Clinically-Oriented Wearables for the DM Population

Now you can wear your heart (and health tracker) on your sleeve

BY JOHN D. MILLER, BS, BIJAN NAJAFI, PHD, MSC, AND DAVID G. ARMSTRONG, DPM, PHD, MD

Introduction

As many avid followers of technology innovation know, the line between medical devices and consumer electronics is becoming increasingly blurred. From wearable robots and always-on computing to memory engineering or next-gen implants, we arguably live in a time more exciting and innovative than at any time in our history. Just as the understanding and utilization of penicillin allowed the human race to expand longevity and increase quality of life, so too will these next generation man/machine augmentations improve our quality of existence. With this in mind, the phrase ‘you are what you wear’ will take on an altruistic meaning far greater than originally intended over the next coming decades.

Peripheral Neuropathy: a Silent Subversion to Health

Sensory and fine motor deficits are common among aging populations, with peripheral neuropathies affecting nearly 30% of all Americans over the age of 65.[1] Diabetes-related polyneuropathy is one of the most common causes of peripheral neuropathy and is present in roughly 50% of all diabetic persons.[2,3] Oftentimes, the true nature of these deficits goes unnoticed until end-stage complications escalate to overt pathology, such as the development of a neuropathic ulcer, Charcot breakdown, or an injury-inducing fall. Due to this patient population’s significant risk for ulceration and falls[2,3], the early detection of at-risk characteristics is of great value to the healthcare system.[4,5]

While the 10g Semmes-Weinstein monofilament has been a gold standard among clinicians for testing epicritic sensation in the lower extremity, newer modalities for sensory and functional examination are increasing in popularity. Efforts to use digital gait tracking to record and identify troublesome kinematics have been ongoing for decades. Continued advancements in battery life, wireless communication, and reduction in the transistor size of the sensors allows the once costly and space-restrictive traditional ‘gait lab’ to be replaced with a few body-worn Bluetooth sensors and a portable laptop computer. Use of these trackers, such as those made by Biosensics, allows a clinician rapid and time-efficient investigation of a patient’s gait pattern in the clinical setting. Continued use of these modalities may prove useful in documenting patient improvement following surgical intervention or during a course of physical therapy.

Fall Prevention and Real-Time Wearable Proprioceptive Protection

Whether in the clinical office or as part of daily at-home health monitoring, the ability to quickly report imminent, credible threats to health is an invaluable step in maintaining a high quality of life. Elderly patients with diabetic neuropathy exhibit reduced joint proprioception in the lower extremity.[6] In tandem with loss of epicritic sensation and decreased upper-body balance, these patients are at extreme risk for obstacle collision and falls.[6-8]

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Patients with diabetes-related neuropathy are known to exhibit abnormal gait characteristics including reduced postural stability.[9-11] Interestingly, slight gait abnormalities that may otherwise go undetected by current measurement standards can be exacerbated to a detectable level when the patient is asked to do something outside of regular testing conditions. For example, when tested with reciting a mental task or walking over uneven or obsta-

Continued on page 68

Wearables *(from page 67)*

cle-filled surfaces, irregularities and hesitancies in gait patterns become more apparent.[6,7,10,12]

Using these techniques in a virtual reality setting where risks to patients can be minimized, researchers have identified parameters such as reaction time and toe clearance that appear to have a high correlation with neuropathy severity.[7] With further refinement, these testing algorithms may become the standard methods for early risk identification in elderly and neuropathic populations, likely providing a threshold by which pre-emptive integration of physical therapy or and other life-adjusting regimens may be assigned.[7]

Use of interactive virtual reality programs has shown utility beyond the detection of at-risk patients. Virtual proprioceptive and exercise interventions (aka "exergaming") in physically frail, older adults have been proven to enhance gait stability and upper torso balance.[13] These improvements are likely the result of increased peripheral afferent input, and will likely see increased use in the home setting.[14] Use of wearable sensors, or even visual sensors such as the widely popular Xbox Kinect system, with continued exploration of 'live' sensory training systems, could revitalize lost proprioception and provide patient-specific training to optimize function and achieve real-world goals.[15,16] Thus the use of virtual reality and wearable sensors is just the tip of the iceberg in soft tissue and gait-risk assessment, with their eventual use likely extending far into the therapeutic range.

