Competency, Risk, and Acceptance of Upper Limb Prosthetic Technology

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Learning Objectives

Upper Limb Prosthetic Overview

Learning Objectives

- Critical Challenges
- Etiology/Population
- Technical Characteristics
- Clinical Considerations
- What Defines an Upper Limb Expert?
Critical Challenges with Upper Limb

Learning Objectives

- Small Population
- Difficult to Receive Training
- Cosmetic Appearance
- High Functionality Need
  - Lower is more Passive
- Greater amount of Patient Variability

Distribution by Level

Much Smaller Numbers

- 8.2 % are Upper Limb
  - Number is Declining
- Hand & Fingers 61,000/yr
- 41,000 Amp of Hand & Arm
- 70% Distal to Elbow
- 77% Trauma, 8.9% Congenital, 8.2% Tumor, 5.8% Disease
Compared to Lower Extremity Distribution is Different

**Distribution by Level**

<table>
<thead>
<tr>
<th>Level</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>Partial Hand</td>
<td>2%</td>
</tr>
<tr>
<td>Wrist Disarticulation</td>
<td>.7%</td>
</tr>
<tr>
<td>Transradial</td>
<td>4.4%</td>
</tr>
<tr>
<td>Elbow Disarticulation</td>
<td>.2%</td>
</tr>
<tr>
<td>Transhumeral</td>
<td>2%</td>
</tr>
<tr>
<td>Shoulder Disarticulation</td>
<td>1%</td>
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</tbody>
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Much Smaller Numbers
Upper Limb Rejection Rate
High Even with Technology

- Rejection Rate Still 29-56%
  - More for Transhumeral
  - 64.7% less than 12 Hours
  - 41.2% 9 am to noon
- Comfort & Relative Utility
  - Directly correlated to Usage
  - Related to Training
- Golden Period 30 Days
  - 93% Wear before 42% After
- Ext Power Higher Acceptance
  - 80% TR, 69% TH, 72% High Level
  - Better Comfort, Cosmesis, & Function

Studying the Prosthesis & Patient Relationship
Upper Limb Acceptance Rates
Berger, 1958

- 1630 Amputees
  - 826 (51%) Transradial
  - 668 (41%) Transhumeral
  - 89 (5%) Shoulder Disarticulation
  - 47 (3%) Bilateral

- 75% Transradial Acceptance
- 61% Transhumeral Acceptance
- 35% Shoulder Disarticulation

- All body powered
- Full time wear 12 hours per day

Upper Limb Acceptance Rates
Malone, 1984, “Golden Period”

- 47 Patients, VA Arizona
  - Ages 4-82 yrs, 31 median
  - 21 Left, 26 right
  - 32 TR, 13 TH, 1 PH, 1 IT
  - 32 Trauma, 5 Elec, 4 Neuro

- 20 IPOP <30 days, 19 Later >30days
  - 42% Acceptance after 30 days
  - 93% Acceptance before 30 days

- Some Experimental issues with Split Means & Groups, But.....?
Upper Limb Acceptance Rates
Millstein & Heger, Toronto, 1985 (28 years ago)

- 164 Adults Amputees; 1974-1981
  - 18 High Level
  - 130 Transradial
- Worker’s Compensation Board
  - Toronto, Canada
- Average Age 39, 18-70
- Transradial Rejection
  - Body Power: 0-66%
  - External Power: 20-63%
- Transhumeral Rejection
  - Body Power: 7-72%
  - External Power: 28-31%

Millstein & Heger, Toronto, 1985 (28 years ago)

- n=70, 34 responded Upper Limb
  - Jan, 1975 - May,1982
  - 6 Question Survey
  - Queensland, New Zealand
- 38.2% Never Wore Prosthesis
- 61.8% (21) Wore Regularly
- 41.2% (14) Wore from 9:00am-12:00pm
- 26.7% Wore less than 9 hours
- 55.9% Not High Activities
- 38.2% Using Tools (2.9% picking up Coin)
- 41.2 % Work, 29.4% Meals
- 38.2% Unhappy with Number, 29.4% unhappy with how they do them.

