

# Research and Evidence-Based Medicine Committee: 2010-11

# Evidenced-Based Medicine: Where Does it Fit in Foot and Ankle Surgery?

MODULE: Choosing the Appropriate
Statistical Analysis Tool



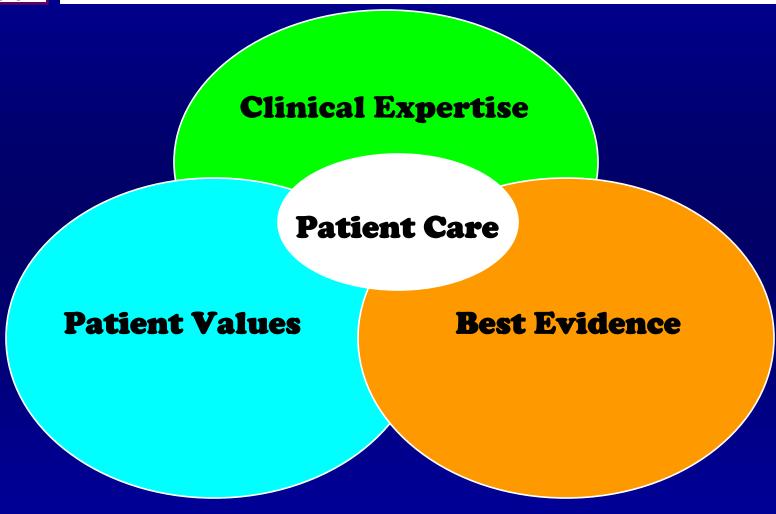
#### Evidence-Based Medicine

- ✓ The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of the individual patient
- ✓ It means integrating individual clinical expertise with the best available external clinical evidence from systematic research

Dr. David Sackett, 1996



#### Evidence-Based Medicine



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# Fundamental Principles

- ✓ Evidence is never enough
- **✓** Hierarchy within EBM

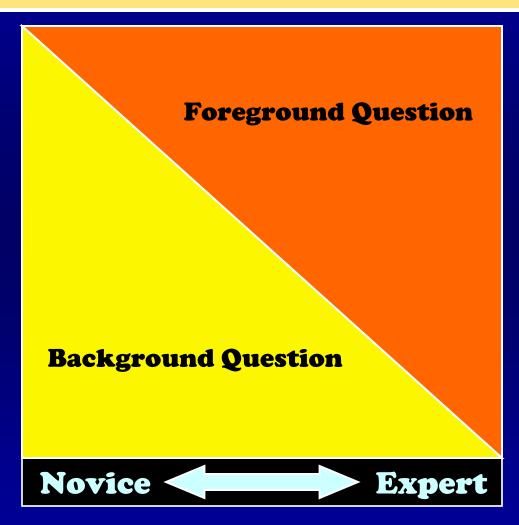


# Steps In EBM Process

- **✓ Clinical Problem**
- **✓ Question**
- **✓** Resource
- **✓** Evaluation
- **✓** Patient



# Asking the Question



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# Hierarchy of EBM

**Meta-Analysis** 

Systematic Review

Randomized Controlled Trial

**Cohort Studies** 

**Case Control Studies** 

Case Series/Case Reports

**Animal Research/Laboratory Studies** 

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# "P.I.C.O."

- ✓ Patient + Problem
- **✓** Intervention
- **✓** Comparison
- **✓** Outcome



# Levels of Evidence

- ✓January 2003
  - Journal of Bone and Joint Surgery American
- ✓ February 2005
  - American Academy of Orthopaedic Surgeons



### JBJS Am Levels of Evidence

- ✓I, II, III, IV, V based on design
- **✓**Types
  - Therapeutic
  - Prognostic
  - Economic
  - Decision Analysis



### JBJS Am: Levels of Evidence

- **✓ Randomized Control Trial** 
  - Level I or II
- **✓** Cohort
  - Level II or III
- **✓ Case Control** 
  - Level III
- **✓ Case Series** 
  - Level IV
- **✓** Expert Opinions
  - Level V

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### Levels of Evidence in Orthopaedic Journals

- ✓ Journal of Bone and Joint Surgery Am + Br
- ✓ Journal of Orthopaedic Trauma
- ✓ Journal of Shoulder and Elbow Surgery
- ✓ American Journal of Sports Medicine
- ✓ Journal of Prosthetics and Orthotics
- **✓** Foot and Ankle International
- ✓ Journal Hand Surgery
- ✓ Journal of Athroplasty

