First steps in the development of a biofeedback device to monitor gait retraining kinematics in patients with knee osteoarthritis

Master thesis
Physiotherapy Science
Program in Clinical Health Sciences
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"ONDERGETEKENDE

Wytse Brongers

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Master thesis, Physical Therapy Sciences, Program in Clinical Health Sciences, Utrecht University, Utrecht, 2018

ABSTRACT

Background: A higher external knee adduction moment (EKAM) is associated with an increased progression of knee osteoarthritis (KOA). Gait modifications, such as medial thrust (MT) and trunk lean (TL), reduce EKAM, reduce pain and improve knee function. MT and TL can only be monitored accurately using expensive three-dimensional (3D) gait analysis, which makes this unsuitable for application in clinical practice. Furthermore, the end-users' needs, values, and requirements are essential in developing technology. Studies have suggested to use an Inertial Measurement Unit (IMU) to monitor gait kinematics. This study aims: 1) to identify the needs, values, and requirements of the end-users of a biofeedback gait monitoring device, 2) to determine the validity of the IMU for quantifying the tibia and trunk angle during MT and TL, respectively, in patients with KOA.

Methods: A mixed methods study design was used. Focus groups were conducted to identify the end-users needs, values and requirements on a gait monitoring device. Themes were identified using multiple data analysis. Validation was conducted by comparing the tibia and trunk angle between the IMU and 3D gait analysis. Pearson correlation coefficient and Bland and Altman plots were used for statistical analysis.

Results: Identified themes of needs, values and requirements are: type of biofeedback, performance features, material, time investment, and fitting of the device. For validation, 28 patients with KOA were analysed. A correlation ($r=0,899$, $p<0,001$) and good agreement was found between the IMU and 3D for measuring the trunk angle. No correlation ($r=0,075$, $p=0,741$) and agreement was found between the IMU and 3D for measuring the tibia angle.

Conclusion: Identified themes for a biofeedback device can guide development of future technology to monitor gait retraining. IMU seems to be a valid and useful technology for quantifying of the trunk angle to monitor TL kinematics in patients with KOA. MT cannot be measured accurately by quantifying the tibia angle with an IMU. It is recommended that future studies focus on multiple IMUs to measure the MT accurately.

Clinical Relevance: First steps in the development of a biofeedback device to monitor gait kinematics in patients with KOA.

Keywords: Knee Osteoarthritis, Gait, Biofeedback, Technology

INTRODUCTION

Symptomatic knee osteoarthritis (KOA) is a chronic and progressive joint disease which affects 250 million people worldwide.[1] The prevalence of KOA is increasing due to an increased prevalence of obesity and aging of the general population.[2] Currently, 12.1% of the elderly (≥60 years) in the United States suffer from symptomatic KOA[3], which most commonly occurs in the medial compartment of the knee.[4,5] Patients with symptomatic KOA experience pain and impairments in their daily activities.[5–7]

Several studies have shown that an increased joint load on the medial compartment of the knee is associated with increased progression of medial KOA.[8,9] The external knee adduction moment (EKAM) is commonly used as a surrogate measure to reflect the compressive load of the medial compartment of the knee.[8,10–13] A greater EKAM peak and impulse during gait are associated with a decreased cartilage thickness of the medial tibia and femur.[14,15]

Gait retraining is an effective treatment strategy to reduce load in the medial compartment of the knee during gait.[10–13,16] Most effective gait retraining strategies to reduce the EKAM peak and impulse in patients with KOA are leaning the trunk in the direction of the stance leg during gait (trunk lean [TL]) and medializing the knee during the stance phase (medial thrust [MT]).[10–12] Pilot studies on gait retraining resulted in pain reduction (29% - 37%) and improvement of the knee function (28% - 32%) post-training compared to baseline.[13,17]

A major challenge lies in teaching patients gait modifications such as TL and MT. Real-time biofeedback systems can form an effective aid in teaching gait modifications known to lower the EKAM.[18–22] However, systems that give feedback of the EKAM are still dependent on a combination of 3D gait analysis with force plates, which is the gold standard for measuring joint moments.[23] These systems are not routinely used in a clinical setting, because 3D gait analysis systems are expensive and measurement procedures are time consuming. There is a clear need for a biofeedback device to monitor gait retraining without the use of 3D gait analysis.