Burrough & Brook, 1985
Upper Limb Acceptance Rates  
Biddess & Chau, 2007, P & O Int., Toronto, Canada  
- 40 Article Meta-analysis  
- Review of 25 Years of Literature Composite rejection 1 in 5  
- Passive Rejection: 6-100%  
- Body Powered: 16-66%  
  - Mechanical Hands: 80-87%  
- External Powered: 0-75%  
- 22-97% Socket Discomfort  
- 50% Mechanical Failure (India)  
- 38% Financial Constraints  
- 72% would Reconsider w/ Improvements  
- 89% say they are more Functional  

Shoulder Disarticulation Acceptance Rates  
Uellendahl & Farnsworth, JPO, 2008  
- 39-65% Rejection Rate  
- Acceptance Related to Socket Comfort  
- Not one design that works for all  
- Dynamic Emulation  
- Advocated Myo, Body, & Hybrid Designs.
Technologic Seduction

Belief that New Technology will Drive Acceptance

Hoped to Increase Function and also Acceptance

Unintended Consequences

- Complexity, Anxiety, Fewer Practitioners, Longer Delay, Loss of Clinical Self-Efficacy

Third Party Payors asking for Evidence of Acceptance

I have seen the Enemy......
And he is Us!

Commodore Perry 1813, Lake Erie: "I have seen the enemy and they are ours"
Systemic Issues
Are we getting Better?

- Smaller Numbers of Prosthetists fit Upper Extremity Prosthetics

- Is Quality, Consistency, and Timeliness for Upper Limb Prosthetic fitting at the Average O & P Provider Diminishing?

- Are Outcomes Improving?

- High Tech Parts offer Greater Capability w/Cost, but are "We" Improving Systemically?

- Third Party Payers ask Why?

Smaller Numbers of Clinicians Fit Upper Ext.

- Only 3,580 ABC Clinicians
- 32% are Prosthetists
- 36% are Orthotists Prosthetists
- Roughly 10-15% consider fitting Arm Prostheses
- Estimate only 150 Prosthetists
- Growing Number of “Specialists”
- Are Acceptance Rates Improving
Increasingly Specialists are Used
Does this affect Timeliness?

- Prosthetists think “Specialty”
  - Difficult to Cover all cases
  - Fewer Educated
- Patients or Specialists travel long Distances
  - Delayed Time of Delivery
  - Poor Service & Outcomes
- Perhaps there is Shadow Diffusion
  - Greater Differentiation
  - Preserve Status

Greater Perceived Fitting Complexity
Competition can be intimidating

- More Active Use & Cosmetic
- Materials & Construction
- Molding Techniques
- Harnessing & Suspension
- Mechanical & Electronic Components
- May be Latent Competition
High Tech Differentiated Products

- Upper Ext. Captures Media & Research Attention
- Active Robotic Actuators
- Direct Osseointegration
- Direct Brain Driven Control
- Requires Constant Updates
- Must have Social Network to Keep Up

Population Decline vs. Healthcare Practice

- Small Numbers of Patients
  - 92% are Lower Extremity
  - Population only 26,000
  - Only 2,200 Total Usage
- Healthcare dictates higher Volume
- Greater Risk; Higher Rejection Rate
Relatively High Rejection Rate

- Roughly 30-70% of Patients Reject Upper Prosthesis
- Cosmetic, Comfort, Gadget Tolerance, Expense, Repair
- Relative Complexity vs. Relative Advantage
- Significant as Devices become High Tech
- Insurance asks Why Pay?

Porter’s Five-Force Analysis
Homophilic-Similar in Group
Heterophilic-Dissimilar out of Group
Change Agents are Facilitators

Upper Limb may be too “Risky” for Early Majority, Late Majority, & Laggards

Initial Learning Studies

• Stark, 2011, Leadership Survey
  • Relationships most Highly Rated
  • Technical, Human, Conceptual

• Stark, 2012, Education
  • Blended Learning Higher in Confidence, Competency, Instruction: Halo Effect
  • Traditional Lower Higher in Preparedness & Positivity of Learning
Upper Limb Practitioner Survey
Goal of Defining Segment Characteristics

- Based on 5 Initial Telephone Interviews
- Define Market Segmentation
- Areas of Concern for Education

- Posted on Survey Monkey
  - March 14-April 19, 2013
  - 154 Respondents, 152 Completed
  - Separated Novice-Intermediate from Expert-Specialists
  - Difference between Institution/Corporate vs. Private Companies

Upper Limb Practitioner Survey
Self-Assessment of Ability

- 71.8% Self-Describe Novice-Intermediates
- 26.2% Self-Described Experts-Specialists

- Smaller Cohesive Group is Driving Development
- Larger Group is more Fragmented
- Different Values between Groups
Upper Limb Practitioner Survey
Experience and Consultants

- 17.84 years of Experience
- 15.56 as a Specialist
- 2.28 Yrs Training for Specialist?
- Self-Reporting Inaccuracy?

