

# **CENTRO DE PREVENCION Y SALVAMENTO DEL PIE DIABETICO “ SAN ELIAN “**



**Preliminary outcomes  
of PBK use in several conditions from a  
diabetic foot center population**



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# Background

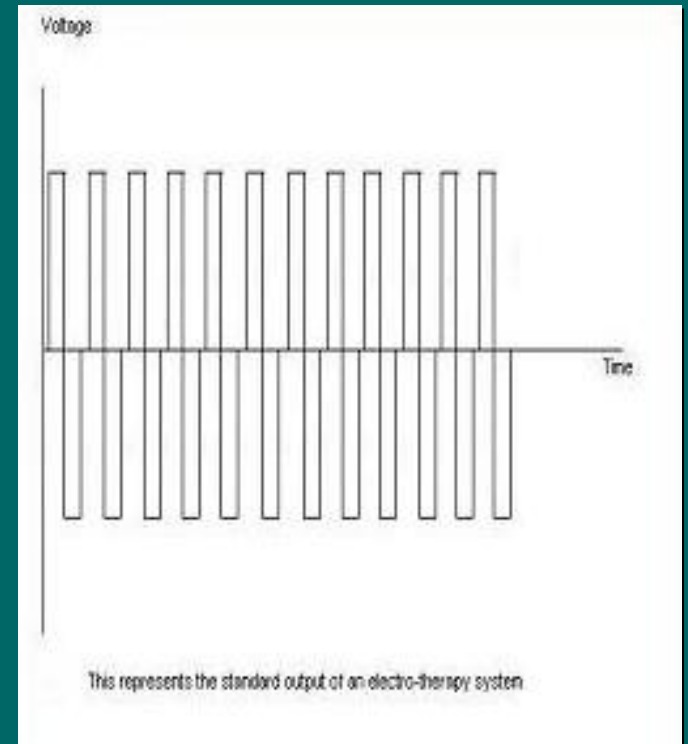
Diabetic Foot it is a complex disease, where many variables interact continuously. Several treatment modalities are currently developing and under assessment. The use of tissue electrical stimulation is another newer field to be explored.

# Current Clinical Uses

- Pain relief
- Spasms or muscular damage
- Arthritis
- Neuropathic pain
- Vascular pathologies
- Back pain

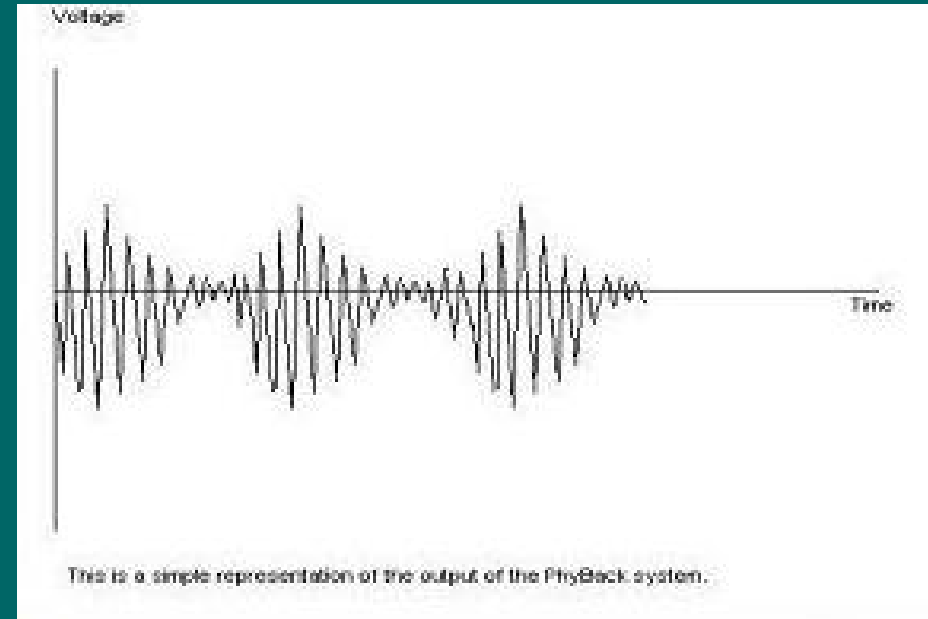
# Standard Electro-therapy Systems

- Use galvanic or faradic currents
- Square waves in a simple manner OF-ON
- Useful for short term pain control or
- Relaxing muscles