Exploring the needs, values and requirements of the end-users are essential in developing a biofeedback to monitor gait modification. Implementation of eHealth technology in the clinical setting often fails, due to lack of information on the end-users' needs.[24] Consequently, those needs are not met in the design and implementation of the accompanying technologies.[24] It seems that many eHealth technologies have a low uptake and impact in health care practices.[25,26] In addition, the end-user plays a major role in developing and evaluating technology and is essential in achieving a successful implementation.[27] Therefore, the end-user needs to be involved in the development of biofeedback equipment to assure the use is effective and efficient in clinical practice.

Several studies have shown that it is feasible to use a portable Inertial Measurement Unit (IMU) to monitor gait kinematics in healthy participants.[28–31] An IMU includes a triple-axis accelerometer, triple-axis gyroscope and a triple-axis magnetometer.[32] Portable devices in the clinical setting offer an inherent advantage over laboratory equipment[33], since portable sensors can be used in the subject's natural environment.[34] The tibia angle can be used as a parameter to reflect the MT and the trunk angle to reflect the TL in patients with KOA.[12,35] IMU seems useful to monitor MT and TL. Currently, the validity of IMUs in measuring the tibia angle and trunk angle in patients with KOA to reflect MT and TL, respectively, is not known.

The objectives of the current study are to determine the needs, values, and requirements of the end-users of a biofeedback gait monitoring device, and to determine the validity of an IMU for measuring the tibia and trunk angle in patients with KOA.

METHODS

Study design:

A mixed methods study design was used according to the first two steps of the Centre for eHealth Research and Disease Management Roadmap (CeHRes-roadmap): contextual inquiry and value specification (Figure 1).[36] The CeHRes-roadmap was designed for research and development of eHealth technologies and improves the uptake and impact. [36] The study protocol was approved by the Máxima Medical Center Ethical Committee (NL42762.015.12), The Netherlands.

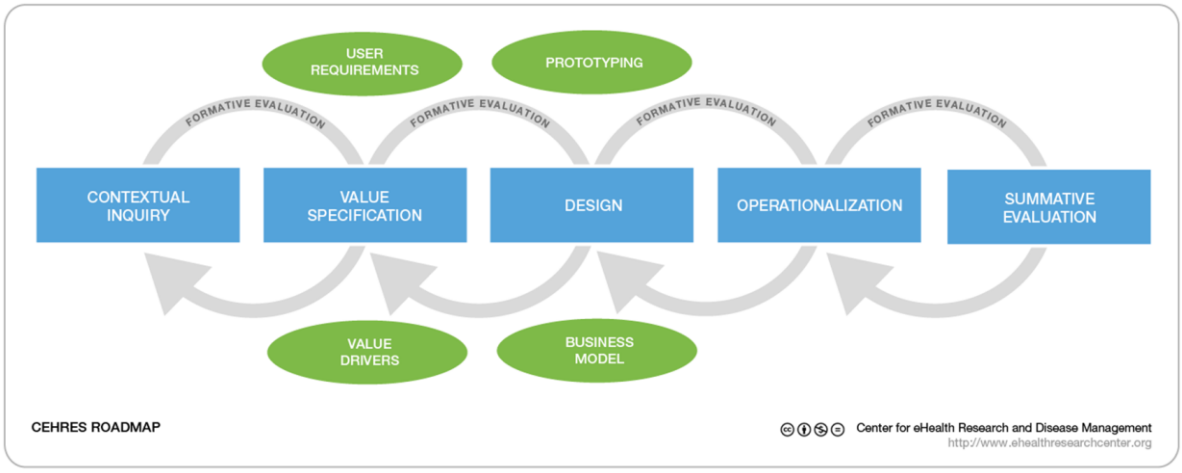


Figure 1. CeHRes-roadmap.[28]

An explorative literature search was performed a priori (contextual inquiry) into the use and availability of devices to monitor MT and TL gait kinematics. This study focused on the next step (value specification), and was divided into two phases:

- Phase one: to determine the end-users needs, values, and requirements for a biofeedback device to monitor gait kinematics, such as MT and TL.
- Phase two: to determine the concurrent validity of the IMU for quantifying the tibia angle and trunk angle during MT and TL gait retraining, respectively, in patients with KOA.

