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

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Abstract — **Although total knee arthroplasty improves functional mobility in persons with end-stage knee osteoarthritis, many subjects have reported 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 cause artificial behavior in gait among the patients. Moreover, clinically relevant situations are difficult to simulate in a stationary gait lab. In contrast to this, inertial sensors may be used as a supplement for unobtrusive gait monitoring. However, recent notable approaches found in literature concerning knee function analysis have not been adapted to a clinical context and therefore not validated in a clinical setting yet.**

The aim of this paper is to present both 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 the results of an evaluation study to estimate knee angles during walking with reference to Gold standard gait lab data using a vision system.

Our 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 to our context is shown in the results.

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 knee endoprosthesis to re-establish knee joint function and reduce pain.

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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 on the one hand and a high expectation of functional outcome on the other hand. However, there are only few studies that evaluate the beneficial effects of less invasive uni-compartimental 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 imprecise 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 to gain insight into knee function during ordinary and sportive activities as soon as marginal changes in everyday life like stair ascent and descent, at which the greatest difference is expected.

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 for use with patients in real life environments, and therefore have not been validated in practice yet. A research group has continuously developed a system [14, 15, 16] with a rigid-body link model [17] for defining the knee joint center, showing good results in lab settings. Both approaches use Grood's definition [18] 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 [19]. 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 [20, 21] but angular rotation, considered to be of high importance by the physicians in our research group, cannot be analyzed by the DPKT directly [22]. 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 [23].

Fig. 1. Recommended positions of the thigh and shank sensors

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 tend to walk artificially well under lab conditions in simulated situations, being under supervision, 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 develop a wearable system that can be used for medical examinations prior to surgery and during rehabilitation in the post-operative phase, and
- to validate our system using the current Gold standard in human gait analysis, a marker-based vision system, with regard to the exemplary parameter a knee angle measurement during walking.

III. Methods

A. System Design

A specific sensor system that fit our requirements is the SHIMMER [24] – 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 the analysis of knee joint motion at least two sensors nodes are required: one on thigh and one on the shank [25]. The sensors have to be attached on a position where the motion gap between the sensor and the skin can be minimized as mentioned in [16].

We chose to attach the thigh sensor superior and lateral of the knee cap over the iliotibial tract and the shank sensor on the skin below and medial of the tibial tuberosity in order to gain optimal bone proximity. Both sensors are attached with kinesiotape as shown in Fig. 1, allowing for flexibility during muscle motion and thus comfort and – being a certified medical product – minimizing 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 neither constrained nor influenced significantly by the system.

For practicability and unobtrusiveness reasons, the authors have deliberately chosen not to use a goniometer.

B. Data Processing

Data calibration, synchronization and logging are done in this case by a self-made software tool, connected to the sensor nodes via Bluetooth. Optionally, the data can be logged to the microSD-card on the SHIMMER.

Fig. 2. Screenshot of the software component **(muss hell)**

The calibration method of the sensor nodes should not depend on the initial attachment positions only because the sensors could slip out of the initial position and will not be replaced every time in absolutely the same position by the physicians. 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 [26] in combination with an adaption for gyroscopes and magnetometers was employed.

Afterwards, the calibrated data have to be set into anatomical context [27]. 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 from the base system. Smart interplay of accelerometer and gyroscope data together with appropriate filtering 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, we used the arcos cosine of the accelerometer in rest (norm of the vector nearly 1) 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 made may risk blurring clinical gait pathologies.

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

C. *Clinical validation*

Preliminary test runs had been done 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) have been equipped with our system during marker-based video gait analysis, as 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, our system (running on 100Hz) was validated in a prospective study setting against it.

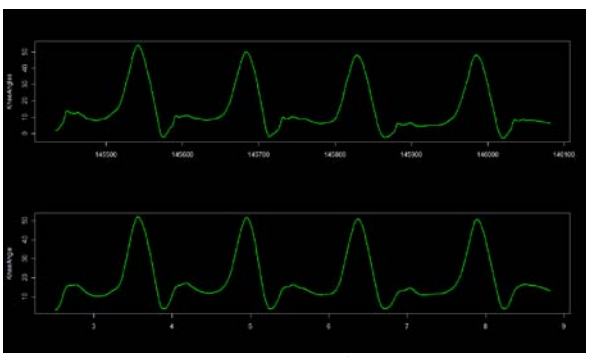

Fig. 3. Knee joint angle measurement of an exemplary patient (age: xx, pathology: rupture of anterior cruciate ligament…) using KINEMATIC WEAR (top) vs. VICON (bottom) **heller**

All relevant data for our validation 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 was developed prior to this study and advanced independently of the test data set used.

