Intelligent wearables that turn everyday activity into physical rehabilitation

IEEE SA RTM Presentation
February 8, 2022
Knee Osteoarthritis

Inflicts: severe pain, swelling, and stiffness on 14M in the US

Leads to: 850,000 knee replacements and $27B in healthcare expenditure every year

Arthritis Foundation, 2017
70% Physical Therapy Compliance Failure

Most patients fail to attend all prescribed therapy sessions or comply with their home-based training regimens.

Reasons include: 1) Lack of time due to work or family commitments; 2) Distance to PT; 3) Challenges with coverage/cost
KneeStim

Dynamically strengthening muscle during everyday activity

Bringing physical therapy to the patient

KneeStim Testing @ Clinique Romande de Réadaptation, Switzerland
Applying Adaptive AI to Rehab Technology for Improved Efficacy, Outcomes, and Convenience

Standard NMES
Passive, stationary therapy with uncomfortable stimulation pulses for 15 minutes

KneeStim
Ongoing stimulation therapy seamlessly integrates into normal activity at home or work
Programming Challenge: Accommodating the Unforeseen Without Creating Infinite States

- People don't move in predictable, perfect gait cycles in real life
- Injury impacting one part of the chain results in compensatory alterations throughout the chain -->
- Pre-programming for infinite eventualities leads to unwieldy and unresponsive software
The Human Musculoskeletal System is a Complex Hierarchical State System

Each movement represents the collaboration of interrelated groups of joints and muscles working simultaneously.

Movements = states

Muscle activations and relaxations = tasks
99% Accurate on quadriceps stimulation timing and location

Up to 2 Hours of aggregate stimulation provided per day to users

40% Faster quadriceps strength recovery with movement-synchronous stimulation compared to passive stimulation

Sadeh, 2017

Moran, 2017
Providing therapy and collecting compliance data.

*My Dashboard*

**Today, April 10**

- **Daily Pain Log**
  - Left: 😞
  - Right: 😞
  - View Log History
- **Daily Steps**
  - Goal: 4,000
  - 3,691
- **Stride Length**
  - Goal: 24"
  - 23"
- **Walking Speed**
  - Goal: 1.5 mph
  - 1.5 mph
- **KneeStim Device**
  - Avalon
  - Send Reports
  - Update your physician

**Walking Speed**

- **Your Average Speed**
  - 1.5 mph
  - You can do it!
  - Walking Speed can improve the flexion of the knee. Walk at a similar speed throughout the day. Avoid going too fast. If your knee begins to hurt, simply slow down.

**Daily Goal**

- **Avoid**
  - 3 mph
  - 14+ mph

Chart showing daily activity data from 6:00 AM to 6:00 PM.
Momentum & Acclaim from Industry

2020
- FDA Q-Sub Mtg
- MC
- TMC
- Startup Programs
- uspto
  - Fifth US Utility Patent Granted

2021
- ACE
  - Tailored MedTech QMS Beta
- Finalized v1 Model
- Transitioned to 3D Printing

2022
- Houston Methodist
  - Finalizing Validation Trial
- Runner Up
  - Wear It Innovation Award 2021
- Semi-Finalist
- Arkathon Program
  - Top 3 Ortho
- Winner
  - INNOSPARK Artificial Intelligence Prize Winner
- Winner
  - AiQ
  - Innovation Labs Semi-Finalist
- Winner
  - Innovation Challenge
- Winner
  - Cycle 2020
- Winner
  - For Such A Time As This OrthoChallenge
- Winner
Determined Management Team & Scientific Advisors

Management

Josh Rabinowitz  
Co-Founder & CEO  
Market strategy, execution, business development, and strategic partnerships

Herbie Kirn  
Co-Founder & CSO  
Start-up veteran; prior exit w/ $12M raised 55+ patents in control systems & embedded design

Mike Russell  
PT CCO  
Start-up vet: 8 early stage/start-up team builds and launches. Total exit values = ~$1B; total sales run rates of early stage/start-ups = ~$600M

Scientific Advisors

Dr. Anthony ("AJ") Johnson  
Orthopedic Sports Medicine Director

Dr. J. Michael Bennett  
Orthopedic surgeon & sports medicine specialist

Dr. Shou-Hsiu ("James") Chang  
Director, UTH Health NeuroRecovery Research Center
Why Articulate Labs and Why Now?

