Smartphone Sensitivity in Objective Balance Testing

The Science Behind Sway Balance™
Clinical Research Report

July 23rd, 2013
INTRODUCTION

Entrusted with player health and safety, athletic trainers and clinicians rely on their education, training and the latest information to make one of the toughest calls faced on the field - the call to put a player back in the game after a big hit. With increasing awareness, a greater emphasis is being placed on measures that help objectively identify and manage potential head injuries. To help athletic trainers and healthcare professionals make the right call, Sway Medical developed an FDA-cleared mobile software system that analyzes balance using the triaxial accelerometer of any iOS device to evaluate a key symptom of concussions.

The Sway Balance™ software utilizes the built-in low power MEMS accelerometer to estimate stability by having the patient press the device against their chest and perform a standardized static balance test. Sway establishes an individualized normal balance score to objectively track changes in stability for each user. All test results are stored securely for longitudinal analysis of individual and group scores. The ease of access to a simple software download on an existing device make the Sway Balance™ System a mobile, cost-effective and accurate measurement tool.

NEED FOR BALANCE

The need for more accurate, accessible and cost-effective assessments of balance and vestibular function are well documented by researchers and medical professionals. Clinical balance testing tools currently used are limited either by concerns of portability, storage, expense and accuracy. Force platforms are regarded as the most objective measure, but adoption has been slow due to high up-front cost and poor mobility.

Standardized subjective protocols such as the Tinetti, Berg, Rhomberg and BESS protocols are more widely used, but lack an objective outcome that can be used to compare across large populations with different test administrators. The development of portable electronic devices that can measure acceleration of the center of mass (COM) have been described in several clinical research projects1,2,3, however a cost-effective and easily distributable system have yet to pass the regulatory hurdles necessary to be used in a clinical setting.

The emergence of mobile smartphones equipped with accurate accelerometers presents an opportunity for healthcare professionals to conduct readily available and highly accurate evaluation of postural sway without the need for peripheral hardware.
**HOW TO SWAY**

The user is instructed to simply hold the smartphone against the chest and perform a pre-selected balance test. Thoracic sway is monitored during the balance test by recording variability in device acceleration through the low powered MEMs accelerometer. Sway Balance™ uses proprietary algorithms recorded from the 10-second balance test to evaluate postural sway. Upon completion of a test, the user is provided with a score on the scale of 0-100, with 100 indicating no motion detected. Comparison against a baseline or previous test allows the health care professional to track recovery or determine variation from normal for that individual. Sway recommends three initial tests to establish a proper baseline with periodic follow up tests.

**SWAY CLASSIFIED AS A MEDICAL DEVICE**

The Sway Balance™ System is a medical device and received a 510(k) clearance by the Food and Drug Administration (FDA) and is intended for use by qualified individuals to assess sway as an indicator of balance.

Sway Medical operates with product quality, performance, safety and privacy of users in mind. Sway Medical complies with all current medical device quality standards and regulations including ISO 13485, 21 CFR 820, 21CFR Part 11, and HIPAA/HITECH. Sway Medical has taken appropriate measures to ensure all HIPAA rules and regulations have been addressed, and a commitment to security and privacy of all patient data is maintained.

**INDICATIONS OF USE**

The Sway Balance™ System is intended for use to assess sway as an indicator of balance. Individual suitability for assessment must be judged on a case by case basis, by a qualified individual including those certified and/or licensed in their state to prescribe and/or use balance devices such as certified athletic trainers and coaches, physical therapists, nurses and physicians.

Conditions affecting postural sway include nausea, headache, orthopedic injury, ear infection, medications, head injury, dehydration and fatigue. The Sway Balance System can be used wherever an iOS mobile operating device is available.
**SWAY CLINICAL RESEARCH**

**DEVICE SENSITIVITY**

Apple iPhone, iPod Touch and iPad ST Microelectronics accelerometers have shown consistent sensitivity measures in product conformance trials performed by the manufacturer\(^4\). MEMs accelerometers have also exhibited levels of sensitivity in FDA cleared class II medical devices for the use of human motion monitoring\(^5\). Device sensitivity testing is not available from mobile phone manufacturers to ensure consistency with the accelerometer manufacturers.

Additional testing of iOS device sensitivity was completed by the Wichita State University Mechanical Engineering Department to determine accelerometer sensitivity in a random sample of iOS devices\(^6\). Sensitivity levels were reported well within the manufacturers acceptable range and demonstrated consistency through low coefficients of variability. Consistency across a random sample of devices indicates that a downloadable application can be expected to accurately record acceleration values.

**CALIBRATION**

An individual device verification feature on the Sway Balance™ application was implemented to ensure accelerometer measures have not been altered by mechanical failure. The verification tool is available in the Sway Balance™ settings menu to allow the user to perform a three-second accelerometer verification to ensure the device is not recording abnormal accelerometer values outside of the sensitivity threshold. The Sway verification feature is a unique approach to provide individual users confidence in Sway to provide accurate measure that can be used in medical treatment decisions.

**SWAY RELIABILITY**

Accuracy and consistency are both critical to the value of the Sway Balance™ System. Reliability was shown in clinical studies analyzing test-retest variability of the Sway System in independent research studies of 30, 57 and 75 subjects\(^7,8,9\) and has been shown previously in the literature using accelerometer measurements\(^10\). These results demonstrated strong test-retest reliability with no significant difference following significantly lower scores in an initial trial, suggesting a single familiarization test may be necessary to establish a consistent baseline and remove the learning effect.

**SWAY VALIDITY**

Sway Balance™ validity was established through the evaluation of the software in progressively more difficult balance conditions\(^9\) as well as during balance testing on foam pads of varying density\(^11\). Results were consistent...
with the hypothesis that the more unstable the assessment the lower the balance score compared to more stable conditions. For each measure, as the balance task became progressively more difficult, the Sway Balance™ System recorded a significant ($p < 0.003$) decrease in the balance score. Significant differences in balance scores on foam pads of varying densities were also found, with the thicker/less dense pads relating to lower stability scores and the more dense foam pads showing high stability.

**FORCE PLATFORM COMPARISON**

Sway Balance™ has been shown to provide more accurate scores than those collected with force platform technology$^{9,12}$, the current market gold standard in postural sway assessment. Sway provided more accuracy in differentiating between balance conditions and showed within-subject significant differences between foam and no-foam conditions in stable (two foot) and less stable (single foot) conditions. The force platform did not show significance between the same conditions.

**SWAY ON THE FIELD**

The Sway Balance™ assessment has shown strong agreement ($r > 0.83$) with the Balance Error Scoring System (BESS) in determining an individual’s level of balance$^{13}$. The BESS test has been shown to correlate with force-platform technology as an effective means of testing balance to determine potential head injuries$^{14}$. The objective nature of a standardized Sway protocol provides a more comparable score, without the inherent bias of the test administrator and the low inter-rater reliability seen through interclass coefficient (ICC) scores typically associated with BESS. Sway is an effective sideline tool due to its objective metrics, simple user interface and the time it takes to complete a test.

![Tandem Leg BESS Comparison](image1)

![Single Leg BESS Comparison](image2)

**CONCLUSION**

The ease of access to a simple software download on an existing device, make the Sway Balance™ System a mobile, cost effective and accurate measurement tool. Now, qualified health professionals in high school, collegiate, and professional team settings can incorporate a truly multifactor assessment that includes neurocognitive, symptom evaluations, and now objective balance testing for real-time decision making.
REFERENCES


