Diabetic Foot Ulcer/ The Use Case for PCR+CCM

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Etiology Of Soft Tissue Defects

Trauma	Degloving injuries	Tendon and nerve injuries	Burn scar and contracture revision
Chronic wounds	Congenital anomalies	Oncologic excision	Infection

Diabetic Foot Syndrome

- The World Health Organization:
  - “Ulceration of the foot associated with neuropathy and different grades of ischemia and infection”
  - Clinical triad of neurological, vascular, and musculoskeletal changes in the foot of a diabetes mellitus individual.

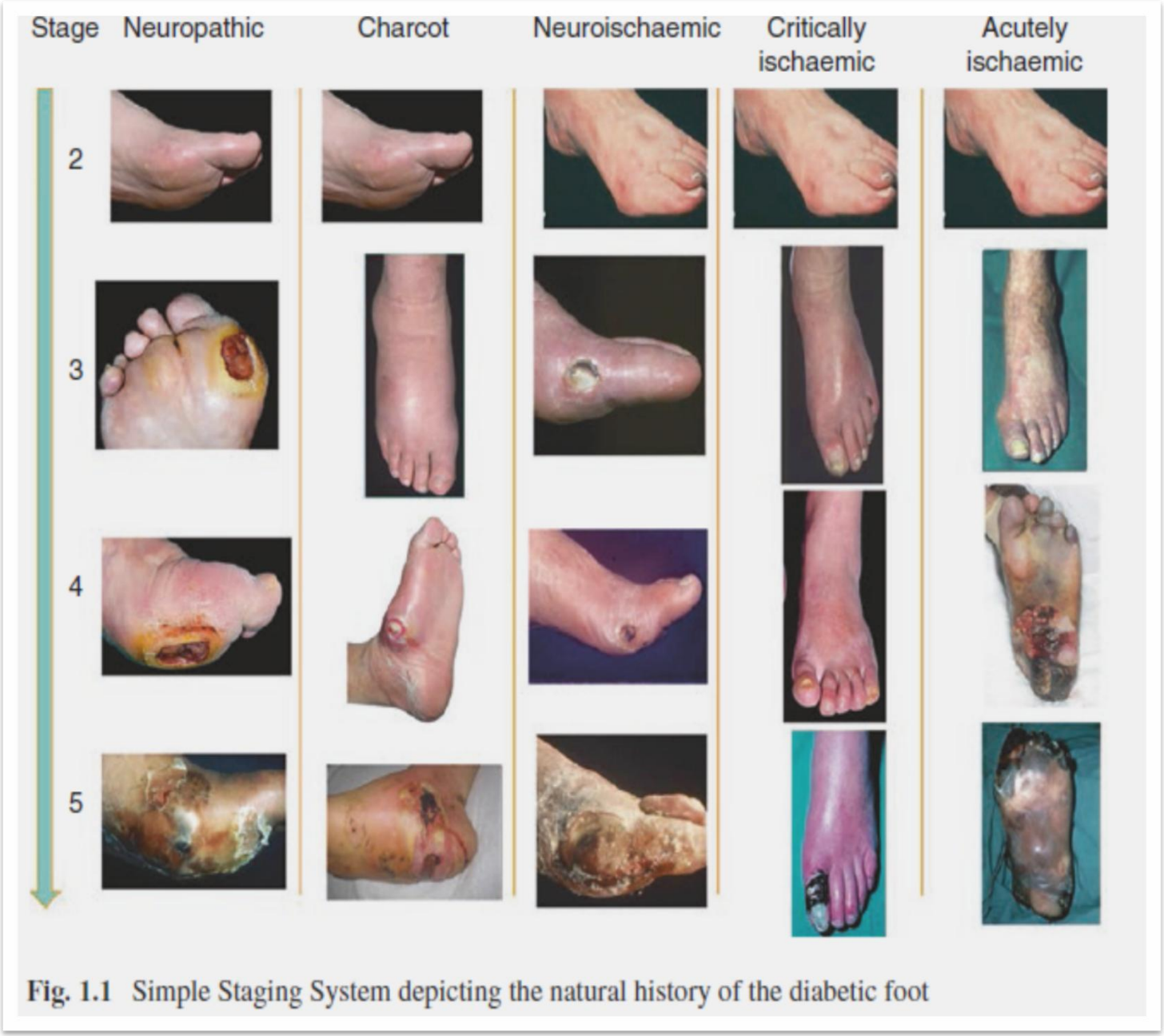
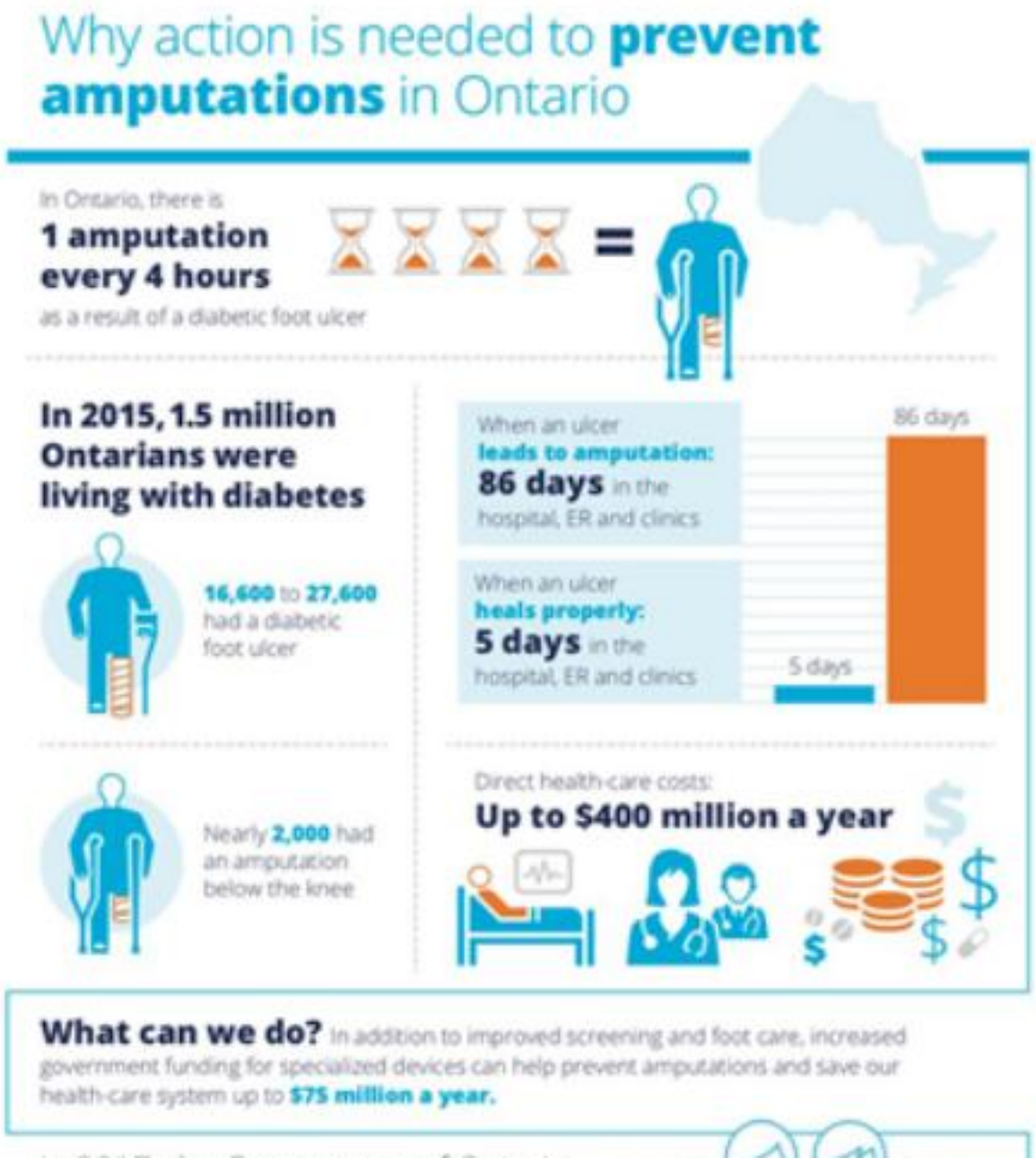


