CLINICAL EVIDENCE REPORT
HUBER®

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Document HISTORY

Version number	Date	Section #	Description of modification
1.0	07/03/2006		Initial distribution HUBER Medical
2.0	19/01/2011		HUBER Medical new version : HUBER MOTION LAB MD
2.1	19/01/2011		Accessories further described
3.0	01/06/2012	11 15-16	Update on clinical investigations List of the publications and communications done on HUBER
4.0	24/09/2014		HUBER new version: HUBER 360 Update on clinical investigations Precision about selection of data and related claims
4.1	15/10/2014		Modifications according to LRQA report : Alignment of the format with the expectations of MEDDEV 2.7.1 Clarification on data contents

INFORMATION ABOUT THE CLINICAL EXPERT

I, THE UNDERSIGNED, DECLARE THAT I HAVE:

• THE SUITABLE TECHNICAL OR PROFESSIONAL QUALIFICATIONS TO ACT IN THIS CAPACITY (FOR MORE INFORMATION, REFER TO THE ENCLOSED *CURRICULUM VITAE*).

• FULLY EXAMINED THE DATA PROVIDED BY THE APPLICANT AND HAVE PROVIDED REFERENCES TO THE LITERATURE TO SUPPORT STATEMENTS MADE THAT ARE NOT SUPPORTED BY THE APPLICANT'S ORIGINAL DATA. THIS REPORT PRESENTS AN OBJECTIVE ASSESSMENT OF THE NATURE AND EXTENT OF THE DATA.

• PROVIDED A REPORT BASED ON MY INDEPENDENT ASSESSMENT OF THE DATA PROVIDED

• BASED MY RECOMMENDATIONS, REGARDING SUITABILITY FOR REGISTRATION, ON THE DATA PROVIDED HEREWITH. I HAVE CONSIDERED THE ATTACHED DATA AND HAVE RECOMMENDED AS TO SUITABILITY FOR REGISTRATION OF THE INTENDED USE AND INDICATION FOR USE ACCORDING TO THE DEVICE LABELLING INFORMATION DOCUMENTS.

I FURTHER DECLARE THAT THIS EXPERT REPORT REPRESENTS MY OWN VIEW.

FURTHER, I DECLARE THE FOLLOWING TO BE THE FULL EXTENT OF THE PROFESSIONAL RELATIONSHIP BETWEEN MYSELF AND THE APPLICANT: **PHD, RESPONSIBLE OF THE SCIENTIFIC RESEARCH AT LPG SYSTEMS**

CLINICAL EVALUATION REPORT: DEC_HUBER

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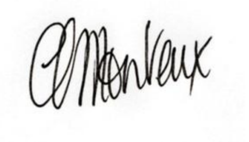

DATE: OCTOBER 15TH, 2014

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1. GENERAL DETAILS

First launched during the last quarter of 2002, the non medical version of HUBER went on the market in April 2003. It is a piece of equipment designed to help fitness and to work out the muscle chains for sport (preparation and advanced training in various sports activities).

Client feedback and results obtained with various populations, lead the manufacturer (LPG Systems, Valence, France) in 2006, to consider applying to have HUBER placed on the list of medical equipment in line with European directive, FDA rules, and other country-specific requirements.

In 2010, an upgraded version of the device (HUBER MOTION LAB MD) was launched with the introduction of additional accessories to make the treatment easier for the patient and for the therapist considering post-marketing studies and analysis of user's information.

In 2014, a new version of the device with substantial modifications and named HUBER 360 came out. In the rest of the text, HUBER and HUBER 360 device names are indifferently used for the same meaning.

2. DESCRIPTION OF THE DEVICE AND ITS INTENTED APPLICATION

2.1. Description of HUBER®

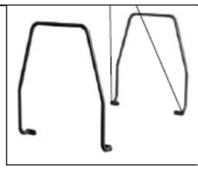
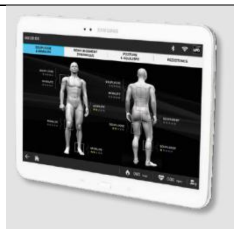
HUBER is a physiotherapy/rehabilitation tool designed and produced by the French company, *LPG SYSTEMS*. It is equipped with unique, and patented, cutting-edge technology. First versions and upgraded version are shown in *Fig 1*. The equipment comprises an oval motorized platform with rotary oscillating movements equipped with sensors *(Fig.2)* that works in different ranges and at different speeds and a system of handles *(Fig.3)* equipped with sensors that measure the energy used. Results can be visualized via a screen featuring a target *(Fig. 4)*. The platform throws the user off balance and requires he/she to make postural adjustments to regain balance. HUBER has a set of different programs of use to adapt to different users' needs. The concept is designed to work on the deep muscles of the spine, to increase joint mobility, improve balance by acquiring stability in an unsteady environment and to develop motor coordination.

HUBER 360 is an ergonomic evolution of the previous versions HUBER MOTION LAB MD (HML MD).

Figures/ improvements	Previous version HML MD	New version HUBER360
Fig 1 : HUBER versions - Previous version (HUBER MOTION LAB MD) and new version (HUBER 360)		
Fig 2: Oscillating platform -Variable range -Adjustable speed -Rotates in both directions - HUBER360: Equipped with sensors		
Fig 3: Handles - Multitude of different possible positions. - Equipped with sensors to measure exertion levels (when pushing & pulling, two handles are independent of each other)		
Fig 4: Screen - Clear view of exertion levels left and right - Effort can be adjusted in line with initial calibration		

The technical characteristics of the devices are summarized in the following table:

	HUBER MOTION LAB MD	HUBER 360
Dimensions Length*width*height	1,93 x 1,29 x 2,06 m	1.7 x 1.08 x 2.1 m
Weight	310 Kg	285 Kg
Column hight	2,06 to 2,49 m	
Maximum weight authorized on the platform	150 Kg (130Kg if U=100V)	140 Kg
Tension	100-230V	200-230V
Frequency	50/60Hz	50/60Hz
Power	420W	2 Kw
Platform oscillation speed	40±10% round.min-1	1tr.s-1
Max. amplitude	10°±1°	10°±1°
Strength Measurement	0 to 100daN /handle	0 to 85 Kg / handle 0 to 165 Kg on the platform

Accessories of the HUBER360	**Figure**
Guardrail can be positioned on the apparatus to improve practical protocol (posture, comfort)	
HU-PADS 2 foot pads with variable angle of elevation (10° increments) and rotational position (15° increments)	
HU-PULSE A GEONAUTE® heart rate meter that displays the operator's pulse on the screen to help select the correct intensity	
HU-SEAT - An articulated stool for those with limited mobility - Angle adjustable from 0 to 15 degrees - Safety lock on the platform	
TABLET with integrated HUBER360 application allows patient management, exercices downloading and remote setting of parameters	
WEDGE for stability test, can be positioned on platform	

2.2. HUBER® intended application

HUBER is used to work on muscle chains, coordination, posture and balance by requiring the user to remain steady in an unsteady environment.

HUBER has a set of different programs for different levels of use to adapt to different users' needs. The equipment is interactive, allowing calibration and regulation of effort. In this way, personalized objectives can be set for each individual, while at the same time regulating the muscle chain motor activity. This is made possible thanks to different operating modes: a "free level" program or predefined menus. In this way, the user learns to manage his/her motor organization in a constantly moving environment taking into account gravity and the force applied to the handles.

Working with the HUBER system has several points in common with concepts used in neuro-locomotor rehabilitation:

- The approach is a global one: the whole body is involved due to global and coordinated musculo-skeletal activity, while at the same time seeking the user's active participation and spatial awareness.
- Treatment is conducted following an "evaluation – treatment – evaluation" procedure, with personalized patient treatment programs, in order to avoid pathological reactions.
- Educating muscle tone is also targeted, in order to achieve adequate stability and to regain mobility.
- Search for "lost movements" and reprogramming the motor image by using proprioceptive and visual stimulation.
- Stimulating troubled sensitivity: Deep sensitivity is stimulated by weight-bearing and a search for alignment via exercises with visual feedback (on a 3D rotating platform in our case).
- Improving balance by looking for balance reactions and the right alignment, while retaining joint mobility.
- Training coordination assisted by visual feedback.

HUBER is designed for trained physiotherapists, physical medicine and functional therapy departments and sports medicine centres.

3. INTENDED THERAPEUTIC AND/OR DIAGNOSTIC INDICATIONS AND CLAIMS

HUBER (GMDN 33599) can be used in the following domains - for prevention, therapy to improve coordination, balance and strength and to regain fitness. When used for therapy, a qualified health professional will prescribe use of the equipment, depending on the patient's condition.

In other domains, it can be used by anyone who has a health certificate with no contraindications to physical activity. In all cases, HUBER must be used on the advice of a professional either in this person's presence or autonomously.

HUBER is 510(k) exempt, **FDA registered as**:

- IKK 890.1925 Isokinetic testing and evaluation system as rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints.
- BXB 890.5380 Powered exercise equipment intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity.

The equipment must not be used by anyone for whom physical activity is contraindicated.

For fitness, upkeep or preventive sessions, the user must hold a health certificate showing physical activity is not contraindicated.

In a therapeutic context, a preliminary assessment before starting to use the equipment will decide which indications or contraindications to use. These may include:

- Joint inflammation
- Rheumatic disorders in the acute phase
- Recent traumatisms
- Infection of the musculoskeletal system
- Fever
- Veinous thrombosis
- Discopathy in the acute phase
- Neuro-psychological problems preventing comprehension of questions or other serious psychological disorders
- Cardio-vascular disorders and any other chronic, progressive disorder where exertion is contraindicated
- Major anatomic deformation

Precautions:

- The session must always start with a warm-up.
- The parameters must be set to suit the user's morphology and physical condition.
- For patients with artificial joints, the range and speed settings should be left low.
- The exercises should not be performed while holding the breath.
- Maximum effort is not performed while the platform is moving.
- If any discomfort is felt, the exercise should be stopped immediately.
- If there is pain in the shoulder rotator cuff, this may worsen if the hands are placed too high compared to the body.

The equipment must not be used by anyone suffering from a medical disorder without supervision from a qualified professional in their country of practice and under their exclusive responsibility.

4. CONTEXT OF THE EVALUATION AND CHOICE OF CLINICAL DATA TYPES

4.1. Uniqueness of the device and related data

Marketed since 2003, HUBER devices *classed IIa*, registered ANSM in France, are endowed with an unique and patented high technology, CE marking and therapeutic claims approved from FDA for rehabilitative exercise device. We consider that there is no equivalent technology delivering such type of exercise training and we particularly refute any confusion with vibration equipment. Given the specificity of HUBER and its unique nature, (there is nothing equivalent on the rehabilitation and physical medicine market), clinical or pre-clinical data coming from scientific literature are limited.

To date, there is about 20 articles regarding HUBER published in French or European or International medical reviews and gathered by LPG Scientific Department (Cf § BIBLIOGRAPHY). Some of the articles result from clinical trials whose promotor was LPG Systems. Those articles are completed by abstracts communicated in medical congresses (Cf § COMMUNICATIONS). Among the 14 collected studies (APPENDIX 1 to 14), 5 of them have been published in peer review and 2 of them are indexed in PUBMED database.

1. *Selection of the data*

All the data regarding the HUBER technique and gathered by the Scientific Department have been reviewed. The reason for believing that all relevant references, both favourable and unfavourable, have been identified is that all data described in the following chapter came from evaluations sponsored and/or followed by LPG Systems and by expertise coming from different partners. LPG SYSTEMS has always built partnerships with different health professionals – doctors of different specialties (rehabilitation medicine, orthopedic surgeons, etc..), university-hospital researchers, physiotherapists, medical societies. With HUBER, LPG SYSTEMS remains the partner of these health professionals, who helped us in collecting data.

Only evaluations involving a certain number of volunteers or patients are described (internal reports, scientific articles or abstracts communicated in medical congresses: APPENDIX 1 to 14). Articles which are only descriptive or testimonials are not taken into account in the following chapters but are listing in the APPENDIX 15 to 22.

5. SUMMARY OF THE CLINICAL DATA AND APPRAISAL

Clinical studies performed on healthy volunteers or patients are presented here below in chronological order (APPENDIX 1 to 14).