For the acquisition of all measured values a motion capturing system with eight infrared cameras (Vicon Motion Systems Ltd., MX-20, MX-40, Oxford, UK) with a sample rate of 200Hz was used. Furthermore, gait motion was recorded with two high-speed video cameras with 100Hz. Kinematic data acquisition was done with 16 reflecting markers (diameter: 14mm=0.55inch) attached to the volunteer/patient with double-sided, medical cello tape according to the Marker-Model "PlugInGait kinematic model V 2.3" **[???]**. For data preparation the commercial software tool named VICON-Nexus 1.5.1 respectively Polygon 3.1 (VICON Motion Systems Ltd., Oxford, UK) was chosen **[???]**, which uses 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 rerun at a slower and a higher speed, four times each. Due to the restricted camera range of the VICON system, only the gait cycles in the middle of each track were compared (normal speed=3, slow=4, fast=2 cycles).

IV. Results

Table I shows the results in terms of correlation coefficient and covariance between our KINEMATICWEAR prototype and the established VICON motion system as reference. The overall correlation of all angular measurements is **0.00 (0.00).** Fig. 3 shows an example of a patient's knee joint angle value time series as measured with our KINEMATICWEAR system in comparison with the VICON reference system.

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

Walking speed	Correlation (SD)
Lower	**0.0 (0.0)**
Comfortable	**0.0 (0.0)**
Higher	**0.0 (0.0)**

V. Discussion

Our system described in this paper gives an example of how clinical evaluation may be supported employing a cost-effective pervasive health approach [28] 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 **0.00** referred to the gold standard reference system indicates a sound quality and a high degree of correspondence. Keeping in mind that the high degree of accuracy of a video motion capturing system is not accomplishable with an inertial system, our system has – from a clinician's point of view – reached entirely satisfying results that are suitable for our purpose.

One limitation of our study is that compared walking speeds differed from subject to subject, yet these variations are conditioned by our study design.

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. (hier fehlt noch was…)

VI. CONCLUSION

We have developed and evaluated a system to monitor a patient's knee function in everyday life over extended periods of time, which therefore provides the possibility to identify problems that are not recognized in a supervised lab inspection or clinical visit. 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.

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

Currently we are conducting a study to deploy our 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.

REFERENCES

[1] M. A. Hassaballa, A. J. Porteous, I. D. Learmonth, “Functional outcomes after different types of knee athroplasty: kneeling ability versus descending stairs,” *Med Sci Monit*, vol. 13, no. 2, February 2007.

[2] G. P. Hopper, W. J. Leach, “Participation in sporting activities following knee replacement: total versus unicompartmental,” *Knee Surg Sports Traumatol Arthrosc*, vol. 16, no. 10, pp. 973-979, 2008.

[3] J. N. Insall, L. D. Dorr, R. D. Scott, W. N. Scott, „Rationale of the Knee Society clinical rating system,“ Clin Orthop Relat Res, vol. 248, pp. 13-14, November 1989.

[4] J. Dawson, R. Fitzpatrick, D. Murray, A. Carr, “Questionnaire on the perceptions of patients about total knee replacement,” *J. Bone Joint Surg Br*, vol. 80, no. 1, pp. 63–69, January 1998.

[5] S. M. Isaac, K. L. Barker, I. N. Danial, D. J. Beard, C. A. Dodd, D. W. Murray, “Does arthroplasty type influence knee joint proprioception? A longitudinal prospective study comparing total and unicompartmental arthroplasty,” *Knee*, vol. 14, no. 3, pp. 212-217, June 2007.

[6] H. J. Luinge, P. H. Veltink, “Measuring orientation of human body segments using miniature gyroscopes and accelerometers,” *Medical & Biological Engineering & Computing*, vol. 43, no. 2, pp. 273-282, 2005.

[7] N. Yaikwawongs, N. Limpaphayom, V. Wilairatana, “Reliability of Digital Compass Goniometer in Knee Joint Range of Motion Measurement,” J Med Assoc Thai, vol. 92, no. 4, pp. 517-522, 2009.

[8] R. Takeda, S. Tadano, A. Natorigawa, M. Todoh, S. Yoshinari, “Gait posture estimation using wearable acceleration and gyro sensors,” *Journal of Biomechanics*, vol. 42, no. 15, pp. 2486-2494, 2009.

[9] B. Kemp, J. M. W. Janssen, B. van der Kamp, „Body position can be monitored in 3D using miniature accelerometers and earth-magnetic field sensors,“ *Electroencephalography and clinical Neurophysiology*, vol. 109, no. 6, pp. 484-488, 1998.

[10] A. M. Sabatini, “Quaternion-Based Extended Kalman Filter for Determining Orientation by Inertial and Magnetic Sensing,” *IEEE Transactions on Biomedical Engineering*, vol. 53, no. 7, pp. 1346-1356, July 2006.

[11] R. Williamson, B. J. Andrews, “Detecting absolute human knee angle and angular velocity using accelerometers and rate gyroscopes,” *Med. Biol. Eng. Comput.*, vol. 39, no. 3, p. 1-9, 2001.

[12] J. Favre, X. Crevoisier, B. M. Jolles, K. Aminian, “Evaluation of a mixed approach combining stationary and wearable systems to monitor gait over long distance,” *Journal of Biomechanics*, vol. 43, no. 11, pp. 2196-2202, 2010.

