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Development and clinical validation of an unobtrusive ambulatory knee function monitoring system with inertial 9DoF sensors

M. Schulze, T. Calliess, M. Gietzelt, K.H. Wolf, T.H. Liu, F. Seehaus, R. Bocklage, H. Windhagen and M. Marschollek

***Abstract* — Patients suffering from end-stage knee osteoarthritis are often treated with total knee arthroplasty, improving their functional mobility. A number of patients, however, report continued difficulty with stair ascent and descent or sportive activity after surgery and are not completely satisfied with the outcome. State-of-the-art analyses to evaluate the outcome and mobility after knee replacement are conducted under supervised settings in specialized gait labs and thus can only reflect a short period of time. A number of external factors may lead to artificial gait patterns in patients. Moreover, clinically relevant situations are difficult to simulate in a stationary gait lab. In contrast to this, inertial sensors may be used additionally for unobtrusive gait monitoring. However, recent notable approaches found in literature concerning knee function analysis have so far not been applied in a clinical context and have therefore not yet been validated in a clinical setting.**

The aim of this paper is to present a system for unsupervised long-term monitoring of human gait with a focus on knee joint function, which is applicable in patients' everyday lives and to report on the validation of this system gathered during walking with reference to state-of-the-art gait lab data using a vision system (VICON Motion System).

The system KINEMATICWEAR - developed in close collaboration of computer scientists and physicians performing knee arthroplasty - consists of two sensor nodes with combined tri-axial accelerometer, gyroscope and magnetometer to be worn under normal trousers. Reliability of the system is shown in the results. An overall correlation of 0.99 (with an overall RMSE of 2.72) compared to the state-of-the-art reference system indicates a sound quality and a high degree of correspondence. KINEMATICWEAR enables ambulatory, unconstrained measurements of knee function outside a supervised lab inspection.

I. INTRODUCTION

AMONG the musculoskeletal diseases gonarthrosis has a high prevalence and, for the persons affected, is known to frequently cause lasting functional limitations accompanied by a significant reduction in the quality of life. In advanced stages of the disease, gonarthrosis is often treated surgically with a knee endoprosthesis to re-establish knee joint function and reduce pain.

Recent trends show that patients who are elected for knee endoprosthetic surgery become ever younger and more active, implicating the need for alternative bone-conserving surgical techniques and high expectations regarding functional outcome. However, there are only few studies that evaluate the beneficial effects of less invasive knee endoprosthesis. Isaac et al. show that patients with unicondylar prosthesis have a better functional outcome for kneeling and walking downstairs [1]. Hopper et al. report that such patients are able to reach their pre-operative activity level more frequently than those with total endoprosthesis [2]. So far, these outcome studies have mostly used subjective self-rating scales like knee scores [3, 4] or have measured static parameters [5], but there is a lack of objective parameters. Especially, measurements suitable for daily use are missing, promising to gain insight into knee function during ordinary and sportive activities as well as marginal changes.

A. *Related work*

Recent studies have shown that inertial sensors provide the ability to capture human body orientation [6], knee joint range [7] and posture [8]. Several groups have worked on capturing the body position of a human [9, 10] and detecting the knee angles [11] via inertial sensors.

Recent approaches concerning knee motion using inertial sensors [12, 13] achieve good results under lab conditions, but face practicability challenges when transferred to a real life setting with patients. Therefore, they have not yet been validated in clinical practice. Kobashi et al. have been continuously developing a system [14] using a rigid-body link model [15] for defining the knee joint center, showing good results in lab settings. Both approaches use Grood's definition [16] to calculate knee joint angles by estimating relative posture between the thigh and the shank.

