SAFETY, BIOENERGETIC AND HEALTHCARE COST EFFICACY OF THE C-LEG MICROPROCESSOR PROSTHETIC KNEE

A Review of the Literature

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OBJECTIVE

Following this presentation, the participant will recall & understand strengths/weaknesses of literature available (as of Dec 2010) associated with microprocessor prosthetic knees in the areas of:

- Healthcare Cost
- Safety
- Energy Efficiency in Gait
1.8 million U.S. amputees

- ≈14% (.25M) UE amputees
- Remaining 86% are LE involved ≈ (1.35M)

- ≈26% (357,000) have TFA
- ≈28% (378,000) have TTA
- ≈33% (446,000) Toe Amp
- ≈13% (175,000) Other LE

- ≈95% of the 357,000 persons with TFA are:
  - Elderly
  - Dysvascular
MORE MPK'S BEING USED, BEING RX'D

- Efficacy?
- Numerous outcome papers covering many areas
- What is known?
  - Could we possibly evaluate every area studied?

Team interest:
- Safety
- Bioenergetic Efficiency in Gait
- Cost
KEYWORDS

1° Search Terms:

- Microprocessor Controlled Prosthetic Knee
- C-Leg

2° Search Terms:

- Safety
- Falls
- Stumbles
- Balance
- Energy Efficiency
- Cost

Timeline of 1995-2009 selected

1. Default Boolean Search
2. Deselecting map term to subject heading (stops MeSH search)
DATABASES

Medline ("Pubmed")
  • via Ovid Interface

CINAHL
  • via EBSCO Host Interface

Cochrane & Embase
  • had none so not included

Manual search of journals in NU RERC SSC (from 2006)
  • In case database search missed key papers
ARTICLE & SCREENING

References exported to Endnote
- Eliminate duplicates

Screen for inclusion/exclusion

Classify as:
- Pertinent
- Not Pertinent
- Uncertain pertinence

Inclusion:
1. Comparative study
2. MPK used in one arm of trial
3. Must address one pre-selected key area (safety, energy efficiency, cost)

Exclusion:
1. Endoprosthetic knees (TJA)
2. Editorial Papers
3. Paper does not address key area
4. Duplicate paper
n=45 studies retrieved from database search
n=3 studies retrieved from manual search
Total N=48

Potentially appropriate studies for classification of pertinence
n=34

Duplicate studies eliminated
n=14

Studies eliminated as not pertinent
n=16

Pertinent articles for energy efficiency
n=8

Pertinent articles for safety
n=7

Pertinent articles for cost effectiveness
n=3
QUALITY ASSESSMENTS

PEDro Scale

**methodologic quality** (safety & energy efficiency topics)
reliable in rehabilitative clinical trials

0-10 score

- \( \uparrow \text{scores} = \uparrow \text{methodologic quality} \)
- \( >6/10 = \text{high methodologic quality} \)
- \( < 6/10 = \text{low methodologic quality} \)

Bias Risk is:

- **Low**
  - High internal validity.
  - Study conclusions not likely altered if methods changed.
- **Moderate**
  - Study conclusions not likely altered if methods changed.
- **High**
  - Study conclusions likely or very likely altered if methods changed.
Cost efficacy - methodologic quality

- PEDro scale & SIGN 50 could not be used.
- used internally consistent/valid grading system specifically for assessing methodologic quality of health economic evaluations
  - rates economic studies on internal & external validity
  - numeric score facilitates comparisons
  - Differentiates b/t lower & higher quality evaluations
    - 16 criteria to score from 0 (low quality) to 100 (high quality)

Grade literature for Recommendation (A to D)
Following methodologic quality & bias risk assessments, level & grade of evidence determined by Center for Evidence Based Medicine model

Effect Size
Cohen effect sizes: small (0.2), medium (0.5), large (0.8)
HEALTHCARE COST EFFICACY
Scores: 81, 82, 91/100

Cost Utility Scores = high effect size
Total Cost = low effect size

Translation, regardless of new or experienced prosthetic user, the C-Leg costs more, but is worth funding.
Why? The higher initial costs will be made up in terms of satisfaction (QOL, etc), less time lost from work (societal productivity), less funds lost to trips and services to healthcare (i.e. prosthetic adjustments).

Grade of Recommendation = B

Strengths: samples (20, 26, 100), mixed methods/similar conclusions, some projections as long as 8yrs

Limitations: heavy reliance on modeling vs. actual costs over time, socialized medicine vs. US model, countries with good outcomes now facing economic downturn

3 STUDIES: SWEDEN, ITALY, NETHERLANDS

Socialized Medical Reimbursement Models
BIOENERGETIC EFFICIENCY IN GAIT
SAMPLE STUDY
Seymour et al. POI 2007

MPK vs. NMKM (n=13)

• Energy Expenditure
  • SSWS & FPWS Treadmill

• Obstacle course
  • Carrying load & hands free

• QOL: SF-36
  • Use of C-Leg shows “minimal quality of life” impairment
C-Leg vs. NMKM (n=15)

- Energy efficiency & total daily energy expenditure
  
  [Link](http://www.unu.edu/unupress/food2/uid05e/uid05e00.htm)

- Gait Biomechanics

- Balance
  (Sensory Organization Test-SOT)

- PEQ
  (Improvement on PEW [QOL])
OF 8 STUDIES...

