Reliability and validity of IMU-based foot progression angle measurement under different gait retraining strategies

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Francine Urbanus

Master Thesis

Delft University of Technology

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By

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Preface

In this thesis you will find a reliability and validity study of a relatively new tool for measuring the foot progression angle. Measuring the foot progression angle precisely is important for gait retraining for patients who experience knee pain due to knee osteoarthritis. It would be great if this thesis would attribute to less knee pain in these patients.

This thesis is written for my master's degree in Biomedical Engineering at the Technical University of Delft. It is written as a research paper and will be submitted for publishing. The data was collected during a three month internship at the University of Sydney, Australia. Here, I experienced what it is like to work in a multidisciplinary team. First I would like to thank all the participants who participated in my study. I especially would like to thank Nicole D'Souza, Tomoki Ohashi and Alex O'Conner for their help in testing the research set-up. I would like to thank my supervisors Milena Simic and Jane Grayson for their excellent supervision and a wonderful time in Sydney. And of course, I would like to thank my TU Delft supervisor Jaap Harlaar, who guided me through finishing my master's with his feedback and advice. At last, I want to take the opportunity to thank my family and friends who supported me along the way.

Francine Urbanus

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Abstract

Background

Gait retraining strategies are used to reduce medial compartment load in people with medial knee osteoarthritis. Two key gait retraining strategies are based on changing the foot progression angle (FPA). The FPA can be measured using a pressure sensitive walkways (PSW), but inertial measurement units (IMUs) are considered more suitable for routine clinical use.

Research question

The purpose of this study was to evaluate the reliability and validity of an IMU system to measure FPA under different gait retraining strategies in a potential clinical setting.

Methods

Twenty healthy participants (14 females, 6 males, mean age=33.7 years, SD=10.3 years) walked along a ± 8.5 m long path using different gait strategies (2x natural gait, 1x toe-out -and 1x toe-in gait) during four 90 second trials. FPA was measured simultaneously with the IMUs (Opal, APDM, Portland, USA) and a PSW (Zeno™ Walkway, ProtoKinetics, Havertown, USA), the latter considered the reference standard.

Results

Test-retest intraclass correlations (ICCs) for the IMUs and the PSW were indicative of good and excellent reliability respectively (IMU ICC=0.89; PSW ICC=0.97). This difference in reliability was also reflected by a higher standard error of measurement (SEM) for IMUs compared to the PSW (IMUs SEM=1.6°, PSW SEM=0.96°). Minimal detectable change (MDC) was 4.5° for the IMUs and 2.7° for the PSW. The repeated measures ANOVA indicated a significant effect of gait type on FPA ($p<.001$), whereas the measurement instrument did not affect FPA ($p=.875$). Bland-Altman plots indicate good agreement of both systems for the baseline condition, though the IMUs seem to consistently overestimate the FPA value compared to the PSW. We conclude that IMUs are reliable and valid measurement systems for measuring FPA in natural gait, toe-out and toe-in gait. Differences between the systems are significant for all gait strategies, so systems should not be used interchangeably.

Significance

The IMUs provide a promising tool for clinicians and researchers aiming to quantify FPA for gait retraining.

1. Introduction

Biomechanical interventions can be used to assist in the management of chronic conditions, and interest has emerged around gait retraining interventions for people with medial knee osteoarthritis (KOA) [1]. The most researched intervention with a demonstrated ability to reduce indices of knee load is walking with an altered foot progression angle (FPA). FPA is defined as the angle of the longitudinal axis of the foot relative to the line of the body's overground progression during gait [2]. Changing the FPA to either an internally oriented position (toe in) or an externally oriented position (toe out) has been shown to reduce pain in KOA patients after a gait retraining program of six weeks [2,3]

