CHAPTER **2**

THE USE OF SUPARTZ™ FOR ANKLE JOINT ARTHRITIS

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One of the largest challenges in orthopaedic and podiatric surgery continues to be the treatment of osteoarthritis and treatment of articular cartilage damage. Millions of Americans suffer from osteoarthritis of the knee and hip. This often times will require arthroplasty and total joint replacement. The ankle joint is also affected many times and arthroplasty of the ankle has yet to effectively establish itself in the United States.

For many years orthopaedic surgeons have been utilizing a commercially available hyaluronan for knee osteoarthritis.[1-3] The articular cartilage of any joint is comprised of high contents of proteoglycans, hyaluronan, and collagen matrix. It has been known for a number of years that with articular cartilage damage and arthritis of the joint that there is a decrease in the concentration of hyaluronan along with decreased viscosity and concentration of nutrients.[3-5] This leads to vulnerability to the peripheral articular cartilage of any articular cartilage lesion that are present leading to further and larger breakdown. Exposure of subchondral bone results in exposed sensory nerve endings and pain.

The injection of Supartz™ into the knee has proven successful in Europe and the United States. Patients that suffer from mild to moderate osteoarthritis of the knee are injected weekly for five weeks with the Supartz™ formula.[1,6,7] They are allowed to participate in physical therapy that will provide active and passive range of motion, but they are required not to have any axial loading of the joint. A partial to non-weight bearing status is required for the entirety of the treatment.

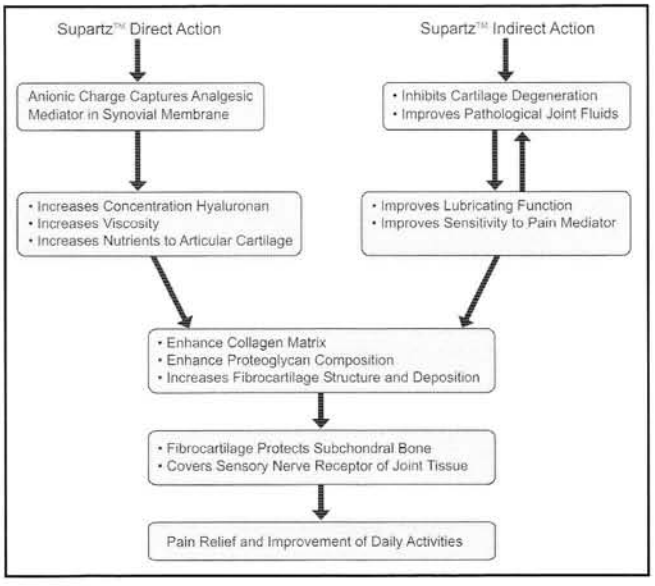

Figure 1. Direct and Indirect Mechanism of Action of Supartz™.

The authors have reported on the utilization of arthrodiastasis as an alternative treatment for ankle joint osteoarthritis. This technique has been utilized and is described in the literature as a treatment for Legg Calves Perthes Disease, knee joint contracture, ankle equines, and is also being performed on patients with ankle joint arthritis.[8-13] It is utilized as a form of off-loading of deforming forces and decompression of abnormal joint pressures. Patients have responded well with decreased treatment times and are able to be full weight bearing.

The utilization of Supartz™ often relieves pain in the knee that further delays the need for surgery. Arthroscopy, articular cartilage lesion debridement, and joint arthoroplasty have also proven successful for varying degrees of osteoarthritis. Supartz™ injection therapy increases the concentration of hyaluronan to promote articular cartilage healing and placement of a less durable fibrocartilage component. This often will delay the surgical intervention or eliminate the need for surgery entirely.

CONTENTS AND MECHANISM OF ACTION OF SUPARTZ™

Supartz™ is a commercially available hyaluronan from Smith & Nephew Orthopaedics. It is currently FDA approved in the knee joint as a treatment for mild to moderate osteoarthritis. Use in the foot and ankle is an off-label use at this time. Several studies are in progress to investigate the affects in treatment of ankle osteoarthritis. (Figure 1)

Supartz™ is a prescription medication that is dispensed in a 2.5ml prefilled sterile syringe. The contents include sodium hyaluronate, sodium chloride, dibasic sodium phosphate dodecahydrate, and sodium dihydrogen phosphate dihydrate. Sodium hyaluronate is the active ingredient and Supartz™ provides the most

