

Use of Hearing Aids Embedded with Inertial Sensors and Artificial Intelligence to Identify Patients at Risk for Falling

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Objective: To compare fall risk scores of hearing aids embedded with inertial measurement units (IMU-HAs) and powered by artificial intelligence (AI) algorithms with scores by trained observers.

Study Design: Prospective, double-blinded, observational study of fall risk scores between trained observers and those of IMU-HAs.

Setting: Tertiary referral center.

Patients: Two hundred fifty participants aged 55–100 years who were at risk for falls.

Interventions: Fall risk was categorized using the Stopping Elderly Accidents, Deaths, and Injuries (STEAR) test battery consisting of the 4-Stage Balance, Timed Up and Go (TUG), and 30-Second Chair Stand tests. Performance was scored using bilateral IMU-HAs and compared to scores by clinicians blinded to the hearing aid measures.

Main Outcome Measures: Fall risk categorizations based on 4-Stage Balance, Timed Up and Go (TUG), and 30-Second Chair Stand tests obtained from IMU-HAs and clinicians.

Results: Interrater reliability was excellent across all clinicians. The 4-Stage Balance and TUG showed no statistically significant differences between clinician and HAs. However, the IMU-HAs failed to record a response in 12% of TUG trials. For the 30-Second Chair Stand test, there was a significant difference of nearly one stand count, which would have altered fall risk classification in 21% of participants.

Conclusions: These results suggest that fall risk as determined by the STEADI tests was in most instances similar for IMU-HAs and trained observers; however, differences were observed in certain situations, suggesting improvements are needed in the algorithm to maximize accurate fall risk categorization.

Key Words: Artificial intelligence—Balance—Fall risk—Hearing aids—Inertial measurement unit sensors—Sensorineural hearing loss.

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INTRODUCTION

Among US seniors, falls are a leading cause of injury and death (1). Some 27.5% of adults aged 65 years and older fall each year resulting in 3 million emergency room visits, 950,000 hospitalizations, and 32,000 deaths (2). The estimated medical costs alone exceed \$50 billion annually (3). A single fall has been estimated to cost \$9,000 to \$30,000 depending on the healthcare setting and severity of the fall (4,5). Adding to this total are costs stemming from loss of independence such as in-home caregivers and assisted-living facilities. Due to the substantial human toll and financial burden of falls, much effort has gone into the identification of those at risk for falls, designing preventative measures, and implementing therapeutic interventions. As environmental and rehabilitative measures can substantially reduce fall risk, early identification of those at heightened risk for falls is a foremost priority. Indeed, in a cross-sectional study of patients at risk of falling due to dizziness, those who completed physical therapy were associated with an 86% reduction in risk of falls (6).

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Numerous methods have been proposed for identifying those at risk for falls (7). A variety of fall risk assessment screening tools have been proposed encompassing patient (eg, orthopedic, neurological, and vision) and environmental factors that contribute to fall risk. The 1-year risk of falling doubles for every added risk factor: 8% for zero risk factors, 19% for two risk factors, 32% for three risk factors, and 78% for four risk factors (8). The most significant predictor of falling is a previous fall episode; thus, priority should be placed on preventing the initial fall (9). As fall victims have typically experienced a pattern of near falls before injury, measurement of a patient's mobility pattern during activities of daily life is the most direct means of assessing risk. This has led to the exploration of wearable devices, including inertial measurement units (IMUs) with one or more accelerometer and/or gyroscopic sensors affixed to the body to identify movement patterns indicative of heightened fall risk (10–14). Because statistical and threshold-based analyses lead to high levels of false alarms, machine learning (ML) and artificial intelligence (AI) algorithms have been used to refine the interpretation of sensor data (15,16).

Conceptually, a pair of ear-worn devices working in tandem has advantages over inertial sensors positioned elsewhere on the body. Compared with sensors placed on the wrist or leg, ear-worn sensors are subject to fewer extraneous movements. Also, ear-worn devices such as hearing aids offer multiple benefits, including hearing rehabilitation and being a conduit for information and entertainment (music, books, audio, web access, etc), and are a favorable site for monitoring biometrics reflective of brain function (17–19). In addition, because increasing hearing loss is associated with a greater risk of falling (20), coupling a fall detection device with a hearing aid may be especially beneficial. Recent reports have suggested that hearing aid use is associated with a reduced risk of falling (21,22).

