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# Establishing the Relationship Between Clinical Outcome and Extent of Osseous Bridging Between Computed Tomography Assessment in Isolated Hindfoot and Ankle Fusions

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## Abstract

**Background:** Determining the success of joint fusion operations is often a diagnostic dilemma, and many factors may be considered. Most would agree that the broad categories of clinical success and radiographic success are likely most useful to determine the overall success of a joint fusion operation. Very little evidence exists to assist the surgeon in determining what constitutes a successful radiographic fusion. The aim of this study was to determine the extent of osseous bridging as measured by computed tomography (CT) that was associated with a good clinical outcome as measured by the 12-Item Short Form (SF-12), Foot Function Index (FFI), and American Orthopaedic Foot & Ankle Society (AOFAS) clinical outcomes questionnaires at 24 weeks.

**Methods:** Patients who had isolated joint fusions were evaluated (n = 275) to determine the correlation of extent of osseous bridging with clinical outcome. The extent of osseous bridging across the joint in question was categorized as absent (0%-24%), minimal (25%-49%) moderate (50%-74%), or complete (75%-100%). Clinical outcome scores included the SF-12, FFI, and AOFAS outcomes score.

**Results:** Patients evaluated to have at least minimal osseous bridging at fusion sites (25%-49%) on CT reported a clinically important improvement in SF-12, FFI, and AOFAS, whereas those with “absent” osseous bridging (0%-24%) did not report a clinically important improvement in outcome scores.

**Conclusion:** This study suggests that osseous bridging of greater than 25% to 49% at the fusion site measured by CT may be necessary to consider a hindfoot or ankle fusion clinically successful.

**Level of Evidence:** Level IV, case series.

**Keywords:** arthritis, arthrodesis, fusion, outcome, computed tomography scan

Determining the success of a joint fusion operation is often a diagnostic dilemma, and many factors may be considered. Most would agree that the broad categories of clinical success and radiographic success are likely most useful to determine the overall success of a joint fusion operation. Clinical success may be defined as improved pain and function and absence of need for further surgery, while radiographic success may be defined as imaging evidence of bone growth across the intended bones to be fused.<sup>4,8,10</sup>

Clinical assessment tools are available to measure clinical success, such as the 12-Item Short Form (SF-12),<sup>12</sup> Foot Function Index (FFI),<sup>1</sup> and American Orthopaedic Foot & Ankle Society (AOFAS)<sup>11</sup> clinical outcome questionnaires.

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These tools have been assessed and, in some cases, validated to measure improvements in clinical outcome by way of numerical scores before and after an intervention such as a hindfoot and ankle fusion. Thus, if a patient has a good clinical outcome as measured by clinical outcome scores, there is almost always radiographic evidence of bone growth across the joint intended to be fused and this indicates no need for further surgery. However, in the absence of good clinical outcome, surgeons often look to the radiographic evidence of a successful fusion to assist in determining the need for further surgery.

Unfortunately, only a few studies have reported detailed results regarding what constitutes a successful radiographic fusion. Most clinical trials assessing the outcomes of treatment targeted at fusion or fracture repair have used a combination of radiologic end points, clinical end points, and other outcome assessments, such as the AOFAS Hindfoot and Ankle Score, FFI, and Pain Outcomes instrument. Radiographic imaging, either alone or in combination with clinical criteria, has been used in almost all studies on assessment of healing status.<sup>2</sup> Standard radiographs, however, may not be optimal for quantitative evaluation of fusion and healing, and the ability to determine union on radiographs has been recently questioned.<sup>3</sup>

The emerging role of modern computed tomography (CT) to assess fusion and healing is promising given its ability to detect osseous bridging across the healing site in 3 dimensions, and thus CT is the best currently available imaging method for assessment of osseous fusion.<sup>3,6,7</sup> Unfortunately, little literature exists regarding the extent of osseous bridging identified by CT that is necessary to establish a successful clinical outcome. Recent studies suggest that at least a third to half of the joint surface area must achieve osseous bridging to establish a clinically successful fusion.<sup>3,7</sup>

This study attempted to determine the extent of osseous bridging that was necessary to achieve a successful hindfoot or ankle fusion using clinical and radiographic data from a large randomized control trial.<sup>5</sup> Specifically, the aim of this study was to determine the extent of osseous bridging as measured by CT that was associated with a good clinical outcome as measured by SF-12, FFI, and AOFAS clinical outcome questionnaires at 24 weeks.

