Chapter 9

General Discussion

9.1 Introduction

The aim of this thesis was to evaluate the feasibility and quality of new ambulatory movement analysis systems, motivated by application in clinical motor function assessment. Ambulatory movement analysis systems have been introduced and applied to measure kinematics and kinetics in a laboratory-free setting [1-3]. Given their ability to measure motion in diverse settings, these systems have the potential to play an important role in objectifying and quantifying the assessment of motor function in clinical practice. In this thesis, the applications of an inertial and magnetic measurement system (IMMS) and an instrumented force shoe (IFS) were addressed in spasticity assessment, gait analysis, and the measurement of mechanical loading in children with cerebral palsy (CP) and adults with osteoarthritis (OA) of the knee.

A key question concerning the clinical implication of the studies described in this thesis is whether the new ambulatory movement analysis systems are potentially useful in clinical practice. In this general discussion, this question will be addressed based on the following criteria: the accuracy and precision of the measurement systems, the validity at impairment level, the importance of the ambulatory movement analysis systems in clinical decision-making, and risk and discomfort involved [4,5]. Furthermore, recommendations will be made for future research and development of ambulatory systems for clinical application, and finally the main conclusions of this thesis will be summarized.

9.2 Accuracy and precision of the ambulatory movement analysis systems

Accuracy describes the degree of closeness to the true value ('the golden standard'), whereas precision refers to the degree to which repeated measurements produce the same results [5]. Accuracy and precision outcomes should be interpreted with respect to clinically relevant differences.

9.2.1 Accuracy and precision of the IMMS to measure joint angles

The orientation of each individual sensor of the IMMS can be obtained with Kalman filter algorithms that fuse the data from the gyroscopes, accelerometers and magnetometers. Chapter 2 demonstrated that the sensors of the IMMS were technically very accurate for the measurement of 3D orientation in spasticity tests. Compared with an optoelectronic motion capture system, the difference was within one degree. High technical accuracy of IMMS has also been reported in other studies [6-8]. The fusion algorithm applied in the analysis described in Chapter 2 relied on the magnetometers for observation of the sensor heading (i.e. the vertical direction). However, when a non-homogenous earth magnetic field is present, the calculation of the sensor orientation may be negatively affected [6,9,10]. In the spasticity assessments, no influence of a non-homogenous earth magnetic field was expected because of the avoidance of ferromagnetic materials in the surroundings.

Since a non-homogenous earth magnetic field is likely to be present in most applications, in Chapters 4 and 7 the orientations of the IMMS sensors were calculated without relying on information from the magnetometers. In Chapter 4, the Kinematic Coupling algorithm (KiC) [11] was used to obtain orientation from the gyroscopes and accelerometers in the IMMS sensors on the foot, shank and thigh. This algorithm maximally neglected the use of the magnetometers, and thereby excluded any influence of a non-homogenous earth magnetic field. It was based on the assumption that the movements of the proximal and distal segment are equal in the joint. The relative heading (i.e. distal segment with respect to the proximal segment) can be observed as long as the joint is moving. The use of this algorithm was essential for calculation of the ankle and knee kinematics, since a non-homogenous earth magnetic field was measured at 20 cm from the floor. In Chapter 7, a slightly different algorithm was applied without using the magnetometers. In this case, angular velocity measured with the gyroscopes was integrated to orientation, with correction for inclination from the accelerometer data [12]. In contrast to the KiC, no joint assumptions were applied, however knowledge about initial and final conditions of segments, such as zero velocity and vertical position of the foot at each stride, were used. In both cases, the algorithms resulted in accurate orientations without the use of magnetometers, showing that it is possible to apply the IMMS also in case of a non-homogeneous earth magnetic field.

When using IMMS, the anatomical accuracy of 3D body segment orientation and joint angles is highly dependent on correct anatomical calibration of the sensor units of the IMMS with respect to the body segments. This was the case when measuring the angle of catch (AOC) in spasticity tests (Chapter 2), and measuring segment orientation and joint angles in gait analysis (Chapters 4 and 7). The anatomical calibration is a mathematical transformation between the technical coordinate system of the sensor and the anatomical coordinate system of the body segment [1,13-17]. A well known concern of ill-defined anatomical coordinate systems of body segments is cross-talk in joint angles [18,19].

