

# Toward Personalized Orthopedic Care: Validation of a Smart Knee Brace

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## Keywords

Wearables · Validity · Inertial measurement unit · Agreement · Gait

## Abstract

**Introduction:** Wearable technology offers a promising solution to advance current rehabilitation strategies for post-operative orthopedic care. The aim of this study was to determine the level of agreement and concurrent validity of a smart knee brace compared to the gold standard measurement system GAITRite<sup>®</sup> for assessing lower limb gait parameters. **Methods:** Thirty-four healthy participants were fitted with the smart knee brace (Digital Knee<sup>®</sup>) on their dominant limb. Gait parameters (stride length, stride time, and gait velocity) were measured simultaneously using the Digital Knee<sup>®</sup> and the GAITRite<sup>®</sup> electronic walkway. Two walks were performed at a comfortable speed and two at a fast-walking speed. **Results:** At a comfortable walking speed, stride time was moderately valid ( $ICC_{2,1} = 0.66$  s), and stride length and gait velocity demonstrated poor validity ( $ICC_{2,1} = 0.29$ ;  $ICC_{2,1} = 0.41$ ). All gait parameters demonstrated poor validity at a fast-walking speed ( $ICC_{2,1} = -0.16$  to  $-0.01$ ). Bias ranged from  $-0.08$  to  $0.28$ , with more clinically acceptable percentage errors at a comfortable walking speed (14.1–30%) versus at a fast-walking speed (26.4–42.6%). Gait velocity and stride length had substantially higher biases in the fast-walking speed compared to the comfortable walking speed ( $0.28 \pm 0.39$  m s<sup>-1</sup> vs.  $0.02 \pm 0.21$  m s<sup>-1</sup>;  $0.15 \pm$

$0.23$  m vs.  $-0.04 \pm 0.17$  m). Limits of agreement were considered narrower for stride time compared to stride length and gait velocity. **Conclusion:** The Digital Knee<sup>®</sup> is a promising approach to improving post-operative rehabilitation outcomes in patients with osteoarthritis. The Digital Knee<sup>®</sup> demonstrated good agreement and moderate concurrent validity for measuring gait metrics at a comfortable walking speed. These findings highlight the opportunity of the wearable sensor as an intervention for post-operative orthopedic care. This was a laboratory-based study; thus, further research is required to validate the wearable sensor in real-world contexts and in patients with knee pathologies. Further, refinement of the algorithm for measuring gait metrics at slow- and fast-walking speed with the Digital Knee<sup>®</sup> is warranted.

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## Introduction

Wearable technology offers a promising solution to advance current rehabilitation strategies for orthopedic care. Provision of a continuum of care for common musculoskeletal knee pathologies requires follow-up using outcome measurements to determine rehabilitation progress, mobility status, and for monitoring symptom progression. In the clinical setting, current patient data collection occurs during appointments, providing only a snapshot of a patient's rehabilitation progress. Assessment methods utilize

outcome-based tests that provide discrete, non-continuous measures [1], deemed “macro-level data.” Typical physical therapy assessment methods are primarily subjective, making them susceptible to variations in patient and clinician perspectives and leaving little room for accurate patient evaluation [2]. Consequently, the quality of diagnosis and treatment suffers [3]. To address this limitation, a shift toward leveraging technological solutions can offer more comprehensive and continuous “micro-level” (quantitative) data, enabling a more robust evaluation.

Despite its potential, no wearable sensing technology has yet been successfully integrated into routine physiotherapy practice. In response, a custom-built wearable sensor has been developed, with an integrated accelerometer and goniometer, and embedded into a commercially available knee brace which is paired with a mobile application. This device presents an opportunity to enhance access to care and improve rehabilitation outcomes by pairing digital health solutions with current practice. Gait analysis is one of the most common applications of wearable technology in clinical settings and is used by clinicians due to its usefulness for diagnosing and monitoring health conditions. It has been used in both the pre-operative and post-operative stages of care and is a useful functional outcome measure for determining rehabilitation progress [4]. The emergence of wearable sensors offers real-time, cost-efficient gait analysis for clinical uses.