## Methods

Between April 2007 and January 2010, a blinded, multicenter, prospective, randomized, controlled pivotal clinical trial was performed at 37 different clinical sites across the United States and Canada in accordance with Food and Drug Administration (FDA) good clinical practice guidelines in a population of patients requiring either hindfoot or ankle fusion.<sup>5</sup>

After approval was granted by all applicable regulatory bodies including the US FDA, Health Canada, Institutional

Review Board, and Research Ethics Board, eligible subjects who satisfied the entry criteria (Table 1) were administered appropriate informed consent and thereafter enrolled. A standard computerized model was used to randomize subjects into 1 of 2 groups: standard rigid internal fixation plus autologous bone graft or Augment Bone Graft (Wright Medical Inc, Memphis, Tennessee). Patients were stratified for surgical site (hindfoot or ankle) as well as nonunion risk factors, diabetes, obesity (body mass index  $>30 \text{ kg/m}^2$ ), smoking (any routine use in the past 5 years), or revision surgery as the healing risk factor components.

For this study, a subset of patients from the master study who had isolated joint fusion were evaluated ( $n = 275$ ); thus, patients who had double or triple fusion were not evaluated. All patients were monitored throughout a 52-week study period. Clinical and radiographic outcomes were assessed at various time points, including 24, 36, and 52 weeks. Health-related quality of life was assessed with the SF-12.<sup>12</sup> Joint-specific clinical outcomes were assessed with the AOFAS outcomes score<sup>11</sup> and FFI.<sup>1</sup> CT was performed and evaluated at 9, 16, 24, and 36 weeks postoperatively, with the primary end point defined as the degree of fusion based on the 24-week CT scans since 16-week scans were nondiscriminatory for fusion.

Patients were categorized at week 24 as a “clinical success” if they did not have a revision surgery and had reduced pain on weight bearing at this time point or as a “clinical failure” if they had a revision surgery or did not have reduced pain on weight bearing. This categorization was used to establish clinically important differences in the various outcome assessment tools used in this study, as described below.

Radiologic outcomes were evaluated with 4, 16, and 64 multidetector CT. The imaging parameters included isometric volumetric acquisition with 0.5- to 0.7-mm detector collimation, 15- to 20-cm targeted field of view, 130 to 140 kVp, and 200 to 400 mA. The field of imaging included the ankle and/or mid- to hindfoot. Axial source images were created with 0.5- to 0.7-mm slice thickness. This data set was then reconstructed into direct axial, coronal, and sagittal images with 2-mm slice thickness at 2-mm intervals. CT images were received by the independent radiologist reviewer in DICOM format. Potential identifying information (if any) was removed. Images were then posted to a PACS webserver, where they were available for evaluation.

The radiologist assessed the extent of osseous bridging across the joint in question using a semi-quantitative method (SQM) for assessing osseous bridging, as described below. The SQM consisted of assessing the length of the joint surface and the length of the fused portion of the joint for each slice that passed directly through the joint. This was performed in only 1 reformatted plane and typically in the sagittal plane. If the final extent of osseous bridging was not conclusive, other planes were evaluated. Fusion of a joint

**Table 1.** Study Entry (Inclusion/Exclusion) Criteria.**Inclusion Criteria**

1. The patient signed the institutional review board–approved informed consent form.
2. The patient had a bone defect in the hindfoot or ankle requiring fusion using open operative technique with supplemental bone graft, requiring 1 of the following procedures:
  - Ankle joint fusion (tibiotalar fusion)
  - Subtalar fusion
  - Calcaneocuboid fusion
  - Talonavicular fusion
3. The fusion site was able to be rigidly stabilized with no more than 3 screws across the fusion site. Supplemental screws external to the fusion site(s) were also allowed.
4. The patient was independent and ambulatory and could comply with all postoperative assessments.
5. The patient was at least 18 years of age and was considered to be skeletally mature.

