

Fast Gait Analysis and Treatment of Peripheral Neuropathy

Healthcare

WalkJoy
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Blain Tomlinson
CEO

BIO:

Blain has over 18 years of medical devices experience. Prior to starting up WalkJoy™, he was founder and COO of CPaiR Inc., an EMS medical device company, Executive Director of the St. Joseph Health System’s Mission Innovation Institute, Executive Director of the Adam Williams Traumatic Brain Injury Foundation and Vice President of Healthcare for O’Melveny and Meyers Consulting. Blain also consulted to Defense Advanced Research Program Agency (DARPA), where he helped secure investment capital for medical device start-ups. Blain co-founded the Orange Country Life Science CEO Roundtable and co-founded a lecturer series on Entrepreneurship at the University of California

Irvine’s Henry Samueli School of Engineering. Blain graduated Magna Cum Laude from Carroll College and serves on the Board of the Boy Scouts of America - Marine Vocational Program and the Health Alliance Foundation of Stemedica.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Tomlinson, what is the basic concept of WalkJoy?

Mr. Tomlinson: We actually have two products. WalkJoy and WalkingHealth. WalkJoy treats patients who have peripheral neuropathy. There are about 25 million people in the United States with the disease and over 320 million worldwide. A third of the patients are diabetic, another third results from chemotherapy and autoimmune, and the rest are idiopathic, meaning no one knows why it happens. People with peripheral neuropathy lose all of the feeling in their feet, cannot keep their balance and become chronic fallers. They also develop chronic foot ulcers which are the leading cause for lower limb amputation. The WalkJoy units provide a secondary signal to healthy nerves that helps restore their balance and so they walk more normally. When patients walk more, foot ulcers are reduced and they can resume a more normal life. I’ve seen patients cry after only taking twenty steps.

The second product is called WalkingHealth, which we developed after designing all of the algorithms for WalkJoy. WalkingHealth enables any physician, physical therapist or healthcare provider to perform fast gait analysis in their office, at the patient’s home, or anywhere else. It is important

for rehabilitation and can identify people who are at risk of falling so proactive therapy can begin sooner. There are studies showing that through someone’s gait, we can predict the onset of Alzheimer’s months before they show any cognitive problems.

CEOCFO: How does the neuropathy product work?

Mr. Tomlinson: Basically, we provide the central nervous system a secondary signal upon heel strike through healthy nerves that tells the patient’s brain where their feet are. It fits just below the knee cap and as soon as the heel strikes the ground, it vibrates against the tibia where healthy nerves signal the strike to the brain. This restores what is called the gamma efferent feedback loop or sensory motor feedback loop. In layman’s terms, the sensory system is compromised, but the motor system is not. The patient knows how to walk, they just need that secondary signal and within a matter of milliseconds of getting that signal, their motor system takes control and they start to have a near normal gait.

CEOCFO: How does that help with other problems, such as ulcers?

Mr. Tomlinson: Neuropathy patients tend to either shuffle or stomp down when they walk rather than the normal heel-to-toe rock-off gait. They can’t feel their feet touching the ground, so they stomp around trying to get some kind of sensory feedback. This action increases the pressure on certain parts of their feet, so the blood does not have time to come back to restore the tissue, creating pressure points or hot spots. Foot ulcers are caused by repeated hammering on the same tissue over and over and over. When you have a normal heel-to-toe rock-off

in your gait, you spread out the pressure points in the foot which avoid developing those hot spots. As I mentioned, foot ulcers are the number one reason for lower limb amputation.

CEOFCO: What have been the treatments in the past?

Mr. Tomlinson: There is no cure for neuropathy. The only current treatments address pain mitigation. About 50% of neuropathy patients suffer from severe pain as the nerves die. There are drugs for the pain and a few devices that attempt to restore blood flow to the nerves, but WalkJoy is the only product on the market that helps restore balance and gait.

CEOFCO: What has been the reception from the medical community?

Mr. Tomlinson: It has been fabulous and a fun run thus far. Out of 400 applications to StartUpHealth - GE Health, we were one of 13 companies selected into the 2013 class. We won the "Most Innovative Company of the Year" award in the Long Term Care LinkTank Innovation Competition; we won the Cleveland Clinic "Future of Medicine Award" and recently won the Louisville Innovation Summit Competition. GE Ventures selected 26 start-up CEOs to be in an ongoing Leadership Class and I'm very honored to have been invited to join this group. None of this would have happened without our Team which consists of some of the world's top specialists in this area. As I mentioned, we have had patients take 20 steps and start to cry. Others say things like "Oh my God, this works. I have my freedom back. I'm not afraid to walk anymore."

CEOFCO: What was the most difficult part of the technology to put together?