Recently, Starkey Hearing Technologies developed an enhanced hearing aid embedded with inertial measurement units and powered by artificial intelligence to automatically detect falls as well as measure and decipher different gait, strength, and mobility parameters. Preliminary testing of a binaural pair of devices in a small cohort of healthy young adults who simulated falls and near falls showed good accuracy with few false positives during activities of daily living (23). In another preliminary study, the device was shown to be more accurate in measuring step counts than pedometers or wrist-worn monitors (24). Prior to assessing this novel ear sensor for continuous monitoring of activities of daily living for signs of heightened risk of falling among a large cohort of seniors, we undertook the present study as a means of validating the accuracy and reliability of the devices based on national guidelines for fall risk assessment.

The Center for Disease Control and Prevention (CDC) has developed a multidimensional fall risk algorithm called Stopping Elderly Accidents, Deaths, and Injuries (STEADI), which was based on the American Geriatrics Society (AGS) and British Geriatrics Society (BGS) guidelines for fall prevention (25). The CDC STEADI protocol utilizes a multifactorial approach to assess fall risk using validated tools such

as two fall risk questionnaires and three assessments of functional mobility including the 4-Stage Balance test to evaluate balance, 30-Second Chair Stand Test to evaluate strength, and the Timed Up and Go (TUG) test to evaluate gait. Several studies have shown the STEADI algorithm to be reasonably predictive of future falls (26,27), and a systematic review has shown that individual fall risk assessments can reduce the rate of falls by 24% (28). However, fall risk evaluation and management implementation in clinics has significant, variegated barriers limiting the practical use of fall risk guidelines, including the perception of increased time to perform guidelines, limited resources, and failure to identify needs (29,30). Improving guidelines accessibility through self-administration would effectively reduce several barriers to fall risk detection and therefore a fall risk plan of care. Fall risk plans of care can reduce falls by 40%, highlighting the great impact effective fall risk assessments can have on patients' morbidity, mortality, quality of life, and overall healthcare burden given the high cost of falls (31).

The goal of the present study is to compare STEADI algorithm results collected by trained observers to the results computed by IMU-HAs in a large cohort of people over the age of 55 who screened positive for increased fall risks using the STEADI algorithm questionnaires.

Study Design

All data were collected by Stanford University researchers at university and community locations. All participants were provided written informed consent; the study protocol was approved by the Research Ethics Board of Stanford University (IRB Protocol Number 60900). Participants for this study were recruited primarily from electronic and printed flyers. These were posted in the Audiology clinic at the Stanford Ear Institute and within the local community in locations such as an assisted living community. Participants meeting inclusion criteria completed a demographics survey, completed a hearing assessment, were fitted with the IMU-hearing aids, and then instructed on how to complete the CDC STEADI functional mobility assessments while wearing the IMU-HAs. Assessments were scored in real time by a trained observer. Trained observers were defined as having formal training in CDC STEADI assessments. Assessments were video recorded and scored by two remote, trained observers at a later date to give three scores for each mobility assessment. Statistical analysis was then performed.

Inclusion Criteria

Inclusion criteria for participants required the following: age 55 or older, English speaking, and screened positive for fall risk. This was determined by CDC-recommended individual self-report to one or more "3 Key Questions": 1) Fell in the past year? 2) Feel unsteady when standing or walking? and 3) Worries about falling? Two hundred fifty participants were recruited in this manner, with ages ranging from 55 to 100 years (mean age = 78.3 years, standard deviation = 9.6 years, median = 78.6 years, interquartile range = 71.6–84.5 years) and fall history recorded (58% reported falls in the past year, among whom the average

number of falls was 2.2 falls; standard deviation = 1.7). Other demographics information is listed in Table 1.

Study Protocol

All participants first underwent hearing tests using traditional audiological procedures. Pure-tone thresholds were obtained using the Hughson-Westlake procedure (32) for sound frequencies ranging from 250 to 8000 Hz. The participants were then fitted with bilateral IMU-HAs according to the NAL-NL2 fitting formula (33). The IMU-HAs were equipped with embedded IMUs and AI algorithms to track participant movements and physical activity. The IMU data were streamed to a smartphone application via Bluetooth Low Energy (BLE) link, which was paired to the HAs worn by the participant. The combination of the IMU-HAs and the smartphone application are defined here as the HA application.

