

Postural Assessment, Functional Testing, and Patient Reported Outcome Measures in Older Adults with a Novel Ankle Brace Compared to Contemporary Braces

Olivia Raspotnik PT, DPT, Christian Wilhelm PT, DPT, Kimberly Beren Shepler, Abbis Jaffri PT, MS, PhD

Abstract:

Introduction: High incidence of falls in the geriatric population causes significant risk for injury and increasing healthcare costs. Currently, no gold standard brace is established for stability in older adults. The purpose of this study was to evaluate patient preferences, functional testing, and center of pressure (COP) sway in different orthotic conditions, providing information on stability and balance for the aging adult.

Methods: This was a laboratory-based crossover study with 18 subjects (12F;6M, age: 74.67±5.26 years, height: 167.85 ± 10.36 cm, mass: 76.76 ± 16.92kg). Four orthosis conditions were evaluated: participant's own shoe, TayCo Brace, a balance brace (BB), and walking/CAM boot. For each orthotic condition, 3 single leg balance (SLB) trials and Timed-Up and Go (TUG) test were completed. Participants rated each brace for overall perceived stability and comfort.

Results: There were significant differences ($p=0.001$) between TayCo and CAM boot in AP COP excursion, but no significant difference ($p>0.05$) between TayCo, BB, and participant own shoes. There were significant differences ($p=0.02$) between TayCo and BB in ML COP excursion, but no significant differences ($p>0.05$) between TayCo, CAM boot, and participant's shoes. There were significant differences ($p=0.02$) between TayCo and BB as well as between ($p=0.002$) TayCo and CAM boot in overall COP velocity, but no significant difference ($p>0.05$) for participant's own shoes. For perceived stability, participants found the walking boot to be significantly ($p<0.05$) less stable than their own shoes, TayCo brace, and BB. For perceived comfort, they found significantly ($p=0.034$) more comfort in their own shoes compared to the TayCo brace but found TayCo brace to be significantly more comfortable ($p<0.01$) than the BB and the CAM boot.

Discussion: TayCo Brace provided improved balance with the smallest COP excursion overall and showed higher patient perceived outcomes compared to other conditions. The CAM boot was the worst for perceived and measured outcomes.

Introduction:

Falls in the aging population is a major dilemma that continues to escalate.. Falls lead to potential injury, decreased quality of life, and increased health-care cost. According to CDC, 1 in 4 older adults fall each year which resulted in over 34 million falls in 2019. 1 in 5 of these falls result in an injury², most often a fracture or a head injury. Fractures usually occur in the wrist, arm, ankle, and most frequently the hip. In fact, 95% of hip fractures are caused by falling³ and unfortunately 25% of those who sustain a hip fracture because of a fall will die within 6 months of the injury, and 10-15% will have lower life expectancy after the fall.⁴

Foot and ankle problems are common in the elderly. Multiple studies have shown that foot issues may lead to increased fall risk, and it's been reported that approximately 30% of community dwelling adults report foot problems, which is significant.⁵ Additionally, if an adult sustains a fall and subsequent fracture, this could prolong recovery and continue a cycle of injury, weakness, and increased fall risk. Interventions utilizing footwear are suggested as a non-surgical management to reduce the risk of falls in older adults.⁶ Ankle foot orthosis (AFOs) are used to provide external stability to the ankle and foot complex and are used in many different clinical groups, including the geriatric population to provide stability during the performance of functional activities.⁷ Daily use of AFOs during the functional activities in older adults is gradually increasing because of their ability to provide stability by reducing the mediolateral sway at foot and ankle complex and potential of decreasing fall risk.⁸ Some AFOs such as CAM/walking boots are very commonly used after ankle or foot injury, as well as surgery as they provide offloading as well as protection to the area that is healing.⁹

The TayCo brace is a novel balance brace made of semi-moldable plastic that fits outside of normal shoes. On either side of the ankle complex, there are support struts as well as an inferior strap beneath the shoe and support straps around the distal tibia, plantar, and dorsal midfoot. These constructs allow for flexibility and fitting of the brace to anything from regular tennis shoes to steel toed boots. TayCo brace is purported to provide more mediolateral stability while allowing ankle motion in the sagittal plane. The brace can be locked

in neutral dorsiflexion, partially unlocked to allow for partial range of motion, or fully unlocked to allow for full motion. The hinge system embedded in the design of TayCo brace allows the clinician to set certain parameters of stability and mobility as required for particular post-injury or surgery condition.