STUDY	SOURCE	INVESTIGATOR	OBJECTIVE
1. Physiological and biomechanical expert report	Internal report 2001 APPENDIX 1	Pr PORTERO (Institut de la Performance Humaine IPH, CHU Pitié Salpétrière, Paris)	**To test muscles solicitation and cardio-respiratory response during a session**
2. Study on coordination and force in healthy subjects (amateur sports enthusiasts, those with a sedentary lifestyle and the elderly)	Internal report 2004 Communication 2005 APPENDIX 2	Dr FERRET (CEREC, Lyon)	**To evaluate the evolution of coordination and strength during a training program on subjects of different sex, age and level of sport activity.**
3. Study of balance and posture in sportsmen & women of different levels	Internal report 2004 Communication 2005 APPENDIX 3	Pr FAINA (Italian Olympic Committee, Rome)	**To evaluate the evolution of balance and posture in sportsmen & women after a training program**

4. Study of balance, posture and muscle function in healthy individuals	Peer review PUBMED indexed *Annales de Réadaptation et de Médecine Physique 2007*	Pr THOUMIE (Rothschild Hospital, Paris) Pr PORTERO (IPH, CHU Pitié Salpétrière, Paris)	**To evaluate balance, posture and muscle function in healthy individuals before and after a training program**
5. Study of balance and posture in elderly subjects	French review of Physiotherapy 2006	Pr SAGGINI (University of Chieti, Italy)	**To evaluate balance and posture in the elderly after a training program**
6. Advantages in physical medicine and rehabilitation	Communication 2006 APPENDIX 6	Dr MAERTENS (Fraiture Neurological and Rehabilitation Centre, Belgium)	**To test the interest of using HUBER in a Rehabilitation Centre**
7. Possible use of HUBER® to treat Chronic Low Back pain	Communication 2006 APPENDIX 7	Dr BOJINCA (Cantacusino Hospital, Bucarest, Romania)	**To Assess the efficacy of the HUBER® system-physical exercise, compared to a classical exercise program, in the treatment of uncomplicated chronic low back pain**
8. Using the HUBER technique for the rehabilitation of patients with multiple sclerosis	Communication 2006 APPENDIX 8	Dr MAERTENS (Fraiture Neurological and Rehabilitation Centre, Belgium)	**To test the interest of using HUBER in patient with multiple sclerosis**
9. Interest for neuro-muscular reprogramming	Communication 2008 APPENDIX 9	Stéphane FABRI (Centre de Rééducation Spécialisée, Montpellier; France)	**To optimize the neuromuscular reprogramming and to help the return to the socio professional and sports activities**
10. Interest for predictive evaluations of the sprain ankle	Peer review *Journal de Traumatologie du Sport 2009* APPENDIX 10	Stéphane FABRI (Centre de Rééducation Spécialisée, Montpellier; France)	**To provide reliable, reproducible and non- operator-dependent assessments that will identify potential topics victim of a sprain ankle**
11. Study on core muscle endurance	Review *Journal of the American Chiropractic Association 2010* APPENDIX 11	Dr. Dennis Enix (research division, Logan College of Chiropractic, St. Louis; USA)	**To study participants' ability to perform sustained core muscle contraction**

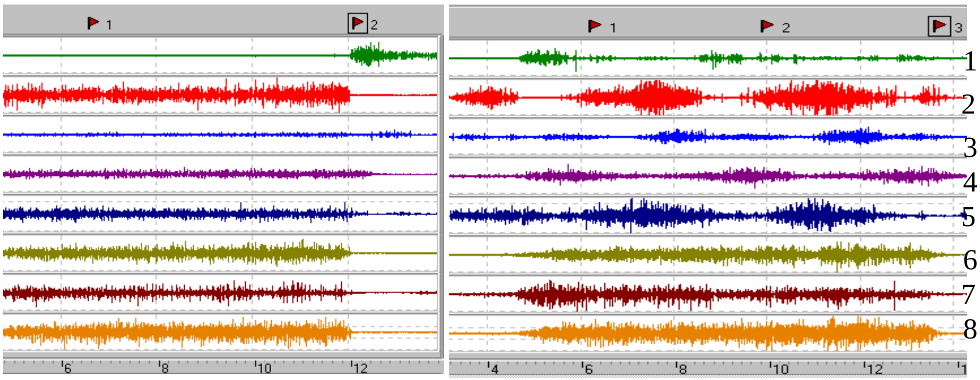
12. Study on metabolic responses and body composition	<u>Peer review</u> *Gazzetta Medicina Italiana Archivio per le Scienze mediche 2014* APPENDIX 12	Dr Jean Bernard FABRE (esp-consulting, Mimet)	**To evaluate the metabolic responses during a HUBER session and to test the effects of a 8-week HUBER program on metabolic adaptations and body composition.**
13. Study on coronary heart disease (CHD) patients	<u>Peer review</u> PUBMED indexed *American Journal of Physical Medicine and Rehabilitation 2014* APPENDIX 13	Dr Thibaud GUIRAUD (Clinique Saint Orens; France)	**To investigate safety, tolerance, relative exercise intensity, and muscle substrate oxidation during sessions performed on a Huber in CHD patients**
14. Study on healthy elderly women	<u>Peer review</u> *Gerontology submitted 2014* APPENDIX 14	Pr Goran MARKOVIC (Motus Melior Rehabilitation Centre., Zagreb, Croatia)	**To evaluate the chronic effects of HUBER on neuro-musculoskeletal structure and function (including skeletal and muscle mass, balance, mobility, strength and locomotor ability), as well as cognitive performance in elderly population.**

1. Physiological and biomechanical expert report

In October 2001, an assessment was conducted in the laboratories of the "Institut de la Performance Humaine" in Paris overseen by Professor Pierre PORTERO. The aim of the assessment was to establish the precautions for using the HUBER system in biomechanical and bioenergetic terms (Internal report in APPENDIX 1).

An EMG analysis of the main target muscles involved in the exercise under study showed differing behaviour between the muscles of the lower limbs, the spine and the upper limbs (see diagram below). When the platform is not moving, all the muscles are active and the intensity of the activity is constant throughout the exertion. When the platform is moving, there is clear muscle coordination in the lower limbs with regular alternation between the antagonist muscles such as the soleus and tibialis anterior; synchronization between the tibialis anterior and the back muscles (erector spinae), and the same phenomenon between the soleus and the quadriceps femoris.

For the muscles of the upper limbs, their activation is generally continuous and regular (isometric) throughout the exertion, just as for the non-moving platform. However, for certain subjects, asynchronous activity of the biceps brachii was noted in relation to the dorsal muscles.



Left: Recording of an exertion of 50% of the maximum force - immobile platform. Right: Same exertion - 50% of maximum force but with platform turning in a clockwise direction. In the right diagram, the flags denote the moment when the platform tilts forward. Muscle 1 soleus; 2 tibialis anterior; 3 biceps femoris; 4 vastus lateralis; 5 erector spinae; 6 deltoideus; 7 biceps brachii; 8 triceps brachii.

The lower limbs, adapting to the movement of the platform, generate contractions in the form of rhythmic bursts. This provides relative stability for the pelvic girdle and a stable area of support for the dorsolumbar area of the spine. The oscillating appearance of the EMG peaks diminishes progressively as one moves up the body.

Furthermore, a bioenergetic protocol has been established. This represents a "typical" training session. Cardio-vascular parameters are recorded continuously throughout the test session. An example showing the development of the cardiac frequency (FC) and the oxygen volume (VO2) is presented in Figure 1. The simultaneous modification of these two parameters during the different exercise phases is shown. According to this example, the parameters recorded are sensitive to the intensity of the effort. For each of the experiments, the FC and VO2 values have been averaged out for all subjects (n=6). The average FC has been correlated to the average VO_2 for all experiments. Figure 2 shows a linear relationship between these two parameters with an excellent regression coefficient ($R^2 = 0.9715$).

According to the bioenergetic analyses and under the experimental conditions described, the HUBER system is a tool that requires a non-negligible cardio-respiratory response. Using the rotation function of the platform increases the physiological response. Using the muscles in isometric mode (especially for the upper limbs) uses the anaerobic metabolism and stimulates the adaptative mechanisms linked to this type of contraction.

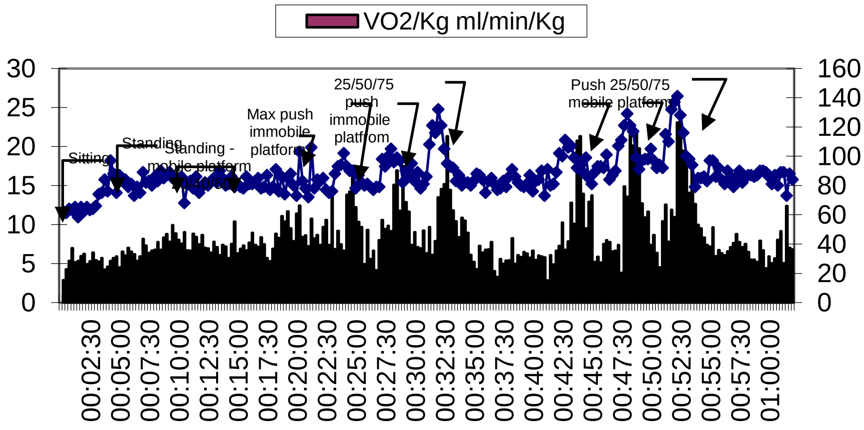


Figure 1 - Example of a set of typical tests showing changes in a subject's FC and VO_2.

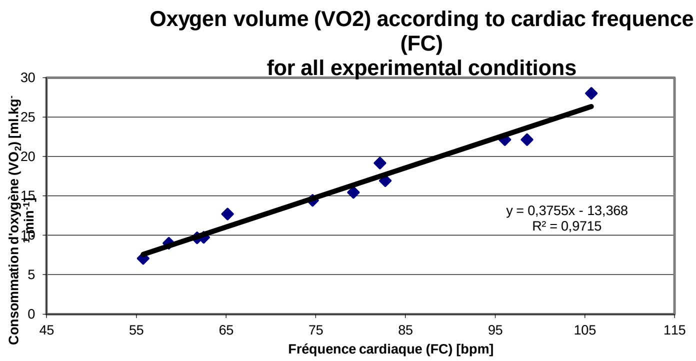


Figure 2 - Linear relationship between FC and VO_2.

2. Study on coordination and strength in healthy subjects

This study was conducted in a clinical evaluation Center in Lyon (CEREC: Centre d'Etudes de Recherche et d'Evaluations Cliniques) by Dr Jean-Marcel Ferret, the doctor for the 1998 French football team. The objective was to measure, according to age, sex and physical activity, strength and coordination before and after 5 weeks training on HUBER®. The results were presented at the Anti-Aging World Conference in March 2005 Monte Carlo (Abstract and internal report in APPENDIX 2).

The initial assessment carried out on 102 subjects divided into 6 groups, sedentary young men aged 18-25 (group 1), young sportsmen aged 18-25 (group 2), sedentary young women aged 18-25 (group 3), young sportswomen aged 18-25 (group 4), older sedentary men aged 50-60 (group 5) and older sportsmen aged 50-60 (group 6), made it possible to record accurate information on the strength and coordination of each of the subjects depending on the group they belonged to.

A second assessment, performed 5 weeks later for the first 4 groups, showed the effects of the training (10 sessions using the HUBER system).

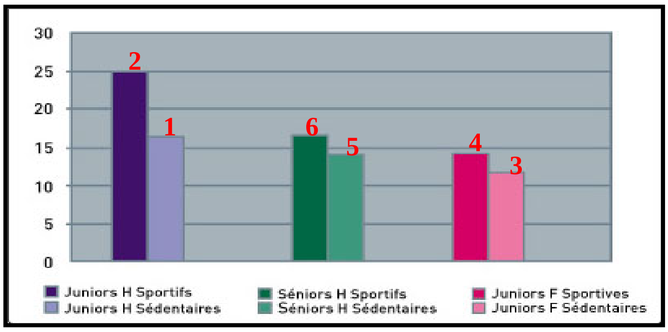
Before the training, the groups had very different levels of strength (Figure 1) depending on:

- **Age**: the young men were stronger than the older men.
- **Sex**: the young sportsmen were stronger than the young sportswomen and the same for the sedentary groups.
- **Physical activity:** the sporty subjects were stronger than the sedentary ones (especially among the young people).

