

# New Hand, Wrist Implants Promise Durability

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Contributing Writer

SAN ANTONIO — New prosthetic joint options for rheumatoid arthritis patients are a welcome alternative to conventional silicone implants for relieving pain and restoring function and stability, according to experts at the joint annual meeting of the American Society for Surgery of the Hand and the American Society of Hand Therapists.

New ball-and-joint prostheses relieve arthritic pain and restore articular and bony anatomy, providing more natural hand or forearm-wrist function and appearance and greater stability than provided by silicone implants, which break apart over time and may cause inflammation, said Dr. Richard A. Berger, a professor of orthopedics at the Mayo Clinic College of Medicine, Rochester, Minn., and consultant to Avanta Orthopaedics, San Diego.

Experience with silicone joint implants since their approval in the 1980s have shown that over time the implants tend to break apart, an outcome that can aggravate further inflammatory processes already underway in the joint, said Dr. Berger.

The newer implants promise both to remain structurally intact and to restore articular and bony anatomy, providing a more normal appearance to disfigured hands, said Dr. Robert D. Beckenbaugh, professor of orthopedics at the Mayo Clinic College of Medicine and consultant to Ascension Orthopedics Inc., Austin, Tex.

Dr. Berger noted that the Avanta uHead, replicating the distal ulnar head in the forearm, and the Scheker, a distal radioulnar joint (Aptis Medical, Louisville, Ky.), serve the same purpose but are used in patients with a different degree of problems. The uHead implant is a simple ball on a stem used to replace the end of the ulna when the patient has sufficient bone stock and soft tissue, he said. The Scheker ball-and-socket is used in patients with advanced degenerative rheumatoid disease because it connects directly to the ul-

nar rather than requiring bone stock or soft tissue to hold it in place.

The Avanta uHead joint is fabricated from a cobalt chrome-molybdenum alloy, and the stem is coated with titanium to promote osseointegration. Provided in right and left configurations and several sizes, the device stem is designed for snap-fit or can be cemented into the socket, which Dr. Berger noted improves the interface in rheumatoid disease patients with soft bone tissue, resulting in a more stable joint than without cement.



Hand disabled by rheumatoid arthritis before use of PIP Pyrocarbon Implants.

The Scheker prosthesis consists of a metal radial plate, socket, and ulna stem as well as an ultra-high-molecular-weight polyethylene ball for complete replacement of the joint, resulting in renewed range of motion that enables patients to use their hands for turning and lifting.

An initial clinical trial by Dr. Berger and Dr. William P. Cooney III, also a professor of orthopedics at Mayo Clinic College of Medicine, followed 26 patients with 28 ulnar head replacement arthroplasties for 30 months. Patients were an average of 51 years old, and all of them presented with pain, instability, or weakness or a combination of symptoms. Eighteen patients got “press-fit” implants, and 10 got cemented implants. At follow-up, 80% of patients were satisfied and reported no pain; 100% experienced improvement in symptoms, but 15% still had mild pain and one patient reported no pain relief. Postoperative pronation and supination of the forearm

were 75 degrees and 70 degrees, respectively, and grip strength improved by 10%. There were two acute complications—an ulna shaft nondisplaced split fracture during impaction of the device and an acute dorsal sensory ulnar nerve neuropraxia—and four chronic complications: a neuroroma, two cases of residual instability, and one case of implant loosening, all of which required revision surgery. The Mayo Clinic wrist score was used to assess outcomes, which were excellent in 4 patients, good in 18, and poor in 6.



Surgical placement of the PIP Pyrocarbon Implants enable hand flexion in same patient.

Other options for treatment of hands disabled by arthritis or trauma are pyrocarbon implants for the proximal interphalangeal (PIP), trapeziometacarpal, and metacarpophalangeal (MCP) joints. Both the PIP pyrocarbon total joint and the MCP pyrocarbon total joint prostheses (Ascension Orthopedics) are made from a low-friction pyrolytic carbon-coated graphite substrate compound that has low wear properties and is biologically compatible with bone tissue, said Dr. Beckenbaugh.

