Mycetoma Research Center - WHO Collaborating Center on Mycetoma - University of Khartoum, Sudan

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Mycetoma Case Management

An Advanced Clinical Training Manual for Healthcare Providers

Mycetoma Research Center

University of Khartoum

WHO Collaborating Center

on Mycetoma & Skin NTDs

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An Advanced Clinical Training Manual for Healthcare Providers

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Preface

Mycetoma: A Flesh-Eating Disease

Mycetoma remains one of the most enigmatic, neglected, and devastating conditions in tropical medicine. Formally recognised by the World Health Organisation (WHO) as a Neglected Tropical Disease (NTD) in 2016, it is an infection that imposes a severe, interlocking burden on patients, families, and healthcare systems across endemic regions. Characterised by its insidious onset and a slow, painless progression, mycetoma often evades early clinical detection, leading to extensive tissue destruction, severe physical deformities, and profound social stigma. For the vulnerable rural populations most frequently affected, this disease does not simply damage limbs; it shatters livelihoods, disrupts education, and perpetuates a multi-generational cycle of poverty and social exclusion.

To effectively combat this complex medical and socioeconomic challenge, frontline healthcare providers must be equipped with comprehensive, evidence-based expertise that spans advanced laboratory sciences, nuanced clinical management, and holistic patient rehabilitation.

This **Mycetoma Case Management: An Advanced Clinical Training Manual**

for Healthcare Providers was developed through a collaborative academic partnership between the Mycetoma Research Centre at the University of Khartoum and many other collaborators. It is designed to serve as a practical guide for clinicians, medical and health professionals, and public health officers working at every level of the healthcare system.

Structure of the Manual

The material is organised into five specialised modules, guiding the medical and health workers from fundamental scientific concepts to complex therapeutic interventions:

Module 1: Background, Epidemiology & Pathogenesis

Lays the scientific foundation of the disease, focusing on the biological distinctions between fungal (eumycetoma) and bacterial (actinomycetoma) forms. It outlines the geographic distribution across the global "Mycetoma Belt," environmental reservoirs, occupational hazards, the disease burden, and the host-pathogen interactions that govern tissue destruction.

Module 2: Clinical Presentations

Details the physical and visual signs of mycetoma, focusing on the pathognomonic clinical triad: a painless subcutaneous mass, multiple interconnected sinuses, and grain-bearing discharge. It also provides a robust differential diagnosis framework to distinguish mycetoma from conditions that mimic it.

Module 3: Diagnostic Framework

Outlines a multi-tiered diagnostic workflow designed for settings ranging from rural clinics to tertiary reference hubs. It covers macroscopic grain analysis, specialised microscopic staining protocols, mycological/bacterial cultures, histopathology, molecular testing, and advanced radiological imaging.

Module 4: Therapeutic Management & Protocols

Provides standardised treatment guidelines. This includes combination antibiotic regimens for actinomycetoma and long-term medical-surgical strategies for eumycetoma, highlighting first-line agents such as Itraconazole and recent advancements such as Fosravuconazole. It also details precise intra-operative surgical techniques and criteria for amputation.

Module 5: Patient Monitoring, Complications & Rehabilitation

Establishes a rigorous evaluation matrix to monitor patient progress, manage drug-induced toxicities, and treat secondary infections. Crucially, it introduces holistic rehabilitation strategies, including psychosocial support and economic reintegration models.

Mycetoma affects the poorest of the poor in poor remote rural communities

A Call to Action

The ultimate goal of this manual is to reduce the time between a patient's initial clinical presentation and the start of targeted, species-specific therapy. By standardising case management, improving diagnostic accuracy, and optimising surgical outcomes, healthcare providers can prevent deep bone invasion, preserve body function, and eliminate the need for radical amputations.

We dedicate this manual to

The healthcare workers providing care in endemic communities

The patients whose resilience drives our shared commitment

To global health equity and the elimination of mycetoma.

The frontline health workers and advocates

Module 1

Background, Epidemiology & Pathogenesis

Learning Objectives

- Define mycetoma and distinguish its bacterial and fungal forms at the molecular and clinical levels.
- Know the disease burden.
- Identify the mycetoma geographical distribution, the environmental reservoirs, occupational risk factors, and modes of transmission.
- Understand the host immune response and the pathophysiological mechanisms governing tissue and bone destruction.

Massive foot actinomycetoma

Background

The Global Challenge of Mycetoma

Mycetoma is a chronic, progressive, and highly destructive granulomatous disease that stands out as one of the most devastating and neglected conditions in tropical medicine. Formally classified as a Neglected Tropical Disease (NTD) by the World Health Organization (WHO) in 2016, it is characterised by an exceptionally insidious onset. Because it begins as a small, painless subcutaneous nodule, patients frequently dismiss the early signs of infection. Over months or decades, however, the pathogen slowly and relentlessly breaches natural anatomical barriers, invading deep into the skin, fascia, muscles, and eventually the bone matrix.

The Multidimensional Impact of Mycetoma

The consequences of this progressive destruction extend far beyond the clinical presentation, creating severe and interlocking burdens across multiple levels of society:

The Mycetoma Destabilisation Cycle

Medical and Health System Burdens

Managing mycetoma places immense strain on healthcare systems in resource-limited endemic settings. Because the disease requires highly specialised diagnostic tools, such as histopathological and mycological cultures identification and advanced imaging, and long-term, complex treatment regimens combining prolonged, expensive antimicrobial or antifungal therapies with extensive, complex surgical excisions, local health infrastructure is often overwhelmed.

Socioeconomic Destabilisation

Mycetoma predominantly targets young adult males, agricultural labourers, and herdsmen during their peak productive years. When the disease results in massive tissue destruction, severe deformities, and functional disabilities, these individuals lose their capacity to perform manual labour. The financial shock of losing the primary breadwinner, compounded by catastrophic out-of-pocket healthcare costs, rapidly plunges whole families into a devastating cycle of poverty.

The disease has massive socioeconomic impacts.

Social Isolation and Educational Loss

The physical deformities and chronic, malodorous discharging sinuses associated with advanced mycetoma frequently trigger profound social stigma and discrimination. Patients face severe isolation, exclusion from communal life, and abandonment. For afflicted children or young adults within families strained by medical debt, the disease frequently cuts their schooling short, resulting in a permanent loss of education, diminished future opportunities, and a fractured social life.

Ultimately, mycetoma acts as both a consequence and a driver of systemic marginalisation, reinforcing a multi-generational cycle of disease, financial ruin, and social exclusion in the world most vulnerable endemic communities.

A high rate of educational attrition is a definitive

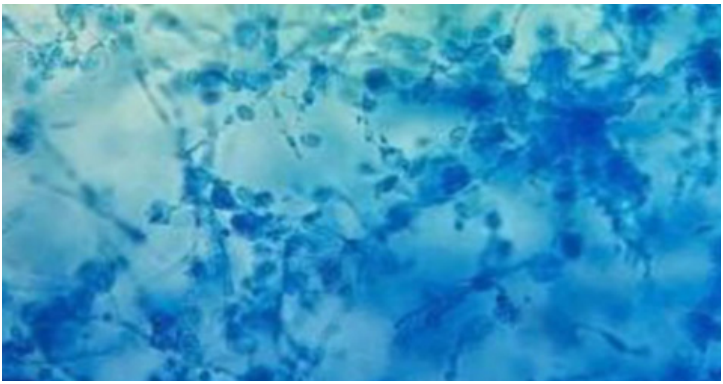
socioeconomic hallmark among young mycetoma patients.

Mycetoma Aetiology

Accurate case management depends entirely on distinguishing between the two distinct aetiological forms of the disease: eumycetoma and actinomycetoma. While their early clinical presentations are similar, their biological kingdoms are completely distinct, so a misdiagnosis can lead to treatment failure.

Eumycetoma

Caused by true fungi. Globally, the premier causative organism is *Madurella mycetomatis*, which accounts for approximately 70% of black-grain eumycetoma cases. Other notable fungal pathogens include *Trematosphaeria grisea*, *Falciformispora senegalensis*, and *Scedosporium apiospermum*. Under microscopy, these organisms exhibit thick, septate hyphae measuring 2 to 6 micrometres in diameter.