Motion tracking and analysis algorithms (MTAA) were developed using artificial intelligence based on machine learning methods for the IMU-HA application to automatically detect and score performance on the STEADI test. The MTAA were trained using IMU data recorded from the hearing aids in lab studies. The development included augmentations of the recorded IMU signals with various noise signals to ensure the algorithms are robust to interdevice variability and natural differences in head posture or device orientation. The MTAA includes IMU signal sampling, initial processing, and head posture correction, performed in real-time on the IMU-HAs. This output is then sent via the Bluetooth link to the mobile phone, where real-time STEADI test scoring is performed using the MTAA output.

Following the fitting of the HAs, all participants completed the CDC STEADI functional mobility assessments focusing on gait, balance, and strength assessment (25). This encompasses three key assessments: the 4-Stage Balance test, the 30-Second Chair Stand test, and the Timed Up and Go (TUG) test. During testing, and to ensure patient safety,

the Starkey AI-based Fall Detection Algorithms and Fall Alert feature were also enabled on the IMU-HAs. These assessments are described below.

4-Stage Balance Test

In the 4-Stage Balance test, the participants performed a sequence of four distinct balance positions. Each position progressively increased in complexity. The first position was the side-by-side position. The second position was the instep position. The third position was the tandem position. The final position was the one-foot stance position. Participants were asked to hold each position for a duration of 10 seconds. The performance at each position was then evaluated on a pass-fail basis; participants were required to maintain balance for the full 10-second duration to pass the test. If a participant touched an external feature, such as a wall or chair, or repositioned their foot to a better position during any of the stances, a failure was recorded. To establish an overall pass, participants were required to successfully complete a minimum of three of the four stances.

Timed Up and Go Test

In the TUG test, participants began by sitting in a chair measuring 17 in height or 43.2 cm, not touching a wall. They were then required to stand up, walk a 10-ft distance, perform a 180-degree turn, and subsequently return the same 10-ft path to their initial seated position (34). Successful completion of the TUG test necessitated participants to execute this sequence within a timeframe of under 12 seconds based on CDC recommendations within the STEADI protocol. Participants were allowed to use assistive devices, including canes and walkers, during the test. Participants were allowed a demonstration and test trial if needed.

30-Second Chair Stand

In the 30-Second Chair Stand Test (CS), participants repeatedly transitioned from a seated to a standing position and back, without utilizing their arms for support, for a duration of 30 seconds. The chair used for this test was 17 in in height (43.2 cm). Participants were scored based on the number of full standing transitions achieved by each participant within the allotted 30-second timeframe. In cases where a participant was in the process of standing when the 30-second mark was reached, it was counted as a successful stand if they were over halfway standing. The pass-fail criteria for this test were adjusted to account for age and sex according to CDC STEADI guidelines.

Scoring and Rating

Each test in the STEADI mobility assessment was scored in two ways. First, the performance of each participant was scored and rated by three trained observers. All trials were video recorded. Second, the performance of each participant was scored and rated by the IMU-HA application.

Statistical Analysis





Our first analysis was to ensure reliability across the three raters; we did so using an intraclass correlation coefficient (ICC[35]). In this measure, ICC values greater than

TABLE 1. Demographics

| | Percentage |
|---------------------------------|------------|
| Biological sex at birth | |
| Female | 62.4 |
| Male | 37.6 |
| Education level | |
| High school | 10.4 |
| College | 44 |
| Postgraduate | 32.4 |
| Professional | 13.2 |
| Ethnicity | |
| American Indian/Alaska Native | 0.4 |
| Asian/Pacific Islander | 12.4 |
| Hispanic/Latino | 2.8 |
| White | 81.6 |
| Other | 2.8 |
| Presence of hearing loss | |
| Yes | 94 |
| No | 6 |

Presence of hearing loss was defined as having at least one frequency greater than 25 dB HL at 500, 1000, 2000, or 4000 Hz.

