The Importance of Sufficient Graft Material in Achieving Foot or Ankle Fusion

Christopher W. DiGiovanni, MD, Sheldon S. Lin, MD, Timothy R. Daniels, MD, FRCSC, Mark Glazebrook, PhD, MD, FRCSC, Peter Evangelista, MD, Rafe Donahue, PhD, William Beasley, CCRP, and Judith F. Baumhauer, MD, MPH

Investigation performed at 37 clinical sites in North America

Background: Nonunion, an important complication following foot and ankle arthrodesis, causes substantial morbidity and disability. In patients undergoing hindfoot and ankle arthrodesis, autogenous bone graft (autograft) or a suitable alternative is often used to promote osseous fusion across the joint. This study assessed the importance of adequate graft material in the fusion space to achieve joint fusion during ankle and hindfoot arthrodesis.

Methods: This study used data from a previously published clinical trial of grafting material (recombinant human platelet-derived growth factor-BB with beta-tricalcium phosphate [rhPDGF-BB/β-TCP] or autograft) for healing in hindfoot and ankle arthrodesis to correlate the amount of graft fill at 9 weeks with ultimate healing. Patients who received supplemental graft material for ankle or hindfoot arthrodesis for end-stage ankle or hindfoot arthritis were stratified according to nonunion risk factors and surgical fusion site. Patients underwent arthrodesis using standard rigid internal fixation. Graft fill was defined as "adequate" if the material occupied ≥50% of the cross-sectional area of the fusion space on a computed tomography (CT) scan made at 9 weeks. Fusion was defined as osseous bridging of ≥50% of each articulation on a CT scan made at 24 weeks. Three hundred and seventy-nine patients with 573 joints (383 managed with rhPDGF-BB/β-TCP and 190 managed with autograft) that underwent arthrodesis had complete follow-up with 9-week and 24-week CT scans available.

Results: Overall, 472 (82%) of 573 joints had adequate graft fill; of those, 383 (81%) were successfully fused at 24 weeks compared with 21 (21%) of 101 joints without adequate graft fill ($p < 0.0001$). Absolute fusion rate differences (joints with adequate fill minus those without adequate fill) were consistent across joints (61% to 63%) and for graft materials. The overall odds ratio (OR) of successful fusion in joints with adequate graft fill compared with those without adequate graft fill was 16.4 (95% confidence interval, 9.6 to 27.9).

Conclusions: This study demonstrates an association between the amount of graft material and successful hindfoot and ankle arthrodesis. Graft material filling of ≥50% of the fusion space at 9 weeks, regardless of type or origin, was associated with significantly higher fusion rates at 24 weeks.

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

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Nonunion is a common, important, and devastating complication following foot and ankle arthrodesis that can cause substantial morbidity and disability. Positive resolution often requires a reoperation in the form of revision arthrodesis, after which rates of success are lower than for the index procedure[1-3]. The rate of nonunion following primary arthrodesis of the ankle or foot approximates 10%[4], but has been reported to be as high as 41% in high-risk patients[5].

Disclosure: Two authors, the statistician (R.D.) and the certified clinical research professional responsible for organizational management of the study (W.B.), are employees of BioMimetic Therapeutics, Inc. (Wright Medical, Inc.); both were blinded to treatment assignments in the parent clinical trial until after the database had been locked and the analysis plan finalized. The remaining authors received funding from BioMimetic Therapeutics, Inc. to cover research costs and/or were working as consultants for BioMimetic Therapeutics, Inc. The sponsor did not control the drafting and writing of the manuscript. On the **Disclosure of Potential Conflicts of Interest** forms, *which are provided with the online version of the article*, one or more of the authors checked "yes" to indicate that the author had a relevant financial relationship in the biomedical arena outside the submitted work and "yes" to indicate that the author had other relationships or activities that could be perceived to influence, or have the potential to influence, what was written in this work.