In the same way, the groups were very different as regards coordination (Figure 2) depending on:

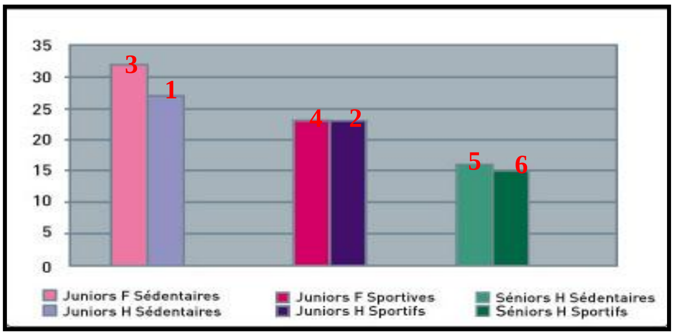
- **Age**: the young men were more coordinated than the older men.
- **Sex**: for the young sedentary subjects, the women were better coordinated than the men.
- **Physical activity:** for the young subjects (men and women) and the older subjects, the sedentary subjects were better coordinated than the sporty subjects.

Figure 1 - Max. strength at baseline
Total score for all groups



Key:
1= Younger sedentary males
2= Younger sporty males
3= Younger sedentary females
4= younger sporty females
5= Older sedentary males
6= Older sporty males

Figure 2 - % coordination at baseline
Total score for all groups



After 10 training sessions on HUBER, the average improvement in muscle strength was 24%; the increase was greater among the sedentary groups than the sports groups (Figure 3).
For the coordination score, the average improvement was 106%; the increase was greater among the sports groups than the sedentary groups (Figure 4).

Figure 3 - Improvements in max. strength with HUBER® training sessions
Groups 1 – 4 = young people, 10 sessions

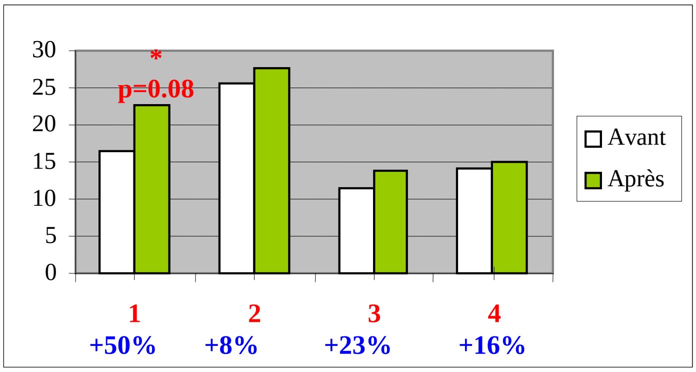
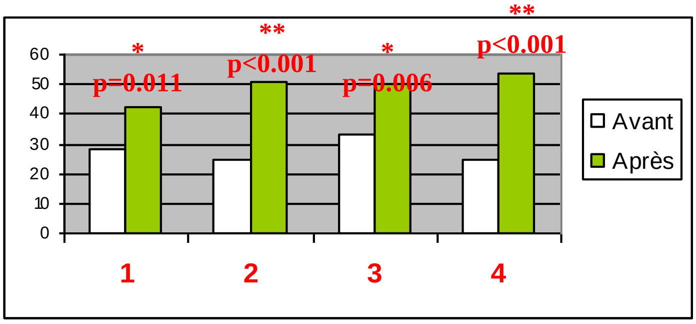


Figure 4 - Improvements in coordination with HUBER® training sessions
Groups 1 – 4 = young people, 10 sessions



Key:
1= younger sedentary males
2= Younger sporty males
3= Younger sedentary females
4= younger sporty females
**= significant*
**= very significant*

A complementary analysis performed at baseline on 133 subjects (65 subjects aged 18-25, 43 subjects aged 25-50 and 25 subjects aged 50-60) showed an inversely proportional correlation between age and coordination rate, independent of sex and physical activity (cf. table 1 and Figure 5). In other words, **coordination worsens progressively with age**.

Table 1 – Total coordination score for each age group (baseline)

		18-25	25-50	50-60	P value
Total coordination score	**N**	65.00	43.00	25.00	
	Mean	**26.56**	**23.73**	**15.69**	0.002
	Standard deviation	15.05	11.71	5.40	

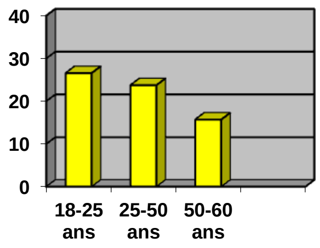
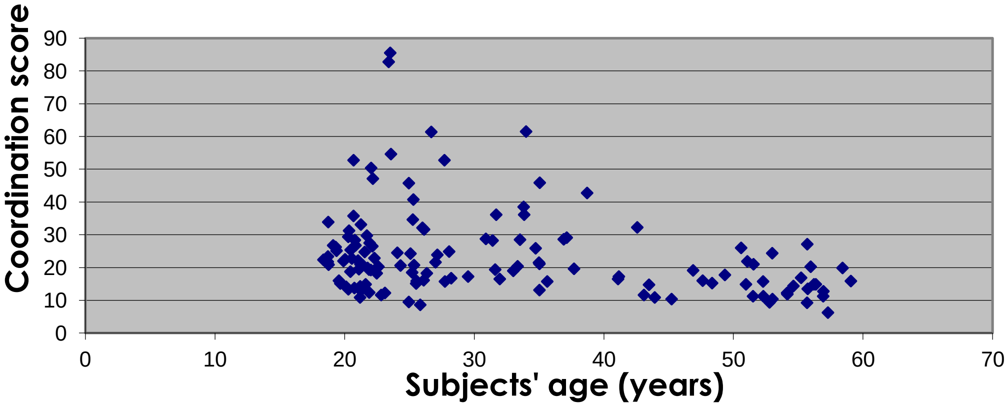
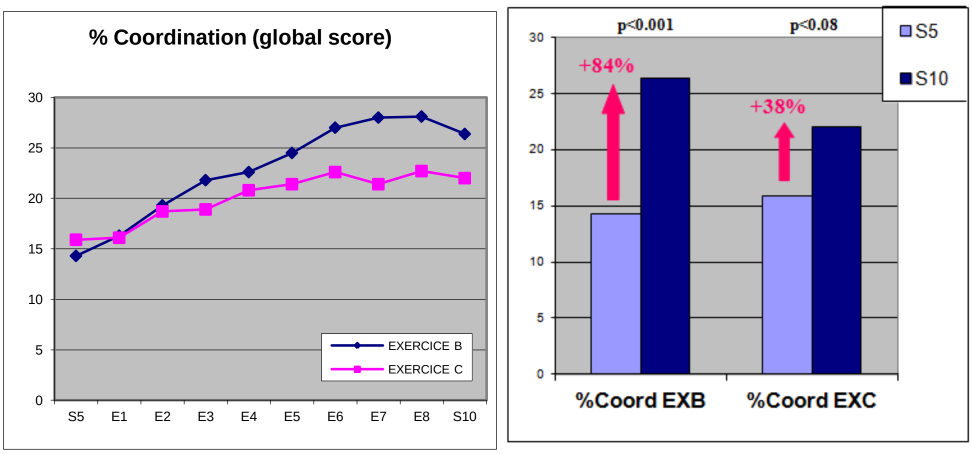


Figure 5: Total coordination score depending on age (baseline)



Finally, a study conducted on 10 older subjects (aged: 53.7 ± 6.5 years) showed that training on HUBER improves coordination by 61% on average depending on the exercise performed (Figure 6). No changes were seen for strength.

Figure 6 – Significant increase in the motor coordination of older subjects when training on HUBER®



In conclusion, evaluating the coordination achieved with the HUBER system for the different age groups makes it possible to draw up an accurate description of the person tested depending on their age (coordination worsens considerably among the older subjects), sex (coordination is slightly better among sedentary women) and physical activity (sporty subjects were stronger and have lower coordination scores).

HUBER also improves coordination in older subjects: 10 sessions of training enabled them to achieve coordination scores similar to those observed at baseline for the young population.

3. Study of balance and posture in sportsmen & women

This study was conducted by Professor Marcello FAINA from the Italian National Olympic Committee in Rome. It has been presented at the 15th World Congress of Aesthetic Medicine in May 2005 in Rome, Italy (Abstract and study summary APPENDIX 3).

Objective : To analyze the possibility to include HUBER in postural rehabilitation training for sporty subjects (effect on postural adjustment, coordination, neuromuscular and mechanical characteristics).

Population : The study has been conducted on 22 sporty subjects of different levels and aged between 18 to 41.

- 6 windsurfers (juniors national level)
- 5 fencers (national level)
- 2 tireurs arc (olympic and national level)
- 1 golfer (amateur level)
- 5 fitness amateurs
- 3 swimmers (amateur level)

Training on HUBER: 60 days, 2 sessions per week, 1h each session (total of 16 sessions).

Evaluations (before and after training):

- Baropodometry: measure of the plantar pressures and gravity centre oscillations during 4 exercises in a standing position, open or closed eyes (monopodal and bipodal support).

- Dinamometry: measure of the maximal force maximal during isometric contraction of upper and lower limbs (muscles internal and external rotation).

Results: After training on HUBER, the area of gravity centre oscillations decreases significantly. This result reflects an improvement in subjects' stability (monopodal exercise and eyes closed - MPOC) (Figure 1). Regarding maximal force of upper limbs muscles (for internal rotation), there is a significant difference between right and left for fencers before training (Figure 2). This result is also observed with muscles for external rotation and only for fencers. After training on HUBER, the left maximal force increases in fencers and the significant difference observed before training disappears (Figure 3). No modifications are seen for all sports put together, probably due to their asymmetrical and symmetrical characteristics.

Figure 1 - Improvements in stability with **HUBER**® training sessions (left= sn and right= dx)

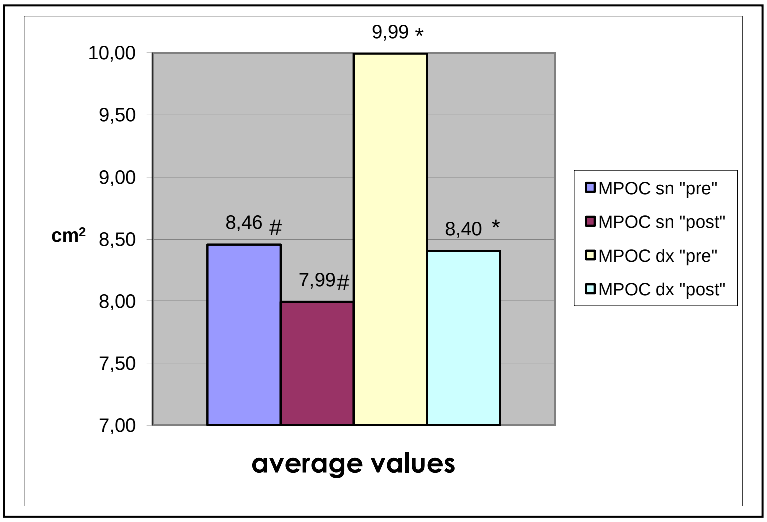
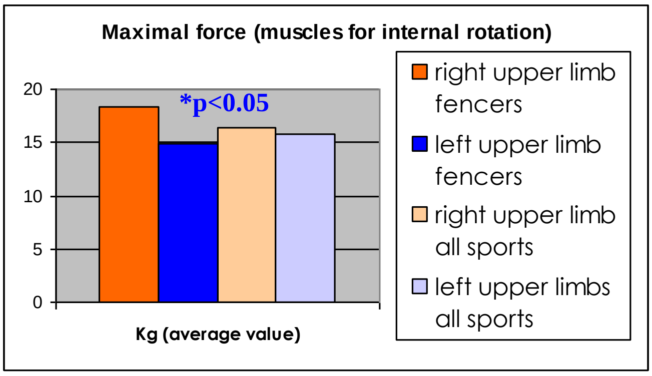
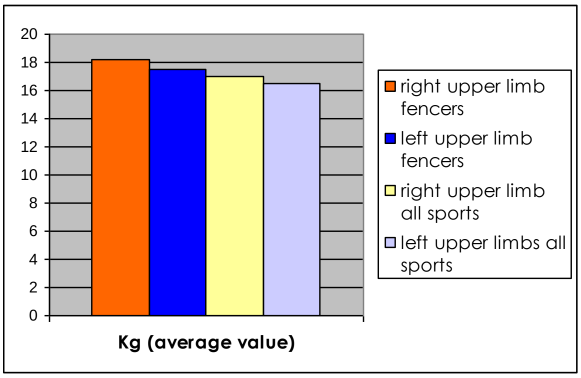


Figure 2 (left)- Significant difference between right and left for max. strength in fencers

Figure 3 (right)- Increase in max. strength on the left side in fencers after training on HUBER®





Conclusions: After 2 months training on HUBER, stability in standing position, right/left coordination and balance recovery of sporty subjects are improved. Regarding maximal force, muscle groups are re-balanced. HUBER has an important role in postural re-education.