Different Groups
- Novice/Intermediate
- Expert/Specialist
- Private/Institution-Corporate

- 8.41 Patients/year Average
  - Experts/Specialist-24.85 ave
  - Novice/Intermediate-2.98 ave

Upper Limb Practitioner Survey
External and Internal Consultants

- Segmented Groups
  - Expert-Specialist, ES Group
  - Novice-Intermediate, NI Group
  - Institutional-Corporate Group
  - Private Group

- Average 1.31 Internal, 2.13 External
  - Experts in Private Setting On Their Own
  - Experts in Institutional Setting 2X More Experts than average
  - Almost 3X more than Private
  - Novices are Even
Upper Limb Practitioner Survey
Private vs. Institutional Customers

59.73% at Privately Owned Clinics
- Fewer Ext. Linkages; More Isolated
- Need more Patient Consultant Support
- Desire L-code Assistance
- Want Durability & Servicing

39.92% at Institution, Corporate, Manufacturer
- Have more Ext. Linkages
- Not Isolated; Research Exposure
- Need Technical, Therapy Help
- Not L-Code Conscious
- Want Research & Development Info

More Novice-Intermediates at more Private Clinics -66%
- Proportionally
- What are they Learning?

Expert Proportion-44% Private
- Some Transition to Manufacturers & Consultants
- May or may not be Customers?
- Small Numbers
Upper Limb Practitioner Survey
Diffusion of Innovation Groups

• Based on Diffusion of Innovation
  - Innovator
  - Early Adopter
  - Early Majority
  - Late Majority
  - Laggard
• Should be Distributed
  - May not be evenly Matched
• Expert-Specialist Tend to Have
  More Innovative Tendencies
• Novice-Intermediate Tentative
  - Need Bundling & Technical Help

Upper Limb Practitioner Survey
Experts are more Innovative

• #1 is “Innovator”
• #2 is “Early Adopter”
• #3 is “Early Majority”
• #4 is “Late Majority”
• #5 is “Laggard”
  - Experts more Innovative
    - More World View; Risk Taker
    - Self-Dependent; Fewer Population-16%
    Typically
• Novices more Laggards
  - Less Worldly; Risk Adverse; Reject?
  - Need Assistance; Greater Population-68%
  Typically
Upper Limb Practitioner Survey
Reasons for lack of Clinical Confidence

In your opinion, what are the top two reasons prosthetists are not as confident with Upper Limb Prosthetics? Please pick (2) Two.

- Pick 2 answers from 7 Choices
- 90.8% “Too Few Patients to Practice and Develop a System of Fitting”
- 62.42% “Lack of Personal Confidence or Knowledge” with Upper Limb

Must “Bridge the Gap” of Technical Dissonance
- Contact with Experts
- Increase Tech Knowledge
- Targeted Learning Module Development

Upper Limb Practitioner Survey
Asking for Help & Confidence

“Somewhat Agree” that they confer with others
“Somewhat Agree” that they have a group to ask questions
“Somewhat Disagree” that they are apprehensive to ask
“Definitely Agree” that they are able to fit patient
“Somewhat Agree” that they are Equally Adept with Body Power
“Somewhat Agree” that they are not up to date on External power
All answers indicate Strong Outward Confidence
Upper Limb Practitioner Survey
Areas of Concern

- Asked to pick 2 of 7 Choices
- 45.54% Componentry Knowledge
- 37.58% Patient Training
- 35.56% Patient Variation
- 31.54% Functional Adjustment
- All areas that should be covered
- Not often touched on with Interdisciplinary team

Upper Limb Practitioner Survey
Areas of Concern: Experts vs. Novices

- Expert-Specialist Ratings
  - Patient Variation
  - Patient Training
  - Socket Design
- Novice Intermediate Ratings
  - Componentry
  - Patient Training
  - Fitting Adjustment/Patient Variation
- E-S Group Needs Case by Case Consultation
- N-I Group Needs Systematic Instruction
Upper Limb Practitioner Survey

Body-External Power; Group Innovativeness

- “Somewhat Agree” that External Power is Less Durable & Less Dependable
- “Somewhat Disagree” that Body Powered is Out Dated
- “Agree” that Patients Need Both Body & External Power
- Different Groups Have Different Opinions about Inherent Innovativeness

