Wireless Instrumented Crutches for Force and Movement Measurements for Gait Monitoring

Emilio Sardini, Mauro Serpelloni, and Matteo Lancini

***Abstract*— This paper describes the design, development, and characterization of two wireless instrumented crutches for gait monitoring in order to provide clinicians quantitative parameters of upper limbs' contributions during walking. These parameters could be used to teach orthopedic patients to correctly use these supports and minimize problems connected to their usage. These instrumented crutches allow monitoring axial forces and shear forces, tilt angles, and time of impact on the ground in real time. Each crutch is composed of three strain-gauge bridges for measuring axial and shear forces, a conditioning circuit with transmission module, a triaxial accelerometer, a power management circuit, two batteries, and a biofeedback. The data are wirelessly transmitted via Bluetooth without needing any further readout unit, from the crutches to a personal computer, where the data are processed and displayed by a program created in LabVIEW. Each instrumented crutch was tested to assess the response of the accelerometer and the three strain-gauge bridges using a setup designed *ad hoc*. The mean experimental standard deviation was about 42 mV for axial forces corresponding to about 8 N and about 35 mV for shear forces corresponding to about 4 N. Hysteresis, linearity, and drift were calculated, and the obtained accuracy was about 8–9 N for axial forces and 4–5 N for shear forces. Furthermore, the crutches were tested during a walking activity of ten healthy subjects along a straight path for several trials. These crutches were used for a common analysis usually reported in the literature for weight bearing evaluation. The subjects were monitored performing a nonweight bearing (NWB) and a partial weight bearing (PWB) during a three-point gait. The results showed a mean of 102% ± 16% for NWB tests and a mean of 19% ± 14% for 10% PWB tests; these values are in agreement with similar studies in the literature. The simplicity that includes only constitutive strain gauges and a separable circuit board allows the achievement of the objectives of simplicity, ease of use, and noninvasiveness. Therefore, these crutches could be used as a support tool for controlling the use of crutches during walking not only in hospitals but also at home.**

***Index Terms*— Accelerometer, assistive healthcare, biomechatronics, biomedical measurements, biomedical transducers, force measurement, forearm crutches, gait analysis, instrumented crutches, instrumented walking aids, limb rehabilitation, strain gauges, tilt monitoring, wireless sensor.**

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I. Introduction

In recent years, new systems, strategies, and protocols for rehabilitation after orthopedic surgical operations are growing, driven by the growth of the elderly population and the necessity to be more effective, for example, reducing costs and maintaining or improving the quality of these procedures. Thus, rehabilitation could allow functional recovery for the subject with less cost to the national health system [1], [2]. Therefore, systems able of giving quantitative parameters for the monitoring of rehabilitation activities after orthopedic surgical operations are having a growing interest. In fact, in order to expedite the rehabilitation period and avoid further and long-term damage to the affected limb, it is becoming important to constantly monitor the patient following his/her rehabilitation activities not only in the hospital but also at home [2]. As reported in the literature, in recent years, new devices have been designed, manufactured, and tested for the monitoring of rehabilitation activities after orthopedic surgical operations; these devices can be part of external measurement systems (wearable, integrated in common objects, etc.). In particular, among the external measurement systems, sensing of walking aids seems to generate numerous benefits for both the clinician and the patient; the instrumentation of a walking aid can provide quantitative gait analysis of orthopedic patients in order to instruct them in the early stage to the correct use. For example, it is widely recognized that excessive loading of the lower limb following certain types of surgery can disrupt the operated tissues and put the healing bones at risk of mal-union [3] the knowledge of the loads ensures that the patient loads their affected limb at the prescribed level [4]. One of the most common mobility aids is definitely the crutch. In fact, the use of crutches for the rehabilitation of a lesion on the lower limb is often adopted in the clinical environment. Forearm crutches are routinely used after many operations for the lower limb (including the repair of fractures and fixation of the prosthesis). It is widely recognized that the improper use of crutches may lengthen the recovery period or even cause further damage [3], [5]–[7]. Usually, in the early stages of rehabilitation performed in the hospital, physical therapists teach the patient to use crutches correctly. The physiotherapist usually carries out the correct execution of an exercise using only visual analysis. Therefore, the perception of the loads on the patient's lower limbs, the movement, the drag, the synchronism, etc., are usually subjected to considerable errors. Analytical techniques for quantitative gait analysis are widely used in the literature in different applications. These include the use of scales or force platforms [8], [9], in-shoe pressure monitors [7], [8], [10], and optical measurement systems [11], [12]. However, such systems allow measuring static positions or dynamic positions for small intervals of time and space. Inertial measurement units could be adopted [13]–[15], but they cannot give direct information on kinetic parameters. If the therapist wants to monitor the use by the patient during a walk for an extended period in various environments (for example, the unbalance of the weight on the two crutches or the position or the dragging on crutches, etc., outside the hospital laboratory), this is typically done only through visual observation without any quantitative analysis. However, the knowledge of quantitative gait parameters during all the day in every contests (home, supermarket, street, etc.) could give the possibility to control the correct crutch use. This can give benefits for both the clinicians and the patients, helping to instruct the patients to the correct use for a faster functional recovery. In the literature, few instrumented aids for walking have been studied. In [16], a system for monitoring vertical forces during walking for patients using sticks is described. This system uses capacitive sensors placed under the soles of the shoes and one optical sensor inside the stick. The information on characterizations and on operations of the stick sensor are not reported. The vertical forces on the shoes are monitored in real time; however, the sensor located on the stick and those placed under the soles of the shoes are connected between them and to a transmission unit placed at the waist of the patient through wires. Another work that uses crutches sensorized with load cells connected by cables to the measuring system is [17]. However, the use of cables on walking aids for a long time could be considered as limiting the movements and invasive; the cabled connections may obstruct patient's movements and make the system impractical at home. In [18], the monitoring system comprises a crutch with wireless sensor, force sensing resistor (FSR), positioned on the tip of the crutch to monitor the contact with the ground, and an inertial sensor to monitor the crutch angle to the vertical. The force measurements are not considered. The sensorized crutch is part of a more complex system that allows monitoring and controlling the movement of an exoskeleton. The FSRs are also used in [4]; in this work, wireless sensorized crutches allow monitoring the axial load, the position of the hand on the handle, and the angles. However, as also reported in [4], FSRs have several problems for gait analysis and require periodic calibration activities. This may be a limitation for use in nonhospital environments if the clinicians require accurate data for the quantitative gait analysis using the crutches. In addition, in all the previous devices, some functions that clinicians consider important are not implemented, such as the measurement of shear forces that can provide an important indication regarding their use. These forces provide a better understanding of the reaction forces of the crutches on the ground and then they permit to monitor any nonaxial forces, any drag of crutches, unwanted loads on the elbows, etc. In the literature, the gait analysis of orthopedic patients is usually executed in laboratory with optical systems and/or force plates or instrumented mats, as reported previously. Using these techniques [6], [17], [19], the common kinematic and kinetic quantities identified for gait analysis are those able to study the biomechanical dynamic movements, such as crutch movements (positions, angles, velocities, and accelerations) and forces acting on the crutches (the values of the vertical component, the horizontal anterior–posterior component, and the horizontal medial–lateral component of ground reaction forces to lower limbs or identification of weight bearing asymmetry of the crutch). Therefore, in the proposed solution, we chose to measure, in real time, tilt angles, walking period, and axial and shear forces representing the vertical component, the horizontal anterior–posterior component, and the horizontal medial–lateral component of ground reaction forces to lower limbs. Furthermore, the crutches are easy to use and simple to set up, in order to reach the acceptance of patients and therapists. In [20], the proposal of instrumented crutches has been presented and a brief description of the operation is shown along with few preliminary results. On the other hand, this paper describes, comprehensively and in detail, the design, development and characterization of the two proposed crutches that are instrumented with wireless sensors; the operation and the conditioning circuit are clearly detailed, the block diagrams are shown, then both instrumented crutches have been tested extensively, and the results are analyzed. Each crutch is composed of three strain-gauge full bridges, a conditioning and transmission circuit, a triaxial accelerometer, a management circuit for the batteries, and a biofeedback. These instrumented crutches allow monitoring axial and shear forces, antro-posterior and medio-lateral angles, and walking period, in real time. The data are wirelessly transmitted via Bluetooth to a computer, without further additional readout unit. The therapist can observe the data of the crutch in real time using the LabVIEW graphical user interface (GUI) on a remote computer, while the patient can receive a biofeedback using a vibratory notification when the shear loads exceed a threshold, indicating the imbalance of weight on a different level from the sagittal. However, the biofeedback operation can be changed easily; the physiotherapist can prefix either the thresholds or any other specific events that could occur. Thus, the instrumented crutch can provide clinicians and patients a tool to objectively monitor and receive feedback on the use. These instrumented crutches are different from those previously researched and developed to be less invasive (requires no additional equipment to be attached to the patient or the shoes, as all the electronics are connected to the crutch). These instrumented crutches can be used both for clinical training and for long-term home monitoring. Furthermore, the instrumented crutches allow monitoring the inclination with respect to the ground and the time of impact of the crutches with the ground. In addition, a biofeedback signal can be set by the physiotherapist, who has in charge of the identification of the threshold values of the measured quantities activating the biofeedback. Therefore, the proposed wireless instrumented crutches can provide quantitative data for gait analysis of orthopedic patients in order to instruct them in the early stage to the correct use. These crutches can be a