4. Study of balance, posture and muscle function in healthy individuals

This study was conducted by Professor Pierre PORTERO at Pitié Salpétrière Hospital in Paris (Institut de la Performance Humaine IPH). It has been published in: *Annales de Réadaptation et de Médecine Physique 2008 ; 51: p67-73. Changes in balance and strength parameters induced by training on a motorised rotating platform: A study on healthy subjects. COUILLANDRE A., DUQUE RIBEIRO M.J., THOUMIE P., PORTERO P.* (APPENDIX 4)

Aim of the study: The aim of the study was to analyse the effects of training performed on the Huber1/SpineForceTM device intended to improve, postural control and muscle function.

Subjects: Twelve healthy adults (divided into a sedentary group and an active group) took part in a two-month training programme (involving three sessions a week) on the SpineForceTM whole body rehabilitation device.

Method: Instrumental assessment of postural control (on a Satel1 platform) and muscle function (on a Cybex Norm1) was performed before and after training. Postural control in various conditions was measured using a position parameter (the mean anteroposterior position of the centre of foot pressure [CoP]) and two stability parameters (maximum CoP displacement and CoP sway area). Assessment of the muscle function was performed during knee and spine extension and featured maximum voluntary isometric contraction (MVIC), root mean square (RMS) and neuromuscular efficiency (MVIC/RMS) measurements.

Results: For static postural control, we observed a more forward CoP position in the maximum backward inclination condition ($p < 0.01$) and a decrease in maximum CoP displacement in the ‘‘eyes closed on foam’’ and ‘‘maximum anterior inclination’’ conditions. In this latter condition, a lower CoP sway area was also noted ($p < 0.01$; Figure below). In terms of muscle function, a greater MVIC for knee extension was observed in the sedentary group only ($p < 0.05$). These changes were not correlated with each another ($p < 0.05$). However, the value of the pretraining maximum CoP displacement predicted its final value ($p < 0.05$).

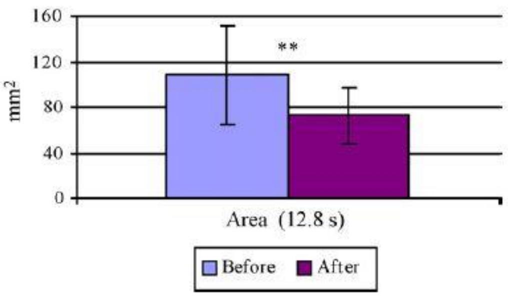


Fig. 3. CoP sway area in a standing position with maximum forward inclination, eyes open, for 12.8 s. Mean and standard deviation (± S.D.) for the entire population before and after training. $**p < 0.01$.

Conclusions and perspectives: This study on the effects of training on the HUBER system shows that the results are coherent with the literature data in the areas of physical exercise, balance problems and falls. Overall, the effects of training are positive in the two main functional areas monitored here: force and balance. The improvements obtained over eight weeks were greatest in subjects in poor initial physical condition. Training on the HUBER system (with its whole-body approach to locomotor system function) modified parameters linked to static balance and muscle function in healthy subjects who did not do any sport.

The CoP moves forward in a maximum backward lean stance, suggesting a postural reorganisation and weight transfer onto the front of the foot. Subjects also become more stable in maximum forward lean stance and when standing on foam with their eyes closed. For all subjects, the pretraining value of the maximum CoP displacement can predict its post-training value. Given the reasonable results for static balance parameters in healthy subjects, even better outcomes can be anticipated for subjects with pathologies (such as for with sensory disabilities) or elderly subjects following the same training programme.

The progress could be even more marked if the initial sway was significant. Patients presenting sensory disabilities, and elderly subjects would be less hindered by their problems with this type of training. However, additional studies with this type of population would be necessary. This type of training moderately improved the strength of the quadriceps and erector spinae muscles. However, other muscles (such as the scapular muscles) are probably significantly recruited during this training.

The combination of different postures during HUBER exercises probably contributes to development of the locomotor system's various functional potentials. Additional measurements would allow the confirmation of these hypotheses. One of the major perspectives is the possibility of adapting the experimental protocol to study certain pathologies.

In fact, a few protocol modifications (choice of the material, condition of uses, parameters monitored and the study population) might give workable results in the therapeutic field and would be likely to improve the quality of life for the elderly and patients with neurological, lumbar- and scoliosis-related problems. Furthermore, it would be interesting to analyse the persistence of the training effects. Application of this device in the management of subjects at risk of falls appears to be particularly interesting.

5. Study of balance and posture in elderly subjects

The overall balance of the body and the posture are totally dependent on the spine, its bearing and sturdiness. Aging is often associated with fragility, characterized by a gradual degradation of the subject's postural and homeostatic capacities and by a reduction in strength and muscle resistance leading to an imbalanced body and deterioration of the posture.

A study conducted in Italy, *"Aging and balance: Analysis of possible improvement with HUBER System"* has been published in the French medical review *Le Rachis N°4, Septembre 2010, p. 22* (APPENDIX 5).

This study was conducted by Professor Raul SAGGINI (Chair of Physical and Rehabilitative Medicine, G. D'Annunzio University at Chieti).

Aim: To described the characteristics of the postural alignment and balance of a sample of aging individuals with obvious balance problems and set as its objectives to compare use of the HUBER system with a more classic balance rehabilitation technique (proprioceptive platform and isotonic training).

Methods: 40 subjects (divided into 2 age brackets: 55-65 and 65-75) were randomized into 2 groups: Group A: 3 months' training with HUBER®; Group B: 3 months' training with a classic rehabilitation protocol (isokinetic). The subjects were assessed before the training (T0), after 3 months' of training, 3 sessions per week (T1), 6 and 12 months after the end of the training (T2 and T3). Assessment included an analysis of each subject's walk (Dynamic Foot System), a stabilometry test (stabilometry platform), measurement of the energy used during a 400m walk (K4 Cosmed) and an isokinetic analysis of the extension-flexion of the trunk (Cybex TEF System).

Results: The cinematic data of walking show an improvement in the spatio-temporal parameters at T1 and in particular an improvement in step symmetry for group A, whatever the age bracket (0.84+ 0.1 vs. 093+0.09; p<0.05 and 0.73+0.2 vs. 0.9+0.27, p<0.01 respectively). At T2, the observed improvement remained significant (0.84+ 0.1 vs. 094+0.13; p<0.05 and 0.73+0.2 vs. 0.9+0.68, p<0.05 respectively). However at T3 (12 months after training finished), the values had returned to the baseline values. Group B showed no significant changes at any evaluation time.

Data regarding the changes in energy used show interesting results for the 55-65 age group in Group A. All these subjects showed a significant reduction in the energy used during a 400m walk. This reduction remained significant at T2 but had disappeared at T3 (cf. Figure 1). Group B showed no significant changes at any evaluation time. No modifications were observed for either group for oxygen volumes and heart rate.

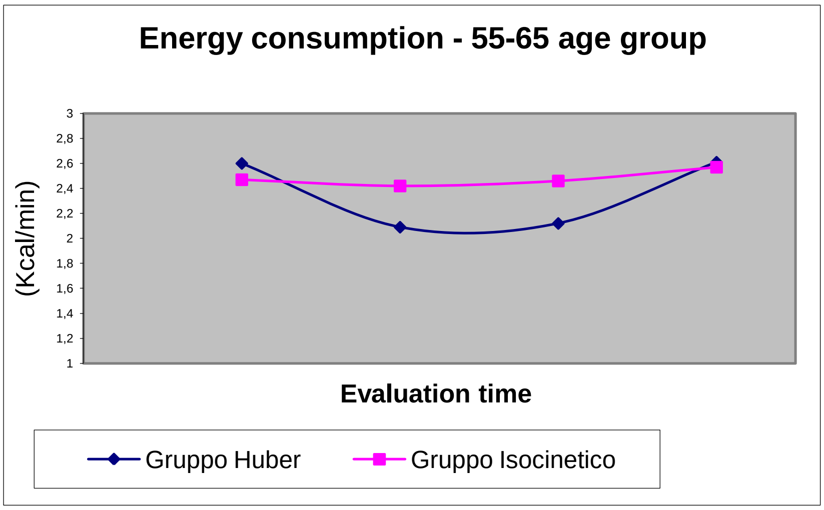


Figure 1 - Energy consumption measured for both groups for a 400 meter walk.
Improvement was observed in Group A (HUBER) (T0 vs. T1 p<0.05), this improvement continued to T2 (p<0.05). At T3, the values returned to baseline T0. Group B (isotonic training) showed no significant modification.

The results of the isokinetic trunk extension/flexion test are reported in figures 2 & 3. The subjects aged 55 to 65 showed a significant improvement at T1 whatever the training (group A: p<0.01 and group B: p< 0.05). The increase in the trunk's work capacity also persisted at T2. Subjects aged 55 to 75 only showed a significant improvement at T1 if they had been trained on HUBER (p< 0.05). This improvement continued at T2.

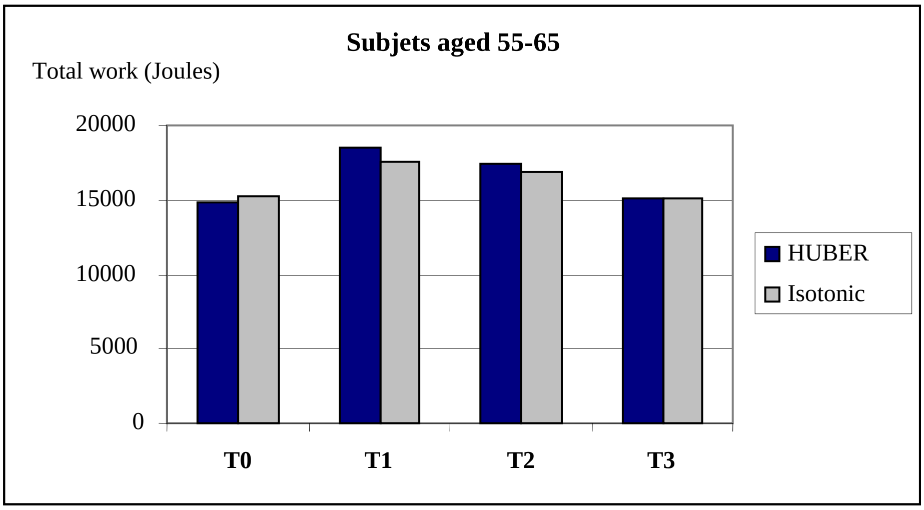
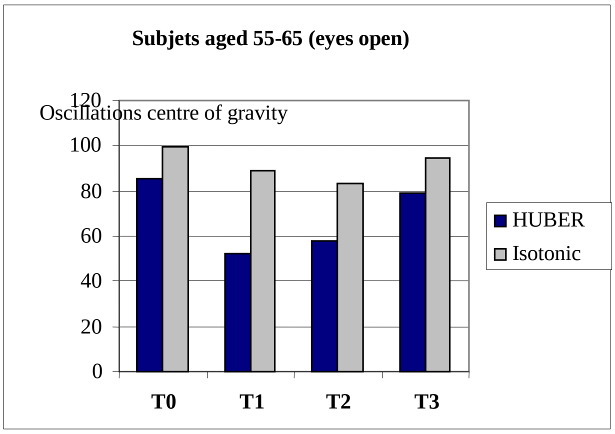
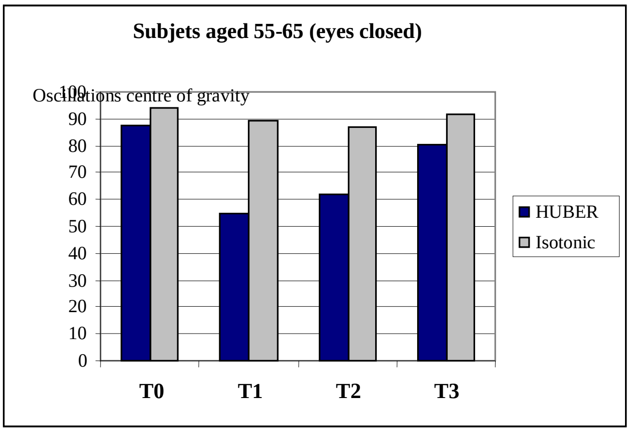


Figure 2 - Results for the Cybex TEF (subjects aged 55 to 65). The subjects showed significant improvement at T1 whether it be with Huber ($p<0.01$) or with isotonic training ($p<0.05$). Whatever the group, the improvement continued and was just as significant at T2.