TABLE I Summary Statistics for the Cross-Sectional Area Measurements of Graft Fill in the Joint Space for a Random Sample

Joints	No. of Joints	Graft Fill in Fusion Space (%) Min.	Max.	Mean and Stand. Dev.	95% CI	P Value	C Statistic
All joints (n = 38)						<0.0001	0.997
≥50%	19	52	100	85 ± 15	78-92		
<50%	19	8	55	32 ± 15	25-39		
rhPDGF-BB-β-TCP treated joints (n = 26)						<0.0001	1.000
≥50%	13	52	100	85 ± 15	75-94		
<50%	13	8	47	28 ± 15	19-37		
Autograft treated joints (n = 12)						0.0003	1.000
≥50%	6	61	98	85 ± 16	68-103		
<50%	6	19	55	40 ± 13	26-54		

Historically, surgeons have relied on autogenous bone graft (autograft)[3,6-8], allograft[9,10], or, more recently, suitable orthobiologic alternatives to promote osseous fusion. This treatment is largely based on observation (Level-IV and V evidence) and has often been reserved for patients considered at higher risk for nonunion. A recent logistic regression analysis of 159 studies that provided outcome data from foot and ankle arthrodesis found a trend toward higher union rates for joints managed with cancellous and structural autograft compared with those in which no graft was used[11]. The majority of those reports were retrospective case series. Level-I studies that compared autograft with alternative materials demonstrated no significant difference in fusion rates between the materials evaluated[12-14]. Interestingly, to our knowledge, no prospective, randomized controlled trial has directly compared outcomes of foot and ankle arthrodesis with and without the use of autograft. The likelihood of clinically successful fusion appears to be directly related to the degree of critical fusion mass achieved after surgery[15-17]. It seems reasonable to assume that anything having the potential to increase the fusion mass across a given joint would be a positive adjunct to any fusion procedure[16-18].

Our hypothesis was that the addition of graft material to a fusion site would increase the chances of reaching the critical fusion mass. The purpose of this study was to determine the importance of adequate graft material to achieve fusion in ankle and hindfoot arthrodesis, where an *adequate* amount was defined as graft material that occupied ≥50% of the cross-sectional area of the gap between bones.

Materials and Methods

Study Design

Complete data on 379 patients (573 joints) were retrospectively accessed from a prospective trial that compared graft materials for the promotion of bone healing in foot and ankle arthrodesis. We report on the relationship between graft fill and healing. The reference trial was conducted between April 2007 and January 2010 and was prospectively registered at ClinicalTrials.gov (NCT00583375).

The detailed methodology and primary results of the clinical trial are reported elsewhere[14]. Briefly, patients having ankle or hindfoot arthrodesis were enrolled if they required supplemental bone graft, met the inclusion criteria (see Appendix), and provided informed consent. Patients were first stratified by nonunion risk factors (diabetes, a body mass index [BMI] of >30 kg/m^2, smoking, and revision surgery) and surgical site (ankle or hindfoot). Patients then underwent arthrodesis using standard rigid internal fixation and were treated with either recombinant human platelet-derived growth factor-BB (rhPDGF-BB; 0.3 mg/mL) combined with beta-tricalcium phosphate (β-TCP) as a graft material (AUGMENT Bone Graft; BioMimetic Therapeutics) or autograft, which was harvested from the iliac crest (11.7%), distal end of the tibia (16.1%), proximal part of the tibia (50.4%), calcaneus (13.9%), or another lower-extremity site (8.0%). Investigators used sterile, graduated surgical cups to measure the amount of graft material used, and this was recorded.

Radiographic Measurement

Computed tomography (CT) was performed for all patients at 9 and 24 weeks. Images were independently assessed by 1 fellowship-trained, board-certified, musculoskeletal radiologist, blinded to the patient, graft material received, surgeon, and site. CT examinations were acquired in a volumetric isotropic data set utilizing noncontrast, multidetector acquisition, 130 to 140 kVp, 200 mAs, 0.5 to 0.7-mm collimation, and 0.3-mm interval. The data set was reconstructed into 3 orthogonal planes (axial, sagittal, and coronal) with a slice thickness of 2 mm at 2-mm intervals. Scans made at 24 weeks were read first to minimize potential bias due to type of graft material, which was evident on 9-week scans.