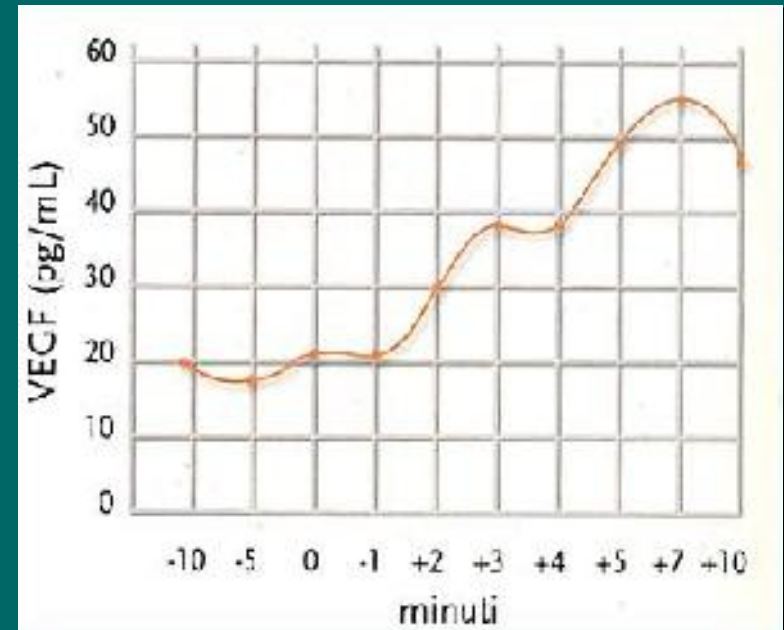
# PBK System

- Does not use current
- Extremely short volts impulses
- Billionths of a second
- Timing and power



# PBK effects

- Cell and tissue alarm status
- Local release of  $TNF\alpha$  &  $IL-B1$
- Local release of VEGF & increase of NO



# In Brief

- **Standard Electro-therapy**

1. *Relaxes muscle*
2. *Removes pain for a short time*

## **PBK Therapy**

1. *Relaxes muscle*
2. *Stimulates VEGF*  
*Dilates vessels – more blood flow*
3. *Grows new vessels*
3. *Stimulates anti-inflammatories which reduces pain immediately*
4. *Attacks **the cause of the pain**, not just the symptoms*
5. *Removes pain for a long time*
6. *Improves muscle strength, mobility and flexibility*

# Background

## A In Vivo Journal published paper

- Ferroni P, Roselli M, Martini F, et al. Biological effects of a software-controlled Voltage Pulse Generator (PhyBack PBK-2C) on the Release of Vascular Endothelial Growth Factor. *In vivo* 2005;19:949-958.
- Debreceni L, Gyulai M, Debreceni A, Szabo K. Results of transcutaneous electrical stimulation (TES) in cure of lower extremity arterial disease. *Angiology* 1995;46:613-8.





# Ethics

- Because there is no reported side effects with the use of controlled electrical stimulation (PBK), and there is published basic research showing a release of VEGF and good proinflammatory response. We start to use PBK in some selected patients within a comprehensive care in our center.

## Objective

To analyze the use of PBK in several conditions from a diabetic foot Center population.



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## Patients and Method

### Population

All diabetic and non diabetic patients who presented a medical condition where PBK was indicated

### Site

San Elian Center for prevention and Salvage of the Diabetic Foot

### Lapse

01 apr 2007 to 01 Aug 2007

### Design

Prospective and descriptive study



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## Patients and Method

### Primary Measurements

- Improvement of clinical conditions
  - Diabetic Foot patients
    - Total wound healing in Ischemia Neuropathy
    - Neuropathy symptoms
  - Non Diabetic
    - Muscle contractures
    - Pain

### Secondary Measurements

- Amputations
  - Major & minors



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# San Elian Wound Care Protocol

## **Initial assessment**

- **PEDIS classification for Research**
- **San Elian Wound Score & Grading**
- **Tampico Classification \***

## **Initial treatment**

- **Surgical debridement of necrotic tissues and abscess**
- **Wound cleanse with NpHSS \***
- **Hi- tech dressings**
- **Broad spectrum antibiotics**
- **Body Homeostasis**

\* Martínez-De Jesus FR, Ramos-de la Medina A, Armstrong D, Stephanie W, et al. Efficacy and safety of neutral pH superoxidized solution in severe diabetic foot infections. International Wound Journal. (in press) 2007.