**Exclusion Criteria**

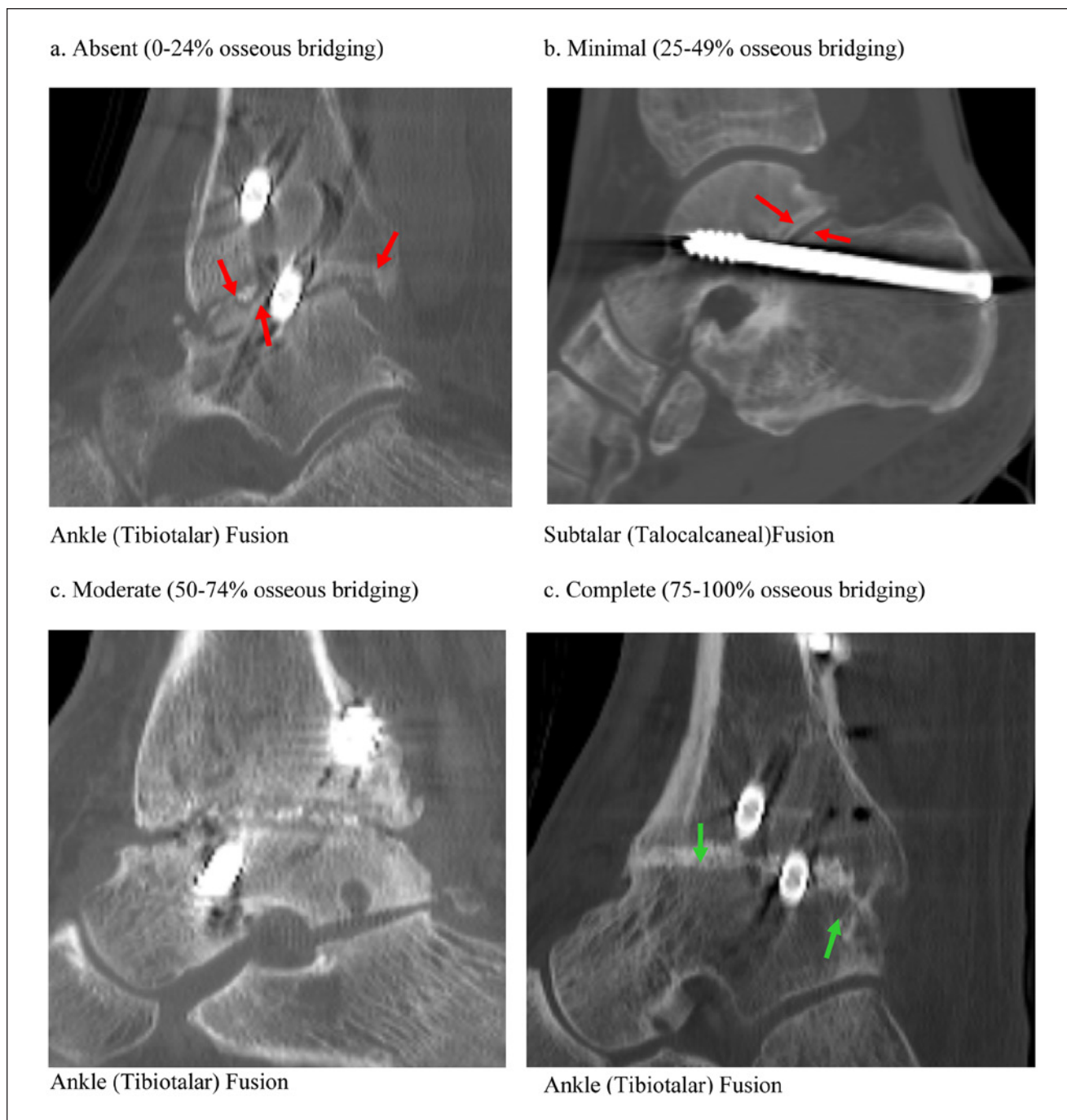
6. The patient had previous surgery of the proposed fusion site.
7. The fusion site required plate fixation, more than 3 screws, or more than 9 cc of graft material.
8. There was radiographic evidence of bone cysts, segmental defects, or growth plate fracture around the fusion site that may have negatively affected bony fusion.
9. One or more untreated malignant neoplasms were present at the surgical site, or the patient was currently undergoing radio- or chemotherapy.
10. The patient had a preexisting sensory impairment (eg, diabetes with baseline sensory impairment) that limited the ability to perform objective functional measurements. Diabetic patients who were not sensitive to the 5.07 monofilament (Semmes-Weinstein) were excluded.
11. The patient had a metabolic disorder known to adversely affect the skeleton, other than primary osteoporosis or diabetes (eg, renal osteodystrophy or hypercalcemia).
12. The patient used chronic medications known to affect the skeleton (eg, glucocorticoid >10 mg/d). Nonsteroidal anti-inflammatory drug use was excluded during the first 6 weeks postoperatively.
13. The patient had a neuromuscular or musculoskeletal deficiency that limited the ability to perform objective functional measurements.
14. The patient was physically or mentally compromised (eg, currently being treated for a psychiatric disorder, senile dementia, Alzheimer's disease, etc) to the extent that the investigator judged the patient to be unable or unlikely to remain compliant.
15. The patient had an allergy to yeast-derived products.
16. The patient had received an investigational therapy or approved therapy for investigational use within 30 days of surgery or during the follow-up phase of this study.
17. The patient was a prisoner, was a known or suspected transient, or had a history of drug/alcohol abuse within the 12 months prior to screening for study entry.
18. The patient was pregnant or a female intending to become pregnant during the study period. A urine pregnancy test was administered within 21 days of the surgical visit to any female unless she was postmenopausal, had been sterilized, or was practicing a medically accepted method of contraception.
19. The patient was deemed morbidly obese (body mass index >45 kg/m<sup>2</sup>).

