2021 43rd Annual International Conference of the
IEEE Engineering in Medicine & Biology Society (EMBC)
Oct 31 - Nov 4, 2021. Virtual Conference

Objective evaluation of the risk of falls in individuals with traumatic brain injury: feasibility and preliminary validation*

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***Abstract*— Falls are a significant health concern for individuals with traumatic brain injury (TBI). For developing effective preemptive strategies to reduce falls, it is essential to get an accurate and objective assessment of fall-risk. The current investigation evaluates the feasibility of a robotic, posturography-based fall-risk assessment to objectively quantify the risk of falls in individuals with TBI. Five individuals with chronic TBI (age: 56.2 ± 4.7 years, time since injury: 13.09±11.95 years) performed the fall-risk assessment on *hunova*- a commercial robotic platform for assessing and training balance. The unique assessment considers multifaceted fall-driving components, including static and dynamic balance, sit-to-stand, limits of stability, responses to perturbations, gait speed, and history of previous falls and provides a composite score for risk of falls, called silver index (SI), a number between 0 (no risk) and 100 (high risk) based on a machine learning-based predictive model. The SI score for individuals with TBI was 66±32.1 (min: 32, max: 100) – categorized as medium-to-high risk of falls. The construct validity of SI outcome was performed by evaluating its relationship with clinical outcomes of functional balance and mobility (Berg Balance Scale (BBS), Timed-Up and Go (TUG), and gait speed) as well as posturography outcomes (Center of Pressure (CoP) area and velocity). The bivariate Pearson correlation coefficient, although not statistically significant, suggested the presence of linear relationships (0.52 > r > 0.84) between SI and functional and posturography outcomes, supporting the construct validity of SI. A large sample is needed to further prove the validity of the SI outcome before it is used for meaningful interpretations of the risk of falls in individuals with TBI.**

***Clinical Relevance*— Clinical assessments of risk of falls are traditionally based on questionnaires that may lack objectivity, consistency, and accuracy. The current work tests the feasibility of using a robotic platform-based assessment to objectively quantify the risk of falls in individuals with TBI.**

I. INTRODUCTION

Balance dysfunction is one of the most disabling aspects after a traumatic brain injury (TBI), and over 65% of all individuals with TBI have balance impairments [1]. If balance impairments are not adequately treated, individuals with TBI are at a greater risk of falls that may lead to new brain injury or even death. TBI incidence rates rise sharply after the age of 65, primarily due to an increased frequency of falls [2]. This circular causality between TBI and falls is a critical public health concern as there are currently 5.3 million survivors living with the disabling effects after TBI [3]. It is essential to get an accurate and objective assessment of the risk of falls to develop preemptive strategies and interventions to avoid this traumatizing event. Impaired physical function and balance deficits have been identified as a major risk factor for falls. Currently available clinical tools to assess the risk of falls rely on self-report questionnaires. However, these tools are limited by subjectivity or recall errors and lead to a poor estimation of fall risk. For example, commonly used questionnaires such as the Conley Scale [4] and the Falls Efficacy Scale-International (FES-I) [5] ask questions such as, "*Have you fallen in the last three months? Do you have difficulty getting out of a chair?*" Furthermore, these questionnaires are not sensitive to detect a change in a relatively short period (days to weeks). Commonly used clinical tools to assess mobility and balance, including the Timed Up and Go (TUG) test and the Berg Balance Scale (BBS), lack sensitivity and accuracy to prospectively identify the individuals at fall-risk [6]. BBS suffers from floor and ceiling effects, and the TUG test doesn't have well-accepted thresholds for classifying fallers and non-fallers [6].