[13] L. Kun, Y. Inoue, K. Shibata, C. Enguo, “Ambulatory Estimation of Knee-Joint Kinematics in Anatomical Coordinate System Using Accelerometers and Magnetometers,” *IEEE Transactions on Biomedical Engineering*, vol. 58, no. 2, pp. 435-442, February 2011.

[14] K. Kawano, S. Kobashi, M. Yagi, K. Kondo, S. Yoshiya, Y. Hata, “Analyzing 3D Knee Kinematics Using Accelerometers, Gyroscopes and Magnetometers,” presented at the 2007 IEEE International Conference on System of Systems Engineering (SoSE), San Antonio, TX, USA.

[15] S. Kobashi, Y. Tsumori, S. Imawaki, S. Yoshiya, Y. Hata, “Wearable Knee Kinematics Monitoring System of MARG Sensor and Pressure Sensor Systems,” presented at the 2009 IEEE International Conference on System of Systems Engineering (SoSE), Albuquerque, NM, USA.

[16] A. Tomaru, S. Kobashi, Y. Tsumori, S. Yoshiya, K. Kuramoto, S. Imawaki, Y. Hata, “A 3-DOF Knee Joint Angle Measurement System with Inertial and Magnetic Sensors,” presented at the 2010 IEEE International Conference on Systems Man and Cybernetics (SMC), Istanbul, Turkey.

[17] M. Sati, J. A. de Guise, S. Larouche, G. Drouin, “Quantitative Assessment of Skin-bone Movement at the Knee,” The Knee, vol. 3, no. 3, pp. 121-138, 1996.

[18] E. S. Grood, W. J. Suntay, “A Joint Coordinate System for the Clinical Description of Three-Dimensional Motions: Application to the Knee,” *Journal of Biomechanical Engineering*, vol. 105, no. 2, pp. 136-144, 1983.

[19] N. Van den Dikkenberg, O. G. Meijer, R. M. A. Van der Slikke, R. C. Van Lummel, J. H. Van Dieen, B. Pijls, R. J. Benink, P. I. J. M. Wuisman, „Measuring functional abilities of patients with knee problems: rationale and construction of the DynaPort knee test, ” *Knee Surg Sports Traumatol Arthrosc*, vol. 10, no. 4, pp. 204-212, 2002.

[20] L. B. Mokkink, C. B. Terwee, R. C. Van Lummel, S. J. De Witte, L. Wetzels, L. M. Bouter, H. C. W. De Vet, “Construct validity of the DynaPort KneeTest: a comparison with observations of physical therapists,” *OsteoArthritis and Cartilage*, vol. 13, no. 8, pp. 738-743, 2005.

[21] L. B. Mokkink, C. B. Terwee, R. M. A. Van der Slikke, R. C. Van Lummel, R. J. Benink, L. M. Bouter, H. C. W. De Vet, “Reproducibility and validity of the DynaPort KneeTest,” *Arthritis & Rheumatism (Arthritis Care & Research)*, vol. 53, no. 3, pp. 357-363, 2005.

[22] L. L. A. Kleijn, W. L. W. Van Hemert, W. G. H. Meijers, A. D. M. Kester, L. Lisowski, B. Grimm, I. C. Heyligers, “Functional improvement after unicompartmental knee replacement: a follow-up study with a performance based knee test,” *Knee Surg Sports Traumatol Arthrosc*, vol. 15, no. 10, pp. 1187-1193, 2007.

[23] J. N. Belo, S. M. A. Bierma-Zeinstra, C. B. Terwee, E. M. Heintjes, B. W. Koes, “Longitudinal and cross-sectional validity of the DynaPort KneeTest in adults with nontraumatic knee complaints in general practice,” *Journal of Clinical Epidemiology*, vol. 61, no.12, pp. 1271-1278, 2008.

[24] A. Burns, B. R. Greene, M. J. McGrath, T. J. O'Shea, B. Kuris, S. M. Ayer, F. Stroiescu, V. Cionca, “SHIMMER – A Wireless Sensor Platform for Noninvasive Biomedical Research,” *IEEE Sensor Journal*, vol. 10, no. 9, pp. 1527-1534, September 2010.

[25] M. J. Mathie, A. C. Coster, N. H. Lovell, B. G. Celler, “Accelerometry: providing an integrated, practical method for long-term, ambulatory monitoring of human movement,” *Physiol Meas*, vol. 25, no. 2, pp. R1-20, 2004.

[26] M. Gietzelt, K. H. Wolf, M. Marschollek, R. Haux, „Automatic Self-Calibration of Body Worn Triaxial-Accelerometers for Application in Healthcare,“ presented at the 2008 Pervasive Health Conference, Tampere, Finland.

[27] S. Bonnet, C. Bassompierre, C. Godin, S. Lesecq, A. Barraud, „Calibration methods for inertial and magnetic sensors,“ *Sensors and Actuators A: Physical*, vol. 156, no. 2, pp. 302-311, December 2009.

[28] R. Haux, J. Howe, M. Marschollek, M. Plischke, K.-H. Wolf, „Health-enabling technologies for pervasive health care: on services and ICT architecture paradigms,” *Informatics for Health and Social Care*, vol. 33, no. 2, pp. 77-89, 2008.