The effective integration of wearables into clinical practice hinges on several factors. Specifically, devices need to measure parameters they aim to capture, provide users with clinically meaningful outputs, and effectively track changes over time [5]. Wearable sensors derive gait parameters from linear acceleration and angular velocity, which vary across different gait patterns [6]. Thus, the technical validity of wearable sensors needs establishing to be able to replace measurements in the same context as gold standard measuring devices while also providing reliable normative baseline data [6]. This study aimed to determine the concurrent validity and level of agreement between a custom-developed smart knee brace and the gold standard measurement system GAITRite<sup>®</sup>, for assessing lower limb walking patterns.

## Methods

This was a cross-sectional laboratory study with a nested validation study conducted at the Department of Exercise Sciences, University of Auckland. All outcome measures were collected during a single data collection session. This research was approved by the Auckland Health Research Ethics Committee on December 7, 2022 (AH24917). All participants provided written informed consent prior to participating in the study.

### Procedures

Participants completed a short questionnaire on ethnicity, occupation, and physical activity level. Height and weight were measured prior to testing. Participants were then outfitted with the Digital Knee<sup>®</sup> (OPUM Technologies, Auckland, New Zealand) worn on the dominant limb, established by asking which limb participants preferred for kicking a ball [7, 8]. The Digital Knee<sup>®</sup> consists of a Coreflex Contender<sup>®</sup> Post-Op Knee Brace with a clip-on Gen2 Digital Knee<sup>®</sup> sensor shown in Figure 1. A tablet was used to access the OPUM application and login to the participant profile to record and collect data. All data was de-identified on the platform by email address which is linked to a unique user-globally-unique-identifier. All data collected by the OPUM system was stored in OPUM’s cloud infrastructure hosted in Azure, with access controlled via Azure Active Directory Credentials.

Participants were asked to walk across the GAITRite<sup>®</sup> electronic walkway while simultaneously wearing the Digital Knee<sup>®</sup>, twice at a comfortable walking speed and twice at a maximum safe speed. For the latter, the instruction was to walk at a speed faster than you would normally walk. Spatiotemporal gait parameters were derived from the Digital Knee<sup>®</sup> based on its algorithms and the GAITRite<sup>®</sup> system based on parameter availability; these included stride velocity, stride length, and stride time. Stride time was defined as the duration between consecutive initial heel contacts of the same foot, and stride length was the distance between two consecutive heel contacts of the same foot [9].

