surgical technique

AS DESCRIBED BY CHARLES HAMLIN, M.D.

DESIGN RATIONALE

The Ascension[®] PyroDisk[®] is a biarticular convex disc made of PyroCarbon, designed to resurface the thumb carpometacarpal (CMC) joint damaged by arthritis with resultant pain and loss of function. The implant and CMC joint are stabilized by a biologic tendon, transferred and passed through the trapezium, through the implant, and into the first metacarpal. Bone healing to this tendon within the trapezium and the metacarpal give alignment and stability to the implant, which is additionally supported by the prepared concave surfaces of the joint and the convex surfaces of the implant. Goals are pain relief and restoration of motion. As this operation preserves trapezial bone stock, normal thumb length and pinch strength are realistic and achievable goals. Finally, saving the trapezium permits greater choices should revision surgery be indicated.

INDICATIONS

The Ascension PyroDisk is intended to replace the joint between the first metacarpal and the trapezium in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post-fracture deformation, or bone loss which presents as either a painful, unstable thumb or a thumb with limited range of motion.

PREOPERATIVE EVALUATION

A prerequisite of surgery, and essential to its success, is adequate trapezial bone stock, assessed preoperatively by X-ray evaluation and confirmed by inspection during surgery.

STEP 1: Skin Incision, Capsular Opening and Exposure

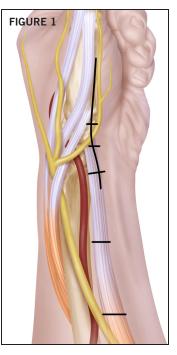
After proper general or regional anesthesia, the hand and arm are prepped and draped in the usual manner with high arm tourniquet control.

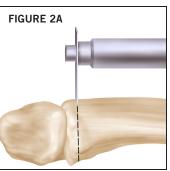
A longitudinal incision is made along the radial base of the first metacarpal, passing ulnarly at the wrist flexion crease. FIGURE 1. Subcutaneous sensory branches of the radial nerve are identified and protected. The capsule is entered in line with the incision from the mid-portion of the metacarpal to the base of the trapezium. Further retraction should be exerted on the capsule alone to prevent any neuropraxic injury to radial nerve branches. At this juncture, the CMC joint is opened transversely and inspected. The scapho-trapezial (ST) joint is also entered, with care taken to protect the branch of the radial artery passing dorsally in this area.

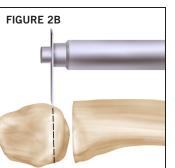
STEP 2: Metacarpal and Trapezial Preparation

Architectural definition of the CMC joint and the trapezium will have been established with preoperative X-rays. Intraoperative assessment of trapezial integrity must









support this, as advanced cases of degeneration with significant joint subluxation often results in erosion of the ulnar side of the metacarpal and the radial side of the trapezium. The trapezium must have adequate size to permit decortications of the distal surface, with residual height to support the implant.

An oscillating saw is used to remove 2-3 mm from the metacarpal base. FIGURE 2A. The cut should be made parallel to the transverse axis of the metacarpal phalangeal (MP) joint. The trapezial saddle is then flattened, using the transverse axis of the MP joint and the metacarpal cut for alignment. **FIGURE 2B.** Minimal resection of the medial and lateral flare, or "horns," of the trapezium and its distal cortical surface is ideal. A complete joint synovectomy is then carried out, along with removal of all small bone fragments. Be sure to remove all degenerative bone which often builds up behind the metacarpal. The terminal insertion of the flexor carpi radialis (FCR) tendon can be seen at the base of the resected joint.

STEP 3: Tendon Passage Preparation

The Awl is now inserted into the flat dorsal aspect of the metacarpal, 1 cm distal to the proximal end of the bone, to make a passage through the metacarpal. FIGURE 3A. The hand Gouge is used secondarily to enlarge and smooth the passage. Gentle brisk turning of the Awl and Gouge without undue pressure minimizes the risk of splitting the metacarpal or fracturing the trapezium. The medullary canal of the metacarpal is also entered with the Awl and Gouge to make a connection with the dorsal circular window. FIGURE 3B.