The purpose of this study was to compare the TayCo brace to the patient's preferred shoes, along with the Balance Brace and the CAM/walking boot. The braces are shown in figure 1. The Balance Brace is a custom made/fitted balance brace that fits inside ones shoe and has straps around the distal tibia. It is a rigid brace, so it does not allow for any movement but provides a lot of stability. The CAM or walking boot is probably the most recognizable brace as it is commonly prescribed after ankle injury and designed with a rocker bottom.⁹

Currently there is no gold standard balance orthosis or brace that provides the most stability in older adults. The primary objective of this study was to assess the novel TayCo brace, compared to commonly used foot and ankle orthosis such as CAM boot, and Balance Brace (BB). The purpose was to evaluate patient preferences, functional testing, and evaluate center of pressure (COP) sway in different orthosis conditions to determine levels of stability, balance, and patient perceptions surrounding use of brace conditions. The hypothesis was that the TayCo brace would demonstrate decreased center of pressure sway and velocity compared to other contemporary braces during bilateral stance, and that patients would report higher levels of comfort, stability, and preference in the TayCo brace compared to traditional balance braces.

Methods

Participants:

Participants for our study were recruited from the local area and consisted of healthy ambulatory older adults aged 65 and older. They had no known neurological or limiting orthopedic conditions and no recent injuries or surgeries to the foot/ankle. We completed a laboratory-based crossover study. Informed consent was obtained after which subjects filled out demographic information. Patients also completed SF-12, Foot and Ankle Ability Measure (FAAM), and the Tegner Activity Scale. This information is all contained in table 1.

Instrumentation:

Timed Up and Go (TUG)

Subjects were provided instructions on the Timed Up and Go (TUG) test and were allowed one practice attempt. The TUG test is a dynamic mobility test, where you record the time it takes for an individual to stand from a chair, ambulate 10ft (3m) and return to sit in the chair as quickly and safely as possible. This test is a reliable and validated test that has been well studied that quantifies dynamic functional mobility and balance impairments in older adults.¹⁰

Balance Testing

Following TUG, the patients completed 3 trials of bilateral quiet stance in their own shoes on instrumented force plate. Orthoses were then donned, with testing order randomly assigned to subjects using Latin square randomization as in table 2 to ensure there was no learning effect. In each condition the patients completed the trials of quiet stance prior to completion of the TUG test. The brace was always donned unilaterally on the left lower extremity. The TayCo brace specifically was set to full range of motion and not locked. A Bertec force plate was utilized for measurement of COP excursion and velocity.

VAS for comfort and stability

After completing balance and TUG trial for each condition, subjects used a VAS scale to rate perceived comfort and stability as well as a simple ranking system rating the braces from least favorite to favorite. Figure 2 shows the force plates used to collect the data. Our independent and dependent variables are listed in table 3 below.

Statistical Analysis

For COP balance, TUG and VAS measure, a one factor repeated measures ANOVA was used to assess the influence of the four walking orthoses. Pairwise post hoc comparisons were performed to identify specific differences. For the preferred rank measure, a non-parametric Friedman's ANOVA was performed to compare

the preference scores for the 4 conditions. SPSS 24.0 software (SPSS, Chicago, IL) was utilized for analysis of variance to identify differences between walking orthoses. The level of significance was set at $p < 0.05$ for all analyses.