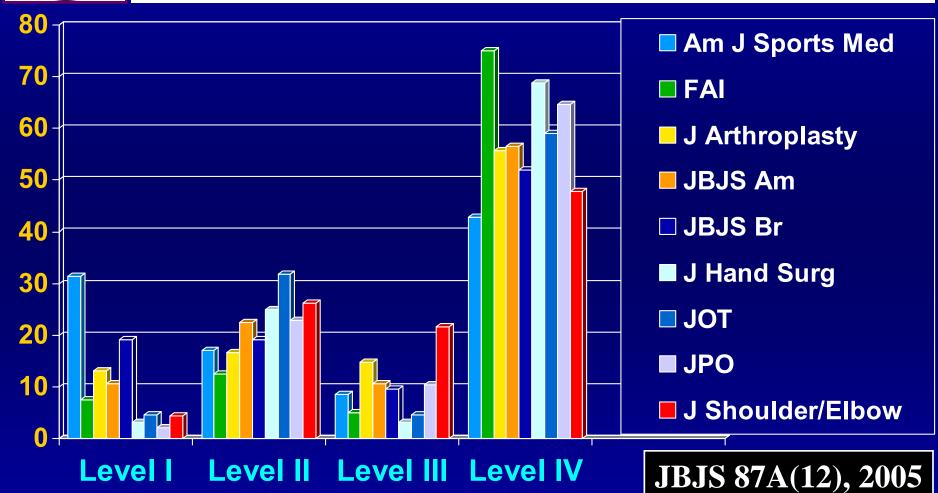
**JBJS 87A(12), 2005** 

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# Levels of Evidence

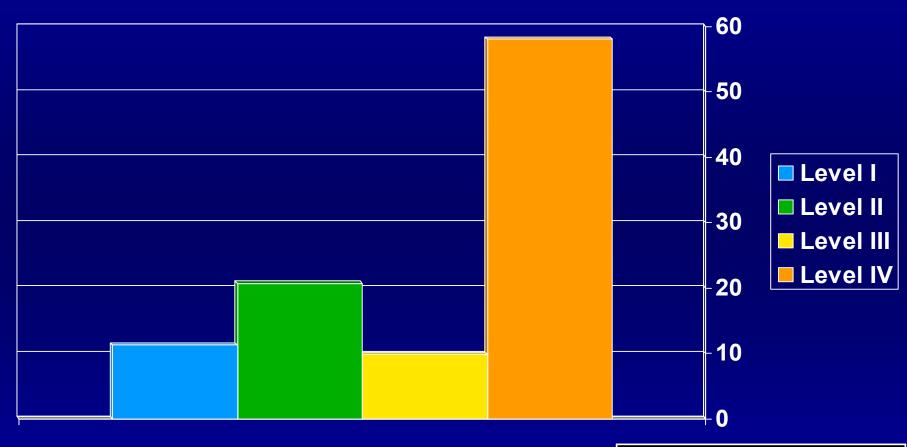


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# Levels of Evidence



**JBJS 87A(12), 2005** 

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# Evaluation of the Foot and Ankle Literature

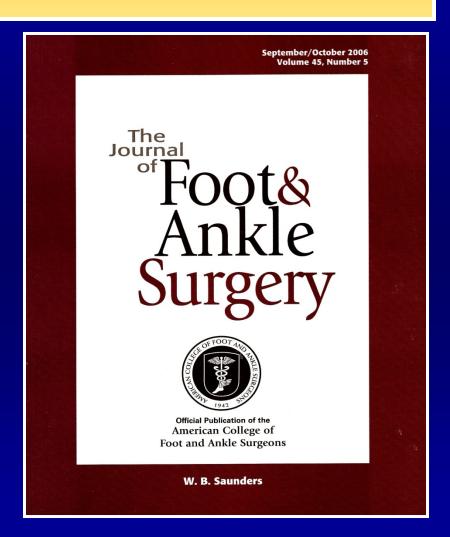
- ✓ Journal Foot and Ankle Surgery
- ✓ Foot and Ankle International



# Evaluation of the Literature

# ✓ Jan/Feb 2005 – Nov/Dec 2010

- 593 Articles
- 19 Level I



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# Evaluation of the Literature

# ✓ January 2005 – November 2010

- 1201 Articles
- 18 Level I

# Foot& Ankle®



www.faijournal.com

INTERNATIONAL

Hallux Metatarsophalangeal Joint Arthrodesis Using Dome-Shaped Reamers and Dorsal Plate Fixation: A Prospective Study

Nicholas R. Goucher, MD; Michael J. Coughlin, MD

Mitchell and Wilson Metatarsal Osteolomies for the Treatment of Hallux Valgus: Comparison of Outcomes Two Decades after the Surgery

