An Immediate Fit Transtibial Prosthesis for Global Rehabilitation

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Acknowledgments & Disclaimer

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The views in this presentation are of Dr. Dillingham, the founder and owner of the iFIT Prosthetics, LLC.
Scope of Problem

• 80% of world’s disabled people live in developing countries

• **Estimated 25 million people** in Africa, Asia and Latin America lacking a prosthetic or orthotic device

• Prosthetic facilities cannot match those in need

World Health Organization “Guidelines for Training Personnel in Developing Countries for Prosthetics and Orthotics Service” 2005
Amputation and Traumatic Injury

- Traumatic injury leading to amputation is greater in developing countries due to issues with:
  - Traffic Accidents
  - Firearms/crime
  - Bomb blasts/landmines
  - Industrial accidents
- Lack of emergency services
- Scarcity of trauma surgeons

Survey of traumatic injury patients at a hospital in Pakistan

Amputation and Traumatic Injury

• In 2004: 300,000 landmine survivors with cost of $3 billion over the next 10 years to rehabilitate

• 30% of landmine casualties required amputation (American Red Cross database)

• 17% transtibial (below knee) amputation

• Less than one in four landmine amputees are fitted with a proper prosthesis

2. ADF Health 2000; 1: 93-98
Amputation and Dysvascular Disease


• Rapid increase in developing countries.
• 387 million people aged 20-79 (8.3%) with Diabetes estimated in 2014
• 77% living in low and middle-income countries

http://www.idf.org/publications/annual-report
Prevalence of Diabetes

The top 10 countries, in numbers of people with diabetes, are:

India
China
USA
Indonesia
Japan
Pakistan
Russia
Brazil
Italy
Bangladesh

Source: Wild et al., 2004

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>People with diabetes (millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2000</td>
</tr>
<tr>
<td>1</td>
<td>India</td>
<td>31.7</td>
</tr>
<tr>
<td>2</td>
<td>China</td>
<td>20.8</td>
</tr>
<tr>
<td>3</td>
<td>United States of America</td>
<td>17.7</td>
</tr>
</tbody>
</table>
Diabetic Foot care Africa and India

- 40-70% of lower limb amputations in world from Diabetes
- 85% of these amputations result from foot ulcer

- India: 40,000 lower limb amputations per year, most due to diabetes
- Tanzania: 33% of patients admitted for diabetic foot ulcers undergo amputation

Diabetes Foot Care: Step-by-Step.
http://www.worlddiabetesfoundation.org/projects/maharashtra-india-wdf03-056
Why are these rates so high?

- Barefoot walking leads to increased pathogens
- Lack of awareness/education
- Lack of trained providers
- Distance to obtain health care
- Delayed treatment when in manageable stage.

Age groups impacted by Diabetes

- Working age group 45-64 most impacted

Reasons:
- Urbanization- altered diet, activity levels and stress
- Lack of education
- Lack of health services
- Seek help too late

Barriers to Prosthetics in Developing Countries

- **Cost**
- **Access**
  - Few prosthetic labs
  - Long distances
- **Materials and tools needed for prosthesis**
- **Lack of trained personnel**
- **Time consuming**
  - Weeks to fabricate with casting, molding, test sockets, etc.
- **Multiple sockets needed during first year after amputation**
Problems for amputees that lack prosthesis

- Impaired work ability
- Impaired family role
- Affects culturally accepted roles and body image in different societies
- Environments are not conducive to mobility
  - Dirt roads
  - Cities not wheelchair friendly
High Quality, Lower Cost, Efficiently Fabricated Prosthetics

- Current efforts
  - Low cost techniques
  - Rapid fabrication
  - 3D printing
  - Salvaging used componentry
  - Local materials
- No ideal solutions presently

Nia Technologies and a software partner to deliver 3D-printed prosthetics and orthotics to children in developing countries.

