ARTICULATE LABS

Intelligent wearables that turn everyday activity into physical rehabilitation

IEEE SA RTM Presentation

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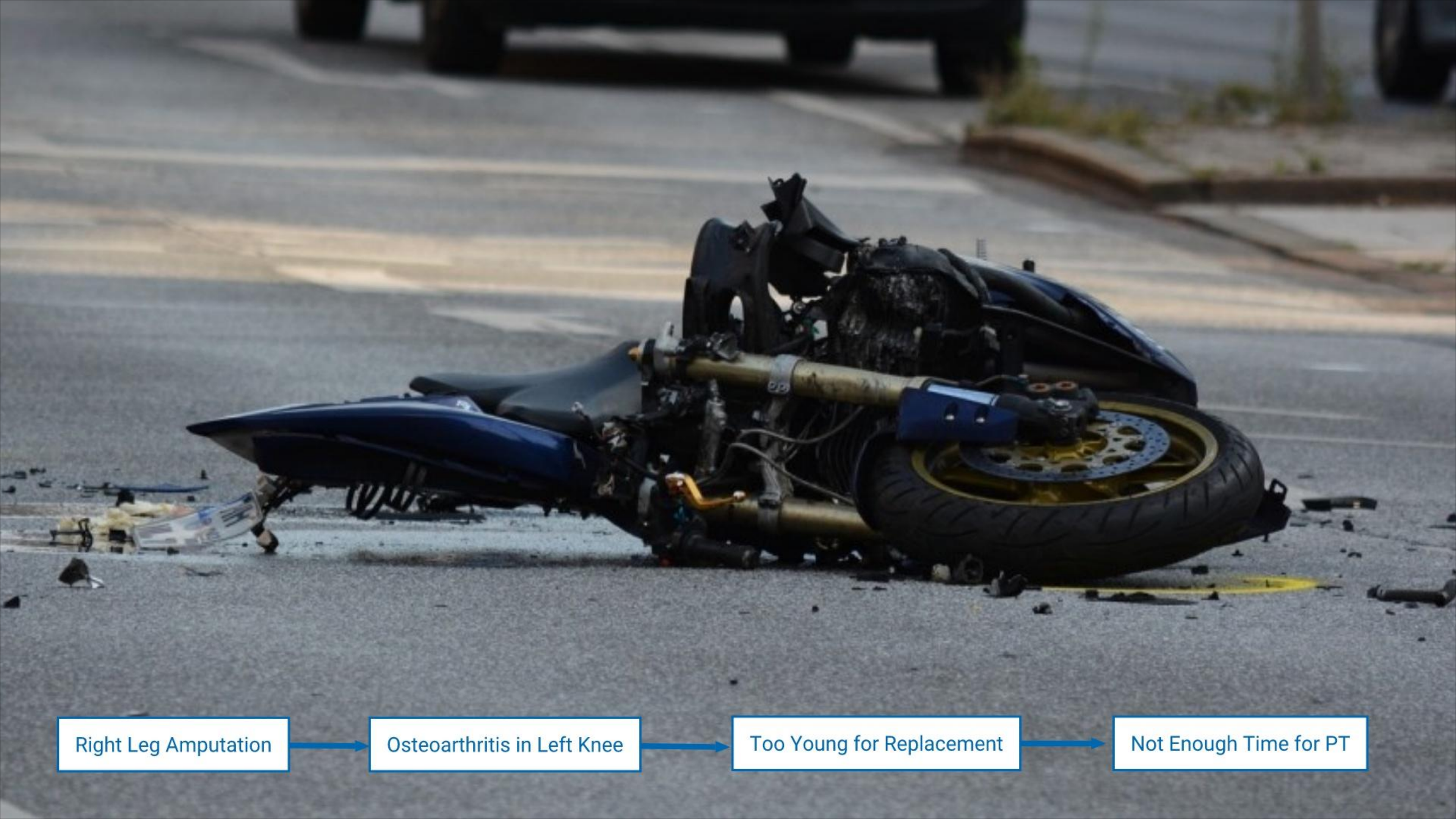
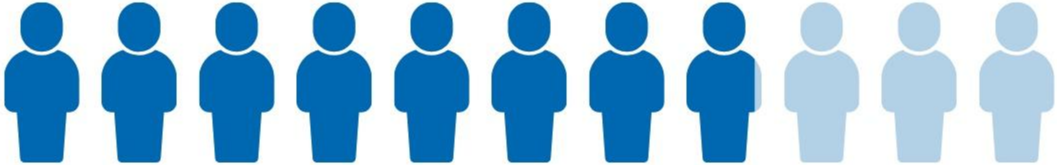