Thermometry and Pressure—'Red Hot' Flags

While the ability to detect a person's risk level based on quantity of neuropathy present is valuable, the ability to accurately predict the subcutaneous development of ulceration may hold greater efficacy in prevention of life-threatening events. One of the latest techniques for the detection of ulcer development is epidermal thermometry.[17-19] Previously, temperature differences between contralateral foot anatomy were shown to accurately identify early episodes of acute Charcot neuroarthropathy of the foot.[18] Newer data for foot temperature-guided therapies are compelling, indicating a relative risk reduction of ulceration by 62-90%.[20-22] In a study of at-home foot temperature monitoring, patients who acquired ulcerations during the trial period had a 4.8 degree greater temperature difference at the site of ulceration than control persons one week prior.[20]

Due to its efficacy in detecting the pyrogenic response of soft tissue inflammation, epidermal temperature detection is now being integrated into a multitude of devices. From in-shoe insoles to at-home bathmats, these devices seamlessly incorporate themselves into a patient's lifestyle. One example, the Boston-based Podimetrics bath mat embedded with sensors allows a brief non-invasive measurement of the blood flow to a patient's feet. Simply standing on the device for 30 seconds (perhaps less than the length of time it takes to brush one's teeth) could be an effective 'early warning system' for high-risk events, and could be easily integrated into a patient's daily routine.[21]

Additionally, pressure-sensing devices such as the Orpyx Surrosense RX insole can alert the insensate wearer to tissue-threatening pedal pressures throughout daily activity. Combining pressure-sensing insoles with a wirelessly connected wrist-worn watch, the insensate wearer is notified of high-pressure moments to plantar tissues and given the opportunity to offload these areas before continued tissue damage occurs.

Biosensors and the New Age of 'Who are You Wearing'?

Recently, the United States Department of Defense has increased its sponsorship of tech health-related startups in the California area. Investing nearly 75 million dollars in the Academic and institutional FlexTech Alliance alone, the Pentagon also expects to see this research greatly benefitting the consumer sector, particularly medical health fields. The focus of most of this funding seems to be directed in one of either two directions: the refinement of small, durable, and flexible sensors light enough to be woven into textiles or adorned directly to the patient's skin, and mobility and strength-enhancing exoskeletons.

The HealthPatch MD is a reusable biosensor made of ECG electrodes and a 3-axis accelerometer.

Large consumer tech giants are also jumping on the wearable health bandwagon. Major software and electronic pioneers such as Google have recently decided to go 'all-in' on advancing diabetes-specific wearable sensor research, providing brief glimpses into the reality of nextgen healthcare technology. Under a new subdivision known as 'Alphabet', Google Life Sciences has teamed up with experts Sanofi, the Joslin Diabetes Center, and Dexcom and promise to bring to the market a dime-sized flexible skin adherent sensor in the next few years. This comes after Google's prior announcement in early 2014 that its Google X research division was working with Novartis eye care division Alcon to develop a smart contact lens which would monitor the wearer's glucose levels and indicate abnormal ranges using an inset, color-changing LED visible only to the wearer.

A second long-term project announced by Google Life Sciences includes the development of a low-cost, bandage-sized glucose sensor that would be connected to the cloud for auto-uploading of patient data. While these projects may seem like far away concepts, their existence on a commercial scale could not be more imminent. With the success of rather 'simple' wearable smart gadgets for heart-rate, GPS, and sleep

Continued on page 70

Wearables (from page 68)

tracking, and following the unveiling of Apple's Healthkit APK for the Apple Watch, it is increasingly likely to imagine these wearable sensors, and health-tracking may see core integration into the next generation of smartphone operating systems.

In fact, one such bandage is already available on international markets and is known as the HealthPatch MD (Figure 1). This device allows patients and their healthcare professionals a 'round-the-clock' investigation into a patient's vital health information. The HealthPatch MD is a reusable biosensor made of ECG electrodes and a 3-axis accelerometer. This device is embedded into a disposable bandage able to track a patient's heart rate, breathing, skin temperature, number of steps, and even the occurrence of syncopal episodes by tracking the patient's body position. Like many others, this uses its own low-power Bluetooth antenna to connect to most 'smart' devices for data logging, and has already attained regulatory clearance in Europe and the United States for commercial sale.