http://niatech.org/news/
RightFit Prosthetics

- Initiated at Johns Hopkins University
- Heat moldable PVC socket
- Liner to prevent skin damage
- Formed directly on patient’s limb
- PVC tubing
- Local materials

http://aac-rerc.psu.edu/wordpressmu/RESNA-SDC/2014/06/05/the-rightfit-prosthetics-initiative-affordable-prosthetic-devices-for-the-developing-world-johns-hopkins-university/
2FT Prosthetics

- PVC tubing cut and heated to produce a foot
- Requires socket fabrication
- Locally available tools/materials

http://www.2ftprosthetics.org/
Problems with these devices

• Materials not durable
• High probability of breakage
• Socket still may need modification
• No alignment system.
  • painful and unstable if not aligned properly
• Requires knowledge to cast/mold socket
• Suspension systems often vague or straps used
3D Printed Limbs

• Shortens fabrication time- 1.5 days
• Low cost materials
• Most companies only fabricate hands
  — Material strength/durability limited
• Some making lower limb pediatrics

https://3dprint.com
3D Printed Limb Limitations

• Requires knowledge of scanning, customization and fabrication
• Need an expensive 3D printer and scanner
• Materials not strong
• Limb scanning does not represent soft tissue and bony geometry of limb
Low cost prosthetics—other companies

- Lowcostprosthesis.org¹
- Neuhof²
- VietCot³
- TATCOT⁴
- Swiss Leg⁵

1. www.lowcostprosthesis.org
5. www.swissleg.com
Ossur IceCast

- Modular system
- Directly on residual limb
- Silicone locking liner - pin suspension
- Requires technical training
- Expensive
- Non adjustable socket

www.ossur.co.uk/prosthetic-solutions/products/sockets-systems/icecast-compact
Jaipur Limb

- Early devices not made to good biomechanical standards
- Many rejected
- Undertrained technicians and hurried fabrication
  - Fit 500 amputees in one month
- Subsequent efforts improved training and manufacture

Low cost prosthetic still needs to provide comfort, stability and durability

Rosenberg, T. Keeping Artificial Limbs Low Cost and High Quality. 2011 NY Times.
Humanitarian Efforts in Haiti

- Estimated 2000-4,000 amputees from 2010 earthquake
- Thousands of limbs donated
- Salvage of parts needed
  - Varied technologies
  - Lengthy time to sift through
  - Trained prosthetist
  - Fabrication facility

Haiti: Reflecting on the First Year of O&P Relief Efforts
By Judith Philipps Otto. 2011. The Edge O&P.
"Most practitioners in the United States wouldn't get to see 700 amputee patients in a lifetime, yet our clinic has served that many in just nine months."
“Prosthetic technology is certainly advancing rapidly, but there’s a catch. For most people, these state-of-the-art devices are neither attainable, nor well suited for day-to-day life.” — Rose Evelyth

Article: “When state of the art is second best” 2012
http://www.pbs.org/wgbh/nova/next/tech/durable-prostheses/
“When state of the art is second best” - Evelyth, R 2012 Article

- Need to develop devices at both ends of the spectrum
- High technology not always practical
- Ultimately, decide what is best for the patient

Surfer wears durable prosthetic leg. Conditions like these would damage today’s myoelectric leg.

“When state of the art is second best”
Evelyth, R. 2012
http://www.pbs.org/wgbh/nova/next/tech/durable-prostheses/
What is Needed-
Modular Advanced System

- One unit that provides safe ambulation without pain
  - Socket
  - Liner
  - Suspension
  - Alignment mechanism
  - Foot and pylon
- High Strength and Durability
- Comfortable socket interface
- Adjustable to allow for residual limb changes without socket modifications
iFIT Prosthetics®- Our Mission

• To produce the highest quality prosthetic devices that enhance the lives of persons with amputations
Background

• Veteran owned Wisconsin-based company founded in 2010

• Developed and tested a transtibial (below knee level) prosthesis system (U.S. Patents # 8470050, 8491667, 8845755)