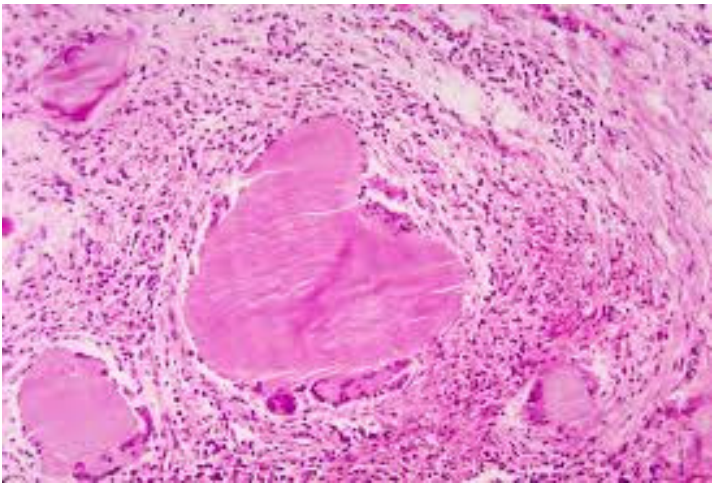


Microscopic appearance of *Madurella mycetomatis'* colony,

Lactophenol Cotton Blue stain ×40

Actinomycetoma

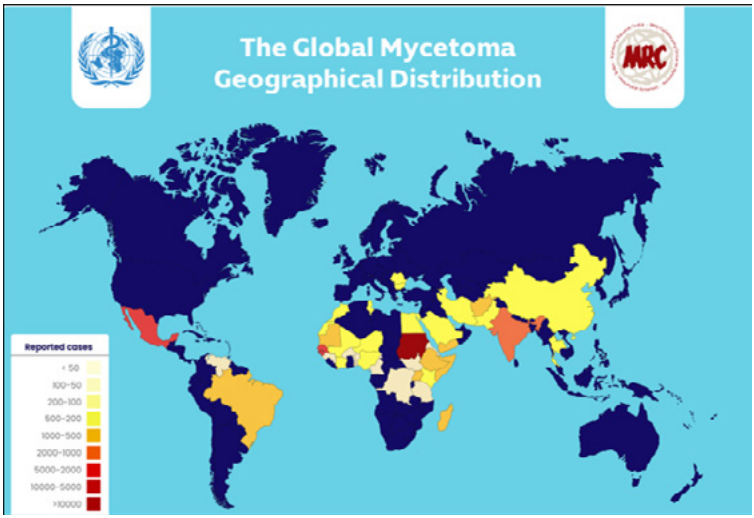
Caused by aerobic, filamentous higher bacteria belonging to the order Actinomycetales. These prokaryotic organisms mimic fungi structurally, with branching growth patterns, but they possess thin filaments measuring less than 1 micrometre in diameter. The predominant global pathogens include *Actinomadura madurae*, *Nocardia brasiliensis*, *Actinomadura pelletieri*, and *Streptomyces somaliensis*.



Microscopic appearance of *Streptomyces somaliensis*, H&E stain × 40

Mycetoma Epidemiology, Environmental Reservoirs & Transmission Dynamics

Mycetoma occurs worldwide, with reports from 102 countries, and is endemic in tropical and subtropical zones clustered within the known "Mycetoma Belt." This geographic zone is bound between the latitudes of 15^0 South and 30^0 North. Endemic countries include Sudan, Somalia, Senegal, Mauritania, India, Yemen, Mexico, and Venezuela. Sudan is considered the mycetoma epicenter.



The Global Mycetoma Geographical Distribution

The Environmental Niche

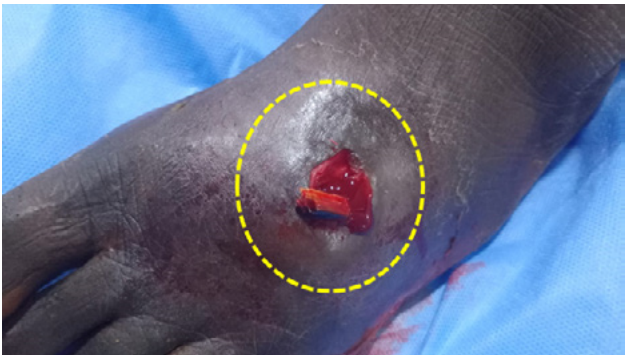
The disease is tied to arid or semi-arid climates characterised by low annual rainfall (typically 50-500 mm) and sharp seasonal temperature fluctuations. The causative organisms are environmental saprophytes that thrive in dry, sandy soils, decomposing organic matter, and acacia thorn trees (*Acacia mellifera* and *Acacia seyal*).

Mycetoma Environment Habitat

Transmission Mechanisms

Transmission occurs via subcutaneous inoculation following minor skin trauma. The classic vector is an environmental thorn prick, a wood splinter, a stone scratch, or an insect bite contaminated with soil saprophytes. There is no documented person-to-person or animal-to-person transmission.

A thorn prick contaminated with soil saprophytes can induce mycetoma



Foreign body discovered within a mycetoma lesion

Occupational Risk Profiles

The disease predominantly affects vulnerable rural populations. Young adult males aged 15 to 40 are disproportionately affected due to their increased exposure during outdoor labour. High-risk populations include agricultural labourers, traditional subsistence farmers, nomadic herders, and children in rural areas. Walking barefoot, wearing inadequate protective footwear, and handling agricultural materials without gloves directly increase exposure risks.

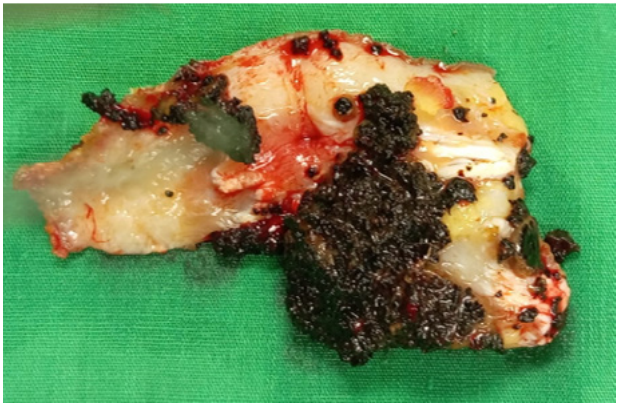
The disease predominantly affects the most vulnerable rural populations.

Mycetoma Pathogenesis& Host-Pathogen Interaction

Following subcutaneous traumatic inoculation, the invading pathogen evades host immune surveillance to establish a localised infection. This triggers a complex series of host-tissue inflammatory reactions, along with the formation of protective grains that shield the causative organism from the host destructive immune responses.

1. Grain Formation (The Protective Matrix)

To survive the host's initial cellular response, the causative organisms aggregate into dense, highly organised colonial structures known as grains. The pathogen produces an extracellular cement substance, a complex matrix composed of proteins, lipids, and melanin. This cement shell acts as a physical shield, protecting the internal hyphae or bacterial filaments from host-mediated enzymatic degradation and blocking penetration by antimicrobial agents.



Surgical biopsy showing a massive number of black grains of

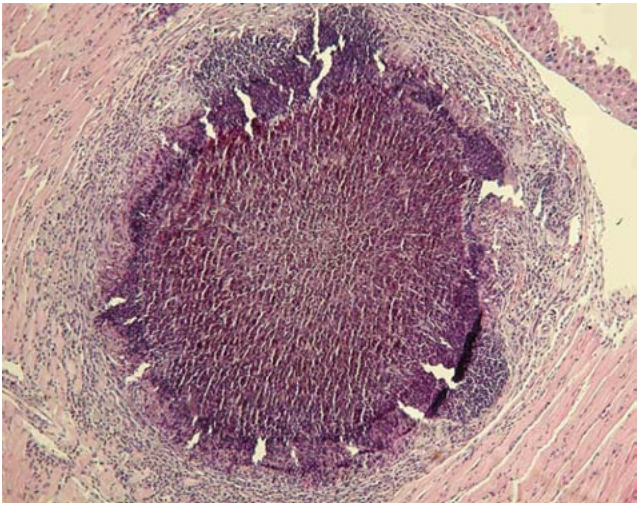
Madurella mycetomatis

2. The Tri-Zonal Granulomatous Tissue Response

The presence of these grains triggers a chronic, specialised granulomatous inflammatory reaction. Histopathological examination of an active lesion reveals a distinct tri-zonal architecture surrounding each grain.