Fig. 1.1 Simple Staging System depicting the natural history of the diabetic foot

Tuttolomondo A, Maida C, Pinto A (2015) Diabetic foot syndrome: immune-inflammatory features as possible cardiovascular markers in diabetes. World J Orthop 6(1):62

DFS Complications

- A lower limb is amputated due to diabetes every 30s
  - *Boulton AJ, Lancet. 2005*
- The total medical cost for treating diabetic foot syndrome in America ranges from $9 to $13 billion.
  - *Rice JB, Diabetes Care. 2014*
- 85% of all amputations in diabetic patients, are preceded by a foot ulceration.
  - *Lep€antalo M, Eur J Vasc Endovasc. 2011*



Diabetic Foot Infections (DFI)

DFI: common problem, High morbidity, including amputation

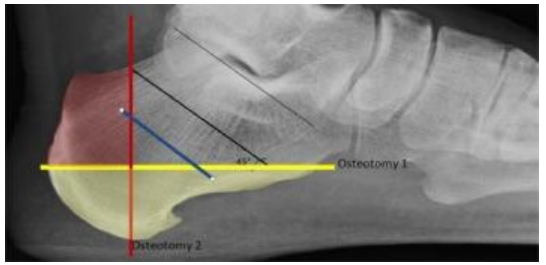
Calcaneus is involved in 7-8% of cases

Charcot arthropathy: 27% of cases complicated by calcaneal osteomyelitis.

Frequently occurs in major gait disorder and the elderly.

Even with Optimized Management

- Secondary amputations after initial calcanectomy are required in up to 67% of the cases, including major amputations in half the cases.



Goals of Lower Extremity Salvage & Reconstruction

Principles of Orthoplastic Surgery for Lower Extremity Reconstruction: Why Is This Important?

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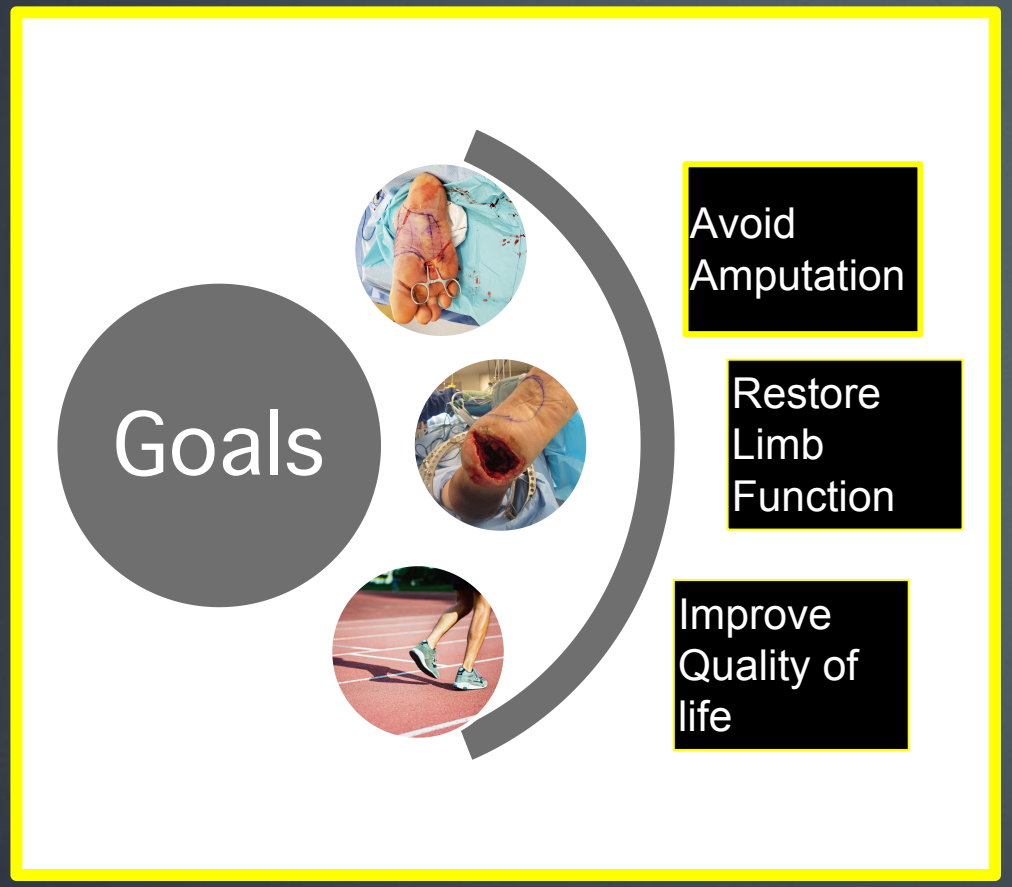
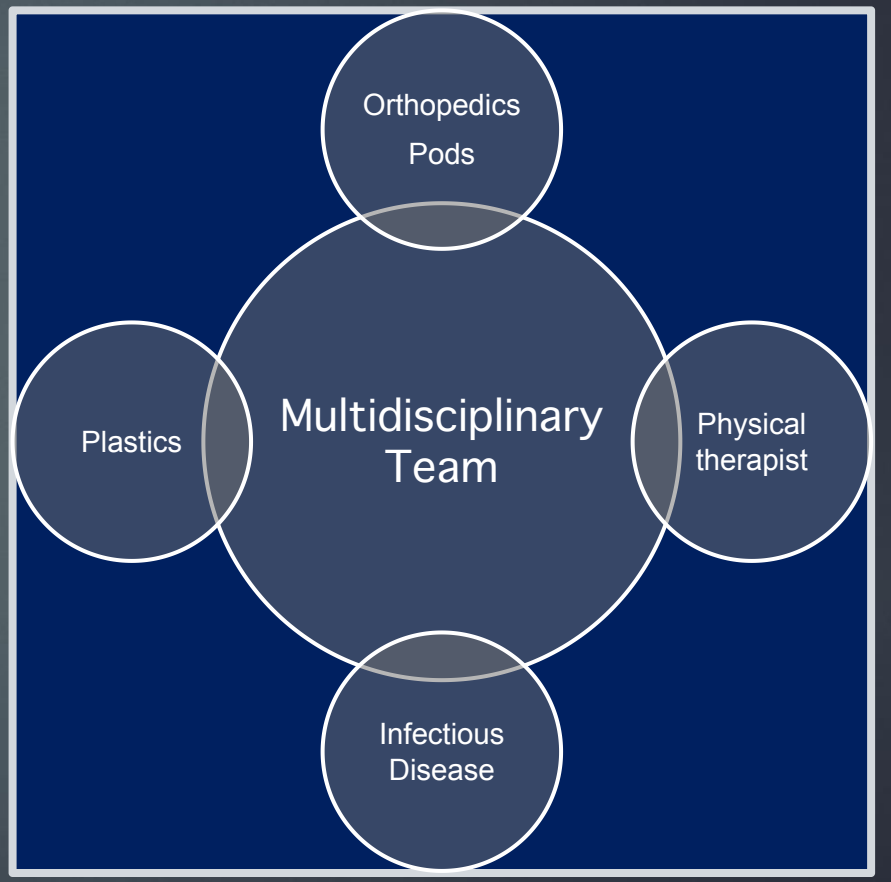
J Reconstr Microsurg





