Amputation Level Determination in the Dysvascular Patient

Clinical Approach and Current Research

Joseph M. Czerniecki, MD
Professor of Rehabilitation
University of Washington

Associate Director
Rehabilitation Research Center of Excellence
Limb Loss Prevention and Prosthetic Engineering
Amputation Level Determination in the Dysvascular Patient

• How are decisions currently being made about choosing amputation level in the dysvascular patient.

• What are the limitations.

• What is the role of the physiatrist in decision making.

• How we might do a better job.
Amputation Surgery to Maximal Functional Outcome

What are the most important factors that determine outcome?
General Model of Functional Recovery after Illness or Injury

- Onset of Injury
- Onset of Recovery
- Maximal Functional Restoration
Rehabilitation of the Amputee

- Onset of Injury
- Decision to Amputate
- Prosthetic Fitting
- Onset of Recovery
- Maintenance of Function
- Wound Healing – Prevention of Complications
When to Amputate? Where to Amputate?

- Ulceration
- Revascularization surgery
- Frequent Clinic visits
- Hospital admission
- Muscle atrophy / joint contracture
- Reduced cardiopulmonary reserve
- Reduction in mobility
Amputation Level Selection
A Team Decision

Outcome

Mortality  Healing  Mobility
Amputation Decision Making: A team decision

- Surgeon - what is the probability the amputation surgery will heal at each major amputation level?

- Surgeon/Anesthesia/Cardiology – what is the mortality risk at each major amputation level?

- Rehabilitation Physician - what will the functional outcome differences be at each major amputation level?

- Patient - balancing the risks of healing probability and impact on function: what is best for me?
“Reasonable people need to know their treatment options, the general risks, benefits, and probable outcomes of each option, and the reasons that the physician has recommended a specific treatment.”

*Informed Consent: James Bernat, Muscle and Nerve, 2001*
Mortality

- Mortality Rates / What time period is important?
  - Peri-operative (30 d)
  - 24 month
  - Overall Trajectory

- Effect of amputation level
## Operative Mortality

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Set</td>
<td>National NSQIP &gt; 9,000 subjects</td>
<td>Single Medical Center</td>
<td>Single Medical Center</td>
<td>National NSQIP 4,600 subjects (crit limb isch)</td>
</tr>
<tr>
<td>30 d Mortality TT</td>
<td>6.5%</td>
<td>4.2%</td>
<td>5%</td>
<td>7.6%</td>
</tr>
<tr>
<td>30 d Mortality TF</td>
<td>12.8%</td>
<td>17.5%</td>
<td>16%</td>
<td>12%</td>
</tr>
</tbody>
</table>

* Multivariate Analysis

30 d Mortality TM 1.6% Stone 2007 / 3% Pollard 2006 +

+ TM data are small case series
Transtibial vs Transfemoral Survival

![Graph showing survival rates for BKA and AKA procedures.]

At Risk

<table>
<thead>
<tr>
<th></th>
<th>BKA:</th>
<th>AKA:</th>
</tr>
</thead>
<tbody>
<tr>
<td>704</td>
<td>310</td>
<td>62</td>
</tr>
<tr>
<td>132</td>
<td>39</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Transmetatarsal Survival

Mean survival 16 months

Figure Legend:

From: *Predictors of Healing and Functional Outcome Following Transmetatarsal Amputations*

## Amputation Wound Healing

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Set</strong></td>
<td>National NSQIP &gt; 9,000 subjects</td>
<td>Single Medical Center</td>
<td>Single Medical Center</td>
<td>National NSQIP 4,600 subjects (crit limb isch)</td>
</tr>
<tr>
<td><strong>30 d Mortality TT</strong></td>
<td>6.5%</td>
<td>4.2%</td>
<td>5%</td>
<td>7.6%</td>
</tr>
<tr>
<td><strong>30 d Mortality TF</strong></td>
<td>12.8%</td>
<td>17.5%</td>
<td>16%</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Wound Complications TT</strong></td>
<td>22.7% +</td>
<td>______</td>
<td>17% #</td>
<td>11.3% #</td>
</tr>
<tr>
<td><strong>Wound Complications TF</strong></td>
<td>11.7% +</td>
<td>___</td>
<td>7% #</td>
<td>7.8% #</td>
</tr>
</tbody>
</table>

* Multivariate Analysis, + re-operation rate, # wound complication rate

**TM Revision rate** - Nguyen 2006 40%, Landry 2011 35%, Stone 2007 35%
Mortality / Wound Healing and Amputation (Summary)

- Mortality rate is extremely high
- Mortality risk increases ➔ proximal amputation
- Predictive Models of mortality are being developed
    https://www.surgery.wisc.edu/research/clinical-research-program/amputation_mortality_predictor.uta
- Wound complications and revisions ➔ distal amputation
The Rehabilitation Assessment and its Contribution to Amputation Level Recommendations
Rehabilitation Assessment