Mladen Madjarevic, MD, PhD; Robert Kolundzic, MD, PhD; Danijel Matek, MD; Igor Smigovec, MD; Tomislav Crnkovic, MD; Vladimir Trkujla, MD

Scarl Osteotomy for Hallux Valgus Deformity: An Intermediate Followup of Clinical and Radiographic Outcomes

First Metatarsophalangeal Joint Arthrodesis as a Treatment for Failed Hallux Valgus Surgery

jerry sperga verma, vol.o. victoric y Conginia, 201 Metatarsophilangeal Joint Arthrodesis Hater Failed Keller-Brandes Procedure Patrick Vienne, MD: And Sukihankar, MD: Philippe Faire, MS; Clemen M.L. Werner, MD:

Ankle Arthropathy of Hemochromatosis: A Case Series and Review of the Literature

Mark B. Davie, FRCS (Tr. and Onth.): Terry Sudm, FRCS (Onth.)

Health-Related Quality of Life in Patients with Transtibial Amputation and Reconstruction with Bone Bridging of the Distal Tibia and Fibula

Michael S. Pinzur. MD Marco A. Guedes S. Pinto, MD; Matthew Saltzman, MD; Fabio Batista, MD: Frank Gottschalk, MD; Dainius Juknelli, MD

Bone Graft Harvest from the Proximal Tibia in Foot and Ankle Arthrodesis Surgery Michael R. Whinteboure, MRCS., BSr. Ben J.A. Lankeuzer, MA, FRCS (Tr. and Ordon.): Jan G. Whom, FRCS: Sephen Hopple, FRCS, FRCS (Orth.)

Navicular Stress Fractures: A Prospective Study on Athletes

Mid-Term Results of Titanium Hemi-Great Toe Implants
Kurt Frederick Knukel MD: Andrea Goole Menaer MD

Responsiveness of the Foot Function Index, AOFAS Clinical Rating Systems, and SF-36 after Foot and Ankle Surgery

Kinematic MRI of the Normal Ankle Ligaments Using a Specially Designed Passive

Positioning Device
Osamu Tokuda, MD; Hitomi Awaya, MD; Kotaro Taguchi, MD; Naofiuni Matsunga, MI

Location Modalities for Focused Extracorporeal Shock Wave Application in the Treatment of Chronic Plantar Fasciitis

Ronald Dorotka, MD; Manuel Sabeti, MD; Esther Simone Schubert, MD; Klemens Trieb, MD

Biphalangeal Fifth Toe

Etiologic Factors Associated with Symptomatic Achilles Tendinopathy

George B. Holmes, MD; Johnny Lin, M.

Continued on Table of Conten

American Orthopaedic Foot and Ankle Society

Swiss Foot and Ankle Society

The Japanese Society for Surgery of the Foot

The Korean Society of Foot Surgery Australian Orthopaedic

Australian Orthopaedic Foot and Ankle Society

Argentine Society for Foot and Leg Medicine and Surgery

Italian Society
of Medicine and Surgery of the Foot and Ankle

Brazilian Society of Foot Surgery

Belgian Society of Medicine and Surgery of the Foot

Israeli Orthopaedic Foot and Ankle Society

New Zealand Orthopaedic

South African Foot Surgeons Association

Spanish Society of Medicine and Surgery of the Foot

Turkish Society

of Orthopaedic Surgery and Traumatology

Canadian Orthopaedic Foot and Ankle Society Taiwanese Orthopaedic Foot and Ankle Society

November 2006 / Volume 27 / Number 11

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# Evaluation of the Literature

# "Target your reading to particular issues related to the patient"



#### EBM Literature Sources

- **✓** Cochrane Database
- **✓** Medline
- **✓** UpToDate
- **✓** Best Evidence
- **✓OVID**



### AGAINST - FOR

- √"Old Hat"
- ✓ Cook Book

  Medicine
- **✓ Population Studies**
- ✓ Lack of Gold Standard
- **✓** Access Difficulty

- **✓** Strong Evidence
- **✓** One Part
- **✓** Patient Decision
- **✓** Evidence Pyramid
- ✓ Trained Professionals



#### SELECTION OF THE APPROPRIATE STATISTICAL TOOL

- ✓ There are 3 steps in deciding which appropriate statistical tool should be used to evaluate for significance for a given data set.
- ✓ Follow the pathway that leads you down the appropriate pathway by following the "pathway slide" numbers at the top left of the slide.
- ✓ Each pathway slide will be followed by a slide that provides definitions.



#### STEP #1: Start Here

Pathway Slide # 1

What Type of Data Is It?