In Chapters 2, 4 and 7, anatomical calibration of the IMMS was performed with three different methods: using (i) the functional axes calculated from angular velocity (based on helical axes [20-22]) measured during a flexion/extension movement (knee) and plantar/dorsal flexion movement (ankle, Chapter 2); (ii) a known reference posture (Chapter 2: supine, using sensor axes; Chapter 4 and 7: upright, using gravity); and (iii) careful alignment of sensors with body segments using bony landmarks (pelvis and shank [1], Chapter 4).

A functional axis, defined during a passive, non-weight-bearing, flexion/extension movement, does not have to be aligned with palpated anatomical bony landmarks, such as the femur epicondyles, or with the knee axis during gait [23-26]. However, a functional calibration is preferable, because a knee axis defined by palpation of the epicondyles may be subject to considerable variation, due to the large condylar surface and soft tissue artefacts [23,27-29]. Moreover, a functional axis has been shown to have low repeatability errors [17,30].

The results of Chapter 4 show that the anatomical accuracy of IMMS in patients is mainly limited by the static reference posture, since patients may not be able to stand upright due to joint deformities or stability problems. The challenge in the application of IMMS for the measurement of joint kinematics is to further improve the anatomical calibration of the sensors, to a level equal to, or even greater than optoelectronic anatomical accuracy [31].

An extensive study of the precision of IMMS for the measurement of joint kinematics, either in spasticity tests or gait analysis, is lacking in this thesis. However, the reliability of the IMMS with regard to AOC measurements has recently been studied by Paulis et al. [32]. They compared the test-retest and inter-rater reliability of Tardieu scale scores for the elbow angle in stroke patients, measured with IMMS and goniometry. Their results can be generalized to AOC measurements in the Spasticity Test (SPAT), since a similar protocol and procedure was used. They concluded that IMMS has a higher reliability than goniometry, due to the objectivity and the minimal influence of an examiner. This is in line with the results presented in Chapter 2.
Furthermore, in Chapter 4 the IMMS joint kinematics showed similar standard deviations to the joint kinematics from the optoelectronic reference system. This implies an equal inter-trial variability of the IMMS with respect to the reference system.

In summary, the IMMS is an accurate technique to measure 3D orientation. Accuracy and precision of joint angle measurement with IMMS highly depends on correct anatomical calibration of the sensors, which is still a challenge in patients with joint deformities.

9.2.2 Accuracy of IFS and IMMS in measuring the knee moments

In Chapters 6 and 7, the IFS was applied to measure the ground reaction force (GRF) and centre of pressure (CoP) during gait, as required to estimate the external knee adduction moment (KAdM). It was found that the IFS was accurate in measuring the GRF and CoP of patients with knee OA. This was in line with the results of other studies of the IFS in healthy subjects [2,33,34]. Furthermore, Chapter 6 showed that it is mainly the accuracy of GRF and CoP in medio-lateral direction that affects the estimation of the KAdM.

When applying the ambulatory movement analysis system, consisting of IFS and IMMS, for KAdM measurement, information about joint positions is lacking. However, the position of the knee joint with respect to the CoP is required for the calculation of the KAdM. Therefore, a linked-segment model was introduced (Chapters 6 and 7). In Chapter 6, the IFS in combination with this linked-segment model for joint position estimation (with orientation from an optoelectronic system) was found to be a promising approach for estimation of the KAdM with an ambulatory system.
In the study described in Chapter 7, segment orientations from IMMS were applied in this linked-segment model. In this way, the entire ambulatory movement analysis system was used to estimate the KAdM in the gait of patients with knee OA. Both chapters showed

that the accuracy of the KAdM, measured with an ambulatory system, was mainly affected by a difference in assumptions of joint centre positions in the linked-segment model. For example, in the linked-segment model the centre of the ankle joint is fixed in the heel segment, whereas in the laboratory-based protocol the ankle joint is defined as the midpoint of the malleoli. Furthermore, the KAdM estimated with the linked-segment model was very sensitive to the magnitude of fixed segment lengths. An inaccuracy in medio-lateral direction of only 1 cm could already result in a difference of 20% in the KAdM. Differences observed in OA patients, compared to healthy controls, are in the same order of magnitude, which means that the ambulatory system is yet not accurate enough to discriminate between healthy subjects and patients. It will be a challenge to improve the accuracy of joint position estimation with an ambulatory system.