Phase one: Needs, values and requirements of the end-users

Subjects

Physiotherapists were recruited using the researcher's professional network and the Julius Centre for primary care. Two focus groups were formed with six to seven physiotherapists per group.[37,38] To be eligible for participation, physiotherapists had to meet the following criteria:

- Currently working in primary care,
- At least one year experience in treating patients with KOA.

Data collection

A convenience sampling technique was used. Focus groups with physiotherapists were structured using the Nominal Group Technique (NGT).[39–41] This technique ensures a discussion with relative equal participation of the focus group members, intends to create an interactive exchange of ideas and generates priorities during the session.[42] Focus groups were supervised by a non-experienced moderator (WB). Therefore, a pilot focus group was performed and evaluated before the two focus groups were conducted. Discussions in each focus group were ended by the moderator when no new information was gathered and thus data-saturation was reached.[43] Maximum duration of a focus group was two hours.[44] The main question presented during the focus group sessions was: ''*What are the physiotherapists needs, values and requirements to use a biofeedback device to monitor gait retraining [MT and TL] in patients with KOA in clinical practice?''*. Physiotherapists were asked to generate ideas based on domains of The Unified Theory of Acceptance and Use of Technology (UTAUT) model: performance expectancy, effort expectancy, social influence and facilitating conditions.[45]

Analysis

Data was analysed using multiple data analysis.[46] Each subject ranked a top five of the generated items/statements in terms of importance. The most important item/statement scored five points, the second four points, the third three points, the fourth two points and the fifth scored one point. Ranked items/statements were aggregated into groups (themes) of similar subject matter.[46] The top five themes scoring the most points are presented in the final ranking. Four independent researchers replicated this transformation of items/statements into themes for validation and to increase credibility by demonstrating the reliability of the content analysis.[46]

Phase two: Validity

Cross-sectional data from Gerbrands et al. 2016 were used to determine the validity of the IMU for measuring MT and TL kinematics.[12]

Study population

Patients with KOA were recruited via an advertisement in a local newspaper. Patients were included if they met the following criteria:

- Diagnosed with radiographic and symptomatic KOA according to the American Rheumatism Association classification criteria[47],
- 60 years or older.

Exclusion criteria:

- Inability to walk without the use of supportive devices,
- Orthopedic or neurological impairments leading to aberrant gait.

All patients signed informed consent.

Sample size

A priori sample size calculation (G*power) was performed with an effect size of 3.1 degrees, an alpha of 0.05, and a power of 0.95.[48] Sample calculation showed that this study required eight patients.[12]

Equipment

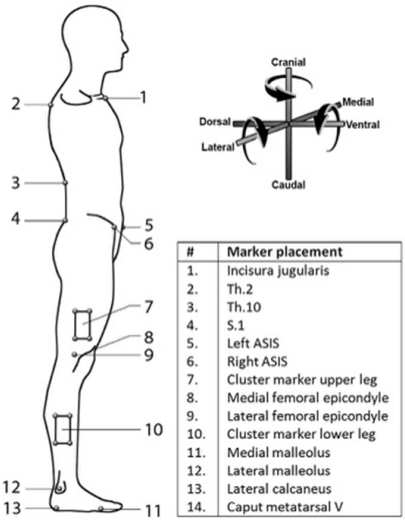
A wireless active 3D-system (Charnwood Dynamics Ltd., Codamotion CX 1, sampling rate: 100Hz) was used as the gold standard to determine MT and TL kinematics of the most affected leg and the torso. A recessed force plate (Advanced Mechanical Technology, Inc., OR 6-7, sampling frequency: 1000Hz) measured the ground reaction force of one step per trial. An IMU (Dynaport Hybrid, McRoberts, Den Haag) was used to measure the tibia and trunk angle.

Questionnaires

Using a baseline questionnaire patient's descriptive characteristics such as age, gender, weight, height, BMI, knee pain and function (Dutch version of the Knee injury and Osteoarthritis Outcome Score questionnaire[49]), and physical activity (The Dutch version of the Physical Activity Scale for Elderly[50]) were assessed.

Experimental protocol

A protocol was used for sensor and marker placement (Figure 2.).[12] Both the 3D gait analysis and the IMUs were used at the same time and attached by the same investigator.



