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SIAMOC position paper on gait analysis in clinical practice: General requirements, methods and appropriateness. Results of an Italian consensus conference

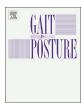
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Review

SIAMOC position paper on gait analysis in clinical practice: General requirements, methods and appropriateness. Results of an Italian consensus conference



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$A\;B\;S\;T\;R\;A\;C\;T$

Gait analysis is recognized as a useful assessment tool in the field of human movement research. However, doubts remain on its real effectiveness as a clinical tool, i.e. on its capability to change the diagnostic-therapeutic practice. In particular, the conditions in which evidence of a favorable cost-benefit ratio is found and the methodology for properly conducting and interpreting the exam are not identified clearly.

To provide guidelines for the use of Gait Analysis in the context of rehabilitation medicine, SIAMOC (the Italian Society of Clinical Movement Analysis) promoted a National Consensus Conference which was held in Bologna on September 14th, 2013. The resulting recommendations were the result of a three-stage process entailing i) the preparation of working documents on specific open issues, ii) the holding of the consensus meeting, and iii) the drafting of consensus statements by an external Jury. The statements were formulated based on scientific evidence or experts' opinion, when the quality/quantity of the relevant literature was deemed insufficient.

The aim of this work is to disseminate the consensus statements. These are divided into 13 questions grouped

in three areas of interest: 1) General requirements and management, 2) Methodological and instrumental issues, and 3) Scientific evidence and clinical appropriateness.

SIAMOC hopes that this document will contribute to improve clinical practice and help promoting further research in the field.

1. Introduction

Gait Analysis (GA) is recognized as a useful assessment tool in the field of human movement research. However, doubts remain on its real effectiveness as a clinical tool, i.e. on its capability to change the diagnostic-therapeutic practice. In particular, the conditions in which evidence of a favorable cost-benefit ratio exists, and the methodology for properly conducting and interpreting results, are not clearly defined. With the aim of providing guidelines for the use of GA in the context of clinical medicine, SIAMOC (Italian Society of Clinical Movement Analysis) promoted a National Consensus Conference which was held in Bologna, Italy, on September 14th, 2013. The purpose of the conference was to produce evidence-based recommendations to assist a) practitioners in managing gait examination and interpreting its results, and b) administrators in defining appropriateness and remuneration.

Recommendations should stem from scientific evidence. If the quality/quantity of knowledge is not deemed as sufficient, it is justifiable to appeal to a process of consensus, by integrating the opinion of experts with the available literature, following the procedure defined by established guidelines. For Italy, an official National Guidelines System is available (http://www.snlg-iss.it/home_en#) and used for reference.

For the Consensus Conference, three areas of interest were considered as a priority: 1) *General requirements and management*, 2) *Methodological and instrumental issues*, and 3) *Scientific evidence and clinical appropriateness*. Three working groups were then set up and asked to answer a total of 13 questions through preparatory documents. These were publicly discussed in front of a multi-professional Jury. The Jury independently evaluated the quality of the sources and the methodology applied by the working groups.

The following sections summarize the process that led to the identification of the Consensus topics, the definition and set-up of the working groups, and the formulation of the final consensus statements for each question.

2. Methods

2.1. Identification of the topics for the consensus

To define the topics of interest for the Consensus Conference, SIAMOC appointed an Organizing Committee made by three senior members (two physicians and a rehabilitation engineer). The Organizing Committee listed 10 topics of possible interest (see Annex 1 in Supplementary material) that were sent to the SIAMOC registered members (70 people). Each receiver had to rate the interest in each of the topics, on a 0–10 scale, with the possibility to express comments and suggestions. Thirty-one questionnaires (44%) were returned, whose scores are summarized in Annex 1 in Supplementary material. Responders had different professional backgrounds (48% physicians, 42% engineers, 10% physiotherapists), which were representative of the expertise in SIAMOC. Based on the answers received, three main areas of interest were identified, each including a set of issues for a total of 13 questions (Table 1).

