The Northern Ohio Foot and Ankle Journal *Official Publication of the NOFA Foundation*

A Literature Review of Cartiva Synthetic Cartilage Implant (SCI) for Treatment of Painful Osteoarthritis (Hallux Rigidus) of the First Metatarsophalangeal Joint.

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The Northern Ohio Foot and Ankle Journal 4(16):1-5

Abstract*:* Hallux rigidus is osteoarthritis (OA) of the first metatarsophalangeal joint (MPJ). It is the most common arthritic condition of the foot and second only to hallux valgus as a condition associated with the hallux. Females are more commonly affected than males, in all age groups, and the condition typically develops in adults between the ages of 30 and 60 years old. Cartiva is a new surgical implant that has been adopted to successfully treat joint immobility and restore foot function and quality of life to patients (9). The Cartiva Synthetic Cartilage Implant (SCI) has a high-water content and coefficient of friction like intact, healthy cartilage (1). Additionally, the Cartiva SCI has a high compressive modulus, making it resistant to compression and shear forces (1,2). Research has found this viscoelastic implant to withstand the repetitive compression and shear forces present in both the knee and first MPJ (10).

Key words: Synthetic Cartilage Implant (SCI), osteoarthritis (OA), first metatarsophalangeal joint (MPJ) and hallux rigidus

Accepted: September, 2017 **Published:** October, 2017

Hallux rigidus is a syndrome with symptoms related to degeneration of the first MPJ. The symptoms result from cartilage wear, altered joint mechanics and osteophyte formation on the dorsal aspect of the first metatarsal head. The pain in hallux rigidus usually derives from impingement of dorsal osteophytes, from shoe-related pressure on prominent osteophytes, or both. Irregularity of the articular cartilage can result in pain at the end of motion with activity (2). The US Food and Drug Administration (FDA) has approved the Cartiva SCI for treatment of painful osteoarthritis of the first MPJ, the most common site for OA in the forefoot according to a company new release. This is the first synthetic cartilage device approved by the FDA, the company notes. The FDA's Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee recommended approval of the implant back in April. The Cartiva implant is a molded cylindrical device containing polyvinyl alcohol (PVA)and saline that is implanted into the first metatarsal head via press-fit implantation. The implant is also approved in Europe, Canada, and Brazil (1). The FDA approval was based on the 236-patient, multicenter, prospective, randomized MOTION study comparing the Cartiva device with arthrodesis of the first MPJ. The Cartiva SCI patient group had clinical success of 80% for the composite primary endpoint of pain, function and safety at 24 months compared with 79% success for the fusion group, the company said in the news release (3). The Cartiva implant group also saw a 93% reduction in median pain, a 168% improvement in median

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function of sporting activities, and a 65% improvement in activities of daily living. The patients also experienced a 26% improvement in range of motion from baseline (11). "The landmark MOTION study clearly shows Cartiva SCI to be a safe and effective alternative to fusion for patients wishing to maintain motion in their great toe," Judith Baumhauer, MD, from the University of Rochester Medical Center, in New York, and principal investigator on the MOTION study, said in the release (4).

Etiology

The true etiology of hallux rigidus is not known. Most commonly, hallux rigidus is thought to be caused by chronic overuse of the first MPJ. Multiple theories have been proposed for the underlying etiology. Some authors have associated hallux rigidus with athletic activities involving running; in this case, the disorder possibly results from repetitive hyperextension of the first MPJ with chronic gradual attenuation of the plantar plate and subsequent instability. Hallux rigidus has also been seen as a long-term sequela of acute injuries to the first MPJ, such as turf toe. Several authors have suggested traumatic injury to the articular cartilage—either acute trauma or chronic, repetitive, minor injury—as the underlying mechanism (4). Clanton et al found hallux valgus and early hallux rigidus to be a long-term sequelae. After more than 5 years of follow-up, Clanton and Seifert found that among 20 athletes with previous turf-toe injury, half suffered from persistent symptoms. In 1933, Kingreen reported that osteochondritis dissecans led to development of hallux rigidus. Goodfellow proposed that the development of an osteochondrosis in childhood creates a defect and secondary slow-remodeling collapse, leading to abnormal motion in the forefoot. McMaster reported on 7 adolescent patients who had an articular defect of approximately 5 mm located directly beneath the dorsal lip of the proximal phalanx; this defect was associated with symptoms of hallux rigidus (5). Lambrinudi proposed the so-called metatarsus primus elevatus, in 1938. Theoretically, an abnormally elevated first metatarsal causes excessive flexion of the great toe during gait and subsequent development of flexion contracture at the first MPJ. These abnormal mechanics cause hallux rigidus. Others, such as Jack, in 1940, postulated that with the elevated first metatarsal, increased overload of the second metatarsal occurs, with compensatory contracture of the flexor hallucis brevis. This contracture pulls the proximal phalanx inferiorly, driving its dorsal rim into the metatarsal head and leading to localized degenerative changes in the articular cartilage. Hypermobility of the first ray leading to flexor spasm and impingement of the proximal phalanx on the metatarsal head is another proposed theory (6). Yet other researchers, such as Jansed, in 1920, have implicated flatfoot. In 1986, Mann first theorized that a flat first metatarsal head restricts the medial and lateral motion of the first MPJ, creating increased stress in the sagittal plane. This restriction of motion, he said, accelerates the degenerative process. Others have proposed that flattening of the head is a secondary result (4).