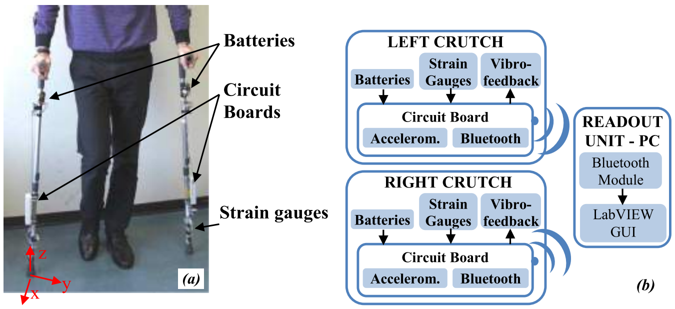

Fig. 1. (a) Picture of the wireless instrumented crutches. (b) Block diagram.

viable solution for patient monitoring for the entire recovery period including its potential use in the home environment. The description of the wireless instrumented crutches and the preliminary experimental results are reported in the following.

II. Wireless Instrumented Crutches' Description

In Fig. 1(a), an image of a person using the instrumented crutches is shown. These two crutches have an identical architecture, and therefore, both crutches can be used simultaneously or each crutch can be used individually. Each instrumented crutch [Fig. 1(b)] consists of: 1) strain-gauge bridges for measuring axial and shear forces; 2) a circuit board, which integrates a triaxial accelerometer used as a tilt sensor and detects the impact on the ground; 3) a conditioning circuit for processing the signals and wirelessly transmit data to a readout unit; 4) a battery power supply; and 5) a vibratory biofeedback. In the presented configuration, a personal computer (PC) equipped with a Bluetooth module was used. However, any device with Bluetooth can be used for receiving data and managing the crutches. A program in LabVIEW has been developed for the simultaneous management and visualization in real time of the received data from the two crutches. The power supply of the crutches is by means of batteries, and each crutch is independent of the other in terms of energy. The crutches are developed using commercial components to minimize the potential cost.

A. Sensors' Implementation Description

The axial and shear forces are measured by 12 strain gauges integrated in each crutch and connected in Wheatstone bridge configurations to form three full bridges. The strain gauges are marketed by RS, RS 2 mm with a gauge factor (G) of about two. Each strain gauge has a resistance of 120 Ω and size 6×2.5 mm (active length: 2 mm). As shown in Fig. 2(a), the crutch is usually composed of two tubular elements that are used to adjust the height depending on the patient's height. The two elements are fixed together by a pin. Since the forces on the crutch due to reaction forces with the ground are mainly developed in the lower part, the strain gauges were positioned on the second portion at distances of about 15 and 6 cm, respectively, from the ground [Fig. 2(b)]. The strain gauges were mounted on the bottom of the crutch with an ethyl-based cyanoacrylate adhesive (commercialized by Omega), and then covered with a viscous putty (AK22 commercialized by HBM)

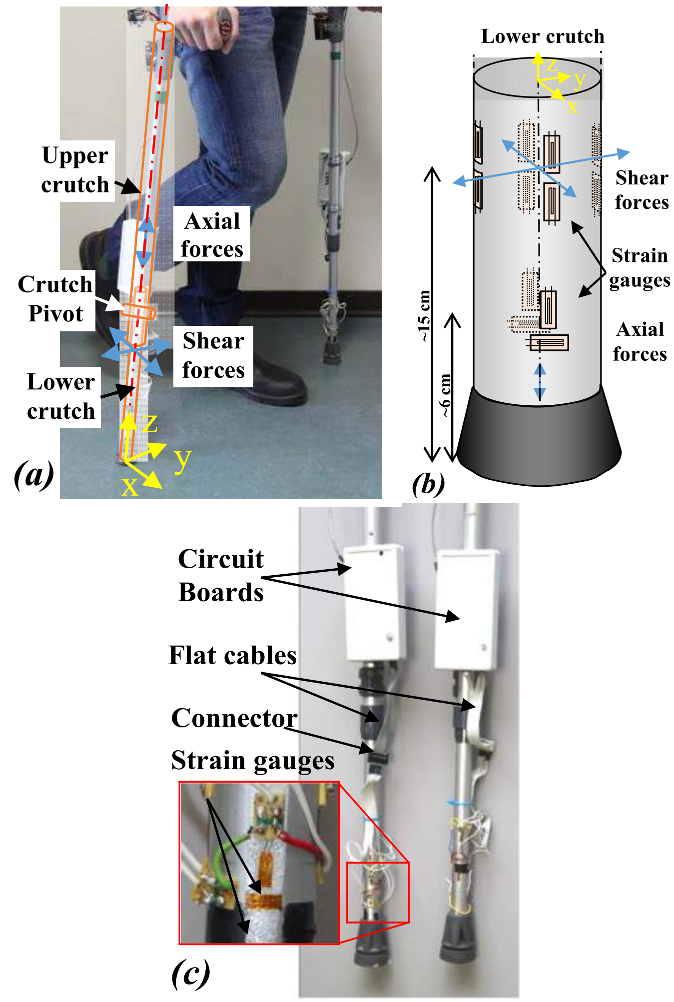

Fig. 2. (a) Crutch constitutional elements and forces. (b) Image of the strain-gauge positions. (c) View of mounting solution.