Graft fill was determined on 9-week CT scans. Utilizing the plane(s) orthogonal to the joint, contiguous 2-mm slices were evaluated for joint length available for fill and joint length containing graft fill (e.g., a joint 2 cm wide had 10 slices assessed). The percentage of graft fill was determined semiquantitatively by mental summation of graft fill present in each of the individual slices

TABLE II Successful Fusion in Ankle or Hindfoot Joints According to Amount of Graft Material*

Adequate Graft Material†	Failure (no. of joints)	Success* (no. of joints)	Total No.
Yes	89 (19%)	383 (81%)	472
No	80 (79%)	21 (21%)	101
Total	169 (29%)	404 (71%)	573

*Successful fusion was demonstrated with ≥50% osseous bridging on a CT scan at 24 weeks. †Graft material was considered adequate when it occupied ≥50% of the cross-sectional area of the fusion space on a CT scan at 9 weeks.

TABLE III Successful Fusion, with or without Adequate Graft Material, Stratified by Type of Joint and by Type of Graft Material Used*

Parameter	No.	Fusion with Adequate Graft Fill†	Fusion without Adequate Graft Fill†	Fusion Rate Difference‡ *(percentage points)*	Total No. of Fusions†
Joint type					
Ankle	150	107/143 (75%)	1/7 (14%)	61	108/150 (72%)
Subtalar	203	139/165 (84%)	8/38 (21%)	63	147/203 (72%)
Calcaneocuboid	90	57/68 (84%)	5/22 (23%)	61	62/90 (69%)
Talonavicular	130	80/96 (83%)	7/34 (21%)	62	87/130 (67%)
Graft material					
rhPDGF-BB/β-TCP	383	252/318 (79%)	14/65 (22%)	57	266/383 (69%)
Autograft	190	131/154 (85%)	7/36 (19%)	66	138/190 (73%)

*A successful fusion demonstrated ≥50% osseous bridging on a CT scan at 24 weeks. Adequate graft fill means graft material occupied ≥50% of the cross-sectional area of the fusion space on a CT scan at 9 weeks, and inadequate fill occupied <50%. †The values are given as the number that had fusion divided by the number with the stated graft fill. ‡Difference = (fusion with adequate graft fill) − (fusion without adequate graft fill).

and was partitioned into 2 groups: "adequate" if the graft material occupied 50% to 100% of the cross-sectional area of the available fusion space, and "inadequate" if the graft material occupied 0% to 49% of the cross-sectional area of the available fusion space. For a summation of approximately 50%, a visual percentage was estimated for each slice, and average graft fill across the joint was calculated. Areas with no graft fill were defined as the areas of the joint where a gap existed and contained no graft particles. A random sample (38 joints) showed nearly perfect separation between those classified as <50% graft fill and those classified as ≥50% graft fill ($p < 0.0001$) (Table I). The mean cross-sectional area measurement for joints classified as ≥50% was 85%, significantly greater than the mean cross-sectional area of 32% for joints classified as <50% ($p < 0.0001$).

Joint fusion was determined by measuring the percentage of osseous bridging on 24-week CT scans, which was calculated in the same manner as described for graft fill above. The radiologist was blinded to the surgeon assessment of clinical healing status. Fusion was declared if ≥50% of each articulation was considered to be bridged by osseous trabeculation. To determine intraobserver reliability, the radiologist reread all CT scans available at 24 weeks (585 joints) at least 3 months after the initial reading. The kappa value was 0.87, with 95% concordance and 0.987 tetrachoric correlation.

