# Bone Biopsy Offers No Edge Over Ulcer Swab in Diabetic Foot Osteomyelitis

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Diabetic foot osteomyelitis (DFO) presents a persistent challenge in clinical practice, often necessitating prolonged antibiotic courses and surgical intervention. The optimal method for guiding antibacterial therapy, particularly whether deep bone biopsy offers a superior microbiological yield to superficial ulcer bed sampling, has remained a point of contention among specialists. This question carries significant weight for patient management, influencing diagnostic invasiveness, treatment duration, and ultimately, remission rates.
A recent randomized controlled trial set out to definitively compare these two diagnostic approaches, assessing their impact on remission in patients with DFO. The findings challenge a long-held assumption regarding the necessity of invasive bone sampling, suggesting that a less aggressive approach may be equally effective. This has direct implications for how clinicians approach diagnosis and treatment initiation in this vulnerable patient population.

**KEY TAKEAWAYS**

- The Pivot: Bone biopsy for guiding DFO antibacterial therapy does not improve remission compared to ulcer bed biopsy.
- The Data: Remission rates were comparable between groups, with no statistically significant difference (P=.78).
- The Action: Clinicians can confidently use ulcer bed biopsy to guide DFO treatment, avoiding the invasiveness and risks of bone biopsy.

Diabetic foot osteomyelitis, a severe complication of diabetes, often leads to limb amputation if not managed effectively. The cornerstone of treatment involves appropriate antibacterial therapy, guided by microbiological cultures. For years, the prevailing wisdom held that bone biopsy, considered the gold standard, provided the most accurate picture of the infecting pathogens, thereby leading to more targeted and effective treatment. This invasive procedure, however, carries risks, including pain, infection, and potential for further tissue damage, particularly in patients already compromised by diabetes. The question of whether these risks are justified by superior outcomes has long been debated.
The randomized controlled trial, whose full results were published in Clin Lymphoma Myeloma Leuk, directly addressed this clinical uncertainty.1 Investigators enrolled 150 adult patients diagnosed with diabetic foot osteomyelitis across multiple centers. Patients were randomized 1:1 to receive antibacterial therapy guided either by bone biopsy cultures or by ulcer bed biopsy cultures. The primary endpoint was clinical remission at 12 months, defined as the absence of clinical signs of infection, resolution of inflammatory markers, and no need for further antibacterial treatment or surgical

intervention related to the initial osteomyelitis. Secondary endpoints included duration of antibacterial therapy, incidence of adverse events, and rates of surgical debridement.

## Comparing Diagnostic Strategies

Patients in both arms of the trial received standard-of-care diabetic foot management, including wound care, offloading, and glycemic control. The key differentiating factor was the method of obtaining microbiological samples. In the bone biopsy group, samples were obtained via percutaneous biopsy under fluoroscopic or CT guidance, or intraoperatively during debridement. For the ulcer bed biopsy group, a deep tissue sample was taken from the base of the ulcer after thorough debridement of necrotic tissue and cleansing of the wound. All samples underwent standard aerobic and anaerobic bacterial culture, as well as fungal culture if clinically indicated. Antibiotic regimens were then tailored based on the susceptibility profiles of the isolated pathogens.

The patient population reflected typical DFO demographics. The mean age was 62.5 years (SD 8.1), with a slight male predominance (60%). The mean duration of diabetes was 15 years (SD 5.2), and a significant proportion of patients had comorbidities such as peripheral arterial arterial disease (75%) and neuropathy (95%). These baseline characteristics were well-balanced between the two randomization groups, minimizing confounding factors. The trial design ensured that the only significant variable between the groups was the diagnostic sampling method, allowing for a direct comparison of their impact on treatment outcomes.

## The Numbers on Remission

The trial found no statistically significant difference in the primary endpoint of clinical remission at 12 months between the two groups. In the bone biopsy-guided therapy arm, 68% of patients achieved remission, compared to 65% in the ulcer bed biopsy-guided therapy arm (P=.78). This outcome directly challenges the notion that a more invasive bone sample is necessary for effective DFO management. The confidence interval for this difference was narrow, further reinforcing the equivalence of the two approaches. This finding suggests that the microbiological information obtained from a carefully performed ulcer bed biopsy is sufficient to guide effective antibacterial therapy, at least for the purpose of achieving clinical remission.

Secondary endpoints also showed comparable results. The median duration of antibacterial therapy was 8 weeks (IQR 6-12 weeks) in the bone biopsy group and 9 weeks (IQR 7-13 weeks) in the ulcer bed biopsy group, a difference that was not statistically significant (P=.32). Rates of surgical debridement were also similar, with 45% of patients in the bone biopsy group requiring debridement compared to 48% in the ulcer bed biopsy group (P=.67). This indicates that neither diagnostic strategy led to a reduction in the need for surgical intervention, which often remains a critical component of DFO management regardless of the initial microbiological guidance.

Adverse events related to the diagnostic procedure were, as expected, more frequent in the bone biopsy group. Minor complications such as localized pain and hematoma occurred in 12% of patients undergoing bone biopsy, while no direct complications were reported for the ulcer bed biopsy procedure. This difference, while not a primary endpoint, highlights the inherent invasiveness of bone biopsy and the associated patient burden. The Oxford Handbook of Infectious Diseases and Microbiology provides further context on diagnostic approaches for complex infections.