Algorithms

Two Components

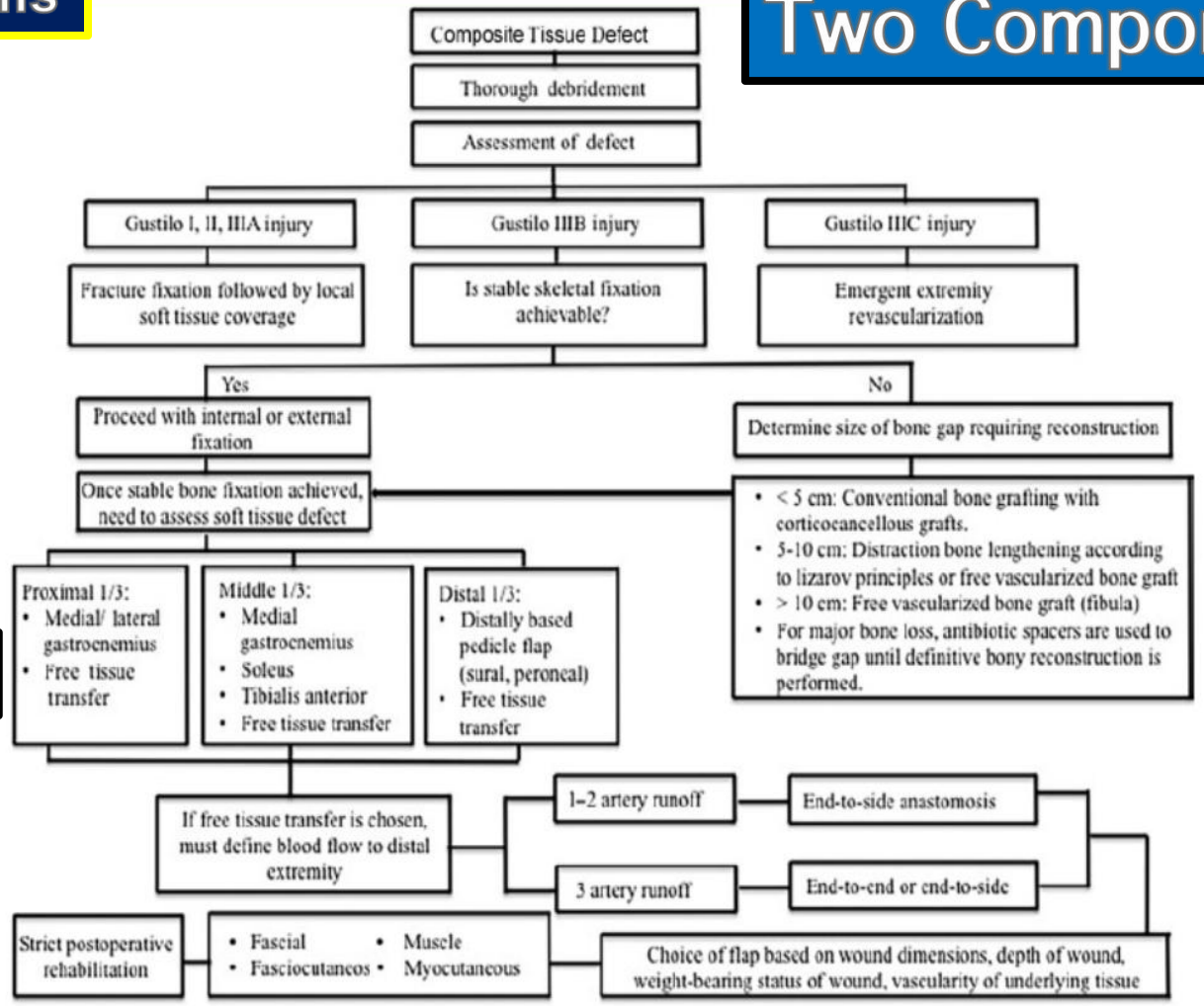


Fig. 1 Algorithm for orthoplastic management of composite defects of the lower extremity below the knee (from Sbitany H, Au AF. Stephen J. Kovach LSL. Orthoplastic approach to composite tissue loss. In: Pu LLQ, Levine JP, Wei F-C, eds. Reconstructive Surgery of the Lower Extremity. St. Louis, MO: Quality Medical Publishing Inc; 2013:1025–1045).[18]