Joint fusion was secondarily determined by the surgeon's global assessment of the patient's progress at 52 weeks, defined as clinical healing status. This assessment included clinical examination, consideration of radiographs and functional outcome scores, and no need for revision surgery. When multiple joints were concomitantly addressed, each individual joint was assessed separately for both fusion and clinical healing. Clinicians were blinded to CT assessment of fusion by the radiologist.

Statistical Analysis

The primary outcome was joint fusion as determined by the percentage of osseous bridging on a 24-week CT scan. The secondary outcome was clinical healing status at 52 weeks. These outcome measures are binary variables and are presented as counts and proportions. The relationship between graft fill and joint fusion on 24-week CT scans was examined via chi-square tests. Fusion rates in joints with adequate graft fill and those without adequate graft fill were compared via chi-square tests and summarized via the odds ratio (OR). The Breslow-Day test for homogeneity of the OR was employed to examine the impact of demographic factors on the relationship between graft fill adequacy and fusion. Logistic regression was employed to examine the impact of graft fill adequacy on joint fusion, adjusting for demographic and other descriptive factors. A p value of <0.05 was deemed significant. No adjustments were made for multiple comparisons.

Results

A total of 379 patients were treated with rhPDGF-BB/β-TCP (249 patients) or autograft (130 patients) and had complete data for CT determination of adequateness of graft fill in the fusion space at 9 weeks and CT assessment of osseous bridging at 24 weeks, resulting in 573 joints (383 treated with rhPDGF-BB/β-TCP and 190 treated with autograft) that underwent arthrodesis and were analyzed for this study.

A total of 472 (82%) of 573 joints had adequate graft fill in the fusion space (i.e., ≥50% of the joint space was filled with graft material), and 101 joints (18%) did not (i.e., the graft material occupied <50% of the cross-sectional area) at the 9-week CT scan (Table II). Of the 472 joints with adequate graft fill, 383 (81%) were successfully fused at the 24-week CT examination, versus only 21 (21%) of 101 joints without adequate graft fill ($p < 0.0001$). The overall OR of successful fusion in joints with adequate graft fill over those without adequate graft fill was 16.4 (95% confidence interval [CI], 9.6 to 27.9).

Overall, 404 (71%) of 573 joints met the end-point criterion of ≥50% osseous bridging on CT scans at 24 weeks and were considered fused (Table II). Of the 404 successfully fused

TABLE IV Clinical Healing Status at Joint Level Following Ankle or Hindfoot Arthrodesis According to Amount of Graft Material

Adequate Graft Material	Not Clinically Healed *(no.)*	Clinically Healed* *(no.)*	Total No.
Yes†	48 (10%)	424 (90%)	472
No	28 (28%)	73 (72%)	101
Total	76 (13%)	497 (87%)	573

*A joint was determined to have achieved clinical healing at 52 weeks postoperatively on the basis of a global assessment of the patient's progress by the surgeon. †Graft material occupied ≥50% of the cross-sectional area of the fusion space on a CT scan at 9 weeks.

TABLE V Clinical Healing Status According to the Volume of Graft Material Used in the Joint

Adequate Graft Material According to Volume of Graft Material Used*	No. Clinically Healed†	No. Not Clinically Healed	Total No.
1 mL			
Yes	14 (93%)	1 (7%)	15
No	5 (83%)	1 (17%)	6
1.5 mL			
Yes	16 (94%)	1 (6%)	17
No	4 (80%)	1 (20%)	5
2 mL			
Yes	70 (95%)	4 (5%)	74
No	9 (47%)	10 (53%)	19
3 mL			
Yes	181 (92%)	15 (8%)	196
No	42 (84%)	8 (16%)	50
4.5 mL			
Yes	6 (75%)	2 (25%)	8
No	1 (50%)	1 (50%)	2
6 mL			
Yes	113 (86%)	19 (14%)	132
No	8 (53%)	7 (47%)	15
9 mL			
Yes	21 (78%)	6 (22%)	27
No	3 (100%)	0 (0%)	3
All joints			
Yes	424 (90%)	48 (10%)	472
No	73 (72%)	28 (28%)	101