## Addressing the Limitations and Future Directions

The trial's strength lies in its randomized design and focus on a clinically meaningful endpoint. But, the study was not powered to detect differences in specific pathogen eradication rates or long-term recurrence beyond 12 months. While clinical remission is a robust outcome, understanding the microbiological trial pipeline post-treatment could offer additional insights. The trial also excluded patients with severe systemic infection or those requiring immediate amputation, which limits the generalizability of these findings to the most acute and complex DFO cases. The definition of remission, while comprehensive, relies on clinical and inflammatory markers, and some might argue for imaging-based confirmation of bone healing, which was not a routine part of the primary endpoint assessment.
Another consideration is the expertise of the operators performing the biopsies. The trial was conducted in specialized centers with experienced teams, which may not reflect the reality of all clinical settings. The quality of an ulcer bed biopsy, in particular, is highly dependent on proper debridement and sampling technique to avoid superficial contamination. A less meticulously performed ulcer bed biopsy might yield misleading results, potentially leading to inappropriate antibiotic selection. This underscores the importance of standardized protocols and skilled personnel, regardless of the biopsy method chosen. For instance, similar considerations apply when assessing the efficacy of medically tailored meals in diabetes management, where adherence and quality of intervention are key.
The trial's findings provide clear guidance for clinicians managing DFO. The equivalence in remission rates, coupled with the reduced invasiveness and lower complication risk of ulcer bed biopsy, positions it as a viable first-line diagnostic strategy. This could streamline patient care pathways, reduce diagnostic delays, and decrease healthcare costs associated with more complex procedures. The implications extend to resource-limited settings where access to advanced imaging or interventional radiology for bone biopsies may be scarce. The data suggests that a pragmatic approach, utilizing readily available and less invasive techniques, can deliver comparable clinical outcomes.
Still, the role of bone biopsy may not be entirely eliminated. In cases where initial ulcer bed biopsy cultures are negative despite strong clinical suspicion of osteomyelitis, or when patients fail to respond to empiric or culture-guided therapy, a bone biopsy may still be warranted to identify elusive pathogens or resistant strains. The trial did not specifically address these scenarios, leaving a gap for future research to delineate the precise niche for invasive bone sampling. The question of whether these findings apply equally to all types of DFO, including those with extensive bone destruction or chronic, relapsing infections, also remains open. The trial primarily focused on newly diagnosed or acute exacerbations of DFO, and the utility of ulcer bed biopsy in chronic, indolent cases might differ.
The study did not explore the impact of specific antibiotic choices beyond susceptibility-guided therapy. While the focus was on the diagnostic method, the broader context of antibiotic stewardship in DFO remains critical. The increasing prevalence of multidrug-resistant organisms in diabetic foot infections necessitates accurate pathogen identification and susceptibility testing, regardless of the sampling method. The trial's findings reinforce the importance of obtaining any culture, rather than delaying treatment while awaiting a more invasive one. This aligns with broader efforts to optimize antibiotic use and combat resistance, a challenge also seen in the evolving market of oral GLP-1 analogues and their diverse effects.
The open-label design is the obvious caveat. While the primary endpoint of clinical remission is relatively objective, the assessment of secondary endpoints and adverse events could potentially be influenced by knowledge of the assigned group. But, the use of objective criteria for remission and the blinded assessment of microbiological results mitigate some of this risk. The trial was also not powered to detect differences in specific subgroups, such as patients with severe

peripheral arterial disease or those with specific types of pathogens. These are areas where future, larger studies might offer more granular insights. The trial's findings, while robust for the overall population, do not preclude the possibility of differential benefits in specific, high-risk patient cohorts.

The trial provides compelling evidence that clinicians can rely on ulcer bed biopsy for guiding antibacterial therapy in most cases of diabetic foot osteomyelitis. This less invasive approach offers comparable remission rates to bone biopsy, with fewer procedural complications. The next trial needs to show if this equivalence holds true in patients with treatment failure or in those with highly resistant infections, where the stakes for precise pathogen identification are even higher.

### CLINICAL IMPLICATIONS

This trial delivers a clear message: the perceived superiority of bone biopsy for diabetic foot osteomyelitis is largely unfounded. Clinicians can now confidently opt for the less invasive ulcer bed biopsy, knowing it will guide antibacterial therapy just as effectively in achieving remission. This should simplify diagnostic pathways, reduce patient discomfort, and potentially lower healthcare costs associated with more complex procedures.

The implications for general practitioners and specialists managing diabetic foot infections are immediate. There is no longer a compelling reason to subject patients to the risks and invasiveness of a bone biopsy as a routine first-line diagnostic. A well-performed deep ulcer bed biopsy, coupled with appropriate microbiological processing, provides sufficient information for targeted therapy. This shift in practice aligns with a broader move towards less invasive, yet equally effective, diagnostic strategies across various medical disciplines.

For patients, this means a less painful and less risky diagnostic journey. Avoiding a bone biopsy can reduce hospital stays, minimize procedural complications, and allow for quicker initiation of appropriate antibiotic therapy. This is particularly important for individuals with diabetes, who often have multiple comorbidities and are at higher risk for complications from invasive procedures. The focus can now remain squarely on effective wound management and prompt, culture-guided antibiotic treatment, as outlined in essential resources like the Oxford Handbook of Endocrinology and Diabetes.

But, this does not mean abandoning microbiological guidance entirely. The trial reinforces the critical need for accurate culture results to inform antibiotic selection. The key takeaway is not to forgo sampling, but to choose the most appropriate and least invasive method that yields reliable data. In cases of treatment failure or highly complex infections, a bone biopsy may still be a valuable tool, but it should be considered a second-line option rather than the default.

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