Soft Tissue

Osseous

Principles of Wound Management

+ GOOD PERFUSION

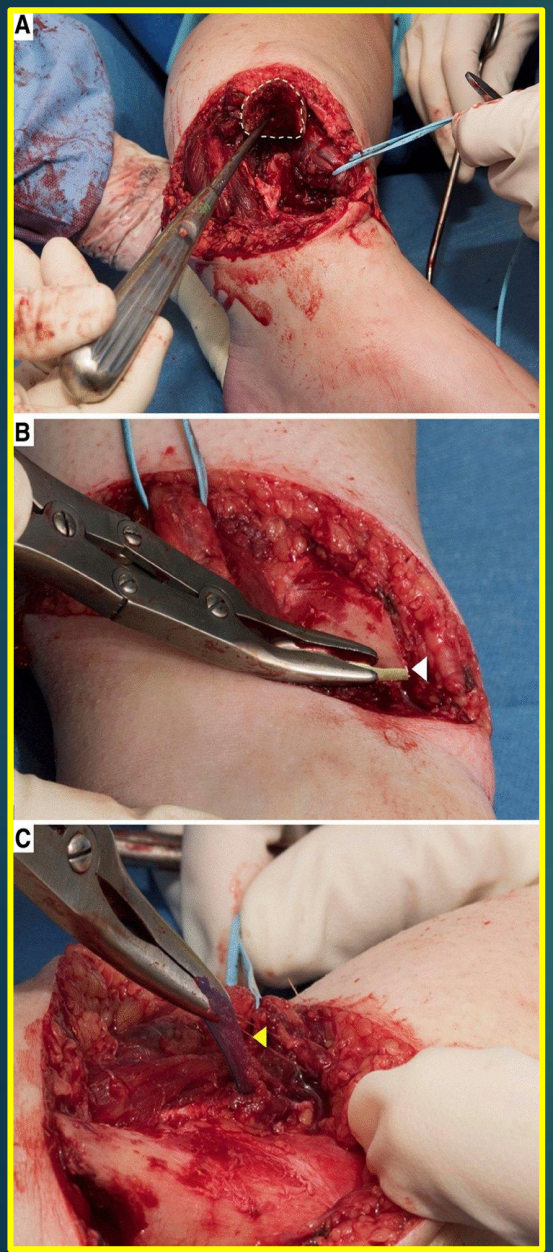
- Debridement
- Skeletal Stabilization
- Bone Gap Reconstruction
- Soft Tissue Defect Reconstruction
- Post Operative Rehabilitation