Type I Tissue Reaction

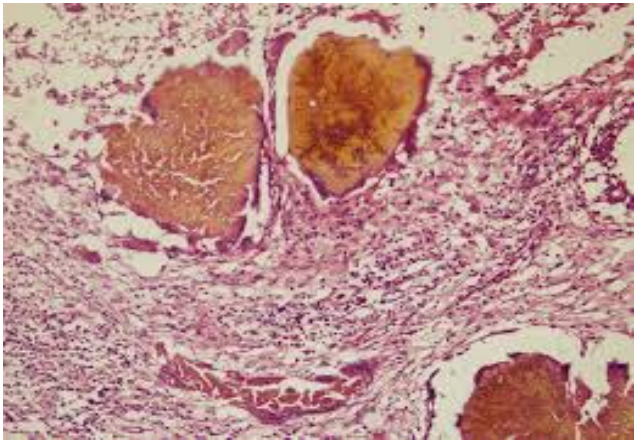
The Neutrophilic Core: The innermost layer directly enveloping the grain. It is composed of dense clusters of polymorphonuclear neutrophils (PMNs). In some instances, neutrophils tightly adhere to the grain surface, forming a degranulation zone.



Type I Tissue Reaction

Type II Tissue Reaction

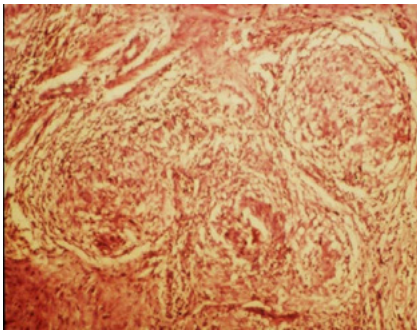
The Granulomatous Layer: This intermediate zone is populated by histiocytes, plasma cells, lymphocytes, epithelioid cells, and foreign-body giant cells. This layer represents the host attempt to process and clear the massive antigenic load presented by the grain.



Type II Tissue Reaction

Type III Tissue Reaction

The Fibrotic Ring: The outermost zone, comprised of dense, reactive fibrous connective tissue, active fibroblasts, and neocapillaries. This tissue capsule represents the host ongoing attempt to isolate and contain the infection. However, this dense fibrosis also chokes local microvascular blood flow, creating an ischemic environment that limits the delivery of systemic medications to the core lesion.

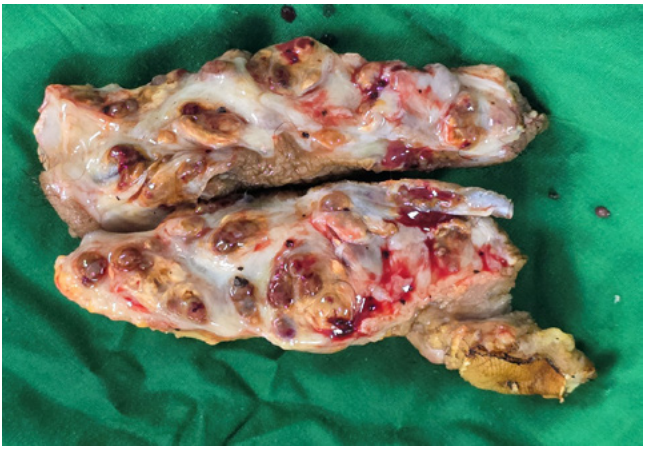


Type III Tissue Reaction

3. Tissue Destruction and Anatomical Extension

As the grains multiply, the local inflammatory pressure expands. The lesion slowly breaches natural anatomical boundaries, extending along fascial planes, muscular margins, neurovascular bundles and bone. This destructive process is driven both by mechanical pressure and the release of lysosomal enzymes from host cells.

Unlike conventional pyogenic infections, mycetoma does not respect tissue barriers; it breaks directly through muscles, tendons, and deep fascia. Once it reaches the periosteum, it triggers an aggressive osteolytic process, activating osteoclasts to create cystic cavities within the bone matrix. Despite this profound tissue destruction, the process remains localised; systemic dissemination, bacteremia, or fungemia are rare.



Massive tissue destruction, fibrosis and local spread of the mycetoma granuloma

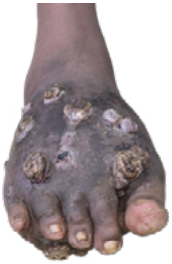
Module 2

Clinical Presentations

Learning Objectives

- Master the visual and physical recognition of the pathognomonic clinical triad.
- Establish a clinical diagnosis of mycetoma.
- Construct a comprehensive differential diagnosis to differentiate mycetoma from mimicking conditions.

Eye eumycetoma



Massive foot actinomycetoma

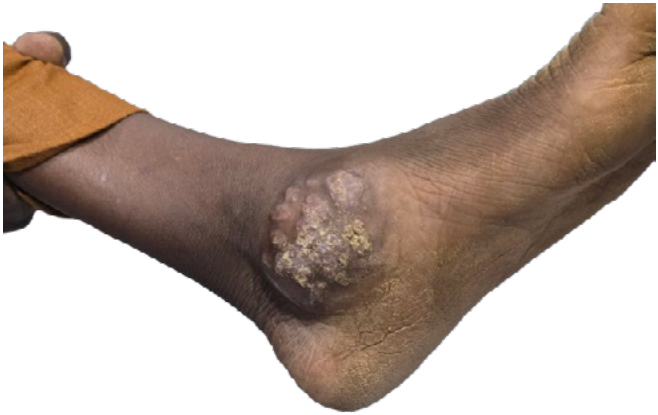
The Pathognomonic Clinical Triad

A classic, fully developed case of mycetoma presents with a distinct, unmistakable triad of clinical features:

1. Painless Subcutaneous Mass

The infection begins as a small, firm, non-tender subcutaneous nodule, most probably at the site of minor trauma. The overlying skin may appear normal, hyperpigmented, or slightly indurated. This mass expands over months or years, slowly anchoring itself to the underlying deep fascia, muscles, and bones.

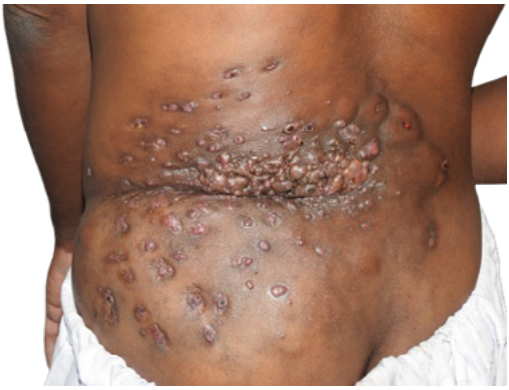
Clinical Warning: The lack of acute pain or systemic symptoms, such as fever, chills, or malaise, in the early stages frequently leads patients to minimise their condition. This delay in seeking medical attention often lasts until the lesion has caused significant structural damage. Pain typically emerges only in advanced stages due to secondary bacterial infection, nerve compression, or bone compression.



Painless firm subcutaneous mass of eumycetoma

2. Multiple Interconnected Sinuses

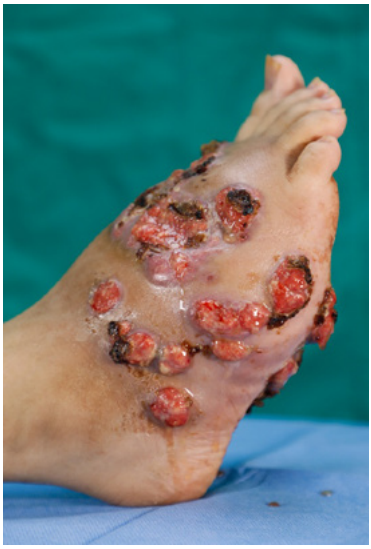
As the deep granulomas expand and liquefy, they track toward the surface, breaching the dermis to form multiple active sinus tracts. These sinuses intermittently erupt to discharge fluid, then close and heal with characteristic puckered, inverted scars, while new tracts break open nearby. This creates an uneven, nodular appearance across the skin surface.