*Total volume of material used per patient was provided by the surgeon and was then divided by the number of joints in that patient that received graft fill to estimate the volume of graft material used per joint. Adequate graft material (i.e., "yes") indicates graft material occupied ≥50% of the cross-sectional area of the fusion space on a CT scan at 9 weeks. †Determined to have achieved clinical healing at 52 weeks postoperatively on the basis of a global assessment of the patient's progress by the surgeon.

joints, 383 (95%) had adequate graft fill, and 21 joints (5%) did not. In contrast, only 89 (53%) of 169 joints that were not fused had adequate graft fill and 80 joints (47%) did not.

Arthrodesis was performed on ankle, subtalar, calcaneocuboid, and talonavicular joints. Fusion rates among the different joints that had adequate graft fill ranged from 75% to 84% on the 24-week CT scan (Table III), compared with fusion rates of only 14% to 23% in joints without adequate graft fill. The difference in fusion rates (i.e., those with adequate graft fill minus those without adequate graft fill) ranged from 61 to 63 percentage points and was consistent across all joints.

When rhPDGF-BB/β-TCP was used, fusion was observed in 79% and 22% of joints with and without adequate graft fill, respectively—a difference of 57 percentage points (Table III). A similar disparity was observed with autograft, with fusion rates of 85% with adequate graft fill and 19% without—a difference of 66 percentage points.

The OR of successful fusion of joints with adequate graft fill over those without adequate graft fill demonstrated a benefit of adequate graft fill across all factors evaluated (Fig. 1). There were no significant differences in ORs based on type of graft material used, graft harvest site, joint type, number of joints fused, sex, age, BMI, history of diabetes, or smoking status. The OR of successful fusion with adequate graft fill was significantly lower in joints that had previously undergone surgery other than fusion at the fusion site (OR, 3.8; 95% CI, 1.0 to 14.5) compared with those that had not (OR, 22.0; 95% CI, 12.2 to 39.7; $p = 0.0124$). The OR also varied significantly by primary diagnosis, from 7.0 (95% CI, 3.1 to 15.8) in joints with posttraumatic osteoarthritis to 92.3 (95% CI, 15.5 to 550.1) in joints with rheumatoid arthritis ($p = 0.0312$), indicating that patients with rheumatoid arthritis showed the greatest improvement in rates of fusion with adequate graft fill. These ORs, which are larger than the relative risk, should not be interpreted as actual risk.

In a secondary evaluation of overall clinical healing status, 497 (87%) of 573 joints were determined to be clinically healed by 52 weeks (Table IV). Ninety percent (424) of 472