segment was defined as loss of distinctness of graft with subjacent cross-trabeculation to exposed subchondral bone or bridging trabeculation across the former joint space (Figure 1a). All obscured portions of the joint secondary to beam hardening and the actual hardware crossing the joint were excluded from evaluation. In addition, if offset or subluxation of a joint surface was present, only the apposed portions of the joint were included. The SQM scoring was determined by a global categorization of estimated osseous bridging to 1 of the following CT osseous bridging groups (Figure 1):

- Absent (0%-24% osseous bridging)
- Minimal (25%-49% osseous bridging)

- Moderate (50%-74% osseous bridging)
- Complete (75%-100% osseous bridging)

The relationship between CT osseous bridging and clinical outcome success was determined in 2 steps. First, clinically important differences in the outcome measures were determined by examining the differences in mean scores between patients determined to be clinical success and those determined to be clinical failure. Second, the average outcome scores were computed for the 4 CT osseous bridging groups, and these groups were compared both statistically (using analysis of covariance) and clinically (by comparing them with the clinically important differences determined above). As such, 2 criteria would need to be met to determine



**Figure 1.** Examples of individual computed tomography (CT) slices demonstrating the categorization of estimated osseous bridging to 1 of the following CT osseous bridging groups: absent (0%-24% osseous bridging), minimal (25%-49% osseous bridging), moderate (50%-74% osseous bridging), and complete (75%-100% osseous bridging).

whether differences in CT osseous bridging were related to clinical benefit: Differences in outcomes scores for the 4 groups would need to demonstrate statistically significant differences (relative to hypothesis testing method) and clinically important differences (relative to benchmarks established by comparing known clinical successes and failures).