to preserve the integrity from accidental impacts. A flat cable then connects the bridges and a multipole connector to the circuit board attached to the second part of the crutch [Fig. 2(c)]. Each bridge allows measuring a force as shown in Fig. 2(b) and (c); the opposite position of two strain-gauge bridges allows measuring the shear forces relative to the ground both in the zx plane and in the zy plane.

The tilt angles and the ground impact recognition are measured using a triaxial accelerometer (LIS3LV02DL-STMicro). At this stage, some design considerations have been made. In the clinical environment, physical therapists teach patients to use crutches to a safe speed (0.4 [4], 0.3 [16], and 0.6 steps/s [17]), which is slower than normal walking speed. This ensures that the movement of the crutch is almost exclusively characterized by a static acceleration (acceleration of gravity 9.81 m/s^2) that is predominant on dynamic accelerations (acceleration due to a rapid change of the speed), which are less than 1 m/s^2 [21] and in basic analysis neglected [4], [22]. Therefore, it is possible to monitor the crutch angle monitoring the vector acceleration of gravity with the triaxial accelerometer. This is true for the entire step cycle except for the time at which the crutch hits the

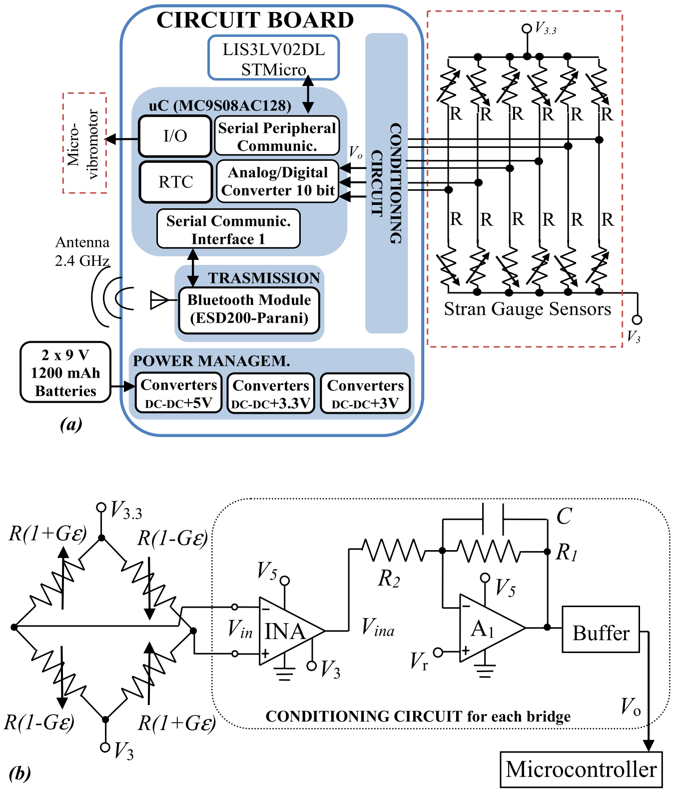

Fig. 3. (a) Block diagram of the circuit board for each wireless instrumented crutch. (b) Schematic of the conditioning circuit for each bridge.

ground. In this case, the spikes due to the shock have a short duration of about 60–70 ms with amplitudes of about 6 m/s^2. Therefore, the presence of these spikes can be minimized using a low-pass filter as reported in Section IV. However, it is possible to exploit this phenomenon to monitor the time at which the crutch impacts on the ground, and then it is possible to calculate the time between two consecutive impacts representing the cycle time of crutches movement during a single step. Therefore, this was implemented by looking for the impact of the crutch with the ground. With the aim to study the spikes due to the impacts, an analysis on the raw data was made considering all the tests carried out on the subjects that participated in the experimental phase. The tests allowed evaluating the spikes characteristics, having an average value of 6.2 m/s^2 with an experimental standard deviation of about 1.2 m/s^2. Therefore, the crutch impact with the ground is implemented in the system by identifying the point of passage over a fixed threshold value. In the presented configuration, we tested a threshold of 4 m/s^2; however, this value is not critical; in fact, even lower values of about 2–3 m/s^2 can be adopted.

B. Hardware Architecture of the Instrumented Crutches

Fig. 3(a) shows the block diagram of the circuit board for each wireless instrumented crutch. An 8-bit microcontroller (S08AC128-Freescale) deals with the operations of conditioning, conversion, and management of communication with the accelerometer. The force signals are acquired using the integrated 10-bit analog-to-digital converter (ADC). The microcontroller programs and manages the triaxial accelerometer via serial peripheral interface (SPI) communication, whereas the wireless data communication to the host computer is achieved using serial communication interface communication to a Bluetooth module. The Bluetooth (ESD200) is marketed by Parani, and it is connected to an antenna integrated on the printed circuit board. Two batteries are implemented for having high strength and low volumes, and they are connected in series for powering each crutch. The two batteries have 9 V and 1.2 Ah each. This configuration permits a continuous operation for one day or interspersed throughout more days; this allows utilization outdoors as well. The battery voltage is regulated by a dc–dc regulator (TPS62163), which allows having a fixed voltage of +5 V for the circuit board power supply (microcontroller and conditioning electronics for the sensor signals). This component is a switcher power converter with a high-efficiency of about 95%, permitting low power dissipation. Furthermore, this solution allows having a high range (from 0 to 5 V) for the force sensor signals. However, two components (transmitter and accelerometer) have a power supply of 3.3 V. Therefore, a dc–dc regulator (LM3670) of +3.3 V is used to power the transmitter and the accelerometer. This component is also a high-efficiency step-down regulator (about 95%). The use of the two step-down regulators, switch type, allows maintaining high conversion efficiency.