Right Leg Amputation
Osteoarthritis in Left Knee
Too Young for Replacement
Not Enough Time for PT

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

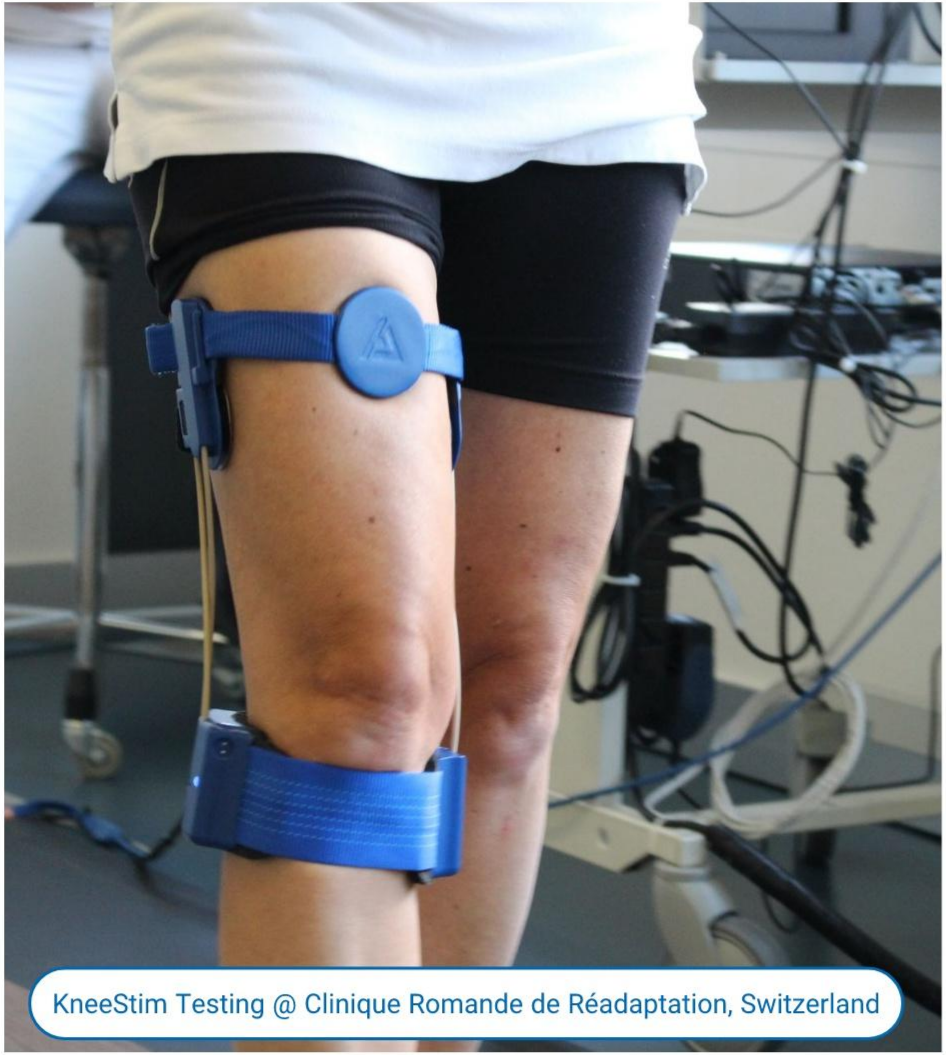
70%



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 Testing @ Clinique Romande de Réadaptation, Switzerland