Press 'Print' to Wear

The use of 3D printing as a means of pre-operative planning is already well illustrated. While many fields such as neurology and plastics are finding uses for individualized surgical techniques, 3D printing has already been shown to be an effective mechanism for pre-operative planning in diabetes-related Charcot reconstruction. Using 3D CT reconstructions of the patient's deformities, surgeons are able to practice their osteotomies and evaluate without the risk of harming the patient while determining the most effective levels and angles for deformity reduction.[23]

In addition to pre-surgical planning, 3D printed constructs have already made their commercial presence known in the facilitation of in-house, custom orthoses and shoe modifications. Using portable 360-degree scanners to take digital 'molds' of the patient's foot, these in-office printers are able to generate a therapeutic and patient-specific device without relying on an external production company. Many existing orthotic companies advertise the use of additive manufacturing or (3D printing) techniques in the fabrication of their devices. Whether any benefit exists in terms of patient outcomes regarding fabrication techniques remains to be seen. However, the current belief stemming from the 'do-it-yourself' (DIY) and 'home-brew' communities suggests that 3D design and printing technologies permit the designer the ability to inexpensively and rapidly create patient-tailored therapeutic devices at the press of a button.

Exoskeletons and the 'Human-Chine'?

Complicating the health of the elderly and diabetic populations are chronic co-morbidities such as abnormal BMI, joint arthritis and degeneration of muscle tissue. The combined effect of many of these disease states renders the patient in a less-active physical state, further limiting return to a healthy state. Additionally, patients with diabetes-related amputation or Charcot deformity often experience reduced quality of life secondary to their reliance on prosthetics and bulky orthoses post-amputation.

Figure 1: HealthPatchMD

To counter this, the latest developments in powered exoskeleton and prosthetic devices envision a future where limitations in ambulation are essentially non-existent.[24] Patients suffering from below-knee amputations are now able to benefit from advanced powered ankle devices which use transdermal sensors to replicate in-phase muscle activation. These devices effectively recreate the kinematics of normal gait, and allow ambulation in some of the most challenging conditions such as spontaneous running, walking backwards, or while traversing stairs.[24,25] It is likely that these devices will also play a large part in enhancing not only the physical abilities of healthy individuals but also increasing their mobility and independence.

Future Predictions and the new 'Digital' Exam

While techniques have yet to see widespread implementation into the daily lives of diabetic or geriatric patient populations, many are already commercially available and readily used in the healthy and athletic populations. The modern world faces generations who have spent a majority of their adult lives directly interacting and evolving with digital and electronic trends. As manufacturing costs continue to improve alongside intuitive, aesthetic design, it becomes almost impossible to imagine a world in which most of its population has a number of physiological processes either directly monitored or supported in real-time using digital adjuvants.

However, the continued improvement and implementation of wearable medical devices by industry and the health-minded consumer will no doubt lead to their ubiquitous appearance in the clinical setting. With consultation regarding these wearable devices and review of their data likely becoming an increasing expectation of a physician's in-office time, the creation of a new patient medical history is inevitable. This 'digital' history will be a required addition to the standard physical and past medical history currently practiced by all medical professionals in the routine clinical examination. While constant-monitoring devices are likely to offer great benefit to patient care, their logistic use in the clinical setting is yet to be fully understood. **PM**

Continued on page 72

Wearables *(from page 70)*

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John Miller is a 4th year podiatry student at Des Moines University College of Podiatric Medicine and Surgery. John performed a one-year research rotation at SALSA in 2014. He has authored numerous articles on the treatment of the diabetic foot and the future role of technology in medicine.

Dr. Najafi has been serving with the University of Arizona, Department of Surgery and Department of Biomedical Engineering (Tucson, USA) since April 2012. He serves as Professor of Surgery and the Director of interdisciplinary Consortium on Advanced Motion Performance (iCAMP), is a member of the Arizona Center on Aging (ACOA), and Associate Member of Arizona Cancer Center (AZCC). He received a PhD degree in Bioengineering followed by a postdoctoral fellowship in applied biomechanics at the Swiss Federal Institute of Tech (EPFL, LMAM, Lausanne, Switzerland), and in Neuroscience at Harvard University (Neuromotor Control Lab).

Dr. Armstrong is Professor of Surgery at The University of Arizona. Dr. Armstrong also holds a Master’s of Science in Tissue Repair and Wound Healing from the University Of Wales College Of Medicine and a PhD from the University Of Manchester College Of Medicine, where he was appointed Visiting Professor of Medicine. He also co-founded the Southern Arizona Limb Salvage Alliance (SALSA). Dr. Armstrong has produced more than 415 peer-reviewed research papers in more than two dozen scholarly medical journals as well as over five dozen book chapters, and is co-editor of the American Diabetes Association’s (ADA) Clinical Care of the Diabetic Foot.