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ORAL PRESENTATIONS

flexibility (seat and reach) pre- and post-treatment in case and in control groups. All evaluations of muscle performance were performed on a platform (Ergo Jump, BoscoSystem, RI) that measures jump time and contact time.[7]

Protocol of treatment

Case Group: the subjects were submitted to 0.485 MHz capacitive-resistive radio-frequency by specific sequence:

– 10 minute of capacitive modality;
– 10 minute of resistive modality;
– 10 minute of capacitive modality.

This sequence was performed on the quadriceps muscle using TECAR® device bilaterally by the same operator using the technique of circular massage.

Control Group: in this group TECAR® device placebo, was used.

For ethical reasons and to increase the statistical power of the study, after 7 days the subjects belonging to Case Group were treated with the protocol of the subjects belonging to Control Group and vice versa by a Cross-Over study design. In this way the subjects of both groups were treated by both modalities of treatment

Results

Having a normal distribution and using the crossover design, in which every subject is the control of himself, we can use the t-test to analyze the sample.

We observed an average increase statistically significant of CPK, Myoglobin, Lactate in both treatment groups, but we have detected a less increase in Case Group (Table I).

By counting of ecographic spots, it was observed how the case group have had an average increase statistically significant of signal spots.

An average statistically significant decrease of power (w/kg) was observed in the control group (with P=0.004).

In all other parameters were not observed significant differences in both groups.

From the analysis of the data, we can see an increase of intramuscular capillary blood flow and a less impact on myofibrils structures submitted to mechanical stress generated by intensive eccentric work of the tests.

Table I. – Statistically significant values in Blood Analysis Values

Name of the test	Case group	Control group
CPK	A.I = 11.874 IU/L p<0.05	A.I = 12.63 IU/L p<0.05
Myoglobin	A.I = 27.28 ng/ml p<0.05	A.I = 66.97 ng/ml p<0.05
Lactate	A.I = 2.49 mg/dl p<0.05	A.I = 3.55 mg/dl p<0.05

Table II. – Statistically significant of signal posts

Spot/mm	Right quadriceps	Left quadriceps	Significant statistical (p)
1 mm	2.75	2.5	P <0.005
3 mm	1.7	1.375	P <0.0005 P <0.0005
>3 mm	1.375	0.875	P <0.0005 P <0.005

Conclusion

We can assume that the application of 0.485 MHz radiofrequency, in capacitive-resistive modalities by using TECAR® device, at the end of muscle performance, have an effective action for the reduction of recovery time after sequences of repeated muscle exercises.

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Effects of reduced lumbar load by the use of a vertical traction device on dynamic subjects

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Aim

Although a large number of rehabilitation methods exists and are extensively used in the daily practice of physiotherapists and physicians, there is often a lack of understanding (not to mention of theoretical background) on why a given method is working and it is actually providing an effective aid to the patient. The field of lumbar traction devices is no exception. Traction as a therapeutic intervention in the treatment of low back pain has existed for many years. Its use has progressed from simple manual static traction to intermittent motorized traction.

In the most recent European guidelines [1] on the management of acute and chronic non-specific low back pain, the use of this modality of treatment is not generally recommended. This may result from the poorly-designed studies on lumbar traction in the scientific literature. Most often, the studies include a comparison of heterogeneous populations, an application of several treatment modalities in each treatment session, an uncertainty about appropriate dose of traction and an apparent lack of a valid sham intervention.

Nevertheless the knowledge on the effects of the lumbar traction has improved in the last years. We know by now that, among its biomechanical and neurophysiological effects, there are a separation of the intervertebral motion segment and a modulation of nociceptive input in either the ascending or descending pathways. These effects have been observed either during a low load and a high load traction. Accordingly, these effects, and their outcomes on the signs and symptoms, seem particularly beneficial on patients with radicular pain and neurological deficit.

Over the last decade a different lumbar traction has been used by physiotherapists with good subjective clinical results. This traction is a "Vertical Ambulatory Traction Device" (VAT-D), designed so that the patient can remain in the standing position and be "in motion". This device is called the "Vertetrac" from Meditrac Medical Equipment Ltd. Israel. We know by now that studies on this apparatus exist, but none has corroborated their clinical results with mechanical and bioelectrical measures on the patients and the apparatus.