In summary, the IFS is an accurate technique to measure the ground reaction force and centre of pressure. However, measurements of joint moments, such as the KAdM, are limited by the accuracy of joint position estimation via the IMMS and need to be further improved.

9.3 Validity at impairment level

Validity is defined as the soundness or the appropriateness of a test or instrument in measuring what it is designed to measure [35]. Validity at impairment level refers to whether the measurement outcome really reflects the impairment [5]. Therefore, it should be in line with clinical terminology, and correspond with the expected expression of the impairment.

9.3.1 The angle of catch and spasticity

Since, according to Lance's definition [36,37], spasticity is velocity-dependent, different stretch velocities in spasticity tests might result in different reflex responses of the muscle and, consequently, in different AOCs [38-40].

Interestingly, in recent years there has been an ongoing discussion about the definition of spasticity, as well as the scales that should be used to measure spasticity at joint level. The definition proposed by the SPASM consortium (2005) includes all afferent-mediated positive features of the upper motor neuron syndrome [41,42]. In contrast, the traditional definition according to Lance only concentrates on the velocity-dependent increase in stretch reflex activity [36]. The Ashworth scale has been found to be insufficient as a measure of spasticity because of its poor relationship to reflex muscle activity [43]. As alternatives, the Tardieu scale and the SPAT (simplification of the Tardieu scale) have been recommended [39,40,44,45].

In Chapter 3, the IMMS was used to measure the joint angular velocities during the slow and fast passive stretch tests of the SPAT [45]. The mean velocities of the fast stretch tests were significantly different from the mean velocities of the slow stretch tests. However, the slow passive stretch tests were sometimes performed too fast, compared to the description in the SPAT protocol (mainly in the hamstrings muscle test). Furthermore, the variability within the group for the fast stretch tests was high, resulting in large standard deviations (approximately 80^{o}/s). This may be due to the mass and size of the body segments (not equal between patients), the strength and experience of the two examiners, the range of motion (as a result of shortened muscle) and the resistance experienced due to visco-elasticity of the tissue and joint deformities.

In the majority of the fast stretch tests in children with CP, the catch was preceded by a burst in muscle activity (measured with electromyography (EMG)), which was not present in the slow stretch tests (Chapter 3). This showed that muscle activity, due to the stretch

reflex response, was the main cause of the catch. Consequently, it can be concluded that the AOC can be used to quantify spasticity, when spasticity is defined according to Lance's definition [36]. Therefore, the AOC can be considered as a valid measurement at the level of impairment, and IMMS appears to be a valid measurement instrument for this assessment.
Recently, the relationship between velocity, AOC and spasticity in the assessment of elbow muscles in CP has been studied by Wu et al. (2010) [39]. They found that, with increasing velocity, the EMG-onset occurred earlier, and peak resistance torque and torque change rate increased. However, the AOC decreased (i.e. the catch occurred later and closer to the range of motion) due to the increased velocity. It was concluded that the increased resistance experienced at higher stretch velocity was partly due to the induction of stronger stretch reflex responses, but also partly due to higher position-dependent mechanical resistance [39]. These results reflect the complexity of spasticity assessment, and the need for further research on the expression of spasticity at joint level.

It has been demonstrated that a passive stretch test alone is insufficient as a method of assessment for spasticity during active motor tasks, and also for the measurement of motor control [46]. However, spastic muscles have been found to be shorter and slower during gait than non-spastic muscles [37,47,48], implying that there is a relationship between the results of the physical examination and measurements at activity level. The precise role of spasticity in active motion is an ongoing topic of debate in research [37,49,50]. Despite the fact that spasticity is abnormal from a neurophysiological point of view, treatment for spasticity is not always required. Occasionally, a spastic pattern can even be functionally useful, i.e. as an aid to walking or dressing [51]. Although stretch velocities of passive tests are of similar magnitude as peak velocities during gait, the degree to which spasticity may impede active movement is also affected by the type and direction of movement, as well as the state of voluntary muscle activation in the agonist and antagonist muscles [37]. Furthermore, several other factors, such as restrictions in muscle length, reduced strength, or poor selective control, interact with spasticity and produce gait limitations in patients with CP [37].

