



CLINICAL RESEARCH ARTICLE

Consensus on surgical aspects of managing osteomyelitis in the diabetic foot

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Background: The aim of this study was to develop consensus statements that may help share or even establish 'best practices' in the surgical aspects of managing diabetic foot osteomyelitis (DFO) that can be applied in appropriate clinical situations pending the publication of more high-quality data.

Methods: We asked 14 panelists with expertise in DFO management to participate. Delphi methodology was used to develop consensus statements. First, a questionnaire elicited practices and beliefs concerning various aspects of the surgical management of DFO. Thereafter, we constructed 63 statements for analysis and, using a nine-point Likert scale, asked the panelists to indicate the extent to which they agreed or disagreed with the statements. We defined consensus as a mean score of greater than 7.0.

Results: The panelists reached consensus on 38 items after three rounds. Among these, seven provide guidance on initial diagnosis of DFO and selection of patients for surgical management. Another 15 statements provide guidance on specific aspects of operative management, including the timing of operations and the type of specimens to be obtained. Ten statements provide guidance on postoperative management, including wound closure and offloading, and six statements summarize the panelists' agreement on general principles for surgical management of DFO.

Conclusions: Consensus statement on the perioperative management of DFO were formed with an expert panel comprised of a variety of surgical specialties. We believe these statements may serve as 'best practice' guidelines until properly performed studies provide more robust evidence to support or refute specific surgical management steps in DFO.

Keywords: osteomyelitis; foot infection; foot ulcer; forefoot; diabetic foot; diabetes; consensus; Delphi methodology; consensus

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U lceration of the foot, usually as a consequence of peripheral neuropathy, often accompanied by peripheral arterial disease, is a common and growing problem worldwide. Recent data from the United States show that the annual incidence of a foot ulcer among medicare beneficiaries with diabetes is 6.0% (1). Over half of the foot ulcers become infected and at initial presentation, diabetic foot osteomyelitis (DFO) of the underlying bone complicates approximately 20% of these foot ulcers (2). The presence of DFO causes substantial morbidity, dramatically increases health care costs (3), and significantly increases the risk of requiring a major (i.e. aboveankle) amputation (4).

Guidelines from the Infectious Disease Society of America (IDSA) and the International Working Group on the Diabetic Foot (iwgdf.org/guidance) have provided evidence-based consensus on various aspects of the diagnosis and management of diabetic foot infections, including DFO (5, 6). Guidance in these documents relevant to surgery highlighted the urgency of operations for severe foot infections and recommended prompt consultation with surgeons for debridement, drainage, possible revascularization, or more complex foot reconstructions (see recommendations 38-41 (5)). The level of evidence for each of these surgery-related recommendations was 'low'. Thus, despite the fact that surgery for DFO is common, there is little high-quality research to provide surgeons with more specific guidance or 'best practice sharing' on the various surgical aspects of managing DFO.

In light of this, we endeavored to establish consensus recommendations on the fundamental aspects of DFO management that are especially relevant to surgeons. We herein describe how we used Delphi methodology to establish a consensus on various recommendations. It is our hope that these recommendations will: 1) provide helpful guidance on various aspects of surgical management of DFO, while awaiting future high-quality studies and 2) help identify, and possibly prioritize, key areas of uncertainty or practice heterogeneity that might merit more rigorous further evaluation.

Methods

Selection of topics and participants

We selected the 14 panel members using three criteria. First, we attempted to find representatives of all disciplines involved in the surgical management of DFO, including podiatry, orthopedic surgery, plastic surgery, vascular surgery, and general surgery. Second, we sought experts with extensive and direct clinical experience in the management of DFO (Table 1). Finally, we preferentially chose panelists with an appointment at an academic health care institution, involvement in clinical training programs, or experience of publishing original manuscripts in peer-reviewed journals on the topic of diabetic foot complications or foot reconstruction. Our intent was to select surgeons who had read and thought critically about the surgical management of DFO.