Results

There was no significant difference ($p > 0.05$) between the TayCo (22.5 ± 9.63 cm), Balance Brace (23.70 ± 8.36 cm) and participant's own shoes (24.05 ± 8.26 cm) in AP COP excursion. However, there were significant differences ($p = 0.001$) between the TayCo and walking boot (32.5 ± 9.73 cm) in AP COP excursion [Figure A]. There were no significant differences ($p > 0.05$) between the TayCo (10.83 ± 5.15 cm), walking boot (14.28 ± 7.58 cm), and participant shoes (13.20 ± 5.20 cm) in ML COP excursion. However, there were significant differences ($p = 0.02$) between the TayCo and Balance Brace (14.27 ± 6.25 cm) in ML COP excursion [Figure B]. There were also significant differences ($p = 0.02$) between the TayCo (13.75 ± 5.29 cm/s) and Balance Brace (15.9 ± 6.13 cm/s), as well as between ($p = 0.002$) the TayCo and walking boot (20.36 ± 8.47 cm/s) in overall COP velocity, but no significant difference ($p > 0.05$) for the participant's own shoes (15.59 ± 5.79 cm/s) [Figure C]. TUG times were found to be significantly higher ($p < 0.05$) for the walking boot (10.76 ± 3.4 sec) compared to the TayCo brace (7.52 ± 1.22 sec), Balance Brace (7.41 ± 1.18) and the participant's own shoes (7.3 ± 0.97) [Figure D]. There were no significant differences ($p > 0.05$) between the other orthotic conditions for TUG times. For participants stability perception, participants found the walking boot (1.43 ± 1.53 cm) to be significantly ($p < 0.05$) less stable than participants' own shoes (5.82 ± 1.77 cm), TayCo brace (5.07 ± 1.82 cm), and Balance Brace (3.92 ± 1.64 cm) [Figure E]. For participants perceived comfort, they found significantly ($p = 0.034$) more comfort in their own shoes (6.54 ± 0.80 cm) compared to the TayCo brace (5.05 ± 1.23). However, they also found the TayCo brace to be significantly more comfortable ($p < 0.01$) than both the Balance Brace (4.01 ± 1.55) and the walking boot (1.76 ± 1.53) [Figure F].

Discussion

The intent of this study was to determine if the novel TayCo brace is effective in improving patient control and stability during balance and functional tasks. COP AP and ML excursion as well as total COP velocity in bilateral favored the use of TayCo brace when compared to other orthotic conditions.

The TayCo brace not only shows favorable results in this study for providing stability as well as participants preferred TayCo as the most comfortable and stable brace after their own shoes. As the brace is donned externally, the risk of skin irritation or breakdown is less compared to orthoses placed on the inside of the shoes or during casting.¹¹ This is extremely beneficial not only for patient safety, but also for function as patients can wear comfortable shoes and the brace acts as an external support. Furthermore, in cases where individuals are cleared to return to work, they can wear the appropriate footwear that their worksite might require compared to a walking boot, which are not allowed on most work sites if more manual labor is involved according to OSHA's footwear standards.¹² This brace has been proposed for use by its developers for athletics, balance, chronic ankle instability, surgical recovery from fracture, or a neurologic population. The brace is very lightweight which is extremely beneficial for those patients who are weak and allows for more function compared to heavier brace options. The brace is reimbursed by insurance, similar to other brace conditions so the cost will depend on individuals' insurance plans.

The Balance Brace has mixed evidence with some studies showing improved stability and decrease fear of falling, and other studies showing no significant fall reduction risk.¹²⁻¹⁴ Our study demonstrated no significant results in favor of the Balance Brace compared to CAM boot, however, the TayCo brace demonstrated improved stability in medial-lateral sway compared to Balance Brace. In all other outcomes it measured similarly to the TayCo and participant's own shoes.

The TUG test allowed us to determine the effectiveness of the braces in lowering fall risk in community dwelling older adults.¹⁵ From our results, we were able to gather that the TayCo brace, the Balance Brace, and

the participants normal shoes all had comparable TUG times, while the walking boot condition had significantly higher TUG times, indicating an increased risk for falls compared to the other conditions. The CAM/walking boot is designed to improve gait mechanics and patterning as well as provide offloading.¹⁶⁻¹⁷ However, a study by Ready et al investigated secondary negative effects of this brace.¹⁸ They found that 67% of patients in their study experienced secondary site pain following use of this brace, ranging from the low back to contralateral hip, knee, or ankle pain.¹⁸ As well, even 3 months after use of the boot, some patients still experienced detriments.¹⁸ They attributed this to the rocker bottom leading to altered posture, balance, and leg length discrepancy as well as increased weight.¹⁸ All of these secondary effects following use of a walking boot, along with the findings of our study demonstrate that the use of this walking boot may be detrimental to patient's overall health status.