# San Elian Wound Care Protocol

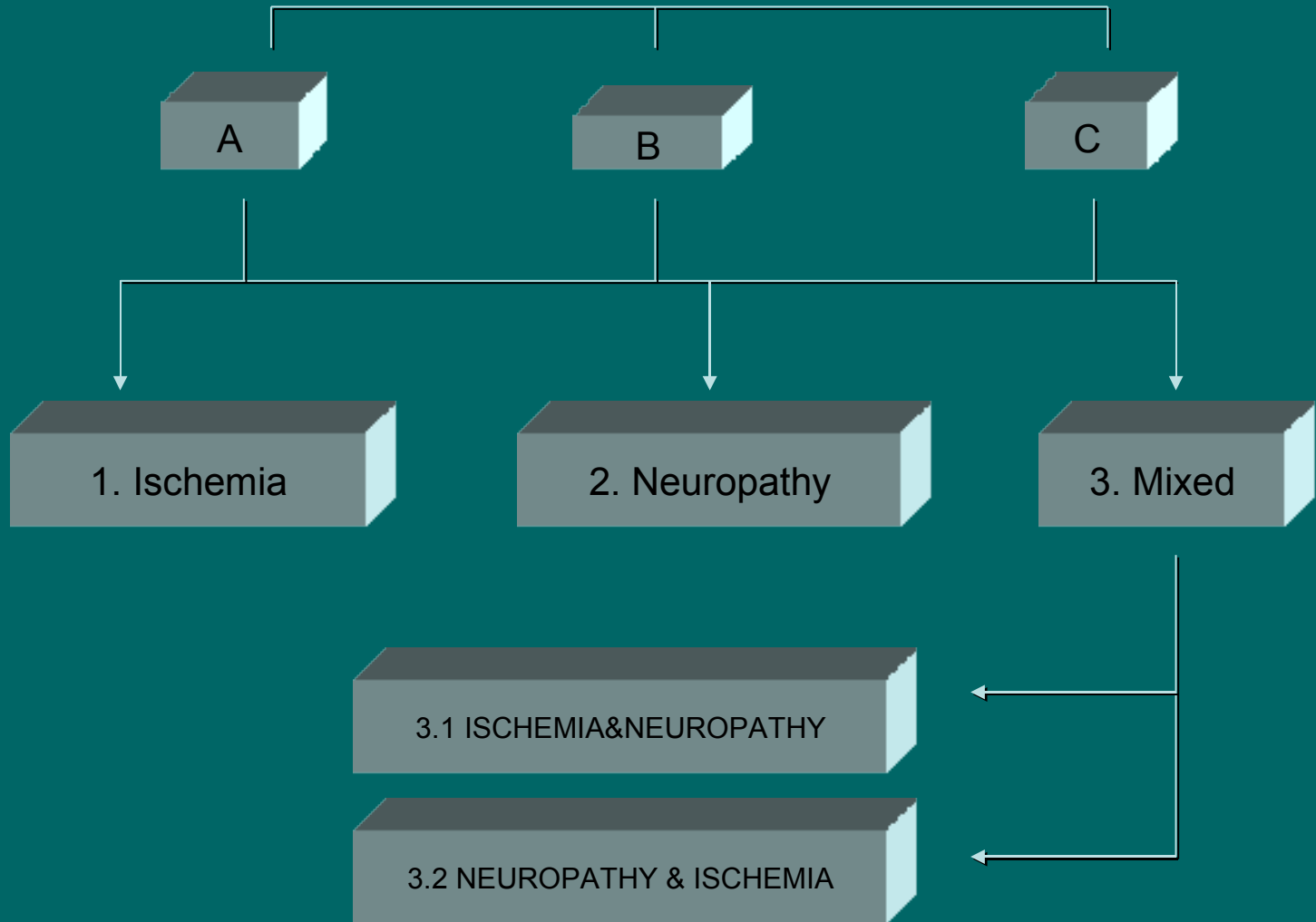
- **Initial Treatment**
  - **Etiology**
    - **Treat limb ischemia & Infection**
      - Endovascular
      - By-pass
    - **Reduce Edema**

## **Subsequent**

- **Treatment focused on Wound healing phase**
  - **Hydrofiber Ag dressings**
  - **Promogram®**
  - **Topical O2**
  - **VAC**
  - **Keratinocytes skin cultures EPIFAST®**
  - **Skin grafts, flaps, traction**