The "DynaPort Knee Test" (DPKT) captures knee motion during predetermined activities using accelerometers and evaluates execution quality based on an ordinal scale [17]. Unfortunately, those scores can hardly be transformed into useful expressions beyond comparisons, as the authors mention in their paper. Validations of the DPKT show good results [18, 19] but angular rotation, considered to be of high

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M. Schulze, T.H. Liu and M. Marschollek are with the Peter L. Reichertz Institute for Medical Informatics, Carl-Neuberg-Str. 1, 30625 Hannover, Germany (phone: +49 (0)511 532-5292; fax: +49 (0)511 532-5297; e-mail: mareike.schulze@plri.de, michael.marschollek@plri.de).

M. Gietzelt and K.H. Wolf are with the Peter L. Reichertz Institute for Medical Informatics, Mühlenpfordtstr. 23, 38106 Braunschweig, Germany (e-mail: matthias.gietzelt@plri.de, klaus-hendrik.wolf@plri.de).

H. Windhagen, T. Calliess, R. Bocklage and F. Seehaus are with the Department of Orthopedic Surgery, Hannover Medical School, Anna-von-Borries-Str. 1-7, 30625 Hannover, Germany (e-mail: henning.windhagen@ddh-gruppe.de, tilman.calliess@ddh-gruppe.de, raphael.bocklage@ddh-gruppe.de, frank.seehaus@ddh-gruppe.de).

importance by the physicians in our research group, cannot be analyzed by the DPKT directly [20]. As a system developed for lab use, no statement can be made about the quality of gait and knee motion during everyday life of the patients [21].

In summary, we may conclude that the combination of accelerometers, gyroscopes and magnetometers in one casing fused with the aid of appropriate filtering is the first choice with regard to our research objectives.

II. OBJECTIVES

Considering the well-known fact that patients being supervised in a lab setting strive to walk especially well, thus presenting with artificial gait patterns, the overall aim of our work is to design an unobtrusive system for continuous sensor-based monitoring that measures knee joint function and can be used outside standard lab settings in an unsupervised environment.

With regard to this paper, the aims of our work were:

- to present a wearable system *(KINEMATICWEAR)* that can be used for medical examinations prior to surgery and during rehabilitation in the post-operative phase, and
- to validate the system using the state-of-the-art standard in human gait analysis, an electro-optical marker-based motion capturing system, with regard to the exemplary parameter *knee angle measurement* during walking.

III. METHODS

A. System Design

A specific sensor system that fits our requirements is the SHIMMER [22] – a small mobile wearable system (including accelerometers, gyroscopes and magnetometers) providing a low power microprocessor, a 450mAh battery, microSD flash memory card with 2GB and a wireless connection via Bluetooth.

For analysis of the knee joint's motion at least two sensors nodes are required: one on the thigh and one on the shank [23]. The sensors have to be attached to a position where the motion gap between the sensor and the skin can be minimized as mentioned in [16].

Within this investigation sensors were attached to the thigh using kinesiotape, superior and lateral of the knee cap over the iliotibial tract. The shank sensor was placed on the skin below and medial of the tibial tuberosity in order to gain optimal bone proximity (Fig. 1). Due to its flexibility during muscle motion, Kinesiotape is comfortable and – being a certified medical product – minimizes the danger of skin irritations. The reasons for using kinesiotape instead of a brace or sleeve are on the one hand that the knee movement is neither supported nor constrained by the kinesiotape, and on the other hand that it is possible to measure knee joint motion directly in three dimensions without movement artifacts caused by the material. It is crucial that knee motion is not influenced significantly by the system.

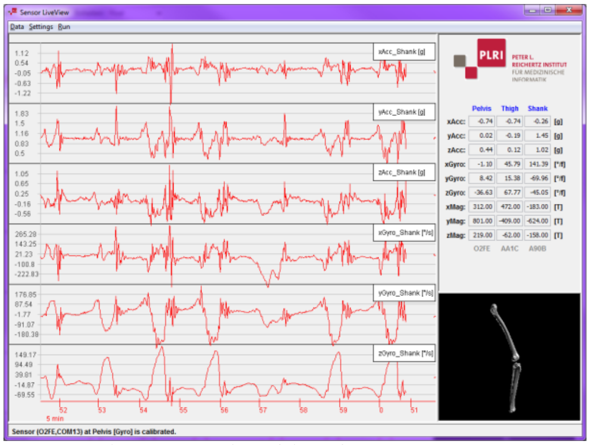
Fig. 1. Recommended positions of the thigh and shank sensors (embedded under blue kinesiotape). The markers for the vision reference system are visible on the lower limb

For practicability and unobtrusiveness reasons, we deliberately chose not to use a goniometer.