The participants reported their perceived comfort and stability with the different conditions, the majority of participants rated their normal shoes first, followed by the TayCo brace, the Balance Brace, and the walking boot last in both comfort and perceived stability on VAS and overall ranking. The patient perception of stability is meaningful because it has been previously reported that feelings of less stability resulted in lower balance performance¹⁹. As well, there are many barriers that are present for older adults with adherence to medical device prescription related to comfort, confidence, perception of device use, environmental factors and even the look or design of equipment.²⁰⁻²¹ This includes having to navigate slippery surfaces after a storm, crossing the road under pressure, and unkept or rough terrains that make it difficult to independently navigate even without an assistive device.²¹ They also found that the stigma associated with mobility devices can make them feel ashamed or helpless as they have more difficulty performing activities independently.²¹ This is extremely important for us to recognize as healthcare providers that are prescribing orthotics, slings, braces, or assistive devices with recommendations for wear or use. Addressing these areas will help patients improve adherence, especially over longer periods of time. If a patient feels uncomfortable with the device recommended, they

likely will not use it as prescribed, leading to increased risk of injury or often increased risk of falls.²⁰⁻²¹ With our study, the TayCo brace was shown to be the second in comfort and stability only to the patient's own shoes. As well, as the TayCo brace is donned externally outside the participant's own shoes, they can continue to wear supportive footwear they like which could lead to increased compliance and comfort during wear.

This study has several important clinical implications, not only for physical therapists, but also for physicians and surgeons when considering brace/orthotic prescription. The TayCo brace offered reduced COP excursion and velocity, as well as comparable TUG times and perceived comfort and stability compared to their normal shoes. Thus, the TayCo brace may provide a better alternative to other commonly available orthoses options, especially the CAM boot, due to the improved clinical outcomes observed in this study and subsequent decreased risk for falls. TayCo is a novel brace, and it seems that it provides a viable solution to preserve mobility after an orthopedic procedure and at the same time provide stability and function for our patients. Comfort and stability also play a role in patient adherence which is a benefit of the TayCo brace. If the device they are using most closely compares to their normal shoes, they may be more likely to regularly use it. Conversely, the CAM boot had significantly worse results in terms of balance, TUG times, perceived stability and comfort. The CAM boot is arguably the most commonly prescribed orthotic device prescribed post surgically, however based on these results, other options should be considered.

Limitations of this study include a smaller sample size of only 18 participants. All patients were also of a high level of function and minimal fall risk according to their TUG time scores, but we did not assess balance through a different outcome measure, which could be an area for future research. Finally, as the older adults had no known balance issues at this time, we are unable to determine whether the results can be applied to other clinical populations with impairments without further research.

Conclusion

The TayCo Brace provided improved balance and patient perceived outcomes compared to other conditions. If the brace can decrease fall risk while keeping individuals functional, and also allowing for stability and mobility, clinicians and surgeons should take this into consideration before making decision about orthotics for older adults.

Future research could be directed at other orthotics or braces that are on the market that are commonly prescribed. There are also adjustments that can be made to the TayCo brace positioning as it can be locked in neutral, allow for partial ROM, and full ROM. Full ROM was utilized in this test. Studies could also examine the effect on standardized balance measures, functional transfers, gait mechanics/gait speed, and higher-level activities such as running or jumping. Studies could also examine different patient populations that this brace is designed or marketed towards including younger age, athletics, chronic instability, post-surgical/orthopedics, and neurologic (CVA, SCI, PD).

References

- 1 CDC. Older adult falls. <https://www.cdc.gov/falls/> Accessed Mar 20, 2022.
- 2 CDC. Facts about falls <https://www.cdc.gov/falls/facts.html> Accessed Mar 20, 2022.
3. Hayes WC, Myers ER, Morris JN, Gerhart TN, Yett HS, Lipsitz LA. Impact near the hip dominates fracture risk in elderly nursing home residents who fall. *Calcif Tissue Int* 1993;52:192-198.
4. Kortbeek JB, Al Turki SA, Ali J, et al. Advanced trauma life support, the evidence for change. *Journal of Trauma and Acute Care Surgery*. 2008;64(6):1638-1650.
5. Menz HB, Morris ME, Lord SR. Foot and ankle risk factors for falls in older people: a prospective study. *J Gerontol*. 2006;61A(8):866-870.
6. Najafi B, de Bruin ED, Reeves ND, Armstrong DG, Menz HB. The role of podiatry in the prevention of falls in older people: a JAPMA special issue. *Journal of the American Podiatric Medical Association*. 2013;103(6):452-456.
7. Tyson SF, Kent RM. Effects of an ankle-foot orthosis on balance and walking after stroke: a systematic review and pooled meta-analysis. *Archives of physical medicine and rehabilitation*. 2013;94(7):1377-1385.
8. Yalla SV, Crews RT, Fleischer AE, Grewal G, Ortiz J, Najafi B. An immediate effect of custom-made ankle foot orthoses on postural stability in older adults. *Clinical Biomechanics*. 2014;29(10):1081-1088.
9. Banerjee S, Ryce A. Orthotic walking boots for patients with fractures or ligament injuries: a review of clinical effectiveness and cost-effectiveness. *CADTH*. 2019;1-14
10. Shirley Ryan Ability Lab. Timed up and go. <https://www.sralab.org/rehabilitation-measures/timed-and-go#older-adults-and-geriatric-care> Accessed June 1, 2022.
11. Skin care issues related to orthotic device wear. <https://braceworks.ca/2016/07/11/devices/lower-limbs/afo/skin-care-issues-related-to-orthotic-device-wear/>. Accessed December 18, 2022