2.2. Set-up of the multidisciplinary working groups

For each area of interest, a separate working group was formed. To identify the participants, SIAMOC sent out a public call among its members asking to express the willingness to actively participate. Fifty people accepted and, based on their responses, the Organizing Committee set up the three groups. Efforts were made to balance the proportions among engineers, medical doctors, and physiotherapists, also considering the specific topics of the groups. For each group, the Organizing Committee appointed a coordinator and a supervisor from within the Committee itself. Table 2 gives the final composition of the three groups.

2.3. Preparatory documents and jury conclusions

Each group was first required to address each question through literature search and, in case of insufficient or missing evidence, by reaching an internal agreement. Different search strategies were

 Table 1

 Areas and Critical Questions that were addressed with the Consensus Conference.

Area	Critical Questions
Area 1 General issues and management	Question 1.1: How would you define Gait Analysis? Question 1.2: What are the essential and accessory professional profiles for a Clinical Gait Analysis Laboratory? Question 1.3: What training is required for the personnel of a Clinical Gait Analysis Laboratory? Question 1.4: Which characteristics should a Clinical Gait Analysis Laboratory have for accreditation and which procedures should be followed? Question 1.5: What are the minimum health services provided by a Clinical Gait Analysis Laboratory and their costs?
Area 2. Methodological and instrumental issues	Question 2.1: What is the minimum equipment needed for performing a clinical gait analysis examination? Question 2.2: Is there an appropriate commercial instrumentation for clinical gait analysis? Question 2.3: What are the recommended procedures to verify the quality of the measurements performed by the equipment, once installed in the laboratory? Question 2.4: What are the best practice guidelines for using gait analysis instrumentation with patients? Question 2.5: Is it necessary to adopt a standard procedure for the conduction of the examination?
Area 3: Scientific evidence and clinical appropriateness	Question 3.1: What are the pathologies suitable for clinical gait analysis? Question 3.2: What are the effects of gait analysis on decision making? Question 3.3: What are the effects of gait analysis on outcome?

Table 2
Members of the working groups.

Working Group 1:	Working Group 2:	Working Group 3:
General issues and	Methodological and	Scientific evidence and
management	instrumental issues	clinical appropriateness
Medical doctors: 6 Engineers: 5 Physiotherapists: 3 Motor Scientist: 1	Medical doctors: 6 Engineers: 10 Physiotherapists: 2	Medical doctors: 9 Engineers: 5 Physiotherapists: 3

Table 3
Members of the Jury.

Beghi Ettore (President	IRCCS Istituto di Ricerche Farmacologiche Mario
of the Jury)	Negri, Milano
Basaglia Nino	Azienda Ospedaliero-Universitaria di Ferrara, Italy
Beretta Giovanna	SC Medicina Riabilitativa e Neuroriabilitazione A.O.
	Ospedale Niguarda Ca' Granda, Milano
Cappozzo Aurelio	Dipartimento di Scienze del Movimento Umano e
	dello Sport Università degli Studi di Roma "Foro
	Italico"
Cecchetto Simone	Area della Riabilitazione dell'A.P.S.S. della Provincia
	Autonoma di Trento
De Tanti Antonio	Centro Cardinal Ferrari Fontanellato, Parma
Ferro Salvatore	Servizio Presidi Ospedalieri Direzione Generale Sanità
	e Politiche Sociali, RER
Galizio Enrico	Studio Medico Legale Galizio-Massimelli. Torino
Macellari Velio	Istituto Superiore di Sanità, Roma
Melazzini Mario	Regione Lombardia, Centro Clinico Nemo, Ospedale
	Niguarda, Milano
Muller Bertran	INEFC and UB, Barcelona/Spain.
Zerbinati Paolo	MuldiMedica Holding, Castellanza
	=

performed depending on the questions. Where applicable, each published contribution was assessed in terms of quality of evidence using the Critical Appraisal Skills Program (CASP) (http://www.casp-uk.net/). The overall quality of each paper, defined by the total CASP score (CASP_{tot}), was classified into four classes: poor (CASP_{tot} lesser than 25%), mild (between 25% and 50%), good (between 50% and 75%), excellent (greater than 75%). Annexes 2, 3 and 4 in Supplementary material report the literature search strategies, the exclusion/inclusion criteria for article selection, and summarizes how the consensus within each working group was achieved. On this basis, the group finally drafted a conclusive document that was presented to the Jury. The Jury was formed by the experts listed in Table 3. Within the Jury, agreement was reached by consensus after discussion of each individual question.