KneeStim

Dynamically strengthening muscle during everyday activity

Bringing physical therapy to the patient

Applying Adaptive AI to Rehab Technology for Improved Efficacy, Outcomes, and Convenience

Standard NMES

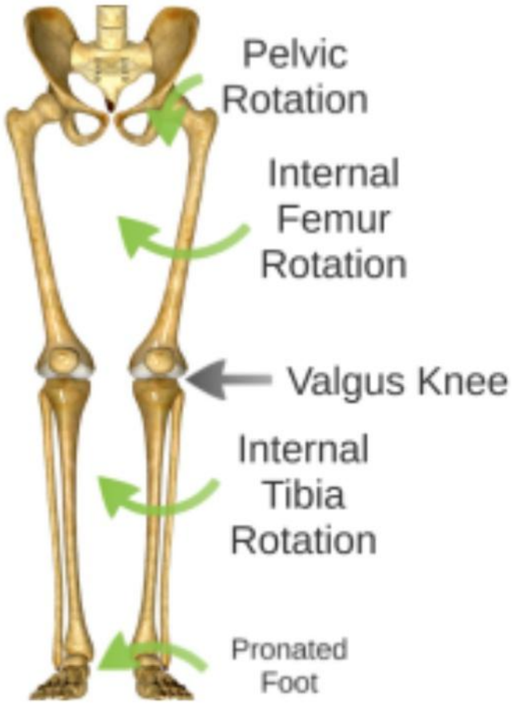
Passive, stationary therapy with uncomfortable stimulation pulses for 15 minutes

KneeStim

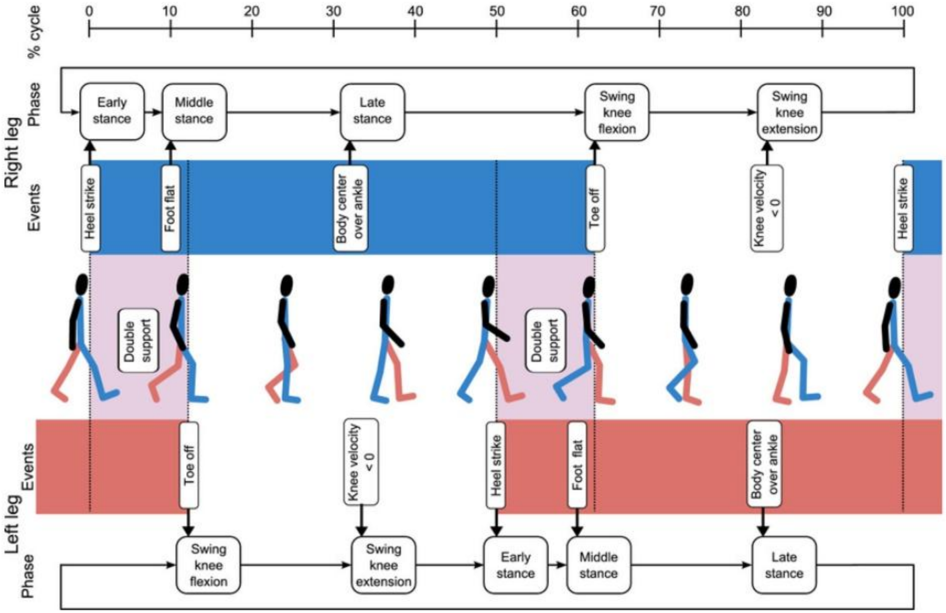
Ongoing stimulation therapy seamlessly integrates into normal activity at home or work