12. OSHA personal protective equipment, footwear. <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.136>. Accessed Dec 10, 2022.
13. TayCo Brace. <https://www.taycobrace.com/>. Accessed Mar 20, 2022.
14. Carey S. Groundbreaking Study Reveals Custom Brace Is Missing Link in Improving Balance and Reducing Fear of Falling for Seniors. Cision PR Newswire. <https://www.prnewswire.com/news-releases/groundbreaking-study-reveals-custom-brace-is-missing-link-in-improving-balance-and-reducing-fear-of-falling-for-seniors-300827644.html>. Published Apr 9, 2019. Accessed Apr 16, 2022.
15. Shumway-Cook A, Brauer S, Woollacott M. Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test. *Phys Ther.* 2000;80(9):896-903.
16. Hunt KJ, Goeb Y, Esparza R, Malone M, Shultz R, Matheson G: Site-specific loading at the fifth metatarsal base in rehabilitative devices: Implications for Jones fracture treatment. *Am J Phys Med Rehabil* 2014;6:1022-1029
17. Simpson MR, Howard TM: Tendinopathies of the foot and ankle. *Am Fam Physician* 2009; 80:1107-1114.
18. Ready LV et al. Associated joint pain with controlled ankle movement walker boot wear. *J Am Acad Orthop Surg.* 2018;2(12):1-7.
19. Shenoy A, Peng TH, Todd RM, et al. Rate of perceived stability as a measure of balance exercise intensity in people post-stroke [published online ahead of print, 2022 Feb 1]. *Disabil Rehabil.* 2022;1-7.
20. Tuazon JR, Jahan A, Jutai JW. Understanding adherence to assistive devices among older adults: a conceptual review. *Disabil Rehabil Assist Technol.* 2019; 14(5): 424-433
21. Lee D, Tak SH. Barriers and facilitators of older adults' usage of mobility devices: a scoping review. *Educ Gerontol.* 2022 doi 10.1080/03601277.2022.2084309.



Figure 1
Bracing conditions utilized during study. Braces were randomized for each participant



Figure 2

Bertec Force plates utilized for measuring COP excursion and velocity during bilateral stance trials.

Patient Demographics	
Sex	12 females; 6 males
Age (years)	74.67 ± 5.26
Height (cm)	167.85 ± 10.36
Weight (kg)	76.76 ± 16.92
SF-12 - Physical function (average)	50.41
SF-12 Mental function (average)	55.744
FAAM ADL section (average)	75
FAAM Sports sub-section (average)	21.875
Tegner Activity Scale (average)	3.278

Table 1

Patient demographics outlining patient information collected during the study

Subject 01	Tayco	Moore	Walking boot
Subject 02	Walking boot	Tayco	Moore
Subject 03	Moore	Walking boot	Tayco
Subject 04	Tayco	Moore	Walking boot
Subject 05	Walking boot	Tayco	Moore
Subject 06	Moore	Walking boot	Tayco
Subject 07	Tayco	Moore	Walking boot
Subject 08	Walking boot	Tayco	Moore
Subject 09	Moore	Walking boot	Tayco
Subject 10	Tayco	Moore	Walking boot
Subject 11	Walking boot	Tayco	Moore
Subject 12	Moore	Walking boot	Tayco
Subject 13	Tayco	Moore	Walking boot
Subject 14	Walking boot	Tayco	Moore
Subject 15	Moore	Walking boot	Tayco
Subject 16	Tayco	Moore	Walking boot
Subject 17	Walking boot	Tayco	Moore
Subject 18	Moore	Walking boot	Tayco

Table 2

Latin square randomization utilized for patient orthotic order to prevent learning effect

Independent Variables
Normal shoes
TayCo Brace
Balance Brace (BB)
CAM/Walking Boot

