

Comparative Outcomes and Complications of Synthetic Cartilage Implant for Hallux Limitus or Rigidus in Patients Receiving Adjunctive Procedure for Hallux Valgus Treatment

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Statement of Purpose

The purpose of this study was to compare post-surgical outcomes and complications in patients receiving a Cartiva Synthetic Cartilage Implant for hallux limitus and rigidus correction with those of patients receiving that correction in addition to an adjunctive Scarf osteotomy for hallux valgus correction.

Level of Study

Level 3 Retrospective Cohort Study

Introduction

New techniques and implants for first ray procedures are ever expanding, however, their indications and outcomes are not well-documented. According to its website, the Cartiva Synthetic Cartilage Implant (SCI) is marketed to patients as a solution to first metatarsophalangeal joint pain which is superior to other treatment options due to preserved motion, quick procedure, and smooth recovery. The Cartiva SCI claims to preserve motion by reducing pain without sacrificing movement as compared to fusion surgery.² It is a quick procedure, 40% faster than the alternative fusion surgery.⁴ It also leads to a smooth recovery by allowing patients to bear weight immediately without casts or crutches.⁴

The patient identification tool per the Cartiva SCI website describes its indications as follows: 1) Painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus, 2) Grade 2, 3, or 4 hallux rigidus according to the Clinical-Radiographic System for Grading, 3) Current motion of the great toe (since the Cartiva Synthetic Cartilage Implant preserves existing motion), and 4) good alignment of the great toe. Contraindications are listed as follows: 1) Inadequate bone stock due to significant bone loss, avascular necrosis, and/or large osteochondral cyst (>1 cm) of the metatarsophalangeal joint, 2) Physical conditions that would tend to eliminate adequate implant support, such as insufficient quality of quantity of bone resulting from cancer, congenital dislocation, osteoporosis or osteopenia, prior cheilectomy resulting in inadequate bone stock, 3) Lesions of the first metatarsal head greater than 10mm in size, 4) Systemic and metabolic disorders leading to progressive deterioration of bone such as cortisone therapies, immunosuppressive therapies, uncontrolled diabetes, 5) Tumors or foot deformities of the supporting bone structures, 6) Painful sesamoid arthritis, 7) Known allergy to polyvinyl alcohol, 8) Active infection of the foot, 9) Diagnosis of active gout with tophi.³

The focus of this study involves the first explicit indication listed. It includes painful degenerative or post-traumatic arthritis with or without the presence of mild hallux valgus, which is defined by an intermetatarsal angle of less than 13 degrees between metatarsals 1 and 2 of the foot.¹ The purpose of this retrospective cohort study was to compare post-surgical outcomes and complications in patients receiving a Cartiva SCI for hallux limitus and rigidus correction with patients receiving that correction in addition to an adjunctive Scarf osteotomy for hallux valgus correction.

Methods

All procedures and radiographs, conducted by the same surgeon, were retrospectively reviewed. All 9 patients included in this study had mild hallux valgus deformities, with intermetatarsal angles less than 13 degrees, in addition to hallux limitus or rigidus. The adjunctive procedure selected for hallux valgus correction for the comparative cohort also receiving the Cartiva SCI was the Scarf osteotomy, performed with the same surgical technique, fixation, equipment, and osteotomy angles. 6 patients, 7 feet, were included in the Cartiva only cohort, and 3 patients, 3 feet, were included in the Cartiva and Scarf Osteotomy cohort. The AOFAS Hallux-MPJ Scoring system was used, incorporating both subjective and objective information for assessment of outcomes and complications.

