



**TISUGEN**

# OA Disease Process

- Pain starts as a small ache that gets progressively worse
- Patient pursues medical advice
- X-rays evidence a gap narrowing in the knee joint
- Future x-rays show joint continues to degenerate

We all get about 75,000 miles on our knees – injury can expedite development of OA



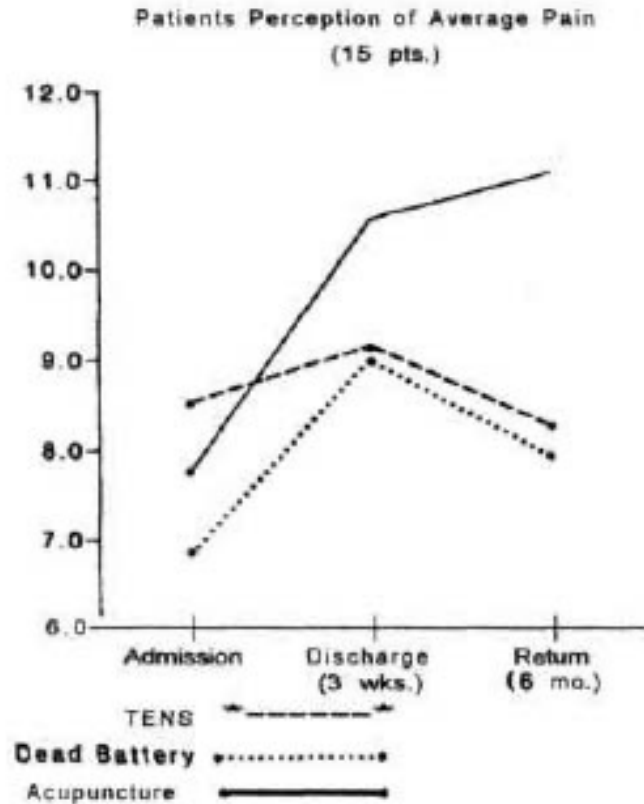
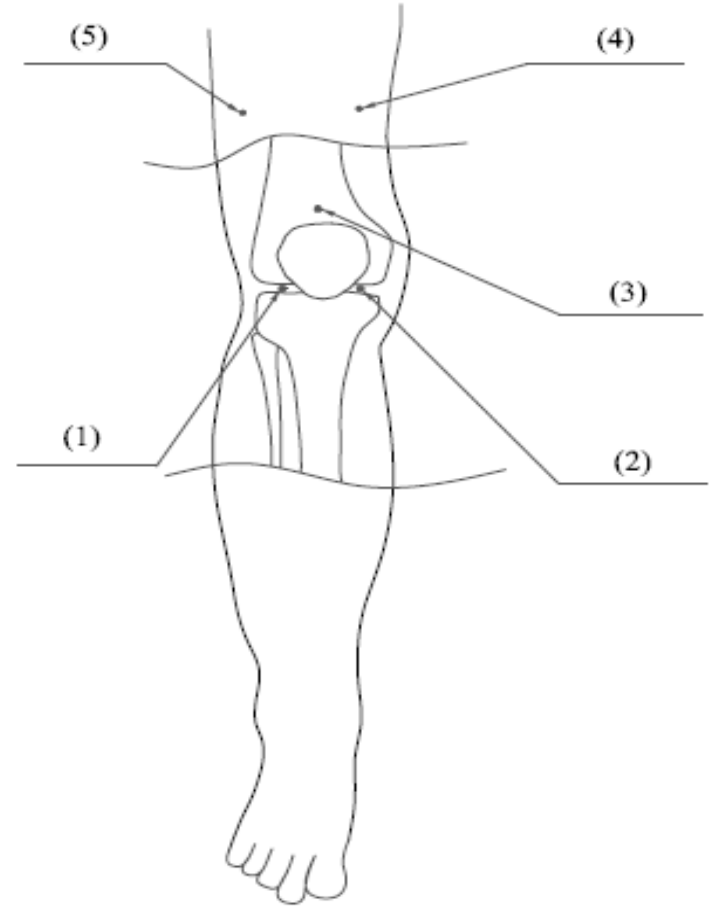
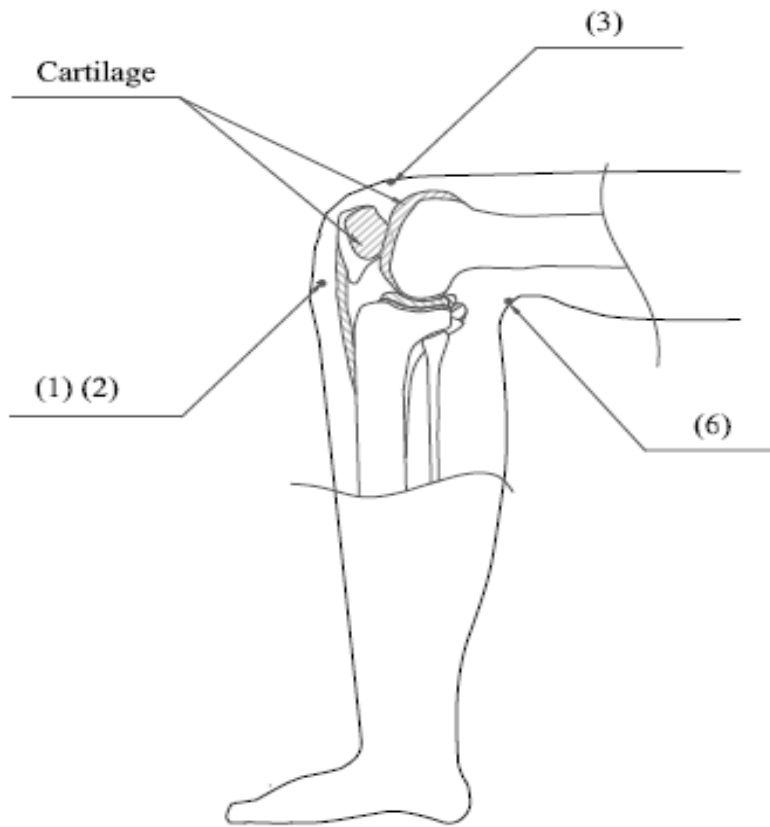