Multiple active and healed sinuses

3. Purulent or Serosanguinous Discharge Embedded with Grains

The active sinuses continuously or intermittently expel a thin, serosanguinous, or thick, purulent fluid. This discharge carries the visual signature of the disease: the grains. These grains represent the physical colonies of the underlying pathogen. Capturing and examining them is the first step in establishing a provisional clinical diagnosis.



Multiple sinuses with discharge containing yellow grains of *Actinomadura maduae*

Massive perineal, scrotal and inguinal eumycetoma with lymphatic obstruction

Fascial palsy due to ear eumyectioma

Comprehensive Differential Diagnosis

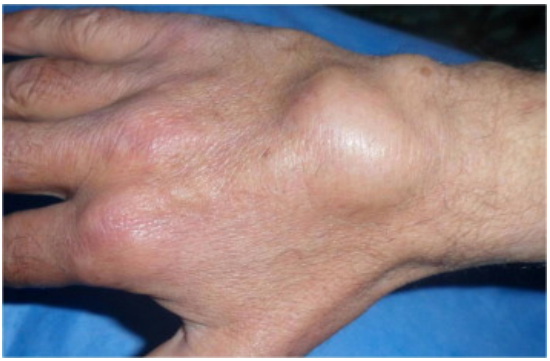
Because mycetoma presents as a chronic soft-tissue and bone deformity, it can closely mimic several other infectious and neoplastic pathologies. Clinicians must carefully differentiate it from the following conditions:

- **Chronic Bacterial Osteomyelitis**

Often presents with localised bone pain, swelling, and discharging sinuses. Still, it usually lacks the specific nodular subcutaneous massing, presents with systemic inflammatory markers (such as elevated CRP or leukocytosis), and its discharge does not contain organised grains.

- **Bone/Soft Tissue Tuberculosis**

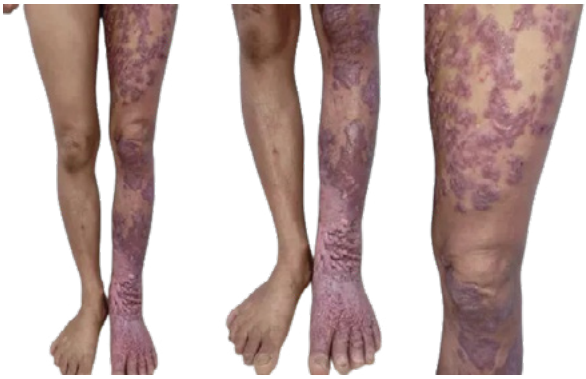
It can cause chronic cold abscesses and sinus formation. Differentiation relies on chest radiographs, Tuberculin skin tests (Mantoux), GeneXpert assays, and the absence of macroscopic grains in the discharge.



Soft tissue tuberculosis

- **Deep Fungal Infections (Chromoblastomycosis, Blastomycosis, Sporotrichosis**

Chromoblastomycosis typically presents with verrucous, cauliflower-like cutaneous plaques rather than deep-seated subcutaneous masses with deep fascial tracking. Sporotrichosis follows a distinct nodular lymphocutaneous chain configuration along lymphatic drainage routes.



Case of Chromoblastomycosis

- **Malignancies (Kaposi Sarcoma, Squamous Cell Carcinoma, Osteosarcoma**

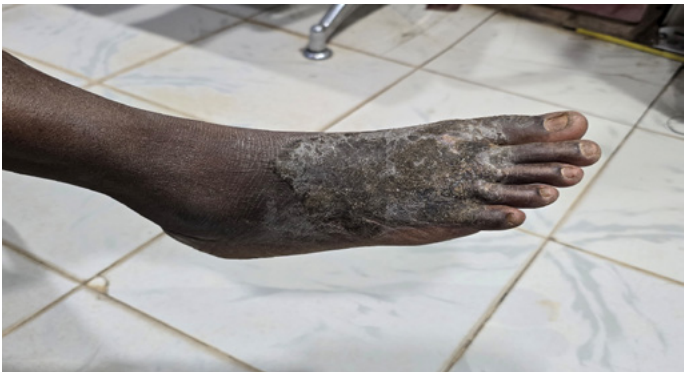
Neoplastic masses can ulcerate, become secondarily infected, and cause severe osteolytic bone destruction. However, they lack true sinus tracts and do

not discharge grains. A deep-tissue biopsy for histopathology remains the definitive tool for ruling out malignancy.

Soft tissue sarcoma

- **Foreign Body Granulomas**

Chronic localised inflammatory responses to retained thorns, splinters, or silica can mimic early-stage, closed mycetoma nodules. Ultrasound and surgical excision confirm the absence of a live, grain-producing microbial pathogen.



Case of dermatitis

Module 3

Mycetoma Diagnosis

Learning Objectives

Deploy a multi-tiered diagnostic framework ranging from field clinics to advanced reference laboratories.

Multi-Tiered Diagnostic Workup Protocol

Diagnostic capacity varies significantly across different levels of healthcare infrastructure. To address this, a tiered approach ensures that accurate screening begins at the primary care level, with definitive identification supported by secondary and tertiary facilities.

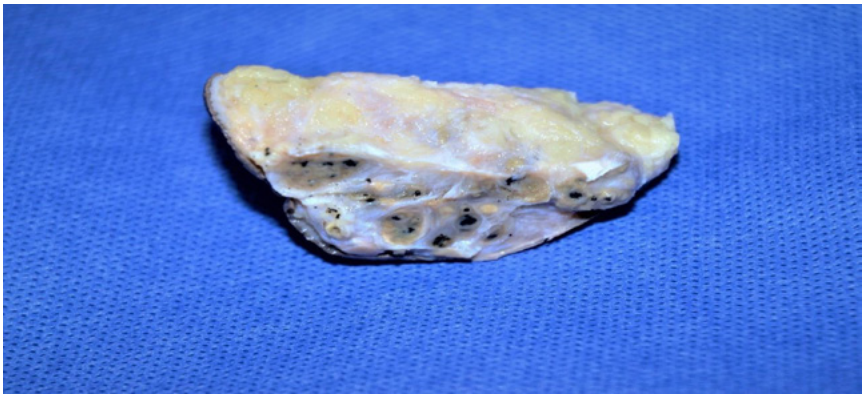
Step-by-Step Diagnostic Methodologies

1. Macroscopic Grain Examination

Collect discharging fluid directly from an active sinus using a sterile gauze pad or by washing the sinus opening with sterile normal saline. Pour the collection into a sterile Petri dish to visually inspect the grains. Note their colour, size, and texture:

Grain Color	Texture & Size	Most Likely Pathogen	Classification
Black	Firm, hard, brittle; 0.5 - 2mm	*Madurella mycetomatis*	Eumycetoma (Fungal)
Yellow/ White	Soft, round; 1-2mm	*Actinomadura madurae*	Actinomycetoma (Bacterial)
White/ Cream	Soft, tiny; <0.5	*Nocardia brasiliensis*	Actinomycetoma (Bacterial)

Grain Color	Texture & Size	Most Likely Pathogen	Classification
Red / Pink	Firm, irregular; 0.2 - 0.5mm	*Actinomadura pelletieri*	Actinomycetoma (Bacterial)



A surgical biopsy specimen showing black grains of *Madurella mycetomatis* within the granuloma.