### Statistical Analysis

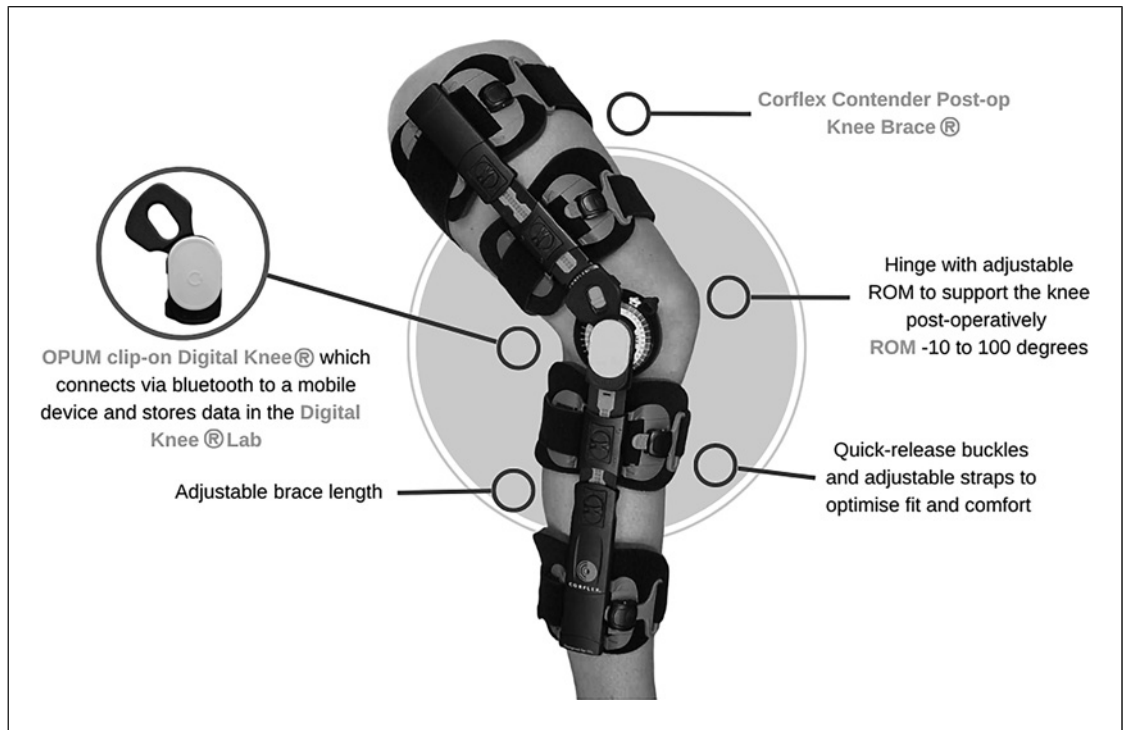
Concurrent validity of the Digital Knee<sup>®</sup> was established by comparing it with gait parameters from the GAITRite<sup>®</sup> using intraclass correlation coefficients (ICC<sub>2,1</sub>). ICC estimates and 95% confidence intervals were calculated based on a single-rating, absolute-agreement, 2-way random-effects model (ICC<sub>2,1</sub>) to determine concurrent validity between the mean gait parameter outputs of the Digital Knee<sup>®</sup> and GAITRite<sup>®</sup> [10]. The following pre-determined classification for ICC values was used: poor (<0.50), moderate (0.50–0.74), good (0.75–0.89), and excellent (>0.90) [10]. Paired *t*-tests were used to determine the mean difference in gait parameter measurements between the Digital Knee<sup>®</sup> and GAITRite<sup>®</sup>. To ensure statistical power of ICC values, a sample size of at least 30 participants was required for determining agreement between measurement systems [11]. Bland-Altman plots were used to calculate the mean of differences (bias) and 95% limits of agreement (LOA) between the two instruments. Percentage errors of <30% were used to determine if the Digital Knee<sup>®</sup> was clinically acceptable compared to GAITRite<sup>®</sup> [12]. The percentage errors (PE) were calculated as shown below:

$$PE = 100 \times (1.96 \times SD_{\text{bias}}) / ((\text{mean}_{\text{DigitalKnee}^{\circledast}} + \text{mean}_{\text{GAITRite}^{\circledast}}) / 2)$$

Significance was set at  $p < 0.05$ . All analyses were conducted [13] using R version 4.1.2 with the following packages: ggplot2, blandr, and fmsb.

## Results

Thirty-four healthy participants were recruited for this study. Participant characteristics are in Table 1.



**Fig. 1.** Coreflex Contender<sup>®</sup> Post-Op Knee Brace and mounted OPUM Digital Knee<sup>®</sup>.

### Concurrent Validity

Only stride time demonstrated moderate validity during comfortable walking speeds ( $ICC_{2,1} = 0.66$ ) (Table 2) and diminished in fast walking ( $ICC_{2,1} = -0.01$ ), indicating poor validity. Additionally, poor validity was observed in gait velocity and stride length across both comfortable and fast-walking speeds ( $ICC_{2,1} = -0.16-0.41$ ;  $-0.04-0.29$ ).

### Agreement

Table 2 shows the means ( $\pm$ SD) of the spatiotemporal gait parameters for both instruments. Stride time had the smallest mean difference across both comfortable and fast-walking speeds. Mean bias for gait speed, stride length, and stride time ranged from  $-0.08$  to  $0.28$ , with percentage errors more clinically acceptable at a comfortable walking speed (14.1–30%) compared to fast-walking speed (26.4–42.6%). Gait velocity and stride length showed a substantially higher bias in fast-walking speed ( $0.28 \pm 0.39$  m s<sup>-1</sup>;  $0.15 \pm 2.3$  m) compared to all gait parameters, with clinically unacceptable percentage errors observed in gait velocity (42.6%) but clinically acceptable percentage errors for stride length (26.4%). At a comfortable walking speed, gait velocity, stride length, and stride time had lower mean bias ( $-0.04-0.02$ ), supported by clinically acceptable percentage errors

