Walter Reed Army Medical Center and Veterans Administration Amputee Healthcare & Prosthetics Workshop

Lower-Limb Prostheses II
Study I

MFCL Level Test
Validation Study

- MFCL (Medicare Functional Classification Level)
  - Inter-rater reliability of three standard methods for determining the MFCL
Question

• Which methods are more consistent for determining the MFCL?
  – Variability between raters
Purpose of the Study

- Define most repeatable source for determining the MFCL for purposes of prescription rationale and reimbursement
Study Design

- Validation Study
  - 3 Methods for measurement
    - Standard method (intuitive assessment of K levels)
    - Amputee Mobility Predictor (AMP)
    - Six minute walk test
  - Raters for each test
  - Patients see all raters (in random order)
    - Sample sizes determined using statistical methods
Measures / Methods

• Examine variability in the scores for each method
• Consistency between the determined MFCL for the different methods and different raters
Study II

Prosthetic Knee Study
Prosthetic Knee Study

• Comparison of a conventional knee system and a microprocessor controlled knee (C-Leg) for traumatic injury amputees from acute care stage at WRAMC into the VA.
Study Questions

• Are there benefits to using a microprocessor controlled knee mechanism?
  – Biomechanical advantages?
  – Patient Satisfaction / Perception?
Study Design

• Randomized crossover study
  – ½ C-Leg (as first prosthesis)
  – ½ Mauch SNS (as first prosthesis)
• Same prosthetic socket and foot for both legs
• Convenience sampling as subjects cycle through WRAMC
• Combination of subjective/objective measures
Primary (Null) Hypotheses

• No patient preference between C-Leg and the SNS.
• No difference in amount of use between C-Leg and the SNS.
• No difference in gait patterns when starting out with the C-Leg.
Training of Research Personnel

• Conference
  – prosthetists for standardized set-up of prostheses
  – therapists for standardized training of persons using the prostheses
  – experimentalists for standardized data collection
  – senior physicians in charge of amputee care
Measurement Tools

- Clinical tests - PEQ, AMP, SF-36
- Accelerometer/step counter
- Gait analysis
  - kinematics, kinetics, simple energy cost measures, time distance measurements
Time course of measurements

• Clinical Testing / Gait analyses
  – At WRAMC at time of fitting
  – Six months
  – One year
  – Eighteen months

• Step Counter Tests
  – Bimonthly
Study III

Prosthetic Socket Study I
Short Term Study at WRAMC
Prosthetic Socket Study

• Comparison of a vacuum assisted system and a urethane liner with sleeve suspension
Study Questions

• Are there benefits to using a vacuum assisted socket system over a urethane liner (TEC)?
  – Blood flow and volume advantages
  – Patient Satisfaction / Perception?
Study Design

- Randomized crossover study
  - ½ VASS (as first system)
  - ½ urethane liner (TEC) (as first system)
- Same prosthesis, same foot for both
- Convenience sampling as subjects cycle through WRAMC
- Combination of subjective/objective measures
Primary (Null) Hypotheses

• No patient preference between VASS or urethane liner with sleeve suspension.
• No difference in use between conditions.
• No difference in daily volume fluctuations between the two conditions.
Measurement Tools

• Clinical tests - PEQ, AMP, SF-36
• Accelerometer/step counter
• Volume measurements
• Blood flow?
• Tissue oxygenation?
Time course of measurements

• All at WRAMC
  – Volume measurements weekly
  – Blood flow and tissue oxygenation at monthly intervals until discharge
• Crossover into the VA at six months
• Interim analysis
Study IV

Prosthetic Socket Study II
Long Term Study at VA
Prosthetic Socket Study

• Comparison of a vacuum assisted system and urethane liner with sleeve suspension
Study Questions

• Are there benefits to using a vacuum assisted socket system over a urethane liner (TEC)?
  – Blood flow and volume advantages
  – Patient Satisfaction / Perception of socket fit
Study Design

- Randomized study
  - ½ VASS
  - ½ urethane liner (TEC)
- Same prosthesis, same foot for both
- Recruitment of existing amputees through the VA system
- Combination of subjective/objective measures
Primary (Null) Hypotheses

- No patient preference between VASS or urethane liner with sleeve suspension.
- No difference in use between conditions.
- No difference in daily volume fluctuations between the two conditions.
Measurement Tools

- Clinical tests - PEQ, AMP, SF-36
- Accelerometer/step counter
- Volume measurements
- Blood flow?
- Tissue oxygenation?
- Video/Photographic record of tissue on residual limb
- Adverse events
Time course of measurements

• All at VA (monthly exam)
  – Volume measurements
  – Video/photographs
  – Step counter
  – Blood flow and tissue oxygenation
  – Tissue quality
  – Adverse events
Potential Problems

• Defined clinical team
  – Getting the team to “buy into” the project

• Standardization
  – Fitting
  – Training
  – Data collection tools
  – Administration

• Funding

• Political support

• No clear definition for a microprocessor
Additional Notes

• Medical teleconferencing
  – Patient acceptance
  – Staff “buy in”
  – Assistance of transfer from WRAMC to VA
• Consensus on crossover?
• Integration with database group
• Need DoD/VA technology committee
  – Assists in defining terminology and indications for new componentry
VA and DoD Research Leading Tomorrow’s Healthcare

- Stay focused on helping soldiers and veterans
- Clinical questions drive research questions
- New technology and energy into patient care
- “Follow Me”