Delphi technique

The authors first constructed an initial open-ended questionnaire seeking questions that would elicit opinions on clinical practices regarding the management of DFO. All questions and subsequent statements assumed forefoot osteomyelitis without significant peripheral artery disease or orthopedic/podiatric hardware. The panelists provided responses to this questionnaire in writing or by a telephonic interview. We then used the responses to create statements that we asked the panelists to rate using a nine-point Likert scale: 1 = completely disagree, 2 = strongly disagree; 3 = disagree, 4 = somewhat disagree, 5 = neutral, 6 = somewhat agree, 7 = agree, 8 = stronglyagree, 9 = completely agree. They were also provided space for additional comments or explanations of their scoring, identification of exceptions, or any other feedback.

The first round of the questionnaire involved a total of 63 items in the following four sections: 1) Initial Diagnosis and Selection of Patients for Operative Management (statements 1–18); 2) Operative Management (statements 19–41); 3) Postoperative Care (statements 42–56); and 4) General Principles (statements 57–63). A priori we defined 'consensus' as a mean Likert score of ≥ 7 (7).

We then conducted a second round of scoring on those items with a mean Likert score between 6.40 and 7.0. This follow-up modified scoring survey included survey items based on panelist feedback, along with the group average for the item and the panelist's previous personal score for that item.

Results

Response rate and number of rounds

Thirteen panelists participated in the initial round. An additional panelist was added after the initial round to represent vascular surgery. The overall response rate of selected panelists was 95% (39 of 41 possible responses). At the end of the first round, a total of 33 items reached our defined consensus cut-off: 19 items had a mean score of 6.50. Among the items, 16 scored a weighted mean between 6.50 and 6.99, and we then did an additional round of scoring on these. After this additional scoring round, we achieved consensus (mean Likert score \geq 7) on five more statements, for a total of 38 consensus statements. These consensus statements included 7 statements concerning the initial diagnosis and selection of patients for operative management, 15 statements about intraoperative management, 10 statements on postoperative management, and 6 general statements on general strategies and principles relevant to surgical management of DFO (Tables 2-5).

Summary of statements reaching consensus

The consensus panel initially agreed on seven statements relevant to the initial diagnosis of DFO and patient selection (Table 2). The presence of visible, chronically exposed trabecular bone within a forefoot ulcer was deemed sufficient to establish the diagnosis of DFO. A magnetic resonance imaging (MRI) or biopsy of a specimen of bone (for culture or histopathology) were identified as second-line diagnostic modalities of choice for

Me	mber	Specialty	Title	Location
1.	Javier Aragon-	General	Head, Department of Surgery	La Paloma Hospital (Las Palmas de
	Sanchez, MD	surgery	Head, Diabetic Foot Unit	Gran Canaria, Spain)
2.	David G. Armstrong,	Podiatry	Professor of Surgery	University of Arizona (Tucson,
	DPM, MD, PhD		Director, Southern Arizona Limb Salvage Alliance	Arizona)
3.	Christopher E.	Plastic	Professor of Plastic Surgery and Orthopedic Surgery	Medstar Georgetown University
	Attinger, MD	surgery	Co-Director, Center for Wound Healing	Hospital (Washington, DC)
4.	Robert Frykberg,	Podiatry	Chief of Podiatry and Residency Director	Phoenix Veterans Affairs Health Care
	DPM, MPH			System (Phoenix, Arizona)
				University of Arizona College of
				Medicine (Phoenix, Arizona)
5.	Paul J. Kim, DPM	Podiatry	Associate Professor of Plastic Surgery	Medstar Georgetown University
			Center for Wound Healing	Hospital (Washington, DC)
6.	Howard Kimmel,	Podiatry	Senior Clinical Instructor, Department of Surgery	Case Western Research University
	DPM			School of Medicine (Cleveland, Ohio)
7.	Lawrence Lavery,	Podiatry	Professor of Plastic Surgery, Orthopedic Surgery,	University of Texas Southwestern
	DPM, MPH		Physical Medicine and Rehabilitation, Biomedical	(Dallas, Texas)
			Engineering	
8.	William Marston, MD	Vascular	Chief of Vascular Surgery	University of North Carolina (Chapel
		surgery	Professor of Surgery	Hill, North Carolina)
9.	Roya Mirmiram,	Podiatry	Chief of Podiatry	New Mexico Veterans Affairs Health
	DPM			Care System (Albuquerque,
				New Mexico)
10.	Michael S. Pinzur,	Orthopedic	Professor of Orthopedic Surgery and Rehabilitation	Loyola University Chicago Stritch
	MD	surgery		School of Medicine (Maywood,
				Illinois)
11.	John S. Steinberg,	Podiatry	Associate Professor of Plastic Surgery	Medstar Georgetown University
	DPM		Co-Director, Center for Wound Healing	Hospital (Washington, DC)
12.	James S. Wrobel,	Podiatry	Associate Professor of Internal Medicine	University of Michigan Health System
	DPM			(Ann Arbor, Michigan)
13.	Dane K. Wukich, MD	Orthopedic	Professor of Orthopedic Surgery	University of Pittsburgh School of
		surgery	Chief, Division of Orthopedic Foot and Ankle Surgery	Medicine (Pittsburgh, Pennsylvania)
			Professor, Rehabilitation Science and Technology	
			Medical Director, University of Pittsburgh Medical	
			Center Mercy Center for Healing and Amputation	
			Prevention & Comprehensive Foot & Ankle Center	
14.	Thomas Zgonis,	Podiatry	Professor of Orthopedics, Division of Podiatric	University of Texas Health Science
	DPM		Medicine and Surgery	Center at San Antonio (San Antonio,
				Texas)

