Rethinking Domain Generalization Baselines

Clinical gait analysis: a gender medicine perspective

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***Abstract*—Gait measurements are conducted in highly specialized human motion laboratories to monitor different kinds of locomotion pathologies. A data-driven, personalized approach to medicine requires that clinical gait analysis is conducted taking into account the sex/gender of the subject(s) under investigation. The aim of this contribution is to increase the awareness about the importance of a gender perspective in clinical gait analysis. An example is provided to explain why a clinical gait dataset from chronic low-back pain patients should be re-analyzed through a gender lens.**

Keywords—Locomotion, walking, biomechanics, human movement, gender-specific medicine.

I. Introduction

Clinical gait analysis is used as a routine part of patient management in hospitals and medical centers providing high standard services. It is a special instrumented investigation of gait, which added to the clinical history, physical examination and other investigations, provides a detailed assessment of a patient with a walking disorder. Indeed, gait analysis employed in the clinical setting allows for a more accurate assessment of gait deviations than the simple visual assessment of a patient's locomotion abilities [1]. Measurements of spatio-temporal gait parameters (cadence, duration of gait phases, double support), kinematic analysis of the knee, ankle and hip joints, and non-invasive electromyography (EMG) of the muscles involved in walking can be performed.

Besides its use in treatment decision-making, clinical gait analysis is widely accepted as a unique research tool to carry out longitudinal studies on specific cohorts of patients, since it can provide quantitative outcome measures at different time points. Hence, not only it may be useful in the follow up of a single patient, but also for objectively evaluating the effectiveness of surgical alternatives, therapies, or rehabilitation programs, as evaluated on specific populations of patients.

Gender medicine is an emerging research area, that is introducing new awareness on how diseases differ between women and men in terms of prevention, clinical signs, therapeutic approach, prognosis, as well as psychological and social impact [2]. Until recent years, this has been a neglected dimension of medicine.

Although there were pioneering work in gait analysis, motivating the development of separate biomechanical reference databases for males and females [3], this suggestion has remained largely unapplied.

The author of the present work dedicated many years in acquiring, processing and interpreting gait signals from patients affected by different neurological diseases (Parkinson [4], cerebral palsy [5][6], multiple sclerosis, mild ataxia [7], normal pressure hydrocephalus [8]) or other conditions altering locomotion patterns (diabetes [9], total hip arthroplasty [10], total knee arthroplasty [11]). After all the time spent in close contact with patients, mounting EMG probes and other sensors on their bodies and monitoring their gait patterns, always working side-by-side with the clinicians that were curing them, this contribution aims to share some first considerations about the opportunity of using a gender-specific approach to clinical gait analysis. The focus is on the fact that the data analyses might be incomplete, or biased, if patients' gender is not taken into proper consideration.

II. Comparing the Incomparable

A. Gender matching

In a large number of clinical studies, it is considered appropriate to balance gender in the datasets. As an example, to obtain a "sound" experimental protocol that involves 20 subjects, an equal number of females (F) and males (M) are recruited in the study (10 F and 10 M).

On the other hand, if a pathological ("experimental") population has to be compared with a control ("reference") population of healthy individuals, these latest subjects are selected to be gender-matched (as well as age-matched) with respect to the patients of the experimental population. As an example, if the experimental population include a total of 60 subjects, among which there are 20 F and 40 M, the control population should also include 20 F and 40 M. By the way, this is not always easily obtainable from a practical point of view. Indeed, in clinical studies, patients' caregivers are frequently enrolled as control subjects for practical reasons, since they are "already available", and most often accompany the patient at the experimental site. Wives/husbands/partners are preferably involved as control subjects, rather than daughters/sons or parents that would not be age-matched with respect to the patients analyzed. However, in pathologies with a clear gender-difference in prevalence it may be difficult to form a gender-matched control group, solely based on patients' caregivers. As an example, a significantly higher incidence rate of Parkinson's disease was found among men with the relative risk being 1.5 times greater in men than women. This means that the experimental group will typically include a higher percentage of men, while the control group will mainly include female subjects (wives/partners of the patients). Therefore, the experimental and reference groups will not be gender-matched. This may cause a bias in data interpretation, particularly in those studies that relies on gender-dependent measurements.

However, even when clinical protocols adopt a gender-matched design, after data collection, researchers frequently do not analyze the data separately for females and males, nor they estimate the possible dependencies of their data on sex/gender. Usually, the focus remains at the "group" level, e.g. comparing pathological and control populations as a whole (without distinguishing data from women and men).

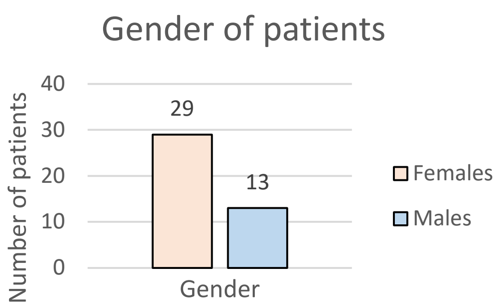

Fig. 1. Gender of chronic low back pain patients, desumed a-posteriori from their first names.