The conditioning circuit of each bridge is composed as in Fig. 3(b). Aiming to reduce the current required to power supply each bridge, we chose to reduce the voltage supply of the bridge. However, the two fixed voltages of 5 and 3.3 V were not sufficient, because the power supply between the voltages 5 and 3.3 V was still high. Therefore, we choose using a high-efficiency (about 98%) dc–dc regulator (TPS62698) of 3 V to have a fixed voltage supply of the bridge and a fixed reference for the conditioning circuit. Thus, the four strain gauges are connected in full bridge and supplied between the voltages V3.3 = 3.3 V and V3 = 3 V. With this configuration, we avoided to add resistors that could increase the signal noise. Having the strain gauges a nominal resistance of about 120 Ω, the current is 1.25 mA for each bridge branch. Considering Fig. 3(b), the amount of relative resistance variation is $G\varepsilon$, where G is the gauge factor and ε is the mechanical strain. This results in a maximum unbalance bridge voltage V_{in} given by the following approximated expression:

$$V_{\text{in}} \propto (V_{3.3} - V_3) \cdot G\varepsilon. \tag{1}$$

A high amplification is necessary. All the conditioning circuits are powered from 5 to 0 V with the aim to have a high range for the force sensor signals. The full bridge is connected to an instrumentation amplifier marketed by Texas Instruments, INA118. The INA118 is a low-power general-purpose instrumentation amplifier offering excellent accuracy. Since the shear forces generate imbalances of the bridge in both directions, it is chosen to keep the reference to a dc–dc regulated voltage of 3 V. This allows having at the output (V_{ina}) a voltage of about 3 V when the bridge is balanced. In the following, the relationship between unbalanced bridge voltage (V_{in}) and INA118 output (V_{ina}):

$$V_{\text{ina}} = A \cdot V_{\text{in}} + V_3. \tag{2}$$

The gain (A) is set to about 10 000. The next stage is an active filter of the first order obtained with the amplifier TLV2264 marketed by Texas Instruments. The amplifier is supplied between +5 V and ground. The capacitor $C = 200$ nF allows obtaining a cutoff frequency of about 40 Hz. The cutoff frequency of 40 Hz allows the suppression of noise components due to power lines and transmissions in high frequency that can be addictive to the signal in the upstream part of the circuit, which has not been possible to shield. The two resistors $R1$ and $R2$ allow the gain adjustment permitting a regulation of the output signal proper for the ADC acquisition. In fact, the shear forces can imbalance the bridges in both directions, whereas the axial force is just in one direction. Since the power supply is between +5 V and ground, the voltage V_r is used as the reference for the signal in the condition of balanced bridge

$$V_o = -\frac{R_1}{R_2} \cdot \frac{1}{1 + j\omega R_1 C} \cdot V_{\text{ina}} + \left(1 + \frac{R_1}{R_2}\right) \cdot V_r. \tag{3}$$

V_r is obtained using the fixed voltage reference of the 3 V dc–dc converter and adjustable through a voltage divider. In this phase, the signal of the bridge was amplified 10 000 times, and therefore, only a simple level adjustment is required to make it compatible with the dynamic input of the ADC. The output voltage from the active filter is input to a buffer stage obtained with a voltage follower with the amplifier TLV2264. Then, the output signal from the buffer is sent to the input channel of the microcontroller ADC.

C. Software Architecture of the Instrumented Crutch

The firmware is written in C language using the CodeWarrior software offered by Freescale. The firmware implemented in the crutches is identical for both crutches, hence the system still works correctly if the crutches are exchanged. In Fig. 4(a), a schematic associated with the activities of the acquisition and transmission is shown. Initially, the firmware loaded into the microcontroller executes the initialization of variables and peripherals, including Bluetooth initialization. Once connected to the readout unit (PC), the program performs a cycle of fixed duration (30 ms) in which the program reads the data from the accelerometer, acquires the signals from the three bridges, performs a simple algorithm to enable or not biofeedback, and sends data to the Bluetooth for transmission to the PC. The Bluetooth allows a communication (serial port profile) between circuit board's Bluetooth and PC's Bluetooth. All the data are communicated only with a serial number in order to evaluate on PC if there was a loss of data. If required, the communication can be interrupted by the user interface also used for recording and displaying the data from the crutches in real time. The measuring cycle, where each value of the sensors is conditioned, acquired, and transmitted to the reading unit, has a length of slightly less than 30 ms [Fig. 4(b)]. From Fig. 4(b), it is noted that the system can then take less than 30 ms to perform the operations of acquisition and transmission. The microcontroller after sending the data is placed in sleep mode waiting the interrupt that wakes up and restarts the cycle. This saves energy, which in the case of domestic applications can be important. To further reduce energy consumption, the communication to the host computer with the Bluetooth positioned in the crutch could not be enabled for applications in open environment or when it is not required the data transmission, but only the operation using biofeedback.

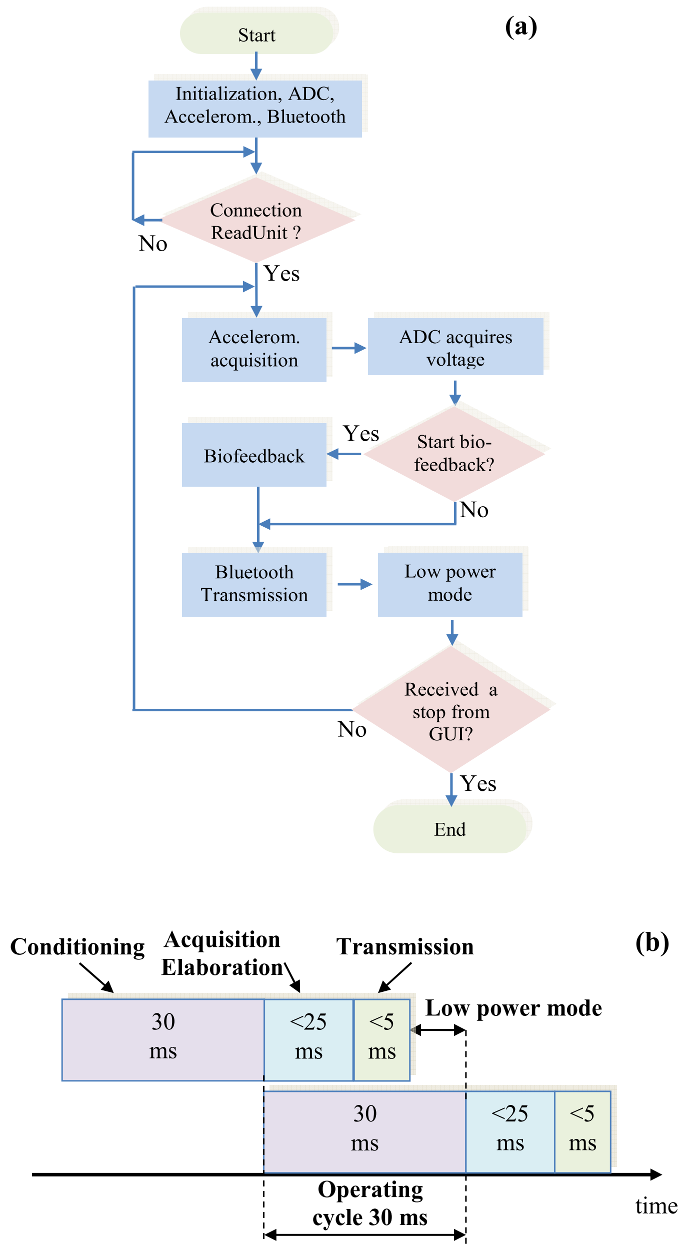

Fig. 4. (a) Schematic flowchart associated with the acquisition and transmission activities. (b) Schematic of an operation cycle.