Although the assessment of spasticity is still an ongoing topic of research, a better standardization and objectivity of the existing tests via measurement instruments may contribute to the interpretation of the outcomes of spasticity tests and to a better understanding of spasticity.

9.3.2 Joint kinematics and gait deviations

In clinical practice, gait analysis is performed to assess gait deviations in patients such as children with CP [52]. Quantitative 3D gait analysis can provide objective measurements that are difficult to observe accurately with the eye [4,24]. It is obvious that the IMMS should be accurate and precise enough to reflect the gait deviations that impair the patient's functioning, and that are the focus of the treatment.
From the results presented in Chapter 4, we concluded that mainly the transverse plane angles are subject to offsets, due to the anatomical calibration of the IMMS. However, the anatomical calibration of an optoelectronic marker system, using bony landmarks, also has a lower reliability in knee and hip rotation angles [31]. Therefore, it is questionable whether these joint angles always reflect the impairment or whether they are subject to measurement errors. These joint angles should be interpreted with care, regardless of system or protocol.

In contrast to the traditional optoelectronic systems, gait analysis with IMMS can be performed in a laboratory-free setting, where patients are not impeded by the limited space of a gait laboratory. Since it allows the patients to walk more naturally without the feeling of being observed, this might better reflect the disability that patients experience in daily life. Furthermore, the measurement of many consecutive gait cycles may give a better estimate of the average walking pattern. Apart from gait, other functional tasks, that are limited due to impairment, can easily be measured (such as climbing stairs).

9.3.3 The external knee adduction moment and internal knee joint-loading, pain and function

The KAdM is frequently considered to be an indicator of knee joint-loading in patients with knee OA, and associated with disease severity and malalignment [53-56]. The knee joint is highly loaded during daily life [57], and the knee is one of the most affected joints in OA [58]. Although the understanding of the initiation and progression of knee OA is limited, there is increasing evidence that it is (partly) driven by biomechanical forces [58-63]. The pathological response of tissues to such forces results in further joint deterioration, more symptoms, and reduced functioning [58].

The aim of many types of treatments for knee OA is to reduce the load on the diseased compartment of the knee [64-66]. Hence, gait modifications have also been assumed to minimize loading on the affected side of the knee, in order to decrease the rate of progression of knee OA and to decrease the pain experienced by the patients [67-70]. Interestingly, the results of Chapter 8 indicated that the KAdM is sensitive to gait alterations, such as a change in posture and walking speed. It is expected that these biomechanically observed effects in healthy subjects will be similar in an elderly population. However, since elderly people tend to walk more slowly [71], and patients with OA are often overweight [72], this should be subject to further research.

Although the KAdM has often been accepted as a measure of medio-lateral knee joint-loading, its direct relationship to internal joint-loading and degeneration of the cartilage is not yet fully known. This implies that it is still questionable whether the KAdM is a an accurate measure for internal loading and in what way interventions affect the internal loading and the cartilage. Studies investigating the internal characteristics of the knee joint have reported ambiguous results on the relationship of the KAdM with medial contact force, measured by an instrumented knee implant [73,74]. A significant positive correlation of the KAdM with bone distribution in the medial and lateral side of the tibia has been reported [75-78], however no association could be found with cartilage volume [77,79]. In a modelling approach, medial compartment-loading has been found to be mainly determined by the orientation of the ground reaction force [80]. In contrast, forces acting on the lateral compartment result from the actions of muscles (mainly quadriceps and gastrocnemius) and ligaments.

The relationship between KAdM, pain, and function is also not yet clear. A stronger reduction in functional ability has been found in knee OA patients with more pronounced varus knees (i.e. a knee adduction angle) than patients with less pronounced varus knees, or with valgus knees (i.e. a knee abduction angle) [81]. In medial OA, the KAdM has been reported to be significantly related to disease severity, although pain was only found to be related to gait speed, and not to the KAdM [82]. Moreover, disabling knee pain in older patients in primary care does not always represent radiographically defined OA [83]. However, the results of a recent study [84] showed that the impulse of the KAdM is related to an increase in pain during weight-bearing activities such as walking, thereby restricting walking performance, resulting in disability by reducing gait velocity. The researchers concluded that the reduction in the KAdM impulse during gait could result in pain relief.