This may preclude important knowledge discovery in the gait pathophysiology of female and male patients. By the way, it is worth noticing that gait biomechanics is intrinsically different between women and men, even from a merely "physical" point of view, due the average difference in their height, leg length, as well as in the structure of the main lower limb muscles. In spite of that, the great majority of clinical gait studies, perform averages across the whole population (pooling males and females together), hiding any possible gender-effect. Only a few studies specifically focus on gender differences, but only related to healthy (reference) populations of adults or children [12][13][14]. There are scarce reports of gait measurements separated by gender in pathological populations.

B. *Gender mismatch in biomechanical data: when it is more convenient to sweep the dirt under the carpet.*

In some cases, researchers are perfectly aware that they have not collected data in a gender-matched manner, for many different practical reasons. Afterword, the same researchers typically analyze the data, and write an article draft, seeking for a rapid publication in a peer-review journal, constricted in a "publish-or-perish" routine. In this context, they can decide to bypass the gender-matching problem, by simply avoiding declaring the sex/gender of the patients included in the study. If none of the reviewer will notice/criticize the lack of data relative to gender matching, the submitted article might proceed towards the last publication steps. Future studies may try to quantify this phenomenon.

C. *An example of clinical gait data that should be re-analyzed taking into account gender*

Low back pain affects millions of people worldwide, but little is known on how specific gait alterations may concur to its insurgence and persistence over time.

Starting from the author's own experience, a specific clinical gait study carried out on a population of patients affected by chronic low back pain is critically revised using a gender perspective.

The study in question was designed to investigate the gait alterations in a sample population of chronic low back pain patients and to demonstrate the effectiveness of the medical care they received [15]. Revising that work, it emerged the following:

- In the Methods section it was stated: "We analyzed a population of 42 patients that had physiatrist examination and rehabilitation treatment. Patients have been examined (in basal conditions and after rehabilitation and physical therapy) through the Visual Analog Scale (VAS) score - for the intensity of the perceived pain - and by means of gait analysis with the system Step32, DemItalia, Italy. They were equipped with foot-switches and knee goniometers and were asked to walk for 2.5 minutes at their natural pace, and then, after a resting period of 3 minutes, to walk again for 2.5 minutes at a higher pace (as fast as they could, still feeling safe). Foot-switch signals were converted to four-level signals, and finally processed by an algorithm able to classify the different gait cycles used by the subject."
- In the Results Section it is stated: "More than 71 % of patients showed a tendency to walk with the knee extended during the load acceptance phase (Fig. 1). Therapy was successful for 15 patients that reduced this tendency. Of the remaining patients, 23 did not change their walking style, while 4 worsened it. Moreover, as shown by Fig. 2, patients significantly improved their cadence when walking at self-selected speed (paired t-test, p = 0.0019)."
- In the Discussion Section it was stated: "The VAS score showed a decrement of pain severity in all the patients, but this element resulted to be uncorrelated with the quantitative improvements demonstrated by gait analysis. Gait analysis made possible the documentation of changes in the walking style of patients, thus not limiting the evaluation of the therapy outcome to the subjective decrement of pain that patients reported."

As it can be observed, there is no mention to the number of female and male patients included in the study protocol. The clinicians subsequently enrolled all the patients that were seeking care at the healthcare facility for chronic low back pain. However, nothing was reported/analyzed related to the patients' gender.

In the present contribution, after inferring the gender of the patients from their given names, it was possible to label, a-posteriori, the female and male subjects belonging to the population. The number of female/male patients is shown in Fig. 1.

Then a statistical analysis was applied to establish if the number of females and males belonging to the experimental population was different (significance level $\alpha = 0.05$). In particular, a χ-square test was applied, using the Excel function CHISQ.TEST, as shown in Table I.

The statistical test performed showed that the number of females is significantly different from the number of males seeking care for chronic low back pain ($p<0.05$) in the examined population. In particular, it is evident that a higher number of females (29 patients) suffered from chronic low back pain with respect to males (13 patients).

TABLE I. STATISTICAL ANALYSIS: χ-SQUARE TEST

Sex/ Gender	Table Column Head		
	Observed	*Expected*	*p-value*
F	29	21	CHISQ.TEST(Observed_range, Expected_range)[a] = 0,0135
M	13	21	
TOT	42	42	

[a] Excel function: CHISQ.TEST

This gender-related information was completely missing in the previous analysis of the dataset. From the above considerations, it is evident that the dataset should be re-analyzed to take into account this important information. The gait data should be re-calculated separately for females and males, while it would be of the uttermost importance to include this gender perspective in the interpretation of the results.

It is worth mentioning that in anonymized datasets, collected after EU general data protection regulation 2016/679 (GDPR), it may be impossible to retrieve the gender information from the first name of the patients. This issue should require additional attention from the scientific community.

III. CONCLUSIONS

Gender awareness raising is important in clinical gait analysis to avoid biases in data interpretation.

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