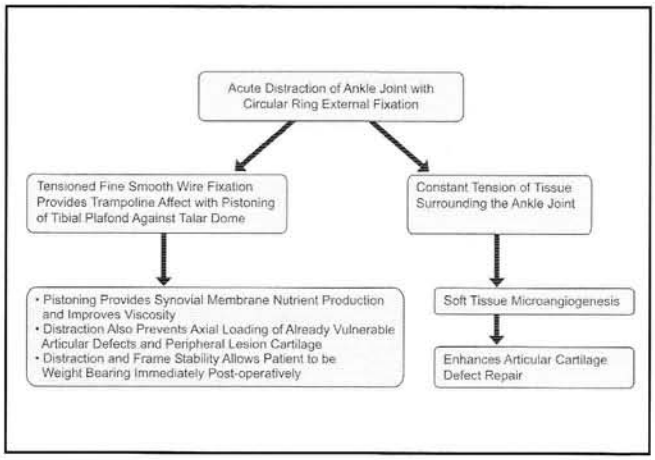

Figure 2. Arthrochondrodiastasis of Ankle Joint.

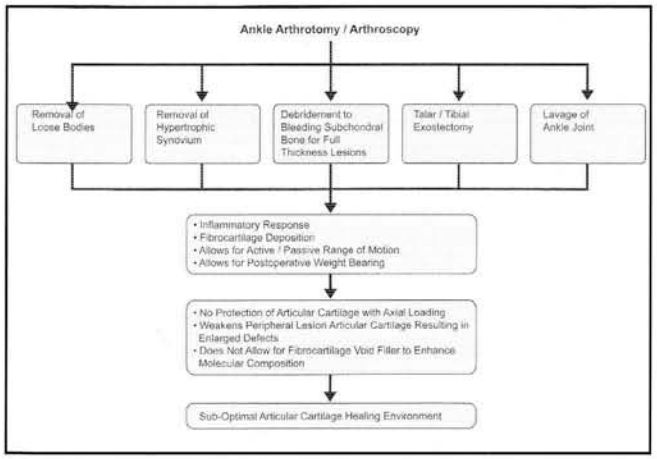

Figure 3.

active ingredient in comparison to similar products on the market. The vehicle components of Supartz™ provide the solution with an anionic charge that helps inhibit the inflammatory process by capturing analgesic mediators within pathological synovial fluids.

The utilization of Supartz™ for osteoarthritis has a direct and indirect mechanism of action.[2,3,7,14] The direct mechanism of action is the capability to capture analgesic mediators within pathologic synovial fluid. In addition it provides the articular cartilage with an environment of hyperviscosity that helps improve nutrient concentration and provides a protective barrier for sensory nerve receptors. This directly inhibits pain from exposed subchondral bone. The high concentration of active ingredient of hyaluronan influences scaffolding and a matrix for increased fibrocartilage repair of full thickness defects. Proteoglycan synthesis is enhanced and participates in repair of articular cartilage defects as well as provide an increase in the integrity of the repair.

Indirect mechanisms of Supartz™ included the inhibition of further breakdown of damaged articular cartilage by providing lubrication to the joint. This often results in a reduction of pain sensitivity and improved function.

Many European studies have critically analyzed the number of injections required to be therapeutic and beneficial. All studies were evaluated in patients with osteoarthritis of the knee and it was determined that five injections provides the optimal amount of the active ingredient of hyaluronan to promote articular cartilage repair.

UTILIZATION IN THE ANKLE JOINT

The indications for the use of Supartz™ in the ankle is an off label use and is not currently an FDA approved treatment. It should be utilized in symptomatic mild to moderate osteoarthritis of the ankle joint. The physician will determine the need for treatment based on a conjunction of symptoms, clinical examination, and radiographic examination. Often time's patients will have significant evidence radiographically of joint asymmetry, articular cartilage damage, subchondral sclerosis, cystic presence and presence of effusion. These same patients often do not have any pain or symptoms and daily function is not compromised. Clinical correlation is required for proper initiation of Supartz™ injection therapy.

Precautions are taken in those patients that have allergies to avian products. Supartz™ should not be used in an area of active infection.[14] A sterile arthrocenthesis of the joint is required on a weekly basis.