In conclusion, although the relationship of the KAdM with internal knee-joint loading is still under debate, the KAdM is sensitive to gait modifications and shown to be related to disease severity. Measurement of the KAdM can be done non-invasively, and may be used as an objective method to evaluate the loading in patients with OA and to gain insight into the role of biomechanical forces in progression of OA.

9.4 The importance of ambulatory movement analysis systems in clinical decision-making

The importance of the ambulatory movement analysis systems for clinical practice is the degree to which the systems may optimize clinical decision-making. It comprises the added value of the ambulatory systems with regard to the measurement systems and methods that are currently used. Additionally, the risk and discomfort of the ambulatory systems for the patient and examiner should be evaluated. This also applies to whether or not the systems significantly change the function of what is measured.

9.4.1 The instrumented spasticity test in cerebral palsy

Since decision-making with regard to spasticity-reducing treatments is based (among others) on physical examination, accurate, quantitative and objective assessment of the spasticity is essential [40,43]. In Chapter 2 it was concluded that goniometry is a reasonably accurate method with which to measure the joint angle in a static situation. However, subjective joint-repositioning and inaccurate readout are the disadvantages of goniometry in the assessment of spasticity. This section describes the possible role of IMMS in spasticity assessment.

IMMS can improve the AOC measurement and the performance of the SPAT, because of its objectivity and accuracy of joint angle measurement. Furthermore, IMMS can be used to give feedback on stretch velocity (Chapter 3). Since velocity is an important factor in spasticity, feedback on stretch velocity might improve further standardization of the assessment of spasticity. A constant velocity is difficult to achieve with a manual muscle stretch. However, guidelines could be developed about mean and maximal velocity with respect to threshold velocities evoking spastic reflex activity, and physicians should receive the necessary training.

In clinical practice, spasticity tests are often only used for the general assessment of spasticity in a muscle, without taking into consideration the exact absolute difference between the AOC and the range of motion. However, when comparing pre- and post-intervention (e.g. in the case of botulinum toxin type A), the accuracy and reliability of the AOC is important, and should be greater than the expected effect of the treatment on the AOC. This implies that the IMMS will optimize clinical decision-making when an accurate measurement of the AOC is clinically relevant, which depends on the treatment goals for a specific patient.

The aim of instrumentation of spasticity tests by IMMS is to enable objective and accurate measurement of spasticity in the consulting-room of a clinician, without the need for complex measurement systems that can only be used in laboratories (such as the optoelectronic movement analysis systems). For the implementation of IMMS for spasticity assessment in clinical practice, software with a user-friendly interface for the examiner should be developed, including guidelines for sensor placement, anatomical calibrations, a protocol, and feedback on velocity and joint angle. This ensures standardization and easy interpretation, even for less experienced assessors.
Furthermore, the results of spasticity tests can easily be stored in a well-organized digital database, and linked to a digital medical record, which makes it possible to access updated information anywhere and anytime. This will objectify the pre- and post-treatment assessment of spasticity.

9.4.2 Ambulatory gait analysis in cerebral palsy

Gait analysis via IMMS in a laboratory-free setting might improve assessment of the gait pattern. A large number of consecutive gait cycles can be recorded. Moreover, gait data can be derived in a natural environment instead of in a laboratory. This might help to optimize clinical decision-making, because these measurements reflect more accurately the natural gait. It could also provide opportunities for the assessment of even more parameters, such as step-to-step variability, or the effects of fatigue.

Furthermore, the use of functional calibrations instead of the palpation of bony landmarks will result in a decrease in complexity, and thereby decrease the chance of errors in the preparation phase of the 3D gait analysis. Finally, IMMS can be used for multiple successive clinical measurements, such as spasticity assessment (Chapter 2) prior to gait analysis. A protocol and a graphic user interface have already been developed [1], and only need to be optimized for clinical application.

All these features open up the way for more frequent use of 3D gait analysis of kinematics in clinical practice, whereas its has always been limited due to the complexity of optoelectronic systems and the need for a laboratory environment.