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

Sadeh, 2017

Up to 2

Hours

OF AGGREGATE STIMULATION PROVIDED PER DAY TO USERS

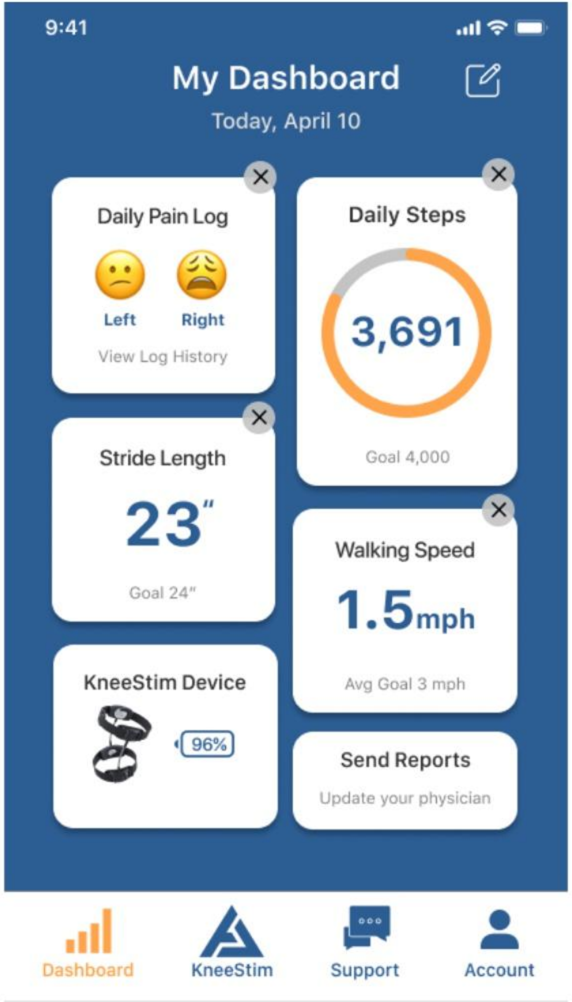
40%

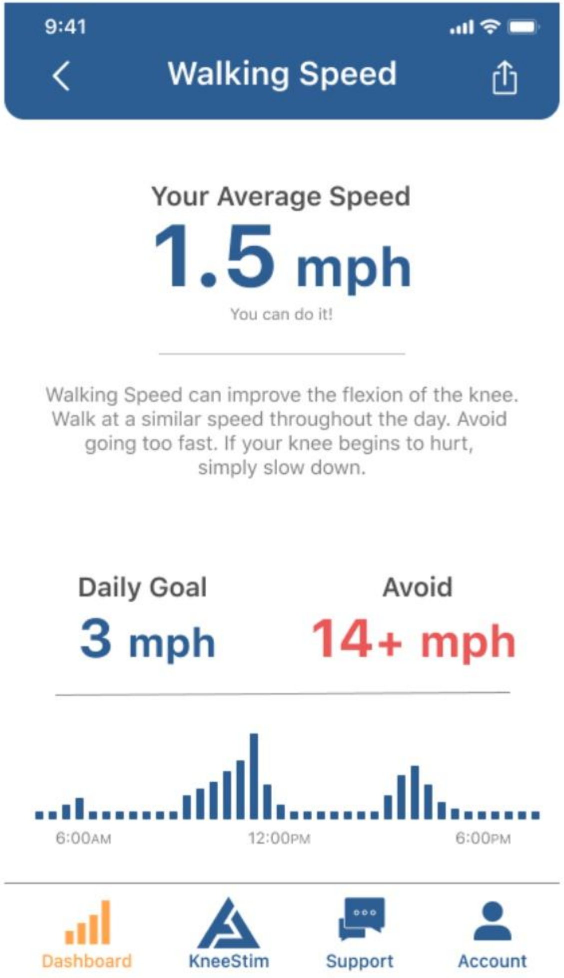
Faster Quadriceps Strength Recovery

WITH MOVEMENT-SYNCHRONOUS STIMULATION COMPARED TO PASSIVE STIMULATION

Moran, 2017

Providing therapy *and* collecting compliance data





Momentum & Acclaim from Industry

Startup Programs

TMC | X

2020

FDA Q-Sub Mtg

NASA iTech 2020 Cycle I Semifinalist — Semi-Finalist

USPTO Fifth US Utility Patent Granted

For Such A Time As This OrthoChallenge — Winner

ACE Tailored MedTech QMS Beta

Innospark Artificial Intelligence Prize Winner — Winner

2021

Astellas Rx+ Healthcare Innovation Challenge — Winner

Transitioned to 3D Printing

2021 AiQ Winner Innovation — Winner

AARP Innovation Labs — Semi-Finalist

Finalized v1 Model

Arkathon Program (Evaluate. Test. Iterate. Succeed.) — Winner

Wear It Innovation Award 2021 Runner Up, Articulate Labs — Semi-Finalist

2022