Dependent Variables
Bilateral Stance on force plates
Anteroposterior sway (AP) COP excursion
Mediolateral sway (ML) COP excursion
Timed Up and Go (TUG) test
Patient comfort and stability – VAS and simple ranking

Table 3

Independent and dependent variables investigated

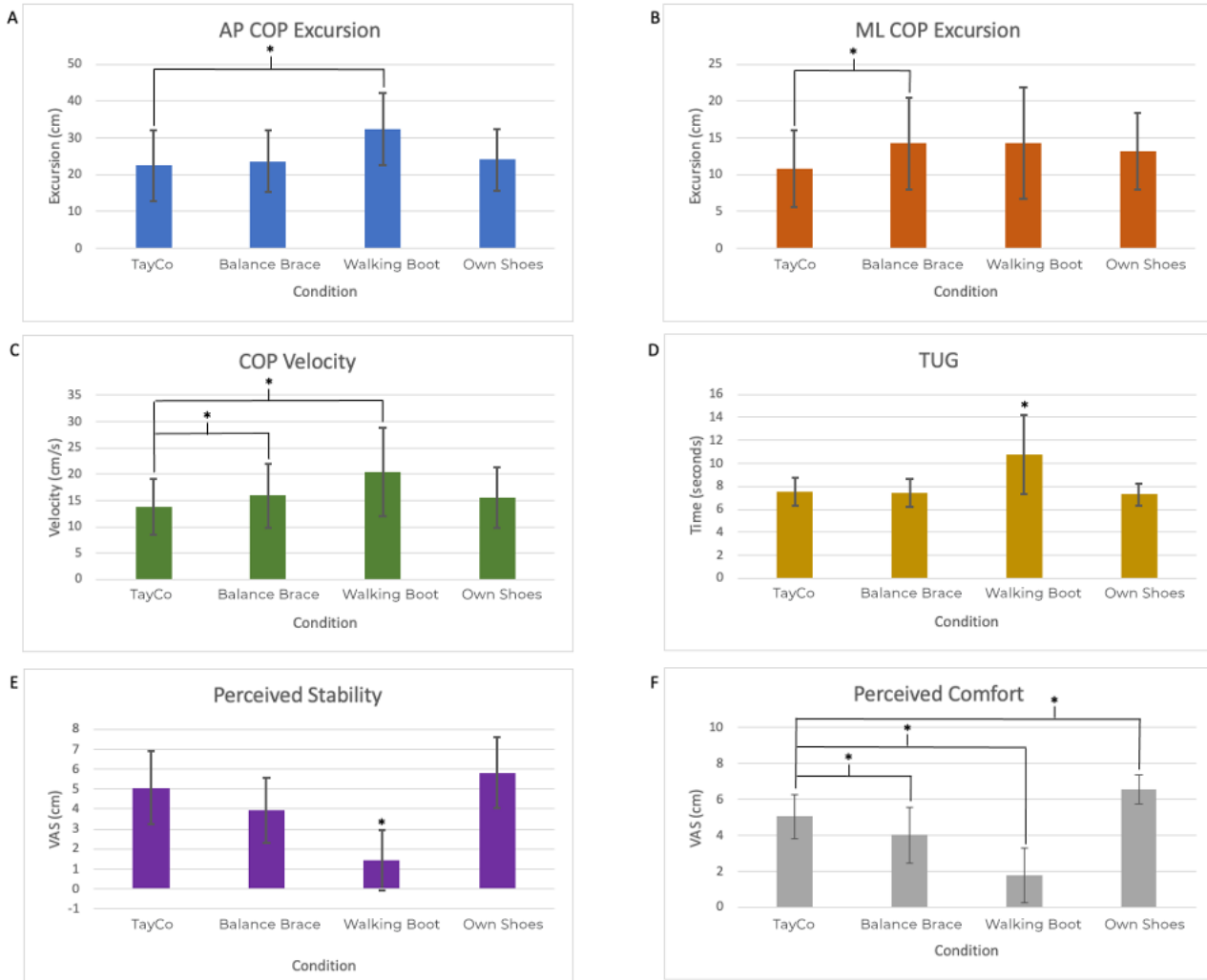


Figure 2A-F, graphs of results for AP COP excursion, ML COP excursion, COP velocity, TUG test, perceived stability, and perceived comfort. In figures 2A, 2B, 2C, and 2E, * indicates statistical significance between different conditions. In figure 2D and 2E, * indicates that one condition was statistically significant compared to all other conditions.