The accuracy of assessing the extent of fusion was not dependent on the number of fixation devices crossing the joint. The independent radiologic assessments specifically excluded the joint surface area consumed by the hardware fixation devices, and, as such, the surface area of the fusion site did not include the space occupied by the hardware.

	week 24 mean score		
	Success n=216	Failed n=59	Clinical Significant Difference
ffi	23	34	-11
aofas	32	26	6
sf12 pcs	41	39	2

**Figure 2.** A comparison of Short Form (SF-12), American Orthopaedic Foot and Ankle Society (AOFAS), and Foot Function Index (FFI) mean clinical outcome scores for patients who were deemed a clinical success using the criteria of improved pain with weight bearing and no revision surgery and patients who were deemed a clinical failure.

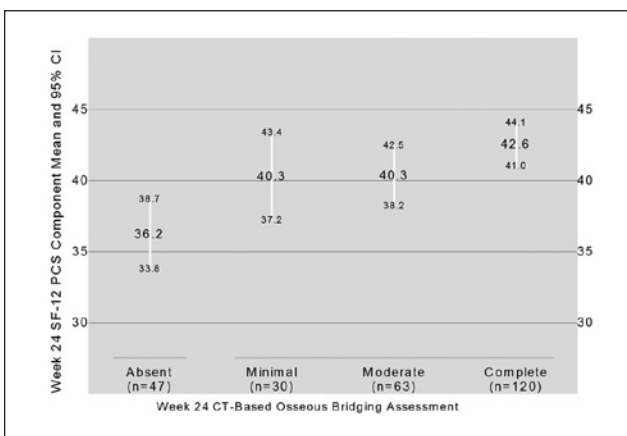
Analysis of covariance with baseline outcome scores was used to estimate the mean outcome scores for the 4 CT osseous bridging groups and corresponding 95% confidence intervals. Pairwise comparisons were made between the 4 groups on the basis of Fisher’s least significant difference approach.

**Results**

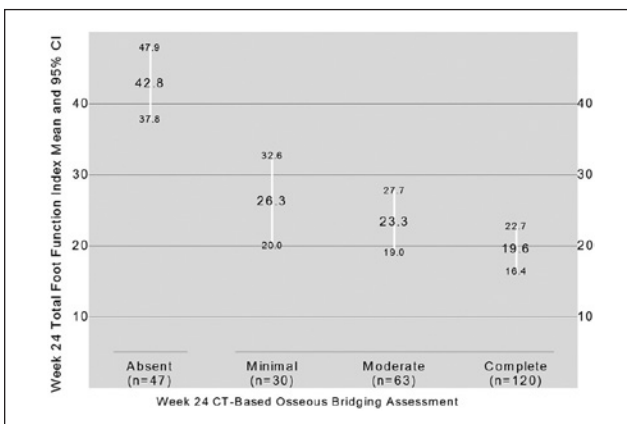
A total of 275 patients with isolated joint arthrodeses were evaluated. At week 24, according to the criteria of improved pain with weight bearing and no revision surgery, 216 patients were deemed a clinical success and 59 patients deemed a clinical failure. Average clinical outcome scores (SF-12, FFI, and AOFAS) at 24 weeks were improved in those patients who were deemed a clinical success compared with those who were deemed a clinical failure (Figure 2). The difference between the mean clinical outcome scores for the group who had clinical success compared with the group who had clinical failure provided clinically important difference scores of 11 points for FFI, 6 points for AOFAS, and 2 points for SF-12 (Figure 2) Average clinical outcome scores also showed improvement as the extent of osseous bridging increased (Figure 3). Likewise, as the amount of osseous bridging increased, the mean outcome score improved. Further, all mean clinical outcomes scores were improved by a clinically important amount (as determined above) in patients with minimal osseous bridging (25%-49%) and higher groups compared with those with absent osseous bridging (0%-24%). However, this clinically important improvement in outcome scores between adjacent groups was not consistent across the 4 groups, as the degree of improvement was less pronounced when moving across the groups with greater degrees of osseous bridging (Figure 3). Figures 4, 5, and 6 show the mean scores for the SF-12 Physical Component Score (PCS) component, FFI, and AOFAS score across the 4 CT osseous bridging groups, along with 95% confidence