Fig. 2. Results of the 3 treatment groups on the visual analogue scale measure of the general level of pain on an average day at admission, discharge, and return visits.

This graph shows that electro-acupuncture out-performed the TENS and TENS with dead battery treatments rather significantly.

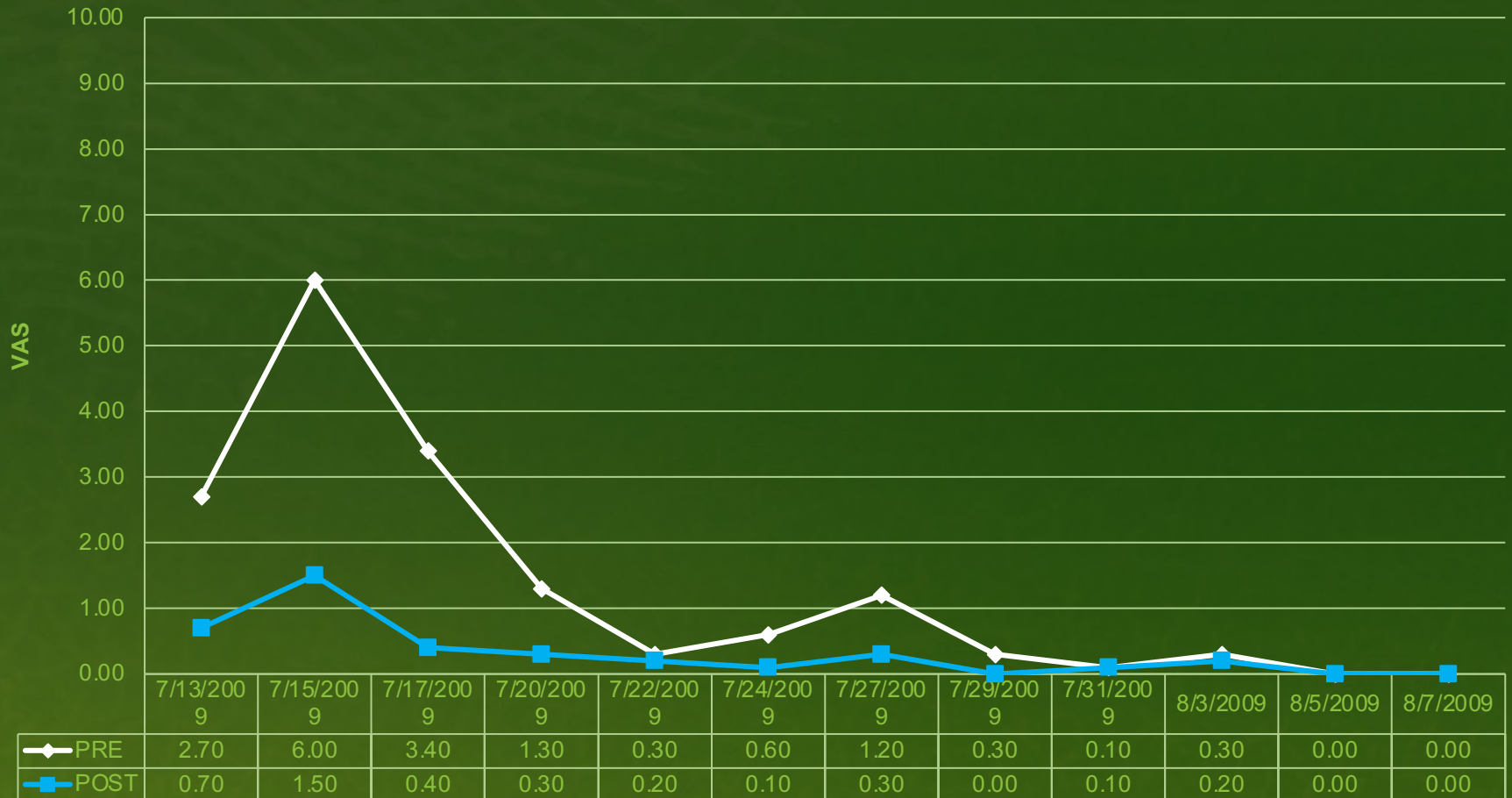


**Figure 1**

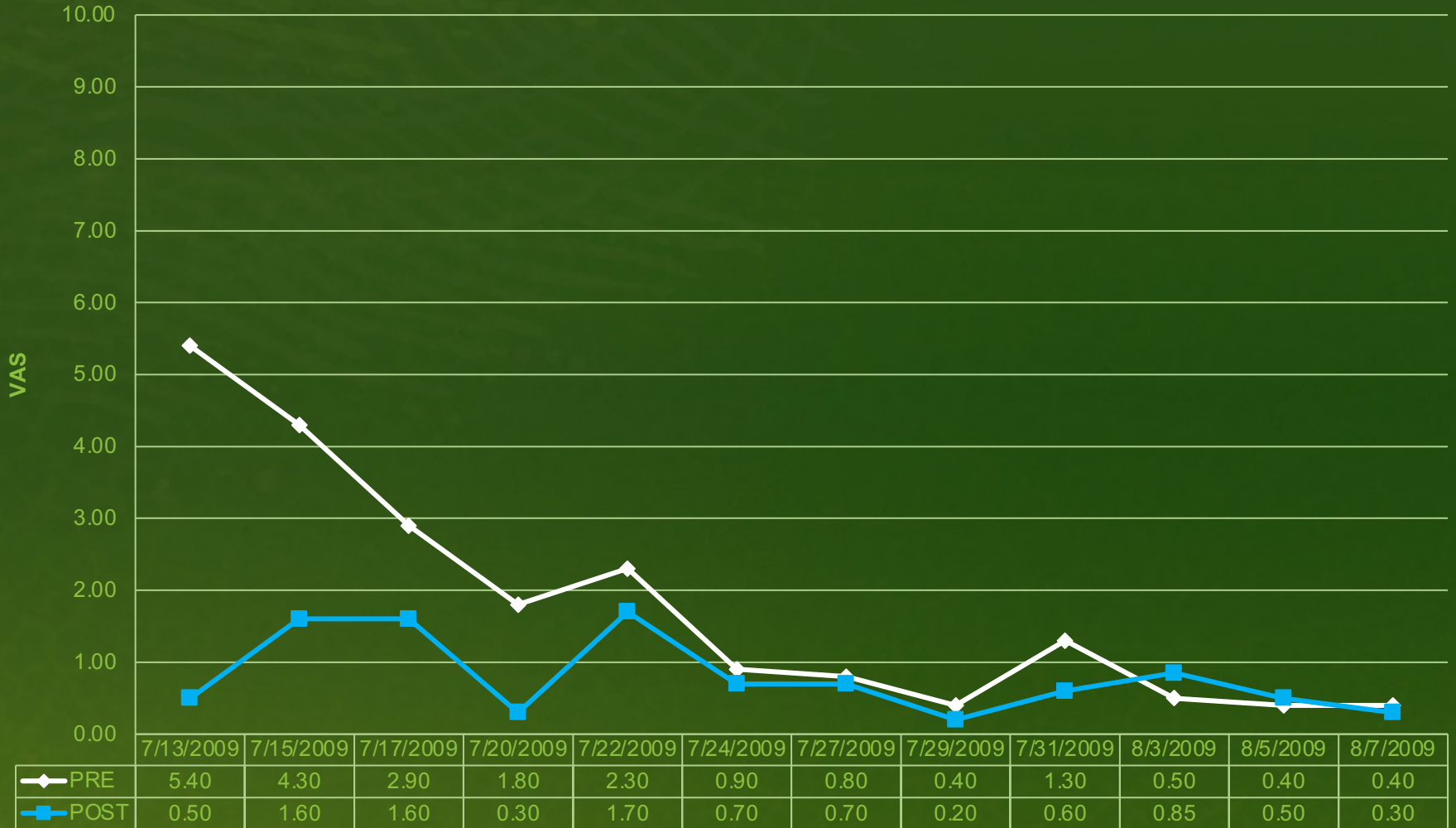
## Artist sketch of insertion points in the knee