**Table 1.** Participant characteristics

Variable	Healthy ( $n = 34$ )
Age, years	26.21 $\pm$ 6.8
Gender	
Female	20 (58.8)
Male	14 (41.2)
Ethnicity*	
NZ European	26 (76.5)
European	4 (11.8)
Pacific	2 (5.9)
Māori	1 (2.9)
Asian	4 (11)
Height, m	1.73 $\pm$ 0.09
Weight, kg	71.68 $\pm$ 13.37
Body mass index	23.97 $\pm$ 3.48
Dominant limb (L/R)	
Left	3 (8.8)
Right	31 (91.2)
Tegner	
Current	6.12 $\pm$ 1.43

Quantitative data reported as mean  $\pm$  standard deviation (minimum-maximum) and categorial data as a percentage  $n$  (%). \*Indicates percentages do not total 100% due to multiple ethnicities recorded across one participant.

**Table 2.** Test-retest agreement and concurrent validity between the OPUM Digital Knee<sup>®</sup> and GAITRite<sup>®</sup> for measuring spatiotemporal gait parameters

Spatiotemporal gait parameter	OPUM Digital Knee <sup>®</sup> , mean ± SD	GAITRite <sup>®</sup> , mean ± SD	Agreement			Validity	
			Bias*, mean difference ± SD	95% LOA	PE, %	ICC <sub>2,1</sub>	95% CI
<b>Comfortable gait speed</b>							
Gait velocity, m s <sup>-1</sup>	1.36 ± 0.17	1.38 ± 0.21	0.02 ± 0.21	-0.39 to 0.42	30	0.41	[0.20, 0.59]
Stride length, m	1.53 ± 0.13	1.48 ± 0.15	-0.04 ± 0.17	-0.38 to 0.29	22.1	0.29	[0.00, 0.44]
Stride time, s	1.13 ± 0.09	1.10 ± 0.09	-0.04 ± 0.08	-0.17 to 0.10	14.1	0.66	[0.41, 0.80]
<b>Fast gait speed</b>							
Gait velocity, m s <sup>-1</sup>	1.65 ± 0.26	1.94 ± 0.25	0.28 ± 0.39	-0.49 to 1.05	42.6	-0.16	[-0.36, 0.08]
Stride length, m	1.63 ± 0.13	1.79 ± 0.18	0.15 ± 0.23	-0.31 to 0.61	26.4	-0.04	[-0.21, 0.15]
Stride time, s	1.01 ± 0.14	0.92 ± 0.06	-0.08 ± 0.16	-0.38 to 0.22	32.5	-0.01	[-0.20, 0.2]
<b>Total</b>							
Gait velocity, m s <sup>-1</sup>	1.57 ± 0.32	1.66 ± 0.37	0.14 ± 0.33	-0.52 to 0.80	40.1	0.39	[0.21, 0.54]
Stride length, m	1.60 ± 0.19	1.63 ± 0.22	0.05 ± 0.22	-0.39 to 0.49	26.7	0.26	[0.10, 0.41]
Stride time, s	1.05 ± 0.13	1.01 ± 0.12	-0.06 ± 0.12	-0.29 to 0.18	22.8	0.49	[0.29, 0.64]

SD, standard deviation; PE, percentage error; SEM, standard error of measurement; %SEM, percentage of standard error of measurement; ICC, intraclass correlation coefficient. \*Difference between the OPUM Digital Knee<sup>®</sup> and GAITRite<sup>®</sup> measurements.

(14.1–30%). However, at a fast-walking speed, only stride length had clinically acceptable percentage errors (26.4%), while gait velocity and stride time had unacceptable percentage errors (32.5–42.6%). LOA were wider across all gait parameters at a fast-walking speed compared to a comfortable walking speed (-0.49 to 1.05; -0.39–0.42), as seen in Figure 2. LOA were considered narrower for stride time (-0.17 to 0.10 s; -0.38 to 0.22 s) than for gait velocity (-0.39 to 0.42 m s<sup>-1</sup>; 0.49 to 1.05 m s<sup>-1</sup>) and stride length (-0.39 to 0.29 m; -0.31–0.61 m).