Outcome measure	Clinically significant difference	Visit Week	Mean score and 95% confidence interval				P-value for differences between groups
			Absent (0-25% osseous bridging)	Minimal (25-50% osseous bridging)	Moderate (50-75% osseous bridging)	Complete (75-100% osseous bridging)	
SF-12 PCS component	2	24	36 (34-39)	40 (37-43)	40 (38-42)	42 (41-44)	0.0028
FFI	11	24	43 (38-48)	26 (20-33)	23 (19-28)	20 (16-23)	<0.0001
AOFAS total score	6	24	63 (58-67)	69 (64-75)	73 (69-76)	77 (74-80)	<0.0001

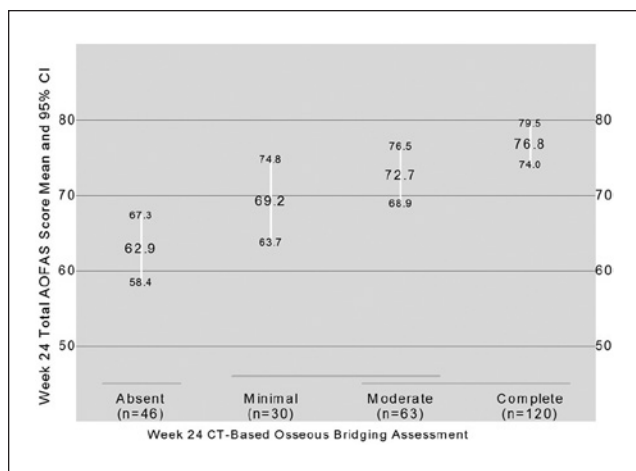
**Figure 3.** A comparison of Short Form (SF-12), American Orthopaedic Foot and Ankle Society (AOFAS), and Foot Function Index (FFI) mean clinical outcome scores in patients who were subdivided into their computed tomography osseous bridging groups (absent, minimal, moderate, and complete).



**Figure 4.** Mean scores for the Short Form (SF-12) PCS component across the 4 computed tomography (CT) osseous bridging groups, along with 95% confidence intervals (CI).



**Figure 5.** Mean scores for the total Foot Function Index across the 4 computed tomography (CT) osseous bridging groups, along with 95% confidence intervals (CI).



**Figure 6.** Mean scores for the total American Orthopaedic Foot & Ankle Society (AOFAS) score across the 4 computed tomography (CT) osseous bridging groups, along with 95% confidence intervals (CI).

intervals. Numbers of patients in each CT osseous bridging group who possessed the outcome measure under examination are also displayed.

The lines connecting the CT groups denote which groups are considered to be not statistically significantly different. For example, for the FFI plot, the Absent group makes up a single group, and the other 3 groups are connected, implying that the mean for the Absent group is significantly different from the other 3 groups but any differences among the other 3 groups are not significant when compared with the adjacent group. The same general trend holds for the SF-12 PCS component. For the AOFAS score, the Absent group stands apart from the other 3 but Minimal and Moderate are not different, and Moderate and Complete are not different, but Minimal and Complete are different.