For gait retraining interventions to be clinically implemented, valid and reliable measurement tools need to be available in a clinical setting. Currently, FPA is measured in a variety of ways. The most comprehensive method is 3D motion capture using markers on the foot tracked by infrared cameras [4]. This is commonly considered as the gold standard for the tracking of human movement [5]. However, these motion capture systems are costly, require a fixed laboratory, are sensitive to optical occlusion and require time consuming analysis to yield results. Alternatively pressure sensitive walkways (such as the GAITRite® (Franklin, USA), the Strideway™ (Tekscan, Boston, USA) and the Zeno™ Walkway (ProtoKinetics, Havertown, USA)) can collect and analyse spatiotemporal parameters from foot pressure data including the FPA [6]. Wearable inertial measurement units (IMU) include an accelerometer, a magnetometer and a gyroscope. A wide range of IMUs, each featuring their own distinctive characteristics, are commercially available by companies such as APDM (Portland, USA), Xsens Technologies B.V. (Enschede, the Netherlands), Technaid S.L. (Madrid, Spain), IMeasureU (Auckland, New Zealand) and Noraxon (Scottsdale, USA). IMUs are insensitive to occlusion and do not require a specified lab or examination room. When placed on the lower extremities, IMUs can measure spatiotemporal data including the FPA [7]. Therefore IMUs seem particularly well suited for measuring the FPA in a wide range of clinical practises that aim to apply gait retraining in patients with KOA.

Although motion capture is considered the gold standard, a pressure sensitive walkway (PSW) designed to measure foot imprints is considered to perform equally well [8]. Yielding valid FPA measurements using IMUs is dependent on both their proper attachment of the IMU to the foot (for anatomical calibration) and accurate signal processing of the sensor signals. To assess whether IMUs are a viable option for the attainment of FPA measurements, the validity and reliability of these measurements needs to be established. The purpose of this study is therefore to determine the reliability and validity of FPA measurements based on IMUs, by comparing IMUs' performance in FPA analyses to the highly accurate and established PSW methodology using the gait strategies that are used for gait retraining in KOA.

2. Methods

2.1 Study design

This was a test-retest reliability and validity study to evaluate FPA measured by IMUs against a PSW serving as the reference standard. This study was approved by the university's institutional review board, and all participants provided written informed consent prior to participation.

2.2 Participants

Twenty healthy adults (14 females, 6 males) were recruited from the surrounding university and community via electronic media and word of mouth in April 2019. Overall, participants had a mean age of 33.7 years (SD=10.3 years), and were of normal weight [9] on average (BMI=23.4, SD=3.8). Only participants who could walk independently without aids, and complete at least 10 trials of walking for 90 seconds on a flat surface were included in the study. Participants were excluded if they had pain that affected lower limb movements, neurological conditions affecting gait or balance, or were unable to understand and speak English. In order to obtain an intraclass correlation (ICC) of 0.7 or higher, a sample size of at least 18 participants was required [10]. All twenty participants met the inclusion criteria and completed all trials for the baseline, toe-in gait and toe-out gait conditions. Because this study investigates reliability and validity of the instruments and nothing about the participants, each leg is observed as an independent test subject. So, 40 legs were observed in this study.

2.3 Procedures

2.3.1 Instrumentation

Concurrent gait data was collected using two systems: i) a pressure sensitive walkway (PSW), the Zeno™ Walkway (ProtoKinetics, Havertown, USA); and ii) a wearable wireless IMU-based system, the Opal sensors (APDM, Portland, USA). The PSW had a width and length of 1.22 m and 3.66 m respectively (4′ by 12′) and was wired to the host computer to communicate via ProtoKinetics Movement Analysis Software (PKMAS). For the IMU-based system 7 sensors were used; 1 lumbar, 2 upper leg, 2 lower leg and 2 feet sensors. A more detailed description of the locations can be found in table 1. The system makes use of a docking station to charge and configure the sensors and a wireless access point to communicate between the sensors and the host computer. The sensors are shaped similarly to a watch, are of a small size (55 mm x 40.2 mm x 12.5 mm) and weigh 25 grams. The sensors recorded movement with triaxial accelerometers, gyroscopes, and magnetometers [11]. The PSW measured at a sampling rate of 120 Hz and the IMUs at 128 Hz using the Moveo Explorer software (by APDM). All data were

collected and combined in Matlab R2018b (MathWorks®, Natick, USA) and for statistical calculations IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, N.Y., USA) was used.