B. Data Processing

In our setup, data calibration, synchronization and logging were performed using a self-developed software application (*KINEMATIC Visualizer*), input from the sensor nodes is acquired via Bluetooth. Optionally, the data can be logged to the microSD-card on the SHIMMER.

The calibration method of the sensor nodes should not rely on the initial attachment positions since the sensors may possibly slip out of their initial position. Also, it is near impossible to place them in the exact same position for different examinations. As the offset and sensitivity may also vary with temperature and battery charge, the calibration should take place frequently. Further development of our automatic self-calibration method concerning accelerometers [24, 25] in combination with an adaption for gyroscopes and magnetometers was employed.



	Pelvis	Thigh	Shank	
xAcc:	-0.74	-0.74	-0.26	[g]
yAcc:	0.02	-0.19	1.45	[g]
zAcc:	0.44	0.12	1.02	[g]
xGyro:	-1.10	45.79	141.39	[°/f]
yGyro:	8.42	15.38	-69.96	[°/f]
zGyro:	-36.63	67.77	-45.05	[°/f]
xMag:	312.00	472.00	-183.00	[T]
yMag:	801.00	-409.00	-624.00	[T]
zMag:	219.00	-62.00	-158.00	[T]
	O2FE	AA1C	A90B	

Sensor (O2FE,COM13) at Pelvis [Gyro] is calibrated.

Fig. 2. Screenshot of the software component

Afterwards, the calibrated data have to be set into anatomical context [26]. Therefore, transformations of the coordinate systems from sensor-axes to bone-axes must take place. For synchronization of the two sensor nodes the timestamp was provided by the base system. Smart interplay of accelerometer and gyroscope data together with appropriate filtering adapted to each sensor characteristics is needed to counteract common problems like noise, transients and drift. Noise and transients were filtered out with a band pass filter. Concerning the drift of the gyroscope, the arc cosine of the accelerometer in rest (norm of the vector nearly 1) was used and a linear model to de-trend the gyroscope data in each gait cycle. We deliberately decided not to apply the commonly used Kalman filter in this case, due to the fact that the estimations it provides may risk blurring clinical gait pathologies.

As provided by electro-optical marker-based motion capturing systems, the software tool also has a real-time and post-visualization interface to support the clinicians in interpreting the data, analyzing knee function and also identifying pathological gait patterns (Fig. 2).

C. *Clinical validation*

Preliminary test runs have been performed by attaching the thigh and shank sensor to a goniometer for joint angle comparison. Subsequently, some field test runs with healthy volunteers took place in the gait lab simulating gait activities of daily living like walking, starting, stopping, stair climbing, standing up and sitting down.

Afterwards, volunteers and patients (*n*=10, five healthy volunteers and five patients with different conditions affecting their knee function) were equipped with KINEMATICWEAR for a marker-based video gait analysis, as it is usually performed during clinical rehabilitation to assess treatment progress. Due to the fact that the marker-based method is established and well-known for its accuracy, the presented system (running on 100 Hz) was validated against it in a prospective study setting (Fig. 3).