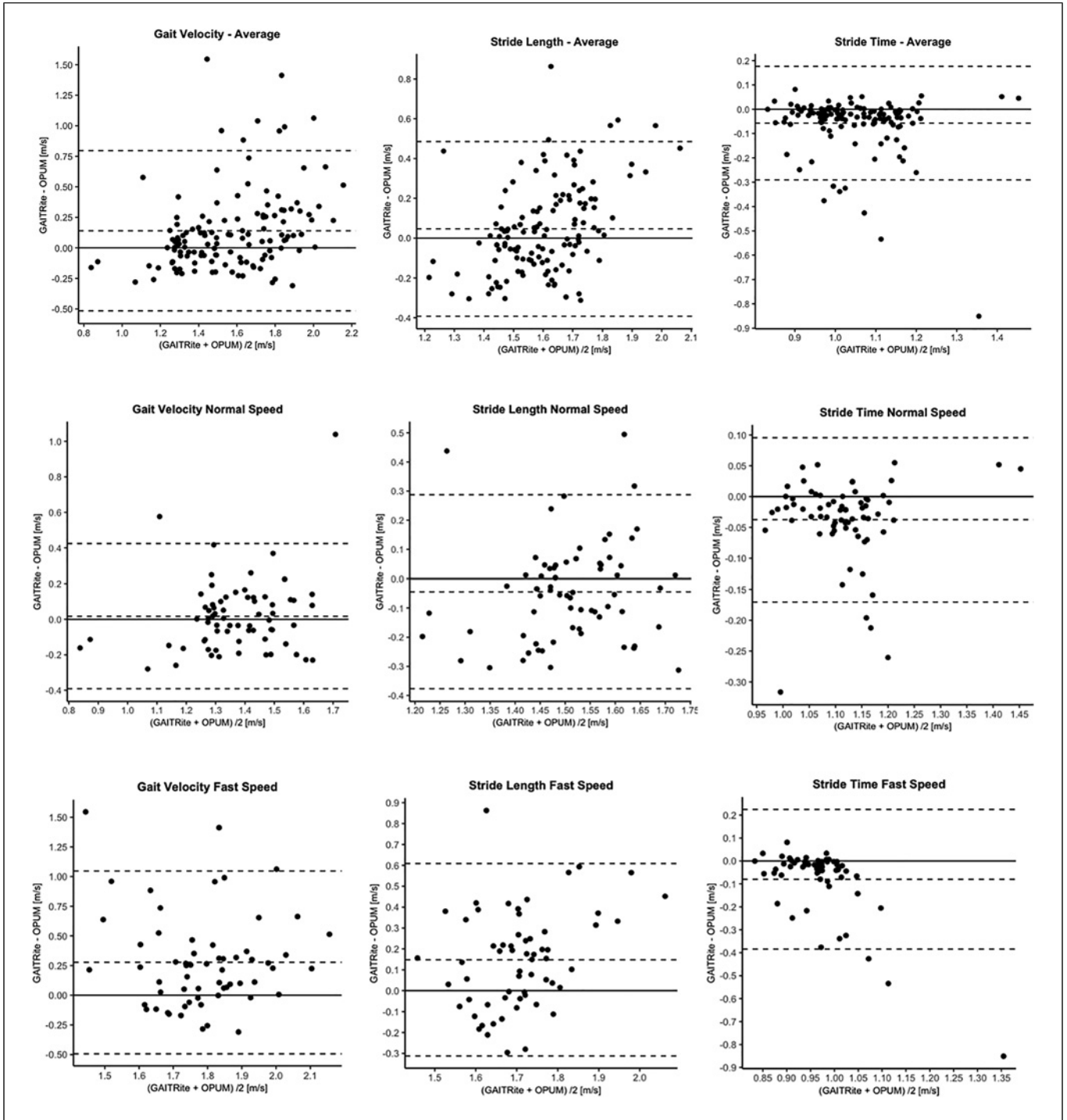
## Discussion

The aim of this study was to determine the level of agreement and concurrent validity of the Digital Knee<sup>®</sup> compared to the gold standard measurement system GAITRite<sup>®</sup> for measuring spatiotemporal gait parameters. The GAITRite<sup>®</sup> system has been widely demonstrated to be a reliable and valid evaluation tool for measuring spatiotemporal parameters in the assessment of gait [14, 15]. Establishing the validity of the Digital Knee<sup>®</sup> compared to GAITRite<sup>®</sup> is key to determining its suitability prior to clinical use as an assessment or rehabilitation tool.