- **Surgical Centers Want to Optimize Reimbursement and Manage Disease Progression**
  
  >10,000 knee replacements cancelled per week during COVID lockdown

  Bundled payments encourage surgical facilities to find revenue sources before and after surgeries

- **Expansion in Remote Therapeutic Monitoring Specifically Favors Devices Like KneeStim**

  10% of all PT sessions missed or cancelled; +20% since COVID

  Remote patient monitoring expanded to include physical therapists & analysis of remotely collected physiologic data

- **Patients Want Personalized, Efficient Care**

Bokinskie, 2015; Bedard, 2020, Losina, 2012; Definitive Healthcare, 2019; McKinsey, 2020
Backup Slides -->
AL Raising $1M Toward FDA Approval & Market Launch

Raising up to $1M on Convertible Debt: 6% Int.; 20% DOC; $4M valuation cap; 18 mo. term

**Budget & Timeline**
- FDA Prep: 3 months, $150,000 - $200,000
- Launch Prep: 4-6 months, $175,000 - $300,000
- Soft Launch: 12 months, $675,000 - $1,500,000
- National Launch: TBD, $5M+

**Value Created**
- 510(k) app submitted
- FDA clearance earned
- Initial sales
- Clinical proof earned
- Profitability
- Market validation

**Primary Tasks**
- Complete documentation
- Complete QMS setup
- Conduct QC/safety
- Initiate validation trial
- Implement initial sales, marketing, distribution plans
- Expand IP suite
- Expand provider network
- Manufacture initial KneeStims
- Local Launch - Texas (DFW/Houston)
- Activate MD/PT network
- Sell first 1,000 units
- Begin developing v2/DTC version
- Expand team - grow sales management, replace vendors
- Finalize distribution agreements
- Begin developing ball-and-socket focused device
- Evaluate exit opportunities
### Regulatory Approval
- **Straightforward FDA approval** - Class II 510(k)
- Predicate device identified
- **Clear EU approval path** - CE Class Ila; working with CRR on submission
- Building SaMD-specific documentation

### Reimbursement
- Applicable reimbursement codes already in place for DME rental and in-clinic use (HCPCS & CPT)
- Remote monitoring codes expanded to include physical therapy following COVID-19 outbreak

### Intellectual Property
- Five patents granted in U.S. [Utility]
- One core patent granted by EPO; nationalized in CE, DE, FR & UK
- IP claims applicable to all joints and conditions
- Improvement/blocking patents pending

### Proof of Concept
- Initial proof-of-concept study [UT-Austin]: KneeStim demonstrated 99% accuracy on stride detection, 100% accuracy on targeted muscle contraction for users with gait impacted by PFPS (n = 12)

### Ongoing Research
- **Ongoing partnership and trial** with Swiss partner following Arkathon prize
- Finalizing validation trial with Houston Methodist (post-TKA patients; n = 50)
- Additional LOIs from two hospital systems

### Market Interest
- 65% of interviewed MDs interested or highly interested in KneeStim and would Rx to 30-50% of their knee patients (avg. 150 / mo.)
- 55% of knee patients interested or highly interested in KneeStim; 80% willing to pay out-of-pocket
High KneeStim Interest from Patients and Providers

65% of MDs interviewed were interested or highly interested in prescribing KneeStim

55% of knee patients interviewed were interested or highly interested in using KneeStim

Seen as applicable to 30-50% of their patients; ~150 patients / month / MD

62% willing to pay out-of-pocket for faster and/or more convenient rehab

35,000+ prescribers in US
Intellectual Property Granted

- Covered Rehab Platform Extends to Other Joints and Conditions
- Possible Through AL's Unique Expertise in Intelligent, Efficient Control Systems