TABLE 2. Agreement ratings between trained observer and IMU-HA application for different foot placements during the 4-Stage Balance test

| 4-Stage Balance Test | | |
|---|---|-----------|
| Direction | Foot Placement | Agreement |
| Side: Stand with your feet side-by-side. |  | 94.8% |
| Instep: place the instep of one foot so it is touching the big toe of the other foot. |  | 93.1% |
| Tandem: place one foot in front of the other, heel touching toe. |  | 82.6% |
| One foot: stand on one foot—whichever foot you prefer. |  | 79.4% |

This table delineates the specific foot placement challenges presented during each stage of the 4-Stage Balance test, accompanied by directional images. The agreement percentages reflect the consistency between ratings given by the trained observers and the IMU-HA application for each respective stage.

or equal to 0.9 are associated with excellent reliability. Comparisons between the trained raters and the IMU-HA application were performed using linear regression to examine the relationship between these measures, and paired *t* tests were used to compare the mean values. Individual raters' comparisons are included in supplemental materials. Finally, sensitivity and specificity values were obtained to compare the pass-fail rates between the trained raters and the HA application. Ground truth sensitivity and specificity

were scored by the trained observers. In cases where data were missing due to participant or application error, a mixed effect model was used to address unbalanced data.

RESULTS

Rater Agreement

Our data indicate that the in-person rater and the two offline raters demonstrated excellent agreement in their ratings for participant performance on each subtest. Here, we observed ICC values of 0.903 (95% CI 0.881–0.922), 0.978 (0.973, 0.982), and 0.994 (0.992, 0.995) on the 4-Stage Balance test, 30-second chair stand, and TUG test, respectively. Because of the high ICC values, we averaged the ratings of the in-person and two offline raters to obtain a single “trained observer” rating (see also [36]) for a similar application. That “trained observer” rating was used for all subsequent analyses. Individual ratings were scored and analyzed and are provided in Supplementary Table 1, <http://links.lww.com/MAO/C7>.

4-Stage Balance Test

Across all stages of the 4-Stage Balance test, we observed good agreement between the trained observer rating and IMU-HA application. The results are presented in Table 2. Here, the agreement ranged from 82.6% (tandem subtest) to 94.8% (side-by-side subtest) across different stages. On the one-foot subtest, which is not required to pass the 4-Stage Balance test (25), the agreement was 79.4%

Timed Up and Go (TUG) Test

In the TUG test, we observed excellent agreement between the trained observer rating and the IMU-HA application when the IMU-HA application successfully recorded the output of this test. The HA application was unable to record a response in 12% of the participants ($n = 30/250$ total participants). However, when the IMU-HA application successfully recorded a response, we observed a very close correspondence between the time recorded by trained observers and the IMU-HA application ($R^2_{220} = 0.96$; $p < 0.001$; Fig. 1,

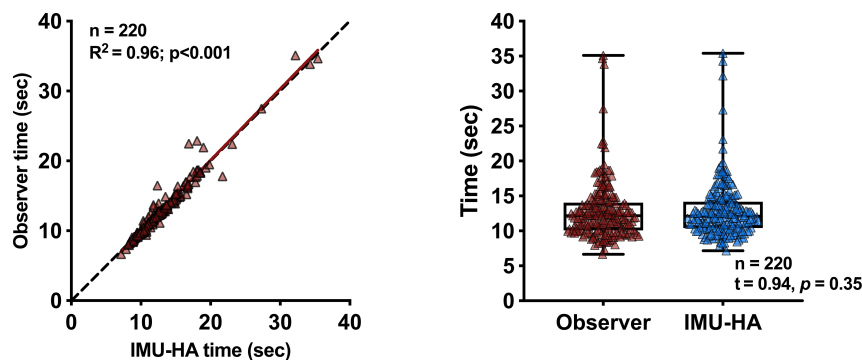


FIG. 1. TUG test. The left panel displays a linear regression plot of the relationship between timings recorded by the trained observers (*y* axis) and those by the IMU-HA application (*x* axis) on the TUG test. The regression line is depicted by the *solid red line*; the *dashed black line* indicates equivalent performance for the observers and the IMU-HA application. Thus, symbols above the dashed line indicate longer TUG times when measured by the observer for a given participant, while symbols below the dashed line indicate shorter TUG times. The *right panel* shows boxplots of the TUG results for the trained observers (*left*) and the IMU-HA application (*right*). The edge of the box represents the interquartile range, with the error bars indicating the entire range. Across both panels, individual data points are represented by *triangles with darker shades*, indicating overlapping data points.

left panel). Moreover, the average durations recorded by the trained observers and the IMU-HA application did not differ significantly ($t_{220} = 0.94, p = 0.35$; Fig. 1, right panel).

