AMERICAN ORTHOPAEDIC FOOT & ANKLE SOCIETY

Foot & Ankle International®
1–8

DOI: 10.1177/1071100717735289
journals.sagepub.com/home/fai

Correlation of Hallux Rigidus Grade With Motion, VAS Pain, Intraoperative Cartilage Loss, and Treatment Success for First MTP Joint Arthrodesis and Synthetic Cartilage Implant

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Abstract

Background: Grading systems are used to assess severity of any condition and as an aid in guiding treatment. This study examined the relationship of baseline motion, pain, and observed intraoperative cartilage loss with hallux rigidus grade.

Methods: A prospective, randomized study examining outcomes of arthrodesis compared to synthetic cartilage implant was performed. Patients underwent preoperative clinical examination, radiographic assessment, hallux rigidus grade assignment, and intraoperative assessment of cartilage loss. Visual analog scale (VAS) score for pain was obtained preoperatively and at 24 months. Correlation was made between active peak dorsiflexion, VAS pain, cartilage loss, and hallux rigidus grade. Fisher's exact test was used to assess grade impact on clinical success ($P < .05$).

Results: In 202 patients, 59 (29%), 110 (55%), and 33 (16%) were classified as Coughlin grades 2, 3, and 4, respectively. There was no correlation between grade and active peak dorsiflexion (–0.069, $P = .327$) or VAS pain (–0.078, $P = .271$). Rank correlations between grade and cartilage loss were significant, but correlations were small. When stratified by grade, composite success rates between the 2 treatments were nearly identical.

Conclusions: Irrespective of the grade, positive outcomes were demonstrated for both fusion and synthetic cartilage implant. Clinical symptoms and signs should be used to guide treatment, rather than a grade consisting of radiographic, symptoms, and range of motion factors.

Level of Evidence: Level II, randomized clinical trial.

Keywords: First metatarsophalangeal joint, hallux rigidus, hemiarthroplasty, synthetic cartilage implant, arthritis, cheilectomy, first MTP fusion

Over the years, multiple grading systems for hallux rigidus have been introduced with differing methods.[2,4,6,7,10] A classification system should aid in prognosis and guide treatment strategies. The grading system should be universally understood and easily applied without difficulty in the interpretation of the grading criteria. It should also provide a common language for research and allow meaningful comparison of treatment options.

Beeson et al[2] conducted a systematic review to critically evaluate the various classification systems for hallux rigidus. The authors criticized hallux rigidus grading systems because none had undergone independent testing to assess reliability and validity. Despite this, the Coughlin and Shurnas grading scale for hallux rigidus is the most commonly used and cited (Table 1). It has been suggested to be prognostic of the severity of great toe arthritis and used to guide treatment.[2,6,7]

The purpose of this study was to assess the relationship between the clinical factors making up this most commonly used hallux rigidus grading scale, including range of motion, pain, and observed intraoperative cartilage loss in patients

with hallux rigidus, to explore the correlation of these factors to grade selection. Comparison of overall treatment success rates by grade was also assessed to determine the utility of the scale in predicting treatment outcomes.

Methods

Patients were enrolled in a prospective, randomized, multicenter, noninferiority clinical trial comparing safety and efficacy of a synthetic polyvinyl alcohol hydrogel implant (Cartiva Synthetic Cartilage Implant; Cartiva, Alpharetta, GA) to first metatarsophalangeal joint (MTPJ) arthrodesis. The clinical trial was prospectively approved by each site's research ethics board, and all patients provided informed consent. Patients were randomized in a 2:1 allotment to synthetic cartilage implant or to arthrodesis and treated accordingly with either an implant placed in the metatarsal head of the first MTPJ or first MTPJ arthrodesis. The efficacy and safety data for the clinical trial have been previously reported.[1] Preoperatively, 202 patients (safety population, Figure 1) underwent clinical and radiographic examination. The previously validated goniometric technique measuring active peak dorsiflexion of the first MTPJ while standing[8] was recorded preoperatively and at 24 months postoperatively (Figure 2). Lateral and anteroposterior standing foot radiographs were taken. Based on the preoperative assessments of first MTPJ motion, radiographic review, and clinical symptoms, all patients were classified as having Coughlin hallux rigidus grade 2, 3, or 4 prior to treatment.

