

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
 - 1/2 C-Leg (as first prosthesis)
 - 1/2 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
 - 1/2 VASS (as first system)
 - 1/2 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
 - 1/2 VASS
 - 1/2 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”