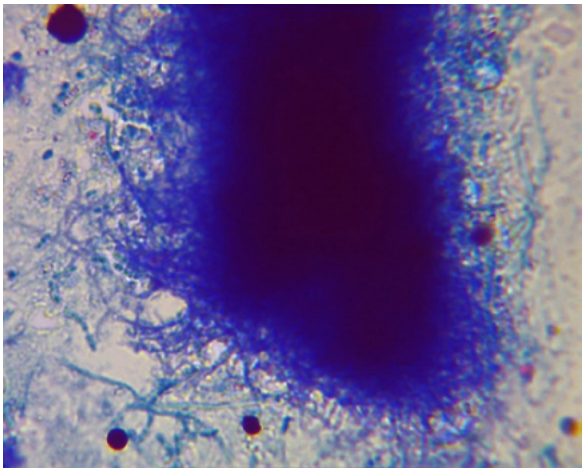
2. Microscopic Examination & Staining Techniques

Direct Potassium Hydroxide (KOH) Mount

Place a recovered grain on a glass slide, add 1-2 drops of 10% or 20% KOH solution, apply a coverslip, and gently warm the slide to crush the grains.

Under 40x magnification:

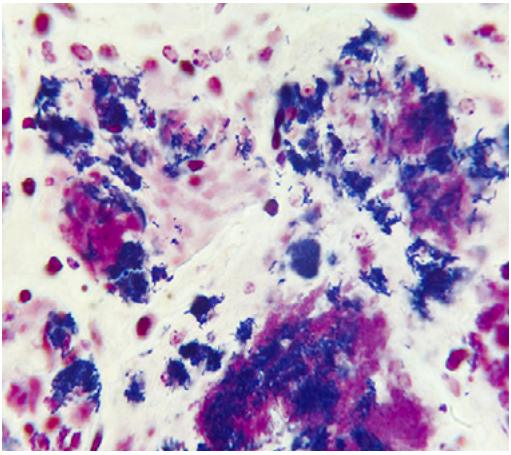
- ***Eumycetoma:*** Reveals thick (2-6µm), branching, septate fungal hyphae, often accompanied by swollen chlamydospores at the margins.
- ***Actinomycetoma:*** Reveals a delicate, dense network of very thin (<1 µm), interwoven branching bacterial filaments.



Microscopic examination of grains mounted in potassium hydroxide

Gram Staining

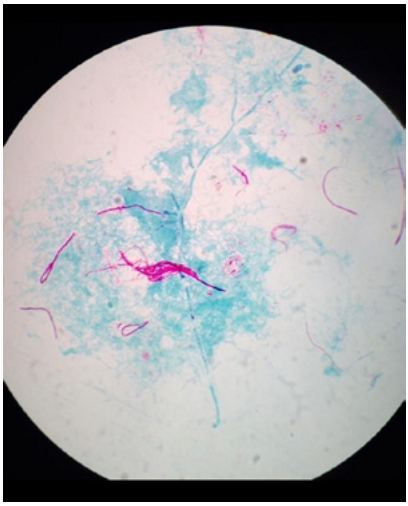
Essential for suspected bacterial cases. Actinomycetoma filaments are consistently Gram-positive, appearing as fine, purple branching networks.



A microscopic view of a specimen showing both Gram-negative and Gram-positive bacteria.

Modified Ziehl-Neelsen (ZN) Staining

Differentiates between bacterial genera. *Nocardia* species are weakly acid-fast, retaining the carbol-fuchsin stain and appearing as pink-red filaments against a blue background, whereas *Actinomadura* and *Streptomyces* are strictly acid-fast negative.



Modified Ziehl-Neelsen (ZN) stained *Nocardia* species

3. Culture and Isolation Protocols

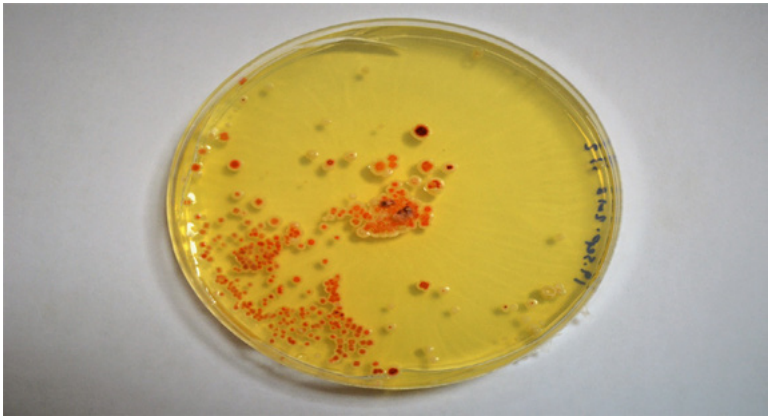
Grains must be prepared before inoculation to eliminate surface contaminants. Wash recovered grains multiple times in sterile normal saline or an antibiotic cocktail solution (for fungal grains).

Fungal Isolation (Eumycetoma)

Inoculate washed grains onto Sabouraud Dextrose Agar (SDA) supplemented with chloramphenicol (to inhibit bacteria). Incubate duplicate cultures at 25^{0}C and 37^{0}C. Monitor for up to 4 weeks. *Madurella mycetomatis* forms slow-growing, leathery, yellowish-brown colonies that produce a characteristic brown, water-soluble pigment that diffuses into the agar.

Bacterial Isolation (Actinomycetoma)

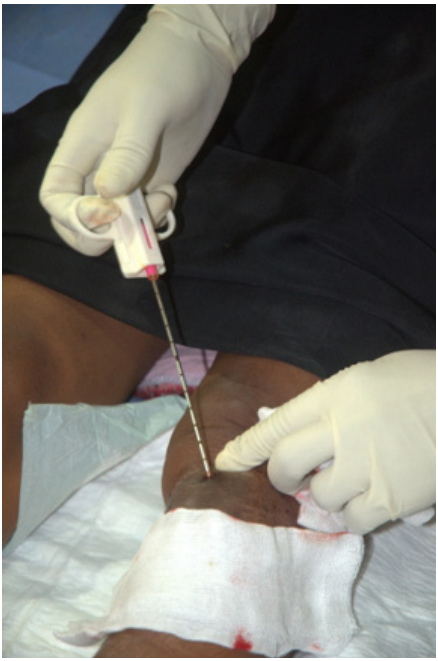
Inoculate grains onto Blood Agar, Nutrient Agar, or Lowenstein-Jensen (LJ) medium. Incubate at 37^0C for 1 to 2 weeks. *Actinomadura madurae* produces cream-colored, folded, waxy colonies, while *Actinomadura pelletieri* yields characteristic deep-red colonies.



Petri dish with actinomycetoma culture

4. Diagnostic Histopathology

When sinuses are closed, a deep tissue biopsy is required. Avoid superficial skin swabs. Samples should be obtained via fine-needle core biopsy or open wedge biopsy under general or regional anaesthesia, ensuring the sample includes deep subcutaneous tissue and visible grains.



Fine needle aspiration technique

- **Staining Profiles:** Process tissue blocks with standard Hematoxylin and Eosin (H&E) to evaluate the host tri-zonal granulomatous response.
- Supplement this with Periodic Acid-Schiff (PAS) and Grocott's Methenamine Silver (GMS) stains to highlight fungal wall structures in eumycetoma.
- To trace delicate actinomycotic filaments in tissue, a Tissue Gram stain (such as the Brown-Brenn method) is highly effective, as it highlights the thin, branching, Gram-positive filamentous bacteria (about 1µm in diameter).

5. Molecular Diagnosis

Molecular diagnostics have transformed the management of mycetoma by bypassing the limitations of traditional culture techniques, which are notoriously slow, prone to contamination, and frequently inaccurate. By extracting and amplifying microbial DNA directly from clinical samples, as extruded

grains or culture isolates, molecular assays deliver rapid, highly specific, and definitive identification of the causative pathogen.

Primary Genetic Targets

In fungal infections, diagnostic assays focus on the Internal Transcribed Spacer regions of ribosomal DNA, which serve as highly accurate genetic barcodes for species-level differentiation. For bacterial cases, testing targets the 16S rRNA gene, enabling precise identification of distinct bacterial genera.