- Clinical Prediction of Functional Outcome at each major amputation level.
- Rehabilitation treatment recommendations to increase function and prevent deterioration in function.
- Recommendations about best environment of care after discharge from surgery.
Conceptual Approach to Functional Outcome Determination

Amputation Surgery

Amputation Level Demands

Rehabilitation

Death

Delayed Healing

Capacity

Outcome
Define comorbidities and identify the functional impact.
Premorbid Functional Status
ICF – International Classification of Function
Functional demands and benefits of Prosthetic Limb types
Clinical Prediction

Biopsychosocial Factors + Environmental Factors + Prosthetic Limb Challenges and Advantages = Functional Outcome Prediction
A Team Decision

Outcome

Mortality  Heating  Mobility
Research into Mobility Outcome Prediction

Co-investigators
Dan Norvell, PhD, Rhonda Williams, PhD, Aaron Turner, PhD, Kevin Hakimi, MD
Primary Research Aim

- Develop and validate a Patient Specific Prediction Model in dysvascular amputees that would allow the prediction of mobility outcome at 1 year based upon peri-operative factors.
Personalized Medicine

• personalized medicine
• noun
• an approach to the practice of medicine that uses information about a patient’s unique genetic makeup and environment to customize the patient's medical care to fit his or her individual requirements.
What is the lowest healing probability you would accept to choose a below knee amputation?

<table>
<thead>
<tr>
<th>Healing Probability</th>
<th>Operative Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>90%</td>
<td>0% (1)</td>
</tr>
<tr>
<td>80%</td>
<td>1%</td>
</tr>
<tr>
<td>70%</td>
<td>2%</td>
</tr>
<tr>
<td>50%</td>
<td>3%</td>
</tr>
<tr>
<td>40%</td>
<td>4%</td>
</tr>
<tr>
<td>30%</td>
<td>5%</td>
</tr>
<tr>
<td>20%</td>
<td>10% (2)</td>
</tr>
<tr>
<td>10%</td>
<td></td>
</tr>
</tbody>
</table>
Is there a need for a mobility prediction model?
# The TT / TF Ratio as an Index of Quality Decision Making

<table>
<thead>
<tr>
<th></th>
<th>Average Ratio</th>
<th>Min</th>
<th>Max</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA</td>
<td>1.5 - 1.6</td>
<td></td>
<td></td>
<td>Bates 2006, Cruz 2003</td>
</tr>
<tr>
<td>England</td>
<td></td>
<td>.73</td>
<td>1.2</td>
<td>Moxey 2010</td>
</tr>
<tr>
<td>NHS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>.81</td>
<td></td>
<td></td>
<td>Dillingham 2005</td>
</tr>
<tr>
<td>Medicare</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Variation in Clinical Practice

- 2009 VHA Amputation Surgery Data (Diabetes PVD)
- AK /BK ratio in different VISNs (AK/BK – 1)
- Increase neg more BK, Increase pos more AK
- Obvious differences in how decisions are made
AMPREDICT I

- Prospective Multicenter Trial

- VAPSHCS, Denver VA, Colorado Health Science Center, Harborview Medical Center
Subjects

• L/E amputation secondary to diabetes, PVD
  – Incident Major Amputation (TM, TT, TF)
  – Cognitive status adequate to participate
  – Some ambulatory mobility
Methodology

• Baseline in the peri-operative period
  – (immediate preoperative – 6wks postoperative)

• F/U at 6 wks, 4 months, 1 year
Demographic Co-variates

- Age
- Gender
- BMI
- Marital status
- Race
- Employment status
- Education level
- Living status
- Socioeconomic status
# Co-Morbidities