Table 1: Number of sensors, positioning and description of position of the IMUs (Opal sensors) used.

1	Lumbar	Centered on the low back, at the base of the spine. Superior aspect of the posterior sacral surface.
2	Upper leg	Lateral aspect of thigh, midline right over the iliotibial band between the muscular tissue, one hand's width above the knee.
2	Lower leg	Medial to the front of the tibia, on the flat surface of the bone, high enough for the strap to wrap just above the widest part of the calf muscle.
2	Foot	Centered on top of the foot, aligned with the second metatarsal.

2.3.2 Assessment

After sensors were attached to the participants as described in Table 1, participants were allowed to get comfortable perambulating on the walkway. All participants were asked to wear their own comfortable shoes. The data collection protocol consisted of four walking trials of 90 seconds each. During the first two trials, participants were asked to walk using their 'natural gait' (normal walking). Between these trials IMUs were taken off and attached again, for test-retest measurements. For the next trial, participants were asked to walk with a toe-out gait, which meant walking with the toes pointing outwards in a way that felt unnatural but not uncomfortable. For the last trial, participants were asked to do the opposite and point their toes inwards (toe-in gait). Each trial started with the participant standing still in the calibration pose (with the longitudinal axis of the feet perpendicular to the coronal plane), to ensure IMU calibration after which both measurement systems were started simultaneously. Participants walked for 90 seconds back and forth on a ± 8.5 m long path including the 3.66 m walkway. After 90 seconds both systems were stopped concurrently.

2.3.3 Outcome measures

Moveo Explorer (IMUs) defines the FPA as "the lateral angle of the foot during the stance phase, relative to the forward motion of the foot during the swing phase" [12]. In PKMAS software (walkway), the algorithm creates an ellipse with the smallest area that completely encloses all of the activated sensors of a footprint first. Then, the direction of the foot was defined by the long axis of the ellipse. The FPA by PKMAS is defined as "the angle between the Direction Of Progression (DOP) and the Foot Angle (degrees)" [13]. Positive FPA values indicate toes pointing outwards, whereas negative values indicate

the toes pointing inwards. Values below -40° or above 40° were assumed to be errors and were deleted from the dataset.

2.4 Statistical analysis

Reliability was assessed using intraclass correlation coefficient (ICC) and standard error of measurement (SEM). ICC and SEM were calculated between the first two trials of the protocol (both normal walking) to assess test-retest reliability for both measurement systems. For further calculations the second trial is used as a baseline, because IMUs were kept in place from the second trial on. ICC estimates and their 95% confidence intervals were calculated based on a mean-rating (k=2), absolute-agreement, 2-way mixed-effects model. The SEM was calculated as $SEM = SD * \sqrt{1 - R_{xx}}$, using the standard deviation (SD) and the reliability of the test (R_{xx}). The SEM value can range from 0 to the value of the standard deviation, with a higher value indicating lower test reliability. To evaluate the reliability of the systems in detecting the change in gait between baseline and the gait modification strategies, comparisons of the FPA between gait types were made. The ΔFPA is calculated by subtracting the baseline FPA per leg from the gait strategy (toe-out gait or toe-in gait). Finally the minimal detectable change (MDC) was determined by $MDC = 1.96 * SEM * \sqrt{2}$. The MDC is described as the least amount of change which is not the result of measurement error [14].

Validity was assessed by calculating repeated measures ANOVA (analysis of variance) test, ICC and Bland-Altman plots. ANOVA tests were performed with one dependent variable, FPA, and two independent variables: "gait type" (baseline/toe-in/toe-out) and "measurement instrument" (IMU/PSW). Mauchly's test indicated that the assumption of sphericity had been violated for both independent variables. Greenhouse-Geisser corrections were applied to the degrees of freedom, such that a valid critical F-value can be obtained. ICC was calculated per system for the two baseline measurements. Bland-Altman plots were created using the mean and the difference in FPA between both measurement systems. 95% confidence intervals were added as limits of agreement. At last, a scatterplot was created using the mean and the difference in FPA between the systems for all gait types combined with a linear regression to identify proportional bias.