The pyrocarbon PIP joint is a bicondylar, semiconstrained prosthesis for total joint replacement with anatomically shaped stems that press-fit into the intramedullary canal to achieve fixation by direct implant-to-bone apposition. The distal component has a biccoped design that allows slight sliding of the proximal condylar component and dorsal extensor to resist subluxation. Distal and proximal components come in four sizes, which can

be matched with smaller or larger opposites to best fit the medullary canal of the patient's proximal and middle phalanx.

The pyrocarbon MCP joint replacement builds on pyrolytic carbon arthroplasty technology developed in 1977 but abandoned 10 years later for lack of funding. The new device uses the original MCP implant's simple ball-and-socket design, which had demonstrated very satisfactory results. A few modifications have been made; for example, the stems were enlarged and shaped to be a better physiologic fit with the medullary canal than the original design, the dorsal surface of the joint design was extended 10% to increase stability against volar subluxation, and the pyrolytic carbon material was strengthened through an improved manufacturing process.

Dr. Beckenbaugh pointed out that the success of ball-and-socket implants requires the capability to construct a stable soft tissue envelope to

allow bony fixation by appositional bone growth. While these implants may be ideal for osteoarthritis, posttraumatic arthritis, and some rheumatoid patients, the old silicone or cemented implants may be preferred for rheumatoid patients with soft medullary tissue and thin cortical bone.

He said that the greatest potential problem with ball-and-socket design is subluxation and/or recurrent ulnar deviation, which can be prevented with careful surgical technique and postoperative care. The new devices require a longer postoperative immobilization (usually 3-4 weeks), compared with silicone arthroplasty, to allow soft tissue to heal and create stability before motion therapy is begun.

All of the prostheses discussed by Dr. Berger and Dr. Beckenbaugh have received approval from the Food and Drug Administration for use in the United States and the CE Mark for approval in Europe. ■

## RA Linked to Cardiovascular Deaths

BY TIMOTHY F. KIRN  
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SAN DIEGO — Rheumatoid arthritis patients have a high rate of ischemic heart disease and high associated mortality, even compared with their siblings, Dr. Namita Kumar said at the annual meeting of the American College of Rheumatology.

The data from a review of death certificates clearly suggest that the increased coronary artery disease death risk seen among rheumatoid arthritis patients, compared with their unaffected siblings, is not due to genetics or upbringing but, rather, to the disease or its treatment, Dr. Kumar noted.

The investigators reviewed certificates from a cohort of rheumatoid arthritis patients and their same-sex, arthritis-free siblings who were involved in a study from 1980 to 1992. They found that during the study period the patients with rheumatoid arthritis were almost twice as likely as their siblings to die. The most common cause of death listed among participants with rheumatoid arthritis was coronary artery disease; in contrast, the most common cause of death for their siblings was malignancy. Fifty-four percent of the 257 rheumatoid arthritis patients died during the period, compared with 28% of the 371 same-sex siblings.

The age of death was not dissimilar (72 years versus 73 years). But the three major causes of death in the rheumatoid arthritis patients were coronary artery disease (35%), all-cause infection (34%), and malignancy (19%). The major causes of death in the siblings were malignancy (38%), all-cause infection (25%), and coronary artery disease (22%).

A similar percentage of patients and their siblings died from stroke (8% versus 10%), noted Dr. Kumar of Freeman Hospital, Newcastle upon Tyne, England.

Genetics, family history, and the environment do not account for the prevalence of ischemic heart disease in rheumatoid arthritis [patients], she said. ■

## Contaminated Lot of Injectable Methotrexate Recalled by FDA

The Food and Drug Administration's MedWatch program has announced a voluntary recall of one lot of Methotrexate for Injection (preservative free) due to the presence of low levels of ethylene glycol.

Bedford Laboratories, a division of Ben Venue Laboratories Inc., last month announced a recall of Methotrexate for Injection (preservative free), USP 1 gram per vial (NDC 55390-143-01), Lot #859142, exp. 09/07. The company was informed by the manufacturer that the active drug substance used to create this lot contained low levels of

ethylene glycol, a solvent used in antifreeze among other products.

Methotrexate is an antimetabolite used in the treatment of adult rheumatoid arthritis, severe psoriasis, and certain neoplastic diseases.

Methotrexate for Injection was distributed to wholesalers and hospitals throughout the United States in October and November 2005.

Bedford Laboratories instructed customers to discontinue distribution and use of this lot, and to call the company at 800-562-4797 with any questions.

—Deeanna Franklin