Upper Limb Practitioner Survey

Specialists see Themselves more Innovative

- Expert-Specialists See themselves as slightly more Innovative by Nature .30
- Novices-Intermediates say Upper Limb Can be Learned by Anyone .63
- Expert-Specialist Disagree that Body Power is Outdated more .64
- Novices-Intermediates See Basic Myo is more Functional for Unilateral .52
Upper Limb Practitioner Survey
How to become an Upper Limb Specialist

- Asked to pick 3 of 9 Choices
- 98.66% Practical Experience
- 58.39% Manufacturer Seminar
- 51.01% Interaction with External Advisors
- Education should provide Patient Exposure, Technical Advice, and Increase Communication

Upper Limb Practitioner Survey
Education of an Upper Limb Specialist

- Asked to pick 2 of 9 Choices
- 81.88% On the Job Experience
- 42.28% Personal Training from Expert
- 34.23% Manufacturer Seminars
- Advantage to Instruction that Provides Direct Interaction
- Education must be Short, Targeted, and Online
On-Line Acceptance Survey

Posted for 4 Weeks, 10 Questions

58 Respondents

15.2% Novices, 39.7% Intermediates, 29.3% Experts, 15.2% Specialists

Acceptance 79.6% Transradial, 57.8% Transhumeral, 32.8% Shoulder Disartic

Similar to Old Numbers 75%TR, 61%TH, 35%SD

Acceptance Factors

Much of the Acceptance Factors are Equally Valued.
Acceptance Factors
Pareto Analysis

Pareto Did not Show Differentiation
Amputation Level, Functional Advantage, Socket & Harness Comfort, Peer & Family Support
Major Grouping at Top but all rated fairly highly
Confusion over Relevance

Weighted 2nd Survey
Weighted Pareto Function, n=41
Assigned 4pts for #1, 3pts for #2, 2pts for #2, 1pt for #4
Functional Advantage, Amputation Level, Comfort, Patient Prosthetist Relationship
Count 1’s & 2’s for Differentiation
Amputation Level, Functional Advantage, Socket/Harness Comfort; 72% of Fitting
Add Training & Pros Relationship 84%
Emotional Differentiation & Technology Readiness
Stark, Doctoral Study, 2015

- 148 O & P Respondents; 16 days
  - 22% Female, 78% Male; 21 yrs exp
- Most considered themselves “Expert”
- Tech Readiness: Optimism, Innovativeness, Discomfort, and Insecurity
- Workplace Differentiation: Reactivity, Cut-off, Fusion
- Relationship of Emotion on Readiness: $R = .366$
  - Strong Relationship: Reactivity & Cutoff on Technology Optimism: $R = .499$
  - Very Strong Relationship: Optimism, Innovation, Insecurity on Workplace Differentiation: $R = .566$
  - Very Strong Relationship: Optimism, Innovation on Reactivity particularly Innovation: $R = .525$
- No Significant Relationship: Readiness and gender, certification, self-assessment, office affiliation, & experience; WDI-some Office & Experience

Hand Motion Emulation and Modeling
Hands

- One Degree of Motion
- Multiarticulation
- Durability vs. Dexterity
- Pinch Strength
- Hand Speed
- Battery Life

Do Devices need to be Hands?
Functional Terminal Devices

- Electric Powered Prehension
- Fine Prehension
- Increased Speed & Power
- Not as Cosmetic
- Interchangible

Sport/Adaptive Solutions
Mini Drive Systems

Michelangelo Hand
Wrist Rotation

Multiflex Wrist

- Multiflex Wrist
- Adaptive Position
- 28 deg; 4 directions
- One Direction Lock
  - Hand Flexion
  - Hook Radial Deviation
Elbows

- Body Powered Lock
- Hybrid Body Power & Electric
- External Power
- Size, Weight, Expense

Osseointegration
Complete Limb Allografting

Targeted Neural Reinnervation
From Brachial Plexus Reinnervation
Targeted Neural Reinnervation
Pattern Recognition Capability

More Simple Pattern Recognition
Transradial & Transhumeral
Direct Neural Control
Go Directly to the Cortex

3-D Printed Prostheses
Direct Force Feedback
Market Trend Analysis

Haptic Feedback

Median nerve  Neural Interface
Ulnar nerve  Nerve injury
Stimulation unit  Silicodermis
Neurointerpreter
Implantable Myosites & Neural Cuffs
Enhance the Signals
Basalt & Nanofiber Composites
Market Trend Analysis

Artificial Skin that can Feel
Hydrophobic Surface

References


Thank you for your attention!

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