#	Marker placement
1.	Incisura jugularis
2.	Th.2
3.	Th.10
4.	S.1
5.	Left ASIS
6.	Right ASIS
7.	Cluster marker upper leg
8.	Medial femoral epicondyle
9.	Lateral femoral epicondyle
10.	Cluster marker lower leg
11.	Medial malleolus
12.	Lateral malleolus
13.	Lateral calcaneus
14.	Caput metatarsal V

Figure 2. Marker placement for modelling of trunk, pelvis, upper leg, lower leg and foot segments. Positive joint rotations correspond to the direction of the arrows. (figure adapted from Gerbrands et al. 2014[11], reprint with approval)

The following instructions were presented for each subject;

- MT (Figure 3, image B): *'Move the most affected knee inwards during stance.'*[12]
- TL (Figure 3, image C): *'At heel strike, lean sideways with the torso towards the foot on the most affected leg and return slowly during stance'*[12]

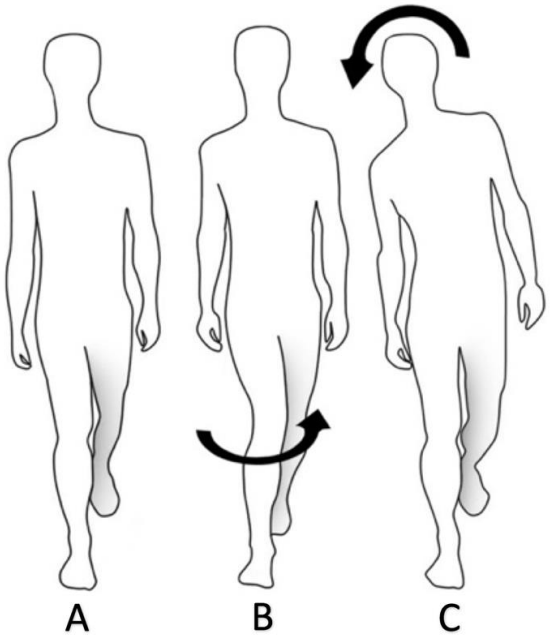


Figure 3. Gait strategies. (A) comfortable walk, (B) MT, (C) TL. (figure adapted from Gerbrands et al. 2017[17], reprint with approval)

Initial measurement started with walking comfortably. The order in which gait modifications (MT or TL) were performed was randomized by picking an envelope. Patients were asked to perform the MT and TL with greatest extent as possible within their own limits of comfort. They practiced per gait strategy until kinematics were performed correctly. Each movement was only performed if the patient felt comfortable, did not experience pain, and had no balance issues. There was a rest period of three minutes between the different gait strategies to reduce possible interference. The aim was to perform five trials for each gait strategy while stepping on the force plate. The investigator gave verbal and visual instructions to make sure that the foot landed properly on the force plate during all trials.

Segment and axes

Kinematics of the foot, lower and upper leg, pelvis and torso were tracked by twenty infrared markers (Figure 3), and modelled as rigid bodies using Visual 3D (C-motion, Inc., Germantown, MD). Hip joint center was defined using the model by Davis et al.[51] Centers of the ankle and knee joints were calculated as midpoint between medial and lateral malleoli and femoral epicondyles, respectively. A local coordinate system was used to calculate ankle, knee and hip rotations with their origin at the joint centre and fixed to the proximal segment. One IMU was placed on the tibia (Figure 2. #10) and one IMU at the back of the torso (Figure 2. #2).

Analysis

Statistical analyses were conducted using SPSS Statistics version 24 (IBM Corp, Armonk, New York). Range of Motion (ROM) of the tibia angle was used to reflect MT and ROM of the trunk angle to reflect TL. Average ROM of five trials of the tibia and trunk angle were compared between IMU and 3D gait analysis (gold standard) by calculating the Pearson's correlation coefficient. Normal distribution of the tibia and trunk angles were checked with a boxplot, Q-Q plot, histogram and Shapiro-Wilk test.[52]

Correlation coefficient r was assessed by the rule of thumb; .00< r <.30 negligible correlation, .30< r <. 50 low correlation, .50< r <.70 moderate correlation, .70< r <.90 high correlation and .90< r <1.00 very high correlation.[53] A predetermined correlation of r > 0.6 between both measurements was considered as reasonable for practical implication.