3. Results

3.1 Outcome measures

All mean FPA results for the systems with their standard deviation and 95% confidence intervals and the mean difference in FPA between the two measurement systems are presented in table 2. In total 7974 steps were detected. 63 steps were removed from the dataset, as they fell outside the acceptable range of values (between -40° and 40°). 86% of these removed steps were measured by the PSW.

3.2 Reliability

Results are presented in table 3. ICCs, SEM and MDC were calculated for baseline test-retest measurements. ICCs for the walkway indicate excellent reliability and ICCs for IMUs indicate good reliability [15]. The error for the IMUs (SEM=1.6°) was larger compared to the error of the PSW (SEM=0.96°), which results in a higher MDC for the IMUs. In table 4 the ΔFPA between the different gait types is evaluated for both measurement systems. The IMUs detected a larger gait alteration between baseline and the gait modification strategies than the PSW did. For both systems the gait alteration between baseline and toe-out gait was significantly positive and the significantly negative between baseline and toe-in gait.

3.3 Validity

The repeated measures ANOVA resulted in a significant main effect of the variable "gait type" ($p<.001$). The results show there was no significant effect of the variable "measurement instrument" ($p=.875$). The ICC for correlation between the two systems for baseline measurements was indicative of good correlation being 0.87 and 0.84 when outliers were included. Bland-Altman plots are shown in figure 1 for all gait types with mean differences between the two systems and limits of agreement. Data were checked for heteroscedasticity, but Kendall's tau (τ) was negative, so the data were considered homoscedastic [16], meaning the observed variance is independent of the variable mean [17]. A scatterplot is shown in figure 2 of the mean FPA against the difference in FPA between the two systems of all gait types combined. A significant ($p<.001$) regression line is fitted to the dots with the following equation; $y = -0.79 + 0.17 * x$ (R^2 =0.234).

Table 2: Mean foot progression angle (FPA), standard deviation (SD), 95% confidence intervals (CI), minimum and maximum values and mean difference in FPA between the two systems, in degrees for IMUs (Opal sensors) and the PSW (Zeno™ walkway) for left and right leg in three conditions: baseline gait, toe-out gait and toe-in gait. All calculations are based on 7974 steps by 40 legs.

Instrument	**Variable**	**Baseline**	**Toe-out gait**	**Toe-in gait**
IMUs	Mean FPA ± SD (95% CI) Min; max	5.6 ± 4.9 (4.0: 7.1) -2.0; 19.5	19.9 ± 6.3 (17.9: 21.9) 8.6; 31.5	-9.9 ± 6.8 (-12.1: -7.7) -29.1; 5.5
PSW	Mean FPA ± SD (95% CI) Min; max	5.2 ± 5.5 (3.5: 7.0) -4.5; 21.4	17.3 ± 6.0 (15.4: 19.2) 9.1; 33.5	-7.2 ± 5.4 (-9.0: -5.5) -18.4; 6.4
IMUs + PSW	Mean FPA ± SD (95% CI) Min; max	5.4 ± 4.9 (3.8: 7.0) -2.5; 20.5	18.6 ± 5.8 (16.7: 20.4) 9.3; 31.7	-8.6 ± 5.8 (-10.4: -6.7) -23.4; 5.9
	Mean difference between systems FPA ± SD (95% CI) Min; max p-value	0.3 ± 3.6 (-0.82: 1.5) -11.3; 7.3 .57	2.6 ± 3.7 (1.4: 3.8) -4.4; 11.7 $p < .001$	-2.7 ± 4.1 (-4.0: -1.3) -13.0; 5.2 $p < .001$

Table 3: Assessment of baseline test-retest intraclass correlation coefficients (ICC) with 95% confidence intervals, standard deviation (SD), standard error of measurement (SEM) and minimal detectable change (MDC) in degrees.