3. Area 1: general issues and management

3.1. Question 1.1: how would you define clinical gait analysis?

Gait Analysis is a process of instrumented measurement and evaluation of walking ability in patients with impairments specific to locomotion [1–16] (see also Annex 2 in Supplementary material). GA aims at answering questions subtending clinical decisions and/or monitoring, and is part of a broader technology of instrumented analyses of human movement. GA, as intended herein, does not refer to a generic method for recording gait parameters, but rather to the way to answer a specific clinical question. Measurements must be related to the individual clinical problem, with the aim of supporting medical decision-making [1]. Therefore, the term Clinical Gait Analysis (CGA) will be used hereinafter.

3.2. Question 1.2: what are the essential and supplemental professional profiles for a CGA laboratory?

The professionals working in a laboratory performing a CGA must have: 1) knowledge of biomechanics and neurophysiology of human movement in both physiological and pathological conditions, 2) knowledge of advantages and limitations inherent in the different techniques adopted for data recording, analysis and interpretation, 3) adequate skills in the practical execution of the assessment, and 4) adequate preparation for data processing and representation.

Based on the above, the professional profiles for a CGA laboratory are:

- Physicians, specialized in areas relevant to the study of movement (Physiatrists, Orthopedists, Neurologists or Sports Medicine physicians):
- Health care professionals with specific interest in the diseases of human neuro-musculoskeletal system (Physiotherapists, Psychomotor Developmental Therapists, Occupational Therapists);
- Biomedical Engineers with specific expertise on the locomotor apparatus and the use of basic instruments involved in CGA;
- Human movement scientists/Kinesiologists (whose health care competences are defined by national rules).

Most patients referred to a GA laboratory carry disabilities that may require the assistance of further healthcare personnel (e.g. nurses) to take appropriate actions during the examination.

The presence or availability of a Biomedical Engineer with experience in GA is highly recommended to improve the functionality of the laboratory, to ensure the continuity of the service and to support the process of continuous innovation [5].

3.3. Question 1.3: what training is required for the personnel of a CGA laboratory?

Instrumented GA requires the knowledge of specific procedures [1] (see also Annex 2 in Supplementary material). Training may be obtained through practice in a GA laboratory, as well as through appropriate educational courses. Therefore, all professionals working in a GA laboratory must possess:

- An academic degree in inherent disciplines and, for graduates in medicine, a proper specialization;
- Experience in a GA laboratory;
- Specific professional training certified by academic laboratories, or achieved through courses offered by recognized scientific or healthcare institutions. Although there is an overall lack of educational programs, a dedicated Clinical Gait Analysis Postgraduate Course was launched as part of the EU CMAster project (http://faber.kuleuven.be/eng/projects/cmaster).

3.4. Question 1.4: what are the characteristics needed in a CGA laboratory to obtain an accreditation and which procedures should be followed?

It is highly advisable that healthcare authorities implement formal accreditation procedures and that GA laboratories working on patients file for such an accreditation [22,23] (see also Annex 2 in Supplementary material).

In the absence of a formal legislation, each laboratory's administrative department should define the procedures for internal accreditation. These must include the definition of specific structural, technological and organizational standards that Gait Analysis laboratories should possess. In addition, procedures ought to define the methodologies to monitor the services' quality. Such standards have been previously provided both by the CMAS (Clinical Movement Analysis Society) [24] and the CMLA (North American Commission for Motion Laboratory Accreditation, Inc.) [25], which are both trustworthy and widely recognised. According to these standards, the following points must be addressed: 1) Laboratory policy (mission and vision), including planned responsibilities and definition of a "product catalog"; 2) Communication with the user and the client in general; 3) Organization

(accessibility, work organization, etc.); 4) Equipment (minimum provision and maintenance); 5) Basic staff training, and continuing education plan; 6) Informative systems; 7) Procedures in use; 8) Verification of results (outcome evaluation); 9) Improvement plans within the context of a quality management system.