9.4.3 Ambulatory assessment of the external knee adduction moment in osteoarthritis

Although biomechanical parameters are becoming increasingly relevant to assess knee OA, the limited availability of gait laboratories still restricts the application of joint moment measurement in a clinical setting. Therefore, the introduction of the IFS and IMMS for the ambulatory measurement of kinetics is a promising development for clinical practice. It enables objective measurements, where these are currently not available.

Use of the ambulatory system to estimate the KAdM can only be clinically successful if the importance of the KAdM as a measurement of knee joint-loading is demonstrated and accepted in clinical practice. It is therefore important to identify those patients who may benefit from a reduction in joint-loading (for instance by means of interventions such as valgus-bracing, heel-wedges and osteotomy), and which compensations may lead to a reduction in knee-load (Chapter 8). A set of easily obtained measurements (body mass, tibia alignment, walking speed) could assist clinicians to decide whether measurement of the KAdM is appropriate [56], to improve clinical decision-making, particularly in patients with malalignment or obesity. A standardized protocol is required for the clinical ambulatory assessment of the KAdM, e.g. including anatomical calibration and standardization of walking velocity in repeated measurements of the KAdM.

9.5 Risk and (dis)comfort of ambulatory movement analysis systems

The advantage of the application of the IMMS in spasticity assessment or gait analysis is the user-comfort. The sensors do not impede or influence the movements, and application is without any risk. They are lightweight and small, fully wearable, and can easily be attached to and detached from the body segment with straps. Recently, wireless sensors have become available, thus even more increasing the user-friendliness of the IMMS.

The environment in which the IMMS is applied is important, when using algorithms that rely on the magnetometers in the sensor units. However, this problem can be solved by implementing algorithms such as those described in Chapters 4 and 7. Also important is the combination of IMMS with EMG measurements in both spasticity assessment and gait analysis. In spasticity assessment, EMG in combination with IMMS (and/or force) can be used for concurrent measurement of the neurophysiological and biomechanical features of spasticity. This provides more insight into the clinical expression of spasticity at joint level, as well as an easy interpretation of the catch as a consequence of muscle activity or the biomechanical properties of tissue. Furthermore, EMG measurements are often used in gait analysis of children with CP. However, the placement of EMG electrodes is subject to guidelines (SENIAM [85]), which may interfere with the optimal placement of IMMS sensors for the measurement of joint kinematics. Moreover, adding more instruments on the body may hinder the performance of the movements that are assessed.

No risks in wearing IFS have been observed in patients with knee OA (Chapter 5). The design of the IFS has recently been changed (compared to the IFS used in the studies in this thesis), by reducing the amount of cables, changing the IMMS sensor position, and minimizing the force/moment amplifier. This optimized IFS design may furthermore improve the user-comfort, although the OA patients have already reported that the IFS was comfortable to walk on.

9.6 Recommendations for future research and development

9.6.1 Instrumented spasticity tests in cerebral palsy

Future research should be carried out to further investigate the expression of spasticity at joint level. Furthermore, a clinical instrument for spasticity assessment should be developed, based on IMMS, for application in clinical practice.

The velocity-dependency and its effect on the AOC should be the subject of extensive research on the assessment of spasticity in the muscles of children with CP, as well as in other patient populations, such as stroke or spinal cord injury. This can be done by measuring the AOC, the EMG and the force at different speeds (e.g. controlled by a dynamometer). Passive or active response from tissues can also be identified by haptic robots and system identification techniques [86]. Additionally, by observing fast passive stretches in healthy controls, it is possible to evaluate the normal behaviour of the muscles, and the influence of passive tissue compared to spastic muscles. These studies will provide more information about the velocity-dependent and position-dependent character of spasticity, and may lead to consensus on the definition of spasticity. Future studies should also investigate whether IMMS are responsive to the measurement of changes in spasticity, due to treatment such as botolinum toxin type A. Moreover, it is necessary to determine in more detail how spasticity affects functions such as gait [49,87].