Intraoperatively and prior to joint preparation, the amount of remaining cartilage was quantified as 100%, 75%, 50%, 25%, or 0% and recorded for the first metatarsal head and proximal phalanx base. The patients then underwent a standardized operative technique for the synthetic cartilage implant (n = 152) or first MTPJ arthrodesis (n = 50) and postoperative protocol as published previously.[1,5,11,12]

Statistical Analysis

All patients' baseline and intraoperative data, irrespective of treatment, were aggregated for analysis. The distributions of baseline active peak dorsiflexion, visual analog scale (VAS) score for pain, and intraoperative cartilage loss category (proximal phalanx and metatarsal head) were compared among patients with Coughlin grades of 2, 3, and 4. Active peak dorsiflexion and VAS pain were evaluated as continuous variables and in categories. Ordinal and categorical variables were summarized using counts and percentages. Continuous variables were summarized using means, standard deviations, and ranges. Statistical significance of associations with Coughlin hallux rigidus grade was evaluated using Spearman rank correlations to assess for strength of correlation of active peak dorsiflexion, VAS pain, and cartilage loss to hallux rigidus grade. Outcomes data were then separated by treatment group to determine composite clinical success (VAS pain reduction, Foot and Ankle Ability Measure Activities of Daily Living [FAAM ADL] subscore, safety, and complications as previously published[1]). Composite clinical success rates were compared between patients undergoing synthetic cartilage implant versus arthrodesis both within and between Coughlin grades using Fisher's and generalized Fisher's exact tests to assess hallux rigidus grade impact on clinical success ($P < .05$).

Results

Of the 202 patients, 59 (29%), 110 (55%), and 33 (16%) were classified as having Coughlin[4] grades 2, 3, and 4, respectively. Table 2 displays the mean baseline first MTPJ range of motion (ROM) and VAS pain scores by Coughlin grade. The mean scores for both measures are nearly identical across grades. Tables 3 and 4 show the distributions of patients with active peak dorsiflexion values and VAS pain scores by the categories and criteria defined in the Coughlin

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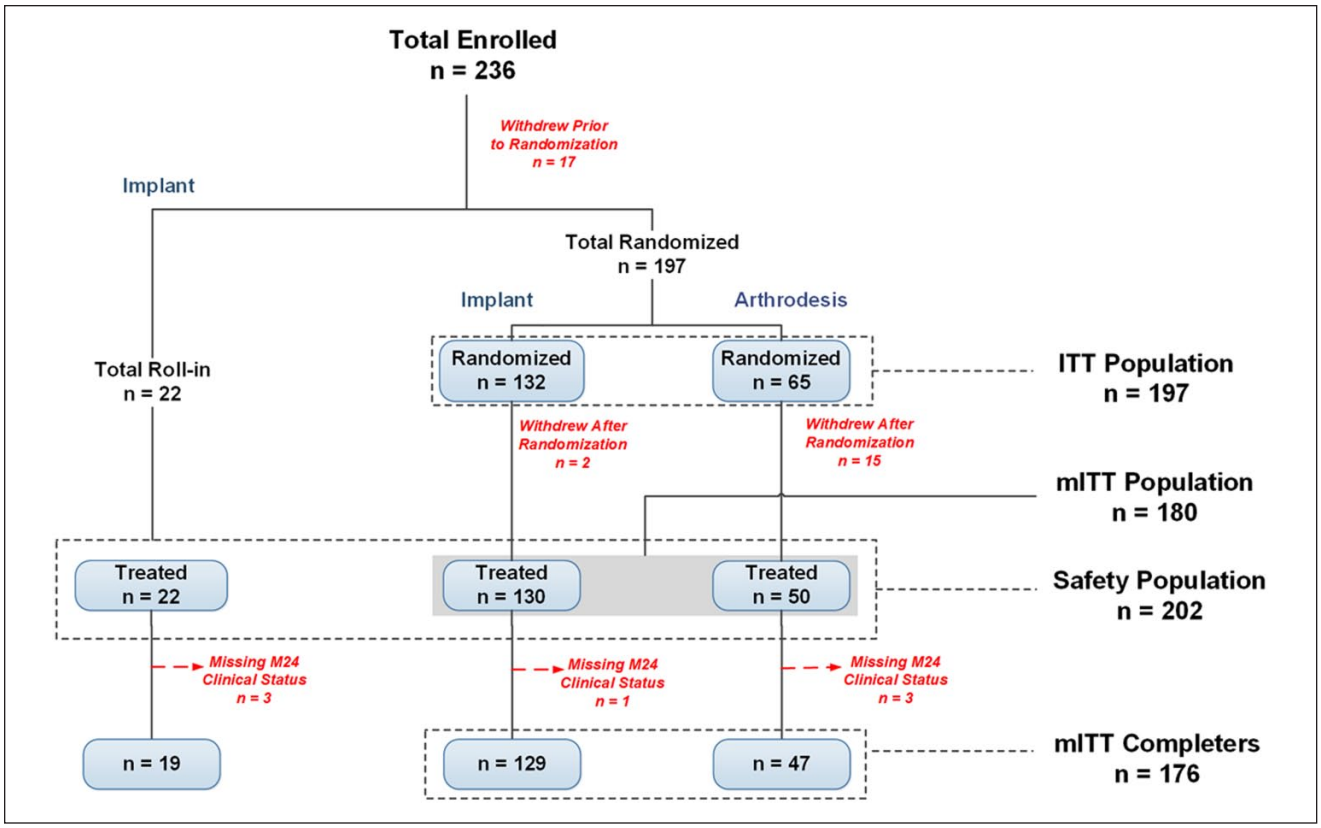