Results

Amongst Cohort 1, the average IM angle remained the same postoperatively at 10.25°. The average IM angle in Cohort 2 changed from preoperative measurements of 12.72° to 9.46° postoperatively. Based on subjective questionnaire, pre-operative AOFAS scores averaged 46.6 total, 49.1 in Cohort 1 and 40.7 in Cohort 2. Post-operative scoring increased to 75.9 total, 72.7 in Cohort 1 and to 83.3 in Cohort 2. The average age within the patient population was approximately 61.90 years total, 62.71 years in Cohort 1 and 60.00 years in Cohort 2. The mean follow up period in years was approximately 0.82 years total, 0.53 years within Cohort 1 and 1.47 years within Cohort 2. No surgical complications such as subsidence, dehiscence, infection, or hallux dislocation, were cited.

	Demographic	Date of Surgery	Foot	Intermetatarsal Angle		AOFAS Scores	
				Preoperative (degrees)	Postoperative (degrees)	Preoperative	Postoperative
Cohort 1 – Cartiva SCI							
Patient 1: IP	74yoF	9/7/2018	R	10.44	10.44	38	60
Patient 2: JS	69yoM	1/7/2019	L	9.34	9.34	57	85
Patient 3: JG	56yoF	1/29/2019	R	11.28	11.28	45	65
Patient 4: GR	57yoM	3/15/2019	R	10.26	10.26	44	80
Patient 5: LP	65yoF	3/22/2019	L	9.38	9.38	55	84
Patient 6: CW	59yoM	7/2/2019	L	10.96	10.96	50	65
			R	10.12	10.12	55	70
Cohort 2 – Cartiva SCI + Scarf							
Patient 1: LC	56yoF	3/7/2018	R	13.88	9.78	37	75
Patient 2: GP	52yoM	3/7/2018	R	11.56	9.46	45	90
Patient 3: BZ	72yoF	4/5/2018	L	12.72	9.14	40	85

	Age (years)	Follow-Up Period (years)	Intermetatarsal Angle		AOFAS Scores	
			Preoperative (degrees)	Postoperative (degrees)	Preoperative	Postoperative
Cohort 1	62.71	0.53	10.25	10.25	49.1	72.7
Cohort 2	60.00	1.47	12.72	9.46	40.7	83.3
Total	61.90	0.82	10.99	10.78	46.6	75.9

Figure 3.0 AOFAS Score Questionnaire

AOFAS Hallux Metatarsophalangeal-Interphalangeal Scale

Patient Name: _____
 Patient MRN: _____
 Date: _____

I. Pain (40 points)

<input type="checkbox"/> None	+40	<input type="checkbox"/> No restriction	+5
<input type="checkbox"/> Mild, occasional	+30	<input type="checkbox"/> Severe restriction (less than 10°)	+0
<input type="checkbox"/> Moderate, daily	+20		
<input type="checkbox"/> Severe, almost always present	+0		

II. Function (45 points)

Activity limitations

<input type="checkbox"/> No limitations	+10	III. Alignment (15 points)	
<input type="checkbox"/> No limitation of daily activities, such as employment responsibilities, limitation of recreational activities	+7	<input type="checkbox"/> Good, hallux well aligned	+15
<input type="checkbox"/> Limited daily and recreational activities	+4	<input type="checkbox"/> Fair, some degree of hallux malalignment observed, no symptoms	+8
<input type="checkbox"/> Severe limitation of daily and recreational activities	+0	<input type="checkbox"/> Poor, obvious symptomatic malalignment	+0

Footwear requirements

<input type="checkbox"/> Fashionable, conventional shoes, no insert required	+10		
<input type="checkbox"/> Comfort footwear, shoe insert	+5		
<input type="checkbox"/> Modified shoes or brace	+0		

IV. Total Score (100 points):

Pain Points + _____
 Function Points + _____
 Alignment Points + _____
 Total Points/100 points _____

MTP joint motion (dorsiflexion plus plantarflexion)

<input type="checkbox"/> Normal or mild restriction (75° or more)	+10
<input type="checkbox"/> Moderate restriction (30° - 74°)	+5
<input type="checkbox"/> Severe restriction (less than 30°)	+0