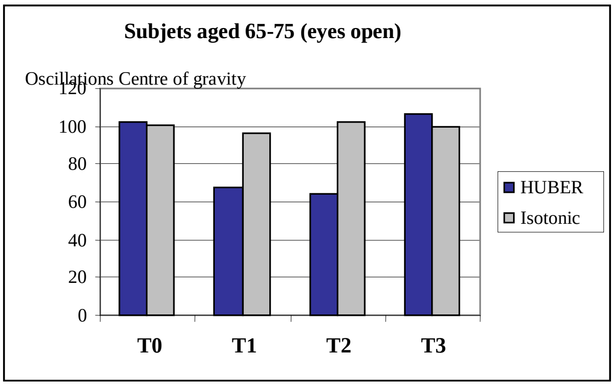
Figure 3 - Results for the Cybex TEF (subjects aged 65 to 75). The improvement was only significant at T1 and T2 only for the HUBER group ($p<0.05$).

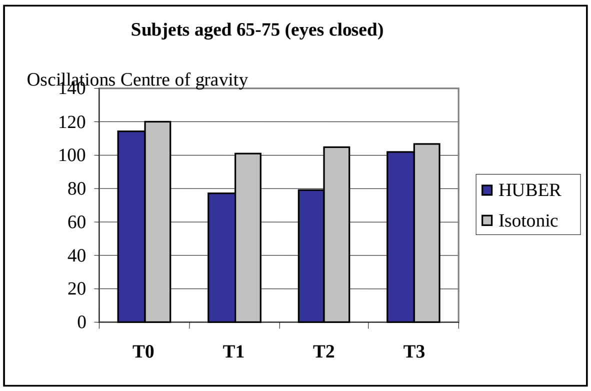
Stabilometry data showed a significant improvement in balance at T1 and T2 for Group A, whatever the age and the sex. Group B showed no significant changes, whatever the age, sex or evaluation time. The results obtained for the 2 groups, irrespective of the sex, are shown in Figure 4.





a) **b)**





c) **d)**

Figure 4 - Results of the stabilometry analysis of the two groups depending on age and measurement conditions (eyes open or closed) at T1 p<0.01 at T2 p<0.02 at T3 n.s. 2b) subjects aged 55-65 eyes closed; T0 n.s., at T1 p<0.01 at T2 p<0.05 at T3 n.s. 2c) subjects aged 65-75 eyes open; T0 n.s., at T1 p<0.05 at T2 p<0.05 at T3 n.s. 2d) subjects aged 65-75 eyes closed; T0 n.s., at T1 p<0.05 at T2 p<0.05 at T3 n.s. 12 months after the end of the training, the values returned to baseline levels (T3).

Conclusion: The study concluded that training on HUBER (3 sessions per week over 3 months) is a global way of confronting the problem of age-related fragility given that the specific rehabilitation protocol acts on the deep muscles of the spine and develops the muscle tone of the lower limbs associating with it motor-vestibular rehabilitation. The effects of training on HUBER resulted in a better locomotion capacity and therefore a better quality of life for subjects aged 55-75.

6. Advantages in physical medicine and rehabilitation

By its action on the muscle chains and by triggering adaptation reflexes in just a few minutes, HUBER is able to act on the loss of motor skills and thus create a means of rehabilitation for neurological and locomotor disorders.

Working with Dr Benoît MAERTENS (Fraiture Neurological Rehabilitation Centre CNRF, Belgium), clinic data has been collected on the use of the HUBER system in Physical Medicine and Rehabilitation. This experience has been presented at the 15th Congress of the European Society of Physical Medicine & Rehabilitation ESPRM; May 16-20th 2006, Madrid (APPENDIX 6).

The initial observations focused on 60 patients (screened for different disorders, including: Multiple Sclerosis, Parkinson's disease, orthopaedic disorders of the lower limbs, amputation of a lower limb, etc.) and representing more than 400 sessions on HUBER, drew the following conclusions:

- Possible use in rehabilitation, even for very elderly patients suffering from disorders of differing degrees of severity.
- It was very well accepted by the patients (seen as enjoyable and stimulating).
- It increased general muscle strength.
- It helped the patients to regain automatic reflexes in contact with the ground (one of the things that had been lost through the disorder).
- Beneficial effect on axial balance (important for rehabilitation of walking ability).
- Dual-tasking: demand on the higher functions.
- Advantages of "% coordination" to evaluate the progress made.

For multiple sclerosis, the HUBER device would appear to be advantageous for:

- Proprioception work on the lower limbs and the spine.
- Global and harmonious or analytical muscle strengthening depending on the patients' specific problems.
- Reworking all the proprioceptive adaptation connections quickly and with quality as part of an exercise that should not reinforce spasticity.

7. Possible use of HUBER to treat chronic low back pain

Numerous authors have established the relationship between lumbar pain and inadequacies of the deep muscles. Others have pointed to the fact that strengthening the deep muscles has an effect on relieving chronic lumbar pain even if it was not always easy to target these muscles correctly in the exercises proposed. The ideal rehabilitation of these muscles should include coordination exercises, as is the case with HUBER.

A controlled study, in collaboration with Dr Mihai BOJINCA (Rheumatology Department, Cantacusino Hospital, Bucharest, Romania) and entitled " *Efficacy of exercise program with the HUBER system compared with classic exercise program in rehabilitation for patients with chronic low back pain"* showed the benefits of HUBER exercise programs (15 sessions). It had been presented at the annual European Congress of Rheumatology of the European League Against Rheumatism (EULAR) in June 2006 at Amsterdam (APPENDIX 7).

Background: Chronic low back pain is one of the most frequent medical problems in the general population. Exercise is generally accepted as treatment for low back pain but the best method is still in debate [1]. HUBER® is a new rehabilitation device with complex actions on different muscular groups, postural equilibrium and mobility improvement. During exercise, HUBER® records variations of effort and co-ordination performance.

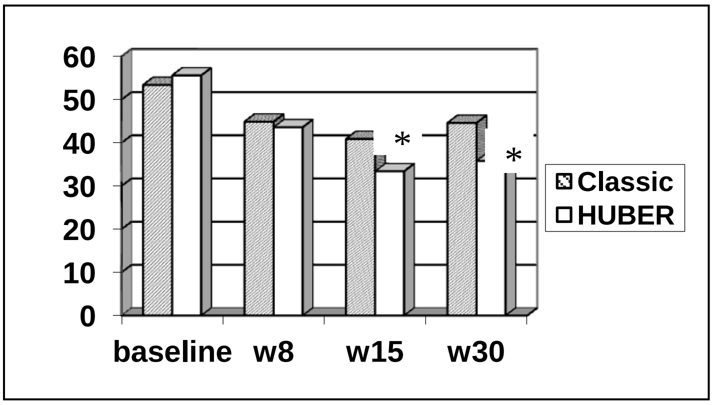
Objective: Assessment of efficacy of the HUBER® system-physical exercise, compared to a classical exercise program, in the treatment of uncomplicated chronic low back pain (cLBP).

Methods: We followed 50 patients with uncomplicated cLBP. Patients have been clinically evaluated and randomized to 2 treatment arms, each including 15 one-hour sessions of: classical physical exercise (25 patients) or HUBER® system physical exercise (25 patients). Patient assessment was performed at baseline, after 8 sessions, after 15 sessions and also at 2 months after the end of the physical exercise program, by physical examination, pain assessment by patient on 100 mm VAS, Schober index and finger-to-floor distance for mobility assessment, Shirado-Ito and Biering-Sorensen tests for trunk musculature force assessment, and quality of life questionnaires (Quebec functional impairment scale). Statistical analysis was performed using the SPSS 11 software.

Results: Mean age was 39.64 ± 10.85 years in the HUBER® arm and 41.16 ± 9.31 years in the classical physical exercise arm (p = NS). After 8 sessions, 15 sessions and at 2 months after end of treatment, both groups had significant improvement ($p < 0.05$) in pain (Figure 1), quality of life (Figure 2) and Biering-Sorensen and Shirado-Ito tests (Figure 3). Patients in the HUBER® group had significantly more improvement as compared to the classic physical exercise group in pain, Shirato-Ito test and Quebec functional impairment scale ($p< 0.05$). No patient in either of the groups had any significant adverse reaction to the treatment.

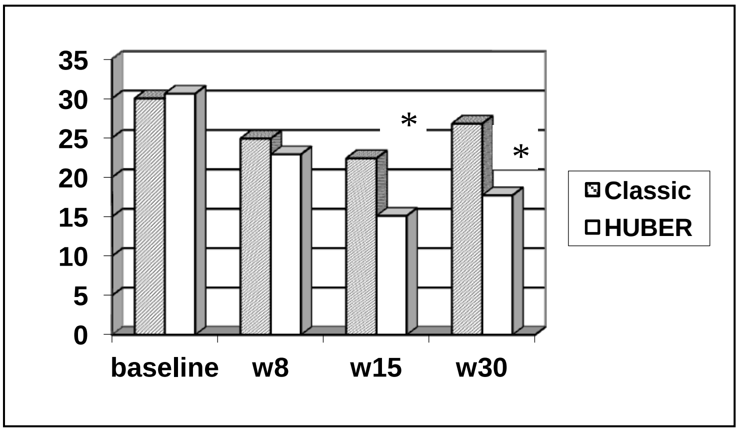
Conclusion: HUBER® physical exercise program is effective and well tolerated in patients with uncomplicated cLBP. Compared to a classical physical exercise program, the HUBER® standardized program induces significantly more improvement in pain, function and muscle strength parameters. These results prove that the HUBER® standardized program is a very useful tool in the management of uncomplicated cLBP.

Fig 1. Pain intensity (assessed by the patient on a 100 mm VAS, where 0 is “no pain” and 100 stands for “worst possible pain”) in the two study groups. Differences between groups are statistically significant at 15 weeks from baseline (end of treatment course) and at 30 weeks from baseline (2 months after the end of treatment course).



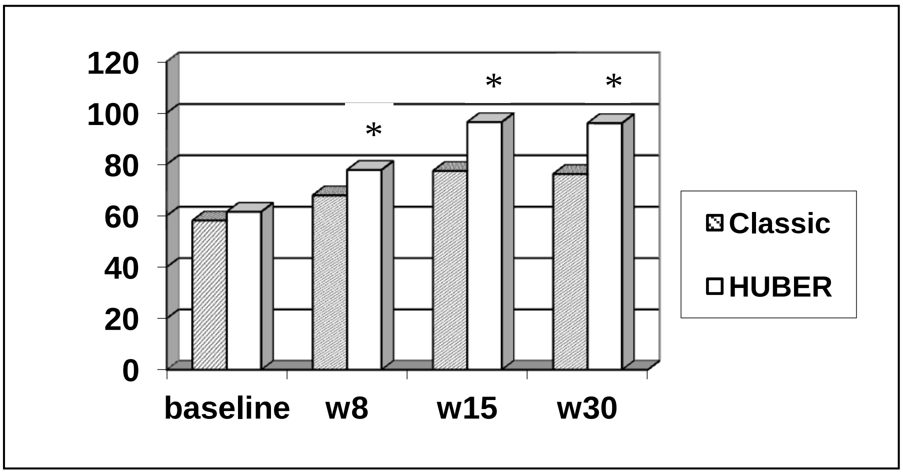
*p<0.05 by independent samples t-test. At baseline, week 8 and week 15 groups include 25 patients each. At week 30 only 35 patients have been assessed (Huber=19, classic=16).