Table 1. Members of the expert panel, listed in alphabetical order

confirmation of DFO when the diagnosis was otherwise uncertain. Surgical resection of affected bone was recommended when any one of the following is present: systemic toxicity; an open or infected joint space; the presence of a prosthetic heart valve; clinical or imaging evidence of substantial cortical destruction, osteolysis, macroscopic bone fragmentation, or necrotic bone; or visible, chronically exposed trabecular bone. No consensus was reached on whether or not the presence of visible cortical bone is sufficient for the diagnosis of DFO or if this should just represent an indication for surgical resection (see Supplementary file). The panel reached consensus on 15 statements regarding specific operative details (Table 3). The majority agreed that any concomitant deep soft tissue infection should be addressed first, and definitive (final) resection of bone should be undertaken 3–7 days after addressing the soft tissue infection. There was agreement that negative pressure wound therapy dressings with instillation should be a consideration but is not required for treatment of deep soft tissue infection (Table 3, also Supplementary file). Panelists reached consensus that any bone resection should be done with a power saw (e.g. micro-sagittal or micro-oscillating saw); this should include all areas of Table 2. Consensus statements for initial diagnosis and selection of patients for operative management of diabetic forefoot osteomyelitis

Item	Statement	Mean rating
A-1	Identifying visible, chronically exposed trabecular bone visible within a forefoot ulcer is sufficient for establishing the diagnosis of DFO.	7.77
A-2	MRI and/or bone biopsy are preferred second-line diagnostic modalities to confirm the presence of DFO when X-rays a clinical exam alone are suspicious but not sufficient to diagnose DFO.	ind 7.93
A-3	Systemic toxicity in the presence of DFO with associated soft tissue infection, represents an absolute indication for surgical resection of bone.	7.93
A-4	Bone resection is recommended when substantial cortical destruction, osteolysis, macroscopic bone fragmentation (sequestria), or necrotic bone is seen on X-ray.	7.69
A-5	Débridement/resection of bone is recommended when visible, chronically exposed trabecular bone is identified within forefoot ulcer.	na 7.31
A-6 A-7	An open or infected joint space represents an absolute indication for surgical resection of bone. DFO in patients with prosthetic heart valves represents an absolute indication for surgical resection of bone.	7.29 7.00

DFO, diabetic foot osteomyelitis.

necrotic, fragmented bone or areas of significant cortical destruction seen on x-ray, and continue until grossly healthy-appearing bone is seen at the resection margin. The surgeon should collect a total of four specimens between the initial and final operations: grossly abnormal bone sent for 1) histopathology and 2) microbiology (gram-stained smear, aerobic and anaerobic cultures) and the proximal-most bone resected (i.e. the bone margin) for 3) histopathology and 4) microbiology. The panel thought that metatarsal head/proximal phalangeal ostectomy was an acceptable alternative to toe/ray amputation for the surgical management of DFO of these bones. Finally, the panelists agreed that a surgeon should consider adjunctive podiatric/orthopedic procedures - including adjunctive tendo-achilles lengthening – for any patient with a major biomechanical abnormality of the affected forefoot, particularly when these pose increased risk of reulceration or transfer ulcers.