Continuous or Discrete

**Go To Pathway Slide #2** 

Categorical - Nominal

Go To Pathway Slide #6

Categorical – Ordinal

Go To Pathway Slide #7

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#### **DEFINITIONS**: What type of data is it?

- ✓ Continuous: when the values/observations belonging to it can take on any value within a finite or infinite interval
  - Example: height; weight; temperature; time
- ✓ Discrete: when the values/observations are distinct and separate (they can be counted)
  - Example: number of patients; blood group



#### **DEFINITIONS:** What type of data is it?

- ✓ Categorical: when the values/observations belonging to it can be sorted according to category
  - Example: male/female
- ✓ Nominal: when the values/observations belonging to it can be assigned a code in the form of a number, where the numbers are simply labels
  - Example: male coded as 1, female coded as 2
- ✓ Ordinal: when the values/observations belonging to it can be ranked (put in order)
  - Example: 0-10 pain scale (0=no pain; 10=worst possible pain)



#### STEP #2: Continuous or Discrete

Pathway Slide # 2 How Many Groups?

1 Group

Go to Pathway Slide #3

1 Group With Paired Data (before/after) Go to Pathway Slide #4 2 Groups With
Different
Individuals
Go to Pathway Slide #5

Greater Than
2 Groups

**ANOVA** 

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#### STEP #3: Continuous or Discrete: 1 Group

Pathway Slide # 3 Normally Distributed?

YES

t -Test

NO

**Wilcoxin Test** 

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#### **DEFINITIONS**

- ✓ Normally Distributed: a frequency distribution defined by a particular mathematical function; a normal random variable
  - Example: height at a given age, gender, race
- ✓ t-Test: a statistical inference used to determine the probability of something occurring by chance



#### **DEFINITIONS**

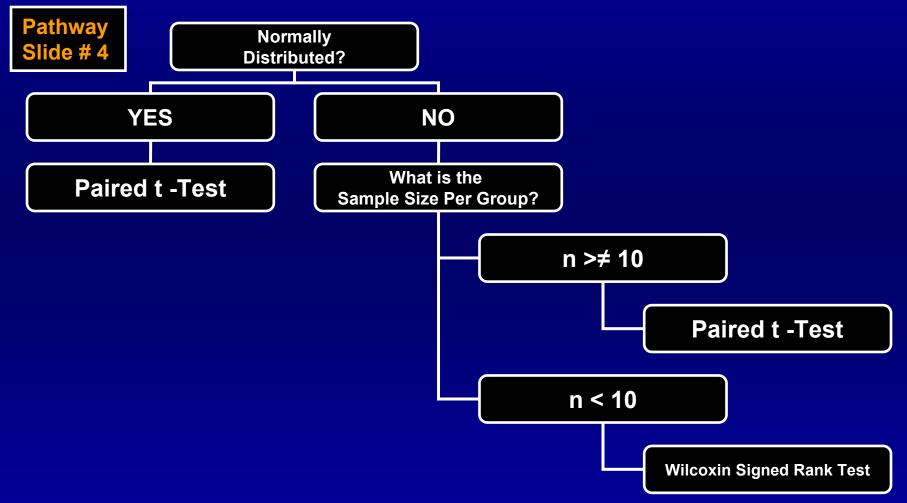
- ✓ Wilcoxin Test: compares two paired groups and calculates the difference between the set of pairs and provides information about the magnitude of the differences
- ✓ ANOVA (Analysis of Variance): a statistical inference to test differences between 3 or more groups or repeated times for a single group

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# STEP #3: Continuous: 1 Group with paired data (before/after)



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#### **DEFINITIONS**

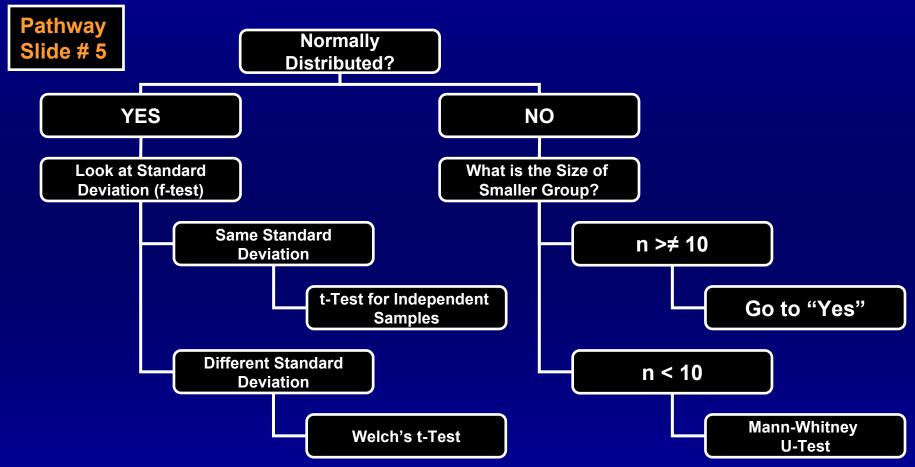
- ✓ Paired t-Test: used to determine whether there is a significant difference between the average values of the same measurement made under two different conditions
- ✓ Wilcoxin Signed Rank Test: designed to test a hypothesis about the median of a population distribution; e.g. before and after data (does not require the assumption that the population is normally distributed)