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Discussion

According to the findings of this study, all patients in both cohorts included within the study noted marked improvement in subjective and functional outcomes. The Cartiva SCI, implanted at the first metatarsophalangeal joint of each of the 10 total feet included in this study, led to less pain and greater range of motion at the joint. The Cartiva SCI was able to aid in sparing the joint in both cohorts as opposed to destroying it with an alternative fusion procedure for the correction of hallux limitus or rigidus. Baumhauer et. al similarly noted through a clinical trial performed to compare the safety and efficacy of the Cartiva SCI to first metatarsophalangeal arthrodesis in patients with advanced-stage hallux rigidus that the Cartiva SCI is an excellent alternative to arthrodesis in patients who wish to maintain first metatarsophalangeal joint motion.²

Subjective and functional outcomes as measured by the AOFAS Scores were more greatly improved postoperatively within Cohort 2 than Cohort 1. Mild hallux valgus deformities were noted in all of the feet included in this study preoperatively, but the underlying deformity was only corrected within Cohort 2. Scarf osteotomies can be done in early degenerative arthritis of metatarsophalangeal joint associated with hallux valgus, as it helps to diminish intra-articular pressure. This decrease in intra-articular pressure relieves the pain and arrests the progression of arthritis.³ While the Z-Scarf osteotomy procedure is indicated for an intermetatarsal angle between 13 and 20 degrees¹, the procedure was chosen as an adjunctive hallux valgus correction in Cohort 2 based on surgeon preference and expertise. A more distal hallux valgus correction procedure was avoided based on the distal implantation site of the Cartiva SCI, as not to interfere with the bone stock in proximity with the insertion site. It is important to note that while no complications of the adjunctive Scarf osteotomy were noted within the three patients included in this study, some complications which can occur include troughing, shortening, stress fractures, avascular necrosis, infection, and hallux varus.¹

Some noteworthy limitations of this study include small sample size, short-term follow up, and procedure selection. Particularly in Cohort 2, the adjunctive procedure for hallux valgus correction was only conducted on three patients total. To further validate the conclusions of this study, additional studies must be conducted with reproducibility in a greater sample size. The longest postoperative follow up period was only approximately one and a half years. While none were cited in this study, it is possible that patients will develop complications in the future. Lastly, though the Z-scarf osteotomy was selected as the adjunctive procedure to correct hallux valgus deformity in Cohort 2 in this study based on surgeon preference, further studies involving other adjunctive hallux valgus correction procedures may be conducted in conjunction with the use of the Cartiva SCI implant to compare outcomes of different adjunctive hallux valgus procedures.

To conclude, we theorize Cartiva implants are an adequate tool for the correction of hallux rigidus and limitus under the correct circumstances and indications. Patients who have hallux limitus or rigidus with an underlying hallux valgus deformity receiving only a Cartiva implant are prone to lesser functional and subjective outcomes.

References

- Banks, Alan S., et al. McGlamrys Comprehensive Textbook of Foot and Ankle Surgery Volume 1. Lippincott Williams & Wilkins, 2001.
- Baumhauer, Judith F., et al. "Prospective, Randomized, Multi-Centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus." *Foot & Ankle International*, vol. 37, no. 5, 2016, pp. 457-469., doi:10.1177/1071100716635560.
- Cartiva Synthetic Implant Patient Information. Cartiva Synthetic Implant Patient Information, 2018, https://www.cartiva.net/wp-content/uploads/2019/05/Cartiva_Patient_Brochure.pdf.
- Glazebrook, Mark, et al. "Treatment of First Metatarsophalangeal Joint Arthritis Using Hemiarthroplasty with a Synthetic Cartilage Implant or Arthrodesis: A Comparison of Operative and Recovery Time." *Foot and Ankle Surgery*, vol. 24, no. 5, 2018, pp. 440-447., doi:10.1016/j.fas.2017.05.002.
- Kundert, Hans-Peter. "Scarf Osteotomy for Correction of Hallux Valgus." *Operative Techniques: Foot and Ankle Surgery*, 2010, pp. 21-34., doi:10.1016/b978-1-4160-3280-9.50007-3.