A high correlation does not necessarily imply a good agreement between measurements.[54] Therefore, Bland-Altman plots were used to graphically display the 95% limits of agreement (LoA) between IMU data and 3D gait analysis. A graphic approach was used to check the assumptions of normality. Differences between both measurements were plotted against the mean of the two measurements and should lie within ± two standard deviations of the mean difference.[54] To determine the agreement between both measurements, discrepancy between measurements (the bias) was set on a mean difference of -5 to 5 degrees. The 95% LoA showed good agreement if the upper and lower bound of all data lies within ± 5 degrees of the mean difference.

All data were checked on missing data. If data was missing, the reason was examined. If there was more than 5% missing data, multiple imputation was performed.

RESULTS

Phase one: Needs, values and requirements of the end-users

Characteristics

In total, twelve physiotherapists (83,3% female) were recruited and divided into two focus groups. Average age was 33 years and working experience was 9,8 years respectively (Table 1). More than half of the physiotherapist (66,7%) had no clinical experience with biofeedback systems.

Table 1. Characteristics of physiotherapists

Characteristics	**Analysed (n=12)**
Age (years) mean ± sd	33 ± 11,5
Average work experience (years) mean ± sd	9,8 ± 10,5
Sex	♀= 10 (83,3%)
Finished academic degree (%)	BSc= 10 (83,3%), MSc= 2 (16,7%)
Experience with biofeedback (%)	4 (33,3%)

Sd= standard deviation, BSc= Bachelor of Science, MSc= Master of Science

Needs, values and requirements

A total of thirty-two items/statements were ranked and transformed into nine general themes. Final five themes were: type of biofeedback, performance features, material, time investment, and fitting of the device (table 2). Multiple biofeedback types were mentioned, visual, haptic and auditory. One or a combination of these biofeedback mechanisms should be translated by the device in a direct or indirect way to the patient. Further, performance features, such as ability to apply a baseline measurement, play games, and an automatic link with patients' electronic healthcare record, seems to be important, according to the end-users. Items/statements were generated from all UTAUT domains: performance expectancy (n=7), effort expectancy (n=6), facilitations conditions (n=5) and social influence (n=1).

Table 2. Top five ranked themes and definitions

Rank	Theme	Definition	Generated items/statements (n=24)	UTAUT domain
1	Type of biofeedback	What type of biofeedback is provided as output	-Visual (direct)* -Haptic and auditory -Multiple: auditory, visual, haptic -Direct/indirect*	PE PE PE PE
2	Performance features	The performance features and technical functions	-Functionality to apply baseline measurements for CW and gait modifications* -Automatic link with EHR* -Games* -Offline functionality, without the use of Wi-Fi/internet connection	PE FC PE FC
3	Material	The material/hardware of the device	-Intuitive hardware product, easy to use/control -Wireless product -Flat, elastic band and flexible	FC FC FC
4	Time investment	Time/effort investment of in using the device	-Quick software start up (<20 seconds) -Attached within 30 sec -Quick, start and go, within 1 minute (sensor placement and start up)	EE EE EE
5	Fitting of the device	Fitting and/or attachment on the subject	-Sticker attachment (max 2 stickers) -Device can only be placed in the correct position -Comfort, able to wear it without resistance and discomfort during walking/training -Client can attach it by them self -Feedback mechanism when the device is attached correctly	EE EE SI EE PE

PE= Performance Expectancy, FC= Facilitations Conditions, EE= Effort Expectancy, EHR= Electronic Health Record SI= Social Influence

*Identical item/statement was identified in both focus groups

Phase two: Validity

Descriptive characteristics

Twenty-four patients (62,5% female) with KOA participated in this study. Average score for function and quality of life was 46,5 ± 9,9 (KOOS) and average score on physical activity was 151,2 ± 72,5 (PASE). Patients' characteristics are presented at table 3.