The mechanics of falls are multidimensional, making fall-risk very challenging to predict accurately. However, the objective biomechanical data such as the center of pressure (CoP), center of mass (CoM), and segmental accelerations recorded during specific postural tasks such as quiet standing (static), perturbed-standing (dynamic), sit-to-stand or walking could provide an objective, accurate and sensitive information that could be incorporated into building predictive models for objectively and accurately assessing the risk of falls [7]. *Hunova* (Movendo Technology, Genoa, Italy), is a robotic balance assessment platform that measures objective biomechanical data from a battery of in-built static and dynamic balance assessments [9]. Using a multidimensional approach, Cella *et al.* developed and validated fall-risk prediction algorithms using clinical assessment parameters and parameters from robotic balance tests performed on hunova [9]. The algorithm uses a linear regression model called Least Absolute Shrinkage and Selection Operator (LASSO). The algorithm was developed and validated using data from a prospective study of 96 older adults living in the community. The algorithm was found to have a good accuracy (receiver operating characteristic (ROC) area under the curve (AUC) 0.80, 95% confidence interval (CI) 0.71–0.89) of predicting fall-risk [9]. The multidimensional parameters (biomechanical data) measured by *hunova* were also found to be significantly correlated with the Short Physical Performance Battery (SPPB) in older adults [8]. The current

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978-1-7281-1178-0/21/$31.00 ©2021 IEEE

investigation aims to evaluate the feasibility of the robotic fall-risk assessment performed on *hunova* to objectively quantify the risk of falls in individuals with TBI. Our secondary goal was to establish the preliminary construct validity on the fall-risk outcome by correlating fall-risk with functional clinical outcomes as well as robotic/posturography outcomes. Our hypothesis is that the robotic assessment will successfully yield the indices for higher risk of falls for individuals with TBI, and the indices will correlate with the functional clinical outcomes and posturography outcomes.

II. METHODS

A. Participants

The Institutional Review Board approved all human subject procedures described in this paper. Five male participants with TBI were recruited. The inclusion and exclusion criteria included – i) age between 18 to 70 years; ii) diagnosed with a non-penetrating TBI; iii) at least six months post injury; iv) no plans to make any drastic changes to medications for at least 4-weeks, v) able to stand unsupported for five minutes; vi) willing to give informed consent and comply with study procedures and verbal instructions. The exclusion criteria included – i) penetrating TBI; ii) a severe cardiac disease or a condition; iii) pre-existing conditions, orthopedic or neuromuscular impairments unrelated to the TBI that may affect the ability to perform balance and mobility tasks; iv) fluctuating blood pressure. Table I summarizes the demographic information for all participants.

ID	*Injury*	*Severity*	*Age*	*Height*	*Weight*	*TSI*[a]
T1	TBI	Mild	53	170.18	69.4	4.45
T2	TBI	Severe	52	175.26	79.38	33.78
T3	TBI	Severe	56	177.8	86.86	10.34
T4	TBI	Severe	56	178	87.09	5.45
T5	TBI	n/a[b]	64	175.26	87.9	11.41
Mean			56.2	175.3	82.13	13.09
Sd[c]			4.71	3.15	7.9	11.95

TABLE I. STUDY PARTICIPANT DEMOGRAPHICS

a. TSI – time since injury

b. not available

c-standard deviation

B. Procedures

1) Robotic Balance Platform

Hunova (Movendo Technology, Genova, Italy) is a robotic device for the functional sensory–motor evaluation and rehabilitation of the ankle, lower limbs, and trunk [8]. *Hunova*

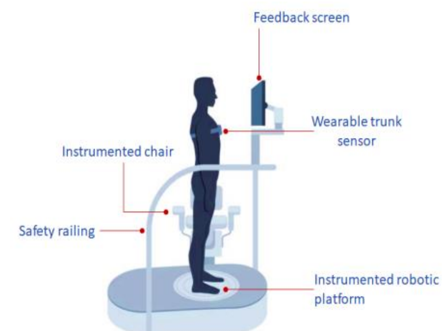

Figure 1. *Hunova* robotic posturography system and its component for assessing risk of falls

consists of two platforms, each with two degrees of freedom (forward/backward and left/right), one under the feet and one at the seat (Fig. 1). The system also includes a wireless 9-axis inertial movement unit (IMU), consisting of a tri-axial accelerometer, gyroscope, and magnetometer, to be placed on the participant's torso to monitor trunk movements. The front display is used to provide feedback during assessments and interventions. The device operates in two modes - static (no movement of the platforms) and dynamic (movements of the platforms). The system is also capable of two operating conditions – active and passive. In the passive mode, the system controls the speed and interaction with the participant (force and torque) and the movements of the platform do not depend on the participant's body sway. In the active mode, the movement of the platform depends on the participant's own body sway and hence the participant controls the movement of the platform. However, the platform can exert a certain resistance to the participant's movement.

