<.002$).

Table 8 shows the preoperative, early postoperative, and final follow-up values for the ROM reported by Goldfarb et al. (15)

Table 8: Reported ROM of the MCP Joints Following Silicone Implant: A Long-Term Follow-Up Study*

	Range of motion (degrees)				
	Index finger	**Long finger**	**Ring finger**	**Small finger**	**All fingers**
Preoperative					
Extension deficit	49	59	59	60	57
Flexion	87	88	85	88	87
Arc of motion	38	29	26	28	30
Early postoperative					
Extension deficit	12	13	12	7	11
Flexion	58	61	59	50	57
Arc of motion	46	48	47	43	46
Long-term follow-up					
Extension deficit	23	27	24	16	23
Flexion	60	66	60	49	59
Arc of motion	37	39	36	33	36

*Adapted from Goldfarb et al., 2003 (15)

The ulnar deviation improved from 26° preoperatively to less than 5° immediately after surgery, but recurred to 16° at the time of final follow-up. This represented a significant improvement compared with the preoperative value ($p=.04$). Nine (18%) of the 50 joints had ulnar deviation of less than 30° at the time of the final follow-up. The average ulnar drift was 10° for the digits with an intact implant and 20° for those with a fractured implant. The difference between these groups was significant ($p<.01$). The authors concluded that encapsulation does not provide sufficient rigidity to prevent recurrence of ulnar deviation.

Bone reaction adjacent to the implant was demonstrated by bone shortening and by bone erosions. All hands demonstrated shortening except for 3 in which the lengths of the proximal phalanges were unchanged and 2 in which the lengths of the metacarpals were unchanged. The index finger had the most

shortening. Bone erosion (radiolucency or cyst formation) was observed in both the metacarpals and the proximal phalanges in about 29% of the implants, with the erosions being observed more commonly in the proximal phalanx ($p<.05$).

The MCP joint space averaged 6.6 mm immediately after the surgery and 4.4 mm at the time of final follow-up. This difference in subsidence was statistically significant ($p=.001$). The authors suggested that this decrease in joint space may lead to stiffness and may partly explain the observed decrease in the ROM of the joints.

Due to the lack of comparative data, we compared the results of the long-term follow-up of the pyrocarbon MCP joint implant (8) with the study by Goldfarb et al. (15) that provided long-term follow-up data for silicone joint implants.

Comparing the improvement in the arc of motion between silicone and pyrocarbon finger joint implants, it appears that pyrocarbon provides and maintains an improvement in the arc of motion. In Cook's study, (8) the arc of motion for each individual finger and the mean for all fingers improved during the early postoperative period as well as at the long-term follow-up. (See Table 3.)

Table 9 shows the improvement in the arc of motion of each MCP joint for pyrocarbon and silicone implants derived from Cook's study (8) and Goldfarb's study (15).

Table 9: Improvement in Arc of Motion for Early Postoperative and Long-Term Follow-Up of Pyrocarbon and Silicone Finger Joint Implants*

		Improvement in arc of motion in degrees				
Implant	**Term of Follow-up**	**Index**	**Long**	**Ring**	**Small**	**All**
Pyrocarbon	Preoperative to early postoperative	+ 4	+13	+1	+2	+4
	Preoperative to final follow-up	+10	+19	+16	+11	+13
Silicone	Preoperative to early postoperative	+8	+19	+21	+15	+16
	Preoperative to final follow-up	-1	+10	+10	+5	+6

*Data were derived from each individual study (case series, no control group) (8;15)

Compared with the preoperative values, both implants improved the ROM for each individual finger at the early postoperative period when silicone implants demonstrated more improvement compared with pyrocarbon implants. However, these satisfactory intermediate results with silicone implants were not maintained at long-term follow-up, whereas the values for ROM with pyrocarbon implant continued to improve for each finger.

Studies on Avanta SR Prostheses

The Avanta finger joint implants are semiconstrained prostheses. The device consists of a distal component made of an ultrahigh molecular weight polyethylene articulating surface and stem, and a proximal component consisting of a cobalt chromium-molybdenum articulating surface. Stems are to be adapted for either cement on non-cement fixation (Appendix 5).