Fig 2. Quality of life (assessed by the patient by self-administration of the Quebec questionnaire) in the two study groups. Differences between groups are statistically significant at 15 weeks from baseline (end of treatment course) and at 30 weeks from baseline (2 months after the end of treatment course).



*p <0.05 by Mann-Whitney U-test. At baseline, week 8 and week 15 groups include 25 patients each. At week 30 only 35 patients have been assessed (Huber=19, classic=16).

Fig 3. Trunk flexor muscle strength (assessed by the Shirado-Ito test) in the two study groups. Differences between groups are statistically significant at 8 weeks from baseline, at 15 weeks from baseline (end of treatment course) and at 30 weeks from baseline (2 months after the end of treatment course).



*p <0.05 by Mann-Whitney U-test

At baseline, week 8 and week 15 groups include 25 patients each. At week 30 only 35 patients have been assessed (Huber=19, classic=16).

8. Advantages in rehabilitation of patients with multiple sclerosis

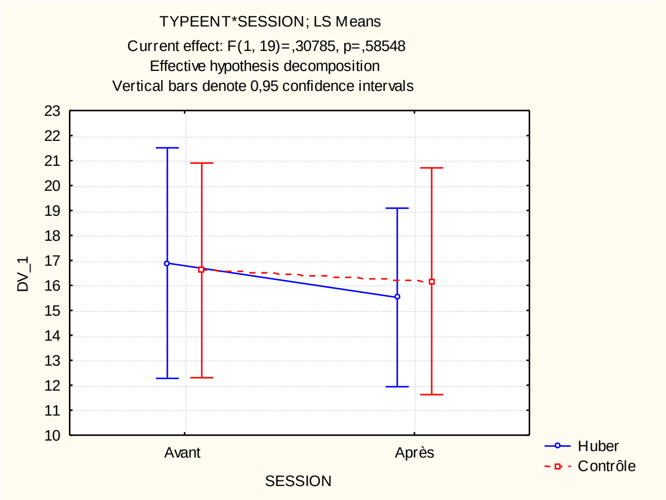
A controlled clinical study entitled *" Using the HUBER® technique for the rehabilitation of patients with multiple sclerosis"* has been conducted and supervised by Dr Benoît MAERTENS. It was presented at the annual meeting of Rehabilitation in Multiple Sclerosis (RIMS) on May 2006 in Barcelona (Spain). (APPENDIX 8).

Purpose: Rehabilitation using the HUBER® device allows a global muscular strengthening and an interesting proprioceptive work. Various neurological and orthopaedic pathologies should be able to benefit from this original device. This study tried to evaluate the possibilities of using HUBER® for the rehabilitation of patients with multiple sclerosis (MS).

Material and Methods: 20 patients suffering from multiple sclerosis in non-active periods with weak or moderate motor deficit, EDSS < 7, where included in a randomized, controlled, cross-over clinical trial in order to specify the effect of this rehabilitation technique on the patient with multiple sclerosis. The program consists in 10 training sessions; 1 session/week. The evaluation of the is carried out on the basis of stabilometric test, 10m walking test, neurological assessment, evaluation scales (EDSS, FIM) and patient's performances with HUBER®.

Results: After training on HUBER® MS patients showed significant improvement of walking ability. The mean result of the 10 m walking test is 1.37 sec ($p < 0.044$) faster. A net negative correlation is noticed between the walking improvement and both the sensory troubles and the functional level before the study.

Conclusion: As well as a global muscular work, the training with the HUBER® system allows to work proprioception and balance in a very specific way. An intense and unique request of psychomotor functions was also noticed. For patients with multiple sclerosis, an improvement of the walking speed is noticed after 10 light training sessions on HUBER®.



9. Interest for neuro-muscular reprogramming

A practical experience entitled *"A new concept of dynamic neuromuscular reprogramming using Huber® device"* has been described by Stéphane FABRI (Centre de Rééducation Spécialisée, Montpellier; France) in *"Traité EMC Kinésithérapie-Médecine Physique-Réadaptation 2007. Rééducation des entorses du genou : traitement fonctionnel. FABRI S., LACAZE F., MARC T., ROUSSENQUE A., CONSTANTINIDES A"* and presented at the 16th European Congress of Physical and Rehabilitation Medicine in June 2008 (Bruges, Belgium) (APPENDIX 9).

Aim: Pathologies like lower Iimb joint traumatisms are frequent in sports activities. Sports activities, alpine skiing in particular, expose very frequently to anterior cruciate ligament rupture (every year, in France, 1 skier out of 3 will suffer from a knee sprain and around 16000 will suffer from anterior cruciate ligament rupture). The neuromuscular reprogramming remains the more important phase in the rehabilitation treatment of the knee joint instabilities. The techniques to improve the proprioception did not evolve since the invention of the pulley- therapy and of the Freeman platform. Today, it seems that motor coordination training using a motorized oscillating pIatform (Huber device) could re present a real innovation in this domain. The goal of our work is to optimize the neuromuscular reprogramming and to help the return to the socio professional and Sports activities.

Methods: The Huber device generates a permanent adaptative regulation of the joint protection, while soliciting preferentially the proprioceptive system and improving static postural control. This new procedure also allows the patients to carry out a double task exercise protocol and to solicit the tonic muscles. The patients (men and women, aged between 25 and 50 years oId) are divided in 2 groups by randomisation: 21 patients in the treatment group and 21 patients in the control group. Each group undergoes 1h30 of rehabilitation a day, 5 days a week, during 10 weeks. The Huber group will undergo 5 rehabilitation sessions with Huber a week (5 x 20 min) instead of the "Proprioceptive" protocol as part of the common rehabilitation program. The investigations will assess: functional response (Lysholm-Tegner scale; IKDC 2000), pain (VAS), imbalance (stabilometry), postoperative knee residual laxity (KT 1000 arthrometer), injured knee oedema/ effusion. An isocinetic evaluation (Biodex) will also be carried out.

Results: All assessments are carried out in the preoperatory and in the 3rd, 6th, 12th, 24th and 52nd postoperatory week. During post-surgical rehabilitation of the knee instability, the neuromuscu!ar reprogramming is practiced on the Huber device, starting with the 21st day. This proprioceptive program starts as soon as the patient is able to put again his foot on the ground and continues on a daily basis until the 3rd month. Initially, the plateau oscillates slowly and with low amplitude and the exercises is not difficult. The exercises are first done in bipodal position and afterwards in unipodal position. Then, there is a progressive increase of the parameters (speed and amplitude) in order to attain a maximum level towards the end of the rehabilitation programme. At this stage, the rotator stabilizing mechanisms are solicited, as well as the patient's knee joints.

Conclusion: The Freeman platforms, extensively used for the knee joint traumatisms, produce motor programs that are not adapted because based mainly on the visual and vestibular system. On the other side, the rehabilitation programme using stable platforms seems to solicit mainly the somesthetics afferents inputs. This type of rehabilitation programme is more effective but more Iimited and more separated from physiology. In fact, all the traditional techniques have the inconvenience to realize an isometric workout at the knee level.

The hypothesis of this trial assesses the possibility of a functional improvement of the knee, after the training of coordination, proprioceptivity and joint stabilisation mechanisms with the HUBER device, by an active anticipation of reflex activities in a complex environment (platform imbalance and the visual feed-back produce a double task, condition). The neuromuscular reprogramming is the principal goal in the rehabilitation treatment of the joint instabilities. It must be progressive and the more possible, physiological. The dynamic, double task exercise protocol is essential but needs the lack of the vestibular system inference. We think that the Huber device is more adapted to the mechanisms of articular stabilities. This device represents at last a real evolution since the works of Freemann.

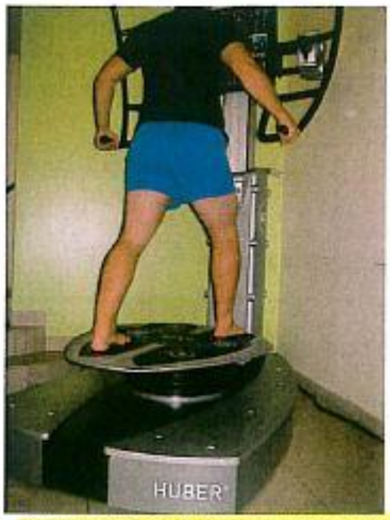


Figure 25. Nouvelle méthode de reprogrammation neuromusculaire dynamique sur appareil Huber® avec plateau motorisé.

10. Interest for predictive evaluations of the sprain ankle

A practical experience entitled "*Predictives evaluations of the sprain ankle. Fifty-eight cases report*" has been described by Stéphane FABRI (Centre de Rééducation Spécialisée, Montpellier; France) in: « *Journal de Traumatologie du Sport 2009, vol. 26, no3, pp. 139-147. Evaluations prédictives de l'entorse de cheville. A propos de 58 cas. FABRI S., DUC A., CONSTANTINIDES A., PEREIRA-DURIF Y., MARC T., LACAZE F."* (APPENDIX 10).

Rational: When an injury comes out, it is seen like a fatality for a sportsman and the medical staff. The ankle sprain is from far the most common pathology. Preventions programs proved their efficiency in many fields. However, it is very hard to put them into practice because there is few or no tools to these persons.

Objective: To provide reliable, reproducible and non- operator dependent assessments that will identify potential topics victim of a sprain ankle in the medium term. We tested 58 young's healthy athletes whose sport practice was up to 2 hours a week.

Methods: Assessments were done on a motor coordination machine (HUBER), on a posturography platform. Analysis of the muscular benefits of each lower limbs were performed thanks to an accelerometer. These analyses have been done in November 2007, January 2008 and March 2008.

Results: Five articulars instability were sorted out. Topics victims of the ankle sprain during the study got a 13% coordination deficiency. The difference is statistically significant. All the tests which have been done on the posturography plateform were not accepted because the evaluation results were not comparables with the 1985 norms of the French Association of Posturology. We were able to see a curve problem with wounded patients during the ground absorption phase and had a stabilisation time shorter than the one for the healthy subjects. This significative difference was up to 110 ms. Pope et al. find out on patients hit by a talocrural sprain, a significative diminution of the dorsiflexion during the previous traumatism report. Willems et al. find these facts and describe others intrinsic factors of predisposition which match our results.

Conclusion: This work proved that it is possible to warn, in a midterm, the sprain of the ankle. These warnings reports must be done in the beginning of the sporting season and will allow determining the athlete's weakness thanks to reliable and reproducible evaluations.

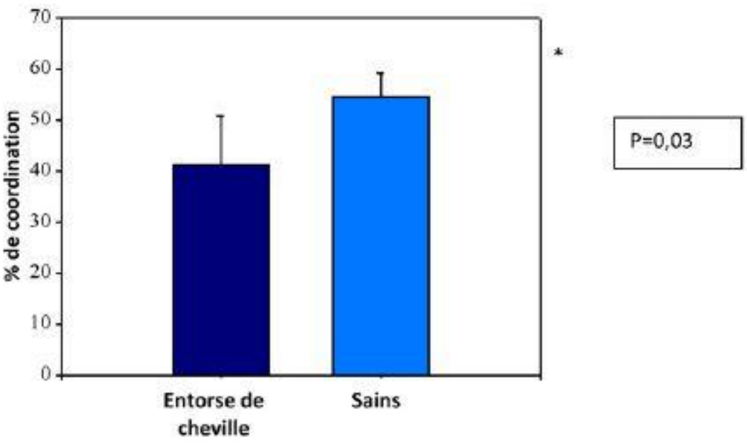


Fig. 11. Coordination entre le membre inférieur lésé des sujets victimes d'une entorse de cheville et chaque membre inférieur des sujets sains.

11. Interest for core muscle endurance

An article published in the Journal of the American Chiropractic Association focus on fall prevention and underlines the interest of using HUBER for Reactive Neuromuscular Training for Low Back Pain Patients (*Fall Prevention, Part IV: Interventions By Carol Marleigh Kline, MA, JACA, January-February 2010 Volume 47, No. 1*) (APPENDIX 11).