In the implemented version, an example of possible operation of the biofeedback has been done. The biofeedback algorithm implemented on both crutches is structured to warn the patient of a possible excessive shear force, arising when there is the imbalance of weight on a different level from the sagittal, for example, due to the drag of crutches, patient

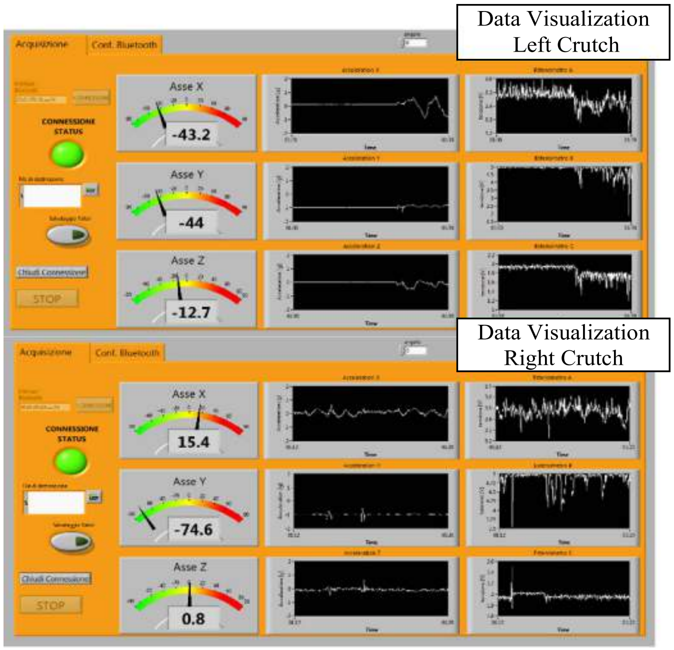

Fig. 5. Image of the realized LabVIEW GUI.

gait instability, excessive loads on the elbows, and so on. To do this, it is necessary to program in advance the reference thresholds at which the physiotherapist wants the biofeedback activated. These parameters can be different for each patient and dependent upon their clinical trials. Therefore, it is the responsibility of the physiotherapist and the doctor to previously define the thresholds that will be programmed into the crutch. The operation is simple; when the two signals coming from the bridges for the measurement of shear forces are acquired, they are compared with the threshold value preset. If the threshold is exceeded, a simple micromotor placed on board of the crutch is activated to provide biofeedback to the patient. This algorithm is continually repeated for both crutches for each program cycle.

D. Readout Unit

In the developed application, the readout unit is a PC that uses a commercial Bluetooth module for the data communication. However, the developed crutches can interface with any commercial Bluetooth module (smartphone, tablet, etc.). The software Virtual Instrument (VI) implemented in a PC is designed using LabVIEW marketed by National Instruments. In Fig. 5, an image of the GUI is shown. The VI can run on any computer allowing managing the communication and saving and displaying the received data. When the exercise is completed, the program allows the shutdown of Bluetooth communication. If necessary, all the received data can be saved to a file for further processing.

Some features of the measurement system are shown here accompanied by design considerations. As reported previously, the operating cycle is about 30 ms; this time, with respect to the execution time for any walking exercise involving crutches, which is always slow, allows considering a real-time acquisition of the monitoring of forces and inclinations.

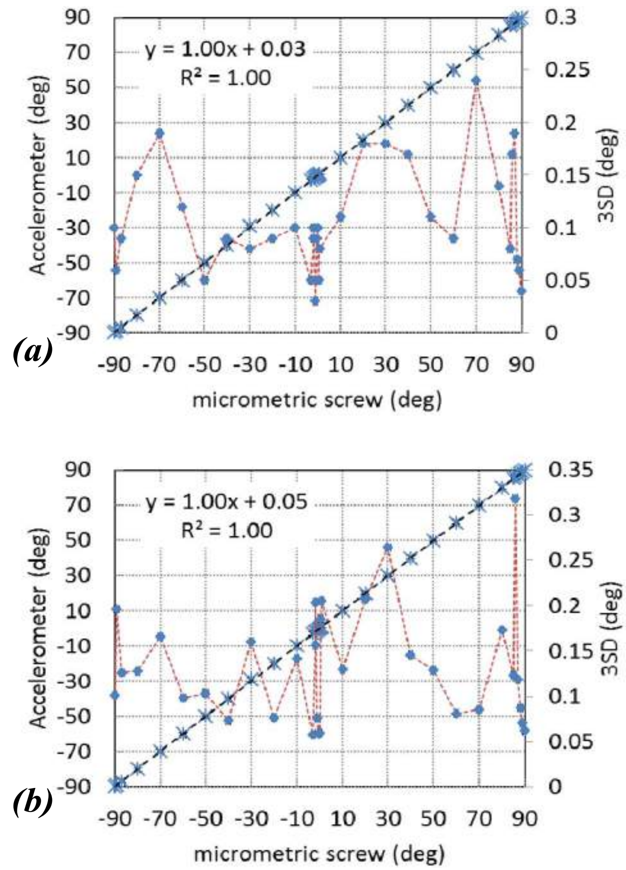

Fig. 6. Antro-posterior angle tests, mean (green dots), and standard deviation—3SD (blue squares) for the (a) left crutch and (b) right crutch.

In addition, the maximum transmission distance between the crutches and the readout unit has been tested up to 10 m in both the open and closed environments, allowing ample space for the subject and no constraints on the position of the readout unit. These features, combined with the simplicity of the proposed crutches that do not influence the subject movements, make the proposed wireless instrumented crutch a valuable aid in monitoring motor exercises during walking.

III. Experimental Setup

Each instrumented crutch was tested to assess the response of the accelerometer and the three strain-gauge bridges using a specifically designed setup. In Fig. 6, the tests conducted on the measurement of angles using the two crutches are reported. The crutches were mounted on a mechanical structure capable of rotating and connected to a micrometric rotation stage (860–0155) commercialized by EKSMA, having a rotation range of 360°, resolution of 0.03°, and reading accuracy of 0.03° for the control of angular positions. The tests were done in static, blocking the mechanical structure to the desired angle and reading the output from the accelerometer for a period of 2 min, totaling 4000 samples. In Fig. 6, as can be observed, the R^2 values are 1.0 and the calculated experimental standard deviation is always below 0.35° for both the crutches. From the data in Fig. 6, the nonlinearity referred to the straight line obtained by least squares is