Mr. Tomlinson: The biggest challenge was identifying the right frequency and speed at which to provide the signal and developing the actuators that provide the vibration signal. You cannot get that off the shelf. We need a vibrotactile actuator that vibrates at a super high rate of speed. That and

developing accurate algorithms to make it fire right when we need it to fire for any gait pattern.

CEOFCO: Is it the same for everyone? Is it an off-the-shelf device or is there customization needed?

Mr. Tomlinson: The beauty of the WalkJoy system is that it orients itself to each patient as they use it. We know the body remembers how to walk, but the feedback that the nervous system provides to the brain has been compromised by neuropathy. As the patient begins to walk with the device and receives the new connection in the feedback loop, they gain confidence with each step

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CEOFCO: How do you reach the portions of the medical community that should be prescribing?

Mr. Tomlinson: We have done a number of physical therapy, podiatry, diabetes trade shows and recently partnered with the largest specialty distributor in Australia. We are working with a large health care provider in the Pacific Northwest, a large equipment distributor, and we are working with a number of VA distributors because the VA and Indian Health Services are impacted with peripheral neuropathy patients. We work closely with StartUpHealth - GE Health who have been very helpful in connecting us to the right people. We also work with LTC Innovation and are in discussions

with more than a few of the largest medical device and rehab companies to structure strategic partnerships.

CEOFCO: Is it a reimbursable item?

Mr. Tomlinson: There are six to seven CPT (Current Procedural Terminology) codes that are reimbursed for the gait assessment, diagnosis, and verification. We are working with CMS to secure an E-code for WalkJoy.

CEOFCO: Would you tell us more about your second item?

Mr. Tomlinson: The second product is WalkingHealth which is based on the algorithms that we created for WalkJoy. It measures the three main

things that are applicable for very fast, easy to understand, and accurate gait assessment. We have developed WalkingHealth to be an off-the-shelf product that any healthcare provider can use. Personnel without professional training can do the test on the patient; then the physician or physical therapist can quickly interpret the results. We can streamline the work flow in the physician's or the physical therapist's office and help them create better outcomes along with a new revenue stream.

CEOFCO: Is the market essentially the same?

Mr. Tomlinson: No, WalkingHealth is a diagnostic device and WalkJoy is a therapy device. Therapists and care

facilities use WalkingHealth to diagnose and document gait aberrations in patients. Medicare will require objective functional outcome data to justify a course of therapy. Documentation will become the key to successful reimbursement and WalkingHealth provides the measurements that demonstrate the efficacy of a course of treatment. If the therapy can't be justified, CMS will reject the reimbursement.

Upon admission and periodically thereafter, Independent and Assisted Living facility administrators use WalkingHealth to identify patients who are potential fall candidates. Upon identification, patients are prescribed a

course of therapy to avoid falls which cost the health care system a lot of money, shorten the patient's life, and increase turnover at the facility.

WalkJoy is a therapy device that is prescribed to peripheral neuropathy patients who have difficulty walking. As I previously said, when patients walk better, their quality of life improves, depression decreases, foot sores heal faster and are less likely, and amputations are reduced.

CEO CFO: What is the actual product that you would be offering there?

Mr. Tomlinson: WalkingHealth. WalkingHealth is the exact same form-factor as WalkJoy. It is the same size, it looks exactly the same, but we take out the actuators that create the vibration. WalkingHealth adds significant value to the Independent and Assisted Living Communities.

When a resident falls they may leave that facility for a higher level of care which costs more and increases resident turnover. Predicting those residents at risk and implementing proactive therapy reduces the number of events and turn over.

CEO CFO: Are you funded for the next steps you need to take or would you be seeking partnerships or funding?

Mr. Tomlinson: We are always looking for smart funding partners that can help us add more value and scale. Currently we are doing strategic partnerships through our distributors and we are in discussion with some other larger corporate partners. We have not sought venture capital money, preferring to self-fund through friends and family and we think we can be cash-flow positive in Q2-Q3 of 2014. We are planning a major roll out in Q1 into about 300 facilities.

CEO CFO: Why should WalkJoy stand out to the medical community?

Mr. Tomlinson: We help solve a significant and growing unmet need. The market is huge and WalkJoy is the only proven device that helps restore gait. There are about 25 million people in the United States and about 320 million people worldwide, and about 1.8 million are diagnosed every year with neuropathy which is on the rise globally. There is no cure for peripheral neuropathy and WalkJoy can reduce falls and foot ulcers. Falls account for over 71% of all healthcare costs for patients over 60 years of age. Falls are deadly, and most falls are treated after the fact. We can help prevent those falls before they occur. The CDC and CMS want everyone over 65 years of age to have an objective gait assessment at least twice a year. Our products are very cost-effective and pay for themselves.

Not for distribution!



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