Table 3. Descriptive characteristics, patients with KOA

Patient characteristics	Analysed (n=24)
Gender, female (%)	15 (62,5%)
Age, (years) mean ± sd	60 ± 6,2
Weight, mean kg ± sd	77,5 ± 13,8
Height, mean cm ± sd	172 ± 9,9
BMI, mean ± sd	26,1 ± 3,4
PASE, mean ± sd	151,2 ± 72,5
KOOS, mean ± sd	46,5 ± 9,9

sd= Standard Deviation, kg= Kilogram, cm=Centimetre, BMI=Body Mass Index, PASE= Physical Activity Scale for the Elderly, KOOS= Knee injury and Osteoarthritis Outcome Score

ROM tibia angle and ROM trunk angle

Mean ROM of the tibia angle measured with 3D gait analysis was 8,0 degrees (95% CI 6,9 to 9,2) and the IMU measured 14,76 degrees (95% CI 12,31 to 17,21). Mean ROM of the trunk angle measured with 3D gait analysis was 15,9 degrees (95% CI 13,82 to 17,88) and the IMU measured 18,1 degrees (95% CI 16,02 to 20,18) (Table 4). Tibia and trunk angle were normally distributed for both 3D gait analysis (Shapiro-Wilk test p=0,358, p=0,312, respectively) and IMU (Shapiro-Wilk test p=0,612, p=0,960, respectively).

Table 4. ROM of the tibia angle and trunk angle measured with 3D gait analysis and IMU

	3D Mean (95% CI)	IMU Mean (95% CI)	Difference Mean (95% CI)
ROM tibia angle	8,1 (7,1;9,11)	14,3 (11.8;16,8)	-6,3 (-9,0;-3,6)
ROM trunk angle	16,1 (14,2;18,0)	18,3 (16,4;2,2)	-2,2 (-3,1;-1,4)

3D= Three dimensional, CI= Confidence Interval, ROM= Range of Motion

Validity IMU for measuring the ROM of the tibia angle and trunk angle

No significant correlation was found between IMU and 3D gait analysis for measuring the ROM of the tibia angle (r=0,075, p=0,741). A significant correlation was found between the inertial and 3D gait analysis for measuring the ROM of the trunk angle. (r=0,899, p<0,001).

Agreement

Mean difference of the ROM of the tibia angle was -6,3 degrees and trunk angle was -2,2 degrees (Figure 4 and 5). From the LoA 95% of the measurements variations were within the range of -18,1 to 5,5 degrees for the tibia angle and the trunk angle within the range -6,1 to 1,7 degrees. Mean differences of the tibia and trunk angle were normally distributed (Shapiro-Wilk p=0,294, p=0,236, respectively). Mean difference of the tibia angle differed more than the predefined mean difference of -5 to 5 degrees. Range of the lower and upper LoA of the tibia angle were higher than the predefined LoA (± 5 degrees), and therefore can be considered as no agreement. Lower and upper LoA of the trunk angle were within the range of the predifined lower and upper bound, and could be considered as a good agreement. Difference between both measurements of the tibia angle tend to get larger as the mean ROM increases. Variability of the mean difference of the trunk angle were consistent across the graph.

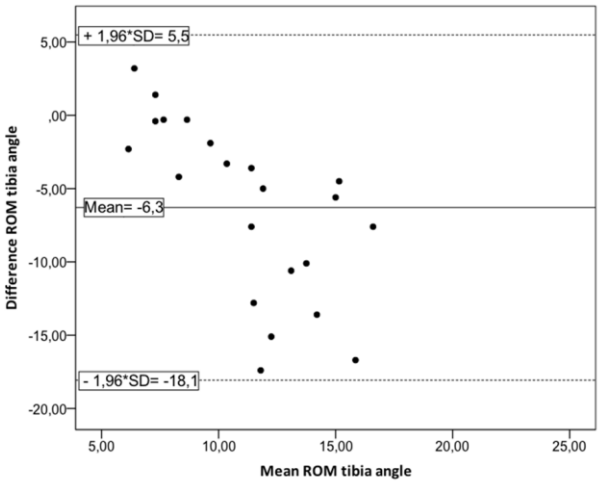


Figure. 4. Tibia angle

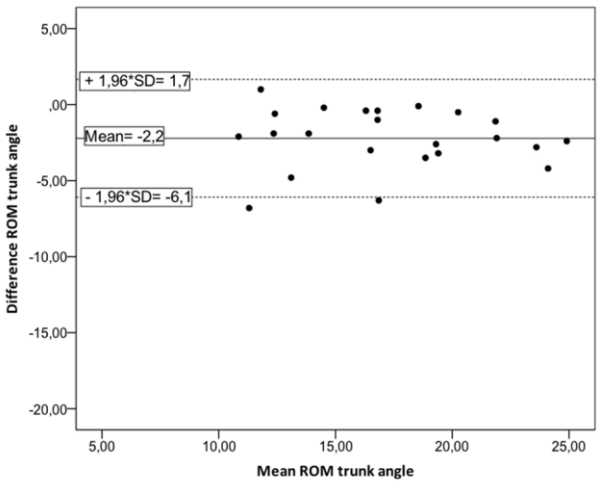


Figure. 5. Trunk angle

Missing data

Five patients were missing completely at random and excluded from the analysis.[55] Missing data was based on sensor failure caused by the individual's abnormal posture proportions or the gait modification was not performed correctly.