	IMUs Baseline test-retest	**PSW** Baseline test-retest
ICC absolute agreement (95% CI) p-value	0.89 (0.79 ; 0.94) p < .001	0.97 (0.95 ; 0.99) p < .001
SEM(°)	1.6	0.96
MDC(°)	4.5	2.7

Table 4: Δ FPA in degrees for toe-out gait and toe-in gait for both systems, difference in Δ FPA between the systems and mean Δ FPA for both systems. Δ FPA is calculated by subtracting the baseline FPA from the toe-out gait or toe-in gait FPA. All variables are in degrees.

	IMUs		**PSW**		**IMUs - PSW**		**IMUs + PSW**	
Variable	Δ FPA toe-out	Δ FPA toe-in	Δ FPA toe-out	Δ FPA toe-in	Difference Δ FPA toe-out	Difference Δ FPA toe-in	Mean Δ FPA toe-out	Mean Δ FPA toe-in
Mean FPA ± SD	14.3 ± 5.4	-15.5 ± 6.7	12.0 ± 4.8	-12.5 ± 5.1	2.3 ± 2.4	-3.0 ± 3.6	13.2 ± 5.0	-14.0 ± 5.6
Median	14.4	-14.1	11.5	-11.6	2.3	-2.5	12.9	-13.4
Min; max	4.0; 26.6	-41.6; -7.0	2.3; 25.1	-30.6; -4.1	-3.1; 7.3	-11.7; 2.9	3.2; 25.1	-36.1; -6.1
95% CI	12.6: 16.0	-17.6: -13.3	10.5: 13.6	-14.1: -10.9	1.5; 3.0	-4.2; -1.8	11.6; 14.8	-15.8; -12.2