Results demonstrated that the Digital Knee<sup>®</sup> has some validity in measuring specific spatiotemporal parameters at a comfortable walking speed but not at fast-walking speeds, compared with the GAITRite<sup>®</sup>. At a comfort-

able walking speed, the ICC values range from 0.29–0.66, suggesting that the Digital Knee<sup>®</sup> is a poor-moderate valid tool for measuring both stride time, length, and gait velocity at a comfortable walking speed. However, when considering absolute measures of spatiotemporal gait parameters at a fast-walking speed, these systems cannot be used interchangeably. At a fast-walking speed, ICC<sub>2,1</sub> values range from -0.01 to -0.16, indicating that variation within the Digital Knee<sup>®</sup> is larger than GAITRite<sup>®</sup> and differences are non-negligible. Furthermore, the moderate concurrent validity for stride time but poor validity for stride length and gait velocity at a comfortable walking speed correlates with the Bland-Altman plots (Fig. 2), which indicate high LOA for stride time but low LOA for stride length and gait velocity. When interpreting agreement between measuring systems, the wider the LOA, the greater the disparity there is between device readings, indicating lower agreement between devices [16].

Previous studies have used GAITRite<sup>®</sup> to validate wearable sensors for measuring spatiotemporal gait parameters on the back [14, 17–21], the shank [22], and the ankle [23, 24] in healthy participants. Overall, there were greater levels of agreement for temporal parameters (stride time, gait velocity) than spatial parameters (stride length) in our study. These findings are comparable to other studies that have validated an IMU against GAITRite<sup>®</sup> [19, 25] or motion capture [24, 26]. Similar findings to our study were reported by Godfrey et al. [19],



**Fig. 2.** *Top panel:* Bland-Altman plots representing the comparison of agreement between the OPUM Digital Knee<sup>®</sup> and the GAITRite<sup>®</sup> gait analysis measurements. Dotted lines indicate bias, and dashed lines indicate the upper and lower 95% LOA. *Middle panel:* Agreement between the OPUM Digital Knee<sup>®</sup> and the GAITRite<sup>®</sup> gait analysis measurements at a comfortable walking speed. *Bottom panel:* Agreement between the OPUM Digital Knee<sup>®</sup> and the GAITRite<sup>®</sup> gait analysis measurements at a fast-walking speed.

who evaluated a body-worn back IMU and found good agreement and correlation for stride time but lower agreement and correlation for stride length and gait velocity. These findings were explained by the method of how the IMU algorithm identifies final contact events in the gait cycle [19]. Stride length is calculated by GAITRite<sup>®</sup> as the distance between two heel contact points of the same foot [23], while the IMU relies on its algorithm. IMUs commonly use machine-learned algorithms or non-machine-learned (conventional) algorithms to detect spatiotemporal parameters [27]. A review by Hutabarat et al. [27] found that most of the devices analyzed used a conventional algorithm to identify gait events or phases. Conventional algorithms utilize a threshold approach, where the gait phase is detected when the IMU signal drops below a certain threshold [28]. Machine-learned algorithms use supervised learning to train statistical models for measuring spatiotemporal gait parameters; however, these algorithms are limited to the specific population, impacting its validity across other populations [29]. Similarly, Rantalainen et al. [24] evaluated a single-mounted IMU on the ankle and showed that temporal parameters were easier to record compared to spatial parameters which they explained as being due to IMU measurements having to double integrate recordings with respect to time to calculate foot displacement, which can lead to errors. This was a similar explanation to that described by Godfrey et al. [19], who reported that greater agreement was found for stride time compared to step time due to the combination of a left and right step within a stride, which has a confounding effect on limb asymmetry. These findings highlight that further refinement of the IMU algorithm is required to better estimate spatiotemporal gait parameters. To further investigate this error, individual steps could be manually observed in comparison to GAITRite<sup>®</sup> to determine step length and foot contact events, rather than the combination of two steps in stride length. This would provide greater insight into whether the IMU can accurately identify each stepping event in the gait cycle. However, this would require the IMU algorithm to be redesigned to measure more than the current gait parameters quantified in this study, i.e., to determine step length and time. The ICC for all temporal parameters in this study ranged from 0.41–0.61, indicating poor-moderate agreement. Thus, these measurements should still be interpreted with caution. However, these findings of poorer temporal parameters measured by the wearable device may be supported by the recommendation that the GAITRite<sup>®</sup> is the more appropriate gold standard tool for measuring temporal rather than spatial parameters [24].