Thus, for all 3 outcome measures, the clinically important change seen between the Absent group and the other 3 groups was also shown to be statistically significant.

## Discussion

This study is the largest study to use validated clinical outcome scores to determine the extent of osseous bridging as measured by CT scans that is necessary to establish a successful hindfoot and ankle fusion. In this study, patients evaluated to have at least minimal osseous bridging (25%-49%) reported a clinically important improvement in SF-12, FFI, and AOFAS, relative to those patients evaluated to have 0% to 24% osseous bridging. Previous studies typically used radiographs as the diagnostic imaging modality of choice, a widely accepted standard for evaluation of fracture healing and union. Only recently have researchers attempted to define fusion as osseous bridging across at

least 50% of the whole cross section of the fused joint or fracture site, but they do not describe their method for arriving at this percentage.<sup>9</sup>

Two other studies have described a quantitative evaluation method that measures the fused portion of the joint as a percentage of the total joint intended for fusion.<sup>3,7</sup> In the study by Coughlin and co-authors,<sup>3</sup> clinical results of subtalar arthrodeses based on the AOFAS, Visual Analog Scale, and SF-12 scores were compared with the percentage of joints fused according to radiography and CT.<sup>3</sup> The study concluded that the progress of the fusion cannot be determined accurately from standard radiographs and suggested that CT is notably more reliable. Dorsey and co-authors<sup>7</sup> were the first to report the extent of osseous bridging correlated with clinical outcome in tibiotalar and subtalar fusion using CT. The authors reported that in 12 clinically unstable joints assessed, the fusion ratios ranged from 0% to 32.8%, whereas 30 clinically stable joints had fusion of at least 33.2%. It is interesting to note that their method differed from that of Coughlin. Dorsey considered the area of the joint traversed by hardware as nonfused, whereas Coughlin excluded this area from measurement. Therefore, the percentage of fusion would have been higher if Coughlin's method were used. The authors<sup>7</sup> found that when using the 33% threshold for defining a stable fusion, the sensitivity, specificity, and accuracy were all 100%, and they concluded that CT scans were more reliable than radiographs in evaluating amount of fusion. This value of 33% falls within the 25% to 49% range necessary for a clinical success defined by the current study.

A weakness of the current study was that we reported the extent of osseous bridging using noncontiguous categorical data (eg, absent, minimal, moderate, or complete) as opposed to contiguous numerical data that would be more precise. Further, we did not validate the clinically important difference thresholds at various points along the continuum of the outcome measures.

In conclusion, this study is the largest series to use established and qualified clinical outcome scores and CT to establish the extent of osseous bridging necessary to consider a hindfoot or ankle fusion clinically successful. The study found that clinically important differences in SF-12 PCS component, FFI, and AOFAS hindfoot and ankle scores are approximately 2, 11, and 6 points, respectively. It appears that the FFI correlated more closely with the radiologic outcome, which is not an unexpected observation, given that the FFI is specific to the hindfoot and ankle fusion outcome. In contrast, the SF-12 is a more general outcome instrument and measures overall quality of life. We agree with others that CT is the best currently available imaging method to evaluate the success of a joint fusion. Further, it is likely that if CT demonstrates 25% to 49% osseous bridging in a hindfoot or ankle fusion, clinical

success is likely. Improved degree of osseous bridging in excess of this threshold is associated with improved outcomes using the measurements employed in this study, although in some cases these improvements are not clinically or statistically significant. The most pronounced improvement in clinical outcome score increase comes from the Absent (0%-24%) to Minimal (25%-49%) categories. The subsequent increases in osseous bridging categories demonstrate improvements, although these increases are generally less pronounced.

### 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. WB and RD were employees of BioMimetic Therapeutics Inc (now owned by Wright Medical Inc) and as such are at conflict. The remaining authors received funds to cover the costs of research through an unrestricted grant and/or were working as consultants for BioMimetic Therapeutics Inc.

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