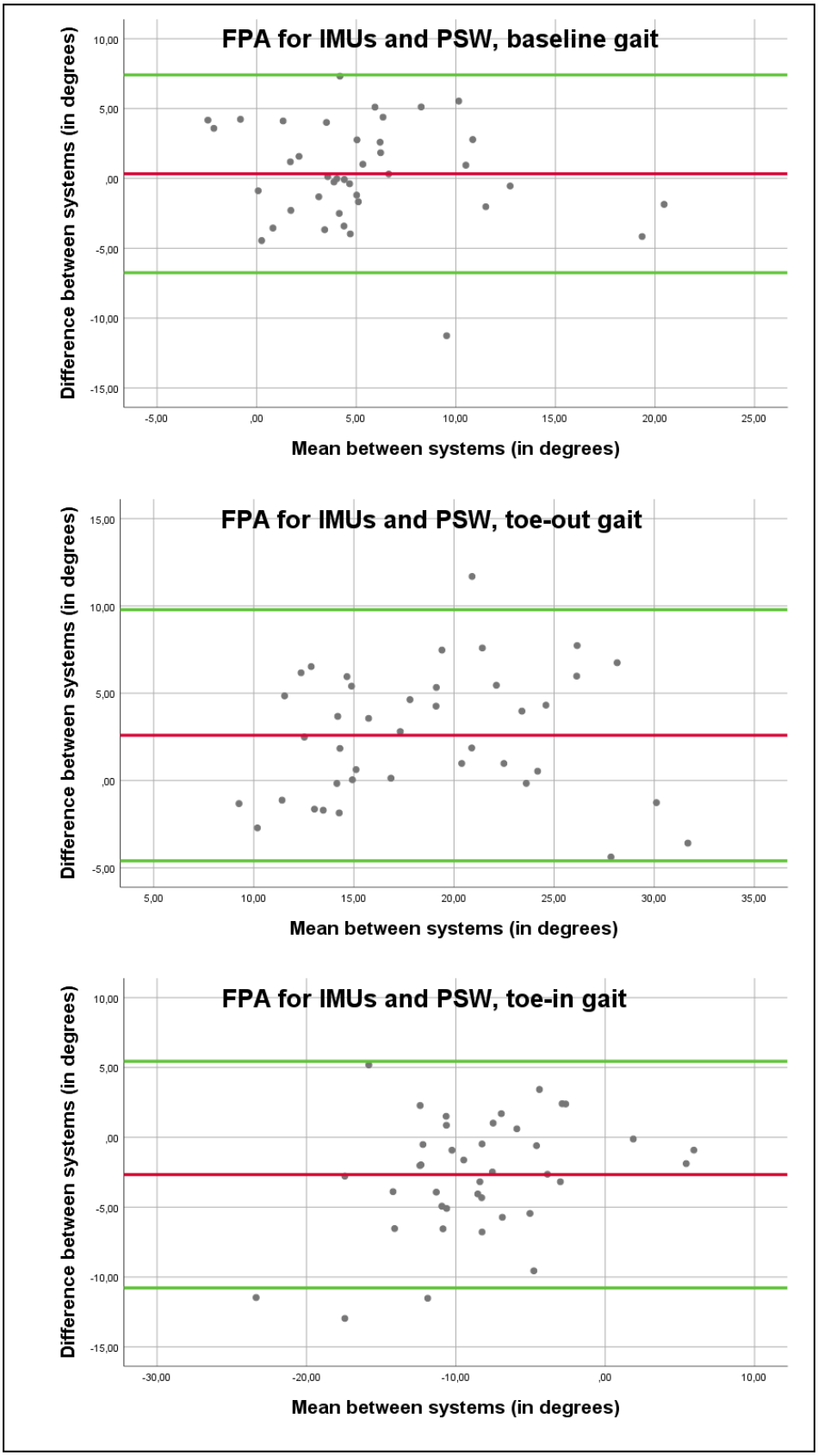

Figure 1: Bland-Altman plots for baseline, toe-out and toe-in gait. Every grey dot represents one leg. Difference in FPA between IMUs (Opal sensors) and the PSW (Zeno™ Walkway) is displayed on the y-axis and the mean FPA for Opal and Zeno™ is displayed on the x-axis. The red line represents the mean difference and the green lines the 95% limits of agreement.