2) Silver Index (SI) protocol for assessing fall-risk

Originally developed to predict and prevent falls-risk in individuals over 65 years old, silver index (SI) is the trademarked name for an assessment that consists of a sequence of robotic evaluations of static and dynamic balance during standing and sitting under different conditions using *hunova* system. The system allows the presentation of different conditions to evaluate the anticipatory, compensatory or reactive, somatosensory components of balance and record objective biomechanical (CoP displacement area,CoP velocity in anterior-posterior (AP) and medial-lateral (ML) directions and trunk accelerations) data during assessments. The following tests are performed in a sequence.

Test 1: Static platform, eyes open (EO). Participant tries to stand still on the platform with EO and maintain their balance for 20 seconds.

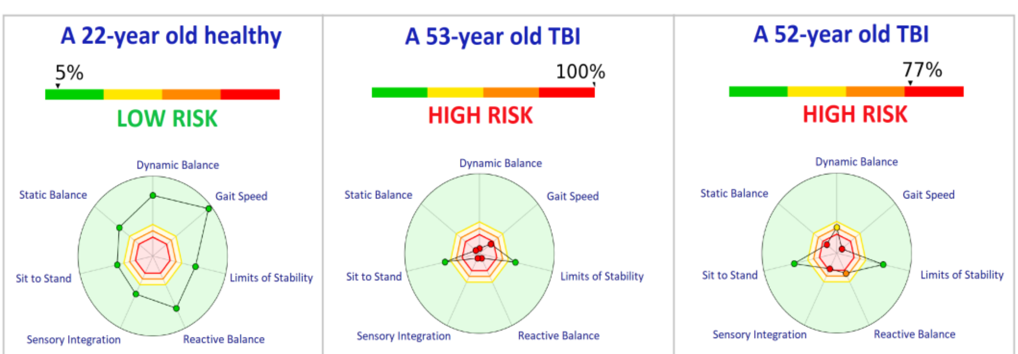

Figure 2. Silver Index scores showing the risk of falls for a 22 year-old healthy female, a 53-year old TBI and a 52 year-old TBI. The plot also shows the regions for different levels of risks with TBI participant scoring poorly during dynamic balance, gait, and sit-to-stand. Note that the healthy participant data is for demonstration purpose only and is not included in the analyses.

Test 2: Static platform, eyes close (EC). Same as Test 1, except with EC condition.

Test 3: Unstable platform, EO. Same as Test 1, except that the platform is unstable and moves in response to the participant's own body sway.

Test 4: Continuous perturbations, EO. Same as Test 1, except that the platform moves following a default circular trajectory (passive mode).

Test 5: Random perturbations, EO. Same as Test 1, except that the platform will generate random perturbation with impulses of 6 degrees in different directions (forward, left, right).

Test 6: Limits of Stability, EO. Participant stands on the platform facing the screen and performs leaning movement in cardinal directions (left, right, forward, and backward) to reach their maximal range.

Test 7: Sit-to-stand. Participant performs five sit-to-stand movements, starting with a seated position in the *hunova* chair with their feet on the platform.

In addition, gait speed during a six-meter walk and history of falls (number of falls during the previous year) are recorded in the software module.

3) *Outcome measures*

Silver Index (SI) – the outcome of risk of falls - Once all tests are completed, the data are run through a predictive model to quantify the risk of falls. The model uses both robotic (biomechanical data recorded from *hunova*) and clinical parameters (age, history of falls, gait speed). Previous work on model validation has shown that the model yields the most accurate degree of risk of falls when both clinical and robotic parameters are considered, compared to the clinical and robotic parameters considered alone [9]. The risk of falls prediction is scaled between 0 to 100%, for four grades of fall-risk as low (0-25%), medium-low (26 – 50%), medium-high (51 – 75%), and high (76-100%), through the application of a logistic function (Fig. 2). The details on the machine learning algorithms, development of the predictive model, its performance, and accuracy are described elsewhere [9].