The panelists reached consensus for a total of 10 statements on postoperative management (Table 4). Delayed primary closure should be attempted whenever possible. When delayed primary closure is not possible, the surgeon should use negative pressure wound therapy dressings to develop a wound bed prior to autogenous skin grafting or for delayed secondary wound healing. Absorbent, non-adherent dressings are the preferred alternative when negative pressure dressings cannot be used. Offloading was identified as an important component of postoperative management and clinicians should ensure this is provided to all patients who have undergone surgery for DFO. A removable cast walker or posterior splint was considered the preferred offloading modality, but open-toed shoes with multidensity inserts were considered acceptable for patients with a single toe or dorsal foot wound. Health care providers should make rollator walkers, crutches, or canes available to patients for

additional support during ambulation. When the bone margin specimen shows either histopathological findings compatible with osteomyelitis or pathogenic microorganisms in microbial culture, clinicians should prescribe postoperative antibiotic treatment. There was a high level of heterogeneity with no consensus on statements describing the timing for the removal of the dressing placed at the time of the initial operation. Similarly, there was no consensus on recommendations on the use of total contact casts or non-removable cast walkers during the postoperative period (see Supplementary file).

The panelists reached consensus approval on six statements regarding overall strategies or principles (Table 5). Multidisciplinary/interdisciplinary teams were identified as important in improving treatment outcomes and reducing leg amputation rates. The importance of establishing a biomechanically stable foot - not simply a healed wound was an important goal in the management of forefoot osteomyelitis. There was agreement that well-established definitions of DFO treatment success and failure are lacking, and that there are no widely accepted guidelines currently available for monitoring postoperative treatment response. Finally, the panelists did not reach consensus on initial statements estimating the major amputation rate associated with DFO in the setting of adequate arterial perfusion and no orthopedic/podiatric hardware when options of <5%, 5-10%, and 10-20% were provided; consensus was reached when statements were modified to estimate a major amputation rate of <10%.

Discussion

Diagnosing and treating DFO is perhaps the most contentious area regarding management of diabetic foot complications (8). Clinicians must usually make decisions without adequate evidence-based data. Thus, it is not surprising, for example, that the reported

Table 3. Conser	sus statements	for operat	ive management	of dia	abetic f	forefoot	osteomvelitis
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Item	Statement	Mean rating
B-1	Concomitant deep soft tissue infection (i.e. abscess, joint space infection) or soft tissue necrosis should be drained/debrided and controlled prior to the definitive bone resection and soft tissue closure/ reapproximation over remaining bone.	7.50
B-2	Negative pressure wound therapy dressings with instillation may be considered for use during the intervals between serial operations done for soft tissue infection with DFO.	7.21
В-3	Whenever feasible, bone resection should continue until grossly healthy bone is seen (specifically, bone with normal caliber, smooth cortical contour, firm density, and punctate bleeding).	8.29
B-4	The extent of bone resection should include all areas of significant cortical destruction seen on plain X-ray and any grossly infected, necrotic or fragmented bone.	8.21
B-5	Grossly abnormal or infected bone should be sent for microbiology.	8.64
B-6	Operative bone specimens sent for microbiology should include microscopic examination of a gram-stained smear as well as aerobic and anaerobic cultures.	7.50
B-7	Grossly abnormal or infected bone should be sent for histopathology.	7.93
B-8	A sample of the proximal-most bone resected (i.e. a bone margin specimen) should be labeled separately and sent for histopathology.	7.29
B-9	A sample of the proximal-most bone resected (i.e. a bone margin specimen) should be labeled separately and sent for microbiology.	7.50
B-10	A power saw is the preferred instrument for transecting bone.	7.00
B-11	The definitive (final) bone resection and any attempted delayed primary closure of skin and soft tissue should be done 3–7 days after soft tissue infection or necrosis has been addressed and appropriate antibiotic therapy has been begun.	7.57
B-12	It is preferable that grossly normal-appearing bone margins are obtained at the time of final planned operative debridement.	8.14
B-13	Partial ostectomy of the distal metatarsal and/or proximal phalanx is an acceptable alternative to ray amputation for selected patients with osteomyelitis if the remaining bone was not radiographically involved and looks normal at surgery, and if abnormal biomechanics of the residual forefoot are not anticipated.	7.93
B-14	Adjunctive tendo-achilles lengthening should always be considered when significant ankle equinus deformity (inability to dorsiflex ankle past neutral) is present.	7.50
B-15	Podiatric/orthopedic procedures should always be considered to address significant forefoot biomechanical issues (e.g. hallux valgus and hammer toe deformities) when these pose risk of reulceration or new ('transfer') ulcers.	7.14