"Older adults with balance problems often suffer from LBP, as well. "Low-back pain (LBP) is rarely explained by a single structural pathology," says Dr. Enix. "It's more likely a result of accumulated biomechanical and pain-related psychological variables. Biomechanical factors that have been identified as playing a key role in the development and chronicity of LBP include poor proprioceptive input and poor muscular endurance of the lumbar and pelvic region.

"Rehabilitation protocols for LBP commonly include neuromuscular and proprioceptive training, which have clinically encouraging results but modest empirical support. Reactive neuromuscular training (RNT) is one form of therapy that is promising but not fully investigated,"adds Dr. Enix. A 2009 study by Enix et al., tested the SpineForce trainer (LPG, Inc., Cedex, France) as a method of increasing core stability. Exercises to isolate the core spinal muscles were performed on an oscillating platform (see Fig. 1) to place those muscles "in a lengthened state relative to their neutral position in the spine," says Dr. Enix. "The muscles reacted to perturbations while being taken through a series of active and resisted ranges of motion designed to isolate weak and imbalanced core muscles and strengthen and stabilize them."

This study used the McGill side bridge test to study participants' ability to perform sustained core muscle contraction over a period of time without undue fatigue, says Dr. Enix. "Sustained contraction tests have been shown to be an indicator of muscular endurance. Core muscle exercises, when performed properly, aid in the development of muscle tone important for spinal stabilization.

Adequate strength and endurance of core body muscles have been shown to be an important element in the prevention and treatment of lower back injury. In this study, participants who trained for 10 minutes three times a week for four weeks showed a significant increase in core muscle endurance."

Fig. 1. SpineForce Reactive Neuromuscular Trainer.

(Left to right): Dr. Dennis Enix, Logan graduate student,

Dr. Kristian Giggey. (Photo courtesy of Dr. Enix)

12. Study on metabolic responses and body composition

This study was carried out at the research center "esp-consulting" (Mimet, France) and supervised by Jean Bernard FABRE and it has been published in: *Gazzetta Medica Italiana Archivio per le Scienze Mediche 2014 January-February;173(1-2):47-56* (APPENDIX 12).

Aim: This study aimed to evaluate the metabolic responses during a whole-body strength training WBST (HUBER) session and the effectiveness of a 8-weeks HUBER program on metabolic adaptations and body composition.

Methods: Three experimental groups followed either a HUBER program (n=15), a walking program (WALK, n=11), or control period (CONT, n=12). The oxygen consumption (VO2), and the rate of lipid oxidation (LipOx) were evaluated during both incremental exercises (HUBER and WALK) before and after both 8-weeks training programs (i.e., HUBER and WALK). Additionally, body composition and anthropometric characteristics were evaluated before and after the experimental period, for each group.

Results: VO2 was similar during HUBER performed at 80% of MVC (15.4 ± 3.9 ml/min/kg),
and during walking at 4.5 km/h (16.8 ± 2.0 ml/min/kg). After HUBER program, VO2 during walking exercise at 4.5 km/h was significantly reduced (-7.2 ± 10.4 %; p<0.01). The reduction of body fat percentage was significantly (p<0.05) greater after HUBER program (-4.94 ± 4.65 %) than after WALK program (-3.17 ± 1.95 %) (Figure 4). In contrast body composition did not significantly change after CONT period.

Conclusion: This study demonstrated that a HUBER session, performed at 80 % of MVC, induced a significant aerobic solicitation and that a 8- week HUBER program efficaciously influenced body composition, anthropometric characteristics, and reduced the energetic cost of walking. These findings suggest that HUBER may be an interesting alternative to combined aerobic and strength training strategies in overweight management.

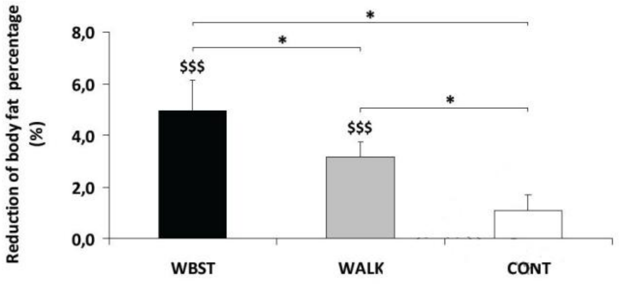


Figure 4: Reduction of the percentage of body fat mass after WBST program (black histogram), walking program (WALK, grey histogram) and after control period (CONT, white histogram). Data are expressed as mean ± SD. $$$: significant reduction from initial values, p<0.01. *: significant differences between PRE and POST values, p<0.05

13. Study on coronary heart disease (CHD) patients

A study entitled: "*Whole-Body Strength Training Using a Huber Motion Lab in Coronary Heart Disease Patients: Safety, Tolerance, Fuel Selection, and Energy Expenditure Aspects and Optimization*" have been carried out in a cardiac rehabilitation Center at Saint Orens Clinic in France. It has been presented in the medical congress of the "European Society of Physical & Rehabilitation Medicine", in September 2013 (Hyères), May 2014 (Marseille) and published in: *Am J Phys Med Rehabil. 2014 Aug 28* (APPENDIX 13).

Objective: The aim of this study was to investigate safety, tolerance, relative exercise intensity, and muscle substrate oxidation during sessions performed on a Huber Motion Lab in coronary heart disease patients.

Design: After an assessment of VO2 peak, 20 coronary heart disease patients participated in two different exercises performed in random order at 40% and 70% (W40 and W70) of the maximal isometric voluntary contraction.

Results: No significant arrhythmia or abnormal blood pressure responses occurred during either session or no muscle soreness was reported within 48 hrs posttest. The authors found a difference between W40 and W70 sessions for mean (standard deviation) ventilation (25.1% [8%] and 32.1% [9%] of maximal ventilation, respectively; $p = 0.04$) and a small difference for mean (standard deviation) heart rate (73 and 79 beats/min, respectively; $p < 0.01$). When compared with the W40, the W70 was associated with higher active energy expenditure (2.4 and 3.1 Kcal/min, respectively; $p < 0.0001$) and a similar mean (standard deviation) oxygen uptake (5.5 and 6.6 ml/min per kilogram, respectively; $p = 0.07$). The qualitative percentages of carbohydrates and lipids oxidized were 71% and 29%, respectively, at W40 and 91% and 9%, respectively, at W70.

Conclusions: Both protocols, which consisted of repeating 6-sec phases of contractions with 10 secs of passive recovery on the HUBER, seemed to be well tolerated, safe, and feasible in this group of coronary heart disease patients.

14. Study on healthy elderly women

This study entitled "*Effects of feedback-based balance and core resistance training vs. Pilates training on balance and muscle function in older women: a randomized-controlled trial*" have been carried out in the Rehabilitation Center Motus Melior in collaboration with School of

Kinesiology, University of Zagreb, Croatia. It has been submitted for publication in "Gerontology" (September 2014). (APPENDIX 14).

Rational: One of the leading public health problems of the modern society is related to aging-induced osteopenia and sarcopenia (loss of bone and muscle mass), and decreased neuromuscular and cognitive function, which leads to balance and motor impairments, increased fall risk and reduced quality of life. Hence, prevention of these aging-induced public-health problems represents an important scientific and practical task.

Aim: The purpose of this project was to evaluate the chronic effects of HUBER treatment on neuro-musculoskeletal structure and function, and cognitive performance in elderly population, and to examine the stability of these treatment effects after a period of detraining. Furthermore, the project was focused on evaluating the effects of longer duration of HUBER treatment on bone health.

Population: 30 elderly women (age: ≥65 years) that had no apparent neuromuscular, metabolic or cardio-respiratory disorders have been selected. After a thorough medial check, the subjects have been randomly divided into 2 groups trained for 2 months, 3 times a week.

- Experimental (HUBER): 16 subjects completed 90% of training
- Control (pilates & stretching): 14 subjects completed 90% of training

Evaluations: Subjects in both groups will perform altogether 24 supervised training sessions lasting ~30-45 min. Additionally, selected sub-group (12 of them) of participants within the experimental group continued to perform HUBER treatment for additional 4 months. Prior to, immediately after the treatment period, and 1 month after cessation of exercise, each subject participated in a 3-day testing session that involved: measurement of body composition (including muscle mass) and body size (by using multi-frequency bioelectric impedance analyser), measurement of postural balance (by using the force plate), measurement of mobility (by using the goniometry and simple clinical tests), measurement of neuromuscular function (by using Biodex isokinetic machine for leg, arm and trunk strength testing, and force plate for power testing), measurement of functional performance (maximal walking speed and raising chair time), and measurement of cognitive function (by using standard questionnaires). The selected sub-group of 12 participants participated in evaluation of bone density at hip and spine segmental level at the beginning and at the end of 6-month HUBER treatment.

Main results

Body morphology: no training-induced changes in body mass were observed in any group. Significant decrease ($p < 0,05$) in body fat percentage was observed in the experimental group.

	CON pre	CON post	EXP pre	EXP post
Body mass (kg)	69,4±9,1	70,1±9,2	71,2±8,1	70,4±8,6
Fat percentage (%)	39,1±8,4	39,7±7,6	39,7±8,8	35,6±8,6*

significant pre-post change

Neuromuscular function: Experimental group significantly ($p < 0,05$) improved performance in all measured neuromuscular qualities, i.e., upper body strength (8%), leg extensor power (14%), trunk extensor strength (31%), trunk flexor strength (30%), trunk lateral flexor strength (24-26%), and balance without (6.5%) and with additional cognitive task (11%). The observed improvements in balance performance were the result of improved postural control in medio-lateral direction. Note that significant Time x Group interaction effects were observed in all variables except chest press (i.e. upper body strength), indicating that the observed performance gains in experimental group were significantly higher compared with those in the control group.

The only significant ($p < 0,05$) performance change in the control group was related to increased upper body strength (6%). Overall, these results clearly indicate superiority of the applied combined strength & balance training program, performed on HUBER device, over traditional exercise programs in improving neuromuscular performance of elderly women.

	CON pre	CON post	EXP pre	EXP post
Chest press (kg)	22,9±6,7	24,4±6,8*	23,0±4,0	24,8±4,4*
Vertical jump height (cm)	8,4±3,4	8,0±3,1	9,0±2,6	10,3±2,5*
Trunk extensor strength (Nm)	336,4±94,4	344,6±101,9	303,8±84,0	397,2±108,3*
Trunk flexor strength (Nm)	360,0±107,1	372,6±113,1	340,3±83,9	441,4±102,2*
Trunk right laterofexor strength (Nm)	252,4±91,3	255,9±87,4	251,1±54,4	313,1±69,2*
Trunk left laterofexor strength (Nm)	271,2±84,3	273,3±88,4	260,2±51,9	327,5±70,7*
*Semi-tandem balance stance***				
Total sway velocity (mm/s)	37,5±8,0	37,7±8,4	37,7±4,6	35,3±5,4*
Antero-posterior sway velocity (mm/s)	22,6±4,5	22,4±3,7	21,7±3,6	21,1±2,9
Medio-lateral sway velocity (mm/s)	25,1±5,8	25,4±7,2	26,1±4,0	23,8±4,3*
*Semi-tandem balance stance with cognitive task***				
Total sway velocity (mm/s)	46,2±10,8	46,5±10,1	44,0±8,6	39,1±7,5*
Antero-posterior sway velocity (mm/s)	26,5±6,6	27,3±9,2	24,7±3,6	22,7±4,6
Medio-lateral sway velocity (mm/s)	31,8±9,0	31,1±11,0	31,5±7,6	26,9±6,0*

significant pre-post change; **inversly scaled variable (lower score means better performance)

6. DATA ANALYSIS

6.1. Performance

HUBER is a device that mobilizes the articulations and recruits the muscle chains in a situation close to that of functional life. The subject, standing on a motorized platform, has to make major or minor postural adjustments in line with the range and speed parameters set for the platform in order to maintain stability. Effort sensors and visual feedback also provide information about motor activity - all this in optimum safety conditions. The exertion parameters recorded on HUBER increase after training for those with a sedentary lifestyle and the quadriceps grow stronger (depending on the exercises carried out) (Ph. Thoumie, P. Portero et col.). Intermuscular coordination improves by adapting agonist/antagonist interplay (P. Portero). The balance is improved and interfere on the posture in healthy subjects (measured on the statokinesigram, Ph. Thoumie, P. Portero et col.) and elderly subjects (R. Saggini et col.; G. Markovic et col.).