<table>
<thead>
<tr>
<th>Patent #</th>
<th>Priority Date</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>US 9,734,296</td>
<td>04/13/2010</td>
<td>Orthotic Support and Stimulus System and Methods</td>
</tr>
<tr>
<td>US 9,289,591</td>
<td>05/06/2012</td>
<td>Joint Rehabilitation Apparatus and Technique</td>
</tr>
<tr>
<td>US 8,972,018</td>
<td>03/20/2013</td>
<td>Adaptive Muscle Stimulation Technique</td>
</tr>
<tr>
<td>US 8,911,505</td>
<td>11/18/2010</td>
<td>Prosthetic Socket Stabilization Apparatus and Technique</td>
</tr>
<tr>
<td>EPO 11 831 357.6</td>
<td>07/11/2016</td>
<td>Orthotic Support and Stimulus System and Methods (EPO)</td>
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All IP filed through Trop, Pruner & Hu, P.C.
Dynamic Gait-Synchronous Neuromuscular Electrical Stimulation of Quadriceps in Patellofemoral Pain Patients
Soroosh Sadeh1, Larry Kim1, Jody L. Jensen2
1The University of Texas at Austin; 2Articulate Labs, Inc.

Introduction
Patellofemoral pain syndrome (PFPS) is one of the most common forms of chronic knee pain to young and active individuals, particularly in female (1). PFPS is an inflammatory condition of the knee, particularly the articular cartilage, and is associated with abnormal movements of the patella (2). Abnormal gluteous activation patterns or quadriceps muscle defects, on the other hand, have long been seen as contributing factors to the development of PFPS (3). Current treatment methods for PFPS include non-pharmacological methods such as physical therapy and pharmacological methods such as anti-inflammatory drugs. These treatments are known to be effective in reducing symptoms and improving function (4). However, the underlying pathomechanics of PFPS are not well understood, and the treatment is often trial and error. Studies have shown that the patellar tendon, a major extensor of the knee, is crucial in maintaining knee stability and function (5). Therefore, understanding the mechanisms underlying PFPS and developing effective treatment strategies are crucial for improving patient outcomes.

Methods
 Patients were recruited from the University of Texas at Austin. All participants were between 18 and 50 years old and had a history of PFPS. The participants were divided into two groups: a treatment group and a control group. The treatment group was treated with a neuromuscular electrical stimulation (NMES) protocol while the control group was not. The NMES protocol consisted of a 12-week intervention period. The effect of the NMES intervention on knee function and pain was evaluated using a combination of clinical and biomechanical assessments. The primary outcome measure was the Visual Analog Scale (VAS) for pain, and the secondary outcome measures included the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Tibial Torsion Test (TTT).

Results
The results showed a significant decrease in VAS pain scores in the treatment group compared to the control group. The KOOS and TTT scores also improved in the treatment group. The biomechanical assessments showed a decrease in patellar tendon force and an increase in quadriceps strength in the treatment group. These results suggest that the NMES protocol is effective in treating PFPS.

Conclusion
The study validated the hypothesis that NMES can be an effective treatment for PFPS. The results suggest that NMES can improve knee function and reduce pain in patients with PFPS. Further studies are needed to determine the optimal NMES protocol and to validate the results in a larger population.

References
Multiple Expansion Applications for Platform Technology

AL Body-Synchronous NMES
- Motion-Augmented Devices
- Static Stimulation Devices

Military Medicine
- Fatigue Detection
- Exercise Optimization
- Injury Prevention
- Expedited Post-Injury Rehab
- Assisted Marching
- Remote/Austere Condition Therapy

Sports Medicine & Space Medicine
- Movement Analysis
- Movement Training
- Post-Injury Rehab
- Pre/Post-Injury Analysis
- Exercise Optimization
- Fatigue Detection
- Mass Maintenance During Spaceflight

I/O Integrations
- Movement Analysis
- Big Data for Kinematics
- Muscle Contraction-Based Control Loops
- Fitness Wearables

Other Anatomical Areas
- Ankle
- Shoulder
- Lower Back
- Neck
- Hip
- Core
- Elbow

Multi-Area Musculoskeletal Conditions
- Stroke
- Multiple Sclerosis
- Cerebral Palsy
- Spinal Cord Injury
- Other Traumatic Injury
- Aging in Place

Ongoing development – KneeStim, StimSock