In contrast to our findings, previous studies have demonstrated excellent validity for gait velocity when measured by body-worn IMUs compared to GAITRite<sup>®</sup> on the back [17, 26], the shank [22], and the ankle [23] at varying walking speeds – fast and comfortable [22, 25]. The average fast-walking speed in this current study was  $1.36 \text{ m s}^{-1}$ , which is comparable to other studies conducted with healthy participants and comparable age range [22]. Greene et al. [22] reported similar average gait velocity measurements at a normal walking speed on the GAITRite<sup>®</sup> ( $1.39 \text{ m s}^{-1}$  vs. our  $1.38 \text{ m s}^{-1}$ ) and the body-worn sensor ( $1.34 \text{ m s}^{-1}$  vs. our  $1.36 \text{ m s}^{-1}$ ). Average walking speeds have been reported as high as  $1.5 \text{ m s}^{-1}$  for healthy 30-year-old individuals and at  $0.87 \text{ m s}^{-1}$  for healthy 90-year-old individuals [30], so it was worth exploring validity at fast-walking speeds. Moreover, Greene et al. [22] suggest that gait speed can affect the validity of wearable sensors [22]. Gait analysis typically compares healthy and pathological gait at comfortable walking speeds [31]. However, individuals with lower-limb orthopedic or neurological pathologies tend to walk at slow-walking speeds [31]. Gait parameters are reduced in amplitude with slow-walking speed [31], and do not often reach steady-state with short-duration walking bouts commonly employed in laboratory-based validation studies [32]. Recent work from the MOBILISE-D consortium explored the effect of walking speed and walking bout duration on performance of various IMU algorithms for gait detection [32]. They concluded that algorithm performance was particularly worse with walking speeds below  $0.5 \text{ m s}^{-1}$ . Slow- or fast-walking speeds will result in non-uniform gait cycles and irregular gait patterns, with more variable signal characteristics [32]. When coupled with shorter walking bouts and the number of gait cycles for evaluation at fast-walking speed, this may explain our findings for the non-negligible validity of gait parameters measured by the Digital Knee<sup>®</sup> at a fast-walking speed. As this study was the first stage of validating the Digital Knee<sup>®</sup>, we opted to assess comfortable walking speed first. However, we acknowledge that short-duration walking bouts over the GAITRite<sup>®</sup> may reduce the steady-state walking phases for analysis and may explain the poor results at fast-walking speed in particular.

Based on our findings, the ability to measure gait parameters in real-time can be used to inform users on gait variations and thereby direct rehabilitation strategies and monitor progress but is dependent on gait speed. The larger biases in the spatiotemporal gait parameters captured at a fast-walking speed support the need to consider the sensitivity of the algorithm to varying gait speeds and bout duration when designing validation studies and for future real-world data collection studies. These findings will be

used to inform the design and testing of a new algorithm for slow- and fast-walking speeds to increase the accuracy of spatiotemporal gait parameters from the Digital Knee<sup>®</sup>.

### Statement of Ethics

This study protocol was reviewed and approved by the Auckland Health Research Ethics Committee (University of Auckland, New Zealand), approval number AH24917. Written informed consent was obtained from all participants prior to participation in the study.

### Conflict of Interest Statement

Annah McPherson was funded by a Callaghan Innovation R&D Experience Grant (2023). Andrew McDaid was the CEO (2016–2023) and founder of OPUM Technologies. Sarah Ward was funded by a Division of Health Sciences Postdoctoral Fellowship (2019–2021) and a University of Auckland New Staff Grant (2022–2024).

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### Author Contributions

A.M. was involved in the acquisition, analysis, and interpretation of the data and drafting and final approval of this manuscript. A.J.M. was involved in the conception and design of the study, interpretation of the data, and drafting and final approval of this manuscript. S.W. was involved in the conception and design of the study, analysis and interpretation of the data, and drafting and final approval of this manuscript.

### Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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