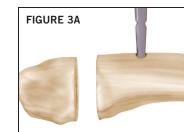
A passage is now made through the trapezium. The Awl is placed beneath the trapezium and directed to the center of the distal resected surface. FIGURE 3C. The Gouge enlarges this hole.

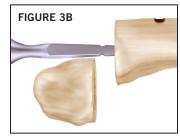
STEP 4: Preparing Joint Surfaces and Trial Reduction

The proper implant diameter is determined by selecting the Trial that best fits the diameter of the metacarpal base. The trapezial surface is not circular so the metacarpal base is the proper reference for sizing. There should be no overhang of the Trial. The thickness of the Trial is related to the amount of bone resected, and a thinner PyroDisk may translate into greater motion.

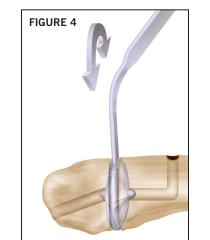
After choosing the appropriate diameter, the corresponding Finishing Shaper is used to create a modest concavity between the base of the metacarpal and the distal surface of the trapezium. FIGURE 4. The center protrusions on the Finishing Shaper are placed in the holes, and a gentle twisting back and forth motion creates a surface that mirrors the convexity of the implant.

Trial fitting of the implant is now achieved by selecting from the six sizes provided. The goal is a gentle rocking and modest gliding of the disc on the trapezium. Intraoperative fluoroscopy confirms proper sizing.











STEP 5: Harvesting the Tendon

Attention is directed to the distal radial flexor surface of the forearm. Two small transverse incisions permit access to harvest one-third to one-half of the FCR tendon from its musculotendinous junction to the tuberosity of the scaphoid. **FIGURE 5A.** By wrist positioning in various degrees of flexion, the tendon can be visualized throughout tendon mobilization. FIGURE 5B. The remaining FCR muscle/tendon unit retains function as an important wrist flexor. Individual preferences for FCR tendon mobilization are respected. The tendon is then passed beneath the tendons of the first dorsal compartment to the rim of trapezium where the entry hole has been made. The goal is to have adequate tendon length and strength to achieve passage through the trapezium and the implant, into the metacarpal, and out the dorsal window, with enough tendon length left to reinforce and create a strong capsular closure.

STEP 6: Implantation

After joint irrigation and injection of local anesthesia, the tendon is passed sequentially through the trapezium into the resected joint, through the selected PyroDisk implant, and into the first metacarpal to exit dorsally from the prepared passage. **FIGURE 6.** The longitudinal tendon and the prepared surfaces of the CMC joint help to restore alignment and give stability to the thumb.

Gentle traction on the tendon prior to closure enhances this stability. **FIGURE 7.** The goal is free rotatory motion of the CMC joint, not a tight or compressed joint. The residual tendon is then folded back to be incorporated into a secure capsular closure using absorbable sutures.

STEP 7: Secondary Deformities

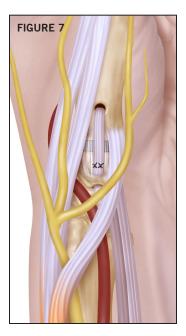
During capsular closure, the insertional integrity of the abductor pollicis longus tendons should be restored. With the completed arthroplasty, assess the stability of the MP joint volar plate. Painful MP joint hyperextension is often a secondary deformity of the damaged CMC joint, wherein subluxation and proximal migration of the first metacarpal leads to an adduction contracture of the thumb and attritional stretching and laxity of ligaments at the MP joint. PyroDisk arthroplasty helps to restore CMC joint alignment and thumb length which can minimize the MP joint symptoms. In the face of significant instability, MP volar plate ligament reconstruction or MP joint arthrodesis may be indicated.