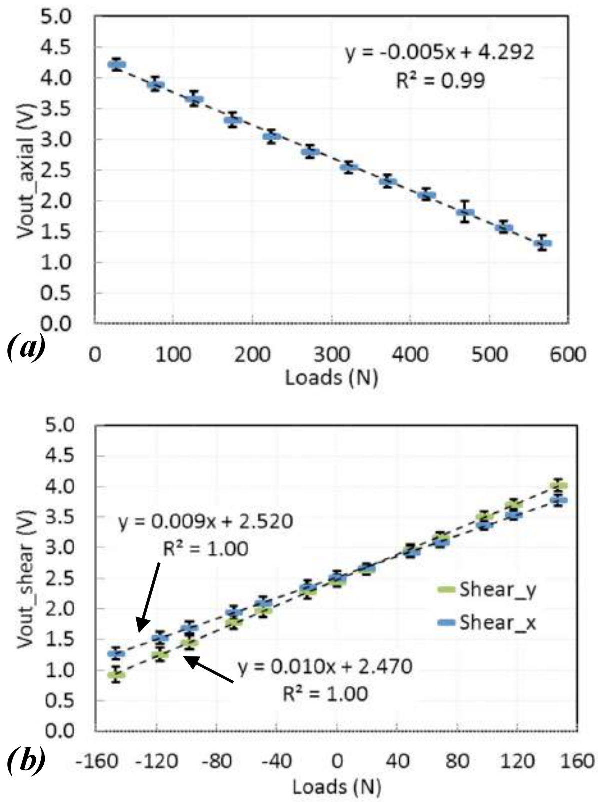

Fig. 7. (a) Axial force tests, conditioning circuit output voltages versus mechanically applied loads (mean and 3SD)—left crutch. (b) Shear force tests, conditioning circuit output voltages versus mechanically applied loads (mean and 3SD)—left crutch.

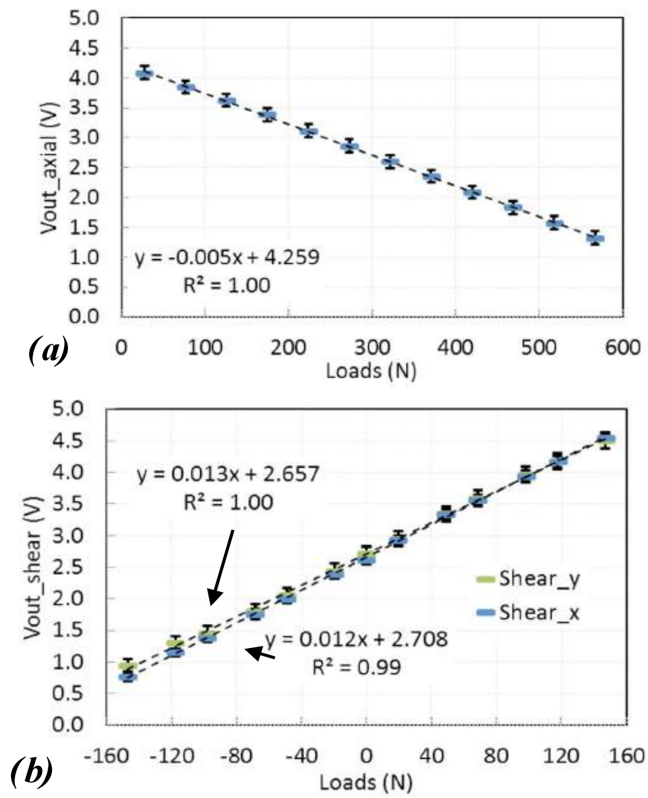

Fig. 8. (a) Axial force tests, conditioning circuit output voltages versus mechanically applied loads (mean and 3SD)—right crutch. (b) Shear force tests, conditioning circuit output voltages versus mechanically applied loads (mean and 3SD)—right crutch.

about 0.8°. Furthermore, consecutive tests carried out both in increasing and decreasing directions have allowed evaluating the hysteresis in the angular measurement that is about 0.16°. Finally, the drift has been evaluated in an interval of 1 h and the calculated value is about 0.0002° obtained for the fixed position at 0°. From what has been achieved, it has been possible to calculate the accuracy of the two crutches in an angular measurement of about 1°, using the generally accepted method of root sum square calculation.

In Figs. 7 and 8, the tests conducted on the strain-gauge bridges are reported. For compression tests, each crutch was mounted on a mechanical structure specifically developed, and then each crutch was subjected to static loads in compression using different masses. We used reference masses (OIML R111) with the following declared loads 2, 5, 10, and 20 kg. The masses were measured using a balance (GABN resolution 10 g), and the measured values are the following: 1.98, 5.18, 10.08, 20.64, and 20.52 kg. For shear tests, each crutch was horizontally fixed to a mechanical structure, and then it was subjected to static loads applied to the terminal part of the lower crutch through the reference masses indicated before. In Fig. 7, the output voltage of the conditioning circuit (Vout_axial), acquired and transmitted to the readout unit, is shown for different applied loads, from about 0 to 600 N. For each loading test, 4000 samples were acquired, and their average and standard deviation recorded. Fig. 8 shows the two output voltages (Vout_shear_x and Vout_shear_y) for the different applied loads from 0 to 160 N in both directions, acquired and transmitted to the readout unit. Analyzing the data obtained for the two crutches, the mean experimental standard deviation is about 42 mV for axial forces corresponding to about 8 N and about 35 mV for shear forces corresponding to about 4 N. For the compressive axial forces, the sensitivity for both crutches is approximately 0.005 V/N in the range from about 0 to 600 N, whereas for the shear forces, the sensitivity is a little different between the two crutches and it is in the interval 0.009–0.013 V/N with the load range from about -160 to $+160$ N. From the data in Figs. 7 and 8, the nonlinearity, referring to the straight lines obtained by least squares, has been derived and the calculated values are reported in Table I. From Table I, we can observe that the nonlinearities are below 6 N. In Table I,

TABLE I
SUMMARY DETAILS FOR THE CONDUCTED ANALYSIS ON THE TWO INSTRUMENTED CRUTCHES

	Hysteresis (N)	Non-linearity (N)	Drift (N) @ 1h	Sensitivity (V/N)	Resolution (N)
Axial bridge – Right Crutch	3.23	5.60	-0.05	0.005	0.96
Shear_x bridge – Right Crutch	1.11	0.42	0.10	0.012	0.4
Shear_y bridge – Right Crutch	1.07	2.46	-0.04	0.013	0.37
Axial bridge – Left Crutch	3.36	5.00	0	0.005	0.96
Shear_x bridge – Left Crutch	0.35	4.22	-0.13	0.009	0.53
Shear_y bridge – Left Crutch	0.26	2.20	-0.06	0.01	0.48

the hysteresis values are reported, which are calculated with consecutive tests carried out both in increasing and decreasing directions. The performed tests have allowed evaluating that the hysteresis values are below 3.5 N. Finally, the drifts have been evaluated in an interval of 1 h and the calculated values are negligible as reported in Table I. From what has been achieved, the accuracies for axial and shear measurements have been evaluated using the generally accepted method of root sum square calculation and considering the previous contributions. For the measurements of the axial forces, the accuracy is about 9 N, whereas for the shear forces, it is about 5 N.