A CGA laboratory should serve a population large enough to collect a sizable number of subjects presenting the sequelae of specific disabling conditions, particularly for severe developmental motor impairments, brain injury, stroke and cerebral palsy (CP), and amputees (see Area 3). This ensures the possibility to achieve and retain over time the adequate skills in specific medical conditions.

3.5. Question 1.5: what are the minimum health services provided by a CGA laboratory and their costs?

Two levels of examination must be considered. At a first level, the clinical evaluation of the lower-limb impairment is combined with the assessment of spatial-temporal parameters, kinematics and kinetics during gait, by using a stereophotogrammetric system and force plates. At a second level, the examination is complemented with dynamic electromyography (EMG) during gait, through surface or fine-wire implanted electrodes.

Services shall be provided upon request of a medical specialist in Physical and Rehabilitation Medicine, Neurology, Orthopedics, or Child Neurology. If one of the clinical question is unclear, the sender should be enquired. Results of the CGA should be incorporated in a document describing the details of the measurements, significant deviations from the reference population, together with a thorough and specific response to the clinical question. The response should not provide specific therapeutic indications.

At present, no reference documentation is available concerning the costs for the services provided by a CGA laboratory. Cost and cost effectiveness analysis studies should be promoted taking into account procedures, equipment, consumables, staff costs (including reporting and product delivery to the sender), and overhead costs.

4. Area 2. Methodological and instrumental issues

4.1. Question 2.1: what is the minimum equipment needed for performing a CGA examination?

By reviewing the equipment available in all SIAMOC Gait Laboratories (as listed on the SIAMOC website) and published reports [1,9,18–20], it is evident that laboratories use a wide variety of instruments. However, given the definition of CGA and referring to Question 1.6 it was agreed that, to date, the *minimum* set of measurement systems are: stereophotogrammetry, force platforms and EMG. Only these instrumentations will be considered in the remaining sections.

4.2. Question 2.2: are there commercial instrumentations available to complete a CGA?

In this section, we will only refer to "direct measurements", i.e. those directly obtained from the instruments: the position of markers for stereophotogrammetry, force and torque for force platforms, and muscle electric potentials for electromyography.

4.2.1. Stereophotogrammetry

Several commercial stereophotogrammetric systems are available for CGA. This conclusion is based on the analysis of the 1) sampling frequency, and 2) spatial accuracy. Regarding the former parameter, most systems exceed the minimum requirement of 20 Hz [27]. Regarding the latter, published reports [28–30] concluded that, when the manufacturer's guidelines are followed, errors in the reconstruction of markers' position have a secondary effect on joint kinematics compared

to other more relevant issues such as the identification of anatomical landmarks and soft tissue artifacts. Since the levels of accuracy declared by manufacturers (typically < 0.5 mm) refer to systems properly installed and calibrated, performances should be verified *in situ* before each experimental session [31].

4.2.2. Force plates

Several commercial force plates are suitable for clinical GA. This conclusion is based on the analysis of: 1) the output available from the systems, and 2) the accuracy in static and dynamic conditions. Regarding the first point, systems exist that provide the 3D components of forces and torques along with the position of the center of pressure. Regarding the second point, a systematic review of the literature (see Annex 3 in Supplementary material) highlighted a very limited number of papers addressing the problem. These studies agreed that commercial products with appropriate accuracy exist, but their performances can decay over time. Periodic *in situ* calibration is therefore recommended to reveal errors in the estimation of the position of the stereophotogrammetric system (i.e. of one or more cameras), with respect to the force plates. Most platforms feature a resonance frequency higher than 500 Hz, which is suitable for GA.