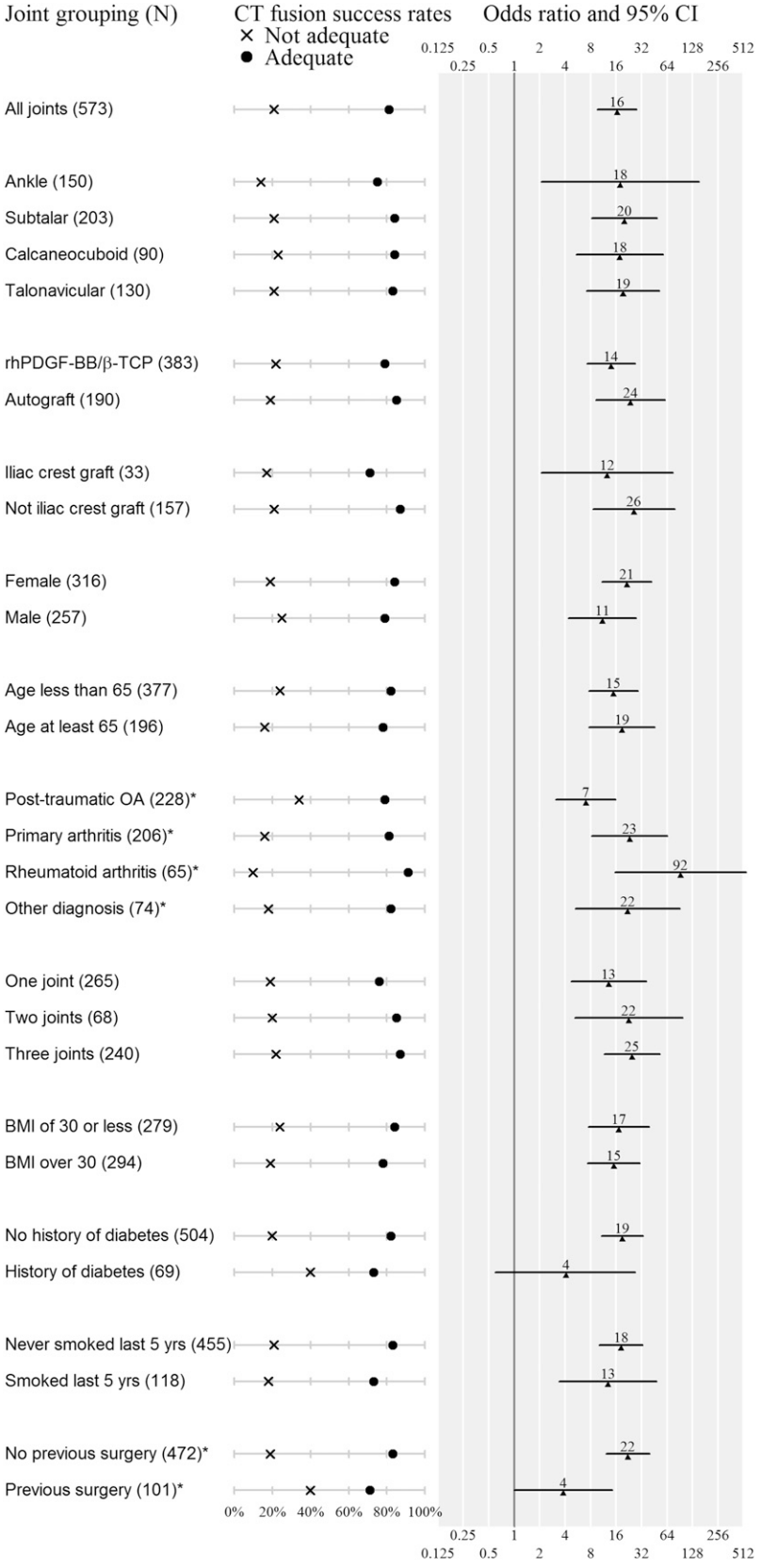

Fig. 1

Impact of demographic factors. The middle column shows the rates of fusion based on the 24-week CT scan (i.e., osseous bridging of ≥50%) for joints with adequate graft fill (i.e., ≥50% of joint space) (solid dot) and joints without adequate graft fill (x). The right column shows the OR (value and point) and 95% CI (black bar) for the rates of fusion for joints with adequate fill compared with those without adequate graft fill. The values to the right of the vertical line at 1 indicate improved fusion success with adequate graft fill. The OR scale is logarithmic. An asterisk denotes a demographic factor with significantly different ORs (Breslow-Day test, $p < 0.05$), indicating that, while fusion rates with adequate graft fill are always better than without adequate graft fill, in some conditions the disparity is higher or lower. OA = osteoarthritis.

joints with adequate graft fill and 72% (73) of 101 joints without adequate graft fill were determined to be clinically healed. Clinical healing status was also evaluated with respect to the measured volume of graft material used in the joint (Table V). Joints with ≥50% graft fill consistently showed greater proportions of clinical healing across the different volumes of graft material used. There was a small-sample exception of 3 joints that received 9 mL of graft material and had <50% graft fill but demonstrated 100% clinical healing, compared with clinical healing in 21 (78%) of 27 joints that received 9 mL of graft material and had ≥50% graft fill.