DFO, diabetic foot osteomyelitis.

percentage of patients with DFO who undergo a surgical procedure ranges from 5% at centers that utilize primary medical management (9), to 20–40% in centers utilizing a selective surgical approach (10, 11), to 100% in centers that adopt a primarily surgical approach (12). While the selection of a primary treatment strategy should continue to be a major focus for clinicians, areas of practice heterogeneity exist throughout all aspects of managing DFO, and the fact that a wide variety of medical and surgical specialties are involved in its management may contribute to such practice heterogeneity.

A dearth of high-quality evidence assessing various aspects of DFO management may be largely responsible for this practice heterogeneity and uncertainty. To date, only two randomized trials specific to DFO have been published. One randomized 52 patients between primary antibiotic therapy versus primary surgical therapy, and found no significant differences in outcomes (13). While it is remarkable that the authors were able to undertake such a trial, the many limitations (14) of this small trial make it difficult to generalize the results. In another study, 40 patients treated without surgery randomized to receive either 6 or 12 weeks of antibiotic therapy again had similar outcomes (15). The four published studies that have described the outcomes of primarily surgical therapy were all retrospective single-center studies and enrolled a total of 424 patients (4, 12, 16, 17). Good-quality evidence is available to support practices relevant, although not exclusive, to DFO management, such as the randomized trials on various offloading modalities for foot ulcers (18-21). Furthermore, several authors have published a case series describing good outcomes with surgical techniques that can be applied to appropriately selected patients with DFO (22-25). Unfortunately, there

Table 4. Consensus statements for postoperative management of diabetic forefoot osteomyelitis

Item	Statement	Mean rating
C-1	Delayed primary closure should be attempted at the final/definitive operation if no residual deep soft tissue infection or necrosis remains and if the residual soft tissue envelope allows tension-free reapproximation of soft tissue over bone.	7.86
C-2	Negative pressure wound therapy dressings are recommended for large soft tissue defects that remain after the final operation for cases in which delayed primary closure is not possible.	7.00
C-3	Autogenous skin grafting is the preferred method of reepithelialization for large epithelial defects when a healthy wound bed is present.	7.29
C-4	Absorbent, non-adherent dressings can be used as an alternative for soft tissue defects that remain after the final operation for cases in which delayed primary closure is not possible and negative pressure wound therapy is not available.	7.21
C-5	Offloading is important to optimize the likelihood of wound healing in the early postoperative period.	8.71
C-6	All patients who have undergone surgery for DFO should be provided with offloading footwear.	8.71
C-7	A removable cast walker (i.e. calf-height fixed-ankle walker) or a posterior splint is the preferred offloading modality following surgery for forefoot DFO.	7.07
C-8	Open-toed shoes with multidensity inserts may be used in select cases following surgery for osteomyelitis of a single toe or those with only dorsal foot wounds.	7.57
C-9	Rollator walkers, crutches, or canes should be made available for additional balance/support during ambulation.	8.14
C-10	Prolonged (6+ weeks) of postoperative antibiotic treatment is indicated after bone resection for DFO if the margin specimen shows an inflammatory cell infiltrate on histopathology <i>and</i> has organisms identified on culture (i.e. <i>positive</i> pathology and <i>positive</i> microbiology).	7.14

DFO, diabetic foot osteomyelitis.

is very little evidence to support many of the most basic aspects of surgical management, such as how to determine the extent of bone that should be resected determined, whether surgical wounds should be closed or left open, and whether is it useful to obtain a bone margin specimen for culture or histology to guide postoperative management.