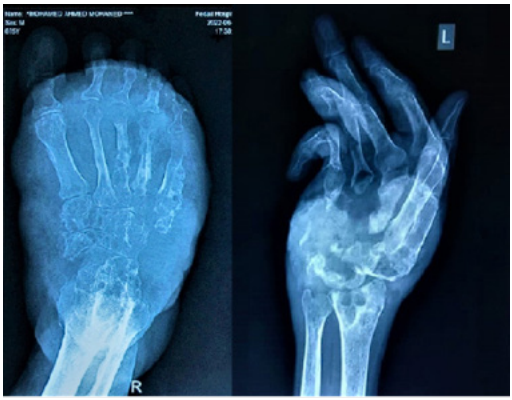
Standard, multiplex, and real-time Polymerase Chain Reaction platforms serve as the foundation of modern reference testing by rapidly isolating the underlying pathogen within hours rather than weeks. Sanger sequencing and Next-Generation Sequencing provide definitive identification and map specific genetic mutations tied to drug resistance. For resource-limited settings, field-friendly isothermal amplification techniques, such as Recombinase Polymerase Amplification, are engineered to run at constant temperatures without sophisticated laboratory infrastructure.

Transitioning to molecular platforms sharply reduces the window between a patient's initial presentation and the start of targeted treatment. By facilitating early, species-specific drug therapy, these diagnostic advancements directly lower the risk of deep bone invasion, preserve vital limb function, and minimise the need for radical surgical amputations.

6. Diagnostic Imaging Modalities

Conventional Radiography (Anteroposterior and Lateral Views): Indispensable for assessing bone involvement. Clinicians should evaluate films for:

- **Soft tissue appearance:** The lesions appear as soft tissue, and some contain calcification.
- **Cortical Scalloping:** The expanding soft-tissue mass directly invades the bone cortex, producing characteristic cortical scalloping before the development of aggressive periosteal reactions.
- ***Periosteal Reactions:*** New bone formation, presenting as a Codman triangle, sun-rays appearance or cortical thickening.
- ***Cavities:*** Multiple round, well-defined osteolytic cavities within the bone matrix. In eumycetoma, these cavities tend to be larger (greater than 1 cm) fewer, with edge sclerosis reflecting a slower, localised bone destruction. In actinomycetoma, they are typically smaller (2 to 5 mm), numerous, and poorly defined.



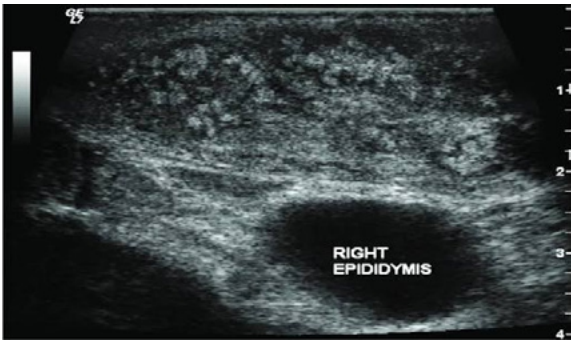
(A) (B)

X-Ray showing features of actinomycetoma (A) and eumycetoma (B)

High-Resolution Ultrasonography

A reliable, non-invasive imaging biomarker that helps differentiate mycetoma from other soft-tissue masses in closed lesions.

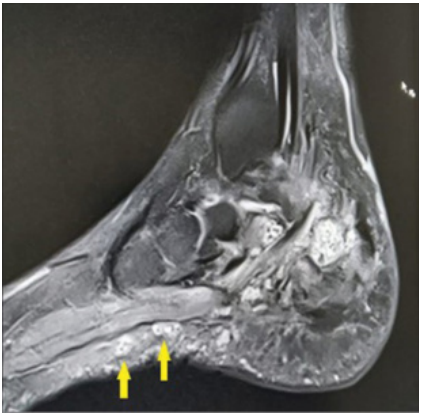
- On sonography, the disease presents as multiple, well-defined, round, hypoechoic areas, representing individual host granulomas, that contain central, highly hyperreflective, sharp echoes, representing the acoustic signatures of the grains.
- Black grains produce sharp, bright reflections with acoustic shadowing, whereas white grains present as softer, more diffuse internal echoes without shadowing.



The ultrasonic appearance of a mycetoma lesion

Magnetic Resonance Imaging (MRI)

MRI is the gold standard for pre-operative planning and mapping deep disease extension. T2-weighted MRI sequences highlight the "dot-in-circle" sign across entire anatomical regions. This imaging maps infiltration through muscle groups, tracking along tendons, and extension into joint capsules or vertebral spaces, allowing teams to determine surgical margins accurately.



Foot MRI examination showing the "dot-in-circle" sign of mycetoma

Module 4:

Therapeutic Management & Protocols

Learning Objectives

- Administer individual pharmacological regimens for both actinomycetoma and eumycetoma.
- Identify, monitor, and mitigate drug-induced laboratory and systemic toxicities.
- Implement combined medical-surgical protocols and define clear criteria for surgical intervention.

Part A: Medical Management of Actinomycetoma

Actinomycetoma is primarily managed medically. It responds well to combination antibiotic therapy, and a complete cure without surgery is achievable in a high percentage of cases.

The Amoxicillin-Clavulanic Acid and Co-trimoxazole Regimen

- Monotherapy should never be used to treat actinomycetoma due to the high risk of inducing bacterial resistance.
- The standard of care is co-amoxiclav (amoxicillin/clavulanic acid) 875/125 mg twice daily, combined with co-trimoxazole (trimethoprim/sulfamethoxazole) 160/800 mg (one double-strength tablet) every 12 hours.

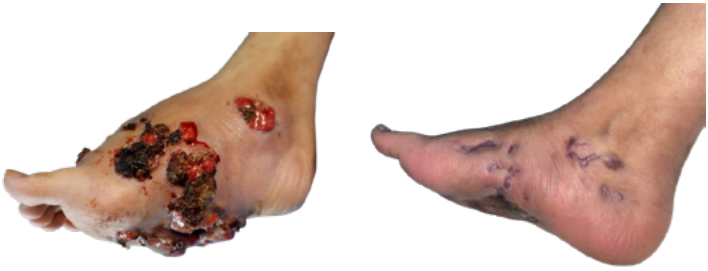
The Welsh Regimen

- This regimen is a second-line treatment due to its potential drug toxicity, combining an aminoglycoside with an antibacterial delivered in structured cycles.
- Each cycle consists of amikacin, typically dosed at 15 mg/kg/day (administered by intramuscular or intravenous injection in two divided doses) for about 3 weeks, alongside continuous co-trimoxazole (trimethoprim/sulfamethoxazole) dosed at 7 mg/kg/day TMP and 35 mg/kg/day SMX for 5 weeks.

- Amikacin intolerance poses a significant clinical challenge due to its association with severe nephrotoxicity and ototoxicity.
- To mitigate these risks, the drug is routinely withdrawn for a two-week rest period during each treatment cycle, while renal function panels and audiometric hearing examinations are mandated at regular intervals to monitor for subclinical organ toxicity.

The Linezolid Combination Regimen

- Administer linezolid 600 mg orally twice daily, paired with oral co-trimoxazole 160 mg TMP/800 mg sulfamethoxazole twice daily.
- Linezolid displays high tissue penetration, making it effective for spinal actinomycetoma, though long-term therapy requires close monitoring for bone marrow suppression.



Foot actinomycetoma pre- and post-treatment

Part B: Medical and Surgical Management of Eumycetoma

Unlike bacterial mycetoma, eumycetoma cannot be cured by chemotherapy alone. Its management requires a coordinated, long-term approach that combines initial medical therapy, planned surgical excision, and postoperative medical eradication.

Standard Pharmacological Protocol

- **First-Line Antifungal Agent:** Itraconazole is the standard therapeutic choice. It must be administered at a dose of 200mg orally twice daily.
- **Administration Guidance:** Itraconazole capsules must be taken with a full meal or an acidic beverage (e.g., cola) to maximise gastric absorp-

tion. Concomitant use of antacids, proton-pump inhibitors (H2 blockers), or gastric acid suppressants significantly lowers drug bioavailability and should be avoided.