The Avanta SR MCP and Avanta SR PIP have been issued licences by Health Canada. According to the USFDA, these prostheses are for use in arthroplasty of the MCP or PIP joints when the patient is either in need of a revision of a failed prosthesis or the patient expects to place his or her hands under loading situations that preclude the use of an alternative implant in the painful osteoarthritic and post-traumatic arthritic joint.

The USFDA approved the marketing of Avanta SR MCP and PIP under HDE after it concluded that these devices are adequate for their intended use, will not expose patients to an unreasonable or significant risk of illness or injury, and that the probable benefit to health from use of these devices outweighs the risk of injury or illness. .

Avanta SR MCP

The Summary of Safety and Probable Benefit of the device by the USFDA includes a prospective randomized clinical study in which 20 patients were implanted with the Avanta MCP finger joint with a maximum length of follow-up of 24 months. Patients were randomized into either the experimental group (received Avanta MCP implant, n=20), or into the control group (received silicone elastomer implant, n=9). The mean age of the patients was 56.3 for the experimental group and 61.9 years for the control group. The experimental group consisted of 18 people with RA, 1 with silicone implant revision, and 1 with OA. The control group consisted of 7 people with RA, 1 with OA, and 1 with polymyositis.

Patients in the control group had no complications. Four joint subluxation, 3 joint dislocation, 1 implant failure, 1 wound dehiscence, and 1 skin necrosis was observed in the experimental group.

In a published study by Linscheid (28), 61 fingers in 25 patients were treated with this implant. Eight implants were implanted in 8 patients with traumatic or degenerative arthritis and 53 implants were implanted in 17 patients with RA. The mean age of the patients was 63 years (range, 45–78 years). The follow-up averaged 30 months (4–60 months).

The results in single joints with traumatic or degenerative arthritis were better than those in the multiple fingers with RA. The average arc of motion, which was 45° preoperatively, increased to 50°. Grip and pinch strength showed little change. Subluxation or dislocation recurred despite repair of the collateral ligaments and recentring of the extensor tendon.

Avanta SR PIP

Linscheid et al. studied the result of arthroplasty with Avanta SR PIP implants in 47 patients (mean age, 58 years; age range, 18–92 years) for a mean follow-up period of 4.5 years (range, 1–14 years). There were 37 fingers with degenerative arthrosis, 16 with traumatic arthrosis, and 13 with RA. The results, based on pain relief, motion, and deformities were good in 32 fingers, fair in 19, and poor in 15.

Poor results were related to extent of the previous extensive injury or static deformity. Preoperatively, all patients had pain as their primary complaint. Postoperatively, 56 joints were free of pain, 6 had mild pain, and 4 had moderate discomfort with activity. Preoperatively, 18 joints had ulnar deviation of 10° to 35° as compared with 3 joints postoperatively. The preoperative average ROM was from 11° to 46° or an arc of motion of 35°. The postoperative average ROM was from 14° to 61° with an arc of motion of 47°, a gain of 12°. The number of complications in this series was significant. The complications tended to

reflect the preoperative conditions. Overall, 19 complications occurred in 66 fingers. Twelve of the 66 joints required revision surgery.

Indications and Contraindications for Pyrocarbon Finger Joint Implants

The USFDA has published the following indications and contraindications when the Ascension MCP and PIP received market clearance:

Indications

Ascension MCP

The Ascension MCP is indicated for use as a total joint replacement of the index, long, ring, and small finger MCP joints that have symptoms of pain, limited motion, or inadequate bony alignment secondary to articular destruction or degenerative disease related to RA, SLE, OA, or post-traumatic arthritis where soft tissue reconstruction can provide adequate stabilization.

Ascension PIP

Ascension PIP is indicated when the patient has pain, limited motion, joint subluxation or dislocation secondary to damage or destruction of the articular cartilage or needs a revision of a failed PIP prosthesis. Patients must have soft tissue and bone that can provide adequate stabilization and fixation under high-demand loading conditions after reconstruction.