Methodologic Quality was generally low:
• 1 had 6/10 (Good), 2 had 5/10, 3 had <5/10 and 2 unscored

Bias Risk was moderate
• 1 low risk, 5 Moderate risk and 2 unscored

Effect size calculated in 2 studies only (predominantly insufficient data)
• High effect (.8 to 1.8)
• 4/8 studies reported statistical improvement (2 case reports)

7/8 studies utilized expired gas analysis (VO2)
• Controlled movement with varied means
• Treadmill, overground floor mounted timing lights or self pace

Also doubly labeled water for free living energy consumption
• TDEE for movement significantly increases
• Disagrees with step count → unresolved

Problems:
• Sample sizes range from 1, 4, 6, 8, 13, 15
• Mean Sample Ages were 20’s, 30’s, 40’s
• Accommodation poorly discussed
  • Not reported in two cases, 10hrs in one case, 3mos and 2-44mos in others

CEBM Evidence Grade: D
**Energy Efficiency in Gait**

- **TFA SSWS:**
  - 0.87 m/sec (52.2 m/min) → 1.04 m/sec (62.4 m/min)

Graph showing energy efficiency (ml/kg/meter) versus gait speed (meters/min) for different knee types and studies.
SAFETY & STABILITY OUTCOMES
SAMPLE STUDY
Kahle et al. JRRD 2008

C-Leg vs. NMKM (n=19)

- Timed Walking Tests
  - SSWS & FPWS
  - Flat & Uneven Terrain
- Stairs
  - Montreal Rehabilitation Performance Profile (MRPP)
  - Qualitative/Observational Performance Assessment
    - Also timed
- Safety
  - Recall and self reported stumbles & falls

Preference

QOL: PEQ

Perceived Function & Prosthesis-Related QOL
- Use of C-Leg shows improvements in both domains
SAMPLE STUDY

C-Leg vs. NMKM (n=15)

- Energy efficiency & total daily energy expenditure
  [Link](http://www.unu.edu/unupress/food2/uid05e/uid05e00.htm)

- Gait Biomechanics

- Balance
  (Sensory Organization Test-SOT)

- PEQ
  (Improvement on PEW [QOL])
SAMPLE STUDY
Hafner et al. APMR 2007

C-Leg vs. NMKM (n=17)
Step count & Distance traveled per day
Step length/symmetry
“Basic Mobility”
   Amputee Mobility Predictor (AMP)
Health
   SF-36
Step symmetry: Level ground
Stair descent/ascent
   SAI (Stair Assessment Index)
Hill ascent/descent
   HAI (Hill Assessment Index)
Timed Obstacle Course: Uneven Ground
Cognitive Demand: Walk & Talk (Cell Phone)
Preference
Safety (PEQ-A) MKM improved safety
   Recall and self reported stumbles & falls
QOL: PEQ SF-36
PEQ MKM improved QOL
AMP & SF-36 no significant differences b/t knees
   Use of C-Leg shows improvements in both domains
Methodologic Quality was generally low:
- 1 had 5/10, 5 had <5/10 and 1 unscored

Bias Risk was moderate
- 6 Moderate risk and 1 unscored

Effect size calculated in 2 studies only (predominantly insufficient data)
- Range of effect sizes (.2 to 1.4)
- 5/7 studies reported statistical improvement (1 case reports)

5/7 studies utilized recall of stumbles/falls/questionnaire
- PEQ-A
- Stumble/fall recall
- Survey

1 study used SOT (Neurocom-dynamic posturography)
1 study used tripping task in motion lab in varied walking conditions

Problems:
- Sample sizes range from 1, 2, 7, 10, 12, 185
  - Mean Sample Ages were 30's - 50's
- Accommodation poorly discussed
  - Ranges, means
  - 30 minutes in one instance

CEBM Evidence Grade: B
Walking Speed
- SSWS
- FPWS

Biomechanics
- Flat Ground
- Ramps
- Stairs
- Uneven Ground
- Effect on Turning, Start, Stop,

Obstacle course performance
- Home environment (living space)
- Outdoor: grass to rock transitions

Subjective
- Satisfaction
- Perceived Function
- Preference
- Body Image

Long term effect on sound limb
LIMITATIONS

Smaller number of studies (7, 8, 3) & sample sizes (n=??)

Heterogeneity in sample size, methods & outcomes prohibits Meta Analyses

Age mean and Etiology does not match “typical” amputee
  • 40's vs 60-70’s
  • Trauma vs. Dysvascular

Accommodation tremendously varied:
  • Not reported
  • Minutes
  • Weeks
  • Mos
  • Yrs

Alignment methods varied or non-reported
LASAR, CPO, NR...
SUMMARY

Compared with Hydromechanical Knee Prostheses, the MPK:

Cost Effective
- Costs more but worth funding because
  - ↓ cost associated with healthcare visits
  - MPK users more societally productive

Reduced metabolic demand (not statistically different)
- “clinically significant”
- On both doubly labeled water & oxygen uptake overground

Improved Safety
- ↓ stumbles
- ↓ semi-controlled falls
- ↓ uncontrolled falls
- SOT score ↑ (Neurocom)
- Found to provide stumble recovery
  - With random tripping
  - Hindfoot stepping on a floor obstacle
REFERENCES


QUESTIONS?

Thank you to USF Researchers
Jason T Kahle & M. Jason Highsmith