Furthermore, the measures that we are interested in here, have never even been monitored in previous studies on "lumbar traction". Firstly, it is difficult to record such measures on a patient in the supine position with the conventional traction; secondly, it is not really relevant to assess biomechanical reactions and neuro-musculo-skeletal signals on a patient in a passive supine position.

On the other hand, with the "Vertetrac", the monitoring of these measures becomes easier because the patient is in the upright position (Figure 1) and, more relevant, because he remains active and functional. With the device on, we can expect the patient to use different strategies to keep his body erect. These changes of strategy might originate from the activation of different receptors of the nervous system (mechanoreceptors, proprioceptors) at the time, generating another different sequence of muscle activation and contraction. Since the superficial muscles tend to be over-activated among the low back pain population, we can expect a decrease of the activation of those muscles and an increase of the activation of the deeper muscles when the apparatus is worn. By the way this is one of the hypotheses that we would like to validate within this project.

As visible in Figure 1, the Vertetrac is composed of two rings separated by two stainless steel rods for applying the traction between the upper and lower part of the body. The lower ring is placed on the bones of the pelvis (iliac crest) while the upper ring is supporting the weight of the upper part of body by pushing the lower ribs. A mechanical system is used to manually increase the distance between the two rings so to apply a vertical force able to decompress the lumbar spine. From a medical point of view the final effect is that to release the pressure on the lumbar spine, on the nerves coming out of the spine and on the intervertebral bearings as well. Such effects were also demonstrated by magnetic resonance imaging. A further pushing mechanism is applied horizontally on the back to recover the physiological lumbar lordosis (frontal convexity of the spine).

Apart from two very rudimental spring scales applied at the factory on the upper part of the rods (Figure 2), there are no means for measuring the forces and torques applied to the spine of the patient, but the experience and practice of the therapist.

The problem to be solved is quite usual in medicine and physiotherapy, that is to acquire a quantitative measure of the effect of a therapy so to optimize, compare the results, enhance the treatment and finally giving better outcomes.

Unfortunately medicine is a field where a good precision is not obtainable in general and physicians are normally accustomed to work with instruments delivering 10% to 30% accuracy, a figure not a single engineer would tolerate in his/her profession.

No surprise the methods for vertebral axial decompression have been "validated" on the basis of subjective feeling of the patient, subjective sensation of pain, subjective appreciation of the therapist and subjective use of so-called "scales" for "measuring" the clinical outcomes. Again, no surprise the results were wandering form patient to patient, therapist to therapist, physician to physician and a real health technology assessment, both on an economical and a clinical basis, was impossible to make to date.

The main scope of this project is to devise a method

Figure 1. – The Vertetrac (from Meditrac website).

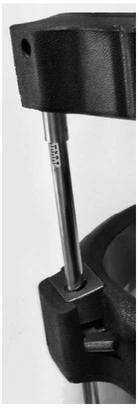

Figure 2. – Spring scale on a rod of the Vertetrac.

and a measurement system able to give the physician and the physiotherapist an objective and quantifiable indication of the effects of the therapy in low back pain using a vertebral traction device. To this end a complete and comprehensive signal acquisition system for the clinical assessment of the Vertetrac device is needed with the aim of giving basis to:

1) provide quantitative and objective data to corroborate the positive clinical subjective findings already described in the literature. Medical scientific literature on low back pain research has already provided evidence that a lumbar traction system can be of help in the treatment of such a disease. Unfortunately the evidence of a quantitative and objective effect is still lacking, while it should be very important to provide a serious assessment of the therapy.
2) improve the clinical use of the system. By giving an objective measure of the effects of the system, the therapist will be enabled to better do a preliminary selection of the patients to be treated so to maximize the results while diminishing the costs. Furthermore the objective data, always corroborated with the clinical expertise of the therapist, will enable the correct selections of the parameters of the therapy (traction force vector, duration, position) to minimize discomfort to the user and maximize outcomes.