In order to develop a reliable clinical instrument for the assessment of spasticity, it is important to determine whether, in addition to IMMS, EMG and force sensors should be included. This will influence the design of the instrument, since the positioning of the IMMS or force sensor should not interfere with the placement of the EMG electrodes. Research is also needed to determine the size of the instrument, the way in which it is attached to the body segment (e.g. straps), and the application for different muscle groups and different patient populations. A protocol should be developed, in which the positioning of the sensors, the anatomical calibration, and the standardized performance of the test are described. This should be embedded in software with a user-friendly graphic user interface, online feedback, automatic detection of the AOC, and interpretation of the test results. The protocol could be based on the SPAT protocol [45] or the modified Tardieu scale [38,88].

Prior to implementation in clinical practice, the need for and added value of an instrument to assess spasticity has to be determined among clinicians. It has to be investigated in which situations and environments the instrument will be used, as well as which protocols and functional outcome measures should be implemented in the software. Finally, the usefulness of the instrument in clinical practice must be evaluated, and compared with the methods that are currently used.

9.6.2 Ambulatory gait analysis in cerebral palsy

The results of the study in Chapter 4 confirmed the feasibility of IMMS for gait analysis, as a good alternative for 3D optoelectronic systems. However, application of IMMS for gait analysis needs to be further investigated in a larger study sample. In such a study, the anatomical calibration as applied in the Outwalk protocol, should be optimized. This may be achieved by the use of a different reference posture (e.g. supine), in combination with the ability to introduce offsets in joint angles when joint contractures are present. Also the application of an IMMS calibration system, based on bony landmarks [14], should be investigated.

The intra-rater and inter-rater reliability of IMMS in gait analysis have to be studied with regard to the reproducibility of sensor placement and the anatomical calibration of IMMS. Furthermore, since it has been suggested that a laboratory-free environment will result in more spontaneous walking of patients, there is a need to compare the gait pattern inside the laboratory with the gait pattern outside the laboratory.

Prior to the implementation of IMMS in clinical practice, the interest and added value of IMMS in clinical gait analysis should be investigated among clinicians. In order to achieve a definitive ambulatory system for clinical gait analysis, it is necessary to take the application of ambulatory measurement of kinetics with the instrumented force shoe [2] into consideration, as described in Chapters 5-7. Finally, the placement of the IMMS sensors in combination with EMG electrodes should be investigated.

9.6.3 Ambulatory assessment of the knee adduction moment in osteoarthritis

The IFS has been found to be accurate in measuring GRF and CoP. However, the application of the linked-segment model, which is sensitive to fixed segment lengths and correct estimation of the segment orientation by means of IMMS, mainly influenced the accuracy of the KAdM measurements. Further research is needed to determine whether the KiC algorithm [11], the magnetic actuators [89], or an IMMS calibration based on bony landmarks [14] can improve the joint position estimation.

Although the effect of the IFS on gait characteristics was clinically irrelevant, the design of the IFS could be further optimized by minimizing the force and orientation sensors, removing cables (i.e. in favour of a wireless system), or the application of pressure insoles [90]. Furthermore, the IFS should be available in different sizes, and IFS for children should be developed.

Finally, the relationship of the KAdM with knee joint-loading, the intra-rater and inter-rater reliability of the KAdM, and its relevance in clinical decision-making, needs to be investigated with musculoskeletal modelling. Musculoskeletal modelling can play an important role in gaining insight into the relationship between the KAdM and internal knee joint-loading, and into the contribution of muscles and ligaments. In order to ensure successful implementation of ambulatory systems in the clinical assessment of patients with OA, the perspective of physicians with regard to KAdM measurements should be investigated.

9.7 General conclusion

In conclusion, IMMS and IFS are accurate techniques that can be applied for 3D motion analysis in a laboratory-free setting, with no burden on the patients. With IMMS, physical examination of spasticity in the consulting-room will be more accurate, objectified and standardized. This may support clinical decision-making and optimize the evaluation of spasticity treatment. Furthermore, IMMS and IFS enable 3D gait analysis (kinematics, ground reaction forces and centre of pressure) when there is no gait laboratory available. This opens up a way for a more frequent use of 3D clinical gait analysis, for example in children with CP and patients with knee OA. Joint moment measurements with ambulatory movement analysis systems are still limited by the accuracy of the calculation of joint centre positions and need to be further optimized. Prior to the implementation of ambulatory movement analysis systems in clinical practice, future research should focus on optimization of the anatomical calibration of such systems, and optimization of user-friendly protocols.

9.8 References

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