Debridement: Soft Tissue

Hydrosurgery

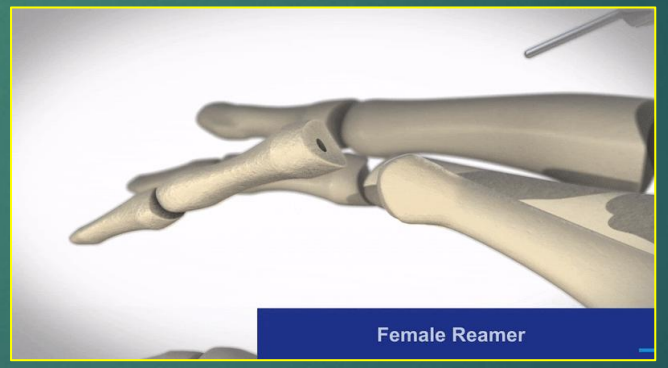
Ultrasonic

Debridement: Bone

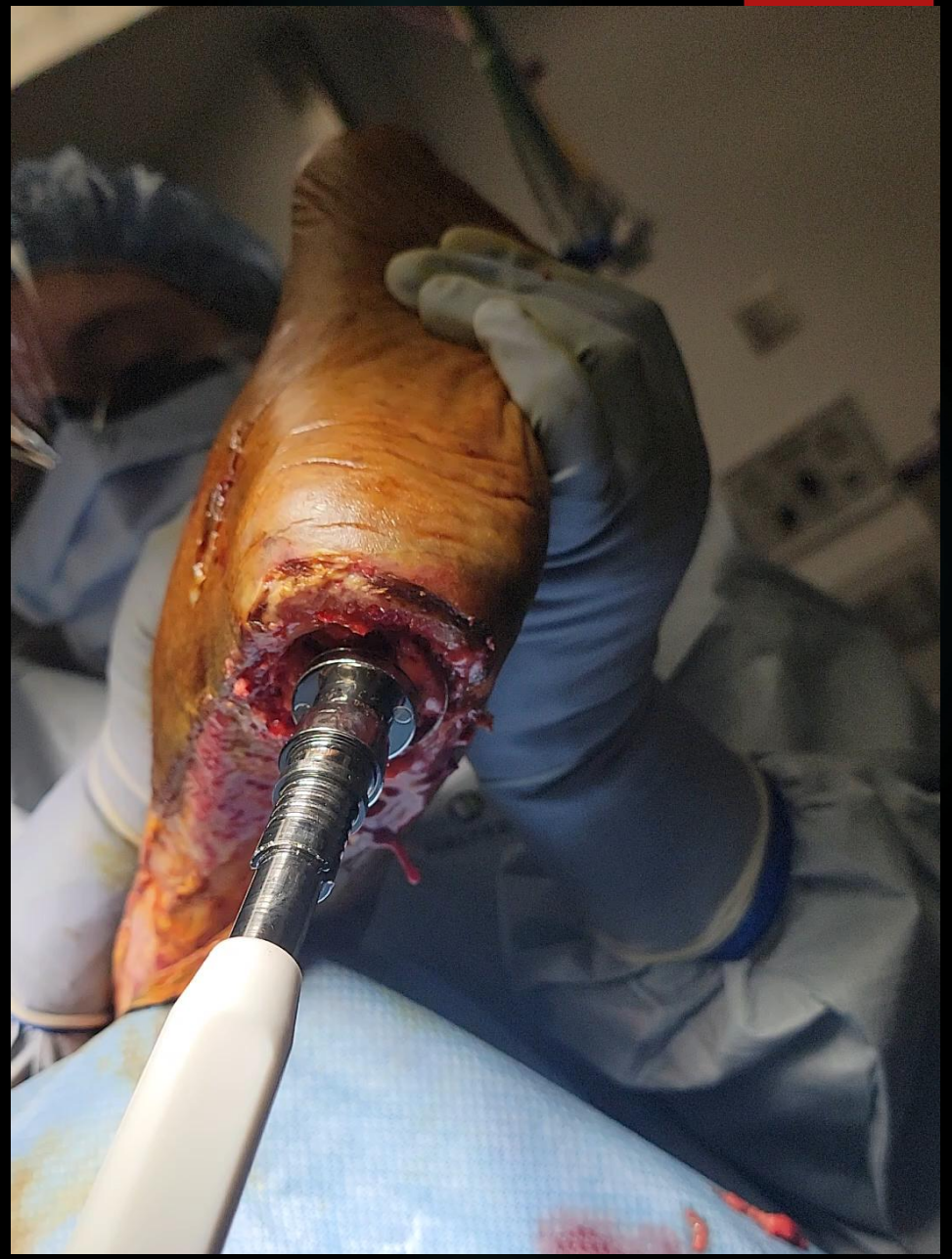


Cutting Burr

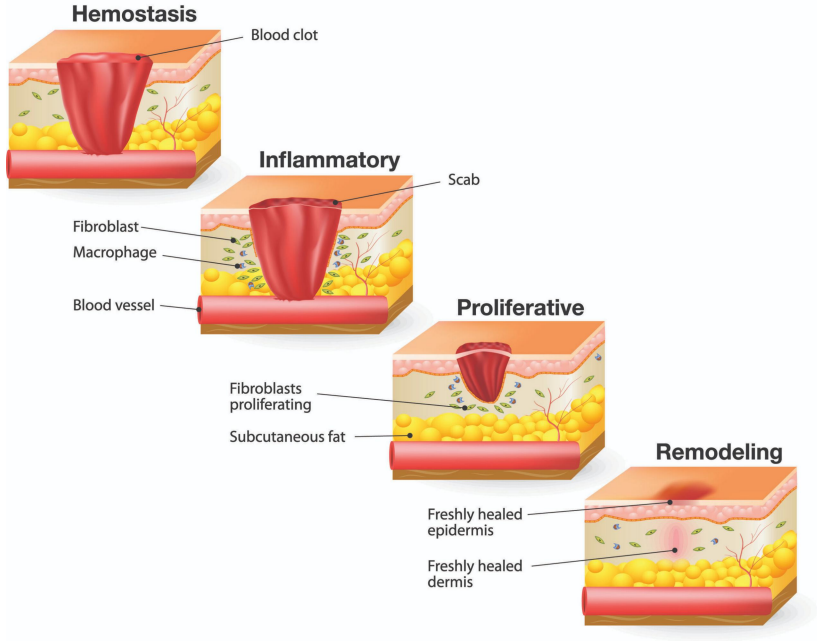
Cup and Cone Reamers



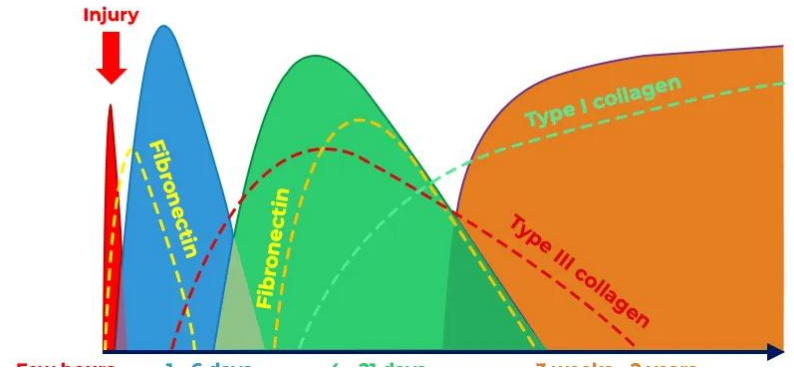
Aspirator System



Chronic wound Physiology

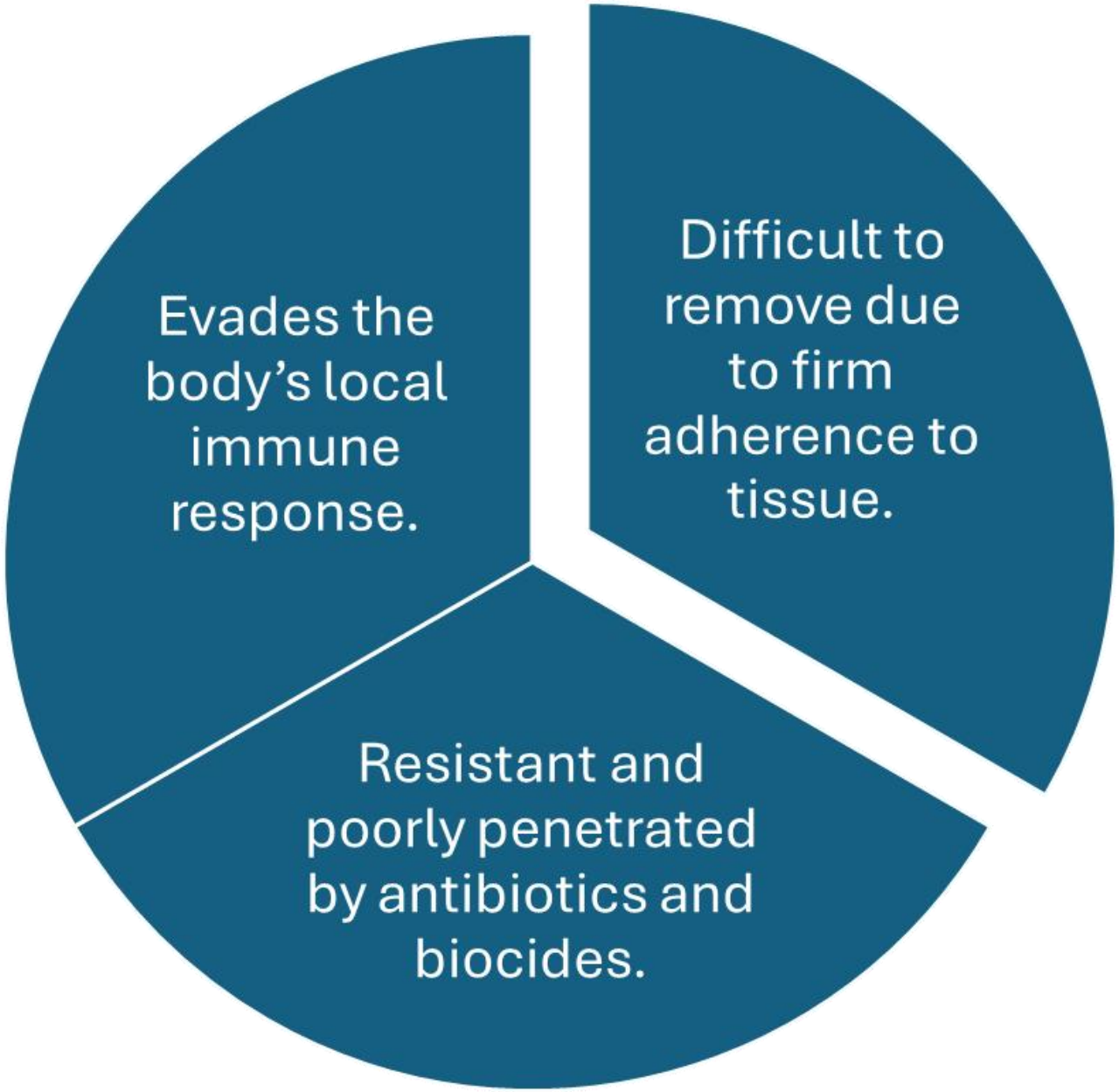


- Wound that is arrested in the inflammatory phase of wound healing and cannot progress further.
- The presence of necrotic tissue, foreign material, and/or bacteria impedes the wound's ability to heal:
  - Production of proinflammatory cytokines, elevated matrix metalloproteases, and excessive neutrophils.
  - The building blocks (chemotactants, growth factors, mitogens, etc.) necessary for normal wound healing are either rendered inert or destroyed.