Discussion

Across all joint locations and for both rhPDGF-BB/β-TCP and autograft, approximately 80% of joints with adequate graft fill achieved successful fusion, whereas only approximately 20% of joints without adequate graft fill achieved fusion, as determined by ≥50% osseous bridging on CT scans at 24 weeks following foot and ankle arthrodesis. Having adequate graft fill within the fusion space resulted in an approximately 60% higher fusion rate. The overall OR of successful fusion in joints with adequate graft fill over those without adequate graft fill was 16.4 (95% CI, 9.6 to 27.9). This phenomenon was observed in all joints examined, in both graft treatments used, for all graft harvest sites, and for various risk factors associated with nonunion.

Despite extensive literature citing the use of autograft or suitable alternatives to promote fusion in ankle and hindfoot arthrodesis, there is a remarkable paucity of Level-I or II studies directly comparing rates of union with the use of autograft and with no graft material. In a recent logistic regression analysis of 159 available studies on ankle and hindfoot fusion, 153 were retrospective case series; only 19 included patients who received graft and patients who did not (although in most, no direct comparison was performed)[11]. The authors reported a trend toward higher union rates for cancellous autograft (OR, 1.39; 95% CI, 0.92 to 2.10; p = 0.11) and structural autograft (OR, 1.52; 95% CI, 0.94 to 2.47; p = 0.09) relative to no graft material. They concluded that their analysis likely underestimated the benefit of autograft, because it seemed typically to have been used in more complex procedures that were likely to have lower union rates if no graft was used. Our study demonstrated that when a surgeon can eliminate bone-to-bone gaps in any joint intended for fusion, whether via the use of autograft or rhPDGF-BB/β-TCP, such a joint has a significantly better chance of ultimately achieving fusion.

Clearly, osseous apposition is required for successful fusion. Graft material is often used to complement a fusion site where full osseous apposition across the joint is lacking. Concern has been raised, however, that overpacking a joint with excessive graft material may hinder the healing process by impairing optimal host bone contact and allowing joint movement that might favor nonunion formation[19,20]. The challenge of good surgical technique is to ensure that a sufficient, or adequate, amount of graft material is used across any joint surface to optimize direct osseous contact where it did not previously exist, rather than "overstuffing" the joint with material that might otherwise distract places where it is not required. Further research to determine the ideal amount of graft material required for a clinically relevant and impactful effect on fusion is warranted.

Approximately 18% of joints in our study had inadequate graft fill as determined by CT across the intended fusion space in procedures that were performed by experienced, fellowship-trained foot and ankle experts. This presumably unintended consequence indicates the difficulty of precise graft material placement across a fusion space. Future research may consider the development of graft materials that are easier to introduce and can be more precisely inserted into the intended fusion space. Alternatively, inadequate graft fill at 9 weeks may be indicative of intensive resorption, a process that is not well understood.

The odds of successful fusion with adequate compared with inadequate graft fill showed no meaningful difference for the graft materials used or for autograft harvested from iliac crest bone versus bone from another site. Furthermore, the OR for successful fusion with or without adequate graft fill also did not differ significantly when stratified by joint type, number of joints fused, sex, age, BMI, diabetes, or smoking status. Joints that had undergone a previous operation (other than fusion) at a fusion site had a significantly lower OR of successful fusion although having adequate graft fill was still beneficial for fusion. Finally, the primary diagnosis also affected the OR of successful fusion with adequate graft fill compared with inadequate graft fill. Joints in patients diagnosed with rheumatoid arthritis revealed significantly higher odds of successful fusion compared with joints diagnosed with posttraumatic osteoarthritis or primary arthritis.