Figure 1. Pivotal trial study patient accountability tree. The safety population consisted of 152 patients (22 roll-in and 130 randomized) treated with synthetic cartilage implant and 50 control patients treated with arthrodesis.

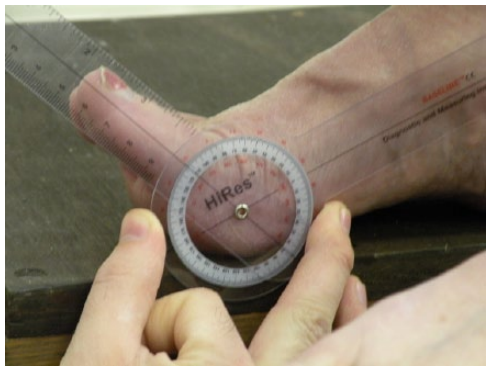

Figure 2. Measure of standing weightbearing first metatarsophalangeal joint active peak dorsiflexion.

scale for each grade. Whereas it might be expected to observe an increase in the percentage of patients with restricted motion corresponding to an increase in hallux rigidus grade or vice versa for patients with less restricted motion, this was not the case across all categories. Likewise, the distribution of patients reporting moderate pain across grades 2, 3, and 4 does not appear to change with an increase in hallux rigidus severity and is similar at 20%, 18%, and 24%, respectively. The same is true for severe pain, with 78%, 79%, and 70% of patients distributed across grades 2, 3 and 4.

Figure 3 displays each individual patient's ROM value and VAS pain score distributed by grade. The median scores for both measures are also nearly identical across grades. The plot shows wide variability outside the upper and lower quartiles for the ROM and VAS pain score values reported across grades 2, 3, and 4. Mean ± SD baseline active peak dorsiflexion ROM for Coughlin grades 2, 3, and 4 are 23.8 ± 8.9 degrees, 22.4 ± 12.7 degrees, and 23.7 ± 10.6 degrees, respectively (Table 2). There was no significant correlation between baseline mean active peak dorsiflexion and Coughlin grade ($r = -0.069$, $P = .327$; Table 5). Mean ± SD baseline VAS pain scores for Coughlin grades 2, 3, and 4 were 70.5 ± 13.9, 68.4 ± 14.1, and 66.3 ± 14.0, respectively (Table 2). There was no significant correlation between Coughlin grade and baseline VAS pain score ($r = -0.078$, $P = .271$; Table 5).

Tables 6 and 7 summarize the amount of proximal phalanx and metatarsal head cartilage remaining. Among grade 4 patients, 21.9% had no proximal phalanx cartilage remaining; however, this was also found in 5.1% of grade 2 patients

Table 1. Coughlin Clinical-Radiographic System for Grading Hallux Rigidus.[4]