<table>
<thead>
<tr>
<th>Score</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Myocardial infarction (history, not ECG changes only)</td>
</tr>
<tr>
<td></td>
<td>Congestive heart failure</td>
</tr>
<tr>
<td></td>
<td>Peripheral vascular disease (includes aortic aneurysm ≥ 6 cm)</td>
</tr>
<tr>
<td></td>
<td>Cerebrovascular disease: CVA with mild or no residua or TIA</td>
</tr>
<tr>
<td></td>
<td>Dementia</td>
</tr>
<tr>
<td></td>
<td>Chronic pulmonary disease</td>
</tr>
<tr>
<td></td>
<td>Connective tissue disease</td>
</tr>
<tr>
<td></td>
<td>Peptic ulcer disease</td>
</tr>
<tr>
<td></td>
<td>Mild liver disease (without portal hypertension, includes chronic hepatitis)</td>
</tr>
<tr>
<td></td>
<td>Diabetes without end-organ damage (excludes diet-controlled alone)</td>
</tr>
<tr>
<td>2</td>
<td>Hemiplegia</td>
</tr>
<tr>
<td></td>
<td>Moderate or severe renal disease</td>
</tr>
<tr>
<td></td>
<td>Diabetes with end-organ damage (retinopathy, neuropathy, nephropathy, or brittle diabetes)</td>
</tr>
<tr>
<td></td>
<td>Tumor without metastases (exclude if &gt;5 y from diagnosis)</td>
</tr>
<tr>
<td></td>
<td>Leukemia (acute or chronic)</td>
</tr>
<tr>
<td></td>
<td>Lymphoma</td>
</tr>
<tr>
<td>3</td>
<td>Moderate or severe liver disease</td>
</tr>
<tr>
<td>6</td>
<td>Metastatic solid tumor</td>
</tr>
<tr>
<td></td>
<td>AIDS (not just HIV positive)</td>
</tr>
</tbody>
</table>

NOTE. For each decade > 40 years of age, a score of 1 is added to the above score.
Abbreviations: ECG, electrocardiogram; CVA, cerebrovascular accident; TIA, transient ischemic attack; AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus.
Other Health Co-Variates

- Lower extremity arterial reconstruction
- Traumatic brain injury
- Joint replacement
- Hypertension
- Post traumatic stress disorder
- Alcohol consumption / Smoking history
- History of treated anxiety or depression
- Premorbid LCI score
- Self Perceived Health Status
Outcome Measures

• Self Care Status (Groningen Activity Restriction Scale)
• Prosthetic Use
• Satisfaction with Life
• Satisfaction with Mobility
• Mobility (LCI-5)
  – Mobility Success
The Locomotor Capability Index

Table 1. The LCI With Items Graded on a 5-Level Ordinal Scale (LCI-5)

No (0), If Someone Helps Me (1), If Someone Is Near Me (2), With Ambulation Aids (3), Without Ambulation Aids (4)

1. Get up from a chair
2. Pick up an object from the floor when you are standing up with your prosthesis
3. Get up from the floor (eg, if you fell)
4. Walk in the house
5. Walk outside on even ground
6. Walk outside on uneven ground (eg, grass, gravel, slope)
7. Walk outside in inclement weather (eg, snow, rain, ice)
8. Go up the stairs with a hand-rail
9. Go down the stairs with a hand-rail
10. Step up a sidewalk curb
11. Step down a sidewalk curb
12. Go up a few steps (stairs) without a hand-rail
13. Go down a few steps (stairs) without a hand-rail
14. Walk while carrying an object
Results

- Screened: 239
- Eligible: 136 (57%) (prev amp, cog, mob)
- Enrolled: 87 (64%)
- Retained: 75 (86% of those enrolled)
- Lost:
  - 8 deaths
  - 4 withdrawals
  - 1 lost to f/u
“Mobility Success” as the Key Outcome Variable
# Mobility Success and Satisfaction with Mobility

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>RD* (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amputation level**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TT</td>
<td>.11 (.02, .20)</td>
<td>.02</td>
</tr>
<tr>
<td>TF</td>
<td>-.11 (-.28, .06)</td>
<td>.21</td>
</tr>
<tr>
<td>Age†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>55-64 years</td>
<td>-.05 (-.32, .21)</td>
<td>.68</td>
</tr>
<tr>
<td>65+ years</td>
<td>-.47 (-.71, -.24)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Anxiety/depression</td>
<td>-.24 (-.42, -.06)</td>
<td>.01</td>
</tr>
<tr>
<td>Self perceived health</td>
<td>.16 (-.02, .35)</td>
<td>.08</td>
</tr>
<tr>
<td>Satisfied with mobility</td>
<td>.20 (.03, .37)</td>
<td>.02</td>
</tr>
</tbody>
</table>

*Risk differences generated from a negative binomial regression model represent an increase (or decrease if negative) in the success rate relative to reference category

**TM = Reference category
## Mobility Success and Satisfaction with Life

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>RD* (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amputation level**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TT</td>
<td>.10 (-.03, .24)</td>
<td>.14</td>
</tr>
<tr>
<td>TF</td>
<td>-.13 (-.29, .04)</td>
<td>.14</td>
</tr>
<tr>
<td>Age†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>55-64 years</td>
<td>-.06 (-.32, .19)</td>
<td>.62</td>
</tr>
<tr>
<td>65+ years</td>
<td>-.46 (-.69, -.23)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Anxiety/depression</td>
<td>-.22 (-.38, -.07)</td>
<td>.005</td>
</tr>
<tr>
<td>Self perceived health</td>
<td>.19 (.05, .32)</td>
<td>.009</td>
</tr>
<tr>
<td>Satisfiewith life</td>
<td>.19 (.07, .30)</td>
<td>.001</td>
</tr>
</tbody>
</table>