DISCUSSION

The aims of this study were to identify the end-users needs, values and requirements for a monitoring device, and to determine the validity of the IMU to measure the ROM of the tibia and trunk angle, to reflect MT and TL respectively. The needs, values and requirements identified are transformed into the following themes, 1) type of biofeedback, 2) performance features, 3) material, 4) time investment and 5) fitting of the device. This study showed that the IMU is a valid and useful instrument to measure the ROM of the trunk angle while performing the TL. In contrast, no correlation and no agreement was found between the IMU and 3D gait analysis for measuring the ROM of the tibia angle while performing MT. Further investigation is needed to measure the MT accurately. It is recommended to determine which kinematics can reflect the MT, and to investigate the use of multiple IMUs to measure the MT accurately.

This study is an attempt to create a thoughtful approach by using both the CeHRes-roadmap and UTAUT-model in the development of a biofeedback device. This contrasts with other eHealth technologies who are mainly developed through ad-hoc procedures, without such an approach.[56] Also, to develop an holistic user-friendly technology, the end-users should be involved in the design and development of eHealth technology.[57] Problems in implementing eHealth technologies are often linked to healthcare providers who are unable to master technology.[58,59] This study involved the end-users input in the first steps of development of new technology and should be considered as a way of overcoming barriers of adaptability.[58] The highest ranked themes were mainly generated from the UTAUT domains; performance expectancy, effort expectancy and facilitations conditions. These domains had a higher priority than the domain 'social influence', according to the end-users. All identified themes could be suitable in the development, the highest ranked themes do not mean that the themes on the bottom of the list are not important. Items from the performance expectancy are showing that the type of biofeedback varies between visual, auditory and haptic biofeedback or a combination of it. Moreover, functionalities to apply baseline measurements, an automatic link with the patients' personal health record and ability to play games seems to be import. Implementation of eHealth technology in the clinical setting often fails due to a lack of information on the end users' needs. [24] Our study identified themes based on the end-users needs, values and requirements and will, thus, contribute in successful implementation in a clinical setting.
Our findings of the IMUs accuracy are consistent with other studies.[60–63] Previous studies that measured knee movements in the sagittal plane or in 3D, showed high correlations and good agreement between IMUs and 3D gait analysis.[60,63] Another study investigated a slightly more complex task; the 'timed up and go test' (TUG) with IMUs and reported good accuracy and agreement.[61] Although, these results are based on healthy participants, measured with multiple IMUs and the participants were not performing tasks like the MT or TL.[60,61,63] However, it seems that the accuracy of kinematic data varies according to the task performed

and the joint/segment that is tracked.[61]

The tibia angle tracked by the IMU was not correlated with 3D gait analysis. This finding is in line with previous studies.[60,61] Jaysrichai et al. 2015 found a poor correlation between measurement of the knee adduction-abduction movement which is comparable to the movement of the tibia angle in the frontal plane during the MT.[60] Single angle change and pendulum movements have better accuracy than lateral displacements and quasi-static conditions.[61] Possible explanations for the absent correlation are measurement errors caused by skin and muscle motion[64] and the consequently overestimating of the IMU on the relative small ROM of the tibia angle (8 degrees). In comparison, studies who found good correlations between IMUs and references tracked bigger ROMs during tasks or joint movements.[60–63]

A strength of this study is the co-creation and engagement of the end-users throughout the development. Focus groups consisted of physiotherapists with experience in treating patients with KOA, as they are the potential end-users. Another strength is that the researcher structured the focus groups with the UTAUT-model and used the CeHRes-roadmap in the overall development. Both models will improve the user acceptance, uptake and impact of the monitoring device in further development and implementation.[36,45] Another strength of this study is the validation of the themes, performed by four researchers to improve the credibility and reliability of the content analysis.[46]