Grade	Dorsiflexion	Radiographic Findings[a]	Clinical Findings
0	40 to 60 degrees and/or 10% to 20% loss compared with normal side	Normal	No pain; only stiffness and loss of motion on examination
1	30 to 40 degrees and/or 20% to 50% loss compared with normal side	Dorsal osteophyte is main finding, minimal joint-space narrowing, minimal periarticular sclerosis, minimal flattening of metatarsal head	Mild or occasional pain and stiffness, pain at extremes of dorsiflexion, and/or plantar flexion on examination
2	10 to 30 degrees and/or 50% to 75% loss compared with normal side	Dorsal, lateral, and possibly medial osteophytes giving flattened appearance to metatarsal head, no more than one-fourth of dorsal joint space involved on lateral radiograph, mild to moderate joint-space narrowing and sclerosis, sesamoids not usually involved	Moderate to severe pain and stiffness that may be constant; pain occurs just before maximum dorsiflexion and maximum plantar flexion on examination
3	≤10 degrees and/or 75% to 100% loss compared with normal side. There is notable loss of metatarsophalangeal plantar flexion as well (often ≤10 degrees of plantar flexion)	Same as in grade 2 but with substantial narrowing, possibly periarticular cystic changes, more than one-fourth of dorsal joint space involved on lateral radiograph, sesamoids enlarged and/or cystic and/or irregular	Nearly constant pain and substantial stiffness at extremes of range of motion but not at mid-range
4	Same as in grade 3	Same as in grade 3	Same criteria as grade 3 but there is definite pain at mid-range of passive motion

[a]Weightbearing and anteroposterior and lateral radiographs are used.

Table 2. Baseline VAS Pain Score and First MTPJ Active Peak Dorsiflexion Values (All Treated Patients = Safety Population).

Coughlin Hallux Rigidus Grade	Baseline Measure	N	Mean	SD	Median	Minimum	Maximum
Grade 2	First MTPJ active peak dorsiflexion (degrees)	59	23.8	8.9	25.0	5.0	50.0
	VAS pain score	59	70.5	13.9	70.0	40.0	100.0
Grade 3	First MTPJ active peak dorsiflexion (degrees)	110	22.4	12.7	20.0	0.0	55.0
	VAS pain score	110	68.4	14.1	68.25	27.75	97.0
Grade 4	First MTPJ active peak dorsiflexion (degrees)	33	23.7	10.6	24.0	5.0	58.0
	VAS pain score	33	66.3	14.0	70.0	39.0	85.0

Abbreviations: MTPJ, metatarsophalangeal joint; VAS, visual analog scale.

Table 3. Baseline Active Peak Dorsiflexion Category by Coughlin Grade (All Treated Patients = Safety Population).

Coughlin Hallux Rigidus Grade	Degrees of First MTPJ Active Peak Dorsiflexion at Baseline, No. (%)				
	<10 Degrees	10-30 Degrees	30-40 Degrees	40-60 Degrees	Total No.
Grade 2	7 (11.9)	44 (74.6)	6 (10.2)	2 (3.4)	59
Grade 3	28 (25.5)	60 (54.6)	13 (11.8)	9 (8.2)	110
Grade 4	3 (9.1)	26 (78.8)	2 (6.1)	2 (6.1)	33
Total No.	38	130	21	13	202

Abbreviation: MTPJ, metatarsophalangeal joint.

Table 4. Baseline VAS Pain Score Category by Coughlin Grade (All Treated Patients = Safety Population).

Coughlin Hallux Rigidus Grade	VAS Pain Score Category[a] at Baseline, No. (%)			
	Mild[b] (0 to <40)	Moderate (≥40 to ≤58)	Severe (>58-100)	Total No.
Grade 2	0 (0.0)	12 (20.3)	47 (79.7)	59
Grade 3	3 (2.7)	20 (18.2)	87 (79.1)	110
Grade 4	2 (6.1)	8 (24.2)	23 (69.7)	33
Total No.	5	40	157	202

Abbreviation: VAS, visual analog scale.
[a]VAS pain score cut points for mild, moderate, and severe as defined by Boonstra et al.[3]
[b]VAS pain score less than 40 was an exclusion criterion for the study; these patients were protocol violations.