Currently the authors are using Supartz™ as an adjunct therapy with surgical intervention. Patients with mild to moderate osteoarthritis undergo either an open arthrotomy of the ankle or arthroscopic approach is utilized. In addition these patients are placed in circular ring external fixation device and the ankle joint is distracted at the time of the surgery. (Figure 2)

The external fixation device is of simple construct with two tibial rings and a foot plate. (Figure 3) Patients are to remain in the circular ring apparatus for the entirety of the five week treatment. They are allowed and required to be weight bearing immediately post-operatively. This procedure is usually performed on an outpatient basis and they are given postoperative analgesic medications.

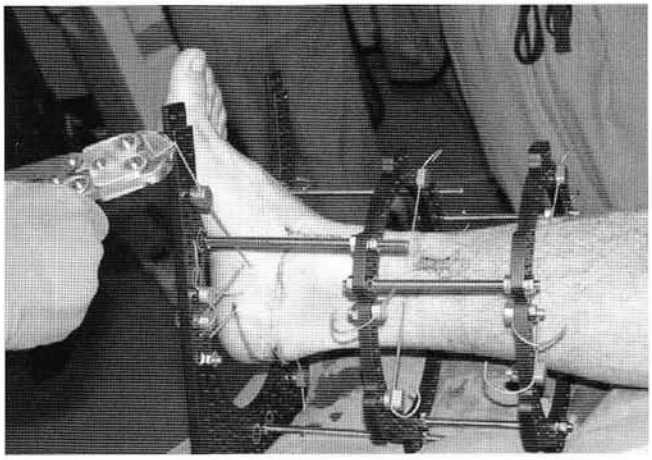

Figure 4.

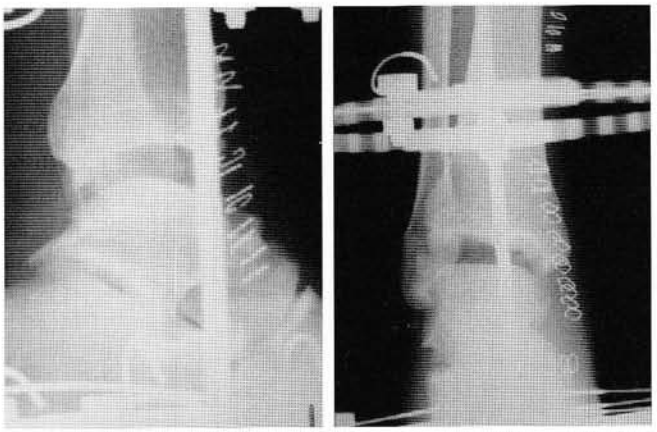

Figure 5.

Figure 6.

The patients are then seen on a weekly basis and Supartz™ is placed in the ankle joint under fluoroscopic guidance. The epidermis is anesthetized with local anesthesia prior to the placement of Supartz™ in a sterile approach. (Figure 4)

Complications of arthrodiastasis include wire site infection, wire site irritation, chronic edema, allergic reaction, and chronic pain. Specific attention is aimed at avoiding more severe complications such as tissue necrosis and iatrogenic ligamentous laxity. Over zealous acute distraction of the ankle joint may cause capillary wall collapse and stretching resulting in vascular blanching and tissue necrosis. (Figure 5)

This is most common in the region of the anterior medial ankle joint region. Pedal pulses and capillary refill around the ankle joint should be evaluated intra-operatively after distraction of the distal tibial ring and the foot plate. If either one of these vascular compromises occur the ankle joint should be reduced back to normal anatomical postion and arthrodiastasis should be performed gradually on a daily basis for one week. Gradual rate of distraction should be 1 mm per day and stopped between day five to seven post-operatively depending on joint distraction radiographically.

Special precaution should also be noted in those patients with arthritis of the ankle joint due to an etiology of ligamentous laxity. Further distraction may result in further instability due to elongation of the lateral collateral ligaments and ankle joint capsule. These patients may require postoperative bracing. Recurrence is not uncommon with symptoms of regenerating pain. Often times these patients will request a repeat distraction with Supartz™ therapy rather than entertain the thought of an ankle fusion.

DISCUSSION

The adjunct approach and utilization of Supartz™ with arthrotomy or arthroscopic surgery in addition to arthrochondrodiastasis with external fixation is a new approach and treatment for symptomatic mild to moderate osteoarthritis of the ankle joint. This technique often ceases pain and the advancement of osteoarthritis. Those patients with more advanced osteoarthritis often require arthroplasty or arthrodesis of the joint.