To reach this objective a multifunctional multisensor device should be developed able to acquire simultaneously:

– he mechanical forces and torques on the instrument. Present commercial Vertetrac devices are only provided with a very rudimental spring scales (Figure 2) to measure the axial force exerted on the two supporting rods. These sensors are in effect not functioning in practical use. Indeed the flexion of the instrument, during application on the body, generates too much friction on the scales so to render them useless. Exactly knowing the mechanical forces on the system (and so the forces applied to the human body) is a clear prerequisite for assessing the instrument.
– the effects on the body position and movement. They must be sensed with a set of accelerometers/inclinometers. The effects of the application of the traction device will result in the blocking of the lumbar spine, the dynamics of which will be greatly affected. The movement, gait and standing station of the subject will change and different muscles will be activated to compensate for this. Regulation of body stability will be affected and the study of it will be of great importance to get a useful insight into the biological effects both in the physio-pathological field and in the therapeutic one.
– the muscle electrical and mechanical activation timing and intensity. As it is presumed that the application of the traction device will modify not only the reciprocal connections between the vertebrae of lumbar spine but also the activation state and dynamical functioning of the muscles involved in, it is necessary to put in place a monitoring system to assess muscular function. From the literature it has been shown that ultrasound imaging may be an important tool to assess the mechanical activation of lumbar spine muscles (namely the "multifidus muscle"). Although ultrasound will be surely employed in the medical research to follow, it is considered important to check the use of a couple of ultrawide band radar sensors (already developed by our group). By using such microwave sensors and a conventional set of electromyography electrodes and amplifiers we intend to replace ultrasound which is not reliable enough to be used during gait or other movements.

The elaboration of the data will be performed offline as the therapy is normally administrated with multiple sessions of 20-30 minutes duration each. The previous considerations should prove why a complete system, for measuring the mechanical forces exerted by the device as well as the biological effects on the patient (electromyogram, stability, etc.), is needed. Only by analyzing the data and signals in the real situation, the therapist may gather useful feedback to assess the therapy and to use the system in a more appropriately way. To this end the device is paired with a sort of data logger system capable of acquiring mechanical and biomedical signals with adequate precision, reliability and sampling frequency for at least 30 minutes. At the end of each session the data will be downloaded to a computer for subsequent elaboration and appropriate presentation to the health personnel (and the patient as well) in a suitable (non technical) way.

Methods

To give an idea of the proposed system, in Figure 3 the positioning and kind of sensors are shown. Two sets of strain gages are glued on the rods of the system to detect simultaneously axial as well as bending force vector on each rod. This will allow to measure the exact forces placed by the upper part of the body on the system and so the supporting action of the device. Timing relationships and symmetry are recorded in real time with a very good time and intensity resolution. The strain gauges used are of the resistor type as those produced by Omega.com (USA). Strain amplifiers are of the conventional type although a multichannel system with a direct digital output has been developed to measure simultaneously axial and bending (torque) force on the rod with the minimum number of sensors.

Two inclinometers/accelerometers are placed on the body, one at pelvis level and another on the head (on a bike helmet). This allows the measure of body stability and position in real time both during standing and during gait. The inclinometers - accelerometers are of common kind like those produced by VTI technologies with an acceleration range between ±3 g and a frequency band between 0 and 9 Hz in narrow band mode. These accelerometers have a direct digital output in synchronous serial mode.

The measurement of biological parameters is accomplished by a set of four EMG amplifiers to monitor muscle electrical activity and two UWB radar motion sensors placed into the upper ring of the Vertetrac to monitor muscle movements. Both the EMG/ECG amplifiers and the UWB radar motion sensors were already developed by our group. The use of the radar motion sensor is considered to replace in part the use of an ultrasound imaging system to detect deep muscle mechanical activation. Indeed ultrasound will be highly unreliable for ambulatory measurements.

As for throughput of the sensors it should be noted that accelerometers, integrated signal (envelope) EMG amplifiers and UWB sensors can be sampled

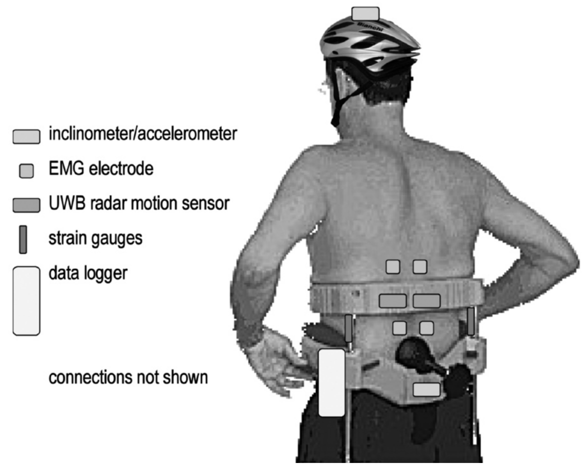

Figure 3. – The instrumented Vertetrac: the VTAS set-up (data logger may be substituted with a direct USB connection with a PC).

Figure 4. – The microcontroller based data logger system.