We undertook the current study with the aim of providing some starting points from which further discussion and investigation on the optimal management of DFO can proceed. The expert panel reached high levels of agreement on many statements, particularly in operative and postoperative management of DFO. In particular, they agreed on several absolute indications for performing surgical resection of bone. The panel also agreed on the importance of obtaining a total of four bone specimens for histopathological and microbiological processing – two from grossly abnormal bone and two from the proximal-most bone margin. They agreed that

Table 5. Consensus statements on general strategies and principles relevant to the surgical management of diabetic forefoot osteomyelitis

Item	Statement	Mean rating
D-1	Multidisciplinary or interdisciplinary team-based management improves DFO treatment outcomes and reduces the risk of major (above-ankle) amputation.	8.64
D-2	Establishing a biomechanically stable foot is of critical importance to wound healing, resolution of forefoot osteomyelitis, and reducing the risk of reulceration.	8.50
D-3	There is no well-established or widely accepted standard definition of treatment success or failure following surgery for diabetic forefoot osteomyelitis.	7.43
D-4	There are no widely accepted guidelines for monitoring postoperative treatment response following surgery for diabetic forefoot osteomyelitis.	7.21
D-5	Inadequate extent of bone resection (i.e. inadequate margins) is one of the most important reasons for treatment failure/persistent DFO.	7.00
D-6	Assuming adequate arterial perfusion and no orthopedic/podiatric hardware, the proportion of patients eventually requiring major (above-ankle) amputation for forefoot DFO should be $<10\%$.	7.00

DFO, diabetic foot osteomyelitis.

delayed primary closure is the preferred wound healing method, in conjunction with procedures to address biomechanical deformities. If delayed primary closure is not possible, the panelists preferred negative pressure wound therapy or absorbent, non-adherent dressings, followed by autogenous skin grafting. Finally, the panelists reached high levels of consensus on various modalities of offloading footwear.

There was a wide distribution of ratings on several items with ultimately did reach consensus as well as many items which did not reach a consensus. Among these areas of uncertainty are some rather fundamental topics. One was the optimal timing for when to remove the dressing placed at the time of the initial operation. Some surgeons felt strongly that the dressing should be removed within 24 hours, while others felt that it should be left in place for several days after the initial operation. Another was the rate of major (above-ankle) amputation that would be expected among patients with DFO and adequate arterial perfusion; panelists initially split between the original statements that provided the options of <5% and 5-10%. Panelists could not reach consensus on the use of total contact casts or non-removable cast walkers. Although these offloading options have been shown to provide significantly better wound healing rates than offloading shoes and removable cast walkers (19, 26, 27), there was no consensus about their use in the early postoperative period.

Our panel agreed that there is no well-established standard definition of treatment success or failure after DFO surgery. Areas of uncertainty include utilization of biomarkers such as (ESR) erythrocyte sedimentation rate; and (CRP) c-reactive protein in establishing diagnosis of DFO (28), the value of various methods of establishing the diagnosis of DFO, and additional relative or absolute indications for surgical resection of bone in DFO. There was also contention regarding statements on postoperative dressings.

We offer two important caveats regarding these consensus statements. First, not all of the expert members endorse all of the statements that reached consensus. Nevertheless, reaching consensus was difficult or impossible unless at least 11 of the 13 members had some level of agreement with any given statement. Conventional Delphi methods were employed in this study, with a mean composite score of at least 7.0 ('agree') required to reach consensus. Furthermore, the statements reaching consensus represent no more than statements of opinion on which there were high levels of agreement among surgeons with experience and expertise in the field. Of course, these statements are by no means definitive, and in some cases are not even supported by previously reported data. Second, it is our intention that these statements provide guidance on the management of most cases of forefoot DFO not associated with peripheral arterial disease or

orthopedic/podiatric hardware. Not all statements can be followed in all patients, and clinical judgment should be combined with a deep understanding of a specific patient's DFO episode when managing individual cases. The management of peripheral arterial disease requires consultation with specialty providers (vascular surgeons, angiologists, interventional cardiologists, or radiologists) in adherence to societal guidelines where appropriate (5). The management of midfoot and heel osteomyelitis, as well as the management of osteomyelitis associated with orthopedic/podiatric hardware, can be very challenging and should involve orthopedic or podiatric surgeons with specific expertise in these areas.

In summary, we identified statements on the perioperative and postoperative management of DFO on which a panel of expert surgeons from various disciplines reached consensus. We hope that these statements may help share or even establish 'best practices' that can be applied in appropriate clinical situations pending the publication of more high-quality data. We will be waiting with interest to see if those data provide evidence to support or refute our consensus statements on various practices within DFO management.

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