Major advantages and benefits of this technique include that it is minimally invasive. Arthrochondrodiastasis preserves the ankle joint and delays the need for fusion or ankle joint arthroplasty. The technique can be performed multiple times and it allows for patients that may require a fusion to mentally prepare for a more invasive and definitive procedure. (Figure 6)

Major disadvantages include surgical intervention with arthrotomy or arthroscopy of the ankle joint. External fixation is required for distraction and maybe bulky.

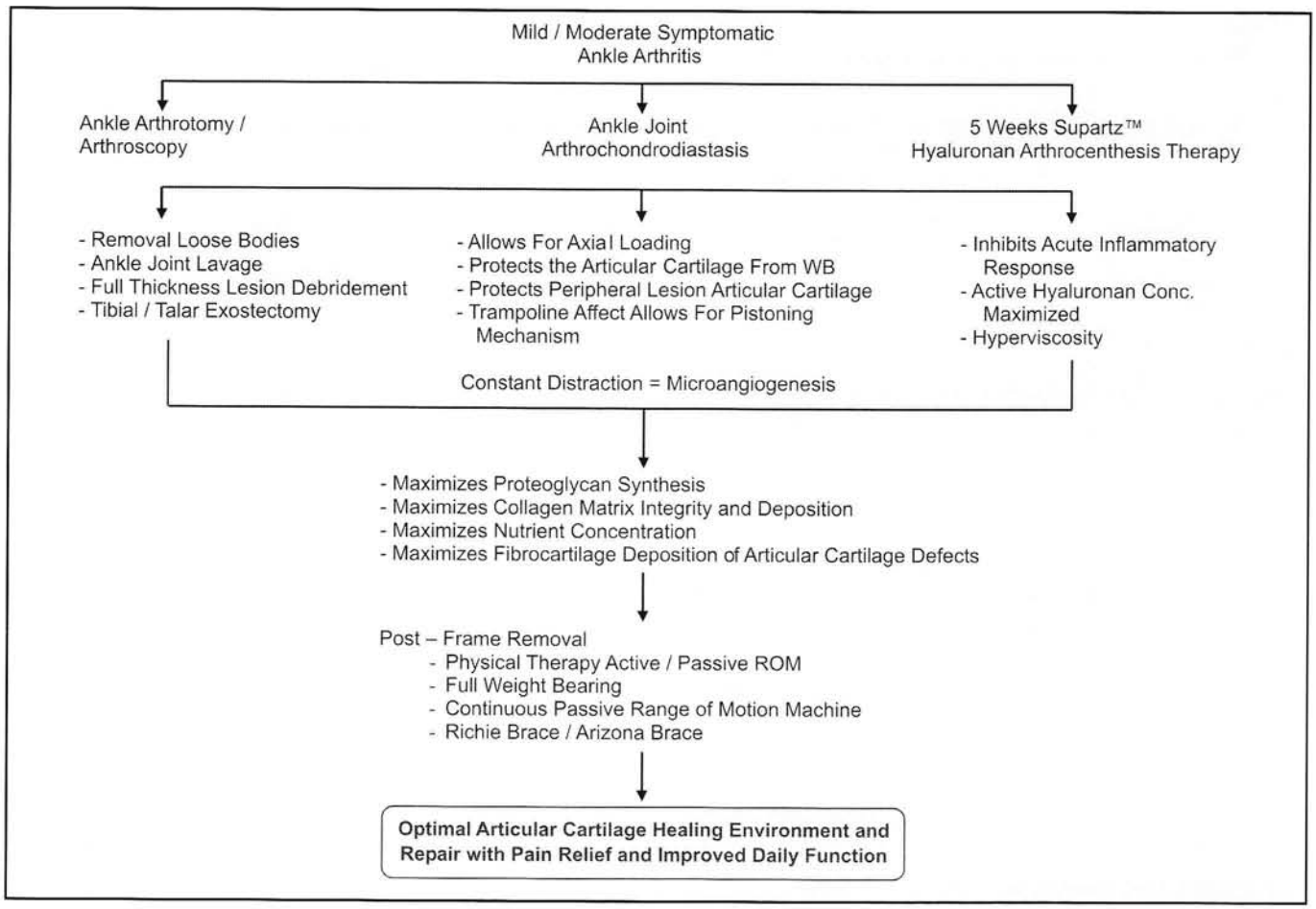

Figure 7. Comprehensive Overview of Arthrochodrodiastasis with Spartz™.

External fixation may also make patients less stable putting them at risk for other injuries. Some patients may require hospitalization for post-operative pain management and deep vein thrombosis prophylaxis. In addition patients are inconvenienced by having to return to clinic on a weekly basis for injection therapy under fluoroscopic guidance.