Contraindications

Ascension MCP and PIP

- Inadequate bone stock
- Sepsis or active infection in the MCP joint
- Nonfunctioning and irreparable musculotendinous system problems
- Physical interference with or by other prostheses
- Procedures requiring modification of the prosthesis
- Presence of the skin, bone, circulatory, and/or neurological deficiency at the implantation site

Summary & Conclusion

Summary of Findings on Effectiveness of Pyrocarbon Finger Joint Implants

A. Pyrocarbon has an excellent track record based on the following evidence:

- Biological compatibility (experience through cardiac valve prosthesis; 15 million patient-years of experience with pyrocarbon cardiac valves)
- Resistance and durability (over 3 million pyrocarbon heart valves have been implanted)

B. Pyrocarbon MCP offers the following benefits (based on Level 4b evidence):

- Low rate of fracture (1 in 16 years)
- Low rate of revision (12% in 16 years)
- High rate of patient satisfaction

- Improvement in finger function (demonstrated in both short-term and long-term follow-up)
- Pain relief
- No evidence of particulate synovitis or intracellular wear particles

C. Pyrocarbon PIP offers the following benefits (based on Level 4g evidence):

- Improvement in the arc of motion
- Pain relief

D. In comparison with the alternative technologies:

The gold standard technology (silicone finger joint implant) has high rates of the following complications:

- Fracture (6%–47% in studies >5 years)
- Silicone synovitis
- Destructive bone changes
- Dislocation

The results of a long-term study (15) on silicone finger joint implants (14 years follow-up) showed that the impressive results at the short-term follow-up with respect to the arc of motion could not be maintained at the long-term follow-up. Complication rates were high: 63% were broken and 22% were severely deformed. Patients were satisfied with the function of their finger in 38% of the hands and only 27% of the hands were pain-free at the time of final follow-up.

Avanta SR MCP and Avanta SR PIP are nonsilicone finger joint implants. However, there are very limited data particularly for long-term follow-up for their safety and effectiveness.

Conclusion

The following factors are important considerations in patient selection:

- The condition of associated soft tissues and ligaments
- The activity level of the patient
- The age of the patient

- Pyrocarbon can be considered for patients in whom soft tissues, capsules, and the collateral ligaments as the primary movers of the finger joints are better preserved. Therefore, it is indicated for young patients with post-traumatic arthritis or OA. Patients with severe RA, in which adjacent ligaments and soft tissues are badly damaged, are not good candidates for pyrocarbon finger joint implants for the restoration of function.

- Silicone finger joint implants are not suitable for patients who are at risk of implant fracture due to high-demand loading conditions and frequent hand movements. For young patients, an implant made of a highly durable and resistant material such as pyrocarbon is expected to reduce the rate of implant fracture.

- The current evidence does not support the use of pyrocarbon finger joint implants for older patients and patients with severe RA. In these patients, silicone arthroplasty can be a final salvage procedure.

Appendices

APPENDIX 1

Abbreviations

ADL	Activities of daily living
DIP	Distal interphalangeal
MCP	Metacarpophalangeal
OA	Osteoarthritis
PIP	Proximal interphalangeal
RA	Rheumatoid arthritis
ROM	Range of motion
SLE	Systemic lupus erythematosus
SSED	Summary of Safety and Effectiveness Data

APPENDIX 2

Measurements in normal hand: Full active ROM of the joints*

Normal ROM (fingers)	Degrees
MCP	0–100
PIP	0–105
DIP	0–85
Total arc	0–290

Normal ROM (thumb)	Degrees
MCP	0-56 (in 85% of population)
IP	(-)5-73
Total arc	0-124

*Adapted from Hume et al. 1990 (10)

Measurements in normal hand: Functional ROM of the Joints in Degrees*

Functional ROM (fingers)	Degrees	Mean±SD
MCP	33–73	61±12
PIP	36–86	60±12
DIP	20–61	39±14
Total functional arc	96–208	164±27
Normal ROM (thumb)		
MCP	10–32	21±5
IP	2–43	18±5
Total functional arc	21–65	40±5

*Adapted from Hume et al. 1990 (10)

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