This study has several limitations. It is difficult to claim whether data saturation was reached or not. The top five themes were based on information from both focus groups. At the same time, two identified themes were based on a single focus group. Those themes scored less points and were not able to reach the final ranking. A failure to reach data saturation has impact on the research quality and content validity.[65] Sandelowski et al. 1995 emphasized that too few or too little data can lower the quality of a focus group.[65] Still, no exact number is offered on how many focus groups should be performed.[66] In future research it is recommended to add at least one extra focus group. Another limitation is that the MT is measured with a single IMU in the frontal plane. The MT requires movements of multiple joints in several planes. Multiple IMUs could measure those joint movements, however multiple IMUs are less practical for clinical use.

In addition, this study aids in doing research on clinical effects of gait modifications using IMUs. Biomechanical studies are mainly focused on reducing the EKAM and not on clinical effects.[10–12,16] Currently, just two pilot studies have been performed, both showing beneficial clinical effects of gait modifications.[13,17] The consistent trend and low discrepancy between IMU and reference for the TL implies that the IMU is applicable for clinical TL training and research. Expensive 3D gait analysis and time consuming procedures can be replaced using an IMU to monitor the TL. A next step is to develop a prototype which is designed in co-

creation with the end-users.

Future research should focus on the next step of the CeHRes-roadmap by developing a prototype to monitor the TL which includes an IMU and is based on the identified themes. End-users remain important during the cyclical development process and should continually stay involved. Further investigations are needed to determine which kinematics can reflect the MT and if a combination of multiple IMUs can measure the MT accurately.

Conclusion

In summary, the type of biofeedback, performance features, material, time investment, and fitting of the device are important themes for a biofeedback device to monitor gait retraining and can guide development of future technology. Quantifying of the trunk angle with an IMU seems to be a valid and useful technology for development of a biofeedback system to monitor TL kinematics in patients with KOA. It is recommended that future studies focus on multiple IMUs to measure the MT accurately.

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SAMENVATTING

Doelstelling: Het ontwikkelen van een biofeedbacksysteem om loopaanpassingen te kunnen monitoren bij patiënten met knie artrose. Het onderzoek is opgedeeld in twee doelenstellingen: 1) het identificeren van de gebruikersbehoefte voor het gebruik van een biofeedback systeem om loopaanpassingen te monitoren bij patiënten met knieartrose. 2) Het bepalen van validiteit van Inertial Measurements units (IMU) voor het meten van de tibia- en romphoek tijdens loopaanpassing zoals de 'medial thrust' (MT) en 'trunk lean' (TL).

Methode: De gebruikersbehoefte voor het gebruik van een biofeedbacksysteem zijn onderzocht middels twee focus groepen en geanalyseerd met multiple data-analyse. De validatie van de IMU heeft plaats gevonden door het vergelijken van de totale bewegingsuitslag van de tibia- en romphoek met de uitkomsten van de driedimensionale (3D) ganganalyse (goudenstandaard). Bewegingsuitslagen zijn geanalyseerd middels de Pearson's Correlatie en Bland & Altman plots.

Resultaten: De volgende thema's omtrent de gebruikersbehoefte zijn geïdentificeerd: type biofeedback, prestatiemogelijkheden, materiaal, tijd investering en pasvorm. Er zijn geen correlaties gevonden tussen IMU en de 3D ganganalyse voor het meten van de tibia hoek tijdens het uitvoeren van de MT ($r=0,075$, $p=0,741$). Een significante correlatie was gevonden tussen de IMU en de 3D ganganalyse voor het meten van de romphoek tijdens het uitvoeren van de TL ($r=0,899$, $p<0,001$).

Conclusie: De geïdentificeerde thema kunnen gebruikt worden in de ontwikkeling van biofeedbacksysteem om loopaanpassingen te monitoren. De IMU is een valide instrument om de romphoek te meten tijdens het uitvoeren van de TL. Het wordt aanbevolen om veder onderzoek te doen naar een valide meetmethode om de MT te monitoren met meerdere IMUs.

Klinische relevantie: De resultaten zijn de eerste stappen in de ontwikkeling van een valide en bruikbaar meetinstrument op loopaanpassingen te monitoren. Daarbij zullen de gevonden thema's bijdragen aan beter gebruikersacceptatie van het toekomstige biofeedback systeem.