Further analysis of the pass/fail outcomes for individual participants showed excellent agreement between the trained observer rating and the IMU-HA application. Using the trained observer rating as the “gold standard,” the IMU-HA application demonstrated a sensitivity of 98.6% for identifying “Pass” ratings. The specificity of the IMU-HA application, as determined by its ability to identify “Fail” ratings, was 92.3%. Taken together, these data show excellent agreement between the trained observer rating and the IMU-HA application when the application successfully recorded the TUG test output.

30-Second Chair Stand Test

While we observed good agreement between the number of stands counted by the trained observers and the IMU-HA application, there was a small but significant difference between the two. Here, the linear regression analysis indicated a strong relationship between the stand counts recorded by the trained observers and the IMU-HA application ($R^2_{249} = 0.93; p < 0.001$; Fig. 2, left panel). However, despite the strong correlation, a small but statistically significant difference was observed between the two groups as the trained observers reported a stand count that was 0.8 units higher than the count produced by the IMU-HA application ($t_{249} = 10.13, p < 0.001$; Fig. 2, right panel).

For the comparative analysis of pass/fail ratings between the in-person observer and the IMU-HA application, the criteria were normalized for age and sex. The analysis revealed an accuracy of 89% in the classifications made by the IMU-HA application compared to the in-person observer rating. The specificity of the IMU-HA application exhibited perfect precision, indicating that when a “pass” classification was made by the IMU-HA application, it was always in agreement with the in-person observer's classification. However, the sensitivity was 78%, highlighting that the HA sometimes classified participants as “fail” when the trained observers classified them as “pass.” Of

the participants who met the passing criteria from the in-person observer, 11% ($n = 21/200$) were misclassified by the IMU-HA application. The specificity was 100%, meaning that all the “fail” classifications by the in-person observer were also identified as “fail” by the HA. This high specificity, combined with perfect precision, underscores the reliability of the HA application in identifying individuals who did not pass the test.

Safety

No falls were detected by the Fall Alert feature of the IMU-HA, and no falls or harm of any sort was reported by the patients or observers while completing the study.

DISCUSSION

On the whole, we observed good agreement between an IMU-HA application and trained observers when evaluating fall risk according to the STEADI protocol. For example, with the three subscales required to assess fall risk on the 4-Stage Balance test, the agreement ranged from 82.6% (tandem subtest) to 94.8% (side-by-side subtest). Thus, we observed good agreement on the whole between the trained observer and the IMU-HA application on this measure. Agreement was lower on the one-foot subtest (79.4%); note that this subtest is considered more difficult and is not required to pass the 4-Stage Balance test (25). In those cases in which we failed to observe agreement, one possible explanation is that near falls with recovery were interpreted as a fall by the IMU-HA application. This observation was previously reported in an HA application that reported a false-positive result when a participant experienced a loss of balance followed by a recovery (23). In contrast, such near falls would not qualify as a loss of balance by clinician criteria and may account for the discrepancies observed here. Notably, near falls are a significant predictor of future fall risk (37). To the extent that near falls contribute to the discrepancies observed here, they raise the possibility that IMU-HA applications may aid in the identification of future fall risk when performing the STEADI protocol.