• Development funds provided by federal grants from National Institutes on Health (NIH) under STTR Phase I, Phase II, Phase IIB
The iFIT Prosthetic System

- Injection molded and mass produced
- Immediately fit
- Adjustable
- High strength polymer
- Integrated socket and alignment system
- Fit with hand tools-no lab required
Supracondylar Socket

- Grasps the leg firmly above knee for increased stability
- Well received by individuals needing more stability
Video
Buckle System

- Fully adjustable circumference
- Safety latch
- Extremely strong
- Design gives biomechanical advantage for easy adjustment
Buckles

- Buckle is notched so that the cables can be interchanged but do not fall out
Video
Cables & Guide

• Cables come in a variety of sizes to fit patients with a wide variety of limb circumferences and shapes
• Guide in back keeps cables in place
Spacers

- Two sizes of spacers developed to accommodate shorter limb lengths.
Pin Suspension

Silicone pin suspension liner

Commercially available
Alignment System
Padded Neoprene Liner

Padding kit: Includes neoprene pads and foam.
Padded Liner Customization

Provide pressure relief to bony areas

Have the patient wear only the neoprene liner, and then place padding accordingly
Customization of Liner Examples

1. Anterior pad for tibia cushioning
2. Lateral crescents for medial and lateral condyles
3. Foam to build up distal end
Custom Fit Injectable Foam Liner

Patients with bony prominences experience an even greater benefit with custom fit foam liner

- Alleviates rubbing and friction to these areas
- Enhances total contact support
- Better comfort
Custom Fit Foam Liner

- Foam is mixed and set within minutes
- Provides a precise and secure fit around the limb
Custom Fit Foam Liner
iFIT System Models

**TT100**
- Lower in cost for international efforts
- ALIGNMENT: Rocker bolt system that attaches to pylon and is adjustable
- Clutch lock

**TT200**
- Same socket as TT100
- Shuttle Lock
- ALIGNMENT: Pyramid adapter
- Pylon and pylon clamp for alignment
- Neoprene or moldable liner
TT100 Cup and Connector
TT200 Cup and Pyramid Adapter
TT200 Shuttle Lock and Pyramid Adapter
Video
Wide Prosthesis

- Used for larger circumferences 34-42cm
- Flap extender
- Side spacers to increase width of prosthesis
- Longer cable set
- Larger padded neoprene liner
“Prosthesis in a Box”
iFIT Kit
(what is included)

• Socket
• Padded Liner
• Padding Kit
• Pylon
• Pylon clamp
• Cables
• Spacers
iFIT Requirements

Tools required:
• Pipe cutter
• Allen wrench
• Torque wrench

Items prosthetist needs to order specific to patient:
• Silicone suspension liner
• Prosthetic foot
Video
## Component and Sizing Chart

<table>
<thead>
<tr>
<th>Limb Measurements (distal patella to end)</th>
<th>Socket</th>
<th>Spacer</th>
<th>Pin TT100</th>
<th>Pin TT200</th>
<th>Neoprene Silicone Liner</th>
<th>Silicone Suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>13-16cm</strong></td>
<td>Medium R or L buckles</td>
<td>2cm</td>
<td>3”</td>
<td>2.5”</td>
<td>Liner with padding kit</td>
<td>Ossur Iceross</td>
</tr>
<tr>
<td><strong>16-18cm</strong></td>
<td>Medium R or L buckles</td>
<td>1cm</td>
<td>2.5”</td>
<td>2.5”</td>
<td>Liner with padding kit</td>
<td>Ossur Iceross</td>
</tr>
<tr>
<td><strong>18-21cm</strong></td>
<td>Medium R or L buckles</td>
<td>None</td>
<td>1.5”</td>
<td>2.5”</td>
<td>Liner with padding kit</td>
<td>Ossur Iceross</td>
</tr>
</tbody>
</table>
## Component and Sizing Chart