Lazaro-Martinez JL, Garcia-Morales E, eit-Montesinos JV, Martinez-de-Jesus FR, ragon-Sanchez FJ. [Randomized comparative trial of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers]. Cir Esp 2007;82:27-

# Tampico Classification Adapted by Mtz. De Jesús



# Results

## Demographics

n ( %) or Means  $\pm$  SD

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- **Age** 66  $\pm$  10.2
- **Gender**
  - Male 10 ( 52.6)
  - Female 9 (47.4)
- **Non diabetics patients** 2
- **Years of diabetes duration** 20.8  $\pm$  7.7
- **HbA1c** 8.5  $\pm$  3.7
- **Neuropathy** 17





# Results

**Tampico Classification** **n=17/19**  
**(Depth,infection,ischemia or neuropathy)** **n ( %)**

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<b>A3</b> superficial mixed mainly neuropathic(MMN)	2(11.8)
<b>B1</b> partial depth,ischemia	1(5.9)
<b>B2</b> partial depth, neuropathic	3(17.6)
<b>B3.2</b> partial depth, (MMN)	2(11.8)
<b>C1</b> entire depth ischemia	2(11.8)
<b>C2</b> entire depth, neuropathic	1(5.9)
<b>C3 .1</b> entire depth, (MM ischemia)	6(35.3)



# Results

## Fasting Glucose

means  $\pm$  SD

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1<sup>a</sup> phase

120  $\pm$  52.6

2<sup>a</sup> phase

143  $\pm$  70.5

3<sup>a</sup> phase

131  $\pm$  32.4

4<sup>a</sup> phase

107.6  $\pm$  8.7

ANOVA  $p < 0.05$



# Results

<b>Condition for PBK use in Diabetic Foot</b>	<b>N=19 n</b>	<b>Success</b>
<b>For Diabetic Foot patients</b>		
Wound healing adjuvant		
Neuropathic ulcer	7	6
Ischemia	8	7
Trombophlebitis and edema	1	1
Knee muscle contracture	1	1
<b>For non diabetics patients</b>		
Lumbar pain	1	1
Neuropatic Pain	1	1
<b>Improvement of medical condition</b>		<b>17</b>



# Results

<b>PBK INDICATION</b>	<b>FAILURE</b>	<b>&gt;50% WH*</b>	<b>100% WH</b>	<b>TOTAL</b>
<b><u>Diabetic Foot Patients</u></b>				
<b>Wound Healing Adjuvant</b>	0	3	4	7
<b>Ischemia</b>	1	2	5	8
<b>Muscle Contracture</b>	0	1	0	1
<b>Trombophlebitis &amp; Edema</b>	0	1	0	1
<b>TOTAL</b>	1	7	9	17

\* WH= Wound Healing

# Results

<b>Outcome</b>	<b>n *</b>
• Edema reduction	6
• Trombophlebitis	1
• Wound healing Adjuvant	15
– Ischemia	8
– Neuropathic wounds	7

\* n= sample from number of events not patients

# Results

Site of Doppler arterial obstruction  
For patients with ischemia

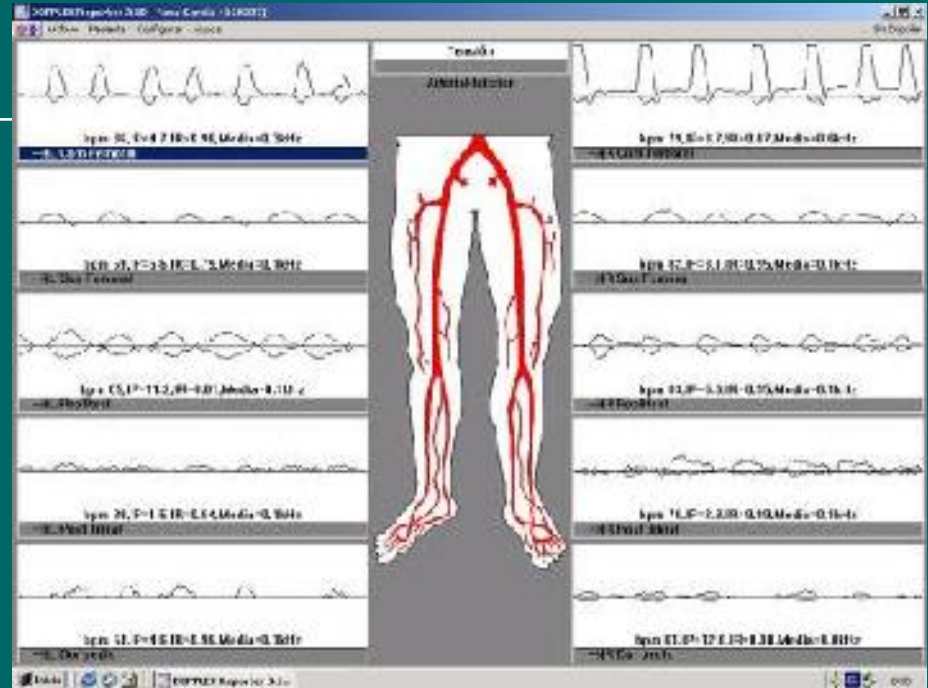
n (%)