IV. Experimental Results

The crutches were tested during a walking activity of ten subjects along a straight path of about 10 m. We decided to adopt the two instrumented crutches for a common analysis usually reported in [6], [23], and [24] for weight bearing evaluation. The subjects were monitored, respectively, to perform a nonweight bearing (NWB) and a partial weight bearing (PWB) of 10% during a three-point gait. In fact, three-point gait crutch walking is commonly used because it permits varied levels of weight bearing, from NWB to full weight bearing for different pathologies [6]. We chose an NWB and a PWB of 10% because they are usually adopted in [6] and [23]–[25]. The ten subjects physically healthy that have taken part in the study are called in the following from Subject1 to Subject10. Healthy subjects are used in this paper as adopted in similar analyses in [3], [23], and [26]. The average age was 30 years with the range from 28 to 55 years, and the average weight was 77 kg, with the range from 54 to 98 kg. The weight bearing analysis was obtained by the two proposed instrumented forearm crutches performing the calculation method of weight bearing, as reported in [4]. Since the aim of the tests was to determine the ability of subjects to perform NWB and PWB, the additional features of the instrumented crutches (biofeedback) were disabled. Each trial was a walk in a straight path using both crutches with one leg raised for the NWB trials or partially loaded for the PWB; so the subject used the crutches to replace the raised limb. To learn PWB, a classical method was used [24] before starting the trials. While bearing weight only on the healthy lower extremity, the subjects have to shift their weight gradually to the opposite site until the value measured by a commercial balance reaches 10% of their body weight. Subjects were told to remember this 10% feeling on their affected side when walking with their forearm crutches [23], [24]. Before the test, to minimize the degree of natural variation in the way in which the subjects perform the task, he is asked to perform a couple of times for the practice. Therefore, the subjects performed the exercise with the protocol specified above for different cycles. At the same time, the PC acquired the signals transmitted by the two crutches. These trials were carried out to study the behavior and the reliability of the two wireless instrumented crutches. During all the tests, the height of the crutches and the gains of the electronic circuit were not changed.

A consumption measurement was carried out before the tests. Fig. 9 shows the current consumption of a crutch, obtained with an oscilloscope by measuring the voltage drop across a resistor of 10 Ω in series with the supply. As seen above, the crutch communicates with the host computer each time the sensors are sampled. In this mode, the crutch consumes an average current of about 65 mA (Fig. 9). In this average current, the Bluetooth component, which is not a low-power Bluetooth, is power consuming. We mean to reduce the power consumption using a Bluetooth low energy in the next prototypes. Furthermore, in an environment external to the clinic, wherein prolonged operation is essential, the communication to a host computer may not be necessary, and in this way, shutting off the Bluetooth crutch could consume a lower average current prolonging the active time. The micromotor (used for biofeedback) consumes approximately 3.3 mA when switched ON. Therefore, with two batteries of 1.2 Ah each, the crutch can work for one day continuously.

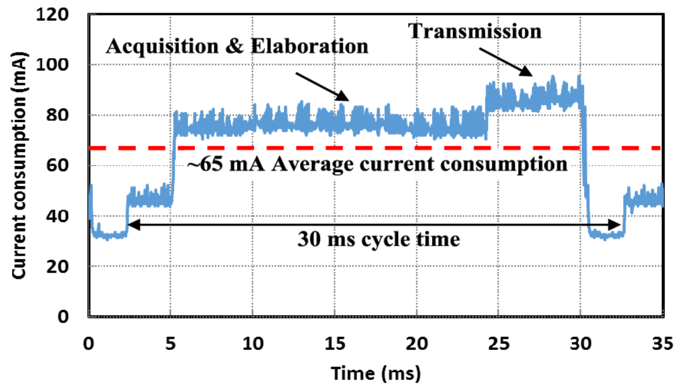

Fig. 9. Current consumption during one cycle.

In Fig. 10, the axial and shear loads, the moment of impact with the ground, and the tilt angles were measured in real time during the execution of the exercises described previously (exported through the graphical interface of LabVIEW). In Fig. 10(a) and (c), the tilt angles and the impact with the ground are shown. The moment of impact with the ground is shown as a variation of the front of the square wave tracked as previously reported from the raw accelerometer data. Then, these raw data have been filtered by a low-pass filter of about 1 Hz (overlapped hybrid mean filter) considering a maximum walking speed of 0.7 steps/s as reported previously. Finally, the data are converted to angles representing the antrum-posterior and medio-lateral angles. In Fig. 10(b) and (d), the axial and shear loads are shown. From the graphs, it is possible to identify the various cycle stages. First (marked as swing phase), the crutch is swung in front of the subject, while the body weight is supported by its healthy limb. Then, when the antro-posterior angle is at its minimum (indicated by the line that separates swing phase to stance), the subject begins to charge the crutch using his body weight; the healthy limb moves forward (marked as stance phase). When the antro-posterior angle is about maximum (indicated by the line separating stance to swing), the subject's weight is removed from the crutches and a new swing phase begins. This cycle is repeated as subject continues to walk. The visible change in the medio-lateral angle is due to variations of the crutches in the frontal plane. From the graphs, the physiotherapists have the availability of direct data or inferable on the

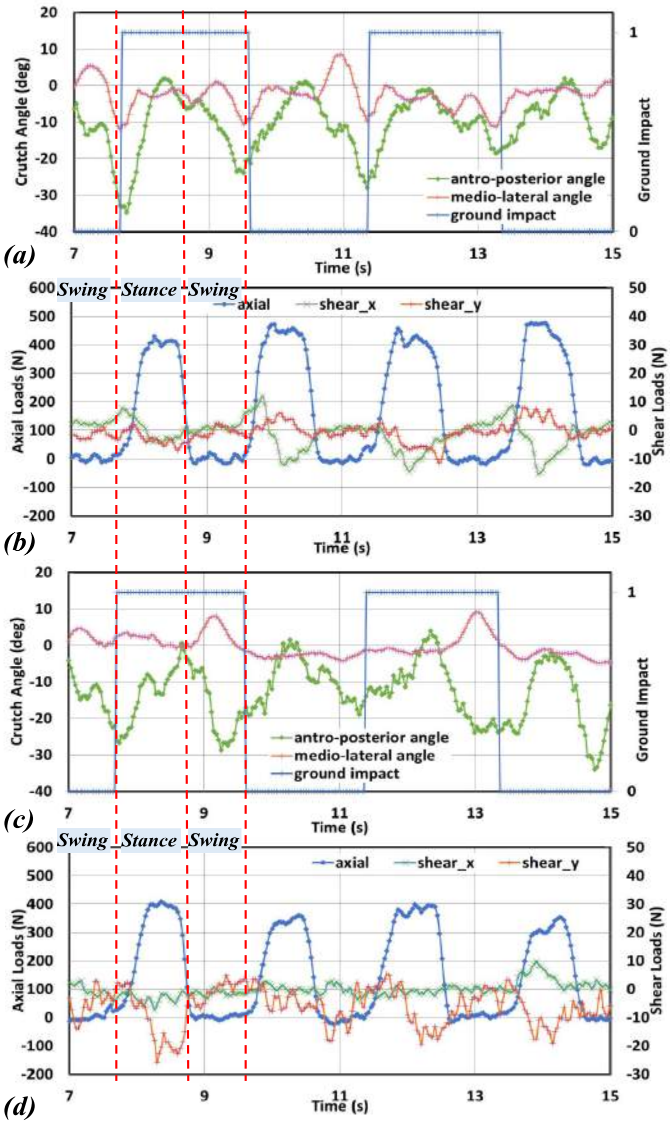

Fig. 10. Axial and shear loads and tilt angles monitored in real time during NWB tests of Subject1. (a) Left crutch angles. (b) Left crutch loads. (c) Right crutch angles. (d) Right crutch loads.