Chronic wounds: Biofilm

- Aggregation of different bacterial species enclosed within a protective glycocalyx that adheres to the wound surface
- 90% of chronic wounds contain bacteria and fungi living within a biofilm construct.
  - Only present in 6% of acute wounds



Biofilm Approach: Modalities

- Frequent debridement, use of mechanical energy, application of appropriate biocides, and/or topical antibiotic.
- Treatments may be more effective when directed by diagnostic information identifying the bacteria and fungi it contains.

PCR Applications in Chronic Wound Management

- Polymerase chain reaction (PCR) has become an invaluable tool in the management of chronic wounds, offering significant advantages over traditional culture-based methods for microbial identification.
- Decrease the potential for BIOfilm

PCR: Diagnostic Applications

Pathogen Identification: (Rhoads et al., 2012).

Rapidly and accurately identify bacteria, fungi, and viruses present in chronic wounds
Identify slow-growing or fastidious organisms frequently missed by traditional culture methods.

Biofilm Detection: (Malone et al., 2017).

Detect microorganisms within biofilms that contribute to wound chronicity.

Antibiotic Resistance Gene Detection: (Dowd et al., 2008)

Identify genes associated with antimicrobial resistance.
Allows for more targeted treatment approaches.

PCR: Clinical Benefits

Rapid Results: (Price et al., 2011)

- Traditional cultures take days to weeks.
- PCR results can be available within hours.

Enhanced Sensitivity: (Tuttle et al., 2011)

- Pathogen detection at much lower concentration than culture methods

Polymicrobial Infection Assessment: (Grice et al., 2010)

- Simultaneous detection of multiple microorganisms
- Comprehensive assessment of the wound microbiome

PCR Emerging Applications

Point-of-Care Testing: (Melendez et al., 2010)

- Development of portable PCR devices allows for real-time diagnosis in clinical settings.

Quantitative PCR (qPCR): (Gardner et al., 2013)

- Enables assessment of bacterial load, which correlates with wound healing outcomes.

Microbiome Analysis: (Kalan et al., 2019)

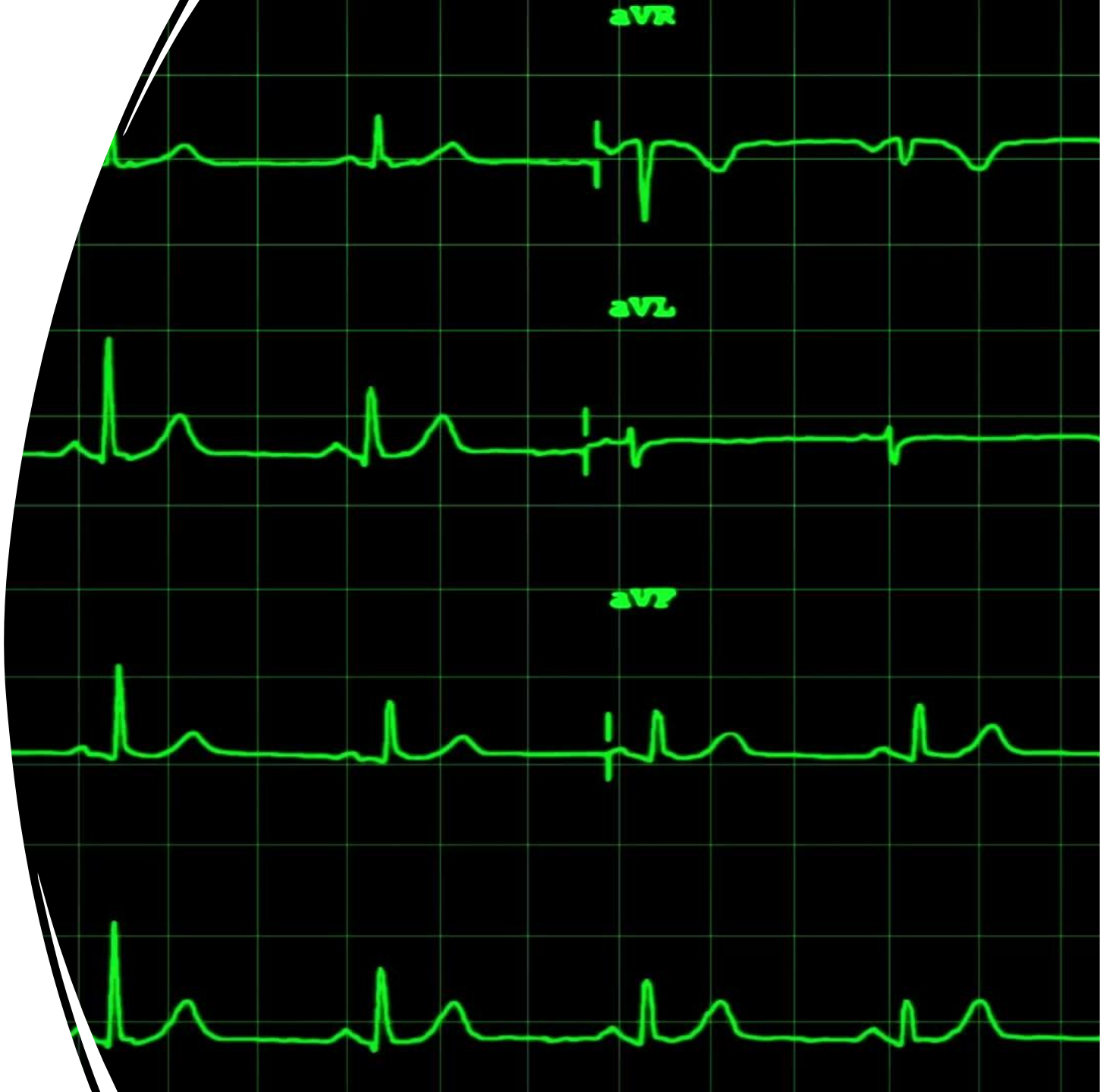
- High-throughput sequencing combined with PCR is revealing the complex microbial communities in chronic wounds and their role in delayed healing.

Laboratory tests: Assessment of Healing Capacity

- Complete Blood Count (CBC):
- Assesses for anemia, infection, and immune status.
- Elevated white blood cell count may indicate infection
  - (Guo & DiPietro, 2010).