Functional outcomes - All participants completed assessments on the BBS and TUG tests. The BBS is a 14-item balance assessment scale, with a maximum score of 56 points. The TUG evaluates mobility through the time required to complete a mobility task consisting of transitions from sitting to standing, walking, and returning back to the seated position.

III. Results

All participants completed SI assessment for fall-risk without any adverse events. The mean SI score for fall-risk was found to be 66±32.1 (min: 32, max: 100), suggesting medium to high fall-risk for the TBI participants. The scatter plots suggested the presence of a linear relationship between computed SI scores and functional outcomes of static and dynamic balance and posturography (biomechanical) outcomes from *hunova* platform (Fig. 3). The bivariate Pearson Correlation Coefficient (PCC) was computed to assess the strength and the direction of linear relationships (Table II). Prior to computing PCC, the test for normality was performed using the Shapiro-Wilk test. All variables except APCoP velocity (static EO) were normally distributed ($p > 0.05$).

Pearson correlation analysis showed that both, the functional outcomes and posturography outcomes showed moderate to high linear correlation with SI (Table II and Fig. 3). The clinical outcomes of functional mobility, BBS (r = -0.72), TUG (r = 0.75) and gait speed (r = -0.74, p = 0.15) showed a firm linear relationship (r > 0.7) with SI. The posturography outcomes, sway area (r = 0.79 for static, r = -0.61 for dynamic), APCoP velocity for dynamic EO (r = 0.77), MLCoP velocity for static EO (r = 0.87) and dynamic EO (r = -0.77), limit of stability area (r=0.52) showed moderate to high linear correlations. In addition, sit to stand time was also found to be strongly correlated with SI (r = -0.84).

	PCC, r	*p- value*
BBS	-0.72	0.17
TUG (sec)	0.65	0.23
Gait speed (m/sec)	-0.74	0.15
Sway Area (static EO) (cm^2)	0.79	0.11
Sway Area (dynamic EO)	-0.61	0.27
MLCoP Velocity (static EO) (cm/sec)	0.87	0.06
APCoP Velocity (dynamic EO) (cm/sec)	0.77	0.13
MLCoP Velocity (dynamic EO) (cm/sec)	-0.77	0.13
Limit of Stability Area (cm^2)	-0.52	0.37
Sit-to-stand time (sec)	-0.84	0.08

TABLE II. Pearson correlation analysis between Silver Index and functional and posturography outcomes