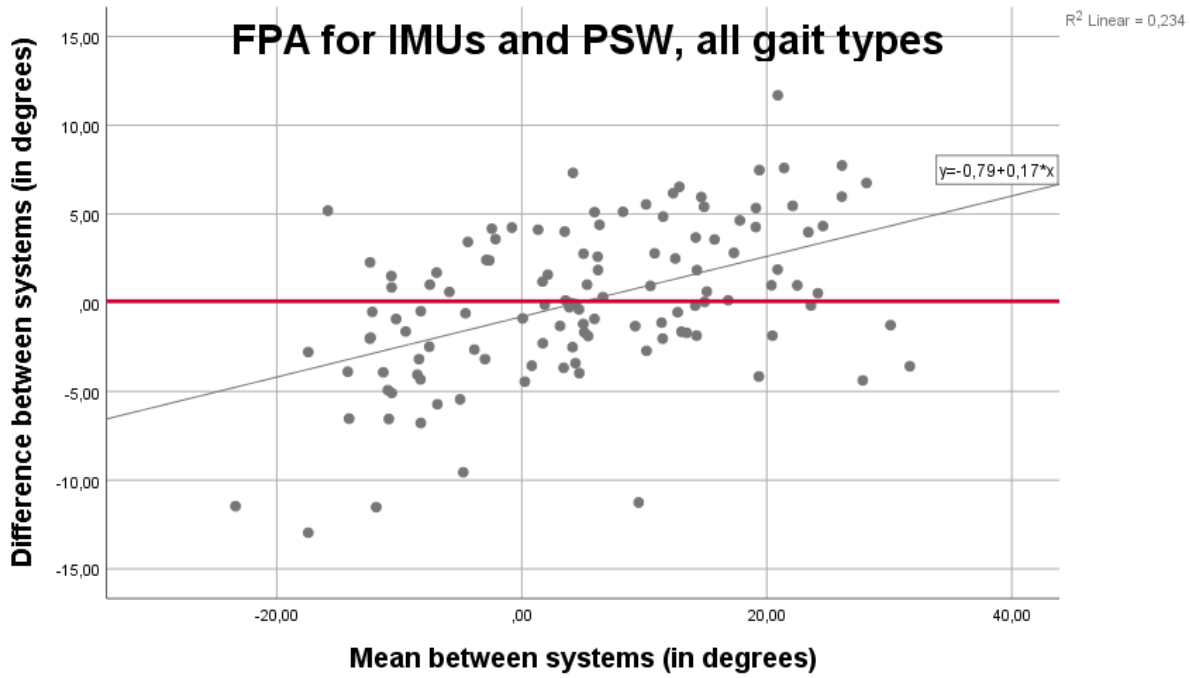

Figure 2: Scatterplot of mean FPA against the difference in FPA between the two systems of all gait types combined. Difference in FPA between IMUs (Opal sensors) and the PSW (Zeno™ Walkway) is displayed on the y-axis and the mean FPA for Opal and Zeno™ is displayed on the x-axis. The red line represents the mean difference. A linear regression line ($y = -0.79 + 0.17 * x$) is fitted to the dots.

4. Discussion

Summary of the main findings

This study included a reliability and validity study of the Opal sensors (IMUs) against the Zeno™ Walkway (PSW). The current data demonstrates that both measurement systems are reliable for measuring FPA in normal, toe-in and toe-out gait. Moreover, the systems have a good agreement in baseline conditions, but a significant difference of 2.7 degrees between the systems was found when performing the gait modification strategies. Nevertheless, these findings are promising for clinicians who use IMUs for gait retraining. One of the advantages of the IMUs is that it is not limited to a lab or even surfaces, so it may be used at home or in outdoor environments. A threshold of 5 degrees should be taken into account when concluding differences.

4.1 Outcome measures

As expected, the mean FPA is most positive for toe-out gait compared to baseline and toe-in gait. Toe-in gait yielded the most negative angle. In this study, the target angle was a FPA that felt unnatural but not uncomfortable. A mean FPA deviation of approximately 12° to 16° was achieved this way. In a previous study the FPA target angle was a deviation of 10° from the baseline FPA [18]. FPA data from this study agrees with FPA in healthy participants in previous research [6].

4.2 Reliability

Both systems seem to be reliable measurement systems for quantifying FPA. Baseline test-retest reliability for the PSW was excellent (ICC=0.97) and for the IMUs was considered of good reliability (ICC=0.89). When outliers were included, PSW test-retest ICC equalled 0.90, which indicates good reliability; the inclusion of outliers did not affect the test-retest ICC for IMUs. From this data, it can be concluded that both systems have a high reproducibility, when walking with a natural FPA. Previous research showed a similar test-retest ICC of 0.98 [19] for FPA during normal walking on the GAITRite®, a pressure sensitive walkway similar to the Zeno™ walkway, which was used in this study. Another study found a lower test-retest reliability for FPA measured with the GAITRite® in older adults (aged between 76 and 87 years), ICC=0.71 (right foot) and ICC=0.82 (left foot), compared to young adults (aged between 22 and 40 years) ICC=0.88 (right foot) and ICC=0.94 (left foot) [20].

After excluding outliers, the SEM for the PSW is smaller (0.96°) than for the IMUs (1.62°), but the latter can still be considered acceptable. The SEM is the amount of error that can be considered as measurement error. The MDC indicated that consequently IMUs are not suitable for precise

measurements smaller than 5° and not for measurements smaller than 3° with the PSW. The MDC is described as the least amount of change which is not the result of measurement error [14]. However, it should be noted that not every step is identical, so part of this MDC is explained by physiological differences. A t-test showed a significant difference between the two measurement systems for toe-in -and toe-out gait.