Laboratory tests: Assessment of Healing Capacity

- Basic Metabolic Panel:
- Evaluates renal function and electrolyte balance which impact healing (Werdin et al., 2009).



Laboratory tests: Assessment of Healing Capacity

Glycated Hemoglobin (HbA1c):

Essential for patients with or at risk for diabetes; values >7% are associated with impaired healing

- (American Diabetes Association, 2020).

Laboratory tests: Assessment of Healing Capacity

Albumin and Prealbumin:

Markers of nutritional status.

Hypoalbuminemia (<3.5 g/dL) correlates with poor wound healing.

- (Stechmiller, 2010).

Laboratory tests: Assessment of Healing Capacity

C-reactive Protein (CRP):

- Non-specific inflammatory marker that may help monitor infection and treatment response (Healy & Freedman, 2006).

Erythrocyte Sedimentation Rate (ESR):

- Another inflammatory marker that may be elevated in chronic wounds, particularly with osteomyelitis (Lavery et al., 2009)

Laboratory tests: Assessment of Healing Capacity

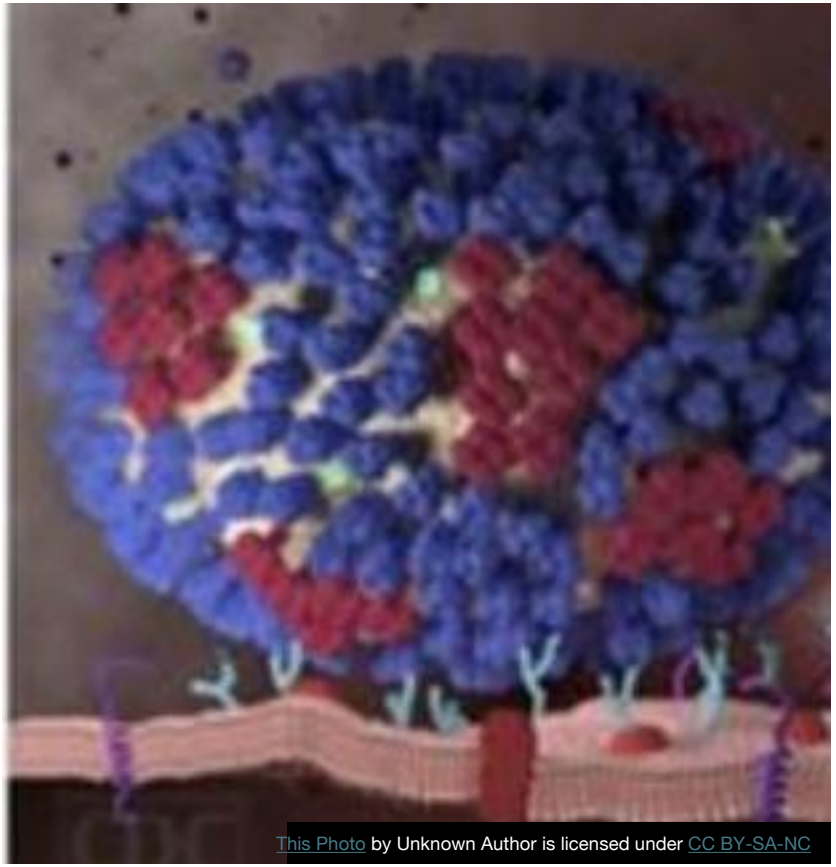
Lipid Profile:	• Important for patients with or at risk for vascular disease (Mustoe et al., 2006).
Protein C, Protein S, Antithrombin III:	• For suspected hypercoagulable states in patients with venous ulcers (O'Donnell & Lau, 2006).
Zinc, Vitamin D, Vitamin B12, Folate:	• When nutritional deficiencies are suspected (Molnar et al., 2014).
Rheumatoid Factor, Antinuclear Antibodies:	• For suspected autoimmune causes of wounds (Alavi et al., 2016)

PCR Technology

- Rapid detection of bacteria directly in clinical specimens
- Early, sensitive and specific laboratory confirmation
- Infections caused by fastidious growth species
- Antibiotic resistance genes or gene mutations

Optimize the therapeutic management of patients

1. detection of pathogens
2. their virulence factors
3. their mechanisms of antibiotic resistance
4. bacterial load



Biological Considerations in PCR Testing

- How PCR amplifies DNA for pathogen detection
- Sensitivity and specificity of PCR compared to traditional culture methods
- Identifying Antibiotic-Resistant bacteria through molecular testing

The Role of PCR in Podiatric Care

- HOW IT DIFFERS FROM TRADITIONAL CULTURE-BASED METHODS
- RAPID PATHOGEN DETECTION FOR TARGETED ANTIBIOTIC THERAPY
- APPLICATIONS IN OSTEOMYELITIS AND SOFT TISSUE INFECTIONS FOR DFU

Why ... cian Office La... R Mac...

Faste... e-d... h early resu...

Increased practice revenue & in... reimbursement opportunit...

...duced hospitalizations and complications

Regulatory Considerations for Physician Office Labs

- **CLIA Certification**: Requirements and categories
- **OSHA Compliance**: Workplace safety and infection control
- **EKRA Compliance** Eliminating Kickbacks in Recovery Act
- **HIPAA Compliance**: Protecting patient data with in-office testing
- **State-Specific Laboratory Regulations**: Licensure and reporting requirements

Case Study – In-Office PCR for DFU Management

- **BEFORE POL PCR**: DELAYED RESULTS, INCREASED HOSPITALIZATIONS
- **AFTER POL PCR**: REDUCED INFECTION RATES, IMPROVED HEALING TIME