<table>
<thead>
<tr>
<th>Mid-Circumference</th>
<th>Top Cable</th>
<th>Socket</th>
<th>Bottom Cable</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 30cm</td>
<td>45</td>
<td>Standard version</td>
<td>30</td>
</tr>
<tr>
<td>30 – 33 cm</td>
<td>45-50</td>
<td>Standard version</td>
<td>30-35</td>
</tr>
<tr>
<td>34 – 37cm</td>
<td>50-55</td>
<td>Wide version</td>
<td>35-40</td>
</tr>
<tr>
<td>37 - 42cm</td>
<td>55-65</td>
<td>Wide version</td>
<td>40-55</td>
</tr>
</tbody>
</table>

Circumference Chart- General Guideline may be adjusted depending on amount of padding used. The shape of the limb (bulbous, cylindrical, or conical) will dictate the lengths of cables used and the liner padding.
Pylon Length Estimation
Lab Testing

• 41 subjects for lab testing
  – 22 subjects were dysvascular amputees
  – 18 due to trauma
  – Diversity of ethnicity and gender

• 60 trials where subject was fit, aligned and walked at facility

• Balance, comfort, and stability identified as strengths of iFIT system
Two Week Home Trial

• Inclusion Criteria
  – 6 months post amputation-healed residual limb
  – Must have own prosthesis
  – Ambulatory either unassisted or with cane
  – Weight under 250 pounds

• Exclusion Criteria
  – Open wounds or skin irritation on residual limb
  – Neurological disorders such as stroke or brain injury that prevent safe gait
  – Severe phantom pain
Two Week Home Trial Study Sample

- **13 amputees** used the iFIT for community use
- 6 dysvascular causes and 7 traumatic injury
- **8 completed** two week follow up appointment
- 5 dropouts/non-responders
Table 1. Results

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Condition</th>
<th>Rating (own)</th>
<th>Rating (trial)</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>55</td>
<td>D</td>
<td>21</td>
<td>—</td>
<td>Lost to follow up</td>
</tr>
<tr>
<td>2</td>
<td>51</td>
<td>T</td>
<td>33</td>
<td>—</td>
<td>Lost to follow up</td>
</tr>
<tr>
<td>3</td>
<td>50</td>
<td>D</td>
<td>27</td>
<td>28</td>
<td>Uses intermittently (7 mo)</td>
</tr>
<tr>
<td>4</td>
<td>64</td>
<td>D</td>
<td>28</td>
<td>30</td>
<td>Uses exclusively (7 mo)</td>
</tr>
<tr>
<td>5</td>
<td>41</td>
<td>T</td>
<td>35</td>
<td>27</td>
<td>Uses after work and weekends (7 mo)</td>
</tr>
<tr>
<td>6</td>
<td>70</td>
<td>D</td>
<td>34</td>
<td>29</td>
<td>Completed 2 week trial then returned</td>
</tr>
<tr>
<td>7</td>
<td>53</td>
<td>T</td>
<td>29</td>
<td>33</td>
<td>Uses intermittently (4 mo)</td>
</tr>
<tr>
<td>8</td>
<td>62</td>
<td>D</td>
<td>21</td>
<td>—</td>
<td>Lost to follow up</td>
</tr>
<tr>
<td>9</td>
<td>37</td>
<td>T</td>
<td>34</td>
<td>—</td>
<td>Lost to follow up</td>
</tr>
<tr>
<td>10</td>
<td>46</td>
<td>T</td>
<td>28</td>
<td>31</td>
<td>Uses intermittently (5 mo)</td>
</tr>
<tr>
<td>11</td>
<td>59</td>
<td>T</td>
<td>26</td>
<td>—</td>
<td>Lost to follow up</td>
</tr>
<tr>
<td>12</td>
<td>24</td>
<td>T</td>
<td>28</td>
<td>21</td>
<td>Completed 2 week trial then returned</td>
</tr>
<tr>
<td>13</td>
<td>56</td>
<td>D</td>
<td>24</td>
<td>29</td>
<td>Uses exclusively (2 mo)</td>
</tr>
<tr>
<td>Mean</td>
<td>51.4</td>
<td></td>
<td>28.3</td>
<td>28.5</td>
<td></td>
</tr>
</tbody>
</table>