From a study focusing on the possible ways of using HUBER in a rehabilitation centre, in particular for neurological and locomotor disorders, (B. Maertens) a statistical analysis was performed using the GLMM model (Generalized Linear Mixed Models). This analysis highlighted the fact that patients' performances on HUBER increase overall in significant fashion as the session progress.

Still in the context of using HUBER in physical medicine and rehabilitation, comments from the field are very interesting:

- Focusing the attention on the exercise helps the patient to regain automatic reflexes in contact with the ground. This translates particularly as an absence of lateralization in the results.
- The "fun" aspect of the activity is very motivating for the patient with "dual-tasking" that places a great demand on the higher functions.

6.2. Safety

To date, and despite the very extensive use of the HUBER technique (the number of subjects treated worldwide is now evaluated at more than two million), no incidents have been reported. Furthermore, an expert report carried out at the Fraiture Neurological and Physical Rehabilitation Centre – the referent centre in Belgium (Cf. APPENDIX 6) leads to the conclusion that using the HUBER system is possible for rehabilitation, even for patients with serious disorders (multiple sclerosis, Parkinson's, orthopaedic disorders of the lower limbs, amputation of a lower limb). People aged over 80 are able to perform simple exercises adequately, in a context of safety that is totally compatible with the context of a physical rehabilitation programme.

The expert report emphasizes the following general warnings:

- Need for an adequate level of understanding.
- Put the hands lower down the handles if shoulder rotator cuff pain is experienced.
- Adapt the protocol to suit the physical and psychomotor capabilities of the patients so the work-out is positive and stimulating without muscle contracture.

Additionally, it has been demonstrated that exercises on HUBER appear safe and feasible in coronary heart disease patients (Cf APPENDIX 13)
Consequently, while remaining vigilant to the onset of possible adverse events, it may be reasonably believed, given the current state of knowledge, that the HUBER technique has few potential risks compared to the benefits it can provide in terms of treatment.

Finally, HUBER distribution is worldwide. Since April 2003 (date of the market launch of the non medical version), more than 2638 HUBER devices have been sold around the world – the majority in France and Belgium.

Number of HUBER machines sold per area since 2003 (*Last statement on 31/08/2014)													TOTAL
	2003	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	
France	98	201	206	91	125	117	106	219	201	155	128	68	
Export	65	124	131	93	107	58	33	35	109	80	64	24	
TOTAL	**163**	**325**	**337**	**184**	**232**	**175**	**139**	**254**	**310**	**235**	**192**	**92**	**2638**

The device has been on sale for 139 months (at August 31rst 2014). On the basis that each HUBER machine in service is used 20 days per month**,** with 3 sessions, on average, performed per day, more than **twenty two million sessions** have been performed worldwide since its market launch (2638x139x20x3 = 22 000 920 sessions).
Taking into account that a course of treatment includes, on average, 10 sessions per subject, we can estimate that more than **2 200 092 subjects** have been treated in the world.

6.3. Product literature and instructions for use

Product literature and Instructions for Use are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact on the use of the device.

Specific training on how to use HUBER is given systematically after the machine is purchased and an advanced training session is also offered. It is provided for users of the technique, in approved training centres of LPG SYSTEMS and its distributors worldwide.

7. CONCLUSION

The clinical data for HUBER, an innovative rehabilitation machine, obtained from patented LPG SYSTEMS machines, has shown the advantages and great range of possible applications. The benefit/risk ratio for this technique appears particularly satisfactory, since to date, no incidents – in line with the definition given in article L-665-6 of the CSP - have been reported during use of HUBER.

Furthermore, this technique is supported by well-established market experience dating back to 2001 and carried out working closely with health professionals and a very wide distribution network as shown by HUBER's international distribution.

Based on descriptions for indications for use and added features/accessories, risk analysis and usability report conclusion (see separate AR1002 document), this new device does not raise any new issues of safety and effectiveness. Thus, the modifications of the device have no impact on initial clinical evaluations.

In conclusion, the identified objectives of the overall evaluations have been met:

STUDIES	OBJECTIVES	RESULTS/ CLAIMS
1. Physiological and biomechanical expert report Pr PORTERO (Institut de la Performance Humaine IPH, CHU Pitié Salpétrière, Paris)	To test muscles solicitation and cardio-respiratory response during a session	A session on HUBER increases muscles solicitation and cardio-respiratory response/ **Safety**
2. Study on coordination and force in healthy subjects (amateur sports enthusiasts, those with a sedentary lifestyle and the elderly) Dr FERRET (CEREC, Lyon)	To evaluate the evolution of coordination and strength during a training program on subjects of different sex, age and level of sport activity.	HUBER allows an accurate description of coordination according age, sex and physical activity. A training on HUBER improves coordination in older subjects/ **Improvement of coordination**
3. Study of balance and posture in sportsmen & women of different levels Pr FAINA (Italian Olympic Committee, Rome)	To evaluate the evolution of balance and posture in sportsmen & women after a training program	HUBER improves stability and coordination and rebalances muscles strength in sportsmen & women/ **Improvement of balance**

STUDIES	OBJECTIVES	RESULTS/ CLAIMS
4. Study of balance, posture and muscle function in healthy individuals Pr THOUMIE (Rothschild Hospital, Paris) Pr PORTERO (IPH, CHU Pitié Salpétrière, Paris)	To evaluate balance, posture and muscle function in healthy individuals before and after a training program	HUBER improves balance, posture and muscle function of healthy individuals/ **Improvement of balance**
5. Study of balance and posture in elderly subjects Pr SAGGINI (University of Chieti, Italy)	To evaluate balance and posture in the elderly after a training program	HUBER improves balance, posture and muscle function of elderly subjects/ **Improvement of balance**
6. Advantages in physical medicine and rehabilitation Dr MAERTENS (Fraiture Neurological and Rehabilitation Centre, Belgium)	To test the interest of using HUBER in a Rehabilitation Centre	Patients in rehabilitation centre take advantages of HUBER (different beneficial effects)/ **Improvement of balance, coordination and strength**
7. Possible use of HUBER® to treat Chronic Low Back pain Dr BOJINCA (Cantacusino Hospital, Bucarest, Romania)	To Assess the efficacy of the HUBER® system-physical exercise, compared to a classical exercise program, in the treatment of uncomplicated chronic low back pain	HUBER is effective in the treatment of uncomplicated chronic low back pain when compared to a classical exercise program/ **Improvement of pain and strength**
8. Advantages in rehabilitation of patients with multiple sclerosis Dr MAERTENS (Fraiture Neurological and Rehabilitation Centre, Belgium)	To test the interest of using HUBER in patient with multiple sclerosis	HUBER improves the walking speed of patients with multiple sclerosis after 10 light training sessions/ **Improvement of balance and coordination**

STUDIES	OBJECTIVES	RESULTS/ CLAIMS
9. Interest of HUBER for neuro-muscular reprogramming Stéphane FABRI (Centre de Rééducation Spécialisée, Montpellier; France)	To optimize the neuromuscular reprogramming and to help the return to the socio professional and sports activities	HUBER device is well adapted to the mechanisms of articular stabilities/ **Improvement of coordination**
10. Interest of HUBER for predictive evaluations of the sprain ankle Stéphane FABRI (Centre de Rééducation Spécialisée, Montpellier; France)	To provide reliable, reproducible and non-operator-dependent assessments that will identify potential topics victim of a sprain ankle	HUBER is a tool to warn, in a midterm, the sprain of the ankle/ **Improvement of coordination**
11. Study on core muscle endurance Dr. Dennis Enix (research division, Logan College of Chiropractic, St. Louis; USA)	To study participants' ability to perform sustained core muscle contraction after HUBER	Training on HUBER significantly increase core muscle endurance/ **Improvement of coordination and strength**
12. Study on metabolic responses and body composition JB FABRE (esp-consulting, Mimet)	to evaluate the metabolic responses during a whole-body strength training WBST (HUBER) session and the effectiveness of a 8-weeks HUBER program on metabolic adaptations and body composition.	Training on HUBER efficaciously influenced body composition, anthropometric characteristics, and reduced the energetic cost of walking/ **Improvement of strength**

STUDIES	OBJECTIVES	RESULTS/ CLAIMS
13. Study on coronary heart disease (CHD) patients Dr Thibaud GUIRAUD (Clinique Saint Orens; France)	To investigate safety, tolerance, relative exercise intensity, and muscle substrate oxidation during sessions performed on a HUBER in coronary heart disease patients.	HUBER can be safely used in coronary heart disease (CHD) patients/ **Safety**
14. Study on healthy elderly women Pr Goran MARKOVIC (Motus Melior Rehabilitation Centre, Zagreb, Croatia)	To evaluate the chronic effects of HUBER treatment on neuro-musculoskeletal structure and function as well as cognitive performance in elderly population compared to classical rehabilitation.	Training program performed on HUBER device is more efficient, over traditional exercise programs, in improving neuromuscular performance of elderly women/ **Improvement of coordination, balance and strength**

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- Evolution de la force et de la coordination motrice au cours du vieillissement : Etude d'une nouvelle méthode d'entrainement et d'évaluation. FERRET J.M. Conférence Mondiale Anti-Age ; 10-12 Mars **2004** ; Monaco.

APPENDIX 0

CURRICULUM VITAE

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Citizenship: France

Education:

1997 PhD ; Biology of Reproduction and Development, University of Montpellier I.

1992 « Diplôme d'Etudes Approfondies » Biology of Reproduction and Development, University of Montpellier I.

1991 Master's degree in Biochemistry, University of Nice.

Professional Experience:

1997-2000 Project Leader in a Clinical Research Organization (MDS Pharma Services); Responsible for the set up and follow up of biological analysis of clinical trials: *Organization of the centralized analysis, participation in technical meetings and contact with the sponsor and/or Investigators, training of the Biological Research Associates on operating manual procedures, verification of data base.*

Since 2000 Chief Scientist at LPG Systems company (France): Responsible for the set up, follow up and scientific marketing of clinical studies testing safety and efficacy of LPG devices (CelluM6 and Huber devices) and Secretary of the LPG International Scientific Committee, the COSIRE. Studies on CelluM6: Effect on circulation, edema (lymphedema), skin trophicity (aging skin), adipose tissue (gluteo femoral areas, cellulite), fibrosis (scars, scleroderma, after-effects of radiotherapy), pain (fibromyalgia, ileus post colectomy, DOMS). Studies on Huber: Effect on balance, coordination, strength, body composition.

Last Publications

✓ **Monteux** C., Speziale F. Endermologie e stimolazione tissutale. Hi. tech dermo 3/2009
✓ **Monteux** C. , Speziale F. Endermologie : the medicine of cellular stimulation. La medicina estetica; Anno 33 numero 4; ottobre-dicembre 2009.
✓ **Monteux** C. and Lafontan M. Use of the microdialysis technique to assess lipolytic responsiveness of femoral adipose tissue after 12 sessions of mechanical massage technique. JEADV 2008, 22, 1465-1470.
✓ Gordon C., **Emiliozzi** C. and Zartarian M. Use of a mechanical massage technique in the treatment of fibromyalgia: a preliminary study. Archives of Physical Medicine and Rehabilitation. 2006 Jan; 87(1):145-7.
✓ Ortonne J.P., Queille-Roussel C., Duteil L., **Emiliozzi** C. and Zartarian M. Traitement de la cellulite : Efficacité et rémanence à 6 mois de l'Endermologie® objectivées par plusieurs méthodes d'évaluations quantitatives. Nouvelles Dermatologiques, 2004, vol. 3, 261-269.
✓ Tenna S., **Emiliozzi** C. and Scuderi N. Approche du Lift-6 dans le traitement esthétique du décolleté. Journal de Médecine Esthétique et Chirurgie Dermatologique 2003, vol. XXX, 117; 35-41.
✓ Revuz J., Adhoute H., Cesarini J.P., Poli F., Lacarrière C. and **Emiliozzi** C. Effets cliniques et histologiques d'un appareil, le Lift-6, utilisé dans le vieillissement cutané du visage. Nouvelles Dermatologiques 2002, vol. 21; 335-342.

FOLOWING APPENDIX : See enclosed file