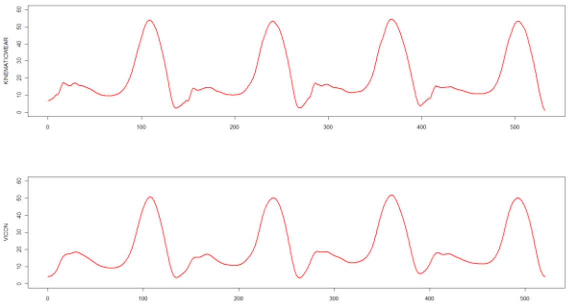


Fig. 3. Knee joint sagittal angle measurement of an exemplary patient while walking (pathology: gonarthrosis) using KINEMATIC WEAR (top) vs. VICON (bottom)

Validation data were collected in the gait lab of the Department of Orthopedic Surgery at Hannover Medical School between August 2011 and February 2012. The joint angle computation algorithm (broadly similar way of proceeding as described in [27]) had already been developed prior to this study, independently of the test data set used.

In addition to KINEMATICWEAR, another motion capturing system with eight infrared cameras (Vicon Motion Systems Ltd., MX-20, MX-40, Oxford, UK) and sampling rate of 200 Hz was used for data acquisition. The movements were also recorded using two high-speed DV cameras with 100 Hz. The PlugInGait marker set and model for the lower extremity (kinetic model V 2.3) was used to generate the kinematic data [28, 29]. This marker set consists of 16 reflective markers with a diameter of 14 mm, attached to the following anatomical landmarks: superior/anterior iliac spine, thigh, lateral epicondyle, shank, lateral malleolus, as well as the second metatarsal head and the calcaneous for left and right leg. No knee alignment device was used. Captured marker data were processed (VICON-Nexus 1.5.1, VICON Motion Systems Ltd., Oxford, UK) and trajectories were labeled using the PlugInGait model under a standardized protocol. Kinematic data were filtered using a Woltring-filter with a mean squared error (MSE) setting of 10.

The subjects walked a distance of 15 meters at a self-selected comfortable speed with eight repetitions. Then, they were asked to repeat this at a lower and a higher speed, four times each. Due to the restricted camera range (marginally 8 m) of the electro-optical motion capture system, only the gait cycles in the middle of each track were compared (comfortable speed=3, lower=4, higher=2 cycles).

IV. RESULTS

Correlation coefficient and Root Mean Squared Error (RMSE) between KINEMATICWEAR and motion capture system of kinematic data (Table 1) were calculated. The overall correlation of all angular measurements is 0.99 and the overall RMSE is 2.72.

TABLE I
COMPARISON OF KNEE SAGITTAL ANGLE MEASUREMENTS WITH *KINEMATICWEAR* AND VICON REFERENCE

Walking speed	Correlation (RMSE)
Lower	0.99 (2.16)
Comfortable	0.99 (2.91)
Higher	0.98 (3.08)

V. DISCUSSION

The system described in this paper gives an example of how clinical evaluation may be supported by employing a cost-effective pervasive health approach [30] for evaluating knee function based on objective parameters, namely by combining supervised sensor-based monitoring in a motion lab with unsupervised sensor-based monitoring.

An overall correlation of 0.99 (with an overall RMSE of 2.72) referred to the state-of-the-art reference system indicates a sound quality and a high degree of correspondence. Keeping in mind that the high degree of accuracy of a motion capturing system is not accomplishable with an inertial system, this system has – from a clinician's point of view – reached entirely satisfying results that are suitable for our purpose.

The walking speeds differed from subject to subject which is a limiting factor in our investigation, yet these variations are caused by the design of the study. Finally, it ought to be stressed that in this context of clinical use and decision-making, individual clinical evaluation remains essential and must take place in due consideration of the patients' personal situation and current feeling.

VI. CONCLUSION

A system for monitoring a patient's knee function in everyday life over extended periods of time has been developed and evaluated. This system provides possibilities for identifying problems that may not be easily recognizable during supervised lab inspections or clinical visits. This applies e.g. to changes in gait symmetry, compensation movements during prolonged walking as caused by tiring as well as changes in activity level.

Our approach has the potential to provide ambulatory, unconstrained measurements of knee function during challenging activities. We expect to observe differences in situations where stability of the knee with a total endoprosthesis is limited.

Currently we are conducting a study to deploy this system outside the lab in order to measure gait activities of everyday life including stair ascent and descent as a useful supplement to the medical examination.

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