4.3 Validity

Both the IMUs and PSW were found to be reliable for the measurement of FPA and both were able to detect changes in FPA with each gait modification strategy implemented, which strengthens the clinical validity. The mean difference between the two measurement systems in baseline conditions is negligible (0.33°). IMUs seem to amplify the ΔFPA compared to the PSW for the gait modification strategy conditions by 15-30%. A significant difference of 2.7 degrees between the systems was found when performing the gait modification strategies. A similar study found a comparable difference in FPA of 2.6 degrees between a foot-worn inertial sensor and a motion capture system [21]. It is unclear whether deformation of the foot (when loading in extreme positions) could have caused a varus or valgus effect on the FPA. ΔFPA amplification could also be caused by sensor movement since the lumbar and foot sensors were placed above clothing and shoes. Sensors were secured as firmly as possible, but little shifting couldn't be avoided. When using the systems interchangeably, which is not recommended, one should apply a correction for FPA for toe-out -and toe-in gait.

The Bland-Altman plot for baseline gait indicates good agreement between the two measurement systems. The other two Bland-Altman plots (toe-out gait and toe-in gait) show a proportional bias. The IMUs amplify the values (more negative with toe-in gait and more positive with toe-out gait) compared to the PSW values. This can be seen in the scatterplot with all gait types combined in figure 2. The regression line shows a positive slope and predicts the difference between the systems significantly well ($B=17$, $p< .001$). The R^2 value shows that 23% of the total variation in the difference between the systems can be explained by the mean between the systems. Which is not high. The limits of agreement of the Bland-Altman plots stayed proportionate, the variability consistent and negligible outliers.

A similar study, comparing spatiotemporal gait parameters between the Opal sensors and the GAITRite®, found a comparable trend where the Opal sensors consistently overestimated the FPA measurements compared to the GAITRite® values, which increased as gait variability increased [22]. Another study, comparing another wearable IMU system to the 3D motion capture found an ICC of 0.94 between the two systems, which is higher than the ICC found in this study (ICC=0.87) [7]. However, the other study used target FPAs with visual feedback, which would reduce the amount of personal variation.

4.4 Strengths and limitations

Strengths of this study include an adequate sample size and many steps as a result of relatively long measurements in multiple conditions. The use of test-retest reliability makes the evidence more credible. The protocol of testing validity under different types of gait is important because those are the conditions used in a gait retraining session, which makes the results clinically meaningful.

The findings of this study should be interpreted in the context of two main limitations. First, all participants were healthy and were asked to walk with an exaggerated toe-in or toe-out angle for the last two conditions. Thus, the accuracy may differ in participants with a movement disorder, e.g. foot drop. Second, at the end of the ± 8.5 m long path participants had to turn around each time until a duration of 90 seconds was achieved. These turns are only recorded by the IMUs and should be automatically deleted from the dataset by the APDM software, but these turns could have influenced the gait of the few steps between the PSW and the turn. As described before, APDM and PKMAS have a different definition and measurement of the FPA. The line of progression is defined by APDM when the foot is in swing phase, and by PKMAS it is calculated on the basis of footprints. Besides differences in measurement precision, the difference in definition may as well be a source of differences in FPA.

4.5 Recommendations for future studies

The results from this study have prompted the transition to a clinical phase where the Opal sensors are used on patients when receiving gait retraining therapy. Further research should be conducted with the acquisition of the FPA using dedicated IMU FPA algorithms or the use of artificial intelligence to make more reliable estimates. A proof-of-concept has been done on a haptic feedback-sensorized shoe in combination with a target FPA [23]. It would be interesting whether this innovation is beneficial for patients with knee OA.

4.6 Final conclusion

The purpose of this study was to evaluate the reliability and validity of FPA measurement using IMUs in gait strategies that are used for gait retraining in KOA. The results suggest that using the Opal sensors as IMUs are sufficiently reliable and valid to measure FPA in gait retraining. There are small yet systematic differences compared to the reference standard that should be accounted for by interpretation. IMUs provide a promising tool for clinicians and researchers aiming to quantify FPA for gait retraining.

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