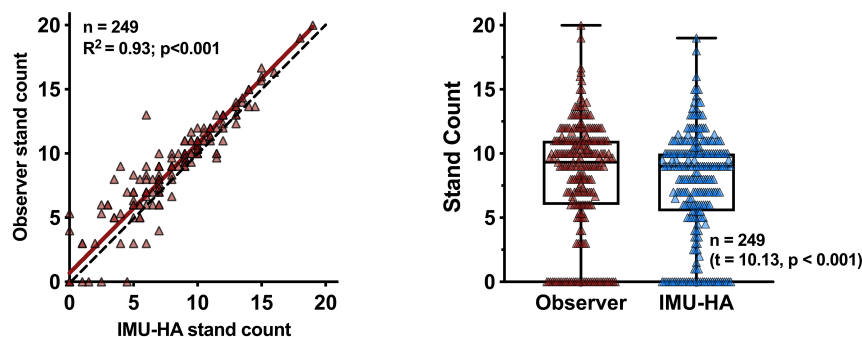


FIG. 2. Thirty-second chair stand test. The left panel displays a linear regression plot of the relationship between the number of chair stands recorded by the trained observers (y axis) and the IMU-HA application (x axis). The regression line is depicted by the *solid red line*; the *dashed black line* indicates equivalent performance for the observers and the IMU-HA application. Thus, symbols above the dashed line indicate more chair stands recorded by the trained observer for a given participant, while symbols below the dashed line indicate fewer chair stands recorded by the trained observer. The right panel shows boxplots of the chair stand test results for the trained observers (*left*) and the IMU-HA application (*right*). The edge of the box represents the interquartile range, with the error bars indicating the entire range. Across both panels, individual data points are represented by *triangles with darker shades*, indicating overlapping data points.

In the TUG test, the IMU-HA score correlated strongly with the trained observer score when the application was able to compute a response, with no difference in the duration between the two groups. However, the HA application failed to record a response in 12% of the participants. As participants, not trained observers, were charged with controlling the app, we speculate that the most likely explanation for this is that some participants had difficulty manipulating the app (eg, starting the app when beginning the TUG). By this logic, participants either need to be better trained to use the app or the application needs to be improved to reduce the likelihood of this occurrence. This is particularly relevant given that failure on the TUG test is likely the most predictive of falls and is the only mobility assessment recommended by both the CDC and the World Guidelines for Falls Prevention and Management for Older Adults: A Global Initiative (38).

In the 30-Second Chair Stand test, there was a close relationship between the number of stands counted by the HA application and trained observer rating. While the relationship between the two was virtually linear, we observed that the IMU-HA application underestimated patient performance on this measure by approximately 0.8 counts relative to the trained observer rating. While this average difference was small, of the participants tested here, 11% would be at risk of pass/fail misclassification from a miscount of one stand. One likely explanation for this small but relevant discrepancy is the difference between the HA application and the trained observers in those cases in which the patient is over halfway to a standing position at the end of the 30-second period. In the STEADI protocol, if a participant is over halfway to a standing position when 30 seconds has lapsed, observers are instructed to count it as a stand. In contrast, it is possible that the HA application did not always count the last partial stand in the full-stand count. An alternative possibility is that the HA application may have caused difficulty in interpreting additional movements associated with standing, such as with individuals who struggle to stand without utilizing their arms, as they may thrust their bodies forward to gain momentum (39). Similarly, some individuals may have incorporated more head movement as they began to experience fatigue, leading to incomplete ratings by the HA application. Thus, while the IMU-HA application is promising, additional improvements may be needed to eliminate the potential for miscategorization of fall risk.

This study has several limitations, including generalizability of data and IMU-HA application data collection errors. These data were collected in a controlled environment with trained observers readily accessible to study participants to demonstrate, correct, and troubleshoot while learning the STEADI assessments and how to use the HA. The translation of these results in real-world settings without real-time technological support or assessment demonstrations will require more user experience research to understand if similar outcomes are possible in more real-world settings. In addition, the study population may not be representative of a more general population: most of the study participants were highly educated, of high socioeconomic

background, and technologically advanced. Thus, further research will be needed to understand how user experience, demographic data, and environment will affect outcomes.

In closing, the agreement between the IMU-HA application and trained observers is encouraging for several use cases. For example, the HA may enable remote assessments of fall risk for patients unable to attend in-person appointments, or who live in low-resource settings. Moreover, as hearing loss is more readily recognized as an independent risk factor for fall risk, HA fittings could allow for another touchpoint in the healthcare system to educate patients on their individual increased risk for falls, or equip them with a fall risk calculator to allow for self-assessment. In this way, increased self-assessment will not only improve awareness of general and personal factors contributing to fall risk, but may also reduce the total number of falls and healthcare burden by giving patients the agency and access required to enact a fall risk plan of care while integrating that care into other aspects of their hearing health.

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