4.2.3. Electromyography

Several systems suitable for CGA are commercially available. Some of them can be used both with surface and fine-wires electrodes. These systems can be characterized by more than twenty technical parameters. Focusing on the most common, based on a systematic review of the literature [32–39] it can be concluded that systems should feature: input impedance > 10M Ω , input noise < 1 µVRMS (corresponding to about 4–6 µVpp) in the useful band of the signal (10–500 Hz), CMRR > 90 dB, and a sampling rate of 1 kHz or higher. Signal filtering should be high pass (10–20 Hz) and then low-pass (400Hz–450 Hz). The A/D digital converter should be at least 12 bit. Concerning electrodes, they should be of the bipolar type, with Ag/AgCl skin contact, and with the diameter to be chosen as a function of the muscle size (but typically comprised between 8 and 10 mm, with 1 to 2 cm interelectrode distance).

4.3. Question 2.3: what are the recommended procedures to verify the quality of the measurements performed by the equipment, once installed in the laboratory?

No data are currently available on quality control of CGA services, despite being relevant in three phases of service provision: 1) *laboratory accreditation* by an independent third party, based on objective measures of precision and accuracy of the measured and estimated variables, as well as on compliance with the good practice rules discussed in Section 2.4; 2) *periodic assessment* of the quality of laboratory performance by the laboratory staff using similar procedures as per the above point 1); and 3) *preparation of reports*, including notes describing the precision and accuracy of the data provided.

4.3.1. Stereophotogrammetry

A complete review of the strategies for quality check is reported in Chiari et al. [28]. Several methods are available to evaluate either the random or the systematic components of the error [31] and to simultaneously check the stereophotogrammetric and the force platforms systems [40]. These methods can be extremely useful to conduct routine tests for maintenance, e.g. monthly. Before each experimental session, it is instead advised to check the correct functioning of the system in a simpler and more immediate way. For this purpose, the full-volume test [41] is suggested as a minimum recommended method; this is performed moving a rod carrying two markers at known distance inside the calibration volume. This information is often provided at the end of system calibration by the manufacturers. It is good practice to check the exact parameters provided by specific equipments. In case of

doubts, it is advisable to run a test with an ad-hoc data analysis.

4.3.2. Force plates

The calibration of a force platform is usually performed by the manufacturer, which is expected to provide a calibration sheet reporting the assessed accuracy and calibration matrix for each specific device. However, the accurate calibration of a force platform is an expensive and time-consuming procedure and not all commercial devices are accompanied by a complete calibration matrix. Moreover, calibration parameters, and thus accuracy, depend on the appropriate installation of the device (e.g. ground anchorage, mechanical isolation, alignment and stability of the support surface) and can change with use and time, due to aging of the components.

Relatively recent literature [40,42–50] suggests the good-practice of in-situ assessment to test the performance of each device, and proposes methods for in-situ calibration of the force plates that can compensate for installation defects and/or for potential modifications due to time and use. Such accurate in-situ assessment and calibration require specialized staff and specific equipment, as this procedure usually implements multiple load measurements in different positions over the force plate and in different directions, exploiting an accurate load cell [45,47–50] as reference; it is therefore neither cheap nor straightforward to implement the procedure autonomously. On the other hand, insitu assessment and recalibration are not intended to be performed frequently (i.e. they can be completed after installation and every few years), and can be delegated to specialized third parties.

When the force platform is integrated with a stereophotogrammetric system, each laboratory can regularly verify and monitor the performance of the platform and its spatial registration in the laboratory reference frame using spot checks [40,42]. The procedure requires little time for completion and inexpensive hardware. Typically, a rigid bar of known geometry is used, mounting reflective markers. The bar is used to apply a concentrated load on the force plate along a line of action visible to the stereophotogrammetric system. This good practice does not allow the quantitative detailed assessment of platform performance, yet it provides a timely quantitative feedback and alerts for corrective interventions.

4.4. Question 2.4: what are the best practice guidelines for using gait analysis instrumentation with patients?

4.4.1. Stereophotogrammetry

In the following section only protocols considered suitable to conduct a full gait analysis are considered. Specialized protocols not including the full lower-limb, e.g. focusing on the foot [127] or on the upper-limb [128] only, are not included.