The rate of fusion, as determined by ≥50% osseous bridging on a 24-week CT scan, was 71%. Using a global assessment of the joint by the surgeon at 52 weeks, 87% of joints in our study were considered clinically healed, consistent with an average of 89% (range, 77% to 97%) reported for 961 ankle arthrodeses across recent studies[3,21-31]. Those studies relied on clinical and radiographic data[3,21,23,25-27,31] or radiographs[22,24,28,30] to define nonunion. CT is a more sensitive tool for identifying nonunions that may otherwise be missed by a surgeon's composite assessment[15-17]. We used a robust criterion of ≥50% osseous bridging on CT to define fusion, consistent with the parent trial[14]. Use of a lower threshold of 25% to 49% trabecular bridging, recently demonstrated to be sufficient for clinically successful fusion[15], would have produced a higher fusion rate.

Interpretation of these study results is subject to certain limitations. The term *adequate* graft fill referred to an amount of graft material that sufficiently filled the joint to promote bone contact and osseous fusion. For this investigation, this was arbitrarily defined as ≥50% of the cross-sectional area of the available fusion space. The study was not designed to determine the critical or minimal amount of graft material required to have a clinically important effect on fusion, although it is clear that the threshold of ≥50% graft fill had a substantial and positive impact on fusion. Also, the term *adequate* is limited to a description of the cross-sectional area of graft fill, and in no way reflects the quality of the surgical procedure or the surgeon's skill. The study

was also not designed to detect differences between strata in the OR for fusion with adequate graft, but all strata showed ORs in excess of 1.0, demonstrating the benefit of adequate graft material for essentially every joint and patient.

This investigation has several strengths. The controlled methodology and rigorous evaluation techniques used in the parent prospective clinical trial allowed accurate and consistent determination of the amount of graft fill across each joint studied. Such methodology ensured that the demonstrated effect on fusion was due to adequate filling of the joints, rather than the graft material used, patient demographics, or other risk factors. Adequate graft fill and successful fusion were also assessed by sequential, high resolution CT for each patient, which provides substantially greater accuracy of data than radiographic examination[16,17,20]. Another strength of this investigation is the robust criterion of ≥50% osseous bridging trabeculation across each articulation on 24-week CT scans to define fusion of each joint. Furthermore, the likelihood of detection bias was minimized with the extensive levels of blinding of the clinicians and the radiologist in this study.

In conclusion, this study demonstrates the substantive value of using some form of graft material in hindfoot and ankle arthrodesis to maximize the likelihood of joint fusion and promote successful clinical union. The presence of sufficient graft material to mitigate gapping across each fusion space better achieved critical fusion masses and significantly higher fusion rates.

Appendix

eA A list of the inclusion and exclusion criteria for the parent randomized clinical trial as described in the study by DiGiovanni et al.[14] is available with the online version of this article as a data supplement at jbjs.org. ■

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Christopher W. DiGiovanni, MD[1]
Sheldon S. Lin, MD[2]
Timothy R. Daniels, MD, FRCSC[3]
Mark Glazebrook, PhD, MD, FRCSC[4]
Peter Evangelista, MD[5]
Rafe Donahue, PhD[6]
William Beasley, CCRP[6]
Judith F. Baumhauer, MD, MPH[7]

[1]Department of Orthopaedic Surgery, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts

[2]North Jersey Orthopaedics Institute, Rutgers, New Jersey Medical School, Newark, New Jersey

[3]Division of Orthopaedic Surgery, St. Michael's Hospital, Toronto, and Department of Surgery, University of Toronto, Toronto, Ontario, Canada

[4]Dalhousie University, Halifax, and Queen Elizabeth II Health Science Center, Halifax, Nova Scotia, Canada

[5]Department of Diagnostic Imaging, Rhode Island Hospital, the Warren Alpert School of Medicine at Brown University, Providence, Rhode Island

[6]Wright Medical Technology, Inc., Franklin, Tennessee

[7]Department of Orthopaedics, University of Rochester School of Medicine and Dentistry, Rochester, New York

E-mail address for C.W. DiGiovanni: CWDiGiovanni@MGH.Harvard.edu

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