- **Fosravuconazole:** A recently introduced oral antifungal agent characterised by high clinical cure rates and an excellent safety profile. The standardised therapeutic regimen consists of a single 200 mg oral dose once per week.
- In cases of documented itraconazole clinical failure or intolerable side effects, clinicians can transition to:

    1. Voriconazole 200 mg twice daily.
    2. Posaconazole 300 mg/day delayed-release tablets.

- These agents offer strong antifungal activity but are constrained by higher costs and limited availability in rural settings.
- **Treatment Duration:** Antifungal therapy is prolonged. It must be administered continuously for 6 to 12 months before surgery to promote the formation of a thick fibrous capsule around the mass and to facilitate good surgical excision. Following successful surgical excision, antifungals must be continued for an additional 6 to 12 months post-operatively until there is complete clinical, radiological, and ultrasonic evidence of cure.

Eumycetoma Treatment Protocol

Surgical Protocols & Strategy in Eumycetoma

Surgery must never be performed as a standalone treatment. Incomplete surgical excision without adequate prior antifungal therapy carries a high risk of local recurrence (> 80%), often leading to more aggressive tissue tracking.

1. Clear Indications for Surgical Intervention

- A localised, well-encapsulated eumycetoma mass that has shrunk and consolidated after a minimum of 6 months of continuous itraconazole/ fosravuzonole therapy.
- Lesions causing severe mechanical dysfunction or severe localised pressure pain.
- Masses threatening major neurovascular bundles or adjacent joints.
- As a life-saving procedure.
- Repetitive debridement to reduce the infection load and the secondary bacterial infection.

2. Surgical Technique: Wide Local Excision

The procedure should be performed under general or regional anaesthesia, utilising a bloodless field maintained by an orthopaedic tourniquet where possible.

Orthopaedic tourniquet in place

Section 1: Surgical Protocol

1. Pre-Operative Planning: Surgical Margin Mapping

- **Imaging Assessment:** Review recent MRI or high-resolution ultrasound maps to determine the exact extent and deepest anatomical boundaries of the mass.
- **Margin Delineation:** Outline a wide surgical field extending at least 1 to 2 cm beyond the palpable boundaries of the lesion.

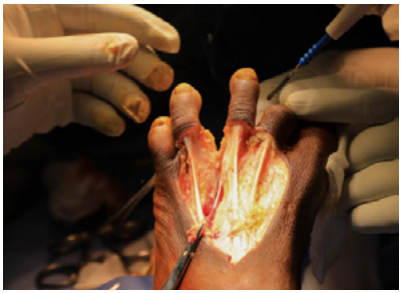
2. Intra-operative Dissection: Capsular Integrity Preservation

- **Approach:** Incise down to the deep fascial planes.

- **Dissection Technique:** Systematically dissect around the fibrous capsule of the mass.

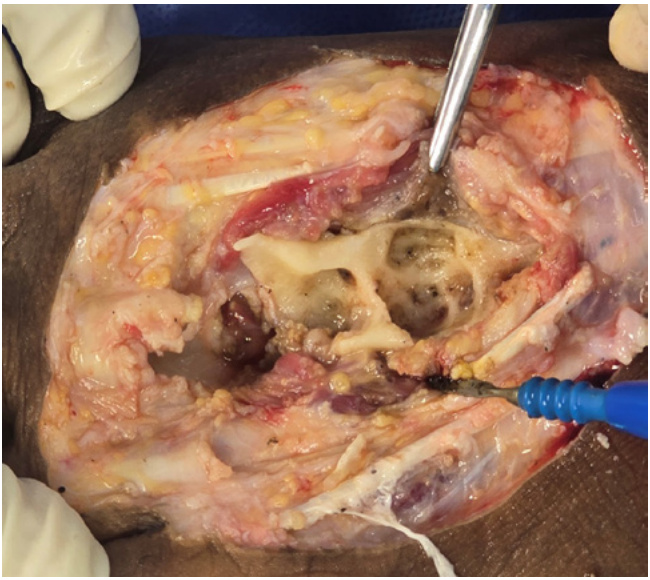
CRITICAL CLINICAL WARNING

Do not puncture or incise the capsule. Disrupting capsular integrity risks spillage of fungal grains into the clean surgical field, markedly increasing the rate of local recurrence.



3. En-Bloc Resection and Bone Scraping: Excision & Debridement

- **Resection Technique:** Excise the mass en-bloc, ensuring a continuous surrounding margin of healthy fascial and muscular tissue.
- **Bone Debridement:** If pre-operative radiographs demonstrate focal cortical bone involvement, use a sharp curette to thoroughly scrape affected bone surfaces until viable, healthy bone matrix is reached.



4. Irrigation and Closed Drainage: Wound Management

- **Hemostasis:** Ensure complete and meticulous surgical hemostasis prior to irrigation.
- **Copious Irrigation:** Thoroughly irrigate the surgical field with abundant sterile normal saline and povidone-iodine solution.
- **Decontamination:** Meticulously inspect and remove any remaining fungal grains or debris from the surgical cavity.
- **Closure Strategy:** Avoid primary wound closure to permit daily open dressing changes with an antiseptic solution.

Section 2: Postoperative Care

1. Immediate Management

- **Dressing Release:** Release or adjust tight dressings 1 hour postoperatively.
- **Ischaemia Inspection:** Inspect the surgical site and surrounding tissue for any evidence of vascular compromise or ischaemia.

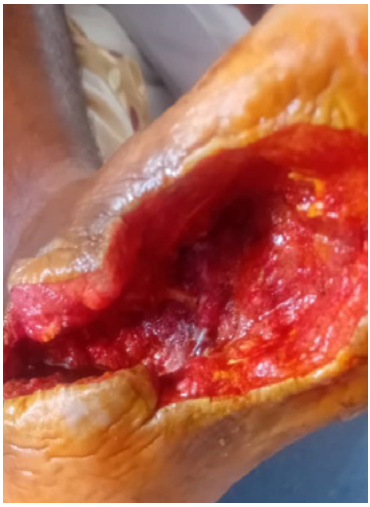
2. Secondary Intention & Wound Maintenance

- **Healing Strategy:** Allow the surgical defect to heal by secondary intention.

- **Monitoring & Dressings:** Dress the wound frequently. Inspect meticulously during each dressing change for signs of localized infection or the reappearance of fungal grains.

3. Delayed Closure Criteria

- **Reconstruction Protocol:** Definitively close the wound using a skin graft or tissue flap only when the surgical site is confirmed clean and completely free of disease recurrence.



A clean and granulating postoperative wound

Section 3: Indications for Amputation

Amputation should be considered a measure of last resort. It is indicated only under the following conditions:

- Total structural destruction of the foot or hand, leaving a non-functional, flail limb.
- Advanced, multi-focal bone cavities that have failed to respond to medical therapy.
- Uncontrolled, life-threatening secondary bacterial septicemia or extensive gas gangrene within the lesion.
- Extensive proximal tracking into deep anatomical cavities (such as the pelvis or retroperitoneum), where local clearance is impossible.
- Patient requests due to disability, deformity, repeated infections, or social stigma.

Module 5:

Patient Monitoring, Complications & Rehabilitation

Learning Objectives

- Establish a regular monitoring framework utilising clinical, radiological, and laboratory indicators.
- Identify, prevent, and treat long-term toxic and infectious complications.
- Implement psychosocial support and economic rehabilitation programs.

Post-Treatment Follow-up Protocol

Patients under active treatment must be evaluated every 6 weeks.

Clinical teams should avoid relying solely on a patient's subjective impressions, utilising instead a standardised matrix of metrics instead:

Monitoring Vector	Favourable Response Indicators	Signs of Treatment Failure/ Progression
Clinical Examination	• Flattened/closed sinus tracts • Complete cessation of grain and fluid discharge • Dramatic softening of the surrounding woody induration • Reduction in mass dimensions.	• Appearance of new active sinus tracts • Sudden return of purulent discharge • Increase in grain output • New localised pain.

Imaging Assessment	• Bone remodeling • Filling of osteolytic cavities with new bone density • Reduction in surrounding soft-tissue swelling on plain films.	• Expansion of existing cavities • New cortical bone erosions • Progressive osteolysis tracking up the skeletal shaft.
Laboratory Safety Panels	• Serum Creatinine and Blood Urea within normal reference ranges • ALT and AST levels are under 2 times the upper limit of normal.	• Rising serum creatinine or declining GFR • Elevation of ALT/AST past 3 times the upper limit of normal (requires immediate medication pause).
Functional & Auditory Tests	• Intact high-frequency hearing	• Patient reports new-onset bilateral tinnitus, vertigo, or difficulty
	• Absence of vestibular or balance disturbances.	• Hearing conversational speech.