Houston Methodist Leading Medicine — Finalizing Validation Trial

Top 3 Ortho

Determined Management Team & Scientific Advisors

Management

Josh Rabinowitz

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

MICHIGAN STATE UNIVERSITY

Herbie Kirn

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

GM
JAM

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

Aveta
Aerogen
410

Scientific Advisors

Dr. Anthony ("AJ") Johnson

Orthopedic Sports Medicine Director

Dell Seton Medical Center at The University of Texas
SAMMC City of Military Medicine

Dr. J. Michael Bennett

Orthopedic surgeon & sports medicine specialist

SUPERDOCTORS
TMC X

Dr. Shou-Hsiu ("James") Chang

Director, UTHealth NeuroRecovery Research Center

UTHealth McGovern Medical School The University of Texas Health Science Center at Houston
TIRR Memorial Hermann Rehabilitation & Research

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

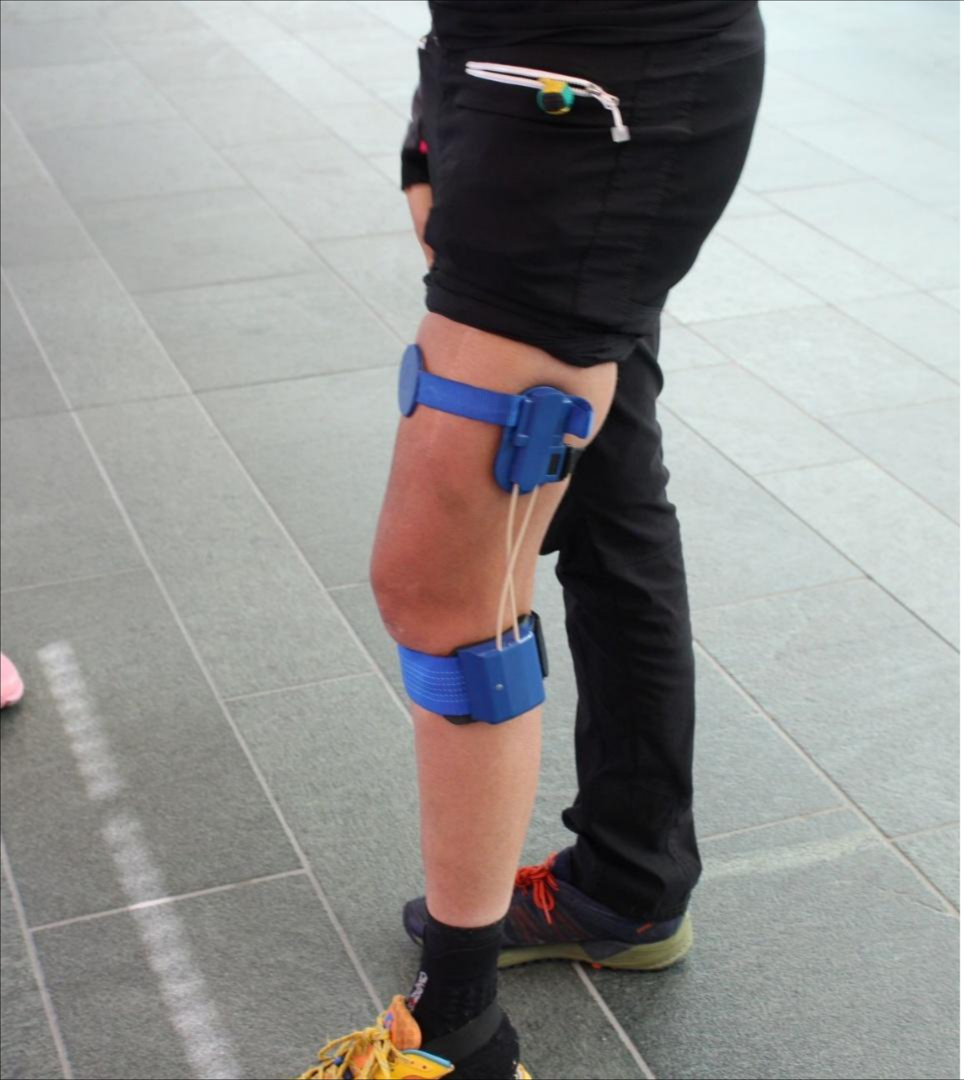
- **Expansion in Remote Therapeutic Monitoring Specifically Favors Devices Like KneeStim**