Pathophysiology

The pathophysiology of hallux rigidus is similar to that of degenerative arthritis in any joint. Overuse, injury or abnormal joint mechanics lead to abnormal stresses on the articular cartilage. In an in-vitro study, Han et al used a magnetic tracking system to monitor the three-dimensional movement of the proximal phalanx while the toe position was changed from a neutral position to full extension. The contact distribution shifted dorsally with increasing degrees of extension. These data are consistent with the observation that chondral erosions associated with hallux rigidus and degenerative arthritis initially affect the dorsal articular surface of the metatarsal (6). Articular degenerative changes are associated with dehydration of the cartilage, which in turn makes it more susceptible to shear and compressive forces. The subchondral bone shares these stresses, which subsequently lead to subchondral bone sclerosis, formation of periarticular osteophytes, and in severe cases, cystic changes. The osteophytes limit first MPJ motion and further compromise the normal mechanics of the joint. This effect can accelerate the degenerative process. In severe cases, the articular cartilage is completely denuded (2).

Signs and symptoms

Signs and symptoms of hallux rigidus include, but are not limited to, pain, swelling and stiffness in or surrounding the first MPJ during use (walking,

standing, bending, etc.). In addition, patients may also complain of diffuse, lateral forefoot pain resulting from increased weight bearing on the lateral foot to offload the hallux. The pain is worse with certain activities and with certain shoes. Hallux rigidus has been associated with a history of athletic activities involving running or kicking. Whether running is a true cause of the disorder or a factor that aggravates the symptoms, it is not known. Dysesthesia along the dorsomedial hallux occasionally occurs as a result of compression by shoes or stretching of the dorsal medial cutaneous nerve. Complaints of stiffness and motion loss are not common, except in adolescents, who often present with complaints of a rigid first MPJ. Dorsal pain caused by external pressure over a prominent osteophyte frequently accompany other presentations. Diffuse arthritic pain usually occurs later and is associated with more severe degenerative changes (3).

Physical Examination

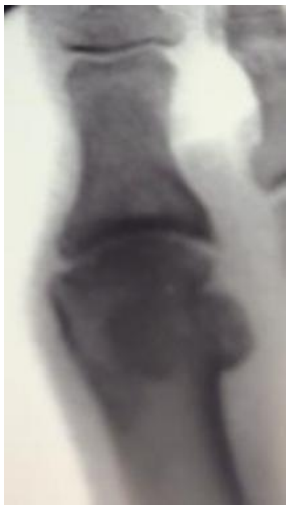
The presence of a tender dorsal osteophyte at the first MPJ (see the images below) usually confirms the diagnosis of hallux rigidus. First MPJ dorsiflexion (DF) is limited by periarticular osteophytes and pain. Dorsal pain with maximum plantarflexion (PF) is common and likely represents irritation of the extensor hallucis longus as it passes over the dorsal osteophyte. Pain and crepitus that occur throughout the entire range of motion (ROM) indicates late-stage degenerative arthritis of the first MPJ. The patient's gait may be slightly antalgic and limitation of first MPJ DF may be noted during propulsion (7).

Classification

Coughlin and Shurnas proposed a classification system based on ROM, as well as on radiographic and examination findings, as follows [22]:
Grade 0-DF of 40-60° (20% loss of normal motion), normal radiographic results and no pain.
Grade 1-DF of 30-40°, dorsal osteophytes and minimal to no other joint changes
Grade 2-DF of 10-30°, mild flattening of the metatarsal head, mild-to-moderate joint space narrowing or sclerosis and dorsal, lateral, or medial osteophytes
Grade 3-DF of less than 10°, often less than 10° PF, severe radiographic changes with hypertrophied cysts, erosions, irregular sesamoids, constant moderate to severe pain and pain at the extremes of the ROM
Grade 4-Stiff joint, radiographs showing loose bodies or osteochonritis dissecans (OCD), and pain throughout the entire ROM (6).

Work up

In patients with hallux rigidus, radiographs show a variable degree of degenerative changes. Early changes typically include dorsal and marginal osteophytes with well-maintained joint space. Severe degenerative changes are seen in more advanced cases. These changes include narrowing of the joint space, marginal osteophytes, sub chondral sclerosis, joint irregularities, cystic degeneration, degenerative involvement of the sesamoid and/or the first metatarsal head and sesamoid enlargement (7).