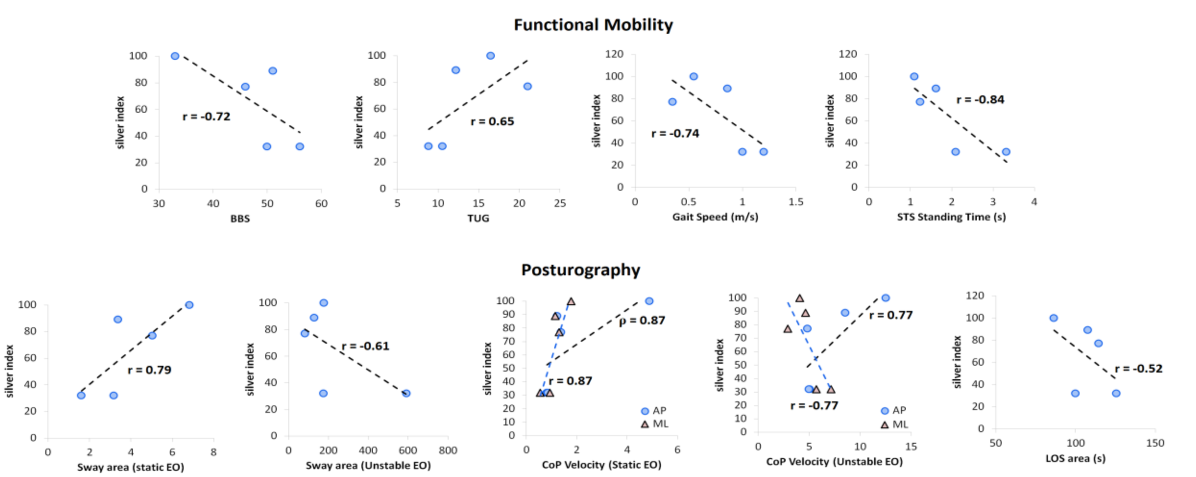

Figure 3. The scatter plot of SI (y-axis) and functional and posturography outcomes (x-axis). The data is fitted with linear regression and the strength of the fit is evaluated using Pearson Correlation Coefficient (r). All outcome variables show moderate (0.3>r>0.7) to high linear (r>0.7) relationship with SI. Note that, for the APCoP velocity (static EO), the correlation value is presented as Spearman's rho (ρ). **LOS- limit of stability*

For the APCoP velocity (static EO), which was not normally distributed (p>0.05), Spearman's rank correlation was used. It was found that APCoP velocity was strongly correlated with SI ($\rho = 0.87$, $p = 0.054$). Due to the small sample size, no statistical significance ($p<0.05$) was achieved for any of the outcomes.

IV. Discussion

The goal of this investigation was to evaluate the feasibility of a novel, objective, robotic assessment of the risk of falls for individuals with TBI. The SI protocol was originally developed and validated for individuals who were 65 years or older [8, 9]. However, before the assessment is used for TBI, the feasibility of the assessment protocol and the validity of the outcomes need to be evaluated for the TBI population who have TBI-specific balance deficiencies [1, 10]. It was found that the SI assessment could be performed in individuals with TBI, and as expected, their risk of falls was found to be medium to high (SI: 66±32.1, min: 32, max: 100). Higher standard deviation and range in the SI scores could be attributed to the small sample size and heterogeneity in population characteristics such as TSI and TBI severity.

It is suggested that the integration of several measures of postural instability can capture the multifactorial nature of fall risk better than a single test [11]. The fall-predictive model behind the SI assessment uses both clinical variables and robotic (*hunova*) parameters and accurately predicts the risk of falls in older adults at higher risk of falls [8, 9]. When applied in individuals with TBI, SI scores show moderate to strong correlations with both functional clinical outcomes (BBS, TUG, gait speed) and robotic parameters (CoP displacement and velocity outcomes) (Fig. 3 and Table II). Lower SI (lower risk of falls) scores were associated with higher performance on the BBS (static and dynamic balance), TUG (mobility), and gait speed, demonstrating the construct validity of SI in individuals with TBI. The objective outcomes derived from *hunova*, the CoP area, and velocities were also correlated with SI. For a static test (platform at rest) with EO, lower values of CoP displacement and velocities in both AP and ML directions suggested a lower risk of falls. This is in agreement with previous studies that suggest that lower CoP excursions and velocities suggest better postural control and stability during unperturbed standing [12, 13]. Interestingly, for dynamic EO conditions when the base of support was perturbed, increased CoP area was correlated with a lower risk of falls, possibly attributing to the ability to generate compensatory responses that could generate elevated CoP displacements. However, these relationships are to be seen as an initial trend only as they may be influenced by the outliers and small sample size. Therefore, a large sample with uniformly distributed TBI-grades (mild, moderate, severe) is required for more meaningful interpretations of the data.

The range (0-100%) and the levels (low to high) at which SI values are presented are advantageous as many of the balance and mobility assessments such as BBS, TUG, and gait speed succumb to the ceiling effects. The inclusion of objective outcomes derived from *hunova* offers the necessary sensitivity required to isolate different grades of balance and mobility impairments that contribute to the risk of falls. Further, objective assessment decreases inaccuracies in fall-risk assessment due to subjectivity and recall-bias that are observed in clinical tools such as FES-I.