Open arthrotomy or arthroscopic surgery allows for removal of loose bodies, hypertrophic synovium and debridement of full thickness lesions of the articular cartilage. These surgical approaches often times relieve symptoms without the need for any adjunct therapy. (Figure 7)

Arthrodiastasis is a form of adjunct treatment that protects the articular cartilage from further breakdown. Arthrodiastasis has been utilized in the treatment of Legg Calve Perthes Disease, knee joint contracture, and ankle equinus. The distraction of the hip joint relieves any axial loading of the hip and allows this self limiting disease to repair itself in a weight bearing fashion.

The use of arthrodiastasis in the ankle joint also helps protect the articular cartilage with relief of axial weight on the articular cartilage. This allows for regions with full thickness damage to be replaced with fibrocartilage that will provide a less durable temporary repair. In addition arthrodiastasis protects the peripheral articular cartilage or already existing full thickness lesion. These areas have decreased resistance to abnormal forces and distraction will prevent further enlargement of lesions that are present.

In addition arthrodiastasis provides an acute microangiogenesis. We know that with any constant traction of bone or soft tissue will result in lengthening based on the laws set forth by Dr. Ilizarov and his colleagues. This microangiogenesis helps restore the ankle joint capsule and provides an increase in the concentration of nutrients through the synovial membrane to the articular cartilage. This will enhance articular cartilage repair through hyperviscosity and hyperangiogenesis.

Many question the use of continuous direct axial arthrodiastasis of the ankle versus a hinged apparatus that would allow the patient to plantarflex and dorsiflex the ankle joint. A valid argument against direct axial arthrodiastasis is that it is well established that range of

motion enhances the synovial membrane activity and nutrient production and provides a state of improved viscosity. In addition the utilization of Supartz™ in the knee is not being utilized with knee joint distraction. Rather it is required that aggressive physical therapy with active and passive range of motion is performed with a non-weight bearing status.

The authors propose the following mechanism with the counter argument of a hinged apparatus. Direct constant axial distraction provides the ankle joint with a closed system. After open arthrotomy is performed the ankle joint capsule is closed in the usual manner and the external fixation device is placed. Placement of tibial fine wires is in a configuration that provides a trampoline affect with micromotion and rebound with axial loading that is required with osseous lengthening. It is this same concept that is utilized to provide a pistoning affect of the distal tibial plafond against a non-axial weight bearing talar dome that will provide the same increase in concentration of reparative nutrients.

In addition, the placement of a hinge between the distal tibial ring and the foot plate will require placement at the exact ankle joint axis of motion. This can be challenging even with the most experienced of surgeons in an already biomechanically and functionally altered axis. The distraction of the ankle and placement of the hinges would be malaligned.

The authors have a study pending publication for use of Supartz™ in conjunction with open arthrotomy and arthrodiastasis. The study includes 65 patients with mild to moderate osteoarthritis of the ankle joint. Patients were placed in Ilizarov external fixation devices and the ankle joint was distracted. Patients remained in a non-articulated distraction mode for approximately 5 weeks and were injected weekly with Supartz™ under fluoroscopic guidance.

Results proved beneficial with patients having reduced amounts of pain. The need for further surgical intervention including fusion, arthroplasty, and a repeat arthrochodrodiastasis procedure ranged between one and three years. All patients went through aggressive rehabilitation upon external fixation removal. This included aggressive passive and active range of motion in addition to the utilization of continuous passive motion. Preliminary data results show a 90% satisfaction rating. About 15% of these patients required functional supportive bracing for edema reduction and stability.

CONCLUSION

The utilization of arthrochondrodiastasis with open arthrotomy and five weeks of Supartz™ hyaluronan injections for ankle joint arthritis has proven beneficial. This combination of techniques has delayed the need for ankle joint fusion and ankle joint arthroplasty. It is a minimally invasive joint preserving technique that enhances articular cartilage repair. It should be considered as an option for those patients that may progress on to more advanced osteoarthritis that may require joint destructive procedures. The combination of arthrochondrodiastasis, arthrotomy, and Supartz™ injection therapy provides the optimal healing environment for articular cartilage repair. Further studies are required to compare the variables involved in this technique. Future design may possibly include a double blind placebo study that would utilize only Supartz injection therapy for ankle arthritis without arthrotomy or arthrochondrodiastasis.

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