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# STEP #3: Continuous: 2 Groups with different individuals



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#### **DEFINITIONS**

- ✓ Standard Deviations: measure of the spread or dispersion of the data
- ✓T-Test for Independent Samples: used to compare two small sets of quantitative data when samples are collected independently of one another
- ✓ Welch's Test (similar to the t-test):

  tests two samples with unequal variances



#### **DEFINITIONS**

- ✓ Mann-Whitney U-Test: compares two unpaired groups; looks at relative ranks of subjects in the two groups
- **✓F-Test:** compares standard deviations



#### STEP #2: Categorical -Nominal

**Pathway How Many** Slide #6 Groups? 2 Groups With 1 Group With 1 Group **Different Paired Data** (before/after) Individuals **Chi-Square Test**; **One Sample Use Fischer's Test McNemar Test Binomial Test** if expected value(s) < 5

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#### **DEFINITIONS**

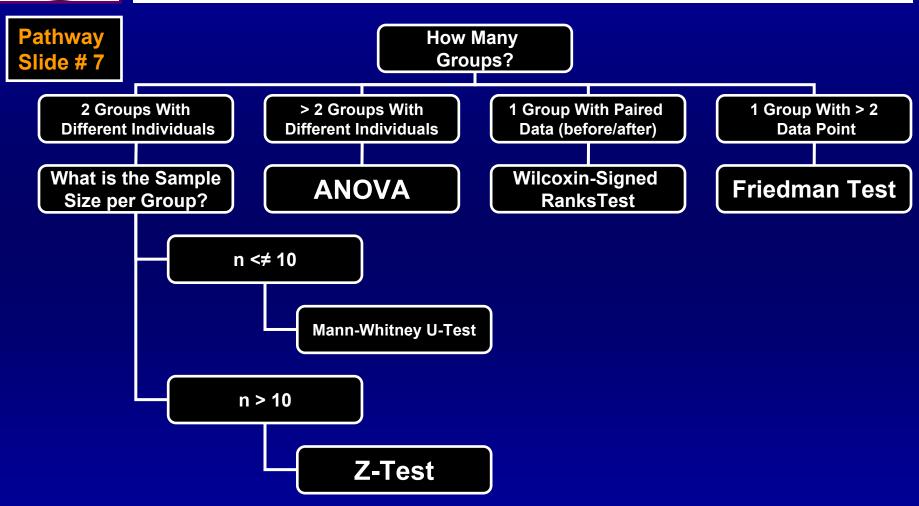
- ✓ One Sample Binomial Test: when there are two possible outcomes
- ✓ McNemar Test: tests the difference between paired proportions; same subjects before and after measurements
- ✓ Chi-Square Test: comparison of two attributes in a sample of data/population to determine if there is any relationship between them
- ✓ Fischer's Exact Test: used to determine if there are nonrandom associations between two categorical variables; used when expected frequencies are small

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### STEP #2: Categorical -Ordinal



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#### **DEFINITIONS**

- ✓ Mann-Whitney U-Test: compares two unpaired groups; looks at relative ranks of subjects in the two groups
- ✓ **Z-Test:** used to compare the mean of a sample with the population mean when the standard deviation is known
- ✓ ANOVA (Analysis of Variance): a statistical inference to test differences between 3 or more groups or repeated times for a single group

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#### **DEFINITIONS**

- ✓ Wilcoxin Signed Rank Test: designed to test a hypothesis about the median of a population distribution; e.g. before and after data (does not require the assumption that the population is normally distributed)
- ✓ Friedman Test: used to detect differences across multiple test attempts



### **CONCLUSIONS**

- ✓ After following this pathway you can be confident that you are using the appropriate statistical tool to establish significance of your data
- ✓ Utilize a computer statistical package to conduct the actual statistical analysis
- ✓ It is a good idea to get a statistician involved in the process



# Where Does EBM Fit with Foot and Ankle Surgery??



#### Where Does EBM Fit?

- **✓** ACFAS
- **✓** Research
- ✓EBM ONLY??
- **✓Your Step**





# THANK YOU!



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