The current investigation is limited by small sample size, and hence, the results should be interpreted cautiously. Further, test-retest reliability and sensitivity of SI need to be evaluated in a larger sample of TBI by performing evaluations at multiple time points.

V. Conclusion

The significance of SI assessment is that it takes several fall-inducing factors (previous falls, gait speed, balance, biomechanical correlates) into account in an objective manner which is not possible in a single fall-risk assessment. The preliminary evidence from the current investigation suggests that it is feasible to use SI protocol for assessing the risk of falls of individuals with TBI.

Acknowledgment

The authors would like to thank Oluwaseun Ibironke for his assistance in the data collection.

References

[1] J. Ponsford, M. Downing, J. Olver, M. Ponsford, R. Acher, M. Carty, *et al.*, "Longitudinal follow-up of patients with TBI: Outcome at 2, 5, and 10-years post-injury," *J Neurotrauma,* vol. 31, pp. 66-71, 2013.

[2] H. J. Thompson, W. C. McCormick, and S. H. Kagan, "TBI in older adults: epidemiology, outcomes, and future implications," *J Am Geriatr Soc,* vol. 54, pp. 1590-5, Oct 2006.

[3] "TBI Incidence and Distribution,," CDC, Ed., ed, 2004-2006.

[4] D. Conley, A. A. Schultz, and R. Selvin, "The challenge of predicting patients at risk for falling: Development of the Conley Scale," *Medsurg Nursing,* vol. 8, pp. 348-54, 1999 1999.

[5] L. Yardley, N. Beyer, K. Hauer, G. Kempen, C. Piot-Ziegler, and C. Todd, "Development and initial validation of the Falls Efficacy Scale-International (FES-I)," *Age Ageing,* vol. 34, pp. 614-9, Nov 2005.

[6] F. Quijoux, A. Vienne-Jumeau, F. Bertin-Hugault, M. Lefevre, P. Zawieja, P. P. Vidal, *et al.*, "Center of pressure characteristics from quiet standing measures to predict the risk of falling in older adults: a protocol for a systematic review and meta-analysis," *Syst Rev,* vol. 8, p. 232, Sep 7 2019.

[7] R. Sun and J. J. Sosnoff, "Novel sensing technology in fall risk assessment in older adults: a systematic review," *BMC Geriatr,* vol. 18, p. 14, Jan 16 2018.

[8] A. Cella, A. De Luca, V. Squeri, S. Parodi, M. Puntoni, F. Vallone, *et al.*, "Robotic balance assessment in community-dwelling older people with different grades of impairment of physical performance," *Aging Clin Exp Res,* vol. 32, pp. 491-503, Mar 2020.

[9] A. Cella, A. De Luca, V. Squeri, S. Parodi, F. Vallone, A. Giorgeschi, *et al.*, "Development and validation of a robotic multifactorial fall-risk predictive model: A one-year prospective study in community-dwelling older adults," *PLoS One,* vol. 15, p. e0234904, 2020.

[10] R. Pilkar, K. K. Karunakaran, A. Veerubhotla, N. Ehrenberg, O. Ibironke, and K. J. Nolan, "Evaluating Sensory Acuity as a Marker of Balance Dysfunction After a TBI: A Psychophysical Approach," *Frnt Neurosci,* vol. 14, p. 836, 2020.

[11] P. Palumbo, L. Palmerini, S. Bandinelli, and L. Chiari, "Fall Risk Assessment Tools for Elderly Living in the Community: Can We Do Better?," *PLoS One,* vol. 10, p. e0146247, 2015.

[12] R. Pilkar, N. Arzouni, and K. J. Nolan, "Postural stability during long duration quiet standing in post stroke hemiplegia," *Bio Sig Proc Contr,* vol. 39, pp. 165-168, 2018.

[13] P. O. Riley, B. J. Benda, K. M. Gill-Body, and D. E. Krebs, "Phase plane analysis of stability in quiet standing," *J Rehabil Res Dev,* vol. 32, pp. 227-35, Oct 1995.