- **REAL-WORLD CLINICAL IMPROVEMENTS**

Implementation Process

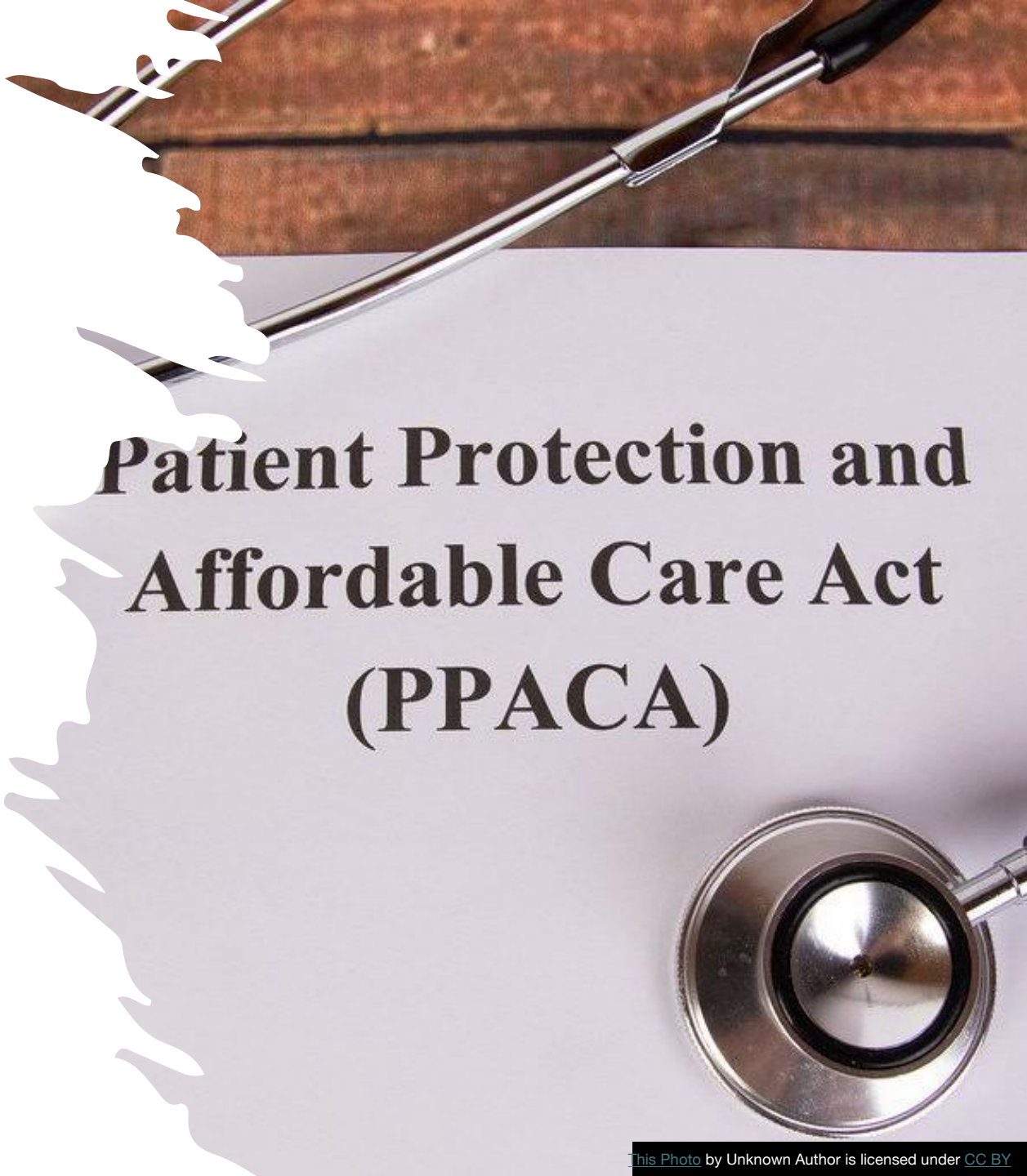
- REGULATORY & CLIA CERTIFICATION
- SITE MAPPING AND EVALUATION
- EQUIPMENT SELECTION & TRAINING
- WORKFLOW INTEGRATION
- STAFF TRAINING AND COMPLIANCE

Why Use a Physician Office Lab (POL) PCR Machine?

- FASTER TURNAROUND TIMES (SAME-DAY RESULTS)
- IMPROVED PATIENT OUTCOMES WITH EARLY INTERVENTION
- INCREASED PRACTICE REVENUE
- REDUCED HOSPITALIZATIONS AND COMPLICATIONS
- REDUCTION IN UNNECESSARY ANTIBIOTIC USE AND ANTIBIOTIC RESISTANCE

Chronic Care Management Under ACA

- **For Patients:**
  - Better health outcomes.
  - Fewer hospital admissions.
  - Improved quality of life.
- **For Providers:**
  - Increased revenue streams.
  - Improved patient satisfaction scores.
  - Reduced care fragmentation.



Chronic Care Management DFU Under : ACA

Coordinated services for Medicare +

- Multiple (2+) chronic conditions
- Expected to last at least 12 months

Goals:

- Improve health outcomes
- Reduce hospitalizations
- Enhance patient satisfaction.

Chronic Care Management DFU Under : ACA

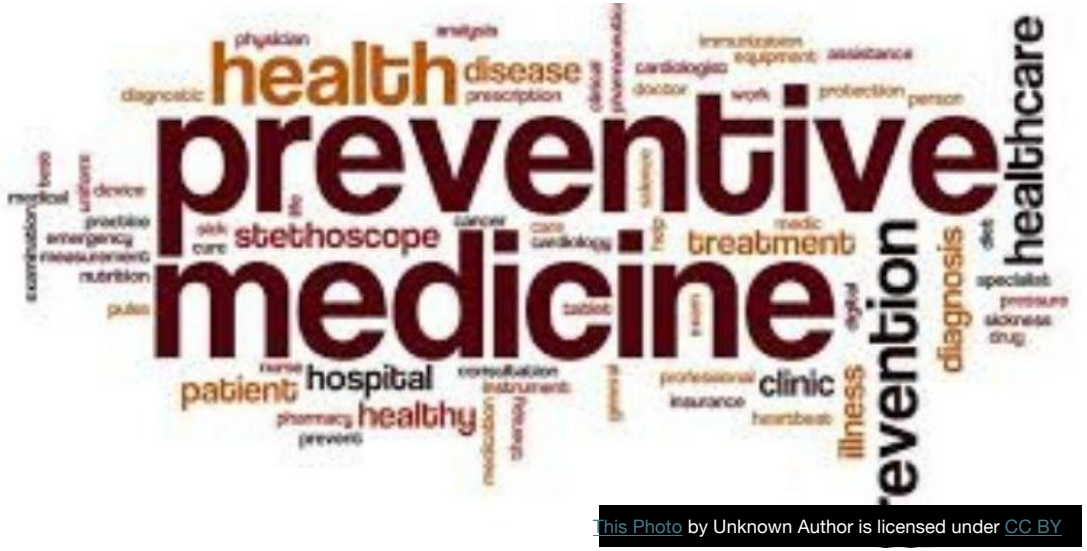
Emphasis on preventive and coordinated care.

- Comprehensive care plan.
- 24/7 access
- Care management services.

Medication management and reconciliation.

Coordination with specialists and other providers.

Regular follow-up and monitoring.



Financial & Operational Impacts DFU/Office

PCR

CCM

- **Reimbursement Rates**: Per PCR
- **Cost Analysis**: POL setup vs. Outsourcing

- **Chronic Care Management** in office vs outsourced
- Increase in **Office Visits vs Full time Employees**

- **ROI Calculation**: Projected earnings per year

Thank you

For additional information regarding

CHRONIC CARE MANAGEMENT

PCR

OFFICE LAB