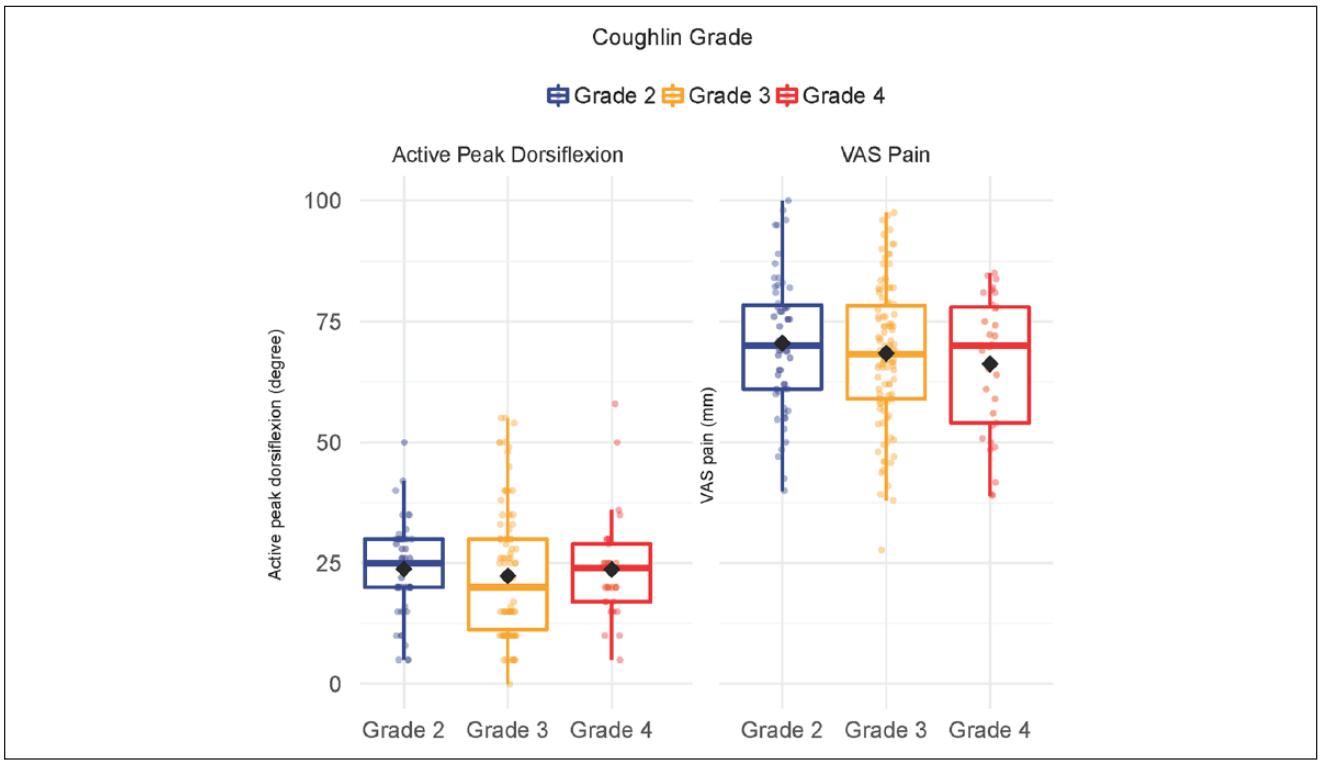

Figure 3. Baseline active peak dorsiflexion value and visual analog scale (VAS) pain score distribution by Coughlin grade: box-and-whisker plot (all treated patients = safety population). Top of each box is the 75th percentile; bottom of each box is the 25th percentile. Top whisker is Q3 + 1.5 * interquartile range (IQR), and the bottom whisker is Q1 − 1.5 * IQR. Horizontal lines inside boxes are median values. Diamonds are mean values. *VAS pain score less than 40 was an exclusion criterion for the study; these patients were protocol violations.

Table 5. Strength of Correlation of First MTPJ Active Peak Dorsiflexion, VAS Pain, and Cartilage Loss to Coughlin Hallux Rigidus Grade (All Treated Patients = Safety Population).

Baseline Observation	No. of Observations	Hallux Rigidus Grade Spearman Rank Correlation Coefficient[a]	*P* Value[b]
First MTPJ active peak dorsiflexion[b]	202	−0.069	.3274
VAS pain	202	−0.078	.271
Cartilage loss—proximal phalanx	200	0.176	.013
Cartilage loss—metatarsal head	201	0.223	.001

Abbreviations: MTPJ, metatarsophalangeal joint; VAS, visual analog scale.
[a]Spearman rank correlation coefficients. P value is Prob > |r| under H0: Rho = 0.
[b]Measured as continuous variable.