D= Dysvascular Related; T= Traumatic Injury
Results of Two Week Home Trial

- No ischemia or skin breakdown noted
- The amputees that continued wearing the device are now at 3-7 months
- Six of the eight rated the iFIT as comparable to their prosthesis
Amputees Lost to Follow Up

Five amputees were lost to follow up:

- Three lived distances greater than 1 hour – had difficulty returning for follow up
- One too busy for follow up, never returned calls
- One person had intervening medical issues and did not return for follow up
Participant from 2 week trial
Who the iFIT is ideal for

• First year after amputation
• Experience fluctuations in limb volume
  • Cardiac and renal disease
• Person wanting a highly durable prosthesis that they can get dirty or wear as a back up
• International needs—modular prosthesis that can be shipped and easily fit
Who should not use the iFIT Prosthesis

- Immediate post operative device
- Persons with:
  - limited hand function/dexterity
  - Reduced vision/ partial blindness
  - Lack of judgment or cognitive insight sufficient to use it safely
  - Persons lacking sensation in their residual limb
- Persons with amputated limbs outside the ranges for fitting:
  - Less than 13cm Patella to End
  - Greater than 21cm Patella to End
  - Circumference < 23 cm and > 42cm
## iFIT Comparison

<table>
<thead>
<tr>
<th></th>
<th>Traditional Prosthesis</th>
<th>iFIT Prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tools Required</strong></td>
<td>Casting material, plaster, cutting tools, pliers, drill, resins and impregnated fiber material.</td>
<td>iFIT socket, pipe cutter, Allen wrench, torque wrench</td>
</tr>
<tr>
<td><strong>Length of Time Needed</strong></td>
<td>1-2 weeks</td>
<td>Immediate- patient can walk out after first visit</td>
</tr>
<tr>
<td><strong>Patient Visits Needed</strong></td>
<td>3-4</td>
<td>2</td>
</tr>
<tr>
<td><strong>Labor required</strong></td>
<td>Intensive. Time needed for evaluation, casting limb, creating test socket, creating and shaping definitive socket, and numerous follow-ups to assess limb changes and modify socket.</td>
<td>Minimal. Pylon must be cut and to appropriate length. Prosthesis is then aligned and liner customized.</td>
</tr>
</tbody>
</table>
Advantages of the iFIT System

• High value = patient satisfaction/cost
• Lower cost than a conventional device
• Adjustable, accommodates volume changes without multiple socket revisions
  • Important during the first year after amputation
• Easily fit and aligned
• Strong and durable
• Single setting
• Minimal tools
iFIT Partnership with Advanced Designs Concepts (ADC) Engineering - Pewaukee, WI

• Seven-year collaboration
• ADC expertise:
  • Rapid prototyping /product development / structural testing
  • Injection molding and production capabilities
Durability and Strength: the iFIT Device Exceeds International Standards (ISO) Testing

- Withstood 3-million cycles of 300 pound loading
- Exceeded maximum requirement (1300 lbs. vs 900 lbs.) without failure
IFIT PROSTHETICS, LLC
Capabilities

- Production of 1000 units per month
- Device modifications/improvements- able to create rapid prototypes for future injection mold pieces
- Access to latest materials for strongest/ lightest device
- Shipment worldwide
- Currently working on a transfemoral system
Summary

• Potentially useful immediate fit transtibial prosthesis
• Mass produced
• Shipped in bulk
• Less need for full service prosthetic facility
• Less training time for prosthetists
• No casting
• Immediately fit