gait: positions, angles, velocities, accelerations, values of the vertical component, horizontal anterior–posterior component, and horizontal medial–lateral component of ground reaction forces to lower limbs. This allows the clinician to monitor the correct use, such as identification of weight bearing asymmetry of the crutch, imbalances weight between one crutch and the other, crutch dragging, and the imperfect alignment of the crutches with the ground.

The aggregate results on the ten subjects are reported in Table II. The measured axial forces were used to calculate at each cycle the percentage of the patient's body weight using [4, eq. (4)] for PWB tests and (5) for NWB tests

$$\mathrm{BW}^{\%}_{\mathrm{PWB}} = 100 * \left(1 - \frac{\max(\mathrm{Fz1}[n] + \mathrm{Fz2}[n])}{M * g}\right) \qquad (4)$$

$$\mathrm{BW}^{\%}_{\mathrm{NWB}} = 100 * \left(\frac{\max(\mathrm{Fz1}[n] + \mathrm{Fz2}[n])}{M * g}\right) \qquad (5)$$

where M is the patient's weight, g is the acceleration due to gravity, n is the discrete time index, and Fz1 and Fz2 are the sampled magnitudes of the axial forces by the two instrumented crutches.

TABLE II
AGGREGATE RESULTS ON THE TEN SUBJECTS. VALUES EXPRESSED AS MEAN (%BW) AND STANDARD DEVIATION (±SD)

	NWB		10%PWB	
	%BW	±SD	%BW	±SD
Subject1	100	6	15	7
Subject2	110	20	26	20
Subject3	99	21	15	11
Subject4	101	11	10	14
Subject5	102	7	16	12
Subject6	106	26	24	13
Subject7	100	22	9	7
Subject8	103	11	35	24
Subject9	101	17	29	21
Subject10	100	17	16	9
MEAN	102	16	19	14

In Table II, the NWB and PWB mean values and experimental standard deviations calculated for each subject are reported. These values are in agreement with the results obtained in previous similar analyses [7], [6], [25]. Furthermore, the calculated PWB values show a difficult for about the 20% of subjects to keep the prescribed weight-bearing limit using forearm crutches. This result correlates with the published data of previous studies [3]. The help of the feedback on patients' performance could lead to a successful strategy to upgrade the gait training [4].

Furthermore, we observed medio-lateral forces (shear forces) reaching the peak of about 56 N and differences between the axial forces measured with the two crutches reaching a peak of 130 N. These values denote an asymmetrical condition in gait walking with crutches; an asymmetrical condition is common in NWB three-point pattern [11], [27]. These asymmetries of gait can lead to distortions in the path of the center of gravity, which produces an increased energy expenditure [27]. Medio-lateral forces are a concern for long-term assistive device users, as it has been shown that high joint loads may lead to upper extremity pain and pathology [11], [17], [27].

During testing, we regularly experienced successful communication between the two crutches and between the crutches and the PC, also with distances of more than 10 m in an indoor environment. Furthermore, there were no loss of data or communication delays.

V. DISCUSSION AND CONCLUSION

In this paper, two wireless instrumented crutches are described and the preliminary results are reported. The crutches allow measuring the axial and shear forces, the antro-posterior and medial–lateral angles, and the impact with the ground. A clinical evaluation of the walk assumed by the patient requires to be done by a clinician who can, using the prototypes, establishing a relationship between the quality of the patient's walk and the measured quantities. Therefore, the proposed crutches can provide quantitative gait analysis of patients in order to instruct them in the early stage to the correct use; in fact, the clinicians can easily use these tools to perform clinical assessments with quantitative mechanical parameters. Furthermore, each crutch has a biofeedback signal (vibration) that can help to facilitate the therapeutic approach. This signal can be obtained by vibratory stimulation achieved with a vibrating micromotor and can be activated by an algorithm and threshold values identified by the clinician who is in charge of the responsibility for the proper use of the crutches. In this way, the patients are encouraged to make correct use of crutches able to restore the physiological state correctly. In addition, clinicians can have available quantitative data on the use of crutches also remotely connecting the PC to the Internet. Important benefits are: 1) reducing the environmental impact created by unnecessary movement of the patient at the hospital; 2) increase the effectiveness in terms of optimizing resource utilization and clinical nursing; and 3) reduction of the social cost of the caregiver.

In this paper, the description of the instrumented crutches and the design choices are clearly indicated. Two prototypes have been manufactured and tested. In the adopted configuration, the performed tests showed an accuracy of the two crutches in an angular measurement of about 1° and about 9 and 5 N for the measurements of the axial forces and shear forces, respectively. The average current consumption is high (about 65 mA), but the chosen batteries permit a continuous activity during all the day. Research activities are in progress to further reduce the power consumption and maximize the performance of the prototype. The crutches were tested during a walking activity of ten healthy subjects along a short straight path for several trials. The obtained results allow moving to the next phase consisting in clinical trials with the analysis of patients and appropriate medical care, for which the proposed crutches have clear benefits compared with alternative systems, including wireless data transfer, biofeedback, quantitative data, and ease of configuration. Every patient who uses crutches can have different characteristics. The measuring ranges are set to satisfy the greatest number of patients; however, the use of the instrumented crutches by very overweight or very thin patients might need an adjustment (increasing or reducing) of the output signal amplitudes. The ten subjects have a similar height; therefore, it was not necessary to change the length of crutches or the sensitivity of the measuring circuits. However, it is possible to manually change the length of each crutch without interfering with the normal system functioning or changing the sensitivity of the measuring circuit. Since the bridge configuration gives a linear behavior, knowing the gain, the correspondent forces can be easily recalculated.

Since the measuring system is composed of few and simple components, the crutches are simple and light. Most of the weight is given by the two batteries, but this could be reduced at the expense of durability. The electronic board is separable, and it is located in an area not affected by the walking. Such electronics could be integrated in a silicon circuit, powered by the battery, which would constitute a device of a few grams; then a small lightweight battery can be further adopted. Therefore, the crutch is proposed to be wireless, lightweight, and portable, and meets the clinical and psychological requirements, such as patient comfort, ease of use, and noninvasiveness.

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