Table 6. Percentage Cartilage Remaining on Proximal Phalanx by Coughlin Grade (All Treated Patients = Safety Population).[a]

Coughlin Hallux Rigidus Grade	Proximal Phalanx Cartilage Remaining Category, No. (%)					
	100%	75%	50%	25%	0%	Total No.
Grade 2	3 (5.1)	12 (20.3)	26 (44.1)	15 (25.4)	3 (5.1)	59
Grade 3	0 (0.0)	18 (16.5)	48 (44.0)	36 (33.0)	7 (6.4)	109
Grade 4	0 (0.0)	5 (15.6)	10 (31.3)	10 (31.3)	7 (21.9)	32
Total No.	3	35	84	61	17	200

[a]Proximal phalanx cartilage remaining category was inadvertently not collected for 1 grade 3 and 1 grade 4 patient.

Table 7. Percentage Cartilage Remaining on Metatarsal Head by Coughlin Grade (All Treated Patients = Safety Population).[a]

Coughlin Hallux Rigidus Grade	Metatarsal Head Cartilage Remaining Category, No. (%)				
	75%	50%	25%	0%	Total No.
Grade 2	7 (11.9)	24 (40.7)	23 (39.0)	5 (8.5)	59
Grade 3	9 (8.3)	39 (35.8)	48 (44.0)	13 (11.9)	109
Grade 4	3 (9.1)	4 (12.1)	14 (42.4)	12 (36.4)	33
Total No.	19	67	85	30	201

[a]Metatarsal head cartilage remaining category was inadvertently not collected for 1 grade 3 patient.

Table 8. Success Rates of Synthetic Cartilage Implant and Arthrodesis of the First Metatarsophalangeal Joint by Coughlin[1] Hallux Rigidus Grade (All Treated Patients = Safety Population).

Composite Clinical Success	Coughlin Hallux Rigidus Grade									Fisher's Exact *P* Value[c]
	Grade 2			Grade 3			Grade 4			
	N[a]	n[b]	%	N[a]	n[b]	%	N[a]	n[b]	%	
Implant	41	28	68.3	85	72	84.7	23	19	82.6	.109
Arthrodesis	18	12	66.7	20	17	85.0	9	8	88.9	.331
Within-grade comparison *P* value[d]			>.99			>.99			>.99	

[a]N = total number of patients in the treatment cohort with respective hallux rigidus grade. Not all patients had complete 24-month data available for calculating composite success; thus, the N differs from the baseline grade categories reported earlier in the text.
[b]n = total number of patients in the treatment cohort with respective hallux rigidus grade who met the composite primary end-point criteria for clinical success (ie, visual analog scale pain reduction ≥30%, maintenance or improvement in function, freedom from radiographic complications, and no secondary operative intervention).
[c]P values were determined using generalized Fisher's exact test.
[d]P values were determined using 2-sided Fisher's exact test.

and in 6.4% of grade 3 patients. In contrast, 25.4% of grade 2 patients had 75% or more of proximal phalanx cartilage remaining, but this was also found in 16.5% of grade 3 patients and 15.6% of grade 4 patients. Similarly, among grade 4 patients, 36.4% had no metatarsal head cartilage remaining, but this was also found in 8.5% of grade 2 patients and 11.9% of grade 3 patients. As might be expected, 52.5% of grade 2 patients had 50% or more of metatarsal cartilage remaining; however, this was also found in 44.0% of grade 3 patients and 21.2% of grade 4 patients. Spearman rank correlations demonstrated statistically significant associations between Coughlin grade and both proximal phalanx cartilage ($r = 0.176$, $P = .013$) and metatarsal cartilage remaining ($r = 0.223$, $P = .001$), with higher hallux rigidus grades having less cartilage remaining (Table 5). Despite a statistically significant finding, the correlations were nonetheless weak ($r < .25$), limiting the predictive value of these associations.

Table 8 summarizes comparisons of composite clinical success rates (VAS pain, FAAM ADL, safety, and complications, previously published[3]) for the 2 treatment arms stratified by Coughlin grades of 2, 3, and 4. Success rates within Coughlin grades, as assessed by generalized Fisher's exact test ($P < .05$), were nearly identical for the implant and arthrodesis, suggesting that for this population of patients, with moderate to severe hallux rigidus, Coughlin

grade does not provide information useful in determining optimal treatment choice.