• left

Deep Femoral 1 (12.5)  
Popliteal 1(12.5)  
Posterior Tibial 6(75.0)

• right

Deep Femoral 2 ( 33.3)  
Popliteal 3(50.0)  
Posterior Tibial 1(16.7)



# Results

<b>Neuropathic Symptoms *</b>	<b>VALUE n</b>
• Muscle decontracture	6
• Pain reduction	5
• Numbness reduction	4
• Tingling reduction	4
• Recovery of sensation	4

\* More than one per patient

# Results

## Amputations

**N=8/17**

n

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- **Minor**

7

- Digits

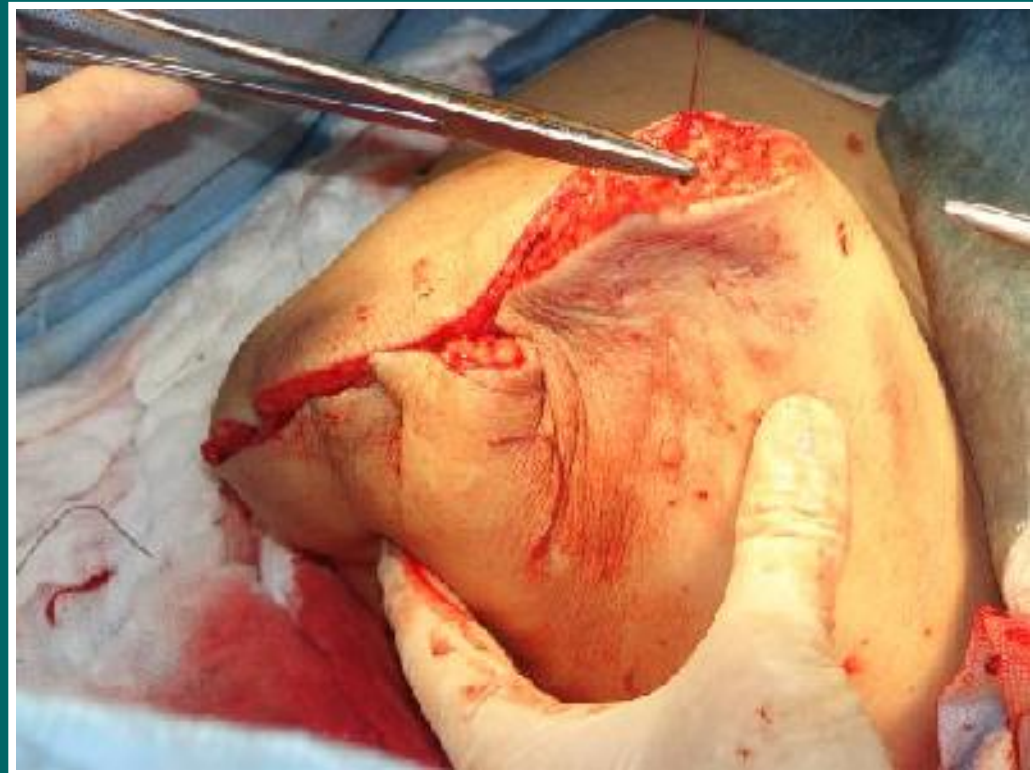
6

- Metatarsal

1

- **Major**

1





# Some pictures of patients at different stages of healing



# Some pictures of patients at different stages of healing



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# Some pictures of patients at different stages of healing



# Some pictures of patients at different stages of healing



# Some pictures of patients at different stages of healing



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# Conclusions

**PBK appears to play a role as adjuvant therapy in improving different conditions in patients cared within a comprehensive care center. PBK Appear to produce an hypoglycemic effect. Further clinical trials are planned in order to increase the evidence level of these promissory preliminary findings**



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