  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



ARTICULATE LABS

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Awards

Arkathon Program — Evaluate. Test. Iterate. Succeed.

astellas Rx+® HEALTHCARE INNOVATION CHALLENGE

2021 AIQ SMART CLOTHING CHALLENGE WINNER IoT/WT INNOVATION WORLD CUP® powered by AiQ

Accelerators

MC · TMC|X · CAPITAL FACTORY

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

	FDA Prep	Launch Prep	Soft Launch	National Launch
Budget & Timeline	3 months $150,000 - $200,000	4-6 months $175,000 - $300,000	12 months $675,000 - $1,500,000	TBD $5M+
Value Created	510(k) app submitted	FDA clearance earned Initial validation readouts	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

Extensive Commercial & Development De-Risking

Regulatory Approval

- **Straightforward FDA approval** - Class II 510(k)
- Predicate device identified
- **Clear EU approval path** - CE Class IIa; 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

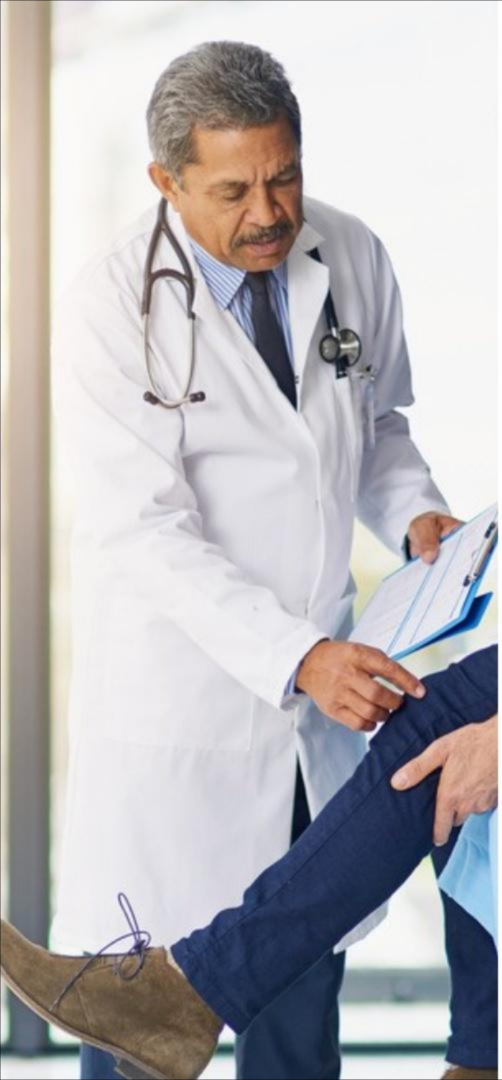
- Initial proof-of-concept study [UT-Austin]: KneeStim demonstrated **99% accuracy on stride detection, 100% accuracy on targeted muscle contraction** for users with gait impacted by PFPS (n = 12)