Discussion

Grading scales are often used within orthopaedics to classify patients and guide prognosis and treatment plans. The Coughlin grading scale has been commonly used to assess the severity of arthritic change in hallux rigidus by ranking the radiographic changes of the great toe and quantifying the first MTPJ stiffness, as well as pain severity and pain location. These clinical assessments have not been validated, but they have been commonly used to "rank" severity of first MTPJ arthritis and guide treatment. This study demonstrates that the active dorsiflexion ROM and VAS pain scales at baseline did not correlate with the Coughlin grade. More important, the Coughlin grade was only weakly correlated with the presence of remaining cartilage as observed within the joint and did not predict the success or failure of clinical treatment (implant or arthrodesis). Therefore, the grading system did not predict arthritis severity or guide treatment.

Strengths of this study include the prospective, randomized, controlled study design and quality of the categorical and longitudinal data collected. The large sample size (implant, n = 152; arthrodesis, n = 50) and low rate of patients lost to follow-up (2%) provided a robust data set to serve as the basis for this analysis. This is in contrast to the methodology of data collection of the Coughlin hallux rigidus scale, where cartilage loss was estimated based on retrospective review of operative reports, preoperative pain was retrospectively assigned a numerical value, and hallux rigidus grade was applied retrospectively at final follow-up.[4]

The limitations of this study include the retrospective analysis of the prospectively acquired data. The original clinical trial was powered to demonstrate noninferiority of the synthetic cartilage implant to arthrodesis, whereas this study retrospectively evaluated success rates by hallux rigidus grade and may not have been powered sufficiently, thus introducing the possibility of a type II error in this subgroup analysis. The patients enrolled in this study were determined by the treating surgeon to be of a severity to require a first MTPJ arthrodesis, and therefore selection bias might have been present. A similar study examining the patients who are being considered for an isolated dorsal cheilectomy or other joint-sparing operations should be undertaken to verify this information in a different patient population. The technique to assess active weightbearing dorsiflexion motion of the great toe has been found to be strongly correlated with the motion demonstrated during normal walking.[8,9] This active ROM technique is different from the passive ROM technique used in the Coughlin study and may result in lower absolute ROM values in this study. Last, this article focused on the clinical assessments of the Coughlin grading scale, and the standing foot radiographs, although taken, were not included in the analysis. The validation of radiographic criteria for the great toe has not been performed or validated. Once validated, however, independent assessment may add additional information to the severity of joint damage.

In conclusion, this study examined the relationship of great toe dorsiflexion motion, pain, and intraoperative cartilage loss findings with a commonly used clinical and radiographic grading scale for hallux rigidus. The weak correlations of motion, VAS pain, and intraoperative cartilage loss to Coughlin grade suggest that clinical symptoms and signs rather than Coughlin grade should be guiding the treatment options for our patients and that grade assessment may underinterpret the severity of arthritic change within the first MTPJ.

Acknowledgments

Special recognition to Nick Cullen, MBBS, FRCS; Mark Davies, BM, FRCS, FRCS; Howard Davies, MBChB, MSc, FRCS; James Davis, MBBS, FRCS; Anna Fox, MBChB, MSc, FRCS; Andrew Goldberg, MBBS, FRCS, MD, OBE, FRCS, FRCSI; Gordon Goplen, MD, FRCSC; Murray Penner, MD, FRCSC; and all the MOTION study coordinators from the United Kingdom and Canada.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. The authors were consultants for the Pivotal Trial Study for Cartiva. Judith F. Baumhauer, MD, MPH, reports personal fees and other from Cartiva and nonfinancial support from Cartiva during the conduct of the study. Mark Glazebrook, MSc, MD, PhD, FRCSC, reports grants from Cartiva during the conduct of the study. Chris M. Blundell, MBChB, FRCS, reports grants from Sheffield Teaching Hospitals NHS Trust during the conduct of the study. M. Elizabeth Pedersen, MD, FRCSC, reports other from Carticept during the conduct of the study. Anthony Sakellariou, MBBS, FRCS (Tr & Orth), reports grants and nonfinancial support from Carticept during the conduct of the study. Matthew Solan, FRCS (Tr & Orth), reports nonfinancial support and other from Cartiva during the conduct of the study. Alastair S. E. Younger, MBChB, MSc, ChM, FRCSC, reports grants from Cartiva during the conduct of the study. Timothy R. Daniels, MD, FRCSC, reports personal fees from Carticept during the conduct of the study. ICMJE forms for all authors are available online.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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