*Risk differences generated from a negative binomial regression model represent an increase (or decrease if negative) in the success rate relative to reference category

**TM = Reference category
## Rates of Mobility Success

<table>
<thead>
<tr>
<th>Outcome</th>
<th>TM (N=26)</th>
<th>TT (N=42)</th>
<th>TF (N=7)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility “Success”</td>
<td>9 (35%)</td>
<td>17 (41%)</td>
<td>2 (29%)</td>
<td>.78</td>
</tr>
</tbody>
</table>

*P-value based on chi-square test.
# Multivariate Prediction Model of Mobility Success

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Coefficient</th>
<th>P-value</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amputation level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TT</td>
<td>.488</td>
<td>.45</td>
<td>1.6 (.47, 5.7)</td>
</tr>
<tr>
<td>TF</td>
<td>-.127</td>
<td>.92</td>
<td>.88 (.08, 9.4)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>-.142</td>
<td>.001</td>
<td>.87 (.80, .94)</td>
</tr>
<tr>
<td><strong>Alcohol consumption score</strong>†</td>
<td>-.435</td>
<td>.02</td>
<td>.65 (.46, .94)</td>
</tr>
<tr>
<td><strong>Previous treatment anxiety/depression</strong></td>
<td>-1.56</td>
<td>.03</td>
<td>.21 (.05, .84)</td>
</tr>
<tr>
<td><strong>Self-perceived health good to excellent</strong>††</td>
<td>1.04</td>
<td>.096</td>
<td>2.8 (.83, 9.6)</td>
</tr>
</tbody>
</table>

AMPREDICT I: Results for the logistic regression for 12-month mobility success (n=81).

*TM = Reference category
† based on 0 to 12 point AUDIT-C score
††Very poor to fair = Reference category
### AMPREDICT as a Clinical Tool

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Case #1</th>
<th>Case #2</th>
<th>Case #3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmetatarsal</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Transtibial</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Transfemoral</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Age</td>
<td>65</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Alcohol Score</td>
<td>4</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Previous treatment for anxiety or depression</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Self-perceived health good to excellent</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Predicted Probability of Mobility Success:</strong></td>
<td><strong>15.5%</strong></td>
<td><strong>59.2%</strong></td>
<td><strong>80.1%</strong></td>
</tr>
</tbody>
</table>

*Predicted probabilities are based on regression coefficients from the logistic regression model.*

**Area Under Receiver Operating Curve = .86**

**This demonstrates Good to Excellent discriminative ability for the mobility outcome.**
• Conclusions
  – Predictive Model has very good characteristics
  – Important potential clinical utility
  – Mobility success is associated with satisfaction with mobility AND satisfaction with life.
AMPREDICT the next Steps

• Newly Funded 4 year Prospective Multicenter Grant

• Validate Model
  – Geographical and Temporal Validation
  – Prospective Multicenter trial
    • Dallas
    • Houston
    • Portland
    • VAPSHCS
Challenges of Mobility Outcome Assessment

- LCI – 5
- Mobility Success
- Single item mobility Outcome
How would you rate your current level of mobility? (pick one of the following that most closely describes you).

6  I am able to walk in the community, with no ambulation aids, unlimited distances.
5  I am able to walk in the community, with no ambulation aids, limited distances.
4  I am able to walk in the community with ambulation aids.
3  I am able to walk inside my house with ambulation aids and use a wheelchair for community ambulation.
2  I am not able to walk but could get around my house and the community with a wheelchair.
1  I am not able to walk but could get around my house with a wheelchair but not get out into the community.
0  I am housebound and mostly bedridden and required help for all household transfers and mobility.
Summary

• Physiatrists have an important role to play in the team decision about amputation level selection

• Prediction of mobility outcome is our primary contribution at each major amputation level

• Currently the prediction is based upon clinical evaluation
  – Knowledge of the advantages and limitations of prosthetic componentry
  – Knowledge of the requirements necessary to utilize prostheses at each major amputation level
  – A biopsychosocial assessment of the patient noting limitations and strengths
  – From the ICF model - a knowledge of “environmental factors”
What does the future hold?
The Future

• The provision of personalized health care

• Valid, sensitive, specific prediction models on your smart phone.
  – Predict mortality
  – Predict wound healing
  – Predict functional mobility

• “informed consent” that assists the patient and provider in making the best decision that incorporates the patients needs and priorities
Thank-you
Figure 1. The ‘Physical Activity for People with a Disability’ model based on the ICF (Adapted from Van der Ploeg et al. [18]).
Change in LCI mobility scores from *pre-morbid* function to 12 months post amputation.