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

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

35,000+ prescribers in US

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

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

AL Market Research; MD n = 40; Patient n = 105

Intellectual Property Granted

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

Patent #	Priority Date	Title
US 9,734,296	04/13/2010	Orthotic Support and Stimulus System and Methods
US 9,289,591	05/06/2012	Joint Rehabilitation Apparatus and Technique
US 8,972,018	03/20/2013	Adaptive Muscle Stimulation Technique
US 8,911,505	11/18/2010	Prosthetic Socket Stabilization Apparatus and Technique
EPO 11 831 357.6	07/11/2016	Orthotic Support and Stimulus System and Methods (EPO)

All IP filed through Trop, Pruner & Hu, P.C.

Proof of Concept Study Poster

Presented at the 2018 American College of Rehabilitation Medicine's Annual Conference

Dynamic Gait-Synchronous Neuromuscular Electrical Stimulation of Quadriceps in Patellofemoral Pain Patients

Soroosh Sadeh[a], Larry Kirn[b], Jody L. Jensen[a]

[a]The University of Texas at Austin; [b]Articulate Labs, Inc.

THE UNIVERSITY OF TEXAS AT AUSTIN

WHAT STARTS HERE CHANGES THE WORLD

Introduction

Patellofemoral pain syndrome (PFPS) is one of the most common forms of chronic knee pain in young and active individuals, particularly in females (1). PFPS is an overuse injury causing pain in the anterior side of the knee joint, underneath the patella and on the articular surface of the femur.

Abnormal muscle activation patterns or quadriceps muscle deficit, is one of the most frequently identified neuromuscular factors associated with PFPS. Delayed activation of the vastus medialis (VM) or a relative activity of VM compared to vastus lateralis (VL), VM: VL ratio, have been widely studied in clinical settings and have been a major focus in rehabilitation strategies (2,3). In terms of kinematics, PFPS patients show lower knee flexion angle compared to healthy individuals during different dynamic tasks (4,5). This may eventually increase the susceptibility of this population to common knee injuries and more serious chronic pathologic conditions such as osteoarthritis (6). Neuromuscular Electrical stimulation (NMES) is widely used as an intervention for PFPS.

Therefore, the goal of the present study was to investigate the feasibility of gait-synchronous NMES of quadriceps muscles to co-activate VL and VM muscles during swing phase of walking. Moreover, the authors were interested to evaluate the short-term impacts of NMES intervention on quadriceps activation and kinematics of walking.

It was hypothesized that following the NMES intervention the difference between the onset times of VL and VM muscles would decrease during the swing phase of walking. Moreover, it was hypothesized that the average knee range of motion, maximum knee flexion angle, and maximum knee extension angle would increase following the intervention.

Methods

- Twelve volunteers (2 males) medically diagnosed with PFPS aged 19-50 years old participated in this study.
- Twenty retro-reflective markers were placed on the palpable anatomic landmarks of the legs in preparation for motion capture (7,8).
- Wearable bands of microphones model MSI 2-1002785-1 (Articulate Labs, Inc.) were placed over the VL and VM muscle bellies in order to record the mechanomyographic (MMG) activity of the muscles.
- Then, each participant completed four 6-minute trials of normal walking with 10-minute resting period in between the walks.
- During trial one, participants walked back and forth on a straight line in front of the VICON cameras without wearing the stimulator.
- During trial two, participants wore the wearable knee stimulator, KneeStim (Articulate Labs, Inc.), without experiencing stimulation.
- During trial three, the stimulator was on for the entire swing phase of each stride and electrically stimulated VM and VL muscles of the symptomatic leg of the participant.
- A Final trial identical to trial one was done in order to observe any changes to the gait and/or VM/VL contraction patterns originating from the stimulation.
- A high pass filter with 80Hz cut-off frequency was used to remove the artifacts of heel strike (HS) (9).
- The absolute value of the MMG signal was calculated. And to normalize the signal, MMG amplitudes of the both channels (including VL and VM) were divided by its maximum value respectively.
- MMG onset times were detected during each stride by correlating the tibia acceleration and the amplitude of the MMG signal.
- The instants at which the MMG amplitude exceeded three standard deviations from its baseline was detected as the onset time of the muscle.
- The onset times were normalized to the stride period.
- Kinematic events of movement such as HS and Toe off (TO) were detected for each stride.
- Finally, the kinematic gait events including the valid TOs and HSs along with MMG onset times were transferred into a single array with the same sampling rate in order to plot the desired graphs.
- A one-way repeated measures analysis of variance (ANOVA) was performed to determine the effects of electrical stimulation on the quadriceps muscle onset times, maximum and minimum knee flexion angles, range of motion, and difference of VL and VM muscle onset times of the symptomatic leg over the four trials. A level of significance of $p \leq 0.05$ value was set. All the statistical analyses were done implementing the SPSS software version 24.0.