# Pilot Study

CASE ID: PL03

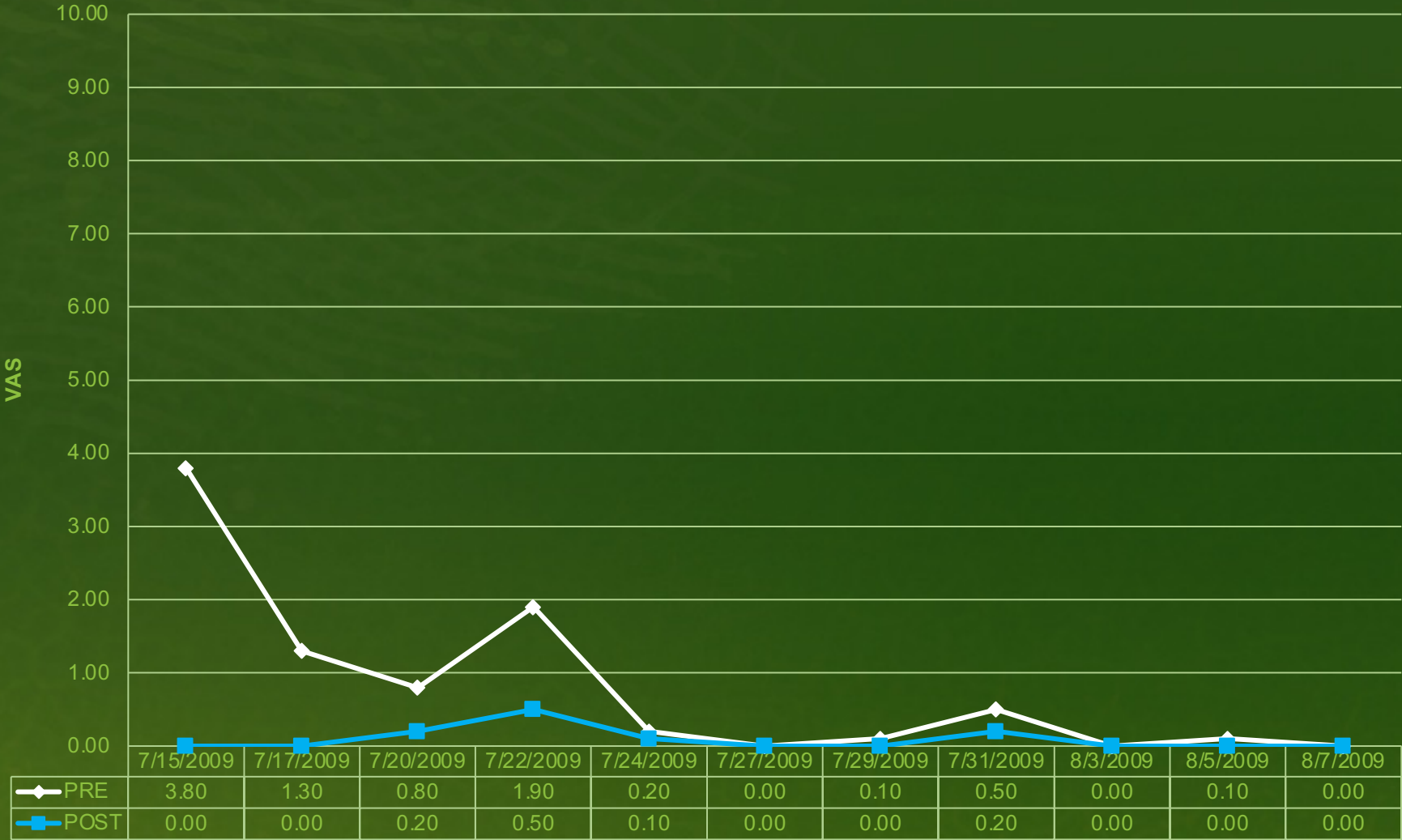


# CASE ID: PL05





# CASE ID: PR05

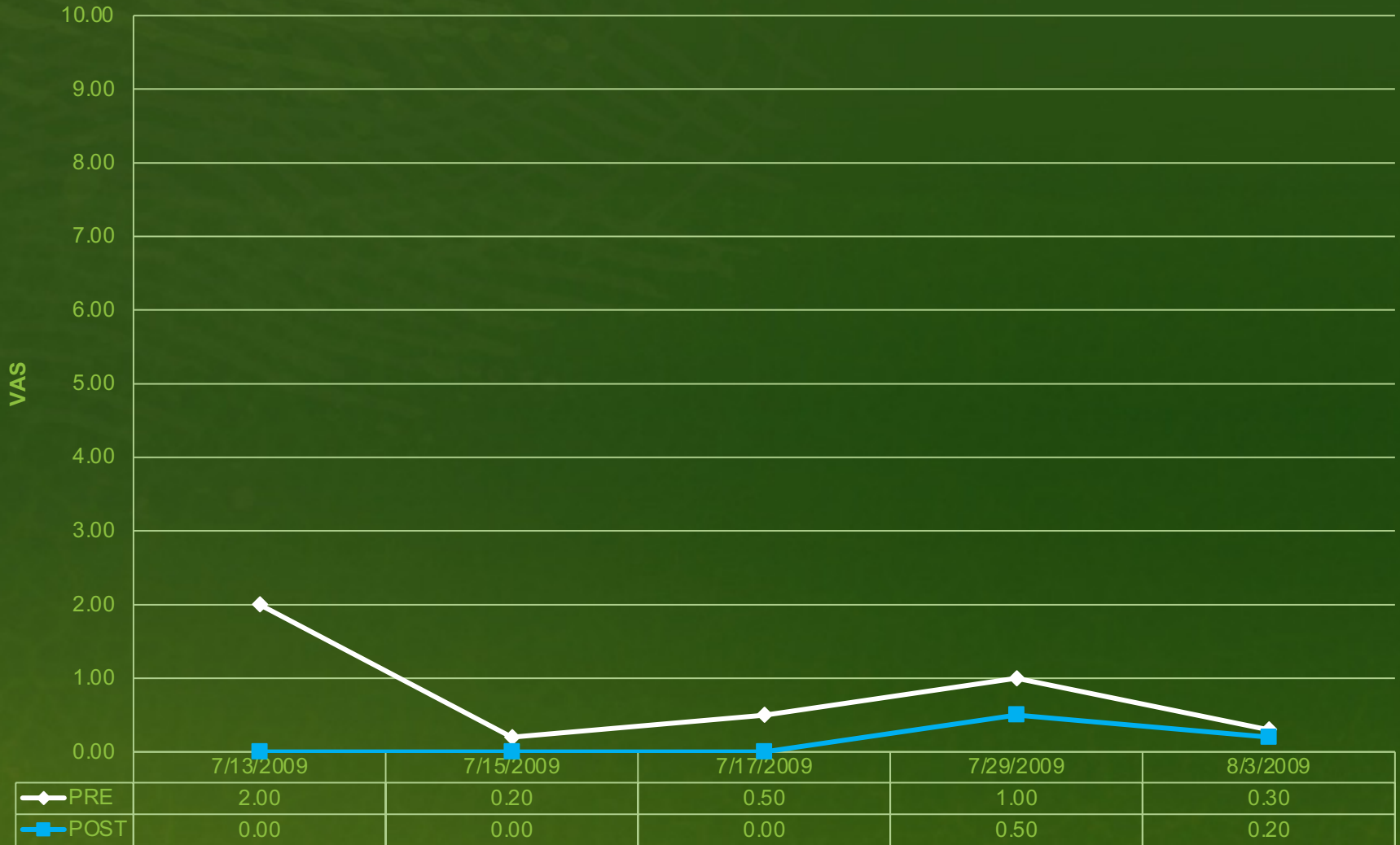


# CASE ID: PR08

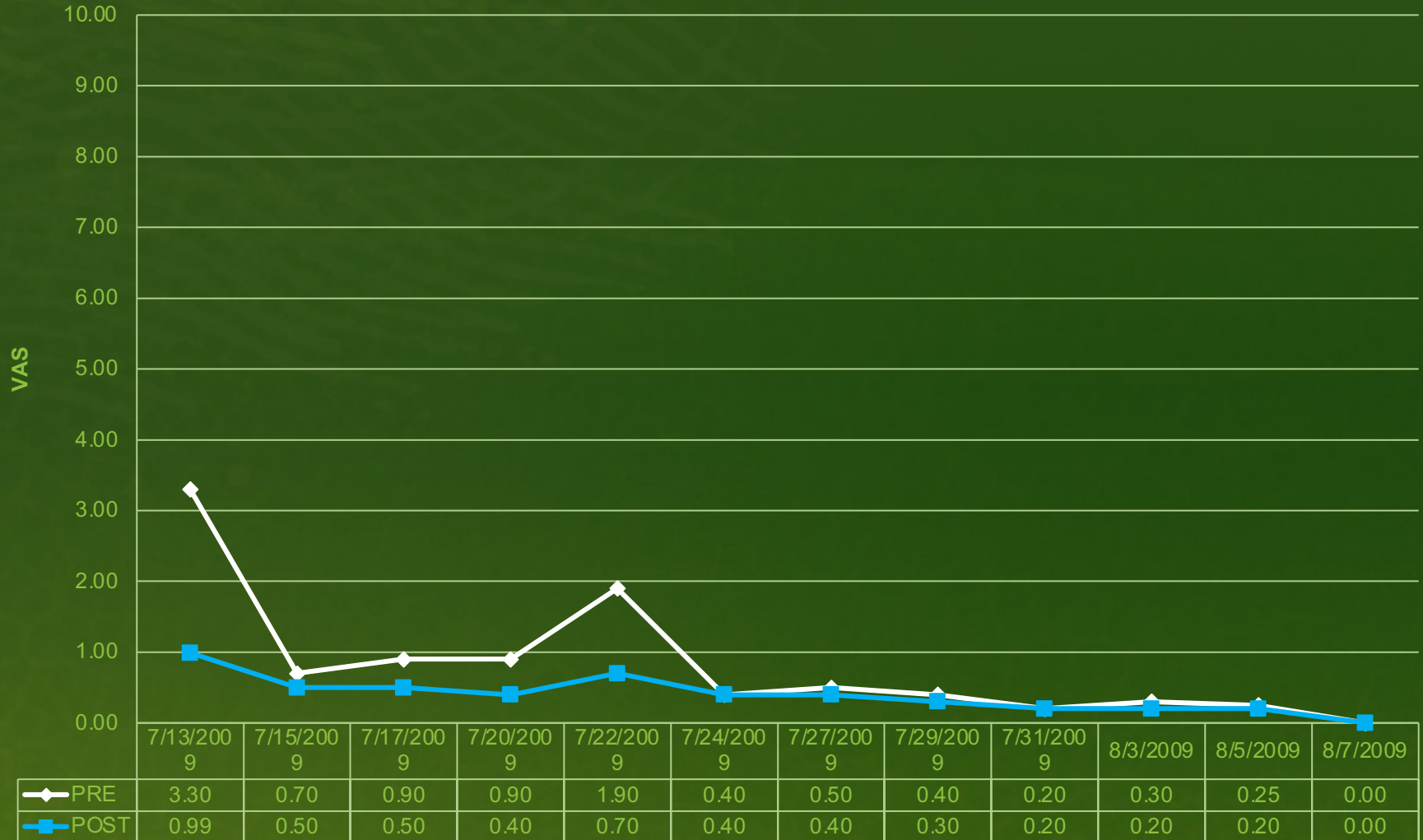




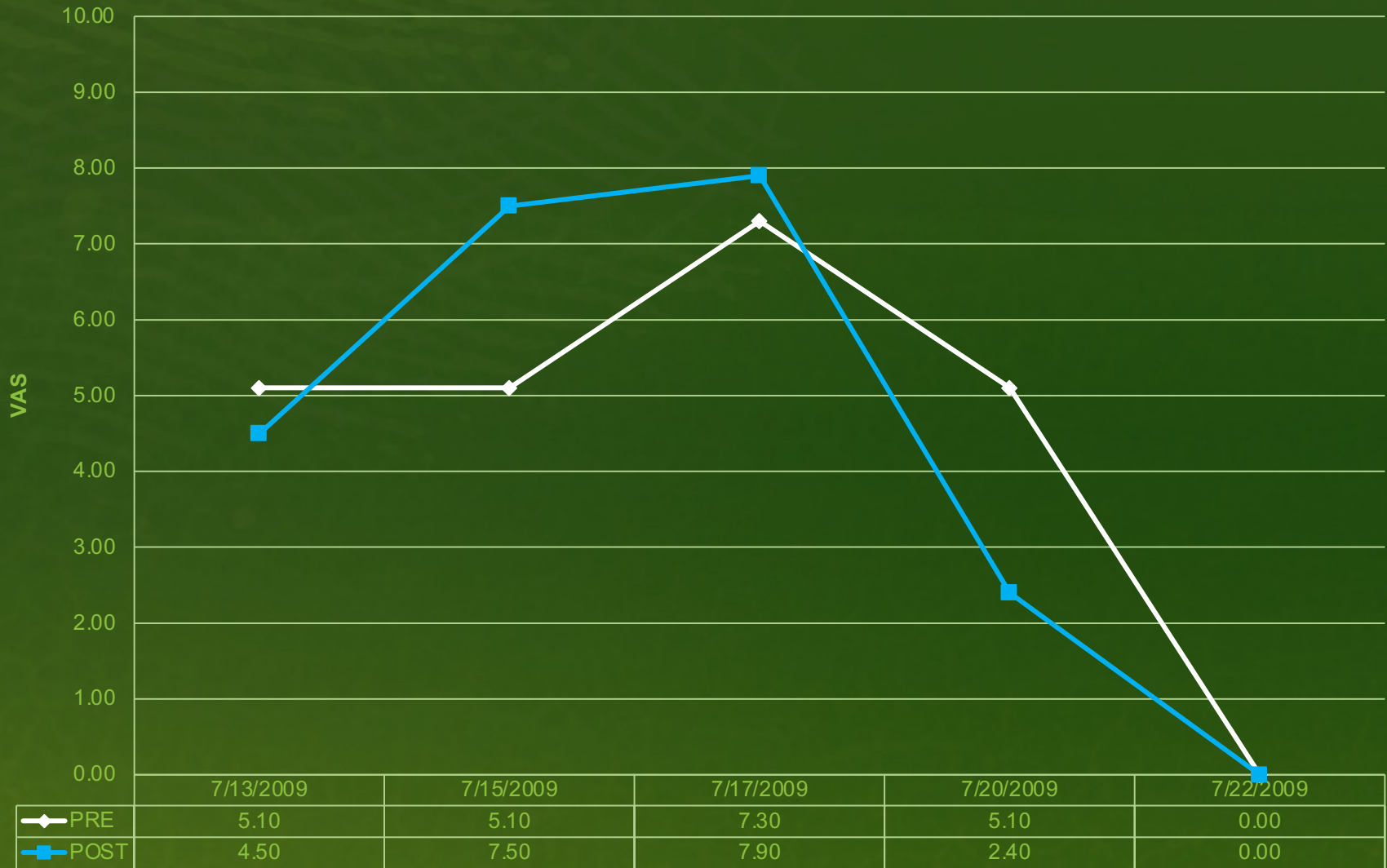
# CASE ID: PR12



## CASE ID: PR13

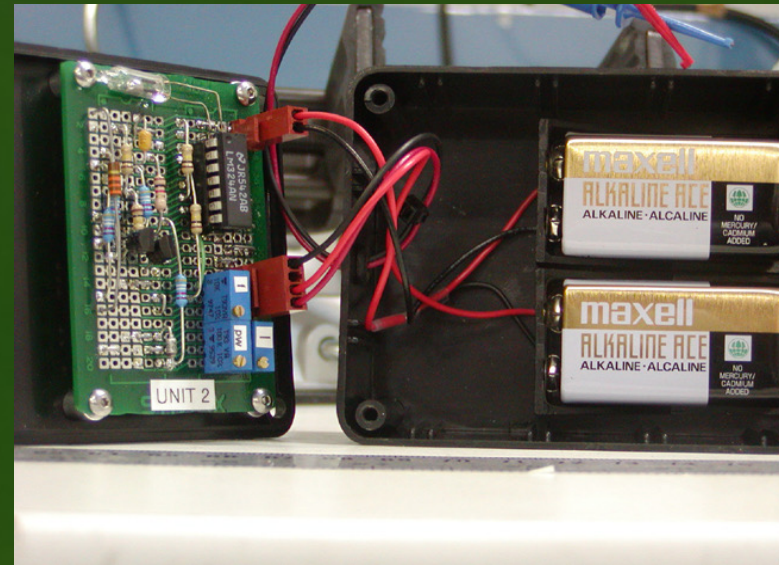


# CASE ID: PL10



# Phase I

- Percutaneous Electrotherapy Stimulation for Treatment of Osteoarthritis
- The **Phase I** device and orthotic includes:
  - Phase I electrode assembly
  - Battery-powered miniature electrical stimulator
  - Leads that attach to pre-inserted electrodes for delivery of therapeutic electrical stimuli
  - Custom unloading brace to facilitate pain relief



# Revenue Potential

## Present Markets

- Phase I and Phase II for *in vivo* and *in situ* analgesia and tissue repair and regeneration
- Other Transcutaneous applications under development (i.e., Laser/TENS, TENS/Ultra-sound)
- Initial market: **knee osteoarthritis (OA)**

## Future TISUGEN Markets

- Hip OA analgesia and tissue regeneration
- Hand and foot OA analgesia and tissue regeneration
- Degenerative spinal disc analgesia and tissue regeneration
- Eye tissue stabilization and repair (e.g., macular degeneration “dry”)
- Other musculoskeletal joint/tissue repair and regeneration



# Medical Reimbursement

- Two reimbursement codes exist within CMS (Medicare) for Device-1844 Single upright off-loading knee brace, custom made. (L-1844 D.M.E. Fee Schedule: \$1,700.00 \*)
  - E-0762 TENS electric stimulation for OA. (E-0762 D.M.E. Fee Schedule: \$1,100.00 \*)
- Total reimbursement: \$2,800.00
- Projected Selling Price: \$1,500.00 ASP

\* These are averages and they vary by region



# Market Size (Knee OA Market only)

	<i>U.S. Market Potential</i>	<i>Int'l Market Potential</i>
Individuals	1,250,000 (est.)	12,500,000 (est.)
TISUGEN Market Share %	2%	2%
TISUGEN Market Share #	25,000	250,000
Total Potential Revenue	\$40 M (per year)	\$400 M (per year)

Assumed targeted procedures at \$2 billion

2% penetration = \$40 M annual revenues

5% penetration = \$100 M

- 10% penetration = \$200 M

# Capital Required

\$3.5 million

- Phases I and II clinical trials
- Support product launch and commercialization in US > Q2/2015
- TISUGEN sales specialists, top Ortho reps (5 year 1 > 20 total)
- Industry partnerships in other markets (hip, knee, elbow, etc)

## Exit Strategy

- Acquisition by major medical device company or IPO

**THANK YOU**