Based on a systematic review conducted by the working group (please refer to Annex 3 in Supplementary material for the complete list of the studies selected), consensus was achieved on the following statements:

- a) there are several valid clinical protocols of motion analysis which allow for an estimation of spatiotemporal or kinematic variables (segmental or joint) from the position of reflective markers placed on various segments of the patient's body [129-132]; clinical services should only use protocols with a record of publications supporting their validity;
- b) markers placement must be performed by personnel with specific experience, and applying validated protocols. To improve test reliability, analyses on the same patients over time should be conducted by the same examiner. When the same examiner cannot be repeatedly involved, the analyst should evaluate inter-session differences taking into considerations the intra- and inter-rater variability [29,132–135];
- based on the predicted reliability of the method, the number of trials for a given activity should range from 5 to 10 [136–138];

 d) angles during static postures can be used as first-order, macroscopic indicators of a correct anatomical calibration;

- e) the most reliable kinematic data are: hip flexion-extension, knee flexion-extension, ankle flexion-extension, ab-adduction and rotation of the pelvis. Therefore, great attention must be paid to the interpretation of results for pelvic tilt, internal-external rotation of the hip, ab-adduction and internal-external rotation of knee and ankle [12,131,135,139];
- f) it is helpful to check for the presence of *crosstalk* at the angles of the knee (flexion being interpreted as abduction), that may indicate an incorrect identification of anatomical landmarks [140,141].

4.4.2. Electromyography

From the systematic analysis of the literature (Annex 3 in Supplementary material) consensus was achieved on the following points:

- a) for sensors placement, skin should have no hair in excess [32,51], it should be properly cleaned (with ethanol and acetone, among others) and then gently abraded to ensure a good contact with the electrode and reduce skin impedance (maximum recommended impedance $10k\Omega$) [51];
- b) a limited number of papers provide comprehensive guidelines about surface electrode placement for the larger lower-limb muscles [51–53]. Indications are not always in agreement and sometimes different landmarks are proposed. The most frequently cited procedure is the one from Hermens et al. [51];
- c) for deep muscles, fine-wire electrodes are typically used [53,54]. This is the solution of choice in all cases where, after recording the signal, doubts remain for clinical decision making [55–57]. Due to cross-talk from the neighboring Vasti, special attention is recommended in the placement of surface electrodes aiming at detecting signals arising from Rectus Femoris [58–60];
- d) if the EMG system is not wireless, the use of elastic bands and/or tapes is recommended to secure cables to the skin and avoid artifacts due to unstable contacts and/or movements of cables. It is advisable, in any case, to visually inspect the acquired signal to recognize motion artifacts that may be attenuated with subsequent filtering;
- e) electrodes should be positioned between the innervation zone and the muscle-tendon junction as shown in [34,61,62], on minimal crosstalk areas [52], and aligned along the direction of muscle fibers (accordingly to muscle anatomy) [34];
- f) inter-electrode distance should be equal to or less than 20 mm [51]. When bipolar sensors are applied on small muscles, the distance should not exceed ¼ of the length of the muscle fibers;
- g) crosstalk is a signal distortion due to the superimposition of signals from multiple neighboring muscles placed beneath the measured area [56,63,64]. Crosstalk can sometimes be reduced by minimizing the interelectrode distance [34,60,61,64]. Minimal crosstalk areas for electrode placement have been described in [52,53]. In general, crosstalk removal remains an unsolved issue [60,64];
- h) electrodes can move relative to the skin and cause signal noise that can be limited through a high-pass filter, although more sophisticated techniques are also available [65];
- i) the assessment of the raw EMG signal does not provide reliable conclusions independently from the assessor. Several parameters extracted from the raw EMG signal [34,64,66-69] are available, including:
- root-mean square (RMS) or average rectified value-ARV as indicators of signal amplitude [34];
- rectified full wave EMG signal [34];
- envelope, as the result of low-pass filtering the full-wave rectified signal [34,64]. With respect to gait at spontaneous cadence, the cutoff frequency appears to be 9 Hz [34,64]. Descriptors can be calculated from the envelope [34,64,67]; the exact type of filter,

order and cut-off frequency should be declared in the clinical report;

 on/off detection: estimation of the time intervals in which the muscle is active (on) and inactive (off) with respect to resting values [66,69-71].