Management

Nonsurgical techniques can often be used to successfully treat patients with varying degrees of hallux rigidus. When the condition is refractory to nonoperative treatment methods, there are several procedures that can be utilized. The choice of operation depends on the degree of involvement, ROM, the individual's activity level and the surgeon's and patient's preference. Options include the following:
-Joint-sparing procedures, such as cheilectomy, with or without proximal phalanx osteotomy (Moberg procedure). Dorsal cheilectomy is indicated in patients with mild to moderate arthritic changes with less than 50% involvement of the joint surface

-Metatarsal osteotomy
-Joint arthroplasty: Excisional arthroplasty, or the Keller procedure, is associated with several potential complications and is not generally recommended.
-MPJ arthrodesis is an excellent procedure that is indicated in most cases of advanced hallux rigidus. An absolute contraindication for operative treatment is poor peripheral circulation. Active infection should be considered a relative contraindication.
-Cartiva Synthetic Cartilage Implant (SCI) (9).

Procedure

Cartiva is a synthetic cartilage implant designed to act as a replacement for arthritic joint tissue. The gel material mimics the quality and density of bone, eliminating the problematic side effects of metal implants, which can damage or become absorbed by the bone over time. After the osteophytes are removed from the first MPJ, a small (1cm) hole is drilled into the head of the first metatarsal. Next, the Cartiva gel implant is injected into the drill hole, which expands to fill the space and overflows just a couple millimeters over the edge of the metatarsal head. This acts as a cap on the joint, decreasing the bone-on-bone contact responsible for arthritic pain.

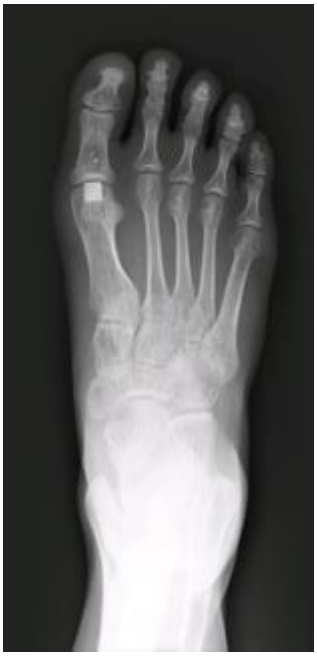
Steps

1. EXPOSING THE MPJ
2. OSTEOPHYTE RESECTION
3. IDENTIFYING THE TARGET IMPLANT POSITION AND LOCATION.

The placer should be positioned relatively central but it can be slightly asymmetrical so as to be placed over the worst area of arthritic involvement on the metatarsal head.

4. CREATING THE METATARSAL HEAD CAVITY
5. PREPARING THE IMPLANT FOR INSERTION
6. IMPLANT INSERTION
7. CAPSULE REPAIR
8. POST-OPERATIVE MANAGEMENT

Subjects receiving the Cartiva implant should have their wound bandaged and placed in a stiff soled shoe. Weight bearing may begin immediately as tolerated by the subject, as there are no specific weight bearing restrictions for the device. Range of motion exercises should begin immediately to avoid stiffness (13).



Contraindications

The Cartiva Synthetic Cartilage Implant (SCI) should not be implanted in subjects with the following conditions:
-Active infection of the foot
-Known allergy to PVA
-Inadequate bone stock
-Diagnosis of gouty tophi
-Any significant bone loss, avascular necrosis, and/or large osteochondral cyst (> 1cm) of the first MPJ (13).
-Lesions of the first metatarsal head greater than 10 mm in size
-Physical conditions that would tend to eliminate adequate implant support (e.g., insufficient quality or quantity of bone resulting from cancer, congenital dislocation, or osteoporosis), systemic and metabolic disorders leading to progressive deterioration of bone (e.g., cortisone therapies or immunosuppressive therapies), and/or tumors and/or cysts >1cm of the supporting bone structures (12).

Complications

-Infection, inflammation, pain, swelling, joint effusion,
-Metatarsal irritation, fibrosis, joint instability, joint malalignment, periarticular cyst, bone cyst,

-Bone loss, sesamoid irritation, sesamoid fracture,
-Fracture, osteonecrosis, avascular necrosis, implant fracture, implant loosening
-Implant dislocation, implant dislodgement, implant subsidence,
-Revision or conversion to fusion, allergic reaction to PVA,
-Progressive OA, incorrect implant placement, and damage to adjacent or surrounding tissues.

Study: Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus.

A prospective, randomized (2:1), controlled, noninferiority clinical trial was performed to compare the safety and efficacy of a small synthetic cartilage bone implant to first MPJ arthrodesis in patients with advanced-stage hallux rigidus. This study showed equivalent pain relief and functional outcomes. The synthetic implant was an excellent alternative to arthrodesis in patients who wished to maintain first MPJ motion. The percentage of secondary surgical procedures was similar between groups. Less than 10% of the implant group required revision to arthrodesis at 2 years (12).

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