Management of Serious Complications

1. Secondary Bacterial Infections

Chronic, open mycetoma sinus tracts serve as direct entry points for secondary bacterial pathogens, commonly *Staphylococcus aureus*, *Streptococcus pyogenes*, and *Pseudomonas aeruginosa*. These secondary infections can trigger acute cellulitis, painful erysipelas, or deep necrotising soft-tissue infections.

Management:

- Do not rely solely on empirical antibiotic therapy.
- Obtain deep sinus tract swabs or fluid aspirates for culture and antibiotic sensitivity testing.
- Administer targeted narrow-spectrum systemic antibiotics

- Perform regular sterile wound dressing changes
- Manage local oedema via limb elevation.

2. Aminoglycoside-Induced Nephrotoxicity and Ototoxicity

Prolonged administration of Amikacin during the Welsh Regimen poses a risk of irreversible damage to the proximal renal tubules and the stria vascularis of the inner ear.

Prevention and Mitigation:

- Standardise serum creatinine assessments before the start of every new cycle of treatment. If serum creatinine rises significantly above the patient's baseline, suspend Amikacin immediately and maintain the patient on oral Co-trimoxazole monotherapy until renal function stabilises.
- Screen for subclinical ototoxicity by conducting simple tuning fork tests (Weber and Rinne) or bedside audiometry at the end of each intensive phase.
- The emergence of persistent bilateral tinnitus or high-frequency hearing loss is an absolute indication to permanently discontinue Amikacin therapy.

3. Antifungal-Induced Hepatotoxicity

Azole antifungals, particularly itraconazole and voriconazole, are extensively metabolised by the liver and can cause drug-induced liver injury (DILI), ranging from asymptomatic transaminitis to severe hepatitis. Early recognition, baseline assessment, and structured laboratory monitoring are essential to prevent severe hepatic impairment and optimise therapeutic efficacy.

Baseline Evaluation

- Obtain baseline Liver Function Tests (LFTs)—specifically serum transaminases (ALT, AST), alkaline phosphatase (ALP), and total bilirubin—before initiating antifungal therapy.
- Identify any underlying liver disease or pre-existing risk factors.

Clinical Management Protocol for Elevated LFTs

1. Initial Assessment & Dose Modification

Before altering the antifungal regimen, immediately screen for concurrent hepatotoxic agents or metabolic enhancers that may exacerbate liver toxicity.

- **Action:** If no contributing hepatotoxic drugs or enhancing agents are identified, immediately reduce the antifungal dose to 100 mg twice daily (BD).
- **Duration:** Maintain this reduced dosage regimen for two weeks.
- **Re-evaluation:** Repeat liver function tests (LFTs) at the end of the 2 weeks.

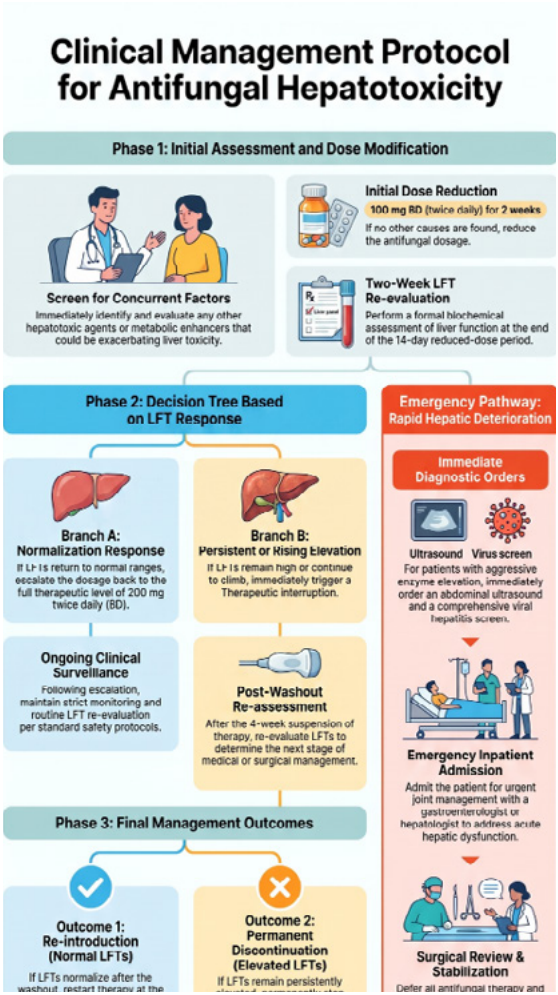
2. Stepwise Management Based on LFT Response

- If LFTs normalise:
  - » Safely escalate back to the full therapeutic dose of 200 mg twice daily (BD).
  - » Maintain strict ongoing clinical surveillance and routine LFT re-evaluation per standard monitoring protocols.
- If LFTs remain elevated or continue to rise:
  1. **Therapeutic Interruption:** Immediately suspend antifungal therapy for a 4-week washout period.
  2. **Biochemical Re-assessment:** Re-evaluate LFTs at the end of the 4 weeks.
  3. **Targeted Interventions:**
     - **LFTs Normalise:** Re-introduce antifungal therapy at the lower dose of 100 mg twice daily (BD) under intensive liver function monitoring.
     - **LFTs Remain Persistently Elevated:** Permanently discontinue medical therapy and refer the patient for surgical management evaluation.

3. Pathway for Rapid Deterioration or Acute Hepatic Impairment

- If the patient exhibits rapid, aggressive liver enzyme elevation or presents with clinical signs of acute hepatic dysfunction at any stage:

1. **Urgent Diagnostics:** Order an immediate abdominal ultrasound and a comprehensive viral hepatitis screen.
2. **Emergency Inpatient Care:** Admit the patient immediately for urgent joint management alongside a gastroenterologist/ hepatologist.
3. **Surgical Review:** Defer all further antifungal therapy and evaluate suitability for surgical intervention once the acute hepatic event is stabilised.



Holistic Care: The SAAI'D Model for Rehabilitation and Reintegration

Medical or surgical clearance of a mycetoma lesion represents only a partial victory. Because this disease targets marginalised rural populations, its long-term impact extends into the psychological, social, and economic spheres of a patient's life.

- **Psychosocial Interventions:** Due to visible physical deformities, malodorous discharge, and gait abnormalities, mycetoma patients frequently suffer from severe social stigma, abandonment by family networks, profound depression, and functional isolation. Clinical management teams must incorporate basic mental health screening and supportive counseling into routine follow-up visits. Community-wide health education campaigns are essential to deconstruct local myths, emphasising to families that mycetoma is an environmentally acquired infection and is completely non-contagious.

- **Vocational and Economic Rehabilitation:** Prolonged illness or surgical amputation frequently strips young adult patients of their ability to perform heavy agricultural labour, leading to sudden financial insecurity. Healthcare providers should actively connect recovered or structurally disabled individuals with specialised socioeconomic initiatives, such as the Mycetoma Vocational and Entrepreneurship Training Centre (SAAI'D) at the Mycetoma Research Centre in Khartoum, Sudan.

- **Rebuilding Livelihoods:** The SAAI'D framework provides tailored, accessible training programmes in sustainable crafts, including artisan leatherworking, textile design, weaving, and small-scale manufacturing. By pairing therapeutic hand-eye rehabilitation with micro-enterprise development skills, the programme enables amputees and individuals with permanent mobility limitations to produce competitive, marketable goods. This training helps patients achieve financial independence, shifts their identity from passive medical patients to active economic contributors, and supports their safe, dignified reintegration into their communities.

Further Reading

Mycetoma Policies and Management Guidelines for Service Provision and Essential Good Clinical Practice

https://mycetoma.edu.sd/wp-content/uploads/2023/01/policies_and_management_guidelines2018.pdf

Mycetoma Standard Operating Procedures (SOPs)

https://mycetoma.edu.sd/?page_id=5896

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