4.5. Question 2.5: is it necessary to adopt a standard procedure for CGA?

Consensus was achieved on the absence of a standard procedure for the execution of CGA, which can explain the differences observed between the results provided by different laboratories. A standard procedure must consider the following aspects: 1) reconstruction of skeletal movement during gait, 2) estimation of inertial parameters of body segments, 3) measurement of external forces, 4) timing and amplitude of muscle recruitment, 5) use of metrics for the description of gait mechanics (i.e. the conventions for the representation of the articular kinematics and dynamics). The understanding of gait in normal subjects and patients would benefit from the availability of public databases. The following sections describe further consensus points that might facilitate the definition of such standard procedure.

4.5.1. Reconstruction of skeletal movement during gait

Five review papers [12,28,29,72,73] have been published that provide a comprehensive review about a) bone pose estimation, b) the extraction of quantitative kinematic and kinetic variables from stereophotogrammetry and force platforms, and c) the effect of soft tissue artifact.

Consensus exists on the use of Anatomical Coordinate Systems calculated through "anatomic calibrations", based on the coordinates of at least three anatomical landmarks. In some cases, functionally defined centers and/or axes of rotation can be used as well. This approach is viable when there is a constant and generalizable relationship between anatomy and function among individuals, such as for the hip center of rotation [74,142].

4.5.2. The estimation of inertial parameters of body segments

Estimations of inertial parameters for each body segment is made possible by adopting anthropometric models and regression equations [75–81]. Given the small accelerations typical of gait, consensus was achieved on the limited effect of the uncertainty in body segment parameters estimation during gait dynamics assessment. However, some attention must be paid to the prosthetic leg of amputees during the swing phase, as a direct measure of the inertial parameters of the prosthesis may be required in this case [82].

4.5.3. The metric for the description of gait mechanics

CGA should assess if the patient fulfills three fundamental aspects of gait, namely: 1) physical exertion, 2) maintenance of balance, and 3) preservation of the structures of the musculoskeletal system. Consensus was reached on the absence of CGA variables that can summarize all these determinants. It is therefore recommended to support research efforts aimed at defining such a metric [83].

4.5.4. Normative data

Normative data should be available [143] for the interpretation of CGA results of a given subject. According to the literature [84] normative values based on mean and standard deviation, for every phase of gait, lead to an underestimation of the actual intra-session and intersubject variability. This stems from the assumption of a normal distribution of data and from considering the points of a curve as unrelated. The literature supports the adoption of modern statistical techniques, such as Bootstrap, that allow to overcome these methodological pitfalls [84,85].

4.5.5. Reference population

It was agreed that when the goal of the analysis is the assessment of functional limitations, the reference population for a patient should comprise asymptomatic subjects with the same sex and belonging to the same age range (e.g. childhood, adult, or elderly). It is therefore necessary to give the operators normative data following the same logic [86]. It should also be possible to compare data collated on persons with different anthropometric characteristics [144,145]. While it might be plausible to have separate normative data for people with normal weight and obese, within each of these categories normalization by body mass and stature appears sufficient.

4.5.6. Pace (step cadence)

Gait can be achieved using different paces. The most obvious distinction is given by the speed of progression. Therefore, normative data must be provided for speed classes. It should also be noted that an individual's rate of progression correlates with the height. It follows that also the speed parameters should be subjected to normalization [85,86,144]. Of course, care should be taken in treating the EMG vs speed correlation, as reported in [146,147].