Results

Device co-contracted VL and VM on 99% of all measured swing phases. Device initiated stimulation at 37% of swing phase and terminated at 104%. Although the device's physical presence reduced range of motion (ROM) by 5°, ambulant stimulation increased ROM by 3°. Minimum knee flexion angle significantly decreased between trial two and trial four ($p<0.05$); maximum knee flexion angle did not change. The difference of muscles' onset times (VL-VM), VL, and VM onset times did not change after intervention ($p>0.05$).

Figure 1. KneeStim Device (Articulate Labs, Inc.)

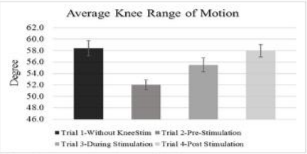


Figure 2. Average Knee Range of Motion. Average Knee range of motion slightly decreased in trial two when the participants wore the KneeStim device. Following NMES intervention the knee range of motion increased when trial two was compared to the final trial. These changes were not statistically significant. The error bars indicate the standard error of the mean of each sample mean.

Figure 3. Minimum Knee Flexion Angle. The asterisk indicate statistical significant differences of the sample means. This measure is equivalent to maximum knee extension angle. Following NMES intervention it can be interpreted that the maximum knee extension angle significantly increased.

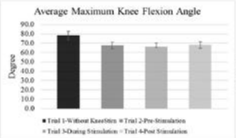


Figure 4. Maximum Knee Flexion Angle. Maximum knee flexion angle did not change following the intervention.

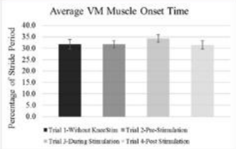


Figure 5. Average VM Muscle Onset Time. The average VM muscle onset time did not change following the intervention.

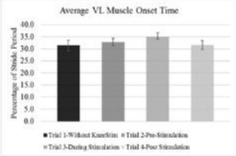


Figure 6. Average VL Muscle Onset Time. The average VL muscle onset time did not change following the intervention.

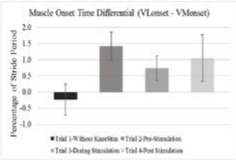


Figure 7. Muscle Onset Time Differential (VLOnset – VMOOnset). Wearing the device in trial two caused slight delayed activation of VL compared to VM. This value slightly decreased during trial three when the KneeStim was co-contracting the two muscles for the entire swing phase. In trial four the time differential of VL and VM slightly decreased compared to trial two.

Conclusion

A single session ambulant, gait-synchronous NMES is feasible and can be useful for altering muscle activation patterns. NMES intervention to co-contract VL and VM muscles starting at the beginning of each stride showed significant increase in maximum knee extension angle and slight increase in range of motion during normal walking in individuals with PFPS. The latter outcome in long term can be crucial in prevention of more serious chronic pathologic conditions such as osteoarthritis Future research should focus on a long-term rehabilitation method for PFPS population implementing NMES with more accurate pain and gait kinematic assessments while using a variety of dynamic tasks.

References

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* This study was approved by the IRB at the University of Texas at Austin

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