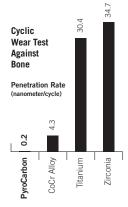
POSTOPERATIVE GUIDELINES

After skin closure, the incisions are dressed and a modest thumb spica cast is applied, with the thumb in the mean or "fist" position. The thumb interphalangeal joint may remain free. At a week, the cast may be changed and the skin sutures removed. A new cast is applied for an additional 2-3 weeks. At 3-4 weeks postoperatively, a soft neoprene splint is provided for graduated use. The thumb may be unprotected at 6-8 weeks, depending on patient comfort and confidence. Ongoing improvement in comfort and strength may be expected for 3-6 months.

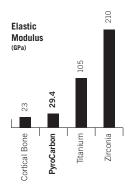








Wear testing shows that PyroCarbon-on-bone articulation wear is significantly less than that of medical grade metals and ceramics.



The elastic modulus of PyroCarbon closely matches that of cortical bone



Histological examination after 7 mos. of articulation with PvroCarbon PHS showed a layer of healthy fibrous pseudocartilage. Sample had no evidence of particulate synovitis.²

design interpositional

- ▶ maintains thumb height
- ► preserves trapezium
- minimal bone removal
- ► bone-friendly material
- ► open pathway for revision



advanced material PyroCarbon

"Thumb carpometacarpal joint arthroplasty with the Ascension PyroCarbon biarticular disk re-establishes proper alignment of the thumb. In preserving trapezial bone stock, chances of thumb shortening, weakness and resultant intercarpal instability are minimized."

- Charles Hamlin, MD

Clinical Results':

STUDY POPULATION

- ► 47 patients underwent CMC arthroplasty with Ascension PyroDisk
- ► Average follow-up of 24 months

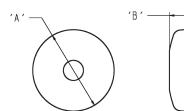
RESULTS SHOW

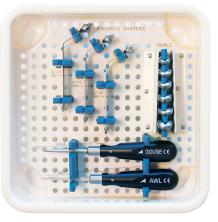
- ► High Pain Relief: preoperative average 8.4, postoperative average 1.1 (VAS)
- ► High Patient Satisfaction: 100% of patients satisfied with results, 72% highly satisfied
- Increased Key Pinch Strength: preoperative average 9.8 lbs, postoperative average 12.3 lbs
- > High Function Score: high Kapandji score with daily living activities

¹ Data provided by C. Hamlin for investigator initiated study.

² CJ Bravo, MD, RD Beckenbaugh, MD and KB Hormel, RN; "Early Experiences of CMC Arthroplasty PyroCarbon HemiSphere Implant," Poster presented at AAHS 2005

Ascension[®] PyroDisk[®]





At Ascension Orthopedics,

the surgical experience.

we are dedicated to *transforming*

Dimensions (mm) CATALOG

NUMBER	SIZE	DIAMETER	HEIGHT
PYD-420-145	145	14 mm	5.5 mm
PYD-420-165	165	16 mm	5.5 mm
PYD-420-167	167	16 mm	7.0 mm
PYD-420-168	168	16 mm	8.0 mm
PYD-420-187	187	18 mm	7.0 mm
PYD-420-189	189	18 mm	9.0 mm

A DISK

B. DISK

14

16

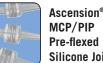
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Instrumentation

CATALOG NUMBER	DESCRIPTION
INS-420-01	Instrument Set
AWL-420-00	Awl
GOU-420-00	Gouge
SHP-425-14	Finishing Shaper, Size 14
SHP-425-16	Finishing Shaper, Size 16
SHP-425-18	Finishing Shaper, Size 18
TRL-420-145	PyroDisk Trial, Size 145
TRL-420-165	PyroDisk Trial, Size 165
TRL-420-167	PyroDisk Trial, Size 167
TRL-420-168	PyroDisk Trial, Size 168
TRL-420-187	PyroDisk Trial, Size 187
TRL-420-189	PyroDisk Trial, Size 189

Additional solutions for the hand:









Ascension[®] **PyroCarbon**







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CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician for investigational use only. LC-04-427-001 rev C ©2009

Ascension[®] PyroDisk[®] surgical technique



Extremities