5. Area 3: scientific evidence and clinical appropriateness

5.1. Question 3.1: what are the clinical conditions suitable for clinical gait analysis?

Despite the large number of studies in which GA was performed, cerebral palsy, acquired lesions of the central nervous system (stroke, degenerative diseases, trauma) and prostheses in lower limb amputations are the only clinical conditions for which published literature of sufficient quality is available to support the use of CGA as a diagnostic or prognostic tool [1,9,15,16,87–126] (see also Annex 4 in Supplementary material). Moreover, with the exception of cerebral palsy (CP), the published observations relate to isolated cases or to a very limited number of patients.

5.2. Question 3.2: what are the effects of gait analysis on decision making?

Following a careful evaluation of the available literature, the following statements have been agreed upon:

- 1. In *cerebral palsy*, the use of GA combined with an expert clinical evaluation can influence the planning of functional surgery, leading to modification of the clinical decision in case of disagreement or reinforcing the decision in the event of agreement (*class I, level of evidence B*)[16,86–91,94,95,97–99,101–106].
- 2. In *adult brain injuries*, the use of GA combined with an expert clinical evaluation can influence the planning of functional orthopedic surgery, neuromuscular blocks and/or rehabilitation programs (*class I, level of evidence C*) [93,96].
- 3. In patients wearing prostheses after lower limb amputations the clinical utility of GA, albeit reasonable, still remains to be proven (class III, level of evidence C); however, this does not preclude its use for scientific research, for choices regarding the construction of the prosthesis and for the planning of general models of rehabilitation [88,100].

5.3. Question 3.3: what are the effects of CGA on outcome?

The efficacy of CGA on two specific aspects of outcome assessment have been analyzed:

The individual clinical outcome, intended as the impact of CGA on treatment decisions and, indirectly, on the evolution of the deficit [16,90,91,97,99,101-103];

The social outcome made by the consumption of health care resources [111].

Table 4 Recommendations for research activity.

1. Future clinical trials should contain a precise definition of the study population, in order to allow analysis on homogeneous groups of patients in terms of etiology, clinical features, time interval between the onset of the disease and intervention being studied, and patients subdivided by age group.

- 2. The studies must include patients realistically representing clinical practice and a number of subjects appropriate to the objectives proposed, in order to ensure a proper analysis of significance and generalizability of the results obtained.
- 3. Randomized controlled trials are advocated to test whether, compared to conventional treatment plans, the support of gait analysis in the decision-making process improves the benefits of the already available treatments, and it is recommended that outcome measures include both functional aspects of gait and degree of satisfaction of patients and their care-givers. Where RCTs could not be performed (for ethical or organizational reasons) prospective cohort studies with long-term observation should be planned and organized.
- 4. The studies must include follow-up at an appropriate time interval according to the different conditions and the considered treatment. In case of evaluation of surgical interventions, studies must include also follow-up at a distance greater than one year after surgery.
- Cost-Benefit Analyses shall provide data on the appropriate cost/benefit ratio in the use of gait analysis in relation to different levels of complexity of the therapeutic decision-making (functional surgery, neuromuscular blocks, and rehabilitation plans).

5.3.1. Individual clinical outcome

- 1. In *children with CP* the use of CGA combined with an expert clinical assessment is capable to favorably influence the outcome of functional surgery (*class I, level of evidence B*).
- 2. In *children with CP* there is no sufficient evidence that the use of CGA combined with expert clinical evaluation may improve the outcome of patients undergoing non-surgical treatments (neuromuscular blocks, rehabilitation programs) (*class IIb, level of evidence C*).
- 3. In *adult patients with acquired brain injuries* there is no sufficient evidence that the use of GA combined with expert clinical evaluation can improve the outcome of patients undergoing functional surgery (class IIb, level of evidence C).

5.4. Consumption of health care resources

The use of GA can result in savings of resources for the health care of CP. No conclusion can be drawn about the other clinical conditions examined (*class IIa*, *level of evidence C*).

6. Recommendation for future research

The lack of adequate scientific documentation for the correct use of GA in clinical practice stands in contrast with its high potential as a tool for scientific research. Therefore, the Jury formulated several recommendations for future research. These are summarized in Table 4.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.gaitpost.2017.08.003.

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