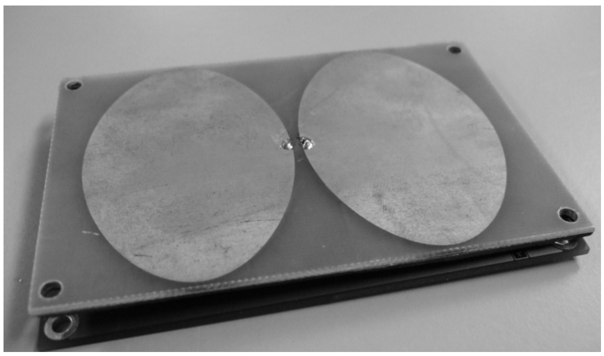

Figure 5. – The UWB radar sensor.

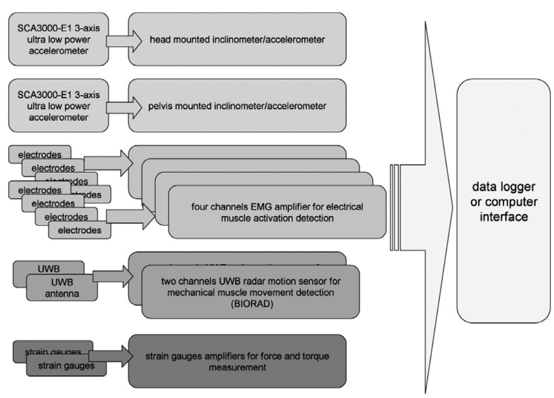

Figure 6. – Schematic block of the VTAS system.

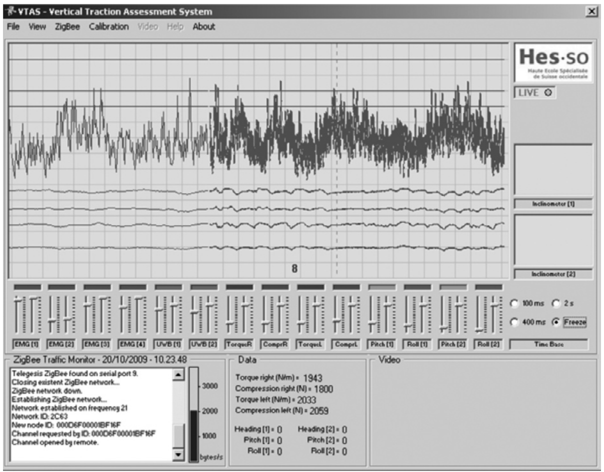

Figure 7. – The signal panel showing EMG and strain gauges signals: the connection between computer and acquisition system is guaranteed by a ZigBee radio channel.

at 200 Hz each (considering the pass band of each) for a total 1600 samples/sec. Strain gauges may also be sampled at 200 Hz as fast impulsive forces and torques are not expected. The total sampling data flow is then in the order of 2 000 samples/s or 40 000 bits/s considering a 12 bit conversion accuracy. Considering a maximum duration of 30 minutes per session, the maximum memory for data recording is in the order of 7 MByte for each acquisition.

Apart from the assessment of the Vertetrac device and other VAT-D systems, the project is strategic for the implementation of a more general system for spine dynamic stability assessment which will be used in many other applications in rehabilitation and clinics.

As the system will permit the study of human lumbar mechanical dynamics and the overall stability control of human standing it is quite interesting here to highlight a possible line of research which will be started into the VTAS project and that may have significant development in the future.

Results

From this monitoring system, we would like to get a better understanding on how the Vertetrac is actually affecting the neuro-muscular-skeletal systems of the body, and to which extend. Today, some of the mechanical and neurophysiological theories behind the conventional traction seem to make consensus among the scientific literature. However, with this device being applied in the standing position, these theories might be insufficient to explain its real effect.

From our point of view, when applied with immediate relief on a symptomatic subject, we expect to observe a transfer in the recruitment of the musculature of the abdomen and low back in favor of the deeper stabilizer muscles. Therefore, this system will allow us to evaluate the amount of muscle activation being present before, during and after the application of the VAT-D on the superficial and deep muscles and to correlate those measures with the changes of position of the subject .

These results could serve as baseline for treatments targeted on the activation of the deeper stabilizer muscles. They could also bring valuable information on the relationship of the different systems (neuromuscular system; mechanical system) of the body, both on asymptomatic and symptomatic subjects.[2-16]

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